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RESEARCH

Comparative evaluation of flexible and navigable suction sheath (FANS), percutaneous nephrostomy (PCN), and conventional ureteral access sheath (UAS) during retrograde intrarenal surgery: a randomized controlled trial

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Abstract

Purpose Optimizing drainage during retrograde intrarenal surgery (RIRS) is crucial for procedural efficacy and safety. Flexible and navigable suction ureteral access sheath (FANS) offers active intrarenal suction without external access, while percutaneous nephrostomy (PCN) provides reliable but invasive drainage. This study compared the efficacy and safety of FANS versus PCN tube drainage during RIRS as compared to conventional ureteral access sheath (UAS).

Methods This randomized controlled trial included 217 adult patients with renal stones (14–27 mm) undergoing RIRS. Patients were randomized into three groups: (UAS, $n=72$), PCN ($n=72$), and FANS ($n=73$). Outcomes assessed included operative time, stone-free rate (SFR), complications, and postoperative recovery.

Results SFR was significantly higher with PCN (97.2%) and FANS (98.6%) versus UAS (81.9%; $p<0.001$). The mean operative time was shorter with PCN (48 ± 14 min) than UAS (58 ± 13 min) and FANS (58 ± 11 min; $p<0.001$). Loin/suprapubic pain and hematuria were more frequent with UAS, whereas infectious and major complications were infrequent and similar. On stepwise multivariable analysis, lower Hounsfield units and use of PCN (OR 7.756, 95% CI 1.655–36.346) or FANS (OR 17.25, 95% CI 2.156–138.024) independently predicted stone-free status.

Conclusions PCN and FANS are both effective and safe drainage strategies during RIRS and outperform conventional UAS in SFR. FANS provides a minimally invasive, entirely endoscopic alternative to PCN with comparable safety and efficacy.

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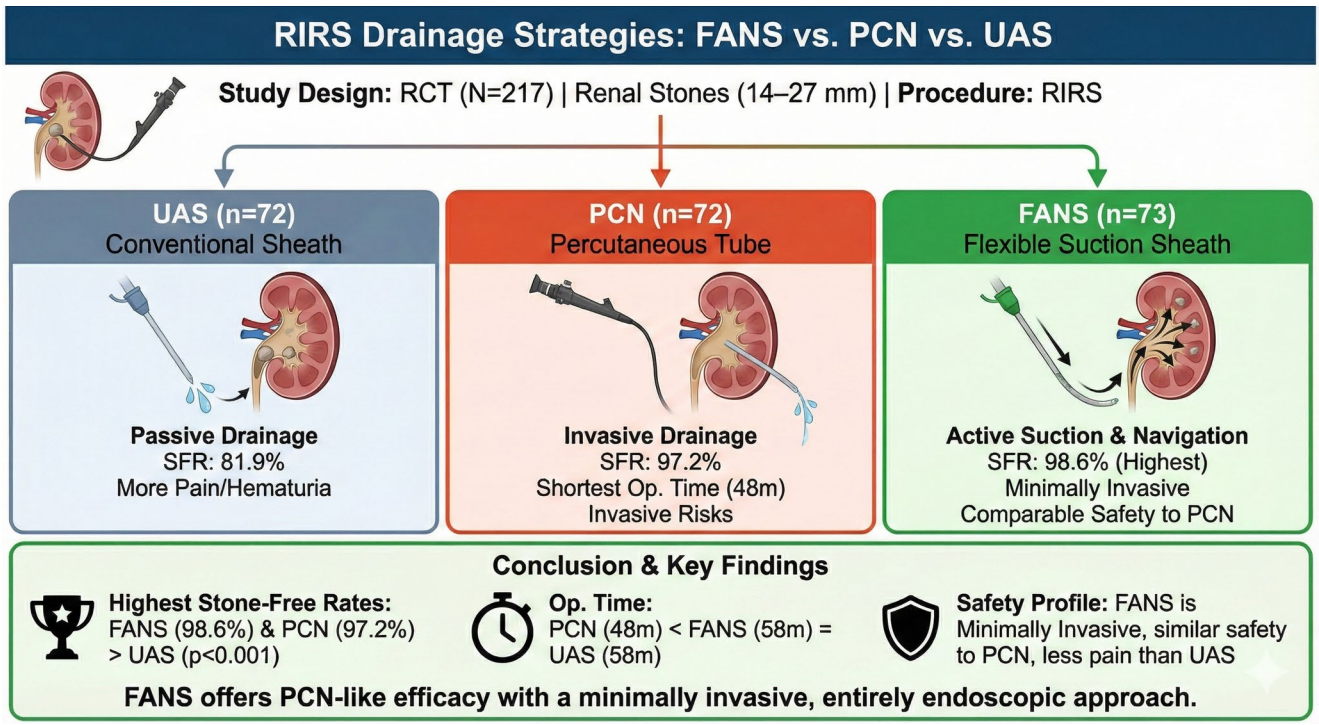
Graphical abstract



Keywords Retrograde intrarenal surgery · Flexible and navigable suction · Percutaneous nephrostomy · Ureteral access sheath · Stone-free rate · Renal stones

Introduction

Urolithiasis is the most prevalent urinary tract disorder worldwide and places a substantial financial burden on healthcare systems. Its clinical impact is reinforced by a 10-year cumulative recurrence rate of around 50%. Epidemiologic data also indicate that kidney stone prevalence has nearly tripled over the past three decades and continues to rise each year [1]. Established treatment options include extracorporeal shock wave lithotripsy (ESWL), percutaneous nephrolithotomy (PCNL), and ureteroscopic lithotripsy. Over the last 20 years, broader use of ureteral access sheaths (UAS) and advances in flexible ureteroscopy—particularly improved digital optics and the introduction of single-use instruments—have expanded the scope of ureteroscopic stone surgery, positioning it as the preferred approach for many stone presentations. Current guidelines recommend flexible ureteroscopic lithotripsy (FURL) as first-line therapy for 1–2 cm renal stones and as an alternative for stones measuring 2–4 cm [2].

