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Research Article

The Effect of Extra Corporeal Shock Wave Therapy versus Ultrasound Therapy in Patients with Myofascial Pain Syndrome in Trapezius Muscle

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Abstract

Aim: To evaluate the effect of extracorporeal shock wave therapy (ESWT) versus ultrasound therapy (US) in myofascial pain syndrome (MPS) of trapezius muscle

Methods: Sixty patients with active myofascial trigger points (MTrP) in the trapezius muscle were included. Patients were randomly allocated into two groups , group I consisted of 30 patients received four sessions of combined radial and focus ESWT protocol (once/week) and group II consisted of 30 patients treated with ultrasound therapy for total of 12 sessions over 4 weeks (3 sessions /week). The efficacy of the therapy was evaluated prior to therapy and 4 weeks after treatment initiation using the number of active trigger points , visual analogue scale of both local and referred pain, the tenderness grading scale, Neck Disability Index Scale (NDI), The Constant-Murley score (CMS),the Hamilton Anxiety Rating Scale (HAM-A) and patients' satisfaction after therapy .

Results: There was no significant difference found between groups in age, sex, occupation and disease duration. There were no withdrawals from the study or any significant complications. In both Groups there was significant improvement in all clinical parameters compared with baseline after 4weeks of therapy initiation. When comparing both groups after 4 weeks of therapy, there was significant improvement in all clinical parameters in Group 1 more than that in Group II.

Conclusion: ESWT is effective to relieve pain, anxiety and improves function in patients with myofascial pain syndrome. Further studies with a larger number of participants and longer follow up period will be needed.

INTRODUCTION

Myofascial pain is a notable health problem about 85% of the general population some point in their lifetime, the estimated prevalence is 46% [1,2]. It includes a collection of the sensory, motor, and autonomic symptoms such as local and referred pain, decreased range of motion, and weakness. The effect of myofascial pain can be quite severe as they suffer not only from decreased functional status as a result of the musculoskeletal pain but, also they suffer from impaired mood and decreased quality of life [3].

Detection of one or more myofascial trigger points (MTrP) is required to ascertain the diagnosis of MPS. An MTrP is a distinct, focal, hyper excitable spot in a taut band of skeletal muscle which is palpable and tender during physical examination. The pain of MPS is usually associated an active MTrP. An active MTrP is clinically characterized with spontaneous pain in the focal area and/or referred pain to distant sites in specific patterns [4].

Myofascial pain syndrome is a problem frequently experienced in cervical, thoracic and lumbar vertebral portions besides, shoulder blade area. Neck and upper back pain is the most common complaint in MPS and in most cases are due to trigger point in trapezius muscle. The basic diagnostic method of MPS is determined by physical examination such as localized muscle tenderness, typical referred pain, palpable intramuscular taut band, muscular twitching response along with subjective symptoms of the patients. In addition, method of assessment of pain threshold using algometry can be helpful in diagnosing myofascial pain syndrome [5,6].

The aim in the treatment of MPS is to deactivate the trigger point and relax the tight muscle bands. The goal is to decrease muscle tension and thus, improve function and power [5,6],breaking of the vicious cycle of pain-spasm-ischemia-pain, which is one of the factors incriminated in the physiopathology of MPS [7].

Depending on the clinical status of the patient, there are many other invasive and non-invasive therapies available. The main options of treatment include medications (analgesics, muscle relaxants and anti-depressants), heat therapy, exercise, stretch and spray therapy, ischemic compression, therapeutic massage, biofeedback, transcutaneous electrical nerve stimulation (TENS), ultrasound (US), interferential (IFA) current, low-energy light amplification by stimulated emission of radiation (LASER),

extracorporeal shock wave therapy (ESWT), MTrP injections, dry needling, and acupuncture .The role of exercise programs in the management of MPS is significant and of particular mention [8].

The use of Extracorporeal Shock Wave Therapy (ESWT) for the management of musculoskeletal diseases is developing rapidly and attracting increasing attention. In the past 10 years, ESWT has become the management of choice for many orthopedic disorders such as plantar fasciitis, lateral epicondylitis of the elbow, calcific tendinopathy of the shoulder and long bone fractures non-union [9].

