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A randomized comparative study of flexible ureterorenoscopy versus mini-percutaneous nephrolithotomy for treatment of renal stones 2 cm or less

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Abstract

Background: Flexible ureterorenoscopy (fURS) and mini-percutaneous nephrolithotomy (mPCNL) have been increasingly used for the treatment of renal stones. However, current guidelines do not recommend one modality over the other. The aim of this study is to compare the safety and efficacy of treatment with fURS versus mPCNL for renal stones sized 2 cm or less.

Materials and methods: A prospective, randomized, comparative study was conducted between January 2019 and July 2021 at 3 tertiary care urology centers. Inclusion criteria were adult patients with renal stone(s) ≤ 2 cm with inappropriateness or failure of extracorporeal shock-wave lithotripsy. Subjects were assigned to 1 of 2 treatment groups, either mPCNL or fURS. Two primary outcomes were assessed: (1) initial success rate, defined as the absence of clinically significant residual fragments (>2 mm) on kidney ureter bladder x-ray and ultrasound on the first postoperative day; and (2) complications, which were reported according to the Modified Clavien-Dindo classification system. Secondary outcomes included final success rate, defined as the absence of clinically significant residual fragments on noncontrast computed tomography on the 90th postoperative day; operative time; auxiliary procedures and blood transfusion rates; hemoglobin drop; and length of hospital stay.

Results: One hundred eighteen procedures were analyzed (59 in each group). The initial success rate of the mPCNL group (93%) was significantly higher than that of the fURS group (70%). Complications occurred more frequently with mPCNL than fURS (44.1% vs. 18.6%, respectively). Final success rate, operative time, and length of hospital stay were comparable between the 2 groups.

Conclusions: Mini-percutaneous nephrolithotomy is more effective than fURS as a single-step treatment for renal stones <2 cm because of its higher initial success rate and lower auxiliary procedure rate. However, mPCNL results in significantly higher complication rates than fURS.

Keywords: Endourology; Flexible ureterorenoscopy; Mini-percutaneous nephrolithotomy; Retrograde intrarenal surgery; Urolithiasis

1. Introduction

Since the early 2000s, flexible ureterorenoscopy (fURS) and miniaturized percutaneous nephrolithotomy (mPCNL) have become the leading treatment modalities for small and mid-sized renal stones (≤2 cm), as they offer higher stone-free rates (SFRs) than shock-wave lithotripsy (SWL), as well as lower morbidity and invasiveness than conventional percutaneous nephrolithotomy.[1–4] However, the choice between fURS and mPCNL for treating stones in this size range requires more research. Most currently available studies comparing the 2 modalities are either retrospective, nonrandomized or focus only on lower pole stones.[5,6] The term "endourology" is mentioned in both the latest European and American guidelines as a first-line therapy for mid-sized renal stones, along with SWL, although the term is nonspecific as it refers to all percutaneous (conventional and miniaturized) and ureteroscopic interventions with no suggestion as to which might be more appropriate.[7–9]

This study aimed to compare the treatment outcomes of renal stones of 2 cm or less with either fURS or mPCNL.

2. Materials and methods

We conducted a prospective, randomized, comparative study from May 2019 to July 2021 across 3 tertiary care urology centers in 2 governorates in Egypt. Inclusion criteria were adult patients who had renal stone(s) with a maximum diameter of ≤2 cm as measured by noncontrast computed tomography (NCCT), with inappropriateness or failure of SWL (examples of SWL inappropriateness: patient preference; distal obstruction; contraindications for SWL). Exclusion criteria were pregnancy, uncorrectable bleeding diathesis, and inability to give consent. A preoperative sterile urine culture was mandatory.

The data that support the findings of this study are available from the corresponding author, A.R., upon reasonable request.

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Sample size calculation was carried out using G*Power 3 software,[10] based on the study by Jain et al. (2021),[5] which showed a significant difference in SFR between mPCNL and fURS (77.5% vs. 45%, respectively; $p = 0.003$), with 90% power and a two-sided significance p value of 0.05. The calculated minimum sample size was 100 patients with a 1:1 ratio for each arm or 50 per group.

Randomization was achieved by the Sequentially Numbered, Opaque, Sealed Envelope method as described by Doig and Simpson[11] using permuted, unstratified blocks of 2 different sizes (4 and 6). Personnel who created the envelopes neither took part in the trial nor had any contact with the surgeons or researchers regarding the allocation steps. Envelopes were opened immediately before surgery.

