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ORIGINAL PAPER

Comparison of the effectiveness and safety of MPL 9000 and Lithostar Modularis shockwave lithotriptors: treatment results of 263 children

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Abstract In this study, we aimed to compare the treatment results of two different shock wave lithotripsy (SWL) machines used in the management of pediatric urolithiasis. Between January 1993 and October 2004, Dornier MPL 9000 (electrohydraulic) had been used, and since then Siemens Lithostar Modularis (electromagnetic) has been used. The last evaluation was done 3 months after SWL treatment in terms of the success rate, use of anesthesia and complications. A total of 263 children (171 boys and 92 girls), with an age range of 9 months–14 years (mean age 8.1 ± 3.8 years) were included in this study. Of the patients treated with the Dornier MPL 9000, 60.1% (173/104) required general anesthesia and 69 needed sedation. In contrast, for all patients treated with the Lithostar Modularis necessitated only sedo-analgesia (90 children). The hospital stay was shorter for Siemens Lithostar Modularis than those of Dornier MPL 9000 (26.2 vs. 35.5 h, $P = 0.03$). The success rate for the electromagnetic unit (86.5%) was almost identical that achieved with the electrohydraulic unit (85.2%) in the stones for the different location. Success rates were compared for stone burden subsets, the differences were insignificant for both lithotriptors ($P > 0.05$, for all). The electromagnetic unit had a significantly higher success rate for distal ureteral calculi (86.2 vs. 54.5%, $P = 0.034$). The efficiency quotients (EQ) for distal ureteral calculi were significantly different in favor of electromagnetic machine (56 vs. 40%). The complication rates for SWL were not significantly different for electrohydraulic and electromagnetic lithotriptors (8.7 and 6.2%, respectively). This study showed that SWL treatment was effective and safe in pediatric urolithiasis using both electrohydraulic and electromagnetic machines. Electromagnetic machine was more effective than electrohydraulic one for distal ureteral calculi. Additionally, the electromagnetic lithotriptor has significant clinical advantages over the electrohydraulic lithotriptor in terms of anesthesia requirements, hospitalization duration and fluoroscopic targeting.

Keywords Comparative study · Pediatric urolithiasis · Dornier MPL-9000 · Shock wave lithotripsy · Siemens Lithostar Modularis

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Introduction

Pediatric urolithiasis is a rare entity in developed countries [1]. However; it occurs more commonly in underdeveloped countries. In an epidemiological report from Turkey, it was documented that urolithiasis was considered an endemic disease in children younger than 14 years [2]. Because children with stone disease are at risk for a longer period than adults, their cumulative likelihood of stone recurrences may be higher. Thus, with continuing advances in technology stone management has evolved from invasive procedures such as open surgery into less invasive techniques such as shock wave lithotripsy (SWL), ureteroscopy, and percutaneous nephrolithotomy [3].The first report of success using SWL on children was presented by Newman et al. [4]. Since then, acceptable success rates, high safety profile, and minimal morbidity has made SWL to be the preferred first line of treatment for pediatric urolithiasis [5, 6]. The advent of second- and third-generation lithotriptors, which are dry head lithotriptors and equipped with advanced imaging systems, has made the visualization of especially ureteral stones much easier. Additionally, the use of an acoustic membrane and lens system resulted in repetitive shock waves of moderate intensity. As a result, using the newer generation lithotriptors, SWL with minimal anesthesia is applicable to the preponderance of pediatric patients with a high retreatment rate [7, 8].

In a retrospective clinical study, we compared the efficacy of two different lithotriptors: the electrohydraulic-based Dornier MPL 9000 and the electromagnetic-based Siemens Lithostar Modularis for the treatment of pediatric stone disease. Comparisons between two lithotriptors were made in regard to treatment parameters, use of auxiliary procedures, complications, success rate and efficiency quotient (EQ).

