original article

Outcomes with ureteral access sheath in retrograde intrarenal surgery: a retrospective comparative analysis

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BACKGROUND: Retrograde intrarenal surgery is used for treatment of urinary system stones. The ureteral access sheath (UAS) is used to decrease intrapelvic pressure, help with access of multiple instruments, and facilitate drainage and removal of the fragmented stones.

OBJECTIVES: Assess the effect of the UAS on the outcomes of retrograde intrarenal surgery.

DESIGN: A retrospective patient data review.

SETTING: Training and research hospital in Turkey.

PATIENTS AND METHODS: We reviewed the data of patients who had undergone retrograde intrarenal surgery between 2012-2019. Patients who had kidney anomalies, were <18 years old, and who had ureteral and urethral strictures were excluded from the study. The demographic characteristics, stone type, complications, intraoperative and postoperative data of the patients were reviewed. A successful outcome was defined as being stone free or having clinically insignificant residual fragments (<3 mm). The use of the UAS was compared with other procedures in terms of efficiency and safety. Factors determining UAS usage were assessed by multivariate analysis.

MAIN OUTCOME MEASURES: Stone free rate and complication rate in patients who underwent retrograde intrarenal surgery.

SAMPLE SIZE: 1808 patients met inclusion criteria.

RESULTS: The UAS was used in 1489 procedures, while other methods were used in 319 procedures. Operation time was 46.9 (17.3) minutes and 42.9 (19.0) minutes with other methods. Postoperative double J stent usage rates were 88.2% and 63% in the UAS and other methods, respectively. The rate of successful outcome was 88.2% and 81.2% in the UAS and other methods, respectively (P<.001). The rate of complications was similar in both groups (P=.543). In a multivariate analysis, UAS usage was directly proportional with stone size and inversely proportional with preoperative JJ stent usage

CONCLUSION: The UAS can be effectively and successfully used in retrograde intrarenal surgery for treatment of urinary system stones. UAS usage should be considered for the patients who have large stones (2 cm) and do not have a preoperative double J stent.

LIMITATIONS: Retrospective design.

CONFLICT OF INTEREST: None.

Urinary system stone disease is a significant health problem with a prevalence of 10-15% worldwide.[1] Several methods such as shock wave lithotripsy (SWL), percutaneous nephrolithotomy (PNL), open and laparoscopic surgeries, and retrograde intrarenal surgery (RIRS) are used in the treatment of urinary system stones. RIRS is a recently developed method that is more effective than SWL and safer than PNL.[2,3] Its usage has increased with advanced technology and surgical experience. Although at first, RIRS was used for treatment of urinary system stones that are <2 cm, nowadays it is also used for treatment of larger stones.[4] The success rate for RIRS is quite high with studies reporting 63-87% stone-free rates.[5]

Despite being quite successful, RIRS has several disadvantages. Firstly, irrigation fluid that is used for visualization may increase intrapelvic pressure, which can become an important issue in cases with larger stones that require prolonged operation time. High intrarenal pressure may cause renal extravasation and complications such as bleeding, hematoma, urinoma, sepsis, postoperative pain, and focal parenchymal scarring.[6] Secondly, multiple instrument entries may be needed for extracting fragmented stones, which may increase complications and prolong operation time.[7-9]

Various methods have been developed to address these issues. The ureteral access sheath (UAS) developed by Hisao Takayasu and Yoshio Aso in 1974 is one of them.[10] UAS decreases intrapelvic pressure, helps with access for multiple instruments, and facilitates drainage and removal of the fragmented stones.[11,12] UAS placement is a crucial step of RIRS. Ureteral wall injury and stricture may occur due to long-term usage of UAS.[13] Although there have been studies aimed at validating UAS use in RIRS, to the best of our knowledge, our study has the largest population for a single center study that has investigated the effectiveness and safety of UAS use in RIRS.

PATIENTS AND METHODS

The data of patients that underwent RIRS between 2012-2019 was reviewed retrospectively. Patients who had kidney anomalies, were <18 years old, and who had ureteral and urethral strictures were excluded from the study. The procedures in which UAS was used were compared with procedures in which other methods were used. All of the procedures were performed by the same experienced surgical team.

