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International Journal of Scientific Study
July 2015 • Vol 3 • Issue 4

Contents

ORIGINAL ARTICLES

International Journal of Scientific Study
July 2015 • Vol 3 • Issue 4

International Journal of Scientific Study
July 2015 • Vol 3 • Issue 4

International Journal of Scientific Study
July 2015 • Vol 3 • Issue 4

REVIEW ARTICLES

CASE REPORTS

International Journal of Scientific Study
July 2015 • Vol 3 • Issue 4

CASE PICTORIALS

Original Article

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Autoanalyzer Generated Spurious Basophilia in Adolescents and Adults

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Abstract

Background: Failure of hematology auto analyzers to ascertain accurate basophil count is not uncommon. In a few instances, a report of basophilia is given by the automated counters in case of those patients who neither have these diseases nor true basophilia.

Objectives: This study tries to countercheck the basophil counts given by the auto analyzers: Beckman Coulter AcT.5Diff and Beckman Coulter HmX, by peripheral smear examination and to find the significance of association between the spurious basophilia and the hematological and technical factors.

Materials and Methods: Samples of 130 cases and an equal number of controls matched for age group, sex, automated instrument used for processing the sample, and the day on which the sample was processed, were analyzed. For every case, 500 cell differential count was made. In 48 of 130 cases, manual absolute basophil count was done using toluidine blue. Technical details such as the machine model used, sample processing time, sample related parameters such as the basophil percentage, automated and manual basophil absolute count, abnormality flagged by the machine, and abnormalities detected on peripheral smear examination were analyzed. Statistical analyses include formation of frequency tables with percentages, summary statistics such as mean, standard deviation, standard error of the mean, 95% confidence intervals, tests such as Mann-Whitney U Test, Chi-square test, Binomial test, and independent samples *t*-test.

Results: Significance value was <0.05 in cases processed in AcT.5Diff, standing time >1 h, hemoglobin level of ≥15 g/dl, nucleated red blood cells (nRBC), leukopenia, leukocytosis, neutrophilia, neutrophilic shift to left, reactive lymphocytes with/without relative lymphocytosis, thrombocytopenia.

Conclusion: The auto analyzer gives a significantly higher percentage of cases of spurious basophilia. The association of spurious basophilia is significant with prolonged standing time, hemoglobin concentration ≥15 g/dl, nRBC, leukopenia, leukocytosis, neutrophilia, neutrophilic shift to left, reactive lymphocytes with/without relative lymphocytosis, thrombocytopenia.

Key words: Basophils, Hematology, Leukocyte count, Leukocyte disorders

INTRODUCTION

Basophils in peripheral blood are known to be increased in allergic reactions, myeloproliferative diseases, inflammatory conditions, etc.[1,2] Failure of hematology auto analyzers to ascertain accurate basophil count is not uncommon.[3] In a few instances, a report of basophilia is given by the automated counters in case of those patients who neither have these diseases nor true basophilia. If the report is issued to the patient, without being counterchecked, it may result in an unnecessary evaluation of the patient. Hence, it is essential to scrutinize every case of basophilia with meticulous microscopic examination of the peripheral smear. Thus, in some cases, there may be discordance between the basophil counts generated by the automated instrument and the peripheral smear examination.[4–6] Though basophils are easily recognized in routine Romanowsky stains, their low percentage makes the usual visual differential counts made up to 100 white blood cell (WBC), imprecise.[7,8] Hence, in this study,

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we counted 500 WBC for differential counting and for doing the absolute basophil count manually we used the metachromatic stain toluidine blue for highlighting the granules of the basophils. Since the hematological values differ between the subjects belonging to the age groups of ≤9 years and ≥10 years, we studied both the groups separately. Our experience with the pediatric population has already been documented.[9]

Objectives

This study tries to countercheck the basophil counts given by the auto analyzers: Beckman Coulter AcT.5Diff and Beckman Coulter HmX by peripheral smear examination, and to find the significance of association between the spurious basophilia and the hematological and technical factors.

MATERIALS AND METHODS

Cases of age ≥10 years, whose basophil percentage on automated results is ≥2% of WBC on two consecutive readings, in addition to a basophil differential count of <2%, done on 500 cells on peripheral smear by two independent observers and controls matched for age group, sex, automated instrument used for processing the sample, and the day on which the sample was processed, which show basophil percentage of <2% on both the automated results and the peripheral smear examination were included in the study. The cases and the matched controls whose automated results and the peripheral smear examination are concordant with the diagnosis of basophilia were excluded.

After getting approved by the Institutional Ethics Committee, the study was done on the samples of 130 cases and equal number of controls submitted in the hematology laboratory in Chettinad Hospital and Research Institute for routine investigations during the period of 14 months, from December 2012 to January 2014. There was no need for obtaining consent from the patients/control subjects because of complete anonymization of the samples. The blood samples anticoagulated with Ethylenediaminetetraacetic acid were used, and they were processed in automated hematology counters Beckman Coulter AcT.5Diff and Beckman Coulter HmX. Peripheral smears of the cases were examined by Dr. Femela Muniraj and Dr. Vijay Amritraj independently, and differential counts on 500 cells were made for each case. In 48 of the 130 cases, absolute counts of basophils were done manually using a diluting/staining fluid composed of 10 ml of 0.05% toluidine blue in 0.9% saline, 2.75 ml of 95% ethyl alcohol, and 0.25 ml of solution of saponin saturated in 50% ethyl alcohol. This fluid was used by Mitchell and is a modification of that used by Moore and James.[8,10,11] One volume of the anticoagulated blood sample was diluted with 10 volumes of the fluid mentioned above. Both the chambers of the improved Neubauer chamber were charged simultaneously with this diluted sample and absolute basophil count, and total leukocyte count (TLC) were done simultaneously on the 4 corner squares of each chamber, altogether making up 8 corner squares, each having 16 smaller squares. Absolute basophil count/TLC was calculated using the formula n × 12.5 per cubic mm, derived from (n × 10) ÷ (8 × 0.1), wherein, n = number of basophils/total leukocytes in 8 corner squares, 10 is the dilution factor, 8 is the number of squares counted, 0.1, i.e., 1 mm × 1 mm × 0.1 mm is the dimension of each square.

Both the automated instruments were used in accordance with the standard operating procedures of the laboratory. Once every day, the commercial quality control samples were processed in each instrument, and the internal sample integration was checked. The quality of the results had been assured by periodic calibration of the machines AcT.5Diff and HmX on prescribed dates; ensuring the results of the commercial quality control samples to be within the prescribed range. The coefficient of variation (CV%) for AcT.5Diff and HmX was 2.46% and 0.00%, respectively.

For both the cases and the controls, technical details such as the machine model which is used, sample processing time, sample related parameters such as the basophil percentage, automated and manual (for cases only) basophil absolute count, abnormality flagged by the machine, if any, and abnormalities detected on peripheral smear examination were analyzed. Statistical analyses used in the present study include formation of frequency tables with percentages, summary statistics such as mean, standard deviation, standard error of the mean; 95% confidence intervals (CI) tests such as Mann-Whitney U Test, Chi-square test, Binomial test, and independent samples *t*-test. All statistical analyses were carried out using the International Business Machines Statistical Package for the Social Sciences (IBM SPSS) Version 21 software.

RESULTS

Descriptive Analysis of Basophils (Table 1)

The percentage of basophils given by the automated counter ranged from 2% to 22.9% for the cases and from 0% to 1.7% for the controls; the mean was 5.815% (95% CI = 5.070-6.560) for the cases, and 0.535% (95% CI = 0.468-0.602) for the controls; $P < 0.001$. The basophil percentage for the cases on peripheral smear ranged from 0% to 1.6%; the mean was 0.205% (95% CI = 0.148-0.262). The absolute count of basophils as per counter ranged from 60 to 3400 per cubic mm for the cases and from 0 to 120 per cubic mm for the controls; the mean was 466.462 per cubic mm (95% CI = 388.536-544.388) for the cases and 42.692 per cubic mm (95% CI = 37.802-47.582) for the

Table 1: Descriptive analysis of basophils and standing time of samples

Parameter	Group						Independent samples *t*-test	
	Cases			Control				
	Mean	SD	SE	Mean	SD	SE	*t*-value	*P*
Percent of basophils as per automated counter	5.815	4.331	0.380	0.535	0.391	0.034	13.844	0.000
Absolute count of basophils as per counter (per cubic mm)	466.462	453.306	39.758	42.692	28.442	2.495	10.638	0.000
Percent of basophils on P. S.	0.205	0.329	0.029	-	-	-	-	-
Manual absolute count of basophils (per cubic mm)	27.344	23.865	3.445	-	-	-	-	-
Standing time of sample (minutes)	94.669	70.827	6.212	38.046	18.185	1.595	8.829	0.000

P. S.: Peripheral smear, SD: Standard deviation, SE: Standard error

controls; $P < 0.001$. The basophil count calculated manually for the 48 cases ranged from 0 to 87.5 per cubic mm; the mean was 27.344 per cubic mm (95% CI = 20.592-34.096).

Technical Parameters versus Spurious Basophilia

The automated counter AcT.5Diff had given the spurious basophilia report in the majority of the cases (89.23%) (116/130); $P = 0.000$ (Table 2a). The average standing time of the sample was 94.669 min for the cases (95% CI = 82.493-106.845) and 38.046 min for the controls (95% CI = 34.920-41.172); $P < 0.001$ (Table 1). The standing time of the sample was ≥2 h in 26.92% (35/130) cases and none of the controls; $P < 0.001$. The standing time was ≥1 h but <2 h in 33.08% (43/130) cases, 11.54% (15/130) controls; $P < 0.001$ (Table 2b).

Table 2a: Descriptive analysis of technical parameters-Machine model

Machine model	Cases		Binomial
	N	%	*P*
AcT.5Diff	116	89.23	0.000
HmX	14	10.77	

Table 2b: Descriptive analysis of technical parameters-Standing time of sample

Standing time	Group				Mann-Whitney U-test	
	Cases		Control			
	N	%	*N*	%	U-value	*P*
≥2 h					6175.000	0.000
Yes	35	26.92	0	0.00		
No	95	73.08	130	100.00		
≥1 h, <2 h					4092.5	0.000
Yes	43	33.08	15	11.54		
No	87	66.92	115	88.46		

Hematological Parameters versus Spurious Basophilia (Table 3)

Hemoglobin was ≥17 g/dl in 25.38% (33/130) cases, 1.54% (2/130) controls; $P < 0.001$. It was ≥15 g/dl but <17 g/dl in 18.46% (24/130) cases and 8.46% (11/130) controls; $P = 0.018$. Red blood cells were normocytic normochromic in 87.69% (114/130) cases and 85.38% (111/130) controls; microcytic hypochromic in 2.31% (3/130) cases and 7.69% (10/130) controls; macrocytic normochromic in 10% (13/130) cases and 6.92% (9/130) controls; $P = 0.690$ (Tables 3 and 4). Nucleated red blood cells were present in 5.38% (7/130) cases and none of the controls; $P = 0.007$. The TLC was normal in 51.54% (67/130) cases and 80% (104/130) controls; leukocytosis was observed in 26.92% (35/130) cases and 16.92% (22/130) controls; leukopenia in 21.54% (28/130) cases and 3.08% (4/130) controls; $P < 0.001$ (Tables 3 and 4). Neutrophilia was present in 21.54% (28/130) cases and 12.31% (16/130) controls; $P = 0.048$. Neutrophilic left shift was present in 22.31% (29/130) cases and none of the controls; $P < 0.001$. Eosinophilia was noted in 6.15% (8/130) cases and 14.62% (19/130) controls; $P = 0.026$. Absolute lymphocytosis was present in one case and one control (0.77% each); $P = 0.317$. Lymphocytic preponderance was seen in 21.54% (28/130) cases and 6.92% (9/130) controls; $P = 0.001$. Reactive lymphocytes were observed in the peripheral smear in 61.54% (80/130) cases and 3.85% (5/130) controls; $P < 0.001$. Platelet count was normal in 60% (78/130) cases and 86.92% (113/130) controls; thrombocytosis in 2.31% (3/130) cases and 1.54% (2/130) controls; thrombocytopenia in 37.69% (49/130) cases and 11.54% (15/130) controls; $P < 0.001$ (Tables 3 and 4).

DISCUSSION

The modern era hematology analyzers combine various techniques such as electronic impedance, conductivity, absorption spectrometry and flow cytometry for cell counting, and differential analysis.[4] However, still the automated hematology analyzers are known to give erroneous basophil counts, which is confirmed by interpretation of peripheral smear/cytogram/flow cytometry.[4,7,12,13] The machine Beckman Coulter HmX is superior to Beckman Coulter AcT.5Diff in giving a lesser frequency of spurious basophil counts, as is documented in our previous study.[9] Beckman Coulter HmX employs volume, conductivity and scatter to differentiate the leukocytes, whereas Beckman Coulter AcT.5Diff employs volume and cytochemistry for differential analysis without staining the basophil granules. Differential scattergram is

Table 3: Descriptive analysis of hematological parameters

Parameter	Group				Mann-Whitney U-test	
	Cases		Control			
	N	%	*N*	%	U-value	*P*
Hb≥17 g/dl					6435.000	0.000
Yes	33	25.38	2	1.54		
No	97	74.62	128	98.46		
Hb≥15<17 g/dl					7605.000	0.018
Yes	24	18.46	11	8.46		
No	106	81.54	119	91.54		
RBC predominant morphology					8306.500	0.690
Normocytic normochromic	114	87.69	111	85.38		
Microcytic hypochromic	3	2.31	10	7.69		
Macrocytic normochromic	13	10.00	9	6.92		
nRBC					7995.000	0.007
Present	7	5.38	0	0.00		
Absent	123	94.62	130	100.00		
TLC					5807.000	0.000
Leukopenia	28	21.54	4	3.08		
Leukocytosis	35	26.92	22	16.92		
Normal count	67	51.54	104	80.00		
Neutrophilia					7670.000	0.048
Present	28	21.54	16	12.31		
Absent	102	78.46	114	87.69		
Neutrophilic shift to left					6565.000	0.000
Present	29	22.31	0	0.00		
Absent	101	77.69	130	100.00		
Eosinophilia					7735.000	0.026
Present	8	6.15	19	14.62		
Absent	122	93.85	111	85.38		
Absolute lymphocytosis					8385.000	0.317
Present	1	0.77	1	0.77		
Absent	129	99.23	129	99.23		
Relative lymphocytosis					7215.000	0.001
Present	28	21.54	9	6.92		
Absent	102	78.46	121	93.08		
Reactive lymphocytes on P.S.					3575.000	0.000
Present	80	61.54	5	3.85		
Absent	50	38.46	125	96.15		
Platelets					6148.500	0.000
Thrombocytopenia	49	37.69	15	11.54		
Thrombocytosis	3	2.31	2	1.54		
Normal count	78	60.00	113	86.92		

nRBC: Nucleated red blood cells, TLC: Total leukocyte count, P. S.: Peripheral smear

Table 4: Descriptive analysis of RBC morphology, TLC and platelet count

Parameter	Cases		Chi-square test	Control		Chi-square test
	N	%	*P*	*N*	%	*P*
RBC predominant morphology						0.000
Normocytic normochromic	114	87.69	0.000	111	85.38	
Microcytic hypochromic	3	2.31		10	7.69	
Macrocytic normochromic	13	10.00		9	6.92	
TLC						0.000
Leukopenia	28	21.54	0.000	4	3.08	
Leukocytosis	35	26.92		22	16.92	
Normal count	67	51.54		104	80.00	
Platelet count						0.000
Thrombocytopenia	49	37.69	0.000	15	11.54	
Thrombocytosis	3	2.31		2	1.54	
Normal count	78	60.00		113	86.92	

RBC: Red blood cells, TLC: Total leukocyte count

sensitive and is known to reduce the chances of spurious results, which explains the superiority of Beckman Coulter HmX.[3,14] Delayed processing time is a proven cause of spurious basophilia.[15] A delay of even 1 h is significantly associated with spurious basophilia in our study.

Cases having a hemoglobin level of ≥15 g/dl and cases having nucleated red cells are significantly associated with spurious basophilia. This is because the differential leukocyte count is done after lysing the red cells, and when there is incomplete lysis of the red blood cells (RBC), in the presence of high hemoglobin concentration, nucleated RBC (nRBC), it results in spurious elevation of the basophil count.[3] Abnormality in RBC morphology does not have any significant association with spurious basophilia. The majority of the cases, as well as the controls, had a normal RBC morphology.

The percentages of leukopenia and leukocytosis, neutrophilia, neutrophilic shift to the left are found to be higher in the cases having spurious basophilia, and the percentage of normal TLC is higher in the control group. This is because the granules of the neutrophils present in the cases with or without leukocytosis, especially when exhibiting a toxic change in the setting of sepsis is interpreted as basophil granules. This has already been observed in our previous study in the pediatric population.[9] Of the 28 cases of leukopenia, 9 cases had coexisting thrombocytopenia and reactive lymphocytes. In four cases of leukopenia, there were reactive lymphocytes, and the standing time was prolonged. In three cases of leukopenia, thrombocytopenia and prolonged standing time were also seen. In nine cases, leukopenia, thrombocytopenia, reactive lymphocytes and prolonged standing time were present. In two cases, leukopenia was noted along with reactive lymphocytes. In only one case, isolated leukopenia was seen. Eosinophilia may be associated with true basophilia. However, eosinophilia does not have any association with spurious basophilia in this study. In the study by Mitchell, eosinophil count was directly proportional to the basophil count in some cases and had an inverse relationship in some cases.[8] The presence of reactive lymphocytes with/without relative lymphocytosis has a significant association with spurious basophilia. In our study, all the cases, which had relative and absolute lymphocytosis, had reactive lymphocytes on peripheral smear. Conversely, not all the cases, which showed reactive lymphocytes, had lymphocytosis. The association of spurious basophilia with the cases having abnormal leukocytes has been documented, and our observation is consistent with it.[4,12,13,16] The

proportion of thrombocytopenia is higher in the cases, and the normal count is higher among the controls. However, all the 49 cases of thrombocytopenia had coexisting abnormalities such as prolonged standing time, the presence of reactive lymphocytes, and hemoglobin concentration of ≥15 g/dl, neutrophilia and neutrophilic shift to the left. None of the cases had isolated thrombocytopenia. This explains the reason for the association of thrombocytopenia with spurious basophilia.

CONCLUSION

Our study emphasizes the importance of peripheral smear examination of the cases especially those which are flagged by the automated counter. In this study, spurious basophilia is significantly associated with the auto analyzer AcT.5Diff, sample standing time of ≥1 h, hemoglobin level of ≥15 g/dl, nRBC, leukopenia, leukocytosis, neutrophilia, neutrophilic shift to left, reactive lymphocytes with/without relative lymphocytosis, thrombocytopenia.

Based on our previous study in pediatric age group, we summarize in terms of basophil counts, the similarities and differences between pediatric and adolescent/adult age groups who had spuriously elevated basophil counts.

Pediatric (≤9 years) versus Adolescent/Adult (≥10 years) Age Groups[9]

The percentage of basophils on peripheral smear ranges from 0% to 1.2% (mean = 0.191%) in pediatric population and from 0% to 1.6% (mean = 0.205%) in adolescent/adult population. The manual basophil count is similar in both groups; range from 0 to 87.5 per cubic mm; mean is 27.344 per cubic mm. The basophil percentage on automated counter ranges from 2.1% to 27.9% (mean = 7.973%) in pediatric group and from 2% to 22.9% (mean = 5.815%) in adolescent/adult age group. The automated absolute basophil count ranges from 50 to 4590 per cubic mm (mean = 1160.143 per cubic mm) in pediatric group and from 60 to 3400 per cubic mm (mean = 466.462 per cubic mm) in adolescent/adult group. The basophil counts are almost similar in both the age groups. Beckman Coulter AcT.5Diff auto analyzer had given the maximum number of cases in both the groups. Irrespective of the age, prolonged standing time of ≥1 h, Hb ≥ 15 g/dl, neutrophilia, neutrophilic shift to left, reactive lymphocytes with/without lymphocytosis, and with/without leukopenia/thrombocytopenia are significantly associated with spurious basophilia in both the age groups. RBC morphology and eosinophilia did not have an association with spurious basophilia. The TLC and platelet count show association with spurious basophilia in adolescent/adult age group; whereas, they do not have any association with it in the pediatric population.

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Original Article

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Clinical and Microbiological Study of Intertrigo

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Abstract

Background: Intertrigo is a common disorder affecting any age from infancy to old age and is frequently the reason for dermatology consultations.

Methods: A total number of 150 patients with intertrigo attending dermatology outpatient department were included in the study after ethical clearance. A thorough history, regarding occupation, seasonal variation, and any associated disease was recorded. Complete general physical, systemic, cutaneous examination and laboratory investigations were done to identify the etiologic agent.

Results: Maximum number of cases (70%) belonged to 21-60 years of age. Male to female ratio was 1:3.1. Housewives (59.33%), constituted the majority of all occupations. The majority of patients (66.67%) presented with chronic duration. Intertrigo was commonly associated with obesity (18.67%) and diabetes mellitus (10%). The most common site involved was toe web space (76.67%) in particular 4th and 5th toe web space. Of 150 cases, *Candida* constituted majority (51.33%) of cases. Bacterial culture revealed 14.67% cases of *Pseudomonas* followed by *Staphylococcus aureus*, *E. coli, Klebsiella*, *Streptococci*, and *Proteus*. Mixed growth was seen in 8.67% cases. The majority of *Pseudomonas* isolates (93.55%) were sensitive to piperacillin-tazobactam, and resistance was highest to gentamicin (54.84%). All isolates (100%) of *S. aureus* were sensitive to amoxicillin-clavulanic acid and gentamicin and highest resistance was noted for erythromycin (35.71%).

Conclusion: This study concludes that intertrigo is a common chronic condition presenting at any age, affecting both sexes, commonly seen in housewives. Intertrigo can affect various skin folds among which toe web space is the most common region involved. Intertrigo can be caused by a variety of organisms mainly *Candida*, bacteria or both of them.

Key words: *Candida*, Intertrigo, *Pseudomonas*

INTRODUCTION

The word "intertrigo" comes from the Latin word inter=between and terere=to rub and reflects the rubbing together of skin to skin, to create maceration and irritation, hence friction dermatitis or chaffing.[1] Heat, moisture, and the retention of sweat produce maceration and irritation. The moisture initially comes from eccrine sweat that cannot evaporate in the intertriginous areas because of reduced air circulation following which epidermis becomes eroded.[2-5]

Lateral toe webs are the most common sites of infection.[6] Other sites include finger web, submammary, retroauricular, vulval, and labiomental regions.[7-10] Among the pathogens, *Candida*, Gram-negative bacteria such as *Pseudomonas aeruginosa*, *Escherichia coli*, *Proteus mirabilis*, *Morganella morganii*; and Gram-positive bacteria such as *Staphylococcus aureus*, Group A beta-hemolytic streptococci, *Staphylococcus saprophyticus* are implicated.[4,5,11,12]

Differential diagnosis of intertrigo includes diaper dermatitis, nutritional dermatitis, candidiasis, psoriasis, seborrheic dermatitis, congenital syphilis, granuloma gluteale infantum, Letterer-Siwe disease in infants and children and fungal infections, erythrasma, contact

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dermatitis, psoriasis, pemphigus, Hailey-Hailey disease, subcorneal pustular dermatoses, acanthosis nigricans, and acrodermatitis enteropathica in adults.[13]

Treatment includes patient education, correcting precipitants, treating inflammation, and secondary infection. The mainstay of treatment remains topical and systemic antifungals. Most of the broad-spectrum antifungals that are available for the treatment of superficial infections belong to azole class. These include imidazoles, triazoles, and allylamines such as naftifine and terbinafine. Terbinafine exerts a primary fungicidal action against dermatophytes and a number of yeasts and molds.[3,5,14,15] The present study was undertaken to study the clinical spectrum and predisposing factors of intertrigo, to identify the causative fungal or bacterial agent and to know the sensitivity pattern of isolated bacteria to antibiotics.

MATERIALS AND METHODS

A total of 150 patients with intertrigo including both sex and all age groups were included in the study. Detailed history, clinical examination, and systemic examination to rule out any systemic diseases were done. Relevant laboratory investigations such as potassium hydroxide (KOH) examination, gram staining, fungal, and bacterial culture along with antibiotic sensitivity for bacteria were done. Scrapings from the lesions were taken with the blunt edge of scalpel blade, and the specimen was used for KOH examination and gram staining.

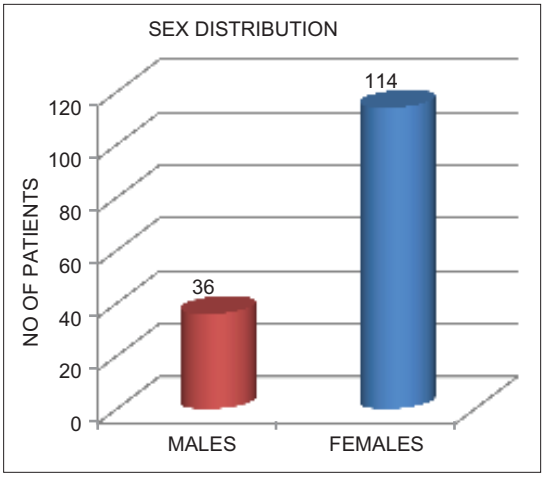
A part of the specimen was planted for culture by furrowing it into the Sabouraud's Dextrose Agar and incubated at 37°C for 4 weeks, and the morphology was studied. A colony of *Candida* from the culture medium was incubated with human serum at 37°C. This was observed after 2-4 h for the germ tube under the microscope. The presence of bacteria, their staining characteristics, and their arrangement was noted by Gram's Method. All the organisms isolated were tested for antibiotic sensitivity by Disc Diffusion Technique.

RESULTS

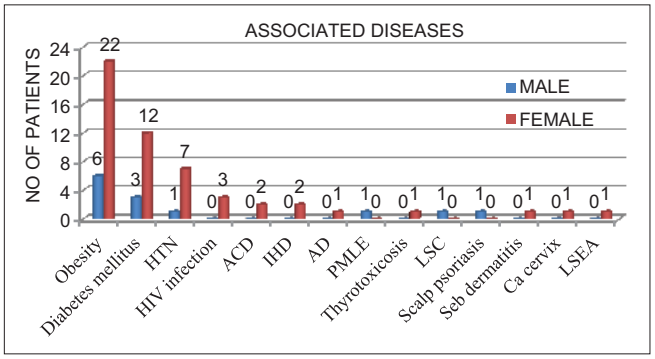
The maximum number of cases, i.e., 105 (70%) cases belonged to the age group of 21-60 years. The youngest case was 17-day-old, and oldest was 83 years. Females constituted about 114 (76%) cases and males 36 (24%) with male to female ratio of 1:3.1 as depicted in Graph 1. Among the occupation, majority of patients were housewives i.e., 89 (59.33%) followed by 17 (11.33%) patients who did not belong to any occupation as they were aged less than 6 years, 16 (10.67%) servants, 12 (8%) agriculturists followed by 6 (4%) students, 4 (2.66%) clerks, 2 (1.33%) officials, and 1 (0.67%) barber, lab technician, police, and tailor.

About 115 (76.67%) cases belonged to lower, 24 (16%) middle and 11 (7.33%) belonged to upper socioeconomic status; whereas 84 (57.33%) belonged to rural areas followed by 64 (42.67%) patients were from urban areas. The majority of cases i.e., 100 (66.67%) presented with duration of more than 60 days, 26 (17.33%) with duration of 16-60 days, and 24 (16%) with duration of 1-15 days. The diseases associated with intertrigo were obesity - 18.67%, diabetes mellitus - 10%, hypertension - 5.33%, immunocompromised status - 2%, allergic contact dermatitis, and ischemic heart disease - 1.33% each. Thyrotoxicosis, atopic dermatitis, polymorphic light eruption, lichen simplex chronicus, scalp psoriasis, seborrheic dermatitis, carcinoma cervix, and lichen sclerosis et atrophicus accounted 0.67% each as shown in Graph 2.

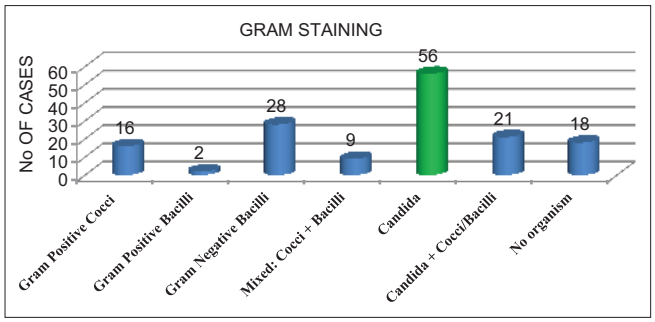
In the present study, out of 150 cases, 115 (76.67%) cases were of toe web intertrigo (Figure 1) followed by 12 (8%) perianal (Figure 2), 8 (5.33%) vulval, 6 (4%) finger web, 5 (3.33%) groin, 3 (2%) retroauricular, and 1 (0.67%) submammary intertrigo. Of 150 cases, 56 (37.33%) cases showed *Candida* (Figure 3) followed by 28 (18.67%) gram-



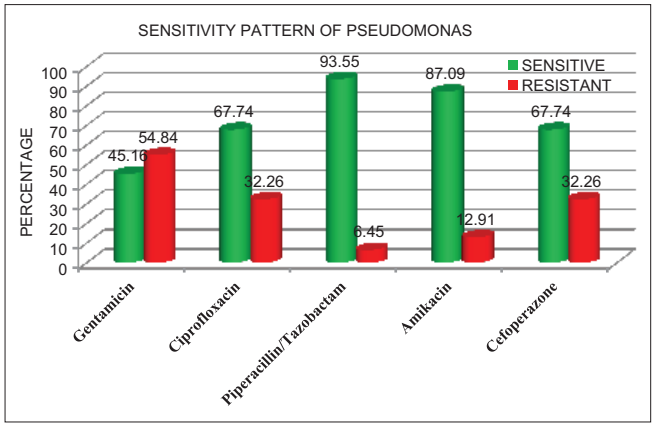
Graph 1: Age distribution



Graph 2: Associated diseases



Graph 3: Gram staining



Graph 4: Sensitivity pattern of *Pseudomonas*

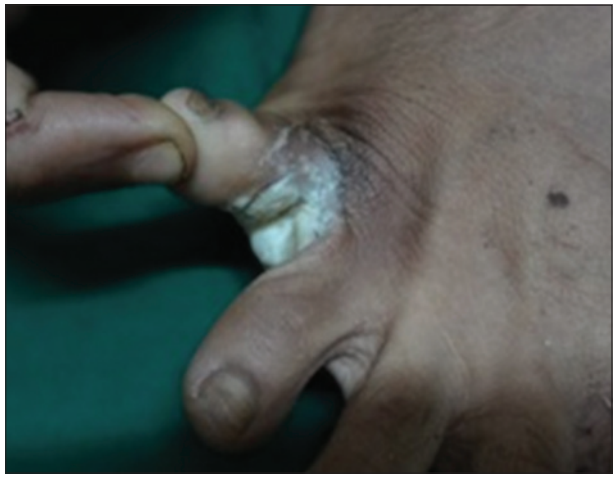


Figure 1: Toe web intertrigo

negative bacilli, 21 (14%) *Candida* and cocci or bacilli, 16 (10.67%) gram-positive cocci, 9 (6%) mixed cocci and bacilli, and 2 (1.33%) gram-positive bacilli; whereas in 18 (12%) cases no organisms were detected as shown in Graph 3. Bacterial culture revealed 22 (14.67%) cases of *Pseudomonas* followed by 16 (10.67%) *Staphylococci*, 9 (6%) *E. coli*, 6 (4%) *Klebsiella*, 2 (1.33%) *Streptococci*, and 1 (0.66%) *Proteus*. Mixed growth was seen in 13 (8.67%) cases, whereas normal skin commensals were found in 7 (4.67%) cases. No growth was seen in 74 (49.33%) cases.

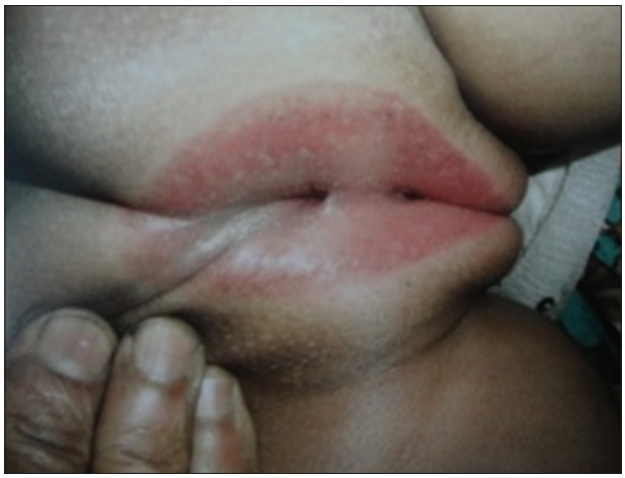


Figure 2: Perianal intertrigo

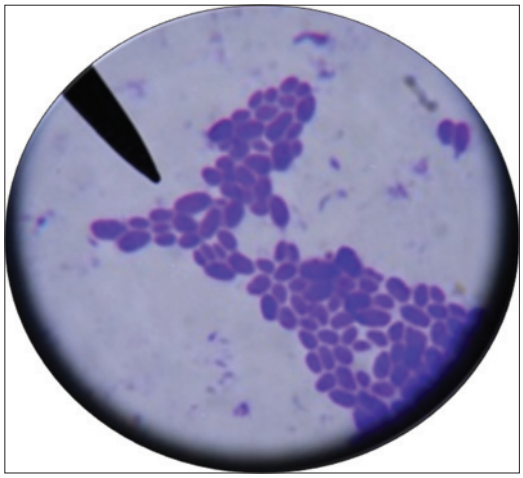


Figure 3: Gram staining shows gram-positive budding yeast cells

Of 31 isolates of *Pseudomonas*, 29 (93.55%) were sensitive to piperacilin-tazobactam followed by 27 (87.09%) to amikacin, and 21 (67.74%) each to ciprofloxacin and cefoperazone. Resistance was highest to gentamicin, i.e., 17 (54.84%) isolates as depicted in Graph 4. In the present study, amoxicillin-clavulanic acid and gentamicin sensitivity were seen in all 28 (100%) isolates of *Staphylococci*, and no resistance was observed. With respect to cefotaxime, ciprofloxacin, and cotrimoxazole; 24 (85.71%), 22 (78.57%), 21 (75%) isolates were sensitive, and 4 (14.29%), 6 (21.43%), 7 (25%) isolates were resistant, respectively. The highest resistance was noted for erythromycin (35.71%) followed by clindamycin (32.14%).

DISCUSSION

The Majority (70%) of patients belonged to the age group of 21-60 years in the present study, which correlates with the study of Ahmad *et al.*, (21-50 years).[6] Whereas Lin *et al.*,

Aste *et al.*, and Keita *et al.*, found that foot intertrigo was common in the age group of 36-81 years, 19-74 years, and 12-48 years, respectively.[3,16,17] The age variations signifies that intertrigo is a common disorder that can affect any individual from infancy to old age. Female preponderance was seen which is consistent with the study of Keita *et al.*, (1:2.1) which can be attributed to housewives (59.33%), who constituted majority group.[16]

Lower socioeconomic class patients comprised 76.67% of the total. The low income, poor nutritional status, poor hygiene, overcrowding could be factors that contribute to intertrigo. The majority of patients, i.e., 89 (59.33%) were housewives. This is on par with the study of Ahmad *et al.*, which showed 33.3% housewives, who engaged themselves in household activities resulting in maceration of toe webs followed by servants and agriculturists.[6] About 66.67% cases of intertrigo cases had a duration of more than 60 days which is in accordance with other studies which makes it a chronic recurrent condition.

Obesity was seen in 18.67% cases in the present study, which is not consistent with the study of Keita *et al.*, which showed 68.8% cases, which can be attributed to racial and geographical differences.[16] Association with obesity in the present study is due to more numerous and deeper skin folds in obese patients. Diabetes was seen in 10%, which is consistent with the studies of Ahmad *et al.*, (6.66%) and Keita *et al.*, (8.88%).[6,16] Increased incidence in diabetics may be due to increased glucose levels in urine, tissue fluids, and sweat, which make them more prone to candidiasis.

There are no studies available in the literature for the comparison of region wise distribution of intertrigo. Toe web space was involved in 76.67% of the cases, in the present study. This is due to the reason that the majority of the study population in the present study constituted females (76%) who engaged in household work, which is an important predisposing factor for toe web intertrigo. In the present study, 4th and 5th toe web space were involved bilaterally in the majority (40.87%) of patients. This is in accordance with the study of Ahmad *et al.* in which bilateral 4th and 5th toe web space were involved in majority (41.76%) of patients.[6]

In the present study, the predominant organism isolated was *Candida,* which accounted for 51.33%. This is consistent with the studies of Lestringant *et al.*, Ahmad *et al.*, Goto *et al.*, and Soghair *et al.*, which showed 57.7%, 60%, 60%, 88.9% cases of *Candida*, respectively.[6,18-20] The predominance of *Candida* in the present study can be attributed to retention of moisture as seen in housewives, increased temperature and maceration in body folds particularly during the summer and monsoon, along with other predisposing factors.

Pseudomonas was isolated in 14.67% of cases, which correlates with the studies of Ahmad *et al.,* and Karaca *et al.,* who isolated in 10% and 16.7% of cases; but is lesser compared to Lin *et al.,* and Aste *et al.,* who isolated in 55% and 46.4% cases.[3,6,17,21] *Klebseilla* isolated (6%) is on par with the studies of Aste *et al.,* (6.2%) and Lin *et al.,* (3.44%).[3,17] Predominance of gram-negative bacteria in the above studies include hot weather, tight-fitting shoes, as well as previous prolonged antibiotic or antifungal therapy. *Staphylococci* were seen in 10.67% cases followed by 1.33% cases of beta hemolytic streptococci. This is consistent with the study conducted by Karaca *et al.,* in which the isolated pathogens were *S. aureus* in 11.9% cases followed by beta hemolytic streptococci in 2.4% of cases.[21] Culture negative cases were 10% in the present study, which can be explained by the fact that intertrigo is mainly of mechanical origin and infection is a secondary phenomenon, which may have not settled yet. Mixed growth can be explained on the basis of the development of complex with time.[22]

In the present study, all isolates of *Staphylococci* (100%) were sensitive to amoxicillin-clavulanic acid and gentamicin, which correlates with the study of Niebuhr *et al.*, which showed 97% and 84% sensitivity, respectively.[23] Least sensitivity (64.29%) was seen for erythromycin, which correlates with Ghadage *et al.*,[24] (41%). The high proportion of strains showing resistance to antibiotics may be explained by the practice of self-medication by patients. All three isolates (100%) of *Streptococci* were sensitive to ampicillin/amoxicillin and ciprofloxacin, which is in accordance with the studies of Malhotra *et al.*, and Ghadage *et al.*[24,25] *Pseudomonas* was the predominant bacteria isolated in present study, most of them (93.55%) were sensitive to piperacillin/tazobactam, which is consistent with studies of Sharma VK *et al.*, (100%) and Asati DP *et al.*, (77.5%).[26,27] With respect to amikacin sensitivity, the present study was not correlating with the studies of Sharma *et al.*, and Asati *et al.*, who reported less sensitivity to amikacin.[26,27] These variations can be attributed to variations in the study populations.

CONCLUSION

Intertrigo is more common in the age group of 21-60 years, with a female preponderance. Among all occupations, housewives are more commonly affected by intertrigo. The majority of patients present with duration of illness of more than 60 days suggesting its chronicity. Predisposing factors contributing are patients with obesity, diabetes, and patients belonging to lower socioeconomic status, rural areas with seasonal aggravation in the rainy season. Toe web space is the most common region involved with

4th and 5th toe web space being more common. Common organisms causing intertrigo are *Candida*, *Pseudomonas*, and *S. aureus*. The majority isolates of *Pseudomonas* are sensitive to piperacillin-tazobactam and amikacin. All isolates of *S. aureus* are sensitive to amoxicillin-clavulanic acid and gentamicin.

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Original Article

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Serum Magnesium Levels in Type 2 Diabetic Patients with Microalbuminuria and Normoalbuminuria

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Abstract

Background: Approximately, one-third of patients with Type 2 diabetes have hypomagnesemia mainly caused by enhanced renal excretion. Magnesium (Mg) deficiency is associated with the poor glycemic control, and Mg supplementation improves insulin sensitivity. Various studies have shown associations between hypomagnesemia and various complications of Type 2 diabetes, including neuropathy, retinopathy, foot ulcers, and albuminuria. In patients with diabetes mellitus who develop microalbuminuria, serum Mg was lower when compared with normoalbuminuric patients. Investigating for serum Mg levels and prompt correction may prevent further complications.

Objectives: The present study was done to know the status of serum Mg in microalbuminuric and normoalbuminuric Type 2 diabetic patients.

Materials and Methods: Nearly, 100 patients of Type 2 Diabetes mellitus attending K R Hospital OPD/inpatients were grouped into equal groups of 50 patients into microalbuminuria and normoalbuminuria. Fasting blood sugar (FBS), postprandial blood sugar (PPBS), HbA1C, renal function test, spot urine albumin creatinine ratio (SUACR), serum electrolytes including Mg levels were compared in both groups.

Results: About 6% of microalbuminuria had hypomagnesemia, and one patient had hypermagnesemia. FBS, PPBS, HbA1c, and SUACR were high and significant in microalbuminuria suggestive of poor glycemic control retinopathy was found to be higher in microalbuminuria group 26% when compared to normoalbuminuria 6%.

Interpretation and Conclusion: In our study, we found that low Mg levels were significantly associated with poor glycemic control and microalbuminuria levels were higher when compared to patients with normal Mg levels. Retinopathy was also significantly associated with hypomagnesemia. Therefore, screening for serum Mg levels in Type 2 diabetes and its correction may help in achieving better glycemic control, which can prevent further diabetic complications.

Key words: Albuminuria, Magnesium, Type 2 diabetes mellitus

INTRODUCTION

Magnesium (Mg) is the fourth most abundant cation in the human body and plays a key role in many fundamental biological processes including metabolism and DNA synthesis. Mg deficiency has been shown to cause endothelial cell dysfunction, inflammation, and oxidative stress, which are major contributors to atherosclerosis.[1] Mg and Type 2 Diabetes mellitus (DM) have a close relationship. Approximately one-third of subjects with Type 2 DM have hypomagnesemia mainly caused by enhanced renal excretion.[2] Mg deficiency is associated with poor glycemic control and Mg supplementation improves insulin sensitivity.[3]

There is substantial evidence of associations between hypomagnesemia and various complications of Type 2 DM such as neuropathy, retinopathy, foot ulcers, and

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albuminuria.[4] The serum Mg in Diabetes mellitus with microalbuminuria was lower when compared with normoalbuminuria subjects.[5-12]

Hence, this study was done to know the status of serum Mg in Type 2 DM subjects with microalbuminuria and normoalbuminuria and its relation to diabetic microvascular complications.

The aims and objectives of the study are:

1. To study the serum Mg levels in Type 2 DM with microalbuminuria and normoalbuminuria subjects.
2. To correlate microalbuminuria and serum Mg levels in diabetic nephropathy.

MATERIALS AND METHODS

The subjects of this study were Type 2 DM, attending to medical OPD/admitted to wards in K R Hospital, Mysore. A comparative study was done using a sample size of 100 Type 2 diabetic subjects using purposive sampling method, from December 2012 to August 2014. Exclusion criteria included hypertension, acute/chronic diarrhea, chronic alcohol consumption, acute pancreatitis, loop/thiazide diuretics, and other nephrotoxic drugs.

Method of Study

Data were collected using a pre-tested proforma meeting the objectives of the study. The cases for the study were selected in accordance with the above mentioned inclusion and exclusion criteria. The purpose of the study was explained to the patient, and informed consent was obtained. Cases with Type 2 DM (as per ADA 2012 Guidelines) were selected and categorized into microalbuminuria and normoalbuminuria based on spot urine protein creatinine ratio. The following investigations such as fasting blood sugar (FBS), postprandial blood sugar (PPBS), HbA1c, fundus examination of eye, urine routine, blood urea, and serum creatinine, electrolytes such as sodium, potassium, chloride, and Mg were also carried out.

Baseline characteristics of the study participants were expressed in percentage. Data were analyzed statistically using descriptive statistics, contingency coefficient analysis, and Student *t*-test. $P < 0.05$ was considered as statistically significant. IBM SPSS (Statistical Package for the Social Sciences) version 20 and Excel were used for data analysis.

RESULTS

About 100 subjects of Type 2, diabetes were grouped into microalbuminuria and normoalbuminuria based on spot urine albumin creatinine ratio (SUACR). Serum Mg levels were measured in both groups (Table 1).

The mean age (years) in microalbuminuria and normoalbuminuria were 53.06 ± 10.93 and 56.12 ± 11.754, respectively. About 66% were males and 34% were females in both groups. Mean FBS (mg/dL) in normoalbuminuria and microalbuminuria were 118.36 ± 40.43 and 164.82 ± 40.39 ($P < 0.01$), and mean PPBS (mg/dl) in microalbuminuria were 161.7 ± 49.43 and 226.52 ± 68.64, respectively ($P < 0.001$). The mean HbA1c (%) in normoalbuminuria and microalbuminuria were 6.37 ± 0.74 and 7.77 ± 1.62, respectively ($P < 0.01$) (Figure 1). The mean SUACR (mg/g) in normoalbuminuria and microalbuminuria were 20.66 ± 4.89 and 44.48 ± 12.64 ($P < 0.01$).

Of 50 microalbuminuria group 3 participants had hypomagnesemia (mean 2.09 ± 0.28 mg/dl) and 1 had hypermagnesemia (2.6 mg/dl). Mg levels were normal in normoalbuminuria group. Hypermagnesemia was seen in one subject of microalbuminuria group, where the serum Mg level was mildly elevated (2.6 mg/dl), and serum

Table 1: Characteristics of study group

Variables	Normoalbuminuria	Microalbuminuria
No. of subjects	50	50
Mean age (years)	56.12±11.754	53.06±10.93
Sex (%)	Male: 66 Female: 34	Male: 66 Female: 34
Mean FBS (mg/dl)	118.36±40.43	164.82±40.39 (*P*<0.01)
Mean PPBS (mg/dl)	161.7±49.43	226.52±68.64 (*P*<0.001)
HbA1c (%)	6.37±0.74	7.77±1.62 (*P*<0.01)
Hypomagnesemia	-	6%
Mean serum Mg levels (mg/dl)	2.086±0.21	2.09±0.28
Mean SUACR (mg/g)	20.66±4.89	44.48±12.64 (*P*<0.01)
Retinopathy (%)	6	26

FBS: Fasting blood sugar, PPBS: Postprandial blood sugar, SUACR: Spot urine albumin creatinine ratio, Mg: Magnesium

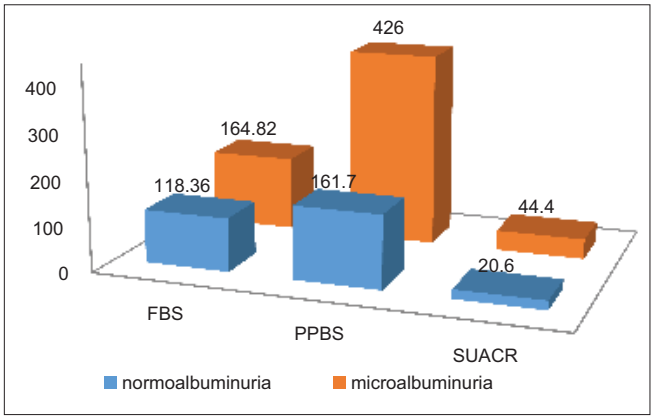

Figure 1: Comparison of normoalbuminuria and microalbuminuria

creatinine was also found to be elevated (1.5 mg/dl). On subsequent days of follow-up, serum creatinine had an increasing trend. USG abdomen suggested of acute on chronic kidney disease (CKD). Hence, it can be assumed that hypermagnesemia was seen due to CKD. The mean value of FBS, PPBS, and HbA1c is higher among the group with serum Mg < 1.7 mg/dl. The mean FBS of both the groups, i.e., serum Mg < 1.7 mg/dl and serum Mg 1.7-2.4 mg/dl is statistically different with *P*-value 0.047. The mean PPBS of both the groups serum Mg < 1.7 mg/dl and serum Mg 1.7-2.4 (mg/dl) is statistically different with *P*-value 0.044. The mean HbA1c of both the groups serum Mg < 1.7 mg/dl and serum Mg 1.7-2.4 (mg/dl) is statistically different with *P*-value 0.022 (Table 2 and Figure 2).

Retinopathy was found in 13 (26%) subjects of microalbuminuria group. The mean serum Mg (mg/dl) levels in microalbuminuria with retinopathy (1.94 ± 0.38) was lower than microalbuminuria without retinopathy (2.14 ± 0.16) (*P* = 0.0112).

Table 2: Microalbuminuria group

Variables	Microalbuminuria group	
	Serum Mg 1.7-2.4 mg/dl	Serum Mg<1.7 mg/dl
No. of subjects	46	3
Mean value		
FBS (mg/dl)	161.41±40.1	209.33±18.9
PPBS (mg/dl)	220.24±67.98	302.33±5.13
HbA1c (%)	7.57±1.52	9.7±1.04
SUACR (mg/g)	43.2±11.8	52.33±3.79
Serum Mg (mg/dl)	1.4±0.1	2.12±0.17

FBS: Fasting blood sugar, PPBS: Postprandial blood sugar, SUACR: Spot urine albumin creatinine ratio, Mg: Magnesium

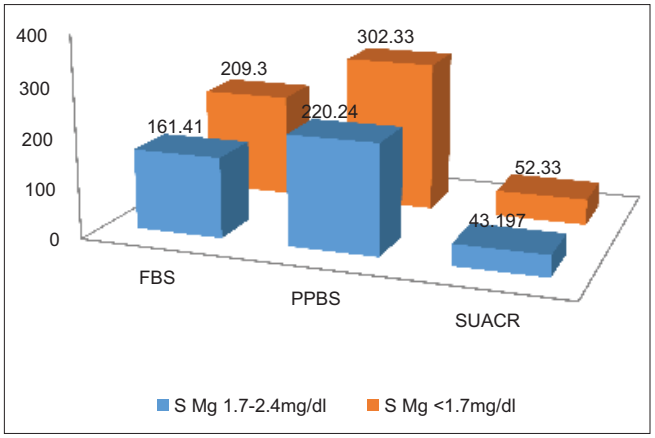

Figure 2: Comparison of fasting, postprandial blood sugar levels, and albuminuria in microalbuminuria with magnesium levels

DISCUSSION

Hypomagnesemia can be seen in Type 2 DM. It was found that Type 2 DM subjects with hypomagnesemia were more prone for complications. In this study, 100 subjects with Type 2 DM were grouped into microalbuminuria (50 subjects) and normoalbuminuria (50 subjects). Serum Mg levels were studied in both groups.

None of the subjects in normoalbuminuria group had hypomagnesium whereas in microalbuminuria group, 3 (6%) subjects had hypomagnesemia, and 1 (2%) patient had hypermagnesemia. In a study conducted by Dasgupta *et al.*, hypomagnesemia was seen in 11% of Type 2 DM subjects, 8.8% in normoalbuminuria, and 13.5% in microalbuminuria. In the present study, the mean serum Mg levels in normoalbuminuria and microalbuminuria were 2.086 ± 0.21(mg/dl) and 2.0 ± 0.24 (mg/dl), respectively. In a study conducted by Corsonello *et al.*, diabetic subjects with microalbuminuria or clinical proteinuria showed a significant decrease in serum ionized Mg with respect to normoalbuminuria group (normoalbuminuria: 0.45 ± 0. 02 mmol/l; microalbuminuria: 0.36 ± 0.05 mmol/l, *P* < 0.001; clinical proteinuria: 0.35 ± 0.04 mmol/l, *P* < 0.001).

The exact cause of hypomagnesemia is unknown, but an increased urinary loss of Mg may contribute to it. Some studies revealed that hyperglycemia contribute to hypomagnesemia by causing depression in the net tubular reabsorption of Mg.[13]

One of the potential pathophysiological mechanisms linking serum Mg to microalbuminuria is an amplification of insulin resistance. It was said that low serum Mg plays an important role in the pathogenesis of insulin resistance. Mg can function as a mild, natural calcium antagonist. Hence, the level of intracellular calcium is increased in Mg deficiency subjects. This increased intracellular calcium may compromise the insulin responsiveness of adipocytes and skeletal muscles leading to the development of insulin resistance.[13] Another study has also found that insulin deficiency or insulin resistance can affect the tubular absorption of Mg, leading to hypomagnesemia in DM subjects.[14] Finally, a vicious circle formed by mutual influence between insulin resistance and hypomagnesemia results in aggravation of insulin resistance which can increase the risk of microalbuminuria.[15]

Other hypothesis such as oxidative stress is becoming increasingly recognized as an important causative factor for microalbuminuria.[16] Mg has been reported to possess antioxidant property.[17] Hence, oxidative stress may be one of the mechanisms that underlie the association between low serum Mg and microalbuminuria. Study has also shown that Mg intake and serum Mg concentration were

inversely associated with systemic inflammation markers, which also play a crucial role in the pathogenesis of microalbuminuria.[18,19]

In the present study, microalbuminuria group had poor glycemic control. The mean FBS, PPBS, and HbA1c in microalbuminuria were 164.82 ± 40.9 mg/dl, 226.52 ± 68.64 mg/dl, and 7.77 ± 1.62 (%), respectively. In a study conducted by Prabhodh *et al.*, mean FBS, PPBS, and HbA1c were 184.42 ± 40.61 mg/dl, 270 ± 38.66 mg/dl, and 8.972 ± 1.82%.

In the present study, the mean FBS, PPBS, and HbA1C in microalbuminuria with hypomagnesemia group, when compared in subjects with microalbuminuria with normal Mg levels was statistically significant ($P < 0.01$). However, microalbuminuria levels in the above group were not significant. The explanation for nonsignificance of microalbumin levels, in the present study, could be due to low sample size and low incidence of hypomagnesemia.

In the present study, retinopathy was found to be higher in microalbuminuria group 26% (13 subjects) when compared to normoalbuminuria 6% (3 subjects). In a study conducted by Padmaja *et al.* (SN-DREAMS, report 12), retinopathy was seen in 31% and 14.1% of microalbuminuria and normoalbuminuria, respectively.

In the present study, the mean serum Mg levels in microalbuminuria with and without retinopathy are 1.94 ± 0.38 mg/dl and 2.14 ± 0.16 mg/dl, respectively ($P < 0.0112$). In study conducted by Dipankar *et al.*, mean Mg levels in microalbuminuria with and without retinopathy were 1.38 ± 0.39 and 2.02 ± 0.29 ($P < 0.001$).[20]

CONCLUSIONS

In the present study, hypomagnesemia was present in 6% of microalbuminuria group. These cases had poor glycemic control when compared with (1) normoalbuminuria group and (2) microalbuminuria group with normal Mg levels. The mean microalbuminuria levels in hypomagnesemia were higher when compared in subjects with normal Mg levels. Retinopathy was present in all hypomagnesemia subjects. Above findings suggest that hypomagnesemia in Type 2 DM are associated with poor glycemic status and microvascular complications.

Hypomagnesemia is related to the glycemic status of DM patient. In such subjects, diabetic complications are invariably present. Several studies have proved correction of hypomagnesemia in DM subjects achieved better glycemic control and reduced risk of complications. Hence, it is essential to investigate for serum Mg status in poorly controlled DM or with associated complications.

In the present study, low incidence of hypomagnesemia in microalbuminuria group may be due to low sample size. Further studies with large sample size are required to prove a definite role of hypomagnesemia in diabetic nephropathy and its correction to prevent progression to end-stage renal disease.

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Original Article

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Blunt Trauma to Abdomen in Rural Setup: A Multiple Case Study

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Abstract

Background: Abdominal trauma accounts for the large number of trauma-related injuries and death. Blunt abdominal trauma accounts for more than half of abdominal trauma.

Aim and Objective: The aim is to study blunt abdominal trauma in the rural area.

Materials and Methods: A prospective study of 68 consecutive cases of blunt abdominal trauma admitted to a referral hospital in a rural area over a period of 2 years were studied. Detailed history, thorough clinical examination and proper investigations were done. Once diagnosed patients were either treated conservatively or surgically.

Observation and Result: Blunt trauma to the abdomen is common in the 3rd decade of life, in males, farmers and due to road traffic accidents. The small bowel, spleen and mesentery commonly injured and mortality maximum within 1st h of admission due to hemorrhagic shock.

Conclusion: Blunt abdominal trauma is on the rise due to easy availability and use of motor vehicles, increase in crime and violence. Sono-radio diagnosis helps in arriving at conclusive diagnosis and aids in treatment. Mortality can be reduced by reducing injury–admission interval, intransit resuscitation of patient and prompt treatment.

Key words: Abdominal trauma, Blunt trauma abdomen, Laparotomy, Mortality, Non-operative management

INTRODUCTION

Since high-speed surface travel is becoming more universally available, it is certain that blunt trauma will continue to comprise an important fraction of the major injuries which the surgeon is called upon to treat.[1] Rapid resuscitation is necessary to save the unstable but salvageable patient with abdominal trauma. Accurate diagnosis and avoidance of needless surgery are an important goal of evaluation. "As the surgeon directs these activities he must seek the answers to two questions. First, does the patient need an abdominal operation? Second, will the patient tolerate the time required for diagnostic maneuvers before surgery is performed?"[2] However, most avoidable deaths result from failure to resuscitate and operate on surgically correctable injuries.[3]

Among the signs, Rob's dictum[4] (1947) was useful, "The absence of peristaltic sounds, confirmed and reconfirmed is a positive indication for laparotomy, but the presence of peristaltic sound is only a valuable guide toward and not a positive indication for conservative management."

When the diagnosis is in doubt, and clinical judgment suggests surgery, exploration provides definitive treatment as well as a diagnosis; moreover, the risks of negative exploration have become acceptable.[5,6] In 1940, Gray Turner gave valuable advice to that undertaking laparotomy for closed abdominal injuries as follows: "The patient will not die from a very big incision, but may very likely succumb if some important injury is overlooked."[7] Hence, the new techniques and diagnostic tools available are important in the management of abdominal trauma, especially blunt trauma. These improved methods and

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diagnostic tools, however, still depend on availability in rural area, experience and clinical judgment for application and determination of the best care for the injured patient.

Aims and Objectives

1. To study the etiology of blunt abdominal trauma in this area.
2. To study different organs injured when a person sustains blunt trauma to the abdomen.
3. To study mortality in relation to various factors.

MATERIALS AND METHODS

A prospective study of 68 consecutive cases of blunt trauma to abdomen admitted to a tertiary hospital in a rural area over a period of 2 years was studied in detail.

Institutional Ethical Committee approval was also taken before starting the study.

Detailed history, time of injury, type of injury, cause of injury, site of injury over the abdomen, injury to admission interval was noted. So also size of vehicle, position of patient and type of impact was noted in road traffic accident. Thorough clinical examination was carried out in all patients. Routine blood and urine examinations were done. Special blood investigations, plain X-ray erect abdomen, ultrasonography (USG) of the abdomen, X-Ray chest, spine, pelvis, intravenous pyelogram, computed tomography (CT) scan were done as required. Patients in shock were resuscitated initially. Line of treatment was then decided upon whether conservative or operative. When there was rising pulse rate, increasing abdominal distention and tenderness, patients were shifted onto the surgical line of treatment.

Results were computed as percentages of total participants. Furthermore, data were internally compared for age and gender, and outcomes were also compared accordingly and was tabulated.

OBSERVATION AND RESULT

Age/Sex

The maximum incidence of blunt abdominal trauma was seen in the 3rd decade (21-30 years) of life. The youngest patient was 2½ years old, while oldest was 63 years old. In the series by Currie, their patients varied from 3 years to 63 years of age.[8] This was followed by 2nd and 4th decade of life (Table 1). Male preponderance was seen. We had 64 (94%) male patients of blunt abdominal trauma while only 4 (6%) females had blunt abdominal trauma in our study.

Occupation

Blunt abdominal trauma was most commonly seen in farmers (21 patients - 30.88%) and was closely, followed by students (18 patients - 26.47%).

Mode of Injury

The most common cause of blunt abdominal trauma was road traffic accident (59%). Similar findings were observed by Jolly *et al.* in their study of blunt abdominal trauma in G. R. Medical College, Gwalior, Madhya Pradesh[9] (Table 2).

Interval between Trauma and Admission

About 70% patients presented to the hospital within 4 h of trauma. Earliest were two patients who came to the hospital within 15 min while one patient got admitted after 4 days.

Clinical Presentation

Of the 68 patients, 6 were unconscious, and all of the remaining 62 patients had pain in the abdomen as the chief symptom. Other clinical presentations were the retention of urine, distention of the abdomen, vomiting, hypotension, constipation, and hematuria (Table 3).

Diagnosis

This process was confirmed by erect X-ray abdomen and USG abdomen. Gas under diaphragm was the most common finding on X-ray, while the collection in the abdomen was the most common finding on USG.

Mode of Treatment

The 49 patients (72%) were treated conservatively while the rest required surgical intervention.

Table 1: Age distribution in blunt trauma to abdomen

Age range (years)	Blunt abdominal injury	
	No. of cases	Percentage
0-10	9	13.3
11-20	12	17.6
21-30	20	29.5
31-40	12	17.6
41-50	7	10.3
51-60	7	10.3
61-70	1	1.4
Total	68	100

Table 2: Comparative analysis of causes of blunt abdominal trauma

Causes of blunt abdominal trauma	Jolly series % of patients	Present series % of patients
Vehicular accident	43	59
Fall from height	23	26
Striking of heavy object	17	3
Kicks/blows/lathi/stick	12	6
Miscellaneous	5	6

Viscera Involved in Blunt Abdominal Trauma

Of 68 patients, 29 had intra-abdominal injury or perforation. Small bowel is the most commonly injured hollow viscus. The spleen is the most commonly injured organ and mesentery was the commonly injured intra-abdominal soft tissue in this study (Table 4).

Blunt Abdominal Trauma and Associated Extra-abdominal Injuries

About 53% patients of blunt abdominal trauma showed associated injuries. Head injury was an associated injury in 22 patients while chest trauma was seen in 14 cases.

Blunt Abdominal Trauma and Hospital Stay

Minimum hospital stay was 1 day while the maximum hospital stay was 32 days, with an average hospital stay of 8 days.

Blunt Abdominal Trauma and Mortality

The most common cause of mortality was hemorrhagic shock. Of 68 patients, 10 died (14.7%). Of these 6 patients died within an hour of admission during resuscitation itself. Mortality was very high in whom, head or head and chest injury was present in addition to blunt abdominal trauma. The most common cause of death is hemorrhage and shock.

DISCUSSION

Abdominal trauma continues to account for a large number of trauma-related injuries and death.[10] Blunt abdominal trauma is on the rise because of easy availability and use of motor vehicles, increase in crime and violence. Blunt abdominal trauma accounts for more than half the cases of abdominal trauma here. So does study done by Williams and Zollinger (Kennedy)[11] on 200 cases of abdominal trauma. The study was done at Massachusetts General Hospital also showed similar findings.[12] Blunt abdominal trauma was commonly seen in the 3rd decade of life, in farmers and had a male preponderance. This is because males are more exposed to outdoor activity and farming while women are still the homely type in a rural area like ours. Road traffic accident is the commonest cause of blunt abdominal trauma. Motor vehicle accidents (75%) and urban violence are the leading cause of blunt and penetrating abdominal trauma to this area of the body.[13] The danger of visceral or fatal hemorrhage in blunt abdominal trauma makes it one of the most important types of trauma and one for which the doctor's decision as to the early correct diagnosis and proper early intervention may be the difference between life and death for the person concerned.[11] During this study, eight patients came in shock. All were promptly resuscitated in the surgical ICU but six patients expired in spite of all our efforts within 1 h of admission. Diagnostic accuracy of the erect X-ray abdomen was 100%. So in rural areas, it is a valuable and simple non-invasive investigation which still holds on its own in this era of CTs and magnetic resonance imaging (MRI). As many as one-third patients with an initial benign abdominal examination will require emergency laparotomy.[14] In our study, 28% patients underwent laparotomy. Laparotomy was carried out to locate and repair injured viscera/organ, inspect abdominal cavity for other injuries, clean peritoneal cavity and control contamination and also to give the patient a definite treatment. Small bowel is the most commonly involved viscera in blunt abdominal trauma.[15,16] So also in our study. The spleen is the most commonly injured organ. Splenic injuries may be life-threatening even in the patient who appears hemodynamically stable with missed intra-abdominal injuries a leading cause of preventable death in trauma patients.[17] Rapid, the initial diagnosis of splenic injuries is, therefore, crucial. Unfortunately, splenic injuries may be subtle and present without abdominal pain or tenderness even in the alert non-intoxicated patient.[18-20] Both the liver and spleen are protected from blunt injury by the lower chest wall. The presence of lower rib fractures may, therefore, suggest injury to the liver or spleen.[21] Associated trauma to head and chest and hemorrhage were the commonest cause of mortality.

Table 3: Clinical presentation seen in blunt abdominal trauma

Clinical presentation	No. of blunt trauma cases
Pain	62
Retention of urine	29
Distention	26
Vomiting	20
Hypotention	18
Hematuria	10
Constipation	12

Table 4: Internal injury seen in blunt abdominal trauma

Involved hollow viscus/solid organs/soft tissues	No. of cases
Stomach	2
Small bowel	4
Large bowel	3
Urinary bladder	2
Urethra	1
Liver	2
Spleen	8
Kidney	1
Pancreas	1
Mesentery	5

CONCLUSION

- Blunt abdominal trauma is on the rise.
- Blunt trauma to the abdomen is common in the

3rd decade of life, in males, farmers and due to road traffic accidents.
- Sono-radio diagnosis helps in arriving at a conclusive diagnosis and aids in treatment in the rural area.
- The small bowel, spleen, and mesentery are commonly injured in blunt abdominal trauma.
- Mortality is commonly due to hemorrhagic shock and is seen more if associated head and chest injuries are present.
- Early admission, intransit resuscitation, diagnosis and prompt and appropriate treatment can save lives.

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Original Article

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Physical and Non-invasive Variables of Emergency Triage in Relation to Outcome of Hospitalized Children

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Abstract

Introduction: Many deaths in under five children occurring in hospitals can be prevented if triage is followed, sick children identified, and treatment is started immediately.

Objective: To study the relationship of the physical and non-invasive variables of emergency triage and assess their predictive value for the severity and outcome of the illness.

Materials and Methods: This prospective study included all the patients between age 1 month and 5 years who were admitted on every 5th day consecutively over the duration of 1 year in a tertiary care hospital in Jammu. Seven physical and non-invasive variables: Heart rate, respiratory rate, systolic blood pressure (SBP), oxygen saturation (SPO2), capillary refill time (CRT), temperature (temp) and level of consciousness were recorded. Association of the variable with severity and mortality was assessed, and the significant variables were then subjected to stepwise multivariate logistic regression analysis.

Results: Of the 513 children studied, 85 (16.5%) died and out of these 57 (67.1%) exhibited all 7 variables in abnormal range and 28 (32.85%) deaths exhibited less than 7 abnormal variables. The probability of a fatal outcome in a child was as high as 95% in children with seven abnormal values. The probability of 19% with the presence of two abnormal variables. High sensitivity was observed throughout from 2 to 7 abnormal variables; however, specificity reduced drastically in <5 abnormal variables. The presence of any five abnormal variables, therefore, was considered to be the most appropriate cut-off between sensitivity and specificity in addition to yielding clinically useful predictive values. Subsequently, on multivariate analysis, altered SPO2, temperature, and SBP independently emerged as significant risk factors.

Conclusion: Any child with five or more of above-mentioned abnormal physical/non-invasive variables should be considered serious as he had a high probability of a fatal outcome.

Key words: Mortality, Pediatric emergency triage, Physical and non-invasive variables, Predictive value

INTRODUCTION

Morbidity and mortality in children particularly in the fewer than five age group is a prime concern of health care providers in developing countries. Deaths in hospitals occur most often within 24 h of admission. Many of these deaths can be prevented if any sick children are identified soon on their arrival and treatment is started immediately.[1] Many strategies have been identified to ensure the survival of such children in developing countries. In this respect "Triage" (derived from the "trier" meaning to pick, sort or choose) as a strategy has shown promising results in identifying and treating severely ill children.[2] Although protocols have been developed for primary and secondary triage, virtually none of these are evidence-based or have validated outcomes of their performance in real-time disasters.[3] Today triage is considered an essential component of every busy Emergency Department (ED),

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as an effort to provide efficient and prompt service in finite resources countries.[4] Triage should occur during the registration process but in majority of situations health care providers perform it after registration.[5] Guidelines for triage vary from center to center but the components of "Ideal" system reflect a delicate balance of prioritizing patients complaints based on brief selected information and findings.[6] Several pediatric prognostic scores are used for research purposes,[7] however, their performance characteristics limit their utility. As a basic requirement of any measurement tool, assessment of triage level should be similar among health professionals working in an ED as discrepancies in the triage level between nurses and physicians have been reported.[8-11] Reliability and accuracy of pediatric triage methods are limited as most previous researchers have studied a small number of participants included adult patients, or involved laboratory assistance, invasive variables.[9,11-13]

The present study was designed to evaluate the physical and non-invasive variables of emergency triage in relation to the outcome of hospitalized under five children of Jammu region (Table 1).

MATERIALS AND METHODS

A hospital based prospective study was undertaken in the department of Pediatrics S.M.G.S. Hospital, Government Medical College, Jammu which is a referral hospital not only for Jammu region but also for surrounding states. The study included all the patients between the age group of 1 month and 5 years who were admitted on every 5th day consecutively for a period of 24 h and over the duration of 1 year. Fifth day was chosen in an attempt to lessen inter-observer variation as the single observer was made responsible to record all the observations. After a detailed history, general physical and systemic examination, the seven physical and non-invasive variables viz. heart rate (HR), respiratory rate (RR), systolic blood pressure (SBP), oxygen saturation (SPO2), capillary refill Ttime (CRT), temperature (Temp.) and level of consciousness were recorded on a predesigned proforma. All the children were followed up till they were discharged. Patients who left against medical advice, absconded or transferred to the other hospitals were excluded from the study. The clinical variables were assessed by standardized methodology: BP – with sphygmomanometer with appropriate sized cuff measuring 1½", 2", 2½", 3". SPO2 was measured by pulse oximeter (Simed S-100, Bothal, W A98011). The oximeter probe was applied to the right thumb. Axillary temperature was measured by a mercury thermometer. Abnormal values for HR, RR, temperature and BP were taken according to standardized Systemic inflammatory response syndrome (SIRS) criteria.[14,15]

The Abnormal values for SPO2, CRT, and AVPU (alert, verbal, painful, unresponsiveness) were based on SIRS and Advanced Pediatric Life Support (APLS).[14,16]

Table 1: Cut-off values to classify physical and non-invasive variables as abnormal

Variable	Abnormal range
Temp	>38°C and <36°C
HR	2-12 months >160 per min 1-5 years >150 per min
RR	<2 months >60 breath/min 2-12 months >50 breath/min 1-5 years >40 breath/min
SBP	Infant <65 mmHg, Child <75 mmHg
SPO2	<90%
Consciousness (AVPU score)	A – Alert (normal) V – Responds to voice (abnormal) P – Respond to pain (abnormal) U – Unresponsive (abnormal)

HR: Heart rate, RR: Respiratory rate, SBP: Systolic blood pressure, SPO2: Oxygen saturation, Temp: Temperature

Statistical Analysis

The association of each of the variable with outcome was assessed using Chi-square. Odds ratio (OR) was calculated along with 95% confidence interval (CI) for each of the variables under study and their significance assessed. Adjusted values for the OR and 95% CI were determined by employing stepwise multivariate logistic analysis. All analysis were carried out using statistical software SPSS 12.0.1 for windows and EPI info version 6.0. The validity of each of the variables was calculated in terms of sensitivity, specificity, and predictive value vis-à-vis mortality.

RESULTS

A total of 513 children between 1 month and 5 years of age, admitted every 5th day over a period of 1 year were the subjects of the study.

The distribution of children with each clinical variable (normal/abnormal) along with outcome status shown in Table 2. Except for HR and RR all other variables were significantly associated with mortality.

- A total of 85 children died (16.5%) and out of these 57 (67.1%) exhibited all 7 variables in abnormal range whereas 28 (32.95%) deaths occurred among the children exhibiting less than 7 abnormal variables. In the group with 7 abnormal variables the sensitivity, specificity and positive predictive values (PPVs) were 67%, 99.3%, and 95% respectively. Subsequently the specificity and PPVs gradually decreased with

Table 2: Association of physical/non-invasive variables with the outcome

Variables	*N* (%)		OR (95% CI)	χ^2	*P* value
	Survived	Died			
HR	279 (93.6)	19 (6.4)	5.34 (2.99-9.62)	40.77	<0.001
	149 (69.3)	66 (30.7)			
RR	142 (34.1)	4 (2.73)	10.05 (3.66-38.44)	28.33	<0.001
	286 (77.9)	81 (22.0)			
SBP	318 (98.4)	5 (1.54)	46.25 (18.19-48.95)	142.35	<0.001
	110 (57.8)	80 (42.89)			
Temp	131 (94.2)	8 (5.7)	4.25 (1.97-10.46)	16.13	<0.001
	297 (79.4)	77 (20.5)			
SPO2	422 (97.3)	12 (12.7)	427.86 (143.13-66.49)	188.49	<0.001
	6 (7.6)	73 (7.6)			
CRT	419 (96.7)	14 (3.3)	236.10 (91.69-632.56)	157.22	<0.001
	9 (11.13)	71 (88.7)			
A (Alert)	353	Nil	1.0	N.A.	N.A.
V (responds to verbal command)	69 (86.3)	11 (13.7)	81.55 (23.14-333.52)	82.91	<0.001
P (responds to painful stimuli)	4 (07.2)	52 (92.8)	0.85 (0.12-7.25)	0.03	<0.001
U (Unconscious)	2 (08.3)	22 (9.17)	N.A.	N.A.	N.A.

