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Original Article

Is fluoroscopy-free single-use flexible ureteroscopy a feasible treatment for kidney stones with abnormal renal anatomy?

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Abstract *Objective:* This study aimed to evaluate the feasibility of the fluoroscopy-free single-use flexible ureteroscopy procedure in the treatment of kidney stones with abnormal renal anatomy compared to normal renal anatomy.
Methods: Forty patients with abnormal (Group A) and 80 patients with normal (Group B) renal anatomy who had 10—20 mm renal stones were included. They were treated with LithoVue single-use flexible ureteroscopy (Boston Scientific, Marlborough, MA, USA) after ureteric dilatation by two different size semi-rigid ureteroscopes. This technique was chosen as the aim was to exclude any ureteric pathology (*e.g.*, stone or stricture), confirm the placement of a safe guidewire, avoid balloon dilatation of the ureter, and achieve safe insertion of a 12 Fr, 35/45 cm ureteric access sheath with optical and tactile sign and without fluoroscopy image for guidance.
Results: The mean ages were 43 years and 45 years in Group A and Group B, respectively. The mean stone burden was 14.62 (standard deviation: 5.35) mm^3 and 14.79 (standard deviation: 4.58) mm^3 in Group A and Group B, respectively. There is no significant difference between both groups according to the mean operative time, hospital stay, or stone-free rate. The stone-free rate was about 93% in both groups when the stone size was between 10 mm and 15 mm, and less than 54% when the stone size was more than 15 mm to 20 mm. In the majority of cases (80.0% in Group A and 92.5% in Group B), we completed the procedure without fluoroscopy. The perioperative complication rates were comparable in the two groups.

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Conclusion: Fluoroscopy-free single-use flexible ureteroscopy, when performed by expert urologists, is a feasible treatment for pre-stented patients with kidney calculi of ≤15 mm with abnormal renal anatomy.

1. Introduction

Stone treatment in kidneys with abnormal anatomy—such as horseshoe, ectopic, malrotated or polycystic kidneys, and kidneys with duplex system or fusion—is technically challenging due to difficulties in accessing the stone [1]. In such cases, single-use flexible ureteroscopy (fURS) is an attractive treatment modality as it has the potential to reduce morbidity while maintaining a high level of efficacy [2]. The placement of guidewires, balloon dilatation of the ureter, ureteric access sheath (UAS) or stent insertion, and scanning of pelvicalyceal system during fURS expose the patient and medical team to considerable amounts of radiation [3]. The growing alertness of the radiation hazards has induced the search for methods to reduce intraoperative surgical team and patient radiation exposure [4]. To date, only few numbers of studies had been reported on retrograde management of patients with renal calculi in anomalous kidneys with the recommendation that fluoroscopy should be available to give the surgeon more safety and contribute to complication avoidance [5,6]. Thus, the aim of this work was to evaluate the feasibility of the fluoroscopy-free single-use fURS procedure in the treatment of kidney stones with abnormal renal anatomy compared to normal renal anatomy.

2. Patients and methods

Between October 2020 and April 2022, 133 patients with renal stones of 10–20 mm in diameter were treated in three specialized urology centers. As 13 patients with a history of ureteric or renal operation, simultaneously bilateral stones, and stones in urinary diversions, as well as those under the age of 18 years were excluded, the remaining 120 patients (40 with abnormal renal anatomy and 80 with normal renal anatomy) comprised the study sample. They were treated with LithoVue single-use fURS (Boston Scientific, Marlborough, MA, USA) and evaluated. The procedures were performed by expert urologists. The study was approved by our Menoufia University Hospital—Faculty of Medicine Ethics Committee (9/2020UROL3). The study was performed under the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. All participants provided their written informed consents before inclusion in the study. They also underwent routine laboratory investigations, including urinary system ultrasonography and spiral CT scan. Demographic and clinical data (age, gender, anatomical abnormalities, symptoms, stone size, side, density, number, and location) were recorded.

In the operating theater, intravenous third generation cephalosporin was given. The patient was placed in the lithotomy position after general anesthesia. Cystoscopy with identification of the target ureteric orifice was verified. A 0.035 inch (1 inch=2.54 cm) straight floppy tip hydrophilic guidewire was insertion. Diagnostic ureteroscopy and ureteric dilatation were performed by the use of two semi-rigid ureteroscopes under direct vision. The first smaller ureteroscope (6–7.5 Fr) was inserted and maintained *in situ* for 2 min, followed by the second larger ureteroscope (8.5–11 Fr) (Aboutaleb technique) [7]. This technique was chosen as the aim was to exclude any ureteric pathology (*e.g.*, stone or stricture), confirm the placement of a safe guidewire, avoid balloon dilatation of the ureter, and achieve safe insertion of a 12 Fr, 35/45 cm UAS with optical and tactile sign and without fluoroscopy image for guidance. If a ureter prevented insertion of the access sheath, we proceeded directly by inserting the single-use fURS over the guidewire. If this strategy also failed, double-J ureteric stent was inserted and was kept *in situ* for 3 weeks before repeating the procedures described above.

