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RESEARCH PAPER

Effects of radial extracorporeal shockwave therapy on spasticity of upper-limb agonist/antagonist muscles in patients affected by stroke: a randomized, single-blind clinical trial

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Abstract

Background: the effects of radial extracorporeal shock wave therapy (rESWT) were assessed on agonist/antagonist muscles in stroke patients with elbow spasticity, the duration of effects and influence on function.
Methods: patients were randomly assigned into groups: control (A, $n = 25$), rESWT on agonist muscles (B, $n = 27$) and rESWT on antagonist muscles (C, $n = 30$) groups. Conventional physical therapy was given to three groups for 3 weeks, six times a week, and besides, rESWT was given at 4-day intervals for five consecutive treatments, B received rESWT on agonist muscles and C received rESWT on antagonist muscles. The primary outcome was Modified Ashworth Scale (MAS) scores. Modified Tardieu Scale, Visual Analogue Scale (VAS), Fugl-Meyer Assessment and swelling scale (SS) scores were secondary outcomes. Indicators were assessed at baseline, after five treatments and after 4 weeks follow-up.
Results: the rate of treatment was determined by changes in MAS, which was 16.0 (A), 70.4 (B) and 63.3% (C) after rESWT treatments, and was 24.0 (A), 74.1 (B) and 66.7% (C) after 4 weeks follow-up. Improvements were achieved for R1 ($P < 0.01$), R2 ($P < 0.01$) and VAS ($P < 0.01$) after five rESWT interventions. At 4 weeks, significant improvements were achieved for R1 ($P < 0.01$) and VAS ($P < 0.01$).
Conclusions: rESWT is an effective therapy for spasticity after stroke, with lasting effects on both agonist and antagonist muscles after 4 weeks. rESWT relieved pain but had no effect on active function or swelling of the upper limbs.

Keywords: *spasticity*, *radial extracorporeal shock wave therapy (rESWT)*, *stroke*, *rehabilitation*, *older people*

Key points

- To separately explore the effects of radial extracorporeal shock wave therapy (rESWT) on either agonist muscles and antagonist muscles in spasticity treatment.
- rESWT is a safe and effective treatment for spasticity in stroke patients.
- More frequent applications of rESWT may have a more lasting effect on spasticity among stroke patients.
- The mechanism of shockwaves in relieving spasticity requires further research.

Introduction

Spasticity is a common symptom after stroke and can affect patients for days or months afterwards. Studies show that spasticity occurs in about 38% of patients post-stroke [1]. Persistent muscle spasticity results in permanent structural changes and skeletal deformities that limit the mobility functions of stroke patients [2]. Effective control and treatment of spasticity after stroke presents a serious clinical problem. Recent studies have indicated that radical extracorporeal shock wave therapy (rESWT) is a new and effective method for treating spasticity [3]. Results of a meta-analysis of five studies [4] revealed that patients' Modified Ashworth Scale (MAS) scores were significantly improved after rESWT treatment.

rESWT has two physical effects: a primary effect, the direct mechanical action on the treatment point; and a secondary, cavitation effect, that is an indirect mechanical effect [5]. Biomechanical changes around joints should not be confined to spasticity muscles and their tendons, and tendons of antagonist muscles may also undergo adhesions and contractures. Most studies report the treatment sites of rESWT as being limited to spastic muscles. As the study by Li [6] suggests, stroke patients receiving rESWT obtained a significant reduction in forearm flexor spasticity muscles, intrinsic muscles and the flexor digitorum tendon of the hand. Vidal *et al.* [3] compared the effects of rESWT alone on spastic or antagonistic muscles in children with cerebral palsy, and there were no differences in the effect. At present, there have been no studies comparing the effects of rESWT separately on agonist muscles with on antagonist muscles when treating stroke-induced spasticity.