HR: Heart rate, RR: Respiratory rate, SBP: Systolic blood pressure, SPO_2: Oxygen saturation, Temp: Temperature, CRT: Capillary refill time, OR: Odds ratio, CI: Confidence interval, N.A.: Not available

decreasing number of abnormal values from 91.4% to 16.4% and 69.4% to 19% respectively. The probability of a fatal outcome in a child which was as high as 95% in children with 7 abnormal variables fell to 19% in the presence of only 2 abnormal variables. The sensitivity was observed high throughout from 7 to 2 abnormal variable. However specificity sharply declined from 5 or less abnormal variables. This was observed as a significant cut-off point for predicting a high probability of fatal outcome (Table 3).

Multivariate analysis was also performed to assess the independent and coupled association of these variables with the risk for morality. It was observed that SPO2, temperature and SBP emerged as independent significant risk factors for the mortality (β coefficient Table 4).

Table 3: Number of abnormal variables and their predictive ability in relation to morality

No. of abnormal variables	Total no. of cases	Expired	Recovered	Predictive ability (%)	95% CI
7	60	57	34	Sens: 67.1	(55.9-76.7)
<7	453	28	425	Spec: 99.3	(97.8-99.8)
				PPV: 95	(85.2-98.7)
				NPV: 93.8	(91.1-95.8)
≥6	82	78	4	Sens: 91.8	(83.2-96.3)
<6	431	7	424	Spec: 97.2	(99.1-97.5)
				PPV: 95.1	(87.3-98.4)
				NPV: 98.4	(96.5-99.3)
≥5	121	84	37	Sens: 98.8	(92.7-99.9)
<5	392	1	391	Spec: 91.4	(88.2-93.8)
				PPV: 69.4	(60.3-77.3)
				NPV: 99.7	(98.4-100)
≥4	315	84	231	Sens: 98.8	(92.7-99.9)
<4	198	1	197	Spec: 46	(41.2-50.0)
				PPV: 26.7	(21.2-50.0)
				NPV: 99.5	(96.8-100)
≥3	392	84	309	Sens: 99.8	(92.7-99.9)
<3	120	1	119	Spec: 27.8	(23.7-32.4)
				PPV: 21.8	(17.5-25.8)
				NPV: 99.2	(94.8-100)
≥2	442	84	358	Sens: 98.8	(92.7-99.7)
<2	70	1	70	Spec: 16.4	(13.0-20.3)
				PPV: 19.0	(15.5-23.0)
				NPV: 98.6	(91.3-99.3)

Sens: Sensitivity, Spec: Specificity, PPV: Positive predictive value, NPV: Negative predictive value, CI: Confidence interval

DISCUSSION

The early identification of severe illness is extremely important for prioritizing treatment to reduce childhood mortality and allow proper utilization of limited resources in the developing world.[14] Emergency triage is the sorting or prioritizing of patients who requires prompt medicare. Various scoring systems - Prism Score and Triage score have been proposed to assist in assessing the severity of illness at the time of presentation to the heath care center. These scoring systems predict the risk of mortality in a given patient.[13,17] However, most of the scoring systems are devised for the ICU patients and they rely not only physical but also laboratory variables many of which are not available in most of the health centers in our country. This makes them unsuitable for practice in developing countries, especially in the ever busy pediatrics EDs. W.H.O. developed guidelines for emergency triage assessment and treatment of sick children suffering from serious infections or severe malnutrition presenting to hospitals in the developing countries. It prioritizes treatment of sick children depending upon the emergency signs (related to airways, breathing, circulation, coma, convulsion, confusion and dehydration) to decrease mortality.[15] Recently in an

Table 4: Standardized regression co-efficient for variables under study

Variables	"β" - coefficient
SPO2	0.727
Temp	0.29
SBP	0.021
HR	0.015
RR	0.004

HR: Heart rate, RR: Respiratory rate, SBP: Systolic blood pressure, SPO_2: Oxygen saturation, Temp: Temperature

attempt to improve the Manchester Triage System by adding vitals to the triage scale it was seen that the outcome predictability remained same.[18] The major limitations of emergency triage application are a requirement of reorganization of the existing health care system and special training of both medical and paramedical staff.[13] Various studies conducted for triage lack uniformity regarding the basic methodology. The heterogeneity in age groups, selection of subjects, or parameters and application of the scoring system by different classes of health workers make the issue further more complex. The fact that poorly equipped healthcare facilities of developing countries may not have the required laboratory assistance for invasive variables or if available they would be time consuming, the physical and non-invasive variables which would be practically feasible to apply were carefully selected for the study and analyzed for the outcome of illness.

Heart Rate

W.H.O. guidelines include Tachycardia, as an important sign for assessing most of the febrile illnesses and cardiac diseases with failure.[15] It was observed that tachycardia had a significant association with the mortality pattern (OR: 5.34; 95% CI: 2.99-9.62). Its significance in relation to mortality was also studied in different age groups of the children i.e. >1-12 months and 1-5 years (OR: 4.80; 95% CI: 3.08-12.92) respectively. These observations differ from the observation of Kumar *et al.*,[13] who did not observe it to be a significant independent risk factor for mortality.

Respiratory Rate

Tachypnea was observed to have a significant association with the mortality pattern (OR: 10.05; 95% CI: 3.66-37.44). Its significance with the risk of mortality was also evaluated with regard to different age groups of the children i.e., 2-12 months and 1-5 years (OR: 3.60; 95% CI: 0.43-79.07) and (OR: 9.26; 95% CI: 2.88-47.15) respectively, which was observed to be maximum in 1-2 months age (93.7%), followed by 2-12 months (33%) and 17.5% in 1-5 years age group. These results differ from the reports available in the literature, Kumar *et al.*[13] did not observe it to be significant independent risk factor for mortality. Further Hooker *et al.* observed that the wide range of 'normal' pediatric RRs makes identification of "abnormal" more difficult.

Systolic Blood Pressure

It was observed that hypotension had a highly significant relation with the mortality pattern (OR: 46.25; 95% CI: 18.19-148.95) which was maximum in the age group of 1-12 months as compared to 1-5 years age (OR: 59.65; 95% CI: 8.64-247.59) and (OR: 37.91; 95% CI: 13.16-147.61) respectively. These results are comparable with observations of Kumar *et al.* (OR: 16.5; 95% CI: 5.7-47.8).[13]

Temperature

Temperature forms an important sign in the pediatric age group for evaluation of severity, diagnosis and management of childhood illness. It was observed that the temperature in the abnormal limits i.e., hypothermia or fever (<36°C/>38°C) had a significant association with the fatal outcome (OR: 4.25; 95% CI: 1.97-10.46).

Oxygen Saturation

<90% was observed to be a highly significant risk factor for mortality (OR: 427.86; 95% CI: 143-1366.49). These results are similar to the observations of Kumar *et al.*[13] (<90%) (OR: 9.3; 95% CI: 15-17.4).

Capillary Refill Time

CRT is an important simple clinical besides indicator for assessment of circulatory status. If prolonged (>3 s) it is considered abnormal. We observed it to be a highly significant risk factor associated mortality (OR: 236.10; 95% CI: 91.69-632.56). The results are comparable to the observations of Kumar *et al.* (OR: 7.8; 95% CI: 4.0-15.2), and Leonard and Beattie.[13,19]

AVPU Scale

AVPU scale helps in easy and quick assessment of coma.[15] AVPU – The acronym; A = the child is alert and awake, V = responds to verbal command, P = responds to painful stimuli (e.g. pinching or pulling frontal hair), U = Unconscious. Maximum mortality was observed in (92.85%) in 'P'–score patients followed by 'U' (91.7%) and subsequently 'V' (13.7%) scores respectively. No death occurred among alert children category A. However, 'V' and 'P' categories had a highly significant association with the fatal outcome of children OR: 81.55; 95% CI: 22.14-333.52 and OR: 85; 95% CI: 0.12-7.25 respectively. These results are comparable with the observation of Kumar *et al.*[13] (OR: 11.0; 95% CI: 5.9-20.6).

CONCLUSION

Triage is a vital and indispensable part of healthcare delivery system which can prevent mortality by quicker

identification of severe childhood illnesses which facilities prompt management as soon as they arrive at the health care center.

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Original Article

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Comparison of Efficacy and Safety of Sequential Combined Spinal Epidural Technique and Spinal Block for Lower Abdominal Surgeries: A Randomized Controlled Trial

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Abstract

Background: Even though, spinal and epidural anesthesia (SA and EA) are still the two most popular regional anesthetic techniques, with proven efficacy in a variety of surgical procedures across the globe, they are fraught with few disadvantages. The combined spinal epidural (CSE) technique has been claimed to overcome the shortcomings of both SA and EA by achieving rapid onset and profound blockade with the facility to modify or prolong the block. Studies comparing the efficacy and safety of spinal and CSE techniques in lower abdominal studies are very scarce.

Objective: The objective was to compare the efficacy and safety of sequential CSE technique and spinal block for lower abdominal surgeries.

Materials and Methods: The study was a randomized, single-blind controlled study, conducted in a tertiary care teaching hospital in South India. Fifty subjects undergoing lower abdominal surgeries were randomized to either SA or combined spinal and epidural anesthesia (CSEA).

Results: The time taken for onset of anesthesia was 5.48 min in spinal anesthesia group, compared to 7.40 min in CSEA group (mean difference of 1.92, 95% confidence interval [CI]: 0.78-3.05, *P*-value 0.001). The duration of analgesia was 115.6 min in spinal, compared to 124.5 in CSE (mean difference of 8.92, 95% CI: 0.87-18.71, *P*-value 0.07). The proportion of subjects who achieved the excellent quality of surgical analgesia was 92% in Group A compared to 88% Group B.

Conclusions: The CSE has got the following advantages over spinal anesthesia: (1) Better hemodynamic stability is seen, such as pulse rate (PR) and blood pressure (BP). (2) The advantage of prolongation and extension of the block when compared to the spinal anesthesia. (3) The provision of post-operative analgesia. (4) The quality of analgesia and onset of action are almost similar in both groups. However, muscle relaxation is comparatively less in CSE technique.

Key words: Combined spinal epidural, Efficacy, Safety, Spinal block

INTRODUCTION

In recent times, the use of regional anesthesia techniques is increasing worldwide. Spinal anesthesia (SA) and epidural anesthesia (EA) are still the two most popular regional anesthetic techniques, with proven efficacy in a variety of surgical procedures across the globe.[1] However, both these techniques are fraught with few disadvantages. Precipitous hypotension and difficulty in controlling the level of analgesia are major disadvantages of spinal block.[2] Apart from epidural block with the catheter technique gives a better control of the level of analgesia and can be used for providing post-operative pain relief by opioids or local anesthetic agents. However, it still has its drawbacks such as the slower onset of action, patchy anesthesia, more doses of local anesthetics, and hazard of cardiovascular and neurotoxicity.[3]

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The combined spinal epidural (CSE) technique, which was introduced by Soresi in 1937, using "single needle – single interspace" technique aims to address these problems. Different methods and techniques of came into use since its inception, each one having its own advantages and disadvantages.[2,4-7]

As the CSE, technique provides the benefits of spinal block with the flexibility of an indwelling epidural catheter to extend the duration of analgesia into the post-operative period.[8] Hence, it has gained increasing popularity for patients undergoing various major surgical procedures below the umbilical level. The procedures include orthopedic surgeries, lower abdominal gynecological surgeries, and lower extremity procedures, etc. The technique is particularly popular in obstetric anesthesia and analgesia.[9-16]

Even though the spinal and CSE techniques are in practice for the last few decades, the studies comparing the efficacy and safety of these two techniques in lower abdominal studies are very scarce from India. The current study was undertaken with the aim of filling this crucial gap in the knowledge, which can aid the clinicians and patients in taking informed decisions about the choice of the anesthetic technique.

Objective

The aim of this study was to compare the efficacy and safety of sequential CSE technique and spinal block for lower abdominal surgeries.

MATERIALS AND METHODS

Study Design

The study was a randomized, single-blind controlled trial involving two intervention groups:

a. Group A: SA
b. Group B: Combined spinal and epidural anesthesia (CSEA)

Study Setting

The study was conducted in a tertiary care teaching hospital in South India (Govt. General Hospital, Kurnool.)

Sample Size

Time for the onset of analgesia was the primary outcome parameter used for sample size calculation. Assuming the mean time for onset of anesthesia in control group as 6 min, to detect 1 unit difference, with 90% power of study and alpha error of 0.05, 23 subjects are needed in each of the treatment groups. To account for refusals, it was decided to include 25 subjects in each group.

Inclusion Criteria

1. American Society of Anesthesiologists (ASA) physical status I and II
2. Aged between 20-50 years
3. Both genders
4. Patients undergoing lower abdominal surgeries.

Exclusion Criteria

1. Critically ill patients (ASA physical status criteria III and above)
2. Patients having neurological, cardiovascular and respiratory, coagulation disorders, other system disorders, emotional instability, unwillingness to participate, and any anticipated difficulty in regional anesthesia were excluded.

Random Allocation

The participants were randomly allocated using computer generated random number sequence, maintained independently by statistician.

Blinding

Since the nature of intervention did not allow the blinding of investigator, the participants were blinded about the nature of intervention.

Ethical Approval

Approval of Institutional Human Ethics Committee was obtained. The procedure, risks, and benefits of the procedure were thoroughly explained to the patient, and informed written consent was sought from them. Only the participants willing to sign the informed written consent were included in the study. Confidentiality, the participants were maintained through the study.

Study Procedure

The pre-anesthetic evaluation of all the participants was done as per the established protocol. All relevant hemodynamic parameters were recorded just before the anesthesia. All patients were pre-meditated with Midazolam l mg IV. The blocks were given in lateral position in both the groups under all aseptic conditions.

a. Group A: Spinal needle 24G is introduced into the subarachnoid space at L_3 L_4 interspace and 3cc of Bupivacaine heavy 05% is injected, spinal needle is withdrawn and the drug is allowed to fix.
b. Group B: Patient was positioned laterally held by the operation theater (OT) assistant skin on the back was cleaned with savlon and spirit in sequence. The cleaned area was draped with a spinal towel. The L_3 L_4 space was identified, and a skin weal was raised with 1% lignocaine solution. The 18G Tuohy needle was introduced into the epidural space using loss of resistance technique by air filled syringe. Four

quadrant aspiration and loss of resistance were done to locate an epidural space. A sterile epidural catheter was introduced through the epidural needle until 3-4 cm of catheter is in epidural space, it is secured and patency checked by aspiration for the absence of cerebrospinal fluid and blood and the catheter is fixed. Now 24G Quinckebabcock spinal needle was taken, and subarachnoid anesthesia is given by injecting 1.5cc of 0.5% hyperbaric bupivacaine with the aim of achieving S_5-T_8 block. The spinal needle was withdrawn and after the subarachnoid drug was fixed (i.e., 15 min). The level of the block was extended to T_6 by injecting the fractioned dose (1.5-2 ml per unblocked segment) of 0.5% bupivacaine into epidural catheter depending on the need. Loss of sensation was tested by pinprick method at 5 min intervals till the maximum level of the block was achieved and thereafter every 15 min; the following observation were made.

Primary Outcome Parameters

1. Time of onset of analgesia as the time taken for analgesia to make its firstobjective appearance.
2. The time taken for analgesia: It is the time taken for the complete spread of analgesia to its upper limit.
3. Duration of sensory blockade: Regression of the upper two dermatomes. It is the time interval between the time of spread of analgesia to the time of regression in upper two dermatomes.

Secondary Outcome Measures

1. The quality of surgical analgesia was assessed and graded as: Excellent - if no supplementary drug required; Good - if one analgesic required; Fair - if more than one analgesic required; and Poor - if general anesthesia is required.
2. The degree of the motor blockade of the lower limb was assessed according to the modified Bromage Scale.
3. Hemodynamic parameters such as PR and BP were monitored at 5 min intervals for 1 h and thereafter every 15 min.
4. Any complication reported or observed was also documented.

Statistical Analysis

The baseline characteristics were compared between the two study groups. Categorical variables were presented as frequency and percentage; quantitative variables were presented as mean and standard deviation. All the primary and secondary outcome variables listed above were compared between the two study groups by estimating appropriate parameters. The statistical significance of the parameters was tested by independent sample *t*-test or Chi-square test, as appropriate. IBM SPSS Statistics, version 21 and Microsoft Excel were used for statistical analysis.

OBSERVATION AND RESULTS

A total of 50 participants, 25 in each of the treatment groups were included in the final analysis. The baseline characteristics are compared between the two study groups. There was no significant difference in the mean age and weight of the patients between the two study groups. The male to female ratio was slightly higher in Group B. The proportion of general surgical procedures was high in Group A, whereas in Group B more gynecological surgeries were performed (Table 1).

The time taken for the onset of anesthesia was shorter in SA group compared to CSEA group. The time taken for onset of anesthesia was 5.48 min in SA group compared to 7.40 min in CSEA group, with a mean difference of 1.92 min (95% CI: 0.78-3.05, *P*-value 0.001). The duration of analgesia was 115.6 min in Group A compared to 124.5 in Group B, with a mean difference of 8.92 min (95% CI: 0.87-18.71, *P*-value 0.07) (Table 2).

The proportion of subjects who achieved the excellent quality of surgical analgesia was 92% in Group A compared to 88% in Group B. The remaining 8% and 12% of the subjects the quality of the anesthesia was good. None of the patients had either fair or value poor quality analgesia. The mild differences in the quality of anesthesia were statistically not significant (Chi-square value 0.22 and *P*- value 0.637).

All the 25 subjects in SA group have achieved grade III muscle relaxation, according to the Bromage Scale. In

Table 1: Comparison of baseline characteristics of two study groups

Parameter	*N*=25		*P* value
	Group A	Group B	
Age (mean±SD)	35.46±8.95395	35.36±9.95774	0.976
Male:Female	0.78:1	1.27:1	0.396
Weight (mean±SD)	53.4±5.05799	51.08±4.97426	0.109
Surgery/gynecology	15/10 (60:40)	10/15 (40:60)	0.257

SD: Standard deviation

Table 2: Comparison of primary outcome parameters in two study groups (unpaired *t*-test)

Parameter	Mean	Mean difference	*P* value	95% CI	
				Lower	Upper
Onset of action					
Group A	5.48	1.920	0.001	0.788	3.052
Group B	7.40				
Duration of analgesia					
Group A	115.60	8.920	0.073	–0.877	18.717
Group B	124.52				

the CSE group, 4 (16%) of the subjects have achieved grade II, 20 (80%) have achieved grade III, and remaining 1 (4%) person has achieved grade V muscle relaxation. The differences in grade of motor blockade were statistically not significant (Table 3).

Hemodynamically, the incidence of hypotension and bradycardia was more in case of SA compared to CSE. In my study, 80% of patients CSE group had only <10% fall in PR compared to only 12% in case of SA. Where 76% of patients had shown fall in PR of 10-30% to the previous value (Chi-square value 22.52, $P < 0.001$). The number of subjects with fall in systolic BP of more than 20 mm of Hg was 11 (44%) in Group A, whereas this number was 1 (4%) in Group B (Chi-square: 21.52, $P < 0.001$) (Table 4).

The proportion of subjects reporting apprehension, nausea and vomiting was more in Group A and 4 (16%) subjects reported backache in Group B against 1 (4%) in Group A. However, these minor differences in the adverse events were not statistically significant (*P* value 0.273) (Table 5).

Table 3: Comparison of hemodynamic parameters in two study groups

Parameter	*N*=25 (%)		Chi square value	*P* value
	Group A	Group B		
Quality of surgical analgesia			0.222	0.637
Excellent	23 (92.0)	22 (88.0)		
Good	2 (8.0)	3 (12.0)		
Fair	0 (0.0)	0 (0.0)		
Poor	0 (0.0)	0 (0.0)		
Muscle relaxation grading (motor block) grade (Bromage scale)			5.556	0.062
0	0 (0.0)	0 (0.0)		
1	0 (0.0)	0 (0.0)		
2	0 (0.0)	4 (16.0)		
3	25 (100)	20 (80.0)		
5	0 (0.0)	1 (4.0)		

Table 4: Comparison of hemodynamic parameters in two study groups

Parameter	*N*=25 (%)		Chi square value	*P* value
	Group A	Group B		
Fall in PR			22.52	<0.001
<10	3 (12.0)	20 (80.0)		
10-20	10 (40.0)	4 (16.0)		
20-30	9 (36.0)	1 (4.0)		
>30	3 (12.0)	0 (0)		
Fall in systolic BP (mmHg)			21.52	<0.001
<10	2 (8.0)	18 (72.0.0)		
10-20	12 (48.0)	6 (24.0)		
20-30	9 (36.0)	1 (4.0)		
>30	2 (8.0)	0 (0.0)		

BP: Blood pressure, PR: Pulse rate

Table 5: Comparison of adverse effects in two study groups

Parameter	*N*=25 (%)		Chi square value	*P* value
	Group A	Group B		
Adverse effects				
Nausea and vomiting	2 (8.0)	0 (0.0)	3.891	0.273
Apprehension	6 (24.0)	5 (20.0)		
Backache	1 (4.0)	4 (16.0)		
PDPH	0 (0.0)	0 (0.0s)		
Seizures	0 (0.0)	0 (0.0)		
Total spinal	0 (0.0)	0 (0.0)		
High spinal	0 (0.0)	0 (0.0)		
Respiratory depression	0 (0.0)	0 (0.0)		

DISCUSSION

The CSE technique has been claimed to overcome the shortcomings of both SA and EA by achieving rapid onset and profound blockade with the facility to modify or prolong the block.[9]

The influence of age, sex, and weight is likely to be very minimal in the study as their distribution was almost similar in both study groups, without any statistically significant difference.

The onset time for sensory analgesia is slightly higher in CSE group, but it was achieved with a considerably lower dose of anesthetic in the subarachnoid space. The duration of analgesia, as measured by two segment regression was found to be longer in case of CSE compared to SA group. This was attributable to prolongation of anesthesia by epidural catheter in few necessary cases, which would not be possible with SA. The quality of surgical analgesia and muscle relaxation following spinal block was slightly superior over CSE. However, there was no significant difference between the two groups and no surgeon had complained or raised the problem of inadequate relaxation or surgical analgesia during the procedure of CSE compared to SA.

Almost all the studies published on the subject have either compared CSE with epidural or compared two different techniques of CSE. Even though many studies documented the clear superiority of the CSE, recent systematic reviews are of the conclusion that the clear superiority of CSE needs to further proved by large scale, well-controlled randomized controlled trials.

Priya *et al.* in their study on 40 patients, undergoing gynecological and orthopedic surgeries, the surgical analgesia and motor blockade occurred significantly early

in CSE group compared to epidural group. Duration of analgesia was significantly shorter in CSE (81.75 ± 11.09 min) as compared to epidural group (120.75 ± 7.56 min). The authors have concluded that sequential CSE is a superior alternative to epidural block.[9]

Gallinger *et al.*, in 88 anesthesia's in patients operated on the lower limb vessels have reported that in comparison to CSEA was characterized by a shorter latent period (12.9 ± 1.3 min vs. 24.7 ± 3.4 min, $P < 0.05$), a lower dose of bupivacaine (lidocaine: 735 ± 89 mg in CSEA and 848 ± 92 mg in EA; bupivacaine: 28.3 ± 7.2 mg in CSEA and 92.6 ± 8.5 mg in EA, $P < 0.01$), and a higher reliability. Hence, recommended CSEA over prolonged EA in operations on the lower limb vessels.[12] In a retrospective analysis of 525 women undergoing cesarean section, Ranasinghe *et al.* have concluded that CSE anesthesia is better than either SA or EA.[17]

Heesen *et al.*, have conducted a systematic review of 10 randomized controlled trials comparing CSE and EA in 1722 women in labor. The authors concluded that a consistent benefit of CSE over EA cannot be demonstrated on the basis of current best evidence and recommended large randomized controlled trials with adequate power.[18]

Hemodynamically, the incidence of hypotension and bradycardia was more in case of SA compared to CSE. Though the bupivacaine is said to produce less hemodynamic changes, gross fall in BP following SA was observed in some cases and in two patients of SA, BP had fallen more than 30% than the previous value, which was due to excessive intraoperative blood loss.

Although the spinal block is given in initially in case of CSE significant hemodynamic changes are not observed because of less extensive spinal block (T8-T9) due to sequential CSE technique combined with the slower onset of epidural block. This allows more time for the compensatory mechanisms to be effective.

Even though, the proportion of subjects reporting apprehension, nausea and vomiting were more in Group A and back ache was more in Group B, there was no statistically significant difference in the proportion of various adverse effects between spinal and CSE group.

Holloway *et al.*, in order to address the concern spinal blockade may have resulted in an increase in frequency of neurological sequel, a questionnaire-based assessment of 222 obstetric units across UK found, no obvious difference in incidence of problems associated with CSE versus the single-shot spinal technique (odds ratio: 1.14, CI: 0.53-2.46).[19]

In the current study, double space technique was used for giving CSE, as it appears to be more convenient to the anesthetist. In case of double space technique we need not to be in a hurry of introducing the epidural catheter following SA and this technique is also economical compared to single space technique as the equipment set of CSE anesthesia is very costly. Moreover, there is likely chance of unilateral anesthesia in case of xylocaine usage for spinal block in single space CSE where there is a delay in passing the epidural catheter.

CONCLUSIONS

The following conclusions can be derived from the current study of comparison between SA and sequential CSEA for lower abdominal surgeries. The CSE has got the following advantages over SA.

- Better hemodynamic stability is seen, such as PR and BP.
- The advantage of prolongation and extension of block when compared to the SA.
- Provision of post-operative analgesia.
- The quality of analgesia and onset of action is almost similar in both groups.

However, muscle relaxation is comparatively less in CSE technique.

Limitations

1. The confounding effect of various other potential confounding factors such as body mass index, other medical conditions present in the patients, type and severity of surgeries could not be evaluated because of lower effective sample size. However, randomization would have ensured minimizing this effect.

Recommendations

1. Further large-scale, well-controlled randomized studies comparing spinal and CSE techniques are needed to guide the clinicians on the choice of regional anesthesia n lower abdominal surgeries.

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Original Article

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Role of Diagnostic Laparoscopy in Chronic Abdominal Pain

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Abstract

Background: Diagnostic laparoscopy has got a considerable impact in managing patients with chronic abdominal pain, with efficacy of >80% in various studies. In our study, also it was possible to achieve definitive diagnosis in 49 (89.1%) patients. It led to initiation of appropriate treatment in this difficult patient group and pain response in terms of positive outcome (relief/reduction of pain after diagnostic laparoscopy) was seen in 92.2% of the patients.

Patients and Methods: Our study included 55 patients with a history suggestive of chronic abdominal pain of 3 months or more duration with unremarkable clinical examination, basic investigations within normal limits, and unyielding imaging studies. Outcome measured included the overall efficacy of diagnostic laparoscopy in finding a cause of chronic abdominal pain; diagnosis made and response to pain after 3 months of procedure.

Results: In our study, we achieved definitive diagnosis in 49 (89.1%) patients. It led to initiation of appropriate treatment in this difficult patient group and pain response in terms of positive outcome (relief/reduction of pain after diagnostic laparoscopy) was seen in 92.2% of patients.

Conclusion: Diagnostic laparoscopy is a better, relatively cost-effective, and efficient method of establishing the diagnosis in patients with chronic abdominal pain.

Key words: Chronic abdominal pain, Diagnostic laparoscopy, Pain relief

INTRODUCTION

Chronic abdominal pain is one of the common presentations, in general, surgical practices. In spite being subjected to myriad of tests, almost 40% of patients remain undiagnosed at the end of it.[1-4] Abdominal pain of longer duration is associated with poor quality of life[5] and significant levels of depressive symptoms.[6] The most common organic conditions include intestinal adhesions,[7,8] especially in patients with a past history of abdominal operations, abdominal tuberculosis,[9] appendicular pathology, biliary causes, mesenteric lymphadenopathy (could also be due to infectious causes of bowel such as colitis, gastroenteritis or enteric fever apart from tuberculosis), and hernia; while functional conditions include irritable bowel disease, functional dyspepsia, and various motility disorders. Abdominal wall pain is also common and frequently mistaken for visceral pain.[10,11] Despite investigations such as ultrasonography, computed tomography scan, etc., it is difficult to reach to an accurate diagnosis and represent a major diagnostic challenge to the surgeon.[12]

With the introduction of laparoscopic surgery, a new tool has been added to our knowledge. The use of this new technology in the diagnosis and management of chronic abdominal pain has been tried earlier by the various author.[13,14] Laparoscopy can identify abnormal findings and improve the outcome in a majority of patients with chronic abdominal pain, as it allows surgeons to see and treat many abdominal conditions that cannot be diagnosed

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otherwise.[4,15] It is a safe and effective tool, which can establish the cause and allows for appropriate interventions in such cases.[16] However, the role of laparoscopy in chronic abdominal pain is still debated by some authors who deny its value in adhesiolysis and consider it controversial and not evidence-based, and therefore, do not recommend it as a treatment for adhesions in patients with chronic abdominal pain.[17,18] Laparoscopic surgery has modified the management of many surgical diseases.[19] Diagnostic laparoscopy is now accepted as the preferred primary approach to many disease processes.[20]

The purpose of this study was to examine and analyze the data collected from a group of patients with chronic abdominal pain to support diagnostic laparoscopy as a primary intervention in similar patients.

Aim

The aim of this study was to assess the utility of performing diagnostic and therapeutic laparoscopy in patients with chronic abdominal pain.

Objectives

- To study the outcome of diagnostic laparoscopy in terms of pain response on follow-up after 3 months of the procedure.
- To find out the efficacy of diagnostic laparoscopy in patients with chronic abdominal pain.

PATIENTS AND METHODS

This study is a descriptive cross-sectional study, which included 55 consecutive patients over a period of 3 years (January 2011 to December 2013) presenting with a history of abdominal pain for 3 or more months. After detailed history from patients and thorough clinical examination, the findings were recorded in the proforma. Basic investigations were done for the patient. Based on the clinical examinations and imaging studies patients were subjected to diagnostic laparoscopy and the necessary surgical methods were employed as per the etiology after taking informed valid written consent. This study also included patients who were admitted to the hospital with a history of chronic abdominal pain for more than 3 months duration with the unremarkable clinical examination, laboratory and imaging studies, and underwent diagnostic laparoscopy. Patients were followed up at regular intervals post-discharge and then 3 months after the procedure. Subjective assessment of pain was done by asking the patients, what occurred to their pain, relief, reduced or no change. The findings and outcomes of laparoscopy were recorded and analyzed. Outcome measured included the overall efficacy of diagnostic laparoscopy in finding a cause of chronic abdominal pain, diagnosis made, post-operative complications, response to pain after 3 months of procedure.

RESULTS

The efficacies of various studies reported in the literature in arriving at a diagnosis are >80% giving an indication that diagnostic laparoscopy has got a considerable impact on managing patients with chronic abdominal pain. In our study, also it was possible to achieve definitive diagnosis in 49 (89.1%) patients. It led to initiation of appropriate treatment in this difficult patient group and pain response in terms of positive outcome (relief/reduction of pain after diagnostic laparoscopy) was seen in 92.2% of the patients (while calculating the pain response (relief/reduction/persistent) out of 55, 51 patients were considered because 2 patients were lost to follow-up and 2 patients expired before follow-up).

In our study, the incidence of chronic abdominal pain was 83.6% in the age group from 13-40. The analysis of pain response in patients shows that the association between age group and pain response is not statistically significant. Our study also showed that chronic abdominal pain is a common problem among the female population with incidence being 85.5%. Patients presented with varied duration of pain ranging from minimum of 4 months in 7 patients (12.7%) to 24 months in 1 patient (1.8%) with mean duration of pain being 8.6 ± 4.2 months. The most common location of pain in the abdomen in our study was right lower quadrant seen in 19 patients (34.5%) followed by diffuse pain in 14 patients (25.5%). The most frequent operative findings were adhesions noted in 43.6% of the patients in our study, and no abnormality was detected in 9.1% of cases (Table 1). The history of previous abdominal surgery was present in 30 patients (54.5%) and not surprisingly, in 21 out of 30 patients, i.e., (70%) adhesions were found. It was observed in our study that most patients with abdominal pain with intra-abdominal adhesions respond well to laparoscopic adhesiolysis. Thus, the most common diagnosis in our study was adhesions due to previous abdominal surgery. The second most common cause of the chronic abdominal pain was abdominal tuberculosis diagnosed in 12 (21.8%) patients. Such high incidence of abdominal tuberculosis during diagnostic laparoscopy is an indirect evidence of it being common in developing a country like India. In our study, 49 (89.1%) patients had pathological findings identified at the time of laparoscopy.

Diagnostic laparoscopy was extended, and therapeutic interventions were carried out based on the findings

obtained on diagnostic laparoscopy to achieve a cure. Various therapeutic interventions that were carried out to achieve cure included Adhesiolysis (43.6%), Appendicectomy (14.5%), Cholecystectomy (1.8%), Cyst aspiration (1.8%), Laparoscopic transabdominal pre-peritoneal hernia repair (1.8%). Thus, in overall 63.5% patients, therapeutic interventions were carried out in our study. Therapeutic interventions were carried out in 33 patients (64.7%) out of 51 and 31 patients (93.9%) gave history of positive response with 2 patients having persistent pain at the time of follow-up after 3 months (Table 2).

Relief of pain was noted in 41 patients (80.4%), 6 patients (11.8%) had reduced pain after diagnostic laparoscopy with overall positive response to pain in 85.4% of patients in our study (Table 3).

In our study, five patients had a negative diagnostic laparoscopy and free fluid was found in pelvis of one patient, which was aspirated and sent for analysis. However, the fluid analysis was normal and hence in all six patients (10.9%) were observed to have no cause/pathology attributable to their chronic abdominal pain, and they were labeled as Idiopathic chronic abdominal pain. However, four out of these six patients (66.6%) responded positively after diagnostic laparoscopy.

Table 1: Showing distribution of operative findings on diagnostic laparoscopy

Operative findings	No. of patients	Percentage
Abdominal tuberculosis	8	14.5
Adhesions due to congenital bands	2	3.6
Free fluid	1	1.8
Inflammatory adhesions	1	1.8
Inflamed appendix	8	14.5
Post-op adhesions	21	38.2
Left indirect inguinal hernia	1	1.8
Mesenteric lymphadenopathy	3	5.4
Mesenteric lymphadenopathy+free fluid	3	5.4
Right ovarian cyst	1	1.8
Thickened gall bladder wall+dense adhesions	1	1.8
No abnormality detected	5	9.1
Total	55	100.0

DISCUSSION

The role of laparoscopy in chronic abdominal pain is still debated by some authors who deny its value in adhesiolysis and consider it controversial and not evidence-based, and therefore, do not recommend it as a treatment for adhesions in patients with chronic abdominal pain.[17,18] Diagnostic laparoscopy makes it possible for the surgeon to visualize surface anatomy of intra-abdominal organs with greater details better than any other imaging modality. However, laparoscopy has got its own limitations such as non-visualization of deep parenchymal organs, processes of retroperitoneal space and the inner surface of hollow organs, and not allowing the surgeon to palpate the organs.[21] Idiopathic chronic abdominal pains are among the most challenging and demanding conditions to treat across the whole age spectrum. Potentially it can be unrewarding for both patients and the medical team. Studies conducted with large community samples or hospital populations imply chronic abdominal pain is a pervasive problem. Abdominal pain was the third most common complaints of individuals enrolled in a large health maintenance organization.[21] All patients included in this study had chronic abdominal pain, they were subjected to laparoscopic evaluation after exclusion of all organic causes of the pain by detailed history, complete clinical examination, laboratory tests, radiographic evaluations, and upper gastrointestinal or

Table 2: Showing final diagnosis, efficacy achieved and positive outcome

Diagnosis	Operative findings	Treatment	No. of patients (%) *n*=51	Positive outcome
Abdominal tuberculosis	Abdominal tuberculosis Mesenteric lymphadenopathy Mesenteric lymphadenopathy+free fluid	ATT	12 (23.5)	10 (83.3)
Adhesions	Adhesions due to congenital bands Inflammatory adhesions Post-op adhesions	Adhesiolysis	24 (47.0)	22 (91.6)
Recurrent appendicitis	Inflamed appendix	Appendicectomy	8 (15.6)	6 (75.0)
Left indirect inguinal hernia	Left indirect inguinal hernia	Trans-abdominal pre-peritoneal hernia repair	1 (1.9)	1 (100.0)
Colitis/gastroenteritis/enteric fever	Mesenteric lymphadenopathy Mesenteric lymphadenopathy+free fluid	Conservative	2 (3.9)	2 (100.0)
Right ovarian cyst	Right ovarian cyst	Cyst aspiration	1 (1.9)	1 (100.0)
Acalculous cholecystitis	Thickened gall bladder wall+dense adhesions	Cholecystectomy	1 (1.9)	1 (100.0)
Idiopathic chronic abdominal pain	No abnormality detected Free fluid	Conservative	6 (11.7)	4 (66.6)

lower gastrointestinal endoscopy were applicable. The study confirmed that in this difficult patient group, laparoscopy could safely identify abnormal findings and can improve the outcome in a majority of cases. The subjective benefit of laparoscopy for both the operating surgeons and for the patients is the definitive answers that no serious pathology is found intra-abdominally. Therefore, the placebo effect of laparoscopy may explain at least partly the patient's pain relief.[22]

These studies prove beyond doubts that diagnostic laparoscopy can be considered as an option in patients with chronic abdominal pain (Table 4). Based on the findings of above studies it is also clear that early diagnostic laparoscopy can prevent the delay in the arrival at a definite diagnosis and institution of appropriate treatment. The efficacies of these studies were >80% giving an indication that diagnostic laparoscopy has got a considerable impact in managing this difficult group of patients. The overall positive outcome seen in the above-mentioned studies after diagnostic laparoscopy compare favorably with the results obtained by us. Hence, it can be concluded that it has an effective diagnostic role in evaluating patients with chronic abdominal pain, in whom conventional methods of investigations have failed to elicit a certain cause. The therapeutic value of diagnostic laparoscopy is also accepted, well-appreciated, and it cannot be underestimated. Being minimally invasive, laparoscopy has solved the problem of delay in the definite diagnosis and has led to considerable reduction in the number of negative exploratory laparotomies. It has also significantly reduced the number of investigation these patients are subjected to, days of hospital stay, which leads to substantial reduction in the cost of the treatment. Diagnostic laparoscopy also solves the problem of dissatisfaction of both the surgeon and the patient which is one of the main issues in the management of these patients.

Table 3: Showing pain response after diagnostic laparoscopy

Pain response (follow-up after 3 months)	No. of patients	Percentage
Relief	41	80.4
Reduced	6	11.8
Persistent	4	7.8
Total	51	100.0

Table 4: Showing comparison of diagnostic efficacy of laparoscopy in various studies

Study	Efficacy (%)	No. of cases	Year of study	Outcome (pain response) (%)
Miller *et al.*[23]	89.8	59	1996	89.3
Salky and Edye[13]	76	265	1998	-
Raymond *et al.*[16]	85.7	70	2003	71.4
Moussa and Mahfouz[24]	78.6	56	2004	80.2
El-Labban and Hokkam[25]	83.3	30	2010	80
Tulaskar *et al.*[22]	82.8	35	2013	81.8
Present study	89.1	55	2014	92.2

CONCLUSION

Laparoscopy has an effective diagnostic role in evaluating patients with chronic abdominal pain, in whom conventional methods of investigations have failed to elicit a certain cause. The therapeutic value of diagnostic laparoscopy is also accepted, well-appreciated, and it cannot be underestimated. Being minimally invasive, laparoscopy has solved the problem of delay in the definite diagnosis and has led to considerable reduction in the number of negative exploratory laparotomies. It has also significantly reduced the number of investigation that these patients are subjected to, days of hospital stay, which leads to substantial reduction in the cost of the treatment. Diagnostic laparoscopy also solves the problem of dissatisfaction of both the surgeon and the patient, which is one of the main issues in the management of these patients.

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Original Article

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Prevalence of Visual Impairment after Blunt Ocular Trauma in a Tertiary Hospital

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Abstract

Background: Ocular trauma is a major cause of visual morbidity. The visual impairment caused due to blunt ocular trauma has been neglected in developing countries.

Purpose: To study the prevalence of visual impairment in victims of blunt ocular trauma presenting to a tertiary hospital.

Materials and Methods: A prospective study was done. The study included 100 patients. Demographic data, detailed history, clinical data, best-corrected visual acuity of all patients were noted at presentation. Patients treated medically and depending on their condition, surgical intervention done as required. Follow-up was done after 1-week, 1-month, 6-months, and 1-year of presentation.

Results: The mean age group of patients was 25 years. When adjusted for sex, males were more affected, that is, of the 100 patients, 83 were male, 27 were female. 23 patients had visual impairment at presentation. Impairment in vision resulted from corneal edema/partial corneal tears (3%), iridocyclitis (4%), cataract (9%), subluxated lens with vitreous herniation (2%), hyphema with vitreous hemorrhage and retinal detachment (2%), commotio retinae/retinal hemorrhages (2%), optic neuritis (1%). 13 patients (who had curable blindness, with vision <6/60) were surgically treated, and vision restored. On 1-year follow-up, two patients had a visual impairment, their vision being 6/9 and 6/12.

Conclusion: Prevalence of visual impairment in our study was 2%, thus requiring its prevention and early management to be a public health priority.

Key words: Morbidity, Trauma, Visual impairment

INTRODUCTION

Ocular trauma, once described as the "neglected disorder," has recently been highlighted as a major cause of visual morbidity.[1] Annually, over 2.5 million Americans suffer an eye injury, and globally more than half a million blinding injuries occur every year.[2] The prevalence of ocular trauma in India was reported as 2.4%.[3] Worldwide, there are approximately 1.6 million people blind from eye injuries, 2.3 million bilaterally visually impaired, and 19 million with unilateral visual loss.[4]

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Ocular trauma is a major cause of preventable monocular blindness and visual impairment in the world.[5] 40,000-60,000 of eye injuries lead to visual loss.[6] Despite its public health importance, there is relatively less population-based data on the magnitude and risk factors for ocular trauma, especially from developing countries.[7]

Purpose

To study the prevalence of visual impairment in victims of blunt ocular trauma presenting to a tertiary hospital.

MATERIALS AND METHODS

A prospective, observational study was done on 100 patients with blunt ocular trauma.

The study duration spanned over a period of 2 years from August 2012 to June 2014.

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Inclusion Criteria

- Patients presenting to ophthalmology outpatient departments of Dr. B. R. Ambedkar Medical College, Bengaluru, India, with history and signs of blunt ocular trauma
- Patients who were willing to give consent.

Exclusion Criteria

- Patient in whom assessment is difficult due to severe head injury with reduced level of consciousness and cooperation
- History of any past ocular pathology, which impairs best-corrected visual acuity (BCVA).

Demographic data, detailed history, clinical data were recorded. Detailed ocular examination which included visual acuity (both distant and near), retinoscopy, anterior segment evaluation with diffuse light, slit-lamp examination, intraocular pressure (IOP) with GAT, gonioscopy with Goldmann three mirror gonioscope, posterior segment evaluation using +90D lens, +78D lens and indirect ophthalmoscope with +20D lens, visual fields by Humphrey Field Analyzer, B-scan, X-ray orbit, computerized tomography/magnetic resonance imaging was done.

BCVA of all patients was noted at presentation and during follow-up. Follow-up was done after 1-week, 1-month, 6 months, 1-year of presentation.

RESULTS

Age

Mean age group of patients in our study was 25 years. There were 8 patients in the age group of 1-10 years, 16 patients in the age group of 11-21 years, 57 patients in the age group of 21-30 of years, 18 patients in the age group of 31-40 years, and 1 patient in the age group of 41-50 years. In our study, young adults were more prone to blunt ocular trauma.

Sex Distribution

Of the 100 patients, 83 were male and 17 were female.

Demography

Study included 22 patients from the rural sector and 78 patients from the urban sector.

Cause of Blunt Trauma

The cause of blunt trauma in our study was road traffic accident as seen in 22 patients, history of fall in 19 patients, history of assault in 32 patients, injury with blunt objects in 21 patients, and miscellaneous causes in 6 patients.

Visual Impairment

Of the 100 patients, 23 had a visual impairment. The best corrected visual acuity of these patients on presentation was as follows:

Best Corrected Visual Acuity on Presentation

In our study, there was 1 patient with visual acuity ranging from 6/12 to 6/18, 5 patients with visual acuity ranging from 6/24 to 6/36, and 16 patients with visual acuity ranging from 6/60 to <6/60.

Cause of Visual Impairment

Cause of visual impairment in our study was noted to be due to corneal edema as seen in 2 patients, partial corneal tear in 1 patient, traumatic iridocyclitis in 4 patients, traumatic cataract in 9 patients, subluxated lens in 2 patients, vitreous hemorrhage with retinal detachment in 2 patients, and traumatic optic neuritis in 1 patient (Figures 1-4).

Of this, 13 were surgically treated and improvement in vision was noted.

On Follow-up

Best corrected visual acuity after 1-week showed 2 patients with visual acuity between 6/6 and 6/9, 11 patients with visual acuity between 6/12 and 6/18, 4 patients with visual acuity between 6/24 and 6/36, 5 patients with visual acuity between 6/60 and <6/60.

Best corrected visual acuity after 6 months and 1-year showed 21 patients with visual acuity of 6/6, 1 patient with visual acuity of 6/9, and 1 patient with visual acuity of 6/12. Thus showing visual impairment in 2 patients at 1-year follow-up (Table 1).

DISCUSSION

Pathogenesis of Blunt Trauma

Blunt trauma to the globe results in anteroposterior compression with simultaneous expansion in the equatorial plane associated with a transient but severe increase in IOP. The impact is primarily absorbed by the lens iris diaphragm and the vitreous base.

Mechanics of Blunt Trauma to Eyeball

1. Direct impact on the globe: It produces maximum damage at the point where the blow is received. It can be due to:
   a. Compression wave force: It is transmitted through the fluid contents in all the directions. Maximum damage is produced at a point distant from the place of impact. This is called contrecoup damage
   b. Reflected compression wave force: After striking

Table 1: BCVA on presentation to the 1-year follow-up

Best corrected visual acuity	Number of patients on presentation	Number of patients after 1-week	Number of patients after 1-month	Number of patients after 6 months	Number of patients on 1-year follow-up
6/6-6/9	0	2	17	21	21
6/12-6/18	1	11	1	1	1
6/24-6/36	5	4	1	0	0
6/60-<6/60	16	5	3	0	0

BCVA: Best corrected visual acuity

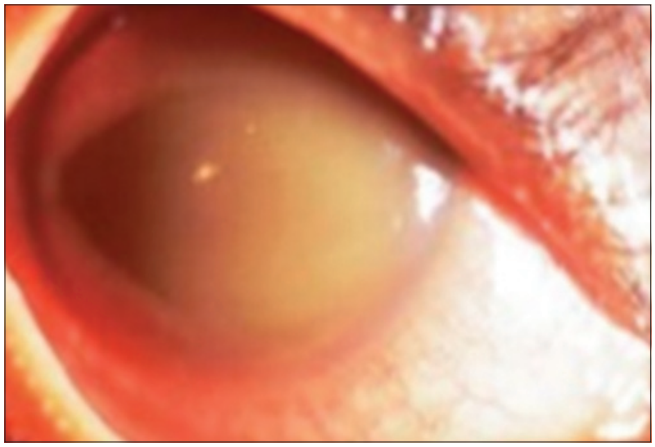

Figure 1: Total hyphema

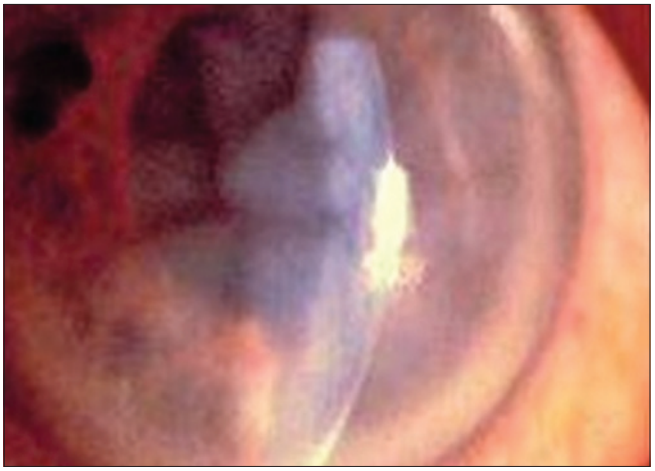

Figure 3: Corneal edema

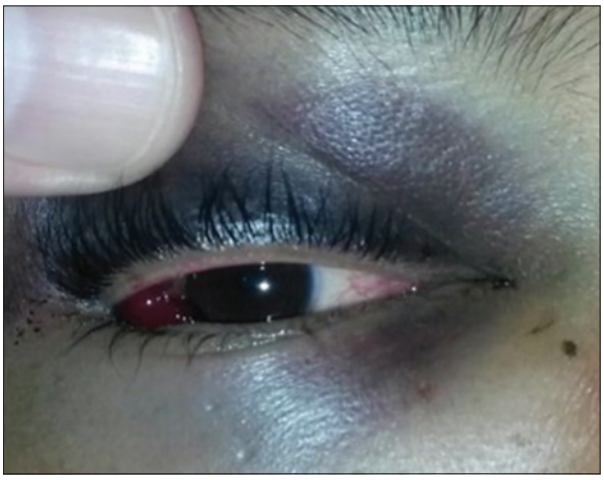

Figure 2: Periorbital ecchymosis with subconjunctival hemorrhage

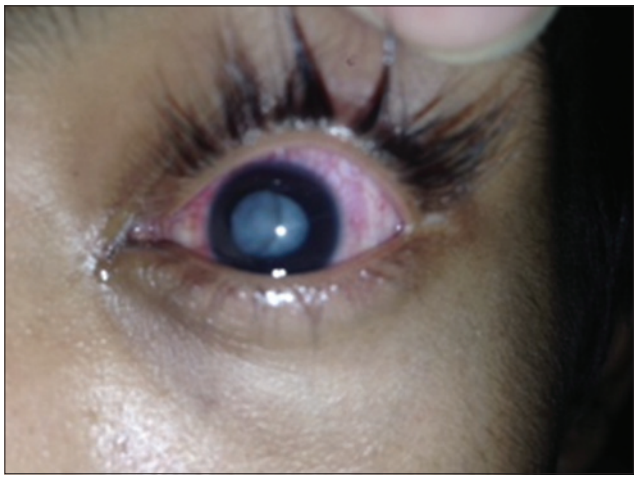

Figure 4: Traumatic cataract

the outer coats of the eyeball, the compression waves are reflected toward the posterior pole and may cause foveal damage

c. Rebound compression wave force: After striking the posterior wall of the globe, the compression waves rebound back anteriorly. This force damages the retina and choroid by forward pull and lens-iris diaphragm by forward thrust from the back.

2. Indirect force: Indirect forces act on the eyeball from the bony walls and elastic contents of the orbit when globe suddenly strikes against these structures.

Our study showed men and young adults to be more prone to blunt ocular trauma. This result was consistent with previous study done by Vats *et al*.[8]

Our study also showed a higher incidence in the urban population as compared to a rural one. In the study by Dandona *et al*.[9] and Nirmalan *et al*.,[10] it showed that a rural population (4.5%) may have a higher prevalence as compared to an urban one (3.97%).[9,10] Since our study was done in urban Bengaluru, our results can thus be substantiated.

The prevalence of visual impairment in our study was 2%. The study done by Glynn *et al*. reports cumulative prevalence of visual impairment (VA <20/40) due to ocular trauma is 8.5 per 1000 persons.[7]

Limitations in our study being loss of one patient on follow-up and its small sample size.

CONCLUSION

Prevalence of visual impairment in our study is 2%. Ocular trauma has to be considered as a public health priority in developing countries like India as most of the patients affected belong to the economically productive age group. As blunt ocular trauma is a major cause of preventable visual impairment, "prevention is better than cure" aptly applies here. Prevention can be done by public awareness and education on the use of helmets while riding, use of protective glasses. Patients presenting with blunt trauma should be promptly and efficiently treated. Reducing the magnitude of visual impairment due to blunt trauma is the responsibility of both the patient and the ophthalmologist.

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Original Article

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Comparative Study of Intra-Cervical Foley Catheter and Vaginal Misoprostol for Pre-Induction Cervical Ripening

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Abstract

Background: Physical and chemical changes in the uterine cervix and the lower uterine segment, which normally precede the onset of labor are referred to as ripening and seem to be essential to normal labor and delivery.

Objective: The aim of this study was to compare the efficacy of intracervical Foley catheter and 50 mcg vaginal misoprostol in pre-induction cervical ripening.

Study Design: A randomized, prospective study was conducted in the Department of Obstetrics and Gynecology, Government Medical College, Srinagar from March 2012 to August 2013. 200 patients at term with a Bishop's score ≤3 with various indications for induction were randomly allocated to receive intracervical Foley catheter (100 pts) or 50 mcg vaginal misoprostol (100 pts). After 6 h post-induction bishop's score was noted and labor was augmented if required. Statistical analysis was done using Chi-square test and *t*-test.

Result: The groups were comparable with respect to maternal age, gestational age, indication of induction, and initial bishop's score. Both groups showed significant change in the Bishop's score, 3.8 ± 1.1 and 3.6 ± 1.1 for Foley catheter and misoprostol, respectively, $P < 0.001$; however there was no significant difference between the two groups. 14 cesarean sections (14%) were performed in Group A and 19 (19%) were performed in Group B (not significant).The induction to the delivery interval was 18.1 ± 3.6 h in Group A and 17.7 ± 4.1 h in Group B ($P = 0.408$). Apgar score, birth weights, neonatal intensive care unit admissions, and maternal side effects showed no difference between the two groups.

Conclusion: This study shows that both Foley catheter and vaginal misoprostol are equally effective in pre-induction cervical ripening.

Key words: Cervical ripening, Foley catheter, Misoprostol

INTRODUCTION

The success of induction of labor depends on the cervical status at the time of induction. It is predicted that the patient with a poor Bishop's score ≤3 have unacceptably higher failure rates.[1,2] Studies have shown that a low Bishop's score is associated with increased rates of cesarean sections, maternal fever, and fetal asphyxia.[2,3] To decrease the induction failure, cervical ripening by any method is the answer. The ripening agents include mechanical dilation and prostaglandin administration. Mechanical dilation was first described with laminaria tents; more recently, the use of a transcervical balloon catheter (Foley catheter) has also been used successfully.[4,5] The Foley catheter is inserted in order to act primarily as a cervical ripening agent, and may have limited effect on uterine contractions due to the release of prostaglandins. Regarding prostaglandin administration, prostaglandin E_2 (dinoprostone) was given vaginally or intracervically has been shown to be an effective ripening agent.[6] In addition, prostaglandin E_1 (misoprostol) has been shown to be effective for cervical ripening.[7]

The purpose of this study was to compare the efficacy of intracervical Foley catheter with vaginal misoprostol for

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pre-induction cervical ripening. Various parameters such as induction delivery interval, maternal and fetal outcome, and the need for augmentation of labor were compared between the two groups.

MATERIALS AND METHODS

This prospective comparative study was carried out in the Department of Obstetrics and Gynecology, Government Medical College, Srinagar from March 2012 to August 2013. Institutional ethical clearance was taken. A sample size of 200 cases was divided by simple randomization into two groups, with each group comprising 100 patients. Group A (100 patients) underwent induction by intracervical Foley catheter and Group B (100 patients) by vaginal misoprostol. Patients at term with various indications for induction of labor were included in the study after a written, valid consent was given by the patients.

Inclusion Criteria

1. Primigravida
2. ≥37 weeks of gestation
3. Singleton pregnancy
4. Cephalic presentation
5. Bishop's score ≤3
6. Intact membranes.

Exclusion Criteria

1. Multiple pregnancy
2. Mal-presentation
3. Absent membranes
4. Antepartum hemorrhage
5. Medical disease e.g. heart disease and renal disease.

Demographic profile, gestation age, last menstrual period was ascertained and correlated clinically. Detailed history and examination was done in each patient. The baseline investigations were done including complete blood count, blood group, kidney, and liver function tests. The pre-induction bishop's score was determined and after 6 h of induction the post-induction bishop score was assessed.

Improvement of bishop's score, induction delivery interval, mode of delivery, and the fetomaternal outcome were noted. Need of augmentation of labor was assessed and implemented by other methods such as rupture of membranes and oxytocin administration. Failure of induction was declared if the patient failed to go in the active phase of labor within 24 h of labor induction.

Student's *t*-test and Chi-square test were used to statistically compare the two groups. Differences with a $P < 0.05$ were considered statistically significant with a confidence limit of 95%.

RESULTS

Group A and Group B had 100 randomized patients each. Both the groups were comparable with respect to the maternal age, gestation age, indication for induction, and pre-induction bishop's score (Table 1).

No statistically significant difference was demonstrated between the two groups.

In this study, improvement in the bishop's score in Group A was 3.8 ± 1.1 ($P < 0.001$) and in Group B it was 3.6 ± 1.1 ($P < 0.001$); however, no significant difference in the mean changes in the two groups could be established (Table 2).

The need for further augmentation of labor was noted in the study. In Foley catheter group, the need for augmentation was required in 67 patients and in misoprostol group it was required in 61 patients. There was no significant difference in the need for augmentation of labor in both the groups (Table 3).

Table 4 shows no significant statistical difference in spontaneous vaginal delivery in both the groups. Group A had 82% spontaneous deliveries whereas Group B had 78%

Table 1: Demographic profile

Variable	*n*=100		*P*
	Group A	Group B	
Maternal age	26.1±2.8	26.2±3.3	0.645
Indication for induction			
Elective	37	36	0.873
Postdatism	39	38	
Oligohydramnios	6	7	
IUGR	7	8	
Gestational diabetes mellitus	5	4	

IUGR: Intrauterine growth restriction

Table 2: Change in Bishop score

Bishop score	Group A	Group B
Mean pre-induction bishop score	2.9±0.7	3.0±0.8
Mean post-induction bishop score	6.7±0.8	6.6±0.8
Mean change in score	3.8±1.1	3.6±1.1
	P=0.000	*P*=0.000

Table 3: Need for augmentation

Need for augmentation	Group A (%)	Group B (%)	*P* value
Spontaneous	33 (33)	39 (39)	
ARM	6 (6)	30 (30)	0.378
Oxytocin	28 (28)	24 (24)	
ARM+Oxytocin	33 (33)	100	
Total	100	100	

ARM: Artificial rupture of membranes

spontaneous deliveries. The induction delivery interval in Group A was 18.1 ± 3.6 h and 17.7 ± 4.1 in Group B. However, the difference was not statistically significant.

The need for operative intervention was also not statistically significant in both the groups. Cesarean section for fetal distress was done in 8 cases (Group A) and 10 cases (Group B). The other indications for Cesarean section being the failure of the progress of labor (five each) and failure of induction (1 and 4, respectively).

Table 5 shows that 1 min and 5 min Apgar score were similar in both the groups. The neonatal birth weights were also comparable in both the groups (2.77 ± 0.51 in Group A and 2.73 ± 0.24 in Group B). 8% of babies in Group A and 11% of babies in Group B got admitted in the neonatal intensive care unit (NICU) (Table 5). However, the morbidity in both the groups were not statistically significant.

DISCUSSION

The result of this study confirms that both Foley catheter and vaginal misoprostol are equally effective in pre-induction cervical ripening. The mean change in bishop's score with Foley catheter 3.8 ± 1.1 ($P < 0.001$) and misoprostol 3.6 ± 1.1 ($P < 0.001$) were highly significant, however, there was no statistically significant advantage of one over the other. Similar observations were made by Oliveira *et al.*[8]

The need for augmentation of labor was 67% in Group A and 61% in Group B. The induction delivery interval showed no significant difference in the two groups. The mean I-D interval was 18.1 ± 3.6 in Foley group and 17.7 ± 4.1 in the misoprostol group. Similar were the observations made by Goonawardane *et al.*[9] and Tuuli *et al.*[10]

The rate of cesarean section in Group A was 14% and 19% in Group B ($P = 0.52$, NS). The most common indication for cesarean section in both the groups was fetal distress. Group A had 8 cases of fetal distress and Group B had 10 cases of fetal distress. Jindal *et al.*[11] in their study found no difference of lower segment cesarean section (LSCS) rate between the two groups. The rate of LSCS in our study is agreeable.[2,4]

Fetal outcome data showed no significant difference between Group A and Group B with respect to birth weight ($P = 0.529$), 1 and 5 min Apgar score ($P = 0.263$), and NICU admission rate (8 and 11, respectively). Thus, the present study showed that the fetal outcome results were also comparable in both Group A and Group B. Similar observations were made by Kashanian *et al.*[12]

Table 4: Mode of delivery and induction delivery interval

Variable	Group A *n*=100 (%)	Group B *n*=100	*P* value
Spontaneous	82 (82)	78%	*P*=0.52
Instrumental	4 (4)	3%	
LSCS	14 (14)	19%	
Total	100	100	
Induction-delivery interval	18.1±3.6	17.7±4.1	*P*=0.408

LSCS: Lower segment cesarean section

Table 5: Neonatal outcome

Variable	Group A	Group B	*P* value
1 min Apgar score	7.8±0.5	7.8±0.6	0.632
5 min Apgar score	9.7±0.6	9.8±0.5	0.263
Mean birth weight (kg)	2.7±0.51	2.7±0.24	0.529
Admission to NICU	8%	11%	0.47
Fetal distress	9%	12%	0.49

NICU: Neonatal intensive care unit

CONCLUSION

This study shows that for cervical ripening there is no difference in efficacy between intracervical Foley catheter and vaginal misoprostol. Furthermore, other factors such as induction delivery interval, maternal and fetal outcome, and the need for further augmentation were similar in both the groups.

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Original Article

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Comparative Effect of Nifedipine, Nitroglycerine, and Metoprolol in Attenuating Rise in Pulse Rate, Blood Pressure, and Cardiac Arrhythmias during Laryngoscopy and Intubation

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Abstract

Background: During laryngoscopy and intubation rise in pulse rate, blood pressure (BP), and cardiac arrhythmias occurs.

Objective: The aim of the present study was to attenuate the rise in pulse rate, BP, and cardiac arrhythmias due to laryngoscopy and intubation with nifedipine, nitroglycerine (NTG), and metoprolol.

Materials and Methods: A total of 40 patients undergoing surgery were randomly divided into four groups. Group 1 control group: No medication, Group 2: NTG 1 mg sublingually given 2 min before intubation, Group 3: Nifedipine gelatin capsule 10 mg sublingually 20 min before intubation, Group 4: Injection metoprolol 2 mg intravenous (IV) 5 min before intubation.

Result: Metoprolol was more effective in attenuating the rise in BP, pulse rate, and cardiac arrhythmia.

Conclusion: All three drugs significantly attenuates the rise in pulse rate, BP, and cardiac arrhythmias during laryngoscopy and in intubation, but metoprolol 2 mg IV 5 min before intubation was more effective than other two drugs.

Key words: Intubation, Laryngoscopy, Metoprolol, Nifedipine, Nitroglycerine

INTRODUCTION

Despite the emergence of new airway devices in the recent years, rigid laryngoscopy and tracheal intubation still remains the gold standard in airway management. In 1940, Reid and Brace first described the hemodynamic response to laryngoscopy and intubation both of which are known to cause sympathoadrenal stimulation.[1] These procedures lead to increase in heart rate (HR), blood pressure (BP), intraocular, and intracranial pressure. The arterial hypertension is due to increase in cardiac output rather than an increase in systemic vascular resistance, and is associated with the transient rise in central venous pressure. Arrhythmias also tend to occur. These changes are of little significance in normal healthy patients but may be dangerous in cases of coronary artery diseases, raised intracranial pressure, intracranial aneurysm, partial or complete heart block, and hypertensive patients.[2-4] Therefore, many drugs are often used in combination with the primary anesthetic in an attempt to decrease these hemodynamic responses associated with intubation so as to limit patient risk.[5,6] The present study was done to compare the effect of nifedipine and nitroglycerine (NTG) in attenuating cardiovascular response due to laryngoscopy and intubation.

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MATERIALS AND METHODS

The study was conducted on 40 patients American Society of Anesthesiologists Grade I and II undergoing general anesthesia.

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The patients were randomly divided into four groups.

Group 1: Total number of patients studied - 10. This group was considered as a control group and no medication was given

Group 2: Total number of patients studied - 10. Patients were given nitroglycerine 1 mg sublingually 2 min before induction of anesthesia

Group 3: Total number of patients studied - 10. Patients were given nifedipine gelatin capsule 10 mg sublingually 20 min before induction of anesthesia

Group 4: Total number of patients studied - 10. Patients were given metoprolol 2 mg intravenous (IV), 5 min before induction of anesthesia.

Investigation

All the patients were routinely investigated for:

- Hemoglobin
- Total leucocyte count
- Differential leukocyte count
- Erythrocyte sedimentation rate
- Blood group and Rhesus factor
- Blood sugar
  a. Fasting
  b. Postprandial
- Blood urea
- Serum creatinine
- Electrocardiography (ECG)

Procedure

Before subjecting the patients for the study, thorough clinical examination and laboratory investigations were done once again. Indication for surgery was noted and written informed consent was obtained.

All the patients were premedicated with 0.01 mg/kg glycopyrrolate and 1 mg/kg promethazine, intramuscular 30 min before surgery.

IV line was secured using dextrose normal saline/ringer lactate and pre-oxygenated for 5 min. Anesthesia was induced with thiopentone sodium 4-7 mg/kg, over 20 s and when eyelash reflex abolished, suxamethonium 1-2 mg/kg was given.

When fasciculation due to suxamethonium disappeared patients were intubated with cuffed lubricated (with xylocaine 2% jelly) endotracheal tube, after laryngeal spray with xylocaine 1%. After the procedure following, four observations were recorded for 15 min *viz*. baseline, after induction at 3, 5, 10, and 15 min after intubation.

- Pulse rate
- Arterial BP
- HR and rhythm by ECG
- Oxygenation
- Input-output charting

After laryngoscopy and intubation anesthesia was maintained with N_2O 66%, oxygen 33%, and vecuronium 0.05 mg/kg body weight.

OBSERVATIONS AND RESULTS

Demographic profile is shown in Tables 1 and 2 which shows that most of the patients belonged to age group 30-40 years followed by those in 40-50 years. Mean weight of the male patients in control and study groups were 59.00 ± 2.70 kg and 61.42 ± 5.04 kg, respectively, while mean weight of the female patients in control and study groups were 47.83 ± 3.92 kg and 52.39 ± 6.74 kg, respectively. There was no significant difference in the demographic parameters between different groups.

Table 3 shows that there was fall in mean systolic arterial pressure after induction of anesthesia in all four groups, *viz*., control, nifedipine, NTG, and metoprolol. This

Table 1: Distribution of patients according to age in various groups

Age	Nifedipine	Metoprolol	NTG	Control
<30	1	0	0	1
30-40	8	3	4	6
40-50	1	4	2	3
50-60	0	1	2	0
>60	0	2	2	0

NTG: Nitroglycerine

Table 2: Distribution of patients according to weight

Groups	Male - weight (kg)	Female - weight (kg)
Control	59±2.70	47.83±3.92
Study	61.42±5.04	52.39±6.74

Table 3: Systolic BP at different times in various groups (mean ± SD)

Time	Group 1	Group 2	Group 3	Group 4
Baseline	123.80±9.86	120.20±8.36	119.00±9.12	121.00±9.82
Induction	85.60±8.53	86.4±8.24	81.40±9.38	84.8±8.37
1 min after intubation	149.00±8.89	132±8.98	135±9.26	139±9.58
3 min	139±9.58	131±9.62	132±8.69	136±9.36
5 min	128±9.43	127±9.28	128±9.34	128±9.58
10 min	126±8.96	123±8.69	124±8.74	126±9.84
15 min	124±9.47	120±8.49	121±9.58	123±8.88

BP: Blood pressure, SD: Standard deviation

fall was statistically insignificant ($P > 0.05$) in control, metoprolol, and NTG groups, but significant only in nifedipine group.

There was also immediate increase in mean systolic arterial pressure after laryngoscopy and intubation in all four groups *viz.* control, nifedipine, NTG, and metoprolol. This rise was significant in the control group ($P < 0.01$), while in nifedipine, NTG, and the metoprolol groups rise was slight but statistically insignificant ($P > 0.05$). On comparing various groups, significant difference was observed between the control group and treatment groups ($P < 0.05$), suggesting that all the groups were effective in attenuating the increased BP response of intubation.

Further, there was a decline in mean systolic arterial pressure in serial recording at 3, 5, 10, 15 min after intubation in all four groups (Table 3).

Similar to the response on systolic BP, there was a decrease in mean diastolic arterial pressure after induction of anesthesia in all four groups *viz.* control, nifedipine, NTG, and metoprolol ($P < 0.05$) (Table 4).

Maximum increase in mean HR after intubation was observed in control group, compared to the treatment groups and the difference in response between the control and treatment groups was statistically significant ($P < 0.05$) (Table 5). The response was maximum in the metoprolol group.

Cardiac dysrhythmias seen in 4 of the control group and 1 each in nifedipine and NTG group, but there was no cardiac dysrhythmias in the metoprolol group. Cardiac dysrhythmias were found in the form of sinus tachycardia, premature ventricular contraction, decrease P-R interval (Details of ECG not shown).

Table 4: Mean changes of diastolic BP at different times in various groups

Time	Group 1	Group 2	Group 3	Group 4
Baseline	86.8±5.46	82.0±5.53	86.00±5.64	85.6±5.59
Induction	85.6±5.85	81.6±5.78	86.4±4.97	84.2±5.28
1 min after intubation	94.7±5.76	94.4±5.68	93±5.78	96±5.26
3 min	92.3±5.91	91.83±4.93	92±5.52	92±5.36
5 min	90±5.36	90±5.74	88±5.97	90±5.42
10 min	88±5.92	88±5.26	86±4.85	89±5.36
15 min	86±4.92	83±5.83	84±5.66	87±5.74

BP: Blood pressure

DISCUSSION

Direct laryngoscopy and tracheal intubation cause an increase in BP and HR.[6] This cardiovascular response is supposed to be due to reflex increase in sympathetic response to mechanical stimulation of the larynx and trachea. This leads to an average increase in BP of 40 50%, and a 20% increase in HR.[7] Significant elevations in serum levels of norepinephrine and epinephrine subsequent to the laryngoscopy, with and without tracheal intubation, have been reported.[8-10] The pressor response to laryngoscopy and intubation also increases myocardial oxygen requirement and risk of cerebrovascular accidents, and can also induce cardiac arrhythmias and pulmonary edema.[11-14] In the past, many drugs have been successfully used for attenuation of these responses.[15,16]

The results of the present study shows that all the three drugs are effective in attenuating the cardiovascular response to laryngoscopy and intubation which is in correspondence with other studies which shows a similar type of response.[17-20]

Our study also demonstrates that metoprolol was more effective in normalizing the HR and decreasing the chances of arrhythmia. This could be due to the release of renin from juxtaglomerular apparatus stimulated by the sympathetic system is blocked by metoprolol.[21] Metoprolol also improves the relationship between cardiac oxygen supply and demand.[22]

CONCLUSION

Hence, we concluded that all three drugs *viz.* nifedipine, NTG, and metoprolol, were able to attenuate the rise in pulse rate and BP due to laryngoscopy and intubation but not completely. NTG and metoprolol decreases the severity of tachycardia rise in BP, significantly and less fluctuations, during and after laryngoscopy, and intubation except nifedipine which cause significant tachycardia during laryngoscopy and intubation.

Table 5: Mean changes of pulse rate at different times in various groups

Groups	Baseline	Induction	1 min after intubation	3 min	5 min	10 min	15 min
Group 1	85±7.48	84±7.59	112±7.53	107±7.36	98±7.46	94±7.15	88±7.45
Group 2	86±7.26	78±7.46	98±6.98	92±7.48	92±7.51	88±6.97	86±7.26
Group 3	84±7.34	76±7.79	102±7.28	96±7.25	94±7.53	93±6.98	90±7.18
Group 4	83±7.89	68±7.58	88±7.59	83±7.95	79±7.82	78±6.95	76±7.39

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Original Article

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Predicting Efficacy and Failure Risk of Non-Invasive Positive Pressure Ventilation in Chronic Obstructive Pulmonary Disease Exacerbation through Arterial Blood Gas Analysis

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Abstract

Background: The purpose of this prospective study was to assess the efficacy and likelihood of failure of non-invasive positive pressure ventilation (NPPV) by means of arterial blood gas analysis (ABG) in patients with exacerbation of chronic obstructive pulmonary disease (COPD) which could predict the need for endotracheal intubation to be instituted at the earliest.

Methods: Risk stratification of NPPV failure was assessed in 50 patients admitted at Chest Disease Hospital in Goa Medical College Hospital units, including intensive care units, NPPV was used in all patients with pH between 7.20 and 7.35 at admission. ABG was done on patients come with COPD exacerbation (at admission, after 1 h, and after 6 h of NPPV). The outcome variable was defined as failure of NPPV due to invasive ventilation or death. The aim was to predict the risk of failure using ABG at the earliest to decide whether or not to intubate.

Results: Clear differences were found between the patients who succeeded and those who failed, with respect to the predictor variables observed at admission and after 1 h of NPPV. After 1 h and 6 h of NPPV, the main factor influencing the outcome was the pH value: If pH <7.25, the odds ratio (OR) for failure is 21.02 ($P < 0.0001$), whereas if pH after 1 h is between 7.25 and 7.30, the OR is 2.92 ($P < 0.005$). Chi-square test value for our study population is $\chi^2 = 5.43$ and the $P < 0.05$ and the response obtained with non-invasive ventilation is not by chance.

Conclusions: pH seems to be a very important variable in predicting failure of NPPV, the current authors evaluated that pH <7.25 after 1 h and 6 h of NPPV in a patient admitted with COPD exacerbation predict the failure risk with 100% specificity.

Key words: Intubation, Non-invasive, Pulmonary disease, Respiratory failure, Ventilation

INTRODUCTION

Non-invasive positive pressure ventilation (NPPV), in patients with exacerbations of chronic obstructive pulmonary disease (COPD) and respiratory acidosis, reduces the intubation rate and mortality.[1-9] Operated by well-trained teams, NPPV is effective and safe in both intensive care settings[10] and general respiratory wards.[8] A randomized, clinical trial showed that NPPV also reduces mortality in COPD patients in the intensive care unit (ICU) within the inclusion criteria for intubation.[6] Nevertheless, two recent consensus guidelines on NPPV in acute respiratory failure (ARF) recommend that NPPV should not be used as a substitute for endotracheal intubation and invasive ventilation when the latter is clearly more appropriate.[11,12] The likelihood of failure of NPPV is crucial in deciding if and when to apply this ventilator technique.

