



Evaluation of ultrathin semirigid ureteroscopy in terms of efficiency and cost compared to flexible ureteroscopy in treating proximal ureteric stones: a prospective randomized multicenter study

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Abstract

Purpose To investigate the outcome and cost-effectiveness of ultrathin 6–7.5-Fr semirigid ureteroscopy in treating proximal ureteric stones compared to flexible ureteroscopy.

Methods Two hundred and twenty patients with a solitary proximal ureteric stone were eligible for ureteroscopy (stone size = 1–2 cm). Patients were randomly subdivided into two groups: Group I included 105 patients who underwent ultrathin semirigid ureteroscopy and group II included 115 patients who underwent flexible ureteroscopy. Both groups were compared regarding successful stone access, operation time, reoperation rates, the financial cost to stone-free, complications, and stone clearance at 4 and 8 weeks.

Results Groups I and II had no significant differences regarding patient demographics, stone criteria, and hospitalization time. In contrast, the mean operative time was significantly longer in group II ($p < 0.001$). The overall scope-to-stone access rate was 89.5%. It was 87.6% compared to 91.3% ($p = 0.32$), while the stone-free rate was 81.9% versus 87.8% ($p = 0.22$) for groups I and II, respectively. Intraoperative and postoperative complications were statistically insignificant between the study groups. The cost/person in Egyptian pounds was 8619 ± 350 in group I, compared to $17,620 \pm 280$ in group II ($p < 0.001$); similarly, the cost to attain the stone-free rate was 8950 ± 720 in group I compared to $17,950 \pm 500$ in group II.

Conclusion Ultrathin semirigid ureteroscopy is safe, durable, and considered a cost-effective method for treating upper ureteric calculi compared to the flexible ureteroscopy and could be considered a first treatment option in developing countries.

Keywords Endourology · Proximal ureter · Urolithiasis · Ureteroscopy

Abbreviations:

ESWL Extracorporeal shock wave lithotripsy
URS Ureteroscopy
F-URS Flexible ureteroscopy
KUB Kidney, ureter, and bladder

US Ultrasound
CTUT Computerized tomography of the urinary tract
LASER Light amplification by stimulated emission of radiation

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MCCS Modified Clavien classification system
EGP Egyptian pounds

Introduction

Proximal ureteric stones could be treated with a wide range of urological procedures, including extracorporeal shock wave lithotripsy (ESWL), ureteroscopy (URS), and ureterolithotomy [1], with a preference for endoscopic procedures in well-equipped endourological centers [2].

Flexible ureteroscopy (F-URS) is the standard treatment modality for treating proximal ureteric stones [3]. However, due to its high cost, routine usage should be justified, particularly in developing countries, where the health system and health insurance differ from other countries.

The production of a smaller new caliber semirigid URS to the endourology theaters, with relatively wide working channels and excellent durability, has motivated the urologists to use it in managing proximal ureteral stones, taking into consideration its safety and efficacy [4, 5].

In the literature, many studies compared the semirigid to the flexible URS in treating proximal ureteric stones, with a wide range of results from the equality of both techniques [6], to the superiority of F-URS [1, 7].

The present study aims to answer the question: Is it cost-effective and reliable to use the ultrathin semirigid six-French ureteroscopes in managing the proximal ureteric stones in the era of flexible endourological instruments?

Patients and methods

A prospective randomized multicenter study between February 2021 and July 2022 was conducted at two tertiary care hospitals. It included all adult patients (> 18 years) with solitary proximal 1–2-cm ureteric stones (between the ureteropelvic junction and the upper border of the sacrum), amenable for ureteroscopy after ethical approval by the author's institutional review board.

The exclusion criteria included patients with bilateral stone disease, a stone in a solitary kidney, renal impairment, pregnancy, ureteral stricture, and history of previous ipsilateral ureteric intervention, including ESWL, endoscopy with double j insertion, or open surgery.

All patients were assessed by complete medical history, routine preoperative laboratory tests, KUB U/S (kidney, ureter, and bladder ultrasound), and KUB x-ray. The diagnosis of stone disease was confirmed by a non-enhanced computed tomography of the urinary tract (CTUT).

The sample size for this study was determined using the G-power software program and a priori analysis, with an effect size of 0.5. A statistical power of 95% and a type II

statistical error of 5% were used in the calculation. The estimated population was 230, divided randomly into two equal groups of 115 patients using the closed envelope method.

