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The effect of optical dilatation before retrograde intrarenal surgery on success and complications: Results of the RIRSearch group study

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Abstract

Aim: The guidelines propose optical dilatation before retrograde intrarenal surgery (RIRS), but there are currently no evidence-based studies concerning the impact of optical dilatation with semirigid ureteroscopy (sURS). The aim of this study was to evaluate the effect of optical dilatation through sURS prior to the RIRS procedure on the success and complications of RIRS.

Methods: A total of 422 patients were included in the retrospective multicentre study. The patients were divided into two groups according to whether sURS was to be performed. Patients' demographics, stone parameters and operative outcomes were compared. Surgical success was defined as no or up to 3-mm residual stone fragments without the need for additional procedures. The independent predictors for surgical success were determined with a multivariable logistic regression model. Results: Of the 422 patients, 133 (31.5%) were in the sURS group and 289 (68.5%) were in the non-sURS group. Stone characteristics and patients' demographics were similar between the groups. Operation time in the sURS group was significantly longer (compared with the non-sURS group, P < .0001). A ureteral access sheath (UAS) could not be placed in four (3.0%) patients in the sURS group, nor in 25 (8.7%) patients in the non-sURS group (P = .03). Compared with the non-sURS group, the intraoperative complication rate was lower in the sURS group (14 [4.8%] vs 1 [0.8%], P = .04). The surgical success rate was higher in the sURS group (P = .002). Nevertheless, sURS had no independent effect on surgical success. We found two independent predictors for surgical success rate: stone number (P < .0001, OR:2.28) and failed UAS placement (P = .035, OR:3.49).

Conclusions: Optical dilatation with sURS before RIRS increases surgical success by raising the rate of UAS placement and reducing the rate of intraoperative complications. We suggest that this method can be routinely applied to patients who have not been passively dilated with a JJ stent.

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1 | INTRODUCTION

Improvements in surgical techniques and endourological devices over recent years have led to significant changes in treatment modalities for kidney stones. Among these, retrograde intrarenal surgery (RIRS) is now considered one of the first-line treatment options, yielding high stone-free rates and lower morbidity for renal calculi, especially up to 2 cm.^{1,2} In the classical application of RIRS, the use of a ureteral access sheath (UAS) can provide significant advantages by decreasing intra-renal pressure, improving visibility, and allowing easy insertion of the endourological equipment into the collecting system. 1,3 However, in some patients, the placement of a UAS is quite difficult. Several strategies are suggested to allow easy insertion of a UAS during RIRS. Some authors have defended routine stent placement before RIRS to provide passive ureteral dilatation. 1,4 Despite its effectiveness and reliability, this method requires a two-stage procedure. The other option, active ureteral dilatation performed by balloon or coaxial dilator before UAS, can cause significant ureteral injury. 1,5 On the other hand, for the past 10 years EAU guidelines have recommended doing optical dilatation with semirigid ureteroscopy (sURS) before RIRS to facilitate the process.^{6,7}

Semirigid ureteroscopy provides optical ureteral dilatation with easier ureteral access and inspection of upper urinary tract anatomy for possible pathologies such as stones, strictures, or tumours. In addition, ureteral diameter and compliance can be evaluated to select the proper UAS size. ^{5,8} However, the effects of optical dilatation on the success and complications of RIRS have not yet been investigated. In this multicentre study, we aimed to evaluate the effects of optical dilatation through sURS on the surgical success and complication rates of RIRS.

2 | METHODS

The present study was approved by the Institutional Ethics Committee of Canakkale Onsekiz Mart University, Faculty of Medicine (Approval number: 26.02.2020/2019-04). A total of 515 patients who had undergone RIRS for renal and upper ureteral stones between February 2016 and January 2020 at four referral centres in Turkey were included in this study. All operations were carried out by senior surgeons with a minimum of five years of experience at these centres. Patients' characteristics including age, gender, the side and size of the stone, body mass index, previous stone treatment history and operative outcomes were entered into each centre's database retrospectively. Patients with incomplete records and/or known renal anatomical abnormalities were excluded from the study. Patients requiring preoperative or intraoperative active or passive ureteral dilatation and undergoing ipsilateral ureteral surgery were also excluded. The remaining 422 patients were included in this study.

