## Failure of ureteral access sheath insertion in virgin ureters: A retrospective tertiary care center study

Mohammad Alkhamees<sup>1</sup>, Ahmed Aljuhayman<sup>1</sup>, Abdulmalik Addar<sup>2,3</sup>, Yahya Ghazwani<sup>2,3,4</sup>, Ahmed Alasker<sup>2,3,4</sup>, Saeed Bin Hamri<sup>2,3</sup>

<sup>1</sup>Department of Urology, College of Medicine, Majmaah University, Al Majma'ah, <sup>2</sup>Division of Urology, Department of Surgery, Ministry of the National Guard - Health Affairs, <sup>3</sup>King Abdullah International Medical Research Center (KAIMRC), <sup>4</sup>College of Medicine, King Saud bin Abdulaziz University for Health Sciences (KSAU-HS), Riyadh, Saudi Arabia

**Abstract Objective:** The objective of the study was to identify the failure rate of insertion of ureteral access sheath (UAS) during primary flexible ureteroscopy (FURS).

**Materials and Methods:** This was a single-surgeon, single-tertiary care center retrospective study. All patients who underwent primary FURS for proximal ureteric or renal stones from November 2014 to May 2018 were included in the study. Patients with a stone burden of more than 20 mm were excluded from the study. A 10/12-Fr coaxial UAS (Bi-Flex, Rocamed) was used. Data collection included age, sex, body mass index (BMI), stone burden and location, previous spontaneous passage of stones, type of anesthesia, and preexisting congenital anomalies. The Chi-square test and *t*-test were used for the statistical analyses. **Results:** One hundred and twelve patients were included in the study. All patients underwent primary FURS. The failure rate of primary UAS insertion was 10.7% (n = 12). No statistically significant difference was found in age, BMI, type of anesthesia, previous history of spontaneous stone passage, and stone burden between the success and failure groups (P > 0.05).

**Conclusions:** We believe that our study opens the door for a multicentric prospective trial. Identifying factors leading to a failed primary FURS and UAS insertion is crucial to properly counsel patients preoperatively about the number of procedures that they might need and to prevent the financial loss associated with failed UAS insertion.

Keywords: Failure rate, ureter, ureteral access sheath, virgin ureter

Address for correspondence: Dr. Mohammad Alkhamees, Assistant Professor, Department of Urology, College of Medicine, Majmaah University, Al-Majmaah 11952, Saudi Arabia.

E-mail: m.alkhamees@mu.edu.sa

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#### INTRODUCTION

The first flexible ureteroscopy (FURS) was performed in the 1960s.<sup>[1]</sup> Recently, FURS has evolved and proven to be a safe and efficient option in the treatment of urolithiasis.<sup>[1]</sup> Ureteral access sheaths (UASs) were introduced to ease

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difficult ureteroscopic entry, and they have the benefit of decreasing intrarenal pressure and facilitating several re-entries and easier access to the proximal ureter and collecting system.<sup>[2,3]</sup> Difficulties are sometimes faced during attempts to access the ureter during FURS mostly because

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of a tight ureter and anatomic abnormalities.<sup>[4]</sup> When these difficulties are encountered, a stent is inserted and another procedure is required to perform lithotripsy. Consequently, the patient will be exposed to an ancillary procedure for definitive management. This will impact the patient and surgeon's satisfaction as well as the misuse of instruments and operating room time. In our study, we aimed to identify the failure rate of the insertion of UAS and predictors of failure during primary FURS. This knowledge will improve preoperative patient counseling as well as help surgeons to identify patients who might benefit from prestenting.

## MATERIALS AND METHODS

## Ethical statements

The Central Institutional Review Board of the Ministry of Health, the Kingdom of Saudi Arabia, approved the study and informed consent was not obtained from the patients because of the retrospective study design.

## Study design and population

This was a single-surgeon, single-tertiary care center retrospective study. All patients who underwent primary FURS for proximal ureteric or renal stones from November 2014 to May 2018 were included in our study. All patients who were included had virgin ureters, and no attempt of active dilatation was made. Patients with a stone burden of more than 20 mm were excluded from the study since stones of this size are better approached via percutaneous nephrolithotomy, as per the guidelines.<sup>[5]</sup>

### Procedure of primary flexible ureteroscopy

We used one type of 10/12-Fr coaxial UAS (Bi-Flex, Rocamed). After performing retrograde pyelography, a safety guidewire was inserted and another guidewire was used to slide the UAS over it under fluoroscopic guidance (working guidewire).

