

Effect of Different Radial Shock Wave Therapy Protocols on Spasticity in Patients with Stroke

Khaled Zaki Fouda^{1*}, Rania Galal Eldeen Abdou^{2,3} and Wanees Mohamed Badawy^{3,4}

¹Department of Basic Science for Physical Therapy, Cairo University, Giza, Egypt

²Department of Physical Therapy for Pediatrics, Cairo University, Giza, Egypt

³Department of Physiotherapy, University of Hertfordshire, New Administrative Capital, Egypt

⁴Department of Physical Therapy for Neuromuscular Disorders and its Surgery, Cairo University, Giza, Egypt

Abstract

Background: Spasticity and a number of other medical conditions are treated by Radial Shock Wave Therapy (RSWT).

Objective: The purpose of the study was to compare the therapeutic effect of introducing two different RSWT treatment protocols on reducing spasticity and increasing the range of motion of the upper limb in stroke patients.

Materials and methods: Forty patients with upper limb spasticity post-stroke were randomly assigned into group A, in which patients received RSWT for the agonist muscles only, and group B received RSWT for both agonist and antagonist muscles. All patients had also received a traditional physical therapy program. Spasticity, Range of Motion (ROM) and pain intensity were evaluated pre and post-treatment.

Results: Post-treatment Wilcoxon signed rank test showed a significant reduction in spasticity ($p < 0.001$) for groups, while there was no significant difference ($p > 0.05$) between both groups in spasticity reduction as indicated by Mann Whitney test. Paired t test revealed a significant improvement ($p < 0.001$) in ROM and pain intensity for both groups post treatment. Furthermore, unpaired t test showed a significant difference ($p < 0.001$) between both groups in ROM and pain intensity.

Conclusion: The RSWT protocols used in this study are equally effective in spasticity reduction. However, the stimulation for both agonist and antagonist muscles is more effective protocol than the stimulation for the agonist muscles only in terms of ROM improvement and pain reduction.

Keywords: Shock wave therapy protocols • Spasticity • Stroke • Range of motion • Pain intensity

Introduction

Stroke was classified as one of the main causes of continuing disability in adults in the world. Stroke results in paralysis of one side of the body by which the rate of admissions to the rehabilitation clinics got increased [1,2]. One of the major symptoms emerged from stroke is spasticity which is characterized by an increase in muscle tone as well as exaggerated tendon jerks [3]. Spasticity following stroke is commonly associated with muscle pain, stiffness, and joint contracture which leads to abnormal limb posture that may cause loss of function [4].

Spasticity post-stroke was more often observed in the upper limbs than in the lower limbs with a more severe degree of spasticity in the upper limb muscles [5,6]. It was developed frequently in the elbow (79%), wrist (66%), ankle (66%), and shoulder (58%) [7]. Many therapeutic interventions have been used in the previous studies to decrease spasticity, including botulinum toxin injections, oral anti-spastic drugs, occupational therapy, chemical neurolysis, and various physical therapy modalities [8].

Shock Wave Therapy (SWT) is a new alternative therapeutic tool that has been used for the treatment of different cases of musculoskeletal and neurological conditions [9-17]. Radial SWT has been reported to be a potential therapeutic intervention to reduce spasticity. Previous studies have used either focused SWT or radial SWT and it has been reported that both of them were effective in reduction of spasticity in stroke patients [10-16]. However, radial SWT has been reported to be superior to the focused SWT regarding the values of the ankle range of motion improvement in stroke patients with plantar spasticity [10].

A meta-analysis study by Oh J, et al pointed out the significant effect of SWT in spasticity reduction with 95% confidence interval (CI) [-1.00 to -0.13] immediately following treatment and 95% CI [-3.07 to -0.55] one week after treatment [18]. Moreover, a systematic review by Dymarek et al confirmed the effectiveness of radial SWT in spasticity reduction and improving motor recovery in stroke patients [19].

Radial SWT differs from a traditional focused SWT as it is a pneumatically generated shockwave with low to medium energy level. The energy scattered from the radial SWT through the tipper is not centering the energy to a targeted point. Therefore, their depth of penetration is less than that of focused SWT (up to 3 cm for radial SWT versus 12 cm for focused SWT) [18,19].

