



An Evaluation of the Efficacy of ESWT and Placebo-ESWT Treatment for Chronic Plantar Fasciitis

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Abstract

The aim of this study was to evaluate the short-term effectiveness on heel pain and daily activities of extracorporeal shock wave therapy (ESWT) and placebo-ESWT in the treatment of chronic plantar fasciitis. A total of 42 patients diagnosed with chronic plantar fasciitis ongoing for at least 6 months were randomly separated into 2 groups. Group 1 (study group, n=21) were administered a total of 5 sessions of ESWT treatment at once a day for days with an EMS (Electro Medical System) Swiss DolorClast Master ESWT device at frequency 10-15 Hz, 2-3 bar pressure with 2000 shocks per session. Group 2 (control group, n=21) were administered placebo-ESWT. The pain levels were evaluated with a Visual Analog Scale (VAS) and the heel pain together with range of movement and activities with Roles-Maudsley (RM) scoring. Comparisons were made of the values pre-treatment and at 1 week and 5 weeks post-treatment. In the VAS values of the study group, a decrease was determined of 43.39% in post-treatment week 1 and of 70.37% in week 5 compared to pre-treatment values. The RM pain score reduced by 28.4% in week 1 and by 56.79% in week 5. In the control group, the VAS scores reduced by 17.13% and 16.03% and the RM scores by 8.86% and 11.4% respectively at weeks 1 and 5 post-treatment. The reductions in the treatment and control groups were found to be statistically significant and when the changes were compared between the two groups, the differences were found to be statistically significant. The treatment group was determined to have made statistically significantly more improvement than the control group. ESWT was seen to be a safe and effective treatment choice with short-term efficacy in the treatment of chronic plantar fasciitis.

Keywords: ESWT, placebo-ESWT, chronic plantar fasciitis.

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Introduction

Plantar fasciitis is a degenerative syndrome which occurs as a result of repeated trauma to the plantar fascia on the calcaneus [1]. It has been reported as the most common cause of inferior heel pain in adults [2] and is seen in approximately 10% of the general population [3]. Although the etiology is not completely known, it is thought to be multi-factorial. It is thought to occur as a result of repeated microtrauma in the calcaneus medial tubercle which then results in an inflammatory process with the effect of traction forces, fibrosis and degeneration [4].

Various conservative treatment methods are applied in the treatment of plantar fasciitis. Approximately 90% of patients are treated successfully with non-surgical methods [5]. The conservative methods applied in plantar fasciitis treatment include non-steroid anti-inflammatory drugs (NSAID), orthotic insoles, heel supports, orthoses, night splints, local cortisone injections, bandaging, stretching exercises and physical therapy.

In 2000, the USA Food and Drug Administration (FDA) approved the use of extracorporeal shock wave therapy (ESWT) as an electro-hydraulic device in the treatment of chronic plantar fasciitis [6].

ESWT is a treatment method based on providing treatment by focusing high amplitude shock waves on a specific part of the body. Although the mechanism of the effect of ESWT has not been completely determined, the stimulation of the nerve endings in the painful points is thought to cause an inhibition in the pain reflex (hyper stimulation analgesia). In addition, ESWT has been shown to provide neovascularization in tissues [7], to stimulate expression of some mediators such as transforming growth factor beta-1 (TGF- β 1), and insulin-like growth factor 1 (IGF-1) and to start the healing process [8].

There have been many studies evaluating the efficacy of ESWT in the treatment of plantar fasciitis and although the majority of these studies have reported effective and successful results [5,7,9-20], some researchers have stated that ESWT has had no effect [6,21-23].

As there have been conflicting results on the subject of ESWT efficacy in the treatment of chronic plantar fasciitis, this study was designed to contribute to the available data by

comparing the efficacy observed in the short-term of ESWT and placebo-ESWT in the treatment of patients with chronic plantar fasciitis.

