



SPEED OF STONE CLEARANCE AFTER SHOCK WAVE LITHOTRIPSY IN PEDIATRIC UROLITHIASIS

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ABSTRACT

The aim of this study is to summarize the first 10 years of experience of extracorporeal shock wave lithotripsy in pediatric patients with urolithiasis.

Single-center, whole-country, retrospective comparative study using data from cohort of pediatric urolithiasis patients who underwent shock wave lithotripsy between 2005 and 2014.

A total of 125 pediatric patients (male/female: 67/58, mean age: 10.22 years, range: 1–18) underwent 142 shock wave sessions in Armenia within the 10-year period, including 104 with primary and 21 with recurrent urolithiasis. In total, 164 stones were detected, involving 96 (58.5%) in boys and 68 (41.5%) in girls. Low-energy shockwaves with a frequency of 1-2 were used to achieve stone fragmentation in most patients. One session comprised of 200 to 3,000 shockwave impulses, required for sufficient stone fragmentation, although some patients required more than 8,000 impulses during four subsequent sessions. All but one (99.2%) cases reported successful stone clearance at 3-month follow-up. In this study were identified, that the younger age was associated with faster stone clearance, which probably was due to the shorter urinary tracts and thinner “barrier” between the device and the stone. Also, children who reported renal colic before lithotripsy had a significantly lower chance to get rid of stones within 2 days than those who did not. This can be explained by the underlying mechanism of the colic, which develops against the background of the spasm of ureteric walls. No significant obstructive, infectious, or other serious complications were observed. Mild macrohematuria during the first post-lithotripsy days and “steinstrasse” were reported practically in all patients, as expected during the postoperative course.

Extracorporeal shock wave lithotripsy proved to be a safe and highly effective minimally invasive treatment of children with kidney stone disease.

KEYWORDS: urolithiasis in Armenia, pediatric urolithiasis, extracorporeal shock wave lithotripsy for pediatric stones.

INTRODUCTION

Urolithiasis is relatively rare in children. It has considerable regional variability with reported incidence ranging from 1 to 3% of all urinary stones increasing both in developing and developed countries [Braun P et al., 2002; Issler N et al., 2017]. Stone occurrence particularly increases in warmer and sunnier regions [Sharma A, Filler G, 2010]. The specialists predict that the global warming will result in an increase in kidney stone disease and stone-related healthcare costs [Brikowski T et al., 2008]. It also has a considerable healthcare

burden for Armenia – a developing country on the boundary of Asia and Europe, due to its dry and sunny climate (2,300-2,500 sunshine hours per year) [Davtyan V, 2016].

The introduction of extracorporeal shock wave lithotripsy (SWL) in 1980 revolutionized the management of urolithiasis not only in adult but also in pediatric patients [Chaussy C et al., 1980]. Since then, more than 3,000 lithotripters have been installed worldwide, and over a million patients a year are treated with this method. The first publications on successful SWL sessions in children were made by Newman D. and co-authors in 1986 with subsequent series published in the late 80's and early 90's of the 20th century [Sigman M et al., 1987; Vandeursen H et al., 1991]. The method has earned a reputation of a proven effective treatment for patients with stones in virtually all parts of the urinary system. The main

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purpose of SWL is to ensure rapid, reliable, safe and minimally traumatic destruction of the uroliths. Over the past three decades, lithotripters have become more widely available, and SWL is now considered as the first line treatment or as one of the first choices of management of upper urinary stones in pediatric patients [Rodrigues N *et al.*, 2002; D'Addessi A *et al.*, 2008; Tekgül S *et al.*, 2019].

Regarding the age aspects, it is noteworthy that in children treated by SWL the stone-free rate is higher than in adults [Gofrit O *et al.*, 2001]. This can be explained by the minimal energy loss in the transmission of shock waves through the small body of the child and by easier discharge of even large stone fragments due to the greater elasticity and suppleness of the ureter in children [Zanetti G, 2011; Jeong U *et al.*, 2013].

In addition, SWL is preferred in children due to its minimal invasiveness, since endoscopic access is difficult due to the smaller diameter of the tubes, comprising the urinary tract [Preminger G *et al.*, 2007]. However, as an additional burden on the child, there is a need for general anesthesia, especially if multiple SWL sessions are necessary [Ozgür T *et al.*, 2003]. Open surgical removal of stones in well-equipped urological clinics is reduced in favor of stone disintegration with lithotripsy [Lopatkin N, Dzeranov N, 2003; Trapeznikova M *et al.*, 2005]. In order to avoid a high percentage of complications and side effects in SWL, including damage to the internal organs (pancreas, intestines, lungs), as well as subcapsular and perineal hematomas, lithotripsy is advisable to apply in specialized centers with extensive experience in the treatment of children with urolithiasis [Hofbauer J *et al.*, 1993].

