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ORIGINAL PAPER

Comparison of dry needling and steroid injection in the treatment of plantar fasciitis: a single-blind randomized clinical trial

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Abstract

Introduction Plantar fasciitis is a common cause of heel pain. Considering different interventions which are applied for patients with plantar fasciitis, dry needling is proposed as a new modality of treatment recently. The aim of this study is to evaluate the effectiveness of dry needling versus steroid injection for plantar fasciitis.

Methods Sixty-six patients were recruited to this single-blind clinical trial study. Participants were randomly allocated to receive 1 ml (40 mg) of Depo-Medrol (methylprednisolone acetate) or dry needling. They were followed up for 12 months and monitored for total perception of pain using the visual analogue scale (VAS), with data obtained in baseline and at three weeks, six weeks, three months, six months and one year after treatment.

Results Mean VAS score before treatment was 6.96 ± 0.87 for the steroid group and 6.41 ± 0.83 for the dry-needling group (P value = 0.54). Steroid injection reduced VAS scores rapidly until three weeks after treatment compared with dry needling (0.32 ± 0.71 and 3.47 ± 1.32, respectively; P value < 0.001). However, patients who were underwent dry needling reported lower VAS scores at the end of follow-up compared with the steroid group (0.69 ± 0.93 and 2.09 ± 1.58, respectively; P value = 0.004). Over the long term, 82.3% and 17.6% of changes in pain were contributed to time since treatment and treatment method, respectively (P values < 0.001).

Conclusions Steroid injection can palliate plantar heel pain rapidly but dry needling can provide more satisfactory results for patients with plantar fasciitis in the long term.

Keywords Dry needling · Steroid injection · Plantar fasciitis · Plantar heel pain

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Abbreviations

FHSQ	Foot Health Status Questionnaire
MSN	Miniscalpelneedle
MTrP	Myofascial trigger points
VAS	Visual analogue scale

Introduction

Plantar fasciitis (plantar heel pain) as a common cause of plantar pain has been associated with lower quality

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of life (QoL) and less energy to do daily tasks [1]. This condition, with a prevalence of 10% of the population [2], predominantly affects elderly and middle-aged individuals [3] and is more frequent in runners or those whose employment requires standing [4]. About 15% of all adult foot complaints are related to plantar fasciitis [5], which presents with insidious pain under the plantar surface of the heel that usually occurs primarily in the morning after a period of inactivity, although different pain patterns have been reported [6]. The origin of the central band of plantar aponeurosis is considered the most common abnormal site in patients with plantar fasciitis [7]. The etiology of plantar heel pain is not precisely understood. Previous studies proposed trauma, inflammation, metabolic, degenerative or nutritional disorders as factors contributing to plantar fasciitis [2, 8]. Recent evidence shows that even after foot amputation, there is risk for plantar fasciitis pain, and this may be related to suture locations of distal plantar fascia in the partial foot [9]. Also reduced ankle dorsiflexion, higher body mass index (BMI) and work-related weightbearing have been reported as main risk factors [10]. Available guidelines do not agree with a specific method for treatment [6], despite a high prevalence of this condition [11]. In recent years, the efficacy of manual therapy, stretching, taping, foot orthosis and splints as noninvasive methods have been indicated. Also the role of some physical agents, such as electrotherapy, laser therapy, phonophoresis and therapeutic ultrasound, have been investigated [12]. The effect of platelet-rich plasma (PRP) injection was recently proposed [13, 14], and other researchers emphasise using leucocyte-reduced PRP to obtain better results [15, 16].

There is evidence of the effects of anti-inflammatory agents: Crawford et al. showed a short-term relief following steroid injection [17], which was significant compared with placebo injection in 65 patients in a randomized clinical trial [18]. In addition, previous studies revealed the benefit of steroid injection compared with other modalities; however, PRP is reportedly more effective than steroid injection for pain [19]. Dry needling is increasingly being used as an adjunct therapy for musculoskeletal pain, and a protocol for this method was introduced by Cotchett et al [20]. The efficacy of dry needling was tested in a 53-year-old man after failure of conventional treatment and reported to cause rapid pain relief over two weeks [4]. Pain reduction was statistically significant in a comparative study using real trigger-point dry needling against sham dry needling, although the study authors suggested adverse effects of this modality must be considered [21]. However, trigger-point dry needling has not been investigated significantly. The aim of this study was to provide evidence for the effectiveness of dry needling for managing plantar fasciitis/heel pain compared with steroid injection as a recently suggested treatment method. Our primary hypothesis was that dry needling is at least as effective as steroid injection with respect to pain relief.