Existing researcher [5,7] has reported that rESWT reduced spasticity long-term, in patients with chronic hemiplegia, for up to 6 months. Comparatively, Moon *et al.* [8] and Bae *et al.* [9] reported that rESWT treatment of muscle spasticity only produced short-term effects that were not maintained after 1–4 weeks. Accordingly, the duration of the effectiveness of rESWT therapy for spasticity remains controversial.

Therefore, the aim of the present study was to investigate the effects of rESWT on agonist muscle group and antagonist muscle group on spasticity, pain, swelling, active function and the duration of in stroke patient with elbow flexor hypertonia.

Methods

Study design

This prospective, randomized clinical study evaluated rESWT effects on upper flexor spasticity after stroke. The study was carried out in the Department of Rehabilitation of Xuhui District Center Hospital, Shanghai, from September 2015 to June 2018. All study participants were required to sign informed consent forms.

Setting and participants

Participants were recruited in four steps: (i) the patient's attending physician was familiar with the criteria for inclusion and exclusion, screened potential subjects and contacted the primary researcher; (ii) the researcher explained the trial to potential participants and discussed the objectives with them, with potential participants being asked for their opinions; (iii) participants were judged for eligibility; and (iv) participants and their relatives were required to sign their informed consent forms.

All patients were referred by the Departments of Rehabilitation of Xuhui District Center Hospital, Shanghai. Eligible patients were randomly divided into three groups: those receiving conventional physical therapy (Group A); those receiving rESWT on agonist muscles in addition to conventional physical therapy (Group B); and those patients receiving rESWT on antagonist muscles in addition to conventional physical therapy (Group C).

Participants were allocated using a unique computer-generated balanced randomization table at a ratio of 1:1:1. The same assessors, who were blinded to the participants, dealt with all patients. All outcome assessors and care providers were different doctors. These individuals did not exchange information during implementation of the experiments, nor were they permitted to inquire about the subject of the intervention.

Inclusion criteria are as follows: (i) met the cerebral infarction or hemorrhage diagnosis standard; (ii) left-limb hemiplegia from first-ever stroke; (iii) elbow flexor spasticity at the I–IV level measured by MAS [10]; (iv) onset time 1–12 months after stroke; (v) aged 35–80 years; (vi) ability to understand command actions; (vii) stable vital signs; (viii) unchanged drug doses that might affect muscle spasticity; and (ix) provided signed informed consent.

Exclusion criteria are as follows: (i) dyskinesia or diseases that directly influence motor function, such as rheumatoid arthritis, joint deformity and spinal-cord injury; (ii) received Botox, alcohol or phenol block treatments; (iii) received elbow joint surgical orthopedic surgery; (iv) experienced spasticity above level I of MAS with straightened elbow; (v) severe hypertension and normal blood pressure after 1 week of therapy (>180/110 mmHg), with atrial fibrillation, unstable angina, serious lung infection (persistent fever, respiratory failure and other unstable vital signs), severe renal failure (CKD stage 4 and above) or severe diabetes (complicated with gangrene, renal injury, retinopathy and other complications); (vi) history of epilepsy; (vii) severe mental disorders; (viii) malignant tumors; and (ix) limb venous thrombosis.

Intervention

Conventional physical therapy included physical therapy and daily life ability training, which referred to the book 'Evaluation and Treatment of Spasm' by Douzulin [11]. All treatments were followed by one-on-one training for 3 weeks, with six sessions per week. Experimental groups were

given five consecutive treatments at 4-day intervals using Master Puls MP100 (Storz Medical Ag-Switzerland). Group B agonist muscles and Group C antagonist muscles were given 6,000 impulses at 0.06–0.07 mJ/mm^2 (1.2–1.4 bar) at 18 Hz. Spasticity muscles in Group B included the muscle bellies of biceps, brachioradialis, pronator teres and the tendon of biceps. Group C included the muscle belly and also the tendons of the triceps.

