Archives of Rehabilitation Research and Clinical Translation (2021) 3, 100119

ACRM
AMERICAN CONGRESS OF REHABILITATION MEDICINE

Archives of Rehabilitation Research and Clinical Translation

Archives of Rehabilitation Research and Clinical Translation 2021;3: 1–8

Available online at www.sciencedirect.com

Original Research

Comparison of the Effects of Physiologic Saline Interfascial and Lidocaine Trigger Point Injections in Treatment of Myofascial Pain Syndrome: A Double-Blind Randomized Controlled Trial

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KEYWORDS
Injections;
Myofascial pain syndromes;
Rehabilitation;
Trigger points;
Lidocaine

Abstract *Objective:* To compare the effects of physiological saline interfascial and lidocaine trigger point injections in the treatment of myofascial pain syndrome (MPS).
Design: Double-blind randomized controlled study.
Setting: Department of Rehabilitation Medicine.
Participants: Eighty patients (N=80; 15 men, 65 women; mean age, 40.4±10.9y) with MPS in the upper trapezius muscle.
Interventions: Patients were randomly assigned to 1 of 2 groups: group 1 (n=40) received ultrasound-guided interfascial injection with physiological saline, and group 2 (n=40) underwent ultrasound-guided trigger point injection with lidocaine.
Main Outcome Measures: The primary outcome was pain scores measured by the visual analog scale (VAS). Secondary outcomes included cervical range of motion (ROM) and adverse effects of the procedure. The outcomes were assessed before treatment and 10 minutes, 2 weeks, and 4 weeks after treatment.
Results: Lidocaine trigger point injection showed higher VAS score improvement at 10 minutes after the procedure (*P*=.037). However, there was no statistically significant difference at other follow-up points. Pain scores significantly decreased at 10 minutes, 2 weeks, and 4 weeks from baseline in both groups. Cervical ROM increased significantly over time in some directions without significant differences between the groups. There were no serious adverse effects in this study.

List of abbreviations: MPS, myofascial pain syndrome; ROM, range of motion; VAS, visual analog scale.
Supported by the Chulabhorn Royal Academy (grant no. RAA 2562/026).
Clinical Trial Registration No. (Thai Trial Register): TCTR20190926003
Disclosures: none.
Cite this article as: Arch Rehabil Res Clin Transl. 2021;3:100119

https://doi.org/10.1016/j.arrct.2021.100119

Conclusion: Physiologic saline interfascial and lidocaine trigger point injections effectively decreased MPS pain in the upper trapezius muscle at 2 and 4 weeks after treatment. However, lidocaine trigger point injection demonstrated better pain improvement at 10 minutes after treatment.

Myofascial pain syndrome (MPS) is a very common musculoskeletal pain disorder occurring in 45%-54% of the general population.[1] MPS originates from muscle and surrounding fascia. Patients usually present with localized pain in various parts of the body, most commonly in the neck, shoulder, and back. Generally, the involved muscles may reveal trigger points which are contraction knots of muscle fibers. A trigger point is a marked tender spot on the taut band of muscle that can be aggravated locally; compression of the trigger point results in pain. MPS affects many aspects of a patient's quality of life, especially in chronic cases.[2]

There are many treatments for MPS, including stretching exercises, ergonomic modifications, pain relievers (eg, paracetamol, nonsteroidal anti-inflammatory drugs, muscle relaxants), physical modalities, and invasive procedures. Physicians also perform dry needling or inject local anesthetic agents into the trigger points to achieve pain reduction.[3] However, some patients do not respond to treatments and progress to chronic states. In a previous study, the average duration of symptoms was 63 months (range, 6-180mo).[4]

Recently, some clinicians have focused on treatment at the fascial plane between the affected muscles. Myofascial release is a manual therapy aiming to normalize stiffened fascia and restore the movement properties of myofascial tissues. Many studies support the efficacy of this technique in chronic musculoskeletal pain.[5] Moreover, there are reports on using an interfascial injection technique with either anesthetic agents or physiological saline to reduce the intensity of pain in patients with MPS.[6-8] However, the number of studies is limited, with no reports comparing physiological saline interfascial and trigger point injections with anesthetic agents. Trigger point injection with an anesthetic agent is widely used for the treatment of MPS, and the therapeutic effects for pain reduction and cervical ROM improvement were interestingly reported in patients with MPS in the upper trapezius muscle.[9]

