

Comparison of semirigid ureteroscopy, flexible ureteroscopy, and shock wave lithotripsy for initial treatment of 11-20 mm proximal ureteral stones

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Summary *Objective: We aimed to retrospectively evaluate the effectiveness and safety of flexible ureteroscopy (f-URS), semirigid ureteroscopy (sr-URS), and shock wave lithotripsy (SWL) to treat single 11-20 mm stones in the proximal ureter.*

Materials and methods: Patients treated at our clinic for 11-20 mm single stones in the proximal ureter who underwent f-URS, sr-URS or SWL as initial lithotripsy methods were compared in terms of their clinical characteristics and treatment outcomes.

Results: A comparison among 201 patients who had undergone f-URS, 119 patients who had undergone sr-URS, and 162 patients who had undergone SWL showed no significant baseline differences in patients' demographic and stone characteristics. Stone-free rates on the 15th day and 3rd month were higher with f-URS (89.6% and 97%, respectively) than with sr-URS (67.2% and 94.1%, respectively) and SWL (41.4% and 79.0%, respectively; all $p < 0.001$). Retreatment rates were significantly higher with SWL than with the other two modalities ($p < 0.001$); auxiliary procedure rates were significantly lower with f-URS than with the other two modalities ($p < 0.001$).

Treatment-related complication rate at the end of the 3rd month was lower with f-URS than with SWL ($p = 0.022$).

Furthermore, f-URS was more effective than sr-URS for treating impacted stones.

Conclusions: We found that f-URS was highly successful as an initial lithotripsy procedure for medium-sized proximal ureteral stones, and it helped achieve early stone-free outcomes with a lower need for retreatment and auxiliary procedures, lower complication rates, and higher effectiveness on the impacted stones compared with sr-URS and SWL.

KEY WORDS: Lithotripsy; Ureter; Ureteroscopy.

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INTRODUCTION

Urinary tract stones are frequently encountered in urology practice. Shock wave lithotripsy (SWL), ureteroscopy (URS), percutaneous nephrolithotomy, laparoscopy, and open surgery are available as the treatment modalities for proximal ureteral stones sized > 1 cm (1, 2).

European Association of Urology guidelines recommend URS and SWL as primary treatments for stones sized

1.1-2 cm. The American Urological Association guidelines recommend URS as the optimal treatment but state that patients must be informed about the increased risk of complications and morbidity associated with URS compared with that with other methods (3, 4). The effectiveness and safety of the available methods for treating large proximal ureteral stones have been compared in various recent studies and meta-analyses (1, 5-8).

The use of flexible ureteroscopy (f-URS) for stones in the proximal ureter has increased due to advances in technology. Flexible URS has been compared with semirigid-ureterorenoscopy (sr-URS) and sr-URS has been compared with SWL; (9, 11) however, comparisons including all three procedures for the treatment of stones in the proximal ureter are not available. This study evaluated the outcomes, safety, effectiveness, and associated complications of f-URS, sr-URS, and SWL as the initial lithotripsy treatment for patients with proximal ureteral stones sized 11-20 mm.

MATERIALS AND METHODS

Following approval by the local ethics committee, patients treated at our clinic between January 2013 and June 2018 for single stones sized 11-20 mm and located in the proximal ureter were retrospectively evaluated. The proximal ureter was defined as the region between the ureteropelvic junction and the sacroiliac joint (12). Patients with multiple stones, history of surgery or anatomical anomalies on the same side, solitary kidneys, concurrent pregnancy, and concomitant intrarenal stones and those aged < 18 years were excluded. Detection of stone and evaluation of the treatments were performed using kidney-ureter-bladder X-ray, ultrasound imaging, and/or contrast/non-contrast computed tomography.

The procedure was selected after patients were informed in detail about possible re-treatment rates, the possibility of shifting to other treatment, and complications. Written informed consents were taken from all patients. In patients for whom URS was chosen, f-URS was pre-

