

MID URETERIC STONE CLEARANCE BY EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (ESWL): A CLINICAL STUDY

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Abstract

Background: In the last 20 years, the management of ureteric stones has changed dramatically from an open operative procedure to endoscopic, minimally invasive and non invasive methods. 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) in mid-ureteric stone in terms of stone clearance, per operative and post operative complications.

Methods: This prospective study was conducted in the Department of Urology, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, between September 2011 and August 2012. Total 30 patients with mid ureteric stone sized less than 10 mm were selected purposively. They were evaluated preoperatively by history, physical examination and relevant investigations. ESWL monotherapy with Siemens Lithoscope (3rd generation) lithotripter was used to treat mid ureteric stone. Statistical analysis was done by using SPSS version 13.0.

Results: Mean age of the patients was 36.73±8.03 years with a range of 20–51 years. Among the patients 18 (60.0%) were male and 12 (40.0%) were female. Seventeen (56.7%) patients had stone in the right ureter and 13(43.3%) had stone in the left ureter. Mean stone size was 8.07±1.32 mm with a range of 6.00–10.00 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 83.3% after one month.

Conclusion: Mid ureteric stone clearance with ESWL is more than eighty percent in with a very low rate of complications. So ESWL may be recommended as safe and first line therapy for mid ureteric stones.

Key words: Extracorporeal Shock-Wave Lithotripsy (ESWL); mid ureteric stone.

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Introduction:

Urinary stone disease, the third most common disease of the urinary tract is a major health care problem due to its high prevalence and incidence and recurrence^{1,2}. The lifetime incidence of kidney stones for 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 morbidity⁵. Ureteral stones frequently cause renal colic and if left untreated can cause obstructive uropathy⁶. 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 endourological treatment of ureteric stones. Regardless of the location of the ureteric stone, access and definitive treatment is commonly achieved with a minimal risk of complications⁷. Treatment of stone disease moved dramatically from an open operative procedure to endoscopic, minimally invasive methods and non invasive methods⁸. In the last 20 years, the management of ureteric stones has radically changed⁹. Now a very few patients

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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. 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-morbidities¹⁰.

ESWL revolutionized the management of calculi in the urinary tract¹¹⁻¹⁵. In 1980 first clinical application of ESWL in the management of kidney stone was done¹². Now this therapeutic approach has been widely used all over the world^{1,6,8,16-18}. It become a safe and accepted method of treatment for urinary tract stones and in 1984 was approved by FDA¹⁹⁻²¹. It has been recommended as a first-line treatment for mid ureteric calculi in several studies and reported 80-90% success rate^{1,19,23-25}. It is a standardized procedure which results in 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 frequently needed and ureteral stenting is still a matter of debate¹. In Bangladesh ESWL was introduced in 1993 with Siemens Lithostar plus lithotripter in BSMMU Hospital, Dhaka²⁵.

The middle ureter was 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. No doubt about the success rate of Ureterorenoscopy (URS) and Intra corporeal pneumatic lithotripsy (ICPL) praise-worthy. But this requires anesthesia, hospitalization and may not always succeed and also there is chance of ureteral injury or perforation. On other hand in situ ESWL in mid-ureteric calculi requires no anesthesia

with low morbidity, low cost and outpatient therapy. It is the first study in 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 is designed to determine the outcome of in situ ESWL in mid-ureteric stone in terms of stone clearance, per operative and post operative complications. It will enrich our knowledge about the management of mid ureteric stone.

Methods:

Patients: The present hospital based prospective study 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. Study aimed to improve the treatment of mid ureteric stone clearance among the Bangladeshi population. The study conducted to find the outcome of the ESWL in mid-urteric calculi in terms of stone-clearance and retreatment. It also studied to find out the success rate of stone clearance of the ESWL in mid-urteric calculi in terms of stone-clearance and retreatment and to identify the complication. Both male and female age >12 years, having single mid ureteric stone, size between 6 mm 10 mm with good excreting kidney and 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 patient of 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 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. After the research protocol is approved by the committee, permission for the study was also taken from the Department of Urology, BSMMU. 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 all the study subjects and they were assured of adequate treatment of any complications developed in relation to the purpose of the study. They also assured about their confidentiality and freedom to withdraw them from the study at any time.

Procedure: Patients attending the urology outpatient clinic having mid ureteric stone disease were the study population. Among them those who fulfill the inclusion and exclusion criteria were selected for the study. The selected subjects were evaluated preoperatively by history, physical examination and all relevant pre ESWL routine investigations were done. All patients having stones <10 mm in size, located in the mid ureter, the segment of ureter overlying the sacroiliac joint. 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 gases which facilitates stone localization. Half an hour before ESWL non steroidal anti-inflammatory analgesic was given in suppository form for analgesia and immediate after ESWL. Some worried and restless patients were sedative. All patients were nothing per oral from morning and given intravenous fluid during and 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 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 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.

