Comparison of a Novel Radially Dilating Balloon Ureteral Access Sheath to a Conventional Sheath in the Porcine Model

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Purpose: Traditional ureteral access sheaths rely on tapered dilators and the Dotter principle of axial force to gain access into the ureter. We compared the performance of a novel balloon expandable ureteral access sheath using radial dilatation with that of a conventional ureteral access sheath.

Materials and Methods: Ten farm pigs underwent randomized placement of the novel sheath in 1 ureter and a conventional ureteral access sheath in the contralateral ureter followed by videotaped ureteroscopy. Acute study end points included maximum and mean force of sheath insertion and removal, saline flow rate and subjective urothelial damage following sheath insertion/inflation. Additionally, blinded reviewers rated urothelial damage on digitally recorded video following sheath removal. Chronic data included gross and histological ureteral analysis at 30 days.

Results: The novel ureteral access sheath inserted with less maximum force (0.36 vs 1.48 pounds, $p < 0.001$) and less average force (0.11 vs 0.49 pounds, $p = 0.001$). The flow rate during 5 minutes was higher in the new sheath (90.0 vs 80.6 cc per minute, $p < 0.05$). Withdrawal forces were not statistically different between the sheaths. The novel sheath also had a lower subjective trauma scale rating (4.2 vs 6.1, $p < 0.05$). Eight blinded reviewers determined that the novel ureteral access sheath resulted in less total urothelial tear length (1.3 vs 2.7 cm, $p = 0.03$) and less visible ureteral damage in all animals except 1 ($p = 0.04$).

Conclusions: The novel balloon expandable ureteral access sheath had easier insertion and a better flow rate, and caused less urothelial trauma in this porcine model. This ureteral access sheath offers a promising new option for ureteral access. A randomized clinical trial is in progress to assess the benefits of this new ureteral access sheath.

Key Words: ureter, swine, calculi, balloon dilatation, wounds and injuries

Ureteral access sheaths have undergone several recent design advances that have increased their popularity, including hydrophilic coatings, tapered dilators, kink resistant designs and a funnel-shaped ergonomic entry port.[1–3] Despite these changes all UASs currently on the market rely on the Dotter principal of axial force for dilatation during insertion. This axial dilatation is potentially traumatic to the ureter and results in failure to place the sheath in up to 30% of patients.[4,5]

A new UAS has been developed that uses a new concept in sheath placement. The new balloon expandable sheath inserts with radial dilatation, a technology that could circumvent the shearing force to the urothelium caused by axial dilatation. We compared a novel BEUS that uses radial dilatation to a CUAS in the porcine model.

MATERIALS AND METHODS

Working with groups at Duke University Medical Center, Naval Medical Center San Diego, Onset Medical, Irvine, California and Boston Scientific, Natick, Massachusetts, a novel BEUS has been developed that uses radial dilatation for insertion. This device consists of a folded, reinforced polymer UAS premounted over a small central balloon dilator (part *A* of figure). The sheath has a lubricious coating and it is inserted in a 9.5Fr configuration into the ureter (part *B* of figure). The tip also has a novel design that eliminates the step-up from dilator to sheath seen in conventional models to further facilitate insertion (part *C* of figure). The sheath contains 2 radiopaque markers that allow placement at the appropriate location in the ureter, including a mark 8 mm from the tip of the balloon dilator and a second mark that indicates the tip of the unexpanded sheath.

After the device is positioned dilute contrast material is injected into a separate port, inflating a high pressure (20 atm) balloon that is maintained inflated for 30 seconds. With complete balloon expansion sheath diameter increases to its full size and the balloon tip retracts inside the sheath to allow easy removal of the dilating balloon (part *C* of figure). After it is deployed in the ureter the BEUS is used in a manner similar to that of a conventional access sheath. In this study a 55 cm 12Fr inner diameter/14Fr outer diameter BEUS was compared to an identically sized CUAS (Cook Urological, Spencer, Indiana).

After obtaining approval from the institutional animal care and use committee 10 female farm pigs were random-

