



# What is the optimal frequency in shock wave lithotripsy for pediatric renal stones? A prospective randomized study

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## Abstract

The aim of the study is to compare the effects of varying frequency rates (60, 90, and 120 SWs/min) on the stone free rate and complication rates of pediatric SWL. 75 children with renal stones were divided into 3 groups depending on the SW frequency applied. Group 1. low (60 SWs/min), Group 2. intermediate (90 SWs/min) and Group 3. high (120 SWs/min) frequency. Patient demographics (age, gender, BMI), stone (location, size, laterality), and SWL (total number of sessions, shock waves, anesthesia time) related parameters were documented. Postoperative success, complication rates, and the need for additional interventions were comparatively evaluated. There was no significant difference regarding the patient demographics, stone characteristics, SWL parameters, postoperative complication rates, need for additional interventions as well as efficacy quotient between all ( $p > 0.05$ ). The stone free rates were significantly lower in cases with high frequency, whereas there was no statistically significant difference between the intermediate and low frequency groups ( $p > 0.05$ ). Although not statistically significant; low frequency application may be more advantageous than intermediate as lower number of high energy shock waves required which may cause less tissue damage. On the other hand, despite lack of a statistically significant difference, relatively longer anesthesia time may constitute a disadvantage for lower frequency. We believe that considering the growing nature of the child kidney application of low frequency (60 SWs/min) will be advantageous. However, we believe that further studies with larger series of cases are needed to make a clear-cut differentiation between low and intermediate SW applications.

**Keywords** Pediatrics · High-energy shock waves · Lithotripsy · Kidney calculi · Urolithiasis

## Abbreviations

SWL	Shock wave lithotripsy
SWs/min	Shock waves per minute
EAU	European Association of Urology
KUB	Kidney–ureter–bladder
USG	Urinary system ultrasonography
BMI	Body mass index

## Introduction

Clinical introduction of shockwave lithotripsy (SWL) during the early 1980s changed the management principles of urinary stones to a certain extent. Following the successful results obtained in adult cases, pediatric SWL was first performed by Newman et al. in 1986 [1]. Regarding the evident increase in the incidence of pediatric stones [2], physicians always tried to apply less invasive procedures for stone treatment in these cases. Although SWL has not yet been approved by the US Food and Drug administration in children; sufficient data based on the well-conducted studies is available to demonstrate the efficacy and safety of this modality [3–9]. At present, SWL is accepted as the first line treatment modality in the majority of symptomatic pediatric upper tract calculi [10].

According to the currently available two nomograms; patient (age, gender, previous history), and stone (size, number, and location) related factors were found to be the independent prognostic factors to predict the stone clearance

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rates after pediatric SWL [10, 11]. Although the success of pediatric SWL seems to be mainly dependent on the stone characteristics; best clinical practice in terms of shock wave delivery rate (frequency) has also been found to be important on this aspect. Related with this issue; however, although current European Association of Urology (EAU) urolithiasis guidelines advise the reduction of the shock wave frequency from 120 shock waves per minute (SWs/min) to 60–90 SWs/min, to increase the stone free rates in adults no specific recommendations on this aspect are available for pediatric cases both in the EAU and also EAU pediatric urology guidelines [12].

Apart from this highly limited data reported so far in the literature, we could not find any single study focusing on the comparative evaluation of varying SWL frequencies as low (60 SWs/min), intermediate (90 SWs/min), and high (120 SWs/min) on the final outcomes of pediatric stone disintegration with SWL.

In this prospective randomized study, we aimed to compare the effects of low frequency (SWL at 60 SWs/min), intermediate frequency (SWL at 90 SWs/min), and high frequency (SWL at 120 SWs/min) rates on stone free and complications rates after SWL in pediatric cases.

## Patients and methods

A total of 75 consecutive pediatric patients presenting with solitary radiopaque renal stones (10–15 mm) to the urology clinic at Dr. Lutfi Kirdar Training and Research Hospital (between Jan 2016 and Jan 2020) were included into the program of this prospective randomized study. The study protocol was approved by the hospital ethics committee and all steps of the current study were planned and applied carefully according to the Helsinki Declaration. Depending on the high energy shock wave delivery rate during SWL management, these children were prospectively randomized (envelope method) into 3 different groups; Group 1 (*n* 25) as low frequency group (SWL at 60 SWs/min), group 2 (*n* 25) as intermediate frequency group (SWL at 90 SWs/min) and group 3 (*n* 25) as high frequency group (SWL at 120 SWs/min).