The radial SWT is a safe and non-invasive therapeutic tool for the treatment of spasticity. It has potential advantages over-focused SWT because radial SWT has a larger treatment zone where specific focusing is less important, it does not need local anesthesia or analgesic, it is inexpensive and comfortable therapy for spasticity in stroke patients [11, 12,20]. Furthermore, in such patients, radial SWT doesn't cause muscle weakness because it does not affect peripheral nerve excitations [13].

Multiple treatment parameters are important in determining the therapeutic effect of radial SWT which includes; energy level or intensity, frequency, number of shots per session and the total number of the treatment sessions [18]. Moreover, an added important factor in treatment of spasticity which is the effective site for application of radial SWT over the treated muscle whether over the muscle belly or the musculotendinous junction [15].

*Corresponding Author: Khaled Zaki Fouda, Department of Basic Science for Physical Therapy, Cairo University, Giza, Egypt; Email: kzfouda2004@yahoo.com

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All these parameters could create many radial SWT treatment protocols, which is not clearly established in the previous literature and remains an area of debate. The best radial SWT protocol has therefore still to be defined in stroke patients. Furthermore, are the radial SWT intervention should be concentrated on the spastic muscle only, or treating the anti-spastic muscle together would have any clinical advantages in the reduction of spasticity? So, the purpose of this study was to compare the therapeutic effect of introducing two different radial SWT treatment protocols on reducing spasticity and increasing the range of motion of the upper limb in stroke patients.

Materials and Methods

Study design

The research design was a pre-post-test, single-blinded (assessor), randomized clinical trial. Before the beginning of the study, participants had a complete explanation of the study objectives and procedures, and they were asked to sign an informed consent. The study was approved by the relevant Research Ethical Committee (REC) (No: P.T.REC/012/002790). The procedures followed during this study were in accordance with the Declaration of Helsinki and the study was registered at the Pan African Clinical Trial Registry (PACTR202107600672683).

The sample size was calculated before the study. Calculation was performed utilizing G*Power 3.1.9.4. statistical software. The calculations found that the required sample size was N=38, based on an 85% power analysis, a two-sided 5% type I error, and an effect size of 0.50. In anticipation of withdrawal, the sample size was raised to 40 participants.

Participants

Forty patients with upper limb spasticity post-stroke were recruited for the study from the outpatient physical therapy clinic of Shebin El-Kom Teaching Hospital and El-Delta physical therapy center Shebin El-Kom, Egypt. Participants included 23 men (57.5%) and 17 women (42.5%) with a mean age of 56.8 years and a body mass index of 28.6 Kg/m².

The inclusion criteria were as follows: patients suffered from unilateral stroke with hemiparesis for the first time, the duration of illness exceeded six months post-stroke, the grade of spasticity in the elbow and wrist flexors exceeding 1+ on the Modified Ashworth Scale [11,15], all patients were medically stable and had no cognitive disability that hinders in understanding the instructions or responding to the commands. To localize the lesion computed topography and/or magnetic resonance imaging were used. Patients were excluded if the affected upper extremity had severe orthopedic disease, joint contracture, surgical procedures, previous treatment of botulinum toxin or other medications used to reduce spasticity, or has any condition contraindicated for the use of radial SWT.

Randomization

Randomization was conducted by a statistician who was not involved in the data collection used a computer-generated random number list. The block size was set at four to eliminate selection bias and reduce subject variability. To assure the hidden allocation, sealed, sequentially numbered opaque envelopes were employed. The first author opened the envelopes and so administered the treatment in accordance with the group assignment. The outcome measures were gathered by the second author, who was unaware of the group assignment.