Risk and benefit: 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. As such there is no potential risk, so proper safety methods were followed during the procedure. This study was bringing fruitful medical information useful for the study subjects and other patients who were undergoing ESWL for mid ureteric stone with much less adverse effects and low cost as compared to other methods. The study subjects were discharged on the same day of the procedure, which is cost effective as well. Hence, the benefit is much more than the risks involved which is very negligible.

Data analysis: After compilation, the data were presented in the form of tables, figures and graphs, as necessary. Statistical analyses of the results was done by using SPSS version 13.0.

Results:

Mean age of the patients was 36.73±8.03 years with a range of 20–51. Among the patients 4 (13.3%) case were in the age group of 20–29 years, 15 (50.0%) cases in the age group of 30–39 years, 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. Among them 16(53.3%) presented with right sided pain, 11 (36.7%) presented with left sided pain and 3 (10.0%) presented with generalized pain. Half of the patients presented with pain associated with vomiting. Blood in urine 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 stone size was 8.07±1.32 mm with a range of 6.00–10.00 mm. Most of the patients (96.7%) had post procedure pain, 15 (50.0%) had haematuria and 9 (30.0%) had fever. During first follow up on 1st week, X-ray KUB showed complete and incomplete stone clearance were 9 (30.0%) and 21 (70.0%)

respectively. During 2nd follow up out of 21 patients, complete and incomplete stone clearance were 16 (53.3%) and 5 (16.7%) respectively. Among the 30 patients who underwent ESWL treatment, after one month, final outcome showed that complete and incomplete clearance were 25 (83.3%) and 5 (16.7%) respectively. Mean shock waves was 2630±74.5 with a range of 2500-3000 and mean energy was 3.3±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 I
Distribution of different characteristics of patients (n=30)

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
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 ± SD	8.07 ± 1.32
Range	6.00 – 10.00
Complications	
Pain	29(96.7)
Haematuria	15(50.0)
Fever	09(30.0)

Table II
Distribution of stone clearance of patients according to post procedure X- ray KUB and session needed

	Frequency (%)
X ray KUB	
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)

Table III
Distribution of subsequent procedure needed for the patients

Subsequent procedure	Frequency (%)
URS with ICPL	03(60.0)
Open ureterolithotomy	02(40.0)
Total	05 (100.0)

Table IV
Mean ± SD of shock waves and energy needed

Shock waves and energy needed	Mean ± SD (Range)
Shock waves	2630 ±174.5 (2500-3000)
Energy (kv)	3.3 ±0.2(3-3.5)

Discussion:

In the present study, the mean 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 and rest 4

(13.3%) were in the age group of 20–29 years. Male and female were 18 (60.0%) and 12 (40.0%) respectively and ratio was 1:0.67. Papadoukakis et al.¹ reported that the peak age in men is 30 years; women have a bimodal age distribution, with peaks at 35 and 55 years. Ghobish et al.²⁸ in their study of 115 males and 17 females showed the mean age of 47±15 and 53±11 years respectively. Ghalayini et al.²⁹ in their study found the mean age of the patients was 39.5 years (11-72 years). Male to female ratio was 3.7:1. Bierkens et al.³⁰ included 63 patients where 42 were men and 21 were women, mean age 52 years with a range 23-78 years. Hossain et al.³¹ studied 500 cases of urinary stone where 100 cases were ureteric stone with a mean age of 42.5 years and range 20 to 65 years and 70.0% were male and 30.0% were female. Tamm et al.³² reported that patients treated for urolithiasis are usually between 30 and 60 years of age and affects men three times as often as it does women. Mean age and male to female ratio of the present study is comparable with the results of Ghalayini et al.²⁹ and Hossain et al.³¹. However, the results from the Ghobish et al.²⁸ and Bierkens et al.³⁰ differ from the study. Like other studies, the present study was also male predominant.

Sixteen (53.3%) presented with right sided pain, 11 (36.7%) presented with left sided pain and rest 3 (10.0%) presented with generalized pain. Half of the patients presented with pain associated with vomiting. Blood in urine is present in 18 (60.0%) patients and absent in 12(40.0%). Seventeen (56.7%) had stone in the right ureter and 13 (43.3%) had stone in the left ureter. Mean stone size was 8.07±1.32 mm with a range of 6.00–10.00 mm. Deliveliotis et al.³³ 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 (range 2-8 mm in length and 2-7 mm in width).

Different authors reported a wide range of complications, from no complication to 25.0% cases. It may be due to most of the study include large number of patients with ureteric stone. In the present, study most of the patients

(96.7%) had post procedure pain, 15 (50.0%) had haematuria, and 9(30.0%) had fever. Shameem et al.²⁵ reported mild to moderate post ESWL pain in all cases and haematuria in 77 (65.2%) and fever in 7 (5.9%), nausea and vomiting in 23 (19.49%) cases. Ghimire et al. (2012)¹⁹ in their study showed that complications were encountered in 25% of cases. Yip et al.⁸ in their study 6 complications including 5 readmissions (2 febrile episodes, 2 severe pain spells, and 1 stent migration) and 1 stricture formation was reported. Ruckdeschel et al.³⁴ in a study of 220 patients reported no complications. Nakada et al.³⁵ in their study showed that 8% of the patients required hospital or emergency room admissions for renal colic. Ehreth et al.³⁶ in their study reported a low overall rate of complications during and after treatment. Present study also showed similar result regarding post ESWL complication.

