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Extremely-slow, half-number shockwave lithotripsy for asymptomatic renal stones <20 mm

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Purpose: To compare the treatment success rate and safety of reduced (30 shocks/min, 1,200 shocks/session) versus standard (60 shocks/min, 2,400 shocks/session) extracorporeal shockwave lithotripsy for the management of renal stones.

Materials and Methods: We retrospectively analyzed 404 patients who underwent extracorporeal shockwave lithotripsy for 5–20-mm renal stones between April 2011 and March 2019. Patients selected the reduced or standard protocol (group R and S) after explaining the potential benefits and disadvantages. The primary outcome was treatment success within 12 weeks, which was defined as no residual fragment or fragments <4 mm on ultrasonography and plain radiograph.

Results: In total, 94 and 310 patients underwent shockwave lithotripsy with a reduced and standard protocol, respectively. The background characteristics of the participants did not significantly differ. The treatment success within 12 weeks was achieved in 78 (83.0%) patients in group R and 259 (83.5%) in group S (p=0.88). The median number of the session was 3 (interquartile range, 2–4) in both groups (p=0.53). The total complication rates were 5.4% in group R and 6.1% in group S. Three (1.0%) patients in group S experienced perirenal hematoma, which was conservatively treated. The reduced protocol was not associated with treatment success in the multivariate analysis adjusted for potential confounders (odds ratio, 0.91; 95% confidence interval, 0.46–1.80; p=0.78).

Conclusions: The new treatment amendment with a slower delivery rate successfully reduced the total number of shocks need to fragment renal stones <20 mm without compromising the stone-free rate.

Keywords: Extracorporeal shockwave therapy; Kidney calculi; Lithotripsy; Nephrolithiasis; Urolithiasis

INTRODUCTION

Shockwave lithotripsy (SWL) is a standard treatment for renal stones. SWL is suitable for small, asymptomatic renal stones as it has a lower complication rate and is less invasive than ureteroscopic retrograde surgery (URS) or percutaneous nephrolithotripsy (PNL) [1]. SWL is recommended as the first-line treatment for renal pelvic or upper/middle pole stones <20 mm and lower pole stone without unfavorable factors [2]. To improve outcome, SWL has undergone various modifications including number and delivery rate of shockwaves. As for the number of shocks, the large number of shock waves may cause kidney damage or damage to other organs [3]. Moreover, the excessive number of shocks at one session may reduce efficacy because stone fragments attenuate the shock wave energy [4]. To date, there is no consensus or recommendation on the ideal number of shock waves [2,5]. Several reports have shown that a slow delivery rate im-

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proves the stone-free (SF) rate and reduces tissue damage [6-12]. These studies compared delivery rates of 60–90 and 120 shocks/min, and treatment guidelines have recommended the use of a delivery rate of 60–90 shocks/min [2]. However, the clinical significance of further slowing the delivery rate has not been investigated.

When SWL is performed for asymptomatic renal stones, the stones are often small and may require less energy to fracture. Less number of shock waves and slower delivery rate would increase tolerance of the treatment. In this study, we compared the treatment success rate and safety of reduced protocol (30 shocks/min, 1,200 shocks/session) versus standard protocol (60 shocks/min, 2,400 shocks/session) SWL for the management of renal stones with a size <20 mm.

MATERIALS AND METHODS

1. Patients

This study was approved by the Institutional Review Board of Ijinkai Takeda General Hospital (approval number: 20200002), and we retrospectively analyzed 559 patients who underwent SWL for asymptomatic renal stones with a size of 5–20 mm between April 2011 and March 2019. Patients with insufficient data (n=3), anatomical abnormalities (n=8), delivery rate > 60 shocks/min (n=120), and changes in delivery rate during the treatment course (n=24) were excluded. Informed consent was obtained from all patients included in the study in the form of opt out in the website.

The selection of the reduced (30 shocks/min, 1,200 shocks/ session) or standard (60 shocks/min, 2,400 shocks/session) protocol was based on discussion between the patient and physician. Our group previously have reported SWL for ureter calculi with a delivery rate of 30/45 shocks/min had a SF rate equivalent to 60/80 shocks/min based on a pilot randomized control trial [13]. After the trial, we recommended reduced protocol SWL for patients with asymptomatic renal stones with a size <20 mm and mainly who underwent SWL for the first time. All the patients were informed that reduced number and frequency of shocks may have less pain and complication but may require additional sessions for fragmentation. Patients who agree with the reduced shockwave number and rate underwent reduced protocol SWL (group R). Patients who disagree with the new protocol received standard SWL (group S).

