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Comparison between the Efficacy of Transureteral Lithotripsy and Extracorporeal Shock Wave Lithotripsy in the Treatment of Distal Ureteral Stone

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ABSTRACT

Objective: To compare the efficacy, cost effect and safety of extracorporeal shock wave lithotripsy (ESWL) and ureteroscopy (URS) for distal ureteric calculi by evaluating stone-free rates, retreatment rates, need for auxiliary procedures, associated complications and technical consideration with respect to patient satisfaction.
Patient and method: 70 patients with single unilateral radiopaque distal ureteric stone ranges from 0.8 cm to 1.2 cm in diameter and ≥1.5 cm in length were enrolled in a prospective randomized trial. Patients were randomized to undergo URS (35) or ESWL (35). The electromagnetic Dornier lithotripter S was used for ESWL and a semi-rigid Olympus ureteroscope, 7° direction of view, angled ocular,8.6/9.8 Fr. x 43 cm, 6.4 Fr. channel was used for URS. Patient and stone characteristics, treatment parameters, clinical outcomes, and patient satisfaction were assessed for each group. **Results:** Patients in the ESWL group achieved a 77.1% overall stone-free rate (SFR) with a 74.3% retreatment rate and no auxiliary procedure was done. Complications occurred in 11.4% of patients treated with ESWL. Patients in the URS group achieved a 97.1% overall SFR with a retreatment rate of 8.6% and an auxiliary procedure rate of 100%. Complications occurred in 31.4% of patients treated with URS. Patient satisfaction was high for both groups, including 94.3% for URS and 77.1% for ESWL. ESWL were already at outpatient clinic so there were no admission or hospital stay. While in URS group patients admitted with mean hospital stay 1.6±0.5 day.
Conclusions: In the treatment of large distal ureteral calculi ≥ 1.5 cm, both URS and ESWL modalities are comparable but URS is recommended as a first option as it is more effective than ESWL regarding stone-free rate and it provides immediate stone clearance with lower retreatment rates and higher patient satisfaction.
Keywords: ureteral calculi; ureteroscopy; extracorporeal shockwave lithotripsy.

INTRODUCTION

The lifetime prevalence of ureteric calculi is relatively high, occurring in approximately 12% of men and 7% of women. The risk is increased with a past history of ureteric calculi and with positive family history. Most patients present between ages 30 and 60, with peak incidence between ages 35-45 [(1)]. American Urology Association (AUA)/European Association of Urology (EAU) Guidelines in Ureteral Stone Management, recommend URS as 1st option and ESWL as 2nd option in treatment of distal ureteral stone greater than 1 cm, overall stone-free rates after URS or ESWL for distal ureteral stones are comparable. However, larger stones achieve earlier stone-free status with URS. Although URS is effective for ureteric calculi, it has greater potential for complications. However, in the current endourological era, the complication rate and morbidity of ureteroscopy have been significantly reduced [(2)].Authors support URS claim that it is highly successful, associated with minimal morbidity, other investigators argue that it requires specialized training, more invasive, requires general or regional anesthesia, and often requires ureteral stent placement. Authors support ESWL claim that it is effective and non-invasive, is associated with less morbidity, and can be done on an outpatient basis with intravenous sedation. Other authors stated that success rates are not as high as those of URS, localization of the stone might be difficult and being stone-free requires a longer time with higher retreatment rate [(3)]. Most of studies also beside our study confirmed that URS has the annoyance of hospitalization, spinal anesthesia, and ureteral stent removal; on the other hands, ESWL involves a higher retreatment rate, long-term follow-up, and frequent visits. Moreover, patients may visit the emergency room to control intolerable pain in the course of the treatment. In our study, we compared ureteroscopic intracorporeal pneumatic lithotripsy versus ESWL in treatment of large distal ureteral stone ≥ 1.5 cm by evaluating stone-free rates, retreatment rates, cost effect, need for auxiliary procedures, associated complications and technical consideration with respect to patient satisfaction.

PATIENTS AND METHODS

This study was performed at Ain Shams University (Urology Department) and El Doaah hospital (Urology Department), From August 2016 to August 2017. It is a prospective randomized study that was performed on 70 patients having radiopaque distal ureteric stone ranges between 0.8-1.2 cm in diameter and ≥1.5 cm in length. Stone size was defined as the largest diameter measured on CT. Distal ureter was defined as the segment between the lower border of the sacroiliac joint and the ureterovesical junction. Both sexes are included,

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aged from 20 to 70 years old, body mass index was less than 30 kg/m2 and stone attenuation was more than 500 Hounsfield unit (HU).

