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The Combined Effect of Extracorporeal Shockwave and Cryoflow Therapy on Rotator Cuff Tendonitis in Stroke Patients: Randomized Control Trial

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ABSTRACT: Objective: The purpose of this study was to evaluate the effect of extracorporeal shockwave therapy (ESWT) and Cryoflow on rotator cuff tendonitis in patients with stroke.

Methods: Thirty patients of both sexes participated in the study. Their age ranged between 50-70 years, were randomly divided into two equal groups. Group A (experimental) treated with the conventional physical therapy program (stretching, strengthening, and mobilization exercises) in addition to ESWT and Cryoflow while group B (control) treated with the same traditional physical therapy program like group A plus sham shockwave and Cryoflow. All patients were treated three times per week for eight weeks. Modified Ashworth Scale used to assess muscle tone of shoulder adductors, digital goniometer to assess shoulder joint abduction and adduction, tensiometer to assess muscle power of supraspinatus, Purdue peg board to assess hand function, and electromyography to assess the amplitude of motor unit action potential of supraspinatus and Visual analogue scale for pain intensity. All dependent variables were assessed twice; before and after the 8-week treatment duration.

Results: Unpaired t-tests revealed significant difference between both groups in post-test for all the tested variables ($p < 0.01$). Similarly, the paired t-tests revealed significant difference between pre-test and post-test in group A for all the tested variables ($p < 0.01$).

Conclusion: conventional physiotherapy combined with shockwave and Cryoflow is superior to conventional physiotherapy alone in treating rotator cuff tendonitis in patients with stroke.

INTRODUCTION

Shoulder pain affects up to 72% of individuals after stroke and is a leading cause of impaired upper-limb function and reduced participation in rehabilitation.¹ A major contributor is spasticity in the shoulder adductors and internal rotators, which disrupts scapulohumeral rhythm, promotes soft-tissue shortening, and increases mechanical stress on the rotator cuff, particularly the supraspinatus tendon.² Supraspinatus tendon pathology (tendinosis or partial tear) is an independent predictor of hemiplegic shoulder pain during the first six months post-stroke.³ Surprisingly, the combined impact of spasticity and tendinopathy frequently results in treatment-resistant shoulder dysfunction, although structural severity does not always correlate with pain intensity, likely due to altered nociception or muscle atrophy.³

Extracorporeal shockwave therapy (ESWT) has emerged as a promising dual-action intervention in this context. ESWT effectively reduces spasticity and enhances passive range of motion in patients with subacute stroke.⁴ For rotator cuff tendinopathy in non-neurological populations, ESWT is well-established, a finding supported by a 2024 meta-analysis validating its superiority in alleviating pain and improving function.⁵ The therapeutic effects of ESWT on supraspinatus tendonitis are attributed to the direct mechanical stimulation of shockwaves; both continuous and intermittent mechanical pressure can mitigate cellular damage, increase tissue extensibility, and reduce fibrosis.⁶ Consequently, ESWT significantly reduces tendinopathy-associated pain, enhances functional capacity, and improves quality of life, making it a safe and effective first-line option.⁷

Cryoflow therapy represents a relatively novel, contact-free cryotherapy modality that delivers a continuous stream of air cooled to subzero temperatures, guided by real-time infrared temperature sensors. This technology minimizes the risk of frostbite, ensures uniform cooling, and allows dynamic scanning of the treatment area for enhanced comfort and precision.⁸ Modern cold-air devices (e.g., Cryoflow) enable controlled, non-contact application that minimizes skin irritation while maintaining therapeutic efficacy for ≥ 15 minutes.⁹ Cryotherapy remains a cornerstone of spasticity management. Local cooling reduces gamma motor neuron activity, suppresses stretch reflexes, and temporarily decreases muscle tone.¹⁰ The clinical application of continuous cold is widely used to diminish the resistance of spastic muscles to rapid stretching and to reduce or abolish clonus.^{11, 12}

