International Journal of Research in Medical Sciences
Ramesh ML et al. Int J Res Med Sci. 2025 Oct;13(10):4015-4021
www.msjonline.org pISSN 2320-6071 | eISSN 2320-6012

DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20252937

Original Research Article

Sheathless and fluoroscopy-free retrograde intrarenal surgery: a single center experience

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Received: 25 August 2025
Revised: 11 September 2025
Accepted: 12 September 2025

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ABSTRACT

Background: This study was done to evaluate the effectiveness and safety of minimally invasive approach to treating renal stones using sheathless and fluoroscopy-free flexible ureterorenoscopic laser lithotripsy (FURSL).
Methods: A prospective study was conducted on 270 patients who underwent FURSL between January 2023 and March 2024. The procedure involved a semi-rigid ureteroscopic assessment with 6 and 8 Fr ureteroscope. A 7.5 Fr flexible URS was inserted into the PCS by side of guidewire sheathless and fluoroscopy-free, followed by the use of a holmium laser to fragment and dust stones in situ.
Results: The study population consisted of 270 patients including 170 males (62.96%) and 100 females (37.04%) with a mean age of 40.65 years (range: 3-70 years) were evaluated. The mean stone size was 17.23 mm (range: 8-41 mm). Complete stone-free status was achieved in 244 (90.37%) patients and clinically insignificant residual fragments (CIRF) in 4 (1.48%), while residual stones were still present in 22 (8.15%) patients. Postoperative complications occurred in 46 (17.4%) cases and were mostly minor, including fever in 34 (12.6%), pyelonephritis in 8 (3.0%), subcapsular hematoma in 2 (0.7%) and steinstrasse in 2 (0.7%). These complications were Clavien I-II, GI in 34 (12.6%) patients, GII in 10 (3.7%), and Clavien IIIb in 02 (0.7%). No major complications were observed. Stone size ≥2 cm, operative time ≥30 minutes, and lasing time ≥20 minutes were significantly associated with a higher rate of complications and lower stone-free rates ($p<0.05$).
Conclusions: Sheathless and fluoroscopy-free FURSL are effective and safe for renal stone management, especially for stones under 2 cm in diameter. This process is a feasible option for avoiding sheath complications, which can protect surgeons from the negative effects of radiation.

Keywords: Flexible ureteroscopy, Fluoroless, RIRS, Sheathless

INTRODUCTION

Retrograde intrarenal surgery (RIRS) has evolved as a minimally invasive alternative to other established treatment techniques such as percutaneous and open nephrolithotomy in the treatment of renal and upper ureteral stones.[1] Technological advancements such as endoscope miniaturization, improved deflection mechanisms, and higher optical quality have led to a surge in the use of RIRS and become one of common endourological surgery.[2,3] Fluoroscopy may assist in insert wires, stents, and ureteral access sheaths, although radiation exposure for patients, surgeons, and operating room staff is a concern.[4] Fluoroscopy-induced ionizing radiation may lead to genetic mutations and malignancies in long-term exposure.[5] The ureteral access sheath (UAS) reduces intrarenal pressure, enhances vision, and extends the lifespan of the ureteroscope. However, there are concerns regarding the safety of routine UAS usage, including potential injury to the ureteric wall such as abrasion, ischemia, and avulsion.[6-8] the growing expertise with RIRS has led to a need to simplify this complex procedure. Several studies have shown that RIRS may be done in a secure manner without fluoroscopy or an access sheath. This study aimed to modify the RIRS approach to reduce costs and radiation exposure for surgeons and personnel in high-volume stone centers.

METHODS

It was a prospective study conducted in the department urology, Narayana medical college Nellore from May 2022 to March 2024.

Inclusion criteria

Patients with renal and proximal ureter calculi and giving consent for procedure during this time period

Exclusion criteria

Patient with ureteric stricture and tumor were excluded.

Between May 2022 to March 2024 on 270 patients who had sheathless and fluoroscopy-free flexible retrograde intrarenal surgery (RIRS) by the same skilled endourologist utilizing 7.5F (distal-tip) flexible ureteroscopes with a shaft diameter of 8.1F and a 3.6F working channel. Patients were informed about treatment alternatives, potential problems, the requirement for a phased process for satisfactory stone removal, auxiliary procedures, and failed procedures.

