ISSN 2218-5836 (online)

World Journal of *Orthopedics*

World J Orthop 2023 July 18; 14(7): 505-588

Published by Baishideng Publishing Group Inc

World Journal of Orthopedics

Contents

Monthly Volume 14 Number 7 July 18, 2023

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World Journal of Orthopedics

Monthly Volume 14 Number 7 July 18, 2023

ABOUT COVER

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NAME OF JOURNAL
World Journal of Orthopedics

ISSN
ISSN 2218-5836 (online)

LAUNCH DATE
November 18, 2010

FREQUENCY
Monthly

EDITORS-IN-CHIEF
Massimiliano Leigheb

EDITORIAL BOARD MEMBERS
http://www.wjgnet.com/2218-5836/editorialboard.htm

PUBLICATION DATE
July 18, 2023

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World J Orthop 2023 July 18; 14(7): 572-581

DOI: 10.5312/wjo.v14.i7.572

ISSN 2218-5836 (online)

ORIGINAL ARTICLE

Randomized Clinical Trial

Instrumented assisted soft tissue mobilization *vs* extracorporeal shock wave therapy in treatment of myofascial pain syndrome

Nourhan Elsayed Shamseldeen, Mohammed Moustafa Aldosouki Hegazy, Nadia Abdalazeem Fayaz, Nesreen Fawzy Mahmoud

Specialty type: Orthopedics

Provenance and peer review: Invited article; Externally peer reviewed.

Peer-review model: Single blind

Peer-review report's scientific quality classification

Grade A (Excellent): 0
Grade B (Very good): 0
Grade C (Good): C
Grade D (Fair): 0
Grade E (Poor): 0

P-Reviewer: Pitton Rissardo J, Brazil

Received: January 9, 2023
Peer-review started: January 9, 2023
First decision: April 26, 2023
Revised: May 10, 2023
Accepted: May 31, 2023
Article in press: May 31, 2023
Published online: July 18, 2023

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Abstract

BACKGROUND

Active myofascial trigger points (TrPs) often occur in the upper region of the upper trapezius (UT) muscle. These TrPs can be a significant source of neck, shoulder, and upper back pain and headaches. These TrPs and their related pain and disability can adversely affect an individual's everyday routine functioning, work-related productivity, and general quality of life.

AIM

To investigate the effects of instrument assisted soft tissue mobilization (IASTM) *vs* extracorporeal shock wave therapy (ESWT) on the TrPs of the UT muscle.

METHODS

A randomized, single-blind, comparative clinical study was conducted at the Medical Center of the Egyptian Railway Station in Cairo. Forty patients (28 females and 12 males), aged between 20-years-old and 40-years-old, with active myofascial TrPs in the UT muscle were randomly assigned to two equal groups (A and B). Group A received IASTM, while group B received ESWT. Each group was treated twice weekly for 2 weeks. Both groups received muscle energy technique for the UT muscle. Patients were evaluated twice (pre- and post-treatment) for pain intensity using the visual analogue scale and for pain pressure threshold (PPT) using a pressure algometer.

RESULTS

Comparing the pre- and post-treatment mean values for all variables for group A, there were significant differences in pain intensity for TrP1 and TrP2 (P = 0.0001) and PPT for TrP1 (P = 0.0002) and TrP2 (P = 0.0001). Also, for group B, there were significant differences between the pre- and post-treatment pain intensity for TrP1 and TrP2 and PPT for TrP1 and TrP2 (P = 0.0001). There were no significant differences between the two groups in the post-treatment mean values of pain intensity for TrP1 (P = 0.9) and TrP2 (P = 0.76) and PPT for TrP1 (P = 0.09) and for TrP2 (P = 0.91).

CONCLUSION

IASTM and ESWT are effective methods for improving pain and PPT in patients with UT muscle TrPs. There is no significant difference between either treatment method.

