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Original Article

Fine-needle Aspiration Cytology in Tuberculous Lymphadenitis: A Study of 200 Cases of Superficial Lymphadenopathy

Himani Patel[1], Kinara Patel[2], Jignasa Bhalodia[3]

[1]Assistant Professor, Department of Pathology, GMERS Medical College, Sola, Ahmedabad, Gujarat, India, [2]Associate Professor Department of Pathology, GMERS Medical College, Sola, Ahmedabad, Gujarat, India, [3]Professor, Department of Pathology, GMERS Medical College, Sola, Ahmedabad, Gujarat, India

Abstract

Background: In developing countries, tuberculous lymphadenitis is one of the most common causes of lymphadenopathy. Moreover, India is one of them. Patients are presenting with the only lymph node enlargement, with or without any symptoms. However, antitubercular treatment cannot be given only on clinical suspicion. Cytomorphology with acid-fast staining proves to be a valuable tool in diagnosing these cases.

Aims: The aim is to study the advantages, limitations, and utility of fine-needle aspiration cytology (FNAC) and various cytomorphological presentations inreference to Ziehl-Neelsen (Z-N) staining in tuberculous lymphadenitis.

Material and Methods: In a study period of January 2015–December 2016, in Pathology Department, GMERS Medical College, Ahmedabad, 200 cases in case of 300 patients with enlarged superficial lymph nodes, clinically suspected to be tuberculous were subjected to cytological evaluation with Hematoxylin and Eosin, Giemsa and Z-N stained smears. In addition, the social status and economic profile of these patients with the clinical presentation were also studied.

Results: Incidence of tuberculous lymphadenitis was 63%. Overall acid-fast bacilli (AFB) positivity was 65.0%. Only necrosis without epithelioid cell granulomas was the most common cytological picture and that showed highest AFB positivity also. Three-fourth of the patients presented in the second to fourth decades of life. Cervical region was the most common site of involvement with solitary lymphadenopathy as the most common presentation in contrast to matted lymph nodes as reported by others.

Conclusions: FNAC is a safe, cheap procedure requiring minimal instrumentation and is highly sensitive to diagnose tuberculous lymphadenitis. The sensitivity can be further increased by complementing cytomorphology with acid-fast staining. In acid-fast staining negative cases, the yield of AFB positivity can be increased by doing Z-N staining on second smear or decolorized smear revealing necrosis or by repeat aspiration. Microbiological assessment should also be done in such cases.

Key words: Cytomorphological patterns, Fine-needle aspiration cytology, Tuberculous lymphadenitis, Ziehl-Neelsen staining

INTRODUCTION

Fine-needle aspiration cytology (FNAC) is almost safe, cost-effective, and conclusive procedure.[1] It provides an alternative to excision biopsy for lymph nodes and is an easy procedure for collection of material for cytomorphological and bacteriological examination.[2] Tuberculous lymphadenitis is a very common cause of superficial lymphadenopathy in India. The aim of this study was to confirm the diagnosis of tuberculosis as well as to describe various cytological pictures of tuberculous lymphadenitis with their relative frequency and to assess the correlation between FNAC and Ziehl-Neelsen (Z-N) staining in diagnosing tuberculous lymphadenitis.

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MATERIALS AND METHODS

A total of 200 patients with enlarged superficial lymph nodes, clinically suspected to be tuberculous, were

Corresponding Author: Dr. Kinara Patel, Department of Pathology, GMERS Medical College, Sola, Ahmedabad, Gujarat, India.
E-mail: drkinarapatel@gmail.com

aspirated for cytological evaluation after thorough clinical examination in a study period of January 2015–December 2016 at GMERS Medical College, Ahmedabad. Aspirations were performed using 22 G needle and disposable 10 ml/5 ml plastic syringe. The smears are fixed with methyl alcohol and stained with Hematoxylin and Eosin, one air-dried smear was stained with Giemsa stain, one smear was stained with Z-N technique, and an additional slide was kept unstained for any further required stain. The cytology smears revealing features of tuberculous lymphadenitis were grouped into four categories: Epithelioid granulomas with caseous necrosis, epithelioid granulomas without necrosis, only caseous necrosis without epithelioid granulomas, and polymorphs with necrosis with or without epithelioid granulomas.[3] In addition, the demographic profile of tuberculous patients with their present and past treatment history and clinical characteristics of lymph nodes was also studied.

RESULTS

Of 200 patients's superficial lymph nodes aspirated, 83 cases showed acid-fast bacilli (AFB) positivity (of which smears initially AFB negative showed positivity by doing Z-N staining on decolorized smears), while 51 cases were AFB negative with cytological picture of tuberculous lymphadenitis, and 74 cases revealed reactive lymph node hyperplasia. We have performed repeat FNAC in case of inadequate sample. Among tuberculous cases, 72% of males and 54% of females were in the second to fourth decades of life with a male-to-female ratio of 1:3 [Tables 1 and 2].

Majority (45%) of the patients came to the institute from DOTS non-area, 25% from DOTS area, and 30 % were from outside Ahmedabad. Forty-eight patients had a history of tuberculosis in the past, and 38 patients were already on ATT at the time of aspiration.

The cervical region was the most common site, involved in 83% cases, followed by axillary (11.4%) and inguinal (5.6%). Only one case presented with generalized lymphadenopathy.

In our study, the most common presentation was single palpable cervical lymph node in 63.3% of cases, followed by multiple unilateral cervical lymphadenopathy in 19.2% of cases and multiple bilateral cervical lymphadenopathy in 7.2% of cases.

Grossly caseous or cheesy material in 50.6% and purulent material was aspirated in 22.9%, blood mixed material in 26.5% of AFB-positive cases, while blood mixed material was the most common aspirate in 65.1% of AFB-negative cases. Of 126 cases showing cytological picture of tuberculous lymphadenitis, smears revealed epithelioid granulomas with caseous necrosis in 23.1% of cases, epithelioid granulomas without necrosis in 16.7% of cases, necrosis only without epithelioid granulomas in 39.7% of cases, and polymorphs with necrosis with or without epithelioid granulomas in 20.1% of cases [Figure 1a-e]. AFB positivity was found in 69.5% of the cases showing epithelioid granulomas with caseous necrosis, 9.5% of cases with epithelioid granulomas without necrosis, 84% of cases with necrosis only without epithelioid granulomas, and 73.1% of cases with polymorphs with necrosis with or without epithelioid granulomas [Table 3]. Overall AFB positivity was seen in 65.0% of cases.

Table 1: Incidence of reactive versus tuberculous lymphadenopathy in male and female

Diagnosis	Male	Female	Total
Reactive lymph node hyperplasia	38	36	74
Tuberculous lymphadenopathy	72	54	126
Total	110	90	200

Table 2: Incidence of tuberculous lymphadenopathy in relation to age and sex

Age group (years)	Male	Female	Total (%)
1–10	08	05	13 (10.3)
11–20	15	12	27 (21.4)
21–30	16	13	29 (23.02)
31–40	18	15	33 (26.1)
41–50	10	06	16 (12.7)
50 and above	5	3	8 (6.3)
Total	72	54	126 (100)

DISCUSSION

Superficial lymphadenopathy is a very common clinical finding, etiology of which can be suspected by clinical signs and symptoms. However, a morphological diagnosis is essential to start antituberculous treatment in cases of tuberculous lymphadenopathy. FNAC lymph node is a simple, non-invasive, cheap tool with high sensitivity in tuberculous cases and can replace excision biopsy for diagnosing tuberculosis in developing countries like India. Tuberculous lymphadenopathy can be seen in patients ranging from early to advanced age. In our study, the youngest patient was 3 years old and the oldest was 67 years old.

In a study by Ahmad *et al.*, the youngest patient was 2 years old and the oldest being 95 years.[4] Majority of the patients (70%) were in the second to fourth decades of life. Similar age distribution was seen in a study by Ergete and Bekele,[2] Purohit *et al.*,[5] and Dandapat *et al.*[6]

Table 3: Various cytomorphological pictures in tuberculous lymphadenopathy

Cytomorphological picture	Number of cases (%)	AFB-positive cases (%)	AFB-negative cases (%)
Epithelioid granulomas with caseous necrosis	29 (23.1)	20 (69.5)	9 (30.5)
Epithelioid granulomas without necrosis	21 (16.7)	2 (9.5)	19 (90.5)
Necrosis only without epithelioid granulomas	50 (39.7)	42 (84)	8 (16)
Polymorphs with necrosis	26 (20.1)	19 (73.1)	7 (26.9)
Total	126 (100)	83 (65.0)	43 (35)

AFB: Acid-fast bacilli

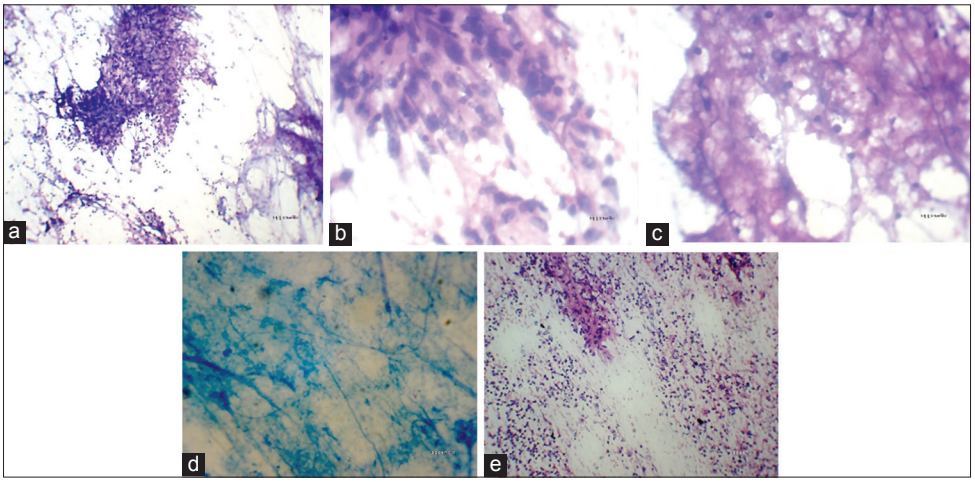

Figure 1: (a) Epithelioid cell granuloma with necrosis (H and E 10×), (b) Epithelioid cell granuloma without necrosis (H and E 40×), (c) only necrosis, no granulomas (H and E 40×), (d) AFB-positive bacilli (Z-N stain 40×), (e) polymorphs with necrosis (H and E 10×)

A slight male predominance with 1:3 sex ratio was seen in our study. Female predominance was noted by Pamra *et al.,*[7] Ergete and Bekele,[2] and Purohit *et al.,*[5] while male predominance was noted by Rajsekaran *et al.*[8] and Ahmad *et al.*[4]

Clinically, in our study, cervical region was the most commonly affected region, involved in 83% of cases. This was in concordance with Bezabih *et al.*[9] who observed cervical involvement in 74.2% of cases. A study conducted by Sharma *et al.*[10] in pediatric age group also showed similar results with female predominance and most common involvement of cervical region (88.2%). While matted lymph nodes were seen in the majority of cases (60%) by Ahmad *et al.,*[4] in our study, 63.3% of cases presented with solitary lymphadenopathy. Single lymph node enlargement was seen in 48.6% of cases of tubercular lymphadenopathy by Aggarwal *et al.*[11] We noted a much higher incidence(55%) of tuberculous lymphadenopathy while Ahmad *et al.*[4] found 38% and Tilak *et al.*[12]found 38.8% cases of tuberculous lymphadenopathy. The high incidence noted by us may be because our institute is a referral center for tuberculosis cases.

Most common cytological pattern seen was necrosis only without granulomas in 39.7% of cases and epithelioid granuloma with caseous necrosis in 23.1% of cases. While in a study by Gupta *et al.* epithelioid clusters with or without Langhan's giant cells with necrosis was most commonly observed cytological pattern in 50.35% of cases.[13] This is also the classic pattern, commonly seen in excision specimens of tuberculous lymph nodes [Figure 1a].

Highest AFB positivity was seen in smears revealing necrosis only without epithelioid granulomas (84%) and polymorphs with necrosis with or without epithelioid granulomas (73.1%) while the lowest was seen in smears showing epithelioid granulomas without necrosis (9.5%). Bezabih *et al.*[9] found the highest AFB positivity in cases showing necrosis only without epithelioid granulomas (69.7%) and the lowest in cases showing epithelioid granulomas without necrosis (20.0%). Similarly, the highest AFB positivity (75.6%) was seen in smears revealing necrosis only without epithelioid granulomas by Gupta *et al.*[13] Maximum AFB positivity (61.6%) was found in smears containing purulent material on aspiration. Similarly, Ahmad *et al.*[4] noted 68.8% AFB positivity in smears containing purulent material on aspiration. In our study, overall AFB positivity was seen in 71% of cases. AFB positivity was observed in 71.7% of cases by Ergete and Bekele,[2] 59.4% cases by Bezabih *et al.,*[9] 45.6% cases by Dasgupta *et al.,*[14] and 19.6% of cases by Aggarwal *et al.*[11] High AFB positivity noted in our study may be because of extensive screening done as in addition to one Z-N stained smear in each case, we got Z-N staining done on second smear or decolorized smear where cytology suggested tuberculosis, especially when necrosis was present. The yield

of AFB positivity can further be increased by doing repeat FNAC of lymph node.[15] AFB-negative cases revealing only epithelioid cell granulomas without necrosis should be clinically correlated with microbiological assessment. Similarly, atypical cells should be ruled out in smears showing necrosis only without epithelioid cell granulomas and AFB negativity and material should be submitted for culture. Microbiological assessment is necessary in AFB-negative cases to confirm the diagnosis of tuberculosis as approximately 10,000–100,000 mycobacterial organism/ml of sample should be presented for smear AFB positivity.

CONCLUSION

FNAC can be performed as outpatient department procedure in superficial lymphadenopathy cases. The procedure is safe, well accepted by patients, very cost-effective and requires minimum instrumentation in comparison to excision biopsy. Diagnostic accuracy as high as 100% in tuberculous lymphadenopathy cases has been reported by Tripathy *et al.*,[16] 84.4% by Dasgupta *et al.*,[14] 83.3% by Dandapat *et al.*,[6] and 87% by Narang.[17] Therefore, even in most remote areas, FNAC can be used for diagnosing tuberculous lymphadenopathy. Coupling FNAC with Z-N staining increases the diagnostic accuracy.

Diagnostic accuracy can be further increased by submitting some material obtained by FNA for culture.

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Original Article

Stress Among Dental Students: A Cross-sectional Study in Saudi Arabia

Najla A Aseeri[1], Fadwa S Alasmari[2], Majed A Alqahtani[3], Saleh A Alqahtani[4], Rafi Ahmed Togoo[5]

[1,2]Final year BDS student, King Khalid University College of Dentistry, Abha, Saudi Arabia, [3,4]Intern, College of Dentistry King Khalid University, Abha, Saudi Arabia, [5]Professor, Department of Pediatric Dentistry and Orthodontics, King Khalid University College of Dentistry, Abha, Saudi Arabia

Abstract

Introduction: Professional dental training can be a stressful experience. Dental education can be very demanding unlike anything students have faced in the past.

Purpose: A cross-sectional study was conducted to determine the level of psychological stress as well as its perceived sources among undergraduate dental students at King Khalid University, Abha, Saudi Arabia.

Materials and Methods: A total of 389 questionnaires were sent to dental students of the 2nd year up to 6th year and internship year through Google Forms application. Overall, the response rate was 77.3%. The questionnaire was based on dental environment stress survey with modification to suit Saudi Arabian culture. Descriptive statistics, Cronbach's alpha reliability test, Mann–Whitney U test, and Kruskal–Wallis test were performed with the resultant data. The significance level was set at 0.05.

Results: Dental students of King Khalid University College of Dentistry displayed high levels of perceived stress. Examination and distribution of grades, course requirements, days' long schedule, lack of time for relaxation, and insecurity concerning future were found to be biggest stressors. Male and female students exhibited similar mean overall DES scores, and students belonging to the 2nd year showed less perceived stress compared to the students of higher academic years.

Conclusion: High level of stress was found among the study subjects. The main reasons of stress were examination and distribution of grades, course requirements, days' long schedule, and lack of time for relaxation. It is essential for dental schools to ensure an environment that reduces stress and promotes the well-being of students.

Key words: Dental psychology, Dental students, Education, Stress, Stressors

INTRODUCTION

By and large professional dental training is perceived as extremely challenging and enormously stressful experience worldwide. Dental students have to undergo extensive preclinical, clinical and interpersonal skills, training to acquire a plethora of knowledge, clinical, and problem-solving competencies.[1] Dental students experience more stress than medical students as have been documented in one of the previous studies.[2] Since the turn of the 21st century, educationists have increased their attention towards understanding stress and stressors among dental students within their educational environment. This has resulted in several published studies that have identified stressors and their physical and psychological consequences during various stages of dental training.[3-7] The type of stressor and the level of stress-induced varies among individuals depending on the psychological makeup, stage of training, curricular aspects, institutional factors, and several other non-academic factors.[8] Individual's personality, emotional intelligence, and societal support profoundly affect the way stress is perceived in dental academic environment.[5,9-11] The commonly reported academic and non-academic sources of dental environment stress (DES) include frequent examinations, clinical and laboratory course requirements, meeting course deadlines,

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Corresponding Author: Rafi Ahmed Togoo, Division of Pediatric Dentistry, King Khalid University College of Dentistry, Abha, Kingdom of Saudi Arabia. Tel: +966-17-2418046 Mobile: +966 542709996. E-mail: ratogo@kku.edu.sa

dealing with patients, high academic expectations, lack of sufficient leisure time, and financial status.[12,13] These stressors are well known to cause a long list of physical and psychological distress symptoms including anxiety, depression, tension, fear, cynicism, headaches, dizziness, fatigue, insomnia, tachycardia, and impairment of immune system.[12-19] All these consequences have a potential to end up in professional burnout[3] and in extreme conditions even suicide. Therefore, it is essential to identify potential stressors in every academic environment, to understand the way students perceive, react and respond to dental stress and plan effective strategies to alleviate them. With this perspective, a study was undertaken with the prime objective of determining the level of psychological stress as well as its perceived sources among undergraduate dental students at King Khalid University.

MATERIALS AND METHODS

A cross-sectional study design with non-probable convenient sampling was used to distribute self-administered questionnaires through "Google Forms application." The study population comprised undergraduate dental students of King Khalid University College of Dentistry (KKUCOD), Bachelor of Dental Surgery (BDS) program. These students were from the 2nd year to the 6th year and internship year of the BDS program. The 1st year students were excluded because it forms the preparatory year, which technically does not belong to the BDS program. Ethical approval for conducting the survey was obtained from the Scientific Research and Ethics Committee KKUCOD, and the study was conducted for 5 months from April 2017 to August 2017. The objectives of the study were communicated in advance to the students, and it was made sure the student participation was voluntary.

The survey was based on DES questionnaire[20] with modifications keeping in mind the Saudi Arabian culture and the targeted undergraduate student population [Table 1]. Before making the modification, several versions of DES questionnaire were reviewed that are already published in the literature[21-26] The modified questionnaire comprised 29 questions related to stress and two questions related to the gender and academic year of the sample population. For ease of understanding, the questionnaire was translated into Arabic language and a "How to answer the questionnaire" was included at the beginning. The responses were divided into five-point Likert scale as "not relevant," "not stressful," "slightly stressful," "moderately stressful," and "very stressful."

The data obtained from Google Forms was analyzed using the Statistical Package for the Social Sciences software (SPSS PC + version 24.0). The reliability of the questionnaire items was assessed by employing Cronbach's alpha test. Descriptive statistics along with Mann–Whitney U test was performed to determine the significant differences between the responses based on gender. Kruskal–Wallis test was performed to ascertain any significant differences of responses based on the academic year; the respondents belong to. The level of significance was set at $P < 0.05$.

Table 1: Questionnaire items

#	Question/stressor
1	Amount of assigned work
2	Difficulty of coursework
3	Competition with classmates
4	Examination and distribution of grades*
5	Completion of course requirements
6	Fear of failing the examination
7	Lack of time to do assigned coursework*
8	Fear of being unable to keep up with workload
9	Learning environment created by faculty
10	Receiving criticism about work
11	Rules and regulations of the school
12	Do you grind your teeth (bruxism)
13	Difference in feedback from different instructors
14	Lack of sufficient break between sessions
15	Long days schedule and lack of time for relaxation
16	Atmosphere at home
17	Taking care of children
18	Postponement of engagement, marriage, or having children
19	Increase in weight and appetite
20	Multiple roles as a spouse, parent, and professional
21	Lack of self-confidence
22	Expectations of professional school versus reality
23	Insecurity concerning professional future
24	Patients inability to complete the prescribed treatment plan
25	Responsibility for comprehensive patient care
26	Patients not available at prescribed times
27	Difficulty in learning appropriate clinical procedures
28	Working on patients with poor personal hygiene
29	Multitasking as student, clinical work, and research

RESULTS

The survey questionnaire was sent to a total of 389 undergraduate students, out of whom 301 responded by way of answering all the questions. The total response rate was 77.3%. The response rate of male and female students was 72.5% and 82.8%, respectively. Maximum respondents belonged to the third academic year (26%) while the least number of respondents belonged to the fifth academic year (12%). The details of the distribution of respondents according to gender and the academic year are given in Table 2. The overall reliability of the questionnaire items was assessed by calculating Cronbach's alpha [Table 3]. Significant internal consistency was observed with all the 29 items of the questionnaire (Cronbach's alpha score = 0.896). In general, the respondents displayed high DES scores for all the stressors appearing in the

Table 2: Distribution of respondents according to gender and academic year

Gender	*n* (%)		
Male	151 (50)		
Female	150 (50)		
Total	301 (100)		
Academic year	**Total *n* (%)**	**Male *n* (%)**	**Female *n* (%)**
2nd	44 (15)	12 (8)	32 (21)
3rd	79 (26)	36 (24)	43 (29)
4th	57 (19)	29 (19)	28 (19)
5th	35 (12)	7 (5)	28 (19)
6th	48 (16)	34 (23)	14 (9)
Interns	38 (13)	33 (22)	5 (3)
Total	301 (100)	151 (100)	150 (100)

Table 3: Cronbach's alpha reliability test

Number of items in questionnaire	Cronbach's alpha based on standardized items	Cronbach's alpha
29	0.899	0.896

questionnaire. The mean DES values for each stressor are presented in Table 4. Questions: Fourth (examination and distribution of grades), fifth (course requirements), 15th (long day's schedule and lack of time for relaxation), and 23rd (insecurity concerning future) were considered the biggest stressors. Similarly, stressors from questions: Third (competition with classmates), 12th (bruxism), 16th (atmosphere at home), 17th (taking care of children), 18th (postponement of engagement, marriage, or having children), 19th (increase in weight and appetite), and 20th (multiple roles as a spouse, parent, and professional) were perceived to be least stressful. Comparing the level of stress between male and female students with Mann–Whitney U test [Table 5] a significant difference was observed for questions: Fourth (examination and distribution of grades), 10th (receiving criticism about work), 11th (rules and regulation of the school), 14th (lack of sufficient break between sessions), 16th (atmosphere at home), 18th (postponement of engagement, marriage, or having children), and 21st (lack of self-confidence). Overall, male and female students exhibited similar mean DES scores [Table 4]. Comparison of means of DES scores between all six academic years by Kruskal–Wallis test [Table 6] revealed a significant difference in responses to all questions except question number three (competition with classmates), six (fear of failing examinations), eight (fear of being unable to keep up with workload), 12 (bruxism), 16 (atmosphere at home), 17 (taking care of children), 19 (increase in weight and appetite), 20 (multiple roles as a spouse, parent, and professional), and 21 (lack of self-confidence). Students from all the academic years considered questions: 13 (difference in feedback from different instructors) and 23rd (insecurity concerning future) as most stressful and questions: 17th (taking care of children) and 20th (multiple roles as a spouse, parent, and professional) as least stressful ones. Students belonging to the 2nd year showed less perceived stress compared to that of other academic years [Table 7].

DISCUSSION

The results of this study indicate that students of KKUCOD displayed high level of perceived DES. This is revealed in their ratings for almost all the items of the questionnaire. Ratings were considerably higher for stressors related to examination, grades, course requirements, long day's schedule, lack of time for relaxation, and insecurity concerning future. Stress related to examination and grades are a universal phenomenon and may have been present since the inception of examinations system. Brown and Van Gelder[27] of University Chicago in a series of publications in 1938 reported of the physiological changes and emotional reactions experienced by students before examinations. Students surveyed in our study are no exception to this stressor. However, the process of examination can be made less stressful by employing alternate methods to conventional examination procedures. One such alternative to written examination scan be online examinations, which is, in fact, being increasingly utilized by dental schools through learning management systems such as Blackboard® and Moodle®. The semester system followed in our school can be a burden on complete course requirements. Steps are being taken to shift from semester system to annual system to ease out the schedule for course requirements.

Moreover, students reported stress due to insecurity concerning their professional future as well. There can be multiple factors responsible for this kind of stress, but in our opinion, increasing competition in Saudi Arabia for joining higher studies may be the foremost one. Stressors that have less influence on one individual can be more stressful for another and vary corresponding to geographic locations. European students reported more concern regarding their professional future,[28] while as examinations and their related stressors were more stress provoking for Japanese students.[29] Men from the upper class reported insecurity about professional failure,[28] also significant stress has been reported due to fear of not being able to endure long hours of clinical chores and due to the challenges of professional life.[30] In the present study too, the students perceived long day's work without enough time for relaxation as a source of stress. The school schedules a break of 1 h at noon; nevertheless, short breaks can be included between clinical and laboratory sessions for students to relax and recuperate.

Table 4: Mean (±SD) DES Scores of respondents according to gender

Respondents	Questions	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10
All respondents		3.78±0.87	3.76±1.0	2.89±1.15	4.14±1.00	4.07±1.03	3.75±1.24	3.84±1.12	3.53±1.19	3.71±1.14	3.72±1.25
Male respondents		3.82±0.83	3.75±0.99	2.90±1.07	4.02±1.05	4.19±0.88	3.87±1.23	3.82±1.12	3.40±1.18	3.73±1.09	3.50±1.29
Female respondents		3.74±0.92	3.77±1.04	2.89±1.23	4.25±0.95	3.95±1.16	3.63±1.26	3.86±1.14	3.65±1.20	3.70±1.21	3.95±1.19
	Questions	**Q11**	**Q12**	**Q13**	**Q14**	**Q15**	**Q16**	**Q17**	**Q18**	**Q19**	**Q20**
All respondents		3.42±1.21	2.23±1.47	3.9±1.25	3.82±1.23	4.12±1.09	2.93±1.70	2.07±1.49	2.63±1.60	2.89±1.63	2.18±1.61
Male respondents		3.59±1.21	2.14±1.43	3.90±1.26	3.52±1.32	4.15±1.10	3.25±1.64	2.02±1.43	2.91±1.60	2.81±1.55	2.06±1.50
Female respondents		3.24±1.20	2.32±1.52	3.91±1.26	4.12±1.07	4.09±1.09	2.61±1.72	2.11±1.57	2.35±1.56	2.97±1.72	2.29±1.73
	Questions	**Q21**	**Q22**	**Q23**	**Q24**	**Q25**	**Q26**	**Q27**	**Q28**	**Q29**	**-**
All respondents		3.35±1.38	3.28±1.34	4.17±1.11	3.19±1.52	3.36±1.40	3.58±1.51	3.16±1.33	3.34±1.46	3.86±1.54	-
Male respondents		3.05±1.41	3.23±1.37	4.09±1.16	3.11±1.47	3.30±1.28	3.54±1.41	3.10±1.19	3.38±1.42	3.90±1.43	-
Female respondents		3.65±1.30	3.33±1.31	4.25±1.07	3.28±1.58	3.41±1.52	3.63±1.62	3.23±1.47	3.29±1.50	3.82±1.65	-

DES: Dental environment stress, SD: Standard deviation

Table 5: Mann–Whitney U Test

Questions	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10
Mann–Whitney U	11012.5	11077.5	11058.5	9868.5	10327.5	10045	11054	9906.5	11280.5	9048.5
Significant (two-tailed)	0.656	0.731	0.715	0.038	0.16	0.077	0.708	0.053	0.951	0.002
	Q11	**Q12**	**Q13**	**Q14**	**Q15**	**Q16**	**Q17**	**Q18**	**Q19**	**Q20**
Mann–Whitney U	9435	10659	11291	8382	10877	9044.5	11165	9120	10799.5	10746
Significant (two-tailed)	0.01	0.344	0.962	0	0.521	0.002	0.811	.002	0.474	0.383
	Q21	**Q22**	**Q23**	**Q24**	**Q25**	**Q26**	**Q27**	**Q28**	**Q29**	**-**
Mann–Whitney U	8622.5	10871.5	10396.5	10488	10397	10382.5	10336.5	10989.5	11018.5	-
Significant (two-tailed)	0	0.539	0.176	0.255	0.206	0.192	0.179	0.648	0.656	-

Table 6: Kruskal–Wallis Test

Questions	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10
Chi-square	26.942	13.769	11.697	16.681	54.785	7.303	27.178	2.374	11.953	17.432
Df	5	5	5	5	5	5	5	5	5	5
Asymp. significant	0	0.017	0.039	0.005	0	0.199	0	0.795	0.035	0.004
	Q11	**Q12**	**Q13**	**Q14**	**Q15**	**Q16**	**Q17**	**Q18**	**Q19**	**Q20**
Chi-square	44.026	7.361	28.885	13.606	27.141	8.714	6.898	13.636	7.943	6.552
Df	5	5	5	5	5	5	5	5	5	5
Asymp. significant	0	0.195	0	0.018	0	0.121	0.228	0.018	0.159	0.256
	Q21	**Q22**	**Q23**	**Q24**	**Q25**	**Q26**	**Q27**	**Q28**	**Q29**	**-**
Chi-square	5.192	28.876	6.846	75.53	39.751	50.092	30.044	31.374	38.689	-
Df	5	5	5	5	5	5	5	5	5	-
Asymp. significant	0.393	0	0.232	0	0	0	0	0	0	-

It was interesting to note that the level of perceived stress was similar between male and female students. This finding was in contrast to those found in previous studies[31-33] wherein female medical/dental students reported higher stress levels. Saxena *et al.*[34] reported that female medical students were able to cope with stress better than males, citing good social support as a reason there for. The number of universities offering dental programs to female students has drastically increased over the years in Kingdom of Saudi Arabia and also the society is opening up, perhaps neutralizing stress on female students. Similar to Al-Saleh *et al.* studied[31] the 2nd year students showed less perceived stress compared to

Table 7: Mean DES scores according to the level of academic year

Academic year	Questions	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10
2nd	Mean±SD	3.18±1.02	3.39±1.20	2.57±1.07	3.98±1.02	3.43±1.09	3.55±1.30	3.36±1.14	3.55±1.30	3.36±1.14	3.25±1.46
3rd	Mean±SD	3.72±0.85	3.75±1.01	2.80±1.08	4.27±0.89	3.84±1.02	4.01±1.26	3.91±1.20	3.57±1.27	3.68±1.19	3.72±1.30
4th	Mean±SD	3.91±0.76	3.67±1.06	3.02±1.29	4.19±0.97	3.93±1.00	3.75±1.20	3.60±1.03	3.54±1.20	3.63±1.25	3.89±1.06
5th	Mean±SD	4.09±0.70	4.11±0.83	3.34±1.26	4.60±0.69	4.51±0.98	3.80±1.13	4.40±0.88	3.63±1.06	4.11±0.99	4.29±0.89
6th	Mean±SD	4.02±0.73	4.06±0.76	2.98±1.02	3.88±1.02	4.60±0.61	3.67±1.15	4.15±0.95	3.58±1.09	4.00±0.95	3.92±1.11
Interns	Mean±SD	3.82±0.90	3.68±0.99	2.76±1.15	3.87±1.30	4.42±0.98	3.47±1.41	3.71±1.21	3.24±1.22	3.58±1.15	3.26±1.35
Academic year	**Questions**	**Q11**	**Q12**	**Q13**	**Q14**	**Q15**	**Q16**	**Q17**	**Q18**	**Q19**	**Q20**
2nd	Mean±SD	2.68±1.07	1.73±1.19	3.02±1.59	3.36±1.40	3.64±1.14	2.32±1.65	1.86±1.29	2.32±1.64	2.73±1.58	2.14±1.62
3rd	Mean±SD	3.18±1.23	2.15±1.44	4.04±1.28	3.62±1.34	3.89±1.23	2.81±1.66	1.86±1.33	2.30±1.56	2.89±1.59	1.97±1.58
4th	Mean±SD	3.60±1.25	2.42±1.64	4.30±1.02	4.12±1.04	4.47±0.87	3.14±1.68	2.07±1.55	2.63±1.57	2.65±1.58	2.11±1.62
5th	Mean±SD	3.77±1.03	2.51±1.72	4.23±0.97	4.09±1.09	4.34±0.94	3.17±1.74	2.60±1.85	3.09±1.63	3.57±1.85	2.71±1.84
6th	Mean±SD	4.19±0.84	2.40±1.35	4.02±1.02	4.10±1.04	4.50±0.74	3.13±1.72	2.35±1.59	3.15±1.54	2.67±1.59	2.44±1.69
Interns	Mean±SD	3.18±1.23	2.21±1.45	3.61±1.13	3.68±1.25	3.92±1.22	3.08±1.78	1.87±1.40	2.61±1.60	3.11±1.64	1.92±1.30
Academic year	**Questions**	**Q21**	**Q22**	**Q23**	**Q24**	**Q25**	**Q26**	**Q27**	**Q28**	**Q29**	**-**
2nd	Mean±SD	3.27±1.45	2.34±1.14	4.02±1.19	2.00±1.57	2.32±1.65	2.41±1.76	2.41±1.59	2.48±1.76	2.66±1.89	-
3rd	Mean±SD	3.46±1.43	3.28±1.34	4.16±1.06	2.47±1.40	3.01±1.48	3.04±1.64	2.82±1.45	2.91±1.51	3.39±1.75	-
4th	Mean±SD	3.37±1.38	3.51±1.34	4.04±1.21	3.44±1.32	3.67±1.27	3.88±1.25	3.58±1.18	3.54±1.32	4.16±1.19	-
5th	Mean±SD	3.63±1.26	3.60±1.12	4.57±0.74	4.11±1.11	4.06±1.11	3.97±1.25	3.86±1.12	4.06±1.11	4.57±1.01	-
6th	Mean±SD	3.35±1.25	3.67±1.24	4.35±0.96	4.04±1.07	3.94±0.91	4.48±0.74	3.27±0.98	3.73±0.92	4.52±0.82	-
Interns	Mean±SD	2.92±1.48	3.24±1.42	3.95±1.39	3.79±1.23	3.45±0.95	4.13±0.96	3.34±0.97	3.74±1.37	4.29±1.06	-

DES: Dental environment stress, SD: Standard deviation

students studying in higher academic years. Students in early years of training are still soaking up the nitty-gritty of the program. As they advance to higher academic levels, their competition increases and so does stress levels.

Tertiary studies are always considered as very stressful for students. DES is no exception to this. The magnitude and sources of DES are dynamic that change over time. It has direct influence on the academic performance, general health, and professional success of a student.[35] Therefore, it is indispensable for dental schools to ease out stress causing factors and ensure an environment that promotes the well-being of students.

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Original Article

Bone Marrow Aspiration Cytology Study in a Tertiary Care Center, Gujarat, India

Mayuri Gohil[1], Kruti Rathod[2]

[1]Tutor, Department of Pathology, Government Medical College, Bhavnagar, Gujarat, India,
[2]Resident Doctor, Department of Pathology, Government Medical College, Bhavnagar, Gujarat, India

Abstract

Background: Hematological disorders are quite frequent in all age groups. Bone marrow aspiration (BMA) is crucial in evaluation, diagnosis, and management of anemia and other hematological disorders, especially in situation where diagnosis remains cryptic after detailed clinical history, physical examination, and peripheral blood analysis. This relatively safe and simple procedure is important particularly in resource-poor center since assess to adjuvant diagnostic techniques is often lacking. The present study aims to analyze the causes of hematological disorders, its spectrum, and indication of BMA findings.

Materials and Methods: This was a retrospective as well as prospective study carried out in the Department of Pathology, Government Medical College and Sir Takhtasinhji Hospital, Bhavnagar, Gujarat, India, over 3 years 6 months. BMA of 141 cases was carried out and examined by the expert. Patient details regarding clinical history, physical examination, and laboratory reports were retrieved.

Results: Of 141 patients, total of 28 cases were excluded from the study due to inadequate material or dry tap. Majority of the patient were of pediatric age group (<15 years). Male-to-female ratio was 1.17:1. The most frequent indication for BMA was unexplained anemia (44.24%) and thrombocytopenia (19.46%), followed by pancytopenia (16.18%) and suspected leukemia (9.73%). 7.96% BMA was absolutely normal without any pathology. Nutritional anemia (52.21%) was the most common pathological finding, followed by immune thrombocytopenia (11.5%), leukemia (8.84%), and aplastic anemia (6.19%).

Conclusion: BMA cytology is a relatively simple, safe, and cheap yet a highly informative and important diagnostic test of wide range of hematological disorders in developing country like India.

Key words: Anemia, Bone marrow aspiration, Leukemia, Pancytopenia

INTRODUCTION

Bone marrow aspiration (BMA) is an invasive but relatively simple and safe procedure, whereby representative specimen of spongy bone marrow is obtained through a needle aspiration for diagnostic evaluations in hematology and stem cell harvest.[1,2] Often times, patients with suspected marrow diseases whose diagnosis remains inconclusive after examination of the peripheral blood with complete blood count, peripheral smear examination, and ancillary tests require BMA. It gives a more complete picture of the reaction of the hemopoietic tissue to anemia than can be gained from peripheral blood smear alone. The procedure may be necessary for the diagnosis and management of hematological and to some extent non-hematological disorder, for staging, prognostication, and evaluation of therapeutic response in some disorders.[3]

Despite being a highly informative test procedure in diagnostic evaluation, there is sparse local literature on its indications and diagnostic utility/findings of BMA. This study therefore evaluated and reports on age and sex distribution, the spectrum of common indications and diagnosis of bone-marrow aspiration among patients seen at Government Medical College and Sir Takhtasinhji Hospital, Bhavnagar, Gujarat, India. This would also serve for possible comparison with findings from other parts of India and beyond.

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Corresponding Author: Dr. Mayuri Gohil, Department of Pathology, Government Medical College, Bhavnagar, Gujarat, India.
Mobile: +91-9909903514. E-mail: drmayurigohil@gmail.com

MATERIALS AND METHODS

This was a retrospective and prospective study carried out over 3 years and 6 months (January 2014 to October 2017), at the Department of Pathology, Government Medical College and Sir T. Hospital, Bhavnagar, Gujarat, India.

BMA was performed by trained pathologist, on those patients who were advised to do so by their consultants. Posterior superior iliac crest was the site of choice for BMA in most of the patients, tibia for infants, and sternum in case of obese. Records regarding the patient detailed information, clinical history, physical examination, clinical indication for the procedure, and all laboratory tests findings including peripheral smear reports were recorded.

The BMA material was collected, and smears were prepared by wedge-spread method and stained with Leishman stain. Wherever needed, special stains such as Myeloperoxidase stain, periodic acid–Schiff stain, and Perl stain were used. Aspirates of inadequate material or dry tap were excluded from the study. All slides were examined by the expert pathologist, and the data were manually collected and subsequently analyzed.

RESULTS

Of 141 patients, who were performed BMA, the material acquired was inadequate for interpretation or diluted with blood in 26 cases, and in 2 cases, there was dry tap which is excluded. Hence, a sample size of the study is 113.

Of 113 cases, the majority of patients 34.52% were of pediatric age group (<15 years). The smallest patient was just 2-day-old baby. 53.98% were males and 46.02% were females having male-to-female ratio 1.17: 1. Table 1 presents age and sex distribution of cases.

In most of the cases, BMA was hypercellular (60.17%). Cellularity of BMA is summarized in Table 2.

The most frequent indication for BMA was unexplained anemia (44.24%), followed by unexplained thrombocytopenia (19.46%), unexplained pancytopenia (16.18%), and suspected leukemia (09.73%) [Table 3].

The most common marrow diagnoses were dimorphic anemia (18.58%) and megaloblastic anemia (18.58%). Overall, 52.21% of cases were having nutritional anemia, 8.84% having hematological malignancy, and 5.30% having infectious etiology like malaria or leishmaniasis. The BMA of youngest 2-day-old baby was diagnosed to have congenital dyserythropoietic anemia. Among all cases, 7.96% BMA was absolutely normal. The spectrum of hematological disorders diagnosed with BMA cytology is shown in Table 4.

Table 1: Age and sex distribution of BMA cases

Age (years)	Number of cases	Male (total 61)	Female (total 52)	Percentage
<15	39	19	20	34.52
15–30	22	10	12	19.46
31–45	25	14	11	22.13
>45	27	18	9	23.89

BMA: Bone marrow aspirate

Table 2: Cellularity of bone marrow in aspirated smears

Marrow cellularity	Number of cases (%)
Hypercellular	68 (60.17)
Normocellular	30 (26.54)
Hypocellular	18 (15.93)

Table 3: Indications of BMA

Indication	Number of cases (%)
Unexplained anemia	50 (44.24)
Unexplained thrombocytopenia	22 (19.46)
Unexplained pancytopenia	19 (16.81)
Suspected leukemia	11 (9.73)
Unexplained spleenomegaly	4 (3.53)
Unexplained fever	5 (4.42)
Others	2 (1.76)

BMA: Bone marrow aspirate

Table 4: Spectrum of hematological disorders diagnosed with BMA cytology

Broad category (%)	Diagnosis	Number of cases (%)
Nutritional anemia (52.21)	Micronormoblastic	17 (15.4)
	Megaloblastic	21 (18.58)
	Dimorphic	21 (18.58)
Aplastic anemia (6.19)	Aplastic anemia	7 (6.19)
Hematological malignancy (8.84)	ALL	5 (4.42)
	AML	1 (0.88)
	CML	3 (2.65)
	CLL	1 (0.88)
ITPs (11.5)	ITP	13 (11.5)
Others (7.96)	MDS	4 (3.53)
	Myelofibrosis	1 (0.88)
	CDA	1 (0.88)
	Hypersplenism	1 (0.88)
	Hemophagocytic syndrome	1 (0.88)
	Essential thrombocythemia	1 (0.88)
Infection (5.3)	Infection	6 (5.3)
Normal BM (7.96)	Normal BM	9 (7.96)

BMA: Bone marrow aspirate, ALL: Acute lymphoblastic leukemia, AML: Acute myeloid leukemia, CML: Chronic myeloid leukemia, CLL: Chronic lymphoblastic leukemia, ITP: Immune thrombocytopenia, MDS: Myelodysplastic syndrome, CDA: Congenital dysplastic anemia, BM: Bone marrow

DISCUSSION

The bone marrow is one of the body's largest organs, constituting 4.5% of the total body weight and weighs 3375 g in an average 75 kg individual.[4] It is the principal site of hematopoiesis. The hematopoietic bone marrow is organized around the vasculature of the bone cavity. Its main function is to supply mature hematopoietic cells for circulating blood in a steady state as well as to respond to increased physiological or pathological demands. BMA is a cytologic preparation of bone marrow cells obtained by aspiration of marrow and a smear of the cells. It is used to diagnose, confirm, and/or stage hematologic malignancies. It helps to evaluate cytopenias, thrombocytosis, leukocytosis, anemias, and iron status. It is also a diagnostic tool in non-hematological disorders such as storage disorders and systemic infections. The spectrum of hematological disorders is very wide. It is an ambulatory procedure performed under local anesthesia with minimal morbidity. It is a safe and useful test in reaching the final diagnosis. The present study determines the indications and spectrum of disorders diagnosed by BMA cytology examination.

Most of the aspirate specimens were taken from the posterior iliac crest. The tibia is the preferred site in children aged <18–24 months.[2,5,6] The sternum was the last choice due to the possible fatal risk of damage to the great vessels during sternal puncture.[6,7]

This study like other studies has shown that BMA cytology can be carried out in all age groups. The age range (2 days to 78 years) as well as the sex ratio of subjects undergoing BMA evaluation is similar to that reported in other studies.[8-10] In our study, the most common age group undergoing BMA was pediatric population (<15 years). The male-to-female ratio was 1.07:1. In a study done by Niazi and Raziq,[11] the majority of the patients were from the age group 1 to 30 years.[11]

In our study, we found that most of the BMA were hypercellular (60.17%) which is comparable to Marwah *et al*.[12] It is due to compensatory erythroid hyperplasia seen in BMA due to peripheral anemias. Though, 7.96% bone-marrow aspiration were absolutely normal without any pathology.

Cytopenias generally result from accelerated peripheral destruction of blood cells as in autoimmune disease, underproduction, or maturation defects.[13] Most times, if the cause is not found peripherally, there is a need for examination of the bone marrow, the site of hematopoiesis. It is therefore not surprising that unexplained cytopenia was the most frequent indication for bone marrow examination in the study. The most common indications for BMA in this study were unexplained anemia and thrombocytopenia, followed by diagnosis and management of pancytopenia and leukemia. Similarly, Damulak and Damen[14] and Tripathy and Dudani[15] also reported anemia as the most common indication for BMA cytology in their studies, but contrast studies by Pudasaini *et al*.[8] and Bashawri[16] showed pancytopenia, diagnosis, and management of leukemia as the two most common indications for this procedure. Mahabir *et al*.[17] reported that the role of BMA in thrombocytopenic patients is to exclude other hematological diseases like leukemia in children and myelodysplastic syndrome in adults. This was corroborated in a survey in which 74% of pediatric hematologists were of the view that bone marrow examination is necessary in acute childhood immune thrombocytopenia, and the main reason cited was the need to exclude other hematological disorders such as leukemia, dysmyelopoietic syndrome, and aplastic anemia.

Both dimorphic anemia and pure megaloblastic anemia were most common pathological findings, which is comparable to other studies. In a study done by Gayathri and Rao,[10] megaloblastic anemia was the most common cause of pancytopenia and was the most common finding in BMA. The increasing incidence of megaloblastic anemia and dimorphic anemia reflects the higher prevalence of nutritional deficiency in developing countries like the US. Microcytic anemia was observed in 15.4% of cases. However, in a study done by Ahmed *et al*.,[9] 23.8% of cases were diagnosed as iron deficiency anemia. Although the most common anemia in our country is due to iron deficiency, there is no need of BMA for diagnosis and management. Hence, the prevalence of dimorphic and pure megaloblastic anemia is a higher side in the study. Thus, bone marrow examination could be used effectively in most cases to determine the cause of anemia.

We found hematological malignancies in 8.84% of cases, of which acute lymphoblastic leukemia (ALL) was the most common diagnosis. In contrast, Egesie *et al*.,[18] Kibria *et al*.,[19] and Gayathri and Rao[10] had reported acute myeloid leukemia more common than ALL.

Aplastic anemia was seen in 7 cases (6.19%). Compared to our study, 19%, 29%, and 14% cases of hypoplastic anemia were seen in other studies.[10,20,21] Infective pathology was seen in 6 cases (5.3%) consisting of leishmaniasis, malaria, and tuberculosis. Similar finding was seen in a study done by Santra and Das.[22] Other studies showed 2.82%, 1.2%, and 0.67% of leishmaniasis,[11,19,20] but the maximum number of cases (14%) were seen in a study done by Khodke *et al*.[21] Recent advances in the treatment of hematologic malignancies have been paralleled by renewed

interest on the part of pathologists and hematologists in methods of obtaining and preparing bone marrow for diagnostic studies.

CONCLUSION

Bone marrow examination is an important investigation to arrive at the confirmatory diagnosis of hematological disorders in resource-poor country like India. The study provides a valuable insight into the causes of anemia or pancytopenia in our country. The procedure remains a veritable tool in the diagnoses and management of a wide range of hematological and some non-hematological diseases.

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Original Article

A Study of Hearing Loss in Chronic Renal Failure

C Balasubramanian[1], B Santhanakrishnakumar[2], Heber Anandan[2]

[1]Associate Professor, Department of Otorhinolaryngology, Thoothukudi Medical College, Thoothukudi, Tamil Nadu, India, [2]Assistant Professor, Department of Otorhinolaryngology, Thoothukudi Medical College, Thoothukudi, Tamil Nadu, India, [3]Senior Clinical Scientist, Department of Clinical Research, Dr. Agarwal's Healthcare Limited, Chennai, Tamil Nadu, India

Abstract

Introduction: It is well known that chronic renal failure (CRF) causes different systemic and otorhinolaryngologic manifestations due to the accumulation of nitrogenous waste products. Hearing loss in patients of CRF is relatively higher in comparison to the general population.

Objective: The objective of this study was to evaluate the severity of hearing loss at different frequencies in patients of CRF.

Materials and Methods: The study subjects were divided into two groups, 50 CRF patients and 50 healthy volunteers in age group 15–60 years, and histories of hearing impairment after the occurrence of renal failure were included in the study. All chronic kidney disease (CKD) patients and controls were subjected to hearing assessment using standard pure tone audiometry.

Results: Hearing loss was present in 80% of patients of CRF than in healthy controls. In the CKD group, 40% were diabetics and 60% were non-diabetics, and in the control group, 32% were diabetics and 68% were non-diabetics. In CKD group, 48% suffered from hypertension and in control group 36% suffered from hypertension.

Conclusion: Our study highlights the prevalence of hearing loss in people suffering from chronic renal failure. Early identification can prevent further deterioration of hearing and improve the quality of life in patients suffering from chronic renal failure.

Key words: Chronic kidney disease, Diabetes, Otorhinolaryngologic

INTRODUCTION

Sensorineural hearing impairment has been reported in chronic renal failure (CRF) patients with a prevalence of 20–40%. The etiopathogenetic mechanisms reported included osmotic alteration resulting in loss of hair cells, collapse of the endolymphatic space, edema, and atrophy of specialized auditory cells and in some complications of hemodialysis.[1] Hearing impairment has been reported in patients with CRF. There are also certain anatomic similarities at an ultrastructural level and evidence for similar antigenicity of the cochlea and kidney.[2-4] Multiple shared risk factors for chronic kidney disease (CKD) and hearing loss include age, diabetes, hypertension, and medications that are both ototoxic and nephrotoxic.

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Moreover, in patients with established CKD, multiple risk factors have been hypothesized to cause hearing loss including the use of ototoxic medications, hypertension, and diabetes, particularly in association with hypertension, electrolyte disturbances, and hemodialysis itself.[5-7] Older adults with moderate CKD have a higher prevalence of hearing loss than those of the same age without CKD according to recent studies.[3] Although several causes and prevalence of renal disease-related hearing loss have been proposed the etiology and proportion are still controversial. The exact pathophysiological mechanism underlying the presence of hearing loss among CKD patients is unknown although several potential mechanisms have been hypothesized. The kidney and the stria vascularis of the cochlea share physiological, ultrastructural, and antigenic similarities that could explain the association between CKD and hearing loss.

Aim

This study aims to evaluate the severity of hearing loss at different frequencies in patients of chronic renal failure.

Corresponding Author: B Santhanakrishnakumar,Department of Otorhinolaryngology, Thoothukudi Medical College, Thoothukudi, Tamil Nadu, India. Phone: +91-9894167045. E-mail: drbskkent@gmail.com

MATERIALS AND METHODS

A prospective study was conducted in the Department of Ear Nose and Throat (ENT), Thoothukudi Government Medical College. The study subjects were divided into two groups, 50 CRF patients and 50 healthy volunteers whose age, sex, and confounding factors were matched. Subjects with age group 15–60 years and history of hearing impairment after the occurrence of renal failure were included in the study. Subjects with a history of hearing loss, diabetes, hypertension, ototoxic drugs intake, and noise exposure were excluded from the study. Cases were evaluated in the department of ENT, interviewing using a uniform pro forma containing information on age, sex, gender, and risk factors including diabetes, hypertension, and history of ototoxic drug use. Blood parameters including Hb% blood urea, serum creatinine, and electrolytes were obtained. All CKD patients and controls were subjected to hearing assessment using standard pure tone audiometry at 250, 500, 1000, 2000, 3000, 6000, 7000, and 8000 Hz. An average of the threshold levels of >26 db was considered as abnormal. A hearing loss of 26–40 db was classified as mild, 41–55 db as moderate, 56–70 as moderately severe, 71–90 as severe, and >90 db as profound hearing loss.

RESULTS

The present study was on hearing loss in chronic renal failure patients. Cases are tabulated as regard to their incidence, age of presentation, sex distribution, and pattern of hearing loss. In chronic renal failure patients group, 21 were females and 29 were males. In control group, 24 females and 24 males were participated. Mean age in the group females 48.5 and males 55.9. In our study, 42% was female and 58% was male in CKD group and 48% was female and 52% was male in control group. Mean age in the group females 48.5 and males 55.9.

Stages in the CKD group are classified as one patient in CKD 2nd stage, 12 patients in stage 3, 14 patients in stage 4, and 13 patients in stage 5 CKD Table 1. In CKD group, 80% suffer from hearing loss and 20% have normal hearing. In control group, 12% suffer from hearing loss and 88% have no hearing loss Table 2. Prevalence of hearing loss in the 2nd stage was 2%, hearing loss in the 3rd stage is 24%, the 4th stage was 14%, and hearing loss in CKD 5th stage is 26%. Among the CKD group, 10% had mild hearing loss, 20% had moderate hearing loss Figure 1, 40% had severe hearing loss, and 36% had profound hearing loss. Within the hearing loss group, 60% had high-frequency hearing loss, 30% had mid-frequency hearing loss, and 10% had low-frequency hearing loss Figure 2. In the CKD group,

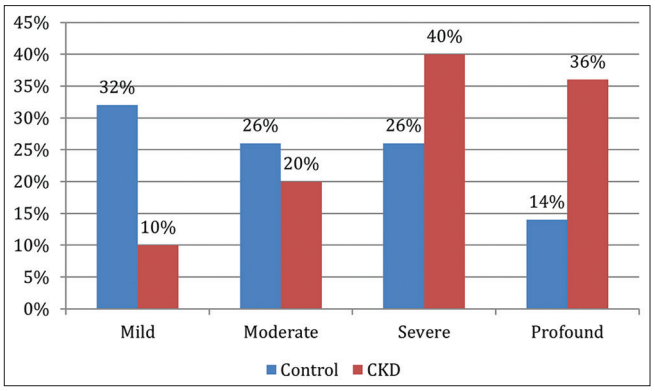

Figure 1: Degree of hearing loss based on pure tone audiometry

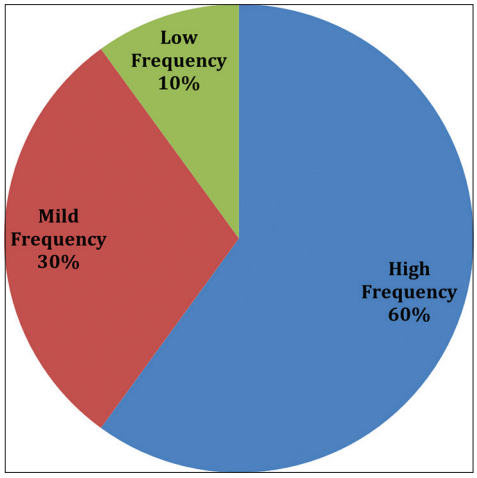

Figure 2: Pattern of hearing loss in chronic kidney disease patients

40% were diabetics and 60% were non-diabetics; in the control group, 32% were diabetics and 68% were non-diabetics. In CKD group, 48% suffered from hypertension and in control group 36% suffered from hypertension.

DISCUSSION

Many different studies conducted here and abroad have demonstrated that quite a few serious ailments can impact our hearing the higher incidence of hearing loss among children and adults with chronic renal failure is well documented in published reports. The pathophysiology between hearing impairment and CKD remains unclear. Over many years', reports were identified link between CRF and hearing loss in patients with rare diseases such as mitochondrial myopathy, lactic acidosis, stroke, Alport syndrome, and Fabry's disease. Untreated hearing loss can have very significant consequences on a person quality of life. People with moderate hearing loss untreated has been found to be affected by anxiety, impaired memory and can be benefitted with hearing aids. The cochlea and

Table 1: Distribution of study patients

Stages of CKD	Number of patients (%)
1	0 (0)
2	1 (2)
3	12 (24)
4	14 (28)
5	13 (26)

CKD: Chronic kidney disease

Table 2: Comparison of hearing loss in study group

Study group	Hearing loss (%)	Normal (%)
CKD	80	20
Control	12	88

CKD: Chronic kidney disease

kidney may have common antigenic similarity between basement membranes of glomeruli and stria vascularis of the inner ear.[8] Several etiological factors have been linked to hearing loss in renal failure.[9,10] Including the use of ototoxic medications, electrolyte imbalances, hypertension, and hemodialysis. A comparison of hearing loss patterns in people with recent and long-standing renal failure will establish the difference between renal failure causing hearing loss and common etiologies causing hearing loss and renal failure. Di Paolo *et al.* indicated a very high incidence of nerve conduction dysfunction in groups of CRF patients.[11] Kochhar *et al.* reported an association between hearing loss and CKD in 27.5% of patients.[12] Hearing loss in CRF patients is related the high sensitivity C-reactive protein, which suggests an inflammatory role in the pathogenesis of hearing loss. Several auditory brainstem response studies of CRF indicate dysfunction of the auditory nerve and pathways. Thus, the auditory nerve may be involved in uremic neuropathy such as peripheral nerves, inflammatory endothelial activation, and dysfunction are some of the underlying causes for the small vessel disease affecting the cochlea and auditory pathway.[13] Samir *et al.*[14] found no correlation between pure tone audiometry findings with serum electrolytes levels. Ototoxic medications including furosemide can affect ionic gradients between the endolymph and perilymph, resulting in edema of the epithelium of the stria vascularis and also by altering the endocochlear potential.[15,16] Qin *et al.* and Gurbanor reported that the characteristic of hearing loss in CKD patients in high-frequency abnormality.[17,18] Prevalence of hearing loss in CKD patients vary from 28% to 77% according to different studies.[19,20] In our study, we observe hearing loss at higher frequencies 60%, mid frequencies 30%, and 10% low-frequency Hz. Gatland *et al.*[21] found 41% hearing impairment in low frequency and 53% in high-frequency range. The higher incidence of bilateral hearing impairment noted in chronic renal failure also indicates electrolytic, osmotic, biochemical, vascular, and immunological changes in the inner ear which leads to severe audiovestibular symptoms and pathology. Bains *et al.* who found that chronic kidney disease patients have a significant bilateral sensorineural hearing loss at all frequencies and more marked in higher frequencies.[22] High-frequency audiometry is a sensitive method for detecting hearing changes in patients with chronic renal failure and can be used to monitor these patients. Our results show a high-frequency hearing loss in patients with renal impairment compared to normal control subjects. Similar results were obtained by Zeigelboim *et al.*, who found a severe high-frequency hearing loss in CRF patients.[23]

CONCLUSION

Hearing loss in chronic renal failure patients does not follow any specific pattern and prevails at high and low frequencies. Patients with chronic renal failure often have multiple comorbidities which make their life miserable. Hearing loss in CKD patients is often not attended well. Our study highlights the prevalence of hearing loss in people suffering from chronic renal failure. Early identification can prevent further deterioration of hearing and improve the quality of life in patients suffering from chronic renal failure.

