CLINICAL SCIENCE

Comparison between two shock wave regimens using frequencies of 60 and 90 impulses per minute for urinary stones

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PURPOSE: Two different regimens of SWL delivery for treating urinary stones were compared.

METHODS: Patients with urinary stones were randomly divided into two groups, one of which received 3000 shocks at a rate of 60 impulses per minute and the other of which received 4000 shocks at 90 impulses per minute. Success was defined as stone-free status or the detection of residual fragments of less than or equal to 3 mm three months after treatment. Partial fragmentation was considered to have occurred if a significant reduction in the stone burden was observed but residual fragments of 3mm or greater remained.

RESULTS: A total of 143 procedures were performed with 3000 impulses at a rate of 60 impulses per minute, and 156 procedures were performed with 4000 impulses at 90 impulses per minute. The stone-free rate was 53.1% for patients treated with the first regimen and 54.8% for those treated with the second one ($p = 0.603$). The stone-free rate for stones smaller than 10 mm was 60% for patients treated with 60 impulses per minute and 58.6% for those treated with 90 impulses per minute. For stones bigger than 10 mm, stone-free rates were 34.2% and 45.7%, respectively ($p = 0.483$). Complications occurred in 2.3% of patients treated with 60 impulses per minute and 3.3% of patients treated with 90 impulses per minute.

CONCLUSION: No significant differences in the stone-free and complication rates were observed by reducing the total number of impulses from 4000 to 3000 and the frequency from 90 to 60 impulses per minute.

KEYWORDS: Kidney calculi; Urolithiasis; Urologic surgical procedures; Extracorporeal shockwave lithotripsy.

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INTRODUCTION

Since its introduction into medical practice in the early 1980s,[1] extracorporeal shock wave lithotripsy (SWL) has remained the most popular method worldwide for the treatment of urinary stones due to its non-invasive nature, high degree of efficacy and low incidence of complications.[2] SWL is currently the method of choice for treating renal stones not exceeding 20 mm and upper ureteric stones smaller than 10 mm. According to the literature, the outcome of treatment after SWL is variable due to the close relation between the final result with the stone burden, the existence of various types of lithotripters, different concepts of success and the way patients are evaluated after treatment. Because of these factors, stone-free rates following SWL vary from 14% to 91%.[3,4]

Many factors are thought to influence the final results of SWL, including patient selection, stone size, stone location and composition, lithotripter type, experience level of the operator, total shock number, energy delivered, shock frequency and method of shock delivery.[5,6] In order to improve results, various modifications in the treatment strategy have been introduced, including voltage stepping, reductions in the rate of shock wave delivery, and improvements in analgesic protocols.[8-12] Additionally, better selection of candidates for this modality of stone treatment is now employed based on stone size and location, low attenuation coefficients measured by computed tomography and a stone skin distance of less than 10 cm.[13,14] The improvement in stone fragmentation observed with the reduction in the frequency of shocks per minute was first suggested by Greenstein[15] and has been reported by many in vitro and in vivo studies.[5,8,9,16-18] A recent meta-analysis reported an observed advantage in treatment with 60 impulses per minute when compared to treatment with 120 impulses per minute but comparisons among 60 and 90 impulses per minute have not been performed yet.[19] Additionally, no protocols have evaluated if the reduction in the frequency of shocks can be followed by a reduction in the total number of shocks delivered. Our purpose is to compare two different shock wave regimens to check if the reduction in the frequency of the impulses per minute can also allow a reduction in the total number of impulses delivered without affecting the final result.

