ORIGINAL ARTICLE

Profile of Acute Epididymo-Orchitis Patients in Arifin Achmad Regional General Hospital Riau Province, Indonesia

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ABSTRACT

Purpose: To evaluate the profile of acute epididymo-orchitis patients.

Materials and Methods: We reviewed medical records of acute epididymo-orchitis patients underwent management in urology ward of Arifin Achmad Regional General Hospital, Pekanbaru, Riau Province, Indonesia. The data collected consisted of age, clinical symptoms, physical examination, radiology examination, managements, length of stay and the complication. Statistical analysis of univariate was used. Approval on the study was obtained from the Ethical Review Board for Medicine and Health Research, Medical Faculty, University of Riau.

Results: There were 21 acute epididymo-orchitis patients in the study in which mostly (57.2%) occured in 2015, mostly (47.6%) in 21-30 years old age group, the most clinical symptom (80.9%) was scrotal pain, most physical examination (71.4%) was swollen scrotum, all theraphy (100%) were ceftriaxon and ketorolac. Hematocrit was mostly supportive test (95.2%) done, the average duration of treatment were in 4-7 days in 57.1% of patients and complication such as testicular abscess was found in 4.8% patients. .

Conclusion: Acute epididimo-orchitis patients in our hospital mostly suffered young man, scrotal pain, scrotal swollen, drug therapy with antibiotic and pain killer, 4 - 7 days in lenght of stay and minimal complication.

Keywords: Acute, Epididymo-orchitis, epididymitis, Orchitis

INTRODUCTION

Acute epididymo-orchitis is an inflammatory process of the epididymis and testes or symptoms that most often occur with acute pain. Acute epididymo-orchitis is caused by a large proportion of sexually transmitted pathogens that radiate upward and uropathogens that spread to the urinary tract. A small portion of acute epididymo-orchitis is caused by bacterial infections such as E.coli through urine that enter the vas deferens. Acute epididymo-orchitis can occur at any age and is the most common cause in men over the age of 35 years. The cause is partially blocked urine flow with increasing age. Sexually transmitted infections are also the cause of acute epididymo-orchitis in young men who are actively having sex.[1]

The most common causes of acute epididymo-orchitis are chlamydia and gonorrhea. These germs usually infect the urethra (urethritis) and can pass through the vas deferens to the epididymis and testes.[1] In addition, viruses are also one of the causes of acute epididymo-orchitis, which is through the bloodstream to the testes. But now it is rare because there are already mumps, measles, rubella (MMR) immunizations that are routinely given to children. Infection of the rare causes of acute epididymo-orchitis is tuberculosis, brucellosis, and in people who have problems with the immune system such as Acquired Immune Deficiency Syndrome (AIDS).[2]

Acute epididymo-orchitis in children who have not entered school age is considered a rare case. Anderson et al. diagnosed acute epididymo-orchitis was only 15% in boys with symptoms of acute scrotum pain. But some new researches had changed this research. Lewis et al analyzed for 2 years various etiologies of acute scrotum pain in boys treated in the emergency room. In this study of 238 boys only 109 were diagnosed with inflammation, 83 of them due to inflammation of the gonads, and 46 boys experienced testicular torsion. Klin et al. estimate the prevalence of acute epididymo-orchitis by 65% of 65 children referred in the past 5 years due to acute scrotum pain.[3] The most common symptom in acute epididymo-orchitis is pain on one side of the testis and discomfort. Pain that is felt often spreads in the scrotum area, groin, thighs, lower back, and can worsen the situation when sitting too long. In addition, there is also a change in sperm color or viscosity. In some patients there is inflammation that can affect the prostate gland, causing discomfort in the

groin, perineum, or thighs and may affect the ability to urinate. Symptoms of a source of infection include urethral pain, pelvic pain, painful urination, or a burning sensation in the bladder (cystitis), fever, perineal pain, pelvic pain, swelling, and redness of the skin. The scrotum can experience swelling in the presence of hydrocele. It is necessary to ask about the history of the disease, physical examination, and urine samples to diagnose acute epididymo-orchitis. Urine culture is a more certain way to see if there is a bacterial infection other disorders.

Management of acute epididymo-orchitis caused by bacteria is by giving antibiotics for 2 weeks, such as doxycycline, azithromycin, ofloxacin, syphroploxaksin, levofloxacin, or trimethhoprim. There is no specific therapy for acute non-infectious epididymo-orchitis. Common therapy for acute epididymo-orchitis includes a one to two day rest, antibiotics, and scrotum evaluation. The goal is to reduce swelling and discomfort.[3] Based on the description above, encourage the author to conduct research on the profile of acute epididymo-orchitis patients.

MATERIALS AND METHODS

We reviewed medical records of acute epididymo-orchitis patients underwent management in urology ward of Arifin Achmad Regional General Hospital, Pekanbaru, Riau Province, Indonesia. The data collected consisted of age, clinical symptoms, physical examination, radiology examination, managements, length of stay and the complication. Statistical analysis of univariate was used. Approval on the study was obtained from the Ethical Review Board for Medicine and Health Research, Medical Faculty, Riau University.

RESULTS

There were 21 acute epididymo-orchitis patients in this study. Table 1 showed the highest incidence of acute epididymo-orchitis occurred in 2015 as many as 12 patients (57.2%) and in 2016 there were 5 patients (23.8 %), and in 2017 there were 4 patients (19.0%) while in 2010-2014 there was no acute epididymo-orchitis.

Table 2 showed the highest incidence of acute epididymo-orchitis occurred in 2015 as many as 12 patients (57.2%) and in 2016 there were 5 patients (23.8 %), and in 2017 there were 4 patients (19.0%) while in 2010-2014 there was no acute epididymo-orchitis.

Table 2 showed that the most acute age group of epididymo-orchitis patients is in the age range of 21-30 years in 10 patients (47.6%) while the least was the age range 1-10 years old patients were not found in this study.

Table 1 Distribution of acute epididymo-orchitis patients by year.

Year	Frequency N=21 (%)
2010	0 (0)
2011	0 (0)
2012	0 (0)
2013	0 (0)
2014	0 (0)
2015	12 (57.2)
2016	5 (23.8)
2017	4 (19.0)

Table 2: Frequency distribution of epididymo-orchitis patients by age

Age (year)	Frequency N=21 (%)
1-10 year	0 (0)
11-20 year	3 (14.3)
21-30 year	10 (47.6)
31-40 year	4 (19.0)
41-50 year	2 (9.5)
>50 year	2 (9.50

Table 3. Frequency distribution of epididymo-orchitis patients based on clinical symptoms.

Symptom	Frequency N=21 (%)
Scrotal pain	
Yes	17 (80.9)
No	4 (19.1)
Swollen testis	
Yes	10 (47.6)
No	11 (52.4)
Fever	
Yes	14 (66.7)
No	7 (33.4)
Nausea	
Yes	5 (23.8)
No	16 (76.2)

Table 4: Frequency distribution of epididymo-orchitis patients based on physical examination.

Physical examination	Frequency N=21 (%)
Swollen scrotum	
Yes	15 (71.4)
No	6 (28.6)
Red scrotum	
Yes	1 (4.8)
No	20 (95.2)
Scrotal pain	
Yes	9 (42.8)
No	12 (57.1)

Table 5: Distribution of epidemiology of orchitis patients based on investigations

Supporting investigation	Frequency N=21 (%)
Urinalysis	
Erythrocyte	
(>2/hpf)	0 (0)
(< 2/hpf)	4 (19.1)
Not done	17 (80.9)
Leukocyte	
(> 5/lpb)	0 (0)
(< 5/lpb)	4 (19.1)
Not done	17 (80.9)
Routine blood	
Leukocyte	
(> 10.000/ mm3)	14 (66.7)
(<5000 /mm3)	0 (0)
(5000-10.000)	6 (28.6)
Not done	1 (4.7)
Hemoglobin	
(14-18 gram/dL)	10 (47.6)
(< 14 gram/dL)	10 (47.6)
Are not done	1 (4.8)
Hematocrit	
(<40%)	20 (95.2)
(>52 %)	0 (0)
Not done	1 (4.8)
Doppler Ultrasoud	
Hypervascularization	1 (4.8)
Avascularization	0 (0)
Not done	20 (95.2)
Conventional Ultrasound	
Yes	8 (38.1)
No	13 (61.9)

Table 6: Frequency distribution of epididymo-orchitis patients based on management

Management	Frequency N=21 (%)
Antibiotic	
Ceftriaxon	21 (100)
Analgesic	
Ketorilac	21 (100)

Table.7 Frequency distribution of epididymo-orchitis patients based on length of stay

Length of stay	Frequency N=21 (%)
1-3 day	8 (38.1)
4-7 day	12 (57.1)
8-10 day	1 (4.8)
11-15 day	0 (0)

Table 8: Frequency distribution of epididymo-orchitis patients based on complications

Complication	Frequency N=21 (%)
Get well	20 (95.2)
Chronic infection	0 (0)
Testicular fibrosis	0 (0)
Testicular abscess	1 (4.8)

Table 3 show the most common clinical symptoms of epididymo-orchitis were scrotum pain in 17 patients (80.9%). While the number of patients at least based on clinical symptoms was nausea / vomiting in 5 patients (23.8%).

Table 4 showed that the most physical examination was swollen scrotum in 15 patients (71.4%). In this study also found the least amount was red scrotum 1 patient (4.8%).

Table 5 showed the highest number of patients based on investigations was hematocrit in 20 patients (95.2%).

Table 6 showed most management based on antibiotics and analgesics were ceftriaxon and ketorolac in 21 patients (100%).

Table 7 showed the highest number of patients based on length of stay is 4-7 days 12 patients (57.1%). In this study, the number of patients at least based on length of stay was 8-10 days 1 patient (4.8%). Whereas patients treated for 11-15 days were not found in this study.

Table 8 showed there were 20 patients (95.2%) who had complete recovery and no patients were found to have chronic infections and testicular fibrosis. And 1 (one) patient (4.8%) had a testicular abscess.

DISCUSSIONS

Based on the results of this study, the highest group who experienced acute epididymo-orchitis were the 21-30 year age group, namely 10 people (47.6%). This is similar to G.A's research. Luzzy and T.S. O'brien 2001 said that 610 cases in the United States occur most often 70% of cases occur at the age of 20-39 years. But all ages were affected this disease (age 4 months to 76 years).[5] Acute epidimitis often occurs in patients who are sexually active young adults. This disease has a substantial impact on American military services. In the early 1970s it was reported that epididymitis causes reduced hours of work in United States military personnel compared to other urological disorders, and at that time epididymitis was the most common cause of someone entering urological services. In older men > 35 years of age, most pathogenic organisms often causes epididymitis is a pathogenic organism that causes UTI, such as E. coli. In a recent study of men > 40 years of age with acute epididymitis, 32% were found to have UTI caused by E. coli.[12]

Based on the results of this study, clinical symptoms of acute epididymo-orchitis patients were scrotum pain in 17 (80.9%) patients. While the least clinical symptoms in cases of acute epididymo-orchitis are nausea and vomiting, in 5 (23.8%) patients. The study was in accordance with Esragul Akinci's (2006)

study which stated that the most common symptoms in acute epididymo-ochitis patients were scrotal pain (94%) and swelling (82%).[13] However, it was different from GA Luzzy and TS O'brien 2001 research. Fever (> 37.5'C) occured in about three-quarters of cases of acute epididimo-orchitis. Shivering is reported in a quarter of those who have a fever, and more often in the elderly. Adjacent testicular involvement and the occurrence of inflammation or hydrocele that often occur. Clinically, orchitis occurs in 58% of patients in all acute epididymo-orchitis patients, scrotum skin erythema 62% and is strongly associated with epididymal swelling. This difference is thought to be due to differences in research sites and differences in time and the sample size taken in conducting research.

The results of this study found that the most physical examination was swollen scrotum which was 15 people (71.4%) and the least obtained was the red scrotum which was 1 person (4.8%). In contrast to Christina B Ching's study which stated that physical examination might fail to distinguish epididymoorchitis from testicular torsion, the physical examination findings associated with acute epididimoorchitis include such as tenderness and induration that occur first in the epididymal tail and then spread, increased hemiscrotum, cremasteric reflection normal, erythema and scrotal cellulitis, reactive hydrocele (if the patient has advanced epididymo-orchitis), testicular enlargement, epididymis that does not heal, in 20-40% of cases associated with acute epididymis. This difference was thought to be due to differences in the samples taken in conducting research. Based on this study, the most investigations performed on acute epididymo-orchitis patients were hematocrit in 20 patients (95.2%) and the least doppler ultrasound was 1 patient (4.8%). This study was different from GA Luzzi (2001) 's study, which says that color flow doppler ultrasound was currently an option in evaluating acute scrotum in 40 patients with acute scrotum pain, color Doppler imaging has a sensitivity of up to 70% for epididymitis with a specificity of 88%, and for testicular torsion the sensitivity is 82% and specificity is 100% .19 In contrast to the Hoosen AA study which stated that the presence of urethritis supports the presence of the epididymis although urethra symptoms rarely occured in only 30% in men who experience acute epididymitis. 70% of patients are usually proven to have leukocyte urethritis (<5 hpf). In Durban 93% of 94 boys with epididymis were detected with urethritis using a slightly lower threshold of leukocytes (> = 4 hpf).[6]

In Taylor-Robinnson's (1996) study, chlamydia culture or chlamydial mAb tests were generally used. In routine clinical practice, the chlamydial enzyme immunoassay test (EIA) is often used as an initial test, if the results are positive, more specific tests should be continued such as immunofluorescence. Tests can be applied to firstvoid urine samples (first urine) and urethral swabs. Unfortunately, the EIA test has low sensitivity (50 ± 70%). Molecular methods that have recently been developed using ligase chain (LCR) or PCR reaction techniques have high sensitivity, and shows that the culture that has been the gold standard for diagnosis, the sensitivity is not more than 70%. It is likely that the use of LCR or PCR in men with <35 years old epididymitis will result in a higher detection rate than previously found.[7] In contrast to Mary AE Garthwhaite's (2017) study which recommended that urethral swabs be taken and sampled mid-stream urine for diagnostic purposes before antibiotic therapy begins, this examination for urine culture is carried out in 54.7% of cases, urine for chlamydia PCR is performed in 17% of cases and urethral swabs are only 5.6% of cases. Since PCR is not yet widely available for routine clinical use, therapy has become a gold standard because of its high specificity and sensitivity.[8] This difference is thought to have occurred because the Taylor-Robinnson and Marry AE study focused on tests to diagnose sexually transmitted infections while this study was conducted to see how many supporting examinations had been carried out.

