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Urolithiasis

Optimal Shock Wave Rate for Shock Wave Lithotripsy in Urolithiasis Treatment: A Prospective Randomized Study

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Purpose: We aimed to compare the effects of a fast shock wave rate (120 shocks per minute) and a slow shock wave rate (60 shocks per minute) on the shock wave lithotripsy (SWL) success rate, patient's pain tolerance, and complications.
Materials and Methods: A total of 165 patients with radiopaque renal pelvis or upper ureter stones were included in the study. Patients were classified by use of a random numbers table. Group I (81 patients) received 60 shock waves per minute and group II (84 patients) received 120 shock waves per minute. For each session, the success rate, pain measurement, and complication rate were recorded.
Results: No statistically significant differences were observed in the patients according to age, sex, body mass index, stone size, side, location, total energy level, or number of shocks. The success rate of the first session was greater in group I than in group II (p=0.002). The visual analogue pain scale was lower in group I than in group II (p=0.001). The total number of sessions to success and the complication rate were significantly lower in group I than in group II (p=0.001).
Conclusions: The success rate of SWL is dependent on the interval between the shock waves. If the time between the shock waves is short, the rate of lithotripsy success decreases, and the pain measurement score and complications increase. We conclude slow SWL is the optimal shock wave rate.

Key Words: *Lithotripsy; Pain measurement; Urinary calculus*

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INTRODUCTION

Shock wave lithotripsy (SWL) is an important, noninvasive treatment for renal and upper ureter stones [1]. Since the introduction of the shock wave lithotripter in the early 1980s, developments to the lithotripter have resulted in many changes in the treatment strategy for urinary calculi. Recent studies have been published concerning improving treatment outcomes and reducing the adverse effects of SWL. The most important issues raised by these studies include gradually escalating the energy power and finding an appropriate shock wave rate [2,3]. According to results reported for *in vivo* and *in vitro* lithotripsy, a shock wave frequency below 120 shock waves per minute appears to result in the best treatment record [4-7]. In clinical practice, it has been suggested that low frequency shock waves can lead to improved treatment outcomes. Yet, studies performed in actual patients or large-scale direct comparisons are negligible. Hence, in the present study, we investigated the optimal frequency rate by prospectively analyzing the clinical outcomes of SWL by shock wave frequency according to the success rate, the total number of sessions to success, the pain score during the procedure, and various post-SWL complications.

MATERIALS AND METHODS

We conducted a prospective study of 165 patients with renal pelvis or upper ureter stones who visited our hospital from October 2009 to September 2011. All study subjects were patients with single, radiopaque stones. Patients in group 1 (60 shocks per min) and group 2 (120 shocks per minute) were classified by use of a random numbers table. Patients with acute urinary tract infection, hemorrhagic disease, accompanying abdominal aortic aneurysm, severe respiratory syndrome, or urinary stones less than 5 mm or greater than 20 mm were excluded from the study.

All of the stones were diagnosed by kidney-ureter-bladder (KUB), intravenous urography, or nonenhanced computed tomography (CT). The size of the stone was measured by its maximal diameter. Treatment sessions were conducted by a single operator with more than 1 year of experience in SWL. The operator checked sex, age, stone side, location, and body mass index (BMI) by medical chart review. Ten minutes before treatment, the operator injected premedication, diclofenac 90 mg intramuscularly, as a pain killer. Before the session, we applied coupling gel and fixed elliptic reflection onto the patient's body.

Each session began with an initial voltage of 10 kV and escalated to 20 to 25 kV. The final energy ranged from 800 to 1000 J. After 500 shocks, we gave the patient a 5-minute break and discussed the patient's inconvenience during the treatment and subsequently adjusted the patient's position and the voltage. At that time, we scored the intensity of pain according to the maximal visual analogue pain scale score during treatment. SWL was performed with a Sonolith Praktis (EDAP Technomed, Lyon, France) model, and all sessions were performed with the patient in the supine position. To accurately measure the pain scale, we injected no analgesics except intramuscular diclofenac 90 mg 10 minutes before performing SWL.

KUB and renal ultrasound were performed for all patients 2 weeks after treatment to determine whether the treatment was success. If the ultrasound results showed perirenal hematoma, an abdominal pelvis CT was performed to determine the grade of renal injury and to decide on a treatment plan.

For post-SWL complications, severe pain was defined as a case requiring a repeat visit to the emergency room or outpatient urology department owing to pain uncontrolled by oral analgesics. Gross hematuria more than 24 hours after treatment was confirmed through the questionnaire completed after 2 weeks at the outpatient clinic. Hospitalization was defined as cases that needed to be hospitalized to control severe pain or for absolute stability or surgical intervention for treatment of grade 2 or higher renal injury.

Treatment success was defined as a maximal diameter of remnant stones of less than 3 mm on KUB. If the maximal diameter of the remnant stone remained greater than 3 mm after the first session, we considered the session a failure and a second session was performed. After the second session, if the remnant stone size was larger than 3 mm, a third session was performed.

