Comparison of the Efficacy of Ureteroscopy through a Flexible Vacuum-Assisted Ureteral Access Sheath with Tubeless-mini Percutaneous Nephrolithotomy for the Treatment of 3–2 cm Renal Calculi

Guanyun Deng[1,3], Kehua Jiang[2], Qing Wang[2], Wenbing Lu[3], Kunyuan Huang[1], Fa Sun[1]*

Purpose: To investigate the efficacy of the flexible vacuum-assisted ureteral access sheath (FV-UAS) combined with disposable flexible ureteroscope (FURS) versus tubeless-mini percutaneous nephrolithotomy (T-PCNL) in the treatment of renal calculi with a diameter of 2–3 cm.

Materials and methods: This retrospective analysis included 270 patients with renal calculi with a maximum diameter of 2–3 cm treated between January 2022 and July 2024. Of these, 146 cases were treated with single-use ureteroscopic lithotripsy through an FV-UAS, while 124 cases were treated by tubeless PCNL (T-PCNL group) through a 16F Amplatz sheath. Perioperative indicators and postoperative stone-free rates (SFRs) were compared.

Results: There was no significant difference in the stone-free rates (SFRs) between the two surgical methods. Using the criterion of a residual kidney stone diameter less than 4 mm, the SFRs at 3 days postoperatively were compared between the two groups: 95% confidence interval (CI), 0.56–2.28; odds ratio (OR) = 1.13; *P* = .724. The SFRs at 1 month postoperatively were: 95% CI, 0.417–2.60; OR = 1.041; *P* = .931. Using the criterion of a residual kidney stone diameter less than 2 mm, the SFRs at 3 days postoperatively were: 95% CI, 0.355–1.055; OR = 0.612; P = .076; the SFRs at 1 month postoperatively were: 95% CI, 0.374–1.320; OR = 0.703; *P* = .271. There was no significant difference in the incidence of systemic inflammatory response syndrome (SIRS) and the need for postoperative analgesia between the two groups (*P* = .813 and *P* = .839, respectively). The surgical duration in the FV-UAS group was significantly longer (*P* < .001). The decrease in postoperative hemoglobin (Hb) levels and hospital stay in the FV-UAS group were significantly lower than those in the T-PCNL group (both *P* < .001).

Conclusion: For treating 2–3 cm renal calculi, both FV-UAS with disposable ureteroscope and 16F tubeless PCNL yield high stone-free rates. FV-UAS–assisted FURS reduces bleeding and hospital stay, whereas 16F tubeless PCNL shortens surgery duration.

Keywords: flexible ureteroscope; renal calculi; tubeless percutaneous nephrolithotomy; flexible vacuum-assisted ureteral access sheath; flexible ureteroscope; renal calculi

INTRODUCTION

Currently, endoscopic treatment options for renal calculi tend to favor flexible ureteroscopic lithotripsy and percutaneous nephrolithotomy. However, for renal calculi with a diameter of 2–3 cm, previous clinical studies and related guidelines have largely favored PCNL[(1)]. It was previously believed that PCNL had a higher stone-free rate and a shorter operative time compared to FURS, but this perspective is gradually changing[(2)]. In recent years, the FV-UAS has been increasingly used to assist FURS. By connecting to a negative pressure system, it can reduce renal pelvic pressure and extract most stone fragments, thereby reducing the infection rate and improving the SFR[(3,4)]. Consequently, FURS is increasingly being applied to manage larger renal calculi. Moreover, with the application of disposable flexible ureteroscopes, medical costs have significantly decreased. For the treatment of larger renal calculi (> 2 cm), many patients have previously declined PCNL in favor of multiple FURS treatments[(5)], as the surgical approach of PCNL indeed causes considerable discomfort. With advancements in surgical techniques, tubeless PCNL has significantly reduced patient discomfort[(6)]. Therefore, the choice of treatment regimen for larger renal calculi (> 2 cm) presents a new challenge. This study retrospectively compares the efficacy of FV-UAS–assisted FURS and tubeless PCNL in the treatment of 2–3 cm renal calculi, aiming to provide better options for clinical treatment.