While ESWT has demonstrated individual efficacy in treating tendinopathy and reducing spasticity, and cryotherapy is well-established for spasticity management, no published evidence currently supports their synergistic application in the post-stroke population. This study addresses this critical gap by investigating a dual-mechanism approach: Cryoflow reduces external mechanical load through temporary spasticity suppression, while ESWT stimulates intrinsic tendon repair via neovascularization and tissue regeneration. If proven effective, this combined protocol could offer a non-invasive, medication-sparing intervention to break the cycle of spasticity-tendinopathy-pain that often leads to treatment-resistant shoulder dysfunction, thereby enhancing upper-limb rehabilitation outcomes and functional independence in stroke survivors. Therefore, this study investigated the combined effect of ESWT and Cryoflow, added to conventional physical therapy, on shoulder spasticity, active shoulder range of motion, supraspinatus strength, motor unit activity, hand dexterity and pain intensity in hemiplegic stroke patients with rotator cuff tendinopathy.

METHODS

Study design:

This randomized controlled trial employed a pre-test/post-test control group design conducted over eight weeks.

Sample size calculation:

G*Power software (version 3.1.9.7; Heinrich Heine University, Düsseldorf, Germany) was used to perform an initial power analysis based on preliminary data for the primary outcome (change in Modified Ashworth Scale score). A minimum sample size of 14 participants per group was needed, assuming a large effect size (Cohen's $d = 1.45$), $\alpha = 0.01$ (two-tailed, adjusted for

multiple comparisons), and power = 0.95. A total sample size of 30 was obtained by enrolling 15 participants each group to allow for probable attrition.

Randomization and blinding

Using computer-generated block randomization, participants were divided into two groups at random (block size = 4). Sequentially numbered, opaque, sealed envelopes were used to preserve allocation concealment. Throughout the data collection process, outcome assessors were blinded to group assignment. Therapists could not be blinded due to the nature of the therapies; however, to improve participant blinding, devices with identical operating noises and visual signals were utilized in the control group. We accept that some participants may have been somewhat unblinded due to the lack of thermal awareness during the sham Cryoflow application; this issue is discussed in the Discussion section.

Participants

Selection criteria: This study included 30 post-stroke patients (both sexes) with shoulder adductor spasticity graded as stage 3 on the Modified Ashworth Scale (MAS). Patients were diagnosed by a physician based on physical examination and Magnetic Resonance Imaging (MRI) and were recruited from the outpatient clinics at Benha university. Inclusion criteria were: (1) age 50–70 years; (2) weight 60–88 kg; (3) medical stability confirmed by vital sign assessment; (4) conscious and cooperative status; (5) absence of significant medical, neurological (beyond stroke), or psychological comorbidities; (6) no disability secondary to orthopedic conditions or prior shoulder surgery; and (7) no impairment of general or special senses.

MRI diagnostic criteria for rotator cuff tendonitis: Inclusion required confirmation of supraspinatus tendinopathy on MRI with the following findings: (a) increased signal intensity on T2-weighted images within the supraspinatus tendon without full thickness tear; (b) tendon thickness >4 mm or irregular tendon margins; and (c) absence of complete rotator cuff tear or advanced fatty infiltration (Goutallier grade ≤ 2).¹³ Clinical correlation required positive Neer and Hawkins-Kennedy impingement signs and localized tenderness over the greater tuberosity.

Groups:

Group (A): experimental group consisted of 15 patients, treated by conventional physical therapy program (Range of motion (ROM) exercises, stretching exercises, strengthening exercises, proprioceptive neuromuscular facilitation (PNF) technique, weight bearing exercises and hand functions exercises) plus ESWT and Cryoflow therapy.

Group (B): control group and consisted of 15 patients, treated by a previous conventional physical therapy program plus sham ESWT and sham Cryoflow therapy, **Figure 1**.

