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Original Article

Comparison of Stone-Free Rate Following Percutaneous Nephrolithotomy and Extracorporeal Shock Wave Lithotripsy for Renal Pelvic Stones (1–1.5 cm) in the Pediatric Population (6–14 Years)

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Abstract

Background: Urolithiasis is increasingly common in children and may lead to long-term renal complications

Objective: To compare stone-free rates and early complications in children with renal pelvic stones (1.0–1.5 cm) treated by mini-percutaneous nephrolithotomy (mini-PCNL) versus extracorporeal shock wave lithotripsy (ESWL).

Methodology: A randomized controlled trial was conducted at Khyber Teaching Hospital, Peshawar (October 2024–March 2025), including 124 children aged 6–14 years. Participants were randomized into two equal groups: mini-PCNL or ESWL. Stone clearance was assessed four weeks post-treatment using X-ray and ultrasonography.

Results: Stone-free status was achieved in 95.1% of mini-PCNL and 61.2% of ESWL patients (RR: 1.55, 95% CI: 1.25–1.91). Minor complications were more frequent with ESWL, including hematuria (12.9%), UTI (16.1%), and abdominal pain (9.6%), while no major complications occurred.

Conclusion: Mini-PCNL achieved higher stone-free rates and fewer complications than ESWL for pediatric renal pelvic stones of 1.0–1.5 cm, supporting its use as the preferred treatment option.

Keywords: Complications, ESWL, Mini-PCNL, Pediatric urolithiasis, Stone-free rate.

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Introduction

Urolithiasis refers to the presence of stones anywhere in the urinary tract, most commonly within the kidney (nephrolithiasis). In contrast, nephrocalcinosis describes diffuse calcium salt deposition in the renal parenchyma rather than discrete urinary calculi [1]. Although relatively uncommon in children, the incidence of these conditions has been steadily increasing worldwide due to changing dietary patterns, environmental factors, and improved diagnostic capabilities [2,3]. Pediatric nephrolithiasis has shown a significant rise in recent decades, leading to higher rates of hospital admissions and greater healthcare burden [4].

Recent epidemiological data indicate that the incidence of kidney stones in the pediatric population has increased from 6% to 10% in the past 20 years, with a disproportionately higher prevalence among adolescent females [5]. The major etiological contributors include metabolic abnormalities, urinary tract infections, dehydration, and genetic predisposition [6]. Clinical manifestations vary with age—infants may present with irritability, vomiting, or hematuria, while older children typically report flank or abdominal pain. In some cases, stones are detected incidentally during imaging performed for unrelated conditions [7].

Percutaneous nephrolithotomy (PCNL) has evolved as a key surgical approach for removing renal stones, particularly those larger than 1 cm. Based on tract size, PCNL is classified into standard (24–30 Fr), mini (16–18/20 Fr), ultra-mini (11–14 Fr), and micro-PCNL (<10 Fr) techniques [8]. ESWL, on the other hand, is a non-invasive method that uses high-energy acoustic pulses to fragment stones, allowing spontaneous passage through the urinary tract. While ESWL has long been considered the first-line treatment in pediatric urolithiasis due to its simplicity and minimal invasiveness, recent studies have shown that its effectiveness decreases for larger or denser stones, and multiple sessions are often required [9,10].

Earlier reports have documented variable success rates: 95% clearance with PCNL and approximately 55–77% with ESWL [10,11]. Current international guidelines, including those of the European Association of Urology (EAU 2025) and the American Urological Association (AUA), acknowledge both mini-PCNL and ESWL as suitable options for stones measuring 1–2 cm but highlight the paucity of comparative pediatric data [12,13].

This study was therefore undertaken to compare the stone-free rate and early postoperative complications of mini-PCNL versus ESWL in children with single renal pelvic stones measuring 1.0–1.5 cm. The research addresses a significant gap in pediatric urolithiasis management by providing evidence from a controlled trial conducted in a South Asian setting where both treatment modalities are available and widely practiced.

Methodology

Study Design:

This study was designed as a randomized controlled trial (RCT) to compare the stone-free rates and early postoperative complications of mini-percutaneous nephrolithotomy (mini-PCNL) and extracorporeal shock wave lithotripsy (ESWL) in pediatric patients. The trial design ensured rigorous comparison by maintaining equal allocation between groups and blinding radiologists for objective outcome assessment. The study period extended over six months, from October 2024 to March 2025.