Surgical procedure

All patients enrolled in our study have consented to use semirigid and F-URS with a possibility of procedure crossover if indicated. Two senior urologists operated on all procedures under spinal anesthesia at the lithotomy position. One gram of cefazolin sodium was administered intravenously on induction of anesthesia. Ultrathin semirigid URS was performed utilizing a 6.0/7.5-French (Fr) ureteroscope (Richard Wolf, Knittlingen, Germany). The procedure started with guidewire insertion into the ureter after check cystoscopy. A semirigid ureteroscope was inserted into the ureter, and stone disintegration was completed utilizing a 30-W holmium: YAG laser. A 365- μ m LASER fiber with an energy output of 0.8–1.5 J at 8–12 Hz, with decreasing the irrigation flow rate and LASER dusting technique (high frequency and low power) to decrease the rate of stone retropulsion. We used the stone forceps in some cases to extract the sizable stone fragments.

We performed F-URS using a 7.5-Fr flexible ureteroscope (Karl Storz, Tuttlingen, Germany). The intramural part of the ureter was dilated using the balloon dilator for all patients (Boston Scientific, Uro-Max Ultra High-Pressure Balloon 12F \times 4 cm). After inserting a 9/11-Fr access sheath (45 cm in males and 35 cm in females) till below the stone (Cook Urological, Spencer, Indiana, USA), the F-URS was inserted into the ureter under C-arm fluoroscopy guidance. The stone was disintegrated similarly to semirigid URS, utilizing the basket (Zero Tip™, Boston Scientific Corp., Natick, MA, USA) in some cases to extract the sizable stone fragments.

At the end of the procedure, we inserted a 26-cm 6-Fr double-J ureteric stent over the guide wire for all patients, to be removed after 2–4 weeks.

The operative time was set starting from the cystoscope introduction to the end of double-J ureteric stent insertion.

Stone status was assessed intraoperatively on fluoroscopy and after 4 and 8 weeks with plain KUB in cases with radiopaque stones; otherwise, a non-contrast CT scan of the abdomen and pelvis was utilized.

We defined the stone-free status as no more stone fragments or the presence of insignificant stone residuals less than 4 mm. Reoperation was defined as a need for another procedure to clear the stone residual exceeding four millimeters or with narrow ureteral calipers necessitating double-J insertion with procedure abortion. Bleeding was accepted as a hemorrhage that confused the endoscopic vision, while ureteral injury was defined as the observation of a mucosal tear.

On patients' discharge, the Accounts Department issued a bill for costs, including materials, drugs, hospital stay, purchase of disposable F-URS, depreciation of semirigid ultrathin URS, laser machine with subsequent maintenance, ancillary procedures, and treatment of postoperative complications [8] (e.g., hospital readmission, CT scan, placement of double-J ureteric stent). Throughout the study period, there was no change in the costs of instruments.

Four weeks after surgery, the primary endpoint was the single-procedure stone-free rate (SFR). The secondary endpoints were the SFR at eight weeks and further treatments. The cost of stone-free status at 4 and 8 weeks postoperatively was calculated in Egyptian pounds (EGP).

The study groups were compared in terms of patient demographics and stone characteristics, successful stone access, operation time, reoperation rates, the financial cost to stone-free status, peri-operative complications according to the modified Clavien classification system (MCCS) [9], and the stone-free status at 4 and 8 weeks.

Statistical analysis

Patients were assigned to treatments following the randomization (from sealed envelopes). The study sponsor prepared the treatment assignments centrally, sealed in opaque, sequentially numbered envelopes, distributed to participating centers, and opened by the principal surgeon before the procedure in the operating room. The urologists were blinded in the follow-up. The study was designed to provide 95% power to evaluate the cost-effectiveness of using the ultrathin semirigid six-French ureteroscopes compared to F-URS in managing the proximal ureteric stones. Statistical significance was assessed at the 5% level (two-sided) for all other comparisons using the Chi-square test for categorical variables and the Student's *t*-test for continuous variables. We expressed the numeric variables in a mean and standard deviation, while categorical variables were expressed in frequency and percentage. All statistical analyses were performed using the SPSS software, version 28.