Retrograde intrarenal surgery (RIRS) continues to advance, and its use for upper urinary tract stones has expanded as outcomes improve and complication rates remain lower than those reported with ESWL and PCNL [3]. The introduction of suction-enabled ureteral access sheaths has added a practical approach to enhancing stone clearance. Early experience with suction-integrated UAS has shown high stone-free rates in the management of renal calculi. The flexible and navigable suction ureteral access sheath (FANs) allows active evacuation of irrigation fluid along with stone dust and fragments. This may support more efficient clearance and help limit intrarenal pressure, with potential benefits for operative workflow and intraoperative safety [4]. Recent clinical studies further report that, during flexible ureteroscopic lithotripsy (FURL), FANs are associated with higher stone-free rates, shorter operative time, and fewer complications than conventional UAS [5].

In parallel, percutaneous nephrostomy (PCN) remains widely used in endourology as a dependable method for renal drainage. PCN provides rapid decompression of the collecting system, prevents pressure-related complications, and is often employed as an adjunct step in patients undergoing RIRS. Although effective, PCN is an invasive technique that adds procedural steps, may increase postoperative discomfort, and carries risks such as bleeding or catheter-related infection [6].

Therefore, the current study aimed to compare the efficacy and safety of FANS versus PCN as compared to UAS

during RIRS with particular interest in whether FANS could provide outcomes comparable to or better than PCN while maintaining the advantages of a less invasive retrograde approach.

Patients and methods

Study design and setting

This prospective randomized study was conducted at Benha University Hospitals on adult patients undergoing flexible ureteroscopy for the management of renal pelvic or calyceal stones with a total of 217 patients. Data collection and follow-up of efficacy, safety, and postoperative complications were carried out over a six-month period from February 2025 to July 2025. Ethical approval was granted by the Research Ethics Committee of Benha Faculty of Medicine. Written informed consent was obtained from all participants before enrollment, and the study was performed in accordance with the Declaration of Helsinki.

Study population and eligibility criteria

Eligible participants were adults of either sex, aged 20–67 years, with renal pelvic or calyceal calculi measuring 14–27 mm on non-contrast CT and a negative preoperative urine culture. Patients were excluded if they had an active urinary tract infection, bilateral stones, urinary diversion or congenital/anatomic urinary tract malformations, or an uncontrolled coagulation disorder.

Sample size calculation

Sample size was estimated using G*Power software (version 3.1.9.7). Calculations were based on Huang et al. [7], who reported stone-free rates of 78.6% with FANs-UAS and 50.5% with TUS. After applying a multiplicity adjustment, the required sample size was 70 patients per group (total, 210). To account for potential loss to follow-up at 1 month, the target enrolment was increased to 75 patients per group (total, 225). The significance level (α) was set at 0.05 with 90% power.

Randomization and blindness

Patients who met the eligibility criteria were randomly allocated into three intervention groups using a computer-generated randomization sequence. Group allocation was performed in a 1:1:1 ratio. Concealment of allocation was maintained through the use of sealed, sequentially numbered opaque envelopes that were opened only after patient enrollment and completion of the baseline assessment. The study was conducted with outcome assessors/data collectors blinded to group allocation. According to the final randomization, 72 patients were assigned to the UAS group, 72 patients to the PCN group, and 73 patients to the FANS group. Each patient underwent the operative technique corresponding to their assigned group as presented in the CONSORT flow chart (Fig. 1).

Patient assessment

All patients were subjected to complete history including personal history, present history including loin pain and hematuria, medical history such as diabetes mellitus, hypertension, and cardiac conditions, and surgical history including previous urological operations. Physical examination included general examination, systemic examination, and local examination for scars of previous operations or local skin disease. Laboratory investigations included complete blood count, bleeding profile, and urine analysis. All patients underwent non-contrast abdominal CT and plain abdominal radiography. When anatomical uncertainty existed, intraoperative retrograde pyelography was used to confirm the collecting system anatomy. The following variables were documented: stone laterality, stone burden, number of stones, hydronephrosis (presence and grade), and stone density measured in Hounsfield units.

Interventions

All procedures were carried out under general anesthesia with the patient in the lithotomy position. Appropriate prophylactic antibiotics were administered preoperatively.

FANS and UAS groups

In both groups, a diagnostic semi-rigid ureteroscopy was first performed to assess ureteral anatomy and allow passive ureteral dilatation. Further dilatation was conducted as needed to permit passage of the access sheath.

