EFFICACY OF COLD PACK THERAPY ON SORENESS BEFORE MYOFASCIAL TRIGGER POINT DRY NEEDLING: A SINGLE-BLIND RANDOMIZED CONTROLLED TRIAL

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Abstract

Background: Myofascial pain syndrome (MPS) is a common condition characterized by pain originating from myofascial trigger points (MTrP) in skeletal muscle. Several treatment approaches exist, including dry needling. However, post-needling muscle soreness is a common adverse effect of dry needling. Previous research has investigated the effectiveness of cryotherapy after needling for treating post-needling soreness; however, it has shown no statistically significant effect. In addition, the impact of cryotherapy before dry needling has not been adequately investigated.

Objective: The study aimed to evaluate the efficacy of cryotherapy applied prior to dry needling in reducing post-needling soreness in patients with upper trapezius MTrP.

Methods: This single-blinded, randomized controlled trial study was conducted among 60 participants diagnosed with upper trapezius MPS at the Rehabilitation Medicine outpatient clinic. They were randomly allocated to one of two groups: (1) cold pack therapy prior to dry needling (intervention group) or (2) no cold pack therapy prior to dry needling (control group). Skin temperature was recorded immediately before needle insertion. Pain intensity was evaluated using a 100-mm visual analog scale (VAS) during needle insertion, 10 minutes after the procedure, and on the second day post-intervention.

Results: The intervention group demonstrated significantly lower VAS scores compared to the control group for pain during needle insertion (0 vs. 60, $p < 0.001$), soreness 10 minutes post-procedure (10 vs. 80, $p < 0.001$), and on Day 2 (0 vs. 40, $p < 0.001$). The intervention group experienced significantly shorter post-needling soreness duration compared to the control group (0.13 vs. 3 days, $p < 0.001$). Additionally, acetaminophen use was not necessary in the intervention group when compared to the control group (0% vs. 24.1%, $p < 0.01$). No adverse events were reported in either group during the study.

Conclusions: Pre-procedure cold pack therapy significantly reduces pain during needle insertion and post-needling soreness at 10 minutes and on Day 2.

Keywords: myofascial pain syndrome, cryotherapy, cold pack therapy, dry needling, post-needling soreness

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Introduction

Myofascial pain syndrome (MPS) is a common condition characterized by pain originating from myofascial trigger points (MTrP) in skeletal muscle.[1] It is frequently encountered in clinical practice, accounting for approximately 30–85% of patients presenting to pain clinics.[1, 2] The people most affected by this condition are between the ages of 27 and 50 years. It is also most commonly seen in patients with chronic tension-type headaches, temporomandibular disorders, pain in the face-jaw region, and in post-whiplash syndrome.[3] A systematic literature review evaluating the prevalence of myofascial trigger points in patients with neck and back pain found that, among patients with spinal pain, those with neck pain had the highest prevalence of myofascial trigger points, with the most common locations being the trapezius, levator scapulae, and suboccipital muscles.[4]

Each MTrP can generate referred pain and/or autonomic manifestations. Several treatment approaches exist, including dry needling[5-9] and trigger point injections.[1, 5, 6] Dry needling is widely used and accepted for pain reduction in MPS, as it effectively deactivates trigger points without leaving foreign substances in the tissue.[6, 9] However, post-needling muscle soreness is a common adverse effect of dry needling, resulting from tissue injury or bleeding at the insertion site. This injury triggers an inflammatory response, leading to localized soreness that may delay patient recovery.[1, 7, 10-12] Previous studies report that post-needling soreness can persist for approximately 1.73 - 1.83 days[13] and may last up to 72 hours.[14] Post-needling soreness is distinct from MPS-related pain; it typically presents as a constant, dull, aching sensation localized to the treated muscle.[7, 11]

Cryotherapy has been shown to induce several physiological changes, including decreased acute inflammation, vasoconstriction of skin and subcutaneous vessels, reduced blood flow, increased blood viscosity, elevated peripheral vascular resistance, and decreased nerve conduction velocity and excitability. Significantly, cryotherapy elevates the pain threshold through neuromuscular mechanisms.[11, 15-17] Despite these potential benefits, previous studies have shown no statistically significant effect of cryotherapy applied after dry needling on post-needling soreness,[11] and the impact of cryotherapy applied before dry needling has not been adequately investigated.

