Original Article

A Comparison of the Efficacy of Diclofenac Phonophoresis and Ultrasound Therapy in Upper Trapezius Myofascial Pain Syndrome: A Double-Blinded Randomized Controlled Trial

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ABSTRACT

Objectives: To compare the pain numeric rating scale (NRS) and active cervical lateral flexion between diclofenac phonophoresis (DPP) and a conventional ultrasound therapy (UST) in treating myofascial pain syndrome (MPS).
Study design: A double-blinded randomized controlled trial.
Setting: Department of Physical Medicine and Rehabilitation, Taksin Hospital, Thailand.
Subjects: Fifty-two participants (41 females, 11 males, mean age 42 years, mean MPS duration 2 months) with myofascial pain syndrome at the upper trapezius muscle
Methods: Participants were allocated by block randomization into 2 groups, the UST Group (n = 26) treated with a conventional UST using a 1-MHz applicator, a standard coupling agent, stroke technique, continuous mode, intensity of 1 watt/cm^2 for 10 minutes, and the DPP Group (n = 26) treated with the same UST technique but using a mixture of 4 grams of diclofenac gel and a standard coupling agent in a ratio of 1:4 instead of the standard coupling agent. Each participant was treated 3 times per week for 3 weeks for a total of 9 treatments. All participants rated their pain on a numeric rating scale (NRS). Active cervical lateral flexion was measured by an assessor prior to the initial treatment and following the final treatment. All participants and the assessor were blinded to the treatments received.
Results: Before the treatments, there was no statistically significance in NRS (p = 1.00) or active cervical lateral flexion (p = 0.75) between the two groups. After the treatments, NRS of the DPP group was significantly lower than the UST group (p = 0.03). However, active cervical lateral flexion was not significantly different between the groups (p = 0.29). Group analysis found that NRS was significantly reduced, by 2.58 in the UST group (p = 0.00) and by 3.46 in the DPP group (p = 0.00). Active cervical lateral flexion motion was significantly increased in the DPP group (p = 0.02) but not in UST group (p = 0.08) after the 3-week therapy.
Conclusions: Diclofenac phonophoresis can reduce pain in myofascial pain syndrome at upper trapezius muscle better than conventional ultrasound therapy.

Keywords*:* phonophoresis, ultrasound diathermy, myofascial pain syndrome, trapezius muscle, diclofenac gel

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Introduction

Myofascial pain syndrome (MPS) is defined as sensory, motor, and autonomic symptoms caused by myofascial trigger points.[1] Myofascial trigger points are hyperirritable spots within a taut band of skeletal muscle.[1] MPS causes a physical and financial burden to society. The prevalence of MPS in middle-aged adults (30-60 years of age) was reported to be 37% in males and 65% in females.[2] MPS treatments include pharmacological intervention, e.g., analgesic drugs, non-steroidal anti-inflammatory drugs (NSAIDs), tramadol, muscle relaxants, antidepressants, anticonvulsants as well as non-pharmacological treatments involving both non-invasive and invasive techniques. Non-invasive techniques include spray and stretch, ergonomic adaptation, laser therapy, transcutaneous electrical nerve stimulation (TENS), ultrasound therapy (UST), massage and ischemic compression therapy, while invasive techniques include dry needling and trigger point injection. Invasive techniques are associated with a risk of adverse events such as pneumothorax, hematoma, soft tissue infection, post injection soreness.[3,4] For that reason, some patients prefer pharmacological treatment and take NSAIDs to reduce pain.

Mechanisms of NSAIDs include analgesic, antipyretic, and anti-inflammatory properties via cyclo-oxygenase (COX) in the arachidonic acid cascade to inhibit prostaglandin production. Most common NSAIDs are available in an oral form which can have gastrointestinal side effects, whereas topical forms do not have such side effects and so can be prescribed for individuals who cannot tolerate the oral forms.[5] To enhance absorption and penetration of topical medications into deeper tissues, phonophoresis (PP), a non-invasive technique, can be applied.[6] Therapeutic effects depend on different factors, e.g., rate and amount administered and the specific topical drug.6 Diclofenac gel is one of the highly effective topical NSAIDs in terms of absorption and penetration via tissues.[6,7] In previous studies, UST significantly reduced pain as measured on the visual analog scale (VAS) and increased the short-term pain pressure threshold (PPT) in MPS.[8,9] Phonophore-

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sis (PP) has been used effectively in the treatment of carpal tunnel syndrome,[10] MPS,[11,12] and osteoarthritis of the knee.[13] A recommended setting of UST for PP is a continuous 1.0 W/cm^2 and 1-MHz frequency application.[13] To demonstrate the efficacy of diclofenac PP (DPP) in reducing pain and increasing neck range of motion (ROM) at trapezius muscle in patients with MPS, this study compared applying UST alone and DPP with diclofenac gel.

