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CLINICAL STUDY PROTOCOL

Effect of Dry Needling Plus Static Stretching on Plantar Flexors Spasticity in Chronic Stroke Patients

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Importance: Stroke is a leading cause of disability worldwide and is often accompanied by complications such as spasticity. Static stretching (SS) is a common physiotherapy intervention for reducing spasticity, whereas dry needling (DN) is a novel approach. However, the combined effects of DN and SS on spasticity have not been thoroughly investigated. Given the pivotal effect of spasticity on daily activities, mitigating spasticity can significantly contribute to restoring patient independence.
Objective: This study will explore the impact of DN plus SS on spasticity, alpha motor neuron excitability, overall function, and quality of life in patients with chronic stroke.
Design, Setting, and Population: A double-blind, randomized, sham-controlled trial will be conducted in patients with post-stroke spasticity in the plantar flexor muscles. Twenty-eight participants will be randomly assigned to either an intervention or control group. The intervention group will receive DN (60s × 3 days/week; 1 week) plus SS (20 min × 5 days/week; 1 week). The control group will undergo sham DN (60s × 3 days/week; 1 week) and SS (20 min × 5 days/week; 1 week).
Exposures: DN plus SS or sham DN plus SS.
Main Outcomes and Measures: Both groups will be assessed at baseline, immediately post-treatment, and after 1 week of follow-up. Outcome measures will include the Modified Modified Ashworth Scale, H-reflex latency, H_{max}/M_{max} ratio, active and passive ankle dorsiflexion range of motion, timed up and go test, and the EuroQol questionnaire.
Results: Results from this randomized, sham-controlled study will provide evidence for the effectiveness of DN in combination with SS for spasticity.
Conclusions and Relevance: The additional impact of DN in conjunction with SS, a widely used method for reducing muscle tone, remains unclear and warrants investigation. This study, with a high level of evidence, aims to address this knowledge gap.

Keywords: Dry needling, Motor neuron excitability, Plantar flexor muscles, Spasticity, Stretch, Stroke

INTRODUCTION

Stroke is a significant global health issue, causing disability and death in numerous adults annually [1]. Defined by the World Health Organization as a cerebrovascular disease leading to brain dysfunction, stroke affects 15 million individuals worldwide each year [2]. In 2019, Iran recorded 102,778 cases of stroke, resulting in 40,912 deaths [3].

Complications arising from stroke, such as muscle weakness, muscle stiffness, and imbalance, significantly impact patients' lives. Balance, which is crucial for performing the activities of daily living, may be compromised in stroke patients due to alterations in muscle tone and spasticity [4]. Spasticity, characterized by a velocity-dependent increase in the tonic stretch reflex, is a common motor disorder post-stroke, manifesting as exaggerated tendon jerks due to stretch reflex hyperexcitability [5], which is assessed using two criteria: H-reflex latency and H_{max}/M_{max} ratio. Spasticity

occurs in 30-80% of stroke patients, typically manifesting 3-6 months after stroke [6]. Immediate initiation of treatment is recommended to prevent spasticity-related complications [7].

Static stretching (SS) is a cost-effective and efficacious remedy for spasticity [8]. In this approach, a specific body part is maintained in a stretched position for an extended period, leading to the elongation of muscle fibers and reduced stretch reflex excitability [9]. Dry needling (DN) is an innovative spasticity treatment that uses a filiform needle without a hole. This needle is inserted near the motor points of the targeted muscles to decrease the spasticity [10-13]. DN shows promise in breaking dysfunctional endplates [14] and has also demonstrated cost-effectiveness in patients with subacute stroke [15] or chronic stroke [16]. Using DN or SS alone can also decrease the excitability of alpha motor neurons [11,17].

The ankle plantar flexors are frequently affected by stroke. Spasticity in the plantar flexor muscles causes a shortening of the heel-off phase and problems in the mid-swing phase of the gait cycle. Given the pivotal role of these muscles in balance, gait, and daily activities, mitigating spasticity can significantly contribute to restoring patient independence [18]. Bani-Ahmed et al. [19] found that prolonged stretching reduces plantar flexor spasticity in patients with stroke. However, although combining therapeutic interventions may sometimes lead to better outcomes than the use of a single intervention, the effectiveness of SS combined with DN remains unclear. Therefore, the aim of this research is to analyze if DN provides any additional effect to SS on plantar flexor spasticity, alpha motor neuron excitability, lower limb function, and quality of life (QoL) in patients with post-stroke spasticity.