#### Data collection and statistical analysis

Data were obtained from patients' medical records and included age, sex, body mass index (BMI), stone burden and location, previous spontaneous passage of stones, type of anesthesia, and preexisting congenital anomalies. Data were entered into an Excel sheet (Microsoft Corp.) and then analyzed using SPSS software (IBM Corp). The Chi-square test was used to compare categorical variables and the *t*-test was used to compare means. P < 0.05 was considered statistically significant.

#### RESULTS

One hundred and twelve patients met our inclusion criteria. All patients underwent primary FURS with virgin ureters. Eighty-two patients (73.2%) were men and 30 patients (26.8%) were women. The baseline characteristics of the overall study population are shown in Table 1. Ninety-six patients (85.7%) underwent general anesthesia, 56 (50%) had a history of spontaneous stone passage, and 5 had preexisting congenital anomalies (solitary kidney, 4 patients; horseshoe kidney, and 1 patient). The failure rate of primary UAS insertion was 10.7% (n = 12). In the failure group, patients' median age was 41.5 years, median BMI was 29.366 kg/m<sup>2</sup>, and median stone burden was 10.5 mm; in addition, 56 patients (50%) had a history of spontaneous stone passage, 2 (16.6%) received spinal anesthesia, and 6 (50%) had their right kidney affected. In the success group, patients' median age was 45.5 years, median BMI was 28.91 kg/m<sup>2</sup>, and median stone burden was 10 mm; in addition, 52% of the patients had a history of spontaneous stone passage and 13% received spinal anesthesia. No statistically significant difference in age, BMI, type of anesthesia, history of spontaneous stone passage, and stone burden was found between the success and failure groups (P > 0.05)[Table 2]. The stone location did not affect the success of UAS insertion (P = 0.510), as well as a history of spontaneous stone passage (P = 1), which was not expected [Table 3]. Sex, type of anesthesia (general anesthesia versus spinal anesthesia), and laterality did not affect the failure of UAS insertion (P > 0.05) [Table 4].

#### DISCUSSION

UASs are widely used during ureteroscopic procedures as they facilitate multiple entries into the collecting system and proximal ureter, improve fluid irrigation, decrease intrarenal pressure, and lower the possibility of scope damage.<sup>[1-6]</sup>

#### Table 1: Baseline characteristics of the overall study population

Baseline characteristic	Mean±SD
Age (years)	46.39±13.73
Weight (kg)	81.01±20.35
Height (m)	1.64±0.12
BMI (kg/m <sup>2</sup> )	29.81±7.47
Stone burden (mm)	11.42±4.95

BMI: Body mass index, SD: Standard deviation

Table 2: Comparison of the mean values of height, weight, body mass index, age, and stone burden and their effect on flexible ureteroscopy

	Failed FURS	Successful FURS	Р
Height	1.70±0.067	1.63±0.134	0.140
Weight	91.82±25.31	79.69±19.42	0.062
BMI	31.63±8.43	29.64±7.39	0.409
Age	41.33±6.99	47.01±14.246	0.178
Stone burden	11.80±3.73	11.372±5.14	0.799

*P* values were obtained using the *t*-test. FURS: Flexible ureteroscopy; BMI: Body mass index

Table 3: Comparison of the effect of stone location and history of spontaneous stone passage on failed flexible ureteroscopy

	Successful	Failed	Р
	FURS, <i>n</i> (%)	FURS, <i>n</i> (%)	
Stone in the upper calyx	5 (100)	0 (0)	0.510
Stone in the middle calyx	12 (80)	3 (20)	
Stone in the lower calyx	24 (88.9)	3 (11.1)	
Stone in the renal pelvis	13 (92.9)	1 (7.1)	
Multiple calyceal stones	23 (95.8)	1 (4.2)	
Stone in the upper ureter	6 (100)	0 (0)	
History of spontaneous stone passage	50 (89.3)	6 (10.7)	1

FURS: Flexible ureteroscopy

Table 4: Comparison of the effect of sex, type of anesthesia, and stone laterality on successful flexible ureteroscopy

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	Failed FURS, <i>n</i> (%)	Successful FURS, <i>n</i> (%)	Р		
Male sex	11 (13.4)	71 (86.6)	0.127		
Female sex	1 (3.3)	29 (96.7)			
General anesthesia	10 (10.4)	86 (89.6)	0.803		
Spinal anesthesia	2 (12.5)	14 (87.5)			
Left side	6 (10.2)	53 (89.8)	0.734		
Right side	6 (12.2)	43 (87.8)			

P values were obtained using the t-test. FURS: Flexible ureteroscopy

Our study tried to identify foretelling factors for the failure of primary FURS to aid urologists in patient counseling and informed consent and to facilitate the decision of prestenting in the selected patients. Unfortunately, we could not identify any patient or stone factors that might help deciding whether to proceed with ureteroscopy or to prestent and delay the definitive management.

