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Comparison of Retrograde Intrarenal Surgery with Ureteral Access Sheath in Stented versus Non-Stented Patients

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Abstract

Objective: To compare the outcomes of retrograde intrarenal surgery in patients with and without preoperative ureteral stenting, and to identify predictors of stone-free rate.

Method: The prospective, observational study was conducted from March to June 2025 at the Pakistan Kidney and Liver Institute and Research Centre, Lahore, Pakistan, and comprised patients aged 16-75 years having renal calculi 1-2cm who underwent retrograde intrarenal surgery with ureteral access sheath. The stented patients were in group A, while the non-stented patients were in group B. Perioperative, clinical and demographic data was noted. At 4-6 weeks postoperatively, non-contrast computed tomography scan of the kidney-ureter-bladder region was done to assess the non-presence of stones. Data was analysed using SPSS 27.

Results: Of the 217 patients, 102(47%) were in group A; 65(66.7%) males and 37(33.3%) females with mean age 41.16 ± 12.96 years. There were 115(53%) patients in group B; 74(69.6%) males and 41(30.4%) females with mean age 43.30 ± 13.66 years ($p > 0.05$). Access sheath insertion was more successful in group A ($p < 0.001$) and the length of hospital stay was shorter ($p = 0.002$) compared to group B. Stone-free rates were better in group A, but the difference with group B was not statistically

29 significant ($p=0.053$). Two factors were strong predictors of stone-free rate: smaller
30 stone size ($p<0.001$) and absence of hypertension ($p=0.049$).

31 **Conclusion:** Preoperative stenting, which improved access sheath success and
32 reduced the length of hospital stay, may offer perioperative advantages towards
33 selected cases. Smaller stone size and absence of hypertension independently
34 predicted better stone-free rate following retrograde intrarenal surgery.

35 **Key Words:** Ureteroscopy, Ureteral stents, Ureteral access sheaths, Kidney calculi,
36 Treatment outcome.

37

38 **Introduction**

39 Urolithiasis is a frequent and recurrent condition among people across the world. The
40 prevalence of urolithiasis is on the increase due to various factors, such as diet,
41 environment and metabolism [1,2]. Technical developments in endourology have
42 greatly improved the management of renal stones. Retrograde intrarenal surgery
43 (RIRS) is one of the preferred methods for treating renal stones, particularly for stones
44 measuring 1-2cm in size. This method offers several advantages compared to other
45 methods, such as percutaneous nephrolithotomy (PCNL), including less morbidity,
46 shorter length of hospital stay (LOS) and faster recovery [3, 4]. One of the most
47 important tools for improving the effectiveness and safety of RIRS is the use of a
48 ureteral access sheath (UAS), which allows for intermittent access, reduced pressure
49 within the kidneys, and reduced trauma to the ureter [5, 6]. However, the insertion of a
50 UAS is not guaranteed, and can be affected by various factors, such as ureteral
51 anatomy, previous procedures and preoperative ureteral stenting [7, 8]. Pre-stenting
52 with a double-J stent has been hypothesised to passively dilate the ureter, thereby
53 improving access sheath placement and surgical outcome [9, 10].

54 The role of preoperative stenting in RIRS remains controversial. Some studies showed
55 that stenting makes UAS placement easier and improves the quality of visualisation.
56 However, stenting may not affect stone-free rate (SFR) significantly, and may cause
57 discomfort to the patient and increase healthcare costs [11,12]. Moreover, patient-

58 related factors, such as the presence of comorbid conditions, like hypertension (HTN)
59 and diabetes mellitus (DM), stone size and location, and RIRS-related parameters may
60 affect the probability of achieving SFR status independently [13].

61 The current study was planned to compare the outcomes of RIRS in patients with and
62 without preoperative ureteral stenting, and to identify SFR predictors.

64 **Patients and Methods**

65 The prospective, comparative, observational study was conducted from March 23 to
66 June 30, 2025, at the Department of Urology, Pakistan Kidney and Liver Institute and
67 Research Centre (PKLI&RC), Lahore, Pakistan. After approval from the institutional
68 ethics review committee (ERC), the sample size was calculated using the World
69 Health Organisation (WHO) calculator [14] on the basis of two-proportion formula:
70 $n = [(Z\alpha/2 + Z\beta)^2 \times (P1(1-P1) + P2(1-P2))] / (P1 - P2)^2$ in the light of literature [15], keeping
71 $P1 = 97.3\%$ (stented), $P2 = 87.8\%$ (non-stented), confidence level 95% ($Z\alpha/2 = 1.96$) and
72 power 80% ($Z\beta = 0.84$). The sample size was inflated by <10% to increase the study's
73 statistical power. As the study involved analysis of prospectively collected
74 observational data without any deviation from standard care, the institutional ERC
75 waived the requirement for individual informed consent. Patient confidentiality and
76 data privacy were strictly maintained throughout the study period. All eligible patients
77 were consecutively enrolled using a non-probability consecutive sampling technique,
78 and they were divided into two groups based on whether they had undertaken
79 preoperative ureteral stenting (group A) or not (Group B).