MATERIALS AND METHODS

Clinical data

A retrospective analysis was conducted on 270 patients with renal calculi (2–3 cm in diameter) admitted from January 2022 to July 2024. They were divided into two groups based on the surgical approach. Patients who underwent FV-UAS–assisted disposable flexible ureteroscope with thulium laser lithotripsy were categorized into the FV-UAS group (n = 146), and those who received a 16F access sheath for tubeless percutaneous

[1]Guizhou Medical University, Guiyang, Guizhou, China.
[2]Department of Urology, Guizhou Provincial People's Hospital, Guiyang, Guizhou, China.
[3]Longli People's Hospital, Qiannan Prefecture, Guizhou, China.
*Correspondence: Guizhou Medical University, Guiyang, Guizhou, China.
Tel: (+86) 0851-85924943. Fax: (+86) 0851-85924943. E mail: sfgmc@sina.com.
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Table 1. Patients' demographic and clinical characteristics

Item(a)	FV-UAS Group (n=146)	T-PCNL Group (n=124)	*P* Value
Age, years; median (IQR)	55.0 (40.00-61.50)	49.0 (40-56.00)	0.089
Female	71 (48.63%)	53 (42.74%)	0.333
Hypertension	15 (10.27%)	12 (9.68%)	0.871
Diabetes	12 (8.22%)	9 (7.26%)	0.769
Lower Pole Stone	88 (60.27%)	76 (61.29%)	0.865
IPA < 45°	37 (42.06%)	26 (34.21%)	0.397
Stone Volume, cm³; median (IQR)	2.84 (2.12-3.97)	3.21(2.26-4.0)	0.104
Average stones CT value, HU; median (IQR)	723.0 (559.00-887.00)	723.0 0 (583.00-854.00)	0.766
Urinary WBC, /µL; median (IQR)	25.00 (0.00-125.00)	46.00 (12.00-96.75)	0.681

Abbreviations: IQR, interquartile range; IPA, infundibulopelvic angle; CT, computed tomography. (a) The data are presented as mean ± SD, median (IQR), and number (percentage).

nephrolithotomy were categorized into the T-PCNL group (n = 124). This study adheres to the World Medical Association Declaration of Helsinki and does not present any ethical issues.

Inclusion criteria

1. Patients meeting the diagnostic criteria for renal calculi according to the urological clinical practice guidelines.
2. All included cases had urinary tract CT results available preoperatively, 3 days postoperatively, and 1 month postoperatively.
3. Patients included in the FV-UAS group did not require pre-placement of a double-J stent.
4. All surgical patients had completed urine culture examinations before the operation.
5. All cases in the T-PCNL group underwent surgery using a 16F tract.
6. Well-controlled blood pressure and blood glucose levels.

Exclusion criteria

1. Incomplete or missing clinical data.
2. Anesthesia and surgical risk assessed as greater than grade 3 according to the American Society of Anesthesiologists (ASA) classification.
3. Presence of urological or spinal deformities that might affect natural stone passage.
4. Age under 18 years.
5. Requirement for a two-stage procedure due to special circumstances, such as ureteral stricture.
6. Complicated by other severe cardiopulmonary diseases or coagulation disorders.
7. Morbid obesity (BMI ≥ 35).
8. Preoperative urine culture positive, with the inability to convert to negative despite antibiotic treatment.
9. In the FV-UAS group, patients in whom the front end of the FV-UAS could not enter the renal pelvis.

Evaluation index and recording method

Preoperative data included gender, age, stone volume, stone CT value, stone location, comorbidities (hypertension, diabetes), and urinary white blood cell levels after anti-infective treatment. The stone volume was assessed using a CT three-dimensional reconstruction system. The method for determining the average CT value of kidney stones was as follows: first, select three positions—upper, middle, and lower—on the largest coronal plane of the stone to measure the CT values. Next, on the largest cross-sectional plane of the stone, select two positions—ventral and dorsal—to measure the CT values. Finally, calculate the average of these five CT values. Stones located at the lower pole or extending to the lower pole were categorized as lower pole renal stones. Among these, those with an infundibulopelvic angle (IPA) less than 45 degrees were statistically analyzed separately[7]. Postoperative data included operative time, SIRS-related indicators[8,9], the number of times analgesics were required for lumbar pain within 24 hours postoperatively[10], the decrease in Hb within 24 hours postoperatively, SFR at 3 days postoperatively, SFR at 1 month postoperatively, and postoperative hospital stay. The operative time was defined as the duration from the start of endoscopic examination to the end of the surgery. SIRS was defined as meeting any two or more of the following criteria[9]: 1) body temperature > 38°C or < 36°C; 2) heart rate > 90 beats/min; 3) respiratory rate > 20 breaths/min or arterial partial pressure of carbon dioxide < 32 mmHg; 4) white blood cell count < 4,000 or > 12,000 cells/µL. A score of 0 was recorded if no analgesics were used within 24 hours postoperatively, and a score of 1 was given for each use[11]. Analgesics included nonsteroidal anti-inflammatory drugs and opioids. The decrease in hemoglobin levels within 24 hours postoperatively was measured in g/L. On the 3rd day and at 1 month postoperatively, patients underwent CT scans. If the diameter of the residual kidney stone was less than 4 mm, the patient was considered to be in a relatively stone-free condition; if the diameter of the residual kidney stone was less than 2 mm or if there were no residual stones at all, the patient was considered to be in a completely