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Original Article

Blood Agar can be an Effective Alternate Media for Solid Culture of *Mycobacterium tuberculosis* in Resource-poor Settings, a Report from Warangal, India

Sireesha Tanniru[1], Lavanya Poonem[2], Mamatha Padde[2], Father Jyothish[3], Chakrapani Chatla[4], Suryaprakash Chakramahanti[5], Malathi Jojula[6]

[1]Research Scholar, Department of Microbiology, Sri Shivani Collage of Pharmacy, Warangal, Telangana, India, [2]Lab Technician, Department of Microbiology, Sri Shivani Collage of Pharmacy, Warangal, Telangana, India, [3]Father, Karunapuram Care and Treatment Centre for PLHIV, Karunapuram, Warangal, Telangana, India, [4]Director, Novita Health N Tech, Hyderabad, Telangana, India, [5]District TB Control Officer, Warangal, Telangana, India, 6Head, Department of Microbiology, Sri Shivani Collage of Pharmacy, Warangal, Telangana, India

Abstract

Introduction: Tuberculosis (TB) diagnosis is mainly based on clinical features and demonstration of *Mycobacterium tuberculosis* (MTb) under microscopy or culture. Solid culture is considered to be gold standard tool in diagnosing MTb. Preparation of Lowenstein and Jensen (LJ) medium for solid culture is time taking and costly.

Purpose: Our cross-sectional study attempts to identify the utility of blood agar (BA) against LJ as medium for solid culture toward reducing cost and time of procedure.

Materials and Methods: Sputum samples were collected at District TB Center, Warangal, Karunapuram Care and Treatment Center for people living with HIV, and processed at Shivani College of Pharmacy in a biosafety Level II laboratory. Sheep BA, LJ, and Middlebrook 7H9 liquid media were used. Samples were homogenized using N-acetyl L-cysteine (NALC) NaOH method; inoculums prepared and processed in the media, incubated at 37°C, and were observed daily for visible growth through naked eyes. DNAs were extracted from all the colonies from BA and sequence confirmed for MTb. Time taken in the growth of MTb and cost were compared for each media.

Results: Sputum samples from 400 TB suspects were tested which included 250 HIV-negative presumptive TB and 150 HIV-TB coinfected. Of 250 HIV-negative samples, 73 were culture positive in liquid culture, 65 on LJ medium, and 61 on BA medium. Of 150 HIV-TB coinfected cases, it was 40, 35, and 37, respectively. The highest yield of MTb in BA was before 10 days compared to >50 days with LJ medium.

Conclusion: BA can be preferred over LJ medium with equal efficacy for the growth of MTb irrespective of HIV status. Lower cost and shorter incubation period of BA may overweigh LJ medium in resource-limited settings.

Key words: Blood agar, Lowenstein and Jensen media, Liquid culture, *Mycobacterium tuberculosis*, Solid culture, Tuberculosis-HIV coinfection

INTRODUCTION

Tuberculosis (TB) is an infectious disease caused by the bacillus *Mycobacterium tuberculosis* (MTb). It typically not only affects the lungs (pulmonary TB) but can also affect other sites (extrapulmonary TB). TB is one of the major killer public health challenge sacross the world. According to the WHO, in 2015, there were an estimated 10.4 million new (incident) TB cases worldwide, of which 5.9 million (56%) were among men, 3.5 million (34%) among women, and 1.0 million (10%) among children. People living with HIV (PLHIV) accounted for 1.2 million (11%) of all new TB cases.[1] Diagnostic tests for TB include sputum smear microscopy, rapid molecular detection, and culture methods. Globally, the use of rapid molecular tests is increasing, and many countries are phasing out the use of smear microscopy for diagnostic purposes; however, microscopy and culture remain necessary for treatment

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Corresponding Author: Dr. Malathi Jojula,Department of Microbiology, Sri Shivani College of Pharmacy, Mulugu Road, Warangal - 506 002, Telangana, India. Tel.: 0870-3255522, Phone: +91-9849630268. E-mail: Jojulamalathi@yahoo.co.in

monitoring. Despite advances in diagnostics, a considerable proportion of the TB cases reported to the WHO are still clinically diagnosed rather than bacteriologically confirmed. In 2015, 57% of the pulmonary cases reported to the WHO were bacteriologically confirmed.[1]

MTb was first isolated by Robert Koch from freshly crushed pulmonary tubercles after 10 days of incubation using heat-coagulated sheep and beef serum medium in tubes.[2] In 1903, MTb isolates were recovered using blood agar (BA),[3] but this was superseded by an egg-based agar which, by the 1920s, became the standard recommended medium for primary isolation of MTb because of the ease in sterilizing the egg-based medium.[4] The culture of MTb is done using solid culture method or liquid culture method. Solid culture is considered to be a gold standard tool in diagnosing MTb. Lowenstein and Jensen (LJ) medium is the most commonly used medium for solid culture. However; many media such as BA and nutrient agar (NA) are available as alternate options to LJ medium.

Drancourt[5] in the report termed as "end of dogma" reported the incidental growth of MTb colonies on BA which led to further research on BA for culture of MTb.[6,7] In addition, the utility of BA against Middlebrook 7H10/11 agar or LJ medium was demonstrated in susceptibility testing of MTb.[8]

In this study, we evaluated the utility of BA against LJ medium, NA, and Middlebrook 7H10 for susceptibility testing of both in terms of cost-effectiveness and time taken for reporting in a resource-limited setting in Warangal, Telangana State of India.

MATERIALS AND METHODS

In this cross-sectional study, 400 sputum samples were collected during 2013 October–2016 June from District TB Center (DTC) and Karunapuram Care and Treatment Center (KCTC), Warangal, India. Early morning sputum samples from 250 presumptive TB patients from DTC and 150 PLHIV/ADIS visiting KCTC with TB symptoms were transported to Sri Shivani College of Pharmacy (SSCP), Warangal, for further processing. In the biosafety Level II laboratory at SSCP, the sputum samples were processed for microscopy with Zeil–Nelson staining and were treated with culture with various media such as sheep BA, LJ, and Middlebrook 7H9 media. Samples were homogenized using NALC NaOH method; the inoculums were prepared and processed in the media, incubated at 37°C. Visible growth was observed on daily basis, and the visible colonies on BA medium were sequenced by DNA extraction method for confirmation of the presence of MTb. Time taken in the growth of the colonies in each of the media was noted.

Data analysis was performed using IBM SPSS v20 package. Descriptive analysis method was employed in generating the outcomes of the study.

RESULTS

There were 40% of females in the study population and 60% of males [Table 1]. The mean age of the study population was 43.4 years. However, the mean age of HIV-positive subset was 34.5 years while that of HIV-negative subset was 46.7 years and the subset with unknown HIV status was 55.9 years. The age of the study population ranged from 9 years to 90 years. The mean age of female subset of the study population was 41.6 years while that of male subset was 44.7 years [Table 1 and Figures 1 and 2].

When analyzed for the utility of the LJ medium and BA against the gold standard test, i.e., liquid culture, the sensitivity, specificity, positive predictive value, and negative predictive value of both the tests were almost similar [Table 2].

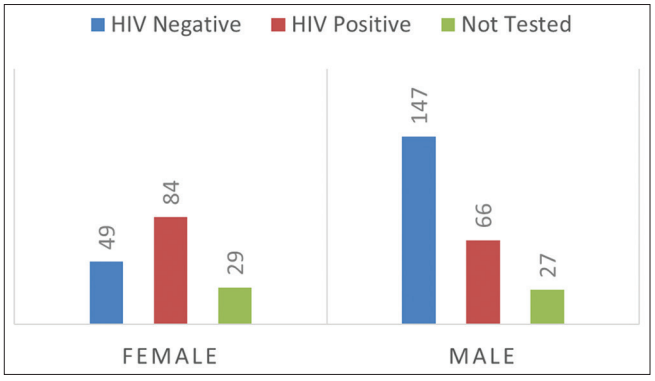

Figure 1: Distribution of study population by gender and HIV status

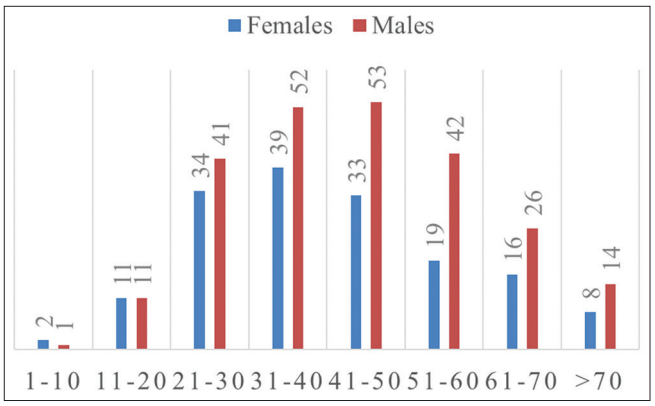

Figure 2: Distribution of study population by gender and age group

Table 1: Demographic profile of the study population by gender, age group, and HIV status

Gender	HIV negative	HIV positive	HIV status unknown	Total (%)
Female	49	84	29	162 (40.3)
Male	147	66	27	240 (59.7)
Total	196	150	56	402 (100)
Age group	**Females**	**Males**	**Total (%)**	
1–10	2	1	3 (0.7)	
11–20	11	11	22 (5.5	
21–30	34	41	75 (18.7)	
31–40	39	52	91 (22.6)	
41–50	33	53	86 (21.4)	
51–60	19	42	61 (15.2)	
61–70	16	26	42 (10.4)	
>70	8	14	22 (5.5)	
Total	162	240	402	
Age group	**HIV negative**	**HIV positive**	**HIV status unknown**	**Total**
1–10	0	3		3
11–20	9	13		22
21–30	31	43	1	75
31–40	32	51	8	91
41–50	40	33	13	86
51–60	45	5	11	61
61–70	26	2	14	42
>70	13	0	9	22
Total	196	150	56	402
Mean age	**HIV negative (years)**	**HIV positive (years)**	**HIV status unknown (years)**	**Grand total (years)**
Females	46.1	33.8	56.5	41.6
Males	47.0	35.3	55.2	44.7
Overall	46.7	34.5	55.9	43.4

The growth of MTb in either medium (BA or LJ medium) did not differ by the HIV status of the patient [Table 3 and Figures 1 and 3].

When analyzed for the duration for observing the growth of MTb in the media, it was seen that 100% of possible growth of MTb has been achieved within 10 days of incubation [Figure 4]. While it took 21 days to achieve 100% of possible positive culture in liquid culture medium, the last possible positive growth in LJ medium went up to >50 days. This clearly demonstrates the benefit of BA over LJ medium for the achievement of the early growth of MTb.

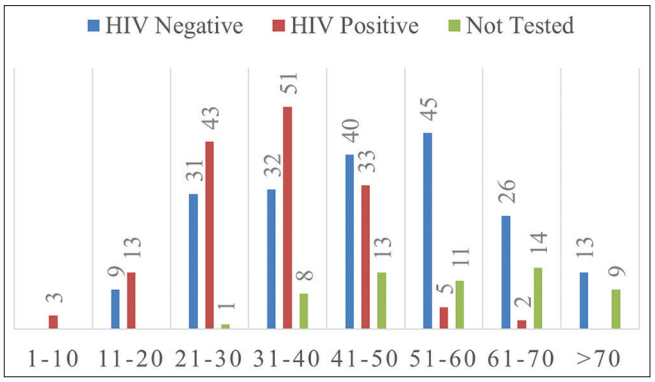

Figure 3: Distribution of study population by HIV status and age group

DISCUSSION

In our study, it is observed that the highest MTb growth yield is achieved by liquid culture in comparison to both LJ media as well as BA medium in identifying 15% more positive MTb growth as expected from a gold standard test. However, when compared between BA and LJ media, the BA medium seems to achieve equal amount of growth of MTb in 1/5 duration taken by LJ medium which is very critical for early diagnosis of MTb in settings where liquid culture cannot be undertaken. Especially among HIV-TB coinfected cases, reduction in time for achieving positive growth (maximum of 10 days in BA compared to >50 days in LJ medium) can have major implications in early diagnosis, early initiation of treatment, and thus saving the lives of PLHIV. Similar studies across the world have shown that the mean time to detect MTb from smear-positive pulmonary sample on LJ slants has been found to be in the range of 19–24 days by most workers.[9-13]

The utility of BA media for the recovery of MTb was reported early in the last century but has been removed from contemporary microbiology manuals.[11,14] However,

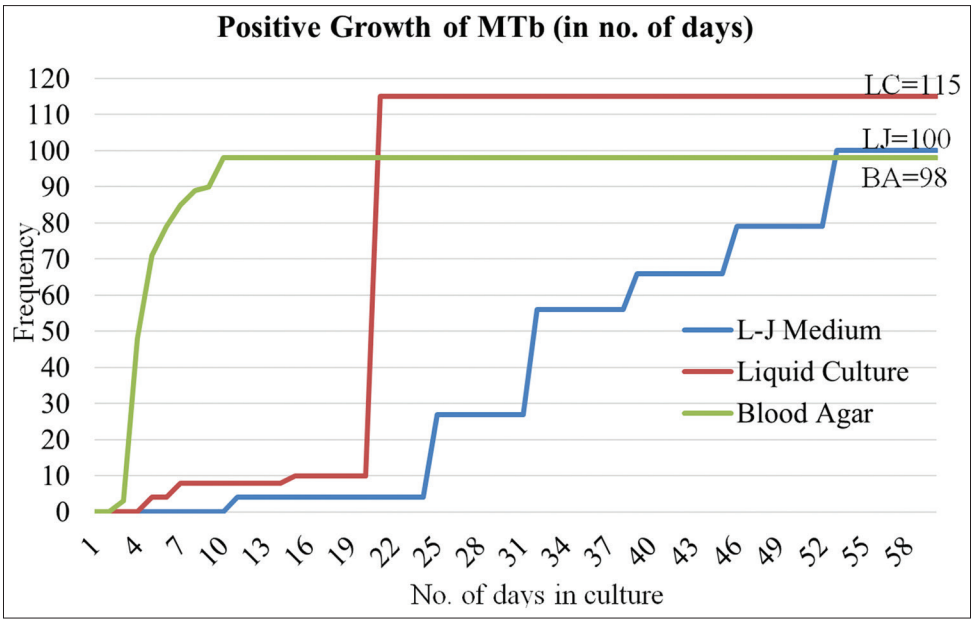

Figure 4: Growth of *Mycobacterium tuberculosis* in culture by LJ and BA media against liquid culture

Table 2: Utility of LJ medium and blood agar medium against the liquid culture

		Liquid culture		
		Growth positive	No growth	Total
L-J medium	Growth positive	97	3	100
	No growth	18	284	302
	Total	115	287	402
Sensitivity		84.3%		
Specificity		99.0%		
Positive predictive value		97.0%		
Negative predictive value		94.0%		
Blood agar	Growth positive	96	2	98
	No growth	19	285	304
	Total	115	287	402
Sensitivity		83.5%		
Specificity		99.3%		
Positive predictive value		98.0%		
Negative predictive value		93.8%		

LJ: Lowenstein and Jensen

Table 3: Differential growth of MTb in blood agar and LJ medium

HIV Status	Growth positive	No growth	Total
LJ medium			
Negative	65	131	196
Positive	35	115	150
Unknown	0	56	56
Grand total	100	302	402
Blood agar			
Negative	61	135	196
Positive	35	115	150
Unknown	2	54	56
Grand total	98	304	402

MTb: *Mycobacterium tuberculosis*, LJ: Lowenstein and Jensen

there have been recent reports, including one from Mathur *et al.* in 2009 which isolated MTb clinical isolates from pulmonary smear-positive patients and suggested that the sensitivity of BA media was equivalent to LJ media.[6]

In our study, MTb growth in BA medium was well comparable to the growth achieved in liquid culture using Middlebrook 7H9 medium with even early achievement of positive culture which helps the laboratories in choosing a right medium when liquid culture facility is not available. The sensitivity and specificity of both BA and LJ media against the gold standard liquid culture are nearly equal which establishes BA as an alternative to LJ medium for solid culture of MTb. We observed that the growth of MTb in either medium (BA or LJ medium) did not differ by the HIV status of the patient.

CONCLUSION

We conclude that BA can be a good alternative medium to LJ medium for achieving the growth of MTb. especially among HIV-TB coinfected cases, reduction in time for achieving positive growth can have major implications in early diagnosis, early initiation of treatment, thus saving the lives of PLHIV, and hence can be preferred over LJ medium in the absence of facility for liquid culture.

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Original Article

A Randomized Clinical Trial of Photocoagulation Compared with Lifestyle Modification in the Management of First and Second Degree Hemorrhoids

R C Thampan[1], V Abdulla[2], C P Musthafa[2]

[1]Associate Professor, Department of General Surgery, Malabar Medical College Hospital and Research Centre, Modakkallur, Kerala, India, [2]Professor, Department of General Surgery, Kannur Medical College, Anjarakandy, Kannur, Kerala, India

Abstract

Purpose: Purpose of study is to compare the effectiveness of photocoagulation with the life style modification. There is much controversy regarding the role of photocoagulation(infrared coagulation) in the management of first and second degree haemorrhoids. According to some well known text books, it is considered to be an easy way of treating early haemorrhoids while others are doubtfull about the effectiveness.

Material and Methods: We have included 200 cases of first and second degree haemorrhoids with out any other anorectal disease for this study.They are divided in to two study groups (A and B) of 100 patients each. Group A patients is treated with IRC (infrared coagulation) and Group B patients with life style modification only.

Result: Statistical analysis of the results is very interesting. IRC is not better than simple life style modification! This is enough for the management of first and second degree haemorrhoids.

Conclusion: Strict life style modification is enough for the management of early haemorrhoids.

Key words: Anal cushion, Hemorrhoids, Infrared coagulation, Lifestyle, Photocoagulation

INTRODUCTION

Epidemiological studies conducted by Johanson *et al.* estimates around 10 million people in the USA are having hemorrhoids (prevalence rate 4.4%).[1] These shows the magnitudes of the problem in western civilization. Whites are more affected than black due to the high socioeconomic status of the former. Increasing age, constipation, pregnancy, and dietary habits influence the etiopathogenesis.

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According to the modern view, hemorrhoid is defined as symptomatic or disrupted anal cushion.[2] Normally anal cushion functions as airtight seal, and it maintains fine continence.[3] It is folded and has uneven mucosa and submucosa above the dentate line. Submucosa consists of vascular (venous plexus and arteriovenous communication), muscular, elastic, and connective tissues (supporting elements).[4] In the prolapsed anal cushion venous stasis occurs due to impaired venous return. Straining at stool produces increases in venous pressure and engorgement of anal cushion while hard stool consistency and aging process are said to be responsible for the fragmentation of supporting structures which lead to the loss of elasticity of it. This leads to the failure of retraction of anal cushion following defecation. Any drugs or a procedure which can revert the changes in the anal cushions is the basis of management.

Corresponding Author: Dr. R C Thampan, Department of General Surgery,Malabar Medical College Hospital and Research Centre, Modakkallur, Atholi, Kozhikode - 673 315,Kerala, India.Phone: +91-9349113541. E-mail: rcthampan@hotmail.com

Hemorrhoids are classified into four types based on clinical prolapse.[5]

- First degree: Internal hemorrhoids bulge into anus without prolapse.
- Second degree: Internal hemorrhoids prolapsed during defecation and spontaneously reduce.
- Third degree: Internal hemorrhoid prolapse, requiring manual reduction.
- Fourth degree: Internal hemorrhoid prolapsed and irreducible.

Diagnosis is made on physical examination.

For the first and second degree hemorrhoids conservative management, sclerotherapy,[6] cryosurgery, laser,[7] rubber band ligation,[8,9] and photo coagulation[10] are advocated while for 3rd and 4th degree hemorrhoid minimal invasive and invasive procedures are done (stapler hemorrhoidectomy,[11] hemorrhoidal artery ligation using Doppler,[12,13] open[14] and closed hemorrhoidectomy[15]).

In this study, we have used infrared coagulation (IRC) (photocoagulation).[16] IRC is used by general practitioners, specialist, subspecialist and doctors of other systems for the management of piles since the operability of this instrument are simple. Redfield Corporation of USA and Lumatec of Germany are manufacturing and marketing it (infrared coagulator) all over the world. Major drawback of this technique is the cost of the device. It varies from 3,00,00 to 6,00,000 (INR) depending on the brand. It consists of one base unit with programmed timer card, handgun with a trigger and light probe with contact tip. Infrared rays are produced by the tungsten - halogen lamp located in the gun is directed to the required site, at the apex of each hemorrhoid by contact tip of the light probe. Heat produced by infrared radiation coagulates protein which leads to eschar formation and scarring at the site.[17] It creates fixing of hemorrhoids. This leads cessation of blood flow to pile mass and size shrinks. The time of exposure can be adjusted (5–3 s) using the timer [Figure 1].

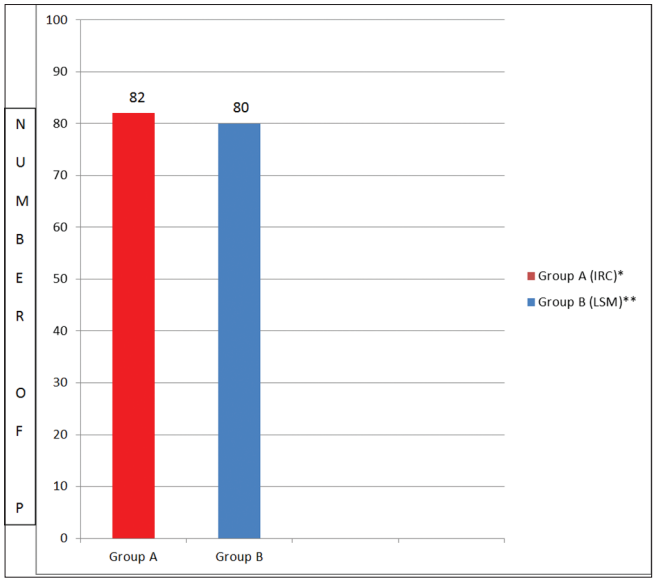

Figure 1: Bar diagram showing percentage of final analysis

Role of lifestyle modification in reverting the pathological changes in the early hemorrhoids is not fully understood. However, fiber-rich diet, fluids, cessation of smoking, alcohol abstinence, and avoiding straining contributes much to the healing of disrupted anal cushion.[18] Fiber with plenty of water makes the stool very soft, this shortens gut transit time and minimizes the straining leads to a reduction in venous stasis and trauma to the anal cushion. Blood supply to the mucosa and submucosa is enhanced by stopping smoking. All these factors retard fragmentation of connective tissue which supports the anal cushion.

MATERIALS AND METHODS

This study was done for a period of 5 years from 2010 to 2015. 200 cases of male adult patients in the age group of 25–45 years are selected for this study [Table 1].

Inclusion Criteria

Male adult patients in the age group of 25–45 years with complaints of itching, bleeding, discharge, or mass per annum which reduces spontaneously is considered for this study. This age group and male sex ensure homogeneity patient population by comparatively having normal anorectal anatomy in all cases. Moreover, functional status of internal sphincter and external sphincter is assessed by evaluating the resting anal pressure (normal value: 40–80 mm hg) and squeeze pressure (normal value: Above 40–80 mm hg), respectively. Patients with abnormal resting and squeeze pressure are excluded from this study.

Exclusion Criteria

Patients with painful hemorrhoids, acutely thrombosed hemorrhoids, anal fissure, fistula-in-ano, anal stenosis, colitis, rectal prolapse, fecal incontinence, and inability to understand the instructions are excluded from this study

They are randomly divided into two groups of 100 each (Group A and Group B). Group A patients are given photocoagulation and Group B patients are treated with lifestyle modification.

IRC is performed in the left lateral position (Sims). They were given bisacodyl 10 mg at bedtime on the previous day. A lubricated slotted proctoscope is introduced gently in the anal canal and lower rectum. The entire quadrant is properly inspected by rotating it. Each internal hemorrhoid

is identified, and IRC is applied at the apex of it at four points above dentate line. The timer is adjusted to 2 s in all cases. A white spot is visible at the site of contact due to coagulation necrosis. Maximum time taken for this procedure is 10 min. It is done as an office procedure. There is no need for rest, and they can have routine activities. Patients acceptance is very high with this procedure. Exposure is repeated after 6 weeks. These patients are evaluated after 3 months for the result. 82 patients had a complete cure and 18 failures.

Group B patients are given counseling regarding the importance of lifestyle modification. No drugs are given. They are strictly advised to adhere to the following instruction for 3 months.

1. Take three glass of water (one glass = 200 ml) 3 h prior or after meals.
2. Avoid straining and prolonged sitting on the toilet.
3. Use abundant vegetables (high fiber diet).
4. Avoid smoking and alcohol.
5. 30 min brisk walking daily.

Selection of patient to this group was taken after considering their social and educational background. Each patient is given counseling for 30 min before enrolling for the study.

A self-reported symptom questionnaire was answered and clinical examination performed after 3 months. 80 patients were fully relieved of the symptoms.

Statistical Analysis

Results were recorded. Observations obtained were analyzed using appropriate statistical methods. $P < 0.05$ was accepted as significant. Groups were compared by X^2 homogeneity test at 5% probability. Results showing normal distribution were given as mean with standard deviation.

RESULT

A total of 242 patients were eligible for enrolling this study, out of which 210 were considered and randomized for the evaluation. Of this 32 were excluded and 20 does not meet the inclusion criteria because of other anorectal diseases and 12 were not willing to participate in the study [Figure 1]. In Group A the cure rate is 82% and in Group B is 80% [Figure 2].

Data analysis gives us some interesting results [Table 2]. In Group B, it is found that in the age group 25–30 years failure rate is high (13 failure out of 15 patients). On further review, it is found that patients of 25–30 years from Group B had not followed the counseling properly. On extrapolating the data, it can be concluded that lifestyle modification is better than IRC. In young adults who are

Table 1: Distribution of cases according to age

Age group (years)	*n*=200
25–30	30
30–35	50
35–40	62
40–45	58

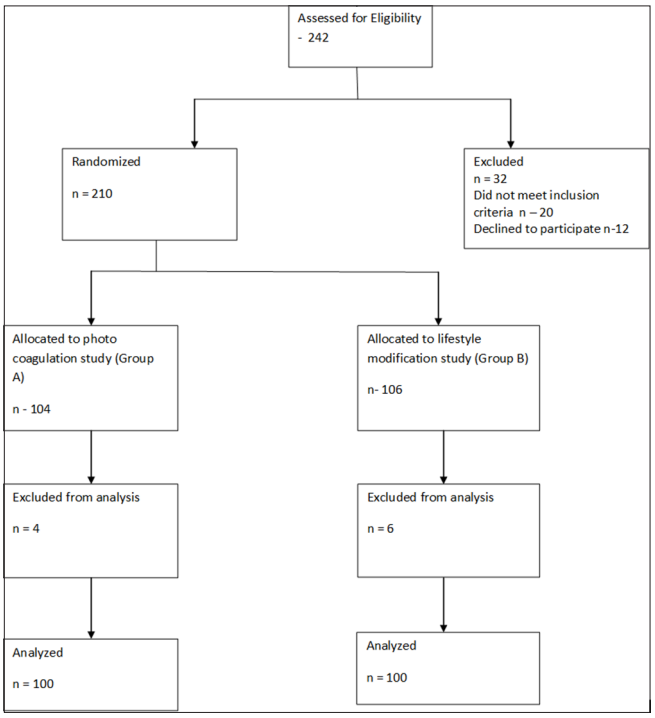

Figure 2: Consort flow diagram for study

Table 2: Comparative analysis of study groups

Age group	Group A			Group B		
	n	Symptom-free (*n*)	Failure (*n*)		Symptom-free (*n*)	Failure (*n*)
25–30 years	15	12 (80)	3 (20)	15	2 (13.33)	13 (86.66)
31–35 years	25	21 (84)	4 (16)	25	23 (92)	2 (8)
36–40 years	31	25 (80.64)	6 (19.35)	31	28 (90.32)	3 (9.67)
41–45 years	29	24 (82.76)	5 (17.24)	29	27 (93.10)	2 (6.89)
	100	82 (82)	18 (18)	100	80 (80)	20 (20)

Values in parenthesis are percentages, Chi-square 0.1583 *P*=999922, Chi-square 49.0933 *P*<0.00001

reluctant to follow lifestyle modification, IRC is considered as a better alternate option.

DISCUSSION

Various modalities and innovations are employed in the management of hemorrhoids. Starting from fiber diet, drugs,[19] heat and cold energy,[20] laser, electric current, radiofrequency ablation, ligating the arteries, mucosal excision, excision, and ligation, etc., are employed according to clinical assessment and expertise of surgeon. Pathophysiologically hemorrhoid plexus is not a disease; it is an essential part of anorectal anatomy. Its role in fine continence (act like airtight seal after defecation) is well established. Around 15% of anal resting pressure is contributed by anal cushion. Only when the individual develops symptoms such as bleeding, discharge, itching, and prolapsed is it considered as a disease. Here the aim of the treatment is to restore the integrity of anal cushion by lowering pressure in the venous plexus which prevents further fragmentation and moreover it enhances the regeneration of connective tissues also.[21] By this size of the pile mass shrinks and symptoms disappears. A segment of patients who had undergone open hemorrhoidectomy complained of mild form of fecal incontinence due to the damage of anal cushion. In this scenario role of lifestyle modification is important. This study confirms that lifestyle modification gives almost the same results as photocoagulation. Hence, this procedure should not be emphasized in the management of the first and second degree hemorrhoids. Manufacturers of IRC instruments, some hospitals and doctors show over enthusiasm to this procedure. The unholy nexus must be controlled by policy makers by implementing effective legislation. The financial loss to the society is very huge due to unwanted healthcare spending. Now healthcare cost has become very expensive worldwide. In US 17% of the annual gross domestic product is spent every year for health.[22] Variation in healthcare provision is not explained by disease, patient's preferences or the dictates of evidence-based practices are frequently cited as evidence of unnecessary or wasteful resource utilization.[23,24] Our study results are an eye-opener to the health policy makers to highlight the importance of lifestyle modification by patients education through multiple awareness programs in the management of hemorrhoids.

CONCLUSION

Since there is no financial burden to the patient, lifestyle modification has important role in the management of the first and second degree hemorrhoid compared to the office procedures like IRC. Patient education and doctors role are very important here. High claims by the manufacturers are doubtful since patient education gives almost the same result.

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Original Article

Role of Dynamic Magnetic Resonance Imaging in Pelviureteric Junction Obstruction Management

T Chandru[1], R Neelakandan[2], K Natarajan[3]

[1]Associate Professor, Department of Urology, Sri Ramachandra Medical Centre, Chennai, Tamil Nadu, India, [2]Assistant Professor, Department of Urology, Sri Ramachandra Medical Centre, Chennai, Tamil Nadu, India, [3]Professor, Department of Urology, Sri Ramachandra Medical Centre, Chennai, Tamil Nadu, India

Abstract

Introduction: Pelviureteric Junction obstruction (PUJO) is one of the most common causes of hydronephrosis and continues to present a challenge to radiologists and urologists, who are unable to accurately predict which patient will benefit from surgery. Dynamic contrast enhanced magnetic resonance (MR) urography has several advantages in the evaluation of PUJO, because, it combines both anatomic and functional information in a single test that does not use ionizing radiation. We have studied whether dynamic contrast enhanced MR imaging (MRI) urography could replace isotope renogram in the functional evaluation of pelviureteric junction obstruction.

Materials and Methods: Symptomatic patients diagnosed to have pelviureteric junction obstruction based on ultrasonogram, intravenous urogram, and computed tomogram were included in the study. Isotope renogram and dynamic MR urography were done in all patients. T ½, time-activity curves, glomerular filtration rate (GFR), and split renal function calculated from isotope renogram. MR findings were evaluated with regard to the GFR and intrarenal transit time of the contrast. Time-intensity curve is then plotted using inbuilt software. Statistical software was used to analyze the data. The findings of isotope renogram and dynamic MRI (DMRI) were correlated individually with the surgical finding and accuracy was compared. Linear regression analysis was performed to correlate the imaging and surgical procedure done.

Results: The calculation of GFR by isotope renogram, showed good correlation with that of DMRI with correlation coefficient 0.93. DMRI was able to pick up the functional status of the renal unit accurately. DMRI had no false positivity, with 20 patients of 21, deemed for pyeloplasty and 11 of 12, deemed for nephrectomy. Correlating with the surgery, the DMRI had a X_2.0.000, with $P = 1.000$, having no statistical significance for the difference compared with surgery.Isotope renogram has a $P = 0.4279$ with respect to surgery, again showing no statistical significance for the difference in number. Comparing DMRI with isotope renogram, DMRI has a significant $P = 0.00$ with good negative predictive value. Thus, it outscores isotope renogram in sensitivity.

Conclusion: Using DMRI, analysis of renal function is similar to renal scintigraphy. DMRI techniques can be combined to establish a one-stop imaging examination that can replace different imaging methods used for morphological, etiological, and functional evaluation of pelviureteric junction obstruction.

Key words: Dynamic magnetic resonance urography, Isotope renogram, Pelviureteric junction obstruction

INTRODUCTION

Congenital ureteropelvic junction obstruction most often results from intrinsic disease. A frequently found defect is the presence of an aperistaltic segment of the ureter. In these cases, histopathologic studies reveal that the spiral musculature normally present has been replaced by abnormal longitudinal muscle bundles or fibrous tissue. This results in failure to develop a normal peristaltic wave for the propagation of urine from the renal pelvis to the ureter. Traditional imaging tests have emphasized detection and grading of hydronephrosis with sonography and determination of renal function and obstruction with scintigraphy. The classification of the kidney as obstructed does not predict progressive loss of function and does not identify which patient will benefit from surgery.[1,2]

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Corresponding Author: Dr. T Chandru, Department of Urology, E-2 Urology Out Patients Department, Sri Ramachandra Medical Centre, Chennai, Tamil Nadu, India.Mobile: +91-9500076471. E-mail: surgchandru@yahoo.co.in

Studies have shown that dynamic contrast enhanced magnetic resonance (MR) urography has several advantages in the evaluation of pelviureteric junction obstruction, because, it combines both anatomic and functional information in a single test that does not use ionizing radiation[3] [Figure 1]. MR imaging (MRI) has progressed significantly in recent years because of the development of both hardware and software that are used to generate high-resolution images. Aim of our study was to find out the extent of pelviureteric junction obstruction (PUJO), functional potential of the kidney and to determine if dynamic contrast enhanced MR urography could replace isotope renogram in the functional evaluation of pelviureteric junction obstruction.

MATERIALS AND METHODS

Symptomatic patients diagnosed to have pelviureteric junction obstruction based on ultrasonogram (USG), intravenous urogram, and computed tomogram were included in the study. 45 patients were included in the study. Informed consent was obtained from all the patients. All

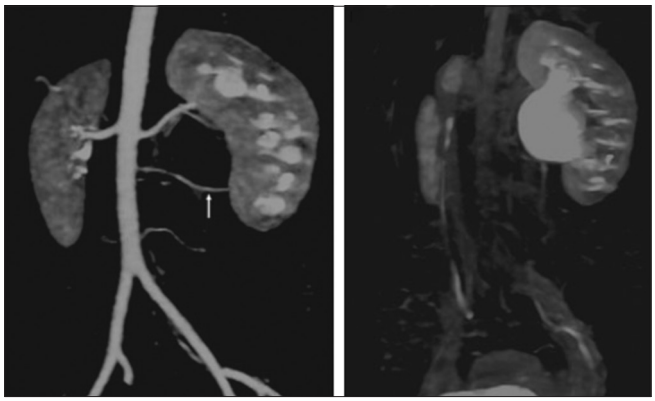

Figure 1: Magnetic resonance angiography showing a vessel crossing at pelviureteric junction

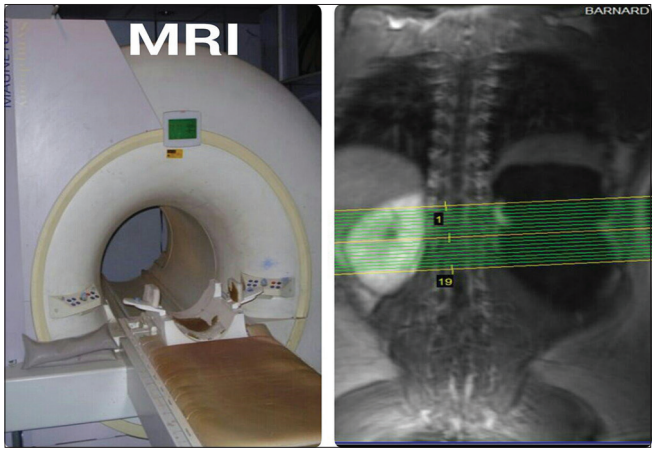

Figure 2: Magnetic resonance imaging

these patients were investigated with isotope renogram and subsequently, subjected to dynamic MRI (DMRI). Patients with structural defects such as duplex system and horseshoe kidney, patients with B/L PUJO previous surgery, patients with pacemaker and metallic implants, and claustrophobic patients were excluded from the study. Diuretic renogram study was performed and results evaluated according to current recommendations.[4] Scintigraphy followed by intravenous (IV) injection of 12 μci/kg technetium-99 m mercaptoacetyltriglycine-3, with a minimum activity of 150 μci. A large field of view gamma camera equipped with low energy all-purpose collimator was used. The window was placed over the photopeak of the tracer and was opened by 20%. A 128 × 128 image matrix was used. Data were collected in 12 s time frames. The scintigraphic examination lasted 40 min, and furosemide was administered along with the tracer (F+0). Region of interests (ROI_s) was placed by an experienced technician who prepares the imaging material for medical evaluation. Time-activity curves were generated from the background corrected count rates [Figure 2].

All MRI was conducted on a 1.5 T Siemens scanner, with the use of a phased-array torso surface coil. The procedure started by obtaining a coronal localizer (scout image) to identify the abdominal aorta and the origins of the renal arteries, followed by a coronal T2 weighted sequence for the whole of both kidneys and six coronal fast spoiled gradient (FSPGR) images at the center of the kidney. Then, DMRI was performed by IV injection with 0.1 mmol/kg gadodiamide (Gd-DTPA) at 3 ml/s, and the coronal scan series was repeated every 30 s for 5 min. Furosemide (0.3 mg/kg) was injected along with the contrast to assess the contrast medium excretion in response to the diuretic. The total amount of contrast was 20–30 ml according to body weight. Finally, excretory MR urography was performed using contrast enhanced T1 weighted 3 D-FSPGR acquisition at 7–10 min after gadodiamide injection to visualize the collecting system and the ureter. The DMRI curve was generated by drawing a ROI, over the kidney, excluding the renal pelvis, using functional software that merges all series, a curve resembling that from isotope renography was obtained [Figure 3]. The DMRI curve plots the enhancement units versus time, and from the curve, the time to peak, the relative maximum units of enhancement and the response to diuretic were obtained. The mean post-processing time was 60 (45–70) min.

In isotope renogram the activity and the T ½ of renal signal decay after furosemide administration of each kidney was categorized as being normal, equivocal, or obstructed, with normal kidney having T ½ of <10 min, equivocal kidneys

had a T ½ between 10 and 20 min, and obstructed kidneys have a T ½ more than 20 min. Glomerular filtration rate (GFR) and split renal function calculated.

MR urography findings were evaluated with regard to the GFR and intrarenal transit time of the contrast material. Renal transit time[5,6] is used to classify the kidney as being - normal: <245 s, Equivocal: >245–<490 s, and obstructed: >490 s. Time-intensity curve is then plotted using inbuilt software. If there is a gross discrepancy between the isotope renogram and MR findings, then, to assess the salvageability of that renal unit, percutaneous nephrostomy (PCN) to be done and PCN fluid analysis to be done after 1 month. Planned procedure, either pyeloplasty or nephrectomy to be decided based on salvageability results of PCN fluid analyst. Statistical software (SPSS. Version 17) was used to analyze the data. The findings from isotope renogram and DMRI were correlated individually with the surgical finding. The accuracy of isotope renogram and DMRI was individually determined and compared. Linear regression analysis was performed to correlate the imaging and surgical procedure.

RESULTS

Total number of patients studied 45. The patients ranged in age from 17 to 45 years, with a mean age of 31.21 years. Two patients had pyonephrosis, hence PCN done, one patient had renal calculus and hence excluded from our study. In all the 42 patients, evaluated with isotope renogram, the intrarenal transit of radiotracer was calculated. Total GFR calculated and split renal functions deduced. With isotope renogram, no information was obtained about the renal parenchymal thickness. DMRI post-contrast T1 weighted coronal images and spoiled gradient were taken. ROI was plotted and time-intensity curves obtained with the help of inbuilt software.

Out of the 42 cases, 9 cases were conservatively managed, as they had good split renal function and unobstructed flow pattern in time-intensity curves. These cases are under follow-up. 33 cases were taken up for surgical intervention. The mean GFR as measured by isotope renogram was 22.5 with a standard deviation of 4.2. The mean GFR as estimated by DMRI was 23.8 with a standard deviation of 3.1. The calculation of GFR by isotope renogram showed good correlation with that of DMRI with correlation coefficient 0.93 [Figure 4]. There was an error in the calculation of GFR using isotope renogram, due to the evaluation of counts using gamma camera. The isotope study and the DMRI were done by the same technician, respectively, for all the cases.

Three patients had a discrepancy of GFR between isotope renogram and DMRI. To decide on the surgical modality to

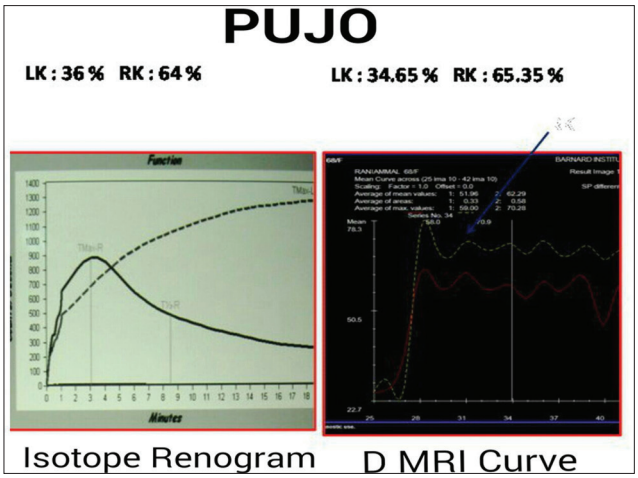

Figure 3: Isotope renogram and dynamic magnetic resonance imaging curves in pelviureteric junction obstruction

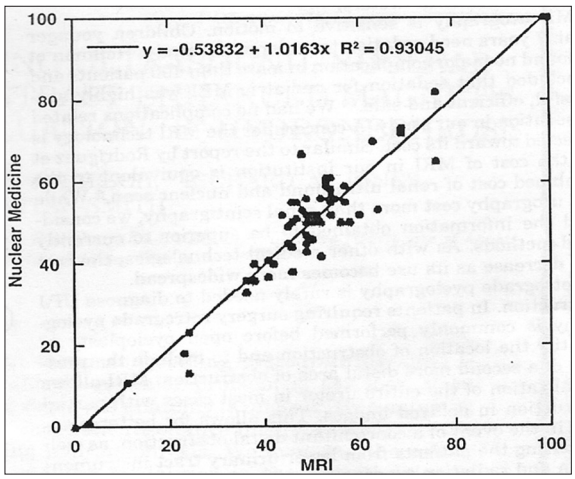

Figure 4: Glomerular filtration rate correlation by isotope renogram and dynamic magnetic resonance imaging

be undertaken, PCN was done on that renal unit. PCN fluid analysis was done after 4 weeks of PCN drainage. All the three patients had a poor quality of PCN fluid, and these patients were deemed to have irreparable renal tubular damage and hence, surgical decision to proceed with laparoscopic nephrectomy was planned. Accuracy of isotope renogram compared to surgery, accurate in 30 patients (90.9%), non-accurate in 3 patients (9.1%). Thus, in these cases, isotope renogram has overestimated the GFR. Two patients could not be evaluated using MRI one due to motion artifact, one due to incidental stone. Out of 33 patients with PUJO, DMRI accurately detected the obstruction in 31 patients (93.93%) and non-conclusive in 2 patients (6.07%). Of 33 patients taken up for surgical intervention, 12 (36.36%) of the patient underwent laparoscopic nephrectomy, while, 21 (63.63%) of the patient underwent pyeloplasty.

Renal transit time detected by either imaging was correlated with each other. 7 Patients had normal transit time and

were conservatively managed with regular follow-up. 2 Patients had renal transit time fallen in the equivocal group. These patients were selected for follow-up. Remaining 33 patients were deemed obstructed and taken up for surgical intervention.

The ureter distal to the obstruction was well visualized in 22 out of 33 patients in MRI, sensitivity 66%. This obviates the role of bulb ureterogram to look for patency or to rule out the double obstruction. This allows for better planning in the event of a concomitant distal obstruction as well as sparing the patient from lower urinary tract instrumentation and radiation exposure. While anatomic imaging of the ureter was not possible with isotope renogram.

DMRI was able to pick up the functional status of the renal unit accurately. DMRI had no false positivity, with 20 patients of 21, deemed for pyeloplasty and 11 of 12, deemed for nephrectomy. Correlating with the surgery, the DMRI had a X_2.0.000, with $P = 1.000$, having no statistical significance for the difference compared with surgery. Isotope renogram has a $P = 0.4279$ with respect to surgery, again showing no statistical significance for the difference in number. Comparing DMRI with isotope renogram, DMRI has a significant $P = 0.00$ with good negative predictive value. Thus, it outscores isotope renogram in sensitivity [Table 1]. DMRI sensitivity: 100%, specificity: 66%, positive predictive value: 96.7%, and negative predictive value: 100%.

DISCUSSION

Standardized protocols for obtaining dynamic radionuclide studies have been proposed.[4,5] However, in practice, local protocols are often followed which causes problems in the comparison of results between different centers. Even the details of how these (GFR, T ½, time to peak activity) parameters are calculated can affect the classification of the drainage pattern.[6] Despite its widespread use, diuretic renal scintigraphy is not a reference standard for the diagnosis of obstruction, since the presence or absence of obstruction cannot be distinguished with this modality in at least 15% of the dilated system.[7,8] Renal scintigraphy estimates overall and differential renal function. Difficulties in the evaluation of patients with poor renal function (serum creatinine >4 mg/dl) and patients with capacious collecting systems are the main limitations of these techniques, along with exposure to ionizing radiation.[9,10,12] In addition, operator variability in the determination of ROI can affect the accuracy of the differential renal function.[7,12] In this study, the calculation of relative renal function by MR urography revealed an excellent correlation with renal scintigraphy ($r^2 = 0.93$). Differences between the MR urography and nuclear estimation of split renal function occurred in cases with significant parenchyma loss or massive dilatation of collecting system. In these instances, MR urography was thought to be more accurate because its greater contrast and spatial resolution allowed us to separate the kidney from background and dilated collecting systems. MR urography was able to detect focal cortical scarring in addition to diffuse parenchyma loss. The advantages of MRI are high soft tissue characterization, capability of direct multiplanar and three-dimensional reformatting, use of non-ionizing radiation, and non-nephrotoxic contrast medium. The disadvantages are motion artifact, cost, and long post image processing time. Similar to the report by Rodríguez *et al.*,[11] the cost of MRI is equivalent to the combined cost of renal USG and nuclear scan.

Table 1: Accuracy of imaging isotope renogram and dynamic MRI

Imaging	Proposed procedure		X^2	*P* value
	Pyeloplasty	Nephrectomy		
Isotope renogram	24	9	0.629	0.4279
DMRI	20	11	0.000	1.000
Surgery done	21	12		

MRI: Magnetic resonance imaging, DMRI: Dynamic magnetic resonance imaging

CONCLUSION

Using DMRI, analysis of renal function is similar to renal scintigraphy, because of superior spatial and contrast resolution. MR urography may be more sensitive than renal scintigraphy in analyzing poorly functioning system. While MR urography, costs more than renal scintigraphy, the information obtained is superior to currently used methods. As with other medical technologies, the cost will decrease as its use becomes more widespread.

DMRI techniques can be combined to establish a one-stop imaging examination that can replace different imaging methods used for morphological, etiological, and functional evaluation of PUJO.

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Original Article

Hematocrit Spectrum in Dengue: A Prospective Study

Anagha A Joshi, B N Divyashree, B R Gayathri

Senior Pathologist, Department of Pathology, Kempegowda Institute of Medical Sciences, Research Centre, Bengaluru, Karnataka, India

Abstract

Aim: Dengue occurs in epidemics in India, severe forms are lethal. Hematocrit aids in prognosis and effective management of dengue. Our study is to assess the impact of age and gender on hematocrit values, and the effect of varying hematocrit values as a prognostic indicator in dengue.

Materials and Methods: A total of 132 serologically proven dengue cases were analyzed over 1 month in November 2016, along with hematocrit and relevant hematology data (obtained from analyzer).

Results: The age range was 5 months to 65 years with male preponderance. Hematocrit ranged from 20.8% to 59.6% (mean 40.2%). Male showed lowest and highest hematocrit.

55% had hematocrit >40%, 27%, had >45%, 58% showed hemocrit above reference range for age and sex, 8% showed hematocrit more than/equal to 20% above the reference range. A higher proportion of males showed increased hematocrit overall. 56% with increased hematocrit over reference range were associated with thrombocytopenia (<1 lakh/cumm).

A comparison of varying hematocrit values with reference range adjusted for age and sex showed a high proportion of false positive in males and false negative in children and females.

Conclusion: Hematocrit is an effective, simple diagnostic and prognostic tool and helps in the early appropriate management of dengue; however, guidelines need to be established to increase its accuracy.

Key words: Dengue, Hematocrit, Prognosis

INTRODUCTION

Dengue is an arboviral infection dengue virus (DENV 1–4) transmitted by aedes mosquito.[1] It shows a wide range of clinical presentation from asymptomatic cases to undifferentiated fever, dengue hemorrhagic fever (DHF)/ dengue shock syndrome (DSS) or non-severe and severe dengue.[1-3] Most cases of dengue are self-limited; however, severe dengue has high mortality if not diagnosed and managed early during the disease.[4] The overall incidence of dengue is 100 million with 2,50,000 cases with DHF and 25,000 deaths per year.[5] The incidence has increased manifold in India due to many causes.[5,6] The diagnosis and management (mostly supportive fluid therapy)[7] are based on clinical and lab parameters with certain lab tests aiding in the early forecast of severe dengue.[8] While serological tests (detection of nonstructural protein 1 [NS1] antigen, immunoglobulin (Ig) M, and IgG antibodies) aid in diagnosis of dengue,[4,7,9] simple, cost-effective, easy tests such as hematocrit and platelet counts have great utility in resource-poor healthcare systems in India[9] for predicting onset of severe dengue.

It is known that there is a rise in hematocrit (due to vascular leakage) before the onset of severe dengue/DHF-DSS. Clinical identification of vascular leakage is difficult and delayed until shock develops.[7] Many studies have focused on hematocrit changes, especially the increase in hematocrit in dengue; however, its utility has not been fully exploited as there are no clear-cut guidelines for hemoconcentration[10] with different studies putting forth varying cutoff values such as >40%,[6,11,12] >45%,[2,5,13-15] and >2% over reference range for age and sex[3] or with other values.[16-19] Some studies have used the more accurate cutoff of a rise in

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Corresponding Author: Dr. B N Divyashree, Flat No. 202, First Floor, Siri Presidency, Maruthi Layout, Bangalore - 560 061, Karnataka, India. Phone: +91-7406729046/+91-9110213154. E-mail: divyashree234@gmail.com

hematocrit of ≥20% above baseline for age and sex.[20-22] A few have suggested more than 10% above baseline value.[23]

Hematocrit rises 3–5 days after fever just before the critical period which lasts for 1–3 days[7,9] the test is most accurate if properly timed test values are considered.[21]

Our study explores the impact of age and gender and varying thresholds of hematocrit[16,24-27] and is a step toward increasing the sensitivity of this lab parameter to aid in better management of dengue cases.[9,21,22]

The aim of our study was

- To analysis of hematocrit values, its comparison with other studies of same and different cutoff values.
- To analyze the factors which influence its accuracy (age and sex) and draw parallels with clinical risk factors in other studies.
- To analyze the impact of these on diagnosis and prognosis in dengue.

MATERIALS AND METHODS

This is a prospective study done on 132 patients with dengue positive serology in hematology section of Kempegowda Institute of Medical Sciences Hospital and Research Centre, Bengaluru, over a 1 month period in November 2016.

All patients with serological confirmation of dengue (NS1/IgM and/or IgG positivity by rapid card method) tested for hematocrit were included in the study.

The patients with concomitant infections such as Malaria and Typhoid along with dengue were excluded from the study.

The hematocrit values along with relevant data (obtained from automated hematology analyzer-Sysmex 1800i) were analyzed. The patient's unique hospital identity number were noted with age and sex. The results of dengue tests were retrieved from microbiology register.

Ethical Committee Clearance

The patients' anonymity was maintained as only the unique hospital identification number of the patient was recorded for the purpose of study along with age and sex. The data available of dengue patients was analyzed. This study was approved by the Hospital Ethical Committee.

RESULTS

In a total of 132 dengue serology positive cases analyzed, the age of patients ranged from 5 months to 65 years with the majority in 12–25 years group. The average age was 32 years [Table 1].

The gender distribution showed a slight male predominance with male:female ratio of 1.2:1 [Table 2].

An analysis of the hematocrit spectrum revealed a range of 20.8–59.6% with an average value of 40.2% in our study. The hematocrit distribution is shown in Table 3. The maximum number of cases were noted in the range of 35–40%. 75/132 (57%) had a hematocrit ≥40%, whereas 37/132 (28%) had a hematocrit ≥45%.

A high hematocrit adjusted for gender in adults and pediatric cases are shown in Tables 4 and 5. This shows an increased proportion of pediatric cases and males with higher hematocrit.

A point of significance that our data showed was that the lowest and highest hematocrit in both adults and pediatric group was seen in males as compared to females of the respective group [Table 6].

An analysis of hematocrit rise over 20% above reference range for age and sex[25] (>45% for pediatric age

Table 1: Adult versus pediatric age pattern distribution

*Age group (years)	Number of cases (*n*) (%)
Adult	86 (65)
Pediatric	46 (35)

*Adult>14 years, pediatric≤14 years

Table 2: Gender wise distribution

Gender	Number of cases (132) (%)
Males	73 (55)
Females	59 (45)

Table 3: Hematocrit distribution

Hematocrit range (%)	Number of cases (132) (%)
20–25	01 (01)
≥25–30	06 (04)
≥30–35	08 (06)
≥35–40	42 (32)
≥40–45	38 (29)
≥45–50	23 (17)
≥50–55	10 (08)
≥55–60	04 (03)

Table 4: *Pediatric age and gender distribution of increased hematocrit

Gender	*n* (%)
Male	20/22 (91)
Female	19/24 (79)
Total pediatric	39/46 (85)

*Pediatric reference range for hematocrit>38%

(≤14 years), >48% for adult females, and >54% for adult males) is shown in Tables 7 and 8.

A analysis was also done with cutoff hematocrits of >40% for age and sex, and of >45% similarly to check their impact as a prognosticator [Table 9].

A analysis was also done on the number of cases with a rise in hematocrit ≥20% over reference range for age and sex[25] and compared with hematocrit over range for age and sex[25] associated with thrombocytopenia ≤1.0 lakhs/cumm as both these are some of the criteria suggestive of onset of dengue hemorrhagic fever/DSS and is shown in Table 11.

Platelet count <1.0 lakhs/cumm is one of the criteria for diagnosis of DHF/DSS. It may be noted that the hematocrit over reference range most correlates with platelet counts of <1.0 lakhs/cumm on comparing with other hematocrit cutoffs (>40% and >45%) as seen in Tables 10 and 11.

DISCUSSION

The study shows a maximum number of cases in young age in accordance with other studies[2,16] with a slight male predominance,[2,12] probably due to occupational exposure and increased recreational activity in men.[28]

Table 5: *Adult gender distribution of increased hematocrit

Gender	*n* (%)
Males	25/51 (49)
Females	13/35 (37)
Total adults	38/86 (44)

*Adult reference range for hematocrit - Males >, Females >

Table 6: Age and gender distribution for highest and lowest hematocrit values

Gender	Age group			
	Adults >14 years		Pediatric ≤14 years	
	Low hematocrit	High hematocrit	Low hematocrit	High hematocrit
Males	26.6	59.6	20.8	51.0
Females	29.7	48.0	27.6	43.3

Table 7: Age distribution of hematocrit rise >20% over reference range

Age group	Number of cases (*n*) (%)
+Adults	06 (07)
++Pediatric	05 (11)

+It included 5 of 51 adult males and 1 of 35 adult females, ++there were 4 of 22 pediatric males and 1 of 24 pediatric females

The hematocrit range was 20.8–59.6%, the average being 40.2%. Studies in adults by Kailash *et al.* and Geethika *et al.* showed ranges of 20.3–51.5% (mean 39.8%) and 25.4–53.2% (mean 38.7%), respectively. Gurdeep *et al.* observed a mean of 35.5% in children.

Our study showed 55% of cases with hematocrit >40% in accordance with others,[12] few recorded a lower proportion of cases.[6,11] We had 27% of cases with hematocrit >45% in accordance with others,[13,15] some showed a lower proportion of cases.[2,5] 8% of cases had hematocrit ≥20% above reference range for age and sex,[25] in accordance

Table 8: Gender distribution of hematocrit rise >20%, above reference range

Gender	*n* (%)
Males	09 (12)
Females	02 (03)
Total	11 (08)

Table 9: Hematocrit distribution (>40% and>45%)

Hematocrit >40%		
Hematocrit >45%		
Group	*n* (%)	*n* (%)
Adults		
Male	40/51 (78)	25/51 (49)
Female	14/35 (40)	05/35 (14)
Pediatric		
Male	11/22 (50)	05/22 (23)
Female	08/24 (33)	01/24 (04)
Total		
Adults	54/86 (63)	30/86 (42)
Pediatric	19/46 (41)	06/46 (13)
Total		
Male	51/73 (70)	30/73 (41)
Female	22/59 (37)	06/59 (10)
Overall	73/132 (55)	36/132 (27)

Table 10: Comparison of different hematocrit cutoff values

Hematocrit values			
Group	>40 (%)	>45 (%)	>Reference range for age and sex (*n*) (%)
Adults			
Male	78	49	25 (49)
Female	40	14	13 (37)
Pediatric			
Male	50	23	20 (91)
Female	33	04	19 (79)
Total			
Adults	63	42	38 (44)
Pediatrics	41	13	39 (85)
Total			
Male	70	41	45 (59)
Female	37	10	32 (53)
Overall	55	27	77/132 (58)

Table 11: Comparison of hematocrit ≥20% above reference range

Group	Hematocrit reference range for age and sex with thrombocytopenia, *n* (%)	
	Hematocrit ≥201%	Hematocrit >reference range with platelet count ≤1.0 lakhs/cumm
Adults		
Male	05/51 (10)	24/51 (47)
Female	01/35 (03)	13/35 (35)
Pediatric		
Male	04/22 (18)	18/22 (82)
Female	01/24 (04)	18/24 (75)
Total		
Adults	06/86 (07)	38/86 (43)
Pediatrics	05/46 (11)	36/46 (78)
Total		
Male	09/73 (12)	42/73 (58)
Female	02/59 (03)	31/59 (53)
Overall	11/132 (08)	74/132 (56)

with others,[5] few showed a higher proportion of cases.[1] The increase in hematocrit in dengue is due to hemoconcentration attributed to plasma leakage induced by cytokine-mediated increase in vascular permeability and damage to vascular endothelium.[26]

Cytokines are produced by DENV infected monocytes, B lymphocytes, and mast cells.[6,21] Endothelial cell dysfunction by virus also leads to increased capillary permeability.[29] This phase of plasma leakage is the critical phase, the onset of which (marked by circulatory and perfusion changes leading to shock) can be predicted with the rise of hematocrit 10–15% above the baseline value. This is considered a significant predictor of severe disease.[17,23,29]

A few studies have noted that there is a higher proportion of cases with increased hematocrit in severe than non-severe dengue[10,18] and also the mean hematocrit values are higher in severe compared to non-severe dengue.[8]

The key issue in the management of dengue lies in the identification of onset of critical phase[17] by continuous monitoring of hematocrit to check for the rise in hematocrit above baseline/reference values. The reference values vary at different ages and between the genders. Thus, accurate hematocrit values obtained from correct interpretation of the result extrapolated against the particular age and gender plays a crucial role in diagnosing precisely the progression to severe dengue and thus treatment of these cases.[22] However, the use of uniform hematocrit values across all ages, both sexes and non-standardization of cutoff values could impact management of dengue adversely.

