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ORIGINAL ARTICLE

The new concept of ureteral access sheath with guidewire disengagement: One wire does it all

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Abstract
Purpose To prospectively evaluate the new Flexor©Parallel™ Rapid Release™ (Cook®, Bloomington, IN, USA) access sheath (UAS) which allows the use of a single wire to serve as both safety and working guide.
Materials and methods Between June and September 2014, adult patients from five European centers who underwent flexible ureteroscopy (fURS) for therapeutic and diagnostic purposes were included. The 12/14Fr Flexor©Parallel™ UAS was evaluated. Data were collected and examined by both univariate and multivariate analyses. The UAS material and usage characteristics were rated per case by the surgeons on a scale from very bad to very good.
Results In total, 134 UASs were used in 67 male and 67 female patients. Fifty percent of ureters (67 patients) were pre-stented. Ninety percent of the procedures were therapeutic. The overall successful insertion rate was 94 %. Pre-stenting status was the only independent factor for a successful access sheath insertion: 98.5 % of the pre-stented patients had a successful UAS placement vs. 82 % of non-pre-stented ($p = 0.001$, C.I. 95 %: 1.2). Evaluation of the material and radiopacity was considered very good in over 90 % of cases. Release of the guidewire, hydrophilic coating, gliding of the endoscope and repeatability were considered very good in over 80 %. There were two (1.4 %) UAS malfunctions and one submucosal lesion reported.
Conclusions The use of the Flexor©Parallel™ Rapid Release™ (Cook®, Bloomington, IN, USA) with usage of a single guidewire in a prospective multicentric scenario was clinically applicable in the majority of cases. Pre-stenting increased the chance of a successful insertion from 82 to 98.5 %.

Keywords Flexible ureteroscopy · Ureteral access sheath · Single-use guidewire · Urolithiasis · Endourology

Introduction

Ureteral access sheaths (UAS) are commonly used in flexible ureteroscopy (fURS). The use of UAS is believed to reduce damage to the ureteroscope during repeated passages of the instrument. Furthermore, UAS use has been shown to decrease the intraluminal pressure during fURS and permit drainage and elimination of dust and stone fragments, which may decrease operative time and costs [1–3]. UAS must be carefully inserted, since they may cause ureteral lesions due to over distension and false passage [4]. The insertion should always be performed under fluoroscopic control over a working guidewire, and it is usually recommended also to use a safety guidewire along the UAS to stabilize the ureter during insertion and allowing the possibility to place a stent after the procedure [5].

We prospectively evaluated the insertion and immediate complications of the new UAS Flexor©Parallel™ Rapid Release™ (Cook®, Bloomington, IN, USA) (Figs. 1, 2), which allows the use of a single wire to serve as both safety and working guidewire.

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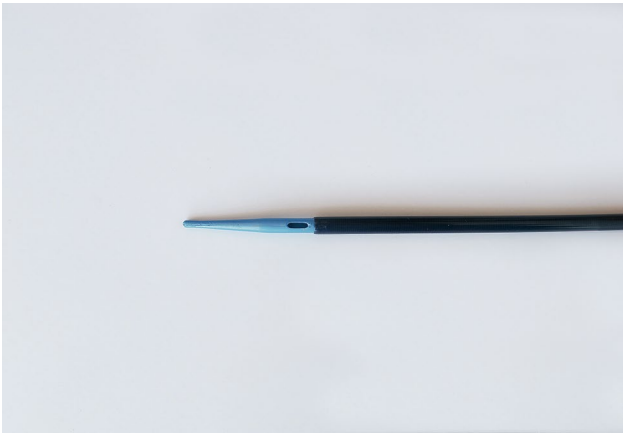

Fig. 1 Flexor parallel access sheath (cook Bloomington USA)