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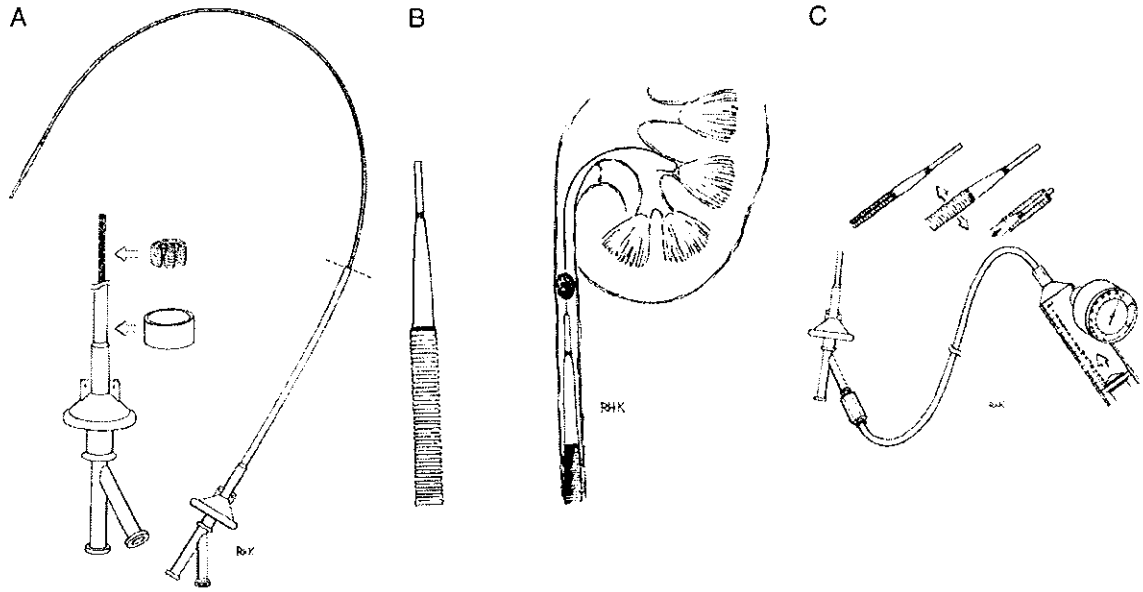

A, BEUS with distal portion (inset) in folded 9.5Fr configuration. *B*, unexpanded sheath inserted over guidewire to just below stone. *C*, high pressure insufflator used to expand sheath to 20 atm, allowing tip to retract into expanded sheath (inset).

ized to undergo placement of the BEUS on 1 side and a similar sized CUAS on the contralateral side. Following the induction of general anesthesia the animals were initially placed in the lithotomy position on a fluoroscopy table and rigid cystoscopy was performed. Retrograde pyelogram was performed with a 6Fr end hole catheter, followed by placement of a 0.038-inch standard guidewire (Cook Urological) into the renal pelvis. The bladder was fully decompressed before all testing and fluoroscopic guidance was used for wire placement. Randomization was performed by coin toss to determine which sheath would be placed into each ureter.

Acute study end points included maximum and mean force of sheath insertion and removal, the saline flow rate and subjective urothelial damage following sheath insertion/inflation. The ureteroscope used in all trials was a DUR™-8 Elite.

Before inserting all sheaths the lubricious coating was activated by dipping the sheath in normal saline and the tip was further lubricated with surgical lubricant. The UAS was inserted over the guidewire to a point just below the ureteropelvic junction using an electronic force transducer to measure the maximum and mean force required for insertion. A ZP-4 digital force gauge electronic force transducer (Imada, Northbrook, Illinois) was connected to the end of either sheath and used to advance the sheath into the appropriate position in the ureter. Force transducer data were analyzed using ZP recorder force data analyzer software, version 1.9 (Imada).

The flow rate was determined by connecting the ureteroscope to a 300 mm Hg pressure irrigation unit. The ureteroscope tip was placed at the distal end of the sheath and irrigation was open fully for 5 minutes. All irrigant draining during the 5 minutes was collected and measured. The sheath was then removed while measuring the mean and maximum force with the electronic force transducer. Digital video footage was filmed while removing the ureteroscope to document the amount of trauma caused by UAS placement and removal. The sheaths were never visible in the acquired video images. This process was then repeated on the contralateral ureter with the opposite sheath. The animals were maintained on antibiotics for 3 days.

Eight blinded reviewers, including 6 fellowship trained endourologists and 2 experienced ureteroscopists, viewed the ureteroscopic video. Each observer rated the degree of trauma on a scale of 1 to 15, determined ureteral tear length in cm and chose which ureter in each animal appeared to have less trauma. The trauma scale was a graded scale that ranged from no trauma to the presence of petechiae, abrasions, and simple and complex tears graded by quantity and length.

After 30 days the animals underwent nonsurvival surgery in which the kidneys and ureters, including a bladder cuff, were harvested. A total of 30 days were selected to allow the detection of significant long-term changes, such as stricture.

Chronic end points included gross and histological evaluation of the ureters at 30 days by a pathologist. Three sections of ureter, including the ureteropelvic junction, mid ureter and ureterovesical junction, were selected for histological analysis. Hematoxylin and eosin stained sections were evaluated using a 5-point semiquantitative histological score to grade the amount of inflammation.

