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EFFECT OF LOW ENERGY VERSUS MEDIUM ENERGY RADIAL SHOCK WAVE THERAPY IN THE TREATMENT OF CHRONIC PLANTER FASCIITIS

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ABSTRACT

Background: Plantar fasciitis (PF) is the most common cause of heel pain and it can often be a challenge for clinicians to treat successfully. Radial shock wave therapy (RSWT) has been introduced recently for treatment of musculoskeletal disorders. Different energy levels of shock wave therapy have been used in the literatures for treatment of PF with no clear settled parameters. Therefore, the purpose of this study was intended to investigate and compare the efficacy of two different energy levels of RSWT on PF patients.

Methods: Forty patients having unilateral chronic PF were recruited for the study from orthopedic outpatient clinics of Cairo University hospitals and National Institute of Neuromotor System Cairo Egypt, with a mean age of (47.15±4.57) years. Patients were randomly assigned into two equal groups. Group (A) treated with low intensity level of 1.6 bars (0.16 mJ/mm^2) RSWT and group (B) treated with medium intensity level of 4 bars (0.38 mJ/mm^2) RSWT. Functional assessment of the foot based on Foot Function Index (FFI) and Present pain intensity was measured during rest by Visual Analogue Scale (VAS).

Results: There was as significant decreased in the total FFI scores from (118.42 ±6.51) to (81.37 ±3.46) for group (A) and from (118.93 ±6.85) to (58.50 ±3.22) for group (B). Also regarding VAS Scores there was as significant decreased in the pain intensity from (5.11 ±0.41) to (2.85 ±0.31) for group (A) and from (4.95 ±0.39) to (2.05 ±0.22) for group (B).

Conclusion: Radial shock wave therapy is an effective modality that should be considered in the treatment of chronic PF, while the medium energy level RSWT is better than the low energy level RSWT in regarding to the measured treatment outcomes.

Keywords: Low energy, Medium energy, Radial shock wave, Treatment, Planter fasciitis

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INTRODUCTION

Plantar fasciitis (PF) is the most common cause of heel pain and accounts for approximately 11% to 15% of all foot symptoms requiring professional care in the adult. It occurs over a wide age range and it is seen in both sedentary and athletic individuals and it can often be a challenge for clinicians to treat successfully.[1,2]

Plantar fasciitis is usually a self-limiting condition and treated non-operatively in the majority of patients, the time until resolution is often 6–18 months, which can lead to frustration for patients and physicians.[3] However, 10% to 20% develop chronic pain and may require surgery which is associated with long recovery times, failure rates as much as 17%, and can be inappropriate for patients who wish to continue weight bearing during recovery. PF is usually diagnosed clinically based on the history of morning heel pain made worse with ambulation on hard surfaces and by the physical findings of pain over the medial aspect of the plantar fascia.[4]

The plantar fascia is a thick, fibrous, relatively inelastic sheet of connective tissue originating from the medial heel, where it then passes over the superficial musculature of the foot and inserts onto the base of each toe. The plantar fascia is the main stabilizer of the medial longitudinal arch of the foot against ground reactive forces, and is instrumental in reconfiguring the foot into a rigid platform before toe-off.[5,6]

Treatment for PF is varied and various physiotherapy treatment protocols have been advocated in the past such as rest, taping, stretching, night splint, silicon heel cups and various electrotherapy modalities in the form of ultrasound, laser and iontophoresis. However PF is often slow to respond to these traditional approaches.[7,8]

Shock wave therapy (SWT) has been widely used for pain relief and treatment of musculoskeletal disorders and it is proposed as a potential method of treating patients with musculoskeletal disorders without the need to stop weight bearing.[9-17]

Radial shock wave therapy (RSWT) has been introduced recently. It can be delivered to the tissue without local or nerve block anesthesia. It is better tolerated by the patient than focused SWT because their point of highest pressure at the tip of the applicator and, thus, outside the tissue. In contrast, focused SWT have their point of highest pressure at the center of their focus which is positioned within the treated tissue.[18,19]

Radial SWT compared with conventional focused SWT, is a low- to medium-energy shock wave generated when a projectile is accelerated by compressed air (1– 5bar) with a low penetration power (less than 5 cm).[20] Radial SWT was recommended over focused SWT for treating of musculoskeletal disorders due to their safety, efficacy and long term treatment success.[21]

