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ORIGINAL PAPER

Comparison of commonly utilized ureteral access sheaths: A prospective randomized trial

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Summary ***Objective:** We aimed to evaluate and compare the functional characteristics, safety profile and effectiveness of two commonly used ureteral access sheaths (UAS) during flexible ureteroscopy.*
***Methods:** After institutional review board approval, patients with proximal ureteral or kidney stones requiring flexible ureteroscopy and UAS were prospectively randomized to group I or group II according to the type of access sheath used. Primary outcome was incidence of intraoperative complications.*
***Results:** Eighty-eight patients were enrolled in the study, 44 patients in each group. Sheath size 12/14 FR was used in both cohorts. Median (IQR) stone size was 10 mm (7-13.5) and 10.5 mm (7.37-14) in group I and II respectively (p = 0.915). Nineteen and twenty patients, in group I and II respectively, were pre-stented. Subjective resistance with insertion of the UAS was observed in 9 and 11 patients in group I and II respectively (p = 0.61) while failed insertion was encountered in one patient in group I. Traxer grade 1 ureteral injury was noted in 5 and 6 patients in group I and II respectively while grade 3 injury was seen in 1 patient for both cohorts (p = 0.338). There was less resistance for UAS placement in pre-stented patients (p = 0.0202) but without significant difference in ureteric injury incidence (p = 0.175). Emergency department visits were encountered in 7 (group I) and 5 patients (group II) (p = 0.534).*
***Conclusions:** The studied UASs were comparable regarding safety and efficacy in the current study. Pre-stented and dilated ureters had less resistance to insertion although this was not reflected on incidence of ureteric injury.*

KEY WORDS: *Ureteroscopy; Urolithiasis; Ureteral Access sheath; Ureteral trauma.*

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BACKGROUND

Ureterorenoscopy continues to be one of the most common procedures performed in urology practice, being a minimally invasive option for treatment of nephrolithiasis and ureterolithiasis. Technological advances in both the size and flexibility of ureteroscopes have been integral to removing larger stones with a higher stone free rate. The continued advancement of the technology surrounding Holmium: YAG lasers, graspers, and baskets have continued to widen the application of ureteroscopy (1, 2).
There are multiple instruments available on the market to aid in the performance of ureteroscopy (3). One tool in the urologist armamentarium is the *ureteral access sheath* (UAS), to access the proximal collecting system. The use of UAS has the proposed advantages of lowering the intrarenal pressure that probably decreases the complications related to infection, increasing irrigation flow and facilitating multiple reinsertions and withdrawals of the ureteroscope during surgery (4, 5). However, these benefits are associated with the cost of increased insertion forces and greater risk for ureteral wall injury, and possible failed insertion. Proposed higher stone free rates with UAS use and cost-effectiveness are too much debated (6-8).
UAS has multiple designs across multiple brands. Although safety has been demonstrated, there have been few studies comparing designs of different companies in the hands of practicing urologists in vivo. We aimed to compare two commonly used UASs regarding functional characteristics, safety profile and effectiveness of each. This information will help guide urologists in product selection when performing ureteroscopy.

METHODS

After *institutional review board* (IRB) and ethical committee approval, patients with proximal ureteral or kidney stones requiring flexible ureterorenoscopy and UAS placement in our tertiary center were enrolled in the prospective clinical trial after signing the informed consent. Patients less than 18 years old or patients with ureteric stricture were excluded. Patients were randomized to the use of Boston Scientific *Navigator HD*^{TM} (NHD) (Group I) or of *Cook Flexor*^{TM} (CF) (group II) UAS. Randomization was performed by investigator using closed envelope technique.
The data of both cohorts were prospectively obtained and analyzed. Traxer grading system for UAS-related injuries was used for classification and comparison of intraoperative ureteric injuries (8). Primary outcome was incidence of sheath related intraoperative complications while the difficulty of UAS placement, *length of procedure* (LOP), post-operative complications, patient-reported complaints/phone calls/*Emergency Department* (ED) visits, postoperative hydronephrosis were Secondary outcomes.
The two UAS brands have a design of outer hydrophilic sheath and smooth-tapered inner coaxial dilator. The CF outer sheath is specialized with coil construction core. The inner dilator of NHD has a stiff body and a more flex-

ible tip while CF inner dilator has a stiff tip tapered to 6 Fr diameter. The NHD is available in 3 sizes of 11/13 Fr, 12/14 Fr, and 13/15 Fr whereas CF is available in 12/14 and 14/16 in addition to smaller diameters of 9.5/11.5 and 10.7/12.5 Fr.

