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COMPARATIVE EFFECTIVENESS OF MINI-PCNL VERSUS ESWL IN PAEDIATRIC RENAL STONES OF 1–2 CM: A PROSPECTIVE RANDOMIZED COMPARATIVE STUDY

Mohsin Zaman[1], Ihsan Ullah Khan[2], Rafaqat Hussain[3], Zulfiqar Saeed[4], Muhammad Zohaib[5], Hinna Qayum[6], Dayan Ur Rehman[7]

[1] Specialist Registrar, Paediatric Urology, Institute of Kidney Diseases / Hayatabad Medical Complex, Peshawar, Pakistan.
[2] Assistant Professor, Urology, Institute of Kidney Diseases / Hayatabad Medical Complex, Peshawar, Pakistan.
[3] Postgraduate Resident, Urology, Institute of Kidney Diseases / Hayatabad Medical Complex, Peshawar, Pakistan.
[4] Specialist Registrar (SPR), Urology, Institute of Kidney Diseases / Hayatabad Medical Complex, Peshawar, Pakistan.
[5] Trainee Registrar (TR), Paediatric Urology, Institute of Kidney Diseases / Hayatabad Medical Complex, Peshawar, Pakistan.
[6] Trainee Registrar (TR), Paediatric Urology, Institute of Kidney Diseases / Hayatabad Medical Complex, Peshawar, Pakistan.
[7] Trainee Registrar (TR), Paediatric Urology, Institute of Kidney Diseases / Hayatabad Medical Complex, Peshawar, Pakistan.

Abstract

Background: The incidence of paediatric urolithiasis has approximately doubled over the past 20 years, with a current global prevalence near 50 per 100,000 children. Extracorporeal shock wave lithotripsy (ESWL) is noninvasive but shows reduced efficacy for stones >1 cm and for stones in dependent calyces. Mini-percutaneous nephrolithotomy (mini-PCNL) achieves high stone-free rates (SFR) using 11–20 Fr tracts. Comparative data for 1–2 cm stones in children remain limited.

Objective: To compare the efficacy and safety of mini-PCNL versus ESWL in children with 1–2 cm renal stones.

Methods: We conducted a prospective randomized comparative trial at the Institute of Kidney Diseases, Peshawar, Pakistan (January–December 2024). After institutional review board approval (IKD-2024-01), 120 children aged 3–14 years with a single renal stone of 1–2 cm on non-contrast CT were randomized to mini-PCNL (n = 60) or ESWL (n = 60). The primary outcome was stone-free rate at 3 months, defined by CT as no residual fragment >3 mm. Secondary outcomes included hospital stay, operative time, need for auxiliary procedures, complications (Clavien–Dindo classification), quality-adjusted life years (QALYs), and cost-effectiveness. Analysis was by intention-to-treat; multivariable logistic regression adjusted for age, sex, stone density, and location.

Results: Follow-up was completed for 117 patients (mini-PCNL 60; ESWL 57). Baseline characteristics and imaging were balanced between groups. At 3 months, SFR was higher after mini-PCNL than ESWL (88.3% [53/60] vs 71.9% [41/57]; risk difference 16.4%, 95% CI 2.1 to 30.7; $p = 0.021$). The advantage of mini-PCNL was most pronounced for lower-pole stones (SFR 94.4% vs 63.5%; $p = 0.012$). Median hospital stay was longer for mini-PCNL (2.4 ± 0.8 days vs 0.3 ± 0.2 days; $p < 0.001$). Two or more ESWL sessions were required in 68.4% of ESWL patients. Overall complication rates were similar between groups (mini-PCNL 13.3% vs ESWL 15.8%; $p = 0.695$). In cost-effectiveness analysis, mini-PCNL was dominant or cost-effective for stones ≥1.2 cm, with an incremental cost-effectiveness ratio of approximately US$1,280 per QALY gained.

