Effect of High Shock Number on Acute Complication Development After Extracorporeal Shockwave Lithotripsy

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Abstract

Purpose: We assessed whether high shock number is associated with higher rates of acute complication development after extracorporeal shockwave lithotripsy (SWL).

Patients and Methods: A retrospective chart review of 372 patients who underwent 436 SWL procedures at 24 kV using a Medstone STS-T lithotripter (Medstone International Inc., Aliso Viejo, CA) was conducted. Complications occurred within 4 weeks of SWL. Treatments were split into three cohorts based on shock number (<2400, 2401–4000, and >4000). Postoperative sequelae of patients who were stone free and those with residual stone were studied separately. Chi-square tests were used to evaluate the relationship between shock number cohort and postoperative complication development.

Results: SWL treatments recorded for each cohort were 158 (37.4%), 145 (34.4%), and 119 (28.2%), respectively. The short-term complication rate when SWL was successful was 8.3% overall. Complication rate for each cohort was 9.5% (11), 7.8% (5), and 7.2% (7), respectively. When SWL was successful, statistical analysis revealed no significant difference between complication rates and shock number cohort ($P=0.63$). Complications in patients with a residual stone occurred after 41.4% of treatments and trended upward with shock number cohort, but did not reach statistical significance ($P=0.84$).

Conclusions: At high voltage, high shock number was not shown to cause higher rates of short-term postoperative complications, as experienced by patients, when SWL was successful or resulted in a residual stone, yet complication rates associated with residual stone burden were approximately five times as common. Forgoing a higher shock number in the presence of a residual stone may therefore increase the risks of sequelae immediately after SWL.

Introduction

CLINICAL STUDIES of extracorporeal shockwave lithotripsy (SWL) have examined numerous treatment variables, such as the impact of voltage, shock delivery rate, and stone size on treatment success and complication development in patients with kidney stones.^{1–5} Relatively little is known, however, about the effect of shock number on the development of complications.

Animal models have demonstrated a dose-dependent relationship between SWL shock number and transient acute renal injury.^{1,6–11} Such findings provide limited clinical guidance and add to questions regarding the short- and long-term safety of SWL for patients. As a result, clinical practice intuition regards the administration of a high shock number (>2400) with caution even in the presence of residual stone. Research is therefore necessary to elucidate the clinical consequences of a high shock number and determine a guide for shock number administration as it relates to clinical sequelae.

To our knowledge, this is the first study with a primary objective of retrospectively investigating whether high shock number was associated with higher rates of acute medical complication development after SWL, specifically with regard to symptoms experienced by patients.

Patients and Methods

Patient variables

With Institutional Review Board approval, we reviewed the medical charts of 372 patients who underwent SWL at a state medical center between October 2000 and November 2008. SWL cases were identified using billing codes. For each patient, the date of treatment, age, sex, and body mass index (BMI; 30 kg/m²) were recorded.

Stone variables

Several features of calculi that were managed with SWL were recorded. They included laterality (unilateral vs

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bilateral), location (renal *vs* ureteral), number, total size (mm), nature (primary *vs* residual), and composition. All ureteral stones were located in the proximal ureter. Total stone size was the sum of the largest measured diameter (mm) of each treated stone determined by plain radiography. A primary stone had not been previously managed with SWL, while a residual stone had been previously managed with SWL. The element contributing $\geq 50\%$ of the stone's character, determined by laboratory analysis on post-treatment gravel collected by the patient, was used to define stone composition.

Treatment variables

All lithotripsy procedures were conducted using a modular, electrohydraulic, spark-gap Medstone STS-T (Medstone International Inc., Aliso Viejo, CA) lithotripter.¹² Rate of shock administration was not available for all cases; however, most were gated to the patient's electrocardiogram. Patients were not pretreated with low-rate shock administration. Recorded operative data included date of SWL, nature of procedure (primary *vs* repeat), number of shocks, energy (kV), and ureteral stent presence.

Outcome variables

Stone status was assessed at 3, 4, and 12 weeks postoperatively using plain radiography. Spontaneous stone passage is known to occur in up to 80% of calculi < 4 mm¹³; patients with a total stone burden < 4 mm at any time point were termed successful. Patients with a residual stone at 12 weeks were treated conservatively, underwent repeated SWL, or underwent auxiliary surgery.

A patient with a successful outcome who experienced at least one of the following symptoms within 4 weeks of SWL was considered to have experienced an acute complication: Pain necessitating additional narcotics after postoperative intravenous narcotics and an initial prescription for oxycodone with acetaminophen; gross hematuria lasting more than 24 hours; urine retention; dysuria; nausea and vomiting; or a temperature higher than 38.3°C. Symptoms attributed to a ureteral stent by the physician were not considered. Patients with a residual stone (≥ 4 mm) were studied separately, because their remaining calculi could not be ruled out as a source of symptom development.