In this study, we compared the treatment effects of physiological saline interfascial and lidocaine trigger point injection on pain, cervical ROM, and adverse events in patients with MPS in the upper trapezius muscle. We hypothesized that 5 ml of physiological saline injected interfascially is more effective in the reduction of pain scores than 2 ml of 1% lidocaine trigger point injection for MPS treatment in the trapezius muscle.

Methods

Setting and participants

This study was designed as a double-blind randomized controlled trial. We enrolled patients from our Department of Physical Medicine and Rehabilitation outpatient clinic, with inclusion and exclusion criteria as shown in table 1.

Table 1 Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
1. Diagnosis of MPS in the upper trapezius muscle in accordance with criteria defined by Travell and Simons[10] (5 major and minimum of 1 minor criteria are required for clinical diagnosis Major criteria: - Regional pain complaint - Palpable taut band in reachable muscles - Spontaneous pain or altered sensation in expected referred pain area for given trigger point - Extreme sensitivity in a point along the taut band - Decrease of measurable range of motion Minor criteria: - Reproduction of spontaneously perceived pain and altered sensation by pressure on trigger point - Local twitch response of the muscle fibers in the taut band by palpation or needle insertion - Pain relief obtained by injection of trigger point or stretching of muscle. 2. Aged 18-60 y 3. No treatment, including injection, dry needling, and physical modalities, in the past 3 mo 4. No pain relievers in the past 48 h	1. Bleeding tendency 2. History of neck and shoulder trauma 3. Other disease affecting neck and shoulder pain, such as fibromyalgia, cervical radiculopathy, or adhesive capsulitis 4. Allergy to lidocaine

All participants were informed of the study protocol and provided their written informed consent. Patients' demographic data and pretreatment outcomes were collected before the intervention. This study was approved by the Human Research Ethics Committee of Chulabhorn Research Institute (Clinical Trial Registry: TCTR20190926003).

Randomization

Participants were randomly assigned to 1 of 2 groups by permuted block randomization (block size 4). The allocation sequence was created by the third author, and each number was sealed in an envelope before being given to the investigator who performed the injection. Group 1 received interfascial physiological saline injection, whereas group 2 underwent lidocaine trigger point injection (fig 1).

Interventions

All participants received palpation on the upper trapezius muscle to locate the trigger point (hypersensitive bundle or nodule of muscle fibers harder than normal consistency) while sitting upright. The most painful trigger point was marked. The skin was then sterilized with an antiseptic agent. A linear array transducer probe[a] was applied in the coronal plane to scan the marked area. We used an in-plane approach injection in which the needle is placed parallel to the long axis of the transducer (fig 2). A 25-gauge 1.5-inch needle was used for all injections.

Participants in group 1 received an interfascial injection with 5 ml of physiological saline injection, similar to that in a study by Kongsakul et al.[8] The needle was inserted into the interfascial space at the area beneath the trigger point. The interfascial space is the plane between the upper trapezius and the underlying muscles (supraspinatus or levator scapulae muscles) (fig 3). We moved the needle only 1-2 times to minimize the mechanical effect. In another group, participants underwent an injection of 2 ml of 1% lidocaine at the same amount as that in a study by Ay et al[9] into the marked trigger point in the upper trapezius muscle. At first, the needle was inserted into the middle part of the muscle depth, then the needle was moved approximately 1-2 cm around the center 5-10 times while injecting the lidocaine (fig 4).

All injections were performed by the first author, who was an expert in ultrasound-guided injection. All participants were blinded to the treatment and were advised to perform upper trapezius stretching exercises during the follow-up period.

Outcome measurement

Assessments at pretreatment and 10 minutes, 2 weeks, and 4 weeks after treatment were conducted by the second author who was blinded to the treatment group. The primary outcome was pain intensity in the upper trapezius muscle using a 10-point visual analog scale (VAS), in which 0 indicated no pain and 10 indicated the most intense pain imaginable.