Once the targeted calyx was identified and the specific calculus was visible, a 200 μm holmium:yttrium-aluminum-garnet laser fiber was inserted for lithotripsy. The laser settings were adjusted to produce pulse energy of 0.5–1.2 J with a pulse frequency of 3–20 Hz. The fragmentation and dusting process were terminated when only very small stone residuals (<3 mm in diameter) were visible.

We fixed an 8 Fr Foley catheter to maintain urinary bladder drainage if the UAS could not be inserted during the procedure. At the end of the procedure, double-J stent of suitable size per length was inserted through a large semi-rigid ureteroscope working channel (5 Fr) under direct vision, and was retained *in situ* for 21–30 days. Under direct vision, the upper coil of the double-J stent was moved into the renal pelvis while the lower part was coiled into the bladder. This technique was easy to implement, had short duration, and avoided the need for intraoperative fluoroscopy.

Perioperative data—operative time, UAS insertion, use of fluoroscopy guidance, double-J stenting, hospital stay, stone-free rate (SFR), and perioperative complications—were collected for all patients. They were managed on a day-case basis unless any complications occurred during the procedure, which were reported according to the Clavien–Dindo classification system [8]. During 1-week and 4-week follow-up appointments, all patients were evaluated. At the first follow-up, ultrasound was performed, whereas after 4 weeks, spiral CT was the imaging modality for radiolucent stones, while kidney, ureter, and bladder plain abdominal radiograph was performed for radiopaque stones. Results were categorized as stone-free (no residual fragments detected or residual fragments of ≤3 mm in diameter) and significant residual stones (>3 mm in diameter) requiring a second step.

To facilitate statistical analysis, all data were collected and tabulated, and were subsequently analyzed using SPSS version 17.0 on an IBM-compatible computer (SPSS Inc., Chicago, IL, USA). Qualitative data were described as numbers and percentages, while quantitative data were expressed as mean and standard deviation. For comparisons of qualitative results, the Chi-squared and Fisher's exact test were performed, whereas the *Z* test was conducted to compare two proportions, and Mann—Whitney *U* test was used to compare two groups comprising quantitative data that were not normally distributed. The significance level was set to less than 0.05.

3. Results

The study sample consisted of 40 patients with stones in kidneys of abnormal anatomy (Group A) and 80 patients with stones with normal renal anatomy (Group B). They were of comparable ages, with mean ages of 43 (standard deviation [SD]: 14) years and 45 (SD: 13) years, respectively. Male to female ratio was 32/8 in Group A while it was 65/15 in Group B. The mean stone burden was 14.62 (SD: 5.35) mm^3 and 14.79 (SD: 4.58) mm^3 in Group A and Group B, respectively, while their mean stone density (based on the CT findings) were 1132.3 (SD: 244.5; interquartile range 714—1517) HU and 977.5 (SD: 311.6; interquartile range 460—1744) HU. Horseshoe kidneys were noted in 13 patients, ectopic kidneys in 11 patients, malrotated kidneys in eight patients, duplex kidneys in five patients, adult polycystic kidneys in two patients, and kidney fusion in one patient. The patient demographic parameters and stone characteristics are summarized in Table 1.

Table 1 Demographic data and stone characteristics of the studied groups.

Demographic data and stone characteristics	Group A[a] (n=40)	Group B[b] (n=80)	p-Value
Age, year			0.62
Mean±SD	43±14	45±13	
Median (IQR)	45 (29—57)	43 (32—58)	
Sex[c]			0.87
Male	32 (80.0)	65 (81.2)	
Female	8 (20.0)	15 (18.8)	
Kidney side[c]			0.57
Right kidney	10 (25.0)	24 (30.0)	
Left kidney	30 (75.0)	56 (70.0)	
Clinical presentation[c]			0.49
Symptomatic	32 (80.0)	68 (85.0)	
Asymptomatic	8 (20.0)	12 (15.0)	
Stone burden in CT scan, mm^3			0.69
Mean±SD	14.62±5.35	14.79±4.58	
Median (IQR)	12.3 (6.0—20.0)	12.4 (6.0—20.0)	
Stone density, HU			0.002
Mean±SD	1132.3±244.5	977.5±311.6	
Median (IQR)	830 (714—1517)	821 (460—1744)	
Stone location[c]			
Pelvis	14 (35.0)	26 (32.5)	0.54
Lower	9 (22.5)	18 (22.5)	0.82
Middle	4 (10.0)	8 (10.0)	0.56
Upper	3 (7.5)	6 (7.5)	0.33
Multiple	10 (25.0)	22 (27.5)	0.33
Stone number[c]			0.33
Single	30 (75.0)	58 (72.5)	
Multiple	10 (25.0)	22 (27.5)	
Stone burden[c]			0.42
10—15 mm^3	28 (70.0)	50 (62.5)	
>15—20 mm^3	12 (30.0)	30 (37.5)	