All patients were assessed using non-contrast computed tomography KUB(CT). On CT KUB stone size was determined by the maximum diameter of a single kidney stone. The operating time was estimated as the time from the beginning of the ureterorenoscopy to the completion of the ureteral stent placement. Clavien-Dindo classification was used to assess complications.[9] Patients with UTIs were treated with culture-specific antibiotics and scheduled for surgery after their urine turned sterile.

At the end of the procedure, patients were examined for immediate stone-free status under direct vision. The first follow-up was done 14 days following the procedure, of double-J removal, then at 6 weeks and 3 months. At follow up x-ray KUB and ultrasonography of abdomen and pelvis were done.[10] Fragments greater than 3 millimeters or symptomatic stones are considered as residual stones.[11]

Procedure

The procedures were carried out under general anesthesia. Patients were put in a lithotomy position, prepped, and draped. Injection cefoperazone sulbactam given to all patient at start of procedure. All surgeries followed the sheathless and fluoroless method. All patients underwent ureteroscopy using a 6 and 8 Fr semirigid ureteroscope, which passively dilated the ureter and assessed for the presence of ureteral stones or strictures. 0.018 guidewire placed in pelvicalyceal system if kink in ureter encountered. In case of ureteral access failure, a 4.5 Fr 26 cm double-J stent was placed, and the treatment was postponed until the next session. A 7 Fr feeding tube was inserted to avoid bladder filling during the surgery. To prevent kinking, the urethra was straightened and the scope was advanced with the direct tip using the thumb and index finger of the left hand. A 7.5 Fr flexible URS (Bioradmedisys™, Pune, India) was inserted into the PCS with or without a guidewire. Pelvicalyceal orientation was completed by entering into all calyxes. In case of inaccessible lower calyx stones irrigation or basket were used to relocate stone. After identifying the stone, a 270 mm laser fiber was gently advanced against it. Lumenis Holmium: YAG Laser Generator was used for lithotripsy. The laser was set to standard lithotripsy settings (0.6-1.2 Joule energy levels and 5-15 Hertz rates) based on the density of the stone. After lithotripsy, the laser fiber was removed, the calyx was flushed with saline using a manual irrigating pump to remove pieces, and an endoscopic check confirmed the stone-free state. The flexible ureteroscope was progressively withdrawn to check the whole ureter for calculi, fragmentation, and substantial ureteral damage. Ureteroscopy done with 8 Fr semirigid ureteroscope a ureteral double-J stent (4.5 Fr/26) was placed into the pcs using a guidewire under direct endoscopic visualization guide wire withdrawn t little to let stent coil in PCS ureteroscope withdrawn slowly simultaneously pushing stent in the procedure was completed when the double-J stent coil was fully visible in the urine bladder. After the procedure, we routinely placed a 4.5 Fr double-J stent for 10-14 days and an indwelling Foley catheter for 12-24 hours. Local ethical committee's approval was taken. All statistical analyses were carried out using the SPSS statistics version 31 program. P values less than 0.05 were considered statistically significant.

RESULTS

In this study, the sample included 270 patients with a mean age of 40.65±14.56 (range: 3-70) years, including 170 (62.96%) males and 100 (37.04%) females who had sheathless and fluoroscopy-free FURLS for management of renal stone between January 2023 and March 2024. The average stone size was 17.23 mm (range: 9-41 mm). Of these patients, 190 (70.37%) had a single stone, whereas 80 (29.62%) had multiple stones. Stones in the renal pelvis were discovered in 145 (53.7%) individuals, whereas 52 (19.25%) and 73 (27.03%) had stones in the lower and upper/middle calyx, respectively. 29 patients (10.74%) had preoperative stents.

Additionally, 35 patients (12.96%) had a history of prior URS, 12 (4.44%) PCNL, 13 (4.81%) ESWL, and 6 (2.22%) open renal stone surgery. Comorbidities included hypertension in 72 individuals (26.66%), diabetes in 48 (17.77%), and chronic renal disease in 18 (6.66%). In addition, 28 individuals (10.37%) were operated on while still on anticoagulant therapy.

