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ORIGINAL ARTICLE

Is mini-percutaneous nephrolithotomy a safe alternative to extracorporeal shockwave lithotripsy in pediatric age group in borderline stones? a randomized prospective study

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Abstract

Purpose The extracorporeal shockwave lithotripsy (ESWL) remains the most common first line of treatment for renal stones in the pediatric population. The purpose of this study is to evaluate and compare the outcomes of the ESWL and mini-percutaneous nephrolithotomy (mini-PCNL).

Patients and methods A total of 108 patients younger than 12 years of age with 1–2 cm single renal stone (pelvic or calyceal) were randomized into two groups, each containing 54 patients. Patients in group A were subjected to mini-PCNL using 16.5 Fr percutaneous sheath while those in group B underwent ESWL using Dornier Compact Sigma.

Results The stone-free rate (SFR) after first session was 88.9% (48 cases) and 55.6% (30 cases) for groups A and B, respectively. The difference is highly statistically significant $P = 0.006$. Two patients (3.7%) in group A needed 2nd session of PCNL, while 18 patients (33.3%)in group B needed a 2nd session, of theses 18 patients six patients needed a 3rd session of ESWL. After the third session of ESWL and second look PCNL the stone-free rates were 92.59% (50 cases) and 88.89% (48 cases) for groups A and B, respectively, ($P = 0.639$), which is statistically insignificant. The mean hospital stay and fluoroscopy exposure were significantly longer in the mini-PCNL group. The complication rate in groups A and group B were (22.2%) and (14.8%), respectively, which is statistically insignificant ($P = 0.484$).

Conclusions According to Clavien grade of complications mini-PCNL is a safe procedure, and after three session of ESWL, mini-PCNL has a similar stone-free rate with a lower retreatment rate. However, the mini-PCNL has more radiation exposure, and requires a longer hospital stay.

Keywords Mini-percutaneous nephrolithotomy · ESWL · Extracorporeal shock wave lithotrips · Pediatric renal stone · Endourology

Abbreviations

PCNL	Percutaneous nephrolithotomy
ESWL	Extracorporeal shockwave lithotripsy
YAG	Neodymium-doped yttrium aluminium garnet
CIRF	Clinically insignificant residual fragments
KUB	Kidneys, ureters and bladder
US	Ultrasonography
SFR	Stone-free rate

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Introduction

The incidence of pediatric renal stones has increased at an annual rate of about 6–10% and is currently 50 per 100,000 [1]. Such stones can be managed either by extracorporeal shockwave lithotripsy (ESWL), retrograde intrarenal surgery (RIRS), percutaneous nephrolithotomy (PCNL), or open, laparoscopic and robotic surgery [2].

ESWL is the first line of treatment for pediatric renal stones because it carries the advantages of a shorter hospital stay, rapid recovery, minimal morbidity, acceptable success rates and generally has a high safety profile [3]. Additionally, the anatomic characteristics of the infant body such as the small size and increased peristalsis and flexibility of the child's ureter make ESWL the main and favored type of treatment [4].

On the other hand, ESWL in pediatric age group need general anesthesia and may also need multiple sessions [5]. Some data suggest a possible increase in the risks of hypertension, diabetes mellitus, arteriosclerosis, and long term renal tubular injury in children treated with ESWL [6].

PCNL is associated with significant morbidity such as sepsis, bleeding, and injury to surrounding viscera [7]. Most of these complications are related to tract formation and size [8]. But advancements in instrumentation such as small nephroscopes and availability of more efficient energy sources for intracorporeal lithotripsy such as the holmium: YAG laser have enabled endourological procedures in children to be safely and effectively performed with mini-PCNL techniques [9].

And yet, the slow acceptance of PCNL in the management of pediatric renal stone is associated with its low safety profile. Because of that, our primary end point in this study was to investigate the safety of the mini-PCNL as regards to possible complications, the need for retreatment and auxiliary treatment compared to ESWL. The secondary end point was to evaluate the effectiveness of both approaches.

