



Original Article

Comparison of the effectiveness of ESWT and ultrasound treatments in myofascial pain syndrome: randomized, sham-controlled study

SEMRA AKTÜRK^{1)*}, ARZU KAYA²⁾, DERYA ÇETINTAŞ³⁾, GÜRKAN AKGÖL²⁾, ARIF GÜLKESEN²⁾, GÜL AYDEN KAL³⁾, TÜLİN GÜÇER⁴⁾

¹⁾ Department of Physical Medicine and Rehabilitation, Faculty of Medicine, İnönü University, Malatya, Turkey

²⁾ Faculty of Medicine, Department of Physical Medicine and Rehabilitation, Faculty of Medicine, Faculty of Medicine, Turkey

³⁾ Department of Physical Medicine and Rehabilitation, Elazığ Education and Research Hospital, Turkey

⁴⁾ Department of Physical Medicine and Rehabilitation, Anadolu Hospital, Turkey

Abstract. [Purpose] The purpose of this study is to compare effectiveness of extracorporeal shock wave therapy (ESWT), ultrasound (US) and sham ESWT in the treatment of myofascial pain syndrome (MPS). [Subjects and Methods] Sixty MPS patients aged 18–60 years were included in the study. The patients were randomized equally into 3 groups. Group 1 received ESWT for 4 session with 3 day-intervals. Group 2 received 4 sessions of sham ESWT. US was applied to Group 3 for 10 sessions. All patients were recommended an exercise program. The patients were evaluated before-post and 6 weeks after treatment. Measurements were made using pressure pain threshold (PPT), pain score (PS) and visual analogue scale (VAS). Patients were evaluated by using SF-36 and HADS (hospital anxiety and depression scale). [Results] A significant posttreatment difference was found in VAS, PPT and SF-36 subparameters in group 1. In group 2, a significant difference was not found in any parameter. In group 3, a significant difference was detected in parameters of VAS and PPT. A significant difference was found between groups 1 and 2 as for subtitles of PPT, VAS, SF-36. [Conclusion] These results suggest that ESWT is as effective as US. ESWT and US are significantly more effective than sham ESWT.

Key words: Myofascial pain syndrome, Ultrasound, Extracorporeal shock wave therapy

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INTRODUCTION

Myofascial pain syndrome (MPS) is characterized with hypersensitive (also called) trigger points found in muscles and/or fascias, pain, spasm, sensitivity, stiffness, fatigue and occasionally autonomic dysfunctions¹⁻³⁾. Treatment in myofascial pain syndrome is generally targeted at trigger points. Medical treatment and physical treatment modalities such as injection therapy, spray and traction techniques, superficial hot and cold applications, ultrasound, massage and TENS are effective in decreasing pain^{4, 5)}. These modalities impair and inactivate trigger points with their thermal or mechanic effects⁴⁾.

Ultrasound is successfully used in the treatment of rheumatic and many muscle diseases. Ultrasound applied at target points in MPS has achieved marked improvement in neck pain^{5, 6)}.

Extracorporeal shock wave therapy is a noninvasive method used recently in the treatment of musculoskeletal diseases. Many investigations have been performed concerning the effectiveness of ESWT in various musculoskeletal diseases. Among

*Corresponding author. Semra Aktürk (E-mail: semrakayakturk@hotmail.com)

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them calcific tendinopathies of rotator cuff, chronic plantar fasciitis, lateral and medial epicondylitis, Achilles tendinopathies and painful heel spurs can be enumerated⁷⁻¹⁰. Various studies have demonstrated effectiveness of radial or focused shock wave therapy in the treatment of myofascial pain¹¹⁻¹⁴.

In the present study, we aimed to compare effectiveness of a new physical therapy modality ESWT and US; a standard therapy in the treatment of patients with MPS.

SUBJECTS AND METHODS

Forty female and 20 male patients (total n=60) aged between 18–60 years (mean age, 34.85 ± 9.25 years) who applied to the outpatient clinic of the Department of Physical Medicine and Rehabilitation with diagnosis of myofascial pain syndrome which were determined according to the criteria defined by Travel and Simons². Patients whose disease persisted for at least 6 months, but didn't receive any treatment for the previous 8 weeks were included in the study. Patients with cardiovascular and/or respiratory system disease or any malignancy, those who received injections at myofascial trigger points within the previous two months or underwent neck or shoulder surgery within a year, individuals diagnosed as fibromyalgia, cervical radiculopathy or myelopathy, pregnant women, acute trauma patients and persons with cooperation deficits were excluded from the study.

