TITLE PAGE

Title: Comparison of the effectiveness of Transcutaneous Electrical Nerve Stimulation and Interferential Therapy on the upper trapezius in myofascial pain syndrome: A randomized controlled study

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TITLE

Comparison of the effectiveness of Transcutaneous Electrical Nerve Stimulation and Interferential Therapy on the upper trapezius in myofascial pain syndrome: A randomized controlled study

ABSTRACT

Objective: To compare the effectiveness of Transcutaneous Electrical Nerve Stimulation (TENS) and Interferential Therapy (IFT) both in combination with hot pack, myofascial release, active range of motion (AROM) exercise and a home exercise program on myofascial pain syndrome patients with upper trapezius myofascial trigger point (MTrP).

Design: One hundred and five patients with an upper trapezius MTrP were recruited to this single-blind randomized controlled trial. Following random allocation of patients to three groups, three therapeutic regimes—control-standard care [hot pack, AROM exercises, myofascial release and a home exercise program with postural advice], TENS-standard care and IFT-standard care—were administered eight times during four weeks at regular intervals. The pain intensity (PI) and cervical range of motions (ROMs) (cervical extension, lateral flexion to contralateral side and rotation to ipsilateral side) were measured at baseline, immediately after the first treatment, before the eighth treatment and one week after the eighth treatment.

Results: The immediate and short-term improvements were marked in the TENS group (n=35) compared to IFT group (n=35) and control group (n=35) with respect to PI and cervical ROMs ($P<0.05$). IFT group showed significant improvement on these outcome measurements than the control group ($P<0.05$).

Conclusion: The TENS with standard care facilitate recovery better than IFT in the same combination.

Key Words: Interferential therapy; Myofascial trigger point; Myofascial pain syndromes; Transcutaneous Electrical Nerve Stimulation; Upper trapezius

INTRODUCTION

Myofascial pain syndrome (MPS) is a common painful disorder of skeletal muscle origin[1] and defined as "Sensory, motor, and autonomic symptoms caused by myofascial trigger points (MTrPs)".[2] MTrPs are hyperirritable spots in skeletal muscle that are associated with hypersensitive palpable nodules in a taut band and they are found in skeletal muscles involved in maintaining posture, fascia, ligaments and tendons.[3,4] They can be divided into either active or latent MTrPs which are activated by emotional, physical and metabolic mechanisms.

A wide range of therapeutic interventions are commonly used to manage MPS including ischemic compression, spray and stretch, strain and counter strain, trigger point pressure release, transverse friction massage, thermotherapy, ultrasound therapy, low-level laser therapy, transcutaneous electrical nerve stimulation (TENS) and interferential current therapy (IFT).[3, 5-7]A variety of therapeutic interventions are also used to manage MTrPs. Myofascial release techniques are used to relax contracted muscle, stimulate the mechanoreceptors, increase the blood flow and neuron conductance.[7,8] Exercises are used to reduce muscle tightness and fear of movement, thereby enhancing confidence in independent movements.[9,7,10,11] These include stretching, strengthening and exercises to improve scapular stability and active range of motion (AROM).[7,12] Exercises to improve AROM are believed to restore normal length and flexibility of muscles.[7] It is claimed that postural advice can prevent recurrent formation of MTrP during and following treatment.[13,14] Hot packs, ultrasound, spray and stretch techniques, TENS and IFT are passive physical therapy modalities that are also is considered to be important to decrease pain and facilitate healing in managing MTrP.[15] Evidence suggests that hot packs, or TENS, or IFT applied over the MTrP alleviates pain and improves the range of motion (ROM).[7,16,17-21,6]

However, evidence suggests that when modalities are given as a single treatment patients experience immediate but not short-to-long term improvement.[22,23] Consequently, active physical therapy, passive physical therapy and postural advice are delivered in combination in an attempt to improve effectiveness, although the effectiveness of this combination therapy is not known.