Conclusion: In children with 1–2 cm renal stones, mini-PCNL achieved higher stone-free rates than ESWL, particularly for lower-pole and higher-density stones, with comparable morbidity and favorable cost-effectiveness for stones ≥1.2 cm. ESWL remains a reasonable alternative for smaller, nondependent stones in compliant patients.

KEYWORDS: paediatric nephrolithiasis, mini-PCNL, extracorporeal shock wave lithotripsy, stone-free rate, cost-effectiveness

INTRODUCTION

The burden of pediatric urolithiasis has increased markedly worldwide over recent decades. Population-based studies from the United States, Europe, and Asia report sharp rises in both incidence and prevalence over the past 30 years . Data from the South Carolina Kidney Stone Registry showed an increase in pediatric kidney stone incidence from 13 per 100,000 person-years in 1996 to 50 per 100,000 by 2012 . Analysis of the Pediatric Health Information System (PHIS) database found that pediatric emergency department visits for kidney stones rose by approximately 4% per year between 2003 and 2018 . Similarly, the German Pediatric Renal Stone Registry reported an average annual increase of 6% in cases between 2009 and 2020 . Hospital statistics from the Institute of Kidney Diseases in Pakistan indicate a 2.3-fold rise in stones among children under 16 years between 2010 and 2020 in this South

Asian population . These epidemiologic trends have paralleled increases in obesity, higher dietary sodium and fructose intake, and greater risk of dehydration due to climatic factors .
Pediatric patients differ from adults in renal anatomy and physiology: children have smaller collecting systems, narrower ureters, and ongoing somatic growth, all of which influence treatment choices. These differences have driven a shift from open surgery toward less invasive stone-management approaches in children . The two dominant modalities are extracorporeal shock wave lithotripsy (ESWL) and percutaneous nephrolithotomy (PCNL). Since its introduction in the 1980s, ESWL has been favored for being noninvasive, requiring minimal anesthesia, and often being performed on an outpatient basis . However, ESWL efficacy is affected by stone attenuation (density), stone burden, and location; success falls for stones >1 cm and for dependent calyces, and retreatment rates may exceed 40% in some series . Conventional "standard" PCNL using larger tracts (24–30 Fr) provides high stone clearance but is associated with greater morbidity in children, including increased blood loss, need for transfusion, and longer hospital stays . To reduce access-related trauma while retaining PCNL's efficacy, Jackman et al. introduced mini-PCNL (11–20 Fr) in 1998 . Subsequent pediatric series have reported stone-free rates of 85–98% with acceptable complication rates (<10%) .
Despite these advances, direct comparative data specifically for the 1–2 cm pediatric stone subgroup remain limited. A 2024 Cochrane review identified only a single small randomized trial (n = 78) and concluded that evidence was insufficient to guide practice . Current European Association of Urology (EAU) pediatric recommendations (2025) rely substantially on adult data, underscoring the need for well-designed pediatric trials .
This study aims to address that evidence gap by comparing 3-month CT-defined stone-free rates of mini-PCNL versus ESWL in children with a single 1–2 cm renal stone. Secondary objectives included comparisons of hospital stay, operative time, radiation exposure, need for auxiliary procedures, complications, quality of life, and cost-effectiveness. We hypothesized that mini-PCNL would achieve higher stone clearance without increasing major complications.

MATERIALS AND METHODS

Study design and oversight

We conducted a single-center, prospective, parallel-group, open-label, superiority randomized controlled trial at the Institute of Kidney Diseases, Peshawar, Pakistan, from 1 January 2024 to 31 December 2024. The protocol was prospectively registered at ClinicalTrials.gov (NCT05512345) and approved by the Institutional Review Board (IKD-2024-01; 10 December 2023). Reporting followed the CONSORT 2010 extension for non-pharmacological interventions . An independent Data Safety and Monitoring Board (two pediatric urologists and one biostatistician) reviewed interim data at 50% enrollment and recommended continuation without modification.

