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Original Research Article

Efficacy of Extracorporeal Shock Wave Lithotripsy in the Management of Lower Ureteric Stones ≤ 2 Cm

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Abstract

Background: To evaluate the efficacy of extracorporeal shock wave lithotripsy (ESWL) in patients with lower ureteric stones by analyzing the clearance rate.

Materials and Methods: This prospective observational study was conducted in patients with lower ureteric stones. 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 41 patients (mean [SD] age: 33.7 [12.16] years) were included in the study. The average clearance rate, irrespective of the stone size, was 90.19% for lower ureteric stones, ($p>0.05$). The ESWL was more successful in group A (stone size <10 mm) Group B patients (stone size 11-20 mm) faced more failure. The average retreatment rate was 45.18%. 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 lower ureteric stones, regardless of the stone size. ESWL can be done in patients with smaller stones up to 10 mm and with overall success rate of 90.19% 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.

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].

The European Association of Urology (EAU) guidelines advocate for medical expulsive therapy (MET), a method involving drug administration to aid in the spontaneous passage of ureteral stones. Medical expulsive therapy offers potential benefits such as relief from symptoms and reduced reliance on surgical interventions along with their associated complications. However, it's important to note that

MET is primarily recommended for small distal ureteric stones [3,4].

Various treatment options are available for ureteric stones, including extracorporeal shock wave lithotripsy (ESWL), percutaneous nephrolithotomy (PCNL), retrograde intrarenal surgery (RIRS), and laparoscopic ureterolithotomy [5]. Among these, ESWL has emerged as the standard practical, noninvasive outpatient procedure for treating renal and proximal ureteric calculi. This is largely due to its high patient compliance and minimal contraindications [6].

The efficacy of ESWL depends on factors such as stone size, fragility, location and composition. The success of ESWL is typically gauged by stone fragmentation and clearance rates [7]. It's worth noting that upper ureteric stones tend to have higher clearance rates compared to stones at other sites [8-10]. However, some studies have shown stone-free rates ranging from 80% to 93% for mid and lower ureteric stones treated with ESWL [11-14]. As a result, there exists some inconsistency in the available evidence.

In light of the above context, the present study aimed to assess the effectiveness of ESWL in patients with ureteric stones at different levels. This was accomplished by analyzing the clearance rate based on factors such as stone size, site, number of treatment sessions required per stone and retreatment rate. By addressing these aspects, the study aimed to contribute valuable insights into the utility of ESWL as a treatment approach for ureteric stones of varying characteristics.

2. Materials and Methods

This was a prospective observational study conducted at the he Department of Urology, Indira Gandhi Institute of Medical Sciences, Patna from September 2009 to December 2011, involving patients with lower ureteric stones. The study was approved by the Institutional Ethical and Scientific Committee A written informed consent was taken from each patient prior to study recruitment.

The inclusion criteria were either sex, age group of >15 years of age having a diagnosis of radio opaque stones, sterile urine, and solitary ureteric stone size $\leq$ 2 cm; confirmed by plain kidney, ureter, and bladder (KUB) x-ray, intravenous pyelogram (IVP) or ultrasonography (USG); no spontaneous passage even 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 (upper, mid and lower ureter) in the patients was noted. The pre-ESWL stenting was done in 3 patients. Of the 3 patients, 2 patients were having bilateral ureteric stones with calculus anuria and one had ureteric stones in the solitary kidney. Patients with lower ureteric stones were treated in prone 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 injection ceftriaxone 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 drink plenty 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 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 ureteric stones $\leq$ 2cm. The secondary endpoints were to analyze the clearance rate with regard to stone size, session per stone, and retreatment rate.

The stone size was determined by the maximum diameter, whether in width or length, as observed on Plain X-ray (KUB) or USG.

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. Comparison of qualitative variables between the groups was done using chi-square test and comparison of quantitative variables between the groups was done using Mann-Whitney U test. A $p<0.05$ was considered statistically significant.

3. Results

A total of 41 patients were included in the study. The table 1 depicts the demographic characteristics of the patients. The age of patients ranged from 15 to 65 years with mean (SD) age of 33.7 (12.16) years. Majority of the patients (36.4%) 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.

Table 1: Demographic characteristics

Parameter	**Number of patients (N=51)**
Age (years), mean (SD)	33.7 (12.1)
Age group (years)	
11-20	06 (12.9)
21-30	20 (39.21)
31-40	14 (27.7)
41-50	06 (12.9)
51-60	4 (7.4)
61-70	1(2.4)
Sex	
Male	33(64.701)
Female	18 (35.8)
Overall stone size (mm), mean (SD)	12.9 (2.1)
Data presented as n (%), unless otherwise specified. Abbreviations: SD, standard deviation.	

For lower ureteric stones, the mean stone size was 9.77 mm and 13.24 mm in group A and group B, respectively. The clearance rate in group A was significantly higher than group B ($p<0.05$). The mean session per stone was 1.65 session per stone was not significant with respect to the stone size ($p>0.05$). The average retreatment rate was 45.18%. The retreatment rate was significantly higher in stones of 11-20 mm size compared to those with stone size ≤10 mm ($p<0.05$) (Table 2).

Table 2: Comparison of ESWL parameters

Lower ureteric stone (N=51)			
Outcome	**Group A (N=10)**	**Group B (N=41)**	**P value**
Stone size (mm), mean (SD)	9.77	13.24	-
Clearance rate	9 (88.88)	37 (90.24)	>0.05
Session/stone ratio	1.44	1.86	>0.05
Retreatment rate	4 (44.44)	17 (45.95)	>0.05
Data presented as n (%), unless otherwise specified.			

