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Lithotripter Outcomes in a Community Practice Setting: Comparison of an Electromagnetic and an Electrohydraulic Lithotripter

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Abstract

Purpose—We assessed patient outcomes using 2 widely different contemporary lithotripters.

Materials and Methods—We performed a consecutive case series study of 355 patients in a large private practice group using a Modulith® SLX electromagnetic lithotripter in 200 patients and a LithoGold LG-380 electrohydraulic lithotripter (TRT, Woodstock, Georgia) in 155. Patients were followed at approximately 2 weeks. All preoperative and postoperative films were reviewed blindly by a dedicated genitourinary radiologist. The stone-free rate was defined as no residual fragments remaining after a single session of shock wave lithotripsy without an ancillary procedure.

Results—Patients with multiple stones were excluded from analysis, leaving 76 and 142 treated with electrohydraulic and electromagnetic lithotripsy, respectively. The stone-free rate was similar for the electrohydraulic and electromagnetic lithotripters (29 of 76 patients or 38.2% and 69 of 142 or 48.6%, $p = 0.15$) with no difference in the stone-free outcome for renal stones (20 of 45 or 44.4% and 33 of 66 or 50%, $p = 0.70$) or ureteral stones (9 of 31 or 29% and 36 of 76 or 47.4%, respectively, $p = 0.08$). The percent of stones that did not break was similar for the electrohydraulic and electromagnetic devices (10 of 76 patients or 13.2% and 23 of 142 or 16.2%) and ureteroscopy was the most common ancillary procedure (18 of 22 or 81.8% and 30 of 40 or 75%, respectively). The overall mean number of procedures performed in patients in the 2 groups was similar (1.7 and 1.5, respectively).

Conclusions—We present lithotripsy outcomes in the setting of a suburban urology practice. Stone-free rates were modest using shock wave lithotripsy alone but access to ureteroscopy provided satisfactory outcomes overall. Although the acoustic characteristics of the electrohydraulic and electromagnetic lithotripters differ substantially, outcomes with these 2 machines were similar.

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Keywords

kidney calculi; ureteral calculi; lithotripsy; equipment and supplies; treatment outcome

The treatment of kidney stone disease has changed dramatically in the last 30 years beginning with the first successful SWL treatment by Chaussy et al in 1980 in Germany.[1] Initial SWL cases were encouraging and SWL quickly gained acceptance as the preferred initial treatment approach for most renal and many ureteral calculi.[1–7]

Since the introduction of the HM3 lithotripter (Dornier MedTech, Wessling, Germany), there has been a substantial effort to improve lithotripter technology and yet outcomes have worsened. Reports of approximately 50% or lower SFRs using SWL are not uncommon.[8–10] Multiple factors may affect this decrease in outcomes but logic points to the design changes that narrowed the focal zone and eliminated the water bath. Lithotripsy with the HM3 device was typically performed with the patient under anesthesia. In an effort to make treatment anesthesia-free manufacturers enlarged the aperture of the shock source, thereby spreading the acoustic field to minimize discomfort at the skin.[11] This resulted in narrowing the focal width, making it more difficult to hit a stone moving due to respiratory excursion.[12,13] Another critical design change came about with the push to make lithotripters more readily transportable. Replacing the water bath with a dry treatment head led to smaller modular systems but necessitates the use of coupling medium such as gels and oils, which tend to capture air pockets that interfere with SW transmission.[14–16]

We assessed the effectiveness of SWL in a high volume private practice, a setting in which lithotripsy is typically the primary initial method of treating uncomplicated stone cases. We had the unique opportunity to test the performance of 2 contemporary lithotripters that represent different concepts in SW delivery. The electromagnetic Storz Modulith SLX has a narrow focal width (approximately 3 to 4 mm) and it generates high acoustic pressure (approximately 50 MPa at PL-7) while the electrohydraulic LithoGold LG-380 has a much broader focal width (approximately 20 mm) and produces much lower pressure SWs (approximately 20 MPa at PL-9).[17,18] The coupling system of the electromagnetic device uses a partial water bath but the electrohydraulic device has a dry treatment head. Because a narrow focal width limits the ability to hit a moving stone and it is difficult to achieve good coupling with a dry treatment head, we examined these divergent technologies representing the advantages and limitations in lithotripter design.