Table 2. Patients' postoperative data.

Item[(a)]	FV-UAS Group (n=146)	T-PCNL Group (n=124)	*P* Value
Operation Time, min; mean ± SD	58.32 ±17.47	45.98 ± 10.78	< 0.001
Postoperative Hb Decrease (g/L), median (IQR)	2.52 (1.09-3.91)	3.80 (2.67-5.27)	< 0.001
Postoperative Hospital Stay, days; mean ± SD	3.24 ± 0.87	4.23 ± 0.70	< 0.001

Abbreviations: SD, standard deviation; IQR, interquartile range. **(a)** The data are presented as mean ± SD, median (IQR), and number (percentage).

Table 3. Patients' postoperative data

Item(a)	FV-UAS Group (n=146)	T-PCNL Group (n=124)	OR (95% CI)	*P*
SIRS	(8) 5.5%	(6) 4.8%	0.877 (0.296-2.600)	0.813
Postoperative Analgesia	14 (9.58%)	11(8.87%)	0.918 (0.401-2.102)	0.839
3-Day SFR (< 4mm)	125 (85.62%)	108 (87.09%)	1.13 (0.56-2.28)	0.724
3-Day SFR (< 2mm)	114 (78.08%)	85(68.54%)	0.612 (0.355-1.055)	0.076
1-Month SFR (< 4mm)	135 (92.47%)	115 (92.74%)	1.041 (0.417-2.60)	0.931
1-Month SFR (< 2mm)	124 (84.93%)	99 (79.84%)	0.703 (0.374-1.320)	0.271

Abbreviations: SIRS, systemic inflammatory response syndrome. (a) The data are presented as mean ± SD, median (IQR), and number (percentage)

stone-free condition[12].

Surgical procedures

FV-UAS group: Following successful general anesthesia, the patient was positioned in the lithotomy position. An 8/9.8F ureteroscope (WOLF) was utilized to insert a guidewire (INNOVEX) into the affected ureter. Subsequently, an FV-UAS was advanced into the upper ureter under the guidance of the wire. Ureteral sheaths of 35 cm and 45 cm were used for female and male patients, respectively. A disposable flexible ureteroscope (INNOVEX) was then introduced, and the tip of the FV-UAS was slowly maneuvered into the renal pelvis under direct visualization until it reached the stone's location. Lithotripsy was performed using a Raykeen thulium laser with a 200 μm fiber to fragment the stone, while the stone powder and larger fragments were aspirated via negative pressure. During lithotripsy, the irrigation pressure of physiological saline was adjusted to 40–50 cm H_2O by gravity[13], the energy was set to 0.6–0.8 J, and the frequency was 15–20 Hz. No stone retrieval basket was used during the procedure. Postoperatively, a double-J stent (INNOVEX) and a urinary catheter were routinely placed.

T-PCNL group: After achieving general anesthesia, the patient was placed in the lithotomy position. A guidewire (INNOVEX) was inserted using an endoscope (WOLF), and a double-J stent (INNOVEX) was placed under the guidance of the guidewire. We used a three-way Foley catheter for urinary catheterization, connected the catheter's end to an infusion set, and instilled normal saline into the bladder to establish artificial hydronephrosis[14]. The instillation pressure was adjusted to 60–70 cm H_2O by gravity. An appropriate renal calyceal fornix was selected for puncture and tract dilation, and a 16F Amplatz sheath was left in place. A 14F nephroscope (WOLF), a 550 μm thulium laser fiber, and a Raykeen thulium laser were employed. During lithotripsy, the nephroscope was connected to a physiological saline irrigation pump with a flow rate set to 0.3–0.4 L/min; the thulium laser energy was adjusted to 0.8–1.2 J, and the frequency was 20–25 Hz. After completion of lithotripsy and stone clearance, the tract sheath was removed without placing a nephrostomy tube, and the skin incision was sutured after appropriate compression using gauze.