Key Words: Myofascial trigger points; Upper trapezius muscle; Instrument-assisted soft tissue mobilization; Extracorporeal shock wave therapy; Myofascial pain syndrome

Core Tip: This is the first study to compare the effects of instrument-assisted soft tissue mobilization (IASTM) *vs* extracorporeal shock wave therapy (ESWT) on trigger points of the upper trapezius muscle in myofascial pain syndrome. The results of the current study revealed no statistically significant differences between the effect of IASTM and ESWT on pain intensity and pain pressure threshold of upper trapezius muscle trigger points. However, both IASTM and ESWT improved pain measures in both groups of patients suffering from myofascial pain syndrome. Based on these results, treatment methods can be selected based on availability, cost, therapist experience, and patient preference.

Citation: Shamseldeen NE, Hegazy MMA, Fayaz NA, Mahmoud NF. Instrumented assisted soft tissue mobilization *vs* extracorporeal shock wave therapy in treatment of myofascial pain syndrome. *World J Orthop* 2023; 14(7): 572-581

URL: https://www.wjgnet.com/2218-5836/full/v14/i7/572.htm

DOI: https://dx.doi.org/10.5312/wjo.v14.i7.572

INTRODUCTION

Myofascial pain syndrome (MPS) is a complex of sensory, motor, and autonomic symptoms that are caused by myofascial trigger points (MTrPs) “muscle knots”[1]. It is the most potent cause of persistent regional pain[2] that affects all ages[3]. MPS commonly affects the neck and shoulder muscles, with the upper trapezius (UT) being the most involved[4]. MTrPs are hypersensitive, palpable spots involving muscle fibers and fascia[5]. They are classified into two clinical types: active and latent. Active TrPs cause persistent pain at rest and referred pain patterns, while latent TrPs cause pain with direct pressure and movement limitation[1]. Patients with myofascial pain represent a large number of musculoskeletal patients. The estimated overall prevalence of active MTrPs is 46.1% ± 27.4%[6]. It has been estimated that around 85% of patients visiting chronic pain clinics and 30% of patients visiting internal medicine clinics have myofascial pain[7].

MPS can be presented clinically after repetitive muscle microtrauma, while other patients have no precipitating factors. Pain onset of pain may be acute or gradual[8]. A physical examination can detect the existence and type of MTrPs by manual palpation[3,8]. The physical therapy for MPS might include stretching exercises, ultrasound[9], massage[10], kinesio tape[11], dry needling (an invasive technique)[12], and muscle energy technique (MET)[13].

Instrument-assisted soft tissue mobilization (IASTM) is one of the techniques used to treat MPS. After an injury, inflammation and proliferation of inflammatory cells occur, during which fibrosis and scar tissue formation in the injured soft tissue may occur[14]. These changes reduce tissue elasticity and cause adhesions, diminishing soft tissue function and pain[15]. In particular, scar tissue limits perfusion to the injured soft tissue, restricting oxygen and nutrients supply and interfering with collagen synthesis and tissue regeneration, which may then cause incomplete functional recovery[16,17] and increase the risk of reinjury[15]. IASTM creates microtrauma to scar tissue or myofascial adhesions using a specially designed instrument to reduce pain and improve range of motion and function. Additionally, it minimizes the stress on the practitioner’s hand and the effort he has to put forth[18].

Extracorporeal shock wave therapy (ESWT) produces mechanical energy through high-pressure air. The mechanical signal is converted into biochemical or molecular biological signals in the tissues by propagating as a longitudinal wave. This mechanism is called mechanotransduction. It has been proven that ESWT has a pain-relieving effect described in plantar fasciitis[19], calcifying tendinitis[20], and MPS[21,22]. ESWT has no serious side effects besides minimal pain, bruising, and swelling, which can be significant after treatment[23].

Currently, no study has compared the effects of IASTM and ESWT in treating myofascial TrPs of the UT muscle in patients with MPS. We hypothesized that there was no significant difference between the two methods on pain and pain pressure threshold (PPT).

MATERIALS AND METHODS

This study was conducted at the outpatient physical therapy clinic, Medical Center of the Egyptian Railway Station. It was registered at Cairo University and approved by the Faculty of Physical Therapy, Research Ethics Committee (P.T.REC/012/003180).

Study design

A single-blinded comparative clinical study.

Sample size calculation

The sample size was calculated using the MedCalc® version 12.3.0.0 program "Ostend, Belgium" and was 38 cases, according to a 95% confidence interval and the power of the study 80% with 5% error. Assuming a drop-out ratio of 5%, the sample size was 20 cases in each group.