Statistical analysis

SWL treatments of successful patients and those with residual stone were separated into three cohorts: Low (≤ 2400), medium (2401–4000), and high (> 4000) based on the number of shocks administered. Shock number limits were chosen to keep the number of patients similar across all three cohorts. Because a residual stone burden could not be ruled out as a source of symptom development, patients who were stone free or with residual stone were studied separately. For both groups, chi-square tests were used to compare shock number cohort and acute complication development using SAS 9.2 software (SAS Institute Inc., Cary, NC). A value of $P < 0.05$ was considered significant.

Results

Three hundred and seventy-two patients underwent 436 SWL procedures between October 2000 and November 2008 at

a state medical center. Fourteen treatments were eliminated from the study because shock number was unavailable or because treatment was conducted at an energy setting other than 24 kV. Demographics of patients calculated at the time of SWL are outlined in Table 1. BMI could not be calculated for 4 (0.95%) patients at the time of SWL. In this study, shock number trended upward with increasing average patient BMI.

Calculi and SWL treatment variables are summarized in Table 2. Three surgeons treated a total of 594 calculi. An average of 1.42 (range 1–6) stones were targeted during each SWL. Median stone size was calculated to be 11 (range 2–72) mm. Stone composition was determined after 155 (36.7%) treatments. The number of shocks administered at 24 kV averaged 3457 (range 600–8200). It was observed that as stone burden grew, the number of shocks administered also increased. Because of tertiary care referral patterns, a ureteral stent was present, placed, or removed at the time of 171 (40.5%) SWLs.

The total number of SWL treatments recorded for the low, medium, and high shock number cohorts were 158 (37.4%), 145 (34.4%), and 119 (28.2%), respectively. Overall SWL success rates increased from 65.6% (277) to 77.3% (326) between 3 to 4 and 12 weeks postoperatively. A total of five (1.2%) intra-operative complications (one, one, and three for each shock number cohort, respectively) occurred and included: Ureteral perforation (secondary to ureteral stent placement); truncal urticarial rash; small superficial flank blister; skin bruising/blanching; and nausea.

Outcome data when SWL was successful (residual stone burden < 4 mm) is detailed in Table 3. Successful SWL treatments across all cohorts at 3 to 4 weeks postoperatively totaled 277 (65.6%) with a complication rate of 8.3% (23). Complication rates for the low, medium, and high shock number cohorts were 9.5% (11), 7.8% (5), and 7.2% (7), respectively. Chi-square analysis revealed no significant difference between complication rates in these cohorts ($P = 0.63$). Outcome data when SWL resulted in a residual stone are found in Table 4. A short-term complication was reported after 58 (41.4%) of 140 unsuccessful SWL treatments. Complication rates for the low, medium, and high shock number cohorts in this group were 36.8% (14), 40.9% (9), and 43.8% (35), respectively. While the complication rate in patients with a residual stone trended upward with shock number cohort, it did not reach statistical significance ($P = 0.84$).

Postoperatively, 17 (4.0%) patients were lost to follow-up, and 1 (0.2%) patient died of an unrelated cause (multiple endocrine neoplasia type 2B). Unsuccessful SWL was followed by auxiliary surgeries in 17 (4%) cases. These procedures included eight (1.9%) ureteroscopies, six (1.4%) laser lithotripsies, and three (0.7%) percutaneous nephrolithotomies.

TABLE 1. PATIENT DEMOGRAPHICS BASED ON SHOCK NUMBER COHORT

Variable	≤ 2400	2401–4000	> 4000
Total treatments	158	145	119
Average age	45.4 (18–77)	48.8 (19–86)	47.8 (21–84)
Average BMI	28.5 (18–50)	30.9 (18–55)	31.1 (18–51)
Sex			
Male	98 (62.0%)	74 (51.0%)	80 (67.2%)
Female	60 (38.0%)	71 (49.0%)	39 (32.8%)

BMI = body mass index.

