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The Comparison of Outcome in Treating Proximal Ureteric Stones of Size 10 mm to 15 mm Using Extracorporeal Shock Wave Lithotripsy as Compared to Ureterorenoscopic Manipulation Using Holmium Laser

Kashif Bangash[1], Arsalan Riaz[1], Hassan Mumtaz[1,*], Farrukh Zaman[1], Inam Malkani[1], Muhammad Danish Qureshi[1], Fayyaz Haider Ali[2], Khursheed Anwar[3]

[1]KRL Hospital, Islamabad Pakistan; [2]Quaid e Azam International Hospital Islamabad, Pakistan; [3]PAEC General Hospital, Islamabad, Pakistan

Abstract

Urinary stone disease or nephrolithiasis, the third most common disease of the urinary tract, is a major health issue due to its high prevalence, occurrence, and recurrence. The hallmark of a stone that obstructs the ureter or renal pelvis is excruciating, intermittent pain that radiates from the flank to the groin or to the inner thigh. Stone size influences the rate of spontaneous stone passage. Our aim was to compare the efficacy & the frequency of stone-free patients after intervention at 1 week after extracorporeal shock wave lithotripsy (ESWL) and ureterorenoscopic (URS) manipulation for proximal ureteric stone (10–15 mm size). This randomized control trial was done in the department of Urology, KRL Hospital Islamabad from 18th Nov 2019 to 18th May 2020. After meeting the inclusion criteria, 100 patients were enrolled and were divided into two groups. The first group was treated with ESWL and the other with URS. Then, procedures were done. Follow-up was noted after 1 week in the stone clinic. The average age of the patients was 39.71 ± 10.17 years. Efficacy in the ESWL group was found in 68% cases while in the URS group, efficacy was noticed in 76% cases ($P > 0.05$). Male patients were three times at a higher risk of recurrence as compared to females. This study concluded that both ESWL and URS are equally effective statistically in terms of the frequency of stone-free patients at 1 week for proximal ureteric stone (10–15 mm size).

Keywords: proximal ureteric stone, extracorporeal shock wave lithotripsy; ureterorenoscopic, manipulation, Endourology, Stoneclinic

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Author for correspondence: Hassan Mumtaz, KRL Hospital, Islamabad, Pakistan. Email: hassanmumtaz.dr@gmail.com

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Introduction

Urinary stone disease or nephrolithiasis is the third most common disease of the urinary tract. It is a major health issue due to its high prevalence, occurrence, and recurrence. The life-span and frequency of kidney stones for both men and women are approximately 13 and 7%, respectively (1).

Ureteral stones may be asymptomatic or the potential symptoms include abdominal and flank pain, nausea and vomiting, urinary tract obstruction, infection, and procedure-related morbidity. Ureteral stones frequently cause renal colic and if left untreated can cause obstructive uropathy (2). According to recent estimates, the prevalence in the US population is 10.6% for men and 7.1% for women (3).

Prevalence of stones is 4–20% and incidence is 0.03–0.1%, in adults (4).

Extracorporeal shock wave lithotripsy (ESWL) and ureterorenoscopy (URS) are the two methods for treating proximal ureteric stones. Surgeons infrequently perform open surgery. ESWL is a well-recognized standard procedure that is particularly effective with small renal stones (≤20 mm). It is commonly performed as an outpatient procedure with a low complication rate and requires no anesthesia. Its efficacy can be compromised by obesity, stone density, composition, size, and location in the kidney. In several studies, it is found that ESWL is a safe and acceptable treatment option for morbidly obese patients with upper ureteral stones (5).

The overall efficacy of ESWL for nephrolithiasis depends mainly on stone size, location, stone composition, patient habit, and the performance of ESWL.

