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The Effect of Dry Needling on Lower Limb Dysfunction in Post-Stroke Survivors

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Abstract:	<p>Background: Spasticity is one of the main complications in post-stroke survivors leading to difficulties in walking and standing resulting in high levels of disability.</p> <p>Objective: The aim of the study was to investigate the effects of deep dry needling on lower limb spasticity in post-stroke survivors.</p> <p>Methods: A randomized clinical trial conducted in post-stroke survivors who were assigned to one of two groups: Deep dry needling (intervention group) and sham dry needling (control group). The primary outcome measures were Modified Modified Ashworth Scale (MMAS) and functional tests (timed up and go test, 10-meter walk test). Secondary outcome measures were active ankle dorsi-flexion range of motion (AROM), passive ankle dorsi-flexion range of motion (PROM), single leg stance test, and Barthel index. All measurements were assessed at baseline (T0), immediately after the third session one week later (T1), and one month after the end of the intervention (T2).</p> <p>Results: We recruited 24 patients (71% male; mean age 57±10 years; 26.4±1.8 kg·m⁻²; time since event: 25.2±12.5 months). There were significant improvements in MMAS, timed up and go test, 10-meter walk test, Barthel scale, and PROM (P <0.05) in the intervention group compared to controls across the time-points. There were no significant improvements in AROM assessments (P >0.05).</p> <p>Conclusions: Deep dry needling decreases muscle spasticity and improves lower limb function and gait speed in post-stroke survivors.</p>

Dear Editor,

Here is our revised version.

We hope it makes you satisfied.

Shortly we will submit the sister paper, related to upper body.

Kind regards

Dr. Ardalan Shariat

The Effect of Dry Needling on Lower Limb Dysfunction of Patients Post Stroke

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Running head: dry needling for patient post stroke

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Ethic Approval: This study was approved by Tehran University of Medical Sciences (IR.TUMS.VCR.REC.1397.721).

Key words: Stroke, Spasticity, Deep dry needling, Sham dry needling.

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Comments of reviewer 1	Answer to the comment
It is recommended in abstract section the objective is corrected to "The aim of the study was to investigate the effects of deep dry needling on lower limb dysfunction in post-stroke spastic patients.	It is corrected.
It must be declared: How many was repeated Timed up and go test for each patient, and patients turns on which side, affected side or intact side? How many was repeated Single leg stance test and which limb, affected or intact limb was tested? How many was repeated 10-meter walk test?	It has been added.
Please explain why ankle ROM were measured in sitting position with some flexion of knee? Seems it is better to measure in supine position with knee extended for evaluating gastrocnemius.	Sorry It was typo. It has been corrected.
Please identify the region of needling in method section?	It has been done
Please identify depth of needling?	Relevant details and reference are added.
Please explain in detail how was applied sham DN?	It has been added.

Comments of reviewer 2	Answer to the comment
<p>Methods:</p> <p>i) Need to inform the reader stroke types and severity whether measured by NIHSS or Fugl-Meyer?</p> <p>ii) Need to inform the reader who measured the primary and secondary outcomes at T0, T1 and T2? Were they part of the study group or independent i.e. blinded?</p> <p>iii) Why were these outcome scales chosen and their relevance? It is insufficient just to say "relevant and reliable" scales</p>	<p>Requested details are added.</p> <p>As it has been noted the patients had the walking ability for at least 10 meters and we also had the FAC cut-off value since FAC classifies walking ability both indoors and outdoors.</p> <p>It has been mentioned that spasticity shows up impaired motor activity performance due to complications related to walking and standing. These outcomes are useful in quantifying advanced functional mobility after a stroke.</p>

<p>Discussion:</p> <p>i) Study Limitation: a) Small study sample increases the chances for Type I and Type II errors. b) Study is still a short duration (4-weeks).</p>	<p>With regards to the limitations of this study (small study sample and short duration (4-weeks) of intervention), we recommend that larger, well controlled studies are conducted, perhaps in conjunction with other rehabilitation therapies, to strengthen the evidence-based for dry needling in this patient cohort.</p>
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The Effect of Dry Needling on Lower Limb Dysfunction in Post-Stroke Survivors

Abstract

Background: Spasticity is one of the main complications in post-stroke survivors leading to difficulties in walking and standing resulting in high levels of disability.

Objective: The aim of the study was to investigate the effects of deep dry needling on lower limb dysfunction in post-stroke spastic patients.

Methods: A randomized clinical trial conducted in post-stroke survivors who were assigned to one of two groups: Deep dry needling (intervention group) and sham dry needling (control group). The primary outcome measures were Modified Modified Ashworth Scale (MMAS) and functional tests (timed up and go test, 10-meter walk test). Secondary outcome measures were active ankle dorsi-flexion range of motion (AROM), passive ankle dorsi-flexion range of motion (PROM), single leg stance test, and Barthel index. All measurements were assessed at baseline (T0), immediately after the third session one week later (T1), and one month after the end of the intervention (T2).

Results: We recruited 24 patients (71% male; mean age 57 ± 10 years; 26.4 ± 1.8 kg·m⁻²; time since event: 25.2 ± 12.5 months). There were significant improvements in MMAS, timed up and go test, 10-meter walk test, Barthel scale, and PROM ($P<0.05$) in the intervention group compared to controls across the time-points. There were no significant improvements in AROM assessments ($P>0.05$).

Conclusions: Deep dry needling decreases muscle spasticity and improves lower limb function and gait speed in post-stroke survivors.

Key words: Stroke, Spasticity, Deep dry needling, Sham dry needling.