The present study aimed to summarize experience of SWL in pediatric urolithiasis in Armenia.

Specific objective: For all children aged up to 18 years-old who underwent SWL in Armenia from 2005 to 2014, we compared demographic and clinical characteristics of those who had stone clearance within two days after SWL versus those who had clearance in more than two days after the intervention.



To overcome it is possible, due to the uniting the knowledge and will of all doctors in the world

MATERIAL AND METHODS

Design: Retrospective observational study, using data from cohort of pediatric urolithiasis patients who underwent SWL between 2005 and 2016.

Setting: Armenia is a small country with population of around 3 million. Since 2005, a lithotripter with the electromagnetic shock wave generator Modulith® SLK (Storz Medical AG, Switzerland) has been installed and operated in the urology clinic of "Izmirlian" Medical Center, Yerevan, Armenia. The SWL sessions in children are being conducted in cooperation with "Arabkir" Joint Medical Center, which has the only pediatric nephrology department in Armenia and refers all children with urolithiasis without contraindications of SWL for shock-wave treatment. Thus, in this paper, the whole experience of pediatric SWL in the Republic of Armenia is presented. The primary admission and examination were conducted at "Arabkir" Joint Medical Center, later the children were consulted in the urology clinic of "Izmirlian" Medical Center and, in case of an indication for SWL, sessions of extracorporeal lithotripsy were performed. Criteria defined by The European Association of Urology Urolithiasis Guidelines for respective years were used for assessment of indications and contraindications of patients. Contraindications for SWL included coagulopathies, a concurrent infection of the urinary tract, obstruction below the stone etc. Visualization and localization of the stones during SWL session itself was possible by ultrasound with the use of mentioned model of the lithotripter. This allowed for minimized radiation exposure of the pediatric patient. X-ray control was used only immediately before and after the SWL session for X-ray positive stones. CT scan was used for stone density measurement whenever available. During SWL session, the maximum allowable number of shock waves per session was used for each person. If total disintegration occurred during the session, then lithotripter was stopped, and number of shock waves was recorded. Propofol was used for in-session sedation of younger children (up to 13 years old), and fentanyl was used for analgesia in older children. Stone clearance was confirmed by ultrasound. Follow-up examinations were performed in 2 weeks, 1 and 3 months after SWL sessions.

Study population: Children (0-18 years old) with urolithiasis undergoing SWL from 2005 to 2014 in Armenia.

Data Collection, Sources, and Statistical Analysis: The study-related data were extracted from patient cards. The statistical analysis was performed using STATA 11 statistical software. Chi-square (χ^2) test was used to test for differences between groups (those who had stone clearance within 2 days versus those who did not have clearance within 2 days after SWL session) for all categorical variables (Fisher exact test was used in some cases due to low number of observations) and Student's *t*-test was used to test differences between groups for continuous variables. Kaplan-Meier survival curve was used to display stone clearance after SWL. The difference between curves for different groups was checked using the Log-Rank test. The normality of the distributions was tested using Kolmogorov-Smirnov test. Statistical significance was set at $p=0.05$ and 95% confidence interval (95% CI) was calculated for all analyses.

Ethics: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration (Br. Med. J., 1954) and its later amendments or comparable ethical standards. For this type of study formal consent is not required. Ethical Approval was secured from the IRB of the Center of Medical Genetics and Primary Health Care.

RESULTS

Descriptive analysis: A total of 125 children and adolescents (67 boys and 58 girls) underwent SWL in Armenia within the 10-year period between 2005 and 2014. The mean age was 10.2 years (range: 1-18). The annual distribution of SWL sessions is shown in figure 1, demonstrating that the number of pediatric patients undergoing SWL has relatively increased.

