

# The effectiveness of extracorporeal shock wave therapy for improving upper limb spasticity and functionality in stroke patients: a systematic review and meta-analysis

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## Abstract

**Objective:** To assess the effectiveness of Extracorporeal Shock Wave Therapy for reducing spasticity and improving functionality of the upper limb in stroke survivors.

**Data sources:** A systematic review of MEDLINE, Cochrane Central Register of Controlled Trials, CINAHL, PEDro, REHABDATA, Scielo, Scopus, Web of Science, Tripdatabase and Epistemonikos from 1980 to April 2020 was carried out.

**Review methods:** The bibliography was screened to identify randomized controlled clinical trials that applied extracorporeal shock waves to upper limb spastic muscles in post-stroke individuals. Two reviewers independently screened references, selected relevant studies, extracted data and assessed risk of bias using the PEDro scale. The primary outcome was spasticity and functionality of the upper limb.

**Results:** A total of 1,103 studies were identified and 16 randomized controlled trials were finally included (764 individuals) were analyzed. A meta-analysis was performed and a beneficial effect on spasticity was found. The mean difference (MD) on the Modified Ashworth Scale for comparison extracorporeal shock wave versus sham was -0.28; with a 95% confidence interval (CI) from -0.54 to -0.03. The MD of the comparison of extracorporeal shock wave plus conventional physiotherapy versus conventional physiotherapy was -1.78; 95% CI from -2.02 to -1.53. The MD for upper limb motor-function using the Fugl Meyer Assessment was 0.94; 95% CI from 0.42 to 1.47 in the short term and 0.97; 95% CI from 0.19 to 1.74 in the medium term.

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**Conclusion:** The extracorporeal shock wave therapy is effective for reducing upper limb spasticity. Adding it to conventional therapy provides an additional benefit.

## Keywords

Spasticity, stroke, ESWT, hemiparesis, extracorporeal shockwave therapy

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## Introduction

Loss of hand function after a stroke is a major cause of long-term disability, making arm rehabilitation research a priority.<sup>1</sup> Upper limb impairment affects between 48% and 77% of people following a stroke, and it affects function and health-related quality of life.<sup>2</sup> This is partly due to the presence of spasticity. This is the consequence of an upper motor neuron lesion, which disrupts the balance of supra-spinal inhibitory and excitatory sensory inputs directed to the spinal cord, leading to a state of disinhibition of the stretch reflex.<sup>3</sup>

The prevalence of spasticity increases over time after the stroke<sup>4</sup> and remains a problem despite various proposed treatments. Extracorporeal shockwave therapy has been used in neurological conditions including stroke for treating muscle spasticity. A recent review<sup>5</sup> showed positive effects of extracorporeal shock waves for reducing lower limb spasticity after a stroke. However, to our knowledge there are no-specific reviews focused on the upper extremity in these individuals.

Extracorporeal shockwave therapy is defined<sup>6</sup> as a sequence of acoustic pulses characterized by high peak pressure (100 MPa), fast pressure rise (<10 ns), short duration (10 µs), and conveyed by an appropriate generator to a specific target area with an energy density ranging from 0.003 to 0.890 mJ/mm<sup>2</sup>. There are two principal types: focused and radial waves.

The aim of this systematic review is therefore to identify and analyse studies that used extracorporeal shockwave therapy to treat upper limb spasticity in adult stroke survivors to evaluate its effectiveness.

## Methods

We conducted a systematic review of the scientific literature to assess the effect of extracorporeal shockwave therapy interventions on stroke survivors. The

PROSPERO (register of systematic reviews) number was CRD42018099194. The guidelines in the Cochrane Handbook for Systematic Reviews of Interventions Version 6 (2019)<sup>7</sup> and PRISMA statement<sup>8</sup> were followed.

The search strategy was formulated using a PICO framework. (P) Adult patients with post-stroke upper limb spasticity, (I) receiving radial or focused extracorporeal shockwave therapy alone, or in addition to another rehabilitation approach, (C) compared to subjects receiving conventional physiotherapy, another rehabilitation approach or extracorporeal shockwave therapy sham; (O) changes analysis of spasticity and functionality outcomes, with or without follow-up post-treatment.

Only randomized clinical trials were included. The studies were published between 1980 (extracorporeal shockwave therapy was not available before that date) and 2 April 2020. English, French, Italian, Portuguese, Chinese or Spanish language studies were included. Comments, reviews, observational studies, books, poster/oral abstract communications, case reports, pre-post studies, systematic reviews and practice guidelines were excluded. We defined conventional physiotherapy as physical treatment interventions to reduce spasticity based on the review by Monaghan et al.<sup>9</sup>

The primary outcome was upper limb spasticity and functionality, although additional outcomes measured before and at any time following extracorporeal shock wave intervention were also used. A computerized search strategy of the following databases was performed: MEDLINE, Cochrane Central Register of Controlled Trials, Physiotherapy Evidence Database (PEDro), Scielo, Tripdatabase, Web of Science, Scopus, CINHAL, Rehabdata, Liliacs and Epistemonikos. In addition, a manual search was performed. We used the MEDLINE search strategy, and adapted it to other databases (see Appendix 1).

Searches for eligible articles and data extraction were conducted independently by two authors (MLL/RC) with a third author in the event of disagreement (JC). Proquest Refworks discarded duplicate articles, and the remaining studies were analyzed for their appropriateness. Selection was initially based on the title or abstract, and subsequently on the full text of the articles. They were thoroughly checked to confirm the selection criteria. We analyzed whether the studies included followed the template for the intervention's description and the replication checklist (TIDieR).<sup>10</sup> The following data were extracted: patient characteristics, general characteristics of the study design, intervention features, targeted muscle, point of application, extracorporeal shockwave therapy parameters, the mean value, the standard deviation and the number of participants in the outcome measurements in each intervention group. Conventional physiotherapy intervention and other treatment approaches were compiled if provided.

The risk of bias assessment was assessed by two authors (PR and PS) using the PEDro scale.<sup>11</sup> In cases of doubt or disagreement, a discussion took place between three reviewers (RC) until a consensus was reached. The PEDro is an 11-item scale, in which the first item relates to external validity (not used to calculate total score) and the other ten items assess the internal validity of a study. The higher the score, the greater the study's risk of bias as assessed by the following cut-points<sup>12</sup> 9–10: excellent; 6–8: good; 4–5: fair; <4: poor.

