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# Mini-percutaneous nephrolithotomy vs flexible ureteroscopy for 1–2 cm lower pole renal stones: a randomised controlled trial

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## Objective

To compare the safety and efficacy of flexible ureteroscopy (f-URS) and ambulatory tubeless mini-percutaneous nephrolithotomy (mini-PCNL) in the treatment of 1–2 cm lower calyceal renal stones.

## Patients and Methods

Patients who underwent f-URS and mini-PCNL for the treatment of 1–2 cm lower calyceal renal stones between October 2020 and November 2023 were evaluated in a randomised controlled trial. A total of 72 patients were included in the study. All patients underwent a computed tomography renal colic scan preoperatively, on postoperative Day 1 (POD 1), and at 3 months follow-up. We compared perioperative outcomes, including operative time and hospital stay. Additionally, we evaluated follow-up outcomes, such as the stone-free rate (SFR) and complications. All patients were discharged home on the same operative day.

## Results

There were no significant differences in preoperative baseline data between the two surgical groups. A significantly longer median operative time was reported in the mini-PCNL group ($P = 0.04$). The median hospital stay was 5 h and 4 h in the mini-PCNL and f-URS groups, respectively ($P = 0.14$). On POD 1, the SFR, defined as the absence of residual fragments measuring 0 cm, was 50% for mini-PCNL vs 11.1% for f-URS ($P < 0.001$). When a total cut-off of <0.4 cm was utilised, the SFR was 75% in the mini-PCNL group vs 22.2% in the f-URS cohort ($P < 0.001$). At 3 months follow-up, the SFR remained favourable for mini-PCNL at 72.2% vs 37.1% for f-URS ($P = 0.003$), with a cut-off of 0 cm, and it increased to 86.1% for mini-PCNL vs 65.7% for f-URS ($P = 0.04$) when a total cut-off of <0.4 cm was applied. There was no significant difference in postoperative complications between the two groups. Two patients (5.7%) in the f-URS group required re-treatment. [Correction added on 5 November 2024, after first online publication: Within the Results section, '<4 cm' has been corrected to '<0.4 cm'.]

## Conclusions

Ambulatory tubeless mini-PCNL and f-URS are effective treatment options for 1–2 cm lower calyceal renal stones. Both techniques have a comparable hospital stay and complication rates, with a significantly better SFR with mini-PCNL.

## Keywords

renal stones, intrarenal surgery, ureteroscopy, percutaneous nephrolithotomy

## Introduction

A significant challenge in stone treatment with retrograde intrarenal surgery (RIRS) and shockwave lithotripsy (SWL) often lies in accessing the lower pole (LP) renal calyx. Selecting the appropriate treatment modality for LP renal calculi can be complex and is debated among urologists [1,2]. The European clinical guidelines recommend RIRS or percutaneous nephrolithotomy (PCNL) for managing 1–2 cm LP renal stones (LPS), particularly when SWL is not feasible [3].

Historically, patients were admitted following PCNL to monitor for potential complications [4]. Since its inception over 25 years ago, miniaturised PCNL (mini-PCNL) has undergone significant evolution, driven by technological advancements and the adoption of smaller instruments [5,6]. Mini-PCNL refers to a range of PCNL techniques using a sheath size from 4.8 to 22 F [3]. Among the mini-PCNL techniques, mini-PCNL that uses sheath sizes of 16–22 F is the most widely adopted and extensively researched. It achieves a stone-free rate (SFR) similar to standard PCNL while mitigating intra- and postoperative complications [7–11]. Compared to standard PCNL, mini-PCNL also increases the likelihood of achieving a totally tubeless exit without requiring a nephrostomy tube or internal stent [9–11].

Although overnight observation was implemented to monitor the risk of haemorrhage and sepsis, large case series and systematic reviews have indicated low complication rates following PCNL, especially in high-volume centres [12,13]. Numerous studies from high-volume institutions have explored the feasibility of ambulatory PCNL, reporting safe and successful implementation. However, widespread adoption has not followed, likely due to regional differences in practice patterns and surgical techniques, which make it harder to generalise their findings [14–16].

Advancements in ureteroscope technology and laser efficiency have established RIRS as the preferred method for treating renal calculi ≤2.0 cm and particularly for 1–2 cm LPS [17]. RIRS has demonstrated an acceptable SFR for medium-sized LPS, with a low complication rate and short hospital stays [6,18].