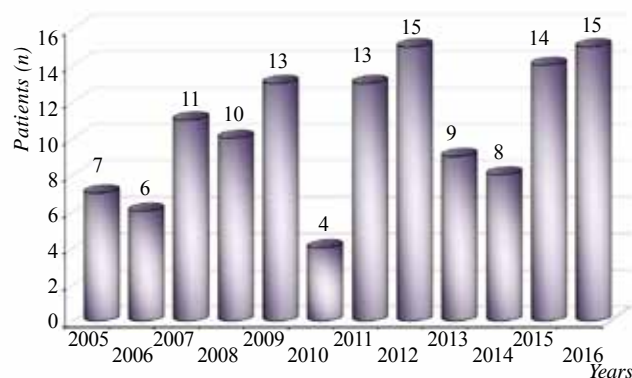


FIGURE 1. Extracorporeal shock wave lithotripsy patients' distribution by years

Low-energy shockwaves with a frequency of 1-2 Hz (strength 30-50 according to the Modulith Storz scale) were used to achieve stone fragmentation in most patients. One session comprised of 200 to 3,000 shockwave impulses, required for sufficient stone fragmentation, although some patients required more than 8,000 impulses during four subsequent sessions. We noticed that the stone density had an influence on the degree of stone fragmentation and effective stone clearance in children. The stones with lower density (less than 600 HU) almost completely disintegrated after less than 2,000 shockwaves with low energy of generator. The medium density stones (700-1,000 HU) required full volume of prescribed impulses. The high-density stones (more than 1,200 HU) required more than one session at a time with maximally allowed energy of impulses, and sometimes even multiple SWL sessions.

Table summarizes the patient characteristics and their possible association with the timing of stone clearance.

In total, 164 stones were detected, including 96 (58.5%) in boys and 68 (41.5%) in girls. Primary urolithiasis was diagnosed in 104 (83.2%) and recurrent urolithiasis in 21 (16.8%) cases. The number of stones was as follows: 1 stone was detected in 102 (81.6%) cases, 2 stones – 8 (6.4%), 3 stones – 14 (11.2%) and 4 stones in 1 case (0.8%). Most of the patients ($n=79$, 63.2%) had stones of <10 mm of length; in 40 patients (32.0%) it ranged from 11 to 15 mm, and six patients (4.8%) had big stones with length of 16-19 mm. Sixty-eight ($n=68$, 54.4%) patients had kidney stones (including 2 cases of stag-horn calculi), while ureteric stones were observed in 67 (53.6%) patients including 46 (68.7%) in the distal ureter and in 21 (31.3%) in the proximal ureter. Forty-nine ($n=49$, 39.2%) patients experienced episodes of renal colic. In terms of illness duration, the patients were distributed as follows: up to 8 weeks – 46 (37.4%) cases, 8-12 weeks – 20 (16.3%), and more than 12 weeks – 57 (46.3%). Thus, the majority of patients was referred for SWL in more than 2 months after the diagnosis of urolithiasis. The duration of illness, however, did not have impact on the clearance speed (Table).

The cohort underwent 142 SWL sessions including 1 session in 113 patients, 2 sessions in 9 patients, 3 sessions in 1 patient and 4 sessions in 2 patients. Necessity of multiple sessions was dictated by the presence of large and/or high-density stones in the kidney (7 cases) or ureter (6 cases). For example, one 17-year-old patient with a stag-

TABLE

Association between the patient characteristics and the timing of stone clearance