In addition to the history of previous SWL and/or other stone removal procedures, exclusion criteria included children presenting with multiple stones, evident hydronephrosis (moderate or severe) untreated active UTI, coagulopathy, bilateral renal stones, nonopaque stones, an anatomic abnormality in the ureter or ureteropelvic junction, nonfunctioning kidney, and severe skeletal malformations. Before SWL, in addition to routine biochemical tests, urinalysis, urine culture sensitivity test, bleeding–clotting times and electrocardiogram, radiologic evaluation with kidney–ureter–bladder (KUB) and/or urinary system

ultrasonography (USG) were performed in all cases. Low dose noncontrast spiral tomography was performed in cases with suspicion of obstruction if needed. Stone size was assessed as the largest diameter on radiographic images, including KUB and USG. Prior to the SWL, an informed consent stating all relevant information about the procedure, including possible adverse effects has been given to the parents and signed by them after careful reading and approval.

The SWL procedure was applied in supine position by using an electromagnetic shock wave generating system (Dornier Compact Sigma; Med Tech, Munich, Germany) up to a total of 2000–2500 SW (depending on the age of the child) per session with the same energy level (level 2, 0.029 J/SW) during all treatments. SWL treatment session was ended when complete fragmentation was noted on USG imaging and when the child became intolerable due to the distressing pain not allowing to stay still. Regarding the management of pediatric stones with SWL in compliance with our routine protocol, sedoanalgesia (ketamine 0.5–1.0 mg/kg and midazolam 0.05–0.1 mg/kg) was applied to limit the risk of distressing pain and patient movements. Stones were localized and treated under sonographic guidance to avoid radiation exposure in this specific population.

All children were evaluated 1 week after each session of procedure with KUB and USG to assess the presence of residual stone fragments and possible relevant obstruction. Depending on the stone fragmentation status, the SWL treatment was ended and follow-up is performed with residual fragments  $\leq 4$  mm. In cases of unsuccessful fragmentation and residual fragments  $> 4$  mm, further treatment with maximum 3 SWL sessions was performed each followed and assessed by USG. Final stone free status was assessed with USG after 3 months following the last session. Success of the procedure was assigned as “stone free” with no detectable stone fragment(s) or as “residual stones” with persistent stone fragments of any size on radiological evaluations.

Patient demographics including age, gender, body mass index (BMI), as well as stone features (location, size, and laterality) were all recorded. In addition, SWL parameters, including, total number of sessions, total number of shock waves, and total anesthesia time were documented. Postoperative complications (according to the modified Clavien classification) as well as the need for additional interventions were evaluated and noted in three groups. The efficacy of treatment at the 3-month follow up was evaluated by the efficacy quotient (EQ). ( $EQ = [\% \text{ stone free} / (\% 100 + \% \text{ retreatment} + \% \text{ auxiliary procedures})] \times 100$ ) [13].

Primary outcome measure was success rate, while secondary outcome measures included anesthesia time, complications, additional interventions, and efficiency quotient.

## Statistical analysis

The NCSS (Number Cruncher Statistical System, Kay-ville, UT) was used for the statistical analysis. The one-way ANOVA test was used for descriptive statistical methods (mean, median, standard deviation, frequency, ratio, minimum, and maximum) as well as quantitative data for normal distributions between three and more groups, whereas the Kruskal–Wallis test was used for quantitative data demonstrating uneven distributions between three and more groups. Chi-square test and Fisher–Freeman–Halton test were used for the comparison of qualitative data. Significance was evaluated at a  $p$  level of  $<0.05$ . Regarding the power analysis of our findings, in a similar study Salem et al. have revealed that a significant value (80% power rate) could be obtained with 21 cases included and evaluated in each arm of the study [14].

## Results

Seventy-five children with a mean age value of  $11.92 \pm 2.59$  (median age 11) years were included into the study program. 39 of the patients were girls and 36 were boys (M/F

0.9). Evaluation of our findings revealed no statistically significant difference regarding both the patient demographics (age, gender, and BMI), stone related factors (stone location, size, and laterality) and SWL parameters (total number of sessions, total number of shock waves, and total anesthesia time) as well between the groups ( $p > 0.05$ ) (Table 1).

