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The effectiveness of extracorporeal shock wave therapy to reduce lower limb spasticity in stroke patients: a systematic review and meta-analysis

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ABSTRACT

Objective: To assess the effectiveness of Extracorporeal Shock Wave Therapy (ESWT) to reduce lower limb spasticity in adult stroke survivors.

Data Sources: A systematic review of Medline/Pubmed, CENTRAL, CINAHL, PEDro database, REHABDATA, Scielo, Scopus, Web of Science, Trip Database, and Epistemonikos from 1980 to December 2018 was carried out.

Review Methods: The bibliography was screened to identify clinical trials (controlled and before-after) that used ESWT to reduce spasticity in stroke survivors. Two reviewers independently screened references, selected relevant studies, extracted data, and assessed risk of bias by PEDro scale. The primary outcome was spasticity.

Results: A total of 12 studies (278 participants) were included (5 randomized controlled trials, 1 controlled trial, and 6 before-after studies). A meta-analysis was performed by randomized controlled trials. A beneficial effect on spasticity was found. The mean difference (MD) was 0.58; 95% confidence interval (CI) 0.30 to 0.86 and also in subgroup analysis (short, medium, and long term). The MD for range of motion was 1.81; CI -0.20 to 3.82 and for lower limb function the standard mean difference (SMD) was 0.34; 95% CI -0.09 to 0.77. Sensitivity analysis demonstrated a better beneficial effect for myotendinous junction. MD was 1.5; 95% CI -2.44 to 5.44 at long-term (9 weeks).

Conclusion: The ESWT (radial/focused) would be a good non-invasive rehabilitation strategy in chronic stroke survivors to reduce lower limb spasticity, increase ankle range of motion, and improve lower limb function. It does not show any adverse events and it is a safe and effective method.

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Stroke; hemiparesis; hemiplegia; extracorporeal shock wave therapy; ESWT; spasticity; hypertonia

Introduction

Stroke often affects sensory-motor networks and descending tracts, as reflected by several signs of upper motor neuron syndrome.¹ One symptom is post-stroke spasticity, usually accompanied by one or more signs such as loss of selective motor control, weakness, and dexterity, as well as slowed movements, lack of coordination, and spastic co-contractions. Spasticity is due to an abnormal processing of a normal input from muscle spindles in the spinal cord.² It is often defined by a velocity-dependent increase in muscle tone and a resistance to passive muscle stretch. It has neural (increased reflex activity) and non-neural (altered visco-elastic properties due to immobilization) components.^{3,4} The prevalence ranges from 25% to 43% at 6 months post-stroke.³

Chronic spasticity can decrease the number of sarcomeres. As a result, the proportion of connective tissue in the muscle and fasciae can increase.⁵ These subjects present fibrosis that have augmented passive muscle stiffness due to structural and

functional adaptations inside the muscle cells.⁶ Soft tissue changes may cause the pulling forces to be transmitted more readily to the muscle spindles, which can intensify sensory input thus increasing spasticity.⁷ It has a potential impact on lower limb function,⁸ which affects passive muscle stretch, range of motion,⁹ and motor unit recruitment during voluntary contraction. In the stance phase of gait, the deformity also produces an inadequate base of support, which is associated with balance impairments. This increases the risk of falls, reduces patient participation in daily activities, and decreases health-related quality of life.¹⁰

Spasticity management includes invasive and non-invasive approaches (functional neurorehabilitation modalities).¹¹ One of the non-invasive treatments is extracorporeal shockwave therapy (ESWT). It consists of an acoustic pulse, with a high peak pressure and a short life cycle.¹² There are two types of ESWT, focused and radial. Focused can be produced by electrohydraulic, electromagnetic, and piezoelectric shock

wave generators. Radial is produced by a pneumatic device located inside the generator.¹³

Basic research has demonstrated the effectiveness of ESWT for tendon and other musculoskeletal disorders.¹⁴ It seems that the sonic impulse of ESWT acts on muscle spasticity differently from normal vibratory stimulation.¹⁵ Sonic impulse, in addition to the vibratory stimulus, can induce non-enzymatic and enzymatic nitric oxide synthesis that is involved in neuromuscular junction formation, neurotransmission, synaptic plasticity,¹⁶ and its retention.¹⁷

Recent reviews have evaluated the effectiveness of ESWT on stroke survivors^{16,18,19}; however, there are methodological deficiencies. In previous reviews,^{16,19} effects of ESWT on spasticity were based specifically on Modified Ashworth Scale (MAS score). Other direct or indirect measures of spasticity were not taken into account, such as composite spasticity score, tibial F_{\max}/M_{\max} ratio, H-reflex latency, and H-reflex recovery curve.²⁰ In addition, there is disagreement between studies on what type and characteristics of the ESWT are the best for spastic muscle, including energy dosage, shock wave generating and directing methods, and use or absence of anesthesia. Nowadays, there is insufficient evidence to recommend ESWT for reducing spasticity in post-stroke subjects. To date, except for botulin toxin on the upper limb, there are no scientific guidelines for the application of different therapies to improve spasticity.²¹ Therefore, the aim of this systematic review is to identify studies that used ESWT to reduce spasticity of adult stroke survivors. This review instead focuses specifically on the lower limb in order to identify the specific treatment parameters by means of optimal ESWT (dose) to reduce the consequences of spasticity in the clinical setting, as well as in the spasticity caused by a stroke (not by other neurological disorders).

Methods

An evidence-based systematic literature review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)²² and the Cochrane Handbook for Systematic Reviews²³ guidelines. The protocol was published on the PROSPERO International prospective register of systematic reviews website (reference number: no. CRD42018083921).

The search strategy was formulated using a PICO framework. (P) Adult patients with lower limb spasticity post-stroke, (I) receiving ESWT alone or with another physical approach, (C) compared with subjects receiving conventional physiotherapy, other approaches, sham approaches or none, (O) analyzed changes in spasticity compared with non-ESWT-treated subjects with or without follow-up. The studies were published in academic journals, dated from January 1980 to December 2018, treatment was applied to humans, and English, French, Italian, Portuguese, or Spanish languages were included. Comments, reviews, transverse studies, poster/oral communications, and practice guidelines were rejected.

Concerning the intervention, both kinds of ESWT (radial and focused) were included in this revision. Conventional physiotherapy is a set of techniques that are defined and

implemented according to the practices of each rehabilitation center. We defined it as the treatment involving any of the following elements to reduce spasticity (stretching and range of motion exercises, orthosis, weight bearing and balancing exercise, gait-training exercises, walking, and functional training). The template for intervention description and the replication checklist was used for the intervention report.²⁴

The primary outcome of this review was spasticity, although additional measures were also taken that should be measured before and at any time following ESWT intervention. We grouped the outcome measures into three categories, classified by the time the ESWT intervention was finished: short-term (the same day of the last session), medium-term (less than 4 weeks after the last session) and long-term (more than 4 weeks after the last session).

A computerized search strategy was performed in the following databases: Medline/Pubmed, Cochrane Central Register of Controlled Trials, Physiotherapy Evidence Database (PEDro), Scielo, Trip Database, Web of Science, SCOPUS, CINHALL, Rehabdata and Epistemonikos. In addition, a manual search was performed in Google Scholar (see [Appendix](#)).

Assessment of paper eligibility and data extraction were independently performed by two authors (AG and RC) and any disagreement was evaluated by a third author (JC). Refworks Proquest discharged duplicate articles, and the remaining studies were analyzed for its appropriateness. Selection was based first on title or abstract, and later on full text publications. They were thoroughly checked to confirm the selection criteria. The following data were extracted: (1) general characteristics of study design, (2) patient characteristics, (3) intervention features, targeted muscle, point of application, and ESWT parameters, (4) outcome measures and assessment. Furthermore, in studies where the information was provided conventional physical therapy intervention was also collected.

Risk of bias assessment of the studies was assessed by two authors (RC and PS) using the PEDro scale.²⁵ In case of doubt or disagreement, a discussion was held between three reviewers until a consensus was reached. The ultimate score was divided into three sections²⁶; high quality (score 6–10), fair quality (score 4–5), and poor quality (score ≤ 3). Furthermore, a Funnel plot was used for assessing publication bias.

Treatment effect sizes were calculated using Revman 5.3²³ software based on mean scores and standard deviations from the randomized studies. When variables were continuous and in the same units, a mean difference (MD) was used. A standardized MD was used if the same construct was measured using different instruments. A random-effects model to conduct meta-analyses and analyzed data were used. As studies were small in size, this mean change from baseline was used when available to allow for a more accurate comparison between control and intervention. The effect size was categorized as 0.2, 0.5, 0.8, and 1.3, considered as small, medium, large and very large, respectively.²⁷ Heterogeneity across studies was tested using the I_2 test, I_2 score $>50\%$ indicated significant heterogeneity. Missing data were first requested by contacting the corresponding author.

A sensitivity analysis was performed when it was possible. In this manner, subgroup analyses were performed in relation to: time of assessment (short, medium, and long term), point of ESWT application, and number of sessions.

Results

The PRISMA diagram (see Figure 1) summarizes the results of the scientific literature search. Finally 12 studies were selected: 5 randomized controlled trials Tirbisch *et al.*, 2015; Taheri *et al.*, 2017; Wu *et al.*, 2018; Yoon *et al.*, 2017; Lee *et al.*, 2018,²⁸⁻³² 1 controlled trial Sawan *et al.*, 2017,³³ and 6 (before-after) studies Rastgoo *et al.*, 2016, Moon *et al.*, 2013; Santamato *et al.*, 2014; Kim *et al.*, 2015; Randinmehr *et al.*, 2017, Sohn *et al.*, 2011.³⁴⁻³⁹ Table 1 provides an overview of the studies included and patient characteristics. Only two authors responded when contacted to get additional information (especially that necessary for the completion of the meta-analysis).

The total population studied included 278 patients, of which 93 individuals were female. Of those patients, 141 participants suffered an ischemic stroke and 71 hemorrhagic. Two studies did not report this information.^{31,38} The mean age of participants ranged from 44.8 to 66.9 years (10 healthy people were excluded³⁹), there were 118 patients with hemiparesis of the left side and 134 of the right. Several authors

did not reported it.^{29,31,33,36,39} Only two studies^{28,39} reported stroke area. According to Royal Dutch Society for Physical Therapy clinical practice guideline,⁴⁰ patients were in chronic phase (>6 months) in 10 studies, in subacute phase (<3 months)³⁵ in 1 study, and in late phase (between 3 and 6 months) in another study.²⁸

The mean PEDro score assessing risk of bias was 4.9 points from 10 (see Table 2), indicating a fair risk. Nevertheless, three studies were highlighted with 8 points. Funnel plot was symmetrical, so the risk of publication bias is low (see Figure 2). All studies excluded patients with fixed muscle contractures >4 MAS score,⁴¹ and included patients with muscles spasticity ≥ 1 . In relation to other criteria such as gait ability, botulinum toxin treatment, and antispastic medication there were differences between studies (see Table 3).

