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RESEARCH ARTICLE

Comparison of the Efficacy of Ultrasound and Extracorporeal Shock Wave Therapies in Patients with Myofascial Pain Syndrome: A Randomized Controlled Study

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ABSTRACT

Objective: Evaluation and comparison of the efficacy of ultrasound [US] and extracorporeal shock wave therapy [ESWT] in the treatment of myofascial pain syndrome.

Methods: Sixty-six patients with active myofascial trigger points in the trapezius muscle were randomized into treatment groups with US and three sessions of ESWT. Efficacy of the therapies were evaluated prior to therapy at 3 weeks and at 3 months of therapy using the Patient Global Assessment and Physician's Global Assessment scales, Neck Pain and Disability Scale, Nottingham Health Profile, and Hamilton Anxiety Scale.

Results: No severe complications were encountered with US and ESWT, and patients tolerated the therapies well overall. Statistically significant improvement was determined in the number of trigger points, pain, quality of life, and anxiety scores in post-therapy evaluations [$p < 0.01$]. Efficacy of therapies in inter-group comparison was evaluated in terms of improvement in the same scores, and the ESWT group had greater improvement when the anxiety scores were excluded [$p < 0.05$].

Conclusion: Our results indicated that both US and ESWT were effective and safe treatment modalities in myofascial pain syndrome. Three sessions of low dosage ESWT was more effective compared to US therapy that could be used as an effective and safe modality in the treatment protocols of myofascial pain syndrome.

KEYWORDS: Anxiety, extracorporeal shock wave therapy, myofascial pain syndrome, quality of life, ultrasound therapy

INTRODUCTION

Myofascial pain syndrome [MPS] is characterized by pain arising from trigger points [TrPs] in tense bands in muscles or fascias in addition to muscle spasm, sensitivity, limited articular motion, timidity, fatigue, and sometimes autonomic dysfunction [abnormal sweating, increased lacrimation, dermal flushing, vasomotor symptoms, and altered heat balance] (1).

This syndrome is one of the most common causes of pain in the musculoskeletal system and is very frequent in the population. Overall ~30–50% of patients presenting with complaints of the musculoskeletal system are reported to have MPS (2).

The exact etiology of MPS is still unknown. Therefore, treatment approaches are mostly symptomatic. The primary objectives of therapy are the inactivation of TrPs, loosening of tense bands, and breakdown of the vicious cycle of pain–spasm–ischemia–pain. Several methods are used for this objective. The most commonly used methods include information and education of patients, non-steroidal anti-inflammatory drugs [NSAIDs], local injections, surface and deep heaters, electrotherapy, and exercise (3).

Ultrasound [US] therapy is one of the frequently used physical therapy modalities on MPS for its heating effect on deep tissues. US therapy is a

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non-invasive treatment method that turns electric energy into mechanical oscillation energy. US is believed to increase local circulation, metabolism, regeneration and flexibility in soft tissues via its thermal and mechanical effects (4).

The search for more effective, cost-effective and non-invasive treatment modalities with less complications and morbidity continues in MPS, as in all other areas of medicine. Extracorporeal shock wave therapy [ESWT] is a result of such searches and used with increasing popularity in muscle skeletal system diseases, calcific tendinitis of the shoulder, epicondylitis, plantar fasciitis, and delayed or absent fusion of fractures (5).

ESWT is considered to activate neovascularization by disrupting microcirculation around the tendon, increasing the secretion of local growth factors, and activating the production of normal cells from stem cells in tendinopathies (5).

In this study, we suggested that the vicious cycle of pain–spasm–ischemia–pain could be broken down by the neovascular effect of ESWT. Therefore, the efficacy of ESWT was compared with US, a standard therapy in MPS (6).

There are no controlled literature studies comparing the efficacy of ESWT in MPS with other related treatment modalities. The objective of our study was to compare the efficacy of ESWT with US in MPS and determine the place of this physical therapy agent in treatment protocols.

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 (7). Patients were excluded from the study if they were diagnosed with fibromyalgia syndrome according to the American College of Rheumatology 1990 criteria (8), had systemic diseases, were pregnant, had cardiac pace maker, a significant cervical disk lesion, cervical radiculopathy and myelopathy, cognitive dysfunctioning, injection into TrPs in the last 6 months, previous history of conservative therapies in the last 4 weeks, history of neck or shoulder surgery in the last 1 year, or could not cooperate.