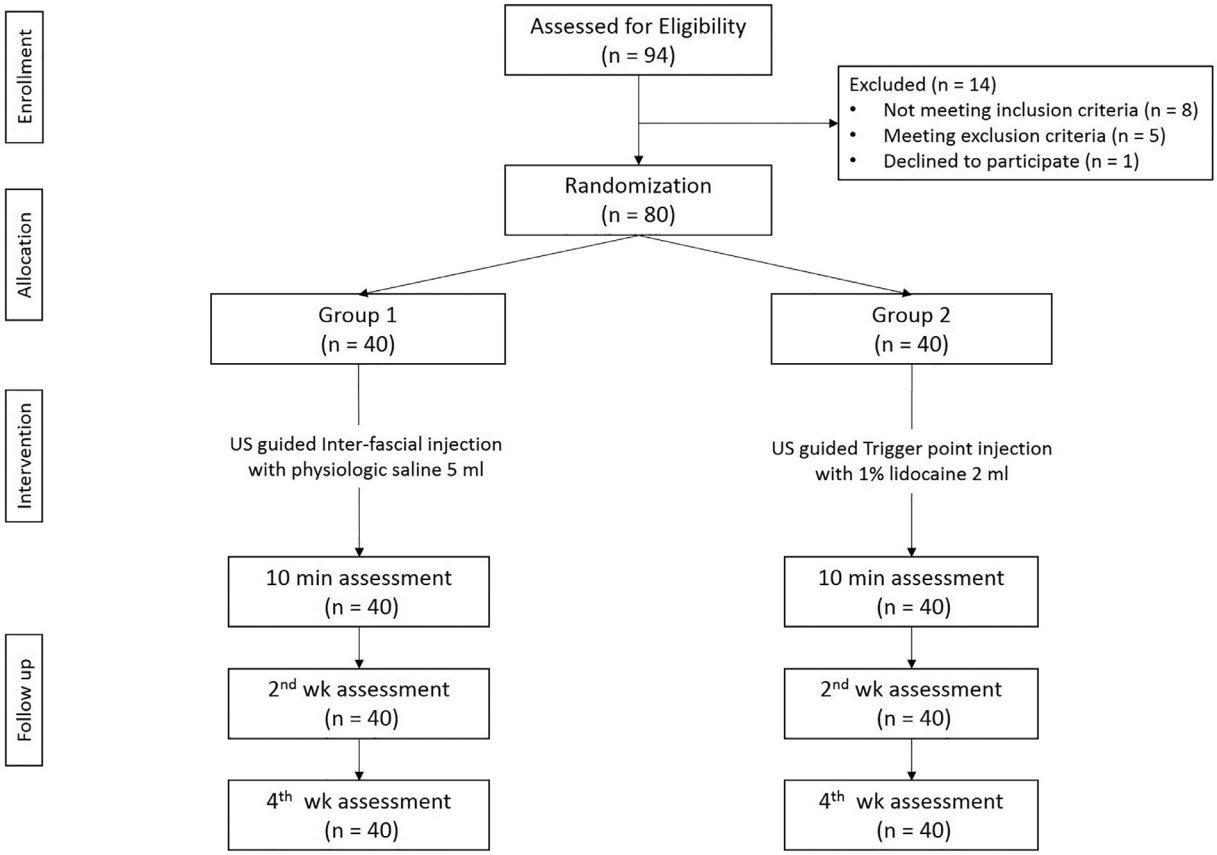

Fig 1 Study flow chart.

