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Contribution of Ureteral Access Sheath Use to The Efficacy of Semirigid Ureterorenoscopy in Upper Ureteral Stones Smaller Than 2 Cm: Experiences of A Single Center

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Research Article

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ABSTRACT

Objective: The aim of our paper is to answer the question that during the ureteroscopy procedure if ureteral access sheath could facilitate operation, could decrease complication rates,operation time,requirement of additional surgery.

Method: The patients were randomly divided into two groups. Group 1 contained 44 patients for whom a UAS was not used and Group 2 consisted of 70 patients for whom a UAS was used during the URS procedure. The operation was continued using the semirigid ureteroscope within the UAS.

Results: There were no statistically significant differences between the two groups in terms of the mean age, BMI, ASA score, mean stone density, previous unsuccessful interventions, history of stone disease, mean grade of hydronephrosis in renal pelvis and mean stone size. the mean operation time was 41 minutes for Group 1 and 30 minutes for Group 2, with a statistically significant difference ($p < 0.001$), consistent with the literature. Similarly, the difference in the mean fluoroscopy time was statistically significant, being determined as six minutes for Group 1 and three minutes for Group 2 ($p < 0.001$).

Conclusions: Use of UAS was statistically significantly superior in terms of many parameters, such as increased stone-free rate, shorter operation time, and reduced requirement of additional surgery. Furthermore, the complication rates did not significantly differ between the UAS and non-UAS groups. We also consider that the advantages of a higher stone-free rate and reduced requirement of secondary interventions make the cost of UAS acceptable.

Keywords: Upper ureteral stone; ureteral access sheath; ureterorenoscopy

2 cm'den Küçük üst üreter taşlarında üreter erişim kılıfı kullanımının semirijit üreterorenoskopi etkinliğine katkısı: Tek merkez deneyimleri

Süreç

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ÖZ

Amaç: Makalemizin amacı, üreteroskopi işlemi sırasında üreteral erişim kılıfının operasyonu kolaylaştırabileceği, komplikasyon oranlarını, operasyon süresini, ek cerrahi gereksinimi azaltabileceği sorusuna cevap vermektir.

Yöntem: Hastalar rastgele iki gruba ayrıldı. Grup 1 UAS(Üreteral akses sheath) kullanılmayan 44 hastadan, Grup 2 ise URS işlemi sırasında UAS uygulanan 70 hastadan oluşuyordu. UAS içinde semirijit üreteroskop ile operasyona devam edildi.

Bulgular: Ortalama yaş, VKİ (Vücut kitle indeksi) , ASA (American Society of Anesthesiologists) skoru, ortalama taş yoğunluğu, önceki başarısız girişimler, taş hastalığı öyküsü, renal pelviste ortalama hidronefroz derecesi ve ortalama taş boyutu açısından iki grup arasında istatistiksel olarak anlamlı fark yoktu. Ortalama operasyon süresi Grup 1 için 41 dakika ve Grup 2 için 30 dakika idi ve literatürle uyumlu olarak istatistiksel olarak anlamlı bir fark ($p < 0,001$) bulundu. Benzer şekilde, ortalama floroskopi süresi farkı istatistiksel olarak anlamlıydı, Grup 1 için altı dakika ve Grup 2 için üç dakika olarak belirlendi ($p < 0.001$).

Sonuç: Taşsızlık oranının artması, ameliyat süresinin kısalması, ek cerrahi gereksiniminin azalması gibi birçok parametre açısından UAS kullanımı istatistiksel olarak anlamlı derecede üstündü. Ayrıca, komplikasyon oranları UAS ve UAS olmayan gruplar arasında önemli ölçüde farklılık göstermedi. Ayrıca, daha yüksek taşsızlık oranı ve ikincil müdahale gereksiniminin azalmasının avantajlarının UAS'nin maliyetini kabul edilebilir kıldığını düşünüyoruz.

Anahtar sözcükler: Üst üreter taşı; üreteral erişim kılıfı; üreterorenoskopi.

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Introduction

Many treatment modalities have been defined for upper ureteral stones (UUS), including medical expulsive therapy following shock wave lithotripsy (SWL), ureterorenoscopy (URS), and laparoscopic and open ureterolithotomy [1,2]. SWL and URS stand out in relation to UUS of smaller than 2 cm. Although SWL is a minimally invasive procedure and has a low rate of morbidity, it has restrictive factors in terms of treatment, such as the reduced success rate depending on stone size and the requirement of recurrent sessions for the elimination of stone fragments [1]. With the advances in technology, development of thinner-diameter URS and the routine use of especially Holmium:YAG laser have increased the efficacy of semirigid URS in the treatment of UUS and reduced the complication rates [3-7]. However, the URS procedure requiring hospitalization, use of anesthesia (general or regional) and skilled and experienced surgeons has led researchers to seek alternative methods that would eliminate these disadvantages and increase the success rate. The most important factor affecting treatment success is the migration of fragmented stones and large stones requiring treatment (>4 mm) to the kidney. One of the main reasons for the stone to migrate to the kidney is increased pressure inside the ureter due to irrigation during URS.

