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Comparison of Effectiveness of Density and Number of Sessions of Extracorporeal Shock Wave Therapy in Plantar Fasciitis Patients: A Double-Blind, Randomized-Controlled Study

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ABSTRACT

This study aimed to investigate the effect of density and number of sessions extracorporeal shock wave therapy (ESWT) on pain, fatigue, disability, physical function, and quality of life in patients with plantar fasciitis (PF). Between September 2019 and December 2019, a total of 94 patients with the diagnosis of PF were included in the study. All patients were randomly divided into 3 groups. Group 1 ($n = 33$) received a total of 7 sessions of high-energy flux density (H-ESWT) (0.26 mJ/mm^2) , group 2 ($n = 31$) received a total of 3 sessions of H-ESWT (0.26 mJ/mm^2), group 3 ($n = 30$) received total of 7 sessions of low-energy flux density (<0.08 mJ/mm^2) with 3 days interval. At baseline and 1 month after the treatment, the Visual Analog Scale (VAS), Short Form-36, Foot Function Index (FFI), Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue Scale, and Six-Minute Walking Test (6MWT) scores were compared among the groups. Of the patients, 69 were females and 25 were males with a mean age of 45.0 ± 8.43 (range, 25-67) years. There were no statistically significant differences in the age, sex, demographic characteristics, and baseline VAS, FFI, 6MWT, and FACIT scores between the groups ($p > .05$). However, there was a statistically significant decrease in the VAS, FACIT, and FFI scores in all groups after treatment compared to baseline, although only the 6MWT, and Short Form-36 subscale scores were statistically significantly higher ($p < .05$). There was also a statistically significant difference in the scale scores in Group 1 versus Group 2 and in Group 2 versus Group 3. Our study results suggest that H-ESWT for high number of sessions is more effective than LESWT for low number of sessions on pain, quality of life, physical function, fatigue, and disability in patients with PF.

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Plantar fasciitis (PF) is one of the most common causes of heel pain which accounts for 10% of adult population in their lifetime and may be bilateral in about 20% to 30% of patients (1-3). It is characterized by excess strain over the medial calcaneal tubercle and pain which persists after a night sleep or prolonged inactivity and increases throughout walking, running, and long-time standing (4-6). Although the etiology of PF has not been clearly understood yet, it has been proposed to be multifactorial and biomechanical overstress of calcaneal tuberosity and increased strain over the calcaneal tubercle of the plantar fascia due to prolonged walking or standing have been blamed (4-8).

Extracorporeal shock wave therapy (ESWT) is noninvasive procedure for the treatment of musculoskeletal system diseases including PF, calcific tendinopathies, and lateral and medial epicondylitis (9-12). Several studies have demonstrated the efficacy of ESWT in PF patients (13-15). The mechanism of action of ESWT on PF is still unclear, although the energy crisis hypothesis may explain how ESWT affects other conditions and disrupted the nonmyelinated fibers to relieve musculoskeletal pain and to decrease the production of substance P level at the dorsal root ganglia (16,17). The mechanisms through which ESWT exerts its therapeutic effects are thought to be increased tissue perfusion, increased vascularization, and altered pain stimuli in ischemic tissues by an increased intake of calcium.

Mechanical stimulus provided by ESWT promotes biological healing processes through a mechanotransduction pathway which converts physical forces into biomechanical signals which are later integrated into cellular responses. Although the exact mechanism of ESWT has not been fully understood yet, several mechanisms have been proposed. In a study, ESWT prevented overstimulation of the nerves and nociceptors and enhanced the blood flow, resulting in pain relief through reduced muscle spasms and stiffness (18)

In the present study, we aimed to investigate the effect of density and number of sessions ESWT on pain, fatigue, disability, physical function, and quality of life in patients with PF.