Our study showed that there was a higher proportion of cases with increased hematocrit in males than in females in accordance with few studies.[24] This was observed across all hematocrit threshold values.

On comparison with adults, children showed a higher proportion of cases in the group where hematocrit was above reference range for the age and sex, and where it was ≥20% above the reference range.

A fewer studies have observed that there is greater vascular permeability in children[8,26,27] and the risk of severe dengue is higher in children and develops faster than adults.[4,6,21,25,26,30,31] While a few studies have noted increased severity in males, this has been disputed by others.[8]

Our study also reveals that the lowest and highest hematocrit values were noted in males (both in adults and children). These observations emphasize the importance of using age and sex-matched hematocrit values[7] for accurate prediction of progression to severe dengue and minimizing error in the diagnosis (attributed to false positives and negatives) which could limit the utility of this test.

Our study noted a higher proportion of false positives in males on comparing with the values obtained by reference range and a higher proportion of false negatives in children and females.

A few studies have observed that timing and frequency of monitoring also influence the accuracy of hematocrit test in diagnosis.[17,21] Daily testing from 3rd day routinely, but 4th–6th hourly for 2 days in DHF has been suggested by few[17] while others recommend testing before and after fluid therapy and every 6th–12th hourly.[21]

A study was done on single, random hematocrit value as baseline value could not be obtained and uniformity in testing was not implemented.

A stable hematocrit over 24 h is considered criteria for discharge by few studies.[9,17]

Limitations of our study reflects pitfalls in the utility of hematocrit in dengue[7,11,20,32] and includes

- Non-availability of baseline and timed hematocrit values.
- Increased prevalence of anemia in India.
- Blunting of hemoconcentration due to fluid therapy.
- Fall in hematocrit due to significant blood loss due to dengue.
- Concomitant conditions causing increased (malignancies) or decreased (other causes of hemorrhage) hematocrit.
- Other limitations exclusive to a study was the relatively small sample size and lack of other similar studies to conform our conclusions.

CONCLUSION

Hematocrit is a highly effective, simple, diagnostic, and prognostic tool in dengue if utilized correctly. It also gives therapeutic guidance by aiding inappropriate selection of fluids.

However, proper guidelines need to be enforced with regard to timing, frequency and threshold values to prevent overdiagnosis of non-severe and underdiagnosis of severe cases which could impact morbidity and mortality in dengue.

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Original Article

A Study of Cardiac Involvement in Organophosphorus Poisoning

Rangaswamy[1], M S Bharath[2]

[1]Associate Professor, Department of General Medicine, Mysore Medical College and Research Institute, Mysore, Karnataka India, [2]Senior Resident, Department of General Medicine, Mysore Medical College and Research Institute, Mysore, Karnataka India

Abstract

Background and Objective: Organophosphorous (OP) poisoning frequently causes ill-health and death, particularly in developing countries. Not many clinical studies have been done to demonstrate the myocardial injury in OP poisoning through assessment of the cardiac biochemical markers. Hence, this is an attempt to study the myocardial injury in OP poisoning and to determine how it affects the outcome.

Materials and Methods: Patients with history of OP poison consumption who fulfil the inclusion and exclusion criteria, getting admitted. **Method of Collecting Data**: A total of 50 cases of OP poisoning meeting inclusion criteria of the present study have been studied.

Results: In this study, which included 50 patients of OP poisoning cases, tachycardia (30%) was the most common clinical sign seen, followed by bradycardia (20%), hypertension (16%), and hypotension (10%). The most common electrocardiographic abnormality seen was ST elevation (32%), followed by sinus tachycardia (30%), Q-T prolongation (24%), and sinus bradycardia (20%). Raised cardiac enzymes (troponin T and creatinine phosphokinase-MB [CK-MB]) were seen in 5 (10%) patients on the day 3. The levels of troponin T and CK-MB were elevated in patients with respiratory failure compared to non-failure ones. Patients who went into respiratory failure showed a mean troponin T and CK-MB levels of 0.0895 ± 0.01 ng/ml and 34.65 ± IU/L, respectively. The mean troponin T and CK-MB level in a patient who died were 0.1142 ± ng/ml and 39.14 ± IU/L, respectively.

Conclusion: OP compound can directly cause myocardial injury during the acute phase. Cardiac complications of OP poisoning can be life threatening and are not fully appreciated. The level of cardiac enzymes correlated well with the severity of poisoning and prognosis, suggesting its use as a prognostic indicator of OP poisoning. Vigilant monitoring of the patients for prominent cardiac manifestations such as QT prolongation, VT or VF, and prompt treatment can save many patients.

Key words: Bradycardia, Creatinine phosphokinase-MB, Electrocardiographic changes, Organophosphorus poisoning, Tachycardia, Troponin T

INTRODUCTION

Organophosphorus (OP) pesticide self-poisoning is estimated to kill around 200,000 people each year, largely in the Asia-Pacific region. This predominantly occurs in rural communities and is often an impulsive act comparable to self -poisoning with medication in the west; the critical difference being the 10–20% case fatality rate (compared to 0.3% in Britain for example).[1] OP poisoning is also of great interest to developed countries vulnerable to terrorist or military attack with nerve agents.[1]

The principal pharmacological action of all OPs is the inhibition of acetylcholinesterase; most patients die from cardiorespiratory failure. However, thereis much variation in the timing of onset and clinical features depending on the particular OP involved. OP poisoning has high inpatient mortality and many patients have cardiorespiratory arrests after admission (38% of patients requiring intubation in one study).[2]Cardiac complications are common and can be fatal if not diagnosed and treated early. The exact pathogenesis of cardiac complications has not yet been defined. A few important studies have been carried out both in India and abroad to study the cardiac complications and

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Corresponding Author: Dr. M S Bharath, Department of General Medicine, K. R. Hospital, Mysore Medical College and Research Institute, Irwin Road, Mysore, Karnataka, India. Phone: +91-8971241203. E-mail: bharathms7@yahoo.com

electrocardiographic (ECG) changes in OP poisoning. The current study was carried out to understand the cardiac manifestations of OP poisoning with special reference to cardiac enzymes.[3]

The cardiac manifestations occur in a majority of affected patients and may range from innocuous ECG manifestations, such as sinus tachycardia, to life-threatening complications including cardiogenic pulmonary edema. Repolarization abnormalities, including ST-segment elevation and T-wave inversion as well as prolongation of the QTc interval, are among the most frequent cardiac manifestations of acute OP poisoning. The mechanisms of OP-induced cardiac toxicity are not fully understood. Aside from direct toxic effects of the OP compounds, an increase in sympathetic and/or parasympathetic activity, hypoxemia, acidosis, and electrolyte abnormalities are thought to be involved in myocardial damage associated with OP poisoning. The reported prevalence of various ECG changes in OP compound is 89.1%.[3]

Both sympathetic and parasympathetic overactivities have been shown to cause myocardial damage.[4] As early as 1974, Yasue *et al.*[5] postulated that parasympathetic overactivity plays a major role in coronary artery spasm, and later, Horio *et al.*[6] induced coronary artery spasm in adult humans with healthy coronary arteries after intracoronary injection of acetylcholine. In a series of 168 cases of OP poisoning reported by Kiss and Fazekas,[7] five had a transient picture of myocardial infarction. Diffuse myocardial damage was found at necropsy in two cases of malathion poisoning (an old-generation OP).[8]

The extent, frequency, and pathogenesis of the cardiac toxicity from OP compounds have not been clearly defined. A study conducted by Kathi *et al.*[3] over a three year period of cardiac complication following organophosphate poisoning; 37 patients, 62.5% (23/37) developed cardiac complication, of which 29.7% (11/37) had ECG changes suggestive of myocardial damage (ST-T changes); the mortality rate was 8.1% (3/37).

CP Dalvi *et al.*[9] studied the correlation of ECG changes in OP poisoning with its prognosis. Abnormal ST-T changes and progressive fall in voltage and/or low voltage were the most common ECG changes encountered. These occurred significantly more often in patients with moderate or severe poisoning ($P < 0.001$). The 17 patients (5 moderate and 12 severe) with a combination of these ECG abnormalities required higher doses of atropine (mean 30 mg), and in the 12 who survived, the ECG took longer (mean 5.5 days) to normalize (despite normal clinical recovery rate) as compared to other cases. All fatal cases in the study had both these ECG changes.

Jian-dong *et al.*[10] studied the dynamic changes of cardiac enzymes and the acute poisoning with OP poisoning in the Department of Emergency, Sichuan Provincial People's Hospital. Fasting serum level of troponin T and cardiac enzymes (creatinine phosphokinase-MB [CK-MB], CK, aspartate aminotransferase, and lactic dehydrogenase) in 92 patients with acute OP poisoning (AOPP) were measured after poisoning 1, 2, 3, 5, and 7 days and were measured 1 time in normal control group as well. There was an increase of different levels in troponin T and cardiac enzymes along with the degree of AOPP. They concluded that the level of cardiac troponin T and cardiac enzymes in patients with AOPP may be as useful markers of degree of poisoning and prognosis.

Ya-ying *et al.*[11] conducted a study at the People's Hospital of Yingshang, Anhui. They studied the applied value of serum cardiac troponin T (cTnT) for diagnosing myocardial lesion in the AOPP. The serum cTnT and CK-MB were significantly higher than that in control group and increased with the degree of poisoning. They concluded that the level of serum cTnT increases significantly with the serious degree of AOPP and was sensitive marker of myocardial injury.

Aims and Objectives

The aims of this study are as follows:

1. To study prevalence and predictors of outcomes of myocardial injury with troponin T and CK-MB as biomarkers in OP poisoning.
2. To correlate the myocardial injury with the clinical severity and outcome in OP poisoning.

MATERIALS AND METHODS

We prospectively studied a series of 50 patients admitted with a history of OP compound consumption. History was taken, general physical examination and a detailed systemic examination was done. Routine blood investigations were sent. Patients are classified into three grades using "Paradeniya OP poisoning scale." Changes in ECG were monitored, and serum CK-MBand troponin T levels were measured at admission and repeated after 3 days and at discharge. Troponin T levels ≥0.10 ng/ml and CK-MB levels ≥40 U/L were considered as statistically significant. The analysis of the data was done using appropriate statistical methods.

Method of Collection of Specimens and Processing

Inclusion criteria

All symptomatic patients having ingested OP compound with mild, moderate, and severe OP poisoning were included in the study.

Table 1: Distribution of patients according to their age group (*n*=50)

Bio-social characteristics	*n* (%)
Age (in years)	
<30	22 (44.0)
30–39	16 (32.0)
≥40	12 (24.0)
Mean±SD	33.06±13.41
Range	19–85

SD: Standard deviation

Table 2: Distribution of patients according to the clinic al features

Clinical sign	*n* (%)
Tachycardia	15 (30.0)
Bradycardia	10 (20.0)
Hypertension	8 (16.0)
Hypotension	5 (10.0)

The most common clinical finding in patients was tachycardia (30%) followed by bradycardia (20%). Hypertension was seen in 8 (16%) patients an d 5 (10%) showed hypotension

Table 3: Distribution of patients according to their ECG changes (*n*=50)

Characteristics	*n* (%)
STE levation	16 (32.0)
Sinus tachycardia	15 (30.0)
QT prolongation	12 (24.0)
Sinus bradycardia	10 (20.0)

Most common ECG finding was ST elevation (32%), Sinus tachyc ardia (30%) and QT prolongation (24%). ECG: Electrocardiographic

Table 4: Distribution of patients according to their trop-T changes (*n*=50)

Trop-T positivity (>0.1 ng/ml)	*n* (%)
Day 1	0 (0.0)
Day 3	5 (10.0)
Discharge	0 (0.0)

Table 5: Distribution of patients according to their CK-MB changes (*n*=50)

CK-MB positivity (>40 U/L)	*n* (%)
Day 1	0 (0.0)
Da y 3	5 (10.0)
Discharge	0 (0.0)

Markers of cardiac markers, troponin T and CK-MB were seen in 5 cases (10%). There was no evidence of raised enzymes in these 5 patients at admission or discharge. CK-MB: Creatinine phosphokinase-MB

Exclusion criteria

The following criteria were excluded from the study:

1. Patients who have ingested other substance in addition to OP.
2. Patients who are known to have pre-existing heart disease such as rheumatic heart disease and ischemic heart disease.
3. Patients who are hypertensives.
4. Patients who are chronic alcoholics.
5. Patients with chronic kidney disease.

Statistical Analysis

Data were entered into Microsoft Excel and analyses were done using the Statistical Package for Social Sciences (SPSS) for Windows software (version 18.0; SPSS Inc, Chicago). Descriptive statistics such as mean and standard deviation for continuous variables and frequency and percentage for categorical variables were determined. The Chi-square test and Fisher's exact test (when appropriate) were used to show the associations between predictor and outcome variables. The level of significance was set at 0.05.

RESULTS

In this study which included 50 patients of OP poisoning, 66% were males and 34% were females. Majority of the patients were in the age group of <30 years, which constituted 44% of the study population. The severe poisoning group predominantly had an older population with a mean age group of 64 ± 15 years, when compared to mild (33.16 ± 10.84 years) and moderate (31.63 ± 10.17 years). Tachycardia seen in 30% of the patients was the most common finding, followed by bradycardia (20%), hypertension (16%), and hypotension (10%). ST elevation (34%) was the most common abnormality seen in ECG, followed by sinus tachycardia (30%), Q-T prolongation (24%), and bradycardia (20%). Q-T prolongation was associated with 47% of patients with respiratory failure and 71.42% of patients with death which was higher than patients without respiratory failure (3.7%) and survivors (16.27%). Positive cardiac enzymes were seen only in 10% of the patient, but all the patients in this group developed respiratory failure. The mean troponin T and CK-MB levels (0.1142 ± 0.06 ng/ml and 39.14 ± 8.23 U/L) were higher for patients who died when compared to the survivors. The similar picture was seen in patients who went into respiratory failure (troponin T 0.0895 ± 0.01 ng/ml and 34.65 ± 11.66 U/L) when compared to those without respiratory failure.

DISCUSSION

In this study, 50 patients of OP poisoning with cardiac manifestation of the poisoning were studied.

In this study, patient in the age group ranging from 19 years to 85 years were included with a mean age of 33.06 ± 13.41

Table 6: Association of markers of myocardial injury with respiratory failure (*n*=50)

Markers	No respiratory Failure (*n*=27)	Respiratory Failure (*n*=23)	*P*
CK-MB at day 3			
Positive	0	5	0.011
Negative	27	18	
Trop-T at day 3			
Positive	0	5	0.011
Negative	27	18	
ST elevation			
Present	9	7	0.827
Absent	18	16	
QT prolongation			
Present	1	11	<0.0001
Absent	26	12	

All 5 patients who had a positive CK-MB on 3rd day developed res piratory failure, 18 of 45 patients (40%) with CK-MB negative developed respiratory failure.
CK-MB: Creatinine phosphokinase-MB

Table 7: Association of markers of myocardial injury with mortality (*n*=50)

Markers	No mortality (*n*=43)	Mortality (*n*=7)	*P*
CK-MB at day 3			
Positive	4	1	0.684
Negative	39	6	
Trop-T at day 3			
Positive	4	1	0.684
Negative	39	6	
ST elevation			
Present	13	3	0.507
Absent	30	4	
QT prolongation			
Present	7	5	0.002
Absent	36	2	

CK-MB: Creatinine phosphokinase-MB

Table 8: Association of duration of ICU stay with mean Troponin T levels and CK-MB levels on day 3

Duration of ICU stay	Mean troponin T level (ng/ml) ± SD	Mean CK-MB level (U/L) ± SD
<7 days	0.0438 ± 0.02	27.13 ± 9.68
>7 days	0.0957 ± 0.07	34.07 ± 10.51

SD: Standard deviation, CK-MB: Creatinine phosphokinase-MB

[Table 1]. Tachycardia (30%) was the most common clinical sign seen in the present study [Table 2]. Bradycardia which is an expected finding in OP poisoning was seen in 20% of the patients. Bradycardia was seen in all the 3 cases of severe poisoning, 6 of 22 (27%) cases of moderate poisoning, and 1 (4%) case of mild poisoning. Hence, bradycardia can be considered as an indicator of the severe degree of poisoning. Blood pressure changes in the form of hypertension (systolic blood pressure [BP] ≥140 and/or diastolic BP ≥90 mmHg) and hypotension (systolic BP ≤90 mmHg) were seen in 8 (16%) and 5 (10%) patients, respectively. Three patients who developed hypotension did not recover and died after a prolonged intensive care unit (ICU) stay [Table 3].[3]

In the current study, abnormal ECG was noted in 22 cases. The most common abnormality found was ST elevation (≥2 mm above the isoelectric line), which was found in 16 patients (32%), followed by sinus tachycardia in 15 patients (30%) and Q-T prolongation (Q-Tc ≥0.42 s in males and ≥0.43 s in females) in 12 patients (24%). Sinus bradycardia was found in 10 cases (20%) [Table 4].

Q-T interval prolongation was associated with 11 of 23 (47%) patients who developed respiratory failure and needed mechanical ventilator as compared to 1 of 26 patients (3.7%) without respiratory failure ($P < 0.0001$). Unlike Q-T interval, ST segment did not show any statistically significant relationship with the outcome ($P = 0.827$ for respiratory failure and $P = 0.507$ for mortality).

Markers of Myocardial Injury

In the present study, cardiac enzymes (troponin T and CK-MB) which are used as an indicator of cardiac injury were positive (troponin T ≥0.1 ng/ml and CK-MB ≥40 U/L) in 5 of 50 patients (10%) (mean value of 0.196 ± 0.03 ng/ml and 52.4 ± 6.84 U/L for troponin T and CK-MB, respectively) on the day 3 of admission [Tables 4 and 5]. All the patients who showed enzyme positivity also had ST-segment elevation on ECG, both of which reverted back at the time of discharge suggesting a transient ischemic process as described by Kiss and Fazekas.[8]

All the 5 patients who showed raised cardiac enzymes developed respiratory failure, and 18 of 27 patients (66%) with normal cardiac enzymes developed respiratory failure ($P = 0.011$). Indicating that patients with raised cardiac enzymes have a higher chance of developing respiratory failure.

Cardiac enzymes were raised 1 of 25 (4%) patients in mild, 3 of 22 (13.6%) patients in moderate, and 1 of 3 (33.33%) patients in severe poisoning. Hence, raised cardiac enzymes were most commonly seen in severe poisoning; however, this relationship was not statistically significant ($P = 0.722$). Of the 5 patients who had raised cardiac enzymes, 1 died. This was also found not to have statistical significance ($P = 0.684$).

The mean troponin-T levels in mild, moderate, and severe group were 0.0412 ± 0.04, 0.0833 ± 0.05, and 0.0886 ± 0.01 ng/ml, respectively. Similarly, the CK-MB levels were 24.04 ± 7.86, 36.40 ± 8.95, and 38.88 ± 4.04 U/L in mild, moderate, and severe cases,

respectively. As can be seen, the troponin T and CK-MB showed increasing levels with increasing severity of poisoning. This trend was also seen in the study conducted by Jian-dong *et al*.[9]

The mean troponin T and CK-MB value also showed a higher value in patients who died when compared to patients who survived. The mean value in a patient who died was 0.1142 ± 0.06 ng/ml and CK-MB was 39.14 ± 8.23 U/L which was higher than the levels seen in survivors (troponin T-0.0565 ± 0.04 ng/ml and CK-MB 28.34 ± 10.056 U/L) [Table 6].

Thus, the higher troponin T and CK-MB values were associated with a higher incidence of mortality and respiratory failure, hence suggesting its use as a prognostic indicator [Table 7].

It was also seen that in patients who developed respiratory failure, higher titers of cardiac enzyme was associated with increased duration of ICU stay. In this study, the mean troponin T and CK-MB levels in patients with ICU stay <7 days were 0.0438 ± 0.02 ng/ml and 27.13 ± 9.68 U/L, and the mean troponin T and CK-MB levels in patients with ICU stay >7 days were 0.0957 ± 0.07 ng/ml and 34.07 ± 10.51 U/L, respectively [Table 8].[12]

CONCLUSION

- The most common clinical sign related to cardiovascular system was tachycardia, as opposed to the expected finding of bradycardia, which was the second most common finding, but was associated with the severe degree of poisoning.
- Most common ECG finding was ST elevation, followed by Q-T prolongation. Prolonged QT interval was found to be indicator of severity and also had a prognostic value in predicting death and respiratory failure.
- Cardiac enzymes when found positive was associated with higher likehood of developing respiratory failure.
- The level of cardiac enzymes correlated well with the severity of poisoning, days of ICU stay and outcome, suggesting its use as a prognostic indicator of OP poisoning.

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Original Article

Prenatal Diagnosis of Congenital Heart Disease by Fetal Echo

M Selvarani

Assistant Professor, Department of Cardiology, Thoothukudi Medical College Hospital, Thoothukudi, Tamil Nadu, India

Abstract

Background: Infant mortality rate in sick neonatal unit is on an increase. By subjecting antenatal mothers to fetal echo, congenital heart disease (CHD) of the fetuses can be screened earlier and the labor and further management of the fetus can be planned in tertiary care centre in coordination with cardiothoracic surgeons.

Aim of the Study: This study aims to screen for CHD *in utero* by 4-chamber view. To pick up the major cardiac anomalies earlier and to counsel the parents accordingly. This will have indirect improvement in both maternal and fetal outcome and finally to reduce infant mortality rate.

Materials and Methods: Antenatal mothers referred for fetal cardiac evaluation were subjected for transabdominal fetal echo evaluation. Gross anomalies which can be detected by 4-chamber views, aortic level short axis views, were arrived at such as ventricular septal defect (VSD), tetralogy of Fallot (TOF), coarctation, and aortic stenosis Wipro GE Logiq 5 Echo machine with transducer frequency between 3.5 and 5 MHz.

Observations and Results: Of the 450 maternal cases studied, 87 (20.4%) were high maternal risk cases and 3 (0.6%) had high-risk fetal factors. Of the above screened fetuses, 4 (0.9%) had echogenic focus in left ventricle, 1 (0.2%) had VSD, 1 (0.2%) had TOF, and 1 (0.2%) had bradycardia.

Conclusions: Fetal echo evaluation is possible as a routine screening. High-risk maternal and fetal cases should undergo fetal echo evaluation. 4-chamber and 5-chamber views at least should be done to diagnose VSD/TOF and other major CHD. Incidence of fetal anomaly is 0.4/1000 according to our study and correlates with published data. Diagnosing CHD in fetal life will have its impact on fetal outcome and improvement in quality of care, both for the mother and the newborn. It gives mental satisfaction for the parent to know their fetal heart condition *in utero* itself. Early intervention after birth will prevent future complications of CHDs.

Key words: Anomalies, Congenital heart disease, Fetal echocardiogram antenatal

INTRODUCTION

Prenatal detection is essential for improving perinatal outcomes of neonates with critical congenital heart disease (CHD).[1] Comprehensive evaluation of the fetal heart includes evaluation of the situs, sagittal and transverse plane imaging, evaluation of the fetal cardiac rate and rhythm and Doppler assessment.[2]

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Period of Study

The study period was from August 2015 to February 2016 – 6 months.

Institute of Study

This study was at the Department of Cardiology, Thoothukudi Medical College Hospital, Thoothukudi.

MATERIALS AND METHODS

Antenatal mothers referred for fetal cardiac evaluation we subjected for transabdominal fetal echo evaluation.[3] Gross anomalies which can be detected by 4-chamber views, aortic level short axis views,[4] were arrived at such as ventricular septal defect (VSD), tetralogy of Fallot (TOF), coarctation, and aortic stenosis[5] Wipro GE Logiq

Corresponding Author: Dr. M Selvarani, 3/268, New Naththam Road, Oomachikulam, Thiruppalai Post, Madurai – 625 014, Tamil Nadu, India. Phone: +91-94434-71956. E-mail: selvarani_40@yahoo.com

5 Echo machine with transducer frequency between 3.5 and 5 MHz.

Fetal cardiac evaluation was done in the following steps:

- Situs[5]
- Cardiothoracic ratio (CTR)[5]
- Axis[5]
- 4-chamber view[6]
- 5-chamber view[6]
- OT views[6]
- Real-time evaluation of valves[5]
- Real-time evaluation of interventricular septum (IVS) and interatrial septa[5]
- M mode[6]
- Color flow mode and Doppler.[6]

Inclusion Criteria

Antenatal mothers 13–24 weeks were included in the study. Viable fetuses were only screened. Twins are also included. High-risk mothers of having fetal cardiac anomalies were also included. All age mothers were included.[7]

Exclusion Criteria

Already diagnosed cases of fetal cardiac anomalies were excluded. Intrauterine device cases were excluded. Those not willing to give consent were also excluded.

RESULTS

Comorbid illness and maternal risk factors – Table 1.
Fetal risk factors – Table 2.
Transabdominal views done – Table 3.
Cardiac abnormalities detected – Table 4.

Table 1: Comorbid illness and maternal risk factors

Maternal factors	Number of cases (%)	Cumulative (%)
High maternal age (>30)	28 (6.2)	6.2
Diabetes mellitus	35 (7.8)	14
Rheumatic heart disease	8 (1.8)	15.8
Congenital heart disease (operated or not operated)	4 (0.9)	16.7
Cardiomyopathy (dilated)	1 (0.2)	16.9
Coronary artery disease	1 (0.2)	17.1
Antipsychotics	1 (0.2)	17.3
Antiepileptics	4 (0.9)	18.2
Systemic lupus erythematosus	0	18.2
H/O TORCH infections	0	18.2
H/O heart disease in sibling	2 (0.4)	18.6
Polyhydramnios	0	18.6
Twins	1 (0.2)	18.8
Syndromic mother with congenital heart disease	0	18.8
Warfarin	2 (0.4)	19.2
Alcohol intake	0	19.8
Irradiation	0	20.4
Teratogen	0	20.4

Table 2: Fetal risk factors

Fetal factors	Number of cases (%)	Cumulative (%)
Fetal cardiac anomaly	0	0
IUGR	1 (0.2)	0.2
Hydrops	0	0.2
Increased nuchal thickness	2 (0.4)	0.6
Absent nasal bone	0	0.6

Table 3: Transabdominal views done

Views	Number of cases (%)
4-chamber view	450 (100)
5-chamber view	450 (100)
Outflow tract view	400 (89)
Valves	410 (91)
IVS	450 (100)
M mode	339 (75)
Color flow mode	450 (100)
Doppler	400 (89)
Aortic arch	450 (100)

IVS: Interventricular septum

DISCUSSION

Detecting fetal cardiac anomaly is most challenging because of moving fetus.[8] Locating fetal heart and getting standard views are also very difficult. Foramen ovale and ductus are seen normally;[9] hence, autism spectrum disorder (ASD) and pathological demand avoidance (PDA) diagnosis are possible only after delivery.[9] Patent foramen ovale will persist even after 1 week.[10] as shown in Figure 1. PDA will close in a day after birth.[10] Fetal circulation and streaming could be visualized by serial Doppler echo. Color flow mapping and pulse Doppler imaging in M mode can be used for the assessment of ventricular function.[11] Doppler assessment across mitral inflow is shown in Figure 2. IVS defects can be diagnosed *in utero*.[11] Valvular abnormalities can be diagnosed easily. Risk factors for having cardiac anomaly are elderly, diabetic mothers and those with CHDs and those on drugs such as antiepileptics and antipsychotics, and warfarin, alcoholic mothers can have fetal anomalies.[12] Those who had TORCH infections during the first trimester, those who are exposed to irradiation and teratogenic agents are also at risk of fetal anomalies and extracardiac anomalies.[13]

SLE mothers have fetal risks of hydrops, genetic abnormalities, IUGR, polyhydramnios, increased nuchal translucency, and absent nasal bone.[14]

Table 4: Cardiac abnormalities detected

Echogenic focus in left ventricle	4
Ventricular septal defect	1
TOF	1
Transposition of great arteries	-
Coarctation of aorta	-
Single ventricle	-
Double outlet right ventricle	-
Aortic stenosis	-
Pulmonary stenosis	-
Atrioventricular canal defects	-
Malposition	-
Bradycardia	1
Other defects	-

TOF: Tetralogy of fallot

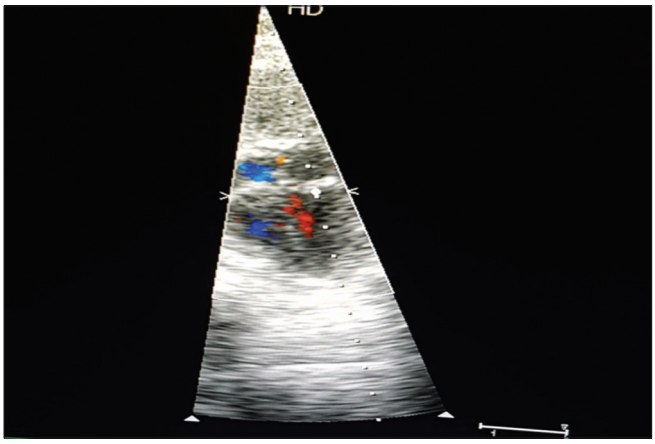

Figure 1: Fetal echocardiogram showing normal apical 4-chamber view with color flow showing foramen ovale

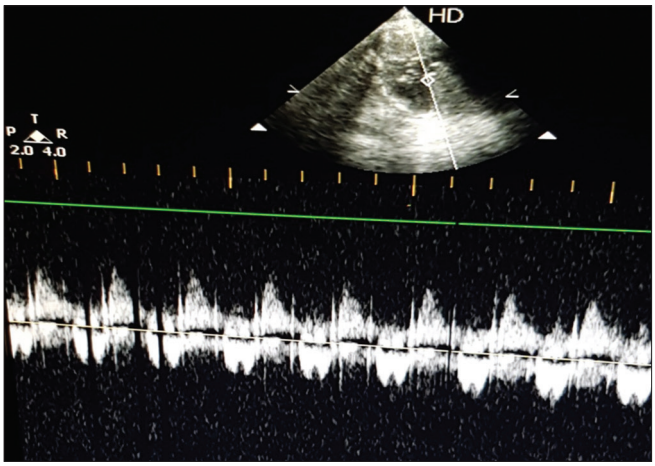

Figure 2: Fetal echocardiogram showing Doppler across mitral valve showing A wave dominance than E wave

Preferred 4-chamber view as screening tool helps in diagnosing at least one-third of cases of CHD.[15]

Prenatal diagnosis depends on the experience of examiner, obesity of the mother, frequency of transducer, abdominal conditions, gestational age of fetus, and fetal position.[16]

Split of data of gestational age of fetus was not collected since some had unknown LMP. It is obtained from the obstetrician's record.

Preferred duration of pregnancy is after 16 weeks in our study. We included AN mother in the second trimester. Term and near term will have poor echo window due to the reflection of ultrasound waves by bones of grown-up fetus.[17] Incidence of GDM and DM is increasing and they have 5 times more chance of having cardiac structural abnormalities.[18] Hence, in our study, special attention was given to diabetic mothers.

Among the total 450 mothers screened, almost all had situs solitus, levocardia. One had muscular VSD. One had TOF. Four had echogenic foci in LV. One had fetal bradycardia without any structural heart disease [rate around 90/mt]. There was no follow-up in that case. No tachycardia except for VPC in one case while recording M mode across the LV cavity level in long axis view. There were no subaortic, aortic, and supravalvular stenosis. No coarctation case was diagnosed. Rhabdomyoma can be diagnosed. In our study, pericardium was normal; no mass and no vegetation were seen. One mother had twin gestation. Both had normal cardiac structure and activity. Thin sheet of pericardial effusion may be a normal finding in fetal echo.

Average time taken for fetal echo was 10–20 mts. 4 chamber, 5 chamber, and aortic views can be seen without much difficulty in almost all cases. Other views were little difficult since fetal movements were exclusive.

The epidemiological data are similar to published series.

Fetal cardiac intervention is possible in advanced centers.

Follow-up and advice given to the parent of CHDs, i.e., VSD and TOF cases. 2D and color flow across VSD is shown in Figures 3 and 4, respectively. TOF was shown in Figures 5 and 6. After delivery, echo was done to confirm the diagnosis. TOF case expired in the postnatal period due to fatal cyanotic spell. A case of Muscular Ventricular defect diagnosed antenatally was delivered and the child is under follow up at higher Centre and planned for device closure later.

There was no PHT in the VSD case.

Neonatal echo screening was done for sick neonates and underweight babies. Larger ASDs were diagnosed without

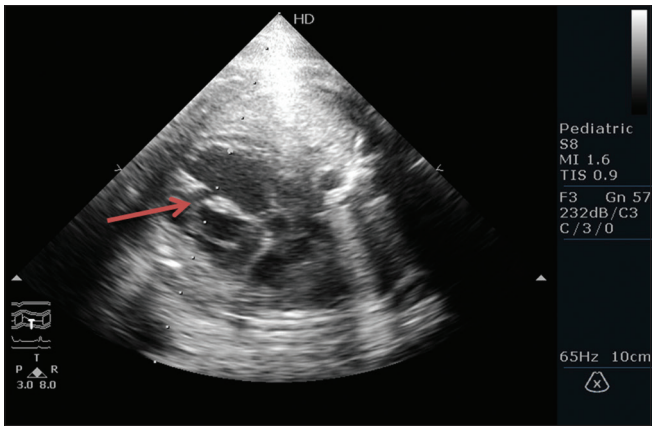

Figure 3: Fetal echocardiogram arrow showing two-dimensional image of mid-muscular ventricular septal defect

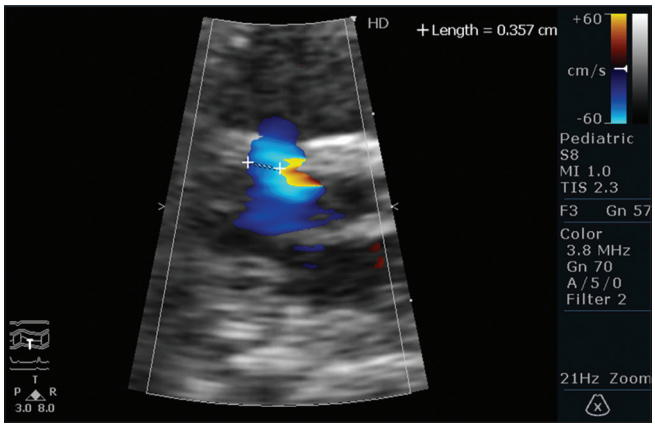

Figure 4: Fetal echocardiogram showing left to right shunt across ventricular septal defect - zoomed view

any difficulties and were advised follow-up at 30 days of life.

Tiny PDAs were found in the neonatal period. They were also advised to come for follow-up at 30 days.

Separate neonatal echo registry was made in the SNN ward and it is not discussed here.

Limitations of the Study

1. Small sample.
2. Not all standard views were possible in every case.
3. Observer variation.
4. Cardiac malpositions may be missed.

CONCLUSION

Fetal echo evaluation is possible as a routine screening. High-risk maternal and fetal cases should undergo fetal echo evaluation. 4-chamber and 5-chamber views at least should be done to diagnose VSD/TOF and other major CHDs. Incidence of fetal anomaly is 0.4/1000

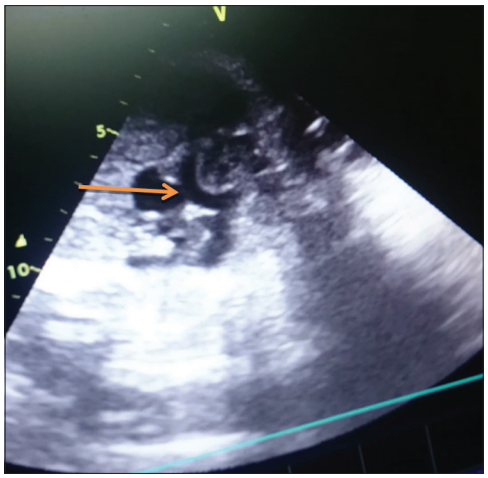

Figure 5: Fetal echocardiogram showing two-dimensional image of tetralogy of Fallot showing large malaligned ventricular septal defect

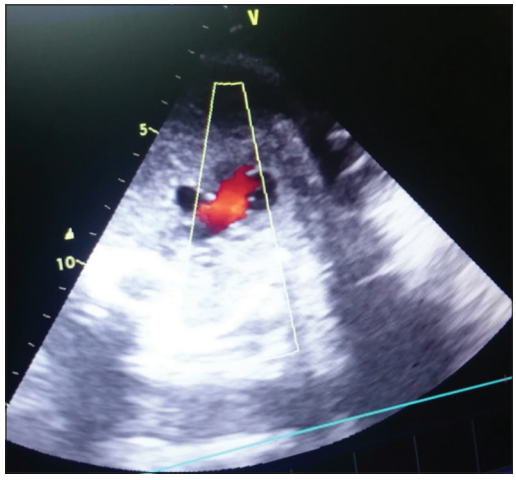

Figure 6: Fetal echocardiogram showing color flow image of tetralogy of Fallot showing large malaligned ventricular septal defect with right to left shunt

according to our study and correlates with published data.[4] Diagnosing CHD in fetal life will have its impact on fetal outcome and improvement in quality of care, both for the mother and the newborn. It gives mental satisfaction for the parent to know their fetal heart condition *in utero* itself. Early intervention after birth will prevent future complications of CHDs.

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Original Article

Comparative Evaluation of Radiotherapy with Concurrent Weekly Cisplatin versus Concurrent Daily Erlotinib and Weekly Cisplatin in Locally Advanced Carcinoma Cervix

Shyamji Rawat[1], M K Advait[2], Pranjil Mandloi[3]

[1]Associate Professor, Department of Radiotherapy, Netaji Subhash Chandra Bose Medical College, Jabalpur, Madhya Pradesh, India, [2]Senior Resident, Malabar Cancer Center Thalassery, Kerala, India, [3]Post Graduate, Department of Radiotherapy, Netaji Subhash Chandra Bose Medical College, Jabalpur, Madhya Pradesh, India

Abstract

Background: Erlotinib is an oral epidermal growth factor receptor tyrosine kinase inhibitor. Early phase clinical trials of Erlotinib in combination with cisplatin-based concurrent chemoradiotherapy (CCRT) in locally advanced carcinoma cervix have demonstrated improved antitumor responses with mild toxicity profile; however, the evidence available on this is limited. We prospectively evaluated the efficacy and safety of Erlotinib (150 mg/day) with CCRT in locally advanced carcinoma cervix and compared with standard CRT.

Materials and Methods: In this prospective, comparative study, 60 locally advanced carcinoma cervix patients received either Erlotinib (150 mg/day) with CRT or CRT. Treatment CRT included cisplatin 40 mg/m2 intravenously weekly concurrently with external beam radiation followed by intracavitary brachytherapy. Tumor response was calculated as per the WHO criteria. Toxicity and adverse events (AEs) were assessed as per CTCAE v 3.

Results: The higher number of patients achieved a complete response in the Erlotinib plus CRT group than the CRT group (28/30, 93.3% vs. 21/30, 70%, $P < 0.05$), which was statistically significant. The AEs commonly encountered in both the treatment groups were majority of Grade 1/2. A higher incidence of diarrhea and skin reaction was noted in the Erlotinib plus CRT group in comparison CRT, whereas the incidence of nausea and vomiting was higher in the CRT group. No Grades 4 and 5 toxicity was observed in Erlotinib with CRT. Erlotinib was observed to be safe with manageable toxicity profile.

Conclusion: Erlotinib 150 mg daily can be safely added to cisplatin-based CCRT in locally advanced carcinoma cervix, to achieve better therapeutic response without potentiating the toxicity.

Key words: Advanced, Carcinoma, Cervix, Epidermal growth factor receptor, Erlotinib, Neoplasms, Squamous cell, Tyrosine kinase inhibitor

INTRODUCTION

Globally, cervical cancer is the fourth most common cancer in women, with an estimated 560,505 new cases and 284,923 deaths in 2015.[1] Cervical cancer is a preventable disease and a major cause of morbidity and mortality, particularly in developing countries.[2] In India, cervical cancer is the second most common cancer, with an estimated 132,314 new cases and 73,337 deaths in the year 2015.[1,3]

In India, population-based cervical cancer screening is largely nonexistent in most regions due to competing healthcare priorities, insufficient financial resources and a limited number of trained providers.[3] With 60–80% of the cases presenting in locally advanced stage,[4-6] management of the carcinoma cervix remains challenging in Indian scenario.

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Corresponding Author: Dr. Shyamji Rawat, Department of Radiotherapy, Netaji Subhash Chandra Bose Medical College, Jabalpur, Madhya Pradesh, India. E-mail: pranjil.mandloi@gmail.com

Several studies have shown the superiority of platinum-based therapy, combined with radiation when compared to radiotherapy alone. Based on these premises the concomitant administration of radiotherapy plus weekly cisplatin is considered standard of care[7] However, despite the benefits obtained with the addition of platinum-based chemotherapy the cure rates of locally advanced squamous cell carcinoma have reached a plateau in recent years.[2,8,9]]

Epidermal growth factor receptor (EGFR) is a 170-kDa transmembrane glycoprotein receptor dimerizes to activate a tyrosine kinase (TK) domain that modulates multiple functions, including cell differentiation, growth, gene expression, and development. The EGFR is frequently overexpressed in cervical dysplasia and cervical cancer, and patients who have high levels of EGFR in their tumors have a poor prognosis.[10] A recent meta-analysis confirmed that EGFR overexpression is closely associated with reduced survival in patients with cervical cancer. Therefore, EGFR represents a valid target for preventing tumor growth and metastasis, and anti-EGFR therapies are been explored to improve outcomes in cervical cancer.[11]

Erlotinib is an oral and well-tolerated drug that reversibly binds to the intracellular catalytic domain of EGFR TK, thereby reversibly blocking EGFR phosphorylation, the signal transduction events and tumorigenic effects associated with EGFR activation.[12] Phase I and II trials of Erlotinib in combination with cisplatin-based concurrent chemoradiotherapy (CCRT) in locally advanced carcinoma cervix have demonstrated improved antitumor responses with manageable mild toxicity profile (diarrhea and rash).[12,13]

In the Phase II trial, majority (94.4%) patients on Erlotinib 150 mg/day in combination with CCRT achieved a complete response (CR). The 2-year and 3-year cumulative overall and progression-free survival rates were 91.7% and 80.6% and 80% and 73.8%, respectively.[13] These findings provided the foundation for the current study. Therefore, the present comparative study was carried out to evaluate the efficacy and safety of Erlotinib (150 mg/day) with CCRT in patients with locally advanced carcinoma cervix and compared with the CCRT alone.

MATERIALS AND METHODS

This was an open-labeled, prospective, comparative study carried out in patients with carcinoma of the cervix, attending Government Cancer Hospital, Netaji Subhash Chandra Bose Medical College Jabalpur (India), during the period of the year 2014–2015. The study was approved by the Institutional Ethical Committee and conducted in accordance with Good Clinical Practice guidelines and the Declaration of Helsinki.

The study included patients with the following eligibility criteria: (1) Histopathologically proven squamous cell carcinoma of cervix, (2) International Federation of Gynecology and Obstetrics Stage IB2-IVA, (3) age 18–80 years, and (4) Eastern cooperative oncology group (ECOG) performance status of 0, 1, or 2.

We excluded the following patients: (1) Age ≤18 years, (2) inadequate hematologic, cardiac, renal, and hepatic functions, (3) history of allergy with similar biological to Erlotinib/Cisplatin, 4) evidence of distant metastases (Stage IVB), (5) prior radiotherapy/chemotherapy/surgery, (6) other synchronous malignancies, (7) uncontrolled infection/any other systemic diseases, (8) not willing for informed consent, and (9) pregnant and lactating females.

Before enrollment, all patients gave a full history and underwent a physical examination, complete blood count with differential, electrolyte assessment, liver and renal function tests, chest X-ray, electrocardiogram, ultrasonography abdomen and pelvis, abdominal and pelvic computed tomography (CT)/magnetic resonance imaging (MRI) and cystoscopy.

Two treatment groups (test group and control group) were defined. Patients were randomly allocated to either group to receive the treatment. Test group received Erlotinib plus CCRT treatment, while the control group received CCRT only.

In the control arm, patients received cisplatin 40 mg/m^2 intravenously weekly concurrently with external beam radiation (EBRT). Patients in the study arm received daily Erlotinib 150 mg plus cisplatin 40 mg/m^2 intravenously weekly concurrently with EBRT.

Radiotherapy Treatment Protocol Schedule (Both Arms)

EBRT was administered to the whole pelvic region using Co60 teletherapy machine (Theratron 780E) followed by the high dose rate (HDR)-intracavitary brachytherapy (ICBT). Cases were treated by conventional radiotherapy schedule as follows: (1) EBRT = 5000 cGy, (2) HDR-ICBT = 700 cGy X 3 # Point A and 3) Total Dose = 8000 cGy in Point A.

EBRT was given for 5 days a week with a total duration of 35 days, and after completion of EBRT, 3 fractions of weekly HDR-ICBT were given. Total duration of completion of the treatment with EBRT and ICRT was 56 days. Portals for EBRT of pelvis: Parallel opposed (anterior-posterior fields)/four field box techniques.

Concurrent Chemotherapy Protocol Schedule

Control group: Cisplatin 40 mg/m2 4 weekly (ceiling dose 70 mg)

In the control group, patients received weekly cisplatin 40 mg/m^2 IV in 300 ml normal saline over 1 h. Premedication with dexamethasone 8 mg, omeprazole 20 mg, and 5-HT3 antagonist as antiemetic was given, with adequate hydration for 2 h before and after the chemotherapy.

Test group: Daily Erlotinib 150 mg OD plus Cisplatin 40mg/m2 4 weekly (ceiling dose 70 mg)

In the test group, patients received daily tablet Erlotinib 150 mg OD before food and were started 1 week before radiation to achieve a stable blood level and were continued until the past day of irradiation. Along with this, weekly Cisplatin 40 mg/m^2 IV in 300 ml normal saline was started from day 1 of radiation.

Patients (in both control and test group) receiving CRT were assessed weekly for symptomatic, clinical improvement, and adverse reactions patients were evaluated at the end of treatment completion and 1st, 3rd, and 6th months follow-up visits.

Parameters evaluated

The tumor response in both the groups was evaluated using the WHO criteria/response evaluation criteria in solid tumors (RECIST version 1.1) criteria. The response outcomes assessed included CR, partial response (PR), progression of disease, and stable disease based on CT/MRI findings. Adverse events (AEs) were assessed and graded by common toxicity criteria for AEs (version 3.0) and Radiation Therapy Oncology Group/European Organization for Research and Treatment of Cancer acute radiation criteria.

Statistical Analysis

Statistical analysis was performed with software (SPSS, version 19). Descriptive statistics were used to express the data. For categorical variables, Chi-square or Fischer exact test were used as appropriate. $P \leq 0.05$ was considered to indicate a statistically significant difference.

RESULTS

The patients were collected from 2014 to 2015, and a total of 60 patients of locally advanced carcinoma cervix were enrolled in this comparative study. 30 patients were enrolled in test arm, and 30 were enrolled in the control arm. The mean age of the patients in the test arm was 45.6 ± 6.3 years, and in the control arm, it was 54.7 ± 10.4 years. In both the groups, majority patients were from lower socioeconomic status and had ECOG status of 1. The baseline characteristics of locally advanced carcinoma cervix patients enrolled in the two treatment groups are summarized in Table 1.

Tumor Response

We observed that higher number of patients achieved CR in the Erlotinib with CRT group than in the CRT alone group (28/30, 93.3% vs. 21/30, 70%). Statistically (Chi-square value = 5.45, P < 0.05) the treatment response observed in the Erlotinib with CRT was significant higher [Table 2].

Safety and Toxicity

All AEs commonly encountered in both the treatment groups were of Grades 1/2/3. A higher incidence of skin reaction [Table 3] and diarrhea [Table 4] was noted in the Erlotinib with CRT group in comparison to CRT alone, whereas the incidence of nausea and vomiting was higher in the CRT group [Tables 5 and 6]. Only <10% of cases in either of the groups developed urinary tract infections. No Grades 4 and 5 toxicity was observed in Erlotinib with CRT group. Erlotinib was observed to be safe with manageable toxicity profile.

Table 1: Baseline characteristics of locally advanced carcinoma cervix patients in the treatment groups

Characteristics	Erlotinib plus concurrent CRT (study group=30)	Concurrent CRT (control group=30)
Age in years (%) Mean±SD	45.6±6.3	54.7±10.4
Age group in years (%)		
30–39	3 (10)	2 (6.7)
40–49	16 (53.3)	6 (20)
50–59	10 (33.3)	8 (26.7)
60–69	1 (3.3)	11 (36.7)
>70	0 (0)	3 (10)
Performance status (%)		
ECOG 1	28 (93.3)	26 (86.7)
ECOG 2	2 (6.7)	4 (13.3)
Tobacco chewer (%)		
Yes	27 (90)	28 (93.3)
No	3 (10)	2 (6.7)
Socioeconomic status		
Lower	28 (93.3)	29 (96.7)
Middle	2 (6.7)	1 (3.3)
FIGO disease stage (%)		
IIA	5 (16.7)	5 (16.7)
IIB	13 (43.3)	9 (30)
IIIA	4 (13.3)	9 (30)
IIIB	6 (20)	3 (10)
IV-A	2 (6.7)	4 (13.3)
Chemotherapy cycles total completed		
3 cycles	0 (0)	4 (13.3)
4 cycles	2 (6.7)	9 (30)
5 cycles	28 (93.3)	17 (56.7)

FIGO: International Federation of Gynecology and Obstetrics, SD: Standard deviation, ECOG: Eastern Cooperative Oncology Group

Table 2: Response to treatment in the test group and control group

Response to treatment	*n* (%)		Chi-square value	*P*
	Erlotinib plus CCRT	CCRT		
CR	28 (93.3)	21 (70)	5.45	<0.05
PR	2 (6.7)	9 (30)		
Total	30	30		

CR: Complete response, PR: Partial response, CCRT: Concurrent chemoradiotherapy

Table 3: Incidence of skin reaction in the test group and control group during treatment period

AEs-skin reaction	*n* (%)			
	Erlotinib plus CCRT (study group=30)		CCRT (control group=30)	
Skin reaction (treatment week)	Grade 1	Grade 2	Grade 1	Grade 2
1st	0	0	0	0
2nd	0	0	0	0
3rd	4 (13.3)	0	2 (6.7)	0
4th	16 (53.3)	3 (10.0)	2 (6.7)	1 (3.3)
5th	20 (66.7)	6 (20.0)	5 (16.7)	1 (3.3)
6th	25 (83.3)	4 (13.3)	5 (16.7)	0
7th	27 (6.7)	3 (93.3)	5 (16.7)	0

CCRT: Concurrent chemoradiotherapy, AEs: Adverse events

Table 4: Incidence of diarrhea in the test group and control group during treatment period

AEs-diarrhea	*n* (%)					
	Erlotinib plus CCRT (study group=30)			CCRT (control group=30)		
Diarrhea (treatment week)	Grade 1	Grade 2	Grade 3	Grade 1	Grade 2	Grade 3
1st	13 (43.3)	14 (46.7)	0	1 (3.3)	0	0
2nd	15 (50)	8 (26.7)	6 (20)	3 (10)	0	0
3rd	5 (16.7)	4 (13.3)	8 (26.7)	3 (10)	1 (3.3)	0
4th	5 (16.7)	1 (3.3)	0	3 (10)	3 (10)	0
5th	1 (3.3)	0	0	5 (16.7)	2 (6.7)	0
6th	1 (3.3)	0	0	2 (6.7)	0	0
7th	0	1 (3.3)	0	1 (3.3)	0	0

CCRT: Concurrent chemoradiotherapy, AEs: Adverse events

DISCUSSION

The findings of the present comparative study indicate that addition of Erlotinib to CCRT results in improved tumor response compared to CCRT in patients with locally advanced carcinoma cervix.

The treatment of carcinoma cervix has witnessed major changes over the past few decades, from radium therapy alone to combination of external beam radiotherapy (EBRT) and ICBT, and finally to CCRT.[9] Backed up with the results of randomized control trials, which showed an improvement in survival with the use of CCRT, the National Cancer Institute issued a clinical alert to establish CCRT as the standard treatment for carcinoma cervix.[9,14]

Cisplatin-based CRT is the standard treatment for cervical cancer.[7,14] However, despite the benefits obtained with the addition of platinum-based chemotherapy the cure rates of locally advanced squamous cell carcinoma have reached a plateau in recent years.[2,8,9] In the further quest for improving the outcomes, biological agents are being explored.

EGFR is frequently overexpressed in human papillomavirus (HPV)-associated dysplasias and carcinomas, suggesting that it might play a role in the activation of signaling pathways.[15] A meta-analysis demonstrated that EGFR overexpression is closely associated with reduced survival in patients with cervical cancer. These results facilitate the individualized management of clinical decisions for anti-EGFR therapies in cervical cancer patients.[11]

Erlotinib is an oral EGFR TK inhibitor that reversibly competes with ATP for binding the TK domain of EGFR, thereby reversibly blocking EGFR phosphorylation, the signal transduction events and tumorigenic effects associated with EGFR activation.[12] Erlotinib has been found to prevent immortalization of cultured human cervical epithelial cells by the complete HPV-16 genome

Table 5: Incidence of nausea in the test group and control group during treatment period

AEs-nausea	*n* (%)					
	Erlotinib plus CCRT (study group=30)			CCRT (control group=30)		
Nausea (treatment week)	Grade 1	Grade 2	Grade 3	Grade 1	Grade 2	Grade 3
1st	0	0	0	0	0	0
2nd	4 (13.3)	0	0	2 (6.7)	0	0
3rd	3 (10)	2 (6.7)	1 (3.3)	6 (20)	3 (10)	5 (16.7)
4th	3 (10)	2 (6.7)	0	5 (16.7)	4 (13.3)	5 (16.7)
5th	3 (10)	1 (3.3)	0	5 (16.7)	3 (10)	2 (6.7)
6th	5 (16.7)	0	0	5 (16.7)	4 (13.3)	1 (3.3)
7th	2 (6.7)	0	0	7 (23.3)	3 (10)	0

CCRT: Concurrent chemoradiotherapy, AEs: Adverse events

Table 6: Incidence of Vomiting in the test group and control group during treatment period

AEs-vomiting	*n* (%)			CCRT (control group=30)		
	Erlotinib plus CCRT (study group=30)					
Nausea (treatment week)	Grade 1	Grade 2	Grade 3	Grade 1	Grade 2	Grade 3
1st	0	0	0	2 (10)	2 (6.7)	0
2nd	4 (13.3)	0	0	4 (13.3)	2 (6.7)	2 (6.7)
3rd	3 (10)	2 (6.7)	1 (3.3)	6 (20)	3 (10)	5 (16.7)
4th	3 (10)	2 (6.7)	0	4 (13.3)	3 (10)	5 (16.7)
5th	3 (10)	1 (3.3)	0	5 (16.7)	3 (10)	2 (6.7)
6th	5 (16.7)	0	0	5 (16.7)	4 (13.3)	1 (3.3)
7th	2 (6.7)	0	0	7 (23.3)	3 (10)	0

CCRT: Concurrent chemoradiotherapy, AEs: Adverse events

or the E6/E7 oncogenes. Erlotinib stimulates apoptosis in cells that express HPV-16 E6/E7 proteins and induces senescence in a subpopulation of cells that did not undergo apoptosis.[16]

Clinical trials have demonstrated encouraging antitumor activity alone or in combination with chemotherapy and exhibited radiosensitizing effects in a variety of malignancies.[17-20] Early phase clinical trials of Erlotinib in combination with cisplatin-based CCRT in locally advanced carcinoma cervix have demonstrated improved antitumor responses with manageable mild toxicity profile (diarrhea and rash, with no hematological side effects).[12,13] Based on the promising antitumor outcomes document in early phase, clinical trials,[12,13] the present study evaluated the safety and efficacy of cisplatin-based CCRT with or without daily Erlotinib in locally advanced carcinoma cervix in India.

In the present comparative study, we found that addition of Erlotinib to the CCRT resulted in improved tumor response rate than CCRT alone in locally advanced squamous cell cervical cancer. The higher number of patients achieved CR in the Erlotinib with CRT group than in the CRT alone group (28/30, 93.3% vs. 21/30, 70%, $P < 0.05$), which was statistically significant. The findings of improved tumor response with the addition of Erlotinib to CRT are similar to the findings of two clinical trials.[12,13]

In the Phase 1 trial, Nogueria-Rodrigues *et al*.[12] evaluated the maximum tolerated dose and the safety of Erlotinib in combination with cisplatin-based CRT in locally advanced (Stage IB-IVA squamous cell carcinoma) cervical cancer. Patients received escalating doses of Erlotinib (50/100/150 mg) combined with cisplatin (40 mg/m^2, weekly, and 5 cycles) and radiotherapy (external beam 4500 cGy in 25 fractions, followed by 4 fractions/600 cGy/weekly of brachytherapy). Out of 12 evaluable patients, 11 (91.7%) experienced a CR and 1 (8.3%) PR at the end of combined treatment. Two of 12 patients have had disease progression after 12 months of follow-up. The most common AEs noted were skin rash followed by diarrhea, which were manageable. Most of the AEs were either Grade 1 or 2, with few of Grade 3. No Grade 4 toxicities or treatment break/treatment-related deaths due to toxicity occurred in the trial. The authors found that the maximum tolerated a dose of Erlotinib that could be given along with cisplatin-based CCRT was 150 mg. The addition of Erlotinib to cisplatin-based CCRT was found to be safe and well tolerated.[12] Since the results were highly encouraging it gave the investigators a boost to proceed to Phase II trial.