The purpose of the current study was to assess the risk of NPPV failure at the earliest with the help of arterial blood gas (ABG) alone and to build a risk chart of failure of NPPV to be used in hospitals.

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METHODS

The study was conducted from period of September 2008 to September 2011. The data were collected from 50 patients affected by COPD exacerbation and respiratory acidosis with pH between 7.20 and 7.35 that were treated by NPPV in addition to standard medical therapy (oxygen supplementation, systemic corticosteroids, inhaled bronchodilators, antibiotics, and diuretics if needed). These patients were admitted to general wards and ICUs where NPPV is the first-line intervention for such patients. The admission criteria for different units were based on the need for an appropriate level of care, but the personnel in each unit were well-trained in the use of NPPV. ABG was done on patients come with COPD exacerbation (at admission, after 1 h, and after 6 h of NPPV). The outcome variable was defined as both success group where patients improved and discharged after NPPV and failure group where patients end up invasive ventilation or death.

The units used NPPV Respironics bi-level positive airway pressure (BiPAP®)|pro 2 via face and/or nasal mask. Every patient who satisfied the criteria with hypercapnic respiratory failure and respiratory acidosis due to exacerbation of COPD was included in the current observational study received NPPV at admission. The definition of COPD exacerbation was in accordance with that of the American Thoracic Society. NPPV failure was defined as the need for endotracheal intubation.

The study used strict inclusion and exclusion criteria to reduce the influence of external factors (Table 1).

Pre-determined Criteria for Endotracheal Intubation Included

1. Worsening of pH and carbon dioxide tension in arterial blood ($PaCO_2$) in spite of correct NPPV administration (e.g. pH ↓0.04 and $PaCO_2$ ↑0.8 kPa, 6 mmHg)
2. The need to protect the airways (coma or seizure disorders) or to manage copious secretions
3. Hemodynamic instability (heart rate, 50 beats/min with loss of alertness, and/or systolic blood pressure, 70 mmHg)
4. Agitation and inability to tolerate the mask.

The following Data were Collected for Every Patient

1. General demographic information (age, sex, weight, and height) and clinical data
2. Data relative to the institution of NPPV, including cause of exacerbation, ABGs (before beginning NPPV, after 1 h, at 6 h, and at discharge), respiratory rate (RR), cardiac frequency, length of stay in hospital, and total hours of ventilation.

Table 1: Inclusion and exclusion criteria

Inclusion criteria
Known case of COPD with supportive or high probability of disease (based on clinical history, smoking history, physical examination, and chest radiography) with Type II respiratory failure
RR >25 breaths/min
Respiratory acidosis with pH between 7.20 and 7.35
PCO_2 >45 mmHg but <75 mmHg
Use of accessory muscles or abdominal paradox
Hemodynamically stable, functional GIT, normal bulbar, and having spontaneous respiratory drive
Exclusion criteria
Patient with PCO_2 of >74 mmHg and severe acidosis of pH <7.20
Recent upper airway or GIT surgery
Fixed upper airway obstruction
Facial trauma
Severe cardiac disease New York Heart Association IV. (Unstable angina, severe cardiac arrhythmias)
Disorders of basal brain nerves/derangement in swallowing or persistent vomiting
Local derangement of face/skin/tongue/upper airway/larynx
Impaired consciousness (GCS <8)
Pneumothorax without ICT
Hemodynamic instability with BP<90 mmHg
HR <60 beats/min
Bronchorrhea (copious secretions)
Pneumonia and other illness which will influence the invasive ventilator requirement

HR: Heart rate, BP: Blood pressure, GCS: Glasgow coma scale, ICT: Insertion of a chest tube, GIT: Gastrointestinal tract, COPD: Chronic obstructive pulmonary disease

Variable Definition and Statistical Analysis

The outcome variable was defined as failure of NPPV due to invasive ventilation or death. Three charts of failure risk were built from the final predictive models obtained using logistic regression; they refer to the proportion predicted to fail with NPPV treatment at admission, 1 h and after 6 h of NPPV. The aim was to predict the risk of failure using ABG at the earliest to decide whether or not to intubate.

RESULTS

A total of 50 patients were recruited and were treated with NPPV for the management of ARF due to COPD exacerbation (Table 2).

NPPV was performed successfully in 46 patients (92%) until the normalization of ABGs. Among the 4 (8%) patients who failed, 2 (4%) patients were intubated and 2 (2%) died without intubation due to a previous "do-not-intubate" order. Among the 2 intubated patients, 1 patient successfully completed the treatment and 1 patient died.

Successful patients had better values of $PaCO_2$, pH, RR, and oxygen arterial tension after 1 h of NPPV compared with patients who failed to improve.

Comparison of ABG Analysis between Success and Failure Group

Comparison of ABG analysis for pH, PCO_2, and SaO_2 were done at baseline, after 1 h and 6 h of BIPAP between success and failure group (Table 3 and Graph 1).

The variables measured that were found to significantly increase the probability of NPPV failure were pH, 7.25 (odds ratio [OR] 51.97, $P = 0.05$), PCO_2 ($P = 0.05$) SaO_2, and RR. After 1 h and 6 h of NPPV, the main factor influencing the outcome was the pH value: If pH <7.25 the OR for failure is 21.02 ($P = 0.0001$), whereas if pH after 1 h is between 7.25 and 7.30, the OR is 2.92 ($P = 0.005$).

Chi-square test value for our study population is $\chi^2 = 5.43$ and the $P < 0.05$ and the response obtained with non-invasive ventilation (NIV) is not by chance. There is a significant association between use of NIV and improvement of the patient with COPD in exacerbation with Type II respiratory failure.

Repeated measures ANOVA test by Greenhouse-Geisser method was used to analyze the data. $P < 0.05$ was taken as statistically significant. Changes occurred in pH, PCO_2, and SaO_2 at 1 h and 6 h after starting the BIPAP had been compared with the same parameters before initiation of BIPAP. The change in pH and PCO_2 after 1 h of starting the NPPV determines the failure risk of NPPV treatment and guides the further course of management.

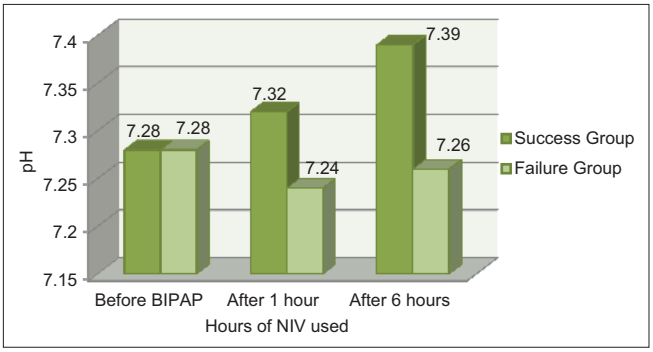
Table 2: Main demographic characteristics at the start of NPPV

Age	Total number	Percentage
51-60	24	48
61-70	21	42
>70	5	10

Table 3: ABG data

Variable	Success group	Failure group	Significance
Before BIPAP			
pH	7.28	7.28	NS
PCO_2	55	57	NS
SaO_2	84	82	NS
After 1 h			
pH	7.32	7.24	S
PCO_2	48	58	S
SaO_2	88	78	S
After 6 h			
pH	7.39	7.26	S
PCO_2	40	58	S
SaO_2	91	80	S

BIPAP: Bi-level positive airway pressure, ABG: Arterial blood gas



Graph 1: pH comparison

DISCUSSION

The author used the data to assess the risk of NPPV failure using at admission, 1 h and after 6 h of ventilation. These values could be used to determine the possibility of failure or success of NPPV in patients with acute decompensate COPD and to help the clinical decision-making process. In particular, given that the Gold Initiative for Chronic Obstructive Lung Disease guidelines suggested an initial trial of NPPV for most patients anyway, the decision to continue or not continue with NPPV can be greatly helped by ABG values obtained after 1 h and 6 h of NIV.[13-20]

The mortality rate in the current study is better than observed in the most quoted controlled trials on NPPV in carefully selected patients with acute exacerbation of COPD.[1-3,5] Data from a multicenter study performed in British respiratory general wards showed that if pH and/or $PaCO_2$ improved after 1-4 h, successful NPPV was probable.

Clear differences were found between the patients who succeeded and those who failed, with respect to the predictor variables observed at admission and after 1 h of treatment.[21-24] In particular, after 1 h of NPPV, the main factor influencing the outcome was the pH value. Since pH seems to be a very important variable in predicting failure of NPPV and there is much discussion about which is the correct cut off to choose, the current authors evaluated that pH <7.25 after 1 h and 6 h predict the failure risk with 100% specificity.[25-27]

CONCLUSION

The efficacy of NPPV in acute exacerbation of COPD is well-documented that international guidelines[28] recommends it as the first choice treatment of ARF with respiratory acidosis. Nevertheless, given that NPPV is used in a variety of care settings, it may be important to know the likelihood of failure of NPPV by means of readily available simple investigation like ABG in patients

with exacerbation of COPD could predict the need for endotracheal intubation to be instituted at the earliest.

Thus, the authors think they could greatly help the decision on clinical management of the patient. Using the ABG alone, it is possible to predict "a priori" the probability of NPPV failure and reduce the useless and prolonged use of NPPV in patients with respiratory acidosis due to COPD exacerbation.

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Original Article

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Role of Multidetector Computerized Axial Tomography in Evaluation of Bronchogenic Carcinoma with Histopathological Correlation

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Abstract

Introduction: The role of imaging ranges from screening for lung cancer in high-risk individuals to staging bronchogenic carcinoma in advanced stages of the disease. Multidetector computed tomography (MDCT) is the modality of choice for evaluating bronchogenic carcinoma. It helps to characterize lung nodules detected by radiography and aids in guided biopsy. This study is aimed at evaluating the imaging characteristics of bronchogenic carcinoma by MDCT with histopathological correlation, its diagnostic accuracy and effectiveness in staging.

Materials and Methods: This is a correlative study. A total of 50 patients with clinical or radiological suspicion of bronchogenic carcinoma referred for CT scan of the thorax to the Department of Radiodiagnosis, K.S. Hegde Medical Academy were taken. The study was carried out from October 2011 to October 2013. Data were collected from 50 cases with suspected bronchogenic carcinoma referred for CT scan of the thorax by purposive sampling using a proforma.

Results: Among the 50 patients included in this study, 10% were females (*n* = 05) and 90% were males (*n* = 45). Hence, we can conclude that the bronchogenic carcinoma has got male preponderance over females. The age distribution of patients with bronchogenic carcinoma in our study is between the age group of <50 and >70 years with a mean age of 60 years. 100% of the patients (*n* = 50) were suspected to have bronchogenic carcinoma on the basis of MDCT evaluation. The histopathological evaluation confirmed the diagnosis of bronchogenic carcinoma in all 100% of the cases.

Conclusion: MDCT has a high positive predictive value suggestive of great diagnostic accuracy in the evaluation of bronchogenic carcinoma. There is significant correlation with the MDCT diagnosis of bronchogenic carcinoma with that of histopathology. MDCT is a useful tool in the staging of bronchogenic carcinoma.

Key words: Bronchogenic carcinoma, Histopathology, Multidetector computed tomography

INTRODUCTION

Before 1900, lung cancers were viewed as "matters of medical curiosity not known to be in any degree influenced by medicine and too rare to be of much practical importance."

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Bronchogenic carcinoma is one of the most common malignant neoplasms all over the world. Deaths due to lung cancer are more than those due to colorectal, breast and prostate cancers put together.[1] The prevention and early diagnosis of lung cancer thus assumes a major public health issue. Bronchogenic carcinoma was considered to be rare in the beginning of the century, but has now reached epidemic proportions. This dramatic increase correlated with the widespread prevalence of cigarette smoking. Bronchogenic carcinoma is the leading cause of cancer deaths in developed countries and is also rising at alarming rates in developing countries.[2] It is increasingly being recognized in India. The prevention and early diagnosis of lung cancer thus assumes a major public health issue.

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Imaging plays a very vital role in the management of patients with lung cancer. The role of imaging ranges from screening for lung cancer in high-risk individuals to staging bronchogenic carcinoma in advanced stages of the disease.[3] Multidetector computed tomography (MDCT) is the modality of choice for evaluating bronchogenic carcinoma.[4,5] It helps to characterize lung nodules detected by radiography and aids in guided biopsy. Most importantly, it accurately stages the tumor because of the superior multiplanar reformatted images and thus helps determine the prognosis. The accurate staging of bronchogenic carcinoma is essential in planning treatment, and it is of crucial prognostic significance.[6] This study was aimed at evaluating the imaging characteristics of bronchogenic carcinoma by MDCT with histopathological correlation, its diagnostic accuracy and effectiveness in staging.

Aims

Aim of the study was:

1. To assess the diagnostic accuracy of MDCT in evaluation of bronchogenic carcinoma
2. To document the various MDCT appearances of bronchogenic carcinoma with histopathological correlation
3. To assess the effectiveness of MDCT in staging bronchogenic carcinoma.

MATERIALS AND METHODS

Source of Data

This is a correlative study. Thirty patients with clinical or radiological suspicion of bronchogenic carcinoma referred for CT scan of the thorax to the Department of Radiodiagnosis, K.S. Hegde Medical Academy was taken. The study was done over a period of 24 months from October 2011 to October 2013.

Method of Collection of Data

Data were collected from 30 cases with suspected bronchogenic carcinoma referred for CT scan of the thorax by purposive sampling using a proforma. All scans are done using GE bright speed 16 slice MDCT with 120 KVp and 300 mAs with 5 mm section thickness, retro reconstruction of 0.625 mm section thickness and reformation. Contrast study is done using 70-80 ml of 350 mg/ml non-ionic iodinated contrast, injected using pressure injector at the rate of 3 ml/s. Sections are taken from the level of lung apices to the diaphragm routinely including the adrenals. Lung lesions are characterized based on the site, size, enhancement pattern, the presence of calcification, cavitation, involvement of the hila, pleura, chest wall or mediastinum. MDCT findings are correlated with histopathological examination of the specimen obtained from fine needle aspiration cytology/biopsy of the lesion.

Inclusion Criteria

1. Patients with clinically or radiologically suspected bronchogenic carcinoma
2. Histopathological correlation is available in patient.

Exclusion Criteria

1. Histopathological correlation is not available in the patient
2. Patients with extra-pulmonary malignancy with lung metastasis.

Technique for CT Study

Patients were kept nil orally 4 h prior to the CT scan to avoid complications while administrating contrast medium. Risks of contrast administration were explained to the patient and consent was obtained prior to the contrast study. Routine anteroposterior topogram of the chest was initially taken in all patients in the supine position with the breath held. Axial sections of 5 mm thickness were taken from the level of lung apices to the diaphragm routinely including the liver and adrenals. In all cases, plain scan was followed by intravenous contrast scan in suspended inspiration. For contrast enhancement, 70-80 ml of 350 mg/ml non-ionic iodinated contrast was injected using pressure injector at the rate of 3-4 ml/s. Sections were taken in arterial (30 s) and portal venous (60-90 s) phases.

Post study retro reconstructions were done at 0.625 mm section thickness. Sagittal and coronal reconstructions were made wherever necessary. Newer techniques in multislice CT like curved planar reformatting, volume rendering, maximum and minimum intensity projections and inversion were done as and when necessary. The scans were reviewed on a direct display console at multiple window settings (i.e. mediastinal window at 350/40; lung window at 1400/600; bone window of 2400/200). The pre and post contrast images were viewed and analyzed by a panel of radiologists.

RESULTS

This study was conducted in the Department of Radiodiagnosis, K.S. Hegde Medical College Hospital, Mangalore from August 2011 to June 2013. The study comprised of a total of 50 patients. Among the 50 patients included in this study, 10% were females (n = 05) and 90% were males (n = 45). Hence, we can conclude that the bronchogenic carcinoma has got male preponderance over

females. The age distribution of patients with bronchogenic carcinoma in our study is between the age group of < 50 and >70 years with a mean age of 60 years. 40% of the patients were in the age group of 50-60 (n = 20), 30% were in the age group of 60-70 (n = 15), 14% were in the age group of more than 70 (n = 7) and 16% were in the age group of <50. Hence, we have observed that bronchogenic carcinoma is more common in the age group of 50-60 years. Of the 50 patients evaluated for bronchogenic carcinoma, 50% patients had patchy ill-defined opacities (n = 25) and 50% patients had larger lesions (n = 25). Hence, it can be concluded that in our study there is an equal distribution of size.

Of the 50 patients evaluated for bronchogenic carcinoma, 44 % patients had right upper lobe opacities (n = 22) and next predominant location of the lesion was left upper lobe with 34% (n = 17) and rest of the lesions elsewhere in the lung parenchyma. Hence, it can be concluded that in our study there is right upper lobe predominance of bronchogenic carcinoma.

In our study, involving 50 patients, 64% of patients had cough (n = 32), 20% patients had loss of appetite (n = 10), 28% patients had dyspnea (n = 14), 8% patients had hemoptysis (n = 4), 34% patients had chest pain (n = 17). Therefore from our study, it is evident that cough, followed by chest pain and dyspnea are the most common symptoms of patients with bronchogenic carcinoma. Our study revealed that 54% of patients had mediastinal lymph nodes (n = 27) and 46% patients did not have mediastinal lymph nodes (n = 23). Hence, mediastinal lymphadenopathy is a finding in patients with bronchogenic carcinoma.

In our study, 100% of patients had lesions which showed heterogenous enhancement on post contrast images (n = 50) and 0% patients had lesions which showed homogenous enhancement on post contrast images (n = 0). Hence, it can be understood that contrast enhancement is a very important feature of bronchogenic carcinoma.

In our study of 50 patients the distribution of various histological types of bronchogenic carcinoma is as follows; 66% of patients had squamous cell carcinoma (n = 33), 28% patients had adenocarcinoma (n = 14), 2% patients had small cell carcinoma (n = 1), 4% patients had undifferentiated large cell carcinoma (n = 2).

Out of the 50 patients included in the study, 100% of the patients (n = 50) were suspected to have bronchogenic carcinoma on the basis of MDCT evaluation. However, the histopathological evaluation confirmed the diagnosis of bronchogenic carcinoma in all 100% (n = 50) of the cases. The positive predictive value of MDCT in evaluating bronchogenic carcinoma is 100% proving that it is indeed a good tool in the evaluation of bronchogenic carcinoma.

In our study 40% of female patients had adenocarcinoma (n = 2), 40% of female patients had squamous cell carcinoma (n = 2) and 20% of female patient had undifferentiated large cell carcinoma (n = 1), 62% of male patients had squamous cell carcinoma (n = 31), 24% of male patients had adenocarcinoma (n = 12), 6% of male patients had small cell carcinoma (n = 3) and 8% of male patients had undifferentiated large cell carcinoma (n = 4). From this, we can conclude that squamous cell carcinoma and adenocarcinoma are seen in female patients, and squamous cell carcinoma is seen more commonly in male patients.

Our study revealed that 70% of squamous cell carcinoma was present in the age group of 50-60 years, 33.3% of adenocarcinoma was present in the age group of 60-70 years, 28.6% of undifferentiated carcinoma was present in the age group of more than 70 years and 12.5% of small cell carcinoma were present in the age group of <50 years. From this we can conclude that adenocarcinoma and squamous cell carcinoma are seen between the age group of 50 and 70 years.

In our study, 58.3% of non-smokers had squamous cell carcinoma (n = 7), 33.3% of non-smokers had adenocarcinoma (n = 4) and 8.3% of non-smokers had undifferentiated large cell carcinoma (n = 1). Among the smokers, 68.4% of them had squamous cell carcinoma (n =26), 26.3% of them had adenocarcinoma (n = 10), 2.6% of them had small cell carcinoma (n = 1) and 2.6% of them had undifferentiated large cell carcinoma (n = 1). Hence, it can be concluded from our study that squamous cell carcinoma is the commonest, irrespective of the smoking history.

In our study, 64% seen in the right upper lobe and 72.7% in left upper lobe segment are squamous cell carcinoma. Adenocarcinoma is also predominantly seen in right upper lobe 66.7.2% of patients with right upper lobe involvement had squamous cell carcinoma (n = 33) and the remaining 33.3% had adenocarcinoma (n = 14). 20% of patients with left upper lobe involvement had adenocarcinoma (n = 08) and 80% had squamous cell carcinoma (n = 2). Chi-square = 2.7, P = 0.811, not significant hence it can be concluded that squamous cell carcinoma presents predominantly in the right upper lobe and left an upper lobe segment of the lung. About 50% of female patients had squamous cell carcinoma (n = 2)

and 50% of the female patients had adenocarcinoma (n = 2). 72% of male patients had squamous cell carcinoma (n = 33) and 28% of male patients had adenocarcinoma (n = 12) Chi-square = 0.854, P = 0.5, not significant. Hence from our study, it is evident that adenocarcinoma and squamous cell carcinoma is equally seen in female patients, and squamous cell carcinoma is more commonly seen in male patients.

Among the non-smokers, 64% had squamous cell carcinoma (n = 7) and the remaining 36% had adenocarcinoma (n = 04). Out of the smokers, 72% had squamous cell carcinoma (n = 26) and 28% had adenocarcinoma (n =10). Chi-square = 0.297, P = 0.7, not significant. Thus, it can be concluded that squamous cell carcinoma commonly affects non-smokers and smokers. Out of the patients who presented with cough, 76% had squamous cell carcinoma (n = 22) and 24% had adenocarcinoma (n = 7). Chi-square = 1.5, P = 0.336, not significant. Cough is a common symptom with patients having squamous cell carcinoma.

DISCUSSION

Bronchogenic carcinoma is a leading cause of death worldwide. Although the underlying etiology for this malignancy is thought to be multifactorial, cigarette smoking is the most important causative factor responsible for at least 85% cancer deaths worldwide. Patients with bronchogenic carcinoma have a poor prognosis with an overall 5 years survival rate of 10-15%. The incidence of lung cancer has seen a steady rise in incidence over the past few years, especially in developing countries like India.[7] In our study, an attempt has been made to ascertain the demographic characteristics, clinical presentation, MDCT characteristics and histological types of bronchogenic carcinoma.

Age Distribution

Bronchogenic carcinoma is seen to be more common in the age group 50-60 years. This is in concordance with studies done by Rawat *et al.*,[8] Karuna and Payal,[9] Krishnamurthy *et al.*[10] and Arora *et al.*[11] The mean age in our study was 55 years which is similar to that found in a study done by Krishnamurthy *et al.*[10] On the contrary, it is slightly less than the mean age seen in studies done by Yousif[12] and Shetty.[7]

Gender Distribution

Male to female ratio is 9:1 in our study (Table 1), which is similar to the study of Rawat *et al*[8] and others.[9-14] In our study, adenocarcinoma and squamous cell carcinoma are equally seen in females and squamous cell carcinoma is more commonly seen in males. This is in concordance with other studies.[10,12,13,15] Cigarette smoking which is a significant etiological factor is probably responsible for the high incidence of bronchogenic carcinoma especially the subtype squamous cell carcinoma in male patients.

Bronchogenic carcinoma is seen more commonly in smokers than non-smokers (Table 2). Similar observations have been reported by other studies. In our study, there is evidence of a strong association between the occurrence of smoking and squamous cell carcinoma. 72% of the smokers were found to have squamous cell carcinoma. Similar results were obtained in the study by Krishnamurthy *et al.*[10] and Arora *et al.*[11]

Cough is the most common presenting complaint among patients in our study (64%) followed by chest pain (34%) and dyspnea (28%). This is in agreement with the study by Arora *et al.* (Table 3). In our study, it was found that majority of the lesions predominantly in the right upper lobe segment (44%). This is in concordance with the study done by Vigg *et al.*[16] here peripheral lesions are found to be more common than central lesions. Our study revealed that squamous cell carcinoma is commonly a right upper lobe lesion (70%) and similar findings were seen in a study done by Shetty.[7] 48% of cases in our study have a lobulated contour which is contrary to the study by Shetty[7] where in most of the lesions had spiculated margins. 6% of our cases showed calcification, which was seen predominantly in patients with squamous cell carcinoma (Table 4). This is in agreement with the study by Shetty.[7] Calcification is associated more commonly with squamous cell carcinoma. 98% of cases in our study showed heterogenous enhancement on post contrast images, which is concordant to the findings in the study by Shetty[7] 54% of patients in our study had metastasis at the time of presentation. This is in concordance with the study by Sukesh *et al.*[17] In our study, the most common site for metastasis was seen to be bones (20%), followed by liver (12%). This is contrary to the study by Dey *et al.*[13] and Shetty.[7] Mediastinal nodal involvement was seen in 54% of cases with bronchogenic carcinoma in our study. Similar findings were seen in studies by Yousif[12] and Shetty.[7] In our study, squamous cell carcinoma was seen to be the most common histological subtype accounting for 66% of cases. This is in concordance with the study by Rawat *et al.*,[8] Prasad *et al.*[18] which revealed that squamous cell carcinoma was the most common histological subtype, followed by adenocarcinoma. However, our findings are contrary to the studies done Devesa *et al.*[19] which showed an increasing trend in the incidence of adenocarcinoma.

Table 1: Comparison of gender distribution between present study and other studies

Gender	Present study	Rawat *et al.*[8]		Krishnamurthy *et al.*[10]	Hassan *et al.*[14]	Yousif[12]	Shetty *et al.*[7]
Male (%)	90	89.2	86	77.5	82.86	71.8	92.5
Female (%)	10	10.8	14	22.5	17.14	28.2	7.5
M:F	9:1	8.2:1	6.1:1	3.5:1	5.5:1	2.5:1	12.5:1

Table 2: Comparison of smoking as an etiological factor between present study and other studies

Personal History	Present study	Dey *et al.*[13]		Arora *et al.*[11]	Yousif[12]	Hassan *et al.*[14]	Shetty[7]
Smokers (%)	76	94	81.6	55	90.2	93.2	92.5
Non-smokers (%)	24	6	17.9	45	6.7	6.8	7.5

Table 3: Comparison of clinical symptoms between present study and other studies

Clinical symptoms (%)	Present study	Rawat *et al.*[8]	Arora *et al.*[11]	Yousif[12]	Hassan *et al.*[14]	Shetty[7]
Cough	64	72.9	92	98.5	89.8	55.5
Chest pain	34	55	52	20.5	62.7	33
Dyspnea	28	50	40	48.2	39	43.2
Hemoptysis	8	25	29	64.1	42.4	-
Loss of appetite	20	56	30	-	47.5	-

Table 4: Comparison of various histopathological types of bronchogenic carcinoma between present study and other studies

Histopathological types (%)	Present study	Rawat *et al.*[8]	Krishnamurthy *et al.*[10]	Hassan *et al.*[14]	Vigg *et al.*[16]	Shetty[7]
Squamous cell carcinoma	66	44.8	15.6	66	50	44.4
Adenocarcinoma	28	19.7	42.6	25.4	45	18.5
Small cell carcinoma	2	16.75	13.2	3.4	30	17.2
Undifferentiated large cell carcinoma	4	8.3	2.3	3.4	5	9.8
Others	0	10.3	7	1.7	-	8.4

CONCLUSION

MDCT has a high positive predictive value suggestive of great diagnostic accuracy in the evaluation of bronchogenic carcinoma. There is significant correlation with the MDCT diagnosis of bronchogenic carcinoma with that of histopathology. MDCT is a useful tool in the staging of bronchogenic carcinoma.

LIMITATIONS

Inter-observer variation as a single radiologist did not review all cases. Patients with bronchoalveolar carcinoma could not be accurately staged due to multifocal involvement which was seen in our cases. MDCT cannot precisely distinguish between reactive hyperplasia and metastatic mediastinal lymphadenopathy.

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Original Article

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Buccal Midazolam versus Intravenous Diazepam in Prolonged Seizures in Children

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Abstract

Background: Seizure episode is a common neurological emergency carrying high morbidity and mortality. It has been shown that prompt treatment of episodes of seizure at home results in need of fewer drugs at hospital and quicker control of the seizure/seizure episodes. Buccal midazolam can be recommended as an alternative to intravenous (I/V) diazepam (DZ) as first choice in situations of difficulty in getting I/V access.

Materials and Methods: Design: Prospective randomized controlled study. Setting: Conducted in the Department of Pediatrics, Government Medical College and Hospital, Amritsar, during the period from January 2009 to December 2009. Total 100 (59 boys, 41 girls) patients were enrolled in the study. In the study group (BMDZ), patients received buccal midazolam (0.3 mg/kg/dose) and in control group (IVDZ), patient received I/V DZ (0.2 mg/kg/dose).

Results: In BMDZ group, 48 (96%) cases of seizures were aborted by giving buccal midazolam and in IVDZ group also an equal number, i.e., 48 (96%) cases of seizures were aborted by giving DZ intravenously ($P > 0.05$). The mean time needed for cessation of seizures in BMDZ group was 96.0 ± 144.69 s (1.60 min) with the lowest time being 30 s and the highest being 790 s, and it was 83.40 ± 124.27 s (1.39 min) in IVDZ group with the lowest being 30 s and the highest being 685 s. The difference in time taken to control seizures between two groups was statistically insignificant ($P = 0.641$). No significant side effects were seen in either group.

Conclusions: It is concluded from the above study that buccal midazolam is equally effective and more convenient as compared to I/V DZ in prolonged seizures while both are comparable in safety.

Key words: Buccal, Diazepam, Efficacy, Intravenous, Midazolam, Prolonged, Seizures

INTRODUCTION

Seizure episode is a common neurological emergency. Because the duration of seizure activity impacts morbidity and mortality, effective methods for seizure control should be instituted as soon as possible, preferably at home.[1]

Seizures continuing beyond 5 min have the potential of progressing into full blown status epilepticus. The potential of neuronal damage and sequelae of status epilepticus are well-known,[2-5] and intervention has been suggested for continuous seizure activity lasting more than 5 min.[6]

The longer a seizure endures, the more likely the development of pharmacoresistance[7] and animal studies suggest a greater likelihood of neuronal damage.[8] As a result, an operational definition of a seizure or intermittent seizures without full recovery of consciousness lasting more than 5 min is used as a guide for intervention.[9]

The value of early treatment in seizures in reducing seizure-related morbidity has been established.[10,11] It has also been shown that prompt treatment of episodes of seizure at home results in need of fewer drugs at hospital and quicker control of the seizure/seizure episodes.[12] The persistence of seizures longer makes it difficult to stop. Stoppage of seizure was 80% when first-line antiepileptic drug was started <2 h and was 40% when treatment was started after 2 h.[13]

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Traditionally, benzodiazepines, barbiturates, or other anticonvulsants have been given intravenously. The main problem in the management of a child actively showing seizure is the delay in reaching a hospital and gaining an intravenous (I/V) access. Rectal diazepam (DZ) offers an alternate method of delivery but has much lower peak concentration, a slower onset of action, less socially acceptable than other routes. Other drugs are associated with known side-effects.

In acute medicine, midazolam has become more popular than other benzodiazepines such as DZ because it is shorter lasting, early onset of action, is more potent, and causes less pain at the injection site. This benzodiazepine that contains an imidazole ring is highly water soluble and is rapidly absorbed from rectal, nasal and buccal mucosa, and is also highly lipophilic at central nervous system.[14-17] When given via buccal route, it is absorbed rapidly with minimal side effects, offers ease of administration, can be given at home by parents/guardians and is socially more acceptable with no delay in the initiation of the emergency treatment. No clinically important side effects were seen in any patient when it was used. Intranasal midazolam has been used at some centers, but it cannot be used in patients with nasal blockage, anatomical abnormalities of the nose, nasal secretions, nasal allergy, etc.

Benefits of Buccal Drug Delivery

To compare with existing available therapies, buccal drug delivery products offer comfort, convenience and control for those who use them - patients, their caregivers, physicians, emergency care workers, and other healthcare professionals are simple and easy to administer are non-invasive, and virtually pain free reduce irritation as they are preservative-free, avoid bio-hazardous waste or needle stick accident risks, demonstrate rapid onset of action and efficient absorption.

Keeping in view the benefits of using buccal midazolam, and use of I/V DZ as the first line treatment to abort seizures in our hospital, we have compared buccal midazolam with I/V DZ.

MATERIALS AND METHODS

The aim of the study was to compare the efficacy of buccal midazolam and I/V DZ in children aged 1 month and over with seizures lasting more than 5 min. This was a prospective randomized controlled study which was conducted in the Department of Pediatrics, Government Medical College and Hospital, Amritsar, Punjab, India during the period, from January 2009 to December 2009. Approval from the Ethics Committee was taken prior to the study. Informed written consent from the parent/guardian was obtained. Efficacy is defined as cessation of seizures within 10 min of administration of the drug and no recurrence in the subsequent 1 h.

Inclusion Criteria

1. Prolonged seizures of more than 5 min duration
2. In children aged 1 month and over.

Exclusion Criteria

1. Patients who have already received I/V benzodiazepine/midazolam in last 24 h.

About 120 patients were included in the study. Of 120 patients 14 did not fill the inclusion criteria, 6 patients did not agree to participate. Hence, total 100 (59 boys, 41 girls) patients were enrolled in the study.

The weight of all the patients was recorded prior to drug administration. In the study group (BMDZ) (Group 1), patients received buccal midazolam (0.3 mg/kg/dose) and in control group (IVDZ) (Group 2), patient received I/V DZ (0.2 mg/kg/dose).

Method used to Administer Buccal Midazolam (0.3 mg/kg/dose)

After opening the midazolam vial (1 mg/ml), a prescribed amount of midazolam was drawn into the syringe. The syringe was taken out of the vial, and the needle was dislodged. The child was placed in the recovery position, and mouth was opened gently by holding chin and applying downward pressure on the lower lip. Any excess saliva was wiped away (without parting the teeth). The nozzle of the syringe was placed between the lower gum and cheek on one side of the mouth (the buccal cavity). The dose was given slowly into the mouth; then the syringe was removed, and lips were closed together. The cheeks were then rubbed on the outside. Midazolam can be given on either side, or both divided approximately into half each side. Midazolam was not given too quickly to avoid choking or swallowing it. The child was maintained in the recovery position. Using a stopwatch, the time taken to control the seizures was noted.

In case, if seizures were not controlled within 10 min of using the drug (buccal midazolam or I/V DZ), then I/V DZ and/or other anticonvulsant drugs (I/V phenobarbitone or phenytoin – as per the protocol) were used to control seizures. Patients in whom seizures recurred within 1 h of cessation of seizures were called as non-responders and received I/V DZ and/or other anticonvulsant drugs (as per the protocol) to control seizures.

Patient's vitals (heart rate, respiratory rate, blood pressure, and hemoglobin oxygen saturation) were monitored continuously and recorded at 0 min, 5 min, 10 min, 15 min,

20 min, 40 min, and 60 min after the drug administration. Children with seizures received routine life support on admission to hospital. During seizure activity, high flow oxygen was provided through a mask. The control group (IVDZ) with the same indication was given I/V DZ at the dose of 0.2 mg/kg/dose @ 1 mg/min.

Statistical Analyses

The following methods of statistical analysis have been used in this study. Data were entered in Microsoft Excel and analyzed using SPSS (Statistical Package for Social Science, Ver. 10.0.5) package.

The results were averaged (mean + standard deviation) for continuous data and the number and percentage of dichotomous data. The proportions were compared using Chi-square (χ^2) test of significance. The proportion of cases belonging to a specific group of the parameter or having a particular problem was expressed in absolute number and percentage. The Student's *t*-test was used to determine whether there was a statistical difference between groups in the parameters measured if the data is normal. A non-parametric test (distribution-free) used to compare two independent groups of sampled data. The test $P < 0.05$ was accepted.

RESULTS

As shown in Table 1, the mean age of patients in BMDZ group was 33.22 ± 39.37 months. In IVDZ group, the mean age of patients was 42.93 ± 49.69 months. It was observed that majority of cases were in age group 1 month to 1 year (47%) and in age group 1-5 years (33%), which means a total of 80% children were having seizures before the age of 5 years, and 20% were having seizures in age group of 5 years and above. However, both groups were comparable with respect to the mean age of cases ($P > 0.281$).

The mean weight of patients in BMDZ group was 11.42 ± 8.16 kg while that in IVDZ group was 13.07±10.50 kg, and the weight in both groups was comparable ($P = 0.382$).

There were 29 males (58%) and 21 females (42%) in group 1 and group 2, 30 males (60%) and 20 females (40%) were present. On applying statistical test (Chi-square), it was observed that both the groups were comparable with respect to sex distribution ($P > 0.05$).

Nearly, 51 cases (24 in BMDZ group and 27 in IVDZ group) had seizures of 5-10 min duration while 49 cases (26 in BMDZ group and 23 in IVDZ group) had seizures of >10 min duration. Patients in BMDZ group presented with seizures of mean duration 13.00 ± 4.94 min while in IVDZ group; it was 12.58 ± 4.72 min, and the difference between them was statistically not significant ($P > 0.05$).

Table 1: Buccal midazolam versus I/V DZ

Route/drug	Buccal midazolam	I/V DZ
Age (mean) (months)	33.22±39.37	42.93±49.69
Weight (kg) (mean±standard deviation)	11.42±8.16	13.07±10.50
Mean duration of seizures (minutes)	13.00±4.94	12.58±4.72
Number of seizures aborted	48	48
Time to control seizures (mean±standard deviation) (seconds)	96.00±144.69	83.40±124.27

I/V DZ: Intravenous diazepam

About 79 (38 in BMDZ group and 41 in IVDZ group) patients had generalized tonic-clonic seizures, 13 (9 in BMDZ group and 4 in IVDZ group) cases had clonic seizures, 7 (2 in BMDZ group and 5 in IVDZ group) cases had partial seizures, and only 1 case had tonic seizures in BMDZ group. The difference between the distribution of cases according to the type of seizures among two groups was statistically not significant ($P = 0.229$).

In both the groups, the response of only the last seizure episode which occurred in the hospital was treated, and the response was observed. While comparing the history of a number of episodes in each group, the difference was found to be statistically insignificant ($P > 0.05$).

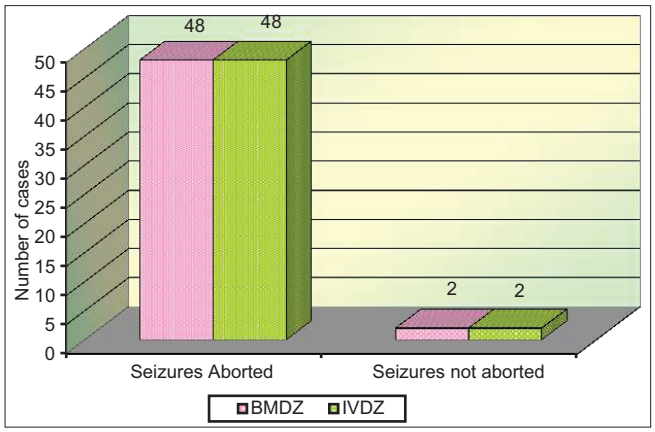
In BMDZ group, 48 (96%) cases of seizures were aborted by giving buccal midazolam and in IVDZ group also an equal number, i.e., 48 (96%) cases of seizures were aborted (Graph 1) by giving DZ intravenously ($P > 0.05$).

The mean time needed for cessation of seizures in BMDZ group (Graph 2) was 96.0 ± 144.69 s (1.60 min) with the lowest time being 30 s and the highest being 790 s, and it was 83.40 ± 124.27 s (1.39 min) in IVDZ group with the lowest being 30 s and the highest being 685 s. The difference in time taken to control seizures between two groups was statistically insignificant ($P = 0.641$).

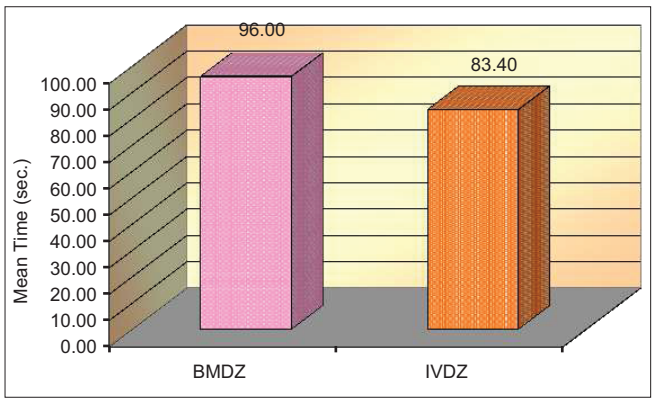
In the groups, two cases each required administration of I/V DZ to control seizures as seizures were not controlled within 10 min of the drug administration. In none of the cases in both groups seizures recurred in the subsequent 1 h. The distribution of cases, according to the diagnoses is shown in Table 2.

DISCUSSION

In this study, 48 (96%) seizures were aborted by buccal midazolam and 48 (96%) seizures were also aborted by I/V DZ. Talukdar *et al.*,[18] selected 60 cases in each group,



Graph 1: Distribution of cases according to seizures aborted



Graph 2: Comparison of mean time taken for cessation of seizures after administration of the drug in two groups

Table 2: Distribution of cases according to diagnosis

Diagnosis	BMDZ		IVDZ		Total	
	No.	%	No.	%	No.	%
Seizure disorder	15	30.00	11	22.00	26	26.00
Febrile seizure	10	20.00	8	16.00	18	18.00
Meningitis	10	20.00	14	28.00	24	24.00
Encephalitis	4	8.00	4	8.00	8	8.00
Neurocysticercosis	1	2.00	4	8.00	5	5.00
MRCP	8	16.00	7	14.00	15	15.00
Others	2	4.00	2	4.00	4	4.00
Total	50	100.0	50	100.0	100	100.00

MRCP: Mental retardation cerebral palsy, IVDZ: Intravenous diazepam

51 out of 60 (85%) seizures were aborted by buccal midazolam and 56 out of 60 (93.3%) by I/V DZ. In a study by Ashrafi *et al.*,[19] who studied 49 cases each on rectal DZ and buccal midazolam, 49% seizures were aborted by rectal DZ within 4 min of drug administration and 88% by buccal midazolam. Kutlu *et al.*[20] studied 19 patients, 84.2% seizures were aborted by buccal midazolam. In a randomized clinical trial by Tonekaboni *et al.*,[21] 92 patients with acute seizures, ranging from 6 months to 14 years, were randomly assigned to receive either buccal midazolam (32 cases) or I/V DZ (60 cases) at the emergency department of a children's hospital. In the midazolam group, 22 (68.8%) patients were relieved from seizures in 10 min. Meanwhile, DZ controlled the episodes of 42 (70%) patients within 10 min. The difference was, however, not statistically significant (P=0.9). In another study by Garnock *et al.*,[22] the time to response was longer with oromucosal midazolam than with I/V DZ, the latter took significantly longer to apply than the former, leading to a significantly shorter overall controlling time with oromucosal midazolam.

In our study, mean time taken by drug, from its administration to cessation of seizures in BMDZ group was 96.00 ± 144.69 s (1.60 min), and it was 83.40 ± 124.27 s (1.39 min) in DZ group. In the study by Talukdar *et al.*,[18] mean time for control of seizures after starting treatment in midazolam group was 1.69 min and 1.13 min in DZ, not counting the time to insert the I/V line. Both studies showed that buccal midazolam was as safe and effective as I/V DZ.

In the present study, it was observed that the mean time taken from receiving patient at hospital to starting treatment was shorter in midazolam group while it was longer in IVDZ group as already prepared solution of midazolam was used, and it did not require extra time for administration. It was also observed that the total time taken by IVDZ group from receiving patient to cessation of seizures was more, than total time taken by buccal midazolam since more than 2 min time was taken for establishment of I/V access in children with seizures. Tonekaboni *et al.*[21] also proved that buccal midazolam is as effective as and safer than I/V DZ in control of seizures.

Buccal midazolam was used in a dose of 0.3 mg/kg in the present study. It is similar to the dose used by Kutlu *et al.*[20] Scott *et al.*[23] used a fixed dose of 5-10 mg and McIntyre *et al.*[24] used 0.5 mg/kg. Talukdar *et al.*[18] used a lower dose of 0.2 mg/kg. Muchohi *et al.*[25] used midazolam at the currently recommended dose (0.3 mg/kg). It was found out that buccal midazolam was safe, there being no significant side effects especially cardio-respiratory that is most worrisome, similar to observations by other studies. Only two cases in each group required administration of I/V DZ to control seizures as it was not controlled within 10 min of drug administration. No serious adverse reaction was observed in both groups. Both Kutlu *et al.*[20] and Melendez *et al.*[26] reported no adverse cardio-respiratory effects in their series of patients. There was no recurrence of seizures in the subsequent 1 h in both the group. Buccal drug delivery is a promising area for continued research with the aim of systemic delivery of orally inefficient drugs.

CONCLUSION

It is concluded from the above study that buccal midazolam is equally effective and more convenient as compared to I/V DZ in prolonged seizures while both are comparable in safety.

Given the ease of administration of buccal midazolam and the results of present study, we recommend the use of buccal midazolam for the hospital/home treatment of prolonged seizures especially when establishing an I/V line becomes difficult and also in the periphery where skilled personnel may not be easily available and transport of the child to a well-equipped center might take time.

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Original Article

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Prevalence and Associated Factors of Tobacco Smoking among Undergraduate Medical and Dental Students in Rajasthan

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Abstract

Introduction: Tobacco smoking is one of the biggest public health problem as well as leading cause of preventable deaths worldwide. It is a common phenomenon among youth, and medical and dental students are also not sparing of it. It not only reduces their work efficiency at present but also increase their disability-adjusted life years in the long run. It may also threaten their professional efficacy to provide adequate patient care and put a negative impact on society as a doctor should be a role model for healthy lifestyle.

Aim: The main object of the study was to assess the prevalence of tobacco smoking and associated factors among medical and dental undergraduate students.

Materials and Methods: It was a descriptive cross-sectional survey, which was conducted in a private medical university in Rajasthan. A pre-structured and pre-tested questionnaire was administered to undergraduate medical and dental students after ethical approval. All the undergraduate students of medical and dental fraternity present on the day of survey and gave consent were included in the study.

Results: The overall prevalence rates of lifetime and current smoking were found to be 20.20% (39.05% among males and 7% among females) and 12.94% (25.24% among males and 4.33% among females), respectively. Individual and family characteristics of study subjects like age, sex, place of residence, fraternity, type of family, and socioeconomic status were significantly associated with habit of smoking ($P < 0.05$), while religion and caste were found to not be significant factors of smoking among students ($P > 0.05$).

Conclusion: The prevalence of tobacco smoking among undergraduate medical and dental students was unacceptably high. Hence, it needs proper education and counseling of students to minimize or eliminate smoking habit in institutions of higher education.

Key words: Dental students, Medical students, Prevalence, Smoking, Tobacco

INTRODUCTION

The tobacco epidemic is one of the leading causes of preventable deaths and is a major public health issue worldwide. The harmful consequences of smoking on health are well-documented. In every 6.5 s someone dies from tobacco use. Research suggests that people who start smoking in their teens (as more than 70% do) and continue for two decades or more will die 20-25 years earlier than those who never smoked. It is not just lung cancer or heart disease that causes serious health problems and death; there are some less publicized side effects of smoking like, psoriasis, cataract, hearing loss, tooth decay, chronic pulmonary obstructive diseases, osteoporosis, stomach ulcers, discolored fingers, deformed sperms, and Buerger's disease.[1]

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Health risks due to smoking result not only from direct consumption of tobacco but also from exposure to second-hand smoke. It was estimated that about six million people were dying annually from tobacco use and over 600,000 deaths due to exposure to second-hand smoke.[2] In 2012, the global prevalence of current tobacco smoking among adults was estimated at around 22%, with smoking rates varying widely across. Smoking prevalence in both high-income and upper-middle-income countries is broadly similar, although slightly higher in high-income countries at 25% and middle-income countries at 22%.[3]

In India, prevalence of current tobacco smoking among youth has been estimated as 14.60% (19% in males and 8.3% in females), while among adults the prevalence of current tobacco smoking has been estimated as 14% (24.3% in males and 2.9% in females).[4] Some earlier studies showed the prevalence of smoking as 9% in undergraduate and 7.1% in post-graduate medical students in India.[5,6]

This study aimed to estimate the prevalence of smoking among medical and dental students at a private medical university in Jaipur, Rajasthan (India) and assess the association between smoking and socio-demographic factors, reasons for smoking and attempts to stop smoking.

MATERIALS AND METHODS

This was a descriptive cross-sectional study, conducted in March-April 2015 among medical and dental undergraduate students of Mahatma Gandhi University of Medical Sciences and Technology, Jaipur, Rajasthan. A sample size was calculated considering the prevalence of substance abuse among medical students as 45.87% from a recent study by Padhy *et al.*[7] in Bhubaneswar, Orissa. With alpha as 0.05 and an error margin as 4.58%, the appropriate sample size was 475.

A pre-structured, pre-tested questionnaire was used to collect information. After obtaining ethical clearance from the Institutional Ethics Committee, all undergraduate medical and dental students of the university were invited to participate in the study. Informed consent was obtained, and all possible measures were taken to ensure the confidentiality of the participants. The questionnaire were distributed and then collected by the data collection team.

Inclusion Criteria

All undergraduate students of medical and dental fraternity who were present on the day of data collection and gave valid consent were included.

Exclusion Criteria

Undergraduate students of medical and dental fraternity who were absent on the day of data collection or did not give valid consent were excluded from the study.

Statistical Analysis

The data obtained were entered on Microsoft Excel 2010 spreadsheets and analyzed. The results were presented in Tables 1-6, and Chi-square test was used for finding the association. A $P < 0.05$ was considered to be statistically significant.

RESULTS

A total of 510 respondents (370 from medical fraternity and 140 from dental fraternity) were participated in the study, out of them 210 (41.18%) were males and 300 (58.82%) were females. The prevalence of lifetime tobacco smoking was found to be 20.20% (39.05% among males and 7% among females; 23.24% among medical undergraduates and 12.14% among dental undergraduates), while prevalence of current tobacco smoking found to be 12.94% (25.24% among males and 4.33 % among females; 15.14% among medical undergraduates and 7.14% among dental undergraduates) (Tables 1 and 2).

Table 3 shows the association of individual and family characteristics of the respondents with the tobacco smoking. It was found that age, sex, place of residence, fraternity, type of family, and socioeconomic status were significantly associated with habit of smoking ($P <0.05$), while religion and caste were found not to be associated significantly ($P > 0.05$). The habit of smoking found more common with the advancement of age. Students in the age group <20 years had a lower prevalence of current

Table 1: Sex-wise prevalence of tobacco smoking among respondents

Sex	*n* (%)	
	Lifetime smoking	Current smoking
Male	82 (39.05)	53 (25.24)
Female	21 (7.00)	13 (4.33)
Total	103 (20.20)	66 (12.94)

Table 2: Faculty-wise prevalence of tobacco smoking among respondents

Fraternity	*n* (%)	
	Lifetime smoking	Current smoking
Medical	86 (23.24)	56 (15.14)
Dental	17 (12.14)	10 (7.14)
Total	103 (20.20)	66 (12.94)

Table 3: Determinants of smoking: Individual and family characteristics

Variables	*n* (%)			Chi-square (df)	*P* value
	Yes	No	Total		
Age					
<20 years	12 (8.05)	137 (91.95)	149 (100)	14.863 (2)	0.000
21-25 years	39 (12.62)	270 (87.38)	309 (100)		
26-30 years	15 (28.85)	37 (71.15)	52 (100)		
Sex					
Male	53 (25.24)	157 (74.76)	210 (100)	46.078 (1)	0.000
Female	13 (4.33)	287 (95.67)	300 (100)		
Place of residence					
Hosteller	45 (15.57)	244 (84.43)	289 (100)	11.546 (2)	0.003
Day scholar with parents	10 (5.99)	157 (94.01)	167 (100)		
Day scholar at rented room	11 (20.37)	343 (79.63)	54 (100)		
Fraternity					
Medical	56 (15.14)	314 (84.86)	370 (100)	5.071 (1)	0.024
Dental	10 (7.14)	130 (92.86)	140 (100)		
Religion					
Hindu	52 (12.65)	359 (87.35)	411 (100)	0.158 (2)	0.954
Muslim	6 (14.29)	36 (85.71)	42 (100)		
Others	8 (14.04)	49 (85.96)	57 (100)		
Caste					
General	42 (14.43)	249 (85.57)	291 (100)	1.738 (2)	0.419
OBC	18 (11.92)	133 (88.08)	151 (100)		
SC ST	6 (8.82)	62 (91.18)	68 (100)		
Type of family					
Nuclear	37 (9.92)	336 (90.08)	373 (100)	10.276 (1)	0.001
Joint	29 (21.17)	108 (78.83)	137 (100)		
Socioeconomic status of family					
Upper	11 (27.50)	29 (72.50)	40 (100)	11.320 (4)	0.023
Upper lower	19 (16.10)	99 (83.90)	118 (100)		
Middle upper	22 (10.48)	188 (89.52)	210 (100)		
Middle lower	9 (8.74)	94 (91.26)	103 (100)		
Lower	5 (12.82)	34 (87.18)	39 (100)		

smoking of 8.05%, in comparison to 21-25 years age group (12.62%) and 26-30 years age group (28.85%). The prevalence of current smoking was significantly higher among males (25.24%) in comparison to females (4.33%). It was also higher (20.37%) among day scholars who were residing at a rented room in comparison to hostellers (15.57%) and day scholars who were living with parents (5.99%). The prevalence of current smoking was twice more common among medical undergraduates (15.14%) than dental undergraduates (7.14%). The smoking was more common among students of joint families (21.17%) in comparison to nuclear families (9.92%). The prevalence of current smoking was higher among students who belonged to upper class (27.50%) and upper lower class (16.10%) followed by lower class (12.82%), middle upper class (10.48%), and middle lower class (8.74%).

Cigarette (81.82%) was the most common form of tobacco smoke used by respondents followed by hukka (22.73%) and bidi (6.06%). About 15.15% of students were using other forms of tobacco smoke (Table 4).

Table 4: Types of tobacco smoking used for consumption

Types of smoking*	*n* (%)
Cigarette	54 (81.82)
Bidi	4 (6.06)
Hukka	15 (22.73)
Other	10 (15.15)

*Multiple responses

The present study revealed that among current smokers 46.97% of students smoke daily or almost daily, while 53.03% students smoke sometimes. Duration of smoking was found <1-year among 43.94% of current smokers, while it was 1-5 years among 48.48% and 6-10 years among 7.58% of current smokers. It was observed from the present study that 19.70% current smokers started to smoke between 12 and 18 years of age, while rest (80.30%) started to smoke after 18 years of age. The most common reason of smoking was found "for fun" (37.88%), followed by peer pressure (30.30%), to relieve tension (18.18%), and to show off (13.64%). Highest numbers of smokers were inspired from friends (59.09%), 22.73% self-inspired, 12.12% inspired from celebrities, and 6.06% inspired from parents and other family members. It was an important finding of this study that 100% students, who smoke were

aware of harmful effects of tobacco smoking and majority of them (68.18%) got this knowledge from electronic media followed by newspaper (42.42%), other sources (31.82%), and friends (24.24%). Among current smokers, only 36.36% wanted to quit smoking, while others felt that they were not addicted to it. The study showed that 21.21% users expend more than 500 rupees per month on smoking, 39.39% users expend Rs. 201-500, 25.76% users expend Rs. 101-200 and 13.64% users expend <Rs. 100 per month. Source of money was pocket money among 62.12% of smokers, from friends in 18.18% smokers and from other sources in 19.70% of smokers (Table 5).

It was observed from the present study that among non-smokers 3.15% students quitted smoking and 5.18% students tried but not started to smoke, while 91.67% students never tried the tobacco smoke. Among those who quitted 64.29% students quitted before 1-year of use, while the rest (35.71%) quitted between 1 and 5 years of use. Among non-smokers, it was found that 59.91% students did not smoke due to their belief that smoking adversely affects health, while 17.79% believed that tobacco smoke was not a good thing. About 6.53% students were not smoking due to family and society factors and 4.28% due to lack of money. Among non-users only 2.70% students wanted to smoke in the future while, 22.07% did not sure about the use of tobacco smoke in future (Table 6).

DISCUSSION

In the present study, prevalence of lifetime and current tobacco smoking among undergraduate medical students was found to be 23.24% and 15.14%, respectively, which was much lower when compared with earlier foreign studies among medical students like, Zhu *et al.*[8] in China (lifetime smoking 53.9% and current smoking 26.8%), Al-Kaabba *et al.*[9] in Riyadh, Saudi Arabia (lifetime smoking 39.8% and current smoking 17.6%), Chkhaidze *et al.*[10] in Georgia (lifetime smoking 49.5%), and an Indian study by Padhy *et al.*[7] in Bhubaneswar, Orissa (lifetime smoking 45.87%). Our study showed higher prevalence of smoking among medical students as compared to earlier studies in India like, Ramakrishna *et al.*[5] in Orissa (lifetime smoking 9.8% and current smoking 3.7%), Rai *et al.*[11] conducted during an inter-state cultural event (Pulse 2003) at AIIMS Delhi (lifetime smoking 20.9% and current smoking 5.3%), and a multi-centric study by Goel *et al.*,[12] where they found overall smoking prevalence of 8%.

In the present study, prevalence of lifetime and current tobacco smoking among undergraduate dental students was found to be 12.14% and 7.14%, respectively, which was also much lower when compared with earlier studies among

Table 5: Distribution of smokers according to their habits

Characteristic	*n* (%)
Frequency of smoking	
Daily or almost daily	31 (46.97)
Sometimes	35 (53.03)
Duration of smoking	
<1 years	29 (43.94)
1-5 years	32 (48.48)
6-10 years	5 (7.58)
Age at which start smoking	
12-18 years	13 (19.70)
>18 years	53 (80.30)
Reason of smoking	
Peer pressure	20 (30.30)
For fun	25 (37.88)
To show off	9 (13.64)
To relieve tension	12 (18.18)
Inspired from	
Friends	39 (59.09)
Parents other family members	4 (6.06)
Self	15 (22.73)
Celebrities	8 (12.12)
Are you aware of harmful effect of smoking?	
Yes	66 (100.00)
Source of knowledge*	
Newspaper	28 (42.42)
Electronic media	45 (68.18)
Friends	16 (24.24)
Other	21 (31.82)
Do you want to quit smoking?	
Yes	24 (36.36)
No	42 (63.64)
Monthly expenditure on smoking	
Rs. <100	9 (13.64)
Rs. 101-200	17 (25.76)
Rs. 201-500	26 (39.39)
Rs. >500	14 (21.21)
Source of money	
Pocket money	41 (62.12)
Friends	12 (18.18)
Others	13 (19.70)

*Multiple responses

Table 6: Distribution of non-smokers according to their habits

Characteristic	*n* (%)
Past history of smoking	
Quitted	14 (3.15)
Tried but not started	23 (5.18)
Never tried	407 (91.67)
Duration of smoking before quitting	
<1 year	9 (64.29)
1-5 years	5 (35.71)
Reason for not smoking	
Due to some disease	51 (11.49)
Lack of money	19 (4.28)
Due to family and society	29 (6.53)
Not a good thing	79 (17.79)
It adversely affect health	266 (59.91)
Would you like to smoke in future?	
Yes	12 (2.70)
No	334 (75.23)
Don't know	98 (22.07)

dental students like, Fotedar *et al.*[13] in Himachal Pradesh (lifetime smoking 15.1% and current smoking 9.09%) and Singh *et al.*[14] in Jaipur, Rajasthan (lifetime smoking 25.11%).

In our study, it was found that males had higher (5.8 times) prevalence of current smoking as compared to females. Similar results were found in earlier studies conducted in India.[5,7,11,14] Our study revealed that religion and caste were not significantly associated with the smoking habit though these factors were not analyzed in previous studies. Prevalence of smoking was found more among medical undergraduates as compared to dental undergraduates. This might be due to female predominance in a dental fraternity.

Prevalence of smoking was found more among those students who were not living with their parents. This reflected that social and family values play a potential role in the development of smoking habit among youth. Similar findings were observed by Padhy *et al.*[7] in their study. Prevalence of smoking was more among students of joint families. This might be due to close attention on children in nuclear families. Similar findings were observed by Padhy *et al.*[7] in Bhubaneswar, Orissa.

It was observed in the present study that the prevalence of smoking was more among students from more affluent social class and lower social class. Students from middle class less likely involved in smoking habits. This might be due to more concern of money and lack of freedom in middle class.

Although the majority of students started smoking after attainment of 18 years of age, but some of them started between 12 and 18 years of age, which was alarming to policy makers. It means that the anti-smoking campaigns must start at schools to eliminate smoking among students. The most common reason reported for smoking was "for fun," which showed negligence toward self-health. Another reason was "peer pressure" which was also a reason of relapse for most of those who wanted to quit. More than half of smokers were inspired from their friends. Hence, antismoke campaign for behavior change should be focused on small groups instead of the individual student.

Our study showed that the majority of the smokers did not want to quit smoking due to the belief that they were not addicted to it, although all were aware of harmful effects of tobacco smoke. They got this knowledge largely from electronic and print media. The majority of smokers expend Rs. 100-500 per month and the main source of money was pocket money.

CONCLUSION

It is clear from this study that too many medical and dental students continue to use tobacco smoking. Keeping in view their important role in future, some preventive measures should be applied to eliminate smoking among future to-be doctors and health policy makers. Hence, it is suggested that smoking prevention programs or campaigns should be implemented in institutes of higher education as a first step for getting them involved in smoking cessation.

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Original Article

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Pattern of Co-Morbidities in Multiple Chronic Diseases in Children

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Abstract

Introduction: In adult the magnitude of chronic disease is studied before many times but a little is known about the multiple chronic conditions in the children. Our study shows the prevalence and pattern of chronic diseases and co-morbidities in children.

Materials and Methods: Subject identified with the chronic disease, came to the hospital in January 2014 to December 2014, were analyzed. The relationship between urgent health care and co-morbidities is analyzed using logistic regression.

Results: From the study, more than 80% children had a single chronic condition and more than 19% children had two or more chronic conditions, in which asthma with allergic rhinitis was more prevalent. It is clear that as the number of chronic condition increases in the child, they need significant health care. The children with >4 chronic conditions had 3.57 times the odds of a significance as compared with those children having one chronic disease ($P < 0.0001$).

Conclusion: Study showed that the increase in the number of chronic conditions in children were associated with greater risk of mortality and morbidity and needs urgent health care.

Key words: Allergic Rhinitis, Asthma, Children, Co-morbidities, Health care

INTRODUCTION

Multiple chronic conditions in the population have raised attention in many nations,[1] and this comprises a significant clinical problem toward the public health sector.[2,3] The problem of multiple chronic conditions among developed and developing countries has rapidly escalated to become a most important public health and medical fact.

The combined effects of increasing life expectancy and the aging of population undoubtedly will further increase the associated societal burden of chronic illnesses among future populations of older people. There are so many studies, those are a concern with adults especially for older adults; two-third of whom have been shown that they live with 2 or more diseases.[4] As people with MCC suffer suboptimal health outcomes, and it raises the health care expenses, additional concentration on this population is critical to improve health care quality and expenditure. Individual managing the multiple chronic conditions required a lot of addition resources like financial and emotional support with a higher level of medical treatment to successfully manage the diseases.[5] By understanding the prevalence and pattern of these co-morbid condition or multiple chronic conditions, is important to provide effective and efficient health care to the patient and their family.

To date, no one has attempted to offer an action-oriented framework that outlines national strategies to maximize care coordination and improve health and quality of life for little individuals with MCC and a little is known to the multiple chronic conditions in these little individuals. Hence, this study was done to find out the pattern of multiple chronic conditions in children so that individuals managing these disease in children can manage them more effectively and efficiently to decrease mortality and morbidity in children.

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MATERIALS AND METHODS

The study was done in Teerthanker Mahaveer Medical College and Research Centre, Moradabad. Uttar Pradesh, total numbers of pediatric subjects were taken 1085 children who came to the emergency/Pediatric Department. Children were identified with ICD-9 code for chronic condition, were taken in the study group between the period from January 2014 to December 2014, as other researchers have used similar condition.[6]

The information about the patients were obtained from the emergency and pediatric department and then characteristics of disease and treatment were entered on a predesigned proforma, from the case sheets of the patients prepared and maintained by the consultants concerned. Logistic regression analysis was done to compare odd of the significant event by the number of chronic diseases present continuing for age and gender.

OBSERVATIONS AND RESULTS

From the Table 1, the author concluded that the majority of children in the sample (80.65% n = 1085) had only one chronic condition over the study time. Among 875 children admitted for only one chronic condition, 190 children (17.51%) had 2 chronic diseases, only 16 cases for 3 chronic conditions, i.e., 1.47% and 0.37% children for 4+ chronic disease (4 cases).

Illustration from Table 2, those who were admitted for single chronic condition, the prevalence of asthma was 35.31% (309 cases), was by far most ubiquitous of the disease for which the patient came in the hospital. Allergic rhinitis and allergy (unspecified) patients were 22.29% and 8%, respectively (195 cases and 70 cases) other chronic disease such as epilepsy 6.97%, congenital heart disease 6.06%, hypertension 5.03%, diabetes Type II 4.91%, cerebral palsy 4%, and diabetes Type I 2.97% had a little prevalence as compared to asthma and allergic rhinitis but neoplasm, sickle cell anemia, chronic nephritis, rheumatoid arthritis, rheumatic heart disease, cystic fibrosis, and other disease; each accounts for only < 2%.

From Table 3, a most frequent combination of 2 chronic conditions was asthma with allergic rhinitis, i.e., 34.74% (66 cases). Asthma was again dominating in this group. Second most prevalent combination was asthma and allergy (unspecified) accounting for 14.21% (27 cases). Other combination of asthma with epilepsy, diabetes type 2, congenital heart disease, hypertension, and cerebral palsy were 7.89, 4.74%, 4.74%, 4.21%, and 4.21%, respectively. While with Allergic rhinitis most prevalent combination was with unspecified allergy, i.e. 11.05% (21 cases) next with epilepsy, i.e., 5.26%.

Table 1: Children with chronic conditions and significant cases

Number of conditions	Cases (%)	Significant cases (%)
1	875 (80.65)	184 (21.03)
2	190 (17.51)	57 (30.00)
3	16 (1.47)	6 (37.50)
4+	4 (0.37)	3 (75.00)
Total	1085	

Table 2: Children came for one chronic disease

Chronic condition	Cases	Percentage
Asthma	309	35.31
Allergic rhinitis	195	22.29
Allergy (unspecified)	70	8.00
Epilepsy	61	6.97
Congenital heart disease	53	6.06
Hypertension	44	5.03
Diabetes Type 2	43	4.91
Cerebral palsy	35	4.00
Diabetes Type 1	26	2.97
Neoplasm	17	1.94
Sickle cell anemia	8	0.91
Chronic nephritis	4	0.46
Rheumatoid arthritis	3	0.34
Others	3	0.34
Rheumatic heart disease	2	0.23
Cystic fibrosis	2	0.23
Total	875	100

There are three chronic conditions were evident in 16 children, and Table 4 provides an idea of the most prevalent combination of disease in this group. Asthma with allergic rhinitis and allergy (unspecified) was accounting 37.5% next to asthma with allergic rhinitis and epilepsy, i.e., 18.75%.

Table 1 shows that with an increase in the number of chronic condition required significant health care like hospitalization or emergency care. Most of the children (75%) with 4+ chronic conditions had more fatality, so they need immediate management. By the Table 5, when controlling the age and gender, the odds of having significant health problem with increased number of chronic disease raising from 21.03% for children with one chronic condition to 75% for children with 4 or more chronic condition. Those with 4 or more conditions had 3.57 times the odds of a significant event as compared to the one chronic condition children.

DISCUSSION

The burden of chronic disease in children has been studied in limited fashion over the past decade. One study on 5001

Table 3: Children came for two chronic disease

Chronic condition combination		Cases	Percentage
Asthma	Allergic rhinitis	66	34.74
Asthma	Allergy (unspecified)	27	14.21
Allergic rhinitis	Allergy (unspecified)	21	11.05
Asthma	Epilepsy	15	7.89
Allergic rhinitis	Epilepsy	10	5.26
Asthma	Diabetes Type 2	9	4.74
Asthma	Congenital heart disease	9	4.74
Asthma	Hypertension	8	4.21
Asthma	Cerebral palsy	8	4.21
Allergic rhinitis	Hypertension	4	2.11
Allergic rhinitis	Congenital heart disease	4	2.11
Asthma	Neoplasm	3	1.58
Asthma	Diabetes Type 1	2	1.05
Asthma	Sickle cell anemia	2	1.05
Others		2	1.05
Total		190	100

Table 4: Children came for three chronic disease

Chronic condition combination			Cases	Percentage
Asthma	Allergic rhinitis	Allergy (unspecified)	6	37.5
Asthma	Allergic rhinitis	Epilepsy	3	18.75
Asthma	Epilepsy	Cerebral palsy	2	12.5
Allergic rhinitis	Allergy (unspecified)	Congenital heart disease	2	12.5
Asthma	Diabetes type 2	Hypertension	1	6.25
Allergic rhinitis	Diabetes type 2	Hypertension	1	6.25
Asthma	Allergy (unspecified)	Congenital heart disease	1	6.25
Total			16	100

Table 5: Odds of having significant event

Number of conditions	Odds ratio	*P* value
1	Reference	Reference
2	1.43	<0.0001
3	1.78	<0.0001
4+	3.57	<0.0001

children[7] reported the extent of single condition chronic disease in different cohorts of children and estimated the prevalence of chronic disease ranging from 12% to 26%. Asthma was the most prevalent physical conditions that were dominant among children with 1 chronic condition from the data set. From this study, author also found the same that asthma was a most prevalent chronic condition. Little information is available in the literature regarding multiple chronic conditions beyond a national study conducted some years ago involving a household sample 18000 children <18 years of age, author suggested that 19% of children had 1 or more chronic conditions.[8] Fewer than 5% or children had 2 or more chronic conditions and <1% had 3 or more such conditions. In this study, Asthma and allergies predominated in the findings. Author of the current study found the same results, but the prevalence of disease differs from previous research as a previous study done in the normal population and this study was done in those children who came to hospital, i.e., diseased children. Both these studies used self-report data. Newacheck and Stoddard[8] used in 1988, national child health interview survey for the study, and Van Cleave *et al.*[7] used the national longitudinal survey of Youth Child cohorts for 1988-2006 in this study.

These data are very important and useful for the policy makers and pediatrician, who deal with the chronic conditions in the children. These findings are based on the physician diagnoses. In this sample, about 17.51% children had 2 chronic conditions and very few, i.e., <2% for 3 or 4+ conditions. In those with 2 or more conditions, asthma was almost always evident.

Our data also suggest that in the intervening years from 1988 to 2006, the prevalence of co-morbidities in children increased from 5% in earlier Newacheck and Stoddard study to 12% in data. However, in our study it was 17.51%, which is on higher side it may be due to that this study conducting in developing country and author's data are hospital based, not self-reporting or population survey. In our data asthma and allergic rhinitis comprise the most prevalent combination in those children with 2 or 3 chronic conditions. A different finding from the earlier Newacheck and Stoddard study that our data suggest that in children

allergy accompanying asthma are evident to a significant degree. This observation is corroborated in studies that have shown that sensitivity to allergens is high in vulnerable communities.[9,10]

Other research in adult population has demonstrated that individuals with multiple chronic diseases have increased utilization of the health care system and often have much higher individual demands of health care literacy, financial needs, and resource needs to manage the conditions adequately,[10] furthermore clinical systems caring for these individuals require greater investment in integrated communication systems and coordination of care.[5,11] Our study offers insight into the pediatric population, and this co-morbid chronic condition showed same as for adult studies that children with multiple chronic conditions demand more and advance health care system.[12,13]

CONCLUSION

During the study period, asthma was the most prevalent condition in children and being most prevalent with a combination of allergic rhinitis and same was most prevalent with allergy (unspecified). With increase in the number of chronic disease, increase the need of urgent health care and required advanced management that range from 21.03% single chronic disease to 75% in 4 or more chronic disease, so it is clear that if the number of chronic condition increase in the children will increase the risk for poor outcome or increase the fatality in children.

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Original Article

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Dexmedetomidine as an Intrathecal Adjuvant with Hyperbaric Bupivacaine: A Randomized Double Blinded Case Control Study

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Abstract

Introduction: Spinal anesthesia is commonly used for abdominal and lower limb surgeries. Dexmedetomidine, the new highly selective α2 agonist, is now being evaluated as a potential neuraxial adjuvant. This study has been designed to evaluate the addition of 15 mcg of dexmedetomidine to 0.5% hyperbaric bupivacaine 3 ml intrathecally for elective abdominal and lower limb surgeries.

Aims and Objectives: To evaluate the onset and duration of sensory and motor block, the effect on hemodynamics, post-operative analgesia, and adverse effects of intrathecal dexmedetomidine with 0.5% hyperbaric bupivacaine.

Materials and Methods: A total of 40 patients (ASA PS I and II) undergoing elective lower abdominal and lower limb surgeries at the Basaweshwar Teaching and General Hospital, Gulbarga, between January 2012 and May 2013 were randomized into one of the two groups. Each patient received 3.5 ml drug consisting of 3 ml 0.5% hyperbaric bupivacaine and 0.5 ml normal saline (Group I) or 15 μg dexmedetomidine in 0.5 ml normal saline (Group II). Onset and duration of the sensory block, motor block, hemodynamics, pain, and sedation were assessed intraoperatively and postoperatively for 24 h. The incidence of adverse effects was recorded.

Results: The mean duration of motor block in Group I and II were 265.5 and 510.5 min, respectively. The mean duration of sensory regression to L1 in Group I and II were 257.25 and 469.5 min, respectively. Time to 2-segment regression in Group I and II were 88.5 and 138.75 min, respectively. The mean duration of analgesia in Group I and II were 238.5 min and 438 min, respectively. The patients in Group II had significant prolongation of the motor and sensory block ($P < 0.001$).

Conclusion: Intrathecal dexmedetomidine in the dose of 15 μg significantly prolongs the anesthetic effects of bupivacaine and can be beneficial in surgeries of long duration, precluding the need for an epidural or general anesthesia.

Key words: Alpha 2 agonist, Dexmedetomidine, Spinal anesthesia

INTRODUCTION

Spinal anesthesia is used extensively for lower abdominuteal and lower extremity surgeries as it is easy to learn, has a definite end point of visualization of cerebrospinal fluid, minuteimizes the stress response, provides optimal operative conditions with minute intraoperative blood loss, and less post-operative morbidity and post-operative analgesia.[1,2] Fear of post-surgical pain is a major concern for patients undergoing surgery. Adjuvants are drugs that increase the efficacy or potency of other drugs when given concurrently. Neuraxial adjuvants are used to improve or prolong analgesia and decrease the adverse effects associated with high doses of a single local anesthetic agent. In addition to their dose-sparing effects, neuraxial adjuvants are also utilized to increase the speed of onset of neural blockade (reduce latency) and prolong the duration of the neural blockade. Neuraxial adjuvants include opioids, sodium bicarbonate ($NaHCO_3$), vasoconstrictors, alpha-2 adrenoceptor agonists, cholinergic agonists, N-methyl-d-aspartate antagonists,

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and γ-aminoisobutyric acid receptor agonists.[3] Intrathecal administration of clonidine has been shown to significantly increase the duration of anesthesia produced by isobaric or hyperbaric bupivacaine with bradycardia, hypotension, arrhythmias, dry mouth as its side effects.

