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ORIGINAL PAPER

Extracorporeal shock wave lithotripsy *vs* percutaneous nephrolithotomy, complication rate and recurrence rate in management of pediatric renal stone, a prospective randomized trial

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Summary

Background: *The mini-percutaneous nephrolithotomy (PNL) technique has introduced notable advantages, establishing it as a compelling option compared to extracorporeal shock wave lithotripsy (SWL) in managing renal stones in the pediatric population. We aimed to compare the outcomes of both techniques as regards effectiveness, morbidity, and stone recurrence.*

Methods: *A prospective, randomized superiority trial included 128 pediatric patients with a solitary renal stone measuring 10-20 mm. Group I included patients who underwent mini-PNL (n = 65), while Group II included those managed with SWL (n = 63). The primary endpoint was the stone-free rate (SFR) eight weeks after the procedure, while the secondary endpoints were operative time, hospital stay, and postoperative complications. The stone recurrence rate was assessed at 2-year follow-up.*

Results: *The mean age of the patients ± SD was 8.48 ± 4.08 years, and the mean size of the stones was 17.13 ± 2.45 millimeters. The study arms had comparable demographics and stone characteristics. The mean operative time was significantly lower in Group I than in Group II (51.38 ± 14.02 min vs. 63.70 ± 16.90 min, respectively; P = 0.001). We reported a perioperative complication rate of 26.2% in Group I, compared to 20.6% in Group II, with a statistically insignificant difference (p = 0.461). SFR was 93.8% and 41.3% for groups I and II, respectively (p < 0.001). The stone recurrence was reported in 4 cases (6.1%) in Group I compared to 10 cases (15.8%) in Group II (p = 0.005).*

Conclusions: *Our study demonstrates that Mini-PNL has a higher stone-free rate than SWL for managing renal stones of 10-20 mm in children. While both techniques have comparable complication rates, mini-PNL has higher intraoperative complications and longer hospital stays. Additionally, stone recurrence is more common after SWL compared to mini-PNL.*

KEY WORDS: *Children; Kidney; Stone; Percutaneous; Shock wave; Lithotripsy.*

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INTRODUCTION

Extracorporeal *shockwave lithotripsy* (SWL) has traditionally been regarded as the primary treatment for pediatric urolithiasis smaller than 20 mm. (1). There is an increasing inclination towards using endourological techniques in managing pediatric urolithiasis, owing to technological advancements and the smaller size of instruments. SWL, *percutaneous nephrolithotomy* (PNL), and *retrograde intrarenal surgery* (RIRS) have become standard treatment options for both adults and children with urinary stones. SWL remains the preferred method for pediatric renal stones because it is the least invasive option for treating pediatric urolithiasis (2, 3). However, the elevated rates of retreatment and the possible adverse biological effects on developing kidneys and surrounding tissues may restrict the applicability of SWL (4). When compared to PNL and *ureteroscopy* (URS), studies indicate that SWL has a lower incidence of complications, particularly in pediatric patients; the complication rate following SWL in children ranges from 1.5% to 35%. The most common complications include renal colic and steinstrasse (5). Mini-PNL is generally recognized as the preferred treatment for most renal stones in children. It demonstrates efficacy and safety, exhibiting a complication rate ranging 15% to 39%. While most complications are minor, factors such as operative duration, sheath size, and partial staghorn formation are independent predictors of complications as shown in multivariate analysis (6).

We aimed to compare the outcomes of mini-PNL and SWL in treating pediatric renal stones between 10 and 20 mm in diameter, as regards effectiveness, morbidity, and stone recurrence.

PATIENTS AND METHODS

A prospective, randomized, superiority trial was conducted at the *Department of Urology, Al-Azhar University Hospital, Assuit, Egypt*, from December 2021 to November 2024, having received approval from the local Ethics Committee (approval number is MD/AZ.AST./URO016/5/217/3/2023).

Informed written consent for participation in the intervention and inclusion in the study was obtained from all parents.

Patient enrollment and patient allocation

The study included all pediatric patients (under 18 years of age) presenting with a solitary renal stone measuring between 10 and 20 mm in diameter and amenable to surgical intervention. Group I included patients who underwent mini-percutaneous nephrolithotomy (mini-PNL), while Group II included those managed with extracorporeal *shock wave lithotripsy* (SWL).

