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Original Article

What is the optimal treatment for lower ureteral stones larger than 1 cm?

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Abstract ***Purpose***: To compare the treatment options for lower ureteral stones larger than 1 cm.
Methods: The records of 449 patients with lower ureteral calculi larger than 1 cm were reviewed retrospectively. Of these patients 342 (76.1%) were treated with extracorporeal shock wave lithotripsy (ESWL) (group 1), 66 (14.7%) with pneumatic lithotripsy (PL) (group 2) and 128 (28.5%) with ureterolithotomy (group 3). Eighty-seven (19.5%) patients underwent any of the two treatment modalities because of unsuccessful primary treatment.
Results: The overall stone-free rates were 32.4, 90.9 and 95.3% for ESWL, PL and ureterolithotomy, respectively. These values were 84.4% for primary PL and 96.7% for primary ureterolithotomy. The re-treatment rate (46.4%) and secondary procedures were much more frequent in the ESWL group. There was no difference in the complication rates of the three groups.
Conclusions: Pneumatic lithotripsy with ureteroscopy seems to be an appropriate treatment for larger ureteral stones. While ESWL can be tried as a first treatment option because of its non-invasive nature, lower success and higher re-treatment rates limit its usefulness. Ureterolithotomy is still a reasonable alternative for these large or unfragmented stones.

Key words extracorporeal shock wave lithotripsy, lower ureteral stones, pneumatic lithotripsy, ureterolithotomy.

Introduction

Advances in shock wave technology and ureteroscopic lithotripsy have changed the management of ureteral calculi in the last decade. Although there are several treatment options for lower ureteral calculi including extracorporeal shock wave lithotripsy (ESWL), ureteroscopy with different intracorporeal lithotriptors, stenting alone and open ureterolithotomy,[1] ESWL is accepted as first line therapy in many institutions.[2–8] However, treatment of lower ureteral stones larger than 1 cm remains controversial because the stone-free rates of ESWL therapy appear to be closely related to the size of stone.[8,9] In addition, the impaction of such large stones and the requirement of more shock waves, can remove the non-invasiveness of this technique and limit its use. Ureteroscopy and intracorporeal lithotripsy have also been shown to be safe and effective treatments for these patients.[10] Open ureterolithotomy still remains as an alternative, especially after treatment failure with other modalities.[11]

To evaluate the treatment success of ESWL, pneumatic lithotripsy (PL) and ureterolithotomy and to determine the most appropriate treatment for this specific stone subgroup, we reviewed our experience with 449 patients with lower ureteral calculi larger than 1 cm.

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Methods

From July 1988 to March 1998, we treated 449 patients for lower ureteral calculi which were larger than 1 cm with either ESWL, PL or ureterolithotomy at Gazi University School of Medicine, Department of Urology. Of these patients, 267 (59.5%) were male and 182 (40.5%) were female with a mean age of 40.4 years (range, 8–77). All patients underwent evaluation with a plain abdominal X-ray; intravenous pyelography, urine culture and sensitivity testing, renal ultrasound and retrograde pyelography were performed if needed. Patients were

divided into three groups according to the treatment modality. Group 1 included 342 patients (63.8%) who underwent ESWL, group 2 included 66 patients (12.3%) who underwent pneumatic lithotripsy and group 3 included 128 patients (23.9%) who underwent open ureterolithotomy. In 362 of these patients (80.5%) treatments were performed primarily and in 87 patients (19.5%) secondarily, after unsuccessful primary treatment. Patients' characteristics are shown in Table 1. Extracorporeal shock wave lithotripsy was performed with a Siemens Lithostar (Siemans, Erlanger, Germany) plus after the introduction of the ESWL unit to our clinic in June 1990. Open surgical removal of the large ureteral calculi was the mainstay of treatment until the introduction of ESWL. Later, ureterolithotomies became the last treatment option after failed primary endoscopic or ESWL treatments. Pneumatic lithotripsy came into clinical use after 1995. Treatment selection was done according to the technical equipment existing at the treatment time, clinical experience and patient's preference. Extracorporeal shock wave lithotripsy was the treatment of choice in patients with systemic diseases and in recurrent stone formers. However, patients who had morbid obesity and prolonged obstruction due to the calculi underwent ureteroscopic or open surgery. In addition, patients who had evidence of anatomical obstruction were treated via an open surgical approach with the correction of underlying pathology.