Patients and methods

Sample size was calculated using the Stata program "StataCorp. 2001. Statistical Software: Release 7.0. College Station, TX: Stata Corporation," and had the following settings: the type-1 error (α) was set to 0.05 and the power (1-β) at 0.8. Results from a previous study Zeng et al. [10] showed that complication rate, primary end point in our study, for the mini-PCNL group was 16 and 45.5% for the ESWL group. Calculations based on these values produced a minimal sample size of 44 cases for each group.

Between June 2012 and December 2016, 212 pediatric patients were presented to urology department at Ain Shams University Hospital with renal stone. Of those, 108 patients were included in the study based on the following inclusion and exclusion criteria:

Inclusion criteria are:
- Children from ages 2 to 12
- Single renal stone "pelvic or calyceal"
- Stone diameter between 1 and 2 cm in the longest axis of ultrasound

The exclusion criteria are:
- Children younger than 2 years old
- Stone larger than 2 cm
- Radiolucent stones
- Unfavorable anatomy for ESWL such as narrow infundibular neck and acute infundibular angle
- Co-existing renal anomalies
- Uncorrectable bleeding disorders
- Musculoskeletal deformities
- Patients with ureteral stones or ureteral obstructions

The parents, from which consent forms were obtained, were fully informed about both procedures chances for success or complication. Patients were randomized according to a simple 1:1 randomization and alternated between the two groups. Group A patients were subjected to mini-PCNL, and group B patients to ESWL.

All patients were assessed preoperatively by detailed medical history, physical examination, urinalysis, urine culture, radiography of the kidneys, ureters and bladder (KUB), renal ultrasonography (US) and a computerized tomography of the urinary with contrast to assess the favorable anatomy for ESWL, as well as a routine preoperative evaluation. The study design and workflow is summarized in CONSORT flow chart (Fig. 1).

Mini-PCNL technique

After the induction of general anesthesia, a 5-Fr open-ended ureteral catheter was advanced to the renal pelvis, left in situ,

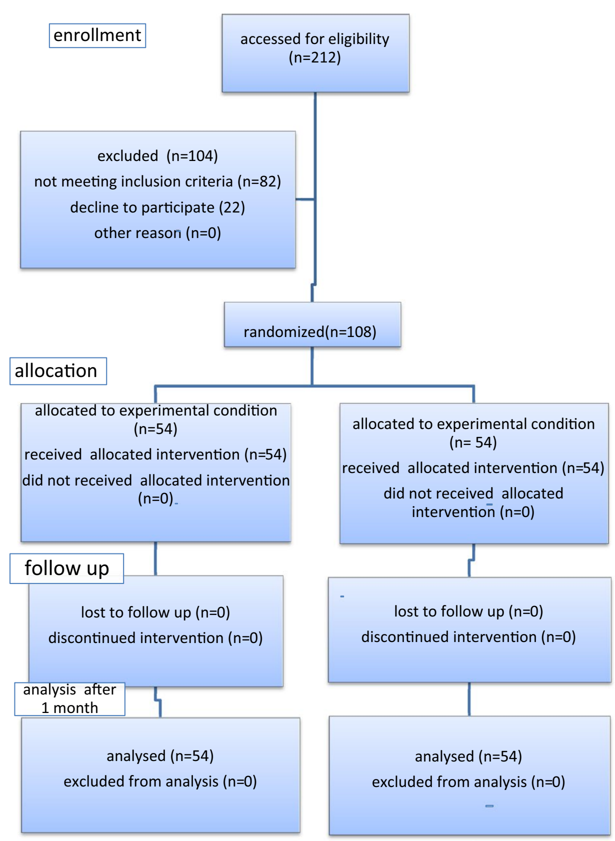


Fig. 1 Consort flow chart

and a retrograde pyelogram was performed. A Foley catheter was inserted and taped to the ureteric catheter.

Patients were then repositioned in the prone position. The renal collecting system was opacified, and a mobile fluoroscopy C-arm was used to identify the calyx to be punctured. Using a 18G sheathed needle, the selected calyx was punctured under fluoroscopic guidance. Following successful access, a 0.035″ guidewire was advanced through the puncture needle into the kidney and down the ureter (in cases where there was difficulty passing the guidewire down the ureter, it was passed into the upper calyx).