Patients undergoing FURS for ureterolithiasis or nephrolithiasis must be counseled thoroughly about the procedure they are about to undergo. Some patients undergoing stone surgeries believe that the one procedure will be enough to remove all the stones. However, the possibility of failure is there, and patients must be aware of this. Providing this knowledge to the patient will help to increase patient compliance and satisfaction. Factors that need to be addressed include successful UAS insertion and the possibility of needing an additional procedure later. Moreover, these factors might have a significant financial impact on the health-care system.

The topic of successful UAS insertion and the need for pre-stenting has not been addressed enough. Few small studies and one large multicenter retrospective study have tackled this topic.<sup>[4,7,8]</sup> The use of FURS has emerged as a favorable method in stone management because of its efficiency in cases of complex stones and in demanding patients such as those with a solitary kidney, bleeding diathesis, and pregnancy.<sup>[9,10]</sup> In 1990, it was reported by Jones *et al.* that stenting after failed FURS leads to a higher chance of stone removal the second time and reduced the need for ureterolithotomy. They also reported a failure rate of 11% for primary URS with a 9.5-Fr or 11-Fr semi-rigid ureteroscope.<sup>[11]</sup> In 2014, Mogilevkin et al. performed a prospective bicentric study in an attempt to predict factors leading to successful UAS insertion.<sup>[12]</sup> They reported that age, previous ipsilateral procedure, and the presence of an indwelling double-J stent were positive predictors of success. Their findings were statistically significant (P < 0.05). However, sex, BMI, and the side of surgery did not affect their outcomes. They used the 14-F Flexor-Cook UAS. In our study, we used the 10/12-Fr coaxial UAS by Rocamed, and we targeted patients with virgin ureters. Moreover, no active dilatation was done in our cohort, which might explain the difference between our findings and theirs. In addition, Mogilevkin et al. suggested that patients who underwent previous FURS had a higher success rate of UAS insertion, which was not the case in our population, as all of them had virgin ureters and never had previous FURS.

Furthermore, we assumed that a history of spontaneous stone passage might predict successful UAS insertion. On the contrary, in our population, this variable was found to not be statistically significant. Age, sex, BMI, laterality, and type of anesthesia (general or spinal) did not have any statistical significance in predicting the failure of primary UAS insertion.

Our study, to the best of our knowledge, is one of few that has tried to identify predictors of UAS insertion for primary FURS and the only one that used a small 10/12-Fr coaxial UAS, which is one of the smallest UASs available on the market. A lower rate of failure was observed in another study by Fuller *et al.* (7.7%). Such a low rate of failure was attributed to attempting to dilate the ureter by methods such as balloon dilation and lubriglide serial ureteral dilators that were not attempted in our population.<sup>[8,12]</sup>

This study has some limitations. First, because our affiliation is a referral center, we had a limited number of patients with virgin ureters, which made recruitment slightly difficult; hence, the limited sample size cannot be representative of the true population. Second, our study was based on a single surgeon's experience with fellowship training in stone management; thus, it does not represent simpler and more common cases that urologists experience. Finally, this was a retrospective study so that a prospective study might show different results.

## CONCLUSIONS

We could not find any statistically significant difference between the success and failure groups regarding patient demographics, stone characteristics, and type of anesthesia. We believe that our study along with the previously mentioned studies will open the door for multicentric prospective trials to identify factors associated with primary FURS failure. Identifying factors that lead to failed primary FURS and UAS insertion is crucial to properly counsel patients preoperatively about the number of procedures that they might need and to prevent the financial loss associated with failed UAS insertion.

#### **Geolocation information**

King Abdulaziz Medical City, Riyadh, Saudi Arabia.

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## Conflicts of interest

There are no conflicts of interest.

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