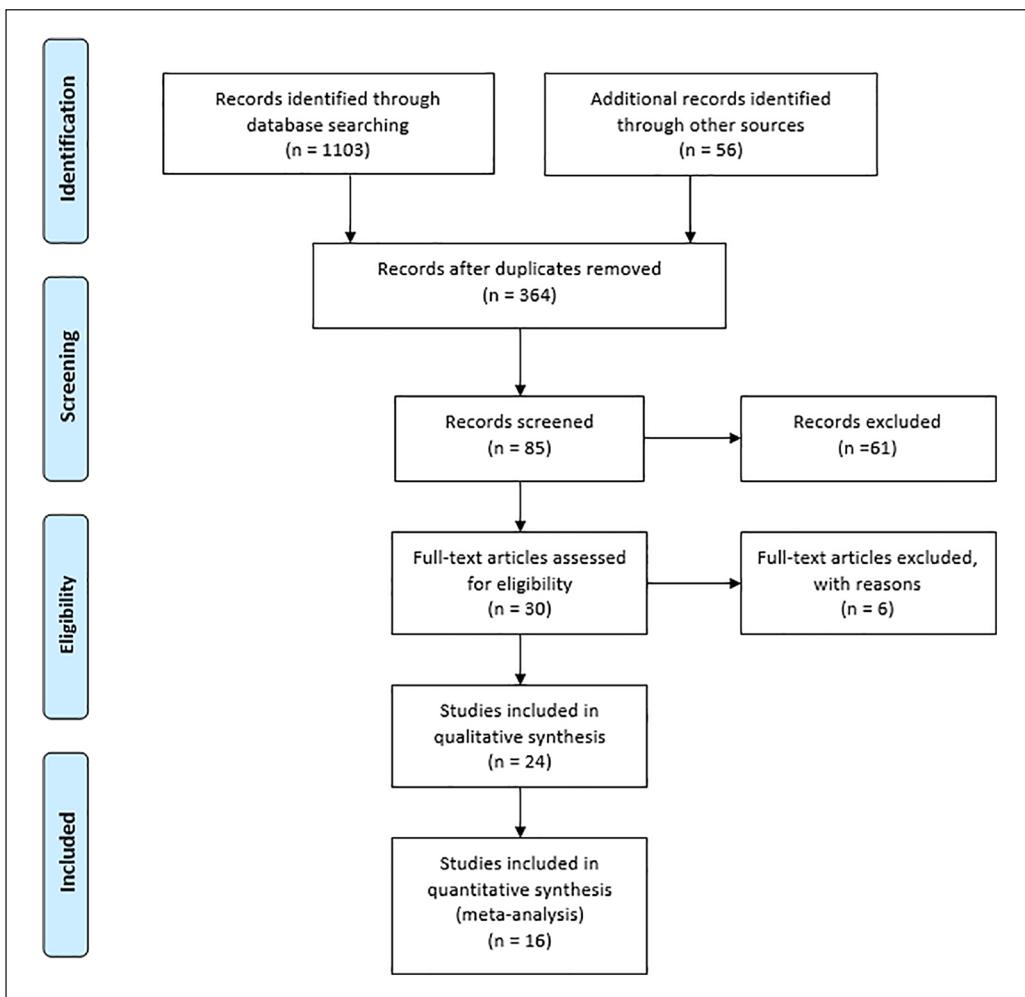
The treatment effect sizes were calculated using the Revman 5.3<sup>13</sup> software package, based on the mean scores and standard deviations in the studies. Post-intervention effects were analyzed by calculating the change between the baseline and the immediate post-intervention assessment, and persisting effects by computing the change between the baseline and the last follow-up assessment. These changes were compared between groups. When the outcomes were continuous and the same units, a mean difference was used, otherwise a standardized mean difference was used. The effect size was categorized as 0.2, 0.5, 0.8 and 1.3, considered as small, medium, large and very large, respectively.<sup>14</sup> Funnel plots were used to illustrate the risk of publication bias.

The heterogeneity was assessed visually by means of forest plots and by reporting the  $I^2$  statistic. In addition, if heterogeneity is considered significant  $>70\ I^2$ , sensitivity or subgroup analysis was carried out to distinguish its sources. The fixed-effect model was applied by default, and the random-effect model was used in cases of substantial heterogeneity. When there was insufficient data for quantitative analysis, the review only represents and summarizes the evidence. Missing data was requested by contacting the corresponding author.

## Results

The PRISMA diagram (see Figure 1) summarizes the results of the scientific literature search. Sixteen randomized controlled trials were included: these were by Bae et al.,<sup>15</sup> Santamato et al.,<sup>16</sup> Fouda et al.,<sup>17</sup> Dymarek et al.,<sup>18</sup> Kim et al.,<sup>19</sup> Li et al.,<sup>20</sup> Yoon et al.,<sup>21</sup> Duan et al.,<sup>22</sup> Guoxing et al.,<sup>23</sup> Guo et al.,<sup>24</sup> Fouda et al.,<sup>25</sup> Kamaluddin et al.,<sup>26</sup> Park et al.,<sup>27</sup> Wu et al.,<sup>28</sup> Ahmed et al.,<sup>29</sup> and Li et al.<sup>30</sup> Studied identified but not included are shown in Appendix 2. No author responded when contacted for additional information. The mean PEDro score assessing risk of bias was 7.25 points (range 3–9) from 10 criteria (see Supplemental Table S1), indicating a good score. Nevertheless, four studies with 9 points were found.

An overview of the studies included and the patients' characteristics was provided (see Table 1). The total population analyzed included 764 individuals, of whom 262 were female, 412 had suffered an ischemic stroke and 280 were hemorrhagic. Two studies did not report this information. The mean age of the participants ranged from 47 to 69 years old, there were 161 patients with left side hemiparesis and 200 had right side hemiparesis, and seven studies did not specify. Only one study reported brain area stroke.<sup>28</sup> Most patients were in the chronic phase (>six months) except in the studies by Duan et al.,<sup>22</sup> Guoxing et al.,<sup>23</sup> Kamaluddin et al.<sup>26</sup> which were in the subacute phase, Guo et al.,<sup>24</sup> which were in late phase and Li et al.<sup>30</sup> included both. All the studies included patients with a Modified Ashworth Scale<sup>31</sup> muscle spasticity score  $\geq 1$ , and excluded patients with fixed muscle contractures = 4 score points.



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

As regards the type of extracorporeal shockwave, four studies used focused waves and twelve used radial waves (see Table 1). All authors were guided by an ultrasound pointer guide before applying the extracorporeal shockwave therapy. Only two studies performed extracorporeal shockwave in isolation, while thirteen studies combined it with conventional physiotherapy, and Guo et al.<sup>24</sup> added mirror therapy. Santamato et al.<sup>16</sup> performed extracorporeal shockwave after botulinum toxin injection, and Wu et al.<sup>28</sup> compared both therapies (see Table 2).