Afterwards, the track was dilated sequentially using fascial dilators and a 16.5 Fr sheath was advanced over its metal dilator under fluoroscopic guidance. Standard 12-Fr rigid nephroscope (Karl Storz) was used for stone fragmentation and retrieval. The holmium: YAG laser was used to perform the stone fragmentation and stone retrieval forceps to extract the fragments, in addition to hand wash. Retrograde was done at the end of the operation to assess the integrity of the collecting system. Stone clearance was assessed at the end of the procedure by a combination of fluoroscopy and rigid nephroscopy. The procedure was done by the same surgeon.

Once satisfactory stone clearance was achieved, a cut tip, a Nelaton catheter (12ch), was placed as a covering nephrostomy and clamped routinely for 24 h then removed. The end flushing ureteric catheter was removed 48 h after the procedure.

24 h after treatment, patients were routinely evaluated by (KUB) and ultrasonography to assess the need for a second look, and then again at 1 month to identify stone-free rates.

Asymptomatic residual fragments smaller than 5 mm were designated as clinically insignificant residual fragments (CIRF).

ESWL technique

After general anesthesia, lithotripsy was performed by an electromagnetic shockwave lithotripter (Dornier Compact Sigma). The lung and genitourinary fields were shielded for all patients. Fluoroscopy was used to localize the stone and to monitor fragmentation.

The dispensed shockwave begins at 14 kV and escalates to its maximum power level of 20 kV. The maximum number of shocks given per session was between 1000 and 2500 depending on patient age (1000 waves per session for children younger than 5 years and 2500 waves per session for older children, with a frequency of 70 shocks/minute) [11]. The ESWL session is stopped when no visible stone is detected, or when tiny fragments are the only visible stone remnants, or when the desired number of shocks had been given.

Patients were assessed 2 weeks after the ESWL session by KUB and US to assess stone-free status. Additional ESWL sessions were performed in the presence of fragments > 5 mm or in the case of a failure in the initial session.

In the case of ESWL failure after three sessions, patients were offered other treatment modalities.

ESWL was considered a success when it achieved a stone-free status or resulted in clinically insignificant residual fragments < 5 mm after maximum three sessions without a need for auxiliary procedure.

The following data were recorded: patient age, gender, BMI, patient's complain, stone location and diameter, stone clearance rate, need for retreatment, auxiliary procedures, operative and postoperative complications, duration of the procedure and general anesthesia, hospital stay and fluoroscopy time.

The collected data were revised, coded and entered to the Statistical Package for Social Science (IBM SPSS) version 20. Qualitative data were presented as number and percentages while quantitative data were presented as mean, standard deviations and ranges. Comparisons between the two groups were done using Student's *t* test for parametric quantitative variables and Wilcoxon Mann–Whitney test for non-parametric continuous variables, while qualitative data were compared using χ^2 test or alternatively, the Fisher exact test when the expected count in any cell was found to be less than 5. The confidence interval was set to 95% and the accepted margin of error was set to 5%. The *P* value was considered significant as the following: $P > 0.05$: Non significant, $P < 0.05$: Significant and $P < 0.01$: Highly significant.

Results

There were no statistically significant differences between the two groups with regards to the patients' demography, their presentation and stone characteristics, showed in Table 1.

After the first session, the SFR between patients in both groups was highly statistically significant which became statistically insignificant after the third session. In contrast, the difference of SFR for patients with pelvic stones between the two groups after the first session was statistically insignificant. On the other hand, in patients with calyceal stones, the difference in SFR after the first session was highly statistically significant but became statistically insignificant after the third session as seen in Table 2 and Figs. 2, 3 and 4.

So, the need for retreatment "second session" in group B was higher than group A and this was statistically highly significant. The result was also statistically significant for patient with pelvic and lower calyceal subgroups as seen in Table 3.