Evidence suggests that combining active physical therapy with passive physical therapy and postural advice is likely to improve outcomes associated with MPS.[7,16.17,24,25,18,26] A study by Hou and colleagues[7] evaluated therapeutics combinations of hot pack plus AROM; hot pack plus AROM plus ischemic compression, hot pack plus AROM plus ischemic compression plus TENS, hot pack plus AROM plus stretch with spray; hot pack plus AROM plus stretch with spray plus TENS, and hot pack plus AROM plus IFT and myofascial release. They found that pain and ROM were improved when TENS or IFT was added to combination therapies although it was difficult to assess the relative contributions of the two modalities because of a lack of standardization of other treatments across groups. Moreover, effects were assessed immediately after treatment in a clinic rather than longer-term with the inclusion of postural advice. The aim of the present study was to compare the effectiveness of TENS and IFT both in a combination of standard care consisting of hot pack, AROM exercise, myofascial release and a home exercise program in managing MPS patients with MTrPs.

METHODS

Study design and setting

The study was a single-blind randomized controlled trial carried out in the service unit of the Department of Physiotherapy, Faculty of Allied Health Sciences, University of Peradeniya during July 2012 to February 2015. This study compared the effectiveness of TENS with standard care, IFT with standard care and standard care alone (as control intervention) in managing MPS patients with MTrPs. Ethical clearance was obtained from the Ethics Review Committee of the Faculty of Medicine, University of Peradeniya and the study was registered as a clinical trial with the Sri Lanka Clinical Trial Registry (SLCTR).

Participants

Participants were recruited from patients referred for physiotherapy treatment of MPS and MTrP from the orthopedic clinic and sports medicine clinic of the Teaching Hospital, Peradeniya. Individuals expressing an interest in taking part were given a participant information sheet and were screened for eligibility by the principal investigator who is a physiotherapy practitioner. Inclusion criteria were patients between 18 and 65 years of age who could read and understand a daily newspaper published in the Sinhala language and had at least one unilateral active upper trapezius MTrP diagnosed by the presence of a sensitive (tender) spot in a palpable taut band with reproduction of pain when the sensitive spot was compressed.[27-30] Exclusion criteria were patients taking analgesics within 48h prior to the first physiotherapy treatment, and/or patients who had been diagnosed with fibromyalgia, sensory disorders, radiculopathy/myelopathy, disc disease, psychological disorders, degenerative joint diseases, fracture or dislocation of the

cervical vertebrae. All participants signed a consent form before participating and were aware that they could withdraw from the study at any time without giving a reason.

Data from a pilot study that involved 28 participants was used to calculate the sample size necessary using the G* Power software.[31] Estimates were that to detect a significant difference in the improvement of range of motion between two test groups TENS (mean improvement = 13.8, SD=10.1) and IFT (mean improvement = 8.1, SD=4.3), with a power of 80% (beta 0.2), alpha at 0.05 and with a 10% loss to the follow up, it would be necessary to enroll 35 patients for each group.

Randomization

It was planned that 105 participants with unilateral shoulder pain due to at least one MTrP in the upper trapezius muscle would be enrolled onto the study and allocated to one of three treatment interventions using computerized block randomization and allocation group concealed in envelops. The three intervention groups were: standard care (control group); standard care and TENS (TENS group); or standard care and IFT (IFT group). The participants were blind to the allocation to treatment groups following randomization, and hence the study was a single blind trial. The principal investigator acted as both outcome assessor, taking all study measurements, and as therapist administering all study treatment.

Interventions

The intervention period was 4 weeks. Participants were asked to attend the clinic two times per week resulting in a total of eight treatment sessions.[9] A protocol and a study operation manual were developed and a pre-study was conducted to verify whether the measurement procedures

and delivery of interventions were feasible. This pre-study involved 15 patients with myofascial pain syndrome with at least one upper trapezius MTrP and they were not included in the main trial. During the trial, the interventions were administered during each clinic visit by the principal investigator. The standard care was administered first, which lasted 30 minutes and this was followed by 20 minutes of TENS or IFT depending on random allocation of patients. In addition, all patients were provided with a home program of self-administered treatment.

