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Original Article

Multi-aspect analysis of ureteral access sheath usage in retrograde intrarenal surgery: A RIRSearch group study

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Abstract *Objective:* To evaluate the effect of ureteral access sheath (UAS) use and calibration change on stone-free rate and complications of retrograde intrarenal surgery (RIRS).
Methods: Data from 568 patients undergoing RIRS for kidney or upper ureteral stones were retrospectively included. Firstly, patients were compared after 1:1 propensity score matching, according to UAS usage during RIRS (UAS used [$^+$] 87 and UAS non-used [$^-$] 87 patients). Then all UAS$^+$ patients (n=481) were subdivided according to UAS calibration: 9.5–11.5 Fr, 10–12 Fr, 11–13 Fr, and 13–15 Fr. Primary outcomes of the study were the success and complications of RIRS.
Results: Stone-free rate of UAS$^+$ patients (86.2%) was significantly higher than UAS$^-$ patients (70.1%) after propensity score matching (p=0.01). Stone-free rate increased with higher caliber UAS (9.5–11.5 Fr: 66.7%; 10–12 Fr: 87.0%; 11–13 Fr: 90.6%; 13–15 Fr: 100%; p<0.001). Postoperative complications of UAS$^+$ patients (11.5%) were significantly lower than UAS$^-$ patients (27.6%) (p=0.01). Complications (8.7%) with 9.5–11.5 Fr UAS was lower than thicker UAS (17.2%) but was not statistically significant (p=0.09). UAS usage was an independent factor predicting stone-free status or peri- and post-operative complications (odds ratio [OR] 3.654, 95% confidence interval [CI] 1.314–10.162; OR 4.443, 95% CI 1.350–14.552; OR 4.107, 95% CI 1.366–12.344, respectively).

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Conclusion: Use of UAS in RIRS may increase stone-free rates, which also increase with higher caliber UAS. UAS usage may reduce complications; however, complications seemingly increase with higher UAS calibration.

1. Introduction

There is a growing body of literature that recognizes the importance of minimally invasive methods such as retrograde intrarenal surgery (RIRS) in the management of renal stone disease [1]. RIRS provides endoscopic treatment of renal stones with the help of fiber-optic, laser, and radiation technologies, without any incision. The American Urology Association and the Endourological Society recommend RIRS as a treatment option in patients with a total non-lower pole renal stone burden lower than 20 mm [2]. There is an increasing trend for RIRS in the treatment of kidney stones [3].

The main challenge faced by surgeons is that the technique is a sophisticated method requiring the use of many different instruments at the same time. One of the auxiliary instruments frequently used during RIRS is the ureteral access sheath (UAS). It is a key instrument in RIRS for reasons such as enabling repeated access to the kidney and regulating intrapelvic pressure by providing irrigation outflow [4]. However, insertion difficulties and UAS-related complications make the use of a UAS controversial.

There is no clear evidence for an overall benefit or harm of UAS use, and much uncertainty still exists about the use of UAS and ideal UAS diameters that facilitate stone extraction and protect against complications. The aim of this study was to evaluate the effects of UAS usage and caliber changes on the success and complication rates of RIRS.

2. Patients and methods

2.1. Patients

Following approval from Çanakkale 18 Mart University Ethics Committee (Number: 18920478—050.01.04-E.2000095544), data from 772 consecutive patients who underwent RIRS between 2014 and 2020 for kidney or upper ureteral stones were reviewed. This retrospective multicenter study was conducted with patients from four different referral centers. Patients whose records had missing data (n=161), who were with renal abnormalities (n=13), who underwent bilateral RIRS (n=9), or had a different simultaneous surgical procedure (for kidney stone or other indications, n=21) in the same session were excluded from study. The final cohort consisted of 568 patients.

The cohort was divided into two groups according to UAS use during RIRS, where Group 1 comprised patients for whom UAS was used during the procedure (UAS^+), and Group 2 comprised patients who underwent RIRS without the use of UAS (UAS^-). In order to avoid any possible mismatch bias, 1:1 propensity score (PS) matching was performed. The PS was calculated with covariates of surgeon, age, stone localization, stone burden, multiple stones, preoperative double-J stent presence, stone density (Hounsfield unit [HU]), and basket catheter use status.