Auxiliary treatment was required in four patients (7.4%) in group A in comparison to six patients (11.11%) in

Table 1 Patient characteristics, presentation and stone character

Patient characteristics	Group A No. = 54	Group B No. = 54	P value
Age			
Mean ± SD	6.48 ± 2.94	5.52 ± 2.69	0.215
Range	3–12	2–11	
Gender			
Female	20 (37.0%)	14 (25.9%)	0.379
Male	34 (63.0%)	40 (74.1%)	
BMI			
Mean ± SD	20.15 ± 2.05	20.30 ± 2.20	0.799
Range	17–23	17–23	

Patient complaint	Group A		Group B		P value
	No.	%	No.	%	
Hematuria	22	40.7	30	55.6	0.276
Pain	16	29.6	10	18.5	0.340
UTI	16	29.6	14	25.9	0.761

Stone characteristics	Group A No. = 54	Group B No. = 54	P value
Side			
Left	24 (44.4%)	18 (33.3%)	0.402
Right	30 (55.6%)	36 (66.7%)	
Pelvic	40 (74.1%)	42 (77.8%)	0.750
Lower Calyceal	14 (25.9%)	12 (22.2%)	0.750
Mean maximum stone diameter in u/s, cm			
Mean ± SD	1.59 ± 0.29	1.48 ± 0.26	0.147
Range	1.1–2	1.1–2	

group B ($P = 0.639$) which is statistically insignificant. In group A, all four patients required an auxiliary ESWL to be stone free. While in group B, four patients underwent mini-PCNL and two patients underwent ureteroscopy for stein-strasse formation to become stone free.

There were 12 total complications in group A (22.2%) and 8 in group B (14.8%) which is statistically insignificant ($P = 0.484$). In group A, six patients developed postoperative fever (11%) which required antibiotic and antipyretic, two patients (3.7%) suffered from significant bleeding requiring blood transfusion and a second look, two sustained renal pelvic perforation (3.7%) and were treated by leaving nephrostomy tube longer and another 2 (3.7%) developed perinephric hematoma that was treated conservatively. In group B, 2 patients developed post ESWL fever (3.7%) which required antibiotic and antipyretic, 2 patients (3.7%) complained of severe colicky pain that resolved with analgesic injection and four patients (7.4%) developed stein-strasse (two patients were treated conservatively and the other two failed to respond to conservative treatment and were further treated with ureteroscopy). we can summarized the complications according to Clavien classifications in Table 4.

There was a high statistical significant difference between the two groups for the duration of the procedure, duration of general anathesia, mean fluoroscopy time and the mean hospital stay in Table 4.

Discussion

The reported incidence of kidney stones in pediatric population is 50 cases per 100,000 child and is increasing [12].

Pediatric urolithiasis is often associated with metabolic and anatomic abnormalities or infectious disease. Consequently, the risk of recurrence is higher [13]. Because of that, it is important that the treatment be minimally invasive with a high SFR and a lower retreatment rate [6].

Although ESWL is utilized as the first line of treatment in children, any residual stone from the procedure can lead to recurrence, which challenges the professional ideal of minimizing the need for retreatment, especially in this age

Table 2 Stone-free rate

All patients	Group A		Group B		*P* value
	No. (54)	%	No. (54)	%	
Stone free after 1st session					
Positive	48	88.90	30	55.60	0.006
Negative	6	11.10	24	44.40	
Stone free after 2nd session					
Positive	50	92.59	42	77.78	0.125
Negative	4	7.41	12	22.22	
Stone free after 3rd session					
Positive	50	92.59	48	88.89	0.639
Negative	4	7.41	6	11.11	
Pelvic stones	Group A		Group B		*P* value
	No. (40)	%	No. (42)	%	
Stone free after 1st session					
Positive	34	85.0	26	61.9	0.095
Negative	6	15.0	16	38.1	
Stone free after 2nd session					
Positive	36	90.0	34	81.0	0.412
Negative	4	10.0	8	19.0	
Stone free after 3rd session					
Positive	36	90.0	38	90.5	0.956
Negative	4	10.0	4	9.5	
Lower calyceal stone	Group A		Group B		*P* value
	No. (14)	%	No. (12)	%	
Stone free after 1st session					
Positive	14	100.0	4	33.3	0.009
Negative	0	0.0	8	66.7	
Stone free after 2nd session					
Positive	14	100.0	8	66.7	0.096
Negative	0	0.0	4	33.3	
Stone free after 3rd session					
Positive	14	100.0	10	83.3	0.26
Negative	0	0.0	2	16.7	

group. Furthermore, the long term safety of ESWL has been questionable [6].