80 Those included were patients of either gender aged 16-75 years who were diagnosed
81 with renal calculi measuring 1-2cm based on imaging, and underwent RIRS using
82 UAS. Patients were excluded if they had a history of previous stone surgery, including
83 RIRS, ureteroscopy, percutaneous nephrolithotomy (PCNL), mini-PCNL or
84 laparoscopic ureterolithotomy, a history of pyeloplasty, or the presence of a ureteral
85 stricture identified either clinically or radiologically. No patient meeting the inclusion
86 criteria was excluded after initial recruitment.

87 Data was collected from the hospital's electronic medical records (EMR) and surgical
88 logs by trained postgraduate residents.

89 The collected data included demographic and clinical characteristics (age, gender,
90 body mass index [BMI], comorbidities, smoking history, residential status, family
91 history of stones), preoperative parameters (estimated glomerular filtration rate
92 [eGFR], stone size, stone laterality, stone location), operative details (access sheath
93 insertion success, operative time in minutes), and postoperative outcomes (LOS in
94 days, SFR on the basis of computed tomography (CT) scan of the kidney-ureter-
95 bladder (KUB) region).

96 All the procedures were performed under general anaesthesia (GA) by experienced
97 consultant urologists. A disposable 9/11 Fr UAS (OTU™) was inserted following
98 retrograde pyelography. Subsequently, a flexible ureteroscope (from the same
99 manufacturer) was advanced to access the renal pelvis and calyces. Laser lithotripsy
100 was achieved using a 30W Holmium: YAG laser system (Quanta) to fragment the
101 stones. Ureteral stents were selectively placed postoperatively based on intraoperative
102 findings. The patients were subjected to non-contrast CT KUB 4-6 weeks after the
103 operation to determine SFR. A patient was considered to be stone-free if there were no
104 residual fragments or fragments <4mm. SFR was defined as no residual fragments or
105 clinically insignificant residual fragments (CIRF) <4mm [16]. For logistic regression,
106 this outcome was coded as: 1 = stone-free/CIRF <4 mm, and 0 = CIRF ≥4mm.

107 The main outcome was SFR post-RIRS, determined by non-contrast CT KUB. CT
108 KUB scans were interpreted by institutional radiologists as per routine clinical
109 practice. Although formal blinding to stenting status was not implemented, the
110 radiologists were not involved in clinical care decisions, reducing the risk of
111 assessment bias. Secondary outcomes were success of UAS insertion, operating time,
112 LOS, and the effect of preoperative stenting on these measures.

113 Data was analysed using SPSS 27. Continuous variables were assessed for normality
114 using Shapiro-Wilk test. Normally distributed variables were presented as mean ±
115 standard deviation, whereas non-normally distributed variables were reported as

116 median with interquartile range (IQR). Categorical variables were presented as
117 frequencies and percentages. For comparison, normally distributed variables were
118 compared using the independent t-test, and non-normally distributed variables were
119 compared using the Mann Whitney U test. Categorical variables were compared using
120 the Chi-square test or Fisher's exact test, whichever appropriate. In order to find
121 independent SRF predictors, binary logistic regression was carried out with stepwise
122 forward conditional method. The dependent variable was SFR, coded as 1 = stone-
123 free/CIRF <4mm and 0 = residual fragments $\geq$ 4mm. Covariates involved were stone
124 size, HTN, success of access sheath insertion, location of the stone, operative time,
125 LOS, DM, ischemic heart disease (IHD) and smoking history. $P < 0.05$ was considered
126 statistically significant.

128 Results

129 Of the 217 patients, 102(47%) were in group A; 65(66.7%) males and 37(33.3%)
130 females with mean age 41.16 ± 12.96 years. There were 115(53%) patients in group B;
131 74(69.6%) males and 41(30.4%) females with mean age 43.30 ± 13.66 years ($p > 0.05$).
132 Gender distribution, BMI, comorbidities, smoking history, family history of
133 urolithiasis, preoperative eGFR, and stone size showed no significant differences
134 between the groups ($p > 0.05$). However, residential status varied significantly
135 ($p = 0.008$), with a higher proportion of semi-urban dwellers in group B (Table 1).

136 Stone laterality did not differ significantly between the groups ($p = 0.117$), although a
137 linear-by-linear association suggested a possible trend ($p = 0.044$). Similarly, the
138 anatomical stone location (renal pelvis, mid-pole, lower pole, upper pole) showed no
139 meaningful intergroup differences ($p = 0.769$) (Table 2).