Reports from high-volume centers with static machines suggest stone clearance rates of 86–89%, 71–83%, 73–84%, and 37–68% for stones in the renal pelvis, upper calyx, middle calyx, and lower pole calyx, respectively (6). The use of ESWL not only reduced hospitalization time and morbidity but is also cost effective (7). The URS is a form of minimally invasive surgery using a small telescope that is passed through the urethra and into the ureter to remove a stone.

Laser pneumatic lithoclast is required for fragmentation of stones which then allows the smaller pieces to be removed with a grasping device. Pneumatic and laser lithotriptors are most preferred and most frequently used in intracorporeal lithotripsy during endoscopic management of the ureteral stone. Holmium Laser lithotripsy gained popularity and is established as the standard modality. Holmium laser is a kind of new laser commonly used in urological surgery. It can crush all kinds of stones, irrespective of their composition and density. It causes a little ureteral mucosal damage and is cost-effective as well (8). A combination of URS and intracorporeal lithotripsy has proven to be a viable alternative to ESWL. However, some urologists recommend URS manipulation as the treatment of choice. For proximal ureteric stones, the debate still continues as to whether ESWL or URS manipulation should be the first-line treatment. However, the ESWL is better in terms of decreasing hospital stay and there is no requirement of anesthesia. The ESWL is desirable in poor countries because of its noninvasiveness, low morbidity, and utility in patients unfit for open surgery (9).

The purpose of this study was to compare the stone-free rate at 1 week after ESWL and URS manipulation in the treatment of proximal ureteric stones (10–15 mm size). Several different studies report the success rate of the above two procedures differently. For example, in one study population, the proportion of stone clearance using the ESWL was 0.492 and in another group, it was 0.881 using the URS (10, 11).

It is estimated that 68% of the stones of about 5 mm size and 47% stones of over 5–10 mm size may pass spontaneously, and stones of over 10 mm size need intervention (12).

Our objective was to check whether ESWL is safe alternative to URS or not.

Material and Methods

This Randomized Control Trial was done during 6 months, that is, from November 18, 2019, to May 18, 2020, in the Department of Urology, KRL Hospital, Islamabad. The sample size was calculated using the WHO calculator. Population proportion of clear the stone in group 1 (ESWL) was 0.492 (10) and population proportion of clear the stone in group 2 (URS) was 0.881 (11). Level of significance was 5%, and the power of test was 80%.

Sampling technique used was (nonprobability) consecutive sampling. The total sample size was 100, which was randomized into two groups through the lottery method.

Inclusion criteria

Patients over 16 years of age up to 70 years; both male and female patients, having proximal ureteric stone of 10–15 mm size with normal renal function (serum creatinine 0.7–1.5 mg/dL); or patients being diagnosed with solitary proximal ureteric stones were included in our study.

Exclusion criteria

Patients with solitary functioning kidney, patients with renal failure, pregnant women, patients having deranged coagulation profile, patients with sepsis, patients with any comorbidities, patients with multiple stones, or patients having severe hydronephrosis (renal pelvis > 6 mm diameter and cortex < 1 cm on ultrasound kidney ureter bladder [KUB]) were excluded from our study.

Data collection procedure

Patients who fulfilled the inclusion criteria from indoor and outdoor departments of Urology, KRL Hospital, Islamabad, were included in the study after obtaining permission from the Ethical Committee and the Research Department of Urology, KRL Hospital, Islamabad. A detailed explanation about the procedure was given to the patients and a written informed consent was obtained explaining the risks and benefits of the study.

Computed tomography (CT) scan KUB plain was done in patients for follow-up. ESWL patients had a single session. Time frame from presentation to treatment in each group was 1 week. Patients in the URS group were stunted during the procedure. ESWL patients commonly require many

sessions, which is very costly. It causes financial burden and psychological trauma for the patients. One session of ESWL and follow-up after 1 week was decided upon before continuing with ESWL sessions or shifting to URS.

