Retrograde intrarenal surgery with flexible and navigable suction ureteral access sheaths vs. percutaneous nephrolithotomy for 2–3 cm kidney stones

Is less invasive better?

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ABSTRACT

INTRODUCTION: The management of renal stones measuring 2–3 cm remains a clinical challenge, with percutaneous nephrolithotomy (PCNL) traditionally favored over retrograde intrarenal surgery (RIRS) due to higher stone-free rates (SFR); however, advancements in flexible ureteroscopy and the introduction of flexible and navigable suction ureteral access sheaths (FANS-UAS) have expanded the role of RIRS for larger stones. This study compares the efficacy and safety of PCNL vs. FANS-UAS-assisted RIRS for medium-sized renal calculi.

METHODS: This retrospective study included 116 patients (50 RIRS, 66 PCNL) with 2–3 cm renal stones treated at a single institution. RIRS was performed using an 11/13 Fr FANS-UAS, while PCNL followed standard techniques. Outcomes assessed included operative time, hospitalization, hemoglobin drop, SFR (defined as no fragments ≥1 mm on three-month computed tomography), and complications (Clavien-Dindo).

RESULTS: Baseline characteristics were comparable between groups ($p>0.05$). RIRS demonstrated significantly shorter operative times (63.1±11.3 vs. 97.3±15.1 minutes, $p<0.001$) and hospitalization (28.3±17.9 vs. 81±24.8 hours, $p<0.001$), with less hemoglobin drop (0.4±0.5 vs. 2.1±1.7 g/dL, $p<0.001$). SFRs were similar at three months (70% RIRS vs. 74.2% PCNL, $p=0.677$). PCNL had higher complication rates, including three grade III events (vs. none in RIRS), although this was not statistically significant ($p=0.277$).

CONCLUSIONS: FANS-UAS-assisted RIRS offers comparable SFRs to PCNL for 2–3 cm stones, with advantages in operative efficiency, hospitalization, and perioperative safety. These findings suggest RIRS as a viable minimally invasive alternative, warranting further randomized trials to validate its role in this setting.

INTRODUCTION

The growing burden of kidney stone disease presents significant challenges to healthcare systems worldwide, as it increasingly affects diverse patient populations regardless of demographic factors.[1] Surgical treatment has transitioned from open nephrolithotomy to minimally invasive procedures, such as retrograde intrarenal surgery (RIRS) and percutaneous nephrolithotomy (PCNL), driven by technological advancements and innovations. The primary goal of these developments is to enhance treatment success by employing less invasive methods and enabling patients to return to everyday life as quickly as possible.[2]

Stone size remains a key factor in determining the appropriate minimally invasive treatment. The European Association of Urology (EAU) guidelines position RIRS as the preferred intervention for nephrolithiasis cases with stone burdens <2 cm.[3,4] Current literature reveals heterogeneity in the management of >2 cm renal stones, with high-volume centers increasingly reporting RIRS outcomes rivaling PCNL for select cases, challenging traditional size-based treatment paradigms.[1,5]

PCNL is highly effective in achieving stone-free outcomes for large kidney stones, but is considered more invasive compared to RIRS. This is due to potential complications, such as bleeding, the need for blood transfusion or angioembolization, and the risk of organ damage

during access, given the kidney's proximity to the lungs, spleen, intestines, and liver;[2] however, with the introduction of flexible and navigable suction ureteral access sheath (FANS-UAS), RIRS has been effectively and safely applied to large kidney stones, offering shorter operative times and reduced postoperative complication rates.[6]

This study aimed to evaluate and compare the outcomes of PCNL and RIRS, in which the FANS-UAS was used, for the management of renal stones measuring 2–3 cm. The principal aim of this study was to investigate the clinical safety and effectiveness of the increasingly adopted FANS-UAS-assisted RIRS technique in comparison to PCNL for managing medium-sized renal calculi.

METHODS

This retrospective study included patients with kidney stones measuring 2–3 cm in diameter who underwent either RIRS with FANS-UAS or PCNL at Sakarya University between November 2023 and December 2024. The study was approved by the institutional ethics committee (approval no: E-43012747-050.04-450925-101).

Patients with renal anomalies or those who underwent preoperative nephrostomy were not included in the study. Only patients undergoing their first surgical intervention for renal stones (either primary or recurrent stone formers) were included, while those with prior stone-related procedures (e.g., ureteroscopy, PCNL, or shockwave lithotripsy) were excluded. This criterion was implemented to eliminate potential confounding effects from previous interventions on operative outcomes.