The parameters of extracorporeal shockwave intervention differed between studies. During a

single application, the energy flux density ranged from 0.03 to 1.95 mJ/mm<sup>2</sup>. The number of impulses ranged from 1.000 to 6.000 (groups of muscles), with 1.500 shots the most widely used. The frequency of shots ranged between 4 and 18 Hz, and 4/5 Hz was the most extensively used. Two studies did not report these data. The energy levels oscillated between one and four bars. Fouda et al.<sup>25</sup> compared two energy levels, for radial extracorporeal shockwave (2 bar, 0.1 mJ/mm<sup>2</sup>, low energy) versus radial extracorporeal shockwave (four bar, 0.18 mJ/mm<sup>2</sup>, medium energy). The results favoured the medium energy group (see Supplemental Table S2).

**Table I.** General overview of selected studies and patient characteristics.

Author, reference, country	n	Groups (n)	Setting	Patients characteristics				Affected side (right/left)	Affected brain area
				Age (years) mean (SD)	Gender (male/female)	Stroke type (ischemic/haemorrhagic)	Time since stroke (months) mean (SD)		
Bae et al. <sup>15</sup> Korea	32	fESWT Belly + CP (11) fESWT Junction + CP (12) CP (9)	Two centres	53.40 ± 16.8	5/4	3/6	25.10 ± 14.6	Not reported	Not reported
Santamato et al. <sup>16</sup> Italy	32	BTX-A + ES (16) BTX-A + fESWT (16)	Two centres	56.70 ± 12.4 63.10 ± 7.03	15/8 10/6	13/10 Not reported	22.00 ± 8.2 9.30 ± 3.97	Not reported	Not reported
Fouda et al. <sup>17</sup> Egypt	30	sham rESTW + CP (15) rESTW + CP (15)	Two centres	64.4 ± 6.99 51.83 ± 6.80	9/7 15/0	6/9	10.50 ± 2.12 14.60 ± 9.21	Not reported	Not reported
Dynarek et al. <sup>18</sup> Poland	60	sham rESTW (30) rESTW (30)	Single	52.72 ± 5.90 60.87 ± 9.51	15/0 15/15	5/10	12.20 ± 8.12 30/0	Not reported Not reported	Not reported
Kim et al. <sup>19</sup> Korea	34	sham rESTW (17) rESTW (17)	Single	61.43 ± 12.74 66.11 ± 15.79	19/1 10/7	1/1	51.53 ± 26.13 22.17 ± 18.26	15/15 9/8	Not reported Not reported
Li et al. <sup>20</sup> China	60	rESWT-3 sessions + CP (20) rESTW-1 session + CP (20)	Single	65.88 ± 8.27 55.35 ± 3.05	7/10 12/8	8/9 10/10	28.82 ± 33.33 61.70 ± 9.73	10/7 7/13	Not reported Not reported
Yoon et al. <sup>21</sup> Korea	80	sham fESWT + CP (26) sham fESWT + CP (26)	Single	56.80 ± 3.00 55.95 ± 2.64	15/5 14/6	10/10	66.65 ± 9.56 66.95 ± 10.04	6/14 4/16	Not reported Not reported
Duan et al. <sup>22</sup> China	48	fESWT Belly + CP (26) fESWT junction + CP (28) rESTW + CP (24)	Single	64.40 ± 13.8 58.70 ± 15.7 63.10 ± 11.8	23/3 26/0 27/1	No reported	63.50 ± 94.1 100.30 ± 98.3 66.80 ± 51.9	Not reported	Not reported
Guoxing et al. <sup>23</sup> China	56	CP (24) sham rESTW + CP (28)	Single	50.64 ± 8.57 51.87 ± 9.35	13/1 12/12	7/17	48.29 ± 12.30 (days) 50.67 ± 14.27 (days)	9/15 11/13	Not reported Not reported
Guo et al. <sup>24</sup> China	80	rESTW + CP (28) rESTW + CP (30)	Single	54.16 ± 12.39 52.78 ± 12.04	18/10 17/11	9/15 1/14	53.62 ± 12.54 (days) 52.88 ± 13.19 (days)	16/12 15/13	Not reported Not reported
Fouda et al. <sup>25</sup> Egypt	40	MT + fESTW + CP (30) CP (30)	Single	67.15 ± 11.23 66.79 ± 11.02	17/11 16/14	1/14 12/18	3.41 ± 0.79 3.23 ± 0.82	3/13 3.13 ± 1.02	Not reported
Kamaluddin et al. <sup>26</sup> Indonesia	30	rESWT + CP (20)	Two centres	68.72 ± 10.56 69.72 ± 11.13	18/12 16/14	15/15 13/17	3.49 ± 0.93 11.46 ± 1.68	Not reported	Not reported
Park et al. <sup>27</sup> Korea	30	CP (15) rESWT + CP (15)	Single	55 ± 4.05 54.90 ± 4.50	20/0 15/0	8/12	10.69 ± 1.24 1.90 ± 0.79	9/6 10/5	Not reported Not reported
Wu et al. <sup>28</sup> Taiwan	40	sham rESTW + CP (15) rESTW + CP (20)	Single	56.40 ± 6.03 60.01 ± 11.1	7/8 13/8	14/1 11/9	1.80 ± 0.81 5.80 ± 3.1	6/9 11/10	5 Cortex, 13 subcortex, 2 brain stem 1 Cortex, 18 subcortex, 1 brain stem
Ahmed et al. <sup>29</sup> Egypt	30	BoNT-A + CP (20) rESTW + CP (15)	Multicentre	65.00 ± 4.8 64.20 ± 5.1	10/5 9/6	10/10	6.10 ± 3.5 18.10 ± 7.2	10/11 1/10	Not reported Not reported
Li et al. <sup>30</sup> China	82	CP (25) rESWT + CP agonist (27) rESTW + CP antagonist (30)	Single	61 ± 13 63 ± 10 61 ± 12	22/3 20/7 21/9	15/0 20/5 24/3 22/8	9.40 ± 2.29 21 < six months, 4 > six months 21 < six months, 6 > six months 27 < six months, 3 > six months	9/16 7/20 15/15	Not reported Not reported

fESWT: focused extracorporeal shockwave therapy; rESWT: radial extracorporeal shockwave therapy; n: individuals number; CP: conventional physiotherapy; SD: standard deviation; BTX-A: botulinum toxin; ES: electrical stimulation; MT: mirror therapy.