FANS group: An Elephant Type II flexible, navigable suction ureteral access sheath (11–13 Fr) was advanced over a safety guidewire under endoscopic guidance, and the tip was positioned within the renal pelvis or the targeted calyx. The sheath was connected to a vacuum system set at 2–7 kPa, and irrigation was maintained at 80–200 mL/min using a peristaltic pump. Flexible ureteroscopy (Sevita®, outer diameter 7.5 Fr) and laser lithotripsy (Holmium: YAG laser, 272-µm fiber, 1.0–1.2 J, 15–30 Hz) were performed using a dusting technique, with active evacuation of fragments through the suction system.

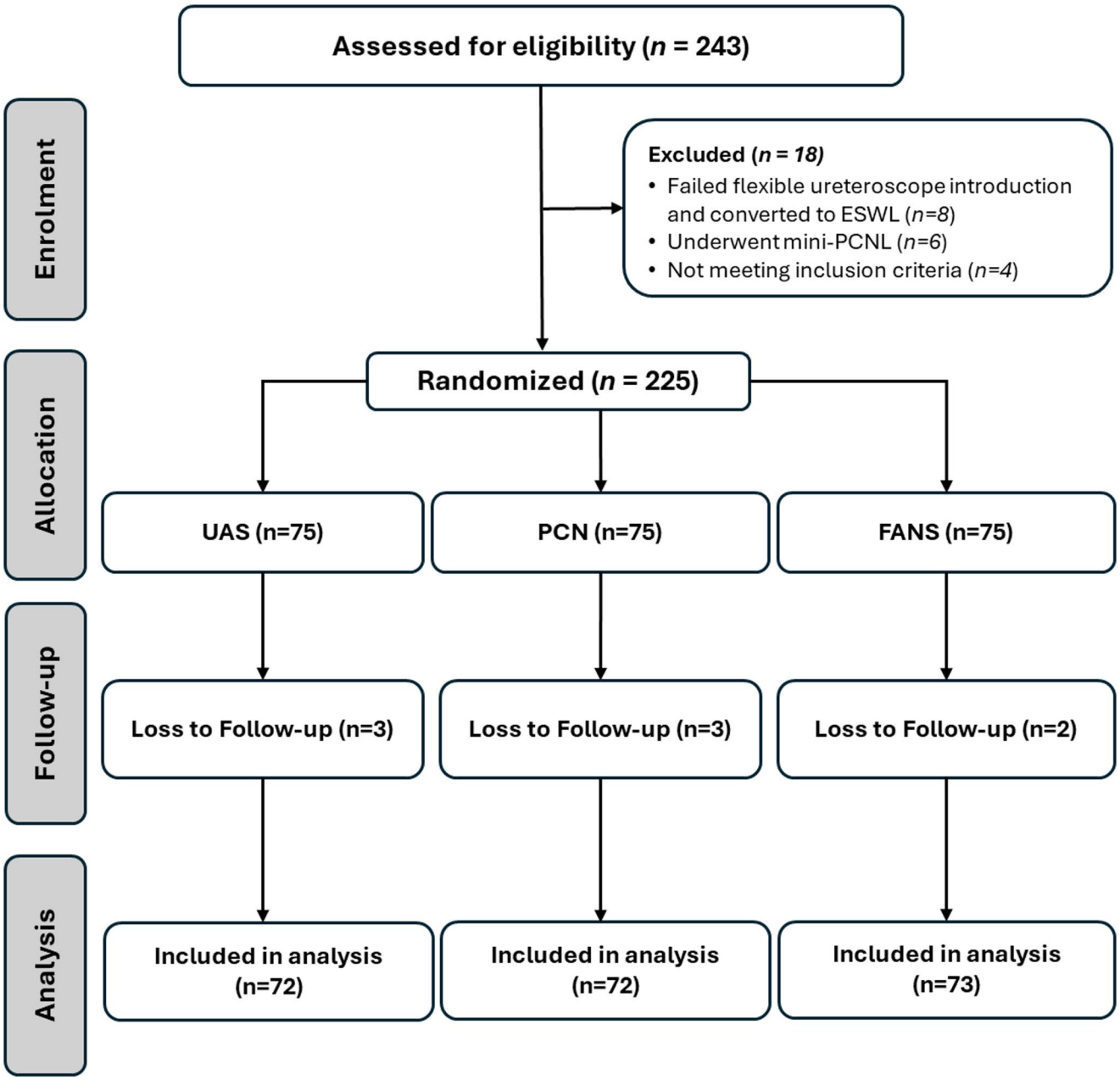


Fig. 1 CONSORT flow chart of eligible patients

UAS group: A Boston Scientific ureteral access sheath (11–13 Fr) was inserted in a similar manner following diagnostic ureteroscopy and dilatation. Flexible ureteroscopy and laser lithotripsy were then performed using identical laser settings and irrigation parameters but without suction capability.

PCN Group: In the PCN group, a safety guidewire was placed cystoscopically, followed by flexible ureteroscopy. Under ultrasound guidance, an 8 Fr PCN was inserted trans-papillary into the lower calyx to provide continuous drainage. The nephrostomy tract was adjusted under direct endoscopic visualization when needed to avoid obscuring the operative field. Lithotripsy was performed using the same laser settings as in the other groups. Drainage was passive and relied on gravity drainage through the nephrostomy tube. At the end of the procedure, the PCN was left open for 2 h and subsequently removed if the patient reported no flank pain or leakage.

Double-J Stenting: A postoperative double-J ureteral stent was routinely placed in the FANS and UAS groups, with a planned indwelling duration of 21–30 days. In the

PCN group, double-J placement was performed selectively based on intraoperative judgment and patient condition.

