Factors Determining Stone-free Rate in Shock Wave Lithotripsy Using Standard Focus of Storz Modulith SLX-F2 Lithotripter

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OBJECTIVES To calculate the efficiency quotient (EQ) of the latest mobile Storz Modulith SLX-F2 lithotripter and to identify the factors determining the stone-free rate.

METHODS A retrospective review of a prospectively collected database of the first consecutive 533 patients undergoing shock wave lithotripsy (SWL) from June 2009 to February 2010 was performed. A total of 16 patients with radiolucent stones and 43 patients with incomplete follow-up were excluded. The patients were followed up with plain radiography to assess the stone-free status. Univariate and multivariate analyses were performed to identify the factors determining the stone-free rates.

RESULTS Follow-up was complete for 474 patients, with a mean age of 54.2 ± 14.5 years. The success rate after a single SWL session was 82.7% (renal 82.2% and ureteral 83.3%; $P = .81$). The retreatment rate was 14.7% (renal 15.2% and ureteral 14.2%; $P = .79$). The stone-free rate was 77% (renal 74.1% and ureteral 80.9%; $P = .10$). Of the 474 patients, 43 had pre-SWL ureteral stents, and 13 required post-SWL ureteral stenting; 35 patients required post-SWL curative procedures. The EQ was 0.66, and the modified EQ was 0.62. On multivariate analysis, the stone-free patients had a smaller stone size (9.5 vs 10.3 mm, $P = .02$), younger age (53.1 vs 58.0 years, $P = .002$), right-sided stones (83.6% vs 71.0% $P = .001$), and the absence of a ureteral stent (78.7% vs 64.3%; $P = .001$).

CONCLUSIONS The mobile Storz Modulith SLX-F2 lithotripter has an acceptable EQ of 0.66. In the present study, smaller stones (<10 mm), younger age, right-sided stones, and the absence of ureteral stents were associated with significantly greater stone-free rates. UROLOGY xx: xxx, xxxx.

Since its invention, shock wave lithotripsy (SWL) remains one of the first-line options for the management of upper urinary tract calculi.[1] However, the latest generation of electromagnetic (EM) shock wave lithotripters with smaller focal areas and greater peak pressures has been criticized for lower stone-free rates and greater retreatment rates owing to the difficulty in keeping the stone in the smaller focal zone.[2] One such lithotripter is the mobile Storz Modulith SLX-F2 lithotripter, which has an EM cylindrical shock wave generator with dual focal zones (Table 1). It has been reported to have a success rate of 83%-86% and a stone-free rate of 70%-76%.[3,4] Although the efficiency quotient (EQ) of the original electrohydraulic human model 3 (HM3) lithotripter is 0.64-0.67, there is a wide variation among the reported EQs of the EM Storz Modulith lithotripters (0.57-0.67).[5] Therefore, the first objective of the present study was to calculate the EQ of the latest fourth-generation mobile Storz Modulith SLX-F2 lithotripter using its standard focus.

In addition to the type of lithotripter used, other factors, such as stone size (burden), location, and composition have been found to influence the stone-free rates after SWL.[6,7] Recent efforts in identifying factors affecting the stone-free rates have concentrated on the computed tomography (CT) findings of the stone density measured in Hounsfield units and skin-to-stone distance.[8,9] However, not all patients have undergone CT scans before referral to SWL. Therefore, the second objective of the present study was to identify the factors determining the stone-free rate after SWL.

PATIENTS AND METHODS

A retrospective review of a prospectively collected SWL database was performed for 533 consecutive patients undergoing SWL using the standard focus of the mobile Storz Modulith SLX-F2 (Storz Medical, Kreuzlingen, Switzerland) from June

Funding Support: *This work was supported in part by the Northeastern American Urological Association Young Investigator Award and Montreal General Hospital Foundation Award to S. Andonian.*

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Submitted: January 2, 2011, accepted (with revisions): March 7, 2011

0090-4295/xx/$36.00
doi:10.1016/j.urology.2011.03.005

Table 1. Technical specifications of Storz Modulith SLX-F2 (Mobile)