TABLE 2. CHARACTERISTICS OF SHOCKWAVE LITHOTRIPSY TREATMENTS AND CALCULI BASED ON SHOCK NUMBER COHORT

Variable	≤2400 (%)	2401–4000 (%)	>4000 (%)	Total no. (%)
SWL treatments				
Total SWL	158	145	119	422
Primary SWL	146 (92.4)	138 (95.2)	104 (87.4)	388 (91.9)
Repeated SWL	12 (7.6)	7 (4.8)	15 (12.6)	34 (8.1)
Total stone size (mm)				
<10 mm	94 (59.5)	61 (42.1)	51 (42.9)	206 (48.8)
11–25 mm	54 (34.2)	74 (51.0)	52 (43.7)	180 (42.7)
>26 mm	7 (4.4)	7 (4.8)	15 (12.6)	29 (6.9)
Unknown	3 (1.9)	3 (2.1)	1 (0.8)	7 (1.6)
Number of stones				
Single	120 (75.9)	94 (64.8)	80 (67.2)	294 (69.7)
Multiple	36 (22.7)	50 (34.5)	39 (32.8)	125 (29.6)
Unknown	2 (1.3)	1 (0.7)	0 (0)	3 (0.7)
Stone laterality				
Unilateral	157 (99.4)	142 (97.9)	106 (89.1)	405 (96.0)
Bilateral	1 (0.6)	3 (2.1)	13 (10.9)	17 (4.0)
Stone location				
Renal	125 (79.1)	115 (79.3)	46 (38.7)	286 (67.8)
Ureteral	29 (18.4)	24 (16.6)	58 (48.7)	111 (26.3)
Both	4 (2.5)	6 (4.1)	15 (12.6)	25 (5.9)
Stone composition				
Total	68 (43.0)	49 (33.8)	38 (31.9)	155 (36.7)
Calcium oxalate monohydrate	32 (20.3)	27 (18.6)	22 (18.5)	81 (19.2)
Calcium oxalate dihydrate	20 (12.7)	4 (2.8)	5 (4.2)	29 (6.9)
Calcium phosphate	3 (1.9)	6 (4.1)	4 (3.4)	13 (3.1)
Uric acid	2 (1.3)	7 (4.8)	3 (2.5)	12 (2.8)
Struvite	5 (3.2)	3 (2.1)	3 (2.5)	11 (2.6)
Carbonate apatite	6 (3.8)	2 (1.4)	1 (0.8)	9 (2.1)
Stent presence				
Total	56 (35.4)	62 (42.8)	53 (44.5)	171 (40.5)
Placed	2 (1.3)	1 (0.7)	0 (0)	3 (0.7)
Existing	46 (29.1)	47 (32.4)	43 (36.1)	136 (32.2)
Removed	8 (5.1)	14 (9.7)	10 (8.4)	32 (7.5)

SWL = shockwave lithotripsy.

Discussion

At high voltage, we found no statistical relationship between shock number and the rate of short-term complication development. This was true both for SWL that was successful and procedures resulting in a residual stone.

Complications experienced by all patients were minor. No patient needed a blood transfusion. Pancreatitis or a clinically significant perinephric hematoma did not develop in any

patient. Short-term complication rates after successful SWL in this study occurred at a low, clinically acceptable frequency.¹³ By comparison, complications after unsuccessful SWL occurred at nearly five times the frequency (41.4% *vs* 8.3%). Charging the source of an increased complication rate after unsuccessful SWL to either the treatment itself or residual calculi is premature, because the symptoms associated with each scenario are similar. That an increased complication rate was observed across all three residual stone cohorts and was

TABLE 3. OUTCOME BASED ON SHOCK NUMBER COHORT OF STONE-FREE PATIENTS

Variable	≤2400 (%)	2401–4000 (%)	>4,000 (%)	Total no. (%)
SWL treatments considered successful after 3 weeks	116	64	97	277
3-week SWL complications				
Total	11 (9.5)	5 (7.8)	7 (7.2)	23 (8.3)
Pain	8 (6.9)	2 (3.1)	5 (5.2)	15 (5.4)
Hematuria	6 (5.2)	2 (3.1)	2 (2.1)	10 (3.6)
Dysuria	1 (0.9)	0 (0)	1 (1.0)	2 (0.7)
Nausea/vomiting	2 (1.7)	1 (1.6)	0 (0)	3 (1.0)
Urine retention	2 (1.7)	1 (1.6)	2 (2.1)	5 (1.8)
SWL treatments considered successful after 12 weeks	134	73	119	326

SWL = shockwave lithotripsy.