Results

In total, 220 patients were included in our study, the mean age in years \pm SD was 34.19 ± 7.99 , and the stone size in millimeters was 14.75 ± 2.66 . The study population was subdivided into group I (ultrathin semirigid URS), $n = 105$, and group II (F-URS), $n = 115$ (Fig. 1).

There were no significant differences between the study groups regarding patient demographics and stone criteria, as illustrated in Table 1.

Regarding the operative data, the mean operative time was significantly longer in group II; it was 84.5 ± 8.5 min compared to 62.9 ± 11.7 min for group I ($p < 0.001$).

The overall scope-to-stone access rate was 89.5%. In semirigid URS, the stone was accessible in 87.6% of patients, and the stone-free rate was reported at 78% and 81.9% after four and eight weeks, respectively; similarly, the scope-to-stone access was reported at 91.3% in F-URS group with a stone-free rate of 83.5% and 87.8%, after four and eight weeks, respectively. The difference was statistically insignificant (Table 2).

The overall hospitalization time was 1.68 ± 0.81 days. It was comparable between groups I and II with no statistically significant difference ($p = 0.35$) (Table 2).

We reported an overall complication in 78 cases (35.5%), comparable between groups I and II; similarly, intraoperative and postoperative complications were statistically insignificant between the study groups, as shown in Table 3.

The mucosal injury was reported in 3.2% (7/220) when we proceeded for double-J ureteric stenting and rescheduled for another URS session.

The total failure rate was 11.4% (25/220), with an insignificant difference between the study groups ($p = 0.24$) (Table 2). The most common cause was stone access failure due to failure to advance the ureteroscope (narrow caliber of the ureter) in 5.5% (12/220) and failure in the guidewire passage due to ureteral tortuosity in 1.8% (4/220), where patients were managed with ESWL. We reported stone migration in 0.9% (2/220) in the semirigid URS group; a double-J stent was inserted for one patient due to long operative time and was referred for ESWL later, where the other patient was managed with F-URS. We reported a secondary procedure in 25 cases (11.4%); of them, 17 cases underwent ESWL, 5 cases underwent F-URS, and 3 underwent semirigid URS with insignificant *p*-value between the study groups (Table 2).

There were no technical failure, avulsion of the ureter, or scenarios necessitating open surgery; most reported complications were MCCS grades I and II managed conservatively. Hospital readmission was mandatory in seven cases (3.2%): five patients were admitted due to fever and loin pain and two were due to hematuria. All cases were managed conservatively.

Regarding the improvement in hydronephrosis, 75% of patients with preoperative hydronephrosis improved after semirigid URS compared to 76.1% after F-URS ($p = 0.98$) (Tables 1 and 2).

At the time of purchase, the disposable F-URS was listed at EGP 13500, the Uromax balloon at EGP 680, UAS at EGP 590, and the ultrathin semirigid URS at EGP 130000. The expenditure on ancillary equipment was EGP 1247800, of which EGP 1155000 was on disposables and ancillary procedures and EGP 92800 was on laser probes [10]. The cost

