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Original Article

Ultrasound-guided prolotherapy versus corticosteroid injections for the treatment of patients with plantar fasciitis: A randomized controlled trial

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ABSTRACT

Objectives: The study aimed to compare the effectiveness of ultrasound-guided corticosteroid injection (CSI) and ultrasound-guided dextrose prolotherapy (DP) in treating patients with plantar fasciitis (PF).

Patients and methods: This single-center, randomized controlled, double-blind trial was conducted with 38 patients (24 females, 14 males; mean age: 48.2±6.1 years; range, 30 to 57 years) with PF between March 10, 2021 and June 10, 2021. Patients with definitive PF fulfilled the eligibility requirements and were included in the study. Block randomization was used to assign each patient to CSI and DP treatment arms. Patients in the CSI and DP treatment arms received methylprednisolone and dextrose, respectively. Lidocaine injection was used for local anesthesia, and ultrasound was used to guide these minimally invasive procedures. Patients were followed up after one (short term) and three months (middle term). Primary outcomes were pain severity and foot function.

Results: In both groups, we detected a significant improvement in pain severity and foot function index in the middle term, which was slightly more profound in the DP group. In contrast to the CSI arm, DP did not appear to alleviate pain in the short term. We observed a waning treatment effectiveness in the CSI arm over time.

Conclusion: Both CSI and DP were effective in treating PF by reducing pain and improving foot function index in the middle term. While CSI ensures better short-term outcomes, its effectiveness tends to wane over time. On the contrary, DP does not provide significant short-term relief but is more effective in the middle term. Further trials are needed to support these findings.

Keywords: Corticosteroid injection, foot function index, plantar fasciitis, prolotherapy.

Tubercle of calcaneus is the site of origin for plantar fascia, and microtears at this site may result in plantar fasciitis (PF), which may result in heel pain.[1-3] Features such as high body mass index (BMI), foot deformities (e.g., pes planus), and prolonged standing or walking may contribute to the development of PF.[4] Conservative therapies such as weight loss, physical therapy, and night splints are effective in about 90% of cases; however, a significant number of patients suffer from refractory disease and may benefit from injection therapies (e.g., local corticosteroid injection, platelet-rich plasma injection, and prolotherapy) and surgery as the last resort.[5-7] However, the best treatment for PF has not been determined yet, and the results are inconsistent.[8]

Due to its anti-inflammatory effects, corticosteroid injection (CSI) has been commonly used to relieve PF symptoms. However, its long-term use is associated with consequences such as fat pad atrophy and plantar fascia tears.[5,6] Furthermore, dextrose prolotherapy (DP) leads to pain reduction and ligament recovery with acceptable efficacy.[9] Similar to platelet-rich plasma injection, some studies suggest that DP exerts its healing effect by increasing the level of platelet-derived growth factor, which is required for the initiation of the healing process.[10-12] The plantar fascia is best visualized by ultrasonography, and this modality is used to deliver the injection to the appropriate site, which is characterized by decreased echogenicity.[13,14]

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In addition, it was shown that delivering therapy with an ultrasound-assisted technique results in better outcomes.[15]

The beneficial effect of CSI in treating PF is established throughout the literature, whereas few studies investigated the overall effectiveness and treatment outcomes with DP.[16-18] It has been demonstrated that DP reduces chronic musculoskeletal pain and is useful in primary care practice,[19,20] but this is seldom compared to corticosteroids, particularly in PF patients. We hypothesized that patients receiving DP would have comparable or equivalent results with CSI; thus, DP could be a potential alternative for patients with contraindications for corticosteroid use. Therefore, the current study was designed to determine and compare the effectiveness and treatment outcomes of CSI and DP in patients with PF.