In the entire cohort, we excluded patients with untreated *urinary tract infections* (UTI) and coagulopathy. For the mini-PNL Group, we excluded patients with severe orthopedic deformities, congenital renal anomalies, comorbidities that would contraindicate general anesthesia or prone positioning, as well as concomitant pathologies requiring intervention during the same surgical session, such as pelvi-ureteric junction obstruction and stones located within a calyceal diverticulum. In the SWL Group, patients with distal obstruction and renal artery aneurysms were excluded.

The sample size for the present study was determined using the G*Power software application (*G*Power for Mac OS X*), with an effect size set at 0.5 and a statistical power of 80%. The estimated population consisted of 130 individuals, who were randomly assigned to two equal parallel groups through the block randomization method.

All patients underwent a comprehensive assessment, which included a detailed medical history, routine preoperative laboratory tests, KUB X-rays (kidney, ureter, and bladder), and ultrasounds. A non-enhanced *computed tomography* (CT) scan of the urinary tract confirmed the diagnosis of stone disease. A contrast-enhanced CT study was considered when detailed calyceal anatomy was needed.

Surgical procedure

Mini-PNL technique

The procedure was conducted under general anesthesia, with each phase guided by fluoroscopic imaging. All instruments, including dilators, dilator sheaths, trocars, graspers, and a mini nephroscope, were supplied by *Karl Storz, Germany*. The patients were positioned in lithotomy, and a 5 F retrograde ureteric catheter was advanced into the pelvi-calyceal system. Subsequently, a Foley catheter was inserted, the size of which was determined based on the patient's age and urethral diameter, and it was secured to the ureteric catheter to prevent accidental displacement during the intervention.

Following this, the patient was repositioned to a prone position, ensuring that appropriate cushioning was utilized at potential pressure points. The pelvi-calyceal system was opacified through the injection of radiographic contrast via the ureteric catheter. A mobile fluoroscopy C-arm facilitated the identification of the specific calyx designated for puncture, allowing for the insertion of the initial puncture needle. A wire was then passed down the ureter if anatomically feasible, after which the puncture needle was removed.

An incision was made in the skin using an 11 F blade scalpel, followed by dilation of the tract with a metal dilator up to 18 F. An Amplatz sheath (20 F) was then inserted, and a 16 F nephroscope was introduced through the sheath for examination of the collecting system.

Continuous irrigation was maintained using an isotonic solution. The stones were localized and subsequently fragmented using a pneumatic lithotripter, with fragments being extracted from the collecting system using pediatric nephroscope forceps (5 F). The completeness of the stone clearance was assessed through both direct endoscopic visualization and fluoroscopic guidance. Finally, a *double-J* (DJ) ureteral stent (*6 F, 24 cm, Percuflex; Boston Scientific*) was placed as clinically indicated, and a nephrostomy tube was positioned within the collecting system to ensure adequate drainage.

SWL technique

The procedure was performed under general anesthesia or sedoanalgesia in older children, using the Richard Wolf PiezoLith 3000Plus lithotripter. Patients were placed in a supine position, and ultrasound was utilized for stone localization to minimize radiation exposure.

The shockwave therapy began at an initial power level of 14 kV and gradually increased to a maximum of 20 kV. The maximum number of shocks administered per session ranged from 1,000 to 2,500, depending on the patient's age. Specifically, 1,000 shocks were given per session for children younger than 5 years, while 2,500 shocks were provided for older children, at a frequency of 60 to 90 shocks per minute. The session was stopped either when no visible stones or when the desired number of shocks was reached.

Outcome and follow-up

In the mini-PNL group, *complete blood count* (CBC) was performed within the first 24 hours. KUB X-ray and ultrasound after 24 hours and at 1, 3, 6, 12, 18, 24 months.

In the SWL group: KUB X-ray, and ultrasound after 2 weeks, 3, 6, 12, 18, 24 months post last session.

We defined the *stone-free rate* (SFR) as residual fragments less than 4 mm or absent residual fragments (7).

