# Original Article

# Retrograde intrarenal surgery combined with flexible vacuum-assisted ureteral access sheath versus traditional ureteral access sheath for 1-2 cm lower calyceal renal stones: a prospective, randomized controlled study

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Abstract: Objective: To evaluate the efficacy and safety of retrograde intrarenal surgery (RIRS) combined with a flexible vacuum-assisted ureteral access sheath (FV-UAS) in patients with 1-2 cm lower calyceal renal stones. Patients and methods: In total, 203 patients with calyceal stones were prospectively randomized into two groups (Clinical trial registration number: ChiCTR2200056402). Of them, 101 patients were assigned to the FV-UAS group and 102 to the traditional UAS group (control). The primary outcome was the stone-free rate (SFR) on postoperative day 1 and in the 4th week. Secondary outcomes included operative time, length of postoperative hospital stay, hospitalization costs, and procedure-related complications. Results: No significant differences were noted in baseline demographics and preoperative clinical characteristics between the two groups (all P > 0.05). Postoperative data indicated that the SFRs on both postoperative day 1 and week 4 were significantly higher in the FV-UAS group than in the traditional UAS group (86.1% vs. 70.6%, P = 0.007; 92.1% vs. 82.4%, P = 0.038, respectively). Hospitalization costs were also lower in the FV-UAS group than in the traditional UAS group (\$2524.1 vs. \$2635.4, P < 0.001). Furthermore, the incidence rates of postoperative fever, perirenal hematoma, and urosepsis were significantly lower in the FV-UAS group than in the traditional UAS group (fever: 2.0% vs. 8.8%, P = 0.031; hematoma: 0.0% vs. 4.9%, P = 0.024; urosepsis: 1.0% vs. 7.8%, P = 0.018). Conclusions: Our findings suggest that the combination of FV-UAS and RIRS offers a promising treatment approach for 1-2 cm lower calyceal renal stones. This method results in higher SFRs, lower complication rates, and reduced hospitalization costs, making it a valuable technique for clinical adoption.

**Keywords:** Retrograde intrarenal surgery, flexible vacuum-assisted ureteral access sheath, lower calyceal renal stone, stone-free rate, intrarenal pressure

### Introduction

Renal stones are among the most common conditions encountered in urology. Currently, the incidence of renal stones in China is approximately 7.54%, with a notable upward trend. Recurrence rates are approximately 11.8% within 5 years and up to 60% within 10 years [1]. Due to the unique anatomical structure of the lower calyx, stones in this location have always posed a particular challenge in the treatment of urinary tract calculi [2]. Fortunately, technological advancements and the emergence of mini-

mally invasive modalities continue to revolutionize endourology [3].

Lower calyceal renal stones (i.e., those located in the kidney's lower pole) have distinctive anatomical and clinical characteristics: (1) Anatomy-dependent: The dependent position of the lower calyx, influenced by gravity, hinders spontaneous stone passage. A narrow infundibulum and an acute angle between the calyx and renal pelvis make stone clearance more difficult. (2) Asymptomatic or chronic symptoms: Often asymptomatic unless complica-

tions such as obstruction or infection arise. It may result in recurrent urinary tract infections (UTIs), hematuria, or vague flank discomfort. (3) Higher recurrence risk: Urine stagnation in the lower pole fosters stone growth/recurrence. Moreover, diagnosis typically involves (1) Imaging: non-contrast computed tomography (CT: one size, location, and density (HU units), and less-sensitive KUB X-ray and ultrasound used for follow-up. (2) Clinical assessment: assessing symptoms (e.g., pain, hematuria, UTIs) and conducting a 24-h urine metabolic workup to evaluate stone risk factors). For renal stones > 2 cm, percutaneous nephrolithotomy (PCNL) is the gold standard, given its high SFR [4]. However, PCNL is invasive and associated with a significant risk of complications, such as severe bleeding, pain, and injury to renal or adjacent structures due to nephrostomy tract dilation [5, 6]. Kumar et al. reported that minimally invasive PCNL (MPCNL) led to more complications, longer operative times, and extended hospital stays than retrograde intrarenal surgery (RIRS) or extracorporeal shock wave lithotripsy (ESWL) for treating 1-2 cm lower calyceal stones [7]. RIRS is currently the guideline-recommended and preferred option for treating upper urinary tract stones < 2 cm in size [8]. In recent years, with advancements in endoscopic techniques and laser technologies, RIRS has become increasingly used for managing complex upper urinary tract stones. Nonetheless, two major limitations remain: elevated intrarenal pressure (IRP) and the presence of residual fragments [9].

