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Research article

Surgical outcomes of patients who underwent retrograde intrarenal surgery using a ureteral access sheath to manage kidney stones sized 1–2 cm compared between patients who did and did not undergo preoperative ureteral stenting

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ABSTRACT

Objective: To investigate the surgical outcomes of patients who underwent retrograde intrarenal surgery (RIRS) using a ureteral access sheath (UAS) to manage kidney stones sized 1–2 cm compared between patients who did and did not undergo preoperative ureteral prestenting.

Materials and methods: This retrospective cohort study included 166 patients (aged ≥18 years) who underwent RIRS at Siriraj Hospital (Bangkok, Thailand) during February 2015–February 2020. All patients had renal calculi (stone size: 1–2 cm) located within the pelvicalyceal system. 80 and 86 patients were allocated to the prestent and non-prestent groups, respectively. Patient baseline characteristics, renal stone details, operative equipment, stone-free rate (SFR) at 2 weeks and 6 months, and perioperative complications were compared between groups.

Results: All patient baseline characteristics were similar between groups. At 2 weeks after surgery, the overall SFR was 65.1%, and the SFRs in the prestent and non-prestent groups were 73.4% and 59.5%, respectively ($p = 0.09$). At 6 months after surgery, the overall SFR was 80.1%, and the SFRs in the prestent and non-prestent groups were 90.7% and 79.3%, respectively ($p = 0.08$). The incidence of perioperative complications was not significantly different between groups.

Conclusions: There was no significant difference in the SFR between the presenting and non-prestenting groups at both the 2-week and 6-month postoperative time points. There was also no significant difference in intraoperative and postoperative complications between groups. The SFR was higher at 6 months than at 2 weeks in both groups with no additional procedure.

1. Introduction

The benefits of using a ureteral access sheath (UAS) in retrograde intrarenal surgery (RIRS) include shorter operative time, simplified entry/reentry of the ureter, facilitates active extraction of stone fragments, lower intrapelvic pressure during procedure, and eliminates the need for periodic bladder emptying [1–3]. In contrast, use of a UAS can increase the ureteral injury rate and is associated

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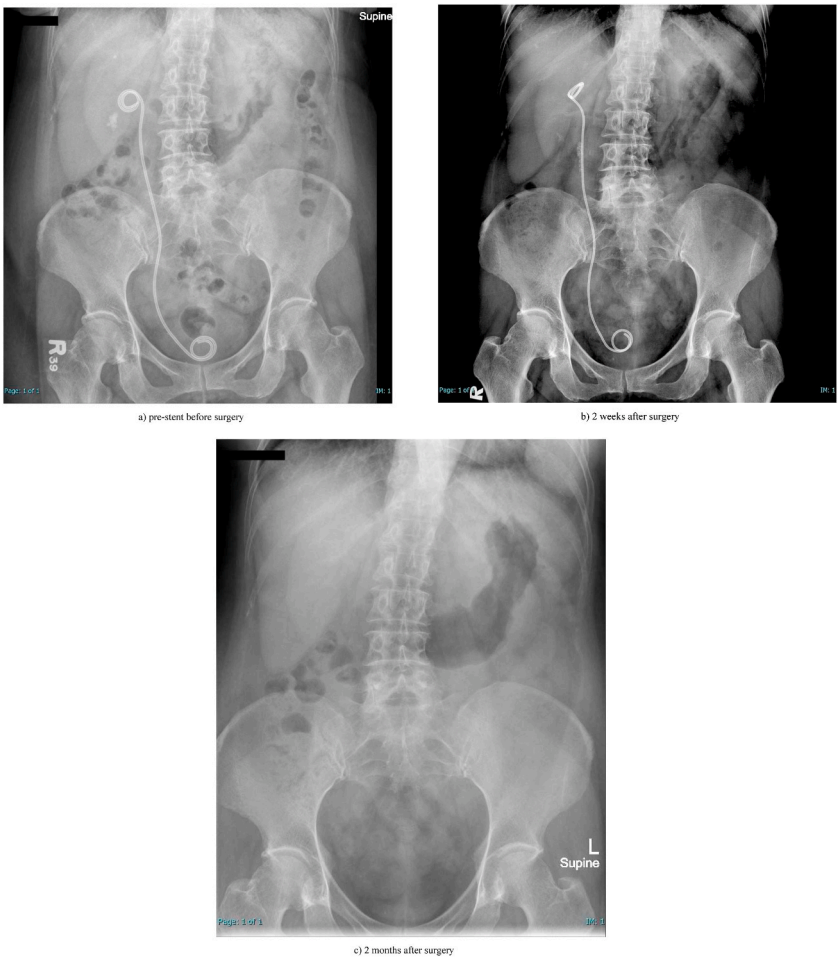
with higher postoperative pain after RIRS when a postoperative ureteral stent is not placed 1.