Data analysis

Data were entered and analyzed in statistical software Statistical Package for Social Sciences (SPSS), version 22. Frequency and percentage were computed for categorical variables like age groups, gender, presenting complaints, laterality of stone, pain associated with vomiting, and efficacy. Mean and standard deviation were computed for quantitative measures like age, number of stones, and stone size. Chi-square test was applied to compare proportion of stone-free rate between groups. Gender, age groups, and presenting complaints were used for the stratification. After stratification, a Chi-square test was applied. $P \leq 0.05$ was considered significant.

Work

This work has been reported in line with Consolidated Standards of Reporting Trials (CONSORT) Guidelines.

Results

In patients treated with ESWL, the mean age of the patients was 40.78 ± 10.19 years, whereas in patients treated with URS the mean age of the patients was 38.52 ± 10.44 years. Thirty-six patients (48%) treated with ESWL were male while 14 (56%) were females. Similarly, 39 patients (52%) treated with URS were male while 11 (44%) were females. In the ESWL group, the mean body mass index (BMI) of the patients was 25.24 ± 3.91 kg/m^2 while in patients in the URS group, the mean BMI of the patients was 25.22 ± 4.048 kg/m^2. In the ESWL group, the left side of location of stone was noted in 29 (48.3%) patients and the right site of location was noted in 21 (52.5%) patients. Similarly, in the URS group, the left side of location was noted in 31 (51.7%) patients and the right site of location of stone was noted in 19 (47.5%) patients as shown in (Tables 1 and 2)

In the ESWL group, the mean stone density in patients was 727.54 ± 178.52 while in the URS group, the mean stone density of the patients was 869.06 ± 302.22. This difference was statistically significant, that is, P = 0.005. The mean size of stone of the patients in the ESWL group was 12.57 ± 1.67 mm while in the URS group, the mean size of stone of the patients was 12.44 ± 1.67 mm. This difference

Table 1: Summary statistics of age (years), gender, BMI (kg/m^2) and frequency distribution of side of stone between study groups.

Variable and Subcategory		Study Groups		Total
		ESWL	URS	
Age (years)	n	50	50	
	Mean	40.78	38.52	
	Standard Deviation	10.19	10.44	
Gender	Male	36	39	75
		48.0%	52.0%	100.0%
	Female	14	11	25
		56.0%	44.0%	100.0%
BMI (kg/m^2)	n	50	50	
	Mean	25.24	25.22	
	Standard Deviation	3.91	4.048	
Site of stone	Left	29	31	60
		48.3%	51.7%	100.0%
	Right	21	19	40
		52.5%	47.5%	100.0%

BMI = body mass index; ESWL = extracorporeal shock wave lithotripsy; URS = ureterorenoscopy.

Table 2: Comparison of density and size (mm) of stone between study groups.

Variable and Subcategories		Efficacy	Study Groups		Total	P
			ESWL	URS		
Stone size	10–12	Yes	16	15	31	0.609
			69.6%	62.5%	66.0%	
		No	7	9	16	
			30.4%	37.5%	34.0%	
	13–15	Yes	12	12	24	0.092
			66.7%	92.3%	77.4%	
		No	6	1	7	
			33.3%	7.7%	22.6%	
Stone density	≤ 800	Yes	21	13	34	0.710
			70.0%	65.0%	68.0%	
		No	9	7	16	
			30.0%	35.0%	32.0%	
	>800	Yes	13	25	38	0.137
			65.0%	83.3%	76.0%	
		No	7	5	12	
			35.0%	16.7%	24.0%	

ESWL = extracorporeal shock wave lithotripsy; URS = ureterorenoscopy.

was statistically insignificant, that is, P = 0.692 as as shown in (Table 3)

In the ESWL group, efficacy was achieved in 34 (68%) patients, while in the URS group, efficacy was achieved in 38 (76%) patients. This difference was statistically insignificant, that is, P = 0.373, according to our Table 3.

Statistically insignificant difference was found between the study groups and efficacy of the patients stratified by age and gender, that is, site and size of stone and stone density in Table 4,, that is, P > 0.05.