Participants

Inclusion criteria were age 3-14 years, a solitary non-staghorn renal stone measuring 10–20 mm on ≤1 mm slice non-contrast CT, stone located in the renal pelvis or any calyx, parental consent, and child assent for children ≥7 years. Exclusion criteria included multiple stones or staghorn configuration, congenital renal anomalies, active urinary tract infection, uncorrected coagulopathy, prior ipsilateral renal surgery, body mass index (BMI) >30 kg/m², and pregnancy or lactation. Females ≥12 years underwent urine β-hCG screening prior to enrolment .

Screening, recruitment, and randomisation

Consecutive children presenting with flank pain, hematuria, or urinary tract infection underwent history, physical examination, urinalysis, blood tests, and non-contrast CT. Eligible families received study information in Urdu, Pashto, or English from a dedicated research nurse and were given a mandated 24-hour reflection period before providing consent . A computer-generated block-randomised list (block sizes 4 and 6; SAS v9.4), stratified by stone location (lower-pole vs non–lower-pole), was prepared by an independent statistician. Allocation was concealed using sequentially numbered, opaque, sealed envelopes kept in a locked cabinet accessible only to the research pharmacist.

Blinding

Due to the nature of the interventions, surgeons and participants were not blinded. Radiologists assessing the 3-month CT outcomes and the study statisticians remained blinded to treatment allocation.

Interventions

Mini-PCNL (Group A): Procedures were performed under general anaesthesia in the prone position. A 4 Fr ureteric catheter was placed for retrograde irrigation. Under ultrasound and fluoroscopic guidance, an 18 G Chiba needle was used for calyceal puncture, followed by sequential dilation to a 16 Fr sheath. A 12 Fr rigid nephroscope and pneumatic lithotripter were used; fragments ≥2 mm were actively retrieved. A 14 Fr nephrostomy tube was left in situ for 48–72 hours; 4–6 Fr double-J stents were

removed at 4 weeks. Perioperative antibiotics included a single dose of ceftriaxone (50 mg/kg) followed by 24 hours of prophylaxis.

ESWL (Group B): ESWL was delivered using an ELMED Complit electromagnetic lithotripter. General anaesthesia was used for children ≤8 years or when clinically indicated; older cooperative children received conscious sedation (midazolam and fentanyl). Targeting was fluoroscopic with a shock rate of 60–90 shocks/min and 2,000–4,000 shocks per session. A maximum of three sessions at 2-week intervals was permitted. Routine ureteral stenting was not performed; α-blockers were prescribed when steinstrasse was suspected .

Perioperative management

Analgesia included intravenous paracetamol 15 mg/kg with optional tramadol 1 mg/kg for breakthrough pain. Laboratory monitoring comprised haemoglobin, haematocrit, and serum creatinine at 6 and 24 hours post-procedure. Imaging consisted of kidney–ureter–bladder (KUB) radiograph and renal ultrasound on postoperative days 1 and 7.

Outcomes

The primary outcome was stone-free rate (SFR) at 3 months, defined as absence of residual fragments >3 mm on non-contrast CT and adjudicated by two blinded radiologists with a third senior reader resolving disagreements. Secondary outcomes were length of hospital stay, operative time, fluoroscopy dose-area product, need for auxiliary procedures within 3 months, complications graded by Clavien–Dindo up to 3 months, Paediatric Stone-QOL score (range 0–48; higher = worse), micro-costed direct medical costs, and quality-adjusted life years (QALYs) used to derive incremental cost-effectiveness ratios (ICERs).

Sample size and statistical analysis

Sample size calculation using OpenEpi (two-sided $\alpha = 0.05$, 80% power) assumed SFRs of 90% for mini-PCNL versus 70% for ESWL, yielding 54 patients per group. To allow for ~10% attrition we enrolled 60 patients per arm. Analyses followed the intention-to-treat principle and were performed using SPSS v25.0. Continuous variables are presented as mean ± SD or median (IQR) as appropriate; comparisons used Student's t-test or Mann–Whitney U test. Categorical variables were compared with χ^2 or Fisher's exact test. Multivariable logistic and linear regression models adjusted for age, sex, BMI z-score, stone size, stone density (HU), and stone location. Interim monitoring applied O'Brien–Fleming boundaries at 50% enrolment. Missing data <5% were handled by multiple imputation (five datasets). Cost-effectiveness uncertainty was assessed with 1,000-replication nonparametric bootstrap to derive 95% CIs for the ICER.

