Safety and efficacy of ureteroscopy and laser lithotripsy with a single-use 7.5Fr ureteroscope: a multicenter prospective pilot study

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Introduction The treatment of kidney stone disease (KSD) has evolved significantly with the introduction of minimally invasive endourological techniques. Advancements in technology, particularly the transition from fibreoptic to digital and single use systems and the development of smaller-diameter instruments, has improved intraoperative view and efficacy in stone treatment. The miniaturization in single-use scopes represent a recent innovation, offering potential benefits, especially in challenging cases. However, there is limited evidence on their safety and clinical outcomes. This study aims to evaluate the efficacy and safety of stone treatment using a single-use 7.5 Fr flexible ureteroscope.

Material and methods Consecutive patients with urinary stones undergoing flexible ureteroscopy with a 7.5 Fr single-use flexible ureteroscope across five tertiary endourology centers were included. Data on patient demographics, stone characteristics, intra- and postoperative outcomes were prospectively collected and analyzed. Procedures were performed by experienced endourology surgeons following standard protocols.

Results 50 patients with a mean age of 54.5 years (IQR: 25–65.8) and a male to female ratio of 34:16 underwent flexible ureteroscopy (FURS). Mean cumulative stone size was 18.9 mm (SD ±10.9 mm) with a mean stone volume of 2031.2 mm^3 (SD ±2869.4 mm^3) and mean Hounsfield units of 1087.4 (SD ±384.9). 36 (72%) had multiple stones and a bilateral FURS was performed in 9 cases (18%). 24 patients (48%) had a preoperative stent inserted. A ureteral access sheath was used in 22 (44%) cases and 46 (92%) patients had a postoperative stent inserted. The median operative time was 60min (IQR: 53–90), 32 patients (64%) were stone free after the first procedure (SFR for <2 cm and ≥2 cm stones was 85.2% and 36.2% respectively), perioperative and postoperative complications (Clavien ≤II) were observed in 3 patients (6%).

Conclusions This multicentric study demonstrates the safety and efficacy of using the 7.5Fr single-use flexible ureteroscope for urinary stone treatment. While the results are promising, larger studies are needed to validate these findings further.

Key Words: kidney calculi ‹› ureteroscopy ‹› single-use scope ‹› clinical outcomes ‹› laser

INTRODUCTION

Technological advancements have revolutionized the management of kidney stone disease (KSD), leading to a significant shift from traditional open surgery towards minimally invasive endourological procedures. The evolution from fiberoptic to digital systems has notably improved the intraoperative view, enhancing precision and efficiency [1]. Furthermore the miniaturization of ureteroscopes enables an increased probability for successful primary access to the pelvicalyceal system [2], therefore potentially less need for pre-stenting and an improved outflow of irrigation fluids [3]. There is an ongoing trend of miniaturization in flexible ureteroscopy in the past decades towards smaller shaft and tips size in fibre optic and digital ureteroscopes [4]. The introduction of single-use scopes, combined with the ongoing trend of scope miniaturization, has led to further advancements in endoscopic stone surgery and can be especially advantageous in challenging cases involving difficult access to the renal pelvis due to complex anatomy, cases with high risk of damage to the scope and in the presence of multi resistant urinary infection [5, 6]. However, evidence on the safety and clinical outcomes of stone treatment with these small single use scopes is scarce. We have therefore conducted a multicentre study to analyse the clinical outcomes of flexible ureteroscopy and stone treatment using a 7.5 Fr single use flexible ureteroscope at our institutions.

MATERIAL AND METHODS

This multicentric study included consecutive patients with urinary stones treated by flexible ureteroscopy with a 7.5 Fr single use flexible ureteroscope (Shenzhen HugeMed Medical Technical Development Co., LTD.) at five large tertiary endourology centers: Fundació Puigvert, Barcelona Spain; AZ Klina, Brasschaat, Belgium; Amsterdam UMC, University of Amsterdam the Netherlands; University Hospital of Ghent, Ghent, Belgium and University Hospital Southampton NHS Trust, Southampton, UK. The study was registered as an audit within the respective hospitals. A retrospective analysis of prospectively collected data was performed. Patient demographics, stone characteristics, intra- and postoperative data were collected prospectively and analyzed retrospectively.

