Original Article

Outcome of extracorporeal shock wave lithotripsy in the treatment of mid ureteric stones

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Abstract

Urinary stone disease is a major problem due to its high prevalence and incidence and recurrence. The present study aimed to determine the outcome of in situ Extracorporeal Shock-Wave Lithotripsy (ESWL) for mid-ureteric stone in terms of stone clearance, per operative and post operative complications involving 30 patients with mid ureteric stone with less than 10 mm in diameter in the Department of Urology, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka between September 2011 and August 2012. Seventeen (56.7%) patients had stone in the right ureter and 13(43.3%) had stone in the left ureter. Mean of stone size was 8.07 mm with a range of 6-10 mm. Most of the patients (96.7%) had post procedure pain, 15(50.0%) had haematuria and 9(30.0%) had fever. Final outcome of treatment showed that complete stone clearance was seen in 83.3% patients after one month. Mid ureteric stone clearance with ESWL was more than eighty percent with a very low rate of complications. ESWL may be recommended as safe and first line therapy for mid ureteric stones.

Key words: Extracorporeal Shock-wave lithotripsy, renal stone, mid ureteric stone

Introduction

Urinary stone disease or nephrolithiasis, the third most common disease of the urinary tract is a major health problem due to its high prevalence, incidence and recurrence.^{1,2} The lifetime incidence of kidney stones for

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men and women is approximately 13% and 7% respectively.^{3,4} Although stones may be asymptomatic, potential consequences include abdominal and flank pain, nausea and vomiting, urinary tract obstruction, infection, and procedure-related morbidity.⁵ Ureteral stones frequently cause renal colic and if left untreated can cause obstructive uropathy.⁶ There is no exact data about its prevalence among the Bangladeshi population but the problem is quite common.

Technological advances and innovation by physicians have improved the endo-urological treatment of ureteric stones. Regardless of the location of the ureteric stone, access and definitive treatment is commonly achieved with a minimal risk of complications.⁷ Treatment of stone disease moved dramatically from an open operative procedure to endoscopic, minimally invasive methods and non invasive methods.⁸ In the last 20 years, the management of ureteric stones has radically changed. Now a very few patients undergo surgery for stones in the kidney or ureters. This is due to availability of less-invasive interventions, such as extracorporeal shock-wave lithotripsy (ESWL), ureteroscopic stone removal and percutaneous nephrolithotomy.⁹ Each of these options has advantages and disadvantages depending on the characteristics of the stone or stones such as size, number, location and composition as well as patient factors such as renal anatomy, body habitus and co-morbidities.¹⁰

ESWL revolutionized the management of calculi in the urinary tract.¹¹⁻¹⁵ In 1980 first clinical application of ESWL in the management of kidney stone was done.¹² Now this therapeutic approach has been widely used all over the world.^{1,6,8,16-18} It has become a safe and accepted method of treatment for urinary tract stones and has been approved by FDA in 1984.19-21 It has been recommended as a first-line treatment for mid ureteric calculi in several studies and success rate is reported to be 80-90%.1,19,23-25 It is a standardized procedure where stone free rates depend on the size, composition and the location of the stone as well as the type of the lithotripter.^{1,26,27} However, more than one session is frequently needed and ureteral stenting is still a matter of debate.¹ In Bangladesh ESWL was introduced in 1993 with siemens lithostar plus lithotripter in BSMMU Hospital, Dhaka.²⁵

The middle ureter is defined as the segment of ureter

overlying the sacroiliac joint. The anterior position of middle ureter and the underlying bony pelvis make localization of middle ureteral stones problematic. Moreover, attenuation of shock-wave energy by the pelvic bone in the supine position may make shock-wave treatment less successful. The treatment of mid-ureteric calculi has been altered markedly by recent development in shock wave lithotripsy. There is no doubt about the success rate of ureterorenoscopy (URS) and intra corporeal pneumatic lithotripsy (ICPL). But this requires anesthesia, hospitalization and may not always succeed and also there is chance of ureteral injury or perforation. On the other hand in situ ESWL in mid-ureteric calculi requires no anesthesia, can be done as outpatient basis with low morbidity and low cost. It is the first study regarding the outcome of ESWL in mid ureteric stone among the Bangladeshi patients, although it is practiced by many urologists all over the world. This study was designed to determine the outcome of in situ ESWL in mid-ureteric stone in terms of stone clearance, per operative and post operative complications and also to enrich our knowledge about the management of mid ureteric stone.

