



ORIGINAL ARTICLE



The efficacy of flexible ureteroscopy for large volume stones and hazards of ureteral access sheath usage: A prospective randomized study

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ABSTRACT

Objectives: We aimed to assess the stone free rate of flexible ureteroscopy and laser lithotripsy (FURL) in upper urinary tract stones (UUTS) >20 mm and the risk of complications from ureteral access sheath (UAS) usage.

Methods: This is a prospective randomized clinical trial that included patients with UUTS larger than 20 mm who underwent FURL after randomization into two groups: group A (UAS) and group B (non-UAS). Data were collected for patients' demographics, stone parameters, operative and postoperative complications, and the outcome of FURL regarding stone-free rate (SFR) and perioperative complications, with a 6-month follow-up. Stone clearance was defined as the absence of fragments or the presence of fragments smaller than 2 mm on follow-up CT scans of the urinary tract (CTUT).

Results: One hundred and fifty-nine patients were evaluated. The mean stone size was $27.08 \pm$ 6.185 mm. Complete stone-free status was achieved in 84.9% of the patients. No significant difference was detected between both groups regarding operative time or SFR. The ureteric injury was identified in 13 (8.1%) patients (10 in group A and 3 in group B, p: 0.0481). Five of them, from group A, revealed hydronephrosis after stent removal. Postoperative pain and fever were documented in 50 and 22 patients, respectively, without significant differences between both groups. Postoperative sepsis occurred in 7 patients (2 in group A, 5 in group B, p: 0.380) who required supportive care.

Conclusion: FURL without UAS is a safe and efficient treatment for upper urinary tract stones larger than 20 mm in the form of lower risk of ureteric injury.

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KEYWORDS

Flexible ureteroscopy; laser lithotripsy; ureteral access sheath; ureteric injury

Introduction

Many factors, such as stone site and size, patients' comorbidities and previous modalities of treatments, should be considered to properly manage upper urinary tract stones (UUTS). Despite percutaneous nephrolithotripsy (PCNL) being considered the standard treatment modality for renal stones >20 mm, it carries serious complications like bleeding and adjacent organ injury. Therefore, the new trend is directed toward less invasive modalities of treatment for UUTS like flexible ureteroscopy and laser lithotripsy (FURL) [1,2]. The advancements in holmium laser and the progression of flexible ureteroscopy have enhanced the treatment of renal stones, with smaller diameters, improved imaging modalities, and better deflection mechanisms. Its use has been more frequent as endourologic procedure for renal stones with high success rates. However, these success rates decrease with larger stone volume [3].

Most of previous studies confirmed the safety and efficacy of FURL for renal stones <20 mm, while for larger volumes they were deficient. Therefore, FURL has no consensus as regard its safety and efficacy for large volume stones. The ureteral access sheath (UAS) offers numerous benefits. It enables quick, safe, and repeated entry into the collecting Furthermore, it aids the extraction of small fragments, thereby increasing the stone free rate (SFR). Additionally, it enhances visibility by optimizing irrigation flow and reduces intra-renal pressures through proper drainage around the scope - reducing the risk of infectious complications. However, these advantages may not be guaranteed without risks when treating large stones [4,5]. These risks may be in the form of potential trauma to the ureter during insertion, leading to mucosal injury or avulsion. Prolonged procedures with overstretching of the ureter by UAS could potentially compromise ureteral blood flow and cause the reperfusion injury after its withdrawal resulting in longterm issues like ischemia and stricture [6,7]. The use of a UAS during FURL for large UUT stones is still controversial, lacking precise recommendations and requiring further studies to determine its safety and effectiveness without significant complications [8]. Therefore, the aim

of this study was to assess SFR of FURL for UUTS >20 mm as primary outcome and the risk of complications from UAS usage as secondary outcome.