2. SWL procedures

The patients were treated with Dornier (Dornier Medical Systems, Kennesaw, Georgia) Delta II Farsight (before December 2012) and GEMINI (after January 2013) with elec-

tromagnetic shock wave emitter. Because Delta II Farsight had a minimum delivery rate of 60 shocks/min, a virtual ECG with a pulse rate of 30 beats per minute was used, and shocks were virtual ECG-gated. Dornier was utilized to technically support the establishment and use of virtual ECG.

Diclofenac sodium suppository 50 mg was inserted into the rectum 30 minutes before the treatment, and additional analgesic drugs were administered during treatment based on demand. Stone localization was performed via ultrasonography in all cases. Treatment was carried out with a shock wave power level of 10.00 kV with Delta II Farsight and 10.50 kV with GEMINI in all cases. Each group underwent 1 session for 40 minutes (i.e., 1,200 shocks for group R and 2,400 shocks for group S).

The patients were evaluated via plain radiography of the kidney, ureter, and bladder (KUB) and abdominal ultrasonography on the next day of every session. SWL was again performed on the second day after treatment if treatment success was not obtained. The same delivery rate was used unless patients denied it. The next sessions were performed every other day as well.

3. Data collection and outcomes

The following data were collected from the patient's records: age, sex, body mass index (BMI), the site where the stone was located, maximum stone diameter, and Hounsfield unit assessed via computed tomography (CT) scan, number of stones, and stone burden (sum of all the stone diameters). SF was defined as no residual fragments or fragments <4 mm of target stones on ultrasonography and KUB radiography. Serum creatinine was evaluated before and on the next day of treatment. After the treatment for renal stones, all patients underwent ultrasonography for follow-up every 12 weeks. The treatment success was SF within 12 weeks after SWL sessions without the need for any auxiliary treatment.

4. Statistical analysis

All statistical analyses were performed using EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R ver. 2.13.0 (The R Foundation for Statistical Computing, Vienna, Austria) [14]. Moreover, it is a modified version of R commander ver. 1.6-3 (The R Foundation for Statistical Computing), which includes statistical functions for biostatistics.

The chi-square test and Mann–Whitney U test were used for categorical and continuous variables, respectively. A logistic regression analysis was conducted for univariate and multivariate analysis. According to the previous reports [15-17], age, sex, BMI, maximum stone diameter, multiple or single

Table 1. Background characteristics of the patients

Variable	Reduced protocol (n=94)	Standard protocol (n=310)	p-value
Age (y)	61.0 (48.0–68.0)	58.0 (49.0–68.0)	0.45
Sex, male	63 (67.0)	202 (65.2)	0.81
Body mass index (kg/m^2)	23.1 (21.5–25.2)	23.1 (21.2–25.5)	0.71
Pretreatment creatinine (mg/dL)	0.80 (0.65–1.25)	0.78 (0.68–0.89)	0.76
Side, right	36 (38.3)	121 (39.0)	1.00
Maximum stone size (mm)	9.7 (7.0–11.7)	8.9 (7.1–11.0)	0.39
Stone burden (mm)	13.7 (9.6–17.8)	14.5 (9.8–18.3)	0.54
Multiple stones	59 (62.8)	198 (63.9)	0.90
Location of the largest stone			0.33
Pelvis	7 (7.4)	30 (9.7)	
Middle or upper calyx	27 (28.7)	110 (35.5)	
Lower calyx	60 (63.8)	170 (54.8)	
Hounsfield unit	818 (550–1143)	784 (576–1078)	0.69
Lithotripter			
Delta II	13 (13.8)	99 (31.9)	<0.001*
GEMINI	81 (86.2)	211(68.1)	
No. of sessions	3 (2–4)	3 (2–4)	0.53
No. of shocks	3,600 (2,400–4,800)	7,200 (4,800–9,600)	<0.001*

Values are presented as median (interquartile range) or number (%).
*p<0.05.

