

Original Research Article

FANS-ASSISTED VERSUS CONVENTIONAL RETROGRADE INTRARENAL SURGERY FOR RENAL CALCULI <2 CM: A PROSPECTIVE COMPARATIVE COHORT STUDY

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ABSTRACT

Background: Retrograde intrarenal surgery (RIRS) is a minimally invasive treatment for renal calculi. Flexible and navigable suction ureteral access sheath (FANS)-assisted RIRS uses active suction to evacuate irrigation fluid and stone fragments and maintain visualisation during lithotripsy. This study compared FANS-assisted RIRS with conventional RIRS for renal calculi <2 cm.

Materials and Methods: This prospective, single-centre, non-randomised comparative cohort study included consecutive adults undergoing RIRS for renal calculi <2 cm between April 2025 and June 2026. Patients underwent conventional RIRS or FANS-assisted RIRS at the treating surgeons' discretion. Co-primary outcomes were stone-free rate (SFR) and postoperative sepsis within 30 days. SFR was defined as the largest residual fragment ≤ 2 mm on postoperative non-contrast computed tomography (NCCT); sepsis was defined as documented infection with an acute SOFA increase ≥ 2 from baseline.

Results: Among 224 patients, 136 underwent conventional RIRS and 88 FANS-assisted RIRS. SFR was 77.9% and 84.1%, respectively (RR, 1.08; 95% CI, 0.95–1.22; $p=0.258$). Postoperative sepsis occurred in 8.1% and 3.4% (RR, 0.42; 95% CI, 0.12–1.47; $p=0.158$). Documented postoperative infection was lower with FANS (14.7% vs 4.5%; $p=0.016$). Among patients with residual fragments >2 mm, the largest residual fragment was smaller with FANS (8.1 ± 2.1 vs 7.4 ± 1.4 mm; $p=0.008$, $n=30$ vs $n=14$), and reinterventions were less frequent with FANS (14.0% vs 3.4%; $p=0.010$). Operative duration was longer with FANS (53.4 ± 14.6 vs 66.2 ± 16.1 minutes; $p<0.001$).

Conclusion: FANS-assisted RIRS was associated with numerically higher CT-defined SFR and lower SOFA-defined postoperative sepsis, although neither co-primary endpoint differed significantly. FANS was associated with lower documented infection, smaller residual fragments, and fewer reinterventions, but longer operative duration. Further randomised studies are warranted.

Keywords: Retrograde intrarenal surgery; ureteral access sheath; Renal calculi; Stone-free rate; Postoperative sepsis; Intrarenal pressure.

INTRODUCTION

Urolithiasis is a common global health problem with substantial geographic variation. The Global Burden of Disease Study 2021 estimated approximately 106 million incident cases worldwide in 2021, with men

accounting for approximately two-thirds of cases.^[1] Recent meta-analytic evidence also demonstrates substantial global prevalence while emphasising methodological heterogeneity.^[1,2]

Treatment selection for renal calculi depends on stone size, location, number, composition, anatomy, patient factors, and expertise. For stones measuring

10–20 mm, shock wave lithotripsy (SWL), retrograde intrarenal surgery (RIRS), and percutaneous nephrolithotomy (PCNL) may all be considered, whereas PCNL is generally preferred for stones >20 mm.^[3] RIRS therefore has an established role for stones <2 cm, while treatment remains individualised.

RIRS avoids the percutaneous tract required for PCNL but may be limited by fragment accumulation, impaired visualisation, repeated irrigation, and instrument manipulation. Continuous irrigation can increase intrarenal pressure (IRP), promoting pyelovenous and pyelolymphatic backflow and potentially contributing to infectious complications.^[3,4] Effective drainage while maintaining visualisation is therefore an important technical consideration.

FANS systems combine flexible access with active suction to evacuate irrigation fluid, fragments, and debris. Prospective comparative studies and randomised trials have reported favourable clearance and perioperative outcomes with suction-assisted systems, while systematic reviews have reported variable benefits across different stone populations.^[5–9] Differences in stone burden, location, sheath characteristics, suction protocols, operative technique and SFR definitions may explain this heterogeneity.