Patients

Forty male and female patients were referred by orthopedic surgeons with a diagnosis of MPS in the neck with active TrPs of the UT muscle. Their ages ranged from 20 years to 40 years[24]. They were randomly assigned into two equal experimental groups, using a simple randomization method (patients enrolled consecutively in group A or B). Group A (n = 20) received ISTAM on TrPs of the UT muscle (TrP1 and TrP2), and group B (n = 20) received ESWT on TrPs of the UT muscle (TrP1 and TrP2). Each patient signed an informed consent before starting the study.

All patients received four treatment sessions, twice per week over 2 weeks[25]. Both groups received a post isometric relaxation technique for the UT muscle. Patients were evaluated before treatment and 2 days after treatment for neck pain intensity and PPT of the UT TrPs (TrP1 and TrP2).

Patients were included if they had MTrPs of unilateral UT muscle (TrP1 and TrP2) that exhibit the following characteristics[26,27]: (1) A taut band within a muscle; (2) Extreme tenderness at a point within the taut band; (3) Reproduction of the patient's pain; (4) Referred pain; (5) Eliciting a localized twitch response; (6) Muscle weakness; (7) Limited range of motion; and (8) Autonomic signs (erythema, lacrimation, pilo-erection). To make a diagnosis, the first three characteristics must be present[26,27].

Patients with malignancy, cervical spine fractures, cervical radiculopathy, myelopathy, or vascular syndromes (such as vertebrobasilar insufficiency) were excluded[28]. Also, patients were excluded if they received any other treatment, in the form of physical therapy or medication, that would interfere with the results of this study and if they exhibited any contraindication for IASTM and ESWT[29].

Assessment procedures

All patients were evaluated before and 2 days after treatment by a research assistant who was unaware of the treatment program given to each patient. The patients were positioned comfortably in a prone position on a plinth with sufficient exposure to the UT muscle. The head was slightly tilted ipsilateral to the side being palpated. Using a pincer grasp, the free margin of the UT fibers was held firmly. Once the palpable band was located, it would be firmly rolled between fingers and thumb. Local tenderness and referral pattern were noted. The process was carried out for two points (TrP1 and TrP2). TrP1 was palpated in the angle between the neck and shoulder[30], while TrP2 was palpated halfway between the spinous processes of the C5/C6 vertebrae and the acromion process of the scapula using a small pincer grip[31]. Manual palpation of the muscle is the most reliable method of diagnosing a MTrP[32].

Assessment of pain intensity using the visual analogue scale

The visual analog scale (VAS) is a self-reported pain measurement scale. It consists of a 10 cm long line, and the extremes of the line are labeled as no pain and most severe pain. It is valid, reliable, and suitable for clinical practice[33]. The patient was asked to mark a point on the VAS, and then this number was taken for statistical analysis[34].

Assessment of PPT using pressure algometer

The pressure algometer is a valid and reliable tool to determine PPT. An algometer is a force gauge with a spring-operated plunger. The gauge is attached to a short metal pole with a round 1 cm rubber tip. The device is calibrated in kilograms of pressure per centimeter squared (kg/cm^2). The gauge has a range of 0 to 10 kg/cm^2. Once a measurement was recorded, the device was reset to 0 to take another measurement[21,35].

The research assistant positioned the tip of the algometer (Greenwich, CT, United States) at the TrP and increased the pressure by 1 kg/s. When the patient indicated discomfort, the pressure value was recorded in kg/cm^2. The procedure was repeated three times at 60 s intervals, and the mean of these measurements was taken for statistical analysis.

Treatment procedures

Treatment procedures for group A: This group of patients received IASTM with an M2T blade. Upon a table in front of the patient, his or her forehead resting on his or her forearm. Before treatment, a lubricant (petroleum jelly) was applied to the skin around the neck area, and the M2T blade was cleaned with an alcohol pad.

Following the localization of TrP1 and TrP2, the M2T blade was positioned at a 45° angle. For about 3 min, slow strokes were applied along the muscle from its origin to its insertion without discomfort or pain. The strokes were longitudinally parallel to the muscle fibers. If patients experienced burning sensations after the session, they were instructed to apply an ice pack to the treated area[24].