Relating to ESWT type, six studies used focused^{29,31,33,35,36,39} and five used radial^{28,32,34,37,38}; and Wu³⁰ compared both. Eight studies performed conventional physiotherapy in addition to ESWT^{28-33,35,37} (see Table 4). The parameters of ESTW intervention differed between studies. The frequency oscillated between 2 and 10 Hz, being 4/5 Hz the most used. Two studies^{33,39} did not report it. The pressure energy levels oscillate between 0.03 and 0.340 mJ/mm², which corresponds to a high-energy level according to the classification of Rompe.⁴² The number of shots ranged from 1.500 to 2.000, being 1500 shots the most used.^{29-31,33,35,36,39} Targeted muscle was triceps surae

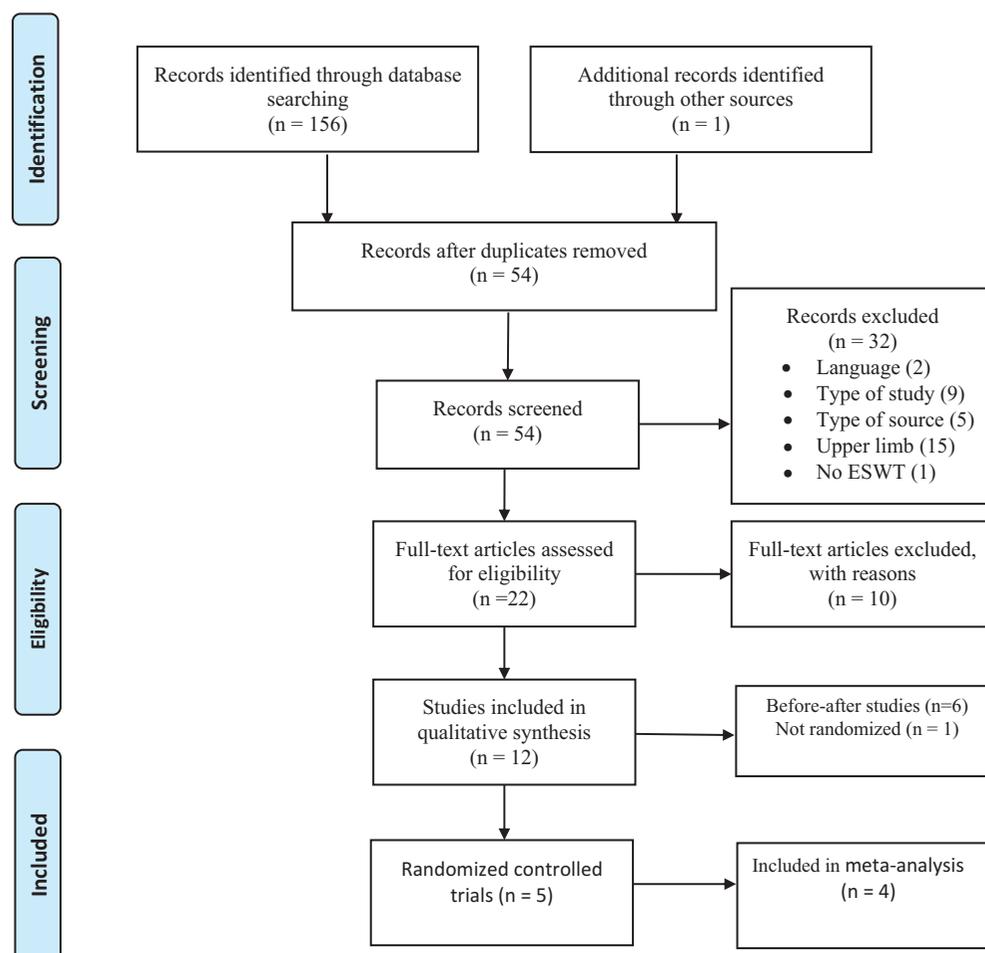


Figure 1. PRISMA diagram of the process used to identify studies.

Table 1. General overview of selected studies and patient characteristics.

Study	Type	N	Groups (n)	Intervention	Age (years), mean (SD)	Gender (male/female)	Type of stroke (ischemic/hemorrhagic)	Patient characteristics		
								Time since onset, mean (SD)	Affected side (right/left)	Affected area
RCTs										
Tirbisch <i>et al.</i> , 2015 (France) (27)	RCT	8	CG (4) EG (4)	CP rESWT + CP	61.2 (11.12) 49.5 (8.74)	2/2 1/3	3/1 3/1	3.43 (1.63) months 3.97 (0.83) months	3/1 3/1	3 Sylvian 1 Capsule-lenticular
Taheri <i>et al.</i> , 2017 (Iran) (28)	RCT	25	CG (12) EG (13)	CP fESWT + CP	54.9 (9.4) 56.5 (11.6)	8/4 9/4	11/1 11/2	25.8 (9.9) months 33 (21.4) months	not reported	not reported
Wu <i>et al.</i> , 2017 (Taiwan) (29)	RCT	31	rESWT (16) fESWT (15)	rESWT + CP fESWT + CP	59.6 (11.3) 60.3 (9.9)	9/7 9/6	10/6 10/5	55.7 (26.1) months 53.2 (26.7) months	9/7 7/8	not reported
Yoon <i>et al.</i> , 2017 (Korea) (30)	RCT	44	CG (18) fESWT belly (13) fESWT MTJ (13)	CP + sham ESWT fESWT belly + CP fESWT junction + CP	59.5 (16.9) 61.0 (12.2) 66.9 (4.9)	16/2 13/0 13/0	Not reported	38.7 (30.2) months 99.1 (85.1) months 51.1 (36.0) months	not reported	not reported
Lee <i>et al.</i> , 2018 (Korea) (31)	RCT	18	CG (9) EG (9)	CP + sham ESWT CP + ESWT	44.11 (4.07) 50.89 (8.81)	9/0 7/2	2/7 4/5	10.44 (9.11) months 12.89 (8.99) months	5/4 6/3	not reported
Non RCTs										
Sohn <i>et al.</i> , 2011 (Korea) (38)	trial (before-after)	20	CG (10)* EG (10)	fESWT fESWT	25.8 (3.1) 44.9 (11.3)	4/6 6/4	– 2/8	– 53.4 (23.9) months	– Not reported	2 cortical, 3 thalamic, 5 basal ganglia
Moon <i>et al.</i> , 2013 (Korea) (34)	trial (before-after)	30	EG (30)	fESWT + CP	52.6 (14.9)	17/13	16/14	2.7 (1.6) months	12/18	not reported
Santamoto <i>et al.</i> , 2014 (Italy) (35)	trial (before-after)	23	EG (23)	fESWT	57.6 (10.8)	15/8	12/11	24.9 (11.9) months	not reported	not reported
Kim <i>et al.</i> , 2015 (Korea) (36)	trial (before-after)	10	EG (10)	rESWT + CP	64.10 (4.01)	5/5	5/5	17.60 (2.36) months	5/5	not reported
Ratsgoon <i>et al.</i> , 2016 (Iran) (33)	trial (before-after)	17	EG (17)	rESWT	52.1 (11.1)	14/3	12/5	17.1 (6.9) months	4/13	not reported
Radinmehr <i>et al.</i> , 2017 (Iran) (37)	trial (before-after)	12	EG (12)	rESWT	59 (13)	7/5	Not reported	34.3 (20.6) months	5/7	not reported
Sawan <i>et al.</i> , 2017 (Egypt) (32)	Controlled trial (not randomized)	40	CG (20) EG (20)	CP + sham ESWT CP + ESWT	44.8 (5.9) 50.6 (6.7)	22/18	40/0	Range 6–18 months	not reported	not reported

CG, control group; EG, experimental group; fESWT, focused extracorporeal shockwave therapy; MTJ, miotendinous junction; CP, conventional physical therapy; RCTs, randomized controlled trials; rESWT, radial extracorporeal shockwave therapy; SD, standard deviation.

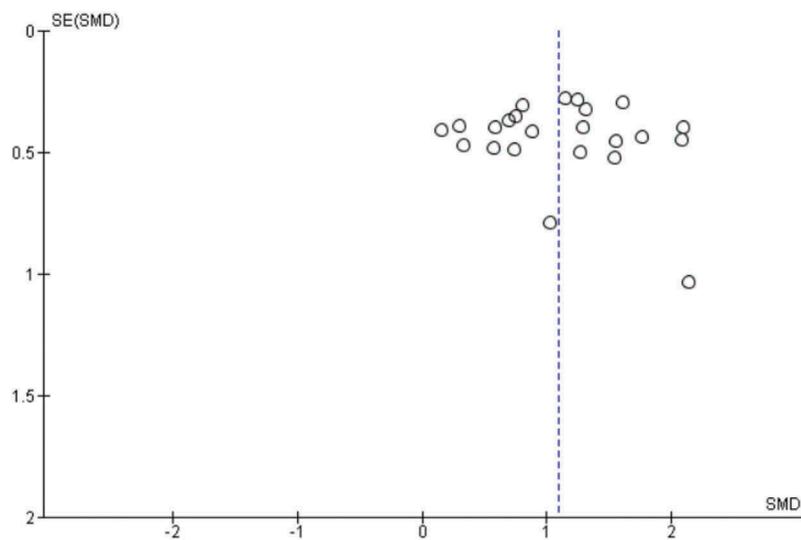
*Healthy participants.

Table 2. Risk of bias assessment of selected studies by PEDro scale (25).

Items	Sohn <i>et al.</i> , 2011	Moon <i>et al.</i> , 2013	Santamato <i>et al.</i> , 2014	Tirbish <i>et al.</i> , 2015	Kim <i>et al.</i> , 2015	Ratsgoo <i>et al.</i> , 2016	Taheri <i>et al.</i> , 2017	Wu <i>et al.</i> , 2017	Yoon <i>et al.</i> , 2017	Radinmehr <i>et al.</i> , 2017	Sawan <i>et al.</i> , 2017	Lee <i>et al.</i> , 2018
Eligibility criteria were specified ^a	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Random allocation	no	no	no	yes	no	no	yes	yes	yes	yes	no	yes
Concealed allocation	no	no	no	yes	no	no	yes	yes	no	no	no	yes
Baseline comparability	no	no	no	yes	no	no	yes	yes	yes	yes	yes	yes
Blind subjects	no	no	no	no	no	no	no	yes	no	no	no	yes
Blind Therapists	no	no	no	no	no	no	no	no	no	no	no	no
Blind assessors	no	no	no	yes	no	no	no	yes	no	yes	no	yes
Adequate follow-up ^b	yes	yes	yes	yes	yes	yes	yes	yes	yes	no	yes	yes
Intention- to treat analysis	yes	yes	no	yes	yes	yes	no	no	no	no	yes	no
Between groups comparisons	no	no	no	yes	no	no	yes	yes	yes	yes	yes	yes
Point estimates and variability	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
PEDro score	3	3	3	8	3	3	6	8	5	5	5	8

^a This criterion influences external validity, but not the internal or statistical validity of the trial. This item is not used to calculate the PEDro score

^b Defined an adequate follow-up as less than 15% drop-outs. The PEDro score mean is 4.9 points

**Figure 2.** Funnel plot of all studies.

for all studies except one³¹ in which the semitendinosus muscle was targeted. With reference to application point, seven studies applied ESWT on muscle belly, three of them applied on the myotendinous junction,^{28,29,35} Yoon³¹ compared both, and one applied³⁷ on the plantar fascia. Number of ESWT sessions oscillate between one single session or ≥ 3 sessions. Frequency was principally 1 session/week, and duration of treatment ranged from 1 to 3 weeks, with only one study that lasted 6 weeks. The total number of sessions of ESWT was wide, ranging from 1 to 9 (see Table 5).

The primary outcome was spasticity. It was assessed clinically and electro-physiologically. The secondary outcomes were related to muscle architecture, range of motion, gait (ability/speed), clonus, pain, and lower limb functionality. Considering evaluation-time, it ranged from immediately or one hour after last session^{28,29,32,36,38,39} to 6 months (see Table 6).