MATERIALS AND METHODS

In this institutional review board approved, consecutive case series study we prospectively recruited 355 patients from a clinical urology practice in southern Indiana. The first 155 patients underwent SWL using the LithoGold LG-380 electrohydraulic lithotripter. After this device was replaced 200 patients were treated with the Modulith SLX electromagnetic lithotripter. In each group patients under general anesthesia underwent lithotripsy at 60 SW per minute using a stepwise power ramping protocol incorporating a 3-minute pause in SW administration.[19] Treatment was initiated at PL-3 (150 SWs) followed by a 3-minute pause before treatment was resumed at escalating steps using 50 SWs per step to a maximum setting of PL-9. Imaging was repeated every 500 SWs. Lithotripsy was halted when the surgeon considered that the stone was broken to completion or a maximum number of SWs were delivered (3,000 by the electrohydraulic and 4,000 by the electromagnetic lithotripter). Multiple surgeons involved in the study were assisted by the same technical team. The lithotripsy protocol was proposed by the Indiana University researchers but the First Urology group performed patient recruitment, lithotripsy, followup timing and the choice of additional procedures.

Followup was done at 2 to 4 weeks by plain x-ray of the kidneys, ureters and bladder. Paired preoperative and postoperative films were analyzed by a dedicated genitourinary radiologist. The SFR was defined as no residual fragments remaining after single session SWL without an ancillary procedure.

In the electrohydraulic and electromagnetic groups patients were excluded from the study due to multiple stones (41 and 38), unclear stones on preoperative imaging (11 and 3) and loss to followup (10 and 16, respectively). In addition, in the electrohydraulic group patients were excluded due to recent SWL (7), age less than 18 years (4), missing postoperative data (3), recent URS, duplicate enrollment and bladder tumor (1 each). One patient in the electromagnetic group was excluded due to ultrasound followup only. Thus, lithotripsy outcomes were assessed in 76 and 142 patients treated with the electrohydraulic and electromagnetic devices, respectively.

Data were analyzed with JMP® 10.0. We used the t-test or chi-square test, or generalized linear models as appropriate with significance considered at $p < 0.05$.

RESULTS

The table lists the clinical characteristics of the patient population. The distribution of renal vs ureteral cases did not differ between the lithotripters (Fisher exact test $p = 0.08$). Mean ± SD stone size was larger in the electrohydraulic group (8.5 ± 3.4 vs 7.4 ± 3.5 mm, Wilcoxon rank sum test $p = 0.007$). Followup was 14 days or less in 63.2% and 56.9% of cases in the electrohydraulic and electromagnetic groups, respectively (see table). Overall SFR was similar in the electrohydraulic and electromagnetic groups (29 of 76 patients or 38.2% and 69 of 142 or 48.6%, $p = 0.15$) with no difference in the stone-free outcome for renal stones (20 of 45 or 44.4% and 33 of 66 or 50%, $p = 0.70$) or ureteral stones (9 of 31 or 29% and 36 of 76 or 47.4%, respectively, $p = 0.08$, see table). The mean number of SWs used to treat patients with the electrohydraulic lithotripter was lower than the number using the electromagnetic lithotripter (3,040 ± 196 vs 3,270 ± 481, $p < 0.001$). However, outcomes did not correlate with the number of SWs ($p = 0.56$). Using the electrohydraulic device 5 renal and 5 ureteral stones did not break. Using the electromagnetic device 17 of the 22 stones that did not break were ureteral stones.

In the electrohydraulic and electromagnetic groups 53 (69.7%) and 102 patients (71.8%), respectively, underwent only 1 SWL session. Of patients who were not stone free after a single SWL session 22 of 47 (46.8%) treated with the electrohydraulic device and 40 of 73 (54.8%) treated with the electromagnetic device underwent ancillary procedures (see table).

URS was the most common additional procedure performed in the electrohydraulic and electromagnetic groups (18 of 22 cases or 81.8% and 30 of 40 or 75%, respectively). Counting the number of initial and repeat SWL treatments plus ancillary URS and stent placement, the overall mean number of procedures performed in the electrohydraulic and electromagnetic groups was similar (1.7 and 1.5, respectively).

DISCUSSION

Stone-free outcomes were less than 50% for each study lithotripter. By current standards, for highly successful endoscopic stone removal and against the historical backdrop of the exceptional outcomes of SWL monotherapy using the HM3 lithotripter, we had anticipated a much better result. However, the perception of what represents an acceptable SWL stone-free outcome may largely depend on the treatment setting. This study provides an opportunity to address the reality of using SWL as the primary option to treat solitary uncomplicated renal and ureteral stones in a setting where patients are at first reticent to undergo an invasive procedure and the surgeons are facile with a proven surgical alternative to repeat SWL, namely URS.[20]

The Modulith SLX electromagnetic and the LithoGold LG-380 electrohydraulic lithotripters represent widely different concepts in lithotripter design and yet outcomes were similar using these 2 instruments. The 2 lithotripters differ in the mechanism used to generate SWs. They differ in the acoustic pressures and focal volumes that they produce and they use different methods to couple the shock source to the patient.