Statistical analysis

All statistical analysis was performed using the commercially available SAS Version 9.4 (*Statistical Analysis Software*) (*SAS Institute Inc., Cary, NC, USA*). Frequencies and percentages were used to describe categorical variables while medians and interquartile ranges (or means and standard deviations where appropriate) were used to describe continuous variables. A chi-square test or Fisher's exact test were used to test for comparison of categorical variables according to the expected cell counts while two-sample t-test (or Wilcoxon rank-sum test when appropriate) was used for comparison of quantitative variables. The significance level was set at a p-value < 0.05.

Results

Between February 2017 and February 2020, 88 patients were prospectively enrolled in the study. Forty-four patients were included in each group. Sheath of 12/14 French was used in both cohorts.

Patients' demographics were comparable with no statistical significance between both cohorts except for higher rate of preoperative alpha blocker use in group II. Median (IQR) stone size was 10 (7-13.5) mm and 10.5 (7.37-14) in group I and II respectively (p = 0.915). Thirty-nine patients had ureteric stents previously inserted (pre-stented) at the time of flexible ureteroscopy, nineteen and twenty patients, in group I and II respectively (Table 1).

Median (IQR) operative time was 54 (41-78) and 51 (36-72) minutes in group I and II respectively (p = 0.302). Subjective resistance with insertion of the UAS was observed in 9 patients in Group I vs. 11 patients in group II (p = 0.61). There was one failure of insertion of the UAS in group I. There was a statistically less resistance for placement of the UAS noted in pre-stented patients' cohort (p = 0.0202). It was also noted that patients with preoperative hydronephrosis had significantly less resistance to UAS placement (p = 0.0493). There was no significant difference in resistance to insertion between patients who had preoperative alpha blocker use or not (p = 0.34).

Regarding sheath-related ureteric trauma, a total of 13 (16%) injuries were observed; 7 and 6 injuries in group I and II respectively. Out of 13 patients with ureteric injury, 8 patients were not previously stented (p = 0.175). Taxer grade 1 ureteral injury was noted in 6 patients in the group I vs 5 patients in Group II. Taxer Grade 3 injury was seen in 1 patient for both cohorts (p = 0.338) (Table 2).

Need for opioid analgesia and patients' phone calls were comparable between both groups (p = 0.247, 0.669 respectively) Return to the ED was encountered in 7 and 5 patients from group I and II respectively (p = 0.534). The complains were mainly related to pain and hematuria. There was no association with sheath complication and return to ED. Within follow up of 3 months, one patient in group 2 had persistent hydronephrosis although imaging has excluded occurrence of ureteric stricture.

Table 1.
Preoperative patient criteria in both groups.

		Group I (n = 44)	Group II (n = 44)	P value
Age, years, mean (SD)		59.1 (2.3)	53.9 (2.5)	0.13
Sex, n (%)	Male	21 (48%)	25 (57%)	0.393
	Female	23(52%)	19(43%)	
Stone size, mm, median (IQR)		10 (7-13.5)	10.5 (7.37-14)	0.915
Stone side, n (%)	Right	18 (40%)	14 (32%)	0.414
	Left	24 (54.5%)	27 (61.3%)	
	Bilateral	2 (4.5%)	3 (6.8%)	
Alpha blocker use, n (%)		15 (34%)	28 (63%)	0.005
Stone location, n (%)	Renal	41	45	0.305
	Upper ureter	7	13	
	Mid ureter	0	1	
	Lower ureter	2	3	
Hydronephrosis, n (%)		23 (52%)	30 (68%)	0.127
Preop UTI, n (%)		6 (13.6%)	12 (27.2%)	0.112
Pre-stenting, n (%)		19 (43.1%)	20 (45.4%)	0.83

Table 2.
Perioperative outcome data.

		Group I (n = 44)	Group II (n = 44)	P value
Operative time, min, median (IQR)		54 (41-78)	51 (36.5-72.25)	0.302
Anesthesia time, min, median (IQR)		100 (74.5-121.5)	104 (76.5-118.5)	0.779
Resistance to introduction, n (%)		9 (20.4%)	11 (25%)	0.61
Failed insertion, n (%)		1 (2.27%)	0	0.314
String on stent		23 (52%)	25 (56.8%)	0.66
Op. sheath complication, n (%)		7 (15.9%)	6 (13.6%)	0.763
Ureteral injury grade, n (%)	Garde 1	6 (13.6%)	5 (11.3%)	0.338
	Grade 2	0	0	
	Grade 3	1 (2.27%)	1 (2.27%)	
Need for Opioid analgesia, n (%)		16 (36.3%)	11 (25%)	0.247
Phone calls, n (%)		22 (50%)	20 (45.4%)	0.669
ED-return, n (%)		7 (15.9%)	5 (11.36%)	0.5344
PO Hydronephrosis, n (%)		0	1 (2.27%)	0.314

Discussion

The benefits of the UAS in ureteroscopy and *retrograde intrarenal surgery* (RIRS) are still controversial. De *Coninck et al.*, in their systemic review, showed that UAS helps increasing flow of irrigation and decreasing intrarenal pressure but the impact of UASs on stone-free rates, ureteroscope protection or damage, postoperative pain, risk of ureteral strictures, and cost-effectiveness are still controversial (4).