Lower pelvicalyceal anatomy as a predictor of success in managing LPS has been the subject of various theories [19]. Although the structure of renal anatomy may affect the success of flexible ureteroscopy (f-URS) for LPS, its relevance is not as well understood for SWL [20]. The significance of LP anatomical parameters has been studied, including infundibular width, infundibular length, LP infundibulopelvic angle, and calyceal pelvic height [20–22]. The question of which procedure, mini-PCNL or RIRS, offers superior safety and efficacy remains a matter of ongoing debate. While data indicates a higher SFR with mini-PCNL for LP and non-LP calculi, there is controversy surrounding complication rates [17,23].

The primary objective of this clinical randomised controlled trial (RCT) was to compare the efficacy of ambulatory mini-PCNL vs f-URS for 1–2 cm LPS based on SFR in a single session. Our secondary aim was to assess complications, operative time, and the need for secondary procedures.

## Patients and Methods

### Study Design and Hypothesis

The study was approved by the Thunder Bay Regional Health Sciences Centre's Research Ethics Board (TBRHSC REB #2019536) and is registered on ClinicalTrials.gov under the identifier NCT04389853. We conducted a prospective RCT comparing ambulatory tubeless mini-PCNL and f-URS for treating 1–2 cm solitary renal LPS as determined by preoperative CT.

We hypothesised that ambulatory mini-PCNL and f-URS may yield comparable clinical outcomes in terms of safety and SFR. The primary objective of the study was to compare the SFR in a single session. The secondary objectives included comparing complications, operative times, postoperative pain, and the need for secondary procedures between the two procedures. All surgeries were performed by a single endourologist (H.E.). Participants provided informed consent, understanding the risks, benefits, expected outcomes, and that they would be randomised to a study group.

### Sample Size and Randomisation

The primary statistically significant endpoint in this study was the SFR. Based on the literature, we anticipated a 6.5% difference in SFRs between the two groups. With a type I error (alpha) of 0.05 (two-tailed) and a type II error (beta) of 0.2 (power of 80%), we calculated a required sample size of 72 patients (36/group). [Correction added on 5 November 2024, after first online publication: In the preceding sentence, 'two/group' has been corrected to '36/group'.] Stratified-blocked randomisation was used to assign participants to one of the two groups based on predetermined LPS size grouping (1–2 cm).

### Study Population

Between October 2020 and November 2023, a total of 72 patients were enrolled (36/group). [Correction added on 5 November 2024, after first online publication: In the preceding sentence, 'two/group' has been corrected to

'36/group'.] The inclusion criteria were a symptomatic single LPS measuring 1–2 cm in its largest diameter, medical fitness, and the presence of a caregiver.

Patients were excluded if aged <18 years, pregnant, morbidly obese, or had anomalous renal anatomy, ureteric stones, stones >2.0 cm, multiple kidney stones, a solitary kidney, or a history of urinary tract surgeries. Exclusions also applied to those with previous SWL on the same stone, a pre-existing ipsilateral ureteric stent, untreated active UTI, severe cardiopulmonary disease, conditions unfitting for procedures, or uncorrected coagulopathy (where anticoagulants or antiplatelets could not be withheld before surgery). All participants underwent a CT renal colic scan preoperatively, on postoperative Day 1 (POD 1), and at the 3-month follow-up, with the exception of one patient who did not attend the 3-month CT scan due to COVID-19 concerns.

The SFR was determined using two criteria: no visual remnants (zero fragments) and fragments <0.4 cm [24,25]. This cut-off was selected because stones ≤0.3 cm and smaller stone fragments are unlikely to require intervention for passage. We further subcategorised SFR based on the following fragment sizes: 0 cm, >0 to <0.20 cm, and 0.20 to 0.39 cm. All preoperative CT scans were read by an attending radiologist and reviewed by a urologist. The radiologist assessing SFR was blinded to the treatment groups. Secondary procedures were indicated for unmanageable pain, postoperative obstruction, or infection.

## Preoperative Evaluation

Preoperative data included patient demographics, medical history, physical examination, and anticoagulation or antiplatelet therapy use. Preoperative CT scans were reviewed, and stone characteristics, including three-dimensional stone size [width [w], length [l], and height [h]) and stone density, were recorded. Stone volume was calculated using the ellipsoid formula: $\pi \times l \times w \times h \times 0.167$ [26].

## Surgical Technique

At our institution, mini-PCNL cases are typically scheduled as outpatient procedures. The primary goal is to achieve a totally tubeless procedure (no nephrostomy tube or internal stent) unless an intraoperative indication arises that necessitates their use. Operative time was calculated from the induction of anaesthesia to the completion of the JJ stent placement in the f-URS group or skin closure in the mini-PCNL arm.

Laser lithotripsy was performed in four patients (two/group) using a 100 W holmium:yttrium-aluminium-garnet (Ho:YAG) laser and a PowerFlex 200-µm laser fibre between October and November 2020. Subsequently, we transitioned to using the MOSES™ technology P120 H laser system (Lumenis® Pulse; Boston Scientific, Marlborough, MA, USA) and a 200-µm laser fibre until November 2023.