The study was performed in compliance with principles of Helsinki Declaration and approval of the local ethics committee was 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 three groups by pulling the envelopes by the order of admission to the outpatient clinic.

Four sessions of ESWT were applied to Group 1, and sham ESWT was applied to Group 2 patients. US was applied to Group 3 patients. Twenty patients were included in each group. Detailed physical examinations were performed and a standard evaluation form was completed by all patients. All of the participant's age, gender, socioeconomic status, occupations, exercise capacities, personal and family history findings were recorded.

A total of 4 sessions ESWT was performed using Storz medical masterpulse MP200 device adjusted to following settings: 1.6–3.0 bar, 200–400 shocks/trigger point, total of 2,000–3,000 shock/session, maximum 3 min/session with at most 3 day intervals between sessions. D20 transmitter (Ø 20 mm) headpiece was used.

A total of 4 sessions sham ESWT 1.0–1.3 bar for 3 min/session, without application of shock waves applied to second group.

Active continuous US treatment for 2 weeks for 5 days a week for a total of 10 sessions each session lasting for 5 minutes at a dose of 1.5 w/cm² applied to third group.

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. All patients were evaluated by the same physiatrist before the treatment (1. control) at the end of the treatment (2 weeks later) (2. control) and four weeks after the treatment (3. control). Pressure pain threshold (PPT) was measured using algometer developed by Fischer and pain score measurement was performed with digital palpation. Measurements of pressure pain threshold was measured, by increasing the pressure 1 kg/sec and the same site was examined for at most two times at one minute intervals. Pain score (PS) was evaluated as the intensity of pain felt when nail bed was pressed manually with a thumb till it whitens (nearly 4 kg pressure) and scored between 0 and 3 points (0: no pain, 1: mild pain, 2: marked pain, 3: severe pain making the patient to startle).

For evaluation of disability and efficacy of treatment before the treatment and at each posttreatment control visits visual analogue scale (VAS) and SF-36 tests were performed. For the evaluation of anxiety and depression related to chronic pain hospital anxiety and depression scale (HADS) was performed at 1, and 3. control visits.

All patients were recommended an exercise program consisting of traction and isometric exercises to be applied during treatment period at treatment unit and afterwards at home. The program focused on daily gentle unresisted isometric cervical flexion, extension and rotation exercises (about 3 sets of 10 repetitions of each exercise daily). Exercise was then progressed in each direction with low isometric resistance, increasing the exercise parameters toward 3 sets of 10 repetitions in supine and sitting positions. Stretching exercises: while seated, the subject performed stretching exercises for the upper trapezius, scalene, semispinal muscle of head and sternocleidomastoid muscles; each stretch for 25–30 seconds.

Visual analogue scale (VAS) measures severity of patient's pain and its validation and reliability studies have been performed. VAS scale evaluates patient's pain perception on a scale of 10 vertical or horizontal lines from 0 (no pain) to 10 points (the most severe pain)¹⁵.

Hospital anxiety and depression scale (HADS) is applied to determine the risk for anxiety and depression and to measure their level and severity. It comprise a total of 14 questions which measure anxiety and depression. The minimum and maximum scores to be obtained for anxiety and depression are 0 and 21 points, respectively¹⁶.

Short Form-36 (SF-36) is the most frequently used generic quality of life scale in the field of medicine and consists of 8 subscales with 36 items which evaluate physical and mental health. These subscales include physical functioning (PF), difficulty in physical role (DPR), pain, general health perceptions (GHP), vitality, social role functioning (SRF), restriction of emotional role functioning (REF) and mental health (MH)¹⁷.

Table 1. Baseline characteristics of ESWT, Plasebo ESWT and US groups

	ESWT n (%)	Plasebo n (%)	US n (%)	Total n (%)
Gender				
Female	15 (75)	13 (65)	12 (60)	40 (66.7)
Male	5 (25)	7 (35)	8 (40)	20 (33.3)
Age	33.45 ± 8.02	35.45 ± 8.07	35.65 ± 11.03	
Marital status				
Single	7 (35)	7 (35)	8 (36.7)	22 (36.7)
Married	13 (65)	13 (65)	12 (63.3)	48 (63.3)
Educational status				
Not literate	1 (5)	2 (10)	2 (10)	5 (8.3)
Elementary school	2 (10)	2 (10)	4 (20)	8 (13.3)
Secondary school	7 (35)	11 (55)	10 (50)	28 (46.7)
University	10 (50)	5 (25)	4 (20)	19 (31.7)
Occupation				
Hard worker	0 (0)	1 (5)	1 (5)	2 (3.3)
Homemaker	12 (60)	9 (45)	12 (60)	33 (55)
Employed	1 (5)	0 (0)	1 (5)	2 (3.3)
Others	7 (35)	10 (50)	6 (30)	23 (38.3)