Materials and methods

This is a prospective RCT which was approved by ethics committee of our institute with Code number: MS-368-2022. Based on Sarwar Mahmood et al. (2019) [9], power and sample size calculation Software (Version 3.1.2, Vanderbilt University, Nashville, Tennessee, USA) was used to calculate the sample size. All adult patients over 18 years old, with UUTS >20 mm indicated for endoscopic management, were included. All patients provided a written informed consent for inclusion in the study after explaining the indication, possible complications, and benefits from planned procedures. Stone size was defined as the longest axis of solitary stone or the cumulative diameter of multiple stones on non-contrast CTUT. Patients younger than 18 years or with UUTS less than 20 mm were excluded from this study. Also, those patients who had ureteric stricture or tight ureter not liable for dilatation were excluded. A total of 170 patients were included within one year of the study. Every patient underwent one of the two techniques according to computer generated block randomization, and they were adhered to the ethical guidelines of Declaration of Helsinki and its amendments.

All patients underwent preoperative evaluation before being enrolled in this study. They were subjected to history taking and local examination. Also, all of them had routine laboratory investigations with urine analysis and culture to exclude urinary tract infections. The radiological investigations in the form of abdominopelvic ultrasound, X-ray KUB, and CTUT to assess the stone size, number, site, side, and density by Hounsfield unit (HU).

All procedures were performed by surgeons who are expert in FURL treatment using the 7.5fr flexible ureteroscope (Boston Scientific, USA) and a 10/12fr 46 cm length UAS (Navigator, Boston Scientific, USA) if used. Holmium YAG laser lithotripsy was performed using 220 mm laser fibers with laser settings of stone dusting (0.5 J and 15-20 Hz). All patients received antibiotics one-hour prior to surgery as prophylaxis with ceftriaxone 1000 mg, or adapted antibiotic in patients with positive urine culture which was cleared before the procedure. The procedure was done under general or spinal anesthesia. The patients were scrubbed in the lithotomy position. The procedure started with pan-cystoscopy to pass a 0.035fr hydrophilic guidewire through the targeted orifice and ureteral catheter followed by retrograde pyelography study. For group A patients: sequential ureteric dilatation was performed till 12fr using Teflon ureteric dilators (Amecath) followed by

inspection of the whole ureter with semirigid ureteroscopy 7.5fr to check ureteral integrity before UAS insertion. UAS was inserted and kept below the stone of upper ureter or above the ureteropelvic junction in case of renal stone. If UAS was not successfully placed or there was any resistance, the procedure was performed without UAS or JJ ureteric stent was placed for FURL later on, but such cases would be excluded from the study. For group B: no ureteric dilatation was performed, but another safety guidewire was inserted. As in group A, the whole ureter was inspected with semirigid ureteroscopy 7.5fr. Then, 7.5fr FUR was passed on the working guidewire using railway technique then the guidewire was removed leaving the safe one. In both groups, the plan was to do complete stone dusting using Holmium laser from the start and avoid stone fragmentation as long as possible to limit the fragments migration to multiple calyces and lower the risk of residual stones. Despite this manner consumed long time, it was the most suitable for large stone volume. During stone dusting with laser in handful cases, the stone was fragmented unintentionally and became too small to continue the dusting. In such situation, stone basket was used to retrieve those fragments, in addition to some cases with lower calyceal stone and difficult angulation, it was used to bring it into renal pelvis. After completion of the procedure, the FUR was withdrawn gradually through the whole ureter followed by retrograde pyelography to assess its condition and to detect any injuries or extravasation. Ureteric status was defined based on the optical vision at the end of the procedure into either: no injury, mucosal injury, false passage, or perforation. JJ stent was routinely inserted for 3 weeks [10].

Operative time was defined as the minutes from insertion of the guidewire to the completion of ureteral stent placement. Lasing time was the time used for dusting the stones using the Holmium-YAG laser. Radiation time is the time of using the fluoroscopy in minutes. In addition, UAS duration, the time from its insertion till its removal, was documented in minutes. The hospital stay was the time from the day of operation until discharge. Postoperative laboratory test including creatinine was recorded. Postoperative pain was evaluated using the numerical pain rating scale (0-10) as 0: no pain, 1-3: mild, 4-6: moderate, 7-9: severe, and 10 is the worst possible pain. Postoperative complications were evaluated and graded based on Clavien-Dindo classification for surgical complications. Stone-free status was determined by non-contrast CTUT 3 weeks after FURL and before stent removal. We defined stone clearance as fragments <2 mm on CTUT which was performed for all patient postoperatively before stent removal under local anesthesia [11]. In case of significant residual stones ≥2 mm, it was managed

accordingly with either alkalinization, shockwaves lithotripsy (SWL), or another FURL [11].

