OMT Trigger Point Statistical Analysis Plan 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 comparative study of muscle energy technique and lidocaine injections on treating trigger points

Introduction

Myofascial pain syndrome is one of the most common musculoskeletal disorders seen in the aging US population [1,2]. It's 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]. Studies have showed that the upper trapezius is one of the most common muscles affected by myofascial pain syndrome [8,9] leading to referred pain manifesting as headaches and stiff neck.

Currently, there are a variety of treatment options for MTPs including lidocaine injections, dry needling, osteopathic manipulative treatment, massage therapy, ultrasound therapy, and pharmacotherapy ~~etc~~. There have been many studies investigating the safety and efficacy of dry needling and lidocaine trigger point injection techniques in the treatment of MTPs[10–18]. It has been demonstrated that both dry needling and lidocaine injections were equally effective in reducing symptoms associated with MTPs; the mechanical disruption of the taut fibers due to the effect of the needle and the depth of adequate penetration resulted in more pain reduction, rather than the substance actually delivered into the muscle [19–24]. Some authors also suggested the importance of a local twitch response (LTR); which is an observable contraction of the taut region of the muscle band upon stimulation during dry needling technique, indicating maximum effectiveness of the treatment [19,25]. However, a recent systemic review found that LTR during dry needling treatment was unnecessary and not required for management of myofascial pain syndrome [26].

On the other hand, there has been less 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 [27]. A recent study exploring the traction-compression-stretch technique (TTCE) compared to ischemic compression showed some, albeit minor, increased outcome measures (pain pressure threshold) warranting clinical investigation [6]. 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 for treating trigger points[3,27–29].

There is no consensus as to which treatment method is superior, leaving the method of treatment up to the discretion of the individual physician, rather than the characteristics of the trigger point itself. Often, determination of treatment method is dependent upon the training received by a physician. There are currently no studies evaluating the efficacy of these various treatment options, specifically osteopathic manipulative treatment vs. trigger point injections. Thus, the intention of the present study was to compare the efficacy of muscle energy techniques vs. lidocaine for the treatment of MTPs in the upper trapezius region.

Study Objective

The primary aim of this study is to compare osteopathic manipulative treatment and lidocaine injection technique for treatment of myofascial trigger points in the upper trapezius region.

Study Design

The study is a prospective cohort study containing of participants between ages 25-65 age range that presented to Atlanticare Regional Medical Center pain management clinic and Philadelphia College of Osteopathic Medicine Osteopathic Clinic between November 2021 and February 2022 with trigger point in the upper trapezius muscle.

Inclusion Criteria: Subjects were recruited into the study if they met all of the following criteria:

- Age between 25 and 65 years.
- Previous or current diagnosis of MTP in the upper trapezius region according to the criteria set by Simons et al.[3]
- 1 active/latent MTP 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: Subjects that exhibited any of the following criteria were 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 eligible participants were screened at their respective clinic with the above criteria. Subjects who agreed to participate in the study provided informed consent. At this time, they were given a demographic survey and pre-intervention survey. This survey included a standard pain intensity evaluation using a 0-10 pain scale and a quality-of-life assessment measured by the neck disability index. After enrollment and pre-intervention assessment, the appropriate intervention was administered to

the patient; patients at the Philadelphia OMM clinic received muscle energy treatment, while patients at the Atlanticare Pain Management clinic received lidocaine with dry needling.

Participants presenting to the PCOM OMM clinic were treated with the muscle energy technique of post isometric relaxation on the symptomatic upper trapezius by a board-certified osteopathic physician. After placing patient in a supine position, the shoulder on the affected side was stabilized with one arm. Using the other arm, the head was sidebent contralaterally and rotated ipsilaterally until the restriction barrier was encountered. This position was then maintained for 10 seconds while a normal respiratory rhythm was maintained. After 10 seconds the position was extended further into the barrier and held for 30 seconds and process repeated.

Participants presenting to the Atlanticare Pain Management clinic received a lidocaine injection after dry needling into the location of the MTP by a board-certified pain management physician. First, the upper trapezius MTP was identified and isolated. After application of a coolant to numb the area, the isolated trigger point was penetrated using a 30-gauge needle, to a depth adjusted depending on the patient, into the subcutaneous tissue. The duration of treatment was approximately 1-2 minutes. Once the myofascial tension was relieved, 2 mL of 0.5% lidocaine was injected into the MTP.

