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A Prospective, Multi-Institutional Study of Flexible Ureteroscopy for Proximal Ureteral Stones Smaller than 2 cm

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Abstract

Purpose—Flexible ureteroscopy is rapidly becoming a first line therapy for many patients with renal and ureteral stones. However, current understanding of treatment outcomes in patients with isolated proximal ureteral stones is limited. Therefore, we performed a prospective, multi-institutional study of ureteroscopic management of proximal ureteral stones smaller than 2 cm to better define clinical outcomes associated with this approach.

Materials and Methods—Adult patients with proximal ureteral calculi smaller than 2 cm were prospectively identified. Patients with concomitant ipsilateral renal calculi or prior ureteral stenting were excluded from study. Flexible ureteroscopy, holmium laser lithotripsy and ureteral stent placement was performed. Ureteral access sheath use, laser settings and other details of perioperative and postoperative management were based on individual surgeon preference. Stone

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Study received institutional review board approval at each site.

clearance was determined by the results of renal ultrasound and plain x-ray of the kidneys, ureters and bladder 4 to 6 weeks postoperatively.

Results—Of 71 patients 44 (62%) were male and 27 (38%) were female. Mean age was 48.2 years. ASA® score was 1 in 12 cases (16%), 2 in 41 (58%), 3 in 16 (23%) and 4 in 2 (3%). Mean body mass index was 31.8 kg/m^2, mean stone size was 7.4 mm (range 5 to 15) and mean operative time was 60.3 minutes (range 15 to 148). Intraoperative complications occurred in 2 patients (2.8%), including mild ureteral trauma. Postoperative complications developed in 6 patients (8.7%), including urinary tract infection in 3, urinary retention in 2 and flash pulmonary edema in 1. The stone-free rate was 95% and for stones smaller than 1 cm it was 100%.

Conclusions—Flexible ureteroscopy is associated with excellent clinical outcomes and acceptable morbidity when applied to patients with proximal ureteral stones smaller than 2 cm.

Keywords

ureter; kidney; calculi; ureteroscopy; diagnostic imaging

Flexible URS is a common treatment in patients harboring proximal ureteral calculi. The joint clinical guidelines of the AUA and the EAU Nephrolithiasis Panel on the Management of Ureteral Calculi recommend URS in patients with proximal ureteral stones smaller than 2 cm. However, recent meta-analyses, including the AUA/EAU guidelines document as well as a Cochrane Review, showed that there are limited published data on treatment outcomes in patients who undergo flexible URS for isolated proximal ureteral stones.[1,2] The existing literature is limited by an emphasis on semirigid rather than flexible URS, failure to separate the treatment of renal stones from that of proximal ureteral stones and a focus on unique patient populations, eg those with anticoagulation or excessively large stones.[3–5] Studies are further limited by small sample size, variable modes of intracorporeal lithotripsy and a lack of standardization in reporting outcomes. Consequently our understanding of the clinical outcome of flexible URS for proximal ureteral calculi is limited.

Therefore, we performed a prospective evaluation of treatment outcomes for flexible URS in the management of proximal ureteral calculi smaller than 2 cm with standardized preoperative and postoperative assessment. We evaluated the efficacy and safety of flexible URS in the treatment of patients with proximal ureteral calculi.

METHODS

We performed a prospective, multi-institutional cohort study of patients with proximal ureteral calculi smaller than 2 cm undergoing flexible URS. Institutional review board approval was obtained at each site. Patients were identified based on clinic visits or hospital admission and counseled on standard treatment options (SWL and URS). Those who elected URS provided consent and were enrolled in study. Inclusion criteria included age 18 years or greater and a solitary proximal ureteral stone, defined as above the iliac vessels and below the renal pelvis, measuring smaller than 2 cm in maximal axial and/or coronal length on CT. Patients were excluded if they had previously had a stent, had concomitant stones in the distal ureter or kidney, underwent prior ipsilateral upper urinary tract reconstructive procedures, had a history of ipsilateral ureteral stricture, received prior radiotherapy to the

abdomen or pelvis, had neurogenic bladder or were actively pregnant. Demographic, perioperative, intraoperative and postoperative data were collected. Abdominopelvic CT was done to delineate preoperative stone size with measurements captured in the greatest axial and coronal dimensions.

Flexible URS was performed using general or regional anesthesia. Details of the ureteroscopic procedure, such as use of a safety guidewire, ureteral dilation and ureteral access sheath placement, were left to investigator discretion. These details were captured as part of the research record. All stones were fragmented with a holmium:YAG laser using settings selected by the investigator. No antimigration devices were used. In all cases stone analysis was performed and a ureteral stent was placed at the conclusion of the procedure. All procedures were done with the intent of performance in the outpatient setting.