The ureteral access sheath (UAS) is commonly used in RIRS to facilitate stone extraction. A novel development, the flexible vacuum-assisted UAS (FV-UAS) (Wellead Medical, Guangzhou, China), has gained popularity in clinical practice. Because of its flexible tip, FV-UAS can passively bend with the rotation of the flexible ureteroscope (fURS), allowing it to navigate the renal pelvis and access various calyces. Wang DJ et al. [9] reported that FV-UAS provides better IRP control and improved SFRs compared with MPCNL. However, no studies have directly compared FV-UAS and traditional UAS in the context of RIRS for 1-2 cm lower calyceal stones. Therefore, we conducted this prospective study to investigate whether RIRS combined with FV-UAS offers superior clinical outcomes compared to traditional UAS.

#### Patients and methods

#### **Patients**

Patients with 1-2-cm lower calyceal renal stones referred to our institute between June 2022 and May 2024 were enrolled in this study. After applying strict inclusion criteria, the patients were randomly assigned to the treatment groups using the envelope method. Overall, the study included 203 patients, 101 in the FV-UAS group and 102 in the traditional UAS group, based on a power analysis performed to estimate the sample size (Figure 1). The participants' pretreatment evaluation included medical history, physical examination, laboratory investigations (such as urine analysis, urine culture and/or sensitivity, complete blood count, blood urea nitrogen, serum levels of creatinine, C-reactive protein, and procalcitonin), and radiological investigations. Patients with a known UTI received antibiotic treatment until achieving infection control. The study was approved by the clinical research ethics committee of the Affiliated Jiangning Hospital of Nanjing Medical University (ethics approval number: 202200118). Written informed consent was obtained from all participants. The study was conducted in accordance with the principles of the Helsinki Declaration.

#### Randomization and masking

Parallel randomization was conducted by using a stratified approach. Our center enrolled 203 participants randomized in a 1:1 ratio to either the FV-UAS group or the traditional UAS group. Electronic generation of the randomization sequence was then arranged before patient inclusion. Consecutively numbered and sealed envelopes were used for random sequence allocation and concealment. After the patients were subjected to general anesthesia and before ureteroscopy was entered into the urethra, the sealed envelope was opened by a designated nurse to reveal the specific surgical methods to be employed. Subsequently, after the procedure, the same individual automatically recorded the operative data.

# Perioperative and surgical procedures

All patients underwent a plain preoperative abdominal radiography of the kidneys, ureters, and bladder (KUB) and unenhanced CT to