All patients in group 1 were treated on an outpatient basis. Anesthesia or sedation was not needed in any of the patients. The mean shock wave number and intensity received by the patients were 3325 (range, 2500–4000) and 18.7 kV (range, 17.2–19), respectively. Patients who did not have any fragmentation after three sessions were accepted as treatment failure and were managed by either mechanical extraction with ureteroscopy, intracorporeal lithotripsy or ureterolithotomy.

Pneumatic lithotripsy was performed primarily in 45 (68.2%) patients and secondarily in 21 (31.8%) patients after unsuccessful ESWL treatment. All patients were treated under general anesthesia. A 9.5 Fr rigid ureteroscope was used in 41 (62.1%) patients and a 12 Fr rigid ureteroscope was used in 25 (37.9%). Ureteral dilatation was needed in only four (6.0%) patients. Pneumatic lithotripsy was performed with Swiss Lithoclast (Electro Medical Systems, Switzerland). This device uses a 1-mm rigid probe connected to the handpiece which contains a small metal projectile and a foot-switch. Upon activation of the device, compressed air propels the metal projectile within the handpiece against the head of the probe at a pressure of 3 atmospheres and a frequency of 12 Hz. The repeated impact of the probe tip against the stone result fragmentation.

Group 3 included patients who were treated with ureterolithotomy; 62 (48.4%) of these patients underwent ureterolithotomy as a primary treatment whereas 62 (48.4%) and four (3.2%) patients were treated after unsuccessful ESWL and PL, respectively. A double-J stent was inserted in one (0.7%) patient who had an additional stone in the ipsilateral kidney and in six (4.7%) patients in whom some insignificant stone fragments were inevitably left.

After treatment, all patients were evaluated by urine analysis, urine culture, renal function tests and plain abdominal X-ray. Intravenous pyelography was performed routinely after 3 months. Fragmentation of stones smaller than 3 mm was considered successful fragmentation and complete removal of all fragments was considered stone-free.

Chi-square, Fisher's exact test and Student's *t*-tests were used for statistical analysis.

Results

The fragmentation and stone-free rates of both groups based on the intravenous pyelography obtained in the third month are shown in Table 2. The stone-free rates

Table 1 Patient characteristics according to the treatment

	ESWL	PL	Ureterolithotomy	Total
No. patients (%)	342	66	128	449*
Mean age (years)	41.4	36.2	39.6	40.3
Mean stone size (mm)	13.6 + 2.72† (10.3–22.5)	14.2 + 2.49† (10.7–21.8)	14.6 + 2.82† (12.1–26.2)	13.9 + 2.56† (10.3–26.2)
Mean hospitalization time (days)	1.2**	1.7	4.7	3.0

ESWL, Extracorporeal shock wave lithotripsy; PL, pneumatic lithotripsy; *, 87 patients underwent two treatment modalities due to unsuccessful primary treatment; **, mean hospitalization time in patients who developed complications. †$P = 0.07$ (ESWL-PL); †$P < 0.01$ (ESWL-ureterolithotomy); †$P = 0.46$ (PL-ureterolithotomy).

Table 2 Results of different treatment modalities

	ESWL (342)	PL		Ureterolithotomy	
		Primary (45)	Total (66)	Primary (62)	Total (128)
SFR	111 (32.4%)	38 (84.4%)	60 (90.9%)	60 (96.7%)	122 (95.3%)
FR	181 (52.9%)	42 (93.3%)	62 (93.9%)	—	—

( ), Number of patients undergoing treatment modality; ESWL, extracorporeal shock wave lithotripsy; PL, pneumatic lithotripsy; SFR, stone-free rate; FR, fragmentation rate.

Table 3 Re-treatment and secondary procedures

	ESWL	PL	Ureterolithotomy
Single session	97	30	55
Two sessions	45	—	—
Three sessions	39	—	—
Plus PL	21	—	—
Plus ureterolithotomy	62	4	—
Plus ureteroscopic mechanical extraction	15	5	—
Plus double-J insertion	8	4	7
Others*	55	2	—
Total	342	45	62

ESWL, Extracorporeal shock wave lithotripsy; PL, pneumatic lithotripsy; *Others included electrohydraulic lithotripsy, ultrasonic lithotripsy, additional ESWL sessions after three sessions and patients whose data was not available after ESWL.