Radiolucent ureteral calculi, multiple ureteral calculi, cardiac medical problems in ESWL group, morbid obesity, uncorrected coagulopathy, skeletal deformities, untreated urinary tract infection, pregnancy, solitary kidney, previous ureteral reimplantation and ureteral congenital anomalies were all considered exclusion criteria.

The 70 Patients had been sequentially randomized into two groups.

Group A: 35 patients had been treated with URS plus transureteral pneumatic lithotripsy for their distal ureteric stone.

Group B: 35 patients had been treated with ESWL for their distal ureteric stone.

All patients were subjected to preoperative evaluation in the form of full history taken, physical examination, laboratory investigations.

ESWL procedures were performed using the electromagnetic Dornier lithotripter S. Patients were positioned in modified prone position and stones were localized with fluoroscopic guidance. No auxiliary procedures were used before ESWL in any patient. All patients were treated on outpatient basis. All patients were given analgesics ± sedation and the level of shockwave energy was progressively stepped up till satisfactory stone fragmentation within the patient's comfort. Shockwaves were given at fixed rate of 90 /minute for all patients. Patients were reviewed 2 week after the first session using a KUB.

After 2 weeks, if inadequate fragmentation of the stone was observed, treatment was repeated (second session ESWL was done). Patients had been reviewed 2 weeks after the second ESWL session using a KUB, and if there was poor fragmentation after 2 sessions of ESWL or residual fragments that failed to pass, ESWL failure was considered and they were referred to URS treatment. ESWL was considered successful if KUB showed complete clearance of the stones with no residual fragments at the 1st month's (after two sessions) follow-up. Those with an equivocal plain x-ray underwent non contrast CT urinary tract scan as necessary to confirm stone-free status. URS procedures were performed using a semi-rigid Olympus ureteroscope, 7° direction of view, angled ocular, 8.6/9.8 Fr. x 43 cm, 6.4 Fr. channel was used for ureteroscope and pneumatic lithotripsy (Swiss lithoclast) for intracorporeal lithotripsy. The stones were disintegrated with the pneumatic lithotripsy and fragments were either extracted via basket or forceps. 6F ureteric catheter was inserted at the end of the procedure over the guide wire for 24-72 hours provided that the manipulations were minimal with no ureteric injury, while a double (J) stent was inserted if ureteric injury was suspected. A control KUB film was done on the second postoperative day, urine analysis and culture and sensitivity tests were done two weeks after the procedure. In case of failed ureteroscopy due to failure of ureteric orifice visualization or false passage at ureteric orifice, another ureteroscopy trial had to be done after 2 weeks, if failed ureterolithotomy had to be done.

Statistical analysis

Statistical analysis of the mean values of continuous variables was performed using the Student's *t*-test while analysis of the significance of the categorical variables was performed using the chi-square and the Fisher tests. Logistic regression was useful in the prediction of the presence or absence of an outcome based on a set of independent variables. A $P < 0.05$ was considered to indicate statistical significance.

RESULTS

The patient demographics and stone characteristics at inclusion are given in **(Table 1)**. There were no statistically significant differences in any of the variables assessed at baseline between the groups. Results of ESWL versus Ureteroscopy are given in **(table 2).** All ESWL treatments (100%) were performed on an outpatient basis and none of the patients required anesthesia. The mean (range) number of shockwaves delivered during 1st treatment session was 4142.86±375.18, while the mean (range) number of shockwaves delivered during 2nd treatment session was 4384.62±257.20 (3500–4500). The mean operative duration of 1st treatment session was 46.09±4.38 min, while the mean operative duration of 2nd treatment session was 48.77±2.86 min. Overall, 27 patients (77.1%) achieved a stone-free status. In 9 cases (25.7%), one ESWL session was sufficient to achieve complete stone clearance, while in 18 cases (51.4%) two treatment sessions were required. There was treatment failure in 8 patients (22.9%). All ESWL failures were successfully treated with URS. Complications occurred in 4 patients (11.4%); among them 3 patients had recurrent renal colic not responding to usual analgesic and fentanyl was given and 1 patient had fever on the second day post ESWL and treated by IV antibiotic and analgesic antipyretic for 3 days. 27 out of 35 patients were satisfied as they were stone-free, while the remaining 8 patients who had ESWL failure and shifted to URS were not satisfied. The mean cost among ESWL cases was 2185.71 ± 110.86 LE.