The clinical benefit of FANS for renal calculi <2 cm remains less clearly defined. Contemporary pooled analyses include heterogeneous stone populations, and studies use different imaging modalities, residual-fragment thresholds, and definitions of postoperative infection.^[6,8,9] Objective CT-based assessment and standardised infectious endpoints may therefore provide more comparable evidence.

Our study compared FANS-assisted RIRS with conventional RIRS for renal calculi <2 cm, using stone-free rate (SFR) and postoperative sepsis as co-primary outcomes.

MATERIALS AND METHODS

Study design and participants: This prospective, single-centre, non-randomised comparative cohort study was conducted in the Department of Urology, Government Mohan Kumaramangalam Medical College and Hospital (GMKMCH), Salem, Tamil Nadu, India, between April 2025 and June 2026. Consecutive adults undergoing RIRS for renal calculi <2 cm were assessed for eligibility. Patients underwent conventional RIRS or FANS-assisted RIRS. The final cohort comprised 224 patients: 136 conventional RIRS and 88 FANS-assisted RIRS. Patients aged ≥18 years with renal calculi <2 cm and adequate perioperative data were included. Exclusion criteria were anatomical urinary tract abnormalities substantially affecting RIRS, severe urosepsis requiring stabilisation before definitive treatment, gross purulence requiring abandonment of the procedure, matrix stones, uncorrected coagulopathy,

or inadequate postoperative imaging or clinical follow-up. Institutional ethics committee approval was obtained.

Preoperative evaluation: Demographic characteristics, BMI, ASA status, comorbidities, previous stone disease or endourological procedures, and preoperative DJ stenting were recorded. Preoperative infection was assessed by urine culture and susceptibility testing. Patients with positive cultures received culture-directed antibiotics for 5 days before surgery, culture-negative patients received cefoperazone-sulbactam 1.5 g IV as routine perioperative prophylaxis.

Baseline Hb, TLC, Cr, and eGFR were recorded. Preoperative NCCT documented laterality, number, maximum diameter, location, and HU. Stone location was categorised as lower calyx, renal pelvis, upper/middle calyx, or multiple locations; stone density was analysed.

Surgical technique and perioperative management: Procedures were performed under general or spinal anaesthesia in lithotomy position using guidewire-assisted upper-tract access. Conventional RIRS used a 9.5/11.5-Fr UAS. Patients without preoperative DJ stenting did not undergo ureteral dilatation; two patients underwent sheathless RIRS.

For FANS-assisted RIRS, all patients were preoperatively DJ stented and a 10/12-Fr FANS UAS was used. Active intermittent suction through a wall-mounted system evacuated irrigation fluid, fragments and debris. Both groups underwent flexible ureteroscopy with gravity irrigation and 30-W Ho:YAG laser lithotripsy, with settings adjusted intraoperatively. Dusting, fragmentation, basket extraction, or combinations were used. Intraoperative complications were prospectively recorded.

Postoperative IV antibiotics were routinely continued for 48 hours and modified or escalated when clinically indicated. TLC and RFT were assessed on POD1 and CRP on POD2. Patients were monitored for infection, sepsis, AKI, and other procedure-related complications.

Outcomes and definitions: Co-primary outcomes were postoperative sepsis within 30 days and SFR on postoperative NCCT. SFR was defined as the largest residual stone fragment ≤2 mm on NCCT obtained within 30 days.

Postoperative sepsis was defined as documented infection with an acute SOFA increase of ≥2 from baseline within 30 days.^[15] Septic shock was defined as sepsis requiring vasopressors to maintain MAP ≥65 mmHg with lactate >2 mmol/L despite adequate fluid resuscitation.^[15] Documented postoperative infection was defined as a clinically diagnosed urinary or systemic infection occurring within 30 days after RIRS and documented in the medical record, for which therapeutic antimicrobial treatment was initiated or escalated; microbiological confirmation was recorded when available.

Operative time was measured from initiation of cystoscopy/urethral instrumentation to completion of

the procedure, including UAS placement, flexible ureteroscopy, lithotripsy, fragment extraction, and final DJ stent placement.

