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Original Article
Clinical Investigation

Flexible ureteroscopy with novel flexible ureteral access sheath versus mini-percutaneous nephrolithotomy for treatment of 2–3 cm renal stones

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Abbreviations & Acronyms
AUA = American Urological Association
EAU = European Association of Urology
ECIRS = endoscopic combined intrarenal surgery
f-UAS = flexible ureteral access sheath
f-URS = flexible ureteroscopy
KUB = Kidney-ureter-bladder
mini-PCNL = mini-percutaneous nephrolithotripsy
PCNL = percutaneous nephrolithotomy
SFR = stone-free rates
TFL = thulium fiber laser
UPJ = ureteropelvic junction
UTI = urinary tract infection

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Objectives: To assess and compare the effectiveness and safety of flexible ureteroscopy (f-URS) with a novel flexible ureteral access sheath (f-UAS) versus mini-percutaneous nephrolithotripsy (mini-PCNL) in treating 2–3 cm renal stones.
Methods: Retrospectively analyzed consecutive cases that underwent f-URS with f-UAS (12/14 Fr) from January 29, 2022, to November 30, 2022. Consecutive cases that underwent mini-PCNL (18 Fr) from June 5, 2021, to January 26, 2022, were selected as controls. The f-UAS is a novel device with a 10 cm anterior tip that passively bends along with the f-URS to enter the renal calyx. We analyzed demographic characteristics, stone parameters, operative time, stone-free rates (SFR), hospitalization time, and complication.
Results: A total of 96 consecutive cases that underwent f-URS with f-UAS and 96 consecutive cases that underwent mini-PCNL were included in the study. There were no significant differences between the two groups in terms of operative time ($p = 0.06$), stone volume clearance ($p = 0.533$) and complete SFR ($p = 0.266$) on the first postoperative day or residual Stone after 1 month ($p = 0.407$). We observed a significantly shorter postoperative hospital stay (1.4 days vs. 2.1 days; $p < 0.001$) and a lower decrease in hemoglobin levels (0.39 g/dL vs. 0.68 g/dL; $p < 0.001$) in the f-UAS group. The mini-PCNL group had a significantly higher overall complication rate (13.5%) compared with the f-UAS group (5.2%; $p = 0.048$).
Conclusions: In the treatment of 2–3 cm renal stones, f-URS with a novel f-UAS may provide a superior alternative to mini-PCNL, potentially challenging its established status.

Key words: flexible ureteroscopy, mini-percutaneous nephrolithotomy, renal stones, ureteral access sheath.

INTRODUCTION

Percutaneous nephrolithotomy (PCNL) is presently regarded as the preferred treatment for renal stones exceeding 2 cm in size.[1–3] However, with the advancement of endoscopic techniques, an increasing number of urologists are considering flexible ureteroscopy (f-URS) as an alternate method for managing larger than 2 cm renal stones.[4,5] F-URS presents various advantages compared with PCNL, including decreased trauma, lower incidence of complications, and shorter postoperative hospital stay.[6,7] Traditional f-URS has some limitations, such as the potential persistence of stone fragments or dust and the low efficiency of lithotripsy.[8] The self-elimination of residual stone fragments is a time-consuming process that can lead to episodes of renal colic and/or hematuria.[9,10] With the advancements in technology, a novel flexible ureteral access sheath (f-UAS) has been successfully developed and used in clinical practice, yielding favorable surgical outcomes such as improved efficiency and higher stone-free rates (SFR).[11–13] The introduction of the novel f-UAS in f-URS poses a potential challenge to the established role of mini-PCNL in managing 2–3 cm stones. However, there is a lack of comparative studies that assess the effectiveness of f-URS (utilizing an f-UAS) and mini-PCNL.

Therefore, a retrospective study was conducted at a single center to evaluate and compare the effectiveness and safety of f-URS, inclusive of the usage of an f-UAS (12/14 Fr), and mini-PCNL (18 Fr) in the treatment of renal stones measuring 2–3 cm.

