Comparison of Outcomes of Extracorporeal Shockwave Lithotripsy with Ureteroscopic Lasertripsy for Management of Proximal Ureteral Stones

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ABSTRACT

Objective: To compare the outcomes of extracorporeal shockwave lithotripsy with ureterorenoscopy and lasertripsy for managing upper ureteral stones of size 10mm to 15mm.

Study Design: Observational, cross-sectional study.

Place and Duration of the Study: Department of Urology, Sindh Institute of Urology and Transplantation (SIUT), from December 2020 to December 2021.

Methodology: A total of 168 patients with the diagnosis of proximal ureteric stone of size 1-1.5 cm were enrolled for this study. Patients were divided into two groups by simple random method. Group 1 patients underwent ureteroscopic lithotripsy (URS) and lasertripsy while Group 2 patients were subjected to extracorporeal shockwave lithotripsy (ESWL). Patients' demography, operative time, duration of hospitalisation, complication rate and stone-free rates, were recorded for both groups. Frequency and percentages were calculated for categorical variables and mean and standard deviation were calculated for continuous variables. For comparison of continuous variables, one-way ANOVA was applied, and Chi-square test was applied to compare the categorical variables. The p-value ≤0.05 was taken as significant.

Results: The mean age was of 39.55 ± 14.06 years, with the majority falling within the age group of 26 to 40 years. There were more males (116, 69%) than females (52, 31%). Most of the patients did not have a history of diabetes or hypertension. Sixty-two patients had previous history of stones. The average duration of ureteric stone disease was 3.18 ± 3.14 months. The mean size of the ureteric stone was 10.82 ± 3.19mm. The procedure duration was significantly shorter for URS, as compared to ESWL (33.81 ± 15.42 minutes *vs*. 45.00 ± 0.00 minutes, p=<0.01. The overall stone clearance rate was significantly higher after URS (83.3%) as compared to ESWL (64.2%, p=0.05).

Conclusion: URS was a superior treatment option as compared to ESWL. However, the selection of the most appropriate procedure should be based on a tailored approach considering the patient's preference and the size of the stones.

Key Words: *Extracorporeal shockwave lithotripsy (ESWL), Ureteroscopic lithotripsy (URS), Modified clavien classification system (MCCS), Ureteric stone.*

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INTRODUCTION

By the time a person reaches the age of 70 years, the incidence of urolithiasis is reported to range from 11 to 13% in males and 5.6 to 7.0% in women.[1,2] Pain, nausea, and haematuria are the three most typical signs of ureteral stones.

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Urolithiasis can now be treated more effectively and with fewer side effects because of the technology advancements. Urologists have a variety of alternatives for treating ureteral stones ranging in size from 8 to 15 mm, including ureteroscopic lithotripsy (URS), extracorporeal shockwave lithotripsy (ESWL), open ureterolithotomy, and robotic-assisted or laparoscopic ureterolithotomy.[3,4]

ESWL is a non-invasive technique that disintegrates stones without the need of general or regional anaesthesia.[5] In contrast to ESWL, URS is a minimally invasive technique that requires anaesthesia.[6] When used appropriately, both adults and children can benefit greatly from these treatment methods as they are highly effective in treating the intended conditions.[7] Although ESWL is non-invasive, it is not free from complications. Besides, it has suboptional patient compliance due to multiple

sessions to achieve complete stone clearance.[8,9] Nevertheless, URS for stones in the proximal ureter has been linked to less successful outcomes, which are attributed to both more challenging access and retropulsion.

For stone-free rates in treating upper ureteric stones, studies have revealed conflicting results for both ESWL as well as URS. Dell'Atti *et al*. found that the stone-free rate was significantly lower with ESWL as compared to URS, 45.4% and 77.5%, respectively ($p < 0.001$).[10] Cui *et al*. reported no significant difference in stone-free rates for both groups (ESWL and URS, $p=0.61$).[11] A meta-analysis also found heterogeneity in the data regarding outcomes of ESWL and URS, and concluded that it may be the experience and techniques of operating surgeons or may be the nature of the stones associated with variability in the outcomes.[12] So, the effectiveness of URS over ESWL has still not been well established in patients with ureteral stones of size >10 mm. The purpose of this study was to determine the outcomes and effectiveness in terms of stone clearance after ESWL and URS for stone sizes between 10 to 15mm.