Preoperative ureteric stenting is primarily used for internal urinary drainage in patients with obstructive renal stones, hydronephrosis, urinary tract infection, and in patients with a need for passive dilatation of the ureter. However, ureteral stents are associated with complications that include infection, encrustation, hematuria, and discomfort caused by tissue irritation. Previous studies reported that preoperative ureteral stenting improves the stone-free rate (SFR) after ureteroscopic lithotripsy; however, this issue is still being debated within the urologic community [4,5]. Accordingly, the aim of this study was to investigate the surgical outcomes of patients who underwent retrograde intrarenal surgery (RIRS) utilizing a ureteral access sheath (UAS) to manage kidney stones sized 1–2 cm (cm) compared between patients who did and did not undergo preoperative ureteral stenting.

2. Material and methods

The study was approved by Siriraj Institutional Review Board. There were 734 patients who underwent RIRS at the Division of Urological Surgery of the Department of Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand during the February 2015 and February 2020 study period. Of those, 118 patients underwent preoperative ureteral stenting, but only 80 of those satisfied our study's enrollment criteria (aged 18 years or older, renal calculi located within the pelvicalyceal system, and stone size 1–2 cm [cm]). All procedures performed by the same experienced surgeon. To retrospectively compare prestented patients with non-prestented patients, we used statistical software to randomly select non-prestented patients from the cohort of non-prestented RIRS patients. In the end, 80 and 86 patients were included in the prestented and non-prestented groups, respectively, for this retrospective chart review. Preoperative ureteral stents were placed for the following reasons: inability to pass UAS or flexible ureterorenoscope, previous operation for renal or ureteral calculi, upper urinary tract infection, or hydronephrosis. Stone size was measured via plain kidney, ureter, bladder (KUB) radiography or non-contrast-enhanced computed tomography (CT). In patients with a single renal calculus, the largest diameter of the stone was recorded at the stone size. In patients with multiple stones, a summation of the largest diameter of each stone was used to quantify the overall stone size. SYNAPSE 5 (Fujifilm Corporation, Tokyo, Japan) was the



a) pre-stent before surgery

b) 2 weeks after surgery

c) 2 months after surgery

Fig. 1. X-ray imaging of pre and post surgery. a) pre-stent before surgery. b) 2 weeks after surgery. c) 2 months after surgery.

radiographic program used to assess stone size.

Before starting the RIRS procedure, antibiotic prophylaxis with third-generation cephalosporins or fluoroquinolones in patients with penicillin allergy was administered intravenously. Patients were positioned in the lithotomy position. Cystoscopy was performed after which a Sensor™ PTFE-Nitinol Guidewire with Hydrophilic Tip (Boston Scientific Corporation, Marlborough, MA, USA) was passed into and through the ureter towards the renal pelvis to serve as a safety guidewire. Under fluoroscopy, a dual lumen catheter was entered into the ureter using the guidewire as a guide. An Amplatz Super Stiff® Guidewire (Boston Scientific) was then entered into the ureter via the second lumen of the dual lumen catheter. The dual lumen catheter was then removed leaving the Sensor™ PTFE-Nitinol Guidewire and the Super Stiff® Guidewire in the ureter. A UAS (11/13 French size [Fr] or 12/14 Fr) was then placed over the Amplatz Super Stiff® Guidewire and passed through the ureter up to the proximal ureter to facilitate access to the kidney. The Amplatz Super Stiff® Guidewire was then removed. Flexible ureteroscopy (fURS) with a holmium: yttrium-aluminum-garnet (Ho: YAG) laser lithotripsy device with a 272-μm laser fiber was used to obliterate the stone(s). The laser lithotripsy technique used (fragment and basketing, dusting, or popcorn) depended on the appearance of the stone. Dusting or popcorn was used for soft stones, and fragment and basketing was used for hard stones. A 1.9 Fr tipless stone basket was used to extract as many residual stone fragments as possible. The final step of the procedure was to remove the UAS, and then carefully inspect the ureter for ureteral injury as the fURS was being withdrawn. The ureteral stent (6 or 7 Fr) was left indwelling in the patient in the vast majority of cases after successful RIRS.