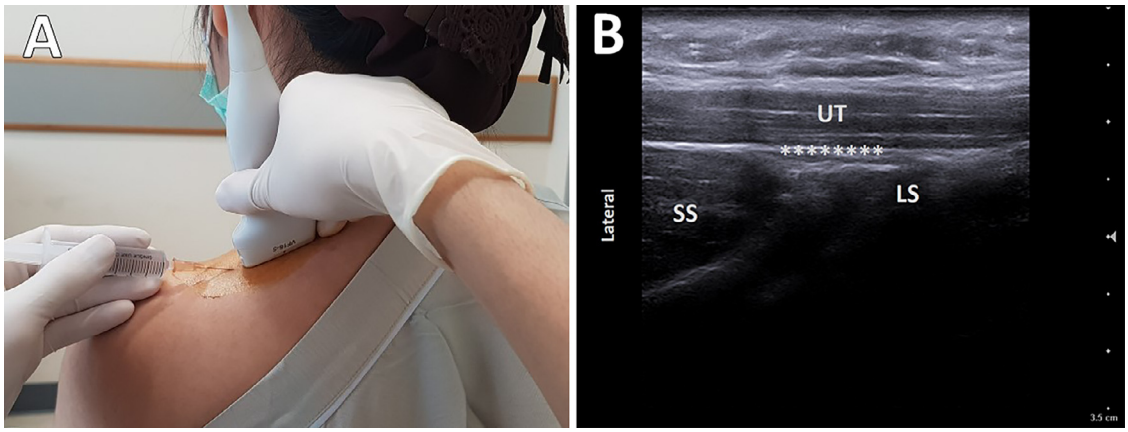

Fig 2 (A) Example of coronal probe position over the upper trapezius muscle with the in-plane needle position. (B) Long-axis of the upper trapezius muscle (UT) and surrounding structures: supraspinatus muscle (SS), levator scapulae muscle (LS), and interfascial space (asterisks).

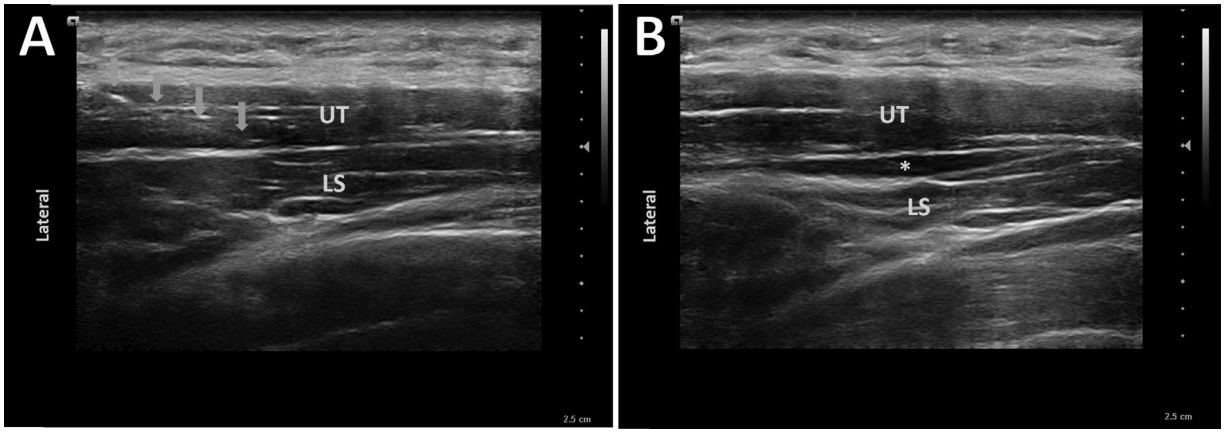

Fig 3 (A) Physiologic saline interfascial injection showing the needle (arrow), upper trapezius muscle (UT), and levator scapulae muscle (LS). (B) Physiologic saline layer after injection (asterisk).

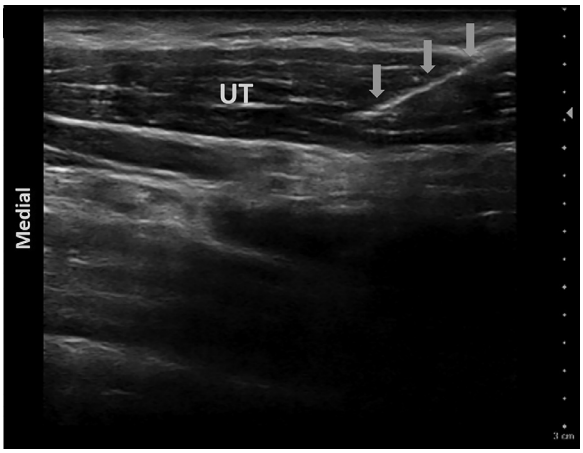

Fig 4 Lidocaine trigger point injection showing the needle (arrow) and upper trapezius muscle (UT).