140 A highly significant difference was observed in UAS insertion success in favour of
141 group A ($p < 0.001$). Operative time between the groups was not significantly different
142 ($p = 0.522$). In contrast, LOS was significantly shorter in group A compared to group B
143 ($p = 0.002$). A higher SFR was observed in group A 94 (92.2%) out of 102 patients

compared to group B 96 (83.5%) out of 115 patients, but the difference was not statistically significant ($p>0.05$) (Table 2).

Binary logistic regression model showed that a smaller stone size was strongly associated with achieving SFR ($p<0.001$), while HTN emerged as a negative predictor ($p=0.049$) (Table 3). No other demographic, clinical, or intraoperative variable improved the model's predictive performance.

Multicollinearity diagnostics demonstrated no concerning inter-variable correlations, with all variance inflation factors (VIF) being <2.0 and tolerance values >0.60 . The final model was statistically significant ($p<0.001$), accounting for 23.6% of the variance in stone-free rate (Nagelkerke $R^2=0.236$), and correctly classified 190 (87.6%) (Supplementary Table 1).

Discussion

The current study sought to compare postoperative outcomes of RIRS with UAS in patients who did and did not receive preoperative ureteral stenting. The results did not show any statistically significant differences between the groups in terms of age, gender distribution, BMI, stone diameter, preoperative renal function and comorbidity status. Although the stented group demonstrated a trend towards better SFR, the results were not statistically significant. To put the results in perspective, they were compared with existing literature¹⁷⁻²⁰ (Table 4).

The current results indicate that although studies, such as Assantachai et al. [17] demonstrated marginally better SFR in the pre-stented group, the findings were not statistically significant. On the contrary, Sari et al.[18] demonstrated significantly better SFR in the UAS group. However, this was not the case in the pre-stenting group because pre-stenting was less commonly performed in the UAS group. The study by Singh et al. [19] and the meta-analysis done by Amorim et al. [20] further emphasised the point that neither UAS nor pre-stenting improved SFR or operative time. These comparisons, when considered in total, further support the notion that while preoperative stenting may theoretically aid in the process of ureteral dilation and the

easier passage of UAS in the RIRS procedure, the routine use of preoperative stenting in UAS-based RIRS should be tailored on an individual basis. The current prospective study, using a real-world population and a standardised UAS-based RIRS procedure, further supports the notion that preoperative stenting in the context of UAS-based RIRS does not impact clinical outcomes by demonstrating similar results regardless of preoperative stenting status.

The strengths of the current study include its prospective design, standardised procedure, and the presence of a control group. However, the study does have its limitations that include the fact that it was single-centre research and did not assess long-term outcomes in the context of stone recurrence. Additionally, the study did not assess the cost-effectiveness and the impact on postoperative pain. Future research in the field would benefit by conducting multicentre randomised controlled trials (RCTs), cost-effectiveness analyses, and assessing the impact on the quality of life and postoperative pain.

Conclusion

Preoperative stenting of the ureter improved access sheath insertion success, and reduced LOS in RIRS. Although there was no significant difference in SFR, smaller stone size and absence of HTN were independent predictors for SFR.

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Table 1: Baseline characteristics of the study population (n=217).

Variable	Stented Group (n = 102)	Non-Stented Group (n = 115)	p-value
<i>Age (years)</i>	41.16 ± 12.96	43.30 ± 13.66	0.240 ¹
Gender			
- Male	65 (66.7%)	74 (69.6%)	0.924 ²
- Female	37 (33.3%)	41 (30.4%)	
BMI	24.0 (4.0)	24.0 (4.0)	0.431 ³
Diabetes Mellitus	10 (9.8%)	11 (9.6%)	0.953 ²
Hypertension	16 (15.7%)	20 (17.4%)	0.736 ²
Smoking History >5 pack-years	13 (12.7%)	22 (19.1%)	0.202 ²
Ischemic Heart Disease	1 (1.0%)	2 (1.7%)	0.633 ²
Residential Status			
- Rural	48 (47.1%)	51 (44.3%)	0.008 ²

- Urban	46 (45.1%)	38 (33.0%)	
- Semiurban	8 (7.8%)	26 (22.6%)	
Family History of Stones	19 (18.6%)	20 (17.4%)	0.813 ²
Stone Size (cm)	1.6 (0.7)	1.7 (0.6)	0.273 ³
Pre-op eGFR	78.5 (40.0)	87.0 (32.0)	0.247 ³

¹Independent samples t test (mean $\pm$ standard deviation [SD]), ²Chi square test (n (%))³, Mann Whitney U test (median (interquartile range [IQR])).