The laser technique primarily utilised was dusting (0.4–0.5 J × 50–70 Hz) in both RIRS and mini-PCNL. Stone extraction was achieved using a vacuum cleaner effect (without any suction) and/or a 1.5-F retrieval basket in the mini-PCNL group, or a 1.5-F retrieval basket in the f-URS group.

Mini-PCNL was conducted under general anaesthesia, beginning with the lithotomy position and the insertion of a ureteric catheter under fluoroscopy. Subsequently, the patient's position was changed to prone. Access to the kidney was achieved using either triangulation or, occasionally, the 'bull's eye' technique. A 16.5/17.5-F dilator and sheath and 12-F nephroscope (Karl Storz SE & Co. KG, Tuttlingen, Germany) were utilised for mini-PCNL procedures. All calyces were visually inspected for sizable residual stones using f-URS in an antegrade fashion.

The attending urologist's decision for a totally tubeless exit or a tubeless exit (without a nephrostomy tube but with antegrade insertion of a ureteric stent) and rationale for stent insertion were documented at the conclusion of the procedure. Additionally, a gelatine matrix haemostatic sealant was administered into the tract.

The f-URS procedures were conducted under general anaesthesia using either a single-use (Innovex® Anqing Medical, Anqing, China) or reusable ureteroscope Flex-XC (Storz). The stones were treated *in situ* in the LP of the kidney, with no relocation to other calyces.

A 10–12-F ureteric access sheath was used in all f-URS procedures, with a 100% success rate for insertion. At the end of the procedure and once all calyces had been assessed, a ureteric stent was placed and removed 1–4 weeks postoperatively in patients in whom a secondary procedure was not planned. An intraoperative intravenous dose of ketorolac was given routinely to all patients in both arms.

Once transferred to the recovery room, patients were asked to provide a pain score on a scale of 1–10 using the visual analogue scale (VAS). In cases where opioids were administered, we recorded the number and quantity administered. The VAS was collected by a specialised recovery room nurse who was blinded to the type of procedure.

All patients were discharged from the hospital on the same operative day, and their length of hospital stay was recorded. A full blood count was performed both before and after the procedure, and the difference between the two counts was documented. Predetermined discharge criteria included: whether the patient was deemed medically fit, had a caregiver, and met post-anaesthesia care unit discharge

criteria [27]. Before discharge, patients were also required to have acceptable laboratory results, tolerate a diet, and ambulate independently. Patients were provided discharge instructions, including 1 week of light activities and the need to seek medical advice for worsening pain or fever.

### Follow-Up

A postoperative CT renal colic scan was performed as outpatient imaging on POD 1 and at the 3-month follow-up. Pain evaluation was conducted by a research fellow during the POD 1 CT renal colic scan, which aimed to detect postoperative complications and determine the SFR. Following this, all participants received a follow-up telephone call from the research fellow to discuss the results of their POD 1 CT scan results and to inquire about their recovery progress.

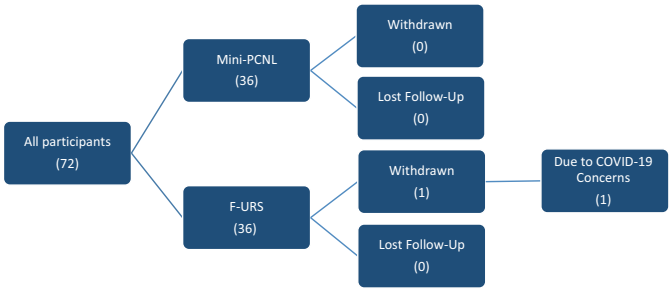
Postoperative complications and emergency room (ER) visits were recorded over 90 days. The complications were categorised according to the Clavien–Dindo scale. Study participants were also given the option to utilise Seamless MD (www.seamless.md), a digital care platform that facilitates remote monitoring and personalised guidance. The platform alerts a team of nurse practitioners if patients report any changes in their health status (such as fever, renal colic, or haematuria), enabling earlier intervention if necessary.

To determine the percentage of stone reduction, the primary and secondary stone volumes were subtracted, and the result was divided by the primary volume and then multiplied by 100.

### Statistical Analyses

In our study, continuous variables were expressed as medians and ranges, while categorical variables were described using frequencies and percentages. Statistical analysis was carried out using the IBM® Statistical Package for the Social Sciences (SPSS®), version 23 (IBM Corp., Armonk, NY, USA). To compare differences between the two groups the chi-squared test was employed to evaluate the categorical variables, and the nonparametric Mann–Whitney *U* test for continuous data. A $P < 0.05$ was considered statistically significant.