ferred mostly for patients with grade 3 and 4 hydronephrosis or with stones closer than 5 cm to the ureteropelvic junction. On the other hand, sr-URS was preferred mostly for patients with stones located more than 5 cm away from the ureteropelvic junction by considering the cost. Furthermore, several factors such as the repair process of the device or the intensive use of the f-URS device were effective factors in the device selection in our clinic. To conclude, the device to be used was decided following the joint evaluation of factors such as patient and stone characteristics, socioeconomic reasons, and choice of surgeon. Patients with active infections were treated after administering antibiotic therapy and obtaining clean urine cultures. For the analysis, patients were stratified by lithotripsy procedure into f-URS, sr-URS, or SWL groups. The patient characteristics included in the analysis were age, sex, side, stone size (recorded as the longest of axial, coronal, or sagittal diameters), body mass index (BMI, kg/m²), operation time (in minutes), stone-free rate (SFR %) on the 15th day and 3rd month, length of hospital stay (in days), complication rate, and need for retreatment and auxiliary procedures. In this study, local inflammation and swelling associated with impacted stones in the sr-URS and f-URS groups was confirmed through endoscopy as previously described (13). The preoperative and postoperative outcomes of the selected ureteroscopy type were assessed.

Treatment success required achievement of a complete stone-free state or the presence of clinically insignificant residual fragments < 3 mm, which was also considered to be a stone-free state.

The 15-day follow-up evaluation included the outcomes of the first session of any procedure. The 3-month follow-up included evaluation of any auxiliary procedures. Effectiveness was determined on the basis of the percentage of procedures that resulted in a stone-free state at 3 months. The efficiency quotient was calculated using the formula: = (stone free % × 100)/[100 + retreatment (%) + auxiliary procedures (%)]. Perioperative complications were graded based on the modified Clavien classification system.

SWL

SWL was performed as an outpatient procedure using an electrohydraulic extracorporeal lithotripter (*Multimed Classic, Elmed, Ankara, Turkey*). The procedure and its effectiveness have been previously described (7, 14). Intramuscular nonsteroidal anti-inflammatory medication was administered prior to the procedure, and fluoroscopy and/or ultrasonography was used as the focusing method, with patients in the prone position. The procedure was concluded after seeing fragmentation on fluoroscopy or after a maximum of 3,000 shock waves. Patients without clearance after three sessions were referred for other modalities or follow-up. Additional sessions were not scheduled earlier than 15 days.

sr-URS

The procedures were performed under general anesthesia using a 6/7.5 F sr-URS device (*Richard Wolf, Knittlingen, Germany* or *Karl Storz, Tuttlingen, Germany*).

Lithotripsy was performed using a Medilas H20 holmium laser (*Dornier Med-Tech GmbH, Wessling, Germany*). An energy of 0.8-1.5 joules and a frequency of 8-12 Hz were preferred. Insertion of a 4.8-F, 26-cm ureteral stent was not standard but was performed based on the surgeon's judgment. Ureteral stents were removed after 2-4 weeks. In cases where stones in the proximal ureter were pushed back to the kidney, the procedure was switched to f-URS in the same session. Such patients were considered sr-URS failures and were not included in the f-URS group as the intervention was intrarenal. Switching from sr-URS to f-URS was accepted as an auxiliary procedure.

f-URS

The procedures were performed under general anesthesia using a 7.5-F f-URS device (*Flex X2; Karl Storz GmbH, Tuttlingen, Germany*). A 0.038-inch floppy guidewire was advanced past the stone through the ureteral orifice following cystourethroscopy. In some cases, a 9.5-11-F access sheath (*Elit Flex, Ankara, Turkey*) was passed over the guidewire. Either a 20 watt Dornier Medilas H-20 or a 30 watt Medilas H Solvo holmium laser at a wavelength of 2.1 μm (*Dornier Med-Tech, Wessling, Germany*) was used. Insertion of a 4.8-F, 26-cm ureteral stent was not standard but was performed depending on the surgeon's choice. The ureteral stent was removed in 2-4 weeks. Push-up of the stone was not considered as a complication or failure in the f-URS procedure and lithotripsy was continued in the intrarenal area.

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics 17.0 (*IBM Corporation, Armonk, NY, USA*). Kolmogorov-Smirnov test was used to evaluate whether the distribution of continuous quantitative variables was normal. Levene test was used to determine whether the precondition of homogeneity of variances was fulfilled. Descriptive statistics were reported as means ± standard deviation for quantitative variables and as numbers and percentages (%) for categorical variables. The significance of differences in quantitative variables that met the assumptions of the parametric test statistics was evaluated using one-way analysis of variance (ANOVA). The significance of differences in the quantitative variables that did not meet the assumptions of the parametric test statistics was evaluated using Mann-Whitney U test for two independent groups and Kruskal-Wallis test for more than two independent groups. If the results of the Kruskal-Wallis test were significant, Conover's test of multiple comparisons was used to determine the reason for the difference. Categorical variables were evaluated using Pearson's chi-square, Fisher's exact probability, chi-square with continuity correction, or likelihood ratio tests. A P value of < 0.05 was considered statistically significant.