All surgical procedures were conducted by the same surgeon. Patients in the FV-UAS group were required to remain in bed for 6 hours postoperatively, while those in the T-PCNL group were instructed to stay in bed for 24 hours. Nursing care included observation for symptoms such as fever, uncontrolled bleeding, dyspnea, and lumbar pain. If there were no signs of infection, other organ damage, or gross hematuria, the urinary catheter was removed, and the patient was discharged. Both groups of patients underwent urinary system CT re-examination on the third postoperative day and at one month postoperatively, and the double-J stent was removed one month after surgery.

Statistical analysis

The sample size was calculated using PASS software to ensure that it met the research requirements. Data analysis was conducted using SPSS 20.0 statistical software. Quantitative data that conformed to a normal distribution were described using mean and standard deviation; for data with a skewed distribution, the median and interquartile range (IQR) were used. For quantitative data that met the criteria of normal distribution and homogeneity of variances, a two-independent-sample t test was employed; for data that did not meet normality or had unequal variances, the Mann–Whitney *U* test was used. For categorical variables, the chi-square test was applied to infer whether there was a difference between proportions, and the results were reported with OR, 95% CI, and P value. If the main assumptions of the chi-square test were not met, Fisher's exact test was used. Statistical significance was set at $P < .05$, and a 95% confidence interval was calculated to describe the effect size.

RESULTS

A total of 270 cases with complete data were included. In the FV-UAS group, there were 71 females and 75 males, with a median age of 55 years (IQR, 40–61.5). There were 15 cases of hypertension and 12 cases of diabetes. The median preoperative urine white blood cell count was 25/μL (IQR, 0–125/μL). The median total volume of the stones was 2.84 cm^3 (IQR, 2.12–3.97 cm^3). The median average CT value of kidney stones was 723.0 HU (IQR, 559–887 HU). There were 88 cases of lower pole kidney stones, of which 37 had an infundibulopelvic angle (IPA) less than 45 degrees. In the T-PCNL group, there were 53 females and 71 males, with a median age of 49 years (IQR, 40–56). There were 12 cases of hypertension and 9 cases of diabetes. The median preoperative urine white blood cell count was 46/μL (IQR, 12–96.75/μL). The median total volume of the stones was 3.21 cm^3 (IQR, 2.26–4.0 cm^3). The median average CT value of kidney stones was 723.0 HU (IQR, 583–845 HU). There were 76 cases of lower pole kidney stones, of which 26 had an IPA less than 45 degrees. The two groups showed no significant differences in age, sex, history of hypertension, history of diabetes, presence of lower pole kidney stones, presence of lower pole stones with an IPA less than 45°, stone volume, stone density, and urinary white blood cell count (all $P > .05$; (**Table 1**)).

Postoperative data for the FV-UAS group showed an SIRS incidence of 5.5%, with a mean operative time of 58.32 ± 17.47 minutes, a decrease in Hb of 2.52 (1.09–3.91) g/L within 24 hours postoperatively, and 14 patients requiring analgesics. The mean postoperative hospital stay was 3.24 ± 0.87 days. In the T-PCNL group, the SIRS incidence was 4.8%, the mean operative time was 45.98 ± 10.78 minutes, the decrease in Hb was 3.80 (2.67–5.27) g/L within 24 hours postoperatively, and 11 patients required analgesics. The mean postoperative hospital stay was 4.23 ± 0.70 days (**Table 2**).

