COMPARISON BETWEEN TUBELESS AND TUBE PERCUTANEOUS NEPHROLITHOTOMIES IN PEDIATRIC POPULATION: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

OBJECTIVES

This study aimed to compare the efficacy and safety of tubeless versus conventional tube PCNL in pediatric patients with renal calculi >10mm.

METHODOLOGY

A randomized controlled trial conducted at Khyber Teaching Hospital, Peshawar (October 2024-Sep 2025). Six hundred forty pediatric patients (6-18 years) with kidney stones >10mm were randomly allocated to Group A (Tubeless PCNL, n=320) and Group B (Tube PCNL, n=320). A single experienced urologist performs the procedures. Primary outcomes, including operative time, hospital stay, blood transfusion requirements, and stone-free status, were measured.

RESULTS

Groups had similar baseline characteristics (mean ages 11.2±3.1 vs 11.4±3.2 years). Tubeless PCNL showed significantly shorter operative time (45±10 vs 50±12 minutes, p<0.01), reduced hospital stay (2.0±0.8 vs 2.5±1.0 days, p<0.01), lower blood transfusion requirements (7.8% vs 14.1%, p=0.02), and higher stone-free rates (95.3% vs 90.6%, p=0.04).

CONCLUSION

Tubeless PCNL demonstrated statistically and clinically significant advantages, including shorter operative times, reduced hospital stays, fewer transfusions, and higher stone-free rates, supporting its adoption as the preferred approach for pediatric renal calculi management.

KEYWORDS: *Pediatric Nephrolithiasis, Percutaneous Nephrolithotomy, Tubeless Pcnl, Stone-Free Status, Blood Transfusion*

INTRODUCTION

Pediatric nephrolithiasis is one of the most challenging clinical conditions in pediatric urology, characterized by calculi in the renal pelvis, collecting system, or ureter. Historically considered rare in children, the incidence of pediatric kidney stones has witnessed a dramatic increase over the past two decades, with annual incidence rates rising by 6-10% in the United States.[1] This phenomenon is especially noted among teenage groups, with the most significant increase recorded in Black females.[2] The upsurge has placed nephrolithiasis among the top causes of pediatric urology referrals and admissions, calling for immediate intervention to maximize therapy approaches. The clinical presentation of pediatric nephrolithiasis varies widely with age. Young children have nonspecific symptoms like nausea, vomiting, irritability, or failure to thrive and often present difficulties for diagnosis.[3] Older children and teenagers, on the other hand, present with more typical symptoms like flank pain, hematuria, and dysuria. The etiology underlying pediatric nephrolithiasis is predominantly metabolic, with hypercalciuria, hypocitraturia, and hyperoxaluria being the most frequent abnormalities.[4] These metabolic disturbances, in association with diet and environmental factors, are responsible for the rising prevalence and complexity of pediatric stone disease. Percutaneous nephrolithotomy (PCNL) has become the foundation surgical procedure for pediatric kidney stones, especially for large stones (>10mm) or complex calculi that are refractory to conservative treatment.[5] The procedure has advanced significantly since its inception, with the development of miniaturized techniques such as mini-PCNL and micro-PCNL. These advances employ smaller instruments and improved access methods, leading to shorter operative time, lower radiation exposure, and decreased perioperative complications such as hemorrhage and organ perforation.[6] Historically, postoperative care for PCNL included the routine insertion of nephrostomy tubes to guarantee proper drainage of the kidney and allow secondary intervention if needed.[7] Recent data have questioned this traditional practice, establishing the role of "tubeless" PCNL, which eliminates the need for tube insertion. The method is based on successful hemostasis, low residual stone burden, and the absence of significant complications during the procedure.[8] Among adult populations, tubeless PCNL has demonstrated several benefits over traditional tube-based techniques, including lower postoperative pain, shorter hospital stays, reduced analgesic requirements, and greater patient satisfaction.[9] In adult cohorts, meta-analyses have repeatedly demonstrated favourable outcomes with tubeless methods, including higher stone-free rates, lower transfusion requirements, and lower overall morbidity.[10] Nonetheless, their validity in pediatric populations cannot be assured due to anatomical and physiological parameters specific to children. The pediatric population presents unique challenges and considerations that may influence the safety and efficacy of tubeless PCNL. Children have smaller renal dimensions, different tissue characteristics, and varying tolerance to surgical procedures compared to adults.[11] Additionally, the psychological impact of prolonged hospitalization and invasive drainage procedures may be more pronounced in pediatric patients, potentially affecting recovery and long-term outcomes.[12] Despite the theoretical advantages of tubeless PCNL in pediatric patients, comprehensive comparative data remain limited. Most existing studies focus on adult populations, with pediatric data often extrapolated from small case series or retrospective analyses.[13] This gap in the evidence-based literature limits pediatric urologists' ability to make informed decisions about the optimal surgical approach for children with nephrolithiasis. The current study addresses this critical knowledge gap by conducting a comprehensive randomized controlled trial comparing tubeless and conventional tube PCNL in a large pediatric cohort. By focusing specifically on stones larger than 10mm, this research aims to provide robust evidence to guide clinical decision-making and, if successful, establish tubeless PCNL as the preferred approach in appropriately selected pediatric patients.