All patients underwent a preoperative radiologic evaluation with non-contrast computed tomography (NCCT). Stone characteristics

What's known

One of the most important steps of retrograde endoscopic surgery for renal and upper ureteral stones is ureteral access sheath (UAS) placement. For the past ten years EAU guidelines have recommended doing optical dilatation with semirigid ureteroscopy (sURS) before RIRS to facilitate the process. However, the effects of optical dilatation on RIRS success and complications have not yet been investigated. What's new We found that facilitating UAS placement and leading to a low complication rate, optical dilatation with semirigid ureteroscopy before surgery may increases the success rate of surgery.

were recorded from NCCT findings. Stone size was determined by the largest diameter of the main stone. The mean Hounsfield unit was calculated using the elliptical region of interest incorporated into the largest stone area in an axial image of NCCT.⁹

The patients were divided into two groups based on the use of sURS. Patients' demographics and operative outcomes were compared between groups. Intraoperative and postoperative surgical complications were noted. The primary outcome was to define whether optical ureteral dilatation with sURS before the procedure provides high surgical success as well as a low complication rate. The secondary outcome was to evaluate independent predictors that could affect surgical success.

2.1 | Surgical technique

Written informed consent was obtained from all the patients. A retrograde pyelography was performed in all patients to control the entire renal collecting system. A 0.035-inch safety guidewire was placed.

In group 1 (sURS group), a second hydrophilic guidewire was inserted into the ureteral orifice through the sURS's (8f or 9f Fr, Karl Storz, Rietheim-Weilheim, Germany) working channel. A semirigid ureteroscope was gently passed between these two guidewires ("railroad" technique). The optical ureteral dilatation was done with sURS, and the entire ureter was assessed for anatomy, additional pathologies and calibration of the ureter. Then, a UAS of an appropriate diameter was placed just below the ureteropelvic junction for renal stones and just below the stone for upper ureteral stones under fluoroscopic guidance.

In group 2 (non-sURS group), the UAS was inserted directly by gliding over the working guidewire. First, a 10-12 f or an 11-13 f UAS was tried. If these sizes were unable to pass to the collecting system or there was stenosis in the ureter during sURS (for group 1), a smaller UAS (9.5-11.5 Fr Flexor, Cook Urological, Spencer, IN) was tried under fluoroscopic control. If all attempts failed, insertion of a bare flexible URS (fURS) was tried over guidewire. If this attempt

Demographic and clinical data

was unsuccessful, the procedure was stopped, a JJ stent was placed and the patient was scheduled for reoperation after three or four weeks.

After the UAS was placed, renal stones were fragmented by a holmium:YAG laser. Laser energy and pulse frequency were varied based on stone burden and density. If possible, lower pole stones were repositioned into the upper or middle calyx. Stone fragments over 2-3 mm were extracted by a nitinol basket catheter. A JJ stent was usually left in place according to surgeon preference.

A urinary ultrasound and KUB radiography were performed in the follow-up visit the first month after surgery. An NCCT was performed in suspicious and necessary cases. Stone-free status was defined as no residual fragments or the presence of residual fragments up to 3 mm. Surgical success was defined as patients' achievement of stone-free status after a single lithotripsy session without the need for additional sessions or ancillary procedures.

2.2 | Statistical analysis

All statistical tests were performed using SPSS Statistics Version 24 (IBM, Armonk, NY, USA) software. The sample mean was used to determine the average of collected data as quantitative variables met the normal distribution; otherwise, the sample median was used. A chi-square test was performed for nominal variables in the groups. A Student's t test was applied to allow group comparison when the normality assumption was satisfied for both groups. If the normality assumptions were not satisfied for either group or both groups, the equivalent nonparametric Mann-Whitney U test was applied.

Binomial logistic regression was then performed analysing the statistically significant univariate factors. Predictors that obtained significance for surgical success were entered into a multivariable logistic regression model to determine the independent predictors.