**Fig. 1** Participant flow diagram.




## Results

The participant flow diagram is presented in Fig. 1. None of the patients in the mini-PCNL arm were lost to follow-up. Conversely, one patient from the f-URS group dropped out at 3 months postoperatively because of COVID-19 concerns. Patient demographics, stone characteristics, and preoperative variables are listed in Table 1. The median LPS size was 1.4 cm in the mini-PCNL group vs 1.25 cm in the f-URS group ($P = 0.13$). There was no significant difference in median stone density ($P = 0.3$).

None of the participants had preoperative stents or preoperative hydronephrosis. Four patients in the mini-PCNL group and eight in the f-URS group were using antiplatelet or anticoagulant medications before surgery. However, all participants were able to hold their medications prior to surgery as per the cardiologist's recommendations.

### Operative and Perioperative Data

All patients in the mini-PCNL group underwent a single puncture, with the triangulation technique utilised in 34 patients (94.4%) and the 'bull's eye' technique in two (5.6%). An access sheath was used in all f-URS procedures.

Intraoperative and perioperative data are included in Table 2. The median (range) operative time was 55 (27–114) min in the mini-PCNL group and 49 (18–116) min in the f-URS cohort ($P = 0.04$). The mini-PCNL group had a median percentage of haemoglobin drop (intraoperative blood loss) of 7.4% vs 4.3% in the f-URS group ($P = 0.004$). The median (range) hospital stay was 5 (3–7) h in the mini-PCNL group versus 4 (3–6) h in the f-URS cohort ($P = 0.14$). No overnight admissions or blood transfusions occurred in either study arm.

In all, 33 (91.7%) mini-PCNL patients were discharged home totally tubeless, without the need for a nephrostomy tube or intraoperative stent insertion, while three (8.3%) required intraoperative stent insertion. The reasons for intraoperative stent insertion were migrated stone fragments to the ureter (two patients) and one case of submucosal ureteric injury caused by the guidewire.

All stents were removed at 1–4 weeks postoperatively. One case of ureteric injury was observed in the f-URS group, attributed to ureteric access sheath placement, and classified as Grade I according to the endoscopic ureteric injury grading system. In the recovery room, no significant differences were observed between both cohorts in terms of pain scores and analgesia requirements.

A total of five ER visits were documented, with no significant difference observed between both groups ($P = 0.16$). In the mini-PCNL group, four patients (11.1%) visited the ER, with

**Table 1** Patient demographics and preoperative findings.

| Variable | | Mini-PCNL (36 patients) | F-URS (36 patients) | *P* |
|---|---|---|---|---|
| Age, years, median (range) | | 61 (36–83) | 65 (27–87) | 0.06 |
| Gender, *n* (%) | Male | 23 (63.9) | 22 (61.1) | 0.81 |
| | Female | 13 (36.1) | 14 (38.9) | |
| Side, *n* (%) | Right | 14 (38.9) | 12 (33.3) | 0.62 |
| | Left | 22 (61.1) | 24 (66.7) | |
| Body mass index, kg/m$^2$, median (range) | | 22.1 (16–38) | 21.8 (17–40) | 0.76 |
| Comorbidities, *n* (%) | None | 22 (61.1) | 21 (58.3) | 0.94 |
| | HTN | 7 (19.4) | 9 (25) | |
| | HTN + DM | 4 (11.1) | 3 (8.3) | |
| | HTN + DM + CAD | 3 (8.3) | 3 (8.3) | |
| Stone size, cm, median (range) | | 1.4 (1–2) | 1.25 (1–2) | 0.13 |
| Stone volume, cm$^3$, median (range) | | 754 (126–2968) | 648.5 (121–2317.7) | 0.08 |
| Stone density, HU, median (range) | | 952.5 (350–1357) | 829 (218–1384) | 0.3 |
| Preoperative creatinine, mmol/L, median (range) | | 75.7 (45.5–162.3) | 79.3 (53.2–268.2) | 0.43 |
| Preoperative haemoglobin, g/L, median (range) | | 146.5 (94–174) | 140.5 (99–169) | 0.1 |
| Preoperative haematocrit, median (range) | | 0.44 (0.31–0.51) | 0.41 (0.3–0.5) | 0.053 |
| White blood cells, × 10$^9$/L, median (range) | | 7.4 (4.16–12.17) | 7.2 (0.41–12.4) | 0.43 |

*CAD, coronary artery disease; DM, diabetes mellites; HTN, hypertension; HU, Hounsfield unit.*