To analyze statistics about sex, age, stone size, location, shock wave number, mean voltage and total energy verification, total numbers of shock wave to success, intensity of pain during treatment, number of complications, and the success rate of each session, we used Student's t-test, Chi-square test, and Fisher's exact test with PASW ver. 18.0 (IBM Co., Armonk, NY, USA). Values of $p<0.05$ were considered statistically significant.

TABLE 1. Patient, stone and shock wave lithotripsy characteristics

Characteristic	Group I (n=81) 60 shocks/min	Group II (n=84) 120 shocks/min	p-value[a]
Sex			0.384
Male	47	46	
Female	34	38	
Age (yr)	47.25±12.08	43.76±14.10	0.089
Body mass index (kg/m^2)	24.21±3.39	25.49±3.81	0.052
Stone size (mm)	9.74±4.25	9.25±3.54	0.379
Stone side			
Right	36	41	0.185
Left	45	43	
Stone location			
Renal pelvis stone	45	43	
Upper ureter	36	41	0.815
Total no. of shock wave	3,199.79±559.41	3,162.28±904.82	0.783
Mean voltage (kV)	14.53±1.81	14.12±1.21	0.085
Total energy (J)	799.64±195.05	771.48±232.05	0.372

Values are presented as mean±SD.
[a]:Student's t-test.

RESULTS

The study consisted of 165 patients: 93 male (56.4%) and 72 female (43.6%). Sex, age, BMI, stone size, side, location, total number of shock waves, mean voltage (kV), and total energy did not differ statistically between the two groups (Table 1).

When comparing the success rate of the first session for renal pelvis stones, 36 of 45 group I patients had a successful first session (80%), whereas 24 of 43 group II patients did so (55.8%) (p=0.015). For upper ureter stones, the first session was successful in 30 of 36 group I patients (83.3%) but in only 26 of 41 group II patients (63.4%) (p=0.049). For both total renal pelvis stones and upper ureter stones combined, the first session was successful in 66 of 81 group I patients and 50 of 84 group II patients. This was a statistically significant difference (p=0.002) (Table 2).

The number of successful treatments for renal pelvis stones and upper ureter stones were both significantly lower in group I. The total number of successful treatments was also significant lower in group I (p=0.001) (Table 3).

The pain intensity during the procedure was 2.88±1.38 in group I but 4.07±1.98 in group II. The results showed a statistically significant difference (p=0.001) (Table 4). There were a total of 24 cases of complications after the procedure in group I, whereas there were 49 such cases in group II (p=0.001) (Table 5).

DISCUSSION

The principle of SWL for stone fragmentation is that mechanical and dynamic forces penetrate and disrupt the stone by the mechanisms of cavitation, shear, and spalling. Of those, the cavitation phenomenon is the most important. This theory is that the pressure changes create air bubbles in both the liquid and the tissues. The collapse of the bubbles leads to stone fragmentation [8]. Zeman et al. [9] reported that cavitation increases with an increased rate of shock waves. It follows that with an increase in the rate of shock wave delivery, more bubbles will exist at any given time in the water and tissues. The bubbles that are not reflected on the stone decrease the shock wave energy by energy scattering and absorbing.

TABLE 3. The number of shock wave lithotripsy sessions to treatment success

Stone location	Group I 60 shocks/min	Group II 120 shocks/min	p-value[a]
Renal pelvis stone	1.24±0.53	1.63±0.79	0.009
Upper ureter stone	1.19±0.47	1.53±0.78	0.021
Total	1.22±0.50	1.58±0.77	0.001

Values are presented as mean±SD.
[a]:Student's t-test.

TABLE 2. Summary of each session successful treatment according to stone location

	Stone location	60 shocks/min group I	120 shocks/min group II	p-value
1st session	Renal pelvis stone	36/45 (80.0)	24/43 (55.8)	0.015[a]
	Upper ureter stone	30/36 (83.3)	26/41 (63.4)	0.050[a]
	Total	66/81 (81.5)	50/84 (59.5)	0.002[a]
2nd session	Renal pelvis stone	7/9 (77.8)	11/19 (57.9)	0.305[a]
	Upper ureter stone	5/6 (83.3)	8/15 (53.3)	0.336[b]
	Total	12/15 (80.0)	19/34 (55.9)	0.107[a]
3rd session[c]	Renal pelvis stone	2/2 (100.0)	8/8 (100.0)	-
	Upper ureter stone	1/1 (100.0)	7/7 (100.0)	-
	Total	3/3 (100.0)	15/15 (100.0)	-

Values are presented as number (%).
[a]:Chi-squere test, [b]:Fisher's exact test, [c]:3rd session of cases, p-value measurement was impossible due to lack of number of patients.