Based on the results of this study, the most management in acute epididymo-orchitis patients was ceftriaxon and ketorolac, which were 21 patients (50%). This study is in accordance with the research conducted by Mary AE Martinwaitel (2007) as many as 89 cases of acute epididymo-orchitis were identified over a period of 6 months. Of these, only 53 sets of records are available for review. The age range of patients is 18-87 years with an average age of 38 years, 26 patients aged <35 years and 27 patients> 35 years (11 patients > 50 years). Of the patients who came to the emergency department 28% had been started using antibiotic therapy by general practitioners. Examinations to identify causative pathogens include midstream urine (MSU) samples for culture (54.7%) urine for chlamydia polymerase chain reaction (PCR; 17%) and urethral swabs (5.6%). Oral antibiotics were prescribed in 81 cases. Of all patients who were given antibiotics 46.5% were given ciprofloxacin alone (mean age 52 years range 18-87 years), 25.5% were given doxycycline, (mean age 30 years range 18-45 years) and 21% were given ciprofloxacin in combination with doxycycline, (mean age 32 years range 18-49 years). The dosage regimen has been documented and the duration of treatment also varies.[9]

Based on the results of this study, the highest number of patients who underwent treatment during their stay at RSUD Arifin Achmad, Riau Province was 4-7 days, namely 12 patients (57.1%) and the least was 8-10 days, namely 1 patient (4.8%) . This study is in accordance with Pilatz A's study which says a cohort study using semen parameters that were disrupted during the course of epididymitis, but

would recover spontaneously after successful treatment, and most cases of orchitis due to mumps disappear spontaneously within 3-10 days with antibiotics according to the majority of cases of bacterial orchitis it can heal without complications

Based on the results of this study of 21 patients there was 1 patient who experienced complications. Complications that occur in this patient are abscesses (4.8%). And the rest had a complete repair or recovery of 20 patients (9.2%). This study is in accordance with the research of Adrian Rhudd (2017) who said that complications that are rare in men suffering from epididymo-orchitis disease scrotum abscess formation 3-5% .23 Not unlike the research of GA Luzzy (2001) which states that in older men > 40 years 90% recover within 30 days after treatment. However, in a follow-up study of 33 men with severe epididymitis mainly caused by coliform 39% experienced testicular complications including intratesticular abscess and epididymis, testicular infarction and 7 (21%) of them experienced testicular atrophy, in the acute phase of abscess formation 3 (8%) at the beginning where treatment was delayed.[11]

CONCLUSIONS

Acute epididimo-orchitis patients in our hospital mostly suffered young man, scrotal pain, scrotal swollen, drug therapy with antibiotic and pain killer, 4 – 7 days in length of stay and minimal complication.

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ORIGINAL ARTICLE

A Study on Evaluation of Safety and Efficacy of Clonidine as an Adjunct to Bupivacaine in Caudal Block in Paediatric Patients

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ABSTRACT

Introduction: The use of clonidine, as additives to bupivacaine provides pain relief for longer duration than bupivacaine alone. This study was planned to evaluate the safety and efficacy of clonidine as an adjunct to bupivacaine in caudal block in paediatric patients.

Methodology: This was randomized controlled trial where study was done in three groups. In Group : A: was Inj. Bupivacaine 0.25% {0.75ml/kg}, Group : B: Inj. Bupivacaine 0.25% {0.75ml/kg}+ inj. clonidine 1μg/kg and Group : C: Inj. Bupivacaine 0.25% {0.75ml/kg}+inj. clonidine 2μg/kg was given.

Results: There was a statistically significant prolongation in the duration of analgesia in Group B ($p < 0.05$) and Group C ($p < 0.05$) when compared with Group A. None of the patients had hypotension, bradycardia, respiratory depression or urinary retention in all the three groups.

Conclusions: clonidine (1-2 μg/kg) is safe and effective adjuvant in caudal block for pediatric lower limb and lower abdominal surgery.

Key Words: Pediatric, clonidine, bupivacaine, analgesia, caudal block.

INTRODUCTION

The main difference in pain perception between children and adults is related to cognitive-evaluative component which develops throughout childhood and adolescence[1]. A major difficulty is assessment and at times even the identification of pain in children, especially in infants. The younger the child, the greater the difficulty to communicate because the ability to express distress and discomfort is limited. Under treatment of post-operative pain even in the children and newborns may trigger biochemical and physiologic stress response and cause impairments in pulmonary, cardiovascular, neuro-endocrinal, gastrointestinal, immunological, and metabolic functions. An effective pain therapy to block or modify the myriad physiologic responses to stress is now an essential component of modern paediatric anaesthesia and surgical practice.

So, it is now widely accepted that children surely require postoperative analgesia. During the last decade, pediatric pain has received considerable attention, and several methods have been developed both for assessment and relief of pain in children.

Conventional post-operative analgesia techniques for paediatric surgery are administration of opioid injections, oral analgesics or popular in peadiatric patients which may produce unwanted fear in children. Furthermore, administration of such injection require nursing staff and hospitalization, which prevents early discharge to home. Regional anaesthetic techniques and pain management in children have gained established place for providing postoperative analgesia and their field of application is rapidly expanding.

Regional Anaesthesia provide complete pain relief, bring down requirement of inhalational agents drastically, faster and smoother recovery, can be extended in post-operative period.

Bupivacaine is the most commonly used local anesthetic in Caudal block. However, the duration of postoperative analgesia has been limited to 2 to 6 hours. To provide analgesia for longer periods, insertion of catheter in the caudal space is technically more difficult, time consuming, expensive and there is an added risk of infection[2]. So various drugs have been added to local anesthesia to prolong the duration of analgesia provided by a single caudal injection. Addition of opioids and non-opioids like adrenaline, clonidine, benzodiazepines, ketamine, etc. are used along with local anesthetics[3]. However, opioid like morphine is associated with side effects like nausea, vomiting, pruritus, respiratory depression etc. which make their use limited for paediatric patients. The use of clonidine, as additives to bupivacaine provides pain relief for longer duration than bupivacaine alone.

Clonidine, an α- agonist when administered along neuraxis relieves pain through α- receptors located in superficial lamina of spinal cord. When given epidurally, 1-2μg/kg of body weight, intensifies the duration of analgesia without any fall in heart rate, mean arterial pressure, respiratory depression and oxygen saturation[4].

This study was planned to evaluate the safety and efficacy of clonidine as an adjunct to bupivacaine in caudal block in paediatric patients.

Objectives

The study was conducted to evaluate and compare the duration of postoperative analgesia, postoperative sedation, hemodynamic effects and various side effects produced by caudal clonidine in combination with bupivacaine and bupivacaine alone.

MATERIALS AND METHODS

After approval from the In institutional ethics Committee, the present study was conducted in 60 paediatric of either sex belonging to ASA grade I to II in the age group 1 to 10 years scheduled for elective lower abdominal, orthopaedic and genitourinary surgery at Surat Municipal Institute of Medical Education and Research, Surat.

Detailed history, past history, general as well as systemic examination, preoperative assessment and routine investigations was carried out a day before operation. Patients with drug allergy, skin infections at the site of block, abnormalities of sacrum, active central nervous system diseases, history of disorders of blood clotting, and patients with cardiovascular, respiratory, hepatic and renal diseases were excluded from the study.

Informed written consent was taken from parents. We conducted a prospective, randomized controlled study. The patients were randomly allocated in three groups of twenty patients each. In Group : A: was Inj. Bupivacaine 0.25% {0.75ml/kg}, Group : B: Inj. Bupivacaine 0.25% {0.75ml/kg}+ inj. clonidine 1μg/kg and Group : C: Inj. Bupivacaine 0.25% {0.75ml/kg}+inj. clonidine 2μg/kg was given. The children belonging to each group received the following drugs.

Clonidine used in our study was a preservative free preparation available in 150μg/ ml ampoules. All preoperative, intraoperative and postoperative procedures performed as per standard protocol.

The **duration of caudal analgesia** was defined from the time of caudal injection to the time of the first analgesic supplementation, **Respiratory depression** was defined as a oxygen saturation <93 % Patients were assessed for pain with **Observational pain score** and sedation assessed with Four Point sedation score.

These scores were assessed at 0.5, 1, 2, 4, 6, 8, 12, hours postoperatively.

1. Observational Pain Score (OPS)

Behavioral Objectives	None	Moderate	Severe
Crying	1	2	3
Facial expressions	1	2	3
Position of legs	1	2	3
Position of torso	1	2	3
Restlessness	1	2	3

A OPS score of 5 signified excellent analgesia and a score of OPS score 15 signified that the analgesia was ineffective Patients were administered rescue analgesia, syrup paracetamol 10 mg/g when the OPS was more than 12.

Four Point Sedation Score

A Four Point Sedation Score was assigned as follows:

1= Asleep, not arousable by verbal command
2=Asleep, arousable by verbal command, nausea vomiting
3= Drowsy/ not sleeping
4= Alert/ aware

Side effects like nausea, vomiting, bradycardia, hypotension, urinary retention and respiratory depression were noted.

Statistical Analysis: All data are presented as mean (SD) except where specified. Data were analysed using ANOVA for repeat measurements. Continuous variables were analysed using student's t-test. The paired t-test was used for comparisons within the groups and the unpaired t-test for intergroup comparisons. Probability values <0.05 were considered significant.

RESULTS

The prospective, randomized study was carried out on 60 peadiatric patients of either sex between ages of 1 and 10 years, belonging to ASA Grade I and II scheduled for lower abdominal and lower limb surgery at Surat Municipal Institute of Medical Education and Research, Surat.

I the study patients were randomly selected from the routine list and they were divided into three groups of 20 patients each and received the following drugs in the caudal block.

In the study, Intraoperative monitoring was done and postoperatively patients were observed at different intervals for 12 hours. During the study following observations were noted.

Table 1: Age Distribution of Patients.

Age (Yrs)	Group A (n=20)	Group B (n=20)	Group C (n=20)	P Value
Age (mean SD)	4.75±1.96	4.72±1.58	4.85±1.86	0.972
Sex (Percentage)				
Male	18 (90)	15 (75)	19 (95)	0.153
Female	2 (10)	5 (25)	1 (5)	
Weight (kg) (mean SD)	13.6±3.20	13.55±3.06	13.05±3.23	0.831
Duration of surgery(Min) (mean SD)	60.75±11.15	64.5±14.03	62±11.28	0.616
duration of analgesia (hrs) (mean SD)	5.29±0.83	11.82±1.01	11.45±0.93	<0.001
Side Effects (%)				
Nausea	2(10)	2(10)	2(10)	-
Vomiting	2(10)	1(5)	2(10)	-

Table 2: Four Point Sedation Score postoperatively at different time intervals in all the three groups.

	Group A Number of patients				Group B Number of patients				Group C Number of patients				p Value
	1	2	3	4	1	2	3	4	1	2	3	4	
0.5 hr	0	8	12	0	0	13	7	0	0	16	4	0	< 0.05
1hrs	0	1	19	0	0	7	13	0	0	5	15	0	< 0.05
2 hrs	0	0	7	13	0	4	16	0	0	5	15	0	< 0.05
4 hrs	0	0	0	20	0	1	19	0	0	1	19	0	< 0.05
6 hrs	0	0	0	20	0	0	0	20	0	0	18	2	< 0.05
8 hrs	0	0	0	20	0	0	0	20	0	0	0	20	< 0.05
12 hrs	0	0	0	20	0	0	0	20	0	0	0	20	< 0.05

There is no difference in age of the patient in all these groups. The Patients in all the three groups weighed between 5 and 20kg. The difference in weight distribution among the groups was not statistically significant. The mean duration of surgery there was no statistically significant difference in the duration of surgery, among the three groups on intergroup comparison (>0.05)

There was no statistically significant difference in mean heart rate (intraoperatively & postoperatively) , mean arterial blood pressure(intraoperatively & postoperatively) , mean oxygen saturation(intraoperatively & postoperatively) , mean respiratory rate postoperatively among the three groups on intergroup comparison at different time intervals .There was a statistically significant prolongation in the duration of analgesia in Group B ($p < 0.05$) and Group C ($p < 0.05$) when compared with Group A. None of the patients had hypotension, bradycardia, respiratory depression or urinary retention in all the three groups.

The table 2 shows sedation score of all the patients at different time intervals.

We observed a statistically significant difference in the sedation scores of Group C on intergroup comparison with Groups A and Group B from the first hour up to 6 hours postoperatively (p value < 0.05). After 8 hours postoperatively, the mean sedation scores were '4' in all the three groups in the study (p value >0.05) There was no significant difference in the duration of motor block among the four groups.

DISCUSSION

Caudal analgesia provides an excellent means of pain relief to children in the postoperative period. This study was planned to evaluate the safety and efficacy of clonidine as an additive to bupivacaine in caudal block in paediatric patients.

In our study, there were no significant differences in heart rate and mean arterial pressure among the three groups on intergroup comparison at various intervals for the first 12 hours postoperatively ($p > 0.05$) Similar results were observed by samir jamali and colleagues (1993)[5] , Lee jj et al (1993)[6] , Klimscha et al (1997)[7] studied , Dr. Lt.Col. Upadhyay et al (2004)[4] , Hennawy and colleagues (2009)[8] and Jayshreesood et al (2008)[9]

However, Seyedhejazi M et al (2007)[10] found significant differences between two groups in the mean of systolic blood pressure, diastolic blood pressure and heart rate. No such side effects were observed in any of our patients, who all had comparable respiratory frequencies and SpO_2 value above 93% breathing room air, possibly because 1μg/kg and 2 μg/kg clonidine are well below the dose used in the above-mentioned study.