Methods

Participants and study design

This study was a single-blind, randomized clinical trial conducted from April 2013 to April 2015 in the AL Zahra Clinic of Orthopaedics, Isfahan, Iran; 83 patients were enrolled. Eligible patients were individuals > 18 years old, with a history of plantar heel pain of at least for three months and who were diagnosed for plantar fasciitis according to the guidelines of Orthopaedic Section of the American Physical Therapy Association [6]. Exclusion criteria consisted of history of diabetes mellitus, rheumatoid arthritis, flat foot, radiculopathies and foot malignancies, infections, calcaneal spurs and fractures. Patients had previously received conservative treatment only and were randomly assigned to one of two groups: dry-needling and steroid groups, the latter receiving injection of Depo-Medrol (methylprednisolone acetate).

Procedure and intervention

Following standard sterilisation of the skin in the plantar region, local needling was performed into the plantar fascia at the painful point only with a 0.3-mm (30-gauge) needle [4]. Participants were randomly assigned by the research's statistical consultant who was blindwd to the treatment of each group. In the first (steroid) group, 1 ml of methylprednisolone acetate containing 40 mg/ml was injected into the intended site using a 2-ml syringe. The needle was withdrawn immediately after completion of injection. In the dry-needling group, patients received dry needling of intended sites using a 0.30-mm needle that was gradually withdrawn and advanced for 30 seconds in the same location as in the steroid group. Patient tolerance and pain were monitored for possible complications. We identified myofascial trigger points (MTrP) of plantar foot muscles according to points of tenderness on physical examination and patient complaints. Medial aspect of the heel pad were respected in all cases (Fig. 1). Patients were followed up before treatment and at three weeks, six weeks, three months, six months and one year after baseline treatment.