Patients and methods

During a period of 12 years, 263 children with urinary tract calculi were treated with the electrohydraulic or electromagnetic lithotriptor. Between January 1993 and October 2004, Dornier MPL 9000 (electrohydraulic/spark gap, Dornier Medical Systems, Germany), a second-generation machine, had been used, and since then Siemens Lithostar Modularis (Siemens Medical Solutions, Inc.), a third-generation electromagnetic shock wave lithotriptor, has been used. The evaluation of the cases included a history, physical examination, urinalysis, urine culture, serum creatinine, blood urea nitrogen (BUN), serum electrolytes (sodium, potassium, calcium and phosphor) measurements, and coagulation profile. Excretory urography, renal ultrasonography or a combination of these was used to diagnose, locate and define the stone burden, demonstrate renal and ureteral anatomical alterations, and to confirm indications for the SWL. Entry criteria were radiopaque single or multiple stones at any location, radiolucent renal location within the upper urinary tract, $\leq$30 mm in diameter, follow-up at our institution and age less than 15 years. Exclusion criteria were abnormal laboratory profile (serum creatinine, coagulation profile), urinary tract infection (UTI), presence of a nonfunctioning kidney or congenital urinary tract abnormalities such as ureteropelvic junction obstruction, and obstructive megaureter, obstructed urinary tract distal to the stones. Patients with a known UTI received culture-specific antimicrobials before stone treatment. In addition, they received a prophylactic antibiotic from pre-SWL to 3 days after SWL.

Ninety-eight (37.2%) children presented with pain (colicky, flank pain or diffuse abdominal pain), 86 (25.8%) with UTI, and 35 (13.3%) with hematuria.

A total of 60.1% patients (104 children) aged $\leq$10 years had SWL performed under general anesthesia in Dornier MPL 9000 machine. The other children (69 patients) were treated under sedation with ketamine or fentanyl. However, in Lithostar Modularis group, sedo-analgesia was given to all children for SWL treatment. While pentothal sodium 3–4 mg/kg and fentanyl 1–2 μg/kg were administered in children aged $\leq$5 years (21 patients), propofol 1–2 mg/kg and fentanyl 1–2 μg/kg were chosen for children aged >5 years (69 patients).

Double pigtail ureteral stents were inserted in patients with high-grade obstruction, solitary kidney, or stones larger than 25 mm in diameter. The fragmentation was assessed the following week using a plain abdominal radiograph of the kidney, ureter, and bladder (KUB) or by ultrasonography (US) for patients with radiopaque calculi. We determined radiolucent ureter calculi by non-contrast spiral computed tomography (NCCT) according to US examination in five patients who had post SWL dilation. NCCT was done in all children with radiolucent calculi (5 cases) after 3 months post SWL for determining stone-free status in the follow-up period. The treatment was repeated 2 weeks later in renal location and 1 week later in ureteral location if there was an incomplete fragmentation seen on a repeat KUB. Stone-free status was defined as the absence of any visible stone fragments on a good quality KUB obtained 3 months after SWL treatment.

The Dornier MPL 9000 unit features an 80-nF generator and an ellipsoid with a 220-mm aperture.The focal length is 120 mm and the focus size is 34 × 4.2 mm. The Siemens Lithostar Modularis machine has an ellipsoid aperture of 125 mm, focal distance of 14 cm and a focal zone of 12 × 130–13 × 146 mm. Shock waves are generated by an electrohydraulic spark gap electrode that is replaced after every 2,500 shock waves, whereas electromagnetic membrane is replaced after 1.5 million shock waves. Both lithotriptors offers the possibility to localize calculi throughout the urinary tract, either with ultrasound or fluoroscopy. The patients lay in the supine position for all stones above the pelvic brim and in the prone position for those below the pelvic brim.

Efficacy quotient (EQ) was calculated as stone-free percentage × 100/(100% + re-treatment rate percentage + auxiliary procedure percentage) as described previously [9]. We calculated the EQ for each machine and stone location. Additionally, we compared the results of EQ products in the groups to determine whether there was a statistically significant difference.

Statistical analysis

Values are presented as means ± standard deviation. Student's t test for unpaired or chi-square test was used to estimate significance of the differences. The values were considered significant when $P < 0.05$.