Materials and Methods

The study comprised male and female patients aged over 18 years who presented at our clinic between October 2014 and April 2015 with heel pain of ≥ 4 according to VAS which had been ongoing for longer than 6 months, where the pain was determined with palpation over the medial calcaneal tubercle and when no benefit had been gained from at least 3 conservative methods (such as NSAID, heel cushions or orthoses, physical therapy, stretching exercises, corticosteroid injections or bandaging). The presence or absence of calcaneal spurs on direct radiograph was recorded. Patients were excluded if they had undergone physiotherapy and/or steroid injection within the last 6 weeks, if they had a tumoral disease, cardiac arrhythmia or pacemaker, blood coagulation disorders or were receiving anti-coagulant treatment, if a skin lesion, infection or open wound was observed in the area planned for treatment, those determined with neuropathy or radiculopathy findings, fracture sequel in the lower extremity or a metal implant in the application area. In addition, pregnant patients, those with a rheumatism disease (e.g., Ankylosing Spondylitis, Reiter Syndrome, Rheumatoid Arthritis or Psoriatic Arthritis) and those with a history of trauma in the foot area were not included in the study.

In the comparison of 2 groups at a 95% confidence level (Type 1 error share 0.05) and at 80% power (type 2 error share 0.20), the necessary minimum number of patients in each group was calculated as 21. The study comprised 42 willing participant patients aged over 18 years. Informed consent was obtained from all the patients. Approval for the study was granted by the Local Ethics Committee.

The 42 patients diagnosed with chronic plantar fasciitis based on clinical findings and histories were randomly separated into two groups. Lateral radiographs were taken of all patients to determine whether or not calcaneal spurs were present and a record was made of height, weight, body mass index (BMI), age, occupation, educational status, disease history and previous treatments. In the blood tests, evaluation was made for all patients of haemogram, C-reactive protein (CRP), blood glucose, urea, creatine, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels. All the patients in the study group were

administered a total of 5 sessions of ESWT treatment at once a day for 5 days with an EMS (Electro Medical System) Swiss DolorClast Master ESWT device.

Prior to treatment, the point of maximum sensitivity was identified by palpation over the medial calcaneal tubercle in the heel and after the application of ultrasound gel to that point, the application of the treatment was started at a frequency 10-15 Hz, 2-3 bar pressure with 2000 shocks per session to the patients in Group 1. In the same way, for the patients of the control group the point of maximum sensitivity was identified by palpation in the heel and after the application of ultrasound gel to that point, the application of placebo-ESWT was started at a frequency of 0 Hz, 0 bar pressure with 2000 pulses per session. With the pressure applied made by the pneumatic origin ultrasonic waves within the machine used in this treatment, there was radial transmission in the treatment area during the application and local anesthetic was not applied to either group. No additional treatment was administered to any patient.

All the patients were evaluated pre-treatment and at 1st and 5th weeks post-treatment with Visual Analog Scale (VAS) and Roles Maudsley (RM) pain scores. The level of heel pain during daily activities was evaluated with VAS and heel pain together with range of movement and activities were evaluated using RM pain scoring. The changes in the VAS and RM in the treatment group and the placebo group were evaluated at pre-treatment, and at 1st and 5th weeks post-treatment and the differences between the two groups were evaluated statistically. In the statistical evaluation of the data, the paired t-test, the unpaired test, the Pearson Chi-square test and the Fisher Exact Chi Square analysis were used.

Demographic Characteristics of the Patients

The mean age of patients was 47.85±11.59 years in the treatment group and 49.52±10.76 years in the control group. In both groups, 76.2% of the patients were female. No statistically significant difference was determined between the groups in respect of age and gender ($p>0.05$). Occupation of housewife was reported by 66.7% of the patients in the treatment group and by 59.5% of the control group. In the treatment group, mean height was 1.65±0.10 m, mean weight was 82.83±10.09 kg and mean BMI was 30.79±2.41 kg/m². In the placebo group these values were 1.60±0.08 m, 79.33±13.19 kg and 30.76±4.53 kg/m² respectively. No statistically significant difference was determined between the two groups in respect of

height, weight or BMI ($p>0.05$). The educational level of patients in the treatment group was literate in 9.5%, illiterate in 9.5%, primary school in 66.7%, high school in 9.5% and university in 4.8%. In the placebo group, the educational level of patients was literate in 7.1%, illiterate in 7.1%, primary school in 61.9%, high school in 16.7% and university in 4.8%.