Patient characteristics		Total, n (%)	Stone clearance, n (%) [†]		Odds Ratio (95% CI) [§]	P-value
			≤2 days	≥2 days		
Gender	Male	67 (54%)	41 (56%)	26 (50%)	1.57 (0.72–3.44)	0.22
	Female [‡]	58 (46%)	32 (44%)	26 (50%)	–	–
Recurrent urolithiasis	No	104 (83.2%)	61 (83.66%)	43 (82.69%)	1.3 (0.43–1.74)	0.6
	Yes [‡]	21 (16.8%)	12 (16.44%)	9 (17.31%)	–	–
Stone count	1	102 (81.6%)	61 (84.72%)	40 (76.92%)	1.66 (0.67–4.17)	0.27
	>1 [‡]	23 (18.4%)	11 (15.28%)	12 (23.08%)	–	–
Ureter stone	No [‡]	58 (46.4%)	33 (45.83%)	25 (48.08%)	–	–
	Yes	67 (53.6%)	39 (54.17%)	27 (51.92%)	1.09 (0.5–2.38)	0.8
Ureter side	Right [‡]	38 (57.58%)	21 (55.26%)	16 (59.26%)	–	–
	Left	28 (42.42%)	17 (44.74%)	11 (40.74%)	1.17 (0.43–3.2)	0.75
Ureter site	Proximal [‡]	21 (31.34%)	9 (23.08%)	12 (44.44%)	–	–
	Distal	46 (68.66%)	30 (76.92%)	15 (55.56%)	2.66 (0.92–7.72)	0.07
Kidney stone	No [‡]	57 (45.6%)	32 (44.44%)	24 (46.15%)	–	–
	Yes	68 (54.4%)	40 (55.56%)	28 (53.85%)	1.07 (0.52–2.19)	0.85
Kidney side	Right [‡]	31 (47.69%)	19 (48.72%)	12 (46.15%)	–	–
	Left	34 (52.31%)	20 (51.28%)	14 (53.85%)	1.11 (0.41–3)	0.84
Renal pelvis stone	No [‡]	26 (38.24%)	14 (35%)	12 (42.86%)	–	–
	Yes	42 (61.76%)	26 (65%)	16 (57.14%)	1.39 (0.46–4.19)	0.43
Renal calyx stone	No	36 (52.94%)	25 (62.5%)	11 (39.29%)	2.58 (0.95–6.95)	0.06
	Yes [‡]	32 (47.06%)	15 (37.5%)	17 (60.71%)	–	–
Staghorn stone	No	66 (97.06%)	39 (97.5%)	27 (96.43%)	NA	NA
	Yes	2 (2.94%)	1 (2.5%)	1 (3.57%)	NA	NA
Renal colic	No	76 (60.8%)	49 (68.06%)	23 (44.23%)	2.69 (1.28–5.62)	0.01*
	Yes [‡]	49 (39.2%)	23 (31.94%)	29 (55.77%)	–	–
Illness duration	<8 weeks [‡]	46 (37.4%)	23 (31.94%)	23 (46%)	–	–
	8-12 weeks	20 (16.26%)	14 (19.44%)	6 (12%)	2.33 (0.76–7.13)	0.14
	≥12 weeks	57 (46.34%)	35 (48.61%)	21 (42%)	1.67 (0.76–3.67)	0.21
In situ stone	No	62 (49.6%)	41 (56.94%)	20 (38.46%)	2.12 (1.02–4.38)	0.04*
	Yes [‡]	63 (50.4%)	31 (43.06%)	32 (61.54%)	–	–
Accompanying pathology	No [‡]	61 (48.8%)	41 (56.94%)	20 (38.46%)	–	–
	Dilatation	41 (32.8%)	19 (26.39%)	21 (40.38%)	0.44 (0.19–1.00)	0.05*
	Obstruction	19 (15.2%)	11 (15.28%)	8 (15.38%)	0.67 (0.23–1.92)	0.46
	Hydronephrosis	4 (3.2%)	1 (1.39%)	3 (5.77%)	0.16 (0.02–1.66)	0.13
Fragmentation level	Bad (>5 mm)	1 (0.81%)	0 (0%)	0 (0%)	NA	NA
	Some (3-5 mm)	81 (65.32%)	50 (70.42%)	31 (59.62%)	1.61 (0.76–3.42)	0.21
	Full (<3 mm) [‡]	42 (33.87%)	21 (29.58%)	21 (40.38%)	–	–
Anesthesia type	Analgesia [‡]	48 (38.4%)	11 (16.2%)	37 (64.9%)	–	–
	Sedation	77 (61.6%)	57 (85.8%)	20 (35.1%)	8.73 (3.72–20.45)	<0.01*

NOTES: [†] - One patient did not have stone clearance; [‡] - Reference group; [§] - CI = Confidence Interval; * - Statistically significant finding.

horn stone required four SWL sessions due to partial fragmentation after each session with overall 8,100 shockwave impulses corresponding to two full sessions of an adult SWL.

Survival analysis: Timing of stone clearance varied amongst patients. Figure 2A shows the probability of having stone clearance after SWL at different time points with the help of Kaplan-Meier

curve. Probability of having stone clearance during first 2 days was around 42%. Thus, in order to have comparable groups, “2 days after SWL” was decided to be the arbitrary cutoff level for comparison in unadjusted analysis. Additionally, statistically significant difference of the clearance curves was observed between the patients who did not have renal colic and those who had (p=0.01) (Fig. 2B).

Similarly, there was difference between those who had SWL session under sedation and those who had it under analgesia ($p < 0.01$) (Fig. 2C).