After their respective interventions, the patient completed an immediate post-intervention survey, consisting of a 0-10 pain scale. Finally, approximately 7-10 days after the intervention, patients were contacted by telephone to complete the one-week post-intervention survey consisting of a 0-10 pain scale.

Outcome Measures

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.

Data Analysis

The data was analyzed using R software. Values of interest include mean, median, standard deviation, normal distribution, confidence intervals etc. Intergroup and intra-group comparisons were conducted using independent t-tests and paired t-tests, respectively. Alpha level is set at 0.05 and p values less than that will be considered statistically significant. A descriptive analysis of the outcome variables was conducted to compare between the intervention groups. The homogeneity of sociodemographic data (age, sex, comorbid conditions) and outcome measures were analyzed using the Fischer test and Pearson chi square test, respectively.

The outcome measures were analyzed separately in both treatment groups. The contrast between the treatment groups was analyzed. A univariate analysis of the difference of the outcome variables at the different time points (before the intervention, immediately after the intervention, and a week post the intervention) were obtained through the student *t*-tests. A multivariate analysis was carried out using multiple logistic regression models with age, sex, and intervention group (Injection = 0, OMM = 1) factored as the independent variables.

Results

The study was completed at two primary locations. There were a total of 10 eligible participants from the lidocaine treatment group and 21 eligible participants from the OMM treatment group enrolled after screening for the inclusion and exclusion criteria. 1 subject from the lidocaine treatment group was lost during follow-up at one week post intervention and thus excluded from the per protocol analysis of the study. The remaining participants' data were analyzed in SPSS 26. No significant difference was found between the two groups in regard to sociodemographic data (Table 1). At baseline, the OMM group had a mean pain intensity level of 2.76 (SD 1.8) while the lidocaine treatment group had a mean pain intensity level of 7 (SD 2.8). Descriptive statistics of pain intensity between the two groups demonstrate considerable variance (Table 2).

Within the OMM group, an independent samples t-test found a statistically significant difference between the pre-intervention and immediate post-intervention pain levels, $t(20) = 2.10$, $p = .048$. The mean pre-intervention pain level (M = 2.76, SD = 1.84) was significantly higher than the immediate post intervention pain level (M = 1.86, SD = 0.96). An independent samples t-test found a statistically significant difference between pre-intervention and one-week post-intervention pain levels, $t(20) = 2.68$ $p = .014$. The mean pre-intervention level of pain (M = 2.76, SD = 1.84) was significantly higher than one-week post-intervention (M = 1.81, SD = 2.01).

Within the lidocaine group, an independent samples t-test did not demonstrate a statistically significant difference between pre-intervention and immediate post-intervention pain levels, $t(20) = 1.17$, $p = 0.27$. The mean pain level pre-intervention (M = 7, SD = 2.87) was higher than immediately post-intervention (M = 6.60, SD = 2.32). When evaluating the difference in level of pain from pre-intervention to one-week post-intervention, an independent samples t-test was not statistically significant, $t(20) = 2.16$ $p = .062$. The mean level of pain pre-intervention (M = 7, SD = 2.87) was higher than one-week post-intervention(M = 4, SD = 2.18). Pain intensity between the two groups are also demonstrated graphically in Figure 1, with time point one corresponding to pre-intervention, two corresponding to immediately post-intervention and three corresponding to 1 week post intervention.

To investigate the treatment effect between groups across time, a mixed design two factor ANOVA was utilized. As expected, due to small sample size, heterogeneity of covariance matrices was detected. This is considered a limitation of the study. Also, since a repeated measures design was implemented across three time periods, Mauchly's test of sphericity was examined and found to be significant ($p = .042$). This indicates that sphericity cannot be assumed, so a Greenhouse-Geisser statistic was computed. A statistically significant interaction effect was detected, $F(1.65, 56) = 3.90$, $p = .034$. Due to p-value being less than 0.05, we can confidently reject the null hypothesis and accept the alternative hypothesis.