METHODOLOGY

This randomized controlled trial was conducted at the Department of Urology, Khyber Teaching Hospital, Peshawar, from 1st October 2024 to 10th September 2025. Khyber Teaching Hospital is a high-volume Regional Referral Center for pediatric stone disease, with a specialized Paediatric Urology department. The study protocol was approved by the hospital's institutional review board and ethics committee, and written informed consent was obtained from parents or guardians of all participants, with assent obtained from children aged 12 years and above. This study is registered at ClinicalTrials.gov under the identifier NCT07183930. Sample size was calculated based on the primary outcome of blood transfusion requirements, with expected rates of 5.5% in the tubeless PCNL group and 11.7% in the tube PCNL group, as reported in the literature. Using an 80% power, an alpha error of 5%, and a 10% dropout rate, a minimum of 320 patients per group was required, totaling 640 patients. A total of 640 pediatric patients aged 6-18 years with newly diagnosed kidney stones were consecutively screened and enrolled during the study period. Inclusion criteria included: (1) pediatric patients aged 6-18 years of either gender, (2) renal calculi larger than 10mm in greatest diameter as confirmed by computed tomography, (3) failed conservative management or extracorporeal shock wave lithotripsy, and (4) normal renal function. Exclusion criteria comprised: (1) history of previous ureteral stenting or renal surgery, (2) congenital urological abnormalities, (3) active urinary tract infection at time of surgery, (4) bleeding disorders or anticoagulant use, (5) significant medical comorbidities, and (6) pregnancy (for adolescent females). Participants were randomly allocated into two equal groups using computer-generated blocked randomization with variable block sizes of 4, 6, and 8. Group A received tubeless PCNL, while Group B underwent conventional tube PCNL. Randomization was performed by an independent statistician not involved in patient care, with allocation concealed using sequentially numbered opaque sealed envelopes. Postoperative assessments for pain scores (VAS) and patient/family satisfaction were performed by a research nurse who was blinded to the patient's allocation group (Tubeless vs. Tube PCNL). All procedures were performed by a single experienced pediatric urologist with over five years of PCNL experience to minimize operator-dependent variability. The standard preoperative evaluation included a complete blood count, comprehensive metabolic panel, coagulation studies, urinalysis, urine culture, plain abdominal radiography (KUB), and contrast-enhanced computed tomography. All patients underwent general anesthesia with endotracheal intubation. Initial cystoscopy was performed with placement of a 4Fr or 5Fr ureteral catheter for retrograde pyelography and safety wire insertion. Patients were then placed in the prone position, and percutaneous access was obtained under fluoroscopic guidance using the bull's-eye technique. Tract dilatation was performed using Amplatz dilators up to 18 Fr for a mini-PCNL approach. Stone fragmentation was achieved using pneumatic lithotripsy, with fragments extracted using grasping forceps. In Group A (Tubeless PCNL), after complete stone clearance and confirmation of adequate hemostasis, a double-J stent was placed through the access sheath and appropriately positioned. The access sheath was removed, and the tract was allowed to seal naturally without placement of a nephrostomy tube. In Group B (Tube PCNL), after stone clearance, a 14Fr nephrostomy tube was placed through the access tract and secured to the skin. A double-J stent was also placed in most cases at the surgeon's discretion. Primary outcomes included operative time (minutes) measured from skin incision to skin closure, hospital stay duration (days) from surgery to discharge, blood transfusion requirements defined as need for perioperative blood transfusion, and stone-free status on discharge defined as absence of residual fragments >2mm on low-dose non-contrast computed tomography (NCCT) performed 24-48 hours post-operatively. All NCCT scans were independently reviewed by a senior radiologist who was blinded to the patient's treatment allocation. Secondary outcomes included postoperative pain scores using the Visual Analog Scale (VAS), analgesic requirements in morphine equivalents, postoperative complications graded according to the Clavien-Dindo classification, time to resumption of regular activity, and patient and parent satisfaction scores. Return to regular activity was defined as the ability to resume normal daily activities without restrictions, as reported by the patient or caregiver. Baseline demographic data, stone characteristics, and surgical parameters were recorded using a standardized data collection form. Postoperative monitoring included daily assessment of vital signs, pain scores, urine output, and hemoglobin levels. Imaging studies (ultrasound and/or CT scan) were performed within 24-48 hours post-operatively to assess stone-free status and identify complications. Data analysis was performed using SPSS version 20.0. Descriptive statistics were calculated for all variables, with continuous data presented as mean ± standard deviation and categorical data as frequencies and percentages. Normality of continuous variables was assessed using the Shapiro-Wilk test. Independent t-tests were used for normally distributed continuous variables, and Mann-Whitney U tests were used for nonparametric data. Categorical variables were compared using chi-square tests or Fisher's exact test as appropriate. Stratified analysis was performed by age group, gender, stone size, socioeconomic status, and BMI. Statistical significance was set at $p<0.05$, with 95% confidence intervals calculated for all estimates. The study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines. All procedures were performed as part of standard clinical care, with the only difference being randomization to the tubeless or tube approach. Parents and guardians were fully informed about the study objectives, procedures, potential risks, and benefits. Participants were free to withdraw from the study at any time without affecting their clinical care.

