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Safety and efficacy of using traditional ureteral access sheath versus flexible and navigable suction sheath in retrograde intra-renal stone surgery for renal stones ≤ 20 mm: A randomized controlled study

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ABSTRACT

Objectives: To evaluate the safety and efficacy of the Flexible and Navigable Suction Sheath (FANS) in comparison with the traditional ureteral access sheath (T-UAS) during retrograde intrarenal surgery (RIRS) for cases with a single renal stone ≤ 20 mm.

Methods: A total of 140 cases presenting with single renal stones ≤ 20 mm were randomized in a 1:1 ratio to receive either treatment in FANS group or T-UAS group. The primary endpoint was clinically acceptable stone-free status, defined as residual fragments ≤ 4 mm on 1-month non-contrast computed tomography. True stone-free status, defined as no residual fragments, was analyzed as a secondary endpoint, together with operative time and postoperative complications.

Results: Baseline characteristics and mean stone size were comparable between both groups (14.8 ± 3.0 in FANS vs. 15.40 ± 3.20 in traditional group). Clinically acceptable stone-free status at 1 month did not substantially differ between FANS and T-UAS groups (82.9% vs. 77.1%; $p = 0.398$). True stone-free status was also comparable between groups (77.1% vs. 71.4%; $p = 0.742$). Operative time was comparable between groups (52 ± 7 in FANS group vs. 54 ± 12 min in T-UAS group; $p = 0.102$). Postoperative complications were comparable between FANS and T-UAS groups (11.4% vs. 14.3%; $p = 0.614$). Although FANS demonstrated a numerically higher SFR and fewer secondary procedures, these variations were not statistically significant.

Conclusions: In patients undergoing RIRS for single renal stones ≤ 20 mm, FANS did not demonstrate superiority over T-UAS in terms of stone-free rate, operative time, or complication rates. While FANS remains a safe and feasible technique, its incremental clinical benefit in low stone burden appears limited.

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Introduction

Kidney stone disease remains a significant and evolving global health challenge, contributing to morbidity, increased healthcare utilization, and adverse population-level outcomes. Recent analyses based on Global Burden of Disease estimates indicate that urolithiasis continues to represent an important source of disability and mortality worldwide, emphasizing the importance of optimizing treatment effectiveness while minimizing harm [1].

Retrograde intrarenal surgery (RIRS) represents a well-established minimally invasive option for the management of renal stones, particularly when stone size falls within a range suitable for highly effective endoscopic treatment. Current European guidance recognizes retrograde renal surgery as a viable option for renal stones < 20 mm with favourable outcomes [2,3]. Despite its effectiveness, outcomes following RIRS may be affected by residual stone fragments and irrigation-induced increases in intrarenal pressure (IRP), both of which have been linked to postoperative infectious complications [4–6].

Traditional ureteral access sheaths (T-UAS) were designed to enable repeated ureteroscopic access, enhance visualization, and contribute to lowering IRP during RIRS. However, evidence regarding their effect on stone-free rates (SFR) and operative efficiency remains inconsistent, and the use of UAS carries an inherent risk of ureteral wall injury. In addition, traditional UAS depend largely on passive fragment clearance, which may be inadequate in certain anatomical settings or with specific stone characteristics [5].

Flexible and navigable suction sheath (FANS) integrates active suction with irrigation to enable continuous evacuation of stone dust and fragments while potentially maintaining IRP at safer levels. Additionally, flexible or tip-bendable designs enhance navigation within the renal collecting system. Recent evidence, including randomized controlled trials and meta-analyses, has demonstrated higher immediate SFRs and lower rates of postoperative infectious complications relative to traditional sheaths, especially in cases with high stone burden, complex anatomy, or lower calyceal stones [7,8].

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However, the routine application of FANS in RIRS, such as in cases involving single renal stones ≤ 20 mm, remains controversial. In this setting, conventional RIRS is already associated with high success rates, and the incremental advantage of suction-assisted systems may be limited, with potential implications for cost-effectiveness and procedural complexity. High-quality randomized evidence focusing on this population is scarce.

