



CODEN [USA]: IAJPBB

ISSN : 2349-7750

INDO AMERICAN JOURNAL OF PHARMACEUTICAL SCIENCES

SJIF Impact Factor: 7.187

Available online at: <http://www.iajps.com>

Research Article

TO DETERMINE THE STONE CLEARANCE RATE AFTER ESWL VERSUS URSL IN PATIENTS OF UPPER URETERAL STONES HAVING STONE SIZE <15 MM

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Article Received: November 2020 Accepted: December 2020 Published: January 2021

Abstract:

Background: Urolithiasis is an extremely common health condition, with a reported incidence ranging from 11% to 13% of men and 5.6% to 7.0% in women by the age of 70 years. The most common symptoms of ureteral stones are pain, vomiting and hematuria.

Objective: To determine the stone clearance rate after ESWL versus URSL in patients of upper ureteral stones having stone size ≤ 15 mm.

Study Design: Randomized Clinical Trial.

Setting: The study was conducted at department of Urology, Sindh Institute of Urology and Transplantation (SIUT) Karachi.

Duration of Study: 7-June-2020 to 6-Dec-2020.

Patients and Methods: A total number of 76 patients with diagnosis of upper ureteral stones having age 20 to 70 years were included in this study. There were 38 patients in URSL group and 38 patients in ESWL group. URSL was done using a rigid uretero-scope. ESWL was performed in prone position using an electromagnetic lithotripter under fluoroscopic or ultrasound guidance. Post-procedural X-ray KUB was done one week after the surgical procedure to determine the stone clearance in every patient.

Results: The mean age of patients in this study was 46.60 ± 10.83 years. There were 47 (61.84%) male patients and 29 (38.16%) female patients. There were 17 (22.37%) patients who were having hypertension and 12 (15.79%) patients having diabetes mellitus. complete stone clearance occurred in 35 (92.1%) patients in URSL group and in 30 (78.90%) patients in ESWL group (P-value 0.10).

Conclusion: Ureteroscopic lithotripsy (URSL) is a better management option as compare to extra-corporeal shockwave lithotripsy (ESWL) for management of proximal ureteral stones.

Keywords: Ureteral stones, Extracorporeal shockwave lithotripsy (ESWL), Ureteroscopic lithotripsy (URSL).

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Please cite this article in press Syed Rafiuddin Shah et al, To Determine The Stone Clearance Rate After Eswl Versus Ursl In Patients Of Upper Ureteral Stones Having Stone Size <15 Mm., Indo Am. J. P. Sci, 2021; 08(1).

INTRODUCTION:

Urolithiasis is an extremely common health condition, with a reported incidence ranging from 11% to 13% of men and 5.6% to 7.0% in women by the age of 70 years. [1,2] Advances in medicine have enabled us to better treat urolithiasis with few complications. Most urinary stones that pass through the renal calyces to the renal pelvis and subsequently to the ureter cause serious symptoms. [3] The most common symptoms of ureteral stones are pain, vomiting and hematuria. There are many options for urologists to treat ureteral stones that range from 8 mm to 15 mm, including ESWL and ureteroscopic lithotripsy. [4]

ESWL uses high-energy sound waves projected from outside the body through the intervening tissue to break up the stone with no need to insert an instrument through any tissue. [5] In contrast, URSL depends on a ureteroscope inserted into the affected ureter by way of the urethra and bladder. In addition to a camera and other operating equipment, a lithotripsy-capable device, such as a laser, is passed through the uretero-scope to break-up the stone. [6] Studies have found controversial outcomes regarding stone free rate of ESWL and URSL in patients of upper ureteral stones. Dell'Atti *et al.* [7] found significantly lower stone free rate after ESWL as compared to URSL. In that study, stone free rate was 45.4% in ESWL group and 77.5% in URSL group (p-value <0.0001). On the other hand Cui *et al.* [8] did not find any significant difference in stone free rate in ESWL and URSL groups with stone free rate of 92.5% and 97.5% respectively (p-value 0.61). A meta-analysis also found very heterogeneity in data regarding outcomes of ESWL and URSL and concluded that it may be the experience and techniques of operating surgeons or may be the nature of the stones that are associated with variability in the outcomes of ESWL and URSL procedures. So the effectiveness of URSL over ESWL has still not been well established in patients of ureteral stones having stone size >10 mm. [9] The purpose of the proposed study is to determine the stone free rate after ESWL and URSL procedures in patients with upper ureteral stones having stone size ≤15 mm.

OBJECTIVE:

To determine the stone clearance rate after ESWL versus URSL in patients of upper ureteral stones having stone size ≤15 mm.

OPERATIONAL DEFINITIONS:**1. Stone Clearance Rate:**

The clearance of renal stones with no visible residual fragments or fragments smaller than 4 mm in diameter (clinically insignificant residual fragment) after treatment is known as stone clearance. This was determined by using x ray KUB one week after the procedure.