Lithotripter Concept	Description
Shock wave source	Electromagnetic cylinder coil
Shock wave source diameter	300 mm
Coupling System	Water cushion
Method of focusing	Parabolic reflector
Treatment depth	≤180 mm
Shock wave focus size (W × L)	F1: 6 × 28 mm F2: 9 × 50 mm
Shock wave focus pressure	F1: 5-150 MPa F2: 5-90 MPa
Imaging system/ localization	In-line and 30° lateral fluoroscopy In-line ultrasound

2009 to February 2010. Of the 533 patients, 16 with radiolucent stones and 43 (8%) with incomplete follow-up were excluded. The follow-up data were complete for 474 patients with radiopaque stones.

The Modulith SLX-F2 mobile lithotripter, one of the fourth-generation lithotripters, has an EM cylindrical shock wave generator with dual focal zones (Table 1). This unit has the capacity to focus its shock waves using "in-line fluoroscopy," in addition to lateral projection, which could provide some advantages over craniocaudal projections in minimizing localization errors owing to respiratory movement of the kidney.[10] For the mobile Modulith SLX-F2 unit, a mobile C-arm fluoroscopic unit (OEC 9900 Elite, GE Healthcare, Mississauga, ON) with manual adjustments from the anteroposterior to the lateral positions was used to focus using "in-line fluoroscopy." The shock waves were coupled to the patient by water-filled cushions directly abutting the patient with ultrasound-compatible jelly interface.[10] The specifications of this lithotripter are presented in Table 1 (operating manual available from www.storzmedical.com).

Intravenous sedation was used in all patients. Of the 2 focal zones available, the standard narrow focus was used exclusively. The maximal energy level for the renal and ureteral stones was 7 and 9, respectively. A maximum of 3000 shock waves was used at each SWL session.

To minimize radiation, the patients were followed up with plain radiography to assess the stone-free status. Although success was defined as the absence of residual fragments or the presence of fragments <4 mm, the stone-free status was defined as the complete absence of radiopaque stone fragments. Retreatment was defined as repeat SWL performed for the same stone. Therefore, patients presenting for retreatment of the same stone were considered to have SWL failure. The patients requiring post-SWL auxiliary procedures, such as ureteral stenting, were included in the stone-free group if they did not require any other curative procedures, such as repeat SWL or ureteroscopy. Patients requiring post-SWL curative auxiliary procedures, such as ureteroscopy, were considered to have SWL failure and were not included in the stone-free rate. The standard EQ reported by Denstedt et al[11] was calculated using the following formula: EQ = percentage of stone-free patients/100% + percentage of repeat SWL + percentage of post-SWL procedures. This EQ was used to compare with other published EQs. However, this EQ does not take into account other curative auxiliary measures, such as ureteroscopy and percutaneous nephrolithotomy.[8]

Table 2. Retreatment and stone-free rates stratified by stone characteristics

Variable	Total	Retreatment	Stone-Free
Renal	270 (57.0)	41 (15.2)	200 (74.1)
Upper calix	21 (4.4)	2 (9.5)	18 (85.7)
Middle calix	52 (11.0)	6 (11.5)	41 (78.8)
Lower calix	117 (24.8)	26 (22.2)	79 (67.5)
Pelvis	80 (16.9)	7 (8.8)	62 (77.5)
Ureteral	204 (43.0)	29 (14.2)	165 (80.9)
Proximal ureter	112 (23.6)	17 (15.2)	86 (76.8)
Mid ureter	13 (2.7)	3 (23.1)	11 (84.6)
Distal ureter	79 (16.7)	9 (11.4)	68 (86.1)
Laterality			
Left	248 (52.3)	44 (17.7)	176 (71%)
Right	226 (47.7)	26 (11.5)	189 (83.6)
Size (mm)			
<10	252 (53.2)	32 (12.7)	208 (82.5)
≥10	222 (46.8)	38 (17.1)	157 (70.7)
Surgeon			
A	114 (24.1)	13 (11.4)	96 (84.2)
B	93 (19.6)	16 (17.2)	66 (71)
C	169 (35.6)	27 (16)	126 (74.6)
D	98 (20.7)	14 (14.3)	77 (78.6)
Total	474 (100)	70 (14.7)	365 (77.0)

Data presented as numbers, with percentages in parentheses.