Treatment procedures for group B: Patients in this group received ESWT (Unify Elekromedizin, Germany, SN:3012095,2012). All aspects of the procedure were explained to the patient before treatment. The patients were informed that the shockwave machine produces intense pressure when applied and creates considerable noise. The patient requested to speak with the researcher if the intensity was too uncomfortable.

The patient was positioned on a plinth. The treatment area was sufficiently exposed, and a coupling gel was applied. The shockwave unit was calibrated to the correct therapeutic settings. For MTrPs, the settings were 2.0 bars at 15 Hz for 2000 pulses[22,36]. The handheld transmitter head was applied to the area to be treated. Slight pressure was applied with circular movements to treat the TrP sufficiently. The shockwave unit automatically stopped the treatment once all 2000 pulses were delivered. Any residue from the coupling gel was wiped off with a paper towel[22,36].

Post-isometric relaxation technique for UT muscle

All patients in both groups received the post-isometric relaxation technique for the UT muscle. The patient was instructed to lie in a supine position with the cervical spine in opposite lateral flexion to the affected side to lengthen the UT muscle fibers. Sub-maximal resistance was applied to the UT muscle for about 5 s, followed by 3 s of relaxation, and then stretching the UT muscle for 15-30 s to reach a new barrier. This maneuver was repeated four times in each session[37].

Statistical analysis

This study’s data analysis used the SPSS version 26 for Windows (IBM Corp, Armonk, NY, United State). The data distribution was tested *via* the Shapiro-Wilk test. Independent *t*-test and χ^2 test were used to compare demographic data between both groups. A paired *t*-test was used to compare pre- and post-treatment mean values of all variables within both groups. For comparing all the dependent variables pre- and post-treatment between both groups we used an independent *t*-test. The significance level of a P value of ≤ 0.05 was considered statistically significant using 95% confidence intervals.

RESULTS

Descriptive statistics of demographic data for all patients in both groups

The data showed that each dependent variable was normally distributed and did not violate the parametric assumption. Using an independent *t*-test, there were no significant differences between patients in both groups in age (P = 0.16), weight (P = 0.83), height (P = 0.8), and body mass index (P = 0.34). The distribution of males and females in group A was 20% and 80%, respectively. In group B, there was 40% males and 60% females. Comparing the sex distribution for all patients in both groups using the χ^2 test, there were no significant differences (P = 0.17) (Table 1).

Pre-treatment between group comparisons of all variables in both groups

Comparing the pre-treatment mean values between both groups using the independent *t*-test, there were no significant differences in pain intensity for TrP1 (P = 0.55), pain intensity for TrP2 (P = 0.94), PPT for TrP1 (P = 0.18), and PPT for TrP2 (P = 0.58) (Table 2).

Post-treatment between group comparisons of all variables in both groups

Comparing the post-treatment mean values between both groups using an independent *t*-test, there were no significant differences in pain intensity for TrP1 (P = 0.9), pain intensity for TrP2 (P = 0.76), PPT for TrP1 (P = 0.09), and PPT for TrP2 (P = 0.91) (Table 2).

Within group pre-treatment and post-treatment comparison of all variables in group A

Comparing the pre-treatment and post-treatment mean values using paired *t*-test for all variables in group A, there were significant differences in pain intensity for TrP1 (P = 0.0001), pain intensity for TrP2 (P = 0.0001), PPT for TrP1 (P = 0.0002), and PPT for TrP2 (P = 0.0001) (Table 3).

Within group pre-treatment and post-treatment comparison of all variables in group B

Comparing the pre-treatment and post-treatment mean values using a paired *t*-test for all variables in group B, there were significant differences in pain intensity for TrP1 (P = 0.0001), pain intensity for TrP2 (P = 0.0001), PPT for TrP1 (P = 0.0001), and PPT for TrP2 (P = 0.0001) (Table 3).

DISCUSSION

This is the first study to compare the effects of IASTM *vs* ESWT on TrPs of the UT muscle in MPS. The current study revealed no statistical differences between IASTM and ESWT on pain intensity and PPT of UT muscle TrPs. However, IASTM or ESWT improved pain measures in both groups of patients suffering from MPS.