HU of the stone showed highly significance difference regarding the need for 2nd ESWL session as 88.9% of patients who had single ESWL session having HU <1000 and 76.9% of patients who had 2nd ESWL session having HU ≥ 1000 **(Table 3).** Using logistic regression, it was shown that HU of

the stone was the independent factor affecting the need for second ESWL session, as stones with HU ≥1000 had about 44 times higher risk for second ESWL session (OR=43.9, P<0.01), also HU of the stone showed significance difference regarding being stone-free as 100 % of patients who had ESWL failure having stones of HU ≥ 1000.The overall stone-free rate (SFR) in the URS group was 97.1%. A stone-free state was achieved intra-operatively in 32 patients (91.4%). Repeated URS was required in 3 patients (8.6%) after 2 weeks due to the failure of the initial attempt secondary to failure of identification of ureteric orifice in two patients and one patient had a false passage at ureteric orifice due to improper balloon dilation. URS failed in one patient (2.9%) due to failure of identification of ureteric orifice even after 2nd URS attempt and treated by ureterolithotomy. The mean operative duration of 1st URS was 60.29±12.60min, while the mean operative duration of 2nd URS was 67.51±23.55 min. Complications occurred in 11 cases (31.4%). Intraoperative complications occurred in 6 patients and included ureteric injury in three patients, false passage at ureteric orifice in one case and failure of identification of ureteric orifice in 2 patients. Post-operative complications occurred in 5 cases and included self-limited hematuria in 3 patients and post-operative fever in 2 patients.

All URS treatments were performed as inpatient procedures, the mean hospital stay was 1.6±0.50 day (range 1-3 days). All patients required spinal anesthesia. The positioning of double J ureteral stent was required as auxiliary procedure in 5 patients (14.3%) while the remaining 30 patients (85.7%) had ureteric catheter inserted for 24 to 72 hours postoperatively. The mean cost among URS cases was 5514.29±701.74 LE. 33 out of 35 patients were satisfied as they were stone-free, while the remaining 2 patients were not satisfied, one of them who had URS failure and shifted to ureterolithotomy after 2nd URS attempt and the other patient who had 2nd URS attempt because of having false passage at ureteric orifice during 1st URS attempt.

Table (1): Patients' demographics and stone characteristics

Variable	ESWL	URS	p Value
	35	35	
Mean (range):			
Age, years	43.09 ±13.29	43.69±9.77	0.831
Stone size, cm	1.66±0.16 (1.5-2 cm)	1.63±0.17 (1.5-2 cm)	0.522
HU	1024.17±236.85	951.34±231.82	0.198
Male : female ratio	27:8	28:7	0.771
Side of stone; right:left	22:13	17:18	0.229

Table (2): Results of ESWL versus Ureteroscopy

Variable	ESWL	URS	p Value
N (%) patients:			
Overall stone-free	27 (77.1%)	34 (97.1%)	0.028
Stone-free after 1st session	9 (25.7%)	32 (91.4%)	
Stone-free after 2nd session	18 (51.4%)	2 (5.7%)	
Failure	8 (22.9%)	1 (2.9%)	
Retreatments	26 (74.3%)	3 (8.6%)	<0.001
Overall complications	4 (11.4%)	11 (31.4%)	
Intra-operative complications	0 (0%)	6 (17.1%)	0.02
Post-operative complications	4 (11.4 %)	5 (14.3 %)	0.72
Ureteric Catheter	0 (0%)	30 (85.7%)	<0.0001
JJ Stent	0 (0%)	5 (14.3%)	
Analgesic ± sedation	35 (100%)	0 (0%)	<0.001
Spinal anesthesia	0 (0%)	35 (100%)	
Patients' satisfaction	27 (77.1%)	33 (94.3%)	0.04
Mean ± SD:			
1st session duration(minute)	46.09±4.38	60.29±12.60	<0.0001
2nd session duration(minute)	48.77±2.86	67.51±23.55	
Hospital Stay (day)	0	1.6±0.5	<0.0001
Cost (LE)	2185.71±110.86	5514.29±701.74	<0.0001

Table (3): Shows the relation between HU of the stone and the need for 2nd ESWL session

		Patients who had 2nd ESWL session		Patients who had single ESWL session		P
		N	%	N	%	
HU	<1000	6	23.1%	8	88.9%	<0.001**
	≥1000	20	76.9%	1	11.1%	

DISCUSSION

In this study, there was significant difference regarding overall stone-free rate among both groups (77.1% in ESWL group versus 97.1% in URS group) as overall stone-free rate was higher among URS group. The overall stone-free rate in patients treated by ESWL for distal ureteral stone (Mean stone size 1.66 ±0.16 cm, range 1.5-2 cm) after 28 days was 77.1%. These results are going near the results of Zeng et al. [(4)] who achieved 78.1 % overall stone free rate for ESWL in distal ureteral stone (stone size 0.5-2.1 cm) after 28 days.

