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RESEARCH ARTICLE

TREATMENT OPTIONS FOR DISTALLY LOCATED URETERAL STONES-OUR EXPERIENCE

[1,*]Krishna Reddy, S.V. and [2]Ahammad Basha Shaik

[1]Department of Urology, Narayana Medical College, Nellore, Andhra Pradesh, India
[2]Community Medicine & Biostatistics, Narayana Medical College, Nellore, Andhra Pradesh, India

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ABSTRACT

Purpose: To compare the efficacy of different treatment strategies for distal ureteral stones.
Material and Methods: A total 161 patients were included in the study. Based on the treatment modality, patients were divided into four groups. Patients in group 1 (n=38) with stone size of ≤ 10 mm^2 only received conventional treatment including daily hydration of 2500 mL, ciprofloxacin, diclofenac sodium and a spasmolytic agent; group 2 patients (n=39) with stone size of ≤ 10 mm^2 received conventional treatment as in group 1 and tamsulosin 0.4 mg orally daily for 4 weeks; and. Group 3 (n=33) with stone size of ≤ 15 mm^2 underwent extracorporeal shock wave lithotripsy (ESWL), Group 4 (n=51) with stone size of ≤ 15 mm^2 underwent ureteroscopy. Following treatment, all groups were compared in terms of stone-free rate and time to expulsion.
Results: Following treatment, the stone-free rates for groups 1, 2 , 3 and 4 were 47.37%, 56.41%, 63.64 % and 94.12% ($P < .0001$) respectively. The mean expulsion times for groups 1, 2, 3 and 4 were 15.04 ± 3.80, 15.12 ± 2.45, 7.56 ± 4.31 and 1.95 ± 1.08 days respectively ($P < .0001$). Compared to the other treatments, the stone-free rate and mean expulsion time in the ureteroscopy group were significantly increased and decreased respectively.
Conclusion: There are several treatment options for distal ureteral stones. Based on our data, we conclude that ureterorenoscopy should be the standard of care for distal ureteral stones.

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INTRODUCTION

Urinary stone disease is a major health problem that concerns millions of patient's worldwide affecting 2-3% of the human population with a high recurrence rate of almost 50%. Ureteric colic is a urological emergency in terms of the severe pain experienced by the patient. They occur most commonly in men aged between 30 years and 60 years (Romero *et al*., 010; Papadoukakis *et al*., 2006). Until the 1980s, open surgical procedures were the mainstay of treatment of ureteric stone. In the last three decades, the management of urinary stones has undergone a revolutionary change. Ureteral stones account for roughly 20% of all urinary calculi, and 70% of these stones are located in the distal third of the ureter. Uretral stones and their subsequent obstructive uropathy can deteriorate renal function (Lam *et al*., 2002). The patient's symptoms and stone size are not good predictors for renal function loss. Management of ureteral stones includes observation, medical expulsive treatment, extracorporeal shock wave lithotripsy (ESWL), percutaneous antegrade ureteroscopy, retrograde ureteroscopy (especially for distal ureteral stones), and open/laparoscopic ureterolithotomy (Preminger *et al*., 2007). Although current therapeutic options for ureteral stones include both active intervention and conservative wait and watch approaches, the endoscopic treatment of ureteral stones has a high success rate and reliably results in immediate stone removal (Strohmaier *et al*., 1999; Osorio *et al*., 2007). Furthermore, developments in ureteroscopic instrumentation has increased operational success while decreasing severe complications (Geavlete *et al*., 2006; Chow *et al*., 2003). Several reports have suggested that ureteroscopy should be the first choice treatment option for distal ureteral stones and as an alternative method to ESWL or medical treatment modalities, especially flexible ureteroscopic lithotripsy using a variety of lithotripters, including ultrasonic, electrohydraulic, pneumatic, and laser (Erhard *et al*., 1996; Mugiya *et al*., 2000; Harmon *et al*., 1997).

Corresponding author: Krishna Reddy, S.V.,
Department of Urology, Narayana Medical College, Nellore, Andhra Pradesh, India.