Overall, the clearance rate was 90.19% lower ureteric stones. (Table 3) '.

Table 3: Clinical outcomes of according to location of stones

Site	Stone-free rate (%)	Retreatment rate (%)	Auxiliary Procedure (%)	Efficiency Quotient (EQ)
Lower	90.19 (n=51)	45.65	4.34	60.13

The clearance rate at different sessions is shown in Table 4. Out of 51 patients with ureteric stones, 5 cases were declared failure at the end of 3 months. About 32 of the remaining 46 patients (70.66%) had their stones completely fragmented and eliminated after first session. The ESWL was successful in group A with failure in one case. In group B, the ESWL faced more failure.

Double J (DJ) stenting was done in 3 patients. The clearance rate was higher in patients with DJ stenting when compared to the patients without DJ stenting (92.81% vs 88.8%).

Table 4: Comparison between clearance rate at each session

Stone location	Group	Clearance rate at different sessions		
		I	II	III
Lower	A	55.5 (n=5)	44.4 (n=4)	0
	B	54 (n=20)	32.4 (n=12)	13.5(n=5)
Data presented as n (%).				

Most of the patients showed mild irritative symptoms for short period. Post procedural complications were reported in 18.51% (09/51) of patients and majority of them were managed by symptomatic treatment only (7/51). The most common complication was hematuria in 8.02% of patients, followed by transient colic and pyrexia in 4.93% of patients. Majority of the patients responded well to symptomatic treatment and hydration. However, two patients with intractable colic and one patients with steinstrasse required DJ stenting.

4. Discussion

The management of ureteral stones involves various approaches including observation, shockwave lithotripsy, ureteroscopy or PCNL based on the clinical situation. As stone size increases, the likelihood of spontaneous stone passage diminishes. Medical expulsive therapy aimed to facilitate the natural passage of ureteral stones; although the evidence supporting its benefits, even for distal ureteral stones >5 mm, is limited.

Extracorporeal shock wave lithotripsy, beyond reducing morbidity and hospital stays, has been shown to be economically viable [15]. Extracorporeal shock wave lithotripsy stands as an efficient, non-invasive, and convenient method for addressing ureteric stones. While endoscopic removal is preferred for stones exceeding 10 mm in diameter, ESWL is suitable as primary treatment for smaller stones [14]. While ESWL has established its role in managing kidney stones and in upper ureteric stones, its precise role in addressing lower ureteric stones remains less defined. Our study seeks to elucidate its effectiveness in managing lower ureteric stones.

Hypothetically, ESWL can be applied for the treatment of all stone sizes, yet the optimal clearance rate seems achievable for stones <20 mm in size within a normal urinary tract. Despite this, the European Association of Urology (EAU) guidelines suggest the use of ESWL as an equivalent alternative to ureteroscopy for removing of proximal/distal ureteral stones <10 mm, while considering ESWL as a secondary option to ureteroscopy for both proximal and distal ureteral stones >10 mm [16].

Bierkens et al. found ESWL to be beneficial for stone clearance in cases of stones <50 mm2, with a clearance rate of 90.0% and 81.0% for mid- and lower ureteric calculi [12]. A study by Rahman et al. reported a stone clearance rate of 83.3% for mid-ureteric stones (13). Ghafoor et al.studied the efficacy of ESWL for lower ureteric stones and demonstrated stone-size-specific clearance rates of 73.8% for stones <10 mm and 42.8% for stones 11-20 mm [14]

In the context of distal ureteral stones, a retrospective study reported an overall stone clearance rate of 82.6%, with rates of 99% for stone sizes ≤10 mm and 9.4% for stone sizes >10 mm [11]. Hochreiter et al. achieved a 97% success rate with a retreatment rate of 10%, alongside auxiliary procedures in 4% for distal ureteral stone removal [17]. This study also indicated clearance rate of 98% and 94% for stone size up to 10 mm and >10 mm, respectively [17]. In the present study, comparable clearance rates (88.88% and 90.24%) and retreatment rates (44.44% vs. 45.94%) (p>0.05) were observed for patients with stone sizes <10 mm

and 11-20 mm. However, there was a higher session per stone count in the 11-20 mm stone group (1.44 vs. 1.86).

A study by Joshi et al. demonstrated an overall stone free rate of 79.3% after the first session at one month [18], which was consistent with the observations of the present study where 70.6% of patients had their stones completely fragmented and eliminated after first session. Koçakgö et al. evaluated efficiency quotient values based on stone locations, revealing efficiency quotient rates of 45.7% for lower ureteric stones, 55.9% for middle, 65.0% for upper ureteric stones, and a total efficiency quotient of 55.5% [19]. In our study, the efficiency quotient for lower ureteric stones was 60.13%..

ESWL stands as a standard, convenient, and widely accepted treatment procedure. However, research by Baltaci et al. highlighted potential side effects including pain, hydronephrosis, fever, and occasionally urosepsis were frequent side-effects of ESWL that occur during the treatment of large renal stones due to potential difficulties in stone passage, especially when inadequate breakdown occurs [20]. These side-effects were similar to the ones observed in the present study where the most common complication included haematuria, transient colic, and pyrexia (4.9%).

Limitation

The key limitation of the present study is small sample size . A randomized study comparing ESWL with other conventional treatment modalities could provide more robust evidence regarding ESWL's efficacy and safety. Nevertheless, this study significantly contributes to the existing literature on this subject.

5. Conclusion

ESWL is an effective and well-tolerated treatment option for the management of lower ureteric stones, regardless of their size or location. This non-invasive procedure, which can be performed on an outpatient basis, can be regarded as the primary treatment option for distal ureteric stones. .

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