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A Slow Delivery Rate of Shockwaves Causes Less Pain in Extracorporeal Lithotripsy
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Original Article

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Abstract Background : Using a visual analogue scale (VAS), we investigated whether a slow or fast shockwave (SW) delivery rate differently affected pain intensity during shockwave lithotripsy (SWL) in patients with urinary stones.

Methods : This study prospectively enrolled consecutive patients with renal and ureteral stones that was treated by Modulith SLX-MX lithotriptor. SWL was started at a rate of either 60 or 120 SW/min. After the delivery of the first 100 SW, the SW rate was switched to the other rate. After the delivering SW at both rates at the same power level, the SW power was raised one level. Pain evaluation by VAS score after every change in the SW rate was repeated until the highest tolerable power level at either rate was reached.

Results : This study included 50 patients each with renal and ureteral stones. VAS scores at the fast rate were significantly higher than those at the slow rate at all power levels. Stratified by stone location and gender, the scores were significantly higher in patients with renal stones and in female patients. Regarding the overall evaluation, 30 patients felt more pain at the fast rate, while only 4 felt more pain at the slow rate. In 20 patients, the treatment power level was reached at a slow rate while these patients could not tolerate the treatment at a fast rate at one power level lower.

Conclusion : We showed that SWL at a slow SW rate caused less pain than that at a fast rate. We recommend SWL at a slow SW rate because provides better stone comminution with less pain.

Introduction

Since the 1980s, the development of extracorporeal shockwave lithotripsy (SWL) has drastically changed the treatment strategy for urinary stones. Today SWL is widely applied to most patients with urinary stone because of its higher effectiveness, greater convenience, lower complication rate and reduced invasiveness compared to those of the transurethral or percutaneous approach. Since its introduction, SWL has undergone numerous technical refinements to improve the treatment results and minimize patient discomfort. SWL treatments previously used shockwaves (SW) that were synchronously triggered by the patient's electrocardiogram (ECG) to avoid cardiovascular side effects, especially cardiac arrhythmias. Therefore, the delivery rate of SW could not exceed 60-80 SW per minute. However, cardiovascular events during SWL occurred far less frequently expected.[1] Current lithotriptors can be used without synchronization to ECG allowing at a higher rate, for example settings ranging from 100 to 120 SW per minute, is very common today. Consequently, a high frequency rate of SW contributed to shortening the treatment time. Various in vitro[2, 3] and in vivo[4] experimental studies indicated the superiority of treatment by a slower SW rate due to its better stone comminution ability. We previously reported that effective fragmentation was more often accomplished by a rate of 60 SW/min than at 120 SW/min.[5] Similar findings on the superiority of the slow rate treatment have been shown in other clinical studies.[6-9]

The first generation original Dornier HM3 lithotriptor required general or epidural anesthesia or sedation due to severe pain during the SWL procedure. Although the development of new generation SWL models has reduced the pain compared to previous models, sedation or analgesics have often been administered before or during SWL to provide adequate comfort while maximizing treatment effect. There have been many studies related to pain during SWL treatment. However, most of these considered the effect of anesthetic methods or analgesic medication to reduce pain and there has not been any report that assessed the relationship of SW rate and pain intensity during SWL. Thus, this study prospectively investigated whether a fast or slow SW rate differently affected pain intensity during SWL treat-

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ment in patients with renal and ureteral stones. We used a visual analogue scale (VAS) for quantitative evaluation of pain.

Materials and Methods

This study prospectively enrolled consecutive patients with radiopaque solitary stone in the upper urinary tract that was treated by SWL in our institute between July 2005 and June 2006. Renal stones and ureteral stones above the pelvic bone were subjects for treatment. Exclusion criteria were previous SWL treatment at our institute, prior transurethral or percutaneous lithotripsy procedures for the stones of this episode, ureteral strictures, solitary or non-functioning kidney, anatomical abnormalities of the kidney or ureter, pregnancy and coagulopathy. Patients with cystine stone, staghorn calculus, infectious stone, cardiac pace maker or percutaneous nephrostomy placed prior to SWL were also excluded. Patients with radiolucent stones were excluded because of difficulty in follow-up with plain x-ray of the kidneys, ureters and bladder (KUB). Laboratory investigations included urinalysis, urine culture, serum creatinine level and coagulation profile. We checked all patients by intravenous pyelography or enhanced computed tomography for anatomical evaluation. If the patients had urinary tract infection, it was treated by appropriate antimicrobial drugs prior to SWL treatment. SWL was performed in both outpatient and inpatient settings. Double pigtail ureteral stent (6Fr.) was inserted prior to SWL if patients had renal colic, obstructed pyelonephritis or stones more than 20 mm in maximum diameter. All participants gave written informed consent before SWL treatment.