TABLE 4. Visual analog pain scalescore during the treatment

	Group I (n=81) 60 shocks/min			Group II (n=80) 120 shocks/min			p-value
	1st	2nd	3rd	1st	2nd	3rd	
VAS score, 0-10	2.74±1.33	3.37±1.62	4.00	3.63±1.57	4.92±2.37	5.66±2.64	
Total		2.88±1.38			4.07±1.98		0.001[a]

Values are presented as mean±SD.
[a]:Student's t-test.

TABLE 5. Complications of post shock wave lithotripsy

	Group I (n=81) 60 shocks/min			Group II (n=84) 120 shocks/min			p-value[a]
	1st	2nd	3rd	1st	2nd	3rd	
Severe pain	9	-	-	15	-	1	
Steinsterasse (on KUB)	8	3	-	4	4	-	
Hydronephrosis (on kidney USG)	3	-	-	1	3	-	
Gross hematuria (>24 h)	1	-	-	3	-	-	
Perirenal hematoma	-	-	-	-	-	5	
Hospitalization	-	-	-	8	5	5	
Total		24			49		0.001

KUB, kidney-ureter-bladder; USG, ultrasonography.
[a]:Chi-squere test.

The mechanism of stone fragmentation by bubble collapse crushes the stone and simultaneously causes injury to the kidney and surrounding thin-walled vessels. As a result, it causes hemorrhage, secretion of cytokines and inflammatory cellular mediators, and the organization of the inflammatory response, which forms scars and ultimately results in chronic tissue function loss [10].

A recently announced animal model study showed that decreasing the shock wave frequency decreases the tissue damage. Delius et al. [11] reported that renal parenchyma hemorrhage was caused by rapid frequency lithotripsy in an animal experiment using canine kidney. Paterson et al. [12] reported that histologic changes resulted from rapid frequency shock waves to rabbit kidney. Greenstein and Matzkin [5] reported an experimental model with artificial ceramic stone setting comparing the success rate of 30, 60, 90, 120, and 150 shock waves per minute. They concluded that the most effective mode of shock wave delivery was 60 shocks per minute at the high energy level.

There are also recent research results at the clinical level. Yilmaz et al. [13] showed an optimal frequency rate in a study of 170 total persons divided into 3 groups, with 120 shocks per minute, 90 shocks per minute, and 60 shocks per minute. They concluded that the efficacy of lithotripsy relied on the interval of the shock waves and that when the shock wave interval was short, the success rate of lithotripsy was decreased. Lithotripsy using low frequency resulted in less kidney tissue damage, a lower repeat SWL rate, and a lower need for analgesics or sedatives. Considering the time cost, however, they suggested that the optimal frequency rate is 90 shocks per minute.

The clinical results of our research were similar to these other studies. In the analysis of the treatment success rate, the success rate of the first session was significantly lower in the 120 shocks per minute group than in the 60 shocks per minute group. The second session results were similar. The success rate of group I was 80.0% but that of group II was 55.9%. In addition, considering the total number of sessions as an indicator of success, the slow shock waves group showed excellent performance.

The advantage of low-frequency lithotripsy is well verified in the assessment of treatment-related pain. By confirming the amount of pain during treatment at each session, we showed that the pain intensity of the high-frequency lithotripsy group was significantly higher than that of the low-frequency lithotripsy group. This suggests that low-frequency lithotripsy is an effective treatment that can decrease the patient's pain during the procedure without the use of additional analgesics.

The degree of pain after treatment shows a similar outcome. When comparing the patient groups according to which patients visited an outpatient or emergency room complaining of severe pain after the first session, we saw that the number of patients from the low-frequency lithotripsy group (9 patients, 11.1%) was significantly lower than that of the high-frequency lithotripsy group (16 patients, 19.0%). Also, in the low-frequency group, we found no patients with perirenal hematoma shown by ultrasonography. By contrast, in the high-frequency group, we found 5 cases out of 15 that proceeded to a third session, which suggests that the low-frequency shock wave offers better stability concerning the probability of renal damage.

In terms of a laboratory parameter for renal damage, N-acetyl-beta-D-glucosaminidase (NAG) may be a good factor. When proximal tubular cells are injured as the result of any disease process, including glomerular proteinuria, nephrolithiasis, hyperglycemia, interstitial nephritis, transplant rejection, or nephrotoxic agents such as antibiotics, antiepileptics, or radiocontrast agents, the urine level of NAG increases. Thus, it is used as a reflection of proximal tubular cell necrosis. Successive measurements of urinary NAG during the longitudinal follow-up of the patients may enhance the clinical use of this index as an indicator of ongoing tubular injury [14,15]. Although we observed significant results concerning success rate and degree of pain during treatment, a limitation of this research is we did not use laboratory indexes such as the urinary NAG level as a method of objectively proving the degree of renal damage.

CONCLUSIONS

The success rate of SWL is closely related to the shock wave interval. Our clinical research confirms that when the shock wave interval is short, the success rate decreases. Regarding complications, the longer the shock wave interval time, the lower the degree of pain and the lower the frequency of accompanying side effects. As a result, slow SWL is the optimal shock wave rate.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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