Procedures

Eligible patients were randomly assigned into 2 equal groups (n=20) (Figure 1). Group A (agonist muscle stimulation) received radial SWT at wrist and elbow flexors muscles only, while group B (agonist-antagonist muscle stimulation) received radial SWT for both elbow and wrist flexors and extensors muscles respectively. The patient assumed the supine lying position, the elbow flexors muscles were stimulated at the middle of the anterior surface of the arm at the muscle belly, while the extensor muscle of

the elbow was stimulated at the middle of the posterior surface of the arm at the muscle belly. The flexors muscles of the wrist were stimulated at the middle two third of the anterior surface of the forearm at the muscle belly and the forearm is supinated, while the extensors muscles of the wrist were stimulated at the middle two third of the posterior surface of the forearm at the muscle belly and the forearm was pronated.

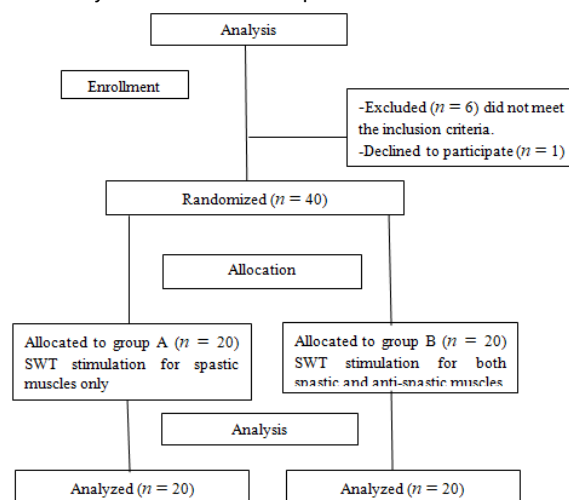


Figure 1. Participants flow chart.

Each group of muscles was stimulated with radial SWT (Model Swiss DolorClast® Master, Electro Medical Systems, SA, Nyon, Switzerland) at the following parameters: (1) the energy level was 0.12 mJ/mm² which equivalent to 2.5 bar intensity, (2) the number of shoots was 1500 for each muscle group, (3) the frequency was 8 Hz [18]. The patients were given only one session of radial SWT per week for 4 weeks. The Evo Blue hand piece which provides constant energy density was used during muscle stimulation.

All patients had also received a traditional physical therapy program for 45 minutes which consisted of proper positioning of the extremities, mobility training, range of motion exercises, standing up and balance training, and training of daily living activities to improve functional status. The traditional physical therapy program was given for 4 weeks, 3 sessions per week, and every other day. All measurements after treatment were recorded immediately after the end of the last radial SWT session.

Outcome measures

Spasticity: Modified Ashworth's Scale (MAS) was used to assess elbow and wrist flexors spasticity at the baseline and 4 weeks immediately after treatment. The patients assumed the supine lying position with a supinated forearm during the evaluation of elbow and wrist flexors spasticity. The MAS is a six points ordinal scale ranging from 0 (normal muscle tone) to 4 (Affected part(s) rigid in flexion or extension). The MAS 1+ was substituted by 2, and 2, 3, and 4 were substituted by 3, 4, and 5, respectively for convenience in the statistical analysis [21]. The MAS was reported as a valid and reliable tool for spasticity evaluation [22,23].

Passive range of motion: Passive range of motion (PROM) of the elbow and wrist joints were evaluated at the baseline and 4 weeks immediately after treatment by using a digital goniometer (Model 12-1027, version 7-08, Fabrication Enterprises, Inc., White Plains, NY, USA). For evaluation of the elbow joint PROM, the patient assumed a supine lying position with supinated forearm and the elbow PROM was measured from the maximum elbow flexion (represent zero point) then moving toward elbow extension. While during the evaluation of the wrist joint PROM, the patient assumed a supine lying position with a pronated forearm and the hand was outside the bed. The wrist joint PROM was measured from the maximum wrist flexion (represent zero point) and moving toward the neutral position then wrist extension, summing up both angles. The digital goniometer was recorded as a valid and reliable tool for ROM evaluation [24].

Pain intensity: Visual Analogue Scale (VAS) was used to assess pain intensity during passive ROM evaluation at the baseline and 4 weeks immediately after treatment. It consists of a line of 10-cm long with two ends; the first showing “no pain” and the other showing “worst pain ever”. The VAS showed good validity and reliability for pain assessment [25].

