Is 10/12 Fr Ureteral Access Sheath more Suitable for Flexible Ureteroscopic Lithotripsy?

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Purpose: To choose the ideal ureteral access sheath (UAS) size for an unstented ureter in flexible ureteroscopic lithotripsy (FURL).

Materials and Methods: A retrospective study was conducted in patients treated with FURL for renal calculi from 2005 to 2020. The patients were divided into two groups: smaller (10/12 Fr) vs. larger (12/14 Fr) calibre UAS. The outcomes were the insertion success rate, systemic inflammatory response syndrome (SIRS) complication rate after the operation, ureteral wall injury, operative time, and stone-free rate.

Results: Of the 1573 patients enrolled, 10/12 Fr UAS was used in 957 patients (Group A), and 12/14 Fr UAS was used in the remaining patients (Group B). The insertion success rate was significantly better in Group A (91.2% vs. 86.9%, $P = .006$), with no significant difference between the groups regarding the stone-free rate, postoperative pain, operative time or hospital stay. The severity of visible ureteral lesions with 10/12 Fr UAS was significantly lower than that with larger UASs (80.1% vs 85.2%, $P < .001$). Despite the lack of a significant difference in the incidence of SIRS between the two groups, the incidence of SIRS in the 10/12 Fr group showed a sharp increase with stones > 2 cm (17.0% vs. 8.5%, $P = 0.037$).

Conclusion: The use of 10/12 Fr UAS was beneficial with respect to insertion success rate, avoiding ureteral wall injury and not increasing postoperative infectious complications in FURL. We recommend the use of a smaller calibre (10/12 Fr) UAS in patients with renal calculi < 2 cm.

Keywords: ureteroscopy; ureter; lithotripsy; ureteral access sheath; infectious complications

INTRODUCTION

With the development of ureteroscopy (URS), including miniaturization of the ureteroscope, advanced fragmentation technology and improved extraction devices, URS is rapidly becoming the most common method for the treatment of urinary calculi in the world.[(1)] Both EAU and AUA recommend flexible ureteroscopy lithotripsy (FURL) as the first-line treatment for proximal ureteral and renal calculi < 2 cm.

During routine FURL, high levels of intrarenal pressure may be related to urinary system infection and bleeding complications as well as to renal function damage. (2, 3) Several studies have shown that the placement of ureteral access sheath (UAS) can improve the surgical efficiency, facilitate ureteroscopy, and reduce the intrarenal pressure and postoperative complications of FURL.[(4-6)]

However, in the case of non-prestent FURL, the probability of UAS failure to enter the ureter is 9.8% to 22.0%, and the larger the diameter is, the higher the failure rate.[(7)] Additionally, the use of large UASs increases the possibility of ureteral wall injury, which may lead to the formation of ureteral strictures.[(8)] Although prestenting can effectively improve the success rate of UAS implantation, ureteral stents have a negative impact on the quality of life of the vast majority of patients.

To adapt to different conditions of the ureter and equipment, surgeons can select various UAS lengths (13-55 cm) and diameters (10/12 Fr-16/18 Fr). Currently, 10/12 Fr and 12/14 Fr UAS are mainly used in flexible ureteroscopes in our department for the treatment of urolithiasis. We conducted a retrospective single-centre study to compare the efficacy and safety between these two different UAS sizes to determine whether 10/12 Fr UAS is more suitable for FURL.

MATERIALS AND METHODS

Study Population

After Institutional Review Board approval, we identified 1573 FURL procedures performed between May 2005 and February 2020 at our institution. All eligible patients were divided into two groups based on the use of the different sizes of UAS: COOK Medical Flexor 12/14 Fr (wider) and 10/12 Fr (narrower). The size of

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Table 1. Patients' demographics and baseline characteristics in the study

Variables	10/12 Fr UAS (N=957)	12/14 Fr UAS (N=616)	*P*-value
Age, years; mean±SD	51.0 ± 13.5	52.1±14.1	.139[a]
Sex, N (%)			.095[b]
Male	599 (62.6)	411 (66.7)	
Female	358 (37.4)	205 (33.3)	
BMI , kg/m^2; mean±SD	25.4 ± 2.9	25.2 ± 3.2	.109[a]
ASA ; mean±SD	2.1 ± 0.4	2.2 ± 0.4	.071[a]
Stone size, mm; mean±SD	16.2 ± 3.3	16.2 ± 3.7	.800[a]
Stone location, N (%)			.453[a]
Upper calix	67 (7.0)	32 (5.2)	
Medium calix	118 (12.3)	66 (10.7)	
Lower calix	287 (30.0)	198 (32.1)	
Pelvis	188 (19.6)	119 (19.3)	
Multiple	297 (31.0)	201 (32.6)	
Laterality, N (%)			.091[b]
Left	551(57.6)	328 (53.2)	
Right	406 (42.4)	288 (46.8)	
Stone CT value, Hu; mean±SD	834.1±170.5	828.6 ± 172.6	.542[a]