Outcome measures

The MAS and the Modified Tardieu Scale (MTS) were used to evaluate spasticity. For statistical purposes, MAS '1' and '1+' were substituted by '1' and '2', and '2' and '3' were substituted by '3' and '4', respectively. The effectiveness of treatment depended on the change level of MAS before and after treatment and follow-up, and the specific criteria are as follows [12]: (i) complete response (CR) if the original level degrades ≥2 or reduced to level 0; (ii) partial response (PR) if the original level degrades 1; and (iii) no response (NR) if the original level did not change or upgrade. The formula used was: Effective rate = (excellent + effective)/total number of cases × 100%. MTS [13] measures spasticity using two parameters: angle of fast-stretch R1 and angle of relatively slow-stretch R2. Range of motion was measured using a goniometer.

Pain was evaluated using the Visual Analogue Scale (VAS), from a 10 cm horizontal axis (from 0: 'no pain', to10: 'worst pain possible') [14]. The swelling scale scores were given according to a 4-point scale [15] (0: absent, 1: minimal, 2: moderate, 3: severe) to evaluate the degree of wrist swelling. Fugl-Meyer Assessment (FMA) [16] was used to evaluate the degree of motor-function recovery after stroke; it comprised 12 tasks, scored according to a 3-point ordinal scale (0–2; maximal score = 24), and was used to assess the motor function of affected wrists and hands to evaluate movement, reflex and coordination quality. Only the upper limb items of the FMA were used.

All measurement indicators were evaluated 24 h before treatment, 24 h after final treatment and after 4 week follow-up. Change in MAS was defined as the primary endpoint of the study. Secondary endpoint was the comparisons of MTS and other treatment outcomes among the three groups.

Statistical methods

Statistical analyses were performed using SPSS Statistics for Windows (ver. 22.0, SPSS Inc, US). Data were analyzed according to the intention-to-treat principle. Statistical description of MAS was carried out according to numbers (percentages) and median (interquartile range). Secondary indicators were described as the mean (±standard deviation—SD). A Chi-squared test was used to test for changes in clinical efficacy of MAS. Statistical significance was set at a P-value <0.05.

After intervention, changes in primary and secondary indicators among the groups were compared using Friedman analysis, and statistical significance was set at P-value <0.05. The Wilcoxon rank-sum test was used for the post hoc test and the statistical variable was Z. The adjusted P-value by formula calculation was $(1-\alpha_{\text{adjusted}}{}^3 = 0.95)$, so statistical significance was set at a P-value $< \alpha_{\text{adjusted}} = 0.017$ for the post hoc test. Repeated measures ANOVA was used to analyze differences within groups pre- and post-intervention. Values <0.05 were considered statistically significant ($P < 0.05$).

Results

Participant characteristics

Of the 120 patients screened, 86 met the inclusion criteria. In total, 82 cases were used in the statistical analysis. Sample characteristics are presented in Table 1.

Primary outcome

The effective rate of treatment was determined by the changes of MAS. T0, T1 andT2 was the endpoint of baseline 24 h after the fifth intervention and 24 h after 4 weeks follow-up, respectively. Table 2 shows the change of MAS between groups.

After 5 interventions (T1–T0), scores were compared and a significant difference was found among the three groups ($\chi^2_{0.05} = 19.01, P < 0.01$). In Group B, 7.4% of participants achieved CR, 63% achieved PR and 29.6% achieved NR, and the effective rate of the group was 70.4%. Comparatively, in Group C, 3.3% of patients achieved CR, 60% achieved PR and 36.7% achieved NR, and the effective rate of Group C was 63.3%.

After 4 weeks follow-up (T2–T0), comparison between groups showed a statistically significant difference remained among the three groups ($\chi^2_{0.05} = 16.703$, $P < 0.01$). Among the patients in Group B, 7.4% reached CR, 66.7% reached PR, 25.9% reached NR and the total effective rate was 74.1%. Among the patients in Group C, 6.7% reached CR, 60.0% reached PR and 33.3% reached NR, and the effective rate was 66.7%.