Discussion

Our randomized control trial was conducted at the Department of Urology, KRL Hospital, Islamabad, to compare the efficacy (frequency of stone-free patients) at 1 week after ESWL and the URS manipulation for proximal ureteric stone (10–15 mm size).

The ESWL and the URS are currently accepted treatment modalities for distal ureteral calculi. Some investigators favor the ESWL while others (8–10) prefer the URS. For both treatment modalities, stone-free rates of more than 90% have been reported (13).

The American Urological Association Ureteral Stones Clinical Guidelines Panel has found both ESWL and URS to be acceptable treatment options for the patients, based on the stone-free results, morbidity, and re-treatment rates for each respective therapy (13).

Urolithiasis is one of the leading causes of morbidity of the urinary tract system globally. In the last few decades, the treatment of urinary tract stones has been revolutionized with the introduction of minimally invasive techniques. For a few decades, the ureteral stones were managed by open ureterolithotomy. Then, with time, there was refinement of the semirigid URS, the ESWL machines, laparoscopic procedures, and the flexible URS, resulting in an enormous change in the management of ureteral stones (14, 15).

The number of previous randomized trials of the URS versus the ESWL for proximal ureteric stone is very limited (16). Most of them were retrospective in design. These

Table 3: Comparison of density, size of stone (mm), and outcome between study groups.

Variable and Subcategories		Study Groups		P
		ESWL	URS	
Density	n	50	50	0.005
	Mean	727.54	869.06	
	Standard Deviation	178.52	302.22	
Size of stone (mm)	n	50	50	0.692
	Mean	12.57	12.44	
	Standard Deviation	1.67	1.65	
Outcome	Yes	34	38	0.373
		68.0%	76.0%	
	No	16	12	
		32.0%	24.0%	

ESWL = extracorporeal shock wave lithotripsy; URS = ureterorenoscopy.

retrospective reviews have been the only evidence for advocating the merits of one treatment over the other.

In this study, the average age of the patients was 39.71 ± 10.17 years. In patients treated with the ESWL, the mean age of the patients was 40.78 ± 10.19 years, whereas in patients treated with the URS, the mean age of the patients was 38.52 ± 10.44 years. Male-to-female ratio of the patients was 3:1. Among patients treated with the ESWL, 36 (48%) were male, while 14 (56%) were females. Similarly, in patients treated with the URS, 39 (52%) were male while 11 (44%) were females.

According to Manzoor et al., the average age of the patients was 42.54 ± 14.07 years. There were 289 (72.6%) males and 109 (27.4%) females (11). Another study by Iqbal et al. (17) showed that the mean age in ESWL and URS groups was 39.21 ± 13.36 and 43.13 ± 13.65 years, respectively. Mean stone size was 10.47 ± 3.7 mm (ESWL) and 13.6 ± 6.6 mm (URS). There were no significant differences regarding age, gender, BMI, and the comorbidities of patients in both groups. Hatroom demonstrated that out of 90 patients, there were 64 (71.1%) males and 26 (28.9%) females with a male-to-female ratio of 2.5:1. Their age ranged from 17 to 58 years and the mean age was 36.9 ± 11.7 years (18).

The available literature on ureteral stone disease shows that males are at the greatest risk of developing urolithiasis. The incidence rate among men is two times higher and the prevalence rate about four times higher compared to women (19). In the developing countries, the male-to-female ratio ranges from 1.15:1 in Iran (14) and 1.6:1 in Thailand (20) to 2.5:1 in Iraq (21) and 5:1 in Saudi Arabia (22).

In our study, efficacy was achieved in 72 (72%) patients. In the ESWL group, efficacy was achieved in 34 (68%) patients while in the URS group, efficacy was achieved in 38 (76%) patients. Although this difference was statistically insignificant, the URS group in our study showed higher efficacy as compared to the ESWL group. Some of the studies are discussed below with their respective results.

