

## Original Article

# Effect of Extracorporeal Shock Wave Therapy on Lower Limb Spasticity in Stroke Patients

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## Abstract

**Background:** This study aims to evaluate the effect of extracorporeal shock wave therapy (ESWT) on lower limb spasticity in stroke patients.

**Methods:** Twenty-eight eligible patients with ankle plantar flexor spasticity were randomly assigned to two groups. ESWT group received 1 session per week for 3 weeks of ESWT along with oral anti-spastic medications and stretching exercises. The control group received only oral anti-spastic medications and stretching exercises similar to ESWT group. At baseline, weeks 1, 3 and 12, spasticity was assessed and compared between the two groups using Modified Ashworth Scale (MAS), clonus score, passive range of motion (ROM) of joint, pain score, 3-m walk duration and lower extremity functional score (LEFS). Three patients were lost during follow-up; 25 patients completed the study and were analyzed.

**Results:** After one session of ESWT treatment, MAS, pain, ROM and LEFS improved significantly compared to baseline. After three weeks of ESWT treatment, MAS, pain and 3-m walk duration improved significantly compared to week 1. At week 12, MAS, pain, ROM, 3-m walk duration and LEFS improved significantly compared to the control group after controlling baseline values. The trend of decrease in pain score and MAS was significantly different between the groups. The trend of increase in ROM and LEFS was significantly different between the groups.

**Conclusion:** ESWT significantly improved lower limb spasticity, pain, passive ROM, 3-m walk duration and LEFS immediately and 12 weeks after treatment. So, ESWT in combination with oral anti-spastic medications and stretching exercises could be useful for improvement of spasticity in stroke patients.

**Keywords:** Anti-spastic, extracorporeal shock wave therapy, spasticity, stroke

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## Introduction

Spasticity is defined as a velocity-dependent increase in tonic stretch reflexes with exaggerated tendon jerks, clonus, and spasms; it affects movement and may cause muscle pain, stiffness, loss of joint range and loss of function.<sup>1,2</sup> Spasticity is a major cause of disability in patients with a variety of central nervous system diseases and trauma.<sup>3</sup>

Stroke is one of the leading causes of death in the world; according to the World Health Statistics, in 2012, stroke was the third cause of years of life lost due to premature mortality globally.<sup>4</sup> Spasticity is a common symptom after stroke and usually occurs within the first few days or weeks in about 30% of patients.<sup>5</sup> This disorder can cause discomfort, stiffness and limitations in physical activities and daily life, affecting the patients' quality of life.<sup>6,7</sup>

Several therapeutic interventions are available to control

and reduce spasticity, including pharmacological treatment, physical therapy, occupational therapy, orthopedic surgery, and neurosurgery. Currently, there is no specific guideline for stratification and individualization of therapeutic interventions, and these interventions have different indications and advantages. Also, sometimes spasticity cannot be controlled due to the side effects of oral drugs and the invasiveness of local treatment methods.<sup>8,9</sup> Therefore, new noninvasive treatment methods for spasticity are greatly needed.

Extracorporeal shockwave therapy (ESWT) was first applied to patients to break up kidney stones;<sup>10</sup> currently, however, it is considered as a new reversible therapeutic method for spasticity. It has been demonstrated as an effective method for treatment of musculoskeletal diseases and several inflammatory tendon diseases.<sup>11–14</sup> Previous studies have shown the effect of ESWT in improving spasticity in children with spastic cerebral palsy.<sup>15–18</sup>

Recently, a number of studies have applied ESWT to stroke patients with spasticity. Some of these studies applied ESWT to treat upper limb spasticity and others applied it for lower limb spasticity. These studies show that ESWT is effective in treating spasticity and improving some parameters, although the improvement more significant immediately after ESWT and diminished with time.<sup>19–23</sup>

The diversity of findings from previous studies that have applied ESWT to stroke patients with spasticity, as well as the limited data on its therapeutic effect on lower limb spasticity for stroke patients, necessitate further trials to assess the therapeutic effects

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of ESWT on lower limb spasticity. Thus, the present study was designed to evaluate the effects of ESWT on the gastrocnemius muscle in stroke patients with lower limb spasticity.