MATERIALS AND METHODS

Patients

A retrospective analysis was conducted on all patients who underwent treatment for renal stones or upper ureteral stones using f-URS with an f-UAS during the period from January 29, 2022, to December 30, 2022. Inclusion criteria: age 18–70 years, utilization of an f-UAS (12/14 Fr, 36 cm for females; 46 cm for males; Woek, Nanchang, China), 2–3 cm renal stone or upper ureteral stones. Exclusion criteria: Uncontrolled urinary tract infection, simultaneous bilateral surgery, renal dysfunction, nephrectomy of remaining or solitary kidney, scoliosis, severe cardiac disease, and diabetes mellitus; as well as incomplete follow-up information. We implemented a 1:1 control group design based on the total number of patients. The control group (mini-PCNL group) consisted of consecutive cases that underwent mini-PCNL at our institution from June 5, 2021, to January 26, 2022. Inclusion criteria: 18 Fr renal pathways. Exclusion criteria: second-stage surgery (have a nephrostomy tube). The remaining inclusion and exclusion criteria were consistent with those used for the f-URS group. Both groups consisted of consecutive cases that were performed by one experienced surgeon, but at different time periods. The study was approved by the local Ethics Committee (2022-037).

Kidney–ureter-bladder (KUB), abdominal non-contrast computed tomography (NCCT), and urinary ultrasonography were performed for all patients preoperatively. The stone burden was assessed using NCCT in bone window mode. Patients who tested positive for urinary tract infection (UTI) in their preoperative urine cultures were administered suitable antibiotic treatment. In addition, they underwent a subsequent culture or microscopic examination prior to surgery to ascertain the successful management of the UTI. Patients with negative urinary tract cultures received prophylactic antibiotics half an hour prior to surgery.

Stent (6 Fr) was routinely placed for 1 month. NCCT was conducted on all patients within 1 day after the surgery. Additionally, a 1-month follow-up assessment was planned for all patients, which included an NCCT scan after the stent removal at the end of the 1-month postoperative period. At 1 month postoperatively, patients with remaining stones will undergo additional evaluation at 3 months postoperatively. This evaluation may involve NCCT, ultrasound, or abdominal radiography. However, data at 3 months postoperatively were not collected because of possible discrepancies in the assessment methods. The stone-free status was defined as a NCCT showing zero-stone fragments.[14] The postoperative stone-free status was independently assessed by both an urologist and a radiologist. The treatment methods were blinded to both the radiologists and the urologists.

Surgical techniques

F-URS group (Video S1)

Flexible ureteral access sheath (f-UAS) (Woek, Nanchang, China): the f-UAS is a novel ureteral access sheath with a 10 cm front end that bends passively in conjunction with the f-URS. It has a bending angle capability of approximately 270°, while consistently maintaining the cylindrical shape of the tube lumen even during bending. Additionally, the f-UAS can be connected to a vacuum suction device. (Supplementary information: A surgery video).

General anesthesia and lithotomy position was taken. The urologist adjusts the patient's position according to each situation, including head-low or foot-high, right-sided tilted, or left-sided tilted position during surgery. Ureteroscopy (9.8 Fr, Karl Storz, Germany) was used to assess ureteral conditions under a safety guidewire (VALENCA, Hunan, China). The upper ureteral stone was pushed back into the kidney. The f-UAS was inserted into the ureter using a safety guidewire as a guide. With the aid of the f-URS (8.6 Fr, Woek, Nanchang, China), the tip of the f-UAS was positioned in the renal pelvis or calyces, in close proximity to the stone. Attach the f-UAS to the vacuum device and set the negative pressure value to 2–7 Kpa. However, the urologist adjusted the actual intraoperative negative pressure value through a pressure adjustment vent based on each circumstance. The irrigation volume was adjusted to a range of 80–200 mL/min. Lithotripsy was conducted utilizing the holmium: yttrium aluminum garnet (Ho:YAG) laser (Moses Laser, Yokneam, Israel) with a 200 μm fiber, delivering energy of 1.0–1.2 J and operating at a frequency of 15–30 Hz. During lithotripsy, the f-URS was repeatedly moved in and out to facilitate the extraction of stone fragments through the action of irrigation fluid during the withdrawal process.