Treatment modality (RIRS vs. PCNL) was assigned based on a standardized institutional protocol, considering stone characteristics (location, density in Hounsfield units [HU]), renal anatomy, and patient comorbidities. All cases were discussed in a multidisciplinary team meeting involving senior urologists with ≥10 years of experience in endourology.

The procedures were performed by three fellowship-trained endourologists, each having performed >200 RIRS and >150 PCNL procedures independently. To minimize bias, surgeons proficient in both techniques participated in the study. Treatment allocation was determined through a shared decision-making process that integrated clinical parameters with patient preferences.

For all patients meeting the inclusion criteria, both RIRS and PCNL options were thoroughly discussed during preoperative counseling. This discussion included comparative risks (bleeding, infection, need for secondary procedures), anticipated recovery times, and stone-free probability based on individual stone characteristics (HU density >1000 favoring PCNL, unfavorable infundibulopelvic angles suggesting PCNL). Special consideration was given to comorbidities (e.g., bleeding diatheses automatically excluding PCNL). Final treatment selection reflected joint agreement between the surgical team and informed patient choice after reviewing all options. This standardized counseling protocol ensured consistent evaluation while respecting patient autonomy.

The patients were assigned to two groups: group 1 (n=52) underwent RIRS with the assistance of an 11/13 Fr FANS-UAS (ClearPetra) as the ureteral access sheath, whereas group 2 (n=66) underwent standard PCNL. Two patients in the RIRS group continued their postoperative care at another center, leading to incomplete followup data, and were not included in the final analysis. Consequently, the study included 116 patients.

Demographic data, including sex, age, and body mass index (BMI), along with stone-specific parameters, such as location, size, and HU values, were recorded for each patient. Preoperative urine culture results and hemoglobin levels were also documented. Before the operation, all patients included in the study had sterile preoperative urine cultures, ensuring no underlying infections.

A standard conventional approach was employed for all PCNL procedures. Following the administration of general anesthesia, patients were positioned in the dorsal lithotomy position to begin the procedure. Cystoscopy was used to access the bladder, and the ureteral orifice on the operative side was identified. A 5 Fr ureteral catheter was then advanced over a guidewire. The external portion of the ureteral catheter was secured to the Foley catheter with silk sutures.

After completing the initial steps, the patient's position was changed to prone to allow access for the percutaneous phase of the procedure. Contrast material was administered through the ureteral catheter, and the renal pelvicalyceal system was visualized using a C-arm fluoroscope. Percutaneous access to the kidney was achieved with an 18 G Chiba needle.

After the guidewire was advanced into the pelvicalyceal system, Amplatz dilatation was used, and a 30 Fr access sheath was subsequently inserted to complete the tract preparation. A nephroscope (26 F Storz; Karl Storz GmbH & Co. KG, Tuttlingen, Germany) was used to access the stones within the pelvicalyceal system. Stone fragmentation was achieved using a combina-

tion of ultrasonic and pneumatic lithotripters (Lithobox Zero), and the resulting small fragments were removed manually with forceps. At the conclusion of the procedure, a nephrostomy catheter was placed in all patients under C-arm fluoroscopy guidance.

In the RIRS procedure, before the insertion of FANS-UAS, the ureter was accessed using an 8 Fr semirigid ureteroscope (Karl Storz, Tuttlingen, Germany), and hydrodilatation was performed up to the renal pelvis. The approximate length of the ureter was calculated using the ureteroscope, and the FANS-UAS was then placed over the guide without fluoroscopy.

In cases where the FANS-UAS could not be advanced to the renal pelvis, a double-J catheter was placed via the guide, and the procedure was postponed for three weeks. Three patients had their operations delayed for three weeks due to the inability to advance the FANS-UAS during the first attempt; however, the FANS-UAS was successfully placed without complications in their second session.

Subsequently, the Hugemed (HU 30S 7.5 Fr) flexible ureteroscope (FURS) was passed through the flexible access sheath to reach the pelvicalyceal system. The stones were visualized and dusted using a 273 µm laser with a Ho-YAG (Quanta 30) device. Depending on the stone density, the fragmentation was carried out using energy settings of 1–2 J, a frequency of 5–10 Hz, and a power of 5–20 W. The stones were thoroughly dusted until no fragments remained, allowing small residual pieces and dust to pass spontaneously. Following the procedure, a 4.8 Fr double-J catheter was placed over the guide, and the process was concluded.