**Table 2.** Assessment of outcomes and results.

Author	Evaluation	Tool	Period	Groups	Results
Outcome					
Bae et al. <sup>15</sup>	Spasticity elbow joint Activities of daily living	MAS, MTS K-MBI	T0 before treatment T1 after session T2 after one week T3 after four weeks	Group A (CP + active rESTW, belly) Group B (CP + active rESTW, junction) Group C (CP)	<b>MAS</b> elbow Better group <b>B</b> <b>MTS</b> elbow Better group <b>B</b> K-MBI*
Santamato et al. <sup>16</sup>	Spasticity fingers joint Spasms Pain intensity	MAS SFS VAS	T0 before treatment T1 after two weeks T2 after four weeks T3 after 12 weeks	Group A (botulinum toxin BTX-A + electrical stimulation) Group B (botulinum toxin BTX-A + FESTW)	<b>MAS</b> Better group <b>B</b> <b>SFS</b> Better group <b>B</b> VAS Better group <b>B</b>
Fouda et al. <sup>17</sup>	Spasticity wrist and fingers joint Pain intensity pROM	MAS VAS Digital goniometer	T0 before treatment T1 after treatment immediately	Group A (CP + sham rESTW) Group B (CP + active rESTW)	<b>MAS</b> wrist and finger flexors Better group <b>B</b> VAS Better group <b>B</b> pROM Better group <b>B</b>
Dymarek et al. <sup>18</sup>	Spasticity elbow, wrist and fingers joints Temperature distributions	MAS Electromiography surface IRT of carpal flexor muscles	T0 before treatment T1 after treatment immediately T2 after 1 hour T3 after 24 hours	Group A (active rESW) Group B (sham rESW).	<b>MAS</b> elbow, wrist and fingers joint Better group <b>A</b> sEMG flexor carpi radialis and flexor carpi ulnaris Better group <b>A</b> IRT of CFM*
Kim et al. <sup>19</sup>	Spasticity shoulder joint Pain intensity Motor function pROM	MAS FMA-UE, CS Goniometer	T0 before treatment T1 after treatment immediately T2 after two weeks T3 after four weeks	Group A (active rESW) Group B (sham rESW)	<b>MAS</b> * <b>VAS</b> Better group <b>A</b> FMA-UE*and CS*
Li et al. <sup>20</sup>	Spasticity wrist and fingers joints Motor function	MAS FMA-UE hand and wrist	T0 before treatment T1 after one week T2 after four weeks T3 after eight weeks T4 after 12 weeks T5 after 16 weeks	Group A (CP + active rESTW-1 session) Group B (CP + active rESTW) Group C (CP + sham rESTW)	<b>MAS</b> fingers Better group <b>A</b> and <b>B</b> at <b>T4</b> . Better group <b>A</b> at <b>T5</b> <b>MAS</b> wrist Better group <b>A</b> and <b>B</b> at <b>T3</b> . Better group <b>A</b> at <b>T4</b> and <b>T5</b> <b>FMA-UE</b> hand function Better group <b>A</b> Wrist function Better group <b>A</b> <b>MAS</b> elbow Better group <b>A</b> and <b>B</b> <b>MTS</b> Better group <b>A</b> and <b>B</b>
Yoon et al. <sup>21</sup>	Spasticity elbow joint	MAS MTS	T0 before treatment T1 after one week	Group A (CP + active rESTW, belly) Group B (CP + active rESTW, junction) Group C (CP + sham rESTW)	Comparison between <b>A</b> and <b>B</b> * <b>MAS</b> elbow Better group <b>A</b> <b>FMA-UE</b> Better group <b>A</b>
Duan et al. <sup>22</sup>	Spasticity elbow joint	MAS FMA-UE	T0 before treatment T1 after two weeks	Group A (CP + active rESTW) Group B (CP)	<b>MAS</b> elbow Better group <b>B</b> at <b>T1</b> and <b>T2</b> <b>FMA-UE</b> Better group <b>B</b> at <b>T3</b>
Guoxing et al. <sup>23</sup>	Spasticity elbow joint Motor function Activities of daily living	MAS FMA-UE MBI	T0 before treatment T1 after two weeks T2 after four weeks	Group A (CP + sham rESTW) Group B (CP + active rESTW) MBI Better group <b>B</b> at <b>T3</b>	<b>MFI</b> Better group <b>B</b> at <b>T3</b>

(Continued)

**Table 2. (Continued)**

Author	Evaluation		Groups	Results
	Outcome	Tool		
Guo et al. <sup>24</sup>	Spasticity wrist joint Motor function	MAS FMA-UE	T0 before treatment T1 after four weeks T2 after 12 weeks T3 after 24 weeks T4 after 48 weeks	Group A (mirror therapy) no analyzed Group B (CP + active rESTW) Group C (CP + active rESTW + MT) Group D (CP)
Fouda et al. <sup>25</sup>	Spasticity wrist and fingers joints pROM Pain intensity	MAS Goniometer VAS	T0 before treatment T1 after treatment immediately	Group A (CP + rSTW, low energy level) Group B (CP + rSTW, medium energy level) Group C (CP)
Kamaluddin et al. <sup>26</sup>	Motor function	FMA-UE hand and wrist	T0 before treatment T1 after treatment immediately	Group A (CP + rESTW) Group B (CP)
Park et al. <sup>27</sup>	Spasticity wrist tone, stiffness and elasticity Motor function	MAS Myotonometer MyotonPRO FMA-UE	T0 before treatment T1 before treatment T1 after treatment immediately	Group A (CP + active rESTW) Group B (CP + sham rESTW)
Wu et al. <sup>28</sup>	Spasticity wrist and elbow joints Motor-function pROM	MAS MTS Tardieu Angles (degrees) FMA-UE	T0 before treatment T1 after one week T2 after four weeks T3 after eight weeks	Group A (CP + active rESTW) Group B (CP + botulinum toxin BoNT-A)
Ahmed et al. <sup>29</sup>	Spasticity wrist and fingers joint Hand grip strength	MAS H/M ratio of flexor carpis ulnaris Dynamometer	T0 before treatment T1 after treatment immediately	Group A (CP + active rESTW) Group B (CP + sham rESTW)
Li et al. <sup>30</sup>	Spasticity elbow joint Motor function Pain intensity Wrist swelling	MAS, MTS FMA-UE VAS SS	T0 before treatment T1 after 24 hours treatment T2 after four weeks	Group A (CP + active rESTW, agonist) Group B (CP + active rESTW, antagonist) Group C (CP)

CP: conventional physiotherapy; MAS: modified Ashworth scale; MMAS: modified modified Ashworth scale; K-MBl: Korean modified Tardieu scale; MBI: modified Barthel index; VAS: visual analogue scale; FMA-UE: Fugl-Meyer assessment upper limb section; CPN: carpal flexor muscles; SFs: spasm frequency scale; pROM: passive range of motion; SEMG: electromiography surface; IRT: infrared thermal imaging; CS: Constant-Murley scale; SS: swelling scale; rESTW: radial extracorporeal shock waves therapy; ER: external rotation; CMAP: compound motor action potential; RCTs: randomized controlled trials.

