

Safety and Efficacy of Flexible and Navigable Suction Ureteral Access Sheath in Retrograde Intrarenal Surgery: A Prospective Study

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ABSTRACT

Introduction: This study was aimed to evaluate the stone-free rate and complications following retrograde intrarenal surgery using the flexible and navigable suction ureteral access sheath for nephrolithiasis.

Methods: A prospective observational study was conducted at Bir Hospital, Kathmandu, Nepal, between April 2025 and January 2026. Patients aged over 16 years with nephrolithiasis undergoing retrograde intrarenal surgery with flexible and navigable suction ureteral access sheaths were enrolled. Laser lithotripsy was carried out with Thulium Fiber Laser or Holmium:Yttrium-Aluminum-Garnet laser. Stone free rate was assessed at 4 weeks using X-ray and ultrasonography of the kidneys, ureters, and bladder. Complications were graded by the Clavien–Dindo and ureteric injury was graded using Traxer ureteric injury classification systems.

Results: Sheath negotiation to the kidney was achieved in 151 (74.75%) with access to all calyces in 193 (95.54%) of cases. Median operative duration was 43.6 minutes. Stone volume of less than 1000mm³ found to have better stone free rate than volume less than 1000 mm³. Post-operative fever occurred in 8 (6.34%) of cases. Major grades (Grade III and above) of ureteric injury were not seen.

Conclusions: Use of flexible and navigable suction ureteral access sheaths resulted in high stone-free rates and low infectious complication rates. Stone volume was associated with better stone-free rates, whereas stone location and operative duration showed similar stone-free rates.



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INTRODUCTION

Flexible and navigable suction ureteral access sheaths (FANS) represent an evolving advancement in the armamentarium of Retrograde Intrarenal Surgery (RIRS).¹ These sheaths can be manoeuvred into desired calyces, enabling aspiration of fluids and stone fragments.^{2,3} Studies have shown the use of FANS to be associated with improved stone free rate (SFR) and lower infective complications with reduced need of auxiliary procedures.^{2,4,5}

Despite the rapid adoption of FANS, several concerns regarding their use still exist. These include inconsistent evidence on whether FANS reliably reduce the operating time and post-operative complications.^{6,7} Furthermore, there remains a lack of consensus on suction pressure levels and factors affecting SFR

with use of FANS.^{7–10} Therefore, this study was conducted to evaluate the peri-operative complications and efficacy associated with the use of FANS during RIRS.

METHODS

This prospective observational study was conducted at the Department of Urology, National Academy of Medical Sciences (NAMS), Bir Hospital, Kathmandu, Nepal, from April 2025 to January 2026. Ethical approval was obtained from the Institutional Review Board of NAMS (Ref. No.- 1133/2082/83) and informed written consent was taken from all participants.

Patients over the age of 16 years with nephrolithiasis undergoing RIRS using FANS were included. Patients with positive

preoperative urine culture, ureteral stricture, conversion to Percutaneous Nephrolithotomy (PCNL), simultaneous procedures such as endopyelotomy or endoureterotomy, bilateral procedures and failed negotiation of the FANS sheath into the pelvicalyceal system (PCS) were excluded. Preoperative imaging was performed using non-contrast CT of the kidneys, ureters, and bladder (NCCT KUB), and stone location, size, volume, and density were recorded. The minimum sample size was calculated using the single-population proportion formula, $s = z^2 pq / e^2$, assuming a stone free rate of 91% based on the prospective study by Shrestha et al on RIRS, a 95% confidence interval and a margin of error of 5%, with required sample size of 126.¹¹ The sampling was consecutive sampling method meeting the inclusion criteria.

