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Low-Energy Radial Extracorporeal Shock Wave Therapy for Chronic Plantar Fasciitis: A Randomized Control Trial

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Abstract: The purpose of this study was to investigate and clarify the value of low-energy radial extracorporeal shock-wave therapy (rESWT) to become a routine modality in the treatment of pain and functional disability associated with chronic plantar fasciitis**.** This study was double-blind, randomized, placebo-controlled trial. Forty six adult patients with unilateral plantar fasciitis were randomly assigned into two equal groups. The active treatment group (group I) received a total 3 treatments of shock wave exposure (3x2000 impulses) with 0.16 mJ/mm^2, 2.5 bars and frequency of 8Hz given at weekly interval and the placebo group (group II) received the identical treatment protocol but shame exposed to shock-wave therapy. Pain and limitation of foot function were measured by Visual Analog Scale and Ankle-Hind Foot Scale respectively. The results revealed significant reduction of pain in both groups after 3 weeks of treatment (P=0.000 and 0.005 respectively). However there was a significant improvement in foot function in group I both after 3 weeks of treatment and 6weeks of follow up (P=0.000). Despite the small number of patients in this trial, low-energy rESWT was an effective non-invasive treatment method for chronic plantar fasciitis and may help the patients to avoid surgery.

Key wards: Plantar fasciitis · Low-energy radial extracorporeal shock wave therapy · rESWT

INTRODUCTION

Plantar fasciitis is defined as a tensile overload of the plantar fascia at its origin on the medial tubercle of the calcaneus [1]. The plantar fascia is a thick fibrous tissue on the bottom of the foot that protects sensitive plantar structures such as nerves, vessels, muscles and tendons and in addition, is responsible for maintaining the plantar arch. The symptoms of plantar fasciitis usually start as a dull intermittent pain that most often progress to a sharp persistent pain with the first steps in the morning or after period of prolonged sitting. This pain is aggravated by continuous weight bearing and becomes progressively more sever. Its onset is insidious and not always associated with a specific incident or trauma [2]. The etiology of plantar fasciitis is unknown and probably multifactorial [3]. Plantar fasciitis is the most common foot disorder affected men and women of middle age equally [4]. Treatment advocated for plantar fasciitis have included rest, ice, stretches, nonsteroidal anti-inflammatory drugs (NSAIDs) [5], corticosteroid injection, iontophoresis of dexamethasone and various orthosis [6]. However, evidence of the effectiveness of all these treatment modalities is limited due to lack of well-designed and conducted comparative studies [7].

Radial extracorporeal shock wave therapy rESWT has been introduced into medicine as an effective and easy method to apply shock wave technology [8,9]. It represents an alternative to focused shock wave treatment, allowing for a broader application. Radial shock waves are generated ballistically by accelerating a bullet to hit an applicator, which transforms the kinetic energy into radially expanding shock waves [8, 9]. Compared with these radial shock waves, the focused shock waves show deeper tissue penetration with significantly higher energies concentrated to a smaller focus [8-12]. Despite numerous publications and clinical trials one orthopedic application of shock wave therapy (SWT), which still remains highly equivocal, is the treatment of chronic plantar fasciitis [13] and much controversy exists surrounding its mechanism of action, treatment protocol and clinical efficacy [14].

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The SWT has been used for the management of plantar fasciitis when conventional physical therapy was not effective in relieving pain and other symptoms. Although the application of low energy SWT to treat musculoskeletal disorders is controversial, there has been some limited, short term evidence of its effectiveness for treatment of chronic plantar fasciitis [14, 15].

In a review of the current published literature on the use of SWT for treatment of plantar fasciitis, several clinical trails were found. Among a plethora of nonrandomized publications, there are only six placebo-controlled trails which have reported extremely variable results [16]. A meta-analysis done by Ogden *et al*. [17] found that those published studies that fulfilled the criteria for acceptable methodology with sufficient duration showed that direct application of shock waves to the origin of the plantar fascia is a safe and effective non-surgical method for treating chronic, recalcitrant heel pain syndrome [18]. However other studies [19-22] have reported no statistically significant differences in the degree of improvement between groups on measured outcomes.

Rompe *et al*. [22] concluded that future research is needed to study whether shock wave therapy is appropriate to introduce earlier in the care pathway plan of plantar fasciitis patients.