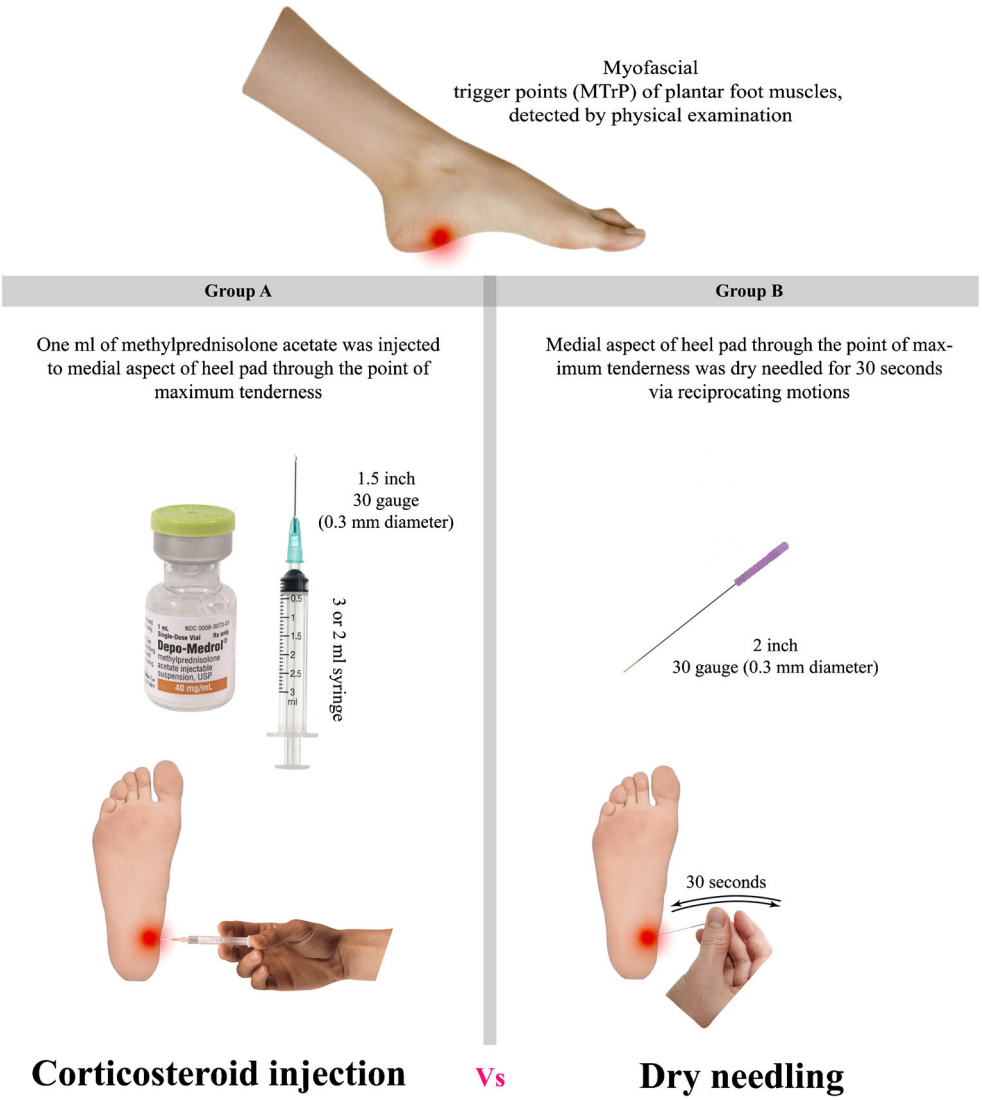

Fig. 1 Study interventions for the randomised groups

Measurements

Data, including basic patient demographic information and pain intensity, were collected at office appointments. Participants were asked to evaluate their overall perception of plantar pain intensity on the visual analogue scale (VAS) (0 no pain; 10 maximum pain experienced) before treatment and at each follow-up [22].

Outcomes

The primary outcome was pain intensity in the plantar fascia evaluated by one study investigator. There was no secondary outcome in this study.

Randomisation

A study co-ordinator uninvolved in treatment or patient care assigned eligible patients a number from 0 to 70 in order of their admission to the clinic. Each number was randomly assigned to one group (steroid or dry needling) before study initiation. Computer software (Excel 2010; Microsoft, Redmond, WA, USA) was used for this blocked randomisation.

Blinding

This study was a single-blind, randomised clinical trial in which all patients (if possible) and persons who recorded measurements and statistics were blinded.

Statistical analysis

Statistical methods

Nonprobability sampling (convenience method) was used to select patients with unilateral plantar fasciitis admitted the clinic of orthopedics between April 2013 and April