Table 1 Descriptive statistics for the mean values of age, weight, height, body mass index, and sex distribution of all patients in both groups

	Group A *n* = 20	Group B *n* = 20	*t* value	*P* value	Significance
Age in yr	31.20 ± 4.15	29.10 ± 5.12	1.43	0.16	NS
Weight	72.55 ± 7.65	73.35 ± 14.23	-0.22	0.83	NS
Height	168.40 ± 5.90	169.05 ± 9.83	-0.25	0.80	NS
BMI in kg/m^2	25.50 ± 2.25	24.80 ± 2.29	0.98	0.34	NS
Sex distribution	20% male and 80% female	40% male and 60% female	χ^2 = 1.91	0.17	NS

NS: Non-significant; BMI: Body mass index. Group A: Patients treated with instrument assisted soft tissue mobilization; Group B: Patients treated with extracorporeal shock wave therapy.

Table 2 Independent *t*-test for comparison of pre- and post-treatment mean values between both groups

Treatment period	Group A *n* = 20	Group B *n* = 20	*t* value	*P* value	Significance
Pre-treatment					
Pain intensity for TrP1	6.05 ± 1.90	6.38 ± 1.50	-0.61	0.55	NS
Pain intensity for TrP2	7.15 ± 1.90	7.20 ± 1.56	-0.08	0.94	NS
PPT for TrP1	17.08 ± 4.99	14.83 ± 5.31	1.38	0.18	NS
PPT for TrP2	15.72 ± 5.75	14.68 ± 6.13	0.55	0.58	NS
Post-treatment					
Pain intensity for TrP1	3.75 ± 1.69	3.82 ± 1.53	-0.13	0.9	NS
Pain intensity for TrP2	4.06 ± 1.45	3.93 ± 1.22	0.31	0.76	NS
PPT for TrP1	30.75 ± 18.12	22.82 ± 9.55	1.7	0.09	NS
PPT for TrP2	27.93 ± 9.90	28.29 ± 10.08	-0.11	0.91	NS

Data are presented as mean ± SD unless otherwise indicated. NS: Non-significant; PPT: Pressure pain threshold; TrP: Trigger point. Group A: Patients treated with instrument assisted soft tissue mobilization; Group B: Patients treated with extracorporeal shock wave therapy.

Effects of IASTM on pain intensity and PPT

The results of the current study confirmed the results of previous studies. This proved the effectiveness of IASTM in decreasing pain intensity and increasing PPT in MTrP in the UT muscle. El-Hafez *et al*[25] showed a significant difference between pre-treatment and post-treatment within the group of patients treated with IASTM twice a week for 4 weeks, regarding pain intensity and PPT. In like manner, other studies showed that using IASTM twice a week for 2 weeks, significantly improved pain and PPT of active MTrPs of the UT muscle[38,39]. Also, IASTM induced thinning of the UT muscle when applied for six sessions at 1-day intervals[38].

Moreover, after one session, IASTM induced immediate significant results concerning decreasing the resting pain[40, 41] and increasing the pain threshold in the neck and lower back[40]. Erden *et al*[42] stated that adding IASTM to the conventional physical therapy program for 8 wk was superior to conventional physical therapy alone for patients with myofascial pain with upper and mid back TrPs in the improvement of pain intensity and PPT. The effect of IASTM on pain could be explained by increasing blood flow, which removes pain substrates[43-45]. Furthermore, IASTM stimulates the A-beta sensory fibers and blocks the A-delta and C-fibers. As for the “gate control theory”, this blocks substance P from pain receptors *via* presynaptic inhibition at the dorsal horn[46]. Also, it improves collagen fiber bundle formation and orientation, which decreases cell matrix adhesions within the MTrP, which explains the increased PPT after using IASTM[47].

Effect of ESWT on pain intensity and PPT

In the same manner, the group that received ESWT showed a significant improvement in pain and PPT after four sessions of treatment. This was in agreement with previous evidence investigating the effect of ESWT on MTrPs of the UT muscle in MPS cases.

