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Investigation of the efficacy of extracorporeal shock wave therapy in post-stroke patients on spasticity, functionality and range of motion: a randomized controlled trial

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Abstract

Background & Objective: Spasticity is among the most frequent and most serious symptoms requiring treatment in stroke patients. The aim of this trial was to determine the effects of extracorporeal shock wave therapy (ESWT) on spasticity and upper extremity function in stroke patients. *Methods:* A total of 48 stroke patients, each having experienced a stroke at least 6 months prior, were randomly assigned to two groups: the control group (n=24) and the ESWT group (n=24). Patients in the control group received only a conventional treatment program, while those in the ESWT group received radial ESWT (rESWT) in addition to the conventional treatment. Both groups underwent treatment sessions twice a week for two weeks. Spasticity severity, upper extremity functionality, and range of motion were evaluated both before and after treatment. *Results:* Statistically significant improvements were observed in spasticity severity, upper extremity functionality, and range of motion values in both groups after treatment ($p<0.05$). However, the groups were not superior to each other ($p>0.05$).
Conclusion: Based on the results of the study, we concluded that adding rESWT to conventional treatment did not contribute to greater improvement in upper limb spasticity and functionality in stroke patients.

Keywords: Spasticity, stroke, functionality, extracorporeal shock wave therapy

INTRODUCTION

A stroke is described as an acute neurological disorder of vascular etiology, the symptoms of which vary depending on the region of the brain affected.[1] It often disrupts sensory-motor networks and descending pathways, leading to diverse manifestations of upper motor neuron syndrome.[2] Among these symptoms, post-stroke spasticity is the most prominent, often accompanied by other signs such as, weakness, spastic co-contractions, loss of selective motor control, lack of coordination, slowed movements and impaired dexterity. Spasticity is the result of abnormalities in the way that normal sensory input is processed by the spinal cord.[3] Spasticity is typically characterised by a speed-dependent increase in muscle tone and resistance to passive stretching of the muscle. It involves both neural components, such as increased reflex activity, and non-neural components, such as changes in viscoelastic properties due to immobilization.[4,5] Estimates of the incidence of spasticity range from 25% to 43% at six months after stroke.[4]

Management of spasticity includes both invasive and non-invasive methods, encompassing various functional neurorehabilitation modalities.[6] One such non-invasive treatment is extracorporeal shock wave therapy (ESWT), which involves the application of an acoustic pulse with high peak pressure and a brief duration.[7] ESWT can be classified into two types. Focused ESWT is generated by piezoelectric, electromagnetic, or electrohydraulic shockwave generators, while radial ESWT (rESWT) is provided by a pneumatic device integrated within the generator.[8]

Basic research has demonstrated the efficacy of ESWT in the treatment of tendon and other musculoskeletal disorders.[9] The sonic impulse of ESWT appears to have a distinct effect on muscle spasticity compared to conventional vibratory stimulation.[10] In addition to its vibratory

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effects, the sonic impulse can stimulate both non-enzymatic and enzymatic nitric oxide synthesis, which plays a critical role in neuromuscular junction formation, neurotransmission, and synaptic plasticity.[11]

Several studies in the literature have examined the effectiveness of ESWT following stroke. These studies show ESWT to be effective in decreasing spasticity and improving ROMs, but have some methodological limitations.[11-13] For instance, questions remain regarding the optimal type of ESWT for specific spastic muscles, the appropriate dosage, and the duration of treatment. Consequently, there is a need for more high-quality trials to further investigate this treatment modality, which is commonly utilized for managing spasticity in stroke patients. In this regard, the aim of this study is to evaluate the effectiveness of ESWT in combination with conventional treatment on spasticity severity, upper extremity functionality (UEF) and ROM in stroke patients.

METHODS

Study design

Conducted in a rehabilitation centre for the disabled, the study design was a randomised 1:1 parallel group trial. The study protocol had Waset ethics committee approval (No: 322). Written and verbal informed consent was obtained from all participants prior to enrolment. The study was administered in adherence to the tenets of the Declaration of Helsinki.

Participants

The participants of this study were patients diagnosed with stroke by a specialist neurologist and referred to a rehabilitation center for treatment. The inclusion criteria were patients aged 50–80 years who were diagnosed with stroke at least six months ago, had a first stroke, had spasticity in the elbow and wrist flexor muscles (i.e., biceps brachii and flexor carpi radialis), had stable vital signs, had a mini-mental status score ≥ 24, had a fixed dosage of drugs used in the treatment of spasticity, and had an upper extremity score of at least 1+ according to the Modified Ashworth Scale (MAS).[14,15] These muscles were selected because they are commonly involved in post-stroke upper extremity spasticity and represent the primary elbow and wrist flexors. Patients who received Botox treatment, underwent upper extremity surgery, had an additional neurological disorder, were included in another treatment program, and for whom ESWT was contraindicated (presence of a pacemaker, pregnancy, open wounds, large vessel and nerve involvement, and joint replacements) were excluded from the study.