RESULTS

A total of 482 patients, 119 who underwent sr-URS, 201 who underwent f-URS patients, and 162 who underwent SWL for initial lithotripsy, were included in the analysis. The groups did not differ in age, sex, side, *American*

Society of Anesthesiologists (ASA) score, BMI, the presence of hydronephrosis, or stone size ($p \geq 0.05$). Patients in the SWL group exhibited shorter operation time and length of hospital stay than those in either URS group ($p < 0.001$). The success rate was higher with f-URS than

with either sr-URS or SWL ($p < 0.001$) and was higher with sr-URS than with SWL ($p < 0.001$, Figure 1).

Stones were either intraoperatively pushed back into the kidney, or optimal fragmentation was not achieved, in 24 sr-URS procedures; a stone-free state was achieved in 21 of the 24 patients following a switch to f-URS. Any extra related complication was not seen in this switch. In 152 (75.6%) of the 201 patients who underwent initial f-URS, the lithotripsy procedure was initiated after insertion of an access sheath.

A ureteral stent was inserted for 20 patients to passively dilate the ureter since access could not be achieved. These patients were re-treated at least two weeks later; 6 patients were treated with sr-URS and 14 patients with f-URS. Insertion of the ureteral stent may cause bias in evaluations since there were patients who underwent stent insertion before SWL for reasons such as renal colic, and there were some groups who prefer stent insertion before ureteroscopy to passively dilate the ureter. Therefore, this process should be considered as a part of the procedure and not considered as failure. The patients were included in the groups according to the subsequent procedures. Retreatment rates were significantly higher with SWL than with the other modalities ($p < 0.001$). The auxiliary procedure rate was significantly lower with f-URS than with sr-URS or SWL (both $p < 0.001$). Auxiliary procedures were performed in 28 sr-URS patients. The high rate resulted from conversion to f-URS in 20.2% of the sr-URS procedures. SFRs were higher with URS than with SWL procedures ($p < 0.001$). The highest efficiency quotient was 0.89, which was achieved in the f-URS group (Table 1).

A maximum of three sessions were performed for each SWL procedure. The mean number of shockwaves and the power decreased at each subsequent session, but the complication rate increased (Table 2). Hydronephrosis had a negative effect on treatment success in the SWL group patients (odds ratio = 40.042, 95% confidence interval: 9.108-176.035; $p < 0.001$).

Regarding complication rates, there was no significant difference among the three groups on the 15th day after the initial procedure ($p = 0.066$); however, a significant difference was observed at the end of the 3rd month ($p = 0.022$). The mentioned difference was caused by the higher complication rates associated with SWL than with f-URS ($p = 0.006$). However, all three groups showed no differences with regard to the distribution of complications based on the *modified Clavien classification system* (MCCS) ($p > 0.05$). Although SWL was associated with a higher overall complication rate, the complications were minor as per MCCS. Sepsis developed in one patient each in the f-URS and sr-URS groups and required monitoring in the intensive care unit. None of the patients died

Figure 1. Stone-free response achieved on the 15th day and 3rd month after the initial lithotripsy procedure.

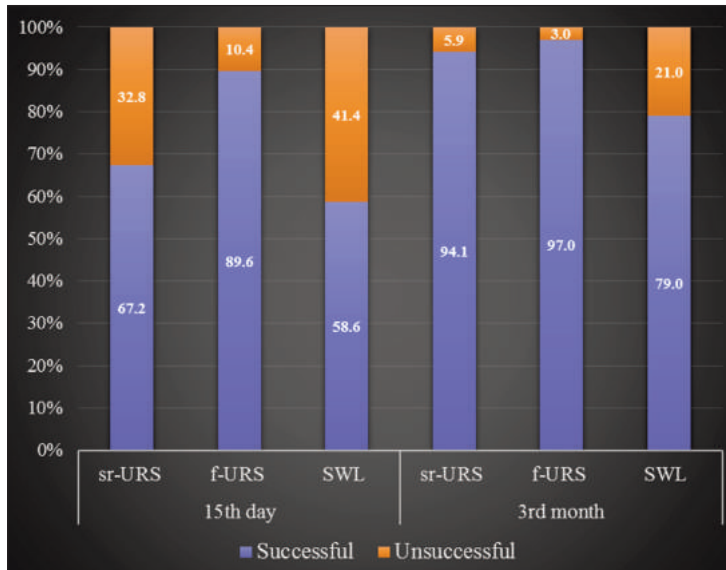


Table 1. Patient characteristics, interventions, and treatment outcomes on 15th day and 3rd month after the initial lithotripsy treatment.

