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Effectiveness of Four Different Treatment Modalities in the Treatment of Chronic Plantar Fasciitis During a 36-Month Follow-Up Period: A Randomized Controlled Trial

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ABSTRACT

No consensus has been reached about the best treatment method of plantar fasciitis and the results of the treatment methods have been inconsistent. The objective of the present study was to compare the therapeutic effects of extracorporeal shock wave therapy, platelet-rich plasma injection, local corticosteroid injection, and prolotherapy for the treatment of chronic plantar fasciitis using a randomized, controlled, prospective study. We performed a randomized controlled prospective clinical study of 4 groups. The first group received extracorporeal shock wave therapy, the second group received prolotherapy, the third group received platelet-rich plasma injection, and the fourth group received a local corticosteroid injection. The study included 158 consecutive patients with a diagnosis of chronic plantar fasciitis with a symptomatic heel spur. The clinical outcomes were assessed using the visual analog scale and Revised Foot Function Index. At the end of the follow-up period, the mean visual analog scale scores for all 4 groups were similar to the mean visual analog scale scores before treatment. At the end of the follow-up period, no significant improvement was noted in the Revised Foot Function Index score in any of the groups. The corticosteroid injection was more effective in the first 3 months and extracorporeal shock wave therapy was an effective treatment method in the first 6 months in regard to pain. The corticosteroid injection lost its effectiveness during the follow-up period. The effect of prolotherapy and platelet-rich plasma was seen within 3 to 12 months; however, at the 36-month follow-up point, no differences were found among the 4 treatments.

Plantar fasciitis (PF) is a common cause of heel pain and has been defined as a tensile overload of the plantar fascia at its origin on the medial tubercle of the calcaneus (1). The pain is usually caused by collagen degeneration at the origin of the plantar fascia (2). The cause of degeneration is repetitive microtears of the plantar fascia at the calcaneal enthesis and is thought to be caused by biomechanical overuse from prolonged standing or running (2). Soft tissue ossification can also be present as a heel spur at the origin of the plantar fascia (3). The prevalence of heel spur has ranged from 30% to 70% in patients with heel pain (3).

Nonoperative treatment options of PF includes plantar fascia and gastrocnemius–soleus muscle stretching, nonsteroidal antiinflammatory drugs (NSAIDs), local corticosteroid (CS) injections, heel cups, arch supports, night splints, electrotherapy, lidocaine needling, prolotherapy (proliferation therapy), autologous blood injection, platelet-rich plasma (PRP) injection, and extracorporeal shock wave therapy (ESWT) (4). No concensus has been reached regarding the best treatment method for PF, and the results of the different treatments have been inconsistent (5). CS injections reduce the inflammation and swelling of the soft tissue around the plantar fascia (5). ESWT is a noninvasive procedure that uses single-pulse acoustic waves generated outside the body to a specific site in the body (6). Although the mechanism of ESWT is not completely understood, direct stimulation of healing, neovascularization, direct suppressive effects on nociceptors, and an

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hyperstimulation mechanism that would block the gate-control mechanism have been described in explaining its effects (7). Prolotherapy works by improving ligament mechanics and decreasing pain through an inflammatory mechanism (8). PRP is hypothesized to release high concentrations of platelet-derived growth factors that enhance tendon healing, because growth factors are released after platelets become activated to initiate the tissue healing response (9).

The aim of the present study was to compare the therapeutic effects of ESWT, PRP, local CS injection, and prolotherapy during a 36-month follow-up period for the treatment of chronic proximal PF (CPPF) with a duration of ≥12 months, using a randomized controlled prospective study. To the best of our knowledge, no reported studies have investigated and compared the effectiveness of these 4 treatment modalities.

Patients and Methods

We performed a randomized controlled prospective clinical study of 158 consecutive patients with a diagnosis of CPPF with a symptomatic heel spur with a duration of ≥12 months from December 2010 to February 2013. The patients were randomized into 4 groups, with the first group receiving ESWT, the second, prolotherapy, the third, PRP injection, and the fourth, a local CS injection.

All the patients joined the present study voluntarily without any monetary offering. All the patients were informed about the procedure and possible complications and the objectives of the present study. All patients provided written informed consent before participating in the study. The institutional review board approved the study. All cases were evaluated according to the inclusion and exclusion criteria (Tables 1 and 2). All the patients had unilateral symptoms.

The diagnosis of CPPF was determined from the patients' history of plantar heel pain during the initial steps after a period of inactivity or the first steps in the morning, pain after prolonged weightbearing, physical examination findings (heel pain with palpation of the proximal insertion of the plantar fascia), positive windlass test, positive dorsiflexion–eversion test, and ultrasound (US) evaluation findings. All patients first underwent conservative treatment such as plantar fascia and gastrocnemius–soleus muscle stretching, NSAIDs, heel cups, and night splints for 6 months. The patients who did not experience benefit from these conservative methods at the end of the 6-month follow-up period were allocated to the 4 study groups. The pretreatment and posttreatment collected data included the patients' self-assessments of heel pain, activity, and function level, use of analgesics, radiographic evaluation findings, US evaluation findings, adverse events, and complication data.