The total operation time was defined as the duration from the moment the bladder was accessed with the ureteroscope (URS) after anesthesia induction until the double-J catheter was placed at the end of the procedure for RIRS, and from the moment the bladder was accessed with cystoscopy until a nephrostomy catheter was inserted to ensure postoperative drainage in PCNL. For the three patients requiring delayed FANS-UAS placement (initial placement failure), only the operative time of the definitive RIRS procedure was included in the primary analysis. The duration of initial double-J stent placement (mean: 8±2 minutes) was excluded, as it represented a separate, minimal intervention. Since all RIRS procedures were performed without fluoroscopy, no comparison of fluoroscopy times was made between the groups.

A decrease in hemoglobin was calculated as the difference between the preoperative hemoglobin value and the first hemoglobin measurement taken postoperatively. Stone-free status was assessed through a two-phase imaging protocol. On postoperative day 1, all patients with radio-opaque stones underwent kidney-ureter-bladder (KUB) radiography, where fragments <2 mm were considered clinically insignificant based on KUB's resolution limits. For non-opaque stones or when clinical suspicion persisted, low-dose computed tomography (CT) was obtained.

At the three-month followup, every patient received standardized low-dose CT (2 mm slice thickness), which was graded according to *Journal of Endourology* criteria: complete clearance (grade A, no fragments ≥1 mm), clinically insignificant residual fragments (grade B, 1–3 mm), and significant residual stones (grade C, ≥4 mm). The success rate in this study was defined exclusively as grade A clearance — the complete absence of any residual stone fragments ≥1 mm — as determined by standardized low-dose CT imaging at the three-month postoperative followup.

Postoperative complications occurring in the early period were evaluated and graded using the Clavien-Dindo system.

Statistical analysis was conducted using SPSS software (version 22.0; IBM Corp., Armonk, NY, U.S.). Categorical variables were analyzed using the Chi-squared or Fisher's exact test, based on expected cell counts. For continuous variables, the Student's t-test was applied when assumptions of normality were met; otherwise, the Mann-Whitney U test was used. A two-sided p-value <0.05 was considered indicative of statistical significance.

As this retrospective study compared existing techniques, a formal power calculation was not performed a priori; however, post-hoc analysis determined the study had 98% power (α=0.05, β=0.20) to detect a 34-minute operative time difference — exceeding the 20-minute threshold considered clinically significant based on prior studies linking shorter operating room times to reduced anesthesia risks.[4]

RESULTS

The distribution and comparison of baseline demographic parameters between the RIRS and PCNL groups are detailed in Table 1. Variables such as sex, BMI, age, stone size, HU, and the location of the stones within the pelvicalyceal system were analyzed. All comparisons yielded non-significant results, indicating that the groups were comparable in terms of baseline characteristics (p>0.05).

Table 2 provides an overview of the postoperative results observed in each group. Hospitalization times

were significantly shorter in the RIRS group (28.3±17.9 hours) compared to the PCNL group (81±24.8 hours) (p<0.001). Similarly, operation times were significantly shorter in the RIRS group (63.1±11.3 minutes) compared to the PCNL group (97.3±15.1 minutes) (p<0.001). Sensitivity analysis, including cumulative times (initial stent placement + definitive RIRS) for the three staged cases, showed no significant difference in mean RIRS operative time (65.4±12.7 vs. original 63.1±11.3 minutes, p=0.421), confirming the robustness of our findings.

The hemoglobin decrease was significantly lower in the RIRS group (0.4±0.5 g/dL) than in the PCNL group (2.1±1.7 g/dL, p<0.001). Clinically, three patients (4.5%) in the PCNL group required blood transfusions (all for hemoglobin <7 g/dL with symptomatic anemia), whereas no RIRS patients needed transfusion. Stone-free rates assessed using KUB or low-contrast CT on postoperative day 1 were 76% in the RIRS group and 81.8% in the PCNL group (p=0.492). At postoperative month 3, although the stone-free success rate was numerically higher in the PCNL group (74.2%) compared to the RIRS group (70%), the difference was not statistically significant (p=0.677).

To assess the severity and distribution of postoperative complications, the Clavien-Dindo classification was applied across both groups. In the RIRS group, four patients experienced grade I complications, while eight patients in the PCNL group experienced grade I complications. Fever as a grade II complication was observed in two patients in the RIRS group, and antibiotic therapy was initiated. In the PCNL group, six patients had grade II complications, of whom three experienced fever requiring antibiotics, and three required blood transfusions.