The secondary outcome was active cervical range of motion (ROM), measured by goniometry in all directions: flexion, extension, right lateral bending, left lateral bending, right rotation, and left rotation, in the sitting position. Adverse events and duration of postinjection soreness were also assessed at each follow-up point.

Statistical analysis

Sample size calculations were based on the results from a previous study.[9] In this study, the main outcome was pain score measured by VAS at 4 weeks after treatment. The mean VAS scores ± SD were 2.27±0.98 in the control group and 3.82±0.47 in the intervention group. The results were calculated for sample size to compare 2 independent means. When adopting type 1 error of 0.05, power of 80%, and 2-sided test, our study required 37 participants in each group. Considering a 10% dropout rate, 40 participants were recruited in each group.

Statistical analyses were performed using IBM SPSS Statistics for Windows, version 26.0.[b] Descriptive statistics were calculated as means with SDs for continuous data and frequencies with percentages for nominal data. Data normality was assessed using the Kolmogorov-Smirnov test.

Wilcoxon signed-rank test was used to compare the outcomes before treatment and at each follow-up point. For between-group comparisons, differences in continuous variables between baseline and each follow-up point were tested

Table 2 Participants' demographic data

Characteristic	Group 1(n=40)	Group 2(n = 40)	*P* Value
Age, y	40.10±10.92	40.63±11.16	.881*
Sex, male, n (%)	6 (15)	9 (22.5)	.390†
Trigger point side, right, n (%)	29 (72.5)	25 (62.5)	.340†
Symptom duration, wk	27.30±41.34	35.98±45.74	.597*
VAS	5.15±1.64	5.74±.20	.104*
Flexion, degrees	42.35±8.89	43.60±11.26	.419*
Extension, degrees	45.65±10.69	46.63±10.55	.479*
Left bending, degrees	37.90±7.81	36.13±8.86	.446*
Right bending, degrees	38.03±7.77	35.95±9.27	.467*
Left rotation, degrees	55.55±7.28	54.48±8.77	.606*
Right rotation, degrees	55.63±9.17	55.78±10.09	.855*

NOTE. Data are presented as mean ± SD or as otherwise indicated.
* Mann-Whitney *U* test.
† Chi-square test.

using the Mann-Whitney *U* test. The chi-square test was used for nominal variables for comparisons between groups. Statistical significance was considered at *P* values <.05.

Results

The flow of participants in the study is presented in figure 1. The participants were recruited from October 2019 to April 2020. A total of 80 participants were enrolled in this study, and no participants were lost to follow-up. Each group was composed of 40 participants; demographic data is shown in table 2. There were no statistically significant differences between the groups for demographic data and pretreatment variables.

In both groups, VAS scores decreased significantly at all follow-up points compared with the pretreatment scores (table 3; fig 5). Regarding the between-group comparisons, the change in VAS score 10 minutes after treatment in group 2 was superior to the score in group 1, reaching statistical significance. However, there were no statistically significant differences at the other follow-up points (table 4).

There were statistically significant improvements on cervical ROM in all directions at some follow-up points in group 1. On the other hand, the results showed significant improvements only in left bending, right bending, and left