Extracorporeal shock wave device can transform the impulse sound wave into accurate trajectory shock wave, producing an effective pain-relief effect on extensive human tissue through the orientation and shifting of the therapeutic probe. Upon entering the body, the shock wave can increase the local microcirculation, unblock physiologically closed capillaries, accelerate capillary circulation, improve oxygen contents in cells and help to heal the injured soft tissue [10]. On one hand, this therapy can alter the chemical environment of the affected area, help to generate and release pain-inhibiting chemical substances such as endorphin, disrupt the cell membrane of pain receptor, inhibit the generation and conduction of pain signal and thus reduce the pain sensitivity. On the other hand, this therapy can improve the function of trigger point affected area, decompose metabolic products, stimulate regional muscle groups and block concentric pain conduction. Experimental studies suggested that ESWT enhances osteoblastic activity by causing microtrauma or microfractures, thus enhancing fracture healing [11].

US treatment has both thermal and non-thermal effects. During the absorption of ultrasonic waves in tissues and their reflection among the surfaces, heat energy is produced and provides deep heating that causes a significant increase in the local temperature. Simultaneously, US therapy has analgesic effects, increases nutrition and speeds blood circulation. Moreover, the micro-massage effects of high-frequency sound waves have been demonstrated [12].

There seems to be a lack in the literature to establish the effectiveness of Extracorporeal Shock Wave Therapy when compared therapeutic ultrasound in the treatment of MTrPof upper trapezius muscle. Thus, the current study is aimed at evaluating the effect of extracorporeal shock wave therapy (ESWT) versus ultrasound therapy (US) in myofascial pain syndrome (MPS) of trapezius muscle

MATERIALS AND METHODS

Study population

Patients with active TrPs on at least one side of the trapezius muscle were selected. TrPs were determined according to the criteria defined by Travel and Simons [13].An active TP is a spontaneous focus of pain, accentuated with pressure, and which the patient recognizes as familiar [14]. Patients were excluded from the study if they were diagnosed with fibromyalgia syndrome according to the American College of Rheumatology 1990 criteria [15], had significant cervical disk lesion, cervical radiculopathy and myelopathy, severe coagulopathy or on systemic therapeutic anticoagulants, children, cognitive dysfunction, received injection into TrPs in the last 6 months, had previous history of conservative therapies in the last 4 weeks, history of neck or shoulder surgery in the last 1 year, Severe life-threatening primary conditions involving the cardio-cerebrovascular, liver disease, Cardiac pace maker, Malignant tumor in the treatment area, refused entering in the study or could not cooperate. Ethics committee of Dubai Health Authority approval and written informed consents were obtained.

Detailed physical examinations were performed and evaluation forms were filled. Demographic features including age, occupation and level of education were recorded in each patient. Routine biochemical examinations in addition to examinations of complete blood count and erythrocyte sedimentation rate were performed.

The prospective, randomized controlled study was conducted in a tertiary hospital. The study design and the information documents were approved by the Ethics committee of Dubai Health Authority. Patients received oral and written information about the two treatments and gave informed consent to participate in the study. Patients were informed that they were free to leave the study, without explanation and without any negative impacts on their future treatment. Every precaution was taken to protect the privacy of research subjects and the confidentiality of their personal information. There are no known additional risks associated with patient participation in the study, other than the normal risks associated with these common treatments.

Grouping and interventions

Sixty MPS cases either referred or primary diagnosed in physical medicine and rehabilitation department, Dubai hospital between March 2015 and March 2016 were recruited and randomly allocated into an ESWT treated group (Group I) and US treated group (Group II) by their visit sequence numbers, 30 in each group. All patients in both groups were given specified home program of shoulder stabilization exercises to be performed daily. The same independent experienced therapist carried out all interventions. No pain medications, braces or tapes were used by any of the patients.

