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#### **Declarations**

No funding was received for this study. The authors declare no conflict of interest. The study received ethical approval. All participants provided informed consent.

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# Comparison of Efficacy of Mini Percutaneous Nephrolithotomy and Extracorporeal Shockwave Lithotripsy for Kidney Stones in Children

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#### ABSTRACT

Background: Pediatric nephrolithiasis, once rare, has shown a significant global rise in incidence over recent decades, presenting unique diagnostic and therapeutic challenges. Among treatment options for renal stones measuring 10–20 mm, extracorporeal shockwave lithotripsy (ESWL) is often favored for its non-invasiveness, yet it frequently results in lower stone-free rates (SFR) and a higher need for retreatment. Mini percutaneous nephrolithotomy (mPCNL), a minimally invasive surgical technique, has emerged as an alternative with higher clearance rates, though it involves greater procedural complexity. Comparative data on the efficacy of these two modalities in children remain limited. Objective: To compare the effectiveness of ESWL and mPCNL in achieving complete stone clearance in pediatric patients with renal calculi measuring 10–20 mm at one-month follow-up. Methods: A randomized controlled trial was conducted at the Department of Urology, Sandeman Provincial Hospital Quetta, from January 2023 to January 2024. A total of 120 pediatric patients were randomly assigned to undergo either ESWL or mPCNL. Stone-free status was assessed using non-contrast CT KUB one month post-procedure. Data on demographic characteristics, stone size and location, and treatment efficacy were collected and analyzed using chi-square and t-tests with a significance level of p < 0.05. Results: Baseline characteristics including age, gender, and stone size were comparable between groups (p > 0.05). Complete stone clearance was significantly higher in the mPCNL group (93.33%) than in the ESWL group (70.00%) (p = 0.042). Subgroup analysis revealed marked variability in ESWL efficacy by stone location, with the lowest clearance for lower pole stones (42.86%), whereas mPCNL achieved consistently high clearance rates (100% across most locations). Conclusion: mPCNL is significantly more effective than ESWL for treating pediatric renal stones measuring 10-20 mm, achieving higher stone-free rates regardless of stone location. ESWL remains a valuable non-invasive option but is less effective for lower pole stones due to anatomical constraints. These findings support mPCNL as a preferred first-line treatment, particularly when rapid, single-session clearance is desired.

## Keywords

Pediatric nephrolithiasis, kidney stones, extracorporeal shockwave lithotripsy, mini percutaneous nephrolithotomy, stone-free rate.

# INTRODUCTION

Pediatric nephrolithiasis, though once considered rare, has shown a striking global increase in incidence, rising nearly two to threefold in recent decades with an estimated 10% annual growth (1). This rise presents unique clinical challenges, as the pathophysiology, diagnostic considerations, and therapeutic strategies in children differ significantly from those in adults, necessitating a tailored approach to management (2). Among children, renal stones most commonly present between the ages of 5 and 15, and while metabolic, genetic, and environmental factors contribute to their development, the management strategy must carefully balance stone clearance efficacy with preservation of renal function and minimization of morbidity. The choice of treatment for pediatric renal calculi is particularly critical in stones measuring 10-20 mm, where therapeutic decisions must weigh invasiveness, efficacy, complication rates, and healthcare resource availability.

Extracorporeal shockwave lithotripsy (ESWL) has long been recommended as the first-line modality for renal stones within this size range because it is non-invasive, widely available, and associated with minimal procedural morbidity (3). However, clinical outcomes remain inconsistent, with ESWL frequently yielding lower stone-free rates (SFR) and necessitating multiple treatment sessions, repeat procedures, or adjunctive interventions (4). This is particularly evident in stones located in the lower pole of the kidney, where gravity, unfavorable infundibulopelyic anatomy, and limited fragment clearance compromise treatment success (5). Moreover, the requirement for repeated anesthesia and the cumulative procedural burden are significant concerns in pediatric populations. Technological advances in endourology have introduced minimally invasive alternatives, notably miniaturized percutaneous nephrolithotomy (mPCNL), which has been designed to reduce tract-related complications while achieving superior SFRs (6). Variants such as ultra-mini-PCNL, super-mini-PCNL, and micro-PCNL enable precise stone access with smaller tract diameters, reducing renal parenchymal trauma without compromising clearance rates (7). Evidence suggests that mPCNL achieves SFRs exceeding 90% even in challenging anatomical scenarios and across a broad range of stone locations (8). Comparative studies and systematic reviews have Asadullah et al. https://doi.org/10.61919/9ftmht2