All procedures were performed by senior consultant under general anaesthesia with the patient in the dorsal lithotomy position, and a single prophylactic antibiotic (Inj. Ceftriaxone) was administered. Rigid cystoscopy was performed and a 0.035" hydrophilic guidewire (Terumo, Japan) was advanced to the collecting system. FANS (10/12 Fr, Wellead Medical, China) was negotiated under fluoroscopic guidance to the proximal ureter. A flexible digital ureterorenoscope (7.5 Fr; Indovasive, Biorad Medical, India) was then introduced, and FANS was advanced into the kidney under visual guidance. Suction apparatus was connected with pressure set between 150-180 cm H₂O. FANS was navigated into the desired calyx using "scope deflection at tip" technique for easily accessible calyces and "sheath advancement" technique for difficult lower-pole (LP) calyces.¹²

Laser lithotripsy was performed using either a Thulium Fiber Laser (Fiber Dust 60 W; Quanta System, Italy) or a Ho:YAG Laser (Pulse 120 H; Lumenis Inc., Israel) with a 200-μm fibre and the choice was as per surgeon's discretion. Laser settings were: dusting 0.6–0.8 J at 12–15 Hz; fragmentation 0.8–1.0 J at 8–10 Hz; pop-dusting 0.7 J at 40 Hz. Irrigation was performed under gravity at 40–60cm height with use of intermittent manual pump (TraxerFlow; Rocamed, Monaco) for evacuation of stone fragments. Endoscopic and fluoroscopic assessment was performed at the end of procedure to evaluate intra-op stone clearance and incidence of ureteric injury. The decision to place double-J (DJ) stent at the end of procedure was at the surgeon's discretion.

Operative duration was defined as the time from insertion of FANS via the external urethral meatus to its withdrawal at the end of the procedure. Laser parameters including total laser energy consumption lasing ablation speed, and lasing duration were recorded.¹³ Operative complications were graded using the Clavien–Dindo classification; ureteric injury was assessed by Traxer Ureteric Injury Grade.^{14,15} DJ stents were removed at two weeks. Stone-free status was defined as the absence of any clinically insignificant residual fragment (CIRF) larger than 4mm on kidney, ureter, and bladder radiograph (X-ray KUB) and ultrasonography kidney, ureter, and bladder (USG KUB)

performed at 4 weeks.

Categorical variables were reported as number and percentage; continuous variables were reported as mean ± standard deviation (SD) or median with interquartile range (IQR), as appropriate. Statistical analysis was performed using SPSS version 23.0 (IBM Corp., Chicago, IL, USA) with statistical significance set at $p < 0.05$.

RESULTS

During the study period 202 were planned for RIRS during the study period of which 76 were excluded for not meeting the inclusion criteria; FANS could not be negotiated beyond vesico-ureteric junction in 18 patients and there was failure to negotiate pelvi-ureteric junction in 33 patients. Successful FANS placement to the kidney was achieved in 151 (74.75%) of planned cases. FANS could be navigated to desired calyx in 193 (95.53%) of cases after successful negotiation into the kidney. In 35 (27.77%) stones were present in lower pole and median stone volume was 486.2 mm³ (Table 1).

Table 1. Demographic and stone characteristics (N=126).

Variables	n(%)	Median(IQR)
Age in years		
Mean±SD	43.4±13.07	
Gender		
Male	71(56.35)	-
Female	55(43.65)	-
Laterality		
Left	67(53.17)	-
Right	59(46.83)	-
Stone location		
PUJ	29(23.01)	-
Pelvis	22(17.46)	-
Upper pole	14(11.11)	-
Inter pole	16(12.69)	-
Lower pole	35(27.77)	-
Multiple	10(7.93)	-
Stone size (mm),	-	14.30 (7–24)
Stone volume (mm ³)	-	486.20 (193–2021.70)
Hounsfield Units,	-	927.60 (631–1532)
Preoperative stenting	31(24.60)	-

SD: Standard Deviation; IQR: interquartile range; PUJ: pelvi-ureteric junction.

Median operative duration was 43.6 minutes, and median active suction duration following lithotripsy was 12.6 minutes. Stone relocation was required in 4 cases of LP stones due to difficult lithotripsy.

Grade I ureteric injury occurred in 10 (7.93%), and grade II injury occurred in 4 (3.17%) patients, with no major grades (III and above) of ureteric injury documented in any patients. All instances of ureteric injuries occurred in patients who were not pre-stented, with all cases managed successfully with DJ

stenting alone. Post-operative fever was recorded in 8 patients (6.34%). No cases of uro-sepsis were documented in any patient. There were three readmissions; two for febrile episodes and one

for subcapsular haematoma presenting with flank pain. All the cases were managed conservatively (Table 2).