Plain KUB radiography was the most commonly used imaging modality after completion of the procedure as shown in Fig. 1; however, non-contrast-enhanced CT-KUB was performed in cases of non-opaque or semi-opaque stone. SFRs were evaluated at 2 weeks and 6 months after RIRS as early and late follow-up, respectively. Stone-free was defined as an absence of stone fragments or the presence of stone fragments less than 2 mm in diameter.

Complications were categorized into two types: intraoperative and postoperative. Intraoperative complications were described according to endoscopic classification of ureteral wall injury after RIRS using UAS [6] (please see Appendix). Regarding the post-operative complications observed in this study, fever was defined as febrile state with hemoculture that showed no growth, and urosepsis was defined as hemoculture that showed positive growth for bacterial organism. No patients in this study had bleeding that required blood transfusion.

2.1. Statistical analysis

All statistical analyses were performed using PASW Statistics 18.0.0 software (SPSS, Inc., Chicago, IL, USA). Categorical data were compared using chi-square test or Fisher's exact test, and the results are given as number and percentage. Comparisons of continuous data were performed using unpaired *t*-test for normally distributed data, and using Mann-Whitney *U* test for non-normally distributed data. Normally and non-normally distributed data are presented as mean plus/minus standard deviation and median and range, respectively. A *p*-value less than 0.05 was considered statistically significant for all tests.

Table 1
Patient demographic, clinical, and renal stone characteristics compared between the non-prestent and prestent groups.

Variables	Non-prestent group (n = 86)	Prestent group (n = 80)	*p*-value
Age (years), mean ± SD	55.2 ± 12.6	58.3 ± 12.9	0.117
Gender, n (%)			0.566
Male	36 (41.9%)	38 (47.5%)	
Female	50 (58.1%)	42 (52.5%)	
BMI (kg/m^2) Mean ± SD	26.5 ± 4.7	25.2 ± 5.5	0.115
Comorbidities, n (%)			
Diabetes mellitus	24 (27.9%)	18 (22.5%)	0.534
Hypertension	50 (58.1%)	41 (51.3%)	0.462
Dyslipidemia	32 (37.2%)	31 (38.8%)	0.965
Gout	3 (3.5%)	4 (5.0%)	0.712
Coronary artery disease	4 (4.7%)	2 (2.5%)	0.683
Preoperative eGFR, n (%)			0.322
eGFR <60	17 (19.8%)	22 (27.5%)	
eGFR >60	69 (80.2%)	58 (72.5%)	
Kidney side, n (%)			0.302
Right kidney	39 (45.3%)	29 (36.3%)	
Left kidney	47 (54.7%)	51 (63.8%)	
Total stone size (mm), (mean ± SD)	13.6 ± 3.4	13.5 ± 3.8	0.879
Total stone size in lower pole	13.2 ± 3.5	13.1 ± 3.6	0.867
Total stone size in non-lower pole	13.9 ± 3.3	14.1 ± 4.1	0.835
Stone location, n (%)			0.162
Lower pole	38 (44.2%)	45 (56.3%)	
Non-lower pole	48 (55.8%)	35 (43.8%)	

A *p*-value <0.05 indicates statistical significance.
Abbreviations: SD, standard deviation; BMI, body mass index; eGFR, estimated glomerular filtration rate.