The duration of the disease was recorded as 8.3 ± 2.6 months in the treatment group and 9.2 ± 2.8 months in the placebo group. Calcaneal spurs were observed in 47.6% of the patients in Group 1 and in 52.4% of Group 2. No statistically significant difference was determined between the 2 groups in respect of calcaneal spurs or disease duration ($p>0.05$). When previous treatments were evaluated, no statistically significant difference was determined between the groups in respect of the use of NSAID, heel support or insoles or the application of stretching exercises, physical therapy or cortisone injections ($p>0.05$).

Results

In the ESWT treatment group, the mean VAS values at pre-treatment, at the first and second follow-up examinations were 9.00 ± 1.09 , 5.09 ± 1.94 and 2.66 ± 1.42 respectively. The mean RM values at pre-treatment, at the first and second follow-up examinations were 3.85 ± 0.35 , 2.76 ± 0.76 and 1.66 ± 0.79 respectively (Table 1). In comparison with the pre-treatment VAS values, the values at the first and second follow-up examinations were determined to have decreased by 43.39% and 70.37% respectively. In the RM pain scores, a decrease of 28.4% was determined in the first week and of 56.79% at the second follow-up in the fifth week. The changes observed in the RM and VAS scores in the treatment group were evaluated as statistically significant ($p=0.0001$).

In the placebo group, the mean RM pain scores at pre-treatment and at first and second follow-up examinations were 3.76 ± 0.43 , 3.42 ± 0.50 and 3.33 ± 0.65 respectively and the mean VAS scores were 8.61 ± 1.32 , 7.14 ± 1.52 and 7.23 ± 1.89 (Table 2). In comparison with the pre-treatment RM values, the values at the first and second follow-up examinations were determined to have decreased by 8.86% and 11.4% respectively. In the VAS pain scores, a decrease of 17.13% was determined in the first week and of 16.03% at the second follow-up in the fifth week. The changes in the RM pain score in the control group between the pre-treatment value and the first follow-up examination value and between the pre-treatment value and the second follow-up examination value were found to be statistically significant

($p_1=0.005$, $p_2=0.004$). The decreases observed in the VAS pain values at both the first and second follow-up examinations compared to pre-treatment values were found to be statistically significant ($p=0.0001$). When the decreases in the VAS and RM pain scores observed in the treatment group were compared with the values determined in the control group, a statistically significant improvement was observed in the treatment group compared to the placebo group ($p=0.0001$).

In four (19%) of the 21 patients in the treatment group, pain was reported, which started during the application of ESWT and lasted 1-5 minutes. In 1 session, 1 patient (4.8%) developed redness which lasted 2-3 minutes and 1 other patient (4.8%) developed slight ecchymosis in the application area in a single session. No additional treatment was required for any of the side effects, all of which recovered spontaneously.

Table 1. Treatment group-the changes in the RM and VAS values examined with the paired t-test

		n	Mean±SD	SE
Pair 1	RM pain score 1	21	3.86±0.36	0.07825
	RM pain score 2	21	2.76±0.77	0.16768
Pair 2	RM pain score 1	21	3.86±0.36	0.07825
	RM pain score 3	21	1.67±0.79	0.17366
Pair 3	VAS 1	21	9.00±1.09	0.23905
	VAS 2	21	5.09±1.95	0.42485
Pair 4	VAS 1	21	9.00±1.09	0.23905
	VAS 3	21	2.67±1.43	0.31117

Pre-treatment values= RM pain score 1 and VAS 1;

Post-treatment first follow-up (week 1)= RM pain score 2 and VAS 2

Post-treatment second follow-up (week 5)=RM pain score 3 and VAS 3

Table 2. Placebo group-the changes in the RM and VAS values examined with the paired t-test

		n	Mean±SD	SE
Pair 1	RM pain score 1	21	3.76±0.44	0.09524
	RM pain score 2	21	3.43±0.51	0.11066
Pair 2	RM pain score 1	21	3.76±0.44	0.09524
	RM pain score3	21	3.33±0.66	0.14365
Pair 3	VAS 1	21	8.62±1.32	0.28848
	VAS 2	21	7.14±1.53	0.33299
Pair 4	VAS 1	21	8.62±1.32	0.28848
	VAS 3	21	7.24±1.89	0.41349