Secondary outcomes included UAS use, residual fragment size among patients with fragments >2 mm, complete radiological clearance (defined as no detectable residual stone), fever, culture-proven UTI, documented infection, antibiotic escalation, AKI, ICU admission, prolonged hospitalisation, infection-related readmission and postoperative complications. Reintervention was defined as any additional endourological procedure within 30 days for residual stone, obstruction, infection, or another procedure-related indication. Complications were graded using Clavien-Dindo; grades $\geq$ III were considered major.^[16] Prolonged hospitalisation was defined as $\geq$ 3 days.

All patients underwent postoperative NCCT within 30 days for SFR assessment. Additional clinical or radiological follow-up beyond 30 days was performed when clinically indicated.

Statistical analysis: Statistical analysis was performed using IBM SPSS Statistics for Windows, version 29.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean $\pm$ SD or median with IQR according to distribution, and categorical variables as n (%). Continuous variables were compared using the independent-samples t-test or Mann-Whitney U test, and categorical variables using Pearson chi-square or Fisher exact test, as

appropriate. Relative risks (RRs) with 95% CIs were calculated for co-primary and clinically relevant binary outcomes, with FANS-assisted RIRS as the index group and conventional RIRS as reference. All tests were two-sided, with $p < 0.05$ considered significant. Baseline characteristics were examined because of non-randomised allocation. Missing data were not imputed.

Bias and ethical considerations: Consecutive recruitment, predefined eligibility criteria, prospective data collection, and predefined outcome definitions were used to reduce selection and measurement bias. Non-randomised allocation and observed baseline differences were recognised as potential sources of confounding.

RESULTS

Patient characteristics: A total of 224 patients were included: 136 conventional RIRS and 88 FANS-assisted RIRS. Baseline characteristics are summarised in Table 1. Groups were similar for most demographic, clinical, and stone characteristics. Previous endourological procedures were more frequent in the conventional group (26.5% vs 12.5%, $p = 0.010$), while preoperative DJ stenting was more frequent in the FANS group (100% vs 67.6%, $p < 0.001$). Mean stone density was also higher with FANS (1093 ± 227.6 vs 1021 ± 207 HU, $p = 0.018$).

Table 1: Baseline demographic, clinical, and stone characteristics

Variable	Conventional RIRS (n=136)	FANS-RIRS (n=88)	p value
Age, years	44.8 $\pm$ 11.6	45.2 $\pm$ 10.9	0.794
Male	82 (60.3%)	51 (58.0%)	0.728
Female	54 (39.7%)	37 (42.0%)	
BMI, kg/m ²	24.1 $\pm$ 3.4	24.4 $\pm$ 3.1	0.497
ASA I	79 (58.1%)	49 (55.7%)	0.545
ASA II	45 (33.1%)	34 (38.6%)	
ASA III	12 (8.8%)	5 (5.7%)	
Diabetes mellitus	29 (21.3%)	18 (20.5%)	0.876
Hypertension	36 (26.5%)	19 (21.6%)	0.407
CKD	8 (5.9%)	6 (6.8%)	0.778
CAD	11 (8.1%)	4 (4.5%)	0.300
Solitary kidney	2 (1.5%)	0	0.521
Previous stone disease	42 (30.9%)	18 (20.5%)	0.085
Previous endourological procedure	36 (26.5%)	11 (12.5%)	0.010
Preoperative DJ stent	92 (67.6%)	88 (100%)	<0.001
Right-sided stone	71 (52.2%)	45 (51.1%)	0.876
Left-sided stone	65 (47.8%)	43 (48.9%)	
Single stone	103 (75.7%)	63 (71.6%)	0.490
Multiple stones	33 (24.3%)	25 (28.4%)	
Maximum stone size, mm	15.1 $\pm$ 3.2	15.9 $\pm$ 3.4	0.080
Stone density, HU	1021 $\pm$ 207	1093 $\pm$ 227.6	0.018
Stone location, n (%)			0.730
Lower calyx	51 (37.5%)	31 (35.2%)	
Renal pelvis	43 (31.6%)	25 (28.4%)	
Upper/middle calyx	25 (18.4%)	13 (14.8%)	
Multiple locations	17 (12.5%)	14 (15.9%)	

Preoperative infection and laboratory characteristics: Preoperative infectious and laboratory findings are shown in Table 2. Positive urine culture occurred in 16.2% of conventional and

13.6% of FANS patients ($p = 0.605$). Baseline Hb, TLC, Cr, and eGFR were comparable between groups.