All patients had schedule for regular follow-up visits at 1 week, 1 month, 3 month, and 6 month using abdominopelvic ultrasound, urine analysis and culture and creatinine. When hydronephrosis was revealed by ultrasonography after stent removal, CT abdomen, and pelvis with IV contrast were performed to assess the possibility of associated ureteric stricture.

Statistical analysis

Data were statistically described in terms of mean ± standard deviation (± SD), median and range, or frequencies (number of cases) and percentages when appropriate. Comparison of numerical variables between the groups was done using Student t-test for independent samples. For comparing categorical data, Chi-square (χ^2) test was performed. Correlation between various variables was done using Spearman rank correlation equation. Accuracy was represented using the terms sensitivity, and specificity. Receiver operator characteristic (ROC) analysis was used to determine the optimum cut off value for UAS duration in predicting the occurrence of hydronephrosis. Twosided p values less than 0.05 were considered statistically significant. IBM SPSS (Statistical Package for the Social Science; IBM Corp., Armonk, NY, USA) release 22 for Microsoft Windows was used for all statistical analyses.

Results

One hundred and fifty-nine patients (79 in group A and 80 in group B) were included in our study, and their data were analyzed (Figure 1). There was no statistically significant difference between both groups regarding patients' demographic data in term of age, sex, body mass index (BMI), clinical presentations, and pre-stenting (Table 1). Presenting cases (19 patients, 11.9%) had ureteric stents for either fever or uremia (48 hours) before treating their stones on the same hospital admission. Our patients had UUT stones with mean size 27.08 ± 6.185 (20–45) mm. Both groups were comparable in the term of stone size, site, number, and density (Table 2). Both groups showed no significant differences regarding operative and lasing times, however, the radiation time was significantly longer in group A (Table 3). In addition, there was no significant impact on the optical vision of the procedure in both groups. There were no significant differences between pre- and post-operative creatinine in both groups

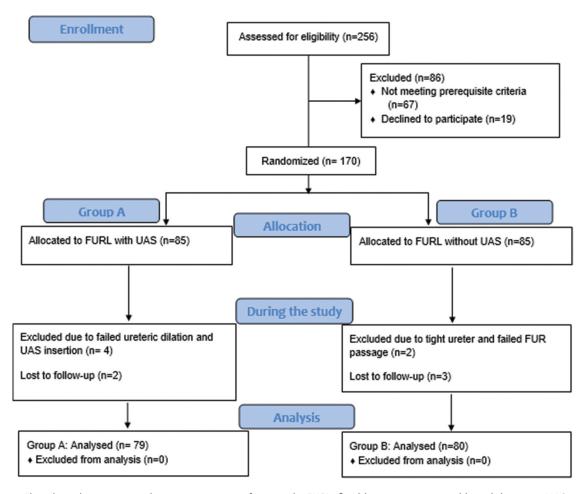


Figure 1. Flowchart demonstrates the consort criteria of our study. FURL: flexible ureteroscopy and laser lithotripsy, UAS: ureteral access sheath.

Table 1. Patients demographics for both groups.

| Patients Parameters | Total (n = 159) | Group A (UAS) $(n = 79)$ | Group B (non-UAS) ($n = 80$) | P-value | |
|---------------------|------------------------|---------------------------|--------------------------------|---------|--|
| Age (years) | | | | 0.524 | |
| Mean ± SD, Range | 41.74 ± 13.280 (19-73) | 41.06 ± 12.608 (20-70) | 42.41 ± 13.959 (19-73) | | |
| Sex (n, %) | | | | 0.686 | |
| Male | 86 (54%) | 44 (55.7%) | 42 (52.5%) | | |
| Female | 73 (46%) | 35 (44.3%) | 38 (47.5%) | | |
| BMI | | | | 0.411 | |
| Mean±SD, Range | 28.84 ± 4.531 (20-41) | $28.54 \pm 4.050 (21-40)$ | 29.14 ± 4.968 (20-41) | | |
| Presentation (n, %) | | | | 0.193 | |
| Asymptomatic | 51 (32%) | 25 (31.6%) | 26 (32.5%) | | |
| Pain | 85 (53.4%) | 39 (49.3%) | 46 (57.5%) | | |
| Hematuria | 5 (3.1%) | 5 (6.3%) | 0 (0%) | | |
| Fever | 10 (6.2%) | 5 (6.3%) | 5 (6.2%) | | |
| AKI | 8 (5%) | 5 (6.3%) | 3 (3.7%) | | |
| Pre-stenting (n, %) | 19 (11.9%) | 9 (11.3%) | 10 (12.5%) | 0.512 | |

UAS: ureteral access sheath, BMI: body mass index, AKI: acute kidney injury.