Statistical analysis: The SPSS (Version 22) for Windows was used to conduct statistical analysis. Means and Standard Deviations (SD) were reported to present patients' characteristics, as well as the outcome variables. Wilcoxon signed rank test and Mann-Whitney U-test were used to compare the effects within and between groups for categorical data. While Dependent t-test and Independent t-test were used to compare the effects within and between groups for continuous data. The significance level was set at $\alpha < 0.05$.

Results

Participants' characteristics of both groups were presented in Table 1. There were no significant differences ($p > 0.05$) between both groups concerning age, weight, height, Body Mass Index (BMI) and duration after stroke onset as indicated by Independent t-test (Table 1).

Table 1. Participants' demographic characteristics.

Variables	Group A (mean \pm SD)	Group B (mean \pm SD)	P
Age (year)	56.70 \pm 2.47	57.05 \pm 2.35	0.65
Weight (kg)	81.85 \pm 4.29	80.45 \pm 2.67	0.32
Height (cm)	168.85 \pm 2.73	167.75 \pm 4.96	0.20
Body mass index (Kg/m ²)	28.71 \pm 1.12	28.62 \pm 1.17	0.79
Duration after stroke onset (months)	9.55 \pm 1.60	10.05 \pm 1.39	0.29
Affected Side (Right/Left)	8/12	7/13	0.74
Sex [Male/Female]	11/9	12/8	0.74
Stroke type [n (%)]			
Ischemic	16 (80)	15 (75)	-----
Hemorrhagic	4 (20)	5 (25)	

Note: $p > 0.05$ indicates no significance, SD: Standard Deviation

Wilcoxon signed rank test revealed that there was a significant reduction ($p < 0.001$) in elbow flexors and wrist flexors spasticity for both groups, when comparing the pre-treatment values versus the post-treatment values for each group as shown in Table 2. Also, the percentage of improvement in elbow flexors and wrist flexors spasticity post-treatment was 49.18% and 41.89% respectively for group A. While, it was 54.83% and 45.83% respectively for group B.

Table 2. Comparing mean values of spasticity pre and post-treatment within groups A and B (Wilcoxon signed rank test).

	Group A (agonist muscle stimulation)			Group B (agonist-antagonist muscle stimulation)		
	Pre-test mean rank \pm SD	Post-test mean rank \pm SD	P	Pre-test mean rank \pm SD	Post-test mean rank \pm SD	P
Elbow flexors spasticity (MAS)	3.05 \pm 0.22	1.55 \pm 0.51	<0.001	3.10 \pm 0.30	1.40 \pm 0.50	<0.001
Wrist flexors spasticity (MAS)	3.70 \pm 0.47	2.15 \pm 0.87	<0.001	3.60 \pm 0.50	1.95 \pm 0.75	<0.001

Note: $p < 0.05$ indicates significance, SD: Standard Deviation of the mean rank, MAS: Modified Ashworth's Scale.

Mann Whitney U-test revealed that there was no significant difference between elbow flexors spasticity values ($p = 0.78$) and wrist flexors spasticity values ($p = 0.58$) at the pre-treatment evaluations when comparing both groups. Also, there was no significant difference between elbow flexors spasticity values ($p = 0.41$) and wrist flexors spasticity values ($p = 0.45$) at the post-treatment evaluations when comparing both groups as shown in Table 3.

Table 3. Comparing mean values of spasticity between both groups at pre- and post- treatment evaluations. (Mann Whitney U-test)

	Pre-treatment			Post-treatment		
	Group A mean rank \pm SD	Group B mean rank \pm SD	P	Group A mean rank \pm SD	Group B mean rank \pm SD	P
Elbow flexors spasticity (MAS)	3.05 \pm 0.22	3.10 \pm 0.30	0.78	1.55 \pm 0.51	1.40 \pm 0.50	0.41
Wrist flexors spasticity (MAS)	3.70 \pm 0.47	3.60 \pm 0.50	0.58	2.15 \pm 0.78	1.95 \pm 0.75	0.45

Note: $p > 0.05$ indicates no significance, SD: Standard Deviation of the mean rank, MAS: Modified Ashworth's Scale.