Ethics:

Prior to initiation, ethical approval was obtained from the Research Ethics Committee of Khyber Teaching Hospital, Peshawar (Approval No: [insert number]). The study was conducted in accordance with the Declaration of Helsinki, and informed written consent was obtained from the parents or guardians of all participants. Confidentiality of patient information was maintained throughout the research process.

Setting:

The study was carried out at the Department of Urology, Khyber Teaching Hospital, Peshawar, a tertiary care center that caters to a large pediatric population from Khyber Pakhtunkhwa and adjoining regions. All diagnostic and interventional procedures were performed within the hospital's urology and radiology units using standardized protocols and equipment.

Participants:

A total of 124 pediatric patients, aged 6 to 14 years, presenting with solitary renal pelvic stones measuring 1.0–1.5 cm were enrolled through consecutive sampling from the urology outpatient and inpatient departments. Eligible participants were randomized in a 1:1 ratio into two groups—Group A (mini-PCNL) and Group B (ESWL)—using sequentially numbered, opaque, sealed envelopes to ensure allocation concealment. Exclusion criteria included children with prior renal surgery on the same kidney, renal or urinary tract anomalies, bladder pathology, active urinary tract infection, ureteric strictures, calyceal stones, or high-density stones (>1000 Hounsfield units).

Variables:
The primary outcome variable was the stone-free rate at 4 weeks following the final treatment session, defined as the absence of detectable stones or the presence of residual fragments ≤4 mm without symptoms, infection, or obstruction. Secondary variables included stone-free status at 7 days, number of ESWL sessions required, need for auxiliary procedures, and 30-day postoperative complications graded according to the Clavien–Dindo classification. Independent variables such as age, gender, body mass index (BMI), and stone size were also recorded to control for potential confounders.

Data Sources/Measurement:
Baseline assessment involved X-ray kidney, ureter, and bladder (KUB), renal ultrasonography, and non-contrast computed tomography (CT) KUB to confirm stone size and location. Laboratory investigations included urinalysis with culture, complete blood count, and renal function tests (serum urea, creatinine, and electrolytes). Post-intervention evaluation was performed by radiologists blinded to group assignment using plain X-ray and ultrasound imaging at 4 weeks to determine the stone-free status. Data were collected prospectively using a predesigned proforma.

Bias:
Selection bias was minimized through random allocation and concealed sequence generation. Performance bias was controlled by assigning all surgical procedures to a single experienced urologist using standardized operative protocols. Detection bias was reduced by blinding radiologists responsible for postoperative imaging assessment. Attrition bias was avoided as there were no losses to follow-up

Study Size:
The sample size was calculated using the WHO sample size calculator, assuming a 95% stone-free rate in the mini-PCNL group and a 77% rate in the ESWL group, with a 95% confidence level and 85% study power. Based on these parameters, a total of 124 patients (62 per group) were required to detect a statistically significant difference between the two interventions.

Quantitative Variables:
Continuous variables such as age, BMI, and stone size were measured on a ratio scale and expressed as mean ± standard deviation (SD). Categorical variables, including gender, treatment group, stone-free status, and complications, were expressed as frequencies and percentages. Stone-free outcomes were further analyzed using relative risk (RR) and risk difference (RD) with 95% confidence intervals (CI).

Statistical Methods:
All statistical analyses were conducted using SPSS version 20.0. Independent sample t-tests or Mann–Whitney U tests were applied for continuous data depending on distribution normality. Categorical data were analyzed using the Chi-square or Fisher's exact test. Multivariate logistic regression was used to adjust for potential confounders, particularly age and stone size, in predicting the stone-free outcome. Statistical significance was defined as a p-value less than 0.05.

Results

Participants
A total of 124 pediatric patients fulfilling the inclusion criteria were enrolled and randomized equally into two study groups, with 62 children each undergoing mini-percutaneous nephrolithotomy (mini-PCNL) and extracorporeal shock wave lithotripsy (ESWL). All participants received their assigned intervention and completed the scheduled follow-up period, resulting in a 100% retention rate. No patient was excluded or lost to follow-up during the study. The uniform adherence to protocol and complete dataset ensured the reliability of outcome evaluation and statistical analysis.