## Materials and Methods

This prospective randomized controlled trial was performed from June, 2015 to January, 2016, on 28 hemiplegic stroke patients with gastrocnemius muscle spasticity. This study was done in Kashani hospital in Isfahan, and patients referred to the Rehabilitation department by neurologists were reviewed to select eligible patients. Twenty-two patients (78%) had ischemic stroke, and six (22%) had hemorrhagic stroke. Patients of both genders aged 18 to 70 years were eligible if the duration of stroke was more than one month and their gastrocnemius spasticity was greater than grade+1, according to Modified Ashworth scale (MAS) and ability to walk 10 meters. The exclusion criteria were: presence of dynamic ankle contracture, surgery on the lower limb in the past 12 months, injection of botulinum toxin or phenol into the affected gastrocnemius during the previous six months, presence of another explanation for the pain (e.g. fracture, complex regional pain syndrome, or radiculopathy), presence of an unstable medical condition or uncontrolled systemic disease, pregnancy, or severe inflammation in treatment site. The study protocol was approved by the Institutional Review Board and Ethics Committee of Isfahan University of Medical Sciences. Participation in the study was voluntary and informed consent was obtained from consenting subjects before treatment. This study is registered at the Iranian Registry of Clinical Trials (IRCT2016010225803N1).

Using a randomizer software "Random Allocation", the eligible patients were randomly allocated to two groups. Group 1 included 14 patients who received the treatment regimen, consisting of ESWT, oral anti-spastic medications and stretching exercises. Group 2 included 14 patients who received the treatment regimen consisting of oral anti-spastic medications and stretching exercises. ESWT was applied by an electromagnetic type Dornier AR2 machine (Dornier MedTech GmbH, Wessling, Germany). The pressure pulses were focused at musculotendinous junction of medial and lateral head of the gastrocnemius on the spastic side and a total of 1,500 pulses were delivered to gastrocnemius. The energy flux density was 0.1 mJ/mm<sup>2</sup> and the repetition frequency was 4 Hz. Also, patients in group 1 received weekly one session of ESWT over the three-week treatment period. Oral anti-spastic medications and stretching exercises were similar for both groups. Tizanidine hydrochloride was the oral anti-spastic used at a daily dosage of 2mg for first 4 days and then 4 mg until the end of treatment. Stretching exercises included 30 min/day, 5 weekly sessions over the treatment period. Patients in both groups were visited at the end of weeks 1, 3 and 12, and they were not allowed to change the dose of anti-spastic medication during the study.

Collected data included age, gender, type of stroke, duration of stroke, pain score, grade of gastrocnemius spasticity, passive range of motion (ROM) of joint, clonus score, 3-m walk duration, and lower extremity functional score (LEFS). Pain score was estimated by the Visual Analogue Scale (VAS) using a vertical 10-cm long line on paper (pain-free state to worst imaginable pain). The grade of gastrocnemius spasticity was assessed by MAS. Using a goniometer and summing up the angles, the angles of the maximum plantarflexion and the maximum dorsiflexion were measured as the passive range of motion of joint. The LEFS was

measured by lower extremity functional index.

Statistical analyses were done using SPSS software (SPSS, Inc., Chicago, IL, USA, version 20). Descriptive data are reported as mean  $\pm$  SD or number (percent) as appropriate. Independent sample t-test was used to compare age, duration of stroke, pain score, MAS, ROM, clonus score, 3-m walk duration and LEFS between the groups. Chi-square test was used to compare gender and type of stroke between the groups. Paired sample t-test was used to compare pain score, MAS, ROM, clonus score, 3-m walk duration and LEFS within groups at each time point in contrast to baseline values. Repeated measures ANOVA and analysis of covariance were used to compare the trend of pain score, MAS, ROM, clonus score, 3-m walk duration and LEFS between and within the groups. The level of significance was considered to be below 0.05.