All treatment was performed in a supine position with Modulith SLX-MX electromagnetic lithotriptor (Storz, St. Louis, Missouri) and the stone location was focused by a fluoroscopic imaging. All treatments were performed by one urologist (Y.K.). Neither anesthesia nor analgesic was used prior to the treatment. During one SWL session, each patient experienced both slow rate (60 SW/min) and fast rate (120 SW/min). SWL treatment was started at power level 1 (the weakest power level) and at either 60 or 120 SW/min without synchronization to ECG. Patients were alternately assigned to either starting SW rate according to the treatment order, and not strictly randomized. After the first 100 SW were delivered, the patients were asked to evaluate their pain intensity on a 0- to 10-cm VAS score (0 = no pain, 10 = unbearable pain). Then SW rate was switched to the other rate and the next 100 SW were delivered. Then the patients were asked again to evaluate their pain intensity on VAS score. After a total of 200 SW at the two rates with the same power, the SW power was raised one level and SW was delivered at each rate in a similar order (60 then 120 SW/min or 120 then 60 SW/min). Pain evaluation using VAS after 100 SW at every changing in SW rate was repeated until reaching the highest tolerable power level at either SW rate or power level 6 (the maximal power level), whichever came first. Energy levels of 1 to 6 in this SWL device are equal to about 25 to 110 MPa, linearly. If the patients complained of intolerable pain during treatment, diclofenac (50mg) suppository or intramuscular injection of pentazocine (15mg) was used. The use of analgesics was deemed as the end of pain evaluation. The power level just before the occurrence of intolerable pain was defined as the treatment power level in those patients. The maximum number of SW in one session was limited to 4000. SWL was also terminated when complete fragmentation was achieved on fluoroscopic imaging prior to reaching 4000 SW. After the treatment, patients were asked which SW rate was more painful overall. Retreatment of SWL was performed after an interval of a week for renal stones and an interval of 3 days for ureteral stones if residual fragments were 4 mm or greater or stones were not broken. We compared the VAS score at each rate with the same treatment power level.

Statistical analysis

Continuous variables are presented as the mean plus or minus standard deviation. All statistical analyses were performing using commercially available software (Stat View 5.0 for Windows, SAS Institute Inc., Cary NC). Statistical analysis was conducted using Wilcoxon t-test and Mann-Whitney U-test, and p value < 0.05 was accepted as significant.

Results

This study included 50 consecutive patients (33 men and 17 women) with a mean age of 57.2 ± 13.1 years (range 22 to 82). Mean body mass index in these 50 patients was 26.0 ± 4.4 kg/m^2. Twenty-five patients each had renal and ureteral stones, respectively. Mean stone size calculated by the major and minor axis was 11.4 × 8.0 mm and renal stones were significantly larger than ureteral stones (13.0 × 9.3 vs 9.8 × 6.8 mm, p=0.045). The laterality of stone was right in 21 patients and left in 29. Thirty-eight patients underwent SWL in situ, while the other 12 patients underwent ureteral stent insertion prior to SWL. The mean number of SW was 3609 ± 847 shots. After SWL treatment, none of the patients developed febrile urinary tract infection and only 1 woman developed subcapsular hematoma after treatment with 2500 shots. Due to intolerable pain, 3 patients received diclofenac (50mg) suppository during the treatment.

Relations between VAS scores and SWs power levels in all patients were shown in Fig. 1. At a rate of 60 SW/min, VAS scores were evaluated in 50, 44, 36 and 20 patients at power level 1 to 3, level 4, level 5 and level 6, respectively. Similarly, at a rate of 120 SWs/min, VAS scores were evaluated in 50, 47, 42, 29 and 18 patients at power levels 1 and 2, level 3, level 4, level 5 and level 6, respectively. VAS scores gradually rose in proportion to the power levels at both rates and VAS scores at the rate of 120 SW/min were significantly higher than those at 60 SW/min at all power levels. The highest tolerable treatment power level was level 3 in 6 patients, level 4 in 9, level 5 in 16 and level 6 in 19. Stratified by a stone location, VAS scores in the patients with renal stones were significantly higher at rate of 120 SW/min than at 60 SW/min except at power level 6 (Fig. 2). In patients with ureteral stones, VAS scores at power level 3 to 6 were significantly higher at rate of 120 SW/min than 60 SW/min. If we compare patients with renal and ureteral stones, VAS scores were significantly higher in patients with renal stones than in those with ureteral stones at a rate of 60 SW/min at power levels 4 and 5, and at rate of 120 SW/min at power levels 1 and 4 (Fig. 2). VAS scores tended to be higher in female patients than in male patients (Fig. 3). VAS scores were significantly higher in female patients at rate of 60 SW/min at levels 4 and 6, and at rate of 120 SW/min at level 4 (Fig. 3). Starting SW rate (60 or 120 SW/min) was not related to changes in VAS scores.