Table 3 Effect of the interventions compared with baseline

Parameter	Baseline	10 Minutes	2 Weeks	4 Weeks	*P* Value (10 Min/Baseline)	*P* Value (2 Weeks/Baseline)	*P* Value (4 Weeks/Baseline)
VAS							
Group 1	5.15±1.64	3.83±1.66	2.85±1.98	2.58±2.26	.001*	<.001*	<.001*
Group 2	5.74±1.20	3.51±1.80	2.76±2.30	2.26±2.13	<.001*	<.001*	<.001*
Flexion							
Group 1	42.35±8.89	41.57±10.81	42.45±9.58	44.65±8.28	.661	.944	.043*
Group 2	43.60±11.26	45.23±10.18	43.20±10.04	45.30±11.02	.089	.706	.316
Extension							
Group 1	45.65±10.69	47.10±12.38	49.17±10.72	49.60±11.44	.280	.044*	.026*
Group 2	46.63±10.55	48.33±10.62	49.65±11.73	49.00±12.78	.147	.088	.090
Left bending							
Group 1	37.90±7.81	38.43±6.70	40.38±8.18	40.80±7.93	.524	.033*	.059
Group 2	36.13±8.86	37.88±9.22	38.33±8.66	39.88±7.34	.078	.064	.006*
Right bending							
Group 1	38.03±7.77	37.90±6.45	37.73±6.68	40.58±7.41	.623	.791	.005*
Group 2	35.95±9.27	38.10±8.76	38.40±9.33	39.33±9.05	.060	.056	.011*
Left rotation							
Group 1	55.55±7.28	56.85±8.01	58.73±8.03	59.70±7.32	.321	.032*	.003*
Group 2	54.48±8.77	56.65±10.12	58.05±8.00	58.25±8.27	.009*	.007*	.005*
Right rotation							
Group 1	55.63±9.17	56.83±8.18	57.88±7.94	59.85±7.16	.325	.194	.010*
Group 2	55.78±10.09	56.18±9.94	58.13±8.98	58.35±8.59	.663	.112	.063

NOTE. Data are presented as mean ± SD. Wilcoxon signed-rank test was used for intragroup comparisons.
* *P*<.05.

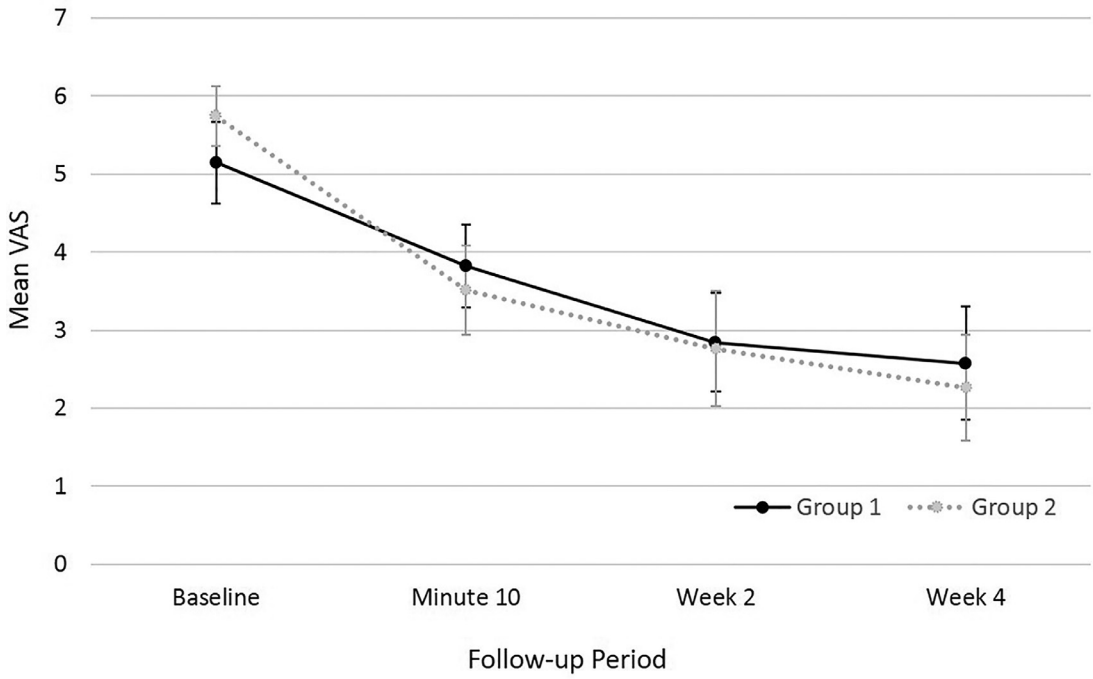

Fig 5 VAS score outcomes in the 2 intervention groups.