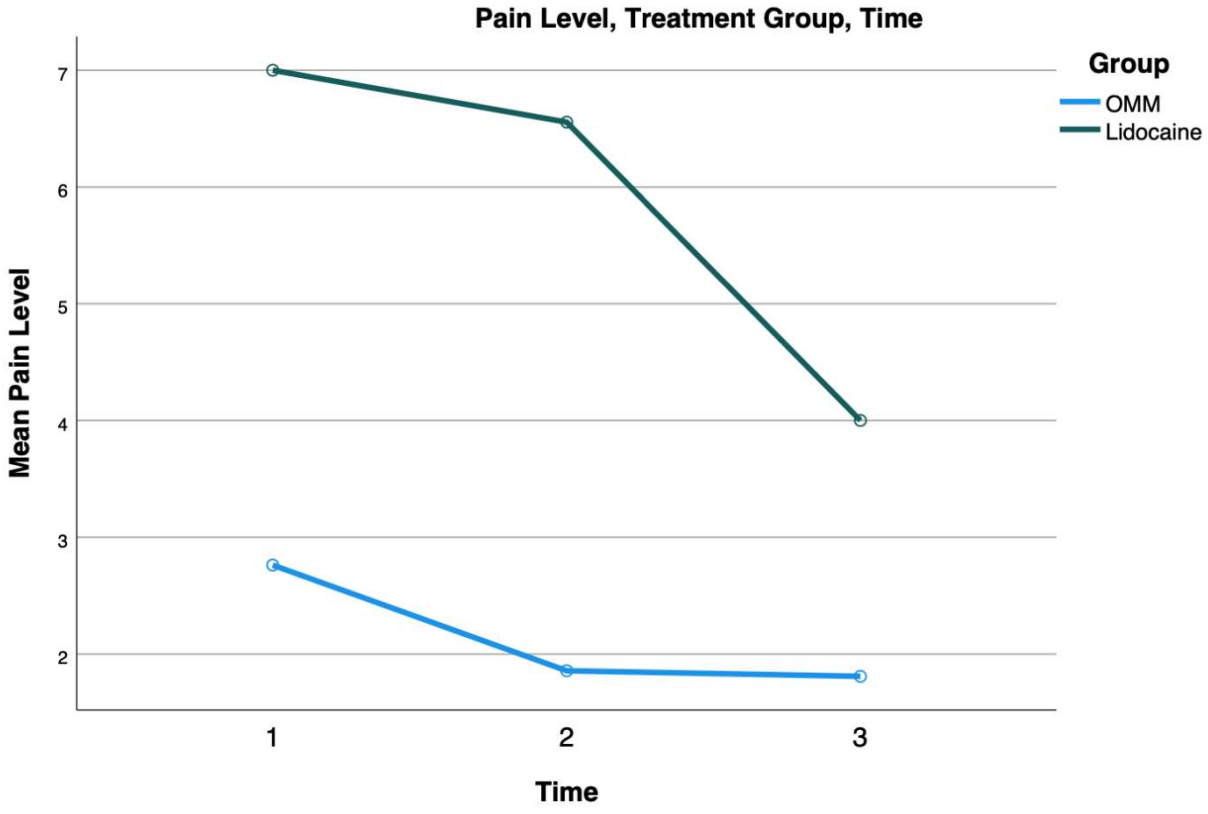
Table 1.

Sociodemographic Data	Mean (SD) or Number (%)		P value
	OMM (n = 21)	Lidocaine (n = 10)	
Sex (%), n = 31 (100%)	21 (100)	10 (100)	
Male, n = 7 (22.6%)	5 (23.8)	2 (20)	
Female, n = 24 (77.4%)	16 (76.2)	8 (80)	
Age, y			
Subjects from 20 – 29 y, n = 22 (71%)	21 (100)	1 (10)	
Subjects from 30 – 39 y, n = 1 (3.2%)	0	1 (10)	
Subjects > 60y, n = 8 (25.8%)	0	8 (80)	
Ethnicity			
Caucasian, n = 20 (64.5%)	11 (52.4)	9 (90)	
African American, n = 1 (3.2%)	1 (4.8)	0	
Latino or Hispanic, n = 4 (12.9%)	3 (14.3)	1 (10)	
Asian, n = 6 (19.4%)	6 (28.6)	0	
Pain Intensity			
Pre-intervention	2.76 (1.8)	7 (2.8)	
Post-intervention (immediate)	1.86 (0.9)	6.6 (2.3)	0.026
Post-intervention (one week)	1.81 (2.0)	4 (2.2)	0.062

Table 2.