Table 2. Stone parameters for both groups.

| Stone parameters | Total (n = 159) | Group A (UAS) $(n = 79)$ | Group B (non-UAS) ($n = 80$) | P-value | |
|--------------------|--------------------------------|--------------------------------|--------------------------------|---------|--|
| Size (mm) | | | | | |
| Mean±SD, Range | 27.08 ± 6.185 (20-45) | 27.95 ± 6.027 (21-45) | $26.23 \pm 6.257 (20-44)$ | 0.080 | |
| Number | | | | | |
| Mean±SD, Range | 1.67 ± 0.816 (1-4) | 1.65 ± 0.785 (1-4) | 1.69 ± 0.851 (1-4) | 0.747 | |
| Side (n, %) | | | | 0.45 | |
| Right | 87 | 47 | 40 | | |
| Left | 72 | 32 | 40 | | |
| Site (n, %) | | | | 0.892 | |
| LC | 34 (21.4%) | 17 (21.5%) | 17 (21.3%) | | |
| MC | 27 (17%) | 15 (19%) | 12 (15%) | | |
| UC | 25 (15.7%) | 10 (12.7%) | 15 (18.8%) | | |
| UPJ | 17 (10.7%) | 9 (11.4%) | 8 (10%) | | |
| UU | 30 (18.9%) | 16 (20.3%) | 14 (17.5%) | | |
| Multiple | 26 (16.4%) | 12 (15.2%) | 14 (17.5%) | | |
| Density (HU) | | | | | |
| Mean±SD, Range | 1,074.92 ± 294.283 (330-1,660) | 1,103.43 ± 277.783 (450-1,620) | 1,046.76 ± 308.872 (350-1,660) | 0.226 | |

UAS: ureteral access sheath, LC: lower calyceal, MC: middle calyceal, UC: upper calyceal, UPJ: ureteropelvic junction, UU: upper ureter.

Table 3. Peri-operative parameters for both groups.

| Peri-operative parameters | Total (n = 159) | Group A (UAS) $(n = 79)$ | Group B (non-UAS) $(n = 80)$ | P-value | |
|--|--------------------------|--------------------------|------------------------------|---------|--|
| Operative time (min) | | | | | |
| mean±SD, range | 52.01 ± 11.026 (35-82) | 52.85 ± 10.941 (35-82) | 51.18 ± 11.115 (35-76) | 0.340 | |
| Radiation time (min) | | | | | |
| mean±SD, range | $2.24 \pm 0.656 (1-4)$ | $2.50 \pm 0.601 (1-4)$ | 1.99 ± 0.614 (1-4) | 0.000 | |
| Lasing time (min) | | | | | |
| mean±SD, range | 42.34 ± 10.098 (30-78) | 41.78 ± 9.321 (32-80) | 45.43 ± 11.223 (32-75) | 0.432 | |
| UAS time (min) | | | | | |
| mean±SD, range | 35.89 ± 10.610 (20-67) | 35.89 ± 10.610 (20-67) | _ | _ | |
| Ureteral injury (n) | | | | 0.0481 | |
| No | 146 | 69 | 77 | | |
| Mucosal injury | 8 | 7 | 1 | | |
| False passage | 2 | 1 | 1 | | |
| Perforation | 3 | 2 | 1 | | |
| Sepsis (n) | 7 (4.4%) | 2 (2.5%) | 5 (6.2%) | 0.380 | |
| Hospital stay (hr) mean±SD, range | 24.06 ± 13.245 (5-96) | 20.48 ± 12.868 (5-72) | 27.60 ± 12.723 (24-96) | 0.001 | |
| SFR (%) | 135 (84.9%) | 65 (82.2%) | 70 (87.5%) | 0.786 | |
| Residual stones (mm) mean±SD, range | $0.62 \pm 1.586 \ (0-7)$ | $0.66 \pm 1.632 (0-7)$ | $0.58 \pm 1.549 (0-7)$ | 0.742 | |
| Hydronephrosis (%) | 5 (3.1%) | 5 (6.3%) | 0 (0%) | 0.039 | |
| Other treatment | | | | | |
| No | 129 | 61 | 68 | | |
| Medical | 12 | 5 | 7 | | |
| ESWL | 7 | 3 | 4 | | |
| URS | 3 | 2 | 1 | | |
| Stent | 5 | 5 | 0 | | |