Standard Care (Control) Group

Standard care consisted of hot pack treatment followed by active range of movement (AROM) exercises and myofascial release treatment. A hot pack was placed on the patient's cervical, paraspinal and upper thoracic areas (including the upper trapezius muscle with a MTrP) for 20 minutes. This was followed by AROM exercise for cervical spine joints. Participants were asked to actively flex the neck so that the head dropped towards the non-painful (contralateral) trapezius muscles causing stretch of the affected side. Patients then rotated the head towards the affected (ipsilateral) side. This exercise was repeated 5 times. Myofascial release was performed with the patient supine and the principal investigator sitting behind the patient's head. The principal investigator placed their hands on the upper shoulders of the patient and stretched the upper trapezius muscle of the affected side downward and outward. This unilateral stretching and traction of the shoulder portion involving the upper trapezius with the MTrP were applied for 90-300 seconds until tightness was released.[7,32]

Participants were then provided with advice on correct posture (standing, sitting, sleeping, working) and treatment exercises (AROM, stretching, strengthening and scapular stability

exercises for upper trapezius) to carry out at home each day until the completion of final measurement.[33-35] For each exercise, the participants were asked to perform one set of 10 reps three times a day. The patients were trained on correct posture and how to undertake exercises by the principal investigator at the end of the first treatment session. Participants were checked for competency and any errors in techniques of performing these, and if noted those were corrected before they were sent home. Participants were asked to maintain a diary of home exercises and this was checked by the principal investigator at each treatment session.

TENS Group

Patients allocated for TENS first received standard care, including advice for continuing exercises at home. Immediately after the completion of myofascial release they received 20 minutes of TENS administered using a TENS device (SI No: 4270, Technomed Electronics, Tamil Nadu, India) to deliver asymmetrical rectangular biphasic pulsed electrical currents at a pulse repetition frequency (rate) of 100Hz and pulse duration (width) of 250μs. Pulse amplitude was set at a level to produce a strong but non-painful TENS sensation but without visible or noticeable muscle contraction (i.e. conventional TENS). TENS was administered using a single channel and two electrodes (40mm x 50mm), with the negative electrode (cathode) placed on the MTrP of the upper trapezius muscle, and the positive electrode placed on the insertion of acromial tendon [7] (Figure 1).

[Insert Figure 1 here]

IFT Group

Patients allocated for IFT first received standard care, including advice for continuing exercises at home. Immediately after completion of myofascial release they received 20 minutes of IFT using a dual channel IFT device (SI No: 4270, Technomed Electronics, Tamil Nadu, India). IFT was administered using the quadripolar technique with electrodes placed around the MTrP of the upper trapezius muscle[7] (Figure 2). One channel delivered sinusoidal 'carrier currents' at a frequency of 4000Hz and the other channel delivered currents at a frequency of 4100Hz. This generated an amplitude modulated interference wave of 100Hz (i.e., beat frequency). Pulse amplitude was set at a level to produce a strong but non-painful TENS sensation but without visible or noticeable muscle contraction.

[Insert Figure 2 here]

Measurements

All measurements were taken by the principal investigator. Demographic data and the history of MPS were collected following enrollment. Cervical ROM and pain intensity were measured at baseline, immediately after the first treatment (within 5 min), before the eighth treatment and one-week after the eighth treatment. The principal investigator palpated and marked the MTrP.[36] Three measurements of cervical ROMs (cervical extension, cervical rotation to ipsilateral side and cervical lateral flexion to contralateral side) were made using a two-arm portable universal goniometer (DN FORMED Brno,s.p.o, Hudcova 76a, 612 48, Brno-Medlánky). The accuracy and reliability of the universal goniometer to measure cervical movements has been established.[37, 38] The average of the three measurements was used for computations. Pain

intensity over the affected upper trapezius at rest was recorded using a 100 mm visual analogue scale (VAS) with the anchors “no pain at all” at 0 mm and “worst pain imaginable” at 100 mm.[16,39]