Accordingly, this investigation aimed to compare the efficacy and safety of T-UAS and FANS during RIRS for single renal calculi ≤ 20 mm, with particular focus on stone-free outcomes and postoperative complications.

Materials and methods

This study was designed as a randomized, controlled trial and was conducted at a tertiary Urology center between June and December 2025. Adult cases with single renal calculi ≤ 20 mm in maximum diameter were consecutively recruited until the target sample size was achieved. The study protocol received approval from the Ain Shams University institutional review board (Approval No. MS 401–2025). The study was retrospectively registered at ClinicalTrials.gov (NCT07286071) after initiation of recruitment. The study was conducted in accordance with the Declaration of Helsinki, and written informed consent was secured from all participants.

Cases were eligible if they were ≥ 18 years of age, of either sex, and had a single renal stone ≤ 20 mm confirmed by non-contrast computed tomography (NCCT), making them candidates for (RIRS). Any urinary tract infections were treated preoperatively when present. Exclusion criteria included a history of open renal surgery, major renal trauma, solitary kidney, known ureteral stricture, or pelvi-ureteric junction obstruction.

Randomization was performed using a computer-generated sequence. Allocation concealment was ensured

Cases were randomized using a computer-generated random number sequence with a 1:1 allocation to the T-UAS or FANS groups in RIRS. Allocation concealment was ensured using sealed opaque envelopes prepared by an independent investigator not involved in recruitment or intervention. Patients and the radiologist assessing postoperative NCCT were blinded to group allocation. Surgeons were not blinded due to the nature of the intervention.

A standardized preoperative assessment was conducted for all cases, consisting of medical history, physical examination, and laboratory investigations (CBC, serum creatinine, electrolytes, coagulation profile, hepatic function tests, urinalysis, and urine culture). Imaging studies included KUB radiography and NCCT to assess stone size in

maximum diameter, location, laterality, and density (Hounsfield units).

Surgical technique

All procedures were performed with patients in the lithotomy position under general anesthesia by experienced endourologists using a standardized operative technique.

A 0.035-inch hydrophilic guidewire was initially introduced, followed by serial ureteral dilatation under fluoroscopic guidance up to 14 Fr. In cases of failed ureteral dilation, a temporary ureteral stent was inserted, and the procedure was rescheduled after 2 weeks while maintaining allocation to the same study group.

In the FANS group, retrograde intrarenal surgery (RIRS) was performed using a suction-enabled ureteral access sheath (11 Fr inner diameter $\times$ 13 Fr outer diameter, 55 cm; ClearPetra®, Wellead Medical Company, Guangzhou, China). The sheath was advanced to the renal pelvis or an adjacent calyx. Continuous suction was applied through a calibrated vacuum system, with pressure maintained between 2–7 kPa and adjusted intraoperatively at the surgeon's discretion.

In the T-UAS group, RIRS was performed using a conventional ureteral access sheath (11/13 Fr $\times$ 46 cm; Boston Scientific Navigator™ HD, USA), positioned just below the ureteropelvic junction.

Irrigation flow was standardized between 50 and 100 mL/min in both groups by a manual syringe. All procedures were performed using a single-use digital flexible ureteroscope (9.5 Fr $\times$ 68 cm; LithoVue™, Boston Scientific, USA). Laser lithotripsy was carried out using a Lumenis Pulse™ MOSES™ 120 H Holmium: YAG laser system. Lithotripsy was primarily performed using a dusting strategy to achieve fine fragmentation and facilitate spontaneous clearance with typical settings of 1.0–1.2 J energy and 15–30 Hz frequency, delivered via a 200- μ m MOSES™ laser fiber (Lumenis GmbH, Germany).

No routine use of auxiliary extraction devices (e.g. baskets) was performed.

At the end of each procedure, a 6 Fr double-J ureteral stent was inserted in all patients according to institutional protocol to minimize ureteral edema and ensure standardized postoperative management. Postoperative data were collected prospectively. NCCT was performed at 1 month postoperatively, and stent removal was carried out during the corresponding outpatient follow-up visit.