Instrumentation:

Evaluation instruments:

- 1-Electromyography: Neuropac apparatus
- 2- Purdue Pegboard: Lafayette, U.S.A.
- 3-Digital goniometer: U.S.A.
- 4-Tensiometer: Lafayette, U.S.A

Therapeutic instruments:

- 1) Shock Master (Master Plus MP200), STORZ Medical AG, type BS, Model 2007 IPX1, S.N: BS. o738, made in Switzerland.
- 2- Purdue Pegboard Test Its specifications are; - Lafayette, Model No. 32020 Made in USA.
- 3) Cryoflow 1000IR, Model ICE-CT, S.N622-0824, made in EC.

Procedures: All patients were informed and participated in several trials with the equipment to assure them psychologically and to be familiar with the steps of the experiment. The treatment program has been carried out for eight weeks, three times per week (day after day), the time of session for every patient was one hour.

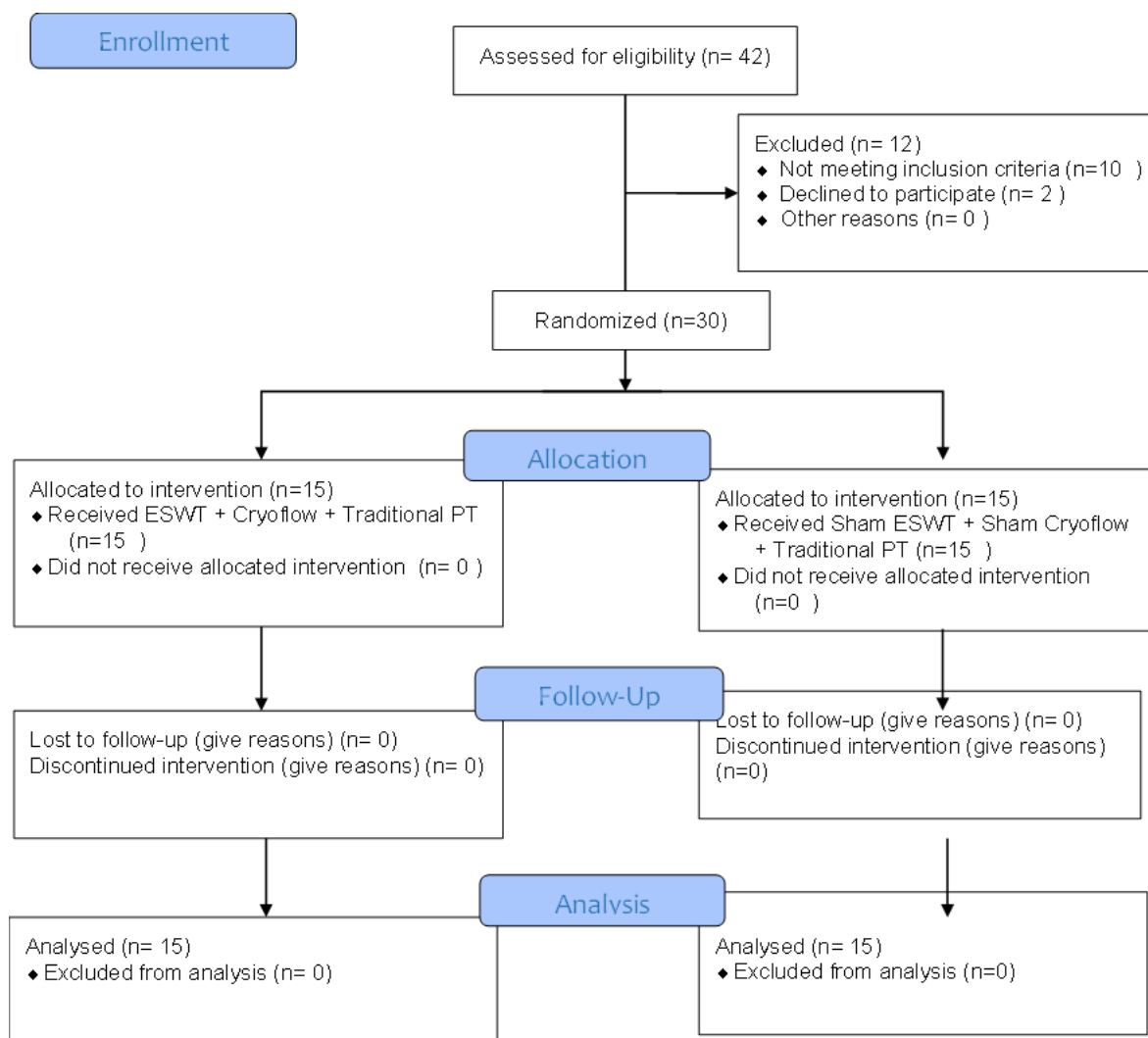


Figure 1: CONSORT 2010 Flow Diagram

Evaluation procedures: Each patient underwent identical clinical assessments immediately before initiating treatment and upon completion of the 8-week program:

Spasticity: Assessed using the MAS which is valid and reliable; all participants were grade 3 at baseline.¹⁴

Range of Motion: Shoulder abduction and adduction were measured using a digital goniometer, with three trials averaged per movement.

Hand Function: Dexterity was evaluated using the Purdue Pegboard Test; patients completed practice trials before formal assessment, and the mean number of correctly placed pins per minute was recorded.¹⁵

Muscle Activity: Surface EMG electrodes were placed over the supraspinatus muscle following SENIAM guidelines; participants performed standardized submaximal contractions, and peak amplitude of motor unit action potentials was recorded.¹⁶

Pain intensity: Assessed using a 10-cm Visual Analog Scale (VAS), anchored by "no pain" (0) and "worst imaginable pain" (10).

Treatment procedures: Group (A): Each patient was treated according to the following protocol: a) Stretching exercises for shoulder flexors, adductors and internal rotators from side lying and sitting positions while the patient was relaxed, supported