Secondary outcomes

Comparison within groups showed that all of the secondary indicators in each group changed significantly ($P < 0.01$) except the VAS in Group A and SS in Groups B and C (Table 3). After 5interventions (T1-T0), a comparison between groups showed that all secondary indicators were significantly different ($P < 0.01$), excepting FMA and SS scores. The post-hoc test showed that Group A was significantly different from Group B for R1, R2 and VAS ($P < 0.01$). Comparison between Group A and Group C also revealed the same results ($P < 0.01$).

After 4 weeks follow-up (T2–T), comparison between all groups revealed an R1 angle and VAS scores well all significantly different ($P < 0.01$). The post hoc test showed

Table 1. Baseline characteristics of three groups

	Group A	Group B	Group C	Statistical significance
Participants, *n*	25	27	30	—
Age (years), mean (SD)	61 (±13)	65 (±10)	61 (±12)	—
Gender, *n* (%)				
male	22 (88)	20 (74)	21 (70)	—
female	3 (12)	7 (26)	9 (30)	—
Course disease, *n* (%)				
≤30d	1 (4)	3 (11)	1 (3)	—
>30d, ≤90d	11 (44)	9 (33)	17 (57)	—
>90d, ≤180d	9 (36)	9 (33)	9 (30)	—
>180d	4 (16)	6 (22)	3 (10)	—
Diagnosis, *n* (%)				
Cerebral infarction	20 (80)	24 (89)	22 (73)	—
Cerebral hemorrhage	5 (20)	3 (11)	8 (27)	—
Side of stoke, *n* (%)				
Left	16 (64)	20 (74)	15 (50)	—
Right	9 (36)	7 (26)	15 (50)	—
MAS, median (IQR)	2 (1–2)	2 (1–2)	2 (1.75–2)	—
MTS-R1, mean (SD)	119.9 (±17.2)	114.8 (±14.3)	118.0 (±12.7)	—
MTS-R2, mean (SD)	151.8(±18.5)	154.4(±19.9)	152.6(±21.4)	—
FMA, mean (SD)	12.5 (±10.9)	10.1 (±5.6)	14.1 (±12.6)	—
VAS, mean (SD)	0.7 (±1.0)	2.5 (±1.4)	2.2 (±1.4)	—
SS, mean (SD)	1.7 (±0.9)	0.9 (±0.8)	1.3 (±0.8)	—

SS, swelling score; IQR, Interquartile Range; –, there were no statistical differences, $P > 0.05$.

Table 2. Comparison of change of MAS

Group	T_1–T_0, *n* (%)						T_2–T_0, *n* (%)					
	CR	PR	NR	Total	Effective rate (%)	Statistical significance	CR	PR	NR	Total	Effective rate (%)	Statistical significance
Group A	1 (4.0%)	3 (12.0%)	21 (84.0%)	25	16.0	**	2 (8.0%)	4 (16.0%)	19 (76.0%)	25	24.0	**
Group B	2 (7.4%)	17 (63.0%)	8 (29.6%)	27	70.4		2 (7.4%)	18 (66.7%)	7 (25.9%)	27	74.1	
Group C	1 (3.3%)	18 (60.0%)	11 (36.7%)	30	63.3		2 (6.7%)	18 (60.0%)	10 (33.3%)	30	66.7	
Total	4 (4.9%)	38 (46.3%)	40 (48.8%)	82	51.2		6 (7.3%)	40 (48.8%)	36 (43.9%)	82	56.1	

T_0, baseline test; T_1, testat 24 h after the fifth intervention; T_2, test at 24 h after 4 weeks follow-up; CR—if the original level degrades ≥2 or reduces to level of 0; PR—if the original level degrades1; NR—if the original level does not change or upgrades; **, there were statistical differences among the three groups, $P < 0.01$.

that Group A was significantly different from Group B and Group C, respectively ($P < 0.01$).