2.2. Peri- and post-operative assessments

All patients were evaluated preoperatively with non-contrast CT. Maximum stone diameters were measured on the axial, coronal, and sagittal planes. Stone volume was calculated with the ellipsoid volume formula (axial diameter $\times$ coronal diameter $\times$ sagittal diameter $\times$ 0.167 $\times$ π) [5]. For patients with multiple stones, stone burden was calculated as the sum of all stone volumes. Stone locations were classified according to CT images as follows: renal pelvis; upper, middle, and lower calyx; and upper ureter, which was defined as the part above the upper limit of the sacroiliac joint. The stone density was evaluated by HU measurement using CT bone windows [6], with the highest HU value used for stone density. Stone-free status was evaluated within postoperative 1 month by kidney, ureter, and bladder imaging, ultrasonography, or CT and second-look flexible ureterorenoscopy, if necessary. Fragments larger than 3 mm were considered residual stones.

2.3. Surgical technique

All patients were provided informed consents for RIRS. As a standard procedure, preoperative urine cultures were obtained, and positive cultures were treated before the operation. All patients received antibiotic prophylaxis with second-generation cephalosporins. All operations were performed under general anesthesia in the lithotomy position. All operations were performed by five different surgeons who have at least 5 years of experience and the surgical technique used was similar. All surgeons prefer to use UAS in their daily clinical practice. If they run into a UAS insertion failure, they continue sheathless by back-loading the scope over a guidewire or postpone the operation with double-J stent insertion.

Two 0.89-mm hydrophilic nitinol sensor guidewires were consecutively inserted in the ureter (one safety guidewire and one for working). The UAS coaxial system was placed under fluoroscopy control on the ureter, over the working guidewire (Group 1). Group 2 was consisted mostly patients whom UAS could not be placed and less patients whom UAS not be preferred to use during RIRS.

First, a 10–12 Fr or a 11–13 Fr UAS was tried. If these sizes were unable to pass to the ureter and the endoscope fit for, a smaller UAS was tried. If all attempts failed or UAS not be preferred to use, the flexible ureteroscope was back-loaded over working guidewire. If this final attempt was unsuccessful, the procedure was stopped and a double-J stent was placed and the patient was scheduled for reoperation after 3 or 4 weeks. Reoperation was done with same steps described above. A 270 μm laser fiber and the standard lithotripsy settings according to stone density were used. At the end of the procedure, a ureteral double-J stent was inserted in the ureter via the guidewire.

2.4. Statistical analyses

Variables were checked with the Kolmogorov-Smirnov normality test. The Mann-Whitney *U* test and Student's *t*-test were used to evaluate the significance of differences in the continuous data according to normality. A Chi-square test with Yates correction and Fisher's exact test were used to evaluate the significance of differences in the categorical data. PS matching was performed to ensure the similarity of the groups in terms of patient and stone characteristics, and then the above tests were applied again. Also, Spearman's correlation analysis was used to identify possible associations. Receiver operating characteristic curves and area under the curve were used to assess the predictive performance of UAS calibration changes. Multivariate analysis (logistic regression) was used to explore the predictive value of UAS-related parameters. Statistical analyses were performed applying a significance level of 0.05 and 95% confidence interval (CI). All analyses were carried out using SPSS software, version 22 (IBM Corp., Armonk, NY, USA).

3. Results

3.1. Patient characteristics

UAS was used during RIRS in 481 patients, whereas 87 patients underwent RIRS without UAS. After 1:1 PS matching, Group 1 consisted of 87 UAS^+ patients, and Group 2 consisted of 87 UAS^- patients. The comparison of preoperative characteristics of the groups before and after PS matching are shown in Table 1. The groups were not significantly different in terms of age, body mass index, or gender. The significant differences between groups in terms of stone burden, localization, stone number, preoperative double-J stent presence, and perioperative basket usage were eliminated with PS matching.

3.2. Operating and postoperative outcomes

All outcomes of RIRS are shown in Table 2. The postoperative complications, stone-free rates, and need for an auxiliary procedure significantly favored the use of UAS both before and after PS matching.

3.3. UAS calibration subgroups

We also evaluated the surgical results according to the UAS calibration that was used during surgery. The UAS calibers were 9.5–11.5 Fr for 69 patients (14.3%), 10–12 Fr for 269 patients (55.9%), 11–13 Fr for 139 patients (28.9%), and 13–15 Fr for four patients (0.8%). Comparisons of perioperative complications and stone-free status according to UAS calibers are shown in Table 3. It was found that perioperative complications developed more frequently with a thicker UAS. However, the difference between the calibration groups did not meet conventional levels of statistical significance (p=0.62). Stone-free rates were significantly higher with a thicker UAS (p<0.001). In the

Table 1 Change in patient characteristics according to access sheath usage status.