Therefore, Rassweiler et al[12] recommended the use of a modified EQ to include both pre- and post-SWL ancillary procedures: EQ modified = percentage of stone-free patients − percentage of curative auxiliary measures/100% + percentage of repeat SWL + percentage of pre-SWL auxiliary measures + percentage of post-SWL adjuvant measures.

Statistical Analysis

The data were analyzed using the Statistical Package for Social Sciences for Windows, version 14 (SPSS, Chicago, IL). Descriptive data are presented in terms of the mean and standard deviations. The Student t-test was used to compare continuous variables, such as age, stone size, fluoroscopy time, and energy. Fisher's exact test was used for categorical variables, with 2-tailed $P < .05$ considered statistically significant. Factors with a significant effect on retreatment and stone-free rates on univariate analysis were further analyzed in multivariate analysis using logistic regression analysis.

RESULTS

Follow-up was complete for 474 patients (57.8% men), with a mean age of 54.2 ± 14.5 years (Table 2). The mean stone size was 9.51 ± 3.87 mm (range 5-25). Only 5 patients (1.1%) had stones >20 mm. Stratified by location, 248 (52.3%) were left-sided and 270 (57.0%) were located in the kidney. The renal stones were significantly larger than the ureteral stones (10.5 ± 3.5 vs 8.7 ± 1.62 mm, respectively, $P = .001$). The overall success rate after a single SWL session was 82.7% (renal 82.2% and ureteral 83.3%; $P = .81$). The retreatment rate was 14.7% (renal 15.2% and ureteral 14.2%; $P = .79$). The stone-free rate was 77% (renal 74.1% and ureteral 80.9%; $P = .10$). Also, 43 (9.1%) patients had pre-SWL ureteral stents, and 13 (2.7%) required post-SWL ureteral stenting. The 35 patients who underwent

Table 3. Factors determining stone-free rate

Variable	Residual Fragments	Stone-Free Status	*P* Value
Age (y)			.002
Mean	58	53.1	
95% CI	55.3-60.7	51.7-54.5	
Stone size (mm)			.02
Mean	10.3	9.5	
95% CI	9.7-11	9.2-9.8	
Fluoroscopy time (min)			.4
Mean	2.5	2.4	
95% CI	2.3-2.8	2.3-2.5	
Energy used			.91
Mean	6.8	6.8	
95% CI	6.6-7.0	6.7-6.9	
Shock waves (n)			.21
Mean	2993	2979	
95% CI	2983-3003	2959-2999	
Sex			.1
Male	71 (25.9)	203 (74.1)	
Female	38 (19.0)	162 (81.0)	
Laterality			.001
Left	72 (29.0)	176 (71.0)	
Right	37 (16.4)	189 (83.6)	
Size (mm)			.02
<10	44 (17.5)	208 (82.5)	
≥10	65 (29.3)	157 (70.7)	
Stone location			.08
Upper calix	3 (14.3)	18 (85.7)	
Middle calix	11 (21.2)	41 (78.8)	
Lower calix	38 (32.5)	79 (67.5)	
Renal pelvis	18 (22.5)	62 (77.5)	
Proximal ureter	26 (23.2)	86 (76.8)	
Mid ureter	2 (15.4)	11 (84.6)	
Distal ureter	11 (13.9)	68 (86.1)	
Auxiliary stents			.001
Yes	20 (35.6)	36 (64.3)	
No	89 (21.3)	329 (78.7)	
Urologist			.34
A	18 (15.7)	96 (84.3)	
B	27 (29.0)	66 (71.0)	
C	43 (25.4)	126 (74.6)	
D	21 (21.4)	77 (78.6)	

CI, confidence interval.

Data presented as numbers, with percentages in parentheses, unless otherwise noted.

ureteroscopy and laser lithotripsy as curative auxiliary procedures were considered to have SWL failure and were not included in the stone-free rate. Therefore, the EQ was 0.66, and the modified EQ was 0.62. For stones ≥10 mm, the EQ was 0.60 and the modified EQ was 0.57.