SD, standard deviation; IQR, interquartile range; HU, Hounsfield unit.
[a] Group A: flexible ureteroscopy with abnormal renal anatomy.
[b] Group B: flexible ureteroscopy with normal renal anatomy.
[c] Values are presented as n (%).

Analysis of our operative data revealed no significant difference between the two groups with respect to the mean operative time, hospital stay, or SFR. As shown in Table 2, SFR was about 93% in both groups when the stone size was between 10 mm and 15 mm, and less than 54% when the stone size was more than 15 mm to 20 mm. Extracorporeal shockwave lithotripsy (ESWL) or second look fURS was performed for significant residual stones. Double-J stent was inserted preoperatively in 87.5% of patients in Group A, while it was required in 62.5% cases in Group B. All patients with ectopic pelvic kidneys, horseshoe kidneys, and kidney fusion were preoperatively stented. One patient with adult polycystic kidneys, four patients with duplex kidneys, and five patients with malrotated kidneys were also stented preoperatively. After 3 weeks, we completed the procedure without the access sheath (sheathless) in all patients with ectopic pelvic kidneys and kidney fusion. Access sheath insertions were performed successfully in 19 (47.5%) patients in Group A who had horseshoe kidneys, malrotated kidneys, duplex kidneys, and adult polycystic kidneys, while this procedure was needed in 74 (92.5%) cases in Group B. In the majority of cases (80% in Group A and 92.5% in Group B), we completed the procedure without fluoroscopy. Thus, fluoroscopy guidance was required in only eight (20%) patients in Group A and six (7.5%) patients in Group B, due to difficult passage of strictures or kinked ureter or to confirm intrarenal anatomy.

As can be seen from Table 2, the perioperative complication rates were comparable in the two groups and included: a postoperative hematuria (Clavien—Dindo classification Grade II) in 14 patients (which was managed conservatively by bed rest, hemostatic drugs, and intravenous fluids), UAS superficial ureteric injury described by post-ureteroscopic lesion scale by Schoenthaler et al. [9] (Clavien—Dindo classification Grade I) in eight patients (which healed completely, confirmed by diagnostic ureteroscopy during double-J removal), and urinary tract infection (Clavien—Dindo classification Grade II) in six patients (and managed by intravenous broad spectrum antibiotic according to urine culture).

4. Discussion

Renal anomalies can result in pain, urinary stasis, and recurrent urinary tract infection, which may induce stone formation in 10%—36% cases [10]. For management, various minimally invasive modalities have been described

Table 2 Operative and postoperative data among the studied groups.

Variable	Group A[a] ($n=40$)	Group B[b] ($n=80$)	p-Value
Operative time, min			
Mean±SD	68.68±28.4	64.37±22.28	0.31
Median (IQR)	60 (30–108)	58 (35–99)	0.29
Need for DJ ureteric stent, n (%)	35 (87.5)	50 (62.5)	0.42
UAS insertion, n (%)	19 (47.5)	74 (92.5)	0.01[c]
Use of fluoroscopy guidance, n (%)	8 (20.0)	6 (7.5)	0.04[c]
Hospital stay, h			0.72
Mean±SD	17.85±4.94	19.3±7.72	
Median (IQR)	10 (6–24)	11 (8–32)	
Stone-free rate, n/N (%)			
Stone burden (10–15 mm^3)	26/28 (92.9)	46/50 (92.0)	0.71
Stone burden (>15–20 mm^3)	6/12 (50.0)	16/30 (53.3)	0.17
Lower calyx	6/9 (66.7)	16/18 (88.9)	0.38
Postoperative complication, n (%)			
Postoperative hematuria (Grade II[d])	5 (12.5)	9 (11.2)	0.62
Ureteric wall injury (Grade I[d])	3 (7.5)	5 (6.2)	0.22
UTI (Grade II[d])	2 (5.0)	4 (5.0)	0.85

SD, standard deviation; IQR, interquartile range; DJ, double-J; UAS, ureteral access sheath; UTI, urinary tract infection.
[a] Group A: flexible ureteroscopy with abnormal renal anatomy.
[b] Group B: flexible ureteroscopy with normal renal anatomy.
[c] Statistically significant at $p<0.05$.
[d] According to the Clavien–Dindo classification.

including percutaneous nephrolithotomy (PCNL), ESWL, laparoscopic pyelolithotomy, laparoscopic guided PCNL, or fURS [11]. When ESWL is performed, however, stone localization can be difficult due to the overlying bony structures, and impaired drainage can impede the passage of the fragments resulting in reduced SFR (<68% at 3-month follow-up) [12]. During PCNL, on the other hand, there is an increased risk of iatrogenic injury due to the abnormal relationship of the kidney to the adjacent bowel [13].