Ethics committee approval was obtained. Patients were informed orally prior to the study and written informed consents were obtained.

Patients were referred to our study and evaluated for whether or not they met inclusion/exclusion criteria. Patients who met inclusion/exclusion criteria were randomized into two groups by pulling the envelopes by the order of admission to the outpatient clinic.

Three sessions of ESWT was applied to the first group [Group 1] and US therapy was applied to Group 2 patients. Detailed physical examinations were performed and a standard evaluation form was completed by all patients. 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.

ESWT

Three sessions of ESWT therapy were administered at 3-day intervals to the TrPs of the subjects in the ESWT group using Minilith SL1 shock wave generator [Storz Medical, Tägerwilen, Switzerland; ED = 0.25 mJ/mm^2, 1000 shock wave] device.

US

US was used in the second group at 1.5 Wt/cm^2 dosage in pulse mode for 5 min with the 1 MHz, 5 cm^2 diameter-cap of device [Intelect Advanced System, Chattanooga, TN] 5 days a week for 2 weeks, for a total of 10 sessions.

Treatments were performed by the same physiotherapist, on a wooden desk, between the hours 08:00 and 12:00 in a room at 24 °C temperature. Evaluations were performed by an independent physician blinded to the patients and treatments. All patients were evaluated prior to therapy, at 3 weeks and 12 weeks of therapy. Response to treatment was evaluated by the number of TrPs, the Patient Global Assessment [PGA] and Physician's Global Assessment [MDGA] scales, the Neck Pain and Disability Scale [NPADS], the Nottingham Health Profile [NHP], and the Hamilton Anxiety Evaluation Scale [HAM-A].

Evaluation of treatment efficacy

Number of TrPs

Each patient was asked to point his finger to the most painful zone in the affected trapezius. All areas of tenderness were marked with a pen. Subsequently, the characteristics of the TrP were evaluated by the examiner through palpation of the zone pointed out by the patient. Zero points were assigned when the examiner noticed an increased consistency of the TrP in absence of pain, one point when the consistency was increased but the patient reported pain only after an explicit question from the doctor,

two points when the consistency was increased and the patient spontaneously reported pain, or three points when the consistency was increased and the patient manifested withdrawal from palpation.

The PGA and MDGA are 0–10 cm long visual scales questioning neck pain patient experiences during resting and motion in the last week. A score of "0" indicates no pain, whereas a score of "10" indicates severe, unbearable pain. Patient opinions were evaluated in PGA scale and evaluating physician opinions were evaluated in MDGA scale (9).

The NPAD scale is 10 cm long consisting of 20 subtitles and two different edges [0 = no pain, 10 = most severe pain] and is administered by asking the patient to mark his/her level of pain. The distance between this point and lowest end of the line is measured in centimeters and the numerical value indicates the level of pain of the patient (10).

The NHP scale consists of 38 questions on pain [eight questions], physical activity [eight questions], fatigue [three questions], social isolation [five questions] and emotional state [nine questions]. Evaluation is performed according to the percentage of the yes answers. Total score ranges between 0 and 100 (11).

The 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 0 and 4 and the total score of the scale ranges between 0 and 56 (12).

Statistical evaluation

Statistical analyses were performed using the Statistical Package for the Social Sciences 16.0 software [SPSS], Chicago, IL. Distribution of variables was assessed with one-sample Kolmogorov–Smirnov test. χ^2 and McNemar's tests were used in the inter-group comparison of discontinuous variables, student's *t*-test in the inter-group comparison of continuous variables with normal distribution, and Mann–Whitney U-test in the latter without normal distribution. Repeated measure analysis of variance was used in the intra-group comparison of continuous variables with normal distribution with more than two repetitive measurements, and Friedman test in those without normal distribution. A two-tailed $p < 0.05$ was considered statistically significant.

RESULTS

A total of 120 patients were referred to our study; 50 were excluded for not meeting the inclusion criteria, and four refused to participate in the study (Figure 1). A total of 66 patients were included in the study. The average age of patients was 35.07 ± 12.23 and 37.00 ± 11.51 years in Group 1 and Group 2, respectively. No statistically significant differences were detected in the level of education, duration of symptoms, or mean body mass indices among groups [$p > 0.05$; Table 1].