3 **RESULTS**

The study consisted of 422 consecutive patients (133 in group 1; 289 in group 2) that met the inclusion criteria. Of these, 179 (42%) were females and 243 (58%) were males, with a mean age of 48.8 ± 14 (14-80) years. Patients' demographics, baseline stone status and characteristics and operative outcomes are presented in Table 1.

Group 1 (sURS group) and group 2 (non-sURS group) patients' comparisons are also listed in Table 2. There was no statistically significant difference between the two groups in terms of stone or patient characteristics. However, the mean operation time was significantly longer in the sURS group (87.1 \pm 37min vs 67.3 \pm 27 min, P < .0001). Fluoroscopy times were similar between the groups (P = .53). The UAS was unable to be placed in four (3.0%) patients in the sURS group and 25 (8.7%) patients in non-sURS group (P = .03). In the non-sURS group a fURS was unable to be inserted through a working guidewire in two patients (0.7%) whose UASs were unable to be placed as well. The JJ stent was placed and reoperation was

TABLE 1 Demographic and clinical data						
Characteristic	Number					
Patients, n	422					
Age, mean \pm SD (range)	48.82 ± 14.0 (14-80)					
Gender						
Male, n (%) 243 (57.6%)						
Female, n (%) 179 (42.4%)						
BMI (kg/m ²), mean \pm SD 27.16 \pm 4.4						
Side						
Right, n (%)	214 (50.7%)					
Left, n (%)	208 (49.3%)					
Stone burden						
Stone size (mm), mean \pm SD (range) 13.45 \pm 5.4 (4-35)						
Stone number, mean \pm SD (range)	1.56 ± 0.8 (1-6)					
Multiple stone rate, n (%)	180 (42.7%)					
Stone density(HU), mean \pm SD	1026 ± 327					
Localisation						
Upper calyx, n (%) 24 (5.0%)						
Middle calyx, n (%)	35 (7.3%)					
Lower calyx, n (%)	135 (28.3%)					
Pelvis, n (%)	184 (38.6%)					
Proximal ureter, n (%)	99 (20.8%)					
Operation time (min), mean \pm SD (range)	69.21 ± 26.5 (20-150)					
Fluoroscopy time (s), mean \pm SD	$14.33 \pm 27.2 (0-256)$					
Surgical success rate, n (%)	369 (87.4%)					
Semi-rigid URS usage, n (%)	133 (31.5%)					
Access sheath usage, n (%)	n usage, n (%) 393 (93.1%)					
Complication rates	n rates 179 (42.4%)					
Intraoperative, n (%)	15 (3.6%)					
Postoperative, n (%)	28 (6.6%)					

planned for these patients. While the surgical success was 94.7% in the sURS group, it was 84.1% in the non-sURS group, and this was statistically significant (P = .002). The intraoperative complication rate was lower in the sURS group than in the non-sURS group (1 [0.8%] vs 14 [4.8%], P = .04). In the sURS group, the stone could not be properly visualised in one (0.8%) patient due to intraoperative bleeding. The complications observed in the non-sURS group included eight (2.7%) mucosal injuries requiring stent insertion, two (0.6%) postoperative prolonged haematuria, two (0.6%) collecting system perforations requiring JJ stent placement, one (0.3%) inability to reach stone and one (0.3%) converted to percutaneous nephrolitomy in the same session. Although postoperative complications were lower in the sURS group compared to the non-sURS group, this was not statistically significant (5 [3.8%] vs 23 [8.0%], P = .10). The postoperative complications for the sURS group were fever requiring antibiotics (n = 2, 1.5%), renal colic requiring analgesic treatment (n = 2, 1.5%), gross haematuria not requiring transfusion (n = 1, 0.7%). In the non-sURS group, postoperative complications included fever requiring antibiotics (n = 7, 2.4%), renal colic requiring