The technological refinement in fURS and laser fibers has increased the use of this technique in cases of stones associated with renal anomalies [14]. In our study, we placed the floppy tip guidewire into the collecting system under direct ureteroscopic vision and without balloon dilatation, thereby precluding the need for fluoroscopy. Preoperative double-J stenting was conducted in 35 (87.5%) patients in Group A and 50 (62.5%) patients in Group B. Successful access to stone without the UAS occurred in 21 (52.5%) patients in Group A compared to only 6 (7.5%) in Group B members. Thus, our findings confirm that single-use fURS introduction without the UAS in abnormal kidney after double-J stenting and ureteric dilatation by two differently sized ureteroscopes is feasible, and does not require fluoroscopy or pose any difficulties in most cases.

In the literature published, fURS techniques advise retrograde studies of the ureter, intrarenal navigation, and UAS insertion under fluoroscopy guidance [6]. However, if these recommendations are followed, radiation exposure of the patient, surgeon, and other operative teams is significant, increasing the risk of carcinogenesis [15]. Urologist can be safely exposed to fluoroscopy-induced radiation for 2500–5000 s per year. However, as this range is very low, it is unattainable in practice. For this reason, most guidelines adhere to the reduced fluoroscopy protocol guided by the as low as reasonably achievable (ALARA) principle [16,17]. To facilitate further reduction in endoscopic radiation exposure, fluoroscopy-free fURS was developed, and the existing data indicate that protocols relying on tactile and visual feedback also offer promising results [18,19].

According to our results, there was no significant difference between patients with normal and abnormal renal anatomy according to patient gender, stone side, burden, location, mean operative time, or hospital stay. The stone density was significant ($p=0.002$) but findings supported by Majdalany et al. [20] indicated that stone density is not an influential factor in the era of high power lasers. Our protocol is also in line with that utilized by Aldoukhi et al. [21] who recommended setting the laser system parameters according to the stone density. Likewise, the outcomes we attained are supported by the findings reported by Grasso et al. [22] and Portis et al. [23] who achieved 76%–94.6% SFRs based on fragments of <4 mm after ureteroscopic laser lithotripsy. However, as noted by Takazawa et al. [24], the success of fURS declines as the treated stone burden increases. The fURS deflection capacity, coupled with thinner laser fiber and the development of nitinol stone extractors, has allowed the access and more effective treatment of stones located in abnormally positioned calyces.

The postoperative complication rates in the two patient groups are also in line with the outcomes reported by Lavan et al. [25] following a systemic literature review, whereby the overall complication rate after ureteroscopy for stone disease in anomalous kidneys was 17.2%, 14.8% of which were less than or equal to Clavien–Dindo Grade II complications.

According to our findings, single-use fURS introduction in the abnormal kidney after double-J stenting and ureteric dilatation by two different sized ureteroscopes without balloon dilatation or UAS insertion was convenient and could be performed without any difficulties in the majority of cases. We obtained a high SFR with minimal complication rates, reinforcing the conclusion reached by other authors that fluoroscopy-free fURS may be a feasible procedure for the treatment of stones of ≤20 mm in diameter by experienced urologists [26,27].

As this is the first multicenter study as a part of which evaluation of fluoroscopy-free single-use fURS for treatment of kidney stones with abnormal renal anatomy was performed and the outcomes were compared with those attained in patients with normal renal anatomy, we recommend further large prospective multi-centric studies with a long-term follow-up period. As more data become available, we expect this technique to be more widely used in clinical practice. Still, it is worth noting some of the limitations of this technique, one of which is the need for an experienced urologist, as well as two semirigid ureteroscopes of different sizes for diagnostic ureteroscopy (which may not be affordable for all centers, as it increases the cost of the procedure).

5. Conclusion

Fluoroscopy-free single-use fURS, when performed by expert urologists, is a feasible treatment for pre-stented patients with kidney calculi of ≤15 mm with abnormal renal anatomy.

Author contributions

Study concept and design: Hamdy Aboutaleb.
Data acquisition: Mohamed Sultan.
Data analysis: Ahmed Zaghloul.
Drafting of manuscript: Yasser Farahat, Fouad Zanaty.
Critical revision of the manuscript: Maher Gawish.

Conflicts of interest

The authors declare no conflict of interest.

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