and covered by sheet except the area of stretching. b) Active strengthening exercises of shoulder extensors and external rotators. c) Weight bearing exercises applied from sitting and quadruped positions. d) Neuromuscular Facilitations Technique (PNF) was applied from sitting and supine position for the whole upper limb. e) Training of hand dexterity and manipulative skills of wrist and hand of the patients were applied by using Purdue pegboard f) ESWT with frequency 7Hz, 2.5-3bar and 15 minutes in duration and Cryoflow with temperature 14°C for 15min three days per week, day after day for 8 weeks.

Treatment steps by ESWT and Cryoflow were as follow: The patient and the instrument were prepared before the application, the patient was asked to assume sitting position on a chair, the Cryoflow apparatus was set and applied for 15min at 4°C on tendonitis region before ESWT application. After that, ESWT was applied on the patient's, the suitable frequency was set 7Hz, 2.5-3 bar for 15 min duration. at the end of session, the appliance was turned off and the current was disconnected, the patient was advised to rest for 10 minutes after the application and before leaving the treatment room.

Group (B): patients received the same traditional physical therapy program with sham application of ESWT or Cryoflow

All adverse events were systematically recorded at each session. Minor events (e.g., transient erythema, brief discomfort during ESWT) were documented and controlled conservatively. Any major adverse event would have triggered immediate protocol review and participant withdrawal; however, no serious adverse events occurred in either group.

Statistical Analysis: The results of the two groups were statistically analyzed to compare the difference within each group and the differences between the two groups. The statistical package of social sciences (SPSS, version 10) was used for data processing using the P-value 0.05 as a level of significance.

RESULTS

The mean $\pm$ SD age was 54.1 ± 7.2 versus 54.7 ± 6.3 years, and weight 76.8 ± 8.7 versus 76.3 ± 6.8 kg for group A versus group B, respectively. No significant difference was found for the demographic data between both groups ($p > 0.05$).