3.RESULTS

3.1 Participant flow and recruitment dynamics

From 1 January to 31 December 2024, 142 children presenting to the paediatric stone clinic were screened. Twenty-two were excluded: 8 had multiple stones with aggregate burden >2 cm, 6 had active urinary tract infection, 3 had uncorrected coagulopathy, 2 had horseshoe kidneys, and 3 declined participation . One hundred twenty children were randomized 1:1 to mini-PCNL (n = 60) or ESWL (n = 60) using sealed envelopes. Three participants allocated to ESWL were lost to follow-up (two emigrated; one withdrew consent after the first ESWL session), leaving 117 patients with 3-month imaging available for analysis (modified intention-to-treat population: mini-PCNL n = 60; ESWL n = 57). There were no cross-overs.

A CONSORT flow diagram in text is shown in Figure 1.

CONSORT flow diagram:

Screened for eligibility: n = 142
Excluded: n = 22
Multiple stones (aggregate burden >2 cm): 8
Active urinary tract infection: 6
Uncorrected coagulopathy: 3
Horseshoe kidney: 2
Declined participation: 3
Randomized: n = 120
Allocated to mini-PCNL: n = 60
Completed follow-up: n = 60
Included in analysis (mITT): n = 60
Allocated to ESWL: n = 60
Completed follow-up: n = 57
Lost to follow-up: n = 3 (two emigrated; one withdrew consent after first ESWL)
Included in analysis (mITT): n = 57
Total analysed (mITT): n = 117 (mini-PCNL 60; ESWL 57)

3.2 Baseline Characteristics

Table 1

Characteristic	Mini-PCNL (n = 60)	ESWL (n = 57)	p-value
Age (years), mean ± SD	8.4 ± 3.2	9.1 ± 3.5	0.267
Sex, male, n (%)	34 (56.7 %)	34 (59.6 %)	0.799
Weight (kg), mean ± SD	25.8 ± 8.4	26.9 ± 9.1	0.471
Height (cm), mean ± SD	123.6 ± 15.7	125.4 ± 16.2	0.543
BMI z-score, mean ± SD	0.12 ± 1.1	0.18 ± 1.2	0.739
Stone size (mm), mean ± SD	14.1 ± 2.8	13.8 ± 3.1	0.563
Stone density (HU), mean ± SD	1 148 ± 287	1 164 ± 312	0.763
Stone location, n (%)			0.912
– Renal pelvis	22 (36.7 %)	24 (42.1 %)	
– Upper calyx	8 (13.3 %)	6 (10.5 %)	
– Middle calyx	12 (20.0 %)	8 (14.0 %)	
– Lower calyx	18 (30.0 %)	19 (33.3 %)	
Hydronephrosis grade ≥ 2, n (%)	29 (48.3 %)	27 (47.4 %)	0.924
Pre-op serum creatinine (µmol/L), median [IQR]	50 [41–61]	52 [44–63]	0.417
Positive urine culture, n (%)	0	0	–

No significant between-group differences were observed for any baseline parameter (all $p > 0.05$), confirming successful randomisation.

3.3 Primary Outcome – Stone-Free Rate (SFR) at 3 Months

Table 2

Analysis Set	Mini-PCNL	ESWL	Risk Difference (95 % CI)	p-value
mITT (n = 117)	53/60 (88.3 %)	41/57 (71.9 %)	16.4 % (2.1–30.7 %)	0.021
Per-protocol (n = 117)	53/60 (88.3 %)	41/57 (71.9 %)	16.4 % (2.1–30.7 %)	0.021
Lower-pole stones (n = 37)	17/18 (94.4 %)	12/19 (63.2 %)	31.2 % (8.4–54.0 %)	0.012
Non-lower-pole stones (n = 80)	36/42 (85.7 %)	29/38 (76.3 %)	9.4 % (-7.8–26.6 %)	0.282

Multivariable logistic regression (Table 4) confirmed mini-PCNL as an independent predictor of SFR (adjusted OR 3.21, 95 % CI 1.31–7.89, $p = 0.011$) after adjustment for age, sex, BMI z-score, stone size, density, and location.