MATERIALS AND METHODS

1. Study design

The study will be a randomized, sham-controlled trial design, ensuring that patients and assessors remain blinded to the interventions.

2. Informed consent

Participants will receive comprehensive information about the study objectives and interventions. Medical interventions will be provided to patients without any associated fees, and participants will have the right to withdraw from the study at any point without penalty. In both groups, SS will be administered as the fundamental treatment. Prior to study initiation, the assessor will obtain both oral and written consent. Patient confidentiality will be strictly maintained, with personal information securely stored in a coded computer. Only the first author will have access to the final data set.

3. Study population

The study aims to enroll 28 eligible patients with chronic stroke, recruiting participants between May 2024 and December 2024.

4. Inclusion and exclusion criteria

Men and women aged 40–65 years with chronic stroke (i.e., ≥ 6 months post-stroke onset and with a Modified Modified Ashworth Scale (MMAS) score for the ankle plantar flexor muscle group of ≥ 1) will be included in the study. Patients will report no pain in the lower limbs. Patients will have had no Botox injections in the plantar flexor muscles within the last 6 months, will have no contraindications for DN, and will have no history of other neuromuscular system disorders. Further, eligible participants must demonstrate the ability to comprehend and follow instructions, and the ability to walk independently for 10 meters with or without an assistive device. Exclusion criteria comprise individuals: with a passive range of motion limitation > 10% in ankle dorsiflexion compared to the less affected leg; with no visible H-reflex on electromyography (EMG); unable to comply with treatment protocols; absent for two consecutive treatment sessions; or incapable of completing the pre- and post-study assessments.

5. Procedures

The study will take place at the Rofeideh Rehabilitation Center in Tehran. Following ethics committee approval, individuals attending physiotherapy clinics will be invited to participate. Eligibility will be assessed, and after obtaining informed consent, patients will be randomly assigned to either the intervention or control group. Assessments will occur at baseline, immediately post-treatment, and after 1 week of follow-up. To ensure confidentiality, all patient information will be coded and securely stored in a computer. This manuscript protocol is developed based on the SPIRIT 2013 Checklist (Table 1).

6. Randomization and blinding

Patients will be randomly assigned to either the intervention group (SS plus DN) or the control group (SS and sham DN). The randomization process will use sealed envelopes. Each envelope will contain a designation for either group A or group B, with 14 envelopes marked as A and 14 as B. Each patient will draw one envelope to determine their assignment to either the intervention or control group. The patients and the assessor will be blinded to the group assignments. Only the physiotherapist administering the interventions will be aware of the group allocations. Importantly, the assessor responsible for evaluating outcomes will be different from the physiotherapist providing the interventions. An informed consent form will be signed by the study participants, such

Table 1. The SPIRIT study protocol

Time point	Enrollment	Allocation	Post-allocation		
	–T1	T0	T1	T2	T3
Enrollment					
Eligibility screen	*				
Informed consent	*				
Demographic data	*				
Allocation		*			
Intervention					
DN+SS			*		
Sham DN+SS			*		
Assessment					
MMAS		*		*	*
H latency		*		*	*
H_{max}/M_{max}		*		*	*
Ankle DF ROM		*		*	*
TUG		*		*	*
Euro QoL		*		*	*

DN = Dry needling; SS = Static stretching; MMAS = Modified Modified Ashworth Scale; DF ROM = Dorsiflexion range of motion; TUG = Timed up and go test; Euro QoL = European quality of life; –T1 = Pre-study, screening/consent; T0 = Pre-study/Baseline, randomization; T1 = Study/intervention; T2 = Study, after one week intervention; T3 = One-week follow-up.

that participants will be aware of their random allocation to intervention groups in which a type of needle will be used in combination with an orthosis.