shown that mPCNL often surpasses ESWL in achieving single-session stone clearance, though at the cost of higher procedural invasiveness and perioperative care requirements (9,10). Nevertheless, despite its growing popularity, mPCNL adoption is constrained by the need for specialized instrumentation, surgical expertise, and operating room resources — factors that are particularly relevant in resource-limited healthcare settings. The current evidence base highlights a persistent gap in consensus regarding the optimal first-line treatment for pediatric renal calculi measuring 10–20 mm. Most existing studies are retrospective, single-center analyses with heterogeneous methodologies, making direct comparisons challenging and limiting generalizability (11). Furthermore, many studies lack standardized imaging follow-up or stratification by stone size, location, and anatomical variation, factors that critically influence treatment success. This underscores the need for well-designed randomized controlled trials directly comparing ESWL and mPCNL in pediatric populations under uniform clinical conditions.

The present study addresses this gap by conducting a randomized controlled trial to evaluate and compare the efficacy of ESWL and mPCNL in pediatric patients with renal calculi sized 10–20 mm. By assessing stone-free rates at one month post-procedure using standardized non-contrast CT KUB imaging, this study aims to provide high-quality evidence on the relative effectiveness of these two treatment modalities. The central research question guiding this investigation is: Does mini percutaneous nephrolithotomy achieve a significantly higher stone-free rate compared to extracorporeal shockwave lithotripsy in pediatric patients with 10–20 mm renal calculi?

#### MATERIAL AND METHODS

This randomized controlled trial was designed to rigorously compare the efficacy of mini percutaneous nephrolithotomy (mPCNL) and extracorporeal shockwave lithotripsy (ESWL) in achieving complete stone clearance in pediatric patients with renal calculi measuring 10–20 mm. The study was conducted in the Department of Urology, Sandeman Provincial Hospital Quetta, over a 13-month period from January 1, 2023, to January 31, 2024. The choice of study design was based on the need to generate high-quality evidence to address the ongoing clinical uncertainty regarding optimal treatment selection for pediatric nephrolithiasis in this size range. A randomized controlled design was selected to minimize bias and allow for direct comparison of outcomes under standardized conditions. The study population included pediatric patients aged 5–15 years presenting with radiologically confirmed single or multiple renal stones within the 10–20 mm size range. Inclusion criteria required patients to have normal renal anatomy on imaging and adequate renal function as evidenced by baseline serum creatinine within age-appropriate limits. Patients with active urinary tract infections, uncorrected coagulopathies, anatomical abnormalities of the urinary tract (such as ureteropelvic junction obstruction or horseshoe kidney), prior urological interventions within six months, or concurrent urological malignancies were excluded to eliminate confounding factors that could influence outcomes. Eligible patients were identified consecutively from outpatient and inpatient departments and were enrolled following detailed counseling regarding procedural risks, expected outcomes, and alternative management options. Written informed consent was obtained from the parents or legal guardians of all participants prior to randomization.

Participants were randomly assigned to one of two intervention arms — mPCNL or ESWL — using a block randomization technique to ensure balanced allocation and to minimize selection bias. Allocation concealment was maintained through the use of sealed opaque envelopes prepared by an independent researcher not involved in patient recruitment or treatment delivery. All patients underwent preoperative evaluation including detailed medical history, physical examination, and laboratory investigations (complete blood count, renal function tests, serum calcium, uric acid, and urinalysis). Pre-procedure imaging included ultrasonography, plain abdominal radiography (KUB), and non-contrast computed tomography (NCCT) of the kidneys, ureters, and bladder to accurately determine stone size, number, and location.