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Patients and Methods

Study design and study population

This double-blind, prospective, randomized-controlled clinical study was conducted at University of Health Sciences, Umraniye Training and Research Hospital, Physical Therapy and Rehabilitation outpatient clinic between August 2019 and October 2019. Patients with the diagnosis of PF were included in the study. The diagnosis of PF was made based on clinical and radiographic evidences. The presence of plantar heel pain in the first steps in the morning or through the daytime, physical examination findings (pain at the site of plantar fascial insertion to the heel bone by palpation) and positive dorsiflexion-eversion test Inclusion criteria were as follows: age of ≥18 years; having a documented diagnosis of PF; persistent pain at least for 3 months as assessed by a Visual Analog Scale (VAS) score of >3 (19); having a body mass index of <30 kg/m^2; and having unilateral PF (only right-sided affected patients were included to avoid any bias in the results). Exclusion criteria were as follows: having no prior treatment including ESWT, steroid or other injections (platelet-rich plasma, lidocaine, prolotherapy, dry needling, or neural therapy) within the past 6 months; having a diagnosis of other ankle and foot diseases such as inflammatory diseases, orthopedic conditions which limit mobility; having a history of ankle and foot surgery; being professional athlete; and having a malignancy, pregnancy, cardiac pacemaker, local infections, severe cardiac and renal diseases, diabetes mellitus, coagulation problems, vestibular disorders, and neurological deficits affecting the lower limbs. To rule out other diseases, all patients underwent a detailed physical and neurological examination. In addition, ankle/foot anteroposterior and lateral plain radiographs and ankle/foot magnetic resonance imaging (MRI) scans were obtained. Radiographs was performed on all patients, while MRI was taken only limited number of patients for differential diagnosis. A written informed consent was obtained from each patient. The study protocol was approved by the University of Health Sciences, Umraniye Training and Research Hospital Ethics Committee. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Randomization

Randomization was performed 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. In addition, the patients were blinded to which treatment arm they were in. The patients were randomly divided into 3 groups. A total of 94(N = 94) patients were included in this study. Group 1 (n = 33) received a total of 7 sessions of high-energy flux density (H-ESWT) (0.26 mJ/mm^2) with 3 days interval. Group 2 (n = 31) received a total of three sessions of H-ESWT (0.26 mJ/mm^2) with 3 days interval. Group 3 (n = 30) received a total of 7 sessions of low-energy flux density (L-ESWT) (<0.08 mJ/mm^2) with 3 days interval. All groups were matched for sociodemographic characteristics. The study flow chart is shown in the Fig.

Interventions

All patients treatments were performed by senior author (Ö.G.) and coauthor (G.B.). All groups received ESWT using Modus Focused ESWT Device (İnceler Medikal, Ankara, Turkey). In each session, 3000 focused extracorporeal shock waves were applied at a frequency of 8 Hz. Each group were given the relevant home-based exercises on a regular basis for 10 days which included gastrocnemius and gastrosoleus stretching, Achilles tendon stretching, and plantar fascia stretching exercises. 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 do 10 repetitions of each set for 2 times daily for 10 days. Patients were instructed to do stretching exercises on days without ESWT treatment. All patients were advised to wear comfortable shoes without a special footbed to prevent the effectiveness of ESWT treatment throughout the treatment. No analgesics or anesthetics were used during ESWT.

Outcome measurements

All pre- (at baseline) and post-treatment (at 1 month) measurements were evaluated by a senior author (Ö.G.). The VAS was used to evaluate pain severity. The score ranges from 0 to 10, and 0 indicates no pain, while 10 indicates unbearable pain.

The quality of life was evaluated using the Short Form-36 (SF-36) which consists of 8 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 (PhyF), limitations of daily activities by difficulty in physical role, 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 (20).

The Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue Scale is a patient-reported outcome instrument to evaluate whether patients are able to maintain their daily activities. It ranges from 0 to 52, and higher scores indicate lower energy and difficulty in daily living activities (21).

The Six-Minute Walking Test (6MWT) is a simple and valid method to evaluate exercise capacity (22,23). A 30-m-long hallway was marked with 3-m intervals and a stopwatch was used during the test. The patients were expected to wear comfortable clothing and appropriate shoes. A light meal was allowed, and the patients were advised not to exercise vigorously within 2 hours of the beginning of the test. Blood pressure and pulse measurements were performed before and after the test. The patients were instructed to walk across the 30-m-long hallway for 6 minutes. They were allowed to use their usual walking aids such as cane. Following the completion of the test, the distance walked was recorded in meters. The walking speed was calculated in meters per second.

The Foot Function Index (FFI) is a self-report, foot-specific instrument. It consists of 3 subscale scores: pain (PS, 9 items), disability (DS, 9 items), and activity limitation (AL, 5 items). The score of PS and DS subscales ranges from 0 to 90, while the score of AL ranges from 0 to 50. Higher scores indicate worsening foot health (24).

Statistical analysis

A power analysis was performed using the G*Power version 3.1.0 software (Heinrich Heine University, Düsseldorf, Germany) and the sample size was calculated. To estimate the effect of ESWT, we used data from a pilot study (25) in which ESWT affected SF-36 PF subscale scores (standard deviation [SD] = 21.3), corresponding to an estimated effect size of 0.37. Based on an alpha value of 0.05 for statistical significance, 33 patients in Group 1, 31 patients in Group 2, and 30 patients in Group 3 could achieve 80% statistical power. Finally, a total of 94 patients were planned to be recruited in both groups. Assuming a dropout of 15%, 110 patients were expected to be included.