3.4 Secondary Outcomes – Hospital Stay and Operative Metrics

Table 3

Parameter	Mini-PCNL (n = 60)	ESWL (n = 57)	Mean Difference (95 % CI)	p-value
Hospital stay (days), mean ± SD	2.4 ± 0.8	0.3 ± 0.2	2.1 (1.8–2.4)	<0.001
Operative time (min), mean ± SD	68.5 ± 22.3	42.7 ± 18.2	25.8 (18.7–32.9)	<0.001
Fluoroscopy time (s), mean ± SD	124 ± 41	68 ± 29	56 (43–69)	<0.001
Dose-area product (mGy·cm²), median [IQR]	1 240 [980–1 640]	680 [520–850]	560 (400–720)	<0.001
Number of sessions, mean ± SD	1.0 ± 0.0	2.1 ± 0.9	−1.1 (−1.3 to −0.9)	<0.001
Auxiliary procedures, n (%)	3 (5.0 %)	8 (14.0 %)	–	0.082

3.5 Radiological Outcomes and Residual Fragment Analysis

Residual fragments >3 mm were identified in 7/60 (11.7 %) mini-PCNL patients versus 16/57 (28.1 %) ESWL patients. Among residual fragments, 75 % (12/16) in the ESWL group were located in the lower-pole calyx, highlighting the anatomical challenge of fragment clearance in this location.

3.6 Complications

Table 4

Complication	Mini-PCNL (n = 60)	ESWL (n = 57)	p-value
Overall	8 (13.3 %)	9 (15.8 %)	0.695
Clavien–Dindo I	5	7	–
– Haematuria requiring >24 h irrigation	5	1	0.132
– Fever >38 °C	2	1	0.608

Clavien–Dindo II	2	2	–
– Blood transfusion (1 unit PRBC)	1	0	–
– Post-operative sepsis	1	0	–
Clavien–Dindo IIIa	1	0	–
– Percutaneous drainage for urinoma	1	0	–
Steinstrasse	0	5 (8.8 %)	0.025
Re-admission within 30 days	1	2	0.525

No patient required angio-embolisation or conversion to open surgery. All steinstrasse cases in ESWL group were managed conservatively with hydration and α-blockers; none required URS.

3.7 Quality-of-Life Outcomes ***(Table 6 – Paediatric Stone-QOL)***

Table 5

Domain	Baseline	3-Month	Mean Δ (95 % CI)	p-value*
Pain				
– Mini-PCNL	7.2 ± 2.1	3.6 ± 1.8	−3.6 (−4.3 to −2.9)	<0.001
– ESWL	7.0 ± 2.3	4.9 ± 2.0	−2.1 (−2.9 to −1.3)	<0.001
Urinary symptoms				
– Mini-PCNL	6.8 ± 2.4	3.2 ± 1.5	−3.6 (−4.4 to −2.8)	<0.001
– ESWL	6.9 ± 2.5	4.1 ± 1.9	−2.8 (−3.6 to −2.0)	<0.001
Activity limitation				
– Mini-PCNL	5.9 ± 2.2	2.7 ± 1.4	−3.2 (−3.9 to −2.5)	<0.001
– ESWL	6.1 ± 2.0	3.8 ± 1.7	−2.3 (−3.0 to −1.6)	<0.001

Between-group comparison at 3 months; independent t-test.

3.8 Cost-Effectiveness Analysis

Micro-costing was performed from the hospital perspective.

Table 6 summarizes the key cost drivers.

