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Optimizing Flexible Ureteroscopic Surgery for Renal Stones Using Bendable Access Sheath and Suction: An Institutional Experience

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ABSTRACT
This prospective study examines the efficacy and safety of flexible ureteroscopic surgery (fURS) for renal stones, employing a novel bendable ureteral access sheath with integrated suction. Conducted between February and August 2024 at Mamata Hospital, Khammam, the study enrolled 50 patients, consisting of 34 males and 16 females with a median age of 48 years. Prior to surgery, all patients underwent diagnostic CT imaging and had double-J stents placed two weeks before the procedure. The surgeries were performed using a 10/12 F bendable ureteral access sheath designed to improve access and facilitate stone removal. Key findings reveal a remarkable stone-free rate of 94% at 3 weeks post-surgery, underscoring the effectiveness of the bendable sheath with suction in enhancing surgical outcomes. The study also highlights the importance of technological advancements in fURS, which contributed to reduced complications and improved surgical efficiency. However, the research acknowledges challenges such as the need for further refinement of the flexible access sheath and limitations in current suction models. These limitations suggest that while the technology is promising, it is not without its areas for improvement. In conclusion, this study supports the integration of bendable access sheaths with suction as a valuable innovation in renal stone management, offering the potential to set new standards in achieving high stone-free rates with minimal complications. These findings have significant clinical implications, suggesting that continued innovation in fURS technology could lead to improved patient outcomes and a reduction in the need for reintervention.

INTRODUCTION

Over recent years, retrograde intrarenal surgery (RIRS) has undergone significant advancements, primarily driven by technological innovations aimed at improving patient outcomes in the treatment of renal stones[1]. RIRS has become a favored approach for managing stones up to 20mm in size, offering a minimally invasive option compared to other treatments like percutaneous nephrolithotomy (PCNL) and extracorporeal shock wave lithotripsy (ESWL)[2]. However, despite its increasing use, RIRS still faces challenges, notably the presence of residual fragments (RFs) and a risk of complications such as postoperative infections and sepsis[3]. Residual stone fragments remain a significant concern after RIRS, as they can lead to recurrence and necessitate further procedures. Recent data from a large multicenter registry revealed that 21.7% of patients undergoing RIRS had residual fragments and more than half of these patients required additional intervention[4]. This highlights the limitations of current techniques in achieving complete stone clearance, emphasizing the need for continued advancements to improve clinical outcomes and reduce the incidence of residual fragments and other complications. Patients with RFs are at risk of stone regrowth, recurrent urinary tract infections and persistent discomfort, which may overshadow the benefits of minimally invasive surgery[5]. To address these ongoing challenges, there has been a growing focus on new technologies designed to enhance the effectiveness of RIRS. One promising development is the use of suction devices, such as vacuum-aided sheaths and ureteral access sheaths (UAS), which are designed to improve stone-free rates (SFR) by aiding in the removal of stone debris while simultaneously reducing intrarenal pressure and temperature during the procedure[6]. Lowering intrarenal pressure is critical, as it helps minimize the risk of fluid absorption, infection and sepsis, which are significant concerns during and after RIRS. These suction devices are showing potential not only in improving stone clearance but also in reducing the overall complication rate by providing better control over the surgical environment[7]. In addition to suction devices, flexible and navigable sheaths (FANS) have emerged as a novel approach to overcoming some of the limitations associated with traditional RIRS techniques. FANS are designed to provide greater flexibility and easier navigation within the kidney, allowing for better access to stones located in hard-to-reach areas of the renal calyces[8]. These sheaths may also help regulate intrarenal pressure and temperature, similar to suction devices, and their flexibility makes them more adaptable to complex renal anatomy. This innovation could potentially lead to higher stone-free rates and lower complication rates by improving both the surgeon's ability to reach and remove all stone fragments and by reducing the risks associated with elevated intra renal pressure during the procedure[9]. This study presents a prospective study aimed at evaluating the effectiveness of FANS in improving RIRS outcomes in adult patients with renal stones. By exploring the impact of this technology on stone-free rates, residual fragment rates and postoperative complications, the study seeks to determine whether FANS can set a new standard in endourological procedures. The findings may provide valuable insights into how technological advancements like FANS could enhance the safety, efficacy and overall success of RIRS for renal stone management.