Outcome measures

The primary endpoint was clinically acceptable stone-free status, defined as residual fragments ≤ 4 mm on NCCT at 1 month postoperatively. True stone-free

status, defined as no residual fragments, was analyzed as a secondary endpoint. Residual fragments were further categorized into four grades: Grade A (no residual fragments; absolute stone-free), Grade B (≤ 2 mm; relative stone-free), Grade C (2.1–4 mm; relative stone-free), and, Grade D (> 4 mm; significant residual stones). Secondary analyses included evaluation of true stone-free status (0 mm) and residual fragments ≤ 2 mm. Operative time was defined as the interval from initial cystoscopy to successful placement of the double-J stent, readmission, and postoperative Complications were classified according to Clavien – Dindo classification [9].

Sample size calculation

The sample size was calculated using G*power software version 3.1.9.7 based on a previous study by Chiang et al. [10], who reported an immediate clinically acceptable SFR of 82% in the S-UAS group compared to 60.4% in the traditional UAS group. The minimum sample size needed to detect such a difference between the studied groups was 136 patients (68 patients per group). Alpha and power were adjusted at 0.05 and 0.8, respectively.

Statistical methods

All data management and statistical analyses were performed using SPSS version 27 (IBM, Armonk, New York, United States). The Shapiro – Wilk test, together with visual assessment of distribution plots, was used to determine the normality of quantitative variables. Parametric quantitative variables were reported as means with SD, whereas non-parametric variables were presented as medians with ranges.

Categorical variables were summarized as frequencies and percentages. Between-group comparisons were performed using the Independent t Test for parametric quantitative variables and the Mann – Whitney U Test for non-parametric variables. Categorical variables were analyzed using either the Chi-square test or Fisher's exact test, as appropriate. All statistical tests were two-tailed, and a p -value < 0.05 was considered statistically significant [11].

Results

In this study, 188 patients were assessed for eligibility. Of these, 48 patients were excluded before randomization: 17 had multiple renal stones, 13 had stone size > 20 mm, 8 had a history of open renal surgery, 5 had solitary kidney, 3 had pelvi-ureteric junction obstruction, and 2 had a history of ureteral stricture. The remaining 140 patients were randomized equally to the FANS group ($n = 70$) and T-UAS group ($n = 70$). No patients were lost to follow-up, and all randomized patients were analyzed in their assigned groups. Figure 1.

There were 54 pre-stented cases (26 FANS and 28 traditional UAS) with failed access sheath insertion due to failed ureteric dilation. temporary ureteral stent was inserted, and the procedure was rescheduled after 2 weeks. Table 1.

Both groups were comparable regarding baseline demographic, clinical, and stone characteristics. Mean stone size was similar between groups (14.8 ± 3.0 in FANS vs. 15.40 ± 3.20 in traditional groups, respectively; $p = 0.254$), as demonstrated in Table 1.

At the one-month follow-up, NCCT confirmed stone-free status in 58 cases (82.9%) in FANS group