Outcome assessment

The primary outcomes were efficacy and safety. Efficacy was evaluated by the stone-free rate (SFR) on non-contrast CT (2–3 mm slice thickness) performed 15 days after surgery. Stone-free status was defined as Grade A on the ABC grading system (residual fragments < 4 mm). Safety was assessed by the frequency of intraoperative and postoperative complications. Secondary outcomes were operative time and length of hospital stay. In the FANs and conventional UAS groups, operative time was recorded from the start of diagnostic semi-rigid ureteroscopy to double-J stent placement; in the PCN group, it was recorded from the beginning of PCN puncture to completion of the procedure. Hospital stay was calculated as the number of days from surgery to discharge.

Table 1 Baseline characteristics among the studied groups

		UAS ($n=72$)	PCN ($n=72$)	FANS ($n=73$)	*P*-value
Age (Years)	Mean ± SD	41 ± 11	42 ± 9	40 ± 10	0.716
Gender					
Males	n (%)	46 (63.9)	39 (54.2)	41 (56.2)	0.458
Females	n (%)	26 (36.1)	33 (45.8)	32 (43.8)	
Hypertension	n (%)	7 (9.7)	3 (4.2)	4 (5.5)	0.424
DM	n (%)	4 (5.6)	3 (4.2)	2 (2.7)	0.646
Previous Renal Surgery	n (%)	31 (43.1)	19 (26.4)	19 (26)	**0.043***
Loin Pain	n (%)	72 (100)	71 (98.6)	73 (100)	0.664
Hematuria	n (%)	15 (20.8)	11 (15.3)	13 (17.8)	0.658
UTI	n (%)	15 (20.8)	14 (19.4)	13 (17.8)	0.899
Creatinine (mg/dL)	Mean ± SD	1.03 ± 0.23	0.97 ± 0.18	0.98 ± 0.2	0.236
Side					
Right	n (%)	41 (56.9)	28 (38.9)	39 (53.4)	0.071
Left	n (%)	31 (43.1)	44 (61.1)	34 (46.6)	
Largest Diameter (mm)	Mean ± SD	23 ± 2	22 ± 3	22 ± 2	0.367
Stone Site					
Upper Calyx	n (%)	10 (13.9)	13 (18.1)	9 (12.3)	0.604
Middle Calyx	n (%)	12 (16.7)	10 (13.9)	11 (15.1)	0.897
Lower Calyx	n (%)	7 (9.7)	12 (16.7)	8 (11)	0.403
Pelvis	n (%)	62 (86.1)	59 (81.9)	64 (87.7)	0.604
Hounsfield unit	Median (range)	967 (250–1700)	978 (450–1700)	978 (250–1667)	0.937
Pre-Op Stenting	n (%)	5 (6.9)	4 (5.6)	4 (5.5)	0.94

UAS Ureteral Access Sheath, *PCN* Percutaneous Nephrostomy, *FANS* Flexible and Navigable Suction Ureteral Access Sheath, *DM* Diabetes Mellitus, *UTI* Urinary Tract Infection; *: Significant P-value; 1: Significantly different from UAS group; 2: Significantly different from PCN group; 3: Statistically significant from FANS group.

Statistical methods

Data were managed and analyzed using SPSS version 27 (IBM, Armonk, NY, USA). Normality of continuous variables was evaluated using the Shapiro–Wilk test in addition to visual inspection of data distribution. Depending on distribution, continuous data were reported as mean ± standard deviation or as median (range), while categorical variables were presented as frequencies and percentages. Between-group comparisons of continuous variables were performed using one-way ANOVA for normally distributed data and the Kruskal–Wallis test for non-normally distributed data. Categorical variables were compared using the chi-square test or Fisher's exact test, as appropriate. Univariate and stepwise multivariate logistic regression were used to identify predictors of stone-free status, with results expressed as odds ratios and 95% CIs. All tests were two-sided, and a P value < 0.05 was considered statistically significant.

Results

CONSORT flow chart of the studied patients is illustrated in Fig. 1.

Baseline characteristics

Among the baseline characteristics, previous renal surgery was significantly more common in the UAS group (43.1%) compared to the PCN (26.4%) and FANS (26%) groups ($P=0.043$). On the other hand, the remaining variables showed no statistically significant differences among the three groups. These included age, gender distribution, hypertension, diabetes mellitus, loin pain, hematuria, urinary tract infection, and serum creatinine levels (all with $P>0.05$). There was also no significant difference in the side of stone laterality, the largest stone diameter, or the stone site—whether upper calyx, middle calyx, lower calyx, or pelvis, the Hounsfield unit, or the rate of pre-operative stenting ($P>0.05$) (Table 1).

Intraoperative characteristics

Among all intraoperative variables, post-operative stenting showed a statistically significant difference between groups. It was performed in 100% of patients in the UAS and the FANS group, while only 34.7% of the PCN group underwent post-operative stenting ($P<0.001$). Operative time was significantly longer in the UAS and FANS groups (both 58 min) compared to the PCN group (48 min) ($P<0.001$). All other intraoperative variables showed no statistically significant differences between the three groups including mucosal injury, bleeding, failed procedures, perforation, and false passage ($P>0.05$) (Table 2).