In relation to clinical assessment of spasticity, 10 studies used MAS,⁴³ three studies used Tardieu Scale,⁴⁴ and others recorded self-reported spasticity by the Visual Analogue Scale (see Table 7). Four studies measured spasticity electrophysiological by H-reflex

latency⁴⁵ and their parameters of H_{\max}/M_{\max} ratio (0.5–1 ms). The amplitude of the H-reflex indicates the degree of excitation and inhibition of the spinal cord motor neurons.⁴⁶ H-reflex latency is usually decreased and H_{\max}/M_{\max} ratio is increased⁴⁷ in patients with spasticity. It was obtained by stimulating the tibial nerve on popliteal fossa eliciting a reflex response in the triceps surae muscle and recording the resulting reflex compound muscle-action potential using an electromyography electrode (see Table 8).

Range of motion was measured in eight studies^{28–30,33–36,38} by a goniometer (digital or manually) although there were differences in the measures reported in relation to: active/passive movement, total/dorsiflexion range, and the knee position as it influences soleus or gastrocnemius extensibility (see Table 9). Peak torques and torque threshold angles were measured by dynamometry in two studies.^{35,38} In relation to muscle architecture, such as fiber and fascicle length, perimeters, and fiber angles, three studies^{32,34,36} assessed them mainly by ultrasonography (echography). This method uses high-frequency sound waves to image internal body structures or objects, and currents

Table 3. Inclusion criteria.

Study	Inclusion criteria		
	Stroke phase	Clinical	Other criteria
RCTs			
Tirbisch <i>et al.</i> , 2015 (France)	Subacute/late (≤6 months)	Ankle plantar flexor muscles spasticity MAS ≥ 1+	≥18 years
Taheri <i>et al.</i> , 2017 (Iran)	Chronic (> 6 months)	Ankle plantar flexor muscles spasticity MAS >1+	Ability to walk 10 m
Wu <i>et al.</i> , 2017 (Taiwan)	Chronic (> 6 months)	Ankle plantar flexor muscles spasticity MAS >1+	≥18 years ability to walk alone, with or without an orthosis
Yoon <i>et al.</i> , 2017 (Korea)	Chronic (> 6 months)	Semitendinous muscle spasticity MAS > 1+	–
Lee <i>et al.</i> , 2018 (Korea)	(≥ 3 months)	Ankle plantar flexor muscle spasticity MAS > 1	–
Non RCTs			
Sohn <i>et al.</i> , 2011 (Korea)	Chronic (> 6 months)	Ankle plantar flexor muscles spasticity MAS >1	–
Moon <i>et al.</i> , 2013 (Korea)	Subacute/late (≤6 months)	Ankle plantar flexor muscles spasticity MAS >1+	18–80 years' old stroke at least one month prior to the study
Santamato <i>et al.</i> , 2014 (Italy)	Chronic (> 6 months)	Ankle plantar flexor muscles spasticity MAS >1	> 18 years
Kim <i>et al.</i> , 2015 (Korea)	Chronic (> 6 months to 2 years)	Ankle plantar flexor muscles spasticity MAS ≥1	Ability to walk independently plantar fasciitis (ultrasound plantar fascia thickness > 4 mm from the standard point of the calcaneus rim)
Ratsgoo <i>et al.</i> , 2016 (Iran)	Chronic (> 6 months)	Ankle plantar flexor muscles spasticity MMAS ≥ 1	≥ 18 years ability to walk independently (with or without walking aids)
Radinmehr <i>et al.</i> , 2017 (Iran)	(> 1 month)	Ankle plantar flexor muscles spasticity MMAS ≥1	Ability to walk independently taking no antispastic medication
Sawan <i>et al.</i> , 2017 (Egypt)	Chronic (> 6 months)	Ankle plantar flexor muscles spasticity MAS 1–2	Medically and physiologically stable

MAS, Modified Ashworth Scale; RCTs, randomized controlled trials.

that are underwater. Other studies also measured foot contact area³⁰ and tension of the medialis gastrocnemius,³⁷ evaluated by a myotonometer⁴⁸ (see Table 10).

Motor function of lower limb was measured in three studies. Two of them^{32,35} were evaluated by the Fugl-Meyer Assessment Scale (lower-limb section),⁴⁹ and other one²⁹ by the Lower Extremity Functional Scale.⁵⁰ Five studies assessed gait by different tools, two of them^{30,33} used 10-m walk test,⁵¹ one²⁹ used 3-m walk test,⁵² one used³⁷ the Functional Gait Assessment,⁵³ and another one³⁴ by the Timed Up and Go Test.⁵⁴ Furthermore, pain and adverse effects were assessed in three studies by the visual analogue scale⁵⁵ (see Table 11). Regarding clonus, only two studies^{29,35} assessed it (see Table 12). In addition, only two studies assessed pain^{29,37} and five studies reported on possible adverse effects^{28,30,36,38,39} (see Tables 13 and 14).

Effects of extracorporeal shock waves therapy (ESWT)

Concerning the effect on spasticity, a first forest plot comparing before and after ESWT was possible for all studies, showing a positive effect that favors ESWT intervention (see Figure 3). Secondly, a comparison was performed between ESWT plus conventional physiotherapy (CP) versus CP alone by spasticity (MAS) in four randomized studies^{28,29,31,32} (see Figure 4), favoring the addition of ESWT to CP to reduce MAS score. The sham performed in two of these studies was not taken into account since it was shown that the placebo in ESWT does not seem to have any effect.³⁵ The MD by short-term assessment was 0.48; 95% confidence interval (CI) 0.10 to 0.85; by medium-term was MD 0.77, 95% CI 0.18 to 1.36

and by long term MD 0.66, 95% CI 0.06 to 1.08 to 1.26. The total MD effect was 0.58, 95% CI 0.30 to 0.86. There were statistically significant differences for the H-reflex latency (immediate evaluation) by Randimehr³⁸ and $H_{max} M_{max}$ ratio by Sawan.³³ There were statistically significant differences for ultrasonographic evaluation in two studies.^{32,36}

Regarding range of motion, five studies had significant differences favoring ESWT. Three studies^{28,29,32} were meta-analyzed (see Figure 5) and had positive effects at short, medium and long term. Wu³⁰ compared radial vs focused ESWT with significant differences favoring radial ESWT for this variable.

Three studies evaluated the lower limb function, and two of them^{29,32} were meta-analyzed (see Figure 6) showing a greater beneficial effect for ESWT. Six studies evaluated gait (ability/speed), but a meta-analysis was not possible although in five of them ESWT had positive effects.^{29,33,34,37} Two sensitivity analyses were carried out for number of ESWT sessions (see Figure 7) and application point of ESWT (see Figure 8).

Peak eccentric torque and torque threshold angle, were analyzed by Moon³⁵ at the velocities of 60, 180, and 240°/s, and they were better immediately after ESWT treatment.

Discussion

The evidence base for extracorporeal shock wave therapy in stroke survivors is continuing to grow and would be another way to reduce spasticity. Specific aspects, however, are still largely under-explored and little is known about the delivery of shock wave interventions. For this reason, 7 nonrandomized studies were included from 12 studies that passed the filtering criteria of this review. This gives a more global and

Table 4. Interventions.

Study	Comparison		Conventional Physical Therapy	Pharmacological Therapy
	CONTROL GROUP	EXPERIMENTAL GROUP		
RCTs				
Tirbisch <i>et al.</i> , 2015	CP	rESWT +CP	Techniques of verticalization, active movements of neurodevelopmental type, stretching and posture techniques and cryotherapy (1 h/day; 5 days/week; 3 weeks)	It was an exclusion criteria a change in anti-spastic drug dose or treatment
Taheri <i>et al.</i> , 2017	CP	fESWT+ CP	Stretching exercises (30 min/day; 5 days/week; 12 weeks)	Oral antispastic medication: 2 mg/day of tizanidine hydrochloride during 4 days and 4 mg/day until the end of treatment
Wu <i>et al.</i> , 2017	rESWT + CP	fESWT + CP	Rehabilitation program of the target area remained unchanged from 2 months prior to participation to the end of the follow-up period	Regimens and dosages of anti-spasticity medication were not adjusted and remained unchanged
Yoon <i>et al.</i> , 2017	CP + sham ESWT	fESWT belly + CP	Physical therapy for spasticity received by the patients was noted and the notes were maintained throughout the study.	Anti-spasticity medication was noted and the notes were maintained throughout the study.
Lee <i>et al.</i> , 2018	CP + sham ESWT	rESWT + CP	Physical therapy and range of motion exercises	Antispastic pharmacological therapy did not change the dose during study
Non RCTs				
Sohn <i>et al.</i> , 2011	fESWT (healthy adults)	fESWT (stroke patients)	No	Antispastic pharmacological therapy did not change the dose during study
Moon <i>et al.</i> , 2013	no	fESWT + CP	ROM exercises, stretching and physical therapy	Medication for spasticity was not changed
Santamato <i>et al.</i> , 2014	no	fESWT	No physiotherapy treatment was performed after ESWT	Exclusion criteria was the use medications that could have an impact on study findings (ex. previous botulinum toxin injection into the affected leg muscles or any intensive rehabilitative treatment in the 5 months before recruitment or treatment with GABAergic medications, benzodiazepines, or muscle relaxants).
Kim <i>et al.</i> , 2015	no	rESWT	Stretching exercises of the plantar fascia and Achilles tendon were executed for 6 months starting from the last day of ESWT intervention	Not reported
Ratsgoo <i>et al.</i> , 2016	no	rESWT	No	It was an exclusion criteria the use of anti-spastic drugs, or local injection of botulinum toxin type A in the past 3 months.
Radinmehr <i>et al.</i> , 2016	No	rESWT	No	It was an inclusion criteria not to take antispastic medication
Sawan <i>et al.</i> , 2017	CP + sham ESWT	fESWT + CP	Ankle-foot orthosis, stretching, ROM, weight bearing and balancing exercises, gait training exercise walking, and functional training (1 h/day; 3 days/week; 6 weeks)	Not reported

fESWT, focused extracorporeal shockwave therapy; MTJ, miotendinous junction; CP, conventional physical therapy; RCTs, randomized controlled trials; rESWT, radial extracorporeal shockwave therapy; ROM, range of motion.

Table 5. Extracorporeal shock wave therapy (ESWT) settings.