We defined the stone recurrence as an acute symptomatic episode with imaging confirmation or self-reported passage of a stone, or detection of a new stone by imaging in a symptomatic child during follow-up.

The primary endpoint was the *stone-free rate* (SFR) eight weeks after the procedure. The secondary endpoints were operative time, hospital stay, and postoperative complications.

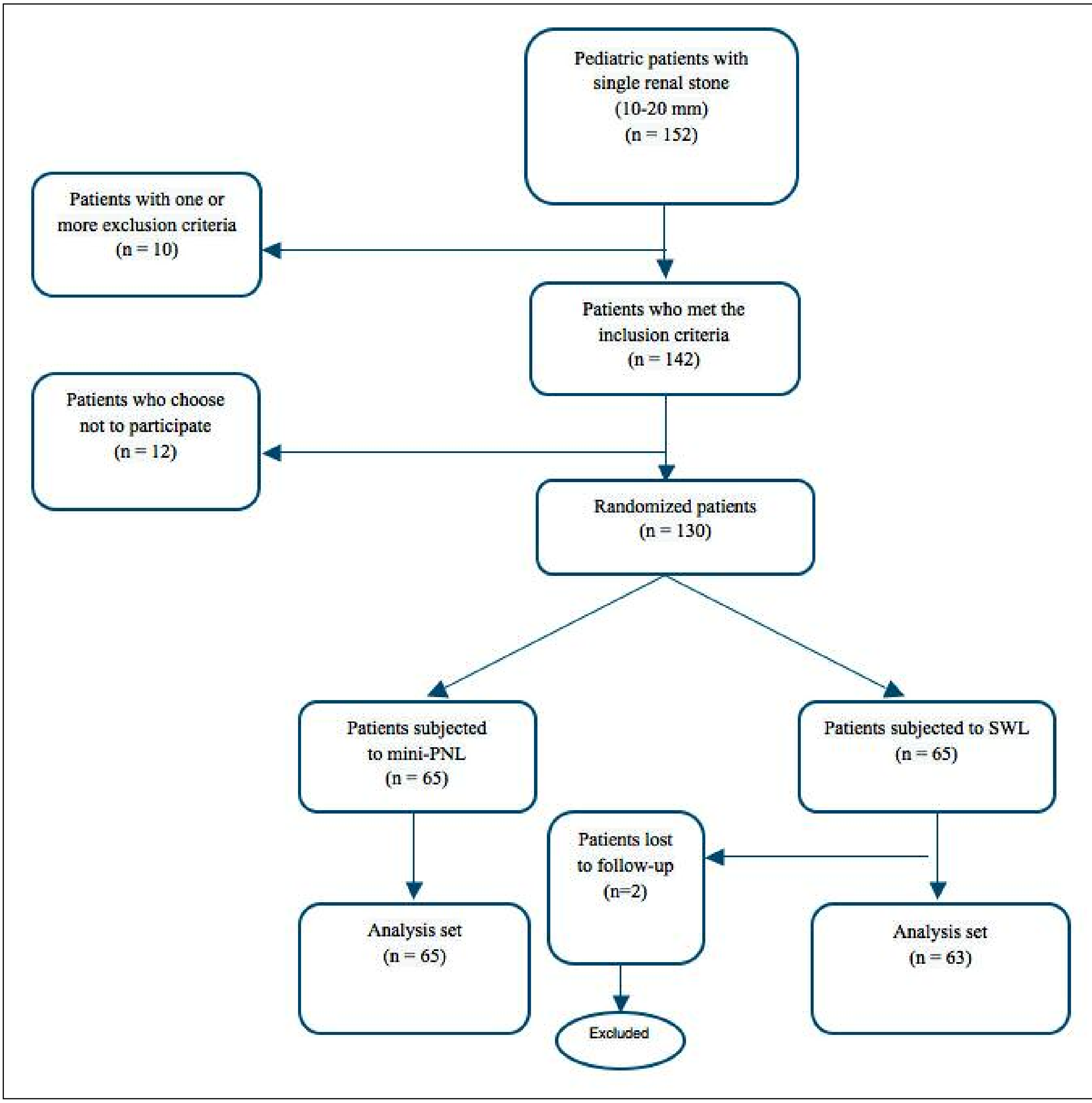
Metabolic workup was performed for all children and included serum calcium, phosphorus, sodium, chloride, serum *parathormone* (PTH), vitamin D, creatinine, urea, and uric acid; in addition to urine analysis, 24-hour urine analysis, and stone analysis.