Table 2: Preoperative infectious and laboratory characteristics

Variable	Conventional RIRS (n=136)	FANS-RIRS (n=88)	p value
Positive urine culture	22 (16.2%)	12 (13.6%)	0.605
Symptomatic UTI	12 (8.8%)	9 (10.2%)	0.725
MDR organism	5 (3.7%)	2 (2.3%)	0.555
Hb, g/dL	13.2 ± 1.5	13.3 ± 1.4	0.618
TLC, cells/μL	7840 ± 1920	7710 ± 1850	0.616
Cr, mg/dL	0.96 ± 0.22	0.94 ± 0.19	0.484
eGFR, mL/min/1.73 m ²	86.4 ± 18.7	88.1 ± 17.9	0.500

Operative outcomes: Operative outcomes are summarised in Table 3. UAS use and basket extraction were similar between groups. Mean operative time was longer with FANS (66.2±16.1 vs

53.4±14.6 minutes, $p<0.001$), and procedures lasting >60 minutes were more frequent (61.4% vs 23.5%, $p<0.001$). Intraoperative complications were uncommon and similar (2.3% vs 4.4%, $p=0.485$).

Table 3: Operative characteristics

Variable	Conventional RIRS (n=136)	FANS-RIRS (n=88)	p value
UAS used	134 (98.5%)	88 (100%)	0.521
Basket extraction	41 (30.1%)	30 (34.1%)	0.536
Operative time, min	53.4 ± 14.6	66.2 ± 16.1	<0.001
Operative time >60 min	32 (23.5%)	54 (61.4%)	<0.001
Intraoperative complication	6 (4.4%)	2 (2.3%)	0.485

Co-primary outcomes: SFR, defined as the largest residual fragment ≤ 2 mm on postoperative NCCT, was 84.1% with FANS versus 77.9% with conventional RIRS (RR 1.08, 95% CI 0.95–1.22; $p=0.258$).

Postoperative SOFA-defined sepsis occurred in 3 (3.4%) FANS patients and 11 (8.1%) conventional RIRS patients (RR 0.42, 95% CI 0.12–1.47; $p=0.158$). Co-primary outcomes are summarised in Table 4.

Table 4: Co-primary outcomes

Outcome	Conventional RIRS (n=136)	FANS-RIRS (n=88)	RR (95% CI)	p value
Stone-free rate ≤ 2 mm	106 (77.9%)	74 (84.1%)	1.08 (0.95–1.22)	0.258
Postoperative sepsis	11 (8.1%)	3 (3.4%)	0.42 (0.12–1.47)	0.158

Secondary outcomes: Secondary outcomes are shown in Table 5. Complete radiological clearance was 78.4% with FANS versus 66.9% with conventional RIRS ($p=0.063$). Although overall SFR did not differ significantly, the largest residual fragment among patients with residual fragments >2 mm was smaller with FANS (7.4±1.4 mm vs 8.1±2.1 mm; $p=0.008$; $n=14$ vs $n=30$), and reinterventions

were less frequent with FANS (3.4% vs 14.0%; $p=0.010$). Fever, culture-proven UTI, antibiotic escalation, AKI, septic shock, ICU admission did not differ significantly between groups.

Documented postoperative infection within 30 days was significantly less frequent with FANS (4.5% vs 14.7%, $p=0.016$).