Introduction

Stroke is a serious clinical condition leading to a major cause of long-term disability in survivors.^{1,2}

According to the World Health Organization, there were 42.4 million post-stroke survivors in 2015.^{3,4} Disability affects 75% of post-stroke survivors causing limitations to daily activities and reducing quality of life.⁵ Spasticity is the leading cause of disability in patients affecting 60% of the cohort.⁶ Patients with lower limb spasticity have various difficulties in walking and standing resulting in high levels of disability.^{7,8} Indeed, the spasticity of the lower extremity is associated with a reduction in functional independence.⁹

Currently, existing therapies for the elimination of spasticity include anti-spasticity drugs such as baclofen, dantrolene, tizanidine, and diazepam, which treat the symptoms of the condition and may lead to side effects, or in extreme cases, may contribute to increased dysfunction.¹⁰⁻¹² The emergence of dry needle therapy, a relatively new technique, has recently shown promise.^{13,14} This treatment method is widely used in managing myofascial pain, trigger points, and soft tissue injuries including tendinitis.¹⁵⁻¹⁸ Dry needling (DN) uses a thin sterile stainless-steel needle, without the use of injectate, to penetrate the skin and stimulate trigger points, neural tissue, muscles and connective tissue for pain relief and functional improvement.^{19,20} This stimulation disrupts the endplate zone of the nerves and improves blood flow leading to improvements in motor function and control.^{21,20}

In recent years, the use of DN has increased in the treatment of post-stroke survivors.¹⁴ According to a case report and case series, DN is effective in the upper body of post-stroke survivors for improving function.^{14,22} Further work has shown a positive impact of DN on the gastrocnemius and soleus muscle groups in the lower limb following stroke.^{23,24} However, few randomized clinical trials (RCTs) have focused on DN in the lower extremities of post-stroke survivors.^{25,26} Longer term studies currently do not exist and, due to the possible placebo effect of dry needling,²⁷

studies should compare DN to a sham treatment to minimize the risk of bias. Therefore, the aim of this randomized clinical trial was to determine the effects of DN on lower limb spasticity and dysfunction in post-stroke survivors in the short and longer-term compared to sham treatment. We hypothesized that post-stroke survivors receiving three weekly treatment sessions of DN would exhibit a greater reduction in spasticity and improvement in function in the short- (one week) and longer-term (one month) compared to matched patients who received sham treatment only.

Methods

Study design

A double blind, sham controlled, parallel group, randomized controlled trial. The study protocol was approved by the review board, Sports and Exercise Medicine Research Center, and the Ethical Committee of Tehran University of Medical Sciences (TUMS) All patients were informed about the study aims and procedures, and provided full written consent prior to participation in the study.

Population

The inclusion criteria were: 1) age between 18 and 75 years; 2) first hemiplegic **ischemic** stroke; 3) stroke occurred at least six months prior to trial recruitment; 4) Able to walk without support for at least 10 meters 5) MMAS spasticity score ≥ 1 ; 6) **Ambulation ability ≥ 3 based on the Functional Ambulation Classification (FAC) test** 7) taking no antispasmodic drug; and 8) be able to understand and follow the instructions. The exclusion criteria were: 1) have any contraindications to dry needling; 2) have cognitive alterations; 3) history of diabetes or neurological pain; 4) fixed muscle contractures at the ankle joint; 5) currently receiving other treatment protocols; and 7) do not consent to participate in the study.

Outcome measures

The primary outcome measures were the Modified Modified Ashworth Scale (MMAS), and functional tests (timed up and go test, 10-meter walk test). Secondary outcome measures were ankle active extension range of motion (AROM), ankle passive extension ROM (PROM), single leg stance test, Barthel index, fascicle pennation angle and muscle thickness of the gastrocnemius muscle. All measures were assessed at baseline (T0), immediately after the third session of DN (one week; T1), and after one month (T2). The changes in mean scores after the intervention were compared between groups at each timepoint.

Procedures

The baseline characteristics were recorded including sex, age, weight, height, BMI; duration elapsed from stroke and hemiplegic side. A qualified sports medicine specialist delivered the DN in three sessions spaced across one week, with at least 48 hours between treatment sessions.

Measurements

Modified Modified Ashworth Scale

MMAS is an established method for assessing spasticity in post-stroke patients.^{28,29} A score of '0' indicated without an increase in muscle tone; '1' indicated a slight increase in muscle tone, '2' indicated a marked increase in muscle tone; '3' indicated considerable increase in muscle tone, passive movement difficult; and '4' indicated the affected part rigid in flexion/extension.³⁰ The MMAS has low levels of inter- and intra-rater variability in post-stroke patients.^{31,32} The validity and reliability of the Persian version of the MMAS has been previously established.³³ Assessment was carried out in a supine position, the assessor moved the ankle passively from maximum possible plantar flexion to maximum possible dorsiflexion. MMAS was performed once to avoid causing changing in spasticity.³⁴

Timed up and go test

This test is used to evaluate functional ability. The patient is seated in an arm chair and following a command from the assessor, the patient must stand, walk 3 meters forward, turning toward the affected side, and return to the chair. The time to complete the task is recorded by the assessor. The validity and reliability of the test has previously been reported.³⁵ Tests were carried out three times and the best performance was used for data analysis.

Single leg stance

This test measures the ability to stand on one leg and maintain balance. The patient was asked to put their hands on the pelvic and try to stand on one leg. The duration the patient could hold the stance was recorded. The validity and reliability of the test has been previously reported.³⁶ Tests were performed three times and the lowest data was used for analysis.

10-meter walk test

This test is used to assess walking speed with the patient being timed during a 10m walk along a corridor. Previous work has demonstrated the validity and reliability of the test.³⁷ Three assessments were performed and the best time was reported.

Barthel index

The Barthel questionnaire was used to determine the magnitude of disability and dependency for undertaking daily activities. This questionnaire includes 10 items relating to the presence or absence of fecal incontinence or urinary incontinence and asks about help needed with grooming, toilet use, feeding, transfers (e.g. from chair to bed), walking, dressing, climbing stairs and bathing. Scoring is by summing the patient's scores for each item. Possible scores for each question range from 0 – 20 and lower scores reveal a greater dependency on others.³⁸ The validity and reliability of this scale have been previously reported.³⁹

Range of motion

Active and passive ankle dorsiflexion were measured in the **supine** position with knee **extension** using a standard manual goniometer. The assessor aligned the fulcrum of the device along the lateral malleolus, with the stationary arm of the device along the fibula and the moveable arm parallel to the fifth metatarsal bone.