BMI: Body mass index, eGFR: Estimated glomerular filtration rate.

Table 2: Intergroup comparison of clinical and operative parameters.

Variable	Stented Group (n = 102)	Non-Stented Group (n = 115)	p-value
Side of Stone Involvement			
- Left	52 (51.0%)	43 (37.4%)	0.117 ¹
- Right	42 (41.2%)	58 (50.4%)	
- Bilateral	8 (7.8%)	14 (12.2%)	
Stone Location			
- Renal Pelvis	40 (39.2%)	44 (38.3%)	0.769 ¹
- Mid-Pole	32 (31.4%)	32 (27.8%)	
- Lower Pole	18 (17.6%)	27 (23.5%)	
- Upper Pole	12 (11.8%)	12 (10.4%)	
Access Sheath Insertion Success	102 (100%)	77 (67.0%)	<0.001 ¹
Operative Time (minutes)	69.5 (25.0)	70.0 (15.0)	0.522 ²
Hospital Stay (days)	1.0 (0.0)	1.0 (1.0)	0.002 ²
Stone Free Status (CT KUB)			
- Stone Free	94 (92.2%)	96 (83.5%)	0.053 ¹
- Residual Fragments (<4 mm)	8 (7.8%)	19 (16.5%)	

¹Chi square test (n [%]), ²Mann Whitney U test (median [interquartile range [IQR]]).

CT: Computed tomography, KUB: Kidney-ureter-bladder,

Table 3: Binary logistic regression identifying predictors of stone free rate (SFR) post-RIRS.

Predictor Variable	B (SE)	Wald χ^2	p-value	Odds Ratio (Exp(B))	Interpretation
Stone size (in cm)	-3.192 (0.782)	16.666	<0.001	0.041	Smaller stones $\rightarrow$ higher SFR
Hypertension (Yes vs No)	-0.971 (0.493)	3.877	0.049	0.379	HTN reduces odds of stone-free rate

RIRS: Retrograde intrarenal surgery, HTN: Hypertension. **Model summary:** Nagelkerke $R^2 = 0.236$, -2 log likelihood = 134.149.

298 **Table 4: Comparison of findings with relevant published literature.**

Study	Study Design & Sample	Pre-stenting Done	SFR (Pre-stented vs Non-stented)	Operative Time	Conclusion
Our Study (2025)	Prospective observational study, two-group comparison, n=217	Yes (47%)	92.2% vs 83.5% (p = 0.053)	Comparable between groups	Pre-stenting improved access sheath success and reduced hospital stay; SFR improvement was not statistically significant.
Assantachai et al. (2023) [17]	Retrospective, n=166	Yes (48%)	90.7% vs 79.3% at 6 months (p = 0.078)	40 mins both groups (p = 0.848)	Pre-stenting may reduce injury risk; SFR better but not statistically significant.
Singh et al. (2023) [18]	RCT, n=81	All pre-stented	78.1% vs 80% (UAS vs no UAS; p = 0.829)	Similar (p = 0.484)	UAS offers no SFR benefit even with pre-stenting.
Sari et al. (2020) [19]	Retrospective, n=1808	4.8% in UAS group	88.2% vs 81.2% (p < 0.001)	Longer with UAS (p < 0.001)	UAS improves SFR, but stenting inversely affects UAS usage.
Amorim et al. (2024) [20]	Meta-analysis (5 RCTs, n=466)	Mixed	No significant SFR difference (RR 1.05, p = 0.10)	NS difference in time (p = 0.36)	UAS reduces infection risk; no SFR benefit.

299 SFR: Stone-free rate, NS: Not significant, RCT: Randomised controlled trial, UAS: Ureteral access
300 sheath.

301 -----
302
303 **Supplementary Table 1: Variables entered into stepwise logistic regression model.**

Variable	Wald	p-value	Entered in Final Model
Stone size (cm)	16.666	<0.001	Yes
Hypertension	3.877	0.049	Yes
Access sheath insertion	1.575	0.210	No
Stone location	2.269	0.519	No
Operative time	0.414	0.520	No
Hospital stay	0.564	0.453	No
Diabetes	2.027	0.155	No
Smoking	0.798	0.372	No

Family history	0.913	0.339	No
Ischemic heart disease	0.351	0.553	No

All the listed variables were included as candidate predictors in the forward stepwise binary logistic regression model. The dependent variable was coded as 1 = stone-free/CIRF <4mm and 0 = residual fragments $\geq$ 4mm. Variables not marked “Yes” were excluded during stepwise selection based on statistical criteria. No multicollinearity concerns were detected (all VIF < 2.0).

CIRF: Clinically insignificant residual fragments, VIF: Variance inflation factor.

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