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Evaluation of the Therapeutic Effect of Extracorporeal Shockwave Therapy in Chronic Plantar Fasciitis

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Abstract

Background: Plantar fasciitis is a common pain syndrome of the foot associated with severe discomfort and often results in the patient's limitation. Extracorporeal shock wave therapy (ESWT) is a widely used treatment option which offers an alternative to other conventional methods. The objective of this study was to evaluate the effectiveness of ESWT in the treatment of plantar fasciitis.

Material and methods: Thirty-two participants were enrolled in a prospective, randomized, placebo-controlled and double-blinded study. All participants were randomized into two groups. Therapy group received 3 sessions of focused ESWT in a weekly interval. Control group received placebo intervention with the same frequency. Outcomes of the follow-up were taken after the last treatment session and again in a 3-month follow-up. Evaluation of the treatment was achieved with the Visual Analog Scal (VAS) and Roles and Maudsley score.

Results: Treatment with ESWT provided superior results in evaluation with (VAS) and also with Roles and Maudsley score when compared with the placebo treatment. Decrease of pain in the first few steps in the morning was 29.9% after the last therapy and 63.2% in the 3-month follow-up in the therapy group. In the control group the decrease was 11% and 23.7% respectively. Decrease of pain in the normal daily activities was 29.0% after the last therapy and 63.0% in the 3-month follow-up. In the control group the decrease was 8.7% and 24.3% respectively. Satisfaction with the therapy results measured by Roles and Maudsley score improved by 28.1% after the last treatment and by 46.9% in the 3-month follow-up in the therapy group. In the control group the improvement was 6.3% and 18.8% respectively.

Discussion: Although the biologic effects of ESWT are not yet fully understood, the clinical evidence of its efficiency is being proved in a growing number of studies. It is not surprising that for this reason, ESWT is often being compared to other treatment approaches such as corticosteroid injections. Another frequently discussed topic regarding the use of the ESWT in plantar fasciitis is the possible time-dependent cumulative effect.

Conclusion: Focused ESWT is an effective modality in the treatment of patients suffering from chronic plantar fasciitis in both short and long period.

Keywords: Focused extracorporeal shockwave therapy (ESWT); Plantar fasciitis; Visual analog scale; Roles and maudsley score

Introduction

Plantar fasciitis is a very common musculoskeletal foot disorder characterized by pain in the inferomedial aspect of the heel, where the origin of the plantar fascia lies [1]. In the past plantar fasciitis was considered an inflammatory disease. Histological findings from recent studies, however, are proving that there are degenerative, noninflammatory processes occuring during this painful condition [2]. Diagnosis of plantar fasciitis usually consists of the history and physical examination of the patient. Patients diagnosed with plantar fasciitis may walk with their affected foot in an equine position to relieve pressure on the painful side of the heel. Pressure on the medial plantar calcaneal area will usually cause sharp pain [3]. In most patients, pain is the worst upon the first steps in the morning and decreases during the day. This might be explained by a slight contraction of the plantar fascia during the night and initial stretching during morning walking [4].

Imaging methods such as magnetic resonance, ultrasound imaging or radiography might be used to aid in the diagnosis of plantar fasciitis but they are routinely not necessary. Plain radiography might help to identify a subcalcaneal spur although it does not confirm the diagnosis of plantar fasciitis itself (Figure 1) [3,5]. Current treatment options for plantar fasciitis involve lifestyle modification with avoiding high impact activities, oral analgesia, specific stretching of plantar fascia and Achilles tendon, orthotic devices such as night splints to assure the neutral position of the food during sleep or heel inserts to soften the impact on the painful area [6]. Corticosteroid injections into the area of pain are very often used as a treatment for plantar fasciitis even though they have been associated with severe side effects. In 1998 Acevedo and Beskin reported that in a group of 765 patients suffering from plantar fasciitis, 51 were later diagnosed with a rupture of the plantar fascia and 44 (86%) of those were associated with corticosteroid injection [7]. Furthermore, multiple injections of corticosteroids may cause heel pad atrophy, especially in elderly patients [8].