MATERIALS and METHODS

This prospective, investigator-led study was conducted at the Urology Department of Mamata Hospital, Khammam, from February 2024 to August 2024. A total of 50 patients diagnosed with renal stones via computed tomography (CT) were included. All patients had double J (DJ) stents placed two weeks before the procedure and the surgeries were performed using a 10/12 F bendable ureteral access sheath with integrated suction capabilities. Approval from the institutional review board (IRB) was obtained and patient consent was secured for inclusion in an IRB-approved anonymized database.

Patient Selection and Exclusion Criteria: Inclusion criteria for the study were patients aged 18 years or older with normal renal anatomy, suitable for flexible ureteroscopy (fURS) with flexible and navigable suction ureteral access sheath (FANS). Patients with ureteral stones, abnormal renal anatomy, or insufficient data records were excluded. Only patients who were urine culture-negative preoperatively were included in the study. Patients on anticoagulant or antiplatelet therapy had their medication stopped five days before fURS, with resumption at the surgeon's discretion.

Baseline and Operative Characteristics: The study cohort comprised 34 males and 16 females, with a median age of 48 years. The median stone volume was 1100 mm^3, calculated using the ellipsoid formula (length×width × depth×p×0.167) and the median stone hardness was 900 Hounsfield units (HU). Stones were located in various positions within the kidneys, including the upper, mid and lower poles, as well as the renal pelvis. Surgical procedures were performed under general anesthesia in all 50 patients. All surgeries were conducted by a single surgeon using a thulium fiber laser and a reusable flexible ureteroscope. The thulium fiber laser settings were adjusted based on stone hardness: 1.5 joules of energy at 10Hz for stones with hardness greater than 1000 HU and 1 joule at 9Hz for stones less than 1000 HU. Stone fragmentation with suction was employed for 42

patients, while dusting with suction was used for 8 patients.

Intra Operative Observations and Complications: Intra operative assessments revealed mild blood oozing in 6 patients and ureteral mucosal injury in 1 patient. No cases of extravasation were noted in retrograde pyelograms. DJ stents were placed in 47 out of the 50 patients postoperatively; 3 patients were not stented. No significant intraoperative complications were recorded.

Postoperative Management and Follow-Up: Postoperatively, 8 patients developed fever and 5 patients experienced stent-related pain, but no patients developed hematuria beyond 24 hours. The median hospital stay was 1 day. Follow-up for residual stones was conducted 15 days after surgery using ultrasonography and X-ray KUB, revealing a 94% stone-free rate. Residual stones were identified in 3 patients: 2 had stones measuring 3mm and 1 had a 5 mm stone. No reinterventions were performed.

Statistical Analysis: Data analysis included standard statistical methods to evaluate patient demographics, stone characteristics, surgical outcomes and complications. Continuous variables were reported as medians and interquartile ranges (IQR), while categorical variables were presented as frequencies and proportions. The primary outcome was the stone-free status (SFS), assessed 15 days postoperatively. Statistical significance was determined with a p-value of <0.05.

RESULTS and DISCUSSIONS

The landscape of retrograde intrarenal surgery (RIRS) continues to evolve with advancements such as the introduction of suction-assisted flexible ureteral access sheaths. Our study provides valuable insights into the efficacy and safety of these innovations. Here, we integrate our findings with detailed tables that illustrate patient demographics, operative characteristics and outcome. Our patient cohort predominantly consisted of middle-aged individuals with a slight male predominance (68.0%). All patients were preemptively treated with antibiotics and prestented, ensuring optimal conditions for the procedure. The distribution of stone volumes and locations underscores the complexity of cases addressed. Most stones were $\leq$1500 mm³ (82.0%), with a significant number located in the renal pelvis (36.0%) and others distributed across various locations (Table 1). Our study utilized a standardized approach with general anesthesia and a single reusable scope across all cases. The use of a 10/12 F ASTER sheath and Thulium fiber laser facilitated efficient stone fragmentation and dusting. Notably, there was no need for sheath replacement due to malfunction, and the suction mechanism performed effectively in all cases. The median operative time of 55 minutes is consistent with reports from similar studies, highlighting the procedure's efficiency (Table 2).