PATIENTS AND METHODS

The randomized controlled double-blind trial was conducted with adult patients 18 years of age or older and with a definitive PF diagnosis confirmed by ultrasound (plantar fascia thickness ≥4 mm) at the physical medicine and rehabilitation clinic of the Shiraz University of Medical Sciences (Emam Reza Clinic) between March 10, 2021 and June 10, 2021. Patients with relevant underlying diseases, including ankylosing spondylitis, rheumatoid arthritis, gout, and reactive arthritis, were excluded. Additionally, patients who used analgesic agents such as nonsteroidal anti-inflammatory drugs within one week before randomization were excluded. Unilateral foot symptoms recalcitrant to conservative therapy, such as weight reduction, physical therapy, and night splints, had to be present for at least six months. Patients with any type of injections within last six months, lactating or pregnant patients, and those with coagulation disorders were excluded. Overall, 50 patients were referred to our clinic, of which 12 were not eligible due to the described exclusion criteria. Hence, the study was conducted with 38 patients (24 females, 14 males; mean age: 48.2±6.1 years; range, 30 to 57 years). Written informed consent was obtained from each patient. The study protocol was approved by the Shiraz University of Medical Sciences Ethics Committee (date: 16.09.2019, no: 1398.397). The protocol and the methodology for this study was approved by Iranian Registry of Clinical Trials under IRCT20210305050582N1. The study was conducted in accordance with the principles of the Declaration of Helsinki. The CONSORT (Consolidated Standards of Reporting Trials) flow diagram is presented in Figure 1.

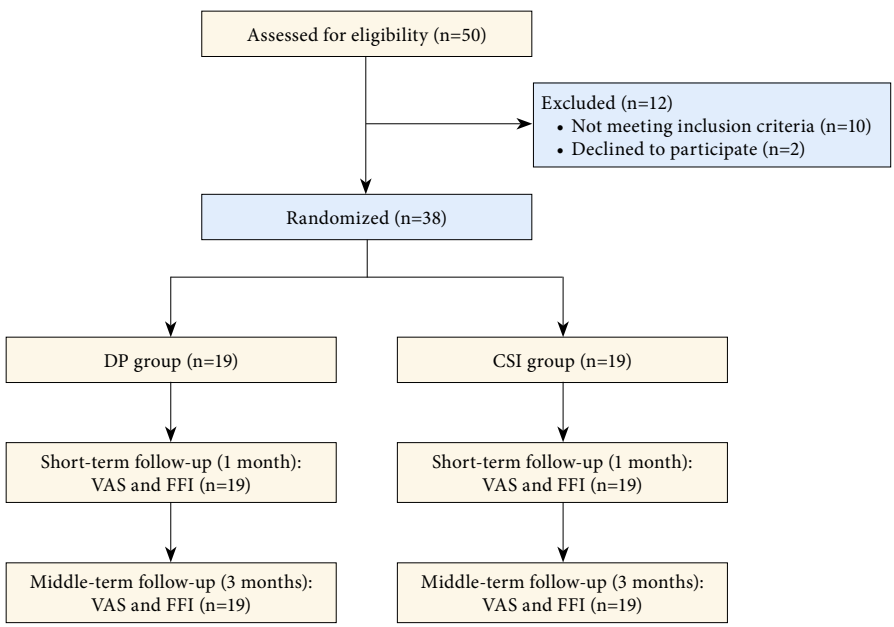

Figure 1. The CONSORT patient enrollment flow diagram.

DP: Dextrose prolotherapy; CSI: Corticosteroid injection; VAS: Visual Analog Scale; FFI: Foot function index.

Patients were enrolled in the study by two physicians. A computer program was used by another researcher for block randomization. The same researcher divided the subjects into two equal groups with 19 participants, who received either DP injections or CSIs. Identical syringes and techniques (e.g., preparation, local anesthesia, and ultrasound guidance) were used, and treatment allocation was concealed from both care providers and participants throughout the study.

We administered 40 mg of methylprednisolone acetate and 1 mL of lidocaine 2% to the patients in the CSI group, whereas patients in the DP group received 1 mL of dextrose 50% solution and 1 mL of lidocaine 2% from the medial aspect of the heel. The ultrasound was used to guide the injections, and the probe was placed vertically to view the plantar fascia. The primary outcomes were pain severity and foot function index (FFI). These patient-reported outcome measures were collected via validated questionnaires immediately after the intervention, at one month (short term) and three months (middle term) after injection for both groups. We used a Visual Analog Scale (VAS) to grade the severity of pain, with 0 indicating no pain and 10 reflecting severe pain. The FFI with 23 questions was used to estimate the overall foot condition and function in the participants.[21] Likewise, each question in the FFI received a score from 0 (no impairment) to 10 (severe impairment). The secondary outcomes were severe treatment complications, including infection, tendon rupture, and nerve injury, which were accessed via medical history, direct observation, and physical examination. According to the results of a study by Uğurlar et al.,[18] the minimum required sample size for each group was 18 (α=0.05, β=0.2).

