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ORIGINAL ARTICLE

Indications, preferences, global practice patterns and outcomes in retrograde intrarenal surgery (RIRS) for renal stones in adults: results from a multicenter database of 6669 patients of the global FLEXible ureteroscopy Outcomes Registry (FLEXOR)

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Abstract

Purpose To collect a multicentric database on behalf of TOWER research group to assess practice patterns and outcomes of retrograde intrarenal surgery (RIRS) for kidney stones.

Methods Inclusion criteria: age ≥ 18 years, normal renal/calyceal system anatomy, calculi of any size, number, and position. Study period: January 2018 and August 2021. Stone-free status: absence of fragments > 2 mm, assessed post procedure according to the local protocol (KUB X-Ray and/or ultrasound or non-contrast CT scan).

Results Twenty centers from fifteen countries enrolled 6669 patients. There were 4407 (66.2%) men. Mean age was 49.3 ± 15.59 years. Pain was the most frequent symptom indication for intervention (62.6%). 679 (10.2%) patients underwent RIRS for an incidental finding of stones. 2732 (41.0%) patients had multiple stones. Mean stone size was 10.04 ± 6.84 mm. A reusable flexible ureteroscope was used in 4803 (72.0%) procedures. A sheath-less RIRS was performed in 454 (6.8%) cases. Holmium:YAG laser was used in 4878 (73.1%) cases. A combination of dusting and fragmentation was the most common lithotripsy mode performed (64.3%). Mean operation time was 62.40 ± 17.76 min. 119 (1.8%) patients had an intraoperative injury of the ureter due to UAS insertion. Mean postoperative stay was 3.62 ± 3.47 days. At least one postoperative complication occurred in 535 (8.0%) patients. Sepsis requiring intensive care admission occurred in 84 (1.3%) patients.
Residual fragments were detected in 1445 (21.7%) patients. Among the latter, 744 (51.5%) patients required a further intervention.

Conclusion Our database contributes real-world data to support to a better understanding of modern RIRS practice and outcomes.

Keywords Kidney calculi · Flexible ureteroscopy · Retrograde intrarenal surgery · Lithotripsy · Laser

Introduction

Current advancements in endoluminal endourology for the upper urinary tract have expanded the role of retrograde intrarenal surgery (RIRS) in guidelines from an alternative to first line intervention for renal stones up to 2 cm in diameter [1, 2]. New instruments such as high-power Holmium:YAG lasers, Thulium fiber lasers (TFL), and single-use ureteroscopes have been introduced in an attempt to improve safety, efficiency, and comfort for both patients and surgeons [3]. Additionally, RIRS can be safely performed under spinal anesthesia with outcomes similar to general anesthesia [4, 5]. Technological advancements bring with it newer concerns of how this could be best applied

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to clinical practice of RIRS to achieve a trifecta outcome of high stone free rate (SFR), minimal complications and maximum cost-effectiveness.

Even though RIRS has been standardized [6] and is reproducible [7], surgeons across the globe often need to adopt and adapt evidence with experience to suit their realm of practice, which can be a limitation for evidence based practice and may impact outcomes of a procedure [8].

We aimed to collect a multicentric, global database to assess the current indications for RIRS, instruments used, trends and preferences of lasers and lasing techniques at different centers and assess intra- and postoperative outcomes when this procedure is performed in the hands of experienced endourologists at their place of practice in different ethnic population and geographic locations.

Materials and methods

Enrolment protocol

As part of an endeavor of the TOWER group (Team of Worldwide Endourological Researchers, research wing of the Endourological Society), an initiative by author (VG) was launched in October 2021 to invite experienced endourologists who are specialists in RIRS from across the globe to participate in the creation of a retrospective registry for patients undergoing flexible ureteroscopy (F-URS) for renal stones only. This invitation was open to any participants who had experience of performing at least 500 flexible ureteroscopy cases and were practicing in a training institute where resident training is provided. We identified and included experienced surgeons and included resident training centers to compare and contrast outcomes between experienced and trainee surgeons.

Inclusion criteria and data collection

The participant team (consultant and resident) contributed to the database created, maintained and regulated as per Institutional board review approval (#AINU 08/2022) obtained by Asian Institute of Nephrology and Urology, Hyderabad, India. All patients signed informed consent to gather their anonymize data.