	sr-URS (n = 119)	f-URS (n = 201)	SWL (n = 162)	p-value
At the end of the 15th day				
Age	43.9 ± 13.1	44.5 ± 13.1	43.6 ± 12.6	0.774 ^a
Gender (female/male)	32/87	49/152	35/127	0.586 ^b
Side (right /left)	59/60	96/105	79/83	0.950 ^b
ASA score	1.65 ± 0.73	1.73 ± 0.68	1.70 ± 0.70	0.415 ^c
Anticoagulant use, n (%)	1 (0.8%)	7 (3.5%) ^e	0 (0.0%) ^e	0.010 ^d
BMI (kg/mm ²)	25.1 ± 2.5	25.3 ± 2.7	24.8 ± 2.1	0.186 ^a
Presence of hydronephrosis, n (%)	102 (85.7%)	178 (88.6%)	129 (79.6%)	0.059 ^b
Stone size (mm)	13.9 ± 2.6	13.6 ± 2.4	13.4 ± 2.6	0.062 ^c
Operation time (minutes)	41.6 ± 13.7 ^{f,g}	50.2 ± 10.9 ^{e,f}	30.9 ± 3.9 ^{e,g}	< 0.001 ^e
Complication, n, (%)	22 (18.5%)	24 (11.9%)	15 (9.3%)	0.066 ^b
Length of hospital stay	1.5 ± 1.6 ^g	1.3 ± 1.1 ^e	0.3 ± 1.1 ^{e,g}	< 0.001 ^e
SFR (day 15)	39/80 (67.2%) ^f	21/180 (89.6%) ^{e,f}	95/67 (41.4%) ^e	< 0.001 ^b
Efficiency quotient	0.51	0.89	0.24	
At the end of the 3rd month				
Additional intervention				
Retreatment	8 (6.7%) ^g	8 (4.0%) ^e	75 (46.3%) ^{e,g}	< 0.001 ^b
Auxiliary procedure	28 (23.5%) ^f	9 (4.5%) ^{e,f}	42 (25.9%) ^e	< 0.001 ^b
Total complications *	22 + 2 (20.2%)	24 + 3 (13.4%) ^e	15 + 25 (24.7%) ^e	0.022 ^b
Emergency department visit	5 (4.2%) ^g	4 (2.0%) ^e	23 (14.2%) ^{e,g}	< 0.001 ^b
Total operation time (min) *	44.9 ± 17.8 ^{f,g}	53.3 ± 17.5 ^f	61.4 ± 33.0 ^g	< 0.001 ^e
Total length of hospital stay(day) *	1.6 ± 1.6 ^g	1.4 ± 1.4 ^e	0.9 ± 1.8 ^{e,g}	0.001 ^b
3 rd month SFR *	7/112 (94.1%) ^g	6/195 (97.0%) ^e	34/128 (79.0%) ^{e,g}	< 0.001 ^b
Mean number of interventions	1.3 ± 0.5 ^{f,g}	1.2 ± 0.4 ^{e,f}	1.9 ± 1.0 ^{e,g}	< 0.001 ^e

*first + additional procedures; ^a one-way ANOVA; ^b Pearson's chi-square test; ^c Kruskal-Wallis test; ^d likelihood ratio; ^e $p < 0.05$; f-URS vs. SWL; ^f $p < 0.01$; sr-URS vs. f-URS; ^g $p < 0.01$; sr-URS vs. SWL. sr-URS = semirigid ureteroscopy; f-URS = flexible ureteroscopy; SWL = shock wave lithotripsy; ASA = American Society of Anesthesiologists; BMI = body mass index; SFR = stone-free rate.

Table 2.
Properties of the shock wave lithotripsy sessions.