7. Sample size

G Power 3.1 software was used for the sample size calculations, with H_{max}/M_{max} ratio, H-reflex latency, and MMAS designated as the primary outcome measures. Based on previous studies, a medium effect size of 0.3 for H_{max}/M_{max} ratio, a moderate effect size of 0.5 for H-reflex latency, and a high effect size of 0.8 for MMAS were considered [20,21]. Setting $\alpha = 0.05$ and power at 80%, the calculated total sample sizes were 24, 20, and 10 individuals for each outcome measure. The largest calculated sample size is selected for the study. To account for potential withdrawals during assessment and treatment (i.e., allowing for a 20% drop-out rate), a total of 28 individuals will be recruited (14 individuals per group).

8. Interventions

A licensed physiotherapist, with a Bachelor of Science degree in physiotherapy and legal qualifications for DN, will administer the interventions. In the intervention group, DN will be administered for 60 seconds [11], followed by 20 minutes of SS for the plantar flexor muscles using a specially designed orthosis [17]. The precedence of DN over SS is justified by the potential of DN to break dysfunctional endplates in the plantar flexors, thereby enhancing the effectiveness of SS and increasing the range of stretching. During the study, patients will not use drugs or physical therapy interventions for the calf muscles.

1) Dry needling

For DN, a sterile needle (size 0.30 mm × 0.50 mm; SMC®, Seoul, Republic of Korea) will be used. Each patient will lie prone on a bed with their ankle hanging over the edge, and the 'fast-in, fast-out' technique will be applied to the medial and lateral heads of the gastrocnemius muscle for 60 seconds [11,12]. The DN location will be determined by drawing a line from the center of the popliteal cavity to the heel (Fig. 1). Two centimeters medial and lateral to the proximal third of this line, the needle will enter the medial and lateral heads of the gastrocnemius [11]. DN will be administered once a day, on alternate days for a week (i.e., a total of three sessions).

2) Static stretching

To perform SS, a specially designed orthosis will be used, crafted by a technical orthopedic expert. The upper plate of the orthosis accommodates the calf, while the lower plate supports the sole of the foot. Adjustable screws connect these plates, allowing for a customizable range of motion (Fig. 2). During stretching sessions, each patient will lie supine with extended knees, avoiding ankle contraction, while the orthosis is adjusted to maximum ankle dorsiflexion [22]. SS will be conducted once a day, five times a week (i.e., a total of five sessions).

In the control group, each treatment session will include Sham DN (using a 10 g monofilament) for three sessions,

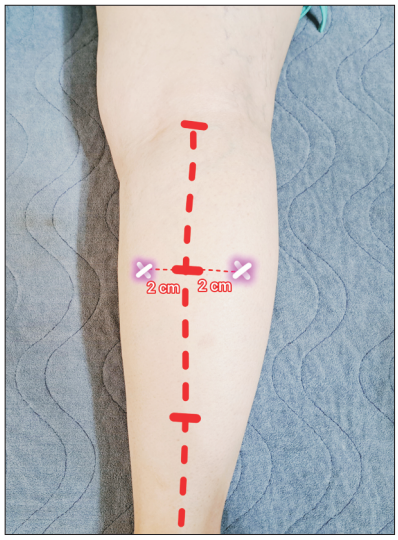

Fig. 1. Dry needling on medial and lateral heads of gastrocnemius muscle.

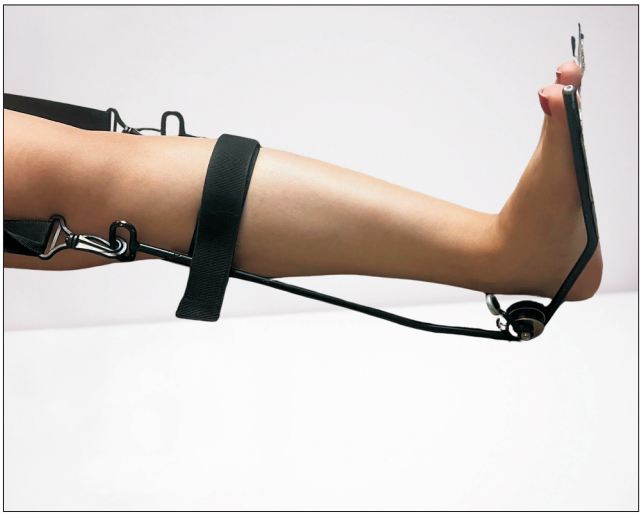

Fig. 2. Stretching orthosis.

along with 20 minutes of SS for five sessions [23]. To perform sham DN, the monofilament will superficially touch the skin, and manipulation will not be performed.