Unpaired t-tests revealed significant difference between group A and group B in post-test for all the tested variables (MAS, hand function, shoulder abduction, shoulder adduction, muscle power for supraspinatus, EMG of supraspinatus, and VAS) with p values < 0.01 . Similarly, the paired t-tests revealed significant difference between pre-test and post-test in group A for all the tested variables (MAS, hand function, shoulder abduction, shoulder adduction, muscle power for supraspinatus and EMG of supraspinatus) with p values < 0.01 . **Tables 1, 2.**

Table (1): Unpaired t-tests for comparing the dependent variables between group A and group B in pre- and post-tests

Unpaired t-tests for comparing the dependent variables between group A and group B in pre- and post-tests					
Dependent variables		Group A Mean $\pm$ SD	Group B Mean $\pm$ SD	T-value	p-value
MAS	Pre-test	2.8 ± 0.5	2.9 ± 0.5	0.38	0.707
	Post-test	1.7 ± 0.3	2.4 ± 0.5	-3.95	0.001*
Hand function	Pre-test	8.9 ± 1.1	8.7 ± 1.5	0.414	0.682
	Post-test	15.2 ± 1.1	10.8 ± 1.6	8.78	0.001*
Shoulder abduction	Pre-test	30.4 ± 1.7	30.7 ± 1.1	-1.3	0.96
	Post-test	42.8 ± 1.5	37.9 ± 1.8	8.21	0.001*
Shoulder adduction	Pre-test	25.9 ± 3	25.5 ± 3	0	1.00
	Post-test	39.3 ± 3.5	32.9 ± 3.2	7.61	0.001*
Muscle power of supraspinatus	Pre-test	18.9 ± 1.1	18.7 ± 1.5	0.414	0.682
	Post-test	32.2 ± 1.1	26.6 ± 1.6	8.78	0.001*
EMG of supraspinatus	Pre-test	0.6 ± 0.1	0.6 ± 0.1	0.374	0.711
	Post-test	1.5 ± 0.1	0.8 ± 0.1	15.19	0.002*
VAS	Pre-test	6.26 ± 1.48	6.73 ± 1.7	0.79	0.43
	Post-test	3.0 ± 1.46	5.66 ± 1.79	4.45	0.0001*

Group A: experimental group, Group B: control group, VAS: visual analogue scale MAS: Modified Ashworth Scale, EMG: electromyography, SD: standard deviation; (*) Alpha level of significance is set at $p < 0.01$

Table (2): Paired t-tests for comparing the dependent variables between pre-test and post-test in group A and B

Paired t-tests for comparing the dependent variables between pre- and post-tests in group A and B					
Dependent variables		Pre Mean $\pm$ SD	Post Mean $\pm$ SD	T-value	p-value
MAS	Group A	2.4 $\pm$ 0.5	1.7 $\pm$ 0.3	10.46	0.001*
	Group B	2.9 $\pm$ 0.5	2.8 $\pm$ 0.5	2.82	0.014
Hand function	Group A	10.9 $\pm$ 1.1	15.8 $\pm$ 1.1	-23.44	0.001*
	Group B	10.7 $\pm$ 1.5	13.8 $\pm$ 1.6	-12.91	0.01
Shoulder abduction	Group A	30.4 $\pm$ 1.7	42.8 $\pm$ 1.5	-16.11	0.001*
	Group B	30.7 $\pm$ 1.1	37.9 $\pm$ 1.8	-18.33	0.01
Shoulder adduction	Group A	25.9 $\pm$ 1.7	39.3 $\pm$ 1.5	-16.11	0.001*
	Group B	25.5 $\pm$ 1.1	32.9 $\pm$ 1.8	-18.33	0.01
Muscle power of supraspinatus	Group A	18.9 $\pm$ 1.1	32.2 $\pm$ 1.1	-23.44	0.001*
	Group B	18.7 $\pm$ 1.5	26.6 $\pm$ 1.6	-12.91	0.01
EMG of supraspinatus	Group A	0.8 $\pm$ 0.1	1.5 $\pm$ 0.1	-29.79	0.001*
	Group B	0.6 $\pm$ 0.1	0.9 $\pm$ 0.1	-15.9	0.01
VAS	Group A	6.26 $\pm$ 1.48	3.0 $\pm$ 1.46	14.31	0.0001*
	Group B	6.73 $\pm$ 1.7	5.66 $\pm$ 1.79	2.54	0.02

