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Original Research Article

A comparative study on the outcome between extra corporeal shockwave lithotripsy (ESWL) and Holmium: YAG LASER ureteroscopic stone removal for upper ureteric stones of sizes ranging between 1cm to 1.5cm: a prospective randomised study

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Abstract: To compare the outcomes of semirigid ureterorenoscopy with extracorporeal shock wave lithotripsy (ESWL) for the treatment of upper ureteric stones of 10 to 15 mm. A total of 70 patients with radioopaque solitary upper ureteric stone who underwent ESWL or URS with holmium: YAG laser were enrolled in this study. Each group treated with ESWL and URSL for upper ureteric stones were prospectively compared in terms of retreatment and stone free rates, and complications. 77.14% (n = 35) of patients who underwent ESWL therapy was stone free at the end of 2nd session. This rate was 85.71% (n = 35) for patients of URS group ($p > 0.05$). Retreatment was required in 51.43% of patients who underwent ESWL. The retreatment rate of cases who were operated with URS was 2.86% ($p = 0.0000037$, $p < 0.05$). Overall complications did not vary significantly between the 2 groups. URS and ESWL have similar outcomes for the treatment of upper ureteric stones of 10–15 mm. ESWL has the superiority of minimal invasiveness and avoiding general anethesia. Ureterorenoscopy (URS) with intracorporeal laser lithotripsy has the advantage of obtaining an earlier or immediate stone-free status. But it is an invasive procedure & needs hospitalization. Complication rates are comparable between these groups.

Keywords: Semirigid ureterorenoscopy, Shock wave lithotripsy, Upper ureteric stones.

INTRODUCTION

Technological developments have drastically changed the management of ureteral calculi in last two decades. Although ESWL has been recommended as the first-line treatment for proximal ureter calculi smaller than 1cm [1], the optimal treatment modality for proximal ureteral stones of various sizes has not yet been defined.

Whereas ESWL has been used as the first-line treatment in patients with <10 mm proximal ureteral stones, owing to its lower rate of complications and noninvasiveness [1], it has the disadvantage of a higher retreatment rate and longer period until stone clearance.

With technical advances in endoscopy and LASER lithotripters, URS has been reported to have a better chance of stone clearance with a single procedure even for proximal ureteral stones >10 mm [2-4].

The Holmium: Yttrium, Aluminum, Garnet laser was developed in early 1990s. Clinical studies in both children and adults have shown holmium: YAG laser to be effective in the treatment of ureteric calculi in vivo as well [5-7].

In order to make recommendations on the optimal treatment choice for proximal ureteral stones, in our study we will analyze the outcomes of the two treatment modalities from an objective viewpoint such as stone-free rates, complications etc.

MATERIAL AND METHODS

This present study was carried out in the Department of Urology in Nil Ratan Sircar Medical College & Hospital for a period of nearly 1.5 years starting from January 2015 to June 2016. Altogether 70 patients were included in this study.

The patients were randomised and alloted into 2 groups namely group 1(patients treated by ESWL) and group 2(patients treated by LASER URSL).

The upper ureter has been defined radiologically as the segment between the ureteropelvic junction and the superior margin of the sacroiliac joint.

Stone size and density (in HU) were determined by noncontrast computed tomography.

ESWL was performed by using the 3rd generation DORNIER COMPAC lithotripter as an outpatient procedure. Analgesia was ensured by intravenous aqueous solution of diclofenac sodium. To ensure patient tolerability, maximal voltage and shock wave was set at 16 KV and 2,000 to 2,500 shocks at a time respectively. The patients were evaluated 4 weeks after the 1st session by X-RAY KUB to assess stone passage; if residual stones observed, repeat ESWL performed. In case of no breakage of the stone after 2 sessions, the patients were advised about salvage treatment options. URS is performed with 6/7.5 Fr, 6° semirigid ureterorenoscope under general or spinal anesthesia. We first passed guide wire (0.035 inch) with the help of cystoscope. Ureteroscope is negotiated and advanced into the ureter with the help of pathfinder. Stones are fragmented to approximately 3mm fragments with the help of end firing type of 365micrometer laser fibre.Setting of laser machine was set at 0.6-0.8joule with frequency of 10-20Hz. D-J stent was put in the ureter after stone fragmentation in all cases irrespective of any complications as an institutional protocol. We removed the D-J stent after 4-6 weeks.

Stone fragmentation was considered successful if the stone could be fragmented to small (<4 mm) passable fragments or fragments small enough to be retrievable with forceps.

Treatment outcome (stone-free rates) was compared between the two groups. Stone-free status has been defined as an asymtomatic patient with stone fragment ≤3 mm on digital x-ray KUB.

