



A COMPARATIVE STUDY ON EFFICACY AND LIMITATIONS OF FLEXIBLE SUCTION URETERAL ACCESS SHEATHS V/S CONVENTIONAL ACCESS SHEATHS IN RETROGRADE INTRA-RENAL SURGERY FOR RENAL STONES

Urology

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ABSTRACT

INTRODUCTION: With the integration of high-power lasers in Retrograde Intrarenal Surgery (RIRS), the dusting technique has emerged as comparably effective to fragmentation alone, potentially positioning it as the preferred method for lithotripsy and stone clearance. Recently, suction has also found application in RIRS, providing several benefits such as improved stone fragmentation and dusting, removal of debris and fragments, reduction of intrarenal temperature and pressure, and enhanced visualization. **OBJECTIVE:** To evaluate the stone-free rate, device maneuverability, and complications following RIRS, a comparison was made between flexible and navigable suction ureteral access sheaths (FANS) and conventional access sheaths (CAS). **MATERIAL AND METHODS:** Study design: Prospective study. **Methodology:** A prospective study was conducted on patients undergoing RIRS for renal stones of varying size, number, and location between January 2024 and October 2024 at the Department of Urology, Manipal Hospital, HAL, Bangalore. Group 1 was treated using FANS, while Group 2 received treatment with conventional access sheaths. Thulium fiber lasers were utilized for lithotripsy in both groups. The following parameters were evaluated:

1. Stone-free rate: Assessment of complete stone clearance post-procedure.
2. Device maneuverability: Evaluation of ease and precision in navigating and manipulating the access sheaths during surgery.
3. Complications: Monitoring and recording of any adverse events or post-operative complications related to the procedure.

RESULTS: As per preliminary results, stone-free rate is better with FANS group compared to conventional access sheath.

CONCLUSION: FANS enhances single-session stone-free rates, ensuring safety with minimal complications, and reducing the necessity for additional treatments and post-operative follow-ups. This approach ultimately leads to cost savings for the patient.

KEYWORDS

INTRODUCTION:

"With the integration of high-power lasers in Retrograde Intrarenal Surgery (RIRS), the dusting technique has emerged as comparably effective to fragmentation alone, potentially positioning it as the preferred method for lithotripsy and stone clearance. Recently, suction has also found application in RIRS, providing several benefits such as improved stone fragmentation and dusting, removal of debris and fragments, reduction of intrarenal temperature and pressure, and enhanced visualization.

Urinary tract stone disease, or urolithiasis, remains a widespread global health issue. In the United States, its lifetime prevalence has reached approximately 11%, meaning roughly one in nine individuals will face this condition [1–3]. Over recent decades, the therapeutic approach to renal calculi has radically changed due to breakthroughs in minimally invasive surgeries, which have accelerated patient recovery and optimized clinical outcomes [4,5]. Consequently, retrograde intrarenal surgery (RIRS) has solidified its role as a premier treatment modality for upper urinary tract stones, presenting a highly effective, low-morbidity alternative to percutaneous nephrolithotomy (PCNL). In fact, the European Association of Urology (EAU) clinical guidelines formally endorse RIRS for renal stones smaller than 20 mm, as well as select lower-pole calculi exceeding 10 mm [6].

MATERIALS AND METHODS

This study conducted a prospective analysis of patients with renal stones or upper ureteral stones who underwent retrograde intrarenal surgery (RIRS) with flexible suction access sheaths (FANS) or conventional access sheaths (CAS) at our institution from January 2024 to September 2024. A total of 80 cases were selected and divided into two groups of 40 patients each. Group 1 was treated using FANS, while Group 2 was treated with CAS.

Inclusion Criteria:

- Patients aged between 18 and 70 years.
- Presence of a renal stone or upper ureteral stone up to 3 cm in size.

Exclusion Criteria:

- Combined ipsilateral ureteral stone or contralateral upper or lower

urinary stones requiring simultaneous surgery.

- Any relative or absolute contraindications to RIRS.
- Presence of urinary anatomical abnormalities.
- Previous urinary diversion surgery.