Statistical analysis

Data were analyzed using IBM SPSS version 23.0 software (IBM Corp., Armonk, NY, USA). Descriptive analysis was used to determine frequency, mean, and standard deviation (SD) for each variable. The paired t-test (or its nonparametric equivalent) was used to compare the changes within groups. The independent sample t-test was employed to compare the means between the groups. To find possible correlations for the categorical variables (e.g., sex), Pearson's chi-square test was used. A p-value <0.05 was considered statistically significant.

RESULTS

An evaluation of the sex distribution revealed no significant difference between the two treatment arms (p=0.36). The mean age in the CSI and DP groups was 48.21±6.15 and 48.82±5.88, respectively, without statistical significance (p=0.8). Similarly, the comparison between BMI measurements in the CSI and DP groups yielded no statistical difference (p=0.58). Other potential confounders in the CSI and DP groups were assessed, including cigarette smoking (n=4 *vs.* n=3), underlying diseases such as diabetes (n=8 *vs.* n=6), and chronic use of medications (n=8 *vs.* n=6), and found no significant

TABLE 1
Baseline demographic and clinical characteristics for each treatment arm

	DP group (n=19)			CSI group (n=19)			
Variables	n	%	Mean±SD	n	%	Mean±SD	*p*
Sex							0.36*
Male	6	31.5		8	42		
Female	13	68.5		11	58		
Underlying disease							0.36*
Yes	6	31.5		8	42		
No	13	68.5		11	58		
Cigarette smoking							0.50*
Yes	3	15		4	21		
No	16	85		15	79		
Age (year)			48.8±5.9			48.2±6.2	0.80
Body mass index (kg/m^2)			27.73±2.30			27.75±2.27	0.58
Visual Analog Scale			7.73±1.28			7.89±1.19	0.69
Foot function index			76.42±7.29			75.05±7.36	0.57

DP: Dextrose prolotherapy; pts: patients; CSI: Corticosteroid injection; SD: Standard deviation; * These p-values were calculated using the chi-square test, the remaining were elicited by the independent sample t-test.

variation (p>0.05). The baseline VAS in the DP and CSI at admission were 7.73±1.28 and 7.89±1.19, respectively, with no statistical difference (p=0.69). Likewise, the mean FFI of the DP and CSI groups was not different at admission (76.42±7.29 and 75.05±7.36, respectively; p=0.57). These demographics and clinical data are summarized in Table 1.

Within-group analysis for the CSI group revealed that VAS was significantly lower in the short term (3.78±0.19) and middle term (4.63±1.11) compared to the measurement at the admission, which was 7.89±1.19 (p<0.001). However, the short-term VAS was significantly lower than its middle-term mean in this treatment arm (p=0.05). In the DP group, VAS improvement was not significant in the short term (p=0.29), although it was significantly lower in the middle term compared to admission and short-term measurements (3.21±1.03, 7.73±1.28, and 7.15±1.21, respectively; p<0.001).

Furthermore, a similar trend was observed for the FFI. The mean FFI for the CSI group at admission, short term, and middle term was 75.05±7.36, 35.00±5.70, and 39.00±5.90, respectively. The mean FFI for the DP group at admission, short term, and middle term was 76.42±7.29, 70.70±6.12, and 35.00±6.12, respectively. We compared the FFI within the CSI group, and the reduction was significant in the short term and middle term (p<0.001). However, no significant difference was found between short-term and middle-term scores (p=0.13). As for the DP group, FFI was significantly lower in the middle term compared to admission (p<0.001) and short-term measurements (p<0.001). Likewise, the short-term FFI was significantly lower than the admission FFI (p=0.03).

Moreover, the means of the VAS and FFI were compared between the two groups, as depicted in Figure 2 and 3. The recorded VAS and FFI for the DP group in the short term were 7.15±1.21 and 70.70±6.12, respectively, whereas these values for the CSI group were 3.78±0.19 and 35.00±5.70, respectively. We found a significant difference in VAS and FFI values between the two groups in the short term and middle term. A greater short-term improvement in VAS and FFI was observed in the CSI group. Conversely, in the middle term, the mean VAS was statistically lower in the DP group compared to the CSI group (3.21±1.03 *vs.* 4.63±1.11, p<0.001). Similarly, DP was statistically associated with a lower FFI in comparison to CSI (35.00±6.12 *vs.* 39.00±5.90, p=0.05). These results are presented in Table 2.