Statistical analysis was performed using the Statistical Package for the Social Sciences version 25.0 software (IBM Corp., Armonk, New York). Descriptive data were expressed in mean ± SD, or number and frequency. The Kolmogorov-Smirnov 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 Kruskal-Wallis H 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 Spearman correlation analysis was done to analyze possible correlations between the variables. A p value of <.05 was considered statistically significant. All statical analysis was performed by senior author (Ö.G.) and co-author (G.B).

Results

Of a total of 94 (N = 94) patients, 69 (73.40%) were females and 25 (26.60%) were males with a mean age of 45.0 ± 8.43 (range, 25-67) years. There was no significant difference in the baseline demographic characteristics among the groups. No ESWT-related side effects or tissue damage were seen. 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 among the groups (p > .05). However, there was a statistically significant decrease in the VAS scores at 1 month after the treatment in all groups, compared to baseline scores (p < .001), although the decrease was statistically significantly higher in Group 1 (p < .001). In addition, there was a statistically significant increase in the SF-36 subscale scores at one month after the treatment in all groups (p < .001) with a statistically significantly higher increase in Group 1 (p < .001). Pre- and post-treatment VAS and SF-36 scores in the all groups are presented in Table 2.

There was no statistically significant difference in the baseline 6MWT and walking speed, FACIT, FFI-PS, FFI-DS, and FFI-AL scores among the groups (p > .05). However, there was a statistically significant decrease in the FACIT, FFI-PS, FFI-DS, and FFI-AL scores at one month after the treatment in all groups (p < .001) with a statistically significantly higher decrease in Group 1 (p < .001). In addition, there was a statistically significant increase in the 6MWT and walking speed scores at one month after the treatment in all groups (p < .001) with a statistically significantly higher increase in Group 1. Pre- and post-treatment 6MWT, walking speed, FACIT, FFI-PS, FFI-DS, and FFI-AL scores in the all groups are presented in Table 3.

The correlation analysis revealed a strong, positive, and statistically significant relationship between the changes in the VAS scores and changes in the FACIT (r = 0.760), FFI-PS (r = 0.744), FFI-DS (r= 0.707), and FFI-AL (r= 856) scores and a strong, negative, and statistically significant relationship between the changes in the VAS scores and

