

Systematic review of ureteral access sheaths: facts and myths

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The aim of the present paper was to review the literature on all available ureteral access sheaths (UASs) with their indications, limitations, risks, advantages and disadvantages in current modern endourological practice. Two authors searched Medline, Scopus, Embase and Web of Science databases to identify studies on UASs published in English. No time period restriction was applied. All original articles reporting outcomes or innovations were included. Additional articles identified through references lists were also included. Case reports, editorials, letters, review articles and meeting abstracts were excluded. A total of 754 abstracts were screened, 176 original articles were assessed for eligibility and 83 articles were included in the review. Based on a low level of evidence, UASs increase irrigation flow during flexible ureteroscopy and decrease intrapelvic pressure and probably infectious

complications. Data were controversial and sparse on the impact of UASs on multiple reinsertions and withdrawals of a ureteroscope, stone-free rates, ureteroscope protection or damage, postoperative pain, risk of ureteral strictures, and also on its cost-effectiveness. Studies on the benefit of UASs in paediatrics and in patients with a coagulopathy were inconclusive. In the absence of good randomized data, the true impact of UASs on surgery outcome remains unclear. The present review may contribute to the evidence-based decision-making process at the individual patient level regarding whether or not a UAS should be used.

Keywords

urolithiasis, nephrolithiasis, ureteroscopy, retrograde intrarenal surgery, ureteral access sheath, systematic review

Introduction

During the past three decades, there have been many technological advances in the surgical treatment of kidney stones, one of which is the development of flexible ureteroscopy (URS). The development of flexible ureteroscopes, as well as ancillary equipment such as baskets, graspers, ureteral access sheaths (UASs), and improvements in lithotripsy with holmium:yttrium-aluminum-garnet (Ho:YAG) laser have led to an expansion of the indications for UASs. The UAS was developed in 1974 by Hisao Takayasu and Yoshio Aso to facilitate the insertion of the ureteroscope into the ureter. They referred to the UAS as a 'guide tube', coated with polytetrafluoroethylene with a diameter of 3 mm and a length of 38 cm, through which a completely passive flexible ureteroscope was advanced [1]. Afterwards, the UAS benefited from a more streamlined and kink-resistant design to facilitate ureteral insertion in a safer way. As a

result of technological advancements in flexible URS, UASs are now produced with varying characteristics including various lengths, diameters, materials, dilator tip designs, radiopaque markers and stiffness. The most common reasons cited by urologists for using a UAS are to facilitate repeated entrance into the ureter and collecting system, to lower the intrapelvic pressure, to protect the ureteroscope and to protect the ureter when extracting stone fragments.

In the present review, we aimed to verify these cited benefits based on scientific evidence, and to give a complete overview of all available UASs with their indications, limitations, risks, advantages and disadvantages in current modern endourological practice.

Methods

Two authors (V.D.C. and E.X.K.) performed a bibliographic search of the Medline, Scopus, Embase and Web of Science

databases in October 2017. The search terms ('ureter' OR 'ureteric' OR 'ureteral') AND ('access sheath' OR 'sheath') were used and the filters 'English' and 'humans' were applied. No time period restriction was applied. All original articles reporting outcomes or innovations were included. Additional articles identified through references lists were also included. Case reports, editorials, letters, review articles and meeting abstracts were not considered eligible. A consensus between V.D.C. and E.X.K. was found relating to the thematic structure of this systematic review, and only articles that provided genuine added value were selected. Figure 1 is a flowchart summarizing the selection process. Because of the heterogeneity of study outcomes, a narrative synthesis rather than a quantified meta-analysis of data was performed.

Results

Ureteral Access Sheath Characteristics

Ideally, a UAS should ensure atraumatic insertion into the urinary tract. It should be resistant to buckling and kinking, while maintaining a minimal inner-to-outer diameter ratio, and should allow unimpeded ureteroscopy insertion. The specifications of currently commercially available UASs are summarized in Table 1. All contemporary UASs are composed of an inner tapered dilator and an outer hydrophilic-coated sheath to ensure minimal friction with tissue during insertion [2]. They do not differ in terms of friction force with tissue [3]. Most contemporary UASs have a reinforced coil construction to

resist buckling and kinking [4]. Notably, there is no advantage in terms of insertion success rate between non-reinforced vs reinforced UASs [5]. With the dilator in place and no guidewire inserted, contemporary reinforced UASs resist buckling against longitudinal forces up to 5.1 newtons (N) [3].

A key innovation was the introduction of a UAS with a slit and a notch in the exposed part of the dilator, allowing the transformation of a coaxially backloaded working guidewire into an extraluminal diverted safety guidewire in a one-step release mechanism [6,7]. The advantages are potential reductions in material costs and operating time, as only one guidewire is needed, whereas two guidewires are required for conventional UAS insertion [8]. Additionally, the vacant dilator lumen at the connection hub offers the possibility of contrast medium opacification during UAS insertion. Two shortcomings are the increased risk of dilator bending at the notch when high insertion forces are applied and the risk of inadvertent dislocation of the working guidewire during UAS insertion [7,9]. Those shortcomings may potentially lead to UAS insertion failure and ureteral damage. Nonetheless, the UAS should be inserted under fluoroscopic control, and high insertion forces should be avoided. To date, no prospective study has assessed either whether a UAS with single-wire diversion leads to a reduction in fluoroscopy and operating time, or insertion success rates are similar to those of conventional UASs.