Statistical analysis was done by SPSS version 20 & EPI INFO version 6.The Student t test was used for comparison of the normally distributed variables between the two groups (ESWL & URSL). Proportions of patient characteristics, complication rates, and operative data of the two groups were compared using the Chi-square test.

RESULTS

- Mean age is 34.2 in Group 1(ESWL) & 41.4 in Group 2(URSL). There is no statistically significant difference between the 2 groups.
- Males were predominant in both the groups by a ratio of around 1.7:1. There is no statistically significant difference between the two groups.
- Mean stone size was 12.49mm & 12.47mm in Group1 & Group2 respectively. There is no statistically significant difference between these groups based on stone size.
- Mean session no in 1st group was 1.51 & 1.03 in group 2. Mean session no. was significantly high in group 1 ($p<0.001$).

Table-1: Number of Session

Groups	No of session, N (%)		Total
	1	2	
Group1(ESWL)	17 (48.57%)	18(51.43%)	35(100%)
Group2 (URSL)	34(97.14%)	1 (2.86%)	35(100%)

Table-1A: Mean no. of session

	Mean no of session	P
Group1(ESWL)	1.51	<0.001
Group2 (URSL)	1.03	

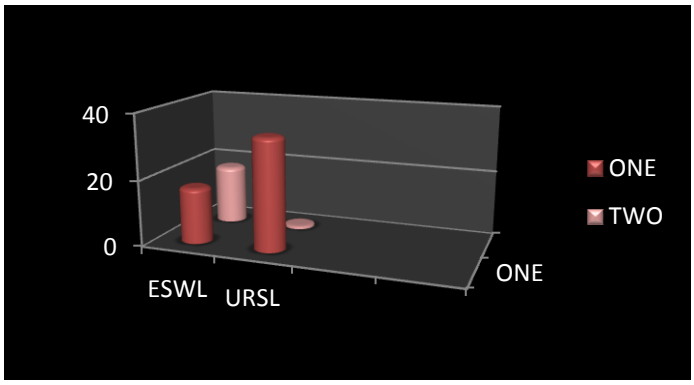

Fig-1: Bar Chart Showing Distribution of the No. Of Sessions for the Two Modalities

- There was higher rate (82.86%) of stone clearance after 1st session in group 2 as compared to group 1, where only 48.57% patients were stone free after 1st session. **This difference was statistically significant (p=0.003).**

Table-2: Stone clearance after 1st session

Groups	Stone clearance after 1st session, N(%)	
	Yes	No
Group1(ESWL), N=40	17(48.57%)	18(51.43%)
Group2 (URSL), N=38	29(82.86%)	6(17.14%)

x^2 =9.13, df=1, p=0.003

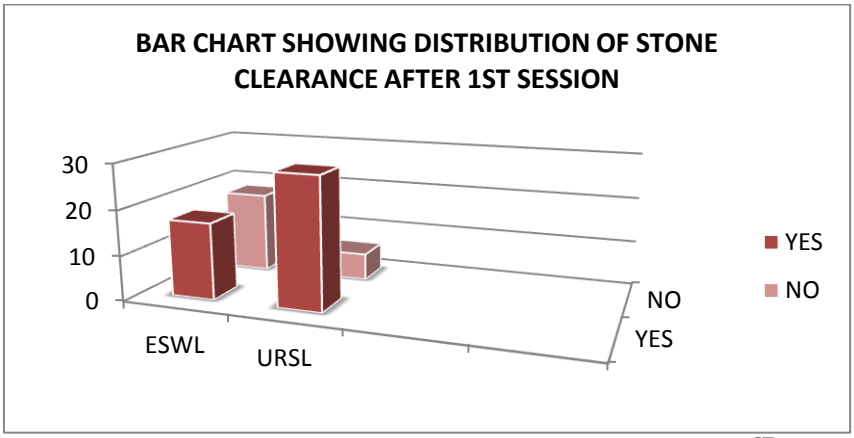

Fig-2: BAR Chart Showing Distribution of Stone Clearance after 1ST Session

- With further sessions group 2 achieves higher overall stone clearance rate (85.71% vs 77.14%). But this change was not statistically significant.
- Retreatment with same modality was required significantly more in group 1. In group 2 only 1 patient required repeat URSL.