Ultrasonographic parameters

The most common pennate muscle affected by spasticity following stroke is the gastrocnemius medialis muscle²⁴ which is the main contributor to gait dysfunction. Muscle architecture (i.e. pennation angle and muscle thickness) affects muscle function⁴⁰ and these factors are often used to estimate the amount of force-generating capability.⁴¹ Using ultrasonography imaging is a safe, cost effective, and non-invasive method for characterizing muscle architecture.^{24,42}

The gastrocnemius muscle was evaluated via ultrasound imaging (Sonosite MicroMax Ultrasound System, Bothell, WA, USA, Real-time, B-mode). The reliability of the fascicle pennation angle and muscle thickness of the gastrocnemius muscle has been previously studied.⁴³ To evaluate ultrasonographic muscle measurements we asked patients to lie in a prone position, with their feet hanging off the bed, but being kept stable via an orthosis at maximum plantar flexion (Figure 1).^{44,45} The 5–10-MHz linear transducer was coated with a water-soluble transmission gel and positioned at the midpoint of the medial gastrocnemius muscle belly, between the medial and posterior borders at 30% of proximal tibial length.⁴⁶ While taking images, minimal pressure was

maintained on the skin surface to avoid compression of the muscle fibers. During each session, assessments were performed on two occasions for each participant and the average value was calculated.

Medial gastrocnemius muscle thickness was measured from the distance between the superficial and deep aponeuroses, and the pennation angle was measured at the fascicular insertion at the deep aponeurosis (Figure 2).

Dry needling

The DN protocol was performed using disposable sterile stainless-steel needles (size, 0.30 mm×50 mm; SMC, Seoul, Korea) with patients in the prone position with their ankles hanging from the bed. The fast-in and fast-out technique was adopted and each muscle was needled for one minute.^{14,22} The depth of needling was determined according to the clinician's judgment (according to the depth of the tissue underling the skin).⁴⁷

For DN of the lateral head of the gastrocnemius muscle, a pillow was placed under the patient's leg, and the muscle was needled 2 cm lateral to the middle of the proximal segment of a line connecting the heel to the popliteal crease. A point located 2 cm medial to the one third of distal segment was needled for the medial head of the gastrocnemius muscle (Figure 2).

Randomization and blinding

Patients were allocated to two groups by computer generated randomization in blocks of 20 in a 1:1 ratio. The patients were randomized to 1 of 2 groups: dry needling (intervention group) and sham dry needling (control group). A research assistant not involved in any other part of the study opened the sealed opaque envelopes and assigned the patients to their respective treatment group. The DN and sham DN was performed by a trained practitioner who was independent to the study.

The sham treatment was applied exactly at the same area of the standard DN with blunted dry needling. Assessment was performed by an independent, experienced physiotherapist who was unaware of the allocated intervention. Participants were blinded to the treatment allocation.

Sample size

The required number of samples was calculated using the following formula:

$$n_1 = \frac{(\sigma_1^2 + \sigma_2^2 / \kappa)(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2}$$

The sample size for each of the dependent variables was calculated individually and the largest number was considered as the sample size for our study. We calculated that the sample size for each group should be n=11, which according to the probable rate of loss during the treatment period, 10% was added to account for likely attrition rates, therefore n=12 was selected.

Where:

n_1 = sample size of Group 1= 11

n_2 = sample size of Group 2= 11

σ_1 = standard deviation of Group 1= 23

σ_2 = standard deviation of Group 2= 22.6

Δ = difference in group means=-19.4

κ = ratio $n_2/n_1=1$

$Z_{1-\alpha/2}$ = two-sided Z value (eg. Z=1.96 for 95% confidence interval).

$Z_{1-\beta}$ = power= 85%

(Group 1 = Control, Group 2 = Intervention group)

Statistical analysis

Data were entered into the Statistics Package for Social Sciences (SPSS v22; IBM, NY, USA). All continuous data was presented as mean \pm [standard deviation (SD)]. Data normality was checked for each variable by the Kolmogorov-Smirnov test. Baseline characteristics between groups were compared using an independent t-test. Differences over time between the experimental and control groups were assessed by a 2 \times 3 (group by time) repeated measures analysis of variance. Bonferroni post hoc adjustments were carried out where necessary, and partial eta² (η_p^2). Effect sizes were also calculated, with 0.25, 0.40, and >0.40 representing small, medium, and large effect sizes, respectively.⁴⁸ *P*-values less than 0.05 were considered as significantly different.

Results

Initially 22 post-stroke survivors (71% male; mean age 57 \pm 10 years; 26.4 \pm 1.8 kg·m⁻²; time since event: 25.2 \pm 12.5 months) were eligible for the study. Patients were randomly assigned to the intervention or sham groups (11 participants per group). Patient physical characteristics are reported in Table 1. There were no significant differences between groups for any of these parameters.

Timed up and go test (TUG)

A significant group by time interaction ($F(2, 44) = 5.118, P < 0.001, \eta_p^2 = 0.189$) showed that the two groups responded differently to the intervention. Mean TUG test reduced from 33.82 to 25.06 seconds after one week in the intervention group. This improvement remained after one month.

Ten-meter walk

A statistically significant group-by-time interaction [$F(2, 44) = 49.955, P = 0.02, \eta_p^2 = 0.164$] showed that the two groups responded differently to the intervention. The mean time to complete ten meters improved from 19.1 to 12.2 seconds in the intervention group and was unchanged in the controls.

Single leg stance (SLS)

A significant group-by-time interaction showed that two groups responded differently to the intervention [$F(2, 44) = 11.941, P < 0.001, \eta_p^2 = 0.351$]. A significant main effect was evident [$F(2, 44) = 18.674, P < 0.001, \eta_p^2 = 0.459$] showing how the intervention improved SLS.

Active range of motion (AROM)

A non-significant group-by-time interaction for AROM was not evident showing that the two groups were unchanged following the intervention [$F(2, 22) = 0.423, P = 0.658, \eta_p^2 = 0.019$].