Study	Type of ESW			Parameters of ESW intervention				Application		Period of ESW treatment (sessions/week; weeks)
	Generator head	Source	Manufacturer	Number of pulses or shots/muscle	EFD or Pressure	Frequency (Hz)	Involved muscles	Point of application	no. sessions (sessions/week; weeks)	
RCTs										
Tirbisch <i>et al.</i> , 2015	Radial	Pneumatic	Swiss Dolor Clast (EMS, Switzerland)	2000	0,03 mJ/mm ² 2,5 bars	10 Hz	G	Myotendinous junction	nine sessions (three sessions/week; 3 weeks)	
Taheri <i>et al.</i> , 2017	Focused	EM	Dornier AR2 machine (Dornier MedTech GmbH, Germany)	1500	0,10 mJ/mm ²	4 Hz	MG LG	Myotendinous junction	Three sessions (1 session/week; 3 weeks)	
Wu <i>et al.</i> , 2017	Focused Radial	EM Pneumatic	Duolith SD1 (Storz Medical, Switzerland)	1500	0,10 mJ/mm ² 2,0 bar	5 Hz	G S	Muscle belly	Three sessions (1 session/week; 3 weeks)	
Yoon <i>et al.</i> , 2017	Focused	EM	Dornier Aries; (Dornier MedTech, Germany)	1500	0,0–68–0,093 mJ/mm ²	5 Hz	ST	Muscle belly Myotendinous junction	Three sessions (1 session/week; 3 weeks)	
Lee <i>et al.</i> , 2018	Radial	Pneumatic	Dornier Aries; (Dornier MedTech, Germany)	2000	0.1 mJ/mm ²	4 Hz	MG	Not reported	1 session	
Non RCTs										
Sohn <i>et al.</i> , 2011	Focused	EH	HMC EVOTRON (SwiTech, Switzerland)	1500	0.1 mJ/mm ²	Not reported	MG	Muscle belly	1 session	
Moon <i>et al.</i> , 2013	Focused	PE	PiezoWave (Richard Wolf GmbH, Germany)	1500	0.089 mJ/mm ²	4 Hz	MG LG	Myotendinous junction	3 sessions (1 session/week; 3 weeks)	
Santamato <i>et al.</i> , 2014	Focused	EH	EvoTRON RFL03000 (Sanuwave AG, Switzerland)	1500	0.10 mJ/mm ²	2 Hz	MG LG S	Muscle belly	1 session	
Kim <i>et al.</i> , 2015	Radial	Pneumatic	Shock Master 500 (APSUN Inc., Gymna Uniphy, Belgium)	1500	0,089 mJ/mm ²	4 Hz	PF	Not reported	3 sessions (1 session/week; 3 weeks)	
Ratsgoo <i>et al.</i> , 2016	Radial	Pneumatic	(BTL Industries Ltd, United Kingdom)	2000	1,5 bars	5 Hz	MG LG S	Muscle belly	1 session	
Radinmehr <i>et al.</i> , 2016	Radial	Pneumatic	3n Plus Version 2.0 (Zimmer Medizin System, Germany)	2000	0,340 mJ/mm ² 60 mJ (1 bar)	5 Hz	AT G	Muscle belly	1 session	
Sawan <i>et al.</i> , 2017	Focused	not reported	Not reported	1500	Not reported	Not reported	MG	Muscle belly	6 sessions (1 session/week; 6 weeks)	

AT, Achilles tendon; EFD, energy flux density; EM, electromagnetic; EH, electrohydraulic; G, gastrocnemius; LG, lateral head of the gastrocnemius; MG, medial head of the gastrocnemius; PE, piezoelectric; PF, plantar fascia; S, soleus; ST, semitendinosus; RCTs, randomized controlled trials.

Table 6. Assessment characteristics.

Study	Outcome	Tool	Evaluation	Variables	Period
RCTs					
Tirbisch <i>et al.</i> , 2015	Spasticity Range of motion	MAS Tardieu Scale	MAS score for soleus and for gastrocnemius Y angle X score pROM extensibility MAS score for gastrocnemius VAS score pROM Clonus score 3-m walk duration (s) LEFS index MAS score for gastrocnemius Tardieu angle pROM Mean dynamic plantar contact area (cm ²) Gait speed (m/s) MAS grade or score Modified Tardieu Score	MAS score for soleus and for gastrocnemius Y angle X score pROM extensibility MAS score for gastrocnemius VAS score pROM Clonus score 3-m walk duration (s) LEFS index MAS score for gastrocnemius Tardieu angle pROM Mean dynamic plantar contact area (cm ²) Gait speed (m/s) MAS grade or score Modified Tardieu Score	T0 baseline T1 (after session 1) T2 (end of treatment/week 3)
Taheri <i>et al.</i> , 2017	Spasticity Pain Range of motion Clonus Gait ability Lower limb motor function Spasticity	MAS VAS Goniometer Clonus scale 3-m walk test LEFS MAS Tardieu Scale Hand-held goniometer Tekscan platform (Boston, USA) 10-m walk test MAS Modified Tardieu Scale	MAS score for soleus and for gastrocnemius Y angle X score pROM extensibility MAS score for gastrocnemius VAS score pROM Clonus score 3-m walk duration (s) LEFS index MAS score for gastrocnemius Tardieu angle pROM Mean dynamic plantar contact area (cm ²) Gait speed (m/s) MAS grade or score Modified Tardieu Score	T0 T1 (after session 1/week 1) T2 (end of treatment/week 3) T3 (9 weeks post-treatment)	
Wu <i>et al.</i> , 2017	Range of motion Dynamic foot contact area Gait ability Spasticity	Hand-held goniometer Tekscan platform (Boston, USA) 10-m walk test MAS Modified Tardieu Scale	MAS score for soleus and for gastrocnemius Y angle X score pROM extensibility MAS score for gastrocnemius VAS score pROM Clonus score 3-m walk duration (s) LEFS index MAS score for gastrocnemius Tardieu angle pROM Mean dynamic plantar contact area (cm ²) Gait speed (m/s) MAS grade or score Modified Tardieu Score	T0 T1 (1 week post-treatment) T2 (4 weeks post-treatment) T3 (8 weeks post-treatment)	
Yoon <i>et al.</i> , 2017	Spasticity Range of motion Lower limb motor function Muscle architecture	MAS Goniometer FMA scale Ultrasonographic measurement	MAS score pROM FMA scale: lower limb section ATL MFL MT PA	T0 T1 (after session 1/week 1) T2 (after session 2/week 2) T3 (end of treatment/week 3) T0 _{T1} (30 min after single session) T2 (1 week post-treatment) T3 (4 weeks post-treatment)	
Lee <i>et al.</i> , 2018	Spasticity Range of motion Lower limb motor function Muscle architecture	MAS Goniometer FMA scale Ultrasonographic measurement	MAS score pROM FMA scale: lower limb section ATL MFL MT PA	T0 T1 (after session 1/week 1) T2 (after session 2/week 2) T3 (end of treatment/week 3) T0 _{T1} (30 min after single session) T2 (1 week post-treatment) T3 (4 weeks post-treatment)	
Non RCTs					
Sohn <i>et al.</i> , 2011	Electrophysiological effects	Medelec Synergy (Viasys healthcare, USA)	F-wave min. Latency (ms) H-reflex latency (ms) H-M ratio Tibial nerve conduction velocity (m/s) CMAP latency (ms) CMAP amplitude (mV) MAS score VAS score MAS score CS pROM PET (Nm) ITAs at 60, 180, and 240°/s	F-wave min. Latency (ms) H-reflex latency (ms) H-M ratio Tibial nerve conduction velocity (m/s) CMAP latency (ms) CMAP amplitude (mV) MAS score VAS score MAS score CS pROM PET (Nm) ITAs at 60, 180, and 240°/s	T0 T1 (immediately after single session)
Moon <i>et al.</i> , 2013	Spasticity Pain Spasticity Clonus Range of motion Biomechanical effects	MAS VAS MAS Clonus scale Goniometer Isokinetic dynamometer Biodex system 4 (Biodex Medical System, USA) FMA scale MAS Goniometer Ultrasonographic measurement Linear transducer (MyLab 70X Vision, Esaote) Not reported	F-wave min. Latency (ms) H-reflex latency (ms) H-M ratio Tibial nerve conduction velocity (m/s) CMAP latency (ms) CMAP amplitude (mV) MAS score VAS score MAS score CS pROM PET (Nm) ITAs at 60, 180, and 240°/s	T0 T1 sham T2 (end of treatment /week 3) T3 (1 week post-treatment) T4 (4 weeks post-treatment)	
Santamato <i>et al.</i> , 2014	Motor function Spasticity Ankle movement Muscle properties Electrophysiological effects	FMA lower limb MAS score pADFM Echo intensity (Heckmatt grades) F-wave min. Latency (ms) Tibial nerve conduction velocity (m/s) CMAP latency (ms) CMAP amplitude (mV)	F-wave min. Latency (ms) H-reflex latency (ms) H-M ratio Tibial nerve conduction velocity (m/s) CMAP latency (ms) CMAP amplitude (mV) MAS score VAS score MAS score CS pROM PET (Nm) ITAs at 60, 180, and 240°/s	T0 T1 (immediately after single session) T2 (4 weeks post-treatment) T0 T1 (4 weeks post-treatment)	

(Continued)

Table 6. (Continued).

Study	Evaluation			Period
	Outcome	Tool	Variables	
Kim <i>et al.</i> , 2015	Plantar fascia thickness	US imaging system (Accuvix V10, Samsung Medison)	Plantar fascia thickness	T ₀
	Spasticity	Myotonometer (Neurogenic Technologies Inc.)	Tension (displacement) of medial gastrocnemius (mm)	T ₁ (6 weeks post-treatment) T ₂ (6 months post-treatment)
Ratsgoo <i>et al.</i> , 2016	Pain	VAS	VAS score	
	Gait ability	FGA test	FGA score	
	Leg circumference	Metric tape	Leg circumference (mm)	T ₀
	Muscle architecture	Ultrasonographic device (Medison X8, Medison Co)	Pennation angle muscle thickness (mm) fascicle length (mm)	T ₁ (after single session 1) T ₂ (30 min)
Radimwehr <i>et al.</i> , 2017	Spasticity	MMASVAS	MMAS score	T ₀
	Gait ability	TUG test	TUG score (s)	T ₁ (30 min)
	Ankle movement	Manual goniometer	pROM	
	Spasticity	MMAS	MMAS grade	T ₀
	Electrophysiological effects	EMG Medelec machine (TD50 TEK Amodel, England)	H _{max} /M _{max} ratio	T ₁ (immediately after single session)
	Range of motion	Ankle biplane goniometer (A Bissel Health Care, model 7524)	aROM/pROM for gastrocnemius and soleus	T ₂ (1 h after single session)
Sawan <i>et al.</i> , 2017	Biomechanical effects	Hand-held dynamometer (North Coast Medical, model 2845)	PPFT (Nm) at slow and high velocity	
	Gait ability	TUG test	TUG score (seconds)	T ₀
	Electrophysiological effects	EMG (Neuroscreen plus v. 1.59 mm Etich Jseger GmbH, Germany)	H _{max} /M _{max} ratio of the soleus	T ₁ (end of treatment /week 6)
	Range of motion	Digital goniometer (Model SR 360 Flexometer) 10-m walk test	Dorsiflexion active ROM 10-m walk time (seconds)	

ATL, Achilles tendon length; CMAP, compound muscle action potential of tibial nerve; CS, clonus score; FGA, functional gait assessment; MAS, Modified Ashworth Scale; MFL, muscle fascicle length; MMAS, modified modified Ashworth Scale; pROM, passive range of motion; MT, muscle thickness; PA, pennation angle; pADFM, passive ankle dorsiflexion motion; PET, peak eccentric torque; PPFT, passive plantarflexor torque; TTA, torque threshold angles; TUG, Timed Up and Go Test; T₀: baseline.

Table 7. Effectiveness of extracorporeal shock wave therapy (ESWT) on clinical spasticity.

