

# Effectiveness of Radial Extracorporeal Shock Wave Therapy in Reduces Muscle Spasms in Stroke Patients; A Systematic Review and Meta-Analysis

Isam Ali Hameedi<sup>1\*</sup>, Azadeh Shadmehr<sup>1</sup>, Tahir Alsaadawi<sup>2</sup>

<sup>1</sup>Physical Therapy Department, School of Rehabilitation, Tehran University of Medical Sciences, Tehran, Iran.

<sup>2</sup>Imam Alsadeq Teaching Hospital, Ministry of Health, Babylon, Iraq.

\*Correspondence to: Isam Ali Hameedi (E-mail: isam\_jettar@yahoo.com)

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## Abstract

**Objectives:** Effectiveness of radial extracorporeal shock wave therapy (rESWT) on pain, range of motion and muscle tone in patients with stroke injuries.

**Methods:** PubMed, EMBASE, Cochrane Library and VIP information were used to collect information for research conducted between the beginning of 2013 and the end of 2022. These studies were randomized controlled trials that used rESWT for muscle spasm in stroke patients with conventional treatments as controls. There are no specific restrictions on the duration of treatment, the type of rESWT, or the severity of symptoms. These studies must have assessed at least one of the following outcome measurements: visual analog scale (VAS) for pain, Ashworth measure for muscle tone or external rotation range of motion (ER ROM). RevMan 5.3 software was used to check the quality of included studies. For continuous variables, mean difference (MD) or standardized MD (SMD) with CI 95% were derived. For dichotomous data, event proportions and sample sizes were extracted.

**Results:** In the conducted investigations, it was found that 7 studies investigated the effectiveness of rESWT treatments after the intervention in comparison with conventional treatment in terms of reducing pain intensity. In total, all 7 studies showed that the rESWT intervention was effective in reducing pain intensity compared to conventional treatments (MD, -0.97 [95% CI, -2.13 to -0.42],  $P < .00001$ ,  $I^2 = 71\%$ ). Compared with traditional treatments, the effectiveness of rESWT plus routine treatments on muscle tone after intervention was assessed in terms of Ashworth criterion in 4 trials (SMD, 1.13 [95% CI, 0.46–1.23],  $P < .00001$ ,  $I^2 = 59\%$ ). ER ROM was used to reflect the ROM, which was assessed in 4 RCTs. Because of the limited number of studies, ER ROM was measured immediately after treatment in all included studies. The pooled result of the included studies showed that the heterogeneity was high and unacceptable (MD, 10.31 [95% CI, 2.47–16.18],  $P < .003$ ,  $I^2 = 81\%$ ).

**Conclusion:** The results of this research indicated that rESWT treatment can be used as a safe and non-invasive method to quickly reduce spasticity and increase joint range of motion in stroke patients. But more research on the long-term effects of rESWT as well as the factors influencing its effectiveness to reduce spasticity and comparison with other new treatment protocols is suggested.

**Keywords:** rESWT, Pain, Range of Motion, Muscle Tone, Muscle Spasms, Stroke

## Introduction

Damage to the upper motor neuron causes certain clinical defects, including muscle relaxation immediately after the complication and spasticity in the later stages of the complication.<sup>1</sup> Spasticity is a common symptom in many neurological conditions, especially in stroke, cerebral palsy and multiple sclerosis.<sup>2-4</sup> According to Lance's definition, spasticity is an increase in muscle tone depending on speed, which is manifested by the intensification of tendon reflexes and is caused by an increase in the excitability of the stretch reflex.<sup>5</sup> The prevalence of spasticity is estimated in 38% of patients after stroke.<sup>6</sup> Normalizing muscle tone is a prerequisite for restoring functional ability. In order to reduce spasticity, various interventions such as drugs, surgical treatment and physiotherapy techniques are routinely used.<sup>7</sup>

Physiotherapy is the first step to treat spasticity and several methods are used to control it.<sup>8</sup> Today, one of the promising methods to reduce spasticity is Extracorporeal RESWT Therapy (ESWT), but it has not yet been used as a common treatment.<sup>9</sup> Some studies claim that ESWT can be used as a safe and non-invasive method to treat spasticity in patients with neurological disorders such as cerebral palsy, multiple sclerosis, and especially stroke patients.<sup>9-11</sup>