Recently, a UAS with an added suction port was introduced in an attempt to increase stone fragment evacuation during

Fig. 1 Flow chart of the literature search.

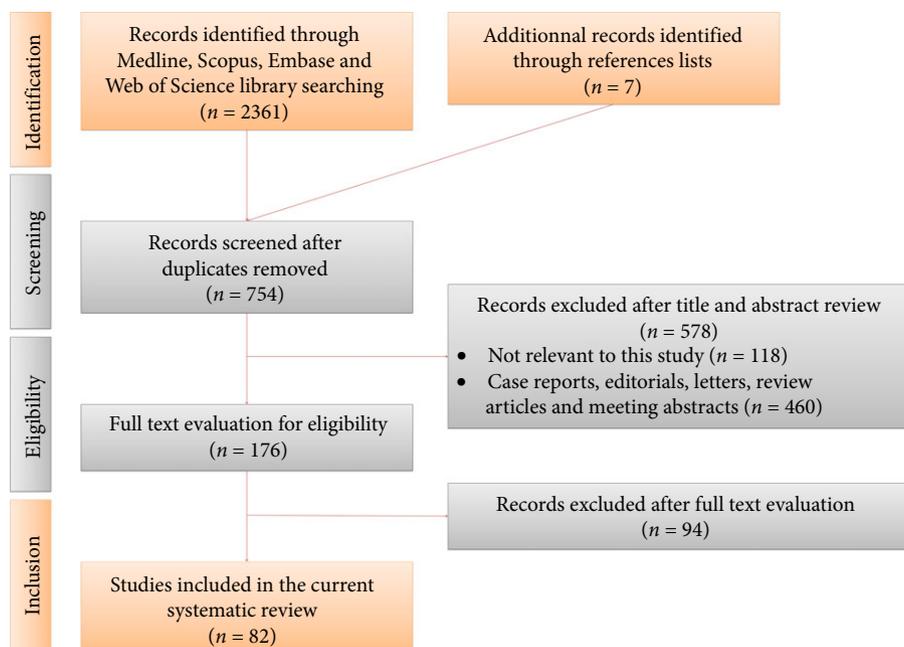


Table 1 Material properties of commercially available ureteral access sheaths.

Name	Retrace®	Flexor®	Flexor® Parallel® Rapid Release™	Flexor® DL Dual Lumen	Navigator™ HD	BIFlex™ EVO	zUropass™	Fortis® HD	Proxis®	Aquaguide®	ClearPeira™
Manufacturer	Coloplast® Denmark	Cook Medical® USA	Cook Medical® USA	Cook Medical® USA	Boston Scientific® USA	Rocamed™ France	Olympus® Japan	Applied Medical® USA	Bard® USA	Bard® USA	Well Lead™ China
Inner/outer diameter, F	10/12, 12/14	9.5/11.5, 10.7/n.a., 12.0/n.a., 14.0/n.a.	9.5/n.a., 10.7/n.a., 12.0/n.a., 14.0/n.a.	9.5/14, 12.0/17.5	11/13, 12/14, 13/15	10/12, 12/14	10/12, 11/13, 12/14, 13/15	12/16, 14/18, 16/18	10/12, 12/14	12/14, 13/15	10/n.a., 11/n.a., 12/14, 13/n.a.
Sheath length, cm	35, 45	13, 20, 28, 35, 45, 55	13, 20, 28, 35, 45, 55	13, 20, 28, 35, 45, 55	28, 36, 46	35, 45	24, 38, 46, 54	20, 28, 35, 45, 55	25, 35, 45	25, 35, 45, 55	18, 26, 36, 40, 46, 55
Outer/inner coating	n.a.(Hydro)/n.a.	AC® (Hydro)/PTFE	AC® (Hydro)/PTFE	AC® (Hydro)/PTFE	n.a.(Hydro)/n.a.	Hydromer® (Hydro)/n.a.	PTFE (Hydro)/n.a.	n.a.(Hydro)/n.a.	n.a.(Hydro)/n.a.	n.a.(Hydro)/n.a.	n.a./n.a.
Exposed dilator length [9], mm	52	23	23	n.a.	24	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Taper length/tip diameter	9/5.0	11/5.6	11/5.6	n.a.	20/5.1	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Gap between dilator and leading edge of the sheath [9]	0.75 mm (10/12-F model)	0.65 mm (9.5/11.5-F)	0.65 mm (9.5/11.5-F)	n.a.	0.22 (11/13-F model)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Friction force [4,9]	0.7 N	1.1 N	1.1 N	n.a.	0.7 N	n.a.	n.a.	1.2 N	n.a.	n.a.	n.a.
Radiopaque marker	Yes	No	No	No	Yes	Yes	Yes	No	Yes	No	No

Hydro, hydrophilic coating; N, Newton; n.a., not available; PTFE, polytetrafluoroethylene. Material properties as given by the manufacturer or as measured with indication of reference.

