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original article

Ten-year experience in the management of distal ureteral stones greater than 10 mm in size

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SUMMARY: **Ten-year experience in the management of distal ureteral stones greater than 10 mm in size.**

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Aim. *Extracorporeal shock wave lithotripsy (ESWL) and semirigid ureteroscopy lithotripsy (URSL) have become standards of treatment for ureteral calculi. The aim of this retrospective study was to compare ESWL vs. URSL in terms of safety and efficacy for treatment of large distal ureteral stones ≥ 1cm.*

Patients and Methods. *This investigation assessed 637 patients with distal ureteral stones (10 to 15mm in size). 313 in the ESWL group were treated on an outpatient basis using the LithoDiamond machine without anaesthesia. URSL was performed in 324 patients with a 6-8 Fr semirigid ureterorenoscope and YAG laser under spinal anaesthesia. A successful outcome was defined as the patient being stone free 1 month after treatment. For all patients the parameters, including stone-free rate, operation time, complications, were inserted retrospectively in this study after review of medical records and operating room logs.*

Results. *The stone-free rate after URSL was 77.5% and 45.4% after ESWL treatment (p<0.001). The mean operative time between two groups was 74.7±9.8 for URSL group and 38.3±7.6 for ESWL group. The average number of office visits was 4.2 and 2.6 in patients treated with ESWL and URSL, respectively. Double j stents were inserted in 28.7% of patients. Twenty-one patients needed rehospitalisations for major complications. However, the differences in the overall complication rate were not statistically significant, with a rate of 16.3% for URSL and 14.4% for ESWL (p=0.246).*

Conclusion. *We have shown that URSL has enough safety and efficacy for the treatment of distal ureteral stones ≥ 1cm. URSL is associated with higher stone clearance rate as compared with ESWL.*

KEY WORDS: Shock wave lithotripsy - Ureteral stones - Ureteroscopy - Lithotripsy - Efficacy.

Introduction

The optimal choice for treatment of distal ureteral stones depends on stone size, location, composition, clinical factors, equipment availability, and surgeon experience (1). Extracorporeal shock wave lithotripsy (ESWL) and semirigid ureteroscopy (URS) lithotripsy have become standards of treatment for ureteral calculi (2). Since 1980 ESWL is a clinically proven treatment of non-invasive, with low cost, few complications and shorter hospitalization (2). URS lithotripsy is more invasive treatment, and needed anaesthesia, but significantly better in terms of operative time and stone-free rate (3). However, medical expulsive therapy using α-adrenoceptor antagonists (alpha-blockers) has recently emerged as an alternative strategy for the initial management of small distal ureteral stones (4). When calculi are ≤ 10mm, located in the distal part of the ureter, and with no clinical evidence of infection and pain, conservative pharmacological expulsive therapy may be indicated to accelerate spontaneous passage of ureter stones (5, 6). Few studies comparing ESWL and URS lithotripsy in the treatment of large distal ureteral stones (> 10mm) are available (7). The best way to care for large stones in this tract of ureter is uncertain (8, 9). The aim of this retrospective study was to compare ESWL vs. semirigid ureteroscopy laser lithotripsy (URSL) in terms of safety and efficacy for treatment of large distal ureteral stones.

Patients and methods

From August 2005 to September 2015, 637 patients with only one single lower ureteral stone, 10 to 15 mm

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in size, referred to our Department of Urology were retrospectively evaluated for this study participation. Lower ureteral was defined as the ureteral segment between uretero-pelvic junction and upper margin of sacro-iliac joint. Eligible patients were 18 years or older, were diagnosed to have a single, unilateral, radiopaque, proximal ureteral stone (range 10-15 mm in maximum diameter), and agreed to undergo the treatment proposed. Exclusion criteria included patients having severe hydronephrosis, urinary tract infection, fever, bilateral ureteral stones, an extra stone in the upper urinary system, history of any intervention on the corresponding ureter, urinary tract abnormalities, coagulopathy, pregnancy, renal insufficiency, patients treated with concomitant medications such as alpha-blockers. Radiologic evaluation of the urinary system included abdominopelvic sonography, and/or non-contrast spiral computerized tomography (CT). Intravenous contrast was performed if needed. The stone size was calculated on the sonography or CT by using a digital ruler and the greatest dimension of the stone was taken into consideration as stone size. Of the 637 eligible patients, 313 chose ESWL as the primary treatment approach and 324 chose URSL. ESWL was performed using LithoDiamond machine (High Medical Technologies, Milan, Italy) as an outpatient procedure. The initial voltage of each shock wave was 12 Kv, which was gradually increased to 16 kv. The maximum of shock waves limited to 3.500. Patients were generally evaluated one/two weeks after the ESWL session by ultrasound urinary tract with/without CT to assess stone passage. If the stone did not completely break patients were asked about additional treatments ESWL or URSL, and treated according to their preference. URS was performed using a 6-8 Fr., 12° semirigid uretero-nefroscope (Karl Storz, Tuttlingen, Germany) under spinal anaesthesia by four experienced surgeons. A holmium YAG (yttrium-aluminum-garnet) laser (DEKA medical lasers, Florence, Italy) with its 200 μm quartz fiber was used for lithotripsy. Generally, the laser machine was set to produce 0.5 to 1 J of energy per pulse with a pulse frequency of 5 to 10 Hz. In patients with large residual stone, an incomplete treatment, significant mucosal edema, stone impaction and ureteral trauma, a double-J (DJ) stent was placed to drain the urine until the patient was stone free on follow-up evaluation. Otherwise, in all other patients a ureteral catheter was placed for about 12 or 24 hours to prevent ureteral obstruction by blood clots and/or mucosal edema. A successful outcome was defined as the patient being stone free 1 month after treatment. Patient demographics, including age, sex, stone side and size (maximum diameter) were retrospectively reviewed. For all patients the parameters, including stone-free rate, operation time, complications, were inserted retrospectively in this study after review of medical records and operating room logs. Statistical analysis was carried out with Student's t-test for parametric data and Chi-square test and Fisher's exact test for non-parametric values. A $P < 0,05$ was considered to indicate statistical significance.