The stone-free patients were significantly younger than the patients with residual fragments (53.1 vs 58.0 years, $P = .002$; Table 3). Furthermore, the stone-free patients had a significantly smaller mean stone size (9.5 mm, 95% confidence interval 9.2-9.8, vs 10.3 mm, 95% confidence interval 9.7-11, respectively; $P = .02$). Therefore, stones <10 mm resulted in significantly greater stone-free rates than stones ≥10 mm (82.5% vs 70.7%, respectively; $P = .02$). Right-sided stones resulted in significantly greater stone-free rates compared with left-sided stones (83.6% vs 71.0%, respectively, $P = .001$). Furthermore, patients without ureteral stents had significantly greater stone-free rates (78.7% vs 64.3%, $P = .001$). The stone location, patient sex, fluoroscopy time, SWL energy, and number of shock waves delivered did not significantly affect the stone-fee rates (Table 3). Similarly, the stone-free rates did not differ significantly among the 4 urologists performing SWL. On multivariate analysis, smaller stone size, right-sided stones, younger age, and the absence of a ureteral stent continued to be significant determinants of stone-free status.

COMMENT

In the present study, the EQ of the Modulith SLX-F2 was 0.66, and the modified EQ was 0.62. This is comparable to previous published EQs of 0.57-0.67 for the Modulith SL20 and 0.64-0.65 for the Modulith SLX model (Table 4). Furthermore, the latest fourth-generation mobile EM lithotripter seems to have similar efficiency to the original electrohydraulic HM3 lithotripter, with an EQ of 0.64-0.67.[5] Similarly, another study comparing the Modulith SLX-F2 and the Dornier HM3 found no significant differences in the stone-free rates at 1 and 3 months, regardless of the stone size cutoff for residual fragments (<4 and <2 mm).[13] It is important to note that in the present study, stone-free status was defined as the complete absence of fragments on plain radiography.

In the present study, only 13 stones were midureteral, making it difficult to compare this group with those with proximal and distal ureteral stones. Nonetheless, the stone-free rates for the proximal, mid-, and distal ureteral locations were 76.8%, 84.6%, and 86.1%, respectively. In another study of the Modulith SLX-F2 lithotripter for ureteral stones, the stone-free rate was 96.1%, 97.8%, and 97.9% for the proximal, mid-, and distal ureteral stones, respectively.[14] However, the average number of SWL sessions was 1.37, 1.47, and 1.22 for the proximal, mid-, and distal ureteral stones, respectively.[14]

In a published abstract examining the predictors of the stone-free rate using the Modulith SLX-F2 lithotripter, the number of shocks, stone location, and stone size were all significant predictors of a stone-free outcome on multivariate analysis ($P < .05$).[3] In the present study, stone size (9.5 vs 10.3 mm, $P = .02$), but not location, was associated with stone-free status. Similarly, in another study, although stone size, location, and patient sex were significant determinants of stone-free status on univariate analysis, only stone size maintained significance on multivariate analysis.[15] The lack of significance of stone location in the present study could have been related to the small sample size. Furthermore, in the present study, 7 locations were used to compare the retreatment and stone-free rates. In the study by Albala et al,[3] only 3 locations (renal, lower pole, and ureteral) were used to achieve significance. Thus, a larger sample size with fewer locations might show location as a significant determinant of a stone-free outcome.

In the present study, similar to previous reports, the stone-free patients were significantly younger (53.1 vs