Table 2. Operative and post-operative characteristics (N=126).

Variables	n(%)	Median(IQR)
Operative duration (min)	-	43.6(29–73)
Stone relocation	4(3.17)	-
Laser Energy		
Ho:YAG	41	-
TFL	85	-
Total energy (J)	-	9,500(2,000–88,000)
Lasing duration (min)	-	19.4(4–37)
Energy consumption (J/mm ³)	-	21.1(14.8–36.4)
Laser ablation speed (mm ³ /s)	-	0.6(0.4–1.2)
Active suction duration (min)	-	12.6(5–23)
Exit strategy: DJ stent placed	98(77.77)	-
Ureteric injury (Traxer grades)		
Grade I	10(7.93)	-
Grade II	4(3.17)	-
Infectious complications		
Fever	8(6.34)	-
Culture-positive UTI	3(2.38)	-
Urosepsis	0(0)	-
Clavien–Dindo complications		
Grade I	14(11.11)	-
Grade II	3(2.38)	-
Grade IIIa	1(0.79)	-
Median hospital stays (days)	-	1.8(1–3)
Readmissions	3(2.38)	-
Auxiliary Procedure	0(0)	-
Stone-free rate	123 (97.61)	-

IQR: Interquartile Range; Ho:YAG: Holmium:Yttrium-Aluminum-Garnet; TFL: Thulium Fiber Laser DJ Double-J, UTI urinary tract infection.

The SFR at 4 weeks was 97.61%. In rest of the cases, patients were not symptomatic. No auxiliary procedure was required during the study period in any patients. On evaluating potential factors that could affect SFR, stone volume of less than <1000 mm³ had higher SFR (98.86% for volume <1000 mm³ vs. 94.73% for volume ≥1000 mm³). Similarly, stone location, stone density, pre-stenting, operative duration, suction duration, and laser type had similar SFR (Table 3).

DISCUSSION

FANS, with its ability to negotiate the desired calyx, facilitates lithotripsy with simultaneous dust and fragment removal, thus resulting in a high immediate SFR.^{16,17} Meta-analyses have consistently shown that this high immediate SFR translates to a high overall SFR.^{18,19}

However, scepticism exists regarding the omission of pre-stenting, particularly when access to the desired calyx is critical.²⁰ In this study, successful FANS placement in the kidney was achieved in 74.8% of cases, with the majority being not pre-stented (75.4%). Recent studies have also shown similar high rates of successful FANS placement without pre-stenting,

which implies that pre-stenting is not mandatory with FANS.^{21,22} Similarly, we found that FANS was able to access the desired calyces in 96% of cases, which suggests that, with appropriate technique, the target calyx can be reached. Recent literature reported that when the “sheath advancement” technique is employed, as in our study, the ureteroscope can be deflected at a higher angle compared to the “scope deflection at tip” technique, which results in the ability to access even difficult LP calyces.¹² With the use of FANS, the reported rates of stone relocation for LP stones are 7–13%, which is low compared to non-FANS studies of 14–21%.^{7,8,23} Stone relocation for LP stones was required in 3.17% of cases in our study. A study by Shrestha et al. found that stone relocation did not result in a higher SFR in LP stones when FANS was used ($p=0.4$).⁸ As the need for stone relocation decreases with the use of FANS, the operative challenges associated with basketing and the additional cost of accessories may also decrease.¹¹

The existing literature demonstrates that operative duration with the use of FANS is comparable to that with traditional access sheaths.^{9,24,25} Factors affecting operative duration in these studies were shown to be stone size, lithotripsy techniques, surgeons’ experience, and sheath size rather than the type of sheath. The

operative duration of 43.6 minutes in our study is comparable to that reported in other studies with similar stone burden.^{1,26} Despite taking additional time for active suction, the ability to passively aspirate dust during lithotripsy, leading to the negation of the “snow-storm effect” and avoidance of procedural breaks, may have contributed to a comparable operative duration with conventional access sheaths.^{27,28}

Table 3. Analysis of factors affecting stone-free rate (N=126).