Statistical analysis was performed using the SPSS®, version 10.0 with $p < 0.05$ considered statistically significant. The 2-sided Student t test was used for parametric variables and the Wilcoxon signed ranks test was used for nonparametric variables.

RESULTS

The novel BEUS inserted with less maximum force (0.36 vs 1.48 lb, $p < 0.001$) and mean force (0.11 vs 0.49 lb, $p = 0.001$) compared to the CUAS. There was no significant difference in mean or maximum withdrawal force. The flow rate was better with the BEUS (90.0 vs 80.6 cc per minute, $p < 0.05$). The novel sheath also had a lower acute subjective trauma

scale rating (4.2 vs 6.1, $p < 0.05$, table 1). In the objective analysis of the ureteroscopic video footage blinded reviewers determined that the BEUS resulted in less total urothelial tear length (1.2 vs 2.6 cm, $p < 0.05$), a decreased trauma rating (3.7 vs 5.6, $p = 0.058$) and less damage on the BEUS ureter, as graded by most reviewers in all ureters except 1 ($p < 0.05$, table 2).

Gross examination of the ureters demonstrated a single animal with periureteral abscesses and ureteral strictures bilaterally, although each ureter was patent. This animal had bilateral moderate hydronephrosis but preserved renal parenchyma. The acute trauma scale in this animal was 9 for the CUAS and BEUS with a total tear length of 12 and 7 cm, respectively. In the remaining animals the kidneys and ureters were grossly normal. One animal died of anesthetic complications and, therefore, it was excluded from chronic histological analysis. There was no statistically significant difference in the degree of chronic inflammation seen on microscopic evaluation between the 2 sheaths at any level of the ureter (table 3).

DISCUSSION

The popularity of the UAS has been increasing recently as a body of research has demonstrated the potential advantages associated with its use. Studies have demonstrated that use of an access sheath results in lower pressures at all sites of the collecting system during irrigation.[6,7] Other advantages noted with the traditional UAS have been improved ureteroscope longevity, simplified ureteral reentry, decreased operative time, lower total cost of the procedure, a better irrigant flow rate, better visualization, simplified stent placement and an improved stone-free rate.[3,5,8–12] However, there have been arguments against the routine use of a UAS for upper tract endoscopy because of concerns about ureteral ischemia and potential urothelial trauma from the shearing force of a CUAS on the distal ureter.[4]

Previous studies using a laser Doppler probe to measure blood flow in the porcine ureteral wall during surgery with a UAS demonstrated that with a 12/14Fr and larger UAS there was a greater than 50% decrease in blood flow initially, followed subsequently by a slow, compensatory return of blood flow with time.[13] Also, the reliance of all currently available sheaths on axial dilatation means that shear force is created in the ureteral wall, which may result in urothelial injury, including abrasions, lacerations and even full-thickness tears. This potential ureteral trauma combined with ischemia has raised concerns about long-term complications, such as ureteral stricture or perforation.[13] Similarly this reliance on axial dilatation makes it difficult to insert the sheath in patients with delicate ureters who have not undergone previous stent placement. In fact a conventional sheath may not be inserted in up to 30% of patients who have not undergone prior ureteral stent placement.[5] In our experience patients at risk for CUAS insertion failure include young males with tight ureteral orifices, patients with duplicated systems and those with small caliber ureters.

During the current study the novel BEUS was much easier to insert, requiring less than a quarter of the maximum and mean force for insertion. The novel configuration has 2 significant engineering advances that likely account for this easier sheath placement. 1) The device is inserted in a 9.5Fr configuration that creates much less resistance with the urothelium. 2) The tip design does not have a step-up from dilator to tip, which is seen in conventional sheaths. Eliminating this step-up removes a lip that may catch on the urothelium and result in shearing during insertion. The lower force required for insertion means that less shearing force is applied to the ureter, resulting in less urothelial trauma. Less shearing force combined with radial dilatation is likely the etiology of the decreased urothelial trauma seen with the BEUS. If easier insertion and decreased urothelial trauma are supported during additional studies in humans, this sheath may overcome some of the remaining limitations seen with the CUAS.