No grade III complications were observed in the RIRS group, whereas three patients in the PCNL group experienced grade III complications. Double-J stents were placed in two patients due to urine leakage lasting more than 12 hours, and one patient underwent treatment by interventional radiology for an arteriovenous fistula. Both groups were free from grade IV and V complications during the postoperative period. No statistically significant difference was found between the groups regarding complications classified by the Clavien-Dindo system (p=0.277).

Table 1. Patient demographic data

	RIRS	PCNL	p
n	50	66	
Male/female	32/18	43/23	0.898
Age (y)*	47.8±7.9	46.2±6.1	0.245
BMI (kg/m²)*	27.5±5.2	26.9±3.1	0.710
Stone size (mm)*	24.5±1.8	24.8±1.4	0.297
Hounsfield units	980.7±137.5	1011.2±89.3	0.177
Stone locations**			0.792
Lower	18	18	
Middle	3	7	
Upper	7	8	
Pelvic	10	15	
Multicalyceal	12	18	

*Mean ± standard deviation. **The pattern of stone presence in the kidney. PCNL: percutaneous nephrolithotomy; RIRS: retrograde intrarenal surgery.

Table 2. Postoperative outcome analysis

	RIRS	PCNL	p
Hospitalization* (h)	28.3±17.9	81±24.8	<0.001
Operative time* (min)	63.1±11.3	97.3±15.1	<0.001
Hemoglobin drop* (g/dL)	0.4±0.5	2.1±1.7	<0.001
Stone-free rate**, n (%)	38/50 (76%)	54/66 (81.8%)	0.492
Success rate***, n (%)	35/50 (70%)	49/66 (74.2%)	0.677
Post-op complications			0.277
Clavien grade I	4	8	
Clavien grade II	2	6	
Clavien grade III	0	3	
Clavien grade IV-V	0	0	

*Mean ± standard deviation. **Outcomes observed on day 1 after surgery. ***Complete stone clearance (Grade A, defined as no fragments ≥1 mm) at the 3-month postoperative followup. PCNL: percutaneous nephrolithotomy; RIRS: retrograde intrarenal surgery.

DISCUSSION

The principal goal in urinary stone treatment is to ensure maximal stone clearance while reducing morbidity to the lowest possible level. Consequently, endourologic techniques, with reduced invasiveness, have become the standard in contemporary urinary stone management.[7] PCNL marked a paradigm shift in kidney stone surgery, rendering open kidney stone surgery obsolete. Its most significant advantage lies in being a minimally invasive surgical technique that allows the introduction

of large instruments into the renal pelvicalyceal system via a nephroscope to fragment and remove stones from the body;[8] however, despite its advantages, PCNL involves controlled renal trauma, as dilation up to 30 Fr is performed, which increases the risk of complications such as bleeding and cortical tears.

Although technological advancements have reduced the size of instruments used in PCNL since its inception, it remains a procedure with a risk of complications despite its high stone-free rates.[8] The American Urological Association (AUA) and EAU guidelines currently advocate for the use of PCNL as the treatment of choice for kidney stones >2 cm, primarily due to its superior ability to achieve stone-free outcomes.[9]

Recent advancements in laser technologies and flexible ureteroscopes have introduced a novel approach to the surgical management of large kidney stones. RIRS has become a cornerstone in treating kidney stones due to its high reliability, effectiveness, and low morbidity rates.[10] This technique is increasingly preferred for managing kidney stones across all anatomical locations and age groups. It is particularly advantageous for patients with bleeding or coagulation disorders and those with renal anomalies, making it the preferred treatment option in such cases.[11]

In RIRS, as stone size increases, operation time tends to lengthen, and the risk of complications, such as urinary tract perforation, renal effusion, urinary tract infection, and uremic syndrome, rises.[3] RIRS may not be able to fully eliminate stones >2 cm in a single treatment session. Studies indicate that single-session stone clearance rates can drop to as low as 62% as stone size increases.[12] In cases where complete clearance is not achieved, prolonged operative times may lead to additional surgical interventions or complications, such as infection and bleeding, further increasing the risk.[12]

Ureteral access sheaths (UAS) have been introduced recently to reduce surgical complications associated with RIRS;[13] however, traditional UAS are unable to reach the calyces within the pelvicalyceal system, making it challenging to completely clear large calyceal stones. UAS with a suction bendable tip has been developed to address this limitation. These FANS-UAS can be maneuvered into the calyces using a flexible ureteroscope, allowing fragmented stones to be efficiently removed through suction. Furthermore, these devices have been shown to reduce operative time, prevent elevated intrarenal pressure, and decrease complications, such as sepsis and bleeding.[3]