Two primary outcomes were assessed: (1) initial success rate, which was defined as the absence of clinically significant residual fragments (>2 mm) on kidney ureter bladder x-ray and ultrasound on the first postoperative day; and (2) complications, which were reported according to the Modified Clavien-Dindo classification system.[12] Secondary outcomes included final success rate, which was defined as the absence of clinically significant residual fragments on NCCT on the 90th postoperative day; operative time; auxiliary procedures and blood transfusion rates, drop in hemoglobin, and length of hospital stay.

Procedures were performed by 8 experienced urologists after thorough preoperative evaluation, including confirmation of sterile urine. For the fURS arm, after insertion of a guidewire, and if the ureter permitted a 9.5/12-Fr. rigid ureterorenoscope (Karl Storz, Tuttlingen, Germany), another wire was inserted, and the Flex-X^{2S} Uretero-Reno-Fiberscope (Karl Storz, Tuttlingen, Germany) was used to treat the stone. A ureteral access sheath was optionally used depending on the ureter calibration and expected operative time. If the ureter did not accommodate the 9.5/12-Fr. rigid ureterorenoscope, a double-J was inserted, the procedure was considered unsuccessful, and another procedure was planned after 2 weeks.

Mini-percutaneous nephrolithotomy was performed in the prone position under fluoroscopic guidance. Track dilatation was accomplished using Amplatz dilators (Cook Medical LLC, Bloomington, IN) up to 18 Fr. The 12-Fr. MIP-M Percutaneous Nephroscope (Karl Storz, Tuttlingen, Germany) was used as the primary scope. If a residual stone was present in a calyx that was not accessible by rigid nephroscope through the original puncture, and if the situation allowed, particularly in terms of operative time and intraoperative blood loss, the 15.5-Fr. flexible cysto-urethro-fiberscope (Karl Storz, Tuttlingen, Germany) was used, or another puncture was performed. A 16-Fr Nelaton Catheter (Amecath, Cairo, Egypt) was placed at the end of the procedure in case of significant pelvicalyceal perforation, bleeding, or residual fragments that required another mPCNL. The ureteral catheter was exchanged with a double-J in case of significant pelvicalyceal perforation or residual fragments that required SWL.

In both procedures, stones were disintegrated with a 273-μm diameter holmium:Yag laser. Laser settings were standardized for all procedures with adjustment to either stone dusting (energy = 0.4–0.5 J; frequency = 17–20 Hz), fragmentation (energy = 1.2–1.5 J; frequency = 17–20 Hz), or popcorning (as fragmentation with longer pulse width) according to stone size and density and could be changed intraoperatively according to the response to fragmentation. A ZeroTip basket (Boston Scientific, Marlborough, MA) was used to retrieve extractable fragments that appeared larger than 2 mm. Other options used for stone retrieval during mPCNL were stone extraction forceps and active washout using irrigation fluid.