Complications were generally minimal, with no cases abandoned or requiring blood transfusions. Intraoperative bleeding was noted in 12% of cases but did not impede the surgical process. A small number of patients experienced fever or mild loin pain postoperatively, with the median hospital stay being 1 day. Importantly, there were no cases of sepsis or persistent hematuria, and no readmissions within 30 days, reflecting a favorable safety profile (Table 3). Traditional RIRS techniques often struggle with residual fragments (RFs), particularly in the lower pole of the kidney, leading to higher reintervention rates. However, our study suggests that the combination of active suction and flexible sheath maneuverability can mitigate this challenge by effectively evacuating stone debris and minimizing RFs, as shown by the absence of reintervention in our patient cohort (Table 4). The table compares the effectiveness of suction-assisted flexible ureteroscopy (FURS) with traditional FURS in terms of residual fragments and reintervention rates after retrograde intrarenal surgery (RIRS) for renal stones. Suction-assisted FURS shows a significant improvement, with only 6% of patients having residual fragments after the procedure and none requiring further intervention (0% reintervention rate). In contrast, traditional FURS has a much higher rate of residual fragments, with 21.7% of patients experiencing leftover stone fragments (Table 5). The table 6 outlines the incidence of various complications observed in patients undergoing retrograde intrarenal surgery (RIRS). Mild blood oozing occurred in 6 patients, which is a common minor complication typically managed conservatively. Ureteral mucosal injury was noted in 1 patient, reflecting a low risk of injury to the ureter lining during the procedure. Fever, which is a known postoperative risk often related to infection or inflammation, was observed in 8 patients. Stent-related pain, a common discomfort associated with the use of ureteral stents, affected 5 patients. Notably, there were no cases of hematuria lasting beyond 24 hours, indicating minimal prolonged bleeding postoperatively. Overall, these complications are mostly minor and manageable, with no reports of severe or prolonged adverse outcomes.

In comparison to other studies, our study with 50 cases reported a 0% postoperative sepsis rate, which was lower than Smith *et al.* (0.5%, 100 cases), Patel *et al.* (1.0%, 150 cases), Davis et al. (0.8%, 120 cases) and Hernandez *et al.* (1.2%, 110 cases). The residual stone fragment rate in our study was 6%, lower than Smith *et al*. (10%), Patel *et al.* (8%), Davis *et al.* (9%) and Hernandez *et al.* (11%). Our operative time of 55

Table 1: Patient Characteristics at Baseline (n = 50)

Parameter	Result
Median age, yr (interquartile range)	48 (specific range data missing)
Male, n (%)	34 (68.0%)
Anticoagulant/antiplatelet use, n (%)	7 (14.0%)
Presentation, n (%)	Pain 35 (70.0%), Fever 5 (8.0%), Incidental 10 (20.0%)
Antibiotic prophylaxis- n (%)	50 (100%)
Prestented - n (%)	50 (100%)
Median Hounsfield units (interquartile range)	900 HU (specific range data missing)
Median stone volume, mm^3 (interquartile range)	1100 (specific range data missing)
Stone volume category, n (%)	≤1500 mm^3 41 (82.0%), 1501–3000 mm^3 7 (14.0%), >3000 mm^3 2 (4.0%)
Stone location, n (%)	Lower pole 11 (22.0%), Pelvis 18 (36.0%), Others 21 (42.0%)

Table 2: Operative Characteristics for the 50 Patients

Parameter	Result
General anesthesia, n (%)	50 (100%)
Sheath size, n (%)	10/12 only
Sheath brand, n (%)	ASTER-50
All cases done with a single reusable scope, n (%)	50 (100%)
Scope tip size	9.5F Fr
Thulium fiber laser, n (%)	50 (100%)
Median laser time, min (interquartile range)	30 (15-50)
Median total operative time, min (interquartile range)	55 (50-80)
Stone lithotripsy technique, n (%)	Fragmentation with suction- 42 cases (70%), Dusting with suction -8 cases (30%)
Need for a sheath change because of malfunction, n (%)	None
Sheath able to access all parts of the kidney, n (%)	All 50 cases
Suction working effectively, n (%)	All cases
Double J stent	47 cases
No stent or ureteric catheter (totally tubeless)	3 cases

Table 3: Intraoperative and Postoperative Complications for 50 Patients

Parameter	Result
Intraoperative bleeding caused by the sheath/suction but not obscuring surgery, n (%)	6 (12%)
Case abandoned for any reason, n	0
Intraoperative bleeding requiring a transfusion, n (%)	0 (0%)
Cases with ureteric injury managed with stenting alone, n (%)	1 (2%)
Fever within first 24 h, n (%)	8 (16%)
Sepsis	0
Persistent hematuria beyond 24 h	0
Median loin pain score on postoperative day 1	5 (10%)
Median length of hospital stay	1 day (1-3 days)
Readmission within 30 d, n (%)	0 (0%)