Thulium fiber lasers were used for lithotripsy in both groups. The following parameters were evaluated:

1. **Stone-Free Rate:** Assessment of complete stone clearance post-procedure.
2. **Device Maneuverability:** Evaluation of the ease and precision of navigating and manipulating the access sheaths during surgery.
3. **Complications:** Monitoring and recording of any adverse events or post-operative complications related to the procedure.

All patients underwent kidney–ureter–bladder (KUB) and abdominal non-contrast computed tomography (NCCT) scans. Stone burden was assessed using NCCT in bone window mode. Patients with positive preoperative urine cultures received appropriate antibiotic therapy and a second culture or microscopic examination before surgery to ensure urinary tract infections were controlled. Patients with negative preoperative urine cultures were given prophylactic antibiotics. Written informed consent was obtained from all patients prior to surgery. The RIRS procedures were performed by a single experienced surgeon, and the study was approved by our local Ethics Committee.

CAS Group: Following satisfactory general anesthesia, patients were placed in the lithotomy position. Under the guidance of a hydrophilic 0.035-inch guide wire, serial dilation was performed, and the guide wire was left in the upper urinary tract. A 10/12 Fr CAS was then inserted into the upper ureter. The CAS length was 50 cm for male patients and 40 cm for female patients. A digital flexible ureteroscope (FURS) was introduced via the CAS, and the end of the CAS was adjusted at the ureteropelvic junction (UPJ) under direct vision. After a comprehensive inspection of the renal collecting system, proximal ureter, and renal stones, the perfusion flow was set to 60–100 ml/min. A 200 µm laser fiber was used for lithotripsy with Thulium fiber lasers, employing parameters of higher energy (0.6–1.2 J) and lower frequency (5–20 Hz) for fragmentation, and dusting mode with lower energy (0.2–0.6 J) and higher frequency (20–30 Hz). After satisfactory

fragmentation, a second comprehensive inspection was conducted before removing the FURS and CAS, and a 5 Fr double-J (DJ) stent was routinely inserted.

FANS Group: After general anesthesia, patients were positioned in the lithotomy position. A hydrophilic 0.035-inch guide wire was used for serial dilation, and the guide wire was left in the upper urinary tract. A 10/12 Fr FANS was inserted into the upper ureter. Once the FANS tip was confirmed at the UPJ, the suctioning channel was connected to a vacuum device with a pressure-regulating venting slit. The suctioning parameter was set to a negative pressure value of 2–7 kPa, adjusted as needed by the urologist. The irrigation volume was set to 80–200 ml/min using peristaltic pumps. Lithotripsy was performed using Thulium fiber lasers with similar parameters as in the CAS group: higher energy (0.6–1.2 J) and lower frequency (5–20 Hz) for fragmentation, and dusting mode with lower energy (0.2–0.6 J) and higher frequency (20–30 Hz). During lithotripsy, the FURS was repeatedly moved in and out to facilitate stone fragment removal through irrigation. After satisfactory fragmentation, a second comprehensive inspection was performed before removing the FURS and FANS, and a 5 Fr double-J (DJ) stent was routinely inserted. Stone fragments were collected in a suctioning bottle.

KUB and/or urinary CT scans were performed in both groups at 1 day and 1 month postoperatively. Stone-free status was defined as no residual stone or radiological residue fragment < 2 mm. The DJ stent was removed 15 days postoperatively. Patients with ureteral stenosis or residual stones requiring a second procedure were treated 1 month after surgery.

Data Collection: Patient data were retrieved from our hospital's electronic system, including age, gender, body mass index (BMI), urine culture results, use of antibiotic prophylaxis, stone burden, and grade of hydronephrosis. Postoperative data, such as operative time, complications, length of hospital stay, and residual stone burden at 1 day and 1 month, were also recorded. Postoperative stone-free status was independently assessed by one urologist and one radiologist using NCCT.