Patients underwent a preoperative non-contrast CT (CTKUB) for diagnostic imaging. Pre-operative urine cultures were performed and patients with positive urine culture received antibiotic treatment based on sensitivity analysis.

The procedures were conducted by an experienced endourology team across all centers. Following an initial cystoscopy, a safety wire was placed, and a semirigid URS was performed at the surgeon's appraisal. Flexible ureteroscopy was performed using the HU30S (Shenzhen HugeMed Medical Technical Development Co., LTD.) 7.5 Fr single use flexible ureteroscope. The decision to place a ureteral access sheath (UAS) was made by the surgeon, utilizing a 9.5 Fr/11.5 Fr, 10Fr/12Fr or 12Fr/14Fr access sheath. Laser lithotripsy was executed with either a Holmium:YAG, pulsed Thulium:YAG or a Thulium fiber laser, with a laser fiber size ranging from 150–275 μm with settings of 0.4–1 J and 5–50 Hz, employing fragmenting, dusting, and pop-dusting techniques. Fragment retrieval was carried out using a nitinol basket (NCircle 1.5F or Ngage, Cook Medical, Bloomington, IN, USA, or Dakota, Boston Scientific Corporation). Postoperatively, a 6Fr or 7Fr ureteral stent was inserted if deemed necessary, for example, in cases of planned second-look procedures, extended procedural duration, or utilization of UAS. Stone-free rate (SFR) was defined as achieving stone clearance with fragments <2 mm on postoperative imaging, which included plain X-ray, CTKUB or Ultrasound scan at 4–8 weeks postoperatively. Complications were assessed following the Clavien–Dindo classification system.

Surgeons were also asked to rate the HugeMed ureteroscope for visual quality, scope placement, deflection, manoeuvrability, overall performance, and comparison with their current scope. This was evaluated on a scale from very good (5), good (4), fair (3), poor (2) and bad (1).

Data collection was performed using Microsoft Excel 2016 (Microsoft, Redmond, WA, USA), and statistical analysis was conducted utilizing SPSS version 26 (IBM, Armonk, NY, USA).

RESULTS

Fifty patients with a mean age of 54.5 years (IQR: 25–65.8) and a male to female ratio of 34:16 underwent flexible ureteroscopy and laser lithotripsy (FURSL). The mean cumulative stone size was 18.9 mm (SD ±10.9 mm) with a mean stone volume of 2031,2 mm^3 (SD ±2869,4 mm^3) and mean Hounsfield units of 1087,4 (SD ±384.9). Twelve patients (24%) had a positive pre-operative urine culture which was treated with treatment course of antibiotics. Thirty-six patients (72%) had multiple stones and bilateral FURS was performed in nine cases (18%).

Twenty-four patients (48%) had a preoperative stent. Stones were located in the renal pelvis

in 18 patients (36%), in the lower pole in 16 patients (32%), in the mid pole in 7 patients (14%), in the upper pole in 6 patients (12%), in the pelvic ureteric junction (PUJ) in one patient (2%) and 5 patients (10%) presented with stones in the ureter. A ureteral access sheath (UAS) was used in 22 (44%) cases and a postoperative stent placed in 46 (92%) patients. The median operative time was 60 min (IQR: 53-90), 32 patients (64%) were stone free after the first procedure (SFR of stones <2 cm and ≥2 cm was 85.2% and 36.2% respectively), perioperative and postoperative complications were observed in three patients (6%) (Table 1). These included one minor ureteral lesion (grade 1) needing a stent, and two urinary tract infections needing antibiotics.

On a scale of 1 to 5, all surgeons rated the visual quality, scope placement, deflection, manoeuvrability, overall performance as good (4) or very good (5). When asked to compare with their existing scope, most rated this new scope as very good or good.

