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Safety of single-use flexible ureteroscopy for dusting of upper urinary tract calculi in children

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Abstract

Background Flexible ureteroscopy offers numerous advantages, such as increased reach, superior stone-free rate, reduced risk of bleeding, minimal surgical trauma, and faster recovery time. There are few studies discussing the effectiveness of single-use flexible ureteroscopy in children, and none so far have addressed its safety. This study aims to evaluate the effectiveness and safety of a single-use flexible ureteroscope for treating upper urinary tract stones in children.

Methods This study included children with single upper urinary tract stones measuring less than 2 cm who underwent single-use flexible ureteroscopy between October 2020 and January 2023. We assessed the following patient characteristics: age, gender, stone type, size, position, pre and postoperative stent placements, use of a ureteral access sheath, stone-free rate, operation duration, and the rate of complications. A patient was considered stone-free if there were no residual stone particles larger than 3 mm after surgery.

Results Flexible ureteroscopy and holmium laser lithotripsy were undertaken for 44 participants, with an average age of 8.5 years (range: 2–16 years). The typical stone size was 14 mm (range: 6–20 mm). The average operation time was 74 min (range 35–110 min). Ureteral access sheaths were used in 81.8% (36 out of 44) of procedures. After a single FURS session, 86.36% (38 out of 44) of patients achieved stone-free status. Postoperative JJ stent application was noted in 86.4% (38 out of 44) of patients. Complications were categorized using the Calvien system, revealing that 25% (11 out of 44) of patients experienced mild hematuria, colic, and low-grade fever (Calvien I). No severe side effects like mucosal avulsion or ureteral perforation were reported.

Conclusion In the short-term, single-use flexible ureteroscopy is a safe and effective method for managing single renal and proximal ureteric stones, measuring 2 cm or less, in children.

Keywords Retrograde intrarenal surgery, Flexible ureteroscopy, Children

1 Background

Children suffering from urolithiasis have a heightened risk of recurring stone formation, necessitating treatments to eliminate their existing stone burden [1]. Various treatment modalities have been selected based on

several factors, such as the patient's age, stone size and number, location, and urinary tract anatomy [2]. The accessibility of smaller devices enables endoscopic procedures to effectively remove upper urinary stones [3]. Although retrograde intrarenal surgery (RIRS) is increasingly employed for adults, there are minimal reports of its usage in treating renal stones in children. Flexible ureteroscopes (FURSs) come in various designs, such as fiber optics and digital ureteroscopes. FURS possess numerous advantages, such as a superior visual field, heightened resolution, high stone-free rate, reduced

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hemorrhage risk, less surgical trauma, and fast recovery [4]. The Ho:YAG laser is often the preferred method in flexible ureteroscopic lithotripsy due to its ability to fragment stones into pieces that can be manually removed or naturally passed [5]. As per our research, this is the pioneer study evaluating the short-term effectiveness and safety of single-use flexible ureteroscopy in treating renal and proximal ureteral calculi in children.

2 Methods

We conducted a prospective study on the efficacy of single-use flexible ureteroscopy for treating children with individual renal or upper ureteric stones under 2 cm. This study, conducted from October 2020 to January 2023, received approval from our local university ethics committee under the number 34219/10/20. We strictly adhered to the principles of the Declaration of Helsinki, taking into account any updates since its conception. Guardians were presented with the potential benefits and risks associated with the procedure, and we obtained their informed consent before proceeding.

2.1 Exclusion criteria

Unmanaged urinary tract infections (UTIs), distal ureter obstruction, impaired renal functions, kidney location abnormalities, urinary tract duplications, urinary tumors, and reconstructive surgery in the anticipated access tract region were excluded. The evaluation included a comprehensive medical history, clinical examination, routine blood tests, urine analysis, and urine culture. Low-dose non-contrast computed tomography (NCCT) and urinary ultrasonography were also conducted. The stone size was defined by the longest diameter measured by CT.

2.2 Procedures

We administered preoperative antibiotics to all patients. Two weeks prior to flexible ureteroscopy, we inserted a JJ ureteral stent in seven toddlers, pre-school patients, and six school-aged children. All procedures were performed under general anesthesia. After proper sterilization, patients were placed in a lithotomy position. In pre-stenting scenarios, we used a pediatric cystoscope (Karl-Storz SE & CO. KG, Tuttlingen, Germany) to insert a guidewire and remove the JJ stent. We utilized a semi-rigid 6 Fr ureteroscope (Karl-Storz SE & CO. KG, Tuttlingen, Germany) during ureteroscopy to verify ureteral dilation. We proceeded if the ureteroscope could be inserted easily; otherwise, we resorted to ureteral stenting. The access sheath (UAS), Coloplast 10/12 Fr (Coloplast Corp., Minneapolis, MN, USA), was placed over the guidewire under fluoroscopic observation. The obturator was then extracted. If the UAS insertion did not go smoothly, we opted for ureteral stenting or, if possible,