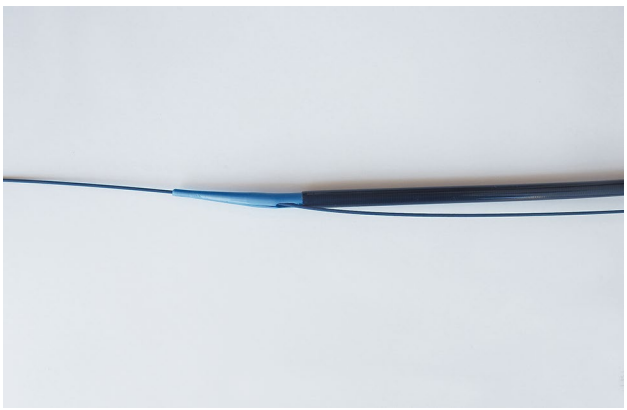

Fig. 2 Flexor parallel access sheath with one wire

Materials and methods

In accordance with institutional ethics review boards (IRB), a prospective cohort was conducted between June and September 2014. Adult patients from five European centers (Spain, Italy, Germany, Denmark and Greece) who underwent fURS for treatment or diagnostic purposes were included in this cohort. Cases with ureteric stones were excluded. In the diagnostic procedures, the UAS was inserted to perform the diagnosis in a low-pressure system allowing a clear vision. Furthermore, a previous ureter assessment with semirigid ureteroscopy was performed. All surgeries were performed by experienced endurologists who assessed the success of the 35-cm 12/14Fr Flexor©Parallel™ UAS insertion. All the UAS placements were done under fluoroscopic guidance over a single 0.035- or 0.038-in hydrophilic guidewire. The working wire was inserted through a slit on the sheath dilator that allowed the wire to remain parallel to the sheath while introducing it (Figs. 1, 2). A 35-cm 12/14Fr Flexor©Parallel™ was introduced up to below the ureteropelvic junction. Satisfactory placement was achieved when insertion was performed either in a single attempt or after ostium dilation. If a successful insertion was accomplished, removing the inner taper dilator of the sheath disengaged the UAS, thereby turning the working wire into a safety guidewire. If the UAS placement was not successful, the surgery was either performed using UAS in a standard fashion with double guidewires, or postponed with a double-J stent placement. At the end of each, the ureter was carefully inspected to identify possible lesions secondary to the access sheath placement.

Demographics and perioperative data as indications, gender and pre-stented status were prospectively collected and examined by both univariate and multivariate analyses. Furthermore, along with reported complications, evaluation of the material, insertion, radiopacity, release of the guidewire, hydrophilic coating, gliding of the endoscope and repeatability of UAS insertion were rated by the surgeons per case on a scale from very bad to very good.

Results

In total, 134 patients, 67 males and 67 females, were included. FURS was diagnostic and therapeutic in 10 and 90 % of cases, respectively. The diagnostic procedures included ten renal pelvis and calyceal system biopsies as well as three inspections of the renal pelvis for clots and possible AVM (artero-venous malformation). All the therapeutic procedures (121) included renal stone treatment. A preoperative stent was in place in 67 cases (50 %). The overall 12/14 Flexor©Parallel™ successful insertion rate was 94 %. All UAS was correctly placed below the ureteropelvic junction. Ureteral orifice dilatation was performed in 19 patients, and in 4 of these, a UAS could still not be placed. Five pre-stented and 14 non-pre-stented patients needed ostium dilatation, the difference being statistically significant ($p = 0.023$). Pre-stenting was an independent predictive factor for successful UAS insertion, with 98.5 % of pre-stented vs. 82 % of non-pre-stented patients having a successful UAS placement, respectively ($p = 0.001$, C.I. 95 %: 1.2). Gender and indication did not appear to affect the success of the insertion ($p = 0.803$) and neither the fURS indication ($p = 0.895$). There were two (1.4 %) UAS malfunctions that happened in non-pre-stented patients; in one case, the guidewire bent breaking the UAS slit; in the second case, the inner taper dilator of the sheath was trapped and the UAS could not be disengaged. In both cases, the UAS was removed without complications and a new UAS was placed in a conventional fashion with two wires. Evaluation of the material and radiopacity was

Table 1 Summarized results

	Males	Females	Pre-stent	Non-pre-stent	Pre-stent males	Pre-stent female	Non-pre-stent males	Non-pre-stent females
Successful UAS insertion	91 %	89 %	98.5 %	82 %	97 %	100 %	83 %	81 %
Unsuccessful UAS insertion	9 %	11 %	1.5 %	18 %	13 %	0 %	17 %	19 %
p value	$p = 0.803$		$p = 0.001$		$p = 0.37$		$p = 0.861$	

Table 2 Surgeon's ratings of the Flexor©Parallel™ UAS material and usage characteristics