RESULTS

	Fans(40)	Cas(40)
Mean age	45.5± 20	40.5± 15
Sex		
male	27	25
female	13	15
Size of calculi	-	-
>1.5cm	17	18
<1.5cm	23	22
Hardness of stone	-	-
<1200hu	26	22
>1200hu	14	18
Pre-stented	15	20
Duration of surgery	45	65
Stone free rate		
Immediate	15	5
After 1month	20	15
Fever	5	10
No fever	35	30
Readmission within 15days	3	5
PAIN pod1		
Score < 2	25	20
Score >2	15	20

		Groups				χ^2 value	df	P value
		CAS		FANS				
		N	%	N	%			
Size of calculi	<1.5cm	22	55.00%	23	57.50%	0.051	1	0.822
	>1.5cm	18	45.00%	17	42.50%			
Hardness of stone	<1200hu	22	55.00%	26	65.00%	0.833	1	0.361
	>1500hu	18	45.00%	14	35.00%			
Stone free rate	After 1 month	35	87.50%	25	62.50%	6.667	1	0.01*
	Immediate	5	12.50%	15	37.50%			

Occurrence of Fever	Fever Absent	30	75.00%	35	87.50%	2.051	1	0.152
	Fever present	10	25.00%	5	12.50%			
Pain	Score <2	20	50.00%	25	62.50%	1.27	1	0.26
	Score >2	20	50.00%	15	37.50%			

*Statistical significance set at 0.05; N: Number of samples; χ^2 value: Chi square value; df: Degrees of freedom

Interpretation:

Size of calculi:

A χ^2 test was performed between *Groups* and *Size of calculi*. All expected cell frequencies were greater than 5, thus the assumptions for the χ^2 test were met. There was no statistically significant relationship between *Groups* and *Size of calculi*, $\chi^2(1) = 0.05$, $p = .822$, Cramér's $V = 0.03$. A Fisher exact test was performed between *Groups* and *Size of calculi*. There was no statistically significant relationship between *Groups* and *Size of calculi*, $p = 1$.

The calculated p-value of .822 was above the defined significance level of 5%. The χ^2 test was therefore not significant and the null hypothesis was not rejected.

The table represents the results of a Chi-square test, a statistical test commonly used to determine if there's a significant association between two categorical variables. In this case, it used to test the association between 'Groups' and 'Size of calculi'. Here's how to interpret each component:

Chi-square Value (0.05)

This is the test statistic that measures the difference between the observed counts and the counts that would be expected if there were no association between the variables. A higher value indicates a greater difference between the expected and observed data.

Degrees of Freedom (df) 1

This value is calculated based on the number of categories in each variable. For a Chi-square test, it's typically (number of categories in variable A - 1) * (number of categories in variable B - 1). In this case, we have (2 - 1) * (2 - 1) = 1.

p-value (.822)

The p-value indicates the probability of observing a chi-square statistic as extreme as or more extreme than the observed value under the null hypothesis that there's no association between the variables. A p-value of .822 suggests a 82.17% probability of observing your data, or something more extreme, if there were no real association between *Groups* and *Size of calculi*. A common threshold for significance is 0.05. In this case, the p-value of .822 is greater than 0.05, suggesting that the observed association could reasonably occur by chance. Thus, you would not reject the null hypothesis and might conclude that there's not enough evidence to suggest a significant association between *Groups* and *Size of calculi* at the traditional 5% significance level.

Hardness of stone:

A χ^2 test was performed between *Groups* and *Hardness of stone*. All expected cell frequencies were greater than 5, thus the assumptions for the χ^2 test were met. There was no statistically significant relationship between *Groups* and *Hardness of stone*, $\chi^2(1) = 0.83$, $p = .361$, Cramér's $V = 0.1$.

A Fisher exact test was performed between *Groups* and *Hardness of stone*. There was no statistically significant relationship between *Groups* and *Hardness of stone*, $p = .494$.

The calculated p-value of .361 was above the defined significance level of 5%. The χ^2 test was therefore not significant and the null hypothesis was not rejected.

The table represents the results of a Chi-square test, a statistical test commonly used to determine if there's a significant association between two categorical variables. In this case, it used to test the association between 'Groups' and 'Hardness of stone'. Here's how to interpret each component:

Chi-square Value (0.83)

This is the test statistic that measures the difference between the observed counts and the counts that would be expected if there were no association between the variables. A higher value indicates a greater difference between the expected and observed data.