Pre-treatment values = RM pain score 1 and VAS 1;

Post-treatment first follow-up (week 1) = RM pain score 2 and VAS 2

Post-treatment second follow-up (week 5) =RM pain score 3 and VAS 3

Discussion

Many placebo-controlled clinical studies have been published reporting that ESWT is a successful treatment in the treatment of plantar fasciitis with success rates reaching 94% [5,10-17,19,20]. However, some researchers have reported that ESWT showed no difference in effect from a placebo in the treatment of plantar fasciitis [6,21-23]. In addition, differences have been found in respect of patient selection criteria, the amount of energy applied in treatment, the localization methods of shock waves and the number of shocks and repeated shocks. In this study an evaluation was made of the short-term efficacy of ESWT and placebo-ESWT on heel pain and daily living activities.

The majority of the patients in the current study were middle-aged female housewives with a high BMI. These findings are in parallel with those of a study by Roxas in which plantar fasciitis was seen more often in females aged 40-60 years and obesity (especially BMI>30) was indicated as a risk factor related to plantar fasciitis [4]. Similarly, Ozdemir et al found a positive correlation between BMI and plantar fasciitis [24].

Although calcaneal spurs are observed at a high rate in plantar fasciitis cases, it has been reported that there is no relationship between the presence and size of spurs and clinical findings [25] and calcaneal spurs have been determined in 27% of asymptomatic subjects [3]. In studies by Prichasuk and Subhadrabandhu, the incidence of calcaneal spurs was determined as 65.9% in patients with plantar heel pain and 15.5% in normal cases [26]. In the current study, calcaneal spurs were determined in 47.6% of the treatment group and in 52.4% of the control group. This difference may be due to low numbers in the study group.

In a prospective, randomized, placebo-controlled, double-blind study by Ogden et al, a success rate of 56% was determined in the 3rd month in chronic plantar fasciitis cases [10]. In a meta-analysis by Ogden et al of chronic plantar fasciitis cases unresponsive to conservative treatment, it was recommended that ESWT be selected before surgical treatment or even before cortisone injection [27].

In a prospective, randomized, placebo-controlled, double-blind multi-center study by Buch et al, it was reported that ESWT provided a significant improvement in RM pain score and side-effects such as local swelling and petechial related to the treatment were rarely seen [11]. In

the current study, pain, redness and ecchymosis in the treatment application area were observed in very few cases in the treatment group and as no additional treatment was required for any side-effect, ESWT can be considered a safe treatment with a low rate of side-effects.

Wang et al followed up a treatment group for 60-72 months and a control group for 34-64 months to examine the long-term effects of ESWT in a placebo-controlled study. Significant improvements were observed in pain and function and as a result it was reported that ESWT was a safe and effective method for the treatment of plantar fasciitis [19].

In the treatment of chronic persistent plantar fasciitis, Gerdesmeyer et al applied radial effect ESWT (EMS Swiss DolorClast) treatment at 0.16 mj/mm^2 and 2000 shocks for 3 sessions at intervals of 2 weeks \pm 4 days. In this placebo-controlled, randomized multi-center study of 245 patients, the application was made to the placebo group by a special piece on the device blocking the shockwaves. At the 3-month evaluation, the ESWT was reported to have had an effect on pain, function and quality of life of the patients and at 12th months this effect had increased and continued. At the 12th week the success rate was reported as 61.0% in the treatment group and 42.2% in the placebo group with improvements in the total VAS score of 72% in the treatment group and 44.7% in the placebo group [5]. Although the results of the current study are consistent with those of the previously reported studies, the effect on the placebo group in the current study was lower. The reason for this difference could be that there were only 42 patients in the current study, that Gerdesmeyer et al evaluated daily activity together with first step pain or in the application of the placebo with the dolorimeter. However, the results of both studies evaluated radial ESWT as effective.