Initial followup was done 1 week after treatment, at which time the ureteral stent was removed. At 4 to 6 weeks after treatment postoperative imaging was performed. The imaging regimen required KUB and renal ultrasound. Any residual fragments, hydronephrosis as judged by the attending surgeon and the need for re-treatment or an ancillary procedure were assessed and recorded.

Demographic variables included patient age, race, gender, ASA score, BMI and prior stone disease. Other measured preoperative parameters were stone size (maximal axial and coronal dimensions) and the degree of hydronephrosis (mild/moderate/severe). Perioperative variables included operative time, anesthesia type, laser fiber size, lithotripsy settings (rate/energy), use of active extraction of fragments and a ureteral access sheath, and intraoperative complications. Postoperative variables included postoperative complications, stone composition, need for ancillary procedures and stone-free status on 4 to 6-week postoperative imaging.

RESULTS

We identified 71 patients who met study inclusion criteria (see table), including 44 males (62%) and 27 females (38%). Mean age was 48.2 years. ASA score was 1 in 12 patients (16%), 2 in 41 (58%), 3 in 16 (23%) and 4 in 2 (3%). Mean BMI was 31.8 kg/m^2 and mean stone size was 7.4 mm (range 5 to 15). Hydronephrosis was characterized as none in 6 cases (9%), mild in 36 (51%), moderate in 25 (35%) and severe in 4 (5%). Nine patients (13%) previously underwent ipsilateral stone surgery (URS or SWL). Ten patients were enrolled in study and then received a stent based on the inability to perform URS.

The table lists clinical outcomes. In all cases general anesthesia was used. Mean operative time was 60.3 minutes (range 15 to 148). Ureteral access sheaths were applied in 48 patients (68%). In 2 cases a 365 μm laser fiber was used and in the remainder a 200 μm laser fiber was used. Active stone fragment extraction was performed after laser fragmentation in all cases. In 6 patients dusting was also performed after extracting larger fragments.

Complications occurred intraoperatively in 2 patients (2.8%), including mild ureteral trauma, which was detected visually. In each case no sequelae were related to this endoscopically detected trauma. Postoperative complications developed in 6 patients (8.7%),

including urinary tract infection in 3 (Clavien grade 2), urinary retention in 2 (Clavien grade 3) and flash pulmonary edema in 1 (Clavien grade 4). Four patients were hospitalized overnight for monitoring due to late conclusion of the case, pain control and monitoring renal function in a patient with preoperative renal dysfunction and malaise. Two patients presented to the emergency department after treatment, including 1 for stent pain and 1 with pain after stent removal. Stents were removed 7 to 10 days postoperatively except in 1 patient treated with stage 2 URS 1 month later. One patient was admitted to the hospital after erectile dysfunction presented. This patient, who had pain after stent removal and was found to have mild to moderate pelvicalicectasis, was monitored, discharged home and then lost to followup.

In 64 patients KUB/ultrasound was performed 4 to 6 weeks postoperatively. Seven patients did not present to the scheduled followup and 61 (95%) were stone free. All patients with residual stones harbored those stones in the renal collecting system. In all patients with residual stones initial stone size was greater than 10 mm while residual stones were between 1 and 3 mm. One of these patients required secondary URS to clear the residual stone burden. Stone analysis revealed a predominantly uric acid composition in 4 patients, calcium phosphate in 20 and calcium oxalate in 41. In 6 patients the stone composition was not available. Two patients had residual dilatation of the collecting systems on followup imaging, 1 had mild pelvicalicectasis, which was monitored. Another patient with mild to moderate pelvicalicectasis was rehospitalized but lost to followup.

DISCUSSION

The first iteration of the AUA clinical guidelines on the management of ureteral calculi, published in 1997, indicated that the preferred treatment was SWL for proximal ureteral stones smaller than 1 cm and SWL or URS for stones between 1 and 2 cm. This was based on increased morbidity and lower stone-free rates for the latter approach, which was attributable to the use of rigid URS. The most recent iteration of these guidelines, issued jointly by the AUA and EAU in 2007, showed that SWL and URS were considered acceptable first line treatment options for all proximal ureteral stones smaller than 2 cm.[1] As the authors noted, the change in guidelines reflected recent advances in ureteroscopic technology. These advancements have yielded improved clinical efficiency and decreased procedural morbidity. Technological advances include increasingly miniaturized and flexible endoscopes with improved visual resolution, smaller and more effective instruments with which to manipulate and fragment stones, and increasingly effective laser energy platforms.[6,7] At many centers URS has become the preferred treatment option for proximal ureteral stones.[3,8,9]

Despite the increasing use of URS published data on treatment outcomes of flexible URS for proximal ureteral stones are sparse. A recent meta-analysis within AUA guidelines mentioned stone-free outcomes for URS that were comparable to those of SWL.[1] In particular URS yielded a stone-free rate of 81% for proximal ureteral stones with similar outcomes when comparing those less vs greater than 10 mm (93% vs 87%). However, the meta-analysis showed that these studies were generally small, reported the outcomes of semirigid rather than flexible technology and used variable types of intracorporeal energy

for lithotripsy and different methods to assess postoperative stone clearance.[1,3] In a systematic review and meta-analysis Matlaga et al similarly found a paucity of studies of URS in patients with proximal ureteral calculi,[5] making it difficult to draw any meaningful conclusions about the effectiveness of the intervention.