In the Phase II trial, Nogueira-Rodrigues *et al*.[13] evaluated Erlotinib dose of 150 mg/day in combination with cisplatin-based CRT in locally advanced (Stage IIB-IIIB) cervical cancer. Patients received Erlotinib at a dose of

150 mg/day 1 week before and in combination with cisplatin (40 mg/m^2 administered weekly for 5 cycles) and radiotherapy (4500 centigrays in 25 fractions), followed by brachytherapy (4 fractions at a dose of 600 centigrays weekly). A total of 36 patients completed treatment with Erlotinib and CRT. The median duration of therapy was 77 days and the median follow-up period was 59.3 months. The therapy was well tolerated overall, and 34 patients (94.4%) achieved a CR. The 2 and 3-year cumulative overall and progression-free survival rates were 91.7% and 80.6% and 80% and 73.8%, respectively. The most common AEs were skin rash, diarrhea, and nausea, which were Grade 1 or 2 in the majority of patients. The treatment did not lead to limiting in field toxicity, and there was no therapy related deaths reported. The combination of Erlotinib dose of 150 mg/day in combination with cisplatin-based CRT was found to be safe and exerts significant antitumor activity in locally advanced squamous cell cervical cancer.[13]

Perez Rodrigo *et al*.,[21] in a case report evaluated the effectiveness and safety of the use of Erlotinib in two cases of refractory cervical cancer. They observed that the progression-free survival was 6 months and 4 months in each case with minor adverse effects. They concluded that Erlotinib 150 mg/day presented similar results to those obtained from cisplatin doublets in women with refractory cervical cancer, with minor adverse effects, however, needed validation in larger populations.[21]

In the present comparative study, the AEs commonly encountered in both the treatment groups were majority of Grades 1/2. A higher incidence of diarrhea and skin reaction was noted in the Erlotinib with CRT group in comparison to CRT alone, whereas the incidence of nausea and vomiting was higher in the CRT group. In the Erlotinib group, most patients developed skin reaction during the 3rd or 4th week of treatment. The reactions that occurred in the field of irradiation were mostly desquamous type and were associated with severe itching. It was managed by oral antihistamines, topical emollients, and gentian violet. The desquamation subsided by the end of irradiation and new epidermal layer had formed by the 2nd month of full treatment completion. The skin reactions that developed outside the realm of irradiation were mostly of pimples type, and it developed mainly over the face and nasolabial fold; oral antihistamines and topical emollients were used in their treatment.

Similarly, majority presenting with Grade 1 diarrhea in the 1st and 2nd week of treatment in Erlotinib group and was managed by adequate hydration, antimotility drug, and probiotics. Only <10% of cases in either of the treatment groups presented with complaints of burning micturition fever and their routine urine examination revealed urine sample loaded with pus cells. The patients were diagnosed to have urinary tract infection, and they responded to broad spectrum I/V antibiotics Ciprofloxacin and metronidazole for 5 days. The incidence of urinary tract infections might be due to the unhygienic conditions that the patients live in and may not be due to chemotherapy or irradiation.

In the present study, no Grades 4 and 5 toxicity was observed in Erlotinib with CRT group. The AEs documented in the present study were similar to those events commonly documented in clinical trials.[12,13] Erlotinib was observed to be safe with manageable toxicity profile.

In summary, the addition of Erlotinib (150 mg/day) to standard cisplatin-based CCRT showed improved tumor response in comparison to cisplatin-based CCRT alone in locally advanced carcinoma cervix patients without producing additional toxicity. Although robust multicenter, randomized control trials with larger sample size are needed to validate these interesting results.

The study had limitations; the sample size was small, conducted in a single hospital setting and short-term treatment outcomes were assessed. Data on the long-term safety and survival benefits needs to be explored further.

CONCLUSION

Erlotinib (150 mg daily) can be safely added to cisplatin-based CCRT in locally advanced carcinoma cervix, to achieve better therapeutic response without potentiating the toxicity.

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Original Article

Efficacy of Intra Masseteric Dexamethasone in Reducing Pain and Swelling after Surgical Removal of Mandibular Third Molars

Muniappan Harihara Sabari[1], Gopalakrishnan Suresh Kumar[2], Amalorpavanathan Andrew[3]

[1]Assistant Professor, Department of Dental Surgery, Tirunelveli Medical College Hospital, Tirunelveli, Tamil Nadu, India, [2]Associate Professor, Department of Dental Surgery, Tirunelveli Medical College Hospital, Tirunelveli, Tamil Nadu, India, [3]Professor and Head, Department of Dental Surgery, Tirunelveli Medical College Hospital, Tirunelveli, Tamil Nadu, India

Abstract

Aim: The aim of the study was to compare the efficacy of intra massetrically given dexamethasone through intrabuccal approach in reducing the post-operative sequelae after surgical removal of impacted mandibular third molars.

Materials and Methods: Twenty patients were selected, each of who required surgical extraction of a single impacted mandibular third molar. Patients were in the age range of 18–40 years. Patients were randomly set apart into two groups of 10 each. The experimental group received 8 mg dexamethasone which is injected into the masseter muscle intrabuccally. The control group did not receive any kind of steroids. Facial swelling was measured by an independent examiner preoperatively and 2nd day postoperatively. Visual analog scale is used to measure pain from patient's response.

Results: There is a significant reduction in swelling and pain in the dexamethasone group when compared with the control group.

Conclusion: Intra masseteric injection of 8 mg dexamethasone through intrabuccal approach is a better way to minimize swelling and pain after surgical removal of impacted third molars in the mandible.

Key words: Dexamethasone, Intra massetric, Mandibular third molars

INTRODUCTION

Inflammatory reaction of soft tissue is the end result of any surgical procedures. The most common surgical procedure in oral surgery is surgical removal of an impacted mandibular third molar. The most common post-operative sequelae were pain, trismus, and swelling.[1]

Many different approaches including drains, medications with enzymes, laser therapy, corticosteroids, and muscle relaxants were clinically evaluated in an effort to minimize these post-operative sequelae. Corticosteroids have shown promising results. The two main groups of corticosteroids were the glucocorticoids and the mineralocorticoids. Due to their anti-inflammatory activities, glucocorticoids are of interest here. Furthermore, glucocorticoids have little or no effect on fluid and electrolyte balance.

Extensive medications were used to control these post-operative complications. Corticosteroids have been widely used to reduce the inflammatory sequelae after third molar surgery due to its potent anti-inflammatory property.[2] In the early 1950s Spies *et al.* and Strean and Horton started using corticosteroids to prevent inflammation in oral surgery.[1]

The anti-inflammatory property of corticosteroids was vascular dilatation inhibition, decreasing cellular exudation, reducing liquid transudation, and edema formation. The primary mechanism responsible for these effects includes leukocyte chemotaxis inhibition, blockade of fibroblast and endothelial cells function, and suppression of numerous chemical inflammatory mediators.[3,4]

Corticosteroids in a single large dose or a short duration of therapy were preferred as it causes very few adverse

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Corresponding Author: Dr. Gopalakrishnan Suresh Kumar, 48/136, Kovil Street, Kurinji Nagar, Madurai – 625 014, Tamil Nadu, India. Phone: +91-9444871015. E-mail: omfs007@yahoo.in

effects. The adverse effects are not clinically significant when used in oral surgery cases. Delayed healing and increase in patient susceptibility to infection were noticed in case of prolonged use of corticosteroids. Dexamethasone is the most commonly used form of corticosteroid in dentoalveolar surgery. Dexamethasone is considered more potent than methyl prednisolone because of its longer duration of action.[5]

MATERIALS AND METHODS

A total of 20 patients were selected for whom impacted mandibular third molar removal is needed. The procedure is done under local anesthesia. The study was approved by our Institutional Ethical Committee. Partially impacted mandibular third molars were selected according to Pell and Gregory classification A, B, and C on the radiograph. All the patients selected were 18 years of age or older. Patients on the day of tooth removal should be free of pericoronitis or infection. Patients with the history of immunocompromise, allergy to drug used, pregnancy or lactation or chronic use of any drugs were excluded from the study.

Surgical Procedure

All the surgical procedures for the 20 patients were done by the same surgeon. A standard inferior alveolar nerve block and long buccal nerve block were given using a solution of 2% lignocaine hydrochloride and adrenaline 1:80000. A ward's incision was made for surgical access, 702 straight fissure bur was used to remove bone around the tooth. Whenever necessary the crown or roots were sectioned. After complete removal of the tooth, the socket was irrigated copiously with normal saline and flap was sutured with 3–0 silk. Pressure pack with small gauze piece was applied to the site. Post-operative instructions were given to the patients.

Patients were divided randomly into two groups with 10 patients each. 8 mg dexamethasone was given into the masseter muscle through intrabuccal approach for the treatment group. Dexamethasone was injected preoperatively just before the surgery. No corticosteroid was given to the control patients. The study was not blinded. All the patients were aware of whether they had dexamethasone or not.

All the patients were given amoxicillin with clavulanic acid antibiotic and tab. Aceclofenac every 12 h orally for 5 days. The patients were advised for warm saline gargle from the day after surgery.

Follow-up

Facial measurements were made on three sites: Tragus-commissura labiorum, gonion-lateral canthus, and gonion-commissure labiorum using a measuring tape. Measurements were made preoperatively and postoperatively on the 2nd day on the operated side. Measurements were made by an independent examiner.

The pain was also assessed visual analog scale (VAS) was used to evaluate pain that ranged from "no pain" for 0 to "the worse possible pain" for 10. The pain was evaluated on the 2nd day postoperatively.

Statistical analysis was done using SPSS 15. Nonparametric Mann–Whitney U test was used to compare the difference between facial measurements in the study and control groups.

RESULTS

Mean pain on 2nd day in the control group was 4.6 on VAS and in the study group was 1.95 on VAS. Higher mean pain was recorded in the control group without steroids when compared to the study group given perioperative steroids, and difference between them was found to be statistically significant. Surgical sites were recovered uneventfully. No complications such as muscular necrosis, fatigue, pruritus, nausea, or vomiting followed by steroid injection occurred.

Statistically significant differences were observed between the control and study groups in all day 2 measurements (tragus-commissura labiorum, gonion-lateral canthus, and gonion-commissure labiorum) [Table 1]. In the study group, post-operative edema was significantly reduced.

DISCUSSION

Corticosteroids were used perioperatively for reducing edema, pain, and trismus after removal of impacted mandibular third molars. Parenteral administration of corticosteroids taken before rather than after surgery seems to be more effective than oral administration of steroids.[6]

Although intravenous administration affords excellent and immediate plasma drug levels, this route is infrequently used in an outpatient clinical setting, unless patients are receiving intravenous sedation at the same time.[7] Two other routes of administration other than intravenous are the intramuscular and subcutaneous routes. Intramuscular injections are effective irrespective of the site of injection.[8-10]

Due to religion and cultural restrictions, intramuscular injections at the gluteus or deltoid muscle may not be a convenient procedure. Due to needle phobia, patients may decline receiving injections away from the oral cavity.

Table 1: Outcome difference between study and control groups

2nd day measurement	Median cm (minimum – maximum) control group study group	Asym. significance Group 2-tailed
Tragus-commissura labiorum	12.4 (10.6–15.7) 11.7 (10.6–14.0)	*P*=0.001*
Gonion-commissura labiorum	12.5 (10.5–14.0) 10.5 (9.1–12.4)	*P*<0.001*
Gonion-lateral cantus	12.6 (10.0–14.1) 10.6 (9.4–12.2)	*P*<0.001*

**P*<0.05 was considered statistically significant

The masseter muscle makes a good alternative site. This site of administration is convenient for the surgeon as the injection is given close to the surgical area. For the patient intra masseteric injection is painless as it is usually given after the area was anesthetized. Intra masseteric injection effectiveness does not depend on the patient's compliance.[10]

Markiewicz *et al.* conducted a meta-analysis to measure the effect of corticosteroids on trismus, edema and pain at both early and late post-operative periods after surgical removal of third molars. Markiewicz concluded that perioperative corticosteroids played a key role in mild-to-moderate reduction of edema and good improvement in range of motion.[11]

Brignardello-Petersen *et al.* concluded that low-level laser energy irradiation had no role in decreasing pain, trismus, and swelling after surgical removal of mandibular third molars.[12] The effect of low power laser irradiation after lower third molar surgery is enhanced by simultaneous local intramuscular use of dexamethasone.[13] Intraoral injection of dexamethasone 8 mg at the time of surgery decreases post-operative edema same as dexamethasone 4 mg. No extra benefits obtained by increasing dosage of parenteral dexamethasone from 4 mg to 8 mg.[14]

8 mg of dexamethasone was more efficient in the trismus and swelling control than the lower dosage after surgery.[15] Submucosal injection of dexamethasone 4 mg is comparable to intramuscular injection in reducing the post-operative swelling after impacted third molar surgical removal.[16] Oral bromelain is an effective method in improving the post-operative sequelae after impacted mandibular third molar surgical removal comparable to that of diclofenac sodium.[17]

Vegas-Bustamante *et al.* reported a decrease in pain, trismus, and swelling after injecting methylprednisolone into the masseter muscle.[18] Messer and Keller reported similar results after injecting dexamethasone into the masseter muscle.[19] Nandini in her study proved a decrease in pain, swelling after injecting dexamethasone into the masseter muscle as in the present study.[20] The intra masseteric injection is convenient for an oral surgeon, as it is injected into the area near to the surgical site that is still anesthetized.

In the present study, we found that injecting dexamethasone into the masseter muscle significantly reduced swelling on 2nd day postoperatively compared with controls. All patients had significantly less pain at the evaluation time in the dexamethasone group when compared to the control group.

CONCLUSION

The results obtained showed that dexamethasone injected into the masseter is a better alternative route to that given systemically. Intra masseteric injection technique is less invasive, painless, and more convenient for the oral surgeon.

In the study, we conclude that intraoperative injection of 8 mg of dexamethasone into the masseter muscle significantly reduces pain and swelling postoperatively in surgical removal of mandibular third molar extraction.

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Original Article

Ultrasound and Color Doppler Evaluation of Axillary Lymph Nodes in Breast Carcinoma with Histopathological Correlation

Jyoti Choudhary[1], Rekha Agrawal[2], Arpan Mishra[3], Radhika Nandwani[4]

[1]Post-Graduate Student, Department of Radiodiagnosis, NSCB Medical College, Jabalpur, Madhya Pradesh, India, [2]Associate Professor, Department of Radiodiagnosis, NSCB Medical College, Jabalpur, Madhya Pradesh, India, [3]Assistant Professor, Department of Surgery, NSCB Medical College, Jabalpur, Madhya Pradesh, India, [4]Assistant Professor, Department of Pathology, NSCB Medical College, Jabalpur, Madhya Pradesh, India

Abstract

Introduction: Accurate assessment of the axillary lymph node status and identifying metastatic changes is extremely important in the management of breast cancer.

Aims and Objectives: The aims of this study are to assess the role of ultrasound and color Doppler in diagnosing metastasis to axillary lymph nodes in patients with breast cancer and to correlate with histopathological findings.

Materials and Methods: In this prospective study, 62 female patients of biopsy-proven breast cancer were evaluated by high-resolution ultrasonography (USG) and color Doppler in the Department of Radiodiagnosis, NSCB Medical College, Jabalpur, from March 2016 to March 2017, with 5–10 MHz linear transducer. Lymph nodes were assessed using gray-scale and color Doppler parameters such as nodal size, shape, L/S ratio, border, hilum, echotexture, necrosis, matting, and angioarchitecture. A provisional diagnosis was suggested after the ultrasound examination, and these findings were correlated with the tissue diagnosis obtained on subsequent axillary dissection specimen.

Results: In our study of 62 cases, 39 patients had metastasis in axillary lymph nodes. Lymph node with oval shape (L/S ratio >2), echogenic hilum, homogenous echotexture, and hilar vascularity was considered as significant parameters in detecting non-metastatic (reactive) lymph nodes. Lymph nodes number ≥3, long axis/short axis ratio <1.4, resistivity index >0.7, pulsatility index >1.4, and non-hilar cortical blood flow were most reliable parameters for diagnosing metastatic lymph nodes with a diagnostic accuracy of 75.80%, 69.35%, 79%, 72.58%, and 85.48%, respectively.

Conclusion: This study concludes that USG examination proved as a valuable primary investigation to identify lymph nodes and differentiate non-metastatic and metastatic lymphadenopathy.

Key words: Axillary lymphadenopathy, Breast cancer, Color Doppler, Ultrasound

INTRODUCTION

Axillary lymph node metastases have been one of the most important prognostic parameters in patients with breast cancer. Differentiation between metastatic and non-metastatic axillary lymph nodes is extremely important at the earliest because a delayed diagnosis can lead to upstaging of the disease making a curable lesion incurable.

The sentinel lymph node is the first lymph node to receive lymph drainage from the primary tumor and is also highly predictive for the status of the remaining axillary lymph nodes. But as, the sentinel lymph node biopsy (SLNB) has not found wide acceptance in developing countries due to the requirement of nuclear medicine, frozen section facilities, waiting intraoperatively for frozen section reports, thus prolonging operating time, post-procedure complications (upper limb lymphedema, arm paresthesia,

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Corresponding Author: Dr. Jyoti Choudhary, Room No. 27, PG Girls Hostel, Medical College, Jabalpur - 482 003, Madhya Pradesh, India. Phone: +91-9826152877. E-mail: jyotichoudhary2747@gmail.com

chronic pain, and immobility), and a 5–10% false-negative rate.[1] Therefore, it will be advantageous to evaluate the efficacy of noninvasive procedure such as ultrasonography (USG) and color Doppler in differentiating metastatic from non-metastatic nodes in biopsy-proven breast carcinomas.

Thus, the aim of our study was to use ultrasound and color Doppler imaging for the pre-operative evaluation of axilla in breast cancer and to correlate the findings with the tissue diagnosis obtained on subsequent axillary dissection specimen. The goal was to identify the subset of patients who could be reliably diagnosed on the basis of USG and color Doppler to harbor axillary nodal metastasis. Such patients could be spared a SLNB procedure and offered axillary lymph node dissection (ALND) upfront.

MATERIALS AND METHODS

The study was approved by the Institutional Ethics Committee, and written informed consent was obtained from all 62 female patients who were referred for USG of breast and axilla to the Department of Radiodiagnosis, NSCB Medical College, Jabalpur. The study was undertaken over 1 year from March 2016 to March 2017. All scans carried out on 5–10 MHz linear transducer using Siemens Acuson ×300, Sonoscape SS1600, Philips HD 7XE machine.

Inclusion Criteria

1. Female patients of all age groups with biopsy positive breast carcinoma were included in the study.

Exclusion Criteria

The following criteria were excluded from the study:

1. Post-operative patients, patients on chemotherapy or radiotherapy, and those with prior axillary intervention.
2. Patients with no evidence of axillary lymphadenopathy on ultrasound.

The patients were examined in the supine position with the arm in 90° abduction and external rotation. In this position, the axillary vessels have a nearly straight course facilitating orientation and all parts of axilla could be thoroughly examined.

Color Doppler USG was also performed with low-velocity parameter settings and high gain using a slow scanning technique. Sample volume was adjusted to the vessel size and was centered in the vessel, and the angle of insonation was kept at 60° or less in all examinations. Doppler spectral waveforms were recorded from different vessels whenever possible for each node, and the highest value was selected. Spectral Doppler analysis was performed on the vessel with the most rigorous flow, and the peak systolic velocity, pulsatility index (PI), and resistive index were recorded.

The Axillary Lymph Nodes were Examined Under the Following Headings

Gray-scale USG

- Number of lymph nodes detected by USG
- Size of the largest lymph node
- Shape
- Long-to-short axis (L/S) ratio
- Echogenicity of the hilum
- H/L ratio (long axis of hilum/long axis of lymph node)
- Other ancillary morphlogical changes (necrosis, calcification, and matting of lymph nodes).

Color Doppler USG

- Vessel location
- Flow pattern
- Resistivity index (RI): Peak systolic velocity - end diastolic velocity/peak systolic velocity
- PI: Peak systolic velocity - end diastolic velocity/mean velocity.

Lymph node metastasis was characterized by the following sonomorphological and color Doppler changes:

Gray-scale USG findings

- Increase in size (short axis diameter >7 mm)
- Increase in number (three or more than 3)
- Change in shape (from oval to more round in appearance-L/S ratio <2)
- Altered echotexture (cystic, necrotic inclusions, and disappearance of echogenic hilum)
- Eccentric asymmetric cortical thickening and focal cortical bulge due to subcortical metastatic deposits.

Color Doppler (CD) findings

- Metastatic nodes have a predominantly peripheral non-hilar blood flow pattern
- Pulse Doppler with spectral waveform pattern revealed sharp systolic peaks in metastatic nodes with high RI and PI values.

In Axilla with multiple nodes, the node with minimum L/S ratio and H/L ratio and maximum RI and PI were taken into account. Sensitivity and specificity of various ultrasound and color Doppler parameters were recorded in differentiating non-metastatic from metastatic lymph nodes. All patients underwent modified radical mastectomy. The mastectomy and axillary specimen were evaluated by conventional histopathology. The results of USG and CD ultrasound were correlated with the histopathology of the lymph nodes harvested in the axilla.

RESULTS

In our study, age range from 40 to 49 years had a highest proportion of cases as shown in Table 1. Of 62 patients

with lymph nodes detected on USG, 39 patients revealed metastasis on histopathological examination. Lymph nodes which were suspicious for metastasis had round shape (L/S ratio <2), distorted hilum, eccentric cortical thickening, focal cortical bulge, heterogenous echotexture, intranodal necrotic changes, multiple clumped nodes, peripheral non-hilar cortical or mixed vascularity pattern, and high RI (>0.7) and PI values (>1.4). Correlation of sonographic findings with histopathological findings was performed.

In our study, we observed that the cutoff value of 2 or less for L/S ratio yielded a sensitivity of 79.49% and specificity of 65.22% to detect metastasis [Table 2]. The number of cases with visible hilum on USG was 33. It was observed that H/L ratio ≤0.5 yielded a sensitivity of 90% and a specificity of 91.30% [Table 3].

On color Doppler studies, it was shown that exclusively peripheral non-hilar cortical vascular pattern showed the highest positive predictive value (PPV) of 100% to detect metastatic changes [Table 4]. In our study, we found that the cutoff value of 0.7 for RI yielded a sensitivity of 92.3% and specificity of 56.2% and cut off value of 1.4 for PI yielded a sensitivity of 82.5% and specificity of 65.2% for labeling lymph nodes positive for metastasis [Tables 5 and 6].

Table 1: Age distribution

Age groups (in years)	Number of cases
30–39	13
40–49	26
50–59	11
60–69	9
70–79	3

Table 2: Distribution of L/S ratio on USG with histopathological correlation

L/S ratio	Number of cases without metastasis	Number of cases with metastasis
≤2	8	31
>2	15	8

χ^2=12.39, *P*<0.001. USG: Ultrasonography

Table 3: Distribution of H/L ratio in cases with visible hilum on USG with histopathological correlation (number of patients=33)

H/L ratio	Number of cases without metastasis	Number of cases with metastasis
<0.5	2	9
>0.5	21	1

χ^2=20.73, *P*<0.001 H/L ratio=ratio of long axis of hilum to the long axis of lymph node. USG: Ultrasonography

DISCUSSION

USG is cost-effective, easily available, radiation-free, non-invasive, safe and is a primary investigation in detection of axillary lymph nodes in breast malignancies. Thus, our study confirmed the reliability of ultrasound parameters to detect metastasis.

Size

Nodes with short axis diameters less than the cutoff (0.7 cm) point were considered non-metastatic and those with >0.7 cm had the sensitivity of 94.8%, specificity of 52.17%, PPV of 77.08%, negative predictive value (NPV) of 85.7%, and diagnostic accuracy of 79.03% in diagnosing metastasis to the axillary lymph nodes.

Size alone cannot be as used relevant criteria, as metastatic nodes may be small and acute inflammatory or reactive nodes, quite large. It has been shown that the size of the lymph nodes is not an accurate predictor of metastasis, this implies its poor specificity.

Shape

In our study of 62 patients, 21 had round appearance of axillary lymph nodes, in which 19 cases were positive for nodal metastasis. Benign nodes are oval or elongated

Table 4: Distribution of vascular pattern of axillary lymph node with histopathological correlation

Vascular pattern	Total	Number of cases without metastasis	Number of cases with metastasis	PPV (%)
Hilar	21	20	1	4.76
Central perihilar	9	2	7	77.77
Peripheral non-hilar	28	0	28	100
Mixed	4	1	3	75

PPV: Positive predictive value

Table 5: Distribution of RI on color Doppler ultrasound with histopathological correlation

RI	Number of cases without metastatic lymph nodes	Number of cases with metastatic lymph nodes
<0.7	13	3
>0.7	10	36

χ^2=18.01, *P*<0.001, RI: Resistivity index

Table 6: Distribution of PI on color Doppler ultrasound with histopathological correlation

PI	Number of cases with non-metastatic lymph nodes	Number of cases with metastatic lymph nodes
<1.4	15	7
≥1.4	8	32

χ^2=14.12, *P*<0.001, PI: Pulsatility index

[Figure 1] while malignant nodes are often described as rounded [Figure 2]. This is better described in terms of L/S ratio, i.e., the ratio between the longitudinal axis (L) of the node and the nodal transverse or short axis (S), diameter, which is used to define the nodal shape. The long axis of an oval benign node will be at least 2 times greater than the axial diameter, which is described as L/S >2 or S/L <0.5. In malignant rounded nodes, the value of L/S is <2 or even <1.4.

In our study, using a longitudinal-transverse axis, ratio of 2 or lower resulted in a sensitivity of 79.49% and a specificity of 65.22% in differentiating benign from metastatic nodes.

According to the studies done by Yang and Metreweli[2] using a longitudinal-transverse axis, ratio of 2 or lower resulted in a sensitivity of 67% and a specificity of 71% in differentiating benign from malignant nodes.

Hilum

Normal lymph nodes present a central echogenic hilum. This appearance is due to the abutment of multiple medullar sinuses acting as interfaces. The absence of an echogenic hilum due to replacement or effacement is considered to represent diagnostic criteria of abnormality and is significantly greater in malignancies than in benign lesions.

In our study of 62 patients, 29 had distorted echogenic hilum, which on histopathological examination revealed metastasis in all 29 patients, resulting in 100% PPV [Table 7], while 33 patients retained their hilar echogenicity (23 patients with maintained central echogenic hilum and 10 patients with displaced hilum). Among patients who had hilum present, 11 patients revealed H/L ratio equal to or <0.5. Among these 11 patients, 9 were diagnosed as having metastasis and rest 2 had benign nodes resulting in PPV of 81%.

H/L ratio ≤0.5 yielded a sensitivity of 90% and a specificity of 91.30% to detect nodal metastasis in known cases of breast malignancy. ($P < 0.001$ shows statistically significant association).

Table 7: PPV of the most reliable ultrasound parameters for evaluation of axillary lymph node metastasis

Ultrasound criteria for metastasis	Non-metastatic	Metastatic	PPV (%)
Round shape	1	20	95
Absent echogenic hilum	0	29	100
Eccentric cortical thickening	4	8	66.6
NHBF (in patients with only peripheral vascular pattern)	0	28	100

PPV: Positive predictive value, NHBF: Non Hilar blood flow

According to Dudea *et al.*,[3] the association of round shape and absent echogenic hilum, termed as a stringent criteria for malignancy, had high specificity.

Vanizi *et al.*[4] found H/L ratio <0.5 to be highly suspicious of malignant deposit. He also observed that H/L ratio of <0.30 was found to predict metastatic deposit in the node with a sensitivity of 81%, specificity of 83%, and a diagnostic accuracy of 82%.

Margins

Irregular or angular nodal margins represent a criterion of suspicion for metastasis which usually indicates invasive, extracapsular, and extranodal spread and bears a severe prognosis, while benign nodes are characterized by sharp margins. In our study, 34 patients had irregular nodal margins, of these lymph nodes of 32 patients revealed metastasis.

Number of Lymph Nodes

In our study, patients having axillary metastasis had the number of lymph nodes as diagnosed by ultrasound in the range from 2 to 6, mean 3 ± 0.82 ($P < 0.001$).

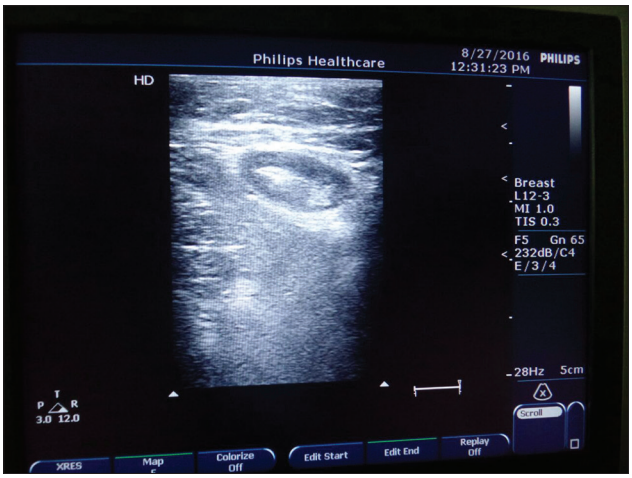

Figure 1: Ultrasonography image showing normal oval shape of axillary lymph node with maintained echogenic hilum

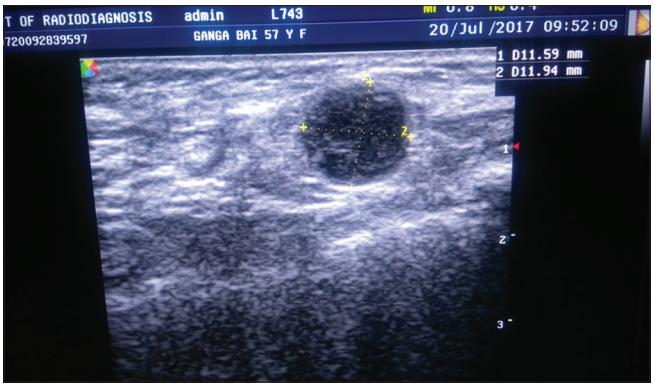

Figure 2: Ultrasonography image showing L/S ratio nearly 1, resulting in roundening of lymph node, suspicious of metastasis

Table 8: Accuracy of various ultrasound and color Doppler parameters for evaluation of metastasis in axillary lymph nodes

USG and CD parameters	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Diagnostic accuracy (%)
Number of LNs 3 or more	74.36	78.26	85.29	64.29	75.80
Size (short axis diameter>0.7 cm)	94.8	52.17	77.08	85.7	79.03
L/S ratio (<2)	79.49	65.22	79.49	65.22	74.1
RI≥0.7)	92.31	56.52	78.26	81.25	79
PI (≥1.4)	82.5	65.22	80.00	68.18	75.80
Non-hilar blood flow	79.49	95.65	96.87	73.33	85.48

USG: Ultrasonography, CD: Color Doppler, PPV: Positive predictive value, NPV: Negative predictive value, RI: Resistivity index, PI: Pulsatility index

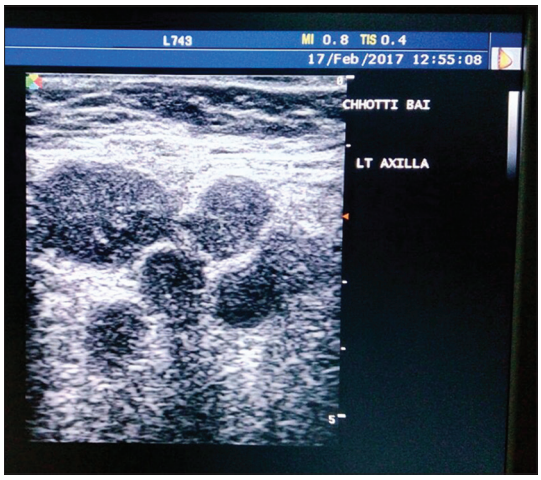

Figure 3: Ultrasonography image showing multiple axillary lymph nodes with loss of hilar echogenecity

Figure 4: Ultrasonography image showing eccentric cortical thickening (8 mm), suspicious of metastasis

A total of 34 patients were diagnosed with three or more than three axillary lymph nodes on USG [Figure 3]. The sensitivity, specificity, PPV, NPV, and diagnostic accuracy of multiple lymph nodes (three or more than three) in diagnosing nodal metastasis were 74.36%, 78.26%, 85.29%,64.29%, and 75.80%, respectively. In the study done by Das and Khanna,[5] the sensitivity, specificity, PPV, NPV, and diagnostic accuracy of nodal metastasis

Figure 5: Ultrasonography image showing focal cortical bulge due to subcortical metastatic deposits

Figure 6: Ultrasonography image with color Doppler of axillary lymphnode showing central hilar vascularity pattern

in multiple lymph nodes (three or more than three) were 69%, 85%, 73%, 82% and 79%, respectively.

Structural Changes

Structural changes are, most often, encountered in malignant nodes and were absent in benign conditions.

Eccentric Cortical Thickening

In our study, lymph nodes of 12 patients had eccentric asymmetrical cortical thickening (>3 mm) [Figure 4], out of these lymph nodes of 8 patients were positive for metastasis. Focal cortical hyperplasia is indicative of partial tumor infiltration and represents a useful, sign for identifying metastatic nodes [Figure 5].

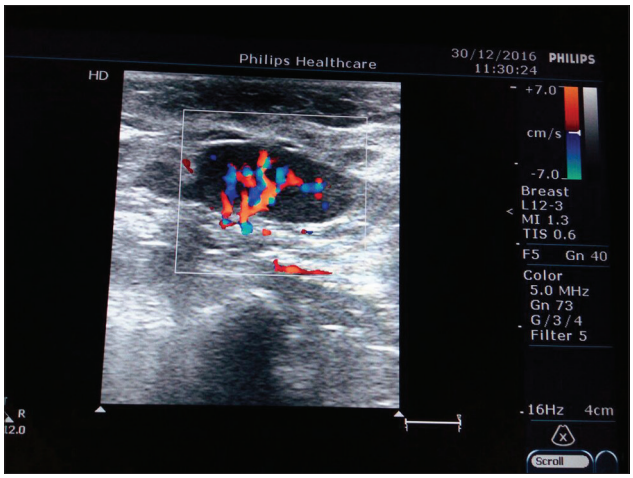

Figure 7: Ultrasonography image with color Doppler showing perihilar branching vascularity in axillary lymph node

Figure 8: Ultrasonography image with color doppler showing peripheral non-hilar cortical vascularity suggestive of metastatic changes

Figure 9: Ultrasound with color Doppler showing mixed vascularity (hilar+peripheral) of axillary lymph node

Intranodal Necrosis

In our study, two patients had intranodal necrosis, one was of coagulative type, and the other was associated with anechoic cystic changes. On histopathological examination,

Figure 10: Ultrasonography image showing pulsed Doppler spectral waveforms obtained from benign non-metastatic nodes with low resistivity index (0.48), low pulsatility index (0.62), and rounded systolic peaks

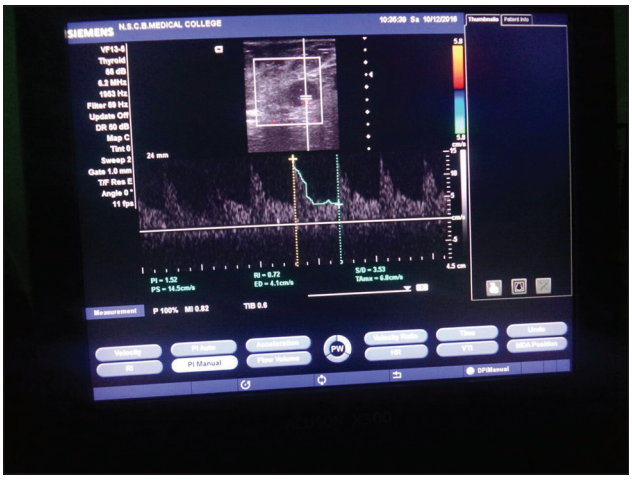

Figure 11: Ultrasonography image showing pulsed Doppler spectral waveforms obtained from metastasis-bearing lymph nodes with high resistivity index (0.72), high pulsatility index (1.52), and sharp systolic peaks

both were positive for nodal metastasis. Dudea *et al.*[3] described that intranodal necrosis indicates metastasis in most instances. It encompasses the coagulation or liquefaction type.

Coagulation necrosis appears as an echogenic focus that casts no shadow and shows no contact with the hilum or continuity with perinodal fat. Although necrotic changes are seen in metastasis, they are also seen in benign inflammatory nodes as well. Therefore, this type of necrosis represents a sign of certainty for pathologic changes, without disease specificity.

Cystic or liquefaction necrosis appears as anechoic areas within the structure of the lymph node. In patients with carcinoma, the presence of a cystic lymph node detected by USG is highly suggestive of locally metastatic disease However, the inflammatory nodes as may also present with non-malignant cystic necrosis.

Matted Lymph Nodes

In our study, 5 patients were diagnosed as having multiple coalesced matted lymph nodes. Moreover, all 5 had metastasis on histoplathological examination resulting in 100% PPV.

Matting of the lymph nodes is suggestive of metastasis. Dudea *et al.*[3] described that the presence of matting suggests extracapsular spread of malignancy. In his study, matting was encountered in 66% of cases with metastasis.

Color Doppler

Vessel location and flow pattern

Hilar vascular pattern

The hilar signal appears as Y-shaped or club-shaped color signals that occupy the central, hilar region of the lymph node. Inflamed or reactive lymph nodes tend to be fed by a single hilar artery [Figure 6]. In our study, of 62 patients, 21 patients had central hilar flow pattern which was fed by single vascular pedicle. Of these, only one patient had metastatic deposits.

Perihilar Vascular Pattern

It was defined as a simple hilar vessel signal with centrifugal branches oriented radially [Figure 7]. In our study, 9 patients had perihilar vascular pattern with multiple vascular pedicles in which 7 patients revealed metastasis.

Peripheral Non-hilar Vascular Pattern

It was defined as circumferential linear vascularity along the periphery of the node with no detectable connection to the hilum [Figure 8]. Metastases to lymph nodes stimulate the development of transcapsular tumor neovascularity, which implant in the subcapsular and cortical sinusoids and the neovessels that they generate penetrate through the lymph node capsule resulting in peripheral vascularity.

Yang and Metreweli[2] evaluated non-hilar cortical blood flow to have a high PPV for metastasis in the setting of an ipsilateral invasive breast cancer.

In our study, peripheral non-hilar cortical blood flow was seen in 28 patients; all 28 patients on histopathological examination had metastatic lymph nodes.

Mixed Vascular Pattern

It was defined as more than one vascular pattern in a lymph node [Figure 9].

In our study, 4 patients showed mixed vascularity, i.e., both hilar as well as non-hilar cortical (peripheral); of these 3, patients revealed metastasis.

Thus, a total number of patients having non-hilar cortical blood flow were 32 (28 peripheral and 4 mixed) The sensitivity, specificity, PPV, NPV, and diagnostic accuracy to detect nodal metastasis were 79.48%, 95.65%, 96.8%, 73.3%, and 85.48%, respectively.

Flow Impedance

Flow impedance is expressed by the values of RI and PI , these are also used as diagnostic criterion to identify metastasis. Theoretically, low impedance, produced by vasodilatation [Figure 10], is encountered in inflammation while vessel compression by tumor cells leads to increased impedance.

RI

The principle of RI is that, in a lymph node, the high resistance of distal vessels produces a low diastolic flow in the feeding artery increasing the difference between the peak systolic velocity and end diastolic velocity.

We observed that mean RI of metastatic nodes was 0.86 ± 0.14 and that of non-metastatic nodes was 0.66 ± 0.21 ($P < 0.001$). The difference was statisically significant and was found to be useful for differentiating benign and metastatic nodes.

We also found that the cutoff value of 0.7 for RI yielded a high sensitivity of 92.10% but low specificity of 56.52%. However, PPV, NPV, and diagnostic accuracy in detecting nodal metastasis were 78.26%, 81.25%, and 79%, respectively.

Dudea *et al.*[3] found that the cutoff value of 0.7 for RI yielded a sensitivity of 86% and a specificity of 70%.

PI

This is a measure of the variability of blood flow in a vessel. In the present study, the mean PI of metastatic nodes was 2.47 ± 1.26 standard deviation ($P < 0.001$) and that of non-metastatic nodes was 1.52 ± 1.16 ($P < 0.001$). A PI >1.4 was found to diagnose metastatic nodes with a sensitivity of 82.5%, specificity of 65.22%, PPV of 80%, NPV of 68.18%, and a diagnostic accuracy of 75.80%.

Dudea *et al.*[3] found that the cutoff value of 1.4 for PI yielded a sensitivity of 80% and a specificity of 86%.

Thus, we have found that pulsed Doppler spectral waveforms obtained from metastasis-bearing lymph nodes tend to have high RI, high PI, and sharp systolic peaks [Figure 11].

CONCLUSION

High-resolution sonographic and color Doppler examination proved as a valuable primary investigation to identify lymph nodes and has a high PPV in differentiating metastatic from non-metastatic (reactive) lymph nodes.

In our study, it was also found that lymph nodes number ≥3, L/S ratio <1.4, RI >0.7, PI >1.4, and non-hilar cortical blood flow were most reliable parameters for diagnosing metastatic lymph nodes with a diagnostic accuracy of 75.80%, 69.35%, 79%, 72.58%, and 85.48%, respectively [Table 8], in patients with known cases of breast cancer. Axillary staging in these patients is very beneficial as it allows the surgeon to proceed directly to ALND and thus avoid an unnecessary SLNB and its complications. Hence USG and color Doppler of axilla serves an important role in the management of patients with breast cancer.

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Original Article

A Clinical Study on Risk Factors of Daytime Urinary Frequency among Women Aged 60 Years and Above

Pendekanti Padmaja

Assistant Professor, Department of Obstetrics and Gynaecology, Kurnool Medical College, Kurnool, Andhra Pradesh, India

Abstract

Background: Daytime urinary frequency is a commonly encountered complaint in women of all ages and more so in the elderly. The causes and risk factors are many depending on the age of the patient. Frequency includes incontinence of urine, urgency, and overflow.

Aim of the Study: The aim of this study is to assess the associated risk factors for daytime urinary frequency among women aged ≥60 years.

Materials and Methods: The definition of the International Continence Society for daytime urinary frequency was used in the study, and associated risk factors were evaluated by recording medical history and sociodemographic variables. A total of 464 women aged ≥60 years were included in a single stage, prospective study based on outpatient department hospital attendance. Frequencies were tested with Pearson χ^2 test using *P* value significant at 0.05.

Observations and Results: Among 464 patients, the age groups of 60–80 years were included, with a mean age of 67.24 ± 3.40. History of hypertension was present in 116 (255), diabetes mellitus was present in 128 (27.58%), allergy to medication in 158 (34.05%), urinary incompetence in 269 (57.97%), and hormonal therapy in 145 (31.25%), which was statistically significant at *P* <0.05 (*P* considered as statistically significant at <0.05). 80.17% of women were sexually active, 27.37% had undergone hysterectomy, and 45.25% of women had undergone other gynecological surgeries.

Conclusions: The prominent risk factors of daytime frequency of micturition were diabetes and hypertension. Other risk factors include urinary incontinence, drug allergies, hormone therapy, and body mass index. Factors such as study marriage, menopause, prior gynecological surgery, and sexual activity were not significant risk factors in causing daytime frequency of micturition.

Key words: Incontinence, Neurogenic bladder, Urgency, Urinary frequency

INTRODUCTION

The frequency of urgency urination is not life threatening but has major impact on the quality of life (QOL) of a woman. Its effects on personal hygiene, psychological, social, and sexual well-being are alarming. When patients present urinary symptoms as "bothersome or troublesome," then they can be considered as not only hygienic but also a social problem.[1] As women refuse to talk these complaints, they are also called as silent epidemic.[2] The prevalence of daytime frequency worldwide is so variant that the data cannot be generalized to a given area or population.[3] The reported prevalence rates seem to vary widely not only between communities but also between studies within a single community. Urinary incontinence (UI) is defined by the International Continence Society (ICS) as "the complaint of any involuntary leakage of urine."[3] The prevalence of UI ranges from 10% to 34%.[4] The potential risk factors for UI include increasing age, increasing parity, vaginal deliveries, obesity, surgery, constipation, menopause, surgeries undergone, and chronic respiratory problems.[5] Comorbid conditions such as urinary tract infections (UTIs), skin problems such as rashes, infections, and sores occur due to constantly wet skin. The definition of "increased daytime frequency" presented by the ICS is that the patient complains of having to void too often

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Corresponding Author: Dr. Pendekanti Padmaja, Department of Obstetrics and Gynaecology, Kurnool Medical College, Kurnool, Andhra Pradesh, India. E-mail: drpadmaja43@gmail.com

during the day. It is a subjective lower urinary tract symptom (LUTS) as perceived by the patient, caregiver, or partner. Frequency, as used in this study, was adapted from the ICS definition. The present study was conducted in an attempt to find the risk factors in women of Rayalaseema, an important geographical part of Andhra Pradesh.

Aim of the Study

The aim of this study is to assess the associated risk factors for daytime urinary frequency among women aged ≥60 years.

Period of Study

The study duration was from May 2005 to April 2008 (3 years).

Institute of Study

The study was conducted at the Department of Obstetrics and Gynecology (OBG), General Hospital attached to Kurnool Medical College, Kurnool, Andhra Pradesh.

MATERIALS AND METHODS

A total of 464 women patients attending the outpatient department of OBG, General Hospital attached to Kurnool Medical College, Kurnool, Andhra Pradesh, with complaints of daytime frequency of micturition were included in the present study. The study was to evaluate the prevalence and determine the associated risk factors regarding daytime urinary frequency in women aged ≥60 years. An Institutional Ethical Clearance was obtained, and Ethical Committee approved questionnaire and consent form were used in collecting the data. Inclusion criteria: (1) Women aged ≥60 years were included. (2) Women with daytime frequency of micturition for more than 3 months duration were included. (3) Women who answered "Yes to the question" "Do you consider that you micturate frequently during the day time?" were only included in the study. (4) Women ready to participate in the study and sign the consent form were included in the study. Exclusion criteria: (1) Women aged <60 years were excluded. (2) Women with complaints of daytime frequency of micturition below 3 months were excluded. (3) Women who answered "NO" to the question "Do you consider that you micturate frequently during the day time?" were excluded from the study. (4) Women refusing to answer the questionnaire and sign the consent form were excluded. The questionnaire was formulated to cover five aspects of clinical history: General background, medical history, obstetric and gynecological history, daytime urinary frequency, and other LUTS. In medical history, comorbid diseases such as hypertension, diabetes mellitus, and thyroid metabolic disorders were elicited. Body mass index (BMI) was calculated for all the women. Thorough clinical history was elicited to determine the type of Urinary Incontinence the patient has;such as: (a) stress incontinence: Leakage of urine on sneezing, coughing, exercise, rising from sitting, or lifting; (b) urge incontinence: Urgency and failure to reach a toilet in time; and (c) frequency of urine during the day/at night. (b) History about dribbling of urine after leaving the toilet was elicited; (c) Loss of bladder control and feeling of incomplete bladder emptying before and after micturition was elicited. (d) Pain or burning sensation on passing urine was elicited. (e) Presence of bladder spasms was elicited. (f) History of neurogenic bladder was elicited. (g) A full obstetric history should be taken in these women. (h) A bladder chart [Table 1] was given to these patients for a minimum period of 3 days. (i) The patients were enquired about sexual dysfunction and QOL. (j) Histories of medication contributing to the symptoms were elicited.

(k) The bowel habit was elicited, and in the past, the desire for treatment was elicited. A thorough gynecological examination was done attention being paid to elicit digital assessment of pelvic floor muscle contraction, perform a bimanual/vaginal examination to assess for the presence of prolapse, signs of vaginal atrophy, abdominal, pelvic, and neurological examination was performed. In all the patients initially, a urinary dipstick testing was done to look for blood, glucose, protein, leukocytes, and nitrites. If a woman has symptoms of a UTI and dipstick testing shows leukocytes and nitrites urine for culture and sensitivity was done, meanwhile antibiotics were prescribed waiting for results. If no symptoms of UTI present but the dipstick is positive, antibiotics are not started. Renal function tests are done where may be indicated. Assessment of residual urine was done in women with symptoms suggesting voiding dysfunction, recurrent UTI, using a bladder scan and ultrasound pelvis. Sometimes, catheterization was used. Urinary flow rates in patients with neurological disease were recorded. Urodynamic studies were done wherever required. All the data were analyzed using standard statistical methods.

OBSERVATIONS AND RESULTS

A total of 464 women with complaints of daytime frequency of urination were successfully included in the present study. The patients belonged to the age group of 60–80 years with a mean age of 67.24 ± 3.40 [Table 2]. 66.90% of the women belonged to the age groups of 60–70 years, 22.84% in the age group of 70–75, and the remaining 21.12% belonged to 75–80% of the study [Table 2].

Table 1: The bladder chart used for the study

Date/time am/pm	Amount in mL	How strong was the urge to go? 0, +, ++	Did you experience accidental leakage?	Comments what were you doing?	Time	Amount in mL or cups	Type what kind?

Medical history of women with daytime frequency of micturition showed that history of hypertension was present in 116 (255), diabetes mellitus was present in 128 (27.58%), medication was present in 158 (34.05%), urinary incompetence in 269 (57.97%), and hormonal therapy in 145 (31.25%) patients which was statistically significant with $P < 0.05$ (P considered as statistically significant at <0.05), [Table 3]. Table 3 shows that the women who suffered from diabetes mellitus and hypertension, drug allergy, and UI suffered more with daytime frequency of micturition than women without these. In addition, women undergone hormone therapy was more likely to report urinary frequency than those who had not received, [Table 3].

Among the 464 women in the study, the BMI was within the normal range 20–29 in 311 patients (67.02%) and above 30 in 153 (32.97%) [Table 4].

The relation between parity and the daytime frequency in the women in the study showed that the incidence decreased according to the parity with 33.83% in women with para 5, 29.31% with para 4, 16.59% with para 3, 11.42% with para 2, and 08.83% with para1 [Table 5].

In the study, the gynecological history and findings showed that 80.17% of women were sexually active, 27.37% had undergone hysterectomy, and 45.25% of women had undergone other gynecological surgeries [Table 6].

In the present study, the prevalence of daytime frequency of micturition cannot be demonstrated as statistically significant, among women who had hysterectomy, and other gynecological surgery. Furthermore, marriage and age of menopause did not significantly increase the risk of the frequency of micturition.

Table 2: The age incidence of the study group (*n*=464)

Age groups	Number (%)
60–65	234 (50.53)
65–70	153 (16.37)
70–75	047 (22.84)
75–80	030 (21.12)

Table 3: The incidence of medical histories in the study (*n*=464)

Medical history	*n* (%)	*P*
Hypertension		
Yes	116–25	0.018
No	348–75	
Diabetes mellitus		
Yes	128–27.58	0.019
No	336–72.41	
Drug allergy		
Yes	158–34.05	0.021
No	306–65.94	
UI		
Yes	269–57.97	0.028
No	195–42.02	
Hormonal therapy		
Yes	145–31.25	0.018
No	319–- 68.75	

UI: Urinary incontinence

DISCUSSION

The present study was a tertiary hospital-based prospective study in which daytime urinary frequency and its risk factors were analysed using cross-sectional population sampling in a single-stage random sampling over a period of 3 years. The study was among the women aged ≥60 years belonging to all the strata of the society. Although the symptom is the same urinary in all women, the underlying causes are so many that to direct the investigations judiciously is difficult for the treating gynecologist. Daytime frequency of micturition is only a subjective symptom, the severity of which fluctuates. Both of these factors make the study difficult to pinpoint the risk factors. However, according to the definition of ICS, it is better to investigate the risk factors and their impact on frequency by taking into consideration the sociodemographic, medical, and gynecological factors on the prevalence of urinary frequency in postmenopausal women aged ≥60 years. In Taiwanese women, the prevalence was noted as 18.8% and age was a risk factor of urinary frequency.[6] A study by Bungay *et al*.[7] concluded that the prevalence of frequency did not significantly increase with age. In the present study, 66.90% of the women belonged to the age groups of 60–70 years, 22.84% in the age group of 70–75, and the remaining 21.12% belonged to 75–80 years. In a Taiwanese study, the prevalence of frequency of micturition among the age groups of 20–59 did not reveal age as a risk factor. [8] In the same study, the authors found diabetes mellitus and hypertension as risk factors for the frequency of micturition. [8] In the present study also, these two diseases are found to be risk factors for daytime frequency of micturition, as the P value for the data was 0.019 and 0.018, respectively

Table 4: The relation of BMI with incidence of daytime frequency of micturition (*n*=464)

BMI	*n* (%)
<20	089 (19.18)
20–24	113 (24.35)
25–29	109 (23.49)
30–34	096 (20.68)
35–39	057 (12.28)

BMI: Body mass index

Table 5: The relation of parity with frequency of micturition (*n*=464)

Parity	Number (%)
1	041 (08.83)
2	053 (11.42)
3	077 (16.59)
4	136 (29.31)
5	157 (33.83)

Table 6: The gynecological history in the study (*n*=464)

Observation	Number (%)
Married	443 (95.47)
Sexually active	372 (80.17)
Menopause	464 (100)
Hysterectomy	127 (27.37)
Other than hysterectomy	210 (45.25)

(*P* significant at <0.05), [Table 2]. In addition, in this study, UI, drug allergies, hormone therapy, and BMI were also associated with the prevalence of frequency in women aged ≥60 years. These last 4 factors were not recognized as risk factors in the study by Hsieh *et al*.[8] among their subjects aged 20–59 years. Nocturia and frequency in patients aged ≥60 years, age, diabetes mellitus, hypertension, drug allergy, and UI were found as risk factors by Hsieh *et al*.[9] In the present study, marriage, menopause, prior gynecological surgery, and sexual activity were not significant risk factors in causing daytime frequency of micturition. Bungay *et al.* noted that there was no specific increase in the prevalence of frequency among women in their peri-menopausal or postmenopausal years. [7] In the present study, the incidence of daytime frequency of micturition increased with the increase in the parity unlike the Taiwanese study by Abrams *et al*.,[10] where the prevalence of daytime frequency was shown to decrease as parity increases and when it is <6. Daytime frequency of micturition affects the QOL even though it is only a symptom and subjective perception by the patient. It also depends on the attitude of the patient, perception of the degree of inconvenience knowledge, and culture of the individual suffering from it. Treatment of this symptom depends on the workup to diagnose the correct cause of the disease and comorbid conditions underlying it.

CONCLUSIONS

The prominent risk factors of daytime frequency of micturition were diabetes and hypertension. Other risk factors include UI, drug allergies, hormone therapy, and BMI. Factors such as study marriage, menopause, prior gynecological surgery, and sexual activity were not significant risk factors in causing daytime frequency of micturition.

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Original Article

Median and Phrenic Nerve Conduction Study in Patients with Type II Diabetes Mellitus

L M Sweety[1], J Chris Angel[2]

[1]Assistant Professor, Department of Physiology, Kanyakumari Government Medical College, Asaripallam, Tamil Nadu, India,
[2]Associate Professor, Department of Physiology, Kanyakumari Government Medical College, Asaripallam, Tamil Nadu, India

Abstract

Background: Diabetes mellitus is an iceberg disease. Unfavorable modification of lifestyle and dietary habits that are associated with urbanization is believed to be the most important factors for the development of diabetes. Diabetic patients, if undiagnosed or inadequately treated, develop multiple chronic complications leading to irreversible disability and death.

Aim and Objective: The aim of this study is to compare the motor median and phrenic nerve conduction study in Type II diabetic patients.

Materials and Methods: Forty-five diabetic patients were recruited and were subjected to do median and phrenic nerve conduction study. Results were statistically analyzed by ANOVA.

Results: There was a significant ($P < 0.05$) increase in latency and decrease in amplitude and nerve conduction velocity of both phrenic and median nerve conduction.

Conclusion: We conclude that like other peripheral nerves phrenic nerve also gets affected in Type II diabetes mellitus.

Key words: Amplitude, Diabetes mellitus, Latency, Median nerve, Phrenic nerve

INTRODUCTION

Diabetes mellitus is characterized by chronic hyperglycemia with disturbances of carbohydrate, fat, and protein metabolism, resulting from defects in insulin secretion, insulin action, or both. Type II diabetes is the most common form of diabetes. Patients with Type II diabetes usually have insulin resistance, rather than absolute, insulin deficiency. Their circulating insulin levels may be normal or elevated yet insufficient to control blood glucose levels within the normal range because of their insulin resistance. The effects of diabetes mellitus include long-term damage and dysfunction of various organs, especially the eyes, kidneys, heart, and blood vessels.[1]

Diabetic neuropathy encompasses a wide, heterogeneous group of clinical and subclinical syndromes. It is one of the major long-term complications associated with diabetes that can cause considerable morbidity and mortality.[2] 50–75% of all ulcerations and non-trauma amputations are a consequence of diabetic neuropathy, and it causes more hospitalizations than all the other diabetic complications.[3,4] Diabetic neuropathy affects the sensory, autonomic, and motor neurons of the peripheral nervous system.[5] Neuropathy generally progresses at a steady state given that the level of impairment directly correlates with the duration of diabetes.[5]

The diaphragm, principal inspiratory muscle is supplied by the phrenic nerve. Phrenic nerve arises from the 3rd, 4th, and 5th cervical segment of the spinal cord. It is a mixed nerve having both sensory and motor component. Diaphragm weakness implies a decrease in the strength of the diaphragm. Diaphragm paralysis is the extreme form of diaphragm weakness. Weakness of the diaphragm most frequently arises from diseases in the phrenic nerve or from myopathies affecting the diaphragm secondary to some disease process.[6]

Reduced muscle strength has been reported in diabetic patients. Bilateral or unilateral diaphragmatic paralysis

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Corresponding Author: Dr. J Chris Angel, Associate Professor, Department of Physiology, Kanyakumari Government Medical College, Asaripallam, Tamil Nadu, India. Phone: +91-9894863443. E-mail: j.chrisangel@gmail.com

has been observed in diabetic patients.[7] In a study, they had reported that the respiratory muscle endurance was impaired, and a greater perception of respiratory exertion was noticed in diabetic patients relative to their matched controls.[8] Moreover, breathlessness on exertion and orthopnea in association with Type II diabetes mellitus has been also reported. Investigation showed that bilateral diaphragmatic paralysis due to phrenic neuropathy may be an important, if rare complication of diabetes and diaphragmatic function should be considered in any patient with unexplained breathlessness and orthopnea.[9]

Hence, this study is aimed to detect the nerve conduction parameter of phrenic nerve and median nerve in Type II diabetes mellitus patients.

MATERIALS AND METHODS

It is a hospital-based cross-sectional study which was done in the Physiology Department of Sree Balaji Medical College Hospital and Research Institution, Chennai. We selected 45 Type II diabetic patients with the age group of 35–55 years. Among them, 15 were males and 30 were females. Ethical Committee clearance was obtained. Well-informed written consent was obtained from all those who participated in the study. We excluded the patients suffering from thyroid diseases, renal disorders, and liver diseases. Based on the duration of diabetes mellitus, all the patients involved in the study were divided into three groups. With <5 years of duration of diabetes belong to one group, 5–10 years of duration in other group, and >10 years of duration in one another group.

The fasting, postprandial blood sugar (PPBS) values, and glycosylated levels of the patients were assessed. All the patients were subjected to do motor median and phrenic nerve conduction study in the research laboratory of the physiology department. All the results were statistically analyzed and tabulated. Statistical analysis was performed using ANOVA.

DISCUSSION

All our patients involved in the study, in spite of having regular medication, were suffering from higher mean values of fasting, PPBS level, and glycosylated hemoglobin (HbA1c), which was also found to be correlated with duration of diabetes [Table 1 and Figures 1 and 2]. The motor median nerve conduction study of both right and left side of all diabetic patients showed an increase in mean latency as the disease progressed [Tables 2 and 3]. Whereas, the amplitude and motor nerve conduction velocity were decreased as the duration of disease increased. This study is in par with the study done by Lewko *et al*.,[10] who also had an increase in nerve conduction velocities as the disease progressed.

Similarly, the nerve conduction parameters of the phrenic nerve also showed almost the same result as that of median nerve. The nerve conduction velocity of phrenic nerve was reduced on both sides. The latency of the nerve conduction increased, whereas the amplitude of the nerve conduction reduced on both sides [Table 4 and Figures 3 and 4]. Our study is in par with the study of Bansal *et al*.,[11] who had suggested that the slowing of nerve conduction velocity indicates the ongoing damage to the myelin sheaths and concluded that nerve conduction velocity is gradually diminished in diabetic neuropathy.