Descriptive Data
Baseline characteristics of the study population are summarized in Table 1. The mean age of participants was 9.5 ± 2 years in the mini-PCNL group and 10.8 ± 2 years in the ESWL group, with a statistically significant age difference ($p = 0.001$). The gender distribution was comparable between the two groups, with males constituting 53.2% in the mini-PCNL group and 56.4% in the ESWL group ($p = 0.65$). Mean BMI values were also similar (18.1 ± 2.4 kg/m² for mini-PCNL and 18.3 ± 2.6 kg/m² for ESWL; $p = 0.72$). The average stone size was 1.3 ± 0.5 cm in the mini-PCNL group and 1.2 ± 0.4 cm in the ESWL group ($p = 0.083$), confirming that both groups were comparable at baseline in terms of clinical and demographic parameters except for age, which was later adjusted for in multivariate analysis.

Outcome Data
The primary outcome measure—stone-free rate at 4 weeks after the final treatment—demonstrated a significant difference between the two groups. The stone-free status was achieved in 95.1% (59/62) of patients treated with mini-PCNL compared to 61.2% (38/62) of those treated with ESWL. This represented a relative risk of 1.55 (95% CI: 1.25–1.91) and an absolute risk difference of 33.9% (95% CI: 18.9–48.9), clearly favoring the mini-PCNL procedure. Logistic

regression analysis indicated that stone size was a significant predictor of achieving stone-free status (p = 0.03), whereas age did not significantly influence the outcome (p = 0.40).

Secondary outcome analysis showed that at 7 days, early stone clearance was achieved in 90.3% of mini-PCNL patients compared to only 43.5% in the ESWL group (RR: 2.07, 95% CI: 1.53–2.81). The mean number of ESWL sessions required for adequate clearance was 1.6 ± 0.7, with 37.1% of patients needing more than one session. Additionally, auxiliary procedures such as ureteric stenting or repeat intervention were necessary in 11.3% of the ESWL group but only in 1.6% of the mini-PCNL group, highlighting the higher procedural efficiency of mini-PCNL.

Main Results

Postoperative complications within 30 days were generally minor and self-limiting but occurred more frequently among ESWL-treated patients. Hematuria (Clavien–Dindo Grade I) was observed in 12.9% of ESWL patients compared to 3.2% in the mini-PCNL group (p = 0.04). Urinary tract infection (Grade II) developed in 16.1% of ESWL patients and only 1.6% of those treated with mini-PCNL (p = 0.01). Abdominal pain requiring analgesia was reported in 9.6% of ESWL patients but was absent among the mini-PCNL group (p = 0.02). Steinstrasse occurred in two ESWL cases (3.2%) and none in the mini-PCNL group. No major complications (Clavien–Dindo grade ≥ III) or cases requiring readmission were recorded in either group.

Subgroup analyses revealed no significant difference in stone-free rates based on gender (p = 0.65), BMI (p = 0.42), or age category (<10 vs. ≥10 years, p = 0.28), suggesting that procedural success was independent of these variables. Collectively, these findings confirm that mini-PCNL offers superior stone clearance, fewer complications, and minimal need for auxiliary procedures compared to ESWL in the pediatric population with renal pelvic stones of 1–1.5 cm.