Statistically significant improvement after 12 weeks compared with baseline TrPs, severity of pain, PGA, MDGA, NPADS, NHP and HAM-A scales scores were observed for all patients both Groups 1 and 2 [$p < 0.01$]; Table 2.

The baseline average TrPs numbers showed a significant improvement in the 3 weeks of treatment for Groups 1 and 2. Besides, compared to each other in terms of improvement rate, it was observed that Group 2 improved more significantly. At Week 3, the improvement in the mean PGA and MDGA scores was significant in Group 2 according to inter-group comparisons [$p < 0.05$]; however, the inter-group difference was not significant at Week 12. The improvement in Group 2 was significantly greater at both Weeks 3 and 12 in terms of the comparison of treatment efficacy by groups in NPADS and NHP scales [$p < 0.05$]. No significant differences were determined between the groups in post-treatment evaluation of anxiety scores [$p > 0.05$; Table 2].

No significant complications were encountered secondary to US or ESWT. Patients tolerated these therapies well overall. Transient sensitivity was determined in the area of application in only two patients of the ESWT group.

DISCUSSION

Our results demonstrated that both US and ESWT provided recovery in severity of pain, number of TrPs, quality of life, and anxiety level. Furthermore, there were lower pain and anxiety level, higher quality of life, and less sensitivity in TrPs in the ESWT group. In Group 2 significant improvements were achieved at 3 weeks.

Several references have reported that MPS is encountered at about the same rate in both sexes (13). However, 62.5% of the patients in Fricton et al.'s study (14) were female, 72.4% in the study of Hong and Hsueh (15), 75% in the study of Graff-Redford et al. (16), and 80% in the study of Cummings and White (17). Overall females were more prone to develop MPS compared to males (18). The 59 patients included in our study consisted of 45 females [76%] and 14 males [24%], and this

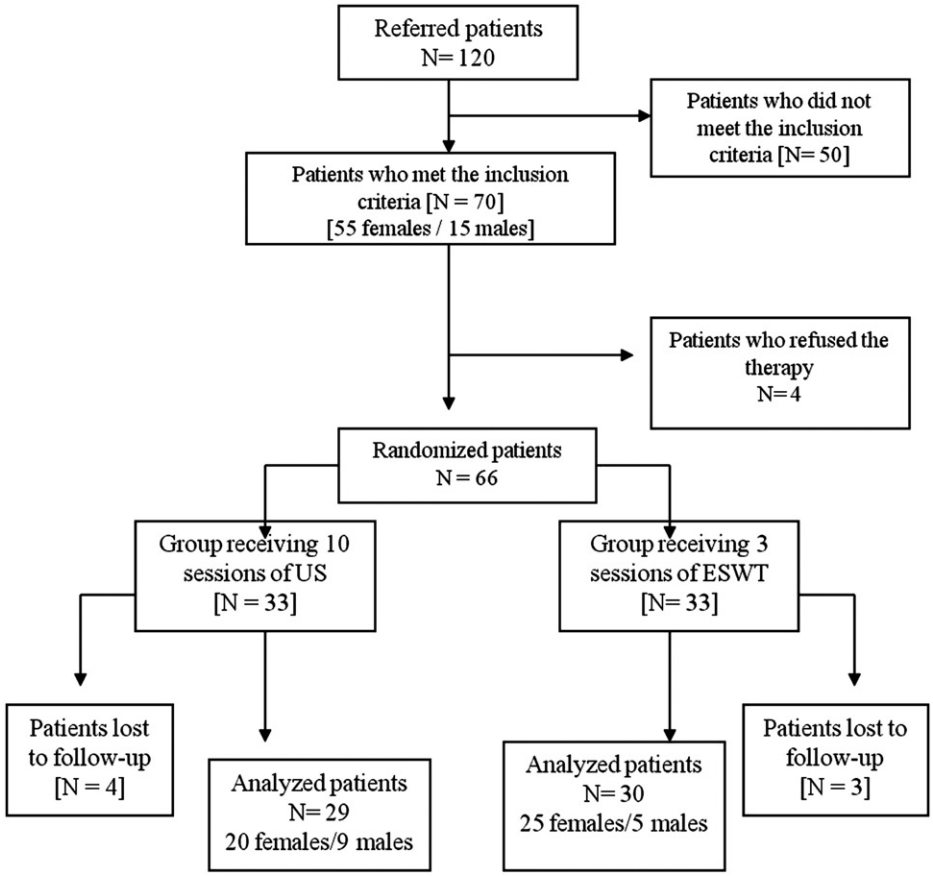

FIGURE 1. Study profile.