## Results

Thirty-two patients were reviewed to select the eligible patients. Four patients were not included (three refused informed consent and one patient was not eligible). Twenty-eight eligible patients were assigned to two intervention groups. Three patients were lost during follow-up, one patient in the ESWT group opted out and two patients in the control group changed the doses of oral anti-spastic medications. Finally, 13 patients in the ESWT group and 12 patients in the control group completed the study and were analyzed (Figure 1).

The patients' mean age was  $55.7 \pm 10.4$  years, 68% (17 patients) were men and 54.8% (8 patients) were women. Table 1 shows the baseline characteristics of patients. Patients in the ESWT group were older, most of the patients in both groups were men and the majority of patients in both groups had ischemic stroke. No significant differences were noted between the two groups in terms of age, sex, duration of stroke or stroke type ( $P$ -value  $> 0.05$ ).

Table 2 highlights the comparison between the two groups in terms of pain score, MAS grade, ROM, clonus score, 3-m walk duration, and LEFS. Pain score in the ESWT group decreased significantly during the study period. It was significantly lower at week 1 compared to baseline ( $P$ -value = 0.01), and at week 3 compared to week 1 ( $P$ -value = 0.005), but similar at week 12 to week 3 ( $P$ -value = 0.81). The trend of decrease in pain score at the four time points in the ESWT group was statistically significant ( $P$ -value = 0.0001). In the control group, pain score was not significantly different between the time points ( $P$ -values  $> 0.05$ ). Also, pain scores were not significantly different between the groups at each time point ( $P$ -values  $> 0.05$ ). The trend of pain score over the time points was not statistically significant between the groups ( $P$ -value = 0.93). After controlling for baseline pain score as covariate, the trend was significantly different between the groups ( $P$ -value = 0.007), and also the difference in the mean pain score between the groups at week 12 was statistically significant ( $P$ -value = 0.009). In both groups, MAS decreased significantly at week 1 compared to baseline ( $P$ -values  $< 0.05$ ). In the ESWT group, it was significantly lower at week 3 compared to week 1 ( $P$ -value = 0.02). Also in this group, the trend was significantly different ( $P$ -value = 0.0001). The trend of MAS in the control group was not significantly different ( $P$ -value = 0.96). The trend of MAS was not significantly different between the groups ( $P$ -value = 0.37); however, after controlling for baseline

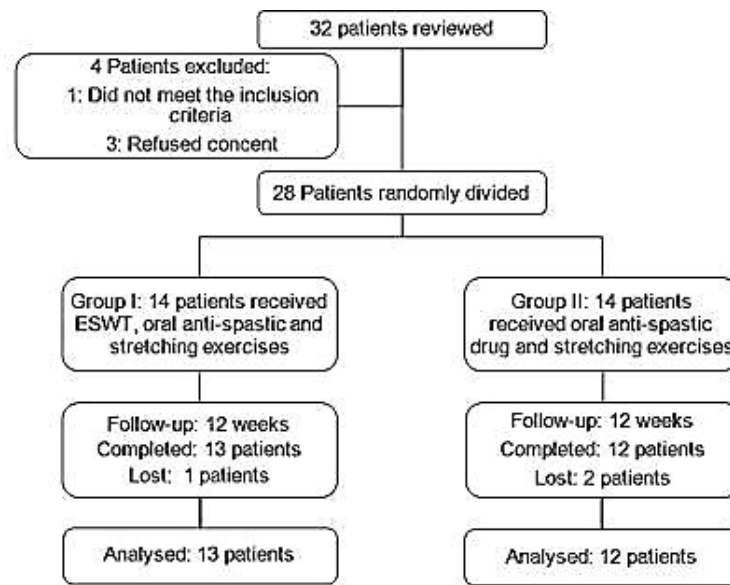


Figure 1. Consort flow chart.

Table 1. Baseline characteristics of study groups.

