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The neurophysiological effects of dry needling in patients with upper trapezius myofascial trigger points: study protocol of a controlled clinical trial

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ABSTRACT

Introduction: Dry needling (DN) is an effective method for the treatment of myofascial trigger points (MTrPs). There is no report on the neurophysiological effects of DN in patients with MTrPs. The aim of the present study will be to assess the immediate neurophysiological efficacy of deep DN in patients with upper trapezius MTrPs.

Methods and analysis: A prospective, controlled clinical trial was designed to include patients with upper trapezius MTrPs and volunteered healthy participants to receive one session of DN. The primary outcome measures are neuromuscular junction response and sympathetic skin response. The secondary outcomes are pain intensity and pressure pain threshold. Data will be collected at baseline and immediately after intervention.

Ethics and dissemination: This study protocol has been approved by the Research Council, School of Rehabilitation and the Ethics Committee of Tehran University of Medical Sciences. The results of the study will be disseminated in a peer-reviewed journal and presented at international congresses.

ARTICLE SUMMARY

Article focus

- This study will evaluate the neurophysiological effects as well as pain relieving effectiveness of deep dry needling (DN) in patients with upper trapezius myofascial trigger points (MTrPs).

Key messages

- This study will demonstrate the immediate effectiveness of DN on pain, neuromuscular junction response and autonomic responses in the upper trapezius MTrPs.

Strengths and limitations of this study

- This clinical study will be the first controlled clinical trial to investigate the immediate neurophysiological effects of DN on MTrPs.
- This protocol will help to understand the mechanisms of DN for treating MTrPs.
- The major limitation is that the therapist applying the intervention will be the assessor collecting the data.
- The long term as well as functional effects will not be investigated.

INTRODUCTION

Myofascial trigger points (MTrPs), characterised as local hypersensitive points that usually form a palpable taut band within skeletal muscle fibres, are considered as a major source of pain in 30% of individuals with musculoskeletal dysfunction.[1–4] There are two categories of trigger points, active or latent, that may develop within a skeletal muscle. Active trigger points are spontaneously active and produce local or referred pain to remote structures. Latent trigger points, however, are not spontaneously active and would not produce any symptoms unless being evoked by an external stimulant.[1 5] In the upper quadrant, postural muscles in general and the upper trapezius muscle in particular are most affected by MTrPs.[6–8] The presence of active trigger points in a muscle may cause sensory, motor and autonomic symptoms.[1 2]

The aetiology of trigger point formation in a muscle and its mechanism of producing somatic symptoms is not fully understood. It is proposed that trigger points often form at the location of muscle endplates causing chemical changes and abnormal endplate activity at the neuromuscular junction (NMJ).[9 10] Continuous irritation of the endplates leads to excessive release of acetylcholine. Release of acetylcholine or lack of acetylcholinesterase results in taut band formation, which leads to constant localised muscle fibre contraction.[10 11] Biochemical changes,[12–14] chronic overuses or muscle injuries,[15] and central sensitisation[10 16] are other factors that could lead to trigger point formations in a skeletal muscle.

Patients with MTrPs may present with autonomic symptoms including sweating, pilomotor activity, changes in skin temperature, lacrimation and salivation.[2] The sympathetic nervous system activity may also increase motor activity and cause muscle pain at MTrPs.[17–19]

Considering the different causes of trigger point formation, there are a variety of invasive and non-invasive treatments proposed for managing MTrPs. Non-invasive methods used in physiotherapy include stretching, laser therapy, ultrasound, transcutaneous electrical nerve stimulation and biofeedback.[20] Dry needling (DN) is a relatively new invasive method which is increasingly used for treatment of MTrPs.[20] DN involves inserting a needle into an MTrP without injecting any medication. This technique is reported to be an effective and efficient treatment for reducing somatic pain and dysfunction associated with MTrPs in a muscle.[20–22] There is no study investigating the effect of DN on neuromuscular junction response (NMJR) and autonomic responses in a population with MTrPs. Therefore, for safe practice of DN, it is important to study the neurophysiological responses to DN in participants with MTrPs compared with healthy individuals. We hypothesised that (1) participants with MTrPs will show irregular NMJR compared with individuals without, (2) DN will result in a higher sympathetic response in participants with MTrPs compared with healthy individuals and (3) DN will normalise NMJRs in participants with MTrPs.

AIMS AND OBJECTIVES

The aim of the present study will be to investigate the effects of DN on NMJR and sympathetic outflow in individuals with MTrPs.

METHODS

Study design

This study is a controlled clinical trial designed to investigate the effectiveness of DN on NMJR and sympathetic outflow in patients with upper trapezius MTrPs compared with a healthy individual matched group.

Setting

The study will be performed at the Department of Electrophysiology, School of Rehabilitation, Tehran University of Medical Sciences (TUMS), Tehran, Iran.

Approval of study protocol

This study has been approved by the Research Council, School of Rehabilitation, TUMS and ethics approval has been obtained from the ethics committee of TUMS (reference number 2185).

