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## EDITORIAL

## Practicing Evidenced Based Medicine for Common Paediatric Problems

KG Mostafa

Every truth is relative to the time and knowledge that is acquired, needs to be refreshed timely. This is especially true for medical science. When a student enters into a medical college and comes out from it there would be an approximate gap of five years. Many a times the knowledge that has been acquired changes. Many a times a medical graduate continues to apply the same knowledge even after ten or twenty years of his graduation. The system, in this country never felt the responsibility of doing compulsory continued medical education (CME). This scenario was also true in many western countries but they felt the need of refreshing the acquired knowledge at medical school and timely started compulsory CME. Applying the acquired knowledge in patient care for better outcome is one of the most important features of medical education. If the acquired knowledge is out of date and applied, the outcome may not be optimal. This is where the concept of Evidenced Based Practice started. Many of us are familiar with this Evidence Based Medicine (EBM) and thanks to the World Health Organization's HINARI initiative, because of which we can update our knowledge in this country. We read recent articles, especially those with randomized double blinded trials and meta- analysis of these studies and the results we say is level I. We also look the Cochrane data base and try to find out whether the knowledge

that we acquired at medical school is still true or not. Many times although there are enough evidences to change our practice, but we are reluctant to follow the rules, maybe because of some fear in our heart. The best example for this is cough mixtures, vitamins, antibiotics in a child with or without signs of pneumonia.

Antihistamines in monotherapy in children as well as in adults; do not alleviate to a clinical extent the symptoms such as nasal congestion, rhinorrhoea and sneezing, or subjective improvement of the common cold. First generation antihistamines also cause more side-effects than placebo; in particular they increase sedation in cold sufferers. Combinations of antihistamines with decongestives are not effective in small children. In older children and adults most trials show a beneficial effect on general recovery as well as on nasal symptoms. However, it is not clear whether these effects are clinically significant[1]. WHO has removed all cough mixtures from the essential drugs list, there is little doubt that relief is offered by these preparations. It is estimated that every year approximately more than eight hundred million taka is spent to buy cough mixtures in under-five year old children which is often more than the country's budget for child health [2]. But we continue to prescribe these medicines and because of our practice, patient and guardians continue to have this over the counter. When will we stop this?



There were many studies each investigating multiple antibiotics with different methodologies. For treatment of ambulatory patients with Community Acquired Pneumonia, amoxycillin was better than co-trimoxazole; there was no difference between azithromycin and erythromycin, or between cefpodoxime and co-amoxycylavulanic acid [3]. Although these statements is generated by looking at the Randomized Controlled Trials which we call Level I evidence, but we continue to use costly drugs (cefpodoxime, co-amoxycylavulanic acid) for outpatient clinics and to children with non-severe pneumonia without thinking whether the caretaker can afford it or not? There is insufficient evidence of benefit to warrant the use of antibiotics for upper respiratory tract infections in children or adults. Antibiotics cause significant adverse effects in adults [4]. In a study of 100 prescriptions with the diagnosis of Upper Respiratory Tract Infections, it was found that 97% of prescriptions from OPD had antibiotics[5]. It is obvious that still we prescribe antibiotics for nasopharyngitis. Overuse of antibiotics and this practice of professionals often motivate the medical shop counter people to give antibiotics whenever someone asks medicine for fever with cough. Let us ask ourselves when are we going to change our practice with the evidences we

read as EBM? When will the health system include a compulsory CME for medical professionals in this country? It is high time for teaching institutions to start compulsory CME for optimal care of patients and education of its students.

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## Original Article

## Outcome of Stapled Gastrointestinal Anastomosis: A Prospective Study

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### ABSTRACT:

**Background:** Gastro-intestinal stapler technique is new in our country. The aim of this prospective study is to compare of stapled gastrointestinal anastomosis with conventional hand suture anastomosis.

**Methodology:** Between July 2011 to December 2012, 100 patients in the department of Surgery, Sir Salimullah Medical College & Mitford Hospital required gastrointestinal resection and anastomosis were selected for the study. Sampling technique was purposive, 50 patients were in stapled group and 50 were in conventional hand sewn group.

**Results:** Mean time (minutes) required in stapled groups in partial gastrectomy  $16.50 \pm 1.20$ , in right hemicolectomy  $18.44 \pm 4.39$ , in left hemicolectomy  $16.42 \pm 1.27$ , in anterior resection  $22.50 \pm 2.16$  and in hand sewn technique partial gastrectomy  $22.75 \pm 1.87$ , in right hemicolectomy  $21.85 \pm 2.31$ , in left hemicolectomy  $23.57 \pm 1.27$ , in anterior resection  $29.20 \pm 1.09$  minutes, that was statically significant ( $P < .001$ ).

**Keywords:** Stapler device, gut anastomosis.

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### Introduction

Gastrointestinal anastomosis is common surgical procedure which is being done on different situations from centuries back. From earlier days it is done manual anastomotic technique by needles and sutures. For last few decades stapled devices are being used to make the

gastrointestinal anastomosis. Stapled anastomosis claims some advantages over hand sewn, such as better anastomotic security, reduced tissue trauma, better blood supply, minimum tissue edema, uniformity of suture, adequate lumen, short operation time and easier anastomosis in difficult place such as deep



pelvis and thoracic cavity. The use of stapled device by our surgeon is very limited. There are limited studies on these topics in our country. This study has been designed a comparative study of stapled technique and traditional hand sewn technique in gastrointestinal surgery in our institute.

#### Materials and methods

Between July 2011 to December 2012, 100 patients in the department of Surgery, Sir Salimullah Medical College requiring gastrointestinal resection and anastomosis were selected for the study. Patients with co morbid disease such as anaemia, jaundice, heart disease and inoperable cases were excluded from the study. The sampling technique was purposive. Fifty patients in hand sewn (control group) and fifty patients in stapled anastomosis group. Ethical clearance of the study was taken from the Ethical Review Committee, Sir Salimullah Medical College.

Data were collected in preform data collection sheet. Data of outcome variable were time required for surgery, post operative complication and post operative hospital stay. Post operative complication was anastomotic haemorrhage, anastomotic leakage, paralytic ileus and surgical site infection.

After collection of data these were analyzed by SPSS-19 (Statistical Package for Social Sciences) version analysis program. Statistical analysis of the mean of continuous variable was performed by unpaired t test. Significant test of categorical variable were performed with Chi-square test with 95% confidence interval to make inference. P value less than .05 was considered as significant.

#### Results

In this study 66 were male and 34 were female. Out of 66 male patients 27(54%) were stapled group and 39(78%) were in

hand sewn group. Among the 34 female patients 23(46%) were stapled group and 11(22%) were in hand sewn group.

The age distribution of the study was  $49.04 \pm 12.04$  years in stapled group and  $53.30 \pm 13.03$  year's in hand sewn group. The age distribution of 100 populations was  $51.17 \pm 12.68$  years.

In stapled group 28(56%) were carcinoma stomach, 09(18%) were carcinoma right colon, 07(14%) were carcinoma left colon and 06(12%) were carcinoma rectum. In hand sewn group 28(56%) were carcinoma stomach, 09(18%) were carcinoma right colon, 07(14%) were carcinoma left colon and 06(12%) were carcinoma rectum.

In the staple group 28(56%) were gastro-jejunal, 16(32%) were colo-colic and 06(12%) were colo-rectal anastomosis. In hand sewn group 28(56%) were gastro-jejunal, 16(32%) were colo-colic and 06(12%) were colo-rectal anastomosis.

Mean time required in stapled group in partial gastrectomy  $16.50 \pm 1.20$  minutes, in right hemicolectomy  $18.44 \pm 4.39$  minutes, in left hemicolectomy  $16.42 \pm 1.27$  minutes and in anterior resection  $22.50 \pm 2.16$  minutes. In hand sewn group partial gastrectomy, right hemicolectomy, left hemicolectomy and anterior resection were  $22.75 \pm 1.87$ ,  $21.85 \pm 2.31$ , and  $23.57 \pm 1.27$  and  $29.20 \pm 1.09$  minutes, the was statistically significant ( $P < 0.05$ ).

Out of 100 patients 77 had uneventful recovery, 33 had post operative complication. 15 patients in stapled group and 17 patients in hand sewn group which was not statistically significant ( $P = 0.09$ ).

Mean post operative hospital stay was  $10.70 \pm 1.07$  days in stapled group and  $11.05 \pm 2.02$  days in hand sewn group.

#### Discussion:

Stapled group was younger than hand sewn group but it was statistically



insignificant. There was male predominance in this study. Time required for anastomosis in this study, stapled group required less time than hand sewn group. The overall difference between two groups was 5.70 minutes and it was statistically significant ( $P<.05$ ). Other studies such as-Didolker et al (1986) difference of 10 minutes, Sarker et al (1994) showed it 8 minutes and Fingerhut et al (1995) also showed it 8 minutes which is close to this study. But Weil and Scherz (1981) showed difference of two groups was 14 minutes, which did not support this study.

In stapled technique needs less time for anastomosis because rapid and easy application (materials for anastomosis are prepared commercially as organized fashion which need single fire only). But in hand sewn technique techniques needs more time because multiples bites require for completion of anastomosis.

Post operative complication in this study was in the form of anastomotic hemorrhage, anastomotic leakage, post operative paralytic ileus and surgical site infection. There were post operative complication in 15 cases of stapled and 17 cases were in hand sewn group. This was statistically insignificant. The finding is similar to Kratcht et al (1993). But Chassin et al (1978), Scher et al (1982), Brennan et al (1982), George et al (1991), Cuk et al (1994) shows some differences. Probably gut disparity, gut edema, excessive gap of knot or excessive tightness may cause these differences.

Mean post operative hospital stay less in stapled. Fazzio et al (1985) and Didolker et al (1996) both shown post operative hospital stay overall 10.6 days. There are some differences with Adloff et al (1980) and Fingerhut et al (1995), they showed post operative hospital stay 18 versus 19.6

days and 13 versus 14 days. Mean post operative hospital stay is less in stapled technique because early appearing of bowel sound, early oral diet and early movement of the patient.

Cost effectiveness not assessed in this study. Isolated cost of only device may indicate it to be expensive. But it should be balanced with the ultimate cost, related to the length of operative procedure, hospital stay price of sutures and others.

#### Conclusions:

After statistical analysis and significance testing, the operating time only significant between two groups. Post operative complication and post operative hospital stay were not significant. It is difficult to make final comment on this small series of study with many limitations. But it can be concluded that stapled at least to some extent is better than hand sewn surgery in gastro intestinal anastomosis.

Table I: Demographic and outcome of the study

	Stapled technique (mean ±SD)	Hand sewn technique (mean±SD)	P
Sex			
male	27(54%)	39(78%)	.09
female	23(46%)	11(22%)	
Type of operation			
Partial gastrectomy	28(56%)	28(56%)	
Right hemicolectomy	09(18%)	09(18%)	
Left hemicolectomy	07(14%)	07(14%)	
Anterior resection	06(12%)	06(12%)	
Time required for surgery (days)	16.50±1.20	22.75±1.87	<.001
Partial gastrectomy	18.44±4.39	21.85±2.31	<.001
Right hemicolectomy	16.42±1.72	23.57±1.27	<.001
Left hemicolectomy	22.50±2.16	29.20±1.09	<.001
Anterior resection			
Post operative complication	15(30%)	17(34%)	.09
Hospital stay(days)	10.70±1.07	11.50±2.02	.08

Table I: Shows the demographic and outcome of the study. The operation time

was less in stapled group stapled group and was statistically significant (<.001)

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## Original Article

## Biochemical and Clinical Assessment of Thyroid Status in Patients with Thyroid Disorders in Satkhira Medical College Hospital Out Patient Department

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Q A Ahmed<sup>6</sup>, MM Rahman<sup>7</sup>, S Afroz<sup>8</sup>

### Abstract:

**Objective of this study:** This study aimed at assessing the thyroid status in Satkhira (Southern Region of Bangladesh near the Bay of Bengal) where the prevalence of goitre is increasing day by day. **Material and Methods:** A cross-sectional study was conducted in Satkhira Medical College Hospital on 150 thyroid patients (136 female, 14 male) referred during the period between January 2016 to December 2017. Their ages ranged between 10 to 60 years. After clinical evaluation and data collection through a questionnaire, serum concentrations of TSH, total triiodothyronine (TT3), and total thyroxine (TT4) were measured by radioimmunoassay. **Results:** The frequency of thyroid disorder was common in the age group between 21-30 years, and higher in females 91% (136) than in males 9% (14). The maximum age group was in 21 to 30 years 80(3.33%) The common diet taken in the rural and urban area was the rice and wheat. 41.75% of the thyroid patients had family history of thyroid diseases, 38% of the subjects didn't use the iodized salt. The percentage of patients with euthyroid was significantly higher 93 (62%) compared with 42 (28%) of hyper and 15(10%) of hypothyroidism. **Conclusion:** The prevalence of thyroid diseases was found higher in this area, with strong association with the food intake and genetic background, a problem needing to be considered seriously.