DISCUSSION

About 10% of general population experience PF, and its peak incidence is observed in individuals aged 40 to 60 years.[22] Female patients and those with a BMI >25 kg/m^2 are more susceptible to this condition than the general population.[23] These characteristics are consistent with our study population. The majority of the participants in the current study were female. Potential confounders, including sex, age, BMI, cigarette smoking, underlying diseases such as diabetes, and chronic use of medications, were assessed, and no statistical difference was observed between the two groups. The results of the current study showed that both treatment arms led to improvement in patient

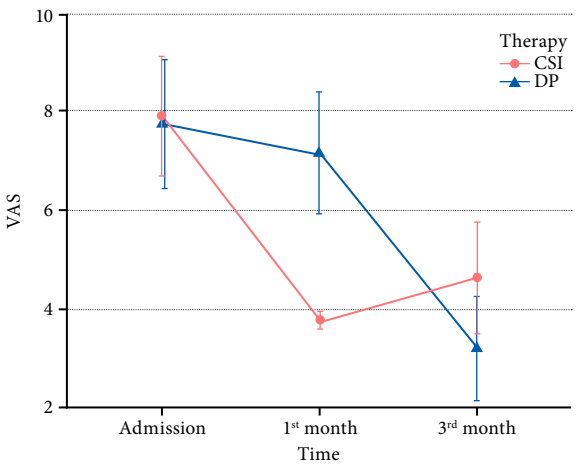

Figure 2. The error bars of VAS changes in the CSI and DP groups over time.

CSI: Corticosteroid injection; DP: Dextrose prolotherapy; VAS: Visual Analog Scale.

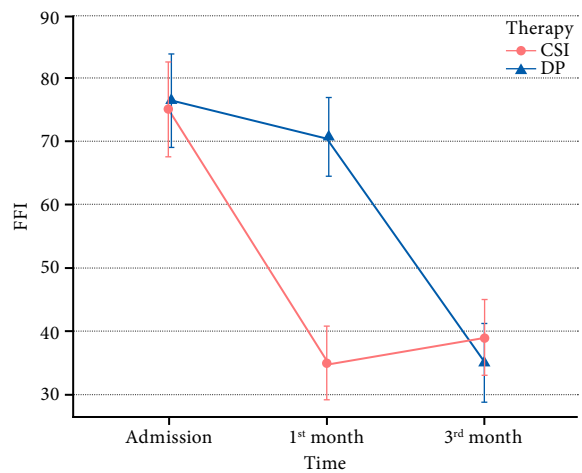

Figure 3. The error bars of FFI changes in the CSI and DP groups over time.

CSI: Corticosteroid injection; DP: Dextrose prolotherapy; FFI: Foot function index.

TABLE 2
A summary of VAS and FFI values and their difference within each group and between the two groups according to follow-up duration

Item	Score at admission	Score at 1 month	Score at 3 months	Admission *vs.* 1 month*	Admission *vs.* 3 months*	1 month *vs.* 3 months*
	Mean±SD	Mean±SD	Mean±SD	*p*	*p*	*p*
VAS in DP	7.73±1.28	7.15±1.21	3.21±1.03	0.29	**<0.001**	**<0.001**
VAS in CSI	7.89±1.19	3.78±0.19	4.63±1.11	**<0.001**	**<0.001**	**0.05**
p-value (between groups)	0.69	**<0.001**	**<0.001**			
FFI in DP	76.42±7.29	70.70±6.12	35±6.12	**0.03**	**<0.001**	**<0.001**
FFI in CSI	75.05±7.36	35±5.7	39±5.9	**<0.001**	**<0.001**	**0.13**
p-value (between groups)	0.57	<0.001	**0.05**			

VAS: Visual Analog Scale; FFI: Foot function index; DP: Dextrose prolotherapy; CSI: Corticosteroid injection; * The p-values for within-group comparison were determined by the paired sample t-test, whereas the independent sample t-test was used for between-group p-values.

symptoms. The patients did not experience any adverse effect during the course of treatment. We found that CSI was more effective than DP in improving VAS and FFI in the short term, but the effect waned and was reversed at the three-month follow-up. In contrast, these measurements were significantly better (lower) in the DP group after three months. This finding suggests a limited and temporary effect for CSI, and a delayed but lasting treatment response in patients receiving DP.