Interventions

Participants in both groups received supervised conventional treatment for 2 weeks, 5 sessions per week for approximately 1 hour. The control group (CG) received only conventional treatment, while the ESWT group (EG) received rESWT in addition to conventional treatment.

In this study, a conventional treatment program was applied to both groups for two weeks, 5 sessions per week under the supervision of a physiotherapist. The conventional treatment program consisted of stretching, range of motion, strengthening, and balance-coordination exercises. Stretching exercises targeted the major upper extremity flexor and extensor muscle groups and were performed in a slow, sustained manner for 20–30 seconds, repeated three times. Range of motion exercises included both active-assisted and active movements of the shoulder, elbow, and wrist joints, performed within the pain-free range. Strengthening exercises focused on proximal and distal muscles of the upper extremity, beginning with low resistance (e.g., using light weights or elastic bands) and progressed gradually by increasing resistance or repetitions according to the patient's tolerance. Balance and coordination exercises included seated and standing activities such as reaching tasks, weight shifting, and functional task practice. All exercises were performed in two sets of 10 repetitions, and the principle of progression was applied by increasing the difficulty level, resistance, or number of repetitions once the patient was able to complete the exercises with proper form and without fatigue.[16]

Participants in EG received rESWT in addition to conventional treatment. rESWT was applied for two weeks, two sessions per week. rESWT was performed with the patient lying supine in a comfortable position with the affected limb in the supination position. The rESWT was applied when the upper extremity joints were in their longest position. The characteristics of the applied rESWT were 3000 pulses, 3 bar, and 5 Hz. The probe of the ESWT was placed on the flexor carpi radialis and biceps brachii muscles of the affected extremity and applied with the help of a conductive gel.[14,15,17]

Outcome measurements

Socio-demographic data were collected by face-to-face interview. Spasticity severity, UEF, and ROM were assessed by the same researcher who conducted the interview. Outcome assessment for both groups was performed by an expert physiotherapist before and 2 weeks after the start of treatment.

Primary outcome

Severity of spasticity

In this study, the severity of spasticity in the elbow and radiocarpal joints of stroke patients was evaluated using the MAS, a five-point scale ranging from 0 to 4. A score of 0 indicates no increase in muscle tone, while a score of 4 signifies complete rigidity of the affected limb during flexion or extension. The MAS score is determined by assessing the degree and location of resistance encountered during manual muscle stretching, providing a measure of muscle tension in the upper limbs of stroke patients. Lower scores indicate reduced spasticity.[18]

Secondary outcomes

Functionality of upper extremity

In our study, UEF status of stroke patients was evaluated using the Fugl-Meyer Assessment Scale (FMAS). The FMAS is a quantitative disability index that measures sensorimotor recovery after stroke, based on Twitchel and Brunnstrom's concept of the stages of motor recovery. This scale assesses five domains, including motor function, balance, sensation, ROM, and pain. In our study, joint pain, passive joint motion, motor, and sensation subscales of FMAS for the upper extremity were used. The items in the scale are scored between 0 (not performing) and 2 (fully performing).[19]

Range of motion

ROM measurements of the affected side shoulder, elbow, and wrist were performed using a universal goniometer. The measurements were repeated three times, and the mean value was taken as the basis. Active ROM was evaluated in all measurements by considering Kendall-McCreary criteria.[20]

Sample size

In this study, the primary outcome was defined as spasticity severity assessed by the MAS. Therefore, the sample size calculation was based on the expected within-group change in MAS scores. Previous clinical studies have suggested that a decrease in MAS of approximately 0.5–1.0 points can be considered clinically meaningful in post-stroke populations.[21-23] Considering our participants' baseline data (SD $\approx$ 0.9) and a conservative expected difference of $\Delta = 0.7$ points between groups, the sample size was calculated. With $\alpha = 0.05$ (two-sided) and 80% power ($\beta = 0.20$), this suggests a minimum of 26 participants per group. Our final sample included 24 participants per group (n = 48), providing sufficient power to detect differences of $\geq$0.73 MAS points.