Methods

This double-blinded randomized controlled trial was approved by the Bangkok Metropolitan Administration Human Research Ethics Committee (Approval number S022h/63).

Participants

Patients diagnosed with MPS at the trapezius muscle based on the Travel and Simon's clinical criteria[6] who visited the Physical Medicine and Rehabilitation outpatient clinic at Taksin Hospital between December 2020 and April 2021 were invited to join the study. After giving their informed consent, they were recruited into the study. The inclusion criteria consisted of age between 18-75 years old. Patients with any of the following were excluded from the study: fibromyalgia, cervical disc herniation, cervical radiculopathy, cervical myelopathy, a trigger point injection or physical therapy during the previous 7 days, a history of neck surgery or trauma during the previous 6 months, a NSAID allergy, a communication disorder as well as women who were pregnant or lactating. Using block randomization, the recruited participants were divided into two groups, the UST group and the DPP group.

Procedure

The assessor, a physiatrist, interviewed participants regarding their demographics and occupation, reviewed their medical records, identified the affected side and duration of MPS, asked about their maximum pain intensity at the affected trapezius muscle, and measured the angle of active lateral flexion of the neck toward the affected side. The assessor was blinded to the treatment that the participants received. All participants were assessed twice: before the first treatment and after the final treatment.

Three physical therapists in the department were assigned to provide treatment according to a randomization process. All therapists used a Sonopuls 190 ultrasound diathermy unit, a 1-MHz applicator in continuous mode with an intensity of 1 W/cm^2 and using a stroke technique on the skin over the affected trapezius muscle for 10 minutes. Ultrasound gel (Hydrosonic gel) was applied in the UST group while a mixture of diclofenac gel (Antenac® gel) and the ultrasound gel in a ratio of 1:4 was applied in the PP Group. The therapist applied the gel at the ultrasound applicator. The gels used in both groups were odorless and light blue in color in a total volume of 15 mL for each use. All participants received 3 treatments per week for 3 weeks, a total of 9 sessions.

Outcome measures

The primary outcome measure was subjective pain intensity which was determined using a numeric rating scale (NRS) where 0 means no pain and 10 means the most severe pain. The assessor asked participants for the maximum pain at that moment. The secondary outcome was active cervical lateral flexion of the neck toward the shoulder of the affected side which was measured using a standard goniometer.[12] If both sides of the trapezius muscle were affected, the assessor measured the side with the worst pain intensity. This trial was double-blinded to avoid bias. Participants did not know which group they belonged to. If participants had ongoing pain during treatment, they were allowed to take acetaminophen (500 mg 1 tablet q 6 hours), but no other pain medications were allowed during the study e.g., tramadol and oral NSAIDs.

Statistical analysis

Demographic data of participants in both groups were analyzed. Quantitative data is shown as means and standard deviations. Qualitative data is shown as frequencies and percentages. STATA version 14 was used for statistical analysis. Mean differences in NRS and active cervical lateral flexion between groups were analyzed using the unpaired t-test for parametric data with a statistically significant confidence level of $p < 0.05$. Before and after treatment analysis within groups was done using the paired t-test for parametric data with statistical significance set at $p < 0.05$.

In cases where participants were lost to follow up or had only an initial assessment, the end of study data was imputed based on the beginning data. This was done to avoid misleading results from using intention-to-treat analysis.

Results

A total of 56 patients were initially screened, of whom 52 were enrolled. All 52 participants were allocated to groups of whom 47 completed the study, a dropout rate of 9.6% (Figure 1). All participants were included in the statistical analysis according to the group to which they were assigned. Most participants in the study (78.8%) were females with a mean age of 42 years and duration of symptoms of 2 months. In the UST group, the mean age was 45 years and the mean duration of MPS was 1.4 months, while in the DPP group the mean age was 40 years and the mean duration was 3 months. The right trapezius muscle was affected less in the UST group than in the DPP group (54% vs. 73%). The most common occupation was office clerk (Table 1).

In this study, an intention to treat analysis was used in table 2, there were no statistical differences in pain on the NRS before treatment between the two groups (mean difference = 0.00, $p = 1.00$). At the end of the study, NRS was significantly reduced in the UST group, 2.58 ($p = 0.00$) and 3.46 in the DPP group ($p = 0.00$), a statistically significant difference (mean difference = 0.88, $p = 0.03$).