Passive range of motion (PROM)

A group-by-time interaction was evident for PROM showing that the two groups responded differently to the intervention [$F(2, 44) = 13.487, P < 0.001, \eta_p^2 = 0.413$]. A mean difference of -5° between T0 and T1 ($P < 0.001$), and 0.4° between T1 and T2 ($P = 0.723$) was evident following Bonferroni correction adjustment.

Barthel index

A significant group-by-time interaction effect showed that the two groups responded differently to the intervention [$F(2, 44) = 22.624, P < 0.001, \eta_p^2 = 0.538$]. The mean Barthel index improved from 68-78 after one week in the intervention group and was unchanged in the controls.

Pennation angle

A significant group-by-time interaction showed that the two groups responded differently to the intervention [$F(2, 44) = 64.199, P < 0.001, \eta_p^2 = 0.745$]. The pennation angle improved from 19.2° to 17.0° in the intervention group and was unchanged in the controls.

Muscle thickness

A significant group-by-time interaction showed that the two groups responded differently to the intervention [$F(2, 44) = 134.148, P < 0.001, \eta_p^2 = 0.859$]. Mean muscle thickness reduced in the intervention group and was unchanged in the controls.

Discussion

We investigated the impact of three sessions of deep DN in the lower limbs of post-stroke survivors. Our randomized clinical trial showed that the intervention improved functional mobility, gait speed, and passive range of motion and balance in post-stroke survivors. We found a decrease in ankle plantar-flexor spasticity in the intervention group which has been reported in previous studies.^{25,26} To our knowledge, only one other study has assessed the impact of DN over a one-week intervention period, however, they targeted the shoulder complex.⁴⁹

Muscular dysfunction following stroke may cause negative secondary changes due to contractures. These changes include a reduction in muscle fiber length, and a decreased number of serial sarcomeres within muscle fibers.^{50,51} Since muscle stiffness is a result of these structural changes,⁵⁰ our findings showing an improvement in passive range of motion due to deep DN is encouraging. Other investigators have also shown the positive impact of deep DN applications on muscular function in post-stroke survivors.^{14,22,26}

Patients with spasticity exhibit impaired motor activity performance due to complications related to walking and standing.²⁵ Increased walking speed, for example, is related to recovery of muscle spasticity.⁵² Improvements in standing and gait performance as a result of increased foot contact have been reported in post-stroke survivors following DN.²⁵ Our findings showing an

improvement in TUG and ten-meter walking test also confirm the positive impact of DN in this patient cohort. Our findings may also explain the improvements in SLS. Moreover, it has been suggested that a decrease in muscle spasticity could lead to improved postural changes including improved directional control and center of gravity displacement.²⁶ We also found improvements in the Barthel index which is associated with an improvement in functional independency including walking on a level surface, and ascending and descending stairs.⁵³

We did not find any improvement in active range of motion which is in agreement with another recent study.²⁵ However, other studies have reported improvements in active range of motion following deep DN in the upper limb.^{14,25} The authors cautiously hypothesized that DN improved the function of central motor neurons and neural drive, however, there is a lack of empirical evidence to support this assertion. It may be that improved function of afferents from treated muscles to sensory and premotor areas of the brain due to DN may be responsible for the observed motor improvements.⁴⁷ However, to detect these changes, it is feasible that more than three sessions of DN are required. Normally stroke survivors display an increased pennation angle and muscle thickness in their affected muscles.⁵⁴ We have shown that muscle thickness and pennation angle can be improved after three sessions of deep DN. Likewise, a recent study showed similar improvements in muscle morphology after only one session of DN.⁵⁵

In conclusion, deep dry needling decreases muscle spasticity and improves lower limb function and gait speed in post-stroke survivors. **With regards to the limitations of this study (small study sample and short duration (4-weeks) of intervention),** we recommend that larger, well controlled studies are conducted, perhaps in conjunction with other rehabilitation therapies, to strengthen the evidence-based for dry needling in this patient cohort.

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The Effect of Dry Needling on Lower Limb Dysfunction in Post-Stroke Survivors

Abstract

Background: Spasticity is one of the main complications in post-stroke survivors leading to difficulties in walking and standing resulting in high levels of disability.

Objective: The aim of the study was to investigate the effects of deep dry needling on lower limb dysfunction in post-stroke spastic patients.

Methods: A randomized clinical trial conducted in post-stroke survivors who were assigned to one of two groups: Deep dry needling (intervention group) and sham dry needling (control group). The primary outcome measures were Modified Modified Ashworth Scale (MMAS) and functional tests (timed up and go test, 10-meter walk test). Secondary outcome measures were active ankle dorsi-flexion range of motion (AROM), passive ankle dorsi-flexion range of motion (PROM), single leg stance test, and Barthel index. All measurements were assessed at baseline (T0), immediately after the third session one week later (T1), and one month after the end of the intervention (T2).

Results: We recruited 24 patients (71% male; mean age 57 ± 10 years; 26.4 ± 1.8 kg·m⁻²; time since event: 25.2 ± 12.5 months). There were significant improvements in MMAS, timed up and go test, 10-meter walk test, Barthel scale, and PROM ($P<0.05$) in the intervention group compared to controls across the time-points. There were no significant improvements in AROM assessments ($P>0.05$).

Conclusions: Deep dry needling decreases muscle spasticity and improves lower limb function and gait speed in post-stroke survivors.

Key words: Stroke, Spasticity, Deep dry needling, Sham dry needling.