The slow acceptance of using PCNL in pediatrics went back to concerns regarding small kidney size, relatively large instruments, radiation exposure, and the risk of major complications [14]. But the mini–PCNL technique bought advantages such reduced pain, hemorrhage and sepsis, and a shorter hospital stay and made it into an attractive option, although this is somewhat limited by the longer operative time [15].

With regards to the first end point of our study on whether the mini-PCNL was a safe procedure in managing borderline pediatric renal stone of 1–2 cm, we found that the complication rates in mini-PCNL group were statistically insignificant in comparison to ESWL group. Complication rates were comparable to those found in published data, which ranged from 15 to 27.7% in mini-PCNL group [15, 17, 21, 29, 30], and from 12.5 to 17.8% in ESWL group. [15, 20, 24] Some reported lower complication rates in ESWL group ranging from 3.7 to 7.2% [24, 27, 29].

One of the main drawbacks of ESWL is the high retreatment rate. In our study the need for retreatment for pelvic and lower calyceal stones were significantly lower in mini-PCNL group as opposed to the ESWL group. Kumar et al. [29] reported that the retreatment in the lower calyceal stones was significantly greater in the ESWL group compared with the mini-PCNL group (41.5% vs 2.8, respectively).

Fig. 2 Stone-free rate

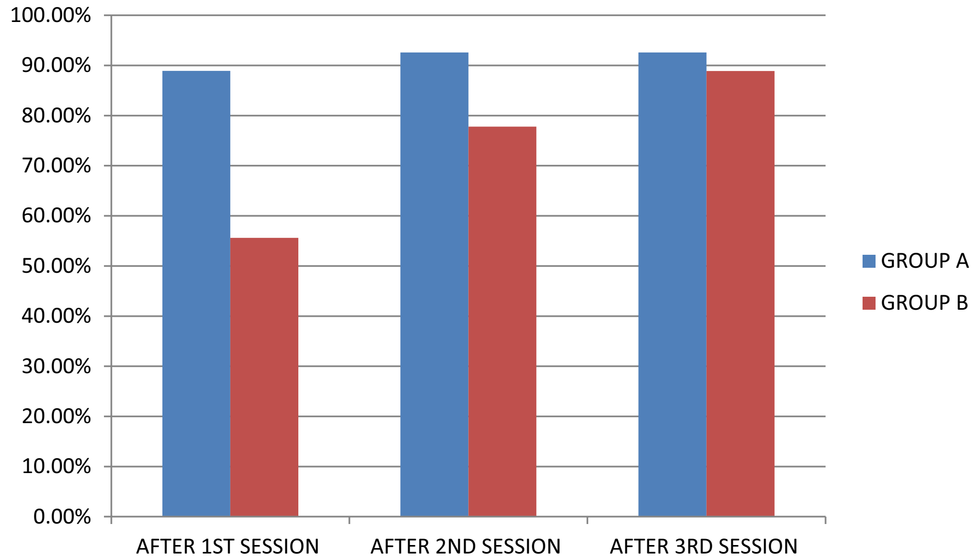
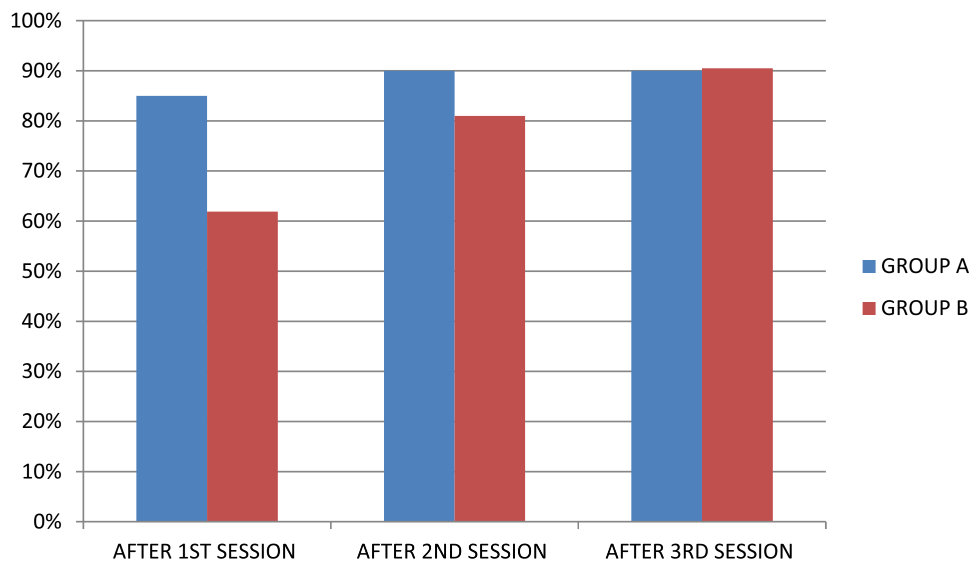