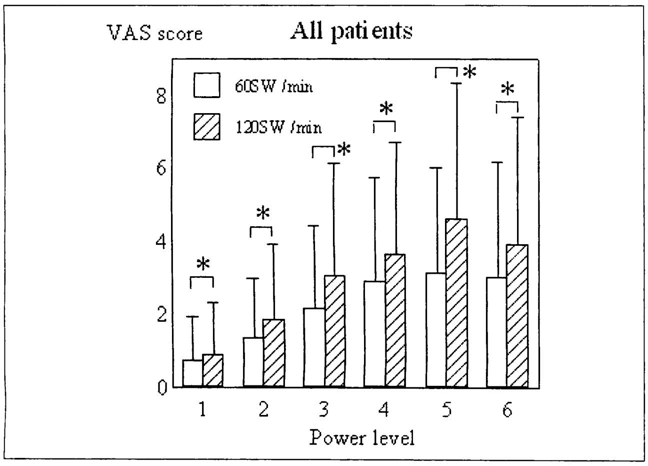

Fig. 1 Relations between VAS scores and power levels at both SW rates for all patients. VAS scores at a rate of 120 SW/min were significantly higher than those at 60 SW/min at all power levels. *p<0.01 (60 vs 120 SW/min)

Regarding the overall evaluation of pain at the treatment, 30 (60.0%) of 50 patients felt more pain at a rate of 120 SWs/min than at 60 SW/min, while only 4 (8.0%) felt more pain at a rate of 60 SW/min than at 120 SW/min. The remaining 16 patients (32.0%) felt the similar degrees of pain at both rates. In 20 patients, the highest tolerable treatment power level was reached at rate of 60 SW/min while these patients could not tolerate treatment at rate of 120 SW/min at one power level lower.

After one SWL session, effective fragmentation, defined as stone free or clinically insignificant residual fragments (less than 4mm) on follow-up KUB, was accomplished in 29 patients (58%) who did not need repeat SWL treatment. The other 21 patients required repeat SWL treatment (9 patients) or other auxiliary procedures (transurethral lithotripsy in 8 and percutaneous nephrolithotripsy in 4). We compared 29 patients (good outcome after one session of SWL) to the other 21 patients (needed repeat SWL or auxiliary procedures) regarding the relationship between the efficacy of SWL and maximum power level. Mean of the maximum power level of the former patients was 4.73, while that of the latter was 5.15. There was no significant difference between the two values.

Discussion

In contrast with Dornier HM-3 lithotriptor, newer generation lithotriptors do not require general anesthe-

