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ORIGINAL ARTICLE

High-Energy Flux Density Extracorporeal Shock Wave Therapy Versus Traditional Physical Therapy Modalities in Myofascial Pain Syndrome: A Randomized-controlled, Single-Blind Trial

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ABSTRACT

Objectives: This study aims to investigate the effects of extracorporeal shock wave therapy (ESWT) on pain, sleep, fatigue, disability, depression, and quality of life (QoL) in patients with myofascial pain syndrome (MPS).

Patients and methods: Between March 2018 and September 2018, a total of 94 patients (16 males, 78 females; mean age 44.2±11.94 years; range, 19 to 74 years) with the diagnosis of MPS were included in the study. The patients were divided into two groups. The treatment group consisted of 49 patients and a total of seven sessions of high-energy flux density ESWT (H-ESWT) (0.26 mJ/mm^2) were given with three days interval. The control group consisted of 45 patients and the treatment of hot pack, transcutaneous electrical nerve stimulation, and ultrasound was given for five days for two weeks. At baseline and one month after treatment, the visual analog scale (VAS), Short Form-36 (SF-36), Pittsburgh Sleep Quality Index (PSQI), Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue Scale, Neck Disability Index (NDI), and Beck Depression Inventory (BDI) scores were compared between the groups.

Results: There were no statistically significant differences in the age, sex, demographic characteristics, and baseline VAS, SF-36, NDI, BDI, FACIT, and PSQI scores between the groups ($p>0.05$). In the ESWT group, there was a statistically significant decrease in the VAS, SF-36, NDI, BDI, FACIT, and PSQI scores after treatment compared to the baseline scores, while only the SF-36 subscale scores were statistically significantly higher ($p<0.05$). There was a statistically significant correlation between the VAS and SF-36 scores and the BDI, NDI, FACIT and PSQI scores after the treatment.

Conclusion: Our study results suggest that H-ESWT is more effective than traditional physical therapy methods on pain, QoL, sleep, fatigue, depression, and disability in patients with MPS.

Keywords: Disability, extracorporeal shock wave therapy, myofascial pain syndrome, quality of life, sleep.

Myofascial pain syndrome (MPS) is a common musculoskeletal syndrome characterized by muscle stiffness, typical pain, intramuscular taut band, local twitch response, and hyperirritable muscle fibers known as myofascial trigger points (MTrPs).[1,2] Upper trapezius trigger points are the most frequent causes of pain in patients with MPS.[3,4] Fischer described the most affected hyperirritable points on the upper trapezius muscle. The pathophysiology of MPS has been thought to be due to shortened muscle fibers and taut bands as a result of increased calcium influx to the muscular fibers or increased acetylcholine secretion in motor end plates.[5]

A growing number of evidence-based studies have suggested treatment modalities for MPS including trigger point injection (TPI), dry needling, stretching, ultrasound (US), manual therapies, superficial hot pack (HP) and cold pack, medical treatments, transcutaneous electrical

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nerve stimulation (TENS), and massage.[6-15] Extracorporeal shock wave therapy (ESWT) is a novel, non-invasive therapeutic modality for musculoskeletal system diseases such as calcific tendinopathies, plantar fasciitis, and lateral and medial epicondylitis[16-19] as well as for MPS.[20-24] Although there are some theories proposed, the mechanism of action of ESWT on MPS still remains to be elucidated. The Energy Crisis Hypothesis may explain how ESWT affects other diseases.[25,26] The ESWT mainly exerts its effects by increasing perfusion of damaged ischemic tissues, increasing vascularization and changing pain stimuli in ischemic tissues via increasing intake of calcium. In this study, we aimed to investigate the effects of ESWT on pain, sleep, fatigue, disability, depression, and quality of life (QoL) in patients with MPS.