completed the procedure without the UAS. We employed WiScope single-use digital FURS (OTU Medical, USA) with a 3.6 Fr working channel and a 7.4 Fr bullet-like tip. After locating the stone, we performed lithotripsy using a 200-m holmium laser optical fiber (Lumenis™ VersaPulse™ Lasers Holmium Laser 100 W). We set the Ho:YAG laser's pulse energy to 0.5–0.8 J and a frequency of 15–20 Hz. The stones were shattered using a dusting technique, and we collected a small fragment or gravel with a Nitinol basket 1.8 fr for analysis. Body-temperature normal saline (0.9%) served as the irrigation fluid, which we applied through gravity and manual pressure irrigation when necessary to improve visibility. We removed the access sheath while ensuring clear visibility and then inserted a JJ stent. Afterward, we installed an overnight urethral catheter.

2.3 Follow-up

Patients were discharged the following morning, with follow-up appointments scheduled for 1 week and 1 month later. All patients underwent urine analysis after 1 week. One month later, they underwent a non-contrast CT scan to check for any significant remaining stones larger than 2 mm. The JJ retrieval was then performed cystoscopically. Patients were considered stone-free if they had no stones or a residual stone larger than 2 mm. Post-operative complications were recorded according to the Clavien–Dindo classification of surgical complications, a system comprised of five categories. Patients experiencing hematuria, fever, or persistent loin pain were advised to visit outpatient clinics at any time.

The sample size and power were calculated using the Epi-Info statistical package, a tool developed by the World Health Organization and the Centers for Disease Control and Prevention, Atlanta, USA. This package is from the 2002 version. The study should enroll a minimum of 40 patients, as it is anticipated to have 80% power with a 95% confidence limit and an alpha value of 0.05. The purpose of these requirements is to decrease the percentage of residual urinary stones by 15% using flexible ureteroscopy [6].

2.4 Statistical analysis

Data were analyzed using IBM SPSS software (version 20.0; IBM Corp., Armonk, NY, IBM Corp.). The median, range, and interquartile range were applied for nonparametric data. Associations between categorical variables were tested with the Chi-square test. If anticipated cell counts were below 5, the Monte Carlo correction or Fisher's exact test was used as a substitute. The Kolmogorov–Smirnov test was utilized to check the normality of continuous data. For irregularly distributed quantitative variables, the Mann–Whitney test was used to compare

two groups. The results were considered significant at a 5% level.

3 Results

The study involved 44 children (26 boys and 18 girls) with a median age of 8.5 years and single upper urinary stones. The median stone size was 14 mm. Types of stones recorded include upper third ureteric stones (25%), renal pelvic stones (22.7%), lower calyceal stones (20.5%), middle calyceal stones (15.9%), and upper calyceal stones (15.9%). Preoperative ureteric stenting was performed on 46% of the toddlers and preschoolers and 20.61% of the older children. The semi-rigid ureteroscope proved difficult to insert in 11 patients, and two patients had trouble with the placement of the FURS. A UAS was implanted in 88.5% of patients. FURS was introduced without UAS in 11.4% of schoolchildren for upper ureter and renal pelvic stones, always reaching the renal pelvis. A stone-free rate (SFR) of 86.4% was achieved after one FURS session. One patient's acute infundibulopelvic angle obstructed stone treatment, resulting in a PCNL procedure. The operating time median was 74 min. Variables such as gender, age,

operating duration, stone site, size, and density showed no significant impact on the SFR. However, a large preoperative stone size (> 1 cm) was associated with residual stones (Table 1). All postoperative complications were Clavien grade I, with 20.4% of patients experiencing them. Postoperative issues include moderate hematuria (9.1%), colic (6.8%), and low-grade fever (4.5%). After the operation, 86.36% of patients had a JJ stent placement. Lower calyceal stones were compared with other stone sites with respect to SFR (Table 2). The standard hospital stay following treatment was 1 to 2 days.