Ho:YAG laser lithotripsy for ureteral stones [10]. Whether this device may improve stone clearance and reduce operating time needs to be investigated in further studies.

One UAS with innate ability of tip deflection up to 180° is commercially available. To date, clinical application of this device has not been reported in the literature.

Impact on Multiple Instrument Reinsertions and Withdrawals

A commonly cited argument in favour of using a UAS is that it facilitates multiple entries and re-entries of a flexible ureteroscope into the upper urinary tract. Indeed, insertion of a flexible ureteroscope without any UAS may be challenging when only a safety guidewire is in place. Nevertheless, this action may be performed by backloading the ureteroscope over a working guidewire under fluoroscopic control or by cannulating the flexible ureteroscope alongside the safety guidewire. Other difficulties that can be encountered are passing narrow portions of the ureter, such as the vesico-ureteral junction or the iliac crossing. These narrow portions can cause buckling of the ureteroscope in the bladder, thus impeding their retrograde insertion. Data to support the hypothesis that unaided multiple re-entries are time-consuming and increase operating costs are controversial [11–13]. Kourambas et al. [14] studied the impact of the use of a UAS on operating time. Analysing 47 patients, they found that procedures last 10 min longer in the absence of a UAS. This difference was statistically significant and represented a saving of \$350 in operating room costs per ureteroscopic procedure at their institution [14]. By contrast, Traxer et al. [15] prospectively analysed 2 239 patients treated with or without a UAS and found that operating time was significantly longer when a UAS was used (80 vs 65 min). They explained the time difference by the fact that UAS usage was not randomized in this study, such that the UAS group had significantly more stones sized ≥ 10 mm than the non-UAS group [15].

Withdrawal of a flexible ureteroscope with stone fragments captured in a basket can be performed through the UAS. The volume of stone fragments that can be extracted per instrument withdrawal is dependent on the inner sheath diameter. A small increase in internal diameter from 10 to 12 F nearly doubles the volume of theoretical spherical fragments that can be extracted (34 mm³ instead of 19 mm³). This decreases the number of withdrawals by more than half when removing fragments of a stone initially exceeding 6 mm in diameter. Whenever a single stone fragment larger than the UAS's internal diameter is present after lithotripsy, it can be entrapped and removed en bloc with the UAS. This can safely be performed if the stone is wedged into the UAS opening, its surface is smooth and it is endoscopically in sight during extraction [16].

Impact on Irrigation

Vision is enhanced during flexible URS by increasing irrigation inflow. This is achieved by raising the hydrostatic column or irrigation pressure, which subsequently increases the intrapelvic pressure [17]. An option for decreasing the intrarenal pressure is to increase irrigation outflow by using a UAS. At a constant intrapelvic pressure, the irrigation inflow rate increases by 35–80% compared with an unsheathed ureteroscope [18].

Using wider UAS diameters, irrigation outflow increases in a non-linear manner when the working channel of the ureteroscope is empty [17,19]; however, when instruments occupy the working channel of the ureteroscope, they limit irrigation inflow and therefore there is no advantage in terms of irrigation outflow with increasing UAS diameters.

Impact on Intrapelvic Temperature

Intrapelvic temperature rises fast when using laser technology at high frequency and energy. This results in alterations of normal cellular functions and cell death [20]. Currently, there is no scientific evidence to support that a UAS provides a cooling effect of the surrounding tissue by increasing irrigation outflow. An alternative would be to increase irrigation inflow by using an irrigation catheter inside or alongside a UAS. This yields the highest flow rate without a rise in intrapelvic pressure [19].

Impact on Intrapelvic Pressure

The physiological intrapelvic pressure and the threshold for pyelovenous backflow are ~5–10 and 40–60 cm H₂O (or 4–7 and 30–45 mmHg), respectively [21]. During flexible URS without a UAS, intrapelvic pressure is highest when the ureteroscope is located in the renal pelvis and lowest when located in the distal ureter (59 cm H₂O and 52 cm H₂O, or 44 and 39 mmHg, respectively, when instrument inflow pressure is 200 cm H₂O) [18]. When forced irrigation is applied to improve vision, intrapelvic pressure may reach up to 446 cm H₂O (or 328 mmHg) [22]. Operating with high pressure levels may result in renal extravasation and cause complications such as bleeding, haematoma, urinoma, sepsis and postoperative pain. The long-term impact of high intrapelvic pressure can be focal parenchymal scarring as a result of vacuolization and degeneration of renal tubules [23].