In our study, there was no significant difference in the mean respiratory rate and mean oxygen satura-

tion among the three groups on intergroup comparison measured at different time intervals for the first 12 hours postoperatively (p>0.05). Similar findings were observed in study conduct by samirjamali et al (1993)[5], Klimscha W, et al (1997)[7], Dr. Lt. Col. Upadhyay et al (2004)[4], TS Yildiz et al (2005)[11], Maria de Lourdes et al (2007)[1], Jayshreesood et al (2008)[9] and Hennawy and colleagues (2009)[8]

The mean duration of postoperative analgesia was 5.95 hrs. in Group A (Bupivacaine alone), 11.82 hrs. in Group B (Bupivacaine clonidine 1 μg/kg), 11.45 hrs. in Group C (Bupivacaine clonidine 2 μg/kg). So the mean duration of postoperative analgesia was statistically highly significant in Group B and Group C, as compared to Group A (p <0.05). Similar findings were observed in study conduct by Samir jamaliet at (1993)[18] Lee jj et al (1993)[23], Constant I et al (1997) [11], Kimscha, et al (1997)[7] Dr. Lt. Col. Upadhyah et al (2004)[4] Maria de Lourdes et al (2007)[1] Jayshree Sood et al (2008) [9]evaluated ,T.S. Yildiz et al (2005)[11] studied ,Hennawy and colleagues (2009)[8] compared ,

In our study, the assessment of sedation was done using four point sedation score. No significant differences were found among the four groups for the pain scores. Similar results were found in studies J.C. De Mey et al (1999)[12]evaluated and Wanda Joshi DO et al (2003)[13]Performed

In our study the Sedation scores were higher in bupivacaine- clonidine (2μg/kg) (group C) up to 6 hours (drowsy but not sleeping, asleep) postoperatively as compared to other groups. In Group C duration of sedation was significantly longer statistically as compared to other groups (p<0.05). Similar results were obtained in studies by Lee JJ et al (1993)[6] They, Klimscha et al (1997)[7], Dr. Lt. Col. Upadhyay et al (2004)[4] and Maria de Lourdes et al (2007)[1].

In our study, nausea occurred in 10 % of patients in Groups A, Group B and Group C. Vomiting occurred in 10 % of patient's In Group A and Group C and 5% of patients in Group B. None of the patients had hypotension, bradycardia, respiratory depression or urinary retention in all the three groups. There is no difference in rate of side effect among three groups. The similar results were also observed by Lee jj et al (1993)[6], Jayshree sood et al (2008)[9] and Hennawy and colleagues (2009)[8]. However, Maria de Lourdes et al (2007)[1] observed higher rate of side effects, vomiting in 17.3% in bupivacain group and 8.7% in clonidine group.

CONCLUSION

From the above study we conclude that the addition of clonidine (1-2μg/kg) to single shot caudal bupivacaine (0.25%) prolongs the duration of postoperative analgesia (11.5 hours) while maintaining hemodynamic stability, respiratory stability, producing minimal side effects, leaving the child calm, quiet comfortable, minimally sedated and easily arousable in the immediate postoperative period. Thus clonidine (1-2 μg/kg) is safe and effective adjuvant in caudal block for pediatric lower limb and lower abdominal surgery.

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ORIGINAL ARTICLE

Effect of Oral Clonidine and Oral Gabapentine as Premedication on Hemodynamic Stress Responses during Laryngoscopy and Tracheal Intubation and Duration of Post Operative Analgesia

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ABSTRACT

Introduction: Direct laryngoscopy and passage of endotracheal tube are noxious stimuli that can provoke stress response in cardiovascular, respiratory and other physiological systems. This study was planned to evaluate the effect of oral Gabapentin and oral clonidine on laryngoscopic stress response and postoperative pain relief.

Methods: 90 patients between the age group 18 to 60 years belonging to ASA class I and II scheduled for lower abdominal surgeries were devided into three groups. Each patient was given 0.2mg inj. Glycopyrolate i.m and oral tab. Clonidine 0.2mg (group C) or oral tab. Gabapentine 900mg (group G) or oral tab. vitamine C (group P) 30 min before surgery.

Results: Oral Clonidine (0.2 mg) when given in premedication provided better attenuation of hemodynamic stress response to laryngoscopy and tracheal intubation compared to oral Gabapentine (900 mg), where hypertensive response was fairly obtunded, but not the tachycardiac response.

Conclusion: Oral Clonidine has better response over tachycardia than Gabapentine, whereas Gabapentine is superior to clonidine for post-operative analgesia.

Key words: Clonidine, Gabapentine, Laryngoscopy, VAS (visual analogue score)

INTRODUCTION

Anesthesiologists have been trying a variety of drugs from their armamentarium to suppress notorious "pressor response." Drugs which can be used to control this hemodynamic response include α2-agonists, vasodilators, beta blockers, calcium channel blockers, lignocaine, and opioids.

Pain is defined as "An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage."[3]

Clonidine is a α2 -adrenergic agonist which decreases central sympathetic outflow and reduces blood pressure by an effect on both cardiac output and peripheral resistance. It tends to attenuate stress response to direct laryngoscopy.

Gabapentin is an antiepileptic drug that has demonstrated analgesic effects in diabetic neuropathy, post herpetic neuralgia and neuropathic pain, affects the nociceptive process by binding to the subunit of voltage dependant calcium channels and reduces excitatory neurotransmitter release in pain pathways, suggests it may have a role in prevention of post-operative allodynia[1].

MATERIAL AND METHODS

The present study was conducted in 90 patients between the age group 18 to 60 years belonging to ASA physical status class I and II scheduled for lower abdominal surgeries at our institute, after approval from the institutional ethical committee of our institute.

Pre-anesthetic evaluation was done by meticulous history taking regarding any present or past major medical illness, past history of any surgical procedure or drug reaction. A detailed general as well as systemic examination was done. The patients were explained about the nature and purpose of the study during preoperative period and informed written consent taken.

Inclusion Criteria

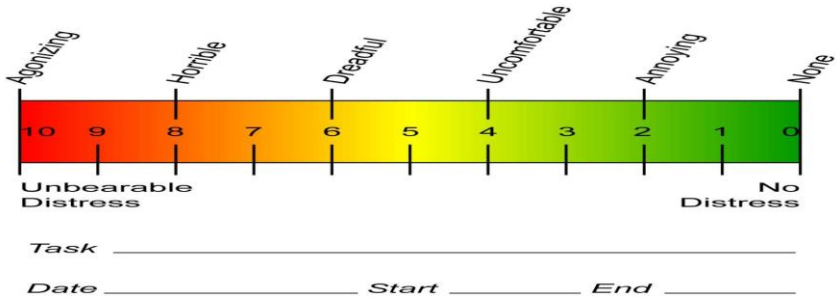
Patients with physical status ASA grade I & II; either sex; aged between 18 to 60 years of age underwent General anaesthesia for any for elective orthopedic or general surgical or gynecological procedures under general anesthesia were included in the study.
All patients were thoroughly examined in pre-anaesthetic clinic and routine investigations were done.

Exclusion criteria: Patients refuse to participate; having history of allergic reaction to any drug used in the study; patient with communication difficulties or not NBM for 6 to 8 Hours before surgery were excluded from the study.

In each group 30 patients were allocated. Baseline monitoring like temperature, heart rate, blood pressure, respiratory rate, spo2 were recorded in recovery room.

All patients were explained about the Visual Analogue Scale (VAS; 0 = no pain and 10=worst pain) for assessing the intensity of pain during postoperative pain interview.

Visual Analogue Scale



Patients were divided into three groups and Premedication was given accordingly-

Group C: Tablet Clonidine 0.2mg orally half hour before surgery & injection Glycopyrrolate 0.2 mg intramuscularly 30 minutes before surgery.

Group G: Tablet Gabapentine 900mg orally half hour before surgery & injection Glycopyrrolate 0.2 mg intramuscularly 30 minutes before surgery.

Group P: Tablet Vitamin C orally one half hour before surgery & injection Glycopyrrolate 0.2 mg intramuscularly 30 minutes before surgery

General anaesthesia was given with Injection Thiopental sodium 4-6 mg/kg iv, injection Succinylcholine 2 mg/kg iv and Maintain on 0_2 +N_20+Isoflurane +Injection Atracurium. Stress response was observed by measurement of systolic and diastolic and mean blood pressure and heart rate before induction and after induction at 1, 2, 3, 4, 5 min interval**.** Postoperative monitoring for heart rate, systolic blood pressure, Diastolic blood pressure, Mean arterial pressure.

Rescue analgesia was given with inj. Diclofenac Sodium 75 mg intravenously when VAS score > 3.Time for rescue analgesia and total dose of analgesic requirement were observed. Patients were monitored and assessed for any postoperative side effects like nausea, vomiting, vertigo, headache, visual disturbances(diplopia, nystagmus), sedation RSS>5.

The results were expressed as mean ± SD. Statistical analysis consisted of ANOVA test with p value less than 0.05 was considered as significant and p value less than 0.01 was considered as highly significant. P value greater than 0.05 was considered as non-significant.

Ramsey Sedation Score

SCORE	DISCRIPTION
0	awake, oriented
1	agitated, anxious
2	awake, co-operative
3	sleeping but co-operative
4	deep sedation, quick reaction to painful stimuli
5	deep sedation, slow reaction to painful stimuli
6	deep sedation, no reaction to painful stimuli

RESULT

There was no statistically significant difference between the three groups in terms of age, weight, gender and duration of surgery.

Heart Rate (Table 1)

In control group baseline heart rate remained high compared to clonidine and gabapentine group ($p<0.05$). Heart rate increased from baseline value during laryngoscopy and tracheal intubation, ($p<0.001$).Similar finding were observed at 1, 2, 3, 4 minutes after intubation ($p<0.001$). At 5 minutes after intubation heart rate remained high compared to baseline value. (table 1)

Systolic, Diastolic And Mean Arterial Pressure (Tables 2,3 and 4)

At pre oxygenation, all groups were comparable for systolic blood pressure ($p>0.05$). Significant decrease in diastolic and mean arterial pressure was observed in clonidine and gabapentine group ($p<0.05$) compared to control group, in which it remained comparable to baseline ($p>0.05$).

Immediately after laryngoscopy and intubation, increase in systolic, diastolic and mean arterial pressure from baseline value in all groups was observed(p<0.001) At 1 minute after intubation, maximum increase in systolic, diastolic and mean arterial pressure from baseline value were seen in all groups(p<0.001). At 2 minute after intubation, increase in systolic, diastolic and mean arterial pressure from baseline value were seen in all group (p<0.001).

Table 1: Heart Rate (Rate/Minute)

	Group C Mean ± SD	Group G Mean ± SD	Group P Mean ± SD	P Value
pre-operative(Baseline)	77.53 ± 6.98	79.80 ± 5.21	82.07 ± 6.02	<0.05
pre-oxygenation	83.87 ± 3.23	81.93 ± 4.35	85.07 ± 4.86	<0.001
immediate after intubation	90.33 ± 5.09	103.93 ± 6.09	111.07 ± 6.72	<0.001
1 min after intubation	97.73 ± 4.92	113.33 ± 7.07	141.80 ± 8.11	<0.001
2 min after intubation	89.67 ± 3.07	105.53 ± 5.93	130.40 ± 6.88	<0.001
3 min after intubation	88.00 ± 3.82	101.33 ± 4.21	121.87 ±7.12	<0.001
4 min after intubation	86.53 ± 4.30	99.07 ±2.91	114.67 ± 7.73	<0.001
5 min after intubation	85.00 ± 3.85	96.53 ± 3.01	108.60 ± 7.11	<0.001

Table 2: Systolic Blood Pressure (Mm Of Hg)

	Group C Mean ± SD	Group G Mean ± SD	Group P Mean ± SD	P Value
pre-operative(Baseline)	122.33 ± 8.64	124.60 ± 9.64	126.27 ± 7.48	>0.05
pre-oxygenation	122.07 ± 10.76	123.53 ± 10.39	127.20 ± 7.35	>0.05
immediate after intubation	134.87 ± 8.85	138.40 ± 8.01	144.33 ± 6.97	<0.001
1 min after intubation	151.53 ± 9.11	155.47 ± 7.01	164.73 ± 6.67	<0.001
2 min after intubation	144.67 ± 7.90	147.13 ± 9.54	157.47 ± 6.26	<0.001
3 min after intubation	140.87 ± 7.62	142.53 ± 8.93	151.87 ± 7.14	<0.001
4 min after intubation	137.53 ± 7.02	137.47 ± 7.70	145.33 ± 7.53	<0.001
5 min after intubation	133.73 ± 6.43	132.73 ± 8.49	140.13 ± 8.53	<0.001

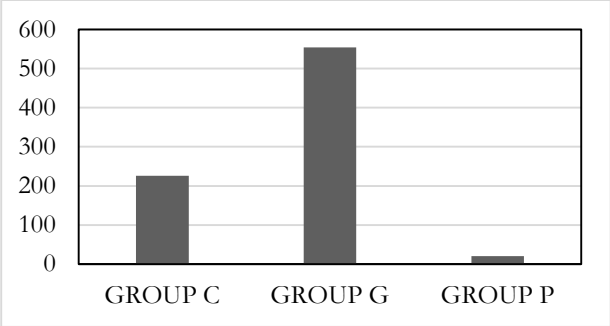
Table 3: Diastolic Blood Pressure (Mm Of Hg)

	Group C Mean ± SD	Group G Mean ± SD	Group P Mean ± SD	P Value
pre-operative	82.47 ± 3.81	82.53 ± 5.04	82.47 ± 2.27	>0.05
pre-oxygenation	74.53 ± 3.86	76.00 ± 4.00	82.87 ± 3.85	<0.001
Immediate after intubation	79.60 ± 4.05	79.73 ± 3.85	85.73 ± 3.67	<0.001
1 min after intubation	86.07 ± 3.73	87.27 ± 3.91	92.80 ± 4.16	<0.001
2 min after intubation	83.80 ± 3.61	84.73 ± 3.26	90.87 ± 4.06	<0.001
3 min after intubation	81.93 ± 3.34	82.87 ± 2.86	88.40 ± 3.94	<0.001
4 min after intubation	78.20 ± 3.80	80.67 ± 3.17	86.20 ± 3.98	<0.001
5 min after intubation	75.67 ± 3.72	77.27 ± 3.38	83.20 ± 3.59	<0.001

Table 4: Mean Arterial Pressure (Mm Of Hg)

	Group C Mean ± SD	Group G Mean ± SD	Group P Mean ± SD	P Value
pre-operative	95.76 ± 4.01	96.56 ± 6.09	97.07 ± 2.83	>0.05
pre-oxygenation	90.38 ± 3.99	91.84 ± 4.19	97.64 ± 3.43	<0.001
Immediate after intubation	98.02 ± 3.76	99.29 ± 3.65	105.27 ± 3.53	<0.001
1 min after intubation	107.89 ± 4.00	110.00 ± 3.22	116.78 ± 4.06	<0.001
2 min after intubation	104.09 ± 3.34	105.53 ± 3.86	113.07 ± 3.61	<0.001
3 min after intubation	101.58 ± 3.63	102.76 ± 3.49	109.56 ± 3.91	<0.001
4 min after intubation	97.98 ± 3.33	99.60 ± 3.09	105.91 ± 4.03	<0.001
5 min after intubation	95.02 ±3.28	95.76 ± 3.69	102.18 ± 4.09	<0.001

Chart 1: Time of 1st Rescue Analgesia



At 3 and 4minutes after intubation, Increase in systolic and mean arterial pressure from baseline in all three group ($p<0.001$). In group C and G diastolic blood pressure returns toward baseline values Whereas in group P diastolic blood pressure increased from baseline($p<0.001$).