Postoperative characteristics and outcomes

Loin or suprapubic pain was significantly more frequent in the UAS (33.3%) and FANS (31.5%) groups compared to the PCN group (9.7%) ($P=0.001$). Postoperative hematuria was also significantly more common in the UAS group (20.8%) compared to PCN (8.3%) and FANS (5.5%) ($P=0.009$). The need for auxiliary procedures was significantly higher in the UAS group (18.1%) compared to PCN (2.8%) and FANS (1.4%) ($P<0.001$). The stone-free rate was significantly higher in the PCN (97.2%) and FANS (98.6%) groups compared to the UAS group (81.9%) ($P<0.001$). Additionally, hospital stay duration was significantly longer in the UAS group (median 1 [range 1–7] days) compared to both the PCN and FANS groups (median 1 [range 1–2] days) ($P<0.001$). The remaining postoperative variables showed no statistically significant differences across the groups, including infection, fever, stent duration, and readmission ($P>0.05$) (Table 3; Fig. 2).

Prediction of stone free status

Univariate logistic regression analyses were conducted for prediction of stone-free status including the following variables: age, gender, hypertension, diabetes mellitus, previous renal surgery, largest stone diameter, stone site in the lower calyx, Hounsfield unit, pre-operative stenting, and intervention type. In the univariate analysis, Hounsfield unit and intervention group were the only significant predictors in which a lower Hounsfield unit was significantly associated with a higher likelihood of achieving stone-free status (OR = 0.998, 95% CI: 0.997–1.000; $P=0.021$). In addition, compared with the UAS group, both PCN and FANS were significantly associated with higher stone-free rates, with ORs of 7.712 (95% CI: 1.672–35.560; $P=0.009$) and 15.860 (95% CI: 2.020–124.830; $P=0.009$), respectively.

Thereafter, a stepwise multivariate logistic regression model was constructed to identify independent predictors of stone-free status while avoiding model overfitting. Variables assessed in the univariate analysis were considered for model building. The multivariate analysis showed that Hounsfield unit and intervention group remained significant independent predictors of stone-free status. A lower Hounsfield unit was independently associated with a greater likelihood of achieving stone-free status (OR = 0.998, 95% CI: 0.996–1.000; $P=0.021$). Regarding the intervention group, both PCN and FANS remained significantly associated with better stone-free outcomes compared with the UAS group. Patients treated with PCN had 7.756 times higher odds of achieving stone-free status than those treated with UAS (95% CI: 1.655–36.346; $P=0.009$), while patients treated with FANS had 17.250 times higher odds of achieving

Table 2 Intraoperative characteristics among the studied groups

		UAS ($n=72$)	PCN ($n=72$)	FANS ($n=73$)	*P*-value
Mucosal injury	*n* (%)	9 (12.5)	2 (2.8)	6 (8.2)	0.094
Bleeding	n (%)	12 (16.7)	5 (6.9)	5 (6.8)	0.08
Failed	n (%)	4 (5.6)	1 (1.4)	3 (4.1)	0.453
Perforation	n (%)	1 (1.4)	1 (1.4)	0 (0)	0.551
False passage	n (%)	3 (4.2)	1 (1.4)	3 (4.1)	0.704
Operative time (Min)	Mean ± SD	58 ± 13 [2]	48 ± 14 [1,3]	58 ± 11 [2]	**< 0.001***
Post-Op Stenting	n (%)	72 (100)	25 (34.7)	73 (100)	**< 0.001***

UAS Ureteral Access Sheath, *PCN* Percutaneous Nephrostomy, *FANS* Flexible and Navigable Suction Ureteral Access Sheath

Table 3 Postoperative characteristics and outcomes among the studied groups

		UAS ($n=72$)	PCN ($n=72$)	FANS ($n=73$)	*P*-value
Infection	*n* (%)	6 (8.3)	2 (2.8)	3 (4.1)	0.341
Fever	n (%)	5 (6.9)	2 (2.8)	1 (1.4)	0.182
Loin or Suprapubic Pain	n (%)	24 (33.3)	7 (9.7)	23 (31.5)	**0.001***
Hematuria	n (%)	15 (20.8)	6 (8.3)	4 (5.5)	**0.009***
Auxiliary procedure	n (%)	13 (18.1)	2 (2.8)	1 (1.4)	**< 0.001***
Stone Free Rate	n (%)	59 (81.9)	70 (97.2)	72 (98.6)	**< 0.001***
Stent duration (Days)	Mean ± SD	24 ± 5	25 ± 5	24 ± 5	0.239
Readmission	n (%)	7 (9.7)	1 (1.4)	2 (2.7)	0.072
Hospital stay (Days)	Median (range)	1 (1–7) [2,3]	1 (1–2) [1]	1 (1–2) [1]	**< 0.001***

UAS Ureteral Access Sheath, *PCN* Percutaneous Nephrostomy, *FANS* Flexible and Navigable Suction Ureteral Access Sheath; *: Significant P-value; 1: Significantly different from UAS group; 2: Significantly different from PCN group; 3: Statistically significant from FANS group.