During first follow up on 1st week, x-ray KUB showed complete and incomplete stone clearance were 9 (30.0%) and 21 (70.0%) 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 were 25 (83.3%) and 5 (16.7%) respectively. In a study by Shameem et al.²⁵ showed that stone free rate was 91.7%. Ghalayini et al.²⁹ in their study reported that fragmentation after a single session was complete in 52% patients, incomplete in 26%, and absent in 22%. Ghimire et al.¹⁹ in their study found the success rate of ESWL was 91.1% for solitary urolithiasis. Bierkens et al.³⁰ in their study reported the success rate of ESWL for mid ureteric stone was 90%. Demirbas et al.³⁶ in their study showed the success rates with smaller stones (d" 10 mm) in the proximal, mid, and distal ureter were 90%, 85.8%, and 90.4%, respectively. Ehreth et al.³⁷ 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%). Ghafoor and Halim³⁸ in their study showed that the clearance rate for ureteric stones treated with ESWL, irrespective of its site and size, was 78.5%. The overall

clearance rate for size ≤ 10 mm stones was 82%. In their study the overall clearance rate for mid-ureteric stones were 92.3%. Mogensen and Andersen²³ in their study found the stone free rates 3 and 6 months after ESWL in patients with mid ureteral calculi were 76.7% and 86.0% respectively. Murota-Kawano et al.³⁹ found that the overall stone free rate was 94.5%. Seitz et al.²⁰ in a study stone clearance was observed in 74.4% cases and additional 4.8% harbored residual fragments ≤ 3 mm after 3 months. Tiselius et al.⁴⁰ reported stone-free ureters within 3 months after ESWL was 97%. In their study the stone-free rates were 96.1%, 97.8%, and 97.9%, for the proximal, middle, and distal ureter, respectively. Watson and James⁴² reported that the overall fragmentation rate after a single treatment was 72%, which increased to 81% with re-treatment. Yip et al.⁸ reported single session stone clearance rates of 100% for middle ureteric stones. In a study by Ghanapragasam et al.²⁴ reported stone clearance 89% for mid ureteric stones. Ruckdeschel et al.³⁴ in a study complete or partial stone clearance at the time of discharge from hospital was achieved in 95% irrespective of the site of the stone and there were no complications. All the previous studies show that they are 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 was 30.0%. After 2nd session of 21 patients, complete stone clearances 53.3% and total 5 patients were needed 3rd session but no one had complete stone clearance. After one month, final outcome showed that complete and incomplete clearance were 25 (83.3%) and 5 (16.7%) respectively. Shameem et al.²⁵ showed that average 1.16 sessions needed for mid ureteric stone clearance. Lamotte et al.⁴³ studied to define the therapeutic approach to ureteric stones. In their study 152 ureteric stones were included. One hundred and three (67.7%) stones were treated in a single session, while 31 (20.3%) required two ESWL sessions. Little variation of result may be due to different stone size and location.

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.²⁵ showed that out of 12 midureteric stones only 1 (8.3%) required endoscopic removal. Ghalayini et al.²⁹ in their study reported that 24 patients in whom ESWL had no impact on the stone, 21 underwent ureteroscopy, and in one case open ureterolithotomy for a patient with a hard 17 mm stone, while spontaneous passage occurred in two patients with small stones. Nakada et al.³⁵ in their study showed that overall, 4% of patients required re-treatment, and 19% of patients required an auxiliary procedure.

In the present study mean shock waves was 2630 ± 174.5 with a range of 2500-3000 and mean energy was 3.3 ± 0.2 kv with a range of 3 to 3.5 kv. Shameem et al.²⁵ showed that the average number of shock wave and energy in kv to treat ureteric calculi were 3230 and 17.2 respectively. Two clinical studies one by Robert et al.⁴⁴ and another Madbouly et al.⁴⁵ have addressed the effect of varying shock wave rate on the efficiency of stone fragmentation. Skolarikos et al.⁴⁶ confirmed the positive effect of lowering shock wave rates in treating ureteral stones, which indicates the necessity of large randomized clinical trials. Result of present study differs 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.

Conclusion:

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 was more than eighty percent in midureteric stones with a very low rate of complications. Hence, taking into consideration the least invasive character and with the simplicity of

the machine, anaesthesia free outpatient 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 to the whole population. Small sample size and following purposive sampling methods instead of random sampling were the limitations of the study. We recommend that stone size should preferably be not more than 10 mm to get a higher stone clearance rate by in situ ESWL and further research should be conducted on larger sample size to establish the findings of the present study.

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