The pretreatment assessments included a complete history, physical examination, and laboratory tests, including complete blood cell and platelet counts, erythrocyte sedimentation rate, C-reactive protein level, prothrombin time, partial thromboplastin time, blood urea nitrogen, creatinine level, and electrolyte level analysis.

The patients who were allocated to the study were advised to avoid using any other conservative treatment, such as plantar fascia and muscle stretching, NSAIDs, heel cups, arch supports, night splints, electrotherapy, and lidocaine needling during their participation in the present study. All the patients were randomly allocated to US-guided ESWT, prolotherapy, PRP, or local CS injection. A randomization schedule was created by a computer program using block randomization of 10 patients. Of the 158 patients, 39 were assigned to the ESWT group, 40 to the prolotherapy group, 39 to the PRP group, and 40 to the local CS injection group. The demographic data of the subjects are summarized in Table 3. The severity of the pain, before and after the injections and ESWT, during the last 24 hours at rest, at the first step in the morning, and during daily activities at the area of plantar fascia origin on the medial tubercle was recorded using a visual analog scale (VAS), ranging from 0 to 10, with 0 indicating no pain and 10 indicating severe pain. The long form of the Revised Foot Function Index (FFI-R), which consists of 68 questions, was used to evaluate overall foot function, foot health, and quality of life before and after the injections and ESWT (10). The 4 subscales of FFI-R are pain and stiffness (19 questions), social and emotional outcomes (19 questions), disability (20 questions), and activity limitation (10 questions) (10).

The patients received 3 injections in the local CS injection, prolotherapy, and PRP groups once each week or 3 ESWT sessions in the ESWT group at the plantar fascia, with an interval of 7 days between the sessions. All the patients in ESWT group received the same dose of ESWT per protocol (6 Hz, 2000 pulse, 4.0 bar energy density) using a Chattanooga Intelect® RPW shockwave radial device (Chattanooga, Surrey, UK) under US guidance. All the injections (local CS, prolotherapy, PRP) and ESWT sessions were performed using real-time US guidance with a linear array transducer. The US evaluation was performed by measurement of the medial, lateral, and central bands of the plantar fascia of the affected foot and nonaffected foot for comparison before

Table 1
Inclusion criteria of the study

Inclusion criteria
Age ≥18 y
Pain on palpation of plantar medial calcaneal tubercle for ≥6 months
Body mass index <30 kg/m^2
Visual analog scale score for pain intensity >5 for participant's self-assessment of pain on first few minutes of walking in morning
Pain worse on waking up in the morning or after a period of rest
Heel spur on lateral radiograph of the foot
Failure to respond to treatment modalities, including plantar fascia and muscle stretching, nonsteroidal antiinflammtory drugs, heel cups, arch supports, and night splints within 4 wk

Table 2
Exclusion criteria for the study

Exclusion Criteria
Pregnancy or lactation
Bilateral plantar fasciitis
Body mass index >30 kg/m^2
Previous surgery for plantar fasciitis
Any previous injection (corticosteroid, platelet-rich plasma, prolotherapy, lidocaine needling), treatment, or surgery to plantar fascia
History of epilepsy, type 1 or 2 diabetes mellitus, or hematologic disease
Previous calcaneus fracture
Arthritis of the foot or ankle joint
History of gout arthritis
History of systemic inflammatory, autoimmune, or peripheral vascular disease, such as deep venous thrombosis or bleeding disorders
Effusion around the ankle joint
History of tarsal tunnel syndrome or achilles tendinopathy
Calcaneal bone tumor or cyst
Radiculopathy or peripheral neuropathy around the ankle joint such as nerve entrapment or tarsal tunnel syndrome
Cardiac, liver, or renal failure
Osteoporosis
Osteomyelitis of the affected limb
Tuberculosis infection
Joint, bone, or skin infection in the affected foot
Spondyloarthritis
Fat pad atrophy
Proximal plantar fibroma
Complex regional pain syndrome
Cardiac pacemaker
Clubfoot, pes cavus, or pes calcaneovalgus
Abnormal erythrocyte sedimentation rate or C-reactive protein level
Known sensitivity or allergic reaction to bupivacaine or acetaminophen
History of foot or ankle injury after plantar fasciitis treatment had started through the 36-month follow-up point

Table 3
Demographic patient data

Variable	ESWT	Prolotherapy	PRP Injection	Corticosteroid Injection
Gender (n)				
Male	22	21	19	17
Female	17	19	20	23
Affected foot (n)				
Right	18	22	23	20
Left	21	18	16	20
Age (y)				
Mean	39.2	37.5	38.4	40.1
Range	21 to 49	25 to 62	19 to 58	21 to 56
BMI (kg/m^2)				
Mean	27.1	26.7	26.6	27.3
Range	24.3 to 29.4	22.2 to 29.7	19.6 to 29.1	21.5 to 29.3
Symptom duration (mo)				
Mean	15.7	13.2	13.9	14.5
Range	14 to 18	12 to 14	12 to 15	13 to 16
Follow-up period (mo)				
Mean	35.7	36.1	36.0	36.2
Range	34 to 38	34 to 38	34 to 38	34 to 38

Abbreviations: BMI, body mass index; ESWT, extracorporeal shock wave therapy; PRP, platelet-rich plasma.