Data processing and statistics

Statistical Package for Social Science (SPSS) version 19.0 (IBM, USA) for Windows was used for data analysis. Data were examined using explorative statistics and the distributions were inspected for violations of normality using graphical methods and the Shapiro-Wilk test. Outliers were detected by box-plots and further examined using the Inter Quartile Range (IQR) formula to make sure that they were not extreme values (i.e., any value beyond more than one-and-half times the length of the box [IQR]). No extreme values were observed in the data sets. Descriptive statistics of the demographic variables and test measurements were calculated. Cervical ROMs and pain intensity showed acceptable distributions and were analyzed with parametric tests.

Baseline data for cervical ROMs and pain intensity were compared across the three intervention groups using one-way ANOVA. Change in cervical ROM relative to baseline was calculated by subtracting the baseline data from measurements taken immediately after the first treatment, before the final (eighth) treatment and one week after the final (eighth) treatment (i.e. one week follow-up). Change in pain intensity was calculated by subtracting measurements taken immediately after the first, before the final (eighth) treatment and at one week follow-up from the baseline data.

The difference-in changes in each outcome relative to the baseline among the three intervention groups were compared using one-way ANOVA with Tukey post-hoc tests. Two-sided α was defined as 0.05 in accepting the statistical significance.

RESULTS

Demographic data

There were 105 individuals that expressed interest in participating in the study. All completed the study and were entered into the analysis (Figure 1). There were no statistically significant differences in age (F (2,102) = 2.87, *P*=0.06, one-way ANOVA) or gender distribution between the groups (Table 1). Significantly higher proportion of participants had pain on the right trapezius muscle (Table 1).

[Insert Figure 3 here]

[Insert Table 1 here]

Pain intensity

One way ANOVA found no significant differences in baseline pain intensity levels reported among the three groups (F (2,102) = 2.96, *P*=0.06) (Table 2). There were significant differences among the groups in the changes (reduction) in pain intensities after the first treatment (PI2), before the eighth treatment (PI3), and one week after the eighth treatment (PI4) (Table 2). Post-hoc analyses revealed that there was a larger reduction in pain intensity in the TENS group compared to the IFT group after the first treatment (*P*<0.05). The reductions in pain intensity in both the TENS and IFT groups were significantly larger compared to the control group (*P*<0.05). Similarly the Tukey tests revealed that there were larger reductions in pain intensity in the TENS group compared to the IFT group in all, during and post-intervention measurements (*P*<0.05).

Further, there was a significantly larger reductions in pain intensity in both the TENS and IFT groups compared to the control group at both of these measurement time points.

[Insert Table 2 here]

Cervical ROM

One-way ANOVA found no significant differences in baseline cervical ROM measurements (i.e. cervical extension, lateral flexion to contralateral side and rotation to ipsilateral side) among the three groups. There were significant differences among the groups in relation to the changes (increase) in cervical ROM after the first treatment (PI2), before the eighth treatment (PI3), and one week after the eighth treatment (PI4) when compared with baseline (Table 3). Tukey tests revealed that there was a larger increase in cervical ROM in the TENS group compared to the IFT group after the first treatment ($P<0.05$). There was a larger increase in cervical ROM in both the TENS and IFT groups compared with the control group ($P<0.05$). Tukey tests further revealed that there were larger increases in cervical ROM in the TENS group compared to the IFT group immediately after the first treatment, before and one week after the eighth treatment ($P<0.05$). There was a larger increase in cervical ROM in both the TENS and IFT groups compared with control at both these occasions.