Each institution obtained its own ethics board approval before contributing and provided anonymized data of adult patients with a normal renal anatomy and pelvic-calyceal system who underwent RIRS as a primary treatment or after failure of a previous treatment for renal calculi of any size, number and pelvic-calyceal position, at their center, between January 2018 and August 2021.

Exclusion criteria applied to any patients with ureteric stones or children/adolescents (< 17 years), those with renal anomalies or musculoskeletal abnormalities which do not allow positioning in lithotomy or supine/split leg position. Further, RIRS procedures done as combined procedure for Endoscopic Combined Intrarenal Surgery (ECIRS) or simultaneous bilateral endoscopic surgery or in prone position were not included. No specific inclusion or exclusion criteria on how to perform the procedure were applied and the RIRS procedure was carried out as per the standard of care and surgical practice of each institute.

Patient follow-up

Patients were assessed post procedure according to the local standard of care, which included KUB X-ray and/or ultrasound or non-contrast computed tomography (CT) scan. The classification of a patient being stone-free was based on the absence of stones or fragments smaller than 2 mm. Intraoperative details and postoperative outcome were assessed.

Secondary treatment

Secondary treatment was considered necessary if significant remnant stones were present, if the upper urinary tract was obstructed by residual stones, or for other reasons dependent on the clinical judgment of the treating physician. Secondary treatment involving repeat RIRS or shock wave lithotripsy (SWL) or percutaneous nephrolithotomy (PCNL) or ECIRS was selected based on clinical assessment and carried out as per the local standard of care.

Data collection and analysis

Anonymized data from each institute were entered electronically into a central database at the AINU office. Data were managed as reported previously. Data included patient demographic characteristics, calculus specification, type of treatment, and postoperative complications and outcomes. Centers treated patients according to their local standard of care. The database was censored for inclusion in October 2021. Subsequently, the database was locked, checked for consistency, and cleaned and an audit took place between October 2021 and July 2022 for data analysis.

Continuous data are reported as mean and standard deviation. Categorical data are presented as absolute numbers and percentage. Where data were missing, the number of patients for whom the values were missing or not available was stated. Therefore, percentages were calculated based on the total cohort. Statistical tests were conducted using the SPSS software package version 25.0 (IBM Corp., Armonk, NY).

Table 1 Patients' baseline characteristics

Characteristics	Numbers
Number of patients	6669 (100%)
Age, years, mean (standard deviation)	49.34 (15.59)
< 40 years old	2111 (31.6%)
41–65 years old	3494 (52.4%)
66–75 years old	731 (11.0%)
> 75 years old	331 (5.0%)
Gender (%)	
Male	4407 (66.1%)
Female	2262 (33.9%)
Ethnicity	
Asian	4225 (63.4%)
Non-Asian	2444 (36.7%)
First presentation of stone	5036 (75.5%)
Symptoms on presentation	
Hematuria	327 (4.9%)
Pain	4178 (62.6%)
Hematuria and Pain	730 (10.9%)
Elevated creatinine	612 (9.2%)
Fever	651 (9.8%)
Incidental Finding of Stone	679 (10.2%)
Pre-stented	3112 (46.7%)
Pre-RIRS stenting dwelling time, days, mean (standard deviation)	5.55 (23.17)
Preoperative Tamsulosin Used	1142 (17.1%)
Diagnostic imaging modality	
CT Scan	5094 (76.4%)
Contrast-enhanced CT scan	814 (12.2%)
X-ray	1562 (23.4%)
Ultrasound	3294 (49.4%)
Stone characteristics°	
HU, mean (standard deviation)	978.94 (333.1%)
Multiple stones	2732 (41.0%)
Size*, mm, mean (standard deviation)	10.04 (6.84)
Upper pole	1474 (22.1%)
Mid pole	2041 (30.6%)
Lower pole	2946 (44.2%)
Renal pelvis	2196 (32.9%)

CT computed tomography, *HU* Hounsfield Unit. *Largest diameter. °The results include stones as per location both for solitary and in those patients (2732) where there were reported multiple stones in different locations