3. Results

Patients included in the prestenting group were underwent preoperative stenting for the following reasons: 36% for inability to pass UAS or flexible ureterorenoscope, 25% for previous operation for renal calculi, 16% for previous operation for ureteral calculi, 14% for upper urinary tract infection, 2% for flank pain, 2% for hydronephrosis, and 5% for an unrecorded reason. The median duration of preoperative ureteral stenting of the 80 patients in the prestenting group was 46 days (range: 7–87). Patient demographic, clinical, and renal stone characteristics compared between the non-prestent and prestent groups are shown in Table 1.

None of the variables described in Table 1 were significantly different between the non-prestent and prestent groups. The median stone size in non-prestent group and prestent group was 13.6 mm (mm) and 13.5 mm, respectively ($p = 0.87$). The incidence of calyceal stone in the lower pole was 44.2% in the non-prestent group, and 56.3% in the prestent group ($p = 0.16$).

Only patients completed follow up for 6 months were included in the study. The post-operative imaging was 98% plain x-ray. The pre-operative imaging was 48% CT scan and 52% plain x-ray. Early outcome was evaluated by SFR at 2 weeks after RIRS, and late outcome was evaluated by SFR 6 months after RIRS. Operative data, stone profiles, and clinical outcomes compared between the non-present and present groups are described in Table 2. The mean operative time was the same in both groups (40 min; $p = 0.84$). After RIRS, 100% and 95.3% of patients in the non-prestent and prestent groups, respectively, underwent postoperative ureteral stent placement ($p = 0.091$). The median duration of stenting before stent removal was 22 days and 18 days in the non-prestent and prestent groups, respectively ($p = 0.928$). Calcium stone consisting of mostly calcium oxalate monohydrate was the most common stone composition (34.1% in the non-prestent group *vs.* 49.3% in the prestent group; $p = 0.207$). The UAS size was significantly different between groups (78.1% of the pre-stented group used 12/14 Fr, and 68.8% of the non-prestented group used 11/13 Fr; $p < 0.001$).

The SFRs at 2 weeks after RIRS were 59.5% in the non-prestent group, and 73.4% in the prestent group ($p = 0.087$). At 6 months after RIRS, the SFRs in the non-prestent and prestent groups were 79.3% and 90.7%, respectively ($p = 0.078$). The SFRs in the prestent group were noticeably higher than those observed in the non-prestent group at both follow-up time points; however, neither difference between groups achieved statistical significance. The SFR increased 19.8% in the non-prestent group, and 17.3% in the pre-stent group from the 2-week follow-up to the 6-month follow-up.

Intraoperative and postoperative complications compared between the non-prestent and prestent groups are given in Table 3. Intraoperative complication occurred in 12.6% of the 166 patients included in this study. Intraoperative complication was defined as ureteral wall injury that was graded according to the endoscopic classification of ureteral wall injury after RIRA using UAS [6] that was proposed by Traxer et al. (please see Appendix). The rate of ureteral injury was non-significantly lower in the prestent group (7.5%) than in the non-prestent group (17.4%) ($p = 0.064$), and most injuries in both groups were grade I injury. Fever and urosepsis were defined as postoperative complications. There was no significant difference between groups regarding the incidence of either of these postoperative complications. At the 6-month follow-up time point, there was no detectable ureteric stricture or new incidence of hydronephrosis or hydroureter in any study patient.

Table 2
Operative data, stone profiles, and clinical outcomes compared between the non-present and present groups.