Study	Outcome measure	Variables	Time points for comparisons	Intragroup differences from baseline (T ₀) in ESWT groups P-value	Between group differences (ESWT vs control) P-value
RCTs					
Tirbisch <i>et al.</i> , 2015	MAS	MAS soleus score	T ₁ (after session 1)	NS	-NS
			T ₂ (end of treatment /week 3)	NS	
	Tardieu Scale	MAS gastrocnemius score	T ₁ (after session 1)	NS	-NS
			T ₂ (end of treatment /week 3)	0.0195	
			T ₂ (end of treatment /week 3)	NS	NS
Taheri <i>et al.</i> , 2017	MAS	MAS gastrocnemius score	T ₁ (after session 1/week 1)	0.02	NS
			T ₂ (end of treatment/week 3)	0.02	NS
Wu <i>et al.</i> , 2017	MAS	MAS gastrocnemius score	T ₃ (9 weeks post-treatment)	NS	0.022
			T ₁ (1-week post-treatment)	0.05^b; <0.001^c	-
			T ₂ (4-week post-treatment)	<0.001^{b,c}	
Lee <i>et al.</i> , 2018	MAS	MAS plantarflexor score	T ₁ (30 min after single session)	NS	0.04^h
			T ₂ (1-week post-treatment)	NS	0.02^h
			T ₃ (4-week post-treatment)	<0.05	0.04^h
Yoon <i>et al.</i> , 2017	MAS	MAS semitendinous score	T ₁ (after session 1/week 1)	<0.05^d	NS
			T ₂ (after session 2/week 2)	<0.05^{d,e}	NS
			T ₃ (end of treatment /week 3)	0.003^{d,e}	NS
	Modified Tardieu Scale	Modified Tardieu Score	T ₁ (after session 1/week 1)	<0.05^d; NS^e	NS
			T ₂ (after session 2/week 2)	<0.05^{d,e}	NS
Sohn <i>et al.</i> , 2011	MAS	MAS plantarflexor score	T ₁ (immediately after single session)	<0.05	-
			T ₂ (after session 3/week 3)	0.002	
Moon <i>et al.</i> , 2013	MAS	MAS plantarflexor score	T ₁ sham	NS	-
			T ₂ (after session 3/week 3)	0.02	
			T ₃ (1-week post-treatment)	0.02	
			T ₄ (4-week post-treatment)	NS	
Santamato <i>et al.</i> , 2014	MAS	MAS plantarflexor score	T ₁ (immediately after single session)	<0.01	-
			T ₂ (4-week post-treatment)	<0.05*	
Ratsgoo <i>et al.</i> , 2016	MMAS	MMAS plantarflexor score	T ₁ (30 min after single session)	<0.01^a	-
			VAS self-reported spasticity	VAS score	<0.001^a
Radinmehr <i>et al.</i> , 2017	MMAS	MMAS plantarflexor score	T ₁ (immediately after end of treatment/week 1)	0.001^{f,g}	-
			T ₂ (1 h after end of treatment /week 1)	0.001^{f,g}	

* Heckmatt grades I, II and III; lower but NS for grade IV;

^aBetween median and interquartiles range

^bWith focused ESWT

^cWith radial ESWT

^dESWT muscle belly

^eESWT muscle junction

^fKnee extended

^gKnee flexed

^hChange score

complementary view on the studies that were meta-analyzed. Risk of publication bias of included studies has been low, so a priori they are representative.

A range of outcome measures and evaluation times were used across the studies. For this reason, we decided to collect them into three groups, short, medium, and long term. Regarding the patient inclusion criteria, they agreed to use the Ashworth Scale, although they did not agree on pharmacological treatment which might affect the results.

Most studies agreed on using 1500 shots with a frequency between 4/5 Hz, more shots may be dangerous as post-stroke

subjects present sensory changes. One parameter that needs to be addressed is the number of ESWT sessions required for treatment success. As five studies used one single session and five used three sessions or more. It seems that three sessions (one/week) are more beneficial at long-term.

The MAS was the most used, and greater efficiency by clinical spasticity assessment was observed, compared to electro-physiological. However, this tool has been criticized as being subjective and it evaluates muscle tone at rest.⁵⁶ In addition, this clinical scale does not determine the cause of the resistance felt during the stretch, that is, neural or non-

Table 8. Effectiveness of extracorporeal shock wave therapy (ESWT) on electrophysiological parameters.

Study	Tool	Variable	Time points for comparisons	Intragroup differences from baseline (T_0) in ESWT groups P-value	Between group differences (ESWT vs. control) P-value
Sohn <i>et al.</i> , 2011	Medelec Synergy (Viasys healthcare, USA)	F-wave min. Latency (ms) H-reflex latency (ms) H-M ratio Tibial nerve conduction velocity (m/s)	T_1 (immediately after single session)	NS	-
Santamato <i>et al.</i> , 2014	Not reported	CMAP latency (ms) CMAP amplitude (mV) F-wave min. Latency (ms) tibial nerve conduction velocity (m/s)	T_2 (4 week post-treatment)	NS	-
Radinmehr <i>et al.</i> , 2017	EMG Medelec machine (TD50 TEK Amodel, England)	CMAP latency (ms) CMAP amplitude (mV) H_{max}/M_{max} ratio	T_1 (immediately after session 1/week 1) T_2 (1 h after session 1/week 1)	NS	-
Sawan <i>et al.</i> , 2017	EMG (Neuroscreen plus v. 1.59mm Erich Jseger GmbH, Germany)	H-reflex latency (ms) H_{max}/M_{max} ratio of the soleus	T_1 (immediately after session 1/week 1) T_1 (immediately after session 1/week 1) T_2 (1 h after session 1/week 1) T_1 (after session 6/week 6)	0.005 NS Not reported	0.001

CMAP, compound muscle action potential; NS, not significant; ms, milliseconds.

neural. The information obtained does not provide clinicians with insight into the patterns of muscle activation neither does it provide links between spasticity and voluntary movement.⁵⁷ Few studies used other tools such as electrophysiological ones. These are more objective than the clinical assessment, although they require more time and are costlier.

To date there is not enough evidence on ESWT decreasing the excitability of alpha motor neuron, according to Manganotti.⁵⁸ The H-reflex latency decreased transiently at finish of ESWT by Randimehr³⁸ and H_{max}/M_{max} ratio were improved at the end of treatment by Sawan³³ but these studies did not perform a follow-up. It agreed with the results observed by Kenmoku^{59,60} in an animal model.

The results of this review support the hypothesis that ESWT affects rheological properties of the spastic muscle. It seems that ESWT acts more in intrinsic hypertonia or spasticity (extracellular-matrix and muscle fibrosis) than a neural level. These findings are consistent with the conclusions reached by Marinelli⁶¹ with multiple sclerosis patients. Studies have shown separation of fixed actin-myosin links by the input of mechanical energy (spalling) as long as the force is perpendicular to the muscle fiber direction.⁶²

Most of the studies performed conventional physiotherapy in addition to ESWT, according by Alwardat.²⁰ The ESWT can be a beneficial option for spasticity as adjunct therapy to other interventions such as motor intervention (stimulating antagonist muscles), task related training, and muscles stretching exercises. This is consistent with two study's findings,^{63,64} that assessed hamstrings shortened in healthy people. They showed that the ESWT performed besides stretching have a significant improvement in flexibility, compared with only stretching, at finish of intervention and a follow up (4 weeks). The results also suggested that the mechanism of ESWT on muscle relaxation might be different from tissue regeneration effect wherein a certain amount of time is required.

A spasticity reduction at short term and maintained at medium and long term was observed in this review. This differs with the results found by Xiang¹⁹ and by Guo.¹⁶ They did not find statistically significant difference by the MAS in 4 weeks. It could be because they included upper and lower limb in the same meta-analysis.

It showed beneficial effects by ankle range of motion at long term, which strengthens our hypothesis. Nevertheless, that few beneficial effects were found by gait. Perhaps the assessment should be made long term (>9 weeks), so the subjects need more time for a new change. Gait speed is a complex functional activity and a multi-modal product of many processes. Ankle spasticity (*equinovarus* foot) restricts articular range of the ankle and the foot positioning in plantar flexion, which limits dorsiflexion. Besides, recent studies have reported that triceps surae is not responsible for the generation of propulsive force. It only supports the body during walking and prevents falls.⁶⁵ It seems logical that triceps surae was the most treated muscle by studies. Therefore, we are surprised that no study assessed balance as ankle strategy could improve if spasticity was reduced.⁶⁶

ESWT can improve the stiffness of connective tissue by directly acting on rheological properties of spastic muscle, improving myofascial viscoelasticity. According to Fischer,⁶⁷ ESWT application, reduced the dense fibrous generation and

Table 9. Effectiveness of extracorporeal shock wave therapy (ESWT) on range of ankle motion.

Study	Tool	Variable	Knee position	Time points for comparisons	Intragroup differences from baseline (T0) in ESWT groups P-value	Between group differences (ESWT vs control) P-value
RCTs						
Taheri <i>et al.</i> , 2017	Goniometer	pROM (°)	Not reported	T ₁ (after session 1/week 1) T ₂ (end of treatment/week 3) T ₃ (9 weeks post-treatment)	0.01 0.0001^a	NS 0.026^b 0.0001^c
Wu <i>et al.</i> , 2017	Hand-held goniometer	pROM (°)	Knee extended	T ₁ (1 week post-treatment) T ₂ (4 weeks post-treatment) T ₃ (8 weeks post-treatment)	<0.001^{g,h} <0.001^{g,h} 0.01^g; <0.001^h	- NS
Lee <i>et al.</i> , 2018	Goniometer	pROM (°)	Knee flexed	T ₁ (30 min after single session) T ₂ (1 week post-treatment) T ₃ (4 weeks post-treatment)	NS	NS
Tirbisch <i>et al.</i> , 2015	Goniometer	pROM (°)	Not reported	T ₁ (after session 1) T ₂ (end of treatment /week 3)	NS	NS
Non RCTs						
Moon <i>et al.</i> , 2013	Goniometer	pROM (°)	Not reported	T ₁ sham T ₂ (end of treatment/week 3) T ₃ (1 week post-treatment) T ₄ (4 weeks post-treatment)	NS	-
Santamato <i>et al.</i> , 2014	Goniometer	pADFM(°)	Knee flexed	T ₁ (immediately after single session) T ₂ (4 weeks post-treatment)	<0.05ⁱ; <0.05^k <0.05ⁱ; NS^k	-
Ratsgoo <i>et al.</i> , 2016	Manual goniometer	pROM (°)	Knee extended	T ₁ (30 min after single session)	0.001	-
Radinmehr <i>et al.</i> , 2017	Ankle biplane goniometer (Bissel Health Care, model 7524)	pROM (°)	Knee extended/flexed	T ₁ (immediately after single session) T ₂ (1 h)	≤0.001^{g,f} ≤0.001^{g,f}	-
Sawan <i>et al.</i> , 2017	Digital goniometer (Model SR 360 Flexometer)	aROM (°)	Knee extended/flexed	T ₁ (immediately after single session) T ₂ (1 h)	0.03^g; 0.05^f NS ^{g,f}	-
		aADFm(°)	Knee extended	T ₁ (end of treatment/week 6)	Not reported	0.006

pROM, passive range of movement (from maximum dorsiflexion to maximum plantarflexion); aADFM, active ankle dorsiflexion motion; pADFM, passive ankle dorsiflexion motion; NS, not significant.

^aTrend within groups by repeated measurements of ANOVA.

^bTrend between groups by repeated measurements of ANOVA after controlling baseline values as covariate

^cWeek 12 by ANCOVA after controlling baseline values as covariate

^eKnee extended

^fKnee flexed

^gWith focused ESWT

^hWith radial ESWT

ⁱHeckmatt grades I,II, III

^kHeckmatt grade IV

Table 10. Effectiveness of extracorporeal shock wave therapy (ESWT) on biomechanical parameters and muscle architecture.