Randomization and blinding

Randomization was performed for 48 stroke patients. The random allocation sequence with stratification by age and gender was generated using ResearchRandomizer.org by an independent researcher who was not involved in recruitment or assessment.[24] Sequentially numbered, opaque, sealed envelopes were then prepared according to this sequence to ensure allocation concealment, and envelopes were opened only after baseline assessments had been completed. Participants were assigned into two groups as EG and CG. Before treatment and after 2 weeks of treatment, all assessments were performed by the same investigator. In this study, both the intervention and the outcome assessments were conducted by the same physiotherapist; therefore, blinding of the assessor was not feasible.

Statistical analysis

The statistical analyses were carried out using IBM SPSS for Windows (version 28). Categorical variables are presented as frequencies and proportions, whereas numeric variables are presented as means and standard deviations. Chi-square test and independent t-test were used for comparison between CG and EG. Categorical variables were compared using chi-squared test, while numerical variables were compared using independent t-test. Two-way mixed design repeated measures analysis of variance (ANOVA) was used for the assessment of group differences over time and the interaction between group and time. Statistical significance was defined as a p-value <0.05.

RESULTS

Of the 60 stroke patients admitted to our centre between July and November 2022, 48 were included in the study and 12 were excluded. Twenty-four patients in each group were randomly assigned to either the CG or the EG if they met the inclusion criteria. The study was completed with all patients having participated and complied. Figure 1 illustrates this process.

The demographic and clinical characteristics of the stroke patients before treatment are shown in Table 1. Regarding the characteristics of the groups, no significant difference was found between the groups ($p>0.05$).

Comparisons between and within groups of FMAS, MAS and ROM measurements before and after treatment are shown in Table 2. In both groups, there was a statistically significant improvement in all FMASs, a reduction in all MASs and an improvement in all ROMs after treatment ($p<0.05$). There was no significant superiority between the groups when group by time interaction was considered ($p>0.05$). When examining the effect sizes obtained in Table 2, the motor function ($\eta^2=0.005$) and sensation ($\eta^2=0.003$) sub-parameters of the FMAS show very small effect sizes. FMAS passive joint movement ($\eta^2=0.056$) and joint pain ($\eta^2=0.023$) have a small effect. Looking at the MAS results, biceps flexion ($\eta^2=0.059$) has a small effect size, while wrist flexion ($\eta^2=0.076$) shows an effect size approaching small to medium. In ROM parameters, shoulder flexion ($\eta^2=0.029$) has a small effect, shoulder external rotation ($\eta^2=0.005$), shoulder abduction ($\eta^2=0.011$), elbow flexion ($\eta^2=0.006$), elbow extension ($\eta^2=0.006$), wrist flexion ($\eta^2=0.002$), and wrist extension ($\eta^2=0.006$) showed very small effect sizes.

DISCUSSION

In this study, the efficacy of ESWT applied in addition to conventional treatment on the severity of spasticity, UEF, and ROM in stroke patients with spasticity in the wrist and elbow flexor muscles was investigated. According to the study findings, there were significant improvements in all parameters both in the group receiving conventional treatment alone and in the group receiving ESWT in addition to conventional treatment. In addition, there was no statistically significant superiority of the improvements between the groups.

Spasticity is a prevalent issue among individuals who have experienced a stroke. It is