\*Not statistically significant differences between groups.

The targeted muscles were the flexor carpi radialis and ulnaris, interosseous hand muscles, followed by the flexor digitorum superficialis, biceps brachii, supraspinatus and subscapularis. One study<sup>30</sup> also shot at the triceps brachii. As regards the application point, most studies applied extracorporeal shockwave to the muscle belly and myotendinous junction in the same session. Two studies compared both sites, and the differences were minimal. The number of extracorporeal shockwave sessions ranged from one to sixteen sessions. The frequency was usually one session/week, and the duration of treatment ranged from two to eight weeks. Li et al.<sup>20</sup> compared one single session to three sessions per week, and three sessions led to better results (see Supplemental Table S2).

For the clinical assessment of spasticity, all studies used the Modified Ashworth Scale except Kamaluddin et al.<sup>26</sup> Four studies used the Modified Tardieu Scale,<sup>32</sup> two used a myotonometer and another one used the Brunnstrom stages of motor recovery (see Table 2). The Modified Ashworth Scale quantifies the resistance felt when muscles are passively stretched. The Modified Tardieu Scale is used to measure the resistance during a rapid passive stretch. Two authors recorded this value at the catch angle, when the elbow was extended passively from maximal flexion. The angle was evaluated three times, and the average value was recorded. Li et al.<sup>30</sup> recorded angle of fast-stretch and slow-stretch, and Wu et al.<sup>28</sup> used the difference between the arrest angle at slow speed and the catch angle at fast speed of the wrist and elbow.

An electrophysiological evaluation of spasticity by H-reflex latency and their Hmax/Mmax ratio parameters was also used by one study.<sup>29</sup> The amplitude of the H-reflex indicates the degree of excitation and inhibition of the spinal cord motor neurons. The H-reflex was performed from the flexor carpi radialis muscle and median nerve. The muscle resting bioelectrical activity was examined using surface electromyography by one author.<sup>18</sup> This was performed to record the level of tension and bioelectrical activity of the flexor carpi radialis and ulnaris muscles under resting conditions. The same author<sup>18</sup> used a thermographic assessment to determine the level of local alterations in trophic conditions. This was connected to blood microcirculation and surface temperature distribution.

Nine studies evaluated the degree of motor function recovery using the upper extremity section of the Fugl-Meyer Assessment.<sup>33</sup> Kim et al.<sup>19</sup> used the Constant-Murley score for the functional evaluation of the shoulder, and two trials evaluated activities of daily living using the Barthel index (see Table 2).

The secondary outcomes were related to the passive range of motion, spasms and pain. The passive range of motion was measured in four studies using a goniometer (digital or manually). Only Ahmed et al.<sup>29</sup> assessed hand grip strength using a hydraulic hand dynamometer and another study<sup>30</sup> evaluated the degree of wrist swelling based on swelling scale scores. Five studies also evaluated pain intensity using the visual analogue scale.<sup>34</sup> Santamato et al.<sup>16</sup> assessed spasms using the spasm frequency scale. Only one study<sup>19</sup> reported after the final intervention mild adverse effects. Three patients had petechiae at the treatment site, which resolved spontaneously, and a small bulla was noted in one patient, which completely healed after a few days with a simple dressing. Three studies<sup>16,24,28</sup> reported no adverse effects or complications were observed (see Table 2).

The time when evaluation took place ranged from immediately post-intervention to 12 months. Follow-up was performed in eight studies. For this reason, we decided to classify them into four groups, according to when the extracorporeal shock wave intervention finished: these groups were (1) very short-term (immediately to 24 hours), (2) short-term (from 24 hours to three weeks), (3) medium-term (from four to 12 weeks) and (4) long-term (more than 12 weeks) (see Table 2).

### *Efficacy of extracorporeal shock waves therapy*

As regards spasticity, an overview was possible of the majority of studies before and after extracorporeal shock wave intervention by means of a forest plot (see Figure 2).

Two comparisons were performed:

1. A comparison of sham extracorporeal shock waves versus extracorporeal shock waves. A forest plot of two studies for spasticity using

the Modified Ashworth Scale was performed. The very short-term and short-term effect size was small (see Supplemental Figure S1). It was shown that sham shock waves do not seem to have any effect on spasticity.

2. A comparison of extracorporeal shock waves plus conventional physiotherapy versus conventional physiotherapy. A forest plot of seven studies for spasticity using the Modified Ashworth Scale was performed. The sham extracorporeal shock waves performed in two of these studies were not taken into account since they were shown not to have any effect. The effect size for the very short term was very large, it was large for the short term and medium term, and medium for the long term (see Figure 3). There is a positive immediate and long term effect, although the heterogeneity was high. A sub-analysis of elbow spasticity assessed by the Modified Ashworth Scale and Modified Tardieu Scale was performed and showed less heterogeneity (see Supplemental Figure S2). A forest plot of four studies for functionality was carried out, and showed a small beneficial effect of extracorporeal shock waves (see Figure 4). A forest plot of two studies for pain using the visual analogue scale showed a significant effect in the short, medium and long term (see Figure 5).

All studies showed statistically significant benefits of extracorporeal shockwave in addition to conventional physiotherapy on decreasing muscle tone. Statistically significant effects on motor function, passive range of motion and pain were harder to achieve (the studies showed positive trends).