ESWT is sound pulses caused by transient and sudden pressure changes that spread rapidly in three-dimensional space. The characteristic feature of these pressure pulses is reaching the maximum intensity (about 100 megapascals) in a very short time (10 ns).<sup>12</sup> Initially, ESWT was used to treat kidney stones, but its use quickly spread to the treatment of orthopedic lesions such as non-union in long bones, plantar fascia inflammation, shoulder calcified tendonitis, tendon inflammatory diseases and spasticity.<sup>13</sup> Two types of ESWT are used, focal (fESWT) and radial (rESWT), whose production mechanism and penetration depth are different. fESWT are produced through electro-hydraulic and piezoelectric electromagnetism, while in rESWT, waves are created through pneumatics, also the penetration depth of rESWT is less than fESWT and its maximum intensity is at the contact surface of the applicator with the body. Another difference between these two types of ESWT is the conduction speed, shape and size of the pulses.<sup>14</sup>

So far, no exact mechanism has been presented to justify the effects of using ESWT in the treatment of spasticity. A group of studies believe that rESWT impulses can have a direct effect on fibrotic muscles and non-reflexive parts of spastic muscles. There are studies that state that the ESWT at the muscle level is able to change the sensory flow of the muscle,

which itself leads to a decrease in the excitability of the muscle at the level of the spinal cord and ultimately causes a decrease in spasticity. The study on non-human samples shows that ESWT can delay neuromuscular transmission at the neuromuscular junction, hence they are considered as possible mechanisms of ESWT effect in reducing muscle spasticity. Considering the necessity of treating spasticity in patients with neurological lesions, the aim of this study is to analyze the available clinical trial studies in relation to the effectiveness or side effects of using rESWT in the treatment of spasticity in stroke patients.

## Methods

### Search Strategy

The method of data collection in this research is a systematic search in PubMed, EMBASE, Cochrane Library and VIP databases from the beginning of 2013 to the end of 2022. Search keywords were “radial extracorporeal rESWT therapy,” “rESWT,” “Muscle hypertonicity,” “Stroke,” and “randomized controlled trial.” Different terms are used in this systematic search. Also, the list of output studies was reviewed and revised several times

### Inclusion Criteria

The inclusion criteria for the systematic study are as follows:

1. The study is RCTs.
2. Patients in these studies have spasticity after stroke.
3. The study group and the control group were treated with conventional treatments and rESWT and the results of the conventional treatment were the same in all of them.
4. There were no restrictions on treatment duration, type of reESWT or symptom severity and energy intensity depended on patient tolerance.
5. The language of the article is English
6. There is no specific restriction on adopting or not adopting a blind method.
7. The authors followed at least 1 of the Ashworth and modified Ashworth outcome indices Ashworth.

### Exclusion Criteria

The exclusion criteria were as follows:

1. The authors used at least 1 of the following outcome indices: Ashworth criterion (muscle tone), VAS (Pain), ER ROM (range of motion)

### Data Extraction

Two reviewers reviewed the abstract, study method and results completely separately and independently. Both of them extracted studies that met the defined criteria and in case of disagreement, a third reviewer was asked for an opinion. Also, 2 other reviewers independently extracted the following data:

First author, year of publication, sample size, details of intervention, follow-up (if applicable), time of measurement and outcome indicators.

The variables investigated in this study are muscle tone, range of motion and pain. Pain intensity was measured via VAS (the lower the score, the better the effectiveness). Joint ROM was measured through ER ROM (the higher the grade,

the better the treatment effect). The Ashworth scale was used to measure muscle tone (the lower the score, the better the effectiveness). Results at multiple follow-up times from the same study were included in subgroup analyzes by time point. When 2 studies used the same group of participants, 2 studies were included only if they used different measures.