Results

Patients characteristics are shown in Table 1. URSL was chosen as primary procedure in 324 patients with stones size 12.8±1.2 mm. DJ stents were inserted in 41 patients owing to an incomplete treatment, stricture (n = 7), significant mucosa edema (n = 18), stone impaction (n = 16), and ureteral trauma (n = 11). The initial stone-free rate of URSL was 77.5% (251/324). Of the 73 (61 men and 12 women) patients who were not stone free, 21 chose ESWL as their first auxiliary treatment and 52 chose URSL. The stone-free rate for the 21 patients choosing ESWL was 61.9 % (13/21) and was 100 % (52/52) for those choosing USRL. ESWL was chosen as primary treatment in 313 patients with stones size 11.5±1.3 mm. The initial stone-free rate of ESWL was 45.4% (142/313). Of the 171 (114 men and 57 women) patients who were not stone free, 97 chose ESWL as their first auxiliary treatment and 74 chose URSL. The stone-free rate for the 97 patients choosing ESWL was 36.1 % (35/97) and was 95.9% (71/74) for those choosing URSL. In this second group of treatment DJ stents were inserted in 27 patients owing to an incomplete treatment, stricture (n = 3), significant mucosa edema (n = 9), sto-

TABLE 1 - BASELINE CHARACTERISTICS, OUTCOMES AND COMPLICATIONS OF URSL vs. ESWL IN 637 PATIENTS WITH DISTAL URETERAL STONES ≥ 1 CM.

Characteristic	URSL	ESWL	*P*-value
Patients, n (%)	324 (50.9)	313 (49.1)	NS
Age (years), mean ± SD	49.4±2.1	46.2±1.5	NS
Sex, n (%)			NS
Male	203 (62.7)	181 (57.8)	
Female	121(37.3)	132 (42.2)	
Stone size, mm	12.8±1.2	11.5±1.3	NS
Stone free rate, n (%)	251(77.5)	142(45.4)	<0.001
Operative time, min	74.7±9.8	38.3±7.6	<0.001
Double-J stent, n (%)	93(28.7)	50(15.9)	<0.002
Mean office visits	2.6	4.2	<0.001
Re-hospitalization, n (%)	10(3.4)	11(3.5)	NS
Major complications			NS
Sepsis, n	2	1	
Intractable renal colic, n	3	5	
Fever, n	3	3	
Haematuria, n	2	2	

SD =standard deviation; URSL = semirigid ureteroscopy lithotripsy; ESWL = Extracorporeal shock wave lithotripsy; NS= not significant.

TABLE 2 - INCIDENCE OF COMPLICATIONS AMONG THE TWO GROUPS OF PATIENTS.

Complication grade	URSL (n: 324)	ESWL (n: 313)	Total (n: 637)
Major complications with re-hospitalization			
Sepsis	2	1	3
Intractable renal colic	3	5	8
Fever	3	3	6
Haematuria	2	2	4
Minor complications with office visits			
Flank pain	9	14	23
Fever	7	3	10
Haematuria	6	2	8
Urinary disorders	21	15	36

URSL = semirigid ureteroscopy lithotripsy; ESWL = Extracorporeal shock wave lithotripsy.

ne impaction (n = 11). The mean operative time between two groups was 74.7±9.8 for URSL group and 38.3±7.6 for ESWL group. The minor problems reported by patients were fever, flank pain, haematuria and urinary frequency and urgency. Twenty-one patients needed re-hospitalizations for extra treatment: 2 patients in the group treated with ESWL and 1 patient in the group treated with URSL occurred a major complication such as sepsis; intractable renal colic and fever were cause of re-hospitalization in 8 patients (5 in the URSL and 3 in the EWSL group) and 6 patients (3 in each group), respectively (Table 2). The average number of office visits was 4.2 and 2.6 in patients treated with ESWL and URSL, respectively. The differences in the overall complication rate were not statistically significant, with a rate of 16.3% (53/324) for URSL and 14.4% (45/313) for ESWL (p=0.246).