Methods

The present hospital based prospective study was conducted in the Department of Urology, BSMMU, Dhaka between September 2011 and August 2012. Total 30 patients with mid ureteric stones attending the stone clinic of outpatient department of urology during the study period were selected purposively. Both male and female aged more than 12 years, having single mid ureteric stone, size between 6 mm to 10 mm with good excreting kidneys, no distal obstruction and having sterile urine were selected for this study. Patients with uncontrolled bleeding disorder, bladder outlet obstruction, multiple ureteric and associated renal stone, stone in patients with single kidney, pregnancy and BMI more than >30 were excluded from the study. The demographic information, relevant history, examination findings and investigation reports of all the study subjects were recorded in a semi structure questionnaire. Any complications during the procedure and hospital admission, if required, were also recorded. Ethical clearance for the study was taken from the Ethical Review Committee of BSMMU prior to the commencement of this study. The aims and objectives of the study along with its procedure, risks and benefits of this study were explained to the study subjects in an easily understandable local language. A written informed consent was taken from each of the study subjects and they were assured of adequate treatment if any complication developed in relation to the purpose of the study. They were also

assured about their confidentiality and freedom to withdraw them from the study at any time.

ESWL monotherapy with Siemens Lithoscope (3rd generation) lithotripter was used to treat the mid ureteric calculi. Patients were instructed to take mild laxative with carbon tablets on the previous night of the procedure to help to reduce intestinal gase which facilitates stone localization. Non steroidal anti-inflammatory analgesics were given in suppository form for analgesia half an hour before ESWL and immediately after ESWL. Some worried and restless patients were sedated. All patients were kept nothing per oral from morning and given intravenous fluid during and upto 2 hours after the procedure. Standard number of shock waves, 2500 to 3000 per session with energy setting of 3 to 3.5 KV was offered to each patient for lithotripsy. All patients were hospitalized during ESWL procedure and was served as day care service. All patients were under antibiotic prophylaxis during the procedure. All patients were advised to come with X-ray KUB after one week and if necessary second session of ESWL was given. In this way third session was given if required and patients were then advised to come after one month to see total stone clearance. In the follow- up study, history taking, clinical examination and relevant investigation were done and data on ESWL treatment, post ESWL morbidity, stone passage and clearance were recorded.

There is no serious physical, psychological, social and legal risk during the ESWL procedure. But there might be minimal pain and discomfort during the procedure and mild haematuria in few patients after the procedure. The study subjects were discharged on the same day of the procedure.

After compilation, the data were presented in the form of tables, figures and graphs, as necessary. Statistical analysis of the results was done by using computer based statistical software, SPSS (SPSS Inc, Chicago, IL, USA). Results were expressed as frequency and mean ± SD.

Results

Mean age \pm SD of the study subjects was 36.73 ± 8.03 with a range of 20–51 years. Among the patients, 4(13.3%) cases were in the age group of 20–29 years, 15(50.0%) cases in the age group of 30–39 years and 11(36.7%) cases in the age group of 40 years and above. Among the patients 18(60.0%) were male and 12(40.0%) were female. The male and female ratio was 1: 0.67. (Table-I)

Among them, 16(53.3%) presented with right sided pain,

Table-1 : Latients demographic prome (II=50	Table-I	: Patients'	demographic	profile	(n=30)
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Variables	Frequency (%)
Age	
20-29	04(13.3)
30-39	15(50.0)
≥40	11(36.7)
Mean ± SD (Range)	36.73 ± 8.03 (20-51)
Sex	
Male	18(60.0)
Female	12(40.0)
Male: Female	1: 0.67

11(36.7%) presented with left sided pain and 3 (10.0%) presented with generalized abdominal pain. Half of the patients presented with pain associated with vomiting. Blood in urine was present in 18(60.0%) patients and absent in 12(40.0%). In the present study out of 30 patients 17(56.7%) had stone in the right ureter and 13(43.3%) had stone in the left ureter. Mean \pm SD of stone size was 8.07 \pm 1.32 mm with a range of 6-10mm. Most of the patients (96.7%) had post procedure pain, 15(50.0%) had haematuria and 9(30.0%) had fever. (Table-II)

Table-II: Patients clinical profile and characteristics of stone (n=30)

Variables	Frequency (%)
Presenting complaints	
Pain	
Right sided	16(53.3)
Left sided	11(36.7)
Generalized pain	03(10.0)
Pain associated with vomiting	15(50.0)
Blood in urine	
Present	18(60.0)
Absent	12(40.0)
Laterality of stone	
Right	17(56.7)
Left	13(43.3)
Stone Size (mm)	
Mean \pm SD	8.07 ± 1.32
Range	6–10
Complications	
Pain	29(96.7)
Haematuria	15(50.0)
Fever	09(30.0)