We hypothesize that applying cold pack therapy (cryotherapy) to the skin before dry needling in patients with upper trapezius MPS will significantly reduce post-needling soreness compared with dry needling alone.

The primary objective of this study was to evaluate the efficacy of cold pack therapy applied prior to dry needling in reducing post-needling soreness intensity in patients with MPS. The secondary objective was to assess its effectiveness in reducing the duration of post-needling soreness and analgesic consumption.

Methods

Study design and participants

This study was designed as a single (assessor)-blinded, randomized controlled trial. Patients with shoulder pain who visited the Outpatient Department of Rehabilitation Medicine at Phramongkutklao Hospital between October 2017 and February 2018 were screened for eligibility. Inclusion criteria were as follows: age between 20 and 60 years, diagnosed with MPS of the upper trapezius muscle by a physiatrist with baseline pain score $\geq$ 40 on a 100-mm visual analog scale (VAS), indicating at least moderate pain;[18] and willing and able to participate in this study. Exclusion criteria included those who had coagulopathy, fever, syncope, history of neck or shoulder surgery, lack of response to previous dry needling treatment, skin infection at the needling site, known allergy to acetaminophen, cold intolerance, cold-induced urticaria, history of Raynaud's phenomenon, paroxysmal cold hemoglobinuria, peripheral vascular disease, use of analgesics within three days prior to the study and diagnosis of fibromyalgia.

Sample size calculation

A literature review revealed no prior studies investigating cryotherapy before dry needling; however, a similar study examined the effect

of cold pack therapy after dry needling in the shoulder region.[11] In that study, the reported mean difference in post-needling soreness intensity between groups was approximately 20 mm on a 100-mm scale. VAS, with a standard deviation (SD) of 25 mm. Using these parameters, we calculated the required sample size for comparing two independent means with the following assumptions: two-tailed $\alpha = 0.05$, power $(1 - \beta) = 0.80$, effect size (Cohen's d) = 0.80, representing a significant effect based on the expected VAS difference and SD, allocation ratio = 1:1. Based on these inputs, a minimum of 26 participants per group (52 total) was required to detect a statistically significant difference in post-needling soreness intensity. To account for an estimated 10–15% dropout rate, we increased the sample size to 30 per group, yielding a total target enrollment of 60.

Randomization

Participants were randomly assigned (1:1) using computer-generated stratified randomization (< 3 months vs. ≥ 3 months) with block sizes of four to either the intervention group (cold pack therapy prior to dry needling) or the control group (no cold pack therapy prior to dry needling).

Ethical Consideration

The trial protocol was approved by the Institutional Review Board of the Royal Thai Army Medical Department (Number R072h/60) and was registered in the Thai Clinical Trials Registry (TCTR 20251028005). All participants gave their written informed consent before participating in the study.

Interventions

All dry needling procedures were performed by the same experienced physiatrist who was blinded to group allocation. Participants were placed in the prone position, a standard for dry needling of the upper trapezius muscle to ensure consistency across participants. After cleaning the skin with 70% alcohol, a circular fan-like dry needling technique was performed using DongBang® acupuncture needles (Chungnam, Korea; 40 mm × 0.25 mm). A single needle was inserted through the skin into the identified MTrP and manipulated in multiple directions, moving back and forth between the subcutaneous tissue and the MTrP. Each participant received approximately 10 needle insertions, and the number of local twitch responses (LTRs) was recorded during the procedure. After treatment, the needle was removed, and light pressure was applied with a sterile cotton ball to control any bleeding at the site.

For cold pack therapy prior to dry needling in the intervention group, a 3M® cold gel pack, size 4 × 10 inches, was used. It was stored in a freezer at 0–10°C before application. The cold pack was applied directly to the skin over the trigger point for 15 minutes prior to the procedure. During cold pack therapy, participants were asked about their perception of cold every 5 minutes, and any adverse reactions (e.g., urticaria) were monitored. After cold pack therapy, the cold pack was removed, and skin temperature was measured with the infrared thermometer HuBDIC Thermofinder FS-300 and recorded.

For post-dry needling instructions, all participants received a patient education leaflet and verbal instructions on self-stretching exercises for the upper trapezius muscle, postural control techniques, and ergonomic recommendations for daily activities. Participants experiencing severe pain or soreness were permitted to take acetaminophen 500 mg (1 tablet every 4–6 hours, up to 6 tablets per day). They were instructed to avoid additional interventions during the study period, such as other analgesics, hot or cold therapy, or physical modalities.