Introduction

Stroke is a serious clinical condition leading to a major cause of long-term disability in survivors.^{1,2} According to the World Health Organization, there were 42.4 million post-stroke survivors in 2015.^{3,4} Disability affects 75% of post-stroke survivors causing limitations to daily activities and reducing quality of life.⁵ Spasticity is the leading cause of disability in patients affecting 60% of the cohort.⁶ Patients with lower limb spasticity have various difficulties in walking and standing resulting in high levels of disability.^{7,8} Indeed, the spasticity of the lower extremity is associated with a reduction in functional independence.⁹

Currently, existing therapies for the elimination of spasticity include anti-spasticity drugs such as baclofen, dantrolene, tizanidine, and diazepam, which treat the symptoms of the condition and may lead to side effects, or in extreme cases, may contribute to increased dysfunction.¹⁰⁻¹² The emergence of dry needle therapy, a relatively new technique, has recently shown promise.^{13,14} This treatment method is widely used in managing myofascial pain, trigger points, and soft tissue injuries including tendinitis.¹⁵⁻¹⁸ Dry needling (DN) uses a thin sterile stainless-steel needle, without the use of injectate, to penetrate the skin and stimulate trigger points, neural tissue, muscles and connective tissue for pain relief and functional improvement.^{19,20} This stimulation disrupts the endplate zone of the nerves and improves blood flow leading to improvements in motor function and control.^{21,20}

In recent years, the use of DN has increased in the treatment of post-stroke survivors.¹⁴ According to a case report and case series, DN is effective in the upper body of post-stroke survivors for improving function.^{14,22} Further work has shown a positive impact of DN on the gastrocnemius and soleus muscle groups in the lower limb following stroke.^{23,24} However, few randomized clinical trials (RCTs) have focused on DN in the lower extremities of post-stroke survivors.^{25,26} Longer term studies currently do not exist and, due to the possible placebo effect of dry needling,²⁷

studies should compare DN to a sham treatment to minimize the risk of bias. Therefore, the aim of this randomized clinical trial was to determine the effects of DN on lower limb spasticity and dysfunction in post-stroke survivors in the short and longer-term compared to sham treatment. We hypothesized that post-stroke survivors receiving three weekly treatment sessions of DN would exhibit a greater reduction in spasticity and improvement in function in the short- (one week) and longer-term (one month) compared to matched patients who received sham treatment only.

Methods

Study design

A double blind, sham controlled, parallel group, randomized controlled trial. The study protocol was approved by the review board, Sports and Exercise Medicine Research Center, and the Ethical Committee of Tehran University of Medical Sciences (TUMS) All patients were informed about the study aims and procedures, and provided full written consent prior to participation in the study.

Population

The inclusion criteria were: 1) age between 18 and 75 years; 2) first hemiplegic ischemic stroke; 3) stroke occurred at least six months prior to trial recruitment; 4) Able to walk without support for at least 10 meters 5) MMAS spasticity score ≥ 1 ; 6) Ambulation ability ≥ 3 based on the Functional Ambulation Classification (FAC) test 7) taking no antispasmodic drug; and 8) be able to understand and follow the instructions. The exclusion criteria were: 1) have any contraindications to dry needling; 2) have cognitive alterations; 3) history of diabetes or neurological pain; 4) fixed muscle contractures at the ankle joint; 5) currently receiving other treatment protocols; and 7) do not consent to participate in the study.

Outcome measures

The primary outcome measures were the Modified Modified Ashworth Scale (MMAS), and functional tests (timed up and go test, 10-meter walk test). Secondary outcome measures were ankle active extension range of motion (AROM), ankle passive extension ROM (PROM), single leg stance test, Barthel index, fascicle pennation angle and muscle thickness of the gastrocnemius muscle. All measures were assessed at baseline (T0), immediately after the third session of DN (one week; T1), and after one month (T2). The changes in mean scores after the intervention were compared between groups at each timepoint.

Procedures

The baseline characteristics were recorded including sex, age, weight, height, BMI; duration elapsed from stroke and hemiplegic side. A qualified sports medicine specialist delivered the DN in three sessions spaced across one week, with at least 48 hours between treatment sessions.

Measurements

Modified Modified Ashworth Scale

MMAS is an established method for assessing spasticity in post-stroke patients.^{28,29} A score of '0' indicated without an increase in muscle tone; '1' indicated a slight increase in muscle tone, '2' indicated a marked increase in muscle tone; '3' indicated considerable increase in muscle tone, passive movement difficult; and '4' indicated the affected part rigid in flexion/extension.³⁰ The MMAS has low levels of inter- and intra-rater variability in post-stroke patients.^{31,32} The validity and reliability of the Persian version of the MMAS has been previously established.³³ Assessment was carried out in a supine position, the assessor moved the ankle passively from maximum possible plantar flexion to maximum possible dorsiflexion. MMAS was performed once to avoid causing changing in spasticity.³⁴

Timed up and go test

This test is used to evaluate functional ability. The patient is seated in an arm chair and following a command from the assessor, the patient must stand, walk 3 meters forward, turning toward the affected side, and return to the chair. The time to complete the task is recorded by the assessor. The validity and reliability of the test has previously been reported.³⁵ Tests were carried out three times and the best performance was used for data analysis.

Single leg stance

This test measures the ability to stand on one leg and maintain balance. The patient was asked to put their hands on the pelvic and try to stand on one leg. The duration the patient could hold the stance was recorded. The validity and reliability of the test has been previously reported.³⁶ Tests were performed three times and the lowest data was used for analysis.

10-meter walk test

This test is used to assess walking speed with the patient being timed during a 10m walk along a corridor. Previous work has demonstrated the validity and reliability of the test.³⁷ Three assessments were performed and the best time was reported.

Barthel index

The Barthel questionnaire was used to determine the magnitude of disability and dependency for undertaking daily activities. This questionnaire includes 10 items relating to the presence or absence of fecal incontinence or urinary incontinence and asks about help needed with grooming, toilet use, feeding, transfers (e.g. from chair to bed), walking, dressing, climbing stairs and bathing. Scoring is by summing the patient's scores for each item. Possible scores for each question range from 0 – 20 and lower scores reveal a greater dependency on others.³⁸ The validity and reliability of this scale have been previously reported.³⁹

Range of motion

Active and passive ankle dorsiflexion were measured in the supine position with knee extension using a standard manual goniometer. The assessor aligned the fulcrum of the device along the lateral malleolus, with the stationary arm of the device along the fibula and the moveable arm parallel to the fifth metatarsal bone.