The study arms were compared regarding patient demographics, stone characteristics, operative time, hospitalization time, hemoglobin drop, perioperative complications according to the *modified Clavien classification system* (MCCS) (8), stone-free status, and stone recurrence rates at 2-year follow-up.

Statistical analysis

The data analysis was conducted using version 29 of the Statistical Package for Social Science (*SPSS Inc., Chicago, IL, USA*). Numeric variables were represented using mean

Figure 1.
Flow chart of the study population.



and standard deviation, while categorical variables were expressed through frequency and percentage. The Chi-square test was utilized to examine the association between two nominal variables. Meanwhile, the Student's t-test was used to determine the significance of difference between the means of continuous variables across different groups. A p-value of less than 0.05 was considered statistically significant.

RESULTS

One hundred twenty-eight patients were included in the study. The mean age of the patients ± SD was 8.48 ± 4.08 years, and the mean size of the stones was 17.13 ± 2.45 millimeters. The entire cohort included 77 (60.2%) males and 51 (39.85%) females.

Group I included 65 patients who underwent mini-PNL, while Group II included 63 patients who underwent SWL (Figure 1).

The study groups had comparable demographics and stone characteristics, as depicted in Table 1.

In Group II, six cases (9.5%) required pre-SWL DJ ureteral stenting in a separate session due to obstructive uropathy. Three SWL sessions were performed for 52 cases (82.5%), two sessions for 9 cases (14.3%), and only one session for 2 cases (3.2%).

The mean operative time was significantly lower in Group I than in Group II (51.38 ± 14.02 min *vs.* 63.70 ± 16.90

Table 1.
Comparison of patient demographics and stone criteria between the study groups.

Parameter	Total (n = 128)	Group I (mini-PNL) (n = 65)	Group II (SWL) (n = 63)	P-value
Age, years	8.48 ± 4.08	8.50 ± 5.02	9.38 ± 4.56	0.1
Gender				
Male	77 (60.2%)	38 (58.5%)	39 (61.9%)	0.452
Female	51 (39.8%)	27 (41.5%)	24 (38.1%)	
Side of stone				
Right	50 (39.1%)	25 (38.5%)	25 (39.7%)	0.389
Left	78 (60.9%)	40 (61.5%)	38 (60.3%)	
Stone size, mm	17.13 ± 2.45	17.29 ± 2.41	16.97 ± 2.52	0.637
Stone radio-density, HFU	1308.04 ± 245.5	1288.76 ± 264.4	1328.42 ± 226.6	0.857
Stone x-ray appearance				
Radiopaque	84 (65.6%)	41 (63.1%)	43 (68.3%)	0.330
Radiolucent	44 (34.4%)	24 (36.9%)	20 (31.7%)	
Preoperative serum creatinine, mg/dl	1.04 ± 0.34	1.02 ± 0.31	1.05 ± 0.37	0.210
Preoperative hemoglobin, gm/dL	13.37 ± 0.78	13.31 ± 0.75	13.44 ± 0.89	0.208

Chi-square test and independent sample t-test were used.

Table 2.
Comparison of Intraoperative, postoperative data, and stone-free status among the study groups

Parameter	Group I (mini-PNL) (n = 65)	Group II (SWL) (n = 63)	P-value
Operative time, min	51.38 ± 14.02	63.70 ±16.90	0.001
Fluoroscopy time,seconds	199.41 ± 98.78	0	< 0.001
Hemoglobin drop, gm	1.24 ± 1.46	0.2±0.1	< 0.001
Hospitalization time.hours	98.16 ± 21.6	6 ± 1.5	< 0.001
SFR at follow-up week 8	61 (93.8%)	26 (41.3%)	< 0.001
Stone recurrence at 2 years	4 (6.1%)	10 (15.8%)	0.005

Chi-square test and independent sample t-test were used.

Table 3.
Comparison between the study groups regarding complications.