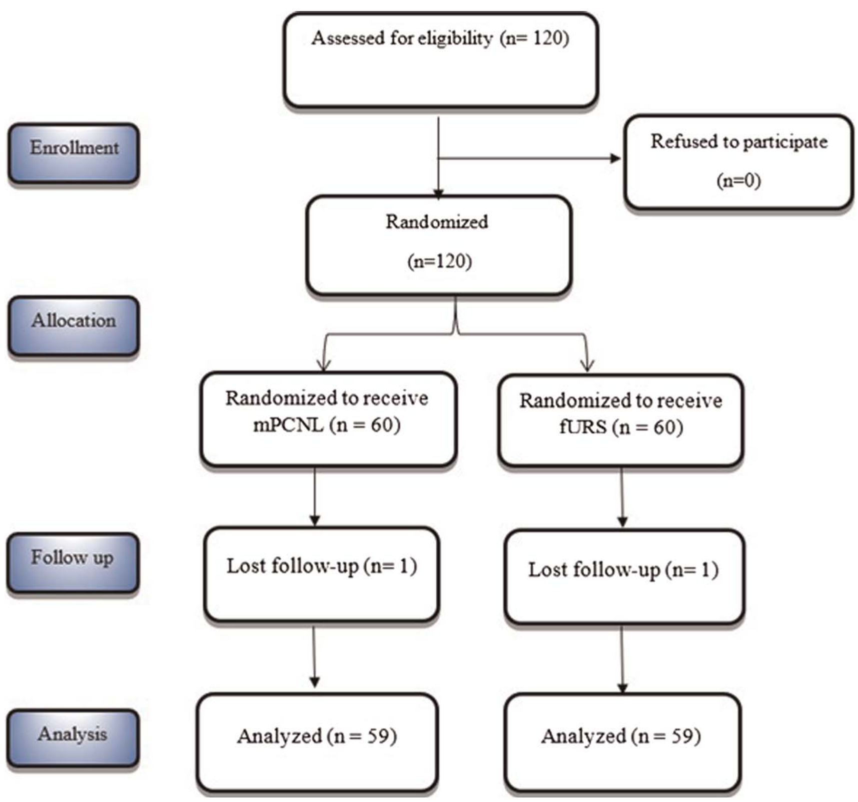

Figure 1. Consolidated Standards of Reporting Trials flow chart used for enrollment in the study. fURS = flexible ureterorenoscopy; mPCNL = mini-percutaneous nephrolithotomy.

Table 1

Preoperative variables.

Parameter	mPCNL (n = 59)	fURS (n = 59)	p
Age, yr, mean (SD)	41.5 (12.3)	45.2 (13.2)	
BMI, kg/m^2, mean (SD)	28 (4.3)	28.3 (3.7)	
Medical comorbidities, n (%)*	12 (20.3)	17 (28.8)	
Previous stone intervention, n (%)†	31 (52.5)	32 (54.2)	
SWL	16 (27.1)	17 (28.8)	
URS	7 (11.9)	11 (18.6)	
PCNL/mPCNL	8 (13.6)	5 (8.5)	
Renal and/or ureteric open surgery	10 (16.9)	10 (16.9)	
Prestenting, n (%)‡	12 (20.3)	13 (22)	
Stone location on preoperative NCCT, n (%)			
Pelvis	27 (45.8)	17 (28.8)	0.057
Lower calyx	21 (35.6)	20 (33.9)	0.847
Middle calyx	1 (1.7)	4 (6.8)	0.364
Upper calyx	0	3 (5.1)	0.244
Multiple locations	10 (16.9)	15 (25.4)	0.260
Multiple ipsilateral stones, n (%)	17 (28.8)	26 (44.1)	0.085
Burden, mm, mean (SD)	15.8 (4.2)	13.93 (4.8)	**0.019**§
HU, mean (SD)	1069 (424)	850 (411)	**0.004**§
Radiolucent stones, n (%)	10 (16.9)	20 (33.9)	**0.035**§
Hydronephrosis, n (%)	28 (47.5)	26 (44.1)	0.712
Grade I‖	20 (33.9)	18 (30.5)	
Grade II‖	6 (10.2)	6 (10.2)	
Grade III‖	1 (1.7)	1 (1.7)	
Grade IV‖	1 (1.7)	1 (1.7)	

P values in boldface format indicate a statistically significant difference (<0.05).
* Include hypertension, diabetes mellitus, ischemic heart disease, chronic kidney disease, and/or bronchial asthma.
† Some cases had more than 1 previous intervention.
‡ Causes of prestenting included obstructive uropathy and obstructive pyelonephritis.
§ Statistically significant.
‖ According to the Society of Fetal Urology grading system (SFU, Fernbach et al. [13]).
BMI = body mass index; fURS = flexible ureterorenoscopy; HU = Hounsfield unit; mPCNL = mini-percutaneous nephrolithotomy; NCCT = noncontrast computed tomography; PCNL = percutaneous nephrolithotomy; SD = standard deviation; SWL = shock-wave lithotripsy; URS = ureterorenoscopy.

Operative time was calculated from the time of cystoscope insertion to the completion of stent placement in case of fURS or, in case of mPCNL, applying a dressing on the track opening. Subjects were treated during the perioperative inpatient period with intravenous levofloxacin, fluids, analgesia, and/or blood transfusion as required. Hemoglobin was assessed 24 hours postoperatively.

Data were analyzed using the Statistical Package for Social Sciences, version 21, standard version (IBM-SPSS, Inc., Chicago, IL) and represented as means, standard deviations, frequencies, and percentages. Comparison of quantitative variables was performed using Student *t* test for normally distributed data and the Mann–Whitney *U* test for nonnormally distributed data. For comparing categorical data, a χ^2 test was performed. Exact test was used instead when the expected frequency was less than 5. A two-tailed *p* value of 0.05 was set as the level of significance.