	ESWT group (n = 13)	Control group (n = 12)	P-value
Age	56.5 ± 11.6	54.9 ± 9.4	0.7*
Sex			0.89 <sup>†</sup>
Male	9 (69.2)	8 (66.7)	
Female	4 (30.8)	4 (33.3)	
Duration of stroke	33 ± 21.4	25.8 ± 9.9	0.3*
Stroke type			0.58 <sup>†</sup>
Ischemic	11 (84.6)	11 (91.7)	
Hemorrhagic	2 (15.4)	1 (8.3)	

Data are mean ± SD, number (%); P-values calculated using \*Independent sample t-test or <sup>†</sup>Chi square test.

values, it became significantly different ( $P$ -value = 0.004). MAS values were not significantly different between the groups at baseline, and weeks 1 and 3 ( $P$ -values > 0.05) but it was significantly lower in the ESWT group compared to the control group at week 12. ROM in the ESWT group was significantly higher than baseline at week-1, and the trend of ROM over the time points was significantly different ( $P$ -value = 0.0001). The mean ROM values were not significantly different between the groups at baseline, and weeks 1 and 3 ( $P$ -values > 0.05); however, it was significantly lower in the control group compared to the ESWT group at week 12 ( $P$ -value = 0.021). The trend of ROM was not significantly different between the groups ( $P$ -value = 0.29), but it became significantly different after controlling for baseline values ( $P$ -value = 0.026). There were no significant differences within and between the groups for clonus score at each time point ( $P$ -values > 0.05). Paired samples t-test showed that in both groups, 3-m walk duration was significantly lower at week 3 compared to week 1 ( $P$ -value < 0.05) while no significance differences were noted within patients in either group at other time points although it became significantly different at week 12

after controlling for baseline values ( $P$ -value = 0.033). Also, 3-m walk duration was not significantly different between the groups at each time point ( $P$ -values > 0.05). The trend of decrease in 3-m walk duration in the ESWT group was statistically significant but it was not significantly different between the groups ( $P$ -value = 0.37) even after controlling for baseline values ( $P$ -value = 0.057). LEFS was significantly better than baseline at week 1 in both groups ( $P$ -value < 0.05), but there were no significant differences within patients at other time points in either group ( $P$ -value > 0.05). LEFS was not significantly different between groups at baseline, and weeks 1 and 3 ( $P$ -values > 0.05) although it was significantly better than the control group at week 12 in the ESWT group. The trend of LEFS was statistically significant within the groups ( $P$ -value < 0.05). The trend was not significantly different between the groups ( $P$ -value = 0.13) but it became significantly different after controlling for baseline values ( $P$ -value = 0.001).

## Discussion

In this study, the treatment effects of ESWT, once a week for three

**Table 2.** Clinical characteristics in 75 patients by group.

	Baseline	Week-1	P <sup>2</sup>	Week-3	P <sup>3</sup>	Week-12	P <sup>4</sup>	P <sup>5</sup>	P <sup>6</sup>	P <sup>7</sup>	P <sup>8</sup>
<b>Pain_VAS</b>											
Group I	4.5 ± 3.4	3.5 ± 3	0.01	2 ± 1.8	0.005	1.9 ± 2	0.81	0.0001	0.93	0.007	0.009
Group II	3.2 ± 3.4	2.8 ± 2.8	0.14	2.8 ± 2.6	1	2.7 ± 2.5	0.34	0.39			
P <sup>1</sup>	<b>0.38</b>	<b>0.55</b>		<b>0.37</b>		<b>0.42</b>					
<b>MAS</b>											
Group I	2.6 ± 0.5	2.2 ± 0.6	0.02	1.8 ± 0.5	0.02	1.5 ± 0.5	0.1	0.0001	0.37	0.004	0.0001
Group II	2.5 ± 0.5	2.2 ± 0.7	0.03	2.1 ± 0.7	1	2.1 ± 0.7	---	0.96			
P <sup>1</sup>	<b>0.58</b>	<b>0.81</b>		<b>0.22</b>		<b>0.022</b>					
<b>ROM</b>											
Group I	35.5 ± 8	39.9 ± 8.5	0.01	42.9 ± 9.5	0.05	47.2 ± 9.6	0.01	0.0001	0.29	0.026	0.0001
Group II	36.3 ± 12.1	41.3 ± 6.1	0.15	37.2 ± 9.1	0.06	36.7 ± 9.3	0.53	0.122			
P <sup>1</sup>	<b>0.85</b>	<b>0.64</b>		<b>0.14</b>		<b>0.01</b>					
<b>Clonus score</b>											
Group I	0.54 ± 0.66	0.46 ± 0.52	0.33	0.38 ± 0.51	0.34	0.31 ± 0.48	0.34	0.23	0.16	0.97	0.75
Group II	0.17 ± 0.39	0.17 ± 0.39	---	0.17 ± 0.39	---	0.17 ± 0.39	---	0.87			
P <sup>1</sup>	<b>0.09</b>	<b>0.12</b>		<b>0.24</b>		<b>0.43</b>					
<b>3-m walk duration</b>											
Group I	28.2 ± 11.5	26.6 ± 11.1	0.34	25.1 ± 9.9	0.04	24.7 ± 10.4	0.01	0.003	0.37	0.057	0.033
Group II	31 ± 13.6	31.4 ± 12.4	0.78	30.2 ± 12.2	0.03	30.5 ± 12.4	0.17	0.43			
P <sup>1</sup>	<b>0.61</b>	<b>0.35</b>		<b>0.31</b>		<b>0.25</b>					
<b>LEFS</b>											
Group I	34.6 ± 8.3	40 ± 9.2	0.002	44.4 ± 8.8	0.05	45.3 ± 10.4	0.62	0.003	0.13	0.001	0.004
Group II	32.3 ± 13.5	33.7 ± 13.5	0.01	33.8 ± 13.3	0.17	33.8 ± 14	1	0.019			
P <sup>1</sup>	<b>0.64</b>	<b>0.21</b>		<b>0.051</b>		<b>0.04</b>					