Table 3 Paired *t*-test comparison for pre- and post-treatment mean values of all variables for all group (A and B) patients

Group	Pre-treatment *n* = 20	Post-treatment *n* = 20	*t* value	*P* value	Significance
Group A					
Pain intensity for TrP1	6.05 ± 1.90	3.75 ± 1.69	6.55	0.0001[1]	HS
Pain intensity for TrP2	7.15 ± 1.90	4.06 ± 1.45	8.32	0.0001[1]	HS
PPT for TrP1	17.08 ± 4.99	30.75 ± 18.12	-3.51	0.002[1]	Sig
PPT for TrP2	15.72 ± 5.75	27.93 ± 9.90	-6.97	0.0001[1]	HS
Group B					
Pain intensity for TrP1	6.38 ± 1.5	3.82 ± 1.53	9.56	0.0001[1]	HS
Pain intensity for TrP2	7.20 ± 1.56	3.93 ± 1.22	12.82	0.0001[1]	HS
PPT for TrP1	14.83 ± 5.31	22.82 ± 9.55	-5.86	0.0001[1]	HS
PPT for TrP2	14.68 ± 6.13	28.29 ± 10.08	-7.03	0.0001[1]	HS

Data are presented as mean ± SD unless otherwise indicated.

[1]Statistically significant.

HS: Highly significant; PPT: Pressure pain threshold; Sig: Significance; TrP: Trigger point. Group A: Patients treated with instrument assisted soft tissue mobilization; Group B: Patients treated with extracorporeal shock wave therapy.

A recent systematic review and meta-analysis showed that ESWT significantly affects pain reduction compared with sham ESWT or ultrasound treatment. However, conventional treatments, such as dry needling, TrP injection, and laser therapy, have no significant differences in pain intensity and neck disability index[48]. Taheri *et al*[49] and Jeon *et al*[50] confirmed that three sessions of ESWT had a comparable effect with laser therapy[49], TENS, and TrP injection[50] for relieving pain in patients with MPS. Choi *et al*[51] reported that combining ESWT with the myofascial release technique improved in pain intensity and PPT more than myofascial release alone.

In addition, Lee and Han[52] compared the effects of ESWT, proprioceptive neuromuscular facilitation, and TrP injection on pain intensity and PPT in patients with UT muscle MPS. In line with the findings of the current study, VAS and PPT showed statistically significant differences among patients in the ESWT group. Ji *et al*[53] examined the VAS and PPT in the UT before and after 4 treatment sessions of ESWT. It showed a significant increase in PPT and a significant decrease in VAS. Moreover, in patients with non-specific neck pain, pain intensity and PPT were significantly improved after applying three ESWT sessions performed once a week for 3 weeks, on the UT muscle TrP[54]. On the other hand, Lee *et al*[55] revealed that two treatment sessions of ESWT in patients with MTrPs in the trapezius muscle significantly reduced the amount of pain, although there was no change in the PPT. Gür *et al*[56] reported that one session and three sessions once a week of low-energy ESWT revealed statistically significant improvements in pain, quality of life, and anxiety scores in patients with MPS. Additionally, the three sessions produced more substantial efficacy. Also, Király *et al* [23] proved the long-term effect of ESWT and reported improvement of resting pain and pain tolerance at the week 3 and week 15 follow-up in patients with MPS who received ESWT at the TrP of UT.

A analgesic effect of shock waves may be explained by increased blood and nutrients flow to the MTrPs, selective destruction of unmyelinated nerve fibers (C nerve fibers)[57], reduced substance P[58], and increased nitric oxide release [59]. The second possible mechanism is hyperstimulation, indicating that a shock wave triggers the release of endorphins and other analgesic molecules by activating the descending inhibitory system[60-62].

Recent studies on animal models focusing on the peripheral nervous system after ESWT application to the musculo-skeletal system *in vivo* pointed specifically to reducing two substances involved in pain perception: calcitonin gene-related peptide and substance P[58,63,64]. The results of these mechanisms of action have resulted in ESWT being well used in treating myofascial pain.

There were some limitations to this study because of the study design and nature of tools. There is no "placebo" group, and the evidence is insufficient to disprove that either the patient's expectation or interaction with the physiotherapist is the cause of all the improvements after both treatments. In addition, this study did not include a follow-up assessment. IASTM and ESWT are performed with MET, which may influence the outcome. Future studies will be required to study the effect of applying IASTM and ESWT without other techniques that may influence the outcome.