To prevent these irreversible and destructive effects of the renal parenchyma, intrapelvic pressure should be kept below 40 cm H₂O (or 30 mmHg). This is achieved using a UAS, which lowers the irrigation pressures transmitted to the renal pelvis and subsequently to the parenchyma by 57% to 75% during flexible URS [24]. Even when an irrigation pressure of 200 cm H₂O (or 147 mmHg) is applied through the

ureteroscope, intrapelvic pressure remains below 20 and 30 cm H₂O (or 15 and 22 mmHg) when 12/14-F and 10/12-F UASs are used, respectively [18].

Intrapelvic pressure is related to irrigation inflow and outflow, which themselves depend on the diameter of the flexible ureteroscope and the UAS. For all different UAS sizes, the lowest intrapelvic pressure and the highest irrigation outflow is achieved with the thinnest flexible ureteroscope. For the same flexible ureteroscope, intrapelvic pressure increases as UAS size decreases. In summary, small-sized UASs can provide low intrapelvic pressures with good irrigation inflow and outflow when using a small-sized flexible ureteroscope [17].

Highest inflow and outflow and lowest pressure are noted when the tip of the UAS and the ureteroscope are in close proximity to one another. Selecting the proper length of a UAS based on the location of the pathology results in a lower intrapelvic pressure and increased inflow and outflow [18].

If a UAS is not used during flexible URS, intrapelvic pressure can also be decreased pharmacologically by intraluminal administration of isoproterenol (a β -agonist) without systemic side effects [25].

Impact on Stone-Free Rate

The impact of the use of a UAS on stone-free rates is controversial. L'Esperance et al. [26] retrospectively evaluated the effect of UASs on stone-free rates during 256 ureteroscopic procedures for renal calculi. They found that UASs significantly improved stone-free rates (79% in the UAS group vs 67% in the non-UAS group); however, in a subgroup analysis on stones per location in the renal pelvis and calices, there was no significant advantage of using a UAS [26]. More recently, Traxer et al. [15] prospectively assessed the stone-free rates either with or without the use of a UAS over a 1-year period. They found no significant difference in stone-free rates between using or not using a UAS (75% vs 50%). Similar findings were reported by Kourambas et al. [14] (79% in the UAS group vs 86% in the non-UAS group) and Berquet et al. [27] (86% vs 87%) 3 months postoperatively. An important limitation of all these studies is that the stone-free rate was determined by non-contrast CT only in a minority of patients.

Ureteral Access Sheath Insertion Success Rate, Pre-stenting and Postoperative Ureteral Stenting

Primary insertion of a UAS is not always possible. Insertion failure is defined as the surgeon's decision to abandon UAS insertion because of high resistance to the retrograde progression of the UAS along the urinary tract. Arguably, the involved cause is a discrepancy between the native ureter diameter and the UAS outer diameter. As a matter of fact,

UASs have an outer diameter of 11.5–18 F, whereas the diameter of the native ureter is ~6–9 F [28].

Case series including >50 patients reported an overall success rate of UAS insertion of between 78% and 97%; these data are summarized in Table 2. To facilitate UAS insertion, passive dilatation by ureteral pre-stenting over several days or active dilatation by means of ureteral dilators is commonly applied. Indeed, pre-stenting has been shown to be a predictor of successful UAS insertion, along with older age, former endoscopic ureteral surgery and smaller stone burden [29,30]. The UAS insertion failure rate in non-pre-stented cases ranges from 16% to 42%, vs 0% to 12% in pre-stented cases [6,29,31,32]. In addition, pre-stenting has been shown to reduce ureteral injuries [33]. The rate of pre-stenting in patients in currently available case series varies from 5% to 100% (Table 2). The optimum duration between JJ stent insertion and UAS usage has not yet been assessed, but most authors recommend at least 5 days of pre-stenting [34–39].

The main shortcomings of pre-stenting are the necessity for at least two separate operating sessions as well as JJ stent-related morbidity; therefore, some authors advise active ureteral dilatation using a semi-rigid ureteroscope, a balloon dilator or serial coaxial tapered dilators, with increasing size in cases of primary UAS insertion failure [26,29,32,40–43]. Alternatively, some authors insert the inner UAS dilator prior to the insertion of the whole UAS unit [26,32,44]. To date, only descriptive studies on active ureteral dilatation are available and nobody has compared the risk of long-term ureteral damages between active and passive dilatation [40]. In a worldwide questionnaire assessment, only 21% of the responders actively dilated the ureter routinely for URS [45]. The rate of active ureteral dilatation in the literature ranges from 0 to 100% (Table 2). Recently, in a porcine model, intra-operative pharmacological relaxation of the ureter by an α -blocker was proposed to potentially increase the primary UAS insertion rate and reduce the need for active ureteral dilatation [46]. Whether this may apply in humans and may facilitate UAS insertion as well as reduce UAS-associated ureteral injuries has not yet been studied.