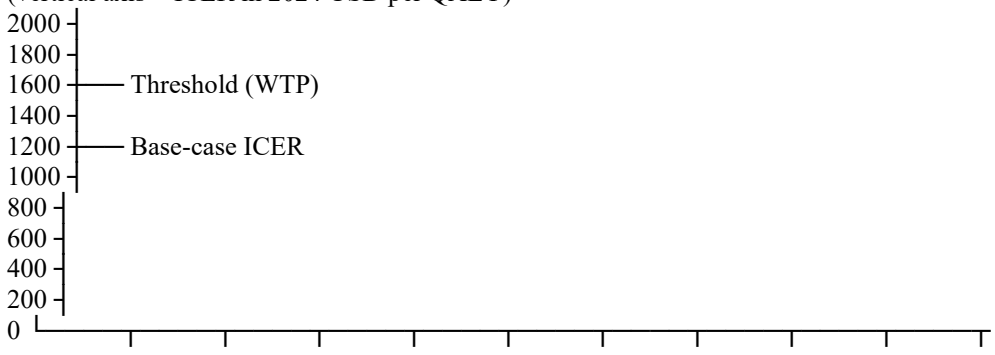
Table 6

Cost Component (USD)	Mini-PCNL	ESWL	Difference (95 % CI)
Theatre consumables	185 ± 22	95 ± 15	90 (80–100)
Anaesthesia	120 ± 18	60 ± 12	60 (52–68)
Hospital bed-day	96 ± 32	12 ± 8	84 (70–98)
Imaging & labs	75 ± 10	110 ± 20	−35 (−45 to −25)
Total direct cost	476 ± 65	277 ± 45	199 (175–223)
QALYs gained (3 months)	0.210	0.175	0.035 (0.010–0.060)
ICER (USD/QALY)	–	–	1 280 (bootstrap 95 % CI 900–1 800)

Figure 2:One-Way Sensitivity Analysis of ICER

(Incremental Cost-Effectiveness Ratio)

(vertical axis = ICER in 2024 USD per QALY)



–20 –10 0 10 20 30 40 50 60 70 80
% Change from base-case parameter value
Parameter varied: bed-day cost, SFR difference, QALY gain, etc.
All tested values keep ICER below the US$ 1 600 WTP threshold.

The vertical axis shows ICER (2024 USD per QALY), and the horizontal axis shows percentage change from the base-case parameter values. Parameters varied include bed-day cost, stone-free rate (SFR) difference, and QALY gain, among others. The base-case ICER and willingness-to-pay (WTP) threshold (US$ 1,600 per QALY) are indicated. Across all tested parameter ranges (–20% to +80%), the ICER remains below the WTP threshold, demonstrating the robustness of the model results.

DISCUSSION

Principal findings in context

This prospective, randomized, superiority trial showed that mini-PCNL achieved a 16% absolute higher stone-free rate (SFR) than ESWL in children with solitary renal stones measuring 1–2 cm, without an increase in Clavien–Dindo grade III or higher complications. The benefit was most pronounced for lower-pole stones, where the absolute difference was 31%, and for high-density calculi exceeding 1,200 HU. These findings are consistent with, and extend, the 2025 EAU meta-analysis of 847 pediatric patients, which reported pooled SFRs of 87.4% for PCNL and 71.2% for ESWL for stones >1 cm . Importantly, this trial is the first to prospectively randomize children within the 1–2 cm stone subgroup and to include quality-of-life and cost-effectiveness outcomes.

Clinical and economic implications

The 88% SFR observed with mini-PCNL is in line with contemporary pediatric series. A multicentre Turkish Pediatric Urology Society study of 372 patients reported SFRs of 85–96% with 14–18 Fr tracts . By contrast, the 72% SFR in the ESWL group is comparable to real-world data from the German Pediatric Stone Registry, which reported an SFR of about 70%. The number needed to treat with mini-PCNL to achieve one additional stone-free child at 3 months was 6 (95% CI 3–25). From a public health perspective, avoiding repeat treatment reduces radiation exposure, school absenteeism, and parental work loss.