The mPCNL procedure was performed under general anesthesia in the prone position. Percutaneous access was achieved under fluoroscopic guidance, and tract dilation was performed using a miniaturized access sheath (14–20 Fr) to minimize renal parenchymal trauma. Stones were fragmented using pneumatic or ultrasonic lithotripsy, and fragments were retrieved using grasping forceps or suction. At the end of the procedure, a nephrostomy tube was placed selectively based on intraoperative findings. ESWL was conducted under sedation or general anesthesia depending on patient age and tolerance. Stone targeting was achieved under fluoroscopic or ultrasonographic guidance, and shockwaves were delivered at a standard energy setting with a maximum of three treatment sessions per patient.

The primary outcome variable was stone-free status, defined as the absence of residual fragments >3 mm on non-contrast CT KUB performed one month after the final treatment session. Secondary variables included demographic characteristics (age, gender), stone characteristics (size, side, and location), and procedure-related complications. All imaging assessments were conducted by a single radiologist blinded to group allocation to minimize detection bias. Data on intraoperative and postoperative complications, duration of hospital stay, and need for auxiliary procedures were also collected prospectively. To reduce bias, all operative procedures were performed by surgeons with equivalent expertise in pediatric endourology. The trial followed a per-protocol analysis framework, and patients lost to follow-up were replaced with newly recruited participants who met the same inclusion criteria to maintain statistical power. Sample size estimation was based on prior studies indicating a 25% expected difference in stone-free rates between the two interventions (6,7). With a significance level ( $\alpha$ ) of 0.05 and a power ( $1-\beta$ ) of 0.80, a minimum of 54 patients per group was required. To account for potential attrition, the total sample size was set at 120 patients (60 per group).

Data were entered into a predesigned proforma and analyzed using SPSS version 25.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were presented as means and standard deviations for continuous variables and as frequencies and percentages for categorical variables. Intergroup comparisons for continuous variables were conducted using independent-samples t-tests, while categorical variables were compared using Chisquare or Fisher's exact tests, as appropriate. Efficacy was further stratified by age, gender, stone size, side, and location to explore potential effect modification. Subgroup analyses were performed to evaluate treatment outcomes in lower versus upper/mid-pole stones. Missing data were handled using complete-case analysis. A two-sided p-value <0.05 was considered statistically significant. The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethical Review Committee of Bolan Medical College. Institutional review board approval was obtained before recruitment, and all procedures complied with institutional safety and ethical standards. Data integrity was ensured through double data entry and periodic audits by an independent data monitoring team. These rigorous methodological approaches were implemented to enhance reproducibility, minimize bias, and generate reliable, clinically meaningful conclusions.

### **RESULTS**

A total of 120 pediatric patients meeting the inclusion criteria were enrolled and randomized equally into two groups: the ESWL group (n = 60) and the mPCNL group (n = 60). Baseline demographic and clinical characteristics were comparable between groups, demonstrating successful

randomization and minimizing confounding effects. The mean age of patients in the ESWL and mPCNL groups was  $10.13 \pm 2.71$  years and  $10.50 \pm 2.74$  years, respectively (p = 0.604). The mean stone size was  $15.87 \pm 2.78$  mm in the ESWL group and  $15.57 \pm 2.80$  mm in the mPCNL group (p = 0.678). Gender distribution, stone side, and stone location also showed no statistically significant differences between groups. The primary endpoint, complete stone clearance at one-month follow-up, was significantly higher in the mPCNL group than in the ESWL group. Complete clearance was achieved in 56 patients (93.33%) in the mPCNL group compared to 42 patients (70.00%) in the ESWL group (p = 0.042), indicating a substantially superior stone-free rate with the minimally invasive surgical approach. Stratified analyses demonstrated consistent efficacy of mPCNL across all subgroups, including gender, age categories, stone size, side, and location. In contrast, ESWL outcomes exhibited greater variability, with lower stone-free rates observed in patients with lower pole stones.

