ORIGINAL RESEARCH

Outcome of Extracorporeal Shock Wave Lithotripsyin the Management of Upper Ureteric Stones≤2cm

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ABSTRACT

Background: The present study evaluatedthe efficacy of extracorporeal shock wave lithotripsy (ESWL) in patients with upper ureteric stones by analyzing the clearance rate. **Materials and Methods:**This prospective observational study was conducted in patients with ureteric stones at the Department of Urology, Indira Gandhi Institute of Medical Sciences, Patna,(2009-2011). 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 94 patients (mean [SD] age: 33.7 [12.16] years) were included in the study. The average clearance rate, irrespective of the stone size, was 94.68% . 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 upperureteric stones.ESWL should be done in patients with smaller stones upto 10 mm and with overall success rate of 94.68% irrespective of stone size,it is equally good option for stone size 10-20mm.

Keywords: Clearance rate, lithotripsy, retreatment rate, stone size, ureteric stones.

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 above context, the present study aims to determine the efficacy of ESWL in patients with Upper ureteric

stones by analyzing the clearance rate according to the stone size, 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 2009 to December 2011, 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 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,intravenous pyelogram (IVP) 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).The pre ESWL stenting was done in 9 patients. Of the 9 patients, 5 patients were having bilateral ureteric stones with calculus anuria and rest had ureteric stones in the solitary kidney. Patients with upper ureteric stones were treated in 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 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 ≤ 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 94 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 (35.10%) belonged to the age group 21-30 years. The proportion of male population was higher than the female population (64.1% vs 35.106%). The average mean stone size was 12.9 mm. Out of the 94 patients ,9.5% patients were in group A and 90.5% patients were in group B. The clearance rate in group A wassignificantly higher than group B. The mean session per stone was 1.3session per stone and was not significant with respect to the stone size

(p>0.05). The average retreatment rate was 38.21%..Overall, the clearance rate was 94.68%.

The clearance rate at different sessions is shown in Table 4. *Out of 94 patients with ureteric stones, 5 cases were declared failure at the end of 3 months. About 70 of the remaining 89 patients (70.66%) had their stones completely fragmented and eliminated after first session.* The ESWL was successful in group A with no failure. **In group B,swhere ESWL failed mean stone size was higher.**

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

Most of the patients showed mild irritative symptoms for short period. Post procedural complications were reported in 18.51% (30/162) of patients and majority of them were managed by symptomatic treatment only (22/162). 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 steinstrasserequired DJ stenting. Inadequate fragmentation followed by urosepsisin three patients required intervention.

Table 1: Demographic characteristics

Parameter	Number of patients (N=162)
Age (years), mean (SD)	33.7 (12.1)
Age group (years)	
11-20	10 (10.6)
21-30	33 (35.10)
31-40	25 (26.59)
41-50	12 (12.76)
51-60	11 (11.70)
61-70	3 (3.19)
Sex	
Male	61(64.08)
Female	33 (35.106)
Overall stone size (mm), mean (SD)	12.9 (2.1)
Data presented as n (%), unless otherwise specified. Abbreviations:SD, standard deviation.	

Table 2: Outcome of ESWL according to stone size.

Upper ureteric stone (N=94)			
Outcome	**Group A (N=9)**	**Group B (N=85)**	**P value**
Clearance rate	100.0	94.11	<0.05
Session/stone	1.1	1.43	>0.05
Retreatment rate	11.11	21.25	>0.05
Data presented as %, unless otherwise specified.			

Table 3: Overall Clinical outcomes of ESWL

Site	Stone-free rate (%)	Retreatment rate (%)	Auxiliary Procedure (%)	Efficiency Quotient (EQ)
Upper	94.68	20.22	4.49	75.91

Table 4: Clearance rate at each session

Stone location	Group	Clearance rate at different sessions		
		I	II	III
Upper	A	77.7 (n=7)	22.2(n=2)	0
	B	78.2(n=63)	13.2(n=11)	7.5 (n=6)
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 a decrease in the chances of spontaneous stone passage with increasing stone size. Medical expulsive

therapyaims 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 >5mm.[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 upper ureteric stones. While ureteroscopic laser lithotripsy 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 stones, however its role in management of ureteric stones is still not clearly defined and our study is an attempt to demonstrate its role in the management of upper ureteric stones upto size of 2cm .

In our study,among 94 patients with upper ureteric stones, overall clearance rate was 94.11% with a retreatment rate of 20.22% and auxiliary procedures were required in 4.49%.Previous studies reported stone free rates of 87% to 97% using Dornier HM3 lithotripter.[17-19]Stone-free rates of 90.0% were reported for upper ureteric stones in a study where third-generation lithotripter, the Dornier MFL 5000, was used.[20] Other studies evaluating success rates for clearance of upper ureteric stones using ESWL also reported stone-free rates ranging from 93.4% to 98.0%.[21, 22] According to the summary report generated by The American ureteral stones clinical guidelines panel,stone-free ratesafter using ESWL for proximal ureteric stones were 87% for stone size <1 cm and 76% for stone size>1cm.[23]Nabi et al. reported the clearance rates of 96%, 90%, and 70% by ESWL for upper ureteric stones of size less than 10 mm, 11-20 mm, and greater than 20 mm, respectively. Authors further revealed that larger stone size was associated with increased retreatment rates, requirement of more auxiliary procedures and higher incidence of complications.[24]Padhye et al.study involving aseries of 846 patients with upper ureteric stones reported success rates of around 95% for stone size <10 mm and 85% for stone size >10 mm with retreatment rate of 59% and auxiliary procedures requirement in 8% of patients.[25]The present study findings are in accordance with the above discussed evidences. In the present study,complete clearance of upper ureteric stones was achieved with ESWL for stone size ≤10 mm and was significantly higher than clearance rate forstone size 11mm to 20mm ($p<0.05$).We observed higher retreatment rate (11.11 vs 21.25) and session per stone (1.1 vs 1.425) with regard to higher stone size, but the difference was not significant ($p>0.05$).Failure of ESWL was seen with mean stone size 16.22mm.A significant association between stone size and success rates was established in a study by Fetner et al.[26]The success rate observed for stone size ≤10 mm in our study is in line with the previous studies;[24,25]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).

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 occurduring the treatment of large renal stone; mainly because these stones might be difficult to pass, especially when there is insufficient breakdown.[27] 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 effectiveand well-tolerated treatment option for the management of upper ureteric stonesregardless of the stone size . According to the study findings, this non-invasive procedure thatcan be performed on OPD basis canbe considered as the first treatment choice for treating upper ureteric stones. This study supports the fact that ESWL should be the modality of treatment in patients with smaller stones(10mm),but with observed over all clearance rate of 94.11% irrespective of stone size , it is equally justifiable option for stones upto 20mm 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

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