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### Introduction:

More than one billion persons are at risk of iodine deficiency worldwide and 200 millions have goitre (Elnour et al., 2000). Although iodine deficiency is the main factor in the aetiology of endemic goitre (Ermans et al., 1969), the additional role of goitrogens has been shown or suspected in some areas. In Bangladesh endemic goiter frequently occur in Northern area of the country, but unlikely it is increasing in Satkhira district close to sea area. We have no explanation why a sea coastal area is going for increasing goitre. We need to evaluate further for the aetipathogenesis of goitre in sea coastal area like Satkhira.

### Materials and Methods:

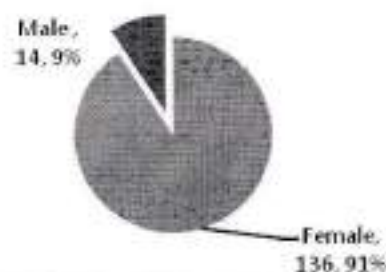
A cross-sectional study was conducted in Satkhira Medical College Hospital between January 2016 to December 2016 upon the thyroid patients (age between 6 years to 65 years) were referred during the said period. Patients using thyroid drugs or other drugs affecting thyroid function were excluded in this study. A pre questionnaire was designed to include data information for all participants. The data were collected by our team members Assistant Professor of ENT, Biochemistry and from Medicine OPD of Satkhira Medical College And Hospital. The clinical evaluation was assessed in ENT OPD. Goitre was diagnosed and graded according to World Health Organization criteria (Delange et al., 1986). After written consent, 5 ml blood was collected by venepuncture in a plain tube from each individual of study population. The blood was allowed to clot at room temperature for 30 minutes. Serum was separated by centrifugation at 1800 rpm for 5 minutes and stored in until analysis. Serum total thyroxine (TT4) and Total triiodothyronine (TT3) were analyzed by

radioimmunoassay (RIA) methods as previously described.

### Results:

150 thyroid patients were included in this study. The frequency of thyroid disorder was common in the age group between 21-30 years, and higher in females 91% (136) than in males 9% (14). The maximum age group was in 21 to 30 years 80(53.33%). The common diet taken in the rural and urban area was the rice and wheat. 41.75% of the thyroid patients had family history of thyroid disease. 38% of the subjects didn't use the iodized salt. The percentage of patients with euthyroid was significantly higher 93 (62%) compared with 42 (28%) of hyper and 15(10%) of hypothyroidism.

Sex distribution of patient n=150



Age distribution of patient n=150

Age group	Frequency
10 -20	23 (15.33%)
21-30	80(53.33%)
31-40	22 (14.66%)
41-50	15(10%)
51-60	10 (6.6%)

Biochemical distribution n=150

Euthyroid	93 (62%)
Hyper thyroid	42 (28%)
Hypothyroid	15 (10%)

### Discussion:

In Bangladesh the prevalence of goitre is high in adults, pregnant women, and



children. Goitres are also very common in Arabian country like South Sudan (Eltom et al., 1985; Eltom et al., 1984; Abdel-Wahab et al., 1984; Osman et al., 1983), and in newborns. Iodine deficiency in Kordofan State in Central Sudan was also reported (Elnagar et al., 1997). FSH, LH, and hCG had been reported to have a thyrotropic action and they suppress TSH level (Goodwin et al., 1992; Yoshimura and Herselman, 1995; Dwalbiet, 2001). This notion may explain our finding of high frequency of goitre in females than in males, which is comparable with the study done by Dawelbiet in 2001. In the present study, the frequency of thyroid disorder was common in the age group between 21-30 years, and higher in females 91% (136) than in males 9% (14). The maximum age group was in 21 to 30 years 80(3.33%). The common diet taken in the rural and urban area was the rice and wheat. 41.75% of the thyroid patients had family history of thyroid disease. 38% of the subjects didn't use the iodized salt. Interestingly, most of our study subjects were from rural areas (88%) 38% of them didn't use iodized salt, and they didn't take iodized salt that was recommended by the WHO in 1993. This notion may explain the higher percentage of goitre in all the euthyroids and 71.4% of the hypothyroids. In this study, 28% of the thyroid patients were hyperthyroid and 10% were hypothyroid most likely due to the presence of some genetic or other factors that contribute to the prevalence of hyperthyroidism in this area, a notion supported by the high frequency of family related disease status. Despite the small sample size in this study which may not completely reflect the situation in this area, these results highlight the situation of the biochemical and clinical status of goitre. However, further studies are

needed to support our findings and to assess the iodine status in this region.

### Conclusion:

The prevalence of thyroid diseases was found higher in this area, with strong association with the food intake and genetic background, a problem needing to be considered seriously.

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## Original Article

## Transfusion Dependent Thalassaemia Patients on Desferrioxamine Treatment- Our Experience in General Hospital Khulna

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### ABSTRACT

**Introduction:** The quality of life of transfusion dependent thalassaemia patients is affected by the disease itself and iron overload complications from repeated blood transfusion. Desferrioxamine has been used to remove the excess iron, resulting in decreased mortality and morbidity. In Bangladesh, a significant proportion of the transfusion-dependent thalassaemia patients are not prescribed desferrioxamine, due to its high cost, especially as it is not subsidized by the government. The aim of this study was to measure the quality of life of thalassaemia patients on desferrioxamine treatment. **Methods:** A cross-sectional study was performed on all transfusion-dependent thalassaemia patients on follow-up at General Hospital Khulna January 2013- July 2014. Quality-of-life scores were measured by using specially designed questionnaires, while diseases related to iron overload complications were obtained from the medical records. Use of desferrioxamine was elicited through interviews and validated by drug records. Quality-adjusted life-years (QALYs) presented were formulated from residual life-years and quality-of-life scores. **Results:** A total of 57 transfusion-dependent thalassaemia patients were recruited, with 38 (67%) male and 19 (33%) female, male female ratio is about 2:1. patients on sub-optimum and optimum desferrioxamine treatments, respectively. QALYs were higher in patients on optimum desferrioxamine than patients on sub-optimum desferrioxamine. QALYs were associated with the level of serum ferritin, iron overload complications and total family income, level of education of parents. **Conclusion:** Optimum desferrioxamine usage reduces iron overload complications and provides a better quality of life.

**Keywords:** Desferrioxamine treatment, iron overload complications, school performance

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## INTRODUCTION

Thalassaemia is a genetic disorder affecting globin chain synthesis with various clinical manifestations, depending on the number and the type of globin chain affected. The more severe forms are beta-thalassaemia major, which warrants regular blood transfusion at an early age, and thalassaemia intermedia which presents later and require less frequent transfusions.

The aim of regular blood transfusions is to eliminate the primary complication of severe thalassaemia by ameliorating anaemia and suppressing erythropoiesis. Blood transfusion given to that patients usually at an early age, many develop complications of iron overload and blood transmitted infections. Among the common diseases that are related to high iron load are heart failure, liver fibrosis, diabetes mellitus, growth retardation and delayed puberty[1]. Iron chelator is needed to remove the toxic iron and desferrioxamine (desferrioxamine clinically known as Desferal [Norvatis]) had been proved to reduce the iron load and the complications of iron overload[2]. Since the introduction of desferrioxamine, the morbidity and mortality related to thalassaemia have been reduced significantly. The quality of life (QOL) should be considered an important index of effective treatment. An assessment of QOL differs from other forms of medical assessment in that it focuses on the individuals' own views of their well-being and assesses other aspects of life, giving a more holistic view of well-being. Several studies had looked into the domains of quality life that is affected by thalassaemia and its treatment. Pakbaz et al suggested that emotional functioning is one of the impaired QOL domain in thalassaemia patients[3]. However, several

other QOL studies in adult thalassaemia had shown that the treatment and cultural differences did not have any major effect on their QOL. A case-control study which measured the QOL in thalassaemia children was conducted in Kuala Lumpur Hospital by Ismail et al, where PedsQL 4.0 was used as the health-related QOL instrument.

The questionnaires were administered to thalassaemia children receiving blood transfusions and to healthy school children of the same age range as the control group. The authors reported that the scores for physical, social and school functioning domains in thalassaemia patients were significantly lower than the healthy controls. However, they did not differentiate the scores according to usage of desferrioxamine and the presence of iron overload complications[4]. A study by Delea et al measured the QOL of thalassaemia patients on desferrioxamine treatment and those on deferasirox, an oral iron chelator. They reported that deferasirox resulted

in a gain of 4.4 quality-adjusted life-years (QALYs) in patients not on desferrioxamine and 2.7 QALYs in patients already on desferrioxamine[5]. In Bangladesh, it is estimated that only about 40%-50% of the transfusion-dependent thalassaemia patients in the government hospitals are using desferrioxamine at the correct dose, and many of these patients had a high iron load in their body[6]. Reasons for not complying to the guidelines are not only due to the inconvenience of injecting desferrioxamine, but also because of the exorbitant cost of this treatment for a long duration. The aim of this study was to show that treatment of transfusion-dependent thalassaemia patients with desferrioxamine would



provide better QOL for patients despite having to bear the cost and inconveniences of desferrioxamine injections. The specific objectives of this study were: (1) to determine the QOL scores of transfusion-dependent thalassaemia patients according to the status of desferrioxamine usage; (2) to describe the socio demographic and disease characteristics of patients based on the status of desferrioxamine usage; (3) to measure QALYs and compare groups of patients according to status of desferrioxamine usage; and (4) to identify factors other than desferrioxamine that is associated with QALYs.

### METHODS

A cross-sectional study was performed on transfusion dependent thalassaemia patients on follow-up at the department of Paediatrics, General Hospital Khulna Bangladesh. All transfusion-dependent thalassaemia patients with complete medical records during the period January 2013- July 2014 were recruited into the study.

The inclusion criteria were patients who were aged six years and above, did not have bone marrow transplant and gave consent. Patients or parents were interviewed on desferrioxamine usage. Patients who were unable to answer the questionnaire themselves were assisted by their parents or guardians. The medical records of the patients were reviewed to determine the serum ferritin levels and to look for the presence of iron overload complications. Data collection was carried out from January 2013- July 2014. Data was processed by using MS Excel

### RESULTS

A total of 57 transfusion-dependent thalassaemia patients were recruited, with 38(67%) male and 19 (33%) female, male female ratio is about 2:1. patients on

sub-optimum and optimum desferrioxamine treatments, respectively. Maximum age group 4 to 8 years 66%. Among them excellent school performance 10(17.5%), good 25(43.85%), satisfactory 8(14.03%), unsatisfactory 14(24.56%), level of education of parents revealed upto primary level 15(26.31%), upto secondary level 31(54.38%), above secondary level 11(19.29%), monthly income of family more than 3500 BDT 43(75.43%), below 3500 BDT 14 (24.56%).

