Extremely-slow, half-number shockwave lithotripsy for ureteral stones

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Abstract

Purpose

To elucidate and compare the treatment success rate and safety of the reduced (30 shocks/min with 1,200 shocks/session) and standard protocols (60 shocks/min with 2,400 shocks/session) of extracorporeal shockwave lithotripsy (SWL) for ureteral stones treatment.

Materials and Methods

This study was a retrospective review of 2410 SWL procedures with reduced or standard protocols (groups R and S) in 1106 patients for ureteral stones between March 2014 and March 2021. The patients chose either group after hearing an explanation of both protocols. The primary outcome was treatment success, defined as the absence of residual fragments on ultrasonography and plain radiography within 30 and 90 days. A multivariate logistic regression and propensity score matching analysis evaluated the association between the reduced protocol and treatment success.

Results

This study included 311 and 544 patients in the reduced (R) and standard (S) protocol groups, respectively. The patient's characteristics were comparable, excluding the lithotripter machine. There was no significant difference between groups R and S in treatment success rates within 30 (63.3% vs. 65.8%, $p = 0.50$) and 90 days (88.7% vs. 91.5%, $p = 0.18$). The overall complication rates did not differ significantly between the groups ($p = 0.45$). The multivariate analysis indicated no significant association between reduced protocol and treatment success within 30 and 90 days ($p = 0.44$ and $p = 0.68$, respectively). Propensity score matching showed no significant difference in the treatment success rates within 30 and 90 days or overall complication rates.

Conclusion

The Extremely slow, half number protocol outcomes are comparable to those of the standard protocol for treating ureteral stones.

Introduction

Shock wave lithotripsy (SWL) is a standard treatment for urolithiasis. The rate and number of the shock waves are the key elements in treatment success, although there is no established consensus or recommendation on the optimal rate and number[1]. Many reports suggested that slower rates (60–90 shocks/min) outperformed faster rate (120 shocks/min), but further investigations are rare[2–7]. Only the manufacturer's recommendations specify the number of shock waves. Small numbers of shock waves may result in ineffective treatment, whereas large numbers of shock waves may induce kidney injury or damage to other organs. Our group has reported the outcomes of an extremely slow rate and a half number of SWL for the treatment of renal stones[8].

In this study, we compared the treatment success rate and safety of the reduced protocol (30 shocks/min with 1,200 shocks/session) to the standard protocol (60 shocks/min with 2,400 shocks/session) of SWL in the treatment of ureteral stones.

Material And Methods

The Institutional Review Board of the Ijinkai Takeda General Hospital approved this study (approval no. 20200002). It was a retrospective review of 2410 SWL procedures with 30 or 60 shocks per minute in 1106 patients with ureteral stones between March 2014 and March 2021. The exclusion criteria were: insufficient data (n = 56), previous treatment of ipsilateral kidney or ureteral stones within one year (n = 97), or variations in delivery rate over the treatment course (n = 82). All patients participating in the study provided informed consent using an online opt-out form. The treatment protocol was either reduced (30 shocks/min with 1,200 shocks/session) or standard (60 shocks/min with 2,400 shocks/session), chosen after a discussion between the patient and the physician.

All procedures were conducted using the Dornier Delta II FarSight and Gemini (Dornier MedTech, Germany) with an electromagnetic shock wave emitter. The stones in the ureterovesical junction were treated using ultrasonography, and the remaining stones were treated using fluoroscopy. Diclofenac sodium suppository 50 mg was inserted into the rectum 30 minutes before the treatment, and analgesics were given as appropriate throughout the procedure. All procedures were conducted at shock wave power levels of 10.00 kV in Delta II FarSight and 10.50 kV in Gemini.

Each group received 1,200 shocks in the reduced group and 2,400 shocks in the standard group over 40 minutes. The patients were evaluated using plain radiography of the kidney, ureter, and bladder (KUB) and abdominal ultrasonography within two weeks. SWL was either discontinued or repeated if the treatment was ineffective. After the patient completed treatment, the stone was examined and treated using another modality, such as ureteroscopy; however, the same delivery rate was used for repeated treatments unless the patient declined.