TABLE 1. Baseline characteristics of Group 1 and Group 2.

Characteristics	Group 1 [29 patients]	Group 2 [30 patients]
Age, year	35.07 ± 12.23	37.00 ± 11.51
Disease duration, months	35.34 ± 31.50	33.83 ± 31.38
Body mass index, kg/m^2	25.09 ± 3.52	25.94 ± 4.63
Marital status, *n* [%]		
Married	20 [69]	17 [56]
Single	9 [37]	11 [37]
Divorced	0 [0]	2 [7]
Educational status, *n* [%]		
Not literate	1 [3]	0 [0]
Elementary school	13 [45]	13 [44]
Secondary school	10 [35]	7 [23]
University/high school	5 [17]	10 [33]
Employment status, *n* [%]		
Employed	2 [7]	5 [17]
Official	5 [17]	10 [33]
Homemaker	15 [52]	11 [37]
Others	7 [24]	4 [13]

Group 1 = 10 sessions of US, Group 2 = three sessions of ESWT.

rate was compatible with previous studies indicating female predominance.

US is a non-invasive treatment method that is often preferred for its thermal and biophysical effects. Heat is the most important and most well-known effect of US. Energy absorption is easier in tissues rich in protein including muscles and tendons compared to tissues rich in lipids. US is used in the treatment of TrPs, tense tendons, and capsular tissues for its effect of increasing collagen elasticity. Analgesic effect of US might be explained by various mechanisms. The increase in blood flow together with vessel dilatation as a result of metabolic changes with thermal effect, reduction of algesic items as a result of rapid change of items between the cell membrane and capillary wall and keeping them away from the zone, the rapid increase in vessel repair process and more durable effect of the analgesic effect due to recovery can be consider as basic mechanisms. The main two mechanisms include increase in blood flow due to dilatation of blood vessels as a result of metabolic alterations secondary to thermal effect of US, decreased formation and removal of algesic substances due to accelerated substance exchange between the capillary wall and cell membranes, and more rapid tissue processing and permanent analgesia secondary to improvement (19). US has been widely used in the treatment of musculoskeletal diseases for more than 60 years (20). There are studies demonstrating that US remains ineffective in cases with calcific

TABLE 2. Comparison of Group 1 and Group 2 with respect to clinical outcomes at baseline and after therapy at Weeks 3 and 12.

	Group 1 [US] Mean ± SD	*p* Value Group 1 [Baseline/Week 3]** [Baseline/Week 12]***	Group 2 [ESWT] Mean ± SD	*p* Value Group 2 [Baseline/Week 3]** [Baseline/Week 12]***	*p* Value Group 1/Group 2 [US/ESWT] Baseline* Week 3** Week 12***
Number of TrPs	2.44 ± 0.78		2.36 ± 0.66		>0.05*
	1.62 ± 0.72	<0.001**	0.93 ± 0.73	<0.001**	<0.05**
	1.44 ± 0.78	<0.001***	1.2 ± 0.84	<0.001***	>0.05***
NHP total	51.89 ± 9.44		52.41 ± 15.4		>0.05*
	29.00 ± 15.4	<0.001**	13.18 ± 11.3	<0.001**	<0.05**
	29.86 ± 20.1	<0.001***	18.51 ± 14.9	<0.001***	<0.05***
HAM-Anxiety	15.17 ± 7.24		14.46 ± 6.15		>0.05*
	9.00 ± 5.17	<0.001**	9.00 ± 5.17	<0.001**	>0.05**
	11.86 ± 7.7	<0.001***	9.33 ± 5.46	<0.001***	>0.05***
NPADS	128.31 ± 16.7		123.60 ± 21.0		>0.05*
	75.89 ± 29.0	<0.001**	40.56 ± 20.5	<0.001**	<0.05**
	7.3.62 ± 37.8	<0.001***	50.90 ± 25.9	<0.001***	<0.05***
MDGA	7.48 ± 1.29		6.66 ± 1.21		>0.05*
	4.06 ± 1.75	<0.001**	1.90 ± 1.24	<0.001**	<0.05**
	4.00 ± 2.26	<0.001***	2.83 ± 1.91	<0.001***	>0.05***
PGA	8.72 ± 0.96		8.20 ± 0.80		>0.05*
	4.90 ± 2.01	<0.001**	2.40 ± 1.32	<0.001**	<0.05**
	4.68 ± 2.73	<0.001***	3.63 ± 2.18	<0.001***	>0.05***

HAM-A, Hamilton Anxiety Scale. Values are mean ± standard deviation (SD) for all variables; where no superscript appears, there is no significant difference.

tendinitis of the shoulder plus inflammation (21), osteoarthritis, and patellofemoral pain (22–27).

