Shock Wave Lithotripsy in Pediatric Stone Disease: A 15-Year Single-Center Experience with 2 Types of Lithotripters

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Abstract
Introduction and Objectives: We report our experience with pediatric shock wave lithotripsy (SWL) using two types of lithotripters: Dornier HM3 (HM3) and Dornier Lithotripter SII (DLS). Study Design: We retrospectively reviewed the charts of children who underwent SWL between 2002 and 2016. Patients were divided into two groups based on the type of the lithotripter: during 2002–2009, we used the electrohydraulic HM3 lithotripter which was replaced in 2009 with the DLS electromagnetic lithotripter. Clinical and perioperative parameters were compared. Results: Our cohort included 107 children who underwent SWL. Average age was 11.5 ± 5.1 years. Average stone size was 10.6 ± 4.9 mm. HM3 was used in 38% of children and DLS in 62% (n = 41 and 66, respectively). There were no significant differences in age, gender, stone size, or location between the groups. The total SFR did not differ statistically between HM3 and DLS (83% vs. 74%, p = 0.35). SFR after one SWL was higher with the HM3 (78% vs. 62%, p = 0.093). Re-treatment rate was 22% and 17% (HM3 vs. DLS, p = 0.61). Complication rates were low, with renal colic being the most common (HM3 10%, DLS 20%, NS).

Conclusions: SWL in the pediatric population using the DLS showed good results with low complication rates that are equivalent to the gold standard HM3.

Introduction

For several decades, SWL has become one of the main treatments for nephrolithiasis. According to several studies, pediatric stone-free rate (SFR) after SWL has been reported to be 60–90% [1–4]. The SFR depends on several factors such as stone location, stone composition, and stone length where stone size ≤12 mm is an independent predictor of SWL success [5]. Lower pole stone, calyceal stones, and stones impacted at the ureteropelvic junction have relatively poorer clearance and lower SFR [6].

The type of lithotripter machine is known to influence SFR in adults. The first-generation HM3 (Dornier MedTech Europe, Germany) is used as the reference lithotripter due to its higher SFR, fewer complications, and secondary treatments [7, 8]. Nonetheless, comparative studies between HM3 and the newer generation lithotripters in pediatric population are sparse, and there is no...
consensus whether one technology is superior to the other. Hence, the aim of our study was to compare the perioperative results of HM3 and DLS lithotripters in children who underwent SWL in our center.

### Materials and Methods

#### Study Type and Data Collection

After receiving institutional review board approval (IRB 0254-16), we retrospectively reviewed all patients in the pediatric age group (i.e., <18 years) who underwent SWL procedures between years 2002 and 2016 in our institution. The exclusion criteria were patients with coagulation disorders, urinary tract infection, and nonfunctioning kidney.

#### Study Protocol

Patients were divided into 2 groups according to the type of the lithotripter used for SWL: during years 2002–2009, we used in our institute the electrohydraulic HM3 lithotripter (Dornier MedTech Europe, Germany) which was replaced at 2009 with the DLS electromagnetic lithotripter (Dornier Lithotripter S, Dornier MedTech). Clinical and perioperative parameters were compared among both groups.

Treatment success was defined as stone-free status or asymptomatic stone fragments smaller than 4 mm with no need of further treatment.

### Results

Our cohort included 107 children who underwent SWL where HM3 was used in 38% of children and DLS2 in 62% (n = 41 and 66, respectively). Average age was 11.5 ± 5.1 years (range 2–18). Most patients were boys. Average stone size was 10.6 ± 4.9 mm (range 4–30). The vast majority of stones were located in the kidney while the remaining in the ureter (81% vs. 19%, respectively). There were no statistically significant variations between both groups regarding demographic features and stone-related parameters (Table 1). Seven children were previously stented and 10 carried a nephrostomy tube. As expected, radiopaque stones were more common than radiolucent ones (72% and 28%, respectively). The mean HM3 stone size in millimeter was slightly larger than that in the DLS group, but this change did not reach statistical significance (11.58 vs. 9.9 mm; p = 0.08). The mean number of shock waves per session was comparable between both groups: 2,604 in the HM3 group and 2,695 in the DLS group (p = 0.22). Seven children underwent pre-SWL kidney drainage in the HM3 group compared to 10 children in the DLS group (NS).