Characteristic	Before propensity score matching			After propensity score matching		
	UAS^+	UAS^-	p-Value	UAS^+	UAS^-	p-Value
Patient, *n*	481	87		87	87	
Age, mean±SD, year	48.5±14.3	47.6±13.9	0.66	51.3±13.6	47.6±13.9	0.16
Gender (male), *n* (%)	279 (58.0)	52 (59.8)	0.85	57 (65.5)	52 (59.8)	0.39
BMI, mean±SD, kg/m^2	27.3±4.3	27.1±2.6	0.75	26.4±3.0	27.1±2.6	0.18
Side (right), *n* (%)	241 (50.1)	36 (41.4)	0.13	39 (44.8)	36 (41.4)	0.65
Stone burden, median (IQR), mm^3	577 (237–1133)	189 (119–781)	0.004	221 (132–918)	189 (119–781)	0.22
Stone density, mean±SD, HU	1004±321	1095±398	0.24	1018±330	1095±398	0.37
Localization, *n* (%)			0.01			0.41
Lower calyx	106 (22.0)	26 (29.9)		20 (23.0)	26 (29.9)	
Multiple localization	63 (13.1)	19 (21.8)		17 (19.5)	19 (21.8)	
Others	312 (64.9)	42 (48.3)		50 (57.5)	42 (48.3)	
Multiple stones, *n* (%)	195 (40.5)	47 (54.0)	0.01	41 (47.1)	47 (54.0)	0.57
Preoperative double-J stent, *n* (%)	152 (31.6)	15 (17.2)	0.007	27 (31.0)	15 (17.2)	0.05
Failed SWL for the same stone, *n* (%)	152 (31.6)	35 (40.2)	0.15	25 (28.7)	35 (40.2)	0.15
Perioperative basket usage, *n* (%)	362 (75.3)	30 (34.5)	<0.001	42 (48.3)	30 (34.5)	0.064

BMI, body mass index; IQR, interquartile range; SWL, shock wave lithotripsy; UAS^+, patients had ureteral access sheath during procedure; UAS^-, patients had no ureteral access sheath during procedure; SD, standard deviation; HU, Hounsfield unit.

Table 2 Comparison of peri- and post-operative outcomes according to ureteral access sheath usage status.

Characteristic	Before propensity score matching			After propensity score matching		
	UAS$^+$	UAS$^-$	*p*-Value	UAS$^+$	UAS$^-$	*p*-Value
Operating time[a], min	74.8±30.2	76.9±44.0	0.48	85.2±36.4	76.9±44.2	0.041
Fluoroscopy time[a], s	16.3±78.5	8.1±6.2	0.06	11.3±9.3	8.9±6.1	0.33
Length of hospitality[a], day	1.6±1.9	1.4±0.8	0.90	1.9±1.7	1.4±0.8	0.079
Overall complications[b], *n* (%)	78 (16.2)	26 (29.9)	0.002	16 (18.4)	26 (29.9)	0.08
Perioperative	35 (7.3)	15 (17.2)	0.005	7 (8.0)	15 (17.2)	0.11
Postoperative	47 (9.8)	24 (27.6)	0.008	10 (11.5)	24 (27.6)	0.01
Stone-free rate, *n* (%)	412 (85.7)	61 (70.1)	$<$0.001	75 (86.2)	61 (70.1)	0.01
Auxiliary procedure, *n* (%)	61 (12.7)	30 (34.5)	$<$0.001	9 (10.3)	30 (34.5)	$<$0.001

UAS$^+$, patients had ureteral access sheath during procedure; UAS$^-$, patients had no ureteral access sheath during procedure.
[a] Values are presented as mean ± standard deviation.
[b] All complication rates were calculated patient-wise. If a patient has perioperative and postoperative complications, only one of them was taken into account.

Table 3 Comparison of results according to different UAS calibers.