Results

Twenty centers from 15 countries enrolled 6669 patients who had RIRS for renal stones, having met the inclusion criteria and were included in the final analysis (Supplementary Table 1). Table 1 shows patients' baseline characteristics. There were 4407 (66.2%) men. Mean age was 49.3 ± 15.59 years. 16% of the patients were in the older age group (> 65 years old) with 5% of the total pool (331 patients) aged > 75 years. Pain was the most frequent symptom indication for intervention in 62.6% of patients. Only 679 (10.2%) patients underwent RIRS for an incidental finding of stones and 5036 (75.5%) patients were first-time stone presenters. Almost half of the patients in our cohort (46.7%) were pre-stented either to relieve symptoms or obstruction or as part of a planned elective RIRS based on surgeons' preference. Mean stent dwelling time was 5.55 ± 23.17 days prior to surgery. In the subgroup of non-pre-stented patients, 1142 (17.1%) patients had Tamsulosin preoperatively. Non-contrast CT scan was the most common diagnostic modality (76.4%) but there were urologists who also relied on x-ray, ultrasonography or a combination of these for planning

intervention. Regarding stone characteristics, 2732 (41.0%) patients had multiple stones. The mean stone size, calculated on the largest diameter, was 10.04 ± 6.84 mm. Stones were in the lower pole, renal pelvis, mid pole and upper pole in 44.2%, 32.9%, 30.6% and 22.1% respectively.

Table 2 shows intraoperative characteristics. 76.9% of patients received antibiotic prophylaxis. Surgery was performed under general anesthesia in 6102 (91.5%) patients, while the remaining patients had spinal anesthesia. Half of the RIRS procedures were preceded by inspection of the ureter with a semirigid ureteroscope. Almost all procedures (99.8%) were performed in the lithotomy position, with the table in flat position in 42.4% of cases. Standing was the most preferred surgeon position (78.2%). Surgery was performed by a consultant in 5100 (76%) patients, by a trainee in 293 (4.4%), and by both surgeons in the remining ones (19.1%). Interestingly, a disposable flexible ureteroscope was used in 4803 (72.0%) procedures. A sheath-less procedure was performed only in 454 (6.8%) cases and 74.9% procedures were performed with a ureteral access sheath (UAS) sized > 8 Fr. Holmium:YAG laser was used in 4878 (73.1%) cases, while TFL in the remaining ones (26.9%) and in the 2696 patients where a laser more than 30 W was used, 19.1% cases utilized a MOSES™ fiber.

Regarding lithotripsy mode, a combination of dusting, pop-corning and fragmenting techniques was the most commonly performed (64.3%). Basket utilization was noted in only 2024 (30.3%) procedures. Mean operation time was 62.40 ± 17.76 min, whilst mean laser time was 25.90 ± 38.77 min. Mean radiation time was 7.76 ± 15.87 min. Only 6 (0.1%) patients had intraoperative bleeding requiring a blood transfusion, and 119 (1.8%) patients had an intraoperative injury of the ureter due to UAS insertion and required a stent.

Table 3 shows postoperative outcomes. A day surgery procedure was performed in 754 (11.3%) patients and mean postoperative stay was 3.62 ± 3.47 days. At least one postoperative complication occurred in 535 (8%) patients. Of the complications, fever/infection requiring antibiotics was the most common complication (61%), whereas sepsis requiring intensive care admission occurred in 84 (1.3%) patients.

Post RIRS follow up was by CT scan in 26.2%, whereas a combination of ultrasound and X-ray was the most common imaging modality. Residual fragments defined as any single fragment more than 2 mm or multiple fragments of any size, were detected in 1445 (21.7%) patients and among these, 701 (48.5%) were asymptomatic and were on observation alone, whilst the remaining required a further intervention. As a reintervention for residual fragments, repeat RIRS was the most preferable option (27.7%).