In the electromagnetic lithotripter acoustic waves produced by displacing a metal plate are focused by an acoustic lens to generate SWs delivered to a narrow focal zone.[11] Electromagnetic lithotripters produce SWs that are exceptionally consistent in focus and amplitude from shot to shot.[21] The focal width of the Modulith SLX lithotripter is approximately 3 to 4 mm and SWs can achieve a pressure of approximately 50 to 90 MPa (P^+).[17] In the electrohydraulic LithoGold LG-380 lithotripter electrical discharge across the tips of an electrode produces a rapidly expanding plasma bubble generating an acoustic wave that is focused by an ellipsoidal reflector to produce a SW. SWs from electrohydraulic lithotripters are inherently inconsistent since the pressure and focus of the acoustic pulse is affected by the path of the arc discharge, particularly as the electrode erodes with use and the gap widens between the electrode tips.[22] To counter the effect of electrode wear, the electrohydraulic lithotripter uses a self-advance mechanism that maintains the width of the spark gap but not its position. As such, the source point of the acoustic wave shifts away from the geometric internal focal point (F1 point) of the ellipsoidal reflector, thereby shifting the position of the external focus (F2 point) along the acoustic axis.[18] Thus, as the electrode ages, the focal plane moves toward the lithotripter and the focal width at the target plane becomes narrower. Initially the focal width of the electrohydraulic lithotripter is approximately 20 mm but after about 3,000 SWs the width at the target plane narrows to approximately 10 mm. Acoustic pressure of the electrohydraulic lithotripter at the target plane is about 20 MPa (P^+) with somewhat higher pressure (approximately 30 MPa) at the focal plane 35 mm distal to the target plane.

As mentioned, the method used to couple the treatment head to the patient differs for these 2 lithotripters. The electrohydraulic LithoGold LG-380 is a typical dry head lithotripter in which the rubber cushion enclosing the reflector must be coupled to the patient using gel. The coupling interface of any dry head lithotripter is prone to failure because air pockets can become trapped in the gel, decreasing the transmission of SW energy and displacing the focus of incoming SWs. With the Modulith SLX electromagnetic lithotripter the patient reclines in a partial water bath, which is a much better and more consistent medium for SW propagation.

Despite the many differences between these 2 lithotripters, the current outcomes did not significantly differ. For the electrohydraulic and electromagnetic devices we noted similar SFRs for stones overall (38.2% and 48.6%), for renal stones (44.4% and 50%) and for ureteral stones (29% and 47.4%, respectively). A limitation of the study is that this was a consecutive patient series with no opportunity to randomize patients between the 2 lithotripters. However, the study design had several notable strengths. The patient base was consistent because the setting was a nonreferral community practice in which all patients were treated by the same group of surgeons. Also, all cases were performed with assistance from the same technical team, which was skilled in operating the 2 lithotripters. In addition, all preoperative and postoperative films were read in blinded fashion by 1 radiologist. Furthermore, the radiologist applied a rigorous, unambiguous definition for stone free, that is no observable stone fragments after treatment.

A feature of potential relevance that stands out in this series is the relatively short postoperative followup to assess the outcome. Time to followup was about 2 weeks for the electrohydraulic lithotripter (mean 15.0 ± 11.6 days) and about 3 weeks for the electromagnetic lithotripter (mean 22.0 ± 27.8 days), and in each group most patients were seen for followup at 14 days or less (63.2% and 56.9%, respectively). Most published studies of lithotripsy outcomes describe followup in the range of 1 to 3 months. Intuitively one would expect continued clearance of residual fragments with time after SWL, as demonstrated in the literature. In the 1986 report of the United States Cooperative Study to assess the efficacy of the HM3 lithotripter the SFR of solitary stones at hospital discharge was 13.9%, which increased to 77.4% at 3 months.[5] Likewise in a prospective, randomized trial Zehnder et al reported that the SFR of solitary stones at postoperative day 1 was 31% and 20% using the modified HM3 and SLX-F2 lithotripters, which increased to 75% and 69%, respectively, at 3 months.[23] In a meta-analysis of randomized, controlled trials that similarly revealed increased SFR with time after SWL the values did not begin to plateau until approximately 8 to 9 weeks after treatment.[24]

However, in the current study in which followup was only about 2 weeks, we found no effect of followup duration on outcome (Wilcoxon rank sum test $p = 0.28$). The timing of followup and choice of ancillary procedures were dictated by the management pattern followed by this physician group. Patients were evaluated 2 to 4 weeks after SWL. If significant fragments remained, the treatment philosophy was to truncate the stone episode by completing stone removal with URS. In this group the surgeons are adept at URS and offer SWL or URS as the potential first treatment. Patients in this setting overwhelmingly elect SWL over URS as initial treatment but are willing to consider URS if the noninvasive option is unsuccessful.