Table 2. PPT, TPS and VAS parameters among ESWT, US and sham ESWT groups

	a ESWT	b Sham ESWT	c US	a-b-c p ^π	a-b p [#]	a-c p [#]	b-c p [#]
PPT-I	2.41 ± 0.70	2.20 ± 0.73	2.55 ± 0.59				
PPT-II	3.44 ± 0.89	2.30 ± 0.80	3.20 ± 0.71	**	**		*
PPT-III	4.43 ± 1.15	2.25 ± 0.85	3.89 ± 0.99	**	**		**
TPS-I	2.50 ± 0.51	2.40 ± 0.59	2.45 ± 0.51				
TPS-II	1.65 ± 0.74	2.35 ± 0.58	1.80 ± 0.52	*	*	*	*
TPS-III	1.20 ± 0.50	2.35 ± 0.58	1.45 ± 0.51	**	**	*	**
VAS-I	6.29 ± 1.81	6.60 ± 1.39	7.31 ± 1.15				
VAS-II	4.76 ± 1.98	6.71 ± 1.23	6.24 ± 1.13	*	*		*
VAS-III	4.01 ± 1.78	6.87 ± 1.39	5.29 ± 1.32	**	**		*

PPT: Pressure pain threshold; TPS: Trigger point pain score; I: Before the treatment; II: At the end of the treatment (2 weeks later); III: One month after the treatment.

π: Kruskal-Wallis test, #Mann-Whitney U test.

*p<0.05, **p<0.01

SPSS 15.0 was used for statistical analysis. Distribution of anthropometric and demographic characteristics of all cases were performed using descriptive statistical methods. In intragroup comparisons three measurements were performed namely before, immediately and one month after the treatment. Firstly Friedman nonparametric variance analysis was done and then the parameters deemed to be significant (p<0.05) were subjected to pairwise (1 vs. 2; 1 vs. 3 and 2 Vs. 3 measurements) comparisons using nonparametric Wilcoxon test. For pairwise comparisons of multiple measurements (3 measurements) using Wilcoxon test in each group limit of significance was accepted as 0.05/number of comparisons (3 comparisons)=0.16 (Bonferroni correction). For other comparisons limit of significance was accepted as 0.05. For intergroup comparisons, priorly three groups were compared using nonparametric Kruskal-Wallis test, then for intergroup comparisons of parameters which differed significantly (p<0.05) nonparametric Mann-Whitney U test with Bonferroni correction was used. For intergroup comparisons of ordinal and nominal variables χ^2 test was used. To this end in each group means of all numerical values of 1, 2 and 3 measurements were subtracted from each other to obtain differences which were then compared between groups using m-nonparametric Kruskal-Wallis test and for intergroup comparisons Mann-Whitney U test was utilized.

Table 3. Comparing pretreatment and posttreatment parameters of SF-36 and HADS among groups

	A	B	C	a-b-c	b	c	c
	ESWT	sham ESWT	US	p ^π	p [#]	p [#]	p [#]
SF-36 GH							
Beginning	51.65 ± 15.05	46.45 ± 15.76	46.95 ± 13.85				
2 week	53.00 ± 13.61	47.20 ± 11.17	47.35 ± 13.66				
6 week	55.25 ± 12.76	44.95 ± 12.48	49.20 ± 12.94	*	*		*
SF-36 PF							
Beginning	68.75 ± 17.46	54.75 ± 20.935	55.25 ± 19.36				
2 week	69.25 ± 19.34	4.75 ± 20.93	57.00 ± 17.35	*			
6 week	75.50 ± 13.06	53 ± 19.82	61.75 ± 21.04	*	*		
SF-36 Pain							
Beginning	41.10 ± 12.27	39.65 ± 6.59	39.65 ± 10.12				
2 week	48.25 ± 14.24	39.65 ± 6.59	43.15 ± 12.67				
6 week	56.80 ± 12.64	36.20 ± 6.81	49.95 ± 9.64	*	*		*
SF-36 DPR							
Beginning	20.00 ± 34.98	17.05 ± 31.51	32.50 ± 36.34				
2 week	37.50 ± 40.95	20.00 ± 32.03	36.25 ± 37.58				
6 week	58.75 ± 37.41	18.75 ± 31.28	47.50 ± 34.31	*	*		*
HADS							
Anxiety-I	6.80 ± 2.76	8.15 ± 4.01	6.55 ± 4.92				
Anxiety-II	6.55 ± 2.64	8.0 ± 4.0	6.25 ± 4.95				
Depression-I	5.30 ± 3.62	7.50 ± 4.34	5.75 ± 4.59				
Depression-II	5.25 ± 3.66	7.95 ± 4.63	5.80 ± 4.67				