In another recent review article, Wong et al have concluded that no evidence exists for higher stone free rate with the use of UAS but facilitates multiple and rapid passages of the ureteroscope during the procedure. According to Wong et al, larger UAS diameters > 12/14 Fr were associated with lower intrarenal pressure and greater efficacy at the cost of increased forces during insertion, greater risk for ureteral wall injury, and lower insertion success rates (6).

Regarding the UAS size choice, *Yoshida et al.* have evaluated different UAS ≤ 10/12 F regarding the intrapelvic pressure in an ex-vivo porcine kidneys. They showed that 9.5/11.5 F UAS were associated with excessive intrapelvic pressure (10). Sener et al have recommended sheath size 10/12 F as the first choice during flexible ureterorenoscopy for good irrigation and lower rate of ureter injury than 12/14 F UAS (11).

De et al. compared the physical characteristics of NHD, CF and other two new single-wire system UASs in ex-vivo study. They reported that NHD is more slippery and more rigid with larger outer diameter while CF had shorter and stiffer tip and appeared less traumatic (more force was required for tip perforation) (12). In a similar ex-vivo study, Patel et al also compared the physical and mechanical characteristics of NHD UAS versus Glideway™ and Pathway™ UASs supplied by Terumo. They reported superiority for NHD regarding safety and ease of use (13). Loftus et al have compared the same two investigated UAS brands in a randomized clinical trial. In contrary of our study, all the patients included in their study were not pre-stented. Loftus et al used different UAS sizes and they crossed over patients who fail insertion of one UAS type to the other. They reported overall sheath placement success rate of 87.8% with no difference between both types although NHD was subjectively easier to insert and was successful in 3 out of 7 (43%) patients who failed insertion of CF. They have reported some factors associated with high-grade (grade 2 or 3) ureteral injury as male gender, difficult subjective insertion, longer time of sheath insertion and high stone burden (14).

In the current study, the insertion success rate was 98.8% with no significant difference between both groups. The two UASs appeared comparable on many fronts, including ease of placement, ureteral injury rates, operative times, and return to ED rates. Of note, our results showed less resistance to insertion was seen with preoperative hydronephrosis and ureteric stenting although no difference regarding ureteric injury. Similarly, *Yuk et al.* have reported that pre-stenting was associated with higher UAS placement success although had no effect on overall operative outcomes (15).

Other studies have investigated the use of alpha blockers on UAS force of placement. Koo et al have reported that preoperative use of alpha blockers was associated with lower UAS insertion force (16). However, contradictory results were reported by Erturhan et al in another study (17). In our cohort, the preoperative usage of alpha blockers prior to UAS placement was not associated with an easier subjective UAS clinical placement.

Study by *Stern et al.* demonstrated that high-grade injury due to UAS placement has around a 1.8% stricture rate and this rate was similar to that reported without use of UAS (8). *Aykant et al.*, in a prospective randomized study, have recently reported the rates of low-grade ureteral injury rate of 23.1% while high-grade injury rate was 8.9%. After 1-year, the ureteral stricture was 1.6%. They reported that use of 12/14 F UAS was associated with higher risk of high-grade injuries although there was no difference in ureteral stricture formation compared to use of 9.5F/11.5 F sheath (18).

There were only two high grade ureteral injuries noted in the current study. All ureteral injuries were treated with stent placement for 2-4 weeks. On follow up, only 1 patient had persistent hydronephrosis and no patients were noted to have ureteral stricture at follow up of 3 months. Our study adds to growing literature that the NHD and CF have similar safety profiles and have a broad range of clinical application.

Limitations of the study include small study group and lack of stone-free rate assessment. Further studies could be used to target stone size and determine the effect of sheath usage on stone clearance rates.

Conclusions

The two commonly utilized ureteral access sheath brands are equally safe and effective for utilization during flexible ureteroscopy and retrograde intrarenal surgery. Prestented and dilated ureters show less resistance to insertion although this was not associated with lower incidence of associated ureteric injury.

Informed consent: The study and informed consent were approved by *Baylor Scott & White Institutional review board* (IRB No: 18-4720). All patients have signed an informed consent prior to participation to the study.

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