PATIENTS AND METHODS

After informed consent, patients with previously untreated renal and ureteric stones were admitted for an initial treatment by SWL between June 2008 and May 2009. Stones smaller or equal to 6 mm were treated only if symptomatic and those bigger than 6mm were treated independently of causing symptoms. Patients were sequentially allocated into two groups; one group received 3000 impulses at a rate of 60 impulses per minute, and the other received 4000 impulses at a rate of 90 impulses per minute. Patients submitted to re-treatment of the same stone were excluded. All treatments were done using the Dornier Compact Delta lithotripter. Stones were located by x-ray or ultrasound. Prior to treatment, patients were submitted to laboratory tests and a cardiologic evaluation when indicated. Urinary infections were treated prior to the SWL session. All procedures were performed under general anesthesia. Briefly, Tramadol 1-2 mg/kg associated to Propofol 2.5-3.0 mg/kg and scopolamine were employed in the majority of the procedures. Patients received 50-100 mg of diluted Tramadol and 20 mg of scopolamine just before the beginning of the SWL session and Propofol was maintained on continuous bomb infusion during the treatment and interrupted three minutes before the end of the session. All patients were maintained under spontaneous breathing, and a facial or a laryngeal oxygen mask was used according to the anesthesiologist's judgment. The potency of the lithotripter was increased progressively by 300 shocks until reaching the final stage, which occurred at a mean of 1500 shocks. The maximum potency employed was level 4 (equivalent to 14 kV) for renal stones and level 6 (16 kV) for ureteric stones.

All patients were treated on an outpatient basis and were discharged from the hospital six hours after treatment. All patients received non-steroidal anti-inflammatory drugs (NSAIDs) and Dipyrone in combination with Hyoscine for three days postoperatively unless contraindicated and were instructed to come to the emergency department in case of severe pain, fever or hematuria.

The final results for each patient were assessed with a kidney and urinary bladder scan (KUB) plus an abdominal ultrasound three months after the procedure. Success was defined as stone-free status or the detection of residual fragments $\leq$ 3 mm on final evaluation. Partial fragmentation was considered to have occurred if a significant reduction in the stone burden was observed but residual fragments bigger than 3 mm remained.

We evaluated overall stone-free rates, the incidence of unchanged stones and the occurrence of partial fragmentation as well as the occurrence of significant complications in both groups.

The sample size required was based on the assumption that the estimated success rate would be 70% in the 3000 impulses at 60 impulses per minute group and 50% in the 4000 impulses at 90 impulses per minute group, with a type I error of 0.05 and a type II error of 0.05 (power of 80%).[8,9] This yielded a projected sample size of 93 stones in each group.

Data were analyzed using the Fisher's exact, Chi-square and Mann-Whitney tests; a level of significance of 5% was adopted.

This study was approved by the committee of ethics of the University of São Paulo Medical School (number 1183/06).

RESULTS

A total of 331 procedures were performed in 302 patients. Thirty-one patients were lost to follow-up; thus, 300 procedures in 271 patients were included in the final analysis (24 patients presented with two different stones and two patients presented with three stones). Nine patients were children (age under or equal to sixteen years-old). A total of 3000 impulses at a rate of 60 impulses per minute were administered to 143 patients and 157 patients received 4000 impulses at a rate of 90 impulses per minute. Patient and stone characteristics are shown in Table 1.

The overall stone-free rate was 53.1% for patients treated at 60 impulses per minute and 54.8% for those treated at 90 impulses per minute ($p = 0.603$). The stone-free rate for patients with stones smaller than 10 mm was 60% for those treated with 60 impulses per minute and 58.6% for those treated with 90 impulses per minute ($p = 0.743$). For stones bigger than 10 mm, the stone-free rates were 34.2% and 45.7%, respectively ($p = 0.483$). Results are summarized in Table 2.

Results according to stone location were grouped into three main stone locations: lower pole stones, pelvic plus upper and medium calyx stones and ureteric stones. No differences were found between the two groups regarding stone location. The results are shown in Table 3.

Table 1 - Patient and stone characteristics.