Ultrasonographic parameters

The most common pennate muscle affected by spasticity following stroke is the gastrocnemius medialis muscle²⁴ which is the main contributor to gait dysfunction. Muscle architecture (i.e. pennation angle and muscle thickness) affects muscle function⁴⁰ and these factors are often used to estimate the amount of force-generating capability.⁴¹ Using ultrasonography imaging is a safe, cost effective, and non-invasive method for characterizing muscle architecture.^{24,42}

The gastrocnemius muscle was evaluated via ultrasound imaging (Sonosite MicroMax Ultrasound System, Bothell, WA, USA, Real-time, B-mode). The reliability of the fascicle pennation angle and muscle thickness of the gastrocnemius muscle has been previously studied.⁴³ To evaluate ultrasonographic muscle measurements we asked patients to lie in a prone position, with their feet hanging off the bed, but being kept stable via an orthosis at maximum plantar flexion (Figure 1).^{44,45} The 5–10-MHz linear transducer was coated with a water-soluble transmission gel and positioned at the midpoint of the medial gastrocnemius muscle belly, between the medial and posterior borders at 30% of proximal tibial length.⁴⁶ While taking images, minimal pressure was

maintained on the skin surface to avoid compression of the muscle fibers. During each session, assessments were performed on two occasions for each participant and the average value was calculated.

Medial gastrocnemius muscle thickness was measured from the distance between the superficial and deep aponeuroses, and the pennation angle was measured at the fascicular insertion at the deep aponeurosis (Figure 2).

Dry needling

The DN protocol was performed using disposable sterile stainless-steel needles (size, 0.30 mm×50 mm; SMC, Seoul, Korea) with patients in the prone position with their ankles hanging from the bed. The fast-in and fast-out technique was adopted and each muscle was needled for one minute.^{14,22} The depth of needling was determined according to the clinician's judgment (according to the depth of the tissue underling the skin).⁴⁷

For DN of the lateral head of the gastrocnemius muscle, a pillow was placed under the patient's leg, and the muscle was needled 2 cm lateral to the middle of the proximal segment of a line connecting the heel to the popliteal crease. A point located 2 cm medial to the one third of distal segment was needled for the medial head of the gastrocnemius muscle (Figure 2).

Randomization and blinding

Patients were allocated to two groups by computer generated randomization in blocks of 20 in a 1:1 ratio. The patients were randomized to 1 of 2 groups: dry needling (intervention group) and sham dry needling (control group). A research assistant not involved in any other part of the study opened the sealed opaque envelopes and assigned the patients to their respective treatment group. The DN and sham DN was performed by a trained practitioner who was independent to the study.

The sham treatment was applied exactly at the same area of the standard DN with blunted dry needling. Assessment was performed by an independent, experienced physiotherapist who was unaware of the allocated intervention. Participants were blinded to the treatment allocation.

Sample size

The required number of samples was calculated using the following formula:

$$n_1 = \frac{(\sigma_1^2 + \sigma_2^2 / \kappa)(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2}$$

The sample size for each of the dependent variables was calculated individually and the largest number was considered as the sample size for our study. We calculated that the sample size for each group should be n=11, which according to the probable rate of loss during the treatment period, 10% was added to account for likely attrition rates, therefore n=12 was selected.

Where:

n_1 = sample size of Group 1= 11

n_2 = sample size of Group 2= 11

σ_1 = standard deviation of Group 1= 23

σ_2 = standard deviation of Group 2= 22.6

Δ = difference in group means=-19.4

κ = ratio $n_2/n_1=1$

$Z_{1-\alpha/2}$ = two-sided Z value (eg. Z=1.96 for 95% confidence interval).

$Z_{1-\beta}$ = power= 85%

(Group 1 = Control, Group 2 = Intervention group)

Statistical analysis

Data were entered into the Statistics Package for Social Sciences (SPSS v22; IBM, NY, USA). All continuous data was presented as mean \pm [standard deviation (SD)]. Data normality was checked for each variable by the Kolmogorov-Smirnov test. Baseline characteristics between groups were compared using an independent t-test. Differences over time between the experimental and control groups were assessed by a 2 \times 3 (group by time) repeated measures analysis of variance. Bonferroni post hoc adjustments were carried out where necessary, and partial eta² (η_p^2). Effect sizes were also calculated, with 0.25, 0.40, and >0.40 representing small, medium, and large effect sizes, respectively.⁴⁸ *P*-values less than 0.05 were considered as significantly different.

Results

Initially 22 post-stroke survivors (71% male; mean age 57 \pm 10 years; 26.4 \pm 1.8 kg·m⁻²; time since event: 25.2 \pm 12.5 months) were eligible for the study. Patients were randomly assigned to the intervention or sham groups (11 participants per group). Patient physical characteristics are reported in Table 1. There were no significant differences between groups for any of these parameters.

Timed up and go test (TUG)

A significant group by time interaction ($F(2, 44) = 5.118, P < 0.001, \eta_p^2 = 0.189$) showed that the two groups responded differently to the intervention. Mean TUG test reduced from 33.82 to 25.06 seconds after one week in the intervention group. This improvement remained after one month.

Ten-meter walk

A statistically significant group-by-time interaction [$F(2, 44) = 49.955, P = 0.02, \eta_p^2 = 0.164$] showed that the two groups responded differently to the intervention. The mean time to complete ten meters improved from 19.1 to 12.2 seconds in the intervention group and was unchanged in the controls.

Single leg stance (SLS)

A significant group-by-time interaction showed that two groups responded differently to the intervention [$F(2, 44) = 11.941, P < 0.001, \eta_p^2 = 0.351$]. A significant main effect was evident [$F(2, 44) = 18.674, P < 0.001, \eta_p^2 = 0.459$] showing how the intervention improved SLS.

Active range of motion (AROM)

A non-significant group-by-time interaction for AROM was not evident showing that the two groups were unchanged following the intervention [$F(2, 22) = 0.423, P = 0.658, \eta_p^2 = 0.019$].