TABLE 2 Comparison of groups with and without semi-rigid URS

URS			
Characteristic	Semi-rigid URS (+)	Semi-rigid URS (-)	P value
Number (%)	133 (31.5%)	289 (68.5%)	
Age, mean \pm SD	47.9 ± 14.7	48.8 ± 13.9	.59
Gender			
Male, n (%)	81 (60.9%)	162 (56.1%)	.35
Female, n (%)	52 (39.1%)	127 (43.9%)	
BMI, mean \pm SD	26.6 ± 2.6	27.3 ± 4.5	.10
Side			
Right, n (%)	73 (54.8%)	143 (49.5%)	.32
Left, n (%)	60 (45.2%)	146 (50.5%)	
Stone size (mm), mean \pm SD (range)	13.0 ± 5.5 (4-35)	13.7 ± 5.3 (4-32)	.22
Stone density (HU), mean \pm SD	977 ± 350	1048 ± 314	.08
Stone number, mean \pm SD	1.67 ± 0.97	1.56 ± 0.79	.22
Localisation	163	314	
Upper calyx, n (%)	8 (5%)	16 (5%)	
Middle calyx, n (%)	11 (7%)	24 (7%)	
Lower calyx, n (%)	42 (26%)	93 (30%)	.53
Pelvis, n (%)	74 (45%)	110 (35%)	
Proximal ureter, n (%)	28 (17%)	71 (23%)	
Failed UAS placement, n (%)	4 (3%)	25 (8.7%)	.03
Operation time (min), mean \pm SD	87.11 ± 36.8	67.29 ± 27.4	<.0001
Fluoroscopy time (s), mean \pm SD	11.09 ± 12.9	13.88 ± 28.9	.53
Surgical success rate, n (%)	126 (94.7%)	243 (84.1%)	.002
Complication rate			
Intraoperative, n (%)	1 (0.8%)	14 (4.8%)	.04
Postoperative, n (%)	5 (3.8%)	23 (8%)	.10

Abbreviations: BMI, body mass index, $kg/m^2;\, UAC,\, ure teral \, access sheath.$

Bold indicates P < .05

analgesic treatment (n = 10, 3.4%), gross haematuria not requiring transfusion (n = 5, 1.7%) and urosepsis (n = 1, 0.3%).

The results of univariate analysis of the factors affecting surgical success are presented in Table 3. Although surgical success was determined to be significantly affected by the optical dilatation through sURS, it was not significant in multivariate analysis (in univariate analysis: P = .002, in multivariate analysis: P = .179). We found two independent factors predicting surgical success in multivariate analysis: stone number (P < .0001, odds ratio: 2.28 and 95%

CI [1.48-3.49]) and failed UAS placement (P = .035, odds ratio: 3.49 and 95% CI [1.04- 11.14]); (Hosmer-Lemeshow test: P = .378).

4 | DISCUSSION

This study carried out the first research investigating the impact of optical dilatation with sURS on the operative outcomes of RIRS. Our study reveals two important issues regarding the use of sURS in patients undergoing RIRS. First, when using sURS, the UAS is more easily placed into the ureter, and the surgical success rate increases. However, it is not an independent predictor of surgical success. Second, intraoperative complication rates are found to be low.

One of the most essential components of RIRS surgery is the placement of the UAS. The use of a UAS positively impacts operative visibility, stone-free rate and operation time without increasing complication rates. 1,3,4,11 Furthermore, several reports have stated that the utilisation of a UAS may have a positive impact on complication rates.^{8,12} However, the insertion of a UAS can sometimes be challenging. The authors recommend various strategies to address this problem. Passive ureteral dilatation made with routine stent placement can be safe and efficient, but this method carries the risks of secondary anaesthesia, an operation and higher costs. 1,11 In addition, stent-related symptoms may be seen, such as prolonged haematuria, flank pain, dysuria and urgency, and patients are usually unwilling to accept presenting when they hear about these side effects.4 Placement of the UAS following active dilatation with a balloon or a coaxial dilator is not routinely recommended because of the risk of significant ureteral injury.^{1,5} For approximately 10 years, the EAU guidelines have advised that sURS before RIRS can be helpful for optical dilatation. Direct visualisation of the whole ureter by semirigid ureteroscopy just before UAS placement not only provides optical dilatation but also allows evaluation of any additional stones, strictures, or tumours in the ureter. 11 Moreover, it can help with evaluation of ureteral compliance and diameter.⁵