Preoperative routine blood tests of all patients were analyzed. Different imaging methods such as kidney-ureter-bladder (KUB) radiography, unenhanced computed tomography (CT), ultrasonography (US) and intravenous pyelography (IVP) were performed preoperatively. All the urine cultures were sterile preoperatively. The stone sizes for opaque and non-opaque stones were defined as the longest diameter of the stone observed in KUB radiography and US, respectively. For multiple stones, the sum of the longest diameters of the stones was defined as the stone size. Informed consent was obtained from all patients before the operation. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

A parenteral antibiotic was applied one hour before operation. Operations were performed under general anesthesia. Semi rigid ureterorenoscopy was performed in modified supine lithotomy position. This maneuver also dilated the ureter. Then 0.035-0.038 inch hydrophilic guidewire was inserted into the ureter. Over the guidewire, the UAS (9.5/11.5 F or 11/13 F) (35 cm or 45 cm) (Elite Flex, Ankara, Turkey) was placed down to the ureteropelvic junction. In the first stage, 11/13 F UAS was used. Unless UAS was placed down to the ureteropelvic junction due to ureteral stricture or narrow ureter, 9.5/11.5 F UAS was used. Flexible ureterorenoscope (Flex-X2, Karl Storz, Tuttlingen, Germany/Karl Storz, Flex X2, GmbH, Tuttlingen, Germany) was moved through the UAS. After access to the stone, lithotripsy was performed with holmium YAG (Ho YAG Laser; Dornier MedTech; Munich, Germany/Dornier Med-Tech GmbH, Medilas H20 and HSolvo, Wessling, Germany) laser and 8-10 Hz. frequency and 1-2 joule pulse energy were used. In cases where UAS could not be placed, a flexible ureterorenoscope was moved via guidewire and access to the stone was supplied. All of these steps were performed under fluoroscopic guidance. Dusting and fragmentation methods were performed. After the fragmentation, the presence of calyces were scrutinized. A postoperative double J (JJ) stent was inserted in cases of intraoperative conditions such as bleeding, extravasation, and the presence of residual fragments. A urethral catheter was inserted at the end of the operation and removed on postoperative first day. The JJ stent was removed three weeks later as an outpatient procedure. Time between starting endoscopy and urethral catheter insertion was defined as the operation time.

Patients that had opaque stones were followed-up with KUB radiography, while patients with non-opaque stones were followed-up with US on the first postoperative day. In patients whose outcome was not successful after the first surgery, a second surgery was performed three weeks later. Unenhanced CT was performed in the third postoperative month. Patients were followed for three months. The outcome was considered successful if the patient was stone-free or had clinically insignificant residual stones (<3 mm) after the intraoperative and postoperative controls. The demographic characteristics, stone, intraoperative and postoperative complications, intraoperative and postoperative data of the patients were reviewed. Complications were recorded as per the Clavien-Dindo classification. The procedures using the ureteral access sheath were compared with other procedures in terms of efficiency and safety.

The statistical evaluation of the data was performed using the IBM SPSS for Windows 22.0 software package (SPSS, Armonk, NY). Continuous and categorical variables were defined as mean and standard deviation and number and percent (%), respectively. The one-sample Kolmogorov-Smirnow test was applied to variables with continuous values. The *t* test was used for the variables of continuous data that had a normal distribution and the Mann-Whitney U test was used for the others. The chi-square and Fisher's exact tests were used for the comparison of frequencies. Multiple logistic regression was used to evaluate factors that might predict use of UAS, complications and outcome. The level of statistical significance was defined as $P<.05$.

Table 1. Patient demographic data and characteristics of the stones.

	Ureteral access sheath (n=1489)	Other methods (n=319)	*P*
Age (years)	46.2 (13.8)	44.9 (13.5)	.112
Gender (M/F)	952 (64) / 537 (36)	220 (69) / 99 (31)	.088
BMI (kg/m^2)	25.9 (3.4)	25.6 (3.3)	.104
American Society of Anesthesiologists score			
I	482 (32.4)	113 (35.4)	.489
II	894 (60.0)	180 (56.4)	
III	113 (7.6)	26 (8.2)	
Preoperative JJ stent	72 (4.8)	40 (12.5)	.010
Stone laterality (R/L)	753 (50.6)/736 (49.4)	150 (47.0) / 169 (52.9)	.25
Stone number	1.32 (0.6)	1.29 (0.7)	.364
Stone size (mm)	15.6 (7.9)	12.53 (5.9)	<.001
Stone localization			.087
Upper calyx	86 (5.8)	15 (4.7)	
Lower Cclyx	373 (25.1)	85 (26.6)	
Mid calyx	153 (10.3)	35 (11)	
Pelvis	295 (19.8)	55 (17.2)	
Multicaliceal	294 (19.7)	48 (15.0)	
Proximal ureter	288 (19.3)	81 (25.4)	

Data are number (%) or mean (standard deviation).