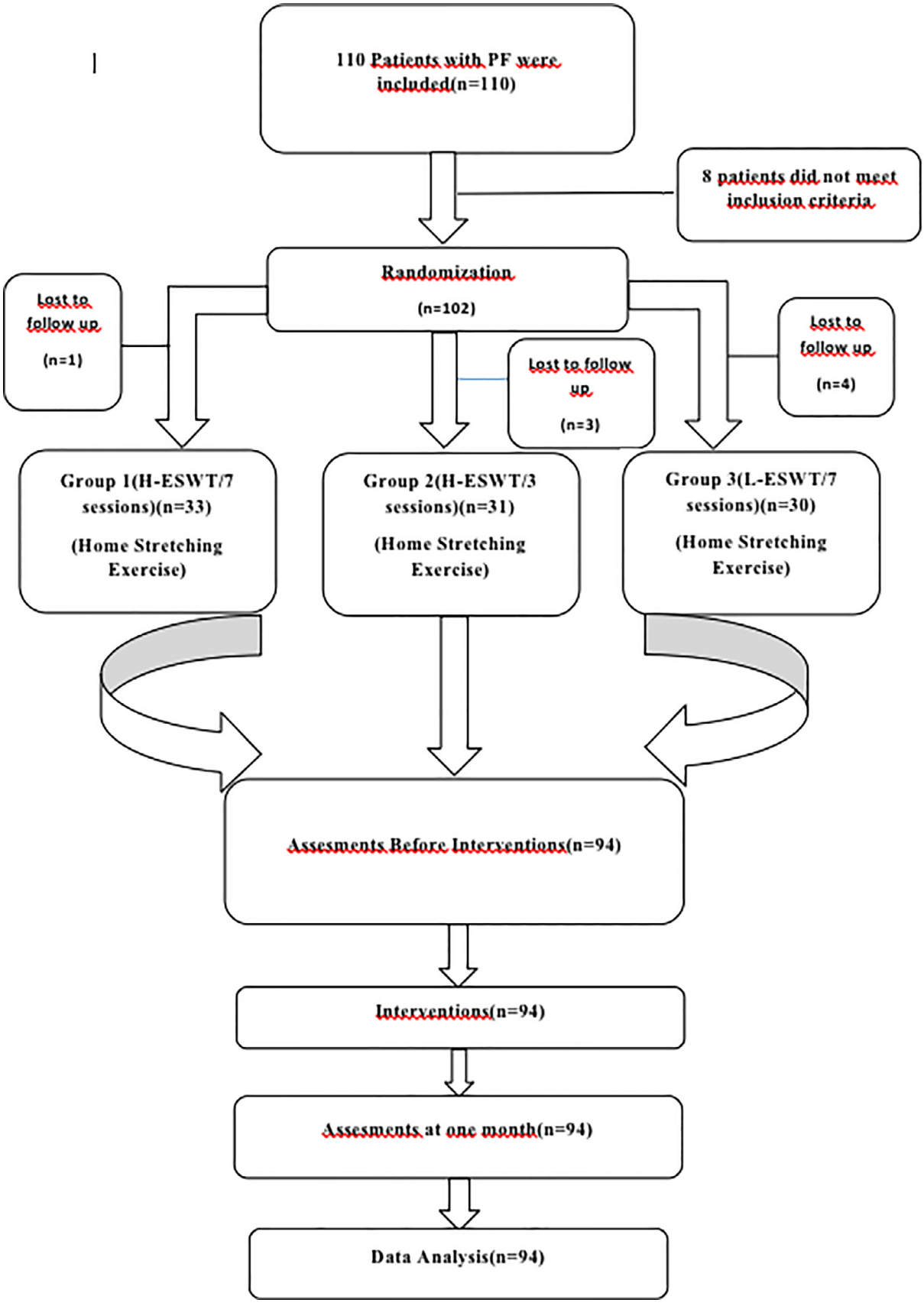

Fig. Study flow chart.

Table 1
Baseline demographic characteristics of the patients

		Group 1 (H-ESWT/7 Sessions) (n = 33)	Group 2 (H-ESWT/3 Sessions) (n = 31)	Group 3 (L-ESWT/7 Sessions) (n = 30)	Total (N = 94)
Age, years, range, (mean ± SD)		28-60 (45.0 ± 8.43)	26-66 (46.8 ± 10.6)	25-67 (46.0 ± 13.0)	25-67 (45.9 ± 10.7)
Sex	Male	6 (%18.2)	5 (%16.1)	14 (%46.7)	25 (%26.6)
	Female	27 (%81.8)	26 (%83.9)	16 (%53.3)	69 (%73.4)
Marital status	Married	26 (%78.8)	25 (%80.6)	27 (%90.0)	78 (%83.0)
	Single	7 (%21.2)	6 (%19.4)	3 (%10.0)	16 (%17.0)
Smoking status	Smoker	18 (%54.5)	24 (%77.4)	12 (%40.0)	54 (%57.4)
	Nonsmoker	8 (%24.2)	3 (%9.7)	8 (%26.7)	19 (%20.2)
Education status	None	7 (21.2)	4 (12.9)	10 (%33.3)	21 (%22.3)
	Read and Write	6 (%18.2)	6 (%19.4)	15 (%50.0)	27 (%28.7)
	Primary school	9 (%27.3)	6 (%19.4)	1 (%3.3)	16 (%17.0)
	Secondary school	12 (%36.4)	13 (%41.9)	7 (%23.3)	32 (%34.0)
	High school	6 (%18.2)	6 (%19.4)	7 (%23.3)	19 (%20.2)

Abbreviations: ESWT, extracorporeal shock wave therapy; SD, standard deviation.

Table 2
Comparison of VAS and SF-36 scores before and after treatment in Groups 1,2,3