Mini-PCNL group

Following the administration of general anesthesia, a 5 Fr ureteral catheter (New Jersey, USA) was inserted into the affected side in a lithotomy position. The patients were positioned in the prone position, and percutaneous access was obtained with the guidance of ultrasound. Subsequently, the guidewire (VALENCA, Hunan, China) was utilized to expand the pathway via the facial dilators, followed by the insertion of an 18F peel-away sheath (Wellead, Guangzhou, China). Lithotripsy was conducted utilizing a ureteroscopy (9.8F, Richard Wolf, Germany) along with a holmium: yttrium aluminum garnet (Ho: YAG) laser (550 μm fiber; energy 1.5–2.0 J; frequency 15–25 Hz). Connect the peel-away sheath to the vacuum device and set the negative pressure value to 2–7 Kpa. However, the urologist adjusted the actual intraoperative negative pressure value through a pressure adjustment vent based on each circumstance.

Statistical methods

Categorical variables were presented as either the number of subjects (n) or percentages (%). The Student's t-test was used to analyze continuous data, which were expressed as the mean ± standard deviation. Statistical significance was set at

$p < 0.05$. All data analyses were performed using SPSS 22.0. Stone clearance efficiency was reflected by the stone volume clearance rate and stone-free rate (SFR).

$$\text{Stone volume clearance rate} = \left(1 - \frac{\text{residual stone volume}}{\text{preoperative stone volume}}\right) \times 100.$$

$$\text{Stone-free rate: SFR} = \left(\frac{\text{No. of complete stone free patients}}{\text{No. total patients}}\right) \times 100$$

RESULTS

From January to November 2022, a total of 123 consecutive cases with 2–3 cm renal stones underwent f-UAS, including five cases of uncontrolled urinary tract infection, two cases of simultaneous bilateral surgery, three cases of renal dysfunction, three cases of nephrectomy of remaining or solitary kidney, one case of scoliosis, one case of severe cardiac disease, and three cases of diabetes mellitus. Nine patients' follow-up information was incomplete. Between June 5, 2021 and January 26, 2022, a total of 127 consecutive cases with 2–3 cm renal stones underwent mini-PCNL, including four cases of uncontrolled urinary tract infection, three cases of second-stage surgery (have a nephrostomy tube), four cases of simultaneous bilateral surgery, one case of renal dysfunction, one case of nephrectomy of remaining or solitary kidney, two cases of scoliosis, one case of severe cardiac disease, four cases of diabetes mellitus, and 11 patients' follow-up information was incomplete. A total of 192 consecutive patients were ultimately included in the analysis, with 96 patients in each group. Patient demographics, preoperative clinical characteristics, and renal stone properties of the two groups exhibited no significant differences (Table 1).

The two groups did not show a significant difference in operation time (f-URS: 79.3 min vs. Mini-PCNL: 76.7 min; $p = 0.06$) and stone volume clearance (f-URS: 99.4% vs. Mini-PCNL: 99.6%; $p = 0.533$) and the complete SFR was also similar between the two groups (f-URS: 85.4% vs. Mini-PCNL: 90.6%; $p = 0.266$). The f-UAS group had significantly shorter postoperative hospital stay (1.4 days vs. 2.1 days; $p < 0.001$) and a lower drop in hemoglobin (0.39 g/dL vs. 0.68 g/dL; $p < 0.001$) compared with the mini-PCNL group. The mini-PCNL group had a significantly higher incidence of total complications (13.5%) compared with the f-UAS group (5.2%; $p = 0.048$). One patient (1.0%) in the mini-PCNL group developed postoperative hemorrhage and required treatment with transfusion and interventional embolization. Intraoperative and postoperative outcomes are summarized in Table 2.