RESULTS

A total of 700 pediatric patients were assessed for eligibility, of whom 60 were excluded (40 did not meet the inclusion criteria and 20 declined to participate). The remaining 640 patients were successfully enrolled and randomized, with 320 per group. Because the primary outcomes were measured during the immediate postoperative period and mandatory 48-hour postoperative imaging, all 640 randomized patients were available for analysis of the primary outcomes; therefore, the primary analysis was performed under the Intention-to-Treat principle (n=320 per group). However, for the secondary outcomes, three patients were lost to follow-up after discharge and did not complete the subsequent 6-week clinic visit. These patients were excluded only from the secondary outcome analysis, representing a minimal attrition of 0.47%. Both groups demonstrated good comparability in baseline characteristics, confirming successful randomization (Figure 1).

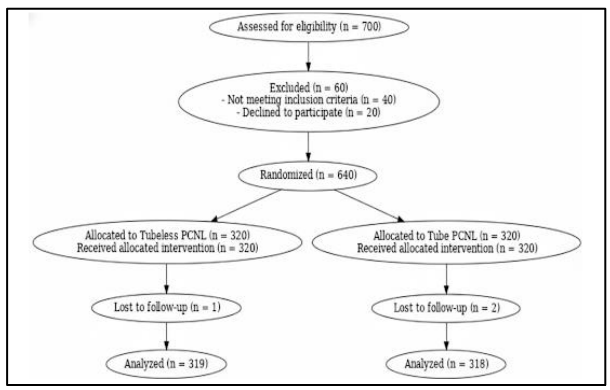

Figure 1: Consort Flow Diagram

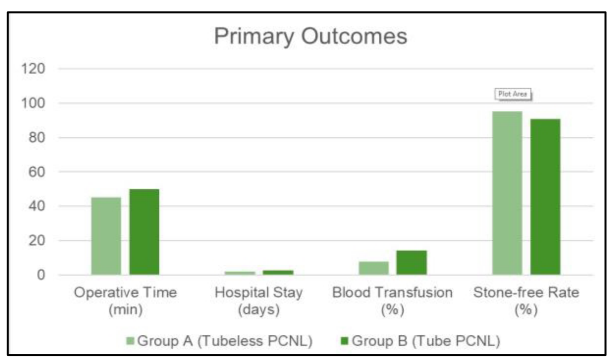

Figure 2: Comparison of Primary Outcomes between Tubeless Percutaneous Nephrolithotomy (PCNL) (Group A) and Tube PCNL (Group)