	60 impulses/ min (143 procedures) N		90 impulses/min (157 procedures) N	
Gender: male/ female	57/74		59/81	
Age: range/ median (years)	10-82	49	6-82	49
Stone side: left/ right	69/74		78/79	
Stones smaller than 10 mm	105	73.4	111	70.7
Stones bigger than 10 mm	38	26.6	46	29.3
Stone size: range/ median (mm)	4-22	8	4-18	9
Medium calyx stones	38	26.6%	50	31.8%
Upper pole stones	26	18.2%	27	17.2%
Renal pelvis stones	18	12.6%	18	11.5%
Lower pole stones	39	27.3%	38	24.2%
Ureteral stones	22	15.6%	24	15.2%

Table 2 - Stone fragmentation after SWL according to stone burden.

Stone burden		60 impulses per minute n	60 impulses per minute %	90 impulses per minute n	90 impulses per minute %	p
Overall	Stone-free	76	53.1	86	54.8	
	Unchanged or residual fragments	67	46.8	71	45.2	
Less than 10 mm n = 216	Stone-free	63	60	65	58.6	
	Unchanged or residual fragments	42	40	46	41.4	0.743
More than 10 mm n = 84	Stone-free	13	34.2	21	45.7	
	Unchanged or residual fragments	25	65.8	25	54.3	0.483

Complications were observed in 17 procedures (5.6%) and were similar in both groups. Pain requiring hospitalization and steinstrasse were each observed in five patients. In one case of steinstrasse, ureteroscopy was necessary to remove the fragments. One patient developed extreme somnolence due to the anesthetic procedure; this patient was maintained in the recovery room until the next day and then discharged home. Complications are shown in Table 4.

DISCUSSION

Shock wave lithotripsy has been the main method used to treat urinary stones since 1980. It is estimated that about 70% of all symptomatic upper urinary stones are treated with SWL, but it is also true that approximately 50% of the patients treated with this modality do not clear their stone burdens.[19-21] In the original HM3 lithotripter (Dornier Medtech, Germany), administration of spinal or general anesthesia was necessary due to the instrument's potency and broad focal zone. More recent generations of lithotripters are less potent and have a smaller focal zone, resulting in less painful treatments that require less analgesia. Nevertheless, the efficacy of treatment with these newer devices is significantly lower when compared to the HM3.[22,23]

Table 3 - Stone fragmentation after SWL according to stone location.

Stone location		60 impulses per minute n	60 impulses per minute %	90 impulses per minute n	90 impulses per minute %	p
Medium, upper pole and pelvic stones n = 177	Stone-free	47	57.3	49	51.6	
	Unchanged or residual fragments	35	42.7	46	48.4	0.570
Lower pole stones n = 77	Stone-free	19	48.7	20	52.6	
	Unchanged or residual fragments	20	51.3	18	47.4	0.259
Ureteric stones n = 46	Stone-free	10	45.5	17	70.3	
	Unchanged or residual fragments	12	54.5	7	29.1	0.190

Table 4 - Complications after SWL.

Complication	60 impulses per minute n	60 impulses per minute %	90 impulses per minute n	90 impulses per minute %	Total n	Total %
Pain	3	1.0	2	0.7	5	1.7
Steinstrasse	2	0.7	3	1.0	5	1.7
Febrile UTI	1	0.3	3	1.0	4	1.3
Bacteremia	1	0.3	0	0	1	0.3
Hematuria	0	0	1	0.3	1	0.3
Somnolence	0	0	1	0.3	1	0.3
Total	7	2.3	10	3.3	17	5.6

The most recent measures introduced to improve the results of SWL include dose escalation, reducing the number of shocks per minute, performing the procedure under more efficient analgesia and limiting the procedure to smaller, less dense stones and those located at a distance of less than 10 cm from the lumbar skin.[3-6,8-12] In spite of these efforts, SWL results remain poor in lower pole stones and stones bigger than 20 mm.