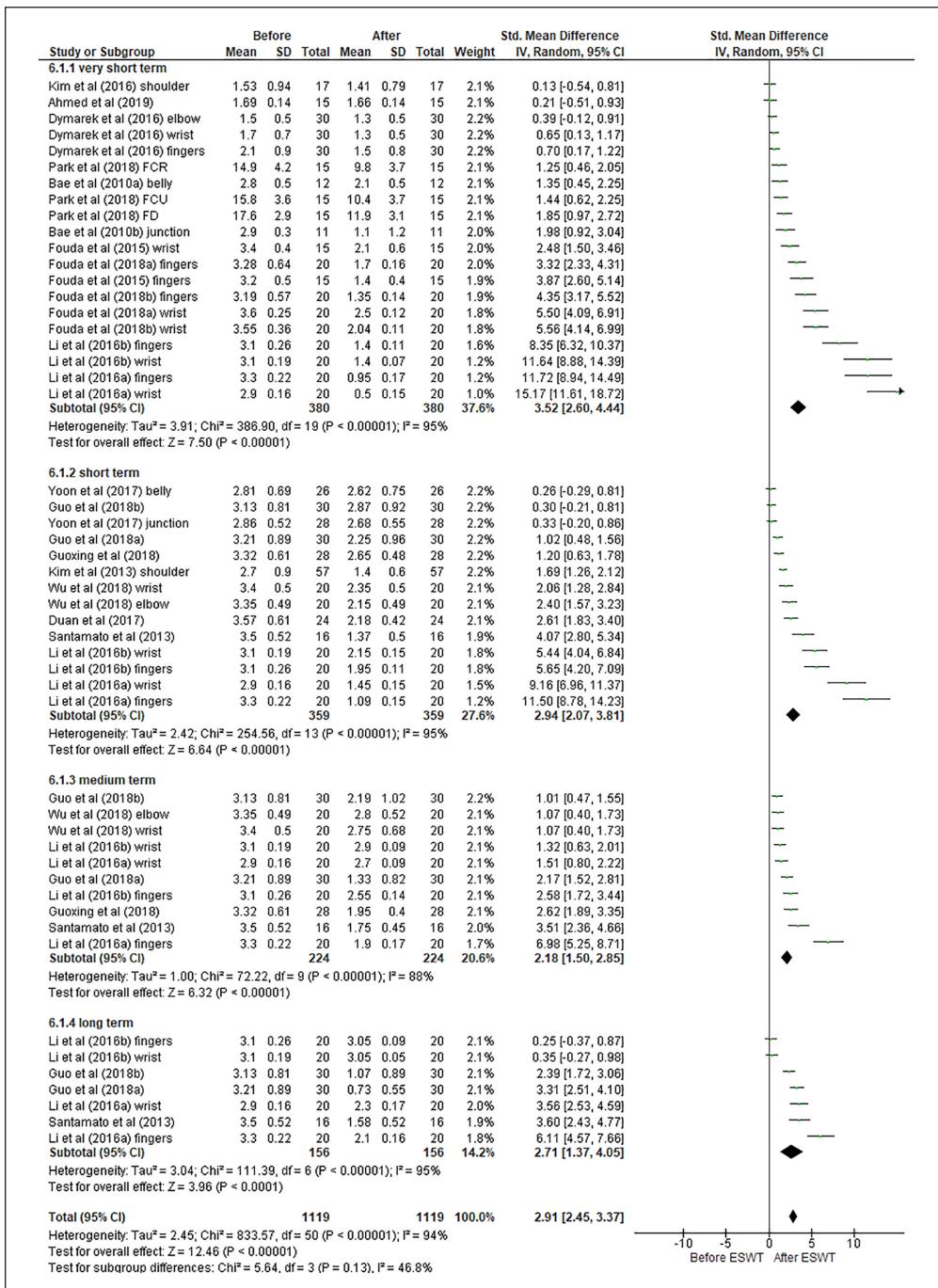
Five funnel plot were performed. Three of them to reduce spasticity assessed by the Modified Ashworth Scale. The funnel plot for extracorporeal shockwave therapy (ESWT) versus ESWT sham (Supplemental Figure S3), the funnel plot for extracorporeal shockwave plus conventional physiotherapy versus conventional physiotherapy (Supplemental Figure S4), the funnel plot for extracorporeal shockwave plus conventional physiotherapy versus conventional physiotherapy for elbow (Supplemental Figure S5). The funnel plot

for extracorporeal shockwave plus conventional physiotherapy versus conventional physiotherapy to improve motor function by upper section of the Fugl Meyer Assessment (Supplemental Figure S6). The funnel plot for extracorporeal shockwave plus conventional physiotherapy versus conventional physiotherapy to improve pain by visual analogue scale (Supplemental Figure S7). The authors suggest that this meta-analysis demonstrates a lower to moderate chances for publication bias.