Data expressed as mean ± SD. VAS; Visual Analogue Scale, MAS; Modified Ashworth scale, ROM; range of motion of joint, LEFS; lower extremity functional score. Group I; received Extracorporeal shockwave therapy, Group II; controls.

P<sup>1</sup>, assessed variables between groups at each time points and was calculated by Independent sample *t*-test.  
P<sup>2</sup>, assessed variables within groups in week-1 compare to baseline and was calculated by Paired sample *t*-test.  
P<sup>3</sup>, assessed variables within groups in week-3 compare to week-1 and was calculated by Paired sample *t*-test.  
P<sup>4</sup>, assessed variables within groups in week-12 compare to week-3 and was calculated by Paired sample *t*-test.  
P<sup>5</sup>, assessed trend of variables within groups by repeated measurements of ANOVA.  
P<sup>6</sup>, assessed trend of variables between groups by repeated measurements of ANOVA.  
P<sup>7</sup>, assessed trend of variables between groups by repeated measurements of ANOVA after controlling baseline values as covariate.  
P<sup>8</sup>, assessed variables between groups in week-12 by ANCOVA after controlling baseline values as covariate.

weeks, on lower limb spasticity in stroke patients were evaluated. The results show that pain score, lower limb spasticity, ROM and LEFS improved significantly immediately after the first ESWT treatment session in our patients, and the effect persisted until the end of the study period. The mechanism of ESWT affecting spasticity remains unclear but as previously reported, improving the stiffness of connective tissue by directly acting on fibrosis of chronic hypertonic muscles might explain the anti-spastic effect of ESWT.<sup>19</sup>

Previous studies performed on stroke patients with lower limb spasticity are limited. In a study by Sohn and colleagues,<sup>20</sup> 10 healthy subjects and 10 hemiplegic stroke patients with ankle plantar flexor spasticity received one session of ESWT on the medial head of the gastrocnemius. After treatment, spasticity, pain, tibial nerve conduction, F wave, and H-reflex results were measured and compared with their values before treatment. The findings showed that after applying ESWT, the spasticity of the ankle plantar flexor improved significantly, but the other variables had not changed. Similarly, in the present study, spasticity improved significantly immediately after treatment.<sup>20</sup> Despite this similarity, there are some differences between our findings and those of Sohn *et al.*<sup>20</sup> First, the controls in our study were stroke patients with spasticity while Sohn *et al.* recruited healthy subjects as controls. Second, patients in that study received one session of ESWT while our patients received one session of ESWT weekly for three weeks. Third, Sohn *et al.* did not follow patients after treatment and the variables were assessed only after treatment compared to before treatment, whereas in the present study, the patients were followed nine weeks after the end of three-week treatment and our findings show that spasticity, pain and ROM of joint in the ESWT group improved compared to controls several weeks after treatment. In summary, despite the differences between these two studies, the immediate effect of ESWT in reducing spasticity was confirmed by both studies; in addition, our study shows long-term therapeutic effects of ESWT on lower limb spasticity for 12 weeks.