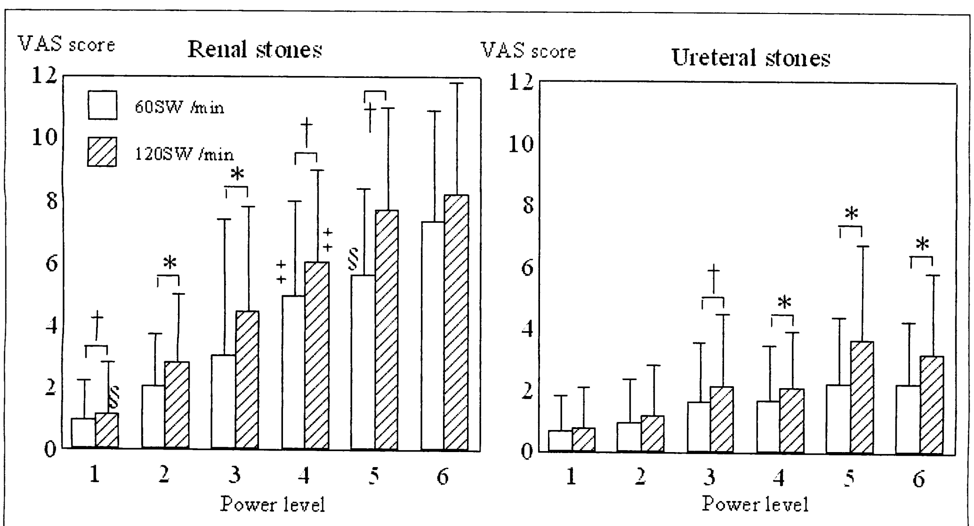

Fig. 2 VAS scores in the patients with renal and ureteral stones. Significant difference in VAS scores was noted between 60 and 120 SW/min for renal stones at power level 1 to 5, and for ureteral stones at power level 3 to 6. VAS scores were significantly higher in patients with renal stones than ureteral stones at rate of 60 SW/min at power levels 4 and 5, and at a rate of 120 SW/min at power levels 1 and 4.
*p<0.01, †p<0.05 (60 vs 120 SW/min), ‡p<0.01, §p<0.05 (renal vs ureteral stones)

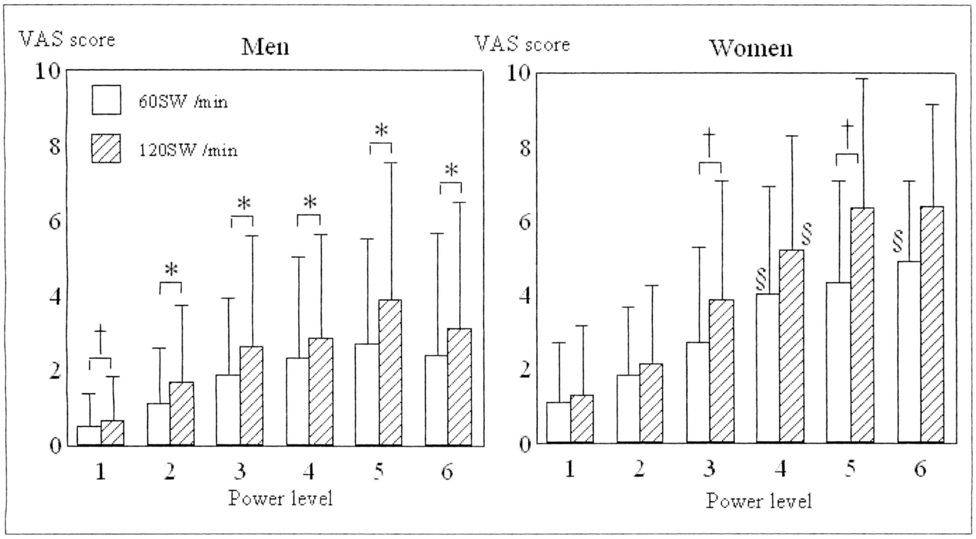

Fig. 3 VAS scores in male and female patients. Significant difference in VAS scores was noted between 60 and 120 SW/min for men at all power levels, and for women at power levels 3 and 5. VAS scores were significantly higher in women than men at a rate of 60 SW/min at power levels 4 and 6, and at a rate of 120 SW/min at power level 4.

*$p<0.01$, † $p<0.05$ (60 vs 120 SW/min), § $p<0.05$ (male vs female patients)

sia but only local or no anesthesia is required due to the tight focal area. For example, SLX-MX lithotriptor used in the present study has a focal area of 6×6 mm in diameter and 28 mm in depth. Nevertheless, nearly 50% of patients experience severe pain during treatment, thus necessitating intravenous anesthesia, analgesics, opioids or intravenous sedation.[10] The pathogenesis of pain during SWL is not fully understood. There are numerous factors influencing the occurrence of pain. Apart from patient-related factors, several mechanical and physical variables may be responsible, including the type and generation of lithotriptors, SW generator and focusing mechanism, the configuration of the SW front, cavitation effects, SW peak pressure, the size of the focal zone, and the area of SW entry at the skin. Pain during SWL is considered to result from two different origins. One is skin pain caused by the direct exposure of SW on the cutaneous pain receptors. The other is visceral or deep origin caused by distension of the renal capsule and musculoskeletal components on the exposure area. Pain during SWL is known to be proportional to the energy power contained in each shockwave that encounters body tissues and transfers a defined quantity of energy at each interface, not only at the skin but also at the water-skin interface.

However, patient-related factors include age, gender, race, education level, residence and tolerance. Because objective quantification of pain is not simple, a face scale or VAS has been applied for the evaluation of pain in most studies investigating the effect of anesthetic methods and analgesic medication during treatment. In the present study, each patient experienced two different rates of SW at the same power level and pain was quantitatively evaluated on a 10-cm VAS. The most interesting finding in the present study was that VAS scores were higher during treatment at rate of 120 SWs/min than at 60 SW/min at all power levels. Moreover, 30 patients felt more pain at a rate of 120 SW/min during SWL, while only 4 felt more pain at a rate of 60 SW/min. Twenty patients could not tolerate treatment at rate of 120 SW/min whereas these patients could tolerate treatment at rate of 60 SW/min at one power level higher.