Table 5: Secondary stone-related and postoperative infectious/renal outcomes

Outcome	Conventional RIRS (n=136)	FANS-RIRS (n=88)	p value
Complete radiological clearance	91 (66.9%)	69 (78.4%)	0.063
Largest residual fragment among patients with residual fragments >2 mm, (n=30 vs n=14), mm	8.1 ± 2.1	7.4 ± 1.4	0.008
Reintervention	19 (14.0%)	3 (3.4%)	0.010
Postoperative fever	23 (16.9%)	12 (13.6%)	0.510
Culture-proven UTI	13 (9.6%)	5 (5.7%)	0.297
Antibiotic escalation	17 (12.5%)	5 (5.7%)	0.094
AKI	5 (3.7%)	2 (2.3%)	0.707
Documented infection within 30 days	20 (14.7%)	4 (4.5%)	0.016
Septic shock	3 (2.2%)	1 (1.1%)	1.000
Vasopressor requirement	3 (2.2%)	1 (1.1%)	1.000
ICU admission	5 (3.7%)	1 (1.1%)	0.407

Hospital stay and postoperative complications: Hospitalisation and postoperative complications are summarised in Table 6. Mean hospital stay was similar (2.10±0.83 vs 2.30±1.01 days, $p=0.110$), while prolonged hospitalisation ≥ 3 days was less frequent with FANS (8.0% vs 19.1%, $p=0.021$). Infection-related readmission and subcapsular collection requiring USG-guided drainage were

uncommon and did not differ significantly. Any postoperative complication occurred in 13.6% of FANS patients and 23.5% of conventional patients ($p=0.069$); major complications were 2.3% and 4.4%, respectively ($p=0.485$). There were no deaths within 30 days.

Table 6: Hospitalisation and postoperative complications

Outcome	Conventional RIRS (n=136)	FANS-RIRS (n=88)	p value
Mean hospital stay, days	2.30 ± 1.01	2.10 ± 0.83	0.110
Prolonged hospitalisation ≥3 days	26 (19.1%)	7 (8.0%)	0.021
Infection-related readmission	13 (9.6%)	5 (5.7%)	0.297
Subcapsular collection requiring USG-guided drainage	3 (2.2%)	0 (0%)	0.269
Any postoperative complication	32 (23.5%)	12 (13.6%)	0.069
Clavien-Dindo grade I	12 (8.8%)	5 (5.7%)	0.386
Clavien-Dindo grade II	14 (10.3%)	5 (5.7%)	0.226
Clavien-Dindo grade ≥III	6 (4.4%)	2 (2.3%)	0.485

Follow-up: All patients underwent postoperative NCCT within the predefined 30-day period for SFR assessment. All predefined 30-day outcome assessments were completed within the study period. Median overall clinical follow-up was 35 [24.75–38] days for conventional RIRS and 33 [21.75–36] days for FANS ($p=0.007$). Follow-up beyond 30 days did not alter the predefined NCCT-based SFR endpoint.

DISCUSSION

In this prospective comparative cohort of 224 patients with renal calculi <2 cm, FANS-assisted RIRS was associated with higher CT-defined SFR and lower SOFA-defined sepsis than conventional RIRS, although neither co-primary outcome differed significantly. FANS was also associated with smaller residual fragments, fewer reinterventions, and lower documented infection, but longer operative duration. Interpretation is limited by non-randomised allocation and baseline differences in pre-stenting, previous endourological procedures, and stone density.

Stone-free rate: FANS-assisted RIRS produced an SFR of 84.1% compared with 77.9% with conventional RIRS (RR 1.08, 95% CI 0.95–1.22; $p=0.258$). Thus, the observed difference did not reach statistical significance. Contemporary meta-analyses have reported variable SFR benefits, and analyses restricted to stones ≤2 cm have not consistently demonstrated an advantage.^[8,9]

Differences among studies may reflect stone burden, location, density, pre-stenting, operative technique, comparator sheath, and SFR definitions. The present study used postoperative NCCT and a strict ≤2-mm threshold, which provides objective assessment but may yield lower SFR than studies using less sensitive imaging or larger residual-fragment thresholds.