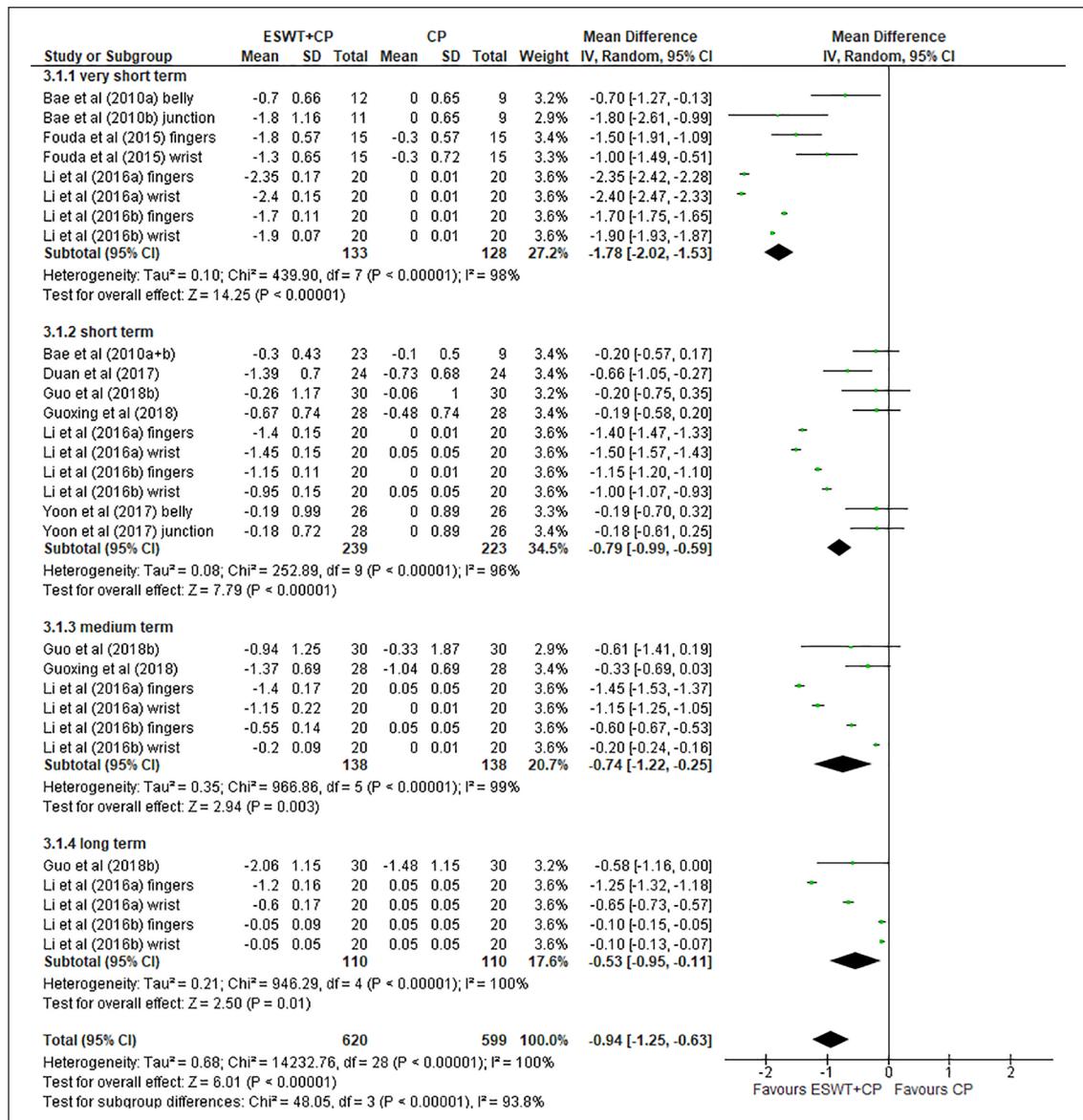
## Discussion

The results of this systematic review suggest that extracorporeal shockwave therapy is an effective non-invasive treatment for reducing upper limb spasticity in stroke survivors. The benefits are greater when it is combined with conventional physiotherapy. However, the effect of extracorporeal shockwave on motor function is limited.

There was sufficient consensus among the authors on outcome evaluation measures. Most authors used the Modified Ashworth Scale to assess spasticity and the upper limb section of the Fugl Meyer Assessment to measure functionality. For secondary outcomes, pain was evaluated by visual analogue scale and passive range of motion by a goniometer. A clinical change in the Modified Ashworth Scale was noted, according to the parameters of Chen et al.<sup>35</sup> and part of the change was maintained over the long term, consistent with the results of Jia et al.<sup>36</sup> The results of this review support the hypothesis that extracorporeal shock waves influence the non-neural component of spasticity, and improve myofascial viscoelasticity, muscle stiffness and connective tissue. Our data show that a combination of shockwave therapy and conventional physiotherapy is more effective in reducing muscle tension in spastic muscles. This is apparent in the lower limb systematic review<sup>5</sup> and is consistent with the results reported by Lin et al.<sup>37</sup> for cerebral palsy. There is as yet no evidence that extracorporeal shockwave therapy reduces alpha motor neuron excitability, a neural component of spasticity. Several authors<sup>16,38-40</sup> support the hypothesis that the combined effects of botulinum toxin plus extracorporeal shockwave affect the



**Figure 2.** Overview of all studies to reduce spasticity before and after intervention. ESWT: extracorporeal shock waves therapy; FCR: flexor carpi radialis; FCU: flexor carpi ulnaris; FD: flexor digitorum; very short term: immediately post treatment; short term: from 24 hours to three weeks; medium term: from four to 12 weeks; long term: more than 12 weeks.

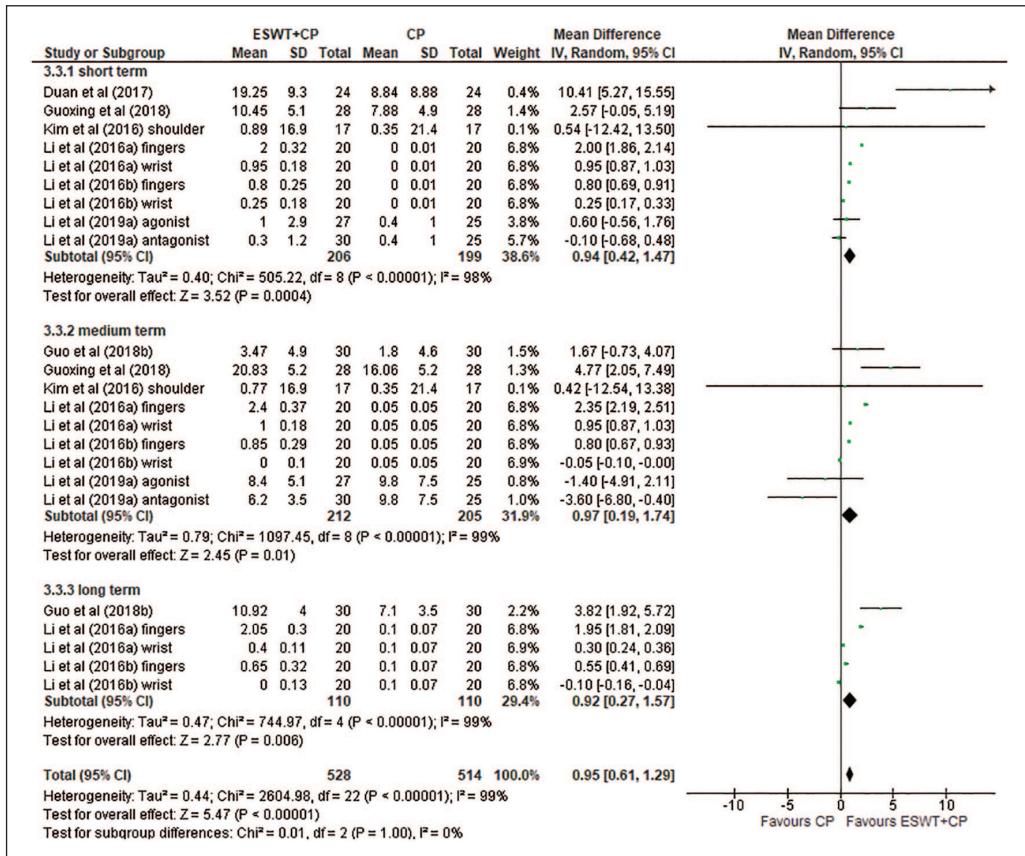


**Figure 3.** Comparison of ESWT plus CP versus CP to reduce spasticity by Modified Ashworth Scale. Li et al. (2016a): 1 session/week × three weeks; Li et al. (2016b): single session. ESWT: extracorporeal shock waves therapy; CP: conventional therapy; very short term: immediately post treatment; short term: from 24 hours to three weeks; medium term: from four to 12 weeks; long term: more than 12 weeks.