Outcome Measures

The primary outcomes were pain intensity during needle insertion (measured with a 0–100 Visual Analog Scale [VAS]) and post-needling soreness intensity at 10 minutes and on Day 2 following the procedure. The secondary outcomes were duration of post-needling soreness (in days) and analgesic consumption (number of acetaminophen tablets used). The other researcher, a 3rd-year PM&R resident, measured both primary and secondary outcomes. VAS was presented on a 10-cm horizontal line, with 0 = no pain and 100

= worst imaginable pain. Participants marked the point on the scale that best represented their pain during needle penetration and post-procedure soreness. On Day 2, participants were contacted by telephone and reminded to record their pain intensity and the duration of soreness in a provided diary. They also reported any adverse events. At a 14-day follow-up, an investigator who was blinded to group allocation collected data on the total duration of post-needling soreness, analgesic use, posture, adherence to ergonomics, and the frequency and accuracy of stretching exercises. If participants continued to experience MPS symptoms in the same or other regions, treatment was provided after study completion.

Statistical analysis

Data was analyzed using descriptive statistics, including means, standard deviations, and percentages, to summarize baseline characteristics. Independent t-tests were used to compare skin temperature and baseline characteristics between groups. Kolmogorov–Smirnov tests were applied to assess data normality. Repeated measures ANOVA were used to compare VAS scores over time between groups. Mann–Whitney U tests and Fisher's exact tests were applied to non-parametric and categorical data, respectively. A p-value < 0.05 was considered statistically significant.

Results

A total of 68 patients with upper trapezius MPS were initially screened for eligibility. Of these, eight participants were excluded due to the following reasons: age > 60 years (n = 4), cervical myelopathy or radiculopathy (n = 3), and previous neck surgery (n = 1). The remaining 60 participants were enrolled and randomly assigned in equal numbers to two groups: cold pack therapy prior to dry needling (intervention group, n = 30) and no cold pack therapy prior to dry needling (control group, n = 30). During the follow-up period, two participants (one in each group) were lost to follow-up due to travel-related reasons, leaving 58 participants (29 per group) for final analysis (**Figure 1**). The missing data were minimal; therefore, analyses were performed using a complete-case approach, excluding participants with missing data. No data imputation was performed. There were no statistically significant differences in baseline demographic or clinical characteristics between the two groups ($p > 0.05$) (**Table 1**).

The intervention group reported significantly lower mean (SD) pain intensity during needle insertion compared with the control group [0 (10) vs. 60 (20); $p < 0.001$]. Additionally, post-needling soreness was significantly lower in the intervention group at 10 minutes [10 (10) vs. 80 (30); $p < 0.001$] and at 2 days [0 (10) vs. 40 (20); $p < 0.001$] after dry needling (**Figure 2**).

Participants in the intervention group experienced a significantly shorter median duration of post-needling soreness than those in the control group (0.13 days vs. 3 days, $p < 0.001$). Acetaminophen use was also significantly lower in the intervention group. All participants (100%) in the intervention group did not require any analgesic medication, compared with 75.86% in the control group ($p = 0.010$). Seven of 29 participants (24.14%) in the control group reported taking 1–3 tablets during the follow-up period. The number of LTRs was slightly lower in the intervention group compared with the control group (median: 6 vs. 7 times, $p = 0.025$) (**Table 2**). There were no significant differences between groups in adherence to self-stretching exercises, stretching frequency, posture correction, or ergonomic practices. No adverse events were reported in either group during the study. All participants tolerated both the cold pack therapy and dry needling procedures well.

Discussion

This randomized controlled trial demonstrated that applying a cold pack prior to dry needling significantly reduced pain during needle insertion, decreased post-needling soreness at both 10 minutes and 2 days after treatment, shortened the duration of soreness, and reduced analgesic consumption in patients with upper trapezius MPS. All reported pain scores during the intervention, including post-dry needling muscle soreness, were distinguished from pain originating from trigger points by the baseline pain