Table 1 Age, stone size, number of shock, treatment times and fluoroscopy times using the electrohydraulic versus the electromagnetic lithotripsy in the patients

	Electrohydraulic		Electromagnetic		P value	
	Renal	Ureteral	Renal	Ureteral	Renal	Ureteral
Renoureteral unit	159	24	56	40	NA	NA
Age (year)	8.3 ± 3.9	8.6 ± 3.5	7.8 ± 3.4	7.5 ± 3.5	0.031	0.923
Stone size (mm)	13.3 ± 5.3	7.3 ± 2.1	12.7 ± 6.0	8.4 ± 3.0	0.751	0.382
Shock number per session	1,949 ± 177	1,956 ± 91	2,192 ± 319	2,377 ± 265	<0.001	<0.001
Treatment time (min)	30.1 ± 6.8	31.3 ± 6.7	30.5 ± 8.2	28.6 ± 5.2	0.089	0.605
Fluoroscopy duration (min)	0	1.3 ± 1.3	2.9 ± 1.2	2.8 ± 1.9	NA	0.194

All parameters are means ± standard deviation (SD)

NA Not applicable

Table 2 Stone location and size in patients treated with SWL

Stone location	Stone size (mm)				Total (%)
	5–10	11–15	16–20	>20	
Upper calyx (*n*)	7	9	4	1	21 (7.5)
Middle calyx (*n*)	18	4	2	1	25 (9.0)
Lower calyx (*n*)	19	16	8	4	47 (16.9)
Renal pelvis (*n*)	49	28	17	5	99 (35.5)
Complex (*n*)	2	4	9	8	23 (8.2)
Upper ureter (*n*)	17	1	–	–	18 (6.4)
Middle ureter (*n*)	6	–	–	–	6 (2.2)
Lower ureter (*n*)	36	3	1	–	40 (14.3)
Total (%)	154 (55.2)	65 (23.3)	41 (14.7)	19 (6.8)	279

Results

During the study period, we treated 263 children (279 renoureteral units) with urolithiasis by SWL. The age range was 9 months to 14 years (mean 8.1 ± 3.8). The stones were located on the right side in 154 (55.2%) cases and on the left side in 125 (44.8%) cases. The male:female ratio was 1.8 (171/92). Children younger than 15 years constituted 3.7% (263 children/7,050 patients) of patients treated at our SWL center during a 12-year period. An applied average voltages in our patients was 18.8 ± 1.3 kV (range 18–20 kV) for Dornier MPL 9000 and 2.7 ± 0.3 kV (range 1–3 kV) for Siemens Lithostar Modularis. Table 1 lists patients' comparative data for the two different machines. Stone location and size in patients treated with SWL were summarized in Table 2.

Of the 173 patients treated with the Dornier MPL 9000, 104 required general anesthesia and 69 needed sedation. In contrast, the Lithostar Modularis necessitated only sedoanalgesia for all patients (90 children). Average hospitalization durations in our series were 35.5 ± 33.6 h (range 6 h–7 days) for Dornier MPL 9000, and 26.2 ± 35.4 h (range 4 h–7 days) for Siemens Lithostar Modularis. The difference between the hospitalization duration for two types of lithotriptor was statistically significant ($P = 0.03$).

Table 3 lists stone-free rates, EQ, re-treatment rates, and complication rates for SWL in stones for different location in both machines. The success rate for the electromagnetic unit (86.5%) was almost identical with that achieved with the electrohydraulic unit (85.2%) in the stones for the different location, and there was no statistically significant difference in success rate in both groups ($P > 0.05$). The electromagnetic unit had a significantly higher success rate than electrohydraulic unit for distal ureteral calculi (86.2 vs. 54.5%, $P = 0.034$). However, when success rates were compared for stone burden subsets, the differences were insignificant for both lithotriptors ($P > 0.05$, for all) (Table 4).

The EQs for SWL were not significantly different for electrohydraulic and electromagnetic lithotriptors except for distal ureteral calculi (Table 3). The EQ was 56% for the electromagnetic unit versus 40% for electrohydraulic unit for distal ureteral calculi.