At 5 minutes after intubation, increase in systolic blood pressure from baseline value were seen in all group ($p<0.001$). In group C and G diastolic blood pressure returns toward baseline values Whereas in group P diastolic blood pressure increased from baseline($p<0.001$).In clonidine and gabapentine group, mean arterial pressure returned back to baseline value ($p>0.05$) compared to control group, in which it still remained higher than baseline ($p<0.001$).

Time of 1st Rescue Analgesia (Chart 1)

Rescue analgesia was required at 225.6 ± 8.63min in group C, 554.06 ± 26.84min in group G and 20.66 ± 5.76min in group P($P <0.001$). Number of analgesic supplements required in group C was 2.13 ± 0.35 times, 1.07 ± 0.25 times in group G and 3.07 ± 0.25 times in group P, thus requirement of total analgesic was more in control group P (225 mg) compared to group C (150 mg) and group G (75 mg) and the difference among three groups was statistically highly significant ($P <0.001$).

Table 5: Adverse Effects

Adverse effect	No. of Patients		
	Gr C	Gr G	Gr P
Nausea/vomiting	3	2	0
vertigo/headache	0	0	0
visual disturbance*	0	0	0
sedation RSS >5	0	0	0

*diplopia, nystagmus

Total doses of analgesic supplements was significantly less in both Clonidine (2.13 ± 0.35) and Gabapentine (1.07 ± 0.25) groups compared to control group (3.07 ± 0.25) ($P <0.001$). Thus total doses of analgesic supplements was less with Gabapentine group compared to Clonidine group ($P<0.05$).

DISCUSSION

Gabapentin, a structural analogue of gamma-amino butyric acid, has been shown to have multi-modal effects which make it a potentially useful drug for premedication in adults, providing postoperative analgesia and preoperative anxiolysis while preventing chronic postsurgical pain, Clonidine has known sedative, analgesic, and anxiolytic properties. Its central sympatholytic action, it tends to attenuate the hemodynamic response to any surgical nociceptive stimulus and to improve overall perianesthetic cardiovascular stability.

In our study, it was observed that, in control group baseline heart rate remained high compared to clonidine and gabapentine group ($p<0.05$) during laryngoscopy and tracheal intubation and at 1, 2, 3, 4 and 5 minutes after intubation (Table 1).

In Gabapentine group, baseline heart rate remained on lower side compared to control group, ($p<0.05$). But during laryngoscopy and tracheal intubation heart rate increased from baseline value, which was statistically highly significant ($p<0.001$). Similar findings were observed at 1, 2, 3, 4 minutes after intubation. At 5 minutes after intubation heart rate remained increased compared to baseline. But increase in heart rate remains lower in comparison to control group and higher in comparison to clonidine group ($p<0.001$) (Table 1).

In Clonidine group, baseline heart rate remained low compared to control group, which was statistically significant ($p<0.001$). But during laryngoscopy and tracheal intubation heart rate increased from baseline value, which was statistically highly significant ($p<0.001$). Similar findings were observed at 1, 2, 3, 4 minutes after intubation. At 5 minutes after intubation, heart rate remained increased compared to baseline (Table 1).

A. Fassoulaki et al[5] (2006) ,Saikat Majumdar et al[6] (2008) ,Seyed Mojtaba, Marashi et al[7] (2009) ,Kumkum and Colleagues et al[9] in 2011, Tahira Iftikhar and Colleagues et al[21] (2011) ,Usha Bafna and Colleagues et al[2] (2011) ,Seyed Mojtaba Marashi and Colleagues et al[15] (2014), Suresh K. Singhal et al[4] (2014) ,Abhishek Chatterjee and Colleagues et al[16] (2015) ,Satyen Parida and Colleagues et al[17] (2015) and Upendra Kumar Kapsey et al[1] (2016) conducted studies and results of present study are consistent with all these studies.

In present study, pre-operative baseline systolic, diastolic and mean arterial pressure were comparable in all three groups ($p>0.05$). At pre oxygenation, all groups were comparable for systolic blood pressure

(p>0.05). Significant decrease in diastolic and mean arterial pressure was observed in clonidine and gabapentine group (p<0.05) compared to control group, in which it remained comparable to baseline (p>0.05).

Immediately after laryngoscopy and intubation, increase in systolic, diastolic and mean arterial pressure from baseline value in all groups more in control than clonidine and gabapentine group was observed, which was statistically highly significant (p<0.001). At 1 and 2 minute after intubation, maximum increase in systolic, diastolic and mean arterial pressure from baseline value were seen in all groups (p<0.001). At 3 and 4 minutes after intubation, Increase in systolic and mean arterial pressure from baseline in all three groups (p<0.001). (Table 2,3,4). At 5 minutes after intubation, increase in systolic blood pressure from baseline value were seen in all group (p<0.001).

The finding of this study correlates with findings of studies conducted by A. Fassoulaki et al[5] (2006) ,Saikat Majumdar et al[6](2008) ,Seyed Mojtaba. Marashi et al[7](2009) ,Kumkum and Colleagues et al[9] (2011) ,Tahira Iftikhar and Colleagues et al[10] (2011) ,Usha Bafna and Colleagues et al[2] (2011) ,Seyed Mojtaba Marashi and Colleagues et al[15] (2014) ,Suresh K. Singhal et al[4] (2014) ,Abhishek Chatterjee and Colleagues et al[16] (2015) ,Satyen Parida and Colleagues et al[17] (2015) and Upendra Kumar Kapsey et al[1] (2016) .

In our study**,** rescue analgesia was given at VAS > 3. The mean time for rescue analgesia was 225.6 ± 8.63 minutes in Clonidine group, 554.06 ± 26.84 minutes in Gabapentine group and 20.66± 5.76 minutes in Placebo group. So, requirement of rescue analgesic was earlier in control group as compared to Clonidine and Gabapentine group. The difference between three groups was statistically highly significant (P < 0.001). Thus, effective postoperative analgesia was significantly prolonged in both Clonidine (225.6 ± 8.63 minutes) and Gabapentine (554.06 ± 26.84 minutes) group as compared to control group (20.66 ± 5.76 minutes).

Total duration of effective post-operative analgesia was more in Gabapentine group as compared to Clonidine group and the difference was statistically highly significant (P<0.001).The finding of this study correlates with findings of studies conducted by Sussan Soltani Mohammadi et al[8] in (2009) ,Shivinder Singh et al[11] , Marashi SM et al[12] in(2012) , F Frouzanfard et al[13] and Smita Musti et al[14] in (2013).

Nausea/Vomiting was seen in 3 patients of clonidine group and 2 patients of gabapentine group but none of the patient in control groups developed nausea/vomiting in our study. None of the patients were developed Vertigo/headache, visual disturbances like diplopia and nystagmus, sedation RSS>5 in any patient of any group.

CONCLUSION

Oral Clonidine (0.2 mg) when given in premedication provided better attenuation of hemodynamic stress response to laryngoscopy and tracheal intubation compared to oral Gabapentine (900 mg), where hypertensive response was fairly obtunded, but not the tachycardiac response. Oral Clonidine has better response over tachycardia than Gabapentine, whereas Gabapentine is superior to clonidine for postoperative analgesia.

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ORIGINAL ARTICLE

A Comparative Study Efficacy of Ondansetron versus Granisetron to Prevent Perioperative Nausea and Vomiting among Patients Under going Gynaecological Surgery under Spinal Anaesthesia in a Tertiary Care Hospital of Western India

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ABSTRACT

Background: A randomized double blind study was conducted to compare efficacy of Ondansetron versus Granisetron among patients undergoing gynaecological surgery under the spinal anaesthesia.

Objective: To compare Ondansetron and Granisetron for prevention of postoperative nausea and vomiting in patients undergoing gynaecological surgery under spinal anaesthesia.

Material and methods: Total 60 consecutive patients, age between 18-58 years, ASA grade I and II undergoing gynaecological surgery under the spinal anaesthesia were randomized into two groups of 30 each. One group received I.V. Ondansetron 4.0 mg and the second received I.V. Granisetron 2.0 mg 5 minutes before induction of anaesthesia. For the first 24 hours postoperatively all episodes of nausea and vomiting were recorded. The observations were tabulated and analysed.

Results: In this study found that during early postoperative period (0-3 hrs) there was no statistically significant difference in the study groups. Statistically significant difference was found in the study groups in the late postoperative period (3-24 hrs).

Conclusion: In the early postoperative period both Ondansetron and Granisetron are equally effective in preventing postoperative nausea and vomiting in patients undergoing gynaecological surgery under spinal anaesthesia. Granisetron is better than Ondansetron in the late postoperative period of upto 24 hrs.

Key words: ondansetron, granisetron, perioperative nausea and vomiting, anaesthesiology

INTRODUCTION

In India Post-Operative Nausea and vomiting (PONV) is a particularly distressing problem for both patients as well as treating Doctors.[1]There are many antiemetic drugs available, despite of it problem still persists and novel methods and medicines continue to be searched for PONV. There is no drug which is 100% effective in prevention of PONV and combinations of various drugs have a lot of side effects.[2] Incidence of PONV less in regional anaesthesia as compared to general anaesthesia but its effects are no less distressing. PONV can add to hospital cost for patient care as it leads to various complications like bleeding, wound dehiscence, electrolyte imbalance, dehydration, aspiration pneumonitis etc. In various study gynaecological surgery has been found as independent risk factor for PONV.[3,4] The incidence of PONV is reported to be between 20-30% in patients underwent to surgery, but it can increase up to 80% in high risk patients.[5]A newer class of antiemetic are 5-HT3 receptor antagonists which have only headache and dizziness as their adverse effects in the doses used for PONV.[4] Ondansetron is commonly used drug for PONV and its quite effective to Prevent PONV.[6] Granisetron, a newer drug, shown to be more potent and longer acting than Ondansetron against emesis caused by Cisplatin.[7]

A randomized double blind study was conducted to compare efficacy of Ondansetron versus Granisetron among patients undergoing gynaecological surgery under the spinal anaesthesia, these are the population of patients which most likely to suffer from PONV.[8]

MATERIAL AND METHODS

In this study sixty (n=60) consecutive patients between age 18-58 years, in ASA grade 1-2, undergoing gynaecological surgical procedure under the spinal anesthesia were randomized to two groups by com-

puter generated random allocation, one group receiving Ondansetron (4 mg intravenously) and the other receiving Granisetron (2 mg intravenously) in perioperative period. All patients' age, weight, height, body mass index (BMI) and the prior history of motion sickness, vertigo, nausea and vomiting will be noted. Patients who refused for participation or patients with prior history of motion sickness, nausea or vomiting, steroid intake within last 24 hours, BMI more than 30, pregnancy or hypersensitivity to anaesthetic drugs were excluded from the study.

All patients underwent detailed pre anaesthetic check-up which included all routine investigations. An informed consent was taken from study participants. Patients were kept fasting from 9 PM the day before the surgery. Baseline parameters were noted after shifting the patient to operation theatre. Preloading with Ringer's lactate (RL) 10-15 millilitre per kilogram body weight was done and prophylactic dose of an antiemetic was given 3-5 minutes before the spinal anaesthesia. Drugs were given by an investigator not involved in post-operative assessment of symptoms in the study. With all aseptic precautions lumbar puncture was done in L3- L4 or L4-L5 space using 25 gauge Quincke's needle in lateral decubitus position in midline, 3.0 ml of 0.5 % hyperbaric Bupivacaine was injected after confirming free flow of Cerebrospinal fluid with an aim to obtain level of anaesthesia till 7th or 6th thoracic vertebra. Standard intraoperative monitoring was done any fall in blood pressure was managed by intravenous (i.v) fluids and injection Mephentermine 3.0 mg i.v. Intramuscular injection of Diclofenac 75 mg was given before shifting the patient for analgesia and prescribed twice a day dose or on request by the patient.

In study nausea was defined as an unpleasant sensation with urge to vomit and vomiting was defined as forceful expulsion of gastric contents from the mouth. Complete response was defined as no nausea or vomiting and no need for rescue antiemetic. Injection Dexamethasone 8.0 mg intravenous was used as rescue antiemetic. All episodes of PONV were recorded by an investigator blinded to the study groups. The results were tabulated and analysed using chi-square test.

RESULTS

As shown in table 1 p value is >0.05 means patients in both the groups were statistically comparable with respect to age, body mass index and duration of surgery and anaesthesia. During early postoperative period (0- 3 hrs) the incidence of PONV in the Ondanseron group was more (nausea – 6; 20.0%, vomiting – 5; 16.66%) as compared to the Granisetron group (nausea 5;16.66%, vomiting 4;13.33%) but the difference was not significant statistically.

Table 1: Demographic profile

Variables	Ondansetron group(n=30)	Granisetron group(n=30)	P value
Age (years)	42.25+8.47	45.24+8.31	>0.05
BMI*	24.82+1.1	24.92+1.4	>0.05
Duration of surgery#	99.88+13.44	97.93+12.56	>0.05

* Kg/Sq. meter; # minutes

Table2: Incidence of PONV in early postoperative period (0-3 hrs)

Parameters	Ondansetron group (n=30)	Granisetron group (n=30)	P value
Nausea	6 (20.00)	5 (16.66)	>0.05
Vomiting	5 (16.66)	4 (13.33)	>0.05
Rescue antiemetic	5 (16.66)	4 (13.33)	>0.05

Figure in parenthesis indicate percentage.

Table 3: Incidence of PONV in late postoperative period (3-24 hrs)

Parameters	Ondansetron group (n=30)	Granisetron group (n=30)	P value
Nausea	10 (33.33)	4 (13.3)	<0.05
Vomiting	9 (30.00)	3 (10.00)	<0.05
Rescue antiemetic	7 (23.33)	2 (6.66)	<0.05

Table 4: Complete drug response in early postoperative period (0-3 hrs)

Study groups	Complete drug response
Ondansetron (n=30)	23 (76.66)
Granisetron (n=30)	24 (80.00)
P value	>0.05

Table 5: Complete drug response in late postoperative period (3-24 hrs)

Study groups	Complete drug response
Ondansetron (n=30)	17 (56.66)
Granisetron (n=30)	26 (86.66)
P value	<0.05

Table 6: Incidence of adverse effects

Adverse effect	Ondansetron group (n=30)	Granisetron group (n=30)
Headache	3 (10.00)	2 (6.66)
Dizziness	2 (6.66)	2 (6.66)
Others	0 (0.0)	0 (0.0)

Similarly, need for rescue antiemetic was in 5(16.66%) patients in Ondansetron group and 4(13.33%) in Granisetron group, which was statisti-

cally insignificant. Complete drug response in both groups in early postoperative period was comparable, 23(76.66%) in Ondansetron group, 24(80.00%), p value > 0.05.