Table 1. *Patient demographics and outcomes of the study*

	(n= 50)
Age (median, IQR)	54.5 (25–65.8)
Male	34 (68%)
Female	16 (32%)
BMI (median, IQR)	27.5 (19.7–30.9)
Stone location	
Pelvis	16
Upper pole	6
Mid pole	7
Lower pole	16
PUJ	1
Ureter	5
Stone composition	
Calcium oxalate monohydrate	12
Calcium oxalate dihydrate	2
Magnesium ammonium phosphate hexahydrate	3
Calcium phosphate carbonate	3
Ammonium urate	2
Cystine	1
Mixed: Calcium oxalate monohydrate and Calcium phosphate carbonate	7
Mixed: Calcium oxalate monohydrate and Calcium phosphate carbonate and Calcium oxalate dihydrate	5
Mixed: Calcium oxalate monohydrate and Calcium oxalate dihydrate	4
Mixed: Calcium phosphate carbonate and Beta calcium phosphate	1
Mixed: Calcium phosphate carbonate and Calcium oxalate dihydrate	2
Mixed: Calcium oxalate dihydrate and Calcium phosphate carbonate	1
Mixed: Calcium oxalate monohydrate and Ammonium urate	1
Mixed: Calcium phosphate carbonate and Magnesium ammonium phosphate hexahydrate	3
Multiple stones	36 (72%)
Cumulative Stone size in mm (mean, SD)	18.9 ±10.9
Stone volume in (mean, SD)	2031.2 ±2869.4
Hounsfield units (mean, SD)	1077.9 ±399
Pre-operative stent	24 (48%)
Operative time in min (median, IQR)	60 (53.2-90)
Ureteral access sheath	22 (44%)
Post-operative stent	46 (92%)
Complications (Clavien Dindo £II)	3(6%)
Stone-free after first procedure	32 (64%)
Stone-free < 20mm	(85,2%)
Stone-free >20mm	(36.8%)

n – number of patients; SD – standard deviation; IQR – interquartile range; BMI – body mass index; PUJ – pelvic ureteric junction

DISCUSSION

To our knowledge this is the first worldwide study reporting on the clinical outcomes on urteroscopy and laser lithotripy using a HugeMed 7.5Fr single use flexible ureteroscope.

The overall SFR was 64% after one procedure. However, it is noteworthy that the mean total stone size was relatively large at 18.9 mm, with a substantial proportion (40%) of patients presenting with a cumulative stone size ≥2 cm. Patients with larger stones were preoperatively counselled on staged retrograde procedures. When analysed separately the initial SFR for stones <2 cm and ≥2 cm was 85.2% and 36.2%, respectively. This emphasises the challenges posed by larger stones in achieving complete clearance after one procedure with retrograde intrarenal surgery (RIRS), as evidenced by the markedly lower initial SFR for stones ≥2 cm compared to smaller stones. These SFRs are comparable to a study analysing the efficacy and safety of flexible ureteroscopy for stones larger than 20 mm that reported stone free rates of 84.1% for stones <20 mm and 58.33% for stones >20 mm [7]. Guidelines recommend RIRS as either the first or second option for treating renal stones, including those larger than 2 cm [8]. However, effectively removing larger calculi can be challenging due to limited intraoperative visibility caused by the snow globe effect obscuring residual fragments. Although the main objective is to achieve high SFRs, residual fragments remain a concern, often requiring further procedures [9]. While there currently is no standard for managing or clearing residual fragments or dust, novel suction technologies in combination with small diameter scopes could improve SFRs especially in large and lower pole stones [9–11].

Smaller scopes increase the probability for successful primary access to renal pelvis [2]. In this

study access to the renal pelvis was successfully achieved in all cases, demonstrating the feasibility and effectiveness of FURSL with the 7.5 Fr single-use flexible ureteroscope. Notably, more than half of the patients (52%) underwent the procedure without pre-stenting, indicating the device's capability to facilitate primary access to the renal pelvis without prior stent insertion.

A recent review concluded that RIRS is a promising alternative to PCNL for kidney stones larger than 2cm, offering patients a less invasive option with favorable outcomes, including low complication rates and acceptable SFR. Furthermore, authors state advanced technologies such as new-generation high-power lasers and suctioning ureteral access sheaths could potentially lead to further improvement of clinical outcomes [12].

Combining these technological advancements with the advantages of small single use scopes can offer a safe and efficient treatment option even in patients with larger stones, however it is essential to consider patient factors, stone characteristics and patients' preference and to counsel the patients accordingly.

Intra or postoperative complications were observed in 3 patients (6%), which aligns with the expected range reported in literature for ureteroscopy procedures [13]. All observed complications were Clavien Dindo ≤II. Two patients had postoperative urinary tract infections or fever that were treated with antibiotics. A ureteral wall injury type one was observed in one patient, where a 10Fr/12Fr access sheath was used, and in three cases a reusable scope was needed to complete the procedure. While the incidence of complications was relatively low, it is crucial to consider potential risks associated with endourological interventions, especially in cases involving larger stones or in patients with complex anatomy.