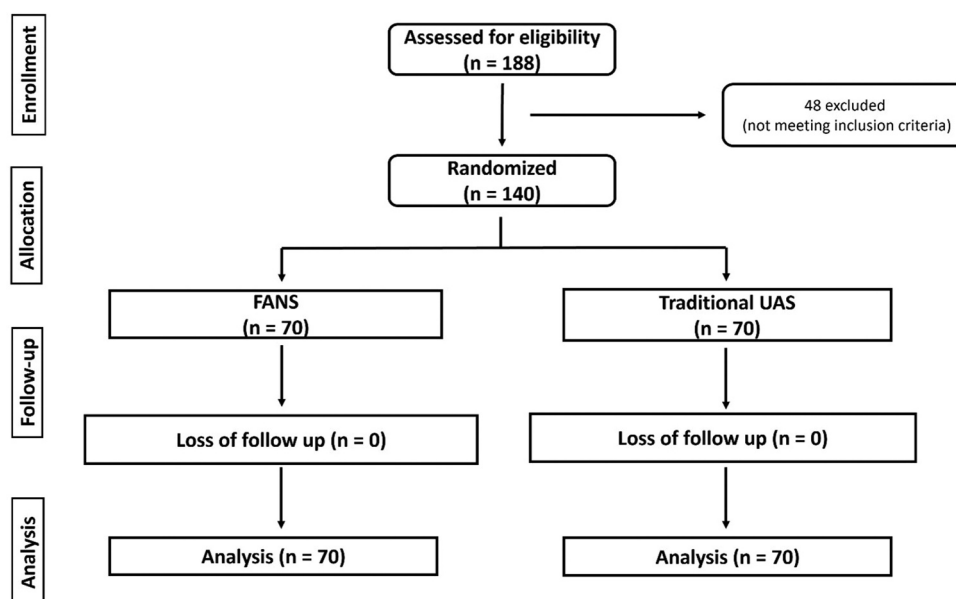


Figure 1. Consort flow diagram of the studied patients.

Table 1. Demographic, clinical, and preoperative stone characteristics in the studied groups.

	FANS (n = 70)	Traditional UAS (n = 70)	p-value
Age (years)	44 ± 9	45 ± 12	0.325
Sex			
Males	34 (48.6)	39 (55.7)	0.398
Females	36 (51.4)	31 (44.3)	
Hypertension	14 (20)	20 (28.6)	0.237
Diabetes	18 (25.7)	22 (31.4)	0.454
CKD	3 (4.3)	8 (11.4)	0.116
Previous urolithiasis	38 (54.3)	40 (57.1)	0.734
Stone size (mm)	14.8 ± 3.0	15.40 ± 3.20	0.254
Stone laterality			
Right	30 (42.9)	28 (40)	0.731
Left	40 (57.1)	42 (60)	
Number of stones			
1	70 (100)	70 (100)	–
Stone location			
Lower calyx	14 (20)	16 (22.9)	0.68
Middle calyx	10 (14.3)	10 (14.3)	1
Upper calyx	10 (14.3)	6 (8.6)	0.288
PUJ	12 (17.1)	14 (20)	0.664
Renal pelvis	26 (37.1)	26 (37.1)	1
Stone density (HU)	870 (500–1580)	920 (430–1590)	0.515
Pre-stenting	26 (37.1)	28 (40.0)	0.728

Data were expressed as mean ± SD and number (%), or Median (range), CKD: Chronic kidney disease, UAS: Ureteral access sheath, mm: millimeter, HU: Hounsfield unit, PUJ: Pelvi-ureteric junction, FANS: Flexible and Navigable Suction Sheath.

and 54 cases (77.1%) in T-UAS group. The absolute difference in SFR was 5.8% (95% CI –7.7 – 18.8), and this variation was not statistically significant ($p = 0.398$). Residual fragment size distribution did not differ between groups. The rate of complete stone clearance (Grade A: no residual fragments) was 77.1% in FANS cases and 71.4% in T-UAS cases, while larger residual fragments (>4 mm; Grade D) were reported in 17.1% and 22.9% of cases, respectively ($p = 0.742$). [Table 2](#).

Operative time was comparable between FANS and T-UAS groups, with mean values of 52 ± 7 and 54 ± 12 minutes, respectively ($p = 0.102$). [Table 3](#).

Postoperative complications were observed in 8 cases (11.4%) in FANS group and 10 cases (14.3%) in T-UAS group, with no statistically marked variation (absolute difference –2.9%, 95% CI –14.1 to 8.5; $p = 0.614$). All recorded complications were minor (Clavien – Dindo grades I – II) and consisted mainly of postoperative fever and urinary tract infection. No major complications (Clavien – Dindo ≥ III), No cases of ureteral perforation, high-grade injury, or cases of sepsis were reported. [Table 3](#).

Ureteral stents were inserted in all cases. The rate of readmission was low and comparable between the FANS and T-UAS groups (4.3% vs. 5.7%, $p = 1.0$). [Table 3](#).

Table 2. Stone free rate and residual fragment size between the studied groups.