Discussion

The present study used evidence-based medicine to investigate the clinical effects of rESWT on improving hemiplegia spasticity after stroke, and to evaluate comprehensively any benefits to overall function. Our results confirmed that rESWT could reduce upper extremity flexor spasticity after stroke when applied to agonist or antagonist muscles.

Spasticity after stroke include muscle hypertonia caused by damage to the central nervous system, and the viscoelasticity of soft tissue around the joint affected by a constant flexed position [17]. MAS and MTS are the most commonly used clinical tools for assessing spasticity. MAS provides a qualitative rating of spasticity [10], while MTS also includes quantitative measurements [13]. Statistically significant MAS score improvements were achieved for both agonist and antagonist muscles after 5rESWT treatments, and the efficiency of agonist group was superior to the antagonist group. After 4 weeks follow-up, the change in MAS was still evident in the rESWT groups. Regarding validity [18] and reliability [19], MTS is better than MAS in assessing spasticity. MTS is comprised of two measurements: R1 and R2. Accordingly, R2 only represents the mechanical resistance of soft tissue viscoelasticity, while R1 represents the summation of both mechanical resistance and dynamic spasticity. Statistically significant improvements in R1 and R2 for both agonistic and antagonistic muscles were seen after 5rESWT treatments. After 4 weeks of follow-up, the angle of R1 in the rESWT groups significantly increased compared with baseline, while the angle of R2 remained unchanged. One possible reason is that rESWT improved the spasticity of agonistic muscles and also alleviated the viscoelasticity of the elbow. After stopping treatment for 4 weeks, the viscoelastic effect on soft tissue gradually diminished, but the

Table 3. Between and within groups differences in secondary outcomes

Variables	Group A	Group B	Group C	Friedman test $P < 0.05$		Post hoc test-Wilcoxon rank-sum test ($P < \alpha_{adjusted} = 0.017$)					
				$\chi 2$	*P*-value	Group A versus Group B		Group A versus Group C		Group B versus Group C	
						Z	*P*-value	*Z*	*P*-value	*Z*	*P*-value
MTS-R1, mean (SD)											
T_0	119.9 (17.2)	114.8 (14.3)	118.0 (12.7)								
T_1	128.7 (22.2)	149.2 (15.9)	141.7 (17.6)								
T_2	127.4(20.2)	140.9(16.4)	139.8(21.5)								
F	4.959	139.40	59.665								
P-value	0.011	<0.01	<0.01								
T_1–T_0	8.9 (14.1)	34.4 (13.0)	23.7 (11.3)	28.542	<0.01	−4.171	<0.01	−3.148	0.001	−3.148	0.002
T_2–T_0	3.6 (15.7)	26.1 (12.5)	21.8 (14.3)	25.717	<0.01	−4.129	<0.01	−3.405	0.001	−1.202	0.229
MTS-R2, mean (SD)											
T_0	151.8 (18.5)	154.4 (19.9)	152.6 (21.4)								
T_1	157.5 (19.1)	171.3 (12.0)	166.6 (16.5)								
T_2	156.1 (18.4)	167.2 (14.8)	164.1 (18.0)								
F	6.192	30.404	24.078								
P-value	<0.01	<0.01	<0.01								
T_1–T_0	5.7 (5.3)	16.9 (13.7)	14 (12.3)	12.327	<0.01	−3.527	<0.01	−2.496	0.013	−0.356	0.722
T_2–T_0	4.3 (10.5)	12.8 (12.5)	11.5 (13.1)	5.596	0.061						
FMA, mean (SD)											
T_0	12.5 (10.9)	10.1 (5.6)	14.1 (12.6)								
T_1	12.9 (11.1)	11.1 (6.4)	14.4 (12.6)								
T_2	22.3 (15.5)	18.5 (7.0)	20.3 (13.2)								
F	41.442	58.861	94.902								
P-value	<0.01	<0.01	<0.01								
T_1–T_0	0.4 (1.0)	1 (2.9)	0.3 (1.2)	0.792	0.673						
T_2–T_0	9.8 (7.5)	8.4 (5.1)	6.2 (3.5)	3.771	0.152						
VAS, mean (SD)											
T_0	0.7 (1.0)	2.5 (1.4)	2.2 (1.4)								
T_1	0.6 (1.0)	0.7 (0.8)	1.0 (0.9)								
T_2	0.4 (0.8)	0.3 (0.5)	0.6 (0.9)								
F	1.513	61.180	33.033								
P-value	0.231	<0.01	<0.01								
T_1–T_0	−0.04 (0.2)	−1.7 (1.2)	−1.2 (1.1)	26.385	<0.01	−4.003	<0.01	−3.535	<0.01	−2.005	0.045
T_2–T_0	−0.3 (1.1)	−2.1 (1.2)	−1.6 (1.4)	25.683	<0.01	−4.064	<0.01	−3.114	0.002	−1.466	0.143
SS, mean (SD)											
T_0	1.7 (0.9)	0.9 (0.8)	1.3 (0.8)								
T_1	1.5 (0.8)	0 (0.7)	1.3 (0.7)								
T_2	1.3 (0.8)	0.7 (0.6)	1.3 (0.7)								
F	5.226	1.711	0								
P-value	<0.01	0.191	/								
T_1–T_0	−0.2 (0.5)	−0.2 (0.6)	0 (0.7)	1.660	0.436						
T_2–T_0	−0.4 (0.8)	−0.2 (0.6)	0 (0.7)	4.277	0.118						

