ORIGINAL RESEARCH

Efficacy of Extracorporeal Shock Wave Lithotripsy in the Management of Mid-Ureteric Stones ≤2 cm

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ABSTRACT

Background: The present study evaluated the efficacy of extracorporeal shock wave lithotripsy (ESWL) in patients with mid- ureteric stones by analyzing the clearance rate. **Materials and Methods:**This prospective observational study was conducted in patients with mid ureteric stones at the Department of Urology, Indira Gandhi Institute of Medical Sciences, Patna,(2019-2021). Patients were divided into two groups according to stone size (mm); group A (up to 10 mm) and group B (11- 20 mm). Dornier Compact Delta II (Dornier MedTech Systems) was the ESWL lithotripter used to fragment ureteric stones. **Results:**A total of 34 patientsmean (SD) age of 33.7 (12.16) yearswere included in the study. The average clearance rate, irrespective of the stone size, was 88.23%,for midureteric stone. The ESWL was successful in group A (stone size <10 mm). In group B (stone size 11-20 mm), the ESWL faced more failure. The average retreatment rate was 38.21%.The most common complication was hematuria (8.02%), followed by transient colic and pyrexia (4.93%). **Conclusion:**ESWL is a safe, effective,non-invasive, and well tolerated treatment for the management of midureteric stones, regardless of the stone location. This study recommends that ESWL should be primary modality of treatment in patients with smaller mid ureteric stones up to 10 mm and with overall success rate of 88.23 irrespective of location and size, it is equally good option for stone size 10-20 mm.

Keywords: Ureteric stones,Shock wave lithotripsy, Clearance rate, Retreatment rate.

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INTRODUCTION

Urinary stone disease is the most prevalent urinary tract condition, having an exceptionally high recurrence rate,[1] characterized by the presence of stones in the kidneys, ureter, urinary bladder, or urethra.[2]

Nowadays, the management of ureteric stones by open surgical lithotomy is rarely indicated with major advancements in minimally invasive endourological treatment options that confer improved stone-free rates, reduction in patient morbidity and better quality of life.[2] European Association of Urology (EAU) guidelines recommend medical expulsive therapy (MET) which involves the administration of drugs to facilitate spontaneous ureteral stone passage. The potential benefits of MET include symptomatic relief and decreased need for surgical interventions and their associated complications. However, the use of MET is only recommended for small distal ureteric stones.[3,4] Extracorporeal shock wave lithotripsy (ESWL), percutaneous nephrolithotomy (PCNL), retrograde intrarenal surgery (RIRS), and laparoscopic ureterolithotomy are currently available treatment modalities for ureteric stones.[5] For the treatment of renal and proximal ureteric calculi, ESWL has established itself as the standard practical, noninvasive outpatient procedure; mainly due to good patient compliance and less contraindications.[6]

Several factors such as stone size, fragility, location and composition affect the outcome of ESWL, which is measured in terms of stone fragmentation and clearance.[7] Multiple studies have shown that the clearance rate is higher for the upper ureteric stones when compared to other sites.[8-10] On the other hand, few studies have reported stone-free rates between 80% and 93% for mid and lower ureteric stones with the use of ESWL.[11-14] Hence, there is inconsistency in the available evidence. In light of the

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above context, the present study aims to determine the efficacy of ESWL in patients with ureteric stones at different levels by analyzing the clearance rate according to the stone size, site, number of treatment sessions required per stone and retreatment rate.

MATERIALS AND METHODS

This was a prospective observational study conducted at the Department of Urology, Indira Gandhi Institute of Medical Sciences, Patna from September 2019 to December 2021, involving patients with ureteric stones. The study was approved by the Institutional Ethical and Scientific Committee. A written informed consent wastaken from each patient prior to study recruitment.