In the FV-UAS group, using a residual kidney stone diameter of less than 4 mm as the criterion (relatively stone-free), the SFR was 85.62% at 3 days postoperatively and 92.47% at 1 month. Using a residual diameter of less than 2 mm, the SFRs at 3 days and 1 month were 78.08% and 84.93%, respectively. In the T-PCNL group, using a residual diameter of less than 4 mm, the SFRs were 87.09% at 3 days and 92.74% at 1 month. Using less than 2 mm, the SFRs were 68.54% at 3 days and 79.84% at 1 month. The SFRs for the two surgical techniques showed no statistically significant differences. Using the criterion of a residual kidney stone diameter less than 4 mm, the SFRs at 3 days postoperatively were: 95% CI, 0.56–2.28; OR = 1.13; $P = .724$; at 1 month: 95% CI, 0.417–2.60; OR = 1.041; $P = .931$. Using less than 2 mm, the SFRs at 3 days were: 95% CI, 0.355–1.055; OR = 0.612; P = .076; at 1 month: 95% CI, 0.374–1.320; OR = 0.703; $P = .271$ (Table 3).

No significant differences were found between the two groups in terms of SIRS frequency (P = .813) or postoperative analgesia requirement (P = .839). The FV-UAS group had a substantially longer operative time than the T-PCNL group ($P < .001$). Additionally, the FV-UAS group exhibited a greater reduction in postoperative hemoglobin decline ($P < .001$) and a shorter duration of hospitalization ($P < .001$) compared to the T-PCNL group (**Table 2**).

In the FV-UAS group, three patients developed postoperative fever, leading to extended hospital stays. Three patients presented with small subcapsular renal hematomas. In the T-PCNL group, three patients exhibited retroperitoneal hematomas of varying degrees, with the maximum estimated blood loss approximately 100 mL, and no blood transfusion was required. One patient developed severe hematuria within 24 hours postoperatively and received a 400 mL blood transfusion.

DISCUSSION

Advancements in endoscopic lithotripsy equipment and surgical techniques have gradually expanded the indications for holmium laser lithotripsy using flexible ureteroscopes. The primary complications of flexible ureteroscopic lithotripsy are urinary tract infection and residual stones, with more severe infections potentially progressing to sepsis[15]. Secondary complications include bleeding during surgery, ureteral injury, and subcapsular renal hematoma. This has led urologists to still prefer PCNL for treating larger renal stones. For patients who are fearful of surgery and refuse PCNL, staged FURS is often chosen[5]. The high initial cost and maintenance expenses of early flexible ureteroscopes also limited the development of FURS[16]. However, several innovations have gradually changed this situation. First, the application of disposable flexible ureteroscopes has significantly reduced the cost of FURS and even eliminated or reduced maintenance expenses[16]. Second, the application of negative-pressure aspiration sheaths and intelligent pressure control devices has reduced the postoperative infection rate of FURS[17]. It was previously believed that increased renal pelvic pressure during surgery was a significant factor in the development of sepsis, and many studies have suggested that reducing renal pelvic pressure can reduce the incidence of infection in FURS[18,19]. Therefore, the use of negative pressure devices has increased the safety of FURS. Third, the application of FV-UAS has shortened the operation time and increased the stone-free rate[19]. The ability of the FV-UAS to extend into the renal pelvis is its advantage over traditional sheaths, ensuring better fluid circulation. The front end of the sheath reaching the stone location also facilitates the aspiration of stone fragments. It is worth noting that thulium lasers have excellent powdering effects on stones, making them well-suited for FV-UAS[20]. During surgery, most of the stone powder can be aspirated through negative pressure, avoiding the need for repeated insertion and removal of the ureteroscope, thus saving time. In this study, all FURS procedures were completed within 2 hours, even for larger stones. Therefore, in combination with FV-UAS, negative pressure devices, and thulium lasers, FURS is gradually being used to treat larger renal stones. In this study, only cases in which the front end of the FV-UAS could extend into the renal pelvis were included, distinguishing it from traditional negative-pressure sheaths. By combining thulium laser and negative pressure, the operator only needs to clear larger stone fragments through negative pressure at the final stage of lithotripsy, while the remaining stone powder is continuously aspirated in real time, greatly improving the efficiency of stone fragmentation and clearance.

PCNL has historically been considered the gold standard for treating renal stones larger than 2 cm in diameter[21], with bleeding and infection being its major complications[22]. The surgical approach has also undergone several improvements aimed at controlling complications and increasing stone clearance rates. First, the transition from standard tract to ultra-mini tract. Research and reviews have shown that mini and ultra-mini channels (14F–20F) have longer operation times compared to standard channels (24–30F) in PCNL, but they also result in fewer complications[23]. Second, the transition from tubed to completely tubeless percutaneous nephrolithotomy. There is literature comparing PCNL with tubeless PCNL[24], highlighting that nephrostomy tubes may cause related complications, while other studies have proven the safety of tubeless PCNL[25]. These studies mention that establishing a puncture channel at the calyceal fornix is key to reducing bleeding and achieving tubeless PCNL. Third, the application of percutaneous nephroscopic negative-pressure sheaths has reduced the manual process of stone clearance, thereby increasing stone clearance efficiency[26].