MATERIALS AND METHODS

This study was conducted randomized and prospectively. All patients signed a written informed consent, and we discussed with them in detail the potential side effects and complications

prior to treatment. The study was approved by the local ethics committee. A total 161 patients with distal ureteral stones that were less than 15 mm^2 were included in the study from February 2012 to July 2014. All patients were diagnosed with distal ureteral stones with smaller than 15 mm^2 based on plain abdominal X-rays and urinary tract ultrasonography as well as with helical computed tomography when necessary. A case history was obtained from all patients; additionally, they underwent a physical examination and a series of measurements, including a complete blood cell count, blood electrolyte analysis, routine urinalysis, and serum urea and creatinine analyses.

Patients who were pregnant or had severe hydronephrosis, a solitary kidney, a urinary tract infection, renal failure, stones greater than 15 mm^2, bilateral ureteral stones, multiple ureteral stones or previous urinary tract surgery were excluded from the study. All the patients′ plain abdominal X-rays and urinary ultrasonography results were reviewed and confirmed by experienced radiologists, and the stone diameters were measured using X-rays, computed tomography and ultrasonography. Patients were divided into four groups based on treatment. Unsuccessful stone expulsion within 4 weeks or change in medical management to surgery due to severe colic or fever due to infection was considered therapy failure and ureteroscopy was scheduled for these patients.

Group 1: Thirty eight patients with stone size of $\leq$ 10 mm^2 were included in this Observation group. Treatment included daily hydration of 2500 mL and ciprofloxacin (500 mg orally, twice a day) for the first 7 days. During the 4-week treatment period, diclofenac sodium (50 mg orally, twice a day) and a spasmolytic agent (hyoscine butylbromide, 10 mg orally, three times a day) were given.

Group 2: Thirty nine patients with stone size of $\leq$ 10 mm^2 were included in this Tamsulosin group and were given tamsulosin 0.4 mg daily orally for 4 weeks. Additionally, these patients received conventional treatment with daily hydration of 2500 mL and ciprofloxacin (500 mg orally, twice a day) for the first 7 days. Diclofenac sodium (50 mg orally, twice a day) and spasmolytic (hyoscine butylbromide, 10 mg orally, three times a day) were also given to the patients in this group.

Group 3: Thirty-three patients with stone size of $\leq$ 15 mm^2 were included in this ESWL (Extracorporeal shock wave lithotripsy) group. ESWL was performed for distal ureteral calculi at our institution using in situ Dornier HM3 ESWL with a Stryker frame modification. All patients were treated as outpatients under sedo-analgesia (meperidine hydrochloride plus diclofenac sodium). Shock waves were given at fixed rate of 84 min^{-1} for all patients. The procedure was ended when satisfactory fragmentation was seen on fluoroscopy or after 3000 shock waves had been delivered.

Group 4: Fifty one patients with stone size of $\leq$ 15 mm^2 were included in this Ureteroscopy group. Ureteroscopy was performed under spinal anesthesia using a 9.5 Fr (Karl Storz GmbH & Co KG, Tuttlingen, Germany) semi-rigid ureteroscope and a 0.035 mm safety guide wire. Patients were covered with antibiotics prior to instrumentation. All stones were located in the distal ureter and fragmented with a Swiss lithoclast (2.4 Fr long probe; 0.8 mm thick). Stone fragmentation was continued until all fragments were < 2 mm in diameter. In the event that fragments were larger than 2 mm, extraction was performed. Fragments < 2 mm were left for spontaneous passage. Ureteral stenting was done if the smaller fragments were more for spontaneous passage. However, in the event of proximal stone migration with ureteral extravasation, a stent was placed. Post-operative treatment of this patient population included daily hydration of 2500 mL, ciprofloxacin (500 mg orally, twice a day) and an analgesic agent for the first 7 days.

Group 1 and 2 patients were followed weekly for 4 weeks, or until alternative treatment (ureteroscopy) was undertaken. Follow-up visits included plain abdominal X-rays, urinary tract ultrasonography, urinalysis, serum urea creatinine and computed tomography if needed. During each visit, stone-free condition, analgesic dose, side effects and complications were recorded. Stone-free condition was defined as the absence of stones on plain abdominal X-rays and computed tomography. Following ESWL, Group 3 patients were reviewed at 1 week after the first session using a plain film. Repeat treatment was applied immediately if there was inadequate fragmentation of the stone (either no fragmentation at all or stone fragments of >4 mm). ESWL was considered successful if the plain film showed complete clearance of the stones with no residual fragments. Stones that showed no or poor fragmentation after two sessions of ESWL, and complicated or residual fragments that failed to pass, were considered as a failure of ESWL and referred for ureteroscopy.