Major complications such as steinstrasse (13 cases), UTI (7 cases), urosepsis (1 case), and subcapsular hematoma (1 case) were seen in 22 (8.4%) patients. Steinstrasse resolved spontaneously in seven patients and spontaneous passage failed in only three children, and these children were successfully treated with ureteroscopic intervention. Symptomatic UTI was successfully treated with oral antibiotics in seven children. One case with urosepsis was hospitalized and treated. The complication rates for SWL were not significantly different between Dornier MPL 9000 and Siemens Lithostar Modularis lithotriptors (8.7 and 6.2%, respectively) (Table 3).

Table 3 Stone-free rates, re-treatment rates, complication and EQ according to lithotriptor type for different stone locations

	Dornier MPL 9000	Siemens Lithostar
Renal		
Stone-free	140/159 (88.1%)	48/56 (85.7%)
Re-treatment	80/159 (50.3%)	28/56 (50%)
Complication	14/159 (8.9%)	4/56 (7.1%)
EQ	56%	56%
Proximal ureter		
Stone-free	7/8 (87.5%)	9/10 (90%)
Re-treatment	3/8 (37.5%)	2/10 (20%)
Complication	–	–
EQ	64%	69%
Middle ureter		
Stone-free	3/5 (60%)	1/1 (100%)
Re-treatment	1/5 (20%)	–
Complication	–	–
EQ	43%	100%
Distal ureter		
Stone-free	6/11 (54.5%)	25/29 (86.2%)
Re-treatment	4/11 (36.4%)	12/29 (41.4%)
Complication	2/11 (18.2%)	2/29 (6.9%)
EQ	40%	56%

EQ Efficacy quotient

Double pigtail ureteral stents were inserted into 33 (11.8%) children. In 18 cases, the decision for ureteral catheterization was based on significant stone bulk (greater than 25 mm diameter), in two solitary kidneys. Additionally, double J stent was inserted in patients in whom the stone caused a severe degree of obstruction and in cases with reconstructive surgery such as pyeloplasty and ureteroneocystostomy.

Discussion

The technological developments in the design of shock wave lithotriptors have precipitated an important change in the management of pediatric urolithiasis. As a result of these developments, SWL is being widely applied in clinical use in pediatric stone disease [1]. Nowadays, lithotriptors are widely available to the majority of urology clinics and have become the first line treatment choice in most children with urolithiasis [5, 10, 11]. The experience gathered in more than 20 years shows that SWL is the preferred treatment choice in pediatric urolithiasis, but SWL in this population is still not an FDA-approved indication [1, 12]. In general, the less powerful lithotriptors with smaller focal points result in lower stone-free rates and/or higher re-treatment rates. This disappointment with the second-generation machines led to the evolution of the third-generation lithotriptors, which have a more powerful generator and have versatile ultrasound and fluoroscopy imaging facilities [12].

There are few comparative studies related to the results of electrohydraulic and electromagnetic lithotriptors [5, 10, 11], because comparing the results achieved with various lithotripsy units at various institutions is difficult due to the variability in patient selection, definition of success and follow-up methodology, and reported auxiliary measures [13]. Prospective randomized controlled trials comparing different lithotriptors are rarely available in the literature [11]. The cost of the devices usually dictates that it is not economically feasible to have more than one device available in a given institution [14]. Since the present study was performed in the same institution with two different machines used in different times, patients' characteristics, inclusion and exclusion criteria were similar, as also operator, follow-up procedure and the definition of success. In the present study, there was no selection bias of patients since only one lithotriptor was used, that is the Dornier MPL 9000 initially (between January 1993 and October 2004) and the Siemens Lithostar Modularis more recently (between November 2004 and January 2007). However, in the present study, there were some limitations such as learning curve in favor of the second device. Because in our stone center, since beginning, the Dornier MPL 9000 had been used for 12 years, it was later replaced with the Siemens Lithostar Modularis and is in use until now.