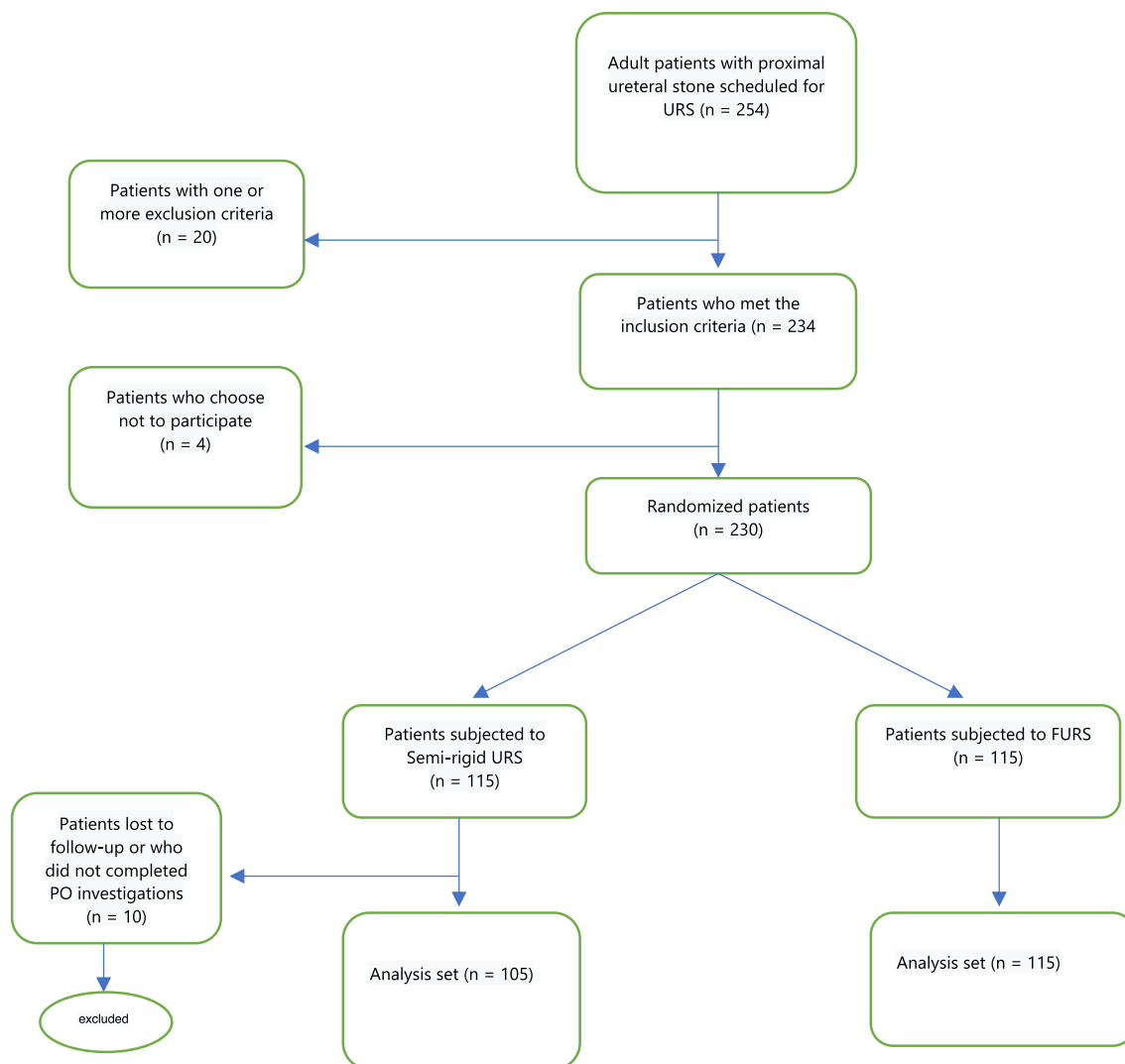


Fig. 1 Flowchart of the study population

of using F-URS and LASER lithotripsy in treating proximal ureteric stones was more than double using the ultrathin semirigid URS with LASER. In group I, the cost/person in EGP was 8619 ± 350 , compared to $17,620 \pm 280$ in group II ($p < 0.001$); similarly, the cost to attain a stone-free rate was 8950 ± 720 in group I compared to $17,950 \pm 500$ in group II, including the cost of reusable semirigid instrument = 35 ± 6 EGP/case (Table 2).

Discussion

Retrograde ureteroscopy (R-URS) is considered the first-line treatment modality for proximal ureteral stones exceeding one centimeter [11]. It is less invasive, easily accesses the stone, has low radiation exposure, and has a shorter

operative time and hospital stay compared to the antegrade URS approach [11].

Conversely, R-URS carries disadvantages, including difficulty in stone visualization due to ureteric wall edema and stone impaction that may lead to ureteric wall injury, perforation, stone retropulsion, and instrument breakdown [10].

Flexible ureteroscopy and LASER lithotripsy are considered the gold-standard treatment modality for proximal ureteral stones, enforced by the continuous advancement in the technical features of flexible ureteroscopes. Conversely, flexible ureteroscopy has many disadvantages, including narrow working channel caliber and low durability with a higher cost than semirigid ureteroscopy [12].