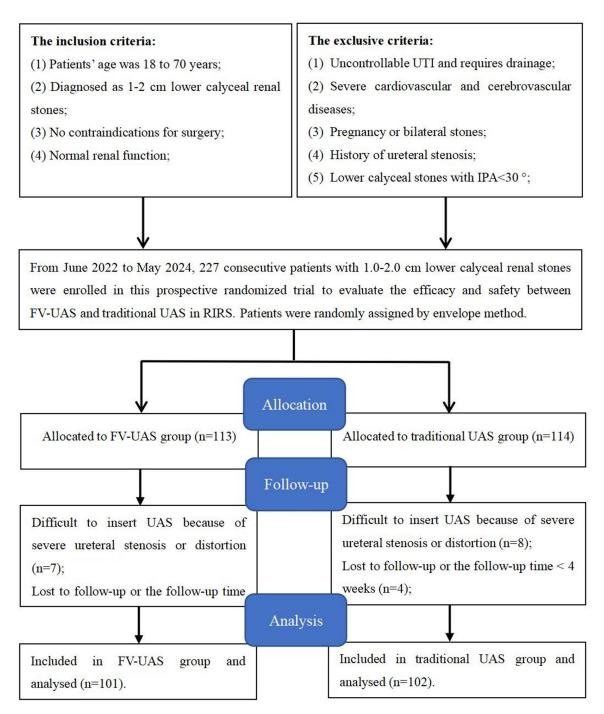


Figure 1. Flowchart for cases selection.

assess hydronephrosis and the size, location, and number of stones. We generally performed preprocedural urine cultures and applied appropriate antibiotic therapy based on the culture-antibiogram test outcomes. Patients with negative urine cultures were treated with broad-spectrum antibiotics before conducting the surgery. The opportunity for operation depended

on a downward trend in infection indicators and a negative urine culture. The stone size was determined by measuring the longest axis on the preoperative radiographs. In the case of the presence of multiple stones, the sum of their longest axes was applied [10]. All procedures were performed by the same urologist in the study. The selection of a specific surgical

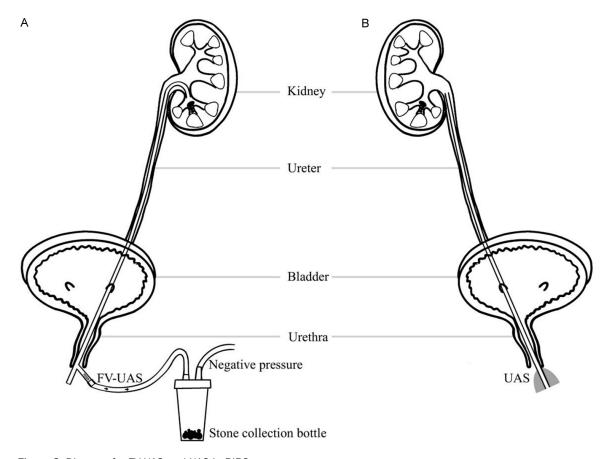


Figure 2. Diagram for FV-UAS and UAS in RIRS.

method to be applied to the enrolled patients was random, excluding any artificial subjective factors.

FV-UAS group. Under general anesthesia, the patient was placed in a lithotomy position for retrograde endoscopic access. A 0.032-inch loach guidewire was introduced into the upper urinary tract, followed by a 10/12 Fr FV-UAS (Female: 36 cm; Male: 46 cm) inserted into the upper diseased ureter (Figure 2A). A 9.2-Fr electronic fURS (PU3022A, Pusen Medical, Zhuhai, China) was inserted through the FV-UAS. A complete inspection of the entire collecting system was performed and negative pressure was connected to suck out infectious substances for the urine culture if deemed necessary. The position of the FV-UAS was adjusted to approach the lower calyceal under the direct vision of the fURS. Then, electronic fURS was applied to fragment large stones by using a 200-µm holmium laser fiber with the energy level set to 0.6-0.8 J and the rate set to 30-40 Hz. By controlling the longitudinal slip of the

FV-UAS, the fURS was repeatedly inserted and withdrawn slowly to continuously suction the fragments from the body. Notably, the fluid irrigation flow rate was set to 80 mL/min. The tail end of the FV-UAS was connected to a central negative pressure suction of the operating room (negative pressure: 85-90 cmH<sub>2</sub>0) so as to control the balance of inlet and outlet water for achieving a clear vision. At the end of the procedure, the collecting system was visually reinspected for the presence of large stone fragments. The FV-UAS and fURS were removed while visually assessing and documenting the presence of any ureteral injury. A 6-Fr double-J stent was placed in all patients. If severe ureteral stenosis or distortion was encountered during the operation and it was found difficult to insert the FV-UAS, balloon dilation was attempted; otherwise, only a double-J stent was placed for dilation.

