Comparing two dry needling interventions for plantar heel pain: a protocol for a randomized controlled trial

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COMPARING TWO DRY NEEDLING INTERVENTIONS FOR PLANTAR HEEL PAIN: A RANDOMIZED CONTROLLED TRAIL

Relevant scientific background

Plantar heel pain (PHP) is a common problem affecting the foot, causing soreness or tenderness in the sole of the foot, and under the heel, sometimes extending into the medial arch.[1] The frequency and incidence of PHP is uncertain, however it is estimated that over the course of a lifetime 10% of the population may suffer from this condition.[2 3] Several pathologies may cause PHP, such as myofascial pain syndrome, plantar fasciitis or heel spur, amongst others.[4] The clinical diagnosis is usually established based on the patient's history and physical examination, including pain during the first steps in the morning or after prolonged rest, as well as pain during prolonged standing or walking.[2 3 5] The identification of the main cause of pain can be challenging as this is often multifactorial,[6] and despite its prevalence, the etiology of PHP is not well understood.[2 3] The presence of myofascial trigger points (MTrPs) within the muscles of the foot and lower leg may play an important role in people in PHP,[7] an implicit assumption underlying many recent studies.[8-11] In addition, there is a lack of consensus regarding the ideal management approach for PHP.[12-14] Clinical practice guidelines support the use of conservative treatment, such as joint and soft tissue mobilization or self-stretching home programs.[2 3] In particular, self-stretching home programs have shown to be effective for addressing PHP.[2 6 15] Furthermore, recent randomized clinical trials (RCTs) have shown that there is an additional effect of reduction of pain severity when self-stretching home programs are combined with ischemic compression[11] and with dry needling.[9] Physical therapy approaches continue to evolve and include the combination of dry needling and electrolysis, known as percutaneous needle electrolysis, with promising results for the treatment of tendon pathologies.[16-18] The percutaneous needle electrolysis technique is a minimally invasive

treatment that consists of the application of a galvanic electrolytic current that causes a controlled local inflammatory process in the target tissue. This promotes phagocytosis and the subsequent regeneration of the affected tissue.[16 17] Currently, percutaneous needle electrolysis is being used in clinical practice to manage MTrPs, however, there are no studies supporting any additional beneficial effects of the same over dry needling.

From a biological point of view, it seems reasonable to hypothesize that subjects may display improvements thanks to the mechanical effects of the needle, and that patients may experience superior benefits when the electrolysis effect is added to the mechanical stimulus provided by the needle. Therefore, the aim of this RCT was to compare the effectiveness of dry needling versus percutaneous needle electrolysis for improving the level of pain, function and quality of life of patients suffering from PHP caused by MTrPs.

METHODS

Design

This study was a prospective, parallel-group RCT with blinded outcome assessment. Participants were recruited from Kuwait City, Kuwait, and both the assessment and intervention were conducted at the Physical Medicine and Rehabilitation Hospital in Kuwait. The study was conducted in compliance with the Helsinki Declaration of Human Rights and ethical approval was obtained by the Medical Ethics Committee of the State of Kuwait Ministry of Health, with reference number 642/2017. The study protocol has been previously published[19] and the trial is registered at Clinicaltrials.com, number NCT03236779. This RCT was reported in accordance with the CONSORT statement for non-pharmacological trials.

Participants

The study subjects were male and female adults, enrolled at the Physical Therapy Department of the Physical Medicine and Rehabilitation Hospital in Kuwait City. Participants were included if they fulfilled the following criteria: 1) diagnosed of plantar heel pain in accordance with the Clinical Guidelines linked to the International Classification of Function, Disability and Health from the Orthopedic Section of the American Physical Therapy Association;[2 3 8 9] 2) aged 21 to 60 years at admission to the study, according to the Kuwaiti Ethical Committee; 3) a history of PHP for over one month, showing no improvements with previous conservative treatment; 4) the ability to walk 50 meters without any support; 5) the presence of MTrPs on plantar and calf muscles based on an initial physical examination carried out by a physiotherapist (MA) with experience and training in MTrPs; 6) accepting treatment from a male physiotherapist; 7) the ability to understand the study and the informed consent, as well as having signed the consent form.