2. Hypertension:

Patients taking anti-hypertensive drugs from atleast last 6 months were labelled as hypertensive.

3. Diabetes Mellitus:

Any patient who was taking either oral or parenteral diabetic treatment from atleast last 6 months was labelled as diabetic

HYPOTHESIS:

Stone clearance rate is high in patients of upper ureteric stones (having size ≤15 mm) treated with ureteroscopic pneumatic lithotripsy (URS) as compared to extracorporeal shock wave lithotripsy (ESWL).

MATERIAL AND METHODS:

STUDY DESIGN: Randomized Clinical Trial.

SETTING: The study was conducted at department of Urology, Sindh Institute of Urology and Transplantation (SIUT) Karachi.

DURATION OF STUDY: 7-June-2020 to 6-Dec-2020.

SAMPLE SIZE:

The sample size for this study is calculated using the following formula;

$$n = \frac{(Z_{\alpha/2} + Z_{\beta})^2 (p_1(1-p_1) + p_2(1-p_2))}{(p_1 - p_2)^2}$$

Frequency of stone clearance using URS procedure (P₁) = 77.5 %⁷

Frequency of stone clearance rate using ESWL procedure (P₂) = 45.4 %⁷

By taking level of significance 5% and power of the test 90%, the calculated sample size for this study is 38 patients in each group. So a total number of 76 patients were selected for this study.

SAMPLING TECHNIQUE: Non probability, Consecutive sampling

SAMPLE SELECTION:**Inclusion criteria:**

- All adult patients having age 20-70 years
- Both genders male and female
- Patients with diagnosis of proximal ureteric stones (diagnosed by the presence of radio-opaque shadow on X-ray KUB) having stone size ≤15 mm.
- Patients with any duration of ureteric stone disease were selected for this study.

Exclusion criteria:

- Patients with diagnosis of distal ureteric stones on X-ray KUB. Because stone

clearance rate is different in patients with proximal and distal ureteral stones.

- Patients with untreated urinary tract infections (UTI) diagnosed history of patient and complete urine analysis report will be excluded. Because these conditions can affect stone clearance rate after the procedure. So these patients were excluded from the study.
- Patients not willing to participate in the study.

DATA COLLECTION PROCEDURE:

After approval from the Hospital ethical committee, patients who presented in stone clinic of Sindh Institute of Urology and Transplantation having diagnosis of proximal ureteral stones and planned for surgical removal of stones fulfilling the inclusion criteria were included in this study until the required sample size of 68 patients is completed. Informed consent was taken from all patients before including them in this study. All patients were informed regarding study protocols and outcomes before including them in study. The patients were chosen randomly for both groups using draw randomization. Patients were divided into URSL or ESWL group on the basis of folded paper picked by them. In URSL group; ureteroscopic lithotripsy was used for the removal of proximal ureteric stones. In ESWL group; extracorporeal shock wave lithotripsy was used for the removal of ureteric stones.

DATA ANALYSIS PROCEDURE:

Data analysis was carried out using SPSS v23.0. Mean and standard deviations were calculated for quantitative variables like age and duration of ureteric stone disease and size of ureteric stone. Categorical variables like gender, frequency of stone clearance, hypertension and diabetes mellitus was presented as frequency and percentage. Chi-square test was used to compare stone clearance between ESWL and URSL groups. Stratification of confounder variables e.g. age, gender, diabetes mellitus, hypertension, duration of ureteric stone disease and size of ureteric stones was done. Post-stratification Chi-square test was applied taking P-value ≤ 0.05 as significant difference.

RESULTS:

A total number of 76 patients were included in this study. There were 38 patients in URSL group and 38 patients in ESWL group. The mean age of patients in this study was 46.60 ± 10.83 years. Minimum age was 20 years and maximum age was 68 years (Table 1). Mean size of ureteral stones was 11.60 ± 2.41 mm.

Minimum stone size was 08 mm and maximum stone size was 15 mm (Table 2).

There were 47 (61.84%) male patients and 29 (38.16%) female patients in this study (Figure 1). There were 17 (22.37%) patients who were having hypertension. While remaining 59 (77.63%) were not having hypertension (Figure 2).

There were 12 (15.79%) patients who were having diabetes mellitus. While remaining 64 (84.21%) patients were not having diabetes mellitus (Figure 3).

Complete stone clearance was achieved in 65 (85.53%) patients. while stone clearance was unsuccessful in remaining 11 (14.47%) patients.

On comparison of stone clearance rate between the groups, complete stone clearance occurred in 35 (92.1%) patients in URSL group and in 30 (78.90%) patients in ESWL group. but this difference was not statistically significant with p-value of 0.10 (Table 3).