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During first follow up on 1st week, X-ray KUB showed complete and incomplete stone clearance in 9(30.0%) and 21(70.0%) patients respectively. During 2nd follow up, out of 21 patients, complete and incomplete stone clearance were 16(53.3%) and 5(16.7%) respectively. After one month, among the 30 patients who underwent ESWL treatment, final outcome showed that complete and incomplete clearance in 25(83.3%) and 5(16.7%) patients respectively. Mean \pm SD of shock waves was 2630 \pm 74.5 with a range of 2500-3000 and mean \pm SD of energy was 3.3 \pm 0.2 kv with a range of 3 to 3.5 kv. Out of 5 patients that had incomplete stone clearance after ESWL treatment, 3 (60.0%) undergone URS with ICPL and 2 (40.0%) undergone open ureterolithotomy. (Table-III)

Table-III: Distribution of stone clearance of patients

 according to post procedure X- ray KUB and session needed

Stone clearance on Xray KUB	Frequency (%)				
1 st Week					
• Complete	09 (30.0)				
• Incomplete	21 (70.0)				
2 nd Week					
• Complete	16 (53.3)				
• Incomplete	05 (16.7)				
Final outcome (After 1 Month)					
• Complete	25 (83.3)				
• Incomplete	05 (16.7)				
Number of sessions					
1 st session					
• Complete	09 (30.0)				
2 nd session					
• Complete	16 (53.3)				
3 rd session					
• Complete	00 (0.0)				

Discussion

In the present study the mean±SD of age of the patients was 36.73 ± 8.03 with a range of 20-51 years. Fifteen (50.0%) cases were in the age group of 30-39 years, 11(36.7%) were in the age group of 40 years and above. Male and female were 18(60.0%) and 12(40.0%)respectively and ratio was 1: 0.67. Papadoukakis et al¹ reported that the peak age in men is 30 years and women have a bimodal age distribution with peaks at 35 and 55 years. Ghobish et al showed in their study on 115 males and 17 females that the mean age was 47 ± 15 and 53 ± 11 years respectively.²⁸ Ghalayini et al found in their study the mean age of 39.5 years (11-72 years) and male to female ratio was $3.7:1.^{29}$ Bierkens et al included 63 patients in their study where 42 were men and 21 were women and mean age was 52 years with a range of 23-78 years.³⁰ Hossain et al studied 500 cases of urinary stone where 100 cases were ureteric stone with a mean age of 42.5 years with a age range of 20 to 65 years where 70% were male and 30.0% were female.³¹ Tamm et al reported that patients treated for urolithiasis are usually between 30 and 60 years of age and affected men three times as often as women.³² Mean age and male to female ratio of the present study is comparable with the results of Ghalayini et al²⁹ and Hossain et al.³¹ But results from the Ghobish et al²⁸ and Bierkens et al³⁰ differ from the study. Like other study, the present study is also male predominant.

Sixteen (53.3%) patients presented with right sided pain, 11(36.7%) patients presented with left sided pain and rest 3(10%) presented with generalized pain. Half of the patients presented with pain associated with vomiting. Blood in urine was present in 18(60%) patients and absent in 12(40%). Seventeen (56.7%) patients had stone in the right ureter and 13(43.3%) had stone in the left ureter. Mean \pm SD of stone size was 8.07 \pm 1.32 mm with a range of 6-10 mm. Deliveliotis et al in a study treated 40 patients with a solitary distal ureteral stone of less than 10 mm in maximum diameter with a mean stone size of 5.1 x 3.5 mm.³³

During first follow up on 1st week, X-ray KUB showed complete and incomplete stone clearance in 9(30%) and 21(70.0%) patients respectively. During 2nd follow up out of 21 patients, complete and incomplete stone clearance were 16(53.3%) and 5(16.7%) respectively. After one month, final outcome showed complete and incomplete stone clearance were 25(83.3%) and 5(16.7%) respectively. In a study by Shameemshowed that stone free rate was 91.7%.25 Ghalayini et al in their study reported that fragmentation after a single session was complete in 52% patients, incomplete in 26%, and absent in 22%.29 Ghimire et al¹⁹ in their study found the success rate of ESWL was 91.1% for solitary urolithiasis. Bierkens et al in their study reported the success rate of ESWL for mid ureteric stone was 90%.³⁰ Demirbas et al in their study showed the success rates with smaller stones (≤ 10 mm) in the proximal, mid, and distal ureter were 90%, 85.8%, and 90.4%, respectively.37 Ehreth et al reported overall stone-free rate at follow up of approximately 90 days was greater in the middle and lower ureter group (83%) than in the kidney and upper ureter group (67%).³⁶ Ghafoor and Halim in their study showed that the clearance rate for ureteric stones treated with ESWL, irrespective of its site and size, was 78.5%.38 The overall stone clearance rate for size 10 mm or less was 82%. Mogensen and Andersen in their study found the stone free rates 3 and 6

