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REVIEW ARTICLE

Clinical Trials assessing various interventions and their effectiveness for plantar fasciitis: a systematic review

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ABSTRACT

Background: Plantar fasciitis (PF) is a chronic inflammatory condition that is caused by frequent trauma and induces severe pain. Frequent trauma is the best noted cause of PF, however, exact cause is unknown. Treatment of PF involves several strategies; either surgical or conservative ones. This study was done to determine the current and most promising future interventions of PF.

Methodology: We conducted a PubMed database search for trials related to the PF. The option of clinical trials was selected to limit the articles. The search process included using of several keywords to obtain all possible trials.

Results: Of the 44 articles obtained, 15 articles were included as they met our inclusion criteria, which were clinical trials and were published after 2010. The articles were summarized according to main points; author and publication year, design of the trial, patients, intervention, combined interventions used, treatment duration and evaluation, results and main findings.

Conclusion: HILT and ESWT were current effective non-surgical treatment for PF. EPRF was an effective surgical strategy, the promising future interventions include HA, APC and PDRN.

Keywords: Plantar fasciitis, PF intervention, PF management.

Introduction

Plantar fascia is a dense structure running almost through the entire length of the foot, it extends from sesamoid bone to the thumb and from the phalanges of the small fingers through the longitudinal septum, as well as through the vertical fibers passing along the arch of the foot in the form of five bands [1,2]. Plantar fascia has a role in the function of the foot as it provides both dynamic and static shock absorption for the longitudinal arch [3]. Plantar fasciitis (PF) is a degenerative syndrome of the plantar fascia, it is a painful inflammatory condition that is caused by frequent trauma at the origin of calcaneus [4,5]. General population sometimes called it "heel spurs" [6]. Heel pain is caused mainly by PF, it was estimated that 11%–15% of foot complaints return to PF [7,8]. PF is more prevalent in men in the age range of 40–70 years than in women [9]. Definite causes of PF are unclear, however, repeated trauma is the best noted cause, there are also several risk factors for PF, including prolonged standing, weight bearing, obesity, long distance running, increased foot pronation, and restricted ankle dorsiflexion [10,11]. PF presentation involves a sharp pain in the anterior part of the calcaneus and on examination, tenderness can be found on the calcaneus medial side [6]. PF associated pain is searing, piercing, or throbbing, especially after a period of inactivity or with the first steps in the morning [12]. Diagnosis of PF depends on physical examination and history of the patient [6]. Treatment of PF involves conservative treatment that aims to reduce pain, restore range of motion and strength, promote healing, and correct training errors [13]. This conservative treatment included both physical and medical therapies, the physical therapy involved stretching, shoe insert, taping, ultrasound, thermal and laser therapy, as well as custom foot orthosis [6], whereas medical therapy included injection of local steroids [10]. Conservative modalities were presented to 90% of the patients; however, chronic

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and persistent cases needed surgical treatment [5]. In this systemic review, the aim was to determine the current and future promising intervention for PF.

Materials and Methods

A systematic review was done to examine the most current and promising intervention for PF by searching for trials conducted on this subject using the PubMed database. Several keywords were used for searching, such as PF treatment, PF recent interventions, PF management; also, the article type was specified to "clinical trials" to minimize the number of unnecessary articles from appearing. The titles of the articles appeared were reviewed on the search and 44 articles were obtained. The inclusion criteria considered for selecting the articles were articles that were published after 2010 with English language, so 19 articles were excluded and 25 articles remained. After revising the abstract of those 25 articles, 10 articles were further excluded as they were original articles and not clinical trials, so in this systematic review, 15 clinical trials were included and the year of publications of these trials was between 2012 and 2018.

