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Ureteral Stricture Outcomes Using Small Ureteral Access Sheath During Retrograde Intrarenal Surgery

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What's known on the subject? and What does the study add?

Ureteral access sheath (UAS) is one of the most important instruments used during retrograde intrarenal surgery. Ureteral trauma due to UAS is an important complication causing serious morbidity in the long-term period. Using the smallest diameter UAS is effective and safe to avoid ureteral trauma. Therefore we emphasise that the most atraumatic instruments should be chosen.

Abstract

Objective: This study evaluated ureteral injury and long-term stricture progression after the smallest ureteral access sheath (UAS) application during retrograde intrarenal surgery.

Materials and Methods: A total of 154 patients who had undergone retrograde intrarenal surgery procedures and applied a 9.5/11.5-F UAS for kidney stones between September 2016 and March 2019 were prospectively included, and intraoperative, postoperative, and late complications were evaluated. Ureteral injuries were visualized using flexible and semi-rigid ureterorenoscopy, and ureteral stricture was assessed by computed tomographic urography at one-year controls.

Results: 56% (n=86) of the patients were males, and %45 (n=68) the mean age was 47±15 years, stone size was 17.1±8 mm, operative time was 56±23 minutes, 80% had ureter wall injury, and 39% and 41% had grade 0 and grade 1 lesions, respectively. Minor complications were developed in 3%, and major complications were seen in 2% of cases. The ureteral stricture was not observed in 1st-year controls.

Conclusion: The routine application of 9.5/11.5-F UAS is safe to use in flexible ureteroscopy without any long-term adverse effects.

Keywords: Ureteral injury, ureteral stricture, ureteral access sheath, long-term complications, patient outcomes

Introduction

In the last few decades, kidney stone surgery has undergone many technological developments, and retrograde intrarenal surgery (RIRS) has become one of the standard treatments for patients with renal stones. The ureteral access sheath (UAS) was developed in 1974 by Takayasu and Aso (1). It is often used during RIRS to facilitate the entry of a flexible ureterorenoscopy (URS) into the renal collecting system. Additionally, it enables easy re-entry into the collecting system, consequently shortening the operating time, improving vision, decreasing intrapelvic pressure, and increasing the flexible ureteroscope's life span (2-5). Currently, UAS are produced with numerous characteristics, including different materials, lengths, tip formation, diameters, stiffness, and radiopaque markers (6). The selection of the UAS among the choices of manufacturers and models typically depends on surgeon choice, cost, and ureteroscope size.

Despite their advantages, there are some critical misgivings concerning UAS use. UAS usage entails a risk of ureteral damage, including the smooth muscle layer after insertion (7). Additionally, the over-distention created by a UAS may decrease blood flow of the ureteral wall and theoretically cause long-

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term ureteral stricture formation (8). Moreover, large-sized UASs have been reported to affect ureteral blood flow more (9). Thus, UASs with small outer and large inner diameters are clinically more practical.

To the best of our knowledge, no prospective study in the international literature has evaluated the effect of UAS -related ureteral injury and possible ischemia on the development of urethral stricture. This study analyzed intraoperative, postoperative complications and the incidence of ureteral injury by using the smallest diameter UAS on the market and the effect of injuries and possible ischemia/inflammatory changes on the risk of ureteral stricture development in the long term.

Materials and Methods

A total of 154 RIRSs for renal stones that a UAS was administered between September/2016 to March/2019 were prospectively included in the study. Patients who were not previously stented were undergone a complete physical, laboratory, and radiological assessment. In the case of urine culture positivity, patients were treated with appropriate antibiotics preoperatively. Exclusion criteria were:

- Previous urinary or stone surgery,
- Any urinary system abnormality including ectopic, horseshoe, or malrotated kidney(s), calyceal diverticulum stones, duplicated collective system,
- Ureteral dilatation,
- Prior unsuccessful sheath administration.

A 9.5/11.5 F UAS (Cook™, Cook Medical, Dublin, Ireland) (length: 35 cm for females and 45 cm for males) were used in surgeries under general anesthesia. A9.5-F semi-rigid ureteroscope (Karl Storz™, Karl Storz, Tuttlingen, Germany) was used routinely for URS to diagnose ureteral stone or stricture before RIRS and for placing a hydrophilic guidewire for the optical dilatation. After the passive dilatation by a semirigid ureterorenoscope, a UAS was inserted over the guidewire under fluoroscopic guidance. Next, inserted a 7.5-F flexible ureteroscope (Karl Storz Flex-X2™, Karl Storz, Tuttlingen, Germany) through the sheath. A 30W Holmium YAG laser (SphinxX™, Lisa, Katlenburg-Lindau, Germany) was used to fragment kidney stones, but the residual fragments were not routinely extracted. The procedure was terminated after inspecting the whole ureteral wall using a 9.5-F semi-rigid URS. JJ stent was removed at 2nd to 4th weeks postoperative if placed during surgery.