Amplitude reflects the size and number of nerve fibers, and its measurement is important for the evaluation of neuropathy. Both latency and conduction velocity depend on an intact, myelinated nerve as myelin and the saltatory conduction are essential for fast action potential propagation in normal subjects. Slowing of conduction velocity or prolongation of latency usually implies demyelinating injury, while the loss of amplitude usually correlates with axonal loss or dysfunction.[12]

Thus, our study proves that like other peripheral nerves, phrenic nerve also gets affected in Type II diabetes mellitus. The reason for increase in latency and decrease in amplitude of both phrenic and median nerve is due to nerve damage caused by hyperglycemia. The pathophysiology of diabetic neuropathy includes increased oxidative stress yielding advanced glycosylated end products, polyol accumulation, decreased nitric oxide/impaired endothelial function, and impaired Na+/K-ATPase activity. Hyperglycemia not only causes mere destruction to nerve fibers but also the repair mechanisms are also defective.[13-15]

Unilateral paralysis might not only present clinically but also bilateral paralysis causes respiratory failure and might end in mortality. Phrenic neuropathy should be considered

Table 1: Basic characteristics of all the diabetic patients

Duration	<5 years (*n*=15)	5–10 years (*n*=15)	>10 years (*n*=15)
Age (years)	42.6±5.6	48.6±4.3	53±2.7
Height (cm)	152.5±9.5	150.5±5.8	154.2±8.1
Weight (Kg)	60±7.1	62±8.3	63±6.4
BMI (Kg/m²)	25.2±4.4	27.6±4.3	26.5±2.8
FBS (mg/dl)	112.5±20*	137.5±34.6*	151.4±47.8*
PPBS (mg/dl)	197.3±48*	215.6±44.2*	218.5±53*
HbA1c (%)	7.21±0.8	7.39±0.9	7.52±1.3

FBS: Fasting blood sugar, PPBS: Postprandial blood sugar, BMI: Body mass index, HbA1c: Glycosylated hemoglobin. *Significant (*P*<0.05)

Table 2: Right side motor median nerve conduction study of all diabetic patients

Duration (years)	Latency (ms)		Amplitude (mv)		Latency diff (ms)	Conduction velocity (ms)
	Wrist	Elbow	Wrist	Elbow		
<5	2.91±0.66	7.1±0.6	5.8±3.9	4.7±4.1	4.21±0.38	49.9±5.5*
5–10	3.1±0.6	7.5±0.9	6±3.3	4.7±2.4	4.4±0.5	48.7±5.1*
>10	4.5±1.8	9.04±2	2.48±2.4	2.19±2.4	4.5±0.3	47.9±3.6*

*Significant (P<0.05)

Table 3: Left side motor median nerve conduction study of all diabetic patients

Duration (years)	Latency (ms)		Amplitude (mv)		Latency diff (ms)	Conduction velocity (ms)
	Wrist	Elbow	Wrist	Elbow		
<5	2.8±0.7	7.1±0.9	6.04±3.3	4.7±4.1	4.26±0.7	49.3±5.9*
5–10	3.39±1.25	7.67±1.3	6.3±3.9	4.3±1.9	4.28±0.5	48.3±4.7*
>10	4.1±2.5	8.2±1.3	4.29±2.5	3.67±2.2	4.6±0.6	45.4±6.08*

*Significant (P<0.05)

Table 4: Motor phrenic nerve conduction study of all diabetic patients

Parameters (years)	Latency (ms)		Amplitude (mv)		Nerve conduction velocity (ms)	
	Right	Left	Right	Left	Right	Left
<5	10.3±4*	9.4±2.8*	0.5±0.6	0.52±0.3	3.4±1.2**	3.7±1.5**
5–10	12±2.4*	10.2±3.1*	0.45±0.4	0.48±0.5	2.4±0.8**	3±0.6**
>10	12.7±5.1*	12.6±4.7*	0.4±0.3	0.32±0.3	2.2±0.6**	2.8±1.3**

**Highly significant (P<0.001). *Significant (P<0.05)

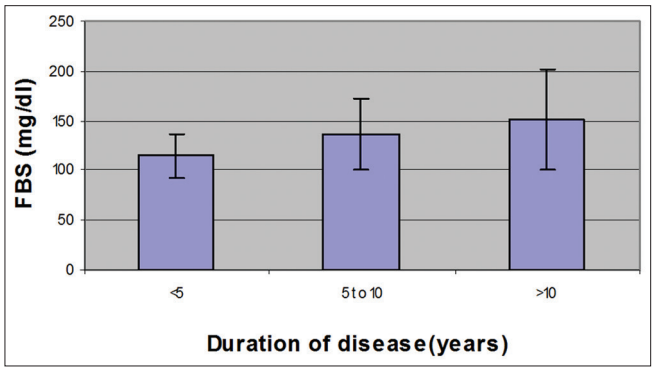

Figure 1: Comparison between fasting blood sugar and duration of disease

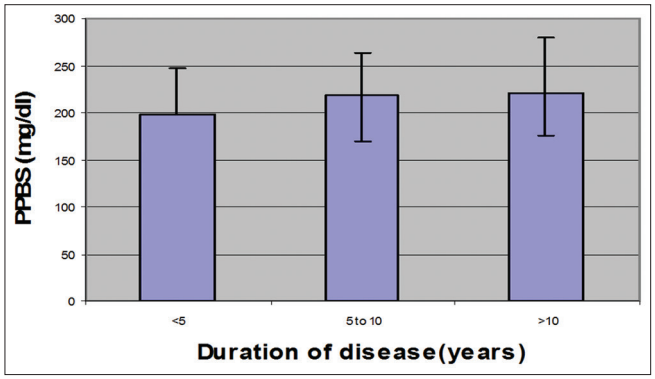

Figure 2: Comparison between postprandial blood sugar and duration of disease

as an important complication of diabetes. Phrenic nerve conduction should be assessed routinely like other peripheral nerves to prevent morbidity and mortality.

RESULTS

Table 1 presents the basic physical characters of all the diabetic patients as age, height, weight, body mass index, and the blood parameters as fasting blood sugar, PPBS, and HbA1c. It is clearly evident that as the duration progresses the blood glucose levels are not under control.

Table 4 summarizes the motor phrenic nerve conduction study of both sides. It is obvious that latency increases (statistically significant) and amplitude decreases with the progression of duration of illness. The nerve conduction velocity is significantly reduced on both sides.

Tables 2 and 3 present the motor median nerve conduction study results among the diabetic patients. Here, also the latency increases, whereas the amplitude decreases. The nerve conduction velocity is also significantly reduced in both sides. Figures 1 and 2 show the glycemic status in diabetic patients of varying duration.

Figures 1 and 2 represent the bar diagram of the glycemic indices, namely, fasting and PPBS and their comparison

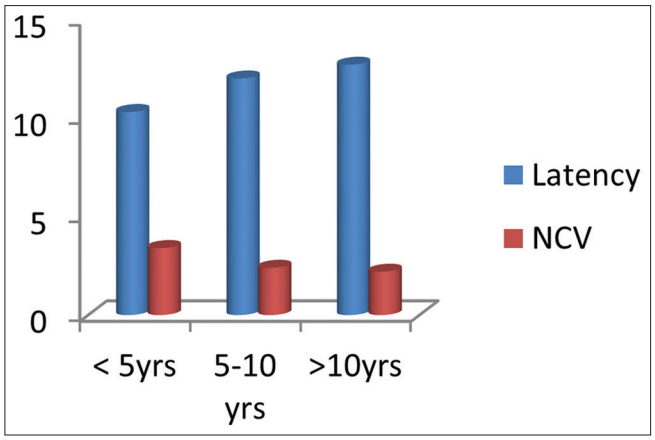

Figure 3: The bar diagram of the right side motor nerve conduction of phrenic nerve

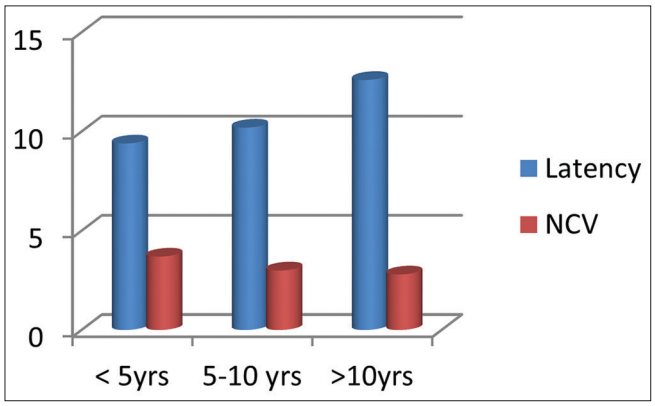

Figure 4: The bar diagram of the left side motor nerve conduction of phrenic nerve

with duration of disease. It can be clearly observed that as duration progresses the glycemic status worsen.

Figures 3 and 4 represent the bar diagram of the right and left side motor nerve conduction of phrenic nerve, respectively. It is obvious that as the duration of the disease progresses the latency increases and conduction velocity decreases.

CONCLUSION

We conclude that like other peripheral nerves phrenic nerve also gets affected in Type II diabetes mellitus.

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Original Article

A Study on Environmental Factors and Comorbid Conditions Associated with Obesity in 5–15 Years Age Group

Riyas Chungathu, G Shrinath

Assistant Professor, Department of Paediatrics, Malabar Medical College Hospital and Research Institute, Modakkallur, Kerala, India

Abstract

Background: Obesity among children is emerging as one of the most serious public health concerns in the recent times. The prevalence of obesity is increasing worldwide over the past three decades. Obesity affects nearly every organ system and often causes serious comorbid disease entities such as hypertension, dyslipidemia, insulin resistance, dysglycemia, fatty liver disease, and psychosocial problems in children. The options of pharmacotherapy as a treatment choice of pediatric obesity are very limited. Hence, establishing a comprehensive management program that emphasizes appropriate nutrition, exercise, and behavioral modification are essential. Role of a pediatrician should expand beyond his clinical setting to the community to educate both the children and their parents for prevention and early treatment of obesity.

Aim of the Study: The aim of the study was to study the environmental factors and comorbid conditions obesity in the pediatric age group.

Materials and Methods: Children aged between 5 and 15 years with obesity were included in the study environmental factors and comorbid conditions were observed and analyzed. All the parents of the children were in eliciting the clinical history and demographic details. All the children were subjected to necessary laboratory tests and ultrasound examinations to understand the base line health status and screen them for underlying comorbid conditions. Wherever clinical features of comorbid conditions are present further investigations were done to get a final diagnosis and treat the children. All the data were anise using standard statistical methods.

Observations and Results: A total of 36054 children registered in the outpatient department of the hospital during the study period of 2 years. Children aged between 5 and 15 years were 3812 (10.57%); children aged between 5 and 10 were 2147 (56.32%), and 1665 were aged between 10 and 15 years (43.67%). 131 (3.43%) children among the 3812 were identified to be obese according to the Indian Academy of Pediatrics 2015 growth charts. Among the 131 children 69 (52.67%) were in the age group of 5–10 years and the remaining 62 (47.32%) in the age group of 10–15 years. There were 66 (50.38%) females and 65 were males (49.61%). The overall mean age (5–15 years) was 08.22 ± 2.4. The mean age of children aged between 5 and 10 years was 7.10 ± 1.75. The mean age of children aged between 10 and 15 years was 12.87 ± 2.68. Among the males, the mean age was 08.50 ± 2.1 and 09.20 ± 1.8 in females. 42/131 (35.11%) children were found to have comorbid conditions more than one comorbid disease was observed in the children of this study group. Males were 25 (59.52%) and females were 17 (40.47%). Psychiatric illnesses were observed in 20/42 children (47.61%) and sleep apnea in 05/42 (11.90%). Other comorbid conditions were hypertension in 15 (35.71%), cardiovascular diseases (CVD) in 2 (4.76%), renal dysfunction in 5 (11.90%), asthma in 19 (45.23%), diabetes mellitus in 4 (09.52%), and thyroid dysfunction in 2 (4.76%) children. Dyslipidemia was observed in 02 (4.76%) and musculoskeletal disorders in 6 (14.28%) children.

Conclusions: Obesity constitutes a complex multifactorial disease associated with a wide spectrum of comorbidities due to a deleterious adipose tissue related metabolic profile and increased physical burdens imposed on various body sites. The common comorbidities were hypertension, sleep apnea, eating disorders, and psychiatric diseases. Even in children who are metabolically healthy multiple parameters and the risk of long-term adverse outcomes such as risk of CVD, osteoarthritis, disability, and psychological comorbidity need to be considered.

Key words: Children, Obesity, Overweight, Physical activity

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INTRODUCTION

Overweight is excess body weight for a particular height whereas obesity is excess body fat.[1] The above conditions occur primarily due to excess calorie intake or insufficient physical activity or both. Simultaneously when various genetic, behavioral, and environmental factors play a role

Corresponding Author: Dr. G Shrinath, Assistant Professor, Department of Paediatrics, Malabar Medical College Hospital and Research Institute, Modakkallur, Kerala, India. E-mail: drshrinathg@gmail.com

in their pathogenesis both the conditions are enhanced. Childhood obesity is the precursor of metabolic syndrome, poor physical health, mental disorders, respiratory problems, and glucose intolerance which can also track into adulthood.[2] In India, we have a unique problem wherein at one end of the spectrum we find obesity in children and adolescents while at the other end malnutrition and underweight. The International Association for the Study of Obesity and International Obesity Task Force estimate that 200 million school children are either overweight or obese.[3] The trend in India is that there is rise in the prevalence of obesity[3] while it has stabilized in western developed nations.[4] It continues to rise in developing countries like India which are in final stages of nutritional stabilization. The third National Family Health Survey of India revealed increasing obesity in north Indian states more than other parts of the country.[5] Obesity is a condition with multiple factors playing their role in its causation and usually described as a phenotype of numerous pathologies.[6,7] Obesity is excess of body fat or adiposity in an individual defined by body mass index (BMI): Body weight divided by height in meters squared (BMI: Kg m^2). Even though BMI does not correlate with adiposity as it does not quantify total body adiposity and does not distinguish between fat and muscle but on a population level, however, BMI does seem to track trends in adiposity as opposed to muscularity.[8-10] In the pediatric age group, gender-specific BMI-for-age percentile curves are used to define overweight and obesity. Children and adolescents with a BMI over the 85th but < the 95th percentile for age and gender are considered overweight and those with a BMI > the 95th percentile are considered obese. Children and adolescents with a BMI > the 99th percentile are considered severely obese.[7-9] The International Obesity Task Force has developed an international standard growth chart which enables comparison of prevalence globally.[10] The WHO estimates after an analysis of 450 nationally representative surveys from 144 countries showed the prevalence of children below age 5-year-old with a BMI >+2 standard deviation (equivalent to the 98th percentile) increased from 4.2% in 1990 to 6.7% in 2010, and is expected to reach 9.1% in 2020.[11] There is strong evidence that childhood obesity leads to adult obesity and its related comorbidities.[9] In a Longitudinal Study of Adolescent Health in USA nearly 40% of obese adolescents became severely obese by 30 years of age (BMI >40 Kg/m^2), when compared to 5% among the normal weight adolescents.[12,13] In another study among native Indians of Arizona Children with highest quartile of childhood BMI had double the incidence of death from endogenous causes in adult life.[14] There is lack of national representative data on obesity in children from India with its widely varying geographical, social, and cultural norms[15]. Here an attempt is made to understand the clinical prevalence of obesity in children attending a tertiary teaching hospital and to observe the comorbidities associated with obesity.

Type of Study

This was a prospective cross-sectional cohort study.

Period of Study

The study period was from November 2015 to October 2017.

Institute of Study

This study was conducted at the Department of Paediatrics, Malabar Medical College Hospital and Research Institute, Modakkallur, Kozhikode, Kerala.

MATERIALS AND METHODS

An institutional Ethical Committee clearance certificate to conduct a prospective cross-sectional cohort study in the Department of Pediatrics of Malabar Medical College Hospital and Research Institute, Modakkallur, Kozhikode, Kerala, a tertiary teaching hospital was obtained. Ethical Committee cleared consent letter was used before commencing the study. The total numbers of children visiting the outpatient department (OPD) were screened for overweight and obesity. Revised Indian Academy of Pediatrics 2015 growth charts for height, weight, and BMI for 5–15-year-old Indian children[16] was used to identify the obese children. All the children identified as obese were subjected to (a) history taking: (1) Food eating habits (regular breakfast, snacking habits, and eating with family meal-time routines). (2) Daily physical activity (sports, walking to school, helping household chores, and playing). (3) Time spent on television, video games, computer, and cell phones. (4) History of body dissatisfaction, depression, loss of control of eating, impaired social relationships, and decrease weight-related quality of life. (5) Binge eating disorder, excessive concern of weight, strict dieting and followed by binge eating. (b) Physical examination: A thorough physical examination was done with a focus to identify endocrinal, developmental, familial, and genetic causes. (1) Vital signs were assessed (both systolic and diastolic blood pressures [SBP and DBP]). SBP and DBP were defined as high when they were ≥ the 90th percentile, according to the task force on high BP in children and adolescents.[17] (2) The height, weight and BMI, and waist circumference (WC) were calculated based on the weight and squared stature in cm. (3) Endocrinal disorders were looked for examined for goiter, Insulin resistance (Acanthosis nigricans), polycystic ovary syndrome (hirsutism and excessive acne), and Cushing syndrome (violaceous striae and moon face). (4) Reproductive system premature puberty (age <7 years in girls and <9 years in boys); apparent micropenis (but normal penis may be hidden in fat), undescended testis/micropenis

(Prader–Willi syndrome). (5) If headache was present fundoscopy was done for evidence of optic edema due to pseudotumor cerebri. (6) Respiratory system (asthma and sleep apnea). (7) Gastrointestinal disorders (hepatomegaly or abdominal pain (gastroesophageal reflux and nonalcoholic fatty liver). (8) Musculoskeletal problems (slipped capital femoral epiphysis and Blount disease). (9) Psychological disorders (binge eating, depression, and bulimia nervosa). (c) Laboratory testing: (1) In overweight children (BMI 85–94th percentile) were ordered fasting lipid-screening test, if risk factors coexisted measurement of serum levels of fasting glucose, alanine aminotransferase (ALT), and aspartate aminotransferase (AST) was ordered. The risk factors included increased BP or hypertension, dyslipidemia and family history of diabetes. (2) In children with obesity (BMI ≥95th percentile) serum levels of fasting lipids, glucose, ALT, and AST were ordered. If the result of fasting glucose screen test is more than 126 mg/dL, counseling and repeating test was done. Glycated hemoglobin value of >40 mmol/mol (5.8%) was used for diagnosing impaired glucose tolerance (5.7–6.4% as prediabetes and >6.5% as diabetes). Fasting plasma glucose (FPG) levels are done to diagnose prediabetes in obese children (values of FPG from 100 to 125 mg/dL were diagnostic of prediabetes and more than 126 mg/dL used to confirm diabetes mellitus). 2 h plasma glucose levels (OGTT) 140–199 mg/dL were taken to diagnose prediabetes and >200 mg/dL as diabetes mellitus. If the undesirable lipid profile was found among the obese children and the total cholesterol level was on the borderline (170–200 mg/dl), the screen test was repeated and if found elevated (≥200 mg/dl), cardiac referral was undertaken. (3) In obese children with BMI (≥95 percentile) blood urea and nitrogen and creatinine levels were estimated to exclude renal dysfunction. (4) Thyroid dysfunction tests were ordered in children with BMI (≥95 percentile) thyroid-stimulating hormone levels were estimated. (d) Ultrasound abdomen: (1) To observe evidence of fatty liver was undertaken. Inclusion criteria: (1) Children aged between 5 and 15 years were included. (2) Children of both genders were included. (3) Children with BMI (≥85 percentile) were included. (4) Children with comorbid conditions such as hypertension, fatty liver, thyroid dysfunctions, and psychological disorders were included. Exclusion criteria: (1) Children below the age of 5 and above 18 years were excluded. (2) Children with acute medical or surgical diseases were excluded. (3) Children convalescing from cute diseases or surgeries were excluded. All the data were analyzed using standard statistical methods.

OBSERVATIONS AND RESULTS

The total numbers of children registered in the OPD of the hospital for various diseases during the study period of 2 years were 36054. Among these, the children aged between 5 and 15 years were 3812 (10.57%). The number of children aged between 5 and 10 were 2147 (56.32%). The remaining 1665 were aged between 10 and 15 years (43.67%). 131 (3.43%) children among the 3812 were identified to be obese according to the Indian Academy of Pediatrics 2015 growth charts[16] and included in this study. Among the 131 children 69 (52.67%) were in the age group of 5–10 years and the remaining 62 (47.32%) in the age group of 10–15 years. Among 131 children included in the study as obese, there were 66 (50.38%) females and 65 were males (49.61%). The overall mean age (5–15 years) was 08.22 ± 2.4. The mean age of children aged between 5 and 10 years was 7.10 ± 1.75. The mean age of children aged between 10 and 15 years was 12.87 ± 2.68. Among the males, the mean age was 08.50 ± 2.1 and 09.20 ± 1.8 in females. The anthropometric data, BMI, WC, and BP and laboratory values are shown in Table 1.

The 131 patients were grouped according to age groups in five categories and their mean height, weight, and their BMI was tabulated in Table 2.

Among the 131 children, 42 (35.11%) were found to have comorbid conditions and the incidence of each of the comorbid condition observed was tabulated in Table 3. More than one comorbid disease was observed in the children of this study group. Among 42 children males were 25 (59.52%) and females were 17 (40.47%). The most common comorbid disorder observed was psychiatric illnesses such as depression manifesting in the form of aggressive behavior, anger, and conduct problems; personality disorders such as low self-esteem, poor self-worth, and issues with socialization; cognitive impairment with poor school performance and altered eating behavior including binge eating, abnormal craving for food and habitual eating in 20/42 (47.61%) of the children. Asthma was observed in 19/42 (45.23%), hypertension in 15 (35.71%), musculoskeletal disorders in 06/42 (14.28%), sleep apnea was observed in 05/42 (11.90%), and renal diseases in 5 (11.90%) children. The next common comorbidities observed were diabetes in 04/42 (9.52%) cardiovascular diseases (CVD), dyslipidemia and hypothyroidism in two children each (4.76%), [Table 3].

In this study, obesity was defined as BMI > or = 95th percentile and overweight as BMI > or = 85th percentile. Pre-hypertension and hypertension were defined as systolic and/or diastolic BP > or = 90th percentile for age, gender, and height and BP > or = 95th percentile, respectively. In children with pre-hypertension or hypertension, repeated measurements were performed. The incidence of comorbid conditions among the 213 children with obesity were categorized according to percentile of BMI is shown tabulated in Table 4.

DISCUSSION

In adults the incidence of obesity has doubled worldwide since 1980, with more than 1.5 billion adults being overweight with BMI >25 kg/m^2 and among them at least 500 million are clinically obese with BMI >30 kg/m.[18,19] Alarming trends of weight gain are reported for children and adolescents, undermining the present and future health status of the pediatric population.[20,21] The WHO has declared obesity a global epidemic, further stressing that it remains an under-recognized problem of the public health agenda.[22,23] Depending on the degree and duration of weight gain, obesity can progressively cause and/or exacerbate a wide spectrum of comorbidities, including Type 2 diabetes mellitus (T2DM), hypertension, dyslipidemia, CVD, liver dysfunction, respiratory, and musculoskeletal disorders, subfertility, psychosocial problems, and certain types of cancer.[24] These chronic diseases are shown to have strong correlations with BMI and closely follow the prevalence patterns of excessive body weight in all studied populations.[24] The risk increases exponentially with increasing BMI over 30 kg/m^2, which is further associated with a graded increase in the relative risk of premature death, primarily from CVD.[25] In this study, hypertension, dyslipidemia, and CVD were observed in 35.71%, 04.76%, and 4.76% of the children, respectively. Fat accumulation intra-abdominally and subcutaneously around the abdomen (central, abdominal, visceral, android, upper body, or apple-shaped obesity) is associated with higher risk for metabolic and CVD, independent of BMI.[26] Certain populations of few ethnic origins, regardless of the country of residence, are predisposed to central obesity and more vulnerable to obesity-related complications.[27] Diagnosing obesity with BMI thresholds as low as 25 kg m^2 and WC (central obesity) >45 cm is a grave risk factor for cardiovascular complications.[28] In this study, the mean WC was 48.8 ± 8.5 [Table 1]. National surveys in the UK have shown that obesity is directly responsible for almost 7% of the overall morbidity and mortality.[29] Even though diabetes mellitus Type 1 account for the most of cases in the obese pediatric population, T2DM constitutes a rather recent phenomenon and, obese children and adolescents are now increasingly diagnosed with impaired glucose tolerance and T2DM.[30] The new term "diabesity" has been introduced following the documentation of diabetes mellitus Type 2 with obesity.[31] Accordingly, anthropometric

Table 1: The overall anthropometric and BP and laboratory values of the study subjects according to gender (*n*-131)

Observation	Total (*n*=131)	Male (*n*=64)	Female (*n*=67)	*P*
Age (years)-mean; SD	08.22±2.4	08.50±2.1	08.35±1.8	0.688
Weight (kg)-mean; SD	56.3±11.2	57.0±11.5	58.7±10.7	0.013
Height (cm)-mean; SD	136.30±11.6	137.25±09.8	134.1±12.1	0.418
BMI (kg/m^2)-mean; SD	30.59±1.3	30.48±1.7	32.79±1.9	0.017
WC (cm)-mean; SD	48.8±8.5	49.5±5.9	46.07±10.1	0.023
SBP (mmHg)-mean; SD	99.7±11.5	99.0±10.9	99.2±12.2	0.050
DBP (mmHg)-mean; SD	58.6±10.4	58.0±10.1	59.7±10.4	0.042
BMI>2 SD-mean; SD	33±5.0	34±2.6	34±7.6	0.012
WC>75th percentile-mean; SD	109±25.8	36±15.5	73±38.4	0.010
High SBP-mean; SD	11±2.6	4±1.7	7±3.7	0.206
High DBP-mean; SD	14±3.3	7±3.0	7±3.7	0.697
Triglyceride levels				
<150 mg/dL	162.34±6.35	164.40±3.20	161.50±40	0.031
>150 mg/dL	132.60±2.30	127.60±42	133.70±10	0.042
Reduced HDL-C				
<40 mg/dL	33.80±5.0	32.50±3.10	34.41±3.20	0.040
>40 mg/dL	44.15±7.20	42.30±2.80	47.60±3.60	0.050
FPG				
<100 mg/dL	85.50±4.30	86.30±4.30	88.45±6.30	0.033
>100 mgd/dL	112.40±6.24	115.0±6.70	113.40±2.38	0.028

BMI: Body mass index, WC: Waist circumference, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, SD: Standard deviation

Table 2: The age group wise gender and anthropometric data (*n*-131)

Age groups-years	Male-66	Female-65	Mean height		Mean weight		Mean BMI	
			Males	Females	Males	Females	M	F
05-07-(36) mean; SD	18	18	115.90±3.20	114.53±2.78	38.31±1.7	36.60±1.4	29.46	28.37
08-10-(33) mean; SD	19	14	132.23±2.80	131.20±2.35	54.10±2.6	54.05±2.3	31.09	31.60
11-13-(30) mean; SD	14	16	146.64±2.48	145.55±2.64	75.21±3.8	70.45±4.8	35.30	33.54
13-15-(32) mean; SD	15	17	159.66±3.65	155.33±2.90	89.32±4.5	80.0±3.10	35.44	33.33

SD: Standard deviation, BMI: Body mass index

indices of central obesity (e.g., WC and waist-to-height ratio) are utilized to better assess the risk for glucose intolerance and T2DM.[32] Liver constitutes 2–3% of the body weight and consumes 25–30% of oxygen in the body. Its function is essential for metabolic homeostasis and a dynamic relation exists between it and the adipose tissue in the body to regulate carbohydrate, protein, and fat metabolism. Insulin resistance developing sue to obesity may cause insulin resistance, hyperinsulinemia, hyperglycemia, and ectopic fat accumulation in the liver (fatty liver). Fatty liver may lead to impaired hepatic function and lead to a spectrum of abnormalities, ranging from elevation of circulating liver enzyme levels and steatosis to cirrhosis, liver failure, and even liver cancer.[33] Non-alcoholic steatohepatitis was introduced by Ludwig *et al.* to describe findings in 20 patients at the Mayo clinic exhibiting a non-alcohol related liver disease which was histologically similar to alcoholic hepatitis.[34] In this study, there were 17 children showed features of fatty in liver on ultrasound examination of the abdomen. Psychological disorders, such as depression, anxiety, and chronic stress, are risk factors for developing obesity, metabolic syndrome manifestations, and CVD.[34] They also can be comorbidities following obesity. In addition, evidence indicates that prolonged and/or intense stress can lead to subsequent weight gain. In this study, the incidence of psychological disorders including depression was 47.61%. Several mechanisms have been proposed to explain links between obesity and mental health in both directions, mainly focusing on over-activation of the hypothalamic-pituitary-adrenal axis and sympathetic nervous system, as well as on the role of health risk behaviors.[35] In the context of a multidisciplinary approach, clinicians should also take into consideration that several widely prescribed antidepressants and antipsychotic agents can induce weight gain (e.g., tricyclic antidepressants, paroxetine, mirtazapine, monoamine oxidase inhibitors, lithium, clozapine, olanzapine, and risperidone).[36] Childhood obesity may also be implicated with cancer and is suggested to have long-term consequences (e.g., increased risk of death from colon cancer), although further research is required on the associations between childhood and different cancers.[37] In this study, there were no cases of malignance reported. Increased body weight due to increase in weight may enhance biomechanical stress on joints resulting in knee osteoarthritis (OA), back pain, and restrictive lung disease. Obesity is a major risk factor for knee OA. Indeed, a recent systematic review by Blagojevich *et al.* reported obesity as one of the main factors consistently associated with knee OA (pooled odds ratio of 2.63, 95% confidence interval [CI]: 2.28–3.05).[38] A prospective population-based study in Finland with a follow-up of 22 years documented a strong association between BMI and risk of knee OA, with relative odds ratio of 7.0 (95% CI: 3.5–14.10; adjusted for age, gender, and other covariates) for obese persons compared to individuals with BMI <25 kg/m^2.[39] In this study, the musculoskeletal disorders were observed in 14.28% of the children. Obesity appears to also increase

Table 3: The incidence of comorbid conditions in the study (*n*-42)

Comorbid conditions	Male	Female
Psychiatric illnesses including altered eating behavior-20 (47.61%)	09	11
Asthma-19 (45.23%)	12	07
Hypertension-15 (35.71%)		
Systolic-8	04	03
Diastolic-7	05	03
Musculoskeletal disorders-06 (14.28%)	04	02
Sleep apnea-05 (11.90%)	03	02
Dyslipidemia-2 (04.76%)	01	01
Hypothyroidism-02 (4.76%)	01	01
CVD-02 (04.76%)	01	01
Renal dysfunction-05 (11.90%)	03	02
Diabetes mellitus-04 (09.52%)		
Prediabetes	01	01
Type 2 diabetes		01

CVD: Cardiovascular diseases

Table 4: The incidence of comorbid diseases according to the percentile of their BMI (*n*-42)

Observations	>99th percentile-34 (15.96%)	95–99th percentile-49 (23%)	90–95th percentile-82 (38.49%)	85–90th percentile-48 (22.53%)
Male-25	10	06	05	04
Female-17	06	05	04	02
Hypertension-15	08	04	02	01
Diabetes-04	07	03	02	02
Hypothyroid-02	01	01	01	01
Dyslipidemia-02	02	01	00	01
Sleep apnea-05	02	01	01	00
Cardiovascular-02	01	01	00	00
Musculoskeletal-06	02	01	01	02
Asthma-20	08	06	03	03
Renal dysfunction-02	02	01	00	00
Psychiatric illnesses including altered eating behavior-20	08	06	03	03

BMI: Body mass index

the risk of hip and hand OA, although these associations are less consistent.[40] Increased body weight and fat accumulation in the abdomen and chest wall can have a significant impact on respiratory physiology leading to deterioration of pulmonary function, attributed primarily to increased mechanical pressure on the thoracic cage and trunk.[41] Obese children may exhibit reduction in lung volumes and respiratory compliance, as well as in respiratory efficiency.[42] In this study, 20 children (45.23%) had respiratory-related diseases like asthma as a comorbid condition. Morbid obesity is associated with decreased total lung capacity, expiratory reserve volume, and functional residual capacity, as a result of mass loading, splinting, and restricted decent of the diaphragm.[43] Obesity is further associated with a spectrum of distinct respiratory conditions including obstructive sleep apnea (OSA), obesity hypoventilation syndrome, asthma, and chronic obstructive pulmonary disease. OSA can lead to various clinical manifestations including snoring, choking episodes during sleep, nocturia, restless and un-refreshing sleep, daytime hypersomnolence, and impaired concentration.[44] In this study, there were 5 children (11.90%) with sleep apnea disorder. The long-term consequences of sleep apnea include are alterations in the central control of breathing, with episodes of central apnea due to progressive desensitization of respiratory centers to hypercapnia. These episodes are initially limited during sleep, but eventually can lead to the obesity hypoventilation syndrome (Pickwickian syndrome) which is characterized by obesity, sleep-disordered breathing, alveolar hypoventilation, chronic hypercapnia and hypoxia, hypersomnolence, right ventricular failure, and polycythemia.[45] Several studies have reported a consistent association between increased BMI and OSA risk with an extremely high OSA incidence among morbidly obese subjects.[46] The treating pediatrician must be recognizing obesity as a disease and appropriate weight loss treatments should be offered to the obese children. Weight management is crucial and should be promptly suggested to the parents and children even when they are otherwise healthy (e.g., metabolically healthy obese patients) to prevent and/or delay the onset of obesity-related complications.[47]

CONCLUSIONS

Obesity constitutes a complex multifactorial disease associated with a wide spectrum of comorbidities due to a deleterious adipose tissue related metabolic profile and increased physical burdens imposed on various body sites. The common comorbidities were hypertension, sleep apnea, eating disorders, and psychiatric diseases. Even in children who are metabolically healthy multiple paWWrameters and the risk of long-term adverse outcomes such as risk of CVD, OA, disability, and psychological comorbidity need to be considered.

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Original Article

Is Circumferential Assessment of Colonic Carcinoma by Computed Tomography Scan and Colonography Enough to Predict the Staging?

P K Ramesh[1], Shafi Ahamed[2]

[1]Associate Professor, Department of General Surgery, KMCT Medical College, Manassery, Kozhikode, Kerala, India, [2]Assistant Professor, Department of General Surgery, KMCT Medical College, Manassery, Kozhikode, Kerala, India

Abstract

Background: The modern treatment of rectal cancer relies on correct diagnosis which is a multidisciplinary approach by medical oncologists, radiation therapists, endoscopists, radiologists, and surgeons. Based on their diagnosis treatment varies from curative versus palliative; radical versus local excision, pre-operative chemoradiation therapy, and postsurgical adjuvant therapy.

Aim of the Study: This study aims to know the role of computed tomography (CT) scan and colonography in assessing the circumferential involvement of colonic carcinoma required for differentiating the stages of colonic carcinoma.

Materials and Methods: A total of 41 patients with colonic carcinoma were investigated with CT scan and colonoscopy to assess the circumferential involvement of the tumor to stage the disease. The final pathological and surgical staging was used as a reference to determine the accuracy of the investigating tools.

Observations and Results: Among the 41 patients, 32 (78.04%) were males and 08 (19.51%) were females. Patients aged 40–50 were 09 (21.95%), aged between 50 and 60 were 19 (46.34%), and aged between 60 and 70 were 13 (31.70%). The mean age was 56.34 ± 3.10. The laboratory investigations of serum carcinoembryonic antigen showed <3.5 ng/mL in 03 (%), 3.5–7.0 ng/mL in 11 (26.82%), 7.0–10 ng/mL in 17 (41.46%), and >10.0 ng/mL in 10 (24.39%) patients. Colonoscopy showed T1 lesions in 3 (7.31%), T2 lesions in 09 (21.95%), T3 lesions in 14 (34.14%), and T4 lesion in 05 (12.19%) patients.

Conclusions: This study showed colonoscopy and CT colonography together have an overall sensitivity of 92.68%, thus has an important role in the diagnosis of colonic carcinoma. Especially, the accuracy helps in staging of T2 and T3 tumors facilitating the choice of treatment.

Key words: Carcinoma, Chemoradiation, Endoscopy, Staging

INTRODUCTION

The incidence rates of colorectal cancer (CRC) are low in India; but apart from geographical variations, the incidences are rising rapidly in India.[1] The world's two most populous countries, China and India, have relatively low incidence rates of 14.2 and 6.1 cases per 100,000 men and women, respectively. However, as their economies have developed, their incidence of CRC has increased.[2] In India, the annual incidence rates (AARs) for colorectal carcinoma in men are 4.4 and 4.1 per 1,00,000, respectively. The AAR for colon cancer in women is 3.9 per 1,00,000. Colonic carcinomas rank 8th and rectal carcinomas 9th among the men in India. Whereas in women, rectal carcinomas do not figure in the top 10 but colonic carcinomas rank 9th.[2] The age-adjusted incidence rates of CRC in all the Indian cancer registries are very close to the lowest rates in the world.[3] In the 2013 report, the highest AAR in men for CRCs was recorded in Thiruvananthapuram (4.1) followed by Bangalore (3.9) and Mumbai (3.7). The highest AAR in women for CRCs was recorded in Nagaland (5.2) followed by Aizawl (4.5).[4] CRCs are classified as those associated with colonic polyposis and those not associated

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Corresponding Author: Dr. Shafi Ahamed, Department of General Surgery, KMCT Medical College, Manassery, Kozhikode, Kerala, India. E-mail: shafiahmadms@gmail.com

with colonic polyposis. Among the colonic polyposis syndromes, familial adenomatous polyposis (FAP) and its variants (Turcot, Gardner, and attenuated FAP) and MYH-associated polyposis are the most common. Hereditary non-polyposis colon cancer or lynch syndrome comprises the non-colonic polyposis category. FAP is characterized by multiple colonic adenomatous polyps appearing in childhood with subsequent transformation to malignancy at an average age of 45 years and is caused by a germline mutation in the APC gene on chromosome 5.[5] MYH-associated polyposis is inherited in an autosomal recessive pattern, with mutations in the base excision repair gene mutY homolog.[6] Environmental factors which play a role in CRCs are 1. Age and gender: Older men are at a high risk (25% higher in men than in women),[7] 2. Ulcerative colitis: The extent, duration, and activity of disease are primary determinants,[8] 3. Ethnicity: The African–American population is at an increased risk, 4. Long-term immunosuppression following organ transplantation, especially renal transplantation: The relative risk is the same as that of the normal population, but aged 20–30 years older,[9] 5. Diabetes mellitus associated with insulin resistance: This linked to the long-term effects of insulin-like growth factors,[10,11] 6. Alcohol consumption: Reduction in alcohol consumption may decrease the incidence of colorectal malignancy, especially among those with a positive family history,[10] 7. Consumption of fresh red meat and processed meat is associated with increased risk,[11,12] and 8. Obesity: [13] Digital rectal examination has a high positive predictive value for the presence of rectal tumors. However, a negative examination does not rule out CRC, as more than 60% of lesions are out of reach of the palpating finger. Laboratory tests include complete blood counts, liver and kidney function tests, carcinoembryonic antigen (CEA) tests, and carbohydrate antigen 19.9 (CA 19.9). Pre-operative CEA levels predict recurrence in patients with stage C (Stage III) disease and in those with stage B (Stage II) disease as well. Rigid sigmoidoscopy instruments limit evaluation to the distal 25 cm of the colon, whereas flexible sigmoidoscopy permits evaluation of the distal 55–60 cm of the colon. Complete colonoscopy (essential) should be attempted in all patients before or after surgery (within a 3-month period if index colonoscopy has not been completed). This is essential to exclude synchronous lesions or polyps. Although computed tomography (CT) colonography can be relatively sensitive and specific in research settings (85%–90%), lesions in the rectosigmoid colon may be missed on CT colonography because of the difficulty in achieving adequate luminal distention in this segment.[14] Histological confirmation of primary neoplasms is preferable, but if this is not feasible, histological confirmation of the metastatic lesion is mandatory before definitive therapy. Pathologic examination should include (essential) the determination of the following, as each of these factors are known to be associated with patient prognosis: Pathologic reporting for gross and microscopic examination includes tumor grade, depth of penetration, number of positive lymph nodes, and number of lymph nodes evaluated (a minimum of 12 lymph nodes should be evaluated). Lymphovascular invasion, perineural invasion, extranodal tumor deposits, status of proximal, distal, and radial (circumferential) margins are additional features to be looked for. For rectal cancers: Circumferential resection margin (CRM) and neoadjuvant therapy effect (tumor regression grade score). A positive CRM is defined as within ≤1 mm. A positive CRM is a more powerful predictor of local recurrence in patients treated with neoadjuvant therapy.[15]

Type of Study

Retrospective study.

Period of Study

This study period was from June 2014 to September 2017.

Institute of Study

This study was conducted at KMCT Medical College, Manassery, Kozhikode, Kerala.

MATERIALS AND METHODS

A total of 41 patients with colonic carcinoma attending the Surgical Outpatient Department of KMCT Medical College Hospital, Manassery, Kozhikode, Kerala, were included in the present study. All the data were collected from medical records section of the hospital.

Inclusion Criteria

1. Patients aged between 40 and 70 are included in the study.
2. Patients of both genders are included.
3. Patients with symptoms of tumor colon are included.

Exclusion Criteria

1. Patients aged below 40 and above 70 were excluded.
2. Patients with a history of surgery on gastrointestinal tract (GIT) were excluded.
3. Patients with other GIT lesions mimicking colonic carcinoma were excluded.

Patients irrespective of gender presenting with symptoms of pain in the abdomen, rectal bleeding, and change of bowel habits for more than 3 months were included and the investigations were analyzed. An Ethical Committee Clearance was obtained. Among the investigations, results of CT scan colonography and flexible colonoscopy to assess the circumferential involvement of the tumor to

stage the disease were used. CT colonography lesions were categorized using the CT colonography reporting and data system[16] as C0: If the study was inadequate. C1: If the study was normal. C2 (indeterminate): Polyps of 6–9 mm and fewer than 3 in number. C3: Lesions include those larger than 10 mm in diameter or if more than three lesions of 6–9 mm are present, for which colonoscopy is recommended. C4: Used to describe a colonic mass with associated luminal narrowing or extracolonic extension, for which urgent referral for consideration of surgery is recommended. The system also recommends categorization of significant extracolonic findings. The final pathological and surgical staging of individual cases was compared to the CT colonography and flexible colonoscopy findings to know the specificity and sensitivity and accuracy of these investigative tools. All the data were analyzed using standard statistical methods.

OBSERVATIONS AND RESULTS

Among the 41 patients, there were 32 (78.04%) males and 08 (19.51%) female patients. Patients aged 40–50 were 09 (21.95%), aged between 50 and 60 were 19 (46.34%), and aged between 60 and 70 were 13 (31.70%). The mean age was 56.34 ± 3.10 [Table 1].

The laboratory investigations of serum CEA showed <3.5 ng/mL in 03 (%), 3.5–7.0 ng/mL in 11 (26.82%), 7.0–10 ng/mL in 17 (41.46%), and >10.0 ng/mL in 10 (24.39%) patients [Table 2]. The mean serum CEA level in the study was 5.20 ± 1.50. Similarly, the serum CA 19.9 levels were >37 U/mL in 14 and >37 U/mL in 27 patients [Table 2]. The mean CA19.9 level was 42.35 ± 2.40 in the study.

On colonoscopy, the tumor lesions were observed at various levels in the patients of this study. The following Table 3 summarizes the breakup of the lesion in the study.

In the present study, colonoscopy showed T1 lesions in 3 (7.31%), T2 lesions in 09 (21.95%), T3 lesions in 14 (34.14%), and T4 lesion in 05 (12.19%) patients [Table 4 and Figure 1a, c and d]. The T colonography showed C0 findings in none, C1 findings in 04 (9.75%), C2 lesions in 24 (58.53%), and C3 lesions in 13 (31.70%) patients [Table 4]. Among the patients with T2, T3, and T4 lesions 38/41 (92.68%), the CGT colonography findings of C2 and C3 were seen. There was statistical significant correlation between the colonoscopy findings and CT colonography findings in the study with a $P = 0.001$. All the patients underwent biopsy and their histopathological reports showed in 32/41 (78.04%) the cell type was adenocarcinoma, in 06 (14.63%) the cell type was mucinous adenocarcinoma, and in 03 (9.75%) it was small cell carcinoma [Table 4].

Table 1: The demographic data and symptoms in the study (*n*=41)

Observations	*n* (%)
Age (years)	
40–50	09 (21.95)
50–60	19 (46.34)
60–70	13 (31.70)
Male	32 (78.04)
Female	08 (19.51)
Pain abdomen	41 (100)
Blood stained stools	36 (87.80)
Change in bowel habits	30 (73.17)
Weight loss	41 (100)
Anemia	23 (56.09)

Table 2: The laboratory investigations of CEA and CA 19.9 serum levels in the study (*n*=41)

Observations	*n* (%)
CEA (ng/mL)	
<3.5	03 (7.31)
3.5–7.0	11 (26.82)
7.0–10	17 (41.46)
>10	10 (24.39)
Carbohydrate antigen 19.9 (U/mL)	
<37	14 (34.14)
>37	27 (65.85)

CEA: Carcinoembryonic antigen

Table 3: The site of lesions in the colon (*n*=41)

Site of lesion	*n* (%)
Sigmoid colon	07 (17.07)
Descending colon	09 (21.95)
Splenic flexure	11 (26.82)
Transverse colon	08 (19.51)
Hepatic flexure	06 (14.63)

DISCUSSION

In the presence of symptoms, specific to colorectal carcinoma needs for screening with available investigative tools arises. In majority of cases, the colonoscopy helps in diagnosis of advanced disease. When the efficacy of endoscopy and barium enema in the diagnosis of colonic carcinoma are compared with colonoscopy, it seems reasonable to conclude that colonoscopy would be the most effective examination for the large bowel and terminal ileum, since it permits direct identification of the tumor, histologic examination through biopsy, diagnosis and removal of synchronic polyps, and staging attempts through endoscopic ultrasound techniques.[17] Barium enema sensitivity for the diagnosis of CRC in patients with positive fecal occult blood testing remains between 50% and 75%.[18] The limitations of colonoscopy are in poor bowel preparation, the presence of blind regions behind large mucosal folds and in segments where intubation was

Table 4: The grading of lesions observed on colonoscopy and CT colonography in the study (*n*=41)

Observations	*n* (%)
Colonoscopy findings	
T1	03 (7.31)
T2	14 (21.95)
T3	19 (34.14)
T4	05 (12.19)
CT colonography findings	
C0	0 (0)
C1	03 (9.75)
C2	25 (58.53)
C3	13 (31.70)
Histopathology	
Adenocarcinoma	32 (78.04)
Mucinous adenocarcinoma	06 (14.63)
Undifferentiated carcinoma	03 (9.75)

CT: Computed tomography

technically demanding. The sensitivity for colonoscopy to detect cancerous and precancerous lesions has been estimated to be >95%.[19] The efficacy of CT scanning to diagnose a primary tumor may be limited by tumor size or location.[19] The limitation of CT colonography is that its interpretation of lesions of <5 mm (and limitation in detection of flat lesions) is not accurate. Other validations by endoscopy, pathological node and tumor analysis, tumor markers, and surgical techniques are used in the definitive clinical staging of colorectal carcinoma in such cases.[20,21] All initial diagnostic investigations require rigorous bowel cleansing preparation. For diagnosing colonic carcinoma, colonoscopy is regarded as the standard method of investigation. Colonoscopy is known to have high sensitivity and specificity for detection of cancer, premalignant adenomas and other symptomatic colonic diseases. Sensitivity can be defined as a diagnostic intervention with very high sensitivity will detect the vast majority of patients with CRC and very few patients with the disease will be missed, whereas specificity is a diagnostic intervention with very high specificity will identify only those patients who truly have CRC and it will not falsely identify as positive, those patients who do not have the disease. When such two investigations are combined, the overall success rate of diagnosing colonic carcinoma is enhanced. Colonoscopy also has the added advantage of biopsy and removal of benign tumors in the same sitting.[22] In the present study, the colonoscopy was used to grade the tumors in 38/41 patients (%). Chaparro *et al*.[23] reported sensitivities ranging from 28 to 100% for all types of polyps measuring more than 6 mm with an overall pooled sensitivity of 66% with CT colonography. Mulhall *et al*.[24] reported sensitivity ranging from 21 to 90% with an overall pooled sensitivity of CT colonography of 83%. The sensitivity and specificity of CT colonography increasing

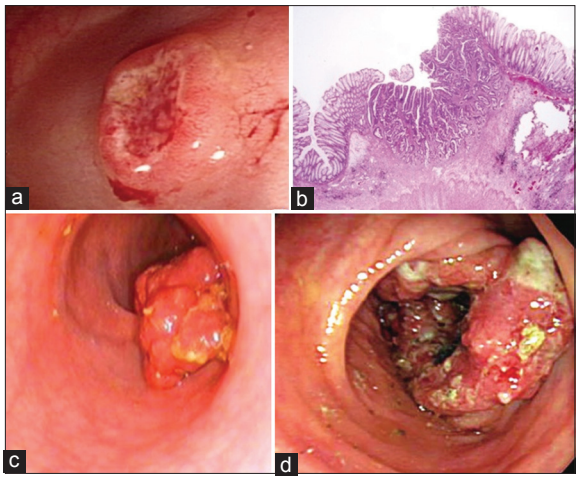

Figure 1: (a and b) The flexible colonoscopy findings in advance colonic carcinoma, (c) the colonoscopy view of the tumor and histopathological picture, (d) the colonoscopy view and corresponding computed tomography colonography picture

with increase in the size of the tumor as reported by Halligan *et al*.[25] In the present study, the sensitivity was 92.68%. The colonoscopy findings I, the study varied from a moderate cauliflower-like growth to extensive growth involving the entire circumference of the colon [Figure 1a and b]. Histopathological reports in this study showed in 32/41 (78.04%) the cell type was adenocarcinoma, in 06 (14.63%) the cell type was mucinous adenocarcinoma, and in 03 (9.75%) it was small cell carcinoma [Table 4] [Figure 1c].

CONCLUSIONS

This study showed colonoscopy and CT colonography together have an overall sensitivity of 92.68%, thus has an important role in the diagnosis of colonic carcinoma. Especially, the accuracy helps in staging of T2 and T3 tumors facilitating the choice of treatment.

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Original Article

A Study of Incidence of Different Types of Groin Hernias in Adults

J Sulaiman[1], Sugirtharaj J Sahayam[2], S Senthurpandian[3], Heber Anandan[4]

[1]Associate Professor, Department of General Surgery, Tirunelveli Medical College Hospital, Tirunelveli, Tamil Nadu, India, [2]Assistant Professor, Department of General Surgery, Tirunelveli Medical College Hospital, Tirunelveli, Tamil Nadu, India, [3]Junior Resident, Department of General Surgery, Tirunelveli Medical College Hospital, Tirunelveli, Tamil Nadu, India, [4]Senior Clinical Scientist, Department of Clinical Research, Dr. Agarwal's Healthcare Limited, Tirunelveli, Tamil Nadu, India

Abstract

Introduction: Inguinal hernia is one of the most common surgical pathologies. Research studies on clinical factors predisposing a person for the development of inguinal hernia, however, remain scarce.

Aim: This study aims to study the incidence and causes of different types of groin hernias in adults and to observe and analyze the complications of hernia repair.

Materials and Methods: A total of 157 cases of groin hernias which were treated in the Department of Surgery, Tirunelveli Medical College Hospital, Tirunelveli, were studied.

Results: About 97.4% were inguinal hernias and 2.52% were of femoral type. About 6.4% were recurrent hernias. Groin hernias are 20 times more common in men than women. The incidence of femoral hernias in female is 28.6%, whereas in men it is only 1.33%. About 21% of cases were seen in the age group between 41 and 50 years. Majority of groin hernias were managed by modified Bassini method (73.65%).

Conclusion: Groin hernias are 20 times more common in men than women. The incidence of groin hernias in women is 4.46%. The ratio of direct-to-indirect inguinal hernias in men is about 1:3. No case of direct hernia was seen in females.

Key words: Bilateral inguinal hernia, Inguinal hernia, Pantaloon hernia, Risk factors

INTRODUCTION

Hernia is an ancient malady as old as man himself. Abdominal wall hernias are common, with a prevalence of 1.7% for all ages and 4% for those aged over 45 years. Inguinal hernias account for 75% of abdominal wall hernias, with a lifetime risk of 27% in men and 3% in women.[1] Repair of inguinal hernia is one of the most common operations in general surgery, with rates ranging from 10 per 100,000 of the population in the United Kingdom to 28 per 100,000 in the United States.[2] In 2001-2, about 70,000 inguinal hernia repairs (62,969 primary, 4939 recurrent) were done in England, requiring more than 100,000 hospital bed days. About 95% of patients presenting to primary care are male, and in men, the incidence rises from 11 per 10,000 person-years aged 16–24 years to 200 per 10,000 person-years aged 75 years or above.[3] Obstructed hernias are the most common cause of intestinal obstruction in India, whereas adhesions are the cause in the west. Although appears innocuous most of the time, it can become life-threatening when it is complicated. Cure of inguinal hernia can only be brought by surgery.[4,5] The surgical repair of inguinal hernia has undergone a series of changes like that of surgery to cure peptic ulcer. The surgical repair was revolutionized when Bassini in 1887 described his technique. Basically, Bassini regarded the posterior wall of the inguinal canal as the weak structure to be repaired. It is well known that he did this by joining the medial part of the arch of the conjoint tendon, to the inguinal ligament. Since then, many modifications have taken place and being practiced. The fact that they are a large variety of operations suggests that many of the questions of both pathophysiology and management of this condition remains unanswered.[6,7]

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Corresponding Author: Dr. J Sugirtharaj Sahayam,Department of General Surgery, Tirunelveli Medical College Hospital, Tirunelveli, Tamil Nadu, India. Phone: +91-9444189593. E-mail: dr.sulaimaan@yahoo.in

Aims

This study aims to study the incidence and causes of different types of groin hernias in adults and to observe and analyze the complications of hernia repair.

MATERIALS AND METHODS

About 157 cases of groin hernias which were treated in the Department of Surgery, Tirunelveli Medical College Hospital, Tirunelveli, were studied. Detailed clinical evaluation, i.e., the duration of illness, precipitating factors, and presenting symptoms with necessary investigations toward the causes were undertaken. In complicated cases, the risk factors for surgery were studied. Emergency surgery was performed for all the cases of obstructed and strangulated groin hernias after resuscitation and uncomplicated hernias were managed electively. All recurrent groin hernias were analyzed separately in terms of incidence, type, and probable cause of recurrence.

RESULTS

Among the 157 cases studied, about 153 cases were inguinal hernias and 4 cases of femoral hernias. Among the 153 cases of inguinal hernias, 143 cases were primary hernias and 10 cases were recurrent hernias. All cases of femoral hernias were of primary type. Of 143 cases of primary inguinal hernias, 105 cases were indirect type, 36 cases were direct, 3 cases were of pantaloons, and remaining one was an interstitial variety [Table 1].

All cases of groin hernias above 12 years of age were included in our study. The youngest patient was 13 years; the oldest among the patients was 78 years old. Maximum number of cases belonged to the fifth decade constituting 21% of the total. In the series studied, inguinal hernias were seen predominantly in males, and there is no different with regard to the sex in femoral hernia [Table 2].

Of 157 cases, 7 cases were female patients. In them, the incidence increased sharply after 50 years of age with the maximum number of cases in the seventh decade.

Of 157 cases, only 16 (10%) cases were found to have predisposing diseases. Benign hypertrophy of the prostate in 6 cases and pulmonary tuberculosis in the other 6 cases, chronic obstructive pulmonary disease was found in 4 cases.

Among the 157 cases, only 20 cases presented with complications, the others as groin swellings. In them, about one-third of the patients had dull aching abdominal pain. In the 20 cases, 10 presented with features of intestinal obstruction, 9 with irreducibility, and the remaining one with strangulation.

Apart from groin swellings, 15 cases (9.57%) were found to be associated with an additional problem in the scrotum and abdomen, necessitating additional surgical attention to those problems. About 7 cases were found to have undescended testis on the same side of hernia and all of them were of indirect type. Hydrocele was associated with 4 cases, whereas atrophic testis, varicocele, lipoma of the cord, and seminoma were found in 1 case each [Table 3].

A total of 148 cases were operated under regional, 2 cases each under epidural and general anesthesia. 5 cases were operated in local anesthesia.

The breakup figures of the various types of repair followed in our institution are given in the table. In our series, there

Table 1: Distribution of cases

Type of hernia	Number of cases
Inguinal	
Primary	
Direct	36
Indirect	103
Pantaloon	3
Interstitial	1
Recurrent	
Direct	7
Indirect	3
Femoral	
Primary	4
Recurrent	-

Table 2: Age and sex distribution

Age group (years)	Male	Female	Total
Up to 20	16	-	16
21–30	22	-	22
31–40	27	2	29
41–50	33	-	33
51–60	30	1	31
61–70	17	4	21
71–80	5	-	5
Above 80	-	-	-
Total	150	7	157

Table 3: Associated problems

Problem	Number of cases (%)
Undescended testis	7 (4.46)
Hydrocele	4 (2.55)
Atrophic testis	1 (0.64)
Varicocele	1 (0.64)
Lipoma of the cord	1 (0.64)
Seminoma in undescended testis	1 (0.64)
Total	15 (9.57)

were 18 cases of bilateral inguinal hernias. 10 patients underwent simultaneous repair and 8 sequential repair. In the 167 repairs, modified Bassini repair was performed in 123 cases, Mcvay in 22, properitoneal mesh repair in 8, Shouldice in 3, Halsted and properitoneal tissue repair in 2 each, and herniotomy alone in 4 cases. Combined prosthetic tissue repair was done in 3 cases [Table 4].

There were 4 cases femoral hernia; all are primary constituting about 2.55%. All the four patients were above 50 years of age. In a male aged 60 years, it presented as obstructed hernia. All the 4 cases had undergone Lotheissen-McVay repair. In our series, there were 10 cases of sliding hernias, 3 pantaloon hernias, 2 giant hernias, and an interstitial hernia. During the period of study, there were 10 cases of recurrent hernia (6.4%). The recurrences were seen only in men and majority of them recurred in the age groups between 31 and 60. The younger patient was 34 years old, while the oldest patient was 77 years old. Of 10 cases, 7 cases hernia recurred after 2 years of repair and in 3 within 2 years. These were 7 cases of direct inguinal hernias and 3 were indirect type. Among the direct type, 4 cases were Type I, 2 cases Type II, and 1 case of Type III recurrence.

An attempt was made to study the probable causes of recurrence. Details of previous surgery were known in 3 cases only. Excessive tension at the line was observed in 6 cases of direct hernias. In all the 3 cases of indirect hernias, the internal ring was found widened or torn. In only 1 case, the posterior inguinal canal was found damaged necessitating the use of prosthesis.

Table 4: Repair methods adopted

Method of repair	Number of repairs
Pure tissue repair	
Modified Bassini	123
McVay	22
Shouldice	3
Halsted	2
Properitoneal	2
Herniotomy alone	4
Prosthetic repair	
Properitoneal mesh	8
Combined	
Modified Bassini with onlay mesh	3

Table 5: Repair adopted

Method	Number of cases
Modified Bassini	5
Properitoneal mesh	2
McVay	1
Halsted	1
Combined: Tissue–prosthetic repair	1
Total	10

Excluding all precipitating causes, different method of repair was adopted according to the defect size and tissue strength and anatomical impediments. Modified Bassini repair was used in 5 cases, properitoneal mesh repair in 2 cases, and the other 3 by McVay, Halsted and combined tissue–prosthetic repair [Table 5].