**Table 2** Operative data and recovery room findings.

| Variable | | Mini-PCNL (36 patients) | F-URS (36 patients) | *P* |
|---|---|---|---|---|
| OR time, min, median (range) | | 55 (27–114) | 49 (18–116) | 0.04 |
| Stent use, *n* (%) | | 3 (8.3) | 36 (100) | <0.001 |
| Intraoperative complications, *n* (%) | | 1 (2.8) | 1 (2.8) | 1 |
| Postoperative haematocrit, median (range) | | 0.4 (0.32–0.51) | 0.41 (0.3–0.46) | 0.62 |
| Postoperative haemoglobin, g/L, median (range) | | 135 (100–170) | 133 (99–158) | 0.84 |
| % Haemoglobin drop, median (range) | | 7.4 (0–13.6) | 4.3 (0–14.9) | 0.004 |
| Postoperative creatinine, mmol/L, median (range) | | 84.5 (55.3–162.3) | 80.5 (53–171.4) | 0.31 |
| Postoperative WBC, × 10$^9$/L, median (range) | | 8.3 (4.5–67) | 7.54 (4.2–15.2) | 0.57 |
| Pain score in recovery, median (range) | | 2 (0–10) | 1 (0–8) | 0.48 |
| Analgesia in recovery, *n* (%) | | 13 (36.1) | 6 (16.7) | 0.06 |
| Frequency of recovery analgesia, *n* (%) | 0 | 23 (63.9) | 30 (83.3) | 0.07 |
| | 1 | 11 (30.6) | 6 (16.7) | |
| | 2 | 2 (5.6) | 0 | |
| Hospital stay, h, median (range) | | 5 (3–7) | 4 (3–6) | 0.14 |

*OR, operative room; WBC, white blood cells.*

**Table 3** The POD 1 findings.

| Variable | | Mini-PCNL (36 patients) | F-URS (36 patients) | *P* |
|---|---|---|---|---|
| Stone-free, *n* (%) | Total <0.40 cm | 27 (75) | 8 (22.2) | <0.001 |
| | 0 cm | 18 (50) | 4 (11.1) | <0.001 |
| | >0 to <0.20 cm | 0 | 1 (2.8) | 0.31 |
| | 0.20–0.39 cm | 9 (25) | 3 (8.3) | 0.04 |
| Residual size, cm, median (range) | | 0 (0–0.8) | 0.65 (0–3.5) | <0.001 |
| Residual volume, cm$^3$, median (range) | | 0 (0–125.85) | 72.5 (0–1813) | <0.001 |
| % of volume reduction, median (range) | | 100 (84.3–100) | 83.5 (19.7–100) | <0.001 |
| Pain VAS score, median (range) | | 0 (0–10) | 0.5 (0–6) | 0.89 |
| Complications, *n* (%) | | 4 (11.1) | 2 (5.6) | 0.39 |
| ER visits, *n* (%) | | 4 (11.1) | 1 (2.8) | 0.16 |
| Re-admissions, *n* (%) | | 3 (8.3) | 0 | 0.09 |

two presenting due to postoperative fever and two due to renal pain. The cause of pain in one case was a migrated stent, with no radiological evidence of any residual stone in both instances. In the f-URS group, one patient (2.8%) presented to the ER with haematuria and clots after restarting anticoagulant medication (Table 3).

There was no significant difference in 90-day complication rates between the groups. In the mini-PCNL group, one case of a Clavien–Dindo Grade I complication involved postoperative renal pain, which was treated conservatively in the ER. A Clavien–Dindo Grade II complication occurred in one patient who presented with a low-grade fever and mild hydronephrosis (without any detected stone fragments) and was admitted and treated with oral antibiotics. Two patients experienced Clavien–Dindo Grade III complications: one presented with renal pain due to a migrated stent without any radiological evidence of residual stones. This patient was admitted, and the stent was removed under local anaesthesia (Clavien–Dindo Grade IIIa). Another case involved a moderate-grade fever postoperatively due to urosepsis, which was treated with stent insertion under general anaesthesia (Clavien–Dindo Grade IIIb).

In the f-URS group, two patients had Clavien–Dindo Grade I complications due to haematuria and clots. One patient was reassured via a telephone call from a member of the urology team, while the other presented to the ER with haematuria and clots after restarting blood thinners and was managed expectantly without requiring hospital admission. Neither group had any Clavien–Dindo Grade IV or V complications. There was no significant difference in re-admission rates between the two groups ($P = 0.09$; Table 3).