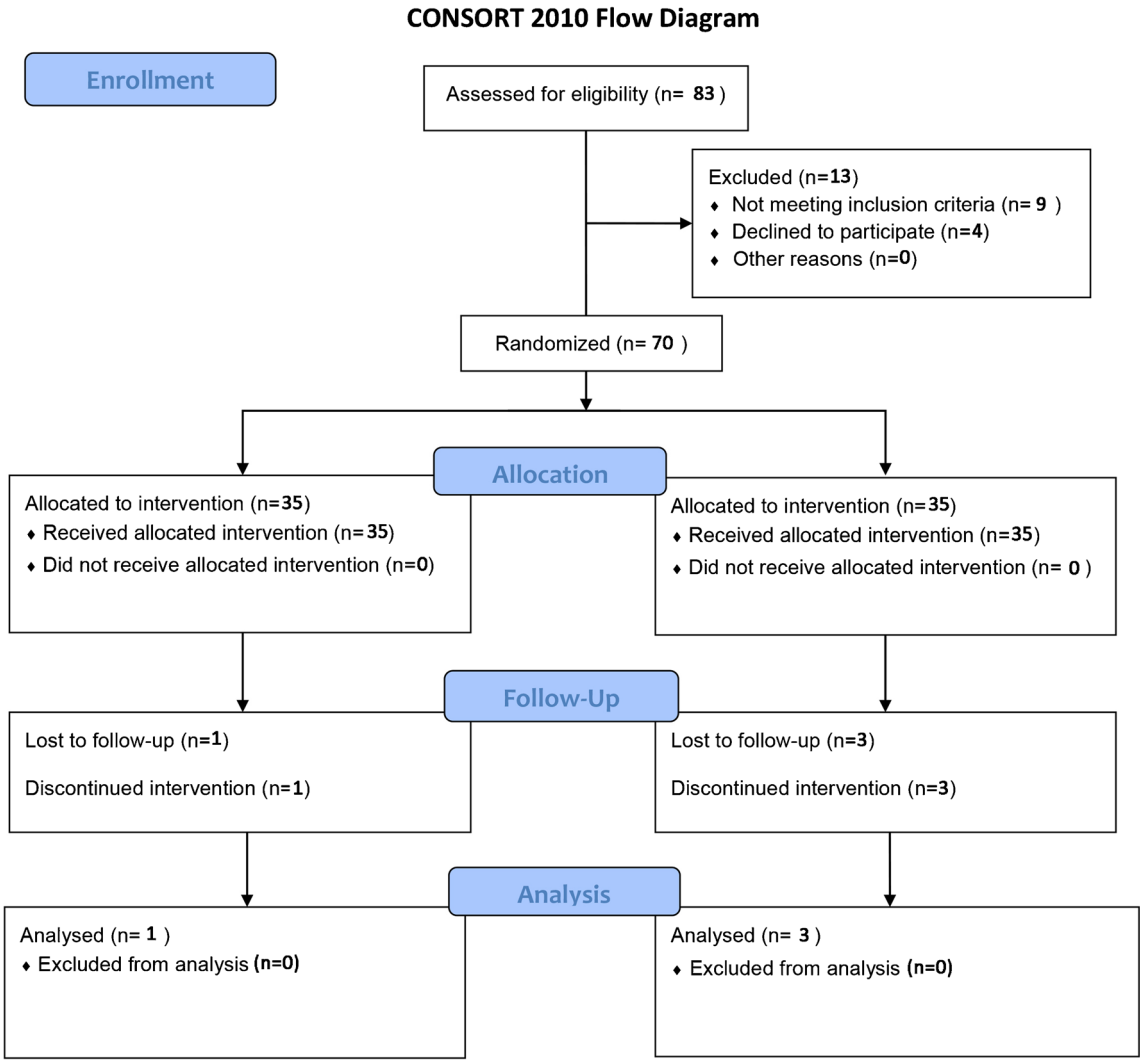

Fig. 2 Patient randomisation process

2015. According to previous similar studies and statistical calculations, the sample size was calculated by using two means comparison formulas for the 35 patients in each group. All patients were treated by the same orthopaedic professionals.

Sample size

Sample size was calculated using a statistical formula considering α=0.05 and β=0.2, expecting at least 5° of difference in the VAS between groups. Sample size was calculated to be 35 in each group. Descriptive statistics and frequencies were determined for continuous and discrete variables, respectively. The Kolmogorov–Smirnov and Shapiro–Wilk tests were performed to assess normal distribution. Repeated measures test was used to evaluate the effectiveness of the two methods of interest over the short term. The same test was used to assess treatment methods during the follow-up period. Independent *t* test was used to compare mean VAS scores between groups at each time point. For all tests, statistical significance was considered as 5%. Statistical analyses were conducted using SPSS statistical software (version 18, Chicago, IL, USA).

Ethics statement/approval

The protocol was approved by the Ethics Committee and review board of the university the authors are affiliated with (reference number: IR.MUI.REC.1396.3.354). We submitted this research project to the Iranian Registry of Clinical Trials (http://www.irct.ir/) with registration number IRCT2017082029132N4. In the first session, an orthopaedic surgeon gave patients sufficient information about the different treatment methods, including possible benefits and complications of each. Patients were free to choose whether they participated in our research, and written informed consent was obtained from all patients at the beginning of the study.

Table 1 Patient demographic data

Variables		Dry-needling group	Steroid group	*P* value*
Gender	Male	14 (21.21%)	14 (21.21%)	0.143
	Female	18 (27.28%)	20 (30.30%)	
Age (year)[1]		39.84 ± 7.96	42.03 ± 10.30	0.097