I: Before the treatment; II: One month after the treatment (6 week); GH: General health perceptions; PF: Physical functioning; DPR: Difficulty in physical role.

^πKruskall-Wallis test, [#]Mann-Whitney U test.

*p<0.05

RESULTS

A total of 60 patients (20 male and 40 female) aged 18–60 years were enrolled in this study. The mean age for the patient groups was 33.45 ± 8.02, 35.45 ± 8.07 and 35.65 ± 11.03 years, respectively. A significant intergroup difference was not found for demographic characteristics, including gender, marital status, educational level of the patients among the groups (p>0.05; Table 1). Distribution of pretreatment examination findings did not differ significantly among groups.

Regarding pressure pain threshold values measured from trigger points did not differ significantly between groups, while a significant difference was observed at the end of the treatment, 2 and 6 weeks after treatment (p<0.05). Intergroup differences were detected between ESWT-sham ESWT and US-sham ESWT groups in terms of trigger point pressure pain threshold values estimated at 2 and 6 weeks after the treatment (p<0.05). However, posttreatment PPT values between ESWT and US groups did not differ significantly (p>0.05) (Table 2).

A significant difference was observed among these three groups in pain score values estimated during palpitation of trigger points at 2 weeks and 1 month after the treatment. Trigger point pain scores estimated immediately, 2 and 6 weeks after treatment differed significantly between ESWT vs. sham ESWT and US groups in favour of the ESWT. In other words, treatment effectiveness on trigger point pain score was higher in the ESWT and US groups relative to sham ESWT group (Table 2).

A significant intergroup difference was found in pain scores measured at the end of the treatment and 6 posttreatment weeks using VAS. In pairwise comparisons a significant difference was seen between ESWT and sham ESWT groups at the end of the treatment, besides at control visits performed at 6 weeks of the treatment a significant difference was obtained between ESWT-sham ESWT and US-sham ESWT groups (p<0.05).

In inquiries performed using short form-36, evaluations made one month after the treatment detected significant differences among 3 groups in subscales of pain and physical functioning (PF). In pairwise comparisons, a significant difference was observed between ESWT-sham ESWT and US-sham ESWT groups as for pain parameter (p<0.05, Table 3).

Pretreatment and posttreatment 2 and 6 week scores of HAD scale which evaluate states of anxiety and depression did not differ significantly among three groups (p>0.05).

DISCUSSION

In our study we have observed marked therapeutic effectiveness on myofascial pain syndrome in both ESWT and US. Besides, superiority of both ESWT and US over sham ESWT was seen.

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. Analgesic effect of US can be explained by various 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 algescic substances due to accelerated substance exchange between the capillary wall and cell membranes, and more rapid tissue processing and permanent analgesia secondary to improvement. US has been widely used in the treatment of musculoskeletal diseases for more than sixty years. However, there are some disadvantages due to heat effect. Except for the general contraindications of heat, US is not applied to fluid-filled organs, especially the heart, eyes and pregnant uterus¹⁸).

US has been used for a long time with proven effectiveness and its effectiveness in the treatment of myofascial pain syndrome has been demonstrated in many studies^{19,20}. Esenyel et al. investigated the effectiveness of ultrasound and injection treatment combined with exercise at trigger points on upper part of the trapezius muscle and detected their equivalent effectiveness²¹. Kısaoğlu et al. evaluated pain using VAS and pressure pain threshold and detected significant drop in VAS values and significant increase in pressure pain threshold values after the treatment performed with ultrasound targeted at trigger points in MPS⁵). However, Draper et al. compared effectiveness of US and placebo US and demonstrated that US decreased stiffness of latent trigger points and achieved a marked pain relief in patients²²).