RESULTS

stones, stone burden, location of the largest stone, stone hardness (Hounsfield unit), and type of lithotripter were considered potential confounder. All tests were two-sided, and a p-value <0.05 was considered statistically significant.

In total, 94 and 310 patients underwent SWL with a reduced and standard protocol, respectively. The median age, sex, and BMI did not differ between the two groups (Table 1). The median largest stone sizes were 9.7 (interquartile range [IQR], 7.0–11.7) in group R and 8.9 (IQR, 7.1–11.0) in group S (p=0.39). Multiple kidney stones were observed in 62.8% and 63.9% of patients in groups R and S, respectively (p=0.90). No difference was observed in terms of stone burden (p=0.54), stone location (p=0.33) and Hounsfield unit (p=0.69). The use of GEMINI lithotripter was significantly more frequent in a reduced protocol.

The outcomes of SWL are shown in Table 2. Treatment success was achieved in 78 (83.0%) patients in group R and 259 (83.5%) in group S (p=0.88). There was no significant difference in zero fragment rate (54.3% vs. 53.5%, p>0.999) The median number of session needed to achieve SF was 3 (IQR, 2–4) in group R and 3 (IQR, 2–4) in group S (p=0.53). Auxiliary treatment for residual fragments or stone street was provided to 2 (2.1%) patients in group R and 4 (1.3%) in group S. All patients underwent URS, and none required to un-

dergo PNL. The total complication rates were 5.4% in group R and 6.1% in group S. Three (1.0%) patients in group S experienced perirenal hematoma, which was conservatively treated. None of the patients in group R experienced perirenal hematoma. Stone street was observed in 4 (4.3%) and 14 (4.5%) patients in groups R and S, respectively, and two patients in group S with stone street required URS. None of the patients in group R and 3 (1.0%) patients in group S required additional analgesic drugs (p>0.999). The change in serum creatinine was not significantly different (p=0.43).

The results of the univariate and multivariate analyses for treatment success are depicted in Table 3. The reduced protocol was not associated with treatment success in the multivariate analysis adjusted for potential confounders (odds ratio, 0.91; 95% confidence interval, 0.46–1.80; p=0.78).

DISCUSSION

This study assessed the outcomes of SWL with a reduced protocol (30 shocks/min with 1,200 shocks/session) vs. standard protocol (60 shocks/min with 2,400 shocks/session) for the management of asymptomatic kidney stones. To avoid prolonged treatment time, we used 40 minutes per session in both groups. Results showed that the success rate of the reduced protocol was comparable to that of the standard protocol. Interestingly, the number of sessions required for SF was similar, even though the reduced protocol only gave

Table 2. Treatment outcomes of the patients

Variable	Reduced protocol (n=94)	Standard protocol (n=310)	p-value
Treatment success within 12 weeks	78 (83.0)	259 (83.5)	0.88
Zero fragment within 12 weeks	51 (54.3)	166 (53.5)	>0.999
No. of sessions for treatment success			0.25
1	9 (9.6)	33 (10.6)	
2	14 (14.9)	73 (23.5)	
3	31 (33.0)	80 (25.8)	
≥4	24 (25.5)	73 (23.5)	
Secondary treatment			
URS	2 (2.1)	4 (1.3)	0.63
PNL	0 (0.0)	0 (0.0)	
Stone analysis			0.57
Calcium oxalate or phosphate	51 (94.4)	131 (89.1)	
Uric acid	2 (3.7)	5 (3.4)	
Cystine	1 (1.9)	2 (1.4)	
Infectious	0 (0.0)	4 (2.7)	
Mixed	0 (0.0)	5 (3.4)	
Not assessed	40	163	
Complications			
Perirenal hematoma	0 (0.0)	3 (1.0)	>0.999
Infection	1 (1.1)	2 (0.6)	0.55
Stone street	4 (4.3)	14 (4.5)	>0.999
Additional analgesic drugs	0 (0.0)	3 (1.0)	>0.999
Creatinine change (mg/dL)	0.05 (0.00–0.09)	0.04 (-0.02–0.09)	0.43

Values are presented as number (%), number only, or median (interquartile range).
Treatment success was defined as fragments of target stones <4 mm.
URS, ureteroscopy; PNL, percutaneous nephrolithotripsy.