The need for postoperative stenting after UAS deployment is debatable [47,48]. The rationale for postoperative stenting is to reduce the risk of symptomatic ureteral outflow obstruction attributable to potential ureteral wall oedema caused by the UAS. This practice is associated with lower overall pain scores and lower hospital readmission rates for urgent ureteral decompression [48,49]. The rate of postoperative stenting varies from 51% to 100% (Table 2). Concerning the duration of postoperative stenting, no consensus has yet been agreed, but 85% of the responders to a worldwide questionnaire study would remove the stent within 7 days [45]. Interestingly, in a study analysing stent withdrawal within 1 day of surgery, operating time was a

predictor of hydronephrosis on day 3 after surgery [45,50]. Based on histological studies showing that ureteral wall oedema was most pronounced at 72 h postoperatively when a 14/16-F UAS was used, it may be safely advised to stent the ureter for at least 3 days [51].

Insertion Force

The insertion of a conventional UAS relies on the guidance of a tapered dilator tip along a guidewire. As the UAS progresses along the ureter, the surgeon needs to apply a longitudinal force depending on both the axial dilating effect of the UAS on the ureteral wall as well as the longitudinal friction forces between the UAS surface and the urothelium. In a model evaluating several contemporary UASs from 11/13-F up to 13/15-F, the longitudinal friction force accounted for 1.0–1.3 N [3]. To the best of our knowledge, the necessary force to overcome the axial dilatation of the ureter has not yet been described. In a subjective assessment, urologists and residents in training applied a mean maximum longitudinal insertion force of 6.6 and 4.8 N, respectively, until they decided to interrupt the insertion trial [58]. A dilating device inserted into the ureter with a native outer diameter of 9.5-F to become a 12/14-F UAS after dilatation has been shown to reduce mean and maximum insertion force fourfold, with proportionally less ureteral trauma compared with a similar-sized (12/14-F) conventional UAS [59]. Currently, this device is not commercially available. Graversen et al. [60] assessed the impact of safety guidewires on 12/14 F UAS insertion and revealed a twofold increase in the mean and maximum insertion force when a safety guidewire was placed outside of the UAS. In that study, the increased insertion force did not translate into an increase in ureteral wall injuries. In a foil model study evaluating several contemporary UASs, aluminium foil was perforated by the tip of UAS dilators at 3.4–3.6 N and by the tip of an empty UAS at 17.4–21.6 N [9]. Based on these results, it is conceivable that the manipulation of an empty UAS may lead to a ureter avulsion before the force would be sufficient to perforate the ureteral or pelvic wall.

Ischaemia and Inflammatory Changes

As described previously, a UAS mechanically dilates the lumen of a ureter. The corresponding increase in intraluminal axial pressure and ureteral wall tension compresses blood vessels that course longitudinally through the ureter, leading to an immediate decrease in blood flow. In an animal model, it took ~20–35 min for the smooth muscle of the ureter to reach a steady state of relaxation after UAS deployment. The resting force of the ureteral wall then decreased and the blood flow was partially restored. Comparing different sizes of UASs, the steady state was reached faster for larger-diameter UASs (12/14-F and 14/16-F) because they created more wall

Table 2 Case series of flexible ureteroscopy reporting about their usage of ureteral access sheaths.

	Number of patients or interventions	UAS size	Deployment of UAS in the series, n (%)	UAS insertion trial for every case	Active ureteral dilatation, n (%)	Pre-stenting, n (%)	Post-operative stenting, n (%)
Bas et al. 2017 [34]	1 411	9.5/11.5 F or 11/13 F	1 129 (80)	No	0 (0)	141 (10)	1 143 (81)
Giusti et al. 2016 [52]	316	n.a.	288 (91)	Yes	0 (0)	85 (27)	316 (100)
Geraghty et al. 2016 [53]	68	9.5/11.5 F or 12/14 F	43 (63)	No	0 (0)	26 (38)	64 (94)
Berardinelli et al. 2016 [54]	356	9.5/11.5 F to 12/14 F	283 (80)	Yes	0 (0)	78 (22)	331 (93)
Viers et al. 2015 [32]	140	11/13 F or 12/14 F	135 (96)	Yes	50 (32)	51 (33)	n.a.
Traxer et al. 2015 [15]	2 239	n.a.	1 500 (67)	No	n.a.	828 (37)	1 970 (88)
Multescu et al. 2015 [35]	126	10/12 F	116 (92)	Yes	0 (0)	9 (7)	n.a.
Kuntz et al. 2015 [40]	151	12/14 F	120 (79)	Yes	151 (100)	8 (5)	145 (96)
Ising et al. 2015 [55]	275	10/12 F	267 (97)	Yes	0 (0)	250 (91)	245 (89)
Elbir et al. 2015 [36]	279	n.a.	265 (95)	Yes	0 (0)	47 (17)	254 (91)
Yuruk et al. 2014 [37]	149	n.a.	115 (77)	No	n.a.	128 (86)	n.a.
Sahai et al. 2014 [56]	242	9.5/11.5 F	24 (10)	No	0 (0)	n.a.	208 (86)
Multescu et al. 2014 [44]	406	10/12 F or 12/14 F	302 (71)	No	n.a.	45 (11)	n.a.
Mogilevk et al. 2014 [29]	248	12/14 F	193 (78)	Yes	104 (42)	104 (42)	n.a.
Jacquemet et al. 2014 [41]	371	n.a.	278 (75)	No	52 (14)	223 (60)	341 (92)
Doizi et al. 2014 [6]	137	12/14 F	113 (83)	Yes	0 (0)	35 (26)	n.a.
Ulvik et al. 2013* [42]	500	n.a.	1 (0)	No	24 (5)	n.a.	325 (65)
Ulvik et al. 2013† [42]	500	n.a.	158 (32)	No	9 (2)	n.a.	380 (76)
Miernik et al. 2012 [38]	153	14/16 F	109 (71)	No	0 (0)	153 (100)	95 (62)
Schoenthaler et al. 2012 [39]	100	14/16 F	63 (63)	No	0 (0)	100 (100)	51 (51)
Kawahara et al. 2012 [31]	61	14/16 F	41 (67)	No	0 (0)	25 (41)	61 (100)
Shields et al. 2009 [30]	221	12/14 F	111 (50)	No	0 (0)	150 (68)	221 (100)
Mahajan et al. 2009 [43]	55	10/12 F	52 (95)	Yes	52 (95)	3 (5)	55 (100)
Hyun et al. 2009 [57]	122	14/16 F	67 (55)	No	n.a.	n.a.	n.a.
L'Esperance et al. 2005 [26]	256	12/15 F	174 (68)	No	26 (10)	n.a.	197 (77)