The inclusion criteria were patients of either sex, age group of >15 years of age having a diagnosis of radio opaque stones, sterile urine, and solitary ureteric stone size ≤2 cm; confirmed by plain kidney, ureter, and bladder (KUB) x-ray or ultrasonography (USG); no spontaneous passageeven after 2 weeks of conservative treatment from initial diagnosis were included in the study. The patients having stone size >2 cm, radiolucent stones, ureteric stones previously treated with ESWL, those having coagulopathy and abnormal renal function, history of surgery for ureteric stone, and pregnant women were excluded from the study.

The patient's demographic characteristics including detailed history-taking, physical examination, laboratory and radiological investigations were collected on a standard proforma. The imaging modalities including plain X-ray (KUB), IVP, ultrasonography (KUB), retrograde pyelography, antegrade pyelography and computed tomography (CT) scan were performed only if needed. The patients having calculus anuria or ureteric stones in solitary kidney were admitted. Patients of ureteric stone with solitary obstructed kidney, bilateral ureteric stones with azotemia, stone with gross hydronephrosis and active infection were included in the study only after normalization of renal function and clearance of active infection.

The eligible patients were divided into two groups according to stone size (mm) as group A (up to 10 mm) and group B (11- 20 mm). Stone location (mid ureter) in the patients was noted. The pre ESWL stenting was done in 3 patients. Of the 3 patients, 1 patient had bilateral ureteric stones with calculus anuria and rest had ureteric stones in the solitary kidney. Patients with mid ureteric stones were treated either in prone or supine position .

ESWL lithotripter, Dornier Compact Delta II (Dornier MedTech Systems) was used in this study. All stones were localized by fluoroscopy. Shocks delivered per ESWL session ranged from 1000 to 3500 at energy level of 8-12 kv, with shock frequency rate of 60-100 shocks per minute. No anesthesia was given. During the procedure, the patients were administered with injectionceftriaxone 1 gm. intravenous (IV), injection diclofenac sodium 1 amp IM stat, and injection ranitidine IV 1 amp stat. The patients were maintained on IV fluids to ensure adequate hydration and urine output followed by injection frusemide IV 1 amp.

Post procedure, all the patients were advised to drinkplenty of water to achieve an urine output more than 2.5 litres. The patients were administered tab tamsulosin (0.4 mg) for three weeks, oral antibiotics for one week, and analgesics on sedation optimization strategy (SOS) basis.

Patients were followed monthly for three months using plain X-ray (KUB) OR USG (KUB). Patients were followed up till complete absence of stones or until an alternative treatment method was applied. Patients were declared stone free when their X-ray (KUB) or USG was normal after the treatment.

The primary endpoint of the study was to determine the clearance rate by extracorporeal shockwave lithotripsy in treatment of mid ureteric stones ≤ 2cm. The secondary endpoints were to analyze the clearance rate with regard to stone size, stone location, session per stone, and retreatment rate.

Upper ureter: The upper ureter is defined as portion of ureter between pelviureteric junction to upper border of sacrum.

Mid-ureter: It is the portion of ureter between upper and lower border of the sacrum.

Lower ureter: It is the area from lower border of the sacrum to the vesicoureteric junction.

Efficacy: Efficacy will be measured in terms of clearance of stones that will be confirmed by X-ray (KUB) and / or USG (KUB).A major parameter to evaluate shock wave lithotripsy performance is efficiency quotient, which is calculated using the formula:100% x percent stone free/100% + percent retreatment + % auxiliary procedures

ESWL Failure: Patients whose stones fail to clear after three sittings and three months of follow up.

STATISTICAL ANALYSIS

Statistical analyses were performed using SPSS Version 22.0. Descriptive analysis was used to present study outcomes. Continuous variables were described as mean and standard deviation (SD), whereas categorical variables were described as number and percentages.

