

ORIGINAL ARTICLE

Effects of Low-energy Radial Extracorporeal Shockwave Therapy (rESWT) on Severity of Pain Among Patients With Plantar Fasciitis

Aliff Latir¹, Armirul Ashraf²

¹ Centre for Physiotherapy studies, Faculty of Health Sciences, Universiti Teknologi MARA Selangor branch, Puncak Alam Campus, 42300 Puncak Alam Selangor, Malaysia

² Department of Physical Rehabilitation Sciences, Kulliyah of Allied Health Sciences, International Islamic University of Malaysia, Bandar Indera Mahkota 25200 Kuantan Pahang Malaysia.

ABSTRACT

Introduction: Pain is a common symptom experienced by patients with plantar fasciitis (PF), affecting their body function, daily activities and quality of life. This quasi-experimental research aimed to examine the effects of low-energy radial extracorporeal shockwave therapy (rESWT) on the pain severity among patients with PF attending the Physiotherapy Clinic, International Islamic University Malaysia (IIUM), Kuantan campus. **Methods:** Twenty-one patients diagnosed with PF were enrolled in a single intervention group receiving three sessions of low energy rESWT (pulses: 2000 impulses, rate: 8 impulses per second, dosage: 0.16 mJ/mm²) in three weeks. Pain severity was assessed by using a pain assessment tool, the visual analogue scale (VAS). The data acquired were analysed using SPSS 21 software. **Results:** There was no significant difference in pain score between genders ($p=0.77$), but there was a significant difference between occupations ($p=0.04$). The pain score was significantly reduced following administration of low energy rESWT ($p<0.01$). **Conclusion:** In three weeks, low energy rESWT treatment reduces the pain severity, thus providing an alternative to a high-energy dosage of rESWT in managing patients with PF.

Keywords: Foot, Plantar fasciitis, Radial extracorporeal shockwave therapy

Corresponding Author:

Aliff Latir, Msc
Email: : aliff533@uitm.edu.my
Tel:+603 32584367

INTRODUCTION

Plantar fasciitis (PF) is defined as an inflammation of the plantar fascia tissue and surrounding structures of the foot resulting in pain over the heel region, affecting 10% of the adult population (1). In western countries, more than a million people are estimated to be affected by PF every year, requiring medical intervention (2). The exact pathophysiological process of this medical condition is still doubtful. However, researchers believed that reduced fascia elasticity, inflammatory changes of the plantar fascia, degeneration of the proximal fascia, and abnormal physiological changes of pain receptor might contribute to the progression of PF (3). Several risk factors have been suggested that may increase the risk of developing PF, which includes age, weight, gender, abnormal walking pattern, and prolonged standing and walking (4).

Extracorporeal shockwave therapy (ESWT) was introduced in the early 1990s as part of the conservative management for PF, allowing shorter rehabilitation period without the necessity of immobilisation or non-weight bearing ambulation, which are common following surgical management such as fasciotomy (5,6). Early experimental studies exploring ESWT in chronic PF have demonstrated negative results, and its clinical effectiveness has been argued (1,7). However, as more studies have been published, it becomes evident that the selection of treatment protocols of ESWT significantly influence the success rate of the treatment (8). In previous studies, the application of ESWT for PF may range from low energy (0.03 – 0.19 mJ/mm²) (9-12) to high energy (>0.20 mJ/mm²) (13-15), with higher energy ESWT have higher chances of reducing PF pain (13-15,17). Besides, the application of local anaesthesia during ESWT has been known to influence the outcomes of the treatment (16,18).

Radial extracorporeal shock wave therapy (rESWT) was developed to deliver a more extensive shockwave area, an alternative to the previous version of focused shock

wave therapy (FSWT). The FSWT penetrate deeper tissues with significantly higher energy concentration to a smaller focus (19) but it is associated with adverse effects which include pain, discomfort and swelling (20). In contrast, the generation of a radial shock wave involves a vigorous ballistic acceleration of a bullet hitting an applicator's head, which converts the kinetic energy into shock waves transmitting and expanding radially through the soft tissue (17). The properties of rESWT make it a practical and feasible tool in treating musculoskeletal disorders (tennis elbow, rotator cuff calcifying tendinitis and PF) (21,22).

Therefore, the **objectives of this study were to** (i) compare the severity of pain between male and female genders, (ii) compare the severity of pain between occupations, (iii) examine the effects of the low energy rESWT protocol (pulses: 2000 impulses, rate: 8 impulses per second, dosage: 0.16 mJ/mm²), administered without local anaesthesia over the tenderness point of the plantar fascia in patients with PF. (NSNP).

