

First worldwide report on safety and efficacy of using small 7.5 Fr scope for pediatric ureteroscopy: prospective pilot series from Europe

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Introduction Although pediatric urolithiasis remains relatively uncommon, its global prevalence is on the rise. Technological advances have led to miniaturization of instruments especially in the form of single use scopes. As the evidence on the use of small single use ureteroscopes in children is scarce, we have conducted a pilot two-center study to analyze the outcomes of pediatric patients treated with the Pusen 7.5 Fr single use scopes at our institutions.

Material and methods This study included consecutive pediatric patients with urinary stones treated with the small Pusen 7.5 Fr single use ureteroscope. The study was conducted at two large European tertiary endourology centers that specialize in pediatric kidney stone management. Patient data and outcomes were prospectively collected, and analysis was performed regarding patient demographics, stone parameters, as well as stone free rate (SFR), operating time, and complications.

Results In this pilot study, 26 patients were included with a median age of 12 years (7.0–16.0) and a male to female ratio of 14:12. The mean cumulative stone size was 15.15 mm (SD ±11.1) and multiple stones were present in 9 (34.6%) patients. Pre-operative stent, access sheath and post-operative stent usage was done in 12 (46.2%), 23 (88.5%) and 13 (50%) patients respectively. The median operative time was 47 minutes (IQR: 40.0–63.8). Following the initial procedure 24 (92.3%) patients were stone free, while no intra or postoperative complications were observed.

Conclusions Our study demonstrates that the use of the small 7.5 single use ureteroscope is safe and efficient for the treatment of urinary stones in pediatric patients with high stone-free rates and no complications noted in our series. While this might become a standard of care in future, to confirm and validate our findings further studies with larger cohorts are warranted.

Key Words: paediatric ↔ children ↔ ureteroscopy ↔ pusen ↔ kidney calculi ↔ single use ureteroscope

INTRODUCTION

There has been a notable rise in pediatric stone disease in the recent years. This is probably attributed to shifts in dietary habits and increased sedentary behaviors [1]. The upward trend has resulted

in a worldwide incidence of as much as 15%, depending on the region and epidemiological data [1, 2]. In terms of gender, it's more prevalent in males during their first ten years of life compared to females in their second decade. Notably, research indicates that the most significant increase has been among

teenage girls [3]. About one third of pediatric patients who present with stone disease might need surgery. Pediatric urolithiasis tends to recur, often linked with metabolic or anatomical anomalies or infections [4, 5, 6]. Given the high possibility of symptoms reappearing (up to 50% within three years), it's crucial to offer treatments that are both highly effective and have minimal side effects [7]. As a result, there's an increasing need on minimally invasive treatment methods, including shockwave lithotripsy (SWL), percutaneous nephrolithotomy (PCNL) and ureteroscopy (URS).

Technological advances have led to miniaturization of instruments especially in single use scopes. These smaller single use digital scopes seem to be advantageous especially in cases with difficult access to the renal pelvis due to challenging anatomy and might therefore be translating into successful endoscopic stone treatment in children [8]. As the evidence on the use of single use ureteroscopes in children is scarce, we have conducted a pilot two-center study to analyze the outcomes of pediatric patients treated with the 7.5 Fr single use ureteroscopes at our institutions.

MATERIAL AND METHODS

Study design and patient selection

This study included consecutive pediatric patients with urinary stones treated with the Uscope 7.5 Fr single use digital ureteroscope (Pusen Ltd., Zhuhai, China). The study was conducted at two large European tertiary endourology centers that specialize in pediatric kidney stone management: Fundació Puigvert, Barcelona Spain and the University Hospital Southampton NHS Trust, Southampton, UK. The study was officially registered as an audit within the respective hospitals. A retrospective analysis of prospectively collected data was performed. Patient demographics, stone location, single and cumulative size, composition, stone-free rates (SFR), operating time, pre and postoperative stent and peri/postoperative complications were documented over two years (December 2021-June 2023).