Table 4. Comparison of Modulith SLX-F2 with other lithotripters

Lithotripter	SW Source	Patients (n)	Mean Stone Size (mm)	RR (%)	SFR (%)	EQ
Dornier HM3[22]	EH	2402	Most <20	6	70	0.64
Sonolith Vision[23]	EM	309	10.8	16.8	75	0.62
Doriner Compact Delta[24]	EM	4621	Most <10	7.2	58.5	0.51
Dornier Lithotripter S[25]	EM	347	12.7	34.0	88.5	0.66
Dornier MFL 5000[25]	EH	347	11.7	51.6	82.4	0.54
Siemens Modularis[26]	EM	2670	NA	NA	79	0.67
Healthtronics Lithotron[27]	EH	256	8	7.7	66	0.59
Medstone STS-T[28]	EH	326	8.2	NA	66	0.59
Modulith SL20[29,30]	EM	1049	11.9	23-32	78/91	0.57/0.67
Modulith SLX-F2[4] (focus NA)	EM	233	12.6	11.5	76.3	0.64
Modulith SLX-F2[3] (focus NA)	EM	599	7	NA	69.8	NA
Modulith SLX-F2[19] (standard vs wide focus)	EM	361	Renal: 14 Ureter: 11	NA	NA	0.553 vs 0.565 0.798 vs 0.626
Present study, Modulith SLX-F2 (standard focus)	EM	474	Renal 10.5 Ureteral 8.7	14.7	77	0.66

SW, shock wave; RR, retreatment rate; SFR, stone-free rate; EQ, efficiency quotient; EM, electromagnetic; EH, electrohydraulic.

58.0 years, $P = .002$; Table 3). Wiesenthal et al[9] showed that age was a significant predictor of stone-free outcome on univariate but not on multivariate analysis. When Abe et al[16] divided 3023 patients with renal and ureteral stones into 4 age groups, they found that older patients were associated with significantly poorer stone-free rates. Similarly, Ng et al[17] found that the overall stone-free rate and that of the renal, but not ureteral, stones were significantly lower in older patients. When patients ≤40 years old were taken as the reference, patients 40-60 years old and patients >60 years old had an odds ratio of 0.66 and 0.62 for being stone-free, respectively.[17] The investigators hypothesized that aging results in sclerotic changes of the kidney, leading to acoustic impedance and, thus, lower fragmentation and stone-free rates.[17] Additional studies are needed to evaluate the effect of aging on the stone-free rates.

The Modulith SLX-F2 is equipped with a wide focus, in addition to the standard narrow focus. In the present study, only the standard narrow focus of the Modulith SLX lithotripter was used. The advantages of a wide focus have yet to be determined. In terms of renal injury, an in vitro model of perfused porcine kidney showed that no difference between the 2 focal sizes.[18] In terms of clinical outcomes, a Japanese trial comparing the standard focus with the wide focus of the Modulith SLX-F2 found that the EQ for ureteral stones was greater when the standard narrow focus was used (0.798 vs 0.626).[19] No difference was found in the EQ for renal stones (0.553 vs 0.565; Table 4). In another study examining the dual focus in the treatment of ureteral stones, patients treated primarily with the standard normal focus had significantly lower retreatment rates than those treated with the large or combined foci (22.3% vs 33%, respectively, $P < .05$). However, these lower retreatment rates might have been because of the significantly smaller stone size of the patients who had received the narrow standard focus.[14] Nonetheless, the standard narrow focus seems to be associated with lower retreatment rates and greater stone-free rates. However, additional randomized trials are needed to examine the indications for the wide focus.

The present study had several limitations. In addition to being a retrospective study, other limitations included the absence of strict criteria for stent placement before SWL. This was because our center is a tertiary referral center to which most community urologists refer patients to undergo SWL. Another limitation was that the database did not capture the frequency of the shock waves. Recent evidence has shown that lower rates (1 Hz rather than 2 Hz) has been associated with greater stone-free rates.[20] Finally, patients were followed up with plain radiography. Although CT has greater sensitivity for detecting residual fragments after SWL compared with plain radiography, CT is associated with greater radiation exposure and cost than plain radiography.[21] Therefore, for radiopaque stones, the investigators have not recommended performing routine CT.[21] Nevertheless, it is possible that small residual fragments could have been missed by only performing plain radiography in the present study.

CONCLUSIONS

In the present study, the mobile Storz Modulith SLX-F2 lithotripter was found to have an acceptable EQ of 0.66. Furthermore, smaller stones (<10 mm), younger age, right-sided stones, and absence of ureteral stents were associated with significantly greater stone-free rates. Prospective trials are needed to confirm these results.

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