Fragmentation of the stone during SWL occurs due to the compressive forces of the waves as well as spalling and cavitation effects.[5,7] Air bubbles form as a result of changes in pressure caused by the waves. The bubbles that are not reflected by the stone decrease the shock wave energy by spreading and absorbing it. For this reason, less of the energy load is present when the next wave arrives. As the frequency of the lithotripter increases, there is less time for these bubbles to spread, and they form bubble piles by joining with each other as described by Huber and Zeman.[23-25] Because of this effect, slowing the shock wave rate would allow bubbles to dissipate and erode the stone before the arrival of new bubbles with a new shock wave, thus facilitating stone fragmentation.[18,23] In vitro and animal studies have shown that reducing the frequency of shocks increased the efficiency of SWL and that the ideal frequency for effective fragmentation was 60 shocks per minute.[15,17]

In the clinical setting, Yilmaz et al.[5] compared patients receiving 120, 90 and 60 impulses per minute and found that the fragmentation rates were similar between 60 and 90 impulses per minute and both were superior to 120 impulses per minute. They conclude that 90 impulses per minute was the most appropriate regimen given the observed fragmentation rates and the duration of treatment.[5] Madbouly prospectively compared patients treated with 120 and 60 impulses per minute and found a statistically significant difference favoring patients treated with 60 impulses per minute even though the slower-rate treatment resulted in a considerably longer procedure.[18] Semins performed a meta-analysis evaluating randomized and controlled studies comparing the outcome of SWL performed at 120 impulses per minute to those performed at 60 impulses per minute and found a significant difference favoring 60 impulses per minute.[19] More recently, Honey et al. performed a multicentric and randomized study showing that reducing the frequency from 120 impulses to 60 impulses per minute resulted in an increase in stone-free patients from 48.8% to 64.9% in upper ureteric stones.[26] Koo et al. prospectively compared treatment with 70 versus 100 impulses in patients with renal radio-opaque stones who were treated with no sedation or anesthesia and found an improvement in the stone-free rate from 25.5% to 67% and a reduction in costs by half.[27] Kimura et al. compared 120 impulses per minute with 90 impulses per minute and found a significant improvement in stone-free rates only for ureteric stones.[28] In contrast, Kato et al. showed that a slow rate of 60 impulses per minute compared to 120 impulses per minute improved the stone fragmentation rate after one session from 47% to 65% but did not increase the final success rate after three months.[29] We can conclude that fragmentation rates are greater at a slower-rate regimen but controversies still exist regarding the final results. Herein, we compared two different regimens of SWL in order to evaluate the possibility of reducing the frequency and total number of shocks while maintaining the same results without significantly increasing the duration of the treatment. We aimed not only a comparison of two different frequencies of impulses but of two different protocols of treatment by SWL.

We did not find a clear advantage to reducing the frequency of impulses from 90 to 60 in terms of patients free of stones at a three-month follow-up neither for stones bigger than 10 mm, as stated by Pace et al.[8] Additionally the stone-free rate was higher among ureteric stones in patients treated at 90 impulses per minute. Probably a significant difference was not reached due to the small number of ureteric stones treated. The stone-free rate in lower pole stones did not differ significantly between the two groups and was higher than the average reported in the literature. One possible explanation for this result is the improvement in analgesia and also the variability in results found among different lithotripters and treatment protocols.

The complication rate was low and similar in both groups. We were surprised by the fact that the stone-free rate for lower pole stones was the same as for stones in other locations of the kidney opposing the current literature. One interpretation of this result is that ultrasonography and KUB are not as accurate as helical CT. This has been a problem regarding studies on SWL: lithotripters are different and have diverse performances; thus, the method of treatment (number of shocks, type of analgesia, patient positioning) and of final evaluation of results varies tremendously, resulting in different and frequently confusing results. We have been performing SWL under general anesthesia since 2006 and we noted that this procedure is safe and causes much less suffering in patients when compared to our previous protocol, which employed intravenous narcotics in combination with NSAIDs. The procedure is much easier for the medical team to perform as patients do not move on the table and deep breathing incursions do not occur. The increase in costs with this regimen is balanced out by the smaller number of re-treatments (unpublished data).

Unfortunately, we did not perform helical tomography to evaluate the final results of the treatment what would have been. We are not currently able to afford the increase in costs generated by the inclusion of non-contrast CT in our protocol. Additionally, the amount of radiation delivered to patients would be high as many of the patients present with multiple small stones or form new stones throughout their follow-up. Consequently, they are submitted to multiple sessions of SWL and performing a CT after each session would be harmful. Thus, all patients were submitted to KUB and ultrasound, which provide an acceptable level of accuracy for the assessment of final results.