In the late postoperative period 10(33.33%) patients had nausea in Ondansetron group where as 4 (13.3%) patients had nausea in Granisetron group, the difference was statistically significant. Vomiting was present in 9(30.0%) patients in Ondansetron group as compared to 3(10.0%) patients in Granisetron group which was statistically highly significant. (Table 3) In the Ondansetron group rescue antiemetic was needed in 7(23.3%), but in the Granisetron group it was needed in 2(6.66%) again significant statistically.

As regards complete response to drug (absence of nausea and vomiting), in the early postoperative period, it was statistically insignificant (Ondansetron 23;76.66%, Granisetron 24;80.00%) In the late postoperative period the difference was statistically significant in favour of Granisetron (Ondansetron 17;56.66%, Granisetron 26; 86,67%) as is evident from table 5.

There was minimal incidence of side effects of headache and dizziness ranging from 3.33%-10.0% across both groups, difference between groups was statistically insignificant (Table 6).

DISCUSSION

From the beginning PONV is a major challenging problem and continues to trouble in spite of many available drugs and advances in surgery as well anaesthesia. It has multiple etiological factors like gynaecological surgery, age, weight, pre - existing disease conditions, history of nausea, vomiting, anxiety or smoking. 5 HT-3 receptor antagonists are effective in preventing emesis caused by radiotherapy as well as chemotherapy. From many years Ondansetron has been widely used for prevention of PONV. A newer drug, Granisetron, has not been studied in local setting for PONV prevention on gynaecology surgery under the spinal anaesthesia. The doses of drugs used were as reported in previously done studies.[9,10] In this study both groups Ondansetron and Granisetron were matching with regards to demographic profile and anthropometric parameters. Other parameters like duration of gynaecological surgery and anaesthesia, intraoperative haemodynamics were also similar.

In early postoperative period (0-3 hrs) both Ondansetron and Granisetron were effective in PONV prevention with statistically non-significant difference (p value>0.05.This is in congruence with the findings of previous studies of Fujii et al [10], Bhattachary et al. [11] Chaudhari et al in his comparative study of Ondansetron and Granisetron to prevention of PONV in elective lower segment Caesarean section and found Granisetron better during 24 hours of postoperative period. [12] In this study during late postoperative period Granisetron was more effective in preventing PONV than Ondansetron with a statistically significant difference. Variance in need for rescue antiemetic and complete response incidence was statistically significant in favour of Granisetron probably because of long duration of action. Fuji et al found similar incidences of PONV with Granisetron in their study.[13] It has been found headache and dizziness are the most common side effects of 5 HT-3 receptor antagonists.[14] No statistically significant difference was found in the incidence of adverse effects in both groups in our study which is similar as found by Fujji et al [13] and Kim et al. [15]

CONCLUSION

In conclusion, both Ondansetron and Granisetron were equally effective on preventing PONV during the early postoperative period in patients undergoing gynaecological surgery under spinal the anaesthesia. In the late postoperative period, however, Granisetron was found better with less incidence of PONV and less need for rescue antiemetic. Also the adverse effects were not found significant with Granisetron as well as Ondasetron.

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ORIGINAL ARTICLE

Socio Demographic and Clinical Factors associated with TB Meningitis among HIV Positive Patients

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ABSTRACT

Introduction: Infection with HIV is associated with increased risk of activation of latent infection of Tuberculosis.. Furthermore, TB Meningitis have found that co-infection with HIV is associated with an increased risk of mortality. The present study was done with the objective of exploring socio demographic and clinical factors associated with TB Meningitis among HIV positive patients.

Methodology: The present study was done among Patients Living with HIV/AIDS (PLHA) admitted patients in medicine department. Records of all HIV positive patients diagnosed with TB meningitis during the study period of one year were obtained. Records of presenting symptoms, Socio-demographic variables, all laboratory investigations including CD4 count, past history of TB and outcome of past TB of these patients were recorded in separate case record sheet and evaluated further for the study.

Results: Maximum of patients (33.33%) were from age group of 31 to 40 years. Males were common among study participants. Previous history of Tuberculosis is important for the patients with TB meningitis in HIV patients. Mean CD 4 count in participants was 140 cells/µL. More than 70% patients of TBM had the CD4 count less than 200 cells/microL. Risk of TBM increased with CD4 count less than 200 cells/microL.

Conclusion: TB Meningitis is mostly affecting HIV patients from age group of 21 to 40 years. Males are commonly affected. Previous history of Tuberculosis is important for the patients with TB meningitis in HIV patients. For TB meningitis patients fever, headache and altered sensorium are common presenting symptom.

Key words: TB, Meningitis, HIV/AIDS, PLHA

INTRODUCTION

Meningitis is the most devastating manifestation of tuberculosis. The HIV-infected individual is at greater risk of developing TB Meningitis (TBM), particularly at a stage of more advanced immunesuppression. Furthermore, most observational studies of TBM have found that co-infection with HIV is associated with an increased risk of mortality. Infection with HIV is associated with increased risk of activation of latent infection, as well as increased risk of rapid progression of primary infection, without an intervening period of latency. Without HIV infection, individuals with latent infection have 10% -20% lifetime risk of developing tuberculosis.[1]

In contrast, the HIV-infected individual will carry a 10% annual risk of progression to active infection, with increasing risk as the CD4+ count declines.[2] Patients with HIV and active tuberculosis have an increased risk of extrapulmonary tuberculosis, and this risk will also increase with declining CD4+ count.[3]

This increased risk of extrapulmonary disease leads to an increased risk of meningitis.

As a consequence of the overlapping HIV and tuberculosis epidemics, in some populations tuberculosis has become the dominant cause of meningitis, more common than acute bacterial infections such as Neisseria meningitidis, Haemophilus influenzae, and Streptococcus pneumoniae.[4]

In a recent case series from the United States, 17% of patients with tuberculous meningitis (TBM) died during the first 9 months of therapy.[5] In countries with a high incidence of tuberculosis, the mortality rate may be greater than 50%,[6] and survivors may be left with significant neurologic disabilities. Diagnostic delays of TBM are also associated with increased risk of mortality.

Several observational studies comparing the clinical presentation of TBM in patients with and without HIV infection have found that presenting symptoms such as fever, headache, vomiting, and weight loss are similar in both groups.[7,8,9]

On examination, HIV-infected patients may be more likely to have lymphadenopathy and hepatosplenomegaly.[7,10] An altered level of consciousness may be more prominent in HIV-infected individuals. Among

patients with TBM in India, impaired cognition was exclusively seen in HIV-infected patients.[8]

The present study was done for exploring socio demographic and clinical factors associated with TB Meningitis among HIV positive patients.

METHODOLOGY

The present study was done among Patients Living with HIV/AIDS (PLHA) admitted patients in medicine department of Surat Municipal Institute of Medical Education and Research (SMIMER), a tertiary care hospital in Surat, Gujarat, India. Records of all HIV positive patients diagnosed with TB meningitis; admitted in medicine department of SMIMER during the study period of one year were obtained.

Prior permission of hospital authority was obtained to access the records and to conduct the study. Records of presenting symptoms, Socio-demographic variables, all laboratory investigations including CD4 count, past history of TB and outcome of past TB of these patients were recorded in separate case record sheet and evaluated further for the study. There were total 21 HIV positive patients diagnosed with TB meningitis were admitted during the study period. Out of these, records of 6 patients were excluded due to incompleteness. Thus finally total records of total 15 patients were included in the study.

Permission of Ethical Committee was Institute obtained before conducting study. Strict confidentiality of all data were maintained at all level of the study. Data was cleaned entered and analyzed in Microsoft Excel.

RESULTS

The present study was a record based study. The complete records of all total 18 HIV positive patients diagnosed with TB meningitis were obtained from the hospital.

Table 1 shows some of the important variables associated with TB meningitis in HIV patients. Maximum number of patients (33.33%) were from age group of 31 to 40 years. Around 72% of patients were from age group of 21 to 40 years. Males were common among study participants. Total 10 (55.56%) patients were residing in rural areas. Around 7 (38.89%) patients were single and 5 (27.78%) patients were currently married. Previous history of Tuberculosis is important for the patients with TB meningitis in HIV patients. 12 (66.67%) of study participants were having previous history of Tuberculosis. Out of these 12 patients, only 3 (25.0%) were properly treated and cured. Mean CD 4 count in study participants was 140 cells/microL. More than 70% patients of TBM had the CD4 count less than 200 cells/microL.

Table 1: Different variables associated with study participants

Variables	Cases (%)
Age (Years)	
<20	1 (5.56)
21-30	7 (38.89)
31-40	6 (33.33)
41-50	2 (11.11)
>50	2 (11.11)
Gender	
Male	13 (72.22)
Female	5 (27.78)
Residence	
Rural	10 (55.56)
Urban	8 (44.44)
Marital Status	
Single	7 (38.89)
Married	5 (27.78)
Divorced	2 (11.11)
Widow/Widower	4 (22.22)
Previous History of TB	
Yes	12 (66.67)
No	6 (33.33)
Outcome of Previous TB (n=12)	
Cured	3 (25.0)
Default	5 (41.67)
Treatment Continue	4 (33.33)
CD4 Level (cells/microL)	
0-50	4 (22.22)
51-100	3 (16.67)
101-150	3 (16.67)
151-200	2 (11.11)
201-250	3 (16.67)
>250	3 (16.67)

Table 2: Neurological manifestation of study participants (N=18) (Multiple responses)

Neurological manifestation	Cases (%)
Fever	17 (94.44)
Headache	16 (88.89)
Altered sensorium	14 (77.78)
Signs of meningeal irritation	13 (72.22)
Convulsion	6 (33.33)
Focal deficit	4 (22.22)

Multiple neurological presenting symptoms were present in patients. Out of total 18 patients, fever was present in 94% patients, headache was present in 88% of patients, altered sensorium was present in 77% of patients and signs of meningeal irritation was found in 72% patients. Altered sensorium is more in our study due to late presentation in hospital

DISCUSSION

Neurological TB, occurs in 5 to 8% in HIV infected patients; five times more frequent than in patients

without HIV. [11] TBM accounts for approximately 1% of all cases of TB.[12]

There were total 18 HIV positive patients diagnosed with TB meningitis during the study period and their records were obtained from the hospital.

Maximum number of patients were from age group of 31 to 40 years. Males were common among study participants. Previous history of Tuberculosis is important for the patients with TB meningitis in HIV patients. 12 (66.67%) of study participants were having previous history of Tuberculosis. Out of these 12 patients, only 3 (25.0%) were properly treated and cured. TBM occurs most often in persons over 45 years, frequently appearing as a reactivation of a latent infection.[13] This could be explained by the young age of our population and the high incidence of TB in our country. Mean CD 4 count in study participants was 140 cells/microL. More than 70% patients of TBM had the CD4 count less than 200 cells/microL.

Patients with HIV and active tuberculosis have an increased risk of extrapulmonary tuberculosis, and this risk will also increase with declining CD4+ count.[3] Clinical features were useful in orientating clinical suspicion towards CNS disease, though they usually were non-specific and not outstanding. In present study, fever, headache and altered sensorium were among the most common presenting symptoms.

Several observational studies comparing the clinical presentation of TBM in patients with and without HIV infection have found that presenting symptoms such as fever, headache, vomiting, and weight loss are similar in both groups.[7,8,9,10,14]

On examination, HIV-infected patients may be more likely to have lymphadenopathy[10] and hepatosplenomegaly.[7] An altered level of consciousness may be more prominent in HIV-infected individuals. Among patients with TBM in India, impaired cognition was exclusively seen in HIV- infected patients.[8] In contrast, studies of adults in Vietnam[14] and Spain[15] found no difference in rates of alerted mental status on presentation. In South Africa, HIV-uninfected children were more likely to have impaired consciousness on initial presentation.[7]

CONCLUSION

TB Meningitis is mostly affecting HIV patients from age group of 21 to 40 years. Males are commonly affected. Previous history of Tuberculosis is important for the patients with TB meningitis in HIV patients. For TB meningitis patients fever, headache and altered sensorium are common presenting symptom. Risk of TBM increased with CD4 count less than 200 cells/microL.

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ORIGINAL ARTICLE

Incidence of Pediatric Urinary Stones in Orphanage Children in Pekanbaru, Riau Province of Indonesia

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ABSTRACT

Introduction: Urinary stones are seldom in children. Currently the incidence of urinary stones in children increases three time folds in the last third decade and occurs in the first decade of life.

Objectives: The aim of this study is to identify the incidence of pediatric urinary tones in orphanage children.

Materials and Methods: We examined urinary stones by using ultrasound in orphanage children of two orphanages in Pekanbaru, Riau Province, Indonesia. Univariate test was used for statistical analysis. Approval on the study was obtained from the Ethical Review Board for Medicine and Health Research, Medical Faculty, University of Riau.

Results: There were 88 orphanage children in the study in which orphanage girls were more (54,5%) than the boys (45.5%), 13 – 15 age group was the most (34.1%) and the least (4.5%)was 4 – 5 age group. The most symptom was flank pain (11.4%), followed by voiding pain (dysuria) (5.7%), bloody urine (hematuria) (5.4%), spontaneously passing stone (2.3%), urinary stone history (1.3%) and family urinary stone history (1.3%). There was no positive result of urinary stone in urologic physical examinations. In all orphanage children, there was no urinary stones found in ultrasound examinations but there were 23.9 of cystitis, less simple kidney cyst and kidney hypoplasia.

Conclusions: Although we found several symptoms and signs of urinary stone but in all orphanage children, there was no urinary stones found in ultrasound examinations but there were 23.9% of cystitis.

Keywords: Children, incidence, orphanage, urinary stone

INTRODUCTION

Urinary stone has been considered as main health problems sufferrred median age men between 20 – 50 years. In adult, urinary stone is not a cause of death but associated to financial burden due health care and loss of job productivity for peak work. In general there are constant of high urinary stone prevalence in last three decades and initial age of diagnosis has been lower. The epidemiology trend differs due to gender in certain geographic area and has been caused by diet changes such as increasing glucose contained food substances, increasing obese incidence, uncertain high temperature due to global warming and high prevalency of urology disorders. Due to all these reasons, urinary stones is often seen as rare conditions in children. Nevertheless, current researches showed that urinary stone incidence in children has been increased three time fold in the last ten years and the problems might occur in the first decade of life[1,2].

