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Treatment Outcomes of Corticosteroid Injection and Extracorporeal Shock Wave Therapy as Two Primary Therapeutic Methods for Acute Plantar Fasciitis: A Prospective Randomized Clinical Trial

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ABSTRACT

The outcome of corticosteroid injection (CSI) and extracorporeal shock wave therapy (ESWT) as primary treatment of acute plantar fasciitis has been debated. The purpose of the present study was to evaluate and compare the therapeutic effects of CSI and ESWT in patients with acute (<6-week duration) symptomatic plantar fasciitis. Of the 116 eligible patients, 68 were randomized to 2 equal groups of 34 patients, each undergoing either ESWT or CSI. The ESWT method included 2000 impulses with energy of 0.15 mJ/mm^2 and a total energy flux density of 900 mJ/mm^2 for 3 consecutive sessions at 1-week intervals. In the CSI group, 40 mg of methyl prednisolone acetate plus 1 mL of lidocaine 2% was injected into the maximal tenderness point at the inframedial calcaneal tuberosity. The success and recurrence rates and pain intensity measured using the visual analog scale, were recorded and compared at the 3-month follow-up visit. The pain intensity had reduced significantly in all patients undergoing either technique. However, the value and trend of pain reduction in the CSI group was significantly greater than those in the ESWT group ($p < .0001$). In the ESWT and CSI groups, 19 (55.9%) and 5 (14.7%) patients experienced treatment failure, respectively. Age, gender, body mass index, and recurrence rate were similar between the 2 groups ($p > .05$). Both ESWT and CSI can be used as the primary and/or initial treatment option for treating patients with acute plantar fasciitis; however, the CSI technique had better therapeutic outcomes.

Ten percent of the general population in their lifetime and 1% of the world population will present to orthopedic surgeons with heel pain due to degenerative changes in the plantar fascia (1–3). The main symptom is severe pain in the medial tubercle of the calcaneus during weightbearing in the morning that decreases during standing and increases with prolonged walking or running (4,5). The main predisposing risk factors are increasing age, increasing body mass index (BMI), certain anatomic risk factors such as leg length discrepancy, increased plantar fascia thickness, pes planus (excessive pronation of the foot), and certain extrinsic factors such as previous injury to the heel, improper shoe fit, and improper running pattern (6,7).

Although the etiopathogenesis of plantar fasciitis is poorly understood, it is probably multifactorial and caused by multiple microtears resulting from an increase in stress and repeated fascia stretching that has exceeded the self-limiting reparable capacity of the body (8,9). The continuous stress and microtears lead to a slight gap between the fascia and calcaneus joint. This small gap can become filled with new reactive bone tissue and form heel spur (10). The spur is not the cause of the pain, but, as stated by Johal and Milner (11), it can accompany the disease. The changes result in fibroblastic proliferation and chronic granulomatous tissues formation, which can ay be accompanied by vascular hypoperfusion, loss of elasticity of the connective tissue, and changes in nerve function and, eventually, lead to plantar fascia enthesis (10,12,13).

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The plantar fasciitis is a self-limiting disorder; however, because of its prolonged course (mean period of 16 to 18 months), patients experience severe pain and disability affecting their quality of life (9). The diagnosis is based on patient history and clinical examination findings (14). The treatment options are rest, cold or warm water compression, nonsteroidal anti-inflammatory drugs, other anti-inflammatory analgesics, plantar stretching exercises, heel pad orthotics, magnetic insoles, therapeutic shoes, night splints, tapings, short plasters, CSIs, ESWT, radiotherapy, platelet-rich plasma injection, botulinum toxin injection, and, eventually, surgical treatment (12,15–17). No conclusive treatment option is available for this painful disease, and physicians and patients will choose a routine treatment option according to their own experience and interests. DiGiovanni et al (18) argued that the controversy regarding choosing a specific treatment option should be clarified by qualitative studies. A questionnaire-based study reported that 75% of the physicians recommend CSIs as the second treatment of choice (19).

Recently, ESWT has been recommended as an appropriate and effective method in the treatment of plantar fasciitis (20). ESWT modalities are capable of producing sonic waves with high amplitude within a short period and propagating them on a small surface (16). Theoretically, this energy could inhibit demyelinated plantar sensory nerves, reduce calcification, increase the proliferation of growth factors, and increase peripheral blood circulation, angiogenesis, and neovascularization in the degenerative tissue of the heel (12,21,22). Despite these theoretical views, the exact therapeutic effect of ESWT has not been substantiated by various clinical trials and a myriad of therapeutic treatment protocol regimens (e.g., the number of impulses, energy amount, shock wave frequency, focusing methods) (10,23–29). Another important debate is the effectiveness of ESWT as a primary therapeutic regimen. The only controlled clinical trial evaluating radial ESWT versus a stretching technique demonstrated that the patients were not satisfied with the radial ESWT technique if it was applied as a primary treatment protocol (22).

Of 30 nonoperative treatment methods recommended for patients with plantar fasciitis, a few studies have compared CSI and ESWT, and a very few studies have compared the 2 methods as the primary technique for treating acute plantar fasciitis. The present clinical trial study was designed to examine and compare the effects of the 2 treatment options, CSI and ESWT, as primary treatment of acute plantar fasciitis.