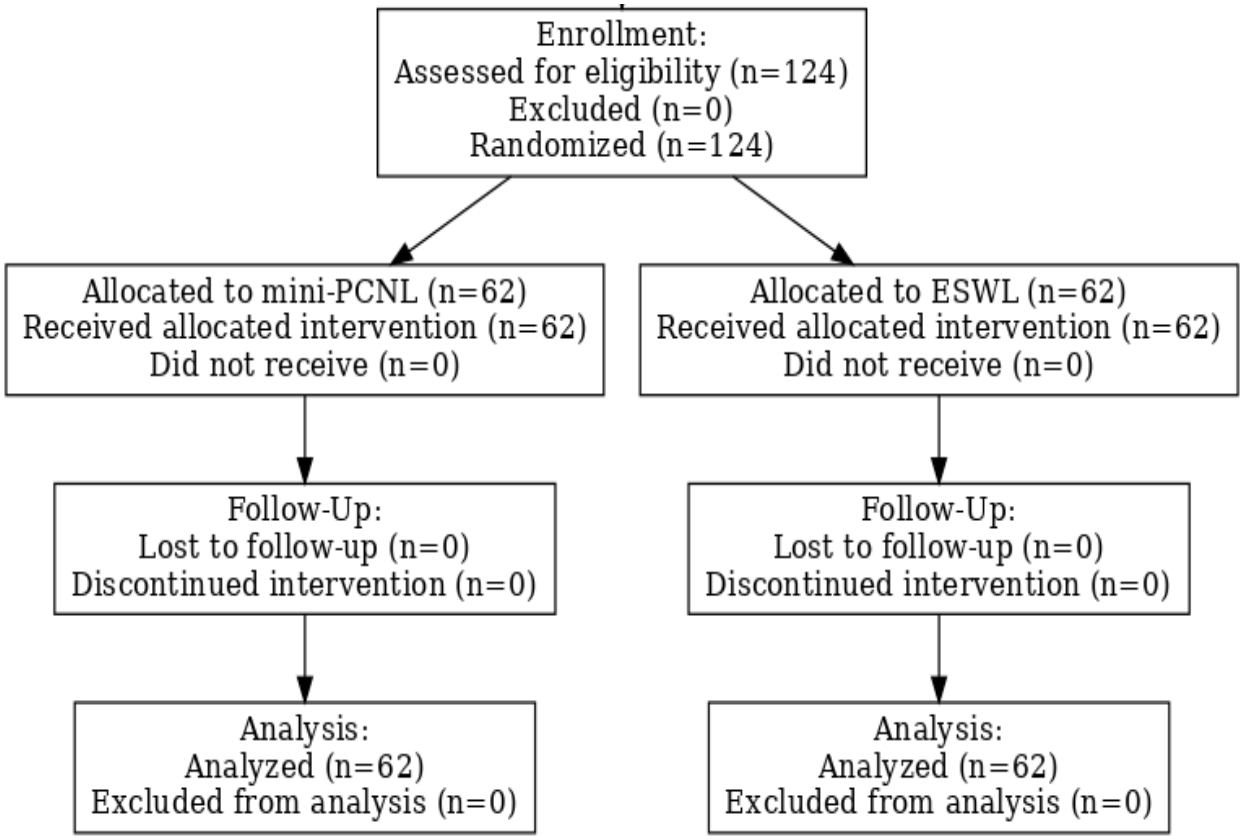


Figure 1: Consort Flow Diagram

Table 1: Baseline Characteristics of Study Participants			
Characteristic	**Mini-PCNL (n = 62)**	**ESWL (n = 62)**	**p-value**
Age (years), mean ± SD	9.5 ± 2	10.8 ± 2	0.001
Gender (Male), n (%)	33 (53.2%)	35 (56.4%)	0.65
BMI (kg/m²), mean ± SD	18.1 ± 2.4	18.3 ± 2.6	0.72
Stone size (cm), mean ± SD	1.3 ± 0.5	1.2 ± 0.4	0.083

Table 2. Stone-Free Rate at 4 Weeks after Final Treatment			
Outcome	**Mini-PCNL (n = 62)**	**ESWL (n = 62)**	**Effect Estimate (95% CI)**
Stone-free at 4 weeks, n (%)	59 (95.1%)	38 (61.2%)	Risk ratio: 1.55 (1.25–1.91)
Not stone-free at 4 weeks, n (%)	3 (4.9%)	24 (38.8%)	Risk difference: 33.9% (18.9–48.9)
Total analyzed, n (%)	62 (100%)	62 (100%)	—

Table 3. Logistic Regression for Stone-Free Outcome			
Variable	**Adjusted OR**	**95% CI**	**p-value**
Age (years)	1.05	0.92 – 1.20	0.40
Stone size (cm)	1.48	1.05 – 2.20	0.03

Table 4: Secondary Outcomes			
Outcome	**Mini-PCNL (n = 62)**	**ESWL (n = 62)**	**Effect Estimate (95% CI)**
Stone-free at day 7, n (%)	56 (90.3%)	27 (43.5%)	Risk ratio: 2.07 (1.53–2.81)
Stone-free at 4 weeks, n (%)	59 (95.1%)	38 (61.2%)	Risk ratio: 1.55 (1.25–1.91)
Mean no. of ESWL sessions ± SD	Not applicable	1.6 ± 0.7	—
Patients requiring >1 ESWL session, n (%)	Not applicable	23 (37.1%)	—
Auxiliary procedures (stent/re-interv), n (%)	1 (1.6%)	7 (11.3%)	OR: 0.13 (0.02–1.08)