When comparing the total SFR, there was no statistically significant difference among both groups: HM3 (83%) or DLS (74%) (p = 0.35). SFR after one SWL session showed better results in the HM3 (78% vs. 62%, p = 0.093). Re-treatment rates were 22% and 17% in the HM3 and DLS2 groups (p = 0.61). The complication rate was relatively low in both groups where renal colic was the most common one (HM3 10%, DLS 20%, NS). Steinstrasse re-

### Table 1. Demographic features and stone-related parameters

|                     | HM3 (group 1), n = 41 | DLS2 (group 2), n = 66 | p value |
|---------------------|-----------------------|------------------------|---------|
| Age (mean), years   | 10.83±5.39            | 11.9±4.90              | 0.27    |
| Gender              | 27 boys               | 34 boys                | 0.16    |
|                    | 14 girls              | 32 girls               |         |
| Stone size, mm      | 11.58±5.32            | 9.98±4.63              | 0.08    |
| Stone radiolucency  | 30 radiopaque         | 47 radiopaque          | 1.00    |
|                    | 11 radiolucent        | 19 radiolucent         |         |
| Side (%)            | Right (54)            | Right (54,5)           | 1.00    |
|                    | Left (46)             | Left (45,5)            |         |
| Metabolic disorder, % | 12                    | 4.5                    | 0.26    |
| Stone location, n (%)|                       |                        |         |
| Upper calyx         | 3 (7.3)               | 5 (7.7)                | 1.00    |
| Middle calyx        | 4 (9.8)               | 9 (13.8)               | 0.76    |
| Lower calyx         | 14 (34.1)             | 19 (28.7)              | 0.51    |
| Renal pelvis        | 10 (24.4)             | 23 (35.4)              | 0.28    |
| Upper ureter        | 4 (9.8)               | 3 (4.6)                | 0.43    |
| Lower ureter        | 6 (14.6)              | 7 (10.8)               | 0.55    |

HM3, Dornier HM3; DLS, Dornier Lithotripter SII.

A comparative analysis was performed between the two groups for demographic features, stone parameters, SWL parameters, SFR, the need for auxiliary procedures, and complications. SFR was defined as a stone-free status or asymptomatic stone fragments smaller than 4 mm with no need of further treatment.

#### SWL Treatment Plan

Children on both groups of SWL machines were given general anesthesia during the procedure. Treatment session with the HM3 started at an intensity level of 6 kV and gradually increased every 100 pulses, while an intensity of 20 kV for kidney stones and 26 kV for ureteral stones. Treatment session with the DLS started at an intensity level of 2 J and gradually increased every 50 pulses by 1 J until an intensity of 6–7 J for kidney stones and 7–9 J for ureteral stones.

#### Data Analysis

Statistical analysis was done using the Fisher exact test to compare categorical parameters. A logistic regression model was conducted using multivariable categorical parameters in attempt to predict SWL SFR. The ROC model was performed. p < 0.05 denoted statistical significance.
quiring ureteral stenting or ureteroscopy was noted in 2 children after SWL with the HM3 and in 1 child with the DLS (NS, Table 2).

When analyzing the entire cohort by using a logistic regression model, the location of the stone was found to be a predictor of SFR. Kidney stones had better SFR compared with ureteral stones (p = 0.019, OR 3.61, 95% CI: 1.2–10.5). In addition, stones smaller than 12.5 mm had a greater SFR, however with borderline clinical significance (p = 0.092, OR 2.3, 95% CI: 0.8–6.1).

### Discussion

The main goal of SWL in children is achieving a stone-free status with minimal re-treatment rates and post-procedure complications. Physiologic factors that are believed to increase pediatric SFR over adults are softer stone composition, relatively smaller stone size, increased ureteral compliance to accommodate residual fragments that gives a better transport ability, and smaller body mass to facilitate SWL transmission [9, 10].

In our study, we observed a total SFR of 78% which aligns with the reported SFR in the literature, ranging from 60% to 90% [2, 6, 11–13]. We compared two different technologies of ESWL:

1. The electrohydraulic lithotripter where an intrinsic source generates a shock wave that is focused by using an ellipsoidal reflector. The pressure pulse originates as a shock wave and remains a shock wave at all times. Since it is a wave, during emission, there can be significant variation in the amplitude of the shock, and there can be some shift in the position of the focal point at the target.

2. The electromagnetic lithotripter uses as an acoustic source an electrical coil in proximity to a metal plate. When the coil is excited by a short electrical pulse, an acoustic wave is generated. Focusing is very accurate, and the variation in measured pressure waves is less than 10% [14, 15].

The shock wave generated using the oldest lithotripter, the electrohydraulic HM3, was believed to produce the best stone disintegration in the adult population. The Dornier lithotripter S II system, which utilizes an electromagnetic shockwave generator, has a much smaller focal area and may be less powerful. For these reasons, patient positioning and stone localization must be exact with the DLS. This might explain why SFR in adults is reported to be lower with electromagnetic lithotripters than with the broad focal area of the electrohydraulic HM3 [7, 8].