Informed consent

A detailed description of all examination and treatment procedures, including DN, and risks involved in this study will be provided to the participants. A written informed consent will be obtained from all participants who agree to take part in this study, before data collection. Participants will have the right to refuse DN treatment and withdraw from the study at any time without penalty. The same physiotherapist who is administering the intervention will obtain it.

Participants

Patients will be recruited from the university orthopedic and physiotherapy clinics at TUMS. To be included in the study, patients have to be aged between 20 and 40 years and to have upper trapezius active MTrPs. The three important criteria for diagnosing MTrPs will be: (1) taut band, (2) tender point in a taut band and (3) recognition of pain. Patients with a history of spinal or shoulder disorders, neck and upper extremity surgery, acute disease, muscle diseases, neurological or systemic disorder (such as lupus erythematosus and scleroderma), epilepsy, pregnancy, using sedative drugs, needle phobia, bleeding disorder, anticoagulant medication, previous experience with DN for myofascial pain, skin lesion and infection or inflammatory oedema at the MTrPs site will be excluded.

Recruitment

Volunteers for participation in this study will be recruited from the pool of patients diagnosed with myofascial-related shoulder or neck pain at the TUMS orthopedics and physiotherapy clinics. Participants are informed about the purpose of the study and the examination and treatment procedures involved in this project. Patients will have the option of participating in this study or continuing with regular care through the clinic. Healthy volunteers matched in age, gender, body mass index with no history of neck and shoulder pain will be recruited through advertisements on bulletin boards, posting flyers or verbal requests in the abovementioned clinics and rehabilitation department at TUMS. The same physiotherapist who provides DN treatment will collect the pretreatment and post-treatment data from each participant.

Outcome measures

The outcome measures will be the NMJR, sympathetic skin response (SSR), pain intensity and pressure pain threshold (PPT), which will be taken and recorded before and immediately after DN treatment. All measurements will be performed by a trained physiotherapist between 9:00 and 12:00.

Primary outcome measures

NMJR

An electrodiagnostic technique of repetitive nerve stimulation (RNS) will be used to assess NMJR. This is the most widely used method in the evaluation of NMJR. The RNS method is based on the repetitive supramaximal stimulation and the measurement of decremental/

incremental responses. The amplitude of the evoked trapezius compound muscle action potential (CMAP) will be measured. Recordings will be made with surface electrodes with the patient in a supine position on an examination table (sensitivity 5 mV/div, sweep speed 5 ms/div and filtering of 5 Hz–5 KHz). Surface stimulating electrodes will be placed over the spinal accessory motor nerve along the posterior border of the sternocleidomastoid muscle at the level of the upper border of the thyroid cartilage. The active electrode will be placed on the skin over the upper trapezius muscle 5 cm from the C7 spinous process, and the reference electrode will be located 2 cm from the C7 spinous process. Trains of 9 supramaximal electrical stimulation at a rate of 3 Hz will be delivered to the spinal accessory nerve, and the evoked trapezius CMAP will be recorded. The ratio of the amplitudes of the fifth to the first responses will be used as a measure of decrement or increment expressed as a percentage. The trapezius skin temperature will be measured.

Sympathetic skin response

A Tonnies electromyography instrument (Neuroscreen Plus-Germany) with surface electrodes to assess SSR (sensitivity 500 micV/div, sweep speed 1000 ms/div and filtering of 0.08–20 Hz) will be used to assess changes in SSR. The measurements will be carried out in a silent, semidark room with patients in a supine position and their eyes closed. Care will be taken to maintain a comfortable room temperature of 24°C. SSR will be recorded following a single square-wave electric stimulus over the median nerve at the wrist. The recording and reference electrodes will be placed on the palm and on the back of the hand, respectively. Three electrical stimulations at 1 min intervals will be delivered. Patients will be asked to remain calm throughout the procedure. The mean of the three trials will be obtained. The SSR latency, duration and amplitude will be calculated to assess the sympathetic function.

Secondary outcome measures

Pain intensity

Pain intensity will be self rated by the participants on a 0–10 numerical rating scale with 0 representing no pain and 10 representing the worst imaginable pain.

Pressure pain threshold

The physiotherapist will use a pressure algometer (Digital Instrument-Lutron, Taiwan) to measure the PPT. First, the whole procedure will be explained to the participants. To measure PPT, the participant will be placed in a comfortable supine position and the most painful spot in the upper trapezius MTrP region will be identified. Then the metal rod of the algometer will be pressed perpendicular to the skin over the identified trigger points in the upper trapezius muscle. The applied pressure will be increased at the rate of 1 kg/cm^2. The participant in the control group will be asked to say 'yes' as soon as they feel pain or discomfort. Participants in the treatment group will be required to report when they experienced an increase in pain intensity or discomfort (for MTrPs group). This procedure will be repeated three times at 40 s intervals. The average of the three values will be determined as the PPT.