Those with an equivocal plain film had non contrast CT as necessary to confirm the stone-free status. When compared to ESWL, ureteroscopy for distal ureteral stones was more time-consuming, entailed routine placement of a ureteral stent, often required spinal anesthesia, more often led to hospitalization and doubled the convalescence period. Following ureteroscopy, group 4 patients were followed with routine biochemical analysis, blood counts and urinalysis. Preoperative aerobic urine cultures were routinely performed. In the event of a urinary tract infection, the patient was treated, and urine cultures were repeated to confirm sterility. The stone-free rate was determined by plain abdominal radiography and computed tomography on postoperative days 1 and 7. If inserted, the D-J ureteral stent was removed during postoperative week 3.

Statistical analysis

All groups were compared in terms of stone-free rate and time to expulsion. All data were entered into MS-Excel and statistical analysis was done using statistical software SPSS (SPSS Inc, Chicago, Illinois, USA) Version 20.0. For categorical variables, the values are represented as number and percentages and to test the association between the groups, Pearson chi-square test was applied. For continuous variables, the values are represented as mean and standard deviation and to test the mean difference between two groups, student's t test was used and to test the mean difference between the three or more groups ANOVA with post hoc test was used.

The Efficiency Quotient Rate (EQ) was calculated using the following formula: EQ = percentage of stone-free patients/100% + percentage of re-treatment patients rate + ancillary procedures rate. (Osorio *et al.,* 2007) All the p values having less than 0.05 was considered as statistically significant.

RESULTS

Of the 161 patients included the study, 97 were male and 64 were female. The mean patient age was 30.67 ± 5.94 (range, 19-43). Four patients in group 1 and five patients in group 2 withdrew from the study due to severe renal colic, infection or fever. These patients underwent immediate ureteroscopy. There were no minor and major complications in group 1 and 2 during treatment. In the ureteroscopy group, there were no intraoperative and major postoperative complications; however there were six post-operative minor complications. Of these patients, twelve had urinary tract infection in second postoperative day.

The patients were treated with antibiotic including Injection amikacin. In post operative period, re-ureterorenoscopy was done in twelve patients for residual fragment. Ancillary procedures like D.J. Stenting was required in 11(33.3%) and 18 (35.2%) of patients in group 3 and group 4 respectively. Re-treatment rate was 4.34% and 5.23% for group 3 and group 4 respectively. Additionally, no statistical difference was found for patient's age, sex distribution. Stone size between groups 1, 2 was ≤ 10 mm^2 and in group 3 and 4 was ≤ 15 mm^2. There was no statistical significant difference in the location of stone on both sides in four groups (p> 0.05) (Figure 1).

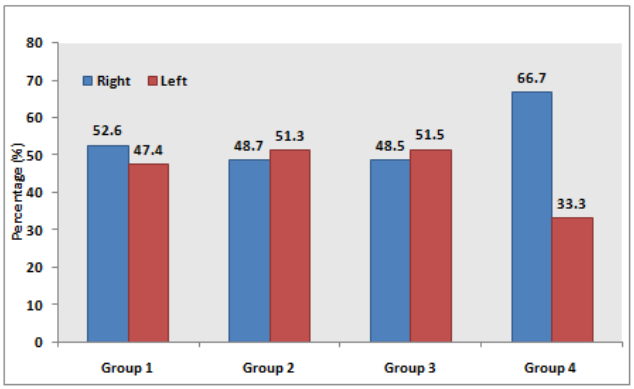

Figure 1. Comparison of stone location in different groups

The stone-free rates for groups 1, 2, 3 and 4 were 47.37%, 56.41%, 63.64% and 94.12% (P < .0001) respectively . The Efficiency Quotient rate for group 4 was 0.91. Across treatment groups, ureteroscopy was significantly more effective in terms of the stone-free rate (P < .0001) (Figure 2). In both the patients with stones smaller than 10 mm^2 and in those with stones larger than 10 mm^2, surgical treatment was also significantly more effective in terms of the stone-free rate (P = 0.025). In groups 1 and 2 (groups treated non-surgically), there was no significant difference in terms of the stone-free rate (P= 0.21); furthermore.