The data were collected from the patient's records, including age, sex, body mass index (BMI), maximum stone diameter, stone location (upper or lower), and attenuation values (Hounsfield unit) assessed by computed tomography (CT). Treatment success was the absence of residual fragments in the ureter on ultrasonography and KUB without auxiliary treatment.

The primary outcome was treatment success within 30 and 90 days of the first SWL session. In contrast, the secondary outcome was the development of complications assessed according to the modified Clavien–Dindo classification system.

All statistical analyses were performed using EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), a graphical user interface for R (R Foundation for Statistical Computing, Vienna, Austria)[9]. The chi-squared test and Mann-Whitney U test compared the categorical and continuous variables. Potential confounding variables were considered age, sex, BMI, maximum stone diameter, stone location, and attenuation values (Hounsfield unit)[10–18]. A logistic multivariate regression analysis evaluated predisposing factors. The propensity score matching (PSM) balanced the potential confounding variables between the groups. Patients were matched according to their baseline characteristics, such as age, sex, BMI, maximum stone diameter, stone location, stone side, stone count, lithotripter machine, and attenuation values. One-to-one nearest-neighbor PSM was performed with a caliper width of 0.2 of the standard deviation of the logarithm of propensity score. The standardized difference measured covariate balance, and an absolute standardized difference of more than 10% indicates imbalance.

All statistical tests were two-sided, and p-values of less than 0.05 were considered statistically significant.

Results

In this study, 311 and 544 patients were included in the reduced (group R) and standard protocol (group S) groups, respectively. Table 1 shows the included patients' characteristics. The median age in group R was 55.9, while it was 54.8 in group S ($p = 0.28$). The median largest stone sizes for groups R and S were 8.1 and 8.2, respectively ($p = 0.60$). The median attenuation value in group R was 928; in group S, it was 972 ($p = 0.070$). There was no statistically significant difference between the two groups in terms of sex ($p = 0.36$), BMI ($p = 0.92$), stone side ($p > 0.999$), or stone location ($p = 0.19$). A Gemini lithotripter was used more frequently in group R than group S ($p < 0.001$). Multiple ureteral stones were detected in 18 patients (5.8%) in group R and 16 patients (2.9%) in group S ($p = 0.046$). However, only the primary stone was treated, and all remaining stones discharged spontaneously.

Table 2 shows the SWL outcomes. Treatment success was achieved in 197 (63.3%) patients in group R and 358 (65.8%) patients in group S within 30 days ($p = 0.50$). Similarly, treatment success was achieved in 276 (88.7%) patients in group R and 498 (91.5%) in group S within 90 days ($p = 0.18$). The median number of sessions required for treatment success in both groups was two ($p = 0.51$). Ureteroscopy was used as an auxiliary treatment in 27 patients (8.7%) in group R and 275 (5.0%) in group S ($p = 0.04$). The overall complication rates were 24.1% and 22.6% in groups R and S, respectively, with no statistical differences ($p = 0.45$). One patient (0.3%) in group R and five patients (0.9%) in group S had pyelonephritis, treated with a ureteral stent and antibiotics. There were no cases of perirenal hematoma. Skin ecchymosis occurred in eight patients (2.6%) in group R and 13 patients (2.4%) in group S; they underwent conservative treatment. In addition, three patients (1.0%) in group R and five patients (0.9%) in group S required additional analgesic drugs.

In addition, predisposing factors for SWL success within 30 and 90 days were analyzed (Table 3). Age ($p = 0.015$) and maximal stone size ($p = 0.003$) were significantly related to treatment success within 30 days, whereas only age (*p* = 0.002) was significantly related to treatment success within 90 days. There was no significant association between reduced protocol and treatment success within 30 (*p* = 0.44) and 90 days (*p* = 0.68).