Table 3. Univariate and multivariate analyses of treatment success

Variable	Univariate analysis			Multivariate analysis		
	Odds ratio	95% confidence interval	p-value	Odds ratio	95% confidence interval	p-value
Age (y)	1.01	0.99–1.03	0.33	1.01	0.99–1.04	0.31
Sex, male	1.26	0.73–2.16	0.41	1.53	0.81–2.92	0.19
Body mass index (kg/m^2)	1.03	0.95–1.12	0.46	1.04	0.96–1.15	0.35
Maximum stone size (mm)	0.85	0.78–0.92	<0.001*	0.87	0.75–1.00	0.06
Stone burden (mm)	0.94	0.90–0.98	<0.01*	0.96	0.88–1.06	0.44
Multiple stones	090	0.52–1.56	0.70	1.01	0.38–2.71	0.98
Location of targeted stone						
Pelvis		Ref.	0.11		Ref.	0.03*
Middle or upper calyx	0.86	0.27–2.72		0.46	0.13–1.62	
Lower calyx	0.49	0.16–1.44		0.25	0.07–0.85	
Hounsfield unit	0.99	0.99–1.00	0.04*	1.00	0.99–1.00	0.51
Reduced protocol	0.96	0.52–1.78	0.90	0.91	0.46–1.80	0.78
Lithotripter, GEMINI	1.58	0.91–2.75	0.11	1.60	0.69–3.71	0.28

*p<0.05.

almost half the energy. The complication rate was extremely low in both groups.

We have previously reported a randomized control trial comparing outcomes of different delivery rate SWL for ureteral stone [13], which motivated us to conduct this study. The trial suggested that SWL with an extremely slow delivery rate may provide good fragmentation efficiency without prolonged treatment time. Although the precise mechanism is not known, the cavitation effect is considered responsible for achieving better outcomes when a slow delivery rate is used. The negative pressure created by shock waves generates a cavitation bubble. The following shocks are attenuated until the bubble disappears, leading to a lower efficacy in cases of high frequency [18]. This study showed that the cavitation bubble disappeared within 1–2 seconds. Thus, a delivery rate of <60 shocks/min may achieve better outcomes. Moreover, small fragments arising from the stone surface act as the cavitation nuclei. The bubble from these nuclei absorbs the part of the energy from shock waves [19]. Thus, shock waves must be provided immediately after the disappearance of bubbles and stone particles. A recent meta-analysis has reported that a delivery rate of 60–90 shocks/min is appropriate. However, the research only compared rates of 60–90 and 120 shocks/min [6]. Only one randomized control study assessed the outcomes of the delivery rate of 30 shocks/min with full power than 60 shocks/min with power-ramping [20]. The SF rate was significantly better in 30 shocks/min group (76%) than in 60 shocks/min group (49%). In the study, the same number of shocks/session was given in both groups, although the way of power ramping was different. Moreover, the study included relatively large, radio-opaque, high attenuation value (≥1,000 Hounsfield unit) renal stones, whereas relatively small renal stones were treated in our study. Although the evaluation of the stone was different, our SF rate was higher in both groups than their results. For the small asymptomatic renal stones, our reduced protocol showed an acceptable success rate as well as the standard protocol.

In this study, the number of sessions needs to achieve SF was similar between the reduced and standard protocol, although the number of shocks in the reduced protocol was halved. There is no consensus on the optimal number of shock waves [2], although each manufacturer advises on shock wave number and energy. A study group has reported that an expanded number of shocks per one session improved SF rate [5,21]. On the other hand, a higher number of shocks per session may be ineffective. Once stones are disintegrated, surrounding fragments may attenuate shock wave transmission [22]. The stone size or hardness should be considered to determine the shock number and energy [16]. Be-

cause patients with small renal stones were included in our study, the small number of shocks in reduced protocol might not affect the outcomes. Another possible reason is that the advantage of a slow delivery rate was counterbalanced by the small number of shocks. Different delivery rates with an equal number of shocks should be further evaluated, but longer treatment times are inevitable.