Dexmedetomidine is a more selective α2-adrenoreceptor agonist that has been recently evaluated as an adjuvant to intrathecal local anesthesia.[4-6] Based on previous animal[7,8] and human studies[5] that suggested a 1:10 dose ratio between intrathecal dexmedetomidine and clonidine, we have conducted the study with 15 μg dexmedetomidine as an adjuvant to intrathecal bupivacaine.

Aim

To evaluate the onset and duration of sensory and motor block, hemodynamic effects, duration of post-operative analgesia, and incidence of adverse effects of intrathecal dexmedetomidine with 0.5% hyperbaric bupivacaine in spinal anesthesia.

MATERIALS AND METHODS

It was a prospective double blinded randomized case-controlled study conducted after Institution Ethical Committee approval and obtaining written, informed consent from all patients included in the study.

Inclusion Criteria

1) Age group 18-60 years
2) ASA Grade I and Grade II
3) Body mass index 18.5-25.

Exclusion Criteria

1) Patients belonging to ASA Grades III, IV, and V
2) Patient refusal
3) Liver and renal dysfunction
4) Patients with cardiac dysrhythmias
5) Patients using adrenergic receptor blockers, calcium channel blockers or with sinus bradycardia
6) Weight >120 kg or height <150 cm
7) Patients with contraindications to spinal anesthesia
8) Allergy to the drugs under study.

A total of 40 patients undergoing elective lower abdominuteal and lower limb surgeries at the Basaweshwar Teaching and General Hospital, Gulbarga, between January 2012 and May 2013 were randomized into one of the two groups.

Patients in Group I: 3.0 ml of 0.5% hyperbaric bupivacaine plus 0.5 ml saline.

Patients in Group II: 3.0 ml of hyperbaric bupivacaine with 15 μg dexmedetomidine in 0.5 ml saline.

In the operation theater, appropriate equipment for airway management and emergency drugs were kept ready. 18 G intravenous cannula was inserted, and the patient was preloaded with 15 ml/kg of lactated ringer's solution. Noninvasive blood pressure, pulse oximeter, and electrocardiogram leads were connected and baseline readings were recorded. Under aseptic precautions, a midline lumbar puncture was performed using a 25G Quincke needle in sitting position and the drug was injected. The drug was loaded by a doctor who took no further part in the study. Neither the patient nor the attending anesthesiologist was aware of the group the patient belonged to. The patient was then immediately placed in supine position. The time for intrathecal injection was considered as 0 and the following parameters were observed - sensory blockade, motor blockade, duration of analgesia and sedation. The pulse rate, systolic and diastolic blood pressure, SpO2, and respiratory rate were recorded for every 2 min for 10 min and then every 5 min throughout the intraoperative period and at the completion of surgery. Hypotension was defined as fall in systolic blood pressure > 20% from baseline or mean arterial pressure <60 mmHg and was managed with injection mephentermine 6 mg intravenous in increments. Bradycardia was defined as heart rate <50/min and this was managed with atropine 0.01 mg/kg intravenously. Respiratory depression defined as respiratory rate <8/min and or SpO2 <85%. This was planned to be managed with bag and mask ventilation or intubation if necessary. Following a subarachnoid block, the sensory block was assessed by loss of sensation to pinprick using 23G sterile needle starting immediately after injection and was continued for every 15 s till loss of pinprick sensation at T_{10} level. Onset of sensory block was taken as the time from intrathecal injection to loss of pinprick sensation at T_{10}. At 20 min interval after SAB, the dermatomal level of sensory block noted, and this was considered as the maximum level of sensory block. Motor block was assessed using Bromage score (1 - Free movements of legs and feet, 2 - Just able to flex knees with free movement of feet, 3 - Unable to flex knees but with free movement of feet, 4 - Unable to move hips, legs or feet). Assessment of motor block was started immediately after the intrathecal injection. It was tested for every 15 s till Bromage Score of 4 was reached. Onset of motor block was taken as the time taken to achieve Bromage score of 4 from the subarachnoid block. The degree of the motor block after 20 min of injection was noted, and this was considered the maximum degree of motor block. Thereafter, motor block regression was noted and duration of motor block was taken as the time from initiation of SAB to return to Bromage score of 1. Sedation was assessed using the Ramsay sedation score from 1 to 6. Pain was assessed using the Visual analog scale. Blood loss was replaced as necessary. The patient was shifted to a recovery room after

completion of surgery. The vital signs were recorded, for every 15 min in the 1st h after surgery and 30 min interval for next 2 h and thereafter at hourly intervals for next 3 hours. Sensory and motor block assessment was done for every 15 min till recovery of pinprick sensation to L1 and Bromage score of 1, respectively. Patients were shifted to the post-operative ward after complete resolution of motor blockade. At the end of the surgery, the degree of pain was assessed using Visual analog scale. In the recovery room, pain assessment was done for every 15 min till score >4 was reached. Whenever the patient complained of pain, the rescue analgesic intramuscular diclofenac 75 mg was given. Duration of effective analgesia was defined as time interval between onset of the subarachnoid block and the time to reach visual analog score ≥4. Patients were monitored for 24 h to detect the occurrence of side effects. Patients were also enquired about the occurrence of transient neurological symptoms, which was described as pain/paraesthesia in the neck, buttocks, legs or pain radiating to lower extremities after initial recovery from anesthesia within 72 h.

OBSERVATION AND RESULTS

The results were computed using the Unpaired *t*-test. $P < 0.05$ was considered significant and $P < 0.001$ was considered highly significant.

The two groups (Groups I and II) were comparable with respect to ASA class, type, and duration of surgery. The groups were similar with respect to the demographic data, i.e., age, height, weight, and sex with $P > 0.05$ (Table 1).

Sensory and motor block parameters were represented as mean ± standard deviation except maximum sensory level attained and number of diclofenac injections in first 24 h postoperatively which were represented as median (Table 2).

There was significant shortening of the time of onset of sensory block, prolongation of time to two segment regression, and sensory recovery time to L1 in the dexmedetomidine group (Group II) compared to the control group. The number of doses of diclofenac injections required in the first 24 h postoperatively were also reduced in the dexmedetomidine group (Group II) compared to Group I. The patients in the dexmedetomidine group also had a significantly quicker onset of motor blockade and prolonged duration of the motor block compared to those in the control group.

The dexmedetomidine group (Group II) had a significant increase in the incidence of bradycardia i.e., 50% of the patients had an episode of significant bradycardia, which was amenable to therapy with single dose of intravenous atropine 0.6 mg. Patients in the Group II had good anxiolysis, desirable sedation (median Ramsay sedation score of 2 vs. RSS of 1 in Group I) (Table 3).

From statistical analysis, it was computed that there was no statistically significant difference in the overall hemodynamic status of both the groups ($P > 0.05$) although a higher percentage of patients in the Group II developed bradycardia at some point in the course (Graphs 1 and 2).

DISCUSSION

Intrathecal dexmedetomidine is thought to produce its analgesic effect by inhibiting the release of C fibers transmitters and by the hyper polarization of postsynaptic dorsal horn neurons.

In our study, the mean time to onset of the sensory block is 294.75 s in Group I and 93 s in Group II. Onset of sensory block up to T10 is statistically significantly faster in Group II compared to Group I. Al-Mustafa *et al.*[6] found that the mean time of sensory block to reach T10 was 4.7 ± 2 min in D10 group (10 μg dexmedetomidine), 6.3 ± 2.7 min in D5 (5 μg dexmedetomidine), and 9.5 ± 3 min in Group N (control). Kim *et al.*[9] observed that the patients in dexmedetomidine group (D) demonstrated a shorter time to reach the peak sympathetic and sensory block level compared to the patients in control Group S ($P < 0.01$).

In the present study, the mean time for two segment regression was 138.75 min in Group II and 88.5 min in Group I. The time for two segment regression is significantly prolonged in Group II ($P < 0.001$). In our study, there is significant difference between the groups in terms of the time to sensory regression to L_1 - with Group II requiring a much longer time (469.5 min) compared to Group I (257.25 min) which is highly significant with $P < 0.001$. Hala *et al.*[10] concluded that dexmedetomidine significantly prolonged time to two segment regression, sensory regression to S_1, in a dose-dependent manner. Al-Mustafa *et al.*[6] found that the regression time to S1 dermatome was 338.9 ± 44.8 min in group D10, 277.1 ± 23.2 min in D5, and 165.5 ± 32.9 min in Group N (control) ($P < 0.001$).

There was an insignificant difference among the groups in maximum level of sensory block. The median of the maximum sensory level reached in both the groups was T_4. Hala *et al.*[10] found that the median and range of the peak sensory level reached were T6 (T3 - T10) in Group B, T5 (T3 - T9) in Group D1, and T7 (T4 - T9) in Group D2, not

Table 1: Demographic data

Variable	Group I (*n*=20)	Group II (*n*=20)	*P* value
Age in years (mean±SD)	40.6±13.57	37.66±10.83	0.683
Height in centimeter (mean±SD)	141.2±3.7	141±3.4	0.846
Weight in kilogram (mean±SD)	46.9±4.7	47.5±3.9	0.679
Sex (out of 20)			
Male	11	12	
Female	9	8	
ASA (out of 20)			
I	15	16	
II	5	4	

SD: Standard deviation

Table 2: Sensory and motor block parameters (values expressed as mean±SD and median were mentioned)

Variable	Group I	Group II	*P* value
Onset of sensory blockade (s)	294.75±115.5	93±35.96	0.0001
Time to two segment regression (min)	88.50±14.51	138.75±75	0.0001
Sensory recovery time to L1 (min)	257.25±56.39	469.50±41.03	0.0001
Maximum sensory level attained (median)	T4	T4	
No. of diclofenac injections in first 24 h post-op (median)	2	1	
Onset of motor blockade (s)	155.25±60.44	57.75±17.73	0.0001
Motor recovery time (min)	265.50±55.72	510.50±45.18	0.0001

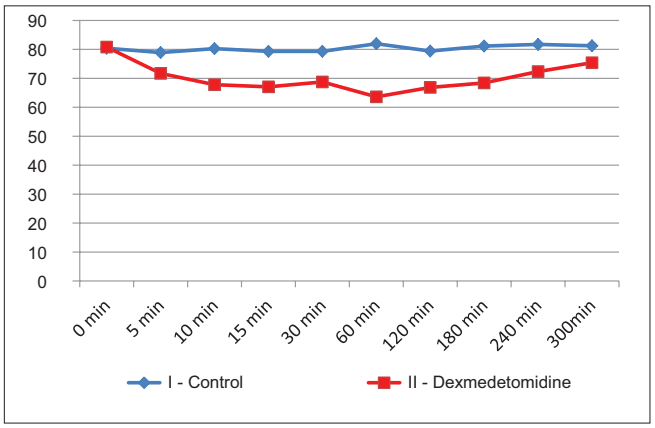
SD: Standard deviation

Table 3: Side effects (values expressed as numbers out of 20)

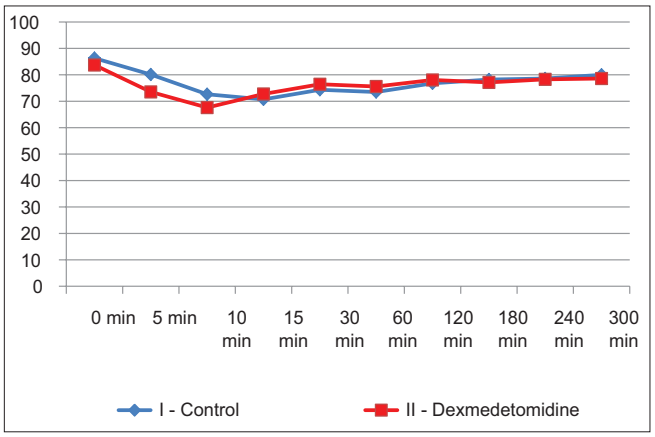
Side effect	Group I	Group II
Bradycardia	2	10
Hypotension	6	7
Excess sedation	0	0
Hypoxia	0	0
Anxiety	5	0
Shivering	3	3
Nausea, vomiting	1	1
Headache	2	3
Urine retention	3	3

statistically different among the groups ($P = 0.08$). Gupta *et al.*[11] found no difference between Group D and R in the highest level of block (T5 and T6, respectively) when dexmedetomidine was added to ropivacaine as intrathecal adjuvant (D) versus control (R).

There is a significant difference between groups in total duration of analgesia with Group II having a much longer duration compared to Group I ($P < 0.001$). Group I has a mean duration of analgesia of 238.5 min, Group II has 438 min. Thus, the analgesic requirement in the first 24 h postoperatively in Group II was significantly lesser than that in Group I. Hala *et al.*[10] concluded that intrathecal dexmedetomidine in doses of 10 μg and 15 μg significantly prolong the anesthetic and analgesic effects of spinal hyperbaric bupivacaine in a dose-dependent manner. Addition of 10 ug or 15 ug increased the duration of analgesia provided by spinal bupivacaine by about 240 or



Graph 1: Mean pulse rate in both the groups at various time intervals



Graph 2: Means of mean arterial blood pressure in both the groups at various time intervals

520 min, respectively. The increased duration of analgesia in their study may be due to the lower dermatomal levels needed in anterior cruciate ligament surgery for pain relief in comparison to our study which included abdominuteal surgeries as well which require higher dermatomal levels of sensory blockade.

The mean time to onset of Bromage 2 motor block is 155.25 s in Group I and 57.75 s in Group II. There is a statistically significant difference among the groups ($P < 0.001$). It correlates with the study by Al-Mustafa *et al.*[6] who found that the mean time to reach Bromage 3 scale was 10.4 ± 3.4 min with 10 μg dexmedetomidine, 13 ± 3.4 min with 5 μg dexmedetomidine, and 18 ± 3.3 min in control group. Kanazi *et al.*[5] also found that the patients who received 12 mg of bupivacaine supplemented with 3 μg of dexmedetomidine intrathecally had a faster onset of the maximum motor block compared to plain bupivacaine.

The median of the maximum motor block attained is Bromage Grade 4 in both the groups. Therefore, there is no statistical difference between the groups in this regard. Hala *et al.*[10] found that all the patients achieved modified Bromage 3 motor block. Kim *et al.*[9] also observed that the peak block level was similar for the two groups receiving either dexmedetomidine 3 μg ($n = 27$) or normal saline ($n = 27$) intrathecally with 6 mg of 0.5% hyperbaric bupivacaine.

The mean duration of motor block in Groups I and II are 265.5 min and 510.5 min, respectively ($P < 0.001$). Thus, there is a significant prolongation of the duration of motor block by dexmedetomidine. Hala *et al.*[10] also found that motor block regression to modified Bromage 0 were significantly prolonged in Group D2 (15 μg dexmedetomidine) than in Group D1 (10 μg dexmedetomidine) and Group B (control) and in Group D1 than in Group B. Al-Mustafa *et al.*[6] observed that the regression to Bromage 0 was 302.9 ± 36.7 min in D10 (10 μg dexmedetomidine), 246.4 ± 25.7 min in D5 (5 μg dexmedetomidine), and 140.1 ± 32.3 min in Group N (control). Onset and regression of motor block were highly significant (N vs. D5, N vs. D10, and D5 vs. D10, $P < 0.001$).

In our study, there is no significant difference between the two groups with respect to intraoperative and post-operative mean heart rates with $P > 0.05$. Groups I and II have comparable values of mean systolic blood pressure, diastolic blood pressure, and mean arterial pressure throughout the intraoperative and post-operative periods with $P > 0.05$. Thus, the hemodynamic stability is maintained even in the presence of dexmedetomidine. Hala *et al.*[10] found that the mean values of mean blood pressure and heart rate were comparable between the three groups throughout the study duration. Al-Mustafa *et al.*[6] also observed that the three groups in their study had comparable hemodynamics throughout the period of study.

The median Ramsay sedation score in both the groups is 2. Therefore, there is no significant difference although 100% of the cases in the dexmedetomidine have a desirable sedation score of 2. Al-Mustafa *et al.*[6] also observed that all the patients in the three groups in their study had a RSS of 2. Hala *et al.*[10] found that the patients in Group B and Group D1 had a median RSS of 2 (2-3) at all assessment times ($P > 0.05$). Patients in Group D2 had a higher median sedation score (3.5-4) between 60 min and 195 min ($P < 0.05$). There was no significant difference in the sedation scores between the groups at the other time points.

The incidence of hypotension and thus the use of vasopressor was significantly higher in Group II (30%) than in Group I (15%) which was insignificant statistically. The incidence of bradycardia and thus the use of atropine was significantly higher in Group II (50%) than in Group I (10%) but it was amenable to therapy with single dose of intravenous atropine 0.6 mg. 25% of the patients in Group I were anxious whereas all the patients of the dexmedetomidine Group (II) were tranquil. All the patients had peripheral oxygen saturation >95% at all times and did not require additional oxygen. No patient had a respiratory rate below 10/min. Three patients each in Groups I and II had shivering, which was managed with intravenous tramadol 25 mg. Complete recovery of sensory and motor function was observed in all the studied patients. 2 weeks after the surgery at the post-operative follow-up visit, patients did not show any neurological deficit.

CONCLUSION

The longer sensory and motor blockade produced by 15 μg dexmedetomidine with hyperbaric bupivacaine and the desirable level of sedation can be beneficial in surgeries of long duration, precluding the need for an epidural or general anesthesia.

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Original Article

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Clomiphene vs Clomiphene and Yoga for Infertile Women: A Comparative Study

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Abstract

Background: Extreme stress can affect hormonal balance, which is definitely a problem when a woman is trying to conceive. Yoga can act as an antidote to the harmful effects of stress hormones. A study was conducted to compare the effects of clomiphene and clomiphene and Yoga in infertile women.

Methods: A prospective study on 60 infertile women was conducted in an infertility clinic of a tertiary care referral center. Eligible women were equally randomized into two groups, Group I (clomiphene and yoga) and Group II (clomiphene alone). Group I practiced yoga daily for six months in addition to Tab clomiphene and Group II was given Tab clomiphene alone for six cycles, Group II practiced yoga daily for 6 months in addition to tab clomiphene. Comparative analysis was made among both the groups.

Result: Ovulation occurred after 3 months of yoga in Group I compared to Group II, where ovulation was observed in the 1st month. About 46.6% versus 33.3% women conceived in Group I and Group II, respectively. All pregnancies in Group I crossed the period of viability but in Group II, 50% crossed the period of viability. Women in Group I reported feeling stronger and more confident; whereas in Group II nausea was complained by 33.3% women 26.6% women complained of headache, and woman 6.6% had abdominal distension and bloating during the study.

Conclusion: Though the results of yoga are comparable to clomiphene, the number of viable pregnancies are more and without any adverse effects by yoga therapy.

Key words: Clomiphene, Infertility, Stress hormones, Yoga therapy

INTRODUCTION

Infertility creates devastating psychological consequences on infertile couples and remains a worldwide problem challenge. Extreme stress can affect hormonal balance, which is definitely a problem when a woman is trying to conceive. Infertile women may have profound psychological effects and becomes more anxious to conceive, increasing their sexual dysfunction.[1] In the reproductive system, hypothalamus produces gonadotropin releasing hormones which stimulates the pituitary gland to produce the peripheral hormones, luteinizing hormone, and follicle stimulating hormone; which in turn stimulates the production of testosterone, estradiol, and sexual behavior.[2] Stress makes the adrenal gland produce glucocorticoids which acts directly on hypothalamus to suppress gonadotropin releasing hormones production and also boost hypothalamic gonadotropin inhibitory hormone production, which acts to reduce hypothalamic gonadotropin releasing hormones, as well as pituitary secretion of sex hormones, thereby suppressing the entire reproductive system.[3] Yoga can act as an antidote to the harmful effects of stress hormones by decreasing the blood levels of cortisol, adrenocorticotropic hormone, norepinephrine and epinephrine, and restoring the optimal reproductive health.[4]

Clomiphene is the selective estrogen receptor modulator that also acts on hypothalamus by binding E2 receptors and thereby creating a state of hypoestrogenicity; this upregulates the hypothalamic-pituitary-ovarian axis.

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We conducted a study to compare the effects of clomiphene and clomiphene and Yoga in infertile women.

Aims and Objectives

The aims and objectives were to compare the efficacy and safety of clomiphene versus clomiphene and yoga on infertile women.

METHODS

A prospective randomized study was conducted over a period of 1½ year, where infertile women between 20 and 35 years were selected from our infertility clinic.

Inclusion Criteria

Women who gave the consent to participate in the study till the completion. The history of oligomenorrhea, hypomenorrhea, or amenorrhea. Normal thyroid function tests, prolactin, hysterosalpingography, and semen analysis. D2 transvaginal ultrasound is indicating PCOS or normal study. Endometrial biopsy is not suggestive of tuberculosis.

Exclusion Criteria

Women with any medical disorders (diabetes, hypertension, epilepsy, asthma, etc.), or past surgeries. Previous stimulated cycles. Eligible 60 women were randomized equally into two groups, Group I (clomiphene and yoga) and Group II (clomiphene alone). Group II was given tab clomiphene 50-100 mg for 5 days starting from D2 to 3 for three cycles. The transvaginal scan was done on day 12 to observe dominant follicle and serum progesterone was done on day 21. Timed intercourse was explained.

Group I, in addition to the tab., clomiphene also practiced fertility yoga for 45-50 min daily for 6 months in our yoga center including holidays. Women were taught 5 exercises - lotus pose meditation (Padmasana), a bridge supporting pose (Setu Bandha Sarvangasana), Cobra pose meditation, Cobbler's pose, and legs up the wall pose. Timed intercourse was explained in both the groups. Comparative analysis was made for the restoration of normal menstruation, ovulatory rates, conception rates, and adverse effects among both the groups.

RESULTS

The normal menstrual cycle was restored in 10 (66.6%) women after 3 months of yoga in Group I and none in Group II.

In Group I, ovulation was documented after 3 months of yoga and maximum number being in 5th month 15 (50%) compared to Group II where ovulation was observed in the 1st month, maximum number was in the 2nd month 11 (36.6%) (Table 1).

A total of 14 women (46.6%) versus 10 (33.3%) women conceived in Group I and Group II, respectively, however, conception occurred in 5th month of yoga in Group I as compared to conception in 2nd month in Group II (Table 2).

All women in Group I crossed the period of viability but in Group II, 5 (16.6%) woman had ectopic gestation, 10 (33.3%) had spontaneous abortion, and only 15 (50%) crossed the period of viability.

It has been observed that fertility yoga was fruitful in women having a long duration of married life and clomiphene was beneficial in couples having married life <5 years (Table 3).

Women in Group I reported feeling stronger, more confident, and powerful; whereas in Group II, nausea was complained by 10 (33.3%) women, 8 (26.6%) women complained of headache, and 2 women (6.6%) had abdominal distension and bloating during the study.

DISCUSSION

Infertile women have a higher level of physical and psychological symptoms, which could include but are not limited to such as insomnia, headache, back pain, fatigue, anxiety, and depression. These symptoms may affect the ability to implant successfully through abnormalities detectable in the immune system. Certain yoga postures

Table 1: Ovulatory rates

Months	Group I (yoga) (%)	Group II (clomiphene) (%)
Ist	0	6 (20)
IInd	0	11 (36.6)
IIIrd	0	9 (30)
IVth	12 (40)	0
Vth	15 (50)	0
VIth	8 (26.6)	0
Total	30	30

Table 2: Conception rates

Months	Group I (%)	Group II (%)
Ist	0	0
IInd	0	6 (20)
IIIrd	0	4 (13.6)
IVth	0	0
Vth	10 (33)	0
VIth	4 (13.3)	0
Total	30	30

Table 3: Comparative analysis of Group I and Group II

Duration of marriage	Group I				Group II			
	Ovulated (%)	Conceived (%)	Total	*P*-value	Ovulated (%)	Conceived (%)	Total	*P*-value
<5 years	2 (25)	0	8	0.1429 (NS)	8 (100)	6 (75)	8	0.1429 (NS)
5-10 years	12 (75)	6 (50)	16	1.000 (NS)	10 (62.5)	2 (25)	16	0.321 (NS)
>10 years	6 (100)	6 (100)	6	0.1000 (NS)	0	0	6	0.1000 (NS)

NS: Non-significant

that specifically target the reproductive organs and pelvic areas help to increase circulation and stimulates the energy in those area.

The study conducted by Berga[5,6] observed the improvement in the reproductive health of women having an anovulatory amenorrhea. These women have high levels of stress hormone cortisol in cerebrospinal fluid. After yoga therapy cortisol had dropped and 7 out of 8 (88%) women achieved normal menses and ovulation compared to 2 out of 8 (25%) in the control group. The present study showed 66.6% resumed normal menses after 3 months of yoga therapy and none in clomiphene group. About 67% versus 56% women had ovulation in yoga and clomiphene groups, respectively.

Domar[7,8] reported that conception rates were boosted to 55% for first 10 weeks compared to 20% for controls after 1-year. Our study observed 46.6% versus 33.3% conception rates in yoga and clomiphene groups, respectively, over a period of 6 months.

CONCLUSION

Yoga focuses on wellness, and people are motivated to improve diet and lifestyle, these two factors increase the chance of conception. The results of fertility yoga along with clomiphene are remarkable. However, viable pregnancy rates are more and without any adverse effects with yoga therapy. It is especially fruitful for infertile women with long duration of married life, the only drawback being time consumption. However, large-scale randomized trials are required actually to compare the efficacy of fertility Yoga and clomiphene.

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Original Article

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Analysis of Results of Titanium Elastic Nails (TENs) and Ender Nails: A Comparative Study

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Abstract

Background: The management of pediatric femoral fractures has evolved toward a more operative approach in the past decade. It has been noticed that problems such as angulation, malrotation, and limb length discrepancy cannot be effectively controlled by non-operative treatment all the time. Among the various operative treatment such as plating, external fixator, rigid intramedullary nailing, and elastic stable intramedullary nailing has become gold standard now. Titanium elastic nails (TENs) and Ender nails are most commonly used.

Purpose: The purpose of this study was to compare the results of TENs and Ender nail in pediatric femoral shaft fracture.

Materials and Methods: During the period of February 2010-March 2014, 82 patients with 82 femoral fractures were included in the study. Patients with bilateral femoral fracture, pathological fracture, non-union, were excluded from the study. All the nails were introduced through retrograde approach after close reduction under image intensifier, where close reduction was not possible, the open reduction was done. Among the 82 patients, TENs were done in 40 patients, and Ender nails were done in 42 patients. Patients were followed up for a period of 2-4 years.

Results: There was no difference between the two groups with regard to demographic profile. No statically difference was found in regard to fracture union, hospital stay, and weight bearing. No difference in result was found according to the Flynn criteria.

Conclusion: As there is no difference between the two groups, Ender nail is a good alternative compared to TENs as it is lower cost.

Key words: Femoral fracture, Nail, Titanium

INTRODUCTION

Throughout the centuries, the goal of orthopedics and traumatology has been to return the patient to his pre-trauma state as quickly as possible. Femoral shaft fracture comprises 2% of all fractures in children and adolescents. For many years conservative treatment with traction and hip spica has been the gold standard for all femoral fractures in children and adolescents with relatively good results. In many occasion, unacceptable alignment and squeal of prolonged immobilization are the end result. At present surgical methods are preferred since they are associated with early mobilization and fast return to function. Although external fixator has the advantages of easier application, early mobilization, and avoid casting; but the most important disadvantages are pin site infection, scarring refracture, and malunion. Open reduction and internal fixation with plate and screws have the advantages of rigid fixation, but the disadvantages are a large scar, possible refracture after plate removal. About rigid nail, the most important thing concern about is osteonecrosis of the femoral head, if piriformis fossa is used as entry portal.

The flexible intramedullary nails (Ender and Titanium elastic nails [TENs]) are ideal for pediatric femoral fracture due to ease of use, prevention of any traction, and cast complications. The treatment outcomes reported by flexible nails are very successful for this age group.[1-3] Technically

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lesser traumatization, use of mostly the retrograde surgical technique, and the lack of harm to the growth cartilage, use of nails with smaller diameter an absence of drilling procedure are among the advantages of flexible nail.[4] Furthermore, the fixation fulfills the three point fixation principle, since the nails are medially and laterally placed. The elasticity and stress distribution of the flexible nails facilitate the callus formation.

The aim our study was to compare the results of TENs and Ender nails.

MATERIALS AND METHODS

This is an institutional based observational prospective study carried out from February 2011 to March 2015, in our institution (IPGMER and SSKM Hospital), after getting permission from the Ethical Committee. All the patients have been counseled about the pros and cons of the study, and the written consent has been taken. The main catchment area of our institution is Kolkata and its suburban area. Among this period, the study was conducted among 82 patients. The patients were randomly selected for TENs and Ender nails. Patients with an open fracture, non-union, fracture more than 3 weeks old and bilateral fracture shaft femur, pathological fracture were excluded from this study. All the patients are within 5-16 years age group. Position of the patient is supine in a free position or on a fracture table with a traction boot. If a fracture reduction can be accomplished by manual traction, a standard table may be used. The fracture is reduced under image intensifier. If the close reduction is not possible, then the open reduction is done. The entry point of the nail is 2.5 cm-3.0 cm proximal to the physis. We generally use an awl to penetrate the near cortex. The nail is introduced with the help of inserter under image intensifier. The fracture is reduced, and the nails are introduced. Advancement of the nails is continued until it is just proximal to the physis. In case of Ender nail, it is just impact over the distal femur (Figures 1 and 2). In case of TENs, nails are cut 1 cm-2 cm away from bone and bent 10-15° and impact over the distal femur (Figures 3 and 4). Patients were followed for a period of at least 2 years.

RESULTS

From February 2010 to March 2015, 82 patients with 82 fracture shaft femur admitted in our institution were included in our study. According to the orthopedic and trauma association (OTA) criteria type 32A: 30 patients in TENS and 32 in Ender group, respectively, type 32B: 8 patients in each group, type 32C: 2 patients in each group (Figure 5).

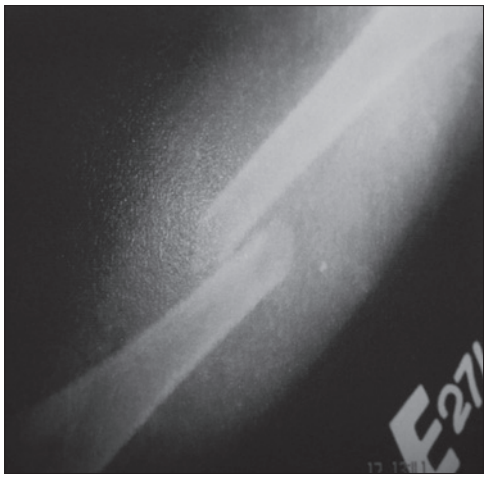

Figure 1: Fracture shaft femur

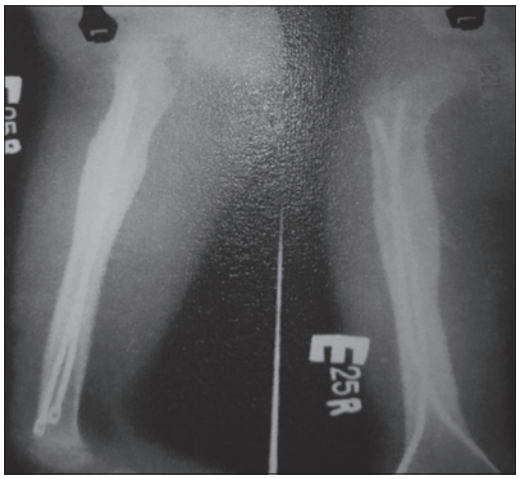

Figure 2: Fracture united after Ender nailing

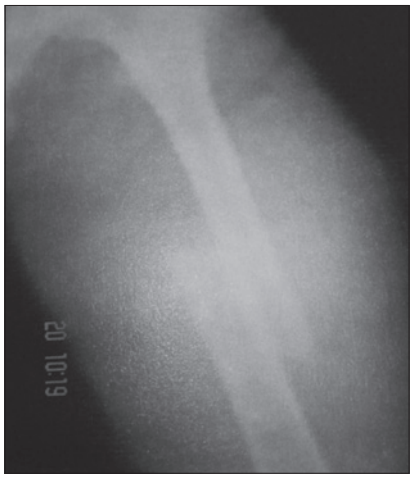

Figure 3: Fracture shaft femur

There was no significant difference between the groups with regard to demographic profile (Table 1). There was no difference between the groups as measured by linear relationship in respect to mechanism injury fall (15 patients

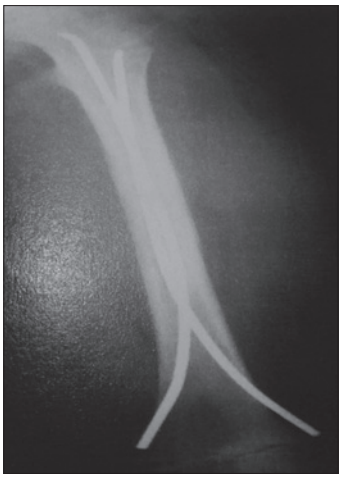

Figure 4: Fracture united after Titanium elastic nailing

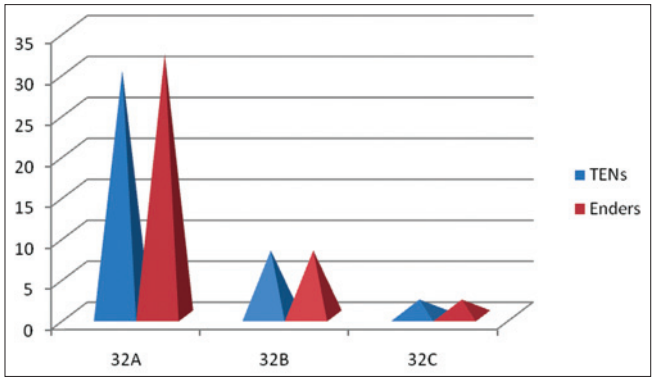

Figure 5: Distribution of fracture

Table 1: Distribution of demographic data

Parameters	TENS (40)	Enders (42)	*P* value
Male gender	23	29	0.278
Mean age	10.5 years	9.9 years	0.250
Associated systematic injury	9	12	0.529
Injury severity score	9.9	6.6	0.087

TENs: Titanium elastic nails

in TENS and 8 patients in Ender), motor vehicle accident (11 and 17, respectively), motor vehicle – pedestrian (6 in each group), sports related injury (2 and 5, respectively), bicycle accident (3 and 1, respectively) and other mechanism (4 and 2, respectively) (Figure 6).

Among the TENS group 15 patients need open reduction (average operative time – 45 min) 25 patients, close reduction done (average operative time – 35 min). Among the Ender nail group, 13 patients need open reduction (average operative time – 40 min), and 29 patients need close reduction (average operative time 25 min). In case of close reduction, blood loss is minimal and in open reduction average blood loss in both cases 80 ml and 70 ml, respectively (Figure 7).

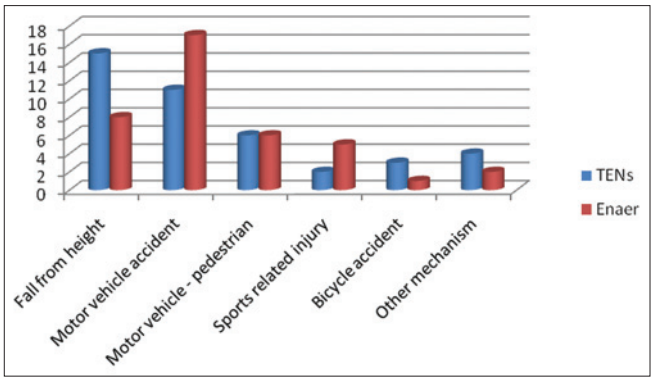

Figure 6: Distribution of mode of injury

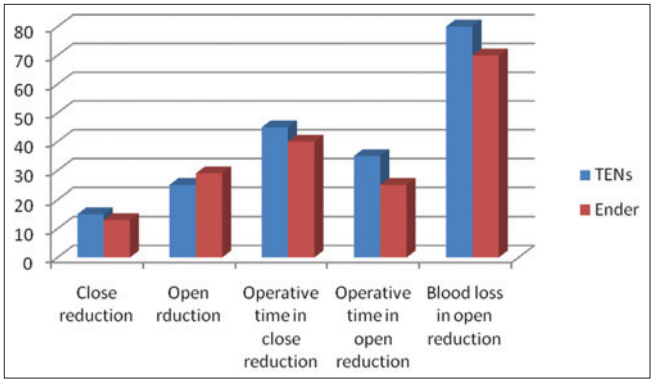

Figure 7: Operative details

Post-operatively there was no difference between the groups in respect of quality of reduction ($P = 0.122$). The average hospital stay was 7.5 ± 4.4 days in TENs group and 6.9 ± 3.5 days in Ender group. The average union time 7.2 weeks was in TENs group and 6.9 weeks in Ender group, respectively. All the patients have a full range of hip and knee motion.

The total number of complication was in TENs group 11 and in Ender group 12. About 8 patients in TENS group have pointed nail, among them 3 patients require surgery. Totally 5 patients, symptoms are gone after removal of nail. 6 patients in Ender group have pointed nail but no patients require surgery. Nearly, 5 patients and 4 patients in TENS and Ender group have a superficial infection, which was treated with antibiotics. Limb length discrepancy was found in 9 patients in TENs group. The average limb length discrepancy is 1.7 cm (1-2.4 cm). Only 2 patients have more than 2 cm limb length discrepancy. In Ender group, 7 patients have limb length discrepancy (average-1.5 cm). No patients have more than 2 cm discrepancy. Malunion (angulations more than 10° in both sagittal and coronal plane) was found 6 patients in TENS group and 2 patients in Ender group. Malunion was particularly seen in long oblique and spiral fracture (Figure 8).

According to the Flynn criteria, among TENs group excellent result seen in 26 patients, good 12 patients and

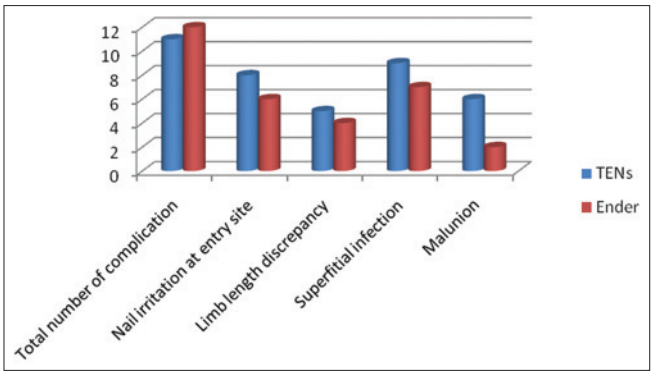

Figure 8: Total number and distribution of complication

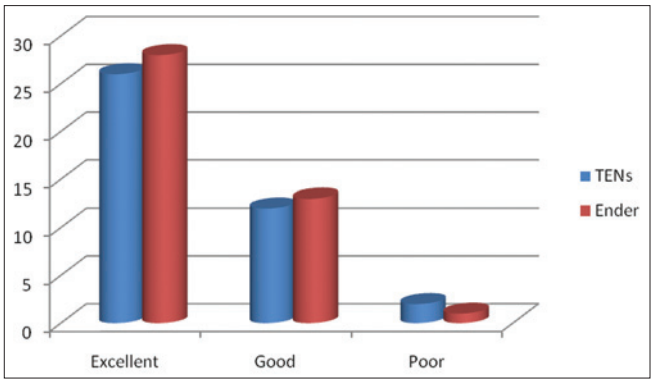

Figure 9: Distribution of result according to Flynn criteria

poor in 2 patients. In Ender group 28 patients have an excellent result, 13 patients have good, and 1 patient has the poor result (Figure 9). There was no statically difference between the groups ($P < 0.001$). Femoral anteversion angle was found equal or close to the opposite side, which had no statically significance.

DISCUSSION

It has been commonly accepted that surgical intervention is indicated for pediatric femoral shaft fracture in case of an open fracture, multiple trauma, concomitant head injuries, burns, and neuromuscular wounding. However, the number of publications suggesting that surgery can also be considered for isolated femoral fractures is gradually increasing. Due to achievements such as earlier return to function, no or less joint flexibility, lesser wound tumor compare to other surgical methods, lesser complications of infection, refracture, and malunion, earlier mobilization in patients with multiple trauma, reduction in the duration and cost of hospitalization, intramedullary nailing has become one of the methods of choice in children too.[1,5-8]

In children, the interventions using flexible intramedullary nails are technically easier than the use of rigid nails.[1,4,9] It allows movement at the fracture site, which helps in callus formation, avoid physis, and blood supply to the femoral head. The use of intramedullary nailing in children can be antegrade or retrograde approach. We were using retrograde approach.

The most common complication of femoral shaft fracture is the discrepancy between lower extremity length, and is frequent between 2 and 10 years of age.[1,7,8] No significant discrepancy was found between the limb length in the intramedullary nailing carried out in older children and adolescents.[4-6] Heinrich[7] reported that 22% of their patients had lengthening over 5 mm, and 11% had shortening under 5 mm. In our study, we found only 2 patients have more than 2 cm limb length discrepancy in TENs group.

Another common complication of pediatric femoral fractures is the malunion. Herdon *et al.* reported that clinically significant malunion developed in 7 of 24 patients who were treated with traction while in 21 patients who were treated with an elastic nail, no significant malunion was seen. In the antegrade elastic nailing series of Carey and Galpin,[1] no significant rotational and angular deformity were found.

Other recognized complication after fixation with TENs is the pain at the entry point of the nail caused by irritation of soft tissue. In order to prevent soft tissue irritation, only a small part of the nail should be left outside the distal metaphyseal cortex and nails must never bent in the soft tissue.[10,11] Linhart WE *et al.*[11] indicated that the technical problem can be minimized if the part or the nail, which is left outside the femur is smaller than 2.5 cm, and the biggest diameter nail is used. The soft tissue irritation by the Ender nail is less because the end of the nail is smooth, and it is flushed with the bone.

Flexible intramedullary nailing produces excellent result in children and adolescents with fewer nail complication rates. There was no significant statically differences in result between TEN and Ender nail group.

CONCLUSION

The cost of Ender nail is much lesser than the TEN. Our study states that there is no significant statically difference between costly TENs and less expensive Ender nail. In our country, less expensive Ender nail is a good alternative to TENs.

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Original Article

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Risk of Type 2 Diabetes Mellitus in Adolescents in a Medical College in Bangalore, India

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Abstract

Introduction: India is home to more than one-sixth of the world's population, and this proportion is expected to increase with time. India is also expected to become the Diabetes Capital of the World, by 2025. Diabetes mellitus (DM), which is a leading cause of morbidity and mortality in developing countries, is an ice-berg disease. More than 50% of the diabetic patients in India are unaware of their diabetic status.

Materials and Methods: In this study, risk assessment of Type 2 DM (T2DM) among adolescents in 1st year medical students was done using the Indian Diabetes Risk Score that includes age, exercise status, waist circumference, and family history of DM.

Results: Of 238 students, 114 (47.9%) were found to be in medium and high-risk category. According to the obesity classification, for Asians 43 (18.1%) were overweight, and 68 (28.6%) were obese.

Conclusion: Information, education, and communication need to be highlighted on healthy lifestyle incorporating a balanced diet and physical activity to reduce obesity in view of reducing the risk of T2DM in the future. Awareness program on diabetes and its prevention are the need of the hour.

Key words: Adolescents, Diabetes mellitus, Obesity

INTRODUCTION

India is home to more than one-sixth of the world's population, and this proportion is expected to increase with time. It is also expected to become the Diabetes Capital of the World, by 2025. Diabetes mellitus (DM), which is a leading cause of morbidity and mortality in developing countries, is an ice-berg disease.[1] More than 50% of the diabetic patients in India are unaware of their diabetic status.

Traditionally, Type 2 DM (T2DM) has been a disease of adults. However, the same now occurs in increased numbers among obese adolescents.[2] The evidence is emerging of growing prevalence of type 2 diabetes among urban Indian children, as well.[3]

The increasing evidence on the risk factors for developing DM has made it possible to develop screening tools, and now, there are several strategies for screening for diabetes in the population.[4]

Living conditions in India have improved considerably including dramatic improvements in food habits and transport facilities. Lifestyle also has changed namely increased television viewing and decreased physical activity. The changing lifestyle was found to be a contributory factor for the rising rates of obesity and associated metabolic diseases like diabetes.[5]

The roots for cardiovascular diseases and T2DM are found in childhood; particularly in children and adolescents with obesity.[6] The prevalence of overweight in adolescents is

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increasing, and this is a major public health problem worldwide, as well as in India. This is associated with urbanization and technological advances that affect lifestyle. Obesity, specifically abdominal obesity is a major trigger factor for insulin resistance. The insulin receptor signaling pathway is altered in the presence of excessive free fatty acids and inflammatory substances, which further leads to metabolic alterations that comprise metabolic syndrome. Metabolic syndrome has been detected in the younger age group with increasing rate.[7] The opportunities are rising for lifestyle interventions in at-risk individuals for prevention or delaying future diseases namely diabetes, hypertension, and coronary heart disease.

Obesity in adolescents and children has risen to significant levels globally with serious public health consequences. In addition to endocrine, cardiovascular, emotional, and social issues, it poses a serious hazard to basic health care delivery system.[8]

Adolescence is a critical time for young people with diabetes when they learn to take increasing responsibility for the management of their disease. Teenagers experience the relationship between their actions and blood glucose readings, which influences their beliefs about diabetes, its treatment and how they will manage it.[9]

This study is an attempt to evaluate the risk of diabetes among 1st year medical students in a medical college, as there are few studies in this area.

MATERIALS AND METHODS

A cross-sectional study was done at Vydehi Institute of Medical Sciences and Research Centre, Bangalore, from September to October 2014. The college Ethical Committee approved the research protocol, and verbal informed consent was obtained from the participants.

The study population consisted of 1st year medical students studying at Vydehi Institute of Medical Sciences and Research Centre. Of 250 medical students in the 1st year of medical college, 238 took part in the study. The exclusion criteria comprised of three students who were chronic absentees, six students who did not give consent for the study, and three students who were above the age of 19 years. They were assessed for Indian Diabetes Risk Score (IDRS).[10] A semi-structured questionnaire was administered to all of them comprising of general information such as age, gender, family, history of diabetes, and physical activity. Anthropometric measurements were taken. Height of all the students was measured using a stadiometer and weight in kilograms with an electronic weighing scale. Waist circumference was also measured in centimeters. Body Mass Index (BMI) was calculated and the students were categorized as overweight and obese, according to the obesity classification for Asians.[11]

The data obtained were tabulated in Excel sheet and analyzed using SPSS version 21. The scoring was done, according to the IDRS criterion. The students were scored with a minimum score of 0 and a maximum score of 100. Depending upon the score obtained the students were divided into three category of diabetic risk, score ≤ 30 were low risk, score of 40-50 were medium risk, and a score ≥ 60 were high-risk candidates for diabetes. The chi-square test was used to study the association among various parameters and the risk of DM.

RESULTS

The mean age of the 238 students who participated in the study was 17.8 ± 0.6 years.

There were 91 (38.24%) males and 147 (61.76%) females. Among the students 124 (52.1%) were in low-risk category, 102 (42.9%) were in medium risk category, of which 73 (71.6%) were females, and 12 (5.0%) were in the high-risk category. A significant association was found between gender and risk (Table 1) ($P < 0.05$).

Among them 121 (50.8%) students had increased waist circumference, 184 (77.3%) students did not take part in any physical activity, 59 (24.8%) had family history of diabetes either in the father, mother or both (Table 2). A significant association was found between physical activity and waist circumference (Table 3) ($P < 0.05$).

According to the obesity classification, for Asians 43 (18.1%) students were over-weight, and 68 (28.6%) students were obese (Table 4). A significant association was found between BMI and physical activity (Table 5) ($P < 0.01$).

A positive correlation was seen between the BMI and waist circumference, that is, if BMI score increases by one then the waist circumference increases by 0.763 cm.

DISCUSSION

The present study revealed that 12 (5%) students are in the high-risk category, 102 (42.9%) in medium risk category and 124 (52.1%) in the low-risk category. In a similar study, conducted in Pune, where 99 female students and 162 male students participated 4%, 76%, and 20% had high, moderate, and low-risk, respectively, for developing T2DM.[12]

Table 1: Distribution of gender and risk of DM

Risk	Gender		Total
	Male	Female	
Low	60 (48.4)	64 (51.6)	124 (52.1)
Medium	29 (28.4)	73 (71.6)	102 (42.9)
High	02 (16.7)	10 (83.3)	12 (5.0)
Total	91 (38.24)	147 (61.76)	238 (100)

χ^2=11.93, DF=2, *P*<0.05. DM: Diabetes mellitus

Table 2: Indian diabetes risk score

Parameters	Number	Percent
Waist circumference		
<80 cm females and <90 cm males	117	49.2
≥80 cm females and ≥90 cm males	79	33.2
≥90 cm female and ≥100 cm males	42	17.6
Physical activity		
No exercise/sedentary life style	184	77.3
Mild exercise	13	5.5
Moderate exercise	27	11.3
Vigorous exercise	14	5.9
Family history		
No family history	179	75.2
One parent diabetic	55	23.1
Both parents diabetic	4	1.7

Table 3: Relation between physical activity and waist circumference

Waist circumference	Physical activity (%)		Total
	Present	Absent	
Normal	97 (82.9)	20 (17.09)	117
Increased	87 (71.9)	34 (28.09)	121
Total	184 (77.31)	54 (22.69)	238

χ^2=4.11, DF=1, *P*<0.05

Table 4: Body mass index

BMI	Number	Percent
Under weight	28	11.8
Normal	99	41.6
Over weight	43	18.1
Obese	68	28.6

BMI: Body mass index

Table 5: Relation between physical activity and BMI

BMI	Physical activity		Total
	Present	Absent	
Under weight	27	1	28
Normal	85	14	99
Over weight and obese	72	39	111
Total	184	54	238

χ^2=19.76, DF=2, *P*<0.01. BMI: Body mass index

In a study conducted in Mangalore, 150 medical students were assessed, out of which 75 were females and 75 were males. A total of 8.6% students had abnormal waist circumferences while 12.4% had a family history of diabetes. In the present study, 50.8% had increased waist circumference and 24.8% had family history of diabetes.[13]

A similar study was conducted in Kolar, on 300 medical students, and it was observed that the mean age was 19.3 ± 1.4 years and 85% students had sedentary lifestyle. In the current study, the mean age was 17.8 ± 0.6 years and 77% students had sedentary lifestyle.[14]

A study among 702 college students at Universidade Federal do Ceará, comprised of 237 students in the age group of 16-19 years of which 70.6% had a sedentary lifestyle, and 22.8% were overweight.[15] In the present study, 43 (18.1%) were overweight and 68 (28.6%) were obese, according to the obesity classification for Asians.

CONCLUSION

Among medical students, 47.9% had moderate to high-risk score for T2DM. Information, education, and communication need to be highlighted on healthy lifestyle incorporating a balanced diet and physical activity to reduce obesity, in view of reducing the risk of T2DM in the future.

The simple and cost-effective IDRS could serve as a basic tool for the grass root health workers to identify at risk individuals at the earliest and enable primary prevention of T2DM.

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Original Article

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Management of Difficult Fractures of Proximal Third of Femur with K Nail In a Secondary Healthcare Facility

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Abstract

Background: Chhattisgarh is largely a tribal state and majority of the people here are poor. Hence, in order to help these poor needy patients, by providing them the best possible orthopedic care, within the economic constraint, this study and effort was made.

Purpose: The purpose of this study was, to come up with economical, easy, simple, quick method with least soft tissue dissection (minimally invasive) or closed reduction and internal of fixation of fracture Femur.

Methods: A total of 30 cases of fracture Femur were managed with the help of Kuntscher nails (K nails), in the Department of Orthopedics, in Chhattisgarh Institute of Medical Sciences, between December 2002 and January 2005, and cases were followed for 10-12 years for restoration of function and complications or deterioration. K nailing was done by the standard procedure for intramedullary nailing.

Results: All the cases healed within 3-6 months of operation. There was a near complete range of hip and knee motion (both active and passive), and a normal gait. The results were similar to internal fixation done with interlocking nailing, in all the parameters including, knee and hip range of movement, both active and passive, thigh and leg girth, muscle wasting, extensor lag and time of union, but the operative time was a half that of interlocking.

Conclusion: By this study, it is concluded that K nail is still indispensable implant, and should not be abandoned completely especially in secondary health care centers in developing countries. It is useful in the management of fractures of proximal one-third of Femur, especially in cases where the patient is unable to buy other costly implants due to financial constraint. It should be one of the preferred implants in a secondary health care, government hospital with limited resources, in the hands of even a less experienced surgeon.

Key words: Femoral fractures, Intramedullary nailing, Secondary care facility

INTRODUCTION

In most of the secondary health care centers in India, there is a provision of a single elective operation theatre, but they lack in advanced equipment such as C-arm compatible, Orthopedic operation table with radiolucent top and traction attachments, fluoroscopic image intensifier unit (C-arm), interlocking nailing sets, locking plate set, and AO femoral distractor etc. Even if they are provided with these equipment, the costly implants in most of the cases have to be bought by the patients. The patients who largely visit these Government run secondary health care centers are very poor,[1] illiterate villagers. Chhattisgarh being a tribal state, they are largely tribal people with little exposure to education and government schemes for their welfare and upliftment, and health care facilities are remotely located and ill-equipped and understaffed.

Chhattisgarh Institute of Medical Sciences (CIMS), a government-run medical college was established in

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November 2001, by the state university, located at Bilaspur, with 100 student admissions a year. It was started in the infrastructure of the existing district hospital.

Kuntscher nail (K nail),[2] Kirschner wire, and stainless steel wires were the only implants provided by the hospital.

K nail was invented by Gerhard Kuntscher (M D). Kuntscher was Professor at the Department of Surgery at Kiel University Hospital in Germany. During the World War II, between 1939 and 1942, Kuntscher worked in Kemi, Finland as the chief medical officer in the German army. There, he used these nails for fixation of femoral fractures of war victims with unprecedented results, and it turned out to be a boon for these morbid and moribund soldiers. During these 4 years, he operated 500 femurs with these nails, and published his research book titled The Technique of Intramedullary Nailing in 1945 along with co-author and his Junior, Richard Maatz who was Reader at his Department in Kiel University. This book was forwarded by Thomas A Russell of Campbell Clinic USA, and he wrote that it was one of the most significant contributions to orthopedic surgery and trauma care in the history of medicine![2]

This worked wonders in the management of femoral fractures for last 5-6 decades until it was improvised as interlocking nail.[3-5] However, we at CIMS were able to prove that it still has a place in developing countries like India and in those patients who cannot afford relatively costly interlocking nail.

Hence, instead of refusing these patients, the required surgery or sending them to tertiary care center which is at least 120 km away. We decided to take them as a challenge and managed them with the available resources.

Hence, we employed K nails for almost any imaginable fracture pattern of proximal one-third of Femur (Figures 1-6) with convincing results.[1,2]

MATERIALS AND METHODS

Thirty cases of fracture Femur were managed with the help of K nails, in the Department of Orthopedics, in CIMS, from December 2002 to January 2005. There were 23 male and 7 female patients. The age range was between 19 and 68 years with average age of 43 years. 18 cases sustained the fracture due to the road traffic accident, 9 cases due to fall and 3 cases sustained it by assault.

These cases were followed for 10-12 years for restoration of function and complications or deterioration.

This is a retrospective study. Blanket consent was taken from all patients at the time of admission that they are

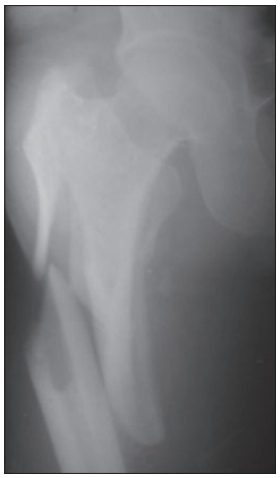

Figure 1: Pre-op plain anteroposterior roentgenogram of proximal end of femur in a young male, showing a comminuted four-part fracture of proximal third of femur (AO Type A3-3 trochanteric fracture)

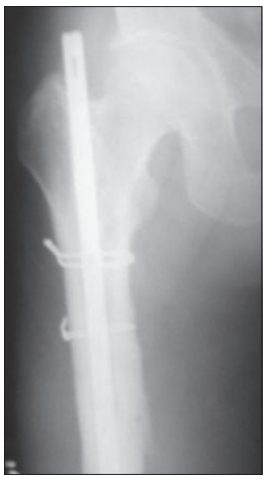

Figure 2: Anteroposterior roentgenogram of the same patient in Figure 1, taken 6 months after operation with K nailing and cerclage wiring, showing sound union of fracture fragments in perfect anatomical position

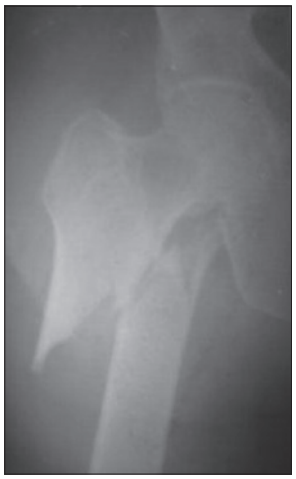

Figure 3: Anteroposterior roentgenogram of proximal third of femur of a patient showing reverse oblique fracture (AO Type A3-3 trochanteric fracture)

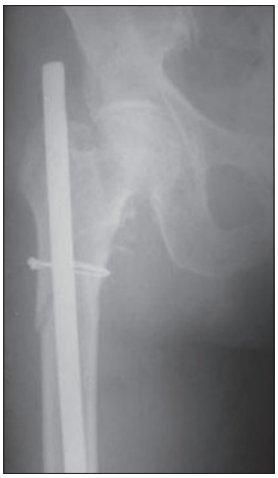

Figure 4: Anteroposterior Roentgenogram of proximal third of femur in the same patient in Figure 3, taken 2 months after operation with a K Nail and cerclage wire, showing good reduction and satisfactory callus

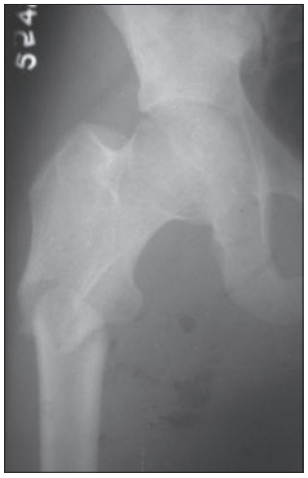

Figure 5: Anteroposterior roentgenogram of proximal third of femur of a patient showing a fracture of the proximal end. (AO Type A3-2 trochanteric fracture)

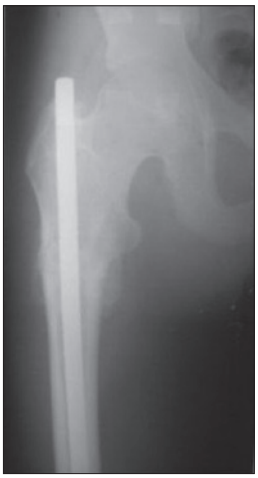

Figure 6: Anteroposterior roentgenogram of proximal end of femur in the same patient in Figure 5, taken 8 months after operation with a K Nail, showing good reduction and excellent union

willing for any type of medical or surgical procedure, and that their treatment information would be used for study and research purposes also, warranting them of the complete secrecy of their entrusted personal information.

An Ethical Clearance Certificate was taken from Ethical Committee of our Medical College for this study.

K nailing was done by standard procedure of nailing,[3] applying AO Principles of internal fixation[4] with due emphasis on exact length and thickness of the nail, so as to span the whole length of the bone and should occupy the entire medullary cavity at isthmus, and should achieve three point fixation of the nail in the bone, in order to provide complete rotational stability of the bone and fracture.

RESULTS

All the cases healed within 3-6 months of operation. There was near complete range hip and knee motion, both active and passive.

It is pertinent to mention here that the C arm image intensifier, fluoroscope was not available at that time in CIMS. Therefore, all these cases were done without it purely relying on clinical and surgical acumen.[1,2,5]

DISCUSSION

The results were similar to internal fixation done with interlocking nailing[1,2,5] or plating, in all the parameters including, knee and hip range of movement (Figure 7), both active and passive, thigh and leg girth, muscle wasting, extensor lag and time of union, but the operative time was one-third that of plating and half that of interlocking.[1,2,5]

K nailing is still indispensable implant, and should not be abandoned completely[1-3,5] in favor of newer, more advanced, strong and biomechanically more favored implants. The more advanced an implant is, the more sophisticated instruments, equipment, it requires. It also requires greater practice and experience to put them in situ. Whereas, K nail is the simplest of the implants, and if the AO principles of fracture fixation are adhered to strictly, and three point fixation is achieved and the nail is thick enough to occupy whole of the medullary cavity, then it is the most preferred implant in a secondary health care provider, government hospital[1,2] which could manage to get only newly recruited little experienced Orthopedic surgeons. K nail should be an important inclusion in the inventory of implants in Orthopedic surgeon's basket, and sometimes when every other advanced implant

Figure 7: Clinical photograph of the same patient whose roentgenograms are shown in Figures 5 and 6, displaying the full range of hip and knee, after 8 months of operation. The surgical scar mark can be clearly seen in the patient's thigh

fails, K nail saves the surgeon and the limb. Especially, in management of fractures of proximal one-third of femur, because most of the time while operating upon a complicated, comminuted fracture pattern especially in elderly osteoporotic patients with many co-morbidities, the surgeon gets very little, anesthesia and surgical time to put in complicated lengthy processed implant, requiring complete inventory of sophisticated instruments and equipment and fully trained and experienced staff[1,2] or in cases where the patient is unable to buy other costly implants due to financial constraint.[5] In such a situation, a K nail serves the purpose and it does not take more than one-fourth to one-third of the total operating time on the limb and it takes only one-third of the time, which is required for plating and half the time required for interlocking.

CONCLUSION

With this study, we came to the conclusion that K nail is still indispensable implant, and should not be abandoned completely. It is still a boon for those patients who are unable to buy other costly implants, and who cannot travel far and wide for definitive fracture management, due to financial constraint.[5]

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Original Article

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An Interventional Study on Awareness Regarding First Aid and Fire Safety Among the Second Year Undergraduate Medical Students of BJ Medical College, Ahmedabad

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Abstract

Background: Providing first aid is helpful for the survival of victim. Medical students are taught to handle these emergencies in hospital setting where all facilities are available. However, this may not be adequate to deal with the emergency conditions (e.g., Road traffic accidents, fire) at the emergency site without hospital facility.

Materials and Methodology: An interventional study was conducted on 50 students of the 2nd year from BJ Medical College, Ahmedabad. They were interviewed by pretested and predesigned proforma after that student were gone through 2-days training of first aid and fire safety and again interviewed by the same proforma.

Results: The awareness among medical students about first aid was poor and about fire safety were average before the intervention, which was significantly increased after the intervention.

Conclusion: Awareness regarding first aid among the medical student was poor and awareness regarding fire safety was average before the training (Intervention) while awareness regarding both first aid and fire safety was significantly increased after the training. Girls having more awareness regarding both fire safety and first aid compare to boys.

Key words: Awareness, Fire safety, First-aid, Medical Students

INTRODUCTION

"Today's Children are tomorrow's citizen". Imparting scientific knowledge to the children is inevitable to build up a healthy society . The preventive aspect of child care is an important part of health promotion, and to protect the child from various emergencies. Enlightening the children regarding various aspects of primary aid to mitigate the serious repercussions of accidents. Increased focus on safety strategies in emergency and public awareness has a direct impact on reducing the mortality rates and improving the general health of the population. All primary school children should receive first aid training starting in first grade. It is the need of the hour to facilitate the children with scientific knowledge.[1] They are more prone to a variety of injuries. Motor vehicle accidents are the leading cause of death in the adolescent's years. Pubescent are especially susceptible to injury when riding snowmobiles, or motorcycles, a sport that is increasing in popularity. Pillion riders may burn their legs on the exhaust pipe. Other causes are drowning and firearms; Hence, first aid is more needed in youngsters.[2] Estimating the burden of injuries is crucial for understanding the magnitude of the problem, developing mechanisms for intervention, allocating physical, human, financial resources for control of the problem throws light to the need of emergency aid. A review of Indian studies and observations by other agencies indicate the ratio of deaths to serious injuries

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needing hospitalization to minor injuries as 1:20:50. In Bangalore and Haryana, this ratio was 1:18:50 and 1:29:70, respectively. The death rate rises rapidly following puberty because of the large number of deadly accidents, homicides and suicides in the 15-24 year age group. These three causes of death in teens should all be preventable by rendering immediate aid to the casualties in order to reduce threatening complications.[3]

"The time for action is now. It's never too late to do something".

Carl Sandburg.

During the past quarter, a significant increase in adolescence forced the world to look into the matter. The major part of the children had an accident on the way to school and back home. Hence, the explanation of the dangers of the road will be extremely effective in the prevention of road accidents. In India, over 80,000 persons die in the traffic crashes annually, over 1.2 million are injured seriously and about 3,00,000 are disabled permanently . During this entire period (4 years) out of 67, 59, 599 admissions, accidental poisoning accounted for a total of 650 cases (0.96%), out of which 130 cases (0.75%) were in 1997, 90 (0.58%) in 1998, 180 (1.2%) in 1999 and 250 (1.25%) in 2000.[4] A study done by Daniels, on 20th April 2009 in America has evaluated about drowning physiology after the rescue. Drowning is the third largest cause of accidental death, involving over 7,000 victims annually. Many of these fatalities could be prevented with proper rescue and follow-up life support procedures. It is important that recreation professionals and other personnel responsible for aquatic programs understand the basic physiological threats present during and following drowning situations.[5] In healthcare, we know that properly administered first aid could save a person's life, which makes the importance of learning first aid and to choose the correct and authorized first aid training . The main aim to give first aid is to save life, to prevent deterioration of the condition and further injury, to prevent conditions that might increase the original injury, to make the victims as comfortable as possible, to arrange for transportation to the hospital. To preserve the valuable life of victim's undergone emergency situations, the blossoms of future should have proper awareness regarding the first aid management.[6] Despite their lack of knowledge, a vast majority (94%) of children agreed that it was very important for them to learn first-aid, and most wanted to learn more.[7] You are never too young to learn lifesaving first-aid skills.[8] The World Health Organization's South-East Asia (SEA) region bears 31% of the world's burden of injury and 27% of injury-related mortality.[9] It is also estimated that the SEA Region accounts for 57% of the global burden of burn injury and 53% of burn mortality.[9] The average response time of providing emergency services in urban areas is 15 min and 20-25 min in rural and tribal areas.[10] First few minutes are very important for the survival of victims. Medical students are taught to handle these emergencies in hospital setting where all facilities are available.[11] However, this may not be adequate to deal with the emergency conditions (e.g. Road traffic accidents, fire) at the emergency site without hospital facility.

Aims

- To evaluate the awareness of the students regarding emergency conditions.

Objectives

- To evaluate knowledge of students
- To know the attitude of students to face the emergency
- To plan for the future activity.

MATERIALS AND METHODOLOGY

The present study is Cross-sectional study, which was conducted in BJ Medical College, Ahmedabad among 100 students of 2nd-year medical students during December 2012 to February 2013. 100 students of 2nd-year medical students were randomly selected from BJ Medical College, Ahmedabad. Consent of Medical students was taken regarding participation in the study. They were interviewed by pretested and predesigned Performa after giving training regarding first-aid and fire safety they were again interviewed with same Performa. The data was compiled and analyzed in Microsoft excel and Epi info software (version 7).

RESULTS

Demographic Profile

The study was done on 100 medical students among them 50% were male, and 50% were female. Among 100 medical student 30% belong to Ahmedabad, 15% from Surat, 10% from Rajkot, 10% outside Gujarat, 6% from Vapi, 10% from Vadodara, 6% from Dahod, 7% Jamnagar, 6% from Bhavnagar. Among the 100 student, 60% were of 20 years age group and 40% were 19 years of age group (Table 1).

The present study showed that before the impartation of knowledge regarding first aid overall knowledge was found to be 33.66 % (male 19.33% and female 14.33%).

After impartation of knowledge regarding, first it was found that overall knowledge was increased up to 85.16% from 33.66% (male 45.75 % and female 39.4%).

It was showed that overall 51.5% increase in knowledge after impartation of knowledge. In the similar study by Sangowawa[12] in Ibadan, Median first aid knowledge scores before and after the intervention were 12 (5 20) and 15 (8 23) ($P = 0.05$). Median first aid skills scores were 11 (2 15) and 15 (7 20) ($P = 0.05$) for controls (Table 2).

The present study showed that before the impartation of knowledge regarding fire safety overall knowledge was found to be 55.33% (male 32.58% and female 22.75%). After impartation of knowledge regarding fire safety, it was found that overall knowledge was increased up to 85.00% from 55.33% (male 44.25% and female 40.75%). It was showed that overall 29.67% increase in knowledge after impartation of knowledge. In the similar study by Abdulrasheed Ibrahim[13], Zaria 73 students (21.5%) had previous knowledge of burn prevention and first-aid, compared with 262 (77.3%) who had no previous knowledge of burn prevention.

DISCUSSION

With the developmental activities of humans and resulting environmental changes, disasters, burns, and accidents are a frequent cause of morbidity and mortality. Due to lifestyle changes, the prevalence of various non-communicable diseases is also rising, which may lead to sudden deaths. In all these situations, if immediate care is given the burden of morbidity and mortality can be reduced significantly. Until a few years ago injuries were generally perceived as acts of chance. Today, injuries are not regarded as just accidents. The term "injury" instead of "accident" is used because they are predictable and preventable.[14]

Table 1: Awareness regarding first aid before and after the intervention there is significant rise is awareness after intervention

Awareness regarding first aid (correct answers)	Pre-test			Post-test		
	Total (*n*=100)	Female (*n*=50)	Male (*n*=50)	Total (*n*=100)	Female (*n*=50)	Male (*n*=50)
What to do first when you are alone and find someone unresponsive?	29 (29.0)	10 (34.5)	19 (65.5)	84 (84.0)	35 (41.7)	49 (58.3)
What to do if somebody is not responding to you even after shaking and shouting?	14 (14.0)	8 (57.1)	6 (42.9)	91 (91.0)	41 (45.1)	50 (54.9)
Location for chest compression in adult?	44 (44.0)	18 (40.9)	26 (59.1)	94 (94.0)	48 (51.1)	46 (48.9)
Location for chest compression in infants?	47 (47.0)	23 (49)	24 (51)	82 (82.0)	34 (41.5)	48 (58.5)
How to give rescue breathing in infants?	10 (10.0)	8 (80.0)	2 (20.0)	73 (73.0)	32 (43.8)	41 (56.2)
Depth of chest compression in adults during CPR?	18 (18.0)	10 (55.6)	8 (44.4)	80 (80.0)	35 (43.8)	45 (56.2)
Depth of chest compression in children during CPR?	23 (23.0)	16 (69.6)	7 (30.4)	79 (79.0)	36 (45.6)	43 (54.4)
Depth of compression in neonate	44 (44.0)	14 (31.8)	30 (68.2)	86 (86.0)	45 (52.3)	41 (47.7)
Rate of chest compression in adult?	30 (30.0)	12 (40.0)	18 (60.0)	98 (98.0)	48 (49.0)	50 (51.0)
Ratio of CPR in single rescuer in adult?	41 (41.0)	19 (46.3)	22 (53.4)	90 (90.0)	50 (55.6)	40 (44.4)
Knowledge about AED?	30 (30.0)	10 (33.3)	20 (66.7)	75 (75.0)	28 (37.3)	47 (62.7)
Knowledge about EMS?	74 (74.0)	24 (32.4)	50 (67.6)	90 (90.0)	41 (45.6)	49 (54.4)
Overall result (%)	33.66	14.33	19.33	85.16	39.4	45.75

CPR: Cardiopulmonary resuscitation, EMS: Emergency medical service, AED: Automated external defibrillator

Table 2: Awareness regarding fire safety before and after the intervention there is significant rise in awareness after intervention

Awareness regarding fire safety (correct answers)	Pre-test			Post-test		
	Total (*n*=100)	Female (*n*=50)	Male (*n*=50)	Total (*n*=100)	Female (*n*=50)	Male (*n*=50)
What claims most lives in fire?	36 (36.0)	16 (44.4)	20 (55.6)	86 (86.0)	38 (44.2)	48 (55.8)
What to do if electrical appliance begins to emit smoke?	94 (94.0)	36 (38.3)	58 (61.7)	97 (97.0)	47 (48.4)	50 (51.6)
Essential elements of fire?	63 (63.0)	27 (42.8)	36 (57.2)	90 (90.0)	44 (48.9)	46 (51.1)
Causes of most of fire cases?	40 (40.0)	16 (40.0)	24 (60.0)	92 (92.0)	43 (46.7)	49 (53.3)
How does a water type extinguisher put out a fire?	56 (56.0)	20 (35.7)	36 (64.3)	81 (81.0)	34 (42)	47 (58)
Color for the dry powder fire extinguisher?	59 (59.0)	26 (44.1)	33 (55.9)	96 (96.0)	46 (47.9)	50 (52.1)
Where would you look for an extinguisher in a building?	64 (64.0)	24 (37.5)	40 (62.5)	82 (82.0)	38 (46.3)	44 (53.7)
Sequence of four steps to be followed in the event of a fire?	25 (25.0)	11 (44)	14 (56)	63 (63.0)	27 (42.9)	36 (57.1)
Phone number for Fire control help in India?	64 (64.0)	28 (43.8)	36 (56.3)	87 (87.0)	42 (48.3)	45 (51.7)
What is latest symbol denoting escape route?	39 (39.0)	15 (38.5)	24 (61.5)	72 (72.0)	42 (58.3)	30 (41.7)
If your clothing get fire what should you do?	86 (86)	36 (41.9)	50 (58.1)	98 (98.0)	48 (49.0)	50 (51.0)
Acronym for using fire safety equipment?	38 (38)	18 (47.4)	20 (52.6)	76 (76.0)	40 (52.6)	36 (47.3)
Overall result (%)	55.33	22.75	32.58	85.00	40.75	44.25

As a result, of this shift in perception, burn injuries have demanded the attention of health policy decision makers' worldwide.[15] Therefore, establishing strategies that increase burn prevention effectively and efficiently are warranted.[16] The result of this study shows significant inadequacies in the knowledge of burn prevention and first aid treatment. This indicates a poor sense of burn safety, constituting a great educational need.[17,18] Stop, drop and roll when your clothes catch fire and immediate cooling of burns with cold water as a first aid measure significantly determines burn outcome. It decreases morbidity and health care costs by limiting the degree of tissue damage. Consequently, the need for surgery and subsequent reconstruction is reduced.[19] The possibility of disfigurement, disability, and death, demonstrate that burn prevention and first-aid knowledge must be aggressively administered.[14,19]

CONCLUSION

From the study, it is concluded that awareness regarding first aid among the medical student was poor, and awareness regarding fire safety was average before the training (Intervention) while awareness regarding both first-aid and fire safety was significantly increased after the training. Girls having more awareness regarding both fire safety and first aid compare to boys.