PATIENTS AND METHODS

This prospective, randomized, single-blind clinical study was conducted at musculoskeletal outpatient clinic of University of Health Sciences Ümraniye Training and Research Hospital between March 2018 and September 2018. A total of 94 patients (16 males, 78 females; mean age 44.2±11.9 years; range, 19 to 74 years) with the diagnosis of MPS were included. Inclusion criteria were as follows: having a diagnosis of MPS according the criteria defined by Travel and Simons;[27] persistent myofascial pain at trapezius levator scapulae, supraspinatus, or infraspinatus at least for six months as assessed by a visual analog scale (VAS) score of >3;[28] and having at least three MTrPs. Exclusion criteria were as follows: no prior treatment including ESWT within the last six months; having a diagnosis of other spinal diseases such as cervical spinal stenosis, spondylolisthesis, cervical hernias, cervical radiculopathy, or myelopathy; previous cervical or lumbar spinal surgery; malignancy; other inflammatory diseases; pregnancy; having a cardiac pacemaker; local infections; severe cardiac or renal diseases; or neurological deficits involving lower extremities. To rule out other spinal diseases, all patients underwent detailed physical and neurological examinations. In addition, cervical, thoracic, and lumbar anteroposterior and lateral plain radiographs and cervical, thoracic, and lumbar magnetic resonance imaging scans were obtained. The study protocol was approved by the University of Health Sciences Ümraniye Training and Research Hospital Ethics Committee. A written informed consent was obtained from each patient. The study was conducted in accordance with the principles of the Declaration of Helsinki.

The patients were divided into two groups. The treatment group (ESWT group) consisted of 49 patients and a total of seven sessions of high-energy flux density ESWT (H-ESWT) (0.26 mJ/mm^2) were given with three days interval. The traditional treatment group (control group) consisted of age- and sex-matched 45 patients and the treatment of HP, TENS, and US was given for five days for two weeks. Data including baseline demographic characteristics of both groups were recorded. The study flow chart is shown in Figure 1.

We used G*Power version 3.1.2 (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany) to calculate the sample size. To estimate

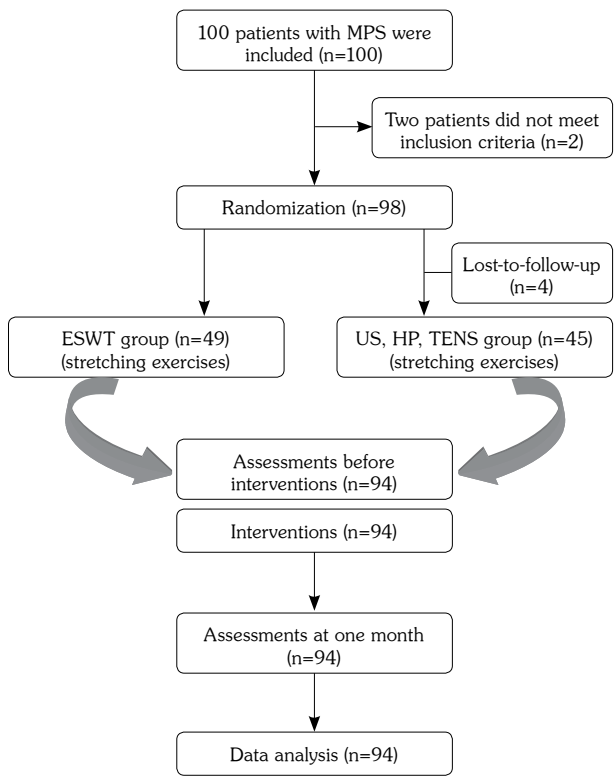

Figure 1. Study flow chart.
MPS: Myofascial pain syndrome; ESWT: Extracorporeal shock wave therapy; US: Ultrasound; HP: Hot pack; TENS: Transcutaneous electrical nerve stimulation.

the effect of ESWT, we used data from a pilot study[29] in which ESWT affected short form-36 (SF-36) physical function subscale scores (standard deviation [SD]=21.3) which corresponded to an estimated effect size of 0.68545.

Based on an alpha value of 0.05 for statistical significance, a total of 37 patients are required in each group to achieve 80% statistical power. Thus, a total of 74 patients were planned to be recruited in both groups. Assuming a dropout of 15%, 100 patients were expected to be included.

The patients were divided into two groups as the ESWT group and control group by random selection using sequentially numbered, opaque, sealed envelopes. The investigators who assessed pre- and post-treatment measurements were not allowed to attend to the intervention period and were blinded to group allocation.

All pre- (at baseline) and post-treatment (at one month) measurements were evaluated by a single investigator. The VAS was used to evaluate pain severity. Scores of this scale range from 0 to 10; while 0 indicates no pain, 10 indicates unbearable pain. All patients were asked to rate their pain level.