Most factor caused urinary stone is hypercalsiuria that becomes sporadic or family. The management principle are increasing fluid intake, simple restriction of animal protein intake, and increasing fruit and vergetable intakes[1,3,4,5]. Until recently there is no publication on urinary stone incidence in children of Pekanbaru, Riau Province, Indonesia.

MATERIALS AND METHODS

We examined urinary stones by using ultrasound in orphanage children of two orphanages in Pekanbaru, Riau Province, Indonesia. Univariate test was used for statistical analysis. Approval on the study was obtained from the Ethical Review Board for Medicine and Health Research, Medical Faculty, University of Riau.

RESULTS

There were 88 orphanage children in the study. Table 1 shows that orphanage girls were more (54,5%) than the boys (45.5%).

Table 1. Distribution of orphanage children according to gender

Gender	Cases (n=88) (%)
Boy	40 (45.5)
Girl	48 (54.5)

Table 2. Frequency distribution of orphanage children according to age.

Age (year)	Cases (n=88) (%)
≤ 3	0 (0)
4 – 5	4 (4.5)
6 – 8	10 (11.4)
9-10	13 (14.8)
11-12	12 (13.6)
13-15	30 (34.1)
16-18	19 (21.6)

Table 2 shows 13 – 15 age group was the most (34.1%) and the least (4.5%) was 4 – 5 age group.

Table 3 shows the most common symptom was flank pain (11.4%), followed by voiding pain (dysuria) (5.7%), bloody urine (hematuria) (5.4%) and spontaneously passing stone (2.3%).

Tabel 4 showed There was no positive result of urinary stone in urologic physical examinations Costo Vertebrae Angle (CVA), supra pubic nor external genital.

Tabel 5 showed in all orphanage children, there was no urinary stones found in ultrasound examinations but there were 23.9 of cystitis, less simple kidney cyst and kidney hypoplasia.

Table 3. Frequency distribution of orphanage children according to symptoms.

Symptoms	Total	Boys	Girls
Flank pain	10 (11.4)	4 (4.6)	6 (6.8)
Voiding pain (dysuria)	5 (5.7)	3 (3.4)	2 (2.3)
Bloddy urine (hematuria)	4 (5.4)	2 (2.7)	2 (2.7)
Urinary Tract Infection (UTI)	-	-	-
Spontaneously Passing stone	2 (2.3)	-	-
Urinary stone history in family	1 (2.3)	-	-
Total	22 (26.1)	9 (13)	11 (13.1)

Figure in parenthesis indicate percentage.

Table 4. Frequency distribution of orphanage children according to physical examination

Urology Status	Case (%)
General condition	88 (100)
-Costo Vertebrae Angle (CVA)	88 (100)
-Supra pubic	88 (100)
- External Genital	88 (100)

Table 5. Frequency distribution of orphanage children according to ultrasound examination of urinary tract

Urinary Tract	Total	Boys	Girls
Kidney			
-stone	0 (0)	0 (0)	0 (0)
-infection	0 (0)	0 (0)	0 (0)
-right kidney simple cyst	1 (1.1)	1 (1.1)	0 (0)
Ureter			
-stone	0 (0)	0 (0)	0 (0)
-infection	0 (0)	0 (0)	0 (0)
Urinary bladder			
-stone	0 (0)	0 (0)	0 (0)
-cystitis	21 (23.9)	12 (13.6)	9 (11.3)
Urethra			
-stone	0 (0)	0 (0)	0 (0)
-infection	0 (0)	0 (0)	0 (0)

Figure in parenthesis indicate percentage.

DISCUSSIONS

Urinary stone in children varies in characteristics according to gender, age and the locations[1,5,6,7]. The study result showed orphanage girls were more (54,5%) than the boys (45.5%) (see in Table 1). This study was similar to several previous studies in Europe and United State of America in which most urinary stone patients in children were girls,[8,9,10].

The study result showed 13 – 15 age group was the most (34.1%) and the least (4.5%) was 4 – 5 age group (see in Table 2). It was different from previous studies showed urinary stone incidences in children was mostly in 0 – 10 year age group[11,12]. Difference in environment, diet and life styles resulted in difference in incidency, urinary stone types and the stone locations [13].

The study result showed showed the most symptom was flank pain (11.4%), followed by voiding pain (dysuria) (5.7%), bloody urine (hematuria) (5.4%), spontaneously passing stone (2.3%), urinary stone history (1.3%) and family urinary stone history (1.3%). (see in Table 3). A study in Aceh (2018) showed there were 31.3% of family urinary stone history in children. Symptoms of urinary stones are not as clear as the ones in adults so that suspicion of urinary stone in children should be increased[14].

The study result showed that there was no positive result of urinary stone in urologic physical examina-

tions Costo Vertebrae Angle (CVA), supra pubic nor external genital (se in Table 4). Physical examination findings of urinary stones are not as clear as the ones in adults so that suspicion of urinary stone in children should be increased[13].

The study result showed in all orphanage children, there was no urinary stones found in ultrasound examinations but there were 23.9 of cystitis, less simple kidney cyst and kidney hypoplasia (see in Tabel 5). A study in (2018) showed mostly (56.3%) urinary stones were upper urinary tract stones followed by lower urinary tract stones (37.5%) and both upper and lower urinary tract stones (6.2%)[14].

In the study result although in all orphanage children, there was no urinary stones found in ultrasound examinations but there were several symptoms but there were 23.9 of cystitis. The both findings might be considered as risk factors that it is useful for further regular ultrasound examinations in detecting urinary stone in children.

CONCLUSION

Although we found several symptoms, no physical signs of urinary stone but in all orphanage children, there was no urinary stones found in ultrasound examinations but there were 23.9% of cystitis. The findings might be considered as risk factors that it is useful for further regular ultrasound examinations in detecting urinary stone in children.

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ORIGINAL ARTICLE

Magnitude and Determinants of Noncompliance for Screening and Management of Diabetic Retinopathy

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ABSTRACT

Introduction: Strategies to reduce visual disabilities due to diabetic retinopathy (DR) include early detection and prompt management. Patient compliance is a crucial a factor to achieve this goal. The aim of the study is to assess the level of noncompliance among diabetic patients towards diabetic retinopathy screening and towards undergoing suggested ophthalmic interventions.

Methodology: Diabetic patients presenting to the tertiary eye hospital of Western India were divided into 2 groups: diabetic retinopathy (DR) screening group (SGR) and diabetic patients with sight threatening (STDR) who were advised intervention (DR treatment group) (TR GR). All patients were interviewed to determine the level of noncompliance and barriers perceived towards noncompliance. P<0.05 was statistically significant.

Results: There were 75 diabetics in SGR and 72 in TR GR. The rate of noncompliance for DR screening was 64% [95% confidence interval (CI):53.1 – 74.9]. The rate of non-compliance for treatment for DR was 56.9% (95%CI 45.5 – 68.3). Rural residents (P=0.03) were statistically significantly more noncompliant towards DR screening. The best-corrected visual acuity in the better eye was associated to noncompliance to STDR treatment (P=0.001)while severity of DR was associated to the noncompliance for DR screening (P=0.05).

Conclusions: Noncompliance towards periodic DR screening as well as recommended ophthalmic treatment among diabetic eye patients is high. Lack of knowledge, cost of intervention and distance to eyecare services were main perceived barriers. Public health strategies to address these barriers could improve compliance for periodic DR screening and STDR management.

Key words: Diabetic Retinopathy; Laser treatment; Noncompliance; Barriers.

INTRODUCTION

Strategies to reduce visual disabilities due to diabetic retinopathy (DR) include early detection and prompt management.[1]However, patient compliance is a crucial a factor to achieve this goal.Best practice guidelines indicated that diabetics should undergo (at least) yearly screening,after the diagnosis of diabetes.[2]Thesescreening visits are key to early detection and timely treatments and are effective atreducing severe vision loss in 90% of patients.[3]

In India, patientcompliance for periodic DR screening is reported to be as low as 43.5%.[4]The uptake of laser treatment even after recommendations by experts was even lower.[5]A lack of knowledgeamong diabetics regarding detection and the high cost of undergoing complete treatment were two main reasonsfor noncompliance.[5]

A study from south India reported that the compliance for DR assessment among known diabetic patients was 55%.[6]However, the rate and determinants of non- compliance towardsDR screening and management separately has not been studied in the western India.

We evaluated the level of knowledge, attitude, perceived patient barriers for periodic DR screening and undergoing recommended interventions among diabetics from aDR clinic ata tertiary eye hospital.

MATERIAL & METHODS

This study was approved by the research and ethics committee of our institute. Thissurvey was conducted at Tertiary eye care institute between Januaryand October 2014. All 6,000 diabetic patients presenting to the hospital during the study period were our study population. Sample size calculations (Raosoft, Inc.) were performed with 5% level of significance, 95% confidence interval (CI) and 10% response distribution. A sample ofat least 136 diabetic patients

were required. We enrolled 75 diabetic patients screened for DR and another 72 DR patients seeking treatment. Diabeticswho presented to theDR clinics for screening but did not haveDR were excluded from the study. Screening patients were classified as patients who had only been advised for follow-up. Treatment patients were classified aspatients who had undergone treatment for DR and follow-up.

All diabetic patients were initially examined for the changes suggestive of DR in the retina clinic and then groupedin various grades of DR. After diagnosis and grading of DR, patients were counselled by a trained and qualified counsellor and given follow up appointments. Their compliance at attending the scheduled follow up appointment was reviewed. The patients who attended the appointments were considered as compliant and they were interviewed for the factors influencing compliance. The patients who didn't attend the retina clinic were labelled as non-compliant, contacted and interviewed for the factors influencing non-compliance. Telephone call or a personal visit by a hospital employee.The details of data collection are presented in Figure 1.

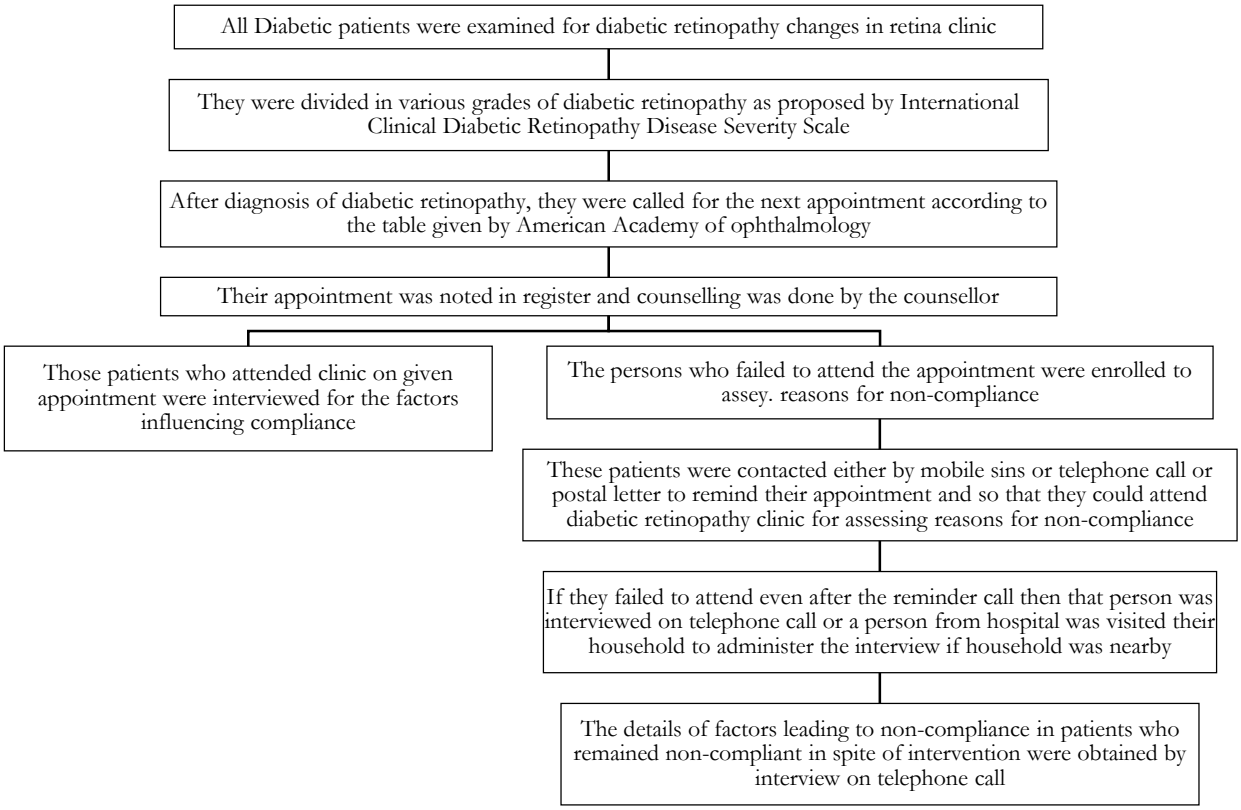

Figure 1: Flow chart showing selection of participants for diabetic retinopathy screening and treatment compliance study

The questionnaire was administered in English or Marathi by trained investigators. The questions were related to patient knowledge, attitude andbarriers to the compliance such as distance, service and cost.One point was given for every affirmative response and zero points for every negative response.

Data analysis was performed with Statistical Package for Social Studies (SPSS 17) (IBM Corp., New York, NY, USA). Univariate analysis with a parametric method was used for analysis. For qualitative variables,frequencies and percentage proportions were calculated. A quantitative variable was first tested for a normaldistribution. If the data were normally distributed, we calculated the mean and standard deviations. If the data were not normally distributed, we calculated the median and 25% quartile. To compare the outcome among different subgroups, we used chi-square test, Fisher's exact test and 2-independent sample t-test as statistical tests. $P<0.05$ was considered statistically significant.

RESULTS

There were 75 diabetic patients in the DR screening group and 72 in treatment group. The profile of both groups is presented in Table1. The rate of non-compliance for DR screening was 64% (95% CI:

53.1 – 74.9). The rate of non-compliance for treatment for DR was 56.9% (95% CI: 45.5 – 68.3).

We associated different independent variables to the non-compliance for DR screening. The age-gr (P = 0.5) and occupation (P = 0.7) were not associated to non- compliance. Female gender (P = 0.02), education (P=0.002) and rural residents (P = 0.03) were statistically significantly associated to non-compliance for DR screening.