Table 1: The demographic and clinical data.

Variables	N (%)	Mean±SD (range)
Case number	270	-
Age (year)		40.65±14.56 (3-70)
Gender		-
Male	170 (62.96)	-
Female	100 (37.04)	-
Stone size (mm)		17.23 (9-41)
Stone number		
Single stone	190 (70.37)	-
Multiple stone	80 (29.62)	
Stone location		
Upper/middle calyx	73 (27.03)	-
Lower calyx	52 (19.25)	-
Pelvis/proximal ureter	145 (53.7)	-
Previous stone related intervention		
USR	35 (12.96)	-
PCNL	12 (4.44)	-
ESWL	13 (4.81)	-
Open renal surgery	6 (2.22)	-
Comorbidity		
Diabetic	48 (17.77)	-
Hypertensive	72 (26.66)	-
Chronic renal disease	18 (6.66)	-
On anticoagulant therapy	28 (10.37)	-
Preoperative double-J stenting	109 (40.37)	-

Table 2: Perioperative outcomes.

Outcomes	n=270
Mean operative time (SD, range), minutes	36.47 (5.75,14-60)
Mean lasing time (SD, range), minutes	24.15 (5.24,8-50)
Postoperative double-J stenting, N (%)	270 (100)
Mean hospital stays (SD, range), hours	26.5 (9,24-96)
SFR, N (%)	
≤10 mm	44/44 (100)
>10-20 mm	146/160 (91.25)
>20-30 mm	44/52 (84.61)
≥30 mm	10/14 (71.14)
Location	
Upper/middle calyx	65/73 (89.04)
Lower calyx	44/52 (84.61)
Pelvis/proximal ureter	135/145 (93.1)
Stone clearance, N (%)	
Complete clearance	244 (90.37)
Clinically non-significant residual stone	4 (1.48)
residual stone	22 (8.15)
Duration of stone clearance, N (%)	
Immediate	124 (45.92)
After 2 weeks	208 (77.03)
After 6 weeks	242 (89.62)
After 3 months	244 (90.37)
The ancillary procedure, N (%)	
RIRS	19 (7.03)
ESWL	3 (1.11)

Continued.

Outcomes	n=270
Complication	
Clavien Grade I, N (%)	
Fever	34 (12.59)
Clavien Grade II, N (%)	
Non-obstructive pyelonephritis	8 (2.96)
Subcupsular hematoma	2 (0.74)
Clavien IIIb, N (%)	
Steinstrasse	2 (0.74)

Table 3: complication according to stone size and location.

Stone characteristics	Complication N (%)
Size	
<10 mm	2/44 (4.54)
10-20 mm	20/160 (12.50)
20-30 mm	16/52 (30.76)
>30 mm	8/14 (57.14)
Location	
Upper/middle calyx	10/73 (13.69)
Lower calyx	10/52 (19.23)
Pelvis/proximal ureter	26/145 (17.93)

Table 4: Univariate logistic regression analysis for SFR and complication.

Variables	SFR (%)	Complication (N)
Stone size (mm)		
<10	100	2
10-20	91.25	20
20-30	84.61	16
>30	71.14	8
P value	0.001	0.04
Location		
Upper/middle calyx	89.04	10/73 (13.69)
Lower calyx	84.61	10/52 (19.23)
Pelvis/proximal ureter	93.1	26/145 (17.93)
P value	0.10	0.41
Operative time		
Less than 30	94.39	9
More than 30	89.18	37
P value	0.04	0.004
Lasing time (minutes)		
Less than 20	93.56	10
More than 20	89.07	36
P value	0.07	0.006

The average operational time was 36.47±5.75 minutes (range: 14-60 minutes), whereas the average lasing time was 24.15±5.24 minutes (range: 8-50 minutes). All patients received postoperative double-J stenting. The mean hospital stay was 26.5±9 hours (range: 24-96 hours). The stone-free rate (SFR) was 90.37%. The initial endoscopic SFR was 45.92%. After 2 weeks, 6 weeks, and 3 months, rates increased to 77.03%, 89.62%, and 90.37%, respectively. Four patients (1.48%) had clinically insignificant residual stones measuring ≤3 mm in diameter. 22 patients (8.15%) had leftover stones measuring more than 3 mm renal pelvis stones had better clearance (93.1%) compared to upper/middle calyx stones (89.04%) and lower calyx stones (84.61%). However, the difference was not statistically significant (p=0.39). Patients with residual stones were treated with ancillary procedures like RIRS (7.03%) and ESWL (1.11%).