Table1: Age group n=57

Age group	Frequency	Percentages
4-8	38	66.6%
9-13	11	19.29%
14-18	08	14.03%

Figure:1 Sex distribution n=57

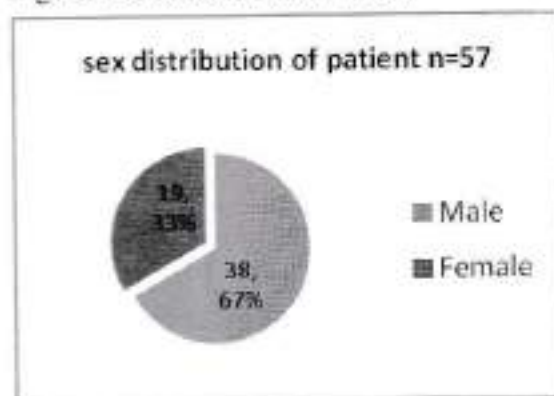


Table 2: School performance n=57

School performance	Frequency	Percentage
excellent	10	(17.5%),
Good	25	(43.85%),
Satisfactory	8	(14.03%),
unsatisfactory	14	(24.56%).

### Discussion:

QALYs in transfusion-dependent thalassaemia patients based on various factors. In a study in Singapore eight dimensions and the MCS and PCS, except for the physical function dimension.[7-8]

The general wellbeing of thalassaemia patients, whether they received desferrioxamine at sub-optimum or optimum dose, was not very much affected. Studies had shown that the QOL for non-chelated and fully-chelated thalassaemia patients differed, where the fully-chelated patients had a QOL almost similar to that of normal children, except with regard to body pain [9]. These patients had been having the disease since childhood, they were not working for a living and as such had not much expectation with regard to physical school performance. In our study 57 transfusion-dependent thalassaemia patient were enrolled in General Hospital Khulna, Bangladesh with 38 (67%) male and 19 (33%) female, male female ratio is about 2:1. Patients on sub-optimum and optimum desferrioxamine treatments. Maximum age group 4 to 8 years 66%. Among them excellent school performance 10(17.5%), and good 25(43.85%). Level of education of most of the parents revealed upto secondary level 31(54.38%) and the monthly income most of the family more than 3500 BDT 43(75.43%).

**Conclusion:** Optimum desferrioxamine dosage could lower the levels of serum ferritin, which was associated with a lower rate of iron overload complications. Although higher income has been associated with a better QOL due to higher living standards, in this study, it also enabled patients to start desferrioxamine treatment early and at optimum dose. Large scale research should be conducted for further evaluation.

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## Original Article

## Efficacy Of Botulinum Toxin-A (Btx-A) In The Treatment Of Overactive Bladder (Oab) Refractory To Conventional Anticholinergics

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### Abstract:

**Background:** To evaluate the efficacy and safety of intravesical injection of Botulinum Toxin-A (BTX-A) in the treatment of overactive bladder (OAB) refractory to conventional anticholinergics. **Methods:** This is a hospital based prospective interventional study during January 2009 to October 2009 where 30 patients refractory to anticholinergics were enrolled. Total 30 patients with OAB according to the selection criteria were evaluated by history, physical examinations and investigations. Informed written consent was obtained from each patient. Patient with lithotomy position and under regional anesthesia, cystoscopy was performed. BTX-A (100 international Unit) was dissolved in 20 mL of 0.9% saline and was injected into the detrusor muscle at 20-30 different sites. At 12 weeks after the injection the maximum cystometric capacity and postvoid urine volume were measured and urodynamic (Qmax and Pdet) study was performed as well as assessment of urgency, urge incontinence, frequency, nocturia and quality of life (QoL) was done. **Results:** Majority of patient were found in the age range 46- 55 years (46.67%). Both male and female suffer from OAB syndrome almost equally (46.67% and 53.39% respectively) with a slight female preponderance. Almost all patients showed marked improvements in their clinical symptoms of frequency, urgency, nocturia and incontinence within 1 week of therapy and continued to show improvements up to their last follow up after 3 months. About 86.67% patients showed improvements of their frequency which is statistically very highly significant ( $p < 0.001$ ). The mean urgency decreased from 6.4 times to 1.6 times/ 24 hours which is statistically very highly significant. The mean decrease in the number of nocturia reduced from 4.30 to 1.53 episodes per night. The improvement of nocturia is statistically significant ( $p < 0.001$ ). After intradetrusor injection of BTX-A 60% patient were dry. The mean decrease in incontinence episodes reduced from 4.8 to 0.40 after 3 months which is significant ( $p < 0.001$ ). The MCC increased by 60%. Mean increase was from 268.53 ml to 347.66 ml which is statistically significant ( $p < 0.001$ ). The reduction of detrusor contractile pressure was observed in all 30 patients with a mean reduction of 54% from the baseline value was observed. The mean detrusor voiding pressure or contractility decreased from 64.33 cm H<sub>2</sub>O to 29.13 cm H<sub>2</sub>O which is statistically very highly significant ( $p < 0.001$ ). **Conclusion:** This study has shown to be not only safe, well tolerated, but it is also very effective with practically no adverse effects with very encouraging results.

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## INTRODUCTION

According to The International Continence Society (ICS) committee (Abrams et al, 2002), the overactive bladder (OAB) is defined as urgency, with or without urge incontinence, usually with frequency and nocturia. In patients with refractory (no improvement with anticholinergics of > 6 months duration) idiopathic detrusor overactivity, there is a gap in treatment between classic anticholinergic agents and surgical treatments (e.g. bladder augmentation or sacral neuromodulation/stimulation). Administration of botulinum neurotoxin type-A (BTX-A) directly into the bladder wall is a new treatment concept, which has been increasingly researched and applied. In this study Botulinum toxin-A (BTX-A) will be applied in the treatment of idiopathic and neurogenic overactive bladder (OAB) syndrome.

## MATERIALS AND METHODS

This is a hospital based prospective interventional study during January 2009 to October 2009 in the department of Urology, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka Medical College Hospital (DMCH), Lab Aid Specialized Hospital and Comfort Nursing Home, Dhaka, Bangladesh. All the patients with bothersome idiopathic and neurogenic overactive bladder (OAB) attending during the study period at Urology outpatient department (OPD) were the study population. A total of 305 patients attended during the study period at the above mentioned institutions and hospitals in Dhaka city with OAB. All patients had history of intake of conventional anticholinergic at least 6 months. Of them 30 patients refractory to conventional anticholinergics were enrolled for the study according to selection criteria. Non-random (purposive)

sampling was applied to collect sample from study population. Key variables were age, sex, frequency, urgency, urge incontinence, nocturia, quality of life (QoL), maximum cystometric capacity (MCC), post voidal residue (PVR), maximum flow rate (Qmax), detrusor pressure (Pdet). Age >18 years with bothersome OAB, failed medical therapy with anticholinergics with no prior intravesical treatment for OAB were included. Total 30 patients with overactive bladder according to the selection criteria during the study period were evaluated by history, physical examinations and investigations e.g. routine urological investigations, USG of kidney, ureter and bladder region (KUB) with maximum cystometric capacity and post voidal residue; and urodynamic study (to see involuntary contraction during filling cystometry, Qmax and Pdet and to exclude infravesical obstructions). Informed written consent was obtained from each patient. Complete blood count (CBC), random blood sugar (RBS), serum creatinine, coagulation profile and urine culture were obtained for all patients. Ultrasonographic and urodynamic variables (Qmax >15 ml/s and Pdet 20-50 cm H<sub>2</sub>O were considered normal) were qualified and quantified. Patient with lithotomy position and under regional anesthesia, with due aseptic precaution cystoscopy was performed. Prophylactic antibiotic was given at induction of anesthesia. BTX-A (100 international Unit) was dissolved in 20 mL of 0.9% saline just before use. Then under cystoscopic control BTX-A was injected into the detrusor muscle at 20-30 different sites with specialized intradetrusor injection needle. At the end of the procedure the patient was catheterized with indwelling catheter. At 12 weeks



after the injection the maximum cystometric capacity and postvoid urine volume were measured and urodynamic (Qmax and Pdet) study was performed as well as assessment of urgency, urge incontinence, frequency, nocturia and quality of life (QoL) was done.

## RESULTS AND OBSERVATIONS

The findings derived from analysis of preinstillation and postinstillation data are presented. Majority of patient with overactive bladder were found in the age range 46- 55 years (46.67%) and the least frequency in the age range 15- 25 years (6.67%) and 56- 65 years (6.67%). The mean age was 44.8 years. The lowest and highest age was 19 and 65 years respectively. Both male and female suffer from OAB syndrome almost equally (46.67% and 53.39% respectively) with a slight female preponderance. Almost all patients showed marked improvements in their clinical symptoms of frequency, urgency, nocturia and incontinence within 1 week of therapy and continued to show improvements up to their last follow up after 3 months. About 86.67% patients (26 out of 30) showed improvements of their frequency.

Preinstillation (episode/ 24hour)	Postinstillation (episode/ 24hour)	Calculated value	p value
Mean $\pm$ SD	Mean $\pm$ SD		
15.6 $\pm$ 1.73	5.7 $\pm$ 1.02	4.81 <sup>S</sup>	<0.001

Mean decrease in the number of frequency reduced from 15.6 to 5.7 episodes which is statistically very highly significant ( $p < 0.001$ ). The reduction in urinary urgency was observed in all 30 patients with a mean reduction of 75% from the baseline value was observed.

Preinstillation (urgency/24h)	Postinstillation (urgency/24h)	Calculated value	p value
Mean $\pm$ SD	Mean $\pm$ SD		
6.4 $\pm$ 0.96	1.6 $\pm$ 0.67	3.94 <sup>S</sup>	<0.001

The mean urgency decreased from 6.4 times to 1.6 times/ 24 hours which is statistically very highly significant. The mean decrease in the number of nocturia reduced from 4.30 to 1.53 episodes per night. Most (60%) of the patients (18 out of 30) claimed that nocturia was not a bothersome complaint to them after 3 months of BTX-A instillation as compared with pre instillation status.

Preinstillation (Nocturia episode/night)	Postinstillation (Nocturia episode/night)	Calculated value	p value
Mean $\pm$ SD	Mean $\pm$ SD		
4.30 $\pm$ 0.70	1.53 $\pm$ 0.77	14.57 <sup>S</sup>	<0.001

The improvement of nocturia is statistically significant ( $p < 0.001$ ) Only 33.33% patients (10 out of 30) had the complaint of incontinence along with other complaints of overactivity of bladder.

Preinstillation (episode/ 24hour)	Postinstillation (episode/ 24hour)	Calculated value	p value
Mean $\pm$ SD	Mean $\pm$ SD		
4.8 $\pm$ 0.77	0.40 $\pm$ 0.52	20 <sup>S</sup>	<0.001

After intradetrusor injection of BTX-A 60% patient were dry. The mean decrease in incontinence episodes reduced from 4.8 to 0.40 after 3 months which is significant ( $p < 0.001$ ). Sonographic and urodynamic studies assessment done at the end of 3rd months showed improvement in MCC in all 30 patients. The MCC increased by 60%. Mean increase was from 268.53 ml to 347.66 ml which is statistically significant ( $p < 0.001$ ). The PVR volume increased about two times from the base line value. The mean increase was from 29.33 ml to 51.83 ml which is statistically significant ( $p < 0.001$ ). The mean decrease in Qmax was from 20.30 ml /s to 15.60 ml/ s after 3 months of BTX-A injection. The mean difference is statistically highly significant ( $p < 0.001$ ). The reduction of detrusor contractile pressure (measured by urodynamic study) was observed in all 30 patients with a mean reduction of 54%



from the baseline value was observed. The mean detrusor voiding pressure or contractility decreased from 64.33 cm H<sub>2</sub>O to 29.13 cm H<sub>2</sub>O which is statistically very highly significant ( $p < 0.001$ ). The reduction of bothersome score was observed in all 30 patients with a mean reduction of 72% from the baseline value was observed. The mean bothersome score decreased from 5.40 to 1.50 which is statistically very highly significant ( $p < 0.001$ ).