Data are presented as mean ± standard deviation

* *P* value < 0.05 is significant; chi-square and independent *t* tests

Results

Descriptive statistics

Eighty-three patients with plantar fasciitis were assessed for inclusion criteria, and 66 patients became eligible; nine patients did not meet inclusion criteria, four declined to participate. In addition to those thirteen patients, another four were excluded during the course of study (one from the steroid group and three from the dry-needling group). Ultimately, there were 32 patients in the dry-needling group and 34 in the steroid group (Fig. 2). There were 28 men (42.4%) and 38 women (57.6%), with no statistically significant gender difference between groups (P = 0.5) (Table 1). Mean age was 39.84 ± 7.96 in the dry-needling group and 42.03 ± 10.30 in the steroid group, with no statistically significant difference (P = 0.34) (Table 1). At the end of sampling, seven patients (10.6%) were younger than 30 years, 27 (40.9%) between 30 and 40, 20 (30.3%) between 40 and 50 and 12 (18.2%) ≥ 50. Figure 3 shows the frequency of plantar fasciitis among our study population according to age and sex. In all age groups, the disease was more common among women, and in two age ranges (<29 years and >50 years), the number of female patients was almost twice as many as male patients (Fig. 3).

Analytical statistics

In this study, pain induced by plantar fasciitis was investigated in six stages (pre-treatment, 3 weeks, 6 weeks, 3 months, 6 months and 1 year after treatment). We consider the first three stages as a short-term period for pain relief and all six stages as long-term assessment. Table 2 presents results of repeated-measures tests. In the short term, time had a significant effect on pain, and 93.1% of changes in pain was due to passing time, regardless of treatment method (P<0.001). Treatment itself had a significant effect on pain, with 56.7% of changes being due to treatment method regardless of passing time (P<0.001). For first three stages of assessment (over time), treatment method had a significant impact on pain; over the long term, the same test shows the significant effect of both passing time and treatment method separately and together. In this sense, 82.3% of changes in pain was due to passing time and 17.6% due to treatment method, regardless of treatment method and passing time (P <0.001).

Table 3 shows means ± standard deviation (SD) of VAS scores before treatment and at each follow-up. Three and six weeks and one year after treatment, mean VAS scores were significantly different between groups: 0.32 ± 0.71 steroid group and 3.47 ± 1.32 dry-needling group (P<0.001); 0.21 ± 0.67 steroid group and 2.66 ± 1.33 dry-needling group (P<0.001); 2.09 ± 1.58 steroid group and 0.69 ± 0.93 dry-needling group, (P = 0.004), respectively. There were no significant differences between groups at the other time points.

Figure 4 shows pain relief over time between groups. Steroid injection quickly reduced pain, but after six weeks of treatment, pain increased; in the dry-needling group, pain reduced slowly, but after six weeks of treatment, pain continued to decline. And at the end of the study, average pain in the steroid group was greater than in the dry-needling group.

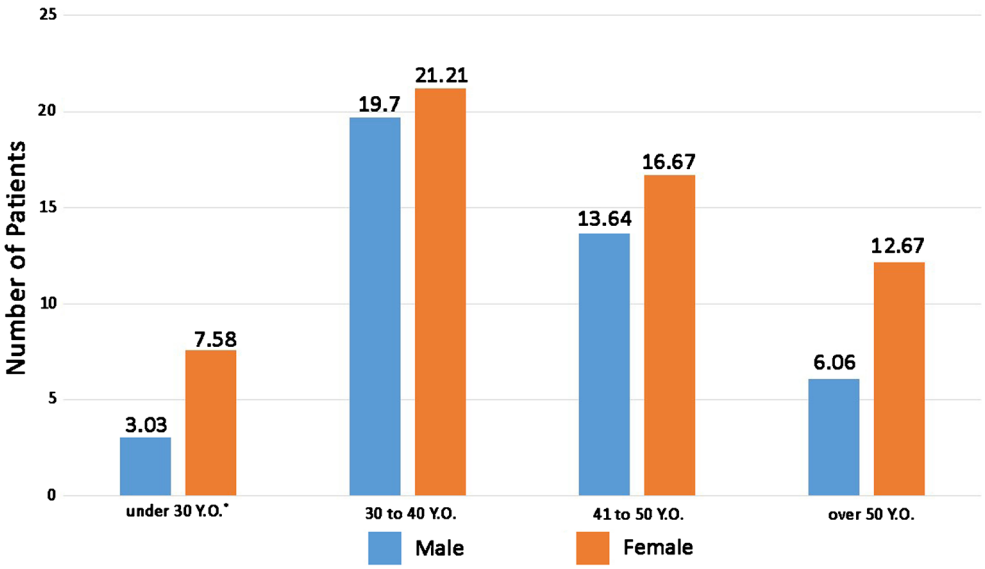

Fig. 3 Frequency of plantar fasciitis according to age group. *Y.O.*years old

Table 2 Effects of time and treatment method on pain relief: repeated-measures test