MATERIALS AND METHODS

This quasi-experimental study was conducted at the Physiotherapy Clinic under the Kuliyyah of Allied Health Sciences (KAHS), IIUM, Kuantan campus. Twenty-one patients with PF attending the KAHS' Physiotherapy Clinic were recruited through a convenience sampling method. The sample size was based on GPower calculation (version 3.1.9.7) with effect size 0.8, alpha error probability 0.05 and power 0.9. For ethical consideration, the University Research Ethics Committee granted ethical approval (IIUM/504/14/11/2/2018-118) and written consent was retrieved from the patients before the trial.

The patients were screened for eligibility criteria; those with age 18 years and above and diagnosed with PF based on the clinical examination i.e. (i) local tenderness/pain on the proximal fascia area near the heel, (ii) exaggerating pain on prolonged weight-bearing position (15 minutes of walking or standing), (iii) history of three months of failed conservative management were enrolled. Patients presented with a foot or ankle dysfunction, foot arthritis, lower extremities infections or tumours, nerve entrapment and vascular abnormalities (varicosities and chronic ischemia) and history of surgical release of plantar fasciitis were excluded from this study.

The study used Radial Shockwave Therapy (EnrafNonius 1650900 ENDOPULS 811, Netherlands), which was calibrated and tested for safety before the data collection. The shockwave was administered by a study-blinded therapist who was trained with the equipment. Ultrasound coupling gel Electro Medical Systems (EMS) was used over the skin area to prevent skin irritation during the procedures. For pain assessment, visual

analogue scale (VAS) was administered to the patients by the same therapist during patients' enrolment and after three weeks of the treatment sessions. VAS is a pain assessment tool consisting of a 100 mm straight line. The patients marked along the line based on their perceived pain severity, where the 0 mm marked no pain, and 100 mm is the maximum pain level.

In the first session, the researchers recorded the demographic data, including gender, age, height, weight and occupation. The patient then lay down on a treatment plinth in a prone position, with the plantar fasciitis foot directed towards the therapist and shockwave machine. The treatment area was marked based on the patient's maximum tender point along the medial side of the foot until the lower tubercle of the calcaneal bone. A conductive gel was used as a treatment medium and applied where the rESWT applicator was directly positioned over the heel region. The patients were informed regarding the sensation during the treatment – bearable pain. Then, a single application of low energy rESWT (pulses: 2000 impulses, rate: 8 impulses per second, dosage: 0.16 mJ/mm²) was administered at the designated location guided by the patient's feedback. Any adverse events were recorded by the researchers during and following each treatment session.

All data were analysed using the Statistical Package for Social Science Software (SPSS) version 21. Objectives i, ii and iii were analysed with independent t-test, one-way ANOVA, and **paired t-test, respectively**. A posteriori test was performed for one-way ANOVA. P-value was set at 0.05 for statistical significance and measurement values were reported as mean \pm standard deviation.

RESULTS

The average age of the patients was 29.6 ± 10.4 years old. Ten were males, and 11 were females. All patients were Malays. In term of occupation, 43% were students, 28% were administration workers, 19% self-employment and only 10% were construction site workers. The results of our study showed that the VAS score did not significantly differ between males and females ($p=0.77$) (Table I). In term of occupation, there was a significant difference in VAS ($F(3,17)=3.479$,

Table I: Comparison of severity of pain between genders among patients with PF

Gen-der	Male (n = 10)	Female (n = 11)	Mean Difference (95% CI)	t-statistic (df)	p-value
Variable	Mean (sd)	Mean (sd)			
V A S (mm)	59.70 (15.89)	57.91 (11.10)	1.79 (-10.63,14.21)	0.302 (19)	0.77

Table II: Comparison of severity of pain between the occupations among patients with PF

Variable	n	VAS (mm)		F-statistic (df)	p-value
		Mean	SD		
Occupation					
Construction site workers	2	80.0	2.8		
Self-employed	4	64.8	4.6	3.479	0.04*
Administration workers	6	54.3	12.9	(3,17)	
Students	9	54.3	12.6		

*Significant, $p < 0.05$

Table III: Comparison of severity of pain pre- and post-ESWT treatment among patients with PF

Pair	Pre-treatment	Post-treatment			
Variable	Mean (SD)	Mean (SD)	Mean Difference (95% CI)	t-statistic (df)	p-value
VAS (mm)	58.76 (13.27)	7.90 (7.37)	50.86 (45.30,56.41)	19.09 (20)	0.00*

*Significant, $p < 0.05$

$p = 0.04$). (Table II). Posteriori analysis using the Tukey test demonstrated the mean score for the site worker ($M = 80$, $SD = 2.8$) was significantly different from the students ($M = 54.3$, $SD = 12.6$). At three weeks follow-up, there was a significant decrease in VAS after rESWT treatment ($p < 0.01$) (Table III). There were no adverse effects or complications reported during or immediately after the rESWT administration.