Patients and Methods

This was a randomized clinical trial study including all patients with heel pain or a possible diagnosis of acute plantar fasciitis who had been referred to our orthopedic clinic from July 2011 to June 2012. The included patients were adults >18 years old, with morning heel pain that was relieved after a short walk, localized tenderness at the tuberosity of calcaneus in dorsiflexion, a symptomatic duration of <6 weeks, and a heel pain score of ≥5 of the visual analog scale (VAS) present at the first steps taken in the morning. Patients were excluded from the study if they had received any treatment during the previous 6 weeks before the beginning of the study; had osteoarthritis, diabetes mellitus, peripheral vascular disease, a history of trauma or calcaneal fracture, chronic heart disease, neurologic, hepatic, and/or metabolic disease, or dermatologic infections or trauma at the heel region; had clinical features suggestive of seronegative spondyloarthropathy, nerve-related diseases (e.g., radiculopathy, tarsal tunnel syndrome), or coagulopathy disorders; were undergoing anticoagulant therapy; or had undergone previous surgery for plantar fasciitis or a spur or CSI, ESWT, or physiotherapy for heel pain. Those for whom ESWT was contraindicated, such as pregnant women, and patients with a hypersensitivity to lidocaine or corticosteroids were also excluded.

All the patients provided written informed consent before enrollment. Of the 116 patients, 9 did not fulfill the inclusion criteria and 23 were reluctant to participate. All the patients underwent lateral and axial radiographs to rule out any possible lesions such as osteomyelitis, tumor, or fracture. The remaining 84 eligible patients were randomized using random blocks to the ESWT (43 patients) or CSI (41 patients) groups (Fig. 1).

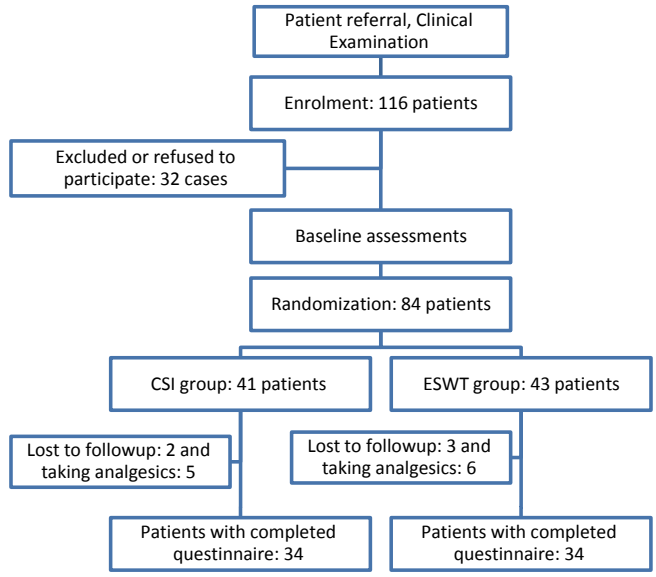

Fig. 1. The research flow chart. CSI, corticosteroid injection; ESWT, extracorporeal shock wave therapy.

ESWT Technique

The treatment protocol was intermediate shock wave therapy with an electrohydraulic shock wave system to apply an energy level of 0.15 mJ/mm^2. Two thousand shock wave impulses were applied for 3 times at weekly intervals. The total dose of 900 mJ/mm^2 was considered for each patient (23,30,31). The patient lay down in a comfortable position; the area of maximum tenderness was marked with a skin marker, and ultrasound gel was applied to the patient's heel as the coupling medium. No anesthetics or narcotics were used during the treatment protocol.

CSI Technique

For the CSI, 1 mL of methyl prednisolone acetate (40 mg) and 1 mL of lidocaine 2% were injected into the site of maximal tenderness at the inframedial calcaneal tuberosity (15,32). Care was taken to avoid injection into the skin, subcutaneous tissue, and/or fat pad.

After Treatment

The patients in both groups were instructed to not participate in any running or long walks for ≥10 days after the treatment and to not undergo any other alternative therapy such as night splints, massages, and/or narcotic or nonsteroidal anti-inflammatory drug usage.

All the patients were examined using the VAS to measure pain at 3, 6, and 12 weeks after treatment (in the ESWT group, the assessment was initiated after the final ESWT session) by another physician who was unaware of the study details. The worst daily pain intensity was recorded on the VAS for each patient at each visit. Pain was recorded on a scale of 0 to 10, with 0 indicating no pain and 10, the highest pain experienced by the patient. An increase of >2 values in the VAS pain score was regarded as disease recurrence. To minimize the interfering factors, the effects of the therapeutic methods on the reduction of pain without reference to gender, age, or BMI were also evaluated.

Statistical Analysis

After data summarizing, the 1-sample Kolmogorov-Smirnov test was used to assess the distribution of VAS score before and after treatment at 3, 6, and 12 weeks. The results indicated a normal distribution of the VAS score, except at the 3-week follow-up visit. Thus, for the comparative studies, the nonparametric statistics of the Wilcoxon signed ranks test and Mann-Whitney *U* test were mostly used to answer the hypotheses of the present study. To examine the VAS score changes before and after treatment at 3 weeks, the independent *t* test was used. The chi-square test was used to compare the success and recurrence rates. The chi-square test was also applies to examine gender frequency, and the independent sample *t* test was used to examine the age frequency. We applied repeated measure analysis of variance to analyze the VAS score trends for the interactions of the groups and demographic variables. SPSS software, version 19 (IBM, Armonk, NY) was used to analyze the data, and $p \leq .05$ were considered statistically significant.