A ureteral access sheath (UAS) is used to reduce intrarenal pressure during URS procedures, provide better visualization of stones, remove stone fragments, and allow repetitive access [8-11]. In this prospective study, we aimed to investigate the contribution of these proven advantages of UAS to the efficacy of semirigid URS in the treatment of UUS.

Material and Methods

A total of 114 symptomatic patients scheduled to have surgery for the treatment of UUS in our clinic between July 2016 and July 2018 were included in this study. Informed consent was obtained from all patients. The patients were randomly divided into two groups. Group 1 contained 44 patients for whom a UAS was not used and Group 2 consisted of 70 patients for whom a UAS was used during the URS procedure. Under general anesthesia induced using the standard technique, a 0.035 inch guide wire was used to engage the ureteral orifice, and then the ureteroscope was advanced into the ureter alongside the guide wire. The guide wire was maintained in the ureter throughout the operation for safety purposes. In the second patient group, a hydrophilic-coated UAS was also placed in the ureter, with the cases that did not allow the passage of the UAS being excluded from the study. The size of the UAS was selected as 36 or 45 cm depending on the gender and height of the patient, and the position of the stone. A UAS with an internal diameter of 9F and external diameter of 11F was placed over a 7.5 pediatric semirigid ureteroscope (Richard Wolf, Knittlingen, Germany) and advanced into the ureter alongside the 0.035 guide wide under fluoroscopy. The guide wire was removed after the placement of the UAS. The operation was continued using the semirigid ureteroscope within the UAS. For stone fragmentation, a 30 w (Quanta Samarate, Italy) Holmium laser was used. In some cases, a 4.7 F 28 cm double-J stent was inserted postoperatively and withdrawn after two to three weeks. The operation was performed by the same experienced surgeons. Table 1 summarizes the demographic data and male-female distribution rates of the patients. A stone-free status stone was considered to be the presence of only fragments smaller than 4 mm. The assessment of stone-free status was undertaken using a non-contrast-enhanced abdominal CT performed at the follow-up session held on average three weeks postoperatively.

The complications were classified as intraoperative and postoperative. According to the Clavien classification, Clavien 1 (hematuria) and Clavien 3 (umbilical laceration) complications were detected intraoperatively. Postoperative complications were determined as hematuria, fever and urinary infection.

The exclusion criteria were the inability to place a UAS, ureteral anomalies, pregnancy, active infection, bleeding diathesis, and the American Society of Anesthesiologists (ASA) score of III or above. Statistical analysis was performed using MedCalc statistics software (version 12.2.1.0, Ostend, Belgium). A p value of <0.005 was considered statistically significant.

Results

In Group 1, the mean age of the patients was 43.5 ± 15.2 years among 20 males (mean age: 44.5 years) and 24 females (mean age: 54.5 years). Of the patients in Group 2, 39 were male and 31 were female with a mean age of 55.7 and 44.3 years, respectively. The body mass index (BMI) was calculated as 26.9 ± 5.2 for Group 1 and 26.4 ± 4.9 for Group 2. The median ASA score was 2 in both groups. The mean stone size was 10.5 cm in Group 1 and 11.5 cm in Group 2. A history of stone disease was present in nine patients in Group 1 and 11 patients in Group 2. The number of previously failed interventions was determined as 29 and 54 for Groups 1 and 2, respectively. There were no statistically significant differences between the two groups in terms of the mean age, BMI, ASA score, mean stone density, previous unsuccessful interventions, history of stone disease, mean grade of hydronephrosis in renal pelvis and mean stone size, right or left kidney localization of the stone, intraoperative complications, preoperative positive urine culture, mean hospital stay, stent requirement, intraoperative migration of the stone to the kidney, and postoperative complications ($p > 0.05$).

According to the perioperative Clavien classification, a Clavien 1 complication (hematuria) was seen in eight patients (11.4%) in Group 1 and three patients (6.8%) in Group 2, and a Clavien 3 complication (mucosal laceration) was observed in 11 patients (15.7%) in Group 1 and five patients (11.4%) in Group 2. In addition, the mean operation time was 41 minutes for Group 1 and 30 minutes for Group 2, with a statistically significant difference ($p < 0.001$), consistent with the literature. Similarly, the difference in the mean fluoroscopy time was statistically significant, being determined as six minutes for Group 1 and

three minutes for Group 2 (p < 0.001). A stone-free status was achieved in 32 patients in Group 1 and 64 patients in Group 2, indicating a statistically significant difference between the groups (p 0.031). An additional surgical intervention was required in 16 and 12 patients in Groups 1 and 2, respectively, with a statistically significant difference (p 0.035). All data are summarized in Table 1.