Preoperatively, various techniques were adopted to prevent further recurrence. As the suture line tension was found to be most important factor producing recurrence, muscle sliding relaxing incision was used in 6 cases, to make the conjoint tendon to come close to the inguinal ligament. Hypertrophied cremaster muscle was excised in 3 cases. Prosthetic repair was used in 3 cases. In both the cases of properitoneal mesh repair, Redivac suction drain was used for first 48 h.

In about one-fifth of the cases, varied complications from spinal headache to ileus were seen. Of the complications listed below [Table 6], wound complications were found in 13 cases and scrotal complications in 6 cases. They settled down in course of time.

There were 2 cases of early recurrence postherniorrhaphy hydrocele was noted in 3 cases, neuropraxia and traumatic orchitis in 2 cases each. One patient died 1 month after herniorrhaphy due to mesenteric vascular thrombosis (Table 7).

Table 6: Complications

Complications	Number of cases
Wound complications	
Wound infection	10
Neuropraxia	3
Scrotal and testicular	
Scrotal edema	4
Traumatic orchitis	2
Urinary tract	
Urinary retention	2
Bladder injury	
Gastrointestinal	
Hiccough	2
Hematemesis	2
Ileus	1
Anesthetic complications	
Postspinal headache	4
Pulmonary	
LRI	2

Table 7: Groin hernias repair: Late complications

Complication	Number of cases (%)
Recurrence	2 (1.27)
Late complications	
Hydrocele	3 (1.91)
Neuropraxia	2 (1.27)
Traumatic orchitis	2 (1.27)
Death	1 (0.64)

DISCUSSION

In the 10 cases of recurrent hernia (6.4%), none were noticed in women. Of 150 cases of groin hernia, in men, 148 cases were inguinal hernias and only 2 cases were of femoral hernia. Of 7 cases found in females, 5 cases were inguinal hernia and 2 cases were of femoral hernias. Maximum number of groin hernias were seen in the age group between 41 and 50 years contributing to 21%. As per the study by Gupta and Rohatgi,[8] 96% inguinal hernias were in males and 4% were females. Children <12 years were included in this study. Study by Charles *et al*.[9] shows that 93.2% of all inguinal hernia cases were males, 6.7% were females. M:F = 13.7:1.

In our series, there were 10 cases of recurrent hernia (6.4%). The recurrences were seen only in men and majority of them were recorded in the age groups between 31 and 60. The incidence of recurrent hernia after primary repair of a groin hernia varies from 1% in specialized centers to 30% in general surveys. During the premesh era, it was estimated that primary inguinal hernia repairs had a 10%–30% recurrence rate and that the rate was 35% for recurrent hernia repairs.[10] The Shouldice repair has been the only tissue repair with an extremely low recurrence rate of 2.2%.[11]

Complicated hernias are fraught with increased mortality with and without operative management. The choice of technique depends on several factors including the type of hernia, anesthetic considerations, cost, period of post-operative disability, and the surgeon's expertise.[12-15] In the primary management of all complicated hernias from surgical reduction and repair accompanied by aggressive pre- and post-operative care is suggested. Elective repair should be deferred in case of advancing age and in case in which groin hernia may be difficult to diagnosis. Transabdominal and preperitoneal approach of surgical procedures are used for reduction and repair of complicated groin hernias.

CONCLUSION

Groin hernias are 20 times more common in men than women. The incidence of groin hernias in women is 4.46%. The ratio of direct-to-indirect inguinal hernias in men is about 1:3. No case of direct hernia was seen in females. Patients with no attendant comorbidities with asymptomatic inguinal hernia at presentation should be offered hernia repair. About 21% of cases were seen in the age group between 41 and 50 years, the reason being the physical strain in this age group aggravating the existing precipitating factors and opening the processes vaginalis sac which is undergoing obliteration. The incidence of complicated hernia is coming down due to the greater awareness of mortality and morbidity in complicated cases.

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Original Article

Severity and Outcome Analysis of Abdominal Vascular Injuries at a Tertiary Care Service Hospital

Col Pawan Sharma[1], Col Animesh Vatsa[2]

[1]Assistant Professor, Department of Surgery, Army College of Medical Sciences and Senior Advisor, (Surgery, Trauma and Surgical Critical Care) Base Hospital, Delhi Cantonment, New Delhi, India, [2]Assistant Professor, Department of Surgery, Army College of Medical Sciences and Cl Spl, (Surgical and Prosthetic Surgeon), Base Hospital, Delhi Cantonment, New Delhi, India

Abstract

Introduction: Abdominal vascular injuries (AVIs) remain the most common cause of morbidity and mortality following penetrating and blunt abdominal trauma. This study was carried out at a tertiary care service hospital to review the institutional experience by analyzing the severity and outcome determinants of these injuries.

Materials and Methods: It was a retrospective observational study over 5 years from January 2012 to December 2016. The data available from the hospital records were analyzed to determine the mortality based on shock, on the number abdominal vessels injured along with other significant associated injuries. The primary outcome measure was survival.

Results: Of 192 vascular trauma patients, abdominal vascular injury was found in 17 (8.85%) cases accounting for 25 injured vessels. Two or more abdominal vessels were injured in four patients. AVI followed blunt abdominal trauma in 85% ofcases. External iliac arteries and inferior vena cava were the most commonly injured artery and vein, respectively. Arteries and veins were injured almost in equal proportions. Surgical interventions carried out were fog arty thrombectomy, vascular repair, autologous or prosthetic interposition graft, or vessel ligation. Five patients died within 24 h of injury as a direct consequence of AVI, whereas 3 patients died later due to associated injuries or other causes.

Conclusion: AVIs are highly lethal and major impact is seen within initial 24 h. In our setup, blunt trauma is responsible for majority of these potentially fatal injuries. Multiple vessel injury and serious associated injuries are responsible for poor outcome. Early recognition, balanced resuscitation, and damage control principle can possibly contribute to better survival.

Key words: Abdominal vascular injuries, Blunt, Penetrating abdominal trauma

INTRODUCTION

Abdominal vascular injuries (AVIs) involving major vessels are uncommon in everyday practice, but whenever encountered, these are highly lethal vascular events. Predictably, exsanguinating hemorrhage is the most important cause of early mortality in such cases. Intra-AVIs are associated with rapid blood loss and pose significant challenges of vascular exposure and control during laparotomy, given the posterior position of the majority of major abdominal vascular structures. Some of these patients may present in Emergency Department (ED) with cardiopulmonary arrest and may necessitate resuscitative ED thoracotomy, aortic cross-clamping, and open cardiopulmonary resuscitation en route to operating room (OR). A thorough knowledge of intra-abdominal vascular anatomy and a familiarity with the techniques of proximal and distal control combined with selective application of primary repair, bypass, or ligation as indicated is extremely essential for the successful management of these injuries.

The main aim of this study was to analyze the mechanism of injury, injury severity, and outcome of patients with

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Corresponding Author: Col Pawan Sharma, Department of Surgery, Trauma and Surgical Critical Care, Surgical Division, Base Hospital, Delhi Cantonment - 110 010, New Delhi, India. Phone: +91-8860602390. E-mail: drpawansharma55@gmail.com

intra-AVI seen following abdominal trauma, to study the effects of resuscitation and damage control surgery (DCS) on the outcome of these injuries, and to review our institutional protocol and experience with these injuries.

MATERIALS AND METHODS

It was a retrospective observational study of 17 consecutive cases of AVIs as a result of either isolated blunt or penetrating abdominal trauma or in a setting of polytrauma, who presented at our Trauma Center over 5 years from January 2012 to December 2016. Data were collected from hospital medical records for patient's age, gender, mechanism of injury, mode of injury, injured vessels, associated injuries, presence of shock at presentation in ED (systolic blood pressure [SBP] ≤90 mmHg), Glasgow coma scale, associated injuries, injury severity score, and mortality. Focused assessment sonography in trauma (FAST) was performed on all cases as primary survey protocol. Contrast-enhanced computed tomography (CECT) abdomen or CT angiography was performed in hemodynamically stable patients.

All the patients who presented with polytrauma with abdominal trauma or isolated blunt or penetrating abdominal trauma along with injuries to named intraabdominal vessels as identified either on CECT scan of abdomen and pelvis, CT angiogram, or during surgical exploration were included in the study. Those cases who died in ED during resuscitation or were found to have mesenteric tears as source of bleed were excluded from the study.

Decisions concerning the restoration of intravascular volume after injury were made using a standard algorithm according to the patient's initial hemodynamic status, response to crystalloid administration, and reassessment of hemodynamic stability using patient's vital parameters, level of consciousness, and urine output.[1] Patients who presented with Class I or Class II shock were infused with crystalloids. Transfusion of packed red blood cells (RBCs) was done in patients who responded only transiently to crystalloid administration. For refractory cases, the massive transfusion protocol was activated with the transfusion ratio of packed RBCs, fresh frozen plasma (FFP), and platelet as 1:1:1.

DCS was performed in the presence of unachievable hemostasis because of refractory coagulopathy, injuries amenable to packing, limited access to a major venous injury, an anticipated need for a time-consuming procedure, and bowel edema.

All statistical calculations, including Chi-square analysis and unpaired *t*-tests, were performed using SSPS version 17, and the data were reported as mean standard deviation. Specifically, we studied the mode of injury, shock as initial presentation, surgical procedure employed to stop bleed or to repair vessel and mortality. Follow-up data including length of intensive care unit stay, duration of ventilatory support, and if the patient died, cause, date, and time of death were recorded.

RESULTS

During the study period of 5 years from 2012 to 2016 from hospital records of the patients, 192 patients had presented to our center with vascular trauma including 17 (8.85%) patients who had sustained a major abdominal vascular injury. In these 17 patients, 25 named vessels were injured with varying degrees of severity. Two or more than two abdominal vessels were injured in 4 patients. During the same period, 681 abdominal trauma patients were admitted in our center, majority (78.35%) with blunt abdominal trauma, responsible for causing AVI in 2.80% of (15/534) cases, whereas penetrating abdominal trauma caused AVI in 1.36% (2/147) of the cases. Predominant mechanism of injury was road traffic accidents seen in 11 cases [Table 1]. The mode of injury was blunt trauma in fifteen (85%) of our patients as compared to penetrating trauma that was seen in the remaining 15%. Sixteen patients were brought within 24 h of injury and the average ED disposition time was 90 min. Injury to either artery or vein was observed in almost equal numbers, the most common arterial, and venous vessels to sustain injuries being external iliac artery [Figure 1] and the inferior vena cava (IVC) in 6 and 4 patients, respectively [Figures 2 and 3]. There were three renal pedicle injuries or avulsions [Table 2]. Single vessel injuries were seen in 13 cases and the remaining 4 cases had injuries to multiple vessels.

FAST was positive in 15 patients. Six patients, who were hemodynamically stable, were evaluated with CECT abdomen pre-operatively and revealed evidence of contrast leak from the injured vessel(s) in 4 cases and evidence of free fluid or blood in the intraperitoneal or retroperitoneal space including pelvis.

All the patients underwent exploratory laparotomy. Seven of the 11 venous injuries were repaired and four were ligated. Fogarty balloon thrombectomy was done in five of the 10 arterial injuries, ligation in 3 and end-to-end and prosthetic graft repair was carried out in one each. All three injured or avulsed renal pedicles were ligated to achieve control of hemorrhage followed by ipsilateral nephrectomy. Perihepatic or pelvic packing was done in 5 cases for associated hepatic or pelvic injuries.

Immediate mortality as a direct consequence of vascular injuries leading to hemorrhagic shock was observed to be 28.5%. Three of them died in OR during surgery and another two died post-operatively within 24 h of injury. Vessel wise immediate, early, and late outcomes are summarized in Table 3. Another three cases died later consequent to coagulopathy, acute renal failure, associated injuries, and sepsis. The overall 30 days survival was 52.9%.

DISCUSSION

AVIs are among the most lethal injuries encountered by modern-day trauma surgeons. The incidence of abdominal vascular injury varies depending on the injury setting. The incidence of abdominal vessel injury in patients with blunt trauma is estimated at approximately 5–10%. A similar incidence of 10.3% is reported in patients with penetrating stab wounds to the abdomen. In our study, the incidence was lower for both blunt (2.80%) as well as for penetrating (1.36%) abdominal trauma, whereas 75% of the patients with AVI sustained blunt trauma resulting in 7 deaths of 8 ($P = 0.338$). Patients with gunshot wounds (GSWs) to the abdomen are likely to have major vessel injury in 20–25% of cases.[2] We had one case of GSW who died of hemorrhagic shock.

Most of the initial experience in vascular trauma has emerged from the battlefields. During World War I, DeBakey and Simeone reported a 2% incidence of AVIs in 2471 patients.[3] Hughes reported seven (2.3%) iliac artery injuries in 304 patients.[4] Rich *et al.* reported 29 patients (2.9%) during the Vietnam conflict.[5] Jawas *et al.* reported 36 (10%) cases of major vascular injuries among 361 war-wounded admissions during second gulf war.[6] Over the past few decades now, these injuries are being reported with greater frequency from the civilian arena. These serious injuries are associated with extremely rapid rates of blood loss and pose challenges of exposure during laparotomy in view of the posterior position of the major abdominal vascular structures.[7] Patients also present in a hyperfibrinolytic state, which exacerbates the coagulopathy associated with the lethal triad of trauma.[8]

In 1984, Feliciano reported a 15% incidence of AVI seen in their trauma center.[9] In our study, 17 patients or 8.85% of 192 vascular injuries were AVIs. During this 5 years' study period, contrary to the existing data in favor of predominance of penetrating injuries by various authors,[10-12] we observed that majority of the injuries were following blunt abdominal trauma. Most of the 17 patients studied were found to have a single vessel injury, whereas four of them had injuries to multiple vessels. Although three of these four patient died, the mortality was not statistically significant ($P = 0.121$). Despite advances in prehospital emergency care trying to ensure these patients arrive with signs of life at trauma centers, few series have appeared before 1980 in the literature describing their management after reaching the hospitals.

The main consequence of these injuries in the vast majority of cases is hemorrhagic shock from intra-abdominal hemorrhage often leading to metabolic acidosis accompanied with coagulopathy and hypothermia, the so-called lethal triad of trauma.[8,13] Metabolic acidosis in trauma patients is the result of lactate overproduction, most often from hypoxia and hypovolemia. Acidosis adds to the overall lethality of preexisting injury primarily by depression of myocardial contractility and by impairment of coagulation. Furthermore, moderate-to-severe hypothermia (below 34°C) inhibits platelet function and slows coagulation factor activation. This self-perpetuating cycle is responsible for 80% of deaths in patients with major vascular injury and must be rapidly corrected to

Table 1: Mode of injury

Mode of injury	No injured
Road traffic accidents	11
Fall from height	3
Crush injury	1
Stab/empalement	1
Gunshot wounds	1
Total	17

Table 2: Injured vessels

Injured vessel	No injured
IVC	4
PV	1
SMV	1
Splenic vein	1
Renal pedicle	3
Common iliac artery	1
Common iliac vein	1
External iliac artery	6
External iliac vein	3
Internal iliac artery	3
Internal iliac vein	1
Total injured vessels	25

IVC: Inferior vena cava, SMV: Superior mesenteric vein, PV: Portal vein

Table 3: Outcome analysis

Injured vessel	Immediate outcome	Early deaths	Late deaths
IVC	3 Survived; 1 died	1	1
PV, SMV, Splenic V	One patient; died	-	-
Renal vessels	3 Survived	-	1
Common iliacs	2 Survived; 1 died	-	1
External iliacs	5 Survived	-	-
Internal iliacs	3 Survived	1	-
25 Vessels	16 Survived, 3 died	2	3

IVC: Inferior vena cava, PV: Portal vein, SMV: Superior mesenteric vein

prevent a dismal outcome. Patients also present in a hyperfibrinolytic state, which exacerbates the coagulopathy associated with the lethal triad of trauma.[8,14] In our series, 12 patients presented with shock resulting in mortality in 7 of them ($P = 0.146$). The remaining eleven patients who were not in shock underwent a detailed pre-operative evaluation to establish the nature and extent of the injuries.

Since 1980, there have been several series dealing exclusively with AVIs. Wiencek and Wilson reported one of the largest series consisting of 254 injuries over 5 years.[15] Asensio *et al*. published one of the largest series in the year 2000 consisting of 302 patients with 504 injured vessels managed in an urban trauma center.[16] In this series, 275 patients (91%) had retroperitoneal hematomas, the vast majority being located in zone I. Exposure for zone I supramesocolic injuries includes medial rotation of the left-sided viscera. This exposes the aorta from its entrance into the abdominal cavity through the aortic hiatus and includes exposure of the origin of the celiac axis, superior mesenteric artery (SMA), and the left renal vascular pedicle.[11,17] An alternative approach is the extended Kocher maneuver that exposes the suprarenal abdominal aorta between the celiac axis and the SMA but does not expose the supraceliac aorta at the hiatus.[10,18] Maneuvers used to expose injuries in zone I inframesocolic include reflecting the transverse colon and mesocolon cephalad, eviscerating the small bowel to the right, and transecting the ligament of treitz along with the loose tissue along the left side of the abdominal aorta until the left renal vein is located. This exposes the infrarenal aorta. To expose the suprarenal and infrarenal vena cava, the avascular line of toldt of the right colon is transected along with a Kocher maneuver sweeping the pancreas and duodenum to the left and incising the retroperitoneal tissues that cover the IVC.[11,19]

Hemodynamically stable patients with blunt trauma and suspected AVIs may benefit from triple-contrast abdominal CT scanning which helps localize a hematoma and evaluate solid organ injuries.[20,21] Stable patients with posterior wounds and most patients with anterior stab wounds should be evaluated with FAST examination to exclude hemoperitoneum, and those with equivocal abdominal signs with stab wounds may undergo laparoscopy to confirm peritoneal penetration. Patients with peritoneal signs or positive FAST and CT findings suggestive of ongoing bleed require exploration. Hemodynamically unstable patients with positive clinical findings and positive FAST also require immediate surgery for control of hemorrhage. If time permits, chest and pelvic radiography should also be performed to exclude bleeding into the chest or pelvic cavities. Many patients arrive with severe physiological compromise secondary to massive blood losses and associated injuries.[18,22] Angiography with or without embolization may be considered in stable patients, particularly in patients with blunt trauma [Figure 4].

Hemodynamically unstable patients with penetrating trauma including GSW of the abdomen should be transported to the OR as soon as possible after ensuring a secure airway and adequate ventilation, and no imaging studies are necessary. Patients with GSWs to the abdomen require laparotomy for evaluation and treatment, although some trauma surgeons prefer selective non-operative evaluation of abdominal GSWs in stable patients.[2] The assessment of hemodynamically unstable patients with blunt trauma to the abdomen may include FAST or diagnostic peritoneal lavage to confirm hemoperitoneum as well as portable chest radiography only if expeditious transport to the OR is not getting delayed.

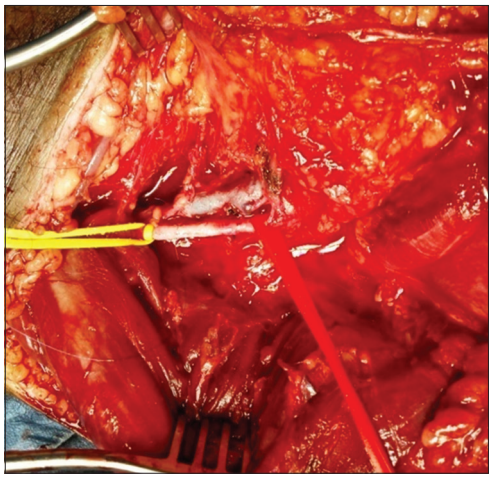

Figure 1: Injury to both left external iliac vessels

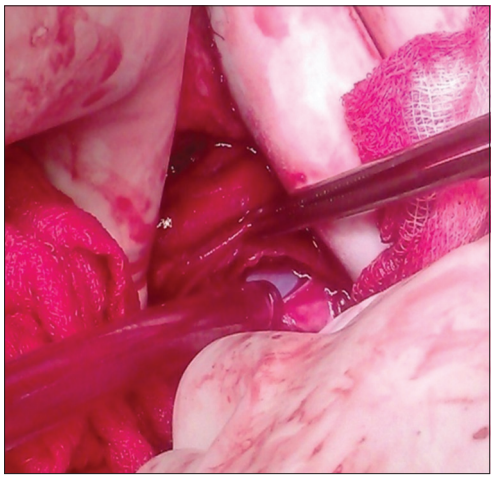

Figure 2: Inferior vena cava injury

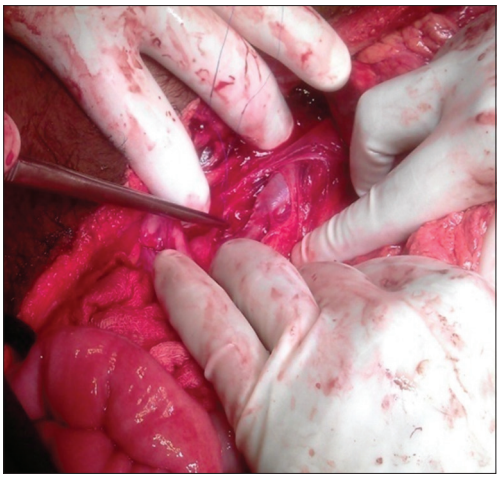

Figure 3: Inferior vena cava injury repaired

Figure 4: Post-nephrectomy right renal artery stump leak-embolized successfully

In a hypothermic traumatic shock swine model, Ding *et al.* demonstrated that temporary intravascular shunts may improve survival in SMA injuries compared with repair by primary vascular anastomosis.[14] Relative to pigs in the primary vascular anastomosis group, the animals treated with temporary shunting required less resuscitation fluid, retained higher SMA flow rates, normalized lactate levels faster, suffered less severe intestine histopathology, and had greater early survival.

Initial resuscitation of a patient with AVIs depends on his or her condition at arrival in the ED. As a possibility of intra-abdominal venous injury exists, lower extremity venous access is not recommended. Patients may require aggressive resuscitation involving the correction of acidosis, active rewarming, and massive blood transfusion for patients presenting with a shock index (heart rate/SBP) of >0.9.[23] FFP, platelets, cryoprecipitate, or recombinant factor VIIa may be required on an individual basis to correct coagulopathy induced by massive transfusion. A planned reoperation 24–28 h after the initial procedure is done complete a damage control sequence that has proven to be an invaluable technique in the management of severe injuries.[19,24,25] In our series, 35% of patients underwent damage control consisting of vessel ligation, bowel stapling, and packing. Similarly, 12% of the patients required prosthetic abdominal wall closure to deal with the sequelae of their ischemic reperfusion injury, massive volume replacement, and to prevent and to deal with the abdominal compartment syndrome.

Injuries to major abdominal vessels are uncommon but highly lethal vascular crises. Predictably, exsanguinating hemorrhage is the most important cause of early death [17,22,26] In our study, 28% of patients died of hemorrhagic shock within 24 h and half of them in OR during damage control resuscitation. Our overall mortality was 47% somewhat higher than the range reported in the literature of 32–46%.[27-29] Exsanguination accounted for 84% of mortality and the vast majority of deaths (136 of 162 patients) succumbed to the operative or perioperative period.[17] Corresponding figures in our series were 5 of 8 deaths. The most commonly injured arteries were the external iliacs, and the most commonly injured vein was the IVC. Injury to the IVC and portal vein had the poorest chance of survival. Despite many recent advances in shock management and damage control, AVIs remain extremely lethal.[15,26,30] In a study by Paul *et al.*, one hundred forty-four patients with one vessel injured had a mortality rate of 18.7%, whereas those with more than one vessel injured had a mortality rate of 48.7% ($P < 0.001$). A total of 46% of 117 patients in shock died compared with 9.6% of 104 patients not in shock ($P < 0.001$).[31] Similar results were observed in our study also with a mortality of 44% with single vessel injury and 75% with two or more than two vessel injuries ($P = 0.121$) [Figure 1]. Seven of 12 patients in shock (58%) died within 24 h, whereas one (10%) patient died out of 10 who were not in shock at presentation ($P = 0.146$). Other significant non-vascular injuries associated with or contributing to mortality were pelvic fracture, thoracoabdominal injuries, severe head injuries, and long bone fractures [Table 4].

Essential to the successful management of these injuries is a thorough knowledge of intra-abdominal vascular anatomy and a familiarity with the techniques of proximal and distal control combined with selective application of primary repair, bypass, or ligation as indicated. Exposure of the abdominal vasculature is difficult due to its protected location, as well as the presence of large retroperitoneal hematomas, which make approaches to these vessels quite difficult. Damage control principles should be observed in most of these patients to obtain desired outcome.

Table 4: Mortality predictors

Associated injuries	No injured	Deaths	*P* value
Pelvic fracture	6	4	0.164
Long bone fractures	4	3	0.121
Thoracoabdominal trauma	3	2	0.658
Severe head trauma	4	3	0.041

CONCLUSION

The surgical exposure and the often-associated intra-abdominal, pelvic, and other associated injuries may challenge the skills and judgment of even the most experienced surgeons. Rapid transportation to a trauma center, early recognition of the injuries, early surgical interventions, excellent knowledge of the anatomy, and good surgical judgment are critical for survival in such injuries. There have been some significant advances in the management of AVIs during the past decade. The introduction of the policy of scoop and run and early surgical control of the bleeding have now become the standard of care and have improved the survival in vascular injuries. The concept of damage control has gained popularity and acceptance, and many non-salvageable patients with vascular injuries have been saved. The recognition of abdominal compartment syndrome and the use of temporary abdominal wall closure with a prosthetic material are also an important step in improving the outcome. Endovascular technology has revolutionized the management of selected patients with specific vascular or solid organ injuries and false aneurysms. Finally, research in new powerful hemostatic agents is promising and may have a major impact in the management of AVI in the future.

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Original Article

A Clinical Analysis of Eagle's Syndrome by its Clinical Features and Therapeutic Response to Surgical Treatment

R T Abdul Salam

Associate Professor, Department of ENT, Government Medical College, Kozhikode, Kerala, India

Abstract

Background: Elongated styloid process is a relatively common disorder and is frequently misdiagnosed. Elongated styloid process with or without calcified stylohyoid ligament causes recurrent throat pain, foreign body sensation throat, dysphagia cervicofacial pain, and referred otalgia. Eagle's syndrome is defined as the symptomatic elongation of the styloid process or mineralization (ossification or calcification) of the stylohyoid ligament complex. Diagnosis is based on history, production of symptoms on palpation of tonsillar fossa with a palpable styloid process, and relief of symptoms with injection of lignocaine into the tonsillar fossa. It is confirmed by radiology.

Aim of the study: The aim of this study is to evaluate the clinical, diagnostic, and therapeutic aspects of elongated styloid process.

Materials and Methods: A total of 42 patients with symptoms of elongated styloid process were included and confirmed by computed tomography (CT) scan and intraoral palpation method. All the patients were thoroughly investigated and the medical and surgical treatment efficacy was evaluated.

Observations and Results: Age of the 42 patients varied from 23 to 68 years. The mean age was 35.65 ± 3.10 years. The most commonly affected age group was 30–39 years. Of the total 42 patients, 18 were males and 24 were females.

Conclusions: Eagle's syndrome is a relatively common disorder that is frequently misdiagnosed. Patients with vague cervico facial pain, throat pain, foreign body sensation throat, referred otalgia, etc., should be palpated for elongated styloid process and investigated for the same. This condition has a female preponderance, and the most commonly affected age group is 30–39 years. CT scan styloid remains a radiological investigation to diagnose elongated styloid process with or without calcified stylohyoid ligament. Medical treatment will not give a long-standing symptomatic relief in elongated styloid process.

Key words: Eagle's syndrome, Elongated styloid process, Stylalgia, Neuralgia

INTRODUCTION

Eagle's syndrome was first documented by Eagle an otorhinolaryngologist.[1] Over a 20-year period, Eagle reported over 200 cases and explained that the normal styloid process is approximately 2.5–3.0 cm in length.[2] Due to his special interest in this syndrome, the condition has been named Eagle's syndrome in his honor. Later, it has also been called as stylalgia, stylohyoid syndrome, styloid syndrome, "elongated styloid process syndrome," "styloid process-carotid artery syndrome," or "styloid process neuralgia."[3] Eagle reported several cases of cervicopharyngeal symptoms associated with a radiographic diagnosis of an elongated, ossified styloid process occurring a few months post-tonsillectomy.[3] He described the symptoms as nagging or aching sensation in the throat, similar to chronic pharyngitis, and pain spreading to the ear and the mastoid region, difficulty in swallowing, and the sensation of a foreign object lodged in the throat.[4] It may develop inflammatory changes or impinge on the adjacent arteries or sensory nerve endings,

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Corresponding Author: Dr. R T Abdul Salam, Department of ENT, Government Medical College, Kozhikode, Kerala, India.
E-mail: abdulsalamrt@gmail.com

leading to the symptoms described. It had been estimated that between 2% and 4% of the general population presents radiographic evidence of an ossified portion of the stylohyoid chain.[5] The majority of these patients are asymptomatic. The cartilaginous element of second arch (Reichert's cartilage) gives rise to styloid process, stylohyoid ligament, lesser cornua, and probably the cranial rim of body of hyoid bone [Figure 1].

The clinical signs associated with a symptomatic styloid process were systematized by Eagle in a series of articles (1937, 1948, 1949, 1958).[1-3] This syndrome was first documented by Eagle over a 20-year period. Loeser and Cardwell[6] mentioned that the pain may also radiate to cheek, eyes, and forehead. They excised the tip of styloid process by an external approach with good results. Marchetti[7] of Padua described a case of ossification in stylohyoid ligament. The length of the styloid process has been studied by Wang *et al.*,[8] Thot *et al.*,[9] Basekim *et al.,*[10] and Jung *et al.*,[11] from radiographs or three-dimension computed tomography (CT). Stylagia[12] published a series of 52 cases, and according to him, the condition is more common than was generally thought. Christiansen *et al.*[13] discussed in detail "styloid process neuralgia myth or fact," and from their series, they believed that there was justification for the concepts that "elongated styloid process can produce pain" which is relieved by amputation of the tip. The length of styloid processes is variable. Kaufmann *et al.*[14] reported that 30 mm is the upper limit for normal styloid process. Moffat *et al.*[15] performed a cadaver study on styloid process and reported that the normal length is between 1.52 and 4.7 cm. Monsour and Young[16] concluded that the diagnosis of elongated styloid process could be made whenever the styloid process was longer than 40 mm. Palpation of the styloid process in the tonsillar fossa and radiological evaluation of the styloid process help in the diagnosis of this syndrome. Russell[17] in 1977 reported that infiltration of 2% lignocaine at the area superficial to the prominence produced by elongated styloid process will relieve the pain and patients reported temporary symptomatic relief. Radiological diagnosis remains the most definitive diagnostic criteria in elongated styloid process. In the literature, various radiological views have been discussed and analyzed by various authors. Brat[18] suggested that transoral view is the best to detect this syndrome. Goldstein and Scopp[19] in 1973 defined some diagnostic criteria based on panoramic X-rays. Three-dimensional (3D) CT is a valuable diagnostic imaging tool in patients with Eagle's syndrome that allows clinicians to evaluate the styloid process in spatial geometry, make accurate length measurements, and explain the problem in detail to patients. For Arellano,[20] Basekim *et al.,*[10] and Heitz *et al.,*[21] CT is the most effective method for evaluating the styloid process length and morphological alterations, since this examination provides two-dimensional and 3D reconstructions of the whole temporomandibular joint.

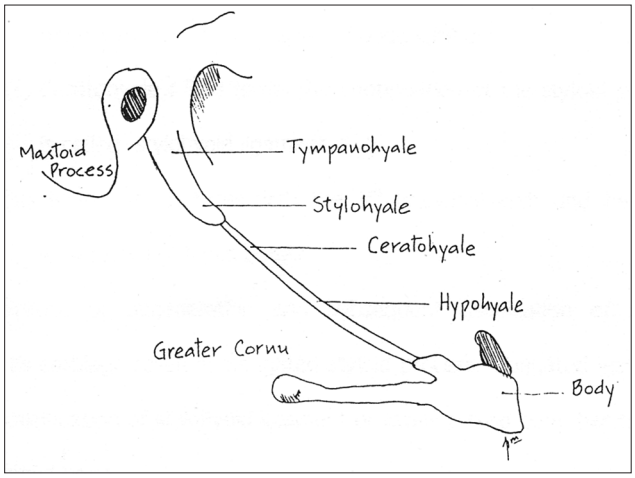

Figure 1: Four divisions of Reichert's cartilage

Type of Study

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

Period of Study

The study duration was between June 2009 and October 20011.

Institute of Study

This study was conducted at Government Medical College, Kozhikode, Kerala.

MATERIALS AND METHODS

A total of 42 outpatients who presented with nagging throat pain, cervicofacial pain, foreign body sensation throat, and referred otalgia that were found to be having elongated styloid process with or without calcified stylohyoid ligament were included in this study. An ethical committee clearance certificate was obtained and a committee approved consent letter was used.

Inclusion Criteria

(1) Patients of all age groups were included. (2) Patients with confirmed elongated styloid process on CT scan were included. (3) Patients willing to undergo either surgery or medical treatment were included. (4) Patients with symptoms of throat pain, cervicofacial pain, foreign body sensation throat, and referred otalgia were included. (5) Patients with unilateral or bilateral symptoms were included.

Exclusion Criteria

(1) Patients with previous history of tonsillectomy were excluded. (2) Patients with diseases of the spine and

neuralgic pain in other parts of the body were excluded. (3) Patients with diabetes mellitus, hypertension, and malignant diseases of the oral or pharyngeal cavity were excluded. A thorough clinical history was taken. Various radiological views for styloid process are compared to select a diagnostic tool. Various medical and surgical treatments with the incidence of complications are also analyzed in the present study. All the patients in the study group underwent clinical examination palpation of tonsillar fossa. Apart from routine blood, urine, blood sugar, and renal function tests, radiological investigations were also done to diagnose elongated styloid process. Radiological evaluation of cervical spine and barium swallow studies were done in selected patients to rule out cervical spine disorders and pharyngoesophageal causes, respectively (Figure 5). All the data were analyzed using standard statistical methods.

Medical Treatment

Of 42 patients diagnosed, 16 patients were not willing for surgery. Hence, medical treatment was tried in these patients with temporary and variable results. Temporary symptomatic relief was obtained in 14 patients with carbamazepine 100–200 mg once/twice daily, amitriptyline 10–50 mg once/twice daily, and weeks to month's diclofenac sodium 50 mg twice/thrice daily for a short course.

Surgical Treatment

Surgical treatment of elongated styloid process was the main mode of treatment. Bilateral excision was done in 19 patients and unilateral excision in 7 patients. In all these patients, styloid process was palpable per orally. CT scan showed elongated styloid process. Surgery was done under general anesthesia using nasotracheal intubation except in 3 patients where nasotracheal intubation was difficult. Hence, orotracheal intubation was done. Patient was placed in Rose's position as in tonsillectomy. Mouth was kept open using Boyle–Davis mouth gag, and tonsillectomy was done by classical dissection and snare method. Superior constrictor was separated at the point where the styloid process was prominent and palpable. The tip of styloid process was then delivered. The periosteum was incised at the tip, elevated, and reflected back. The styloid process was broken and removed with a bone nibbler or Luc's forceps [Figure 2]. After excision, the superior constrictor muscle was closed with catgut sutures and bleeding points were ligated if any. Postoperatively, oral feeding in the form of cold liquid was started after 6 h as in tonsillectomy. Parental antibiotics in the form of ampicillin and gentamicin were given for 2 days. Patients were discharged after 2 days with oral antibiotics and followed up for 1 year at 1 week, 3 weeks, 2 months 6 months, and 1 year.

OBSERVATIONS AND RESULTS

Age and Sex Distribution

Age of the patients varied from 23 to 68 years. The mean age was 35.65 ± 3.10 years. The most commonly affected age group was 30–39 years. Of the total 42 patients, 18 were males and 24 were females. The most commonly affected are middle-aged females. The age and sex distribution is presented in Table 1 and Charts 1-3.

Side Affected

By symptomatology, the condition was unilateral in 36 patients and bilateral only in 6 patients. Intraoral palpation detected palpable styloid process affected side in 30 patients and both sides 12 patients.

Table 1: Age and sex distribution

Age in years	Number of cases	Sex	
		Male	Female
20–29	6	1	5
30–39	17	8	9
40–49	15	6	9
50–59	3	2	1
60–69	1	1	0
70–79	0	0	0
80–89	0	0	0
	42	18	24

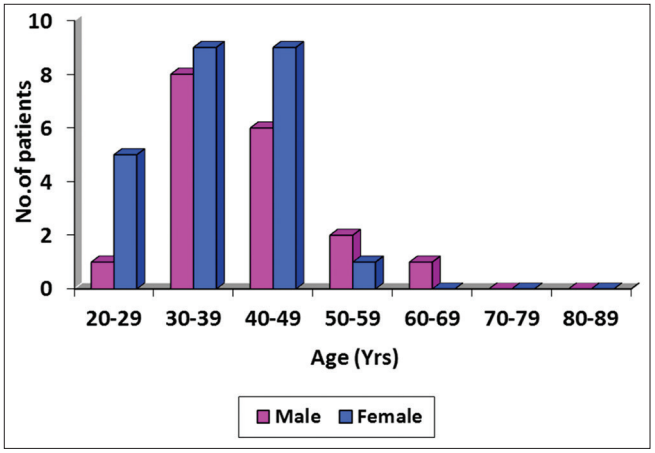

Chart 1: Age and sex distribution

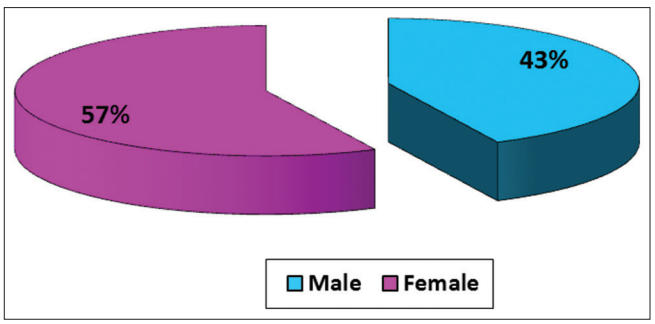

Chart 2: Sex incidence

Symptomatology

Majority of patients reported vague and multiple symptoms and the most common symptom was needle pricking sensation on the affected side of the throat.

71.4 patients complained needle pricking sensation on the affected side of the throat. 61.9% of the study group showed foreign body sensation throat on the affected side, and 47.6% complained of aggravating of the symptoms on swallowing and referred pain in the ipsilateral ear. Pain in the temporomandibular area was reported by 28.6%. Other symptoms include pain on changing the head posture 9.5% and headache 14.3%. In 14.3% of the study group, the symptoms were bilateral. Radiation of pain to the surrounding area was complained by 80.95% Table 2.

Intraoral Palpation

On intraoral palpation, 71.4% were unilateral and 28.6% were bilateral. In all patients, same symptoms were reproduced on intraoral palpation of the elongated styloid process. Elongated styloid process was graded according to the tip of styloid process to the tonsillar fossa. In 4 patients (14.3%), the tip of styloid process was palpable in the upper pole of tonsillar fossa (Grade 1) on the affected side. In 23 patients, the tip was palpable in the middle of tonsillar fossa (Grade 2), and in 15 patients, the tip was palpable in the lower pole of the tonsillar fossa (Grade 3). Among these, two patients had the tip projecting to the tongue base.

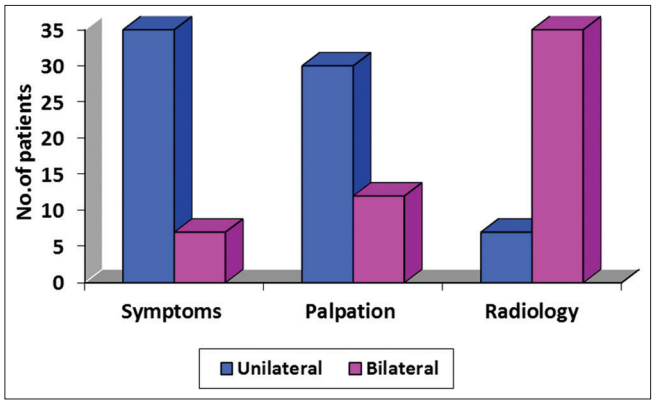

Chart 3: Side affected by symptomatology, palpation, and radiology

Table 2: Incidence of various symptoms

Symptoms	Number of patients (%)
Needle pricking sensation on the affected side of throat	30 (71.4)
Foreign body sensation throat	26 (61.9)
Pain on swallowing	20 (47.6)
Pain on the affected side of neck	14 (33.3)
Pain in the temporomandibular joint area	12 (28.6)
Pain on changing the head posture	4 (9.5)
Headache	6 (14.3)

CT Scan

We compared the commonly used radiological studies such as X-ray lateral view of head and neck for styloid, x-ray skull AP view with open mouth, and orthopantomogram with CT styloid. It was found that CT scan is a very useful diagnostic tool. Unilateral elongated styloid process was visualized in 10 patients (23.8%) and bilateral in 32 patients (76.2%). Of the total 42 patients, 18 patients (43%) had calcified stylohyoid ligament [Figures 3 and 4]. In unilateral cases, calcified stylohyoid ligament was seen in 2 patients, and in bilateral cases, calcified stylohyoid ligament was seen in 16 patients. For calcified stylohyoid ligament, there was no sex predilection. Majority of patients (89%) with calcified stylohyoid ligament were above 40 years.

Treatment

Of 42 patients diagnosed, 26 patients underwent intraoral excision of elongated styloid process under general anesthesia. 16 patients were not willing for the surgery and these patients were treated with drugs such as carbamazepine, amitriptyline, and diclofenac sodium. Bilateral excision was done in 19 patients and unilateral excision in 7 patients.

Complications

Four patients had diffuse swelling behind the angle of mandible extending to submandibular region noticed on the 2nd post-operative day which subsided by itself by the end of 1st week. 1 patient was readmitted with features of parapharyngeal cellulitis 1 week after the surgery, and she was treated with parental antibiotics and other supportive measures.

Follow-up

Patients were followed up at intervals of 1 week, 3 weeks, 2 months, 6 months, and 1 year to know the recurrence or persistence of the symptoms after surgery. On follow-up, 3 patients complained of persistent foreign body sensation throat and they were put on amitriptyline with the improvement of symptoms.

DISCUSSION

Patients who attended ear, nose, and throat (ENT) outpatient department at medical college hospital, Calicut, between June 2009 and October 2011, with nagging throat pain, cervicofacial pain, and foreign body sensation throat were analyzed. Of these, 42 patients were found to be having elongated styloid process. In this study, clinical, diagnostic, and therapeutic parameters of elongated styloid process are discussed.

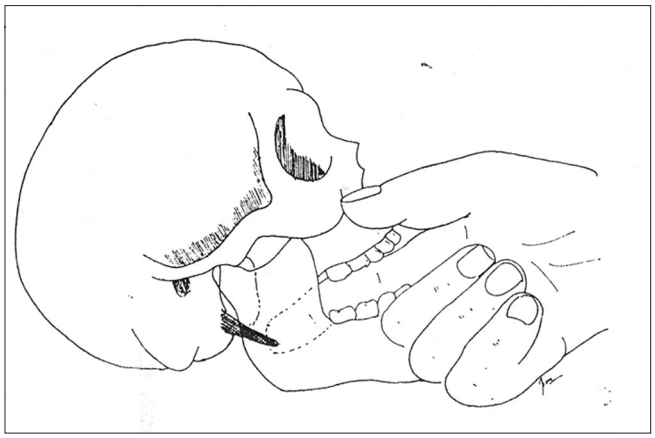

Figure 2: Intraoral palpation

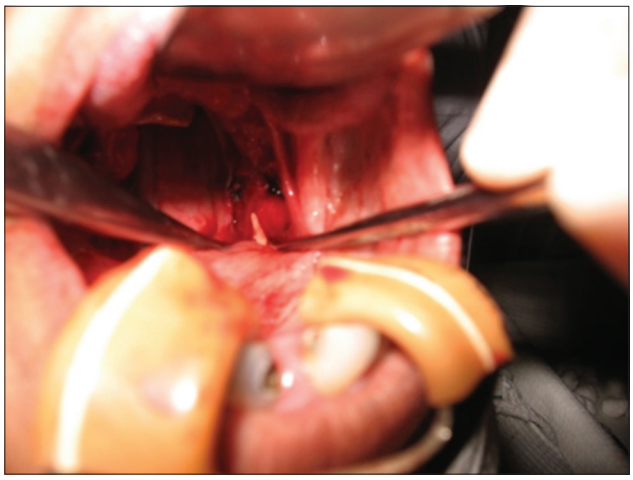

Figure 3: The styloid process at surgery

Figure 4: The computed tomography scan three-dimensional picture with elongated styloid process

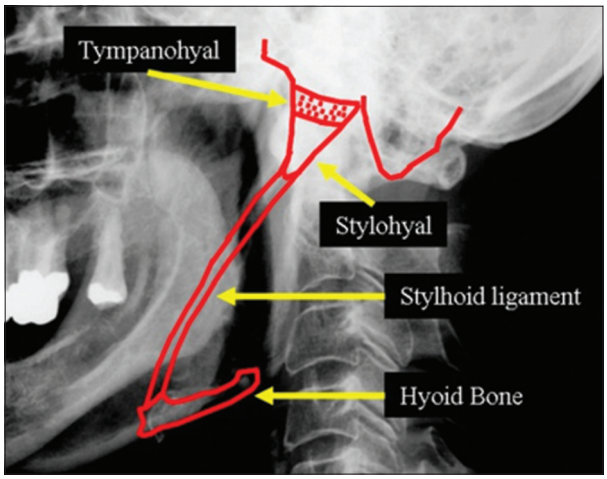

Figure 5: X-Ray of the neck showing schematic representation of the styloid process AQ3

Age and Sex Characteristics

In this study, the youngest patient was 23-year-old and the oldest was 68-year-old. Majority of these were in the 30–39 years age group. Age incidence in our study is compared with some of the major studies in the available literature [Table 3].

According to Stylagia,[12] 20–29 years was the most commonly affected age group. Verma[23] (1995) reported a maximum number of patients in 30–39 and 40–49 years age group. Our study shows a maximum number of patients in 30–39 years of age group and this was also observed by Verma.[23] The female predominance is noted in all major studies in the literature [Table 4], i.e., Strauss *et al.*[24] 87.5%, Verma[23] (1995) 85.5%, Moffat *et al.*[15] 75%, and Stylagia[12] 61.6%. The present study also shows a female preponderance of 57.14% [Table 4].

Side Affected

In the literature, bilateral symptoms were noticed by Stylagia[12] in 25% and Verma[23] (1995) in 67.3%. Moffat *et al.* and Christiansen *et al.*[13] have reported bilateral symptom in none of their series. The present study only 14.28% of the study group has bilateral symptoms, but CT showed 85.71% had bilateral elongated styloid process [Table 5].

Symptomatology

Elongated styloid process is notorious for its diverse symptomatology. All the literatures available have confirmed this diversity. In the present study, the most common symptom was needle pricking sensation on the affected side of the throat (71.4%). The next most common symptoms were foreign body sensation throat on the affected side (61.9%), pain on swallowing, and referred otalgia (47.6%). Verma[23] in 1996 reported pain on swallowing and throat pain as predominant symptoms. Authors like Stylagia[12] and Strauss *et al.*[24] reported cervical pain as the most common symptom. According to Bhide,[22] referred otalgia was the predominant symptom. In this study, the other symptoms noticed were pain on the side

Table 3: Age and sex characteristics

Authors	Total patients	Age in years							
		10–19	20–29	30–39	40–49	50–59	60–69	70–79	80–89
Stylagia[12]	52	7	20	12	8	5	0	0	0
Bhide[22]	41	0	0	18	13	10	0	0	0
Verma[23] (1995)	55	0	0	15	20	20	0	0	0
Present study	42	0	6	17	15	3	1	0	0

Table 4: Sex incidence

Authors	Total number of patients	Males (%)	Females (%)
Stylagia[12]	52	20 (38.4)	32 (61.6)
Moffat *et al*.[15]	4	1 (25)	3 (75)
Bhide[22]	41	18 (43.9)	23 (56.1)
Strauss *et al*.[24]	8	1 (12.5)	7 (87.5)
Verma[23] (1995)	55	8 (14.5)	47 (85.5)
Our study	42	18	24 (57.14)

Table 5: Side affected

Authors	Number of patients	Unilateral symptoms (%)	Bilateral symptoms (%)
Stylagia[12]	55	39 (75)	13 (25)
Moffat *et al*.[18] (1977)	4	4 (100)	0
Christiansen *et al*.[13]	5	5 (100)	0
Strauss *et al*.	8	7 (87.5)	1 (12.5)
Verma[23] (1995)	55	18 (32.7)	37 (67.3)
Our study	42 (85.71%)	36	6 (14.28)

of neck (33.3%), pain in the temporomandibular joint area (28.6%), and pain on changing the head posture (9.5%). A small number of patients also reported other symptom like headache.

Clinical Examination

Apart from other routine general and ENT examination, palpation of the tonsillar fossa for elongated styloid process was a very useful diagnostic method. According to Verma,[23] elongated styloid process was graded according to the relation of the tip of the styloid process and the tonsillar fossa.

1. Grade I: The tip of the styloid process palpable in the upper pole.
2. Grade II: The tip of the styloid process palpable in the middle of the tonsillar fossa.
3. Grade III: The tip of the styloid process palpable in the lower pole and tongue base.

In our study group:

4 patients - Grade I
23 patients - Grade II
15 patients - Grade III

Palpation of the tip of the styloid process in the tonsillar fossa produced aggravation of characteristic symptoms in all these patients.

Radiological Study

Even though the radiological study remains the most helpful diagnostic method in Eagle's syndrome, a single definite radiological view is still not advocated in available literature. Various authors have suggested different radiological views [Table 6].

Orthopantomogram is considered as a very useful view by many authors like Goldstein and Scopp,[19] Baddour,[28] and Carmada *et al*.[29] Exaggerated Towne's view was suggested by Lavine *et al*.,[26] in 1968. In our study, we compared lateral view of head and neck, lateral oblique view, posteroanterior view of skull, orthopantomogram, and CT styloid in a few of our patients. It was found that CT styloid was very useful diagnostic tool and was taken in all our patients. In the study, the longest styloid process measured radiologically by CT was 6.2 cm. CT scan styloid process: In this study, unilateral elongated styloid process was found in 10 patients (23.8%) and bilateral in 32 patients (76.2%). Of the total 42 patients, 18 patients (43%) had calcified stylohyoid ligament. In unilateral cases, calcified stylohyoid ligament was seen in 2 patients (20%), and in bilateral cases, bilateral calcified stylohyoid ligaments were seen in 16 patients (50%). For calcified styloid ligament, there was no sex predilection. Majority of patients (89%) with calcified stylohyoid ligament was above 40 years and increased predilection for calcification of stylohyoid ligament was seen in cases with bilateral elongated styloid process. On comparing the signs and symptoms of patients with elongated styloid process with calcified stylohyoid ligament and elongated styloid process without stylohyoid ligament, it is seen that there is no difference in the symptoms in these two groups. Hence, stylohyoid ligament calcification perse associated with elongated styloid process is not producing any additional symptoms when compared with isolated elongated styloid process without stylohyoid ligament calcification. In this study, we recommend CT scan styloid process as the effective radiological investigation to diagnose elongated styloid process with or without calcified stylohyoid ligament. Diagnostic role of CT scan in Eagle's syndrome was stressed by Baddour[28] and Carmada *et al*.[29] Treatment: Conservative treatment: In the study group of 42 patients, 16 patients (42.9%) were not willing for surgery. In these patients, medical treatment

Table 6: Preferred radiological views by various authors

Brat[18]	Transoral view
Stafne and Hollinshead[25]	AP view skull and lateral oblique view
Lavine *et al*.[26]	Exaggerated Towne's view
Langalis *et al*.[27](1968)	Lateral view head and neck and PA view skull
Baddour *et al*.[28] (1976)	Panoramic view
Goldstein and Scopp[19]	
Carmada *et al*.[29]	
Our study	CT styloid

CT: Computed tomography

was given with carbamazepine 100–200 mg once/twice daily, amitriptyline 10–50 mg once/twice daily weeks to months, and diclofenac sodium 50 mg twice/thrice daily for a short course. Most of the patients reported temporary symptomatic relief. Bhide[22] also reported temporary relief in most of the patients studied with carbamazepine. Injection of 2% lignocaine in the tonsillar fossa also offered some temporary symptomatic relief in most of the patients studied. Steinmann in 1970 described the use of long-acting local anesthetic and steroid solution for conservative management of Eagle's syndrome. Surgical treatment: 26 patients (57.1%) in the study group were subjected to intraoral excision of elongated styloid process under general anesthesia. Most of the authors in the literature also advocate intraoral approach (Eagle 1958,[30] Murthy *et al*.[31] etc.). This is a safe, simple, and more familiar approach to all ENT surgeons with no neck incision and very minimal complications. Intraoral excision does not involve greater morbidity than a routine tonsillectomy. External approach requires a neck incision, and in rare occasions, there is a chance for facial nerve palsy also. Among 26 patients operated, bilateral excision was done in 19 patients (73%) and unilateral excision was done in 7 patients (26.92%). Complications: In 4 patients (9.52%), a diffuse swelling behind the angle of the mandible extending to the submandibular area was observed on 2nd post-operative day which subsided by itself by the end of 1st week. Eagle in 1958 reported this complication in 25 patients of 150 total patients (16.7%). Submandibular swelling was also noticed by Murthy *et al*. in 10% and by Strauss *et al*. in 25% of their patients [Table 7].

In this study, 1 patient (2.4%) was readmitted with features of parapharyngeal cellulitis 1 week after the surgery and she was treated with parenteral antibiotics and other supportive measures. Even though infection of deep neck space is a well-documented complication of intraoral approach, this is a rarely reported complication in the literature. Eagle[1] did not report even a single patient with this complication in his large series of 150 patients. Follow-up: Patients were followed up for 1 year at 1 week, 3 weeks, 2 months, 6 months, and 1 year. 3 of our patients (7.1%) complained persistent symptoms in the form of foreign body sensation throat after surgery, and they were treated with amitriptiline with improvement of symptoms.

Table 7: Complications

Post-operative complications	Eagle	Strauss *et al*.	Murthy *et al*.	Present study
Submandibular swelling	16.67%	25%	10%	9.52%
Surgical emphysema	-	12.5%	15%	-
Deep neck space infection	-	-	-	2.4%

CONCLUSIONS

Eagle's syndrome is a relatively common disorder that is frequently misdiagnosed. Patients with vague cervicofacial pain, throat pain, foreign body sensation throat, referred otalgia, etc., should be palpated for elongated styloid process and investigated for the same. This condition has a female preponderance and the most commonly affected age group is 30–39 years. CT scan styloid remains a radiological investigation to diagnose elongated styloid process with or without calcified stylohyoid ligament. Medical treatment will not give a long-standing symptomatic relief in elongated styloid process. Intraoral excision of the elongated styloid process is the treatment of choice of this condition. This is a safe and easy procedure, which does not involve greater morbidity than a routine tonsillectomy, and is familiar to all ENT surgeons.

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Original Article

A Study of Penetrating Injuries of Abdomen

G Rajendran[1], A Ramesh[2], Heber Anandan[3]

[1]Professor, Department of General Surgery, K.A.P.V Medical College and Mahatma Gandhi Memorial Government Hospital, Trichy, Tamil Nadu, India, [2]Assistant Professor, Department of General Surgery, KAPV Medical College and Mahatma Gandhi, Trichy, Tamil Nadu, India, [3]Senior Clinical Scientist, Department of Clinical Research, Dr. Agarwal's Healthcare Limited, Chennai, Tamil Nadu, India

Abstract

Introduction: Major trauma does not respect and restrict itself to one organ or one system. Evaluation of a patient with abdominal trauma can be a most challenging task that a surgeon may be called on to deal with. Abdominal injuries may be parietal or visceral injuries. Visceral injuries may be intraperitoneal or retroperitoneal.

Aim: The aim of this study is to evaluate the various aspects of penetrating abdominal injuries excluding pelvic organs.

Materials and Methods: This study consists of all penetrating abdominal injuries admitted in the trauma ward of Mahatma Gandhi Memorial Hospital, from March 2015 to November 2016.

Results: A total od 2 stab injuries were the common penetrating trauma accounting for 67.5%. There were 10 cases of bull gore injury, 2 cases of gunshot, one case of road traffic accident, and one case of penetrating injury due to falling on to iron rods in a concrete centering work site. In this study, stab injury is the common mode of producing penetrating abdominal injuries. Liver, small bowel, and spleen are the three most frequently injured organs.

Conclusion: There was no appreciable delay in the management of majority of the patients because of the penetrating nature of injuries. Pancreatic and ureteric injuries had delayed presentations in this study.

Key words: Management, Morbidity, Penetrating injuries

INTRODUCTION

Trauma ranks along with atherosclerotic arterial diseases and malignancy as a major cause of morbidity and mortality. Injury continues to be the leading cause of death in the first four decades of life.[1] High-speed vehicles, decivilization of human race, terrorism, and sports are just few of the predisposing factors of trauma. Major trauma does not respect and restrict itself to one organ or one system. Evaluation of a patient with abdominal trauma can be a most challenging task that a surgeon may be called on to deal with. Abdominal injuries may be parietal or visceral injuries. Visceral injuries may be intraperitoneal or retroperitoneal. The retroperitoneal structures enjoy the safety produced by the depth of domicile but nevertheless suffer from the ominous potential for delayed presentations.[2] Liver, spleen, stomach, small bowel, duodenum, large bowel, pancreas, kidney, ureter, and the retroperitoneal vascular are the organs included in this study and the pelvic organs are excluded. Multiorgan injuries, exsanguinating hemorrhages delayed presentations, and the ominous reputation for high mortality and morbidity are just few of the many reasons which make this topic of penetrating injuries a fascinating one.[3] Although there is no debate that patients with peritonitis or hemodynamic instability should undergo urgent laparotomy (LAP) after penetrating injury to the abdomen, it is also clear that certain stable patients without peritonitis may be managed without operation. The practice of deciding which patients may not need surgery after penetrating abdominal wounds has been termed selective management. This practice has been readily accepted over the past few decades with regard to abdominal stab wounds, yet controversy persists regarding gunshot wounds.[4] Indications for immediate LAP include hemodynamic instability, evisceration, peritonitis, or impalement. Selective non-operative management of stable, asymptomatic patients has been demonstrated to be safe. Adjunctive diagnostic testing-ultrasonography,

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Corresponding Author: A Ramesh,Department of General Surgery, KAPV Medical College and Mahatma Gandhi Memorial Government Hospital, Trichy, Tamil Nadu, India. Phone: +91-9486372719. E-mail: drrameshms21@gmail.com

computed tomography, local wound exploration, diagnostic peritoneal lavage, and laparoscopy are often used in an attempt to identify significant injuries requiring operative management. However, prospective studies indicate that these tests frequently lead to non-therapeutic LAP and are not cost-effective.[5]

Aim

The aim of the study is to evaluate the following aspects of penetrating abdominal injuries excluding pelvic organs.