Unadjusted analysis: The Kolmogorov-Smirnov test confirmed the normality of the distributions. Afterwards, either Pearson's χ^2 test (in few cases Fisher exact test) or Student's t -test were used to check the significance level of the association between dependent ("clearance within 2 days") and independent variables (patient characteristics). Amongst all independent variables, impact on the clearance within 2 days was statistically significant

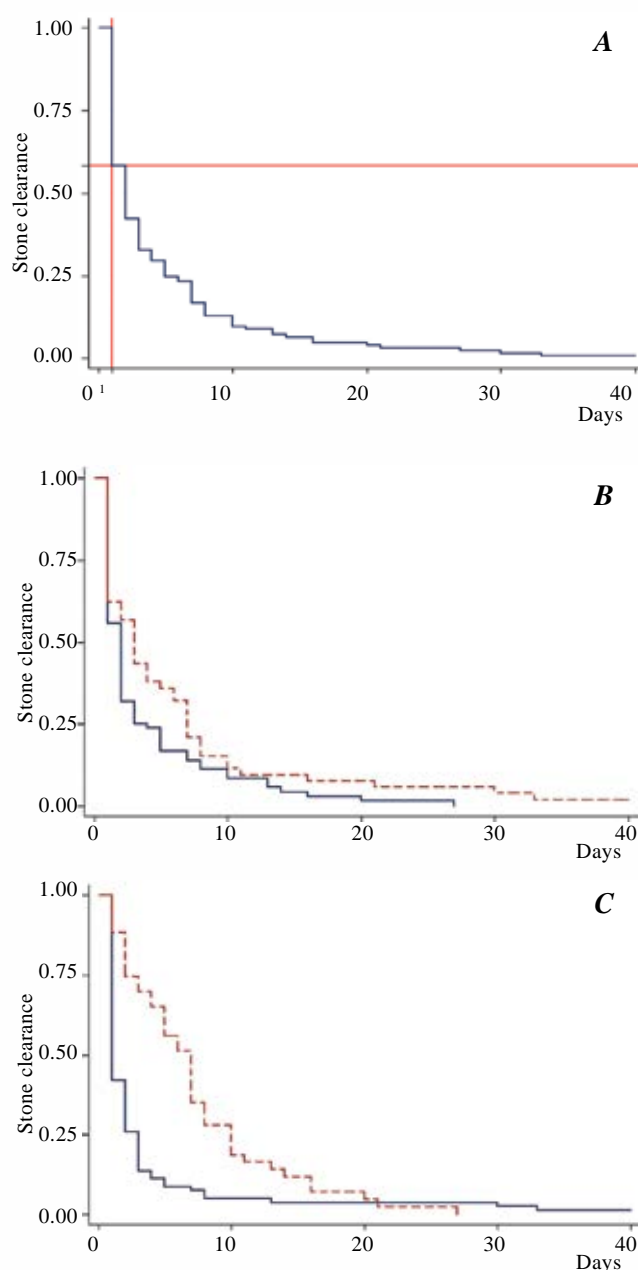


FIGURE 2. Stone clearance probability A) after extracorporeal shock wave lithotripsy, B). comparison by having renal colic (dotted line – presence of renal colic, solid absence); C) comparison by anesthesia type (dotted line – presence of analgesia, solid sedation)

only for "age", "in situ stone" (no any manipulations with stone located in ureter), "having renal colic", "anesthesia type", and "dilatation". Mean age of patients with stone clearance within 2 days after SWL was 7.6 years, while in the second group it was 13.9 years. Mean age difference between two groups was 6.35 years (95% CI 4.51–8.18, $p < 0.001$) indicating that younger age increases chances of having stone clearance within 2 days (faster clearance) after SWL in pediatric population. Those who did not experience renal colic had 2.69 times (95% CI 1.28–5.62, $p = 0.01$) higher odds of having clearance within 2 days compared to those who experienced renal colic. Another factor that was associated with the dependent variable was "in situ stone": those who did not have *in situ* stone had 2.12 times (95% CI 1.02–4.38, $p = 0.04$) higher odds of having clearance within 2 days compared to those who had stone *in situ*. Faster clearance was also associated with anesthesia type. Analysis showed that those pediatric patients who underwent SWL under sedation had 8.73 times (95% CI 3.72–20.45, $p < 0.01$) higher odds of stone clearance within 2 days versus those who required analgesia for conducting SWL (Table). This finding might be confounded by age as sedation was performed in younger children.

In terms of accompanying urological pathologies, urinary tract dilatation was reported in 41 (32.8%), *steinstrasse* (after previous sessions) in 21 (16.8%), hydronephrosis (dilation of the renal pelvis and/or calyces because of obstruction) in 4 (3.2%) patients. Association with clearance speed was detected only for dilatation: patients presenting with urinary tract dilatation had approximately as twice as lower odds of stone clearance within 2 days (0.44, 95% CI 0.19–1.00, $p = 0.05$) compared to those without it (Table).