## DISCUSSION

Intravesical injection of Botox-A provides a new therapeutic choice for patients who cannot tolerate the adverse effects of antimuscarinic drugs. The application of Botox-A in IDO was pioneered by Schurch et al. In her study of 19 patients, 17 patients were completely continent at the end of 6 weeks of follow-up. The MCC of bladder increased from 296.3 ml to 480.5 ml and decrease in maximum detrusor voiding pressure was observed from 65.6 cm H<sub>2</sub>O to 35 cm of H<sub>2</sub>O with no side effects. The duration of effect of botulinum toxin lasted for a mean period of 9 months. Similarly Steinhart et al in their study of Botox-A showed 100% success rate on 20 patients using 200 units of the Botulinum toxin. Radziszewski and Borkowski in their study of 12 patients of refractory IDO showed marked improvement in reduction of frequency, urge incontinence rate with mean MCC increasing from 321.2 ml to 408.3 ml. Similar positive and improved results were observed by Loch et al and Zermann et al using 200 units of botulinum toxin in IDO. In this study 30 patients of OAB were treated with intradetrusor injection of BTX-A. The results of this study showed that majority of patient with overactive bladder (OAB) were found in the age range 46- 55 years (46.67%). Both male and female suffer from overactive bladder (OAB) syndrome almost equally (46.67% and 53.39% respectively) with a slight female preponderance.

Almost all patients showed marked improvements in their clinical symptoms of frequency, urgency nocturia and incontinence within 1 week of therapy and continued to show improvements up to their last follow up after 3 months. About 86.67% patients (26 out of 30) showed improvements of their frequency which is better than the findings of Mohanty et al. Mean decrease in the number of frequency reduced from 15.6 to 5.7 episodes which is statistically very highly significant ( $p < 0.001$ ). The reduction in urinary urgency was observed in all 30 patients with a mean reduction of 75% from the baseline value was observed as observed by Mohanty et al (80%). Most (60%) of the patients (18 out of 30) claimed that nocturia was not a bothersome complaint to them after 3 months of BTX-A instillation as compared with pre instillation status. Only 33.33% patients (10 out of 30) had the complaint of incontinence along with other complaints of overactivity of bladder. After intradetrusor injection of BTX-A 60% patient were dry. The mean decrease in incontinence episodes reduced from 4.8 to 0.40 after 3 months which is significant ( $p < 0.001$ ). All patients to be complete dry longer follow up (6 months) is necessary as shown by NK Mohanty et al ; 0-1 incontinence episode / 24 hr at 6 months follow up ( $p < 0.001$ ).

In this study of intradetrusor injection of Botox-A in management of overactive bladder (OAB), refractory to conventional anticholinergics, has shown to be not only safe, well tolerated, but it is also very effective with practically no adverse effects with very encouraging results. But more randomized controlled clinical trials in future will establish its potential role in clinical urological practice in management of DO and other urological diseases e.g. detrusor sphincter dyssynergia (DSD).

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## Original Article

## Surgical Procedure in Bladder Outlet Obstruction due to Prostatic Enlargement in Satkhira Medical College & Sadar Hospital

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### Abstract

**Background:** In men, obstructive lower urinary tract symptoms (LUTS) are usually due to benign prostatic hyperplasia (BPH). Carcinoma of the prostate causes obstruction when the disease is locally advanced. Failed drug therapy and complications secondary to BPH are the indications for surgical intervention in benign prostatic hyperplasia.

**Methodology:** It was a cross sectional study conducted in Satkhira Medical college & Sadar Hospital consecutive 428 patients who underwent BNI, TURP or Open prostatectomy for BOO in Sadar Hospital, Satkhira, and Satkhira Medical College Hospital & in some private clinic in Satkhira Bangladesh over a period of three years from January 2014 to December 2017. **Results:** Age range was 40-92 years mean age 67 years. 366 patients out of 428 (85%) underwent TURP and 55 (12.85%) patients were subjected to BNI. Only 7 patients required open prostatectomy (Retropubic). Mortality rate was 7 (1.63%). **Conclusion:** Majority of patients who presents with BOO and undergo surgery are above 60 years. TURP is safe in men over 80 years. Obstructive LUTS with or without ARU is the main presentation and significant number of patients are on indwelling catheters for unacceptably long durations.

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### Introduction:

In men, obstructive lower urinary tract symptoms (LUTS) are usually due to benign prostatic hyperplasia (BPH). Carcinoma of the prostate causes obstruction when the disease is locally advanced. Failed drug therapy and complications secondary to BPH are the indications for surgical intervention in benign prostatic hyperplasia [1]. Surgical procedures include bladder neck incision (BNI), transurethral resection of the

prostate (TURP) and open prostatectomy. Patients with clinically malignant prostates and obstructive LUTS are subjected to transrectal biopsy of the prostate and TURP or BNI at the same sitting in our unit. Objectives of this study were to evaluate men who underwent prostatic surgery for bladder outlet obstruction (BOO) in the Satkhira Sadar Hospital, Satkhira and Satkhira medical College Hospital Bangladesh, with regard to their demographic data, clinical



presentation, correlation of digital rectal examination (DRE) findings with histology and various surgical interventions and their complications.

#### Methodology:

It was a cross sectional study conducted in Satkhira Medical college & Satkhira Sadar Hospital, consecutive 428 patients who underwent BNI, TURP or Open prostatectomy for BOO in Sadar Hospital, Satkhira, and Satkhira medical College Hospital & in some private clinic in Satkhira Bangladesh over a period of three years from January 2014 to December 2017. Data were collected in a predesigned questionnaire. Patients were selected for different surgical procedures on DRE findings, prostatic volume by trans-abdominal ultrasound scan (USS) of the prostate gland whenever available and cystourethroscopic findings at surgery. Data was presented by Microsoft excel and SPSS.

**Results:** Age range was 40-92 years mean age 67 years. 366 patients out of 428 (75%) underwent TURP and 55 (24.23%) patients were subjected to BNI. Only 7 patients required open prostatectomy (Retropubic). All patients had obstructive LUTS. In addition to this, acute retention of urine (ARU), chronic retention of urine (CRU), vesical stones and haematuria were present in different combinations. Significant complications related to TURP were documented in 32 patients. They were grouped into immediate (occurring within 24 hours), early (within 2 weeks) and late complications.

#### Immediate complications –

1. Intractable primary bleeding	10
Radiation therapy before sending to ward	2
Blood transfusion only	2
2. Large capsular perforation with intractable bleeding	2
3. ARF necessitating haemodialysis	1
<b>Early complications –</b>	
1. Failed TWOC requiring Re-TURP	20
2. Transient incontinence	9
3. Secondary haemorrhage	15

#### Late complications –

1. Urethral stricture	20
2. Bladder neck contracture	15
3. Incontinence > 6 months	8

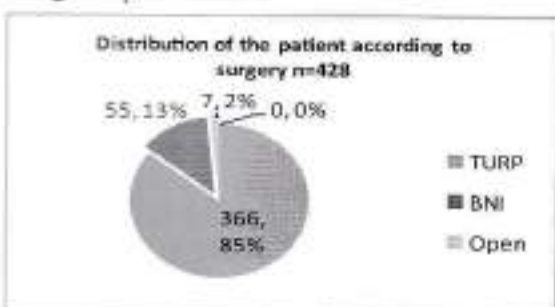
7 patient out of 428 died in this series amounting to a mortality rate of (1.63%). The death was probably due to some medical comorbidities like IHD, MI, HTN, Bronchial Asthma etc.

15 out of 321 (4.67%) TURP patients were transfused during or immediate post TURP. Eleven patients received only one pint of blood each, three patients received 2 pints each and one patient received 6 pints. Bladder neck incision was carried out in 55 patients. Only one patient required TURP due to failed trial without catheter following BNI. All other patients had their indwelling catheters removed on second post operative day successfully. Some of the patients who were scheduled for BNI on DRE were subjected to TURP due to the presence of a median lobe or prominent lateral lobes though the resected volume was smaller.

#### Distributions of patient according to Clinical presentations :

Clinical presentation	Frequency
Acute Retention of Urine	175(40.88%)
Chronic Retention of urine	30(7%)
Pt with indwelling catheter	131(30%)
Haematuria	35(8%)
Known prostatic cancer	10(2%)

#### Surgical procedure :



**Discussion:**

Obstructive lower urinary tract symptoms in men are mainly caused by benign prostatic hyperplasia, carcinoma of the prostate and high bladder neck probably due to underlying adenoma. BPH could be managed either by medical therapy using alpha adrenergic blockers and 5-alpha reductase inhibitors or surgical intervention. Minimally invasive therapies like laser prostatectomy, transurethral needle ablation (TUNA) and transurethral electrovaporization of the prostate (TVP) are advocated for small prostates. In this series patients who were diagnosed to have clinical BPH had been already treated with alpha blockers for variable periods without significant improvement and therefore underwent surgery. Patients with clinically malignant prostates and BOO were subjected to either BNI or TURP together with transrectal biopsy of the prostate. 75% (n=366) of the patients in this study group underwent TURP which is the standard surgical therapy for BPH. Bladder neck incision was carried out in 55 patients as they had either small prostate on DRE with non-occlusive prostatic lobes or high bladder neck on cystoscopy. BNI is a simpler procedure acceptable for smaller prostates [1]. Although open prostatectomy is very rarely practiced in the present era its value in very large prostates over 80 grams is unquestionable. Age range was 40-92 years mean age 67 years The oldest patient in this series was 92 years and TURP was tolerated well with uneventful recovery. None of the patients below 50 years have undergone TURP and these patients had a high bladder neck with or without an underlying adenoma and responded well to BNI. All patients had obstructive LUTS and the longest duration recorded in this group was > 5 years. Majority of the patients had symptoms for more than 6 months. ARU was a frequent association and was seen in 175 (40.88%) patients and 131 patients had an indwelling catheter for

more than one month duration prior to surgery. Digital rectal examination is an essential part in decision making in BOO. DRE would be helpful in detecting prostatic malignancies, neurogenic causes for symptoms and the prostate size which will help to select the appropriate surgical technique although the size is not considered in deciding whether active therapy is required or not. DRE is a test that depends on the experience of the examiner and the sensitivity and specificity in detecting organ confined carcinoma of the prostate are 52% and 81% respectively [2]. No adequate clinical and biochemical evidence were available to prove TURP syndrome and post operative UTI was not included in this study. Intractable primary bleeding was the commonest complication encountered and blood transfusion rate was 4.67% (15 patients out of 321). 7 patients who underwent open surgery in this series had more than 80g prostates. This operation is ideally suited for patients with [1] a large median lobe protruding into the bladder, (2) a clinically significant bladder diverticulum, or [3] large bladder calculi [4].

**Conclusion :**

Majority of patients who presents with BOO and undergo surgery are above 60 years. TURP is safe in men over 80 years. Obstructive LUTS with or without ARU is the main presentation and significant number of patients are on indwelling catheters for unacceptably long durations. This invariably affects their personal and social life and leads to catheter related problems. Although the cancer detection rate is controversial, DRE is an essential basic examination and will be of immense use in centres with substandard facilities. TURP is a safe procedure with low complication rates when done in optimized patients and significant complications could be managed effectively if close observation is maintained. BNI done in a carefully selected group of patients will



have less chances of failure requiring TURP.

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## Original Article

## WHtR (Waist-Height Ratio) Is Better Than WHR (Waist-Hip Ratio) As a Predictor of Metabolic Syndrome

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**Introduction:** Metabolic syndrome (MS), a global epidemic, is a cluster of risk factors for CHD, DM2, stroke and other various medical problems, which affects specially those who lead sedentary and stressful life. **Objectives:** The aim was to evaluate WHR (waist-hip ratio), WHtR (waist-height ratio) for their predictive value of MS. **Materials and method:** In this cross sectional study, 500 participants of 25-55 years were enrolled. The study was carried out in the Department of Biochemistry, BSMMU, Shahbag, Dhaka, Bangladesh. MS was diagnosed by modified NCEP ATP III criteria. Prevalence of MS was measured at 95% CI. Statistical significance was set at  $p < 0.05$ . **Results:** WHR was the most sensitive (99.19% male & 98.59% female), specificity of WHtR was more than WHR in both male and female. ROC curves of predictors were found good ( $AUC > 0.6$ ) for their predictive value of MS; WHtR was revealed better than WHR as an index for MS ( $AUC$  0.667 vs. 0.652 in male; 0.706 vs. 0.681 in female). **Conclusion:** It can be concluded that WHtR can be used as a good and relevant index for MS, also instead of WHR.

