OMT Trigger Point Protocol Cover Page

Trial Name: Treating Trigger Points: Comparing Muscle Energy Techniques vs. Lidocaine Needling Technique for Pain Control and Quality of Life Measures.

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A comparison of effectiveness of muscle energy technique and dry needling injections on quality of life and pain control in treating trigger points

Introduction

Myofascial pain syndrome is one of the most common musculoskeletal disorders seen in the aging US population [1,2]. Its characterized by myofascial trigger points (MTPs) which were first defined by Simons et al. (1999) as hyperirritable nodules in a taut band of skeletal muscle, associated with pain on manual stretching, contraction, or stimulation of the muscle[3]. Trigger points are further classified into active and latent based on their clinical features [4]. Active MTPs are characterized by spontaneous pain at rest with referred pain on palpation whereas latent MTPs produce pain on palpation in addition to restriction of range of motion [2,4–7].

Currently, there are a variety of treatment options for MTPs including lidocaine injections, dry needling, osteopathic manipulative treatment, massage therapy, ultrasound therapy etc. There has been a large amount of research investigating the safety and efficacy of dry needling and lidocaine trigger point injection techniques in treating MTPs. The results suggest that dry needling and lidocaine injections were both equally effective in reducing symptoms associated with MTPs as it was the mechanical disruption of the taut fibers due to the needle effect and the depth of adequate penetration that resulted in pain reduction more than the substance actually delivered into the muscle [8–13]. Some authors also suggested the importance of a local twitch response (LTR); which is an observable contraction of the taut part of muscle band upon stimulation, during dry needling technique as being pertinent for maximum effectiveness. [8,14]However, a recent systemic review found that LTR during dry needling treatment was unnecessary and not required for management of myofascial pain syndrome [15].

On the other hand, there has been fewer research investigating the effects of manual treatment on trigger points. Travell and Simons initially treated trigger points with ischemic compression but later changed their recommendation to applying gentle digital pressure to trigger points [16]. A recent study done on traction-compression-stretch technique compared with ischemic compression showed some, albeit minor, increased outcome measures (pain pressure threshold) warranting clinical investigation [6]. (We can use their comparative model and statistics since it would be similar to our concept)Another study compared active release and muscle energy techniques in treating latent trigger points of the upper trapezius and found that both techniques were equally effective in increasing cervical range of motion and decreasing pain and upper trapezius thickness[7]. Other studies have also shown interest in similar osteopathic manipulative techniques such as counterstrain, myofascial release, facilitated positional release and high velocity-low amplitude thrust techniques in treating trigger points[3,16–18].

Studies have showed that the upper trapezius is one of the most common muscles affected by myofascial pain syndrome [19,20] leading to referred pain manifesting as headaches and stiff neck.

There is no consensus as to which treatment method is superior, with the decision to treat in a certain way/technique largely based upon the training received by the individual physician rather than the characteristics of the trigger point itself. There are currently no studies evaluating the efficacy of the various treatment options specifically osteopathic manipulative treatment vs. trigger point injections. Thus, the intention of the present study was to determine the efficacy rates of muscle energy techniques vs. dry needling in treating MTPs in the upper trapezius region.

Study Objective

The primary aim of this study is to observe whether osteopathic manipulative treatment or traditional lidocaine/dry needling technique is more efficacious or non-inferior and similar in treating myofascial trigger points in the upper trapezius region as it relates to quality of life and improvement in pain scores.

Study Design

The study is a prospective cohort study comprised of participants between ages 25-75 presenting to Atlanticare Regional Medical Center interventional pain department and Philadelphia College of Osteopathic Medicine OMM Clinic between April 2021 and May 2021 with trigger point in the upper trapezius muscle. It is expected that approximately 60 patients will be enrolled to produce approximately 50 evaluable subjects.

Inclusion Criteria: The subjects will only be recruited into the study if they have met all the following criteria:

- Ages between 25 and 60 years.
- Previous or current diagnosis of MTrP in the upper trapezius region according to the criteria set by Simons et al.[3]
- 1 active/latent MTrP in the upper trapezius region

The diagnostic criteria to establish myofascial trigger point is adopted from Travell and Simons[3] and include:

1. Presence of palpable taut band in the skeletal muscle
2. Presence of hypersensitive tender spot in the taut band
3. Presence of local twitch response upon stimulation of the taut band
4. Reproduction of referred pain upon palpation
5. Presence of spontaneous referred pain pattern

Exclusion criteria: Any subject that exhibits any of the following criteria will excluded from the study:

- Pregnancy or immunocompromise
- Fever/infection
- Previous history of whiplash injury
- Previous history of cervical surgery, cervical radiculopathy, or myelopathy
- Severe disc or cervical lesion
- Evidence of cognitive deficit
- Degenerative or inflammatory disease of the cervical spine or shoulder, fibromyalgia, or neuromuscular diseases
- Use of medications (anticoagulants, anti-inflammatory etc.) or illicit drug use (1 week prior to treatment or follow up)
- Received treatment for MPS a month before the study recruitment

All the patients of interest that present to Atlanticare Regional Medical Center pain clinic and Philadelphia College of Osteopathic Medicine OMM Clinic that meet the relevant inclusion and exclusion criteria will be invited to participate in this study. The subjects will be informed of the purpose of the study and asked for informed consent. If recruited into the study, they will be administered a pre-intervention survey. Subjects will then be managed according to standard of care by their point of care physician. Following the intervention they will be administered a post-intervention survey immediately following the intervention and one-week post.