Table 4 Comparison of differences in VAS scores and cervical ROM between the groups

Parameter	10 Minutes−Baseline	2 Weeks−Baseline	4 Weeks−Baseline
VAS			
Group 1	−1.33±1.96	−2.31±2.21	−2.58±2.52
Group 2	−2.23±1.79	−2.98±2.57	−3.48±2.47
P value	0.037*	0.138	1.49
Flexion			
Group 1	−0.78±7.99	0.10±8.00	2.30±7.60
Group 2	1.63±7.80	−0.40±10.73	1.70±9.73
P value	0.161	0.791	0.537
Extension			
Group 1	1.45±9.52	3.53±10.64	3.95±10.72
Group 2	1.70±6.84	3.03±9.30	2.38±11.60
P value	0.859	0.658	0.627
Left bending			
Group 1	0.53±7.15	2.48±7.85	2.90±9.74
Group 2	1.75±5.93	2.20±8.92	3.75±7.88
P value	0.623	0.806	0.686
Right bending			
Group 1	−0.13±7.61	−0.30±7.89	2.55±8.21
Group 2	2.15±6.43	2.45±7.77	3.38±8.32
P value	0.340	0.183	0.825
Left rotation			
Group 1	1.30±±7.20	3.18±8.02	4.15±7.70
Group 2	2.18±4.99	3.58±7.88	3.78±7.76
P value	0.410	0.885	0.740
Right rotation			
Group 1	1.20±6.94	2.25±9.07	4.23±9.05
Group 2	0.40±6.24	2.35±7.67	2.58±7.25
P value	0.806	0.893	0.418

NOTE. Data are presented as mean ± SD. The Mann-Whitney *U* test was used for intergroup comparisons.
* $P<.05$.

Table 5 Adverse events and duration of postinjection soreness

Adverse Event	Group 1 (n=40)	Group 2 (n=40)	P Value
Post injection soreness, n (%)	19 (47.5)	26 (65)	.115*
Soreness duration, d	0.88± 1.04	1.33± 1.44	.142†
Dizziness, n (%)	0 (0)	1 (2.5)	<.99‡

* Chi-square test.
† Mann-Whitney *U* test.
‡ Fisher exact test.

rotation cervical ROM in group 2 (see table 3). However, no significant differences were observed between the groups (see table 4).

Minor adverse events were observed, namely postinjection soreness and dizziness. There was no statistically significant difference between the groups regarding the incidence of adverse events and duration of postinjection soreness (table 5).

Discussion

In this study, the interfascial injection had a therapeutic effect in patients with MPS. Pain scores decreased at 10 minutes, 2 weeks, and 4 weeks after injection, similar to the findings in previous studies. Domingo et al[6] performed interfascial blocks with 8-10 ml of 0.125% bupivacaine in 25 patients with MPS in the upper trapezius muscles, with a significant decrease in pain intensity 10 minutes after injection. Two additional studies[7,11] compared the effect of interfascial blocks with 10 ml of lidocaine vs interfascial pulsed radiofrequency on MPS in the gastrocnemius and trapezius muscles. Patients in the interfascial injection group showed a significant decrease in pain scores during follow-up in both studies. There were 2 differences between our study and the previous studies. First, we used physiological saline for interfascial injection to minimize the anesthetic effect. The second was the comparison group. In this study, we compared interfascial injection with trigger point injection. Kongsagul et al[8] performed a retrospective study of interfascial injection with 5-10 ml of physiological saline in 142 patients with MPS. The physiological saline interfascial injection decreased pain scores in 72.8% of the patients. However, no comparison of this technique was done with other treatments.

Lidocaine trigger point injection is a common and effective treatment in patients with MPS, and several studies support its therapeutic effect.[9,12,13] Our results showed no significant difference in pain improvement between the physiological saline interfascial injection group and the lidocaine trigger point injection group 2 and 4 weeks after injection. However, the lidocaine trigger point injection effect was superior 10 minutes after injection. We believe this result was owing to the anesthetic effect. To our knowledge, ours is the first randomized controlled trial to compare physiological saline interfascial injection with lidocaine trigger point injection.