Concerning the stone free status assessed in all three groups, a statistically significant difference was found between the groups ( $p < 0.05$ , Table 2). Stone free rates were significantly lower in cases treated with high SW frequency when compared with the other two (intermediate and low frequency) groups. However, there was no statistically significant difference between the intermediate and low frequency groups with respect to stone free rates ( $p > 0.05$ ).

Last but not least, there was no statistically significant difference between the three groups regarding the postoperative complication rates (according to the modified Clavien classification) and the need for additional interventions (respectively  $p = 0.499$ ,  $p = 0.276$ ). Some minor postoperative (Clavien Grade 1) complications namely pain, hematuria, and fever were noted in the majority of the cases and well managed by antipyretic as well as analgesic agents. In two cases; however (1 in group 2 and the other in group 3), Clavien Grade 2 complication requiring antibiotic use

**Table 1** Demographics, stone, and SWL data

	Group 60 ( $n = 25$ )	Group 90 ( $n = 25$ )	Group 120 ( $n = 25$ )	$p$
Age (years) Median (min–max)	3 (1–17)	4 (1–11)	3.5 (0–14)	<sup>a</sup> 0.833
Gender; $n$ (%)				<sup>c</sup> 0.326
Female	12 (30.8)	11 (28.2)	16 (41.0)	
Male	13 (36.1)	14 (38.9)	9 (25.0)	
BMI ( $\text{kg}/\text{m}^2$ ), Median (min–max)	18 (13.6–25.9)	15.9 (11.7–28.1)	15.9 (11.9–28.3)	<sup>b</sup> 0.349
Side; $n$ (%)				<sup>c</sup> 0.360
Right	11 (32.4)	9 (26.5)	14 (41.1)	
Left	14 (34.1)	16 (39.1)	11 (26.8)	
Stone size (mm), Mean $\pm$ SD	$10.29 \pm 3.47$	$9.98 \pm 2.50$	$11.23 \pm 3.65$	<sup>b</sup> 0.371
Location; $n$ (%)				<sup>d</sup> 0.961
Lower pole	5 (41.7)	4 (33.3)	3 (25.0)	
Mid calyx	7 (31.8)	8 (36.4)	7 (31.8)	
Upper calyx + pelvis	13 (31.7)	13 (31.7)	15 (36.6)	
Total number of shock waves Median (min–max)	2800 (1200–7800)	3100 (1100–6500)	3400 (1500–7060)	<sup>a</sup> 0.481
Total number of sessions Median (min–max)	2 (1–3)	2 (1–3)	2 (1–3)	<sup>a</sup> 0.592
Total anesthesia time (min) Median (min–max)	50 (17–122)	39 (14–100)	37 (18–84)	<sup>b</sup> 0.164

BMI body mass index

<sup>a</sup>Kruskal–Wallis test

<sup>b</sup>One-way ANOVA test

<sup>c</sup>Pearson Chi-square test

<sup>d</sup>Fisher–Freeman–Halton test

**Table 2** Treatment outcomes according to the groups

	Group 60 (n=25)	Group 90 (n=25)	Group 120 (n=25)	p
Success; n (%)	16 (64.0)	16 (64.0)	8 (32.0)	<sup>a</sup> 0.032*
SFR after first session	10	7	5	
SFR after second session	6	5	2	
SFR after third session	0	4	1	
Complications (Clavien); n (%)	11 (44.0)	7 (28.0)	9 (36.0)	<sup>a</sup> 0.499
Grade 1	11	6	8	
Grade 2	0	1	1	
Additional interventions; n (%)	1 (4.0)	3 (12.0)	5 (20.0)	<sup>b</sup> 0.276
URS	1	3	1	
PNL	0	0	4	
Efficiency quotient (EQ); (%)	%41	%36	%17	<sup>a</sup> 0.143

Success success was defined as stone free status (SFR), Complications according to a modified Clavien Classification, EQ [% stone free/(%100 + % retreatment + % auxiliary procedures)] × 100

\* $p < 0.05$

<sup>a</sup>Pearson Chi square test

<sup>b</sup>Fisher–Freeman–Halton test

was noted. On the other hand, URS was performed in 5 and PNL was performed in 4 cases to render the children stone free after unsuccessful SWL management. Most of the PNL procedures have been performed in cases treated with high frequency due to lower success rates but the difference for this application was not statistically significant between the groups. The type and rate of complications and additional interventions are given in Table 2. In addition, there was no statistically significant difference regarding EQ between groups (Table 2).