	FANS (n = 70)	Traditional UAS (n = 70)	95% CI	p-value
Stone-free rate	58 (82.9)	54 (77.1)	–7.7 – 18.8	0.398
Residual fragment size (mm)				0.742
A (0 mm)	54 (77.1)	50 (71.4)	–	
B (≤2 mm)	1 (1.4)	2 (2.9)	–	
C (2.1–4 mm)	3 (4.3)	2 (2.9)	–	
D (>4 mm)	12 (17.1)	16 (22.9)	–	

Data were expressed as mean and SD, number (%), CI: confidence interval, UAS: Ureteral access sheath, FANS: Flexible and Navigable Suction Sheath.

Table 3. Intra and post-operative findings between the studied groups.

	FANS (n = 70)	Traditional UAS (n = 70)	95% CI	p-value
Surgery duration (min)	52 ± 7	54 ± 12	–	0.102
Postop complications (Clavien)	8 (11.4)	10 (14.3)	–14.1 – 8.5	0.614
Clavien – Dindo grade				0.86
Grade I (Fever)	6 (8.6)	7 (10)	–	
Grade II (UTI)	2 (2.9)	3 (4.3)	–	
No complications	62 (88.6)	60 (85.7)	–	
Readmission	3 (4.3)	4 (5.7)	–	1

Data were expressed as mean and SD, number (%), FANS: Flexible and Navigable Suction Sheath, UAS: Ureteral Access Sheath, CI: Confidence Interval, Postop: Postoperative, UTI: Urinary Tract Infection.

Discussion

RIRS has emerged as a well-established minimally invasive approach for the management of renal calculi ≤ 20 mm. Despite this, residual stone fragments and irrigation-related elevations in IRP continue to represent key challenges. FANS has been developed to overcome these limitations by enabling active fragment evacuation and enhanced fluid outflow. However, the additional clinical benefit in cases with low stone burden remains unclear [4].

In this study, overall SFR did not substantially differ between both groups, with rates of 82.9% in FANS group and 77.1% in T-UAS group. However, FANS group showed a numerically greater SFR relative to T-UAS group. Accordingly, the absence of a substantial variation does not preclude a possible benefit of FANS in higher-risk scenarios. Residual fragment grades on postoperative imaging were also comparable between the groups. The distribution of cases with complete clearance (Grade A) and those with residual fragments of different sizes (Grades B – D) did not differ substantially between the FANS and T-UAS groups. In agreement with our findings, Uslu et al. [12] reported no substantial variation in SFR between both groups. However, they noted that residual stone size was markedly greater in the standard UAS group, which contrasts with our observations. Likewise, Zhu et al. [13] investigated the safety and efficacy of FANS compared with T-UAS during RIRS and found a higher immediate SFR in the FANS group (81.3% vs. 49.4%). Conversely, Liu et al. [14] demonstrated that SFRs on postoperative day 1 and at week 4 were markedly greater in FV-UAS group than in the T-UAS group. Although their results showing greater SFR in FV-UAS group are consistent with our trend, the difference reached statistical significance in their study, unlike the nonsignificant difference observed in our results. These inconsistencies may be related to differences in sample size or methodological factors such as stone size, stone location, procedure technology, and surgical technique. The literature review further showed that inconsistent definitions of residual fragments have been applied in the evaluation of SFR, resulting in variability in outcome reporting despite similar SFRs being observed in clinical practice settings.

In this investigation, mean operative time was comparable between FANS and T-UAS groups (52 ± 7 vs. 54 ± 12 minutes, $p = 0.102$). These findings are in agreement with those of Gonçalves et al. [15], who reported no marked difference in operative time between the two approaches (MD -2.49 ; 95% CI -7.62 – 2.65 ; $p < 0.343$). According to Liu et al. [14] operative time tended to be longer with FANS-UAS; however, the variation did not reach statistical significance, and hospital stay did not differ between groups. Differences in study design, stone size, and operative technique may explain these observations. Liu et al.