We associated different independent variables to non-compliance towards DR treatment. The age-gr (P = 0.85), occupation (P = 0.73), Female gender (P = 0.09) and education (P = 0.3) were not associated to non- compliance. Rural residents (P = 0.01) were significantly associated to noncompliance for DRtreatment.

The best-correctedvisual acuity in the better eye of the participants was statistically significantly associated to the noncompliance for STDR treatment (P = 0.001) and early stages of DR were associated to noncompliance for DR screening (P =0.050). (Table: 2).

The participant response regarding barriers to non-compliance was analysed. (Table 3). Lack of awareness, negative attitude, distance to an eye centre and expense were perceived barriers towards DR screening and undergoing treatment for STDR.

Table 1: Patients profile of the diabetic retinopathy (DR) screening group and diabetic retinopathy treatment group

Variable	DR screening (n = 75) (%)	DR treatment (n = 72) (%)
Age-group		
Less than 40	0 (0)	1 (1.4)
41 to 50	5 (6.7)	7 (9.7)
51 to 60	23 (30.7)	23 (31.9)
61 to 70	38 (50.7)	26 (36.1)
More than 70	9 (12)	15 (20.8)
Gender		
Male	52 (69.3)	43 (59.7)
Female	23 (30.7)	29 (40.3)
Residence		
Urban	51 (68)	47 (65.3)
Rural	24 (32)	25 (34.7)
Education		
None	3 (4)	6 (8.3)
Primary	18 (24)	13 (18.1)
High school	14 (18.7)	15 (20.8)
Intermediate	14 (18.7)	7 (9.7)
College	26 (34.7)	31 (43.1)
Occupation		
None	3 (4)	4 (5.6)
Homemaker	13 (17.3)	10 (13.9)
Labour	14 (18.7)	14 (19.4)
Skilled labour	21 (28)	12 (16.7)
Private business	20 (26.7)	13 (18.1)
Professional	4 (5.3)	19 (26.4)

Table 2: Best corrected visual acuity and severity of diabetic retinopathy in the better eye and non-compliance towards diabetic retinopathy screening and treatment.

Visual acuity	DR screening (n = 75)			DR treatment (n = 72)		
	Compliant	Noncompliant	Validity	Compliant	Noncompliant	Validity
6/6 to 6/18	25	47	P =0.33	3	22	P = 0.001
<6/18 to 6/60	2	1		21	15	
<6/60	0	0		7	4	
Vision threatening DR	1	10	P = 0.05	31	41	-
Non Vision threatening DR	26	38		0	0	

Table 3: Barriers ofnon-compliance for diabetic retinopathy screening and diabetic retinopathy treatment

Barriers	Non compliance for DR* Screening (n = 48)			Non compliance for DR Treatment (n = 41)		
	Number	Percentage	95% CI	Number	Percentage	95% CI
Knowledge	19	39.6	24.1-55.1	18	43.9	28.7 - 59.1
Attitude	17	35.4	20.2 - 50.6	6	14.6	3.8-25.4
Distance	6	12.5	2.0 - 23.0	7	17.1	5.6-28.6
Cost & service	6	12.5	2.0 - 23.0	10	24.2	11.1-37.3

*DR =Diabetic Retinopathy

DISCUSSION

Two-thirds of diabetic patients did not comply with the annual DR screening visit and more than half of the patients with vision threatening DR did not comply with the suggested treatment. Females and those residing in rural area were associated with non-compliance for DR screening and management. Lack of knowledge, distance to eye care services and high cost were perceived barriers for diabetic patients with ocular symptoms.

This is perhaps first study in the western India highlighting an important issue that needs urgent attention to address visual disabilities due to DR.

DR is a leading cause of irreversible blindness in the working age group. Various studies have documented effective screening programs can decrease blindness related to DR. Unfortunately this program suffers from poor compliance from patients and often we receive patients with advanced, untreatable condition especially in developing countries like India. Health seeking behaviour of a community depends on multiple factors and to improve these behaviours, studies need to identify the barriers and address them proactively.

The rate of noncompliance for DR screening in the present study (64%) and treatment for DR (56%) matched rates reported in other regions of India and other developing countries. [9,10]Similar barrier seem to exist in developing countries resulting in noncompliance.

Females were more noncompliant for DR screening and management compared to male diabetics in our study. However element of error cannot be ruled out in this observation. These results correlate with studies from many countries.[11,12]Our observation of greater female non-compliance is in contrast to findings of Kalyangoet al.[13] Our observation other studies reporting similar results on female noncompliance suggests that gender sensitive approaches should be developed to address the barriers to compliance. The indicators to monitor the progress of interventions should also be gender specific similar to the elimination of avoidable blindness due to cataract[14,15].

Patients from rural areaswere more non-compliant compared thatpatients from urban areas. Byun et al[16]found higher rates of non-compliance amongthe rural population. More eye hospitals in an urban area could have made access to eye care easy for diabetic in catchment area of cities compared to the diabetic of rural area.

Less educated patients were more noncompliant toward screening and management. A studyhighlighting the association of low educational levels to the noncompliance for more morbid ailments, supports the associated reported our study.17.

We found noncompliance was higher among individuals with good vision in the better eye. Moore et al18 reported that patients with poor visual acuity in the worse eye had higher compliance in instilling topical glaucoma medication. Early stages of glaucoma and DR spare vision for daily living. Hence, the association of noncompliance to visual status noted in our study is logical.

Those with early stage DR had higher rates of noncompliance. Human tendency is to ignore a condition in the early stages that is not affecting vision could explain our observation19.

Lack of knowledge was a leading perceived barrier for both DR screening and STDR treatment. Many patients with DR remain asymptomatic, unaware that their vision is under threat. Insufficient guidance by the attending primary caregiver and the asymptomatic nature of the condition were the main barriers to regular eye examinations among diabetics in UK.[20]

There were some limitations to our study. We evaluated diabetic patients who had already approached eye care professionals. Their health related behaviour is likely to be different than diabetic patients who have not consulted eye doctors. Therefore the rate and factors associated to noncompliance in the present study should be extrapolated to all diabetic patients.

Noncompliance for undergoing periodic DRscreening as well as recommended eye treatment in diabetic eye patients is high. Lack of knowledge, cost of intervention and distance of eye care services from the patient residence were the main perceived barriers. Public health strategies to address these barriers could improve compliance for periodic DR screening and STDR management.

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ORIGINAL ARTICLE

Incidence and Risk Factors of Tuberculosis among Patients with Type 2 Diabetes Mellitus Attending a Tertiary Care Hospital in Bhubaneswar, Odisha

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ABSTRACT

Background: Type 2 Diabetes mellitus (T2DM) and Tuberculosis (TB) often manifest together leading to complications at various levels.

Methods: In this prospective study**,** we determined the incidence of TB among 1200 patients with type 2 diabetes attending the Capital Hospital of Bhubaneswar. Various socio-demographic factors like age, gender, marital status, literacy status, locality, habits, etc. and clinical profile were assessed.

Results: Out of 1200 patients with type 2 diabetes mellitus, only 13 were having active TB disease, the incidence being 1.08%. Further, 12 were having pulmonary TB. More males with advancing age and sedentary life style were having Diabetes. About 23% of patients had familial history, high BMI levels, hypertension, high FBG levels, cholesterol and triglyceride levels. 30% of T2DM patients were having metabolic syndrome. In our study, age, literacy status, occupation, life style, familial history, habits and stress appeared to be significant risk factors among patients with diabetes. The HbA1C levels were higher among 51% of the diabetes patients. It was observed that while 84% of the patients were taking oral hypoglycemic drugs only 8% were taking Insulin injections. These patients were addicted to either smoking, drinking alcohol and/or chewing tobacco / gutka. The HbA1C levels were higher among 69% of the DM-TB patients indicating poorer glycemic control which is a proven risk factor for TBDM co-morbidity.

Conclusions: Screening for DM in TB patients could improve case detection of diabetes and early treatment, which in turn will lead to better TB-specific treatment outcomes and prevention of diabetes related complications.

Keywords: Incidence; TB; Diabetes patients; Bhubaneswar; Odisha

INTRODUCTION

Type 2 Diabetes Mellitus (T2DM) has become a pandemic and is in fact the bane of the modern times. At present, there are 300 million people affected with diabetes globally and the number is likely to rise two-fold/doubly in the future five years.[1] India has the highest burden of Tuberculosis (TB) and second highest burden of diabetes in the world, with annual TB incidence of 2.2 million cases (range 2.0-2.5 million) and around 63 million people living with diabetes. India has been dubbed the Diabetic Capital of the world with its huge diabetic population. India has the highest number of TB cases and also the highest number of dually infected individuals, in the world.[2,3] The association and synergistic role between T2DM and TB in causing human disease has been recognised since long back.[4-7] Globally, about 10% of TB cases are associated with diabetes. The linkage between T2DM and TB is a challenge for global tuberculosis control.[8, 9, 10] Improved understanding of the bi-directional relationship of the two diseases is necessary for proper planning and collaboration to reduce the dual burden of diabetes and TB. In people with TB, it may be appropriate to actively screen for DM. Prevention, screening, and treatment of both diseases together is more effective.[11-13] A model similar to the TB-HIV program may be the best approach.[14] Recognizing the serious threat posed by Diabetes-TB, the Revised National Tuberculosis Control Program (RNTCP) calls for strengthening collaboration between TB and Diabetes control programs for better management of Diabetic patients with TB and TB patients with Diabetes.[15] The Diabetes epidemic has a huge impact on the dynamics of

epidemiology of TB and poses several challenges to control of TB in a resource-poor country like India. Diabetes/TB burden can be brought under control by timely diagnosis of TB among Diabetics by intensified case finding, by adequate and effective treatment of detected cases and preventive therapy.[16-19] Diabetes epidemic poses a serious threat on control of TB, and the current gaps in knowledge related to diagnosis, prevention and treatment of TB among people with diabetes, this study was carried out to determine the prevalence of TB and risk factors among patients with Type 2 diabetes mellitus in an urban area of Bhubaneswar. In addition, the feasibility, results and challenges of screening patients with diabetes mellitus (DM) for tuberculosis (TB) within the healthcare settings of DM clinic in tertiary care hospital in Bhubaneswar were assessed.

METHODOLOGY

Ethical approval: The detailed plan of study was reviewed and approved by to the Institutional Ethics Committee as well as the Scientific Advisory Committee (SAC) of the ICMR-Regional Medical Research Centre, Bhubaneswar, Odisha. The study has been performed in accordance with the ethical standards.[20] The patients with Type 2 diabetes mellitus attending the Diabetes clinic of Capital Hospital in Bhubaneswar were enrolled after taking written informed consent.

Study Design: This was a prospective study among patients with Type 2 Diabetes mellitus to study the incidence of TB and to identify the risk factors like duration and severity (HbA1c level) of diabetes, socio-economic status, BMI, smoking, alcohol, history of contact with TB patient and Latent TB.

Study period: This study was conducted from Mar.,2015 to Mar.,2017 in the Dept. of NCDs, Regional Medical Research Centre, Bhubaneswar. Study subjects, were recruited from patients who attended the Diabetes clinic at the Capital Hospital, Bhubaneswar.

Capital Hospital in Bhubaneswar is the biggest peripheral public hospital in the State run by the Govt. of Odisha. It caters to the health needs of 1 million of people of Bhubaneswar, along with adjacent districts like Khurda, Nayagarh, Puri and adjoining areas.

Novo Nordisk Education Foundation runs the Diabetes clinic and about 20 patients attend the clinic per week, 80 per patients per month [960/year] and 1920/2 years.

Inclusion Criteria: Patients with Type 2 Diabetes Mellitus (T2DM) of >1 year duration, age 18 years and above, residing in and around the city of Bhubaneswar were included in the study.

Exclusion criteria: Patients below 18 years of age, pregnant or lactating women, patients terminally ill from TB, HIV-positive patients, Diabetic patients who are currently on ATT or with past history of TB, and patients suffering from other diseases like Psychiatric illness were excluded.

In all, 1200 patients with Type 2 diabetes mellitus attending the Diabetes clinic of Capital Hospital in Bhubaneswar were enrolled in the study. Socio-demographic and clinical data were collected from all using standardized forms. Blood samples for screening were collected from adults willing to participate in the study. In this study, the results of screening on the first visit have been described. In addition to a thorough clinical evaluation, following investigations were done. Blood glucose (fasting and post-prandial), HbA1c and lipid profile. Based on HbA1c levels (excellent control <7, good control 7-9, poor control >9), T2DM status was graded and this was compared with X-ray findings and chest symptoms. Classification of the patients' illness for further management was done based on results of sputum smears and chest X-ray.

Screening for active TB: The process of screening for TB was performed when each of the patient visited the clinic. For the purpose of this study, the results of screening on the first visit has been described.

The screening for active TB was followed as per the guidelines of Revised National TB Control Programme (RNTCP), which are based on WHO guidelines on identifying suspected active TB among persons seeking care (Central Tuberculosis Division, 2005; World Health Organization, 2009). For the screening of TB, all patients with diabetes attending the OPD were asked whether they had a history of TB diagnosis and treatment. The response was recorded and the patient was not asked again about TB until completion of TB treatment, if the answer was yes. In cases, where the answer was no, the patient was screened for symptoms by trained staff.

Patients with cough for ≥2 weeks or any suspicion of active pulmonary TB (PTB) or extra-pulmonary TB were categorised as having presumptive TB and were investigated to confirm the disease.

Two same-day sputum specimens from presumptive TB patients were collected in the DM clinic and given to the government-run microscopy centre for sputum smear microscopy by Ziehl-Neelsen staining. Patients with negative sputum smears or extra-pulmonary TB suspects underwent appropriate investigations such as chest radiography to confirm TB. Those diagnosed with TB were referred to the RNTCP for TB treatment. All the patient related da-

ta were recorded on treatment cards and also in an electronic database.[21, 22]

Diagnostic criteria for severity and duration of Diabetes : HbA1C was determined for all patients with type 2 Diabetes. HbA1c levels are routinely measured in the monitoring of people with type 2 diabetes and depend on the blood glucose concentration. Levels of HbA1c reflect the average glucose levels over the prior six to eight weeks and are not influenced by daily fluctuations in the blood glucose concentration. HbA1c is a useful indicator of the control of blood glucose levels in the recent past (over two to three months). The diagnostic criteria being, Normal - below 5.7 %, Pre-diabetes - 5.7% to 6.4% and Diabetes - 6.5% or greater.[23, 24, 25]

Diagnostic criteria for Cat-I and Cat-II : As per RNTCP guidelines and on the basis of the nature/severity of the disease and the exposure of the patients to previous anti-tubercular treatments, TB patients are categorized into two treatment categories, Category (Cat)-I and Category (Cat)-II. Newly diagnosed sputum positive pulmonary TB, Sputum negative pulmonary TB with extensive parenchymal involvement and Severe form of extra-pulmonary TB are included as Cat-1 patients with whereas Sputum smear-positive Treatment failure cases, Relapse cases and Return after interruption are included as Cat-2 patients.[26] Details about category of treatment, i.e., Cat-I or Cat-II and sputum status at the time of diagnosis, i.e., sputum positive, Sputum negative or extra-pulmonary TB were noted from the TB treatment card.

