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Research Article

Effectiveness of High Intensity Radial Shock Wave Therapy in The Treatment of Chronic Plantar Fasciitis

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Abstract

Introduction

Literature is scarce concerning the effectiveness of high dose radial extracorporeal shock wave therapy (ESWT). Therefore, the aim of this study was to investigate its effectiveness on pain, function and pressure pain threshold in patients with chronic plantar fasciitis (PF).

Materials and Methods

Patients with a diagnosis of chronic (pain lasting for more than 3 months) uni- or bilateral PF with a history of failed conservative treatment were included. After a 6-week control period during which no treatment occurred, a 2-week treatment period followed by a three weeks of rest (cicatrization phase) was provided. The treatment period consisted of three radial ESWT sessions (2000 impulses of 10 Hz frequency per session with an energy flux density of 0,275mJ/mm^2) separated by a one-week interval. Patient assessments (pain intensity, foot function and pressure pain threshold (PPT) at the site of maximum local tenderness disability) were conducted at baseline, after the 6-week control phase (pre-treatment) and at the end of the cicatrization phase (post-treatment).

Results

Thirty patients (19 women (63.3%)) with chronic PF and a mean age of 51.9±11 years were included in the present study. No drop-out occurred throughout the study period. No changes were observed at the pre-treatment assessment session except for pain intensity which decreased slightly but significantly ($P<0.05$). At the post-treatment session, highly significant ($P<0.001$) and clinically meaningful changes occurred for pain intensity (-34%), foot function score (-60%) and PPT (+68%).

Conclusions

The present study suggests that high dose radial ESWT is a feasible and effective way to quickly and significantly decrease

pain and disability in most patients with chronic PF.

Keywords: heel pain; plantar fasciitis; extracorporeal shock wave therapy; ESWT; disability

Introduction

Plantar fasciitis (PF) is the most common cause of heel pain in adults and can affect various kinds of individuals (for example, sedentary people and athletes) [1, 2]. It is characterized by several symptoms among which heel pain with the first steps in the morning or deep pain with palpation of a specific point. Although a conservative treatment (rest, analgesics, stretching techniques) is usually effective within a few weeks in decreasing the disabling pain, complementary treatments are sometimes necessary (for example, foot orthotics, corticosteroid injections) [1]. For people in whom pain persists and becomes chronic, extracorporeal shock wave therapy (ESWT) seems to be a good treatment alternative [1, 3-5]. It has been used for 20 years and is now often considered as one of the best indications for ESWT. Regarding the kind of shockwaves, although focal ESWT (which focus on a small area and are thereby characterized by a high tissue penetration power) is sometimes supposed to have effects on deeper structures than radial ESWT (which are transmitted radially and have thereby a spread effect on the tissues), the literature reported that both ESWT are effective and did not conclude on the superiority of focal or radial ESWT [6,7]. However, Chang et al. performed a systematic review and network meta-analysis about the comparison of the effectiveness of focal and radial ESWT and concluded that radial ESWT can be considered as an appropriate alternative because of its lower price and probably better effectiveness [6]. Although several randomized controlled trials (RCTs) have investigated the benefits of ESWT for chronic PF [8], little information is available on treatment effectiveness of high dose radial ESWT (>0.20 mJ/mm^2 [9]) on chronic PF [10] although the dose level might be an important factor to consider [6, 9, 11]. Therefore, the aim of this pilot study was to investigate the effectiveness of high dose radial ESWT on pain, function and pressure pain threshold in patients with chronic PF.

Materials and Methods

Study population

The study population consisted of patients consulting, within a five-month period, with a physical medicine and rehabilitation specialist because of pain symptoms in the heel(s). Patients were eligible for the study according to the following inclusion criteria: diagnosis (based on history, physical examination and confirmed by ultrasonography) of chronic (pain lasting for more than 3 months) uni- or bilateral PF with a history of failed conservative treatment (painkillers, NSAIDs, local corticoid injection and/or physiotherapy). The exclusion criteria were: age of < 18 years, recent foot fracture (<1year), inflammatory rheumatic disease, local infections or malignancy, medical co-morbidity making walk impossible, ongoing treatment for their PF at the time of the consultation, heel skin wound, Achilles bursitis or tendinopathy, tarsal tunnel syndrome, peripheral neuropathy, metallic materials in the lower limb, complex regional pain syndrom (CRPS), metabolic and endocrine disorders likely to influence the patient's clinical evolution, osteoporosis (in order to avoid any osteoporotic fracture) and pregnancy. Further exclusion criteria were: not proficient in French. Patients who seemed eligible for inclusion were informed about the study and invited to participate. Patients accepting to be included in our study gave written informed consent to participate.