The exclusion criteria were: 1) needle phobia; 2) needle allergy or hypersensitivity to metals; 3) the presence of coagulopathy or use of anticoagulants according to medical criteria; 4) the presence of peripheral arterial vascular disease; 5) pregnancy; 6) dermatological disease affecting the dry needling area; 7) the presence of any chronic medical condition which might preclude participation in the study, such as: malignancy, systemic inflammatory disorders (e.g., rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, septic arthritis), neurological diseases, polyneuropathy, mononeuropathy, and sciatica; 8) treatment of plantar heel pain with needling or acupuncture during the last four weeks; 9) history of injection therapy in the heel over the previous three months; and 10) previous history of foot surgery or fracture. Receiving or implementing any form of treatment for the plantar heel pain (taping, night splints, massage therapy or footwear modifications) during the trial was considered withdrawal criteria.

The sample-size calculation initially estimated that 39 participants per group would provide 80% power to detect a minimally important difference of 13 points in the pain domain of the Foot Health Status Questionnaire with a standard deviation of 20 points[20] and an alpha risk at 0.05. Allowing for a 20% loss to follow-up, a minimum of 47 participants was required in each group, equaling 94 participants in total. Based on initial data collection, the drop-out rate was recalculated to be 25% and the sample size was therefore increased to a total of 102 patients.

Patient and public involvement

No patients were involved in the design, recruitment or conduction of this study and the burden of the intervention was not assessed by patients themselves neither.

Randomization

Participants who fulfilled the inclusion criteria received standardized oral and written information, and, after consenting to participate in the trial, they were randomized using block randomization by blocks of 10 patients. Allocation was randomly assigned using a computer program (Randomizer, https://www.randomizer.org/) with random patient file number sequences generated by a third person not involved in the study.

Procedure and interventions

Two study groups were randomly formed. The first was treated with dry needling whereas the second group was treated with percutaneous needle electrolysis. In both groups, during the first session, all participants were taught a self-stretching protocol[11] which has been demonstrated to be effective for the management of PHP,[2 6 11] consisting of self-stretching of the calf muscles and

specific self-stretching for the plantar fascia.[19] The frequency of calf and plantar fascia-specific self-stretching exercises was twice a day, using intermittent stretching lasting 20 seconds, followed by 20-second rest periods, for a total of three minutes per stretch.[11] Compliance with the self-stretching protocol was registered before each treatment session and at the four-week follow-up.

The muscles considered for invasive physical therapy treatment were the soleus, gastrocnemius, quadratus plantae, flexor digitorum brevis and abductor hallucis. These muscles typically refer pain to the heel and are muscles than can be directly palpated or that can be needled precisely and safely without ultrasound guidance. The clinician performed a physical exam to find MTrPs following the criteria by Travell and Simons: 1) the presence of a taut band and 2) identification of an exquisite spot tenderness or a nodule.[7] A flat palpation or pincer palpation technique was used to palpate the MTrPs, depending on the muscle being assessed. If a muscle contained more than one MTrP, the most sensitive MTrP was treated, according to the patient's perceived pain upon palpation. If the patient presented bilateral pain, the clinician treated both sides. The patient's position (supine, prone or lateral decubitus position) depended on each muscle examined and was the same for the assessment as well as for the intervention.

Each participant received four individual physical therapy sessions, once a week. Participants was treated by one physical therapist registered at the Kuwait Ministry of Health (ZA) with five years of practical experience in the field of dry needling and appropriate training in the protocol. The duration of each session was approximately 30 minutes.

Participants were instructed to use the appropriate dose of medication as prescribed by their Physical Medicine and Rehabilitation physician (analgesics and non-steroidal anti-inflammatory medications) and were required to report any changes to the assessor during the evaluations if they took any additional medication or underwent any treatment during the intervention.

Invasive Intervention Groups: Dry Needling and Percutaneous Needle Electrolysis

Specific needles for dry needling were used during invasive treatments (Agu-punt, Spain). Needle length was determined by the location of the MTrP and ranged from 30 to 75mm in length (or longer if necessary, according to the patients' characteristics). The diameter of the needle was 0.25-0.30 mm. If the participant was sensitive to the needle insertion, the level of manipulation was reduced. If this measure proved insufficient for reducing the painful stimulus, needle manipulation ceased altogether and the needle was left in situ.[21 22]

To maintain appropriate hygienic conditions during the invasive treatments, the clinician wore latex gloves and thoroughly cleaned the skin of the area to be needled with an antiseptic solution (70% Propan-2-ol, Skin-des). Upon removal of the needle, the area was firmly compressed for 10 seconds. The needle was discarded after each single use. In both groups, the intervention was terminated in the case of severe adverse effects and if the participant did not wish to continue.