3) Adverse effects

DN can cause minor adverse reactions like bleeding, bruising, and pain during or after DN [24]. A licensed physiotherapist will administer DN to minimize these reactions. While no adverse effects were reported for SS in a previous study [25], we will provide cold packs after SS and DN if required (Fig. 3).

9. Outcome measures

The primary outcome measures will be the MMAS score

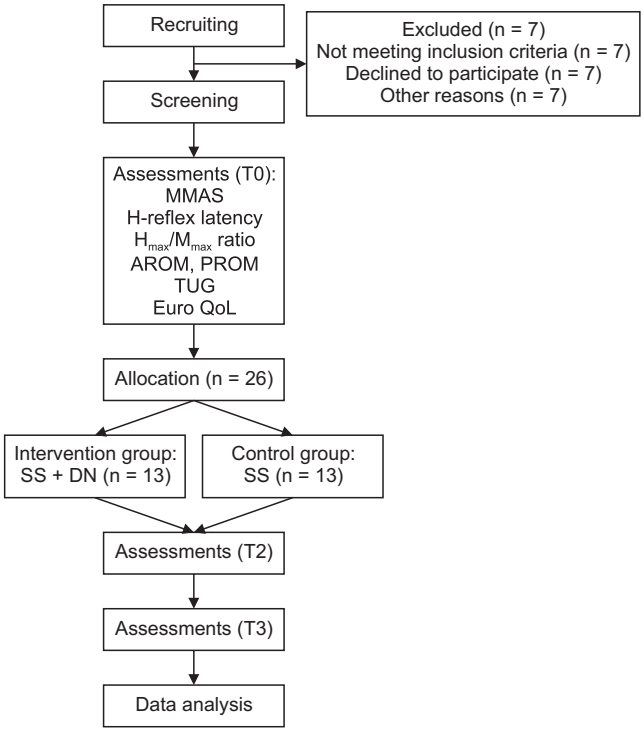

Fig. 3. Diagram of the protocol. DN = Dry needling; SS = Static stretching; MMAS = Modified Modified Ashworth Scale; AROM = Active range of motion; PROM = Passive range of motion; TUG = Timed up and go test; Euro QoL = European quality of life; T2 = Study, after one week intervention; T3 = One-week follow-up.

for the ankle plantar flexors, and H-reflex latency and H_{max}/M_{max} ratio for the gastrocnemius muscle. Secondary outcome measures will be ankle dorsiflexion active range of motion (AROM) and passive range of motion (PROM), the Timed Up and Go (TUG) test, and the European Quality of Life-5 Dimensions-5 Level (EQ-5D-5L) questionnaire.

10. Assessments

Assessments will be conducted at baseline, post-treatment, and after 1 week of follow-up. To evaluate spasticity, the MMAS will be used. Excitability levels in alpha motor neurons will be assessed using H-reflex latency and H_{max}/M_{max} ratio. Ankle dorsiflexion AROM and PROM and the TUG test will be used to assess overall lower limb functionality. The EQ-5D-5L questionnaire will be administered to evaluate patients' QoL. The assessment sequence, with a 3-minute break to promote data quality, will be as follows:

1) Spasticity

To assess plantar flexor spasticity, it is important for patients to have an empty bladder and be in a calm environment. Initially, appropriate instructions are given to patients to ensure relaxation and discourage any assistance

or resistance throughout the movement. Patients should lie supine with their knees extended for a period of 5 minutes. Afterward, the spasticity intensity is measured while the ankle passively moves to its maximum dorsiflexion for one second. The resistance against the passive movement will be graded based on the Persian MMAS [26].