Group (I): Shock waves were applied with the Duolith SD1 device (Storz medical, Tagerwilen, Switzerland) providing electromagnetically generated focused or pneumatically driven radial extracorporeal shock waves. Four weekly sessions of combined focus and radial ESWT protocol were given as follow:

First, applying focus ESWT (1000 shocks; energy flux density (ED) of 0.25 ml/mm2, frequency of 4 HZ total energy flux density, 250 mJ/mm) to the trigger points area, followed by radial shock wave (4000 shocks; frequency 15 Hz; 2.5 bars of pressure, which is equal to 0.1 mJ/mm2; total energy flux density, 400 mJ/mm) to both the trigger points and the surrounding area. Therapy was administered without local anesthesia, since several studies have shown that treatment without anesthesia is superior to treatment with anesthesia [16,17].

Group (II): Ultrasound therapy was applied using (Chattanooga Intelect® Advanced Combo, DJO Global, Vista, CA, USA). US was performed for every trigger point to cover the trapezius muscle over 8 minutes with the following parameters;

(1.5 watt/cm2 dose, 1 MHz frequency, continues mode) with a rate of three sessions a week for 4 weeks (total 12 sessions).

Evaluation of treatment efficacy

Evaluations were performed by an independent physician blinded to both the patients and treatments. All patients were evaluated prior to therapy and after 4 weeks of therapy initiation with the following parameters:

Number of active TrPs: The examiner through palpation evaluated the characteristics of the TrPs, only the numbers of active points were counted.

Visual analogue scale (VAS) of local and referred pain: VAS is a subjective measure for evaluation the pain intensity in which, patients indicate their degree of pain on a scale of 0 (no pain) to 10 (unbearable extreme pain) according to their subjective feelings on a 10-cm scale drawn on paper. On this scale, a higher score indicates a higher degree of pain. The measurement in centimeters was converted to the same number of points ranging from 0 to 10 points.

Tenderness grading scale: It is a proposed grading system for the soft tissue tenderness. It is also a method for documenting patient responses to "provocative" tests, Tenderness grading is as follows: 0- No tenderness 1- Tenderness to palpation without grimace or flinch, 2- Tenderness with grimace sign") to non-noxious stimuli (i.e. superficial palpation, pin prick, gentle percussion), 3- Tenderness with withdrawal (+ " Jump sign"), 4- Withdrawal (+ "Jump sign") to non-noxious stimuli (i.e. superficial palpation, pin prick, gentle percussion) [18].

The Constant-Murley score (CMS): For the evaluation of shoulder joint functions, Its evaluation items have a maximum total score of 100 points, consisting of 15 points for pains, 20 points for the ability to perform daily activities, 40 points for the range of motion (ROM), and 25 points for muscle strength) [19].

The Neck Disability Index (NDI): It is designed to measure neck-specific disability. This questionnaire contained ten individual factors concerning pain and activities of daily living, including personal care, lifting, reading, headaches, concentration, work status, driving, sleeping, and recreation, on a six-point Likert scale. Its reliability and validity is well-established [20].

The Hamilton Anxiety Rating Scale (HAM-A): contains 14 questions regarding the level of anxiety of the patients. This scale allows measurement in the five-point Likert scale. Point obtained to each item is added to obtain a total score. Points of each item ranges between zero and four and the total score of the scale ranges between 0 and 56 [21].

Patients' satisfaction after therapy: A VAS for satisfaction is a horizontal line of 10-cm long. At the beginning and at the end, there are two descriptors representing extremes of satisfaction (i.e. no satisfaction and extreme satisfaction). The exact question was "Are you satisfied with your therapy sessions?" and the patient rated his satisfaction by making a vertical mark on the 10-cm line. The measurement in centimeters was converted to the same number of points ranging from zero to 10 points.

Statistical analysis

The data was computerized and statistical analyses using SPSS version 20.0(SPSS Inc., Chicago, USA). Qualitative data was expressed as number and percent, quantitative data was expressed as mean, standard deviation and range. Chi square test used to compare qualitative variables, Independent t test used to compare quantitative normally distributed data and Mann Whitney test was used to compare quantitative not normally distributed data between the two studied groups. Paired t test used to compare quantitative normally distributed data and Paired Wilcoxon was used to compare quantitative not normally distributed data pre and post treatment in each group. $P < 0.05$ considered as significant statistically.