**Key words:** Metabolic syndromes, NCEP ATP III, WHR, WHtR, ROC curve.

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### Introduction:

Metabolic syndrome (MS), also termed as syndrome X or Insulin Resistance Syndrome, is a cluster of widely prevalent multi-factorial medical disorders that increases the risk of developing cardiovascular disease and diabetes. The metabolic syndrome is also increasing in developing countries including Bangladesh. MS is considered to be a pre-diabetic state leading to DM2; beyond cardio-vascular disease (CVD) and DM2, individuals with MS are also susceptible to other life threatening medical problems

like polycystic ovarian syndrome, fatty liver, cholesterol gallstones, asthma, sleep disturbances and some forms of cancer [1-7].

Central adiposity is a key feature of the metabolic syndrome, reflecting the fact that the prevalence of MS is driven by the strong relationship between waist circumference and increasing adiposity. However, patients of normal body weight may also be insulin-resistant and have the syndrome. Physical inactivity is an important factor of CVD events related mortality[8].



There are different sets of criteria for diagnosis of MS. The first formal definition of the MS was put forward in 1998 by the World Health Organization (WHO). This report was finalized in 1999 for individual having insulin resistance with any two of hypertension, dyslipidemia, central obesity and high urinary albumin excretion rate or high urinary albumin:creatinine ratio[5]. The European Group for the Study of Insulin Resistance (EGIR) and International Diabetes Federation (IDF) published a separate set of criteria thereafter[9,10]. In 2001, the National Cholesterol Education Program Adult Treatment Panel III (NCEP: ATP III, 2001[4] published a new set of criteria based on common clinical measurements: Waist circumference (WC), blood lipids, blood pressure, and fasting glucose[11]. There are so many criteria present for diagnosing MS. But the aim of this study was to evaluate WC, TG and LDL-C as their predictive efficiency to diagnose MS. Though not included in any persisting sets of diagnostic criteria, a new anthropometric parameter WHtR (waist to height ratio) was taken in our study to evaluate also as a predictor of MS. Because, WHtR was tested and found effective in many other studies [12]

#### Materials and Method :

This cross sectional study was done at the Department of Biochemistry, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh by purposive and convenient sampling technique maintaining inclusion and exclusion criteria strictly. A data collection sheet was prepared for this purpose which included all the variables of interest.

Metabolic Syndrome (MS) was defined according to modified NCEP-ATP III[4]. Ethical clearance for the study was taken from the department of Biochemistry and central ethical committee, BSMMU and BMRC. Finally informed written consent of all study subjects were taken free of duress without exploiting any weakness of the subjects.

Data was analyzed by using SPSS version 14.0 for windows. Prevalence of metabolic syndrome in total study subjects as well as in male and female were determined at 95% confidence interval (CI) based on the modified NCEP-ATP III criteria. Statistical significance was set at  $p < 0.05$ . Performance test of all predictors (WHR, WHtR, TAG and HDL-C) were done for detection of MS and ROC curve was also created to evaluate the weight age of predictors in detection of MS, especially to compare WHR with WHtR.

#### Results and Observation :

Of total 500 study subjects male were 334 (66.8%) and female were 166 (33.2%). Age range of the study subjects was 25 to 55 years with mean age ( $m \pm SD$ )  $38.7 \pm 8.4$  yrs in total study subjects,  $39.7 \pm 8.9$  yrs in male and  $36.7 \pm 7.1$  yrs in female. Mean height (cm)  $164.2 \pm 3.0$ , mean body weight (kg)  $67.8 \pm 5.2$ , mean waist circumference (cm)  $92.7 \pm 5.3$ , and mean hip circumference (cm)  $92.7 \pm 5.3$  was found in total study subjects. Mean WHR of total study subjects as well as of male and female were  $1.0 \pm 0.1$ . Mean WHtR of total study subjects as well as of male and female were  $0.6 \pm 0.0$ . Mean BMI ( $kg/m^2$ ) of total study subjects was  $25.4 \pm 2.2$ . The prevalence of MS (95% CI) among the total population was found to be 38.8% (31.9-45.7) and that in male and female doctors were 36.8% (28.3-45.3) and 42.8% (31.3-54.3) respectively.

Performance test of WHR and WHtR were done for prediction of MS and is summarized in Table 1.

Table-1: Summary of the performance tests of WHR, WHtR for prediction of MS

Performance tool	Predictors				
	WHR		WHtR		
	M	F	M	F	T
SEN	99.2	98.6	96.0	88.7	93.3
SPE	70.1	30.2	80.1	91.6	90.2
PPV	38.4	43.2	37.3	42.9	39.4
NPV	93.8	75.0	77.3	57.9	68.3
Accuracy	41.0	44.0	40.4	44.6	41.0
LR+	01.1	01.0	01.0	01.0	00.7
LR-	00.1	00.5	00.5	01.0	01.8

WHR= Waist-Hip Ratio, WHtR= Waist-Height Ratio,

MS= Metabolic Syndrome, M=Male, F=Female, T=Total study subject

Figure-1 show ROC curve of the performance of WHtR as predictors of MS in total population (both sex). ROC curve of the performance of WHR and WHtR as predictors of MS in male and female were shown in Figure-2-5 respectively.

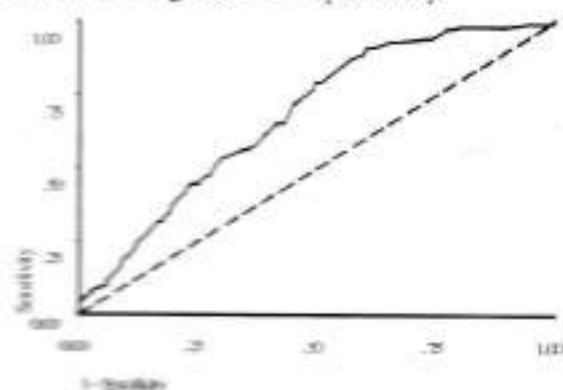


Figure-1: ROC curve for WHtR as predictor for detection of MS in total population (both sex).

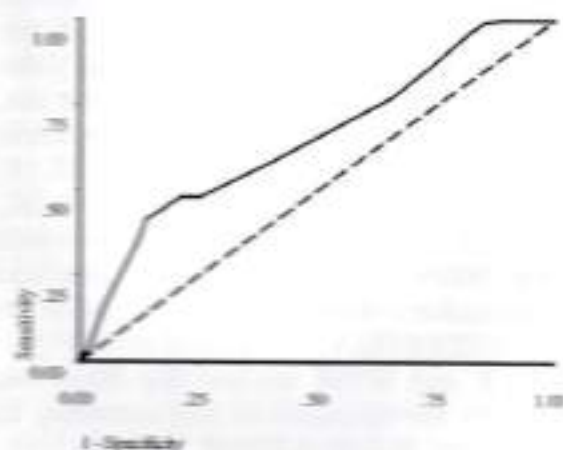


Figure-2: ROC curve for WHR as predictor for detection of MS in male.

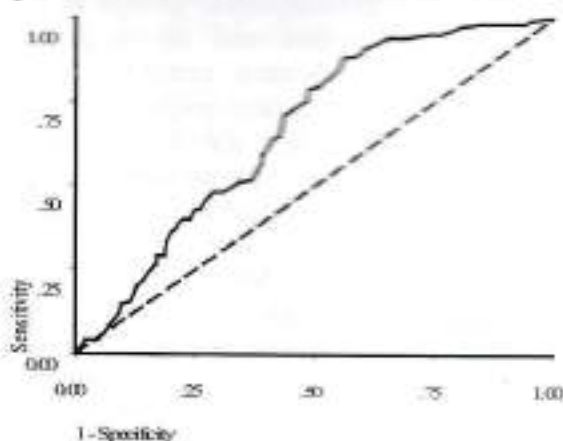


Figure-3: ROC curve for WHtR as predictor for detection of MS in male.

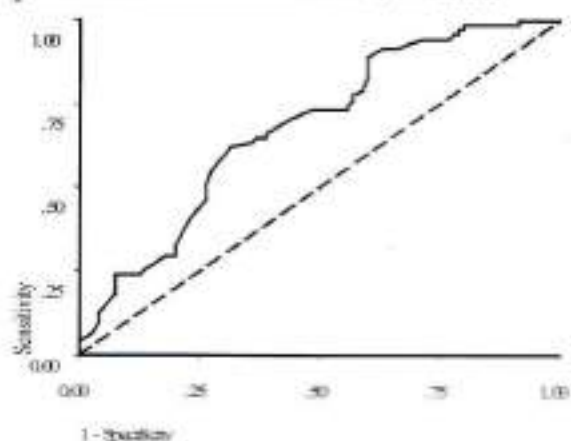


Figure-4: ROC curve for WHR as predictor for detection of MS in female.

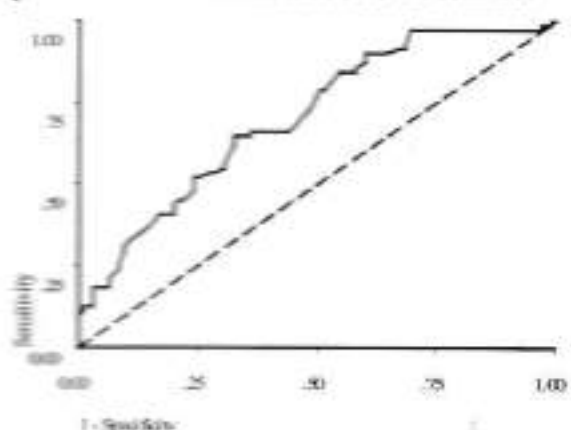


Figure-5: ROC curve for WHtR as predictor for detection of MS in female.

Table-2 shows Area under the ROC curve (AUC) representing the weightage of WHtR and WHR in male, female and in total population (both sex).

Table-2: Area under the Curves of WHtR and WHR in male, female and in total population (both sex)

Predictors	AUC			P-value
	Male	Female	Both	
WHR	.652 (0.6 - 0.7)	.681 (0.6 - 0.8)		.000
WHtR	.667 (0.6 - 0.7)	.706 (0.6 - 0.8)	.682 (0.6 - 0.7)	.000

Parenthesis shows 95% CI



### Discussion :

MS is prevalent in peoples of affluent society who usually live sedentary life and those who have experience of different types of physical and mental stress. Our finding (prevalence of MS 38.8%) was supported by Ramachandran et al (2008). They conducted a study among 2499 participants of mean age  $39.0 \pm 9.0$  yrs and found the prevalence of metabolic syndrome 29.0% [13]. The prevalence rates are also high in population of Venezuela (31.2%) and urban Brazil (25.4%) [14,15] in US population & Mexican Americans [6], in the Sindh province of Pakistan [7]. These also supported our findings.

In this cross sectional study, our aim was to determine the predictive value of WHR, WHtR, TAG and HDL-C for diagnosis of metabolic syndrome among them and to compare WHR and WHtR in regard of their predictive value.

In our study, we have calculated SEN, SPE, PPV, NPV, LR+, LR- & Accuracy of WHR, WHtR, TAG & HDL-C as predictors of MS (Table-1). Dhanaraj et al (2008) found TAG in the overall population SEN 73.3%, SPE 77.8%. In that study WC for men showed SEN 67.3%, SPE 72.3% and WC for women showed SEN 73.5%, SPE 70.65% [16]. Another study was carried out in the department of Biochemistry, Dhaka Medical College, Dhaka in 2010 by Khanam et al. In their study WHR for male showed SEN 100.0%, SPE 10.0% and for female WHR showed SEN 100.0% [17]. But, in their study Mombelli et al found SEN 92.0%, SPE 28.1% in male and SEN 87.4%, SPE 37.6% in female for WHtR [12]. In our study, the most sensitive predictor for male and female was found WHR (99.19% & 98.59%) followed by WHtR (95.93%), TAG (73.98%) & HDL-C (67.48%) in case of male and HDL-C (92.96%), WHtR (88.73%) & TAG (76.06%) in case of female. On the other hand most specific predictor for both male and female was TAG (94.79% &

62.11%) which was followed by HDL-C (67.30% & 33.68%), WHtR (08.06% & 11.58%) and WHR (07.11% & 03.16%). ROC curves of WHR, WHtR, TAG and HDL-C were produced to see the area under the curve (AUC) and to evaluate their predictive value of metabolic syndrome. AUC of WHR were 0.652 (male) & 0.0681 (female), WHtR 0.667 (male), 0.706 (female) & 0.682 (both sex). In one study, according to modified NCEP ATP III criteria, Dhanaraj et al observed AUC of WHR (men 0.671, women 0.691). They did not evaluate WHtR as a predictor [16]. In 2009, Mombelli et al carried a study among Italian population and he selected WHtR as a predictor of MS and found AUC 0.713 in male and 0.701 in female [12]. In our study all those indices were found good (AUC > 0.5) for their predictive value of metabolic syndrome; and it was also revealed that WHtR was better than WHR as an index for metabolic syndrome in all (both sex, male and female) which is in agreement with other previous studies [12,18]. Mombelli et al. found WHtR  $\geq 0.5$  in all, though Weilli et al. found lower threshold for WHtR, but it was in children and adolescents (0.485 in boys, 0.475 in girls) [12,16,18].