SS, swelling score; T_0, baseline test; T_1, test at 24h after the fifth intervention; T_2, test at 24h after 4 weeks follow-up.

relief of hypertonia induced by the central nervous system persisted. The improvement of R1 was consistent with that of MAS.

In accordance with the literature [20], rESWT has an up-to 4-week effect on spasticity; accordingly, a 4-week follow-up period was adopted and our study supports the conclusion that there are lasting effects. The duration of action of rESWT remains controversial. This is possibly due to the varying actions of rESWT on different muscles, the number of applications, the applied site and the characteristics of the subjects.

Studies [18,19] have reported a range of pain types in stroke patients, including complex regional-pain syndromes [21], caused by spasticity. Our findings show that rESWT on agonistic or antagonistic muscles groups relieved pain after five treatments, and that this pain relief remained after 4 weeks follow-up. The downward trend was consistent with the remission of muscle spasticity in patients. Pain reduction is potentially attributable to mechanical stimulation of rESWT, which reduces tissue-inflammation and, therefore, reduced nociceptor activation among the affected muscles and tendons [22, 23].

We found no changes in FMA and SS scores among the three groups. Spasticity can increase blood circulation, which is good for turgid limbs, while improved hypertonia does not lead to less swelling [24]. It should be noted that the benefit of rESWT on overall upper limb function among stroke patients was not definitively established. This may be related to the fact that the course of treatment was not long enough.

Our study has several limitations. First, the follow-up time should be appropriately extended in a future experimental. Second, most observation indicators were used scales, so electrophysiological examination may be considered in future experiments to explore the mechanism of rESWT in relieving spasticity. Finally, the number of sessions, the intensity of treatment and application locations all may affect the treatment results [25], and thus optimal treatment conditions are worthy of further investigation.

Supplementary data

Supplementary data mentioned in the text are available to subscribers in Age and Ageing online.

Declaration of Conflicts of Interest: None.

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Trial registration: Chinese Clinical Trial Registry: ChiCTR-INR-16007917; registered 14 February 2016, http://www.chictr.org.cn/edit.aspx.

Ethical approval: This study was implemented according to the Declaration of Helsinki, Good Clinical practice guidelines and the Consolidated Standards of Reporting Trials. This study was approved by the Ethics Committee of Shanghai Xuhui Central Hospital, Shanghai (reference: 2015–34).

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