Pre-intervention assessment will include pain intensity/evaluation using point system and quality of life measured by the neck disability index.

Post-intervention assessment will include pain intensity/evaluation using point system, administered immediately after the intervention, and one week following the intervention using phone survey or online survey depending on patient preference and comfort.

Intervention

Group1 (PCOM): Will receive the muscle energy technique; trigger point isolated followed by post isometric relaxation muscle energy technique

Group 2 (Atlanticare Regional Medical Center): Will receive lidocaine injection technique

Outcome Measures

1. *Pain intensity*; measured using a point system; where 0 = no pain and 10 = maximum pain. Although this is a subjective measurement by the patient, we are interested in looking at the difference between pre- and post-intervention pain intensity ratings.
2. *Quality of Life*; measured by the Neck disability Index[22] which is used to evaluate neck and upper extremity function. The total score is divided by number of answered questions, subtracted 1 and multiplied by 25, in a scale score that range from 0 to 100, with higher scale scores indicating more disability.

Neck Disability Index score rating[23]:

0-4 points (0-8%) : no disability,
5-14 points (10 – 28%) : mild disability,
15-24 points (30-48%) : moderate disability,
25-34 points (50- 64%) : severe disability,
35-50 points (70-100%) : complete disability

Procedure

Patients that consent to the study and are eligible following the inclusion & exclusion criteria will be recruited into the study. They will fill out the pre-intervention survey in the room. Once the survey is completed, the patient will be placed in a seated position and using palpation, the examiner will identify

the MTrP according to the criteria set by Simons et al. Following the subjective pre-assessment, the intervention will be performed.

Group 1 will be primarily focused on patients from the OMM clinic at PCOM. Patients will be administered muscle energy technique of post isometric relaxation as per the Atlas of Osteopathic Techniques on the symptomatic upper trapezius without treatment of surrounding structures by the osteopathic attending physician.

Group 2 will be comprised of patients from Atlanticare Regional Medical Center pain clinic and will be administered trigger point dry needling and lidocaine injection. The treatment will be administered by the pain clinic attending physician. After application of a coolant to numb the area, the isolated trigger point will be penetrated using a 30-gauge needle, to a depth adjusted depending on the patient, into the subcutaneous tissue. The patient will be warned about possible unpleasant sensations and mild pain associated with contraction of the tight band of muscle. Multiple needle insertions will be attempted to achieve MTrP inactivation, with the needle being withdrawn to the subcutaneous layer but not from the skin during each insertion, approximately lasting for 1-2 minutes [26,27]. Once the fascial tension is relieved, 0.5% lidocaine will be injected, and the needle will be withdrawn from the skin. The procedure will be terminated with hemostasis achieved.

Once the intervention is completed, the patient will be asked about the reduction in pain following the intervention and administered the post intervention survey. A week after the intervention, they will be called/emailed to ask about their pain intensity using the same post intervention survey by the medical students.

Safety Management:

Patients are free to withdraw from the study at any time should they choose to. Since the study procedures are not greater than minimal risk, adverse events are not expected. If any serious adverse effects or unaccounted events may occur, they will be reported to the IRB and patients will be discontinued from the study. The data from withdrawn patients will not contribute to the study statistics.

Data Analysis

The data will be analyzed using SPSS version 27.0 for Windows (IBM Corp. Released 2020. IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp). Values of interest include measures of central tendency, i.e. mean, standard deviation, normal distribution, confidence intervals etc. To be considered a statistically significant finding, the alpha level will be set at 0.05. A descriptive analyses of the outcome variables will be conducted to compare between the intervention groups. The homogeneity of sociodemographic data (age, sex, comorbid conditions) and treatment groups will be analyzed using the Fischer test and Pearson chi square test, respectively.

The outcome measures, reported pain and quality of life, will be analyzed separately using univariate analyses. The differences between the treatment groups across time periods will be analyzed. A two-factor analysis of variance (ANOVA) will be performed for each dependent variable to determine the

difference between treatment groups at the different time points (before the intervention, immediately after the intervention, and a week post the intervention). A 2 x 3 mixed factor design will be used in order to evaluate the between subjects data (intervention type) across the repeated measures (three time periods).

Study Administration

The primary records of data will be in form of pre- and post- intervention surveys. Each survey will contain a random code to link the patient to the survey data and that list will be kept separate from the surveys. All physical copies of data will be stored primarily at Dr. Brendan Kelly's office under lock and key with key access only to them. Data collected through Atlanticare pain clinic will be maintained through one set of copies which will be stored at Dr. Dipty Mangla's office under lock and key with key access only to them. Data collected through PCOM will be maintained through one set of copies which will be stored at Dr. Andrew Levin's office under lock and key with key access only to them. Surveys administered through email will be sent through a secure link and all online data will be encrypted with access only to principal investigators and research personal. All data obtained through email will be stored on the principal investigator's computer which is password protected. All data and records generated during this study will be kept confidential in accordance with Institutional policies and HIPAA on subject privacy and the investigator and other site personnel will not use the data and records for any purpose other than conducting the study. The identifiers and other data will be destroyed 5 years after study completion in compliance with the Atlanticare Regional Medical Center data retention policy.

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