RECOMMENDATION

1. This type of training or workshop should be planned to increase the awareness of medical student about first aid and fire safety in all medical college.
2. Short course regarding fire safety and first aid should be include in UG curriculum.
3. Empowered students can train community leaders such as teachers, sarpanch etc.

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Original Article

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Comparison between Semonts Maneuvere and Beta Histine in the Treatment of Benign Paroxysmal Positional Vertigo

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Abstract

Introduction: Benign paroxysmal positional vertigo (BPPV) is the most common type of vertigo that presents in an ENT clinic. Various repositioning maneuvers and treatment therapies exist for its management.

Objective: The objective of this study was to compare the efficacy of Semont's maneuver with a vestibular suppressant, Beta Histidine in the management of BPPV.

Patients and Methods: This was a Randomized Clinical Trial, which was carried out in ENT Department CMH Quetta and ENT Department PNS Shifa from 1st March 2013 to 1st Sept 2013. Consenting 70 patients with BPPV were included in the study. Based on treatment opted, random allotment of patients in two groups were done i.e., Group A with (n = 35) or group B with Beta Histidine (n = 35). Outcomes were measured by disappearance of vertigo at follow-up examination.

Results: In this study, of 35 cases managed by Semont's Maneuver, 31 (88%) cases showed relief of symptoms after 15 days. Out of 35 cases managed by Beta Histidine, 20 (57%) cases recovered after 15 days.

Conclusion: Semont's maneuver was more effective then vestibular suppressants like Beta Histidine in the management of patients of BPPV.

Key words: Benign paroxysmal positional vertigo, Beta Histidine, Dizziness, Repositioning maneuver

INTRODUCTION

Benign paroxysmal positional vertigo (BPPV) is the most common type of vertigo with a lifetime prevalence of 2.4%.[1] It is characterized by transient episodes of vertigo associated with a predominantly horizontal rotational nystagmus precipitated by change in head position.[2] It commonly affects females greater than males.[3] Its incidence increases with age and reaches peak in sixth and seventh decade.[4] It is considered the most common cause of vertigo in elderly.[1,4,5] Benign paroxysmal positional vertigo may occur as an idiopathic form when it is termed as primary[2] while the common causes of secondary benign paroxysmal positional vertigo are head trauma,[5] viral neurolabyrinthitis, Meniere's disease and Cogan's syndrome.[6]

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The two main hypotheses, which explain the development of BPPV are the cupulolithiasis theory and canalithiasis theory. Cupulolithiasis theory is based on the attachment of otolithic debris to the cupula in the crista ampullaris while the canalolithiasis theory is based on the presence of free-floating debris in the lumen of the semicircular canals (SCC). Simply put, the presence of foreign particles in the SCC is the cause of vertigo.[1,7,8]

Over the years, the treatment of BPPV has seen a dramatic shift from anti vertiginous drugs to various maneuvers as our understanding of the disease has progressed. The Common instructions to patients include the avoidance of positions that induce nystagmus. Drugs like Beta Histidine

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and Cinnarizine reduce the vestibular vertigo.[6] Various maneuvers such as Semont and Epleys are the noninvasive techniques practiced for correction of pathology. Both these techniques aim to dislodge the inorganic fragments located on the cupula of the posterior canal or floating in the canal.[10-12] Mastoid vibrators have also been used in attempts to dislodge the particles from inner ear with variable success.[13]

Dix Hallpike test is virtually diagnostic of BPPV but can induce vertigo.[13] The objective of this study was to compare the efficacy of Semont's maneuver and vestibular suppressant, Beta Histidine in the management of BPPV. A total of 70 patients with BPPV was included and were divided in 2 groups of 35 each. Group A was treated with Semont's maneuver while Group B was treated Beta Histidine. The results of this study were decided on the basis of reduction/absence of vertigo on repeating Dix-Hallpike test on the 15th day of the start of treatment.

PATIENTS AND METHODS

This was a Randomized Clinical Trial carried out in ENT Department CMH Quetta and ENT Department PNS Shifa from March to Sept 2013. Non-probability consecutive sampling technique was used. All patients irrespective of their age and sex with positive Dix-Hallpike test and normal pure tone hearing thresholds were considered having BPPV. The Patients with associated medical illnesses including diabetes mellitus, anemia, cardiovascular disorders such as ischemic heart disease, hypertension, carotid artery stenosis and postural hypotension or history of recent head and neck injury, history of tinnitus, aural fullness and cervical spondylosis were excluded from the study.

Data Collection Procedure

- Permission was sought from hospital Ethical Committee.
- One hundred patients were selected after detailed history, examination and Dix-Hallpike test diagnosis of BPPV on 1st visit.
- Informed written consent was taken from all the patients.
- Hospital registration number, name, gender, age, address and phone number (optional) were noted for future communication.
- Patients were randomly divided into two groups of 78, each using random number table.
- Baseline VAS score was recorded.
- Group A was treated with maneuver by the trainee researcher.
- Group B was treated with Beta Histidine (16 mg) 1 tablet thrice daily.
- The patients were called for re-examination on 14th day by the trainee researcher.
- Presence or absence of subjective symptom of vertigo was assessed clinically.
- All the data was recorded on a specially designed Performa attached as annexure A.

Data Analysis

- Data analysis was done using SPSS version 16
- The variables to be analyzed included quantitative data like age, which were analyzed as mean and standard deviation
- Qualitative data like sex, VAS scale of vertigo at baseline and 15th day and efficacy of a technique was presented as frequency and percentage
- Chi-square test was used to compare the efficacy in both groups
- $P < 0.05$ was considered significant
- Results were explained with the help of charts and tables.

RESULTS

In this randomized control trial, a total of 75 patients of BPPV were included, but five were lost to follow-up. Data of seventy patients has been presented. Group A was treated with Semont's maneuver, and Group B was treated with a vestibular suppressant (Beta Histidine). The mean age in each group are given in Table 1.

There were 16 (46%) males and 19 (54%) in Semont maneuvers group and 18 (51%) males and 17 (49%) females in vestibular suppressant group. In my study all the participant was suffering from sudden, episodic vertigo and most categorized their vertigo of moderate intensity that is 66% in Semont's maneuver group and 71% in BetaHistidine group. After 15 days of treatment, both groups showed significant improvement but the rate of recovery was higher in Semont's maneuver group in which 89% of patients became disease free. In BetaHistidine group, only 57% patients became disease free. In Semont's maneuver group, only 3% patients remained in severe vertigo group while in Beta Histidine group 11% patients remained with severe vertigo. There is no significant difference in vertigo

Table 1: Distribution of age in both groups

Treatment group	*N*	Minimum	Maximum	Mean	Standard deviation
Semont's maneuver	35	38	68	53.2	8.787
Betahistine (vestibular suppressant)	35	39	65	53.4	7.765

at baseline ($P > 0.05$). The status of vertigo at baseline was almost same in both groups. Details are shown in Table 2.

According to the results, there was a significant difference in treatment of both these groups after 15 days of treatment. In patients treated with Semont's maneuver 8% patients became disease free. This was significantly higher ($P < 0.05$) as compared to patients who were treated with Beta Histidine in which only 57% of patients became disease free after 15 days. Similarly the proportion of patients with severe vertigo was considerably higher in Group Band than Group A. Moderate vertigo was suffered by 20% of patients in Beta Histidine group as compared to only 3% in Semont's maneuver group.

Group wise distribution shows that in Semont's maneuver group 31 (88%) patients were completely cured, but in Beta Histidine group 20 patients (57%) were cured after 15 days of treatment. There was a significant association between treatment groups and cure rates after 15 days of treatment. In Semont's maneuver group the complete cure rate was significantly higher (88% vs. 57%, $P < 0.05$) as compared to Beta Histidine group as given in Table 3.

Comparison of cure rates between males and females in Semont's maneuver group as well as betahistidine group showed no significant ($P > 0.05$) association of cure rate and gender, as shown in Table 4.

Table 2: Comparison of vertigo in both groups at baseline and on 15th day

Vertigo in both groups	Treatment group (%)		Total	*P* value
	Semont maneuver	Beta Histidine (vestibular suppressant)		
Vertigo at baseline				
Mild vertigo	2 (6)	3 (9)	5	0.667
Moderate vertigo	23 (66)	25 (71)	48	
Severe vertigo	10 (28)	7 (20)	17	
Total	35 (100)	35 (100)	70	
Vertigo after 15 days				
No vertigo	31 (89)	20 (57)	51	0.033
Mild vertigo	1 (2.5)	4 (11)	5	
Moderate vertigo	2 (6)	7 (21)	9	
Severe vertigo	1 (2.5)	4 (11)	5	
Total	35 (100)	35 (100)	70	

Table 3: Comparison of cure rate after 15 days between both treatment groups

Cured after 15 days	Treatment group (%)		Total	*P* value
	Semont's maneuver	Betahistine (vestibular suppressant)		
Cured	31 (89)	20 (57)	51 (73)	0.006
Not cured	4 (11)	15 (43)	19 (27)	
Total	35 (100)	35 (100)	70 (100)	

DISCUSSION

True vertigo is defined as the feeling of rotation of oneself with respect to the environment or vice versa. It must be distinguished from the feeling of lightheadedness, giddiness or weakness in limbs that people present with commonly in a vertigo clinic. BPPV described in 1921 is one of the most common causes of true vertigo. Although it is primarily an idiopathic disease but secondary causes of BPPV include head trauma, Meniere's disease, vestibular neuritis and Cogan disease among others.[14] BPPV is caused by the abnormal dislocation of otoconia, originating from the macula of the utricle, to the SCC, which is posterior semicircular canal in 86-90% of the cases.[15] These shedded off calcium carbonate crystals induce movement in the SCC triggering off impulses, which are in conflict with other senses.[16] Semont liberatory maneuver, named after the doctor who suggested it, is a simple three-step maneuver that is designed to remove the precipitating particles from their unusual position in the SCC. Different modifications of this maneuver designed to increase the efficacy exist which include repeating the maneuver several times, using mastoid vibrators to mobilize the otoconia or placing restriction on posture and head movements following the maneuver.[17]

Vertigo follows a specific social and demographic pattern. It commonly affects people in the sixth and seventh decade of life while the secondary causes for BPPV are believed to be the cause behind the earlier age of presentation in most cases. In studies also show that an older patient requires more repeated maneuvers for resolution of their symptoms. According to most studies females are more likely to suffer from BPPV but some studies do cite equal incidence in males and females as well.[17,18]

Lifetime prevalence of BPPV is 2.4% while the annual incidence of 0.6%.[1] In specialized clinics, it has a prevalence of 20-30%. Symptoms of BPPV are so sudden acute and unexpected that the patient is often severely distressed and

Table 4: Comparison of cure rate between both groups

Cure Rate in Both Groups	Male	Female	Total	*P* value
Semonts maneuver cure rate at 15 days				
Cured	15 (94%)	16 (84%)	31 (89%)	0.31
Not cured	1 (6%)	3 (16%)	4 (11%)	
Total	16 (100%)	19 (100%)	35 (100%)	
Beta Histidine cure rate at 15 days				
Cured	10 (55.5%)	10 (59%)	20 (57%)	0.845
Not cured	8 (45.5%)	7 (41%)	15 (43%)	
Total	18 (100%)	17 (100%)	35 (100%)	

refuses to work or get out of besssd.[19] It severely impacts a person's quality of life and grades poorly in quality of life questionnaires. It takes an average of 8 visits to various specialty clinics before being diagnosed.[20]

A single two min procedure in the form of Semont's liberatory maneuver or Epleys repositioning maneuver is effective in 60-80% of the cases.[17] In clinical practice, a combination of drugs is used for managing an acutely vertiginous patient.[21] A study done by Revert registry showed that Beta Histidine was the most frequently prescribed medication for management of vertigo.[22,23] Chronic drug administration has no role in the management of BPPV. Vestibular suppressants are prescribed for several days mostly.

Since BPPV can resolve on its own in most cases, watchful waiting or vestibulosuppressant medication is advised. However, it entails weeks or months of discomfort with the ever present danger of a mishap. Vestibular habituation exercise can also be useful in chronic or resistant cases of BPPV, where other maneuvers fail but are in essence a more prolonged version of repositioning maneuvers. Surgery is usually offered as a last choice as it has significant morbidity.[24]

Semont's maneuver requires a little time to be spent with the patient and office space for a couch that is hard to come by, yet it is cost effective, physiologically sound and is actually a liberating experience for the patient. Its beauty lies in its simplicity, lack of complications and ease of replication if required.

The results of our study suggest Semont's maneuver to be the highly effective single treatment approach toward BPPV as 88% of our patients were found to be asymptomatic at the end of second week. These results comply with similar studies conducted in different settings where the rate of recovery varied from 80-94%.[25,26]

A study done by Zhuang, *et al*. had a success rate of 94% after treatment with Semont's maneuver.[25] Similarly another study carried out in china showed that patients managed by Semont's maneuver were more likely to have a complete resolution of their symptoms. No adverse effects of treatment were noted in the study.[27]

Though present prescribing practices favor Beta Histidine however, it does not address the underlying pathology causing BPPV and even though it provides temporary relief complete resolution is elusive.[23] As always, intake of such medication for prolonged periods is not without its side effects including rash and epigastric discomfort.[28] Guneri and Kustutan in his study observed Beta Histidine to be effective in enhancing recovery from BPPV when combined with different repositioning maneuvers. Its efficacy in that trial was noted to be 84%.[27] However, single administration of BetaHistidine resolves symptoms in only 50% of the patients.[8] 5% patients were noted to have adverse effects with the medication.[8] In my study, BetaHistidine was found to be efficacious in only 57% of the patients, which is significantly less than Semont's maneuver but comparable to the results of other studies

CONCLUSION

Semont's maneuver is a non-invasive and very effective procedure for the management of BPPV. It is an office procedure with immediately satisfying results for both patients and doctor. It can be repeated if desirable results are not obtained after the first session. After 15 days of treatment both groups showed significant improvement but it was higher in Semont's maneuver group in which 88% of the patients became disease free as compared to BetaHistidine group in which only 57% patients were disease free. Taking into account the results of my study and the above-mentioned benefits, Semont's maneuver should be recommended as a treatment option for all patients of BPPV.

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Original Article

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Development and Validation of Questionnaire to Assess the Faculty Perception on the Dental Public Health Curriculum in India

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Abstract

Background: The dental academicians being in a unique central position between the students and the decision makers play a significant role in translating the advocacy efforts of the dental council to policy actions. The academicians' opinions, inputs, and their perspectives will help to recognize the strengths and weaknesses in the curriculum. However, this requires a reliable measurement tool to assess and document/report the current gaps in the curriculum in a systematic way. Hence, the present study aims to develop and validate an instrument for the assessment of faculty perception on undergraduate dental public health curriculum.

Subjects and Methods: The Development and validation of the questionnaire was conducted in three phases with 5 academic dental public health (DPH) professionals using mixed-method approach, combining quantitative-qualitative methodologies. First, the conceptual framework was designed using the themes derived from the focus group discussion (FGD) and followed by identification of domains and item pool generation for the instrument. This resulted in a preliminary version of the questionnaire with 6 domains and a section on internal evaluation of teaching and learning practices followed at individual dental institutions, totally comprising of 83 items. Second, an assessment of face and content validity, readability of the core set of the items was performed. The final questionnaire was an online version for pilot testing before actual field implementation.

Results: The new semi-structured, validated questionnaire was developed with 76 items, which was objectively tested and rated as having "very good" face validity with a score of 3.5 out of 4. The content validity was confirmed using Aiken's index for adequacy of the domains coverage (6 domains establishing the comprehensiveness of the new questionnaire) with sufficient number of items to adequately measure the domain of interest.

Conclusion: A new valid instrument for the assessment of faculty perception on undergraduate DPH curriculum has been developed. The use of this type of questionnaire appears to be a valuable tool for dental curriculum research.

Key words: Curriculum, Dental faculty, Questionnaire, Validation studies

INTRODUCTION

Though public health dentistry has a historical significance of emerging in India way back in 1970 as a post-graduate subject, it was officially considered as a subject in the undergraduate (UG) curriculum in 1983 by Dental Council of India (DCI).[1] Even after several decades of its emergence, the subject still encounters a wide spectrum of problems, which are detrimental to satisfactorily fulfill the objectives of the curriculum, to name a few, (a) Poor manpower policy, (b) lack of supportive infrastructure, (c) low priority for research, (d) lack of methods of logistical and financial support, networking, grant seeking mechanisms are not at all covered in curriculum, (e) poor evaluation system with low priority for core dental public health (DPH) competencies. There is a perceived gap between the curriculum mandated by the dental council and the ground reality in the country.

Five major reforms have taken place in the dental curriculum in the last three decades, which were initiated by DCI and Regional Health University. However, yet

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these reforms did not culminate in providing the globally competent UG DPH curriculum.

The dental academicians are in a unique central position between the students and the decision makers and work in highly complex ways of developing and implementing the curriculum. They are expected to take leadership roles to modulate the UG DPH curriculum and play an important role in translating the advocacy efforts of the dental council to policy actions.

Administrators, policymakers, and faculty members interested in curricular reform process need a reliable measurement tool to assess the current DPH curriculum and thus document/report the current gaps in the curriculum in a systematic way. These can be measured by obtaining the faculty members opinions, inputs, and their perspectives to recognize the strengths and weaknesses in the curriculum, thus helping to create evidence-based document with a strong DPH perspective for effective curricular reforms.

In this context, an extensive search in six renowned electronic databases such as PubMed, Medline, Cochrane, Science Direct, Google Scholar, and EMBASE revealed that no standardized questionnaire was available to assess the faculty perceptions on the DPH curriculum.

Only a few studies have reported on the isolated components of dental curriculum, measuring faculty perceptions on implementation of problem-based learning in UG dental curriculum,[2,3] objectively structured clinical examination,[4] extramural rotations and underrepresented minority/low-income students to community-based dental education program[5] and curriculum innovations,[6] there was no exclusive DPH curriculum evaluation questionnaire available in the literatures of either in western countries or in the Indian context.

To address this gap, the present study was taken up to develop, validate and pilot-test the questionnaire. Then, we used the questionnaire to survey research-related issues in regional dental colleges in India in order to gather data that could act as a forerunner to a nationwide study.

SUBJECTS AND METHODS

This study uses a mixed method design, conducted in one of the private dental institution in India. The ethical clearance was obtained from the Institutional Review Board.

Faculty with post-graduation qualification in the subject of public health dentistry having a minimum of 3 years of teaching experience was involved to participate in the study and those not available on the day of the study were excluded.

The study was carried out in three phases:

1. Phase 1: Conducting focus group discussion (FGD) with faculty members to identify the themes to design a conceptual framework for the development of the new questionnaire
2. Phase 2: Development of the questionnaire followed by face and content validation
3. Phase 3: Pilot testing of the online version of the new questionnaire developed.

The study involved purposive sampling method involving all the faculty members (5 faculty members) working in the department of public health dentistry, from the study institution. A written informed consent form was taken from all the participating faculty members. The FGD lasted from 60 to 90 min. The participants were assigned an identification number and were instructed to tell their respective identification number before they could comment, thus maintaining the anonymity. The full discussion was audiotaped using an audio recorder. Content analysis was used to analyze the data. The focus group interviews were transcribed then analyzed manually. The theoretical principles, practical issues, and pragmatic decisions were essentially consider to conceptualize on the content of the scale and the initial item pool included items representing all the domains of the scale.

The formulation of the initial pool of items related to the various domains was a crucial task for developing the scale. The fundamental goal at this juncture was to formulate all content systematically in a sequential manner that is potentially relevant in the new questionnaire.

For the present study, the items/questions reviewed from BDS curriculum ordinance book, journals and electronic media were identified, adapted and compiled in framing the items with most of them on a five-point Likert scale. Later, the questionnaire was tested for face and content validity.

Face validity refers to researchers' subjective assessments of the presentation and relevance of the measuring instrument as to whether the items in the instrument appear to be relevant, reasonable, unambiguous and clear. Practically, the quantitative assessment of face validity was achieved by 10-point criterion, wherein the judging panel scores on the five-point Likert scale from poor to very good with 0 being the least score and 4 being the highest, to objectively measure the satisfaction of each of the criteria indicated.[5] The mean average score of the expert panel is obtained to rate the tool by using an arbitrary scale.

Content validity refers to the conceptualization of the statements for developing the scale for the study. An estimate of the content validity of a test was obtained by thoroughly and systematically examining the test items to determine the extent to which they reflect the content domain.[6]

The items on the scale were rated as strongly relevant, relevant needs modification or irrelevant. The experts reviewed all the items across six key concepts of the DPH curriculum and the items focusing on teaching and learning practices followed at individual dental institutions. The statements that were found to be irrelevant and confusing were deleted, and those that were rated as needs modification were revised. The suggestions made by the panel were incorporated to enhance clarity and readability of the instrument.

The generally, accepted quantitative index for content is the Aiken's V-index. This index was used to quantify the ratings of panel experts constituted for evaluating the items in the instrument. The Aiken's V-index with 0.80 indicates good content validity of the measure.

After the tool was developed, a draft copy of the tool was prepared and was tested for readability by the investigator, Hence, as to ensure that the items of the tool did not have double barrel questions, the items were not contradicting in nature and also further to ensure that there was no repetition of any items with similar meanings.

A pilot study was conducted using the online PDF fillable questionnaire, developed by the investigator using a Software *viz.* Adobe Acrobat Version 10.

RESULTS

Focus group participant's characteristics are presented in Table 1.

Table 1: Participant characteristics

Characteristics	Details
Gender	
Male	1
Female	4
Age	
Mean	34.5 years
Educational status	Master of dental surgery (public health dentistry)
Designation	1 – Professor and Head 2 – Readers 2 – Senior Lecturer
Academic experience	Professor and Head - 11 years Readers - 4 years each Senior Lecturer - 3 years each

The themes derived from the FGD were utilized to construct the conceptual framework for the development of the new instrument. The conceptual framework consisted of six domains and the additional sub-domains, namely, (i) Curriculum aims, goals, objectives and competencies, (ii) curriculum content/subject matter, (iii) innovative methods of teaching/learning, (iv) Other essential skills, (v) curriculum evaluation/assessment methods, and (vi) institutional support, and a section on the teaching, and learning activities followed in their respective institutions.

In the present study, 83 items were identified, adapted and compiled for the formulation of scale to assess the faculty perception on current UG DPH curriculum.

Panels of five subject matter experts were given the questionnaire for face and content validity.

The mean face validity score was 3.5 (out of 4 as the highest score in the arbitrary scale), and it was indicating that the panel of subject matter experts rated the face validity as "very good".

Those 83 items, which were initially screened using face validity with experts were subjected to content validity. If any question had Aiken's index <0.80 (range of 0.60-0.70), that marked them as not relevant, contradicting and confusing were deleted or changed after consultation with the experts (Table 2 and 3). After the validity assessment, out of 83 original questions, 75 items were retained, five were modified, seven were deleted, and one item was split and modified into two separate questions.

The majority of the items in the questionnaire had got the Aiken's V-index score of 1.0, indicating that all the raters giving those items the highest possible rating. However, the Aiken's V-index score for all the 76 items ranged between 0.80 and 1.0.

In the present study, all the items were given a response scale, by using five-point Likert scale for various domains and sub-domains, which includes "strongly disagree" to "strongly agree", "not at all important" to "very important", "not all satisfied" to "very much satisfied" and "poor" to "very good", with 1 being the least score and 5 being the highest.

The final semi-structured questionnaire consisted of a total of 76 items (02 open-ended and 74 close-ended questions) which was framed with six domains for assessing the faculty perceptions on UG DPH curriculum with such as: (i) Curriculum aims, goals, objectives and competencies (25 items [including 23 sub-items]), (ii) curriculum content/ subject matter (21 items), (iii) innovative methods of

Table 2: Content validity of the new instrument with Aiken index

S. No.	Statement	Aiken's index
	Curriculum aims, goals, objectives and competencies	
1.	The DPH curriculum has stated its aims, goals and objectives clearly	1.00
2.	The DPH curriculum is more of a knowledge-based curriculum	1.00
3.	How important do you think these competencies are for an undergraduate student through the Department of Public Health Dentistry (Note: After undergoing training in III and IV BDS, these are the competencies required for the student through the Department of Public Health Dentistry)	
	Competencies (Note: Competency is defined as an ability or fitness or capacity to do a defined task – Webster's Dictionary)	
	a. Knowing clinical dental skills	1.00
	b. Adept in program planning	1.00
	c. Adept in performing preventive procedures	1.00
	d. Having research skills	1.00
	e. Having qualities like leadership and working in teams	1.00
	f. Ability to diagnose and treat dental diseases at a community level	1.00
	g. Advocacy and policy influencing skills	0.80
	h. Grant writing skills	0.80
	i. Ability to critically appraise a document or situation	0.80
	j. Ethics and social perspectives	1.00
	k. Soft skills e.g.: Presentation skills, documentation skills etc	0.90
	l. Any other	1.00
4.	Do you think these competencies are fulfilled in the present training of RGUHS/your university undergraduate DPH curriculum	
	Competencies	
	a. Knowing clinical dental skills	1.00
	b. Adept in program planning	1.00
	c. Adept in performing preventive procedures	1.00
	d. Having research skills	1.00
	e. Having qualities like leadership and working in teams	1.00
	f. Ability to diagnose and treat dental diseases at a community level	1.00
	g. Advocacy and policy influencing skills	0.80
	h. Grant writing skills	0.80
	i. Ability to critically appraise a document or situation	0.80
	j. Ethics and social perspectives	1.00
	k. Soft skills e.g: Presentation skills, documentation skills etc.	0.90
5.	Curriculum content/subject matter	
	a. Theory content	
	i. The DPH curriculum has explicitly defined theoretical components	1.00
	ii. The theoretical component in DPH curriculum is vast and wage	0.60
	iii. The present DPH curriculum prioritizes the theoretical components has must know/desirable to know	1.00
	iv. The theoretical components in present DPH curriculum are adequate for training the students in the DPH competencies required	1.00
	v. The manpower recommended by DCI is adequate for the teaching of theory contents of DPH curriculum	1.00
	vi. The time allocated in the RGUHS DPH curriculum is adequate for the completion of prescribed theory contents	1.00
	vii. The present undergraduate curriculum prioritizes the theoretical contents, which are important from DPH perspective	0.80
	b. Practical/clinical content	
	i. The present DPH curriculum has an explicitly defined practical component	0.80
	ii. The curriculum trains the students in instrumentation component	0.60
	iii. The present DPH curriculum prioritizes the practical components has must know/desirable to know	0.80
	iv. The practical components in present DPH curriculum are adequate for training the students in the competencies required for a public health dentist	1.00
	v. The manpower recommended by DCI is adequate for teaching of practical contents of DPH curriculum	1.00
	vi. The time allocated in the RGUHS DPH curriculum is adequate for the completion of prescribed practical contents	0.90
	vii. DPH curriculum emphasizes more on the use of indices for measurement and quantification of disease than on important DPH skills like research, program planning, etc.	1.00
	viii. UG research in the UG curriculum helps in developing scientific skills and self-learning in students	1.00
	ix. UG DPH curriculum considers training the students to enter clinical research organizations after graduation	0.60
	c. Outreach programs	
	i. The present DPH curriculum explicitly mentions the number and type of outreach programs to be conducted for undergraduate students	1.00
	ii. The outreach program activities in present DPH curriculum are adequate for training the students in the competencies required for a public health dentist	0.90
	iii. The UG DPH curriculum mandates the field visits and emphasizes the importance of the same to the UG students	0.70

(*Contd...*)

Table 2: (*Continued...*)

S. No.	Statement	Aiken's index
	iv. The UG DPH curriculum provides reporting protocol of the field visits in a systematic manner	0.60
	v. The DCI recommends a designated manpower (Doctors and Auxiliaries) for conducting the outreach programs as indicated in DPH curriculum	0.80
	vi. The present manpower recommended is adequate to conduct the outreach programs as per the DPH curriculum	1.00
	vii. The DPH curriculum has explicitly mentioned the time allocation for outreach program activities	0.80
	viii. The outreach program activities in present DPH curriculum are adequate for training the students in the competencies required for a public health dentist	0.90
	ix. The time allocated in the DPH curriculum is adequate for conducting various outreach programs	1.00
	x. The present DPH curriculum states clearly the roles and duties of a student during an outreach program	1.00
	xi. The present DPH curriculum considers posting of undergraduate students to the satellite center	0.80
6.	Innovative methods of teaching/learning	
	a. Does the curriculum mention innovative teaching/learning methods?	1.00
	b. Innovative teaching/learning methods are important component of DPH UG curriculum	0.70
	c. Does the present DPH curriculum allow you to incorporate the innovative teaching strategies without hampering the fulfillment of the syllabus?	1.00
7.	Other skills	
	a. The present UG DPH curriculum encourages personality development and communication skills	1.00
	b. The present DPH curriculum provides efficient training in dental practice management for UG students who wish to start private practice immediately after BDS	1.00
8.	Curriculum evaluation/assessment methods	
	c. The DPH curriculum clearly states type, number and methods of evaluation	1.00
	d. Curriculum considers holistic way of evaluating a student considering his punctuality, class room behavior, meeting deadlines, etc.	0.60
	e. An UG student trained in DPH should possess certain DPH competencies. The present examination system evaluates all these competencies adequately	1.00
	d. The DPH curriculum looks into both summative and formative assessment of the student during the evaluation	1.00
	e. The manpower recommendations of the DCI are appropriate and adequate for evaluation of the UG students' performance in DPH	1.00
	f. The present practical examination pattern stresses on the case history and indices component, which are not the priority DPH competencies	1.00
	g. Components like research, critical appraisal skills, program planning, community diagnosis etc., are not evaluated in the present practical examination system	1.00
9.	Institutional support	
	a. The mechanism of logistical and financial support to promote research in institutions is mentioned adequately in the DPH curriculum	1.00
	b. The mechanism of logistical and financial support to promote research in institutions should be mentioned in the DPH curriculum	1.00
	c. The institution should provide logistical and financial support to promote research among undergraduate students in institutions	0.80
	d. Does your university provide adequate guidelines on mechanism of logistical and financial support to conduct a good quality research?	1.00
10.	Curriculum review	
	a. Has the undergraduate DPH curriculum been reviewed in last 20 years?	1.00
	b. If yes, how frequently was it been reviewed in the last 20 years?	1.00
	c. Indicate 2 best practices that you think are incorporated in the undergraduate DPH curriculum over the last 20 years	1.00
	Section B	
	Teaching/learning skills practices at your institution	
11.	How do you rate the teaching and learning facilities in your institution and mention two reasons/explanations/ comments for the same	1.00
	a. Theory	
	b. Practical	
	c. Outreach programs	
	d. Evaluation/examination	
	e. DPH manpower/faculty	
12.	Name the innovative teaching components that you have incorporated in your institution	0.80
13.	It is unethical practice to bring the patients from other departments to public health dentistry department only to record case history and Indices	1.00
14.	The present DPH curriculum should consider integrating recording of relevant indices by the undergraduate students, during the case history recording process in other departments	0.90
15.	Does your department has at least one individual satellite center/one collaborated with other health organization/NGO?	1.00
16.	Management of satellite centers in your department	0.80
17.	If DPH MDS faculty are posted to satellite center, does it compromise the UG program in your department	1.00
18.	If UG students are posted, what is the nature of work done by the undergraduate students in the satellite center?	0.80
19.	Please mention three components that you would wish to change in the present undergraduate DPH curriculum to make it more suitable to the present need of a DPH cohort	1.00

DPH: Dental public health, DCI: Dental Council of India

Table 3: Validation by five subject experts for developing the new instrument for assessing the faculty perception of undergraduate DPH curriculum

Description	Number of items	Percentage
Number of items screened at face validity	83	100
Number of items screened evaluated by the experts	83	100
Number of items satisfied Aiken's index	76	92.2
Number of items, not satisfied Aiken's index	07	7.8

DPH: Dental public health

teaching/learning (02 items), (iv) other essential skills (02 items) (v) curriculum evaluation/assessment methods (06 items) and (vi) institutional support mechanism (04 items), curriculum review (04 items) with most of the items on a five-point Likert scale with the ratings of 1-5 for the faculty members to rate their perceptions on the curriculum and the teaching and learning activities (12 items).

DISCUSSION

The DCI is currently facing several challenges in a diverse system of culture and geography to empower dental graduates to render quality service on par with international standards.

In community-based dental education, acquiring competency in addressing oral health needs at the community level and deepening their knowledge about the social and local health situation is an important aspect. Students are not only placed in community settings to treat individual patients, however also challenged to consider DPH issues, including the administrative aspects of dental services.[7]

In India, UG DPH curriculum is not competency based in order to meet the growing oral health care demands and producing competent dentists with comparable standards of education, inclusion of professionalism, research culture, critical thinking and communication skills, program planning strategies, other soft skills, and the promotion of skills for lifelong learning takes precedence.

There is a lack of instilling of this core DPH skills in the dental graduates of India and eventually they need further education when they immigrate to other developed countries.

"Delivery" of knowledge is discipline-based and uses conventional instruction methods and it is evident that there is a lack of innovative teaching and learning methods. Assessment of knowledge and skills is more summative than formative.

The present system of DPH emphasizes more on imparting a vast range of subject matter and vague general knowledge but not specific skills. In addition, the curriculum stresses more on traditional measurement, and quantification of disease and indices recording, with minimal credits to research component.

In this context, a search was conducted among the published literatures to find the availability of pre-validated questionnaire to assess the faculty perception on the DPH curriculum. There was neither a gold standard instrument nor a prevalidated questionnaire available.

Hence, this study was conducted to facilitate the development of a new questionnaire considering the comprehensiveness of the various domains that addresses the strengths and weaknesses of the current DPH curriculum.

In any research or program evaluation endeavor, it is important to ensure that the outcomes of interest are clearly defined and that the outcomes are evaluated using valid measures. The purpose of this paper was two-fold: (a) to describe the development of a questionnaire for assessing the faculty perception on current UG DPH curriculum, (b) to validate the newly developed questionnaire.

This is an exploratory study employing a qualitative research design utilizing FGD for the synthesis of the conceptual framework on questionnaire development. The study considered to validate the questionnaire by drawing rigorous methodological protocols from benchmark literatures.[8-11]

The present study, led to the development of a valid instrument for assessing the faculty perception on current UG DPH curriculum. The new questionnaire on considers all the essential dimensions of the UG DPH curriculum that can be evaluated from the faculty perspective and thus identify its strengths and weakness. Using this questionnaire will allow for a deeper insight into the current challenges, and gaps in the DPH curriculum, and may result in a faculty-based measure of process-related curricular review eventually.

The development of this questionnaire was performed in several steps using methods and procedures consistent with best practices for developing psychological measures.

The researchers sought to identify qualitative and quantitative measures that would be valid, practical, and useful for assessment of UG DPH curriculum from a faculty perspective. The researchers then agreed that the new instrument should include the following components: (a) A block of socio-demographic items like gender, current designation, academic experience etc., (b) a section

on comprehensive evaluation of UG DPH curriculum, (c) a separate section on the teaching and learning methods, followed in DPH departments at individual dental institutions. Accordingly, the new instrument was developed with three separate sections as indicated above, that contained six items on socio-demographic details and a separate 76 items sections for assessing the UG DPH curriculum, and teaching and learning practices followed at individual institutions.

Later the questionnaire was tested for face validity objectively, with a panel of five subject matter experts, using the appropriate checklist as described in the literature[12] and accordingly the panel rated the questionnaire as having good face validity.

The researcher also decided to expand the number of items, tapping each of the UG DPH curriculum domains to ensure that we included a sufficient number of items to adequately measure the domain of interest.

The Aiken's index process was used to test for content validity as described in the methodological section[13] and it was considered that the Aiken's index <0.80, the question was deemed as inadequate and was deleted or changed after consultation with the experts. After the validity assessment, out of 83 original questions, 75 items were retained, five were modified, seven were deleted, and one item was split and modified into two separate questions.

The possibility that the construct of the new instrument is multidimensional cannot be excluded since a factor analysis was not performed due to limited sample size. Furthermore, test-retest reliability was not assessed.

In the present scenario, the researcher was concerned about the mode of administration (paper-based, online based) from the perspective of the study results. However, in accordance with research results of the effect of administration mode implementing online surveys in evaluating isolated components of the curriculum in dental and medical fields,[14,15] and owing to the advantages that the online questionnaire carry, the researchers believe that different methods of administration will not substantially change results and thus decided to choose online survey formats.

To the best of our knowledge, this is the first of its kind to explore and develop a new questionnaire to assess faculty perception on the strength and weakness of current UG DPH curriculum, which has not previously been studied in India.

The new questionnaire has the potential to become an important tool to assess faculty perception on UG DPH curriculum and further consider the same for the effective curricular reform process. The questionnaire has been assessed as demonstrating face and content validity with a high level of agreement between the subject matter experts.

However, owing to limited sample size, the study participants could not be divided into a development and a test sample. Moreover, it was not possible to engage in more sophisticated psychometric analyses to test for construct validity and reliability.

The data collected from this questionnaire would help researchers to identify main domains of concern and the degree to which each domain is affected. This could direct stakeholders and policymakers in initiating action in areas of weakness and improving areas of strength.

More research is advocated to appraise the utility of this questionnaire in various other regional, national, and international settings. Moreover, with the addition of future cohorts to our dental curriculum research working group, we expect to have sufficient sample size to further examine the complex psychometric properties of this questionnaire such as construct validity and reliability.

CONCLUSION

Considering all strengths and limitations of this study, it can be concluded that a valid instrument for the assessment of faculty perception on UG DPH curriculum has been developed, to facilitate effective curricular reforms. Thus, it represents a valuable tool for dental curriculum research and may result in a more positive dental curriculum oriented research programs in the future. This study can be an effective mechanism to communicate and convince the education administrators, curriculum review committees at the regional universities and dental council to make them realize the importance of developing such tools from the dental educator's perspective.

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Original Article

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Process Evaluation of Special Immunization Weeks in Rural Areas of Ahmedabad District

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Abstract

Introduction: Vaccine preventable infectious diseases are one of the main causes of morbidity and mortality in children that can easily prevent by immunization. Vaccination is a proven and one of the most cost-effective child survival interventions. All countries in the world have an immunization program to deliver selected vaccines to the targeted beneficiaries, specially focusing on pregnant women, infants, and children who are at a high risk of diseases preventable by vaccines.

Materials and Methods: The present cross-sectional study which was conducted in rural areas of Ahmedabad district in May 2013-September 2013. We have monitored 60 session sites of immunization that were planned during special immunization weeks from May 2013 to September 2013. Totally 60 immunization sessions were evaluated with the help of pre-tested structured questionnaire information was gathered.

Results: Supervision by the higher authority was only in 13.3% of session site. Information, education and communication (IEC) material were displayed only in 25% of session site. Four key messages by auxiliary nurse midwife (ANM) were given in only 38.3% of session site. Duelist was available in 61.6% of session site. About 17% session sites there were no mobilizes. Regarding the availability of vaccine and diluents were available in 76.6% of session site. Reconstitution time was not written on the vial for almost 17% of session site. 81.6% Sessions were conducted as per plan.

Conclusion: There was lack of supervision. There was a lack of providing health education through IEC material. There was a lack of waste disposal measure. Activities like orientation training of ANM training for waste management should be planned and should be repeated at regular interval.

Key words: Process evaluation, Special immunization, Session sites, Vaccines, and logistics

INTRODUCTION

Vaccine preventable infectious diseases are one of the main causes of morbidity and mortality in children that can easily prevent by immunization. Vaccination is a proven and one of the most cost-effective child survival interventions.[1] All countries in the world have an immunization program to deliver selected vaccines to the targeted beneficiaries, specially focusing on pregnant women, infants, and children who are at a high risk of diseases preventable by vaccines.[1] In India Expanded Immunization Program launched in 1978 which is renamed as Universal Immunization Program in 1985. Each year full immunization prevents approximately 4 lakh under-five deaths from vaccine-preventable diseases in India. However, close to 75 lakh children every year miss the benefits of childhood vaccinations. A majority of those missing the opportunity are from among underserved and marginalized populations. Being unvaccinated keeps them at highest risk of catching life-threatening childhood diseases. Globally, every fifth child is unimmunized.[2] Initially, the target was set to cover at least 85% of all infants by 1990.[3] However, the current immunization coverage is only around 75%.[4] Despite program is operating in India since 1978, approximately 10 million infants and children remains unimmunized. It is higher than any other country in the world.[5] In India only 44% of infants receive full vaccination (all doses up to the age of 1-year), and 5% of infants do not

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receive any vaccine.[6] To create awareness on the urgency to vaccinate every eligible child and pregnant women and intensify efforts to improve Routine Immunization (RI) coverage, Indian government has launched special immunization weeks (SIWs). 4 weeks, with 1-week each in the months of April, June, July, and August will be used to hold special immunization sessions specially in high-risk areas across the country.[2] It was realized that only providing vaccine just to achieve targets without giving proper attention on quality of immunization services does not promise a reduction in disease morbidity and mortality. For successful implementation of SIWs all its components such as planning of immunization sessions, cold chain and logistics management, community mobilization, and the appropriate technique of vaccination should also be looked carefully. One of the important elements for improving the immunization is a cold chain and vaccine logistics management which is the backbone of an immunization program. Cold chain and vaccine management are the left and right hands of an immunization program.[7] It requires an in-depth process evaluation. World Health Organization (WHO) is monitoring routine immunization since 2005. Initially, it was only session site monitoring, but from 2009 started house to house. From 2013, some more changes were done as per the need of the program introduction of district level format for RI, introduction of block level format for RI, introduction of monitoring of monitors for RI session and H2H monitoring, change in session site format, change in house to house monitoring format. From January '14, the state has directed government staff and all partners to use the same formats.[8] WHO's focus is to monitor and assess the impact of strategies and activities for reducing morbidity and mortality of vaccine-preventable diseases. Collection, analysis and interpretation of surveillance data is vital to guide vaccination policies and programs and ensure immunization targets are being reached.[9]

Aims

To evaluate the process components of SIWs in district Ahmedabad, Gujarat.

Objectives

- To evaluate planning of immunization sessions
- To evaluate cold chain and logistics management
- To evaluate community mobilization, appropriate technique of vaccination.

MATERIALS AND METHODS

The present cross-sectional study was conducted in rural areas of Ahmedabad district in May 2013-September 2013. We had monitored 60 session sites of immunization that were planned during SIWs from May 2013 to September 2013. 60 sites were randomly selected from 20 PHCs of 4 taluka of Ahmedabad district. At each session site auxiliary nurse midwife/female health worker (ANM/FHW) was interviewed by pretested and predesigned performa and monitored for the vaccine administration and logistic. Data were fed and analyze under Microsoft Excel 2007.

RESULTS

Table 1 shows that of 60 session sites that we had monitored list of beneficiary was available in 61.6% sessions, mobilizers were present in 83.3% sites, ANM was giving four key messages only in 38.3% and information, education, and communication (IEC) material was displayed only in 25% session sites.

Table 2 shows that the status of vaccine administration process evaluation during immunization was found to be satisfactory. Of 60 session sites ANM was administrating the vaccines by correct technique in 91.6%, correct site and route of vaccination was found in 100%, adequate dose of vaccine was found in 100% and correct age of administration was found in 95% session sites.

Table 3 shows status of cold chain, logistics, safety issues at session we found that all vaccines along with diluents available in 76.6%, auto-disable syringes and needle were available at 95.0%, time of reconstitution was written on vial at 88.3%, ANM was using hub cutter and proper disposal of waste in proper manner only at 48.3% session sites. During monitoring no any stick injury to ANM was found.

Table 1: Status of IEC activity and infant mobilization during immunization session

Different parameters	Number *N*=60	Percentage
Duelist of beneficiaries available	37	61.6
Mobilizer present	50	83.3
ANM is giving all four key messages after vaccination	23	38.3
IEC material displayed	15	25.0

IEC: Information education communication, ANM: Auxiliary nurse midwife

Table 2: Status of vaccine administration process evaluation during immunization session

Different parameter	Number *N*=60	Percentage
Correct administration technique	55	91.6
Correct site and route of administration	60	100
Correct dose of vaccine	60	100
Correct age of administration	57	95.0

Table 3: Status of cold chain, logistics, and safety issues etc., at session site

Different parameter	Number *N*=60	Percentage
All vaccines along with diluents available	46	76.6
AD syringes and needle available	57	95.0
Time of reconstitution written on vial	53	88.3
Using hub cutter and proper disposal of waste	29	48.3
Needles stick injury to ANM	0	0.0

ANM: Auxiliary nurse midwife, AD: Auto disable

DISCUSSION

For achieving high coverage of immunization and better function of the system supervision is an essential factor. Supervision by higher authority was only in 13.3% of session site that was much lower may be due to lack of planning of supervision. IEC materials were displayed only in 25%, which also was poor as during vaccination we can provide information about the vaccine and other important health-related issue to the attendant by IEC. Four key messages are essential for success of immunization and must be given to the attendant of the beneficiary because without these messages attendant does not know where to come for next visit, what are the possible side effects. In the present study, we found that four key message by ANM were giving in only 38.3% of the visited site that were unsatisfactory. In 48.3% of the session hub cutter were used and proper disposal of waste were done so there were biowaste problem. List of beneficiary was available in 61.6% of session site. The infant mobilization to session site reduces if we are not preparing the list of due beneficiary infants. Manjunath and Pareek in his study reported that around 9.7% of mothers lacked information about the session as on maternal knowledge and perception about routine immunization.[10] These mothers require active mobilization. Only one or two mobilizer was present in session at 83% sessions and at 17% there were no mobilizers. Regarding the availability of vaccine and diluents were available in 76.6% of the site. This was mainly because of shortage of bacillus calmette-guérin (BCG) vaccine and non-availability of colored bag for waste disposal. In National Immunization Program review no tracking of drop outs and left outs and missing opportunities due to wastage concerns were also identified.[11] In coldchain and logistics at vaccine sites, vaccine vial monitor for polio and pentavalent vaccine and shake test for freeze sensitive vaccine were satisfactory. However, reconstitution time was not written on vaccine vial for almost 17% of the site, which is important for prevention of toxic shock syndrome that may occurs in measles vaccine. Other vaccine safety aspects like the correct site for vaccination, dose and age were satisfactory. Injection safety issue was also good in district. No ANM reported needlestick injury that is because of proper training on vaccine administration. Pandit and Choudhary in his study from the same district in 2004.[12] He has reported more than 19% of annual needle stick injuries among service providers in district Anand, India. 81.6% of sessions were conducted as per plan. About 18.4% of sessions were not conducted as per micro-plan due to various reasons such as session planned in routine immunization, session will be planned few day back, staff deputed for training, staff on leave, and vacant post. Lack of staff and resources for service delivery has also been reported by National Immunization Program review by WHO.[11]

CONCLUSION

In present process evaluation study, we found that. There was the lack of supervision. There was the lack of providing health education through IEC material. There was the lack of waste disposal measure. There was the lack of mobilization of beneficiaries. Planning process and maintaining cold chain process were good. All logistics were available except the shortage of BCG vaccine. The cold chain was properly maintained. Vaccine administration process was good.

RECOMMENDATION

Activities like orientation training of ANM training for waste management should be planned and should be repeated at regular interval. Strengthening the cold chain systems should be done. Vacant posts of FHWs should be filled so that all sessions can be conducted. IEC material should be displayed which provide the opportunity of giving health education to the parents of the beneficiary.

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Original Article

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Prevalence of Diabetes among Tuberculosis Patients at Urban Health Centre, Ahmedabad

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Abstract

Background: When chronic non-communicable diseases proliferate faster than infectious diseases recede, previously uncommon disease interactions can take on population health significance. Recent systematic reviews suggest that Type 2 diabetes mellitus (T2DM) increases the individual risk of *Mycobacterium tuberculosis* (TB) disease.

Materials and Methods: This facility-based cross section study was undertaken in urban health centre Ahmedabad providing directly observed therapy short course therapy for TB patients in Ahmedabad. 85 TB cases of sputum positive, sputum negative, new cases, re-treatment cases, extra-pulmonary cases, multi-drug resistant, and extensive drug resistant registered under Revised National TB Control Program are included in this study. All of these were screened for diabetes.

Results: Out of total 85 patients, 59% were male and 41% were female. Their mean age was found to be 37.50 ± 16.16 years. The mean age of TB was found to be 47 ± 16 among diabetes patients. Frequency of diabetic among TB patients was 15.3%. Out of 85 TB patients most of the patients were belongs to Category I 55 patients. It was found that there was no any significant difference for DM as a comorbid condition with TB between male and female.

Conclusions: The prevalence of diabetes among TB patients in this present study was found 15.29% among them 8.23% were known DM cases and 7.06% were newly diagnosed cases. Age of the patients having diabetes was found to be significantly high.

Key words: Diabetes mellitus, Risk factors, Tuberculosis

INTRODUCTION

Tuberculosis (TB) is present in India since 1500 BC Rig-Veda described disease as "King of diseases."[1] India is the second most population country in the world. Though India is the second most population country in the world, one-fourth of global incident TB cases occur in India annually. In 2012, out of the estimated global annual incidence of 8.6 million TB cases, 2.3 million were estimated to have occurred in India.[2] India account for 26% of all new cases of TB in the world annually. At the same time, India dealing with the highest burden of TB in the world.[3] Incidence of TB was found to be 176/1 lack person in 2012 in India. Prevalence of TB was found to be 230/1 lack population in 2012 in India. The mortality was found to be 22/1 lack population. Prevalence of diabetes was found to be 7.1% in India in the adult population.[2] The number of people in the world with diabetes is projected to increase to 366 million by 2030 with the fastest increase in low- to middle-income countries.[4] Criteria for diagnosis of diabetes is fasting blood sugar level should be >125 mg/dl and 2 h post-glucose load should be >200 mg/dl. There are some reasons or can say associated factors that may lead to development of TB among diabetes patients that are people with diabetes have a weak immune system as a result of chronic disease so they are of higher risk of development of disease from latent infection.[5,6] Based on WHO report people with diabetes have 2-3 times higher chance of developing TB compare to non-diabetic people. There are 25-75% chances of development of pneumonia among diabetes patients.[7] which may predispose to TB. About 10% of TB patient are directly linked to diabetes. People with diabetes which are diagnosed during TB or who are already diagnosed as diabetes have higher chances of death during treatment and

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higher chance of relapse after completion of treatment so screening should be must both in TB patient and diabetes patient *viz.*, this is required because diabetics have higher chances of TB. Further diabetes is complicated by any infection including TB, so to prevent such complication screening should be done. A large proportion of people are diagnosed during or late of treatment, early detection can help to control and prevent future complications. Avicenna in 980-1027 AD had first reported the association between diabetes mellitus (DM) and TB. After that so many studies had been conducted to identify the various factors and comorbidity. India is a developing country, the link of DM and TB is more prominent in developing countries where TB is endemic and the prevalence of DM is rising. There are many studies that suggest diabetes as a risk factor for the TB, but the exact biological process is unknown. The strength of any association between diabetes, dysglycemia, and risk of TB remains debated.[8] A study conducted in Hong Kong and several other small observational studies found that diabetes is associated with increased risk of TB.[9,10]

Aim

To know the prevalence of diabetes among pulmonary and extrapulmonary TB patients in Category I, Category II, multi-drug resistant (MDR) and extensive drug resistant (XDR) patients.

Objectives

- To know the association between TB and risk of diabetes
- To know the frequency of diabetes among TB patients.

MATERIALS AND METHODS

This facility based cross section study was undertaken in urban health center Ahmedabad providing directly observed therapy shortcourse therapy for TB patients in Ahmedabad. 85 TB cases of sputum positive, sputum negative, new cases, re-treatment cases, extra-pulmonary cases, MDR and XDR registered under Revised National TB Control Program are included in this study. Criteria for diagnosis of diabetes was considered as fasting blood sugar level >125 mg/dl and 2 h post-glucose load >200 mg/dl or a self-reported history of diabetes and he/she is on anti-diabetic drugs after diagnosis by a physician. All TB cases were interviewed. Data entry was done in Microsoft Excel 2007 and analyzed under Epi info 7.

RESULTS

In the present study, we had included 85 TB patients among them 35 were female and 50 were male. Out of 85 TB patients, most of the patients were belongs to Category I 55 patients followed by 15, 13, and 02 of Category II, MDR and XDR respectively. Out of 85 TB patients most 74 were sputum positive followed by 09 and 02 of extra-pulmonary TB and sputum negative TB. Out of 85 TB patients 13 were having DM as comorbid condition (Table 1).

In the present study, we have tried to find out the distribution and it's risk factors in TB patients. It was found that there was no any significant difference for DM as a comorbid condition with TB between male and female. The mean age of TB was found to be 47 ± 16 among diabetes patients compared to 37 ± 16 among TB patients, this may be due to late exposure of diabetes after the age of 40 years. Out of 13 TB with diabetes patients 53.8% were having abdominal obesity compare to 15.3% among 85 TB patients, which was highly significant. Among diabetes with TB patients 15.4% were smokers compare to 22.3% smokers in TB which was statistically insignificant. However, when we have taken drinking as risk factor out of 13 patients of diabetes with TB 69.2% were drinkers compare to 37.6% among 85 TB patients, which was found to be significant. When we have taken family history, overweight, Category II, sputum positive at the initiation of treatment as a risk factor in diabetes with TB patients compare to TB patients it was found to be insignificant.

In the present study, we have found that among Category I patients of diabetes with TB 15.39% belongs to Type 1 diabetes and 84.61% were of Type 2 diabetes. Among MDR patients with diabetes all were belongs to Type 2 diabetes.

In the present study, we found that 84.7% patients were having TB without diabetes and 7% were TB with diabetes diagnosed during treatment and were unaware of diabetes before it. Whereas 8.23% were TB with history and disease present before starting treatment (Table 2).

DISCUSSION

Prevalence of the diabetes among TB patients in the present study was found to be 15.29% among them 8.23% were known cases of DM and 7.06% were newly diagnosed cases (Figure 1 and 2). Age of the patients having diabetes was found to be significantly high compare to patients of TB. Older age group from 40 years and above has increased the risk of having DM and TB. The prevalence of diabetes among TB patients was found to be more among females compare to males. The majority of DM cases were found in Category I TB patients (92.30%) among them T2DM was more common that was 84.61%. In the similar study, which was conducted in urban areas of Indonesia among 737 patients revealed the prevalence of diabetes 14.8%

Table 1: Gender wise distribution of the TB patients according to category, sputum status and diabetes status

Variable	Category of the variable	Females *N*=35	Males *N*=50	Total *N*=85
Age groups in years	≤10	03	00	03
	11-20	06	06	12
	21-30	08	15	23
	31-40	07	08	15
	41-50	08	10	18
	51-60	01	05	06
	>60	02	06	08
Treatment category	I	26	29	55
	II	05	10	15
	MDR	06	07	13
	XDR	01	01	02
Sputum status at initiation of treatment	Positive	32	42	74
	Negative	01	01	02
	Extra pulmonary	04	05	09
Diabetes status	DM+TB patients	08	05	13
	Non DM+TB patients	27	45	72

TB: Tuberculosis, MDR: Multi-drug resistant XDR: Extensive drug resistant, DM: Diabetes mellitus

Table 2: Distribution of diabetes and its risk factors in TB patients

Variable	Total *N*=85	DM+TB patients *N*=13	Frequency (%)	*P* value
Male gender	50	5	10	0.167
Mean age**	37.50±16.16	46.84±16.31	-	0.001
Family history	17	02	11.76	0.348
Current smokers	19	02	10.52	0.284
Current drinkers**	32	09	28.12	0.015
Overweight	08	03	37.50	0.073
Abdominal obesity** (high WHR)	13	07	53.84	0.001
Category II (retreatment cases)	31	02	6.45	0.066
Sputum positive at the initiation of treatment	74	12	16.21	0.294

p value < 0.05 indicate significant, p value < 0.001 indicate highly significant, *p* value > 0.05 indicate insignificant, WHR: Waist to hip ratio, DM: Diabetes mellitus, TB: Tuberculosis, N: Number

among TB patients, which was much similar to this study and was also associated with older age.[11] Alisjahbana *et al.* in their study found the prevalence of diabetes 14.8% among TB patients.[11] In the study carried out in Kerala by Balakrishnan *et al.* among 552 TB patients found the prevalence of diabetes 44%. Out of them 23% had previously known DM and 21% were newly diagnosed. Which was much higher almost thrice the prevalence compare to present study. The study also revealed that prevalence was higher among males compare to females, but in present study females were more affected then males.[12] Another study conducted by Raghuraman *et al.* found that the prevalence of diabetes 29% in TB patients.

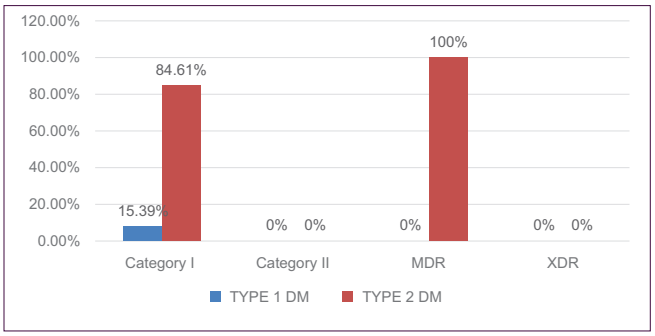

Figure 1: Distribution of diabetes among different categories of tuberculosis (*N* = 13)

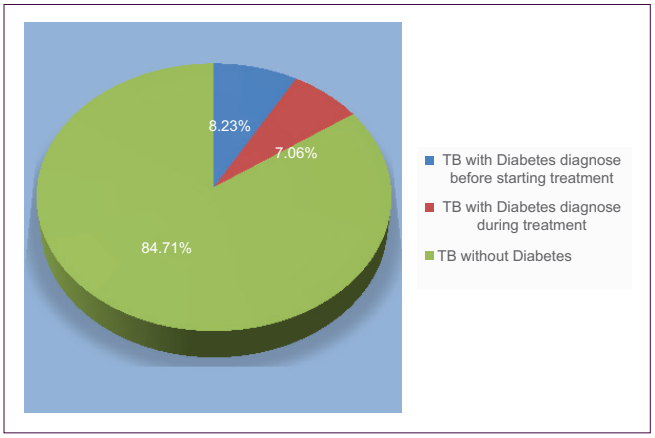

Figure 2: Treatment of diagnosis of diabetes among tuberculosis patients

Out of them known diabetics were 20.7% and new diabetes were 8.3% which was almost double the prevalence compare to present study. The study also suggest diabetes was significantly associated with older age and consumption of alcohol, which was similar to this study.[13] In the present study, we found the prevalence of diabetes 15.29% among TB patient compared to 7.1% among general population, so prevalence of diabetes among TB patient was found to be almost double from general population. On the other hand, studies conducted by Bacakoglu *et al.*,[14] Baldé *et al.*[15] and Banerjee and Banerjee[16] found that TB among diabetics is 2-5 times higher than in the non-diabetic population. Hence, this indicate a positive association between TB and diabetes.

CONCLUSIONS

In this study, we found the high prevalence of diabetes among the TB patients compare to general population suggest that screening of diabetes among TB is necessary and should be performed during the diagnosis of TB. Prevalence of diabetes among TB was found higher among females compare to males and age of the patients having diabetes was found to be significantly high compare to

patients of TB. Family history, overweight, Category II, sputum positive at the initiation of treatment as a risk factor in diabetes with TB patients compare to TB patients was found to be insignificant. Central obesity was found almost thrice among diabetes with TB patients compare to TB patients. Smoking as a risk factor among diabetes with TB patients compare to smoking in TB was found to be statistically insignificant. However, when we have taken drinking as a risk factor for diabetes with TB patients compare to drinking among TB patients, it was found to be significant.

RECOMMENDATIONS

- As diabetes and TB are co-morbid conditions, routine screening of TB patients for diabetes should be carried out in all the health centers
- The linkage between diabetes and TB should be carried out for early detection of both conditions
- As in the present study, abdominal obesity was significantly high among TB patients having DM. Hence, intervention should be directed toward the primary preventive measures.

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Original Article

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Comparison between X-ray and Abdominal Ultrasound Findings of Necrotizing Enterocolitis, its Usefulness in Early Diagnosis, Prognosis, and to Assess, is this is the Time to Change our View of Surgeon's Intervention According to the Bell's Criteria

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Abstract

Introduction: Comparison between X-ray and abdominal ultrasound (AUS) findings of necrotizing enterocolitis (NEC), its usefulness in early diagnosis, prognosis, and to assess, is this is the time to change our view of surgeon's intervention according to the Bell's criteria.

Objective: To compare between X-ray and AUS findings, its usefulness in the early diagnosis, detection, assessment, and prognosis of NEC in preterm babies.

Patients and Methods: This is a prospective study of 60 premature newborns (January 2010 - January 2014) with all signs and symptoms of NEC. Biochemical and radiological changes were taken into consideration for Bell's staging. Our study includes birth weight as per Bell's staging. Antenatal, prenatal, and postnatal findings were noted. Abdominal X-ray and AUS were done and compared for early diagnosis and management. Then our findings were correlated with complications ("surgery and/or death" and "stenosis"). We have also taken 30 premature neonates as a control and done uni- and multi-variate analyses. Sonographic findings as per Dr. Feingold and Dr. Epelman technique were followed. Informed consent from parents was taken.

Results: In our study, AUS done in 30 normal premature newborns and their findings were taken as a reference, normal values of Dr. Feingold and Dr. Epelman were also considered; with these basics we have done AUS in premature neonates with Stages 1, 2, and 3 of NEC. Grouped into those who survived with medical therapy alone (63.3%), medical therapy with complications (10%), medical and surgical therapy without complications (5%), medical and surgical therapy with complications (5%), died before surgery (8.3%), and died after surgery (8.3%). We compared AUS findings with X-ray, AUS showed important features like bowel wall thickening in Stage 1 (80.8%), whereas none by X-ray (0%).

Conclusion: Our study concludes that AUS is superior to plain radiography in the early detection of NEC. Complications like pneumotosis intestinalis, portal venous gas, free fluid collection, intestinal thinning, perforation, and pneumoperitoneum were detected earlier by AUS than by X-ray. Hence, AUS is a reliable tool for early detection, assessment, and prognosis of NEC in preterm infants.

Keywords: Abdominal ultrasound, Bell staging, Necrotizing enterocolitis, Pneumatosis intestinalis

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INTRODUCTION

Necrotizing enterocolitis (NEC) is an inflammatory gastrointestinal disease of unknown etiology that primarily affects the preterm neonate and carries a high mortality rate.[1] NEC is a leading cause of morbidity in neonatal intensive care units (NICU). The pathologic features of NEC

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resemble those of ischemic necrosis, with inflammation beginning in the mucosa and often extending through the bowel wall. The distal ileum and proximal colon are most commonly affected. The incidence of NEC is inversely proportional to the gestational age. Infants of 28 weeks or less gestational age and those of extremely low birth weight (<1000 g) are at a greater risk for NEC.[2] However, approximately 10% of neonates with NEC are born at term, and congenital heart disease is the main risk factor in this group. Other risk factors include perinatal asphyxia, patent ductus arteriosus, indomethacin therapy, and decreased umbilical flow in utero. NEC most commonly manifests within the 1st or 2nd week of life. However, the time of presentation varies with the gestational age; in very premature neonates, NEC may manifest only in the 2nd or 3rd week of life. The symptoms referable to the gastrointestinal tract include feeding intolerance, vomiting, diarrhea, and blood in the stool. However, there may also be non-specific generalized symptoms including lethargy, temperature and blood pressure instability, and apnea. Physical signs include abdominal distention and in more advanced cases, palpable, distended bowel loops, and abdominal wall erythema and edema. Neonates with severe disease may even present in shock. Bell's classification of NEC, which was modified by Walsh and Kliegmanin 1986, relates to the worsening of these clinical and radiological abdominal signs.[3] These staging criteria help pediatricians in the diagnosis, management, and prognostic assessment of NEC, but they are exclusively based on plain abdominal radiography, which remains the "gold standard" for the diagnostic assessment (Figure 1).

Plain abdominal radiography is the current standard imaging modality for evaluation of NEC. Sonography is still not routinely used for diagnosis and follow-up, as it is not widely recognized that it can provide information that is not provided by plain abdominal radiography and that may affect the management of NEC. However, the major advantages of abdominal sonography over plain abdominal radiography are that it can depict intra-abdominal fluid, bowel wall thickness, and bowel wall perfusion. Sonography may depict changes consistent with NEC when the plain abdominal radiographic findings are nonspecific and inconclusive. Thinning of the bowel wall and lack of perfusion at sonography are highly suggestive of nonviable bowel and may be seen before visualization of pneumoperitoneum on plain abdominal radiography. The mortality rate is higher after perforation; thus, earlier detection of severely ischemic or necrotic bowel loops, before perforation occurs, could potentially improve the morbidity, and mortality in NEC. The information provided by sonography allows a complete understanding of the state of the bowel in patients with NEC and may thus make management decisions easier and potentially change the outcome.[4]

Prompt institution of therapy, which includes bowel rest with a nasogastric tube, antibiotics, and adequate hydration (total parenteral nutrition), is essential to limit the clinical progression and the development of complications. Clinical deterioration may result from generalized sepsis or bowel necrosis, which may progress to perforation and the development of peritonitis or intra-abdominal abscesses. Bowel perforation occurs in 12-31% of patients.

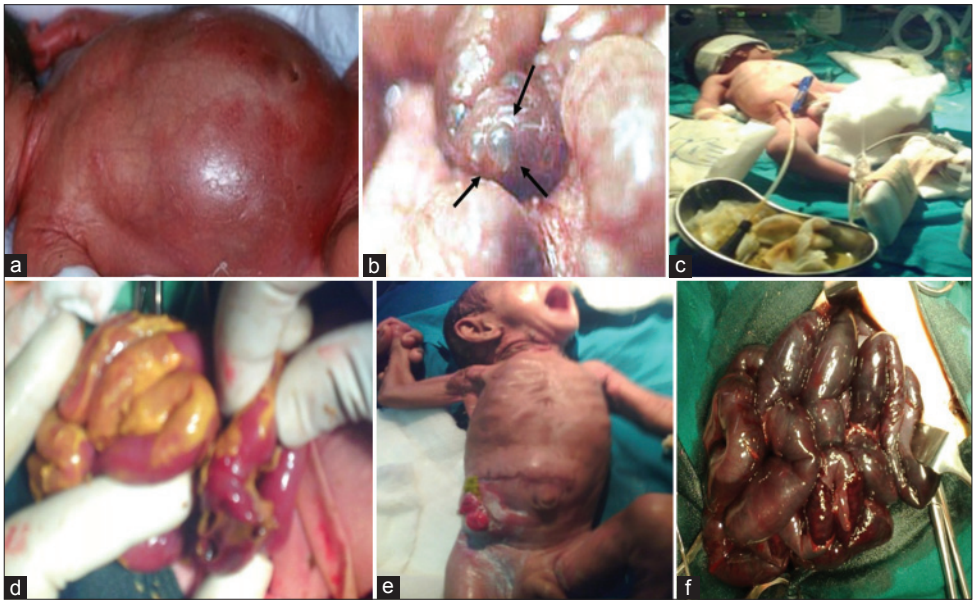

Figure 1: (a) Abdominal wall distension, erythema and cellulitis, (b) pneumatosis bullae with thinning of intestine, (c) peritoneal drainage, (d) bowel wall perforation, (e) colostomy procedure, (f) severe necrotizing enterocolitis with ischemic necrosis and gangrene, (picture B courtesy: Henri R. Ford. MD Vice President and Chief of Surgery)

A continuing challenge to the surgeon and radiologist alike is determining the most appropriate time for surgical intervention in those neonates who are not responding to medical therapy or who have developed complications.

Pneumoperitoneum is the only radiological sign that has been universally agreed on as an indication for surgical intervention, and this is complicated by the fact that not all neonates with bowel necrosis and perforation have free gas at plain abdominal radiography. In abdominal ultrasound (AUS) by using color flow, Doppler study of superior mesenteric artery (SMA) and celiac trunk, flow velocities can be known. It is an early sign of increased blood flow in ischemic and hypoxic intestinal valvulae conniventes. This allows us to study perfusion and non-perfusion areas, helps in detection of ischemic and necrotic bowel walls, thinning and non-perfused bowel walls for the early diagnosis and to know impending perforation.[5]

The overall mortality rate in NEC is between 20% and 40% and is higher in neonates of very low birth weight. Mortality climbs to 64% for the very low birth weight infant once perforation has occurred. Because of the higher mortality rate following perforation, earlier detection of severely ischemic or necrotic loops of the bowel before perforation occurs could potentially improve the morbidity and mortality in NEC. Imaging may, therefore, play an important role in this regard (Figure 2).[6]

There are cases where the abdominal radiograph may show no bowel gas. In others, necrotic bowel and perforation may occur without any radiographic signs. In these circumstances the diagnosis and follow up of nec based on clinical and radiological basis sometimes will be deficient. AUS provides a more detailed understanding of the state of the bowel in patients with NEC and may thus make management decisions easier and potentially change the outcome.[7] In this study, we aimed to prospectively analyze abdominal sonographic findings of premature infants with NEC to investigate whether AUS is superior to abdominal plain radiography in the diagnosis of NEC.

PATIENTS AND METHODS

Patients

This was a single-centric, prospective study conducted in a level 3 neonatal unit in a teaching medical college hospital.

Clinical Data and Management

Inclusion criteria

1. Premature infants of <36 weeks of gestation, born between January 2010 and December 2013 hospitalized in the NICU
2. Absence of congenital malformations
3. Clinical symptoms suggestive of NEC as defined by the presence of abdominal distension, increased gastric residuals (N20% of enteral feeding volume), or blood in the stools (macroscopically or microscopically)
4. Confirmation of the NEC episode using abdominal imaging examinations, including two views (supine view and cross table view) abdominal radiography, and ultrasonography, performed as soon as NEC was suspected and serial follow-up with both.

Antenatal, perinatal, and postnatal data of these preterm babies were taken. The mean gestational age was between 30.5 ± 0.5 and 25% were outborn babies. Also, data regarding umbilical vein catheterization, blood culture positivity before admission were noted. Modified Bell's staging was used to categorize these neonates into Stages 1A, 1B, 2A, 2B, 3A, and 3B. This staging was based on clinical signs, symptoms (vomiting, abdominal distension, abdominal tenderness, bloody stools, and increased gastric residues, generalized features of sepsis), biochemical changes (metabolic or respiratory acidosis, thrombocytopenia), X-ray changes (abnormal shaped distended loops, bowel wall thickening), and ultrasound changes (free or focal fluid collection, free intra-abdominal air, portal venous gas [PVG]). In all these 60 preterm neonates with NEC, their clinical signs, symptoms, biochemical changes, X-ray changes were studied and grouped according to those who survived with medical therapy with or without complications, those who survived with medical and surgical therapy without complications or with complications (like stenosis or malabsorption) and also these neonates were followed to see those who died before surgery and those who died after surgery.[8-11]

Also, in our study, these preterm neonates were categorized based on their weight ranging from 600 to 2400 g and then divided into outborn and inborn, again staging done (as 1A, 1B, 2A, 2B, 3A, and 3B) separately. Mainly, the various changes in X-ray and AUS were studied in detail with their contribution in determining the survival, morbidity, and mortality. It was found that AUS was more sensitive and specific in identifying many features of NEC like bowel wall thickening, free or focal fluid, and PVG. Also, SMA flow could be determined which is a prognostic factor in NEC. Most importantly the percentage of cases of bowel wall thinning found out using NEC were high which indirectly determined impending necrosis and need for surgery along with other indicators like fluid collection, absent peristalsis, pneumatosis intestinalis (PI), and free intra-abdominal air.

Management of these cases were done as in Stage 1, neonates were kept NPO and antibiotic coverage given for 3 days. In Stage 2, neonates were kept NPO and given antibiotics for 10 days and in Stage 3, neonates were kept

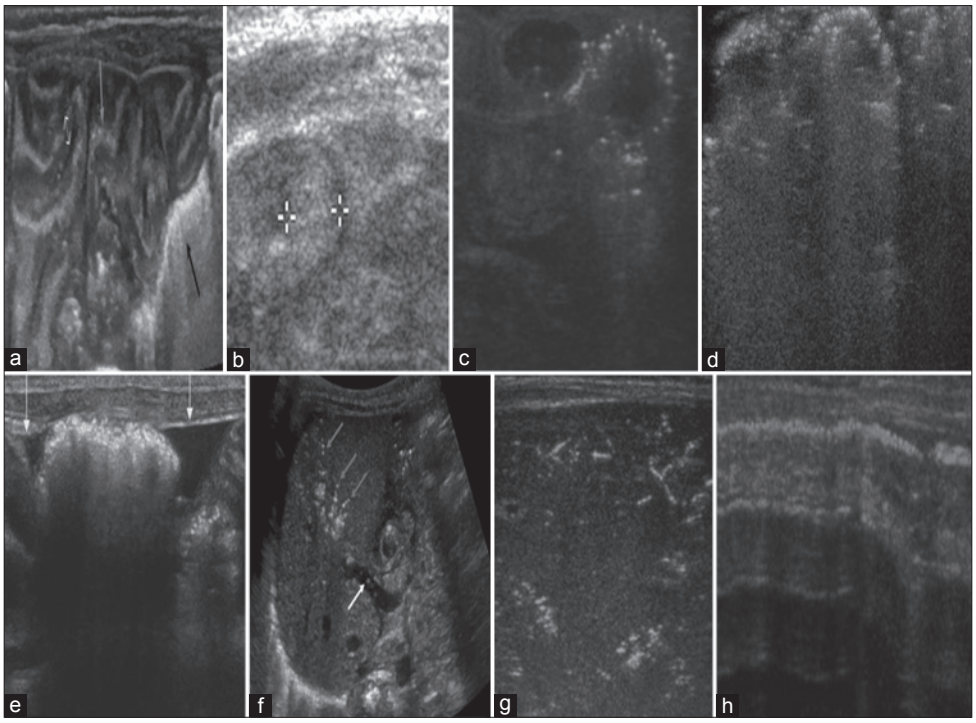

Figure 2: (a) Normal intestinal gut signature (pattern), (b) thickened intestinal wall, (c) pneumotosis intestinalis (PI), (early appearance), (d) massive PI, (e) massive PI, with local fluid collection (white arrows), (f) portal venous gas in portal vein appears as hyperechogenic dots (bold white arrow), hyper echogenic linear dendriform white dots in peripheral portal venous branches in the liver (white arrows), (g) Hyper echogenic linear dendriform white dots in peripheral portal venous branches in the liver, (h) Reverbration artefacts on the liver suggestive of pneumoperitoneum

NPO and were given antibiotics for 14 days and, especially when surgical indications like failure to respond to medical therapy, intestinal perforation, abdominal wall erythema, or abdominal wall thinning surgery was done. Post-surgery, preterm neonates were followed and for those presenting with strictures re-surgery was done and followed up. Post-surgery complication like malabsorption was treated by supplementation with vitamins (especially vitamin D).