While this study showed good clinical outcomes for FURSL with a 7.5 single use ureteroscope, several limitations warrant consideration. Despite being a multicentric study, its sample size remains limited, which may affect the generalizability of the findings. Additionally, the use of heterogeneous modalities for postoperative imaging to determine stone-free status introduces variability and may affect the accuracy of outcome assessment.

Future studies with larger cohorts and standardized imaging protocols are warranted to validate and extend these findings. Perhaps with the use of cost analysis and patient reported outcome measures (PROMS) a true comparison can be made with other procedures [14, 15].

CONCLUSIONS

This study demonstrates that the use of the 7.5 HugeMed single use flexible ureteroscope is safe and efficient for the treatment of urinary stones. However, further studies with larger cohorts are warranted to confirm our findings.

ETHICS

The study was registered as an audit/study in the respective hospitals and parents were consented for the study.

CONFLICT OF INTEREST

The company HugeMed gave the scopes for trial for free but has had no involvement in the study or data collection or analysis. No other external influence was there for this study.

References

1. Tzelves L, Geraghty RM, Hughes T, Juliebø-Jones P, Somani BK. Innovations in Kidney Stone Removal. Res Rep Urol. 2023; 15: 131-139.
2. Hudson RG, Conlin MJ, Bagley DH. Ureteric access with flexible ureteroscopes: effect of the size of the ureteroscope. BJU Int. 2005; 95: 1043-1044.
3. Juliebø-Jones P, Keller EX, Haugland JN, et al. Advances in Ureteroscopy: New technologies and current innovations in the era of Tailored Endourological Stone Treatment (TEST). J Clin Urol. 2022; 16: 190-198.
4. Talyshinskii A, Hameed BMZ, Naik N, et al. Miniaturization of flexible ureteroscopes: a comparative trend analysis of 59 flexible ureteroscopes. Urolithiasis. 2023; 52: 16.
5. Keller EX, De Coninck V, Traxer O. Next-Generation Fiberoptic and Digital Ureteroscopes. Urol Clin North Am. 2019; 46: 147-163.
6. Kumarage J, Khonyongwa K, Khan A, Desai N, Hoffman P, Taori SK. Transmission of multi-drug resistant Pseudomonas aeruginosa between two flexible ureteroscopes and an outbreak of urinary tract infection: the fragility of endoscope decontamination. J Hosp Infect. 2019; 102: 89-94.
7. Karagöz MA, Erihan IB, Doluoğlu Ö G, et al. Efficacy and safety of fURS in stones larger than 20 mm: is it still the threshold? Cent European J Urol. 2020; 73: 49-54.
8. Skolarikos A, Jung H, Neisius A, et al. EAU Guidelines on Urolithiasis. Edn. presented at the EAU Annual Congress Milan 2023.
9. Solano C, Chicaud M, Kutchukian S, et al. Optimizing Outcomes in Flexible Ureteroscopy: A Narrative Review of Suction Techniques. J Clin Med. 2023; 12: 2815.
10. Chen Y, Li C, Gao L, et al. Novel Flexible Vacuum-Assisted Ureteral Access Sheath Can Actively Control Intrarenal Pressure and Obtain a Complete Stone-Free Status. J Endourol. 2022; 36: 1143-1148.

11. Shrestha A, Adhikari B, Panthier F, Baidya S, Gauhar V, Traxer O. Flexible ureteroscopy for lower pole calculus: is it still a challenge? World J Urol. 2023; 41: 3345-3353.

12. Tonyali S, Haberal HB, Esperto F, et al. The Prime Time for Flexible Ureteroscopy for Large Renal Stones Is Coming: Is Percutaneous Nephrolithotomy No Longer Needed? Urol Res Pract. 2023; 49: 280-284.

13. Davis NF, Quinlan MR, Browne C, et al. Single-use flexible ureteropyeloscopy: a systematic review. World J Urol 2018; 36: 529-536.

14. Somani BK, Robertson A, Kata SG. Decreasing the cost of flexible ureterorenoscopic procedures. Urology. 2011; 78: 528-530.

15. Mehmi A, Jones P, Somani BK. Current status and role of patient-reported outcome measures (PROMs) in endourology. Urology. 2021; 148: 26-31. ■