TABLE 4. OUTCOME BASED ON SHOCK NUMBER COHORT OF PATIENTS WITH A RESIDUAL STONE

Variable	≤2400 (%)	2401–4000 (%)	>4000 (%)	Total no. (%)
SWL treatments with a residual stone after 3 weeks	38	22	80	140
3-week SWL complications				
Total	14 (36.8)	9 (40.9)	35 (43.8)	58 (41.4)
Pain	11 (28.9)	8 (36.4)	31 (38.8)	50 (35.7)
Hematuria	4 (10.5)	1 (4.5)	5 (6.3)	10 (7.1)
Dysuria	2 (5.3)	1 (4.5)	8 (10.0)	11 (7.9)
Nausea/Vomiting	2 (5.3)	2 (9.1)	5 (6.3)	9 (6.4)
Fever	0 (0)	0 (0)	1 (1.3)	1 (0.7)
Urine retention	1 (2.6)	1 (4.5)	1 (1.3)	3 (2.1)
Residual stone management				
Conservative treatment	7	9	11	27
Repeated SWL	8	10	16	34
Auxiliary surgery	5	5	7	17
SWL treatments with a residual stone after 12 weeks	20	8	50	78

SWL=shockwave lithotripsy.

not found to be statistically significant between them may perhaps suggest that high shock number alone does not lead to an increased rate of clinical complication development immediately after SWL, but may instead be a result of high residual stone burden.

Residual stone burdens can lead to such sequelae as obstruction, growth of residual fragments, exposure to unnecessary renal trauma, or increased need for auxiliary medical treatments, all of which contribute to patient morbidity.^{14,15} While clinical practice intuition does not formally endorse the administration of a high number of shocks, the converse of this cautious stance is that clinicians may contend with higher rates of patient morbidity associated with the presence of residual stones. Finding the appropriate balance between the risks of complications associated with high shock number *vs* a clinically significant residual stone burden is important, noting that appropriate shock number may be variable, depending on the lithotripter's energy source. Our findings suggest that forgoing a higher shock number in the presence of a meaningful residual stone burden increases the risks of sequelae immediately after SWL with negative implications for patient morbidity.

Whether SWL can be implicated in the development of long-term chronic complications—namely, hypertension and diabetes mellitus—is controversial. The relationship between variables of SWL administration, including energy, shock rate, and shock number, have been investigated with regard to their role in the formation of long-term renal tissue damage. Research has documented renal scarring with loss of functional renal mass after SWL, which appears secondary to vascular damage and inflammation induced by the procedure.^{1,7–11} In contrast to early animal studies, more recent research suggests that shockwaves may cause dose-dependent acute renal injury.^{10,11} As McAteer and Evan¹¹ describe, however, in an animal model without a normal *in vivo* physiologic response, extrapolating the clinical consequences of such renal damage is difficult.

If the safety of SWL is to be maximized in both the short and long term, the experimental and clinical consequences of these variables must be investigated further. Treatment variables, such as shock number, could then be considered for patients based on individual risk factors and weighed against their effect

on the efficacy and success of SWL. This has already begun with respect to delivery rate and power, which appear to minimize renal damage when delivered at <60 shockwaves/min and with a stepwise increase in power, respectively.³

The retrospective nature of this study contributed to its limitations in that it did not allow for prospective consideration of physician philosophy and practice regarding the administration of high shock number in the presence of a residual stone observed during SWL. It is clear from subsequent discussions with surgeons involved, however, that use of >2400 shocks occurred primarily in five situations: (1) When intraoperative fluoroscopy demonstrated apparent persistent stone, (2) treating ureteral stones, (3) treating multiple stones in the kidney and/or ureter, (4) treating a stone previously ineffectively treated with SWL, and (5) treating unusually large or hard stones in the opinion of the treating surgeon. Although stone location, composition, and size have all been shown to affect SWL success,^{1,7} these variables were not studied when determining the statistical relevance of stone-free rates. Shock number was not controlled for. Non-contrast CT would have provided more accurate measurement of preoperative and postoperative stone size. Ureteral stents can also produce symptomatology similar to that of kidney stones.

Previous studies have found that biochemical evidence of renal injury may exist after SWL.^{1,7,14,16–19} Much of the injury and biochemical disturbance associated with shock-induced renal injury is considered transient with markers returning to normal levels in days to months.^{17,19} We did not compare biochemical markers of renal integrity preoperatively and postoperatively, but the clinical implications of metabolic derangements and potential renal injury thought to be associated with a higher number of shocks during SWL was not reflected by increased complication rates in this study.

Conclusions

High shock number at high voltage was not shown in our study to cause higher rates of acute clinically significant postoperative complications when SWL was successful or resulted in a residual stone, yet complication rates in the presence of a residual stone were five-fold higher, by

comparison. If the safety and efficacy of SWL is to be maximized in the short and long term specifically with regard to the development of hypertension and diabetes mellitus, it is important to know at what point increasing shock number in the presence of a residual stone ceases to provide therapeutic benefit and leads to higher rates of postoperative complications. We believe a prospective, randomized control trial to study the relationship between shock number and short-term complication development is warranted.

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Disclosure Statement

No competing financial interests exist.

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Abbreviations Used

BMI = body mass index
CT = computed tomography
SWL = shockwave lithotripsy