METHODOLOGY

This was an observational, cross-sectional study conducted at the Department of Urology, SIUT, over the period of 12 months (December 2020 to 2021) after getting an ethical approval from SIUT Ethical Review Committee. The sample size was determined on frequency of stone clearance rate of 77.5% after URS Group 1 and a stone clearance rate of 45.4% after ESWL Group 2. To achieve a significance level of 5%, 84 patients were included in each group. A total of 168 patients diagnosed with proximal ureteric stones of size 10 to 15mm on ultrasound KUB and CT scan KUB were enrolled in this study after taking informed written consents. The selection process employed a simple random sampling technique to enroll patients of both genders, aged between 20 and 70 years. Patients with stone in distal ureter or in front of transverse vertebral process, patients with chronic kidney disease and untreated urinary tract infections were excluded from this study. Stone clearance rate was defined as the clearance of stones with no visible residual fragments or fragments smaller than 4mm in diameter (clinically insignificant residual fragment) after treatment. This was determined by using x-ray KUB and ultrasound KUB at 2 weeks after the procedure. All post-procedure complications were recorded in accordance to Modified Clavien Classification System (MCCS).

For ESWL, Storz modulith SLX- F2 electromagnetic lithotripter was used. All the patients in Group 2 received outpatient treatment. Prior to the procedure, each patient was administered prophylactic empirical antibiotics and analgesics. The treatment involved delivering 3000 shockwaves to each patient, gradually increasing the power from low to high voltage energy, based on the patient's tolerance. After the completion of the procedure, patients were discharged with instructions to follow up at the outpatient department after two weeks.

Patients in Group 1 underwent a day-care procedure. During the induction of anaesthesia, intravenous antibiotics were given. A 6.5/7Fr semi-rigid ureteroscope was utilised along with a Holmium laser and a 200-micron fiber for fragmentation. Following the procedure, a ureteral catheter and Foley's catheter were both retained for a period of 6 to 12 hours. In cases, where there was suspicion of ureteric trauma or other complications, a Double J stent was inserted. Data regarding patients' demography, duration of disease, comorbid, procedural details, complications according to MCCS, and stone clearance rate, and sessions of procedure were recorded on a pre-designed proforma.

All the data were entered and analysed with IBM SPSS version 26. Continuous variables were measured as mean and standard deviation, and categorical variables were reported as frequencies and percentages. One-way ANOVA was used to compare means of continuous variables and Chi-square test was applied for comparison of categorical variables. The p-value <0.05 was taken as significant.

RESULTS

The patients in this study had a mean age of 39.55 ± 14.06 years, with the majority falling within the age group of 26 to 40 years. There were more males (n=116, 69%) than females (n=52, 31%). Most of the patients did not have a history of diabetes or hypertension, and no previous history of stones. The average duration of ureteric stone disease was 3.18 ± 3.14 months. The mean size of the ureteric stone was 10.82 ± 3.19mm. Out of the total patients, 62 (36.9%) had a history of previous stone disease.

The procedure duration was significantly shorter for URS, with a mean of 33.81 ± 15.42 minutes, as compared to ESWL with a mean of 45.00 ± 0.00 minutes ($p<0.01$). The overall stone clearance rate was significantly higher after URS as (83.3%) compared to ESWL (64.2%, $p=0.05$). In Group 1, 82.1% of patients remained free of complications, while in Group 2, 88.09% of patients had no complications at all. Among patients who underwent ESWL, 8.3% experienced Grade I complications and 3.5% experienced Grade II complications according to the MCCS grading system. The majority of complications in Group 1 were also MCCS Grade I to II (Table I).

DISCUSSION

While SWL and open surgery have slightly decreased in popularity, URS and minimally invasive PCNL methods have experienced significant growth.[13] Currently, the main therapeutic options for proximal ureteric stones are ESWL and URS, each with its own advantages and disadvantages. ESWL is often performed without anaesthesia or special preparations, as preferred by some urologists. On the other hand, URS, despite being more invasive, is claimed to have a higher initial treatment success rate by supporting urologists. It is important to consider all relevant parameters before objectively comparing these techniques.[14]

Table I: Descriptive statistics and stratification among URS and ESWL groups.