Regarding cervical ROM, our study showed improvement in some directions at some follow-up points in both groups. To our knowledge, no previous study has reported the effects of interfascial injection on cervical ROM. Nonetheless, some studies have reported an improvement on cervical ROM after lidocaine trigger point injections.[9,14]

Regarding injection volume, there have been previous reports[6-8,11] using 5-10 ml of physiological saline or anesthetic agents for interfascial injection. All studies showed that interfascial injection had a therapeutic effect in patients with MPS. In this study, we used 5 ml of physiological saline as in the study by Kongsakul et al,[8] which was the only study using physiological saline for interfascial injection. For the trigger point injection group, we used 2 ml of 1% xylocaine for trigger point injection, similar to that in the previous study.[9] Because participants in each group received different volumes of injections, our results may have been obstructed by the volume effects.

The mechanism responsible for the effects of interfascial injection is controversial, with numerous researchers formulating hypotheses. Laimi et al[5] reported that tightened fascial tissue between muscles and its reduced sliding ability are the source of chronic musculoskeletal pain. If we normalize the length and the sliding properties of myofascial tissue, pain should be relieved. Recently, patients with chronic musculoskeletal pain have been treated with the myofascial release technique as a manual therapy aiming to restore impaired function of soft tissues. Ichikawa et al[15] reported that myofascial release could effectively improve the movement function of myofascial tissues, measured by ultrasonography. Therefore, fluid between muscles from an interfascial injection may normalize muscle function and decrease muscle pain. Another hypothesis is the effect on pain nociceptors in the interfascial space, which contains nerve structures.[6] For this reason, physiological saline may alter pain sensitivity or decrease tension in myofascial tissues. However, there is no evidence to support this theory.

The mechanism of trigger point injection effects is still unknown.[9] However, Simons and Travell[10] suggested that a mechanical effect on muscle fibers causes trigger point inactivation. In this study, we attempted to limit this mechanical effect by minimizing the needle movement in the interfascial injection group.

Only minor adverse events, namely soreness and dizziness, were observed in this study, with no significant difference between the groups. There were also no severe adverse effects, such as pneumothorax, air embolism, and vascular injury in either group. We considered that severe complications could be prevented with ultrasound-guided injections.

Study limitations

This study had some limitations. First, the follow-up period was short at only 4 weeks; therefore, long-term effects were undetermined. The second was the lack of a placebo or sham group. Thus, we could not exclude spontaneous resolution effects and placebo effect of the injection. The third limitation was multiple treatment variables between groups, such as different types of solution for injection (saline vs lidocaine), injection volumes (5 vs 2 ml), and needle movement technique (1-2 needle passes vs 5-10 needle passes). Accordingly, these variables could affect the treatment results. Further studies are needed to compensate for these limitations. Moreover, studies using other injectable

solutions, such as hyperosmolar dextrose, for interfascial injection are required to evaluate additional effects.

Conclusions

To our knowledge, this is the first study comparing physiological saline interfascial injection with lidocaine trigger point injection in MPS. In conclusion, physiological saline interfascial injection effectively decreased pain in patients with MPS. Pain improvement at 10 minutes after injection was superior in the lidocaine trigger point injection group. However, the therapeutic effect was not significantly different between the 2 injection techniques at 2 and 4 weeks after injection. Therefore, physiological saline interfascial injection can be considered as a treatment option for patients with MPS in the upper trapezius muscle. Further studies with a placebo-controlled or better variable-controlled design with longer follow-up periods are needed to ratify and elucidate the results.

Suppliers

a. Acuson NX3; Siemens Healthcare GmbH.
b. SPSS, version 26.0; IBM Corp.

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Acknowledgment

We thank Jane Charbonneau, DVM, from Edanz Group (https://en-author-services.edanzgroup.com/ac) for editing a draft of this manuscript.

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