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ORIGINAL RESEARCH

Novel curved ureteric access sheath holds the potential to aid anatomical placement and allow adjustment in the renal pelvis: a feasibility study

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Background: The benefits of ureteric access sheath (UAS) placement during flexible ureterorenoscopy (fURS) for urolithiasis are well recognised. Failure to successfully place a UAS and the potential for ureteric injury are known complications. This feasibility study aims to describe a novel curved UAS, which is postulated to assist the endourologist in negotiating the anatomy of the ureter more easily and to enhance drainage from the kidney.

Methods: The curved UASs were all 35 cm in length and 11/13 French in diameter. The long axis of the curved UAS to the axis of the terminal curved part is 140–150 degrees. This feasibility study consisted of the placement of a curved UAS under fluoroscopy followed by the routine dissection of the kidneys of two adult human cadavers.

Results: Placement in the urinary tract of the curved UAS may be facilitated by the ability to rotate the UAS during retrograde passage over a guidewire. The ability of the curved UAS to be placed in the renal pelvis in an anatomically congruent manner holds the potential to facilitate the targeting of calyxes during fURS.

Conclusion: This paper described a novel curved UAS. Cadaveric kidney observation suggests that UAS introduction may be easier and allow greater targeting of calyceal anatomy during fURS. These postulates deserve investigation in a pilot clinical trial.

Keywords: renal calculi, ureterorenoscopy, ureteral access sheath, endourology

Introduction

UASs are commonly used during fURS and were first developed in 1974 by Takayasu and Aso as a "guide tube" for the scope. The European Association of Urology (EAU) guidelines state that "UASs allow easy and multiple access to the upper urinary tract (UUT) and therefore significantly facilitate URS. UASs facilitate the repeated insertion of the fURS, protect the fURS, improve irrigant drainage, improve visibility, and reduce intrarenal pressure and operating time during retrograde intrarenal surgery (RIRS). A few studies have suggested that UASs can improve stone-free rates.

The benefits of UASs come at the risk of ureteric injury. Traxer at al.⁴ reported that 46.5% of patients undergoing RIRS had ureteric wall injuries, with 13% having high-grade injuries. Beyond ureteric injury, it is estimated that 5.8% of patients have a failed UAS placement.³ Factors that make success more likely include female patients, the preoperative use of alpha-1 antagonists, smaller UASs, and prestented patients. Breda et al.⁵ reported that pre-stenting improved the chance of a successful UAS placement from 82% to 98.5%.

Cho et al.³ postulated that ureteric injury and failed catheterisation are partly due to the angle of the lower ureter. This angle is described as the most lateral portion of the lower ureter relative to the bladder neck. They showed that the more acute this angle, the greater the chance of UAS placement failure. Aspects of UAS design may aid the endourologist in avoiding failed UAS insertion and potential ureteric injury.

We hypothesised that a curved UAS would facilitate insertion by allowing the surgeon to control (via UAS rotation) the angle of the tip of the UAS and "straighten" the ureter. We further hypothesised that the curve would allow adjustment of the UAS in the renal pelvis to aid visibility and target specific renal calyces.

Methods

Device description

The curved UASs were all 35 cm long with an 11/13 French diameter (Figure 1). The straight UASs were identical, except for lacking the curve. The long axis of the curved UAS to the axis of the terminal curved part is 140–150 degrees. The UASs are made

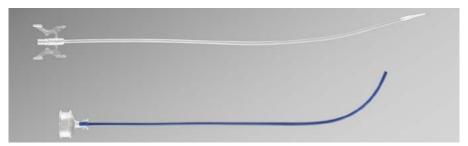


Figure 1: Curved UAS with obturator

Figure 2: Right-sided passage of the curved UAS, initially to negotiate the UVJ, the curve is angled laterally (A) and advanced into the distal ureter (B), and then the UAS is rotated to "straighten out" the ureter by moving it medially to aid the passage of the UAS (C)

* Denotes the tip of the UAS

of polyether block amide (PEBAX). The curved UAS was developed and supplied by Wismed PL, Wroclaw 53-338 Wielka 31/2, Poland.

Cadaver assessment technique

This is a feasibility descriptive study of two dissected, fresh, adult cadaver kidneys. Additionally, before dissection, retrograde pyelography and passage of the curved UAS over a guidewire were performed under fluoroscopy.

The dissection method used followed Cunningham's dissection manual. 12 Following laparotomy, the colon was mobilised, and Gerota's fascia was opened to reveal the kidney. The kidneys and ureters were excised. The kidneys were incised coronally to expose the collecting system.

Ethical approval was obtained from the Cadaver Research Governance Committee (reference number CRCG 2022/002) and the Surgical Department Research Committee (2023/126) of the University of Cape Town.