Several minimally invasive approaches such as botulinum toxin, platelet-rich plasma, extracorporeal shockwave therapy (ESWT), DP, and CSI have been proposed to treat refractory PF.[18,24] In addition, it was shown that ultrasound-guided approach is more effective than palpation-guided injections.[25] Corticosteroids due to their anti-inflammatory properties are extensively used to remedy tendinopathies.[26] However, severe side effects such as calcaneal osteomyelitis, abscess formation, and plantar fascia rupture are associated with corticosteroid injections.[27-29] In addition, its effectiveness tends to wane over time, which prompts reinjections after 12 weeks and results in a high cumulative dose.[30,31] Corticosteroid injections may be contraindicated in some patients due to hypersensitivity, superficial or deep infection, fracture, and uncontrolled diabetes mellitus.[32] These downsides prompted care providers to turn to alternative treatments such as platelet-rich plasma, ESWT, and prolotherapy.[33]

In recent years, a growing number of studies have investigated DP's effectiveness in treating PF, which culminated in the publication of several meta-analyses.[34-36] All these reviews suggest that DP is a safe and effective treatment option for PF. In 2009, Ryan et al.[7] investigated the effectiveness of DP in chronic PF for the first time by conducting a pilot study. A total of 20 patients, 17 of whom were female, received the intervention. Sixteen (80%) patients reported good to excellent outcomes at about 12 months after the intervention. Later, Ersen et al.[37] conducted a randomized clinical trial and compared ultrasound-guided DP with an exercise program. The results at 42 and 90 days of follow-up, indicated that the DP resulted in good to excellent outcomes in most cases (77%) in comparison to the exercise program (17%). Similarly, in another clinical trial by Umay Altaş et al.,[38] DP was associated with a greater improvement in VAS and FFI compared to exercise. A more recent study showed a greater effectiveness for DP than that of the control group receiving saline injection only.[39]

Fewer controlled trials, similar to ours, have compared the effectiveness of DP and CSI. In a study by Raissi et al.,[40] 44 patients suffering from chronic PF were recruited. A numeric rating scale for pain and the Foot and Ankle Ability Measure for foot function were assessed. Although these metrics were different from ours, the results were nearly identical; CSI was associated with better outcomes at short term, whereas both therapies were effective 12 weeks after injection. In a randomized controlled trial by Ugurlar et al.,[18] the therapeutic effect of ESWT, CSI, platelet-rich plasma, and DP in PF was evaluated by comparing VAS and FFI. They enrolled 40 patients each in the DP and CSI groups, and the improvement

trend was similar to ours. Accordingly, DP did not appear to be effective at one month, but it caught up with CSI after three months. Moreover, CSI effectiveness was already reversed at the three-month follow-up. Hyperosmolar dextrose was also compared with other treatments such as platelet-rich plasma and ESWT, which yielded comparable or equivalent results at 12 weeks.[41,42] The results of the aforementioned studies are not conclusive about the superiority of a single intervention. However, they can guide us towards choosing the best alternative therapy, according to availability, indications, and complication profile.

This study had several limitations. The number of enrolled patients was relatively small, and female patients comprised the majority of our participants; thus, the results cannot be generalized, and a consensus recommendation cannot be made. Due to ethical considerations, our trial did not include a placebo group, and its effect was not adjusted for. The patients were followed for three months after the intervention, which is relatively short, and the patients could not be evaluated for relapses. Therefore, we recommend additional studies with a larger study population and longer follow-up to consolidate the findings of this study and determine the best therapeutic approach for PF. Despite these limitations, this study is novel since few clinical trials have investigated the effectiveness of DP in PF patients.

In conclusion, the current study suggests that both the CSI and the DP are effective in treating PF via lowering VAS and FFI. However, effect of the former is short-lived, limited and temporary, whereas the DP is associated with profound improvement at three months. However, more randomized controlled trials are needed to support these claims.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Came up with the idea and conceptualized the study: A.N., M.S.F.; Wrote the initial draft and critically reviewed the manuscript: A.T.; Analyzed the data and interpreted the results: A.T., F.A.; Collected the data: F.A., M.S.F., A.N.; Supervised the whole project: A.N. All authors have read and approved the final version of the manuscript.

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