The QoL was evaluated using the SF-36 which consists of eight subscales and 36 items. It is used to evaluate physical and mental health of the patients. Limitation of physical activity was assessed by physical functioning (PF), limitations of daily activities by difficulty in physical role (DPR), pain severity by bodily pain, rating of health by general health, energy and fatigue by vitality, limitations of daily activities by social functioning, and limitation of regular daily activities by difficulty in emotional role and mental health.[30]

The sleep quality and sleep disturbances within the last month were evaluated using the Pittsburgh Sleep Quality Index (PSQI). This scale ranges from 0 to 21 and higher scores indicate worse sleep quality.[31]

The Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue Scale was used to assess whether the patients were able to maintain their daily activities. It ranges from 0 to 52 and higher scores indicate lower energy and difficulty in daily activities.[32]

The Neck Disability Index (NDI) was used to evaluate disability related to neck pain. This scale ranges from 0 to 50 and higher scores indicate more self-rated disability. The validity and reliability studies of the Turkish version of the NDI have been shown.[33]

The Beck Depression Inventory (BDI) was used to assess severity of depression. It is a 21-item, self-rated scale with a maximum score of 63. Higher scores indicate greater symptom severity. The validity and reliability studies of the Turkish version of the BDI have been shown.[34]

The ESWT group received ESWT using Modus ESWT device (Serial No. 800-1520; Inceler Medical Ltd., Ankara, Turkey). A total of seven sessions of focused ESWT were performed with three days intervals. The ESWT was applied at MTrPs on the trapezius muscle at 500 pulses/trigger point, a total of 1500 to 4500 pulses/session 1.5 to 3 bars with H-ESWT (0.26 mJ/mm^2) in each session. The control group received traditional treatment modalities including HP, TENS, and US five times a week for two weeks. Continuous US at 1 Mhz was applied at a dose of 1.5 watt/cm^2 for six minutes daily. In addition, TENS was applied for 30 minutes and HP was applied 20 minutes daily.

Trapezius stretching exercises were given to all patients in both groups. All patients were instructed about the exercises by physiotherapists and the first set of exercises were performed under the supervision of clinical physiotherapists. All patients were instructed to perform 10 repetitions of each exercise set. These exercises were performed three times a day for two weeks.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 22.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were expressed in mean±SD, or number and frequency. The Shapiro-Wilk test was used for normality test of data. For quantitative variables, the Student's t-test was used to compare normally distributed data between the groups, while the Mann-Whitney U test was used to compare non-normally distributed data between the groups. For intra-group comparison, a paired sample t-test was performed to analyze normally distributed data, while the Wilcoxon signed-rank test was used to analyze non-normally distributed data. The Pearson's correlation analysis was performed to analyze possible correlations between the

variables. A *p* value of <0.05 was considered statistically significant.

RESULTS

Of a total of 94 patients, 49 (52.1%) were included in the ESWT group and 45 (47.9%) were included in the control group. Baseline demographic characteristics of the patients are shown in Table 1.

There was no statistically significant difference in the baseline VAS and SF-36 subscale scores between the groups (p>0.05). However, there was a statistically significant decrease in the VAS scores one month after treatment in both ESWT and control groups, compared to baseline scores (p<0.001), although the decrease was statistically significantly greater in the ESWT group (p<0.001). In addition, there was a statistically significant increase in the SF-36 subscale scores one month after treatment in both ESWT and control groups (p<0.001) with a statistically significantly greater increase in the ESWT group (p<0.001). Pre- and post-treatment VAS and SF-36 scores in the ESWT and control groups are presented in Table 2, Figure 2.

There was no statistically significant difference in the baseline PSQI, FACIT, NDI, and BDI scores between the groups (p>0.05). However, there was a statistically significant decrease in the PSQI, FACIT, NDI, and BDI scores one month after treatment in both ESWT and control groups (p<0.001). However, the decrease in the ESWT group was statistically significantly higher (p<0.001). Pre- and post-treatment PSQI, BDI, NDI, and FACIT scores in the ESWT and control groups are presented in Table 3, Figures 3-6.