Ghalayini et al. [(5)] found that overall stone-free rate in patients treated by ESWL for their distal ureteral stone (Mean stone size 1.04±0.53 cm, range 0.4-2 cm) at 1 month and 3 month were 67% and 81.5% respectively.

On the other hand Verze et al. [(6)] achieved 92.75% overall stone free rate for distal ureteral stone treated by ESWL (Mean stone size 1 cm, range 0.5-1.5 cm), as stones <1 cm had 95.65 % stone free rate, while stones ≥ 1 cm had 89.70 % stone free rate. Also Etafy et al. [(7)] achieved 75% overall stone free rate for distal ureteral stone treated by ESWL (Mean stone size 0.78±0.34 cm, range 0.4-2 cm).

In our study, the HU of the stone showed significant difference as 100 % of patients who had ESWL failure having stones of HU ≥ 1000. Ouzaid et al. [(8)] found a significant relationship exists between increased stone density and poor stone fragmentation with a threshold of 970 HU, above which stones are less likely to be successfully fragmented with ESWL, the stone-free rate for stones of < 970 HU was 96% vs 38% for stones of ≥ 970 HU.

In this study, the overall stone-free rate in patients treated by URS for their distal ureteral stone was 97.1%. These results are going near the results of Etafy et al. [(7)] who achieved 97.5% overall stone-free rate for distal ureteral stone treated by URS. Verze et al. [(6)] achieved 94.85 % overall stone free rate for distal ureteral stone treated by URS.

Our study showed significant difference regarding retreatment among both groups (74.3% in ESWL group versus 8.6% in URS group) as ESWL showed higher retreatment. Repeated ESWL was required in 26 patients (74.3%), in these patients one ESWL session was not sufficient to be stone-free. Among the 26 patients 18 of them (51.4%) were stone free after 2nd ESWL session while 8 (22.9%) failed.

Stone size is an important factor affecting retreatment in ESWL treatment, Verze et al. [(6)] achieved a significantly higher percentage of retreatment in patients with stones of >1 cm. Verze et al. [(6)] showed that 44.88 % of distal ureteral stones treated by ESWL required retreatment, among of these stones 12.12% were <1 cm, while 80.32 % of them were ≥1 cm. In our study, all stones treated by ESWL were ≥ 1.5 cm (range 1.5-2 cm) and showed higher retreatment 74.3%.

In this study, repeated URS was required in 3 patients (8.6%) after 2 weeks due to the failure of the initial attempt secondary to failure of identification of ureteric orifice in two patients and one patient had a false passage at ureteric orifice due to improper balloon dilation. URS failed in one patient (2.9%) due to failure of identification of ureteric orifice even after 2nd URS attempt and treated by ureterolithotomy.

These results are going near the results of Verze et al. [(6)] who achieved retreatment rate of **7.75%** among URS group. A similar retreatment rate for URS was reported by Ghalayini et al. [(5)] with retreatment of 6.7% among URS group.

In our study, ESWL was shown to be less time consuming than URS with a mean operative time of 46.09±4.38 minutes versus 60.29±12.60 minutes respectively.

These results are comparable with results of Pearle et al. [9] who showed that operative time was statistically significantly shorter for ESWL group 34.1±8.2 minutes versus 64.7±37.1 minutes for URS group.

On the other hand, Etafy et al. [7] reported that the average operative time for ESWL was 65.75 ±20.3 minutes and 52.16 ±14.7 minutes for URS in treating distal ureteral stone > 1 cm, this study showed shorter operative time for URS.

In this study, patients who underwent ESWL, no auxiliary procedure was done as this procedure is completely non-invasive. While out of the 35 patients who underwent URS, 30 patients (85.7%) had ureteric catheter inserted for 24 to 72 hours postoperatively and 5 patients (14.3%) had double (J) stent inserted, the double (J) stent was inserted for 4 weeks postoperatively.

Ghalayini et al. [5] reported that 12 patients (10%) of the URS group had a double-J stent while 29 patients (24.2%) had ureteric catheters for 24 hours. Only 4 patients among ESWL group (4.3%) required pre-ESWL double (J) stent for persistent ureteric colic not responding to conservative treatment.

Verze et al. [6] reported that there was no statistically significant differences in the number of patients requiring auxiliary procedures between the ESWL and URS groups (11.02% versus 18.60%).