Study	Tool	Variable	Time points for comparisons	Intragroup differences from baseline (T_0) in ESWT groups <i>P</i> -value	Between group differences (ESWT vs control) <i>P</i> -value
Moon <i>et al.</i> , 2013	Isokinetic dynamometer Biodex system 4 (Biodex Medical System, USA)	PET (Nm) at 60, 180 and 240°/s	T ₁ sham T ₂ (after session 3/week 3) T ₃ (1 week post-treatment) T ₄ (4 weeks post-treatment)	NS <0.05 ^{s,m,f} NS ^s ; <0.05 ^{m,f}	-
Kim <i>et al.</i> , 2015	Myotonometer (Neurogenic Technologies Inc.)	TTAs at 60, 180 and 240°/s	T ₁ sham T ₂ (after session 3/week 3) T ₃ (1 week post-treatment) T ₄ (4 weeks post-treatment)	NS <0.05 ^{s,m,f} NS NS	-
Ratsgoon <i>et al.</i> , 2016	Metric tape	Tension (displacement) of de medial gastrocnemius (mm)	T ₂ (6 weeks post-treatment) T ₃ (6 months post-treatment)	<0.001 <0.001	-
Wu <i>et al.</i> , 2017	Ultrasonographic device (Medison X8, Medison Co., South Korea)	Leg circumference (mm)	T ₁ (immediately after single session) T ₂ (30 min after single session) T ₁ (30 min after single session)	NS 0.03 NS	NS NS
Radinmehr <i>et al.</i> , 2017	Hand-held dynamometer (North Coast Medical, model 2845)	Pennation angle (°) muscle thickness (mm) fascicle length (mm) Mean dynamic plantar contact area (cm ²)	T ₁ (1-week post-treatment) T ₂ (4-week post-treatment) T ₃ (8-week post-treatment) T ₁ (immediately after single session)	<0.001 ^{g,h} <0.001 ^{g,h} <0.001 ^{g,h} ≤0.001 ^e ; >0.05 ^f ≤0.001 ^e ; >0.05 ^f	-
Lee <i>et al.</i> , 2018	Ultrasonographic measurement	PPFT (Nm) at slow (3 s) velocity PPFT (Nm) at high velocity (1 s)	T ₂ (1 h after single session) T ₁ (immediately after single session)	<0.05 ^f <0.05 ^f	-
		ATL MFL MT PA	T ₂ (1 h after single session) T ₁ (30 min after single session) T ₂ (1-week post-treatment) T ₃ (4-week post-treatment)	<0.05 <0.05 <0.05	≤0.001 ^{a,c,d} ; 0.004 ^b ≤0.001 ^{a,b,c,d} 0.004 ^a ; 0.002 ^b ; <0.001 ^{c,d}

ATL, Achilles tendon length; MFL, muscle fascicle length; MT, muscle thickness; PA, pennation angle; PET, peak eccentric torque; PPFT, passive plantarflexor torque; TTAs, torque threshold angles.

^aAchilles tendon length.
^bMuscle fascicle length.
^cMuscle thickness.
^dPennation angle.
^eKnee extended.
^fKnee flexed.
^gWith focused ESWT.
^hWith radial ESWT.
^sAt slow velocity (60°/s).
^mAt moderate velocity (180°/s).
^fAt fast velocity (240°/s).

Table 11. Effectiveness of ESWT on lower limb functionality and gait.

Study	Tool	Variable	Time points for comparisons	Intragroup differences from baseline (T_0) in ESWT groups <i>P</i> -value	Between group differences (ESWT vs. control) <i>P</i> -value
Moon <i>et al.</i> , 2013	FMA scale	FMA lower limb	T_1 sham T_2 (end of treatment/week 3) T_3 (1 week post-treatment) T_4 (4 weeks post-treatment)	NS	-
Kim <i>et al.</i> , 2015	FGA test	FGA score	T_2 (6 weeks post-treatment) T_3 (6 months post-treatment)	<0.001 <0.001	-
Ratsgoo <i>et al.</i> , 2016	TUG test	TUG score (s)	T_1 (30 min after single session)	<0.001	-
Taheri <i>et al.</i> , 2017	3-m walk test LEFS	3-m walk duration (s) LEFS score	T_1 (after session 1/week 1) T_2 (end of treatment/week 3) T_3 (9 weeks post-treatment)	NS 0.003^a 0.003^a	NS ^b 0.033^c 0.004^c
Wu <i>et al.</i> , 2017	10-m walk test	Gait speed (m/s)	T_3 (8 weeks post-treatment)	NS	-
Radinmehr <i>et al.</i> , 2017	TUG test	TUG score (seconds)	T_1 (immediately after single session) T_1 (1 h after single session)	≤0.05 ≤0.05	-
Sawan <i>et al.</i> , 2017	10-m walk test	10-m walk time (sec)	T_1 (after session 6/week 6)	Not reported	0.009
Lee <i>et al.</i> , 2018	FMA scale	FMA lower limb	T_1 (1-week post-treatment) T_2 (4-week post-treatment)	<0.05 <0.05	NS

FMA, Fugl-Myer Assessment; FGA, functional gait assessment; TUG, Timed Up and Go Test; LEFS, lower extremity functional score.

^aTrend within groups by repeated measurements of ANOVA.

^bTrend between groups by repeated measurements of ANOVA after controlling baseline values as covariate.

^cWeek 12 by ANCOVA after controlling baseline values as covariate.

Table 12. Effectiveness of ESWT on clonus.

Study	Tool	Variable	Time points for comparisons	Intragroup differences from baseline (T_0) in ESWT groups <i>P</i> -value	Between group differences (ESWT vs. control) <i>P</i> -value
Moon <i>et al.</i> , 2013	Clonus scale	Clonus score	T_1 sham T_2 (after session 3/week 3) T_3 (1 week post-treatment) T_4 (4 weeks post-treatment)	NS	-
Taheri <i>et al.</i> , 2017	Clonus scale	Clonus score	T_1 (after session 1/week 1) T_2 (after session 3/week 3) T_3 (9 weeks post-treatment)	NS NS ^a	NS NS ^b NS ^c

^aTrend within groups by repeated measurements of ANOVA.

^bTrend between groups by repeated measurements of ANOVA after controlling baseline values as covariate.

^cWeek 12 by ANCOVA after controlling baseline values as covariate.

Table 13. Effectiveness of ESWT on pain.

Study	Tool	Variable	Time points for comparisons	Intragroup differences from baseline (T_0) in ESWT groups <i>P</i> -value	Between group differences (ESWT vs. control) <i>P</i> -value
Kim <i>et al.</i> , 2015	VAS	VAS score	T_2 (6 week post-treatment) T_3 (6 months post-treatment)	<0.001 <0.001	-
Taheri <i>et al.</i> , 2017	VAS	VAS score	T_1 (after session 1/week 1) T_2 (end of treatment/week 3) T_3 (9 weeks post-treatment)	0.01 0.0001^a	NS 0.007^b 0.009^c

^aTrend within groups by repeated measurements of ANOVA.

^bTrend between groups by repeated measurements of ANOVA after controlling baseline values as covariate.

^cWeek 12 by ANCOVA after controlling baseline values as covariate.

Table 14. Adverse effects.

Study	Adverse effects
Sohn <i>et al.</i> , 2011	Mild pain (VAS 3.23 ± 1.28) No other side effects
Moon <i>et al.</i> , 2013	Not reported
Santamato <i>et al.</i> , 2014	Mild adverse effects were reported (injection site pain for five patients, lower limb muscular weakness for two patients) but were resolved in a few days
Kim <i>et al.</i> , 2015	Not reported
Tirbisch <i>et al.</i> , 2015	Mild pain for three out of four patients during the first two sessions (2.667 ± 0.577 in the first and 1.333 ± 0.577 in the second). There were no other side effects. Indeed, there was no hematoma or recrudescence of pain between shock wave sessions.
Ratsgoo <i>et al.</i> , 2016	Not reported
Taheri <i>et al.</i> , 2017	Not reported
Wu <i>et al.</i> , 2017	No adverse events, such as skin petechiae, muscle hematoma, and focal edema were reported during the study period.
Yoon <i>et al.</i> , 2017	Not reported
Radinmehr <i>et al.</i> , 2017	Patients reported no discomfort during the treatment, and none reported any adverse responses
Sawan <i>et al.</i> , 2017	Not reported
Lee <i>et al.</i> , 2018	Not reported

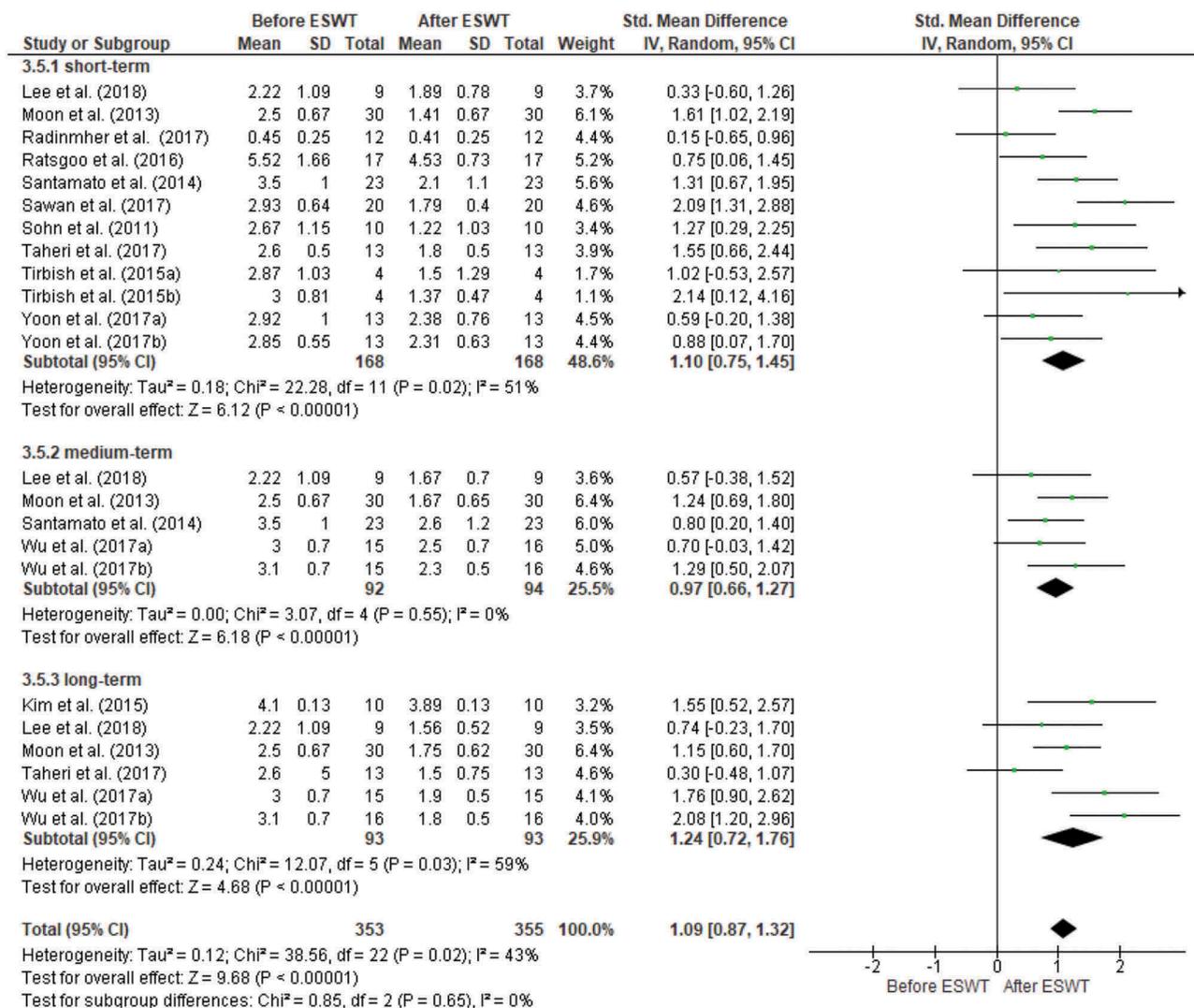


Figure 3. Forest plot of the standard mean difference and 95% confidence interval (95% CI) for spasticity of before and after extracorporeal shock wave treatment (ESWT). Wu *et al.*, (2017a): focused ESWT; Wu *et al.*, (2017b): radial ESWT; Yoon *et al.*, (2017a): belly application, Yoon *et al.*, (2017b): junction application, Tirbish *et al.*, (2015a): soleus muscle assessment, Tirbish *et al.*, (2015b): gastrocnemius muscle assessment.