In our study, there was significant improvement for clinical parameters in the US group. US was effective and ESWT was also effective in the treatment of MPS.

There are several *in vitro* and *in vivo* studies on the use of ESWT in various diseases of the musculoskeletal system. These include calcific tendinopathy of the rotator cuff, chronic plantar fasciitis, lateral and medial epicondylitis, Achilles tendinopathies, painful calcaneal spur, and pseudoarthrosis (28–30). However, we found only one study on the use of ESWT in MPS. In this study, Müller and Licht (31) reported that ESWT was a new effective and safe method in MPS. Our study resembles that of Müller and Licht (31) in terms of reduced pain scores in the ESWT group. Our study was the first investigation to compare the efficacy of US and ESWT in MPS. Significant improvement was shown in all clinical parameters except the level of anxiety in patients which applied ESWT.

There are no recommended ideal dosages, number of shocks, durations of treatment, number of sessions, or treatment regimens of ESWT in MPS; however, the overall approach is to use ESWT at a low dosage and for short durations in pathologies of soft tissues. Schofer et al. (32) studied patients with tendinopathy of the rotator cuff without calcific tendinitis. Statistically significant improvement was reported in both groups of high or low dosage ESWT. In addition, authors have reported no superiority between the groups in terms of treatment efficacy. In our study, we used ESWT at low dosage to minimize the rarely encountered local side effects including cutaneous hyperemia and superficial hematoma.

Zwerver et al. (33) performed a study using the ESWT therapy on 19 athletes with chronic patellar tendinopathy and reported statistically significant improvement at 3 months in the parameters of pain and in sportive parameters. Additionally, patients tolerated the ESWT therapy well at moderate and high dosages in the absence of local anesthesia, and no complications were reported. We also did not administer local anesthesia in our study to evaluate the isolated efficacy of ESWT. Patients tolerated ESWT well at low dosages and no severe complications were encountered.

The shock waves used in ESWT have both mechanical and cellular effects. The most important effect is transient injury or increased permeability in cellular membranes of neurons. These mechanisms might be explained by the analgesic effect of ESWT. Increased blood flow at the site of treatment and increased tissue hydroxyprolin levels have been determined in ESWT. Neovascularization and cellular regeneration is also accelerated in the tissue (34).

The chemical effects of waves other than their mechanical disruptive effects have been suggested to be associated with free radicals (35). Another mechanism suggested for the analgesic effects of ESWT is the reduction in neuropeptides.

Biological effects of ESWT also include its effects on specific growth factors and inflammatory processes (36). Magnetic resonance image studies have not demonstrated any destructive effects of ESWT on the anatomical structures (37).

The vicious cycle of pain–spasm–ischemia–pain observed in MPS is broken down by the constitution of normal vascularization with ESWT. ESWT is adequate to provide transient injury or increased permeability in the cellular membrane of the neurons (32). These alterations occur at sites where ESWT is administered and pain is the most intense, and contribute to the improvement in pain scores. On the other hand, factors including the positive effect of ESWT on inflammatory processes, activation of production of normal tissues from stem cells, and reduction of neuropeptides in painful areas might also have contributed to the clinical improvement observed in our patients.

Both US and ESWT are effective and safe methods in MPS treatment. ESWT may provide additional advantage with respect to requiring less time and fewer sessions and easier application without any side effects. Three sessions of ESWT was more effective compared to US, and could be used as a convenient, economical, affordable, and non-invasive modality in treatment of MPS.

Certain limitations of the present study should be addressed. First, no previous study outlined the dose and procedure of ESWT in MPS. Additionally, we did not have the opportunity to evaluate the tissue effects of ESWT in MPS.

Consequently, our study demonstrated that both US and ESWT were effective and safe therapies in MPS. Our results proved ESWT to be effective and reliable on MPS patients, but randomized controlled study with the inclusion of broad case groups need to be made.

DECLARATION OF INTEREST

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

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