This highlights the need for investigation using solid randomized prospective and confirmatory clinical trails. To further enhance results shown in the previous studied using SWT, the present study was designed as confirmatory evidence trial to investigate and clarify the value of low-energy rESWT to become a routine modality in the treatment of pain and functional disability associated with chronic plantar fasciitis.

MATERIAL AND METHODS

Subjects: Forty six patients (27 females and 19 males) were recruited from rheumatologists, orthopedists in Security Forces Hospital. All potential patients were assessed according to the inclusion and exclusion criteria.

Inclusion criteria included a history of at least 6 months of chronic plantar painful heel syndrome that proved resistant to nonsurgical treatment. Diagnosis was confirmed clinically by physical examination with a typical point of maximum tenderness over the medial tubercle of the calcaneus. To be eligible, participants had to score significant pain of at least 5 or greater on visual analog scale (VAS) scores (with a maximum of 10) during the first few minutes of walking in the morning. All patients had to respect a sufficient washout period after each intervention prior to enrollment. The specific washout phases were determined as at least 6 weeks from last corticosteroid injection; 4 weeks from the last local anesthetic injection, iontophoresis, ultrasound and electrotherapy; 1week from the last intake of (NSAIDs); and 2 days from last heat, ice, massage, stretching, or modification of night splinting and orthotics. Reasons for exclusion on were rheumatic or other systemic inflammatory disease, osteomyelitis, active infection or history of chronic infection in the treatment area, neurological or vascular insufficiencies, nerve entrapment syndrome, disturbance of coagulation or ongoing anticoagulatory therapy, significant bilateral heel pain in need of medical treatment and pregnancy [8,10].

Design of the Study: This study was double-blind, randomized, placebo-controlled trial. The patients who fulfilled the inclusion criteria and provided written informed consent were randomly divided into two equal groups to receive either active treatment (group I) or placebo regimens (group II) according to a computer generated random numbers list. The study was approved by the research committee in security forces hospital. Both the patients and a single outcome assessor were blinded to the therapy received.

Intervention: Low-energy rESWT was provided by Swiss DolorClast, Electro Medical System (EMS), Switzerland; energy flux density (EFD) =0.16 mJ/mm^2 shockwave apparatus with 2000 impulses, 2.5 bars and frequency of 8Hz without local anesthesia (LA). Patients were placed in comfortable position either prone or in the side on the examination table with the affected foot placed in supported position. Prior to shockwave exposure, the area of pain was marked with an X on the skin to assist in focusing the delivery of the shock waves. Group I received a total 3 treatments (3x2000 impulses) given at weekly interval. While group II received the identical treatment protocol; however; shockwaves were prevented from entering the patient's foot by thin foam cushion placed on the therapy head. The cushion was put in place prior to the patient's arrival in the treatment room to maintain blinding. A new cushion was used with each treatment session.

Evaluation and Measurements: Pain intensity was measured using (VAS) score while the function of the foot was measured by American Orthopedic Foot and Ankle Society (AOFAS) Ankle-Hind Foot Scale (AHFS) score (pain and range of motion domains) a validated rating scale which incorporates assessment of function (50%) pain (40%) and alignment (10%). The measurements were performed at the base line, after 3 weeks of treatment and after 6 weeks of follow up (after the completion of treatment). After treatment and at each follow-up visit, blinding was assessed by asking patients to identify which treatment they believed they received. All patients were instructed to eliminate athletic activities and pain medication post therapy until follow up evaluation.

Statistical Analysis: Data were collected on special forms then varied and coded. After checking normality, all data were expressed as mean and standard deviation for all continuous data. Comparative study was conducted between the mean differences in the two studied groups for pain and function scores before as well as after 3 weeks of intervention by using the independent samples t-test**.** Paired t- test was used to determine the difference between pre and post measurements in both studied groups. Statistical testing also includes one-way analysis of variance (ANOVA) to test the difference among pre, post and follow up measurements as time main effects in both studied groups. In case of significance, a tukey test for multiple comparisons was conducted to detect pairs of groups significantly different at the 0.05 level. Data were analyzed using statistical package for social sciences (SPSS) version 10.1.