Table 1 depicts the socio-demographic profile of patients with Type 2 Diabetes mellitus (T2DM)

Parameters	Patients with T2DM (n = 1200) (%)	χ^2 (df), p value
Age (in years)		
<40	240 (20)	251.36 (4), p<0.0001
41 - 50	352 (29.33)	
51 - 60	354 (9.5)	
61 - 70	195 (16.25)	
>71	59 (4.91)	
Gender		
Male	813 (67.75)	150.52 (1), p<0.0001
Female	387 (32.25)	
Marital Status		
Married	1188 (99)	1152.48 (1), p<0.0001
Unmarried	12 (1)	
Illiterate	**188 (15.66)**	237.15(3), p<0.0001
Literacy Status		
Primary school	148 (12.33)	
Secondary school	414 (34.5)	
College & above	450 (37.5)	
Regular job	260 (21.66)	263.39 (5), p<0.0001
Retired	81 (6.75)	
Business	253 (21.08)	
House wife	296 (24.66)	
Students, Others, Laborer, etc.	294 (24.5)	
Nothing	16 (1.33)	
Life style		
Active	404 (33.66)	127.4 (1), p<0.0001
Sedentary	796 (66.33)	
Familiar history		
Yes	242 (20.16)	426.02 (1), p<0.0001
No	958 (79.83)	
Habits		
Smoking	74 (6.16)	891.67 (4), p<0.0001
Alcohol	37 (3.08)	
Gutka/Tobacco	603 (50.25)	
All	161 (13.41)	
None	325 (27.08)	
Reasons for Stress		
Professional / Occupational	451 (37.58)	76.46 (3), p<0.0001
Family	259 (21.58)	
Any other	490 (40.83)	

Statistical Analysis: SPSS version, 2017 was used for statistical analysis. Prevalences are reported with 95% confidence intervals calculated considering the design effect. Mean and standard deviation for continuous variables and proportions for categorical variables are reported. All variables were described as proportions, and differences between groups were compared for statistical significance using the Chi-Square ($\chi 2$) test and t test, as applicable. P values of < 0.05 were considered statistically significant.

RESULTS

Table 1 shows the socio-demographic profile of patients with Type 2 Diabetes mellitus. There is a clear gender bias in patients attending the Diabetes OPD. In all, 67% males and 32% female patients were enrolled in the study. 29% each were in the age group 41-50 and 51-60 years. 16% were in the age group 61-70 years.

Table 2 shows the anthropometric and clinical profile of the adults with Type 2 Diabetes mellitus

Parameters	Adults (n = 1200), (%)	p value
Body Mass Index		
Under weight	42 (3.5)	0.25 (3), p<0.0001
Normal weight	581 (48.4)	
Overweight	497 (41.41)	
Overweight Class I	80 (6.66)	
Hypertension		
Normal (90 - 119/60 - 79)	442 (36.83)	170.64(3), p<0.0001
Pre-hypertension (120 - 139/80 - 89)	359 (29.91)	
Stage 1 (140 - 159/90 - 99)	261 (22.33)	
Stage 2 (>160/>100)	138 (11.75)	
Blood glucose levels / Lipid profile		
IFG	883 (73.58)	141.56 (2), p<0.0001
Cholesterol	477 (39.75)	
Triglycerides	567 (47.25)	
HbA1C		
4 - 6.5	584 (48.66)	250.21 (2), p<0.0001
6.6 – 9	465 (38.75)	
9.1 – 16	151 (12.58)	
Medicine		
Oral Drugs	1016 (84.66)	1455.64 (3), p<0.0001
Insulin	101 (8.41)	
Both (Oral + Insulin)	55 (4.58)	
Ayurvedic/Homeopathy/alternative remedies	28 (2.33)	

Table 3: Profile of patients with diabetes diagnosed with tuberculosis

Variables	Cases (%)	p value
Diabetes patients diagnosed with TB (n=1200)	13 (1.08)	
Gender		
Male	11 (84.61)	$\chi^2 = 4.92$, p<0.027
Female	2 (15.38)	
Mean age of patients	51.307±10.819	$\chi^2 = 1.71$, p<0.191
HbA1C		
6.5 – 9	4 (30.7%)	$\chi^2 = 1.24$, p = 0.27
9.1 – 16	9 (69.2%)	
Type of TB		
Pulmonary	12 (1)	
Extra-pulmonary	1 (0.08)	
Category of treatment		
CAT-I	11 (0.91)	$\chi^2 = 4.92$, p = 0.0275
CAT-II	2 (0.16)	
Bacillary index (Sputum positivity)		
1+	7 (0.58)	$\chi^2 = 6.38$, p = 0.085
2+	3 (0.25)	
3+	1(0.08)	
Negative	2 (0.16)	

This shows that T2DM is more common with advancing age. Among the patients included in the study, 99% were married. About 34% people had studied in high schools and colleges. Thus, it appears that the prevalence of diabetes were more among the literate patients. 21% of these patients had either regular job, business and/or were housewives. Patients having specified jobs had Diabetes owing to desk job. 66% were sedentary whereas 33% were active. Being sedentary is a risk factor for developing Diabetes. 13% of patients were having habits of all types, namely chewing gutkha/tobacco, smoking and alcohol. 50% were addicted to chewing gutka/ tobacco. Around 6% were smokers and about 3% consumed alcohol regularly. More patients with diabetes were found to be addicted to either smoking, drinking alcohol and/or chewing tobacco/ gutkha which is a known risk factor for Diabetes. However, it is difficult to ascertain the number of people actually addicted physiologically to cigarettes and/or alcohol. Excessive alcohol intake reduces insulin sensitivity thereby increasing insulin resistance and the risk of diabetes. 20% of patients with Diabetes had familial history, i.e., at least one member in the family was having Diabetes.

40% of our study subjects were also having stress due to many reasons. While occupational stress appeared to be 37%, familial stress contributed to 21%. Stress is a known factor for many lifestyle diseases like Diabetes, BP, etc.Table 2 shows the anthropometric profile of patients with Type 2 Diabetes mellitus. With reference to BMI, 41% were overweight and 6% were obese. 48% were having normal weight whereas 3% of Diabetic patients were underweight. The variation in BMI levels in patients with Diabetes are highly significant, $p < 0.0001$.

Further, 29% of T2DM patients were having prehypertension, i.e., [120-139/80-89], while 11% were having stage 2 hypertension (>160/>100). Hypertension and Diabetes are common in most of the patients.

Fasting Blood Glucose (FBG) levels were high in 73% of T2DM patients, ranging from 145-250g/dl. Cholesterol and triglyceride levels were also high among 39% and 47% of the patients, respectively. These 3 entities are dangerous and may lead to serious conditions like stroke, heart attack, etc. About 30% of T2DM patients were having metabolic syndrome. Metabolic syndrome is becoming increasingly common. It occurs when a range of metabolic risk factors such as obesity and insulin resistance come together. Metabolic syndrome is a risk factor for diabetes. The HbA1C levels were higher among 51% of the patients, i.e., ranging from 6.6 - 15.

Thus, in our study, age, gender (males), literacy status, occupation, life style, familial history, habits and stress appeared to be significant risk factors among patients with diabetes. Increased BMI, hypertension, blood glucose levels, lipid profile and HbA1C were significant risk factors for TB. It was observed that while 84% of the patients were taking oral hypoglycemic drugs only 8% were taking Insulin injections. About 5% were on both oral hypoglycemic drugs and insulin.

Table 3 shows the profile of patients with diabetes diagnosed with tuberculosis. Out of 1200 patients with type 2 diabetes mellitus, only 13 were having active TB disease, the incidence being 1.08%. Based on the clinical, radiological and bacteriological findings, the diagnosis of active TB disease was confirmed. Among the TB patients, the predominant signs and symptoms were fever, cough, loss of weight, lethargy, pallor and hepatosplenomegaly which correlated with positive chest radiography and respiratory findings. 12 were having pulmonary and 1 was having extra-pulmonary type of TB. 11 were given Cat-I treatment while 2 were on Cat-II, Sputum examination revealed that 7 were having 1+ sputum positivity and 3 were 2+ sputum positivity. Chest X-ray PA (posterior-anterior) view indicated pulmonary involvement along with cavities in some of the patients.

DISCUSSION

In this study, we determined the incidence of Tuberculosis among 1200 patients with Type 2 Diabetes mellitus. More males with advancing age, sedentary life style and high BMI were having Diabetes. These patients were found to be addicted to either smoking, drinking alcohol and/or chewing tobacco / gutka. About 23% of patients with Diabetes had familial history, high BMI levels, hypertension, high FBG levels, cholesterol and triglyceride levels. In our study, age and gender were the strong determinants of TB, with the highest risks found in old people.[27] Several studies have reported that diabetes, smoking and alcohol abuse are the risk factors which can actually raise the risk of developing active TB twice or thrice. It was observed from a mathematical modeling analysis of the effects of smoking on TB infection and mortality that smoking might lead to an excess of 18 million TB cases and 40 million deaths from TB between 2010 and 2050. In India, a major portion of the TB burden can be attributed to smoking (40%) and DM (15%).[28, 29] Majority of the T2DM patients were having Metabolic syndrome. Many of the patients with both DM and TB were on combination therapy with both oral hypoglycemic drugs and insulin and duration of their disease was >10 years. In 69% of the TB-T2DM patients, the glycaemic control was poor as evident from significantly

higher HbA1C levels. Together, these data prove that severe and uncontrolled disease for a longer duration is a risk factor for TB among the diabetes patients with TB as reported in many studies. Only 13 were having active TB disease, the incidence being 1.08%. Some of the patients with TB identified during the study period were on treatment already as they had been diagnosed elsewhere. Good geographical coverage of the TB control programme in Odisha with emphasis on universal access to active TB case finding in the community is probably the reason. Several studies have reported that Diabetes makes a substantial contribution to incidence of TB.[30- 36] Our study shows that the screening of diabetes patients for TB for the first-time is feasible in a tertiary care hospital settings for DM in Odisha routinely. Over a period of 2 years, during which diabetes patients attending the clinic were screened, we detected 13 patients with TB, giving a case rate of 1083 per 1,00,000 screened patients. Moreover, 92% of the patients were highly infectious as they were diagnosed as having smear-positive disease. There is a need for further investigations to determine the relatively less number of new TB cases. TB control efforts might be benefited from active case finding and treatment of latent TB in people with diabetes and increased efforts to diagnose and treat diabetes in populations where diabetes affects the risk of TB to a larger extent.[37, 38] In India, the growing problem of diabetes in this high-risk group population could make prevention of tuberculosis, a priority area in the future.

The strengths of this study are that we could implement the screening process within the routine health care settings. A large number of diabetes patients were registered consecutively, in a robust manner and screened. The early identification of the newly diagnosed patients with co-morbidity helped us to refer these patients to proper care, leading to improved outcomes of TB treatment. Electronic database was used for the recording and reporting. There were a number of limitations and challenges. One limitation of our study was that we were not able to ascertain whether symptoms of other respiratory infections were present along with TB in T2DM. This requires periodic screening at intervals of 3 months, which was not the objective of this study. Further research is needed to determine this and ascertain the average timing of TB screening among diabetes patients. More research is warranted to investigate how the incidence of TB impacts diabetes control efforts in this state. Similarly, the investigations for estimation of HbA1C and lipid profile was done for patients which were costly. Another was few, 10% of patients with symptoms suggestive of TB were reluctant to give sputum specimens, the reason being stigma and/or denial that they might have TB. In India, the screening of TB patients for diabetes is relatively easy and a high rate of detection of DM, ranging from 10%-44% in TB patients has been observed in many studies in different states. However, screening for TB among diabetes patients is less easy, with several studies reporting challenges such as less registration of patients and reluctance to provide sputum specimens. The doctors and/or technical staff, on the other hand, are reluctant for this additional work and do not record the screening systematically.[39, 40] as observed in our study. This study shows the importance of good collaboration between communicable and non-communicable disease programmes.

CONCLUSIONS

Screening for TB among T2DM patients in diabetes clinics would lead to earlier detection of TB, which in turn, would help in early treatment while decreasing the risk of nosocomial transmission. It will further lead to better TB-specific treatment outcomes and prevention of diabetes complications. We, therefore, feel that screening T2DM patients, irrespective of their complaints and symptoms, at regular intervals, for signs and symptoms of TB would go a long way in early detection of the Tuberculosis.

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CASE REPORT

Functional Outcome after Rotational Vascularized Fibular Graft for GCT Right Proximal Tibia

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ABSTRACT

Giant cell tumors (GCT) are locally aggressive tumors with a high rate of recurrence. We here present our experience with wide resection and vascularized autogenous fibula grafting for GCT of proximal tibia.

Keywords: GCT proximal tibia, Rotational vascularized fibular graft

INTRODUCTION

Giant cell tumors (GCT) are locally aggressive tumors with a high rate of recurrence. Recurrences of GCT in autogenous fibular grafts have been rarely reported and pathological fractures through such grafts are even rarer. Wide excision is the management of choice, but this creates a defect at the proximal end of tibia. The preferred modalities for reconstruction of such a defect include vascula-rised/ non-vascularized bone graft, osteoarticular allografts and custom-made prosthesis. We here present our experience with wide resection and vascularised autogenous fibula grafting for GCT of proximal tibia.

CASE PRESENTATION AND METHOD

We report a male, 40 years old with GCT right proximal tibia and right knee flexion contracture. We performed wide resection followed by rotational vascularized fibular graft to femur, and arthrodesis of knee joint. We evaluated anatomical, functional, radiological outcomes of this patient after treatment.

RESULTS

After 3.5 years, the patient has good outcome. There is no pain, no recurrence of tumor, the graft is union and become hypertrophy. Patient can walk with full weight bearing now.

Figure 1: Case of Rotational Vascularized Fibular Graft for GCT Right Proximal Tibia.

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