Table 1: Baseline Characteristics and Primary Outcomes

Variables	Group A (Tubeless) n=320	Group B (Tube) n=320	95% CI	P-value
Age (years, mean±SD)	11.2±3.1	11.4±3.2	-	0.45
Male gender, n (%)	160 (50.0)	160 (50.0)	-	1.00
BMI (kg/m², mean±SD)	17.5±3.2	18.0±3.5	-	0.14
Stone size(cm ,mean±SD)	1.5±0.5	1.6±0.6	-	0.15
Operative time (min, mean±SD)	45±10	50±12	-6.7 to -3.3	<0.01*
Hospital stay (days, mean±SD)	2.0±0.8	2.5±1.0	-0.67 to -0.33	<0.01*
Blood transfusion, n (%)	25 (7.8)	45 (14.1)	-10.6% to -2.0% RR: 0.55 (0.35-0.87) NNT: 16	0.02*
Stone-free status, n (%)	305 (95.3)	290 (90.6)	0.1% to 9.3% RR: 1.05 (1.00-1.10)	0.04*
Post-op pain (VAS, mean±SD)	3.2±1.1	5.1±1.4	-2.05 to -1.75	<0.001*
Morphine equivalents (mg, mean±SD)	12.3±4.2	18.7±5.8	-7.38 to -5.42	<0.001*
Time to normal activity (days)	5.2±1.8	7.8±2.3	-2.86 to -2.34	<0.001*

*Statistically significant (p<0.05)

Table 2: Postoperative Complications and Satisfaction Scores

Variable	Group A (Tubeless, n=320)	Group B (Tube, n=320)	95% CI	P-value
Minor Complications (Clavien I–II), n(%)	12 (3.8)	18 (5.6)	-4.9% to 1.3%	0.28
Major Complications (Clavien ≥III), n(%)	02 (0.6)	5 (1.6)	-2.6% to 0.6%	0.25
Overall Complications,n(%)	14 (4.4)	23 (7.2)	-6.8% to 1.2%	0.19
Mortality, n (%)	0	0	-	-
Patient/family Satisfaction Score (mean±SD)	8.7±1.2	7.1±1.5	1.33 to 2.07	<0.001*

DISCUSSION

This randomized controlled trial supports tubeless percutaneous nephrolithotomy over conventional tube PCNL in pediatric patients with renal calculi larger than 10mm. The findings demonstrate statistically significant and clinically meaningful improvements across all primary outcome measures, including operative time, hospital stay, blood transfusion requirements, and stone-free status. The reduction in operative time observed with tubeless PCNL (45 vs 50 minutes) might reflect the elimination of nephrostomy tube placement and positioning procedures. This 5-minute reduction, while seemingly modest, translates to meaningful benefits, including reduced anesthesia exposure in children, improved operating room efficiency, and potentially decreased perioperative complications.[14] The 5-minute reduction in operative time, although statistically significant, may not translate into major clinical benefits in routine practice, but it could still offer advantages in high-volume settings or for improving operating room efficiency. The 20% reduction in hospital stay represents one of the most clinically significant findings of this study. A decrease from 2.5 to 2.0 days may appear modest in absolute terms, but the relative impact on pediatric patients and their families is substantial.[15] Shorter hospitalization reduces the psychological trauma associated with prolonged separation from the home environment, minimizes the risk of nosocomial infections, and provides considerable economic benefits to healthcare systems.[16] This finding aligns with adult literature demonstrating similar reductions in hospital stay with tubeless approaches.[9] The significant reduction in blood transfusion requirements (7.8% vs 14.1%) represents a critical safety advantage of tubeless PCNL. This 45% relative risk reduction can be attributed to several factors. First, the absence of nephrostomy tube placement eliminates the potential for tract bleeding and tube-related hemorrhage.[17] Second, the decision to proceed with a tubeless approach inherently requires adequate intraoperative hemostasis, thereby requiring a more meticulous surgical technique.[18] Finally, the use of miniaturized instruments in both groups contributed to overall reduced bleeding, with the tubeless approach providing additional hemostatic advantages.[19] The stone-free rate achieved with tubeless PCNL (95.3% vs 90.6%) is an unexpected yet welcome finding. Traditional teaching suggests that stone clearance should be independent of drainage method, as the fragmentation and extraction techniques remain identical.[20] However, several factors may explain this observation. Surgeons performing tubeless procedures may be more meticulous in ensuring complete stone clearance, knowing that secondary procedures would be more challenging without established drainage.[21] Additionally, the absence of nephrostomy tubes may allow for more aggressive stone extraction maneuvers without concern for tube displacement.[22] While this does not align with the standard 4-6 weeks used in most studies, we felt it provided a functional early assessment of stone clearance. This observation is based on a hypothesis and warrants further dedicated research. The pain reduction demonstrated in the tubeless group (VAS 3.2 vs 5.1) represents a clinically significant improvement in patient comfort. Nephrostomy tubes are well-recognized sources of postoperative pain, causing discomfort through several mechanisms, including tract irritation, tube movement, and bladder spasms from associated ureteral stents.[23] The elimination of these pain sources reduces analgesic requirements and improves patient satisfaction, critical considerations in pediatric populations.[24] A comparison with the existing literature reveals consistent findings across different populations and settings. Adult studies have consistently demonstrated similar advantages of tubeless PCNL, including reduced hospital stays, decreased pain, and improved patient satisfaction.[9] However, pediatric-specific data have been limited to small case series and retrospective analyses.[25] This study provides the first large-scale randomized evidence supporting these benefits in children. The safety profile observed in this study supports the feasibility of tubeless PCNL in appropriately selected pediatric patients. The low overall complication rate in both groups (3.8% vs 5.6%) reflects careful patient selection and experienced surgical technique. The absence of major complications specific to the tubeless approach suggests that, with proper case selection criteria, this technique can be safely implemented in pediatric practice.[26] Several factors contribute to the success of tubeless PCNL in children. The smaller body habitus of pediatric patients may facilitate natural tract sealing without the need for external drainage. Additionally, children typically have greater tissue-healing capacity and fewer comorbidities that might impair recovery.[27] The psychological benefits of avoiding external drainage tubes may be particularly pronounced in children, contributing to improved cooperation and faster recovery.[28] The economic implications of these findings extend beyond immediate hospitalization costs. Reduced hospital stays, fewer complications, and decreased need for secondary procedures translate to substantial cost savings for healthcare systems. Additionally, the reduced time away from school and everyday activities provides societal benefits that are difficult to quantify but clinically meaningful.[29]