Abbreviations: BMI, Body Mass Index; ASA, American Society of Anesthesiologists; Hu, Hounsfield Units; CT, Computed Tomography;
[a] Non-normal distribution variables were compared by Mann-Whitney U test
[b] Categorical variables were compared by Chi-square test

the UAS was determined at the surgeons' discretion during surgery. All operations were performed by two skilled surgeons.

Inclusion and exclusion criteria
Patients undergoing FURL for kidney stones with the use of UAS in an unstented ureter were included. Patients with prior impacted ureteral stones, the presence of ureteral stones during surgery, prior ureteroscopies, prior ureteral drainage (ureteral stent or PCN), documented ureteral strictures, prior radiation treatment, the presence of renal or ureteral malignancy or other metabolic diseases, such as renal tubule acidosis or hyperparathyroidism, were excluded from the study. Cases in which wider UASs could not be inserted successfully followed by the use of a narrower UAS, appropriate balloon dilatation or the direct use of flexible ureteroscopy without UAS were also excluded from the study.

Procedures
After admission, a kidney, ureter, and bladder radiograph (KUB) X-ray and a noncontrast CT were performed at the same time. Routine blood, urine and renal function tests as well as urine culture were performed to determine the presence of anaemia, urine infection, renal insufficiency, or any other condition that needed to be treated before surgery. Patients with preoperative positive urine cultures were treated with a complete course of culture-specific antibiotics before the FURL procedure. Prophylactic antibiotics with ciprofloxacin

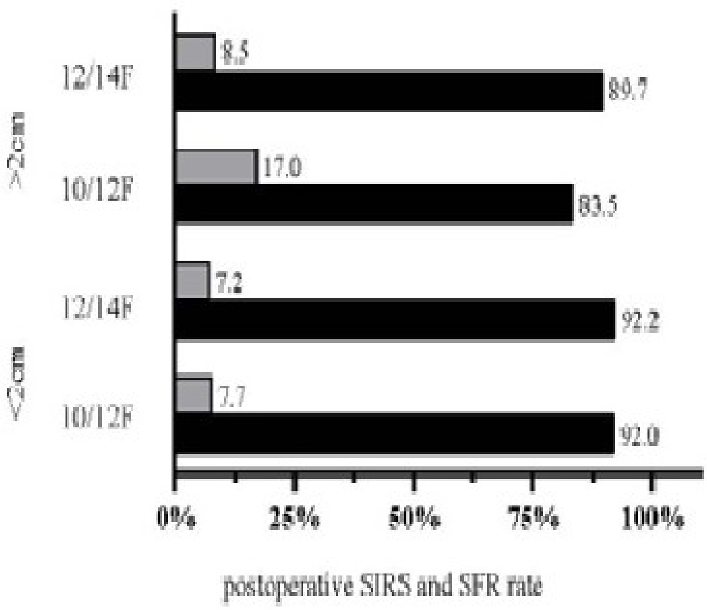

Figure1. Comparison of postoperative SIRS and SFR rate between group A (10/12 Fr UAS) and group B (12/14 Fr UAS) in all patients with stones >2 cm and <2cm separately.

Table 2. Comparison of clinical efficacy and safety

Variables	10/12 Fr UAS (N=957)	12/14 Fr UAS (N=616)	*P*-value
Clinical efficacy			
Insertion success rate, N (%)	873 (91.2)	533 (86.9)	.006[b]
Operative time, min; mean ± SD	24.8 ± 11.3	25.7 ± 9.9	.096[a]
SFR, N (%)	865(90.4)	565 (91.7)	.369[b]
Hospital stay, d; mean±SD	4.0 ± 0.8	3.9 ± 0.8	.174[a]
Safety			
Pain requiring IV/IM analgesics, N (%)	109 (11.4)	78 (12.7)	.447[b]
SIRS, N (%)	91(9.5)	49 (8.0)	.291[b]
Grades of Ureteral Injury, N (%)			< .001[b]
0	190 (19.9)	91(14.8)	
1	705 (73.7)	442 (71.8)	
2	60 (6.3)	81(13.1)	
3	2 (0.2)	2 (0.3)	