Intra-operative ureteral lesion grades were classified, ranging from 0 to 4, according to Traxer and Thomas (7). Additionally, postoperative complications were reported using the modified Clavien-Dindo classification (10).

Residual stones ≤3 mm was accepted as stone-free one month after the procedure. Patients were evaluated by computed tomographic urography in the postoperatively first year. A fixed narrowing ureter with proximal dilatation was considered stricture (11).

This study was reviewed and approved by the Institutional Review Board (University of Health Sciences Turkiye, Ankara Numune Training and Research Hospital - approval number: ANEAH-E-1762, date: 2019). The study was performed in accordance with the most recent version of the Declaration of Helsinki.

Results

A total of 154 patients with a mean age of 47±15 (range: 12-81) years, and 56% (n=86) were males were included in the analyses. The mean surgery time was 56±23 (range: 30-120) minutes, and the mean stone size was 17.1±8 (7-40) mm. The analysis of the ureteral injury revealed that 79.9% of the patients had an injury that was non-significant (grade 0) in 39% and grade 1 in 40.9% of patients. None of the patients had injuries equal to or higher than grade 2. Five patients (3.2%) had Clavien I and II complications in the postoperative period, including hematuria and fever. Grade IV complications developed in 3 patients (1.9%) (sepsis requiring intermediate care/intensive care unit management) (Table 1).

After the 1st-year follow-up controls, none of the patients had a ureteral stricture. In the first session, 118 patients (76.6%) were stone-free, and 30 patients with residual stones underwent a second RIRS session, which revealed an overall stone-free rate of 90.3% (n=139) (Table 2). When a total of 62 patients with grade 0-1 lesions were evaluated, the stone-free rate was found to be 71.2% and it was similar to the total first session stone-free rate (p=0.124).

Discussion

The use of a UAS during RIRS, despite having a few advantages over RIRS without a UAS, also remains controversial equipment

Table 1. Five-point grading system for ureteral injury (7)

Grade	Description
0	No ureteral lesion or only mucosal petechiae
1	Mucosal erosion or a mucosal flap without smooth muscle injury
2	Damage to the mucosa and smooth muscle but no adventitia, with no retroperitoneal tissue visible
3	Injury indicating ureteral perforation involving the full thickness of the ureteral wall, including the adventitia
4	Total ureteral avulsion

in endourological surgery owing to an increased risk of ureteral damage. The normal ureteral lumen is narrower than any UAS in the market (12). The insertion of a UAS dilates the ureteral wall and thus has the risk of causing ureteral injury (mucosal and submucosal edema, hematoma, variable degree mucosal erosions); additionally, the placement of reinforced UAS may produce partial or even complete ureteral transection (13). Another concern about UAS is its effect on ureteral blood flow. Lallas et al. (9) investigated the possible acute ischemic effects of varying diameters UAS using a swine model. Blood flow to the ureteral segment was measured using laser Doppler flowmetry, and UAS remained in the ureter about 70 min. The authors revealed that decreases in ureteral blood flow using a 10/12-F UAS (average; 12%) was minimal compared with an up to 64.5% decrease with larger UAS. The authors reached the nadir blood flow averaging 20.0 to 30.0 min. They concluded that despite its findings safety concerning acute ischemic effect, one should continue to proceed with precautions when selecting the proper-size UAS, as chronic effects remain in controversial. However, there perfusion that occurs after remove of the UAS can reveal the ureteral wall to free radicals and subsequent tissue injury (7). Lildal et al. (14) evaluated the acute inflammatory cytokine expression for cyclooxygenase-2 and tumor necrosis factor-alpha in ureteral tissue and reported significant upregulation after 2 min of UAS deployment, which were 6.5-fold and 8-fold, respectively (14).

First, Traxer and Thomas (7) prospectively assessed the incidence and severity of UAS-related ureteral wall damage, and they generated a classification system in 2013. Their study included 359 patients who underwent RIRS for renal stones, and 12/14-F UAS was used to permit the digital URS. Patients were divided into two groups, including low-grade damage (0 or 1 grade) and high - grade damage (2 to 4 grade), which included smooth muscle layers of the ureter. Low-grade damages were found in 86.6% of patients, grade 2 injuries observed in 10.1% of patients, and grade 3 injuries in 3.3%. They did not report a grade 4 injury. The incidence of postoperative complications was 7%. In a novel study by Loftus et al. (13), 95 patients were randomized to two the same sizes (12/14-F) of different brands of UAS, and they analyzed the incidence of UAS-related ureteral injury. The authors used the same classification system as we used (7), and they validated this 5-point classification system. The end of the study, they found grade 1, 2, 3 and 4 injuries in 47.8%, 13.4%, 10.4% and 0.0% of patients, respectively. The authors concluded that ureteral trauma could be easily assessed using a standardized 5-point scale with good inter-rater reliability. Also, they concluded that not pushing if there is a resistance and switching to a smaller diameter sheath in prolonged applications should be prevent high-grade injuries. In our series, the grade 1 injury rate of 40.9% is also similar to the results with two studies as mentioned above. Unlike the other two studies, we did not observe grade 2 and higher injuries. This is presumably related to our use of a smaller size of UAS. Because pushing against large-size UAS into the narrow ureter during placement, possibly causes high-grade ureteral trauma. Another reason may be a mismatch in the UAS and ureteral tone. Using a larger UAS may require more force during insertion, and a higher pressure would refer to a higher risk of ureteral damage. Koo et al. (15) found that high-grade ureteral damage did not occur in patients in which the UAS force of insertion was <600 G (600 G=5.88 N).