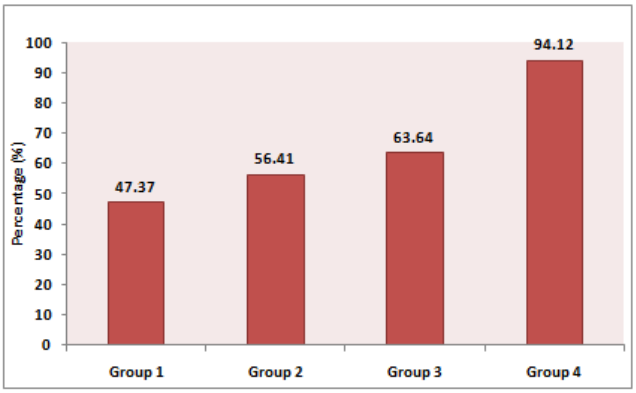

Figure 2. Comparison of stone free rate in different groups

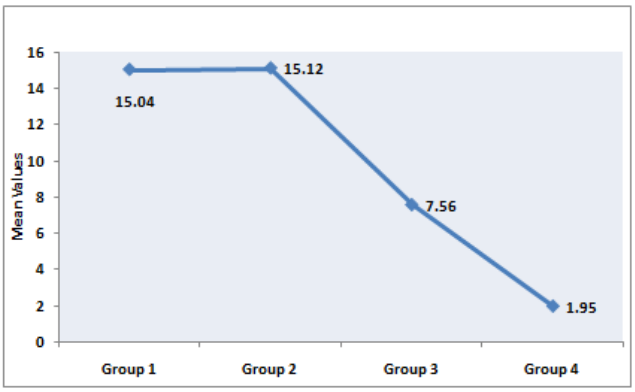

Figure 3. Comparison of mean values of expulsion time in different groups

The mean expulsion times for groups 1, 2, 3 and 4 were 15.04 ± 3.80, 15.12 ± 2.45, 7.56 ± 4.31 and 1.95 ± 1.08 days respectively are shown in Table 1 (Figure 3). Compared to groups 1 and 2, and 3 the expulsion time for the ureteroscopy group (group 4) was statistically different. Ureteroscopy was also significantly more effective than other treatment modalities (P < .001). In group 3 and 4 complications and re-ESWL rate and re-uretroscopy rate was higher as per stone bulk.

DISCUSSION

Most of the ureteric stones pass spontaneously and do not require intervention. Spontaneous passage depends on the stone size, shape, location, and associated ureteral edema, which is likely to depend on the length of time that a stone has not progressed. The vast majority of stones that pass do so within a six weeks period after the onset of symptoms. Due to recent technological advances, there are many options for the treatment of ureteral stones. The factors that determine suitable treatment choices include stone location, number of stones, renal function, surgical experience, additional patient health factors, technological qualification, cost and the patient's decision (Romero *et al.,* 2010, Geavlete *et al.,* 2006). Location and stone size should always be considered before deciding on observation. Small stones that are distally located are more suited to spontaneous passage. Spontaneous passage rate falls significantly for stones larger than 5 mm (Romero *et al.,* 2010, Eshard *et al.,* 1996, Harmon *et al.,* 1997).

Table 1. Comparison of Patients' characteristics, stone-free rate and expulsion time in the four treatment groups

Characteristics	Treatment Group (n=161)				Total Patients	p value
	Group 1 (n=38)	Group 2 (n=39)	Group 3 (n=33)	Group 4 (n=51)		
Age	29.66 ± 6.30	30.64 ± 6.21	30.06 ± 5.24	31.84 ± 5.85	30.67 ± 5.94	0.331
Sex, n (%)						
Males	23 (60.5)	25 (64.1)	17 (51.5)	32 (62.7)	97 (60.2)	0.699
Females	15 (39.5)	14 (35.9)	16 (48.5)	19 (37.3)	64 (39.8)	
Stone Location						0.253
Right	20 (52.6)	19 (48.7)	16 (48.5)	34 (66.7)	89 (55.3)	
Left	18 (47.4)	20 (51.3)	17 (51.5)	17 (33.3)	72 (44.7)	
Stone Diameter (mm^2)	6.83 ± 2.36	7.59 ± 2.69	7.93 ± 3.01	8.34 ± 3.86	7.72 ± 3.13	0.149
Stone-free rate, n (%)	18 (47.37)	22 (56.41)	21 (63.64)	48 (94.12)	109 (67.70)	< 0.0001
Expulsion time (day)	15.04 ± 3.80	15.12 ± 2.45	7.56 ± 4.31	1.95 ± 1.08	9.38 ± 6.54	< 0.0001

P values are for total stone-free rates.