Residual fragments and additional procedures: Although overall SFR did not differ significantly, the largest fragment among patients with residual fragments >2 mm was smaller with FANS (8.1 ± 2.1 vs 7.4 ± 1.4 mm; $p=0.008$, $n=30$ vs $n=14$), and reinterventions were less frequent with FANS (14% vs 3.4%, $p=0.010$). These findings are consistent with the proposed ability of active suction to improve visualisation and facilitate fragment evacuation.

The contemporary literature similarly suggests that suction-assisted systems may improve fragment evacuation and selected secondary outcomes, although effects vary across study populations and definitions.^[8–12]

Documented infection and postoperative sepsis:

Documented postoperative infection was significantly lower with FANS (14.7% vs 4.5%, $p=0.016$). Active suction may facilitate evacuation of irrigation fluid and debris and improve drainage, while reduced IRP has been proposed as a mechanism for lowering infectious risk.^[4–9,11,12]

SOFA-defined postoperative sepsis occurred in 3.4% of patients undergoing FANS-assisted RIRS compared with 8.1% following conventional RIRS (RR 0.42, 95% CI 0.12–1.47; $p=0.158$). Although the observed incidence was lower in the FANS group, the difference was not statistically significant. Thus, the study did not establish a significant association between the use of FANS and a reduction in postoperative sepsis.

All FANS patients were preoperatively DJ-stented compared with 67.6% of conventional patients. Pre-stenting has shown variable associations with postoperative infectious and perioperative outcomes in observational studies.^[13,14] Therefore, the independent contribution of FANS to the lower infection rate cannot be established in this cohort.

Overall, the present data demonstrate an association between FANS use and lower documented postoperative infection; however, the independent contribution of FANS cannot be established because of non-randomised treatment allocation and the imbalance in preoperative DJ stenting, while the effect on SOFA-defined sepsis remains uncertain.

Operative duration: FANS-assisted RIRS was associated with longer operative duration (66.2 ± 16.1 vs 53.4 ± 14.6 minutes, $p<0.001$), and procedures lasting >60 minutes were more frequent. This differs from pooled analyses reporting no consistent difference in operative time.^[8,9]

The longer duration may relate to higher mean stone density in the FANS group, more extensive fragment evacuation or scope manipulation. These factors, together with non-randomised allocation, make attribution to the FANS system alone inappropriate. The potential benefit of fragment evacuation therefore needs to be considered alongside the longer operative duration observed in this cohort.

Baseline differences and potential confounding: Interpretation is limited by non-randomised allocation. Although many baseline characteristics were comparable, previous endourological procedures, preoperative DJ stenting, and mean stone density differed between groups.

All FANS patients were pre-stented compared with 67.6% of conventional patients. Pre-stenting may

influence ureteral access, sheath placement, operative conditions, and postoperative outcomes.^[13,14] The higher stone density in the FANS group may also have influenced fragmentation requirements and operative duration.

Because treatment was selected according to treating surgeons' clinical judgment, selection bias and residual confounding are possible. Differences in infection, residual fragments, reinterventions, and operative duration therefore cannot be attributed exclusively to FANS.

Other perioperative outcomes: FANS showed numerically lower rates of postoperative fever, culture-proven UTI, antibiotic escalation, AKI, ICU admission, septic shock, and major complications, but most comparisons were not statistically significant.

Rare events such as septic shock, ICU admission, and major Clavien-Dindo complications were infrequent, limiting precision. These findings should therefore be considered descriptive.

Mean hospital stay was similar, although prolonged hospitalisation ≥ 3 days was less frequent with FANS. Contemporary meta-analyses have generally not demonstrated a substantial difference in overall hospital stay.^[8,9]

Subcapsular collections requiring drainage were uncommon and the difference was not statistically significant. The small number of events does not permit inference regarding an effect of FANS.