3. Results

The study included a total of 118 procedures (mPCNL = 59, fURS = 59; Fig. 1) for 109 patients. Nine patients had bilateral renal stones that were treated simultaneously: 8 underwent bilateral fURS; another one underwent unilateral fURS and contralateral mPCNL. As shown in Table 1, statistically significant differences were found between the 2 groups in terms of stone burden, Hounsfield unit (HU), and percentage of radiolucent stones. Intraoperative and postoperative variables are showed in Table 2, and complications are showed in Table 3. A nephrostomy tube was inserted at the end of 28 (47%) mPCNL procedures and remained for an average of 31 hours (standard deviation, 31.9). A ureteral access sheath was used in 22 fURS procedures (37.3%).

Overall, 4 cases still had clinically significant residual fragments beyond the third month postoperatively: 2 fURS cases were cleared via SWL 6 months after the primary procedure; 1 case in each group had a residual calyceal stone (mPCNL: 5 mm and 566 HU; fURS: 6 mm and 958 HU in NCCT) followed by periodic observation.

4. Discussion

Minimally invasive endourological procedures, namely fURS and mPCNL, are gaining credibility for the treatment of small and mid-sized renal stones, especially those in the lower pole.[7–9] Despite several studies comparing the 2 modalities, neither has been proven as superior to the other.[3,5,6,14–18]

Table 2

Intraoperative and postoperative variables.

Parameters	mPCNL (n = 59)	fURS (n = 59)	p
Simultaneous contralateral ureterorenal unit pathology treatment, n (%)	1 (1.7)	12 (20.3)	**0.001***
Simultaneous ipsilateral ureteral pathology treatment, n (%)	5 (8.5)	9 (15.3)	0.255
Operative time, min, mean (SD)	83 (33)	72.2 (47)	0.603
Stent duration, d, mean (SD)	12.2 (13.5)	31.8 (25.5)	**<0.001***
Blood transfusion, n (%)	15 (25.4)	0	**0.01***
Hemoglobin drop %, mean (SD)	3.1 (4.1)	−0.14 (1.6)	**<0.001***
Length of hospital stay, hr, mean (SD)	42.6 (33.3)	38.8 (29.6)	0.752
Auxiliary procedures, n (%)	3 (5.1) SWL: 1 mPCNL+SWL: 2	16 (27.1) SWL: 2; fURS: 16; fURS+SWL: 1	**0.001***
Successful procedures, n (success rate, %)			
1st day †	55 (93.2)	41 (69.5)	**0.001***
90th day ‡	58 (98.3)	56 (94.9)	0.619

P values in boldface format indicate a statistically significant difference (<0.05).
* Statistically significant.
† Success defined as the absence of CSRF (>2 mm) at the level of kidney ureter bladder x-ray and ultrasound.
‡ Success defined as the absence of CSRF at the level of non-contrast computed tomography.
CSRF = clinically significant residual fragments; fURS = flexible ureterorenoscopy; mPCNL = mini-percutaneous nephrolithotomy; SD = standard deviation.

Table 3

Complications.

Parameters	mPCNL (n = 59)	fURS (n = 59)	p
Complicated procedures, n (overall complication rate, %)*	26 (44.1)	11 (18.6)	**0.003**†
Intraoperative complications, n (%)*	22 (37.3)	2 (3.4)	**<0.001**†
Postoperative complications, n (%)*	20 (33.9)	10 (16.9)	**0.035**†
Complications according to MCCS			
Grade I, n (%)*	**9 (15.3)**	**7 (11.9)**	
Intraoperative extravasation treated conservatively, n	0	2	
Intraoperative endoscopically visualized perforation treated conservatively, n	3	0	
Intraoperative bleeding treated only with intravenous fluids and/or diuretics, n	6	0	
Postoperative hematuria treated conservatively (observation ± fluids ± diuretics), n	9	2	
Fever/UTI treated conservatively (observation ± antipyretics ± fluids), n	6	4	
Grade II, n (%)*	**15 (25.4)**	**4 (6.8)**	
Intraoperative bleeding treated with blood transfusion, n	13	0	
Fever/UTI treated with change of antibiotic, n	5	4	
Grade III: Intraoperative bleeding treated with procedure termination and retreatment (III b), n (%)	**2 (3.4)**	**0**	
Grade IV/V	**0**	**0**	

P values in boldface format indicate a statistically significant difference (<0.05).
* In some procedures, multiple complications occurred within the same procedure.
† Statistically significant.
fURS = flexible ureterorenoscopy; MCCS = modifed Clavien-Dindo classification system (Dindo et al. [12]); mPCNL = mini-percutaneous nephrolithotomy; UTI = urinary tract infection.