Table 2 Comparison between the lower calyceal stones and the other sites groups according to stone-free rate

Stone site	Total	Stone-free	Residuals	Test of sig.	p
Lower calyx	9 (20.5%)	7 (18.4%)	2 (33.3%)	$\chi^2=0.708$	^{FE} $p=0.586$
Others	35 (79.5%)	31 (81.6%)	4 (66.7%)		

χ^2 , Chi-square test, FE, Fisher's exact

Table 1 Analyses for the identification of factors associated with stone-free rate

	Total (44)	Stone-free (n = 38)	With residuals (n = 6)	Test of Sig.	p
<i>Age (years)</i>					
Min.–Max.	2.0–16.0	2.0–16.0	4.0–15.0	$U=108.0$	0.855
Median (IQR)	8.50 (5.0–11.0)	8.50 (5.0–11.0)	8.50 (5.0–12.0)		
<i>Gender</i>					
Male	26 (59.1%)	24 (63.2%)	2 (33.3%)	$\chi^2=1.907$	^{FE} $p=0.208$
Female	18 (40.9%)	14 (36.8%)	4 (66.7%)		
<i>Stone size</i>					
Min.–Max.	0.60–2.0	0.60–2.0	1.25–2.0	$U=67.0$	0.113
Median (IQR)	1.40 (1–1.8)	1.40 (1.0–1.75)	1.70 (1.40–1.90)		
<i>Operative time</i>					
Min.–Max.	35.0–110.0	35.0–110.0	35.0–108.0	$U=84.50$	0.322
Median (IQR)	74.0 (54–92)	75.50 (55–92)	59.50 (38–88)		
<i>Stone site</i>					
Pelvis	10 (22.7%)	9 (23.7%)	1 (16.7%)	$\chi^2=1.387$	^{MC} $p=0.932$
Lower calyx	9 (20.5%)	7 (18.4%)	2 (33.3%)		
Middle calyx	7 (15.9%)	6 (15.8%)	1 (16.7%)		
Upper calyx	7 (15.9%)	6 (15.8%)	1 (16.7%)		
Upper ureter	11 (25%)	10 (26.3%)	1 (16.7%)		
<i>HU</i>					
Min.–Max.	250–1600	250–1420	680–1600	$U=88.0$	0.393
Median (IQR)	1015 (775–1170)	980 (790–1105)	1150 (750–1200)		
<i>Stone side</i>					
Right	22 (50%)	17 (44.7%)	5 (83.3%)	$\chi^2=3.088$	^{FE} $p=0.185$
Left	22 (50%)	21 (55.3%)	1 (16.7%)		

χ^2 , Chi-square test; FE, Fisher's exact; MC, Monte Carlo; U, Mann–Whitney test; p, p value; IQR, Interquartile range

4 Discussion

Ureteroscopy can now treat stones at an earlier age due to advancements in endoscopic tools [7]. Many flexible ureteroscopes are available, both disposable and reusable. The duration of the procedure is influenced by factors such as the length of time the ureteroscope was used, the location and size of the stone, the use of additional instruments, and the surgeon's experience. While disposable flexible ureteroscopy is not a new concept, many centers are achieving good results using reusable ureteroscopes [8]. Another significant concern is the sterility of the instruments; disposable scopes can ensure complete sterility [9]. In our study, preoperative ureteric stenting was performed in seven out of 15 toddlers and preschoolers (46%) and in six out of 29 older children (20.61%). The semi-rigid ureteroscope encountered difficulty in inserting in 11 patients, while two patients experienced challenges in placing the FURS. Dogan et al. [10] reported balloon dilatation in all 35 patients, with two cases resulting in ureteral perforation. Conversely, Hubert et al. [11] completed all ureteroscopic procedures without necessitating active dilatation. Tanaka et al. [6], with a mean age of 7.9 years, utilized the pre-stenting procedure in 29 out of 50 patients (56%). Alternatively, Yuruk et al. [12] found that a double-J ureteral stent was required prior to surgery in one out of 14 cases. In their study, UAS was employed to facilitate multiple ureteral entries and lower intrarenal pressure. Only 8 participants (18.2%) in this study who had stones less than 1 cm underwent surgery without a ureteral access sheath. According to Singh et al. [13], children with numerous upper urinary stones can benefit from flexible ureteroscopic lithotripsy when utilizing a ureteral access sheath. However, Wang et al. [14] demonstrated no increase in long-term adverse effects despite encountering increased intraoperative difficulties with UAS. The Ho: YAG laser's capability to fragment all types of stones has significantly enhanced the effectiveness of ureteroscopic lithotripsy. The fragmentation duration, SFR, complication rate, and stone retropulsion are all influenced by the laser setup mode [15]. Our technique of choice was the dusting method, as it obviates the need for frequent stone extraction. Theoretically, stone dusting has been associated with a longer operative time and increased stone recurrence from fragments that fail to pass; therefore, some authors advocate for fragmentation into extractable pieces [5]. Ureteroscopic lithotripsy using the Ho:YAG laser boasts a high SFR (97.3%), rendering it a favorable first-line treatment for children, as per Esposito et al. [16]. Additionally, Turunc et al. [17] concluded that the position and size of the stone significantly impact the success of the procedure. Thulium fiber lasers have recently shown superiority over Ho: YAG lasers in several aspects, including smaller fibers, lower pulse energies, and ultra-high pulse rates of up to 2000 Hz. However, issues such