2) H-reflex latency

Recording of the H-reflex will be performed using an EMG device (model SM-930AK; Nihon Kohden Corporation, Tokyo, Japan). Patients will assume a supine and relaxed position, and the designated electrode placement site will be disinfected with alcohol. Surface electrodes (10 mm diameter) will be used. The stimulating electrode will be positioned in the popliteal fossa on the tibial nerve, ensuring that the negative pole is proximal and the positive pole is distal. The recording electrode will be placed in the medial head of the gastrocnemius muscle. The ground electrode will be positioned between stimulating and recording electrodes. The parameters will be set with sweep speed 5 ms/div, sensitivity 200–500 μv/div, and pulse duration 1 ms. Subsequently, by stimulating the tibial nerve with subthreshold intensity, a three-phasic wave with the initiation of the positive phase will be recorded, representing the H-reflex. The H-reflex latency, measured from the time of stimulation to the recording of the wave, will be accurately captured and recorded (Fig. 4).

3) H_{max}/M_{max} ratio

To determine H_{max}/M_{max} ratio, the H-reflex is recorded with the intensity gradually increasing until maximum amplitude is achieved. The device measures the H-reflex amplitude from peak to peak. For recording the M-wave, the electrode placement is similar, but supramaximal stimulation intensity is used. Subsequently, the M-wave's maximum amplitude from peak to peak is measured. The resulting H_{max}/M_{max} ratio indicates the alpha motor neuron excitability, with a higher ratio suggesting heightened neural responsiveness.

4) AROM and PROM

Range of motion will be measured using a simple goniometer (Ghamatpooyan, Tehran, Iran). Patients will lie in a relaxed supine position with extended knees. The assessor will position the stationary arm parallel to the fibula, and the movement arm parallel to the fifth metatarsal. For AROM, patients will be instructed to actively move the ankle to its maximum dorsiflexion. For PROM, the assessor will hold the proximal part of the ankle with one hand and the plantar side of the foot with the other, passively moving it toward maximum dorsiflexion. AROM and PROM will be measured relative to the resting position and recorded with a positive number (Fig. 5). Three measurements will be made and the average recorded.

5) TUG test

The assessor will instruct patients to sit comfortably in a chair with handles, ensuring that the feet are in contact with the ground. Upon command, patients will rise from the chair, walk a 3-meter distance marked on the ground, either with or without an assistive device, make a turn, and return to sit down in the chair. The assessor will use a chronometer to record the time, measured in seconds, from when each patient is directed to stand up until each patient returns to sit down (Fig. 6). The TUG test is reliable and valid for function in patients with stroke [27].

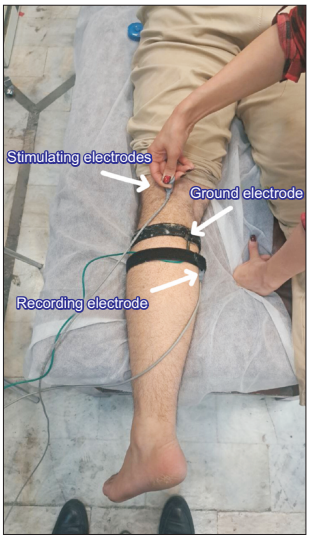

Fig. 4. Electrodes placement to record the H-reflex from the medial head of the gastrocnemius muscle.

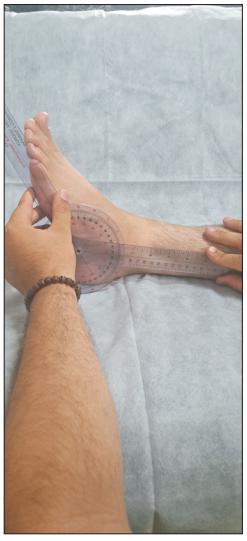

Fig. 5. Measurement of ankle dorsiflexion active and passive range of motion.

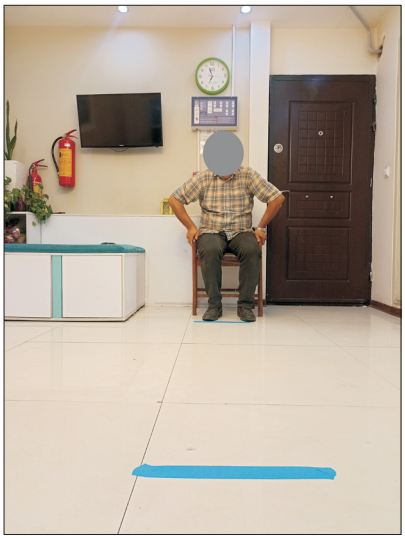

Fig. 6. Timed up and go test.