UAS: ureteral access heath, SFR: stone free rate, ESWL: extracorporeal shock waves lithotripsy, URS: ureteroscopy.

(group A: 0.9 ± 0.05 vs 0.8 ± 0.12 mg/dl p: 0.47, group B: 0.89 ± 0.34 vs 0.97 ± 0.21 mg/dl p: 0.65 respectively).

According to Clavien-Dindo classification of surgical complications (Table 4), 13 patients experienced ureteric injuries (G-IIIa) (10 in group A and only 3 in group B, p: 0.048) were documented and managed with stent placement for longer duration (6 weeks) (Table 3). The majority of patients showed smooth

Table 4. Clavien-Dindo Classification System for post-operative complications.

| Grade | Post-operative complications | Number |
|-------|--|--------|
| I | Loin pain managed with analgesics | 50 |
| II | Fever managed with targeted antibiotics | 22 |
| Illa | Ureteric injury required prolonged stenting | 13 |
| IIIb | Complications required surgical exploration under general anesthesia | 0 |
| lva | Sepsis | 7 |
| IVb | Multiorgan failure | 0 |
| V | Death | 0 |

postoperative periods with mean hospital stay 24.06 ± 13.245 (5–96) hrs, which was significantly longer in group B. However, 50 patients experienced loin pain (G-I) (22 in group A, 28 in group B, p: 0.977) which was mild in 32 patients, moderate in 13 patients and severe in 5 patients. All of them were managed conservatively using analgesics such as paracetamol or narcotics accordingly with good response. Twenty-two (13.8%) patients had postoperative fever (G-II) (8 in group A, 14 in group B, p: 0.344) which was low grade (<38°) in 15 patients and high grade (>38°) in 7 patients. Those patients were managed conservatively with antibiotics based on urine culture and antipyretics with good response except 3 patients, from group B, had to remove the stent earlier due to persistent fever. Another 7 patients had postoperative sepsis (G-IVa) (2 in group A, 5 in group B, p: 0.380) in the form of elevated total leukocytic count (TLC), high grade fever and hypotension, who required ICU admission for supportive care (Table 3).

There were no significant differences between both groups as regard SFR and residual stone volume. However, 5 patients in group A showed significant hydronephrosis on the targeted renal unit. Three of them were associated with renal colic after JJ removal, and the other 2 patients had silent hydronephrosis which was discovered by ultrasound at 1 month follow-up. CTUT was performed and defined ureteric stricture for which retrograde pyelography was done. Three cases were ureteric orifice stenosis, while 2 cases were upper ureteric stricture who required ureteric balloon dilation and stent placement (Table 3). During the course of follow-up, 27 patients required additional treatments either for their residual stones (Alkalinization, another FURL, SWL) or for developed hydronephrosis (stenting) (Table 3).

For more interpretation of our results, different variables were divided into subgroups to identify their correlations and associations with the outcomes. This statistical analysis revealed that non-lower calyceal stones, stones <30 mm and pre-operative stenting were associated with higher SFR and lower residual stone volume. While UAS duration <30 min achieved favorable outcomes than those with UAS duration >30 min (Table 5).