DISCUSSION

Plantar fasciitis (PF) may be idiopathic or associated with a few systemic diseases (seronegative spondylitis, rheumatoid arthritis). PF commonly affects middle-age adults, and both genders are affected equally. Our study demonstrates equal pain intensity between genders, consistent with the results of previous studies. According to Thing et al. (23), PF's prevalence is high among middle-age groups with a similar case reported in both males and females. Goweda et al. (24) also noted that PF cases are highest in people aged 40 to 60 years old with equal distribution between genders.

The severity of pain varied between the different types of occupation. In our study, construction workers recorded the highest VAS score compared to the self-employed, administration and students. High VAS scoring among

these hard-labour workers may be associated with their strenuous nature of works. According to Werner et al. (25), PF is common in assembly plant workers, and its occurrence may be due to excessive pressure over the metatarsal bones, abnormal foot position (excessive pronation of the forefoot), prolonged hours on hard surfaces (walking and standing) and frequent changing of position at work (enter and exit the vehicles). Students on the other hand have recorded the lowest VAS score as compared to the other occupation groups, and this can be explained by the age-related pathophysiological changes that worsen with increasing age. According to Menz (26), the foot of an ageing person will have a common tendency to display pronated foot, increased stiffness of plantar fascia, reduced ankle movement, and reduced muscle strength of intrinsic foot muscle – all contributing to development and progression of plantar fasciitis.

Several authors have highlighted the effectiveness of low energy rESWT, with a significant reduction in VAS score at 3rd, 6th, and 12th-week follow-up (9-12). In our study, the mean VAS score was reduced by 86.6 percent after three weeks of ESWT intervention. Besides, the effects of low energy rESWT is comparable to high-energy rESWT (> 0.2 mJ/mm²) (13,14, 19, 20, 27 - 30). This finding is important because, although high-energy rESWT is associated with more significant pain reduction, it is also associated with several adverse effects (increase in pain, skin irritation, oedema) following treatment (20, 31, 32).

In contrast, there are studies investigated rESWT with conflicting results. In these studies, the application of low energy rESWT does not produce a reduction in pain among patients with PF (7) and does not demonstrate improvement in the Roles and Maudsley score (1). A few factors might explain the conflicting results. Firstly, the energy level may determine the success of rESWT treatment, and the total energy delivered in our study is relatively higher than the previous study (320 mJ/session vs. 180 mJ/session) (7). The energy level determinant is supported by Li et al. (8) study where higher energy rESWT may produce a greater chance of reducing pain. Secondly, these studies had utilised local analgesic during the delivery of rESWT. Application of local analgesic agent may influence the accuracy of the pain location perceived by the patient, thus difficult for the therapist from applying the shockwave over the maximum tenderness point at the foot. It is important to note that our study has administered rESWT without local analgesic, similar to previous studies that produce positive outcomes (9-12).

The mechanism of rESWT in musculoskeletal disorder management is still debatable. Nonetheless, the cavitation process's therapeutic effect can be explained through the analogy of bubbles formation and movement in a liquid medium. The applicator's strong forces over

the tissue (fascia) are believed to induce micro-tissue injury mechanically. The repair of the soft tissue injury provides the theoretical basis for the neovascularisation process resulting in immediate and long-term pain relief following rESWT (3).

The present study has several limitations. Firstly, the small sample size population does not allow for statistical validation. Secondly, the short follow-up period. We only follow-up these patients for only three weeks, thus unable to determine the recurrence rate and the possibility of plantar fascia rupture or osteonecrosis of the calcaneus. Thirdly, **we only include a single intervention group** due to ethical concerns (patients should receive other conservative management). It is recommended that the future studies examine the long-term effects of rESWT and other domains of health such as functional activities (Roles and Maudsley score, American Orthopedic Foot and Ankle Society scores) and quality of life (36-items Short-Form Health Survey).

CONCLUSION

The administration of low energy rESWT with a protocol of three successive treatments within three weeks (pulses: 2000 impulses, rate: 8 impulses per second, dosage: 0.16 mJ/mm²), without anaesthesia over plantar fasciitis region demonstrated a significant reduction in pain score in patients with PF, thus can be an alternative treatment option for the therapist in managing the plantar fasciitis condition.

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