Van Horn et al. reported a comparative study between the unmodified Dornier HM3 and the second generation Siemens Lithostar lithotriptors, and they did not find any significant differences in regard to success and the use of stents, patient age or stone location between the two lithotriptors. While van Horn et al.'s [5] series included only 32 children, the present study included 263 children. To our knowledge, the current study is the first large series comparing lithotriptors at a single institution in the pediatric

Table 4 Success rates for two lithotriptors according to stone sizes

	Stone size (mm)				
	5–10 mm	11–15 mm	16–20 mm	>20 mm	Total
MPL 9000 (success rate)	90%	93.6%	76.7%	46.7%	85.2%
Lithostar Modularis (success rate)	90.5%	77.8%	81.8%	75%	86.5%
P value	0.940	0.067	0.727	0.326	0.784

population. Elsobky et al. [15] compared two-second-generation lithotriptors in pediatric cases, but they did not document any significant difference in terms of treatment results. The first prospective randomized study comparing electrohydraulic (Dornier MFL 5000) and electromagnetic lithotriptors (Dornier Lithotriptor S) at a single center was published by Sheir et al. [11]. They reported that the electromagnetic lithotriptor had significant clinical advantages over the electrohydraulic lithotriptor in terms of treatment time, re-treatment rate and success rate.

The present comparative study of Dornier MPL 9000 (electrohydraulic) with Siemens Lithostar Modularis (electromagnetic) machines showed that there were no significant differences in success rates except for the lower ureteral stones. When success rates were compared for distal ureteral stones, the difference was significantly higher in favor of the electromagnetic unit (54.5 vs. 86.2%, $P = 0.034$). Higher success rate of Siemens Lithostar Modularis in distal ureteral stones is related to better high-resolution fluoroscopic targeting not stone burden.

Matin et al. [10] reported a comparative study (electromagnetic) of Modulith SLX (Karl Storz Lithotripsy, Atlanta, Georgia) and (electrohydraulic) Dornier MFL 5000 lithotriptor (Dornier Medical Systems, Inc., Marietta, Georgia), and they found that the electrohydraulic machine resulted in a higher stone-free rate rather than electromagnetic machine in adult patients (77 vs. 67%). Additionally, Bierkens et al. [16] reported a prospective multicenter comparative study of the five types of machines (Siemens Lithostar, Dornier HM4, Wolf Piezolith 2300, Direx Tripter X1 and Breakstone) and they concluded that the second-generation lithotriptors were less effective than the first generation ones (Dornier HM3). But, the second-generation lithotriptors represent an improvement in SWL for patients with urolithiasis because they involve less need for anesthesia, hospitalization and use of auxiliary procedures compared to the first generation lithotriptor.

Several anesthetic techniques have been used in pediatric series undergoing SWL, e.g., general anesthesia, regional anesthesia, or intravenous sedation. Commonly, general anesthesia is required for first-generation lithotriptors, whereas intravenous sedation will suffice in the case of most second-and third-generation machines [12]. Technical developments of third-generation lithotriptors have resulted in a reduction of the need for anesthesia [17]. Siemens Lithostar Modularis has allowed intravenous sedo-analgesia in all of the patients. However, we used intravenous anesthesia only in 39.9% of our patients who were treated with the Dornier MPL 9000. The children aged ≤10 years SWL were treated under general anesthesia, because sedoaanalgesia is inadequate in these patients in the Dornier MPL 9000 group. Most prepubertal patients require general anesthesia during SWL treatment with different types of lithotriptor. In Ather and Noor's [18] series using the Dornier MPL 9000 for 105 children, 85% cases were treated under general anesthesia. However, of the 173 children treated with the Dornier MPL 9000, 104 (60.1%) required general anesthesia in our series. While hospitalization duration was an average of 26 h with the Siemens Lithostar Modularis, hospitalization lasted an average of 35.5 h with the Dornier MPL 9000. There are some clinical criteria to indicate the outpatient surgical patient's readiness for discharge. In our institution, postanaesthesia discharge scoring system [19] based on five major criteria has been used: (1) vital signs, including blood pressure, heart rate, respiratory rate and temperature; (2) ambulation and mental status; (3) pain, nausea/vomiting; (4) surgical bleeding; and, (5) fluid intake/output. A score of below nine results in delay in discharge. Delaying was related to analgesia type applied (sedoanalgesia or general anesthesia). Naturally, general anesthesia resulted in more delayed recovery.

We conclude that the third-generation electromagnetic lithotriptor represents an improvement in SWL for patients with urolithiasis because it involves less need for anesthesia, hospitalization duration and better fluoroscopic targeting for ureteral stones compared to the second generation electrohydraulic lithotriptor.

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