Results

After abstracts and full articles were reviewed, the articles were summarized under specific titles as follows; author and publication year from recent to older, design of the trial, number of patients, intervention used and combined intervention, treatment duration and evaluation, results and main findings, shown in Table 1. There were three trials that were published in 2018 [14–16], two in 2017 [17,18], two in 2016 [19,20], two in 2015 [21,22], four in 2013 [23–26], and two in 2012 [27,28]. Regarding the trial design, there were five prospective trials [15,16,18,21,24]. The total number of patients included in all trials was 1,284, and they were randomly divided into groups in each trial. The most common interventions investigated were corticosteroid injection which was investigated in four trials [17,19,26,28] and extracorporeal shock wave therapy (ESWT) which was investigated in four trials [18,19,23,27], then low-level laser therapy (LLLT) which was investigated in two trials [14,16]. Other interventions that were investigated in trials varied and included hyaluronic acid (HA) [15], conservative treatment [17], autologous whole blood [17], intense and sham therapeutic ultrasound [20], polydeoxyribonucleotide (PDRN) [21], shoe inserts [22], autologous conditioned plasma [23], radiotherapy [24], taping and iontophoresis [25], silicone insole [26], and a modified endoscopic plantar fasciotomy [27]. There were seven trials that used combination interventions; they include, silicone insole and performing exercise [14,16], exercise only [17], cold therapy [19] and standard therapy (conventional treatment) [20,23,28]. There were two trials that used LLLT, one compared it with high-intensity laser therapy (HILT) [14] and the other compared it with usual care [16]. LLLT in the former trial was used at 904 nm for 3 times/week for a period of 3 weeks, whereas the HILT was performed at 1,064 nm for the same period. In another trial, LLLT was performed at 850 nm in three sessions for 3 times/week and usual care was provided for the control group. The former trial [14] showed that HILT showed significantly better improvements than the LLLT group, another trial [16] of LLLT group showed improvements in walking distance and surfaces, both groups got improvements regarding pain, but the combination of LLLT with usual care was more effective than the usual care alone. One trial [15] compared the effect of HA, either of low or high molecular weight, on patients with no combined intervention. Three different concentrations of HA were applied on patients; 2.5 ml of 0.01% HA, 0.8 ml of 1% HA, and 2.5 ml of 1% HA. Findings showed that HA decreased the pain and five injections of HA caused no serious effects and they were safe. Corticosteroid and ESWT as interventions for PF were investigated in four trials, one trial was in common [19]. Regarding corticosteroid treatment, one trial [17] used 2 ml of 40 mg methyl prednisolone +1 ml lidocaine in corticosteroid group, another group in the same trial used conventional treatment, and the third group used 1 ml autologous whole blood +1 ml lidocain. This trial showed that corticosteroid group showed better results regarding pain at 4 weeks, but at the end of the trial both autologous and corticosteroid groups were effective and caused function treatment, it should be noted that both groups used stretching exercise as combined treatment. In another trial [26], one group used combination of 1 ml betamethasone dipropionate of 6.43 mg and betamethasone sodium phosphate of 2.63 mg +1 ml of lidocaine HCL of 10 mg for corticosteroid group, whereas the other group wore prefabricated full-length silicone insole in daily lives, significant improvements in pain and function were recorded after 1 month in both groups, however, the author recommended using silicone insole as the first line of treatment. The third trial [28] investigated the use of corticosteroid as compared with control, 1 ml of methylprednisolone acetate 40 mg/ml + 1 ml lidocaine 1% were injected to corticosteroid group, whereas for the control group, saline was used instead of methylprednisolone acetate, both groups used standard conservative management. Significant improvements regarding foot function index were seen in both groups in the first month; however, after 2 months, no significant difference was found, also no significant difference in pain was seen, so in this trial, corticosteroid showed no significant improvements over the conservative treatment. The fourth trial that incorporated corticosteroid also involved ESWT [19], cold therapy intervention was combined with corticosteroid. Treatment of ESWT group involved five sessions of ESWT at 3 days intervals with 2 pulses/second with 2,000 shock wave/session, whereas the corticosteroid group received 40 ml of methylprednisolone +1 ml of 1% lidocaine. Both groups showed improvements in pain and foot function index; however, ESWT resulted in