Finally, a propensity score matching analysis examined 213 matched pairs from groups R and S (Table 3). Treatment success was achieved in 134 patients (62.9%) in group R and 138 patients (64.8%) in group S (*p* = 0.76) within 30 days. However, treatment success was achieved in 193 patients (90.6%) in group R and 196 patients (92.0%) in group S (*p* = 0.76) within 90 days. The overall complication rates in groups R and S were 2.4% and 2.0%, respectively, with no statistically significant differences (*p* = 0.29).

Discussion

This study compared the SWL outcomes for ureteral stones between a reduced protocol (30 shocks/min with 1,200 shocks/session) and a standard protocol (60 shocks/min with 2,400 shocks/session). Our findings revealed that the success rate of the reduced protocol was comparable to that of the standard protocol. In multivariate analysis, the predisposing factors for SWL success were age and stone size, consistent with previous reports. According to the multivariate analysis and propensity score matching findings, the reduced protocol had no effect on treatment success. The complication rate was minimal and did not differ significantly between the two groups.

Previous studies, including meta-analyses, reported that a slower SWL delivery rate yielded better results. However, the studies only compared rates of 60, 80, 90, and 120 shocks per minute, and further slower rates have rarely been investigated[2–7]. Thus, there is no consensus or recommendation on the optimal rate of shock waves[1]. *In vivo*, SWL with 30 shocks per minute had a higher success rate than 200 shocks per minute. However, few clinical reports have investigated the success rate of SWL with 30 shocks per minute[19]. Our findings suggest that SWL with an extremely slow delivery rate would provide more effective lithotripsy. Although the effects of lithotripsy should be compared with the same number of shocks, it was not practical to spend twice as much time in clinical practice. Therefore, times for both protocols were matched. Our group recommended the SWL reduced protocol for patients with renal and ureteral stones, comparable to the standard protocol for renal stones[8].

The mechanism by which shock wave rate affects treatment success is unknown. The cavitation effect may be implicated in the association. The negative pressure generated by the shock waves creates cavitation bubbles, which absorb some of the energy from the shock waves. The subsequent shocks decay until the bubbles disappear, which is thought to reduce effectiveness at higher frequencies[20]. Small fragments generated from the stone surface can act as cavitation nuclei, creating bubbles that attenuate the shock waves[19]. Therefore, shock waves would be more effective if provided soon after the bubbles and fragments disappear. Since the cavitation bubble dissipates within 1–2 seconds, a shock frequency of fewer than 60 shocks per minute may produce better outcomes.

Few clinical studies investigated the efficacy of SWL at a further slower rate, with only one randomized control trial (RCT) comparing the outcomes of a 30 shocks/min versus 60 shocks/min delivery rate[21].

After three months, the stone-free rate in the 30 shocks/min group (96.3%) was significantly higher than that in the 60 shocks/min group (63.8%). The disagreement with our results is primarily because both groups in this RCT received the same number of shocks every session. Furthermore, the RCT included relatively large (almost all stones were larger than 10 mm), radiopaque, high attenuation value (≥ 1,000 Hounsfield unit) upper ureteral stones. Our study included relatively small, low attenuation value stones. Finally, the number of sessions in this RCT was restricted to three. After three SWL sessions, ureteroscopy is an auxiliary treatment; however, SWL may continue at the patient's discretion or the urologist. Auxiliary ureteroscopy was performed more frequently in the reduced protocol and considered a treatment failure, although overall treatment success rates were comparable between protocols. Even if SWL had continued, it would eventually fail since patients with difficult-to-treat stones should be converted to ureteroscopy. Additionally, patients on the reduced protocol might be more likely to follow our recommendations.

Although each manufacturer makes recommendations on shock wave number and energy, there is no consensus on the optimal number of shock waves[1]. Acons et al. reported that increasing the number of shocks per session improved the stone-free rate[22]. However, more shocks per session may be excessive and ineffective because disintegrating fragments surrounding the stone may impede shockwave transmission[23]. Several factors, such as stone size and consistency, should be considered to determine the optimal shock number and energy[10]. In general, 1,200 shocks per session are deemed insufficient, yet the reduced protocol achieved comparable outcomes to the standard protocol in our study. Since our study included relatively smaller and lower-density stones, half the number of shocks in the reduced protocol may be sufficient. Another possible explanation is that the slower delivery rate was more efficient, resulting in comparable outcomes with fewer shocks. These assumptions are consistent with the previous RCT described above.

