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Clinical evaluation and monitoring of the effect of extracorporeal shockwave therapy in sub-acute and chronic post-stroke spasticity patients

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Abstract

Introduction. To evaluate the efficacy and maintenance of extracorporeal shockwave therapy (ESWT) in sub-acute and chronic post-stroke spasticity patients in the Suez Canal region.

Methods. An interrupted time series study was conducted; 82 patients were recruited in accordance with the defined inclusion and exclusion criteria. They were divided into 2 subgroups depending on the stroke duration: a sub-acute group (35 patients) and a chronic group (47 patients). ESWT was applied over knee and ankle flexor muscle belly with the following setup parameters: energy: 0.068–0.093 mJ/mm; frequency: 5 Hz; number of shots: 1500. Modified Ashworth score, clonus score, 3-minute walk test, range of motion angle of both knee and ankle joint, and Fugl-Meyer Assessment were established at baseline, after the 1st session, and at the 1st, 4th, and 8th week for the 2 groups.

Results. Regarding the sub-acute group, there was a statistically significant improvement in the modified Ashworth score, clonus score, 3-minute walk test, and range of motion angle of both knee and ankle joint after the 1st session and after the 1st week of intervention. The differences were not statistically significant after 4th or 8th week. The chronic group showed no statistically significant improvement after the 1st session or in the 1st, 4th, or 8th week assessment.

Conclusions. ESWT was more effective in treatment of spasticity in patients with sub-acute stroke compared with those with chronic stroke.

Key words: stroke, spasticity, extracorporeal shockwave therapy

Introduction

Cerebrovascular stroke results from interrupting of a blood vessel in the brain vasculature and is commonly manifested by neurologic deficits, either sensory or motor disturbances, with or without cognitive impairment [1, 2], Every year, there are approximately 100,000 stroke incidents in the United Kingdom, with the majority of those patients discharged from hospital with disabilities [3].

Spasticity, reflecting an upper motor neuron lesion, is manifested in 25% of patients with stroke by the end of the 6th week. It is characterized by an increase in muscle tone and/or muscle stiffness, resulting in painful limitation of movement. It can occur in the short-, medium-, or long-term post-stroke period [4], with affection of elbows, wrists, and ankles (79%, 66%, and 66%, respectively) [5].

Despite its favourable effects in the course of the disease, as in supporting the gait and standing posture of the patients, spasticity can lead to dramatical pain and restrictions in various activities of daily living, as well as increase the caregiver burden. So, many therapeutic interventions have been introduced to treat spasticity, including numerous medications, physical modalities, and occupational rehabilitation and self-rehabilitation programs, together with the use of assistive devices; also; surgery has been proposed in certain cases [2].

Recently, extracorporeal shockwave therapy (ESWT) has been reported as a quite safe, non-invasive modality that appears not to induce weakness or unfavourable effects [2, 6]. It is recognized as a sequence of single high peak acoustic pulses, and its 3-dimensional propagation results in a jet stream phenomenon causing tissue cavitation, while energy is transmitted to the target tissue as a consequence of positive pressure reflection [7, 8].

The exact mechanisms of how ESWT improves spasticity have not yet been clearly understood, but several theories have been proposed, as the role of nitric oxide synthesis, which is involved in the formation of neuromuscular junctions in the peripheral nervous system and plays important roles in neurotransmission [9, 10]. Also, ESWT can directly act on the Golgi tendon to suppress the motor nerve excitability, decreasing the stiffness of the connective tissue by directly influencing the fibrous tissue in chronic hypertonic muscles [11, 12]. Furthermore, the impact of mechanical vibrations may play a key role in the treatment of spasticity [13].

The benefit of ESWT in the treatment of spasticity has been proven in a previous meta-analysis and in article reviews over the past decade, showing improvement of baseline modified Ashworth scale (MAS) scores after 5 ESWT sessions [14, 15].

Although several studies discussed the effectiveness of ESWT in the treatment of upper limb and lower limb spasticity, fewer papers referred to comparing the effect of the timing of the intervention applied. In this study, we aimed to evaluate the efficacy and maintenance of ESWT in lower limb spasticity in sub-acute and chronic post-stroke patients.

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Subjects and methods

Patients and study design

All patients were informed about the research steps and had the right to withdraw at any time. The study was conducted as an interrupted time series design (a variant of pretest-posttest) quasi-study in the Physical Medicine and Rehabilitation Department of Suez Canal University Hospitals, Ismailia, in the period between November 2016 and December 2018. We used an independent sample test to make the comparison.