Dependent t-test revealed that, there was a significant increase ($p < 0.001$) in elbow PROM and wrist PROM for both groups, when comparing the pre-treatment values versus the post-treatment values for each group. Also, there was a significant reduction ($p < 0.001$) in elbow and wrist pain intensity as shown in Table 4.

Table 4. Comparing mean values of passive range of motion and pain intensity pre- and post-treatment within groups A and B (Dependent t-test).

	Group A (agonist muscle stimulation)			Group B (agonist-antagonist muscle stimulation)		
	Pre-test (mean \pm SD)	Post-test (mean \pm SD)	P	Pre-test (mean \pm SD)	Post-test (mean \pm SD)	P
Elbow PROM	64.45 \pm 1.14	94.35 \pm 1.42	<0.001	64.85 \pm 1.30	95.95 \pm 0.88	<0.001
Wrist PROM	51.80 \pm 2.35	73.05 \pm 2.06	<0.001	52.45 \pm 2.01	78.75 \pm 1.55	<0.001
Elbow pain intensity (VAS)	4.79 \pm 0.40	2.70 \pm 0.39	<0.001	4.82 \pm 0.44	2.28 \pm 0.18	<0.001
Wrist pain intensity (VAS)	5.68 \pm 0.30	3.22 \pm 0.21	<0.001	5.59 \pm 0.30	2.60 \pm 0.27	<0.001

Note: $p < 0.05$ indicates significance, SD: Standard Deviation, PROM: Passive Range of Motion, VAS: Visual Analogue Scale.

The percentage of improvement in elbow and wrist PROM post-treatment was 39.02% and 41.89% respectively for group A. While, it was 47.95% and 50.14% respectively for group B. Moreover, the percentage of improvement in elbow and wrist pain intensity post-treatment was 43.36% and 43.30% respectively for group A. While, it was 52.69% and 53.48% respectively for group B.

Independent t-test revealed that there was no significant difference

between elbow PROM values ($p=0.31$) and wrist PROM values ($p=0.35$) at the pre-treatment evaluations when comparing both groups. While there was a significant difference between elbow PROM values ($p<0.001$) and wrist PROM values ($p<0.001$) at the post-treatment evaluations when comparing both groups as shown in Table 5.

Table 5. Comparing mean values of passive range of motion and pain intensity between both groups at pre- treatment and post- treatment evaluations. (Independent t-test).

	Pre-treatment			Post-treatment		
	Group A (mean \pm SD)	Group B (mean \pm SD)	P	Group A (mean \pm SD)	Group B (mean \pm SD)	P
Elbow PROM	64.45 \pm 1.14	64.85 \pm 1.30	0.31	94.35 \pm 1.42	95.95 \pm 0.88	<0.001
Wrist PROM	51.80 \pm 2.35	52.45 \pm 2.01	0.35	73.05 \pm 2.06	78.75 \pm 1.55	<0.001
Elbow pain intensity (VAS)	4.79 \pm 0.40	4.82 \pm 0.44	0.82	2.70 \pm 0.39	2.28 \pm 0.18	<0.001
Wrist pain intensity (VAS)	5.68 \pm 0.30	5.59 \pm 0.30	0.35	3.22 \pm 0.21	2.60 \pm 0.27	<0.001

Note: $p<0.05$ indicates significance, SD: Standard Deviation, PROM: Passive Range of Motion, VAS: Visual Analogue Scale.

Regarding the pain intensity level, there was no significant difference between elbow pain intensity values ($p=0.82$) and wrist pain intensity values ($p=0.35$) at the pre-treatment evaluations when comparing both groups. While there was a significant difference between elbow pain intensity values ($p<0.001$) and wrist pain intensity values ($p<0.001$) at the post-treatment evaluations when comparing both groups as shown in Table 5.

Discussion

Spasticity is a common symptom after stroke, with a prevalence ranging from 30% to 80% of stroke patients [26,27]. Therefore, the present study was conducted to compare the therapeutic effect of introducing two different radial SWT treatment protocols on reducing spasticity and increasing the range of motion of the upper limb in stroke patients.