MATERIALS AND METHODS

This study consists of all penetrating abdominal injuries admitted in the trauma ward of Mahatma Gandhi Memorial Hospital. Once the patient is admitted, the name, age, sex, and mode of injury are noted. The time interval between injury and admission and time interval between admission and surgery are recorded. After resuscitating the patients and if time permits, necessary investigations are carried out. In those who are operated, the operative findings and methods of management are recorded. Cases are followed up till their discharge from the hospital. If death occurs, the cause of death is evaluated. In those patients who died before surgery, the post-mortem findings are noted. The above facts are recorded in a pro forma prepared for this study.

RESULTS

The total number of patients who had sustained penetrating injuries to abdominal organs was 40. During this period, a total number of cases of abdominal trauma managed were 131. Thus, penetrating injuries to abdominal organs account for 30.53% of the abdominal trauma cases. In this study of the 40 patients, 33 were male and 7 cases were females. This gives a male-to-female ratio of 4:7:1. The high incidence of trauma in males may probably be due to the relatively high association of males in acts of violence and vehicular accidents.

Table 1 presents the age and sex incidence in this study. The youngest patient was an 11-year-old boy who had sustained penetrating injuries by stabling by his blood relative? Psychic. More than 50% of the patients belong to the age group between 21 and 40 years which is the most productive part of one's life. The oldest patient was an 80-year-old female who had sustained penetrating injuries by bull gore.

Table 1: Age and sex incidence

Age group	Male	Female	Total
<10	Nil	Nil	Nil
11–20	5	Nil	5
21–30	11	2	13
31–40	8	1	9
41–50	4	2	6
51–60	4	1	5
>60	1	1	2
Total	33	7	40

As given in Table 2, stab injury is the common penetrating trauma accounting for 67.5%. There were 10 cases of bull gore injury, 2 cases of gunshot, 1 case of road traffic accident, and one case of penetrating injury due to falling on to iron rods in a concrete centering work site.

Table 3 presents the associated injuries in penetrating injuries of the abdomen. Ten patients sustained associated thoracic injuries. Seven patients had long bone fractures. Six patients suffered from head injury and one patient sustained cut throat injury. A total of 24 patients had injuries involving other organs. This high incidence of polytrauma with penetrating injuries abdomen indicates the severity of injuries.

Admission and surgery are given in Table 4.

From the Table 4, it can be deduced that 32 cases took <6 h from the time of injury to admission. The fastest to arrive was within 30 min from the injury. The average time duration between admission and surgery was 4 h.

Table 5 presents the different organs injured in the study. Liver injury tops the list with 9 cases. This is followed by small bowel and spleen, accounting for 8 and 6 cases each. There were 5 cases of stomach and 4 cases of colonic injuries. There were 3 cases of duodenal injuries, 3 cases of retroperitoneal hematomas, and one case of ureteric injuries. There were 2 cases of kidney, 2 cases of pancreatic injuries, and also 3 cases of diaphragmatic injuries.

DISCUSSION

Liver Injuries

There were totally 9 cases of liver injury. In this, 7 cases were due to stab injury and 2 cases were due to bull gore. The most common cause of penetrating liver injury in 75 consecutive cases in a study done by Krige *et a*l. was gunshot wounds accounting for 50.60% and stab injuries accounting for 33.90%.[3,6] The incidence of associated organ injuries is a significant factor in patients sustaining liver injuries. In this study, only 2 cases were isolated liver injuries and remaining was associated with other organ injuries. The different ways in which the 9 cases of liver injuries were managed are as follows. Application of gel foam and suture hepatorrhaphy was done in 5 cases. In 2 cases, there was

no active bleeding, and hence, no repair was done. In other 2 cases, omental pack was kept in deep lobar laceration to control bleeding. Peritoneal lavage with normal saline was done in all cases and open drainage was kept in all cases.

In this study, 2 of the 9 cases died, giving a mortality rate of 22.22%. Mortality in one case was due to the severe associated injuries and one died of septicemia at the end of the 4th post-operative day. Two cases developed subphrenic abscess. The mortality rate of 75 consecutive cases in a study done by Krige *et al.* was 10–15%.[3] The incidence of post-operative perihepatic abscess ranges from 3.5 to 22%.[6]

Splenic Injury

There were totally 6 cases of splenic injury. Of these 6 cases, 4 cases were due to stab injury and 2 cases were due to bull gore injury, whereas the series from the 75 consecutive cases in a study done by Krige *et al.* has reported an incidence of gunshot splenic injuries as 7.6% and stab injuries as 7% among penetrating splenic injuries.[3]

In this study, only one case had isolated splenic injuries. Three cases were associated with diaphragmatic injuries, and one case had associated pancreatic injury with retroperitoneal hematoma. One case was associated with stomach and small bowel injury, and one case had associated with transverse colonic injury.

In this study, all the injured spleen have undergone splenectomy, whereas the series from 75 consecutive cases in a study done by Krige *et al.* report 45–50% of injured spleen have undergone repair instead of splenectomy that too splenorrhaphy was accomplished in 51% of patients with a penetrating mechanism of injury. However, in only 36.7% with a blunt mechanism of injury would be expected to undergo splenorrhaphy.[3,7] The grading of the splenic injury has a significant impact on treatment. In our study, of 6 patients, 3 patients were hemodynamically unstable and had associated intra-abdominal injuries, so we could not perform splenorrhaphy for these patients.

In this study, two cases had died in the immediate post-operative period due to hypovolemic shock and multiple organ failure.

Stomach Injuries

There were totally 5 cases of stomach injuries. In this, three cases were due to stab injuries, one case was due to bull gore injuries, and one case was due to accidental gunshot injury, whereas the series from 75 consecutive cases in a study done by Krige *et al.* reported an incidence of gunshot stomach injuries as 17.3% and stab stomach injuries as 12.6%.[3,6]

In this study, isolated stomach injury was present in only two cases. All remaining cases were associated with other organ injuries. Of which, retroperitoneal hematoma was present in 3 cases, liver injury in 2 cases, splenic injury in 1 case, duodenal injury in 1 case and diaphragmatic, and small bowel injury in one case. In one patient after gastrorrhaphy, AGJ and JJ were done. That patient died on 4th post-operative day due to burst abdomen and septicemia. One more patient died of septicemia due to concomitant colonic injury. One patient developed consolidation of left lower lobe with left subphrenic abscess and two patients had wound infection post-operatively both of them were treated conservatively. The incidence of intra-abdominal abscess in patients with penetrating wounds of the stomach

Table 2: Penetrating injuries: Abdomen

Stab injury	26
Bull gore	10
Gunshot	2
RTA	1
Others	1
Total	40

RTA: Road traffic accident

Table 3: Injury of the other organs

Thoracic injuries	10
Long bone injuries	7
Head injuries	6
Others	1
Total	24

Table 4: The analysis of the time interval between injury and surgery

Time interval (h)	Injury - admission	Admission - surgery
<2	15	10
2–4	10	15
4–6	7	7
6–8	3	1
8–10	2	1
10–12	2	2
>12	1	4

Table 5: Different structures affected

Liver	9
Small bowel	8
Spleen	6
Stomach	5
Duodenum	3
Colon	4
kidney	2
Ureter	1
Pancreas	2
Retroperitoneal injuries	3
Diaphragm	3

was 5–10 percent in the series of 75 consecutive cases in a study done by Krige *et al.*,[3] which is in accordance with our study also.

Duodenal Injuries

There were totally 3 cases of duodenal injuries, of which two cases were due to stab injury and one case of bull gore injury. Whereas, Ivaturary *et al.* 1985[8] and Levinson *et al.*[9] give the following figures, gunshot (78%), stab injuries (16%), and shotgun (6%).

All patients were taken up for exploratory LAP. All patients underwent duodenorrhaphy in two layers. One patient underwent a gastrojejunostomy; in two patients, a serosal jejunal patch was kept. Como *et al.*[4] also state that 80% of patients with duodenal injuries require simple duodenorrhaphy. Synder *et al.*[10] could find no difference in the morbidity of simple closure with or without tube decompression. Levison *et al.*[9] in a recent series report a mortality of 16.7% for blunt duodenal trauma and a mortality of 7.5% for penetrating duodenal trauma. The incidence of duodenal fistula in our study was 15% which is slightly more than that reported in other studies.[8]

Pancreatic Injuries

There were totally two cases of pancreatic injuries. Of which, one case was due to stab injuries and one case was due to bull gore injury. Jurkovich *et al.*[11] state that penetrating trauma accounts for two-third and blunt trauma accounts for one-third of pancreatic injuries. In this study, the mortality rate for pancreatic injury was 50%. The combined mortality from several large series of pancreatic trauma patients ranges from 10% to 25%. Our morbidity rate was 70%. In this study, the incidence of pancreatic fistula was 50% which healed with conservative management.

Small Bowel Injuries

There were totally 8 cases of small bowel injuries. Of which, 5 cases were due to stab injury, 2 cases were due to bull gore injury, and 1 case was due to accidental gunshot injury. Whereas, the incidence of small intestinal injury following penetrating trauma exceeds 80% with gunshot wound and 30% with stab injuries that penetrate the peritoneum.[3,12] In this study, only three cases had isolated small bowel injury. In the remaining cases, two cases had associated mesenteric tears, one case was associated with colonic injuries, and other two cases were associated with liver, spleen, and stomach injuries separately. In one case with questionable viability of bowel, we have done resection and anastomoses in two-layers. In our study, two patients had wound infection and two had intra-abdominal abscess, both of them were treated with conservative management.

Colonic Injuries

There were totally 4 cases of colonic injuries, all the 4 cases were due to stab injuries. One patient was a diabetic who had sustained multiple stab injuries in the abdomen. There was injury to caecum, ascending colon, and ileum. The injuries were repaired and a tube cecostomy was done patient died on the 2nd day due to severe sepsis. One patient had injury to transverse colon, duodenum, and liver. All injuries were repaired and defunctioning colostomy was done, and patient expired on 4th post-operative day due to septicemia. One patient had injury at pelvirectal junction. Primary repair and pelvic colostomy were done. Remaining two patients had tear in transverse colon primary repair and defunctioning colostomy was done.

Renal Injuries

There were totally two cases of renal injuries. Both were due to stab injuries. Whereas, the most common cause of penetrating renal trauma in the Parkland memorial hospital study was gunshot wounds accounting for 79% and the remaining were due to stab injury.[3]

The incidence of associated organ (non-renal) injuries is a significant factor in patients sustaining renal trauma. In this study, all penetrating renal trauma had associated organ injuries. Carlton[13] reported an incidence of non-renal injuries of 81% in penetrating renal trauma. In one patient, the renal injury was made out only at autopsy because that patient sustained severe non-renal injury and succumbed mainly due to the severity of the associated non-renal injuries. In this study, one of the two patients died giving a mortality rate of 50%, due to the severe associated non-renal injuries.

Ureteric Injury

There was one case of ureter injury due to stab injury. In this case, the ureteric injury was made out at the initial LAP and hence repaired primarily after keeping a double "J" stent and drained the site of anastomosis externally. This type of management has also been recommended.[14] In this study, there was no mortality in the ureteric injuries.

Retroperitoneal Hematoma

There were 3 cases of mild retroperitoneal hematoma which were associated with other injuries. Nothing specific was done for these hematomas. All patients had uneventful recovery.

Diaphragmatic Injuries

There were totally 3 cases of diaphragmatic injuries. Of which, 2 cases were due to stab injury and one case was due to bull gore injury. All cases were associated with intra-abdominal injuries, of which two cases were associated with splenic injuries, and one case was associated with combined

stomach and splenic injuries. In this study, after LAP only in one case, we had converted into thoracoabdominal incision, and in remaining cases, repair was done through abdominal approach only. The rent was closed with simple sutures with No. 1 silk or with other non-absorbable suture materials or with figure of eight sutures of the same material. In all cases, international classification of disease was done after closure.

Negative Celiotomies

In this study, there were 4 cases of negative celiotomies. Whereas, in Feliciano *et al*.[6] and Shorr *et al*.[12] series, the negative celiotomies were from 5.8% to 7.4%. In this study, after confirmation of peritoneal penetration by wound exploration, exploratory LAP was done in all cases. There was no viscus or vascular injury, and there was no missed injury in our study. All were discharged after an uneventful post-operative period.

Mortality and Morbidity

There were totally 6 deaths in this study of 40 cases, constituting a mortality rate of 13.7%. Morbidity in mild-to-severe forms occurred in all patients who survived. The severe degree of morbidity was occurred in the form of residual abscess, duodenal fistula, pancreatic fistula, post-operative lung infections, etc. The mild form of morbidity was due to wound infection. Feliciano[6] and Krige *et al*.[3] have reported in a series of 300 consecutive patients with penetrating abdominal injuries, an overall mortality rate of 15%. In our study, the mortality rate was 13.7% and it included only those patients arriving to the hospital alive. Hence, the pre-hospital mortality has been excluded and 13.7% mortality rate is comparable with literature.

CONCLUSION

Penetrating abdominal injuries constitute 30.53% of the abdominal injuries. In this study, stab injury is the common mode of producing penetrating abdominal injuries. Liver, small bowel, and spleen are the three most frequently injured organs. There was no appreciable delay in the management of majority of the patients because of the penetrating nature of injuries. Pancreatic and ureteric injuries had delayed presentations in this study. Multiple organ injuries were the rule in retroperitoneal trauma. The overall mortality of penetrating abdominal injuries in this study was 13.7% and morbidity was 80%. Hypovolemic shock due to bleeding and sepsis was the major causes of death.

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Original Article

Mini-external Fixators in Fracture of Short Tubular Bones of Hand

O Ravinathan[1], R Vasantharaman[2], Heber Anandan[3]

[1]Assistant Professor, Department of Orthopaedics, Government Medical College, Pudukottai, Tamil Nadu, India, [2]Associate Professor, Department of Orthopaedics, Government Medical College, Pudukottai, Tamil Nadu, India, [3] Senior Clinical Scientist, Department of Clinical Research, Dr. Agarwal's Healthcare Limited, Tirunelveli, Tamil Nadu, India

Abstract

Introduction: Fractures of the metacarpal and phalanges constitute 10% of all fractures. Nowhere in the body, the form and function are so closely related to each other than in hand. Too often, these fractures are treated as minor injuries resulting in major disabilities.

Aim: This study aims to evaluate the outcome of hand fractures managed with mini-external fixators.

Materials and Methods: This is a prospective study to determine the outcome of phalangeal and metacarpal fractures treated with mini-external fixators. Study consists of 40 patients with fractures of phalanx and metacarpal bones. Pre-operative work-up was done to exclude crush injury of hand beyond reconstruction and with vascular injury. Fracture fixation was done with K-wires and clamps. All our patients were reviewed clinically and radiologically at regular interval.

Result: Types of fracture; 25 were comminuted, 6 transverse, 5 oblique, and 10 spiral. Good results were in 16 cases, fair results in 5 cases, and there are no poor results. Fair results were in fracture with intra-articular extension due to the restriction of movements.

Conclusions: Our overall experiences with mini-external fixators for phalangeal and metacarpal fractures are encouraging; however, we are aware this is a short-term study and would require further evaluation and more inputs.

Key words: Mini-external fixators, Open and unstable fractures, Phalangeal and metacarpal bone

INTRODUCTION

Hand injury is extremely common and accounts for about 15% of the attendance at accidents and emergency departments.[1] Fractures of metacarpals and phalanges are probably the most common fractures in the skeletal system and are often neglected as minor injuries.[2] Diagnosis of phalangeal and metacarpal fractures can be made after careful clinical assessment and radiological examination. Radiological examination should include standard anteroposterior and lateral views of the injured bone.[3] Most of the fractures are treated conservatively, but some form of fixation is often indicated in unstable fractures, intra-articular fractures, open fractures, and multiple fractures. Various implants ranging from K-wires, mini-plates to mini-external fixators are used to treat these fractures.[4] Even though these fractures are small and more often neglected, these fractures causes significant deformity and disabilities. The management depends on the type, site, and pattern of fracture. The treatment options are conservative and operative. We have different types of surgical treatments such as open reduction and fixation with K-wires, plates and screws, screws alone, and external fixators. Since mini-external fixation is less invasive and has the advantage of treating both open and closed fractures, we preferred mini-external fixators for phalangeal and metacarpal fractures. Other advantages of external fixators are gives good stability for fracture, easy for wound care, and early mobilization of joints.[5,6]

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Corresponding Author: Dr. R Vasantharaman,Department of Orthopaedics, Government Medical College, Pudukottai, Tamil Nadu, India. Phone: 91-9842468055. E-mail: drvasantharaman74@gmail.com

Aim

This study aims to evaluate the outcome of hand fractures managed with mini-external fixators.

MATERIALS AND METHODS

This prospective study was conducted at Government Rajaji Hospital. 40 patients with fractures of phalanx and metacarpal bones were selected for this study. Pre-operative work-up was done to exclude crush injury of hand beyond reconstruction and with vascular injury. Pre-operative evaluation was done with complete hemogram, serological investigation for HIV, HBSAG, and radiography. Under local anesthesia under strict aseptic precaution, external fixators were applied. Two 2.0 mm "K" wires were applied on either sides of the fracture site on the dorsolateral aspect of the fingers at 45° angle to bone after provisional reduction under the guidance of image intensifier. The pins were then provisionally connected to a 2.5 mm "K" wire by metal clamps and the fracture reduced. In most cases, simple traction was sufficient, and after reduction, the K-wires were fixed firmly to the connecting bar. Three unstable fractures were fixed with more than two K-wires on either side. If the pins interfered with the soft tissues, they were bent in a dorsal direction through an angle of 40–60°. The skin wounds were not closed and, postoperatively, the injured hand was immobilized in plaster for 10 days to 6 weeks. Standard pin care was taught to the patients and discharged after soft tissue healing. Finger mobilization was started after 48 h and regular wound care was given. Inspection of the wounds and stability of the device were checked at weekly interval regularly. Radiographs were taken immediately after surgery and at 1–2 weeks and 4 weeks to check the position and healing. After bony healing, we removed the external fixators. Mobilization was started after the removal of the plaster splint. Patients were discharged from follow-up when improvement in function had reached a plateau. Recovery was scored on the basis of the total active range of movement of each injured finger separately, using the scoring system of Duncan *et al.*[7] for total active movement (TAM). This adds the active flexion of the metacarpophalangeal, proximal interphalangeal, and distal interphalangeal joints, then subtracts the sum of the extension deficits at these three joints.

RESULTS

Sex ratio is male 28 and female 12. Most of fractures are in dominant hand right side 22 and left side 18. Their mean age was 35 years (15–69). Most had blunt injuries, nine were caused by traffic accident, 10 by machinery, 12 by falling or cutting objects, and five by physical violence and four by a fall. The distribution of the 29 phalangeal and 11 metacarpal fractures; the proximal phalanx of the ring finger was more often involved than that of the other fingers. Types of fracture; 25 were comminuted, 6 transverse, 5 oblique, and 10 spiral. There were 27 open fractures (Table 1-4).

The mean follow-up was 4.4 years (2.3–8.2), and there were no general complications. The external fixators were removed at a mean of 5.8 weeks for phalangeal fracture (3–11) and 6.1 weeks for metacarpal fracture (2–12) after fixation. 10 fractures showed complications during the period of fixation: In six patients, one of the pins became loose, in two part of the device interfered with the soft tissues of the adjacent finger, in one the device restricted movement of the adjacent finger, and in one the fracture became displaced. In five patients, pin loosening was managed by removal of the external fixators as the fractures had healed. In one case, fracture displaced due to pin loosening for which refixation was done. Interference with other fingers was seen only before we had made it our policy to bend the pins. The patient with a displaced fracture required rereduction at a second operation. The mean period of treatment for phalangeal fractures was 7 months and for metacarpal fractures 5 months. Six patients developed joint stiffness. No patient developed reflex sympathetic dystrophy. There were no sinuses after removal of the pins. None of the fingers had rotational or axial deformities. Eight out of the nine fractures of the middle phalanx and 12 of the proximal phalangeal fractures had excellent. Of the eight patients with fair or poor results, five had an injury to the tendon. The mean follow-up was 4 years external fixators were removed after 4 weeks. There were no general complications. There were no rotational and axial deformities. Functions of finger were assessed using TAM of digits scoring method. Good results were in 16 cases, fair results in 5 cases, and there are no poor results. Fair results were in fracture with intra-articular extension due to restriction of movements. Pin is looser was found is one case and it was corrected. There is no pain tract infection. In our study, we had few post-operative complications. One case of stitch abscess and one case of early post-operative infection treated appropriately.

Table 1: Distribution of types of fracture

Diagnosis	Male	Female	Total
Transverse fracture	4	2	6
Oblique fracture	2	3	5
Spiral fracture	6	4	10
Communited fractures	16	3	19

Table 2: Acceptable angulation and shortening of fingers

Fingers	Acceptable shaft angulation (degree)	Acceptable shaft shortening (mm)	Acceptable neck angulation (degree)
Index and long finger	10–20	2–5	10–15
Ring finger	30	2–5	30–40
Little finger	40	2–5	50–60

Table 3: Mode of injury

Mechanism of injury	Mini-external fixation	Conventional method	Total
RTA	16	15	31
Fall	3	3	6
Assault	2	1	3
Total	21	18	40

RTA: Renal tubular acidosis

Table 4: Side of injury

Side	Mini-external fixation	Conventional method	Total
Right	13	9	22
Left	7	11	18
Total	20	20	40

DISCUSSION

A fracture is considered functionally stable when during clinical examination; it is possible to actively move the fractured digit by 50% of range of motion painlessly. The fracture is considered radiologically stable when the radiographs of the fractured fragment in two planes show minimum angulation and displacement.[7] A fracture is considered unstable if it cannot be reduced or maintained in an anatomic or near anatomic position without implant fixation when the hand is placed in the safe or functional position.[8] The four factors that determine the stability are (1) external force, (2) muscle imbalance, (3) fracture configuration or personality, and (4) integrity of soft tissue including periosteal sleeve. The phalangeal fracture is exposed either through a dorsal vertical or a lazy "S" incision. Rarely, one may choose to go through one or both mid-lateral incision.[9] Extensor tendon on the proximal half of the proximal phalanx is incised vertically in the middle while in the distal half the plane is in between central and lateral slip. The incision over the extensor tendon on the middle phalanx is paramedian without violating the insertion of central slip at the base of middle phalanx. Although general anesthesia or regional anesthesia is widely used in hand surgeries, there is a distinct advantage of distal blocks or WASH which facilitates intraoperative movements of the fingers to confirm the rotational alignment. Most phalangeal and metacarpal fractures are treated conservatively.[10] Patients with unstable fractures require operative reduction and stabilization to obtain the optimal position for bone healing and to allow early movement. We used external fixation to help to avoid any additional injury to the bone and soft tissues. The technique is relatively simple, and even greater precision is added by the use of an image intensifier.[11,12] The best site for pin introduction is easily chosen. Predrilling with a drill guide has the advantage that the site and direction of the pins are better controlled. An image intensifier is sometimes necessary because of the brittle nature of the phalanges and metacarpals: What may seem to be a perfect drill hole may lead to incorrect pin placement if it is not checked by the image intensifier.[13,14]

CONCLUSION

External fixation provides an adequate basis for bone healing but does not guarantee good functional outcomes. These seem to depend on the severity of accompanying soft tissue injuries as shown by our fair or poor results in six patients in whom a phalangeal fracture was associated with tendon injuries. The functional results after metacarpal fractures were better than those after phalangeal fractures and fractures of the middle phalanx had better recovery than those of the proximal phalanx. External fixation proved to be a suitable technique for stabilizing unstable, open fractures with severe soft tissue injuries.

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Original Article

How Safe is Laparoscopic Surgery in the Treatment of Acute Appendicitis with Complications Compared to Open Abdominal Surgery?

N K Noorudheen, P K Ramesh

Assistant Professor, Department of General Surgery, KMCT Medical College, Kozhikode, Kerala, India

Abstract

Background: Open abdominal surgery (OAS) is the gold standard in the surgical treatment of acute appendicitis (AA). Appendicectomy with laparoscopy is a safe procedure in uncomplicated cases. It is viewed as a risk in complicated AA by many surgeons. A study was conducted to compare open with laparoscopic procedure in complicated AA.

Aim of the Study: This study aims to study the results and problems encountered in treating AA with complications with laparoscopy and comparing them with OAS.

Materials and Methods: A retrospective study on 68 patients attending the hospital with signs and symptoms of AA with complications was divided randomly into two groups. One group was treated with appendicectomy using laparoscopy and the other group with open abdominal appendicectomy. All the patients were selected such a way that the age, gender, and complications match. Problems encountered while doing the two methods of surgery and results were compared and analyzed.

Observations and Results: A total of 68 patients were divided into two groups with 34 patients each. In Group A (34), males were 22 and females were 12. In Group B, males were 23 and females were 11. The mean age of patients in Group A was 23.16 ± 4.10 and in Group B was 22.80 ± 3.60. The mean time of surgery in Group A was 73.45 ± 1.10 min and in Group B it was 52.95 ± 2.15 min. The hospital stay in Group A was 5.46 ± 2.50 days and in Group B it was 9.30 ± 3.40 days. There was no increase in complication rate in Group A compared to Group B.

Conclusions: Laparoscopic surgery in AA with complications is safe and devoid of post-operative complications when the cases are selected properly. The study observes that there is statistical significance in the duration taken for the surgery and the hospital stay. This study demonstrated no increase in surgical complications between the groups of laparoscopy and OAS after laparoscopy in patients.

Key words: Abscess and appendicectomy, Appendicectomy, Appendicitis, Complications, Laparoscopy

INTRODUCTION

Appendicitis was first described in the 16th century and initially called as "perityphlitis." McBurney described the classical signs and symptoms in 1889. Usage of laparoscopy for acute appendicitis (AA) has increased since 1983.[1] Although the open abdominal surgery (OAS) is the gold standard in the surgical treatment of AA, using laparoscopy has shown that it provides better diagnostic accuracy, reduced use of analgesics, shorter hospital stay, earlier return to daily activities, and a lower rate of wound infection in comparison to OAS for appendectomy.[2-6] Few authors have shown that there is an added advantage in using laparoscopy in elderly patients, morbidly obese patients, and fertile women to treat AA.[7-10] The cosmetic benefit and cost-effectiveness laparoscopy are also observed by few surgeons.[11] Using laparoscopy in complicated AA cases such as peritonitis, appendicular abscess may result in intra-abdominal abscess (IAA) is a debate even today.[12-16] Although some authors have recommended and concluded that laparoscopy is a safe and effective surgical treatment for complicated AA,[17-19] certain facts such as prolonged

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Corresponding Author: Dr. P K Ramesh, Department of General Surgery, KMCT Medical College, Manassery, Kozhikode, Kerala, India.
E-mail: rameshpk99@rediffmail.com

operation time and post-operative stay, increased rate of conversion, and greater complications due to infection have been reported when compared to uncomplicated appendicitis. Therefore, the aim of this study was to study the results and problems encountered in treating AA with complications with laparoscopy and comparing them with OAS by the same surgeon.

Type of Study

Retrospective study.

Period of Study

This study period was from October 2014 to September 2016.

Institute of Study

This study was conducted at KMCT Medical College Hospital, Manassery, Kozhikode, Kerala.

MATERIALS AND METHODS

A total of 68 patients were selected randomly from among the emergency surgical patients with a diagnosis of AA with complications, attending the Department of Surgery of a Tertiary Teaching Hospital, KMCT Medical College Hospital, Manassery, Kozhikode, Kerala. An Ethical Committee clearance was obtained from the Institutional Ethical Committee. The patients were divided into two groups. Group A consisted of patients with AA with complications undergoing laparoscopy surgery and Group B undergoing OAS. The data were collected from the case records obtained from the medical records section of the institute.

Inclusion Criteria

1. Patients aged above 18 years and below 55 years were included.
2. Patients with complications associated with AA were included.
3. The complications were perforation, peritonitis, abscess formation, and gangrene of the appendix.

Exclusion Criteria

1. Patients aged below 18 years and above 55 years were excluded.
2. Patients with other comorbid conditions such as diabetes, hypertension, and thyroid dysfunction were excluded.
3. Patients with previous abdominal surgery were excluded.

The diagnosis of AA had been made by a single senior surgeon by pre-operative clinical presentation and confirmed by ultrasound examination of abdomen. Complications of AA included were defined as the presence of a ruptured gangrenous appendix with or without pus formation. AA associated with peritonitis with perforation was included as complication. All the patients in both groups were subjected to surgical profile laboratory investigations to get clearance for general anesthesia. All the surgeries were done under general anesthesia. Laparoscopy was performed with the three-port approach (two 10 mm, one 5 mm) using Hasson's technique with monopolar dissectors and forceps. The mesoappendix was divided using electrocautery or clips. Pretied suture loops or laparoscopic free ties were used for stump closure. The appendix was extracted within the trocar through the umbilical 10-mm port without using a plastic bag. Gangrenous and ruptured appendices were irrigated with normal saline (at least 2000 mL), and a silastic drain was used for ruptured appendices. All the patients were discharged based on the recovery form symptoms of acute illness, removal of Ryle's tube, when bowel sounds are heard when the patient is able to take oral semisolids and when abdominal rigidity and guarding disappeared. Patients were also followed up 1 week after discharge. Data collected included demographic information, white blood cell (WBC) count, and operation time, length of hospitalization, pathology report, and complications. No case was converted to open abdominal procedure in Group A patients. The parameters of both the groups were compared. All the data were analyzed using standard statistical methods.

OBSERVATIONS AND RESULTS

Total number of patients included in the study was 68 with 34 patients in each group. Group A was in which patients were treated with laparoscopic surgery and Group B in which open abdominal appendicectomy was done. In Group A (34), males were 22 and females were 12. In Group B (34), males were 23 and females were 11. The mean age of patients in Group A was 23.16 ± 4.10 and in Group B was 22.80 ± 3.60. The types of complications were tabulated in Table 1. The comparative data regarding the patients of both groups are not significant. The data of both the groups are almost identical. There was no significant difference in gender and WBC count between the two groups as the *P* value above 0.05 (*P* significant at <0.05) [Table 1].

The mean time of surgery in Group A was 73.45 ± 1.10 min and in Group B it was 52.95 ± 2.15 min. The hospital stay in Group A was 5.46 ± 2.50 days and in Group B it was 9.30 ± 3.40 days. There was no increase in complication rate in Group A compared to Group B [Table 2]. The accuracy of final diagnosis in this study was 100%. The histopathological reports of 25 patients among the 29 patients that underwent computed tomography (CT) scan

abdomen were coinciding with reports of CT scan. The accuracy of CT scan in AA with complications was 86.20%. The duration of surgery and hospital stay were statistically significant in both the groups as P <0.05. The incidence of complications was similar in both the groups and not significant statistically as P >0.05 [Table 2].

DISCUSSION

Laparoscopic surgery for appendectomy was proved to be a safe procedure as a surgical treatment for non-complicated AA. There is controversy regarding its usage in AA with complications.[20,21] Laparoscopy procedure in superior to open appendectomy in terms of post-operative wound infections, analgesia requirement, hospital length of stay, return to work, and overall recovery.[3,22] The post-operative infection rate was much lower in the patients operated by laparoscopy than open method in cases of appendicectomy with complication.[23] The incidence of IAA formation was higher following the uses of laparoscopy for perforated appendicitis with complications.[24-26] There were no incidences of surgical post-operative complications in the present study of both the groups. In the present study, peritoneal lavage was done in all cases of both groups with 3 L 0.9% saline at the end of the procedure and that may be the reason there were no complications postoperatively. This finding is supported by similar study by Gupta *et al*.[27]

Table 1: The demographic data and types of complications in the study (*n*=68)

Observation	Group A	Group B	*P* value
Mean age	23.16±4.10	22.80±3.60	0.131
Gender			
Male	22 (64.70%)	23 (67.64%)	
Female	12 (35.29%)	11 (32.35%)	0.221
Mean duration of symptoms	2.5±1.65	2.1±1.45	0.086
Mean WBC count	12.8±2.7	13.15±1.89	0.430
CT Scan abdomen-29	14 (41.17%)	15 (44.11%)	0.453
Complications perforation	8 (23.52%)	9 (26.47%)	0.611
Gangrene formation	11 (%)	9 (26.47%)	0.732
Peritonitis	12 (35.29%)	13 (38.23%)	0.521
Abscess formation	4 (11.76%)	3 (08.8%)	0.476

WBC: White blood cell, CT: Computed tomography

Table 2: The laboratory data and operative data (*n*=68)

Observation	Group A	Group B	*P* value
Duration of surgery	73.45±1.10	52.95±2.15	0.032
Hospital stay	5.46±2.50	9.30±3.40 days	0.049
Histopathology report			0.165
Perforated appendix	12 (35.29%)	10 (29.41%)	
Gangrene formation	14 (41.17%)	15 (44.11%)	
Appendicular abscess	8 (23.52%)	9 (26.47%)	

The mean time of surgery in Group A was 73.45 ± 1.10 min and in Group B it was 52.95 ± 2.15 min. The other advantages of using laparoscopy for appendicectomy with complications were wide inspection of the peritoneal cavity, debridement, irrigation, and lavage under direct visualization, avoidance of large abdominal incisions, and fewer pulmonary complications.[28] The hospital stay in Group A was 5.46 ± 2.50 days and in Group B it was 9.30 ± 3.40 days. There was no increase in complication rate in Group A compared to Group B postoperatively. In accordance with other studies which propose to consider laparoscopy surgery in AA with complications, this study also gives observations favorable to consider laparoscopy as a first choice in complications associated with AA likewise in uncomplicated cases.

CONCLUSIONS

Laparoscopic surgery in AA with complications is safe and devoid of post-operative complications when the cases are selected properly. The study observes that there is statistical significance in the duration taken for the surgery and the hospital stay. This study demonstrated no increase in surgical complications between the groups of laparoscopy and OAS.

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Original Article

Cytopathological Study of Lymph Node Lesions - A 2 Years Retrospective Study

K Florence, K Suresh, K Lavanya

Department ofPathology, SVS Medical College, Mahabubnagar, Telangana, India

Abstract

Introduction: Fine-needle aspiration cytology (FNAC) is a well-established and popular diagnostic aid for patients presenting with lymphadenopathies. Frequent involvement of lymph nodes in regional and systemic diseases along with their easy accessibility makes FNAC the first line of investigation in evaluating lymphadenopathies. Lymph node enlargement occurs in a wide spectrum of diseases including reactive conditions, infections such as tuberculosis, fungal, and protozoal as well as primary lymphoid malignancies and secondary metastatic tumors. Most common etiology in our country is tuberculosis. FNAC is a highly acceptable, minimally invasive, cost-effective, and rapid investigation of choice that is feasible in our current scenario.

Aims and Objectives: (1) To evaluate various etiologies in lymph node enlargement and (2) to assess the frequency of lymphadenopathy in different age groups and genders.

Materials and Methods: A 2 years retrospective study was done from August 2015 to July 2017 at SVS Medical College and Hospital, Mahabubnagar, on 459 patients with lymph node enlargement in the department of pathology.

Key words: Fine needle aspiration cytology, Lymphadenopathy, Tubercular lymphadenitis

INTRODUCTION

Lymphadenopathy refers to enlarged lymph nodes. It is the most common clinical presentation of patients attending the outpatient department. Fine-needle aspiration cytology (FNAC) is the first line of investigation in evaluating lymphadenopathy due to frequent involvement of lymph nodes in regional and systemic diseases and easy accessibility. The technique is minimally invasive and gives speedy result.[1] Highly acceptable, simple, rapid, and cost-effective procedure that is feasible in our current scenario.[2] It can be used as safe alternative to excision biopsy.[3] Lymph node enlargement occurs in a wide spectrum of diseases including reactive conditions, infections, and malignancy.[4] One of the most common etiologies is tuberculosis which is very rampant in our country.

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AIMS AND OBJECTIVES

1. To evaluate various etiologies in lymph node enlargement.
2. To assess the frequency of lymphadenopathy in different age groups and genders

MATERIALS AND METHODS

A 2 years retrospective study was undertaken from August 2015 to July 2017 at SVS Medical College and Hospital, Mahabubnagar, on 459 patients with lymphadenopathy. FNAC was done on clinically diagnosed cases of lymphadenopathies in the department of pathology. Cases with inadequate or unsatisfactory material for diagnosis were excluded from the study.

RESULTS

Of 459 cases, 402 were found to be inflammatory and 57 were neoplastic. Tuberculosis was the most common disease found in 165 patients followed by reactive non-specific lymphadenitis in 152, acute suppurative lesions in

Corresponding Author: Dr. K. Suresh, Department of Pathology, SVS Medical College, Mahabubnagar, Telangana, India.
Phone: +91-9949911066. E-mail: suresh_harithasa@yahoo.com

Table 1: Gender wise distribution of patients

Gender	Number of cases (%)
Males	218 (47.4)
Females	241 (52.6)

Table 2: Age wise distribution of patients

Age group in years	Number of cases (%)
0–20	151 (32.8)
21–40	181 (39.4)
41–60	75 (16.3)
61–80	52 (11.3)

Table 3: Cytological diagnosis of lymph node aspirations

Diagnosis	Number of cases (%)
Tubercular lymphadenitis	165 (35.9)
Reactive lymphadenitis	152 (33.1)
Acute suppurative lymphadenitis	50 (10.8)
Granulomatous lymphadenitis	35 (7.6)
Metastatic deposits	48 (10.4)
Non-Hodgkin lymphoma	8 (1.7)
Hodgkin lymphoma	1 (0.2)

50, granulomatous lymphadenitis in 35 cases, metastatic tumors in 48, and lymphomas in 9 patients and most commonly involved are cervical group of lymph nodes. Graph 1 shows distribution of cases of lymphadenopathies according to anatomical location. Table 1 shows genderwise distribution of patients. Table 2 shows Age wise distribution of patients. Table 3 shows cytological diagnosis of lymphnode aspirations.

DISCUSSION

Lymphadenopathy is a commonly encountered clinical condition requiring prompt and accurate diagnosis to provide treatment as early as possible. In the present study, a total number of cases were 459 over a period of 2 years. The pattern of these cases varied from non-neoplastic lesions such as tuberculous lymphadenitis, reactive lymphadenitis, acute suppurative lymphadenitis, and granulomatous lymphadenitis to neoplastic lesions including metastatic lymphadenopathy and lymphoma. FNAC is the first line of investigation in the diagnosis of lymph node lesions. It is safe, inexpensive, and highly acceptable to the patient. In our study, an attempt has been made to study the cytomorphological spectrum and also epidemiological pattern of lymph node lesions. Cervical group of lymph nodes was the most common group involved seen in 67.5% cases which is similar to that observed by Sharma *et al.*,[5] Pavithra and Geetha,[2]

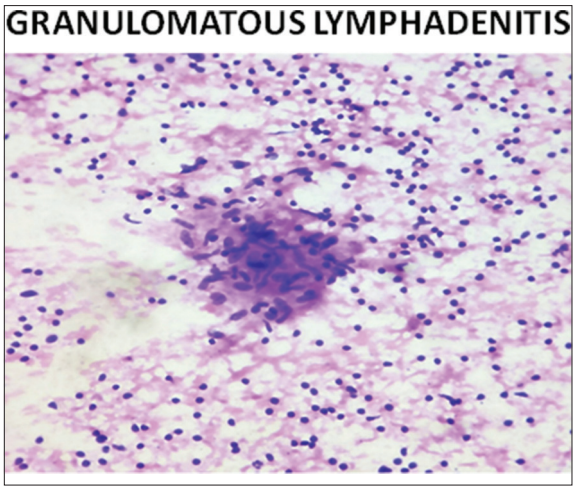


Figure 1: Smear shows epithelioid cell cluster with lymphocytes in the background (H and E ×400)

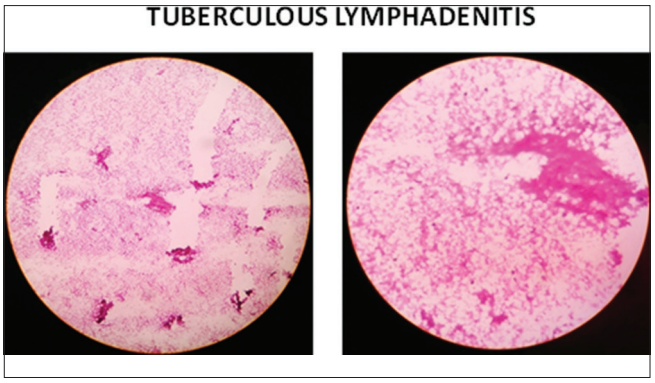


Figure 2: Smear shows caseous necrotic material (H and E ×100 and ×400)

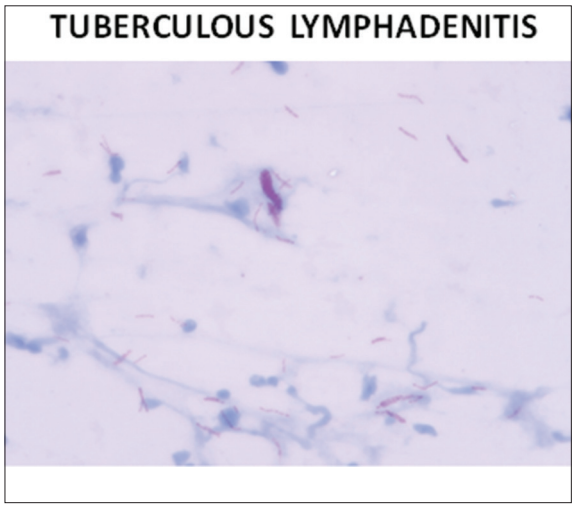


Figure 3: Smear shows acid-fast bacilli in Ziehl–Neelsen stain

and Kochhar *et al.*[6] It was followed by submandibular group of lymph nodes in 10.6% cases and least commonly involved are inguinal lymph nodes seen in only 1.8% cases. Most of the patients in this study were

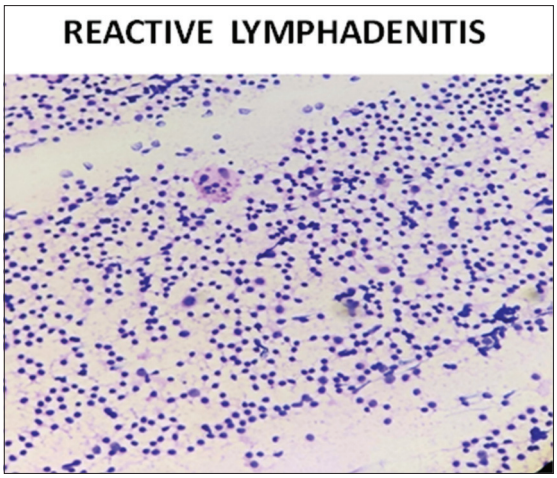


Figure 4: Smear shows lymphocytes in various stages of maturation, tingible body macrophages, and plasma cells (H and E ×400)

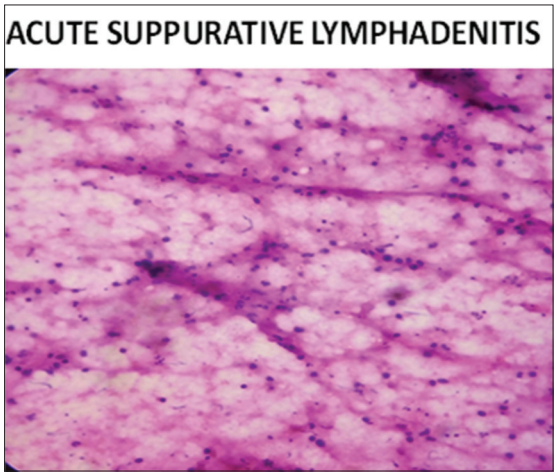


Figure 5: Smear shows neutrophils, lymphocytes in the necrotic background (H and E ×400)

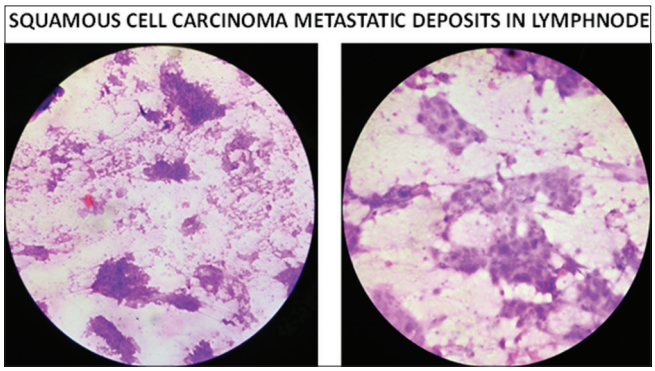


Figure 6: Smear shows clusters of squamoid tumor cells with lymphoid cells in the background (H and E ×100 and ×400)

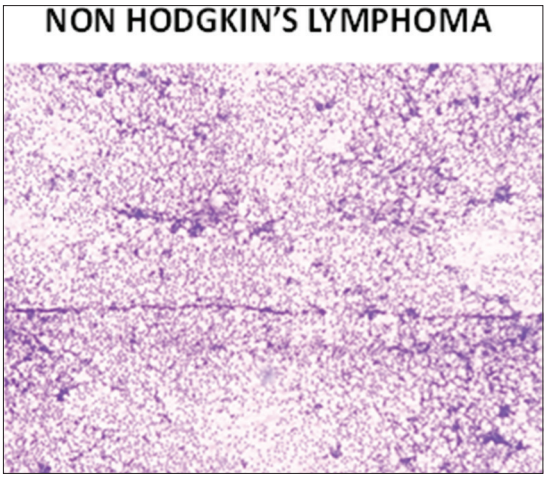


Figure 7: Smear shows monotonous population of slightly enlarged lymphocytes with coarsely granular chromatin (H and E ×10)

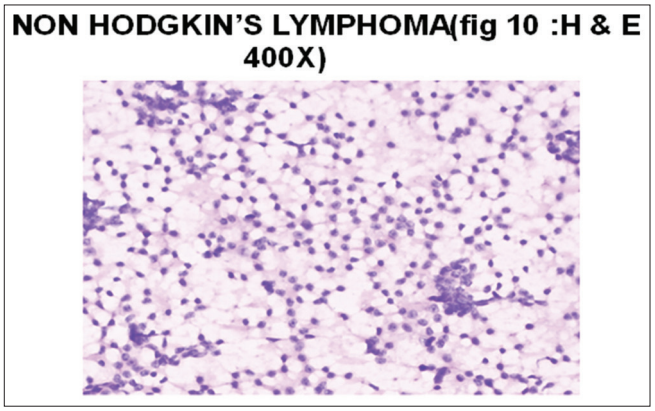


Figure 8: Non-Hodgkin's lymphoma (H and E ×400)

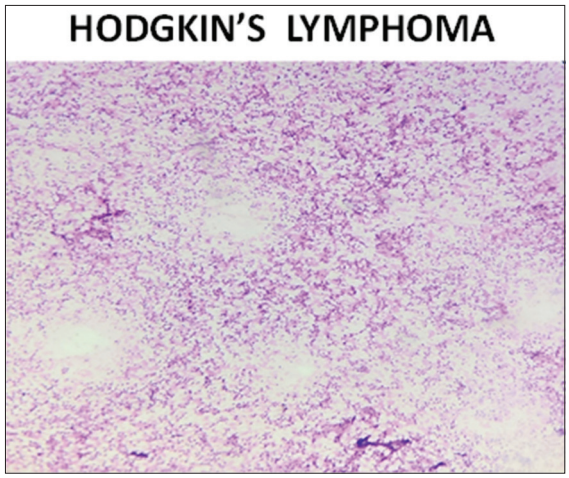


Figure 9: Smear shows polymorphous population of lymphocytes, eosinophils, histiocytes, and Reed-Sternberg cells (H and E ×100)

in the age group of 21–40 years similar to Pandit *et al.*,[7] whereas in the study of Sharma *et al.*,[5] most of them were of 10–19 years and in Gupta *et al.* study,[8] it is 0–20 years. In the present study, females were slightly predominant than males with M: F of 1:1.1 and in Sharma *et al.*[5] study, it is 0.87:1. Tuberculous lymphadenitis [Figure 2] was the

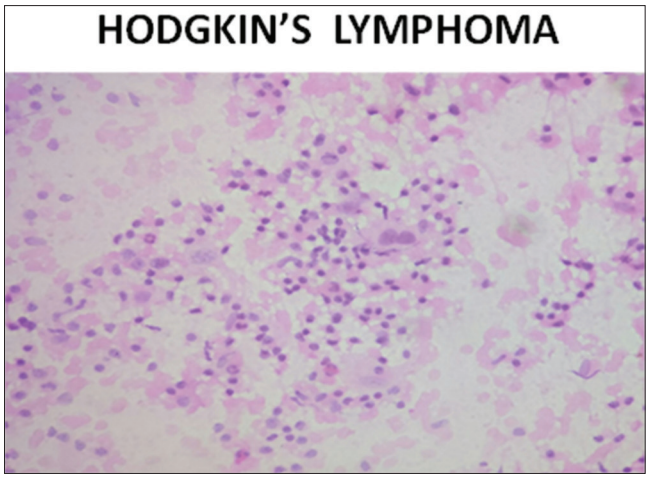
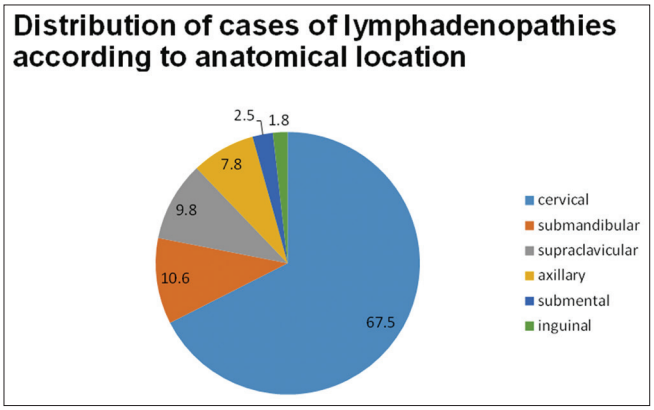


Figure 10: Smear shows binuclear Reed-Sternberg cells with few eosinophils in the background of lymphocytes (H and E ×400)



Graph 1: Distribution of cases of lymphadenopathies according to anatomical location

most common lesion reported in 35.9% cases similar to the study of Sharma *et al.*[5] in which it is about 56.92%. Most of these cases were seen in the age group of 21–40 years with female predominance. Ziehl–Neelsen staining for acid-fast bacilli (AFB) [Figure 3] was seen in 55% cases while Sharma *et al.*[5] reported 22.6% cases. In cases with characteristic caseous necrotic material and scattered epithelioids with or without granulomas or only necrotic material with neutrophilic infiltration were diagnosed as tuberculous lymphadenitis even though AFB were absent in the smears.[9] The second most frequent diagnosis in our study was reactive lymphadenitis [Figure 4] seen in 33.1% cases similar to the study of Sharma *et al.*[5] and Khan *et al.*[10] Acute suppurative lymphadenitis [Figure 5] was observed in 10.8% cases in the present study comparable to other studies of Kocchar *et al.*,[6] Sharma *et al.*,[5] and Patra *et al.*,[11] granulomatous lymphadenitis [Figure 1] was reported in only 7.6% cases in our study. Granulomas can also be seen in a variety of other conditions of lymphadenopathy such as leprosy, fungal infections, sarcoidosis, cat scratch disease, lymphogranuloma venereum, and collagen vascular diseases.[12] Lymph node aspirations in 10.8% cases showed metastatic deposits [Figure 6] with male preponderance and adenocarcinoma being the most common histologic type. Maximum cases of metastatic deposits were seen in the age group of 61–80 years and cervical group of lymph nodes was predominantly involved. A detailed history, clinical examination, radiological investigations, and immunohistochemistry in selected cases may help to locate the primary site of malignancy. The present study also comprised 9 cases, i.e., 1.9% which were diagnosed as lymphoma comparable to observations of Sharma *et al.*,[5] Fatima *et al.*[13] (5.2%), and Hirachand *et al.*[14] (6.1%) among these cases, non-Hodgkins lymphoma (NHL) [Figures 7 and 8] and HL [Figures 9 and 10] constituted 1.7% and 0.2%, respectively. This is also comparable to study by Bhaskaran *et al.*[15] in which NHL and HL constituted 2.23% and 0.74%. These cases were later confirmed by biopsy.

CONCLUSION

FNAC is an excellent first line of investigation to determine the nature of lesion. It is quick, safe, minimally invasive, reliable, and readily acceptable by patient. The present study highlighted the various cytomorphological patterns of lymphadenopathy and revealed a huge burden of tuberculous lymphadenitis.

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Original Article

Peripheral Nerve Dysfunction in Chronic Kidney Disease

G Rathnakumar[1], Jyothis P Jose[2], Heber Anandan[3]

[1]Associate Professor, Department of Medicine, Tirunelveli Medical College and Hospital, Tirunelveli, Tamil Nadu, India, [2]Junior Resident, Department of Medicine, Tirunelveli Medical College and Hospital, Tirunelveli, Tamil Nadu, India, Senior Clinical Scientist, [3]Department of Clinical Research, Dr. Agarwal's Healthcare Limited, Chennai, Tamil Nadu, India

Abstract

Introduction: Peripheral nerve dysfunction is a recognized complication of chronic kidney disease (CKD). The study mainly focuses the incidence, clinical manifestation, and severity of peripheral nerve dysfunction in patient with CKD admitted in our hospital.

Aim: The aims of our study are to evaluate the incidence of overt neuropathy and subclinical neuropathy in CKD patients and to evaluate the clinical manifestations of peripheral nerve dysfunction.

Methods: The study was conducted at the medical wards of Tirunelveli Medical College. Patients with proved clinical, biochemical parameters in favor of CKD, and all patients included in this study were not on dialysis.

Results: Of 74 patients assessed, 48 patients proved to have peripheral nerve dysfunction by electrodiagnostic study and the number of patients affected with peripheral nerve dysfunction is increasing when the duration is increasing (more than 5 years).

Conclusion: Distal symmetrical predominantly sensory motor neuropathy is the most common type of peripheral neuropathy observed in patients with CKD. Loss of ankle reflex and vibratory sensory loss are the most common clinical signs of peripheral neuropathy in patients with CKD. There is predilection for male in the incidence of peripheral neuropathy in CKD when the creatinine clearance was below 15 ml/mt.

Key words: Ankle reflex, Chronic kidney disease, Peripheral neuropathy, Sensory-motor neuropathy

INTRODUCTION

Peripheral nerve dysfunction is a recognized complication of chronic kidney disease (CKD). Most of the time, patients who are having features of peripheral nerve dysfunction would not come out with complaints of it unless it is specifically asked or looked for. At present, the medical treatment for kidney disease is improving and patient's long-term survival is improving.[1] Peritoneal dialysis, hemodialysis, and transplantation have revolution the prognosis of CKD in recent periods. As patient's lifespan is prolonged due to recent improvement in the treatment of CKD, it is essential to know about the complication that can occur in patient surviving for long period with CKD, of which peripheral nerve dysfunction is one of the recognizable and treatable complication of CKD.[2] The etiology of CKD is varying in nature, but the clinical symptoms and signs are of the same. The study mainly focuses the incidence, clinical manifestation, and severity of peripheral nerve dysfunction in patient with CKD admitted in our hospital. Neuropathy occurs in at least 65% of patients who are about to begin dialysis for CKD and is perhaps the most common neurological consequence of chronic uremia. It is a distal, symmetrical, mixed sensory-motor polyneuropathy affecting the lower limbs to a greater extent than the upper limbs. The rate of progression, severity, prominence of motor or sensory sings, and prevalence of dysesthesia are quite variable. Males are developing neuropathy with an incidence several fold greater than females; this difference is unexplained.[3] Individual serological and biochemical

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Corresponding Author: Dr. Jyothis P Jose, Department of Medicine, Tirunelveli Medical College and Hospital, Tirunelveli, Tamil Nadu, India. Phone: +91-9567034720. E-mail:jyothispjose@gmail.com

abnormalities (calcium, magnesium, phosphate, urea, and creatinine) are not correlated well with this or any other neurological manifestation of the uremic state. The chronicity and severity of kidney disease appear to be the important cause to the development of neuropathy. The observation that uremic neuropathy improves with hemodialysis has led most observers to conclude that neuropathy result from the accumulation of a dialyzable metabolite. Due to the varying nutritional status of uremic patients, the possibility that vitamin deficiency is a mechanism of neuropathy should be considered.[4-6] Massive doses of vitamins administered both orally and parenterally have failed to influence clearly the course of neuropathy in informal trails. An inhibitory effect of uremic toxins on endoplasmic flow of transmitters or other essential neural nutrients is another possibility.[7]

Aim

The aim of this study is to evaluate the incidence of overt neuropathy and subclinical neuropathy in CKD patients and to evaluate the clinical manifestations of peripheral nerve dysfunction in CKD patients.

MATERIALS AND METHODS

The prospective observational study was conducted at the medical wards of Tirunelveli Medical College Hospital, Tirunelveli. Patients with proved clinical and biochemical parameters in favor of CKD are included in the study. Inclusion criteria: Patients with CKD not on dialysis, serum creatinine more than 2 mg%, and creatinine clearance <40 ml/mt were included in the study. Exclusion criteria: Patients with other recognizable risk factors for peripheral neuropathy are excluded from the study. After selecting the patients with reference to inclusion and exclusion criteria, the presence of peripheral nerve dysfunction is assessed in them clinically by means of motor and sensory symptoms and sings.

RESULTS

A number of patients affected with CKD were 74. Of 74 patients assessed, 48 patients proved to have peripheral nerve dysfunction by the electrodiagnostic study.

From Table 1, it is learnt that the number of patients affected with peripheral nerve dysfunction is increasing when the duration is increasing (more than 5 years).

48 patients had evidence of peripheral neuropathy by the electrodiagnostic study. 25 patients revealed sensory motor neuropathy, 12 patients had sensory neuropathy, and 11 patients had motor neuropathy [Table 2]. From Table 3, it is observed that the most common type of neuropathy in chronic disease patients is distal sensory motor neuropathy.

A number of patients affected with peripheral neuropathy by the electrodiagnostic study were 48. Of these 48, only 14 patients showed clinical evidence of peripheral neuropathy. Of these 14 patients had both motor and sensory symptoms in the form of loss of ankle jerk and defective vibration sense, 2 patients had numbness both lower limbs, and 1 patient had distal muscle weakness of lower limbs.

72% of males and 66% of females were affected when the creatinine clearance was <15 ml/mt. 20% of males and 25% of females were affected when the creatinine clearance was 15–29 ml/mt. Males were affected more when the creatinine <15 ml/mt. Both sexes were affected equally when the creatinine

Table 1: Distribution of peripheral nerve dysfunction in CKD patients versus duration of disease

Duration of CKD (year)	Total number of patients	No patients with peripheral nerve dysfunction (%)
<1	11	4 (36)
1–3	21	11 (52)
3–5	22	16 (73)
>5	20	17 (85)
Total	74	48

CKD: Chronic kidney disease

Table 2: Distribution of patients affected with percentage with reference to overt and subclinical neuropathy

Overt neuropathy	Subclinical neuropathy	Total
14 (19%)	34 (46%)	48 (65%)

Table 3: Distribution of patients affected with percentage with reference to the type of peripheral neuropathy

Sensory-motor	Sensory	Motor	Total
25 (34%)	12 (16%)	11 (15%)	48 (65%)

Table 4: Distribution of male and female patients affected with reference to creatinine clearance

Creatinine clearance ml/mt	Male (%)	Female (%)
<15	72	66
26-29	20	25
30-59	8	8
Total	100	100

clearance between 30 and 59 ml/mt. From Table 4, it is observed that 72% of males and 66% of females with creatinine below 15 ml/mt showed evidence of peripheral neuropathy.