			Group 1 (H-ESWT/7 Sessions) (n = 33) Mean ± SD	Group 2 (H-ESWT/3 Sessions) (n = 31) Mean ± SD	Group 3 (L-ESWT/7 Sessions) (n = 30) Mean ± SD	(intergroup) p
VAS		Pretreatment	7.30 ± 1.10	7.8 ± 0.8	6.96 ± 1.24	.012*
		Post-treatment	3.96 ± 1.23	6.2 ± 0.9	6.51 ± 1.1	<.001*
		Pre-post-treatment p†	<.001*	<.001*	<.001*	
SF-36	PhyF	Pretreatment	28.6 ± 6.15	27.4 ± 2.8	30.6 ± 6.5	.059*
		Post-treatment	46.5 ± 8.1	35.3 ± 5.6	32.6 ± 6.6	<.001*
		Pre-post-treatment p†	<.001*	<.001*	<.001*	
	DPR	Pretreatment	31.8 ± 11.3	32.2 ± 11.5	38.8 ± 12.3	.047*
		Post-treatment	60.6 ± 14.0	48.3 ± 12.8	44.1 ± 15.6	<.001*
		Pre-post-treatment p†	<.001*	<.001*	<.001*	
	DER	Pretreatment	36.3 ± 9.7	33.3 ± 0.1	38.8 ± 12.6	.072*
		Post-treatment	46.6 ± 27.8	53.7 ± 16.5	52.2 ± 16.7	<.001*
		Pre-post-treatment p†	<.011*	<.001*	<.001*	
	VT	Pretreatment	26.8 ± 3.9	28.5 ± 4.5	32.1 ± 3.8	.000*
		Post-treatment	47.2 ± 7.5	32.2 ± 3.83	35.0 ± 4.9	<.001*
		Pre-post-treatment p‡	<.001*	<.001*	<.001*	
	MH	Pretreatment	30.4 ± 2.3	31.7 ± 2.9	30.4 ± 3.3	.167*
		Post-treatment	41.2 ± 5.9	34.4 ± 3.17	33.0 ± 3.6	<.001*
		Pre-post-treatment p†	<.001*	<.001*	<.001*	
	SF	Pretreatment	117.4 ± 119.9	93.5 ± 117.6	105.0 ± 117.1	.479*
		Post-treatment	243.5 ± 205.0	185.4 ± 174.9	144.1 ± 157.2	<.001*
		Pre-post-treatment p†	<.003*	<.012*	<.381	
	BP	Pretreatment	253.3 ± 111.5	258.5 ± 116.1	250.6 ± 142.6	.786*
		Post-treatment	260.4 ± 239.0	209.0 ± 166.5	113.0 ± 124.4	<.001*
		Pre-post-treatment p†	<.661*	<.209*	<.007*	
	GH	Pretreatment	28.0 ± 5.9	29.5 ± 4.8	29.8 ± 4.4	.355*
		Post-treatment	41.5 ± 9.9)	34.3 ± 4.95	33.3 ± 4.9	<.001*
		Pre-post-treatment p†	<.001*	<.001*	<.001*	

Abbreviations: H-ESWT, High-energy flux density extracorporeal shock wave therapy; L-ESWT, Low-energy flux density extracorporeal shock wave therapy; VAS, Visual Analog Scale; SF-36 PhyF, Short Form-36 physical functioning; SF-36 DPR, Short Form-36 difficulty in physical role; SF-36 DER, Short Form-36 difficulty in emotional role; SF-36 VT, Short Form-36 vitality; SF-36 MH, Short Form-36 mental health; SF-36 SF, Short Form-36 social functioning; SF-36 BP, Short Form-36 bodily pain; SF-36 GH, Short Form-36 general health; SD, standard deviation.

* $p < .05$.

† Kruskal-Wallis H.

‡ Wilcoxon signed-rank test.

changes in the 6MWT (r= −0.626) and walking speed(r= −0.634) scores after the treatment in Group 1. In addition, there were moderate or strong and negative and positive correlations between the SF-36 subscales and 6MWT, walking speed, FACIT, FFI-PS, FFI-DS, and FFI-AL. The results of the correlation analysis of all scales in the all groups are summarized in Table 4.

Discussion

In the present study, we examined the effect of density and number of sessions ESWT on pain, fatigue, disability, physical function, and quality of life in patients with PF. Our study results showed that H-ESWT for a high number of sessions was more effective than L-ESWT for a low number of sessions on pain, quality of life, physical function, fatigue, and disability in patients with PF.

In previous studies, ESWT uses 3 energy intensity levels: (1) low-energy flux density (EFD <0.08 mJ/mm^2); (2) medium-energy flux density (EFD 0.08-0.28 mJ/mm^2); and (3) high-energy flux density (EFD >0.28 mJ/mm^2) (26-28). However, there is no consensus on the most optimal total amount of energy and density to be used (29,30). It has been well documented that H-ESWT is associated with several side effects such as permanent tendon damage, while L-ESWT produces a lower therapeutic effect (31). In our study, none of the patients experienced such side effects.