### Bias Assessment and Quality Classification

To check the quality of the studies included in the present systematic review, the Cochrane Collaboration's tool for assessing the risk of bias in randomized trials<sup>20</sup> was used, using RevMan version 5.3 (Nordic Cochrane Centre, Cochrane Collaboration)

### Statistical Processing and Assessment of Heterogeneity

Statistical processing in this research was such that for continuous variables, mean difference (MD) or standardized MD (SMD) with 95% CI was calculated. For dichotomous data, we derived event proportions and sample sizes. For analysis, the two-sided *t* test was used and the significance level of  $P \leq 0.05$  was considered. Heterogeneity was evaluated by using the  $I^2$  statistic and the Cochran Q statistic with *P*-values.<sup>8</sup> The data were pooled using the random-effects model if significant heterogeneity was present ( $I^2 > 50\%$  or  $P_Q < 0.1$ ); otherwise, a fixed-effects model was used. In the case of significant heterogeneity, subgroup analyses were further conducted to investigate the potential source of heterogeneity on the treatment effect size.<sup>20</sup> The statistical software used was RevMan 5.3 software.

## Result

By using the keywords above, a total of 115 articles were found in the first stage of selection, after removing 52 unrelated articles and 56 duplicate articles, 7 articles remained. Among these articles, 11 articles were removed for the following reasons. (Figure 1, Table 1).

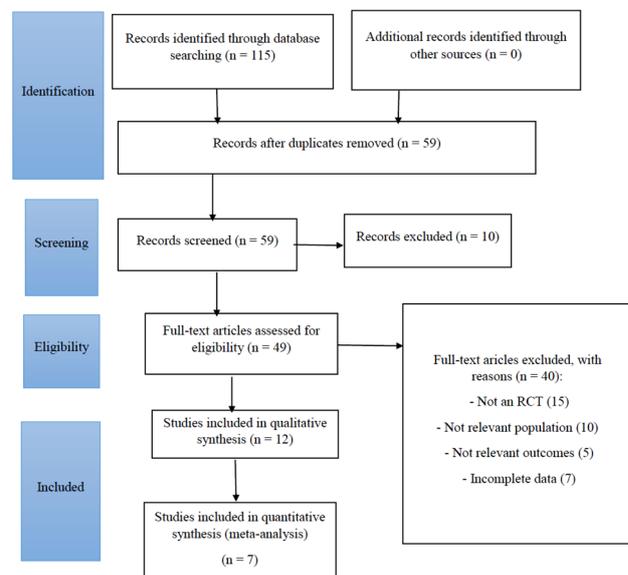


Fig. 1 Study flow diagram, rESWT; RCT, randomized controlled trial.

**Table 1. Studies related to the use of rESWT to reduce spasticity of lower limb muscles in stroke patients**

Author/year of publication	Type of study	Number of treatment sessions	Number of patients	Examined muscles	Number and intensity of pulses	Number of evaluation times	Result
Radinmehr et al. (2017) <sup>15</sup>	Clinical trial before and after	1	12	Gastrosoleus muscles	2000 pulses 0.340 mg/mm <sup>2</sup>	3	Reduction of spasticity
Kim et al. (2013) <sup>16</sup>	Clinical trial before and after	5	57	Subscapularis	3000 pulses 0.630 mg/mm <sup>2</sup>	11	Reduction of spasticity
Fouda et al. (2015) <sup>17</sup>	Clinical trial before and after	5	30	Wrist and finger flexors	1500 pulses 0.230 mg/mm <sup>2</sup>	Before and after treatment	Reduction of spasticity
Daliri et al. (2015) <sup>22</sup>	Clinical trial before and after	1	15	Flexor carpi Radialis	1500 pulses 0.030 mg/mm <sup>2</sup>	6	Reduction of spasticity
Dymarek et al. (2016) <sup>9</sup>	Clinical trial before and after	1	20	Flexor carpi Radialis	1500 pulses 0.030 mg/mm <sup>2</sup>	4	Reduction of spasticity
Wu et al. (2017) <sup>21</sup>	Clinical trial before and after	1	24	Flexor carpi Radialis	2000 pulses 0.340 mg/mm <sup>2</sup>	4	Reduction of spasticity
Fan et al. (2021) <sup>20</sup>	Clinical trial before and after	1	100	Flexor carpi Radialis	2000 pulses 0.340 mg/mm <sup>2</sup>	4	Reduction of spasticity

According to Table 1, only one study evaluated the method before and after the treatment, and the rest of the studies were conducted with the control group. In total, there were 258 participating patients in this research. In these 7 articles, muscle spasm of carpi radialis flexor (4 articles), gastrosoleus (1 article), subscapularis (1 article) and wrist and finger flexors (1 article) has been investigated.