Table 4 Complications

	ESWL	PL	Ureterolithotomy
Ureteral perforation	—	1 (1.5%)	—
Urosepsis	13 (3.8%)	2 (3.0%)	8 (6.2%)
Ureteral stricture	—	—	1 (0.8%)
Colic pain	44 (12.9%)	10 (15.2%)	7 (5.4%)
Wound infection	—	—	2 (1.6%)
Urine leakage	—	—	1 (0.8%)
Total	57 (16.6%)	13 (19.7%)	19 (14.8%)

ESWL, Extracorporeal shock wave lithotripsy; PL, pneumatic lithotripsy.

were 32.4, 90.9 and 95.3% for ESWL, PL and ureterolithotomy, respectively. There was no statistically significant difference between the stone-free rates of PL and ureterolithotomy ($P = 0.18$), whereas both had better stone-free rates than ESWL ($P < 0.01$, $P < 0.01$). Among patients who underwent PL, success rates were better in secondary than primary treatments (90.0 *vs* 84.4%); however, this was not statistically significant ($P = 0.22$). There was also no difference in success rates according to ureteroscope caliber ($P = 1$). Primary or secondary ureterolithotomies were not different from each other in stone-free rates ($P = 0.48$).

Re-treatment and auxiliary treatments were more frequent in patients who underwent ESWL. The re-treatment rate of this group was 46.4%. Pneumatic lithotripsy and ureterolithotomy were performed in 21 and 62 patients, respectively, in whom ESWL treatment was unsuccessful. Four patients in the PL group in whom endoscopic lithotripsy was not successful, underwent open ureterolithomy. The re-treatment and auxiliary treatments of both groups are shown in Table 3. Double-J insertion was the only auxiliary measure in the ureterolithotomy performed group.

The main complications were urosepsis, colic pain and ureteral perforation. Urosepsis was suspected from clinical findings including fever, chills, nausea, vomiting and flank pain. Increased sedimentation rate, leukocytosis, increased white blood cells in urinary sediment and positive urine and/or blood cultures supported the diagnosis. Ureteral perforation occurred in only one patient in the PL group and the patient was treated with a double-J insertion. Complication rates according to the treatment modality are summarized in Table 4. In the PL and ureterolithotomy groups, the treatment type, whether it was primary or secondary, had a slight effect on complication rates. There were no difference in the complication rates of ESWL, PL and ureterolithotomy ($P = 0.32$, $P = 0.25$, $P = 0.37$).

Discussion

The commonly used treatment alternatives for distal ureteral calculi are ESWL, ureteroscopy with different intracorporeal lithotripsies, watchful waiting, stenting alone or open ureterolithotomy. Although there is little

consensus about the most appropriate treatment, ESWL has gained worldwide acceptance as first line therapy for small stones and the success rates for these stones ranges between 59.6 and 96%.[1–8,12–14] However, the efficiency of ESWL may vary according to the stone size, stone composition, impaction of the stone and existence of obstruction.[14,15] Stones larger than 1 cm are often associated with impaction or obstruction. Furthermore, these stones may not have any water–stone interface or expansion chamber which is important for fragmentation.[16] Although ESWL seems to be the least invasive method, success rates for such larger stones can decrease to 50%.[13] In this study, the stone-free and fragmentation rates with ESWL are 32.4 and 52.9%, respectively. Although these findings are supported with the recent data, higher fragmentation rates could better be achieved by intracorporeal lithotripsy. Eden *et al*. found 92.3 *vs* 56.0% and 50.0 *vs* 11.1% stone-free rates with PL and ESWL for stones 9–12 mm and 13–16 mm, respectively.[13] Our stone-free rates with primary and secondary PL were 84.4 and 90.9%, respectively; however, this difference was not statistically significant. It may indicate that prior fragmentation with ESWL (although insufficient for stone clearance) can enhance the effectiveness of PL. However, prior treatment sessions with ESWL or PL may endanger complete stone removal with open ureterolithotomy. Disimpaction and removal of all stone fragments may be difficult because of the surrounding edema and disseminated stone fragments throughout the lower ureter.