Depending on the effect size of the ESWT, the power and alpha value in our study varied; assuming that the effect size would be moderate = power 0.80, and alpha would equal 0.05, we needed at least 34 participants per group. Overall, 92 patients were recruited in accordance with the defined inclusion and exclusion criteria (listed below) and divided into 2 groups depending on the duration of the stroke: the sub-acute group involved 45 patients with spasticity duration between 2 weeks and 6 months, and the chronic group included 47 patients with spasticity duration exceeding 6 months. A total of 10 participants in the sub-acute group did not complete the protocol over the 8-week period.

Included were well oriented, cooperative patients with good ability to communicate; diagnosed with stroke confirmed radiologically with computerized tomography and/or magnetic resonance imaging; between 2 weeks and 6 months from the onset of the cerebral event for the sub-acute cases and more than 6 months for the chronic group. The exclusion criteria involved severe joint contracture, other peripheral nerve disorders or myopathies, pacemaker candidates, having received injections of botulinum toxin, alcohol, phenol within the previous 3 months, and severe medical problems or orthopaedic disease. Regular medications and rehabilitation programs received by the patients were maintained throughout the study.

Intervention protocol

The sites of ESWT application were marked with the use of ultrasound guidance (1st point: muscle belly of semitendinosus muscle, recognized as the knee flexor; 2nd point: muscle belly of each gastrocnemius muscle and the soleus muscles, recognized as the plantar flexors). ESWT was applied at the 2 points in all patients of the study group in the form of 3 sessions at each site, once weekly. The participants sat relaxed in the prone position. ESWT was applied with the following setup parameters: energy: 0.068–0.093 mJ/mm; frequency: 5 Hz; and the number of shots: 1500, as tolerated by the patient [16].

The clonus score and MAS score were determined as follows: we placed the patient in the supine position, then we moved the knee joint (when evaluating semitendinosus muscle) and ankle joint (when evaluating gastrocnemius muscle and soleus muscles) in maximum flexion and then maximum extension (in 1 second); finally, the knee flexors and ankle flexors were scored from 0 (no increase in muscle tone) to 4 (remarked as rigid in flexion), in accordance with the Bohannon and Smith scoring system [17].

Also, we measured the range of motion (ROM) of the ankle and the knee using a new type 8 inch protractor medical ruler, angle ruler goniometer; the angle was assessed 3 times, and the mean value was calculated by the same physician.

The 3-minute walk test was performed as a measure of self-paced walking ability and functional capacity. The patients were encouraged to walk for 3 minutes as fast and safe as they could with/without the use of their assistive device along a hallway in the rehabilitation department (pre-metered with coloured cones every 1-meter distance). They were instructed to take a period of rest when needed, and 2 walks were practised by each patient before recording the result of the test. The score was calculated as the total distance achieved by the participant measured in meters throughout the 3 minutes [18].

To assess the recovery of motor function, we used Fugl-Meyer Assessment (FMA). The scale includes 5 domains (motor, sensory function, balance, joint ROM, and pain) with a total of 155 items. The score, depending on the ability to perform the task, remained within a 3-point scale (0 = did not perform, 1 = partially performed, and 2 = fully performed), with a net total score of 226. The points were divided among the domains as follows: 66 points for the upper extremity and 34 points for the lower extremity in the motor domain (0 = hemiplegic, 100 = normal); 0–24 points in the sensory domain; 8 points for light touch and 16 points for position sense; 0–14 points (6 points for sitting and 8 points for standing) in the balance domain; 0–44 points for joint ROM; and 0–44 points for joint pain [19, 20].

The above-mentioned parameters were evaluated at baseline, after the 1st session, and at the 1st (after the beginning of the intervention), 4th, and 8th week (a total of 5 evaluations in the 2 groups).

Data were analysed with the Statistical Package for the Social Sciences (SPSS) software for Windows, version 25.0 (SPSS Inc., Chicago, USA). Independent samples *t*-test was applied for comparing quantitative (non-parametric) variables between the 2 groups of patients. A chi-squared test served to compare quantitative data between the groups. Repeated analysis of variance (ANOVA) and analysis of covariance were used to compare the trend of MAS, ROM, clonus score, and 3-minute walk test result between and within the groups. The *p*-value of 0.05 was considered statistically significant.

Ethical approval

The research related to human use has complied with all the relevant national regulations and institutional policies, has followed the tenets of the Declaration of Helsinki, and has been approved by the authors' institutional review board or an equivalent committee.