Thirty patients with PF were included in the present study: 19 women (63.3%) and 11 men (36.7%) with a mean age of 51.9 years (SD=11.0) and body mass index of 29.1 kg.m^{-2} (SD=4.53). Eight patients (26.7%) suffered from bilateral PF, twenty (66.7%) presented a plantar calcaneal spur observed on radiographs and five (16.7%) had a previous injection treatment.

Experimental protocol

This was an 11-week longitudinal study divided into three successive phases: a 6-week control period during which no treatment was provided to the patients, a 2-week treatment period and three weeks of rest (cicatrization phase) (Figure 1). The treatment period included 3 radial ESWT sessions separated by a one-week interval. Patient assessments were conducted at baseline, after the 6-week control phase (pre-treatment) and at the end of the cicatrization phase (post-treatment). Considering it was a pilot study, only one side (the most painful one) was assessed and treated.

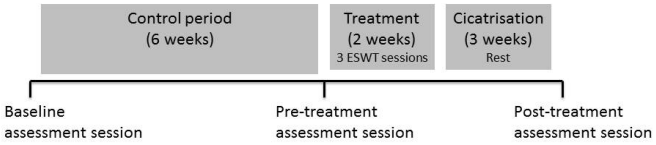

Figure 1. Study process timeline.

The three assessment sessions, each performed by the same investigator (A.F.), included the following components:

Primary outcomes:

- Pain intensity. We used a visual analog scale (VAS) with no graduations that had the words "no pain" at one end and "worst pain imaginable" at the other end. The patient was asked to answer the following question: "Over the last 2 days, how intense was the pain in your foot?" by moving a pointer on the scale according to the subjective feeling of pain sensation. The distance (in centimeters) between the left end of the line (no pain) and the pointer was the VAS pain score (range, 0–10cm).

- Foot function. A French version of the "Foot Function Index" (FFI) was used [12]. It includes 23 items scored on a 10-point VAS related to the impact of foot pathology on pain, function or activity limitation.

Secondary outcomes:

- Pressure pain threshold (PPT) at the site of maximum local tenderness. At baseline, this site was identified manually and recorded using an original frame (Figure 2) so that this specific location could be reproduced precisely at the next assessment sessions; a similar system was used by Chow et al. [9]. The PPT was assessed using the electronic Commander Algometer (JTech Medical, USA) with a $1cm^2$ flat circular probe. The assessment was performed with the subject supine, preventing patient from seeing the foot. He/she was instructed to inform the assessor as soon as a feeling of pain occured by saying "stop". The pressure was applied perpendicular to the skin surface and the pressure was raised at a continuous rate of approximately $10N.s^{-1}$. The dolorimeter was removed as soon as the patient said "stop" and the final force applied was monitored [13]. Two measurements, with 10-second intervals between trials, were carried out; the mean force applied ($N.cm^{-2}$) was taken into consideration for the analyses.

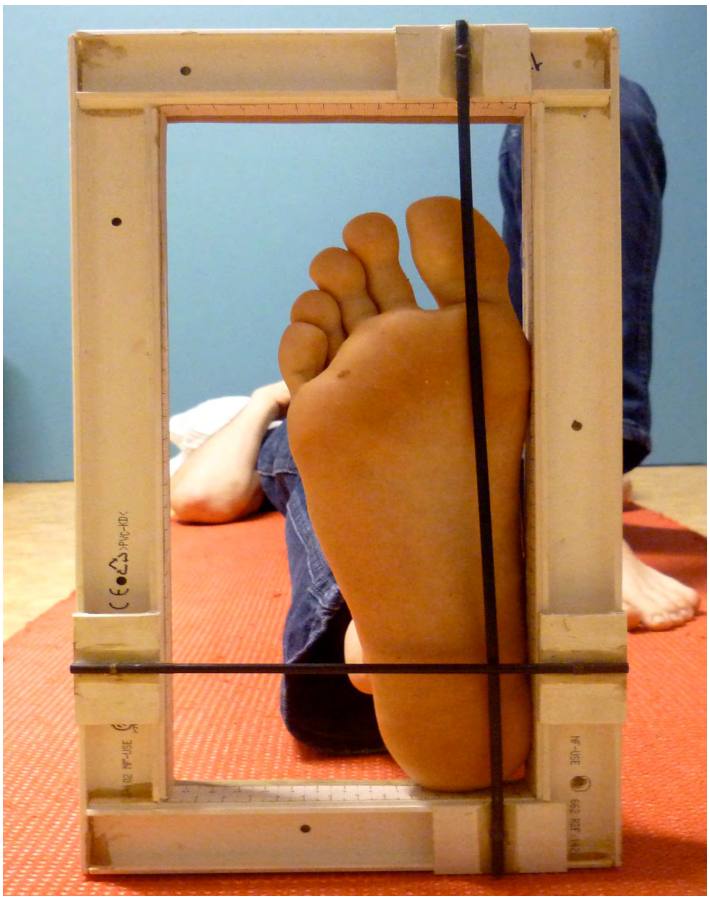

Figure 2. The original frame used to record the most painful point for the PPT measurement and for the treatment.