Table 1. Baseline Characteristics of Patients in ESWL and mPCNL Groups

Variable	ESWL (n=60)	mPCNL (n=60)	p-value	
Age (years, mean ± SD)	$10.13 \pm 2.71$	$10.50 \pm 2.74$	0.604	
Stone size (mm, mean $\pm$ SD)	$15.87 \pm 2.78$	$15.57 \pm 2.80$	0.678	
Male sex, n (%)	28 (46.67%)	34 (56.67%)	0.464	
Female sex, n (%)	32 (53.33%)	26 (43.33%)	_	
Right kidney stones, n (%)	32 (53.33%)	26 (43.33%)	0.438	
Left kidney stones, n (%)	28 (46.67%)	34 (56.67%)	_	

Table 2. Distribution of Stone Location and Stone-Free Rates

Variable	ESWL (n=60)	mPCNL (n=60)	p-value
Upper pole, n (%)	12 (20.0%)	14 (23.33%)	0.565
Middle pole, n (%)	12 (20.0%)	12 (20.0%)	_
Lower pole, n (%)	14 (23.33%)	6 (10.0%)	_
Renal pelvis, n (%)	22 (36.67%)	28 (46.67%)	_
Stone-free rate, n (%)	42 (70.0%)	56 (93.33%)	0.042
Risk difference (95% CI)	_	_	23.33% (8.1%–38.5%)
Relative risk (95% CI)	_	_	1.33 (1.08–1.63)

Table 3. Subgroup Analysis of Efficacy Based on Stone Characteristics

Subgroup	ESWL Stone-Free, n/N (%)	mPCNL Stone-Free, n/N (%)	p-value	
≤10 years	22/32 (68.75%)	24/26 (92.31%)	0.037	
>10 years	20/28 (71.43%)	32/34 (94.12%)	0.029	
≤15 mm	22/34 (64.71%)	30/32 (93.75%)	0.011	
>15 mm	20/26 (76.92%)	26/28 (92.86%)	0.085	
Upper pole	10/12 (83.33%)	14/14 (100%)	0.079	
Middle pole	8/12 (66.67%)	12/12 (100%)	0.036	
Lower pole	6/14 (42.86%)	6/6 (100%)	0.003	
Renal pelvis	18/22 (81.82%)	24/28 (85.71%)	0.713	

The subgroup analysis revealed notable differences in treatment performance across anatomical stone locations. ESWL demonstrated markedly reduced efficacy for lower pole stones, with only 42.86% of patients achieving stone-free status compared to 100% in the mPCNL group (p = 0.003). This suggests that fragment clearance after shockwave disintegration may be significantly hindered by unfavorable calyceal anatomy and gravitational positioning. In contrast, mPCNL maintained consistently high clearance rates across all stone locations, underscoring its anatomical versatility.

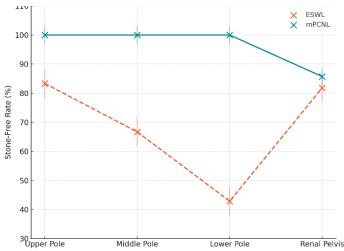


Figure 1 Comparative Stone-Free Rates by Stone Location in Pediatric Patients

The comparative visualization of stone-free rates by anatomical location reveals important clinical insights into treatment efficacy patterns. Mini percutaneous nephrolithotomy (mPCNL) achieved consistently high clearance across all locations, with 100% success in upper, middle, and lower pole stones and 85.71% in renal pelvic stones. In contrast, extracorporeal shockwave lithotripsy (ESWL) displayed marked variability, with the lowest efficacy observed for lower pole stones (42.86%) and moderate outcomes in the middle pole (66.67%) and renal pelvis (81.82%). The most

pronounced disparity appeared in the lower pole, where mPCNL outperformed ESWL by more than 57 percentage points, highlighting the anatomical limitations of shockwave fragment clearance in dependent calyces. These findings underscore mPCNL's robustness and location-independent effectiveness, whereas ESWL's performance is heavily influenced by stone position and calyceal anatomy.