Informed consent

Informed consent has been obtained from all individuals included in this study.

Results

The mean age of patients was 51.8 ± 13.5 years in the sub-acute group and 52.12 ± 6.80 in the chronic group; 78.04% (64 patients) were men and 21.96% (18 patients) were women in the whole studied population. Table 1 shows the baseline characteristics of the subjects.

Most patients were men, with the majority of them had an ischemic stroke in both the sub-acute and the chronic group. No significant differences were noted between the 2 groups in terms of age, sex, or stroke type ($p > 0.0001$). A total of 35 participants were of the sub-acute type (17 males, 18 females), while 47 patients had a chronic stroke (47 males, 0 females).

In the sub-acute group, the MAS scores for ankle joint flexor muscles were significantly decreased after the 1st session and also after the 1st week ($p = 0.05$). The differences

Table 1. Demographic characteristics and baseline clinical features of the sub-acute and chronic group

General characteristics	Sub-acute group (*n* = 35)	Chronic group (*n* = 47)	*p*
Age (years) (mean ± *SD*)	51.8 ± 13.5	52.12 ± 6.80	
Body mass index (mean ± *SD*)	29.21 ± 1.12	28.57 ± 4.65	
Mean time after stroke onset (months)	3.1 ± 0.33	11.3 ± 7.19	0.000
Stroke subtype (*n* (%)) Ischemic Haemorrhagic	 27 (77.1) 8 (22.8)	 37 (78.7) 10 (21.2)	0.3

Table 2. Clinical assessment in the sub-acute and chronic group

	Sub-acute group					Chronic group				
	Baseline	After 1st session	After 1st week	After 4th week	After 8th week	Baseline	After 1st session	After 1st week	After 4th week	After 8th week
MAS (knee flexors)	2.30 ± 1.08 2.30 (1.08)	1.23 ± 0.8*	1.20 ± 1.05*	1.3 ± 0.7*	1.2 ± 1.51	2.6 ± 0.5	2.2 ± 0.9	2.2 ± 0.6	2.3 ± 0.5	2.5 ± 0.5
MAS (plantar flexors)	3.2 ± 0.6	1.4 ± 0.6*	1.2 ± 0.4*	1.3 ± 0.4*	1.8 ± 0.7	3.2 ± 0.6	2.9 ± 0.7	2.8 ± 0.4	2.5 ± 0.4	2.3 ± 0.7
ROM of ankle joint (°)	20 ± 7	39 ± 6*	40 ± 7*	40 ± 6*	30 ± 8	20 ± 7	47 ± 7*	50 ± 7*	40 ± 6*	40 ± 8*
ROM of knee joint (°)	1.42 ± 0.67	1.33 ± 0.8	1.17 ± 0.58*	1.13 ± 0.49*	1.17 ± 0.58*	80 ± 7	80 ± 7	80 ± 8	81 ± 7	80 ± 7
Clonus score	85 ± 7	100 ± 6*	100 ± 7*	102 ± 5*	103 ± 1	1.12 ± 0.64	1.17 ± 0.62	1.27 ± 0.51	1.4 ± 0.59	1.22 ± 0.50
FMA	20.11 ± 5.54	20.75 ± 2.55	21.38 ± 6.12	21.42 ± 2.10	23.312 ± 5.5*	18.18 ± 3.54	19.75 ± 3.55	20.38 ± 5.12	20.42 ± 4.11	20.32 ± 6.56
3-meter walk duration	25.2 ± 11.5	24.7 ± 12.2	23.6 ± 20.1*	25.1 ± 8.1	20.7 ± 17.4*+	28.2 ± 11.5	27.5 ± 12.1	27.6 ± 11.1	27.1 ± 11.9	27.7 ± 10.4

MAS – modified Ashworth scale, ROM – range of motion, FMA – Fugl-Meyer Assessment
* significant difference vs. baseline, + significant difference vs. the 1st week
Significant difference for $p < 0.001$.

were not statistically significant after the 4th or 8th week of intervention, but the scores also did not increase again compared with the basal evaluation. The 3-minute walk result was improved significantly after the 8th week compared with baseline and the 1st week. Table 2 shows the clinical assessment outcomes. Regarding the knee joint flexor muscles, all the clinical assessment scores were improved immediately after the 1st session and also after the 1st week, but without a significant improvement after the 4th or 8th week (without worsening the scores, too). FMA of the lower limb presented increased values after the 8th week, with a significant difference from baseline.

