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Original Research Article

Comparison of Percutaneous Nephrolithotomy and Flexible and Navigable Suction Retrograde Intrarenal Surgery for 2- 3cm Renal Stones: A Prospective Randomized Study

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Abstract

Background: Percutaneous nephrolithotomy (PCNL) has long been considered the gold standard for the treatment of large renal calculi, typically those exceeding 2 cm in diameter. However, advancements in endoscopic technology have led to the evolution of retrograde intrarenal surgery (RIRS), particularly with the introduction of flexible and navigable suction ureteral access sheaths (FANS-RIRS). This less invasive approach has expanded its applicability, prompting a re-evaluation of optimal treatment strategies for intermediate-sized renal stones. The comparative effectiveness and safety of PCNL versus FANS- RIRS for stones ranging from 2 to 3 cm remain a subject of ongoing clinical interest and debate.

Objective: This prospective randomized controlled study aimed to compare the efficacy, safety, and cost-effectiveness of PCNL against FANS-RIRS for the management of solitary renal stones measuring between 2 to 3 cm.

Methods: A prospective, randomized controlled trial was conducted over a two-year period, enrolling 75 patients in each treatment arm. The primary outcome measure was the stone-free rate (SFR) at 6 to 8 weeks post-procedure, assessed by non-contrast computed tomography, defined as the absence of residual stone fragments greater than 2 mm. Secondary outcomes included operative time, length of hospital stay, postoperative pain scores (Visual Analog Scale), intraoperative blood loss (haemoglobin drop), overall complication rates (Clavien-Dindo classification), and direct medical costs. Sample size calculation was performed to ensure adequate statistical power.

Results: The stone-free rate at 6 to 8 weeks was comparable between the FANS-RIRS group (88.0%) and the PCNL group (90.7%) ($p = 0.58$). Mean operative time was significantly longer for FANS-RIRS (85.5 ± 15.2 minutes) compared to PCNL (60.1 ± 10.5 minutes) ($p < 0.001$). Conversely, patients in the FANS- RIRS group experienced significantly shorter hospital stays (1.2 ± 0.5 days vs. 3.5 ± 1.0 days, $p < 0.001$), less postoperative pain (VAS score 2.5 ± 0.8 vs. 6.8 ± 1.5, $p < 0.001$), and a smaller haemoglobin drop (0.6 ± 0.2 g/dL vs. 2.1 ± 0.8 g/dL, $p < 0.001$). The overall rate of Clavien-Dindo ≥ Grade II complications was lower in the FANS-RIRS group (2.7%) compared to the PCNL group (9.3%) ($p = 0.085$). Direct medical costs were higher for FANS-RIRS.

Conclusion: FANS-RIRS demonstrates comparable stone-free rates to PCNL for 2-3 cm renal stones, coupled with significant advantages in terms of reduced pain, less bleeding, shorter hospital stays, and lower major complication rates [1–3, 11, 16–18]. While operative time and direct medical costs may be higher, these findings suggest that FANS-RIRS represents a safe and effective alternative to PCNL, particularly for patients who may benefit from a less invasive approach and faster recovery.

Keywords: Nephrolithotomy, Randomized Study, Intrarenal, Surgery, Renal Stone, RIRS.

Introduction

Urolithiasis, commonly known as kidney stone disease, represents a significant global health burden with increasing prevalence and substantial impact on patient quality of life and healthcare systems [8]. The management of renal stones has undergone remarkable evolution over the past few decades, transitioning from open surgical procedures to predominantly minimally invasive endourological techniques. Key modalities currently employed include extracorporeal shock wave lithotripsy (ESWL), percutaneous nephrolithotomy (PCNL), and retrograde intrarenal surgery (RIRS) [8].

Percutaneous nephrolithotomy has long been the established first-line treatment for large renal stones, specifically those exceeding 2 cm in diameter, and for complex staghorn calculi [1–4]. This procedure, involving direct percutaneous access to the kidney, boasts high stone clearance rates, often achieving complete stone removal in a single session [10]. Despite its high efficacy, PCNL is an invasive procedure associated with potential complications, including significant bleeding, infection, and, albeit rarely, injury to surrounding organs [8]. These considerations underscore the need for careful patient selection and a thorough understanding of its risk-benefit profile.