	Degree of freedom	F	*P* value	Amount of pain variation [b]
Short term				
Time	1.44	846.25	< 0.001	93.1%
Treatment method	1	83.86	< 0.001	56.7%
Time [a] Treatment method	1.44	99.19	< 0.001	
Long term				
Time	3.72	296.78	< 0.001	82.3%
Treatment method	1	13.63	< 0.001	17.6%
Time [a] Treatment method	3.72	53.48	< 0.001	

[a] Interaction between the variables

[b] Pain reduction considering each factor

Discussion

This study compared the effectiveness of corticosteroid injection and dry needling in pain relief for patients with plantar fasciitis. We followed up our patients for one year and investigated pain relief in the short term (until 6 weeks after beginning treatment) and long term (until 12 months after beginning treatment). Participants who received corticosteroid injection presented a rapid and significant improvement in pain relief three weeks after baseline, although patients who were dry needled had pain relief during this period, as well.

The effects of steroid injection on plantar fasciitis are well investigated worldwide in clinical trials [18, 23]. Similar to our work, the evidence of short-term pain reduction at one month of treatment in favour of steroid injection was provided in a double-blind study of 106 patients comparing steroid injection and an anesthetic control [17]. In a previous study, authors reported the benefits of steroid injection over placebo injection at six weeks that was maintained until 12 weeks of baseline in 65 patients with inferior heel pain [18]. It has also been reported that iontophoresis of 4% dexamethasone with traditional modalities is effective on pain reduction in the short term but not the long term in comparison with placebo [24].

Table 3 Visual analogue scale (VAS)

Time	Dry-needling group	Steroid group	*P* value*
Before treatment	6.41 ± 0.83	6.96 ± 0.87	0.54
3 weeks after treatment	3.47 ± 1.32	0.32 ± 0.71	< 0.001
6 weeks after treatment	2.66 ± 1.33	0.21 ± 0.67	< 0.001
3 months after treatment	1.59 ± 1.24	0.56 ± 1.33	0.44
6 months after treatment	1.28 ± 1.46	1.79 ± 1.55	0.65
1 year after treatment	0.69 ± 0.93	2.09 ± 1.58	0.004

Data are presented as mean ± standard deviation

* $P < 0.05$ is significant; independent *t* test

Similarly, we found that dry needling was associated with better improvement in heel pain ultimately when we considered VAS scores at months 12 of follow-up.

The effectiveness of dry needling is not well documented. Recently, Cotchett et al. reported significant plantar heel pain relief in patients who underwent real dry needling compared with counterparts underwent sham dry needling. Details of dry needling were consistent with standards for Reporting Interventions in Clinical Trials of Acupuncture. Two primary outcomes including VAS and three secondary outcomes including Foot Health Status Questionnaire (FHSQ) were measured to reach the goals [21]. Moreover, the effectiveness of miniscalpel-needle (MSN), a new medical instrument for managing plantar fasciitis, has recently been practiced. The procedure is considered acupuncture and a microinvasive method. The authors of that study concluded that MSN pain relief was overall higher than steroid injection, with active pain reduction being reported in the MSN group from the beginning of treatment to 12 months of follow-up; only short-term pain relief was reported in patients receiving steroid injection [23].

Little is known about the possible mechanisms of dry needling for pain reduction, although different pathways of action have been proposed worldwide for acupuncture treatment of acute or chronic pain and is a well-known complementary therapy. Central release of opioid peptides, increased regional blood flow and anti-inflammatory effects of this therapy have been reported previously [25]. We believe similar underlying mechanisms occurred with dry needling in our patients with plantar fasciitis, although the anti-inflammatory effects of steroid injection—at least in the short term—are possibly greater than for the dry needling method. Nevertheless, we believe further investigation is warranted in this field.