WHR and WHtR are not the diagnostic criteria for diagnosis of MS according to modified NCEP ATP III. But we have taken WHR and WHtR as the predictors of MS, because there is variation of value of WC in different diagnostic groups as well as in different sex and ethnic groups. Larger WC indicates central obesity, whereas WHR indicates excessive fat on the upper part of the body or abdomen. So WHR & WHtR can play an important role in diagnosis/ detection of MS in non-obese MS individuals in comparison with the non-obese without MS individuals [16]. WC is also a determinant, but different WC thresholds for the identification of the metabolic syndrome have been reported. Furthermore, determination of an enlarged WC may prove technically problematic



and frequently with poor reliability. When evaluating different WC cutoffs in large populations of European ancestry (by using NCEP ATP III vs. IDF criteria), the prevalence of metabolic syndrome was essentially identical, and cardiovascular disease risk factors status did not vary substantially when subjects were divided on the basis of WC or BMI. The advantage of the WHtR is the opportunity of using a common threshold for different populations. A threshold value of WHtR  $\geq 0.5$  may, in fact provide an optimal common anthropometric index<sup>18</sup>. In our study it was proved that according to performance tests, WHtR was significantly same with WHR; and according to AUC of ROC curve of them WHtR was better than WRH.

#### Conclusion :

All the indices (WHR, WHtR, TAG, HDL-C) were found good for their predictive value of metabolic syndrome; and WHtR was found better than WHR as an index for metabolic syndrome.

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## Original Article

## A Medical Based Study On Feto-Maternal Complication In Obstructed Labor

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**Abstract**

**Introduction:** Obstructed labor is one of the major causes of maternal mortality (8%) in Bangladesh. It is also responsible for high rate of maternal and fetal mortality. **Materials and methods:** This prospective observational study was carried out in Sher-E-Bangla Medical College Hospital, Barisal from September 2011 to February 2012. 50 patients who were admitted with obstructed labor during study period were included in this study. **Results:** In this study, the incidence of obstructed labor was 1.97%. The clinical profile of the patients reveals that 58% were within 20-30 years, 62% were primigravida, only 4% were in regular antenatal checkup, maximum (84%) patients came from poor socio-economic condition, 86% patients did not cross primary education level and most of them (86%) were house wives. On admission, general examination revealed that, majority of the patients were exhausted with rapid pulse, raised temperature, anemic and were dehydrated. The most common cause of obstruction was cephalopelvic disproportion (52%) followed by malposition/malpresentation (46%). Caesarian section was performed in 80% cases, craniotomy was done in 4% cases, 10% patients needed sub-total hysterectomy and repair of ruptured uterus was performed in 6% cases. The post-operative complications in my study population were puerperal sepsis 8%, wound infection 16%, ruptured uterus 10%, burst abdomen and paralytic ileus 2% each, post-partum hemorrhage 12%, VVF 6% and co-existing complication (more than 2 complications at a same time) is 20%. 40% mothers were healthy whereas maternal mortality and morbidity were 8% and 52% respectively. Perinatal outcome was healthy 38% and mortality 62%. **Conclusion:** Obstructed labor, one of the preventable entities still continues to plague the labor and delivery of many women with an increasing frequency and persistently same pattern of associated morbidity. To improve the situation, better access to optimal antenatal and intrapartum care, together with early referral of high risk patients must be facilitated.

**Key words:** Obstructed labor.

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**Introduction**

Each year, 210 million become pregnant, of whom 20 million will experience pregnancy related illness and 5, 00,000

will die as a result of complications of pregnancy or child-birth[1]. Even in the 21st century, obstructed labor still remains life threatening catastrophe all over the



world mostly in the developing countries like Bangladesh. Obstructed labor is one of the major causes of maternal death in our country (8%)[2]. It is a preventable condition and can be overcome if proper steps are taken at appropriate level and appropriate time. Obstructed labor results from unfavorable relations between maternal pelvis and fetus. Every pregnancy and labor is risky and need careful supervision supported by health facilities to avoid maternal and fetal demise. Obstructed labor remains an important cause of not only maternal death but also short and long term disability. It has particular impact in communities in which mechanical problems during labor are common and availability of functioning relevant health services is sparse. Obstructed labor comprises one of the five major causes of maternal mortality and morbidity in developing countries [3,4]. In our country 80% people live in rural areas where most deliveries (90%) are conducted at home. TBAs conducts 63% of deliveries of which 30% are conducted by untrained TBAs and 25% by trained ones[5]. The effect of these deliveries is reflected in the form of high maternal and fetal mortality and morbidity in our country. The causes of obstructed labor are not only the medical cause but also have some socio-economic causes. The medical causes are mainly cephalopelvic disproportion, mal-position, mal-presentation, big pelvic tumor, congenital malformation of the fetus (hydrocephalus). Poverty, social and cultural prejudices, gender based violence, lack of education and less access to essential health care facility also contribute to obstructed labor. Maternal mortality from obstructed labor is largely the result of ruptured uterus or puerperal infection, whereas maternal morbidity is associated with prolonged labor, since both post-partum hemorrhage and infection are more common in women with long labors. Obstetric fistulae (VVF, RVF) are long term problems. Traumatic

delivery affects both mother and child. Obstructed labors also bring a major impact on fetal outcome. They may die in utero, or delivered with severe asphyxia which is the main cause of perinatal mortality.

#### Materials and methods

This prospective study was undertaken with the objective to assess the fetomaternal outcome in obstructed labor in Sher-E-Bangla Medical College Hospital, Barisal over the period of 6 (six) months from September 2012 to February 2013. Among all the patients admitted with obstructed labor in all units of Department of Obstetrics and Gynecology in Sher-E-Bangla Medical College Hospital, Barisal was selected for the study. We included 37 completed weeks term pregnant women with obstructed labor which was due to cephalopelvic disproportion, soft tissue obstruction, mal-presentation of the baby. We also included patients with any immediate or late complication due to obstructed labor. We excluded pregnancy less than 37 weeks, any patients with complications other than obstructed labor such as convulsion, pregnancy induced hypertension, ante-partum hemorrhage and other medical disease and patients with complicated labor due to injudicious use of oxytocin. Our sample size was 50. A semi-structured data collection sheet was already designed for the study. After necessary modification following pre testing, the data collection sheet was used as data collection instrument. Cases were selected with obstructed labor and who fulfill exclusion and inclusion criteria. Patient's details were taken from history charts, records of admission, deliveries, caesarean sections, minor procedures and major procedures registrars. After collection of data they were edited through checking and re-checking. Data analysis was done computer aided statistical software SPSS (statistical program for social science). Data was presented in the form of tables and graphs. Data was

presented with descriptive statistics.

### Result

This study was undertaken with the objectives to evaluate the fetomaternal outcome in obstructed labor patients admitted in the Department of Obstetrics & Gynecology in Sher-E-Bangla Medical College Hospital, Barisal. A total of 105 cases of obstructed labor were admitted into the obstetric ward. Out of these 50 cases were included in this study.

Incidence of obstructed labor is shown in table 1 which is 1.97%. In the study subjects, the highest percentage of the study population is in 21-30 years old ladies. 84% of population comes from a low socio-economic family and 56% did not cross the primary education level. 86% of the patients were house wives and 60% of their husbands were day labor. 62% of our study subjects were primigravida (Table 2) and 48% of them came to hospital within 12-24 hours of labor pain while 36% came within 25-48 hours (Table 3). Only 4% of our study subjects were in regular antenatal checkup. On evaluation of the general condition of the study subjects on admission we found that 58% of the patients had tachycardia, 26% had severe dehydration, 80% had high colored urine and 96% had distended bladder. We also found that in majority cases (68%) fetus presented with severe distress and in almost 90% were with caput formation whereas 82% present with meconium stained liquor. We evaluated that about 54% of obstructed labor is caused due to cephalopelvic disproportion, 44% is caused by mal-positions and mal-presentations, 2% was due to fibroid (Table 4). The maximum mode of delivery of our study subjects was by LSCS (80%) while 10% patient needed sub-total hysterectomy and 6% patient had repair of ruptured uterus. We also found that 10% patients presented with ruptured uterus and another 16% with impending rupture. In 20% patients' bladder was found injured. We noticed that most of the maternal complication (20%) in post operative and

puerperal period are actually co-existing complications that is, more than 2 or more complications were coincided. 24% mother had normal puerperium. Among the other complications wound infection is more.

40% patients were healthy where as maternal morbidity is 52% and 8% mother died. And most of the death was due to hemorrhagic shock (50%), 25% due to septicemia and other causes.

Regarding the outcome of the babies, more than half of the babies (68%) were born with severe asphyxia and significant number of babies (24%) was still born. Among the babies 38% were healthy during discharge.

**Table 1: Incidence of Obstructed labor**

Total number of deliveries	Total number of obstructed labor	Percentage (%)
5325	105	1.97

**Table 2: Distribution of the patient's parity**

Gravida	Frequency (n)	Percentage (%)
Primigravida	31	62
Multigravida	19	38
Total	50	100

**Table 3: Duration of labor pain prior to admission**

Duration of labor	Frequency (n)	Percentage (%)
12-24 hours	24	48
25-48 hours	18	36
>48 hours	8	16
Total	50	100

**Table 4: Causes of obstructed labor**

Cause	Frequency (n)	Percentage (%)
Cephalopelvic disproportion	26	54
Persistent occipito-posterior position	15	30
Deep transverse arrest	3	6
Shoulder presentation	4	8
Face presentation	1	2
Fibroid	1	2
Total	50	100



### Discussion

At the beginning of new millennium modern obstetrics has developed a great, but in developing countries like Bangladesh obstructed labor still remains a great challenge. Obstructed labor is one of the life threatening obstetric complication with significant maternal as well as fetal morbidity and mortality in our country[6]. It is a dilemma for third world countries like Bangladesh resulting from ignorance, negligence and illiteracy.

In developing countries the incidence of obstructed labor is difficult to estimate because most of the reported studies are based on data from tertiary hospitals[7]. In India, its incidence was found ranging from 2-5%[8]. In Eastern Nigeria, study over a period of 5 years (1985-1989) revealed the incidence was 4.7%. In Bangladesh, Tahmina's (2006) study showed that, the incidence was 3.59%[9]. In this study, the incidence was found 1.97% which was statistically consistent with the above mentioned studies (Table 1).

This study was undertaken with the objective to evaluate the maternal and fetal outcome in obstructed labor which revealed that, more vulnerable age group for obstructed labor was 21-30 years is 58%. Though the teen aged girls are more prone to have obstructed labor as their pelvis remains inadequate for child birth in these study 22% of patients were in that age group.

The socioeconomic condition, educational level and occupational status of the patient had a significant relationship with their health awareness, which was reflected by their attendance to antenatal clinic.

Generally obstructed labor is seen in primigravida. In this study, 62% patients were primigravida and 38% were multigravida.

In this study, 48% patients came in the hospital within 24 hours of labor pain, 36% of the patients got admitted themselves after neglected and uncared labor with duration of labor

pain more than 24 hours and 16% of them were passed more than 48 hours. However, Tahmina's study showed most patients (84%) came within 24 hours of labor pain[9].

In the present study, majority of the patients were admitted with considerable mal-handling. Most of them were exhausted with agonizing pain and distress, pulse was rapid in 58% cases and temperature was raised in 60% cases indicating infection. All the patients were anaemic came with moderate to severe dehydration and there was bladder distension in 96% patients. Urine was high colored in 80% patients where as hematuria in 12% cases.