Dry Needling Arm

Once the clinician located the MTrP, the needle was inserted over the same and a rapid needle entry was performed. The chosen technique for manipulating the needle was the technique described by Hong, which consists of a rapid needle entry and exit (fast in/fast out), in order to obtain a local twitch response, lasting 5 seconds employing a rhythmic movement at approximately 1Hz/sec (5 entries).

Percutaneous Needle Electrolysis Arm

The electrotherapy equipment used (Physio Invasiva, PRIM Fisioterapia, Spain) produced a

continuous galvanic current through the cathode while the patient held a hand-held anode.[18] Once the needle reached the relevant treatment area, this was needled in exactly the same manner as in the dry needling group, with the only difference being that the needle was transmitting an electrical current with an intensity of 1.5 mA (intensity was adapted to patient´s characteristics according to their pain tolerance).

Study Variables

An independent assessor (MA) blinded to treatment group allocation conducted all assessments at baseline, and at the 4, 8, 12, 26 and 52-week follow-up. Demographic and disease data were collected at baseline.

The primary outcome was the Foot Pain domain of the Foot Health Status Questionnaire (FHSQ), a validated measure of foot-health status[23] that has been used in similar trials, which evaluated the effectiveness of different interventions for plantar heel pain.[8 24 25] Individual item scores were inserted into a computer program (FHSQ V.1.03) which, after data transformation, provides a score ranging from 0 to 100 for each domain,[26] with greater scores reflecting a better condition.[27] Secondary outcomes were the Foot Function, Footwear and General Foot Health domains of the Foot Health Status Questionnaire, as well as the average and maximum level of pain over the past 48 hours using the visual analogue scale (VAS). Participants were explained that a score of 0 indicated the absence of pain whereas a score of 10 represented the maximum tolerable pain. Additionally, before each treatment session, they were asked to complete the VAS and after each treatment session, participants were asked to score their current pain immediately upon standing up and walking a few steps. The VAS is widely used and is both valid and reliable.[28-30]

Quality of Life (QoL) was assessed with the EQ-5D-5L, which was completed by the participants at baseline and at the 4, 8, 12, 26 and 52-week assessments. The EQ-5D-5L self-report questionnaire is a descriptive system with five questions, each representing one dimension of Health-related Quality of Life, i.e. mobility, self-care, daily activities, pain/discomfort and depression/anxiety. Each dimension can be rated on five levels: no problems, slight problems, moderate problems, severe problems and extreme problems. Together, the results serve to classify people into 1 of 3125 possible health states.[31] These health states are subsequently transformed to quality of life values with the EQ-5D-5L crosswalk value sets.[32]

Statistical Analysis

The statistical analysis was performed using IBM SPSS Statistics (version 25, IBM, Chicago, IL) by intention to treat, with the last observation carried forward. The investigator who performed the analyses was masked to group allocation. The significance level for all statistical tests was set at $P \leq 0.05$.

Chi-squared tests were used to analyse if there were differences in categorical variables between groups at baseline. In addition, independent Student's t-tests and Mann-Whitney U tests were used for parametric and nonparametric quantitative variables, respectively. Chi-squared tests were used to evaluate the compliance of the self-stretching protocol.

Following recommendations to estimate treatment effects in RCTs, linear mixed models adjusted for baseline values were used to test the mean effect of treatment interventions at the follow up at the 4, 8, 12, 26 and 52-week follow-up, for the Foot Health Status Questionnaire and EQ-5D-5L measures. Linear mixed models adjusted for baseline values were used to test the mean effect of treatment interventions at the second session, third session, fourth session, and at the 4, 8, 12, 26

and 52-week follow-ups, for measures of VAS (average and maximum). Individual repeated measures (RM) ANOVAs were used to test time effects within each treatment group for primary and secondary outcomes. Cross-sectionally, at all linear mixed models and RM-ANOVAs, the Bonferroni correction was used to test between-group time point differences or within-group time changes, respectively. The Greenhouse-Geisser correction was applied for correcting against violations of sphericity, whereas eta-squared (η^2) was used to estimate the magnitude of the difference between both groups (0.01 small effect, 0.06 medium effect and 0.14 large effect).[33] Independent t-tests were used to determine any difference between groups for measures of level of pain immediately after each treatment session.

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