The correlation analysis revealed a strong, positive, and statistically significant relationship between the changes in the VAS scores and

Table 1. Baseline demographic characteristics of patients

	ESWT group				Control group				Total			
	n	%	Mean±SD	Range	n	%	Mean±SD	Range	n	%	Mean±SD	Range
Age (year)			45.0±12.0	21-74			43.3±11.9	19-68			44.2±11.9	19-74
Sex												
Male	7	14.3			9	20			16	17		
Female	42	85.7			36	80			78	83		
Marital status												
Married	40	81.6			35	77.8			75	79.8		
Single	9	18.4			10	22.2			19	20.2		
Smoking status												
Smoker	24	49			18	40			42	44.7		
Non-smoker	25	51			27	60			52	55.3		
Education status												
None	0	0			1	2.2			1	1.1		
Read and write	6	12.2			6	13.3			12	12.8		
Primary school	22	44.9			23	51.1			45	47.9		
Secondary school	8	16.3			3	6.7			11	11.7		
High school	10	20.4			10	22.2			20	21.3		
University	3	6.1			2	4.4			5	5.3		
Occupation												
Housewife	31	63.3			25	55.6			56	59.6		
Retired	2	4.1			1	2.2			3	3.2		
Student	1	2			0	0			1	1.1		
Full-time	11	22.4			14	31.1			25	26.6		
Part-time	4	8.2			5	11.1			9	9.6		

ESWT: Extracorporeal shock wave therapy; SD: Standard deviation.

changes in the PSQI (r=0.728), BDI (r=0.614), NDI (r=0.702), and FACIT (r=0.673) scores after the treatment in the ESWT group. In addition, there was a strong, negative, and statistically significant relationship between the changes in the SF-36 PF subscale scores and the changes in the PSQI (r= -0.621) scores after the treatment in the ESWT group. There was also a moderate, negative, and

Table 2. Comparison of VAS and SF-36 scores before and after treatment in ESWT and control groups

	ESWT group		Control group		Inter-group
	Mean±SD	Range	Mean±SD	Range	*p*†
VAS					
Pre-treatment	8.3±1.2	8	8.1±1.3	8	0.457
Post-treatment	3.7±1.7	4	6.5±1.2	7	<0.001*
Pre-post-treatment *p*‡	<0.001*		<0.001*		
SF-36					
PF					
Pre-treatment	33.5±6.2	30	34.4±7.9	30	0.464
Post-treatment	62.4±13.3	60	47±10.2	45	<0.001*
Pre-post-treatment *p*‡	<0.001*		<0.001*		
DPR					
Pre-treatment	33.2±11.9	25	36.7±12.6	25	0.167
Post-treatment	70.4±16.7	75	54.4±18.7	50	<0.001*
Pre-post-treatment *p*‡	<0.001*		<0.001*		
DER					
Pre-treatment	37.4±14.6	33.3	39.3±21.7	33.3	0.512
Post-treatment	78.9±18.9	66.7	56.3±19.9	66.7	<0.001*
Pre-post-treatment *p*‡	<0.001*		<0.001*		
VT					
Pre-treatment	30.2±5.3	30	33.1±6.6	35	0.027*
Post-treatment	60.5±11.4	65	42.6±8.4	45	<0.001*
Pre-post-treatment *p*‡	<0.001*		<0.001*		
MH					
Pre-treatment	32.9±4.8	32	32.6±6.8	32	0.501
Post-treatment	59.6±15.6	60	41.1±10.8	40	<0.001*
Pre-post-treatment *p*‡	<0.001*		<0.001*		
SF					
Pre-treatment	30.6±8.5	25	32.4±9.6	32.5	0.372
Post-treatment	59.1±12.5	62.5	44.5±11.7	37.5	<0.001*
Pre-post-treatment *p*‡	<0.001*		<0.001*		
BP					
Pre-treatment	30.9±6.9	32.5	32.7±8.5	32.5	0.259
Post-treatment	61.6±16.0	62.5	45.5±11.7	45	<0.001*
Pre-post-treatment *p*‡	<0.001*		<0.001*		
GH					
Pre-treatment	29.0±6.5	30	31±6.7	30	0.239
Post-treatment	55.6±13.1	60	40±9.0	40	<0.001*
Pre-post-treatment *p*‡	<0.001*		<0.001*		

VAS: Visual analog scale; SF-36: Short form-36; ESWT: Extracorporeal shock wave therapy; SD: Standard deviation; PF: Physical functioning; DPR: Difficulty in physical role; DER: Difficulty in emotional role; VT: Vitality; MH: Mental health; SF: Social functioning; BP: Bodily pain; GH: General health; † Mann-Whitney U test; ‡ Wilcoxon signed-rank test; * p<0.05.