Few studies have focused on the question whether the type of lithotripter machine influences SFR in children. Raza et al. [16] reported an SFR of 95% using an electrohydraulic lithotripter versus 77% for an electromagnetic lithotripter, similar to what was reported in the adult population. Another comparative study conducted by Elsobky et al. [17] concluded that the re-treatment rate differed significantly between the electrohydraulic and piezoelectric lithotripters, but the SFR did not. To our knowledge, no other direct comparison between electrohydraulic and electromagnetic lithotripters was done in pediatric patients. In our pediatric cohort, SFR after one SWL using the electrohydraulic HM3 was better than the electromagnetic DLS, with borderline clinical significance (78% vs. 62%,

| Complication     | HM3 (group 1), n = 41 | DLS2 (group 2), n = 66 | p value |
|------------------|-----------------------|------------------------|---------|
| Pre-SWL kidney drainage |
| DPT stent        | 1                     | 6                      | 0.25    |
| Nephrostomy tube | 6                     | 4                      | 0.17    |
| Shock waves, n   | 2,604±437             | 2,695±320              | 0.22    |
| SFR, n (%)       |
| SFR after 1 SWL  | 32 (78)               | 41 (62)                | 0.093   |
| Overall SFR      | 34 (83)               | 49 (74)                | 0.35    |
| Re-treatment rate, % |
| Renal colic      | 10                    | 20                     | 0.28    |
| Fever            | 4.9                   | 4.5                    | 1.00    |
| Hematoma         | 0                     | 1.5                    | 1.00    |
| Steinstrasse     | 4                     | 2                      | NS      |

HM3, Dornier HM3; DLS, Dornier Lithotripter SII; SFR, stone-free rate; SWL, shock wave lithotripsy; DPT, double pig tail.
higher than that for stones greater than 10 mm in children [20]. Similar results were seen in our cohort, where a stone size smaller than 12.5 mm predicted a greater SFR with a borderline significance ($p = 0.092$).

The alternatives to SWL are PCNL and ureteroscopy. Both treatment options have been used in the adult population for many years. Rapid advances in technology with development of smaller and more flexible endoscopes as well as tubeless PCNL have now made it possible to apply them for the treatment of pediatric stone disease. These advances bring stone clearance for both URS and PCNL to an overall SFR of 95–100% with minimal complications [21, 22]. Although single-session SFRs of both RIRS and PCNL are significantly higher than SWL, compared with these invasive procedures, pediatric SWL still offers the advantages of a noninvasive procedure, shorter operative time with minimal anesthesia, shorter hospitalization, and a cost-effective procedure [21, 23–26].

When comparing our cohort results with reports from the adult population, SWL using the newer generation electromagnetic lithotripters can be as effective as the older generation electrohydraulic lithotripters with acceptable re-treatment and complications rates. The smaller focal area of the electromagnetic lithotripters compared to electrohydraulic lithotripters might make stone disintegration in children optimal. This might be explained by the shorter skin-to-stone distance in the pediatric population, compared to adults.

Our study has several limitations:

- It was a retrospective study with a relatively small patient population; the DLS system was not applied after 2016 due to nonmedical reasons. Future studies with a larger sample size would improve the results.
- We did not exclude children with a history of urological surgery such as ureteroscopy and PCNL, which might decrease SFR. Children with a history of urological surgery or anatomical abnormalities were found to have lower SFR after SWL when compared to children without these conditions [12]. A retrospective research of 64 patients achieved 90% SFR after excluding these patients [4].
- The majority of our pediatric cohort (90%) were diagnosed by abdominal X-ray and/or ultrasound and not by NCCT because of the potential risks of ionizing radiation [27]. Therefore, we were unable to collect sufficient data concerning the density of the stones in Hounsfield Units (HU). The HU of a stone measured in NCCT has been shown to be a predictive factor for SWL success in children. Stones with lower HU (<1,000) were correlated with better SFR [28].

Conclusions

SWL in pediatric patients is a noninvasive and effective treatment for renal and ureteral stones. The DLS lithotripter showed comparable efficacy and complication rates to the gold standard HM3. SWL should be offered as one of the primary treatment options in pediatric stone disease.

Statement of Ethics

The research complies with the guidelines for human studies and was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. The study protocol was reviewed and approved by the Rambam Medical Center (Affiliated with the Technion – Israel Institute of Technology) Helsinki Committee on Human Research. Approval No. IRB #0254-16. Consent from patients was not obtained because this was a retrospective chart review study that does not affect clinical care of the individuals. This was approved by the ethics committee.

Conflicts of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

Ariel Zisman conceived and designed the analysis, collected the data, performed the analysis, and wrote the paper. Akram Assadi conceived and designed the analysis, performed the analysis, and wrote the paper. Oleg Goldin contributed data and designed the analysis. Kamil Malshy collected the data and designed the analysis. Omri Nativ collected the data and designed the analysis. Shimon Meretyk contributed data and designed the analysis. Gilad E. Amiel conceived and designed the analysis. Michael Mullerad conceived and designed the analysis, performed the analysis, and wrote the paper. Pinhas M. Livne conceived and designed the analysis, performed the analysis, and wrote the paper.

Data Availability Statement

Due to the possibility of compromising the privacy of research participants, the data supporting this study are not publicly available. However, they can be obtained from the corresponding author A.Z. at a_zisman@rmc.gov.il upon reasonable request.