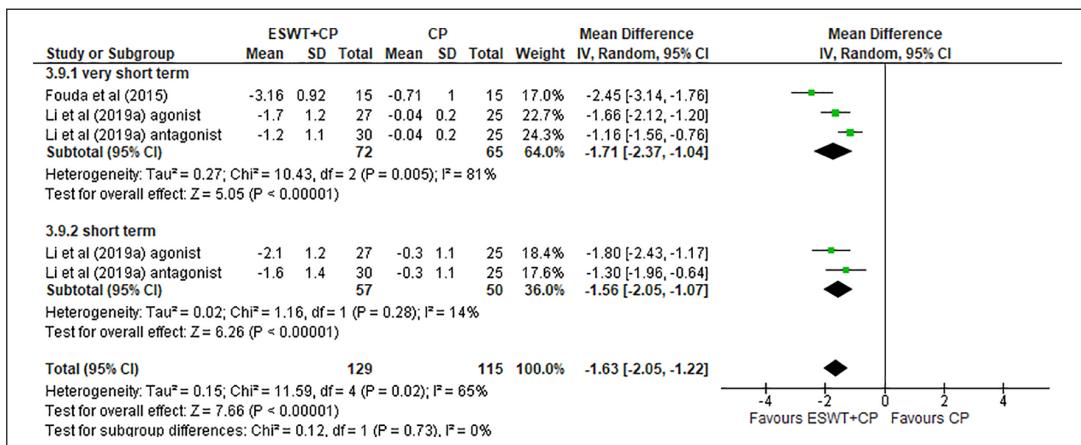
neurological and non-neuronal rheological components in spastic muscles.

The results for motor function of this review show that the changes in the Fugl-Meyer motor

scale are not clinically important according to Page et al.<sup>41</sup> This is probably due to the fact that in most of the studies, the patients were in chronic phase (>six months). Treatment of spasticity maybe



**Figure 4.** Comparison ESWT plus CP versus CP to improve motor-function by Fugl Meyer Assessment upper section. very short term: immediately post treatment; short term: from 24 hours to three weeks; medium term: from four to 12 weeks; long term: more than 12 weeks; ESWT: extracorporeal shock waves therapy; CP: conventional physiotherapy.



**Figure 5.** Comparison of ESWT extracorporeal shock waves plus CP conventional physiotherapy versus CP to reduce pain by visual analogue scale. ESWT: extracorporeal shock waves therapy; CP: conventional physiotherapy.

reveal underlying weaknesses. They would be unlikely to manifest immediate motor improvement of the upper limb after extracorporeal shockwave. They also need more time to improve than in subacute phase (spontaneous recovery). It is important to note that rehabilitative interventions are able to enhance brain repair and stroke recovery even some years after stroke onset. Emerging evidence has enhanced our knowledge of the time window for stroke recovery, which is much longer than previously thought.<sup>42</sup> It may be necessary to treat spasticity and functionality simultaneously for the best results.<sup>2</sup> Possible alternatives could be an intensive treatment of extracorporeal shockwave combined with rehabilitation approaches focused on improving the upper limb motor pattern as proprioceptive neuromuscular facilitation<sup>43</sup> or constraint induced movement therapy, or trunk restraint or mirror therapy.<sup>24</sup>

Spasticity usually appears between one and six weeks after the stroke.<sup>44</sup> According to Duan et al.,<sup>22</sup> Guoxing et al.,<sup>23</sup> and Kamaluddin et al.<sup>26</sup> the results would be optimal given the extracorporeal shock waves therapy at subacute phase. At this stage there is a cortical reorganization and an adaptive plasticity is more probable. A stroke may result in limitations in reciprocal inhibition and excessive agonist-antagonist co-activation.<sup>45</sup> This symptom could be treated by extracorporeal shock waves on the agonist and antagonist spastic muscles together, as performed by Li et al.<sup>30</sup>

There is still some controversy regarding the different types of waves. A recent systematic review<sup>46</sup> reported potential advantages of radial extracorporeal shock waves compared to focused extracorporeal shock waves in spastic muscles. There is evidence to suggest that radial extracorporeal shock waves influence skeletal human cell viability, and regulate the gene expression of muscle cell protein in vitro,<sup>47</sup> and it seems more suitable for treating spasticity.<sup>46</sup>

Most studies agreed on using low energy, because there is no motor or sensory nervous trunk involvement.<sup>48</sup> One parameter that needs to be addressed is the number of extracorporeal shock wave sessions required for the treatment's success, according to Oh.<sup>49</sup> Only one study included in this

analysis reported mild adverse events. According to International Society for Medical Shockwave Treatment (2016)<sup>50</sup> there is no evidence of persistence complications from extracorporeal shock wave therapy. It sometimes causes pain (including headaches-migraines), redness of the skin (blistering) and bruising (haematomas) which usually occurs during and after treatment. There are not contraindications for radial and focused waves with low energy. However, high energy of focused extracorporeal shock waves are contraindicated for patients with severe coagulopathy (they are associated with a risk of bleeding), and in the brain or spine in the treatment area.

There are some limitations to this review, which may affect the generalizability of the results. The first relates to the quality of the studies included, in terms of the level of blinding, sites (single or multicentre) and the small sample size. The inclusion of small studies might lead to Type-I error.<sup>14</sup> According to the recommendations of Walker et al.<sup>51</sup> most articles did not clearly describe how interventions took place or how they were monitored during the trial. Second, the studies did not report the conditions under which spasticity was evaluated. It is important to assess the individuals at the same time, at the same room temperature and after the same level of muscle activity, as these parameters may change the viscoelastic properties of the joint affected. Finally, there was a high level of heterogeneity among the studies, probably due to differences between conventional physiotherapy centres, the treatment doses and its duration. Only one study reported the affected brain area, in our opinion it is an important aspect because the lesion varies in different infarction sites.<sup>52</sup> There were differences in the study population, with a wide variety of ethnicities, probably due to the fact that Asian individuals have another type of energy conductivity and impedance.<sup>53</sup>

In summary, extracorporeal shock wave therapy reduces upper limb spasticity clinically evaluated in stroke survivors both alone and when combined with conventional physiotherapy. Their effects are maintained in the long term. However, the evidence for improved functionality is limited. Extracorporeal shock waves increase range of

motion in the shoulder, elbow and wrist, reduce pain and provide a modern, non-invasive therapeutic option, which may be considered effective and safe. Future research lines should use the two types of extracorporeal shock waves combined in the same treatment session. Radial extracorporeal shock waves should be applied to muscle belly, as it has a more superficial effect. Focused extracorporeal shock waves should be applied to the tendinous joint or muscle motor point, as it reaches a medium level of energy<sup>25</sup> in the focus located deeper within the body tissues.

### Clinical messages

- Extracorporeal shockwave therapy is an effective post-stroke treatment for reducing upper limb spasticity, both alone and in addition to conventional physiotherapy.
- Extracorporeal shockwave therapy may be a beneficial option for reducing spasticity, as an adjuvant therapy to botulinum toxin.

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### Supplemental material

Supplemental material for this article is available online.

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