DISCUSSION

Peripheral neuropathy is a recognized complication of renal failure. These complications can potentially affect both the central and peripheral nervous systems. Common neurological complications in CKD include stroke, cognitive dysfunction, encephalopathy, peripheral, and autonomic neuropathies. These conditions have a significant impact not only on patient morbidity but also on mortality risk through a variety of mechanisms. Understanding the pathophysiological mechanisms of these conditions can provide insights into effective management strategies for neurological complications. This review describes clinical management of neurological complications in CKD with reference to the contributing physiological and pathological derangements.[8] Among the 74 patients, 48 patients showed evidence of peripheral nerve dysfunction either clinically or electrophysiological. 36 male patients showed features of peripheral nerve dysfunction and 12 female patients had evidence of peripheral nerve dysfunction. The duration of CKD varied from 3 months to 7 years. Kumar *et al.* discussed nerve condition study in relation to duration and severity and CKD. They found that reduced suggestive of neuropathy but delayed F-waves and H-reflex are also suggestive of neuropathy.[9] The common type of peripheral neuropathy observed in this study was distal symmetrical sensory-motor peripheral neuropathy, and incidence of this type of sensory-motor neuropathy was 34%. The incidence of sensory neuropathy was 16% and motor neuropathy was 15%. The other types of neuropathy mononeuropathy, truncal neuropathies, and cranial neuropathies are not registered in our clinical study. 65% of study population was suffering from CKD with peripheral nerve dysfunction. The peripheral nerves dysfunction was more prevalent in elder age (>65 years) subjects when compared to subjects with age <65 years.[10] Moreover, the results shown that the rate of prevalence of peripheral nerves dysfunction was observed higher in subjects with longer duration of CKD.

CONCLUSION

The incidence of peripheral neuropathy is 65% in patients suffering from CKD. Distal symmetrical predominantly sensory motor neuropathy is the most common type of peripheral neuropathy observed in patients with CKD. Loss of ankle reflex and vibratory sensory loss are the most common clinical signs of peripheral neuropathy in patients with CKD. There is a predilection for male in the incidence of peripheral neuropathy in CKD when the creatinine clearance was below 15 ml/mt. The incidence of subclinical neuropathy was about 46% and overt neuropathy is 19%. The incidence of peripheral neuropathy is having linear correlation with severity and duration of renal failure.

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Original Article

Presentation and Outcome of Thoracic Injuries at a Tertiary Care Service Hospital

Pawan Sharma[1], CK Jakhmola[2]

[1]Assistant Professor, Department of Surgery, Army College of Medical Sciences and Senior Advisor, (Surgery, Trauma and Surgical Critical Care) Base Hospital Delhi Cantt, New Delhi, India, [2]Professor and Head, Department of Surgery, Army College of Medical Sciences and Consultant (Surgery and GI Surgery), Base Hospital Delhi Cantt, New Delhi, India

Abstract

Introduction: Thoracic injuries account for a substantial proportion of all injury-related admissions, morbidity, and mortality in all service hospitals. It directly accounts for almost one-fifth of deaths resulting from trauma. This study was conducted to analyze the presentation and outcome of thoracic injuries at a tertiary care service hospital.

Materials and Methods: It was a prospective observational study of all the patients of thoracic injuries who presented at our hospital over a period of 3 years. Morbidity and mortality rates were compared and analyzed along with management and outcome. Associated injuries were also recorded and analyzed.

Results: Thoracic injuries comprised 18.2% of all trauma admission and the mechanism was blunt in majority (89.1%) of cases. Vehicular accidents (62.2%) and assault were the most common modes of injury. Rib fracture was the most common chest injury seen in 214 out of the 314 patients while abdominal visceral injuries were the most common associated injuries in polytrauma. Associated extrathoracic injuries caused a higher mortality rate in contrast to an isolated chest injury. Majority of the patients were managed nonoperatively. Intercostal drainage tube insertion was the most common modality of treatment in 82% of the cases, whereas, thoracotomy was required only in 3.18% of the patients. Overall, mortality was 5.41%.

Conclusion: Thoracic injuries can be readily diagnosed in the emergency department and require simple surgical procedures in the majority to prevent immediate mortality and morbidity. Meticulous and repeated clinical evaluation of these patients is required to prevent further worsening and long-term complications.

Key words: Blunt, Penetrating thoracic injuries, Thoracic trauma, Thoracotomy

INTRODUCTION

Thoracic or chest trauma is a major contributor of morbidity and mortality all across the globe. Interestingly, despite high morbidity and mortality, a significant proportion of these injuries are treatable, and consequent mortality is preventable. It is pertinent to note that barely 5–10% of patients with thoracic injuries require major operative intervention.[1,2] More than 90% of these patients can be managed successfully by simple bedside interventions such as needle thoracostomy or intercostal drainage (ICD) tube insertion. Thoracic injuries are the second most common cause of mortality in pediatric population following an injury.[3,4] It is not easy to gauge the true proportion or overall burden of these injuries because of inadequate data in most of the developing countries including ours. Therefore, a comprehensive analysis and interpretation of these injuries are essential to predict the likely outcome. Keeping in view the above, the study was undertaken to assess and analyze the true presentation, pattern and outcome of these injuries.

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MATERIALS AND METHODS

This study was **a** retrospective analysis of all those patients at Base Hospital Delhi Cantt who reported over a period of 3 years from April 1, 2014, to March 31, 2017, with thoracic trauma. All patients with thoracic trauma who were admitted during the above mentioned time period

Corresponding Author: Dr. Pawan Sharma, Department of Surgery, Trauma and Surgical Critical Care, Surgical Division, and ACMS, Base Hospital, Delhi Cantt, India. Phone: +91-8860602390. E-mail: drpawansharma55@gmail.com

and consented to be part of this study were included. All those cases who were either brought dead or suffered cardiac arrest on arrival were excluded. All included patients underwent a thorough clinical examination as per ATLS guidelines, and relevant imaging modalities were performed along with basic hematological and biochemical investigations as part of the detailed evaluation.[5] All these patients were followed up for a period of 30 days to study their survival, morbidity, and mortality.

Informed consent was sought from all the patients included in the study, and ethical clearance was obtained from the Institutional Ethical Committee.

The severity of the injuries was assessed using injury severity score or the ISS.

Statistical Analysis

The entire data were analyzed statistically using SSPS 16.0 utilizing descriptive statistics such as mean, median, and mode. Multivariate analysis was used for the study outcomes. Qualitative data were analyzed with Chi-square test and the quantitative data with student *t*-test. A confidence interval of 95% along with $P < 0.05$ was considered statistically significant.

RESULTS

Thoracic injuries were present in 18.2% ($n = 314$) of all trauma admissions during the entire study period. There was a clear male preponderance with a male to female ratio of 7:1 (275:39). The mean age at presentation was 32.80 years (range: 3–76 years). Majority of patients (84%, $n = 264$) were young in 20–46 years of age group predominant mechanism of thoracic injury was road traffic accidents (RTA) in 62% ($n = 195$) patients. Among patients of RTA, 45% ($n = 88$) were consequent to two or three wheeler accidents, 30% ($n = 59$) were related to 4 wheelers, and the remaining 25% ($n = 48$) were pedestrian of hit and run injury patterns.

Thirty one cases, who were brought with a history of assault, presented with stab injuries with a knife or with other sharp objects, gunshot injuries and assault with heavy wooden or metal rods. Some of the other mechanisms were animal attacks and railway track related injuries. 10% ($n = 31$) of the patients were received within a 1st h (the golden hour) following injury, and the majority of the remaining patients were brought within 12 h of injury.

Out of 314 patients, 82% ($n = 257$) patients were hemodynamically stable on presentation, and 18% cases were clinically and hemodynamically unstable. 60% of the unstable patients became stable following initial fluids or blood resuscitation. Another 22% were transient responders, and 18% did not respond to the initial resuscitation. A large majority (62.2%) presented as polytrauma and the remaining had isolated thoracic chest injuries. Subcutaneous emphysema was one of the presenting features in 15% cases [Figure 1].

Single or multiple rib fractures were the most frequent injury either in isolation (42 cases) or accompanied with one of the thoracic or extrathoracic injuries. Hemothorax and pneumothorax followed next in frequency [Figure 2] whereas, cardiac and esophageal trauma was uncommon [Figure 1]. Needle thoracocentesis was performed in two cases of tension pneumothorax. Blunt cardiac injury was observed in four cases out of which two had pericardial effusion, who were managed with pericardiocentesis. Both these patients were discharged in a stable condition whereas another patient who suffered sternal fracture with a cardiac contusion and severe arrhythmias expired during resuscitation in ICU. The fourth one with cardiac contusion recovered uneventfully. Diaphragmatic injury was seen in six cases whereas esophageal injury was observed in two cases.

The severity of the injuries was assessed using injury severity score or the ISS that was 16.63 ± 6.65 and a median ISS of 14. The mean ISS was found to be 17.2 ± 7.4 in blunt thoracic injuries, whereas, in penetrating injuries group it was 14.5 ± 3.1. Overall, the mean new injury severity score or the NISS was 18.31 ± 8.53 with a median of 20.

Intercostal drainage procedure was the most common surgical intervention performed in almost 82% of the patients of which 14% required bilateral ICD placement. The mean duration of keeping ICD *in situ* was 8.94 days with a median of 7 days (range: 2–34 days). 92% of the patients required ICDs whereas 98% of the pneumothoraces and 99% of the hemopneumothoraces required ICD tube thoracostomy. ICD was also inserted in 65% cases of pulmonary contusions. Elective tracheostomy was performed in view of prolonged ventilation or for tracheal injury in 18 patients. 32 (10.19%) case had to be shifted directly to OT for a single or multiple surgical procedures for either thoracic or other associated injuries. As many as 19% cases had to be shifted to ICU from ED following initial resuscitation and stabilization.

Lifesaving emergency thoracotomies were performed in 10 (3.18%) patients [Table 1]. Fiber optic bronchoscopy or video-assisted thoracic surgery was performed in five patients for a number of indications such as foreign body, mucus plug or blood clot removal from the tracheobronchial tree or thoracic cavity, and for diagnostic

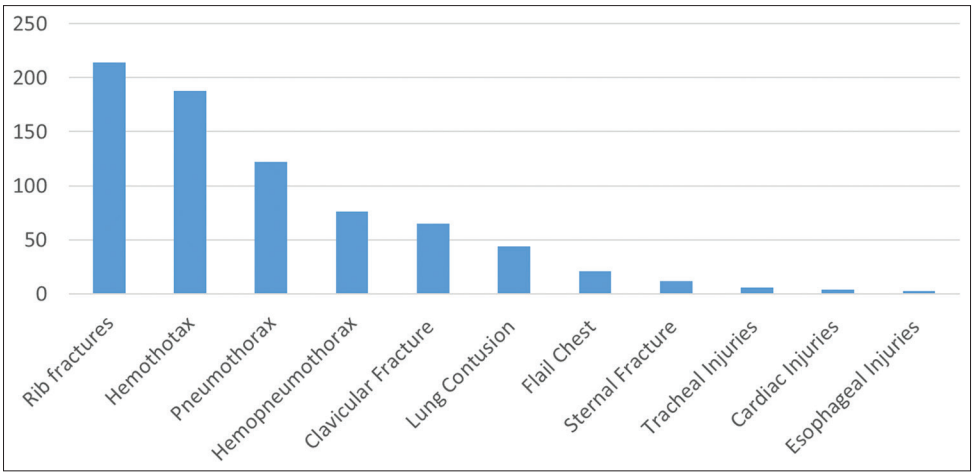

Figure 1: Pattern of thoracic injuries

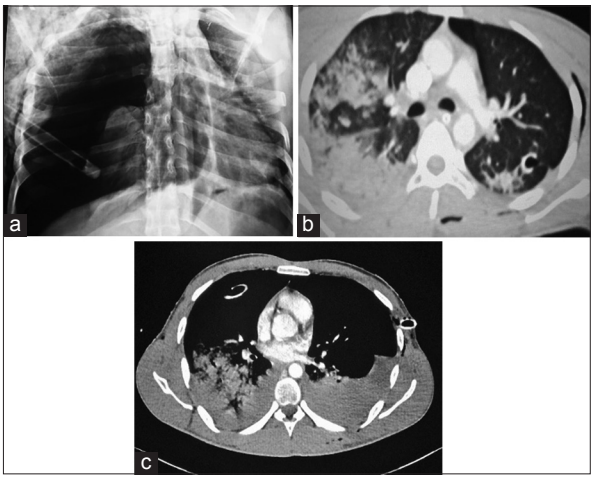

Figure 2: Clockwise from top left. (a) Chest X ray suggestive of right sided pneumothorax with lung collapse and ICD tube in situ, (b) CECT chest suggestive of lung contusion and laceration (right side) with pneumothorax and surgical emphysema (left side), (b) CECT chest showing bilateral hemothorax in a case of blunt thoracic trauma

Table 1: Indications for emergency thoracotomy

Indication	Number of patients
Lung laceration	2
Subclavian vessel injury	1
Penetrating chest injury	4
Diaphragmatic injury	3

and therapeutic approach for a possible diaphragmatic hernia following chest trauma. 45 (14.3%) of the patients received pain relief with thoracic epidural analgesia.

There were overall 16 (5.41%) deaths [Table 2]. The mortality was observed to be higher 5.8% (n = 14) in blunt thoracic injuries as compared to penetrating injuries 2.8% (n = 1). There were six deaths (37.5%) in elderly age group suggesting significantly higher mortality in that age group. The number of deaths within 6 h of admission was 12% and within 24 h was 48%. The main cause of death in the early case was massive blood loss and significant associated injuries.

When morbidity was compared in both blunt and penetrating injury groups, it was found to be similar (14.3% and 14.7%). In all, 45 (14.3%) cases had one or more complications following chest trauma [Table 3].

The mean ICU stay was observed to be 8.2 + 5.2 days (range: 1–36 days) with a median of 7 days, whereas the mean hospital stay was 14.09 ± 8.10 days (range: 1–62 days).

Although the morbidity in the blunt and penetrating trauma group was similar, the difference in the mortality figures was statistically significant [Table 4].

DISCUSSION

Literature is full information on thoracic injuries, and a detailed search is suggestive of RTAs as the main cause of these injuries worldwide, more so in the developing world.[6-8] Our country accounts for as many as 6% of RTA burden of the world. In the present study also, vehicular accidents accounted for almost 62% of all thoracic injuries followed by assault (9.87%). This mechanism of injury is rarely reported in the western literature but is seen more often in developing countries such as ours and other Asian and African nations.

The rate of associated injuries (62.8%) in this study was comparable to that found in the literature. The chest injury was associated with extremity fracture in 16.85%, pelvic fracture in 8.90%, head injury in 7.15%, spinal injury in 9.85%, and maxillofacial trauma in 7.15%. In a study by Shorr *et al.*, they observed the incidence of associated

Table 2: Cause of death (*n*=16)

Cause of death	Percentage of patients
Hemorrhagic shock	2
Sepsis, MODS	3
Severe cardiac dysrhythmia	1
DIC	1
ARDS	5
Pulmonary thrmbo embolism	1
Missed retroperitoneal injury	1
Severe head injury	2

ARDS: Acute respiratory distress syndrome

Table 3: Morbidity (*n*=45)

Complication	Incidence
VAP/pulmonary sepsis	7
LRTI/atelectasis	5
Retained hemothorax	6
ICD reinsertion	12
Wound infection	4
Empyema	2
Delayed pleural effusion	2
Persistent pneumothorax	1
AKI	3
DVT	1
Pressure ulcer	2

Table 4: Outcome analysis (blunt and penetrating injury)

Parameter	Blunt injury	Penetrating injury	*P* valve
Mortality rate (%)	5.8	2.8	0.001
Injury severity score	17.2±7.4	14.5±3.1	NS
Hospital stay (days)	14.2	16.5	NS
Morbidity (%)	14.3	14.7	NS

injuries to the tune of 75%.[9] The most common associated injury was the abdominal trauma in 24.88% which is not the same as head injury, that is described as the most common associated injury in most of the studies.[6,10] Elisabeth *et al.* observed in a nationwide survey in the UK that the number of rib fractures and other associated injuries were related to morbidity and mortality in 27.8% of the blunt thoracic trauma cases.

A data review of 6332 patients from the trauma registry at university hospital San Antonio revealed that 27% patients of polytrauma and those with severe injuries (ISS >15) are more likely to sustain pulmonary contusion in blunt traumatic chest injury.[11]

In our study 59.8% patients had hemothorax, and as many as 63% had single or multiple rib fractures which are consistent with the existing data. 38% cases of hemothorax have been reported in an 11 years study by Al-Koudmani *et al.* in chest injury patients.[12] In our study, 24% of patients had hemopneumothorax. An overview of the literature reveals that single or multiple fractures of the ribs are the most common thoracic injury, followed by lung contusions.[10,13]

Kulshrestha *et al.* observed that the cardiac injuries occur in 1.5–6% case of chest trauma.[14] In the current study, cardiac injuries were present in 1.27% patients. The mainstay of treatment in our study was nonoperative which is in accordance with other studies.[15-17] ICD insertion was the mainstay of management in as many as 82% of the patients. In one of the recent meta-analysis, it was observed that the use of prophylactic antibiotics reduces the risk of infective complications in traumatic chest injuries, mainly penetrating trauma.[18] Post-traumatic empyema has been variably reported from 2% to 25% and Staphylococcus aureus infection with complications as 35–75%.[19,20]

The requirement of mechanical ventilation (5.09%) and open thoracotomy (3.18%) in our study was similar to the previously published data.[6,10] In a study by Richardson, 5% of the patients of chest trauma required thoracotomy.[21] In a study by Locurto *et al.*, the average duration of the ICD tube was 4.5 days.[22] The same was observed to be 8.94 days in our study. Veysi *et al.* in their study found the mean ICU stay to be 4.5 days whereas the mean hospital stay and the mean ICU stay in our study was 14.09 days and 8.20 days, respectively.[6]

In another study by Shah and Solanki, 17% of patients having flail chest were treated with intermittent positive pressure ventilation.[23] There is wide variation in mortality figures among different authors ranging from 6.6% to 18.7%.[6,24] Acosta *et al.* observed the mortality rate to be 9.3% in their series with respiratory failure accounting for as high as 63.5% mortality.[25,26] Pearson *et al.* observed the morbidity figures to be 25.8% with atelectasis to be responsible in 14.6% cases.[10] Other significant causes of morbidity mentioned in literature include retained hemothorax, lung abscess and empyema that is reported to occur in 2–3% in various studies and ours it was 0.6%. Kumar *et al.* observed a mortality rate of 11.6%.[27] The overall morbidity in our study was 14.33%.

Massive blood loss leading to hemorrhagic shock continues to be the most common cause of immediate and early mortality in chest trauma in various studies.[6,26] In our study, the most common cause of mortality was acute respiratory distress syndrome (ARDS) and the overall in their study of 250 patients mortality was 5.41%. Lema *et al.* reported overall mortality to be 4.7% that is slightly lower than the previous studies.[28] Other authors have observed the mortality due to isolated chest trauma in the range of 4–8% and with the involvement of another system, it goes up to 13–15%, whereas in polytrauma, it is as high as

30–35%. Lee reports the figures to be 1.8% in blunt chest trauma.[28] Battle *et al.* describes the extremes of age, three or more rib fractures and other comorbid conditions to be responsible for increased mortality in blunt chest trauma.[29]

The foregoing observations reveal adequately that the presence of comorbidities, elderly age group, polytrauma and severity of injury result in higher morbidity and mortality in traumatic chest injury patients. They are also at additional risk of ARDS, and ventilator associated pneumonia especially in those who are on long-term ventilation. Serial physical examination can reduce the number of missed or occult injuries significantly in these patients.

CONCLUSION

Thoracic injuries are a common occurrence and are major cause of morbidity and mortality in trauma victims. Since vehicular accident accounts for almost 60% of thoracic injuries, there is an immediate need to enforce strict traffic discipline and to educate the society to follow the laid down traffic rules and regulations to prevent these serious and life-threatening injuries. The aim of this study was to reiterate and highlight the fact that majority of the chest trauma is treatable with simple procedures and thoracotomy is rarely indicated. Furthermore, the vast majority of complications and the potential mortality is preventable. Timely intervention and referral to appropriate centers can add to the overall survival and better quality of life of these patients.

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Review Article

Digital Pressurized Metered-dose Inhalers Define Adherence, Prevents Pseudo adherence In Obstructive Airway Disease Management!

Deepak Talwar[1], Prashant Katke[2], Krishnaprasad Korukonda[2]

[1]MBBS, MD, DM (Pulmonary & Critical Care) and Senior Consultant Pulmonologist and Director & Chair, Metro Respiratory Centre, Noida, Uttar Pradesh, India, [2]MBBS, MD, Department of Pharmacology, Medical Services, Glenmark Pharmaceuticals Ltd, Mumbai, Maharashtra, India

Abstract

Aerosol therapy and OAD: Inhalers play a crucial role in the management of patients with obstructive airway disease (OAD), and it is being recognized that the choice of the inhalation device appears to be as important as that of the drug molecule.

Aerosol therapy in OAD management has undergone renaissance with the wide availability of several drug delivery platforms including dry powder inhaler, pressurized metered-dose inhaler (pMDI), soft mist inhalers, and portable vibrating mesh nebulizers. The aerosol dynamics allows targeted drug delivery while avoiding the systemic side effects, first-pass metabolism at 1/10th the dosage under controlled settings without compromising on the quick therapeutic action in most of these cases.

Since OAD remains progressive disease with persistent or diurnal symptoms due to divergent and varied pathobiologic or overplaying risk factors, choice of inhaler therapy in most of these cases remains a clinical challenge. Notwithstanding the clinical challenges of actuator and breath (inhalation) coordination in pMDIs, they have remained the primary choice of therapy in most cases of progressive or recurrent exacerbations who have relatively low inspiratory flow rates (<30 L/min).[1]

However, nonadherence rates for long-term inhaler therapy among adults are estimated to exceed 50%. Nonadherence is associated with unfavorable clinical outcomes and diminished quality of life. Lack of a dose counter makes determining the number of remaining doses in an MDI problematic. The addition of an simple, accurate, and reliable digital dose counter to an inhaler can improve patient satisfaction**.**

Key words: Bronchial Asthma, Digital dose counter pressurized metered-dose inhaler's, Nonadherence, Obstructive airway disease, Pseudo adherence

INTRODUCTION

OAD: Asthma Control Status

Asthma is one of the most common disease encountered in clinical practice. An estimated 300 million people suffer from asthma worldwide, and an additional 100 million new cases will be added by the year 2025 with the bad news further that the Current Asthma status seems to be poorly controlled.[2-4]

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In AP-AIM study by Gold *et al.* [Table 1], it was found that India and China (0% and 2%, respectively) had the lowest proportion of patients with "Well-controlled" asthma. Furthermore, patients with partly and uncontrolled asthma missed significantly more days of work or school in the previous year (an average of 3.7 and 7.9 days) compared to patients with well-controlled asthma (average of <1 day).[5]

The recent REALISE Asia Survey on partly or uncontrolled asthma control status based on GINA suggested questionnaire on asthma control again highlighted the disparity in well control status as just 50%.[6]

Indian asthma patients have a high frequency of reported exacerbations (67%), leading to substantial functional, emotional limitations, and uncontrolled status.[7,8] This depicts poor control of asthma and reflects the inadequate treatment of such patients.

Corresponding Author: Dr. Prashant Katke, Glenmark Pharmaceuticals, Andheri East, Mumbai – 400099, Maharashtra, India. Phone: +91-9890777080. E-mail: prashantkatke@gmail.com

Table 1: Epidemiological surveys assessing asthma control status worldwide

Studies	Region	Uncontrolled (%)	Partly controlled (%)
AIRIAP-2	Asia and India	35	62
AP-AIM	Asia and India	40	60
REALISE-Asia	Asia	50	32
EUCAN-AIM	EU	24	58

AIRIAP-2: Asthma insights and reality in Asia-Pacific, AP-AIM: Asia-Pacific asthma insights and management, EUCAN-AIM: Europe and Canada asthma insights and management

In ARIAP – 2 study, it was significant that inadequate assessment of control is an important factor leading to poorly controlled asthma. Not only do many patients overestimate their level of asthma control but clinicians also tend to do the same. These findings indicate a need for simple, reliable tools to measure asthma control. Furthermore, it was found that out of 4805 individuals screened for asthma, 4663 (97%) individuals had poorly controlled asthma.[9]

ASTHMA CONTROL AND PSEUDO ADHERENCE

Although nonadherence related to device coordination (inhalation-actuation), drug habituation and side effects to the inhaled medication seem to be common risk factors for poor compliance, pseudo or incomplete adherence continues to be playing an equal part in this equation for uncontrolled symptoms and related clinical outcomes.

Pseudo adherence refers to the clinical situation when patients start using the pressurized metered-dose inhaler (pMDI) beyond the stated label dosages for the inhaler canister with consequent exposure and inhalation of "empty" propellant (HFA) sprays that contain declining concentration of active drug, i.e., "Tail"ed sprays.

In a study by Ogren *et al.*, it was found that up to 40% of patients believe they are taking their asthma medication when they actually are activating an empty or nearly empty MDI.[10]

Rubin and Durotoye asked clinic patients how they determined that the MDI was empty, and 72% reported the MDI was empty if there was no sound when the canister was actuated.[11]

Tail off refers to the clinical phenomenon when drug delivery from MDI becomes inconsistent, variable or unpredictable when the recommended doses become exhausted, and the patient is exposed to the aerosol spray containing propellant or excipient's only [Figure 1]. This often leads to suboptimal

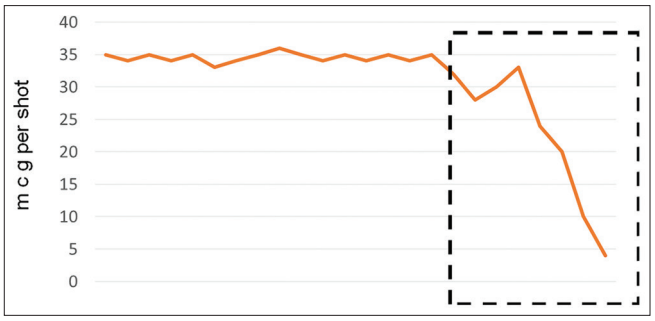

Figure 1: "Tail off" characteristics with inconsistent delivery of medications

response with continued threat of exacerbations or symptoms of dyspnea in patients with chronic obstructive pulmonary disease or bronchial asthma due to overriding, creeping uncontrolled inflammation in the airways.

Current strategies to avoid tail off seem to be rudimentary or predated with patients often "Guesstimating" the content or volume of spray by shake and listening or visualizing the actuation spray. Nearly ≈70% patients continue to follow these "age-old practices" that are not approved, advocated or validated by any regulatory body including food and drug administration (FDA).[12]

In a study by J.B. Connor and Buck, it was found that 87 patients (82%) considered their MDI empty only when nothing came out of it, making it likely that they were inhaling only propellant for many doses, thereby increasing their risk of prolonged bronchoconstriction and airflow limitation requiring urgent care.[13]

PSEUDO ADHERENCE: INTERNATIONAL AND NATIONAL PERSPECTIVE

International Perspective

US FDA in its Guidance statement to the Industry has advocated the incorporation or integration of dose counters in pMDI since accurate and consistent tracking of the doses seems to be only way to determine the remaining doses in the MDI. These dose counters should be engineered to reliably track the doses that have delivered by "complete" actuations to ensure that there is 100 percent accuracy in the dose delivered to the patient in the "right" quantity.[14] Similarly, EMEA has recommended a mechanism to convey information on the "start point" of tail off spray that should be provided with these devices.[15]

National Perspective

The CAPA survey results recently presented @ NAPCON '16 by Singh and Krishnaprasad on behalf of 202

nationally representative sample of pulmonologists in India again highlighted the pertinent issues of non- and pseudo-adherence in real-world clinic settings of India where most doctors (71%, n = 100) agreed that patients utilize the current conventional pMDIs including the dose counter analog devices till the "last" spray thereby exposing them to risk of "persistent" symptoms and/or exacerbations.[7]

Digital pMDIs: Defines Adherence Prevents Pseudo Adherence

The situation is further compounded by the lack of feasible or practical options in real-world settings for the patient to assess and avoid pseudo adherence.[16]

The digital dose countered pMDIs [Figure 2] offer a large digital display for easy accessibility and comprehension by the varied patient population utilizing the device including elderly. Second, the "end" display at the exhaustion of the labeled 120 dosages heralds the start of the subtherapeutic tailed sprays that the patients' needs to avoid. This seems to be of therapeutic relevance in our real-world settings while assessing the current referral cases of partly or uncontrolled cases for any other differential diagnoses.

Digital pMDIsClinical Evidence

The clinical impact of digital pMDI was assessed and reviewed by the DUSS panel involving ≈500 doctors across India, and they found that these devices offer significant improvement in the asthma status that was either newly diagnosed or poorly controlled with conventional therapy or devices.

DUSS ANALYSES

Aim

The aim of the study was to assess the clinical impact and utility of digital pMDIs in newly diagnosed or poorly controlled patients of bronchial asthma.

Study Design

A cross-sectional, national, prescription, retrospective, and cohort analyses as drug utilization surveillance study for Digital pMDIs with DUS survey sheet was carried out @ 500 outpatient centers across India during Sept '16. *Post hoc* analyses for categorical data were carried out by Fisher's Exact Test utilizing QuickCalcsGraphpad Prism version 7 software.

Results

A total of 5195 consecutive patient records on digital pMDIs were available for full set analyses. Baseline demographics included males (69.1%)/females (30.9%), mean age and body weight of 46.7 years and 60.9 kg with many on FB (3791; 73%) compared to SF (1404; 27%) combination. Baseline status and further clinical response

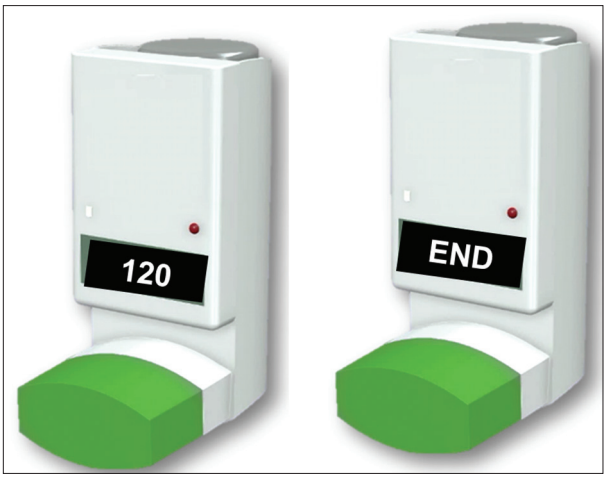

Figure 2: Digital dose counter pressurized metered-dose inhalers with "END" display signifies "START" of "Tail"ed sprays!!

assessment utilizing GINA assessment questionnaire were available for 4575 patients. Patient records with baseline and further clinical response assessment records with GINA Assessment questionnaire for daytime, nighttime, activity limitation and need for rescue medication were taken for analyses. Baseline mod-to severe bronchial asthma status categorized as newly diagnosed or poorly controlled asthma was documented in 2445 (47.1%) and 2750 (52.9%) cases, respectively.

- Baseline Poorly controlled subgroup analyses: Baseline demographic details highlighted the clinical preference for FB compared to SFC formulations in the poorly controlled subgroup [Figure 3].·
  Following therapy with digital pMDI based regimen, "well control" status was observed in 92.7% and 90.3% cases for overall (n = 2942) and baseline poorly controlled patients (n = 1708), respectively, at the end of 8 weeks. For 219 patients with baseline uncontrolled asthma status, initiation with digital pMDI "exclusively" improved well control status in 76.3% cases who were initially on conventional pMDIs devices.

Again the well control asthma status was dramatically and more significantly improved with Xanthines (n = 840) compared to LAMA (n = 369) supplementation in 95.2% and 85.9% cases, respectively (P = 0.0001) [Figure 4]. Adverse events (106, 2%) of mild-to-moderate intensity involving Tremors (34;0.7%), Palpitation (10;0.2%), Mouth ulceration (10;0.2%), and Oral candidiasis (9; 0.2%) were reported. Nebulization was required in two cases with episodic breathlessness and discharged with no consequent sequelae. The authors concluded that Digital pMDIs treats "pseudo severe asthma".[17]

- Baseline newly diagnosed subgroup analyses: A total of 2445 patient records categorized as newly diagnosed Br. asthma were analyzed. Baseline demographics included males (1555;63.5%)/females (791; 32.3%), mean age of 43.7 years prescribed with FB (1863; 76.2%) or SF (582; 23.8%) along with or without xanthines and /or LTRAs/antihistaminics formulations.
  Following therapy with digital pMDI based regimen, uncontrolled status was observed in 5%, 1.5 %, and 1.1% cases for patients on digital pMDI alone, complimentary xanthines, or LTRAs/antihistaminic formulations, respectively [Figure 5].

Adverse events (28, 1.1%) of involving tremors (7; 0.3%), palpitation (1; 0.04%), dysgeusia, (5, 0.2%), dysphonia (4, 0.2%), nausea (3,0.1%), and mouth ulceration (2;0.1%) were reported. Nebulization was required in one case that resolved with no sequelae [Figure 6]. The authors concluded that digital pMDIs offers a simplified solution in tracking nonadherence in real-world settings and avoids or prevents patients from falling prey to pseudo adherence for continued well-controlled status when they are compliant to the doctor instructions.[18]

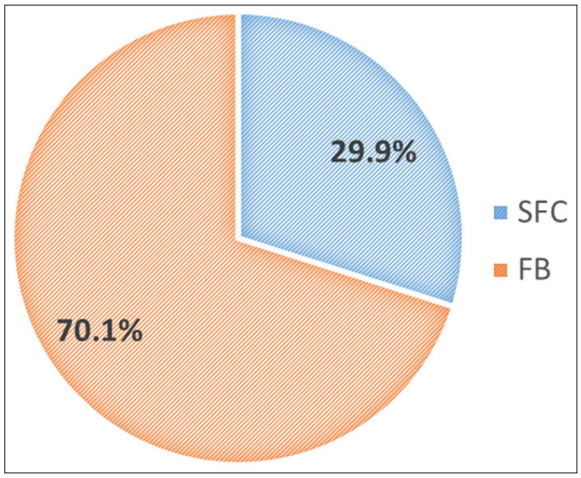

Figure 3: Inhaled corticosteroid/long-acting β-agonist digital pressurized metered-dose inhaler utilization for poorly controlled cases

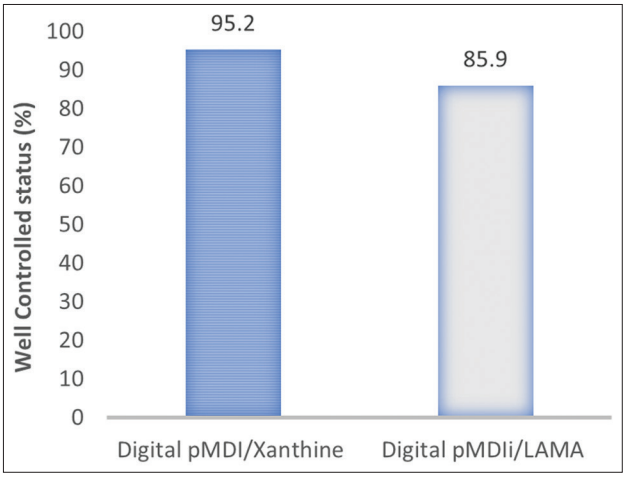

Figure 4: Well-controlled status for poorly controlled grp @8 weeks

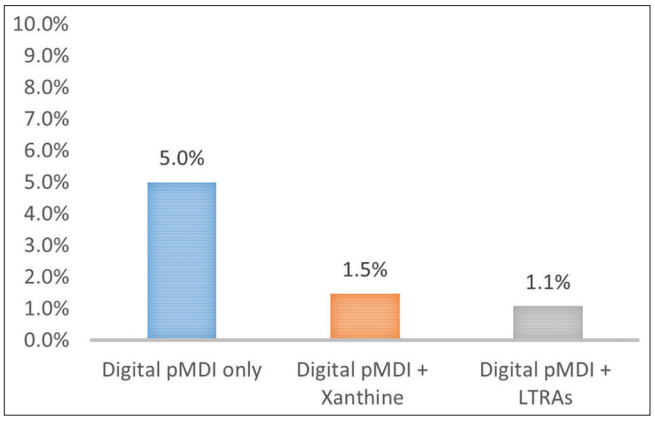

Figure 5: Uncontrolled Br. asthma rates@8 weeks

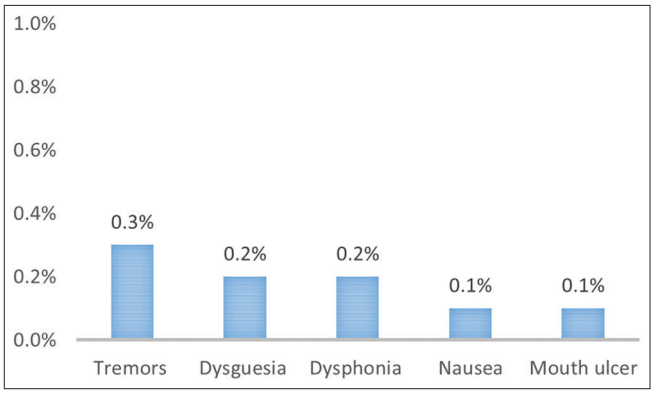

Figure 6: TEAEs observed @8 weeks

CONCLUSION

Current strategies to assess patient adherence or nonadherence remain rudimentary with no precision on the tracking mechanisms for "Tail off" phenomenon. US FDA and EMEA recommend use of pMDIs that offer reliable information on "Tail off" and "dosage delivered." The addition of a simple, accurate, and reliable digital dose counter to an inhaler can improve patient satisfaction by offering reassurance and added confidence that their medication can be relied on, as well as reducing the risk of patients taking a subtherapeutic dose using the inhaler past the label claimed number of doses.

Tracking pseudo adherence reliably and accurately with digital pMDIs "assures" therapeutic response to inhaled corticosteroid/long-acting β-agonist.

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Case Series

Tumoral Calcinosis: A Case Series

Ramesh Kumar Korumilli[1], Jakkula Srikanth[2], Sri Harsha Muvva[2], T Aditya[2]

[1]Professor and Head, Department of General Surgery, SVS Medical College, Dr. NTR University of Health Sciences, Telangana, India, [2]Postgraduates, General Surgery, SVS Medical College, Dr. NTR University of Health sciences Telangana, India

Abstract

Tumoral calcinosis is a rare condition of unknown etiology. It is a misnomer as they are not true neoplasms (as they do not have dividing cells) characterized by the deposition of inorganic calcium with serum exudates in soft tissues in periarticular location within dermis. Only few cases have been reported. Here, we are presenting a series of cases which we have encountered in our hospital with complaints of swelling without pain and no history of trauma. Initial assessment was done with the help of radiological investigations, serum calcium, and phosphate levels. Excision of the tumor was done and histopathological examination confirmed the diagnosis.

Key words: Calcium deposits, Idiopathic, Misnomer, Tumoral calcinosis

INTRODUCTION

Tumoral calcinosis is a rare condition of unknown etiology wherein there is calcium deposition in the soft tissue in periarticular location, i.e. around joints. It is a MISNOMER. The name indicates calcinosis (calcium deposition) which resembles tumor (like a new growth). Virchow initially described calcinosis cutis in 1855. They are not true neoplasms - they do not have dividing cells. They are just deposition of inorganic calcium with serum exudates. Children and adolescents (6–25 years) are the most commonly affected. They are more common around shoulders, hips, and elbows.[1] The name indicates calcinosis (calcium deposition) which resembles tumor (like a new growth).

CASE REPORT

1. A 15-year-old female patient presented to surgical outpatient department with complaints of swelling in the left gluteal region for 6 months. No history of pain and trauma associated with the swelling. On examination, a single, vertically oval, 15 cm × 10 cm, smooth, firm, non-tender, and mobile (both directions) swelling present in the left gluteal region extending into the lateral compartment of the thigh. Clinical diagnosis of soft tissue sarcoma was made; fine-needle aspiration cytology (FNAC) was inconclusive, core needle biopsy showed calcifications with fibrocollagenous stroma and giant cell reaction without signs of malignancy suggestive of tumoral calcinosis. Radiological investigations were done which supported our histological diagnosis [Figure 1].
2. A 55-year-old female patient has come with a complaint of swelling over lateral aspect of thigh right side for 8 months, gradually progressive in nature, no history of pain, and no history of trauma in the past. On examination, an irregular swelling of size 7 × 4 noted over the right anterior superior iliac spine which is non-tender, hard, and freely mobile. A provisional diagnosis of calcinosis cutis was made and the lesion was excised and sent for biopsy which on HPE showed large irregular deposits of calcium in a dense collagenous stroma identified by dense uniform basophilia in dermis [Figure 2].
3. A 60-year-old female patient with a complaint of swelling in the left and right iliac crest for 2 years, gradually progressive in nature and attained the current size. No history of trauma, pain in the past. On examination, the right side swelling is 5 cm × 3 cm over iliac crest and the left side swelling is 2.5 cm × 1 cm over the iliac crest. Both the swellings are freely mobile, non-tender, hard in consistency, and dark

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Corresponding Author: Dr. Plot 70, Gruhalaxmi Colony, Old Kakaguda, Secunderabad - 500 015, Telangana, India. Phone: +91-9885044903. E-mail: rameshkorumilli@gmail.com

pigmentation present over the swelling. Provisional diagnosis was made as calcinosis cutis which was supported by X-ray, computed tomography (CT), and FNAC. Excision done and the tumor was sent for biopsy which confirmed our diagnosis [Figure 3].

4. A 40-year-old male patient came with a complaint of two swellings in the left gluteal region for 15 months with size of 5 cm × 3 cm and 4 cm × 2 cm. No history of pain, trauma, and sudden increase in size associated with the swelling. No history of similar swellings anywhere else on the body. Both the swellings are freely mobile in nature, non-tender, and hard in consistency. FNAC was inconclusive and core needle biopsy showed features of calcinosis cutis. Provisional diagnosis of calcinosis cutis was made which was later confirmed by HPE [Figures 4 and 5].

DISCUSSION

Calcinosis cutis is a term used to describe a group of disorders in which calcium deposits form in the skin. Virchow initially described calcinosis cutis in 1855. Calcinosis cutis is classified into four major types according to etiology: Dystrophic, metastatic, iatrogenic, and idiopathic. A few rare types have been variably classified as dystrophic or idiopathic. These include calcinosis cutis circumscripta, calcinosis cutis universalis, tumoral calcinosis, and transplant-associated calcinosis cutis.[2] The term tumoral calcinosis was originally described by INCLAN in 1943.[3]

In all cases of calcinosis cutis, insoluble compounds of calcium are deposited within the skin due to local and or systemic factors. These calcium salts consist primarily of hydroxyapatite crystals or amorphous calcium phosphate. The pathogenesis of tumoral calcinosis remains unclear and several theories have been proposed. Hyperphosphatemia has been described in some patients[4,5] while local trauma has been implicated in a few cases.[6] No metabolic abnormalities were found in our patient and she denied any history of local trauma.

Patients with dystrophic calcification may provide a history of an underlying disease, a preexisting dermal nodule (which

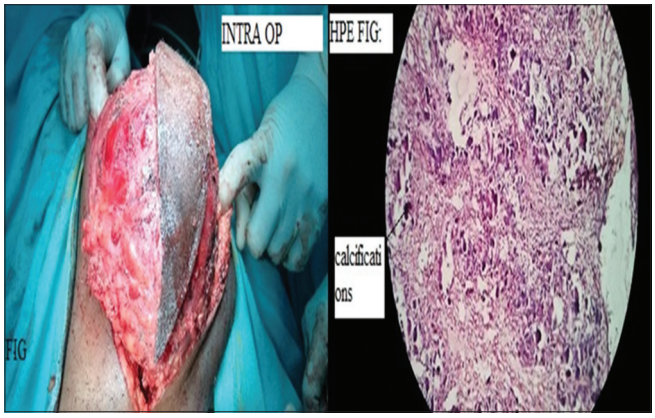

Figure 1: Intraoperative picture and histopathological slide

Figure 3: Cut section image

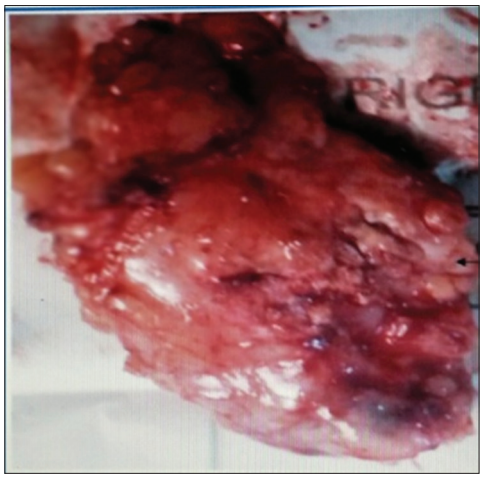

Figure 2: Specimen picture

Figure 4: Pre-operative picture

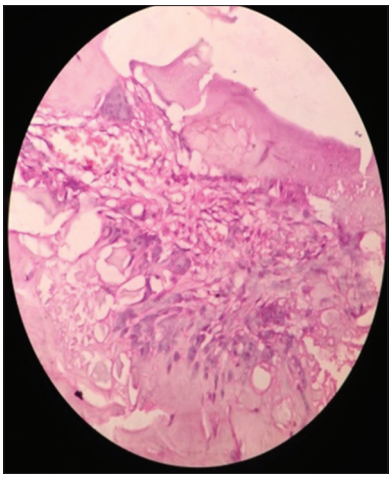

Figure 5: HPE image

represents a tumor), or an inciting traumatic event.[7,8] The patients with metastatic calcification most frequently have a history of chronic renal failure. Cases of idiopathic calcinosis cutis usually are not associated with previous trauma or disease. Those who develop iatrogenic calcinosis cutis generally have a history of recent hospitalization. The clinical presentation of calcinosis cutis can vary according to the diagnosis and underlying process. Tests of serum calcium, inorganic phosphate, alkaline phosphatase, and albumin levels may be helpful. Radiographic examination may demonstrate the extent of tissue calcification. Investigations such as CT scan and magnetic resonance imaging (MRI) are very useful in diagnosing this entity.[9,10] Bone scintigraphy with radiolabeled phosphate compounds (technetium Tc 99m methylene diphosphonate) is useful in evaluating non-visceral soft tissue calcification; this test is more sensitive than plain radiography.[11,12] CT allows for the identification of visceral and non-visceral calcification. CT is infrequently used in evaluating calcinosis cutis and primarily used in assessing tumoral calcinosis. MRI is of limited utility in evaluating calcified structures, but calcific deposits have characteristic patterns. The granulomatous foreign body reaction in tumoral calcinosis is evident.

On biopsy, granules and deposits of calcium are seen in the dermis, with or without a surrounding foreign-body giant cell reaction. Alternatively, massive calcium deposits may be located in the subcutaneous tissue. In areas of necrosis, calcium deposition is frequently found within the walls of small and medium-sized blood vessels. Calcium deposition may be confirmed on Von Kossa and alizarin red stains. Calcinosis cutis is characterized by a central mass of amorphous or granular calcified material surrounded by hyalinized fibrous tissue separating several cavities. The fibrous tissue is bordered by a granulomatous and chronic inflammatory infiltrate. There may be prominent small psammoma-like bodies or calcospherites.[13]

Medical therapy of calcinosis cutis is limited and of variable benefit. When identified, the underlying problem should be corrected.[14] Indications for surgical removal include pain, recurrent infection, ulceration, and functional impairment. A complete surgical excision along with the deposits is the mode of treatment although recurrences are common.

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Systematic Review

Utilization of Pit and Fissure Sealants by Parental Education: A Systemic Review

Radhika Thakkar[1,2], Juhi Patel[3,4], Jay Patel[5,6], Claudia F Santander[7], Haritha V Katragadda[8,9], Malay Parekh[4,10]

[1]2nd Year Graduate Student, Department of Pharmacy and Public Health, St. John's University, New York, USA, [2]Department of Dental Surgery, Hemchandracharya North Gujarat University, Gujarat, India, [3]2nd Year Graduate Student, Department of Public Health, Long Island University, New York, USA, [4]Department of Dental Surgery, Ahmedabad Dental College and Hospital, Gujarat, India, [5]MPH, Department of Pharmacy and Public Health, St John's University, New York, USA, [6]Department of Dental Surgery, SDM College of Dental Science and Hospital, Karnataka, India, [7]AEGD Advanced Education in General Dentistry, Department of General Dentistry, Higher Institute of Medical Science of Havana, Havana, Cuba, [8]MPH, Department of Pharmacy and Public Health, St John's University, New York, USA, [9]Department of Medicine and Bachelor of Surgery, SRM Medical Hospital and Research Centre, Tamil Nadu, India, [10]2nd Year Graduate Student, Department of Public Health, Rutger's University, New Jersey, USA

Abstract

This article discusses the oral health status of children in the United States, including sealant prevalence, and reasons why sealants are underutilized, including current reimbursement levels. The article also explains similarities and differences between sealant use in private practice versus public health settings, as well as the effectiveness and economic aspects of school-based sealant programs. Finally, the article briefly discusses factors related to parents' inclination to obtain sealants for their children. Development of a health communication message, to address the concerns of parents can greatly influence the utilization of sealants and reduce the overall untreated cavities in children.

Key words: Children, Decay, Parental education, Pit and fissure sealants, Prevention, Sealants

INTRODUCTION

In the United States, nearly one-fourth of children and one-half of adolescents experienced dental decay in their permanent teeth as per the data collected by National Health and Nutrition Examination Survey 2011–2012. When compared with many other nations, Americans have good oral health as well as general health because of access to modern technologies.[1] However, when we see the oral health of Americans dental cavities is most prevalent oral disease in children.[1]

According to the center of disease control, 1 of 5 (20%) children aged 5–11 years have at least one untreated decayed tooth.[2] Pit and fissure sealants are still underused despite their documented efficacy in preventing dental caries in children.

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Treatment of tooth decay is essential in children because pain and infection caused due to untreated tooth decay may cause discomfort to children with addition of problems with eating, speaking, playing, and learning in school.[2]

Thorough brushing and flossing helps remove food particles and plaque from the smooth surfaces of teeth, but toothbrushes cannot reach all the way into the depressions and grooves to extract all food and plaque. While fluoride helps prevent decay and helps protect all the surfaces of the teeth, dental sealants add extra protection for the grooved and pitted areas.[3]

Objective

Raise awareness of dental caries and needs for prevention among parents of young children. Influence perceptions, beliefs, and attitudes that may change social norms related to prevention of dental caries.

LITERATURE REVIEW

Dental caries is the localized destruction of susceptible dental hard tissues by acidic by-products from bacterial

Corresponding Author: Dr. Radhika Thakkar, 2127 East Avenue, Apt M, Rochester, New York - 14610, USA. Phone: +12012893974. E-mail: drradhikathakkar@gmail.com

fermentation of dietary carbohydrates. Acid-producing bacteria, known as *Mutans Streptococci*, live in the tissues of the mouth and metabolize sugars.[4] With time progress, the acid produced demineralizes the tooth structure causing caries, but the disease process is initiated within the bacterial biofilm (dental plaque) that covers a tooth surface. Dental caries is a multifactorial disease that starts with microbiological shifts within the complex biofilm and is affected by salivary flow and composition, exposure to fluoride, consumption of dietary sugars, and by preventive behaviors (cleaning teeth).[5]

Risk factors for caries vary by person, even they are changeable. Physical and biological risk factors for caries include quantity and composition of saliva, numbers of cariogenic bacteria in the oral cavity, and fluoride exposure.[6] Lifestyle and behavioral factors include oral hygiene state, consumption and frequency of sugar, inappropriate brushing, and faulty techniques of feeding child and infants. Poverty, inappropriate dental fillings are other factors affecting caries.[6]

As stated by centers for disease control and prevention (CDC) website, at least one untreated decayed tooth is present in children aged 5–11 years about 1 of 5 (20%), whereas 1 of 7 (13%) has the untreated decayed tooth in adolescents aged 12–19 years.[2,7] Pit and fissure sealants have been used for five decades to prevent and control carious lesions on primary and permanent teeth. According to one CDC statistics, sealants have been shown to reduce the risk of decay by nearly 80% in molars. In October 2016, the centers for disease control released a report on the importance of sealants for school-aged children, of which only 43% of children ages 6–11 have dental sealants. Due to this reason, addressing this issue in children is necessary. Sealants are cost-effective as it saves the direct costs such as costs of materials, administrative time, procedure time, and the indirect costs such as the patient's travel time and time off work. In return, it gives benefits, reduction in caries, reduction in number of dental visits, and procedures.[3]

Dental sealants are thin, plastic coatings painted on the chewing surfaces of the back teeth, which have deep grooves and fissures on chewing surfaces.[3] Research studies conducted by CDC concludes that dental sealants are the safe and effective procedure that reduces tooth decay, helps to shield grooved areas of the tooth where fluoride toothpaste is not protective. Sealants are painted on as a liquid and quickly harden to form a shield over the tooth, which act as a physical barrier that stops or inhibits the ingress of bacteria and nutrients.[8]

Many states in the United States of America are running school-based dental sealant program. One of the programs is "Seal," which is running in Michigan. A programmatic framework such as "Seal" is recommended because they are cost-effective, feasible in terms of time and money. In addition, it tries to cover the risk population in majority group as children have more time at school than any other place. State and local governments can easily connect with school. Parents see schools as a trustworthy place so they will accept the service more commonly. They can be modified to work with the less human resource in far distant place. However, Seal program is not experienced so it provides non-continuous and episodic access to care has not developed full trust in the community.[9] Hence, programmers should make a list of enrolling school advance in 1 year, try to get recognition in the community. There is lack of effective collaboration in partners to address the issue. They do not have any data software, which can help them to secure the data and access to past data to evaluate the program efficacy.[9] Provision of incentives to any staff member, children, and dental care providers is not present, so the provision of incentives can facilitate the procedure.

THEORETICAL FRAMEWORK

Social cognitive theory (SCT) would be used to explain how people regulate their behavior through control and reinforcement to achieve goal-directed behavior that can be maintained over time. The cognitive formulation of social learning theory that has been best articulated by Bandura, explains human behavior in terms of a three-way, dynamic, reciprocal model in which personal factors, environmental influences, and behavior continually.[10] SCT synthesizes concepts and processes from cognitive, behavioristic, and emotional models of behavior change, so it can be readily applied to counseling interventions for disease prevention and management. SCT can promote behavior change in the individual as self-control, reinforcement, and self-efficacy constructs are helpful in goal-setting, self-monitoring, and behavioral contracting. Goal-setting and self-monitoring seem to be particularly useful components of effective interventions.[11]

In addition, positive strengths of using SCT are that it puts emphasis on social influence, external and internal social reinforcement. SCT considers the unique way in which individuals acquire and maintain behavior, while also considering the social environment in which individuals perform the behavior.[12]

Why sealants are underutilized?

The factors backing to the adoption of pit and fissure sealants by the oral health provider are multifaceted, which include following: (1) Poor or inconsistent results reported from early scientific studies.[13,14] Clinical experience of first-generation sealants with poor results may have

Table 1: Social cognitive theory application

Concept	Definition	Application
Reciprocal determinism	Behavioral changes result from interaction between the person and the environment	Make aware parent/community about dental sealants, encourage dental care providers to take a part in school dental sealants program
Behavioral capability	Knowledge and skills to influence behavior	Impart knowledge about dental sealant it is simple harmless procedure; provide essential training to dental care providers to work efficiently and faster, enroll in program
Expectations	Beliefs about likely results of action	It is cost-effective procedure, helps to provide good oral hygiene that is essential for basic physical, social health, and individual empowerment.
Self-efficacy	Confidence in ability to act and to persist in action	Build confidence in parents that socioeconomic status will not interfere in procedure it is basic right of child, dental care providers have ability to do correct, positive procedure.
Observational learning	Beliefs based on observing other like oneself and/or visible physical results	Provide information from authentic sources such as ADA, CDC, WHO, and educational video of past procedures done on child.
Reinforcement	Responses to a person's behavior that increase or decrease the chances of recurrence	Give extra credit to enrolling children, incentives to children/dental care providers, provide necessary tools for procedure.

ADA: American dental association, CDC: Centers for disease control and prevention

dejected them from using new generation of sealants that showed improved results, (2) some of the obstacles against the use of sealants start in dental schools, some continue to be deep-rooted in older private practitioners, and some are due to lack of acquaintance about sealants among parents of young children, and (3) some insurance companies may not offer compensation for sealants.[12] As sealants are not unveiled by dental radiographs, insurance companies may be concerned about the likelihood of fraud. In contrast, placements of Class I amalgam restorations are compensated, even within a 2-year period. Representatives of dental insurance companies also have claimed that the core purpose for not providing sealant treatment is that there is "no demand" for such coverage.[12]

Role of Parents in Utilization of Pit and Fissure Sealants

One of the strategies to upsurge sealant utilization is to rise demand for sealants from parents. A resolution to consider these strategies when developing sealant promotion activities of the association was approved by the 2009 CDA House of Delegates.[15] Therefore, to raise awareness about pit and fissure sealants, factors related to parents' inclination to obtain sealants for their children should be considered. According to study conducted by North Carolina Department of Human Resources, parents were more likely to obtain sealants for their children if dentist recommended them, if the parents were more highly educated, and if the parents had dental insurance coverage.[12]

Theory based Health Promotion

Info-graphic (Attachment 1) developed using constructs of SCT [Table 1] can increase awareness of preventive measure of decay.[16]

This sample of infographic can be useful in addressing concerns of parents regarding rationale of pit and fissure sealants. Health communication message is prepared in simple language, which includes information from American Dental Association.[17]

DISCUSSION

To achieve positive outcome in reducing cavities among children, efforts to augment the utilization of pit and fissure sealants should comprise approaches to encourage dentists to educate parents of young children about the benefits of dental sealants.[13] Sealants can be used as a preventive measure for total caries prevention program along with the optimum use of fluoride, reduced frequency of sucrose intake and maintenance of good oral hygiene.[18]

Factors such as the effectiveness of sealants on pit and fissure surfaces, the effectiveness of selected placement techniques, and a risk of developing caries in sealed teeth, follow-up rates should be considered in planning process.[19] Interpersonal communication strategy can show positive results for the program, as it involves multiple stakeholders to address this issue.[20]

CONCLUSION

The main principle underlying the use of sealants is that "prevention is better than cure." Non-diseased teeth even though sealed with pit and fissure sealant are more valuable than properly restored teeth. However, the indiscriminate

use of sealants is not appropriate. Maximizing the cost-effectiveness of this preventive approach is the key in success of pit and fissure sealants.

RECOMMENDATIONS

School authorities may send a flyer of dental sealants including the basic information about dental sealants; it reduces the caries rate, benefits from the procedure. Following this step, parents can be called for a short meeting with one dental care provider along with staff members of the school and children. In the meeting, informative and educating communication using flyers/posters can be carried out. Dental care provider can also show general video of dental sealant procedure done on a child and demonstrates that it is very simple, painless, and effective method for caries prevention. Discussion can be done about the potential benefits gained from the procedure in terms of saving money on a further hectic dental procedure. One of the most important parts of interpersonal communication is the message. It can be conveyed in many ways: speech, body language, tone of voice, gestures and other indicators. Non-verbal messages provide additional information that may not be readily apparent through words. There is a chance to raise questions and get an answer so that the concept is accepted by parents in an easy way and for the long term.

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ATTACHMENT

Attachment 1: Pit and fissure infographic