Group A: experimental group, Group B: control group, MAS: Modified Ashworth Scale, EMG: electromyography, SD: standard deviation; (*) Alpha level of significance is set at $p < 0.01$

DISCUSSION

The current study examined how post-stroke patients with comorbid rotator cuff tendinopathy responded to ESWT and Cryoflow therapy in addition to traditional physical therapy in terms of shoulder adductor spasticity, active shoulder range of motion, supraspinatus muscle strength, neuromuscular activation, hand function, and pain intensity. All evaluated domains supported our hypothesis that this dual-mechanism intervention would produce better clinical and functional outcomes than conventional therapy alone.

The findings of the current study demonstrated a significant reduction in shoulder adductor spasticity in group A on the Modified Ashworth Scale; whereas group B showed a minimal change that did not reach statistical significance at $\alpha=0.01$. This differential response may be explained by dual complementary neuromodulatory mechanisms. ESWT likely reduced spasticity through nitric oxide-mediated vasodilation and decreased excitability of alpha motor neurons at the spinal cord level.^{17, 18} Concurrently, Cryoflow application induced cutaneous cooling that reduced afferent discharge from skin thermoreceptors, thereby indirectly suppressing gamma motor neuron activity and diminishing the stretch reflex arc responsible for hypertonia. The higher spasticity reduction seen in group A can be explained mechanistically by this physiological cascade: cooling $\rightarrow$ reduced afferent input $\rightarrow$ lower gamma loop activity $\rightarrow$ muscle relaxation.^{10, 19}

Our results are consistent with several studies showing that ESWT is effective in lowering spasticity in a variety of neurological groups.^{17, 20} The absence of statistically significant change in group B confirms that traditional physical therapy alone, within this 8-week timeframe, was insufficient to produce meaningful spasticity reduction at the predetermined alpha level.

Active shoulder abduction range of motion increased significantly in group A compared with group B. Similarly, shoulder adduction improved significantly in group A versus group B. These between-group differences may be attributed to the synergistic effect of spasticity reduction and direct tendon healing. Cryoflow-induced analgesia reduced pain-mediated inhibition of voluntary movement, while ESWT stimulated neovascularization and collagen remodeling at the supraspinatus tendon insertion through mechanotransduction pathways involving upregulation of vascular endothelial growth factor (VEGF) and endothelial nitric oxide synthase.⁵⁻⁷ This dual action restored scapulohumeral rhythm by simultaneously addressing the neurological constraint (spasticity) and the musculoskeletal constraint (tendinopathy). Our results are consistent with studies confirming ESWT's short-term benefits on joint mobility in tendinopathy and cryotherapy's positive effects on shoulder function.²⁰⁻²³

Supraspinatus muscle strength, measured by tensiometer, increased significantly in group A compared with group B with a significant between-group difference in same line with Cho et al.²⁴, Neculăș et al.²⁵ and Peake et al.²⁶ Concurrently, EMG amplitude of the supraspinatus increased significantly in group A versus group B. The significant between-group difference in EMG amplitude indicates enhanced neuromuscular activation specific to the experimental intervention. This electrophysiological improvement likely resulted from ESWT-induced regeneration of muscle fibers and reinnervation through growth factor stimulation,^{27, 28} coupled with reduced antagonist co-contraction due to effective spasticity management by Cryoflow.¹⁰ The parallel increases in both EMG amplitude and tensiometer readings confirm true strength gains rather than compensatory strategies. These findings are supported by studies reporting similar EMG amplitude improvements following ESWT in hemiparetic muscles.^{29, 30}

Hand function, assessed by the Purdue Pegboard Test, improved significantly in group A compared with group B, with a significant between-group difference. This distal functional improvement following a proximal intervention may be explained by the biomechanical chain principle: reduced shoulder spasticity and improved glenohumeral stability provided a stable proximal base essential for efficient distal motor control. In stroke rehabilitation, proximal stability is a prerequisite for distal dexterity; by breaking the spasticity-tendinopathy-pain cycle at the shoulder, the combined protocol facilitated more effective hand function without direct hand training.^{31, 32}