On POD 1, the SFR, defined as the absence of residual fragments measuring 0 cm, was 50% in the mini-PCNL group vs 11.1% in the f-URS group ($P < 0.001$). When a total cut-off of <0.4 cm was used, the SFR was 75% in the mini-PCNL group vs 22.2% in the f-URS group ($P < 0.001$). At the 3-month follow-up, the SFR remained favourable for the mini-PCNL group, at 72.2% vs 37.1% for the f-URS group ($P = 0.003$), with a 0 cm cut-off. When a total cut-off of <0.4 cm was applied, the SFR increased to 86.1% for the mini-PCNL group and 65.7% for the f-URS group ($P = 0.04$; Table 4). Notably, one patient in the f-URS group had a residual fragment measuring >0 to <0.2 cm on POD 1, which passed by 3 months postoperatively. At the 3-month CT scan, 13.9% of the mini-PCNL patients had residual fragments measuring 0.2–0.39 cm in comparison to 28.6% who underwent f-URS ($P = 0.13$).

The residual stone burden was significantly higher in the f-URS group than in the mini-PCNL cohort ($P < 0.001$). In the mini-PCNL group, residual stone sizes ranged from 0 to 0.5 cm, with a median size of 0 cm, while in the f-URS group, sizes ranged from 0 to 1.2 cm, with a median size of 0.3 cm ($P < 0.001$). At the 3-month follow-up, none of the participants in the mini-PCNL group required re-treatment. In contrast, two individuals (5.7%) in the f-URS group needed re-treatment for residual stones measuring 0.8 and 1.2 cm. Both patients who required re-treatment underwent a second-look URS for the residual stones.

## Discussion

Lower pole renal calculi represent ~35% of all kidney stones. Several factors influence the treatment of LPS, including the stone's size, composition and LP anatomy, equipment availability, patient preferences, and surgical expertise. In recent years, some institutions and urologists have promoted RIRS as a treatment for large calculi, highlighting fewer complications and better morbidity outcomes. This has sparked a continuing debate on whether RIRS is more effective than mini-PCNL for larger stones [21].

The median LPS size in our study was 1.4 cm for mini-PCNL and 1.25 cm for f-URS, while the median operative time was 55 min for mini-PCNL and 49 min for f-URS. Patients in the mini-PCNL cohort had a median (range) hospital stay of 5 (3–7) h compared to 4 (3–6) h for patients in the f-URS group ($P = 0.14$). None of the patients required an overnight

**Table 4** The 3-month follow-up data.

| Variable | | Mini-PCNL (36 patients) | F-URS (35 patients)* | *P* |
|---|---|---|---|---|
| Stone-free, *n* (%) | Total <0.40 cm | 31 (86.1) | 23 (65.7) | 0.04 |
| | 0 cm | 26 (72.2) | 13 (37.1) | 0.003 |
| | >0 to <0.20 cm | 0 | 0 | – |
| | 0.20–0.39 cm | 5 (13.9) | 10 (28.6) | 0.13 |
| Residual size, cm, median (range) | | 0 (0–0.5) | 0.3 (0–1.2) | <0.001 |
| Residual volume, $cm^3$, median (range) | | 0 (0–41.95) | 14.6 (0–528.5) | <0.001 |
| % of volume reduction, median (range) | | 100 (94.7–100) | 96.9 (61.1–100) | <0.001 |
| Stent duration, days, median (range) | | 22 (5–30) | 21 (7–90) | 0.65 |
| Re-treatment, *n* (%) | | 0 | 2 (5.7) | 0.15 |
| Stone composition*, *n* (%) | COM | 23 (63.9) | 20 (55.6) | 0.74 |
| | COD | 8 (22.2) | 7 (19.4) | |
| | UA | 3 (8.3) | 5 (13.9) | |
| | CP | 2 (5.6) | 3 (8.3) | |
| | Cystine | 0 | 1 (2.8) | |

*COD, calcium oxalate dihydrate; COM, calcium oxalate monohydrate; CP, calcium phosphate; UA, uric acid. *The percentage of stone composition was calculated by dividing by 36, as the stone composition was known for all recruited patients.*

hospital admission. Among patients undergoing mini-PCNL, 91.7% were discharged home without needing a nephrostomy tube or intraoperative stent insertion, while 8.3% required intraoperative stent insertion at the end of the procedure.

The Jin et al. [28] RCT compared the outcomes of URS and mini-PCNL in managing 1–2 cm renal calculi. They reported no significant difference in operating time between f-URS (87.2 min) and mini-PCNL (79.6 min) ($P = 0.124$), both of which were longer than our data. A notable difference between their trial and our data is the duration of hospitalisation. In their study, patients in the mini-PCNL and f-URS groups stayed overnight, with durations of 3.15 days and 5.59 days in the f-URS and mini-PCNL groups, respectively ($P = 0.007$), whereas our study the typical hospital stay was 3–7 h.