We found that, fetal heart sound was absent in 24% cases where as 68% was presented with fetal distress. Caput formation due to obstruction in 90% cases and in 18% cases there were meconium stained liquor. The causes of obstructed labor in the present study population were cephalopelvic disproportion 52%, 30% cases were due to persistent occipito-posterior position, deep transverse arrest was 6% cases, 8% cases were due to shoulder presentation, face presentation was 2% and cervical fibroid was 2%.

After admission, the patients were first resuscitated properly to improve their general condition. Then definitive management was done according to age, parity, cause of obstruction and finally maternal and fetal condition. LSCS (Lower segment caesarean section) was done irrespective of fetal viability in cases where obstruction was due to cephalopelvic disproportion and malpresentations. The patients having signs of impending rupture were also managed by caesarean section. Thus, in this study LSCS were done in 80% of cases, repair of rupture uterus in 6% cases, where as sub-total hysterectomy was done in 10% cases, craniotomy in 4% cases. In Tahmina's study (2006) there were LSCS 85%, craniotomy 9%, evisceration 4 and

sub-total hysterectomy in 2% cases.

Rupture uterus is the most fatal complication of neglected obstructed labor [10]. Among the 5 cases of rupture uterus, in 3 cases local repair was done and 2 cases sub-total hysterectomy was done. In present study, incidence of rupture uterus was 10%. The post operative complications in this study population were wound infection 16%, post partum hemorrhage 12%, puerperal sepsis 8%, vesico vaginal fistula 6% and in 20% cases there were overlapping complications (2 or more complications at a same time).

In our study we found that, 40% patients were healthy where as maternal morbidity is 52% and 8% mother died. The fetal condition at birth is grave in all studies including us. In this study population only 8% neonates were healthy, 68% were asphyxiated and 24% were still born.

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## Original Article

## Bipolar Diathermy Dissection Tonsillectomy In Satkhira Medical College Hospital

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### Abstract:

**Background:** Tonsillectomy is the most commonly performed operation world wide in otolaryngology. There are several methods of Tonsillectomy such as Cold Steel Dissection, Bipolar Diathermy, Laser, Coblation etc. Our preferred method was Bipolar diathermy Dissection. **Methodology:** This was a cross sectional study conducted in Satkhira Medical College Hospital from January 2016 to December 2017. Consecutive 67 patient were taken purposively after fulfilling the inclusion or exclusion criteria. Tonsillectomy done by Bipolar Diathermy Dissection method. **Results:** 30 (44.77%) patient tonsillectomy operating time was 5 to 10 minutes. Intraoperative blood loss was minimum incase of 39 (58.20%) that was 1 to 5 ml. There was no reported primary or reactionary hemorrhage, only 1 patient developed post operative secondary hemorrhage after 16 days of operation, needed re admission and managed accordingly. **Conclusions:** Bipolar diathermy dissection is safe and trusted and established procedure now and have an edge over blunt dissection. There is still controversy about post operative pain and hemorrhage, but case selection, standard diathermy machine, post operative oral hygiene and food habits may reduced the chance of secondary hemorrhage.

**Key words :** Bipolar diathermy, Tonsillectomy.

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### Introduction:

Tonsillectomy is the most commonly performed operation world wide in otolaryngology, for sore throat or purulent follicular exudates. It has been dated back to first century AD by Celsius [1]. Though there is much debate on surgical versus medical management of chronic tonsillitis, as tonsil is a lymphoid tissue and it has got a prophylactic & immunological value in against diseases of upper aerodigestive tract. Tonsil consists of numerous lymphatic follicles surrounding crypts.

Each follicle presents a germinal centre composed of lymphoblasts from which lymphocytes appear in the crypts and are washed out in saliva as salivary corpuscles. Tonsillitis is a disease caused by streptococcus haemolyticus and the disease flourishes in condition of overcrowding and poor ventilation along with poor sanitary and eating habits including thumb sucking and unhygienic bottle feeding after the age of 2 years when child starts handling the nipple [2]. Recurrent infection results in tonsillar

hypertrophy and chronic tonsillitis, producing mouth breathing, nasal discharge, foul breath, and snoring, indicating surgical management. Various modes of surgical dissection has been successfully attempted in the past from guillotine, diathermy, laser to ultrasonic. In our institution, we are performing exclusively bipolar forcep dissection tonsillectomy for the last one years. This procedure is easy to dissect, adequate haemostasis, minimum intra operative bleeding, reduced surgical duration & reduced post operative morbidity.

#### Materials & Method :

In bipolar diathermy, forceps dissection series surgery was performed by coagulating and dissecting with the bipolar forcep only. Blood loss during surgery was measured from blood collected in suction machine and the gauge pieces (fixed size) used in each case. After endotracheal intubation anaesthesia, sand bag was applied between the shoulders to assume Roses Position and Boyle Davis mouth gag applied dissection started after holding the tonsil by Luc's Forcep and pulling it medially and inferiorly, bulge of tonsil identified and incision was made by cautery at anterior superior part just inside the anterior pillar extending superiorly and posteriorly. Care was taken to remain close to cleavage within its capsule. Bleeders were coagulated before dissection, minimum voltage current was used to allow coagulation but to prevent charring. The time of surgery was recorded by anaesthetist from handing over the patient for surgery and to back to him.

#### Results :

The tonsillectomies performed over a year, had male preponderance (57%) and maximum number of cases were from the age group of 10 to 14 years (29.85%) & 5 yrs to 9 yrs was (25.37%). Majority of patient were presented with recurrent sore throat. Operating time was 5 to min incase of 30 patient and 10 to 15 min incase of 20 patient. Intra operative haemorrhage was

minimum (1 to 5 ml) in maximum cases 27 (40.29%) patient.

Table 1: Age distribution of patient n=67

Age group	frequency
5 yrs to 9 yrs	17 (25.37%)
10yrs to 14 yrs	20 (29.85%)
15 yrs to 19 yrs	15(22.38%)
20 yrs to 24 yrs	08(11.94%)
25 yrs or more	07(10.44%)

Figure : operating time n= 67

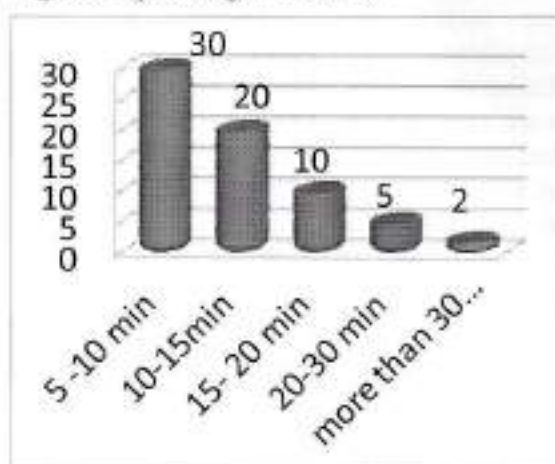


Table 2. Distribution of intra operative blood loss n= 67

Intra operative blood loss	Freuency
1 ml to 5 ml	27(40.29%)
6 ml to 10 ml	25(23.38%)
11 ml to 15 ml	10(14.92%)
16 ml or more	05 (7.46%)

#### Discussion

Various modes of performing tonsillectomy have been undertaken from guillotine, blunt dissection with ligation to bipolar forcep or scissor dissection and also laser or ultrasonics[3-4]. Advantage of surgical bipolar diathermy is many fold: first, blood loss is much less, secondly, duration of anaesthesia/surgical time is reduced significantly almost half or less thirdly, by virtue of the above, it becomes a day care procedure, patient can be discharged after few hours though in our series wound healing was mildly delayed in few cases. Using a bipolar forcep and



which needed cleaning in between but it was hardly time-consuming as compared to Raut et al [5]. Others have also reported a substantial decrease in blood loss and duration of surgery Post operative bleeding has been reported significantly high by other studies [6,7] including Martyn Siodlak who had incidence of 12% haemorrhage and even an audit report showed a bleeding rate of 18% after discharge [8]. Incidence was quite low in our series. We could not find any significant post operative bleeding diathermy dissection, similar observations were reported by Raut et al, Mann et al and Weimert et al [8,9,10] while increase in post operative haemorrhage has been reported by others. Secondary haemorrhage usually occurred within ten days of post operative period but a case of secondary haemorrhage had been reported by Dey on 31st day [8] while Carmody et al attribute poor eating habit after operation as a precipitating factor for haemorrhage [12]. In our series only one patient presented to us with secondary haemorrhage on post operative day. There was a definite increase in post operative pain in intensity and duration in bipolar diathermy cases; similar observation has been recorded by Sood et al [13] and Me Gregor et al [14]. The reason of pain is related to surrounding tissue damage.

### Conclusion

Bipolar diathermy forcep or scissors dissection is safe and trusted and established procedure now and have an edge over blunt dissection. Results depends upon the precision of technique and expertise developed over a time especially coagulating the vessel during dissection before spurt. Considering cost effectiveness, bipolar diathermy is much economical than ultrasonic and laser to provide comparable results in terms of better results, duration of surgery, anaesthesia and overall postoperative morbidity.

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## Original Article

## Management of Pediatric Diaphyseal Femur Fracture with Intramedullary Flexible Titanium Elastic Nail

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### Abstract:

**Background and objectives:** The incidence of pediatric femur fracture is 19 in 100,000 patients and is more common in boys than girls. Femur fracture account for 1.4 % to 1.7 % of all pediatric fracture. Over the few years there has been a marked increase in the use of intramedullary fixation in the management of fracture shaft of femur in children. **Material and Method:** This was a cross sectional study conducted on 12 cases of femoral shaft fractures in Jessore Medical college Hospital from January 2015 to December 2015. All cases were fixed with titanium flexible intramedullary nail under C-arm control. Long leg cast was applied at the time of fixation. The results were evaluated using Flynn's scoring criteria. Two nail were used in every cases. Radiological union in all cases was achieved in a mean time of 8 weeks. Full weight bearing was given after 8 weeks. Patients were evaluated in follow-up study to observe the alignment of fracture, infection, delayed union, nonunion, limb length discrepancy, motion of knee joint, and time to unite the fracture. **Results:** Mean age of all patients was 8.4 years old and average follow-up was 6 months. The results were excellent in 12 patients (100%). Intramedullary fixation by TEN is an effective treatment of fracture shaft of femur in properly selected patients of 6-15 years age group. **Conclusion:** Elastic intramedullary nail used in treatment of diaphyseal fracture shaft of femur yield excellent functional and radiological outcome. It is easy and simple procedure has low rate of complication. It is physal-protective, cost effective, does not involve heavy instrumentation and can be performed in small set up. It has minimal risk of infection and no risk of injury to the neurovascular structure.

**Key words:** Flynn's criteria, pediatric shaft of femur fracture, Titanium Elastic Nail (TEN).

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### Introduction:

Over the past few decades, pediatric femoral fracture have been more appropriately manage with operative treatment rather than conservative treatment because the femur has more rapid recovery and shorter

immobilization[1-5]. Small children less than six years old are treated with early reduction and hip spica while young adolescents more than 15 years old are treated with intramedullary interlocking nail. Children between the age of 6-15 years are treated with traction, hip spica,



flexible / elastic stable retrograde intramedullary nail, or external fixators in case of open fractures [6]. Operative treatment are appropriated to avoid physal, social and psychological complications as well as prolonged immobilization, which include external fixators, plates and screw fixation[8], antegrade intramedullary nailing, and flexible or elastic stable retrograde intramedullary nailing[6,7,8]. Antegrade intramedullary nailing may cause osteonecrosis of the femoral head while external fixators may lead to infection of the pin tract and refracture of the bone. So retrograde flexible or elastic stable intramedullary nailing has become wide spread for the management of pediatric diaphyseal femoral shaft fractures. Early good result using flexible (Ender) or elastic stable (Nancy) intramedullary rods have been reported by several European and American researchers[9-13].