	Session 1	Session 2	Session 3
Number of patients	162	76	35
Presence of hydronephrosis n (%)	129 (79.6%)	75 (98.7%)	34 (97.1%)
Success n (%)	95 (58.6%)	56 (73.7%)	29 (82.9%)
Complication n (%)	15 (9.3%)	10 (13.2%)	8 (22.9%)
Number of shocks	2574.4 ± 332.4	2439.5 ± 315.8	2201.4 ± 373.1
Power (kV)	16.6 ± 1.2	16.3 ± 1.2	15.4 ± 0.4

Table 3.
Complications following the initial procedure based on the modified Clavien classification system.

	sr-URS (n = 119)	f-URS (n = 201)	SWL (n = 162)	p-value
I	12 (10.1%)	11 (5.5%)	9 (5.6%)	0.220 ^a
II	6 (5.0%)	8 (4.0%)	4 (2.5%)	0.517 ^a
III	3 (2.5%)	4 (2.0%)	2 (1.2%)	0.716 ^b
IV	1 (0.8%)	1 (0.5%)	0 (0.0%)	0.411 ^b
V	0 (0.0%)	0 (0.0%)	0 (0.0%)	-

^a Pearson's chi-square test; ^b likelihood ratio test.
sr-URS: semirigid ureteroscopy; f-URS: flexible ureteroscopy; SWL: shock wave lithotripsy.

Table 4.
Intraoperative and postoperative outcomes of ureteroscopic lithotripsy in the treatment of impacted stones.

	sr-URS (n = 41)	f-URS (n = 91)	p-value
Stone size (mm)	15.4 ± 2.6	14.8 ± 2.5	0.246 ^a
Operation time (min)	50.1 ± 20.9	59.2 ± 21.3	0.023 ^a
15 th day SFR	20/21 (51.2%)	17/74 (81.3%)	< 0.001 ^b
Total SFR	5/36 (87.8%)	5/86 (94.5%)	0.284 ^c
Total complication n (%)	12 (29.3%)	14 (15.4%)	0.105 ^b
Length of hospital stay (days)	2.3 ± 2.3	1.6 ± 1.7	0.011 ^a
Retreatment n (%)	5 (12.2%)	6 (6.6%)	0.316 ^c
Auxiliary procedure n (%)	13 (31.7%)	8 (8.8%)	0.002 ^b

^a Mann-Whitney U test; ^b chi-square test with continuity correction; ^c Fisher's exact probability test.
SFR: stone-free rate.

(Table 3). The rate of visit to the emergency department for renal colic or other reasons was significantly higher after SWL than after the URS procedures ($p \leq 0.001$). In addition to the treatments needed to manage the complications occurring after the primary treatment, for temporary relief, four ureteral stents and one percutaneous nephrostomy were needed in sr-URS patients, two ureteral stents and one percutaneous nephrostomy in f-URS patients, and three ureteral stents and one percutaneous nephrostomy in SWL patients. These events were included in the analysis as auxiliary procedures. A sub-analysis was performed to evaluate the difference in outcomes achieved with f-URS and sr-URS in impacted stones. A SFR of 81.3% was achieved with f-URS compared with 51.2% achieved with sr-URS following the first session ($p \leq 0.001$). Stone size, total SFR, and complication and retreatment rates did not differ significantly with the type of URS ($p > 0.05$). However, f-URS was associated with longer operation times ($p = 0.023$), shorter length of hospital stay ($p = 0.011$), and less need for auxiliary treatments ($p = 0.002$) compared with sr-URS (Table 4).