Preoperative non-contrast CT (CTKUB) or Ultrasound scan (USKUB) was performed for diagnostic imaging. Patients with positive pre-operative urine culture received appropriate treatment based on sensitivity analysis.

Surgical technique

At both centers the procedures were performed by an experienced surgeon. After an initial cystos-

copy, placement of safety wire and a rigid URS was performed using a 4.5 Fr Wolf or Storz semi-rigid ureteroscope. The Uscope 7.5 Fr single use ureteroscope (Pusen Ltd., Zhuhai, China) was used for flexible ureteroscopy. A ureteral access sheath (UAS) was placed at the surgeon's appraisal (9.5 F/11.5 F Cook Flexor UAS). Laser lithotripsy was performed with Holmium:YAG or a Thulium super fiber laser and a 150-275 μm laser fibre was used for laser lithotripsy.

The laser settings were maintained at 0.4–1J and 5–50Hz, utilizing fragmenting, dusting and pop-dusting techniques. Fragments were extracted using a nitinol basket (Ngage, Cook Medical, Bloomington, IN, USA or Dakota, Boston Scientific Corporation). A 4.8F or 6F ureteral stent was inserted postoperatively if deemed necessary (example – planned second look, long procedural time or use of UAS). Stone free rate (SFR) was defined as endoscopically stone free and <2 mm fragments on postoperative imaging, which was a plain X-ray or CT scan, or USS at 4–6 weeks post-surgery. Complications were assessed according to the Clavien–Dindo classification system.

Data was collected using Microsoft Excel 2016 (Microsoft, Redmond, WA, USA). Statistical analysis was conducted using SPSS version 26 (IBM, Armonk, NY, USA).

RESULTS

Patient characteristics

In this study, 26 consecutive patients were included, with a median age of 12 years (IQR: 7.0–16.0). The male-to-female ratio was 14:12 (Table 1).

Stone characteristics

The mean cumulative stone size was 15.51 mm (SD \pm 11.1), and multiple stones were present in 9 (34.6%) patients. Stone locations varied, with notable occurrences in the mid-pole (10 patients) and lower pole (8 patients). Partial staghorn stones were found in 2 patients. Stone composition analysis revealed various stone types, including calcium oxalate monohydrate, calcium oxalate dihydrate, calcium phosphate carbonate, magnesium ammonium phosphate hexahydrate, amorphous calcium phosphate carbonate, and brushite.

Treatment outcomes

Preoperatively, 12 (46.2%) patients had stents in place. A UAS was used in 23 (88.5%) cases during

Table 1. Patient demographics, stone characteristics and outcomes

Overall (n = 26)	Results
Age (median, IQR)	12 (7.0 – 16.0)
Male	14 (53.8%)
Female	12 (46.2%)
BMI	18.3 (16.7– 23.5)
Stone location	
Pelvis	5
Upper pole	5
Mid pole	10
Lower pole	8
Partial staghorn	2
PUJ	3
Ureter	1
Stone composition	
Calcium oxalate monohydrate	17
Calcium oxalate dihydrate	8
Calcium phosphate carbonate	16
Magnesium ammonium phosphate hexahydrate	5
Amorphous calcium phosphate carbonate	1
Brushite	1
Multiple stones	9 (34.6%)
Total stone length in mm (mean, SD)	15.15 ±11.103
Pre-operative stent	12 (46.2%)
Operative time in min (median, IQR)	47 (40.0–63.8)
Ureteral access sheath	23 (88.4%)
Post-operative stent	13 (50%)
Complications	0
Stone-free	24 (92.3%)

BMI – body mass index; IQR – interquartile range; SD – standard deviation

the procedures. Postoperative stents were inserted in 13 (50%) patients. The median operative time was 47 minutes (IQR: 40.0–63.8). Following the initial procedure, 24 (92.3%) patients were stone-free. No intra or postoperative complications were observed.