	Evaluation of the material	Contrast injection	UAS radiopacity	Release of the guidewire	Hydrophilic coating	Gliding of the endoscope
Very good	123 (91.8 %)	101 (75.4 %)	121 (90.3 %)	110 (82.1 %)	114 (85.1 %)	107 (79.9 %)
Good	5 (3.7 %)	4 (3.0 %)	4 (3.0 %)	5 (3.7 %)	5 (3.7 %)	8 (6.0 %)
Average	6 (4.5 %)	29 (21.6 %)	7 (5.2 %)	7 (5.2 %)	6 (4.5 %)	6 (4.5 %)
Bad	0	0	0	1 (0.7 %)	0	0
Very bad	0	0	0	1 (0.7 %)	0	0
Non-available	0	0	2 (1.5 %)	19 (7.5 %)	9 (6.7 %)	13 (9.7 %)

considered very good in 92 and 90 %, respectively. Release of the guidewire was considered very good in 82 % of cases, hydrophilic coating in 85 % and gliding of the endoscope in 80 %. Furthermore, besides a submucosal ureteral injury (0.7 %) treated by double-J stenting, no intra- or postoperative complications concerning the use of the UAS were reported. Results are summarized in Table 1 and surgeon's ratings of the Flexor©Parallel™ UAS material and usage characteristics in Table 2.

Discussion

The advantages of UAS for fURS are well known. While permitting fast and multiple re-entries to the upper urinary tract, it reduces damage to the ureteroscope, decreases the intraluminal pressure during the procedure and allows drainage and elimination of dust and stone fragments [1–3, 6]. On the other hand, UAS use has been associated with risk of ureteral injury. Traxer et al. [7] reported a prospective series of routine UAS usage in 359 patients, in which an overall ureteral complication rate of 46.5 % (167 patients) with 13 % severe ureteral injuries was found. In this study, the most significant predictors of ureteral injury were found to be gender, age and pre-stented status. Furthermore, other authors have emphasized that from time to time it may be impossible to insert a UAS due to difficult ureters. The failure rate in these series ranged from 8 to 10 % [8, 9]. In such situations, the insertion of a JJ stent is often required before surgery can be performed at a later stage.

For these reasons, industry has investigated in the development of smaller, more flexible, more hydrophilic as well as more user-friendly access sheaths. The Flexor©Parallel UAS (Cook®, Bloomington, IN, USA) has recently been designed with the intent of a better hydrophilic coating and the possibility of using one single wire serving as both safety and working wire. This concept was evaluated prospectively in a multicentric setting. Although the Flexor©Parallel™ UAS is available in different sizes (9.5–14 Fr internal size) for this study, the 12/14 Fr was used as it is considered the standard UAS and permits the entry of all flexible ureteroscopes in particular the digital ureteroscope which needs an internal 12Fr caliber and is the most employed in the five centers [7, 10]. Our successful placement rate was 94 %. Gender and indication (diagnostic vs. therapeutic) did not appear to affect the success of insertion even in the subgroups of pre-stented and non-pre-stented males vs. females; however, in the overall analysis, a significant difference was found between pre-stented and non-pre-stented patients (98.5 vs. 82 %, $p = 0.001$). The explanation of this is probably due to a passive ureteral relaxation with loss of peristalsis that has been shown to be a favorable predicting factor for an effective UAS insertion [10], subsequently reducing UAS-induced ureteral lesions.

Placement failures occurred due to a narrow ureteral ostium in four cases (3 %), while two cases (1.5 %) had a difficult access of the distal ureter. In these cases, the placement of a JJ stent was mandatory and resulted in a successful UAS placement two weeks after stent placement. These results are comparable to other studies in where the failure

rate of insertion for the 14Fr UAS is up to 22 % despite progressive dilatation [10]. There were two UAS malfunctions (1.5 %) in which the procedure could be finalized by usage of a conventional UAS. In one case, the guidewire bent breaking the UAS slit; in the second case, the inner taper dilator of the sheath was trapped and the UAS could not be disengaged. In both cases, the UAS was removed without trouble or complications and a second UAS was correctly placed.

Our ureteral complication rate was lower than in previously reported series [7]. During removal of UAS, the ureter was visually inspected, and we found only one submucosal injury (0.7 %). This may be due to the high percentage of pre-stented patients in the present series, since pre-stenting has been shown to reduce the likelihood of ureteral injury sevenfold [7].

The present data are in line with a previous reported series with usage of a similar concept of UAS as the Colopast's® Re-trace™, in which the overall insertion rate was 82.5 %, confirming the clinical applicability of the concept a single wire UAS [11]. Furthermore, avoidance of using a second guidewire could potentially reduce the cost of the procedure that may be especially expensive in high volume centers [12]. Although cost studies are prone to support the use of UAS [13], it is known that the use of additional equipment increases fURS expenses. Since costs vary highly among different countries, cost analysis studies may not be uniform, although cost models based in the UK [12] and Turkey [14] reported an added cost of up to $38 for each guidewire use. All this may let us deduce that the use of less equipment as a single guidewire may reduce the overall expenses especially when looking at high volume centers, without compromising the safety and efficiency of the procedure.