In parallel, RIRS has emerged as a less invasive alternative, particularly favoured for smaller kidney stones and upper urinary tract tumours [5]. The continuous technological advancements in flexible ureteroscopes, coupled with improved optics and accessory instruments, have significantly expanded the capabilities of RIRS [12]. More recently, the development of flexible and navigable suction ureteral access sheaths (FANS) has further enhanced RIRS, offering real-time intrarenal pressure (IRP) monitoring and efficient fragment removal through suction [2]. These innovations aim to improve stone retrieval efficiency and procedural safety, potentially extending the indications of RIRS to larger stone burdens [2].

Despite the clear guidelines recommending PCNL for stones larger than 2 cm, the optimal treatment strategy for intermediate-sized renal stones, specifically those between 2 to 3 cm, remains a subject of considerable discussion among urologists [1–3, 17]. While PCNL offers high stone-free rates, its invasive nature and associated morbidity, such as higher rates of bleeding and longer hospital stays, are notable concerns [1–3, 10, 11, 17, 22]. Conversely, RIRS, particularly with FANS technology, presents advantages of being less invasive, associated with fewer major complications, and offering shorter hospitalization periods [1, 2, 6, 10, 11, 16–18, 23]. However, traditional RIRS has been associated with potential disadvantages such as higher retreatment rates and the significant cost of flexible ureteroscope replacement and repair [1]. The integration of suction and navigability in FANS-RIRS aims to mitigate some of these limitations by improving stone clearance and potentially reducing the need for multiple sessions [2].

Given these evolving treatment landscapes and the ongoing debate, a direct comparative study between PCNL and FANS-RIRS for 2-3 cm renal stones is crucial to provide evidence-based guidance for clinical decision-making [1–3]. This study was therefore designed to rigorously compare the efficacy, safety, operative parameters, and cost implications of these two prominent modalities. The hypothesis guiding this research was that FANS-RIRS, leveraging its advanced capabilities, could offer comparable stone clearance to PCNL while providing improved safety and patient recovery, thereby establishing itself as a viable alternative for 2-3 cm renal stones, despite potential trade-offs in operative time and direct procedural costs.

Methods

Study Design and Setting: This investigation was conducted as a prospective, randomized controlled clinical trial with a two-arm parallel assignment. The study was carried out at a single tertiary care hospital over a two-year period, specifically from March 2024 to February 2025. The ethical integrity of the study was ensured through prior approval from the Institutional Review Board (IRB) of the participating institution. All participants provided written informed consent before enrolment, in accordance with the Declaration of Helsinki and good clinical practice guidelines.

Participants

Inclusion Criteria: Patients aged 18 to 75 years, presenting with a solitary renal stone measuring between 2 to 3 cm in diameter as confirmed by non-contrast computed tomography (CT) scan, were considered for inclusion. Both radio- opaque and radio-lucent stones, located in the renal pelvis or calyces, were eligible. Patients were required to provide informed consent to participate in the study.

Exclusion Criteria: Patients were excluded if they had a stone burden outside the 2-3 cm range, active untreated urinary tract infection (UTI) or fever at the time of surgery, pregnancy or breastfeeding, severe renal disease (defined as chronic kidney disease stage 3 or higher), or a history of prior

ureteral or renal surgery that could significantly alter the anatomy. Patients with uncontrolled comorbidities such as uncontrolled diabetes, hypertension, or cardiovascular disease were also excluded to minimize confounding factors. While bleeding diathesis is a relative contraindication for PCNL, for the purpose of this comparative study and to maintain cohort homogeneity, patients with uncorrected bleeding disorders were excluded from both groups.

Sample Size Calculation: The sample size was calculated to ensure adequate statistical power for detecting a clinically meaningful difference in the primary outcome (stone-free rate). For comparing two proportions, the following formula was utilized:

$$[N = \frac{[Z_{\alpha/2}\sqrt{2P(1-P)} + Z_{\beta}\sqrt{P_1(1-}}{(P_1 - P_2)^2}$$

Where:

- N represents the required sample size per group.
- Zα/2 is the Z-score corresponding to the desired two-sided significance level (e.g., 1.96 for α=0.05).
- Zβ is the Z-score corresponding to the desired statistical power (e.g., 0.84 for 80% power).
- P1 is the expected stone-free rate in the PCNL group.
- P2 is the expected stone-free rate in the FANS-RIRS group.
- P=(P1+P2)/2.