DISCUSSION

As only about 22% of upper ureteral stones are spontaneously passed, surgical intervention is usually required (15). Given the ineffectiveness of medical expulsion therapy, nearly all patients with stones of the size treated in this study require intervention (16). The method chosen to treat upper ureteral stones depends on factors including stone size, pain severity and duration, presence of obstruction, cost, quality of life, surgeon experience, and available resources (17). SWL and URS are most commonly used methods; both the procedures have specific advantages and disadvantages and variable outcomes have been reported (8, 18). SWL was previously preferred even for stones sized < 10 mm, but the outcomes with SWL and URS have been currently reported to be comparable and either can be recommended as the primary treatment (18). URS may provide higher SFRs for stones sized > 10 mm, but it is associated with higher complication rates than SWL. This short-term study is consistent with previous reports of higher success and lower complication rates with f-URS compared with sr-URS and SWL. A recent meta-analysis has reported that URS-associated complications have been decreasing without any corresponding decrease in SFR because of improved technology, flexible devices, better tools, and the use of holmium YAG lasers (8). A prospective study of over 9600 patients reported increased success rates and decreased complications in the treatment of proximal ureteral stones using flexible devices (19). The risk of pushing a stone into the kidney is increased if it is located near the ureteropelvic junction; this occurred in 22% of the sr-URS procedures in this study. The switch to f-URS involves increased time, effort, and cost. Possible hemorrhage and loss of clear vision (10, 20) can make it difficult to switch to f-URS in the same session. However, even if the stone is pushed back with f-URS, intrarenal stones can be accessed, providing the opportunity to complete the treatment without additional interventions as opposed to sr-URS and SWL. Moreover, the superiority of f-URS is obvious in cases of concomitant upper ureteral and renal stones (21), which were not included in this study. The high rate of intraoperative conversion to f-URS in this study explains the large percentage of auxiliary procedures that were performed in patients initially treated with sr-URS. f-URS offers advantages such as being easily maneuvered in the ureter and, in particular, is less affected by a long urethra in males and by the restricted motion in the proximal urethra, unlike sr-URS. Besides, a conversion can be made from sr-URS to f-URS in appropriate cases when the stone is pushed back. In this study, a conversion from sr-URS to f-URS was made in 24 (20.1%) patients, and despite prolonged operation times, stone-free states were achieved in a single session in 21 (87.5%) of the 24 patients. These results suggest that, even if the procedure is initiated with sr-URS, f-URS must be available during the procedure to save patients from undergoing additional sessions. Even though SWL is less invasive than f-URS, it cannot be used in patients with bleeding diathesis and morbid obesity or in pregnant patients. It is accompanied by high radiation exposure from fluoroscopy, is affected by stone composition, and requires repeated application to

achieve a stone-free state (22). The use of radiation in f-URS is decreasing, and some reports have described a successful use f-URS with no radiation exposure (23). Success rates with a single SWL session are low, but stone-free outcomes comparable to those with URS can be achieved with repeated sessions. Repetition improved the SWL success rate in this study, but it remained lower than that achieved with URS. The stone-free outcome with SWL was not lower than that reported in previous studies, but SWL was not as effective as f-URS in this patient series because of the quality of the ureteroscopy devices and experience of the surgeons. Other investigators have reported fewer complications after SWL than URS. In this study, treatment-associated complications were more frequent with SWL than with f-URS or sr-URS because of the occurrence of renal colic in our SWL group patients. It was generally of mild severity but often resulted in a visit to the emergency department for outpatient treatment. Our results are in line with previous studies reporting renal colic as a frequent complication of SWL (24, 25) The low complication rates associated with URS might result from the use of advanced, flexible ureteroscopy devices and the experience of the surgeons at our clinic, who have performed nearly 3,000 f-URS procedures. The occurrence of renal colic was not been monitored in all studies, which would also contribute to a low incidence of complications. The safety of f-URS in elderly patients with comorbidities compared with that of SWL and sr-URS may also make it the preferred choice for initial lithotripsy in that population (26). Although the cost of f-URS is high, it offers cost benefits because of its high success rate, low complication rate, low need for retreatment, and short recovery time. The treatment of impacted stones is challenging and is associated with decreased success and increased complication rates with both URS and SWL (27, 28). Endoscopy is the most objective method to identify impacted stones, and we evaluated the effectiveness of URS for treating impacted stones in the proximal ureter. Better results were observed with f-URS than with sr-URS, similar to the report of Legateme *et al.* (13). Length of hospital stay was greater with sr-URS than with f-URS, which probably reflects the more frequent occurrence of sr-URS complications. When used as the initial treatment, f-URS also provided greater success with fewer auxiliary procedures than sr-URS, and beginning the treatment of impacted stones with f-URS appears to be advantageous overall. The study had some limitations such as not including stone composition in the comparison and not being able to perform a cost analysis. The single-center retrospective design and lack of randomization limit the ability to generalize the findings. Other limitations include not considering development of lower urinary tract symptoms and the need for analgesics, which might have influenced treatment selection. Finally, late complications such as ureteral obstruction might have been missed because of the short follow-up.

CONCLUSIONS

In this patient series, f-URS was found to be more effective than sr-URS and SWL for initial lithotripsy of 11-20-

mm proximal ureteral stones. f-URS helped achieve a better success rate at 15 days with less need for retreatment and auxiliary procedures and better effectiveness for impacted stones compared with sr-URS and SWL. These results support the need for a prospective randomized controlled trial to provide sufficient evidence to recommend f-URS as the initial procedure for lithotripsy of proximal ureteral stones.

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