Fig. 3 Stone-free rate for pelvic stone



Similarly, Elsheemy et al. [17] reported the retreatment was significantly greater in the ESWL group compared with the mini-PCNL group for both pelvic and lower calyceal stones (46.2% vs 7.7% and 66.7 vs 6.7, respectively).

Kumar et al. [29] and Elsheemy et al. [17] reported that the auxiliary procedure rates was significantly greater in the ESWL group compared to the mini-PCNL group (14.2 vs 5.6%, respectively) and (9.4% vs 1.9, respectively). This data is different from our study, which was statistically insignificant for both groups and could owe to the high success rate of pelvic stone treatment in the ESWL group.

Regarding our second end point, the effectiveness and success of the treatment was best indicated by the high SFR. In the mini-PCNL group, the SFR after the second look was 92.59% for 50 cases. Most of the published data dealing with mini-PCNL reported success rates in the same neighborhood ranging from 83.3 to 100% [15–21]. The SFR in the ESWL group after the first session was comparable to most literature ranging from 43.8 to 60% [17, 22, 23]. SFR improved in most of the published data with repetition of ESWL as in ours with variable success rates ranging from 71 to 95.8% [17, 18, 22–28].

Treatment of the lower calyceal stones showed the advantage of mini-PCNL compared with ESWL. In our study the SFR for lower calyceal stones after the first session was a 100% in the mini-PCNL group, which was statistically highly significant in comparison to ESWL group. Comparable results were reported by Elsheemy et al. [17]; the SFRs for calyceal renal stone after the first session was 93.3% and 16.7% for (< 0.001) which increased after the third