[14], proposed that variations in operative time may arise from differences in the mechanism of stone management between T-UAS and suction-assisted systems. During conventional T-UAS procedures, prolonged laser lithotripsy is usually necessary to produce 'dust-like' fragmentation (<1 mm) that permits spontaneous passage through the urinary tract. Conversely, FANS-UAS facilitates active removal of larger stone fragments (2–4 mm) through suction-assisted irrigation. This method may decrease lithotripsy time but may require additional time for controlled fragment aspiration. Consequently, redistribution of operative steps may produce comparable total operative times between the two techniques.

Overall postoperative complication rates were comparable between both groups, with no statistically marked variation detected. The distribution of Clavien – Dindo complication grades was also similar. While the FANS group exhibited a numerically lower complication rate than the T-UAS group, this variation did not reach statistical significance. Consistent with our findings, Chiang et al. [16] reported similar complication rates between the groups. Additionally, Gonçalves et al. [15] observed a lower incidence of complications in FANS group, including a reduced rate of postoperative fever. In contrast, Liu et al. [14] reported markedly lower rates of perirenal hematoma, postoperative fever, and urosepsis in the FVUAS group relative to T-UAS group. These discrepancies may be related to variations in sample size or methodological factors, including stone complexity, procedure technology, and surgical technique. Similarly, Kadian et al. [17] found that the use of FANS-UAS was correlated with a substantially lower risk of fever, sepsis, re-intervention, and overall complications.

Readmission rates were low and similar between FANS and T-UAS groups. The requirement for a secondary procedure was also comparable between groups. Despite the lack of statistical significance, the FANS group showed a lower rate of readmission, possibly related to the lower level of residual stone and the higher SFR in the FANS group relative to T-UAS.

This investigation emphasizes the real-world clinical value of FANS in stone clearance during RIRS compared with T-UAS. The use of FANS may be particularly beneficial in cases involving larger, multiple, or lower calyceal stones where early clearance is important.

This study has several limitations that should be acknowledged. First, IRP was not directly measured, precluding assessment of pressure-related mechanistic advantages. Second, the follow-up period was relatively short and limited to one-month imaging, which restricted evaluation of long-term outcomes such as recurrence, and late complications such as ureteral stricture. Third, stone composition analysis was not performed, and stone volume was not

assessed, which may have influenced treatment outcomes.

Additionally, intraoperative stone-free status was not recorded, limiting assessment of immediate procedural efficacy. Intraoperative adverse events, such as ureteral mucosal trauma were also not systematically evaluated. Finally, as this study was designed as a superiority trial, the absence of statistically significant differences should not be interpreted as evidence of equivalence between the FANS and T-UAS techniques. The study was powered to detect a relatively large difference in stone-free rate based on previous data. Therefore, it may have been underpowered to detect smaller but clinically meaningful differences between FANS and traditional UAS.

Conclusion

Although FANS offers a sound physiological rationale, it did not demonstrate superiority over traditional UAS in achieving clinically acceptable stone-free status, defined as residual fragments ≤ 4 mm, or true stone-free status in patients with single renal stones ≤ 20 mm. Further studies focusing on higher stone burden and longer follow-up are warranted.

Abbreviations

CKD	Chronic Kidney Disease;
DJ	Double-J (stent);
CI	Confidence Interval;
EAU	European Association of Urology;
RIRS	Retrograde Intrarenal Surgery;
FANS	Flexible and Navigable Suction Sheath;
FV-UAS	Flexible Vacuum-Assisted Ureteral Access Sheath;
GBD	Global Burden of Disease;
HU	Hounsfield Unit;
CT	Computed Tomography;
ID	Inner Diameter;
IRP	Intrarenal Pressure;
KUB	Kidney, Ureter, Bladder (radiography);
min	Minute(s);
NCCT	Non-Contrast Computed Tomography;
OD	Outer Diameter;
PASS	Power Analysis and Sample Size (Software);
PUJ	Pelvi-Ureteric Junction;
UAS	Ureteral Access Sheath;
SD	Standard Deviation;
SPSS	Statistical Package for the Social Sciences;
T-UAS	Traditional Ureteral Access Sheath;
SFR	Stone-Free Rate;
UPJ	Ureteropelvic Junction;
UTI	Urinary Tract Infection.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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