DISCUSSION

PCNL is widely regarded as the preferred treatment for large stones as recommended by the guidelines of the American Urological Association (AUA) and the European Association of Urology (EAU) both guidelines recommend PCNL as the primary surgical approach for stones larger than 2 cm in size.[1,2] The size range of greater than 2 cm is still considerable. However, recent technological advancements in f-URS, such as the introduction of digital ureteroscopy, UAS, and laser technologies, have substantially improved SFR while simultaneously reducing complications in patients. These advancements have broadened the f-URS, allowing for its utilization in the treatment of large and intricate stones.[13,15]

TABLE 1 Patient demographics and preoperative data.

	f-URS group	Mini-PCNL group	*p* value
Age (years), mean (SD), range	49.3 (11.9), 25–74	50.6 (11.4), 25–71	0.45
Gender (*n*, male/female)	50/46	52/44	0.772
BMI (kg/m^2), mean (SD), range	23.6 (2.7), 16.4–29.9	23.4 (2.7), 17.9–28.8	0.691
Preoperative Double-J stent, *n* (%)	9 (9.4%)	5 (5.2%)	0.267
Grade of Hydronephrosis[a], *n* (%)			0.610
I	65 (67.7%)	56 (58.3%)	
II	19 (19.8%)	24 (25%)	
III	9 (9.4%)	12 (12.5%)	
IV	3 (3.1%)	4 (4.2%)	
Stone property			
Largest stone size (mm), mean (SD), range	24.4 (1.6), 21–28	24.1 (1.9), 21–28	0.193
Stone volume (mm^3), mean (SD), range	5553.7 (467.6), 4711–6781	5607.3 (541.8), 4782–6822.4	0.464
Highest stone density (HU), mean (SD), range	1362.6 (252.8), 892–1983	1319.5 (221.4), 894–1938	0.211
Stone location, *n* (%)			0.848
Upper ureter	5 (5.2%)	3 (3.1%)	
Renal pelvic	25 (26.0%)	20 (20.8%)	
Upper calyx	7 (7.3%)	10 (10.4%)	
Middle calyx	17 (17.7%)	17 (17.7%)	
Lower calyx	31 (32.3%)	36 (37.5%)	
Multiple calyx	11 (11.5%)	10 (10.4%)	
Positive urine culture, *n* (%)	10 (10.4%)	12 (12.5%)	0.65

[a]Grignon Grading system.

TABLE 2 Intraoperative and postoperative data.

	f-URS group	Mini-PCNL group	p value
Operation time (min), mean (SD), range	79.3 (10.3), 61–113	76.7 (8.7), 65–117	0.06
No use basket	80 (83.3%)	96 (100)	<0.001
Postoperative hospital stay (days), mean (SD), range	1.4 (0.6), 1–3	2.1 (0.7), 1–4	<0.001
Residual stone			
Largest residual stone (mm), mean (SD), range	0.45 (1.1), 0–4	0.33 (1.2), 0–7	0.497
Residual stone volume (mm^3), mean (SD), range	33.3 (90.3), 0–364	24.4 (103.5), 0–785	0.527
Stone volume clearance rate[a] (%), mean (SD), range	99.4 (1.6), 93.1–100.0	99.6 (1.8), 86.7–100.0	0.533
Complete stone-free rate[b], n (%)	82 (85.4%)	87 (90.6%)	0.266
Residual Stone after 1 months, n (%)	2 (2.0%)	4 (4.2%)	0.407
Hemoglobin drop[c] (g/dL), mean (SD), range	0.39 (0.25), 0–1.3	0.68 (0.60), 0–5.8	<0.001
Total complications[d], n (%)	5 (5.2%)	13 (13.5%)	0.048
Fever (>38°C)	4 (4.2%)	7 (7.3%)	
Emesis	1 (1.0%)	4 (4.2%)	
Infection	0	3 (3.1%)	
Transfusion	0	1 (1.0%)	
Interventional embolization	0	1 (1.0%)	0.316

[a]Stone volume clearance rate $= \left(1-\frac{\text{residual stone volume}}{\text{preoperative stone volume}}\right)\times 100\%$. [b]Stone-free rate (SFR): $\text{SFR} = \left(\frac{\text{No. of complete stone free patients}}{\text{No. total patients}}\right)\times 100\%$. [c]Hemoglobin drop = Postoperative Hemoglobin − Preoperative Creatinine. [d]Clavien grade classification; Some cases had simultaneous complications.