Reports from high-volume centers with static machines suggest stone clearance rates of 86–89%, 71–83%, 73–84%, and 37–68% for stones in the renal pelvis, upper calyx, middle calyx, and lower pole calyx, respectively (6).

Saleem achieved stone-free rate of 88% with URS and 60% with ESWL for stone size greater than or equal to 1 cm (23). One study by Manzoor et al. (11) documented that success rate was 49.2% for ESWL and 57.8% for URS (P = 0.008). The re-treatment rate was significantly higher in the ESWL group than in the URS group (40% vs. 11 and 18% in URS group).

Fong et al. experienced an overall stone-free rate of 50% in ESWL and 80% in URS (24). Wu et al. suggested that URS achieved excellent results and should be considered as first-line therapy for proximal ureteric stones greater than 1 cm in size (25).

In one study, the success and stone-free rate after ESWL was 85%, while it was 100% in the URS group. There was statistical significance between the two treatment groups (18).

Kawano et al. found that 83.6% of patients with proximal ureteric stones became stone-free after one session of ESWL (26). Tawfick achieved a 92% stone-free rate with the ureteroscopic lithotripsy of proximal ureteric stones, and the initial stone-free rate for in-situ ESWL was 58% (27).

Table 4: Comparison of outcome between study groups stratified by age, gender, and site of stone.

Variable	Subcategory	Efficacy	Study Groups		Total	P
			ESWL	URS		
Age (years)	≤ 30	Yes	5	12	17	0.115
			50.0%	80.0%	68.0%	
		No	5	3	8	
			50.0%	20.0%	32.0%	
	>30	Yes	29	26	55	1.000
			72.5%	74.3%	73.3%	
		No	11	9	20	
			27.5%	25.7%	26.7%	
Gender	Male	Yes	24	30	54	0.323
			66.7%	76.9%	72.0%	
		No	12	9	21	
			33.3%	23.1%	28.0%	
	Female	Yes	10	8	18	0.943
			71.4%	72.7%	72.0%	
		No	4	3	7	
			28.6%	27.3%	28.0%	
Stone site	Left	Yes	17	22	39	0.316
			58.6%	71.0%	65.0%	
		No	12	9	21	
			41.4%	29.0%	35.0%	
	Right	Yes	17	16	33	0.787
			81.0%	84.2%	82.5%	
		No	4	3	7	
			19.0%	15.8%	17.5%	

ESWL = extracorporeal shock wave lithotripsy; URS = ureterorenoscopy.

Ureteric stones are often more difficult to locate and, therefore, more difficult to target with the shock wave. However, several studies have demonstrated a stone-free rate close to 100% for the treatment of proximal ureteral stones with ESWL (28). However, stone-free rate appears to decline to 70% for mid-ureteral stone for many lithotripters (29).

Andreoni et al. (21) used the URS to treat patients with stone size less than 15 mm and achieved an initial stone-free rate of 70%. While shock wave application is contraindicated during pregnancy, Lifshitz et al. successfully treated 10 pregnant women by using ureteroscopy and intracorporeal lithotripsy and did not note any obstetric or urological complications (30).

Urologists who favor URS claim that although it is an invasive procedure, it has, in contrast to ESWL, a greater success rate at the first treatment session. Patient preference should always be a great concern. Some patients might have certain fears regarding the anesthesia required and the invasiveness

of URS. Others might prefer to have the stone removed and the pain alleviated more rapidly without the possibility of multiple treatment sessions and prolonged stone clearance period such as with the ESWL. The availability of the equipment, experience of the surgeon with both modalities, and the patient preference will determine the choice (11).

Conclusion

This study concluded that both ESWL and URS are equally effective statistically in terms of the frequency of stone-free patients at 1 week for proximal ureteric stones (10–15 mm size). Although the difference is insignificant, the URS group showed higher stone-free frequency than the ESWL group.

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