Table 5. Subgroups analysis and comparison with the outcomes.

| | Residual stones (mm) | | | | |
|---------------|----------------------|----------|---------|--------------------------------|--|
| | | SFR (%), | Mean | Complications | Additional treatment |
| Variables | Result (n) | P value | P value | (fever, sepsis, stricture) (n) | (Alkalinization, SWL, another FURL, stent) (n) |
| Stone size | | | | | |
| ≤30 mm | 120 | 87.5% | 0.47 | 27 | 19 |
| >30 mm | 39 | 76.9% | 1.08 | 7 | 8 |
| P value | | 0.034 | 0.036 | 0.651 | 0.862 |
| Stone site | | | | | |
| LC | 60 | 76.7% | 0.98 | 16 | 13 |
| Non-LC | 99 | 89.9% | 0.39 | 18 | 14 |
| P value | | 0.024 | 0.023 | 0.944 | 0.89 |
| Stone number | | | | | |
| Sigle | 84 | 84.5% | 0.64 | 20 | 10 |
| Multiple | 75 | 85.3% | 0.59 | 14 | 17 |
| P value | | 0.88 | 0.824 | 0.656 | 0.762 |
| Stone density | | | | | |
| ≤1000 | 67 | 88.1% | 0.46 | 14 | 7 |
| >1000 | 92 | 82.6% | 0.73 | 20 | 20 |
| P value | | 0.378 | 0.299 | 0.322 | 0.237 |
| BMI | | | | | |
| ≤25 | 37 | 86.5% | 0.62 | 6 | 4 |
| >25 | 122 | 84.4% | 0.61 | 28 | 23 |
| P value | | 0.759 | 0.982 | 0.065 | 0.0532 |
| Pre-stenting | | | | | |
| Yes | 19 | 94.7 | 0.421 | 3 | 7 |
| No | 140 | 83.5 | 1.23 | 31 | 20 |
| P value | | 0.045 | 0.045 | 0.048 | 0.054 |
| UAS | | | | | |
| duration | | | | | |
| ≤30 min | 33 | 85.8 | 0.421 | 4 | 6 |
| >30 min | 46 | 80.4 | 0.932 | 11 | 9 |
| P value | | 0.783 | 0.034 | 0.047 | 0.056 |

LC: lower calyceal, UAS: ureteral access sheath, SFR: stone free rate, SWL: extracorporeal shock waves lithotripsy, FURL: flexible ureteroscopy and laser lithotripsy, BMI: body mass index.



Discussion

Most authors recommend the PCNL as the first line of treatment for UUT stones >20 mm [12]. Despite achieving a high SFR, there are significant complications associated with PCNL, such as bleeding and adjacent organ injury. In addition, it is restricted or not recommended for patients facing challenges like long-term anticoagulant therapy and morbid obesity [12,13]. Therefore, there was a necessity for alternative treatment options for UUTS >-20 mm with high efficacy and enhanced safety. With advancements in endoscopy and laser technology, along with growing surgical expertise, FURL has emerged as a good option for large renal stones compared to PCNL. However, it typically involves a greater number of procedures per patient [14]. UAS is an auxiliary tool for FURL which adds many advantages; however, in lengthy procedures, direct insertion or ureteric overstretch and ischemia may carry risks to the ureter [6]. Moreover, the reperfusion, which occurs after UAS withdrawal, releases oxygen free radicals which are harmful to the ureter [14]. The relationship between the duration of ureteral stretch and the potential risk of damage in the ureter is not clearly known. Adnan Gücük et al. 2018 used catheters equivalent to different diameters of UAS into rabbit ureters endoscopically for different durations. Then, they assessed the possible permanent effects in the ureter via both gross and microscopic examination. They concluded that the UAS diameter and duration should be considered as the use of large UAS for long duration caused histological changes and narrowing in the ureteric diameter [15]. Sometimes, the ureter may not be dilatable enough to deploy the UAS and the trial to insert the UAS without proper dilation carry serious consequences. Olivier Traxer et al. 2013 reported 46.5% risk of UAS-related ureteral injury in patients who underwent retrograde intrarenal surgery for renal stones especially if not pre-stented. 13.3% of them were severely injured involving the smooth muscle layer [6]. Therefore, not all UAS benefits are assured without complications in UUTS >-20 mm. This rationale motivates us to study the safety and efficacy of FURL in UUTS >-20 mm and the necessity of UAS usage.

Fathi et al. 2023 observed 82-90% SFR for FURL in patients with renal stones >20 mm retrospectively without significant difference between UAS (60 patients) and non-UAS (52 patients) groups [16]. Our study could be considered the first prospective RCT comparing the UAS vs non-UAS in UUTS >-20 mm managed with FURL. Our study revealed that FURL provided 84.9% SFR with 13.8% risk of fever and sepsis. 3% of patients had ureteric stricture due to UAS usage which might be related to prolonged ureteric stretch and ischemia. There were no statistical differences between both groups regarding SFR, fever, and sepsis. However, UAS group showed significantly more ureteric complications [17].