Description of the intervention

The three ESWT sessions were conducted by the same therapist (A.F.). The shockwaves were delivered by using the Swiss DolorClast® Power (Electro Medical Systems, Switzerland) which provides radial shockwaves. Using a compressed air pulse, a projectile in the handpiece ("Power Plus") is accelerated to high speed. As it strikes the applicator in the handpiece, the projectile generates a shockwave which radially spreads from the tip of the applicator to the treatment area. A concave applicator with a 15 mm diameter delivering more focused waves was used.

The patients were instructed to lie supine on an examination table with the ankle in a neutral relaxed position. After having applied coupling gel over the site of maximum local tenderness (localized by means of the original frame) to minimize the loss of shockwave energy, the extremity of the handpiece was applied on the skin at this precise point, with the handpiece perpendicular to the plantar fascia. The patients received 2000 impulses of 10 Hz frequency per session (thereby, the total number of shocks during the treatment period was 6000) with an energy flux density of $0,275mJ/mm^2$ and an air pressure set at 0,35 to 0,4 MPa (3,5-4 Bars) without local or systemic anesthesia or sedation before or after the application. The same procedure was followed for each of the three sessions.

Following each ESWT session, the participants were allowed to resume their daily activities. However, they were instructed to lighten their hard and painful tasks (for example, prolonged standing position, physical activities). Before the post-treatment assessment session (cicatrization period), no activity restriction was prescribed (except for painful activities). In case of pain, patients were allowed to take only type I (paracetamol) or II (weak opioid drugs such as tramadol) painkillers (no NSAIDs).

Data analysis

The results were expressed as mean and standard deviations for normally distributed quantitative variables and as medians and inter-quantile ranges (P25-P75) for skewed quantitative variables. The normality of the quantitative variables was assessed graphically and using the Shapiro-wilk test. Numbers and percentages were used for qualitative variables.

The minimum sample size was estimated using power-based sample size calculations. Based on an estimated baseline pain intensity (VAS score) of 50 and standard deviation of 20, the minimum sample size was estimated at 30 participants to detect a 30% pain intensity decrease on the retest when α is < 0.05 and power is 95%.

Outcomes at the different time points were compared by analysis of variance (ANOVA) for repeated data followed by multiple comparisons. Non-parametric Friedman test (followed by

Wilcoxon signed ranks test) was applied when appropriate. All results were considered to be significant at the 5% critical level (P<0.05).

Statistical analyses were performed using Statistica (StatSoft Inc. Tulsa, OK, USA).

Results

No drop-out occurred throughout the study period. The pain intensity change from baseline to post-treatment is presented in Figure 3. A significant decrease of pain intensity from baseline to pre-treatment (P=0.014) and from pre-treatment to post-treatment (P<0.001) were observed. A closer look at the changes that occurred from pre-treatment to post-treatment revealed a mean decrease of pain intensity score of 33.9% and that thirteen patients out of thirty had a decrease of pain VAS score equal to or higher than 60% (21/30 when the cut-off was a pain intensity decrease of 30%).

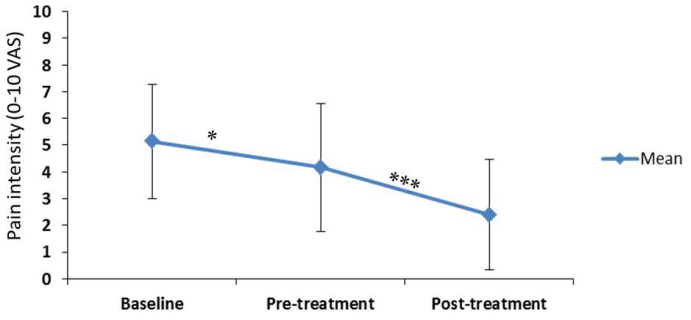

Figure 3. Mean (SD) pain intensity (VAS 0-10cm) at baseline, and at the pre-treatment and post-treatment assessments (* = P<0.05 and *** = P<0.001).