Perioperative problems occurred in 46 individuals (17.03%), mostly Clavien I (12.59%), Clavien II (3.70%), and Clavien IIIb (0.74%). Complications included fever (12.6%), pyelonephritis (2.96%), subcapsular hematoma (0.74%), and steinstrasse (0.74%). Complications occurred in 4.54% of study participants with stones <10 mm, 12.50% with stones 10-20 mm, 30.76% with stones 20-30 mm, and 57.14% with stones >30 mm. The distribution of complication based on stone position was as follows (Table 3): renal pelvis: 21.37%; lower calyx: 13.46%; upper/middle calyces: 10.95% (statistically insignificant).

Stone size ≥2 cm, surgical duration ≥30 minutes, and lasing time ≥20 minutes was significantly linked with greater complication rates and worse SFR on univariate logistic regression analysis (p<0.05) (Table 4). In contrast, the location and quantity of stones had no effect on SFR or complications (p>0.05).

DISCUSSION

Since advent of flexible ureterorenoscope, retrograde intrarenal surgery (RIRS) has become most preferred alternative to PCNL for management for renal stone for both patient and urologist.[1,3,12,13] As compared to PCNL, RIRS provide short hospital stay, minimal affliction, less blood loss and parenchymal damage.[14]

Fluoroscopy has many benefits, including improving procedural safety by helping with the navigation of stones, the placement of wires, stents, and UAS.[15] However, the radiation exposure of patients, surgeons, and operating room staff during the procedure has become a clinical concern because the long-term effects of fluoroscopy-induced ionizing radiation may be dangerous, with a potential risk of genetic mutation. Radiation's biological effects might be classified as deterministic or stochastic.

The likelihood of being exposed to radiation-induced cancer and genetic consequences is stochastic, meaning that its probability rises with dose rather than the degree of severity. The threshold radiation level is linked to the deterministic impact. As the dose rises above the threshold, the damage becomes more obvious and more severe. To reduce their exposure to radiation, surgeons wear protective gear like lead aprons. Surgeons who perform endourological treatments are exposed to the highest amount of radiation, even with the adoption of protective precautions.[16]

By allowing numerous reentries into the kidney, UASs theoretically can greatly speed up RIRS and enhance the possibility that the kidney will remain stone-free. Additionally, UASs lower intrarenal pressure, which may improve eyesight during the procedure and protect the scope from injury.[17] Due to the UAS's placement in the ureter, a delicate luminal organ, there is a chance that the ureteral wall may sustain damage of varying degrees, from a straightforward urothelial abrasion to wall ischemia and ureteric avulsion. Ureteral injury with UAS insertion resulting in more postoperative persistent hematuria, use of ureteral stents, post-operative pain, and even contributing to ureteral strictures.[18-21]

In all the patients in our study, flexible URS without a fluoroscopic guide was completed effectively. It did not require fluoroscopy because the first guidewire was placed using a semirigid ureteroscope under visual guidance. Flexible URS scope was advanced in ureter b the side if guidewire under direct vision. The stones were then reached, and fragmentation was carried out under direct vision. To avoid stone retrieval, we employed a dusting mode during the process, in which the stones were broken up into minuscule fragments or a fine powder till stone pieces were tiny enough to pass on their own. In the method we applied, we did not use a ureteral access sheet, dispensing with the need for fluoroscopy and thereby avoiding exposure to the harmful effects of radiation.