Parameter	Group I (mini-PNL) (n = 65)	Group II (SWL) (n = 63)	P-value
Overall complications	17 (26.2%)	13 (20.6%)	0.461
Intraoperative complications	7 (10.8%)	0 (0)	0.007
Postoperative complications	10 (15.4%)	13 (20.6%)	0.439
MCCS grading of complications			
Grade I			
Perforation	3 (4.6%)	0	0.084
Transient u_rine leak	4 (6.2%)	0	0.045
Persistent renal colic	0	3 (4.8%)	0.075
Subcapsular hematoma	0	2 (3.2%)	0.144
Grade II			
UTI	6 (9.2%)	4 (6.4%)	0.544
Hematuria (blood transfusion)	4 (6.2%)	0	0.084
Grade IIIb			
Steinstrasse	0	4 (6.4%)	0.039
Readmission (within 8 weeks)	0	5 (7.9%)	0.021

Chi-square test was used.

min, respectively, p = 0.001), and the mean radiation exposure and hospital stay were significantly lower in Group II, as illustrated in Table 2.

Postoperative mean hemoglobin drop was higher in Group I (1.24 ± 1.46 gm/dl) compared to Group II (0.2 ± 0.1) (p < 0.001). Blood transfusion was necessary for frank hematuria and significant hemoglobin drop in 4 cases (6.2%) in Group I compared to no cases in Group II, with a statistically significant difference (p = 0.039).

We reported a perioperative complication rate of 26.2% in Group I compared to 20.6% in Group II, with a statistically insignificant difference (p = 0.461).

However, intraoperative complications were significantly higher in Group I, being reported in 7 cases (10.8%), compared to no cases in Group II p = 0.007). On the other hand, postoperative complications were comparable between the study arms being reported in 15.4% and 20.6% in Group I and II, respectively (p = 0.439), as depicted in Table 3.

Most reported complications were MCCS grades I and II and were managed conservatively. Hospital readmission was required for 5 cases in Group II (6.4%), including one patient admitted due to UTI requiring medical treatment, and four patients with loin pain and "*steinstrasse*" who underwent ureteroscopy (Table 3).

The stone-free rate after eight weeks was 93.8% and 41.3% for group I and II, respectively, with a statistically significant difference (p < 0.001) (Table 2).

Significant residual stones in the mini-PNL Group (n = 4) were treated with SWL,

while patients with failed SWL (n = 37) were later managed with mini-PNL.
The stone recurrence was reported in 4 cases (6.1%) in Group I compared to 10 cases (15.8%) in Group II, with a statistically significant difference ($p = 0.005$).
The metabolic abnormality among stone recurrence cases was idiopathic hypercalciuria in 7 children (50%), hypercalcemic hypercalciuria in 3 children (21.4%), hyperoxaluria in 3 children (21.4%), and hypocitraturia in one child (7%).