Regarding the FFI, no significant change (P=0.06) was observed from baseline to pre-treatment. In contrast, a significant (P<0.001) improvement (mean decrease of the FFI of 59.5%) was observed from pre-treatment to post-treatment (Figure 4). Following the pre-treatment assessment, 16 patients out of the 30 had a decrease of the FFI score equal to or higher than 60% (26/30 when the cut-off was a pain intensity decrease of 30%).

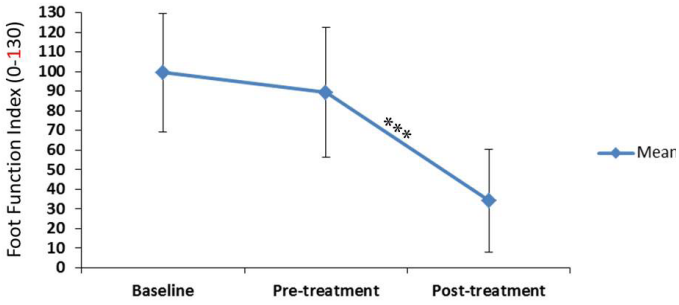

Figure 4. Mean (SD) Foot Function Index score at baseline, and at the pre-treatment and post-treatment assessments (*** = P<0.001).

Similar findings were observed for the PPT (Figure 5), the mean increase of PPT reaching 68.4% between pre-treatment and post-treatment. Following the pre-treatment assessment, 12 out of the 30 patients had an increase of PPT equal to or higher than 60% (19/30 when the cut-off was set at 30%).

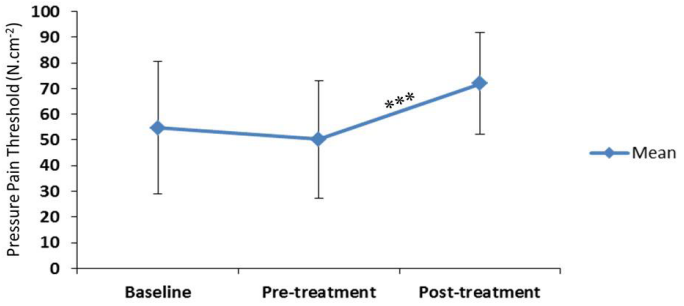

Figure 5. Mean (SD) Pressure Pain Threshold (PPT) at baseline, and at the pre-treatment and post-treatment assess.

Discussion

Several studies have investigated the effectiveness of radial ESWT in chronic PF [4]. According to the literature [6, 9, 10], the energy dose to be used is an important factor, a low energy density resulting in a possible ineffectiveness of ESWT and a too high energy density (>0.28 mJ/mm^2 according to Rompe et al.[10]) being contraindicated in the treatment of tendon disorders because of the risk of morphological alterations within tendon and paratenon [11] and because it might interfere with the repair potential of the cells [14]. Whereas low (<0.10 mJ/mm^2) and medium (ranging from 0.10 to 0.20 mJ/mm^2) energy flux density were used in most studies investigating ESWT in chronic PF, only scarce information exists regarding the feasibility and benefits of a high energy flux density (>0.20 mJ/mm^2) pointing out the relevance of the present pilot study. We showed that radial high dose (0,275mJ/mm^2) ESWT is feasible without local analgesics and effective to quickly and significantly decrease pain and disability in most patients with chronic PF. In a different study population (patients with knee osteoarthritis), Zhao et al. also described the effectiveness of high dose ESWT [15].

Our results are in accordance with previous studies in which radial ESWT was found to be effective in similar populations [9, 16-18] although a lower energy dose (≤0.16mJ/mm^2) was used. The extent of the heel pain intensity decrease was lower in the present study (-33.9%) than in the studies of Ibrahim et al. (-92.4% at 4 weeks) [17] and Gerdesmeyer et al. (-72.1% at 12 weeks) [16]. Beside the difference in energy dose, the fact that the final outcomes were measured three weeks after the last ESWT session is another difference likely to explain the difference in the results. Indeed, maximal metabolic effects are often considered to occur after several months and benefits

might be even more pronounced at the 12-month follow-up than at the 12-week follow-up [16]. The characteristics of the participants might also partially explain the somewhat lower results found in the present study. Indeed, inclusion criteria used in the studies regarding effectiveness of ESWT in chronic PF generally include pain lasting more than 6 months (versus more than 3 months in the present study) and it is known that as initial treatment ESWT is not as effective as in a later stage [19].