In a study of 50 patients by Ibrahim et al, the patients in the treatment group were administered with a total of 2 sessions one week apart of shock waves at 8 Hz frequency, 3.5 bar pressure, 0.16 mj/mm^2 energy and 2000 shocks. After 4 weeks the VAS score in the treatment group was determined to have improved by 92.5%, at 12th weeks by 87.3% and at 24th weeks by 93.9%. The RM score at the same time points improved by 68.1%, 61.7% and 64.9% respectively [20]. In the placebo group, the VAS scores were observed to have improved by 15.2% at 4th weeks, 13.5% at 12th weeks and 17% at 24th weeks and the RM scores improved by 6.3%, 16.8% and 16.8% respectively. In the current study, although a statistically significant decrease was determined in the VAS and RM pain scores evaluated in

the 1st and 5th weeks, with the applied shock wave frequency, higher number of sessions and frequency and lower pressure, a smaller effect was determined in both the treatment and control groups. This difference may be due to differences in the treatment applied and the evaluation of the VAS score. In the current study, the level of pain in daily living activities was evaluated. However, despite these differences, radial effect ESWT was found to be safe and effective in the treatment of chronic plantar fasciitis in this study.

In prospective, randomized, placebo-controlled studies by Buchbinder, Speed and Haake et al, it was stated that ESWT showed no difference from the placebo in the treatment of plantar fasciitis [6,22,23]. Buchbinder et al reported that although improvements were observed in pain, function and quality of life in both the treatment and placebo groups after 6 and 12 weeks of ESWT treatment in a study of 166 chronic plantar fasciitis patients, no significant difference was determined in the cumulative intervals [6]. In studies by Haake et al, success rates were reported of 34% in the ESWT group and 30% in the placebo group after 12 weeks and ESWT was reported to have no effect in the treatment of chronic plantar fasciitis. In the same study, after 1 year of follow-up the success rates were similarly reported as 81% in the ESWT group and 76% in the placebo group and it was concluded that the disease could enter spontaneous remission or it could be associated with additional conservative treatment methods and the long-term placebo effect [23].

In a study by Marks et al, ESWT was administered at 500 shocks in the first session then in the 2nd and 3rd sessions, 0.16 mj/mm² and 2000 shocks. Success was reported at 56.2% in the ESWT treatment group and at 44.4% in the placebo group, with no statistically significant difference between the two groups [21].

Weil et al compared ESWT in chronic plantar fasciitis cases and cases where percutaneous plantar fasciotomy was applied. After a mean follow-up period of 8.4 months, no difference was determined between the groups and it was indicated that ESWT could be used before the surgery [7].

In studies by Othman et al comparing ESWT and endoscopic plantar fasciotomy (EPF), it was reported that the EPF group were able to return to daily activities at mean 6 weeks and the ESWT group at mean 2 weeks [28]. Despite obtaining good results in the EPF group, it can lead to minor complications and therefore it was reported that ESWT could be a primary

treatment method before surgical applications in the treatment of chronic plantar fasciitis where conservative treatment methods have not been successful, because of the lack of morbidity and the early return to daily living activities.

In a study of athletes with chronic plantar fasciitis by Saxena et al, a statistically significant improvement was observed in the VAS and RM pain scores in both the ESWT and EPF groups compared with the placebo-ESWT group, which was more evident in the EPF group. Due to the early return to activity, ESWT was recommended especially before surgery in athletes with chronic plantar fasciitis [29].

Comparisons of studies in literature are difficult because of the differences in patient selection, whether or not ESWT has been used together with physical therapy methods, the amount of energy applied the methods of localization of the shock waves, the numbers of shocks and numbers of repetitions.

From the results of this study, it was concluded that ESWT was effective on heel pain and daily living activities in a short period. The effect which started in the first week and continued to increase in the 5th week was evaluated as statistically significant compared to the placebo. Further comparative studies with a greater number of subjects are required to determine the protocol for the most effective application in terms of effective dose, frequency of application and number of sessions.

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