Variables	n(%)	SFR (%)
Stone volume (mm ³)		
< 1000	88(69.84)	87(98.86)
≥ 1000	38(30.16)	36(94.73)
Hounsfield units		
< 1000	73(54.94)	71(97.26)
≥ 1000	53(45.06)	52(98.11)
Stone location		
Non-lower pole	91(72.22)	89(97.80)
Lower pole	35(27.78)	34(97.14)
Prestenting		
Yes	31(24.60)	30(96.77)
No	95(75.40)	93(97.89)
Operative Duration		
<60mins	29(23.02)	28(96.55)
>60mins	97(76.98)	95(97.93)
Laser		
Ho:YAG laser	41(32.54)	40(97.56)
TFL	85(67.46)	83(97.64)

SFR: stone-free rate; Ho:YAG: Holmium:Yttrium-Aluminum-Garnet; TFL: Thulium Fiber Laser.

One of the concerns with the use of conventional access sheaths is the rise in intra-renal pressure (IRP) due to the inability to control outflow. Increasing IRP has been implicated as one of the factors associated with infectious complications, including uro-sepsis.²⁹ The reported incidence of uro-sepsis with conventional access sheaths ranges from 0.5% to 11.1%.³⁰ The use of suction can lower IRP, leading to a reduction in infectious complications.³¹ Current literature supports the use of FANS to reduce infectious complications, with most studies showing no incidence of uro-sepsis when FANS is used.^{19,32} In our study, post-operative fever was observed in only 6.34% of cases, with no cases of uro-sepsis.

A multicentre randomized controlled study comparing FANS with conventional access sheaths found a higher incidence of ureteric injury with the use of conventional access sheaths.¹ Another study evaluating the influence of pre-stenting in FANS found a higher incidence of Traxer grade I injury among patients who were not pre-stented.²¹ We also found a higher incidence of only low-grade ureteric injuries in patients who were not pre-stented. These findings suggest that mucosal injuries can occur with the use of FANS, particularly when patients are not pre-stented. However, major grades of ureteric injuries are uncommon with proper placement of FANS.

A major drawback of conventional access sheaths is the inability

to retrieve residual fragments, potentially affecting SFR. Studies comparing FANS with conventional access sheaths have consistently demonstrated that SFR is significantly higher when FANS is used, with reduced re-intervention rates.^{1,33} In the current study, SFR was 97.61%, with re-intervention not required in any cases. With the use of conventional access sheaths, SFR depends on multiple factors beyond stone burden, such as stone location, laser type, and lithotripsy technique.^{34–36} Studies have shown that factors found to affect SFR with conventional access sheaths, such as laser type and lithotripsy technique, may not affect SFR when FANS is used.^{8,21,37} Similarly, in our study, stone volume of more than 1000 mm³ was associated with a lower SFR. SFR was also comparable between LP and non-LP stones. Current literature evaluating the outcomes of FANS in LP stones is limited. A multicentre study showed SFR to be independent of stone location when FANS was used (LP 96.6% vs. non-LP 98.4%, $p = 0.6$).⁸ The two trials, which are in the early phase of recruitment, aim to assess the utility of FANS for LP stones, the results of which would clarify the role of FANS in LP stones.^{38,39}

Our study has certain limitations. NCCT KUB is the preferred imaging modality for assessing SFR post-operatively. However, plain radiography and ultrasonography may serve as the initial imaging approaches, with NCCT KUB reserved for patients with residual fragments identified on X-ray KUB or USG, which potentially reduces the cost as well as radiation exposure.⁷ Also, long-term outcomes were not assessed in this study; therefore, concerns regarding the delayed occurrence of ureteric stricture cannot be fully addressed. However, this study can serve as a foundation for conducting a prospective comparative study between conventional and FANS ureteral access sheaths in the future for better identification of the effectiveness and safety of FANS and to appropriately identify the factors affecting the overall outcomes of FANS in RIRS.

CONCLUSION

Use of FANS during RIRS is associated with high SFR with low infectious complications. Only stone volume was shown to affect SFR when FANS is used, while factors such as stone location and laser type did not affect SFR. Successful negotiation of 10/12 Fr FANS inside the kidney could be achieved in about three fourth of patients without pre-stenting.

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