Regarding disability, contrary to other studies in which the (modified) Roles & Maudsley score was reported [16, 17], we followed the change of the FFI disability score (as Chow et al. did [9]) because it is a widely used evaluation method which was reported to be correlated with clinical and radiological parameters in PF [20]. In accordance with the literature in which substantial functional improvements are reported following radial ESWT for chronic PF, a drastic decrease of the disability score (-60%) was observed in the present study. The PPT measured also significantly and clinically changed. Our results are in accordance with some previous studies although they used the algometer in a different way [16, 18]. The change observed in the present study is of clinical importance considering the fact that pain during walking and standing is one of the main complaints of PF.

When using a cut-off of 60% of improvements as in Gerdesmeyer's and Aquil's paper to consider the treatment as successful [8, 16], our study suggests that the high dose radial ESWT was a success in half of the included patients. This percentage is in accordance with the range (34% - 88%) reported in the review of Wang [21] and the results presented by Aquil et al. (8) but differ from the one reported by Ibrahim et al. who reported a success rate of heel pain improvement reaching 92% [17]. If the ESWT could be considered as successful in "only" half of the participants of the present study, one has to keep in mind that additional participants reported clinical significant improvements (outcome improvement higher than 30%).

Although this study and the previous ones about the effectiveness of radial ESWT in chronic PF are globally in agreement, a comparison of these studies revealed that the number of ESWT sessions (often ranging from one to three) and the total number of impulses administered (ranging from 3800 to 6000) also differ between studies [8, 10] underlying the absence of consensus regarding the optimal parameters to be used for chronic PF (as for other conditions).

Several hypotheses have been proposed to explain the effectiveness of ESWT [10]. The short-term analgesic effects might be explained by the gate control theory rather than an activation of the endogenous opioid system [22]. The mid-(long) term might result from the dysfunction/destruction of unmyelinated sensory nerve fibers occurring and by some central effects (for example, a decrease of the number of neurons immunoreactive to some neuropeptides and substance P within the dorsal root ganglia [10]). Diffuse noxious inhibitory control, based on an inhibition of the spinothalamic tract cells, is another pain-relieving mechanism sometimes evoked [9]. ESWT is also supposed to induce internal microdisruption of fascial tissues that would result in an increase of neo-vessels and angiogenesis-related markers such as eNOS (endothelial nitric oxide synthase), VEGF (vessel endothelial growth factor) and PCNA (proliferating cell nuclear antigen) [23-25] improving the circulation, favoring tissue regeneration and thereby limiting the risk of recurrent pain episodes. A liberation of neuropetides causing a local neurogenic inflammation preventing a re-innervation of the sensory nerve endings is also hypothesized. The extracellular cavitation phenomenon might also have an influence by increasing the membrane permeability, favoring metabolic actions on tissues and inducing the liberation of proteins and mediators which influence pain; it might also damage local nerve endings and influence the transmission of pain signals [9]. A recent review on the biological effects of ESWT concludes that an optimal dosage stimulates cell proliferation and activates and enhances healing processes via neovascularization, collagen synthesis and expression of differentiation critical genes [26]; the activation of a complex network of molecules (for example, cytokines and metalloproteinases) might also be involved [26]. Beside these biological effects, a placebo effect might also be postulated. Indeed, important improvements have been reported in some patients included in the placebo group of some previous studies [16, 27].

Some study limitations have to be considered when interpreting our results. First, the fact that this is a prospective cohort study rather than a RCT is one of the main shortcomings of the present work; however, considering that literature is scarce regarding the effectiveness of high dose radial ESWT, conducting this pilot study was relevant. Furthermore, the 6-week control period enabled us to confirm the absence of changes over time of our outcomes when no treatment was applied (except for the pain score for which a statistically (but not clinically) significant decrease was observed). Second, the lack of an assessment during the treatment period and during the cicatrization phase, prevented us from investigating the acute pain and disability changes during these periods; indeed, Chow et al. showed progressive improvements from one session to another [9]. Third, there was not a long-term follow-up; although some authors reported 12 [16, 18] or 24-months follow-up [17], a recent review concluded that ESWT long-term efficacy remains unknown due to a lack of studies (3). Fourth, although there was no drop-out in the present study, one cannot conclude about the tolerability of the method as the discomfort during treatment was not evaluated. Finally, despite the significant improvements observed in the present study, a few patients did not report any improvement. Although several variables have been reported to influence negatively (for example, age [28], psychological status [28]) or positively (for

example, the presence of calcaneal bone marrow edema on pretherapeutic MRI [29] or the absence of a plantar calcaneal spur [18]) the outcomes, no consensus about them has been reached. Therefore, further studies are necessary to identify the factors which might predict the success or fail of ESWT treatment.

Conclusion

The present study suggests that high dose radial ESWT is a feasible and effective way to decrease quickly and significantly pain and disability in most patients with chronic PF.

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