DISCUSSION

The miniaturization of surgical instruments and the introduction of flexible ureteroscopes have made it possible to treat urinary stones in children endoscopically throughout the whole urinary tract. Whereas in the past only lower ureteral stones were treated with semirigid ureteroscopy, and extracorporeal shock wave lithotripsy (SWL) was the primary treatment method for kidney stones up to 2 cm in pediatric cases [9]. SWL's effectiveness, however, diminishes notably with the growth in stone size and number [10]. Often multiple sessions are required to reach stone free status which can first be reached after a couple of weeks after SWL treatment [11]. For bigger stones percutaneous nephrolithotomy

is a viable treatment option with higher SFR after a single procedure [12], however it bears the risk of major complications such as bleeding or kidney injury [13].

In recent years retrograde intrarenal surgery (RIRS) has emerged as a practical and noteworthy treatment option. In comparison to SWL, RIRS has a higher SFR but demands a longer surgical duration and hospitalization [14]. Compared to PCNL in treating extensive stones, RIRS has a lower SFR. However, in terms of overall effectiveness, both RIRS and PCNL showcase comparable SFR [15, 16]. The growing accessibility and miniaturization of endourological instruments has enabled the endoscopic management of urinary stones in pediatric patients [9]. These advancements have partly come in the form of single-use flexible ureteroscopes such as Uscope 7.5 Fr (Pusen Ltd., Zhuhai, China) [17]. The smaller single-use scopes may offer advantages in cases with difficult anatomy and therefore reduce the risk of ureteric and scope damage, and especially useful in cases of multi resistant urinary infection [18].

Our study demonstrates that RIRS with the Uscope 7.5Fr single use scope is a safe and efficient treatment option for urinary stones in pediatric patients with a stone free rate of 92.3% after the first procedure and no intra or perioperative complications. For both patients in whom stone free status could not be achieved after the first procedure the total stone length was >35 mm (56 and 35 mm) and a staged procedure was planned after parental counselling.

A preoperative stent was placed in 46.2% of patients. However, some of the patients initially presented at centers not specialized for pediatric stone surgery, where they were initially stented and then referred to our centers for the final stone treatment. While in a UAS was used in 88.4% of the patients a postoperative stent was inserted in only 50% of the patients. The use of smaller ureteroscopes allows for the use of smaller UAS with the same effect, since the cross-sectional space between the UAS and the scope and therefore the space for fluid outflow remains nearly the same. Although the use of UAS has proven safe and can lead to a reduction of intrarenal pressure and temperature in children, there still is the concern of ureteric injury [19, 20, 21]. The use of smaller UAS leads to a lower rate of ureteric injuries [19, 22] and might lead to less need of post operative stent placement.

While this study is the first study to report outcomes of endoscopic stone treatment pediatric patients with a 7.5 Fr single use flexible ureteroscope and was carried out in high volume endourology centers with data retrieved for consecutive patients, it was

a small pilot study. Larger prospective studies with standardized outcomes are warranted to validate our findings in addition to having long-term follow-up to look at relevant outcomes. Previous French study in paediatric age group shows the advantage and cost-effectiveness of single use scope compared to reusable scopes [23]. Efforts must therefore be done to balance the cost of using scopes and consumables which are best suited for the given healthcare [24]. With centers now pushing for ureteroscopic treatment for larger stones [25], and advent of newer lasers [26], smaller sized ureteroscopes are going to further enhance this technique [27], giving a stiff competition for percutaneous techniques [28]. Furthermore, SFR was, in most cases, assessed with non-CT modalities acknowledging that this could have overestimated the SFR. However, we deemed the use of additional radiation and therefore CT scans was not justifiable in our pediatric patient cohort.

CONCLUSIONS

Our study demonstrates that the use of the smaller 7.5Fr single use ureteroscope is safe and efficient for the treatment of urinary stones in pediatric patients with high stone-free rates and no complications noted in our series. While this might become a standard of care in future, to confirm and validate our findings further studies with larger cohorts are warranted.

CONFLICTS OF INTEREST

BS is a consultant for Pusen, but the company has had no involvement in the study or data collection or analysis. No other external influence was there for this study.

ETHICS

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

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