RESULTS

A total of 34 patients were included in the study. The table 1 depicts the demographic characteristics of the patients. The age of patients ranged from 15 to 55 years with mean (SD) age of 33.7 (12.16) years. Majority of the patients (35.29%) belonged to the age group 21-30 years. The proportion of male population was higher than the female population (64.1% vs 35.8%). The average mean stone size was 12.9 mm.

Out of the 34 patients, of which 17.64% patients were in group A and 82.35% patients were in group B.. The clearance rate in group A wassignificantly higher than group B patients ($p<0.05$). The mean session per stone

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was 1.3session per stone was not significant at any location with respect to the stone size (p>0.05). The retreatment rate was significantly higher in patients with midureteric stones of 11-20 mm sizecompared to those with stone size ≤10 mm (p<0.05) (Table 2). Overall, the clearance rate was 88.23% for mid ureteric stones, respectively (Table 3).

The clearance rate at different sessions is shown in Table 4. Out of 34patients with mid ureteric stones, 4 cases were declared failure at the end of 3 months. About 20 of the remaining 30 patients (70.66%) had their stones completely fragmented and eliminated after first session. The

Most of the patients showed mild irritative symptoms for short period. Post procedural complications were reported in 18.51% (7/34) of patients and majority of them were managed by symptomatic treatment only . The most common complication was hematuria in 8.02%of patients, followed bytransient colic and pyrexia in4.93% of patients. Majority of the patients responded well to symptomatic treatment and hydration. However,four patients with intractable colic and two patients with steinstrasse required DJ stenting. Inadequate fragmentation followed by urosepsisin three patients required intervention.

Table 1: Demographic characteristics

Parameter	Number of patients (N=34)
Age (years), mean (SD)	33.7 (12.1)
Age group (years)	
11-20	5 (14.7)
21-30	12(35.29)
31-40	8 (23.52)
41-50	5 (14.70)
51-60	4(11.76)
Sex	
Male	104 (64.1)
Female	58 (35.8)
Overall stone size (mm), mean (SD)	12.9 (2.1)
Data presented as n (%), unless otherwise specified. Abbreviations:SD, standard deviation.	

Table 2: ESWL parameters

Mid ureteric stone (N=34)			
Outcome	**Group A (N=6)**	**Group B (N=28)**	**P value**
Clearance rate	100.0 (n=6)	85.71 (n=28)	<0.05
Session/stone	1.0	1.53	>0.05
Retreatment rate	-	41.66 (n=5)	<0.05

Table 3: Clinical outcomes according to mid ureteric location of stones.

Site	Stone-free rate (%)	Retreatment rate (%)	Auxiliary Procedure (%)	Efficiency Quotient (EQ)
Middle	88.23 (n=17)	41.66	0	68.17

Table 4: Clearance rate at each session

Stone location	Group	Clearance rate at different sessions		
		I	II	III
Middle	A	100 (n=6)	0	0
	B	58.3 (n=14)	33.3 (n=8)	8.4(n=2)
Data presented as n (%).				

DISCUSSION

The management of ureteral stones consist of observation, shockwave lithotripsy, ureteroscopy or PCNL based on the clinical situation. There is decrease chance of spontaneous stone passage with increasing stone size. Medical expulsive therapy aims

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to facilitate spontaneous passage of ureteral stones, however, the strength of evidence with respect to the benefit of MET in ureteral stones is low, even for distal ureteral stones >5 mm.[15]

Along with decreasing morbidity and hospital stay, ESWL has been proven to be economically viable.[16] Extracorporeal shock wave lithotripsy is an efficient, non-invasive, and convenient method for treating ureteric stones. While endoscopic removal should be the preferable option for stones greater than 10 mm in diameter, ESWL can be regarded as a primary treatment for smaller stones.[14] Extracorporeal shock wave lithotripsy is an established modality for management of kidney and upper ureteric stones, however its role in management of id and lower ureteric stones is still not clearly defined and our study is an attempt to demonstrate its role in the management of mid ureteric stones .