In our study we prospectively assessed outcomes of flexible URS for proximal ureteral stones smaller than 2 cm. Importantly all subjects in this prospective study followed a uniform postoperative pathway to evaluate stone clearance. We report an excellent 95% rate of stone clearance using flexible URS.

We also report low morbidity with infrequent medical complications and no significant surgical complications in patients treated with URS. A criticism of URS includes its more invasive nature relative to SWL. However, we observed no increased rate of perioperative or postoperative complications. Furthermore, our data are consistent with complications in prior studies of semirigid URS, including ureteral trauma, postoperative fever and colic in a few patients.[10–12]

The strength and the unique feature of our investigation are its prospective design with a well-defined postoperative evaluation protocol to enable uniform reporting of outcomes. We used a multicenter design to optimize the number of patients who met our strict entry criteria. Study limitations include the lack of a control arm, specifically patients treated with SWL. However, it is notoriously difficult to accrue stone forming patients for a true randomized, controlled trial.[13] Also, while our study was multi-institutional, there was insufficient power to enable subgroup analysis to evaluate the usefulness of, for instance, access sheath use.

While procedures were generally standardized, techniques varied among centers in terms of access sheath use, precise duration of stent placement, postoperative medications, etc. It was not feasible to standardize all parts of perioperative and postoperative care for a large group of surgeons with mature practice patterns. Although we standardized our postoperative imaging strategy, the accuracy of renal ultrasound to detect stones may be user dependent and, therefore, it may have varied among centers. KUB and renal ultrasound are inferior to CT for detecting renal and ureteral stones and as such we may have overestimated the stone-free rate.[14,15] In a previous study of URS for ureteral and renal stones using holmium laser lithotripsy and active fragment extraction with the goal of clearing all stone Portis et al used CT exclusively for followup imaging.[16] Only 64.7% of patients with a solitary ureteral stone in whom retrieval of all fragments was attempted had no residual fragments on postoperative CT using the strictest criteria.[16]

Finally, our experience may not be generally applicable since there is significant variability in urologist comfort with flexible URS to treat proximal ureteral stones. For instance, those who trained after 1980 were more likely to choose URS for proximal ureteral stones instead of SWL and rural urologists were more likely than their urban counterparts to select SWL for these stones.[17] Others also confirmed that time since training influences the use of flexible URS for proximal ureteral stones and those stating a preference for rigid ureteroscopes were more likely to choose SWL to treat proximal ureteral stones.[18]

Institutions participating in this study were self-selected and are all centers where flexible URS is frequently performed. Ultimately this may limit the generalizability of our findings. Nevertheless, current residency training in flexible URS will ensure increased comfort with these techniques and likely decrease any residual surgeon prejudices against its use for proximal ureteral stones.

While semirigid URS is useful in select patients with shorter ureters, eg women, we believe that flexible URS is necessary to the armamentarium to treat these stones based on the inability to access proximal stones in many patients and to enable the retrieval of small retropulsed fragments from the kidney.

CONCLUSIONS

Flexible URS can achieve excellent stone-free rates with minimal procedural morbidity in patients harboring proximal ureteral stones smaller than 2 cm. As our health care system continues to investigate value based approaches to medical care, these findings are particularly important. The data provided by this multi-institutional, prospective study can serve as a benchmark for future analyses and may help better inform clinical guideline recommendations.

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Abbreviations and Acronyms

ASA	American Society of Anesthesiologists
AUA	American Urological Association
BMI	body mass index
CT	computerized tomography
EAU	European Association of Urology
KUB	plain x-ray of kidneys, ureters and bladder
SWL	shock wave lithotripsy
URS	ureteroscopy

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Demographics and clinical outcomes

No. pts	71	
No. male (%)	44	(62)
No. female (%)	27	(38)
Mean age (yrs)	48.2	(28–82)
No. ASA score (%):		
1	12	(16)
2	41	(58)
3	16	(23)
4	2	(3)
Mean kg/m^2 BMI (range)	31.8	(21–45)
Mean mm stone size (range)	7.4	(5–15)
Mean mins operative time (range)	60.3	(15–148)
No. access sheath use (%)	48	(68)
No. complications (%):		
Intraop*	2	(2.8)
Postop†	6	(8.4)
No. stone free (%)‡	61	(95)

*Ureteral abrasion or minor bleeding from sheath.

†Urinary tract infection in 3 patients, urinary retention in 2 and flash pulmonary edema in 1.

‡Excluding 7 patients without followup and including 1 with 2, 3 mm fragments on KUB with negative ultrasound.