could degrade the fibrous envelope. ESWT could reduce capsule formation and may induce fibrotic tissue restoration or reabsorption. Moreover, ESWT increases the blood supply to the tissue and modulates the growth factors activation. It can also induce non-enzymatic and enzymatic nitric oxide synthesis.⁶⁸

Morphological assessment of neuromuscular junction by electron microscopy showed that ESWT destroyed end plates in neuromuscular junction. Although all end plates remained in contact with axon terminals, end plates of ESWT exposed muscles were significantly thinner, and the interval between junction folds was increased.⁶⁰

No studies found serious complications after the treatment as a previous study had reported.⁶⁹ Three studies reported mild adverse effects during application of ESWT such as mild pain and lower limb muscular being these symptoms solved in few days.

There are some limitations to this review, which will affect the generalizability of the results. The first limitation is that the small sample size of participants in the included studies

may have affected the validity of the results in meta-analysis, as it was shown that the small studies inclusion might lead to Type-I error.²⁷ Furthermore, there are five of the included studies with a risk of bias (PEDro score ≤ 3 points). This result should be interpreted with caution because only four studies were of 'high' quality and it is possible that both 'fair' and 'poor' quality studies exaggerate the real size of the treatment effect. Concerning the recommendations performed by Consensus-Based Core Recommendations from the Stroke Recovery and Rehabilitation Roundtable,⁷⁰ most of studies did not adequately provide complete information. Finally, a great diversity or variability was found in the parameters related to the intervention (s), as well as in those related to the evaluation procedures. In the present review, a certain grouping was opted, although other types of classifications or groupings could have been carried out.

Further research from well-designed and high-quality studies with a large number of participants is required to standardize the treatment parameters and demonstrate the optimal ESWT approach for health-care decision-making.

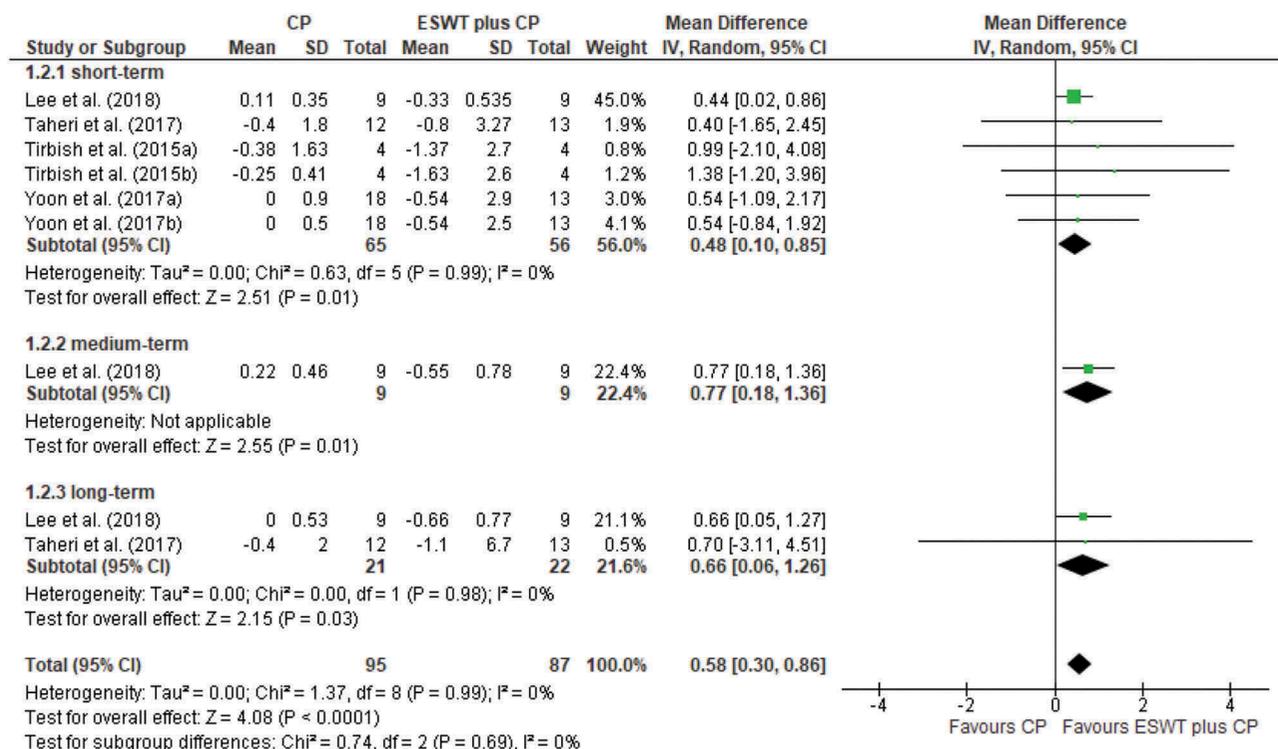


Figure 4. Forest plot of spasticity by modified Ashworth Scale. Comparison between extracorporeal shock waves therapy (ESWT) plus conventional therapy (CP) vs CP. Yoon *et al.* (2017a): belly application ESWT, Yoon *et al.* (2017b): junction application ESWT, Tirbish *et al.* (2015a): soleus muscle assessment, Tirbish *et al.* (2015b): gastrocnemius muscle assessment.

Conclusions

Extracorporeal shock wave therapy added to conventional physiotherapy reduces clinically spasticity. It increases range of motion and lower limb function on lower limb in chronic stroke survivors at short and long term. ESWT is a modern, non-invasive therapeutic tool, which could be considered effective and safe. To ensure efficacy, the use of ESWT requires accurate identification of the area to be treated using ultrasound or radiographic guidance.⁷¹ This allows the most favorable therapeutic effect and avoids damage to the surrounding tissue.¹⁵

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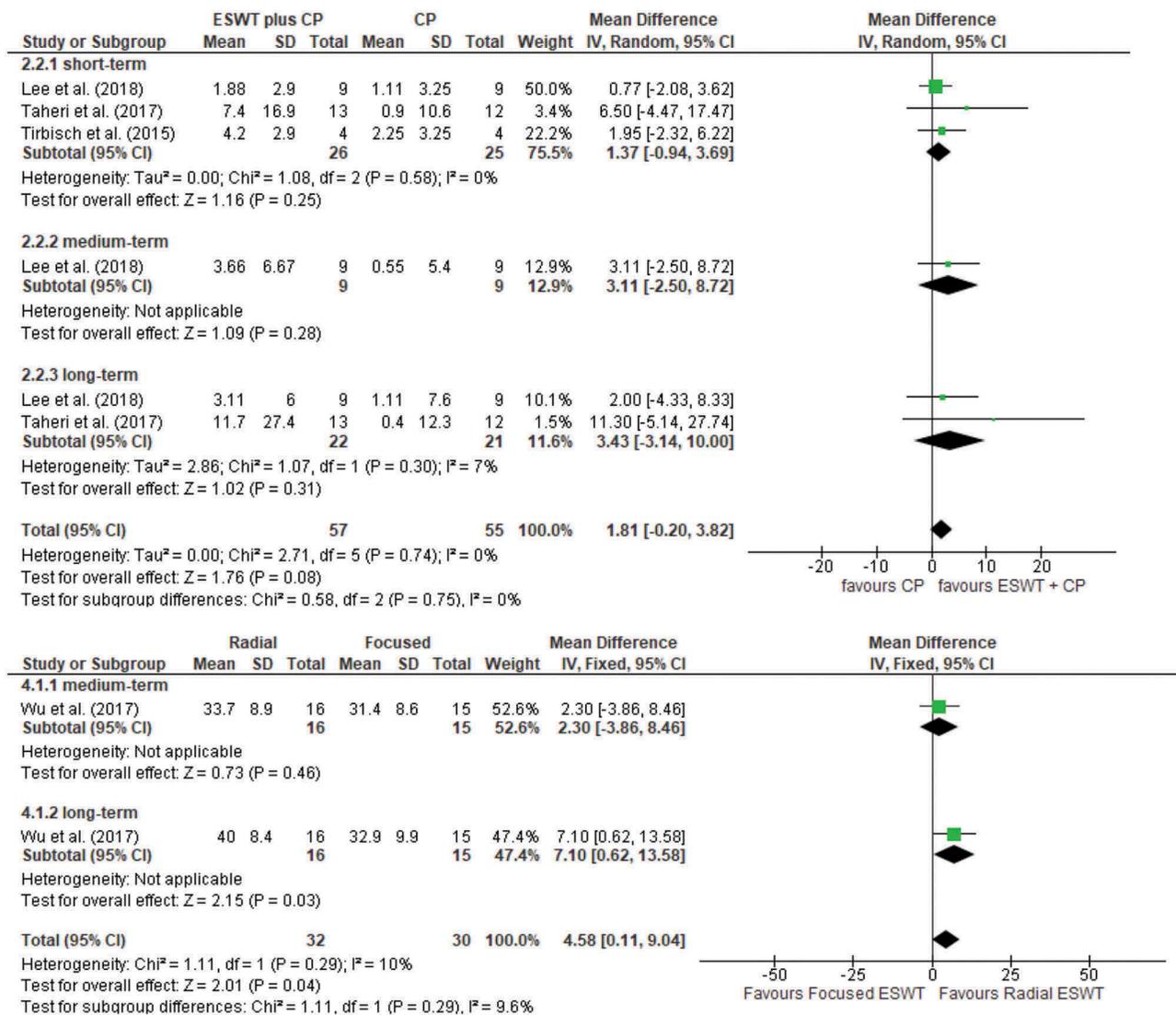


Figure 5. Forest plot of range of motion of extracorporeal shock waves therapy (ESWT) plus conventional therapy (CP) vs CP and comparison between radial ESWT versus focused ESWT.