Similar to previous studies, in our study we observed significant improvement in PPT, VAS and AS values at the end of the treatment in the US treatment group. A significant difference was observed in the subscales of GH, DPR and SRF of SF-36 measured before and 2 and 6 weeks after treatment. A significant difference was detected in pain parameter of SF-36 values estimated 2 and 6 weeks after treatment relative to pretreatment values and a marked improvement was observed in posttreatment values.

As demonstrated in various studies, radial or focused shock wave treatment has been successfully applied with a wide indication in the treatment of myofascial pain. Gleitz indicated that ESWT is a novel and effective treatment modality in refractory cases with MPS. They have shown that especially focused ESWT has an energy penetration capability of nearly 5–10 cm and it is reliable in the prevention of referred pain¹¹).

In a study encompassing 30 patients, Müller et al. used focused ESWT and measured pain response in MPS. They evaluated VAS before and 3 months after the treatment and indicated that focused ESWT was effective in the diagnosis and treatment of the disease²³). Similarly, we also detected a significant difference between PPT, VAS and AS scores estimated before and 2 and 6 weeks after the treatment in the ESWT group, while a prominent improvement was seen in posttreatment values relative to pretreatment estimates. Gür et al. performed a study with 108 patients and applied ESWT for one or three sessions and observed posttreatment decrease in trigger points and improvement in anxiety scale scores in both groups. While in the group which received 3 sessions of ESWT they noticed decrease in pain scores 3 weeks after the treatment¹²). We also found significant difference in intergroup comparisons of pain parameter of the SF-36 scores. In another study, ESWT was compared with TENS and trigger point injection and ESWT was reported to be as effective as TENS and trigger point injection on VAS scores¹³). Additionally, in our study significant improvements were obtained in many parameters of SF-36 (AS, VAS, PPT, pain, physical functioning, social functioning, difficulty in physical role) in both ESWT and US groups.

In a study, focused ESWT was compared with placebo and in the ESWT group, a marked improvement was observed in VAS, algometer measurements and SF-36 scores calculated 3 months later¹⁴). Also in our study, a significant change was not detected in VAS, AS, PPT scores and none of the parameters of SF-36 of the patients in the sham ESWT group. Posttreatment differences obtained in all parameters were examined so as to determine the group with more prominent changes and then intergroup comparisons were performed. Any significant difference between ESWT and US was not found regarding any parameter. Based on this outcome we can say that ESWT and US have similar efficacies in the treatment of MPS.

There are no suggested ideal dosages, number of shocks, durations of treatment or treatment regimens of ESWT in trigger points; however, the common approach is to use ESWT at a low dosage and with short durations in pathologies of soft tissues. In this study we applied ESWT at low dosages in accordance with the literature.

The shock waves used in ESWT have mechanical and cellular effects. Transient injury or increased permeability in cellular membranes of neurons is the most important effect. These mechanisms may be explained by the analgesic effect of ESWT. Biological effects of ESWT also include its effects on specific growth factors²⁴). Neovascularization and cellular regeneration is also accelerated in the tissue²⁵). On the other hand, shock waves can destroy cells by means of free radicals. Structural changes occurring within the cytoplasm and the mitochondria, with an energy flux density of 0.5 mJ/mm², have been demonstrated in electron microscopic studies. Some adverse effects might occur during treatment like pain, haematoma, migraine attacks, feeling dizziness, sensitivity and irritation of the tissues. In addition, petechiae, bleeding and haematomas might be seen. Acute soft tissue infections, malignomas, pregnancy, epilepsy and blood coagulation diseases are some of the contraindications^{26,27}).

The main disadvantage of ESWT is that no valid therapy schemes yet exist. Our study has demonstrated that four sessions

of ESWT treatment is effective as US on the treatment of myofascial pain syndrome and decrease clinical manifestations together with symptoms.

A limitation of our study is that our study population contained small number of patients, larger patient groups should be studied to generalize the results. Additionally, we were not able to evaluate the effects of ESWT on tissues in MPS.

In conclusion, all of these findings suggest that as a new treatment in MPS, ESWT is an effective and safe treatment modality. ESWT may satisfy further advantage with respect to requiring less time and fewer sessions. However, larger-scale studies which will demonstrate effectiveness of ESWT are needed.

Conflict of interest

None.

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