Previous reports have demonstrated that tissue damage increases with the frequency and number of shock waves[21, 24, 25]. In the current study, the complication rates were not statistically different. However, the fewer shocks and slower delivery rate may have had protective effects on the tissues. The complications were only Grade 2 fever, which seemed due to a urinary tract infection, necessitating transurethral stenting. Since all these patients had ureteroscopy following infection cure, SWL was considered unsuccessful. However, whether SWL caused infection is debated because ureteral stones were already present before the procedure.

The reduced protocol has additional advantages. First, the reduced shock numbers are cost-effective. The head of lithotripter therapy is expendable and must be replaced every 500,000–600,000 shock waves. The replacement cost is between $10,000 and $20,000; therefore, reducing the shock number from 2,400 to 1,200 would save $25 to $50 every session. Second, a slower delivery rate reportedly reduced pain and analgesic drug use[26]. The major concern with a slower delivery rate is increased treatment duration, but our reduced protocol demonstrated the same success rate with the same treatment as the standard protocol[21, 27]. Thus, our reduced protocol may be useful for pain-sensitive patients, such as children. Unfortunately, however, we could not examine this issue because the pain scale was not recorded.

In the multivariate analysis, age and stone size were independent predictors of treatment success. Interestingly, the stone size affected the success rate within 30 days, which has not previously been reported. In contrast, other variables, such as stone location, attenuation value, or BMI, were not associated with SWL success. Because the target stones in this study were relatively small, some small stones might pass spontaneously without being disintegrated. Thus, age and stone size were independent predictive factors within 30 days. However, this does not explain the success rate within 90 days. Second, the small stone was difficult to target, which might affect the measurement of the stone size and attenuation values. Another possibility is observer bias in measuring attenuation values, particularly for small stones[28]. Finally, the cut-off may be implicated as age, stone size, BMI, and attenuation value were included as continuous variables, and the stone location was classified into upper and lower. A statistical difference may have been found with an appropriate cut-off value.

There are some limitations to this study. First, there was a selection bias because of the retrospective study design. Although there was no statistically significant difference between the two studied groups, unexamined bias might exist. Furthermore, due to a lack of rigorous specifications before initiating treatment, the follow-up schedule or the number of treatments was inconsistent among protocols. Second, it was unclear how much the slow SWL delivery rate exclusively influenced the success rate because both numbers and rates were reduced. Third, ultrasonography and KUB were used to assess treatment success rather than CT scanning, which has the highest accuracy. However, it is impossible in daily clinical practice to screen all patients on CT after each procedure due to radiation exposure's cost and adverse effects. If the stone is not identified by KUB or ultrasonography and there is no hydronephrosis, there should be no clinical concerns. Actually, we previously reported the usefulness of ultrasonography for the detection of ureteral stone[29]. Finally, only acute complications were evaluated, while the long-term effects remain unclear. Despite several limitations, this study demonstrates the potential benefits of the new protocol with a slower delivery rate and half the number of shocks. Therefore, further prospective randomized trials are warranted to evaluate our reduced protocol and determine optimal SWL.

Conclusion

The safety and efficacy of the proposed reduced protocol (30 shocks/min with 1,200 shocks/session) is comparable to the standard protocol (60 shocks/min with 2,400 shocks/session) for the treatment of ureteral stones.

Abbreviations

SWL
Shock wave lithotripsy
KUB
plain radiography of the kidney, ureter, and bladder
BMI

body mass index
CT
computed tomography
PSM
propensity score matching
RCT
randomized control trial

Declarations

Conflicts of interest

The authors declare no conflict of interest.