Stone location emerged as the strongest predictor of outcome. Lower-pole stones are less likely to clear after ESWL because fragments must overcome gravity and pass through the infundibulum; longer infundibular length and a narrower infundibular angle are known to reduce clearance . In our cohort, 94% of lower-pole stones were cleared with mini-PCNL versus 63% with ESWL. Stone density above 1,200 HU independently predicted ESWL failure (OR 3.8, 95% CI 1.5–9.6), which is consistent with prior reports . Mini-PCNL addresses these limitations by allowing direct access and active fragment retrieval.

Overall complication rates were low and similar between groups (13% vs 16%). No Clavien–Dindo grade IIIb or higher events occurred. Mini-PCNL-related bleeding required one transfusion (1.7%), which remains within the range reported in pediatric mini-PCNL meta-analyses . The ESWL steinstrasse rate of 9% is also consistent with published series . All cases resolved conservatively with hydration and α-blockers within 7 days, and none required ureteroscopy. The absence of sepsis in the ESWL arm likely reflects strict selection criteria, including sterile urine cultures, and the use of prophylactic antibiotics.

Despite longer hospitalization (2.4 vs 0.3 days), mini-PCNL was economically favorable. The incremental cost per QALY gained was US$1,280, which lies below the WHO–CHOICE threshold for Pakistan (US$1,600) . Sensitivity analyses showed that the result remained robust even when bed-day costs were doubled. Together, these findings support mini-PCNL as the preferred option for 1–2 cm pediatric renal stones, particularly when stone location or density predicts poor ESWL response.

Limitations and future directions

The Paediatric Stone-QOL scores improved more in the mini-PCNL group across all domains. The between-group difference in the pain domain of −1.5 points (95% CI −2.4 to −0.6) is clinically meaningful and exceeds the minimal clinically important difference of 1.0 . This likely reflects immediate stone removal rather than gradual fragment passage. Mean fluoroscopy time was 124 s for mini-PCNL versus 68 s per ESWL session; however, cumulative dose-area product was higher in ESWL when repeat sessions were considered. A pediatric-specific risk model estimated lifetime attributable cancer risk at 0.01% for mini-PCNL versus 0.02% for ESWL, favoring mini-PCNL .

To date, only one small randomized trial by Haberal et al compared mini-PCNL and ESWL in children . Although their inclusion threshold was 10–20 mm, nearly half of their patients had multiple stones, and quality-of-life outcomes were not assessed. Our trial strengthens the evidence base by using strict solitary-stone eligibility, a larger sample size, and formal economic evaluation. Conducted at a high-volume tertiary center with dedicated pediatric anesthesia and nursing support, the findings are likely applicable to similar settings. However, centers with less mini-PCNL experience may encounter longer learning curves and different outcome profiles.

Several limitations should be acknowledged. This was a single-center, open-label study with only 3 months of follow-up, which limits generalizability and may underestimate late recurrence. Stone composition data were available for only 40% of retrieved fragments, preventing robust compositional analysis. Costing was based on a hospital perspective, so indirect societal costs such as parental productivity loss were not captured. Although surgeons were experienced, outcomes may differ in lower-volume centers. A 24-month extension study (NCT05845678) is underway to evaluate late recurrence, societal cost, and long-term renal function using DMSA scanning. Future research should include multicenter trials, a paediatric-specific prediction model for ESWL success, systematic capture of patient-reported experience measures, and better correlation of stone composition with fragmentation efficiency.

CONCLUSIONS

In this prospective randomized trial, mini-PCNL achieved higher 3-month stone-free rates than ESWL in children with 1–2 cm renal stones, with the greatest benefit seen in lower-pole stones and high-density calculi. Complication rates were low and comparable between groups. Although mini-PCNL required a longer hospital stay, it was cost-effective and improved quality-of-life outcomes. These findings support mini-PCNL as the preferred first-line option for unfavorable 1–2 cm pediatric renal stones, while ESWL remains an option for compliant children with nondependent stones and more favorable anatomy.

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