Discussion

In parallel with the technological developments in UAS, the hydrophilic coating and integration of a central dilator system into the outer sheath have provided an ease of use and at the same time minimized the risk of ureteral trauma and stenosis in multiple insertions. By decreasing the pressure during lithotripsy, UAS offers both better image quality and prevention of stone migration to the kidney. Furthermore, additional apparatus, such as UAS is needed to facilitate the operation and reduce the operation time in cases of large stone size, stones fragmented into multiple pieces, and pathologies related to the ureteral orifice. UAS also has the ability to perform ureteral dilatation in a single step. For these reasons and in light of scientific data, use of UAS during semirigid or flexible URS is supported. UAS also facilitates the removal of stones [12-15], as well as providing a solution for complicated cases that require multiple insertions into the ureter orifice due to the large prostate size [16]. Nevertheless, there are also publications suggesting that UAS is responsible for the development of postoperative complications, including recurrent hematuria, ureteral strictures, and urinary extravagation [11,17]. At the same time, previous studies reported a higher number of postoperative complications in the UAS group [18,19]. However, in the current study, no statistically significant difference was observed between the two groups concerning intraoperative (p = 0.53) and postoperative (p = 0.16) complications.

Table 1. Demographic data belong to patients whom the procedure applied with and without ureteral access and corresponding p values.

	without ureteral access (n=44)	with ureteral access (n=70)	p value
Mean Age ± SD	43.5 ±15.2	38.4±16.2	0,068
Gender (%)			
Male	20 (44.5)	39 (55.7)	0.381
Female	24 (54.5)	31 (44.3)	
Mean BMI ±SD	26.9±5.2	26.4±4.9	0.678
Median ASA score	2	2	0.854
Mean stone diameter ±SD	10,5	11,5	0,524
History of prev. stone (%)	9 (20.4)	11 (15.7)	0.375
History of prev. unsuccessful procedure (%)			
none	29 (65.9)	54 (77.1)	0.378
ESWL	13 (29.6)	15 (21.5)	
URS	2 (4.5)	1 (1.4)	
Side (%)			
Right	25 (56.8)	34 (48.6)	0.535
Left	19 (43.2)	35 (50.0)	
Bilateral	0 (0)	1 (1.4)	
Mean stone density, HU±SD	784.1±199.9	761.0±216.2	0.507
Preoperative positive culture (%)	5 (11.4)	7 (10.0)	0.934
Median degree of hydronephrosis	1	2	0.185
Median procedure duration, min.	41	30	<0.001
Median fluoroscopy duration, sec.	6	3	<0.001
Stone free rate, <4 mm, (%)	32 (72.7)	63(90.0)	0.031
Stent requirement (%)	39 (88.6)	67 (95.7)	0.287
Additional intervention (%)	16 (36.3)	12 (17.1)	0.035
Median hospital stay, days	2	2	0.368
Intraoperative complication rate (%)			
none	36 (81.8)	51 (72.9)	0.536
bleeding	3 (6.8)	8 (11.4)	
mucosal laceration	5 (11.4)	11 (15.7)	
Intraoperative stone migration (%)	7 (15.9)	16 (22.8)	0.509
Post-operative complication rate (%)			
none	40 (90.9)	62 (88.6)	0.166
bleeding	2 (4.5)	6 (8.6)	
fever	2 (4.5)	0 (0)	
urinary infection	0 (0)	2 (2.9)	

SD, standart deviation; BMI, body mass index; ASA, American Society of Anesthesiologists; ESWL, extracorporeal shock wave lithotripsy; URS, ureteroscopy; HU, Hounsfield unit.

De Sio et al.[20] used UAS in distal ureteral stones and compared the results with the control group. The authors reported no statistically significant difference between the two groups in terms of operation time and stone-free rate. However, the sample size was very small, including only 12 cases in the UAS group and 16 cases in the control group selected from the medical archive. Thus, a limitation of that study could be considered as the possibility of bias. Furthermore, since distal ureteral stones do not have the risk of migration to the kidney, the use of apparatus with additional cost in cases except selected ureteral pathologies may be a further subject for discussion.

In a study performed evaluating the use of UAS in UUS, Kourambas et al.[21] found statistically significant lower rates of dysuria, suprapubic pain and urgency symptoms in the UAS group.

Limitations

The limitations of our study include only upper ureteral stones and not being compared with distal ureteral stones. At the same time, the fact that it was not calculated in the hounsfield unit, which gives an idea about the hardness of the stones, can be stated as another limitation.

Conclusion

The results of the current study revealed that use of UAS was statistically significantly superior in terms of many parameters, such as increased stone-free rate, shorter operation time, and reduced requirement of additional surgery. Furthermore, the complication rates did not significantly differ between the UAS and non-UAS groups. We also consider that the advantages of a higher stone-free rate and reduced requirement of secondary interventions make the cost of UAS acceptable. However, further studies are needed to develop the most effective method in the treatment of UUS.

Informed consent: Informed consent was obtained from all individual participants included in the study.

Ethical approval: All procedures performed in this study 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.

Conflict of interest: None of the authors have any potential conflict of interest

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Contribution: All named authors have seen and approved the mention of their names in the paper, contributing directly to the work

Conflict of interest

There is not a conflict of interest.

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