UAS, ureteral access sheath. *Only the Haukeland University Hospital series. †Only the Oslo University Hospital series.

tension and thus induced a quicker stress relaxation. A small (10/12-F) UAS had a smaller impact on ureteral wall tension, whereby 75% of the baseline flow was maintained, compared with 35% for larger-diameter UASs. After 70 min of UAS deployment, there was an almost complete recovery of vascularization for the 10/12-F UASs, compared with 70% of baseline flow for larger UASs. At 48 and 72 h after removal of a 14/16-F UAS, there was histological evidence of overall ureteral wall thickening, with pronounced acute inflammatory reaction in all wall layers as well as in the peri-ureteral soft tissues [51]. Another study examined the expression of the acute inflammation cytokines cyclooxygenase-2 (COX-2) and TNF- α in ureteral tissue, and demonstrated a significant 6.5-fold and eightfold upregulation of COX-2 and TNF- α after 2 min of UAS deployment, respectively [51,61]. Currently, there are no publications describing the influence of this acute inflammatory reaction on the ureter in the long term.

Impact on Ureteroscope Protection

A frequently mentioned argument for using a UAS is that it protects and reduces the strain on flexible ureteroscopes. To date, studies on ureteroscope durability have not evaluated this hypothesis and have merely mentioned the risk of ureteroscope damage at the interface between the deflection tip and the tip of the UAS [44,62,63].

Coagulopathy

Few authors have evaluated the impact of a UAS in the setting of uncorrected bleeding diatheses or patients requiring continuous anticoagulation/antiplatelet therapy. Turna et al. [64] retrospectively compared 37 patients in whom anticoagulation therapy was not discontinued before surgery with a control group. They noticed that a UAS was used more frequently in the anticoagulation group (22% vs 3%), without encountering any haemorrhagic complications [64]; however, these results should be interpreted with care because safety and complications of using a UAS were not primary endpoints.

Children

Singh et al. [65] were the first to report the use of a UAS in the paediatric literature. All patients were rendered stone-free in a single operative setting using a 14/[not available]-F UAS in all patients. They noticed no peri-operative or postoperative complications after a mean follow-up of 10 months [65]. Later, Wang et al. [66] retrospectively reviewed the safety and outcomes of UAS use in children. A UAS was used in 40 of the 96 patients (42%). The size was 11/13 F in 37% of patients, 12/14 F in 52% and 13/15 F in 11%. The use of a UAS was associated with a higher stone burden, preoperative symptoms (nausea/vomiting, abdominal/flank pain, haematuria or febrile UTI), history of non-ureteroscopic stone procedures (shockwave lithotripsy or

percutaneous nephrolithotomy), stone site and post-URS stent use. Stone-free rates were similar for both groups. Intra-operative complications (perforation, submucosal wire and stent migration) were significantly more common when a UAS was used (15% vs 2%). After a median follow-up of 11 months, they observed no differences in long-term adverse effects [66].

Kokorowski et al. [67] assessed patient exposure to radiation during paediatric URS in a prospective study. They reported a mean entrance skin dose of 46.4 mGy, which is more than double than that of CT of the abdomen and pelvis. The most important determinant of radiation dose was total fluoroscopy time, followed by dose rate settings, child anteroposterior diameter and source to skin distance. Using a UAS significantly increased fluoroscopy time. The authors advise a judicious use of fluoroscopy with proper dose rate settings and to maximize the source to skin distance [67].