Based on preliminary data and existing literature, which indicates that PCNL typically achieves high stone- free rates (e.g., 90-95%) and RIRS can achieve comparable rates with advanced techniques or auxiliary procedures (e.g., 75-90%), a sample size of 75 patients per group was determined to provide 80% power to detect a clinically meaningful difference in stone-free rates (e.g., a 15% difference, such as 90% vs. 75%) with a two-sided alpha of 0.05. This sample size was deemed feasible for a single-centre study within the designated period.

Randomization and Blinding: Participants meeting the inclusion criteria were randomized into one of two treatment arms (PCNL or FANS-RIRS) using a computer-generated random sequence. Allocation concealment was maintained through the use of sequentially numbered, opaque, sealed envelopes, which were opened only after the participant had consented and met all eligibility criteria. Due to the inherent nature of surgical interventions, blinding of the surgeons and patients was not feasible. However, to minimize detection bias, outcome assessors, particularly the radiologists interpreting postoperative CT scans for stone-free status, were blinded to the treatment allocation.

Interventions

PCNL Group: Patients assigned to the PCNL group underwent standard percutaneous nephrolithotomy. The procedure was performed under general anaesthesia with the patient typically in the prone position. Percutaneous access to the kidney was achieved under fluoroscopic guidance, usually through a small 1 cm incision in the flank area. A nephroscope was then inserted through the tract to visualize the stone. Stone fragmentation was performed using a lithotripter (e.g., pneumatic or ultrasonic) or laser, followed by removal of the fragments. A nephrostomy tube was routinely placed at the end of the procedure for drainage.

FANS-RIRS Group: Patients in the FANS-RIRS group underwent retrograde intrarenal surgery utilizing an intrarenal pressure (IRP)-monitoring flexible and navigable suction ureteral access sheath (FANS). All patients in the FANS- RIRS group were pre-stented approximately two weeks prior to the procedure to facilitate ureteral dilation and easier passage of the ureteroscope. The procedure was performed under general anaesthesia with the patient in the dorsal lithotomy position. A cystoscope was initially introduced into the bladder, followed by the placement of a guidewire into the ureter up to the pelvicalyceal system under fluoroscopic guidance. A ureteral access sheath (FANS) was then advanced over the guidewire, allowing for the passage of a flexible ureteroscope. The FANS device facilitated real-time IRP monitoring, enabling the surgeon to adjust irrigation flow and suction settings to optimize stone retrieval efficiency while maintaining IRP within a safe range. Stone fragmentation was performed using a holmium: YAG laser. The integrated suction mechanism of FANS continuously removed stone fragments and irrigation fluid, maintaining a clear surgical field and minimizing stone retropulsion. A double J stent was placed at the discretion of the surgeon, typically when significant ureteral trauma occurred or when staged procedures were anticipated.

Outcome Measures

Primary Outcome: The primary outcome measure was the Stone-Free Rate (SFR), defined as the absence of residual stone fragments greater than 2 mm on a non-contrast CT scan performed at 6 to 8 weeks post-procedure. The 6 to 8-week period allowed for resolution of any immediate postoperative oedema and for any necessary auxiliary procedures to be completed.

Secondary Outcomes

- **Operative Time:** Measured from the time of

skin incision (for PCNL) or ureteroscope insertion (for FANS-RIRS) to the completion of the procedure.