Stratification of age was performed. In patients having age 20-49 years, complete stone clearance occurred in 17 (94.4%) patients in URSL group and in 13 (81.25%) patients in ESWL group (p-value 0.23). In patients having age ≥ 50 years, stone clearance occurred in 18 (90%) patients in URSL group and in 17 (77.27%) patients in ESWL group (P-value 0.27) [Table 4].

Stratification of gender was performed. In male patients (N=47), stone clearance occurred in 24 (96%) patients in URSL group and in 18 (81.8%) patients in ESWL group with p-value of 0.26. In female patient's (N=29) complete stone clearance occurred in 11 (84.6%) patients in URSL group and in 12 (75.0%) patients in ESWL group with p-value of 0.52 (Table 5).

Stratification of duration of disease was done. In patients having duration of ureteral stone disease ≤ 6 months (N=49), stone clearance was achieved in 19 (90.4%) patients in URSL group and in 22 (78.6%) patients in ESWL group (p-value 0.26). in patients having duration of ureteral stone disease > 6 months (N=27), stone clearance was achieved in 16 (94.1%) patients in URSL group and in 8 (80%) patients in ESWL group (p-value 0.25) [Table 6].

Stratification of stone size was also performed, in patients having stone size 8-11 mm (N=37), stone clearance was achieved in 18 (94.7%) patients in URSL group and in 14 (77.7%) patients in ESWL group (p-value 0.13). In patients having stone size 12-15 mm (N=39), stone clearance occurred in 28

(89.4%) patients in URSL group and in 23 (72.7%) patients in ESWL group (p-value 0.12) [Table 7].

Stratification of hypertension and diabetes mellitus was also performed; there was no significant effect of these confounder variables on the stone clearance rate between the groups.

Table 1. Descriptive Statistics of Age of Participants

Age of Patients (Years)	
Mean	46.60
S.D.	10.83
Minimum	20
Maximum	68

Table 2. Descriptive Statistics of Size of Ureteral Stones

Size of Ureteral Stones (mm)	
Mean	11.60
S.D.	2.41
Minimum	08
Maximum	15

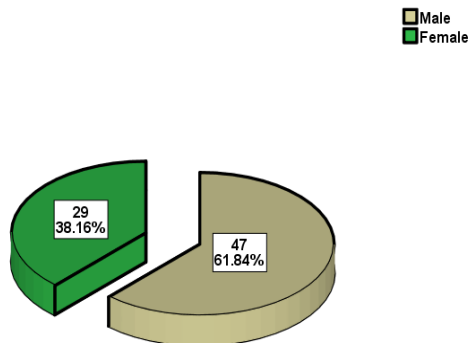


Figure 1. Frequency of Gender

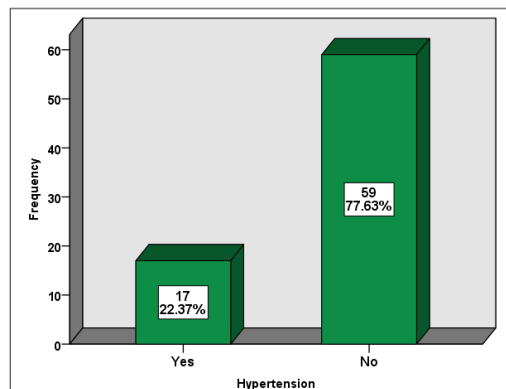


Figure 2. Frequency of Hypertension

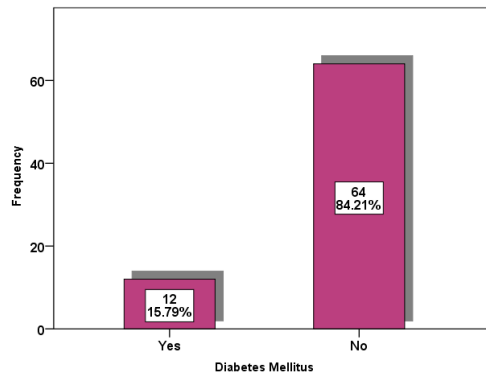


Figure 3. Frequency of Diabetes Mellitus

Table 3. Comparison of Stone Clearance Rate Between the URSL and ESWL Groups.