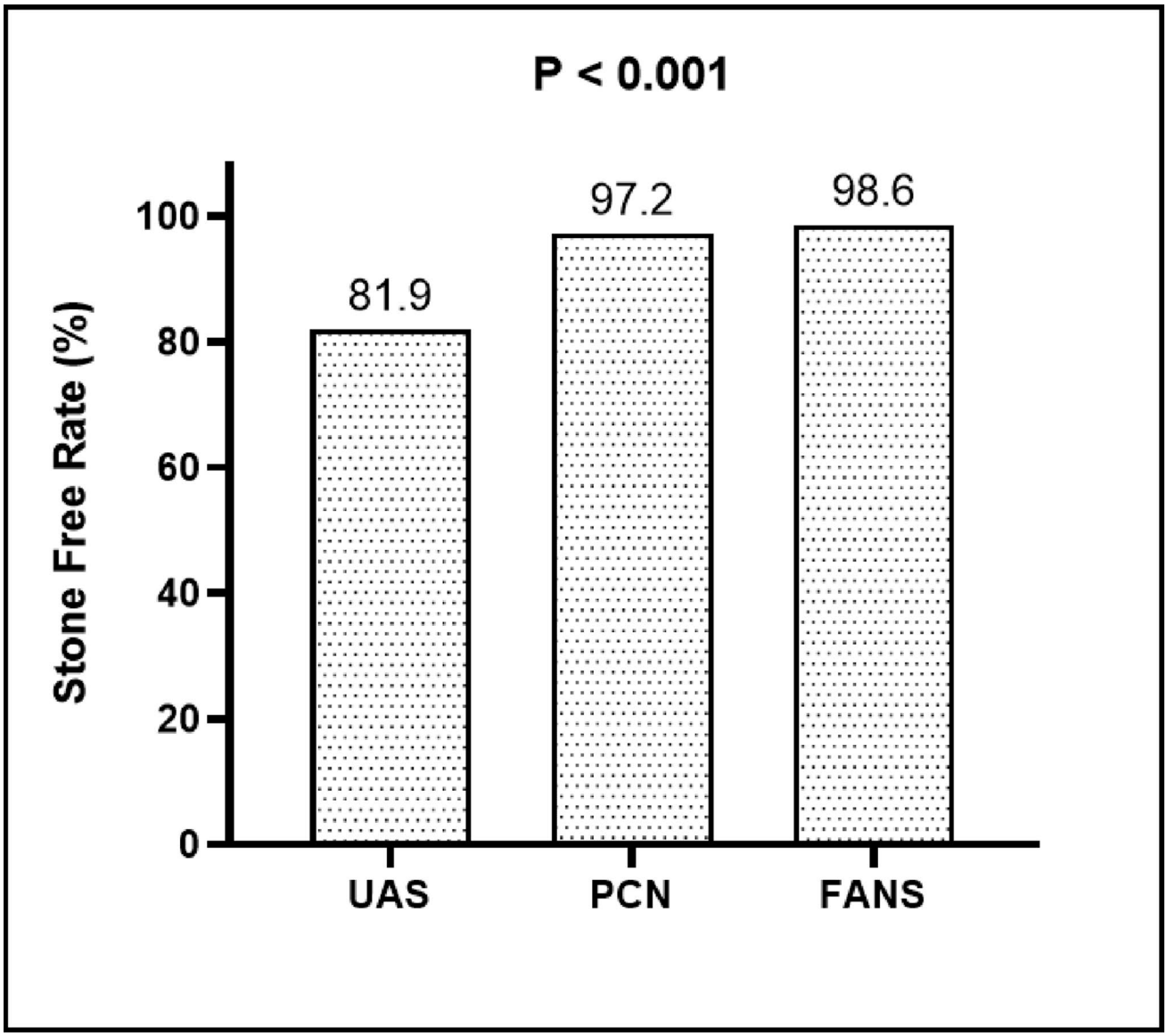


Fig. 2 Stone free rate among the studied groups

stone-free status (95% CI: 2.156–138.024; $P=0.007$) (Table 4; Fig. 3A, B).

Discussion

Intrarenal drainage during RIRS is closely linked to operative efficiency and postoperative results, particularly in intermediate-sized renal stones where irrigation flow and intrarenal pressure may affect visibility and fragment clearance. PCN provides dependable decompression through a percutaneous tract, but the need for renal puncture and the morbidity associated with it continue to drive interest in less invasive endoscopic options. FANS is one such approach, combining ureteral access with active suction to improve visualization and evacuate dust and fragments without an external tract [8]. Accordingly, this randomized study was designed to directly compare PCN and FANS during RIRS with respect to efficacy and safety.

In the present cohort, PCN and FANs showed broadly comparable safety and procedural performance. SFRs were high in both groups (97.2% with PCN and 98.6% with FANs), supporting the effectiveness of each approach for the stone sizes studied. Although the absolute difference was small, multivariable regression identified the FANs technique as more strongly and independently associated with stone-free status than PCN, which is consistent with a modest benefit from suction-assisted drainage in maximizing intrarenal clearance.