In our study, among 34 patients with mid ureteric stones, overall clearance rate was 88.23% with a retreatment rate of 44.66% and auxiliary procedures were required in 4.49%however, a higher success rate achieved even for bigger stones (> 10 mm) can be attributed to better stone localization and use of standard lithotripter (Dornier Compact Delta 2).

Rahman et al. reported the stone clearance rate of 83.3% for mid ureteric stones which was similar to the stone clearance rate of 88.2% observed in this study.[13] Bierkens et al. reported that the ESWL is beneficial for stone clearance of stones <50 mm2, with a clearance rate of 90.0% and 81.0% for mid- and lower ureteric calculi.[12] Ghafoor et al. reported that the overall clearance rate for mid-ureteric stones was 92.3% and as per the stone size, clearance rate was 91.6% for stone size of <10 mm and 100% for stone size of 11-20 mm.[14]However, we observed clearance rate of 100% for stones <10 mm and 85.71% for stones 11-20 mm. With regard to stone size, we observed higher retreatment rate ($p<0.05$) and session per stone ($p<0.05$) in group of stone size 11-20 mm as compared to stones <10 mm.

Even though hypothetically ESWL can be used for treatment of all stones, the optimum clearance rate can be achieved in a stone that is <20 mm in size and presents in a normal urinary tract.[17]However, the European Association of Urology (EAU) guidelines recommends use of ESWL as an equivalent alternative to ureteroscopy for removal of proximal/distal ureteral stones <10 mm, and considers ESWL as a secondary option to ureteroscopy for both proximal and distal ureteral stones >10 mm.[18]

A study by Joshi et al. demonstrated an overall stone free rate of 79.3% after first session at one month.[19] These results were consistent with the observations of the present study wherein 70.6% of patients had their stones completely fragmented and eliminated after first session. A study by Koçakgö et al. evaluated efficiency quotient values based on stone locations, and showed that efficiency quotient rates were 45.7% for lower ureteric stones, 55.9% for middle, 65.0% for upper ureteric stones and total efficiency quotient was found to be 55.5%.[20] In this study, the efficiency quotient for mid- ureteric stones was 68.17%..

ESWL is a standard, convenient, and most-accepted treatment procedure. However, Baltaci et al. showed that pain, hydronephrosis, fever, and occasionally urosepsis were frequent side-effects of ESWL that occur during the treatment of large renal stone; mainly because these stones might be difficult to pass, especially when there is insufficient breakdown.[21] These side-effects were similar to the ones observed in the present study where the most common complication were haematuria, transient colic, and pyrexia (4.9%).

LIMITATION

The key limitation of the present study is small sample size. The present study was a single-arm study; instead of which a randomized study comparing ESWL with other conventional treatment modalities can provide better evidence on efficacy and safety of ESWL. Despite the above limitations, this study is a significant contribution to the existing limiting literature on the subject.

CONCLUSION

ESWL is an effective and well-tolerated treatment option for the management of mid ureteric stones regardless of the stone size and stone location. According to the study findings, this non-invasive procedure that can be performed on OPD basis can be considered as the first treatment choice for treating mid ureteric stones. This study supports the fact that ESWL should be the primary modality of treatment with smaller stones (10 mm), but with observed clearance rate of 88.23% for ureteric stones irrespective of stone size and location, it is equally justifiable option for stones up to 20 mm as well.

ABBREVIATIONS

CT: computed tomography
DJ: double J
ESWL: Extracorporeal shock wave lithotripsy
IVP: intravenous pyelogram
KUB: ureter, and bladder
MET:medical expulsive therapy
PCNL: percutaneous nephrolithotomy
RIRS: retrograde intrarenal surgery
SD: standard deviation
USG:ultrasonography
OPD: Out patient Department

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Statement of ethics: The study was approved by the Institutional Ethical and Scientific Committee. This study conformed to the provisionsof the Declaration of Helsinki. All participants provided informedconsent in this study.

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