Surgical intervention of plantar fasciitis should be considered as the last treatment option for patients who did not respond to non-invasive methods [4]. The rates of complications vary within affected individuals. In general, they occur more frequently in those patients where the symptoms were more severe and chronic [9]. Another treatment option which is currently available for patients suffering from plantar fasciitis is extracorporeal shockwave therapy (ESWT). Since 1980, high

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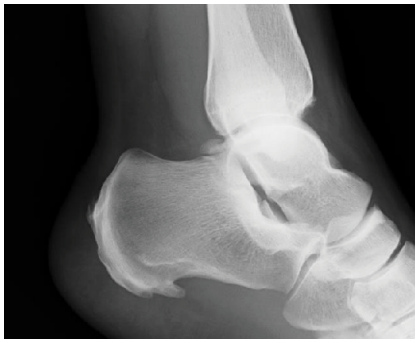

Figure 1: Projectional radiography of calcaneal spur of one of enrolled patient.

energy extracorporeal shockwaves were used for the treatment of kidney stones. Because of the transcutaneous application of high energy to the patient's body, much research has been done regarding the possible side effects of this therapy. From these early applications treatments using ESWT, the basis for regenerative effects of tissue s were discovered and ESWT was introduced in the field of orthopedics [10]. In 1995, the treatment of plantar fasciitis with the use of focused extracorporeal shockwave was reported [11]. This treatment method involves delivering shock waves from the applicator onto the painful area to stimulate healing processes and cause analgesia [12].

Materials and Methods

Study design

The study design was prospective, randomized, placebo-controlled and double-blinded. All data for the purpose of the study were collected from April 2019 to October 2019. Both the patients and investigator who collected data for the treatment results were blinded. ESWT treatment and sham were applied by a physician who was not involved in further outcomes evaluation. Informed consent was obtained from all patients. The treatment method is consistent with the ethical guidelines of the 1975 Declaration of Helsinki adopted by the General Assembly of the World Medical Association (1997-2000) and by Convention on Human Rights and Biomedicine of the Council of Europe (1997) [13,14].

Participants

A total of thirty-two patients with chronic heel pain deriving from plantar fasciitis were enrolled in the study. All patients were randomly distributed into two groups of 16 patients. Randomization was performed by block randomization using a computer-generated algorithm before the first treatment. Mean age, Body Mass Index (BMI), mean duration of heel pain and sex were recorded.

Inclusion criteria

The required criteria for participants to be included in the study were that plantar fasciitis had to be proven by tenderness at the origin of the plantar fascia, typical pain in the first steps in the morning and pain during palpation of the medial part of the heel >5 on VAS. The participants also had to evaluate their limitation of activities by 4 points using the Roles, et al. score [15]. All participants must have suffered from plantar fasciitis for at least 3 months and undergone at least three other conservative treatment types without significant pain relief. The participants had to be at least 18 years old. Furthermore, proven heel spur was neither inclusion or exclusion criteria.

Exclusion criteria

Exclusion criteria included coagulation problems, pregnancy, thrombosis, cancerous diseases, rheumatologic disorders, polyneuropathy, acute inflammation and/or infection in the treatment area, local and/or systemic neurologic disorders, diabetes mellitus, previous plantar fascia surgery or previous rupture of the plantar fascia. Previous treatment of ESWT was also considered as one of the exclusion criteria [16].

Treatment

Focused shockwave therapy was applied with BTL-6000 FSWT device (BTL Industries Inc.). In the therapy group, the total amount of 2000 shocks per treatment with the energy flux density of 0.20 mj/mm^2 were applied to the area of maximum pain on the medial part of the heel based on a patient's feedback. The position of the applicator was adjusted during the treatment if necessary. Three treatment sessions were performed, each in a weekly interval. Ultrasound gel was used as a coupling medium for the shock waves.

The control group received the same amount of shocks in the same time period between individual interventions. The device was set to its minimal energy flux density settings of 0.01 mj/mm^2. To ensure that no energy was transmitted from the applicator to the patient, ultrasound gel was not applied during the sham procedure. Both interventions were performed without the application of local anesthesia.

Outcome measures

To evaluate the success rate of the intervention, Visual Analog Scale (VAS) and a modified Roles and Maudsley score were used. The VAS is an instrument for measuring the subjective perception of pain intensity. To measure the outcome for this study, patients had to evaluate the heel pain during the first few steps in the morning and heel pain during normal daily activities. The scale ranged from 0 to 10 points, where 0 points represented no pain perception whatsoever and 10 points represented the most imaginable pain [16].

Additionally, a modified Roles and Maudsley score method was used to evaluate the satisfaction of patients with the treatment. The results of treatment were classified on a 4-level grading scale as follows: 1) Excellent results - no pain, 2) good results - occasional discomfort, 3) fair results - some discomfort after prolonged activity, 4) poor results-pain limiting activities [15]. Both evaluation methods were performed before the first intervention, after the last intervention, and in the 3-month follow-up.

Results

Thirty-two patients were randomized into two groups. The therapy group (n=16) received treatment with ESWT and the control group (n=16) received a sham intervention. All patients of both groups completed all three interventions and also participated in a 3-month follow-up evaluation. We did not face any serious complications or side-effects during or after the treatment in any patient. Complaints from some patients of mild pain during treatment procedure did occur but this did not last more than 24 hours.