RESULTS

Distribution of age and sex

Sixty participants were studied; there was no withdrawal due to side effects of therapy. The participants were 5 men and 55 women, the age ranged from 21 years to 55 years. The mean age of group I was 41.5 ± 8.46 years old and group II was 39.77 ± 8.88 years old. There was no significant difference found between groups in age, sex, occupation and disease duration (Table 1).

As shown in table (2), we compared the clinical and functional parameters (trigger points numbers, VAS of local pain, VAS of referred pain, tenderness scale, NDI,CMS, HAM-A scale) in both groups before and after 4weeks of therapy. There was no significant difference between the two groups in all the parameters before initiation of therapy. In both groups, there was significant improvement in all clinical and functional parameters compared with baseline after 4weeks of therapy initiation.

When comparing both groups after 4 weeks of therapy, there was significant improvement in all clinical and functional parameters in Group 1 more than that in Group II .No significant complications were encountered secondary to ESWT or US therapy. Patients tolerated both well.

In table (3), we compared patient overall satisfaction after 4 weeks of therapy we found significantly higher satisfaction in Group I than Group II ($p<0.001$).

The mean difference in clinical parameters, functional outcomes and patients' satisfaction among the two groups pre and post treatment were plotted on a graph (Figure 1),which showed Group 1 to have significantly better outcomes in all parameters as compared to Group II

DISCUSSION

The aim of this study was to examine the effectiveness and clinical usefulness of ESWT by comparing the ESWT implemented group with the ultrasound therapy implemented group with trapezius MPS patients as the subjects.

Ultrasound is a widely used physical treatment modality technique that has been used to treat myofascial pain by converting electrical energy to sound waves in order to provide heat energy to muscles giving analgesic effect besides, increasing local metabolism, circulation, regeneration and extensibility of connective tissue with its assuming thermal and mechanical effects [22,23].