Characteristic	$<$10—12 Fr UAS	$\geq$10—12 Fr UAS			*p*-Value
	9.5—11.5 Fr	10—12 Fr	11—13 Fr	13—15 Fr	
Overall complications[a], *n*/*N* (%)	6/69 (8.7)	71/412 (17.2)[b]			0.09[c]
Perioperative	4/69 (5.8)	17/269 (6.3)	12/139 (8.6)	1/4 (25)	0.62
Postoperative	4/69 (5.8)	43/412 (10.4)[b]			0.23[d]
Stone-free status, *n*/*N* (%)	46/69 (66.7)	234/269 (87.0)	126/139 (90.6)	4/4 (100)	$<$0.001

UAS, ureteral access sheath.
[a] All complication rates were calculated patient-wise. If a patient has perioperative and postoperative complications, only one of them was taken into account.
[b] Unbalanced distribution of patients to the UAS caliber groups did not allow a caliber group-wise analysis. Therefore, the surgeries were gathered into two supergroups: surgeries with $<$10—12 Fr UAS, and surgeries with $\geq$10—12 Fr UAS.
[c] Fisher's exact test, others Chi-square.
[d] Chi-square test with Yates correction.

post-hoc analysis, there was a significant difference between 9.5—11.5 Fr and 10—12 Fr UAS ($p<0.001$). However, the difference between all other groups was not statistically significant ($p=0.23$).

Unbalanced distribution of patients to the UAS calibration groups did not allow a caliber group-wise analysis. Therefore, the surgeries were gathered into two supergroups: surgeries using thinner than 10—12 Fr UAS and surgeries using thicker than 10—12 Fr UAS. Overall results and postoperative complications according to this group analysis are shown in Table 3. Additionally, a statistically significant positive correlation was found between UAS calibration and stone-free status ($r=0.209$, $p<0.001$).

3.4. Predictive analyses

The area under the ROC curve of the UAS calibration change in regard to stone-free status was 0.652 (95% CI: 0.584—0.721; $p<0.0001$). The UAS of 10—12 Fr showed the best performance in discriminating stone-free status of patients, with 84.7% sensitivity.

Results of multivariate analyses are shown in Table 4. Multivariable logistic regression analysis indicated that both the use of UAS (odds ratio [OR]: 3.654; 95% CI: 1.314—10.162) and increase in calibration (OR: 2.387; 95% CI: 1.431—3.984) were independently associated with stone-free status. Also, UAS non-usage was an independent factor predicting both perioperative (OR: 4.443; 95% CI: 1.350—14.552) and postoperative (OR: 4.107; 95% CI: 1.366—12.344) complications.

4. Discussion

The most obvious finding of our multicenter cohort analysis was that the use of UAS during RIRS significantly increased

Table 4 Multivariable analyses of UAS related parameters to predict RIRS outcomes.

Outcomes	OR	95% CI for OR		*p*-Value
		Lower	Upper	
Stone-free status				
Usage	3.654	1.314	10.162	0.013
Calibration increase	2.387	1.431	3.984	0.001
Peri-operative complications				
Non-usage	4.443	1.350	14.552	0.014
Calibration increase	1.613	0.925	2.815	0.092
Post-operative complications				
Non-usage	4.107	1.366	12.344	0.012
Calibration increase	1.215	0.713	2.066	0.470

UAS, ureteral access sheath; OR, odds ratio; CI, confidence interval; RIRS, retrograde intrarenal surgery.

the stone-free rate of patients. Our results reflected those of L'Esperance and colleagues [7], who also found that the stone-free rate of patients using UAS (79%) was significantly higher than those who had the surgery without UAS (67%). However, our findings were not supported by the previous worldwide multicenter study from the Clinical Research Office of the Endourological Society [8]. That study's univariate analysis of 2239 patients revealed that the stone-free rate was significantly higher in the group without the use of UAS, but the difference between the groups was determined to be insignificant by inverse probability weighted regression adjustment analysis. As a conclusion, the authors emphasized that the use of UAS had no effect on stone-free status. These findings may be somewhat limited by the evaluation of residual stones. Residual stones were often evaluated with kidney, ureter, and bladder radiography or urinary ultrasound. When necessary, the diagnosis of residual stone was confirmed with non-contrast CT or second-look ureterorenoscopy. This lack of standardization is also valid for our study due to its multicenter design.

A recent meta-analysis also including the results of the two studies mentioned above showed that the use of UAS had no effect on stone-free status of patients [9]. These findings raised intriguing questions regarding the designs of the studies included in the meta-analysis. Assimos [10] noted that only two of the eight studies included in the meta-analysis were randomized clinical trials. However, when these two studies were evaluated, it was noted that not all of the compared studies provided a definition of RIRS. Pardalidis and colleagues [11] treated impacted lower-third ureteral stones using UAS, and Kourambas and colleagues [12] performed semi-rigid ureteroscopy on some patients.