In summary, for treating renal stones of 2–3 cm in diameter, to balance stone fragmentation efficacy and reduce complications, we chose a 16F Amplatz sheath for tubeless PCNL. In our data, all patients in the T-PCNL group successfully completed the surgery without major bleeding or sepsis. The decrease in hemoglobin postoperatively was within a safe range. Only a few experienced SIRS and required extended treatment time, with the majority meeting discharge criteria within 3–4 days. Since no nephrostomy tube was placed postoperatively, patients experienced significantly reduced back pain, and there was no significant difference in the use of analgesics compared to the FV-UAS group ($P > .05$). Hemorrhage and infection are critical indicators for endoscopic urologic surgery and key factors in evaluating outcomes. In this study, the decrease in Hb levels was used to assess hemorrhage. The data show that the Hb decrease in the T-PCNL group was significantly higher than that in the FV-UAS group, which may be attributed to the greater damage to the urinary system caused by the PCNL surgical approach compared to FURS. Since PCNL necessarily causes trauma to the kidney, this outcome is not unexpected. Urinary tract infection is also a common complication of endoscopic surgery, with the most severe being sepsis or death caused by urinary sepsis. As no such complications were observed in this study, SIRS was used to assess infection. SIRS can occur within hours to 24 hours after surgery, and its observation indicators include temperature, respiration, blood pressure, and white blood cell count, which are also important indicators for evaluating sepsis[27]. Close monitoring of these indicators can lead to earlier treatment of potential sepsis. By comparing the two groups, it appears that negative pressure and clear drainage can reduce the incidence of infection, with no significant difference between the groups. In the PCNL group, drainage of potentially infected urine in the renal pelvis before renal puncture through the double-J stent and urinary catheter may also reduce infection, but these data were incomplete and therefore not tabulated.

Clearing stones in the lower pole of the kidney through urological endoscopic surgery (FURS/PCNL) has always been a challenge, and the lower pole stone-free rate is an important indicator of surgical outcome. It was previously believed that an acute IPA might be associated with a lower stone-free rate[28], but in this study, there was no significant difference in the 3-day and 1-month SFR between the two groups, similar to a previous study. We believe that the stone-free rate in the lower pole with an IPA less than 45 degrees may be related to the degree of hydronephrosis and its location. In specific procedures, severe hydronephrosis may offer more space for FURS and PCNL, facilitating stone removal. Puncturing the calyx with more severe hydronephrosis may not only reduce bleeding but also be more beneficial for clearing stones in the lower renal calyx. However, there is limited research on the impact of kidney puncture site selection or the degree of hydronephrosis on the stone-free rate of urological endoscopic surgery, which warrants further investigation.

This study has limitations: (1) As a retrospective study, the collection of certain data presented challenges, such as the incidence of ureteral injury during FURS, whether patients received additional treatment due to residual stones, and the completeness of quality-of-life assessments. (2) The results may have been influenced by confounding factors, such as bias in the selection of surgical methods, because tubeless PCNL had already become the standard surgical approach before the adoption of FV-UAS technology. (3) The reported SFRs for the two groups were similar, which may differ from other studies. To compare SFRs more accurately between the two surgical methods, a larger sample size or multicenter prospective studies may be necessary.

CONCLUSIONS

In summary, for the treatment of 2–3 cm renal stones, FV-UAS combined with FURS and 16F tubeless PCNL both offer high stone-free rates, minimal pain, and few complications. FV-UAS combined with FURS has the advantages of less bleeding and shorter hospital stay, while 16F tubeless PCNL has the advantage of shorter operation time.

SUMMARY

For 2–3 cm kidney stones, both FV-UAS–assisted FURS and 16F tubeless PCNL achieve high stone-free rates. FV-UAS–FURS leads to less bleeding and a shorter hospital stay, while tubeless PCNL offers a shorter surgery time.

CONFLICT OF INTEREST

The authors report no conflict of interest.

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