Cabrera et al. [23] conducted a meta-analysis involving 587 patients to evaluate the efficacy and safety of mini-PCNL versus f-URS for treating 1–2 cm LPS. Operative time was similar for both groups (mean difference [MD] 2.45 min; $P = 0.87$); however, the length of hospital stay was shorter with f-URS, although not significantly different (MD 41.94 h, 95% CI −34.01 to 117.89; $P = 0.18$).

In another study focusing on 1–2 cm LPS by Ur Rehman et al. [29], the mean hospital stay after f-URS was 1.1 days vs 2.3 days after mini-PCNL ($P < 0.001$), with stents inserted in all cases. These results demonstrate potential discrepancies in defining operative time. Additionally, the length of hospital stay may vary considerably between institutions due to differences in clinical protocols and financial compensation policies.

Percutaneous nephrolithotomy poses a greater risk of bleeding and postoperative pain than f-URS due to its invasiveness. Notably, tract miniaturisation reduces bleeding and the need for blood transfusions. Although bleeding can be impartially assessed by measuring the drop in haemoglobin, the blood transfusion rate is a reliable marker for bleeding severity [17].

In our study, the median percentage haemoglobin drop was higher for mini-PCNL (7.4%) than f-URS (4.3%) ($P = 0.004$). Furthermore, there was no significant difference in pain scores or analgesia requirements between the two groups in the recovery room or on POD 1. In their systematic review, Dorantes-Carrillo [17] found that a decrease in haemoglobin drop is not fully overcome by tract miniaturisation. Patients who underwent mini-PCNL had a higher haemoglobin drop than those who underwent f-URS (MD 3.5 g/L, 95% CI 0.5–6.5 g/L; $P = 0.02$). However, transfusion rates were comparable (risk difference 0.01, 95% CI −0.01 to 0.02; $P = 0.45$); which is similar to our study.

These findings contrast with the Jin et al. [28] RCT data, which demonstrated no significant difference in haemoglobin drop. However, pain scores assessed by VAS were lower for f-URS compared to mini-PCNL at 6 and 24 h postoperatively ($P < 0.001$).

The lack of a universally accepted definition of SFR within endourological societies, coupled with discrepancies among studies, highlights the variability in the available data for comparative analysis. Moreover, the imaging modalities used to determine SFR differ among the literature. The low-dose, non-contrast CT scan outperforms other modalities in assessing SFR. Additionally, several studies have shown that predictors of SFR following f-URS in LPS are multi-faceted, including stone characteristics, LP anatomy, and procedural aspects such as the use of a ureteric access sheath or the type of ureteroscope utilised. Stone variables that may influence the outcome include number, size, volume, density, and composition [19–23].

We found that when defining SFR as the absence of residual fragments measuring 0 cm on POD 1, the SFR was 11.1% for f-URS and 50% for mini-PCNL ($P < 0.001$). However, with a total <0.4 cm cut-off, the SFR was 22.2% for f-URS and 75% for mini-PCNL ($P < 0.001$). Notably, at the 3-month follow-up, the SFR remained higher for mini-PCNL (72.2%) compared to f-URS (37.1%) ($P = 0.003$), when a cut-off of 0 cm was used. This rate increased to 86.1% for mini-PCNL vs 65.7% for f-URS when a cut-off of <0.4 cm was applied.

In their systematic review of LPS, both Dorantes-Carrillo et al. [17] and Cabrera et al. [23] found that the success rate was significantly higher in the mini-PCNL group, with relative risk of 1.09 (95% CI 1.00–1.19; $P = 0.05$) and odds ratio of 1.67 ($P = 0.05$), respectively. However, there were differences in the definitions for SFR, the type of imaging used, and discrepancies in the timing of postoperative imaging.

Our findings corroborate those of the Ur Rehman et al. [29] RCT, which involved 150 patients with 1–2 cm LPS. Stone clearance, defined as the absence of residual stone material on non-contrast CT at 4 weeks postoperatively, was achieved in 92% of mini-PCNL patients compared to 78.67% of f-URS patients ($P = 0.021$). In their RCT, Jin et al. [28] defined SFR as the absence of residual fragments ≥0.3 cm on ultrasonography or radiograph on POD 1 and on CT at 3 months. Contrary to our results, there was no significant difference in SFR during the first week between f-URS (74.5%) and mini-PCNL (76.4%) ($P = 0.754$), nor at 3 months (97.3% in f-URS vs 99.1% in mini-PCNL; $P = 0.622$).