Traditional UAS group. The surgical steps and procedures were similar to that of the FV-UAS group. However, the most distinguishing factor

# RIRS combined with FV-UAS for lower calyceal renal stones

**Table 1**. Comparisons of patients' demographics and preoperative clinical characteristics between two groups

Variables, mean ± SD or n (%)	FV-UAS group (n = 101)	Traditional UAS group (n = $102$ )	P value
Age, years	44.5 ± 6.1	43.2 ± 5.7	0.118
BMI, kg/m <sup>2</sup>	25.1 ± 2.9	24.7 ± 3.1	0.344
Gender			
Male	53 (52.5)	58 (56.9)	-
Female	48 (47.5)	44 (43.1)	0.530
Hypertension history			
No	46 (45.5)	50 (49.0)	-
Yes	55 (54.5)	52 (51.0)	0.620
Diabetes history			
No	39 (38.6)	43 (42.2)	-
Yes	62 (61.4)	59 (57.8)	0.607
Mean stone size, cm	$1.6 \pm 0.4$	1.5 ± 0.5	0.117
Essence (Hounsfield units)	981.7 ± 103.6	965.4 ± 116.7	0.294
Hydronephrosis			
Mild	74 (73.3)	68 (66.7)	0.305
Moderate	18 (17.8)	23 (22.5)	0.402
Severe	9 (8.9)	11 (10.8)	0.654
Urine culture			
Negative	65 (64.4)	61 (59.8)	-
Positive	36 (35.6)	41 (40.2)	0.504
Upper urinary stone operation histories <sup>a</sup>			
No	84 (83.2)	87 (85.3)	-
Yes	17 (16.8)	15 (14.7)	0.678

BMI = body mass index; SD = standard deviation; <sup>a</sup>Upper urinary stone operation histories include flexible ureteroscope lithotripsy, percutaneous nephrolithotomy or open surgery for stone.

was that the traditional UAS could only be placed at the ureteropelvic junction (UPJ) (Figure 2B). Meanwhile, we attempted to move the lower calyceal renal stones to the middle calyceal with the help of a stone-removal basket before lithotripsy, whereby stone fragments of size > 2 mm were removed.

# Postoperative follow-up

An ultra-low-dose CT was performed on the first day after surgery to search for any residual stones. A stone-free status (SFS) was defined as the absence of radiological evidence of stones or the presence of  $\leq$  2-mm asymptomatic fragments in the urinary system [11]. The primary study outcome was the SFR on the 1st postoperative day. SFR refers to the percentage of patients who achieved complete clearance of kidney or ureteral stones after administering a specific treatment (e.g., surgery, lithotripsy). It was typically assessed via imag-

ing (such as through a CT scan, X-ray, or ultrasound) within 4-12 weeks of the treatment. SFR was the key outcome measure applied to evaluate the efficacy of treatment, the selection of the treatment method, and the success of the applied surgical technique. The secondary endpoints were total SFR 4<sup>th</sup> week postoperatively, operative time, postoperative hospital stay, hospitalization expenses, and operation-related complications. Patients with residual stones underwent auxiliary procedures  $\geq 4$  weeks after the surgery. These included external physical vibration lithecbole (EPVL), ESWL, or position therapy [12, 13]. The double-J stent was removed at 4 weeks after the operation.

# Statistical analysis

IBM SPSS Statistics for Windows, Version 22.0 (IBM Corp., Armonk, NY, USA) was used for statistical analysis. Continuous variables are presented as the means  $\pm$  standard deviations.