Degrees of Freedom (df) 1

This value is calculated based on the number of categories in each variable. For a Chi-square test, it's typically (number of categories in variable A - 1) * (number of categories in variable B - 1). In this case, we have (2 - 1) * (2 - 1) = 1.

p-value (.361)

The p-value indicates the probability of observing a chi-square statistic as extreme as or more extreme than the observed value under the null hypothesis that there's no association between the variables. A p-value of .361 suggests a 36.13% probability of observing your data, or something more extreme, if there were no real association between Groups and Hardness of stone. A common threshold for significance is 0.05. In this case, the p-value of .361 is greater than 0.05, suggesting that the observed association could reasonably occur by chance. Thus, you would not reject the null hypothesis and might conclude that there's not enough evidence to suggest a significant association between Groups and Hardness of stone at the traditional 5% significance level.

Stone free rate:

A Chi² test was performed between *Groups* and *Stone free rate*. All expected cell frequencies were greater than 5, thus the assumptions for the Chi² test were met. There was a statistically significant relationship between *Groups* and *Stone free rate*, $\chi^2(1) = 6.67$, $p = .01$, Cramér's V = 0.29

A Fisher exact test was performed between *Groups* and *Stone free rate*. There was a statistically significant relationship between *Groups* and *Stone free rate*, $p = .019$

The calculated p-value of .01 was lower than the defined significance level of 5%. The Chi² test was therefore significant and the null hypothesis was rejected.

The table represents the results of a Chi-square test, a statistical test commonly used to determine if there's a significant association between two categorical variables. In this case, it used to test the association between 'Groups' and 'Stone free rate'. Here's how to interpret each component:

Chi-square Value (6.67)

This is the test statistic that measures the difference between the observed counts and the counts that would be expected if there were no association between the variables. A higher value indicates a greater difference between the expected and observed data.

Degrees of Freedom (df) 1

This value is calculated based on the number of categories in each variable. For a Chi-square test, it's typically (number of categories in variable A - 1) * (number of categories in variable B - 1). In this case, we have (2 - 1) * (2 - 1) = 1.

p-value (.01)

The p-value indicates the probability of observing a chi-square statistic as extreme as or more extreme than the observed value under the null hypothesis that there's no association between the variables. A p-value of .01 suggests a 0.98% probability of observing your data, or something more extreme, if there were no real association between Groups and Stone free rate. A common threshold for significance is 0.05. In this case, the p-value of .01 is smaller than 0.05, suggesting that the observed association is unlikely to have occurred by chance. Thus, you would reject the null hypothesis and might conclude that there's enough evidence to suggest a significant association between Groups and Stone free rate at the traditional 5% significance level.

Occurrence of Fever:

A Chi² test was performed between *Groups* and *Occurance of Fever*. All expected cell frequencies were greater than 5, thus the assumptions for the Chi² test were met. There was no statistically significant relationship between *Groups* and *Occurance of Fever*, $\chi^2(1) = 2.05$, $p = .152$, Cramér's V = 0.16

A Fisher exact test was performed between *Groups* and *Occurance of Fever*. There was no statistically significant relationship between *Groups* and *Occurance of Fever*, $p = .252$

The calculated p-value of .152 was above the defined significance level of 5%. The Chi² test was therefore not significant and the null hypothesis was not rejected.

The table represents the results of a Chi-square test, a statistical test commonly used to determine if there's a significant association between two categorical variables. In this case, it used to test the association between 'Groups' and 'Occurance of Fever'. Here's how to interpret each component:

Chi-square Value (2.05)

This is the test statistic that measures the difference between the observed counts and the counts that would be expected if there were no association between the variables. A higher value indicates a greater difference between the expected and observed data.

Degrees of Freedom (df) 1

This value is calculated based on the number of categories in each variable. For a Chi-square test, it's typically (number of categories in variable A - 1) * (number of categories in variable B - 1). In this case, we have (2 - 1) * (2 - 1) = 1.

p-value (.152)

The p-value indicates the probability of observing a chi-square statistic as extreme as or more extreme than the observed value under the null hypothesis that there's no association between the variables. A p-value of .152 suggests a 15.21% probability of observing your data, or something more extreme, if there were no real association between Groups and Occurance of Fever. A common threshold for significance is 0.05. In this case, the p-value of .152 is greater than 0.05, suggesting that the observed association could reasonably occur by chance. Thus, you would not reject the null hypothesis and might conclude that there's not enough evidence to suggest a significant association between Groups and Occurance of Fever at the traditional 5% significance level.