Morse and colleagues found that distal ureteral stones pass spontaneous 71% of the time, whereas Hübner and colleagues reported an expulsion rate of distal ureteral stones of 45% (Morse and Resnick, 1991). Miller and Kane reported that stones of size <2mm, 2–4mm and 4–6mm passed out by 31, 40 and 39 days, respectively (Miller and Kane, 1999). In our study, the stone expulsion rate in the observational group was 48.7%. This rate was higher in individuals with stones smaller than 10 mm^2 (52.9%), but this rate was not significantly higher than that for stones larger than 10 mm^2. Both observation and treatment of distal ureteral stones have advantages and disadvantages. For observation, the disadvantages are persistent renal colic and frequent physician visits. Furthermore, urinary diversion or urgent intervention is sometimes required. Therefore, observation as the first choice remains controversial. Larger stones are unlikely to have spontaneous passage. Medical expulsion therapy (MET) can be attempted to increase stone expulsion rate. As the ureters are lined by smooth muscle which has alpha adrenoceptors, alphablockers such as tamsulosin may reduce the ureteric spasm and allow normal peristalsis to facilitate stone passage out of the ureter (Hollingsworth *et al*., 2006).

The presence of a ureteral stone often causes ureteral spasm, edema, pain and infection. The purpose of MET is to relax the smooth muscle, relieve pain and decrease edema without impeding peristalsis. Blockage of alpha-receptors, which are located throughout the ureter but are concentrated distally, causes propulsive contractions without blocking physiologic peristalsis (Hollingsworth *et al*., 2006). Various studies have shown that alpha-blockers accelerate the passage of the distal ureteral stones (Hollingsworth *et al*., 2006; Itoh *et al*., 2007; Singh *et al*., 2007). In a meta-analysis on the treatment of ureteral stones with alpha-blockers, it was shown that the use of alpha-blockers increases the rate of spontaneous passage to as high as 44% (Mugiya *et al.,* 2000).

Additionally, in a study by Küpeli and colleagues, it was shown that the addition of tamsulosin increased the rate of distal stone clearance (Kupeli *et al*., 2004). In a study by Erturhan and colleagues, the stone-free rate in individuals with distal ureteral stones was 73.3% following treatment with tamsulosin alone (Erturhan *et al*., 2007). On the other hand, Hermanns and colleagues showed that tamsulosin treatment does not improve stone expulsion rates in patients with distal ureteral stones ≤ 7 mm (Hermanns *et al*., 2009). In our study, the stone-free rate was 59.5% in the tamsulosin group (group 2).

In patients with stones smaller than 6 mm, the stone-free rate was 60.8%, and in individuals with stones larger than 6 mm, it was 57.8%. Ureterorenoscopy was performed in 41.5% of these patients due to the failure of medical treatment. In contrast to the literature, we found no significant difference between the tamsulosin and observational groups for distal calculi of less than 10 mm^2. As mentioned above, the addition of tamsulosin to the medical treatment of distal ureteral stones has been shown to increase expulsion rates. However, there are two parameters that remain controversial: the duration of treatment and problems such as uncontrollable pain, the development of hydronephrosis, and surgical intervention.. Although tamsulosin increases the expulsion of distal ureteral stones, we think that the use of alpha-blockers should not be the standard of care due to the controversial treatment duration and the high need of surgical intervention. Because of improvements in instrumentation coupled with ureteroscopy's quick learning curve, ureteroscopy is the best treatment for ureteral stones. Although extra SWL was historically the first choice treatment for ureteral stones, the 2010 European Association of Urology (EAU) urolithiasis guidelines now list ureteroscopy as the best choice (Tiselius *et al*., 2001; Turk *et al*., 2010).

