The Effectiveness of Shock Wave Lithotripters: A Case Matched Comparison

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Abbreviations and Acronyms

BMI = body mass index

SWL = shock wave lithotripsy

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Purpose: We compared the results of shock wave lithotripsy with a newer electromagnetic lithotripter to those of an electrohydraulic lithotripter using identical treatment and followup criteria.

Materials and Methods: We performed a case matched comparison of 8,565 patients treated from 2003 to 2007 using the Medstone STS™ and the Modulith® SLX machines, matching for stone size, location and patient body mass index. The outcome of interest was treatment success in producing stone-free status. We report treatment characteristics, such as stone site and size, gating and final stone-free rate. Significance was considered at $p < 0.05$.

Results: Overall Modulith SLX and Medstone STS stone-free rates were equivalent (61.1% and 64.5%, respectively, $p = 0.0664$). Matching and logistic regression results showed that differences in the stone-free rate were insignificant for all stones ($p > 0.7592$), lower pole kidney stones ($p = 0.9659$) and ureteral stones ($p = 0.6409$). Medstone STS performed better than Modulith SLX only for distal ureteral stones (83.63% vs 66.67%, $p = 0.0154$). The rate of post-lithotripsy secondary procedures was equivalent ($p = 0.2079$). The difference was insignificant for harder stones ($p = 0.2988$).

Conclusions: Shock wave lithotripsy is equally effective using Medstone STS and Modulith SLX for different stone sizes and most stone sites. Shock wave lithotripsy is more successful for lower ureteral stones using the Medstone STS. To our knowledge this is the first study comparing these 2 commonly used lithotripters.

Key Words: kidney, ureter, calculi, lithotripsy, equipment and supplies

Since the introduction of the electrohydraulic energy based Dornier® HM-3 lithotripter 30 years ago, many newer units have been introduced, of which some use alternative electromagnetic or piezoelectric technology. Newer generation lithotripters are smaller, easier to use and more versatile. However, it was proposed that the clinical effectiveness of third generation lithotripters has deteriorated due to design deficiencies.[1] The shortage of clinical data and standardized testing make direct comparison difficult. Matched pair analysis was advocated as an effective alternative to compare lithotripter efficacy.[2]

The Medstone STS is a second generation, electrohydraulic energy based machine that was initially introduced in the 1980s. The Modulith SLX is a third generation, multifunctional, electromagnetic energy based lithotripsy machine that was introduced relatively recently and few studies of this unit are available.[3–5] We compared the results of SWL with the Modulith SLX electromagnetic lithotripter to those of the Medstone STS electrohydraulic lithotripter using strict matching criteria for stone size and site, and patient characteristics. We hypothesized that Medstone STS efficacy would be superior

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due to physical attributes, such as focal volume and electrohydraulic energy, that are more comparable to those of the first generation Dornier HM-3.

METHODS

Patients

From January 2003 to October 2007 patients with radiological evidence of stones in the kidney or ureter underwent a total of 8,566 SWLs using Medstone (Models STS, STS-C and STS-T), a second generation electrohydraulic lithotripter, and Modulith (Models SLX-T and SLX-F2), an electromagnetic lithotripter. Each site was randomly assigned a machine depending on device availability in that geographic location. Treatment characteristics were recorded, such as stone site and size, need for re-treatment and the final stone-free rate. Outcomes were reported by the treating urologist with the stone-free rate defined by postoperative imaging, including plain x-ray of the kidneys, ureters and bladder in 90% of cases, 2 to 12 weeks postoperatively (median 3). Routine computerized tomography was not done for postoperative imaging to not deviate from standard of care practices and due to increasing concern about radiation exposure in patients with nephrolithiasis.[6]

Statistical Analysis

Analysis was done using SAS®, 9.2. The general incidence and stone-free rate are reported. Patients were matched based on stone size, location and BMI using Matching Macro software (mayoresearch.mayo.edu/biostat/sasmacros.cfm). Matching criteria were stone size within 1 mm, BMI within 5 units and stone site. We analyzed matched sets using conditional logistic regression with lithotripter type as the exposure variable, controlling for the number of shock waves delivered and whether treatment was gated. This matched analysis was done for all stones, lower pole stones, ureteral stones in general and lower ureteral stones. Since stone composition and computerized tomography HU are not available in our database, we divided stones into 2 groups by the number of shock waves used (more and less than 3,000) as a proxy for stone hardness. Matched analysis was done again to measure the difference in lithotripter effectiveness in these 2 stone groups. We divided the number of shock waves delivered into 3 groups, including group 1—less than 2,400, group 2—2,400 to 3,600 and group 3—more than 3,600, and used this uniformly in our analysis.

RESULTS

Table 1 lists treatment distribution, stone site and the stone-free rate for calculi in general by lithotripter. Table 2 shows the stone-free rate for each lithotripter by stone site and size with the p value for differences. Table 3 lists the number of shock waves, average energy and procedure time by lithotripter, stratified by stone size. During the study period 8,565 patients received treatment, including 7,832 with Medstone STS and 733 with Modulith SLX. Mean ± SD stone size was 0.85 ± 0.45 and 0.80 ± 0.37 cm, and mean BMI was 29.50 ± 6.42 and 29.14 ± 6.88 kg/m^2 in Medstone STS and Modulith SLX cases, respectively. Overall we noted no significant difference in the stone-free rate in Modulith SLX and Medstone STS cases (61.1% and 64.5%, respectively, p = 0.0664). Medstone STS showed a better stone-free rate than Modulith SLX only for lower ureteral stones (83.63% vs 66.67%, p = 0.0154). Medstone STS treatment generally involved more shock waves, higher energy settings and more time. The stone-free rate was determined after a single shock wave treatment. Re-treatment or secondary procedures were required after 4.5% of Modulith SLX treatments and 3.6% of Medstone STS treatments, which was not significantly different (p = 0.2079). The complication rate was 1.7% for Medstone STS and 1.6% for Modulith SLX.

Table 1. *Stone site by lithotripter*

	No. Pts Medstone STS (%)	No. Pts Modulith SLX (%)
Kidney:		
Upper pole	468 (5.98)	51 (6.96)
Middle pole	643 (8.21)	61 (8.32)
Lower pole	2,062 (26.33)	193 (26.33)
Pelvis	2,753 (35.15)	231 (31.51)
Ureter:		
Upper	1,440 (18.39)	144 (19.65)
Middle	130 (1.66)	20 (2.73)
Lower	336 (4.29)	33 (4.50)
Stone-free	5,053 (64.52)	448 (61.12)

Using these methods and strict matching criteria we matched each of the 733 patients treated with Modulith SLX with 2 or 3 treated with Medstone STS for a total of 2,696 treated with the latter. Conditional logistic regression analysis revealed no significant difference in the stone-free rate for all stones (p = 0.7592), lower pole kidney stones (p = 0.9659) or ureteral stones (p = 0.6409) between the 2 machines when controlling for gating and the number of shock waves delivered. However, there was a significant difference between the 2 devices for lower ureteral stones, for which Medstone STS performed better when controlling for the same variables (OR 2.510, 95% CI 1.132-5.568, p = 0.0026). Gating was not a significant covariate on any matched analysis (p >0.05). There was also no significant difference between the 2 lithotripters in the stone-free rate for hard calculi using the number of shocks administered as a surrogate marker for hardness (p = 0.2988).

DISCUSSION

Technological advancements in the design of shock wave lithotripters have led to an important change in urolithiasis management. As a result of