Position of the present findings within the contemporary FANS literature: Contemporary evidence supports the technical rationale for suction-assisted RIRS, but the magnitude of benefit varies. The 2026 meta-analysis by Mittal et al. included 15 studies and 3,030 patients and reported higher immediate SFR with FANS, with substantial heterogeneity.^[12] Uy et al. included 34 studies and 7,193 patients and reported higher SFR with lower infection and complication rates.^[8]

Evidence specific to stones ≤ 2 cm is less uniform. The updated 2026 meta-analysis by Cho et al. found no significant SFR advantage in this subgroup, and the 2026 randomised trial of single stones ≤ 20 mm also found no significant difference in clinically acceptable or complete SFR.^[9,10] These findings are directly relevant to the present population.

Conversely, the 2026 network meta-analysis of renal stones ≤ 2 cm reported improved 30-day SFR and lower postoperative sepsis with suction-assisted ureteroscopy.^[11] Differences in patient selection, stone characteristics, SFR definitions, imaging timing, pre-stenting, sheath configuration, suction parameters, and operative technique may contribute to these divergent findings.

The comparator may also influence the apparent effect. Uy et al. reported that the SFR difference was no longer evident in sensitivity analysis when FANS-UAS was compared with a traditional UAS with suction.^[8] This suggests that active drainage and fragment evacuation strategy, rather than sheath design alone, may contribute to observed outcomes.

Strengths: Strengths include prospective consecutive recruitment, predefined eligibility and outcome definitions, restriction to renal calculi < 2 cm, postoperative NCCT with a ≤ 2 -mm residual-fragment threshold, and objective SOFA-based sepsis assessment. The study also evaluated infection, residual fragment size, reinterventions, hospitalisation, and complications.

Future research: Future studies should use randomised allocation, standardised pre-stenting, uniform operative techniques, predefined suction and irrigation parameters, and NCCT at a standardised time point. Stratification by stone size, location, density, volume, and preoperative urine culture would improve comparability.

Because postoperative sepsis is uncommon, adequately powered multicentre studies are needed to determine whether active suction produces a clinically meaningful reduction. Standardised intrarenal pressure and suction measurements may further clarify relationships among drainage, operative duration, and infection.

Overall, FANS-assisted RIRS may improve fragment evacuation and selected perioperative outcomes, while its incremental benefit for CT-defined SFR and SOFA-defined sepsis remains uncertain. Further randomised studies are warranted.

Limitations of the Study:

- The principal limitation is the non-randomised design, with treatment selected by treating surgeons. Differences in previous endourological procedures, preoperative DJ stenting, and stone density indicate potential residual confounding.
- The single-centre setting may limit generalisability to institutions using different operative protocols, access sheath sizes, suction systems, or antibiotic practices.
- The small number of postoperative sepsis events limits precision and the ability to detect differences in this uncommon outcome.
- Operator-level effects could not be formally assessed, and operative technique may vary between surgeons.

Recommendations: The findings of this prospective observational study should be interpreted as hypothesis-generating rather than as evidence for routine adoption of FANS-assisted RIRS. Although FANS was associated with lower documented postoperative infection, smaller residual fragments, and fewer reinterventions in this cohort, neither co-primary endpoint, CT-defined stone-free rate or SOFA-defined postoperative sepsis, differed significantly between groups. The non-randomised treatment allocation and baseline differences, particularly in preoperative DJ stenting, previous endourological procedures, and stone density, preclude attribution of these observed differences to FANS alone. Therefore, the present findings should not be regarded as definitive evidence or as a basis for recommending FANS over conventional RIRS.

Rather, they provide prospective comparative data that may inform future adequately powered multicentre randomised studies. Such studies are required before firm recommendations regarding routine FANS use can be made.

CONCLUSION

In this prospective comparative cohort of patients undergoing RIRS for renal calculi <2 cm, FANS-assisted RIRS showed numerically higher CT-defined SFR and lower postoperative SOFA-defined sepsis than conventional RIRS, although neither co-primary endpoint differed significantly. FANS was associated with lower documented infection, smaller residual fragments, fewer reinterventions, and longer operative duration.

These findings are broadly consistent with contemporary evidence suggesting that potential benefits of FANS may be more evident in fragment evacuation and selected perioperative outcomes, while incremental SFR benefit may be less pronounced for stones <2 cm. Further randomised studies with standardised stone-free definitions and clinically meaningful infectious endpoints are needed.

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