significant improvements and made patients more satisfied. The second trial involved ESWT [18] and was performed against placebo group, ESWT group received two sessions/week with 2,000 impulse per session, whereas the placebo group received the same intervention but with a clasp on the heel to prevent the transmission of the impulses to the patient. There was a significant improvement in the ESWT group regarding pain and activity limitation than the placebo group and it was concluded that ESWT was safe and effective in treating chronic PF in the long term which reached up to 2 years. The third trial involved ESWT [23], also involved APC and conventional treatment, also conventional treatment was combined with the two groups. ESWT group received two sessions of ESWT/week, whereas APC group received 3 ml of APC. Both interventions showed improvements better than that of conventional treatment. The fourth and last trial involving ESWT [27] also involved endoscopic plantar fasciotomy (EPFR) group. ESWT group received 100 graded shocks of 14–18 kV (0.12–0.22 mJ/mm^2) followed by 1,400 shocks of 18 kV (0.22 mJ/mm^2), whereas EPFR group performed surgery according to the surgery protocol. Both groups showed improvements at the baseline, the successful rate was higher in EPFR group than ESWT group, but with no significant difference; hence, the author recommended using either of the two interventions in case of failure of conventional treatment. Of the other interventions used were intense and sham intense therapeutic ultrasound (ITU) [20]. Standard therapy was combined with both interventions, one group received 3.3 MHz of therapeutic US as intensive (ITU) group and sham ITU group was treated with the same protocol but with the energy of 0 joules. ITU resulted in more and rapid heel pain than sham ITU. Another trial [21] investigated the influence of PDRN, the PDRN group received 1.5 ml of PDRN, the placebo group received normal saline. PDRN resulted in significant improvements than the placebo group. Shoe inserts and either of daily plantar specific stretching or high load progressive strength training were investigated in another trial [22], the intervention was performed daily for 3 months. Primary outcomes were better for strength group but no differences were found in the secondary outcome. High load strength training resulted in a faster reduction in pain and improvements. Radiotherapy of different Gy was investigated in a trial [24], where the patients were divided into two groups; one received radiotherapy of a single dose of 0.5 Gy and the other received a single dose of 1 Gy for six single fractions/3 week. The radiotherapy was effective but no significant difference was found between the two groups, so the radiation dose of 0.5 Gy can be used as it resulted in the same effect as 1 Gy. The last trial investigated taping combined with iontophoresis against taping alone [25], the training frequency of the treatment session for both the groups and for each treatment was 1 week for one time in a day. More improvements achieved were found among the group that received taping and iontophoresis.

Discussion

This systematic review was performed to identify the current and promising intervention for PF management. Several interventions were reported in many reviews, including stretching, strengthening, nocturnal dorsiflexion splints, orthoses, anti-inflammatory agents (corticosteroids), ESWT, autologous platelet-rich plasma, shoe inserts, iontophoresis, and surgery (endoscopic fasciotomy) [29–31]. All the previous treatments were included in these studied trials in addition to LLLT, HA, ITU, PDRN, and radiotherapy. By reviewing the 15 trials included in this systematic review, it was found that LLLT combined with usual care was better than usual care alone, and HILT was over LLLT resulting in better improvements. Regarding usage of corticosteroid as a treatment option, it was found that corticosteroid showed no improvements over conservative treatment and showed same results of silicone insole and autologous whole blood and silicone insole was recommended to be the first line of treatment. When corticosteroids were compared to ESWT, it was found that ESWT resulted in significant better improvement and patient satisfaction than corticosteroid. Also, ESWT was found to be safe and effective in treating chronic PF in the long term which reached to 2 years when compared to no treatment. ESWT and APC showed better results than conventional treatment, however, in case of failure of conventional treatment, either of ESWT or EPFR was effective for management showing equal effectiveness, although EPRF showed higher successful rate, this rate was insignificant compared with ESWT. Other several interventions were investigated, such as HA which was safe and resulted in pain reduction, ITU, PDRN, and taping combined with iontophoresis were over sham ITU, no treatment and taping only, respectively. Radiation of 0.5 Gy was as effective as radiation of 1 Gy.

Conclusion

HILT and ESWT resulted in better improvements as non-surgical strategies, also ESWT can be used in case of failure of conventional therapy or EPRF as a surgical option. The promising interventions that can be further investigated and used are HA, PDRN, and APC.

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None.

List of abbreviations

ESWT	Extracorporeal shock wave therapy
HA	Hyaluronic acid
HILT	High-intensity laser therapy
ITU	Intense therapeutic ultrasound
LLLT	Low-level laser therapy
PDRN	Polydeoxyribonucleotide
PF	Plantar fasciitis

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