Due to a difficult or impassable ureter, the failure rates of primary access of UAS range from 6% to 22% in the literature. 1,5,13 Success rates increase when the appropriate diameter is determined with sURS and when a thinner UAS is used where needed. ⁵ However, the preferred UAS must be narrow enough not to damage the ureter but wide enough to clean the stone and provide intrarenal circulation. The most reliable method to determine appropriate UAS diameter is to evaluate the ureter with sURS. Lima et al recommended a routine sURS for passive ureteric dilatation and selection of the correct UAS size.8 In our study, in accordance with the literature the UAS failure rates were 8.7% in the non-sURS group and 3.0% in the sURS group. Diameters of sURS used in the study were 8 or 9.5 fr in circumference at the distal tip and 12 fr in circumference at the proximal tip. We maintain that the mechanism of cascading diameter increase dilates the intramural ureter, the narrowest and least elastic part of the ureter, without damage (see Figure 1).

Despite all these advantages of the UAS, there are some drawbacks. One of these is deterioration of ureteral blood flow. Lallas

TABLE 3 Comparison of surgical success and non-surgical success patients

	Yes		Univariate analysis P-value	Multivariate analysis		
Surgical success		No		P-value	OR	95% CI
Number	369	53				
Age, mean \pm SD	48.8 ± 14.4	46.38 ± 12.5	0.245	.838		
Male gender, n (%)	211 (57.2%)	32 (60.4%)	0.660	.341		
BMI, mean \pm SD	26.99 ± 3.9	27.32 ± 3.1	0.691			
Stone size, mean \pm SD	13.39 ± 5.2	15.15 ± 6.2	0.333			
Stone density	1017 ± 330	1094 ± 299	0.113			
Stone number, mean \pm SD	1.51 ± 0.8	2.19 ± 1.2	<0.0001	<.0001	2.28	1.48-3.49
Stone right side, n (%)	186 (50.5%)	28 (53.8%)	0.656			
Localisation, n (%)			0.168			
Upper calyx	19 (5.4%)	5 (10.2%)				
Middle calyx	32 (9.1%)	3 (6.1%)				
Lower calyx	86 (24.5%)	11 (22.4%)				
Pelvis	122 (34.8%)	23 (46.9%)				
Proximal ureter	92 (26.2%)	7 (14.3%)				
sURS utilisation, n (%)	126 (34.1%)	7 (13.2%)	0.002	.179		
Failed UAS placement n (%)	17 (4.6%)	12 (22.6%)	<0.0001	.035	3.49	1.09-11.14
Operation time, mean \pm SD	72.4 ± 30.6	80.97 ± 36.1	0.153	.354		
Fluoroscopy time, mean ± SD	14.5 ± 13.9	14.3 ± 28.5	0.981			
Complication rate, n (%)						
Intraoperative, n (%)	7 (%1.9)	8 (%15.1)	<0.0001	.654		
Postoperative, n (%)	20 (%5.4)	8 (%15.1)	0.015	.059		

Abbreviations: BMI, body mass index, kg/m^2 ; sURS, semirigid URS; UAC, ureteral access sheath. Bold indicates P < .05.

et al show transient decreased ureteral blood flow following the use of a UAS in animal models. However, they stated that the compensatory mechanisms of the ureteral wall restored the blood flow of the ureter wall and the integrity of the ureter was preserved. The authors concluded that the use of a UAS with RIRS might be safe, but care must be taken in selecting an appropriate sheath size, and the duration of surgery should not be prolonged because of the risk of stricture development. In our study, the duration of the operation was found to be significantly higher in the sURS group than in the non-sURS group (difference between means: 20 minutes, P < .0001). The extended duration of the operation is thought to have been spent on sURS, but the duration of UAS placement was not measured.