Recent developments in miniaturization of semirigid ureteroscopy and holmium: YAG laser encouraged the urologists to favor its use against flexible ureteroscopy

Table 1 Patient demographics and stone criteria of the study groups

Parameters	Total (n = 220)	Semirigid URS group (n = 105)	F-URS group (n = 115)	p value
Age, years	34.19 ± 7.99	33.8 ± 7.7	34.6 ± 8.3	0.45
Gender				0.94
Male	123 (55.9%)	59 (56.2%)	64 (55.7%)	
Female	97 (44.1%)	46 (43.8%)	51 (44.3%)	
BMI, kg/m ²	23.4 ± 2.99	23.2 ± 2.9	23.5 ± 3	0.51
Side of stone				
Right	108 (49.1%)	48 (45.7%)	60 (52.2%)	
Left	112 (50.9%)	57 (54.3%)	55 (47.8%)	0.34
Stone size, mm	14.75 ± 2.66	14.56 ± 2.39	14.93 ± 2.88	0.3
Stone density, HFU	944 ± 295	936 ± 279	951 ± 310	0.69
Stone x-ray appearance				
Radiopaque	128 (58.2%)	59 (56.2%)	69 (60%)	0.57
radiolucent	92 (41.8%)	46 (43.8%)	46 (40%)	
Presence of hydronephrosis	86 (39.1%)	40 (38.1%)	46 (40%)	0.82

Chi-square test was used

Table 2 Intraoperative recordings, stone-free rate, and the cost-effectiveness for the study groups

Parameters	Total (n = 220)	Semirigid URS group (n = 105)	F-URS group (n = 115)	p value
Operative time, min	74.2 ± 14.8	62.9 ± 11.7	84.5 ± 8.5	<0.001
Scope-to-stone access	197 (89.5%)	92 (87.6%)	105 (91.3%)	0.37
URS failure	25(11.4%)	13 (12.4%)	12 (10.4%)	0.65
1. Failure to advance the ureteroscope (narrow caliber)	12 (5.5%)	7 (6.7%)	5 (4.3%)	0.95
2. Failure to pass guidewire (tortuosity)	4 (1.8%)	1 (0.95%)	3 (2.6%)	0.22
3. Stone migration	2 (0.9%)	2 (1.9%)	0	0.1
4. Ureteric mucosal laceration	7 (3.2%)	3 (2.9%)	4 (3.5%)	0.87
Hospitalization time, days	1.68 ± 0.81	1.63 ± 0.71	1.73 ± 0.89	0.35
SFR at follow-up week 4	178 (80.9%)	82 (78%)	96 (83.5%)	0.31
SFR at follow-up week 8	187 (85%)	86 (81.9%)	101 (87.8%)	0.22
Presence of hydronephrosis	21 (9.5%)	10 (9.5%)	11 (9.6%)	0.98
Ancillary procedures				
ESWL	17	9	8	0.85
F-URS	5	1	4	0.1
Semirigid URS	3	3	0	0.14
The cost of using URS and LASER lithotripsy/patient in EP	13,250 ± 312	8619 ± 350	17,620 ± 280	<0.001
Total cost to the stone-free status/patient in EP	13,600 ± 300	8950 ± 720	17,950 ± 500	<0.001

Chi-square test and Student's t-test were applied

in treating proximal ureteral stones, specifically in areas where the financial issue has a considerable concern [13].

Many studies reported the superiority of smaller caliber ureteroscopes (6–7.5 Fr) with higher success rates ranging between 84% and 92.2% compared to 80% and 83.7% for larger caliber ureteroscopes [14, 15].

Accordingly, we have used the smaller caliber, less expensive ultrathin semirigid URS compared to F-URS in

terms of cost-effectiveness for promoting its use in developing countries.

In the current study, the stone-free rate was high and comparable between flexible and semirigid URS (81.9% vs. 87.8%, $p = 0.2$). Similarly, it is comparable to the published works as the stone-free rate was reported in 81.1%, 84.5%, 80%, 90%, and 68% with semirigid URS [1, 4, 5,

Table 3 Perioperative complications and hospital readmission for the study groups

Parameters	Total (n = 220)	Semirigid URS group (n = 105)	F-URS group (n = 115)	p value
Overall complications	78 (35.5%)	40 (38%)	38 (33%)	0.67
Intraoperative complications	32 (14.6%)	18 (17.1%)	14 (12.2%)	0.17
Postoperative complications	46 (20.9%)	22 (20.9%)	24 (20.9%)	0.99
MCCS grading of complications				
Grade I				
Technical/mechanical failure	25(11.4%)	15 (14.3%)	10 (9.1%)	0.29
Ureteric mucosal injury	7 (3.2%)	3 (2.9%)	4 (3.5%)	0.79
Hematuria	16 (7.3%)	9 (8.6%)	7 (6.1%)	0.48
Fever	19 (8.6%)	8 (7.6%)	11 (9.6%)	0.6
Grade II				
UTI	11 (5%)	5 (4.8%)	6 (5.2%)	0.88
Readmission (within 8 weeks)	7 (3.2%)	3 (2.9%)	4 (3.5%)	0.79

Chi-square test was used

7, 14] and it was reported in 93.3%, 91%, 81.4%, 88%, and 87.5% with F-URS [7, 16–18].