as saline irrigation temperature and thermal injury to the tissue at high pulse rates persist [18]. Postoperative consequences in this study included minimal mucosal injury, bleeding that hindered access to the stone (addressed by stent insertion), and subsequent treatment. Galal et al. [19] identified insignificant hematuria, renal colic, fever, less frequent vesicoureteral reflux, perforation, ureter avulsion, and ureteral stenosis as the main consequences of FURS in children. Clavien grade I complications comprised postoperative pain, low-grade fever, and minor hematuria. No instances of ureteric avulsion, extravasation, or urosepsis were reported in this study. In their meta-analysis, Ishii et al. [20] found that only 6 cases (2.12%) of Clavien class III complications were present, with a total complication rate of 12.4%. According to Xiao et al. [21] and Whatley et al. [22], the overall SFR of a single operation with FURS is 89% and 87%, respectively. Lower pole stones pose a particular challenge to urologists due to one or more anatomical variations, such as increased infundibular length, decreased infundibular width, and an acute infundibulopelvic angle, which impede FURS insertion or hinder stone clearance [23]. Cannon et al. [24] reported a SFR of 76% in 21 children with lower pole calculi, with a mean stone size of 10 mm. The overall SFR of single-session FURS in the current study was 38 out of 44 (86.3%), while that for lower calyceal stones were 77.88%. Concerning JJ stent placement following FURS, there is a consensus among urologists to insert a JJ stent whenever stone fragments remain in the upper urinary tract after lithotripsy. Stents aid in fragment passage and help prevent or reduce steinstrasse, which can cause upper tract obstruction, infection, or colic. Thomas et al. [25] utilized ureteric stents in all patients, whereas Herdon et al. [26] performed 23 FURS (79%) without employing a post-ureteroscopy stent. According to Thomas et al. [27], the median hospital stay was 1 day, while Unsal [28] reported an average hospital stay of 2.1 (ranging from 1 to 4) days. In our study group, we refrained from performing ESWL for several reasons. ESWL necessitates general anesthesia in children, and a single patient may require multiple sessions. Additionally, the child's body size may sometimes be too small to accommodate the ESWL machine head, and some parents declined ESWL after consultation. In a non-randomized retrospective study, Mille et al. [29] compared the results of utilizing both single-use and reusable flexible ureteroscopy in children. They found that both scopes exhibited comparable stone-free rates and costs. However, their study did not specifically address the safety of single-use FURS in children. They employed both dusting and fragmentation techniques with another scope (Uscope, PULSEN medical). To our knowledge, few articles discuss the effectiveness of single-use flexible ureteroscopy in children. However, this is the first article to address its safety in this demographic.

5 Conclusion

Single-use flexible ureteroscopy is a safe and efficient method for treating single renal and proximal ureteric stones that measure ≤ 2 cm in children. Factors such as a large stone load and sharp lower calyx angulation may lead to residual stones after employing this technique.

Abbreviations

ESWL	Extra corporal shock wave lithotripsy
FURS	Flexible ureteroscopy
HO:YAG	Holmium:YAG laser
PCNL	Percutaneous nephrolithotomy
SFR	Stone-free rate
RIRS	Retrograde intrarenal surgery
UTI	Urinary tract infection
UAS	Ureteral access sheath

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Author contributions

AS and SN organized and designed the study. OEG, SEG, and AS drafted the manuscript and performed the statistical analysis. AS was responsible for the clinical assessment of the subjects and, together with SN, contributed to the interpretation of the results. All authors contributed to writing of the manuscript. All authors have read and agreed the final version of the manuscript.

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Availability of data and materials

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Declarations

Ethics approval and consent to participate

Was obtained before the start of treatment by the Tanta University ethical committee. Guardians were presented with the potential benefits and risks associated with the procedure, and we obtained their informed consent before proceeding. The study has been performed in accordance with the 1964 Declaration of Helsinki and its later corrections, or comparable ethical standards. The study was approved by the ethical research committee of the Faculty of Medicine—Tanta University under the code: 34219/10/20. Patients' confidentiality was maintained throughout this study.

Consent for publication

Manuscript does not contain data from any individual person (Not applicable).

Competing interests

The authors declare that they have no competing interests.

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