Table 4 Logistic regression analyses for prediction of stone free status

	Univariate		Multivariate	
	OR (95% CI)	*P*-value	OR (95% CI)	*P*-value
Age (Years)	0.98 (0.932–1.032)	0.446	–	–
Gender	0.923 (0.331–2.577)	0.879	–	–
Hypertension	1.123 (0.138–9.132)	0.914	–	–
DM	0.703 (0.083–5.927)	0.746	–	–
Previous Renal Surgery	0.436 (0.156–1.214)	0.112	–	–
Largest Stone Diameter (mm)	0.895 (0.722–1.111)	0.316	–	–
Stone Site (Lower Calyx)	2.328 (0.295–18.34)	0.423	–	–
Hounsfield unit	0.998 (0.997–1)	**0.021***	0.998 (0.996–1)	**0.021**
Pre-Op Stenting	0.952 (0.116–7.829)	0.964	–	–
Intervention				
UAS	R	R	R	R
PCN	7.712 (1.672–35.56)	**0.009***	7.756 (1.655–36.346)	**0.009***
FANS	15.86 (2.02–124.83.02.83)	**0.009***	17.25 (2.156–138.024)	**0.007***

UAS Ureteral Access Sheath, *PCN* Percutaneous Nephrostomy, *FANS* Flexible and Navigable Suction Ureteral Access Sheath, *DM* Diabetes Mellitus, *OR* Odds Ratio, *CI* Confidence Interval; *: Significant P-value; R: Reference group

Safety outcomes were also similar overall, with low frequencies of infection, fever, mucosal injury, and the need for auxiliary procedures. Postoperative hematuria was not increased in the PCN group; rather, it was more frequent in the UAS group and remained low overall across all three techniques. This pattern suggests that postoperative hematuria may be influenced not only by procedural access, but also by differences in postoperative drainage and stenting strategies. Operative time was shorter with PCN, most likely because the nephrostomy tract provides immediate decompression during lithotripsy rather than due to differences in fragmentation. Postoperative symptoms and recovery were otherwise comparable, and length of hospital stay was similar between the two techniques.

In routine practice, both PCN and FANs can provide effective and safe drainage during RIRS. When operative and postoperative outcomes are otherwise similar, the degree of invasiveness becomes an important practical distinction. PCN requires a percutaneous tract and may be accompanied by bleeding, tract discomfort, and catheter-related problems. In contrast, FANs achieves comparable efficacy—and in the regression analysis showed a stronger association with stone-free status—through a fully endoscopic approach. This supports its use as a practical alternative to PCN in patients where percutaneous puncture is best avoided, provided the ureter can safely accommodate a suction-enabled access sheath.

Interestingly, Huang et al. [7] reported that a flexible vacuum-assisted ureteral access sheath used for vacuum-assisted dedusting lithotripsy improved both immediate and

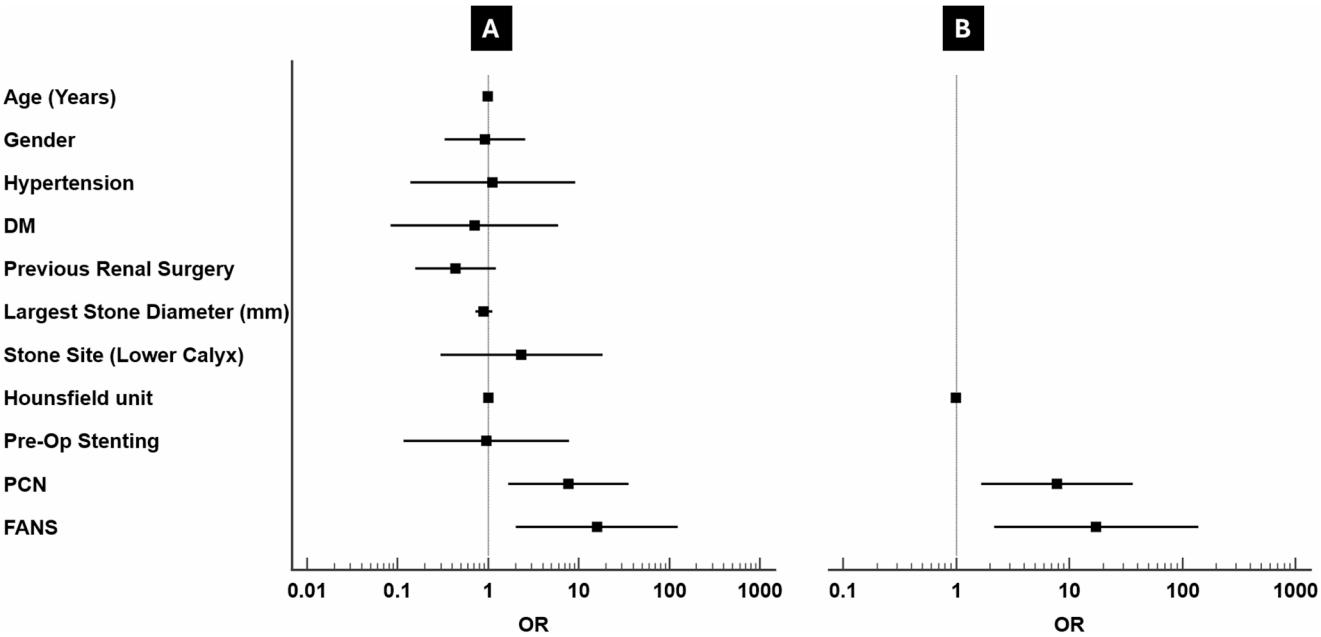


Fig. 3 Forest plot showing odds ratios with 95% confidence intervals for different parameters to predict stone free status; **A** Univariate analysis, **B** Stepwise multivariate analysis

follow-up stone-free rates compared with standard flexible ureteroscopic lithotripsy, without increasing postoperative fever or extending lithotripsy time. They attributed the higher stone-free rates to the flexible intrarenal tip, which can follow the ureteroscope into the target calyx and enable continuous evacuation of irrigation fluid, fragments, and dust. This addresses a common limitation of conventional ureteroscopy, where residual debris may persist in dependent calyces even after adequate fragmentation. The same mechanism may help explain the performance of FANs in our study: its navigable, suction-enabled design allows calyceal access during active lithotripsy, supports a more controlled intrarenal environment, and promotes efficient fragment clearance without the need for an external drainage tract.