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Tables

Table 1. Background characteristics of the patient

Variable	Reduced protocol (n=311)	Standard protocol (n=544)	p-value
Age (year)	55.9 (14.0)	54.8 (14.0)	0.28
Sex, male	244(78.5%)	411(75.6%)	0.36
Body mass index (kg/m2)	24.1(4.3)	24.1(3.8)	0.92
Side, right	145(46.6%)	231(42.5%)	>0.999
Maximum stone size (mm)	8.1(2.5)	8.2(2.5)	0.60
Multiple stones	18(5.8%)	16(2.9%)	0.046*
Location upper	200 (64.3%)	324 (59.6%)	0.19
Attenuation value (HU)	928 (304)	972 (317)	0.070
Lithotripter GEMINI	268	409	<0.001*
No. of sessions	2(1-3)	2(1-3)	0.51
No. of shocks	1200	2400	

Values are presented as median (interquartile range) or number (%)

Table 2. Treatment outcomes of the patients

Variable	Reduced protocol (n=311)	Standard protocol (n=544)	p-value
Treatment success within 30 days	197 (63.3%)	358 (65.8%)	0.50
Treatment success within 90 days	276 (88.7%)	498 (91.5%)	0.18
No. of sessions for treatment success	2 (1-3)	2 (1-3)	0.999
1	133 (42.8%)	240 (44.1%)	
2	73 (23.5%)	129 (23.7%)	
3	38 (12.2%)	69 (12.7%)	
≥4	32 (10.3%)	59 (10.8%)	
Secondary treatment: ureteroscopy	27 (8.7%)	27 (5.0%)	0.04*
Complications	9 (2.9%)	18 (3.5%)	0.70
Perirenal hematoma	0	0	
Skin ecchymosis	8 (2.6%)	13 (2.4%)	
Infection	1 (0.3%)	5 (0.9%)	
Clavien–Dindo Grade 1	8 (2.6%)	13 (2.4%)	
Clavien–Dindo Grade 2	1 (0.3%)	5 (0.9%)	
Additional analgesic drugs	3 (1.0%)	5 (0.9%)	>0.999

Table 3. Multivariate analyses of treatment success within 30days and 90 days

Variable	30 days			90 days		
	Odds ratio	95% confidence interval	p-value	Odds ratio	95% confidence interval	p-value
Age (year)	0.99	0.97-0.99	0.014*	0.97	0.95-0.99	0.002*
Sex, male	0.99	0.67-1.48	0.98	1.04	0.55-1.96	0.90
Body mass index (kg/m 2)	0.99	0.95-1.04	0.76	1.01	0.94-1.09	0.80
Maximum stone size (mm)	0.89	0.83-0.95	0.001*	0.90	0.81-1.00	0.053
Location upper	0.78	0.55-1.10	0.15	1.38	0.79-2.40	0.26
Attenuation value (HU)	1.00	0.999-1.000	0.41	0.999	0.99-1.00	0.28
Reduced protocol	0.85	0.60-1.20	0.44	0.89	0.50-1.57	0.68

Table 4. Background characteristics and treatment success of the patient after propensity score matching

Variable		Reduced protocol (n=213)	Standard protocol (n=213)	p-value	ASD
Age (year)		54.0 (10.0)	54.0 (11.0)	0.86	2.7%
Sex, male		167 (78.4%)	169 (79.3%)	0.90	2.3%
Body mass index (kg/m2)		23.6 (2.3)	23.5 (2.1)	0.55	1.6%
Side, right		95 (44.6%)	98 (46.0%)	0.85	2.8%
Maximum stone size (mm)		7.9 (1.6)	8.0 (1.5)	0.95	2.0%
Multiple stones		5 (2.3%)	5 (2.3%)	>0.999	<0.1%
Location upper		139 (65.3%)	137 (64.3%)	0.92	2.0%
Attenuation value (HU)		920 (200)	913 (204)	0.77	1.2%
Lithotripter GEMINI		186 (87.3%)	183 (85.9%)	0.78	4.1
Treatment success within 30 days		134 (62.9%)	138 (64.8%)	0.76	3.9%
Treatment success within 90 days		193 (90.6%)	196 (92.0%)	0.73	5.0%
Complication	Grade 1	5 (2.4%)	2 (1.0%)	0.29	18.0%
	Grade 2	0	2 (1.0%)		

Values are presented as median (interquartile range) or number (%)