In another study by Moon *et al.*,<sup>23</sup> 30 hemiplegic subacute stroke patients with ankle plantar flexor spasticity were studied. Patients in this study received one session of ESWT weekly with a total of 3 sessions; spasticity, clonus score and ROM were in these patients assessed before and after ESWT and one and four weeks after the end of 3 sessions of ESWT. They reported that spasticity improved significantly immediately and 1 week after ESWT but these changes were not significant at 4 weeks after ESWT. Clonus score in this study did not improve significantly during the study period. Also, compared to the basal evaluation, ROM had increased after the shock wave treatment although the difference was not significant. In the present study, like the one by Moon *et al.*, spasticity improved significantly immediately after ESWT; however, in contrast to that study, we found that during 12 weeks of follow-up, spasticity was significantly improved in patients who received ESWT. Similar to the study by Moon *et al.*,<sup>23</sup> the clonus score in our study did not improve significantly during the study period. Unlike that study, however, our findings showed that ROM improved significantly compared to the baseline during the study period. The differences between the present study and the one by Moon *et al.* can be explained by the differences in treatment regimen: while the patients in our study received oral anti-spastic medications and stretching exercises in addition to ESWT, the patients in that study only received ESWT. Also,

presence of a control group was a superiority of the present study compared to the one by Moon *et al.*, and we showed that ESWT was significantly effective compared to the control group.

In a study by Radinmehr *et al.*,<sup>24</sup> 12 patients with stroke were randomly included and received one rESWT session on plantar flexor muscle. Unlike our study, their patients were assessed only in one group without controls, rESWT was done in one session with a different method, and the patients were followed only one hour after the intervention. In spite of the differences between the study by Radinmehr *et al.* and ours, both studies showed positive effects of ESWT in improving plantar flexor spasticity after intervention.

Similar to our findings, the three previous studies on stroke patients with upper limb spasticity reported immediate therapeutic effect of ESWT in reducing spasticity. Also, Manganotti *et al.*<sup>19</sup> showed significant effects of ESWT until 12 weeks after the treatment and Yoo *et al.*<sup>22</sup> showed significant effects of ESWT until four weeks after the treatment, which are similar to the results of the present study. In contrast, Bae *et al.*<sup>21</sup> reported that the effect of ESWT was not statistically significant one and four weeks after the treatment. The differences between findings may be explained by the differences in patients studied; while we included subjects with lower limb spasticity, Bae *et al.* studied patients with upper limb spasticity.

One of the strengths of the present study is comparing LEFS which was measured by lower extremity functional index. Lower extremity functional index is a practical patient-reported outcome measure to assess functional status in patients with lower limb conditions. We evaluate and compared LEFS to assess the effects of ESWT treatment on lower limb status in stroke patients with lower limb spasticity and we found that ESWT treatment significantly improved functional status in lower limb in these patients, whereas previous similar studies had not assessed this index.

In conclusion, despite the small number of patients which is a limitation of the present study, our findings revealed that spasticity, passive ROM and pain improved significantly immediately after the first ESWT treatment and during 12 weeks of follow-up compared to the control group. So, we conclude that because of the non-invasive nature of ESWT and its much fewer adverse effects, it can be a useful alternative for treating spasticity in stroke patients. Nevertheless, further studies are needed to clarify the mechanism of ESWT for reducing spasticity and unravel the appropriate doses and needed sessions to improve spasticity in stroke patients. These data may be used to prepare guidelines for recommendation of this approach as an appropriate alternative for treating spasticity in stroke patients.

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