Abbreviations: SFR, Stone Free Rate; SIRS, Systemic Inflammatory Response Syndrome.
[a] Non-normal distribution variables were compared by Mann-Whitney *U* test
[b] Categorical variables were compared by Chi-square test

(cephalosporin for patients with abnormal renal function) were administered to all patients before the operation.
All FURL procedures were performed in the lithotomy position under general anaesthesia. A size 3 or 4 laryngeal mask airway was inserted and fentanyl at doses of up to 2 μg/kg given intravenously was administered as required during surgery. The ureteroscopy was performed with an 8/9.8 Fr semirigid ureteroscope (Richard Wolf, Germany), and a 0.035-inch nickel-titanium guide wire (Cook Inc, USA) was inserted into the renal collection system. Under the guidance of fluoroscopy, the UAS with infiltrated inner and outer surfaces was inserted into the proximal ureter along the guide wire. A 7.5 Fr flexible ureteroscope (Storz Flex X2, Germany) was used to find calculi in the pelvis or each calyx of the kidney, and the technique of dusting, working tangentially from the edge of the stone with the laser fibre at a high frequency (HF) with low energy, was then used. Irrigation (90 mL/minute) was performed to keep the visual field clear. After no obvious residual stones were found, the ureteroscope was withdrawn with the sheath, and ureteral wall injury was assessed. A 6 Fr Double-J stent (Cook Inc., USA) was placed after the procedure for approximately 2 weeks. If the ureter was narrow or twisted or UAS entry was difficult, the operation was abandoned, and a 6 Fr Double-J stent was placed.

Evaluations

A complete medical history along with anthropological parameters was routinely collected. Body mass index (BMI) was calculated as weight in kilograms divided by height in metres squared (kg/m^2). Blood samples were taken and tested for blood count and serum creatinine level. Urinalysis and urine culture were also performed before FURL. Stone number, size, location and Hounsfield unit (HU) were assessed by means of a low-dose NCCT scan, an accurate imaging modality for defining stone size and location.
The outcomes were the insertion success rate, systemic inflammatory response syndrome (SIRS) complication rate, ureteral wall injury, postoperative pain, operative time, hospital stay, and stone-free rate. There are four components of SIRS (temperature < 36° or > 38 °C, heart rate > 90 bpm, respiratory rate > 20 per minute, WBC# < 4000 or > 12000 cells/mm3), and at least two of these criteria need to be met. Ureteral wall injury was evaluated according to ureteral injury grading at the end of the operation by watching the surgical video and the description of some surgical records.[9] The operative time was defined as the time from the insertion of ureteroscope to the end of operation. The stone-free rate was defined as no more than a 2 mm residual stone detected by postoperative KUB X-ray approximately 2 to 3 weeks after removing the Double-J stent. The postoperative pain was defined as unbearable postoperative pain, which needs to be treated with intravenous or intramuscular analgesics.

Statistical Analysis

Statistical analysis was performed using a t-test for continuous, normally distributed variables and a Mann-Whitney U test for non-normally distributed variables. For categorical variables, the chi-square test or Fisher's exact test was applied. A $P < .05$ was considered to indicate statistical significance.

RESULTS

Demographic data, date on stone characteristics and preoperative evaluation are shown in Table 1. Of the 1573 patients enrolled, 10/12 Fr UASs were used in 957, and 12/14 Fr UASs were used in the remaining patients. The average age was 51.4 years, and 64.2% were male. There was no significant difference in baseline data between the two groups of patients.
The clinical outcomes and safety of the two groups are presented in Table 2. The insertion success rate was significantly better in the 10/12 Fr UAS group than in the 12/14 Fr UAS group (91.2% vs. 86.9%, $P = .006$), although postoperative pain, operative time and hospital stay were not significantly different. The multivariable logistic regression analysis identified UAS size (95% CI: 1.157–2.231, OR = 1.607, $P = .005$) as an independent risk factor for insertion success rate.
In our study, we did not record any grade IV ureteral wall injury. The number of patients with grade III ureteral wall injury was the same in both groups (2 cases). Regarding mild ureteral wall injury, 80.1% of patients experienced ureteral wall injury during the operation, including 73.7% with a grade I injury and 6.3% with a grade II injury in Group A. The situation was significantly worse in Group B, with 85.2% sustaining ureteral wall injury during the operation, including 71.8% with a grade I injury and 13.1% with a grade II injury

($X2= 25.590$, $P = .000$) (**Table 2**).
There was no significant difference in the incidence of SIRS or SFR between the two groups. Even when considering only patients whose calculi were > 2 cm, there was still no significant difference in SFR between the two groups (83.5% vs. 89.7%, $P = .130$). However, the incidence of SIRS in the 10/12 Fr group showed a sharp increase that was significantly higher than that in the 12/14 Fr group (17.0% vs. 8.5%, P = .037) (Figure 1).