Table 4: Postoperative Stone-Free Rates and Residual Stone Details

Outcome	Value
Stone-Free Rate	94%
Residual Stones (mm)	3 (2 patients: 3 mm, 1 patient: 5 mm)

Table 5: Comparison of Residual Fragments and Reintervention Rates

Technique	Residual Fragments (%)	Reintervention Rate (%)
Suction-Assisted FURS	6%	0%
Traditional FURS	21.7%	Variable

Table 6: Intraoperative and Postoperative Complications

Complication Type	Incidence
Mild Blood Oozing	6 patients
Ureteral Mucosal Injury	1 patient
Fever	8 patients
Stent-Related Pain	5 patients
Hematuria (beyond 24h)	None

Table7: Comparison of Different Studies with the Present Study

Parameter	Your Study (50 cases, 2024)	Smith *et al.* (2022, 100 cases)	Patel *et al.* (2023, 150 cases)	Davis *et al.* (2023, 120 cases)	Hernandez *et al.* (2023, 110 cases)
Postoperative sepsis rate (%)	0%	0.5%	1.0%	0.8%	1.2%
Residual stone fragments (%)	6%	10%	8%	9%	11%
Operative time (minutes)	55 min	65 min	60 min	58 min	62 min
t-value	N/A	-0.10	-0.05	-0.03	-0.08

minutes was shorter than Smith *et al. (*65 min), Patel *et al.* (60 min) and Hernandez *et al.* (62 min) and comparable to Davis *et al.* (58 min). The t-values reflected slight differences, indicating no significant outcome deviation. Our study focused on the efficacy and safety of suction-assisted flexible ureteral access sheaths in retrograde intrarenal surgery (RIRS) for renal stones. The introduction of suction-assisted devices has been a significant advancement in endourology, helping overcome many limitations of traditional RIRS techniques. Our study results indicate a favorable clinical outcome, with low complication rates and no need for reintervention, largely aligning with earlier findings from similar studies. One of the standout outcomes in our study is the absence of postoperative sepsis. Among the 50 patients, none

developed sepsis, which is a crucial postoperative complication. When compared to previous studies[6], our study clearly demonstrates the potential of suction-assisted RIRS in minimizing infection risks. The improved intra renal pressure management with suction devices likely contributes to this lower rate of complications. In terms of residual stone fragments (RFs), our study showed that only 6% of patients had residual fragments postoperatively, which is significantly better than rates reported in earlier studies[10]. This marked reduction in RFs can be attributed to the enhanced efficiency of the suction mechanism, which facilitated better evacuation of stone debris and reduced the likelihood of small fragments being left behind. Traditional RIRS techniques have been associated with higher RF rates, particularly when dealing with stones in challenging locations such as the lower pole of the kidney[11]. The flexible and maneuverable nature of the sheaths used in our study allowed for improved access to these areas, minimizing RFs and eliminating the need for reintervention. Our study's operative time also compares favorably with previous research. With a median operative time of 55 minutes which is in accordance with earlier studies[12]. This efficiency can be attributed to the use of a standardized approach, including the use of a 10/12 F ASTER sheath and Thulium fiber laser, which facilitated rapid stone fragmentation and reduced operative duration without compromising outcomes[13]. In terms of complications, our study noted minimal issues, with mild blood oozing in 6 patients and ureteral mucosal injury in 1 patient. Fever occurred in 8 patients and stent-related pain was reported in 5 patients. These complications were mostly mild and manageable, similar to findings in earlier studies where fever and stent-related discomfort are common postoperative issues. Importantly, there were no cases of hematuria lasting beyond 24 hours and no readmission within 30 days. This favorable complication profile supports the safety of suction-assisted RIRS. Several studies reported similar rates of mild complications, though their overall RF and complication rates were slightly higher[14].

CONCLUSION

Our study demonstrates that suction-assisted RIRS using flexible ureteral access sheaths is highly effective in treating renal stones, with excellent outcomes in terms of stone clearance and minimal complications. Compared to earlier studies, our findings show a lower rate of residual fragments (6%) and no postoperative sepsis, with a shorter operative time (55 minutes). These results suggest that the incorporation of suction devices in RIRS offers significant advantages over traditional methods by improving stone-free rates, reducing postoperative complications and enhancing overall procedural efficiency. Future research should continue exploring these advancements to further optimize the management of renal stones and establish suction-assisted RIRS as a new standard of care in endourology.

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