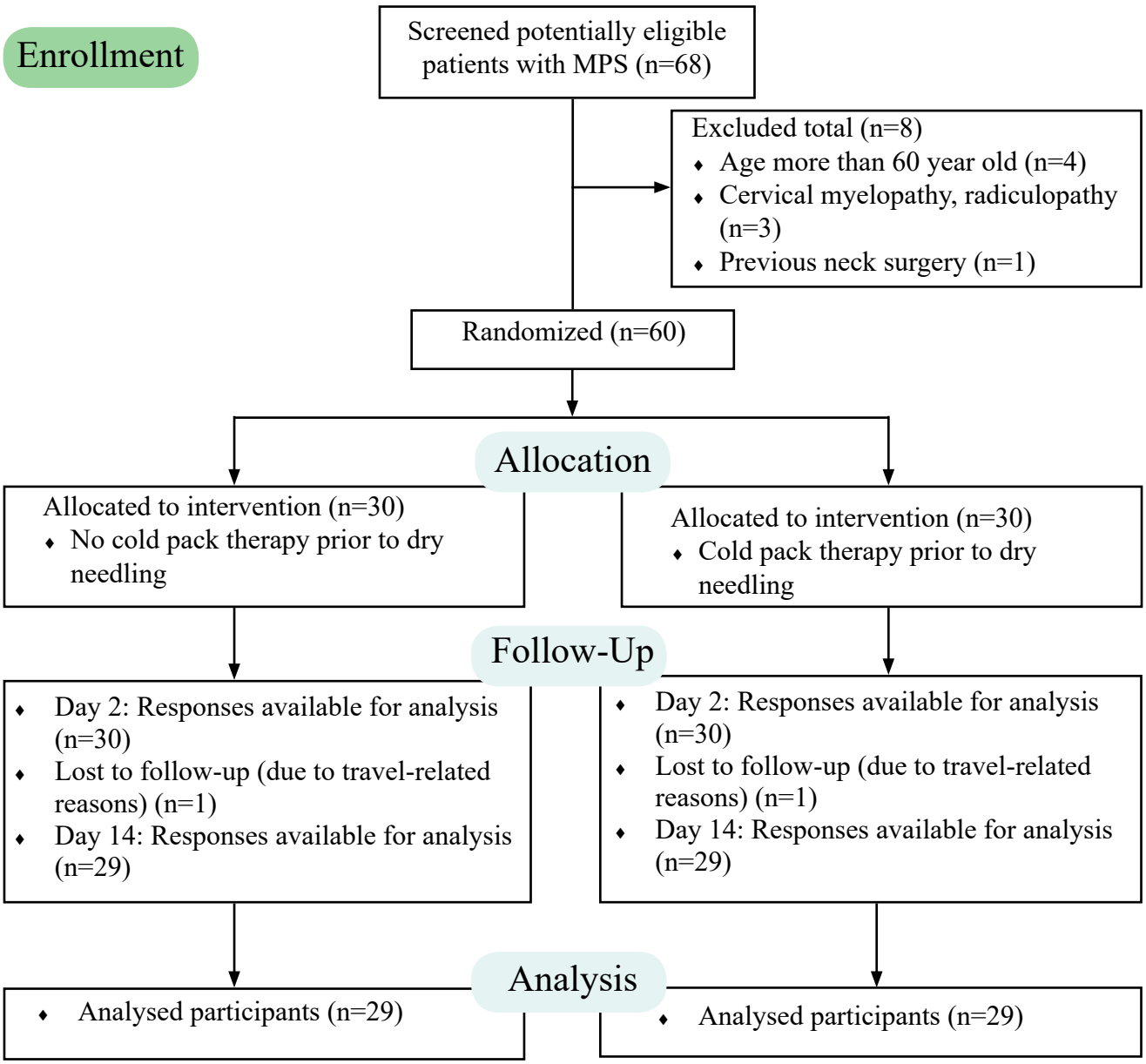

Figure 1. Flowchart of participants through the study

Table 1. Demographic data of participants

	Intervention (n=29)	Control (n=29)	*p*-value
Sex			0.788
Male	12 (41.38%)	11 (37.93%)	
Female	17 (58.62%)	18 (62.07%)	
Age[1] (Years)	31.59±11.53	33.34±12.64	0.582‡
Duration of symptoms			0.865
Less than 3 months	13 (44.82%)	15 (51.72%)	
From 3 months	16 (55.17%)	14 (48.28%)	
VAS before treatment[1]	56.21±11.15	52.76±11.31	0.247‡