Variables	Non-prestent Group (n = 86)	Prestent Group (n = 80)	*p*-value
Operative time (minutes), median (range)	40 (15–105)	40 (10–120)	0.848
Ureteral access sheath size (Fr)	(n = 86)	(n = 73)	***<0.001***
11/13	59 (68.6%)	16 (21.9%)	
12/14	27 (31.4%)	57 (78.1%)	
Postoperative stent (Fr)	(n = 77)	(n = 64)	0.091
6 Fr	77 (100%)	61 (95.3%)	
7 Fr	0 (0%)	3 (4.7%)	
Length of hospital stay (days), median (range)	1 (1–26)	1 (1–17)	0.755
Duration of postoperative stenting (days), median (range)	(n = 73) 22 (1–46)	(n = 62) 18 (1–185)	0.928
Major stone composition			0.207
Calcium oxalate monohydrate	29 (34.1%)	37 (49.3%)	
Calcium oxalate dihydrate	16 (18.8%)	10 (13.3%)	
Calcium phosphate	32 (37.6%)	18 (24.0%)	
Non-calcium	8 (9.5%)	10 (13.4%)	
Stone-free rate at 2 weeks	50 (59.5%)	58 (73.4%)	0.087
SFR of lower pole stone	21 (42.0%)	25 (43.1%)	0.876
SFR of non-lower pole stone	29 (58.0%)	33 (56.9%)	0.734
Stone-free rate at 6 months	65 (79.3%)	68 (90.7%)	0.078
SFR of lower pole stone	29 (44.6%)	33 (48.5%)	0.322
SFR of non-lower pole stone	36 (55.4%)	35 (51.5%)	0.395
Increase in SFR from 2 weeks to 6 months	19.8%	17.3%	0.478

A p-value <0.05 indicates statistical significance.
Abbreviations: Fr, French size; SFR, stone-free rate.

Table 3
Intraoperative and postoperative complications compared between the non-prestent and prestent groups.

Complications	Non-prestent group (n = 86)	Prestent group (n = 80)	*p*-value
Intraoperative complications			
Overall intraoperative complication	15 (17.4%)	6 (7.5%)	0.064
Ureteric injury grade I	9 (10.5%)	2 (2.5%)	0.059
Ureteric injury grade II	5 (5.8%)	3 (3.8%)	0.721
Ureteric injury grade III	1 (1.2%)	1 (1.3%)	1
Postoperative complications			
Overall postoperative complication	26 (30.2%)	14 (17.5%)	0.070
Clavien-Dindo Classification Grade 1	24 (27.9%)	11 (13.8%)	0.036
Clavien-Dindo Classification Grade 3 A	2 (2.3%)	3 (3.8%)	0.673

A p-value <0.05 indicates statistical significance.

4. Discussion

RIRS is a widely used treatment for renal calculi for reasons. The SFRs of RIRS were reported to be comparable to those after percutaneous nephrolithotomy (PCNL), and higher than those after extracorporeal shockwave lithotripsy (ESWL) in patients with small to medium size stones. RIRS is also less invasive and is associated with lower morbidity compared to PCNL; however, PCNL is more commonly used to treat larger stones with a higher risk of major complication [7,8]. Although there are several studies in URS that reported the SFR of renal and ureteral calculi [8–10], data specific to the effect of preoperative ureteral stent on the SFR remains scarce, and especially in renal stone size 1–2 cm [4,11–15]. Jones et al. [11,16] [[,16] were the first to report insertion of a ureteral stent after failure of initial URS to be significantly associated with improved success rate of calculus extraction by second URS. Subsequent studies that were conducted to confirm the results reported by Jones et al. reported similar results [4,11–15]. However, most of those studies reported the SFR specific to ureteral stone or small renal stones [4,11,13–15]. The effect of preoperative ureteral stent on SFR in large renal stone (diameter: 1–2 cm) after RIRS procedure has not yet been reported.

No significant differences were found for any of the evaluated patient and renal stone characteristics listed in Table 1. Previous studies reported stone size and location to be the most significant predictors of SFR after RIRS [17,18]. As shown in Table 2, the UAS size used in the prestent group was significantly larger than that used in the non-prestent group ($p < 0.001$), which corresponds with the finding reported by Hyeong et al. [5]. This finding may be the result of passive ureteral dilation from preoperative ureteral stent [5]. Although the use of a larger UAS improved accessibility, there was still no significant difference in SFRs between groups. We prefer the use of UAS size 11/13 Fr because there is no difference in SFRs or complications. In addition, intrarenal pressure during RIRS was reported not to be significantly different between 11/13 Fr and 12/14 Fr UAS [19]. The benefit of a larger UAS size is to increase the flow of irrigation fluid during the procedure [19]. There was also no significant difference in the ureteral injury rates when using a larger sized UAS [20].