	Group	Mean	Std. Deviation	N
Pre-intervention Pain	OMM	2.76	1.84	21
	Lidocaine	7.00	3.04	9
	Total	4.03	2.96	30
Post-intervention immediate pain	OMM	1.86	0.96	21
	Lidocaine	6.56	2.45	9
	Total	3.27	2.66	30
Post-intervention 1 week pain	OMM	1.81	2.01	21
	Lidocaine	4.00	2.17	9
	Total	2.47	2.27	30

Figure 1.



Discussion

The goal of this study was to demonstrate the efficacy of OMT, compared to lidocaine ~~with dry needling~~ injection techniques, in the treatment of trapezius MTP. The results of the study showed that both lidocaine with dry needling and OMT were successful in reducing pain related to myofascial trigger points. However, neither of the two techniques demonstrated discrete superiority to one another. Although, this was not an intent of the study. The primary outcome of interest was pain intensity levels. There was a larger degree of pain reduction in the OMT group immediately post-intervention whereas lidocaine with dry needling showed larger reduction in one-week post-intervention pain levels. In the ~~wake~~ throes of an opioid epidemic, the search for suitable, effective alternatives that provide non-opioid treatment for pain are an added benefit in patient centered care.

When Travell and Simons first described the concept of myofascial trigger points, they proposed an 'integrated hypothesis' which included local myofascial tissues, genetics, neuromechanical and biochemical factors as precipitating factors in the formation of trigger points[30,31]. In Travell's ATP energy crisis model[32], triggers points were described as focal areas of hypoxia and thus OMT aimed at increasing oxygenation such as gentle traction and pressure release received acceptance. Various studies[30,32–35]have demonstrated the utility of OMT in treating trigger points. As demonstrated in the results, OMT yielded significant reductions in pain intensity immediately post intervention and one week post intervention. The results of this study are in concordance with other similar studies. ~~Although~~ We hypothesized that OMT would ~~be more~~ as effective as lidocaine for treatment of MTP, we demonstrated that these two treatment methods both provide appropriate relief of musculoskeletal pain. This reflects the validity of OMT in the outpatient clinic, which is a suitable alternative for treatment of MTP. Equal efficacy of OMT for MTP treatment gives patients and physicians the option to elect for a non-invasive, low cost treatment.

We specifically note that this is a suitable treatment modality for all physicians, both osteopathic and allopathic, as we merge our skill sets over time in a unified manner. As mentioned, the training of a physician usually dictates the management decisions regarding MTP treatment. This study was conducted in a post graduate training institution that has multiple specialty programs with osteopathic recognition. In the single accreditation system, collaborating with allopathic physicians and exposing allopathic residents to osteopathic treatment options was viewed an advancement for patient centered care and osteopathic awareness. As more allopathic physicians expand their skill sets and complete OMT courses, demonstrating the efficacy of a common treatment modality compared to OMT will assist with treatment choice. Comparable efficacy of both options will help patients choose the option that best meets their needs and physicians choose the option that best augments their skill set.

Being a pilot study, we anticipated a considerable degree of limitations throughout the study. Limitations include but are not limited to low sample size, majority female participants, and substantial difference in mean age between the two groups. Additionally, the OMT intervention group had a significantly lower mean pre-intervention pain level compared to the lidocaine group which made it difficult to do a true comparative analysis between groups. However, as a pilot study, demonstration of OMT non-inferiority compared to a standard treatment modality, creates a stepping stone for future research to investigate the comparative efficacy of OMT on a larger scale and we therefore anticipate future trials with larger number of participants to demonstrate more significant data and results.

Conclusion

Based on our study, OMT has comparable value with lidocaine injection technique as a treatment modality for active TrPs in the upper trapezius region. Both techniques demonstrate considerable decrease in pain intensity from baseline and thus it allows for increased collaboration between osteopathic and allopathic practitioners to promote patient centered care.

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