## Discussion

Concerning the possible effects of SWL frequency rates on stone free status following SWL, although adequate number of studies have been performed in adults, limited information is available in the literature regarding the effect of this parameter on the final outcomes of SWL procedure in pediatric population [14, 15]. In the light of this fact, we aimed to evaluate the possible effects of varying SW delivery rates (frequency) on the final stone free status and complication rates after SWL management of renal stones in children. Patients were prospectively randomized into three groups each with 25 patients; low frequency group (SWL at 60 SWs/min), intermediate frequency group (SWL at 90 SWs/min) and high frequency group (SWL at 120 SWs/min).

Concerning the effect of SW frequency parameter, in a meta-analysis, Li et al. found that decreasing the frequency from 120 to 60 shockwaves per minute could increase the overall success rates in adult cases [16]. Another recently published meta-analysis study again indicated the same favorable effects with shock wave delivery in lower rates.

Application of SWL in adults with intermediate (80–90 SWs/min) and low frequency (60–70 SWs/min) values in this study have been found to result in better treatment outcomes than high frequency delivery rates (100–120 SWs/min) with reasonably limited complications [17].

In their prospective randomized study, Salem et al. compared SWL treatment at frequencies of 80 and 120 SWs/min in pediatric cases and they were able to demonstrate better outcomes in terms of stone fragmentation and clearance rates by using lower frequency rates [14]. In another retrospective study comparing frequencies of 60 and 90 SWs/min, however, authors demonstrated that the low and intermediate frequency of high energy shock waves could provide similar stone clearance rates in children with renal stones [15]. The results of our current study were found to be similar to the previous study outcomes where the stone free rates in cases treated with low and intermediate SW frequency groups were higher than the ones treated with high frequency rates. However, there was no statistically significant difference between stone free rates of low and intermediate frequency groups. Our results indicated well that, similar to adult patients, application of shock waves with low and intermediate frequency during pediatric SWL may provide better outcomes than high frequency application. The authors reported bubble growth along the path of shock wave during SWL [18]. The cavitation bubbles that increase at higher frequency act as a barrier that decrease the efficiency of SWL [19]. The possible explanation for the lower success in high frequency group is abundant cavitation bubbles at higher frequency.

In the current practice, most pediatric patients do require anesthesia to avoid procedure related pain and to prevent movements and reactions (to keep the patients

calm) during the treatment [6, 8, 20]. Unlike the adult cases, procedural time is particularly important for pediatric SWL due to the concerns of anesthesia. Regarding this parameter, Salem et al. found that the anesthesia time was significantly longer in pediatric cases treated with 80 SWs/min compared with the ones treated with 120 SWs/min [14]. A retrospective study comparing the procedure related parameters with 60 and 90 SWs/min delivery rates provided similar stone clearance in pediatric renal stones with similar anesthesia times [15]. In this present study, evaluation of our findings revealed no statistically significant difference regarding of total anesthesia time in all groups.

In their original study, Salem and Kaygısız et al. found no difference regarding the total number of shock waves numbers in all frequency values [14, 15]. In present study, similar to the findings of the above-mentioned trial, we were also not able to find any statistically significant difference regarding of total number of shock waves in all groups undergoing varying value of frequencies.

On the other hand, related with the need for additional procedures after SWL, Salem et al. found that secondary procedure rates were significantly higher in high frequency group when compared with intermediate frequency [14]. Similar additional therapy rates were reported for low and intermediate frequencies application groups in another relevant study [15]. In our study; however, we were not able to show any statistically significant difference between low, intermediate and high frequency rates in terms of seconder therapy rates (Table 2).

In their original trial, Salem et al. noted Clavien Grade 2 level complication as the highest one in 6 cases [14]. Kaygısız et al. however, noted postoperative complications classified as Modified Clavien Grades 1 and 2. There was no significant difference between low and intermediate frequency groups with respect to the percentage of the total complications [15]. Similar to these findings, we did not observe any kind of complication higher than Modified Clavien Grade 2 level and there was no statistically significant difference between the groups in our trial on this aspect (Table 2).

According to the currently available two nomograms gender, stone size, number of stones, age, location of stone, history of previous intervention were found to be the independent prognostic factors for assessing the stone clearance rates in pediatric SWL [10, 11]. In a recently published study, Kızılay et al. stated that BMI could also be a significant factor predicting the final success rates after SWL [21]. However, in our study there was no statistically significant difference in terms of these predictive factors between the three groups (Table 1). These findings in turn gave us the advantage to compare the possible effects of low, intermediate, and high SW application rates during SWL on the stone

free rates and complication rates in pediatric population independent of these prognostic factors.