Discussion

According to current international guidelines, F-URS is a first-line treatment option of kidney stones up to 2 cm [1, 2]. However, the indication of F-URS has been expanded with a good SFR and acceptable complications even in larger stones [9] and in anomalous kidneys [10]. The global flexible and semi-rigid ureteroscopy market is expected to reach USD 1.054 billion by 2023 from USD 768 million in 2017, at a compounded average growth rate of 5.4%[11], an indicator of its rising popularity as an alternative to PCNL for renal stone management for stones in any location [12], adults and children [13] alike and is now being offered for stones greater than 2 cm as well [14, 15]. Of note is that older patients are also being offered RIRS (16%) as RIRS seems to be doable safely even under spinal anesthesia [4, 5, 16]. In fact, Kwon et al. concluded that post-operative pain on first post-operative day was less and renal function was better preserved at follow up [16]. The surgeon's performance was inferior to when done under general anesthesia which may be explained by the inability to effectively control respiratory movement. While Gadzhiev et al. proposed that dusting was better with respiratory control [17], Ho et al. proposed that F-URS can be safely performed without respiratory apnea using anesthetic, and surgical protocols and can improve day-case rates as well as decrease the overall length of stay and respiratory complications [18]. Perhaps, this may be reflective in our series too where 91.2% patients had a general anesthesia, yet in 3289 (49.3%) cases urologists reported using any form of gated respiration.

Expert surgeons in our series were comfortable using Ho-YAG of any watt and TFL and deploy all techniques of lithotripsy as applicable. However, only 30.4% patients were reported to have usage of a basket for fragment extraction. This also shows that with experience, technical and technological advancements RIRS can be done with a high SFR by minimizing the accessories used for stone retrieval, which could translate to less cost and possibly lower operative time and mishaps due to issues such as basket entrapment leading to ureteral injury [19]. The utility of fragment extraction will likely further reduce with newer lasers that are optimized for dusting such as TFL [20] and MOSES 2.0 technology [21]and advancements in on-table stone composition identification with stone dust being reported as good enough for extraction and analysis [22]. The utility of single use ureteroscopes in our study was reported as 27.8%. Despite the improved digital image, slender design with better deflection and availability of locally manufactured scopes, perhaps cost is the limitation to its widespread preferential usage. Analogous to this is that since 4808 patients had a RIRS procedure with reusable scopes, with only 1.3% patients reporting sepsis needing intensive care admission, maybe

Table 2 Intraoperative characteristics of 6669 cases enrolled in global FLEXOR study

Perioperative parameters	Number	Missing data
Preoperative antibiotics	5129 (76.9%)	
Type of anesthesia		
Spinal anesthesia	567 (8.5%)	
General anesthesia	6102 (91.5%)	
Respiratory control		
None	3289 (49.3%)	
Gated	2209 (33.1%)	
Apneic	1171 (17.6%)	
Semirigid URS before RIRS	3344 (50.1%)	
Patient position		
Lithotomy	6654 (99.8%)	
Supine with split leg	15 (0.2%)	
Table position		
Flat	4742 (71.1%)	
Head- up	1596 (23.9%)	
Head-down	331 (5%)	
Surgeon position		
Standing	5218 (78.2%)	
Sitting	1451 (21.8%)	
Performing surgeon		
Consultant	5100 (76.5%)	
Trainee	293 (4.4%)	
Both	1276 (19.1%)	
Urethral access sheath size		
$\leq$8 Fr	1223 (18.3%)	
$>$8 Fr	4992 (74.9%)	
No use of sheath	454 (6.8%)	
RIRS scope type		
Reusable	4808 (72%)	
Disposable	1855 (27.8%)	11 (0.2%)
Use of Holmium Laser	4878 (73.1%)	
Power of Holmium machine (n = 4878)		
$<$30 W	2105 (43.6%)	77(1.5%)
$>$30 W	2696 (55.9%)	
Use of Moses technology	516 (19.1%)	
Thulium fiber laser	1791 (26.9%)	
Lithotripsy technique*		
Dusting	3960 (59.4%)	
Popcorning	2337 (35%)	
Fragmentation	2611 (39.2%)	
Combination	4287 (64.3%)	
Extraction of fragments with a basket	2024 (30.3%)	
Laser Time, minutes, mean (standard deviation)	25.90 (17.76)	
Radiation time, minutes, mean (standard deviation)	7.76 (15.87)	
Radiation dose, centi-gray, mean (standard deviation)	91.69 (236.17)	
Operation Time, minutes, mean (standard deviation)	62.40 (38.77)	
Intraoperative Complications		
Pelvicalyceal system bleeding not requiring blood transfusion	300 (4.5%)	
Pelvicalyceal system bleeding requiring blood transfusion (Clavien grade 2)	6 (0.1%)	
Ureteric injury due to access sheath requiring stenting (Clavien grade 3)	119 (1.8%)	