Another drawback associated with UAS is the risk of ureteral injury during entry. Traxer and Thomas prospectively evaluated ureteral injuries secondary to insertion of a 14F UAS.¹⁵ The authors reported that ureteral wall injuries occurred in 46.5% of the patients, and that the most significant predictor of severe ureteral injury was the absence of stenting before RIRS. However, in another prospective study on 2239 patients treated with fURS, Traxer et al found

that UAS usage did not increase the risk of ureteral wall damage, and postoperative infectious complications were reduced. In a retrospective study in which 4500 RIRS procedures were evaluated, intraoperative incidents occurred during 5.2% of the procedures, and overall complications occurred in 18.9%. The authors reported that they encountered grade 2 and 3 ureteral wall lesions in 4.8% of the cases in which a UAS was used. In our study, while one (0.7%) intraoperative complication (inability to reach stone) was observed in the sURS group, 14 (4.8%) intraoperative complications were observed in the non-sURS groups, and the majority of these complications were mucosal injury (57%). We anticipate that optical dilatation with sURS and selection of the correct UAS size reduce the intraoperative complications. Although the rates of postoperative complications in the sURS group were lower, there was no statistical difference between the sURS and non-sURS groups.

Many studies have investigated factors that predict stone-free and surgical success. In some studies, stone size, presence of lower pole calculi, surgical experience, presence of hydronephrosis, and UAS use are significant predictors of RIRS outcomes, while others

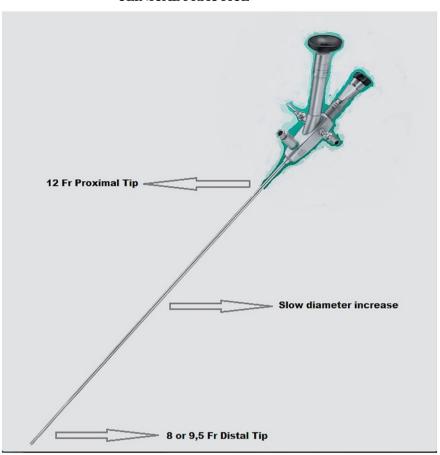


FIGURE 1 While the sURS distal diameter is 8 or 9.5 fr, the proximal diameter is 12 fr with a slow increase in diameter

have only found the number of stones and the number of sites to be significant. $^{17-19}$ Particularly because of the advances in the field of lasers, stone access is the most important factor in making treatment possible. In our series, the mobile lower pole stones were repositioned into the upper or middle calyx. This method may have reduced the impact of localisation on the stone-free rate. In our study, UAS usage and the presence of multiple stones were found as independent predictors for surgical success. Failed surgery rates increased 2.28 times as the number of stones increased and increased 3.49 times when the UAS could not be placed. It is expected that the use of sURS before RIRS increases surgical success by increasing the rate of UAS placement and reducing the rate of intraoperative complications. Finally, we found that the surgical success rate was higher in the sURS group (P = .002). However, our study found that sURS had no independent effects on the surgical success of RIRS.

5 | CONCLUSION

In conclusion, the optical dilatation with sURS, which is also recommended in EAU guidelines, makes a positive contribution to surgical success by facilitating UAS placement and leading to a low complication rate. Although it requires longer surgery time, we recommend this method with acceptable fluoroscopy time, in patients with no previous history of passive dilatation using a JJ stent. However, further randomised prospective studies are needed.

5.1 | Limitations

Our study is retrospective in nature, which may lead to selection bias. We tried to overcome this limitation by including all cases operated for kidney and upper ureteral stones during the study period. The data of four different centres were included in the study. While the multicentric nature of the study increases its quality, doubts about the technique arise from different surgeons operating. However, the surgeons in the different centres had at least five years of experience, and the surgical steps used were similar. Removal of cases using balloons and coaxial dilators from the data ensures consistency in the methods used and shows the direct effect of our technique. Cases involving other conditions were excluded, such as previous same-side ureteroscopy or JJ stent, known renal anatomical abnormalities that may overshadow the effectiveness of sURS for optical ureteral dilatation and selection of the correct UAS size. Other drawbacks of the study are that while operation and fluoroscopy times were calculated, the duration of the UAS procedure was not calculated, and there were no long-term follow-ups or stenosis rates.

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DISCLOSURE

The authors have declared that they have no conflicts of interest.

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