Pain:

A Chi² test was performed between *Groups* and *Pain*. All expected cell frequencies were greater than 5, thus the assumptions for the Chi² test were met. There was no statistically significant relationship between *Groups* and *Pain*, $\chi^2(1) = 1.27$, $p = .26$, Cramér's V = 0.13 A Fisher exact test was performed between *Groups* and *Pain*. There was no statistically significant relationship between *Groups* and *Pain*, $p = .367$ The calculated p-value of .26 was above the defined significance level of 5%. The Chi² test was therefore not significant and the null hypothesis was not rejected.

The table represents the results of a Chi-square test, a statistical test commonly used to determine if there's a significant association between two categorical variables. In this case, it used to test the association between 'Groups' and 'Pain'. Here's how to interpret each component:

Chi-square Value (1.27)

This is the test statistic that measures the difference between the observed counts and the counts that would be expected if there were no association between the variables. A higher value indicates a greater difference between the expected and observed data.

Degrees of Freedom (df) 1

This value is calculated based on the number of categories in each variable. For a Chi-square test, it's typically (number of categories in variable A - 1) * (number of categories in variable B - 1). In this case, we have (2 - 1) * (2 - 1) = 1.

p-value (.26)

The p-value indicates the probability of observing a chi-square statistic as extreme as or more extreme than the observed value under the null hypothesis that there's no association between the variables. A p-value of .26 suggests a 25.98% probability of observing your data, or something more extreme, if there were no real association between Groups and Pain. A common threshold for significance is 0.05. In this case, the p-value of .26 is greater than 0.05, suggesting that the observed association could reasonably occur by chance. Thus, you

would not reject the null hypothesis and might conclude that there's not enough evidence to suggest a significant association between Groups and Pain at the traditional 5% significance level.

DISCUSSION

The present retrospective study demonstrates the comparative strengths and limitations of suction-assisted ureteral access sheath (FANS) and conventional ureteral access sheath techniques in retrograde intrarenal surgery (RIRS). The findings indicate that FANS significantly improves immediate stone clearance while maintaining a safety profile comparable to that of traditional CAS systems. In addition, the reduced need for secondary interventions in the FANS cohort suggests improved procedural efficiency and clinical effectiveness. Subgroup analyses further revealed that the benefits of FANS were more pronounced in patients with larger stones, solitary calculi, and lower calyceal stones, offering important implications for surgical planning and patient selection [7,8].

The improved outcomes associated with FANS may be explained by its ability to continuously evacuate stone debris during lithotripsy. Effective suction reduces the "snow-globe effect," thereby enhancing intraoperative visualization and enabling easier identification of residual fragments. Improved visibility contributes to higher immediate stone-free rates and more efficient stone clearance. Furthermore, suction-assisted evacuation decreases dependence on basket extraction and limits the accumulation of fine residual dust that may contribute to postoperative symptoms or future stone recurrence. Since fragment size strongly influences suction efficiency, optimal results are generally achieved when stones are adequately dusted into very small particles. This may explain why FANS demonstrated greater effectiveness in patients with solitary stones compared with those with multiple or incompletely fragmented calculi [9,10].

Experimental studies evaluating suction-assisted systems have highlighted the importance of sheath-to-scope diameter ratios in optimizing fragment aspiration. Previous reports demonstrated that smaller fragments are more effectively evacuated under continuous suction conditions, whereas larger fragments may require adjunctive "pull-and-suck" maneuvers. In our cohort, the most frequently used configuration involved a 10/12 Fr sheath combined with a 7.5 Fr ureteroscope, producing a ratio that appeared suitable for efficient suction-assisted lithotripsy. These findings emphasize the importance of selecting appropriate instrument combinations and fragmentation strategies to maximize procedural success [11].