Results of the present study revealed that there was a significant decrease of spasticity in both groups post-treatment with radial SWT which was given in addition to a traditional physical therapy program. While, there was no significant difference between the agonist muscle stimulation group and agonist-antagonist muscle stimulation group. Results of this study confirmed the results of other previous studies about the efficacy of radial SWT on reducing spasticity [11-17,21].

Regarding the values of the passive range of motion, results of the current study demonstrated a significant increase in the values of the PROM of the wrist and elbow joints for both groups post treatment. Moreover, there was a higher statistically significant improvement in the values of the PROM of the wrist and elbow joints in the agonist-antagonist muscle stimulation group in comparison to the agonist muscle stimulation group. These findings come in agreement with other previous studies that indicated improvement in the PROM values following treatment with RSWT in stroke patients [10-12,28].

Concerning the pain intensity level that experienced during evaluation of the PROM, results of this study showed a significant decrease in the pain intensity level at the wrist and elbow joints during evaluation of the PROM for both groups after treatment. Furthermore, there was a higher statistically significant reduction in the pain intensity level at the wrist and elbow joints in the agonist-antagonist muscle stimulation group in comparison to the agonist muscle stimulation group. These results come in accordance with

other previous studies which reported a reduction of pain intensity level post-treatment with radial SWT in patients affected by stroke [11,12,29].

The mechanisms of spasticity reduction by SWT are still unclear. However, variable proposed mechanisms have been introduced in the literature, such as stimulation of nitric oxides synthesis, which is involved in neurotransmission and neuromuscular junction formation in the peripheral nervous system [30,31]. Also, SWT could induce a neuromuscular transmission inhibitory effect like botulinum toxin but without muscle weakness [32], stimulates axonal regeneration [33], and induces neurogenesis via stimulating proliferation of neural stem cells [34,35].

Non-reflex component of spasticity, which occurs due to muscle contracture, could lead to changes in the mechanical properties of the muscles and could increase the connective tissue proportion in the muscle [4]. These soft tissues changes lead to more excitability of the muscle spindle and increases spasticity [36]. So, SWT could reduce the stiffness of the connective tissue, which is caused by fibrosis of the chronic hypertonic muscles leading to reduction of spasticity [37].

The improvement in the values of the PROM could be attributed to the decreased spasticity and pain intensity that occurred post treatment. Spasticity is one of the contributing factors, which leads to the development of pain in stroke patients [26]. So, reduced level of spasticity can lead to the reduction of pain intensity level. Furthermore, increased microcirculation and metabolic activities within the treated tissues by SWT [38], the anti-inflammatory effects mediated by SWT via decreasing the level of substance P inside the tissues [39], and induction of nitric oxides synthesis by SWT can increase muscle and tendon neovascularization, which decreases muscle resistance [31]. All these factors could decrease the pain intensity level.

The results of the present study pointed out that the agonist-antagonist muscle stimulation protocol of radial SWT was superior to the agonist muscle stimulation protocol of radial SWT regarding the improvement that occurred in PROM and pain intensity level over the elbow and wrist joints. While, the experimental protocols used in the current study were equally effective in reduction of spasticity over the elbow and wrist flexors in stroke patients.

Limitations

One of the limitations of the study was the small sample size in which the results of our study could not be generalized. Second, the hand function was not evaluated in our study. Third, lack of the long term evaluation effect of the outcomes measures which was not in our focus and it is recommended to investigate this effect in further studies. Also there is no comparison of the size of the effects relative to those obtained with other approaches.

Conclusion

Radial SWT protocols used in this study are equally effective in spasticity reduction. However, the stimulation for both agonist and antagonist muscles is more effective protocol than the stimulation for the agonist muscles only in terms of PROM improvement and pain reduction. So, it is suitable to include this radial SWT stimulation protocol to the treatment plan of the patients affected by stroke.

Disclaimer

None.

Conflict of Interest

Authors declare no conflict of interest.

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