Imaging examinations

Plain abdominal radiographs were performed according to the following protocol at the bedside, anteroposterior view, patient in supine position, vertical X-ray beam, and cross table view with a portable X-ray system multi mobile 2.5 Siemens and Fuji film dry computed radiography systems, exposition data we used 45-50 kV, 4-5 mAs. AUS examinations were carried out at the bedside, by a radiologist and trained neonatologist together, both were aware of clinical staging, baby's condition, X-ray, and ultrasound were looked into twice before giving radiological or AUS report (because we wanted to compare the clinical condition, X-ray, and ultrasound findings), with mobile ultrasound units and high-frequency linear ultrasound transducers (Philips HD 11, 3-12 MHz probe; Son site M-turbo, and 6-13 MHz probe). Sonographic findings as per Dr. Feingold and Dr. Epelman technique were followed. Ultrasound examinations were performed according to the following protocol: Quadrant by quadrant, swipe-scanning in transverse, and sagittal planes. Color Doppler US was used to evaluate intestinal mural blood flow with a standard protocol and parameters included the lowest possible pulse repetition frequency without aliasing, a low wall filter, and the highest Doppler gain settings without flash artifacts. Velocity was set at 0.029-0.11 m/s. For each premature baby, we first read the radiograph and then did the ultrasound examination.

The following items were assessed on plain abdominal radiographs: Only gaseous distension, abnormal shaped distended intestinal walls, bowel wall thickening, intramural air (PI), soapy bubble appearance, fixed bowel loops, and free intra-abdominal air (pneumoperitoneum). In AUS, we looked in detail about Bowel Wall thickening (>2.6 mm) and echo texture striated echogenicity internal halo ("gut signature"), thinning (<1 mm), intramural air (PI, hyper echoic shadow in the mural layers), absent peristalsis (normal 10/min in one quadrant), PVG or punctate and linear, branching areas of echogenicity in the portal branches within the liver, free fluid, focal fluid collection,[12] dirty echogenic fluid collection, free intra-abdominal air (pneumoperitoneum),[13-20] color flow increased over all in bowel wall (compared to normal control group they were having enhanced color flow signals, ring or y,

zebra stripes-shaped abnormal flow pattern, and mural flow with a velocity of 0.085 m/s). Color Doppler signals ranged from 1 to 9 dots/cm^2. There were no significant differences between quadrants with dots per square centimeter, color flow decreased selective bowel wall (no color flow signal in spite of decreasing velocity to 0.015 m/s) or Doppler flow pattern extracted, SMA flow (>80-100 cm/s, if >120 cm/s severe).[21-25]

Statistical Analysis

Statistical methods

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on mean ± standard deviation (min-max) and results on categorical measurements are presented in number (%). Significance is assessed at 5% level of significance. The following assumptions on data is made,

Assumptions:

1. Dependent variables should be normally distributed
2. Samples drawn from the population should be random
3. Cases of the samples should be independent.

Chi-square/Fisher exact test was used to find the significance of study parameters on categorical scale between two or more groups.

Statistical software

The statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0, and R environment version 2.11.1 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables, etc.

RESULTS

Description of Study Population

Total admissions to our NICU over 4 years between January 2010 and December 2013 were 2304. In that 800 (34.5%) were preterm babies, of whom only 60 (7.5%) of preterm babies with signs, symptoms, biochemical changes, X-ray changes, or AUS changes of NEC were taken into study.

Description of the Included Preterm Neonates

Over 4 years, total admissions to the NICU were 2304, among these 800 (34.7%) were premature babies. We have taken only 60 (7.5%) of premature babies, presenting with symptoms of NEC for our study (gastrointestinal symptoms, biochemical changes, and radiological abnormality were taken into consideration in staging).

These neonates were divided based on modified Bell's staging as shown in Table 1. X-ray was done and serially repeated. X-ray changes were gaseous distension, abnormal shaped distended intestinal walls, bowel wall thickening, intramural air, PVG, soapy bubble appearance, free intra-abdominal air, whereas AUS picked up features such as bowel wall thickening, thinning, intramural air (PI), PVG, free fluid, and free intra-abdominal air. All these findings were done in neonates belonging to different groups like those who improved with medical or surgical therapy or both and those with or without complications and those who died before or after surgery. AUS was found to be more superior than X-ray like in those who survived with medical therapy, 10.5% had Bowel wall thickening seen on X-ray, but in AUS 55.2% were detected. PI seen in X-ray was 10.5%, whereas 23.5% by AUS. Bowel wall thinning could be detected only by AUS, which was a predisposing factor for impending necrosis and indication for Surgery. AUS Doppler identified many cases with increased color flow over all or decreased in selective area. SMA flow which was done also aided in diagnosis.

Table 1: Grouped according to Bell's staging

Bell's staging	Number of patients	Percentage
1A	14	23.3
1B	15	25.0
2A	12	20.0
2B	8	13.3
3A	6	10.0
3B	5	8.3
Total	60	100.0

Keeping Bell's staging, X-ray and AUS findings were compared. Of 60 preterm neonates, 29 belonged to Stage 1, in that 1A were 14, 1B were 15. 20 belonged to Stage 2, 12 to Stage 2A, and 8 to Stage 2B. 11 belonged to Stage 3, in that 6 to Stage 3A, and 5 belonged to Stage 3B. X-ray showed Bowel wall thickening in 0% of cases in Stage 1, whereas 14.2% were identified using AUS. In Stage 2 by X-ray, 33.3% of cases of Bowel wall thickening were identified, whereas by AUS, it was 66.6%. In Stage 3A by X-ray, 66.6% of neonates with PVG were identified compared to ultrasound which was 100%. Also by ultrasound other important features like free fluid, focal fluid, and dirty echogenic fluid collection were identified. Incidence of bowel wall thinning cases identified were very high using AUS, additional things like color flow either increased overall, or decreased selective by Doppler as well as SMA flow were identified. Based on birth weight and Bell's staging, the incidence of NEC was classified. In neonates between 600 and 999 g, 21 were there, in that 11 were inborn and 9 were outborn. In neonates between 1000 and 1249 g, 14 were there, among them 8 were inborn and 6 were outborn. In neonates between 1500 and 1749 g, 6 were there, in that 4 were inborn and 3 were outborn. In

neonates between 1750 and 1999 g, 5 were there, in that 4 were inborn and 1 was outborn. In neonates between 2000 and 2400 g, 4 were there, in that 2 were inborn and 2 were outborn. Further, these outborn and inborn were again classified into 3 stages based on modified Bell's classification (Tables 2-7 and Figure 3).

Prognostic Value of Sonography

Plain abdominal radiography is the current standard imaging modality for evaluation of NEC. Sonography is still not routinely used for diagnosis and follow-up, as it is not widely recognized that it can provide information not provided by plain abdominal radiography and which may affect the management of NEC. However, the major advantages of abdominal sonography over plain abdominal radiography are that it can depict intra-abdominal fluid, bowel wall thickness, and bowel wall perfusion. Sonography may depict changes consistent with NEC when the plain abdominal radiographic findings are nonspecific and inconclusive. Thinning of the bowel wall and lack of perfusion at sonography are highly suggestive of nonviable bowel and may be seen before visualization of pneumoperitoneum by plain abdominal radiography. The mortality rate is higher after perforation, thus earlier detection of severely ischemic or necrotic bowel loops, before perforation occurs by AUS, which could potentially improve the morbidity and mortality in NEC. The information provided by sonography allows a complete understanding of the state of the bowel in patients with NEC and may thus make management decisions easier and potentially change the outcome.

We compared AUS findings with X-ray, AUS showed important features like bowel wall thickening in Stage 1 (80.8%), whereas none by X-ray (0%). In Stage 2 AUS detected bowel wall thickening in all cases were 100%, whereas 33.3% by X-ray. In Stage 3A, AUS detected bowel wall thickening in all cases were 100%, whereas 50% by X-ray. In Stage 3B, AUS detected bowel wall thickening in all cases were 100%, whereas 60% by X-ray. Intramural air (PI) detected by AUS in Stages 1A (0%), 1B (28.5%), 2A (66.6%), 2B (100%), 3A (100%), 3B (100%), respectively, whereas in X-ray, it was in Stages, 1A (0%), 1B (0%), 2A (33.3%), 2B (73%), 3A (83.3%), 3B (100%), respectively. PVG identified by AUS in Stages 1A (0%), 1B (0%), 2A (0%), 2B (87.5%), 3A (100%), 3B (100%), respectively, whereas by X-ray, it was in Stages 1A (0%), 1B (0%), 2A (0%), 2B (50%), 3A (66.6%), 3B (100%), respectively. Free intra-abdominal air (pneumoperitoneum) identified by AUS in Stages 1A (0%), 1B (0%), 2A (0%), 2B (12.5%), (66.6%), 3B (100%), respectively, whereas in X-ray, it was in Stages (0%), 1B (0%), 2A (0%), 2B (0%), 3A (33.3%), 3B (100%), respectively.

Table 2: Premature babies grouped according to the survival, morbidity, and mortality

Groups	Number of patients	Percentage
Survived with medical therapy	35	63.3
Survived with medical therapy associated with complications (stenosis)	6	10.0
Survived with medical and surgical therapy without complications	3	5.0
Survived with medical and surgical therapy associated with complications (stenosis or malabsorption)	3	5.0
Died before surgery	5	8.3
Died after surgery	5	8.3
Total	60	100.0

Table 3: Antenatal, perinatal, postnatal data of the 60 premature babies

Data	Number of patients (*n*=60)	Percentage
Antenatal data		
Antenatal corticosteroid therapy received	14	23.3
Oligohydramnios	20	33.3
Fetal heart rate abnormal rhythm	10	16.6
IUGR	16	26.6
Perinatal data		
Gestational age (weeks, mean±SD) (25-36 weeks)	30.5±0.5	
Male gender	35	58.3
Outborn	25	41.6
Apgar score at 5 min (mean±SD)	8±1.2	
Birth weight (grams, mean±SD) (600-2400)	1500±201	
Small for gestational age+IUGR	22	36.6
Postnatal data		
Surfactant received	45	75.0
Respiratory distress	50	83.3
Patent ductus arteriosus (>5 days) (>1.4 mm)	12	20.0
Minimal enteral feeding started	57	95.0
Age of onset (days, mean±SD)	8±2	
Given formula/bovine milk	14	23.3
Starting day of enteral feeding (days, mean±SD)	3±5.1	
Venous umbilical catheterization	15	25.0
Both venous and arterial umbilical catheterization	7	11.6
Severe polycythemia	1	1.6
Blood culture positive cases	8	13.3
Gastrointestinal symptoms started after indomethacin	5	8.3
Gastrointestinal symptoms started after ibuprofen	2	3.3
Death	10	16.6

SD: Standard deviation, IUGR: Intrauterine growth restriction

Cases with bowel wall thinning identified by AUS in Stages 1A (0%), 1B (05), 2A (0%), 2B (25%), 3A (100%), 3B (100%), respectively, whereas none could be detected by X-ray also by AUS we could detect free fluid in Stages 1A (0%), 1B (0%), 2A (0%), 2B (37.5%), 3A

Table 4: Clinical signs, symptoms and biochemical changes according to the survival, morbidity, and mortality

Clinical signs and symptoms	Survived with medical therapy (*n*=38) (%)	Survived with medical therapy associated with complications (stenosis) (*n*=6) (%)	Survived with medical and surgical therapy without complications (*n*=3) (%)	Survived with medical and surgical therapy associated with complications (stenosis or malabsorption) (*n*=3) (%)	Died before surgery (*n*=5) (%)	Died surgery (*n*=5) (%)	*P* value
Increased gastric residuals	35 (92.1)	6 (100)	3 (100)	3 (100)	5 (100)	5 (100)	1.000
Abdominal distension	30 (78.9)	6 (100)	3 (100)	3 (100)	5 (100)	5 (100)	0.761
Vomiting	27 (71.1)	5 (83.3)	3 (100)	3 (100)	5 (100)	5 (100)	0.518
Bloody stools	24 (63.2)	4 (66.7)	3 (100)	3 (100)	5 (100)	5 (100)	0.219
Apnea	25 (65.8)	5 (83.3)	3 (100)	3 (100)	5 (100)	5 (100)	0.313
Respiratory distress	22 (57.9)	5 (83.3)	3 (100)	3 (100)	5 (100)	5 (100)	0.099+
Generalized features of sepsis	10 (26.3)	2 (33.3)	3 (100)	3 (100)	5 (100)	5 (100)	<0.001**
Abdominal tenderness	6 (15.8)	4 (66.7)	3 (100)	3 (100)	5 (100)	5 (100)	<0.001**
Abdominal cellulitis	0 (0)	1 (16.7)	2 (66.7)	1 (33.3)	5 (100)	3 (60)	<0.001**
Absent bowel sounds	1 (2.6)	2 (33.3)	2 (66.7)	2 (66.7)	5 (100)	4 (80)	<0.001**
Biochemical changes							
Metabolic acidosis	38 (100)	5 (83.3)	3 (100)	3 (100)	5 (100)	5 (100)	0.367
Respiratory acidosis	15 (39.5)	4 (66.7)	3 (100)	3 (100)	5 (100)	5 (100)	0.001**
Neutropenia	19 (50)	5 (83.3)	3 (100)	3 (100)	5 (100)	5 (100)	0.017*
Thrombocytopenia	28 (73.7)	5 (83.3)	3 (100)	3 (100)	5 (100)	5 (100)	0.650
Hyperkalemia	19 (50)	4 (66.7)	3 (100)	3 (100)	5 (100)	5 (100)	0.027*
Hyponatremia	23 (60.5)	3 (50)	3 (100)	3 (100)	5 (100)	5 (100)	0.111

Chi-square test/Fisher exact test, significant figures, + Suggestive significance (*P* value: 0.05<*P*<0.10), * Moderately significant (*P* value: 0.01<*P*≤0.05), ** Strongly significant (*P* value: *P*≤0.01)

Table 5: X-ray and AUS feature according to the survival, morbidity, and mortality

Clinical signs and symptoms	Survived with medical therapy (*n*=38) (%)	Survived with medical therapy associated with complications (stenosis) (*n*=6) (%)	Survived with medical and surgical therapy without complications (*n*=3) (%)	Survived with medical and surgical therapy associated with complications (stenosis or malabsorption) (*n*=3) (%)	Died before surgery (*n*=5) (%)	Died after surgery (*n*=5) (%)	*P* value
X-ray changes							
Only gaseous distension	22 (57.9)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	<0.001**
Abnormal shaped distended Intestinal walls	20 (52.6)	6 (100)	3 (100)	3 (100)	5 (100)	5 (100)	0.011*
Bowel wall thickening	4 (10.5)	2 (33.3)	2 (66.7)	2 (66.7)	2 (40)	3 (60)	0.004**
Intramural air (PI)	4 (10.5)	1 (16.7)	2 (66.7)	3 (100)	5 (100)	5 (100)	<0.001**
PVG	0 (0)	2 (33.3)	1 (33.3)	2 (66.7)	4 (80)	4 (80)	<0.001**
Soapy bubble appearance	0 (0)	0 (0)	1 (33.3)	2 (66.7)	4 (80)	5 (100)	<0.001**
Fixed Bowel loops	0 (0)	2 (33.3)	1 (33.3)	2 (66.7)	5 (100)	2 (40)	<0.001**
Free intra-abdominal air	0 (0)	0 (0)	1 (33.3)	1 (33.3)	2 (40)	3 (60)	<0.001**
Ultrasound abdomen							
Bowel wall thickening	21 (55.3)	6 (100)	3 (100)	3 (100)	5 (100)	5 (100)	0.022*
Thinning	0 (0)	1 (16.7)	1 (33.3)	2 (66.7)	4 (80)	2 (40)	<0.001**
Intramural air (PI)	9 (23.7)	6 (100)	3 (100)	3 (100)	5 (100)	5 (100)	<0.001**
Peristalsis absent	0 (0)	1 (16.7)	1 (33.3)	3 (100)	5 (100)	5 (100)	<0.001**
PVG	6 (15.8)	2 (33.3)	3 (100)	3 (100)	5 (100)	5 (100)	<0.001**
Free fluid	0 (0)	0 (0)	1 (33.3)	2 (66.7)	5 (100)	5 (100)	<0.001**
Focal fluid collection	0 (0)	0 (0)	3 (100)	3 (100)	5 (100)	5 (100)	<0.001**
Dirty echogenic fluid collection	0 (0)	0 (0)	0 (0)	1 (33.3)	4 (80)	3 (60)	<0.001**
Free intra-abdominal air	0 (0)	0 (0)	1 (33.3)	2 (66.7)	3 (60)	4 (80)	<0.001**
Colour flow increased overall (bowel wall)	5 (13.2)	6 (100)	3 (100)	3 (100)	5 (100)	5 (100)	<0.001**
Colour flow decreased selective (bowel wall)	0 (0)	0 (0)	1 (33.3)	2 (66.7)	5 (100)	4 (80)	<0.001**
SMA flow (>80-100 cm/s)	3 (7.9)	5 (83.3)	2 (66.7)	3 (100)	5 (100)	5 (100)	<0.001**

Chi-Square test/Fisher exact test, significant figures, +Suggestive significance (*P* value: 0.05<*P*< 0.10), *Moderately significant (*P* value: 0.01<*P*≤ 0.05), **Strongly significant (*P* value: *P*≤0.01), SMA: Superior mesenteric artery, PVG: Portal venous gas, PI: Pneumatosis intestinalis

(83.3%), 3B (100%), respectively. Along with this by AUS we could also detect focal fluid collection and dirty echogenic fluid collection. AUS guided Doppler showed either increased overall flow or decreased selective

Table 6: Comparison of X-ray finding and ultrasound features with modified Bell's staging

X-ray features	NEC Stage 1 (*n*=29) (%)		NEC Stage 2 (*n*=20) (%)		NEC Stage 3 (*n*=11) (%)	
	1A (*n*=14)	1B (*n*=15)	2A (*n*=12)	2B (*n*=8)	3A (*n*=6)	3B (*n*=5)
Only distended intestinal loops	10 (71.4)	8 (53.3)	4 (33.3)	0 (0)	0 (0)	0 (0)
Abnormal shaped Distended loops	1 (7.1)	10 (66.6)	12 (100)	8 (100)	6 (100)	5 (100)
Bowel wall thickening	0 (0)	0 (0)	1 (8.3)	2 (25)	3 (50)	3 (60)
Intramural gas/PI	0 (0)	0 (0)	4 (33.3)	6 (73)	5 (83.3)	5 (100)
PVG	0 (0)	0 (0)	0 (0)	4 (50)	4 (66.6)	5 (100)
Soapy bubble appearance	0 (0)	0 (0)	0 (0)	2 (25)	5 (83.3)	5 (100)
Fixed bowel loops	0 (0)	0 (0)	0 (0)	2 (25)	5 (83.3)	5 (100)
Pneumoperitoneum	0 (0)	0 (0)	0 (0)	0 (0)	2 (33.3)	5 (100)
Ultrasound features						
Bowel wall thickening	2 (14.2)	10 (66.6)	12 (100)	8 (100)	6 (100)	5 (100)
Bowel wall thinning (some areas)	0 (0)	0 (0)	0 (0)	2 (25)	4 (66.6)	4 (80)
Intramural air (PI)	0 (0)	4 (28.5)	8 (66.6)	8 (100)	6 (100)	5 (100)
Peristalsis absent	0 (0)	0 (0)	0 (0)	5 (62.5)	5 (83.3)	5 (100)
PVG	0 (0)	0 (0)	0 (0)	7 (87.5)	6 (100)	5 (100)
Free fluid	0 (0)	0 (0)	0 (0)	3 (37.5)	5 (83.3)	5 (100)
Focal fluid collection	0 (0)	0 (0)	2 (16.6)	5 (62.5)	4 (66.6)	5 (100)
Dirty echogenic fluid collection	0 (0)	0 (0)	0 (0)	0 (0)	3 (50)	5 (100)
Free intra-abdominal air (pneumoperitoneum)	0 (0)	0 (0)	0 (0)	1 (12.5)	4 (66.6)	5 (100)
Colour flow increased over all (bowel wall)	0 (0)	0 (0)	8 (66.6)	8 (100)	6 (100)	5 (100)
Colour flow decreased selective (bowel wall)	0 (0)	0 (0)	0 (0)	3 (37.5)	4 (66.6)	5 (100)
Superior mesenteric artery flow (>80-100 cm/s)	0 (0)	0 (0)	5 (41.7)	7 (87.5)	6 (100)	5 (100)

NEC: Necrotizing enterocolitis, PVG: Portal venous gas, PI: Pneumatosis intestinalis

Table 7: Incidence of NEC according to the birth weight, grouped according to Bell's classification

Weight in grams	Cases	Stage 1A (*n*=14) (%)	Stage 1B (*n*=15) (%)	Stage 2A (*n*=12) (%)	Stage 2B (*n*=8) (%)	Stage 3A (*n*=6) (%)	Stage 3B (*n*=5) (%)	*P* value
600-999	Inborn	3 (21.4)	4 (26.6)	2 (16.6)	1 (12.5)	1 (16.6)	1 (20)	0.987
Total=21	Outborn	1 (7.1)	0 (0)	3 (25)	3 (37.5)	0 (0)	2 (40)	0.027*
I/O=11/9								
1000-1249	Inborn	3 (21.4)	2 (13.3)	1 (8.3)	1 (12.5)	1 (16.6)	0 (0)	0.949
Total=14	Outborn	0 (0)	0 (0)	2 (16.6)	1 (12.5)	2 (33.3)	1 (20)	0.053+
I/O=8/6								
1250-1499	Inborn	1 (7.1)	2 (13.3)	1 (8.3)	0 (0)	1 (16.6)	0 (0)	0.887
Total=10	Outborn	1 (7.1)	1 (6.6)	1 (8.3)	1 (12.5)	0 (0)	1 (40)	0.867
I/O=5/5								
1500-1749	Inborn	1 (7.1)	1 (6.6)	1 (8.3)	0 (0)	1 (16.6)	0 (0)	0.889
Total=6	Outborn	0 (0)	1 (6.6)	0 (0)	1 (12.5)	0 (0)	0 (0)	0.419
I/O=4/3								
1750-1999	Inborn	2 (14.2)	1 (6.6)	1 (8.3)	0 (0)	0 (0)	0 (0)	0.922
Total=5	Outborn	0 (0)	1 (6.6)	0 (0)	0 (0)	0 (0)	0 (0)	1.000
I/O=4/1								
2000-2400	Inborn	1 (7.1)	1 (6.6)	0 (0)	0 (0)	0 (0)	0 (0)	1.000
Total=4	Outborn	1 (7.1)	1 (6.6)	0 (0)	0 (0)	0 (0)	0 (0)	1.000
I/O=2/2								

Chi-square test/Fisher exact test, significant figures, +Suggestive significance (*P* value: 0.05<*P*<0.10), *Moderately significant (*P* value: 0.01<*P*≤ 0.05), **Strongly significant (*P* value: *P*≤0.01), NEC: Necrotizing enterocolitis

flow. Also, SMA flow were detected in Stage 1A (0%), 1B (0%), 2A (41.7%), 2B (87.5%), 3A, and 3B (100%), respectively (Table A).

Babies survived with medical therapy, surgical therapy or both treatment modalities is 63%. of these neonates survived only with medical therapy without complications (e.g., Stenosis) whereas 5% survived with complications after medical and surgical therapy. The deaths before and after surgery were 8.3% (Table 2).

Certain antenatal factors such as antenatal steroids, oligohydramnios, and fetal heart rate abnormal rhythm and intrauterine growth restriction contributed to NEC. The mean gestational age was found to be 30.5 ± 5%. Of the total neonates with NEC, 41.6% were outborn. The mean birth weight was 1500 ± 201 g. Almost half of these neonates had respiratory distress and had received surfactants. The mean age of onset of NEC was found to be 8 ± 2 days. 23.3% were given formula/bovine milk. The mean day of starting enteral feeds were 3 ± days. In these,

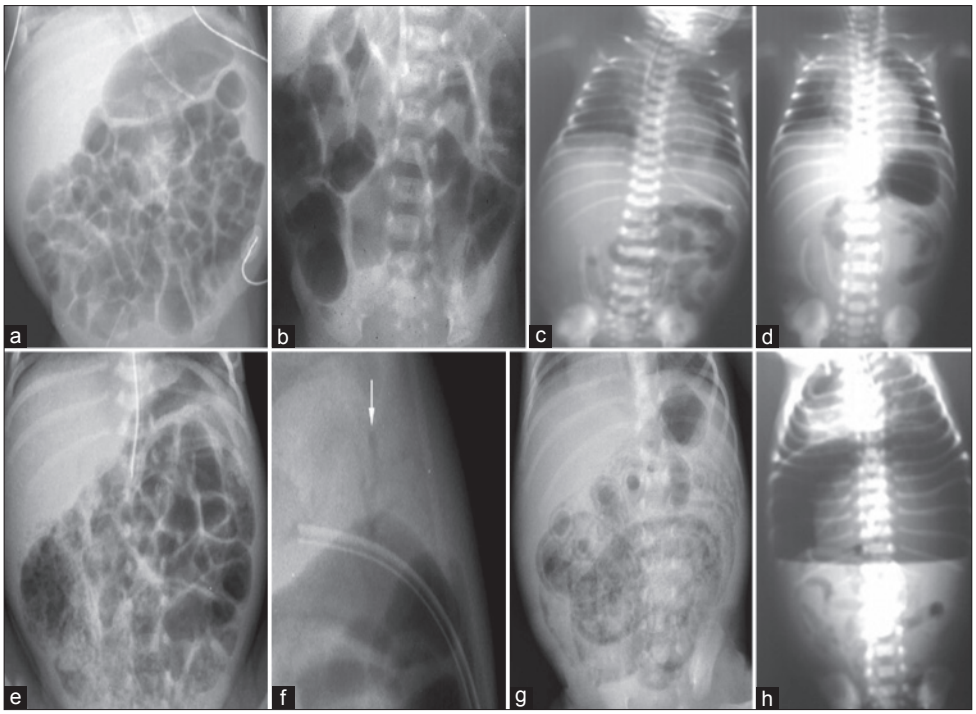

Figure 3: X-ray shows: (a) normal mosaic intestinal patterns, (b) abnormal distended bowel loops, (c) elongated intestinal loops, (d) gasless abdomen with distended loops, (e) pneumatosis intestinalis, (f) portal venous gas, (g) soapy bubble appearance, (h) pneumoperitoneum

Table A: Sensitivity and specificity of sonography and abdominal X-ray

Findings	Stage I	Stage II	Stage III
Sample size-	29	20	11
Bowel wall thickening			
X-ray	0	3	6
Ultrasound	12	20	11
P value	<0.001	<0.001	<0.01
Significance	Difference is very highly significant	Difference is very highly significant	Difference is highly significant
Intramural gas			
X-ray	0	10	10
Ultrasound	4	16	11
P value	<0.05	<0.05	>0.05
Significance	Difference is significant	Difference is significant	Difference is not significant
PVG			
X-ray	0	4	9
Ultrasound	0	7	11
P value	-	>0.05	>0.05
Significance		Difference is not significant	Difference is not significant
Pneumoperitoneum			
X-ray	0	0	7
Ultrasound	0	1	9
P value	-	>0.05	>0.05
Significance		Difference is not significant	Difference is not significant

PVG: Portal venous gas

one-fourth had undergone umbilical vein catheterization and blood culture was positive (Table 3).

Clinical signs, symptoms like increased gastric residuals, abdominal distension, vomiting, bloody stools, apnea, respiratory distress, generalized features of sepsis, abdominal tenderness, abdominal cellulitis, and absent bowel sounds were taken. About 92% of these neonates who survived with medical therapy had increased gastric residuals, whereas it was 100% in neonates with both medical and surgical therapy (Table 4).

DISCUSSION

The importance of AUS have become particularly evident with its usefulness in the assessment of bowel viability especially with color Doppler sonography in neonates with NEC along with other findings like bowel wall thickening or thinning, lack of peristalsis, and abnormalities of perfusion more often found in the lower abdomen, particularly in the right lower quadrant. Although there are limited data available, on the basis of our recent experience we believe that if meticulous attention is paid to technique, abdominal US is, in fact, more sensitive in detecting intramural gas and PVG and possibly even free gas than plain abdominal radiography. Intramural gas is also an early sign that may precede clinical signs. Although intramural gas may be present in other neonatal conditions, it is most commonly seen in NEC, and thus has been considered a virtually pathognomonic sign of NEC.[26,27]

In our study, out of total admissions of 2304 to our NICU over 4 years, from 2010 to 2014, 800 (34.7%) premature infants were taken, among them 60 (7.5%) who had signs, symptoms, biochemical changes, X-rayand AUS changes of NEC were studied. 48.3% belonged to Stage 1, 33.2% belonged to Stage 2, and 18.3% belonged to Stage 3, whereas a study done by Buch. N. A, Ahmed. S. A (an epidemiological study of NEC) Saudi medical journal, 42 babies with NEC showed that 24% belonged to Stage 1, 33% belonged to Stage 2, and 43% belonged to Stage 3.

In another study done by Katherine E. Gregery *et al.* showed that 37% belonged to Stage 1, 28% belonged to Stage 2, and 15% belonged to Stage 3. Statistics of both these studies were close to our study.

The major advantage of AUS in NEC is that it is possible with this modality to visualize the bowel wall directly and assess bowel wall thickness, echogenicity, and peristalsis. In the 30 normal neonates studied by Faingold *et al.*, bowel wall thickness ranged from 1.1 to 2.6 mm.

A clue to differentiating intramural gas from overlapping loops is the white lines that often accompany the black lines of intramural gas. The white lines represent the mucosa and submucosa, which are lifted off the serosa and are contrasted by the subserosal intramural gas and the intraluminal gas. A search for white lines rather than the black lines may often be more fruitful in helping one confirm the presence of intramural gas.[26,27]

In our study, preterm neonates were grouped according to their survival, morbidity, and mortality, and it was found that 63.3%.

Whereas a study done by Oneil *et al.* 1975 showed that 69% premature infants survived with medical therapy alone which correlated with our study.

Resolution of NEC is associated with the dilated bowel gradually returning to a more normal appearance. Persistence of dilatation or a change other than in the normal direction suggests a failure of response to medical therapy or deterioration. An ominous sign is a change from generalized dilatation to an asymmetric distribution where dilatation is confined to a more localized area of the abdomen. The degree and pattern of bowel dilatation are the most important signs for early diagnosis and for follow-up. It is even more worrisome if the asymmetric pattern persists and the dilated loops maintain the same appearance as fixed loops on follow-up plain abdominal radiographs. This suggests the development of full-thickness necrosis and may precede clinical deterioration including signs of peritonitis.[26,27]

In our study, we predominantly compared X-ray findings with AUS findings and we noted that X-ray could identify gaseous distension in 57.5% of neonates who had survived with medical therapy alone and also abnormal shaped distended intestinal walls in 100% of cases with medical or surgical therapy with or without complications. X-ray could identify around 60% of cases with bowel wall thickening, whereas AUS could identify 100% of cases. Only a few cases of PI and PVG could be identified by X-ray, but AUS picked up 100% of cases, especially those with medical and surgical therapy with complications.

Similarly, a study done by Epelman *et al.* showed that AUS could identify free fluid, bowel wall thickening better compared to X-ray.

In our study, we also grouped neonates with NEC based on bell's staging and compared their X-ray and AUS findings.

AUS also aided in color flow Doppler either increased flow or decreased selective flow. SMA flow could also be identified. Similarly, a study done by Shebrya *et al.* showed that 37.3% could be picked up by X-ray compared to 63.2% by AUS. Color Doppler sonography was found to be more accurate than clinical examination and plain abdominal radiography in the prediction of necrosis in neonates with NEC. Our study also grouped the incidence of NEC according to the birth weight ranging from 600 to 2400 g as per Bell's staging, and further classified into inborn and outborn.

The other advantage of AUS is the ability of this modality to directly assess the arterial perfusion of the bowel wall, as this is not possible with plain abdominal radiography.

Limitations

AUS does have some relative limitations:

1. Abdominal US should not be attempted in any neonate who is labile or unstable, and we have refrained from performing AUS if abdominal tenderness is present such that holding the transducer on the abdomen causes the patient severe discomfort. However, using a large amount of gel on the abdominal wall may facilitate performance of the study by enabling images to be obtained without the transducer actually touching the abdominal wall.[26,27]
2. Large amounts of bowel gas may make a sonographic evaluation of the abdomen difficult, although we have found this to be a problem in only small numbers of neonates with NEC. Feingold *et al.* found that the gray-scale and color Doppler sonograms were not interpretable because of large amounts of bowel gas in only two of 32 neonates with NEC or at risk for NEC.[26,27]

CONCLUSION

Our study concludes that AUS is superior to plain radiography in the early detection of NEC. Complications like PI, PVG, free fluid collection, intestinal thinning, perforation, and pneumoperitoneum were detected earlier than X-ray. Early findings in AUS, changes the treatment modality like implementing early advanced medical treatment, early surgical intervention which reduces the morbidity like stenosis, malabsorption (reducing gross resection of intestines), thereby facilitating better outcome and providing good long-term quality of life. Hence, AUS is a reliable tool for early detection, assessment, and prognosis of NEC in preterm infants.

At presentation, the presence of intramural gas in the clinical setting of NEC virtually clinches the diagnosis. In the absence of intramural gas, diagnosis may be much more difficult, especially if the clinical findings are mild and nonspecific. In such patients, interpretation of the plain abdominal radiograph may be a frustrating experience, if the only finding is mild gaseous distention or if there is a suggestion of bowel wall thickening. It is in these patients with mild symptoms and nonspecific findings on plain abdominal radiography that abdominal US may be extremely useful, as it may be able to depict intramural gas not visible on plain abdominal radiographs as well as depict changes in bowel wall thickness, echogenicity, peristalsis, and perfusion that may enable one to confirm or exclude the diagnosis of NEC.[26,27]

Once the diagnosis of NEC has been established, interval plain abdominal radiographs are essential for appropriate follow-up. The disappearance of intramural gas and PVG is not always associated with clinical improvement, and these are thus poor indicators of progress. When to perform abdominal US during follow-up and how often has not been established. In those neonates who respond promptly to medical therapy, abdominal US probably has no role. However, it may play a significant role in two groups of patients. The first group includes those neonates in whom the evolution of changes seen on plain abdominal radiography is not keeping up with the clinical course, and the second group includes those who are deteriorating clinically but have no evidence of pneumoperitoneum seen on plain abdominal radiography. In the latter group, it is always a challenge to decide whether to operate in the absence of Pneumoperitoneum.[26,27] We have found that in both of these groups, AUS provides valuable information regarding the bowel wall and peritoneal cavity that may influence management especially detection of bowel wall thinning which indicates impending necrosis and the need for immediate surgery.

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Original Article

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Mid Term Assessment of Mass Drug Administration for Elimination of Lymphatic Filariasis in Tikamgarh and Chhatarpur Districts of Madhya Pradesh, India

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Abstract

Introduction: Lymphatic filariasis (LF) is a crucial public health menace in India. It is one of the leading causes of long-term permanent disability, accounting for more than 5 million disability-adjusted life years annually. The mass drug administration (MDA) is one of the strategies to eliminate LF in India. 11 districts are endemic for the disease in Madhya Pradesh, which conduct MDA activities annually.

Objectives: (1) To review the progress of activities of the single dose of diethylcarbamazine (DEC) mass administration in Tikamgarh and Chhatarpur districts, (2) to make an independent assessment of the program implementation under process and outcome indicators, (3) to recommend mid-course correction and suggest necessary steps for further course of action.

Methods: An assessment of MDA for LF activities carried out from July 29, 2013 to August 01, 2013 in two districts of Madhya Pradesh. The teams visited the study areas and collected both qualitative and quantitative data to make an independent assessment. The activities carried out as per the standard methodology developed by National Institute of Communicable Diseases, Delhi.

Results: The sufficient number of training for MDA was conducted but without any mechanism for quality check. The impact assessment was done by the local authorities to understand the effect of the MDA. The filarial units in these districts had insufficient staff. There was an adequate supply of DEC tablets. The evaluated coverage with DEC tablets was much lower than that reported by the district officials, and the effective coverage was found to be 64.66% and 65.08% in Tikamgarh and Chhatarpur districts respectively. The tablet intake was not properly ensured by the distributors, and the compliance rate was between 74% and 78%. Lack of awareness was the most common reason reported for the non-compliance followed by improper counseling and absenteeism.

Conclusion: This evaluation study observed that MDA is confined to tablet distribution only and the major issues of implementation in compliance, health education, side effect, and morbidity management need to be addressed.

Key words: Compliance, Coverage, Filariasis, Mass drug administration

INTRODUCTION

Worldwide 1.3 billion people are at risk of lymphatic filariasis (LF) infection, and about 120 million people are affected in 83 countries. It is a major cause of physical and emotional suffering, as well as economic loss. The three species of nematode worm that cause LF are *Wuchereria bancrofti*, *Brugia malayi,* and *Brugia timori*. Bancroftian filariasis accounts for 90% of cases worldwide, including all cases of LF in the Pacific.[1] In India also, it has been a major public health problem next to Malaria. It is estimated that 600 million people are at risk of LF infection in 250 districts across 20 states and union territories in India.[2] LF was classed as one of six infectious diseases to be eradicable by World Health Organization. The disease was recorded in India as

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early as 6th century B.C. by the famous Indian physician, Susruta in his book "Susruta Samhita."[3] The National Filarial Control Program was launched in the country in 1955, with the objective of delimiting the problem, to undertake control measures in endemic areas. The main control measures were mass diethylcarbamazine (DEC) administration, antilarval measures in urban areas and indoor residual spray in rural areas.[4] Andhra Pradesh, Bihar, Jharkhand and Madhya Pradesh are among the worst affected states in the country.[5] Total 11 districts of Madhya Pradesh are affected with Falariasis *viz.* Katni, Datia, Chatarpur, Tikamgarh, Panna, Damoh, Satna, Rewa, Chhindwara, Sagar and Umaria.[6] Present study was carried out to evaluate the coverage, compliance and reasons for non-compliance of mass drug administration (MDA) in Tikamgarh and Chhatarpur districts of Madhya Pradesh.

Objectives

1. To review the progress of activities of single dose of DEC mass administration in Tikamgarh and Chhatarpur districts
2. To make independent assessment of the program implementation with respect to process and outcome indicators
3. To recommend mid-course correction and suggest necessary steps for further course of action.

METHODS

Selection of the Clusters in the Identified District(s)

Sample size covered in each district

The standard guidelines for MDA require that a total of 30 household are covered in each cluster covering four clusters per district. It is assured that at least 600 populations are covered in a single district for MDA evaluation. Therefore, keeping in the mind the standard procedure, in each district 120 households were surveyed.

The MDA assessment was carried out in both rural and urban areas in all three districts, as per the standard methodology. For evaluation of MDA activities in a district, all the Primary Health Care (PHCs) in a district were stratified into three groups (on the basis of reported MDA coverage in 2010): (i) PHC with coverage <50%, (ii) PHC with coverage between 50% and 80%, and (iii) PHC with coverage >80%.

For rural area

A PHC from each category was selected for MDA evaluation, in case there was no PHC in a particular category, and two PHCs from the next category were selected. In the next step, from each category of the PHC, one PHC was selected randomly. Afterward, from each of the selected PHC one village was selected randomly, using currency note for random number generation for the household survey. In each village, 30 households were covered using standard questionnaires developed for MDA evaluation.

For urban area

In the urban areas, the complete list of the wards was arranged. Thereafter, one ward was selected randomly for the evaluation of the program, using currency note for random number generation. In the next step, in each selected ward 30 households were covered.

Data Collection and Analysis

After collection of data from district health authorities and household surveys with the use of standard performa, it was thoroughly scrutinized and analyzed manually and with the help of suitable statistical software.

RESULTS

Assessment of Intra and Intersectoral Co-ordination

The coordination of different sectors of the community is must for the program to be successful. Intra and intersectoral coordination were overall found to be adequate in all districts. District action plan committee meeting was organized involving all the departments. Whose details are recorded but overall coordination of different departments was different. It was found sufficient in Chhatarpur and Tikamgarh districts. Volunteers were used for the DEC distribution and they also performed well, nevertheless teachers, government servants, politicians and community leaders were also urged to come forward and participate by making people aware and setting an example by consuming the drug before the public.

Assessment of Training

Trainings were organized at all level right from district to sub-center level in district Chatarpur and Tikamgarh for medical officers, paramedical workers, drug distributors, lab technicians, etc. The details of the trainings organized are recorded, but again, like last year what it was lacking was, that there was no system found for the quality check and attendance of these trainings.

Staffing

Understaffing was a major hurdle in implementing the program, same person is engaged in many tasks at a time due to vacant posts among all categories of stakeholders, i.e., medical officers, paramedical workers, drug distributors, lab technicians. However, it was more prominent in the staff of morbidity management where still numbers of posts are remaining vacant which need to be filled up at the earliest.

Process Indicators

1. The action plans in all districts were well-prepared and maintained
2. The baseline data on filarial endemicity was collected in all districts
3. Morbidity survey: Active search of lymphedema and hydrocele cases was done by every district. The line listing of all these cases was also maintained and is in records.

The Logistics of the Drugs

The DEC distribution is the core activity in MDA program. To make drugs available is a significant and integral activity for this work. Moreover, record of previous year consumption, the balance of drug and calculation of present year demand was properly maintained. However, no record on the quality check was recovered.

Impact Assessment

The impact assessment is done by the local authorities to understand the effect of the MDA. The work is the responsibility of the local authorities. This assessment is done by the local authorities after the round of MDA to see the effect. Indicators like MF rate etc., are used to see the before and after conditions. However, no such data was collected in any of the two districts about the impact of MDA by the local authorities.

Information, Education and Communication (IEC)

Under IES activities, posters were displayed, and pamphlets distributed. Apart from it announcement on loudspeaker and programs on the radio were organized. All two districts offices reported to have spent money on preparation and printing of IEC materials such as pamphlets, posters, banners were printed and distributed, and wall paintings were done. Loudspeakers were also used as IEC mode.

At the time of fields visits for verification by the monitoring teams, wall paintings were visible at market and public places with pictures on them. The majority of respondents from both rural and urban area said that they have seen things regarding MDA and filariasis in the form of banner and posters, few of them also reported regarding pamphlets.

The newspaper cuttings were also provided by the health authorities/filarial units to the monitoring teams. These were printed in Hindi. Some health officials had also complained of insufficient funds for IEC activities. In Chhatarpur, a new approach since last year was through SMS regarding MDA through mobile.

Whatever IEC activities are carried out there was very limited information to make the community aware of the possible side effects and why these side effects occur. During the field visits, it was found that at the time of drug distribution health worker are not adequately giving the health education to the recipients, which if was given then coverage could have been better.

Regarding the choice of best source of communication, poster and pamphlets are considered as best source of communication in rural areas, on the other hand, majority of urban population have said TV, radio and house to house communication may be best mode of communication for generating awareness.

Coverage and Compliance

The actual drug compliance is determined by interviewing about 600 family members in each district following the sampling technique against the record in the register maintained at district offices. Maximum Distribution coverage was reported in Chhatarpur (86.94%) district followed by Tikamgarh (83.21%). It was also compared with reported coverage by the district health authorities. Coverage compliance gap also calculated which was found almost more than 10% in each district, which should ideally be zero, so still more and more strengthen efforts are needed to make it zero. Effective coverage was also found to be below targeted, which is 85% for the local elimination of filariasis (Table 1). Lack of awareness was the most common reason reported for the non-compliance followed by improper counseling and absenteeism (Table 2).

Management of Side Effects of DEC

Side effects in reality was not that prevalent as its fear was. Only a minor proportion of the covered population had reported any side effect after ingestion of the drug, and if, so it was mostly nausea and vomiting and fever and sometimes diarrhea.

Only a small proportion was told about the side effects and its management, which was supposed to be told to them at the time of distributing drugs. People preferred not ingesting drugs in front of the health worker. Less than 5% of the population had ingested the drug in the presence of distributor. The side effects were properly recorded only in a limited number of cases. Only a few were given management for side effects.

DISCUSSION

The study noted that overall planning for MDA activity was good in both districts. As required, sufficient number of training is being conducted at every district. Attendance is variable. However, there is no mechanism to monitor and evaluate the quality of trainings. The inter and intra-

Table 1: District wise coverage and compliance of drugs

Name of district	Eligible population (%)	Distribution (coverage) (%)	Coverage reported by district authorities (%)	Drug ingested (compliance) (%)	Effective coverage (%)
Tikamgarh (615)	566 (92.03)	471 (83.21)	82	366 (77.70)	64.66
Chatarpur (620)	590 (95.16)	513 (86.94)	80	384 (74.85)	65.08
Total (1235)	1156	984		750	64.87

Table 2: Reason of non-compliance

Reason of non-compliance	*N*=234	%
Lack of awareness	112	47.86
Improper counseling	45	19.23
Absent at the time of drug distribution	27	11.53
Fear of side effects	20	8.54
Forgot	18	7.69
Others	12	5.12

sectoral coordination was good in both districts. The health education activities were not being done satisfactorily.

There was limited knowledge and awareness about LF and MDA among the community members. Similar findings have been reported from other studies in India.[5,7,8] The local modes of awareness generation were utilized in a rural area and the TV and newspapers for IEC activities in the urban area which had limited penetration in the rural population. These findings differ from a previous study done by Lahariya and Mishra[5] Less than 5% of the population had ingested the drug in the presence of distributor. The side effects were properly recorded only in a limited number of cases. Only a few were given management for side effects.[5]

In order to minimize the transmission of filariasis and to ultimately eliminate it from the country. It is required to have DEC coverage of more than 85%, continuously for 5 years, in endemic areas. However, the major difficulty is in achieving such a high coverage. In our study, the effective coverage was found to be 64.66% and 65.08% in Tikamgarh and Chhatarpur districts, respectively. Which was far below the target needed and laid by for the local elimination of filariasis, i.e., sustained effective coverage of at least 85% for 5 years. Prasad *et al.* found in their study better findings than the present study.[9,10] A study done by Kumar *et al.* in Gujarat, the coverage rate was 85.2% with variation across different areas. The compliance with drug ingestion was 89%. The effective coverage (75.8%) was much below the target (85%) but better than our study findings.[11]

In present study, lack of awareness was the most common reason reported for the non-compliance followed by improper counseling and absenteeism. Godale and Ukarande reported in their study that fear of side effects of drugs (45.38%) as the most common reason for non-compliance followed by lack of awareness about LF.[12]

Finally, LF is an area where limited research is being done in India and other endemic countries. There is an urgent need for operational research to find out the solutions for existing problems in the efforts towards the elimination of LF.

CONCLUSION

There appears an immediate need to strengthen the MDA planning and implementation in these districts. This evaluation is a starking example showing that even a well-thought, well-funded and well-planned program may not succeed if the implementation is poor. The focus should be on providing health education, awareness about the side effects and, a strong inbuilt mechanism for side effect management and the morbidity management to make the LF elimination program successful.

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Original Article

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A Case Cohort Study on Clinical Utility of Garenoxacin Mesylate in Recurrent Uncomplicated Urinary Tract Infections: A Retrospective Analyses

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Abstract

Background: Recurrent urinary tract infections (UTIs) are important health issue in both females and males with greater implication on patients quality of life. *Escherichia coli* is most common causative agent of UITs. Fluoroquinolones are often looked upon as empiric therapy for recurrent UTIs.

Aim: Retrospective analyses to assess the clinical utility of fluoroquinolones in recurrent UTIs.

Methods: This retrospective case series cohort study comprised of patients suffering from recurrent UTIs who received fluoroquinolones including garenoxacin. Clinical response or success was judged by subjective assessment for control of presenting symptoms while assessing change in laboratory parameters. Failure was defined as persistence of symptoms or no significant improvement. Any notable side effects or serious adverse events (SAE) observed were also collected for analyses.

Results: Retrospective analyses amongst fluoroquinolone cases revealed 41 patients receiving garenoxacin as first line therapy after being diagnosed with recurrent UTIs. Therapy with garenoxacin was advised for 5 or 7 days in 49% and 49% cases respectively. Clinical success was established in all patients in both the treatment groups. No case of therapy failure was reported. None of the cases reported any SAE.

Conclusion: Fluoroquinolones remains empiric therapy for recurrent UTIs in setting of resistance to other antibiotics. Garenoxacin is a structurally modified new generation quinolone offering clinical utility in recurrent UTIs with better safety profile.

Key words: Fluoroquinolones, Garenoxacin, Urinary tract infection

INTRODUCTION

Recurrent urinary tract infections (UTIs) are significant health issue in both females and males[1] with the diagnosis and management of recurrent UTIs in clinical settings also remaining a therapeutic challenge. Epidemological surveillance studies estimates prevalence of recurrent UTI 20.9% over 6 months and 44% over 1-year period in women.[2] Recurrent UTI is defined as 2 episodes of UTI in last 6 months or ≥3 episodes of UTI in last 12 months in females and more than one episode of UTI in males after the treatment and complete resolution of the previous symptomatic infection.[3-5] Frequency of sexual intercourse is most important risk factor for recurrent UTI in young female and others include age at first UTI ≥15 years, maternal history of UTIs, new sexual partner in the past year and spermicide use in past year.[6] Uncomplicated UTIs are less frequent in males because of factors like longer urethra, larger distance between anus and urethral meatus, antibacterial properties of prostatic secretions. Thus, UTIs in adult male are believed to indicate underlying pathology.[5]

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Clinical features of uncomplicated UTIs includes burning micturition with dysuria, frequency of urination, urgency and pain.[7] Worldwide, most common causative agents of uncomplicated UTI includes *Escherichia coli* (75%), *Klebsiella pneumoniae* (6%), *Staphylococcus saprophyticus* (6%) and others (13%).[8] Various Indian studies also identifies *E. coli* as the most common causative agents of UTI.[9-11] Appropriate

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use of trimethoprim/sulfamethoxazole, nitrofurantoin, fluoroquinolones and β-lactam antibiotics is recommended for treatment of recurrent UTIs.[6] According to a large scale *in vitro* surveillance data resistance rates of *E. coli* isolates from female outpatients were trimethoprim/sulfamethoxazole (17.5%), ampicillin (38%) and that of fluoroquinolones (<4%).[12] Fluoroquinolones are therefore often looked upon as an empiric choice of drugs especially in recurrent UTIs for both male and female in settings of high resistance to other antibiotics. Recurrent cystitis suggested treatment includes 7 days therapy with fluoroquinolones.[6,13]

Garenoxacin a novel desfluoroquinolone with modified structure activity relationship offers dual inhibition against bacterial DNA gyrase and topoisomerase IV, thus requiring mutations in both the enzymes for resistance to occur and also offers broad spectrum coverage against Gram-positive, Gram-negative or Enterobacteriaceae while offering lower minimum inhibitory concentration 90% (MIC_{90}) values compared to other fluoroquinolones.[14,15]

The present study was conducted to evaluate retrospectively the clinical utility of fluoroquinolones in management of UTIs while being prescribed as an empirical antibiotic therapy in UTIs.

METHODS

A retrospective case series cohort was analysed to evaluate role of fluoroquinolones including garenoxacin as an empirical therapy for adults with UTIs. Cases were identified from database of all adult patients who were treated for UTIs between August and December 2014, where the provisional diagnosis was made by attending physician. Case of UTI was defined as patient with ≥1 symptoms of dysuria, increased frequency of micturition, urgency, hesitancy, lower back pain, lower abdominal pain.[16] Dysuria was defined as pain, burning or discomfort on urination.[17] Amongst these cases recurrent UTI was defined as patient with ≥2 episodes in last 6 months for both males and females. Epidemological, demographic, medical history, prior history of antibiotic or fluoroquinolone use, treatment, clinical outcome and adverse event data was gathered for analyses. Additionally cases with intact laboratory data in terms of urine microscopy and urine culture were further analysed. Therapeutic response was assessed as clinical success or complete resolution signifying significant improvement or complete resolution of symptoms at the end of therapy. Failure was defined as persistence of symptoms or no significant improvement. Serious adverse event (SAE) defined as hospitalization or prolonged hospitalization, disability, death, congenital anamoly, or medical abnormality of significance was confirmed to be reported to central or regional pharmacovigilance center by the doctor.

Statistical Analysis

Descriptive statistics was used to tabulate the data with percentage rate calculated for all categorical nominal and ordinal data variables.

RESULTS

Between August and December 2014, 90 cases of uncomplicated UTIs were identified. Amongst these 90 cases, β-lactam or fluoroquinolones were advised in 30 and 60 cases of uncomplicated UTI. All of the recurrent UTI cases ($n = 41$) treated with garenoxacin mesylate were further analysed (Figure 1).

Baseline Demographics

Out of 41 cases analyzed 49% were male and 51% were female (Table 1). Associated significant comorbidities were noted in 41% cases which included diabetes and hypertension. There was no history of functional urinary tract abnormalities and tuberculosis. Associated concomitant risk factors were noted in 66% cases which included history of smoking and alcohol consumption. Concomitant medications included oral hypoglycemic agents and anti-hypertensives, none of the cases were prescribed antibiotics or fluoroquinolones other than garenoxacin. None of the cases had history of hospitalization or were prescribed fluoroquinolones for treatment of previous episodes of UTI.

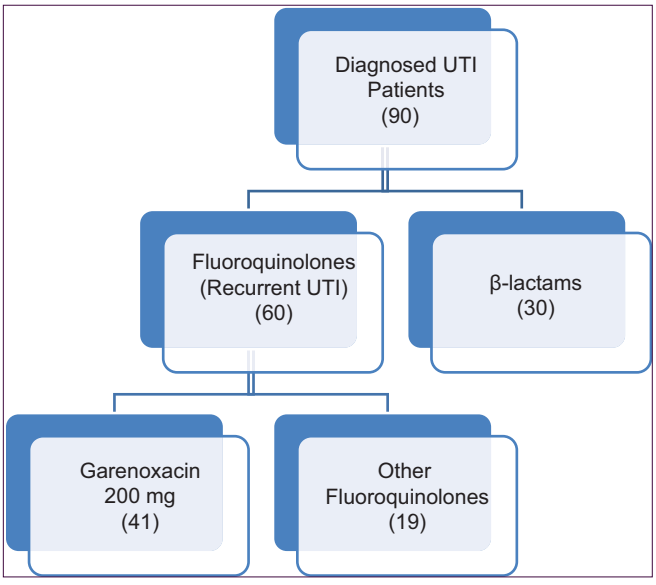

Figure 1: Therapy of choice for uncomplicated urinary tract infections

Table 1: Baseline demographics and clinical data for the study population receiving garenoxacin

Total number of cases	41
Mean age	39.2 years
Mean weight	65.8 kg
Gender (%)	
Males	20 (49)
Females	21 (51)
Medical history (%)	
Diabetes	7 (17)
Hypertension	10 (24)
Clinical features (%)	
Dysuria	41 (100)
Increased frequency of urination	21 (51)
Lower abdominal pain	13 (32)
Laboratory parameters (%)	
Pyuria (>10 WBCs/hpf)	41 (100)
Hematuria (>3 RBCs/hpf)	8 (19.5)
Urine culture	8 (19.5) (*E. coli*)

E. coli: Escherichia coli, WBCs: White blood cells, hpf: High power field, RBC: Red blood cells

Clinical Results

The cases included in the study presented with the complaints of dysuria (100%), increased frequency of urination (51%), hesitancy (29%), itching (34%), fever (100%), chills (41%), lower back pain (36.5%), lower abdominal pain (32%), foul smell (2.5%). Pyuria defined as >10 white blood cells/high power field (WBCs/hpf) was noted in all cases (100%) at baseline.[18] Microscopic hematuria defined as >3 red blood cells (RBCs)/hpf was noted in 19.5% cases at baseline.[19] Baseline urine culture revealed *E. coli* isolates in 19.5% cases (Table 1). Garenoxacin was administered to these cases at a dose of 200 mg for 5-7 days. Complete resolution of pyuria (all cases <5 WBCs/hpf) and microscopic hematuria (all cases nil RBCs/hpf) was documented in all cases at end of suggested duration of therapy.

Therapy with garenoxacin was advised for 5 or 7 days in 49% and 49% cases respectively. Clinical success was noted in all cases at the end of both 5 and 7 days therapy. Also, 1 case required 14 days therapy to establish complete resolution. No case of therapy failure was reported (Figures 2 and 3).

Safety Profile

None of the cases reported any adverse event or SAE, which required discontinuation of therapy or hospitalization.

DISCUSSION

Recurrent UTIs are important health issue in both females and males.[1] Majority cases of recurrent UTIs are due to reinfection (>80%) and also includes relapse cases. Reinfection is recurrent UTI with previously isolated

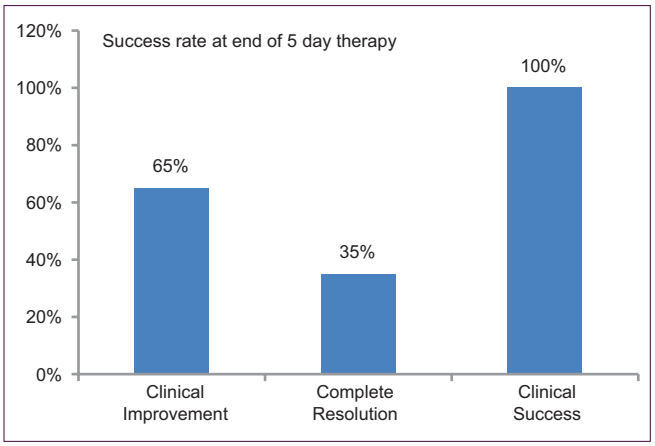

Figure 2: Clinical response with 5 day therapy for garenoxacin

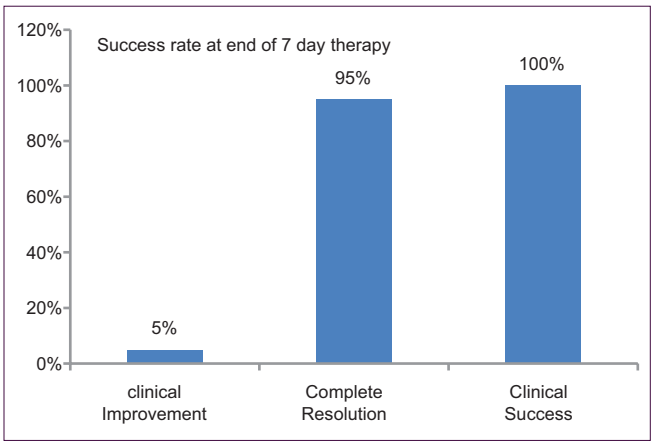

Figure 3: Clinical response with 7 days therapy for garenoxacin

bacteria or other bacteria after treatment with negative urine culture. Reinfections are believed to occur from extraurinary sites like vagina and rectum. Relapse is recurrent UTI with the same organism within 2 weeks after adequate therapy.[6] Further, uropathogenic *E. coli* invades urothelial cells and forms quiescent intracellular bacterial reservoirs or intracellular bacterial community which can explain reinfection with genetically identical bacterial strain, bacterial persistence and recurrence of UTIs.[2,4] A systemic review for the diagnostic accuracy of uncomplicated UTI signs and symptoms estimates sensitivity with dysuria (80%), increased frequency (88%), urgency (67%), lower abdominal pain (50%) and specificity with fever (92%), hematuria (85%), flank pain (69%) and lower abdominal pain (50%).[7]

Management guidelines of recurrent UTIs includes a course with trimethoprim/sulfamethoxazole or fluoroquinolones (ofloxacin, ciprofloxacin, norfloxacin).[6] Treatment guidelines suggest recurrent cystitis should be managed with pretreatment urine culture and 7 days fluoroquinolone therapy.[13] The study findings are consistent with respect to management of recurrent UTIs as suggested in the guidelines.

Garenoxacin a novel fluoroquinolone offers unique structure activity relationship at position 8 in the form of difluoromethyl ether linkage offering high potency against Gram-negative pathogens including Enterobacteriacae causing UTI.[20] Garenoxacin offers lowest MIC_{90} values amongst fluoroquinolones against most of these common uropathogens. Garenoxacin demonstrates urinary excretion of 41.8% and believed to exhibit bactericidal action against uropathogens, while demonstrating lower MIC_{90} values including *E. coli* (0.06 mcg/ml), *K. pneumoniae* (0.5 mcg/ml), *S. saprophyticus* (0.06 mcg/ml), *Proteus mirabilis* (1 mcg/ml) compared to other fluoroquinolones.[14,15]

Garenoxacin was also found to be superior in terms of safety profile. A post-marketing surveillance study done at Japan by Hori and Maki in 6412 patients confirmed the superior tolerability profile of garenoxacin with minimal or negligible incidence of gastrointestinal, cardiovascular or central side effects.[21]

The findings of this retrospective analysis are exploratory and need to be further confirmed in larger multicenter, randomized, double blind clinical trial settings especially for recurrent uncomplicated UTI or pyelonephritis cases.

CONCLUSION

Fluoroquinolones are suitable alternative for uncomplicated or recurrent UTIs. Garenoxacin, a structurally modified fluoroquinolone offers higher potency against Gram-negative or Enterobacteriaceae uropathogens. Clinical success reported in present study with garenoxacin in recurrent UTIs is well backed by optimal pharmacokinetic and pharmacodynamic parameters demonstrated with garenoxacin including high urinary excretion rate and lower MIC_{90} values against the uropathogens.

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Original Article

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Assessment of Visual Function of Truck Drivers Travelling on National Highway of Central India: A Prospective Study

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Abstract

Introduction: Truck drivers are most responsible and simultaneously most vulnerable for highway accident. This might be due to several reasons, but the impaired visual function can be one of the major causes for mishaps.

Purpose: The purpose of the present study was to assess and analyze the visual function of drivers on national highway (NH).

Materials and Methods: The prospective study was done on drivers passing through NH 200 at Bilaspur (C.G.). Drivers were examined for visual acuity, color vision, and fields.

Results: Totally 1041 drivers were examined out of which 834 (80.11%) were found fit for driving. 196 had refractive error (18.82%), 11 cataract (1.05%), 3 corneal opacity and 2 squint were noted. 14 (1.34%) drivers had defective color vision.

Conclusion: According to the present criteria 20% drivers were unfit; in India criteria for driving safely is to be revised and regular monitoring and better visual examination parameters should be given more importance for issue and renewal of driving licenses.

Key words: Assessment, Drivers, Visual

INTRODUCTION

India has large and diverse transport industry. It caters to the needs of 1.1 billion people. In 2007, the transport sector contributed about 5.5% to the nation's Gross domestic product, with road transportation contributing the major share. India as a developing nation has a vast and exhaustive network of national highways (NH) connecting various parts of the country. Transportation of goods in India is mainly dependent on roads. Road transportation carries almost 90% of the country's passenger traffic and 65% of its freight. The India's highway network density is 0.66 km of per square kilometer of land which is similar to that of the United States (0.65) and much greater than China's (0.16) or Brazil's (0.20).[1]

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Safety on highways depends on the drivers of the heavy motor vehicle driving to the fullest in the highways.

Truck drivers are most responsible and simultaneously most vulnerable for highway mishaps. They are responsible for their own and live of others as well, on the road.[2]

Our study was conducted in association with Bilaspur traffic police and Bilaspur truck owner association.

In this study, we assessed the visual function of drivers on NH 200 at Bilaspur (C.G.).

MATERIALS AND METHODS

The protocol was approved by the local ethics committee and written informed consent was obtained from each patient. The study was prospective in design. The study was done on all the truck drivers passing through NH 200 at Bilaspur (C.G.). Inclusion criteria were all the truck drivers passing through the NH 200 at Bilaspur between 9 am and 5 pm between the dates of 2/04/2010 and 6/04/2010.

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All the drivers were examined by an ophthalmologist for visual acuity (Landolt's C, Snellen's charts), color vision (Ishihara plates) and visual fields (confrontation method). Drivers, having unaided or with glass visual acuity less than 6/6 in either eye were examined by pin hole to read the Snellen's chart.

The vision requirements for driving safety in India is BCVA 6/18 binocularly data as obtained from report vision requirements for driving safety prepared for International Council of Ophthalmology (ICO) 30th World Ophthalmology Congress, Brazil, 2006.[2]

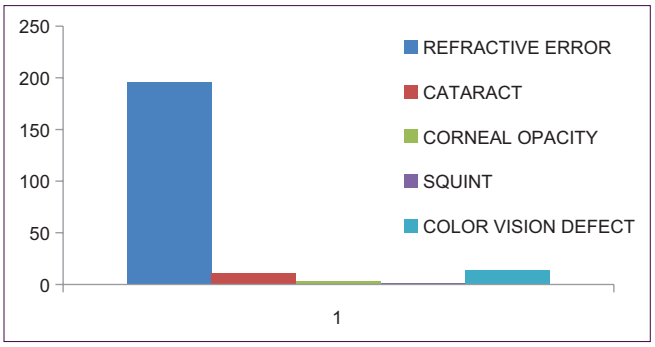

Figure 1: Visual defects in truck drivers

RESULTS

Totally 1041 drivers were examined out of which 834 (80.11%) were found fit for driving.

Criteria adapted as per data obtained for India from a report prepared for ICO 30th World Ophthalmology Congress, Brazil, 2006.[2]

The mean age of drivers was 32 years (range 18-60 years). Figure 1 is showing the results of visual function defects.

196 drivers had refractive errors (18.82%). Among 196 refractive errors, 144 (73.46%) were not wearing any corrective glasses while 52 (26.53%) were wearing under corrected glasses.

Nearly 11 (1.05%) drivers had cataract. Three drivers had corneal opacity and two had a squint. 14 (1.34%) drivers had defective color vision.

DISCUSSION

ICO recommends various visual functions to be tested. Report prepared for the ICO at the 30th World Ophthalmology Congress, Sao Paulo, Brazil, February 2006 suggested criteria and rules.[2] It stresses the need for binocular (both eyes open) measurements and the need for a gray zone in which decisions will be based on individual consideration, rather than on the application of strict numerical criteria. It also stresses the interaction of visual and non-visual parameters. For visual acuity, the commonly used threshold of 20/40 (0.5, 6/12) is accepted. For visual fields, a binocular field of at least 120° horizontal and 40° vertical is suggested. Contrast sensitivity screening is listed as desirable.

There is a relationship between age and driving safety according to Keltner and Jhonson.[3] The Department of Motor Vehicles Driver Record Study at California reported during the period of 1972-1974, an incidence of two accidents per 100.000 miles in 20-year old drivers. This number decreased to 1/100.000 for the age group 30-60 years and increased again after that age to reach 2/100.000 at the age of 70 years. Younger drivers are prone for speeding, whereas older persons are probably more easily distracted or fail to appreciate and respond to a potentially dangerous situation. These factors are all non-visual. The person's physical condition, hearing and slowing of reactions with age, play a definite role.[4]

Visual acuity is the visual parameter that is most easily and, therefore, most widely measured. It is often considered for a gross measure of vision. Its limitation is that it only tests the central macular area. For optical problems like defocusing or opacities, it is adequate. For retinal problems which are quite prevalent in the older population, visual acuity is only a partial measure since the foveal function does not predict perifoveal function. The 20/40 (0.5, 6/12) standard is the criterion most widely used. We believe this to be reasonable, not because one becomes an unsafe driver at 20/50 (0.4, 6/15) but because it includes a safety margin for adverse conditions.

Szlyk *et al.* compared the driving performances of 20 patients with juvenile macular dystrophy (Stargardt disease or cone-rod dystrophy) and visual acuity between 20/40 and 20/70 with 29 control subjects with normal vision. The ratio of individuals involved in accidents in the group of central vision loss was comparable to that of the control group.[5]

Contrast sensitivity may be reduced due to optical factors like cataract. Contrast problems may also result from retinal problems (age-related macular degeneration, glaucoma, etc.) that are also common among the elderly. If the contrast sensitivity loss is caused by optical problems (defocus, scatter), both visual acuity and contrast sensitivity will be affected. Brabyn *et al.* showed that some people in an elderly population may have 20/20 (1.0, 6/6) acuity on a high contrast chart in good illumination, but will easily drop to 20/200 (0.1, 6/60) or below with low light, low contrast and glare.[6] Mäntyjärvi and Tuppurainen suggest to include simple tests for contrast sensitivity and glare sensitivity in the requirements for a driving license in older drivers.[7]

In patients with lens opacities, the problems are not only the reduction of central vision and the visual field restrictions. Poor contrast sensitivity and glare also play a very important role. Owsley *et al.* studied the impact of cataract on driving in an older population (274 with cataract and 103 cataract free drivers).[8] Drivers with a history of crash involvement were eight times more likely to have a serious contrast sensitivity deficit in the worse eye (defined as a Pelli Robson score of 1.25 or less) than those who were crash free. They concluded that severe contrast sensitivity impairment played a major role in car accidents even when it was present in only one eye.

Wood *et al.* simulated three conditions of visual impairment in 14 young, visually normal, individuals: Monocular vision, cataract and peripheral field restriction. Using modified swimming goggles the extent of visual fields, and low contrast visual acuity were significantly decreased. In this study, simulated cataract caused the greatest reduction in driving performance, followed by binocular visual field restriction even though the drivers still satisfied the visual requirements for driving licensure. Monocular vision did not significantly affect the driving performance.[9]

Glare sensitivity may result from optical problems, such as cataract, or from retinal problems. In the first case stray light and disability glare are important; in the latter case, glare recovery time is important. A recent European study validated the use of a new stray light meter in an international population study.[10]

The Guidelines of the European Commission have dropped color vision requirements.[11] They are still in use in some states in the USA, in Bulgaria, Columbia and provinces in Canada. Studies by Verriest *et al.* have shown that abnormal color vision is not incompatible with safe driving.[12] The problem of recognizing traffic lights is overcome by the standardized position of the different lights, appropriately chosen colors and in some countries by the differences in their sizes.

Our study has several limitations. In our study, Snellen's acuity chart was used due to non-availability of logMAR chart. Contrast sensitivity (Pelli Robson chart, MARS hand held chart), Glare sensitivity, diplopia, night vision tests can also be included. Contrast sensitivity testing was not done which is the limitation of our study.

CONCLUSION

- According to the present criterion ≈ 20% drivers were unfit; in India criteria for driving safely is to be revised and modified including other criteria (visual field, contrast sensitivity) which most of the western countries have.
- Abnormal color vision is incompatible with driving safely, but the problem can be overcome by the standardized position of traffic lights.
- Regular monitoring and better visual examination parameters should be given more importance for issue and renewal of driving licenses.
- Frequent ocular examinations are recommended for older drivers.
- Ocular examination for drivers should be more frequent in various parts of different highways in the country to increase the safety margin of our NHs.

ACKNOWLEDGMENTS

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Original Article

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Clinico-anatomical Approach for Instrumentation of the Cervical Spine: A Morphometric Study on Typical Cervical Vertebrae

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Abstract

Introduction: Seven cervical vertebrae form the skeleton of the neck. These bones are the part of the axial skeleton. Four out of seven cervical vertebrae are typical on the basis of commonly prevailing characteristics. These centrally positioned and well-stacked bones support and position the head. The craniovertebral and intervertebral articulations provide the necessary flexibility.

Aim: The aim of the present study was to observe the morphology and morphometry of typical cervical vertebral body.

Materials and Methods: The present study was carried out on 240 adult dry human typical cervical vertebrae obtained from the Department of Anatomy of four medical colleges in Bihar to observe the dimensions of the vertebral bodies.

Result: Height of the vertebral bodies was observed to be larger at lower levels. Maximum anteroposterior length and transverse length were observed at C_6 and C_5, respectively.

Conclusion: Knowledge of both morphology and morphometry of typical cervical vertebrae is imperative for developing instrumentation related to the cervical spine. Ethnic variations have been reported in these dimensions.

Key words: Cervical vertebrae, Instrumentation, Morphology, Morphometry, Variations

INTRODUCTION

Cervical curvature plays an integral role in the proper functioning of the cervical spine. The summation of small movements occurring at the cervical intervertebral joints accounts for the high mobility and flexibility of the neck as an entity. The skeleton of the neck comprises seven small cervical vertebrae out of which four (C_3-C_6) are typical. Each vertebra consists of an anterior vertebral body and a posterior neural arch. The vertebral body has a central part of cancellous bone and a peripheral cortex of compact bone. The margins of upper and lower surfaces of the vertebral body are thickened to form vertebral rings. The neural arch is constituted by pedicles, laminae, spinous process, and articulating facets. The vertebral bodies are connected anteriorly by a long strong strap like anterior longitudinal ligament and a similar posterior longitudinal ligament. Fractures and dislocations of the spine are serious injuries as they may be associated with damage to the spinal cord or cauda equina. Instrumentation of the cervical spine is often used for the orthopedic management of pathologies resulting in cervical instability as well as for the decompression of neural structures. One of the most frequent and complex procedures for this is the placement of transpedicular screws.[1-4] The neural arches of adjacent vertebrae articulate with each other though facet joints which form synovial joints. Remaining portions of the neural arch of consecutive vertebrae are joined together by ligamentum flavum and other ligaments which are collectively termed as posterior ligament complex. Size of the vertebral bodies and both direction and size of the articular facets are different in different regions of the vertebral column. Previously morphometric studies of the cervical, thoracic, and lumbar vertebrae have been undertaken, and they have highlighted the importance of such studies in the development of vertebral

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column instrumentation.[5-8] Majority of these studies focus exclusively on the pedicle as this is the site where vertebral column fixation surgeries are most frequently implemented. Only a few studies describe the characteristics of the remaining elements that comprise the vertebra.[9,10] Most spinal surgeons agree to have adequate knowledge of spinal column morphology to avoid damage to the vertebral artery, spinal medulla, or nerve roots during fixation interventions involving posterior cervical spine.[11] Ethnic differences in dimensions of cervical spine have been reported across various populations. This study was taken up as no such citable previous study was performed in the state of Bihar.