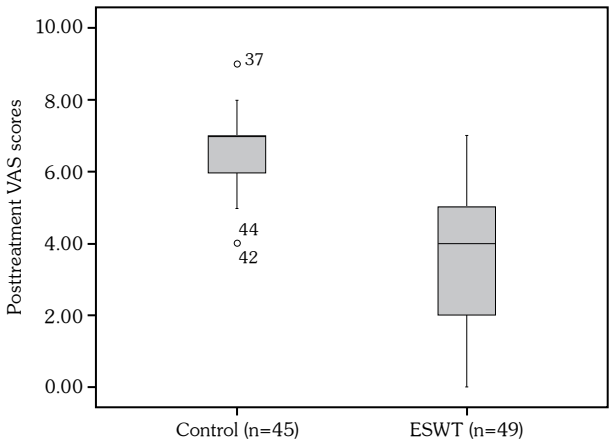

Figure 2. Differences of VAS values between ESWT and control groups after treatment.
VAS: Visual analog scale; ESWT: Extracorporeal shock wave therapy.

statistically significant relationship between the changes in the SF-36 PF and the changes in the BDI (r= -0.512) scores after the treatment in the ESWT group. In the control group, there was a moderate, positive, and statistically significant relationship between the changes in the SF-36 PF and the changes in the BDI (r=0.424) scores. The results of the correlation analysis of all scales in the ESWT and control groups are summarized in Table 4.

DISCUSSION

In the present study, we investigated the effects of ESWT and conventional physical therapy modalities such as US, TENS, and HP on QoL, sleep, mental health, neck disability, and fatigue in MPS patients.

The main goal of MPS treatment is to break the vicious cycle of pain-spasm-pain through the elimination of trigger points. For this purpose, thermal and/or mechanical effects of HP, TENS, and US are used.[27] Due to the thermogenic effects of US, elasticity of the collagen tissue and blood flow temporarily increase, contributing to the broken vicious cycle of pain and muscular spasm.[35] In addition, non-thermal effects of US provide muscular analgesia which can be attributed to decreased nociceptive input to the central nervous system.[36]

In general, the effect of ESWT on tissues can be explained by the mechanotransduction.

Table 3. Comparison of PSQI, BDI, NDI, and FACIT scores before and after treatment in ESWT and control groups

	ESWT group	Control group	Inter-group
	Mean±SD	Mean±SD	*p*†
PSQI			
Pre-treatment	15.5±1.9	15.1±2.1	0.386
Post-treatment	8.2±2.4	11.8±2.0	<0.001*
Pre-post-treatment *p*‡	<0.001*	<0.001*	
BDI			
Pre-treatment	12.4±2.8	11.4±4.7	0.234
Post-treatment	5.7±1.9	8.9±3.6	<0.001*
Pre-post-treatment *p*‡	<0.001*	<0.001*	
NDI			
Pre-treatment	45.6±7.8	43.5±7.3	0.171
Post-treatment	22.2±7.8	33.5±6.6	<0.001*
Pre-post-treatment *p*‡	<0.001*	<0.001*	
FACIT			
Pre-treatment	25.6±4.2	24.3±2.8	0.075
Post-treatment	11.4±3.8	18.7±3.0	<0.001*
Pre-post-treatment *p*‡	<0.001*	<0.001*	

PSQI: Pittsburgh Sleep Quality Index; BDI: Beck Depression Inventory; NDI: Neck Disability Index; FACIT: Functional Assessment of Chronic Illness Therapy-Fatigue Scale; ESWT: Extracorporeal shock wave therapy; SD: Standard deviation; † Student t-test; ‡ Paired sample t-test; * p<0.05.

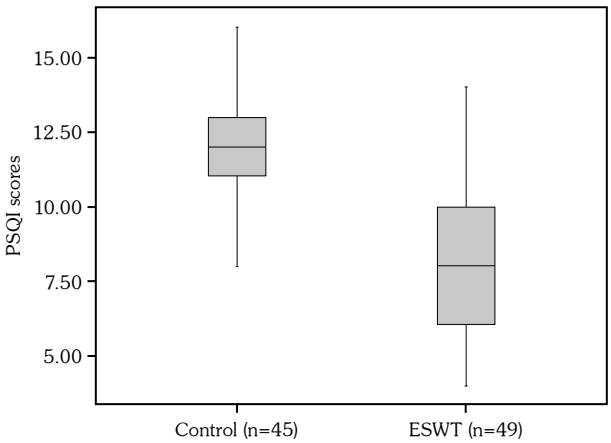

Figure 3. Differences of PSQI values between ESWT and control groups after treatment.