RESULTS

Of 1808 procedures, the UAS was used in 1489 procedures, and other methods were used in 319 procedures. The preoperative JJ stent usage rate was 4.8% and 12.5% with UAS vs other methods, respectively (P=.01). The stone sizes were 15.6 (7.9) with UAS and 12.5 (5.9) with other methods ($P<.001$) (**Table 1**). Operation time was 46.9 (17.3) min with UAS and 42.9 (19.0) minutes with other methods ($P<.001$) (**Table 2**). Postoperative JJ stent usage rates were 88.2% and 63% with UAS vs other methods, respectively ($P<.001$). The rate of successful outcome was 88.2% and 81.2% with UAS vs other methods, respectively ($P<.001$). All of the successful patients were stone free. The differences were statistically significant ($P<.001$). However, the rate of complications were 13.5% with the UAS and 12.2% with other methods (P=.543). Most of the complications were minor complications.

In the multivariate analysis, which included factors of the univariate analysis that were statistically significant, stone size and preoperative JJ stent usage were independent factors affecting UAS usage. The UAS usage was directly proportional with stone size and inversely proportional with preoperative JJ stent usage (**Table 3**).

DISCUSSION

Advancements in technology hav provided invaluable improvements for surgeries that aim to remove urinary system stones. One of the latest developments in this area is RIRS. The usage of UAS in RIRS provides further advantages by decreasing the intrarenal pressure and the time loss due to multiple instrument entry into the ureter, which may be required if fragmented stones are present.

The extent of decrease in operative time facilitated by the use of UAS varies in different studies. Kourambas et al reported that UAS usage shortened operation time for 10 minutes, which in turn reduced the cost $350 per operation.[12] However, a prospective multicenter study of 2239 patients by Traxer et al reported longer operative time in UAS group, however we should keep in mind that the number of stones that were ≥10 mm was higher in their UAS group.[14] In another study researching effects of UAS size on success, operation time was shorter in the group where UAS was not used.[15] However, similar to the study by Traxer et al, the stone size was higher in the UAS group.[15] In our study, operation time was also longer in the UAS group, which we attribute to larger stone size as well as higher population size in the UAS group. The relationship between stone-free rates and the UAS usage is not very clear. Although there are various studies that reported stone-free rates between 74-86% in UAS groups and 67-87% in non-UAS group, there are other studies that UAS size has no effect on success.[11-16] In our study, the rate of successful outcomes was significantly higher in the UAS group.

It is known that in RIRS, UAS can decrease intrarenal pressure due to irrigation. However, this decrease in intrarenal pressure may lead to decreased ureteral blood flow resulting in ischemia due to increasing distention.[17] Moreover, UAS may damage ureter during entry.[13,17] In a study researching the relationship between UAS-associated complications, it was reported that UAS did not increasing the risk of ureteral damage.[14] In another study of 63 patients, postoperative ureteral stricture was not reported during 2 months follow up.[18] Traxer et al reported 46.5% ureteral injury in their study of 359 patients. In another study, serious damage including smooth muscle injury was seen in 48 (13%) patients.[13] The same study reported that men and elders were at higher risk for UAS-related damage and that preoperative JJ stent decreased UAS-related ureter damage.[13] Lallas et al showed that UAS caused a temporary reduction in ureteral blood flow by putting a pressure on ureter wall. They also reported that ureteral blood flow was restored by compensatory mechanisms and ureteral integrity was protected. In addition, they showed that prolonging operation time and selecting appropriate UAS size were important for preserving the urethral blood flow.[17] Barbour et al investigated hydronephrosis after ureterorenoscopy in a study of 234 patients. In their study, UAS was used in 22% of procedures and postoperative JJ stent was used in 93% of patients (mean use was for seven days). They reported that after 4-12 weeks follow up, hydronephrosis was seen in 15% of patients.[19] While hydronephrosis due to transient edema without anatomical obstruction was seen in 8% of patients, hydronephrosis due to residual stone was seen in 6.5% of patients, and stricture disease was seen in 0.9% of patients.[19] In another study investigating usage of different sizes of UAS in RIRS, asymptomatic hydronephrosis was seen in one patient and there was no significant difference between

Table 2. Intraoperative and postoperative data.

	Ureteral access sheath (n=1489)	Other methods (n=319)	*P*
Average operation time	46.9 (17.3)	42.92 (19.04)	**<.001**
Average scope time (sec)	34.4 (36.9)	34.4 (30.6)	.576
Postoperative JJ stent	1313 (88.2)	201 (63.0)	**<.001**
Average hospitalisation time (day)	1.1 (0.7)	1.1 (0.8)	.58
Successful outcome	1321 (88.2)	259 (81.2)	**<.001**
Stone-free	1321 (88.2)	259 (81.2)	**<.001**
Residuel fragment (≥3 mm)	168 (11.8)	60 (18.8)	**<.001**
Complication rate	201 (13.5)	39 (12.2)	.543
Complications	201 (13.5)	39 (12.2)	
Early postoperative complication[a]			
Fever (1)	100 (49.76)	14 (35.9)	
Bleeding (1)	37 (18.41)	7(17.95)	
Urinary tract infection (2)	37 (18.41)	12 (30.76)	
Perirenal hematoma (3a)	6 (2.98)	0	
Stent migration (3b)	8 (3.98)	4 (10.26)	
Steinstrasse (3b)	8 (3.98)	2 (5.13)	
Sepsis (4b)	2 (0.99)		
Death (5)			
Late postoperative complication[a]			
Ureteral stricture (3b)	3 (1.49)		