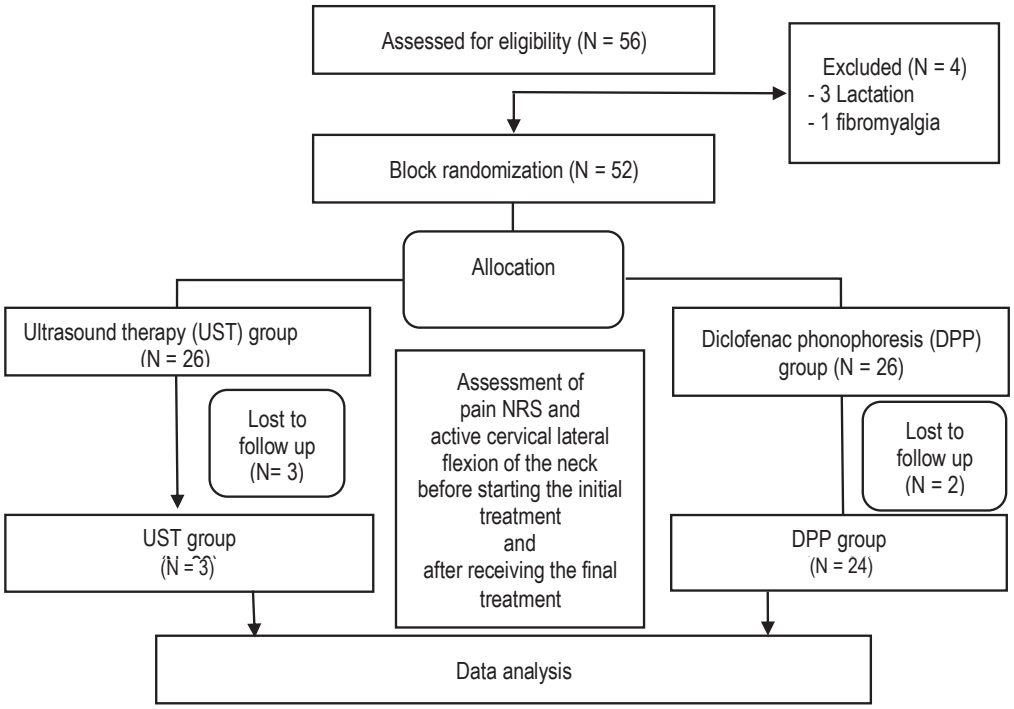

Figure 1. Schematic flow diagram of the study

Table 1. Comparison of demographic data of participants with myofascial pain syndrome (MPS) at the trapezius muscle between the ultrasound therapy (UST) and the diclofenac phonophoresis (DPP) groups.

	UST group (n = 26)	DPP group (n = 26)
Age (years)[1]	45 (10)	40 (9)
Gender[2]		
Female	21 (81)	20 (77)
Male	5 (19)	6 (23)
Affected side[2]		
Right	14 (54)	19 (73)
Left	12 (46)	7 (27)
Duration of MPS (months)[1]	1.4 (2)	3 (4)
Occupation[2]		
Office clerk	16 (61)	13 (50)
Healthcare worker	2 (8)	10 (38)
Laborer	4 (15)	1 (4)
Housewife	2 (8)	2 (8)
Salesperson	2 (8)	0 (0)

[1]Mean (SD), [2]number (%)

At the beginning of the study, there were no differences in active cervical lateral flexion toward the affected side between the groups. After the 3-week therapy, active cervical lateral flexion motion had significantly increased in the DPP group (p = 0.02), but the change was not statistically significant in the UST group (p = 0.08) (Table 2).

Six participants in the UST group reported taking acetaminophen as an add-on drug therapy to relieve pain, whereas only 1 participant in the DPP group did so. No participants in DPP group had side effects from the topical diclofenac gel, e.g., skin allergy.

Discussion

UST in one of the noninvasive treatments for MPS. It produces a high-frequency sound wave that increases local mechanisms, circulation and extensibility of connective tissue through a deep heat mechanism. DPP is a form of UST that facilitates transdermal penetration of diclofenac gel to

Table 2. Comparison of outcome parameters between the ultrasound diathermy (UST) group and the diclofenac phonophoresis (DPP) group