On the other side, Denstedt et al. [10] performed a prospective trial of non-stented versus stented ureteroscopic lithotripsy, and concluded that patients without a stent have significantly fewer symptoms in the early post-operative period, while there were no differences in terms of complications and stone free status.

In the present study, all ESWL cases done without anesthesia, just analgesic ± sedation was enough to achieve a successful session. While, all URS cases had spinal anesthesia (100%).

Verze et al. [6] reported that, all ESWL treatments were performed on an outpatient basis and none of the patients required anesthesia or sedation. While among URS treatments, general anesthesia was used in 30 patients (22.05%) and local anesthesia was used in 90 (66.17%). In 16 patients, only intravenous sedation was used (11.76%).

In this study, patients treated by ESWL were already at outpatient clinic so there were no admission or hospital stay. While in URS group, patients were admitted and the periods of hospital stay varies from one day to three days according to the condition of the case.

Ghalayini et al. [5] showed that (88%) of the patients among ESWL group had treatments as an outpatient procedure but all patients needed frequent follow-up visits, while the majority of the patients among URS group had treatments as an inpatient procedure (80%).

Our study showed that, overall complications among ESWL and URS groups were (11.4 % and 31.4 %) respectively. There was a highly significant difference between ESWL and URS cases regarding intraoperative complications (ESWL 0% vs. URS 17.1%). But there was no significant difference between both groups regarding post-operative complication (ESWL 11.4 % vs. URS 14.3 %).

Verze et al. [6] reported that overall complications occurred in 15.32% and 19.11% of ESWL and URS groups respectively. While Ghalayini et al. [5] showed minor complications occurred in 3.3% and 8.3% of the ESWL and URS groups, respectively.

There was a significant difference regarding patient satisfaction among both groups (77.1% in ESWL group versus 94.3% in URS group) as patient satisfaction was higher among URS group. These results are going near the results of Ghalayini et al. [5] who reported that patient satisfaction was high for both groups, including 80% for ESWL and 94% for URS as patient satisfaction was higher among URS group.

On the other side, Pearle et al. [9] reported that patient satisfaction was 94% for ESWL and 87% for URS as patient satisfaction was higher among ESWL group.

The present study showed that ESWL had lower cost in comparison to URS. Patients who had one ESWL session paid 2000 LE (Egyptian pound), while those who had two sessions paid 2250 LE. The mean cost among ESWL cases was 2185.71 ± 110.86 LE, while the mean cost among URS cases was 5514.29 ± 701.74 LE as minimal cost among URS was 4500 and maximum cost was 8000 LE (Egyptian pound), this range due to difference among hospital stay, auxiliary procedure done or retreatment needed.

On the other side regarding cost analysis, Pearle et al. [9] revealed that ESWL was more costly than URS by $1,255 provided that both modalities done as outpatient procedure, although the profile changes remarkably if convalescence and the potential for an overnight hospital stay are added to the formula as hospital stay in case of

URS group (25% of URS group needed hospital stay) added an additional charges.

Grasso et al. analyzed the cost of URS and ESWL for patients with ureteral calculi. When they compared outpatient ureteroscopic lithotripsy with ESWL monotherapy, treatment costs were similar[(11)].

CONCLUSIONS

In treatment of large distal ureteral calculi ≥ 1.5 cm, both URS and ESWL modalities are comparable but URS is recommended as a first option as it is more effective than ESWL regarding stone free rate and it provides immediate stone clearance with lower retreatment rates and higher patient satisfaction, but URS requires anesthesia, longer hospitalization, and associated with a higher incidence of complications. ESWL can be good alternative for ureteroscopy as ESWL has advantages of non-invasiveness, shorter operative time, lower cost, no hospital stay as it can be performed on an outpatient basis, quicker convalescence, no need for ureteral stent insertion and no need for anesthesia with fewer complication. ESWL often requires multiple treatment sessions and most of patients needed frequent follow-up visits. Treatment decisions have to be drawn individually taking into account patients preference for earlier stone-free status, acceptance of invasive procedure, physical health, personal experience and local equipment. We believe that ureteroscopy is preferable to ESWL for treatment of distal ureteral calculi since it is significantly more efficient with higher patient satisfaction. HU of the stone showed significance regarding being stone-free among ESWL group as 100 % of patients who had ESWL failure having stones of HU ≥ 1000, also HU was an important factor affecting the need for second ESWL session, as stones with HU ≥1000 had about 44 times higher risk for second ESWL session. This means that when planning ESWL treatment for large distal ureteral stone ≥ 1.5 cm, we can depend on HU as an important factor in predication of its clearance and retreatment. For best result of ESWL treatment, we recommend distal ureteral stone of HU < 1000.

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