The SFRs reported in the literature vary widely (54–96%) for renal stones sized 1–2 cm after a single session of RIRS [18]. This observed difference in rates may be due to differences in how 'stone-free' was defined, and differences in the imaging method used during follow-up. Previous studies reported a residual stone size of 4 mm [21] and 2 mm [22] to be clinically significant residual stone. Imaging modalities for detecting stones include plain radiography, ultrasound, and CT scan, and each of these methods has a different sensitivity and specificity [23]. Plain radiography and ultrasound have lower sensitivity (48–63%) for overall size of renal stone, so there is a higher likelihood that they could miss a small residual stone [23]. Kanno et al. reported that the sensitivity of plain radiography and ultrasound decreased as the size of the renal stone became smaller. For stone size $\leq$5 mm, the sensitivity of plain KUB and ultrasound were 12% and 78%, respectively [24]. CT scan has a higher sensitivity and specificity, but the patient's increased exposure to radiation makes the use of plain radiography or ultrasound more favorable. In this study, the overall SFR at 2 weeks and 6 months of follow-up was 73.4% and 90.7% in the prestent group, and 59.5% and 79.3% in the non-prestent group – all respectively, which translates to a 17.3–19.8% increase in SFR after a longer period of follow-up. This result suggests that there is no need for additional intervention to remove residual fragments during the first 6 months after RIRS. Moreover, our study defines the SFR as $\leq$2 mm of residual stone size, which is lower than the sizes reported from other studies [11,12].

Hyeong et al. [5] and Sung et al. [25] both reported that preoperative ureteral stenting was not significantly associated with stone clearance. However, Netsch et al. [11] and Kawahara et al. [12] both found that preoperative ureteral stenting improved the SFRs after RIRS. This difference among studies may be due to differences in knowledge, technology, and instruments that were available at the time these studies were conducted.

In our study, the SFRs at 2 weeks after RIRS were not significantly different between the prestent and non-prestent groups (73.4% *vs.* 59.5%, respectively; $p = 0.087$). The SFRs at 6 months after surgery were also not significantly different between the non-prestent and prestent groups (79.3% *vs.* 90.7%, respectively; $p = 0.078$). This result is in agreement with Bal et al. [26] who reported that preoperative ureteral stenting before RIRS may not benefit the one-month postoperative SFR [26]. Interestingly, we found that the SFR in both groups improved with a longer duration of follow-up with no additional procedure. Specifically, the SFR increased 19.8% in the non-prestent group, and 17.3% in the pre-stent group from the 2-week follow-up to the 6-month follow-up.

There was no significant difference in overall intraoperative or postoperative complications between the prestent and non-prestent groups ($p = 0.064$ and $p = 0.070$, respectively), which was also reported from previous studies [11–13]. Most cases of ureteral injury in

this study were grade I injury. The incidence of ureteral injury resulting from UAS insertion was lower in the prestent group (7.5%) than in the non-prestent group (17.4%), but there was no significant difference between groups. It should also be noted that a larger sized UAS could be used in the pre-stented group (12/14 Fr) than the size that could be used in the non-prestented group (11/13 Fr). Traxer et al. [6] reported that the incidence of ureteral injury grade III can be decreased by prestenting. Our results were unable to support this assertion because the incidence of grade III injury was too low in our study.

4.1. Limitations

This study has some mentionable limitations. First, the retrospective design of our study rendered it vulnerable to missing or incomplete data and to certain biases. Second, our data was collected from a single center. Third, our center is a university-based national tertiary referral center, which is routinely referred cases that are thought to be untreatable at other levels of care. This factor should be taken into consideration when considering generalizing our findings to other levels of care.

5. Conclusions

The results of this study revealed no significant difference in the SFR between the presenting and non-prestenting groups at both the 2-week and 6-month postoperative time points. There was also no significant difference in intraoperative and postoperative complications between groups. The SFR was higher at 6 months than at 2 weeks in both groups with no additional procedure.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper

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