Passive range of motion (PROM)

A group-by-time interaction was evident for PROM showing that the two groups responded differently to the intervention [$F(2, 44) = 13.487, P < 0.001, \eta_p^2 = 0.413$]. A mean difference of -5° between T0 and T1 ($P < 0.001$), and 0.4° between T1 and T2 ($P = 0.723$) was evident following Bonferroni correction adjustment.

Barthel index

A significant group-by-time interaction effect showed that the two groups responded differently to the intervention [$F(2, 44) = 22.624, P < 0.001, \eta_p^2 = 0.538$]. The mean Barthel index improved from 68-78 after one week in the intervention group and was unchanged in the controls.

Pennation angle

A significant group-by-time interaction showed that the two groups responded differently to the intervention [$F(2, 44) = 64.199, P < 0.001, \eta_p^2 = 0.745$]. The pennation angle improved from 19.2° to 17.0° in the intervention group and was unchanged in the controls.

Muscle thickness

A significant group-by-time interaction showed that the two groups responded differently to the intervention [$F(2, 44) = 134.148, P < 0.001, \eta_p^2 = 0.859$]. Mean muscle thickness reduced in the intervention group and was unchanged in the controls.

Discussion

We investigated the impact of three sessions of deep DN in the lower limbs of post-stroke survivors. Our randomized clinical trial showed that the intervention improved functional mobility, gait speed, and passive range of motion and balance in post-stroke survivors. We found a decrease in ankle plantar-flexor spasticity in the intervention group which has been reported in previous studies.^{25,26} To our knowledge, only one other study has assessed the impact of DN over a one-week intervention period, however, they targeted the shoulder complex.⁴⁹

Muscular dysfunction following stroke may cause negative secondary changes due to contractures. These changes include a reduction in muscle fiber length, and a decreased number of serial sarcomeres within muscle fibers.^{50,51} Since muscle stiffness is a result of these structural changes,⁵⁰ our findings showing an improvement in passive range of motion due to deep DN is encouraging. Other investigators have also shown the positive impact of deep DN applications on muscular function in post-stroke survivors.^{14,22,26}

Patients with spasticity exhibit impaired motor activity performance due to complications related to walking and standing.²⁵ Increased walking speed, for example, is related to recovery of muscle spasticity.⁵² Improvements in standing and gait performance as a result of increased foot contact have been reported in post-stroke survivors following DN.²⁵ Our findings showing an

improvement in TUG and ten-meter walking test also confirm the positive impact of DN in this patient cohort. Our findings may also explain the improvements in SLS. Moreover, it has been suggested that a decrease in muscle spasticity could lead to improved postural changes including improved directional control and center of gravity displacement.²⁶ We also found improvements in the Barthel index which is associated with an improvement in functional independency including walking on a level surface, and ascending and descending stairs.⁵³

We did not find any improvement in active range of motion which is in agreement with another recent study.²⁵ However, other studies have reported improvements in active range of motion following deep DN in the upper limb.^{14,25} The authors cautiously hypothesized that DN improved the function of central motor neurons and neural drive, however, there is a lack of empirical evidence to support this assertion. It may be that improved function of afferents from treated muscles to sensory and premotor areas of the brain due to DN may be responsible for the observed motor improvements.⁴⁷ However, to detect these changes, it is feasible that more than three sessions of DN are required. Normally stroke survivors display an increased pennation angle and muscle thickness in their affected muscles.⁵⁴ We have shown that muscle thickness and pennation angle can be improved after three sessions of deep DN. Likewise, a recent study showed similar improvements in muscle morphology after only one session of DN.⁵⁵

In conclusion, deep dry needling decreases muscle spasticity and improves lower limb function and gait speed in post-stroke survivors. With regards to the limitations of this study (small study sample and short duration (4-weeks) of intervention), we recommend that larger, well controlled studies are conducted, perhaps in conjunction with other rehabilitation therapies, to strengthen the evidence-based for dry needling in this patient cohort.

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Figure1. Ultrasonographic gastrocnemius muscle measurements