Pain intensity (VAS) decreased significantly more in Group A versus Group B ($p < 0.001$), demonstrating analgesic synergy between ESWT and Cryoflow. While ESWT encouraged long-term pain relief through mechanotransduction-driven tissue remodeling (VEGF/eNOS upregulation, neovascularization), Cryoflow probably offered instant analgesia through gate-control mechanisms and decreased peripheral nociceptive transmission.^{5,7,33} Improved movement tolerance and functional improvements were made possible by this dual approach, which successfully broke the cycle of spasticity, tendinopathy, and pain.

These findings align with recent studies confirming the efficacy of cryogenic and shockwave modalities in managing chronic tendinopathy-related pain.³⁴⁻³⁶

The absence of statistically significant within-group improvement in group B for any variable is clinically meaningful. It indicates that 8 weeks of traditional physical therapy alone was insufficient to produce robust changes in this chronic stroke population with comorbid rotator cuff tendinopathy. This finding underscores the treatment-resistant nature of hemiplegic shoulder dysfunction when spasticity and tendinopathy coexist and highlights the necessity of multimodal interventions targeting both components simultaneously.³⁷

STUDY LIMITATIONS:

There are a number of limitations to this study that should be noted. First, the sample size was limited ($n=30$), which may limit generalizability to larger post-stroke populations and reduce statistical power for subgroup analysis. Second, the long-term durability of therapeutic effects is unknown because the follow-up period was restricted to 8 weeks immediately following intervention. Third, although outcome assessors were kept blind during data collection, therapist blinding was not possible because of the active nature of ESWT and Cryoflow therapies. Fourth, the lack of heat sensation during sham Cryoflow application may have partially unblinded some participants, thereby increasing placebo-mediated effects, even though the control group used sham equipment with matched aural and visual cues. Lastly, results may not apply to people with milder or more severe spasticity profiles because the inclusion criteria were limited to patients with MAS grade 3 spasticity.

CONCLUSIONS

patients with post-stroke hemiplegia and comorbid rotator cuff tendinopathy showed significant improvements in shoulder adductor spasticity, active range of motion, supraspinatus strength, neuromuscular activation, hand function, and pain intensity, when ESWT and Cryoflow therapy were added to traditional physical therapy. dual-mechanism approach, successfully broken the spasticity-tendinopathy-pain loop.

FUTURE RESEARCH

The current study's limitations should be addressed by future research in a number of strategic ways, including: (1) conducting multicenter, adequately powered trials with larger sample sizes to improve external validity and enable subgroup analyses by

stroke chronicity, lesion location, and baseline functional status; (2) incorporating extended follow-up assessments (≥ 6 and ≥ 12 months) to assess the durability of therapeutic effects and identify potential predictors of long-term response; and (3) combining multidimensional pain assessment tools (e.g., McGill Pain Questionnaire, Brief Pain Inventory) with VAS to more fully capture the sensory, affective, and functional aspects of post-stroke shoulder pain; (4) examining dose-response relationships for Cryoflow (temperature gradient, application duration) and ESWT (energy flux density, pulse count, session frequency) to determine ideal treatment parameters; (5) investigating the effectiveness of this combined protocol in patients with different degrees of rotator cuff pathology (partial vs. full-thickness tears) and across the entire spectrum of spasticity grades (MAS 1–4); and (6) assessing cost-effectiveness and implementation feasibility in various healthcare settings to support evidence-based adoption in clinical practice.

LIST OF ABBREVIATION:

ESWT: Extracorporeal shockwave therapy, MAS: Modified Ashworth Scale, MRI: Magnetic Resonance Imaging, ROM: Range of motion, VAS: Visual Analog Scale, PNF: Proprioceptive neuromuscular facilitation, VEGF: Vascular endothelial growth factor.

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