Determining the incidence of strictures following UAS use is difficult. It is often challenging to tell whether a stricture was present before stone formation, resulted from the stone, causing edema and ischemia, or resulted from UAS use. For this reason there have been few studies of the incidence of ureteral strictures following UAS use. One group reported a 1.7% stricture rate associated with UAS use.[14] However, it has been argued that the actual stricture rate may be higher since fewer than half of the studied patients were included in the analysis.[3,4] In the current study 1 pig that was noted to have ureteral tears bilaterally upon UAS removal (1 of each type) showed bilateral strictures. Since ureteral stents were not placed following UAS placement this animal likely had urine extravasation followed by abscess development and subsequent stricture for-

TABLE 1. *Acute study end points*

	BEUS	CUAS	p Value
Insertion force (pounds):			
Max	0.36	1.48	<0.01
Av	0.11	0.49	<0.01
Flow rate (cc/min)	90.0	80.6	0.03
Withdrawal force (pounds):			
Max	1.99	.98	0.09
Av	0.83	0.46	0.16
Trauma scale	4.2	6.1	0.01
Total tear length (cm)	1.1	3.5	0.11

TABLE 2. *Blinded reviewer data on videotaped urothelial trauma following UAS insertion and removal*

	BEUS	CUAS	p Value
Mean trauma score	3.7	5.6	0.058
Total tear length (cm)	1.2	2.6	0.028
No. ureters favoring BEUS vs CUAS	7	1	0.035

TABLE 3. *Ureters with each histological subtype by location*

	No. Ureterovesical Junction		No. Mid		No. Ureteropelvic Junction	
Grade	BEUS	CUAS	BEUS	CUAS	BEUS	CUAS
0	5	6	6	6	2	3
1a	0	0	0	0	3	3
1b	3	2	2	2	2	2
2	1	1	0	0	2	1
3	0	0	1	1	0	0

Grading scale: 0—normal, 1a—scattered mild chronic inflammation, 1b—focal mild-moderate inflammation, 2—diffuse moderate inflammation and 3—marked inflammation.

mation. Although placing a stent may have prevented the stricture, it was decided to not leave stents in this study to preserve the natural histology. The strictures in this animal confirm the common belief that, if any ureteral split or tear is noted following active ureteral dilatation, an indwelling stent should be placed.

A known advantage of CUASs is that they have improved flow compared to ureteroscopy without a sheath.[7] A high irrigant flow rate is an important part of any ureteroscopic procedure because the increased flow allows improved visibility and, hence, improved efficiency and safety during the procedure. In this study the BEUS further improved the flow rate by 11% compared to the CUAS. Since this model did not include stone treatment, there was no bleeding or stone fragments. For this reason it is impossible to determine whether this improved flow rate would translate into better visibility in a clinical setting. The reasons for this improved flow rate are not immediately apparent but they may be related to the fact that upon expansion the folded sheath is not completely round and the slightly eccentric sheath may allow easier bulk flow of irrigant fluid.

To our knowledge this study represents the initial animal experience with a new concept in ureteral access sheaths. A novel aspect of this study is that ureteral trauma was assessed in 2 ways. In the first method a nonblinded reviewer rated urothelial injury and total tear length acutely at surgery. In this analysis the ureter that underwent BEUS placement had a significantly lower trauma score (4.2 vs 6.1, $p = 0.01$) and lower, although not significant, difference in tear length (1.1 vs 3.5 cm, $p = 0.11$). In the second method 8 blinded reviewers rated tear length, trauma score and which of the paired ureters had the least trauma by watching video footage of each ureter while removing the ureteroscope. This technique is a novel method for assessing urothelial trauma and we believe that it represents the best opportunity to prevent any reviewer bias. There was good correlation between reviewers and in all animals except 1 with most reviewers rating the BEUS side as having equal or less urothelial trauma ($p = 0.04$). There was a significantly lower total tear length in the BEUS ureters (1.2 vs 2.6 cm, $p = 0.03$) and a trend toward a lower trauma score (3.7 vs 5.6, $p = 0.058$).

A limitation of this study is that the devices were tested in a porcine model. Animals were selected to approximate the size of humans but how the susceptibility to trauma compares between pig and human ureters is not fully known. There are potential limitations with the BEUS device. The insertion process requires balloon inflation as a separate step. The impact of this factor on total sheath insertion time was not evaluated in this study but it might be increased in some patients. Also, because of the significant ease of insertion, the sheath could be advanced beside the stone and dilatation could force the stone outside the ureter. In contrast, although it was not statistically significant, the withdrawal force was somewhat greater and in a larger sample size this might have attained statistical significance. Another limitation of this study is that the device was not specifically tested in a strictured ureter. A model for use in the strictured ureter is currently under construction.

CONCLUSIONS

This novel BEUS was safe and easy to use in the porcine model. Due to its smaller size at insertion and its reliance on radial dilatation this ureteral access sheath resulted in a significant decrease in urothelial trauma and in easier insertion than standard access sheaths. The easier insertion, less traumatic radial dilatation and better flow rate make this device a promising new option for ureteral access. Human trials are currently under way to confirm these advantages.

Abbreviations and Acronyms

BEUS	=	balloon expandable UAS
CUAS	=	conventional UAS
UAS	=	ureteral access sheath

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