**Table 2.** Comparisons of surgical outcomes and postoperative clinical characteristics between two groups

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Variables, mean ± SD or n (%)	FV-UAS group (n = 101)	Traditional UAS group (n = 102)	P value
Operative time, min	53.7 ± 4.9	$54.8 \pm 5.1$	0.119
Postoperative hospital stay, days	$2.1 \pm 0.7$	2.2 ± 0.5	0.243
Hospitalization expenses, USD	2524.1 ± 209.0	2635.4 ± 251.3	0.001**
Initial SFS (postoperative 1st day)			
No	14 (13.9)	30 (29.4)	-
Yes	87 (86.1)	72 (70.6)	0.007**
Total SFS (postoperative 4th week)			
No	8 (7.9)	18 (17.6)	-
Yes	93 (92.1)	84 (82.4)	0.038*
Complications			
Fever	2 (2.0)	9 (8.8)	0.031*
Low back pain	3 (3.0)	7 (6.9)	0.194
Perirenal hematoma	0 (0.0)	5 (4.9)	0.024*
Urosepsis	1 (1.0)	8 (7.8)	0.018*
Stone compositions			
Calcium oxalate	56 (46.2)	52 (48.8)	0.524
Calcium phosphate	20 (28.7)	21 (18.7)	0.889
Struvite or carbonated apatite	21 (21.3)	23 (30.0)	0.761
Uric acid or cysteine	4 (3.8)	6 (2.5)	0.527

SD = standard deviation; SFS = stone-free status;  $^*P < 0.05$ ,  $^{**}P < 0.01$ .

The groups were compared for patient demographics, follow-up, and surgical outcomes using independent samples t-test. The Shapiro-Wilk test was applied to test the normality of the initial data. A chi-squared test was performed to compare the groups for other preand postoperative clinical characteristics. P < 0.05 was considered to indicate statistical significance.

# Results

Demographics and preoperative clinical characteristics

In total, 203 patients with lower calyceal renal stones were randomly assigned to the FV-UAS group (n=102) or the traditional UAS group (n=102). The two groups were comparable in terms of demographics and preoperative clinical characteristics (**Table 1**). The mean stone size was 1.6 and 1.5 cm in the FV-UAS and traditional UAS groups, respectively, with no statistically significant difference (P=0.117). Similarly, no significant differences were observed between the two groups in mean age at diagnosis, body mass index, sex distribution,

history of hypertension or diabetes, stone composition, degree of hydronephrosis, urine culture results, or previous upper urinary stone surgeries (all P > 0.05).

# Postoperative clinical characteristics

Postoperative clinical outcomes for both groups are presented in Table 2. No significant differences were observed in operative time or length of postoperative hospital stay between the two groups (P > 0.05). However, hospitalization costs were significantly lower in the FV-UAS group than in the traditional UAS group (\$2524.1 vs. \$2635.4, P < 0.001). Moreover, the SFRs on postoperative day 1 and at the 4-week follow-up were significantly higher in the FV-UAS group than in the traditional UAS group (86.1% vs. 70.6%, *P* = 0.007; 92.1% vs. 82.4%, P = 0.038, respectively). Postoperative complications were classified according to the modified Clavien classification system and included fever (≥ 38.5°C), pain, perirenal hematoma, and urosepsis [19]. The incidence rates of fever, perirenal hematoma, and urosepsis were all significantly higher in the traditional UAS group than in the FV-UAS group (fever: 8.8% vs. 2.0%, P = 0.031; hematoma: 4.9% vs. 0.0%, P = 0.024; urosepsis: 7.8% vs. 1.0%, P = 0.018). No significant differences were found between the two groups in stone compositions (P > 0.05).