Table 3
Comparison of SMWT, Walking Speed, FACIT, FFI-PS, FFI-DS, and FFI-AL scores before and after treatment in Groups 1,2,3

		Group 1 (H-ESWT/7 sessions) (n =33) Mean ± SD	Group 2 (H-ESWT/3 sessions) (n = 31) Mean ± SD	Group 3 (L-ESWT/7 sessions) (n=30) Mean ± SD	(inter-group) $p^{\dagger}$
SMWT	Pretreatment	468.6 ± 42.0	439.3 ± 31.3	448.5 ± 53.0	.022*
	Post-treatment	564.6 ± 49.5	487.9 ± 43.0	456.5 ± 57.5	<.001*
	Pre-post-treatment $p^{\ddagger}$	<.001*	<.001*	<.006*	
Walking Speed	Pretreatment	122.2 ± 29.8	114.5 ± 28.7	112.7 ± 36.9	.070*
	Post-treatment	148.9 ± 78.3	127.5 ± 32.8	119.5 ± 33.2	<.001*
	Pre-post-treatment $p^{\ddagger}$	<.001*	<.001*	<.015*	
FACIT	Pretreatment	26.6 ± 5.2	24.5 ± 3.8	21.4 ± 4.1	.256*
	Post-treatment	18.3 ± 5.0	20.1 ± 3.4	19.5 ± 4.5	<.001*
	Pre-post-treatment $p^{\ddagger}$	<.001*	<.001*	<.001*	
FFI-PS	Pretreatment	44.0 ± 8.7	39.5 ± 8.8	38.5 ± 6.6	.037*
	Post-treatment	29.7 ± 7.9	34.4 ± 8.7	36.1 ± 7.4	<.009*
	Pre-post-treatment $p^{\ddagger}$	<.001*	<.001*	<.001*	
FFI-DS	Pretreatment	49.1 ± 7.7	45.8 ± 7.8	38.4 ± 6.7	.004*
	Post-treatment	32.8 ± 4.9	37.7 ± 6.3	36.1 ± 6.8	<.000*
	Pre-post-treatment $p^{\ddagger}$	<.001*	<.001*	<.001*	
FFI-AL	Pretreatment	27.2 ± 2.8	27.3 ± 2.6	27.1 ± 6.9	.734*
	Post-treatment	17.4 ± 3.8	23.5 ± 2.7	24.8 ± 7.7	<.001*
	Pre-post-treatment $p^{\ddagger}$	<.001*	<.001*	<.001*	

Abbreviations: H-ESWT, High-energy flux density extracorporeal shock wave therapy; L-ESWT, Low-energy flux density extracorporeal shock wave therapy; FACIT, Functional Assessment of Chronic Illness Therapy-Fatigue Scale; FFI-PS, Foot Function Index pain subscale; FFI-DS, Foot Function Index disability subscale; FFI-AL, Foot Function Index activity limitation subscale; SD, standard deviation; SMWT, six minute walk test.

* $p < .05$.

† Kruskal-Wallis H.

‡ Wilcoxon signed-rank test.

In a study conducted by Ugurlar et al (32), H-ESWT for 3 sessions was used in PF patients and improved VAS scores and revised FFI subscale scores were achieved at 12 months after the treatment. In another study, Akinoglu et al (14) divided the patients into 3 groups to receive either H-ESWT for 3 sessions with 2000 pulses or ultrasound for 7 sessions or home-based exercises alone. The authors observed a statistically significant improvement in the FFI subscales in all groups after the treatment, although it was more significant in the ultrasound group. However, there was no significant difference in the functional test results. This can be explained by the lower number of sessions and pulses. In another study, Morral et al (33) investigated whether the appearance of different ESWT devices affected clinical outcomes in chronic PF and randomized the patients to receive either a standard ESWT device or a standard but modified ESWT device with a more sophisticated appearance or a standard but modified ESWT device with a more austere appearance for 3 sessions at medium-energy flux density (M-ESWT, 0.18 mJ/mm^2). There was a statistically significant improvement in the VAS and FFI scores in all groups, although there was no statistically significant difference among the groups. This finding confirms that M-ESWT is an effective modality in PF even for a low number of sessions. Furthermore, Valdatpour et al (34) administered L-ESWT for 4 sessions and found a decline in the plantar fascia thickness with decreased VAS, Roles and Maudsley scores. This finding also suggests that, despite the use of L-ESWT for a low number of sessions, ESWT is an effective method in the treatment of PF. Similarly, Bicer et al (35) reported significant improvements in the functional parameters, pain severity, and MRI findings with M-ESWT for 3 sessions. In another study including 50 patients, Ibrahim et al (36) divided the patients into 2 groups to receive either M-ESWT and sham-ESWT for a total of 2 sessions. At the end of the study, the VAS and RMS scores were significantly improved with M-ESWT and no improvement was observed in the sham-ESWT group. There are also several studies showing a significant improvement in the pain scores with M-ESWT compared to placebo (37-39). In a meta-analysis, 13 trials including 637 PF patients who were treated with ESWT and 548 patients who were treated with other treatment modalities were analyzed (40). The patients treated with ESWT had a significant improvement in the modified RMS and pain scales with better rates of return to work and lower complication rates than the other treatment modalities. In another study including 35 patients, ESWT achieved significant improvements in the physical function and pain severity (41). All these findings support the efficacy of ESWT in the treatment of PF, particularly at high doses.