There are a number of treatment parameters that can be varied during SWT likes pressure, energy flux density, time interval between treatments, number of impulses or shocks and treatment impulse frequency. The exact relationship between these treatment parameters is often unclear. The most important parameter of SWT for the outcome of treatment is the energy which is measured by bar or millijoules per square millimeter (mJ/mm^2) which is the most common standardized measurement of energy in the field and sometimes called the "energy flux density".[22]

Different energy levels have been used in the literatures for treatment of PF and it was proven to be effective.[19-22] Within the available literature, there are only few clinical trials with no clear settled parameters tried to compare different energy levels of SWT on musculoskeletal disorders. Therefore, the purpose of this study was to investigate and compare the efficacy of two different energy levels of RSWT on PF patients.

MATERIALS AND METHODS

Subjects

Forty patients having unilateral chronic planter fasciitis were recruited for the study from orthopedic outpatient clinics of Cairo University hospitals and National Institute of Neuromotor System, Cairo Egypt. Their age ranged from (20–55) years. Patients were randomly assigned into two equal groups, with the following inclusion criteria: patients had been clinically diagnosed as planter fasciitis cases of not less than three months, maximum tenderness felt over the medial tubercle of the calcaneus, pain with first steps upon waking was greater than or equal to 5 on a 0-to-10 visual analogue scale (VAS)[13,15] and body mass index (BMI) ranged from (18 – 32).[23]Patients were excluded if they had previous surgical history for plantar fascia, history of pathologies around ankle /foot, auto immune or systemic inflammatory disorders, fixed deformities of foot, ankle and knee joints, impaired circulation of the lower extremities and peripheral neuropathies, neurological disorders leading to impaired balance and coordination, pregnancy, previous corticosteroids injection in heel. A written informed consent was signed by each participant before the beginning of the study. Confidentiality and anonymity of patient's data was considered and they have the right to withdraw from the study at any time.

Instrumentations

Radial Shock Wave Therapy

Intellects® RPW Shockwave by Chattanooga Corporation was used. It has the following technical specifications, compressed air output (1.4-5) bars, frequency (0.5-21 Hz), pulses or shots (10–10,000), size of applicator 15 mm and penetration depth (0-50 mm). It has unique optimal energy level adjustment feature that allows gradual ramping of the intensity during treatment which provide inherent safety as demonstrated by the manufactures guidelines.

Foot Function Index

The modified English version of the original Foot Function Index (FFI) comprised 17 items rated on VAS scale separated into three subscales: pain (5 items), disability (9

items) and limitation activity (3 items) was used to evaluate the foot function. It was reported as a valid and reliable measure of the impact of pathologies on foot and ankle function.[24,25]

Visual Analogue Scale

Visual Analogue Scale was used to assess the present pain intensity during rest. It consists of a 10-cm straight line anchored at one end by a label such as "no pain" and at the other end by a label such as "the worst pain imaginable". It was reported as valid and reliable tool for pain assessment.[26,27]

Procedure

The aims and procedure of the study was explained to each patient before participation

Evaluative procedure

- Subjects' ages were recorded and their weight and height were measured
- Functional assessment of the foot based on FFI carried out pre and post treatment.
- Present pain intensity was measured during rest pre and post treatment by VAS. The patient was instructed to simply mark the line to indicate pain intensity and the provider then measures the length of the line to the mark on the scale.

Treatment procedure

The patients were positioned in supine lying, with the foot supported on the edge of the bed. The point of maximum tenderness over the medial plantar fascia insertion was clinically located and identified by a marker then the applicator was placed perpendicular to the identified area by using specific ultrasound coupling gel. Subjects in group (A) treated with: 2000 shots or impulses of radial shock waves, a frequency of 8 Hz. and the intensity level was 1.6 bars (0.16 mJ/mm^2) (low energy treatment group). While subjects in group (B) treated with: 2000 shots or impulses of radial shock waves, a frequency of 8 Hz. and the intensity level was 4 bars (0.38 mJ/mm^2) (medium energy treatment group). Both groups were treated for four sessions with one week interval. All patients were advised to perform active stretching of the gastrocnemius and plantar fascia at home and to continue on the same activity level throughout the study.