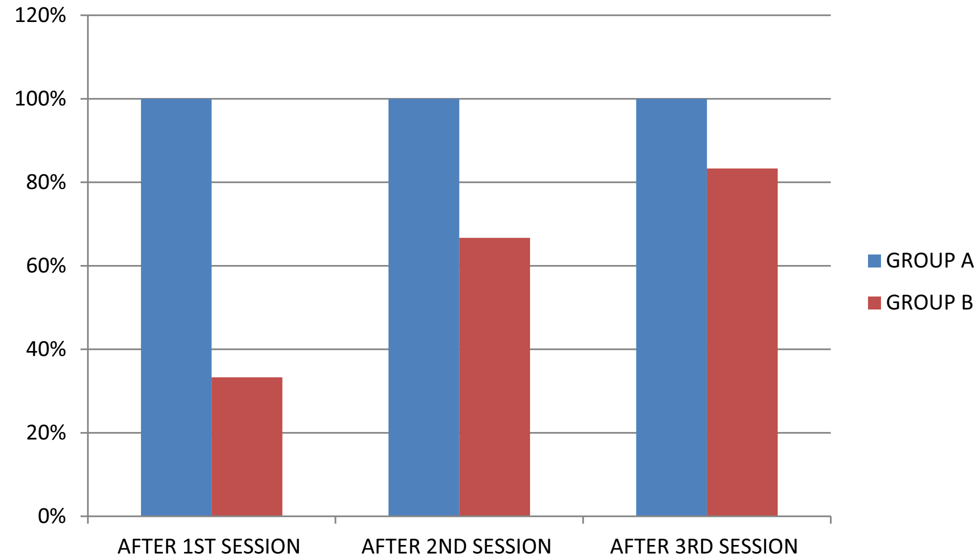


Fig. 4 Stone-free rate for lower calyceal stone

Table 3 Need for re-treatment

Re-treatment	Group A		Group B		*P* value
	No.	%	No.	%	
All patients	2	3.7	18	33.3	0.005
Pelvic	2	5.0	12	28.6	0.045
Calyceal	0	0.0	6	50.0	0.033

session to 93.3% and 66.7% for PCNL group and ESWL group, respectively. On the other hand, the difference in SFR for renal pelvic stone between both groups was statistically insignificant. Elsheemy et al. [17] reported the SFRs for pelvic renal stone after first session at 87 and 50%, and 94.9 and 84.6% after the third session for PCNL and ESWL group, respectively.

Table 4 Complications according to Clavien classifications, Fluoroscopy time, hospital stay, time of the procedure and duration of anesthesia

Complication grade	Group A No. %	Group B No. %	*P* value
I	2 (3.7%) pelvic perforation 2 (3.7%) perinephric hematoma	2 (3.7%) stein-strasse	
II	6 (11%) fever 2 (3.7%) bleeding	2 (3.7%) fever	
III	0	2 (3.7%) stein-strasse	
IIIa	0	0	
IIIb	0	2	
IV	0	0	
V	0	0	
Total complications	12 (22.2%)	8 (14.8%)	0.484

	Group A		Group B	*P* value
Fluoroscopy time in second	Mean ± SD	268.89 ± 66.35	79.07 ± 19.37	0.000
	Range	160–420	60–120	
Time of the procedure in minute	Mean ± SD	74.54 ± 8.61	25.06 ± 6.05	0.000
	Range	60–90	15–35	
Anesthetic exposure in minute	Mean ± SD	93.59 ± 9.49	40.65 ± 7.04	0.000
	Range	75–110	25–50	
Hospital stay in hours	Mean ± SD	63.70 ± 11.09	4.89 ± 0.97	0.000
	Range	40–84	4–7	

The mean fluoroscopy time was significantly higher in mini-PCNL group in comparison to ESWL group. This result is comparable with Karatag et al. [16] in group A and Hatipoglu et al. [22] in group B. Shorter mean fluoroscopy time was reported by Resorlu et al. [21] in mini-PCNL.

The mean hospital stay was longer in mini-PCNL group compared to ESWL group. Resorlu et al. [21] and D'Souza et al. [15] reported comparable results: 3.1 ± 1.2 days and 3 days, respectively, in mini-PCNL group. Others reported longer hospital stays [19, 30]. Hatipoglu et al. [22] reported longer mean hospital stay at 8.4 ± 2.3 (6–10) h per one session in the ESWL group.

We encountered several limitations in our study. The use of US to measure the longest axis of stone, the use of KUB and US to determine the SFR, lack of metabolic work up, shorter follow-ups and the lack of data on stone composition that could affect treatment outcome that we consider more significant.

Conclusion

Our study showed that mini-PCNL is a viable safe option for the treatment of borderline stones in pediatric patients. It has a definite advantage in lower calyceal stones. Additionally, the lower need for retreatment and auxiliary procedures in all stones add another benefit.

Author contributions AT Project development, Data management, Manuscript writing and editing; AF Project development, Data management; MS Project development, Data management; MM Project development, Data management; DM Project development, Data management; MH Data collection, Data analysis; HA Project development, Data management.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

The research involving human participants All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Ethical approval The study was approved by the local ethical committee of the hospital.

Informed consent Informed consent was obtained from all individual participants included in the study.

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