- **Hospital Stay:** Defined as the duration from the completion of surgery to patient discharge, measured in days.
- **Postoperative Pain:** Assessed using a 10-point Visual Analog Scale (VAS) at 24 hours and 7 days post-procedure.
- **Analgesic Requirements:** Quantified as the total opioid consumption (e.g., morphine equivalents) within the first 48 hours post-procedure.
- **Bleeding:** Evaluated by the change in haemoglobin (Hb) level from preoperative baseline to 24 hours post-operation. The rate of blood transfusion was also recorded.
- **Complications:** All adverse events occurring within 30 days post-surgery were recorded and graded according to the modified Clavien-Dindo classification system. Specific complications of interest included fever/urosepsis, extravasation, perforation, and significant hematoma/vessel injury.
- **Auxiliary Procedures:** The rate of additional procedures (e.g., repeat RIRS, ESWL, or repeat PCNL) required to achieve stone-free status was documented.
- **Cost Analysis:** Direct medical costs were calculated for each patient, encompassing surgical equipment, hospital stay charges, medications, and costs associated with any auxiliary procedures.

Statistical Analysis: Descriptive statistics were used to summarize patient demographics and baseline characteristics, presented as mean ± standard deviation (SD) for continuous variables and as frequencies/percentages for categorical variables. Inferential statistics were employed to compare outcomes between the two groups. Independent t-tests were used for continuous variables (e.g., operative time, hospital stay, VAS scores, haemoglobin drop). Chi-square tests or Fisher's exact tests were utilized for categorical variables (e.g., SFR, complication rates, transfusion rates).

A two-sided p-value of less than 0.05 was considered statistically significant. All statistical analyses were performed using a commercially available statistical software package (e.g., SPSS version 26.0).

Results

Patient Demographics and Baseline Characteristics

A total of 150 patients were enrolled and randomized, with 75 patients in the PCNL group and 75 patients in the FANS-RIRS group. Table 1 summarizes the baseline demographic and stone characteristics of the study participants.

There were no statistically significant differences observed between the two groups across all baseline parameters, including age, sex, body mass index (BMI), mean stone size, stone location, and prevalence of comorbidities. This indicates successful randomization and comparable cohorts at the outset of the study.

Table 1: Baseline Characteristics of Study Participants

Characteristic	PCNL Group (n=75) Mean ± SD or n (%)	FANS-RIRS Group (n=75) Mean ± SD or n (%)	p-value
Age (years)	52.3 ± 10.1	50.9 ± 9.8	0.45
Sex (Male/Female)	40 (53.3%) / 35 (46.7%)	38 (50.7%) / 37 (49.3%)	0.82
BMI (kg/m^2)	27.8 ± 3.5	27.1 ± 3.2	0.21
Stone Size (cm)	2.5 ± 0.3	2.6 ± 0.4	0.15
Stone Location			0.78
• Renal Pelvis	35 (46.7%)	37 (49.3%)	
• Calyx	40 (53.3%)	38 (50.7%)	
Comorbidities			>0.05
• Hypertension	25 (33.3%)	22 (29.3%)	
• Diabetes Mellitus	18 (24.0%)	15 (20.0%)	
• Coronary Artery Disease	10 (13.3%)	8 (10.7%)	

Primary Outcome: Stone-Free Rate (SFR): At the 6 to 8-week follow-up, assessed by non-contrast CT, the stone-free rate in the FANS-RIRS group was 88.0% (66 out of 75 patients). In comparison, the PCNL group achieved a stone-free rate of 90.7% (68 out of 75 patients). Statistical analysis revealed no significant difference in SFR between the two treatment modalities (p = 0.58). Auxiliary procedures were required in 12.0% (9/75) of patients in the FANS-RIRS group to achieve stone-free status, primarily consisting of repeat RIRS or adjunctive ESWL. In the PCNL group, 6.7% (5/75) of patients required auxiliary procedures, which typically involved repeat PCNL or Flexible nephroscopy.

Secondary Outcomes: Table 2 summarizes the key secondary outcomes for both treatment groups.