#### Discussion

Currently, multiple minimally invasive treatment options are available for managing lower calyceal renal stones [14]. Among them, ESWL offers advantages such as cost-effectiveness, convenience, and better patient compliance. However, its efficacy is limited for 1-2 cm lower calyceal stones, with lower SFRs during followup [15]. Although PCNL provides satisfactory SFRs, the anatomical challenges of the lower calyx and the often minimal hydronephrosis make percutaneous access difficult and elevate the risk of postoperative bleeding [16]. Consequently, RIRS has become the preferred treatment modality for 1-2 cm lower calyceal stones. Despite its utility, RIRS combined with traditional UAS and disposable fURS presents technical limitations. Factors such as the anatomical positioning of the lower calyx, respiratory movements during lithotripsy, and the bending limitations of the fURS and laser can make direct targeting of the stones difficult. In some cases, the laser can only fragment a portion of the stone, risking injury to the renal mucosa and obscuring the surgical field. These technical challenges can prolong operative time, elevate IRP, and increase the risk of complications such as perirenal hematoma and urosepsis [17]. Furthermore, the need to manually extract stone fragments with a basket often results in RFs being left behind, especially those that settle at the bottom of the kidney, leading to lower overall SFRs [18].

Improving SFRs, reducing IRP, and minimizing postoperative complications remain key challenges in minimally invasive lithotripsy. FV-UAS is a new device developed based on the vortex suction principle used in PCNL [19]. Its most significant innovation lies in the design of its distal end (**Figure 2A**). The 10 cm flexible and bendable tip can follow the movement of the fURS, bending up to 180°. The soft, non-metallic 3-mm tip minimizes trauma to the renal calyceal mucosa. Its proximal end features a Y-shaped design with components including an expansion tube, connector, sheath, and operat-

ing handle. A longitudinal slit in the handle serves as a pressure-regulating vent, and a stone collection bottle connects the sheath to the operating room's central negative pressure suction system.

Unlike conventional UAS, the FV-UAS is not fixed at the UPJ; instead, its flexible head can move with the fURS into upper, middle, and most lower calyces, facilitating the direct evacuation of stone fragments [20]. Smaller fragments (< 2 mm) can be continuously suctioned during lithotripsy, while larger fragments (2-3 mm) can be removed through a combination of fURS withdrawal and negative pressure suction. Chen et al. validated this mechanism in 2022, reporting significantly improved SFRs with FV-UAS [21]. Our study confirmed these findings, showing significantly higher SFRs on both postoperative day 1 and week 4 in the FV-UAS group compared with the traditional UAS group (86.1% vs. 70.6%, *P* = 0.007; 92.1% vs. 82.4%, P = 0.038, respectively).

IRP control is another critical concern in RIRS. Studies have shown that FV-UAS can effectively reduce IRP during surgery [22, 23]. The operator can dynamically regulate the negative pressure according to intraoperative findings, including the degree of collection system distention and presence of infection, thereby maintaining a clearer field of view and reducing the risks of postoperative sepsis and perirenal hematoma [24]. In our study, complication rates such as fever, perirenal hematoma, and urosepsis were significantly lower in the FV-UAS group than in the traditional UAS group (fever: 2.0% vs. 8.8%, P = 0.031; hematoma: 0.0% vs. 4.9%, P = 0.024; urosepsis: 1.0% vs. 7.8%, P = 0.018). From an economic perspective, the cost of FV-UAS is comparable to that of traditional UAS. However, since the use of stone baskets can often be avoided, the overall hospitalization cost is reduced, as reflected in our findings (\$2524.1 vs. \$2635.4 dollar, P < 0.001).

This study does have some limitations. IRP was not monitored in real-time and was instead estimated based on the surgeon's experience, such as the degree of collection system filling. Additionally, the relatively short follow-up period may have affected the accuracy of long-term outcome assessments. Finally, this was a single-center study with a limited sample size,

which may introduce sampling bias. Long-term, large-scale, multicenter clinical studies are necessary to validate our findings and establish optimized protocols.

#### Conclusions

Our study demonstrates that the combination of FV-UAS with RIRS represents a promising alternative for the treatment of 1-2 cm lower calyceal renal stones. This approach yields higher SFRs, fewer complications, and reduced hospitalization costs. Given these advantages, FV-UAS merits broader clinical adoption. However, further large-scale, multicenter prospective studies are warranted to confirm and expand upon these findings.

#### Disclosure of conflict of interest

None.

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