Conclusion: This comparison of two different regimens of SWL using 3000 shocks at a rate of 60 impulses per minute and 4000 shocks at 90 impulses per minute showed similar stone-free rates at a three-month evaluation. Significant complication rates were low and similar in both groups.

REFERENCES

1. Chaussy C, Schuller J, Schmiedt E, Brandl H, Jocham D, Liedl B. Extracorporeal shock-wave lithotripsy (ESWL) for treatment of urolithiasis. Urology. 1984;23:59-66, doi: 10.1016/0090-4295(84)90243-7.
2. Skolarikos A, Alivizatos G, de la Rosette J. Extracorporeal Shock Wave Lithotripsy 25 years later: complication and prevention. Eur Urol. 2006;50:981-90, doi: 10.1016/j.eururo.2006.01.045.
3. Albala DM, Assimos DG, Clayman RV, Denstedt JD, Grasso M, Gutierrez-Aceves J, et al. Lower pole I: a prospective randomized trial of extracorporeal shock wave lithotripsy and percutaneous nephrostolithotomy for lower pole nephrolithiasis-initial results. J Urol. 2001;166:2072-80, doi: 10.1016/S0022-5347(05)65508-5.
4. Renner C, Rassweiler J. Treatment of renal stones by extracorporeal shock wave lithotripsy. Nephron. 1999;81 Suppl 1:71-81, doi: 10.1159/000046302.
5. Yilmaz E, Batislam E, Basar M, Tuglu E, Mert C, Basar H. Optimal frequency in Extracorporeal shock wave lithotripsy: prospective randomized study. Urology. 2005;66:1160-4, doi: 10.1016/j.urology.2005.06.111.
6. Larcher P, De Cobelli O, Carmignani L, Franchini V, Meroni T, Panizzuti M, et al. Prognostic parameters in extracorporeal lithotripsy. Arch Ital Urol Nefrol Androl. 1989;61:361-5.
7. Weizer AZ, Zhong P, Preminger GM. New concepts in shock wave lithotripsy. Urol Clin N Am. 2007;34:375-82, doi: 10.1016/j.ucl.2007.07.002.
8. Pace KT, Ghiculete D, Harju M, Honey RJ. Shock wave lithotripsy at 60 or 120 shocks per minute: a randomized, double-blind trial. J Urol. 2005;174:595-9, doi: 10.1097/01.ju.0000165156.90011.95.
9. Chacko J, Moore M, Sankey N, Chandhoke PS. Does a slower treatment rate impact the efficacy of extracorporeal shock wave lithotripsy for solitary kidney or ureteral stones? J Urol. 2006;175:1370-3, doi: 10.1016/S0022-5347(05)00683-X.
10. Zhou Y, Cocks FH, Preminger GM, Zhong P. The effect of treatment strategy on stone comminution efficiency in shock wave lithotripsy. J Urol. 2004;172:349-54, doi: 10.1097/01.ju.0000132356.97888.8b.
11. Tiselius HG. Cutaneous anesthesia with lidocaine-prilocaine cream: a useful adjunct during shock wave lithotripsy with analgesic sedation. J Urol. 1993;149:8-11.
12. Mitsogiannis IC, Anagnostou T, Tzortzis V, Karaktzas A, Gravas S, Poulakis V, et al. Analgesia during Extracoporeal Lithotripsy: Fentanyl Citrate versus Parecoxib Sodium. J Endourol. 2008;22:623-6, doi: 10.1089/end.2007.0344.
13. Joseph P, Mandal AK, Singh SK, Mandal P, Sankhwar SN, Sharma SK. Computerized tomography attenuation value of renal calculus: can it predict successful fragmentation of the calculus by extracorporeal shock wave lithotripsy? A preliminary study. J Urol. 2002;167:1968-71.
14. Pareek G, Armenakas NA, Fracchia JA. Hounsfield units on computerized tomography predict stone-free rates after extracorporeal shock wave lithotripsy. J Urol. 2003;169:1679-81, doi: 10.1097/01.ju.0000055608.92069.3a.
15. Greenstein A, Matzkin H. Does the rate of extracorporeal shock wave delivery affect stone fragmentation? Urology. 1999; 54:430-2, doi: 10.1016/S0090-4295(99)00176-4.
16. Weir MJ, Tariq N, Honey RJ. Shockwave frequency affects fragmentation in a kidney stone model. J Endourol. 2000;14:547-50, doi: 10.1089/08927790050152113.
17. Paterson RF, Kuo RL, Lingeman JE. The effect of shock wave delivery on the efficiency of lithotripsy. Curr Opin Urol. 2002;12:291-5, doi: 10.1097/00042307-200207000-00006.
18. Madbouly K, El-Tiraifi AM, Seida M, El-Faqih SR, Atassi R, Talic RF. Slow versus fast shock wave lithotripsy rate for urolithiasis: a prospective randomized study. J Urol. 2005;173:127-30, doi: 10.1097/01.ju.0000147820.36996.86.
19. Semins MJ, Trock BJ, Matlaga BR. The effect of shock wave rate on the outcome of shock wave lithotripsy: a meta-analysis. J Urol. 2008;179:194-7, doi: 10.1016/j.juro.2007.08.173.
20. Kerbl K, Rehman J, Landman J, Lee D, Sundaraum C, Clayman RV. Current management of urolithiasis: progress or regress? J Endourol. 2002;16:281-5, doi: 10.1089/089277902760102758.
21. Ng CF, Thompson TJ, McLornan L, Tolley DA. Single center experience using three shockwave lithotripters with different generator designs in management of urinary calculi. J Endourol. 2006;20:1-4, doi: 10.1089/end.2006.20.1.