A few studies have compared mPCNL and fURS in terms of first-day success or SFRs. Jain et al.[5] (2021) found a significantly higher SFR with mPCNL (77.5% with mPCNL, and 45% with fURS; $p = 0.003$), whereas Kirac et al.[14] (2013) reported comparable success rates. In the current study, the mPCNL group had a significantly higher first-day success rate than the fURS group (93.2% vs. 69.5%, respectively; $p = 0.001$).

Most studies, including 6 meta-analyses, concur that mPCNL is superior to fURS in terms of final success or SFR.[1–3,5,6,14–21] On the contrary, our study demonstrates comparable final success rates for both procedures (98.3% for mPCNL and 94.9% for fURS; $p = 0.619$). Interestingly, the rates in this study are higher than most rates reported in the literature.[3–6,14–18] This difference may be attributed to the relatively long follow-up duration (3 months) and extensive auxiliary procedures (19/118, 16.1%) in the present study.

Mini-percutaneous nephrolithotomy was associated with a significantly higher rate of complications than fURS in this study ($n = 26$, 44.1% vs. $n = 11$, 18.6%, respectively; $p = 0.003$), in agreement with 2 other studies.[15,18] In contrast, a recent randomized controlled trial found a significantly higher rate of postoperative complications after fURS than mPCNL (40% vs. 22.5%; $p = 0.03$),[5] and other studies have reported comparable complication rates between the 2 procedures.[2,3,6,14,17,19–23] Generally, complication rates among recent publications range between 8%–40% for mPCNL and 4%–30% for fURS.[6,16,17]

The current study revealed a significantly higher rate of auxiliary procedures after fURS than after mPCNL ($n = 16$, 27.1% vs. $n = 3$, 5.1%, respectively; $p = 0.001$). Of the few studies comparing the rate of auxiliary procedures after fURS and mPCNL, comparable rates were reported in one meta-analysis and one retrospective study,[18,23] whereas fURS was associated with a significantly higher rate in one randomized controlled trial.[3]

Recent publications have reported significantly longer operative times with fURS as compared with mPCNL.[15,18,23] However, mPCNL resulted in significantly longer operative times than fURS in 2 retrospective studies.[15,16] Other studies, similar to the present study, found no significant difference between the 2 procedures.[2,3,17,19–22]

In this study, length of hospital stay was comparable between mPCNL and fURS, in agreement with some studies.[5,6,21] Other studies have reported significantly longer hospital stays after mPCNL.[2,3,14–16,18–20,22]

Similar to this study, several studies have found that mPCNL resulted in a significantly greater drop in hemoglobin than fURS[5,14,15] and a significantly higher blood transfusion rate.[3,14] On the other hand, a few studies have found no a significant difference in hemoglobin drop [6] or transfusion rate.[20]

Limitations of this study include the nonuniform distribution of some preoperative variables and the involvement of multiple surgeons. Moreover, pain score, analgesic requirement, cost, stone composition, and effect on quality of life were not assessed.

In conclusion, mPCNL is more effective than fURS as a single-step treatment for renal stones less than 2 cm as reflected in its higher first-day success rate and lower auxiliary procedure rate. However, mPCNL results in significantly higher morbidity than fURS.

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Statement of ethics

The study was conducted according to the principles of Declaration of Helsinki and International Conference on Harmonization and Good Clinical Practice (ICH-GCP), registered at ClinicalTrials.gov Protocol Registration and Results System in April 2019 under ID NCT03932370, and was approved by the local Ethics Review Board under number 17200369. All patients signed informed consent prior to participation in the study.

Conflict of interest statement

The authors declare that they have no conflicts of interests.

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None.

Author contributions

All authors contributed to the study conception and design. Material preparation, data collection and analysis, as well as writing of the first draft of the manuscript, were performed by AD. All authors commented on previous versions of the manuscript and read and approved the final manuscript.

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