Additionally, in the guidelines published by Preminger and colleagues, URS is the treatment of choice for mid and distal ureteral stones smaller than 10 mm (Preminger *et al*., 2007). The ureteroscopy is the treatment with the highest stone-free rate after a single procedure for distal ureteral stones (Preminger *et al*., 2007; Tiselius *et al*., 2001). Thus, patients with ureteral stones also prefer URS over other treatments due to immediate cessation of pain and disability. In fact, Perchel and colleagues reported patient satisfaction in 100% of ureteroscopy cases (Peschel *et al*., 1999). Ureteroscopes and different lithotripsy methods have greatly improved the urologist's ability to treat ureteral stones, regardless of their location in the ureter (Kadir *et al*., 2005). The availability of gadgetry and experience gained by urologists in endoscopic procedures has made ureteroscopic lithotripsy safe and effective in treatment of ureteric stones at any level (Weimin Yu, 2010). The clinical availability of smaller caliber ureteroscopes has allowed the indication of ureteroscopy to expand greatly. Ultrasonic, electrohydrolic, laser and pneumatic lithotripters are widely used methods of lithotripsy. The effectiveness of ureteroscopy is well known in the treatment of distal ureteral stones when pneumatic lithotripters

are used. (Romero *et al*., 2010; Tiselius *et al*., 2001; Peschel *et al*., 1999).

In our study, we also used a pneumatic lithotripter that is a widely used and comparatively inexpensive. In a study by Ceylan and colleagues, they reported a 95.0% success rate for 209 distal ureteral stones (average size of 8.7 mm^2) treated with URS (Ceylan *et al*., 2005). Tuğcu and colleagues reported a success rate of 96.7% in their group of patients with distal ureteral stones (average size of 9 mm^2) (Tuğcu *et al*., 2006). In our study, the average stone size was 7.8mm^2, and our success rate for ureteroscopy was 95.6%. This result shows that ureteroscopy is more effective than observation and alpha-blockers for the treatment of distal ureteral stones smaller than 10 mm. Stone size and localization affect ureteroscopy success (Preminger *et al*., 2007; Tunc *et al*., 2007).

If the location of the stones is near the distal proportion of the ureter, ureteroscopy success is more likely (Romero *et al*., 2010; Tiselius *et al*., 2001; Tunc *et al*., 2007; Ather *et al*., 2009) Thus, distally located stones smaller than 10 mm are more suitable for ureteroscopy. The ureteroscopy also has a lower complication rate, morbidity and mortality compared to other treatments. In addition, it is much more effective. Factors included male sex, proximal ureteral stone, large stone size, surgical inexperience and symptoms for more than three months may increase the complication rate (Fuganti *et al*., 2008; Abdelrahim *et al*., 2008). In our study, there were no major or minor complications in patients treated with URS. Thus, we think that it is unnecessary to treat patients with alpha-blockers for distal ureteral stones of any size, unless the patient cannot tolerate ureteroscopy.

Shock wave lithotripsy (SWL) and ureteroscopy (URS) are both effective treatments for removal of distal ureteral calculi, associated with high success rates and limited morbidity. The American Urological Association Ureteral Stones Clinical Guidelines Panel has found both to be acceptable treatment options for patients, based on the stone-free results, morbidity, and retreatment rates for each respective therapy Ojas *et al*., 2003). However, costs and patient satisfaction or preference were not addressed, and the report was based on data derived from older endoscopic and lithotripsy technology. Each of these treatment options has valid advantages and disadvantages. Both modalities are reasonable treatment options for the majority of patients with distal ureteral calculi. Whereas SWL is less invasive, the high, immediate success rate with minimal morbidity and decreased cost makes URS a very valid competitor.

The results of treating patients with larger stones favor URS. About composition, calcium oxalate monohydrate, brushite, cystine and matrix are unfavourable compositions for ESWL (Krishna Reddy *et al*., 2014). Tao Li and colleagues in their meta-analysis suggested that URS pneumatic ureteroscopic lithotripsy had large advantages over extracorporeal shock wave lithotripsy in the treatment of lower ureteral stones (Tao Li *et al*., 2014). Extracorporeal shock wave lithotripsy had a higher incidence of colic pain than pneumatic ureteroscopic lithotripsy. Finally, impacted stones are often more resistant to fragmentation. Whether hydronephrosis affects the outcome of ESWL remains controversial. A body mass index of over 30 has been found to be an independent factor in predicting failure of ESWL treatment in ureteral stones. In summary, we believe that in situ ESWL provides optimal first line therapy for distal ureteral calculi, while ureteroscopy is better reserved as a salvage procedure should ESWL fail.

Conclusion

In our conclusion ureteroscopy has shown to be the most effective in our study. The advantages of ureteroscopy are its low complication rate, short expulsion time, and high stone-free rate after a single application and high patient satisfaction. Therefore, we believe that ureteroscopy should be the standard treatment for distal ureteral stones smaller than 15 mm^2.

Conflict of Interest

None declared.

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