In this study, we recruited the patients with plantar fasciitis who failed common conservative therapies for at least three months, such as analgesics orally (e.g., nonsteroidal anti-

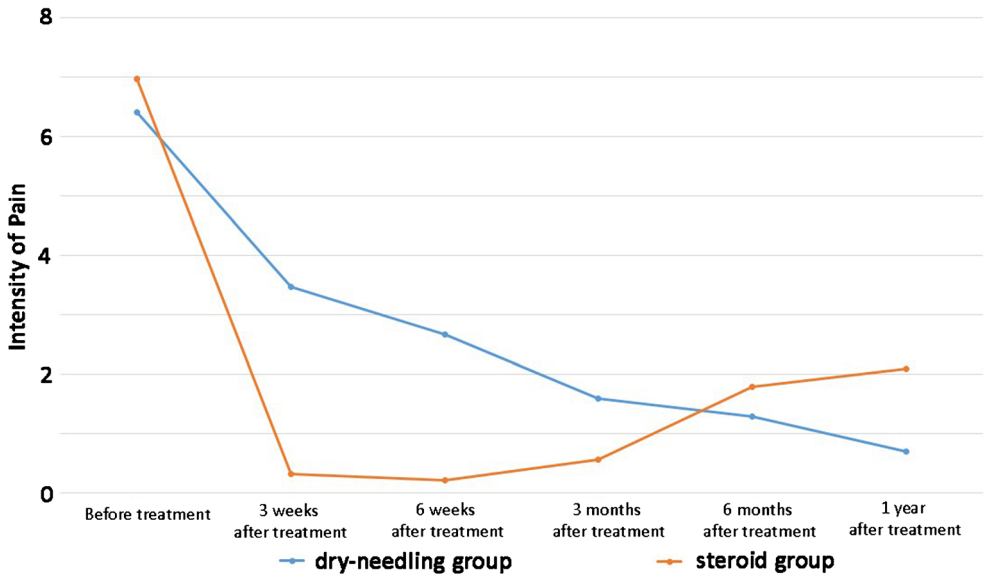

Fig. 4 Follow-up evaluation of pain between treatment groups

inflammatory drugs), tendon or plantar fascia stretching and orthoses (in some cases). Patients underwent no prior interventions, such Botulinum toxin injection or plantar fasciotomy, before involvement in the study. The effects of such modalities have been investigated before and reported to be effective in pain relief [26, 27]. Moreover, to achieve more accurate results, primary X-ray imaging was done, and patients suspected of having calcaneal spurs or evidence of fracture or malignancy were not entered in to the study: research is already available regarding the association of calcaneal spurs and heel pain [28].

The effect of improvement of heel pain over time should not be neglected. Plantar fasciitis is a said to be a self-limiting disability in which 90% of patients will improve with conservative therapies, and pain relief is usually achieved within one year regardless of treatment [29]. We found that over the short term, 93.1% of pain variations could be explained with passing time, regardless of treatment method, and 56.7% of pain variations were due to therapy regardless of passing time. The separate effect of time and treatment method were 82.3% and 17.6%, respectively, over the long term. These findings are similar to those reported in the mentioned study [29] and are in agreement with the effect of time on heel-pain healing.

There are some limitations to our study. We used the medial plantar region of the heel as the location for steroid injection and dry needling, where most pain had been focused on. We did not guide needles using ultrasonography or other imagery techniques. While there are no robust criteria in the literature for exact identification of painful trigger points, using imaging techniques, we could be sure of locating the needle tip in soft tissue and monitoring some complications. Fat-pad atrophy, rupture of the plantar fascia and lateral plantar nerve injury are the common reported complications of steroid injection [30]. Further investigation is warranted using an upgraded, reinforced methodology.

Conclusions

This study suggested that dry needling was superior to steroid injection in patients with plantar fasciitis at the end of one year of follow-up. Pain reduced gradually in dry-needled patients, and endpoint VAS scores were lower than in the steroid group, although rapid and short-term effects of steroid injection was also found. Clinicians should manage patients with plantar fasciitis according to the latest recommendations considering patient clinical features and need for treatment.

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Compliance with Ethical Standards

Ethical approval The protocol of this study was approved by the Ethics Committee and the review board of the Isfahan University of Medical Sciences. This study was performed only on human. This article does not contain any previous phases on human participants or animals performed by any of the authors. The manuscript has not been submitted to other journals. The manuscript has not been published previously (partly or in full), No data have been fabricated or manipulated (including images) to support our conclusions. We have not used any data, text or theories presented by others.

Conflict of Interest The authors of this study have no conflict of interests.

Informed consent Informed consent was obtained from all individual participants included at the beginning of the study.

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