Table 5: Complications			
Complications	**Mini-PCNL (n = 62)**	**ESWL (n = 62)**	**p-value**
Hematuria (Grade I)	2 (3.2%)	8 (12.9%)	0.04
Urinary tract infection (Grade II)	1 (1.6%)	10 (16.1%)	0.01
Abdominal pain requiring analgesia (Grade I)	0	6 (9.6%)	0.02
Stein Strasse (Grade II)	0	2 (3.2%)	0.15

Discussion

This randomized controlled trial compared the outcomes of mini-percutaneous nephrolithotomy (mini-PCNL) and extracorporeal shock wave lithotripsy (ESWL) in pediatric patients with solitary renal pelvic stones measuring 1.0–1.5 cm. The findings revealed that mini-PCNL achieved a significantly higher stone-free rate (95.1%) compared to ESWL (61.2%) at four weeks, with fewer postoperative complications. These results are consistent with recent pediatric series reporting clearance rates above 90% for mini-PCNL, while ESWL typically yields lower success and often requires repeated sessions [12,13,14].

Historically, ESWL has been the first-line approach for pediatric urolithiasis due to its non-invasive nature and reduced perioperative risks [15]. However, several recent studies have questioned its efficacy for renal pelvic stones larger than 1 cm or with high density, showing clearance rates between 53–70% and frequent retreatments [16]. In contrast, mini-PCNL offers direct stone removal and improved visualization, resulting in superior outcomes even for moderately sized stones. The present study supports these findings, demonstrating that mini-PCNL provides definitive clearance in a single session and minimizes the need for auxiliary procedures (1.6% vs. 11.3% in ESWL).

Complications in this study were generally minor (Clavien–Dindo grade I–II) and managed conservatively. ESWL-treated patients showed higher incidences of hematuria (12.9%), urinary tract infection (16.1%), and abdominal pain (9.6%), whereas mini-PCNL had lower rates and no major complications. Similar safety profiles have been reported in multicenter analyses, confirming that miniaturized PCNL techniques are safe and effective for children when performed by experienced surgeons [17,18,19].

The timing of outcome evaluation—four weeks after the final treatment—was selected according to the European Association of Urology (EAU) Urolithiasis Guidelines 2025, which recommend this interval to allow spontaneous passage of residual fragments while avoiding unnecessary delays in detecting treatment failure or complications [20]. Several contemporary pediatric studies have adopted this follow-up window, ensuring comparability of results across trials [21].

Although the study's single-center nature and relatively small sample size limit generalizability, its randomized design, blinded imaging evaluation, and complete follow-up strengthen the validity of the conclusions. Future multicenter trials with larger cohorts and longer follow-up periods are warranted to evaluate long-term outcomes such as recurrence rates, renal growth, and functional preservation. Cost-effectiveness analysis would also be valuable, especially in regions where ESWL remains more accessible and resource-friendly.

Conclusion

Mini-PCNL demonstrated significantly higher stone-free rates and lower postoperative complication rates compared to ESWL in children with renal pelvic stones measuring 1.0–1.5 cm. Both procedures were safe, but ESWL required multiple sessions and resulted in a greater frequency of minor complications. Given its superior efficacy and safety, mini-PCNL should be considered the preferred treatment option for pediatric renal stones within this size range, particularly in centers with the necessary expertise and equipment. Further multicenter studies with extended follow-up are recommended to confirm these findings and assess long-term renal outcomes.

Authors' Contributions

All authors meet the ICMJE criteria for authorship. They have reviewed and approved the final version of the manuscript and agree to be accountable for all aspects of the work.

Author 1: Substantial contribution to conception and design, drafting the manuscript, final approval, agreed to be accountable for all the work.
Author 2: Substantial contribution to conception and design, data acquisition, drafting the manuscript, final approval, agreed to be accountable for all the work.
Author 3: Analysis and interpretation of data, drafting the manuscript, final approval, agreed to be accountable for all the work.
Author 4: Analysis and interpretation of data, critical revision, final approval, agreed to be accountable for all the work.
Author 5: Substantial contribution to conception and design, drafting the manuscript, final approval, agreed to be accountable for all the work.
Author 6: Substantial contribution to conception and design, data acquisition, drafting the manuscript, final approval, agreed to be accountable for all the work

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