Some scholars have utilized f-URS for the treatment of renal stones larger than 2 cm. However, it is imperative to take into account the potential existence of residual stone fragments, as they can give rise to complications such as renal colic, hematuria, the need for additional interventions, and even stone regrowth.[4,9,10,16–19] Elevated intrarenal pressure (IRP) during f-URS has posed a significant clinical challenge. The frequent occurrence of high IRP often leads to pyelovenous backflow, which ultimately increases the risk of sepsis.[20] But reducing the irrigation flow to avoid high IRP can negatively impact surgical visualization during f-URS. These factors also contribute to the limited promotion of f-URS as a treatment option for stones larger than 2 cm. A novel f-UAS has the potential to expand the indications for f-URS by addressing issues such as residual stone fragments, high IRP, inefficiency, and inadequate surgical view. This technology offers a promising solution to these challenges.[12,13] The utilization of the novel f-UAS in f-URS has the potential to challenge the current role of mini-PCNL.

The use of novel f-UAS can enhance the efficiency of f-URS. The f-UAS enables the closest possible proximity to the stone, so stone fragments measuring ≤1 mm were efficiently eliminated from the body by the gap between the f-URS and the 12/14 Fr f-UAS, and stone fragments ranging from 1 to 4 mm were effectively expelled through the repeated withdrawal of the f-URS, aided by the action of irrigation fluid. This principle may be analogous to that of PCNL, where stones are removed from the body by means of irrigation fluid during the withdrawal of the nephroscope.[21] It has been reported that the novel f-UAS considerably enhances the efficiency of f-URS in comparison to traditional UAS, and it also improves the SFR.[11,12] Utilizing a larger diameter 14/16F f-UAS in f-URS might facilitate the extraction of larger stone fragments, potentially reducing the duration of the operation. However, utilizing a larger diameter f-UAS may carry the risk of causing ureteral injury and ischemia.[22] Several studies have identified the benefits of mini-PCNL compared with standard-PCNL, including decreased complications, shorter hospital stays, and a higher likelihood of tubeless procedures. However, it is important to note that mini-PCNL is associated with a lower SFR and longer operative time.[23] Some studies have combined f-URS with PCNL and have found that PCNL achieved a higher SFR.[5] However, in this study, with the utilization of the novel f-UAS, there was no significant difference in the SFR between the two groups.

No significant difference in operation time was observed between the two groups. The f-URS group showed longer duration for lithotripsy and stone extraction, while the mini-PCNL group took more time during the preparation phase (from ureteral catheter placement to successful puncture). The size of the fiber imposes limitations on the laser parameters, resulting in a significantly lower lithotripsy power in the f-URS group compared to the mini-PCNL group. It is important to note that low power results in longer operation times.[24] Incorporating a thulium fiber laser (TFL) has the potential to address this issue.[25,26] Moreover, the repetitive process of withdrawing the f-URS to extract additional stone fragments was significantly more time-consuming in the f-URS group than in the mini-PCNL group. After the completion of ureteral catheter insertion, patients in the mini-PCNL group underwent a transition from the supine to the prone position. This process, particularly challenging for obese patients, is time-consuming and demanding. Undoubtedly, utilizing a flexible cystoscope to place ureteral catheters directly in the prone position has the potential to decrease operative time. The choice of puncture method is also a determinant of surgical complications and procedure time. The process of establishing access in mini-PCNL is relatively time-consuming, particularly as puncturing becomes notably more challenging in obese patients. Ultrasound-guided renal puncture was performed in this study, requiring a specific level of ultrasound proficiency and carrying a certain risk of puncture-related bleeding. Endoscopic combined intrarenal surgery (ECIRS) has been described in several studies, involving renal puncture performed while visualizing the renal papilla using an f-URS. ECIRS reduces the risk of puncture-related bleeding.[27]