Baseline Characteristics	Therapy group	Control group
Mean age	53.19 ± 14.1	54.69 ± 8.9
Mean BMI	24.91 ± 2.5	24.99 ± 3.0
Mean duration of heel pain (months)	20.12 ± 8.7	22.34 ± 10.6
Females	10 (62.5%)	11 (68.8%)
Males	6 (37.5%)	5 (31.2%)

Table 1: Baseline characteristics of the patients.

There were no significant (P<0.01) differences between both groups regarding the baseline characteristic of the age, sex, BMI or duration of heel pain before treatment (Table 1). The difference between the therapy group and the control group in baseline VAS for pain during the first few steps in the morning was not significant (P<0.01) with 7.3 ± 1.1 and 7.4 ± 1.0 respectively. Also, the difference between the groups was not significant (P<0.01) for pain during normal daily activities with 6.3 ± 1.1 in the therapy group and 6.4 ± 1.4 in the control group.

Participants from the therapy group reported a significant (P<0.01) decrease in pain during the first few steps in the morning evaluated with VAS in both evaluations. The mean change was from a baseline of 7.3 ± 1.1 to 5.1 ± 1.1 (29.9%) after last treatment and to 2.7 ± 1.7 (63.2%) in the 3-month follow-up.

In the control group, the difference was not significant (P<0.01) in the evaluation after the last intervention, decreasing from 7.4 ± 1.0 to 6.6 ± 1.0 (11.0%) but it was significant (P<0.01) when compared with the 3-month follow-up decreasing to 5.6 ± 1.1 (23.7%) on VAS. Results of this evaluation are shown in Figure 2.

Evaluation with VAS of pain during normal daily activities demonstrated significant (P<0.01) difference in the therapy group from baseline of 6.3 ± 1.1 to 4.4 ± 1.0 (29.0%) after last treatment. In the 3-month follow-up it decreased to 2.3 ± 1.7 (63.0%). No significant (P<0.01) difference was found in the control group while evaluating the pain during normal daily activities. From the baseline of 6.4 ± 1.4 the pain decreased to 5.9 ± 1.4 (8.7%) after the last intervention and then to 4.9 ± 1.4 (24.3%) in the 3-month follow-up (Figure 3).

Baseline value of the Roles and Maudsley score was identical for all patients since score 4) poor results - pain limiting activities, was one of the inclusion criteria. We achieved significant (P<0.01) results in the therapy group. There was an improvement to 2.9 ± 0.8 (28.1%) after the last treatment and further improvement to 2.1 ± 0.8 (46.9%) in the 3-month follow-up. Significant (P<0.01) differences were not achieved in the control group neither in the evaluation after the last intervention with the score being 3.8 ± 0.4 (6.3%) nor in the 3-month follow-up with score 3.3 ± 0.8 (18.8%). Results of this evaluation are shown in Figure 4. Data summary regarding the results of both groups are shown in Table 2.

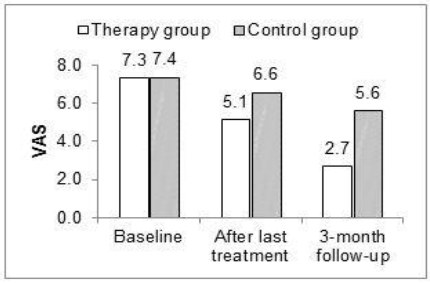

Figure 2: VAS evaluation of pain in the first few steps in the morning. Data for both groups are visualised in box plots.

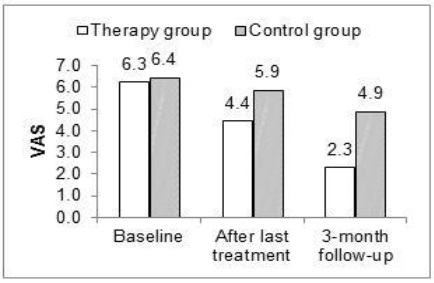

Figure 3: VAS evaluation of pain during normal daily activities. Data for both groups are visualised in box plots.

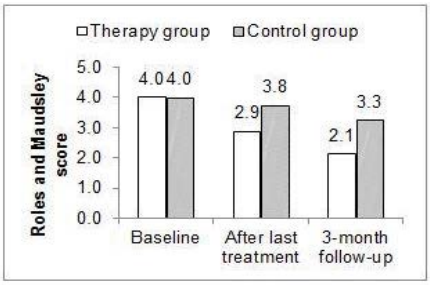

Figure 4: Evaluation with Roles and Maudsley score. Data for both groups are visualised in box plots.