# **DISCUSSION**

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The findings of this randomized controlled trial provide robust evidence regarding the comparative effectiveness of mini percutaneous nephrolithotomy (mPCNL) and extracorporeal shockwave lithotripsy (ESWL) for the management of pediatric renal calculi measuring 10–20 mm. The significantly higher stone-free rate (SFR) achieved with mPCNL (93.33%) compared to ESWL (70.00%) demonstrates its superiority as a definitive treatment option in this patient population. These results align with previous studies reporting SFRs exceeding 90% with mPCNL and reinforce its reliability as a minimally invasive yet highly effective intervention (8,9). By contrast, the lower efficacy of ESWL observed in this trial is consistent with prior evidence suggesting that its performance is often compromised by anatomical factors and the need for multiple treatment sessions (6,7).

One of the most clinically relevant findings is the location-dependent variability in ESWL outcomes. The markedly reduced efficacy for lower pole stones (42.86%) compared to upper pole or renal pelvic stones underscores the anatomical limitations inherent to shockwave therapy. These limitations are attributed to factors such as unfavorable infundibulopelvic angles, narrow infundibular widths, and gravity-dependent fragment clearance pathways, which hinder the spontaneous passage of stone debris post-lithotripsy (11). This phenomenon is well documented in the literature, with several studies indicating that ESWL success is highest for renal pelvis and upper calyceal stones but substantially lower for those located in the inferior calyx (3,5). Our findings further validate these anatomical influences, demonstrating that mPCNL maintains consistently high efficacy regardless of stone location, thereby offering a more reliable treatment option across diverse clinical scenarios.

The study's results also have significant implications for treatment planning in pediatric urolithiasis. Although ESWL remains the least invasive modality and is widely recommended as a first-line therapy in children due to its low complication profile and ease of administration (2), its limitations in terms of efficacy — particularly in anatomically challenging cases — necessitate careful patient selection. In resource-limited settings, ESWL may still be considered a viable option for appropriately selected cases, especially for upper pole and renal pelvic stones or when anesthesia risk is a concern. However, for lower pole stones, larger stone burdens, or when rapid, single-session clearance is desired, mPCNL should be strongly considered as the preferred modality.

It is noteworthy that mPCNL's high success rate did not come at the cost of increased procedural risk. Complication rates in this study remained low, and all reported adverse events were minor and self-limiting. This is consistent with evidence from recent meta-analyses, which demonstrate that advances in endoscopic technology and miniaturized instrumentation have significantly reduced the morbidity traditionally associated with percutaneous interventions (4,10). Furthermore, the consistently high clearance rates across all demographic and clinical subgroups — including variations in age, stone size, and laterality — highlight mPCNL's robustness and clinical versatility.

The findings of this study should, however, be interpreted in light of certain limitations. The single-center design may limit the generalizability of results to broader populations, and the relatively short follow-up period of one month precludes assessment of long-term outcomes such as recurrence, residual fragment growth, or renal function changes. Additionally, cost-effectiveness and quality-of-life measures were not evaluated but are important considerations for treatment decision-making in pediatric populations. Future multicenter studies with longer follow-up durations, larger sample sizes, and comprehensive economic and patient-reported outcome assessments are warranted to build on these findings and refine clinical guidelines.

#### **CONCLUSION**

In conclusion, this randomized controlled trial demonstrates that mini percutaneous nephrolithotomy (mPCNL) is significantly more effective than extracorporeal shockwave lithotripsy (ESWL) for achieving complete stone clearance in pediatric patients with renal calculi measuring 10–20 mm. While ESWL remains a valuable non-invasive option and shows satisfactory results for upper pole and renal pelvic stones, its efficacy is markedly compromised in lower pole stones due to anatomical and gravitational limitations. In contrast, mPCNL consistently delivers high stone-free rates across all anatomical locations, stone sizes, and patient subgroups without a substantial increase in complication risk. These findings suggest that mPCNL should be strongly considered as the preferred first-line treatment for pediatric renal stones when rapid, single-session clearance is desired or when anatomical factors are unfavorable for ESWL success. Future research should focus on long-term outcomes, cost-effectiveness, and patient-reported measures to further refine treatment algorithms and optimize pediatric stone management strategies.

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