## Methodological Quality and the Risk of Bias within Studies

In Figure 2, the bias diagram is shown in a summary form. Out of 7 studies, 5 studies have a good method to reduce bias. These studies have a low risk of selection bias, performance bias, diagnosis bias, attrition bias, reporting bias and other biases. One of the included studies<sup>13</sup> had a high risk of bias in the randomization design and one study was at risk of other biases.<sup>14</sup>

## Pain Intensity

In total, all 7 studies<sup>15-21</sup> showed that the rESWT intervention was effective in reducing pain intensity compared to conventional treatments (MD, -0.97 [95% CI, -2.13 to -0.42],  $P < .00001$ ,  $I^2 = 71\%$ ).

## Muscle Tone

In total, all 7 studies<sup>15-21</sup> showed that the rESWT intervention was effective in reducing pain intensity compared to conventional treatments in terms of ASHWERTH CRITERION in 4 trials<sup>15,17-19,20</sup> (SMD, 1.13 [95% CI, 0.46-1.23],  $P < .00001$ ,  $I^2 = 59\%$ ).

## Range of Motion

ER ROM was used to reflect the ROM, which was assessed in 4 RCTs.<sup>17,20</sup> Because of the limited number of studies, ER ROM

was measured immediately after treatment in all included studies. The pooled result of the included studies showed that the heterogeneity was high and unacceptable (MD, 10.31 [95% CI, 2.47-16.18],  $P < .003$ ,  $I^2 = 81\%$ ).

## Study Limitations

The limitation of this study was the short-term follow-up of the effectiveness of the treatment. The average follow-up time for effective treatment in the studies was four weeks. Considering that the meta-analysis was done on the findings before and immediately after the intervention, the findings of this study cannot confirm the long-term effectiveness of rESWT. Therefore, it is recommended that in the future, clinical trial studies with higher quality are designed that are carefully designed and especially examined in terms of the control group

## Discussion and Conclusion

The present meta-analysis study showed that the degree of anxiety scale decreases significantly immediately after the application of rESWT. Also, there is a significant increase in joint range of motion immediately after shock therapy. Investigating the use of rESWT to reduce spasticity in Fargani motor neuron lesion patients, especially stroke patients, is a new approach in the treatment of these patients. Considering the various advantages of rESWT, including the ease of use, being safe and non-invasive, and its relatively low cost compared to other spasticity treatment methods, including botulinum toxin injection, it seems that this method can be a suitable alternative to reduce spasticity in Stroke patients.

Also the results of the this study also indicated that immediately after applying the rESWT, the range of motion of the joint increases significantly, despite the fact that spasticity appears in the undamaged upper motor neuron, but secondary changes in the muscles of the peripheral nerves and joints occur after the occurrence of spasticity. And many

**A**

	Random Sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of outcome assessors reduces (detection bias) and personnel (performance bias)	Blinding of outcome assessors reduces (detection bias)	Incomplete outcome (data bias)	Selective reporting (reporting bias)	Other bias
Radinmehr et al. (2017)	+	+	+	+	+	+	+
Kim et al. (2013)	+	+	+	?	+	+	+
Fouda et al. (2015)	?	+	+	?	+	+	+
Daliri et al. (2015)	+	+	?	-	?	+	+
Dymarek et al. (2016)	+	?	?	+	+	+	-
Wu et al, (2017)	+	+	+	+	+	+	+
Fan et al. (2021)	+	+	?	+	?	?	+

**B**



Fig. 2 Risk of bias (A) table and (B) summary.

spasticity treatments are focused on improving these secondary changes.

The results of this review study showed that based on these studies, it is not possible to achieve a single agenda for the treatment of patients in terms of the number of treatment sessions, the intensity and the number of pulses, on the other hand, in none of the studies, there is no documented reason for choosing the number of sessions and the intensity of pulses. Due to the fact that applying at least 1500 pulses per day is necessary to induce the cellular effects of rESWT and applying 2500 pulses daily can cause tissue necrosis.

The results of this meta-analysis showed that rESWT therapy can be used as a safe and non-invasive method to quickly reduce spasticity and increase joint range of motion in stroke patients. More studies on the long-term effects of rESWT application, as well as factors influencing the effectiveness of rESWT therapy to reduce spasticity and comparing different treatment protocols are necessary in the future.

## Conflicts of Interest

None. ■

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