[1]Mean±SD, * significant $p<0.05$, ‡ Independent t-test

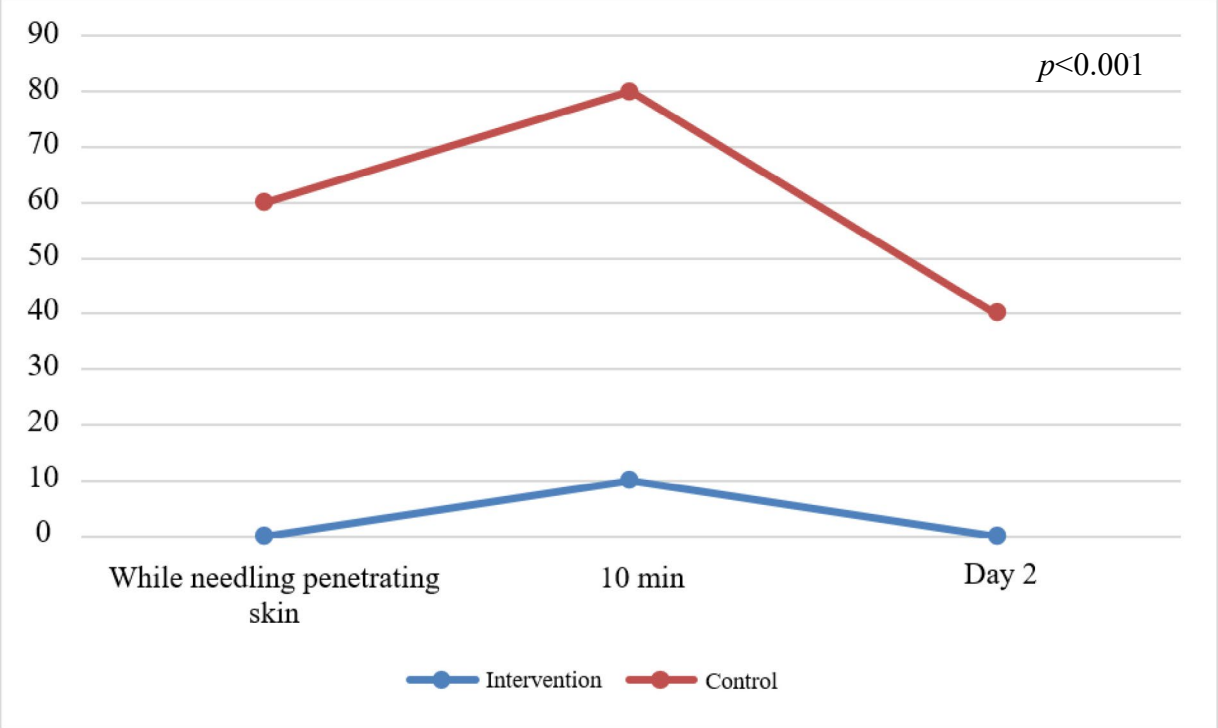

Figure 2. Comparison of the visual analog scale after treatment

Table 2. Comparison of treatment outcomes between groups

	Intervention (n = 29)	Control (n = 29)	*p*-value
Skin temperature (°c) [1]	16.90±0.96	36.65±0.40	<0.001*‡
Local Twitch response (times)[2]	6 (2-9)	7 (2-9)	0.025*¥
Duration of soreness (days)[2]	0.13 (0-1)	3 (2-4)	<0.001*¥
Acetaminophen (tabs)			0.010*†
0	29 (100.00%)	22 (75.86%)	
1	-	3 (10.34%)	
2	-	3 (10.34%)	
3	-	1 (3.45%)	

[1]Mean±SD, [2]Median(min-max), ‡ Independent t-test, † Fisher's exact test, ¥ Mann Whitney U test
* Significant $p < 0.05$

score and the timing of measurement. To the best of our knowledge, this study is the first to evaluate the efficacy of cold pack therapy applied before dry needling in the management of MPS.[12] Previous studies investigating cold pack therapy applied after dry needling did not report significant benefits in reducing post-needling soreness.[11] One such study on the asymptomatic deltoid muscle demonstrated no difference in soreness levels between participants receiving post-needling cold pack therapy and those receiving no cold pack therapy. This lack of effect may be attributed to two main factors: timing of intervention, as the inflammatory process triggered by tissue trauma may have already begun by the time cold pack therapy was applied, diminishing its effectiveness; and the temperature and duration of application, as the previous study did not