The main challenge in performing PCNL as outpatient surgery is effectively managing postoperative complications. In our hospital, patients usually receive a follow-up call the day after surgery from a member of the urology team and are monitored for complications using the Seamless MD digital

care platform. We observed similar complication rates: 11.1% in mini-PCNL compared to 5.6% in f-URS ($P = 0.39$). Neither group had Clavien–Dindo Grade IV or V complications. All patients received proper counselling about stent-related symptoms, along with routine prescriptions of alpha-blockers, anti-inflammatories, and anticholinergics. We noticed a dramatic decrease in ER visits due to stent-related symptoms after implementing the Seamless MD programme, which allowed patients to discuss concerns with a nurse and receive more support. There was no difference in the re-admission rate between both groups ($P = 0.09$).

This observation was supported by larger systematic review studies that confirmed no differences between the two procedures in the overall complication rates [17,23]. In the Jin et al. [28] RCT, evaluating the safety and efficacy of f-URS vs mini-PCNL, there was no difference in the overall postoperative complications (persistent haematuria, moderate fever, and urosepsis).

At the 3-month follow-up in our study, none of the mini-PCNL patients required re-treatment, whereas 5.7% in the f-URS group needed re-treatment for residual stones. In their RCT trial, Ur Rehman et al. [29] reported 2.7% in mini-PCNL vs 13.3% in f-URS who required secondary interventions for residual stones >0.4 cm. Similarly, Dutta et al. [14] reported secondary intervention rates of 4% and 6% in mini-PCNL and f-URS, respectively.

Nephrolithiasis can significantly impact patients' quality of life (QoL). Studies evaluating outcome measures have primarily concentrated on objective parameters, such as the SFR. In recent years, there has been a significant focus on patient-centred care. One method of capturing the patient experience is through patient-reported outcome measures (PROMs). The Wisconsin Stone Quality of Life Questionnaire (WISQOL), Urinary Stones and Intervention Quality of Life (USIQOL), Ureteric Stent Symptom Questionnaire (USSQ), Cambridge Ureteric Stone PROM (CUSP), and Cambridge Renal Stone PROM (CReSP) are some of the disease-specific PROMs in endourology [30]. The impact of renal calculi on PROMs warrants comprehensive exploration in upcoming studies.

Our RCT has some limitations. Being a single-centre study, its findings may not be broadly generalisable. The study also has a relatively small sample size. We recruited 72 patients to meet the criteria for statistical power; however, one patient missed their 3-month follow-up CT scan. Given that the differences in outcomes are sufficiently far apart compared to the expected variations, the absence of data from a single patient is unlikely to meaningfully impact the results. Moreover, the calculation for the percentage of stone reduction could be erroneous as stones are fragmented and can theoretically show larger volumes postoperatively, particularly on the POD 1 CT scan. We did not conduct a cost analysis to determine which procedure was more cost-effective or report PROMs related to QoL.

Implementing an ambulatory PCNL programme might not be practical for all healthcare institutions or patients. The attending urologist must possess the expertise and training to handle a high volume of cases. Skilled and experienced medical staff are needed to ensure that the perioperative process is tailored to accommodate the complexity and distinctive characteristics of PCNL. Establishing precise inclusion and exclusion criteria is imperative to guarantee the highest level of patient safety.

The present study has notable strengths despite its limitations. Low-dose CT scans were utilised to measure stone burden pre- and postoperatively, providing standardised and accurate results. Moreover, the timing of postoperative CT scans remained consistent across cohorts. Lastly, the study was conducted by a single surgeon with simultaneous patient groups, ensuring consistent surgical techniques and minimising variability.

## Conclusion

The optimal treatment for 1–2 cm LPS remains a topic of global debate and controversy. Ambulatory mini-PCNL and f-URS are effective surgical options for 1–2 cm LPS, offering similar hospital stays and complication rates. However, mini-PCNL is more likely to achieve a higher SFR than f-URS. Based on our findings, we recommend mini-PCNL for this patient group due to its greater efficacy and comparable safety to f-URS. Further studies with larger sample sizes are necessary to validate our results. We advocate for the inclusion of mini-PCNL in urological guidelines.

## Disclosure of Interests

Hazem Elmansy is an Investigator for Urotronic Inc. (Laborie) and Zenflow Inc. He previously received honoraria and a research grant from Boston Scientific. The other co-authors do not have a conflict of interest to disclose.

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Abbreviations: (f-)URS, (flexible) ureteroscopy; ER, emergency room; LP, lower pole; LPS, LP renal stones; MD, mean difference; (mini-)PCNL, (miniaturised) percutaneous nephrolithotomy; POD 1, postoperative Day 1; PROM, patient-reported outcome measure; QoL, quality of life; RCT, randomised controlled trial; RIRS, retrograde intrarenal surgery; SFR, stone-free rate; SWL, shockwave lithotripsy; VAS, visual analogue scale.