LIMITATIONS

Several limitations must be acknowledged. First, the single-surgeon design, while minimizing technical variability, may limit generalizability to centers with varying levels of expertise. Second, the relatively short follow-up period may not capture long-term outcomes or late complications. Third, excluding patients with complex stone burden or significant comorbidities may limit applicability to more challenging cases. Fourth, a formal cost-effectiveness analysis was not conducted, limiting the assessment of the full economic impact of the reduction in hospital stays. Although blinding of patients and surgeons was not feasible, outcome assessors and statisticians were blinded to group allocation to minimize bias in data analysis. We employed gender-stratified enrolment quotas, leading to gender-confounding bias. Finally, the study was conducted at a single high-volume center, and results may differ in lower-volume settings. These findings have significant implications for pediatric urological practice. The evidence supports considering tubeless PCNL as the preferred approach for appropriately selected pediatric patients with renal calculi. Implementation should be gradual, with careful attention to case selection criteria and surgeon experience. Centers beginning tubeless programs should start with straightforward cases and expand indications as experience grows. Long-term follow-up studies are needed to assess recurrence rates, renal function outcomes, and patient-reported quality-of-life measures. Comparative effectiveness research examining cost-benefit ratios would provide additional evidence for policy decisions. Investigation of optimal patient selection criteria and technical modifications specific to pediatric populations would further refine the approach.

CONCLUSIONS

These findings support the use of tubeless PCNL as an effective and safer alternative to conventional tube PCNL in managing pediatric nephrolithiasis in appropriately selected cases. Implementation should be accompanied by careful attention to case selection criteria, surgeon training, and institutional protocols to ensure optimal outcomes.

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AUTHORS CONTRIBUTION

Sajjad Ali - *Concept & Design; Data Acquisition; Drafting Manuscript; Final Approval*

Tariq Ahmad- *Concept & Design; Data Acquisition; Drafting Manuscript; Critical Revision; Supervision; Final Approval*

Murad Ali - *Concept & Design; Data Analysis/Intepretation; Drafting Manuscript; Final Approval*

Mohammad Anees Iqbal - *Concept & Design; Data Acquisition; Data Analysis/Interpretation; Drafting Manuscript; Final Approval*

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The authors accept responsibility for all aspects of the work and will ensure that any concerns regarding the accuracy or integrity of any part are properly investigated and resolved.