Recently published were one of the largest prospective studies reporting the outcome of RIRS for renal stones with and without UAS and a study that had a design very similar to ours [13,14]. In terms of UAS usage and UAS caliber, the studies showed no significant differences between the groups for stone-free status. However, our results were very encouraging. We found that as the UAS calibration increased, the stone-free rate also increased. Calibration increase was an independent predictive factor for stone-free status, and the highest predictive value was with 10—12 Fr UAS. Our results are the first findings in the literature showing that 10—12 Fr UAS is superior to other UAS calibers in terms of stone-free status. Moreover, Al-Qahtani and colleagues [15] noted that 12—14 Fr UAS is also considered a universal UAS because it accepts all endoscopes that are available in the endourology field.

Clear prospective evaluation and classification of ureteral wall injuries due to insertion of UAS caused controversy over the use of UAS during RIRS [16]. Thus, UAS insertion-related complications of RIRS have been reported more frequently, and Stern and colleagues [17] reported 52.4% ureteral injury secondary to UAS placement in 59 RIRS cases using 12—14 Fr UAS. Insertion complications ranged from mild ureteral mucosal erosion to total ureteral avulsion, which can result in kidney loss. However, the vast majority of UAS insertion-related complications reported in the studies mentioned above were low-grade mucosal lesions that would not require additional intervention. It is probable that many of these injuries heal in the early postoperative period, while the patient has been stented. Stern and colleagues [18] examined the intermediate- and long-term effects of high-grade UAS injuries, and reported that only one patient developed *de novo* ureteral stricture after approximately 3 years of follow-up. In our study, perioperative complications were less common in the group using UAS. Also, the usage of UAS was determined to be an independent factor predicting the development of perioperative complications. Is it possible that a non-significant variable in univariate analysis may be significant in multivariate analysis? Statisticians reported that there may be two reasons for this: sampling error or suppression [19]. We have re-examined our data and concluded that this may be due to an unknown variable that "suppresses" the true relationship between the use of UAS and complications. Although not statistically significant, we think that the observation of more frequent perioperative complications with thicker UAS use was a clinically meaningful result. However, only 13—15 Fr UAS^{+} patient perioperative complication rates were higher than those without UAS. In summary, although there is an increase in complication rates with increased UAS calibration, these rates do not prevent advocating the use of a UAS thinner than 13—15 Fr.

Nonetheless, postoperative infectious complications of RIRS can be more severe than perioperative complications [20]. Preclinical studies that demonstrated an intrapelvic pressure reducing effect of UAS usage are available in the literature [21,22]. However, a pilot clinical study did not provide direct evidence of UAS use affecting intrapelvic pressure [4]. Conversely, the use of UAS during RIRS has been shown to reduce postoperative infectious complications [8]. In a meta-analysis including the results of four studies, the incidence of postoperative complications in UAS^{+} patients was significantly higher than in UAS^{-} patients [8]. In our study, the incidence of postoperative complications was significantly higher in the UAS^{-} group. Presumably, the surgeon's attitude should also be considered a variable that may help explain these results. In other words, UAS use during RIRS may give a false sense of security and cause loss of endoscopic judgment.

The main limitation of our study is the retrospective design. Therefore, we could not fulfill the need for randomized data in the literature [23]. However, the data for the study were obtained from an elaborate RIRSearch database that were prospectively collected. The imbalance between the groups that may have been caused by the relatively low number of UAS^{-} patients was overcome by matching groups and obtaining robust statistical results. However, PS matching between groups could not be applied in UAS calibration subgroups because there were not enough patients. Another main limitation stemmed from UAS^{-} group. There were more patients had UAS insertion failure instead of patients who underwent sheathless technique. UAS insertion failure stood out as a complication promoter before starting the actual procedure.

5. Conclusion

The use of UAS in RIRS may increase stone-free rates. There was an increase in stone-free status with higher caliber UAS use, where a 10—12 Fr UAS was the most effective. In addition, the use of UAS may reduce complication rates. However, complication rates seemed to increase with higher UAS calibration.

Author contributions

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Conflicts of interest

The authors declare no conflict of interest.

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