FANS-UAS can be flexed at wide angles, allowing access to most calyces within the pelvicalyceal system through the ureteroscope. Additionally, negative pressure aspiration enhances the efficiency of fluid circulation in the pelvicalyceal system, providing a clear surgical vision while effectively removing stone fragments from the body.[3] This study directly compares two different surgical approaches for managing kidney stones 2–3 cm in size: PCNL, the established treatment for larger stones, and RIRS using FANS-UAS, an emerging procedure gaining popularity due to its various advantages.

Recently, there has been a significant increase in research focused on examining the efficacy and safety of FANS-UAS in RIRS procedures for both adult and pediatric patients. In a recent retrospective study by Turedi et al, pediatric patients who underwent RIRS were compared between FANS-UAS and traditional UAS groups.[14] The FANS-UAS group demonstrated shorter operative times, reduced anesthesia requirements, fewer treatment sessions, and higher initial success rates. No meaningful differences in complication rates were observed between the groups.

Gauhar et al published a multicenter, prospective study conducted across eight centers, comparing conventional UAS with FANS-UAS in RIRS surgeries for pediatric patients.[15] The study concluded that RIRS procedures performed with FANS-UAS were safe, effective in achieving stone clearance, and associated with a low complication rate.

In an international, multicenter, randomized, prospective study, Zhu et al compared the efficacy and safety of FANS-UAS with traditional UAS for renal and ureteral stones <3 cm in size.[16] The study demonstrated several advantages of FANS-UAS, including reduced postoperative fever, higher stone-free rates, and improved quality-of-life outcomes.

Chen et al recently published a study comparing traditional UAS with flexible suction UAS in RIRS for kidney stones ranging from 2–4 cm.[3] In this retrospective study, which included 238 patients, a statistically significant difference was observed in favor of the flexible suction UAS group regarding operative time, as well as the stone-free rates on the first and 30th postoperative days.

In a recent retrospective study by Erkoc et al, patients with kidney stones ≥2 cm were divided into two groups: aspiration-assisted UAS and traditional UAS.[11] The comparison revealed a statistically significant advantage for the aspiration-assisted UAS group regarding stone-free rate, operative time, and postoperative fever incidence.

In a retrospective study by Chen et al comparing mini PCNL (m-PCNL) and RIRS using FANS-UAS for

kidney stones measuring 2–3 cm, RIRS was found to have advantages, such as a shorter hospital stay and less postoperative hemoglobin decrease.[6] Additionally, fewer postoperative complications were observed with RIRS, suggesting that it could be a superior treatment option to m-PCNL for managing stones in this size range.

In this study, we compared RIRS and PCNL performed using FANS-UAS for the surgical management of 2–3 cm kidney stones, focusing on efficacy and safety. Statistically significant advantages were observed in the RIRS group regarding hospital stay, operative time, and postoperative hemoglobin decrease; however, stone clearance success and postoperative complication rates were statistically similar between the groups. Notably, Clavien-Dindo grade III complications were reported in three patients in the PCNL group: one required an interventional radiology procedure for an arteriovenous fistula, and two underwent double-J stent placement due to postoperative urine leakage. No grade III complications were observed in the RIRS group.

Limitations

Several limitations should be acknowledged in this study. First, the retrospective design and limited sample size may affect the generalizability of our findings. Second, two RIRS cases (4% of the initial cohort) were excluded from the final analysis due to incomplete followup data after being referred to other centers. Third, the use of KUB radiography on postoperative day 1 (for radio-opaque stones) may have underestimated small residual fragments, although this was mitigated by standardized low-dose CT at three-month followup. Fourth, the involvement of multiple surgeons, despite all being high-volume endourologists, could introduce technical variability. Finally, the non-randomized design carries inherent selection bias, although we mitigated this through standardized patient counseling and multidisciplinary case selection.

CONCLUSIONS

According to this study, RIRS using FANS-UAS has emerged as a promising alternative for the surgical treatment of kidney stones measuring 2–3 cm. With acceptable stone-free rates, shorter hospitalization, and reduced duration of surgery, RIRS provides both surgeons and patients with a less invasive option for managing large kidney stones, yielding favorable outcomes. Prospective randomized studies are needed to support the findings.

COMPETING INTERESTS: The authors do not report any competing personal or financial interests related to this work.

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