[Insert table 3 here]

DISCUSSION

This study found that immediate and short-term relief of myofascial pain in the upper trapezius can be achieved using a combination of hot pack, AROM exercise, myofascial release and a home program in patients. Larger immediate and short-term improvements were found for cervical ROM and pain intensity when TENS or IFT was added to this standard care with TENS producing larger improvements than IFT. We found that higher proportions of patients experienced MPS in their right trapezius muscles and this is consistent with previous reports. [40] It has been suggested that differences in muscular activity between the left and right limbs and morphological differences in the left and right hemibody may contribute to this laterality.[41]

Treating MPS and MTrPs using a combined therapeutic approach is not novel. Hou and his team[7] claimed that IFT was superior to TENS when added to combination therapy for immediate improvements in cervical myofascial pain and trigger-point sensitivity. However, IFT was combined with hot pack, AROM exercise and myofascial release whereas TENS was combined with hot pack, stretch and spray and AROM exercise. Our study built on that of Hou and his team [7] by standardizing the combination therapy between groups so that a direct comparison between the addition of IFT or TENS could be made.

The combinations of interventions used in the present study were evidence based and used as a standard care package within our clinic. Evidence suggests that hot pack reduces pain and minimizes muscle spasm as a consequence of increased activation of primary afferent fibers.[7,42] AROM exercise cause gentle stretching which reduces subcutaneous tightness by movements of superficial tissues over deep tissues and thus aiding joint movement.[7] Ma and his colleagues

[34]compared the effects of miniscalpel-needle release, acupuncture needling, and stretching exercise to trigger point in individuals diagnosed with MPS and did not find improvements in cervical ROM after the two week stretching exercise. In contrast, a randomized controlled trial by Oliveira-Campelo and his team [43] found that stretching produced short and medium term effects on cervical ROM and pressure pain sensitivity in myofascial pain located in the upper trapezius muscle. Stretching exercises are used to reset muscle length which may be maintained over time using strengthening exercises, scapular stability exercises and postural awareness.[44,12,11] We added a home exercise and postural habit program in an attempt to sustain any improvements in MTrP symptomology. Reducing the likelihood of reactivating MTrP in the longer term is likely also to decrease anxiety and postural alterations associated with developing MTrP in the future, thus increasing confidence in movement. Moreover, postural habits are known to perpetuate myofascial trigger point pain and our home programme may have helps participants to be more aware of their posture during the study period.[45] However, our follow up was limited to only one week after the final 4 week treatment session and therefore cannot be considered as a sustained recovery.

The addition of TENS or IFT showed immediate improvements in all outcome measures compared with standard care. Evidence suggests that both TENS and IFT have similar mechanisms of action and when used in clinical practice for pain relief may in fact be generating identical physiological effects.[46] We delivered TENS and IFT at a strong non painful intensity and this is known to reduce pain by activating low threshold cutaneous afferents leading to inhibition of nociceptive transmission in the central nervous system (i.e. closing the pain gate). [46] TENS and IFT can improve blood microperfusion and reduce muscle spasms although evidence

for these effects is not consistent.[46] The present study observed larger short-term increases in cervical ROM and reductions in pain intensity after the addition of TENS than IFT. One possible reason for the superiority of TENS may have been electrode location. TENS was administered with the negative electrode (cathode) over the MTrP and the positive electrode (anode) over the insertion of acromial tendon. This enabled current to precisely target the MTrP. In contrast, IFT was delivered using 4 electrodes (tetrapolar/quadripolar technique) placed around MTrP. No one electrode was located directly over the MTrP and this may have reduced current density delivered precisely to excitable tissue associated with the MTrP. Though early studies have recommended bipolar method since it reaches deeper tissues and more comfortable compared to the tetrapolar manner,[47,48] Flori and his colleagues[49] suggest that tetrapolar manner is more effective as it produced a higher accommodation threshold.