	Descriptive	URS	ESWL	p-value
Age (years)	39.55 ± 14.06	41.40 ± 13.72	37.69 ± 14.19	0.087[a]
Age category				
11-25 years	29 (17.3%)	11 (37.9%)	18 (62.1%)	0.358[b]
26-40 years	65 (38.7%)	31 (47.6%)	34 (52.3%)	
41-55 years	46 (27.4%)	28 (60.8%)	18 (39.1%)	
56-70 years	25 (14.9%)	13 (52%)	12 (48%)	
71-85 years	03 (1.8%)	01 (33.3%)	02 (66.6%)	
Gender				
Male	116 (69%)	55 (47.4%)	61 (52.5%)	0.317[b]
Female	52 (31%)	29 (55.7%)	23 (44.2%)	
Diabetes mellitus				
Present	25 (14.9%)	09 (36%)	16 (64%)	0.129[b]
Hypertension				
Present	32 (19%)	12 (36%)	20 (62.5%)	0.116[b]
Previous history of stone				
Present	62 (36.9%)	31 (50%)	31 (50%)	>0.99[b]
Duration of ureteric stone (month)	03.188 ±3.14	02.25 ± 1.65	04.11 ± 3.92	<0.001[a]
Size of ureteric stone (mm)	10.82 ± 3.19	10.64 ± 3.50	11.01 ± 2.87	0.459[a]
Procedure time (minutes)	40.40 ± 11.81	33.81 ± 15.42	45.00 ± 0.00	<0.001[a]
Successful stone clearance	124 (73.8%)	70 (83.33%)	54 (64.28%)	0.005[b]
No. of procedure	01.19 ± 0.55	01.04 ± 0.21	01.33 ± 0.73	0.001[a]
Modified Clavien Classification System (MCCS)				
None	143 (85.1%)	69 (82.1%)	74 (88.09%)	0.114[b]
Grade I	13 (7.7%)	06 (7.14%)	07 (8.3%)	
Grade II	05 (3%)	02 (2.3%)	03 (3.5%)	
Grade III	06 (3.6%)	06 (7.14%)	00	
Grade IV	01 (0.6%)	01 (1.19%)	00	

[a] *One-way ANOVA,* [b] *Chi-square.*

Kartal *et al.* compared flexible URS (f-URS), semirigid URS (sr-URS) and ESWL for treating proximal ureteric stone and reported no significant baseline differences in patients' demographic and stone characteristics, while stone-free rates were higher with f-URS 97% than with sr-URS (94.1%) and ESWL (79.0%, p <0.001).[15]

In a separate study, the reported hospitalisation time, procedure time, success rate and cost were significantly higher in URS group when compared with ESWL. The complication rate was also significantly higher after URS (p <0.001).[16]

Rehman *et al.* performed a similar study over 150 adults. In contrast to this study's results, they reported better outcomes for ESWL in terms of mean procedure time (p = 0.001), but stone-free rates were better for URS group.[17] One more study from Pakistan reported stone- free rate of 83.5%, four weeks after semirigid URS, and MCCS Grade I complications in 27% patients.[18]

In a randomised controlled trial from Egypt, URS plus Holmium YAG lasertripsy was compared to ESWL, and the study reported stone-free rates to be higher for URS against ESWL, and both the procedures were recommended as safe for treating proximal ureteric stones.[19] For stones <10mm, stone-free rates were reported at 67.5% and 81.8% for ESWL and URS, respectively.[20]

In this study, significant difference was observed in mean operative time (p<0.001) and stone free-rates (p=0.005); semirigid URS with lasertripsy was observed to be superior over ESWL. Grade I to II MCCS complications were observed in 10.7% patients in this study; only one (0.59%) patient experienced Grade IV complication (urosepsis) that was managed by institutional infectious and intensive care protocol.

CONCLUSION

Ureteroscopy is a safe and superior treatment option as compared to ESWL (extracorporeal shockwave lithotripsy). However, the selection of the most appropriate procedure should be based on a tailored approach considering the patient's preference and the size of the stones. While URS offers a higher success rate and is considered less invasive, it is crucial to take into account individual patient factors and considerations. A personalised decision-making process is essential to optimise outcomes in ureteric stone management.

ETHICAL APPROVAL:
An approval was granted by SIUT- Ethical Review Committee on August 13, 2020 (Approval No. SIUT-ERC-220/A-225).

PATIENTS' CONSENT:
Informed written consents were acquired from all participants of the study.

COMPETING INTEREST:
The authors declared no competing interest.

AUTHORS' CONTRIBUTION:

GM: Conception, designing, data acquisition and analysis, drafting.

NAM: Study design, data analysis, literature review and search, drafting.

MM: Data acquisition, literature search and review.

HHQ, MF: Data acquisition, literature search, drafting.

ASH: Critical review of the draft and final approval.

All authors approved the final version of the manuscript to be published.

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