MATERIALS AND METHODS

Two hundred and forty adult dry human typical cervical vertebrae were obtained from the Department of Anatomy of four medical colleges in Bihar to observe the dimensions of the vertebral bodies. Sex of the bone was not considered in the study. Only those vertebrae which were intact in all aspects were included in the study. Damaged, malformed, and vertebrae with signs of previous fractures were excluded from the study. All the measurements were conducted by using a sliding Vernier Calliper with 0.1 mm accuracy. Dimensions of the body were recorded in the following manner:

(a) Height: Distance between superior and inferior borders of the vertebral bodies at the midline
(b) Anterior-posterior length (APL): Distance between the anterior surface and posterior surface of the body at the midline
(c) Transverse length (TL): Distance between two lateral surfaces of the vertebral body (Figures 1-4).

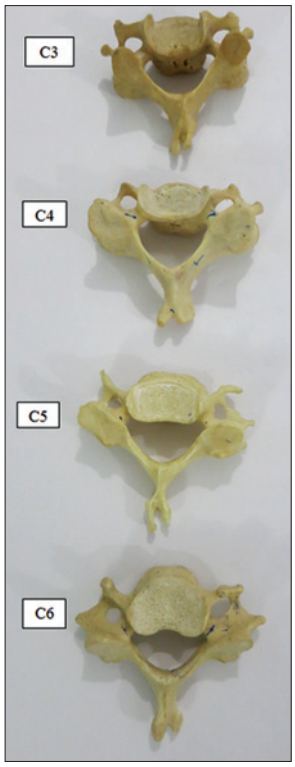

Figure 1: Vertebrae C_3-C_6

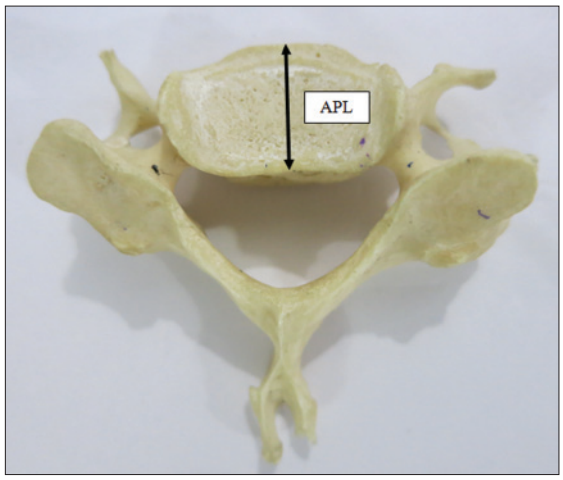

Figure 2: Recording of anteroposterior length (mm)

RESULTS

Out of 240 cervical vertebral bodies studied, the maximum and minimum APL were observed at C_6 and C_3 respectively. TL was greatest at C_5 and smallest at C_3. The maximum body height was recorded at C_6 and lowest at C_4 (Tables 1 and 2).

DISCUSSION

Cervical spine instrumentation requires minute precision and thorough anatomical knowledge for a successful outcome. The management of spinal trauma either in isolation or a part of the polytraumatized patient is a difficult venture. Several authors have described the various parameters of the vertebral column in general by methods such as computed tomography scans and three-dimensional (3D) reconstructions. It has also been previously demonstrated that vertebral dimensional differences exist among different races,[12] and in this study, we have observed vertebral dimensions in Bihar region. The APD of a cervical vertebral body is an important parameter for the anterior fixation of bicortical screws.[9] In this study, we have observed that body height of typical cervical vertebra was minimum in C_4 and maximum in C_6. The APL was maximum and minimum at C_6 and C_3, respectively. The TL was greatest and least at C_5 and C_3, respectively. The exact dimensions of bodies of cervical vertebrae are an important tool in the planning of management and treatment of diseases related to the cervical spine. Knowledge of normal dimensions of vertebral bodies helps us to understand various clinical conditions such as stenosis and other space occupying

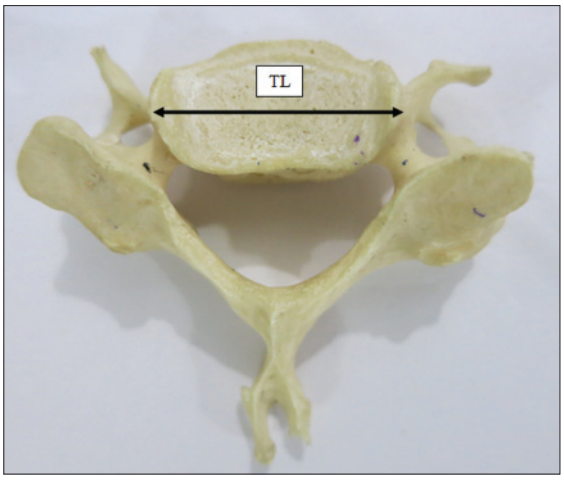

Figure 3: Recording of transverse length (mm)

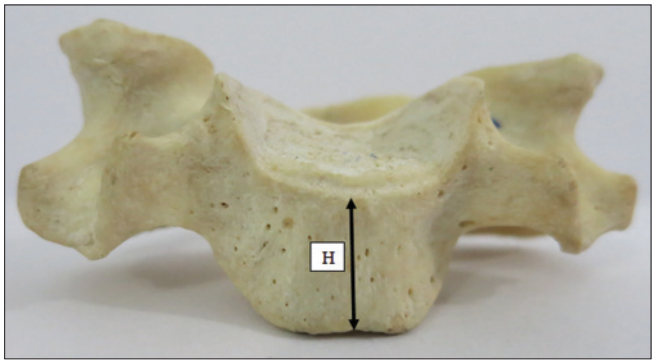

Figure 4: Recording of height of vertebral body (mm)

lesions. Growth of the vertebral body may be related to genetic, racial, postural, and occupational factors. Body of cervical vertebrae from C_3-C_6 is somewhat box-shaped. Vertebral bodies appear to grow more in height than in depth and APL of a vertebral body is always greater than height. Variations in the components of the spine are so great that this subject has interested specialists from several fields. Spinal posture depends upon the anatomical and functional integrity of the vertebrae and if this integrity is lost clinical symptoms may develop.

CONCLUSION

Morphometry of vertebral bodies is useful for surgeons and orthopedicians who perform plate fixation during anterior cervical spine surgery. Variations in racial data must be taken into consideration during surgical procedures. Morphologic characteristics of the cervical vertebrae are responsible for the natural cervical lordosis curvature and the mobility of the cervical column. However prior to instrumentation, the orthopedic assessment of the spine should include evaluation of both skeletal and neurological injuries and a careful examination of both spinal and non-spinal injuries.

Table 1: Comparison of the values of the typical cervical vertebrae observed in this study

Parameter	*n*	Maximum	Minimum
Height	240	C_6	C_4
APL	240	C_6	C_3
TL	240	C_5	C_3

C=Cervical vertebra, APL: Anterior-posterior length, TL: Transverse length

Table 2: Morphometric characteristics of the typical cervical vertebral bodies

Cervical vertebra	Mean±SD (mm)		
	APL	TL	Height
C_3 (*n*=60)	13.6±0.18	22.8±0.21	8.9±0.11
C_4 (*n*=60)	14.4±0.15	23.6±0.28	8.1±0.10
C_5 (*n*=60)	15.2±0.21	26.4±0.30	10.1±0.17
C_6 (*n*=60)	15.8±0.19	25.2±0.23	11.3±0.16

C: Cervical vertebra, APL: Anterior posterior length, TL: Transverse length, SD: Standard deviation

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Original Article

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Dimensions of Glenoid Fossa of Scapula: Implications in the Biomechanics of an Implant Design

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Abstract

Introduction: The entire upper extremity is connected to the axial skeleton through the scapula by various strong muscles and two joints, the sternoclavicular and acromioclavicular. The clavicle appears to play the role of a strut that defines the distance between the torso and the scapula. Nevertheless, the true biomechanical function of the clavicle is not clearly understood. Attempts have been made by several authors to understand the shoulder suspension complex and to explain the pathobiomechanics of certain shoulder injuries.

Aim: The aim of the present study was to observe the glenoid fossa of the human scapula.

Materials and Methods: The present study was conducted on eighty dry adult human intact scapulae obtained from the Department of Anatomy of four different medical colleges in the state of Bihar. Dimensions of the glenoid fossa of each in two axes were recorded and compared bilaterally.

Result: Vertical glenoid diameter is higher than horizontal glenoid diameter due to shape and diameters on the right side were larger than those of the left side.

Conclusion: Dimensions of the glenoid fossa are important both surgically and biomechanically, as orthopedicians require the utility of an implant for shoulder arthroplasty. Knowledge of variations of the glenoid cavity is essential for evaluating pathological conditions, osseous lesions and osteochondral defects related to the shoulder joint.

Key words: Arthroplasty, Glenoid fossa, Implant, Scapula

INTRODUCTION

The scapulae are a pair of triangular, large, flat bones that are situated dorsally in the ribcage in relation with the second to seventh ribs. The scapula has three borders, three processes, and three angles. The glenoid (Gk. *Gléne* "socket") fossa is oriented at the lateral angle of the bone. During development, the glenoid fossa shows slight concavity at 20 mm crown rump length. The process of scapular development and ossification are extremely variable. Individuals may experience different rates of ossification, and some may never obtain the complete fusion of the scapula with the acromial process (*os acromiale*). The shoulder joint is a synovial joint of ball and socket variety and by virtue of evolution; it has gained mobility at the cost of stability. It is a complex assembly of muscles, tendons, ligaments, cartilages and bones. For the functional integrity of the joint, all these structures should be healthy and must work in accordance with each other. If any one of these structures is diseased or injured, it can have a negative ripple effect on the functioning of the others. The two articulating surfaces of the shoulder joint are the hemispherical head of the humerus and the glenoid fossa of the scapula. The stability of the humeral head on the glenoid fossa is provided by the musculotendinous cuff. The scapula is surrounded by muscles and is further protected from injury by its vicinity to the thoracic wall. In polytrauma

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patients, fracture of the scapula is an indicator of severe thoracic trauma including occasional rupture of the thoracic aorta. Isolated fractures are rare and are usually due to an isolated blow from the back directly targeting the scapula. Associated ipsilateral fracture of the clavicle may occur in a quarter of the cases and can result in a floating shoulder. Shoulder arthroplasty is a common orthopedic intervention in the clinical management of shoulder arthritis. Compared to fractures of the clavicle and scapula, fracture of the glenoid rim is a completely different entity as it is usually a result of dislocation of the glenohumeral joint. Knowledge of the shape and morphological parameters of both the articulating surfaces is essential for a successful shoulder arthroplasty as otherwise there would be loosening of the joint necessitating revision surgery.[1] The fibrocartilaginous glenoidal labrum can be detached leading to a Bankart's lesion.[2] Surgical treatment in glenohumeral arthritis requires a thorough knowledge of both morphology and morphometry of glenoid fossa especially when a prosthesis has to be used. As no such previous citable research was available in Bihar, this study was taken up with the aim of providing morphometric data for anatomists, anthropologists, forensic experts, and orthopedicians.

MATERIALS AND METHODS

Eighty dry adult human intact scapulae were obtained from four medical colleges in Bihar. Specimens that were malformed or showed signs of previous pathology in any part of the bone were excluded from this study. Sex of the bone was not considered. Bones were bilaterally equal in number. Morphometry of the glenoid fossa was performed using sliding Vernier callipers. Measurements of the glenoid fossa were taken along two different axes; vertical and horizontal. Vertical glenoid diameter (VGD) was taken along the maximum vertical length of the glenoid fossa between its superior and inferior borders. Horizontal glenoid diameter (HGD) was taken along the maximum horizontal breadth of the glenoid fossa around its midpoint between the anterior and posterior borders (Figures 1 and 2) .

Observation

The results are well explained in Tabular form. Table 1 gives information about Statistical analysis of bilateral VGD and HG. Along with that Table 2 depicts the Comparison of VGD with other workers and Table 3 provides information about the Comparison of HGD with other workers

DISCUSSION

Anterior dislocation of the shoulder joint is perhaps the commonest of dislocations in the human body and is more common in adults than in children. It results due to a direct force pushing the head of the humerus out of the glenoid cavity and thereby injuring the latter consequently. Scapular fractures may be related to any of the following: Body, neck, processes, articular fractures, and fractures involving the associated clavicle. Fractures involving the glenoid rim may be treated operatively to restore the joint surface and to avoid long-term instability of the glenohumeral articulation. Shoulder arthritis presents a unique challenge to the orthopedic surgeon as there may be stripping of the glenoidal labrum from the glenoid fossa. Due to the complex anatomy of the concerned region it is relevant to understand the dimensions of the screw and implants to be utilized as they must have access to the posterior cortex in the neck region of the scapula. Total shoulder replacement has often yielded poor results due to eccentric loading of the glenoid leading to loosening and early failure. Multiple procedures have been recommended to solve this problem including total arthroplasty, hemiarthroplasty and

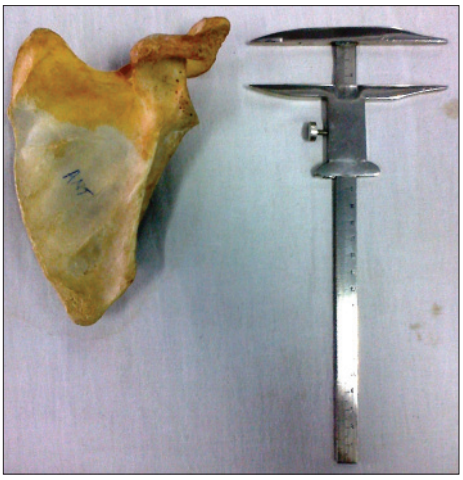

Figure 1: Scapula and sliding Vernier Calliper with 1 mm accuracy

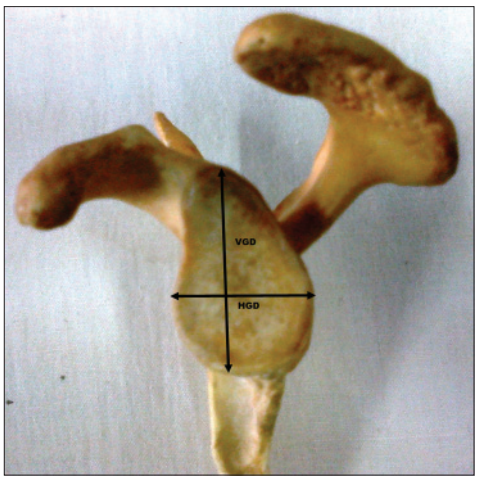

Figure 2: Measurements of the glenoid fossa in two axes. VGD: Vertical glenoid diameter, HGD: Horizontal glenoid diameter

Table 1: Statistical analysis of bilateral VGD and HGD

S. no.	VGD				HGD			
1	R	Mean=3.62 cm	L	Mean=3.32 cm	R	Mean=2.42 cm	L	Mean=2.25 cm
2	R	Range=3.5-3.9	L	Range=3.1-3.6	R	Range=2.3-2.6	L	Range=2.1-2.5
3	R	SD=0.17	L	SD=0.18	R	SD=0.13	L	SD=0.14

R: Right, L: Left, SD: Standard deviation, VGD: Vertical glenoid diameter, HGD: Horizontal glenoid diameter

Table 2: Comparison of VGD with other workers

Authors	Race	Mean (cm)	SD
Coskum	Turkish	3.36	0.4
Piyawinijwong	Thai	3.36	0.31
Von Schroeder	Canadian	3.6	0.4

SD: Standard deviation, VGD: Vertical glenoid diameter

Table 3: Comparison of HGD with other workers

Authors	Race	Mean (cm)	SD
Coskum	Turkish	2.4	0.25
Piyawinijwong	Thai	2.7	0.31
Von Schroeder	Canadian	2.9	0.3

SD: Standard deviation, HGD: Horizontal glenoid diameter

shoulder arthrodesis. For treating the displaced fractures of the glenoid fossa, most authors have recommended open reduction and internal fixation to restore joint congruity and to prevent post-operative arthrosis. The current standard of treatment in shoulder arthritis offers limited goal for functional improvement and only a modest improvement in pain. Glenoid reconstructions using implants may be considered. Morphometric parameters of the glenoid fossa in our study were recorded and statistically analyzed. On the right side, mean VGD and mean HGD were 3.62 and 3.42, respectively. On the left side, mean VGD and mean HGD were 3.32 and 2.25, respectively. Our data obtained is in accordance with the research of previous workers.[3-10] As there are variations in scapular morphology, individualized adjustments may be required for reverse shoulder prostheses.

CONCLUSION

Anatomical knowledge of variations in the glenoid fossa is a pre-requisite for successful management of shoulder surgery. Dimensions of glenoid fossa exhibit racial variations hence are important parameters for selecting appropriate shoulder implants. Scapular measurements can be used for comparative anatomy and manufacturing of prosthetic products. Further, this study may also be helpful for orthopedic surgeons during surgical interventions on the shoulder and for biomechanical engineers during designing of implants for reverse total shoulder replacement surgery.

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Original Article

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Biliary Tract Obstructive Diseases: A Comparative Evaluation by Ultrasonography and Magnetic Resonance Cholangiopancreatography (Magnetic Resonance Imaging)

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Abstract

Background: Biliary disorders are one of the common problems routinely seen in clinical practice. Hence, the study was carried out to compare two non-invasive, non-radiating modalities (ultrasonography [USG] and magnetic resonance cholangiopancreatography [MRCP]) for the evaluation of biliary duct system and to compare the diagnostic accuracy between USG and MRCP in the patients suspected of obstructive biliary tract pathology.

Materials and Methods: Patients suspected of biliary pathology were examined first by real time USG with convex (3-5 MHz) transducer, then MRCP with 1.5 Tesla magnetic resonance imaging.

Result: Of 50 patients majority of the case were found 51-60 year age groups. Among 60% were female, and 40% were male. Predominant symptoms in the study group were jaundice in 46 patients (92%). Overall malignant obstruction was more common then benign (68% vs. 32%). USG was found sensitive in 81.2% and specific in 100% cases while MRCP was sensitive in 93.7% and specific in 97% in benign lesion as a cause of obstruction while among malignant lesion as a cause of obstruction USG was found 94.1% sensitive and 68.7% specific and MRCP was 97% sensitive and 93.7% specific. On USG, intra-hepatic biliary radicals were found to be dilated in all except one patient i.e. 98% while it was 100% on MRCP. Overall 10 cases were falsely diagnosed by USG while only 2 cases were falsely diagnosed by MRCP among all 50 cases.

Conclusion: USG is considered the first choice option in the diagnostic imaging of obstructive biliary disease. However, owing to its low sensitivity in most of the benign stenosis and distal common bile duct disease, where the clinical and laboratory suspicion is strong and unsupported by ultrasound and/or in the presence of conditions affecting ultrasound performance, and for a thorough staging evaluation of malignancy, MRCP is highly accurate and superior diagnostic modality in establishing diagnosis of obstructive biliary pathologies.

Key words: Biliary obstruction, Magnetic resonance cholangiopancreatography, Ultrasound

INTRODUCTION

Biliary disorders are one of the common problems routinely seen in clinical practice. These include cholelithiasis, choledocholithiasis, malignancy, strictures, etc. Ultrasonography (USG) is actually a routine examination in daily practice, and it is the first line imaging modality of choice in many clinical presentations as well as asymptomatic patients, as a screening tool.[1] It is an accurate, safe, non-invasive, repeatable imaging modality, which is highly sensitive and specific for the detection of many biliary tract diseases.[2] Magnetic resonance cholangiopancreatography (MRCP)[3] is a new non-invasive and safe modality for imaging the biliary tree and investigating biliary obstruction. MRCP refers to selective

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fluid-sensitive magnetic resonance imaging (MRI) of the biliary ducts that show fluid in the biliary and pancreatic ducts. MRCP evaluate the biliary ductal system without the use of ionizing radiation that produces both high-quality cross-sectional images of ductal structures and projection images of biliary tree that are similar in appearance to those obtained by invasive radiographic methods, such as endoscopic retrograde cholangiopancreatography (ERCP).[4] MRCP has proved effective in demonstration bile duct dilatation, strictures, and choledocholithiasis.

Sometimes specific diagnosis by USG is not possible and in such condition alternative imaging may be useful to assess the extent and character of the disease process. When the site or cause of biliary obstruction is not apparent, as in cholangiocarcinoma or distal common duct obstruction, further evaluation with MRI with MRCP is indicated.

So, the study was carried out to compare two non-invasive, non-radiating modalities (USG and MRCP) for the evaluation of biliary duct system and to compare the diagnostic accuracy between USG and MRCP in the patients suspected of obstructive biliary tract pathology.

MATERIALS AND METHODS

This prospective study was conducted on 50 patients, who were referred to the Radiology Department of NSCB Medical College Hospital, Jabalpur from September 2012 to October 2013. All patients of any age, sex, and profession who had undergone USG and MRCP with strong clinical suspicion of biliary obstruction and altered liver function test were taken as study subjects. All patients with medical jaundice and cirrhosis of the liver were excluded. Permission from the Ethical Institute Committee was obtained prior to the study and informed consent of study subjects was taken before undergoing screening for USG, and subsequent MRCP was done.

It was recommended that a patient undergo a period of fasting (at least 6-8 h) prior to upper abdominal imaging of the biliary tree.[5]

Patients suspected of biliary pathology were examined first by real time ultrasonographic (GE-LOGIQ 3 Expert and Siemens-Sonoline 50 MCMD 01AA) with convex, high frequency (3-5 MHz) transducer. We used transverse, sagittal or slightly oblique right sub-costal scan with the patients placed on the left side in a 45° inclined position The liver, gall bladder, pancreas, intra-hepatic and extra-hepatic bile ducts were evaluated to look for the abnormality of intra and extra-hepatic biliary channels, the common bile duct (CBD), level and possible cause of obstruction. In most cases THI was applied, mainly for better visualization of the CBD subsequently followed by MRCP with MRI (GE-HDx Signa 1.5 Tesla [T]).

For all MRCP with MRI patients: 1.5 T GE Signa HDx MRI machine was used for the study. All patients were imaged with a body phased-array receives coil. Slice thickness was 1 cm with a 37" field of view and 256 × 192 matrix were taken from right dome of diaphragm to lower edge of liver following are sequence used after the localizer: T2SSFSE-axial/coronal, axial T2FRFSE, 2D FIESTA axial/coronal, coronal 3D FSE (respirated trigged), Additional; T1-axial/coronal and 3D reconstruction was performed by MIP post-processing. Mean performances time was 20-25 min. Patients with a metallic implant, cardiac pacemaker and claustrophobia were excluded from the study. Findings of USG and MRCP were compared. Radiological diagnosis was confirmed by post-operative findings/biopsy/histopathology.

RESULTS

A total of 50 patients satisfying the inclusion criteria were included in the study. A descriptive comparative analysis of imaging findings in each modality was compared, and results were derived. Majority of cases were found in 51-60 years age group (28%) and age group range was 1-90 years and incidence of biliary tract obstructive disease was more in female (60% cases) as compared to male (40%). Predominant symptoms in the study group were jaundice in 46 patients (92%) and pain abdomen in 40 patients (80%).

In our study group tumors comprised the largest group of cases 34 (68%) followed by choledocholithiasis 9 (18%) cases and benign biliary stricture 4 (8%) cases (Table 1).

On USG, intra-hepatic biliary radicles (IHBR) were found to be dilated in all except one patient i.e. 98% while it was 100% on MRCP (Table 2). Excessive bowel gasses hindered evaluation of the hepatobiliary system in one patient.

Common hepatic duct and proximal CBD was dilated on USG in 92% cases and in MRCP 100% cases. On USG and MRCP distal CBD was found to be dilated in 50% and 84% cases respectively (Table 3).

In our study, most common level of obstruction detected by both modalities was Hilar and intra-hepatic CBD. The level of obstruction was diagnosed accurately both by MRCP and USG.

Of a total of 16 benign cases, 13 cases were detected by USG and 16 cases were detected by MRCP while, among total 34 malignant cases, USG detected 37 cases and MRCP detected 34.

The most common benign cause of obstructive jaundice was choledocholithiasis (9) followed by benign biliary stricture in 4 cases, and choledochal cysts were 3 cases.

USG missed 1 case of benign biliary strictures, and 2 cases of distal CBD stone, while MRCP missed 1 case of distal CBD stone and falsely detected 1 case of benign biliary stricture.

The most common malignant cause of obstructive jaundice was cholangiocarcinoma (14) in which hilar cholangiocarcinoma was common, followed by infiltrating GB carcinoma in 10/50 cases, and pancreatic carcinoma in 7/50 cases. In our study, USG missed 1 case of pancreatic head mass and 1 case of periampullary carcinoma.

5 cases of distal CBD mass were falsely detected on ultrasound, with a diagnostic accuracy of USG (90%) as compared to 98% in MRCP. MRCP missed 1 cases of periampullary carcinoma and falsely detected 1 case of cholangiocarcinoma.

In our study on USG 2 case of distal CBD stone were falsely reported as distal CBD mass because evaluation of distal CBD was not possible due to overlying bowel gases, while MRCP falsely reported 1 case of distal CBD stone as distal CBD mass.

USG was found sensitive in 81.2% and specific in 100% cases while MRCP was sensitive in 93.7% and specific in 97% in benign lesion as a cause of obstruction while among malignant lesion as a cause of obstruction USG was found 94.1% sensitive and 68.7% specific and MRCP was 97% sensitive and 93.7% specific.

Overall 10 cases were falsely diagnosed by USG while only 2 cases were falsely diagnosed by MRCP among all 50 cases.

Table 1: Distribution of cases according to final diagnosis and their comparative evaluation of USG and MRCP

Sl. no.	Cause of obstruction	Final diagnosis (histopath/ surgical) (%)	USG (%)	MRCP (%)
1.	Choledocholithiais	9 (18)	7 (77.7)	8 (88.8)
2.	Benign billiary stricture	4 (8)	3 (75)	5 (125)
3.	Choledochal cyst	3 (6)	3 (100)	3 (100)
4.	Infiltrating GB mass	10 (20)	10 (100)	10 (100)
5.	Periampullary carcinoma	3 (6)	2 (66.6)	2 (66.6)
6.	Cholangiocarcinoma	14 (28)	19 (135.7)	15 (107.1)
7.	Pancreatic head of carcinoma	7 (14)	6 (85.7)	7 (100)
	Total	50	50	50

GB: Gall bladder, USG: Ultrasonography, MRCP: Magnetic resonance cholangiopancreaticography

Table 2: Distribution of cases on the basis of level of dilatation and obstruction of biliary tree

S. no.	Biliary tree dilatation	USG	MRCP	Level of biliary obstruction	USG	MRCP
1	IHBR	49	50	Hilar and intra-hepatic	25	25
2	Common hepatic duct	46	50	Supra-pancreatic	12	12
3	Proximal CBD	46	50	Intra-pancreatic	13	13
4	Distal CBD	25	42	-	-	-

IHBR: Intra-hepatic biliary radicals, USG: Ultrasonography, MRCP: Magnetic resonance cholangiopancreaticography, CBD: Common bile duct

DISCUSSION

Obstructive jaundice can be caused by the obstruction of the bile duct with gall stones, strictures, malignancy, etc. Obstructive jaundice is common amongst females and choledocholithiasis are the commonest benign cause.[6] In our study, IHBR were visualized in 100% cases on MRCP as compared to sonography (98%). Dilatation of the IHBR found in all 50 cases by MRCP as compared to 49 cases on sonography and there was a declining trend observed in the ability of sonography to visualize the biliary tree as we moved distally (Table 2). Visualization of the proximal ducts was possible in 91.6% cases and dropped to 63.3% for distal CBD. Decreasing the diagnostic performance of sonography was because of difficulty in visualizing

Table 3: Diagnostic performance of USG for different causes of obstructive jaundice

Cause of obstruction	Diagnostic performance of USG (%)				Diagnostic performance of MRCP (%)			
Cause of obstruction	Sensitivity	Specificity	PPV	Accuracy	Sensitivity	Specificity	PPV	Accuracy
CBD stone	77.7	100	100	96	88.8	100	100	98
Benign stricture	75	100	100	98	100	97.8	80	98
Choledochal cyst	100	100	100	100	100	100	100	100
Proximal CBD mass	100	100	100	100	100	100	100	100
Distal CBD mass	100	88.6	54.5	90	100	97.7	85.7	98
Infiltrating GB mass	100	100	100	100	100	100	100	100
Pancreatic head mass	85.7	100	100	98	100	100	100	100
Periampullary Ca	66.6	100	100	98	66.6	100	100	98
Benign lesion	81.2	100	100	94	93.7	97	93.7	96
Malignant mass	94.1	68.7	86.4	86	97	93.7	97	96

USG: Ultrasonography, MRCP: Magnetic resonance cholangiopancreaticography, CBD: Common bile duct, GB: Gall bladder

the distal CBD and the pancreatic region mainly due to interference by bowel gasses. Similar observations were also made by Vicary *et al.*[7] who opined that limitation in the sonographic evaluation of the distal biliary tree and pancreas was due to bowel gasses besides the operator's experience. MRCP was better in showing the distal biliary tree. The distal CBD was visualized in 42/50 patients (84%) as against 40/50 (80%) patients by sonography. In eight cases, non-visualization of the distal CBD on MRCP was caused by complete cut-off at the level of hilum due to malignant masses. Both ultrasound and MRCP seem to have sensitivity and specificity of nearly 100% for detecting the presence of a biliary obstruction. Regan *et al.*[8] in their prospective study on MRCP demonstrated biliary dilatation in 100% cases. A recent meta-analysis of 67 published controlled trials by Romagnuolo *et al.*[9] have shown both sensitivity of 95% and specificity of 95% for detecting the presence of a biliary obstruction. According to our study most common site of obstruction was hilar and intra-hepatic (50%) was comparable to Kumar *et al.*[10] who found a variable range of accuracy ranging from 27% to 95% for detecting the level of obstruction by ultrasound. The extent of the lesion could be determined in 100% of patients by MRCP as compared to only 66% by sonography. When considering only mass lesions, an extent of biliary involvement could be completely assessed in 10 cases by sonography while it was detected in all 34 cases by MRCP.

MRCP showed good accuracy and an optimal capability of evaluating tumor extent as reported by Manfredi, who analyzed only hilar malignant stenosis of the biliary structures, reported an accuracy of 89% in the assessment of their extent.[11] Our finding is also in concurrence with the study conducted by Soto *et al.*[12] who suggested that in case of mass lesions, when MRCP is combined with MRI, a complete staging information can be obtained about the tumor size, bile duct involvement, and vascular invasion. Hall-Craggs *et al.*[13] in a prospective study comparing MRCP with conventional cholangiography found that MRCP predominantly demonstrates dilated ducts proximal to the stricture and does not distend the stricture itself. It was found that the stricture itself was not visualized, and it was not possible to assess the length and extent of the stricture.

Cholangiocarcinoma comprised maximum number of cases, (n = 14 [28%]) in our study (Table 1) with hilar and proximal CBD (n = 8) and distal CBD cholangiocarcinoma (n = 6) forming a majority of these masses. The second most common cause of obstruction was Infiltrative G.B mass 10/50 (20%) cases. In our study, choledocholithiasis comprised third common cause (n = 9 [18%]) of obstruction. In our study, ultrasound was found to have sensitivity 81.2%, specificity 100%, and diagnostic accuracy of 94% for benign and 86% for malignant lesion for detecting the cause of obstruction while MRCP correctly detected cause of obstruction in all 100% cases with sensitivity: 93.7%, specificity: 97%, positive predictive value (PPV): 93.7% and the diagnostic accuracy of 96%. Upadhyaya *et al.*[14] in a prospective study of comparative assessment of imaging modalities in biliary diseases found that MRCP had the accuracy of 87.5% for assessing the cause. Vaishali *et al.*[15] found the overall diagnostic accuracy of 89.65% for detection of the cause of obstruction. Aube *et al.*[16] found sensitivity of 90.5% and specificity of 87.5% of MRCP in etiological diagnosis. In our study, MRCP showed more promising results than ultrasound in assessing the nature of disease i.e. benign or malignant. Our results are comparable to Ghimire *et al.*[17] who found sensitivity: 67%, specificity: 91%, PPV: 71%, and negative predictive value (NPV): 73%, for ultrasound in the detection of benign lesions.

Romagnuolo *et al.*[9] has found MRCP to be less reliable (88%) for the differentiation between benign and malignant obstruction. In our study, the most common benign cause of biliary obstruction was choledocholithiasis comprising 9/50 cases (Table 1).

In our study, ultrasound was found to have sensitivity: 77.7%, specificity: 100%, PPV: 100% and diagnostic accuracy of 96% for choledocholithiasis while MRCP correctly detected 8/9 cases of choledocholithiasis with sensitivity: 88.8%, specificity: 100%, PPV: 100% and the diagnostic accuracy of 98%. Ferrari *et al.* in their study showed the diagnostic accuracy of 80.15%, with a sensitivity of 71.08% and a specificity of 95.83% that were in concordance with our study. Ferrari *et al.*[18] have found that MRCP has a diagnostic accuracy of 93.89%, sensitivity of 93.97% and specificity of 93.75% in the diagnosis of choledocholithiasis. Two false negative cases on USG were due to hindering of distal CBD evaluation by bowel gas shadow and obese body habitus. Pasanen *et al.*[19] found that the sensitivity of ultrasound for choledocholithiasis varies widely from 20% to 80% with a high specificity of approximately 98%.

Other authors like Mendler *et al.*[20] have also found decreasing sensitivity of MRCP in detecting stones according to the stone size: 67-100% for stones >10 mm size, 89-94% for stones measuring 6-10 mm, and 33-71% for bile duct stones <6 mm in size).

In our study for stricture ultrasound detected 3 out of 4 cases of post-operative stricture with diagnostic accuracy: 98% sensitivity: 75% and specificity: 100% while MRCP detected 5/4 cases of biliary strictures with sensitivity, specificity and diagnostic accuracy of 100%, 97.8%, and 98%, respectively. In contrast to our study, Pandit *et al.*[21]

in their study found accuracy of ultrasound in detection of benign stricture was 31% but results are comparable to a study done by Lomas *et al.*[22] who compared MRCP and ERCP in 78 patients with obstruction and reported a sensitivity and specificity of 86.4% and 82.4% respectively for benign stenosis. The high specificity was attributable to the capability of USG to detect true negatives in benign stenosis, thus showing the cause of the obstruction by calculi or malignant stenosis. The low sensitivity figures are to be related to intrinsic limitations of the methodology, which, though showing the indirect signs of stenosis, did not allow optimal visualization of the distal CBD and the ampullary region, which is where benign stenosis are often localized. Both USG and MRCP detected all the three cases of the choledocal cyst and gave information of involvement confidently similar findings were discussed by Kim *et al.*[23] in their study.

CONCLUSION

USG is considered the first choice option in the diagnostic imaging of obstructive biliary disease. However, owing to its low sensitivity in most of the benign stenosis and distal CBD disease, where the clinical and laboratory suspicion is strong and unsupported by ultrasound and/or in the presence of conditions affecting ultrasound performance, and for a thorough staging evaluation of malignancy, MRCP is highly accurate and superior diagnostic modality in establishing diagnosis of obstructive biliary pathologies. MRCP is more sensitive and more likely to detect choledocholithiasis, CBD strictures and malignant pathologies as compared to USG. Sensitivity, specificity and accuracy of MRCP for choledochal cyst are same as in USG. However, the potential applications of MRCP in the detection of obstructive biliary pathologies are limited by the expanse and availability of technology due to its high cost and lack of expertise available in operating the machine.

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Review Article

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Community Water Fluoridation: Revisiting a Cost-Effective Measure

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Abstract

Community water fluoridation (CWF) is one of the options for the prevention of dental caries. The equitable nature of this measure is a proven strength. As this measure, presently requires implementation in the low-income countries due to the increase in the incidence of dental caries, an overview of the economic aspects becomes a mandate. Thus, this review addresses the cost-effectiveness of this measure on the global scale, as capital costs and operating costs are different for each country depending on the availability of water and fluoride resources. The feasibility of fluoridation of drinking water, the availability of central water supply, and the population served will determine the cost-effectiveness of this measure for each country.

Key words: Community water fluoridation, Cost-effectiveness analysis, Equitable, Prevention

INTRODUCTION

Prevention is the solution for controlling health care costs and improving national health.[1] In preventive dentistry, fluoride is a benchmark in caries reduction. The history of water fluoridation is a classic example of clinical observation leading to community-based public health intervention.[2] Water fluoridation, has been a major contributor to the documented decline in dental caries in the 1950s-1980s, with the fluoridated dentifrice.[3] Although, average annual expenditure on fluoride toothpaste is related not only to the price of toothpaste per region but also to the number of people using toothpaste and the amount used per person per year.[4] A study concluded that fluoride toothpaste is prohibitively expensive for the world's poorest people in developing nations.[5] Significant health inequalities can result due to the issues of affordability of this essential preventive care product and thus, indicates the need for community water fluoridation (CWF) that facilitates more uniformly distribution of fluoride.

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The behavior of fluoride ions in the human organism is a classic example of the double-edged sword since it acts as a preventive factor for caries and a causative factor for fluorosis above a threshold concentration.[6] However, with routine monitoring, this "mass medication" of CWF is the most equitable option for the low-income countries, regardless of age, educational attainment, or income level.[7]

STATUS OF CWF IN THE VARIOUS COUNTRIES

Populations in many developing countries do not have access to fluorides for the prevention of dental caries for practical or economic reasons.[8] About 210 million people benefit from fluoridated water across the globe. Water fluoridation has been supported by World Health Organization (WHO), which recommends water fluoridation wherever, it is politically and technically feasible. Where water fluoridation is not possible, WHO recommends salt fluoridation as a next best option. Currently, some 40 countries have artificial water fluoridation schemes in existence.[9]

In Vietnam, water fluoridation at a concentration of 0.7 mg Fluoride/Liter (F/L) has been available in Ho Chi Minh City since 1990. A step-by-step approach was used for implementing this measure, and fluoridation has resulted in a decrease of dental caries in children, but 70% of the rural population does not benefit from the water fluoridation program.

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In Brunei (high-income country), water fluoridation at a concentration of 0.5-0.7 mg F/L was implemented in 1987; currently, approximately 95% of the population receives benefits of water fluoridation. Toothpaste containing fluoride is also available in the country; also fluoride varnishes are applied to children within the school setting.

A survey indicated that 83% of children in Singapore used toothpaste containing fluoride. Thus, Ministry of Health decided to lower the concentration of fluoride in water from 0.7 to 0.6 mg F/L in 1992 and further to 0.5 mg F/L in 2008. Other vehicles of fluoride are also available to the population of Singapore. A multi-disciplinary committee was established in the country, and its responsibilities were to generate recommendations, through the review of literature for the Ministry of Health as the island has one central water supply for the whole population. Effectiveness in dental caries reduction and enamel fluorosis status is assessed every 10 years through an oral health survey. In Hong Kong, the treatment of public water supply for total population consists of chemical coagulation, sedimentation, filtration, pH correction, chlorination, and fluoridation. The water fluoridation experience has been similar to that of Singapore. CWF is not currently adopted in Italy because in some areas throughout the country, water naturally contains fluoride, reaching the optimal levels for caries prevention. Furthermore, the expansion of the use of bottled water, with a wide range of fluoride concentration, is the major source of drinking water in this country.[10] Nepal has not implemented any automatic fluoridation systems, but with the multiple sources of water supplies and the inability to utilize a central supply system, this method is not feasible at this time. Besides, CWF requires an epidemiological surveillance, with regard to the distribution network and monitoring of water at the processing plant and at the consumer end to ensure that the correct amount of fluoride is being delivered to the user. Government-subsidized community fluoride prevention programs may face privatization in some countries, and careful management of the situation should be considered. In countries, where water fluoridation is limited and is not feasible to implement, salt or milk fluoridation can be considered.[11]

COST-EFFECTIVENESS

The average annual cost of water fluoridation in the United States was calculated in 1989 workshop as $0.51 per person (range: $0.12-$5.41). In 1999, this cost would be $0.72 per person (range: $0.17-$7.62).

Following estimates are required for conducting a cost-effectiveness analysis of CWF:

Capital Costs

Fluoridation schemes require capital expenditure to:

- Establish a plant and equipment
- Consultant engineering fees
- To replace and upgrade those facilities when necessary.

Operating Costs

Annual running costs:

- Fluoride materials
- Labor
- Maintenance.

Cost-effectiveness takes account of the outcomes in terms of the health units gained. This analysis can give, a cost to effect ratio for a particular intervention, incremental cost-effectiveness to compare different scenarios for the same intervention, and can further lead to a cost-benefit analysis where a monetary value can be assigned to each health outcome, although it is difficult. The study of the effect unit for CWF is in terms of number of teeth prevented from decay, the number of individuals prevented from decay, or as treatment cost that could be avoided.

Factors reported to influence the per capita cost include:

- Size of the community (the larger the population reached, the lower the per capita cost)
- The level of tooth decay in population
- Age and treatment of the water treatment works
- Number of fluoride injection points in the water supply system
- Amount and type of system feeder and monitoring equipment used
- Amount and type of fluoride chemical used, its price, and its cost of transportation and storage; and
- Expertise of personnel at the water plant.

In 1998, York Health Economics Consortium study concluded that calculating capital and revenue costs for water fluoridation for a population is simple. However, one needs to discount the costs to determine equivalent annual costs of installations life. Discounting of costs is done for the monetary values of the health outcomes. The expected reduction in the tooth decay will help one to estimate the cost-effectiveness of CWF. Population projections and knowledge of underlying status will make it possible to predict decay, restorations, and the extractions of the teeth prevented within 14 years of installation of the system for those born after fluoridation. As the outcome measures the health of the population, more is the population, more will be a denominator and better (lower quantity) will be the cost-effectiveness ratio[12] (Table 1).

Reduction on an average by 25% in tooth decay in children, i.e., 6 years and over and adults up to 65-years-old were

reported in an economic evaluation. They also calculated for a "worst case" scenario based on only a 12% reduction and best case scenario based on 29% average reduction. The costs in this study included the capital and operating costs. The American Dental Association reported the price of $54 for the filling of the single decayed tooth surface by 1995. Including the costs of loss of wages, i.e., an indirect cost; the total cost averted per tooth was calculated to be $72. Using the above-mentioned costs, the three scenarios were estimated (Table 2).

The US researchers concluded a larger population size and the higher incidence of tooth decay existing made this intervention more cost-effective. However, the halo effect of the intervention, i.e., processed and canned foods and drinks, provides a preventive effect for an extra population that cannot be estimated directly. Thus, these economic models are not efficient to include the total health outcome after implementing water fluoridation.[13]

Economic evaluation also forecasts the costs and benefits of CWF as done in Southampton and parts of neighboring Hampshire, as it prepared, to implement CWF in 2008 for 1,95,000 people. The analysis assumed that up to and including the age of 17, fluoridation would reduce the decay by an average of 25%. The analysis included the primary and permanent dentition, but the adults were excluded. They developed an economic model, computed the capital costs, and anticipated 20-year life span of plant and equipment. This figure was estimated to be £1.49 million, and it would further reduce the dental treatment costs of £1.48 million. They based on the analysis of an instance that 36,032 instances of tooth decay were prevented as a direct result of fluoridation. The difference £10,000 was then divided by 36,032 to produce a cost per instance of tooth decay avoided of £0.32. This report identified that a reduction of less than 25% would reduce the cost-effectiveness. The study stated the limitation that the exclusion of adults from the model leads to underestimation of the CWF. It was concluded that decision making for implementing CWF, this economic picture should be considered as "cost neutral."[14]

Another study took into account a rare health outcome, which included a number of extractions avoided under general anesthesia with respect to the effects of CWF. Tooth decay being a common problem in North West of England and each year in Manchester Dental Hospital, 1500 general anesthetics are required for extraction. The cost per case is £160 with a total annual cost of £2,40,000. Fluoridation can reduce these cases to 500-1000/year, i.e., a reduction of 35% and 67% of the cases in Manchester. The cash savings account to £84,000-£1,60,000 per annum. This study included an "opportunity cost" of considerable resources being tied up in hospital's general anesthetic sessions for dental extractions

Table 1: Published estimates of population coverage in countries

Country	Income group (World Bank 2012)	Percentage of population covered by CWF (%)
USA	Higher income countries	64
Canada		43
(Quebec < 3%)		
Republic of Ireland		73
Australia		61
New Zealand		61
Israel		75
United Kingdom		10
Singapore		100
Chile		40
Spain		10
Hong Kong		100
Panama	Upper middle-income countries	18
Malaysia		70
Brazil		41
Argentina		41
Columbia		80

CWF: Community water fluoridation

Table 2: Three scenario estimated for cost-effective measures

Decay reduction Scenario	Population < 5000 (annual cost saving per person)	Population > 20,000 (annual cost saving per person)
12% (worst scenario)	$0.85	$3.52
25% (scenario epidemiological evidence)	$15.95	$18.62
29% (best scenario)	$31.04	$33.71

rather than being available for the treatment of conditions other than tooth decay. This technical resource once freed from the burden of extractions can further be used to reduce waiting lists and delays for the other treatments. North-West region of England was compared with fluoridated West Midlands revealed significant differences amongst the patterns of expenditure on general anesthetic sessions for dental extractions. Similar results were shown by an analysis that stated 27 times greater costs are spent over tooth decay in Liverpool Primary Care Trust (non-fluoridated) as compared to Birmingham Primary Care Trust (fluoridated).[15]

A Scottish study conducted in 1980 reported that CWF resulted in a 49% saving in dental treatment costs for children aged 4-5 years and a 54% saving for children aged 11-12 years. The savings maintained even after the secular decline in the prevalence of dental caries were recognized.[16]

In Africa, a model was developed to determine the economic viability to reduce dental caries in South Africa. The model confirmed that water fluoridation is an economically viable option to prevent dental caries in South African communities even when the caries preventive effectiveness is modest.[17] Even in an era with widespread availability of fluoride from other sources, studies prove water fluoridation continues to be effective in reducing dental decay by 20-40%.[18]

A systematic review of published studies conducted in 2001 by a team of experts on behalf of the U.S. Task Force on Community Preventive Services found that fluoridation was effective in reducing tooth decay among populations. Based on the strong evidence of effectiveness, the Task Force strongly recommends that CWF should be included as a part of a comprehensive population-based strategy to prevent or control tooth decay in communities. Many authors conclude that there is strong evidence that CWF is effective in reducing the cumulative experience of dental caries within communities. On the other hand, some systematic reviews also concluded that caries preventive action should be considered along with increased prevalence of dental fluorosis. However, there was no clear evidence of the other side effects.[19]

Fluoridated water reduces the occurrence of cavities in the population by 20-40%. For some people who are more vulnerable to cavities, including the underprivileged, the elderly, and children with poor eating habits and oral hygiene, it can reduce cavities by up to 64%. Treating cavities is extremely costly. A 20-40% reduction in cavities would save a Québec family of four $320 a year on oral care. Also, being economical for everyone, water fluoridation is beneficial for society as a whole. It lightens the burden on the public health system and private insurers. It also leads to increased productivity and quality of life across society as the need for dental visits and care is reduced. 62% of Québecers supported water fluoridation in a 2010 survey.[20]

Systematic reviews from 2000 to 2007 have confirmed that fluoridation does, indeed, reduce both the severity and prevalence of tooth decay. Tooth decay can be costly to the individual and the public, not only through health insurance premiums, health departments, and community health clinics but also through indirect costs.[21]

A 2004 Canadian study concluded that every dollar invested in water fluoridation saves approximately $38 in dental treatment costs. Results from a Quebec study showed the cost-effectiveness of water fluoridation even with the conservative estimation of a 1% decrease in cavities. According to the United States Centers for disease control and prevention the costs of restorative care to avert disease outweighed the cost of water fluoridation in towns of any size, even with the widespread availability of many forms of fluoride today. Under typical conditions, the annual per person cost savings in fluoridated communities is $16 in communities of under 5,000 people and $19 in communities over 20,000. In Toronto, water fluoridation costs $0.77 annually per person while, in Peterborough, costs are $0.63. The lifetime cost of water fluoridation for one person is less than the cost of one dental filling. A cost analysis by Public Health Services in Hamilton, Ontario, found that water fluoridation reduces the costs for existing dental programs run by the city. The public health team compared four potential methods to deliver fluoride to the city's populations at high risk of oral problems, including children, seniors, and those with low income.[22]

As 69% of Australian population were receiving fluoridated water at the recommended minimum concentration of 0.7 mg/L, the study estimated that extending public water fluoridation to all Australian communities with a population of at least 1,000 people will equate to an Australian coverage of 89%. They evaluated population health impacts and cost-effectiveness of this coverage, compared to the baseline coverage of 69% in 2003. Further, they evaluated population health impacts and cost-effectiveness of extending fluoridation to all communities in Australia, regardless of population size (i.e., 100% coverage of the Australian population). Costs of public water fluoridation include the capital costs of dosing equipment and associated engineering, and the on-going operational costs of chemicals and equipment maintenance. All the three types sodium fluoride, hydrofluosilicic acid or sodium silicofluoride are used in Australia. Costs were separately computed for urban and rural Australia owing to the additional complexities of providing fluoridated water in smaller communities, such as the distance of delivering fluoridated water, hot climate, and retention of trained personnel. Cost for urban areas was A$0.26 per person based on the installation done in

Melbourne and in a trial installation in two remote Australian indigenous communities annual cost of water fluoridation was A$26 per person. Health outcomes were the disability adjusted life years and with the help of Monte Carlo simulation model probability of cost-effectiveness against a threshold of A$50,000 per DALY was calculated. The study concluded 100% probability of extending the coverage of public water supply fluoridation to all communities of 1,000 people will be cost saving to the health sector. 60% more DALYs could be avoided if CWF is extended to all communities in Australia, but the intervention has only a 10% probability of being below the cost-effectiveness threshold of A$50,000 per DALY. The addition of costs of X-ray in the treatment of dental caries adds little to the cost-effectiveness. However, if reduction in caries is demonstrated to be similar to children in adults, then the cost-saving due to fluoridation extended to all communities in Australia, regardless of community size.[23]

Drawbacks of Cost-effectiveness Analysis for CWF

Health outcomes of those born after CWF were included in studies, but there could also be a significant improvement in the health outcome in those born before it, as it might decrease decay in permanent teeth in young children and root surface decay in adults. The diffusion effect is mostly difficult to account for and has not been considered in the economic models. Moreover, none of the models have been including the intangible costs; hours lost from school and the cost of waiting period, for tooth extraction under general anesthesia. Many studies have not accounted for the indirect costs of the loss of wages by the parents when attending to dental needs of their children. These factors lead to an underestimation of the benefits conferred by the CWF.

CONCLUSION

In the scenarios where fluoride can change the chapter of oral health, a political will should be inculcated in developing countries for CWF. Significant disease risk and large population size add to the cost-effectiveness of the intervention. Therefore, larger is the population; more cost-effective is the fluoridation of drinking water. Thus, developing countries need to prioritize the interventions for preventing dental caries according to their affordability, the cost-effectiveness of the intervention, and the existing political will of the country. Availability and the population coverage of the communal water supplies should further guide the decision of adding fluoride to water.

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Review Article

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Implications of Prostate Specific Antigen and its Molecular Derivatives in the Management of Carcinoma Prostate

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Abstract

Carcinoma prostate is the second leading cause of cancer-related deaths in men. In clinical practice prostate, specific antigen (PSA) estimation has been the gold standard for determining the presence of prostate cancer (PCa). Its elevation may indicate the presence of prostate disease but not always prostatic carcinoma. Identification of disease-specific molecular derivatives is the rational approach to addressing the current clinical challenge of whom to biopsy, whom to offer interventional therapy, and to plan the therapeutic strategies. The normal serum level of PSA is between 1.0 and 4.0 ng/ml, in men. The measurable PSA found circulating in the blood exists in complexed (cPSA) or bound form and free form (fPSA). Development of new monoclonal antibodies specific for fPSA and cPSA has allowed more accurate measurement of different molecular forms of PSA and their ratio in serum. Food and drug administration (FDA) has approved the measurement of fPSA in the diagnostic gray zone of 4.0-10 ng/ml. It can also be used as a decision-making tool for repeat biopsy. Measuring the ratio of [-2] pro PSA to total PSA further improves the specificity since they are raised in PCas. Same is true for the ratio of intact to fPSA. Volume based parameters and PSA velocity are other parameters which further refines the decision-making exercise. The present study is a focused review of these parameters of PSA, their implications, limitations, and use in the management of carcinoma prostate.

Key words: Carcinoma, Prostate specific antigen, Prostatic cancer

INTRODUCTION

The carcinoma prostate is the second leading cause of cancer-related deaths in men. Consistent elevation of total prostate specific antigen (tPSA) in serum, as well as a marked decrease in apoptosis and tissue differentiation, are a key factor in the progression of prostate tumor to advanced disease. In clinical practice tPSA has been the gold standard for determining the presence and/or staging of prostate cancer (PCa). As varying amount of tPSA value are found in patients with normal prostate functioning, benign prostatic hyperplasia (BPH), and PCa. High serum tPSA levels are not diagnostic of the presence of prostatic cancer. There is no linear relationship between PSA and PCa stage and metastasis.

PSA is the most notable biomarker and is a member of Kallikrein family. It is also designated as hk3. It is an androgen-regulated protease.

Serum PSA becomes detectable at puberty, with an increase in luteinizing hormone and testosterone. PSA levels vary with age, race, and prostatic volume. Its elevation may indicate the presence of prostate disease, but not all men with the prostatic disease have elevated PSAs. Furthermore, PSA is an organ specific antigen and not cancer specific.

ThePCa prevention trial has concluded that there is no PSA concentration that rules out cancer. The controversy that surrounds the use of this marker is currently being

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debated, because it is unclear whether PSA screening has led to a decline in mortality due to prostatic cancer or it has lead to over diagnosis and over treatment of carcinoma prostate.

A recent large multi-institutional randomized trial looking at the relationship between PSA screening and PCa mortality published in the New England Journal of Medicine (NEJM) demonstrated that PSA-based screening reduced the rate of death from PCa by 20% but was also associated with a high risk of overdiagnosis.

This article discusses the implications of various molecular derivatives of PSA, relevant to carcinoma prostate (PCa) as a diagnostic tool.

CARCINOMA PROSTATE/THE CHALLENGES

PCa is the second leading cause of cancer-related death in men.[1] In the United States (US) approximately 240,000 men are diagnosed with PCa.[2] The prevalence of PCa increases with age. The chances of detecting PCa, in a 50-year-old man, are as high as 60%.[3] The vast majority of men diagnosed with clinically localized PCa are treated with interventional therapies despite studies demonstrating that even without treatment, PCa specific mortality, is low.[4,5] Early detection of PCa relies on the estimation of serum PSA, digital rectal examination (DRE) and ultrasonography.

Although the routine use of serum PSA testing has increased detection of PCa, it has also led to over diagnosis and over treatment, because of its lack of specificity, resulting in high negative biopsy rates.[6]

There is ever increasing need to find out an appropriate biomarker to address these challenges. The prostatic carcinoma is both biologically and clinically a heterogeneous disease that develops amid diverse genetic and epigenetic changes.[7,8] Identification of disease-specific molecular biomarker is a rational approach to addressing the current clinical challenge of whom to biopsy, whom to offer certain interventional therapy, and whom to alter therapeutic strategies.

The National Cancer Institute defines a biomarker as "a biological molecule found in blood, other body fluids or tissues that are a sign of normal or abnormal process or of a condition or disease." A biomarker may be objectively measured and evaluated as an indication of normal biologic processes, pathological processes, or pharmacologic response to a particular treatment or condition.[9-11]

PSA, THE HISTORY

It was first identified and purified in 1970s, but widespread use in clinical urology did not occur for another decade. Before PSA was discovered, serum acid phosphatase was used as a biomarker for PCa. PSA is a 33 kD glycoprotein that acts as a serine protease.[12] Although it is produced by other tissues also in minute quantities, but for all practical and clinical purposes PSA is organ specific, primarily produced by the prostate luminal epithelial cells.

The Function

This androgen regulated protease liquefies semen through its action on gel-forming proteins, Seminoglobulin within the semen following ejaculation, but at present it is unknown why this clotting and its lysing mechanism is important to reproductive physiology.

Seminoglobulin is the predominant seminal vesicle secreted protein and is one of the physiologic substrates for PSA. The primary release of PSA into the seminal fluid results in 10^6-fold higher seminal concentrations than levels measured within the serum. The concentrations found in seminal plasma ranges from 0.5 to 5.0 mg/ml whereas the normal serum concentration in man, at the age of 50-80 years, without prostate disease, ranges between 1.0 and 4.0 ng/ml. PSA expression is strongly influenced by androgen hormones.

The Highlights of PSA

1. Used as screening biomarker for Ca prostate
2. PSA-based screening reduced the deaths from PCa by 20% but also associated with high risk of overdiagnosis
3. PSA is not a perfect marker with less than perfect sensitivity and specificity for the diagnosis of PCa. The U.S. preventive social task force no longer recommends PSA screening for healthy men
4. Despite its limitations, the most accepted and frequently used biomarker for prostatic carcinoma is PSA
5. The protein is very specific to the prostate gland but not specific to PCa. In patients who underwent prostatectomy for PCa, PSA measurement is an excellent test for determination of recurrence[13.]
6. At present, the PSA is the only approved (in 1986), clinically used serum based, PCa biomarker. Its testing is approved for early detection along with DRE in men over the age of 50.[14,15]
7. Research conducted in the early 1990s revealed that PSA combined with DRE is the most effective screening and early detection modality in PCa.[16-19]
8. PSA levels are normally elevated in older men relative to younger men regardless of presence or absence of Cancer. Therefore, a continuous rise in PSA levels

over time from relatively low levels may be more indicative of cancer than moderately increased PSA that is stagnant.[20]

9. Although PCa cells do not produce more PSA than benign prostate epithelium, the PSA elevation seems to be due to disruption of cellular architecture within the prostate gland.
10. The loss of barrier of basal membrane and escape from proteolytic process causes elevation of PSA. It is evident from the fact that such increase also occurs in the presence of prostatitis, prostate manipulation, e.g., DRE, prostatic massage, prostate biopsy, etc.

MOLECULAR DERIVATIVES OF PSA

1. Complexed PSA (cPSA):
   - PSA-ACT (PSA complexed to α_1-antichymotrypsin)
   - PSA-A2M (PSA complexed to α_2-macroglobulin)
   - PSA-API (PSA complexed to α_1-protease inhibitor).
2. Free PSA (fPSA):
   - Pro PSA (pPSA)
     - 7- pPSA
     - 4- pPSA
     - 2- pPSA
   - Benign PSA (BPSA)
   - Other fPSA
     - intact PSA (iPSA)
3. Miscellaneous measurements:
   - PSA density (PSAD)
   - cPSAD
   - PSA transitional zone density
   - PSA velocity (PSAV).

Measurable PSA found circulating in blood, exists either in cPSA or bound and fPSA.[21]

cPSA

Complexed form is bound to three proteins:[22]

1. ACT: α-antichymotrypsin
2. A2M: α-macroglobulin
3. API: α-protease inhibitor.

The majority of protease that enters the serum is bound (70%) to these proteins. Of the cPSA derivatives found in serum PSA bound to ACT (PSA-ACT) is immune-reactive and found in greatest concentration.

A man with PCa have a greater fraction of tPSA that is complexed with prostate inhibitors than a man without PCa, therefore the measurement of cPSA can be used as the marker of PCa. In the tPSA range of 4-10 ng/ml, the measurement of cPSA provided improved specificity as compared to tPSA. It provided similar specificity compared to the percentage of fPSA at a sensitivity range of 95%.

fPSA

Although the majority of serum PSA is found complexed to proteases, 5-35% of PSA exists in free form, called fPSA. It (fPSA) is also immunoreactive and, therefore, measurable. Development of new monoclonal antibodies specific for fPSA and cPSA has allowed more accurate measurement of different molecular forms of PSA and their ratio in serum.

The ratio of fPSA to tPSA is greater when comparing man without PCa but have prostate enlargement (BPH) and those with PCa with no prostate enlargement. The role of percentage of fPSA is more applicable to PSA levels < 10 ng/ml, when DRE gives the impression of benign enlargement of the prostate, and PSA level is minimally raised.

Testing percentage of fPSA is approved by the food and drug administration (FDA) in such diagnostic gray zone of 4-10 ng/ml. of PSA.[23] Free to the total cut-off value of 0.18 (18% free to tPSA) significantly improved the ability to distinguish between subjects with or without cancer prostate compared to the use of tPSA alone.[24]

The percentage of PSA is an independent indicator of presence or absence of PCa over and above the information gained from DRE, age, tPSA, etc., especially in the range of PSA 4-10 ng/ml.[25] ThefPSA and tPSA both decreases in men receiving finasterides, as both decline, the percentage of fPSA is not altered significantly by these medications.[26]

The fPSA also gives prognostic information. Longitudinal measurement of % fPSA changes may add in detection and contribute information regarding disease behavior, e.g., aggressive/non-aggressive and help in decision making.[27]

Limitation of Interpretation of Data

Prostatic manipulations and urethral instrumentation affect the ratio of fPSA to tPSA. The fPSA is cleared more rapidly from serum as compared to cPSA, so PSA estimation is avoided for several weeks fallowing prostatic manipulations such as surgery, biopsy, cystoscopy, etc.[28]

FDA has approved the measurement of fPSA in the diagnostic gray zone of 4-10 ng/ml. However, this can also be used as a decision-making tool for repeat biopsy[29] for an initial biopsy percentage of fPSA ranges from 18 to 25% is commonly suggested.

fPSA and its Isoform/Molecular Derivatives

pPSA

PSA originates with a 17-aminoacid chain that is cleaved to yield a precursor inactive form of PSA called pPSA. The precursor form contains: 7-amino acid proleader peptide and 237 constituents amino acids of mature PSA called [-7] pPSA. Once released the proleader amino acid chain is cleaved at amino acid terminus by hk2 converting pPSA to active 33kD PSA form. Incomplete removal of 7 amino acid proleader chain leads to various clipped form of pPSA such as [-2]pPSA, [-4]pPSA, [-5]pPSA with 2, 4, or 5 amino acids.

With cellular destruction, these inactive forms circulate as fPSA in patients with PCa.[30]

In PCa, these truncated form of pPSA are significantly increased. The decreased PSA processing in PCa may result in a relative increase in pPSA and its cleaved forms particularly [-2] pPSA. Measuring the ratio of these truncated or cleaved forms of PSA to tPSA may serve to differentiate between a man with or without PCa and serve as potential PCa biomarker.

BPSA

Another isoform of fPSA called BPSA is also a cleaved form of PSA that has been identified in tissue from nodular BPH transition zone.[31]

iPSA

In addition to fPSA and BPSA other isoform have been identified in serum. One form of pPSA is found intact and inactive form which does not make a complex with ACT. It is termed as iPSA. It is identified in PCa cells. The ratio of iPSA to fPSA may improve the accuracy of PCa detection.[32]

Volume Based Parameters

Volume based parameters have been evaluated to increase the specificity and to distinguish between BPH and PCa. In such studies, the volume of the prostate gland is determined by ultrasound.

These includes:-

- PSAD: PSA divided by prostate volume
- cPSAD: cPSA divided by prostate volume
- PSA transitional zone density: PSA value divided by transitional zone volume.

PSAD

It may help to distinguish between PSA elevations caused by BPH and those caused by PCa. A direct relationship between PSAD and the chance of cancer has been documented. A PSAD of 0.15 or greater has been proposed for recommending prostate biopsy in men with PSA levels between 4 and 10 ng/ml., and a normal DRE. The usefulness of PSAD in PCa detection has not been confirmed in all studies. An advantage of PSAD is that it has been directly associated with PCa aggression.

PSA/Transitional zone density (volume) is the parameter with the highest sensitivity and specificity for PCa detection between PSA of 4 and 10 ng/ml.

In general, PSA density is an imperfect parameter. They only represent an additional method of risk assessment with potential utility for counseling men with 4-10 ng/ml PSA levels for prostate biopsy or repeat biopsy if the PSA levels are persistently elevated.

PSAV

PSAV is defined as the rate of change, in PSA levels, for the elapsed time between measurements. PSAV > 0.75 ng/ml, per year, is a specific marker for the presence of PCa in men with levels of PSA between 4 and 10 ng/ml.

1. Men with PCa have more rapid rise in PSAV levels than in men with benign disease
2. PSAV may play a role in the prediction of life-threatening PCa
3. A PSA > 0.35 ng/ml/year 10-15 years prior to diagnosis is associated with a 5-fold increased risk of life-threatening PCa more than a decade later
4. A PSASV > 2 ng/ml/year during the year prior to a PCa diagnosis were associated with PCa specific mortality following radical prostatectomy or radical therapy
5. However, a recent meta-analysis suggested that PSAV prior to treatment provided no additional information regarding PCa outcome when compared to PSA alone.

DISCUSSION

The carcinoma prostate is the second leading cause of cancer-related deaths in men. PSA is the most notable biomarker for screening and diagnosis of prostatic disease. It is organ specific but not cancer specific. Its elevation is not always due to prostatic cancer.

Routine use of PSA testing has increased detection of PCa, but it has also led to overdiagnosis and overtreatment. In 1994, PSA was officially approved for cancer screening by FDA and 4.0 ng/ml. was set as the upper limit of normal range. The observed decline in mortality rates both in the US and round the world has been partially attributed to the ongoing screening based on PSA levels. The PSA can be present in free or complexed form. For those with elevated PSA, in the gray zone of, 4-10 ng/ml, patients are more likely to have PCa when the fPSA is less than 20-25% of

total serum PSA levels. pPSA, a precursor form of PSA may serve as an additional indicator in differentiating cancer from the benign process. The ratio of iPSA to fPSA may also improve the accuracy of PCa detection. Volume based parameters such as PSA density can help to determine the timing of prostate biopsy especially in the range of 4-10 ng/ml. The PSA density has been shown to be directly associated with PCa aggression. PSA/transitional zone density is the parameter with the highest sensitivity and specificity for PCa detection in the range of 4-10 ng/ml. PSAV > 0.75 ng/ml per year is a specific marker, for the presence of prostatic cancer in men with levels of PSA in the gray zone. Men with PCa have a more rapid rise in PSAV levels than in men with the benign disease.

CONCLUSIONS

1. pPSA, a precursor form of PSA may serve as an additional indicator in differentiating cancer from the benign process.
2. The ratio of iPSA to fPSA may also improve the accuracy of PCa detection.
3. PSA transitional zone density is the parameter with the highest sensitivity and specificity for PCa detection in the range of 4-10 ng/ml.
4. PSAV > 0.75 ng/ml per year is a specific marker, for the presence of prostatic cancer in men with levels of PSA in the gray zone.

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Case Report

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Malignant Peripheral Nerve Sheath Tumor in Polio Affected Lower Limb: A Rare Case Report

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Abstract

Malignant peripheral nerve sheath tumors (MPNSTs) are highly aggressive soft tissue sarcomas that rarely occur sporadically in the general population. However, in patients with neurofibromatosis-1, they occur with a lifetime incidence of 8-13%. A 28-year-old polio affected male presented with a rapidly growing swelling in the polio affected left lower limb. Fine needle aspiration cytology and incisional biopsy showed features of MPNST. Above knee amputation followed by radiotherapy was given. Though sporadic MPNSTs are described, its presentation in a polio affected limb has not been described in the literature. This is the first such reported case, a rarest of presentation of a rare tumor.

Key words: Malignant peripheral nerve sheath tumors, Neurofibromatosis, Polio, Soft tissue sarcomas

INTRODUCTION

Malignant peripheral nerve sheath tumors (MPNSTs) are highly aggressive soft tissue sarcomas that rarely occur sporadically in the general population. However, in patients with neurofibromatosis-1 (NF1), they occur with a lifetime incidence of 8-13%.[1] They account for 5-10% of soft tissue sarcomas.[2,3] The incidence of sporadic MPNSTs is low, with a lifetime risk of 0.001%.[4] Most MPNSTs are associated with major nerves of the body wall and extremities. These tumors originate from the nerve sheath rather than from the nerve itself.[1] All ages and both sexes may be affected. Sporadic cases are most common between 40 and 50 years of age while those occurring in the setting of NF1 are diagnosed some 10 years earlier.[3] The male and female ratio is 1:1.[2]

CASE DESCRIPTION AND RESULTS

A 28-year-old male patient, who is polio affected individual presented with a history of rapidly growing swelling in the polio affected limb since 4-5 months (Figure 1). He had no other symptoms and co-morbidities. His routine blood investigations were normal. Fine-needle aspiration cytology from the swelling showed features of soft tissue sarcoma probably MPNST. An incisional biopsy was done, which revealed spindle cell tumor suspicious of malignancy. Ultrasound abdomen and chest X-ray were done to rule out metastasis and were found to be normal. Because of the rapidity of the growth, above knee amputation was done (Figure 2). The patient was given radiotherapy and is in the regular follow-

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Figure 1: Pre-op picture of the patient

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Figure 2: Post-op picture of the patient

up. Histopathology section showed spindle cells with a pleomorphic nucleus, and coarse nuclear chromatin, and prominent nucleoli (Figure 3). Immunohistochemistry from the growth showed diffuse cytoplasmic positivity to vimentin, focal positivity for smooth muscle actin and no reactivity for desmin and S-100.

DISCUSSION

Soft tissue sarcomas constitute <1% of overall malignant tumors. The annual incidence rate of soft tissue sarcoma range between 1.4 and 5.0 cases per 100,000. Incidence patterns vary considerably by histologic type and subtype. The incidence for most types of soft tissue sarcoma increases progressively with age.[1] MPNSTs account for up to 10% of all soft tissue sarcomas.[5] Both sporadic and NF1-associated MPNSTs display complex karyotypes and clonal chromosomal aberrations. No clear difference in karyotypic profile between sporadic cases and NF1-associated MPNSTs has been detected.[3] The NFl gene is implicated in sporadic as well as NF1-associated MPNST. TP53 (on 17p13) is frequently inactivated in MPNST through mutations or deletions, correlating with the frequent loss of 17p.[1] One study has reported poor overall patient survival associated with simultaneous gain of 17q and 7p.[3] Morphologically, MPNSTs are monomorphic spindle cell tumors often with alternating myxoid and cellular areas. The spindle cells in MPNSTs are typically focally reactive for S100 protein in 50-70% of cases.[1,3] Etiology and risk factors include genetic factors (NF), radiation (9%) and trauma. The most common sites affected are extremities followed by retroperitoneal/intraabdominal and truncal. In few cases affecting intracranial nerves are also reported.[4] They commonly present with a rapidly enlarging mass. Imaging modalities include computed tomography, magnetic resonance imaging, positron emission tomography scan. Most common sites of metastasis are lungs (extremity),

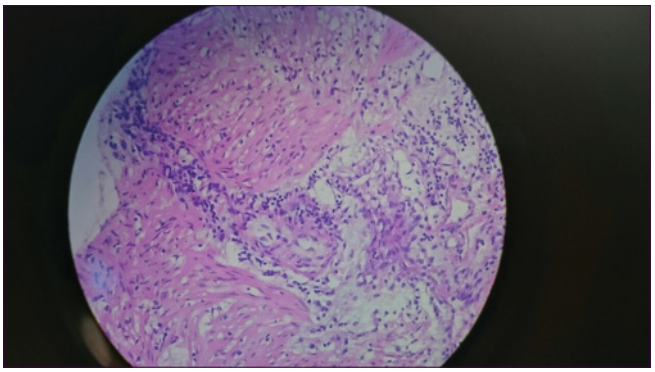

Figure 3: Histopathology picture showing spindle cells

liver (retroperitoneal or visceral) and subcutaneous tissue.[1,2] Treatment is complete surgical excision with or without radiotherapy, or neoadjuvant chemotherapy with surgery.[1,6] Isolated limb perfusion is used for treating extremity sarcomas for whom amputation is the only option for local treatment.[7]

Due to the relative rarity of MPNSTs, there have been few large studies into survival and those reporting 5-year survival lack consistency, with survival rates in the range of 39-85%. Few studies have suggested NF1 as an independent indicator of poor prognosis in MPNSTs.[5] A combination of clinical, pathological, and immunohistochemistry helps in diagnosing these tumors. Primary site, size, and surgical margins are significant for disease-free survival and overall survival.[6] Though multimodality therapy, including surgical resection and adjuvant radiotherapy, is available, the prognosis remains dismal.[8,9]

Recent studies have suggested the overexpression of *CD155,* a poliovirus receptor was observed in various types of soft tissue sarcoma and upregulated *CD155* expression was a significant predictor of local recurrence. Based on these studies, a promising target for oncolytic virotherapy using live attenuated poliovirus for soft tissue sarcoma has been thought.[10]

CONCLUSION

This case report supports the fact that oncolytic virotherapy using poliovirus can be a potential treatment modality for soft tissue sarcomas. Further research is needed to in this regard to consider the same in the near future.

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Case Report

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Fetus Papyraceous in Twin Pregnancy: Incidental Finding during Caesarean Section

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Abstract

Fetus papyraceous (FP) is a rare clinical condition. It is the compressed, mummified, parchment like remains of one fetus of multiple pregnancy which is retained in uterus after demise in second trimester. The incidence is 1 in 17,000-20,000. In twin pregnancy, the incidence of FP is around 1 in 184 to 1 in 200 twin pregnancies. In this particular case the subject is from a rural place having no proper ante natal checkup during her pregnancy. She had a scan in third trimester of pregnancy in which no abnormality was detected and FP found incidentally during caesarean section without any adverse outcome to the mother and living fetus.