In general, the effect of extracorporeal shock wave in living

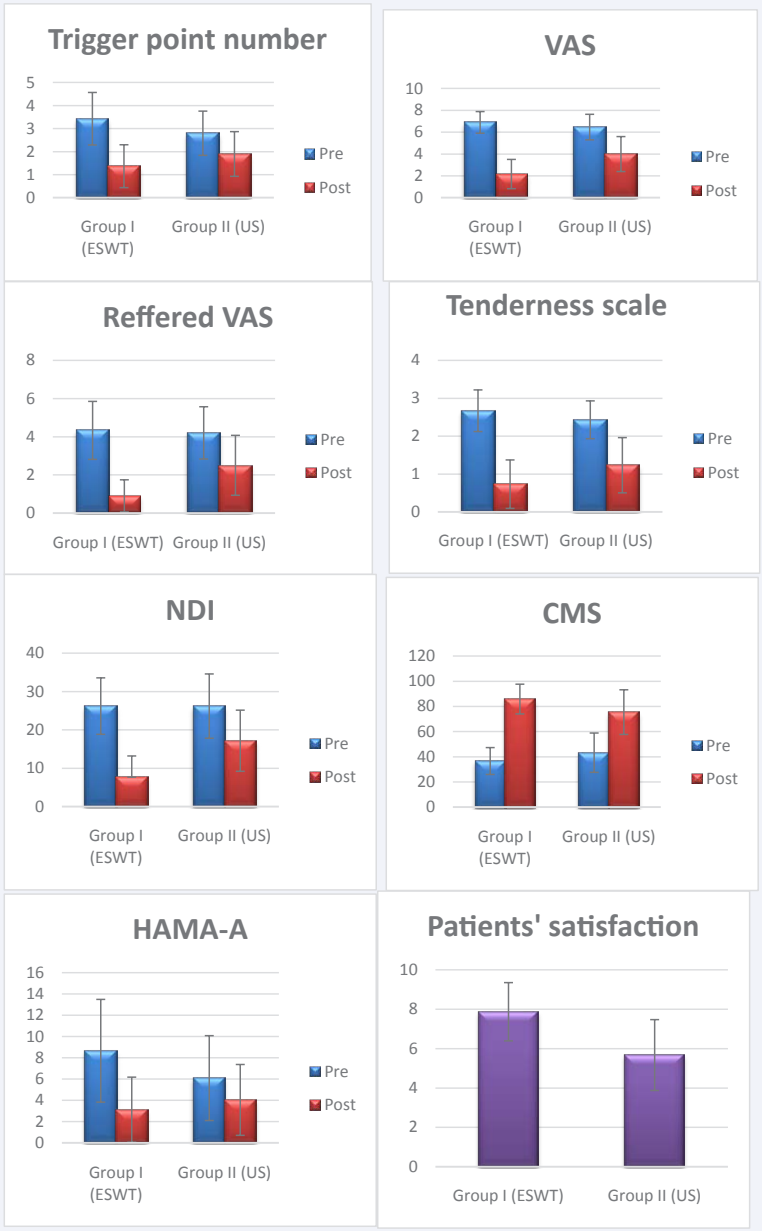

Figure 1 The mean difference in clinical parameters, functional outcomes and patients' satisfaction among the two groups pre and post treatment.

tissues is known to induce distinctive changes within the cells due to transformation of the mechanical signal into biochemical or molecular biologic signal (Mechanotransduction). Until now, although the exact mechanisms of ESWT are not clear, several hypothesis have been proposed on the principles of cellular and molecular biological effects [24].

In their study Zimmermann et al. [24] concluded that ESWT improves circulation in capillary blood vessels and reduces the tension and stiffness of muscles together with the reduction in pain by reducing the over-stimulation of nociceptors and nerves. The vicious cycle of pain–spasm–ischemia–pain observed in MPS is cut down by the establishment of normal vascularization with ESWT [25].

Moreover, Shock waves can possibly influence the neuroplasticity of the human pain memory: The prolonged lack of effective pain therapy could target the reinforcement of negative impulses (pain impulses) in the brain. Long-term persistence of these impulses could lead to the development of a particular pain memory. By triggering minimal pain impulses, ESWT could break through this negative-conditioned pain memory by resetting the pain [26].

On the other hand, Hausdorf et al. [27,28], in their studies concluded that ESWT reduces pain in the tissues of musculoskeletal system through selective destruction of nonmyelinated fibers and producing a transient dysfunction of nerve excitability at the neuromuscular junction .In addition it is effective in reducing the level of substance P in the target tissue as well as reducing the synthesis of substance P in dorsal root ganglia.

Table 1: Demographic data and disease duration in the two groups.

Variable		Group I ESWT (n=30)	Group II US (n=30)	P
Age (years)	Mean ± SD Range	41.5 ± 8.46 21 – 55	39.77 ± 8.88 22 - 54	>0.05 $ NS
Sex	Male N(%) Female N(%)	2 (6.7%) 28 (93.3%)	3 (10%) 27 (90%)	>0.05 # NS
Occupation	HW N(%) Employed N(%)	17 (56.7%) 13 (43.3%)	18 (60%) 12 (40%)	>0.05 # NS
Duration (years)	Mean ± SD Range	4.28 ± 3.06 0.5 – 10	4.26 ± 4.89 0.33 - 25	>0.05 ^ NS

Abbreviations: SD: Stander Deviation; NS: Non-Significant

Table 2: Comparison of the clinical parameters and functional outcomes between the two groups pre and post treatment.