Statistical analysis

Data analysis was performed by SPSS (Version 17) for Windows. Descriptive statistics including the mean and standard deviation was used to describe general characteristics of subjects and outcome variables. Student-t-test was used to determine significant differences between groups. The P-value < 0.05 was taken as significant.

RESULTS

Subjects characteristics of both groups presented in table (1). There were no significant differences between both groups regarding age, body mass index (BMI), duration of symptoms and heel pain (VAS) when taking first steps in the morning as (P>0.05).

Table 1: Subjects characteristics in both groups (A and B)

General Characteristics	Group (A)		Group (B)		Comparison	
	Mean	±SD	Mean	±SD	P-value	S
Age (year)	46.56	± 5.06	47.75	± 4.08	0.418	NS
Body mass index(Kg/m2)	28.94	±1.52	29.15	±1.62	0.674	NS
Duration of symptoms (months)	18.54	±1.02	19.05	±1.26	0.167	NS
Heel pain (VAS) when taking first steps in the morning	7.3	±1.73	7.2	±1.75	0.856	NS
Gender (Male/Female)	(9/11)		(8/12)		-------	------
Affected side (Right/Left)	(14/6)		(13/7)		-------	------

±: SD P: Probability S: Significance NS: Non-significant

There was no significant difference between both groups in the total FFI scores and VAS pre-treatment as (P>0.05). While post-treatment there was a significant decrease in the total FFI scores from (118.42 ±6.51) to (81.37±3.46) for group (A) and from (118.93 ±6.85) to (58.50 ±3.22) for group (B). Also regarding VAS Scores there was a significant decrease in the pain intensity from (5.11 ±0.41) to (2.85 ±0.31) for group (A) and from (4.95 ±0.39) to (2.05 ±0.22) for group (B) as shown in table (2). The percentage of improvement in the measured outcomes was 31.28% for Total FFI and 44.22% for VAS for group (A) as shown in figure (1), while it was 50.81% for Total FFI and 58.58% for VAS for group (B) as shown in figure (2).

Table 2: Comparing mean values for the measured outcomes for both groups

Parameter	Pre-treatment				Post-treatment		
	Group (A)	Group (B)	P-value	S	Group (A)	Group (B)	P-value
Foot function index (FFI) scores							
Pain	36.09 ±1.82	36.65 ±1.65	0.306	NS	24.91 ±0.94	17.05 ± 0.82	0.0001*
Disability	65.32 ±2.9	66.01 ±3.1	0.471	NS	45.41± 2.02	33.11 ±1.7	0.0001*
Activity limitation	17.01 ±1.51	16.27 ±1.45	0.122	NS	11.05 ±0.57	8.34 ±0.49	0.0001*
Total	118.42 ±6.51	118.93 ±6.85	0.810	NS	81.37 ±3.46	58.50 ±3.22	0.0001*
Pain intensity (VAS) at rest	5.11 ±0.41	4.95 ±0.39	0.213	NS	2.85 ±0.31	2.05 ±0.22	0.0001*

±: SD P: Probability S: Significance NS: Non-significant*: Statistically significant

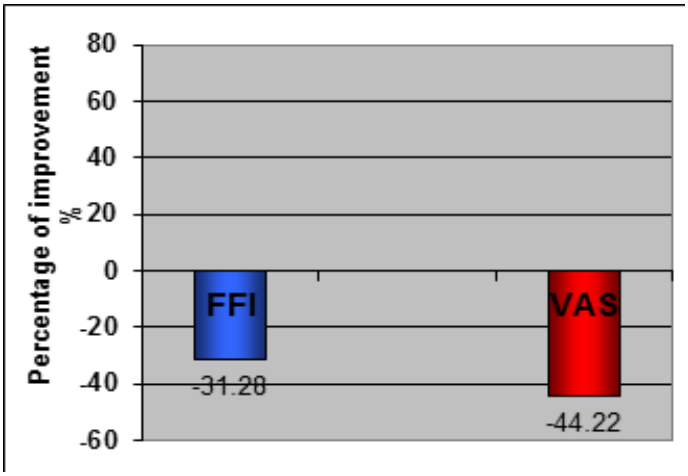

Figure 1 : Percentage of improvement in the total FFI and VAS scores for group (A)