It is hoped that the findings of the present study will catalyse further studies. There is a need for a fully powered randomized controlled trial on the effectiveness of TENS and IFT for MPS and data gather in the present study can be used to calculate sample size. The present study used a unidimensional measurement of pain on a 100mm VAS and this only captures a self-reported unidimentional assessment of pain. Thus, future studies should use multidimensional assessment of pain [50-52] with treatment goals framed as measureable functional outcomes of daily living because these are more relevant to monitoring progress in the clinical setting and can be verified with quantifiable changes in behavior and quality of life. Further, although performed judiciously, carrying out the clinical procedures and measurements by the principal investigator and not using a placebo for the patients of the control group could be considered as limitations of the present study. Any tools used should also be adapted for a Sri Lankan population. A broader

analysis recruiting patients from multiple centers may be useful to generalize the findings to a wider population.

CONCLUSIONS

The addition of TENS or IFT to standard care consisting of a combination of hot pack, AROM exercise, myofascial release, and a home exercise program improved pain and ROM in the immediate and short-term in individuals with MPS. The findings suggested that TENS was superior to IFT.

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Captions for Figures

Figure 1

Location of TENS electrodes

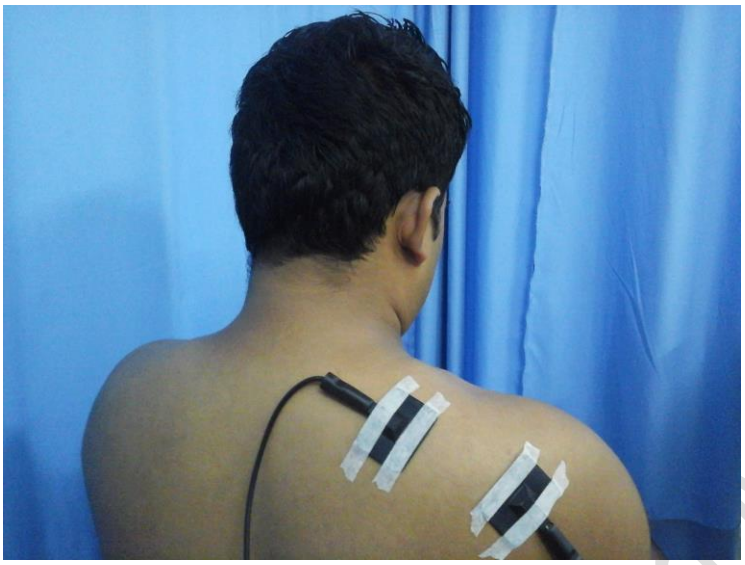

Figure 2

Location of IFT electrodes

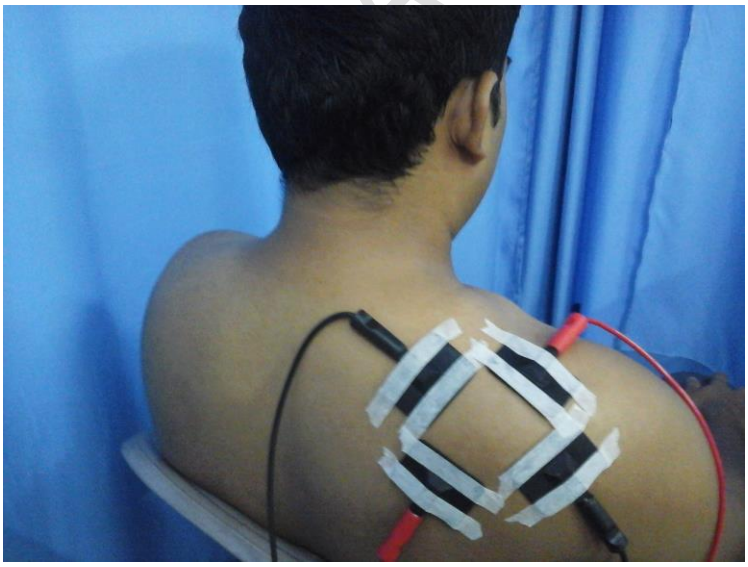

Figure 3

CONSORT study flow chart

(Standard care (control) combination therapy includes a, b, c, and d)

Interferential therapy (IFT)

Figure 3