Table 2. Demographic data of the patients	
Age, Mean ± SD (min-max) years	47±15 (12-81)
Gender	
Male	86 (55%)
Female	68 (45%)
Stone size, Mean ± SD (min-max) mm	17.1±8 (7-40)
Operative time Mean ± SD (min-max) minutes	56±23 (30-120)
Stone-free rate	
Immediate	76.6% (n=118)
Overall	90.3% (n=139)
Ureteral injury	
Overall	79%
Grade 0	39%
Grade 1	40.9%
Complications	
Clavien I-II	5 (3.2%)
Clavien IV	3 (1.9%)

SD: Standard deviation, min: Minimum, max: Maximum

We know that ureteric strictures can develop even after seemingly uncomplicated or complicated endoscopic treatment of urolithiasis (16,17). Also, decreased blood flow related to the usage of UAS theoretically increases the risk of ureteral stricture. Recent literature findings also suggest limiting the duration of ureterorenoscopic surgeries to prevent complications, as complications and stricture risk increase when operative time is prolonged. Loftus et al. (13) suggested that the correlation between ureteral stricture and ureteral injury emphasizes the clinical significance of these injuries. Delvecchio et al. (8) retrospectively evaluated 62 cases who underwent 71 ureterorenoscopic surgeries using UAS and complete follow-up longer than three months. The authors found only one stricture (1.4%) in the left ureteropelvic junction. However, this patient had undergone multiple endoscopic surgeries because of recurrent struvite calculi.

In a recent study, Huang et al. (18) shared their data on ureteral stenosis, in which they evaluated the results of RIRS performed for kidney stones of 2 cm and larger. The authors reported that through the 6-month follow-up, no ureteric stricture was detected. Unlike our study, Huang et al. (18) used 13/15F UASs during the operation, and the follow-up times were shorter than our study. In another recent study, Sari et al. (19) evaluated the efficacy and safety of RIRS in 1489 patients using UAS. The authors reported that they detected ureteral stenosis in 3 patients. In this study, two different sizes of UAS (9.5/11.5 F or 11/13 F) were used, and the patients were evaluated retrospectively. The major difference in our study is that it has a prospective design, and we used the UAS with the smallest diameter in all patients.

In this study, we prospectively evaluated 154 consecutive RIRS procedures with adjunctive use of a UAS after a 1-year follow-up, and we did not detect any ureteral stricture. even though grade 2 or higher ureteral lesions may cause ureteral stricture, we do not detect high-grade injury in our cohort. We speculate that using larger diameter UAS may lead to more frequent ureteral injury, more ureteral ischemia, and more ureteral stricture. Using the smallest diameter, UAS has high protection in terms of all these parameters.

Study Limitations

There are a few limitations to our study. First, as we are aware that the number of patients in our study is low. We think that our research can shed light on higher-volume studies. Latter, the study is of a cohort design. Comparative studies with different sizes of UAS can provide further contribution and information. In parallel with the developments in laser technologies, RIRS is becoming more common for larger stones. Therefore, we can say that the stone size is slightly high in our study.

Conclusion

The results of our study indicate that the 9.5/11.5-F UAS is safe for routine use to ease flexible URS and no cause complications in the long-term periods. However, awareness of the potential ureteral wall damage and the ischemic effects of using unnecessarily larger UAS for long -term periods in patients at risk of damage should be keep in mind.

Ethics

Ethics Committee Approval: This study was reviewed and approved by the Institutional Review Board (University of Health Sciences Turkiye, Ankara Numune Training and Research Hospital - approval number: ANEAH-E-1762, date: 2019). The study was performed in accordance with the most recent version of the Declaration of Helsinki.

Informed Consent: All patients provided informed consent.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: Ö.G., M.B., A.T., Y.A., Concept: Ö.G., M.B., Design: Ö.G., M.B., A.T., Data Collection or Processing: A.A., İ.C.A., M.B., Analysis or Interpretation: Ö.G., M.B., Y.A., Literature Search: A.A., İ.C.A., Writing: Ö.G., M.B.

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