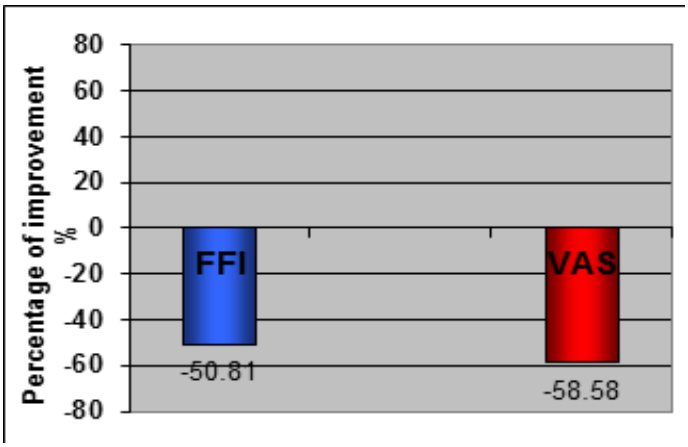

Figure 2: Percentage of improvement in the total FFI and VAS scores for group (B)

DISCUSSION

The purpose of this study was to investigate and compare the efficacy of two different energy levels of RSWT on PF patients to determine which level was superior, that may help to set clear parameters for treatment of PF with RSWT. The principal findings of the present study showed that, both energy levels used in treatment resulted in statistically significant improvement in the measured outcomes for both groups and there is a significant difference between the outcomes of the two energy levels used in treatment, while the medium energy level (0.38mJ/mm^2) RSWT was superior to the low energy level (0.16 mJ/mm^2) RSWT and produced greater percentage of improvement in the measured treatment outcomes.

The results of our study were in agreement with Ibrahim et al. (2010), Greve et al. (2009) and Gerdesmeyer et al. (2008) which provides evidence of the effectiveness of RSWT in the treatment of chronic PF.[14,15,21] Extracorporeal shock wave therapy protocols vary from trial to trial. The different delivery modes of shock waves, single treatment versus multiple treatments and low-energy shockwaves versus high-energy shock waves can influence the outcome of therapy. Therefore, the results reported in a study are only valid for the parameters applied in that study.[28]

The mechanism of how SWT improved the functional outcome measured in chronic PF patients has not yet been clearly determined however suggested variable mechanisms have been proposed, including;

1. Pain relief by means of hyperstimulation analgesia. Overstimulation of the treated site would lead to a diminished transmission of signals to the brainstem that would block the gate-control mechanism.[29] Animal studies showed that SWT has an influence on pain transmission by acting on substance P, [30,31] calcitonin gene-related peptide expression in the dorsal root ganglion[32] and on neurovascular sprouting.[33] The results of the current study may suggest that medium energy level RSWT induces more overstimulation effect on the treated tissue than the low energy level RSWT.
2. Tissue regeneration could be significantly stimulated by SWT. Mechanical and physical impact on tissues exposed to SWT has been found to depend on energy flux density and these tissues could convert SWT stimulation into biochemical signals.[34] Mechanical load on the cytoskeleton leads to cell responses and increased protein synthesis.[35] The mechanical load impacted on the treated tissues with the medium energy level was greater due to increased pressure about (4 bars) compared with the low energy level about (1.6 bars). Healthy human tenocytes responded to SWT, which stimulate cell growth and increased collagen synthesis. [36] SWT has been showed to induce anabolic responses

of tendons and ligaments tissues [37] and increased vascularization in the bone–tendon junction through the release of growth factors.[38]

3. Anti-inflammatory effects mediated by SWT at low and medium energy flux density, nitric oxide is released and it has antalgic, angiogenetic and anti-inflammatory effects which are very useful in clinical treatment, also change of concentration of inflammatory mediators support anti-inflammatory effect of this therapy.[39]

CONCLUSION

Radial shock wave therapy is an effective modality that should be considered in the treatment of chronic PF, while the medium energy level (0.38mJ/mm^2) RSWT is better than the low energy level (0.16mJ/mm^2) RSWT in regarding to the measured treatment outcomes. Further studies are needed to confirm these results and to determine the optimum treatment parameters.

Conflict of interest

We certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Source of funding

This research received no specific grant from any funding agency in the public, commercial, or not / for profit sectors.

Ethical clearance

We certify that this study involving human subjects is in accordance with Helsinky declaration of 1975 as revised in 2008.

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