Discussion

In literature, two treatment options have been accepted for large distal ureteric stones as URSL and ESWL, with different efficacy rates. However, the optimal first-line strategy is still a controversial issue (8). Many studies have been published comparing the two methods with various results (9-11). Stone size and location have had an impact on the success of treatment. Picozzi et al. (12) reported that an increase in the stone diameter of 1 mm beyond 8 mm corresponds to a reduction in the stone-free rate 5% for distal and 8% for proximal ureteral stones. URSL has traditionally been the preferred approach for the treatment of medium and distal ureteral stones, while ESWL has been recommended as first-line therapy for proximal ureteral stones, which are considered less accessible endoscopically (13). Pearle et al. (14) reached opposite conclusions. Despite an equal stone-free rate in both groups, but ESWL was differentiated by shorter operative duration and fewer complications in treatment of distal ureteral stones. Verze et al. (15) evaluated 273 patients with single, distal ureteral stone of 0.5 -1.5 cm, and showed in the ESWL group a 92.70% overall stone-free rate vs. 94.85% in the URSL group. The authors concluded that ESWL should be the preferred treatment for patients with single distal ureteral stone of ≤ 1 cm and URSL should be reserved for stones size > 1cm. Discrepancies between authors are also strongly dependent on the technologies employed, the physician characteristics of the patients and surgeons experience. Surgeon experience and technological advances have been shown to be predictive of success and complication rates in ESWL and URSL. Rioja et al. (16) in a retrospective study of URSL treatments showed that the reduced operative times achieved by an experienced, specially trained surgical team were a significant factor in reducing the rate of complications following URSL. Our study tried to eliminate bias of learning curve, because surgeons had already achieved a great experience in the treatment performed. In literature, the number of severe complications occurred during URSL, mainly injures, has decreased over time due to the technical advances of ureteroscopes and endoscopic lithotripsy devices (17). The major risk of complication during URSL remains the ureteric perforation (2-4%) and ureteric avulsion (0.5-2%) (18). However, ureteral injures have never been reported after ESWL (19). In our department in line with other authors we have also reported 3.4% of ureteral trauma, and there were three cases of ureteric avulsion, not included in this cohort study. Moreover, we reported a stone-free rate for calculi in the distal ureter after one and two treatments with URSL of 77.5% and 100%, respectively. This confirms previous reports about safety and efficacy of URSL with YAG laser treatment in treating proximal and distal ureteral stones (9, 11). Usually, post-operative placement of a ureteral DJ stent after URSL is still a subject of debate. Ureteral stenting was thought by surgeons to prevent post-operative urinary sepsis secondary to ureteral obstruction by residual fragments of stones, blood clots or ureteral mucosal edema (20). However, the main indications for stenting are ureteral stricture, ureteral injury, renal insufficiency, solitary kidney or large residual stone burden (21, 22). Ureteral stenting after uncomplicated URSL treatment is not a routine at our institution. This explains the current low post-operative stenting rates (28.7%). However, a transient ureteral catheter is placed in all patients who had ureteral dilatation through the insertion of access sheath, presented with large and/or impacted stones irrespective of the location. Despite these results of URSL, its more invasive nature, possible associated complications,

and the need for more anaesthesia compared with ESWL resulted to be considered as a second-line or salvage option after an ESWL trial for 48.7% of our patients. This preference continued even after a failed session of ESWL (56.7%). However, we did not compare overall patient satisfaction during the study and that might be an important variable to facilitate treatment planning in these treatments. There are other limitations to this study that should be considered. The time interval of the study analysed was 10 years (2005-2015), and over this period, both techniques and equipment have improved. In particular, recent development of small semirigid URS and ESWL machine have led to a noticeable improvement in the success rate for treating distal ureteral stones. In addition, the analysis did not incorporate stone composition and metabolic evaluations into the assessment. Finally, body mass index data between groups were not reported. These differences can have affected the results of the studies between two procedures and these limitations need to be considered when assessing the outcomes reported in this study.

Conclusion

For large distal ureteral stones, URSL is associated with higher stone clearance rate as compared with ESWL. Although ESWL was associated with a less operating time, but it had higher rate of repeat treatments and auxiliary procedures. However, the complications were similar between two treatments. This study shows that URSL should be the treatment of choice for distal large ureteral stones > 1cm. Ours is a monocentric clinical experience, prospective and randomised clinical trials will be essential to establish the efficacy and the safety of the best treatment regimen.

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