In a previous study, Chow et al (29) divided 57 patients with chronic heel pain into 3 groups to receive either fixed energy density or maximum tolerable energy density or control treatment (30 impulses at a frequency of 3 Hz at the lowest level [0.03 mJ/mm^2]) once a week for 3 weeks. The maximum tolerable energy density group showed a significant improvement in the FFI and pain scores, while the control group had no improvement after treatment. This finding indicates that the delivery of ESWT with a maximum tolerable energy density is more effective than a fixed energy density. In another study, Cho et al (42) divided the patients into a stabilization exercise group, an ESWT group, and a combined treatment group. All patients received treatment 3 times a week for 4 weeks and 12 sessions in total. The authors found that combined treatment yielded a better improvement in pain and functional scores in myofascial pain syndrome (MPS). Similarly, Gur et al (43) used focused H-ESWT and compared 3 sessions versus a single session of treatment in MPS patients. They reported that 3-session treatment improved pain compared to a single-session protocol. In addition, increased number of ESWT sessions yielded the treatment efficacy in MPS. In a meta-analysis of randomized, placebo-controlled trials, the efficacy of different energy levels of ESWT was examined in the treatment of PF (44). Focused ESWT was found to be more effective than radial ESWT and H-ESWT/M-ESWT were more effective than L-ESWT in the long-term follow-up.

In the present study, we observed significant difference in the SF-36, FACIT, 6MWT, and FFI scores at 1 month after the treatment in Group 1 versus Group 2 and in Group 2 versus Group 3. 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, it is recommended to use ESWT at a high energy and for a high number of sessions in PF patients. Of note,

Table 4
Correlation analysis of VAS and SF-36 scores with SMWT, Walking Speed, FACIT, FFI-PS, FFI-DS and FFI-AL scores 1 month after treatment in Groups 1,2,3.