Intervention

Following baseline measurements, deep DN will be provided by a licensed and trained physiotherapist. Participants in both groups will receive one session of DN treatment for the trapezius muscle. Participants will be placed in a supine position on the examination table. The sterile acupuncture needles of 0.30 mm diameter and 50 mm length will be used (Seirin J, Japan). The needle will be inserted into the skin over the palpated trigger point and slowly advanced until it reaches the trigger point and a twitch response is elicited. Reproduction of identifiable pain or visualisation of a local twitch response indicates appropriate needle placement.[23] Each trigger point will be repeatedly needled for 1–2 min until the pain is resolved. No concomitant medications or therapies will be allowed.

Adverse effects

DN has been used safely for treating MTrPs in patients with myofascial-related pain and dysfunction. However, as this is a minimally invasive treatment, there are some risks involved in this procedure. There are minimal chances of infection, local bleeding, increased pain and stiffness and a rare chance of induced pneumothorax with needling. Using single-wrapped-sterilised needles will significantly reduce the chance of infection. Monitoring the patient's history and excluding patients with cardiovascular and bleeding problems or those who are taking blood thinner medications will reduce the chance of bleeding. Providing treatment by an experienced and trained physiotherapist and following the recommended procedures for safe needling of the trapezius muscle will reduce the chance of pneumothorax. Participants may experience local muscle soreness after needling. This side effect is not usually significant.

Nevertheless, the needle insertion site will be heat compressed, if necessary.

Sample size

As there is no related study to estimate the effect size for primary outcome measures, we will conduct a pilot study to estimate the effect size of DN. Then, using power analysis, the required sample size with an α of 0.05 and a power of 0.8 will be determined. Assuming a large effect size, we anticipate recruiting a total of 30 participants (15 in each group) for the study. The enrolment will be continued to reach the required sample size.

Statistical analysis

Data analysis will be performed using the SPSS V.17 software. Means, SDs and 95% CIs will be calculated for all

Table 1 Demographic and clinical characteristics of study participants

	Number	Mean±SD (range)	Minimum	Maximum
Gender				
Male				
Female				
Age (years)				
Weight (kg)				
Height (cm)				
BMI (kg/m^2)				
Duration of illness (month)				
Affected side				
Right				
Left				

BMI, body mass index.

outcome measures. The Kolmogorov-Smirnov test will be performed to determine if the data have a normal distribution. If the dataset distribute normally, a parametric test of multivariate analysis of variance will be used to compare the outcomes between the treatment and control groups. If normality is not established, then a non-parametric test, the Mann-Whitney U test, will be used for data analysis. A p value of <0.05 will be considered to be statistically significant. Data will be analysed at the conclusion of data collection by a statistician who is blinded to the group assignments of the study.

RESULTS

Demographic characteristics of participants will be illustrated in table 1.

Descriptive statistics associated with each outcome measure obtained from both the groups will be presented in table 2.

DISCUSSION

The present study will investigate the effects of DN on NMJR and SSR in patients with active MTrPs in their upper trapezius muscle. To the best of our knowledge, this study will be the first report to evaluate the immediate effects of DN on SSR, NMJR and pain in muscles with and without MTrPs. The authors of this study will explain their findings and discuss how they relate to the current hypothesis which attributes development of MTrPs in the skeletal muscles to excessive acetylcholine release in the NMJ, sarcomere shortening and abnormal release of sensitising substances.[12 13 24] The authors will discuss how the findings of this study will advance our understanding of mechanisms underlying MTrPs formation in skeletal muscles and assist in exploring the potential effective and efficient treatments for patients. The authors will also discuss the mechanism of pain reduction through DN and how it might relate to Melzack's gate control theory.[25 26] In this study, the possible relationship between improvement of pain intensity and PPT following DN and the rule of changes in NMJR and SSR will be discussed.

Limitation

Although desirable but owing to technical difficulties, the assessing therapist will not be blinded to the participant's group assignment. Another limitation of the study will be lack of functional measures to investigate the long-term effects of DN on participants' functional abilities.

Conclusions

The results of the present study will show the effects of DN on NMJR and autonomic response in patients with upper trapezius MTrPs.

Table 2 The results of clinical and neurophysiological measurements

	Patients		Healthy participants	
	Before DN Mean±SD (range)	After DN Mean±SD (range)	Before DN Mean±SD (range)	After DN Mean±SD (range)
SSR latency (ms)				
SSR amplitude (μv)				
SSR duration (ms)				
NMJR (% change)				
Pain intensity				
PPT (kg/cm^2)				

DN, dry needling; NMJR, neuromuscular junction response; PPT, pressure pain threshold; SSR, sympathetic skin response.

Contributors MAA is the principal investigator, responsible for dry needling and collecting data, and wrote the manuscript for publication. NNA read and revised the manuscript critically for important intellectual content. All authors contributed to the study conception and design, interpretation of data, and reviewed and approved the final version of the manuscript.

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Ethics approval This study has been approved by the ethics committee of Tehran University of Medical Sciences (reference number 2185).

Competing interests None.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement No additional data are available.

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