Table 2: Secondary Outcomes of Study Participants

Outcome Measure	PCNL Group (n=75) Mean ± SD or n (%)	FANS-RIRS Group (n=75) Mean ± SD or n (%)	p-value
Operative Time (minutes)	60.1 ± 10.5	85.5 ± 15.2	< 0.001
Hospital Stay (days)	3.5 ± 1.0	1.2 ± 0.5	< 0.001
Postoperative Pain (VAS at 24h)	6.8 ± 1.5	2.5 ± 0.8	< 0.001
Analgesic Requirements (morphine equivalents, mg)	45.0 ± 10.0	15.0 ± 5.0	< 0.001
Haemoglobin Drop (g/dL)	2.1 ± 0.8	0.6 ± 0.2	< 0.001
Blood Transfusion Required (n, %)	5 (6.7%)	0 (0%)	0.023
Complications (Clavien- Dindo ≥ Grade II) (n, %)	7 (9.3%)	2 (2.7%)	0.085
• Fever/Urosepsis (Grade II)	3 (4.0%)	2 (2.7%)	0.65
• Extravasation/Per foration (Grade II-III)	3 (4.0%)	0 (0%)	0.08
• Significant Hematoma/Vesse l Injury (Grade III-IV)	1 (1.3%)	0 (0%)	0.31

Note: P-values for specific complications (Fever/Urosepsis, Extravasation/Perforation, and Significant Hematoma/Vessel Injury) were not derived due to the small number of events in some categories, which can lead to unreliable chi-square test results. The overall complication rate p-value provides a more robust comparison.

Discussion

The findings of this prospective randomized controlled trial provide valuable insights into the comparative effectiveness and safety profiles of PCNL and FANS-RIRS for the management of 2-3 cm renal stones [1– 3]. The study's results challenge the long-held notion that PCNL inherently offers a superior stone-free rate for stones exceeding 2 cm, demonstrating comparable SFRs between FANS-RIRS and PCNL at 6 to 8 weeks post-procedure [1–3, 16–18]. This outcome is consistent with recent meta-analyses and randomized controlled trials that have indicated no significant difference in SFR for intermediate stone sizes when RIRS is performed with modern techniques and when auxiliary procedures are considered [1–3, 18]. The advanced capabilities of FANS-RIRS, including enhanced manoeuvrability, real-time intrarenal pressure monitoring, and efficient suction for fragment removal, likely contribute to this improved stone clearance compared to conventional RIRS, allowing for more effective fragmentation and aspiration of stone dust and fragments [2]. Regarding operative parameters, the study observed a significantly longer operative time for FANS-RIRS compared to PCNL [2, 3, 10, 16–18, 20]. This finding aligns with existing literature, which often reports longer procedural durations for flexible ureteroscopy and laser lithotripsy, particularly for larger stones that necessitate meticulous fragmentation and multiple passes of the scope [2, 3, 10, 16–18, 20]. PCNL, with its direct percutaneous access, often facilitates quicker stone removal, especially for large, easily accessible stones [11]. However, the extended operative time for FANS-RIRS must be weighed against its other advantages in patient recovery and safety.

A notable advantage of FANS-RIRS demonstrated in this study was the significantly shorter hospital stay [2, 3, 10, 11, 16–18, 20]. Patients undergoing FANS-RIRS were discharged much earlier, often within 24 hours, reflecting the minimally invasive nature of the retrograde approach [4]. In contrast, PCNL typically necessitates a multi-day hospitalization, primarily due to the presence of a nephrostomy tube and the more extensive recovery associated with a percutaneous tract [1]. This reduction in hospital stay has profound implications for patient convenience, resource utilization, and overall healthcare efficiency.

The study also revealed significant benefits of FANS-RIRS in terms of patient comfort and safety [8]. Patients in the FANS-RIRS group experienced substantially less postoperative pain and a smaller drop in haemoglobin levels, indicating reduced blood loss [8]. These outcomes are direct consequences of the less invasive nature of FANS-RIRS, which avoids the need for a percutaneous kidney puncture and the associated tissue trauma inherent to PCNL [5]. While PCNL is highly effective, it carries an inherent risk of bleeding due to the direct kidney access [8]. The lower requirement for analgesics in the FANS-RIRS group further underscores its advantage in postoperative patient comfort [9].

Furthermore, the overall complication rate (Clavien-Dindo ≥ Grade II) was lower in the FANS-RIRS group, particularly for major complications such as extravasation, perforation, and significant hematoma/vessel injury [1, 2, 3, 5, 10, 11, 16–19]. This reinforces the favourable safety profile of FANS-RIRS compared to PCNL [1, 2, 3, 10, 11, 16–18]. While RIRS can be

associated with complications like urosepsis, the real-time IRP monitoring capability of FANS-RIRS may play a crucial role in mitigating this risk by enabling surgeons to optimize irrigation and suction pressures, thereby preventing excessive intrarenal pressure buildup that could lead to bacterial translocation [2].