RESULTS

Forty six patients participated in this study, there were no reported treatment complains and no patients dropped out because of adverse effects at base line, the two groups were comparable with respect to age, weight, height, body mass index (BMI) and severity of plantar fasciitis. The characteristics of patients were shown in Table 1, the mean age of all patients was 41.15±6.92 years and the mean BMI was 28.93±3.92 Kg/m^2 indicated that the patients are over weight. There was no significant difference between patients regarding to age and BMI (P>0.05).

When comparing the pre-intervention mean values of pain and foot function for placebo group with that for the active treatment group by using the independent samples t-test, the results revealed a non-significant difference (P=0.197 and 0.912 respectively). While the comparison between post-intervention scores of pain and foot function showed a significant difference between placebo and active treatment groups (P=0.000).

The results of paired t-test (Table 2) revealed significant reduction of pain in both groups after 3 weeks of treatment (P=0.000 and 0.005 respectively). After 3 weeks of treatment and 6 weeks of follow up the percentage of difference from base line was (-32.11% versus -63.63%) and (-10.1% versus -8.48%) for both groups respectively. Regarding the function of the foot, the results revealed significant improvement in group I after 3 weeks of treatment (P=0.000) with high percentage of improvement after 3 weeks of treatment and 6 weeks of follow up (23.71% versus 36.84%) in contrast to (6.6% versus 3.8%) in group II.

Table 1: Characteristics of group I and II with confirmed diagnosis of the unilateral plantar fasciitis

	Sex				
Groups	Male	Female	Age (yrs) (Mean±SD)	BMI (kg\ m^2) (Mean±SD)	Duration of complain
Group I	9	14	40.15±6.77	28.89±4.23	>3 months
Group II	10	13	41.52±7.20	28.96±3.68	>3 months

Table 2: Paired t-test for pain and function of the foot for both studied groups

		Group I			Group II		
Variables		Mean±SD	t- value	P. value	Mean±SD	t- value	P. value
Pain	pre	7.17±1.37	7.74	0.000*	7.69±1.33	3.12	0.005*
	pot	4.87±1.14			6.91±1.16		
Function of the foot	Pre	66.56±10.51	7.18	0.000*	66.22±10.68	2.02	0.06
	Post	82.35±3.17			70.57±4.55		

SD: Standard deviation. *: Significant

Table 3: One-way ANOVA among different times of evaluations for pain and function of the foot

Source		df	SS	MS	F.ratio	P. value
Pain (Group I)	Among Groups	2	239.68	119.84		
	Within Groups	66	93.39	1.42	84.69*	0.000
	Total	68	333.07			
Pain (Group II)	Among Groups	2	8.09	4.04		
	Within Groups	66	91.65	1.39	2.91	0.061
	Total	68	99.74			
Function of the foot (Group I)	Among Groups	2	7105.3	3552.65		
	Within Groups	66	2902.7	43.98	80.78*	0.000
	Total	68	10008.0			
Function of the foot (Group II)	Among Groups	2	234.09	117.04		
	Within Groups	66	3849.22	58.32	2.007	0.143
	Total	68	4083.30			

*Significant at 0.05. F: F value df: Degrees of freedom.
SS: Sum of squares. MS: Mean of squares. P: Probability value.

Table 4: Post hoc-test for mean pain and function of the foot scores for group I at different times of evaluation

	Pain		Function of the foot	
Time of evaluation	Mean difference	P. value	Mean difference	P. value
Pre vs post	2.30	0.000	-15.78	0.000
Pre vs follow-up	4.56	0.000	-24.52	0.000
Post vs follow-up	2.26	0.000	-8.74	0.000

The one-way ANOVA showed a significant difference among mean of pain and function of the foot scores at different times of evaluations for group I (Table 3). A post hock test (Tukey test) for multiple comparisons showed significant differences in mean pain and function of the foot scores between pre and post, pre and follow up as well as between post and follow up measurements (Table 4).

DISCUSSION

The present placebo-controlled study was conducted to investigate and clarify the value of low-energy rESWT to become a routine modality in the treatment of pain and functional disability associated with chronic plantar fasciitis. The present study demonstrated significant improvement of pain scale and functional measurement, after rESWT at follow-up compared to baseline. Furthermore, rESWT proved superior to placebo with regard to the primary outcome measure of changes in VAS score of heel pain and secondary outcome measure at 3 and 6 weeks after intervention. At the time of follow-up the VAS score was reduced by -63.63% in the rESWT group compared with-8.48% in the placebo group. The between-group difference of nearly 30% is considered clinically relevant [23].