6) EQ-5D-5L

The Persian EQ-5D-5L questionnaire will be completed by the physiotherapist [28]. The questionnaire comprises five dimensions: mobility, self-care, usual activities, pain or discomfort, and depression. Each dimension includes five score levels for problems: no problem (1), slight (2), moderate (3), or severe problem (4), or inability to perform tasks (5), as self-reported by patients. The total scores will be encoded into the scoring system as a five-digit code, yielding a calculated score ranging from 1.00 (no problem) to –1.19 (the most severe problem). The EQ-5D-5L questionnaire has acceptable validity and reliability in patients with stroke [29].

11. Data monitoring

An independent committee from various rehabilitation disciplines will monitor the methodology to ensure that the proposed methods are followed and the data are accurately gathered.

12. Data collection and analysis

Statistical data analysis for this study will be conducted using SPSS version 26 software (IBM Corp., Armonk, NY, USA), with a significance level set at 0.05 and a confidence interval of 95%. To assess the normal distribution of the data, the Kolmogorov-Smirnov test will be used. If the data exhibit a normal distribution, the independent t-test will be used to compare the means of continuous quantitative variables between groups before treatment. Conversely, if the data are not normal or discrete, the Mann-Whitney test will be applied. For comparisons of the means of continuous quantitative variables with repeated measurements within a group, the choice between one-way analysis of variance (ANOVA) repeated measures (if the data are normally distributed) or the Friedman test (if the data are not normal or discrete) will be used. Simultaneous comparisons within and between groups involving continuous quantitative data with repeated measurements will be assessed using two-way ANOVA with repeated measures.

RESULTS

The outcomes of this study are anticipated to unveil the efficacy of combining DN with SS in addressing spasticity and enhancing functional outcomes in patients with chronic stroke and plantar flexor spasticity.

DISCUSSION

The ankle's plantar flexor muscles are frequently affected by spasticity in patients with stroke, disrupting dynamic balance and gait [18]. The primary objective of this study is to investigate the combined effects of DN and SS on plantar flexor spasticity, alpha motor neuron excitability, overall lower limb functionality, and QoL in patients with chronic stroke. Our findings could shed light on the potential synergistic impact of these interventions in addressing the multifaceted challenges faced by individuals with chronic stroke.

Mitigating spasticity in the plantar flexor muscles is crucial for enhancing balance and gait. Previous studies investigating the impact of stretching in reducing muscle spasticity in patients with stroke yielded varied results, and used different durations of stretching (ranging from 30 seconds to 30 minutes) in single or multiple treatment sessions, with or without additional therapeutic interventions [19,30]. Despite these contradictions, SS is still used to reduce spasticity, under the assumption that SS effectively elongates muscle fibers and reduces alpha motor neuron excitability [9]. These contradictory findings may also stem from different sample sizes and research methodologies. Moreover, studies using DN at varying frequencies, either alone or in combination with other interventions, reported reductions in spasticity breaking dysfunctional endplates. However, it seems that DN may provide additional benefit to SS in reducing spasticity. Our study contributes to this body of knowledge by introducing the combination of DN and SS, providing a novel approach that may offer unique benefits.

One limitation of the study is the lack of a prolonged follow-up, which may impact generalizability of the study findings. Potential disturbances affecting EMG devices are another study limitation. Efforts will be made to mitigate these disturbances by establishing a quiet environment during data collection.

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AUTHORS' CONTRIBUTIONS

Conceptualization: ME, NGH. Methodology: ME, NGH, KM, NNA, SM. Statistical analysis: ME, SHJ. Writing original draft: ME. Writing, review and editing: ME, NGH, KM, NNA, PHG, SHJ, EL. All authors read and approved the final manuscript for submission.

ETHICAL STATEMENT

Ethical approval for this study has been obtained from the Ethics Committee of Tehran University of Medical Sciences (TUMS) under approval ID IR.TUMS.FNM.REC.1402.097.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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