Variations of UAS Purpose

Variations in the conventional handling of UASs have been described, including: using a UAS during antegrade endoscopic procedures in patients who present with stones or uretero-intestinal strictures as late complications of urinary diversion [68]; JJ stent insertion through the UAS, before the latter was removed at the end of the procedure [69]; use of a UAS for ureteroscopic treatment of small impacted lower third ureteral stones [70]; sequential insertion of a semi-rigid and later flexible ureteroscope over a large 14/16-F UAS for treatment of kidney stones ≥ 2 cm [71]; and UAS insertion under direct vision as a result of UAS dilator replacement by a semi-rigid ureteroscope [72,73]. These techniques have the merit of reducing operating time, with mostly low reported complication rates. Currently, the feasibility of and rationale for these techniques have not been validated.

Impact on Ureteral Damage

The association between the use of a UAS and ureteral damage has been underreported for many years. Traxer and Thomas [33] addressed this deficiency by reporting and classifying UAS-related ureteral injuries in 2013. They endoscopically evaluated the ureteral wall integrity on retrieval of a 12/14-F UAS in 359 patients and found that ureteral wall lesions occurred in almost half of patients, mainly ureteral mucosal erosions without smooth muscle injury. Nevertheless, ureteral smooth muscle layers were involved in up to 15% of patients. Men and older patients were at higher risk of severe UAS-related ureteral injury. Pre-stenting decreased the risk of severe injury by sevenfold in that study [33]. Later, Schoenthaler et al. [74] proposed a post-ureteroscopic lesion scale (PULS) to standardize intra-operative ureteral lesion grade occurring during URS.

Urologists from different countries validated this scale with a video-based multicentre evaluation [74].

Guzelburc et al. [75] studied UAS-related ureteral injuries in 101 patients who were not pre-stented. A 9.5/11.5-F UAS was used in 76% of patients, in the others a 12/14-F UAS was used. According to PULS grading, they found grade 1 and 2 lesions in 38.6% and 2.9% of patients, respectively. Injuries were found in the proximal ureter only and distal ureter only in 45.2% and 40.5% of the patients, respectively [75]. Miernik et al. [38] studied 148 pre-stented patients in whom a 14/16-F UAS was used. They found superficial lesions of the ureteral mucosa in 39.9% of patients, deeper mucosal ureteral lesions in 17.6% and a circumferential perforation in 4.7% [38]. Recently, the correlation between ureteral lesions visualized during URS (using PULS) and the histopathological findings was studied on 44 pig ureters. Histopathological evaluation of ureteral wall lesions after UAS placement revealed a significantly higher degree of severity than observed endoscopically in 72.1% of ureters [76].

Barbour et al. [77] studied hydronephrosis after URS in 234 patients. A UAS was used in 22% of procedures and 93% of patients were stented after the procedure for a median of 7 days. After 4–12 weeks, 15% of cases had evidence of hydronephrosis, caused by transient oedema without anatomical obstruction in 8.0% of patients, obstructing residual stone fragments in 6.5%, and stricture disease in 0.9%. Increasing stone diameter, prior ipsilateral URS, longer operative duration and renal colic symptoms independently predicted hydronephrosis. Conversely, other factors, including stone impaction at procedure, ureteral dilatation, use of a UAS, intra-operative perforation, or use of a stent was not associated with ipsilateral hydronephrosis [77]. Baş et al. [34] reported similar findings when evaluating the factors affecting complication rates of flexible URS and laser lithotripsy for renal and/or proximal ureteral stones in a retrospective study on 1 571 procedures. In all, 9.9% of patients were pre-stented and a 9.5/11.5-F or 11/13-F UAS was used in 79.9% of cases. After a follow-up of 1 month, intra-operative and postoperative complications rates were 5.9% and 7.3%, respectively, including ureteral stricture in two patients. The authors found no significant difference in complication rates regarding the use of a UAS. The only significant factor in multivariate analysis was the presence of congenital renal abnormalities [34]. Similar conclusions were stated in the prospective study by Traxer et al. [15] with the Clinical Research Office of the Endourological Society Ureteroscopy Global Study [15].

Delvecchio et al. [78] analysed the long-term correlation between using a UAS and ureteral stricture formation in 71 ureteroscopic procedures. A total of 28% of ureters were pre-stented. A 10/12-F, 12/14-F or 14/16-F UAS was used in 11.2%, 78.9% and 9.8% of procedures. After a mean follow-up of 332 days, they found only one stricture (at the

PUJ). They concluded that the UAS was not a contributing factor [78].

Impact on Infectious Complications

Traxer et al. [15] examined prospective data from 2 239 patients treated with URS in multiple centres around the world over a 1-year period. Comparing the differences in the outcomes of renal stones treated either with or without the support of a UAS, they found a decrease in infectious complications when a UAS was used: 28.6%, 18.6% and 4.3% for fever, UTI and sepsis, respectively, in the UAS group vs 39.1%, 23.9% and 15.2% in the non-UAS group. They attributed these findings to the decreased intrapelvic pressure when a UAS is applied. An important limitation of that study was that the authors did not record the reason why a UAS was used or not, which may have led to a selection bias.