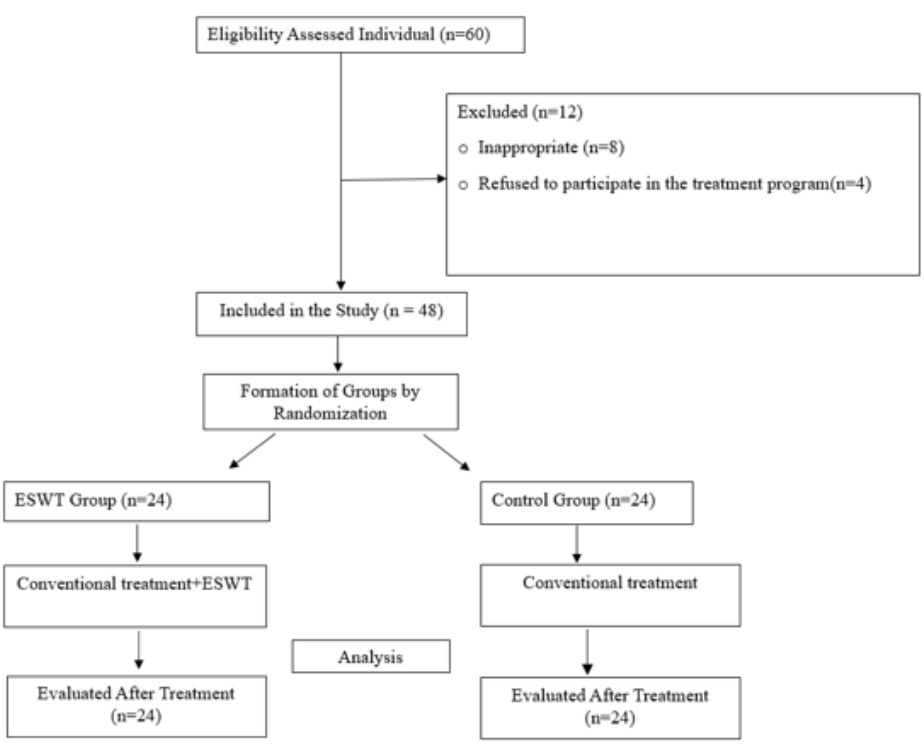

Figure 1. Flowchart of the study

Table 1: Participant characteristics (n=48)

		CG (n=24)		EG (n=24)		p
		N	%	N	%	
Gender	Male	20	83.3	16	66.7	0.182
	Female	4	16.7	8	33.3	
Stroke type	Hemorrhagic	14	58.3	14	58.3	1.000
	Ischemic	10	41.7	10	41.7	
Affected side	Right	13	54.2	14	58.3	0.999
	Left	11	45.8	10	41.7	
Hand dominance	Left	1	4.2	2	8.3	0.999
	Right	23	95.8	22	91.7	
		Mean	**SD**	**Mean**	**SD**	
Age (years)		59.21	5.71	59.96	5.45	0.644
Height (cm)		171.92	7.42	169.83	6.34	0.301
Weight (kg)		81.08	10.29	82.58	9.74	0.606
BMI (kg/m²)		27.41	2.84	28.59	2.65	0.144

CG: Control group, EG: ESWT group, SD: Standard deviation, BMI: Body Mass Index, *p < 0.05.

Table 2: Comparison of FMAS, MAS, and ROM values of the CG and EG groups before and after treatment

		CG		EG		P[1]		
		BT (Mean±SD)	AT (Mean±SD)	BT (Mean±SD)	AT (Mean±SD)	Time	Group* Time	η^2
FMAS (score)	**Motor function**	22.79±9.79	24.29±9.99	24.96±13.90	27.17±14.64	**0.014***	0.626	0.005
	Sensation	8.83±2.036	9.83±1.761	8.08±3.189	9.25±2.418	**<0.001***	0.707	0.003
	Passive joint motion	17.63±4.00	18.83±3.57	16.38±3.94	18.42±3.93	**<0.001***	0.106	0.056
	Joint pain	10.50±4.21	11.42±4.06	11.38±4.38	12.96±4.50	**<0.001***	0.305	0.023
MAS (score)	**Biceps flexion**	1.88±0.90	1.67±0.76	2.04±0.95	1.58±0.72	**<0.001***	0.096	0.059
	Wrist flexion	1.79±0.66	1.63±0.65	1.83±0.82	1.42±0.72	**<0.001***	0.059	0.076
ROM (°)	**Shoulder flexion**	31.04±24.58	33.33±25.40	45.83±45.48	50.83±46.38	**0.003***	0.251	0.029
	Shoulder external rotation	7.29±7.22	7.92±7.36	7.29±8.72	7.71±9.55	**0.025***	0.645	0.005
	Shoulder abduction	10.63±9.59	12.29±9.89	26.67±31.75	28.96±32.17	**<0.001***	0.484	0.011
	Elbow flexion	86.88±33.36	92.92±32.63	91.25±34.77	99.38±36.10	**<0.001***	0.605	0.006
	Elbow extension	9.17±8.43	7.71±8.07	6.88±7.78	4.79±6.16	**0.003***	0.587	0.006
	Wrist flexion	18.96±14.82	22.08±16.01	22.71±16.15	25.42±16.48	**<0.001***	0.737	0.002
	Wrist extension	13.33±13.88	15.00±14.89	13.54±14.41	14.79±15.21	**<0.001***	0.737	0.006

CG: Control group, EG: ESWT group, BT: Before treatment, AT: After treatment, SD: Standard deviation, FMAS: Fugl-Meyer Assessment Scale, MAS: Modified Ashworth Scale, ROM: Range of motion, p[1]: Two-way mixed design repeated measures ANOVA, η^2: effect size, *p < 0.05.

defined as an increase in muscle tone following passive stretching, with the extent of this increase being dependent on the speed of stretching. This phenomenon results from supraspinal disinhibition of the stretch reflexes. ESWT is increasingly utilized in the rehabilitation of post-stroke spasticity. However, studies investigating the effectiveness of ESWT in reducing the severity of spasticity remain limited.[3]