22. Portis AJ, Yan Y, Pattaras JG, Andreoni C, Moore R, Clayman RV. Matched pair analysis of shock wave lithotripsy effectiveness for comparison of lithotriptors. J Urol. 2003;169:58-62, doi: 10.1016/S0022-5347(05)64034-7.
23. Talic RF, Rabah DM. Effect of modification of shock wave delivery on stone fragmentation. Curr Op Urol. 2006;16:83-7, doi: 10.1097/01.mou.0000193374.29942.46.
24. Huber P, Jöchle K, Debus J. Influence of shock wave pressure amplitude and pulse repetition frequency on the lifespan, size and number of transient cavities in the field of an electromagnetic lithotripter. Phys Med Biol. 1998;43:3113-28, doi: 10.1088/0031-9155/43/10/029.
25. Zeman RK, Davros WJ, Garra BS, Horii SC. Cavitation effects during lithotripsy. Part I. Results of in vitro experiments. Radiology. 1990;177:157-61.
26. Honey RJD'A, Schuler TD, Ghiculete D, Pace KT. A randomized double-blind trial to compare shock wave frequencies of 60 and 120 shocks per minute for upper ureteral stones. J Urol. 2009;182:1418-23, doi: 10.1016/j.juro.2009.06.019.
27. Koo V, Beattie I, Young M. Improved cost-effectiveness and efficiency with a slower shockwave delivery rate. BJU Int. 2010;105:692-6, doi: 10.1111/j.1464-410X.2009.08919.x.
28. Kimura M, Shimura H, Sasagawa T. Slow delivery rate improves the outcome of extracorporeal shock wave lithotripsy. Nippon Hinyokika Gakkai Zasshi. 2009;100:625-31.
29. Kato Y, Yamaguchi S, Hori J, Okuyama M, Kakizaki H. Improvement of stone comminution by slow delivery rate of shock waves in extracorporeal lithotripsy. Int J Urol. 2006;13:1461-5, doi: 10.1111/j.1442-2042.2006.01609.x.