Outcome measure	Therapy group	Control Group
	Baseline	
Pain in the first few steps in the morning (VAS)	7.3 ± 1.1	7.4 ± 1.0
Pain during normal daily activities (VAS)	6.3 ± 1.1	6.4 ± 1.4
Satisfaction with the treatment (Roles and Maudsley score)	4	4
	After the last treatment	
Pain in the first few steps in the morning (VAS)	5.1 ± 1.1	6.6 ± 1.0
Pain during normal daily activities (VAS)	4.4 ± 1.0	5.9 ± 1.4
Satisfaction with the treatment (Roles and Maudsley score)	2.9 ± 0.8	3.8 ± 0.4
	3-month follow-up	
Pain in few first steps in the morning (VAS)	2.7 ± 1.7	5.6 ± 1.1
Pain during normal daily activities (VAS)	2.3 ± 1.7	4.9 ± 1.4
Satisfaction with the treatment (Roles and Maudsley score)	2.1 ± 0.8	3.3 ± 0.8

Table 2: Outcome measurement.

Discussion

The use of ESWT in the treatment of plantar fasciitis has been previously investigated in various clinical studies. Although there exists evidence proving its safety and effectiveness, there is still discussion about the characteristics of the individual treatment protocols [16-18]. Therapeutic parameters of these protocols vary across the clinical studies. A systematic review from 2015 reported the use of focused ESWT for treating plantar Fasciopathy with energy flux density ranging from 0.02 to 0.56 mj/mm^2 varying in multiple studies. Most treatments of plantar Fasciopathy in the findings of the same study were performed with energy flux density of 0.20 mj/mm^2 [19].

Besides the issue of ambiguous treatment protocols, there is also the question of the exact principle of the biologic effects of shockwave which it is not yet fully understood. Some authors presume that shockwave is able to relieve pain, caused by insertional tendinopathy, by inducing hyper-stimulation analgesia through initial painful perception [20]. That might be the reason why positive results are noticeable even in a short period, such as those achieved in this study. Interestingly, Gollwitzer et al. reported that this effect might be inhibited by local anesthesia [16].

Findings from animal studies prove that one of the effects of ESWT is also neovascularization at the junction of the tendon and bone which further induces improved blood supply in the treated area and helps in

the process of tissue regeneration [21]. This effect thus plays a potential role in the explanation of long-term improvement of painful conditions such as plantar fasciitis. The results of our study provided statistically significant data regarding the difference in the outcome measures between the group treated with ESWT and the control group. Although considerably lower, certain improvements were noted in the control group as well. This may be explained by spontaneous remission by the placebo effect or by the different qualities of other treatment methods used by participants. With regards to the results obtained in our study, we suggest that ESWT is an effective modality in patients with plantar fasciitis in the short-time period, thus adding to the significance of this opinion already reported in multiple studies [19,17].

Furthermore, number of recent studies reports better results with ESWT when compared with other possible approaches of treatment of plantar fasciitis. Mishra et al. conducted prospective comparative non randomized study comparing ESWT and methylprednisolone injections in 60 patients. In a 6 weeks follow-up 26 (86.7%) patients reported VAS <5 in ESWT group compared to 16 (53.3%) patients in the group that received the injections [22]. In a meta-analysis conducted by Xiong, et al. efficacy of ESWT was compared to efficacy of corticosteroids injections (CSI). Although inter-group differences were not significant, the VAS score was better improved in the ESWT group [23]. In a prospective randomized trial, Lai et al also compared CSI to ESWT in the treatment of plantar fasciitis. In the twelve week follow-up the treatment option with ESWT was more efficient in pain level outcome than the CSI.

Park, et al. investigated the use of ESWT on 25 patients with plantar fasciitis and reported a success rate of 63,3% one week after the last treatment intervention and 80.0% in a 24-month follow-up using the Roles, et al. score [24]. Metzner et al. applied ESWT on 63 patients achieving at least 50% VAS reduction in pain in 50% of all patients in the 6-week follow-up, in 62% of all patients around the 18-month follow-up and in 90% of all patients approximately in the 72 month follow-up [25]. Wang, et al. proposed that effect of ESWT on plantar fasciitis seems to be cumulative an time-dependent. In their study the results in 79 patients in a one year follow-up were 75.3% of complaint-free, 18.8% significantly better and 5.9% slightly better [26].

Conclusion

These findings therefore suggest that improvement continues even in the long period after the treatment. This is considered as a limitation in our study, since the last evaluation of our patients was in the 3-month follow-up. Another limitation of the study was a relatively small sample of the participants. To increase the evidence value of the affectivity of shockwave therapy, further research with a larger sample of participants is necessary.

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