In the chronic group, the ankle joint flexor muscle MAS scores were decreased after the 1st session of ESWT and also after the 1st week assessment but the differences were not statistically significant; the scores also did not increase again compared with the basal evaluation. The 3-minute walk was not improved significantly compared with baseline or the 1st week assessment. FMA of the lower limb showed increasing values immediately after the 1st session, as well as 4th and 8th week after treatment, with no significant differences from baseline.

Discussion

The purpose of this study was to compare the effects of ESWT on the myotendinous junction at the ankle and knee flexors in sub-acute and chronic stroke patients. As for the sub-acute group, there was a statistically significant improvement in MAS, clonus score, 3-minute walk test, and ROM of both knee and ankle joints after the 1st ESWT session and also after the 1st week of intervention, while the differences were not statistically significant after the 4th or 8th week, but the scores also did not worsen again compared with the baseline evaluation. FMA of the lower limb showed increasing values after 8 weeks of treatment, with a significant difference from baseline. However, the chronic group presented no statistically significant improvement after the 1st session or at the 1st, 4th, or 8th week assessment.

So, we concluded that ESWT was more efficient in the treatment of spasticity in patients with sub-acute stroke compared with those with chronic stroke. This is may be explained by the long duration of spasticity in the chronic stroke group, which may need more sessions to be improved.

These findings were in agreement with research by Moon et al. [7] and Bae et al. [11], who indicated that lower limb spasticity significantly improved after the 1st ESWT session of a series. They explained that the effect of ESWT depended on the mechanisms of the shockwave, numbers of application, and the energy per unit area.

Yoon et al. [16] compared the effect of ESWT applied on the muscle belly and myotendinous junction for spasticity in the upper and lower limbs of chronic stroke patients. They found that MAS and the modified Tardieu score of both the belly and the junction groups showed positive effects after the use of ESWT in spasticity in the elbow and knee flexors, but not in the control group. The results also tended to improve after each session until the entire intervention was completed. However, there was no significant difference between the belly and junction groups.

The mechanisms of how ESWT relieves spasticity have not yet been clearly investigated. Variable mechanisms have been proposed, as the role of nitric oxide synthesis, which is involved in the formation of neuromuscular junctions in the peripheral nervous system and plays important roles in neurotransmission, memories, and synaptic plasticity in the central nervous system [9, 10].

Neuromuscular transmission was initiated by ESWT in neuromuscular junctions [13, 21]; also, shockwaves could directly act on the Golgi tendon to suppress the motor nerve excitability [11] and decrease the stiffness of connective tissue by directly influencing the fibrous tissue in chronic hypertonic muscles [12]. Also the action of mechanical vibrations may play a key role in the treatment of spasticity [13].

Among previous studies on upper limb spasticity, Manganotti and Amelio [22] stimulated the wrist flexor muscle once with 1500 times and 0.030 mJ/mm^2, and the finger flexor muscle once with 800 times and 0.030 mg/mm^2; the effects visible immediately after the treatment were maintained until the 12th week. Bae et al. [11] stimulated the belly and musculotendinous junction of the elbow flexor muscle 3 times with 4 Hz, 1200 shots, and 0.12 mg/mm^2; spasticity was relieved statistically significantly only immediately after the treatment, but the result was not statistically significant at the 1st and 4th week in the ESWT group. The reason for the differences in the results from the 2 studies mentioned earlier was assumed to be the variability in the mechanisms of shockwave generation, energy per unit area, the number of applications, applied site, and duration of patients' illness [11].

Limitations

The current study had several limitations. First, the accurate mechanism of ESWT impact on spasticity was not determined. Second, further studies may be needed to focus on a bigger sample size to evaluate the effect of different doses and session numbers on spasticity and maintenance beyond the 8th week in stroke patients and not to be restricted to the spasticity of the upper limb.

Conclusions

Despite the study limitations, to our knowledge, this is the first research to compare the effect of ESWT in the treatment of sub-acute and chronic types of spasticity. We concluded that the time of the manoeuvre initiation influenced the outcome, which was obvious in the improvement of MAS, FMA, 3-minute walk result, and ROM of the joints in the subacute group. ESWT can be a useful alternative in spasticity treatment because it is non-invasive and involves much fewer adverse effects compared with the existing treatment methods and is effective not only in upper limb spasticity, but also in lower limb spasticity, as identified in the present study.

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Disclosure statement

No author has any financial interest or received any financial benefit from this research.

Conflict of interest

The authors state no conflict of interest.

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