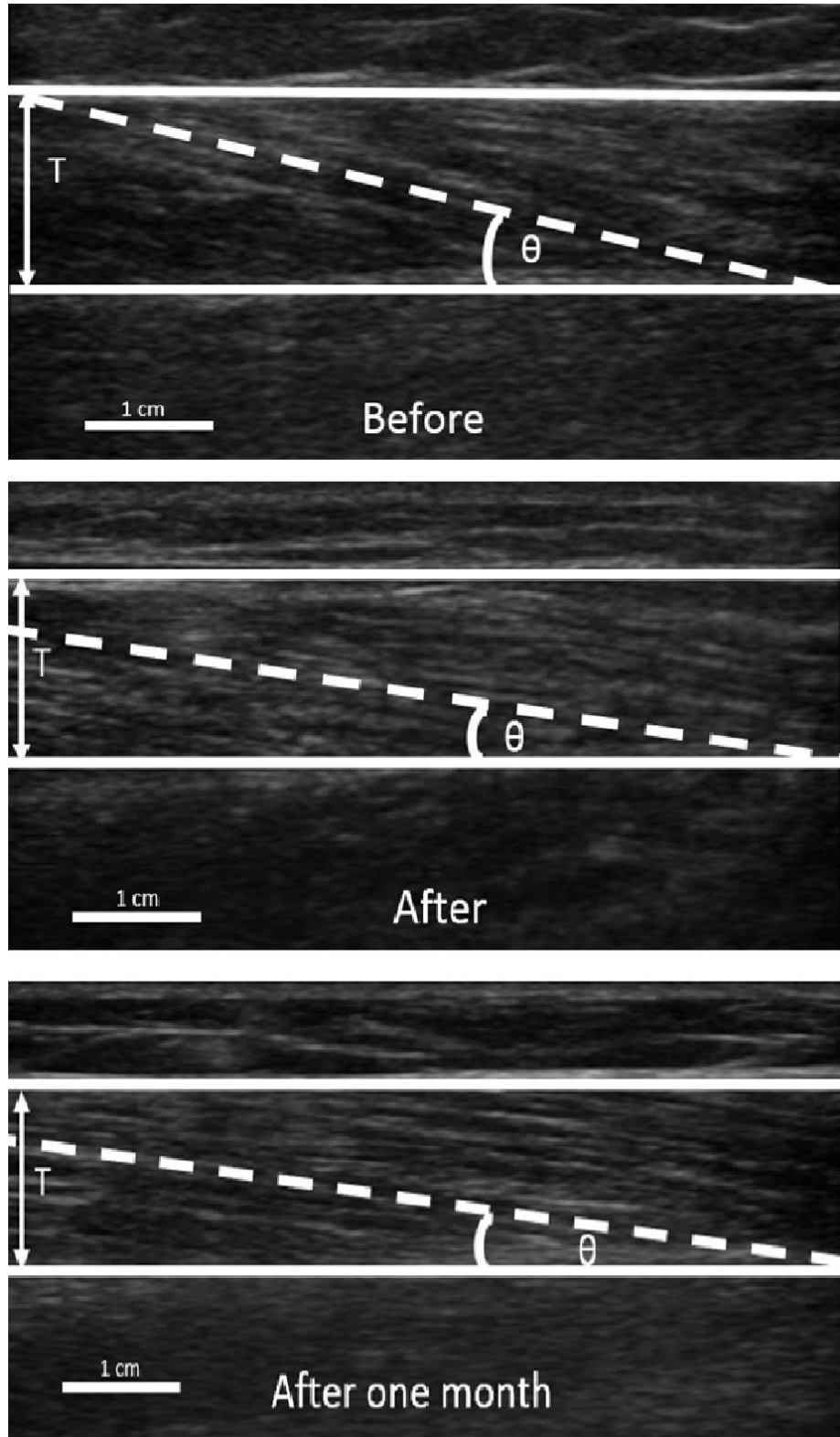


Figure 2. Ultrasound image of the gastrocnemius medialis. Muscle thickness (T) and pennation angle (θ)



Figure 3. Locations for dry needling

Table 1 Baseline clinical characteristics of participants (n=24)

Characteristics	All(n=24)	Experimental (n=12)	Control (n=12)	P-value
Age (year)	57±9.6	58±6.6	55.9±12.1	0.61
Sex (male/female)	17/7	10/2	7/5	0.18
BMI (kg·m ⁻²)	26.4±18	26.5±1.7	26.3±2.1	0.77
Disease duration (month)	25.2±12.5	23.9±13.2	26.4±12.1	0.47
Hemiplegic side (left/right)	12/12	6/6	6/6	1.00

Note: Values expressed as mean± SD unless indicated otherwise; BMI: body mass index. P-values calculated by independent samples t test or chi-square test.

Table 2. Changes in spasticity, range of motion, functional capacity, and quality of ADL in experimental and control groups (n=24) at baseline (T0), after completion of the intervention (T1), and 4 weeks later (T2).

Variables	Experimental Group (n=12)			Control Group (n=12)			Time Effect (P-value)	Group by Time Interaction (P-value)
	T0	T1	T2	T0	T1	T2		
MMAS (score)	2.25±0.8 7	1.33±0.89	1.33±0.89 0	2.50±0.67	2.33±0.78	2.33±0.78	*	*
10-m walk (min)	19.09±1 8.05	12.24±11. 87	12.27±11. 88	20.27±15. 07	18.44±15. 35	18.42±15. 47	*	*
TUG (sec)	33.82±2 4.36	25.06±16. 62	24.99±16. 98	32.13±20. 55	31.41±20. 32	31.21±20. 44	*	*
SLS (sec)	1.10±1.2 1	1.83±1.39	1.98±1.52	.1.07±.61	1.17 ±.58	1.16±.57	*	*
AROM (degree)	5.16±3.7 3	5.33±3.62	5.33±3.65	4.41±2.71	4.58±2.81	4.75±2.86	0.062	0.658
PROM (degree)	12.58±6. 66	17.58±5.9 0	18.00±5.3 4	13.08±4.1 6	12.91±4.2 7	13.41±4.2 1	*	*
BI (score)	67.50±1 0.55	77.91±10. 54	78.75±10. 25	70.83±11. 44	73.33±11. 47	73.34±11. 47	*	*
Pennation angle	19.16±1. 45	16.94±1.4 6	17.03±1.4 3	19.00±1.0 1	18.98±1.0 1	19.01±1.0 8	*	*
Muscle thickness	15.01±1. 09	12.79±.91	12.82±.96	14.90±.84	14.84±.88	14.87±.91	*	*

NOTE. Values are mean + SD. MMAS: Modified Modified Ashworth Scale; TUG: Timed up and go test; SLS: Single Leg Stance; AROM: Active Range Of Motion; PROM: Passive Range Of Motion; BI: Barthel Index; *P<0.05.

Modified Modified Ashworth Scale (MMAS)

A repeated measures ANOVA showed a significant group by time interaction ($F(2, 44) = 11.278$, $P < 0.001$, $\eta_p^2 = 0.339$) demonstrating that the two groups responded differently to the intervention. In the experimental group, the MMAS reduced from 2.58 at baseline, to 1.83 following treatment, and remained the same one week later, demonstrating a reduction in spasticity. There was no change in the control group. A significant time effect [$F(2, 44) = 23.532$, $P < 0.001$, $\eta_p^2 = 0.517$]; was also evident (Table 3).

Table-3 The Modified Modified Ashworth Scale (MMAS). Scores presented as the median value.

MMAS	Intervention Group (n=12)			Control Group (n=12)		
	T0	T1	T2	T0	T1	T2
0	0	2 (16.7%)	2 (16.7%)	0	0	0
1	3 (25%)	5 (41.7%)	5 (41.7%)	1 (8.3%)	2 (16.7%)	2 (16.7%)
2	3 (25%)	4(33.3%)	4 (33.3%)	4 (33.3%)	4 (33.3%)	4 (33.3%)
3	6 (50%)	1(8.3%)	1 (8.3%)	7 (58.3%)	6 (50%)	6 (50%)
4	0	0	0	0	0	0