The complication rate between the two groups was similar. The perirenal hematoma was observed in 0.0% and 1.0% of patients who underwent SWL with reduced and standard protocol. The rate in the current study is lower than that of other reports (4%–9%) [23,24]. Several reports have shown that renal parenchymal damage is less pronounced when shock waves are delivered slowly in a pig model [25,26]. Although there is no strong evidence showing that decreasing the number of shocks or delivery rate reduces complications in humans, the fewer shocks and slow delivery rate has protective effects for the kidney. In the current study, the incidence of perirenal hematomas was extremely low. The outcome might be attributed to the low maximum voltage. Safety was prioritized because most patients were asymptomatic, and they underwent SWL with the hope of preventing future kidney stone events.

Although our study did not show a significant difference regarding the SF rate and complication rate between a reduced and standard protocol, there are other advantages of the reduced protocol. First, a slower rate with a less total number of shocks is cost-effective. The lithotripter therapy head is consumable, and it must be replaced for every 500,000–600,000 shock waves. The replacement cost is about $10,000–$20,000. If the number of shocks is reduced from 2,400 to 1,200, a replacement cost of $25–$50 can be saved per one session. Second, a slow delivery rate decreases pain and the dose of analgesia used [27]. The reduced protocol may be useful for children and individuals who are experiencing extreme pain. Increasing treatment time is the major concern when a longer shock wave interval was used [9,20]. Importantly, our reduced protocol showed a similar SF rate with the same treatment time compared to the standard protocol. Thus, the delivery rate of 30 shocks/min with 1,200 shocks/session can be a good modification without compromising the success rate.

In the multivariate analysis, the stone location was the independent predictor of treatment success. Stone fragments in the lower pole are less likely to pass because of gravity [17]. Other reported indicators, such as stone size and number, attenuation value, or BMI, were not associated with successful SWL. Because target stones in this study were relatively small, the measurement of the stone size and attenuation

values might be compromised. The measurement of the mean HU has the risk of observer bias [28], especially for small stones. The small stone or stone with low attenuation value was difficult to target, which may also adversely affect the outcomes.

This study had several limitations. First, due to its retrospective design, a selection of the protocol was not randomized. Although no statistically significant difference was observed in terms of the characteristics of the patients, the number of individuals who underwent SWL with a reduced and standard protocol remarkably differed, thereby indicating the existence of an unexamined bias. As a retrospective study, more information on patient preference and larger number of cases is necessary to test our hypothesis. Second, the sole effect of the shock wave number or delivery rate was unknown because both numbers and rates were reduced. A different number of shocks and rates should be evaluated to find optimal protocol. Third, we only evaluated asymptomatic, relatively small renal calculi, not large calculi or calculi in the ureter. The effect of the delivery rate for ureter calculi is now investigated in our institution. Fourth, we evaluated post-treatment stone with ultrasonography and KUB instead of CT scan. CT scan has the best accuracy. However, it cannot be performed on all patients in daily clinical practice due to the cost and adverse effect of radiation exposure. Although ultrasonography sometimes overestimates small renal stones, it has acceptable accuracy compared to KUB alone [29,30]. The ultrasonography had the sensitivity of 88% for renal stones >4 mm, albeit 54% for renal stones <2 mm [30]. The influence of reduced protocol on these small residual fragments should be further evaluated. Finally, only acute complications were assessed. The long-term effects of delivery rate, such as hypertension and renal fibrosis, should be further evaluated. Despite these limitations, this study demonstrates the potential benefit of the new protocol with a slower delivery rate and less number of shocks. These results will open new research areas for the SWL protocol. Prospective randomized trials are necessary to further evaluate our reduced protocol and to find out optimal SWL.

CONCLUSIONS

The new protocol (a delivery rate of 30 shocks/min with 1,200 shocks/session) successfully reduced the total number of shocks needs to fragment renal stones <20 mm without compromising the SF rate. The optimal number of shocks and delivery rates should be further evaluated.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

AUTHORS' CONTRIBUTIONS

Research conception and design: Katsuhiro Ito, Yoshihito Higashi, and Hitoshi Yamada. Data acquisition: Katsuhiro Ito, Toshifumi Takahashi, and Takashi Okada. Statistical analysis: Katsuhiro Ito. Data analysis and interpretation: Katsuhiro Ito. Drafting of the manuscript: Katsuhiro Ito. Critical revision of the manuscript: Toru Kanno and Hitoshi Yamada. Supervision: Hitoshi Yamada. Approval of the final manuscript: Katsuhiro Ito.

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