months after ESWL in patients with mid ureteral calculi were 76.7% and 86% respectively.23 Murota-Kawano et al found that the overall stone free rate was 94.5%.39 Seitz et al in a study showed that stone clearance was observed in 74.4% cases and additional 4.8% harbored residual fragments ≤3 mm after 3 months.²⁰ Tiselius reported stone-free ureters within 3 months after ESWL was in 97% cases.⁴⁰ Tiselius showed in their study that the stone-free rates were 96.1%, 97.8%, and 97.9% for the proximal, middle and distal ureter respectively.⁴¹ Watson and James reported that the overall fragmentation rate after a single treatment was 72% which increased to 81% with re-treatment.⁴² Yip et al reported single session stone clearance rates of 100% for middle ureteric stones.⁸ In a study by Ghanapragasam et al reported stone clearance 89% for mid ureteric stones.²⁴

Ruckdeschel et al. in a study found that complete or partial stone clearance at the time of discharge from hospital was achieved in 95% cases irrespective of the site of the stone and there were no complications.³⁴ All the previous studies showed that they were equally comparable with the present study in term of outcome in the form of stone clearance. Among the 30 patients who underwent ESWL treatment, after the first session, complete stone clearance in 30% patients. After 2nd session of 21 patients, complete stone clearances was found in 53.3% patients and 5 patients needed 3rd session but no one had complete stone clearance among these 5 patients. After one month, final outcome showed that complete and incomplete clearance were 25(83.3%) and 5(16.7%) respectively. Shameem et al showed that average 1.16 sessions needed for mid ureteric stone clearance.²⁵ In a study on 152 patients with ureteric stones, Lamotte et al found that in 103 (67.7%) patients, stones were treated in a single session, while 31(20.3%) required two ESWL sessions.43 Five patients that had incomplete stone clearance and among them 3(60.0%) underwent URS with ICPL and 2(40.0%) underwent open ureterolithotomy. Shameem et al showed that out of 12 midureteric stones only 1(8.3%) required endoscopic removal.²⁵ Ghalayini et al reported in their study that, among 24 patients in whom ESWL had no impact on the stone, 21 underwent ureteroscopy, and in one case open ureterolithotomy was done for a patient with a hard 17 mm stone, while spontaneous passage occurred in two patients with small stones.²⁹ Nakada et al in their study showed that overall 4% of patients required re-treatment and 19% of patients required an auxiliary procedure.35

In the present study, mean \pm SD of amount of shock waves was 2630 ± 174.5 with a range of 2500-3000 and mean \pm SD of energy was 3.3 ± 0.2 kv with a range of 3 to

3.5 kv. In a study Shameem et al showed that the average number of shock wave and energy in ky to treat ureteric calculi were 3230 and 17.2 respectively.25 Two clinical studies one by Robert et al⁴⁴ and another by Madbouly et al⁴⁵ have addressed the effect of varying shock wave rate on the efficiency of stone fragmentation. Skolarikos et al confirmed the positive effect of lowering shock wave rates in treating ureteral stones, which indicates the necessity of large randomized clinical trials.⁴⁶ Results of present study differ as it is conducted with third generation lithotripter. ESWL has become a safe and accepted treatment for urinary tract stones and dramatically changed the management of ureteric calculus disease. Today, 25 years after its implementation, various side effects have been reported and studied, but most are rare and do not hamper the effectiveness of this technique.

ESWL is a safe method to treat stones in the urinary tract when proper indications are followed. In the present study after one month, final outcome showed that complete rate of stone clearance was more than eighty percent in mid ureteric stones with a very low rate of complications. So taking into consideration the least invasive character and with the simplicity of the machine, anaesthesia free out patient based treatment ESWL may be recommended as the first line therapy for mid ureteric stones in properly selected cases.

The study was conducted in a single centre in Dhaka city which might not be representative of the whole population. Small sample size and purposive sampling methods rather than random sampling were the limitations of the present study. Based on the findings of the present study it is recommended that, to get a higher stone clearance rate by in situ ESWL, stone size should preferably be not more than 10 mm. To establish the findings of the present study further research should be conducted on large sample size.

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