Li *et al*.[21] investigated the effectiveness of rESWT in patients with chronic stroke. In the results of this study, they reported that rESWT was effective in reducing the severity of hand and wrist spasticity. They also concluded that 3 sessions of rESWT were more effective than a single session, and the effects lasted longer.[21] Park *et al*.[22] investigated the effect of ESWT twice a week for 8 weeks and sham ESWT on upper extremity spasticity in chronic stroke patients. As a result of the study, the severity of spasticity decreased in both groups, but the improvement in the ESWT group was significantly better.[22] Leng *et al*.[23] examined both neural and peripheral components of upper extremity muscles in patients with first-time stroke by applying one session of rESWT and conventional treatment to the study group and only conventional treatment to the control group. As a result of the study, they reported significant improvements in the severity of spasticity immediately and 1 week after the ESWT intervention.[23] In another study, Radinmehr *et al*.[25] concluded that rESWT was effective in reducing plantar flexor spasticity. In our study, we concluded that there were significant improvements in the severity of spasticity in both EG and CG; however, no statistically significant superiority was found between the groups. The absence of a significant difference between the groups may be attributed to the effectiveness of conventional rehabilitation itself, which is known to reduce spasticity, potentially masking the additional effect of ESWT. Moreover, the relatively short treatment duration (2 weeks) and the limited sample size might have prevented smaller intergroup differences from reaching statistical significance.

UEF in stroke patients is critical for performing activities of daily living and needs to be addressed in treatment. FMAS is frequently used to examine UEF status in stroke patients. Trochati *et al*.[26] reported that two sessions of ESWT were effective in reducing muscle tone and improving motor functions in hemiplegia patients in the long term. Li *et al.*[21] reported that 3 sessions of ESWT caused an increase in hand and wrist functionality in patients with chronic stroke. Yuan *et al*.[27] compared the effect of ultrasound-guided stellar ganglion block and ESWT treatment on UEF in ischemic stroke patients and reported that UEF improved in the ESWT group, but the improvement obtained by combining both treatments was greater. Wu *et al.*[28] compared ESWT and botulinum toxin type A treatment in the treatment of the upper extremity after stroke. The trial found that ESWT was at least equivalent to botulinum toxin type A treatment in reducing the severity of spasticity, and that ESWT was more effective in improving wrist and elbow function.[28] In this study, significant improvements in UEF were observed in both EG and CG; however, no statistically significant superiority was found between the groups.

Farah and Sauda[29] treated one group of stroke patients with conventional therapy and placebo ESWT, while the other group received conventional therapy and rESWT. The results of the study demonstrated no improvement in wrist ROM in the placebo ESWT group and a statistically significant improvement in the rESWT group.[29] Taheri *et al*.[30] concluded that three sessions of ESWT application had an immediate effect on ankle ROM in stroke patients, and this effect continued even at the 12th week after treatment. In another study, Kim *et al*.[31] reported that rESWT application for 2 weeks was effective in improving shoulder ROM in stroke patients with subscapularis spasticity. In this study, we observed improvement in ROM in the shoulder, elbow, and wrist in both EG and CG. However, the groups were not superior to each other in terms of post-treatment improvement.

Unlike similar studies in the literature, our study is one of the first in which ESWT was applied with 3000 pulses, 3 bars, and 5 Hz. This protocol was selected because previous studies have reported that these parameters are safe, well-tolerated, and clinically effective in reducing spasticity.[21] In addition, in the literature, ESWT has often been applied to only one muscle, and the range of motion has been analyzed only at the primary joint of that muscle.[32] In our study, however, ESWT was applied to both the biceps brachii and flexor carpi radialis muscles, which are commonly affected in post-stroke upper extremity spasticity.[15] By targeting these two major flexor muscles, we aimed to obtain a more comprehensive effect on upper extremity function and to evaluate all ROM parameters of the shoulder, elbow, and wrist.

The present study has a number of limitations.

Firstly, the duration of the treatment programs in the study was 2 weeks. Secondly, the participants' post-stroke stage was complex; this level may have affected the improvements in treatment. Thirdly, conventional treatment may have masked the effects of ESWT. In this context, we think that future studies should be carried out in a group in which only ESWT is applied in a longer follow-up period.

In conclusion, the present study showed that while both groups improved significantly over time, the addition of rESWT to conventional treatment was not more effective than conventional treatment alone in improving the severity of spasticity and upper extremity function. Furthermore, although no significant short-term benefit was observed in range of motion parameters, future randomized controlled trials with longer follow-up periods are warranted to investigate the potential long-term effects of ESWT in the post-stroke population.

DISCLOSURE

Data availability: The datasets generated are available from the corresponding author on reasonable request.

Competing of interest: None

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