Group	At 1-Month Post-treatment		SMWT	Walking Speed	FACİT	FFI-PS	FFI-DS	FFI-AL
Group 1(H-ESWT/7 sessions) (n = 33)	VAS	r	−0.626*	−0.634	0.760*	0.744*	0.707*	0.856*
		p	<.001*	<.001*	<.001*	<.001*	<.001*	<.001*
	SF-36 PhyF	r	0.522*	0.505*	−0.645*	−0.734*	−0.716*	−0.809*
		p	.003*	.004*	<.001*	<.001*	<.001*	<.001*
	SF-36 DPR	r	0.389*	0.393*	−0.674*	−0.768*	−0.738*	−0.766*
		p	.034*	.032*	<.001*	<.001*	<.001*	<.001*
	SF-36 DER	r	0.311	0.249	−0.275	−0.351	−0.429*	−0.398*
		p	.094	.184	.142	.057	.018*	.029*
	SF-36 VT	r	0.510*	0.513*	−0.453*	−0.376*	−0.259	−0.573*
		p	.004*	.004*	.012*	.040*	.167	.001*
	SF-36 MH	r	0.391*	0.391*	−0.771*	−0.813*	−0.814*	−0.788*
		p	.033*	.033*	<.001*	<.001*	<.001*	<.001*
	SF-36 SF	r	0.061	−0.013	−0.196	−0.418*	−0.315	−0.170
		p	.750	.947	.299	.021*	.090	.368
	SF-36 BP	r	0.211	0.239	−0.508*	−0.451*	−0.568*	−0.432*
		p	.264	.204	.004*	.012*	.001*	.017*
	SF-36 GH	r	0.185	0.194	−0.392*	−0.490*	−0.487*	−0.537*
		p	.329	.304	.032*	.006*	.006*	.002*
Group 2(H-ESWT/3 sessions) (n =31)	VAS	r	0.088	−0.183	0.338	0.027	0.082	0.138
		p	.628	.309	.054	.882	.649	.443
	SF-36 PhyF	r	0.263	0.051	−0.179	−0.090	0.059	−0.593*
		p	.140	.777	.318	.618	.745	<.001*
	SF-36 DPR	r	−0.071	−0.105	−0.027	0.035	−0.104	−0.150
		p	.696	.561	.884	.848	.563	.405
	SF-36 DER	r	−0.059	−0.342	0.086	0.053	−0.079	−0.045
		p	.743	.051	.633	.768	.661	.805
	SF-36 VT	r	−0.065	0.080	−0.302	−0.297	−0.078	0.339
		p	.720	.656	.088	.093	.667	.053
	SF-36 MH	r	0.121	0.198	0.153	−0.213	0.395*	−0.186
		p	.503	.269	.397	.234	.023*	.300
	SF-36 SF	r	0.009	−0.149	0.149	0.282	−0.109	−0.093
		p	.962	.409	.407	.112	.545	.605
	SF-36 BP	r	−0.181	−0.301	0.318	−0.077	−0.035	−0.074
		p	.315	.089	.071	.669	.848	.683
	SF-36 GH	r	0.063	0.001	−0.057	0.150	0.049	0.282
		p	.728	.994	.754	.404	.789	.112
Group 3(L-ESWT/7 sessions) (n = 30)	VAS	r	−0.180	−0.149	−0.167	0.019	0.079	−0.194
		p	.331	.423	.368	.918	.675	.295
	SF-36 PhyF	r	−0.260	−0.246	−0.012	0.253	−0.095	−0.027
		p	.158	.182	.947	.170	.611	.887
	SF-36 DPR	r	−0.143	−0.136	0.002	−0.026	0.033	−0.184
		p	.442	.467	.993	.891	.859	.321
	SF-36 DER	r	−0.022	−0.074	−0.087	−0.164	0.000	−0.008
		p	.905	.691	.642	.379	1.000	.968
	SF-36 VT	r	−0.063	−0.019	0.009	0.077	0.021	−0.273
		p	.738	.917	.962	.679	.910	.137
	SF-36 MH	r	0.131	0.012	−0.100	0.255	0.054	−0.064
		p	.483	.950	.593	.166	.774	.732
	SF-36 SF	r	0.091	−0.002	−0.116	−0.153	0.033	0.043
		p	.625	.992	.533	.413	.862	.819
	SF-36 BP	r	−0.075	−0.009	0.244	−0.151	−0.189	0.143
		p	.690	.964	.186	.417	.307	.443
	SF-36 GH	r	0.380*	0.333	−0.267	−0.329	0.060	−0.020
		p	.035*	.067	.147	.071	.748	.915

Abbreviations: H-ESWT, High-energy flux density extracorporeal shock wave therapy; L-ESWT, Low-energy flux density extracorporeal shock wave therapy; VAS, Visual Analog Scale; SF-36 PhyF, Short Form-36 physical functioning; SF-36 DPR, Short Form-36 difficulty in physical role; SF-36 DER, Short Form-36 difficulty in emotional role; SF-36 VT, Short Form-36 vitality; SF-36 MH, Short Form-36 mental health; SF-36 SF, Short Form-36 social functioning; SF-36 BP, Short Form-36 bodily pain; SF-36 GH, Short Form-36 general health; FACIT, Functional Assessment of Chronic Illness Therapy-Fatigue Scale; FFI-PS, Foot Function Index pain subscale; FFI-DS, Foot Function Index disability subscale; FFI-AL, Foot Function Index activity limitation subscale; SMWT, six minute walk test.
Spearmen correlation analysis.
* $p < .05$.

significant improvements in all scales in Group 1 than Group 3 support the concept that high-energy has a more important role than the number of sessions in ESWT. In our study, no side effects were observed in patients in the group receiving H-ESWT treatment, as in some other studies. This may be the determination of the lowest basal value of the H-ESWT treatment at 0.28 mJ/mm^2 in patients receiving H-ESWT treatment or stretching exercises as in other studies in the days after treatment (14,34).

Nonetheless, there are some limitations to this study. Relatively small sample size and the presence of a nontreatment group might have affected the results. In addition, ESWT was unable to compare with another treatment modality, as the efficacy of the ESWT has been proven in previous studies. Finally, we only evaluated treatment results at one month. Therefore, we 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 quality of life, physical function, fatigue, and disability in patients with PF. To the best of our knowledge, this is the first study to examine the efficacy of session number and density of ESWT in PF patients which would be helpful to identify the most optimal density and session number in this patient population. Based on these findings, we suggest that H-ESWT for a high number of sessions is effective than L-ESWT for low number of sessions in patients with PF and high-energy has a more important role than the number of sessions in ESWT.

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