Data are number (%) or mean (standard deviation). [a]Clavien-Dindo classification of complications in

Table 3. Multivariate logistic regression analysis with use of the ureteral access sheath as dependent variable (n=1808).

	Univariate tests			Multivariate model		
	OR	95% CI	*P* value	OR	95% CI	*P* value
Age	0.993	0.984-1.002	0.11			
Gender	0.798	0.615-1.03	.088			
Body mass index	0.97	0.934-1.00	.104			
ASA score	0.930	0.756-1.144	.490			
Stone localization	0.986	0.907-1.07	.730			
Number of stones	0.906	0.733-1.119	.359			
Stone size	2.822	1.878-4.24	**<.001**	2.87	1.840-4.221	**<.001**
Preop double J stent	0.933	0.913-4.24	**<.001**	0.936	0.916-0.956	**<.001**
Complications	0.893	0.619-1.28	.543			

The final logistic regression model was statistically significant, $\chi^2(2)=72.598$, $P<.001$. The model explained 6.5% (Nagelkerke R^2) of the variance in the data. ASA: American Society of Anesthesiologists.

the groups in terms of complications.[15] We were not able to evaluate ureteral stricture and hydronephrosis since there was no long-term follow-up. Ureteral stricture was seen only in three patients.

Ureteral prestenting may decrease ureter damage due to UAS. The recommended duration for prestenting is at least 5 days.[20] Ureteral prestenting may require additional operation, which may increase cost and anesthesia complications. Although there are studies that recommend active ureteral dilatation (balloon dilator or serial coaxial conical dilator), there are no studies comparing the long-term effect of active and passive ureteral dilatation on ureteral wall.[4,11,21] In our clinic, which is a tertiary care center, we do not perform routine ureteral prestenting. Patients who already have preoperative JJ stents are referred to our clinic. Guide wire is used to prevent ureteral damage during UAS placement.

UAS usage may cause ureteral wall edema, which may result in decreased urine production and excessive pain.[2] A postoperative JJ stent is used to prevent these situations.[2] There is no consensus about the duration of postoperative ureteral stenting. In a study based on histopathologic examinations, ureteral wall edema was most obvious at postoperative 72 hours when 14-16 fr. UAS was used.[17] Based on this, postoperative ureteral stenting for at least three days was recommended. In our study postoperative JJ stent was removed on the 21st day.

In our study, complications were seen in 201 (13.5 %) and 39 (12.2%) patients in group 1 and 2, respectively. There was no statistically significant difference between the groups. When we look at the literature, in the largest patient numbered multicenter study, complication number was 5.9% and 5.1% in the UAS used and unused group, respectively.[14] Most of the complications were minor complications.

To the best of our knowledge, there are no studies on whether UAS had an effect on protection of flexible renoscope. Although UAS may damage the tip of flexible renoscope during deflection, it can be used in patients using anticoagulants without hemorrhagic complications.[22,23]

In a study comparing different sized UAS, there was no significant difference in terms of complication and success rates, but duration of operation varied significantly between the groups.[15] In another study, ureterorenoscope was placed into the UAS and UAS was directly placed into the ureter.[24] This method was reported to significantly decrease both the scopy and operation time, while also significantly decreasing the rate of complications.[24] In our clinic we routinely use 11-13 fr UAS in RIRS. In the case of a narrow ureter or ureteral stricture, 9.5/11.5 F UAS was used.

Our study has several limitations such as absence of long-term follow-up for ureteral wall injuries, definition of UAS indications, and retrospective design of the study. However, our study has the highest sample size for a single-center study, which we believe to be an invaluable addition to the literature.

In conclusion, RIRS is a relatively recently developed method for treating urinary system stones. UAS placement is an important step of RIRS. UAS usage decreases intrarenal pressure, improves visual field, decreases complications, and facilitates surgery. Despite these advantages, UAS usage may result with ureteral injury and stricture. In our study, we concluded that UAS could be effectively and successfully used in RIRS for treatment of urinary system stones. Ureteral access sheath usage should be considered for patients who have large (>2 cm) stones and do not have a preoperative double J stent.

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