Parameters	UST group	DPP group	Mean difference	95% CI	Between groups p-value
Pain numeric rating scale					
At the beginning of the study	6.81 (1.60)	6.81 (1.61)	0.00	-0.91 to 0.91	1.00
At the end of the study	4.23 (1.45)	3.35 (1.83)	0.88	0.07 to 1.70	0.03*
Before and after, p-value	0.00*	0.00*			
Active cervical lateral flexion (degrees)					
At the beginning of the study	27.00 (5.73)	26.50 (7.81)	0.50	-2.70 to 3.70	0.75
At the end of the study	29.81 (5.40)	31.42 (6.60)	-1.61	-4.69 to 1.46	0.29
Before and after p-values	0.08	0.02*			

Mean (SD)

Between groups analysis used the unpaired t-test; within group analysis used the paired t-test, *significance level $p < 0.05$

deeper subcutaneous tissue[6] and may be an option for treating MPS patients who have gastrointestinal side effects from oral forms of NSAIDs.

This double-blinded randomized controlled trial compared the efficacy of DPP and UST in patients with MPS. Prior to the beginning of the three-week treatment, there were no significant differences in the baseline pain of NRS or active cervical lateral flexion between the two groups. At the end of the study, there was a significant difference in pain NRS between the two group, with the DPP group having significantly lower pain NRS scores than the UST group. However, there was no difference in active cervical lateral flexion between the groups. These results suggest that DPP is more effective than UST in reducing pain intensity in MPS at the trapezius muscle, but that it does not improve active cervical lateral flexion. The decrease in pain NRS in the DPP group was in line with the fact that a larger proportion of participants in the UST group took acetaminophen than in the DPP group.

In this current study, following the 3-week therapy pain NRS was significantly reduced in the UST group, a result which is in line with a study done by Majlesi et al,[8] although that study reported a greater reduction in pain. The difference in the level of pain reduction is likely due to the fact that the Majlesi study used a high-power pain threshold ultrasound technique in the treatment of active myofascial trigger points while the present study did not. Several studies have similarly reported that UST can reduce pain and increase PPT,[8,9,14-19] while others have reported no difference between UST and other treatments.[20-23] For example, Srbely and Dickey[9] applied the UST at the trigger point and measured the pain threshold, reporting that pain pressure threshold scores increased an average of 44.4 (14.2%) after UST. Gam et al.[20] reported no difference in pain reduction between the group given UST and the group that received sham UST, but that might be due to the fact that participants in both groups in that study also received massage and exercise. In this study, pain reduction can be attributed exclusively to the analgesic effect of UST via both thermal and non-thermal mechanisms.[19]

In this study, the DPP group had greater pain reduction than the UST group which suggests that diclofenac gel can reach the target tissue and enhance the UST efficacy. NRS was significantly reduced (by 2.58 in the UST group and 3.46 in the DPP group). Active cervical lateral flexion motion was significantly increased in the DPP group, was not statistically significantly changed in the UST group between preintervention and postintervention (after the 3-week therapy). This result is in line with a study done by Ay et al.[6] and Takla et al.[17] Ay et al.[6] found that there were statistically significant improvements in pain severity, the number of trigger point (NTP), PPT, ROM and NPDI scores both with PP and UST. Takla et al.[17] reported that PP was superior to UST in reducing pain, but that none of the treatment groups were found to be superior in increasing range of motion. The efficacy of a topical agent is dependent on its being absorbed through the skin surface and its ability to reach the target tissue.[19] Additionally, PP can decrease pain and NTP better than other techniques.[10-13] Yildiz et al.10 found that ketoprofen PP and splinting for carpal tunnel syndrome resulted in a lower pain score than both sham UST and splinting as well as UST and splinting at the 8th week of treatment. Sarrafzadeh et al.[11] found that phonophoresis of hydrocortisone and pressure release techniques could decrease pain and PPT and could also increase cervical lateral flexion more than UST alone in latent MPS at the upper trapezius muscle. Ustun et al.[12] found that EMLA Cream phonophoresis significantly decreased NTP compared to UST in MPS at the trapezius muscle. Luksurapan et al.[13] found that reductions in VAS scores and improvements in WOMAC scores were greater with piroxicam phonophoresis than with UST.

This study has some limitations. First, the study did not assess long-term outcomes. Second, the study included more than one physical therapist, although they did use the same protocol. Third, this study used NRS for pain assessment. Although all participants were able to communicate very well, NRS is a subjective measurement. Further study is needed to explore clinical outcomes in terms of the carry-over effect after using DPP for certain periods of treatment.

Conclusions

A 3-week treatment with diclofenac phonophoresis provides more pain reduction than conventional ultrasound diathermy in patients with myofascial pain syndrome at the trapezius muscle.

Disclosure

The authors certify that there is no conflict of interest with any financial organization regarding the materials discussed in the manuscript.

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