Uy et al. [5] conducted a large systematic review and meta-analysis showing that FANs-UAS is associated with higher stone-free rates and fewer complications than conventional access sheaths, without an increase in operative time. Their pooled analysis, which included more than 7,000 patients, supports the same overall pattern observed in our cohort and underscores the clinical value of suction-enabled, navigable systems for improving clearance while maintaining safety. Additionally, the prospective multicenter study by Gauhar et al. [9] reported favorable short-term outcomes in a prospective multicenter study of FANs-UAS during RIRS. They documented a 24-hour CT–based stone-free rate of 96.5% when Grades A and B were combined, with transient low-grade fever in 7% of patients, no cases of sepsis, and discharge within 48 h for all participants.

Similarly, Zhu et al. [10] found that suction-enabled, tip-bendable access sheaths improve both efficacy and safety compared with standard UAS. In their international superiority RCT involving 320 patients across multiple countries, the suction-sheath arm achieved higher immediate and 3-month stone-free rates, had lower postoperative fever rates, and required fewer adjunctive basket extractions. Likewise, Cacciatore et al. [11], also found that FANS provides both higher stone-free rates and a more favorable perioperative profile compared with conventional sheaths in RIRS in which FANS use led to shorter operative times, higher one-month CT-based SFR, fewer postoperative complications, and a lower need for re-intervention.

Moreover, Chen et al. [12] showed in a porcine kidney model that a novel flexible vacuum-assisted ureteral access sheath could track the flexible ureteroscope into the renal pelvis and calyces, actively control intrarenal pressure, and achieve significantly higher stone volume clearance rates than a traditional UAS. Although their study was conducted in an ex vivo model using small, standardized stone fragments and manometric measurements rather than clinical endpoints, the mechanistic advantages they demonstrated—direct calyceal access, controlled negative pressure, and efficient evacuation of fragments—provide a physiologic explanation for the superior clearance performance of suction-enabled, flexible access systems.

Furthermore, Alhefnawy et al. [3] also found that PCN-assisted flexible ureteroscopy clearly outperformed conventional UAS. In their cohort, PCN achieved a higher stone-free rate, shorter operative time, and significantly less bleeding than UAS, while overall intra- and postoperative complications remained comparable between groups. These data strongly support the concept that diverting irrigation and fragments through a percutaneous tract not only maintains, but actually enhances, the efficacy and safety of RIRS compared with standard UAS. The authors linked the higher stone-free rate in the non-UAS arm to the percutaneous drainage effect of PCN, which facilitates washout of fine fragments from the collecting system, improves endoscopic visibility, and supports more complete stone clearance.

Kwon et al. [6], demonstrated that performing flexible ureteroscopy in the presence of a PCN significantly improves procedural success. In their cohort, PCN-assisted cases achieved a markedly higher stone-free rate (95.1% vs. 82.0%) without any increase in operative time or complications.

While improved drainage and suction may have contributed to some of the observed advantages, these findings are also likely influenced by differences in procedural invasiveness, access characteristics, and postoperative management, which should be considered when interpreting the comparative outcomes.

Despite its strengths as a randomized comparison of FANS, PCN, and UAS during RIRS, several limitations should be acknowledged. First, the work was performed at a single center, which may reduce external applicability. Second, although procedures were carried out by the same team, operator experience was not quantified or tested as an effect modifier. Third, intrarenal pressure was not measured directly, so any physiologic explanation remains inferential. Moreover, routine double-J stent placement in the UAS and FANS arms, contrasted with selective stenting in the PCN arm, represents a potential confounder particularly regarding stent-related symptoms such as postoperative pain and hematuria. Eventually, the small number of non-stone-free cases led to large odds ratios with wide confidence intervals, reflecting reduced precision. Therefore, while the direction of the association is consistent, the magnitude of effect should be interpreted with caution. Further evaluation in multicentre settings, with standardized intrarenal pressure monitoring and longer follow-up, is needed to better characterize long-term safety for both approaches and to refine patient selection for tailored access strategies.

Conclusions

Both PCN and FANs provided effective and safe drainage during RIRS. FANs achieved a modestly higher stone-free rate while offering postoperative recovery comparable to PCN. These findings suggest that FANs can be a useful, less invasive alternative to PCN when percutaneous access is undesirable.

Author contributions M.A.A. conceived the study, coordinated the trial, participated in study design and methodology, and wrote the first draft of the manuscript. T.M.E.K. contributed to the study concept, methodology, and supervised the clinical conduct of the trial with critical revision of the manuscript. M.F. and M.M. contributed to patient recruitment, perioperative data collection, and follow-up assessments, and assisted in manuscript preparation. I.S.A.M. performed the statistical analysis, contributed to data interpretation, and drafted/edited the Results section and figures. H.S. contributed to oversight of the research workflow, interpretation of findings, and substantive critical revision. All authors reviewed and approved the final manuscript.

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Data availability No datasets were generated or analysed during the current study.

Declarations

Competing interests The authors declare no competing interests.

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