Re-treatment and auxiliary procedures were more frequent for patients who had undergone ESWL. Because of the greater stone burden more shock waves were required for fragmentation and our re-treatment rate was 46.4%. In addition, the need for additional ureteroscopic measures or double-J insertion was higher than for PL. However, the possible traumatic effect and need for dilatation in some patients are disadvantages of intracorporeal lithotripsy, although the orifice was successfully entered in 94.0% of patients in this study with guidance of a ureteral catheter without dilatation. In addition, an anesthesia requirement may bring some risks which are not different from the possible anesthetic complications of any patient who is given anesthesia. However, ESWL seems to be a safer and less invasive technique. The adverse effects of shock waves on the ureter are minimal and it returns to normal within several days.[17] There is also an advantage of performing the procedure on an outpatient basis without any anesthesia. Although many centers use intravenous sedation of some type when treating patients, sedation is not always needed in our practice and none of the patients in group 1 needed sedation or anesthesia. In a subgroup of patients who have a high anesthesia and surgical risk due to coexisting systemic diseases, and in patients who do not accept ureteroscopy or open ureterolithotomy, ESWL treatment may be feasible as an initial treatment modality.

Complications were another determining factor on selection of the treatment modality. Although there was no difference in the complication rates of ESWL, PL and ureterolithotomy ($P = 0.32$, $P = 0.25$, $P = 0.37$), major complications such as ureteral perforation and urine leakage seem to represent more important problems in PL and ureterolithotomy. Recent data support our findings. Naqvi *et al*. found an 8.6% complication rate which included aforementioned major complications with PL.[18] It is evident that ESWL is the least invasive treatment option and can be performed on an outpatient basis. The lithostar lithotriptor has a range of 10–19 kV producing a shock wave pressure of 200–300 bar and generally a maximum 10 000 shocks to the ureter were recommended.[2,8,19] Although there are some studies which perform more than 5000 shocks/session,[5] we believe that 4000 shocks/session with a maximum three sessions are sufficient for ureteral stone fragmentation while minimizing the morbidity. Ureterolithotomy is the most invasive method among these treatments and carries all the disadvantages of open surgery. Because of the longer convalescence period, need for anesthesia and longer hospitalization time, ureterolithotomy must be reserved as the last alternative. However, ureteral strictures, ureteral kinking and anatomic variations can either prevent the clearance of stone fragments after ESWL or limit the access to the ureteral stones by ureteroscopy and these patients can be candidates for ureterolithotomy. In addition, the satisfactory success rates makes this procedure a reasonable alternative, especially after failed primary treatment. Nevertheless, because of the invasive nature, all possible noninvasive techniques should be challenged prior to ureterolithotomy. As a result, the current indications for open ureterolithotomy are very limited. Paik *et al*. have performed only six ureterolithotomies since 1991 and their indications were ureteral stricture, failed primary endoscopic treatment and stones larger than 2 cm.[11] Kane *et al*. had only eight ureterolithotomies among 799 stone treatment procedures with similar indications.[20] We had a total of 128 patients who underwent open ureterolithotomy. Although this seems to be very high, 51.2% of these patients were treated with ESWL or PL prior to ureterolithotomy. Before the installation of the ESWL unit to our department in 1990, ureterolithotomies for large ureteral stones were

common. In the same period ureteroscopic lithotripsy experience was also developing. For these reasons, ureterolithotomies were the dominant of all these treatment modalities. Later on, in the early 90s, prolonged ESWL treatments with several re-treatments were tried and ureterolithotomies after these unsuccessful ESWL treatments were common as functional losses due to prolonged obstruction were feared. Since this time ureterolithotomy rates have decreased considerably while ureteroscopy rates have increased with better patient selection and growing experience.

As a conclusion, it is very difficult to decide on the most appropriate treatment for this subgroup of ureteral stones which are larger than 1 cm. Successful therapy may be achieved with minimum morbidity by ESWL, but stone-free rates are low. We recommend ESWL as the first line of therapy only in patients who have systemic diseases or who are recurrent stone formers. Patients who do not have dilatation of the proximal ureter could also be candidates for ESWL. The financial status, need for hospitalization and convalescence period may also influence the decision. We believe that PL seems to be the best alternative with high success and low complication rates. However, ureterolithotomy continues to represent a reasonable option after failed non-invasive treatment attempts.

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