Conclusion

The use of the Flexor©Parallel™ Rapid Release™ (Cook®, Bloomington, IN, USA) ureteral access sheath with usage of a single guidewire in a prospective multicentric scenario was clinically applicable in the majority of cases with a very low complication rate. Pre-stenting increased the chance of a successful UAS insertion from 82 % in non-pre-stented patients to 98.5 % in pre-stented patients.

Acknowledgments Authors' contribution Alberto Breda MD: Protocol/project development, Data collection or management, Manuscript writing/editing. Esteban Emiliani MD: Data collection or management, Manuscript writing/editing. Felix Millán MD Ph.D…: Data analysis. Cesare Marco Scoffone MD: Protocol/project development, Data collection or management, Manuscript writing/editing. Thomas Knoll MD Ph.D. MSc: Protocol/project development, Data collection or management, Manuscript writing/editing. Palle J. S. Osther MD Ph.D.: Protocol/project development, Data collection or management, Manuscript writing/editing. Evangelos Liatsikos MD Ph.D.: Protocol/project development, Data collection or management, Manuscript writing/editing.

Compliance with ethical standards

Conflict of interest The study was financially supported by COOK®. Alberto Breda is advisor for Karl Storz and Cook Medical, Esteban Emiliani has no competing financial interests, Felix Millán is advisor for Cook Medical, Cesare Marco Scoffone is advisor for Karl Storz, Boston Scientific, Porges Coloplst, Cook Medical and Lumenid, Thomas Knoll is advisor for Cook Medical, Palle J. S. Osther is advisor for Cook Medical, Karl Storz Endoskope, Olympus Boston Scientific, Porges Coloplast and Storz Medical, and Evangelos Liatsikos is advisor for Cook Medical.

References

1. Kourambas J, Byrne RR, Preminger GM (2001) Does a ureteral access sheath facilitate ureteroscopy? J Urol 165:789–793
2. Auge BK, Pietrow PK, Lallas CD et al (2001) Ureteral access sheath provides protection against elevated renal pressures during routine flexible ureteroscopic stone manipulation. J Endourol 18:33–36
3. Stern JM, Yiee J, Park S (2007) Safety and efficacy of ureteral access sheaths. J Endourol 21:119–123
4. Lallas CD, Auge BK, Raj GV et al (2002) Laser Doppler flowmetric determination of ureteral blood flow after ureteral access sheath placement. J Endourol 16:583
5. Türk C, Knoll T, Petrik A et al (2015) EAU guidelines on urolithiasis. Uroweb. http://www.uroweb.org/gls/pdf/22%20Urolithiasis_LR.pdf. Accessed 9 Feb 2015
6. Stern JM, Yiee J, Park S (2007) Safety and efficacy of ureteral access sheaths. J Endourol 21:119–123
7. Traxer O, Thomas A (2013) Prospective evaluation and classification of ureteral wall injuries resulting from insertion of a ureteral access sheath during retrograde intrarenal surgery. J Urol 189:580–584
8. Bourdoumis A, Tanabalan C, Goyal A et al (2014) The difficult ureter: stent and come back or balloon dilate and proceed with ureteroscopy? What does the evidence say? Urology 83:1–3
9. Ambani SN, Faerber GJ, Roberts WW, Hollingsworth JM, Wolf JS Jr (2013) Ureteral stents for impassable ureteroscopy. J Endourol 27:549–553
10. Mogilevkin Y, Sofer M, Margel D et al (2014) Predicting an effective ureteral access sheath insertion: a bicenter prospective study. J Endourol 28:1414–1417
11. Doizi S, Knoll T, Scoffone CM et al (2014) First clinical evaluation of a new innovative ureteral access sheath (Re-Trace™): a European study. World J Urol 32:143–147
12. Somani BK, Robertson A, Kata SG (2011) Decreasing the cost of flexible ureterorenoscopic procedures. Urology 78:528–530
13. Stern JM, Yiee J, Park S (2007) Safety and efficacy of ureteral access sheaths. J Endourol 21:119–123
14. Gurbuz C, Atış G, Arikan O et al (2014) The cost analysis of flexible ureteroscopic lithotripsy in 302 cases. Urolithiasis 42:155–158