Variable		Group I ESWT (n=30)	Group II US (n=30)	P
Trigger points number Pre treatment	Mean ± SD Range	3.43 ± 1.14 2 - 6	2.8 ± 0.96 1 - 5	>0.05 ^ NS
Trigger points number Post treatment	Mean ± SD Range	1.37 ± 0.93 0 - 4	1.9 ± 0.97 0 - 4	<0.05 ^ S
P		<0.001! HS	<0.001! HS	
VAS Pre treatment	Mean ± SD Range	6.9 ± 0.99 5 - 9	6.47 ± 1.17 4 - 8	>0.05 $ NS
VAS Post treatment	Mean ± SD Range	2.17 ± 1.34 0 - 6	4 ± 1.6 1 - 7	<0.001 $ HS
P		<0.001@ HS	<0.001@HS	
Referred VAS Pre treatment	Mean ± SD Range	4.33 ± 1.52 2 - 8	4.2 ± 1.37 2 - 7	>0.05 $ NS
Referred VAS Post treatment	Mean ± SD Range	0.9 ± 0.84 0 - 3	2.5 ± 1.57 0 - 5	<0.001 ^ HS
P		<0.001! HS	<0.001! HS	
Tenderness scale Pre treatment	Mean ± SD Range	2.67 ± 0.55 2 - 4	2.43 ± 0.50 2 - 3	>0.05 $ NS
Tenderness scale Post treatment	Mean ± SD Range	0.73 ± 0.64 0 - 2	1.23 ± 0.73 0 - 2	<0.01 ^ HS
P		<0.001! HS	<0.001! HS	
NDI Pre treatment	Mean ± SD Range	26.2 ± 7.36 12 - 39	26.2 ± 8.38 11 - 39	>0.05 $ NS
NDI Post treatment	Mean ± SD Range	7.67 ± 5.53 2 - 29	17.17 ± 7.97 3 - 31	<0.001 ^ HS
P		<0.001! HS	<0.001! HS	
CMS Pre treatment	Mean ± SD Range	36.67 ± 10.68 17 - 55	43.3 ± 15.62 23 - 80	>0.05 $ NS
CMS Post treatment	Mean ± SD Range	85.9 ± 11.82 51 - 98	75.53 ± 17.74 31 - 98	<0.05 $ S
P		<0.001@ HS	<0.001@ HS	
HAM-A Pre treatment	Mean ± SD Range	8.67 ± 4.83 2 - 18	6.1 ± 3.99 2 - 17	>0.05 ^ NS
HAM-A Post treatment	Mean ± SD Range	3.13 ± 3.06 0 - 11	4.05 ± 3.33 0 - 13	<0.05 ^ S
P		<0.001! HS	<0.001! HS	

Abbreviations: SD: Stander Deviation; NS: Non-Significant; S: Significant; HS: Highly Significant; $: Independent t Test; ^: Mann Whitney Test; @: Paired t Test; Paired Wilcoxon Test

Table 3: Patients' satisfaction after therapy in the two groups.

Variable		Group I ESWT (n=30)	Group II US (n=30)	P
Patients' satisfaction	Mean ± SD Range	7.87 ± 1.48 5 - 10	5.67 ± 1.8 2 - 9	<0.001 $ HS

Abbreviations: SD: Stander Deviation; HS: Highly Significant; $: Independent T Test

Extracorporeal shockwave myocardial revascularization therapy (ESMR) uses low-intensity shockwaves targeted to the myocardium. This leads to the release of angiogenesis-mediating growth factors and induces the recruitment of endothelial progenitor cells leading to increased myocardial perfusion, thus reducing symptoms of myocardial ischemia [29]. In their study Slavich et al. [30], concluded that ESMR is an effective treatment for patients with Refractory Angina Pectoris (RAP), as evidenced by symptomatic and exercise test improvement.

Finally, shockwaves may have a mechanistic approach to break-up the Actine-Myosin links, as they are propagating perpendicularly to the sarcomere contractions [31].

Until now, there is no standardized guideline that clearly defines the number and frequency of sessions needed for execution of either ESWT or US therapy. Moreover, there is no scientific evidence in favor of either radial ESWT or focused ESWT with respect to treatment outcome. However, in their recent review study Ramon et al. [32], concluded that the best ESWT protocol for treating MPS is the combined focus and radial therapy.

Takahashi et al. [33], in their study demonstrated that nearly complete degeneration of epidermal nerve fibers noticed at the fourth week of treatment. Therefore, they suggested that multiple applications of ESWT would provide longer-lasting nociceptive effects.

According to our information, this study is the first to use combined focus and radial extracorporeal shock wave therapy in treating MPS of trapezius muscle and compared them to US therapy.

In this study, we found significant improvement in pain, anxiety and functional outcomes in both therapy groups (ESWT and US therapy). The improvement and patients' satisfaction was more significant in ESWT group compared to US group. Our results showed that four sessions of combined ESWT protocol and 12 sessions of US significantly reduced pain and improved the quality of life of patients with MPS, with no observable adverse effects.