Urinary tract infections (UTI) and postoperative fever are possible complications after FURL due to high intrarenal pressure and the long time consumed for stone dusting especially in large stones. Prolonged FURL for large stone volume without balance between inflow and outflow rises the intrarenal pressure and may cause pyelo-venous, and pyelo-lymphatic backflow or even rupture of the collecting system, possibly leading to peri-renal hematoma or urosepsis [16]. 8.8% risk of UTI and 83.7% SFR were observed in the study of Geraghty et al. 2016 who assessed the FURL for treating renal stones >20 mm in 43 patients with and without UAS. They used different UAS sizes without randomization [18].

The pre-operative stenting could facilitate the procedure of FURL with or without UAS as it dilates the ureter. In addition, pre-stenting provided favorable outcomes in the term of higher SFR, lower residual stone volume, and lower risk of ureteric injury as shown in our study. Fathi et al. 2023 concluded that there were no differences as regard the complications between UAS and non-UAS, however there was significant difference (p < 0.001) among two groups as regard pre-operative stenting for the favor of UAS group [16].

The stone size and site affect the success rate of FURL for UUT stones as the larger stone size, the lower SFR. This was observed in a study conducted by Sarwar Noori et al. 2020, where 135 patients with renal stones were treated with non-UAS FURL and evaluated prospectively. They achieved 90.37% SFR and 17% risk of complications in the form of fever, pyelonephritis, and subcapsular hematoma. They concluded that stone size 2 cm was significantly associated with a higher rate of complications and lower SFR upon univariate analysis [9]. Furthermore, Huang et al. 2020 concluded that single or staged FURL was an accepted treatment modality for the renal stones (2 to 4 cm). The final SFR decreased as stone size increased, and it was only 58.3% for renal stones larger than 4 cm. The lowest clearance rates were observed in lower calyceal stones (87.2%) and multiple calyceal stones (83.5%). The overall complication rate was 15.1%, mainly postoperative fever (9.6%) [19].

Despite our study characterized by randomization, it has some limitations. Studying the impact of different UAS sizes and durations on the ureteric integrity is required for future researches. Moreover, we recommend studying the availability of monitoring the intrarenal pressure during FURL and analyze its correlation with possible complication like fever and systemic inflammatory response syndrome. The vascular pressure wire, which is used by cardiologist to assess the fractional flow reserve in coronary arteries, can be used for intrarenal pressure monitoring and avoid high measurements (40-47cmH2O) especially in prolonged FURL [20]. Additionally, more prospective studies with



a larger number of participants and longer follow-up periods should be carried out to focus on more meaningful data about the feasibility of FURL without UAS in treating large renal stones.

Conclusion

FURL is safe and efficient treatment for stones >20 mm with high SFR either with or without UAS. Despite UAS lowers the hospitalization time, it may carry harm to the ureter especially in lengthy procedure. Therefore, UAS could be avoided in such cases.

List of abbreviations

FURL flexible ureteroscopy and laser lithotripsy.

UUTS upper urinary tract stones. UAS ureteral access sheath.

SFR stone free rate.

CTUT Computed tomography for urinary tract.

SWL shockwaves lithotripsy.

PCNL percutaneous nephrolithotomy. **KUB** x-ray kidney, ureter and bladder.

BMI body mass index. LC lower calyx. UC upper calyx. MC middle calyx. UU upper ureter. URS ureteroscopy.

UTI urinary tract infection. TLC total leukocytic count.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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Data availability statement

All original data and patients' consents are available on request.

Ethical Committee

Ethical committee of the urology department approved the research. As well as the Research Ethical Committee (REC) the Faculty of Medicine, Cairo University approved it on 12 October 2022, Code: MS-368-2022.

Statement of authorship

A. M. Rammah, F. Khaled: Project development and data collection

S. Zamel: Data analysis

M. Abdelwahab, S. Morsy: Data collection

A. Elkady, A. M. Rammah: Manuscript writing and editing.

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