Discussion

Pediatric urolithiasis often occurs with metabolic and anatomical abnormalities. This increases the risk of recurrence, requiring a treatment strategy that should be minimally invasive, with a high stone-free rate and a low retreatment rate (9).
While SWL is commonly used as the primary treatment for renal stones in children, any remaining stones after the procedure can cause a stone recurrence and additional retreatment. Additionally, the long-term safety of SWL remains uncertain (9).
The gradual adoption of PNL in pediatric practice has historically been hindered by concerns related to the small size of pediatric kidneys, the use of comparatively large instruments, the risk of radiation exposure, and the potential for significant complications. However, the advent of the mini-PNL technique has introduced notable advantages, including smaller tract size, diminished postoperative pain, reduced hemorrhage, and abbreviated hospital stays, thereby establishing it as a compelling option for pediatric patients (10).
In the present study, we evaluated the safety and efficacy of SWL and mini-PNL in the management of pediatric renal stone disease with stone sizes ranging from 1 to 2 cm. Our investigation included an assessment of the recurrence rates following both procedures over a two-year follow-up period.
The findings demonstrate that mini-PNL exhibits superior efficacy, achieving a significantly higher SFR of 93.8% in comparison to 41.3% for SWL. Notably, all patients in the SWL arm received treatment utilizing ultrasound guidance, resulting in less radiation exposure in comparison to mini-PNL group.
In the SWL arm, no complications were reported during the procedure; however, 13 patients experienced post-procedure complications, representing a rate of 20.6%. The complications included persistent renal pain in three patients (4.8%), pyelonephritis in four patients (6.1%), "*steinstrasse*" in four patients (6.4%), and subcapsular hematoma in two patients (3.2%).
Conversely, in the mini-PNL group, 17 patients experienced complications, resulting in an overall complication rate of 26.2%. Intraoperative complications occurred in 10.8% of cases, which included renal pelvis perforation in three patients and bleeding requiring blood transfusion in four patients. Postoperative complications occurred in 15.4%, including fever in six patients and transient urine leakage in four patients. Statistical analysis revealed no significant difference in overall and postoperative complication rates between the two groups; however, the mini-PNL group experienced a significantly higher rate of intraoperative complications.
Numerous studies have compared the outcomes of SWL and mini-PNL in the treatment of renal stones in the pediatric population. The success rate for SWL has been reported to range from 43.8% to 84.9%, whereas mini-PNL has demonstrated success rates between 86.6% and 94.3% (11-15). In our study, a lower success rate was noted for SWL. This disparity may be attributed to factors such as the relatively smaller stone size, variations in stone densities, and the specific type of lithotripsy equipment utilized.
Postoperative complications have been reported in 4.9% to 22.2% of mini-PNL procedures, in contrast to a range of 1.1% to 14.8% observed in SWL. Intraoperative complications occur more frequently in mini-PNL procedures, while SWL is associated with a higher incidence of postoperative complications, primarily manifesting as loin pain and "*steinstrasse*" (11-14). The complications we reported were comparable to those identified in the existing literature.
Assessment of stone recurrence after mini-PNL and SWL in pediatric population was part of our study novelty, as they were seldomely assessed in literature. We reported that overall recurrence rate after two years was 15.8% in SWL group and 6.1% in mini-PNL group ($p < 0.005$). The total recurrence was 10.9% and early recurrence noticed in SWL group with two children having recurrence of stone disease at 6 months follow-up. We suspect that the cause is the presence of insignificant residual stones post-SWL, which serve as a nidus for recurrent stones. The most common metabolic abnormality among recurrent cases was idiopathic hypercalciuria that was observed in 50% of cases.
A recent study by *Tasian et al.* at the Children's Hospital of Philadelphia found a recurrence rate of symptomatic kidney stones of 17% in children aged 3-18 years at 3 year from their first renal stone episode. However, the study was limited to recurrent symptomatic cases with flank pain or vomiting (15).

Declarations

Ethical approval and consent for participate: *The research adhered to the ethical guidelines outlined in the Declaration of Helsinki and received approval from the Institutional Review Board of the Authors' Institute (MD/AZ.AST./URO016/5/217/3/2023).*

Consent for publication: *All parents signed the consents.*

Availability of data and material: *Available from the corresponding author on reasonable request.*

Competing interests: *No conflict of interest.*

Funding: *None.*

Authors' contributions: *All authors have made significant contributions to the study's conception, design, methodology, data acquisition, analysis, review, and interpretation. They have all read and approved the final version of the article.*

Ingvarsdottir et al. reviewed 190 individuals with idiopathic kidney stone disease who had their first stone before age 18 between 1985 and 2013, finding a 26% recurrence rate after 5 years. They identified higher urinary calcium excretion as a common metabolic issue among recurrent stone formers, but noted that retrospective data limitations impacted their findings on metabolic risk factors (16).

Limitations of the study

The current prospective randomized superiority trial is subject to several limitations, including the participation of a single surgeon, which may introduce potential bias and limited generalizability. Furthermore, the follow-up period for evaluating stone recurrence was relatively brief, as assessments were conducted only up to two years.

Conclusions

Mini-percutaneous nephrolithotomy demonstrates a superior stone-free rate compared to shock wave lithotripsy in the management of 10-20 mm renal stones within the pediatric population. The overall incidence of procedure-related complications is comparable between both techniques, although it is noteworthy that intraoperative complications and hospital stays were significantly greater following mini-PNL. Furthermore, the stone recurrence rate is higher after SWL than after mini-PNL.

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