Key words: Caesarean section, Fetal death, Fetus papyraceous, Labor, Multiple pregnancy, Ultrasonography

INTRODUCTION

Fetus papyraceous (FP) is defined as a compressed fetus, the mummified parchment-like remains of a dead fetus that died in second trimester[1,2] but the other fetus continues to grow. The amniotic fluid and placental tissue are absorbed, and the fetus compressed between the membranes of living twin. The incidence is around 1 in 184 to 1 in 200 twin pregnancies.[2,3]

CASE REPORT

A 24-year-old primigravida admitted to my hospital with watery discharge p/v for 2 days. The patient was from a rural place around 100 km from Bhubaneswar. She had irregular ante natal checkup at the local primary health center with proper immunization. She had a sonography at 33 weeks of gestation at a local clinic which revealed no abnormality.

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On examination, the vitals were stable. The uterus was term size with longitudinal lie and vertex presentation having regular fetal heart rate. Per vaginal examination revealed short cervix and os admitting the tip of finger.

With above findings a decision for induction of labor was made. An oxytocin drip along with antibiotics started. After 10 h of oxytocin drip there was non-progress of labor and a caesarean section was planned.

She underwent a caesarean section under spinal anesthesia after 12 h of admission. The surgery went uneventful resulting term healthy female child of 2750 g with 1-min Apgar 7 and 5-min Apgar 9.The placenta weighed 375 g along with the umbilical cord. A rudimentary cord was attached to the placenta with a compressed, mummified fetus that was identified as FP (Figures 1 and 2). The FP weight was around 150 g.

Thus, the pregnancy was diamniotic and dichorionic. No complication observed in the post-partum period. Both mother and baby were discharged from the hospital after suture removal on 7th post-op day.

DISCUSSION

FP occurs in subjects with multiple gestations having one, or more of the fetuses die early in the gestational period

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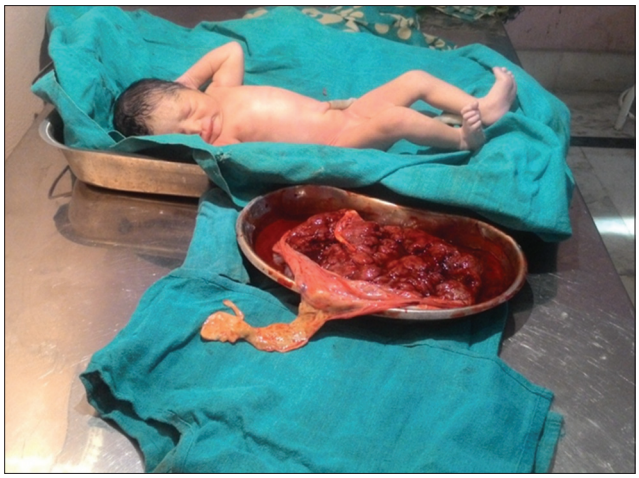

Figure 1: Clinical Picture of Fetus Papyraceous

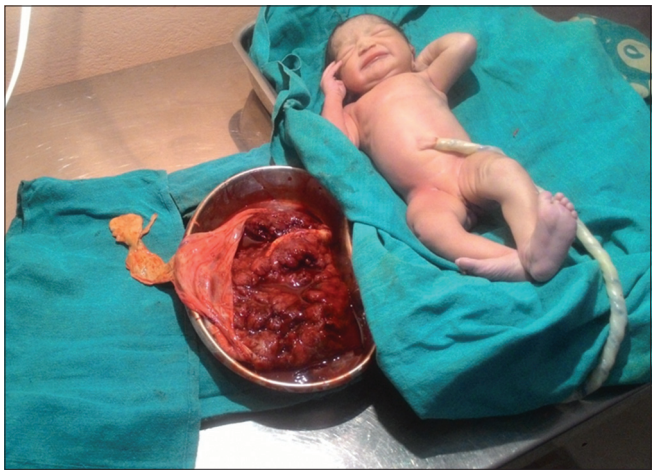

Figure 2: Rudimentary cord was attached to the placenta with a compressed, mummified fetus

(15-20 weeks). The other fetus continue to grow. In most situations the amniotic fluid disappears; the fluid of the dead tissue gradually absorbed and the fetus compressed and became incorporated to the membrane.[4]

Prior to the use of ultrasound the diagnosis of FP could be only made after delivery of the surviving twin. By transvaginal sonography a twin pregnancy can be diagnosed as early as 5 weeks of gestation and FP can be diagnosed with follow-up scan.

In our case, the pregnancy is diamniotic and dichorionic with no adverse effect on mother and the surviving fetus. But sometimes this condition can have adverse effect on both mother and surviving fetus during pregnancy. A study by McPherson *et al.* investigated the association between chronicity and intrauterine fetal demise (IUFD) of one or both fetuses in twin pregnancies. The study was performed on 2,161 twin pregnancies; 86 had at least 1 IUFD and 32 had a double fetal loss. Consequently, they found that monochorionic pregnancies had an increased risk of a single demise (adjusted odds ratio [OR]: 1.69; 95% confidence interval [CI]: 1.04-2.75) and a double demise (adjusted OR: 2.11; 95% CI: 1.02-4.37). 70% of all double demises happened before 24 weeks.[5] They have been put forward that monochorionic twins carry an increased risk of fetal death compared to dichorionic twins. Similarly, double demise occurs primarily before 24 weeks of gestation. In single tone pregnancies whenever there is an IUFD and the fetus stay in utero it triggers intravascular coagulation but in case of FP hematological complications are very low.[6] Malinowski *et al.*, found that none of the live born fetuses had any evidence of hematological abnormalities.[7] In another case reported by Bozkurt and Kara showed no maternal and fetal complications in diamniotic and diachorionic pregnancy with FP.[8]

CONCLUSION

We report a case of FP with no maternal and fetal complication during pregnancy, delivery and post-partum period. The etiology of FP could not be explained. Routine ultrasound with machines having good resolution is important for early diagnosis of FP and thus further obstetric complication can be prevented.

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Case Report

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Karyotypic Variables in Turner Syndrome: A Case Series

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Abstract

Turner Syndrome (TS) is a medical disorder that affects about 1 in every 2500-3000 female live births worldwide. It is a genetic condition in which a female does not have the usual pair of two X chromosomes. Females who have this condition are usually shorter than average and infertile due to early loss of ovarian function. In order to study, about the different types of karyotypic variations that can result in TS, case studies of 10 different probands were analyzed. Analysis of each proband was done with respect to the clinical presentation, as well as a karyotype. It was observed that Mosaic TS had a much higher percentage of occurrence compared to monosomy X. Mosaics varied with respect to genotype combinations, as well as the presence of structural abnormalities on the X chromosome. The variable phenotype reflected the different possible clinical presentations seen in TS.

Key words: Karyotype, Karyotypic variations, Mosaicism, Turner Syndrome

INTRODUCTION

Turner Syndrome (TS) or Ullrich-TS is a genetic disorder encompassing several conditions, of which monosomy X is most common (45,X). It is caused due to chromosomal abnormality, where in complete or a part of one of the X chromosomes is absent.[1] Cases have also been reported with mosaicism, where 45,X cell line is accompanied by one or more other cell lines having a complete or structurally abnormal sex chromosomes (X or Y).[1,2] Structural abnormalities of the sex chromosome (X) can be due to deletions of the short arm q or long arm p (Xp-, Xq- respectively), duplication of the long arm to form isochromosome (isoXq) or formation of ring (rX). Some mosaic females have also shown to carry additional cell lines, with the Y chromosome (45,X/46,XX; 45,X/46,XY).[3] Mortality rates in TS are about 4- to 5-fold higher than in the general population, reducing the life expectancy up to 13 years.[4,5]

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Typical abnormalities in TS include short stature, gonadal dysgenesis (usually, streak gonads reflecting a failure of ovarian maintenance), characteristic facial features, webbed neck, low posterior hairline, a broad chest with widely spaced nipples, nevi all over the body, shortened metacarpal IV, small fingernails, shield-shaped thorax, poor breast development, and elevated frequency of renal and cardiovascular anomalies. Many patients have coarctation of the aorta, cardiovascular abnormalities, lymphedema in fetal life, causing cystic hygroma, and primary amenorrhea (PA) or secondary amenorrhea.[4-7] TS patients with epilepsy have also been reported with frequently associated malformations of cortical development.[2,8]

Some clinical symptoms of TS are inconsistent, even in individuals with non-mosaic 45,X, which might be due to the fact that the physical manifestations of TS patients mainly depends on the karyotype.[1] Phenotypes may be contributed by the parental origin of the X chromosome.[9] Patients mosaic for 46, XX or iXq have been shown to have milder phenotypes.[1,9] While patients with mosaicism for 46, XY cell line or structural rearrangement of the

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Y chromosome mostly have masculinized external genitalia and are at increased risk for having gonadoblastoma and other gonadal tumors.[1,10] The main objective of our study was to analyze the various karyotypes in patients diagnosed with TS and to record the rare phenotypic variations.

CASE REPORTS

This study was conducted in the Division of Human Genetics, St. John's Medical College, Bangalore, a referral center for human genetic disorders. About 10 cases with different phenotypic and genotypic profiles were included into the study. For each case, demographic details, pedigree data, clinical history were collected. Clinical and rare phenotypic features associated with the variable Karyotypes were compiled, recorded and the data were analyzed.

The chromosomal analysis was performed by peripheral blood lymphocyte culture on the basis of G-banding technique at high resolution. Number of chromosome present in a specific number of cells referred to as metaphase spreads are counted followed by careful analysis of the banding pattern of each of the individual chromosomes and the total chromosomal count was determined in 10-15 cells. The banding pattern is compared with an idiogram and then formally presented as "karyotype," which will show each chromosome pair arranged in descending order of size.

Case 1

The patient was a female of 20 years. She had a history of PA. Observations/Examinations (O/E) showed that secondary sexual characteristics were absent with scanty of axillary and pubic hair, breast development was normal, low posterior hairline was absent. She had no webbing of the neck and had normal intelligence. Further, investigations showed that her ECHO results was normal, ultrasound scanning results showed that she had a normal uterus, normal bilateral kidneys, and ovaries were not visualized. Her karyotype was 45,X and hence she was a Turner female with complete monosomy. A pedigree chart is shown in Figure 1.

Case 2

The patient was a female of 25 years. She had a history of PA. She attained spontaneous menarche at the age of 13. O/E showed that she had decreased secondary sexual characteristics, short stature, complete scalp alopecia, but her external genitalia were normal. Further, investigations included the ultrasound scanning results, which showed that she had a normal uterus, normal bilateral ovaries. Her karyotype was 45,XX (52%)/45,X (48%), and hence she had a mosaic TS. A pedigree chart is shown in Figure 1.

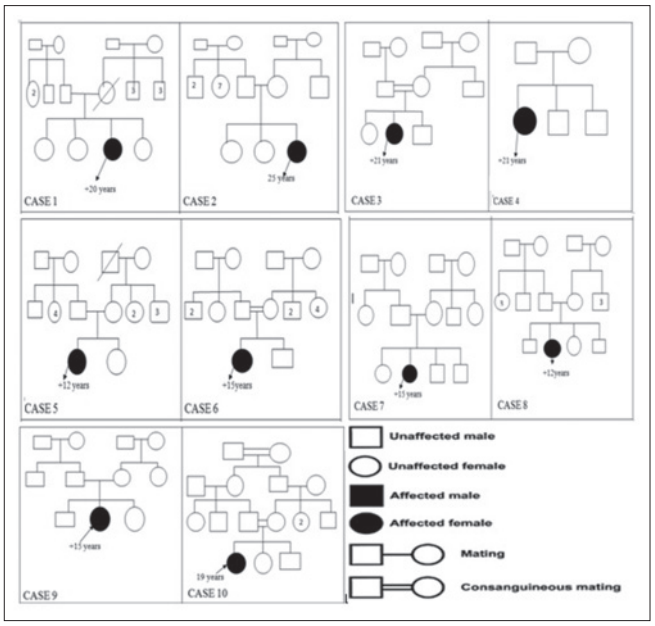

Figure 1: Pedigree charts of the Turner syndrome cases described

Case 3

The patient was a female of 21 years. She had a history of PA. O/E showed that she had decreased secondary sexual characteristics with normal external genitalia. Further, investigations included the ultrasound scanning results, which showed that she had a rudimentary uterus, bilateral streak ovaries (gonadal dysgenesis). Her karyotype was 45,XX (92%)/45,X (8%), and hence she had a mosaic TS. A pedigree chart is shown in Figure 1.

Case 4

The patient was a female of 21 years. She had a history of PA. She attained spontaneous Menarche at the age of 17 years. O/E showed that she had decreased secondary sexual characteristics, short stature with normal external genitalia. Further, investigations included the ultrasound scanning results, which showed that she had a hypoplastic uterus ovaries were not visualized (ovarian dysgenesis). Her karyotype was 45,X, del (Xq-), and hence she had a TS with a structural abnormality. A pedigree chart is shown in Figure 1.

Case 5

The patient was a female of 12 years. She had a history of short stature. O/E showed that she had short stature with delayed pubertal changes. Further, investigations included the X-ray of the wrist, which showed 8 years bone growth, indicating a delayed bone age. Her karyotype was 45,X (80%)/46,X r (X) (ring X chromosome) (20%), and hence she was a Turner mosaic with a structural abnormality. A pedigree chart is shown in Figure 1.

Case 6

The patient was a female of 15 years. She had a history of short stature with PA. O/E showed that she had decreased secondary sexual characteristics, cubitus valgus was present. Investigations involved the hormonal assay, which showed high follicle-stimulating hormone (FSH), thyroid profile showed increased thyroid-stimulating hormone (TSH), which indicated hypothyroidism, decreased bone age was noticed, Barr body was not present in cells (Barr body negative). Her karyotype was 45,X del (Xp-) (52%)/45,X (48%), and hence she was mosaic Turner with a structural abnormality. A pedigree chart is shown in Figure 1.

Case 7

The patient was a female of 15 years. She had a history of PA. O/E showed that she had decreased secondary sexual characteristics, breasts were not developed, cubitus valgus was present on her right side and her external genitalia were normal. Investigations involved the hormonal assay, which showed high FSH, Luteinizing hormone (LH). The uterus and ovaries were not visualized on the ultrasound. Karyotype was 45,X (64%)/46,XY (36%), and hence she was mosaic Turner with mixed gonadal dysgenesis. A pedigree chart is shown in Figure 1.

Case 8

The patient was a female of 12 years. She had a history of short stature. O/E showed that she had short stature and had decreased secondary sexual characteristics. She had normal intelligence. Her external genitalia were normal. Investigations showed decreased bone age. Her ultrasound results showed infantile uterus, streak ovaries. Her karyotype was 45,X (17%)/46,X iso (Xq) (83%), and hence she had a mosaic TS with a structural abnormality. A pedigree chart is shown in Figure 1.

Case 9

The patient was a female of 15 years. She had a history of PA. O/E showed that she had decreased secondary sexual characteristics, hypoplastic breast development. Her external genitalia were normal. Ultrasound results showed hypoplastic uterus and bilateral ovaries were not visualized. Her karyotype was 45,X (4%)/46,X iso (Xq) (88%)/47,X, iso (Xq), iso (Xq) (8%), and hence she had a mosaic TS with a structural abnormality. A pedigree chart is shown in Figure 1.

Case 10

The patient was a female of 19 years. She had a history of PA. O/E showed that she had short stature and had decreased secondary sexual characteristics. She had normal intelligence. Her external genitalia were normal. Ultrasound results showed that she had a hypoplastic uterus and gonadal dysgenesis. Her karyotype was 45,X, complete monosomy. A pedigree chart is shown in Figure 1.

RESULTS

In this study, 10 probands with TS were studied and the corresponding karotypic variables were recorded as shown in Table 1. Among the 10 karyotypes examined, 7 cases showed Mosaic TS (Case 2, 3, 5, 6, 7, 8, 9).

It was noted that 10% of the cases had complete monosomy (45,X), 10% had complete structural abnormality (46,X, del [Xq]). 70% of the females had Mosaic Turner including 20% complete mosaics (46,XX [52%]/45,X [48%] and 46,X, del [Xq]), 10% mosaics with mixed gonadal dysgeneis (45,X [42%]/46,XY [36%]), 40% mosaics with structural abnormalities (45,X [80%]/46,X, r [X] [20%], 46,X, Xp – [52%]/45,X [48%], 45,X [17%]/46,X iso [Xq] [83%], 45,X [4%]/46,X, iso [Xq] [88%]/47,X, iso [Xq] [8%]), as shown in Table 2.

We observed that both the patients with complete monosomy of 45,X entirely differed in their phenotypic characters with only PA in common. The Patients with mosaicism differed in their clinical presentation which seems to be not affected by the percentage of abnormal cell lines. Rudimentary uterus and bilateral streak ovaries were observed in a patient with only 8% of cell lines with 45,X, while the other patient with 48% of 45,X cell lines had completely normal uterus and ovaries, however, both of them were short stature. Turner females with

Table 1: Karyotypic variables

Case no.	Karyotype
1	45, X
2	46, XX (52%)/45, X (48%)
3	46, XX (92%)/45, X (8%)
4	46, X, del (Xq)*
5	45.X (80%)/46, X, r (X) (20%)†
6	46, X, Xp – (52%)/45, X (48%)
7	45, X (42%)/46, XY (36%)
8	45, X (17%)/46, X iso (Xq) (83%)
9	45, X (4%)/46, X, iso (Xq) (88%)/47, X, iso (Xq) (8%)
10	45, X

*long arm of the X chromosome (Xq) deletion, †ring X chromosome, ‡short arm of the X chromosome (Xp) deletion, long-arm isochromosome X derivative

Table 2: Observed percentage of occurrence of the different karyotypic variables

Karyotypic variation	Observed % of occurrence
TS with complete monosomy	20
Structural abnormality	50
TS with complete structural abnormality	10
Mosaic with structural abnormality	40
Mosaic with mixed gonadal dysgenesis	10
Mosaic TS	70

TS: Turner syndrome

structural abnormalities had a severe phenotype, attained early menarche, had hypoplastic uterus and dysgenesis of ovaries. Female with mixed gonadal dysgenesis had no uterus and ovaries however, had normal external genitalia with no breast development. About 75% of the turner patients who were mosaics with structural abnormalities presented with delayed or decreased bone age and 50% of them had ovarian dysgenesis. PA, short stature and decreased secondary sexual characteristics were the most common abnormalities found.

DISCUSSION

TS can vary in its clinical presentation. The various modes of clinical presentations depend on the age of onset as seen in our case studies. We reported 10 different cases of TS with varying severity of the disease. However, the severity of the clinical presentation did not correlate well with the percentage of defected cell lines. The patient belonging to Case 1 despite of having complete monosomy had normal intelligence, normally developed ovaries and no webbing of the neck whereas in Case 2 and Case 3 with only 48% and 8% lines being 45,X respectively TS females presented with slightly more severe clinical symptoms including ovarian dysgenesis. However, Case 10 with complete monosomy had typical TS features. The lack of a second X chromosome leads to the development of streak gonads, because a second X chromosome is essential for full development and functioning of the ovaries.[11]

We observed a higher frequency of Turner Mosiac females with highest number of cell lines having sex chromosome with structural abnormalities i.e. deletions of the short arm q (Xq-) or long arm p (Xp-), duplication of the long arm forming isochromosome (isoXq) or presence of ring (rX). It has been reported that loss of interstitial or terminal long arm material of the X chromosome (Xq) can result in short stature and primary or secondary ovarian failure.[12] This finding correlated well with our Case 4, a 21-year-old TS female with 45,X, del (Xq-) karyotype who was short statured with hypoplastic uterus and ovarian dysgenesis. Deletion of the whole short arm of the X chromosome (Xp) is often associated with short stature with classic stigmata of TS, but the gonadal function is generally preserved.[13] This was seen in our Case 6, a 15-year-old TS female. Case 5, 15 years female with short stature and delayed pubertal changes and delayed bone age was found to have cell line with ring chromosome, resulting in the phenotype due to the functional disomy of genes. The phenotype variability of the patients with ring (marker) X chromosome is mostly dependent on the size of the ring and the presence of a functioning XIST gene, which is expressed exclusively from the inactive X chromosome. Marker or ring X chromosomes (r(X)) lacking a functional XIST have been associated with several clinical features such as mental retardation and a distinct phenotype of short stature, and facial dysmorphism.[14,15] Case 7, a 15 years female had mixed gonadal dysgenesis with 45,X/46,XY mosaicism, which is a rare and probably underdiagnosed condition and its incidence is 1.5 per 10,000 newborns.[16] The different distributions of the 45,X (X monosomy) and 46,XY (male constitution) chromosomal cell lines among the tissues in individuals with this mosaicism presumably reflect the wide variety of phenotype observed as in Case 7. Mixed gonadal dysgenesis is caused by the loss of the Y chromosome due to non-disjunction subsequent to normal disomic fertilization.[17] Most of the TS patients with isochromosome Xq have mild phenotypes[18] and generally show similar characteristics to those with classical 45,X[19] as found in Cases 8 and 9. An isochromosome is a structurally abnormal chromosome consisting of 2 short or 2 long arms; the abnormal transverse misdivision of the centromere yields unbalanced chromosomal constitution, monosomy for the missing arms, and trisomy for the duplicated arms.[19]

Detection of TS is possible in the prenatal period, in children and even in adult females. The specific nature of the chromosomal abnormality, specific genes affected, or the resulting imbalance of the parts of the genome involved results in the phenotypic characteristics associated with the disease.[20,21] The influence of the maternal age may not be related to the birth of TS children.[22] Moreover, it is now known that in 80% of the TS, the paternal X chromosome may have been lost from a 46,XX, or 46,XY zygote.[23] Hence, TS cannot be correlated to maternal age.[24]

In this study, etiological factors may be difficult to pinpoint in view of the increased variability of presentation indicating a range between chromosomal abnormalities to the possibility of an imprinted X-linked gene that influences the phenotype of these individuals. A variable phenotype reflects the different possible clinical presentations seen in TS. Hence, it becomes imperative that once there is a clinical suspicion of TS, irrespective of the age, it must be confirmed by karyotyping to establish the variable karyotypes associated with the syndrome.[25] Thus karyotype will establish the type and also the prognosis in the cases.

This study also confirms explicitly that almost all patients with TS have short stature and loss of ovarian function, but the severity of these problems varies considerably amongst individuals. The genetic counseling in each of these cases will depend on the clinical presentation, karyoptypic variables, early detection, management, and even prevention through prenatal diagnostic facilities.

CONCLUSION

We reported 10 different cases of TS females from 15 to 25 years of age with varying phenotypic and genotypic profiles. We observed a higher percentage of mosaic TS females including complete mosaics, mosaics with mixed gonadal dysgenesis and mosaics with structural abnormalities. We suggest that chromosome analysis for TS should be considered even in patients presenting with normal intelligence and who attained normal puberty however, when the height is short and autoimmune thyroid disease is accompanied. Chromosome analysis for TS is essential in order to plan an appropriate management of the disease early in life.

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Case Report

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Prosthodontic Management of Edentulous Patient with Bucket Handle Fracture: A Clinical Report

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Abstract

Conventional complete denture therapy for patients with severe residual ridge resorption or a patient with an altered denture space caused by disease, trauma or burns could be a challenge. It is in these patients that a prosthodontist should think outside the box and work out of the comfort zone. The neutral zone, though not a new concept, but definitely is a highly ignored and neglected one. Reasons may vary from added appointments to ignorance and skepticism in the concept. However, if followed correctly, it does provide added stability in cases that can use it. The purpose of this article was to discuss a successful denture delivery using the neutral zone technique in a case that presented with a severely resorbed lower ridge along with the bucket-handle fracture.

Key words: Complete denture, Mandibular fracture, Neutral zone, Resorbed ridge

INTRODUCTION

The loss of teeth causes adverse esthetic and biomechanical sequel, a predicament that is worse when the patient is completely edentulous, and the entire periodontal ligament is lost.[1] The unstable complete mandibular denture is a problem, which dentists repeatedly encounter. Over the past many years, numerous articles have appeared in the literature regarding neutral zone, and how one can fabricate a stable denture by this concept. The neutral zone is defined as the potential space between the lips and cheeks on one side and the tongue on the other; that area or position where the forces between the tongue and cheeks or lips are equal.[2] This zone has been given many names such as dead zone,[3] stable zone,[4] zone of minimal conflict,[5] zone of equilibrium,[6] zone of least interference,[7] and potential denture space. Increasing denture stability by using neutral zone of the patient is not only significant in resorbed ridges, but also proves highly useful in unstable denture bases due to other causes such as glossectomy, hyperactive perioral muscles, fractured and/or malunited jaws, or any other neuromuscular condition that can cause unstable denture bases. It is for these patients that the neutral zone concept becomes increasingly significant and proves highly beneficial for the long term without any surgical intervention.

This clinical report presents prosthodontic management of the edentulous patient with bilateral para-symphyseal mandibular fracture with complete denture fabricated using neutral zone concept.

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CLINICAL REPORT

A 75-year-old male patient reported with the chief complaint of old unstable mandibular complete denture and a history of bucket handle fracture in the para-symphyseal region bilaterally one month back. There was no significant medical history. On intraoral examination it was found that he was completely edentulous with moderately resorbed maxillary arch and lower arch showed substantial amount of fibrotic scar tissue on the ridge portion presenting as a bulge in the first molar region; with

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residual ridge, anterior to the scar tissue, severely resorbed (Figure 1). Upon radiographic examination, it was found that there was a mal-union of the fractured part with full fractured segment displaced and rotated downward. The patient was advised for the fabrication of upper and lower complete denture with neutral zone technique as other treatment options like implant-supported complete denture was not feasible due to the age and cost factors.

Primary/Secondary Impressions

Primary impressions were made conventionally with irreversible hydrocolloid and custom tray fabricated. For the upper jaw, border molding was carried out conventionally, and a final impression was made with light body, whereas secondary impression for the lower jaw was made using putty and light body addition silicone impression material. The final cast for the upper jaw and secondary cast for the lower jaw were poured. Custom tray, with auto-polymerizing resin, was then made on this lower secondary cast for a final impression. Border molding with low fusing impression compound was done in sections, with posterior section first then anterior. Anteriorly, the resorbed ridge area was also covered in green stick in the border molding procedure. This was then followed by a definitive impression with light body silicone impression material (Figure 2).

Jaw Relation Procedure

Maxillary and mandibular wax occlusion rims were then fabricated on stabilized record bases in the usual manner. Facebow record and Jaw relation was recorded in the conventional manner, occlusion rims were mounted on Hanau articulator (H2 series).

Neutral Zone Approach

After the mounting, with the maxillary wax rim in place, lower wax rim was completely removed from the record base, and an acrylic shim was made at the established vertical height (in contact with maxillary wax rim). This shim was then perforated to enhance mechanical retention to admix material with which neutral zone of the patient is to be recorded. The patient was made to sit in a comfortable, upright position with the head unsupported. The mandibular compound rim was then inserted into patient's mouth and he was asked to perform a series of actions designed to simulate the physiological functioning, such as asking the patient to smile, grin, wide/large mouth opening, pout/purse lips, count from 60 to 70, talk aloud, pronounce the vowels, sip warm water, swallow, slightly protrude the tongue, and lick the lips. These actions were repeated until the compound became hard and record base with compound rim stable. The occlusal surface of the lower compound rim was then scraped with a sharp blade, to the height of acrylic shim and tried on the articulator with the upper wax rim in place (Figure 3).

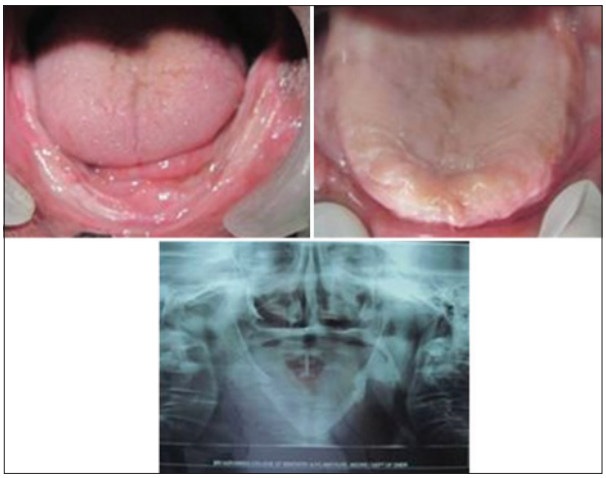

Figure 1: Preoperative photograph and orthopantomogram

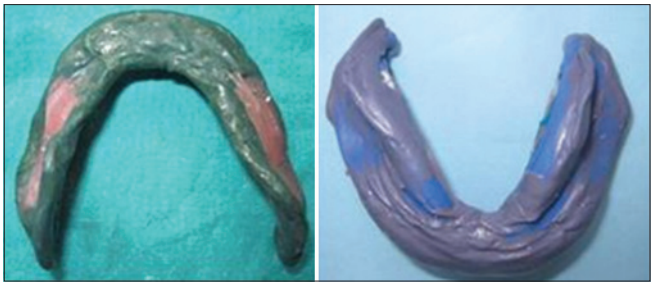

Figure 2: Mandibular final impression

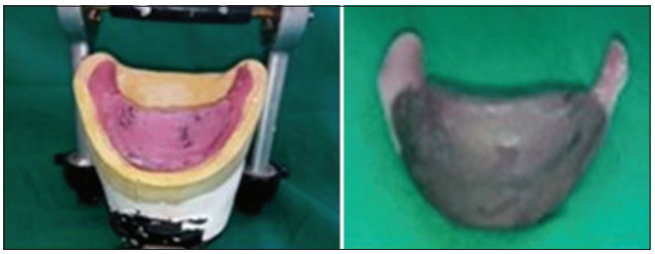

Figure 3: Acrylic shim and neutral zone record in admix material

Neutral Zone Indices

The compound rim was placed on the duplicate master cast. Thick plaster mix was molded around the compound rim, buccally, labially, and lingually; and allowed to set. An intraoral periapical (IOPA) film was coated with petroleum jelly on both the sides and carefully inserted in the plaster mix in the lower central incisor region while the molding procedure. This allowed us to make two sections in the labial index for its easy insertion and removal (Figure 4). Then the molded impression compound rims were removed from the base plate, and the index was replaced and stabilized with wax. The indices preserve the space of the neutral zone. Wax was then poured into the space giving an exact representation of the neutral zone. These newly formed wax rims were then replaced on the articulator.

Teeth Arrangement and Try In

The 0° (cusp-less) teeth were used and maxillary anterior were set first. This was followed by teeth arrangement in the lower wax rim (anterior and posterior). Then the maxillary posteriors were set. Mandibular teeth arrangement was done exactly following the indices. During the setting up of the teeth, their position was checked by putting the indices together around the wax try-in denture. Trimming of the artificial posterior teeth had to be done to accommodate it on the narrow space of neutral zone provided by the patient. Gross balancing was done at this stage to avoid too much trimming of artificial teeth during balancing after denture curing. Wax try-in was done conventionally, and maxillary anteriors were checked for esthetics and phonetics and adjusted accordingly. Since the harmony between the polished denture surface and the surrounding tissues during function is important, it was recorded using metallic oxide impression paste after the try-in (Figure 5). Dentures were processed in the routine manner and were lab remounted. Balancing was done on average values and finished. Polishing for lower denture was done lightly so as to preserve the contour of the flanges (Figure 6).

The patient was recalled periodically to check the tissue response, and the results have been satisfactory.

DISCUSSION

The notion of constructing a complete denture in neutral zone is neither new nor original but, rather, involves an amalgamation of the concepts and ideas of many men into an accomplishable and practical procedure.[8,9]

Complete dentures, in the oral cavity, act as mechanical devices meant for numerous intentions and must be fabricated in understanding with normal neuromuscular function so that it enhances their stability, especially while functioning.[10] As appropriately mentioned by Beresin.[11] "All oral functions such as speech, mastication, swallowing, smiling, and laughing involve the actions of the tongue, lips, cheeks, and floor of the mouth, which are very complex and highly individual. Failure to recognize the cardinal importance of tooth position and flange form and contour often results indentures, which are unstable and unsatisfactory, even though they were skillfully designed and expertly constructed."

This philosophically based complete denture design concept has been shown to be especially effective for mandibular removable prosthesis in affected patients with neuromuscular decline and gross dysfunction or post-cancer or post-trauma anatomic deformity or insufficiency.[12-15]

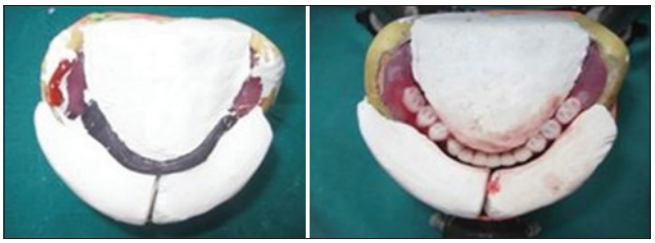

Figure 4: Plaster index of neutral zone

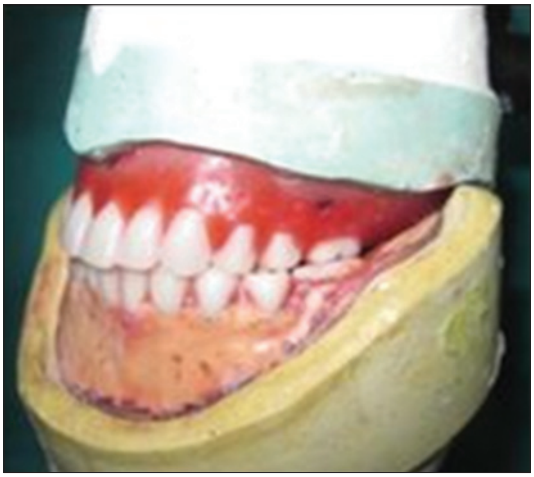

Figure 5: Wax try-in with polished surface impression

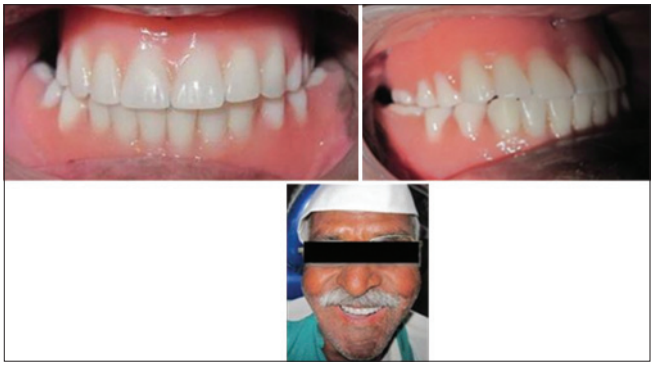

Figure 6: Prosthesis insertion

CONCLUSION

The neutral zone technique for denture fabrication takes advantage of stabilizing potential of surrounding soft tissues improving retention and stability in a compromised situation.

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Case Report

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Scar Endometriosis: A Case Series and Review of Literature

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Abstract

Endometriosis is a common and distressing gynecological problem in women of reproductive age group. Endometriosis is the presence of functioning endometrial tissue outside the uterine cavity, and may be found either inside the pelvis or outside the pelvis. It presents as red, petechial lesions, usually multiple, on the peritoneal surface of the uterus, ovaries, and fallopian tubes. The most common organ that gets involved is the ovary (almost 50% cases) followed by the pouch of Douglas and broad ligament. It can also be present on the bowel, may erode the bowel, and cause passage of blood in stools. In very rare cases, it is found in the thorax, central nervous system and urogenital tract, as also in the skin where previous surgery was undertaken (abdominal surgical scar). Scar endometriosis is rare and difficult to diagnose. Here, we are discussing the pathogenesis, diagnosis, and treatment of this condition along with a review of the literature, so that this paper will increase the awareness of this, often misdiagnosed, rare condition called scar endometriosis.

Key words: Endometriosis, Granuloma, Hemosiderin, Scar

INTRODUCTION

Endometriosis is a common and distressing health problem of women. Its exact prevalence is unknown because it can be diagnosed only after surgery either open or laparoscopy, but it is estimated to be present in 3-10% of women in the reproductive age group, and 25-35% of infertile women. It is seen in 1-2% of women undergoing sterilization or sterilization reversal, in 10% of hysterectomy surgeries, in 16-31% of laparoscopies, and in 53% of adolescents with pelvic pain severe enough to warrant surgical evaluation. Endometriosis is the most common single gynecologic diagnosis responsible for the hospitalization of women aged 15-44, accounting for over 6% of patients.

Endometriosis is the presence of functioning endometrial tissue outside the uterine cavity. It generally occurs in pelvic sites such as ovaries (almost 50%) followed by the uterine cul-de-sac, uterosacral ligaments, posterior surfaces of uterus and broad ligament, and the remaining pelvic peritoneum, bowel, and rectovaginal septum. Extra-pelvic endometriosis can be found in unusual places such as the nervous system, thorax, urinary tract, gastrointestinal tract, and in cutaneous tissues, and its most frequent location is in the abdominal wall.[1,2] Abdominal wall or scar endometriosis usually occurs after surgical procedures, especially after cesarean section.[3] There are reports of endometriosis after tubal ligation, salpingectomy, inguinal hernia repair, ectopic pregnancy, laparoscopy, and hysterectomy.[1,4,5] The incidence of endometriosis after cesarean section has been reported to be 0.03-0.4%.[6,7] A rare case of cutaneous endometriosis has also been reported.[8] Scar endometriosis patients are often referred to the general surgeons because the clinical presentation suggests a surgical cause. We report four cases of scar endometriosis, which were initially diagnosed as stitch granuloma. By presenting this paper, and conducting a review of the literature, we intend to increase the awareness of this rather, rare condition.

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CASE REPORTS

Case 1

A 32-year-old female of para 4, live birth 3 (P4L3) presented with a painful lesion in the stitch line, for the last

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2½ years. The lesion used to increase in size and become more painful during her menstruation. She had a significant history of dysmenorrhea. There was no history of bladder and bowel complaints. She had undergone laparotomy 3 years ago for rupture of the uterus, at an outside center, where rent repair of the uterus and bilateral tubectomy were done. On per abdominal examination, a painful, tender lesion of about 3 cm × 3 cm was found at the upper end of the stitch line (midline vertical), which was smooth surfaced and firm in consistency. The rest of systemic and general physical examination were essentially normal. The ultrasonography (USG) revealed a hypoechoic lesion of size 14 mm × 12 mm above the muscle at the anterior abdominal wall. This was initially suspected to be a stitch granuloma and she was given a course of routine antibiotics and anti-inflammatory agents and asked to come to the gynecologic outpatient clinic regularly, in order to enable us to observe the course of the lesion, but the lesion kept on gradually increasing in size. Fine-needle aspiration cytology (FNAC) of the above lesion showed sheets and clusters of epithelial cells appearing to form glands, degenerated cells, and hemosiderin laden macrophages suggestive of endometriosis (Figure 1).

In view of the above findings, the patient was subjected to surgery during which a mass corresponding to about 3 cm × 3 cm size, found above the rectus sheath was widely excised. The histopathological report confirmed it to be scar endometriosis (Figure 2).

Case 2

A 25-year-old para 3 (P3) female, who underwent lower segment cesarean section 3½ years back presented with a painful lesion at the stitch line (Pfannenstiel incision) for the last 2 years. The lesion used to be more painful and hyperemic during menstruation. She had undergone tubectomy 2½ years ago through the same scar but vertical in the midline (interval sterilization). On per abdominal examination a painful lesion of about 4 cm × 4 cm was found at the right side of the stitch line, which was smooth surfaced and firm in consistency. FNAC revealed hemosiderin laden macrophages and endometrial glands suggestive of endometriosis. The lesion was excised, and histopathological report confirmed it to be scar endometriosis.

Case 3

A 32-year-old woman presented to the surgery clinic with the complaints of pain and swelling on the upper part of cesarean scar for the last 2 years. She had undergone 2 cesarean deliveries in the past, 8 years and 3 years ago. Examination revealed 2 cm × 2 cm mass at the upper part of the cesarean scar. FNAC of mass showed the picture of the endometrium, and so the patient was referred to our unit. She was started on tablet danazol but as the response was partial, she subsequently underwent a wide excision of the mass. Histopathological examination of the excised mass confirmed the diagnosis. Postoperative period was uneventful, but this patient was lost for follow-up after her discharge.

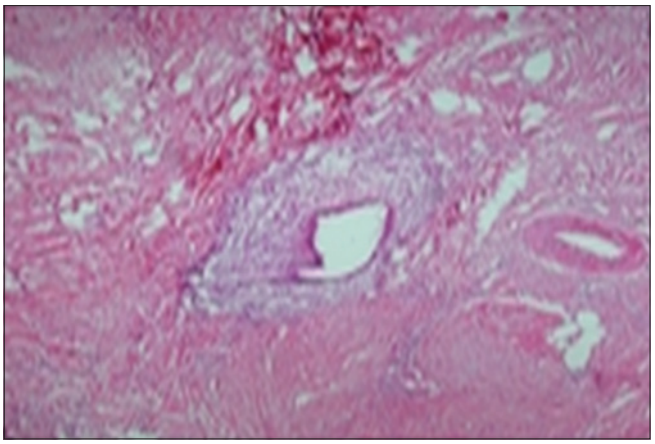

Figure 1: Fine-needle aspiration cytology of scar endometriosis-endometrial glands and stroma in the subcutaneous tissue

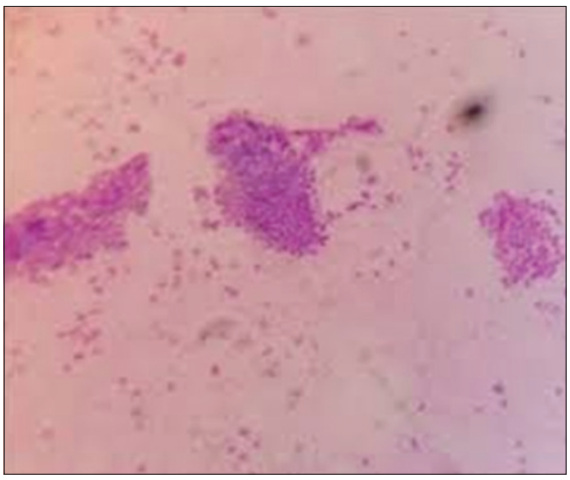

Figure 2: Histopathological exam of scar endometriosis

Case 4

A 33-year-old woman was seen in the surgery clinic with the complaints of swelling and pain at the upper part of cesarean scar for the last 10 years, which was initially present at the time of her menstrual cycle, but later became continuous in nature. She had one prior cesarean delivery 14 years ago, and tubal ligation 10 years ago. Examination revealed a 4 cm × 4 cm tender, subcutaneous mass in upper part of the midline vertical scar. The overlying skin was normal. As a diagnosis of stitch granuloma was made, the patient was taken up for excision of the mass under local anesthesia histopathological examination revealed it to be a case of scar endometriosis and so the patient was referred

to the gynecology outpatient department. The patient's symptoms did not subside even after excision of the mass. As surgery was recently undertaken, we prescribed tablet danazol 200 mg/3 times a day for a period of 4 months. She had no relief whatsoever and so we had to do a wide excision of the mass, and as the defect in the rectus sheath was large, it was closed by prosthetic mesh. The postoperative period was uneventful.

Except one, all the three patients were followed up for a period of 1-5 years following the operation with no signs of recurrence. All patients were seen, and diagnosed between June 2009 and August 2011.

DISCUSSION

Scar endometriosis usually follows previous abdominal surgery especially early hysterotomy and cesarean section. Miraglia *et al.* who analyzed 30 years of incisional endometriosis after cesarean sectio found the incidence of scar endometriosis to be 0.08%.[4] Ectopic pregnancy, salpingostomy, puerperal sterilization, laparoscopy, appendicectomy, episiotomy, vaginal hysterectomy, and hernia repair are other surgical factors for scar endometriosis.[5-7] The reported incidence after mid-trimester abortion is about 1%, as also after cesarean section, ranging from 0.03% to 0.45%.[8] The frequency of scar endometriosis has increased in the recent past because of the increasing numbers of cesarean sections and laparoscopies being performed.[9] Direct mechanical implantation seems to be the most plausible theory for explaining scar endometriosis. During cesarean section, endometrial tissue might be seeded into the wound and under the same hormonal influences, these cells proliferate.[10] The endometrial tissue may have certain abilities that make implantation and transplantation possible during pregnancy. According to this hypothesis, the strongest risk factor for development of scar endometriosis is early hysterotomy for mid-trimester abortions.[11] de Oliveira *et al.* demonstrated that heavy menstrual blood flow and alcohol consumption were positively related to scar endometriosis, and conversely, high parity may be a protecting factor.[12] However, direct implantation of endometrial tissue, cannot explain all cases. There are few cases of primary cutaneous endometriosis without prior surgery, such as at the vulva, perineum, groin, umbilicus, and extremities,[13] as well as nasolacrimal localizations.[14] All four patients of ours presented after an operation on the uterus, three with cesarean sections and one with a laparotomy for rupture of the uterus.

Clinical diagnosis can be made by careful history and physical examination. The patients present with a mass near the previous surgical scars, accompanied by increasing colicky like pain during menstruation.[15] Usually there is a history of gynecological or non-gynecological abdominal operation. In these patients, correct diagnosis depends on careful examination, right questioning and obviously taking endometriosis into consideration. Furthermore, scar endometriosis is a rare entity, and the patients presented with a wide range of duration of cyclical pain from 2½ years to 10 years of the last cesarean section operation. Three patients presented after cesarean section whereas one presented after laparotomy for uterine rupture. The usual presenting symptoms of cyclical pain and increase in the size of mass may be due to hormonal influences that cause changes in size, cutaneous bleeding, and bruising.[16] Our patients also presented with swelling at the scar site and periodic pain at the site, which became continuous later on.

When a proper pre-diagnosis cannot be achieved, scar endometriosis can be easily mistaken for other surgical conditions such as hernia, hematoma, neuroma, suture granuloma, lipoma, abscess, sebaceous cyst, and neoplastic tissue or even metastatic carcinoma,[17] and patients reach the general surgeon first. Often the diagnosis of endometriosis is not suggested until after histology has been performed. Correct preoperative diagnosis is achieved in only 20-50% of these patients.[18] The worth of various methods of investigation, such as USG examination, computed tomography, magnetic resonance imaging (MRI), Doppler sonography or fine-needle biopsy in the diagnosis of scar endometriosis is not clear. Imaging procedures help, rather than confirm, in obtaining a differential diagnosis. USG is the best and most commonly used procedure for abdominal masses, given its practicality and low cost. The mass may appear as a hypoechoic and heterogeneous mass with messy internal echoes. On computed tomographic scanning, the endometrioma (endometriotic mass in subcutaneous tissues) may appear as a circumscribed solid or mixed mass, enhanced by contrast and shows hemorrhage in the lesion. Kinkel *et al.* revealed the sensitivity and specificity of MRI in helping in the diagnosis of endometriomas to be 90-92% and 91-98%.[19] MRI is also a useful modality for pre-surgical mapping of deep pelvic endometriosis. Infiltration of the abdominal wall and subcutaneous tissues is much better assessed by MRI.[20] Tomographic scans and MRI are more useful in demonstrating incisional hernias and differential diagnosis.[21] FNAC was reported in some studies confirming the diagnosis.[22] However, FNAC cytology is a liable method to make the diagnosis of scars, and surgeons must be aware of some diagnoses such as inguinal hernia and re-implantation of potential malignancies during the process. Our opinion of FNAC is that, it is accurate only in cases of large masses, doubtful diagnosis, and atypical clinical presentations.

Histology is the hallmark of diagnosis. It is satisfied if endometrial glands, stroma, and hemosiderin pigment are seen.[23] In general, diagnosis is easy with a microscopic

examination of a standard hematoxylin and eosin-stained slide. Furthermore, the cytologist's experience must be the important point, to clarify diagnosis, and to exclude malignancy.[24]

Local wide excision, with at least 1 cm of margin, is the accurate treatment of choice for scar endometriosis and also for recurrent lesions. Recurrence of the scar is rare, with very few cases having been reported. As expected, the larger and lesions deeper to the muscle or the fasciae are more difficult to excise completely. In large lesions, complete excision of the lesion may entail for closure after resection, the placement of a synthetic mesh, or transfer of tissue.[5] Medical therapy with danazol, progesterone, Gn-Rh agonists, produces only partial recovery, and mostly recurrence occurs after cessation of the treatment with extreme side effects.[25] The incidence of concomitant pelvic endometriosis with scar endometriosis has been reported to be ranging from 14.2% to 26%.[26] Ideally, all patients must be examined for concomitant pelvic endometriosis and at this point, postoperative follow-up should be done for a couple of years and the patient should be under the observation of the gynecologist. Hence, good technique and good care, during cesarean section, may help in preventing endometriosis. All the four patients of ours, who presented to us, were within a gap range of 2 years to 10 years, since the last surgery.

CONCLUSION

We would like to say that one should have a high index of suspicion of scar endometriosis, whenever a woman presents with a painful swelling in the abdominal scar, especially with a history of previous gynecological or obstetric surgery. This condition can be confused with other surgical conditions. Efforts should be made to make a preoperative diagnosis with the help of imaging techniques and FNAC. Medical treatment is not very helpful. Wide excision is the treatment of choice. The patients should be followed up for recurrence.

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Case Report

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Fetus Papyraceous: A Rare Case Report and Review of Literature

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Abstract

Fetus papyraceous (FP) is a rare obstetric complication in multiple gestations. It is defined as a compressed fetus, the mummified, parchment-like remains of a dead twin that is retained *in-utero* after intrauterine death in the second trimester. The data of various reports on FP were collected from internet literature search. Though the maternal and fetal complications in affected cases can be severe, most cases can be managed conservatively without any complications. We report a case of FP with a literature review of maternal and neonatal outcomes and management. Successful outcome is related to careful monitoring during pregnancy.

Key words: Fetal death, Fetus papyraceous, Twin pregnancy

INTRODUCTION

The term fetus papyraceous (FP) is used when intrauterine fetal demise of a twin, early in pregnancy, occurs, with retention of the fetus for a minimum of 10 weeks, resulting in mechanical compression of the small fetus such that it resembles parchment paper.[1] When the fetus dies in early pregnancy, the amniotic fluid, and placental tissue are absorbed and the fetus is compressed between the membranes with the co-living twin. It is usually discovered among the placenta and membranes of its well-developed twin. Appearance of a FP frequently indicates the presence of a hostile intrauterine environment.[2]

FP occurs in subjects with multiple gestations.There is an increase in the incidence of multiple fetal pregnancies as the consequence of advances in assisted reproductive technologies. Prior to antenatal visits and use of ultrasound examination, the diagnosis of FP was only possible after delivery. The advent of real-time ultrasound using the intravaginal probe permitted the diagnosis of multiple gestations as early as 4 weeks after conception. In late second and third trimesters, it is not always possible to diagnose FP by ultrasound examination.[3] But with the advanced ultrasound machines and techniques used today, there are even more early multiple fetal gestations being documented. The death of one twin in first trimester with vanishing twin syndrome is relatively common (up to 29%) and the pregnancy usually continues with little adverse effect on the mother and twin. But, the death of one twin in second or third trimester is more serious with an increased risk for surviving twin and possibility of maternal disseminated intravascular coagulation (DIC). It is emphasized that a close high-risk obstetric management must be used and a careful pediatric follow-up must be done afterward.[4] The sequel of single fetal death in a twin pregnancy depends on gestation and placentation. Conservative management is preferred. Adequate counselling, psychological support, and long-term follow-up are mandatory. If FP is diagnosed antenatally, serial evaluation of the surviving fetus by sonography, biophysical profile, Doppler, and maternal coagulation factors should be done serially. Zygosity and chorionicity evaluation should be performed antenately. The timing and procedure for the termination of a pregnancy with a surviving twin are determined primarily by the maturity of the fetus and type of the placenta.[5] In many cases of FP, there are no complications to the mother or the surviving

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twin. Expectant management with close maternal and fetal surveillance is advised.

Here, we report a case of FP identified on curettage for retained products of conception based on check scan done after normal vaginal delivery in view of ultrasonography (USG) finding of intrauterine death (IUD) of one twin in second trimester.

CASE REPORT

A 25-year-old woman ($G_2P_1L_0$) with 38 weeks of gestation presented to our department, with labor pains. She had pre-eclampsia during the previous pregnancy and an induced preterm delivery of baby weighing 1.5 kg. Baby died 12 hours following birth due to prematurity. During the present pregnancy, first trimester (11 weeks) USG showed dichorionic diamniotic discordant twins. At 17 weeks, USG showed IUD of one twin and live second twin. Serial scans done at 20, 24, and 28 weeks of gestation showed a persistence of dead fetus at the right side of the uterine wall. However, scans done at 32 weeks and 35 weeks gestational age failed to visualize the dead twin due to compression by the live fetus. Throughout the antenatal period, she was followed up regularly for infections, consumptive coagulopathy and also for well-being of the live twin.

On general physical examination, vitals were stable. Abdominal examination showed term size uterus with adequate contractions, cephalic presentation, engaged head, and normal fetal heart rate. On vaginal examination, she was in active labor. Routine investigations and coagulation profile were normal. She delivered vaginally, a live term male baby weighing 2.5 kg within 2 hours of admission without any postpartal complication. As the dead second twin was not expelled within 24 hours following delivery, a check scan was advised which suggested retained products of conception measuring 24 × 18 × 12 mm. The patient underwent check curettage under short general anesthesia on the second post-natal day, and mass measuring 3 × 2 cm (Figure 1) was removed. Histopathology confirmed the diagnosis of FP (Figure 2). Post-procedure patient was stable. She was followed up for 6 weeks every fortnightly, and there were no further complications.

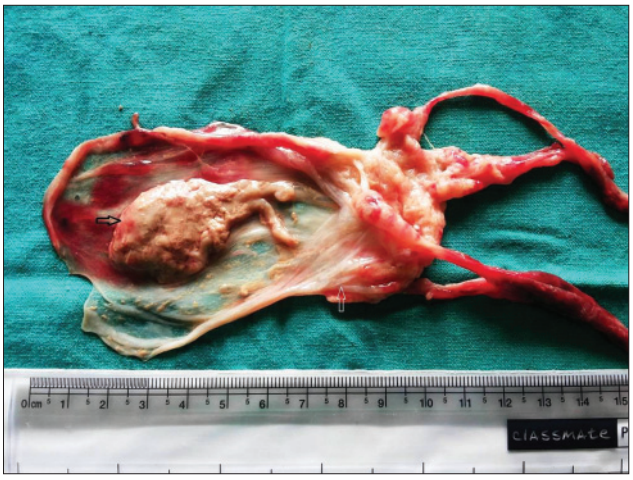

Figure 1: Gross specimen showing dead mummified fetus (black arrow) and the placenta (white arrow)

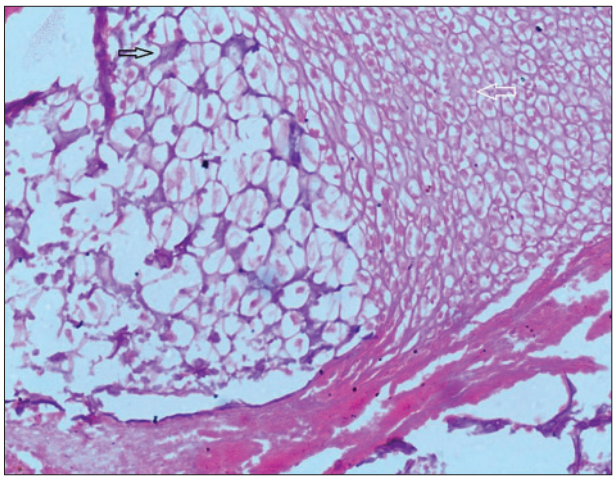

Figure 2: Microscopic appearance showing areas of calcification (black arrow) and areas of ghost cells (white arrow)

DISCUSSION

Being a rare complication, the incidence of FP has been reported at 1 in 12,000 pregnancies and ranges between 1:184 and 1:200 twin pregnancies.[6] But the actual rate of multiple pregnancies is significantly larger than that observed during labor because of the fact that in the course of pregnancy IUD of one or more fetuses may occur.[7] Depending on the gestational period at which fetal death occurs, there are three forms of this complication; vanishing twin syndrome in the first trimester, FP in the second and the macerated twin in the third trimester. In most cases, death occurs in the second trimester.

The only sign of the death of one embryo of a multiple pregnancies in the first 6-8 weeks may be a cyst on the fetal surface of the surviving twin's placenta. After 8 weeks, the death of one embryo, with resorption of amniotic fluid and mummification of the fetal parts, will cause a FP.[8] The degree of compression depends on the time span between fetal death and delivery; the larger the fetus, the more difficult it is to become a FP.[9] Attributable causes for the IUD of one fetus include twin-twin transfusion syndrome, membranous or velamentous cord insertion, true cord knot, cord stricture, placental insufficiency, and congenital anomalies.[10] Cord complications have been

Table 1: Maternal and neonatal outcomes and management of FP

Study	Years	Special features
Airede *et al.*[14]	2005	Healthy female baby weighing 2.5 kg. FP weighing 150 g with obvious musculoskeletal abnormalities
Kursheed *et al.*[4]	2008	Diamniotic dichorionic placenta. Developed pregnancy induced hypertension at 38 weeks gestation treated with methyldopa 500 mg twice daily. Healthy female baby weighing 3 kg. FP weighing about 100 g with placenta 50 g
Manjula *et al.*[15]	2011	Live pre-term female baby delivered by breech presentation weighing 1 kg. Manual removal of placenta with FP weighing 100 g and 8 cm in length. FP obstructed placental expulsion
Rahman *et al.*[5]	2013	Monochorionic monoamniotic placenta. Emergency CS was done in view of breech presentation. Healthy female baby weighing 2.9 kg with FP weighing 700 g delivered
Bozkurt *et al.*[3]	2013	Diamniotic dichorionic pregnancy. Healthy baby weighing 3.2 kg. FP weighing 200 g, measuring 15 cm in length
Dahiya *et al.*[16]	2014	Monochorionic diamniotic twin pregnancy. Healthy male baby weighing 2.8 kg, FP weighing 150 g, 8 cm length. Second fetus was dead with a gestational age of 17 weeks.
Kaur *et al.*[17]	2014	A dead second fetus at 13 weeks 2 days. Emergency CS because of first twin presenting as breech. Female FP weighing 80 g. Diamniotic and dichorionic pregnancy
Mynso *et al.*[18]	2015	Twin FP, about 13.5 and 9.5 cm in length, flattened, parchment-like and compressed. Single healthy male baby weighing 3.1 kg
Present report	2015	Dichorionic diamniotic discordant twins. A live term male baby weighing 2.5 kg. Check curettage on second post-natal day showed mass measuring 3×2 cm, with histopathology confirming FP

FP: Fetus papyraceus, CS: Caesarean section

found in 30%, congenital anomalies in 25% of cases and birth weight discordance has been responsible in 11-12% of cases. In our case, there was discordant growth.

The primary concern of FP is its effect on mother and surviving co-twin. The prognosis for surviving fetuses of a multigestational pregnancy with a spontaneous fetal demise depends on several factors: Number of the fetuses, gestational age at the time of the death, the reason for the death, the chorionicity and the length of time between demise and delivery of surviving fetus/es (Table 1). In dichorionic twins, the prognosis for the surviving twin is relatively better and immaturity is the risk factor. In the case of monochorionic twins, the prognosis is poor and associated with neurological damage in the survivor.[11]

In a the systematic review by Ong *et al.* of prognosis for the co-twin showed the odds of IUD of the co-twin, neurological abnormality and pre-term labor among survivors to be six, four, and two times higher in monochorionic compared with dichorionic pregnancies.[12] But in our case, there was no such complication seen in surviving co-twin.

Maternal complications include pre-term labor, infection from a retained fetus, severe puerperal hemorrhage, consumptive coagulopathy, and obstruction by a low-lying FP causing dystocia leading to caesarean delivery. It is necessary to make a timely diagnosis to prevent severe complications. It is important to reassure the patient that normal outcome is expected in most of the cases. Maternal consumptive coagulopathy as a complication of a late fetal demise is a rarely reported complication.[13] The possible explanation for such a low incidence of consumptive coagulopathy is the short relative interval from death until delivery of the surviving fetus. Gross disruption of the maternal coagulation mechanism rarely develops within 1-month after the fetal death, although, if retained longer, approximately 25% will develop a coagulopathy. However, in many cases of FP, there are no complications to the mother or the surviving twin, similar to our case.

Due to the possible occurrence of several complications, the condition of both the mother and the surviving fetus requires close supervision and specialist obstetric care. It is necessary to document the IUD of one of the fetuses, for legal protection against the accusation of malpractice and having caused neurological damage to the child during birth.

CONCLUSION

Delayed recognition of FP can have a grave prognosis. Hence, early diagnosis and prevention to avoid the possible complications is the best measure. Patients should be followed closely for fetal well-being and the possibility of maternal infection or consumptive coagulopathy by serial ultrasound examinations, hematological, and biochemical monitoring of the mother in the antenatal period and also after the delivery. A complete and careful examination of the placenta is must.

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Case Pictorial

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Use of "Red-dot" System in Diagnosing Unique Fractures by Different Views

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The mandible is the largest and only movable facial bone. It begins as two separate bones and unites anteriorly, when the child approaches 1-year of the age.[1] Its unique shape causes it to fracture easily, typically in more than one place.[2] Based on these features, radiographs are taken as initial aid for diagnosis of fractures especially in resource challenged management system.

A 34-year male patient reported to the Department of Oral Medicine and Radiology with a history of trauma in road traffic accident. On extra-oral examination, abrasion and swelling on left temporomandibular joint and chin region with limited mouth opening was noted with tenderness on palpation. On intraoral examination (Figure 1), active bleeding with clinically missing teeth was noted in the lower anterior region from 32 to 43 and sutures were placed. The sublingual hematoma was also observed in the anterior region. Panoramic radiograph and mandibular anterior topographic occlusal views were taken keeping "ring bone rule" in mind. Panoramic

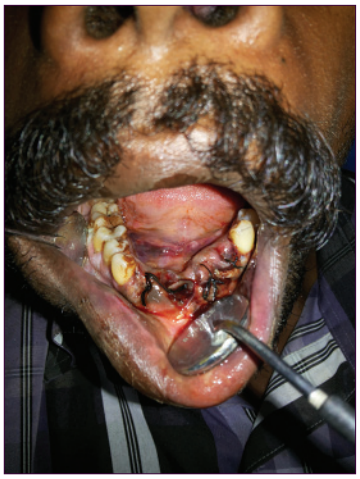

Figure 1: Intraorally clinically missing teeth from 32 to 43 with sublingual hematoma

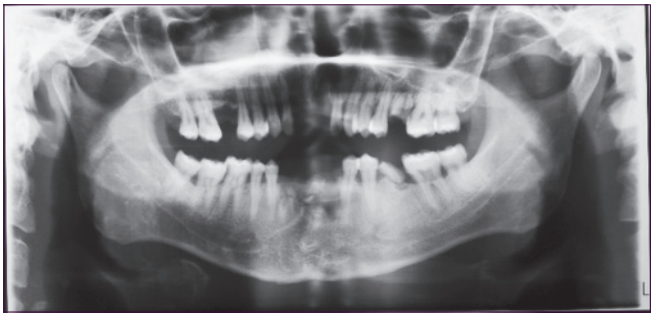

Figure 2: Panoramic view showing empty sockets in relation to lower anterior mandible region from 32 to 42, and root remnant in socket of 43 with no other mandibular fracture

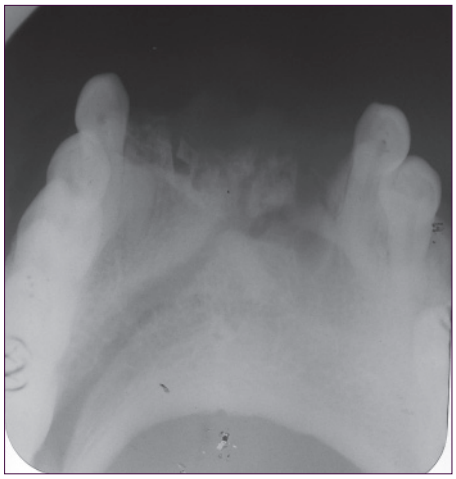

Figure 3: Topographic occlusal view showing a partial radiolucent line extending from alveolar crest of 41 region running obliquely downwards and posteriorly to lower border of mandible in 45 region suggestive of lingual cortical plate fracture

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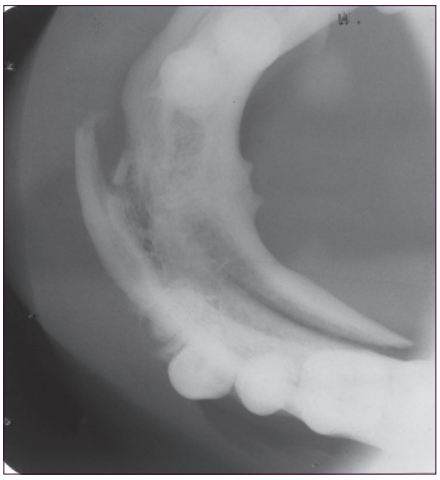

Figure 4: True occlusal radiograph showed two separate fracture lines in anterior mandibular region suggesting two separate buccal and lingual cortical plates fractures

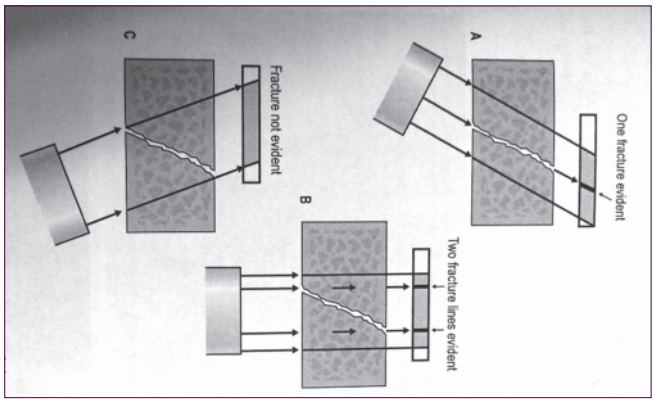

Figure 5: Digrammatic illustration of how position of film and X-ray tube head in relation to a fracture can affect the final image

view (Figure 2) showed empty sockets in relation to lower anterior mandible region from 32 to 42, and root remnant in socket of 43 with no other mandibular fracture. Topographic Occlusal view (Figure 3) showed a partial radiolucent line with progressive increase in width extending from alveolar crest of 41 region running obliquely downward and posteriorly to lower border of mandible in 45 region suggestive of lingual cortical plate fracture. As unexpectedly, no fracture was observed in the panoramic radiograph, according to Red-dot diagnosis, an anterior mandibular true occlusal radiograph (Figure 4) was taken to confirm displacement of fracture segment lingually.[3] Surprisingly, true occlusal radiograph showed two separate fracture lines in the anterior mandibular region. One fracture line was running from 41 region extending lingually with displacement of lingual cortical plate in 45 region as was shown in topographic occlusal radiograph and other fracture line was seen running from 32 region extending facially with displacement of fracture segment in 42 region.

Points to Ponder

1. Because of limitation radiographic images (Figure 5) that at least two views, at different angulations, are required.
2. If displacement and separation are minimal, there may be no radiographic evidence of a fracture at all.[4]

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Case Pictorial

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Parasitic Twin: A Case Report

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Parasitic twin occurs when a developing monozygotic twin embryo does not fully separate, and one embryo maintains dominant development at the expense of the other which becomes vestigial. It occurs in 10% of all conjoined twins.[1] The underdeveloped twin is defined as parasitic because it is wholly dependent on the body functions of the completely formed fetus which called the autosite.[2] The parasitic twin is so malformed and incomplete that it typically consists entirely of extra limbs or organs. Although the vestigial limbs may have bones, muscles and nerve endings, they are not under control of the host.[3]

A 29 years male with a huge mass in left temporal region since birth reported to the department (Figures 1-3). The mass grossly looked like a fetus and was painless having mixed consistency (soft to hard) and slightly movable in all directions. The person belonged to the tea garden community of Assam and was born of a non- consanguineous marriage without any suggestive family or antenatal history. Computed tomography scan revealed (Figures 4 and 5). An incompletely formed parasitic twin communicating with the left petrous and squamous temporal bones of the patient; the host. Hypoplastic phalanges, tarsal bones, tibia, femur, and pelvic

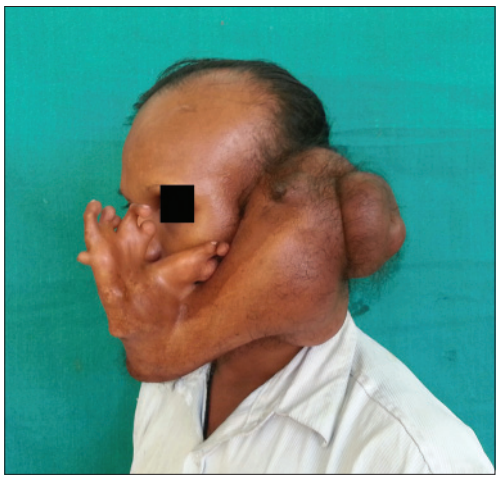

Figure 1: Clinical picture showing the parasitic twin in situ, lateral view

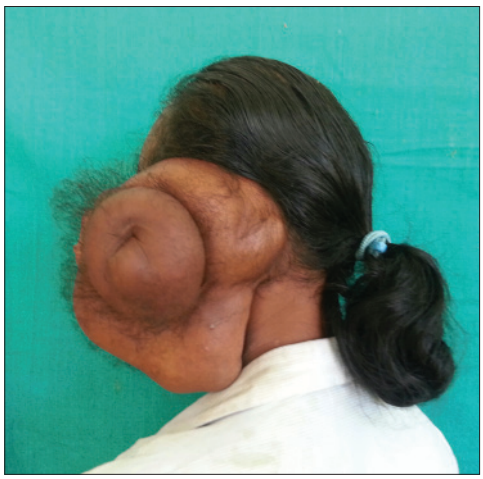

Figure 2: Clinical picture showing the parasitic twin in situ, posterior view

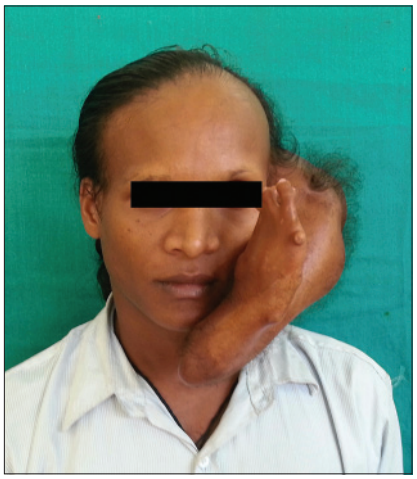

Figure 3: Clinical picture showing the parasitic twin in situ, anterior view

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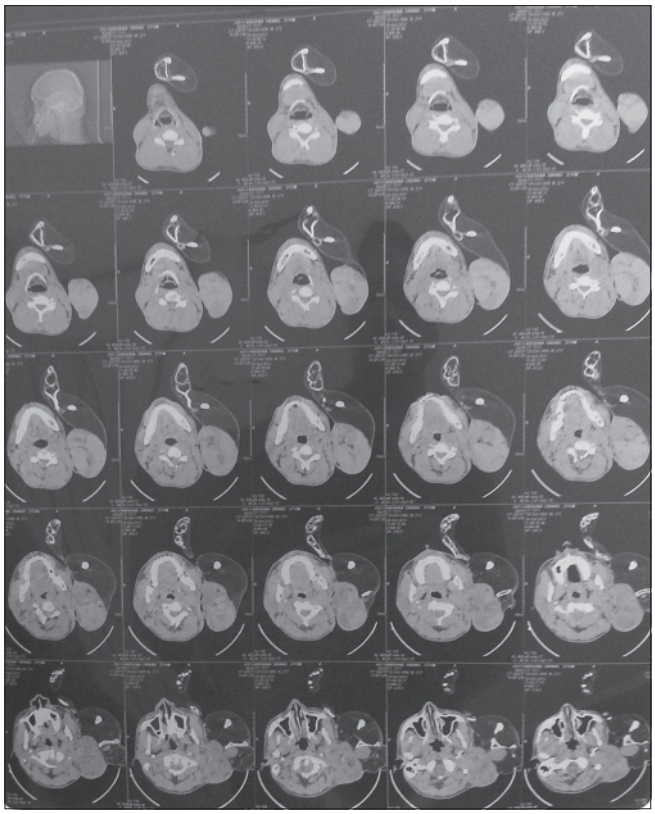

Figure 4: Computed tomography scan showing coronal sections at various levels

bones of the parasitic twin were noted. A cystic component measuring 6.7 cm × 4.2 cm × 7.5 cm was also noted.

- A bony defect in the greater wing of the sphenoid and squamous temporal bones with sclerosis and hypertrophy of left side of the sphenoid, squamous temporal and left petromastoid bones of the host.
- The bilateral cerebral parenchyma of the host appeared normal with non-visualization of a basitemporal lobe in the left side with evidence of fatty components of the parasitic twin.
- Left mastoid air cells and the middle ear cavity were hypoplastic, and the ossicles were absent. Excision was planned as separation was possible, but the patient had refused to undergo surgery.

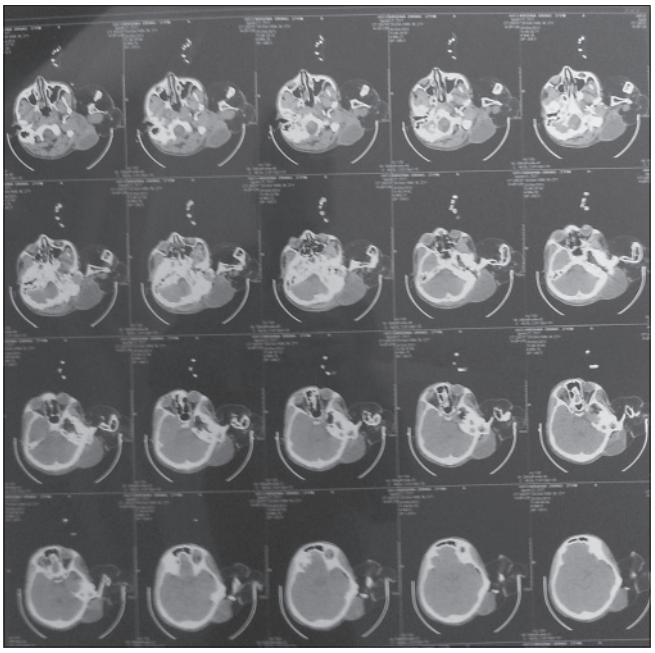

Figure 5: Computed tomography scan showing coronal sections at various levels

Points to Ponder

1. The parasitic twin is a rare condition occurring in 10% of all conjoint twins; the incidence of which is 1.58 per 100,000 live births.
2. The parasitic twin is anencephalic and lacks some internal organs for survival on its own.

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