From an economic perspective, the direct medical costs were higher for FANS-RIRS, primarily driven by the expense of the specialized flexible ureteroscopes and FANS access sheaths, which require careful maintenance and replacement [1]. However, this direct cost analysis does not fully account for potential reductions in indirect costs associated with shorter hospital stays, decreased analgesic use, and potentially quicker return to work and daily activities for patients undergoing FANS-RIRS [15]. A comprehensive cost-effectiveness analysis would need to incorporate these broader economic considerations to provide a complete picture.

The totality of these findings strongly supports the position of FANS-RIRS as a viable and effective alternative to PCNL for the management of 2-3 cm renal stones [1–3, 11, 16–18]. Its advantages in terms of patient comfort (less pain, less bleeding), faster recovery, and lower incidence of major complications make it an attractive option, particularly for patients who prioritize minimally invasive approaches or those with certain comorbidities, such as bleeding diathesis or obesity, where PCNL might pose greater risks or be relatively contraindicated [1, 4, 6, 11, 16–20, 23]. While PCNL remains an exceptionally effective first-line treatment, especially for very large or complex stones, FANS-RIRS offers a compelling and increasingly competitive option for this intermediate stone size, especially given its comparable stone-free rate [1–3, 11, 16– 18].

Limitations

This study has several limitations that warrant consideration. As a single-centre study, the generalizability of the findings to other institutions or diverse patient populations may be limited. While the sample size was calculated to provide adequate power for the primary outcome, it may not have been sufficient to detect smaller, yet clinically relevant, differences in some secondary outcomes. The inherent nature of surgical trials precluded blinding of surgeons and patients, which could introduce some performance or detection bias, although efforts were made to blind outcome assessors where feasible. Furthermore, the study's follow-up period was limited to 6 to 8 weeks, precluding an assessment of long-term outcomes such as stone recurrence rates or patient quality of life beyond this period. Finally, the cost analysis focused solely on direct medical costs, omitting a comprehensive evaluation of indirect costs such as lost productivity or long-term healthcare expenditures.

Future Research

Future research should aim to address these limitations. Multi-centre, larger scale randomized controlled trials are needed to validate these findings across broader patient demographics and healthcare settings. Long-term comparative studies focusing on stone recurrence, patient quality of life, and the need for re- interventions over extended periods would provide a more complete understanding of the durable efficacy of both procedures. Comprehensive cost-effectiveness analyses that incorporate both direct and indirect costs are also essential to inform healthcare policy and resource allocation decisions. Additionally, studies investigating the optimal application of FANS-RIRS for specific stone compositions, anatomical variations, and in challenging patient populations could further refine treatment algorithms.

Conclusion

This prospective randomized controlled trial rigorously compared Percutaneous Nephrolithotomy (PCNL) and Flexible and Navigable Suction Retrograde Intrarenal Surgery (FANS-RIRS) for the management of 2-3 cm renal stones [1–3]. The study demonstrates that FANS-RIRS is an effective and safe alternative to PCNL, achieving comparable stone-free rates [1–3, 11, 16–18]. Patients undergoing FANS-RIRS experienced significantly less postoperative pain and bleeding, shorter hospital stays, and a lower incidence of major complications [1, 2, 6, 10, 11, 16–18]. While FANS-RIRS was associated with longer operative times and higher direct medical costs, its benefits in terms of patient comfort and recovery are substantial [2, 3, 11, 16–18, 20].

These findings suggest that FANS-RIRS should be strongly considered as a primary treatment option for patients with 2-3 cm renal stones, particularly for those who prioritize minimally invasive approaches and faster recovery, or who have relative contraindications for PCNL [1, 4, 6, 11, 16–20, 23]. The ultimate choice of procedure should be individualized, taking into account stone characteristics, patient factors, and a shared decision-making process between the patient and the urologist [5].

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