Study Groups	Stone Clearance		P-value
	Yes	No	
URSL Group	35 (92.1%)	3 (7.9%)	0.10
ESWL Group	30 (78.9%)	8 (21.1%)	

Table 4. Stratification of Age

Age Groups	Study Groups	Stone Clearance		P-value
		Yes	No	
20-49 Years	URSL Group	17	1	0.23
	ESWL Group	13	3	
≥ 50 Years	URSL Group	18	2	0.27
	ESWL Group	17	5	

Table 5. Stratification of Gender

Gender	Study Groups	Stone Clearance		P-value
		Yes	No	
Male	URSL Group	24	1	0.11
	ESWL Group	18	4	
Female	URSL Group	11	2	0.52
	ESWL Group	12	4	

Table 6. Stratification of Duration of Disease

Duration of Disease	Study Groups	Stone Clearance		P-value
		Yes	No	
≤ 6 Months	URSL Group	19	2	0.26
	ESWL Group	22	6	
> 6 months	URSL Group	16	1	0.25
	ESWL Group	8	2	

Table 7. Stratification of Stone Size

Stone Size (mm)	Study Groups	Stone Clearance		P-value
		Yes	No	
8-11 mm	URSL Group	18	1	0.13
	ECWL Group	14	4	
12-15 mm	URSL Group	17	2	0.41
	ECWL Group	16	4	

DISCUSSION:

Both ESWL and ureteroscopy are minimally invasive treatment options for patients with proximal ureteral stones. The use of ESWL began in the 1980s, has a stone clearance rate of nearly 90% and has resulted in the fading of open surgical procedures for ureteral stones [10]. Most of the comparative studies between ESWL and ureteroscopy are not conclusive and sometimes ambiguous. While some studies are in favor of ESWL, others concluded that ureteroscopy is the preferable approach [11]. SWL is the most prevalent intervention for upper ureteral stones; the success rates of this treatment in stones <10 mm range from 85% to 93%. [12] However, its efficacy declines when the stone size is >12 mm and falls below 60%. [13] Thus, the need for repeated treatments in patients with large stones is the most important drawback of SWL.

Stone clearance rates in our study were 30 (78.90%) for ESWL versus 35 (92.10%) for ureteroscopy and not significantly different. This is similar to the findings of Salem, who reported that the initial SFRs for URS and SWL, when applied to stones ≥ 1 cm, were 88% and 60%, respectively. In a study conducted by Cui *et al.* stone clearance rate was 97.5% in URS group and 77.5% in ESWL group. However, in their study stone clearance rate increased to 92.5% after 3 ESWL sessions. Moreover, these authors found similar rate of patients satisfaction after both of these procedures. In present study, in ureteroscopy group we broke stones into pieces <2 mm during surgery, moreover evaluation of stone clearance based on KUB imaging one week later it might improve the stone passage; in ESWL group stone clearance rate evaluated after only one ESWL session [14].

Previous reports correlated the success rate of SWL treatments for stones with the size of the stones. They have reported a significant decline in the success rate of the treatment when the stones exceeded ≥ 12 mm. In general, it can be said that a large stone will be associated with more shock waves per treatment session and an increase in the need for auxiliary procedures following SWL. [15,16]

Stone composition affects SWL results of fragmentation and subsequent elimination. Contrary to calcium oxalate dihydrate stones, which have a better coefficient of fragmentation and thus respond well to SWL, cystine and calcium oxalate monohydrate stones are relatively resistant to SWL treatment. However, it is difficult to predict the response of a stone to SWL based on the pretreatment imaging studies. Since stone analysis for biochemical

structures was not performed for all cases, it was not possible to correlate stone composition and response to SWL. Therefore, a prospective randomized study with a larger number of patients is encouraged in order to verify these results.

Finally, each treatment modality is characterized by particular advantages and disadvantages, with a wide range of factors influencing the choice of treatment. The urologists advocating for SWL typically base their preference on its noninvasiveness, minimal anesthetic requirements, low morbidity, and acceptable efficacy. On the other hand, urologists in favor of URS claim that, although it is minimally invasive procedure, unlike SWL, the initial treatment results in a greater success rate. In practice, the treatment modality is also affected by the access (or lack thereof) to a nearby lithotripter and surgeon preference, which are important factors in an endourologic procedure [17]. Finally, when choosing a treatment option, patient preference should always be a great concern. Some patients might have some fears regarding the anesthesia required and invasiveness of URS. Others might prefer to have the stone removed and the pain alleviated more rapidly, without the potential need for multiple treatment sessions and a prolonged stone clearance period, which are common in SWL. Thus, the required equipment availability, surgeon's experience with both modalities, and patient preference will ultimately determine the treatment choice.

The significance in SFR between SWL and URS can be attributed to the fact that proximal ureteral stones treated with URS did not vary significantly with size, whereas it is negatively correlated with stone size in SWL patients.

Total Intravenous Anesthesia for ESWL has better results than without TIVA for improved fragmentation and allow higher intensity. Even yet there are no guideline for pain relief during ESWL but NSAIDs Opioids and local analgesia gel are used for pain relief. Oral naproxen sodium, Tramadol, diclofenac sodium are used for a safe and effective analgesia for Pain relief during ESWL. ¹⁸ NSAIDs and opioids have no difference in safety or efficacy relief of ESWL for pain.

CONCLUSION:

Ureteroscopic lithotripsy (URS) is a better management option as compare to extra-corporeal shockwave lithotripsy (ESWL) for management of proximal ureteral stones.

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