CONCLUSION

Patients with MPS benefit from IASTM and ESWT combined with MET to reduce pain and improve PPT.

ARTICLE HIGHLIGHTS

Research background

Active myofascial trigger points (MTrPs), commonly occurring in the upper region of the upper trapezius (UT), can be a significant source of neck, shoulder, upper back, and headache pain. This can negatively impact daily routine functioning, work-related productivity, and overall quality of life. With the rising prevalence of musculoskeletal pain and disability, it is critical to identify the most effective interventions to improve patient outcomes. This will reduce the societal burden.

Research motivation

Instrument assisted soft tissue mobilization (IASTM) and extracorporeal shock wave therapy (ESWT) are two treatment methods for MTrPs. Each method was tested independently and compared to another modality. To the author's knowledge, this is the first study to compare IASTM *vs* ESWT on MTrPs of the UT.

Research objectives

This study compared the effects of IASTM *vs* ESWT in patients with UT MTrPs. These findings are critical in guiding the therapist in selecting treatment methods based on availability, cost, therapist experience, and patient preference.

Research methods

Forty patients (28 females and 12 males) with active TrP in the UT muscle were randomly assigned to one of two equal groups (A and B). Group A received IASTM, while group B received ESWT. Each group received treatment twice a week for 2 weeks. Both groups received muscle energy technique for the UT muscle. Patients were assessed twice (pre-treatment and post-treatment) for pain intensity using the visual analog scale and pain pressure threshold (PPT) using a pressure algometer. A paired t-test was used to compare the pre-treatment and post-treatment mean values of all variables within both groups. For comparing all the dependent variables pre-treatment and post-treatment between both groups, we used an independent t-test. The significance level of a P value of ≤ 0.05 was considered statistically significant with a 95% confidence interval.

Research results

In group A (treated with IASTM) as well as in group B (treated with ESWT), there were significant differences between pre-treatment and post-treatment for pain intensity of TrP1 and TrP2 (P = 0.0001) and PPT for TrP1 and TrP2 (P = 0.0002 and P = 0.0001, respectively). There were no significant differences for pain intensity for TrP1 (P = 0.9), pain intensity for TrP2 (P = 0.76), PPT for TrP1 (P = 0.09), and PPT for TrP2 (P = 0.91) when comparing the post-treatment mean values between both groups.

Research conclusions

IASTM and ESWT are effective methods for treating pain and PPT in patients with UT muscle TrPs. However, there is no statistically significant difference between the two methods.

Research perspectives

Future research will be required to investigate the effect of only using IASTM and ESWT without other techniques that may influence the outcome.

ACKNOWLEDGEMENTS

We thank Dr. Ahmed Omar Abdelnaeem and Dr. Nagwa Abuelwafa Ibrahim Hassan for reviewing and giving helpful comments on the manuscript and Dr. Haytham Ibrahim Morsi for helping in statistical analysis.

FOOTNOTES

Author contributions: Shamseldeen NE and Hegazy MMA were responsible for the study conception and design; Shamseldeen NE performed the trial procedure and drafted the manuscript; Hegazy MMA revised the manuscript; Fayaz NA reviewed the design, supervised the process of research, and approved the final version to be published; Mahmoud NF supervised the process of research, helped in writing the discussion, and was responsible for the final revision; All authors approved the final manuscript.

Institutional review board statement: This study was approved by the Research Ethics Committee of the Faculty of Physical Therapy (P.T.REC/012/003180).

Clinical trial registration statement: This study is registered at Department of Physical Therapy for Musculoskeletal Disorders & Its Surgery, Faculty of Physical Therapy, Cairo University.

Informed consent statement: All study participants provided an informed consent statement before enrollment.

Conflict-of-interest statement: All the authors report having no relevant conflicts of interest for this article.

Data sharing statement: No additional data are available.

CONSORT 2010 statement: The authors have read the CONSORT 2010 statement and the manuscript was prepared and revised according to the CONSORT 2010 statement.

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S-Editor: Wang JJ
L-Editor: Filipodia
P-Editor: Wang JJ

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