Regarding the foot function superiority of rESWT compared with placebo was even more pronounced, with increasing of the AHFS score from baseline of 36.84% after shock wave treatment compared with 3.8% in the placebo group, demonstrating a more than 33.04% between-group difference thus proving excellent long-term efficacy and supporting the application of rESWT in the treatment of chronic plantar fasciitis.

Although improvement was noted in placebo group, this phenomenon could simply reflect the spontaneous remission or natural history of plantar fascittis as a self-limiting condition or sustained placebo effects. Standard treatment for plantar fasciitis is conservative, but about 10% of patients fail to respond or heal spontaneously.

Blinding of patients and assessment of the efficacy of the blinding are necessary to control the placebo effect. Many previous trials of SWT for plantar fasciitis did not include blinding or assessment of blinding [3]. The present results are only valid for the therapeutic variables in this study.

There have been a number of randomized controlled trials published recently with varying results. A randomized controlled study performed by Porter and Shadolt [24] reported that corticosteroid injection is more effective and multiple times more effective than SWT in the treatment of plantar fasciopathy that has been

symptomatic for more than 6 weeks. In addition, a recent review on the use of SWT for the treatment of orthopedic diseases found that results on the effectiveness of SWT are controversial [25]. An assessment by the national institute for Health and Clinical Excellence (NICE) about ESWT for plantar fasciitis reached the following conclusion: current evidence on ESWT for refractory tendinopathies (especially tennis elbow and plantar fasciitis) suggests that there are no major safety concerns. Evidence on efficacy is conflicting and suggests that the procedures produce little benefits apart from a placebo response in some patients. Therefore, current evidence on efficacy does not appear adequate to support its use without special arrangement for consent and for audit or research [26].

Canadian Agency for Drugs and Technologies in Health's report on SWT for chronic plantar fasciitis stated that the lack of convergent findings from randomized trials of SWT for chronic plantar fasciitis suggests uncertainty about its effectiveness [27].

Studies that have claimed therapeutic benefit did not fulfill scientific criteria and randomized controlled trials were not able to confirm significant improvement after treatment with SWT.

It is difficult to compare studies, which use different patient populations, designs and treatment protocols. It is unclear if the negative results of other studies are due to insufficient energy levels, possible over treatment, which can produce a lack of/or negative biologic effect, or inclusion of patients who might not benefit from SWT.

The positive results presented in this study contrast those of the previous trials and are in agreement with results reported by Gerdesmeyer *et al*. [28] who concluded that rESWT demonstrated safety and effectiveness with a protocol of 3 sessions, each 2 weeks (±4 days) a part (3×2000 impulses mJ/mm^2) applied without anesthesia to the spot greatest tenderness. The same results was approved by very recent study using different treatment protocol include only 2 sessions with 2000 impulses each were performed 1 week apart [29].

The differences in the results may be explained by a number of factors including technical difference (machine design, shock intensity and frequency and the use of different placebo treatment), as well as differences in subject population, severity of disease and study design.

Radial ESWT has several advantages and should be considered an effective and safe tool in the treatment of chronic plantar fasciitis. As an alternative to surgery, it is a noninvasive technology, which has considerably less complication. It has a relatively short recovery time during which the patients can continue with most employment and activities of daily living, as soon as the day following treatment. Because SWT can be used earlier in the course of this disease, it can aid in reducing patient suffering, loss of time at work and health care costs associated with prolonged treatments and surgery.

There is still much debate over several issues surrounding SWT that have not been adequately addressed by the literature: high versus low-energy SWT, shock wave dosage and number of sessions required for therapeutic effect so that future researches are needed to ascertain the most beneficial protocol for patient care.

CONCLUSION

Low-energy rESWT is proposed as an additional conservative treatment to be used to avoid surgery, when other available conservative methods have failed. Pain relief can be recognized with a single session compared to traditional conservative therapies that require multiple applications and for which clear benefits have not been established. The rESWT is minimally invasive, has a short recuperation period and reports only minor, transient side effects. Also, rESWT may circumvent the need for surgical intervention associated with costs, lost time from work and complications associated with surgery. The results of this study confirm that low-energy rESWT is a safe and effective treatment for patients who have failed previous conservative non-surgical treatment for chronic plantar fasciitis.

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