Table-3: Retreatment Rate

Groups	Retreatment required, N (%)		Total
	Yes	No	
Group1(ESWL)	18(51.43%)	17(48.57%)	35
Group2 (URSL)	1(2.86%)	34(97.14%)	35

x^2 =20.9, df=1, p=0.0000037

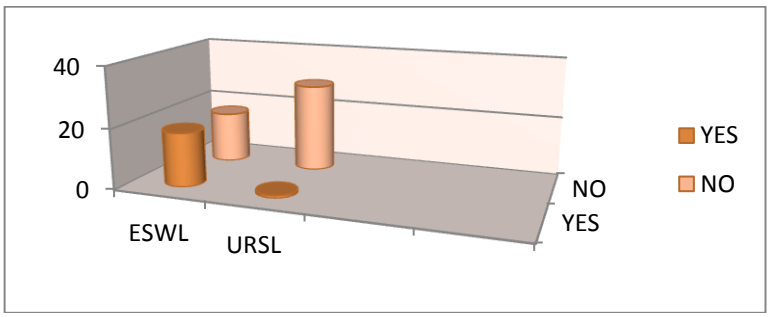

Fig-3: Bar chart showing result of retreatment with same modality in these groups

- 8 patients in group 1 & 5 patients in group 2 subsequently required other treatment modality for management of residual stone.
- Overall complications did not vary significantly between the 2 groups.

Table-4: Distribution of Other treatment modality, when primary modality failed

Other treatment modality	Group 1 (ESWL)N=8	Group 2 (URSL)N=5
URSL	2	-
ESWL	-	1
PCNL	4	1
Laparoscopic ureterolithotomy	-	1
Open ureterolithotomy	1	1
RIRS	1	1

Table-5: Different complications of the 2groups

	ESWL	URSL
Haematuria	2	2
Pain	5	2
Urinary infection	2	3
Steinstrasse	2	1
Urosepsis	1	2

DISCUSSION

Urinary stone disease is a major health issue, affecting approximately 2-3% population worldwide.

Urolithiasis tend to occur more commonly in men aged between 30-60 years [8,9]. In our present series also the mean age was around 37.8.

Urolithiasis occurs most commonly in men. The sex ratios range from 2.5:1 in Japan to 1.15:1 in Iran [10,11]. In our series men were almost 1.7 times more frequent than females.

Nabi G *et al*. [15] in Cochrane review found the stone-free rates were lower in the ESWL group (RR 0.83 95% CI 0.70 to 0.98).

In our present series there were 35 patients in ESWL group & 35 patients in URSL group. Single session success rate was significantly more with URSL (82.86%) as compared to only 48.57% in ESWL group (p=0.003). Overall clearance of URSL also exceeds that of ESWL (85.71% v/s 77.14%), but this difference was statistically insignificant (p=0.356). So, the present series corroborate with the literature findings.

The mean number of sessions required was statistically significantly higher in the ESWL group than that of the URSL group, (1.51 v/s 1.03) (p<0.001).

In the study by Khalil *et al*. [12] the mean number of sessions in the SWL group was statistically significantly higher than that of the URSL group, (1.5 ± 0.8 vs. 1.02 ± 0.15, respectively, $P < 0.01$)

Retreatment rate in ESWL ranges from 15% to as high as 65%.

Fong *et al*. [13] has shown with larger stone size (5-35 mm), the re-treatment rate was significantly higher in SWL group than in the URSL group of patients (14% vs. 2%, respectively). URS resulted in a remarkably higher stone-free rate and lower repeat treatment rate [14].

In present study only 1 patient required repeat URSL. This patient had steinstrasse following 1st procedure, so the procedure was repeated with placement of a DJ stent.

So our study matches to a large degree with previous results as the re-treatment rate was statistically significantly higher in the SWL group in comparison to URSL group (51.43% vs. 2.86% respectively, p=< 0.0001).

Both ESWL & URSL are relatively less associated with major complication.

Nabi G *et al*. [15] analysed in a cochrane review that the rate of complications was lower in the ESWL group (RR 0.44 95% CI 0.21 to 0.92).

In our study, the complication rates in the two groups are 28.57% & 17.14%, without any statistically significant difference between them.

CONCLUSION

After completion of this study, with 70 enrolled patients, at our institute from January 2015 to June 2016 we came to conclude that both ESWL & URSL is safe, effective & achieve an excellent overall stone clearance rate. ESWL has a higher retreatment rate & is associated with longer period till stone clearance, but it has the advantages of being safe, non invasive & can be done without anaesthesia. ESWL carries excellent clearance rates even for stone sizes more than 1cm in the upper ureter with multiple sessions.

Ureterorenoscopy (URS) with intracorporeal laser lithotripsy has the advantage of obtaining an earlier or immediate stone-free status. But it is an invasive procedure & needs hospitalization. Complication rates are comparable between these groups.

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