DISCUSSION

Since flexible ureteroscopy was introduced into modern medicine in the late 1980s, the use of UASs has become widespread due to its many advantages, such as allowing for a clear surgical field, simplifying the surgical process, shortening the operative time, reducing the intraoperative renal pressure, and further reducing infection-related complications.[4-6]
Unfortunately, primary insertion of a UAS is not always successful. In recent years, some studies have reported that the failure rate of UAS insertion is 9.8% to 22.0%.[10] Arguably, the reason is likely the discrepancy between the diameter of the ureter (6-9 Fr) and the outer diameter of the UAS (12-18 Fr). Abandoning the operation due to UAS insertion failure will increase pain and cost. When FURL was carried out in China, double-J stents were routinely placed to dilate the ureter for 2 weeks before surgery to avoid the difficulty of passing the UAS through the ureter during the operation. Although prestenting can greatly improve the success rate of UAS insertion, its routine use remains controversial. The EAU guidelines recommend that ureteral stents should not routinely involve prestenting for all patients undergoing FURL. Prestenting not only increases the cost and cycle of treatment but also increases the occurrence of complications such as infection, haematuria, bladder irritation and urine reflux, which will affect the daily life of patients and increase their psychological burden. Furthermore, 58% of patients reported that stent symptoms had a negative economic impact due to work interruption. In fact, an increasing number of urologists are trying to avoid this incidence and are not routinely performing prestenting.[7] Although active balloon dilatation is another option, potential risks, such as ureteral oedema, postoperative discomfort and secondary stenosis, should not be ignored.[11] Our study showed that in the case of non-preoperative prestenting, the insertion success rate of narrower UASs (10/12 Fr) was significantly higher than that of wider UASs (12/14 Fr) (91.2% vs. 86.9%, $P = .006$). Moreover, the vast majority of patients can undergo complete FURL at one time to avoid pain and economic loss caused by reoperation.
The results of our study indicated the same effect on SFR, operative time and hospital stay between the two different UAS sizes. Some studies have reported that a wider UAS can reduce operative time, but these studies generally used active stone fragment retrieval with basket extraction.[4] The smaller diameter of the access sheaths (inner diameter 10 Fr) allows only small stone fragments (< 3 mm) to be removed. Fragments of this size may be difficult to capture in the basket and will inevitably prolong the operative time. In all of our FURLs, the ‘‘dusting’’ technique was used to treat kidney stones. A recent multicentre prospective study showed that there was no difference in the readmission rate, reintervention rate or symptoms due to residual fragments in the short term between dusting and fragmentation with stone retrieval for kidney stones < 15 mm.[12] Another recent study in which calculi 10-40 mm were treated with ureteroscopy showed that active fragment retrieval using a nitinol basket was not associated with improvements in stone-free rates.[13] Gamal and Mamdouh performed FURL on 46 patients with unilateral renal calculi less than 2 cm. The patients were randomly divided into two groups: Group 1 was treated with dusting for stones using low power (0.2-0.4 J) and high frequency (20-30 Hz), and Group 2 was treated with fragmented stones using high power (1-2 J), low frequency (4-5 Hz) and basket extraction of fragments. The SFRs of the two groups were similar (86% and 89%, respectively), and dusting was associated with a significantly shorter operative time (57 minutes vs 70 minutes, $P = .001$).[14] Another argument for dusting involves the cost of surgery. Regardless of whether the fragments need to be actively retrieved after laser lithotripsy, both operations require guide wires and laser fibres. Dusting procedures can usually be performed with these devices alone. However, extraction requires the use of a grasper or basket further, and in some cases, having a tacit assistant during active fragment retrieval is also critical to shorten the operative duration.
Infectious complications are the most common and dangerous complications of FURL, including sepsis or infectious shock. One of the main functions of UAS is to control the pressure of the renal pelvis to reduce the incidence of infection. It is well known that stones located in different locations (especially in the lower calyces) can result in increased operative difficulty and duration, and a longer operative time can increase the incidence of SIRS. In our study, there was no significant difference in the location of kidney stones between the two groups. When the size of the kidney stone was less than 2 cm, there was no significant disadvantage with respect to infectious postoperative complications of 10/12 Fr UAS compared with 12/14 Fr UAS (7.7% vs. 7.2%, $P = .728$). Nonetheless, when the stone size was larger (> 2 cm), the incidence of SIRS in the 10/12 Fr UAS group increased significantly and was twice that in the 12/14 Fr UAS group (17.0% vs. 8.5%, $P = .032$).
In all ureteroscopies, the irrigation system is the key to visualization. Pressurized saline irrigation is usually used in ureteroscopy, which can increase the pressure of the renal pelvis.[15] There is a large amount of endotoxin in renal calculi, which increases significantly with increasing stone burden.[16] It has been shown that high pelvic pressure can lead to regurgitation; in addition, systemic absorption of irrigation fluid containing bacteria or endotoxins can lead to postoperative fever and/or SIRS. Due to rapid outflow through UAS, its use during ureteroscopy enhances the visibility of the upper urinary tract while maintaining low pelvic pressure (< 40 cmH_2O).[17] In some studies, maximal intrapelvic pressure was similar between 12/14 Fr and 14/16 Fr UAS, and it did not exceed 46 cmH_2O even under manual pumping using the 10/12 Fr UAS.[18] When the instruments occupy the working channel of the ureteroscope, they decrease flow significantly (for a fixed driving pressure). Thus, there is no obvious irrigation outflow with the increase in UAS diameter.[19]
One of the main problems with the use of large UASs is the possibility of ureteral wall injury, which may