PSQI: Pittsburgh Sleep Quality Index; ESWT: Extracorporeal shock wave therapy.

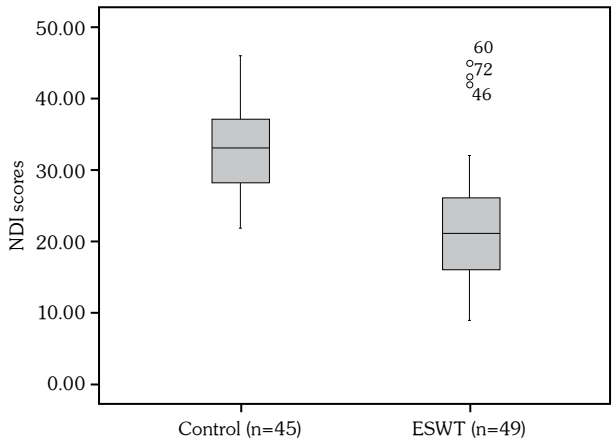

Figure 5. Differences of NDI values between ESWT and control groups after treatment.

NDI: Neck Disability Index; ESWT: Extracorporeal shock wave therapy.

Through this mechanism, ESWT acting as a mechanical stimulus enhances biological healing processes where mechanotransduction converts physical forces into biomechanical signals which are later integrated into cellular responses.[37] Although the exact mechanism of ESWT has not been clearly elucidated yet, several proposals have been made. In a study, ESWT was shown to prevent overstimulation of the nerves and nociceptors and to increase the blood flow, leading to pain relief through reduced muscle spasms and stiffness.[37] In another study, ESWT reduced musculoskeletal pain by disrupting the non-myelinated fibers and decreasing the production of substance P level at the dorsal root ganglia.[38,39]

To date, several clinical studies have proven the positive effects of US on MPS. In their study including 55 patients, Dundar et al.[40] reported that US treatment for 15 days yielded statistically significant improvements in pain, disability, and QoL. In addition, Srbely et al.[41] and Aguilera et al.[42] confirmed improved pain relief in patients with MPS. In another study, Ay et al.[43] divided the patients with MPS into three groups and found statistically significant improvements in pain and

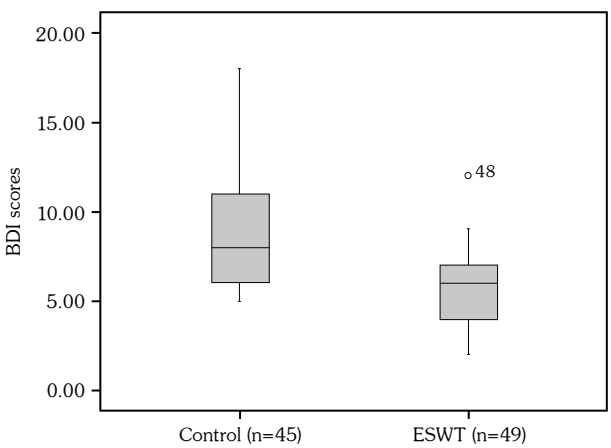

Figure 4. Differences of BDI values between ESWT and control groups after treatment.

BDI: Beck Depression Inventory; ESWT: Extracorporeal shock wave therapy.

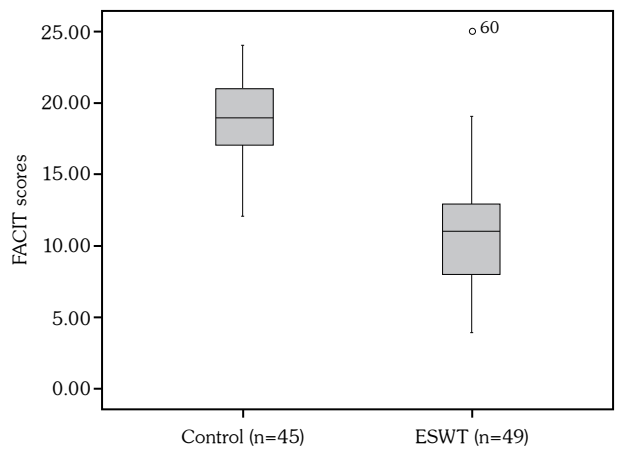

Figure 6. Differences of FACIT values between ESWT and control groups after treatment.