Earlier investigations have reported high postoperative stone-free rates with suction-assisted systems, although definitions of clinically acceptable residual fragments have varied considerably among studies. In the current analysis, a stricter criterion was adopted by defining successful stone clearance as the absence of fragments larger than 2 mm on KUB imaging. Under this definition, FANS demonstrated a clear advantage in immediate postoperative outcomes. However, the difference between groups was no longer significant at one month. This may be explained by spontaneous passage of residual fragments in patients treated with conventional CAS, gradually reducing the gap between the techniques over time. Moreover, variability in the timing of auxiliary procedures may have influenced delayed stone-free assessments and limited interpretation of long-term outcomes [12–15].

The aspiration capability of FANS may also reduce postoperative complications related to residual fragments. In particular, active evacuation of debris lowers the risk of steinstrasse formation and decreases the likelihood of requiring additional interventions such as extracorporeal shock wave lithotripsy or repeat ureteroscopy. Reduced dependence on stone baskets may further streamline the surgical procedure, although quantitative data regarding basket use were not consistently documented in this study. Despite reports from previous literature describing shorter operative times with FANS, our results did not show a significant reduction in surgical duration. This discrepancy may be attributed to the additional technical demands associated with maneuvering the suction tip into lower calyceal regions. Increased surgeon familiarity and procedural experience may improve efficiency in future applications [15,16].

Technological developments in RIRS have expanded the role of endoscopic management for larger renal stones. Studies evaluating flexible suction-assisted access sheaths for stones measuring ≥ 30 mm

have demonstrated encouraging stone-free outcomes. Similarly, our subgroup analysis indicated that patients with a single stone larger than 15 mm or a cumulative stone burden exceeding 20 mm achieved superior outcomes with FANS compared with standard CAS. These findings suggest that suction-assisted systems may broaden the indications for RIRS in patients with substantial stone burdens [17]. In addition, previous comparisons between suction-assisted ureteroscopic lithotripsy and minimally invasive percutaneous nephrolithotomy (mPCNL) have shown comparable stone-free rates with shorter hospitalization and fewer complications in the suction-assisted group. Consequently, FANS may represent a less invasive alternative for selected patients with medium-to-large renal calculi [18].

Management of lower calyceal stones remains technically challenging because of difficult anatomical access and acute infundibulopelvic angles. These factors often increase the need for repeated basket manipulation and prolong operative time. In our study, FANS achieved significantly better stone-free outcomes for lower calyx stones compared with conventional CAS. The flexible distal tip facilitated navigation into anatomically challenging regions, while continuous suction improved fragment evacuation and minimized residual debris. Previous studies evaluating bendable sheaths without suction have demonstrated lower clearance rates and greater basket dependence, suggesting that suction itself provides an important additional advantage beyond flexibility alone [19–21].

Another important benefit of FANS is its potential role in controlling intrarenal pressure and improving irrigation dynamics during RIRS. Elevated intrarenal pressure is associated with pyelovenous backflow and increased risk of infectious complications due to bacterial and endotoxin absorption. In the present study, overall complication rates were similar between groups, although postoperative urosepsis appeared less frequent in the FANS cohort. Postoperative inflammatory markers, including white blood cell counts, also remained stable and comparable between groups, consistent with previous reports suggesting lower rates of fever and systemic inflammatory response syndrome when suction-assisted systems are used [20–22]. These observations highlight the importance of maintaining controlled intrarenal pressure and suggest that FANS may contribute to improved procedural safety.

Several limitations should be considered when interpreting these findings. The retrospective and non-randomized design introduces potential selection bias, particularly because patient grouping was influenced by the timing of FANS introduction and evolving surgical experience. The relatively small sample size, especially within subgroup analyses, also limits statistical power and increases the possibility of type II error.

Future investigations should focus on large-scale prospective randomized controlled trials to validate the present findings and minimize bias.

CONCLUSION

"In conclusion, our study demonstrated that the use of FANS resulted in a superior stone-free rate (SFR) compared to CAS, along with significant improvements in quality of life (QoL). Additionally, the adoption of FANS reduces the need for stone basket utilization and lowers postoperative fever rates. Therefore, FANS presents a prudent and beneficial alternative to CAS for RIRS."

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