Titanium elastic nailing, also known as elastic stable intramedullary nailing, has become the choice of surgical procedure in pediatric femoral shaft fractures because of the various advantages such as early union due to repeated micro motion at the fracture site, less chance of physal damage, early mobilization, early weight bearing, small scar and better patient compliance, (Flynn et al Bhaskar and Sanders et al). The aim of our study was to evaluate the outcome of TENS nailing in cases of femoral shaft fracture in 6-15 years age group children.

**Methods:** The study group consisted 12 children( 10 males, 2 females) in the age between 6 and 15 years with fresh femoral shaft fractures which were fixed with titanium elastic nail (TEN), between January 2015 to December 2015 in Jessore Medical College Hospital and private clinics. The mean age was 8.4 years and right side was more commonly involve than the left. The predominant mode of injury was due to fall from height. The locations of fracture in this group were as follows: 2 fractures were in proximal third,

9 in middle third and 1 in distal third of femur. All the fractures were closed.

The surgery was performed under general anesthesia with the patient in supine position with the help of C-Arm. Two titanium elastic nails of identical diameter were used and the diameter of the individual nail was selected as per Flynn et al criteria (diameter of nail=Width of the narrowest point of the medullary canal on anteroposterior and lateral view x 0.4 mm) and intraoperative assessment. The diameter of the nail was chosen so that each nail occupied at least one third to forty percent of the medullary cavity. The nails were inserted in retrograde fashion with medial and lateral incisions 2-3 cm above the physes. The nails were prebent sufficiently so that apex of the bowed nails rested at the same level on the fracture site to ensure a good equal recoil force. Mini open reduction was required in two cases due to soft tissue interposition. The nails were advanced proximally so that both were divergent and the tips got anchored minimum 1 cm distal to the physes. Cylindrical back slab was given after operation. Post operatively patient's limb was elevated on a pillow. Partial weight bearing was started at around five weeks and full weight bearing by eight weeks depending on the fracture anatomy, quality of reduction, callus response and associated injuries. All patients were followed up radiologically as well as clinically every 3 weeks for first 12 weeks, then one every 3 months. Parameters studied were clinical and radiological fracture of union, mal-alignment, range of motion of the affected side of knee, limb length discrepancy and any other complications found during the study.

Table 1: Flynn et al. scoring criteria for TENS

	Excellent	Satisfactory	Poor
Pain	None	None	Present
Malalignment	<5°	5-10°	>10°
Limb Length Discrepancy	<1 cm	1-2cm	>2cm
Complication	None	Minor	Major and/or lasting morbidity



**Surgical technique:** With the patients lying supine on an orthopedic traction table, under general or spinal anesthesia, the fracture was reduced under the guidance of an image intensifier. The selection of the insertion point for the nails was medial and lateral at the top flare of the medial and lateral condyles so that after insertion they would tend to bend against the flare of the condyles. In addition, the insertion should be posterior to midline of the shaft so that if the nail backout, they will be less likely to enter the synovial pouch. A 5mm incision were made both on the lateral and medial side of the leg extending about two finger breadth above the superior pole of the patella (the superior pole of the patella lies slightly above the level of physis). An entry hole was made with a bone awl on the medial and the lateral cortex of the distal femur, avoiding the physal plate. The diameter of nail should be 2/5 of the internal diameter of the medullary canal (Nail diameter =  $0.4 \times$  canal diameter).

Ideally, the lateral nail should extend to the level of the greater trochanter and the medial nail into the femoral neck. The amount of prebending should be equal for both the nails. (The amount of bending should be three time of inner diameter of the shaft). Both the nail were inserted through the early holes one after another and where driven upto the fracture site. When the nail was at its final position, it was marked with a pen or clamp about 10 to 20 mm from insertion hole. The nail were cut at the marked level and advanced so that they lay against the supracondylar flare of the femur in in order to avoid complications at the insertion site. Then the wound was closed in layer.

#### Results:

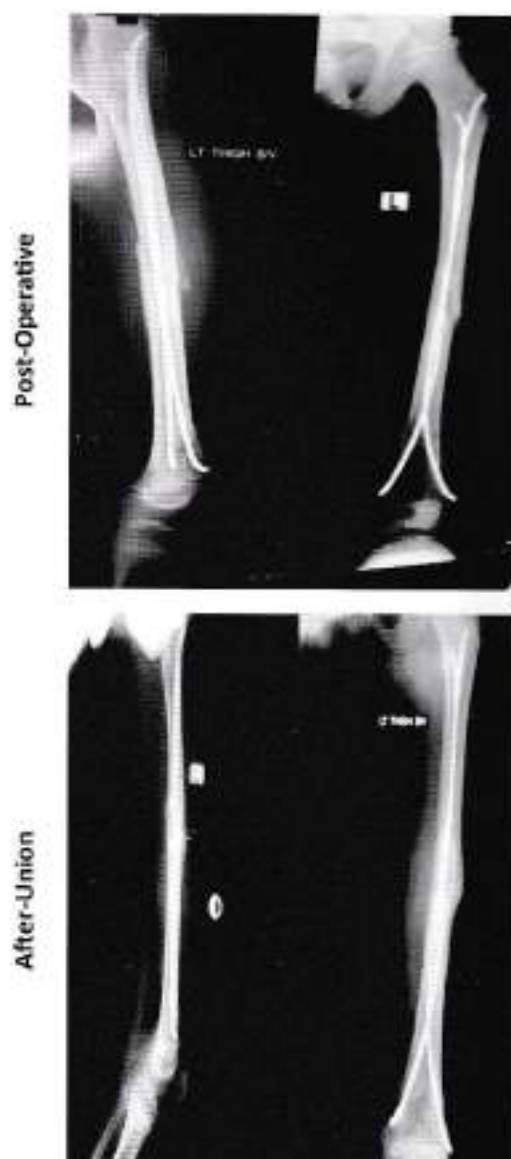
The functional results were assessed according to criteria of Flynn's scoring system and were excellent. The excellent and successful results were considered as satisfactory. The poor results were considered as unsatisfactory. The mean duration of surgery was 35 minutes (range, 25-45mins), the size of nail varies from

2-4mm. The mean duration of hospital stay was 3 days (2-4 days). Apart from the adequacy of fixation, the hospital stay also depended upon the other associated injuries. All the 12 patients were available for evaluation after a mean duration of follow up for 6 months. Partial weight bearing was started after 4 weeks post-operatively in younger children, but it was delayed by another 2 weeks in older children (more than 12 years old). Full weight bearing was allowed, when bridging callus was visible on standard antero-posterior and lateral radiographs with partial obliteration of the fracture line. Union was achieved in all cases between 6 to 10 weeks (average 8 weeks). All the patients achieved full range of knee motions by 6 weeks. Nails can be removed at about eight month to one year post surgery when the fracture line was no longer visible radiologically. The results were excellent in 12 patents (100%) as per the scoring criteria for TENS by Flynn et al. None of the patients developed any angular deformity of greater than five degrees. Limb length discrepancy of less then 1 cm was found in two cases, which was clinically insignificant. One patients developed bursitis at the entry point due to friction caused by cut ends of nail. None of cases developed any infection, joint penetration and nail bending, implant failure, iatrogenic fracture, non-union or any neurovascular complications. No complications were associated with the nail removal procedure and no re-fracture were observed after nail removal till the last follow up.

Pre-operative







### Discussion :

The ideal treatment for pediatric femoral shaft fracture depends upon the age of children, location and type of fracture, availability of facilities, knowledge of surgeon, and financial conditions to some extent[14]. Over the past few decades, management of pediatric femoral fractures has shifted more towards operative intervention because of quicker recovery, shorter rehabilitation period, less immobilization, and less psychological impact to the children[6]. Flexible intramedullary nails can be easily applied, require no exposure of fracture site, and

cause few complications. During insertion of nail, reaming is not done, and nutrient vessels preserved, so there is a theoretical advantage of early healing of fracture. Presence of parents in the hospital reduces their working hours and increases the economic burden of the family. Reeves et al performed a large comparative study between the conservative and operative treatment and showed a much longer mean hospital stay in the conservative group (26 days vs. 9 days) and more complication too. They concluded that intramedullary nailing has a shorter hospitalization, and has psychological, social, educational, and some economical advantages over traction and hip spica. Similarly Sink et al treated unstable pediatric femoral fracture in 27 patients with sub-muscular bridging plates. They found all the fracture united within 12 weeks without any complications. However fractures treated with intramedullary nail have better stability than those treated with sub-muscular bridging plate even though the hospital stay is same in comparable to both techniques. Hensen et al recommended the use of plate osteosynthesis. It has the disadvantage of large soft-tissue dissection, an increase in the risk of infection and delayed union, nonunion, besides a need for secondary large soft-tissue dissection to remove the plate. Reeves et al, Ward et al, Krettek et al suggested the use of external fixation, which provides good stability and early mobilization, but one fourth of his patients developed an infection at the side of the screws and one fifth of the patients were unhappy with the device. In a prospective study, Bar-on et al compared flexible intramedullary nailing to external fixation and found the flexible intramedullary nail better as regards pain, leg-length discrepancy and time for healing of the fracture. Good results with flexible ender nails have been reported in the 5-10- year age group by Heinrich et al and Kissel and Miller. Recent views in favor of flexible intramedullary nailing by Ligier et al have

been supported by Bar-on et al and Flynn et al. Ligier et al reported good results with elastic stable intramedullary titanium nailing of 123 femoral shaft fractures in children. They reported no nonunion or delayed union, only one infection and minimal limb-length discrepancy. Herndon et al reported that malunion developed in seven of 24 patients who were treated with traction while no malunion was observed in 21 children who were treated using TEN. Buechsenschuetz et al 19 documented TEN to be superior in terms of union, scar formation and overall patients satisfactory when compared to traction and casting. Kirby et al on 25 children femoral shaft fracture, which were evaluated in two separate groups of traction plus cast and intramedullary nail, shortening of >2.5cm and malunion were reported in traction and casting group. In studies performed by Aronson and Herndon, the complication of malunion in traction and cast was more frequent than surgical treatment[7]. There were altogether 2 cases of limb lengthening; one case of 6 mm and another case of 8 mm. Overgrowth usually occurs in femoral fracture in children between 2 and 10 years old, both after conservative and operative treatment. This is due to the increased vascularity at the growth plate during the process of fracture healing. According to Shapiro study, the average lengthening is 9 mm and varies from 4 mm to 25 mm, commonly in children between 2 and 10 years old. Griffin et al reported overgrowths most rapidly occurs during the first 2 years after fracture and to a less extent in the next year. Knee motion was recorded to be at pre-injury level in all of our cases. One common disability after femoral fracture is decreased knee motion due to either stiffness or weakness; particularly after non-operative treatment. It is rare after operative treatment because of early mobilization of the knee joint. Regarding the complications, there are no cases of infection, breakage of nail, delayed union, nonunion in our study.

However there was formation of bursa over the side of nail entry in one cases because of friction between the tip of nail and skin. So we can say that the procedure is relatively safe and less complication. As compared to the elastic stable nails, flexible intramedullary nail can easily pass through the entry site, need no pre-bending of nail before insertion and promote early callus formation because of the flexible nature of the nail and micromotion at the fracture site. Because of its flexible nature, the nail can possibly bend inside the canal spontaneously and hold the bone rigidly at three points. Though it may not always hold the fractured bone according to three point fixation; fracture heals without undue complications. We agreed that intramedullary nail could not effectively control the torsion and shift of the fragment, particularly in cases of spiral and comminuted fractures. In these types of cases, we prolong the duration of posterior slab until fracture become stable. The degree of shifting of fragment caused by nail during surgery does influence the outcome of fracture healing a lot. In addition there is no doubt that flexible nail can be more easily inserted inside the fractured bone compared to elastic stable nail (Nancy nail). An ideal treatment for pediatric femoral shaft fracture is the one that controls the length and alignment, is comfortable for the patient and convenient for the family and causes the least negative psychological impact.

**Conclusion:** Titanium elastic flexible intramedullary nail for femoral shaft fracture in pediatric population is an excellent method of treatment in terms of short immobilization and rehabilitation. It is ideal and cost effective with short hospital stay, rapid recovery, very high union rate and minimal complications. In addition to those benefits it has little psychological impact to the children and parents. More sample size, long term follow up and multicentric trials are recommended for better results.



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