FACIT: Functional Assessment of Chronic Illness Therapy; ESWT: Extracorporeal shock wave therapy.

Table 4. Correlation analysis of VAS and SF-36 scores with PSQI, BDI, NDI and FACIT scores one month after treatment in ESWT and control groups.

Group	At one month post-treatment	PSQI	BDI	NDI	FACIT
ESWT	VAS				
	r	0.728	0.614	0.702	0.673
	p	<0.001*	<0.001*	<0.001*	<0.001*
	SF-36 PF				
	r	-0.621	-0.512	-0.304	-0.305
	p	<0.001*	<0.001*	0.034*	0.033*
	SF-36 DPR				
	r	-0.511	-0.404	-0.397	-0.325
	p	<0.001*	0.004*	0.005*	0.023*
	SF-36 DER				
	r	-0.479	-0.431	-0.394	-0.411
	p	<0.001*	0.002*	0.005*	0.003*
	SF-36 VT				
	r	-0.646	-0.516	-0.487	-0.565
	p	<0.001*	<0.001*	<0.001*	<0.001*
	SF-36 MH				
	r	-0.742	-0.602	-0.565	-0.527
	p	<0.001*	<0.001*	<0.001*	<0.001*
	SF-36 SF				
	r	-0.586	-0.522	-0.480	-0.560
	p	<0.001*	<0.001*	<0.001*	<0.001*
	SF-36 BP				
	r	-0.686	-0.506	-0.665	-0.609
	p	<0.001*	<0.001*	<0.001*	<0.001*
	SF-36 GH				
	r	-0.737	-0.604	-0.595	-0.552
	p	<0.001*	<0.001*	<0.001*	<0.001*
Control	VAS				
	r	0.176	0.220	0.386	0.285
	p	0.249	0.147	0.009*	0.057
	SF-36 PF				
	r	0.230	0.424	0.094	-0.081
	p	0.128	0.004*	0.538	0.599
	SF-36 DPR				
	r	-0.011	-0.002	-0.211	-0.180
	p	0.941	0.987	0.163	0.237
	SF-36 DER				
	r	-0.154	-0.109	-0.246	-0.314
	p	0.312	0.477	0.103	0.036*
	SF-36 VT				
	r	-0.229	-0.199	-0.139	-0.149
	p	0.130	0.191	0.363	0.327
	SF-36 MH				
	r	-0.340	-0.095	-0.175	-0.136
	p	0.022*	0.536	0.250	0.373
	SF-36 SF				
	r	-0.302	-0.066	-0.394	-0.166
	p	0.043*	0.665	0.007*	0.276
	SF-36 BP				
	r	-0.402	-0.22	-0.103	-0.077
	p	0.006*	0.146	0.499	0.613
	SF-36 GH				
	r	-0.250	-0.137	-0.150	-0.107
	p	0.097	0.368	0.325	0.485

VAS: Visual analog scale; SF-36: Short form-36; PSQI: Pittsburgh Sleep Quality Index; BDI: Beck Depression Inventory; NDI: Neck Disability Index; FACIT: Functional Assessment of Chronic Illness Therapy-Fatigue Scale; ESWT: Extracorporeal shock wave therapy; PF: Short form; DPR: Difficulty in physical role; DER: Difficulty in emotional role; VT: Vitality; MH: Mental health; SF: Social functioning; BP: Bodily pain; GH: General health; * p<0.05; Pearson's correlation analysis.

disability in both the US and phonophoresis groups. Similarly, in a study conducted by Ilter et al.,[44] a total of 60 patients with MPS were divided into three groups and statistically significant improvements were shown in pain, BDI, NDI, and Nottingham Heath Profile scores in the US group. In another study involving 59 patients with MPS, Kavadar et al.[45] found a statistically significant improvement in pain and BDI scores. Moreover, Yildirim et al.[46] divided 54 patients into two groups and one group received 10 sessions of US treatment and the other group received 10 sessions of placebo US treatment. The authors found a decline in pain scores which was statistically significantly higher in the US group, although there was no statistically significant difference in the BDI scores between two groups.