Similar to adult patients, in our study SWL performed with low and intermediate frequency rates was found to be more successful than high frequency group in pediatric cases. When searching for ideal SW application frequency during pediatric SWL, anesthesia time needs to be considered as an important parameter on this aspect. Despite no statistically significant difference with respect to the total anesthesia time in our groups, median total anesthesia durations showed variations being noted as 50 min, 39 min, and 37 min for 60, 90, and 120 SW delivery rates, respectively. In addition, although there was no statistically significant difference regarding of total number of shock waves in all groups, the median shock wave numbers are found to be less in lower frequency groups which were noted to be 2800 SW, 3100 SW, and 3400 SW for 60, 90, and 120 SW delivery rates, respectively.

The data obtained in our study revealed that the application rates of high energy shock waves may well effect both the success and anesthesia time as well as related possible complications. In other words, physicians need to focus on the advantages and disadvantages of shock wave delivery rates. A precise balance seems to be established depending on the desired outcome based on particularly stone related factors (size, location) in this specific population. As shown in our trial, SWL performed with low and intermediate frequency rates was more successful than high frequency group in these cases. Despite no statistically significant difference with respect to the total anesthesia time in our groups, median total anesthesia durations in low frequency rate were longer than intermediate rate. This finding is important and taking the possible complications of longer anesthesia application into account, we think that the rate of SW delivery need to be chosen depending on the stone size and patient's physical growth status. If the child is well developed with no signs of other pathologies and the stone size is not too large lower of SW delivery could be preferred. This approach will let the child well tolerate the prolonged anesthesia with less risk of adverse biological effects. However, if anesthesia time will pose a risk for the child due to certain reasons higher delivery rates might be preferred with shorter procedural time and acceptable stone free rates.

Besides, *in vitro* and *in vivo* animal studies have proved that slow rates of shock wave delivery are associated with less tissue damage [22–24]. In this case, despite lack of a statistically significant difference; we may say that application of high energy shock waves at a lower delivery rate (60 SW/min) in pediatric cases will be advantageous by limiting the likelihood of a renal parenchymal damage in the growing kidney due to the limited number of shock waves applied. On the other hand; however, prolonged anesthesia time could be the disadvantage of low frequency SW application.

To our knowledge, our study is the first to compare the possible effects of three different frequency rates (low, intermediate, and high) on the final outcomes of treatment in pediatric SWL. Our study may have some limitations. First of all, relatively small number of cases included into the study program may constitute the only critical limitation. However, taking the rare occurrence of stone disease in children into account our trial is the first one comparing the effect of three different shock wave delivery rates on the final outcomes of SWL in this specific population. We believe that although preliminary, our current data will be contributive enough to the existing data in the literature. However, we believe that studies with larger series of pediatric cases are certainly needed to further support our findings.

## Conclusion

In the light of our current findings and the limited data published so far, we may say that low and intermediate shock wave frequency rates during SWL procedure in children may provide more successful outcomes than that of high frequency application rates. There was no significant difference between three groups regarding the total number of sessions, total number of shock waves and total anesthesia time. Besides, no significant difference was noted in term of postoperative complications and the need for additional interventions as well. Although not statistically significant; we may say that the use of low frequency application in kids may be more advantageous than intermediate approach due to the lower number of high energy shock waves required which may in turn cause less tissue damage. On the other hand; however, again despite lack of a statistically significant difference, relatively longer anesthesia time may constitute a disadvantage for lower frequency approach. Taking all these finding together, we believe that considering the growing nature of the child kidney application of shock waves with a lower frequency rate (60 SW/min) will be advantageous for SWL treatment in these cases. However, we believe that further studies with larger series of cases are certainly needed in order to make a clear-cut differentiation between low and intermediate manner SW applications on these aspects.

**Author contributions** MT: Project development, manuscript writing—original draft preparation; AK: Data collection, Manuscript writing; UC: Data collection; AC: Data collection; BE: Manuscript writing; KS: Supervision, manuscript writing review and editing.

## Compliance with ethical standards

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

**Ethics approval** The study protocol was approved by the hospital (Dr. Lutfi Kirdar Training and Research Hospital) ethics committee and all steps of the current study were planned and applied carefully according to the Helsinki Declaration.

**Informed consent** All participants (parent or legal guardian in the case of children under 16) have given informed consent before inclusion in the present study.

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