Whether the stone-free outcomes in this study are comparable to findings reported by others is a reasonable question that proves difficult to answer with certainty. Comparing clinical outcomes in SWL has long been recognized as a challenge because few studies have been done using similar treatment parameters or sharing a common followup protocol or the same criteria to define a stone-free result. Several reports using a rigorous stone-free definition similar to that in the current series suggest that our findings are in line with those of others. One such study is an assessment of the performance of the LithoTron® electrohydraulic lithotripter in which the 2-week SFR was 34.9% and increased to 53.8% at 3 months.[9] Using similar stone-free criteria Ng et al reported a 3-month followup SFR of 40.2%, 46.7% and 50.2% for the Compact Delta, MPL 9000 (Dornier MedTech) and PiezoLith (Richard Wolf, Knittlingen, Germany) lithotripters, respectively.[8] In a separate study they found that the 3-month SFR using the Sonolith® lithotripter depended on the SW rate, that is 35.9% at 120 SWs per minute and 50.5% at 60 SWs per minute.[10] Thus, it appears that the overall 38.2% and 48.6% SFRs that we observed at 2 weeks of followup for the LithoGold LG-380 electrohydraulic and the Modulith SLX electromagnetic devices are comparable to those of several other contemporary lithotripters.

CONCLUSIONS

In this consecutive case study performed at a large suburban urology practice the assessment of 2 widely different types of lithotripters showed similar results. Two-week SFRs using the LithoGold LG-380 electrohydraulic and the Modulith SLX electromagnetic lithotripters (38.2% and 48.6%, respectively) were comparable to outcomes observed by others for various contemporary lithotripters. Although outcomes using SWL alone fail to match the success of URS, patient preference often results in initial treatment using the noninvasive option.

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Abbreviations and Acronyms

PL	power level
SFR	stone-free rate
SW	shock wave
SWL	SW lithotripsy
URS	ureteroscopy

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Table

Patient and stone characteristics, SWL results, and repeat and ancillary procedures by lithotripter

	Electrohydraulic	Electromagnetic	p Value
No. pts	76	142	–
Mean kg/m^2 body mass index (range)	29.1 (21.1–47.7)	29.9 (18–43.9)	0.4
No. renal location (%):	45 (59.2)	66 (46.5)	0.06
Upper pole	2 (2.6)	7 (4.9)	0.4
Mid pole	11 (14.5)	10 (7.0)	0.1
Lower pole	17 (22.4)	31 (21.8)	0.9
Pelvis	15 (19.7)	18 (12.7)	0.2
No. ureteral location (%):	31 (40.8)	76 (53.5)	0.06
Proximal	12 (15.8)	37 (26.1)	0.08
Mid	5 (6.6)	7 (4.9)	0.6
Distal	14 (18.4)	32 (22.5)	0.4
Stone size (mm):			
No. 2 or less (%)	0	2 (1.4)	0.2
No. 2.1–5 (%)	14 (18.4)	47 (33.1)	0.02
No. greater than 5 (%)	62 (81.6)	93 (65.5)	0.01
No. greater than 10 (%)	16 (21.1)	20 (14.1)	0.19
Mean ± SD (range)	8.5 ± 3.4 (3–18)	7.4 ± 3.5 (2–20)	0.007
No. SFR only	29/76 (38.2)	69/142 (48.6)	0.15
SWL/total No. (%):			
Renal stones	20/45 (44.4)	33/66 (50)	0.70
Ureteral stones	9/31 (29)	36/76 (47.4)	0.08
Mean ± SD mm stone size:			
Stone free	7.6 ± 2.5	6.2 ± 3.2	0.005
Not stone free	9.1 ± 3.7	8.5 ± 3.5	0.42
Mean ± SD No. SWs	3,040 ± 196	3,270 ± 481	0.001
No. unbroken stones (%)	10 (13.2)	23 (16.2)	0.55
Mean ± SD days postop followup (range)	15.0 ± 11.6 (3–69)	22.0 ± 27.8 (3–237)	0.28
No. pts not stone free	47	73	0.14

	Electrohydraulic	Electromagnetic	p Value
No. ancillary procedure (%):	22 (46.8)	40 (54.8)	0.39
Repeat SWL only	4 (5.3)	6 (4.2)	
Second repeat SWL	0	1 (0.7)	
URS only	18 (23.7)	30 (21.1)	
Repeat SWL + URS	0	3 (2.1)	
No. stent (%):	34 (44.7)	38 (26.8)	0.008
Stone free only SWL	13 (44.8)	18 (26.1)	
Not stone free	21 (44.7)	20 (27.4)	