Furthermore, there is a growing number of studies demonstrating that TENS yields pain relief in patients with MPS.[47-49] In our study, we found a statistically significant improvement in pain, SF-36, PSQI, FACIT, BDI, and NDI in the HP, TENS, and US group after treatment. These findings suggest that combined traditional physical therapy modalities are more effective in the treatment of MPS compared to individual applications.

In the literature, the ESWT is used at three energy intensity levels: *(i)* low-energy flux density (EFD <0.08 mJ/mm^2); *(ii)* medium-energy flux density (EFD 0.08-0.28 mJ/mm^2); *(iii)* high-energy flux density (EFD >0.28 mJ/mm^2).[50-52] The total amount of energy and density is still discussed by the researchers, and no consensus has yet been reached.[53,54] Of note, H-ESWT may cause side effects such as permanent tendon damage, whereas low-EFD ESTW (L-ESWT) has a lower therapeutic effect.[55] In our study, none of the patients experienced such side effects.

In a study conducted by Müller-Ehrenberg and Licht,[56] focused H-ESWT was used in MPS patients and decreased VAS scores were achieved at three months. In another study, Jeon et al.[22] divided patients into two groups as ESWT and TENS-TPI groups and used focused L-ESWT in the ESWT group for three sessions. The authors found pain relief in both groups, although it did not reach statistical significance. Similarly, Ji et al.[23] used focused L-ESWT for four sessions in MPS patients and found ESWT to be an effective therapeutic modality with reduced VAS scores and pain threshold (PT). In another study, Cho et al.[55] used combined therapy as radial L-ESWT for 12 sessions and stabilization shoulder exercise and found greater improvements in pain and functional scores with combined therapy. In addition, Gur et al.[21] used focused H-ESWT and compared three sessions with a single session of therapy. The authors found that three sessions of therapy improved pain compared to a single-session therapy. Consistent with these findings, Akturk et al.[29] divided 60 MPS patients into three groups and used L-ESWT for four sessions. They found a statistically significant improvement in pain and SF-36 subscale scores in the ESWT and US groups; however, there was no statistically significant difference in the anxiety and depression scores after treatment. Hong et al.[57] also compared ESWT and TPI and used focused L-ESWT for three sessions. The authors found ESWT therapy to be more effective than TPI treatment in terms of pain relief; however, there was no statistically significant difference in disability between the groups. In another study, Park et al.[58] compared H-ESWT and L-ESWT and found improvements in the Verbal Numerical Pain Scale, NDI, neck range of motion (neck ROM), and PT in both groups; however, there was no statistically significant difference in the neck ROM and NDI scores between the groups.

Considering all these findings, the increase in the number of sessions of ESWT treatment and its use in high-energy density may increase its efficacy on pain disability and functional status. Therefore, we used H-ESWT for seven sessions in our patients. In the present study, we found statistically significant improvements in the SF-36, PSQI, FACIT, NDI, and BDI scores and pain relief in our patients with MPS after treatment. Improvements in all these scales indicate the importance of H-ESWT for a high number of sessions in pain management in patients with MPS. In the aforementioned studies, the authors found similar results for pain, QoL, and disability in the US, TPI groups and ESWT groups. This can be attributed to the fact that, in previous studies, L-ESWT was used for fewer sessions. In the present study, the statistically significant results in the ESWT group compared to combined physical therapy group can be explained by the fact that we applied a higher number of sessions of H-ESWT in our MPS patients.

Moreover, in the present study, we found a significant correlation between the VAS and SF-36 subscale scores and the PSQI, BDI, NDI and FACIT scores, compared to the control group. This finding indicates that H-ESWT for a high number of sessions can be a more effective non-invasive treatment modality than combined physical therapy methods.

Nonetheless, there are some limitations to this study. The presence of a non-treatment group and a larger sample size would increase the power of results. We, therefore, recommend further large-scale, long-term studies to confirm these findings and to establish a definite conclusion.

In conclusion, pain management is the mainstay of treatment which is associated with decreased pain and improved QoL, sleep, depression, fatigue, and disability in patients with MPS. Based on our study results, we suggest that H-ESWT for a high number of sessions is effective than traditional physical therapy methods in patients with MPS.

Declaration of conflicting interests

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