Impact on Postoperative Pain

Oğuz et al. prospectively investigated factors related to early postoperative pain after retrograde intrapelvic surgery in 250 patients. A pre-operative JJ stent was in place in 73% of cases and a UAS was used in all patients: 9.5/11.5 F in 62% and 12/14 F in 38% of procedures. The only operation-related factor that correlated with severe pain was the total time the UAS was placed: 46.57 (15–110) min with severe pain vs 41.54 (15–140) min in patients without pain. The size of the UAS, operation time, ureteral injury and pre- or postoperative stenting were not associated with post-URS pain [79]. In contrast, in an older prospective study, Kourambas et al. [14] found no difference in postoperative pain whether a UAS was used or not.

Discussion

The guidelines of the AUA clearly recommend the use of a UAS when performing flexible URS for complex, high-volume renal stones that cannot be treated with percutaneous nephrolithotomy, as these procedures can be lengthy, and prolonged high intra-renal pressures can increase the risk of haemorrhage, infection and fluid absorption. For the same reason, the AUA guidelines recommend the use of a UAS in the setting of uncorrected bleeding diatheses or patients requiring continuous anticoagulation/antiplatelet therapy [80].

In guidelines from the European Association of Urology and the Société Internationale d'Urologie and International Consultation on Urology Disease, there are no clear recommendations on whether a UAS should be used or not [81,82]. Most recommendations are based on expert opinions, since there are few publications on the use of a UAS with high level of evidence. They state that its use depends on surgeon preference.

In our opinion, inserting a UAS should not be a systematic step when performing flexible URS, for the abovementioned reasons. This decision should be made on a patient-specific basis. We generally recommend using a UAS with the smallest possible external diameter (typically 12 F) if the ureteroscope fits into its inner lumen because the benefit of an improved irrigation outflow with increasing UAS diameters is reduced as soon as the working channel is occupied. Furthermore, smaller UAS outer diameters offer the advantage of reducing the mean and maximum insertion force, decreasing the impact on ureteral wall tension, while maintaining low intrapelvic pressure. The disadvantage of using a small UAS is the increased number of withdrawals when removing fragments of a stone; however, this may be avoided by creating smaller fragments during lithotripsy or by using techniques such as stone dusting and popcorning.

Some authors have suggested that the development of a UAS obviates the need for a safety guidewire; however, a UAS is not a guidewire and does not guarantee the absence of complications. The placement of a UAS does not protect against complications or the perforation of the portion of the ureter between the UAS and the renal pelvis. For this reason, we recommend placement of a safety guidewire with UAS usage.

If inserting a UAS is desirable but impossible because of ureteral narrowing, we recommend inserting a JJ stent and postponing the intervention for at least 1 week, allowing passive ureteral dilatation. This increases the UAS insertion success rate to over 88%. We do not recommend using active ureteral dilatation for these cases because the long-term effects are not known.

After using a UAS, we recommend performing systematic evaluation of the urothelial mucosa at the time of extraction of the UAS in order to detect ureteric wall lesions, as they may cause complications in the short and long term. Postoperative stenting is advised because this decreases postoperative pain and hospital readmission rates when used for at least 3 days.

In conclusion, according to the publications reviewed, there is sufficient evidence supporting the hypothesis that using a UAS increases irrigation outflow during flexible URS. Based on a low level of evidence, UASs can lower intrapelvic pressure below 30 cm H₂O (or 22 mmHg), which ensures a secure pressure level during intervention when using forced irrigation. In a single observational study, UAS use reduced the risk of infectious complications such as fever, UTI and sepsis; however, no high-quality evidence was available to confirm this. Furthermore, data on the impact of a UAS on multiple reinsertions and withdrawals, stone-free rates, ureteroscope protection or damage, postoperative pain, risk of ureteral strictures, as well as its cost-effectiveness are inconclusive.

Future randomized prospective studies are warranted because much of the data on UASs are still conflicting. It would also be interesting for future developments to integrate a pressure control system and active suction facility to the UAS, leading to low intrapelvic pressures and sustained efflux of stone fragments.

Conflict of Interest

Olivier Traxer is a consultant for Coloplast, Rocamed, Olympus, EMS and Boston Scientific. Vincent De Coninck is supported by the EUSP scholarship from the European Association of Urology and by a grant from the Belgische Vereniging voor Urologie (BVU). Etienne Xavier Keller is supported by a Travel Grant from the University Hospital Zurich and by a grant from the Kurt and Senta Herrmann Foundation. All other authors have no conflicts of interest to declare.

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Abbreviations: COX-2, cyclooxygenase-2; Ho:YAG, holmium:yttrium-aluminum-garnet; PULS, post-ureteroscopic lesion scale; UAS, ureteral access sheath; URS, ureteroscopy.