lead to the formation of ureteral strictures.[20] Traxer and Thomas described ureteral injury after exposure to sheath-assisted URS and established the five-point scale for ureteral wall injury used in this study.[9] Due to the lack of routine prestenting before FURL in our study, the overall incidence of ureteral injury was higher than that in other studies. However, our study confirmed that reducing the size of the UAS can avoid the risk of ureteral injury, as the risk associated with visible ureteral lesions with 10/12 Fr UASs was significantly lower than that with larger UASs (80.1% vs 85.2%, $P < .001$). Although severe ureteral injuries are rare during the operation, even the external diameter of the smallest UAS exceeds the normal ureter, i.e., 3-4 mm, equivalent to the outer diameter of 9-12 Fr. Some studies have shown that the histopathological evaluation of ureteral wall lesions after UAS placement revealed a significantly higher degree of severity than that observed endoscopically in a porcine model.[21] Additionally, in a swine animal model, Lallas et al. measured the blood flow of the ureter with a laser Doppler blood flow metre. After insertion of the UAS, a lower ureteral blood flow and slower recovery were obtained with a larger UAS.[22] Therefore, the incidence of UAS-related complications of ureteral injury is expected to decrease significantly with the reduction in UAS diameter.

Under the influence of a large UAS, the proinflammatory mediators COX-2 and TNF-a become significantly upregulated in the ureteral wall, which may have an impact on postoperative pain.[23] However, Oguz et al. prospectively investigated factors related to early postoperative pain after retrograde intrapelvic surgery in 250 patients. The only operation-related factor associated with severe pain was the total duration of UAS placement: 46.57 minutes in those with severe pain versus 41.54 minutes in those without pain; the size of UAS, operative time, ureteral injury and prestenting were not related to pain after URS.[24] Our study also showed that even with the use of smaller UAS, the proportion of postoperative analgesia did not improve due to the similar lithotripsy time.

Our study is the first to compare the efficacy and complications between two different sizes of UASs (10/12 vs 12/14 Fr) in previously unstented and unmanipulated ureters, although the study did have limitations. The study was retrospective in nature, which may lead to selection bias. We attempted to overcome this limitation by including all cases of FURL for renal calculi that were dusted during the study period. Unfortunately, we did not assess whether the results were influenced by basketing and digital scopes. The operation was also performed by two different surgeons, which may lead to technical differences. In addition, the choice of UAS size was at the discretion of the surgeon and was not random. However, these limitations do not change the outcome, namely, that 10/12 Fr UAS has an advantage for unstented ureters.

CONCLUSIONS

With the development of technology, the size of the ureteroscope is becoming increasingly smaller. The 10/12 Fr UAS showed an advantage in the insertion success rate and prevented ureteral wall injury in FURL compared with the 12/14 Fr UAS. The 10/12 Fr UAS can provide proper irrigation flow, which does not significantly increase the possibility of postoperative infectious complications. We recommend the use of the 10/12 Fr UAS as a first-line choice in patients with kidney stones less than 2 cm.

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CONFLICT OF INTEREST

The authors report no conflict of interest.

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