The studies on the effects of ultrasound therapy on MPS are very conflicting. Our results are in accordance with the views of Kannan, who found evidence for the positive effect of therapeutic ultrasound in improving lateral flexion of neck and a reduction in the perceived level of pain however he found therapeutic laser to have better effect [23]. Also, Ay et al. [34], in their study found significant improvements in pain, ROM, disability compared to the placebo group in patients with myofascial trigger points in trapezius muscle. However, another study found no difference between the effect of conventional ultrasound or sham ultrasound in the treatment of myofascial trigger points [22].

The study of effect of ESWT in myofascial pain syndrome has been very limited. A study by Müller and Licht [35] found that focused ESWT on MTPs alleviated pain in 95% of the 30 patients at 3 months, (800 impulses of energy level: 0.04-0.26 mJ/mm2; 6 Hz; average 7 treatments, 2 sessions per week). They concluded that focus ESWT appears to be a promising new modality for the diagnosis and management of MPS.

Our study resembles that of Gur et al. [25], in terms of reducing severity of pain, number of TrPs, anxiety level and improving quality of life in both US and ESWT groups when applied to trigger points of patients with MPS. In ESWT Group, improvements were more significant at 3 weeks when compared to US group but in their study three sessions of focus ESWT were administered at 3-day interval.

In their study Jeon et al. [36], concluded that weekly focused ESWT is as effective as TENS and TP injection on 30 patients with MPS in trapezius muscle, measuring the results in terms of pain visual analogue scale (VAS) and McGill Pain Questionnaire, as well as on the Roles and Maudsley scale.

Ji et al. [37], studied the effect of focus ESWT on MPS of upper Trapezius compared to placebo. They treated at taut band (700 impulses) and the surrounding area (300 impulses) at energy levels of 0.056 mJ/mm2 .The treated group received four sessions (2 sessions per week for 2 weeks) of ESWT (0.056 mJ/mm2, 1,000 impulses) while the control group was treated by the same protocol but with low non-significant energy levels applied, 0.001 mJ/mm2 (placebo ESWT).They compared the VAS and pressure threshold before and after 4 therapies, finding a significant drop in VAS and increased pressure threshold in the treated group only.

Cho et al. [38], found that combining ESWT with shoulder stabilization exercises resulted in statistically significant improvements in VAS, CMS and NDI after the four-week intervention.

The inconsistency and heterogeneity between the studies might be explained by the differences in parameters and types of ESWT, methods of outcome evaluation, treatment course, pain duration, and the selection of the control group. As ESWT has a dose-dependent effect, the use of different intensities and impulses may have influenced the treatment results.

It is not known the cause of better effect of ESWT therapy over US therapy but Wang et al.[39], in their study attributed the main physiological benefit of ESWT over US that the shockwaves involve microdestructions – the application of ESWT causes microbreaks in avascular or poorly vascularized tissue, thus stimulating appropriate revascularization and stem cell growth. It also was attributed to its ability to induce the release of enzymes,

which affect nociceptors, resulting in localized analgesia, giving the significant reduction of activity limitations and short duration of the treatment. Moreover, another study concluded that the most probable theory to explain superior effect of ESWT over US in reducing spasticity or tightness in muscles is a direct effect on the fibrosis of chronic hypertonic or tight muscles including mechanical vibration [40]

Limitations of this study include the small number of participants and the short-term period of follow-up. Also, lacks of definitive guidelines on the type, intensity, interval and frequency of ESWT for diseases of musculoskeletal system and the most important limitation is that its mechanism are still inadequate and standardized treatment guideline is yet to be established in order to produce the optimal results. Therefore, continuous efforts to establish the most effective treatment guidelines are needed in the future, and, if relationship between the mechanism and therapeutic adaptability can be investigated more clearly and definitively, it is expected to play more important role in the area of rehabilitative therapy. Moreover, further studies with a larger number of participants and longer follow up period will be needed.

CONCLUSION

In this study, it was found that both ultrasound therapy and Extracorporeal Shock Wave Therapy are effective in reducing pain and improving functions in patients with myofascial pain syndrome of trapezius muscle however, ESWT is much more effective. ESWT is safe, non-invasive, low-cost, easy-to-operate, low adverse reactions and can be repeated safely.

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Informed consent

Informed written consent from all subjects to participate in this study was present before entering the study, as required by the Declaration of Helsinki. This study was approved by the institutional ethics committee.

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