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Figure 3: (A) Cadaveric kidney comparing a traditional straight UAS with the curved UAS, (B) curved UAS, and (C) traditional straight UAS

Results

During cadaveric placement of the curved UAS over the guidewire under fluoroscopy, it was noted that the curve allowed rotation of the UAS. The ability to rotate the UAS gave the impression of having greater control over the position of the UAS's tip. Furthermore, the rotation appeared to allow greater manoeuvrability of the UAS over the three classically described narrowings of the ureter: ureteropelvic junction (UPJ), pelvic brim, and ureterovesical junction (UVJ) (Figure 2).

The coronally dissected kidneys demonstrated the potential anatomical advantage of a curved UAS. Given that the normal anatomy of the ureter is to progress laterally into the renal pelvis, the curved UAS would appear to exploit this anatomy and potentially have the benefit of access and visibility during fURS (Figure 3). Figure 4 attempts to illustrate the potential benefit of the curved UAS in improving the view during fURS and promoting drainage.

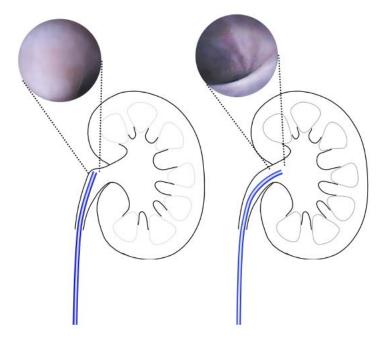


Figure 4: Illustration comparing the fURS view of traditional straight (left) and curved (right) UAS; by rotating the curved UAS, it is possible to improve the fURS view and promote irrigant drainage

Discussion

The mechanical properties of UASs vary considerably by manufacturer and model. Patel et al.⁶ reviewed these varying properties, which include size, flexibility, dilator tip shape and stiffness, lubricity, and radio-opacity.

A sizable body of literature considers ureteric injury with UAS placement. Traxer et al.⁴ noted in a series of 359 patients that superficial mucosal ureteral wall lesions occurred in nearly half following the insertion of a 12/14 Fr UAS. Another study compared the endourologist's visual assessment of injury using the Post-Ureteroscopic Lesion Scale (PULS) with histopathological findings and concluded that endoscopy underestimated the histopathological extent of the injury.⁹

The curved UAS holds clinical potential to reduce ureteric injury by two methods:

- 1. There are three recognised areas of narrowing along the ureter: UPJ, over the iliac vessels, and at the UVJ.¹⁰ The curved UAS allows rotation of the UAS, which may allow more directed longitudinal insertion force to negotiate these areas. This impression requires assessment in a clinical pilot study.
- 2. Once in the renal pelvis, the ability to rotate the curved UAS has the potential to enhance visibility and access to the calyceal anatomy. Additionally, following the anatomical lateral curve of the proximal ureter/renal pelvis may reduce ureteric injury (Figure 1).

Other investigators have applied different design methods to improve UAS placement. Zhang et al.⁷ described a UAS with a soft, flexible tip, allowing the fURS to bend the tip to allow greater targeting of calyces. Sur et al.¹¹ devised a steerable UAS, allowing the endourologist to steer and deflect the tip of the device into all parts of the collecting system.

Controversy exists about where the tip of the UAS should be positioned. Chen et al.⁸ performed computer modelling to ascertain the optimal relation of the UAS, fURS, and the ureter/renal pelvis. Their study concluded that higher irrigant flow and greater stone fragment extraction could be achieved by placing the tip of the fURS and UAS at the same level.⁸ A curved UAS could facilitate this by allowing the fURS to be kept closer to the level of the UAS outlet.

The incidence of failed UAS placement is not well described in the literature. In a large series by Traxer et al.,⁴ failure occurred in 5.8% of patients with an 11/13 Fr UAS. Cho et al.3 considered reasons for failed UAS placement and postulate that failure is seen especially when the UAS cannot be advanced beyond the lateral portion of the lower ureter. A curved UAS holds the potential to negotiate the lateral lower ureter by being able to rotate the UAS to optimise the angle of the UAS tip.

Other strategies described to improve the success rates of UAS insertion include pre-stenting and alpha-1 antagonists. The latter relaxes the ureter, which is postulated to increase the success rate of UAS insertion.³

The limitations of this study should be mentioned. Firstly, the small sample of cadaveric kidney observations may limit the applicability to clinical practice. Secondly, some investigators have looked at the

UAS insertion force. The longitudinal friction force between the UAS and the urothelium has been assessed. In a subjective assessment, urologists applied a mean maximum longitudinal insertion force of 6.6 N.¹ Further studies would need to compare traditional versus curved UAS insertion force to assess if the ability to rotate the curve impacted insertion force.

Conclusion

This paper describes a novel curved UAS. Cadaveric kidney observation suggests that UAS placement may be easier because the rotation of the UAS facilitates the negotiation of the three recognised narrowings of the human ureter. Additionally, the curve may allow the targeting of calyceal anatomy during fURS. These postulates require investigation in a pilot clinical trial.

Conflict of interest

The authors declare no conflict of interest.

Funding source

No funding was received for this study.

Ethical approval

Ethical approval was obtained from the Cadaver Research Governance Committee (reference number CRCG 2022/002) and the Surgical Department Research Committee (2023/126) of the University of Cape Town.

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