control the temperature of the cold pack, and the application duration was 20 minutes. Prolonged cold exposure beyond 15 minutes may trigger the Hunting reaction, alternating between vasoconstriction and vasodilation, and thereby reducing the desired anti-inflammatory effect. [19] In contrast, our study addressed these limitations by applying cold pack therapy before tissue trauma occurred, controlling the temperature (0–10°C), and limiting application time to 15 minutes. These methodological improvements likely explain the significant reduction in soreness and pain observed in our study. Its well-documented physiological mechanisms can explain the observed effects of cold pack therapy. Cold application reduces tissue temperature, leading to vasoconstriction, decreased blood flow, and suppression of local inflammatory responses.[20] These effects help to minimize secondary tissue damage and reduce the release of inflammatory mediators associated with soreness and pain. Furthermore, cryotherapy slows nerve conduction velocity and decreases nerve excitability, which contribute to its analgesic effects. Most importantly, cold exposure increases the pain threshold, thereby diminishing the perception of pain during needle penetration. This explains the significantly lower pain scores during the procedure in the cold pack therapy group compared with the control group.[20]

Our findings suggest that incorporating cold pack therapy into clinical practice before dry needling can significantly improve patient outcomes. Although adding cold pack therapy increases treatment time by approximately 15 minutes, this modest extension is offset by substantial clinical benefits, including reduced procedural pain, decreased post-needling soreness, shorter recovery time, and reduced reliance on analgesics. Moreover, cold pack therapy is an inexpensive, widely accessible, and non-invasive modality, making it a practical adjunct to standard dry needling protocols in both clinical and outpatient settings.

This study had several strengths. It employed an assessor-blinded, randomized controlled design, reducing the risk of bias. Stratified randomization with block allocation ensured balanced baseline characteristics between groups. We also minimized confounding variables by standardizing the dry needling procedure (same clinician, same technique, same needle size and type, same muscle, and same patient positioning). Only one blinded assessor evaluated all outcome measures, further enhancing internal validity. Additionally, we monitored and recorded potential co-interventions, including acetaminophen use, stretching frequency, posture correction, and ergonomic adherence, none of which differed significantly between groups, thereby strengthening the validity of our conclusion that the observed differences were attributable to the cold pack therapy intervention.

Despite these strengths, several limitations should be noted. First, the sample size was calculated based on a study investigating cryotherapy after dry needling, as no prior studies had examined pre-needling cryotherapy. This may have affected the statistical power. Second, participants were not required to discontinue other pain-related treatments prior to enrollment (e.g., physical modalities, acupressure), which may have influenced baseline pain scores. However, baseline VAS scores did not differ significantly between groups, suggesting minimal bias. Third, some participants had MPS in muscles other than the upper trapezius. These cases were managed with stretching exercises during the study and treated with dry needling after the 14-day follow-up period. Fourth, although the treating physiatrist was blinded to group allocation, complete blinding may not have been entirely achievable. The marked reduction in skin temperature following cold pack therapy may have been perceptible during needle insertion, potentially allowing the physiatrist to infer group assignment. This could have introduced performance bias, for example, by unconsciously altering the needling technique. To minimize this risk, the dry needling procedure was highly standardized, and all treatments were performed by the same experienced physiatrist using a consistent technique, needle type, and patient positioning.

Nevertheless, this limitation should be considered when interpreting the results. Future studies may consider using sham cold pack therapy or independent intervention providers to

further enhance blinding. Finally, our findings are specific to adults aged 20–60 years with MPS of the upper trapezius. They may not be generalizable to older adults or to trigger points in deeper or larger muscles, such as those around the hip. Further studies with larger sample sizes and different muscle groups are recommended to validate our findings and explore the generalizability of pre-needling cold pack therapy. Investigating different cold pack therapy durations, application methods, or combination therapies could also help refine treatment protocols and optimize patient outcomes.

Conclusion

This study demonstrates that cold pack therapy applied prior to dry needling significantly reduces pain during needle insertion, decreases post-needling soreness at both 10 minutes and 2 days after treatment, shortens the duration of soreness, and lowers the need for analgesics compared with dry needling alone in patients with upper trapezius myofascial pain syndrome. These findings highlight the clinical value of integrating cold pack therapy into standard dry needling protocols. Incorporating this simple intervention can improve patient comfort, accelerate recovery, and enhance adherence to MPS treatment.

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