Flexi URS has become smaller and has better image quality consequently fluoroless process is become less technically challenging. Numerous studies have shown that reduced radiation and fluoroless protocol during flexible URS can be done safely, including UAS insertion, balloon dilation, and the placement of double-J stents, with no impact on the operation's success, time, or complication rates.[22,23]

Maugeri et al reported SFR 92.3% in group 1 (stone size: <1 cm), 88.3% in group 2 (stone size: >1≤2 cm), 56.7% in group 3 (stone size: 2-3 cm) and 69.6% in group 4 (multiple stones) which is comparable to this study results with overall SFR 90.37% and for ≤10 mm 100%, 10-20 mm 91.25%, 20-30 mm 84.61% and for ≥30 mm 71.14% with stone more than 20 mm associated with poor SFR (p=0.001).[24] Zhang et al who compared flexible and navigable access sheath versus tradition access sheath has reported SFR on 30 days postoperatively 91.2% and 81.3% respectively.[25] This finding is proportionate to comparable studies that determined the SFR of 65% to 92%.[22,24,25]

Although the difference was not statistically significant (p=0.10), we observed that the renal pelvis achieved a finer clearance of stones (93.1%) than the upper/middle calyx stones (89.04%) and lower calyx stones (84.61%). On univariate analysis, there was a significant correlation (p<0.05) between lesser SFR and higher rates of complications for stones >2 cm in size, operative times >30 minutes, and lasing times >20 minutes. Conversely, neither SFR nor complication were impacted by the location or quantity of stones (p>0.05).

The total complication rate observed in this study was 17.03 % Of the complications seen, the majority (12.59%) had a postoperative fever; over half had a stone larger than 20 mm. we observed that stone size and operative duration were independently associated with the development of post-RIRS fever. Antipyretics and intravenous fluids were administered to each patient. Only four patients experienced postoperative UTI; all four had stones larger than 30 mm, and after receiving antibiotics and conservative care, their conditions improved. It was clear that larger stones and longer operating times had a significant role in the development of this type of fever.

Nevertheless, increased pyelovenous and pyelolymphatic absorption may result in systemic inflammatory response syndrome (SIRS), irrigation-induced elevation of intrarenal pressure is still a matter for worry. In addition to bacteria, bacterial endotoxins can also cause fever or SIRS by entering the bloodstream through the absorption of infusion fluid. The size of the stone, the length of the operation, and the irrigation rate are important risk factors for SIRS and post-RIRS fever.[26]

Singh et al has concluded in randomized control trail that use of UAS during RIRS is not associated with improved SFR. RIRS can be performed safely without the use of UAS and without increasing postoperative complications.[23] Geraghty et al found that use of a UAS does not make any difference to the SFR or complication rate for FURSL in large stones (>2 cm) and may not be routinely needed in all cases.[27] The use of UAS had no effect on SFR, according to a study by Traxer et al. While there was a decrease in postoperative infectious complications, the use of UAS did not raise the risk of bleeding or ureteral injury.[28] A systematic review and meta-analysis done by Huang et al for use of the ureteral access sheath during ureteroscopy indicated that the use of UAS during ureteroscopy did not manifest advantages.[29] These findings reported in literature are comparable to this study which shows a significantly lower SFR and a higher risk of fever and UTIs for stones >20 mm compared to smaller ones. It was concluded that sheathless FURLS is a safe and feasible procedure with high SFR and low morbidity, especially for stones <2 cm.

One of our study's shortcomings is the imaging techniques we employed to determine SFR. Despite being the most accurate technique for identifying residual pieces, CT may not be used as often due to practical issues and high costs. Since KUB and ultrasonography have minimal radiation doses, are readily accessible, and low values, they were used as postoperative imaging tests. Because of the variations in imaging technologies accuracy, this might have led to an imprecise assessment of the remaining stones.

CONCLUSION

For the treatment of renal stones, particularly those with a diameter of less than 2 cm, sheathless and fluoroscopy-free FURSL are a safe and efficient option. Thus, FURSL is a workable solution to prevent sheath problems, shielding surgeons from the harmful effects of radiation.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Ramesh ML, Yuvaraju Y, Theja BR, Jagirdar SF, Gaddam Y, Eswar PS. Sheathless and fluoroscopy-free retrograde intrarenal surgery: a single center experience. Int J Res Med Sci 2025;13:4015-21.