In the current study, the overall ureteroscopy failure rate was (11.4%); in most cases (12/25; 48%), failure of the procedure was due to the difficulty in advancing the ureteroscope due to the narrow caliber of the ureter: seven of them from semirigid URS group and five from flexible URS group, with an insignificant *p*-value.

Besides that, stone migration occurred in only two cases who underwent semirigid URS compared to no patients in the F-URS group. This may be attributed to irrigation pressure in the semirigid ureteroscope; the *p*-value remains insignificant. These findings were comparable with other studies with nearby results [7, 16, 19, 20].

Many authors agreed with our finding of significantly longer operative time for the flexible ureteroscopy, adding an advantage for the semirigid ureteroscopy over the flexible one. This finding may be explained in our study by the time of ureteral balloon dilatation, insertion, and removal of ureteral access sheath [7, 16, 19, 20].

Besides advantages, a semirigid ureteroscope does not let the surgeon proceed with the surgery in the case of pushback to a lower pole.

Despite EUA recommendations to avoid routine stenting post-ureteroscopy [21], we put a stent in all cases in our study to avoid the possible complications of the in situ laser fragmentation in the upper ureter and decrease the postoperative emergency room visits, especially with the high load of patients in our hospitals.

The complication rate of semirigid ureteroscopy in treating upper ureteric stones varies from one study to the other. It ranges from 4%, 7.1%, and 7.7% [21–23] to 20%, 22.2%, 37%, and 42.6% [7, 20, 24–26].

The complications rate of the flexible ureteroscopy varies from 10%, 12.5%, 13.5%, and 14% [7, 13, 15, 16] to

31%, 32% [14, 26]. Most of the reported complications were minor. However, some investigators [1, 18, 26, 27] reported major complications for the semirigid ureteroscopy, including ureteral avulsion requiring laparotomy and ureteral repair; some studies also reported major complications for flexible ureteroscopy, including sepsis necessitating ICU admission [17].

In the current study, the overall complication rate was 35.5%. (38% for the semirigid group and 33% for the F-URS group), and all complications were MCCS grades I to II with no statistical differences between both techniques.

We reported hydronephrosis in preoperative imaging for the semirigid URS group in 40 cases (38.1%) that decreased to 10 cases (9.5%) at the end of the follow-up. Similarly, in preoperative imaging for the F-URS group, hydronephrosis was reported in 46 cases (40%) that decreased to 11 cases (9.6%) with no statistically significant difference. The ureteric balloon dilatation and ureteral access sheath during F-URS did not negatively impact post-ureteroscopy hydronephrosis [28].

Depending on the available data in the current study, ultrathin semirigid ureteroscopy in the management of upper ureteric calculi more than ten mm in diameter could be advised significantly when the financial issue has a significant concern, including stone disease management in developing countries as probably it is not cost-effective to use disposables in high-volume centers, where we used disposable F-URS for each patient in group II. However, only one semirigid ultrathin URS for all patients in group I and still works well without the cost of a significant loss.

Limitations

Even though it is a randomized controlled prospective study, it has limitations. First, the ureteroscopy procedures were

performed by two urologists, which could affect the outcomes. Second, it has a short-term follow-up, so another long-term follow-up study may be needed to re-evaluate the possible remote postoperative complications.

Conclusion

Ultrathin semirigid ureteroscopy is a safe and effective treatment of upper ureteric calculi (1–2 cm). Although it has a higher number of minor complications than flexible ureteroscopy, it still has no statistical significance; moreover, its durability and cost-effectiveness give the preference to be used as a first treatment option in developing countries when the financial issue has a significant concern, specifically stone disease management.

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Availability of data and materials Data sets used in this study are available upon reasonable request from the corresponding author.

Declarations

Conflict of interest None of the contributing authors have any conflict of interest, including specific financial interests or relationships and affiliations relevant to the subject matter or materials discussed in the manuscript.

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