Table 2 (continued)

URS ureteroscopy, *Fr* French, *RIRS* retrograde intrarenal surgery. *W* Watt. *More than one technique for a patient was performed

Table 3 Postoperative outcomes of 6669 cases enrolled in global FLEXOR study

Characteristics	Numbers	Missing data
Postoperative stay, *days*, mean (standard deviation)	3.62 (3.47)	
Day surgery	754 (11.3%)	
Overall postoperative complications	535 (8.0%)	
Fever/Infections requiring antibiotics (Clavien grade 2)	407 (6.1%)	
Hematuria requiring blood transfusions (Clavien grade 2)	366 (5.5%)	
Sepsis requiring ICU admission (Clavien Grade 4)	84 (1.3%)	
Post-operative imaging assessment by		
CT scan	1748 (26.2%)	
X-ray	2980 (44.7%)	
Ultrasound	3024 (45.3%)	
Combination	1942 (29.1%)	
Residual fragments	1445 (21.7%)	
Residual fragment subsequent treatment ($n = 1445$)		
SWL	257 (17.8%)	
RIRS	400 (27.7%)	
PCNL	65 (4.5%)	
ECIRS	22 (1.5%)	
Observation alone	701 (48.5%)	
Stone analysis	2845 (42.7%)	

ICU intensive care unit, *CT* computed tomography, *SWL* Shock Wave Lithotripsy, *RIRS* Retrograde Intrarenal Surgery, *PCNL* percutaneous nephrolithotomy, *ECIRS* Endoscopic Combined Intrarenal Surgery

with proper sterilization reusables can still be safely used and it is time to reconsider if this is indeed an indication to change to single use scopes.

Limitations and strength

This is the largest global single registry documenting the utility and outcomes of using F-URS alone for RIRS to treat renal calculi managed by expert endourologists. To our knowledge this is the only dedicated F-URS registry database study since The Clinical Research Office of the Endourological Society (CROES) ureteroscopy registry, which was a global initiative from the Endourological society published in 2014 which highlighted and significantly contributed to knowledge on how ureteric stones can be surgically managed [23].

Albeit this is a retrospective database which has its own bias, analyzing the outcomes of the included patient profiles, demographic features and practices, we will be able to identify the outcomes of RIRS surgery. Since the CROES study in 2014, there have been numerous advancements including the introduction of disposable scopes, new laser technology and expanding indications of RIRS for renal stones.

Our multicentric global Registry data can throw insight into:

(1) How far we have reached in evidence-based practice of RIRS.
(2) How crucial the influence of experience-based practice is over evidence-based practice. This was well illustrated by CROES for semirigid ureteroscopy where urologists showed a universal cooperation for best results [24]
(3) A detailed understanding on nuances of various advancements in techniques and technology have improved SFR for different stone compositions, size and locations.
(4) How evidence from guidelines can be adapted to improve a surgeon's experience for better personalized stone surgery outcomes for patients across the globe.
(5) How important it is to standardize post RIRS imaging, follow-up protocols, and define the best intervention strategy for residual fragments.
(6) Which technical advancements have contributed to minimizing complications whilst improving outcomes.
(7) Identify the areas which are lacking standardization and defining limitations.

Conclusions

RIRS is now indeed a truly well-established global, safe endoluminal intervention going through a transformative change with new innovation redefining its outcomes. Our database contributes real-world data to support this aspect.

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Data availability Data are available on request from the authors.

Declarations

Conflict of interest The authors have no competing interests to declare that are relevant to the content of this article.

Human and animal rights The study was approve by the ethics board of the Asian Institute of Nephrology and Urology, Hyderabad, India (#AINU 08/2022). Each institution obtained its own ethics board approval before contributing and provided anonymized data. All patients signed informed consent to gather their anonymize data.

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