This prospective study was motivated by the results of recent studies showing that a better comminution effect was obtained at a slow SW rate than at a fast rate in a clinical setting.[7-9] They showed that the total number of SW was significantly lower in the slow rate group (60 SW/min) than in the fast rate group (120 SW/min), and that the success rate was higher in the slow rate group. We also reported a better comminution effect at a slow rate of SW delivery (60 SW/min) than at a high rate of delivery (120 SW/min) using an SLX-MX SWL device.[5] Particularly, for patients with stone area less than 100 mm[2] or patients with renal stones, treatment at a slow rate achieved more effective stone fragmentation. Although the exact mechanism of superiority for stone comminution at a slow rate of SW is not fully understood, several mechanisms are advocated[11] and the most plausible one is related to the cavitation phenomenon that is one of the fundamentals for stone fragmentation. Briefly, SW administration causes the creation of gas bubbles in both liquid and tissues. These air bubbles rapidly collapse and the waves formed strike the stone surface, subsequently breaking the stone.[12] These bubbles may act as an air "cloud" barrier to efficient SW energy transmission if persistent air bubbles do not have time to dissipate before the next SW arrives during treatment at a fast rate.[13] We cannot explain why treatment at a rate of 120 SW/min caused more pain than that at 60 SW/min in the present study. Recently, Evan et al. showed that treatment at a fast rate of SW (120 SW/min) induced more extensive renal vascular injury than treatment at a slow rate (30 SW/min)[14] and we speculate that the cavitation phenomenon is related to the difference in the degree of both tissue damage and pain.

VAS scores were higher in patients with renal stones and in female patients than in patients with ureteral stones and in male patients, respectively. In accordance with these results in the present study, several authors have pointed out that stone location and sex difference[10] affected the degree of pain during SWL.[6, 10, 15-17] Robert et al[6] demonstrated that patients with renal stones and female patients had higher VAS pain scores than patients with ureteral stones and male patients, respectively. They suggested that patients with upper ureteral stones do not need sedation or analgesics, whereas patients with renal stones or female patients should receive some medication before SWL treatment. Jeong et al. and Oh et al. investigated the demographic factors that affected the degree of pain during SWL.[16, 17] They showed that age, stone location and sex were related to differences in pain experience.[16, 17] We speculate that the path of SW through the renal capsule causes more pain during the treatment of renal stones compared to ureteral stones. Exposure of SW on the 12th rib also may cause pain during the treatment of renal stones. However, the exact reason for higher VAS pain scores in female patients remains elusive. This sex-related difference may be attributed to women's smaller body size and body mass, which could result in the concentration of greater SW energy in an area near to the nerve plexuses.[18] Several studies described sex differences in sensitivity to noxious stimuli and suggested biological mechanisms underlying such differences.[19] Sex hormones influence pain sensitivity and pain threshold. Pain tolerance in women also varies with the stage of the menstrual cycle. All these biological factors may affect the sex-related difference in the degree of pain during SWL.

We performed SWL in this study without any sedation or analgesics. Generally, there is a risk of insufficient comminution of stones if the SW power could not be raised sufficiently because pain became intolerable during treatment. However, we wanted to assess whether the delivery rate of shockwave, rather than sedation methods, affected the experience of pain during the treatment. If sedation or analgesic was administered before the treatment, it is difficult to assess 'true' pain because of the reduction or disappearance of the pain. To avoid this bias, we studied these effects during treatment without any sedation or analgesics.

A limitation of the present study is that it examined a small population of patients and non-randomized methods were used. Because the SW power level was raised incrementally instead of in a random fashion, the patients might have had a bias toward higher VAS scores in proportion with the increase in the SW power level. Because the patients were aware of the slow or fast rate of SW through the sound of SW delivery, the fast rate might have caused higher VAS scores at each SW power level due to psychological reasons. Despite these limitations, the present study provides some insights into differences in pain intensity depending on differences in SW delivery rate, stone location and sex. Since SWL is not a completely pain-free procedure, future studies on the exact mechanism of pain during SWL are warranted.

Conclusion

We showed that SWL treatment at a slow rate of SW delivery contributed to less pain in a clinical setting. We recommend performing SWL treatment using a slow SW delivery rate because of its better stone comminution with less pain.

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