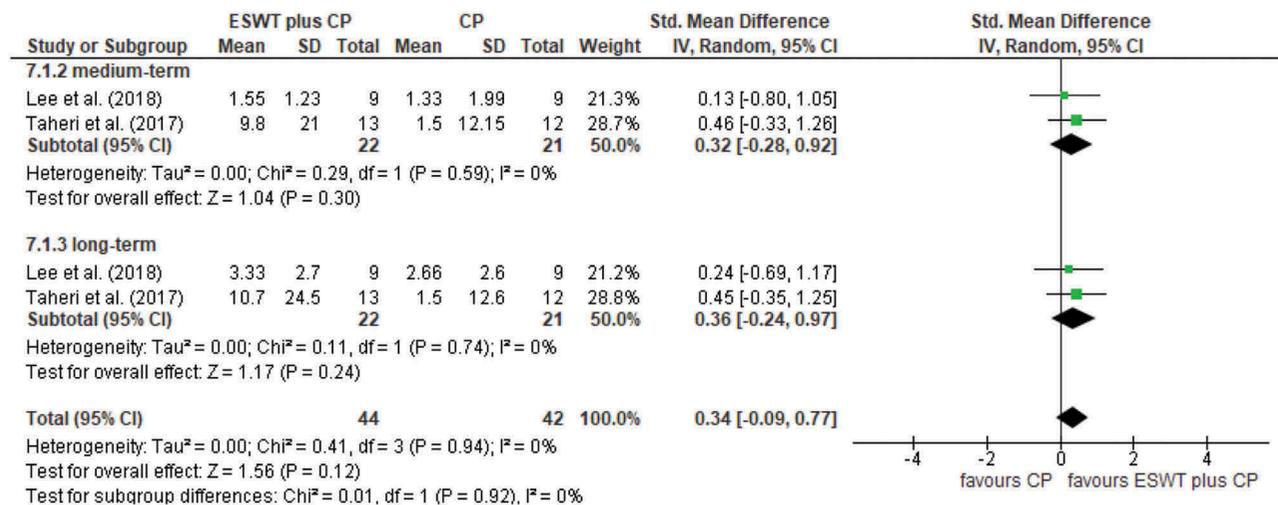


Figure 6. Forest plot of lower limb motor function. Comparison between extracorporeal shock waves therapy (ESWT) plus conventional therapy (CP) vs CP.

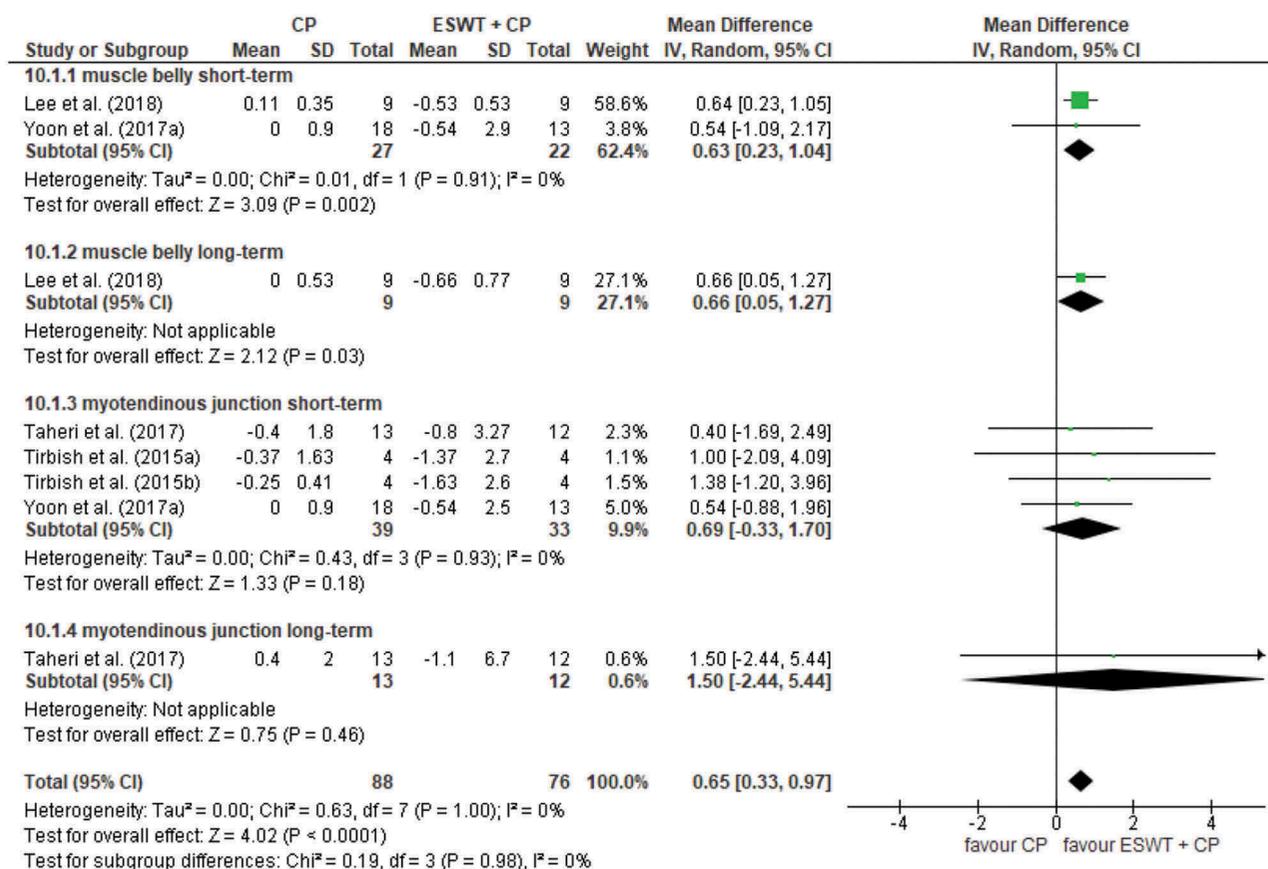


Figure 7. Forest plot of application point. Sensitive analysis of comparison between extracorporeal shock waves therapy (ESWT) plus conventional therapy (CP) vs CP.

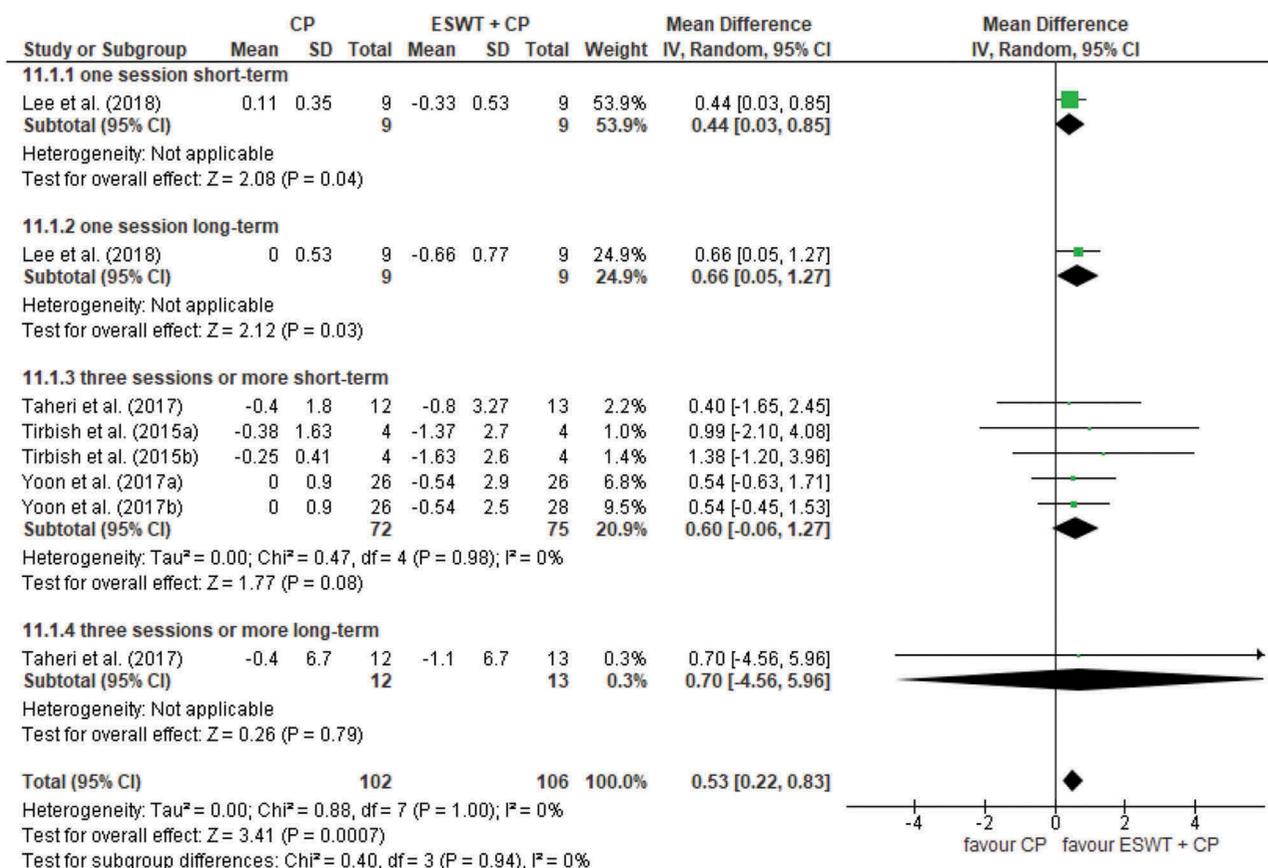


Figure 8. Forest plot of number of sessions. Sensitive analysis of comparison between extracorporeal shock waves therapy (ESWT) plus conventional therapy (CP) vs CP.

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Appendix

Search strategy Pubmed/Medline

#6 Search (shockwave OR shock waves therapy OR “extracorporeal shock waves” OR ESWT OR “Shockwave Therapies”) AND (stroke*[tiab] OR poststroke*[tiab] OR hemiparesis OR hemiplegia OR apoplex*[tiab] OR cerebrovascular disorders [Mesh] OR infarction OR “brain vascular accidents”) AND ((spasticity [tiab] OR muscle hypertonia [tiab] OR “muscular hypertonicity” OR “hypertonia muscle” OR “tone increased) 30

#5 Add Search (shockwave OR shock waves therapy OR “extracorporeal shock waves” OR ESWT OR “Shockwave Therapies”) AND stroke*[tiab] OR poststroke*[tiab] OR hemiparesis OR hemiplegia OR apoplex*[tiab] OR cerebrovascular disorders [Mesh] OR infarction OR “brain vascular accidents”) AND (spasticity [tiab] OR muscle hypertonia [tiab] OR “muscular hypertonicity” OR “hypertonia muscle” OR “tone increased” OR exaggerated)

#4 Add Search (stroke*[tiab] OR poststroke*[tiab] OR hemiparesis OR hemiplegia OR apoplex*[tiab] OR cerebrovascular disorders [Mesh] OR infarction OR “brain vascular accidents”)) AND ((spasticity [tiab] OR muscle hypertonia [tiab] OR “muscular hypertonicity” OR “hypertonia muscle” OR “tone increased OR exaggerated) 22563

#3 Add Search ((shockwave OR shock waves therapy OR “extracorporeal shock waves” OR ESWT OR “Shockwave Therapies”) 5187

#1 Add Search (spasticity [tiab] OR muscle hypertonia [tiab] OR “muscular hypertonicity” OR “hypertonia muscle” OR “tone increased OR exaggerated) 532477

#1 Add Search (stroke*[tiab] OR poststroke*[tiab] OR hemiparesis OR hemiplegia OR apoplex*[tiab] OR cerebrovascular disorders [Mesh] OR infarction OR “brain vascular accidents”) 693911