Associations between the speed of stone clearance and ureter site, as well as the renal calyx stone were marginally significant ($p = 0.07$ and 0.06 , respectively) and require further studies with larger sample sizes.

The vast majority of patients were stone-free within one month post-SWL (Fig. 2A). All but one cases reported successful stone clearance at last follow-up (3 months) with an overall clearance rate of 99.2%. Clearance failure was reported in a patient with bad fragmentation level.

All patients returned to "Arabkir" Joint Medical Center for further post-SWL care according to pediatric guidelines, including antispasmodics, analgesic, antibacterial, and infusion therapy. No significant obstructive, infection or other serious complications were observed. Mild macrohematuria during the first post-SWL days and *steinstrasse* were reported practically in all SWL patients, as expected during the postoperative course [Nazarov T et al., 2007].

DISCUSSION

This single-center, whole-country, retrospective cohort study summarizes the first 12-year experience of SWL in children and adolescents with urolithiasis in Armenia. There was more incidence in boys than girls, which coincided with the reported data of the same geographic region – Iran and Turkey [Alemzadeh-Ansari M *et al.*, 2014; Elmaci A *et al.*, 2014; Senocak C *et al.*, 2018]. We observed urolithiasis in babies as young as 1-year-old suggesting possible formation of urinary stones already in prenatal life [Howles S *et al.*, 2013]. The younger age was associated with faster stone clearance, which probably was due to the shorter urinary tracts and thinner “barrier” between the device and the stone.

We were able to identify also some other factors influencing the speed of stone clearance in children with urolithiasis.

Children who reported renal colic before lithotripsy had a significantly lower chance to get rid of stones within 2 days than those who did not. This can be explained by the underlying mechanism of the colic, which develops against the background of the spasm of ureteric walls [Shokeir A, 2002].

Interestingly, preoperative presence of calculus obstruction (without dilatation of urinary tract) did not have impact on clearance speed whereas urinary tract dilatation significantly decreased it. Thus, SWL seemed to efficiently destroy the obstructing stone into small fragments without injuring the urinary tract wall and the intact urinary tract readily cleared those fragments, while the dilated tract with its weakened walls was not able to provide fast stone clearance. These findings might help with prognosis of the stone clearance speed in pediatric population.

The clearance rate after single SWL session with Modulith® SLK electromagnetic lithotripter was 90.4%. The device provided excellent overall (after multiple sessions where required) clearance rate (99.2%) with only one case of clearance failure among 125 children. This number competes with international literature data on pediatric SWL (using

HM 3, Lithostar or Piezolith lithotripters) with an average success rate of 79.8% reported throughout 32 articles [Brinkmann O, 2001]. We were not able to identify similar data with the use of Modulith® SLK, although several reports were available for its high performance in adult population [Tomescu P *et al.*, 2009; Ceban E, 2012]. Thus, this is probably the first report on efficacy of SWL in children using this device. Only Braun P. and co-authors (2002) published a series of 46 children undergoing SWL with different lithotripters including Modulith® SLK but the authors did not mention the efficacy rate specifically for this device.

In terms of safety, no major adverse events were reported after SWL in our series, although several complications are known, such as colon perforation, hepatic artery rupture, hepatic hematoma, spleen rupture, pneumothorax, acute necrotizing pancreatitis, rupture of abdominal aorta, etc. and the surgeons should be aware of these [Akin Y, Yucel S, 2014].

Strengths and limitations: This study is the first nationwide assessment of pediatric SWL experience including its efficacy (clearance rate). Another strength of the study is that single surgeon performed all SWL sessions on pediatric patients, which eliminates bias related to the differences in techniques by different lithotripter operators. Limitations for this study include lack of other similar studies for comparison of the results. Historical data obtained from patient cards were used for the analysis and it was impossible to eliminate potential errors and bias from original data.

This study presents the first cohort of pediatric urolithiasis in Armenia undergoing SWL and demonstrates that with correct pre-selection of patient high overall clearance rate could be achieved. SWL is more performant in younger age prior to development of organic changes in the urinary tract and faster stone clearance can be observed in these patients. Interdisciplinary team approach implying permanent collaboration between urologists, pediatricians and pediatric nephrologists is essential not only for successful management of pediatric urolithiasis but also for preventing recurrences and complications.

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