The f-URS group had a lower incidence of postoperative complications, including hemoglobin changes. This finding aligns with the results reported by previous researchers.[5] No significant change in postoperative hemoglobin levels was observed in the f-URS group compared with the preoperative values. Perhaps, we can conclude that the appropriate application of negative pressure does not significantly affect hemoglobin levels. Within the mini-PCNL group, one patient encountered a severe complication that necessitated treatment involving a blood transfusion and angio-embolization. In comparison to the conventional f-URS technique, the f-URS group in this study demonstrated higher irrigation velocity, and a vacuum device was also attached to the f-UAS. Studies have demonstrated that incorporating a vacuum device during f-URS significantly improves SFR, reduces IRP, and decreases the occurrence of complications related to infection.[12,28] The f-UAS can passively bend, facilitating access to the renal pelvis and calyces while minimizing the effect of the ureteropelvic junction (UPJ) on IRP. However, the f-UAS may not be able to reach every individual renal calyx, especially when encountering a lower calyx with an infundibulum-pelvic angle less than 30°. In the f-UAS group, the primary function of the basket is to assist in retrieving stones situated in the lower calyx and transferring them to the upper or middle calyx for subsequent lithotripsy, especially in situations where accessing the lower calyx is not possible with the f-UAS. As a result, the utilization of a basket is unnecessary for a considerable majority (83.3%) of patients in the f-UAS group. It can be inferred from these findings that approximately 16.7% of cases using the f-UAS encounter difficulties in accessing the lower calyx. An increased occurrence of complications can prolong the duration of postoperative hospitalization. The duration of postoperative hospital stay was longer in the mini-PCNL group, which is consistent with the findings from previous studies conducted by other researchers.[5,7]

This study has certain limitations. Firstly, the follow-up period was short, possibly providing insufficient time to detect potential ureteral strictures using techniques such as NCCT. Second, this study did not analyze the ergonomic disparities between the two groups, which is one of the factors urologists take into account when selecting a surgical approach.[29] Thirdly, this study is a retrospective study conducted at a single center and includes a limited number of cases. Further investigation is necessary to validate the present findings by conducting prospective randomized trials and multicenter studies involving a larger patient cohort. Nevertheless, to the best of our knowledge, this is the first report on the utilization of f-UAS in f-URS compared to mini-PCNL (18 Fr) for managing renal stones measuring 2–3 cm.

Based on our findings, f-URS with the novel f-UAS (12/14 Fr) demonstrates superiority over mini-PCNL (18 Fr) in the treatment of 2–3 cm renal stones. This superiority is evident in terms of reduced complications and shorter postoperative hospital stays. However, no significant differences were observed in operative time and SFR. These results suggest that the use of f-URS in combination with f-UAS could potentially be a viable alternative to mini-PCNL in certain cases.

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AUTHOR CONTRIBUTIONS

Yujun Chen: Writing—original draft; Data curation; Formal analysis; Validation. **Haibo Xi:** Methodology; Investigation; Funding acquisition; Resources. **Yue Yu:** Methodology; Investigation; Resources. **Xiaofeng Cheng:** Investigation; Visualization; Data curation; Formal analysis. **Heng Yang:** Investigation; Visualization; Data curation. **Wen Deng:** Investigation; Visualization; Data curation. **Wei Liu:** Investigation; Software; Data curation. **Gongxian Wang:** Methodology; Project administration; Resources; Supervision; Funding acquisition; Writing—review & editing. **Xiaochen Zhou:** Supervision; Funding acquisition; Writing - review & editing; Methodology; Project administration; Resources.

CONFLICT OF INTEREST STATEMENT

The author declares that they have no conflicts of interest.

APPROVAL OF THE RESEARCH PROTOCOL BY AN INSTITUTIONAL REVIEWER BOARD

This study did involve humans, and was approved by the local Ethics Committee (2022-037).

INFORMED CONSENT

All study participants, or their legal guardians, provided informed written consent before study enrollment.

REGISTRY AND THE REGISTRATION NO. OF THE STUDY/TRIAL

N/A.

ANIMAL STUDIES

N/A.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher’s web-site:

Video S1.

