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Preliminary Report on the Role of Dry Needling Versus Corticosteroid Injection, an Effective Treatment Method for Plantar Fasciitis: A Randomized Controlled Trial

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ABSTRACT

Plantar fasciopathy (PF) is a common disorder for which there is no consensus regarding an optimal treatment strategy. We hypothesized that dry needling would be as effective as the use of corticosteroid injections for treating PF while avoiding the potential adverse effects of corticosteroids. After approval was received from the institutional review board, patients diagnosed with PF were prescribed a 3-week nonoperative treatment regimen. In addition to using oral and topical antiinflammatory drugs, patients engaged in plantar fascia and gastrocnemius stretching exercises. A study population of 98 patients was planned. An appointment was made in the third week of first-line treatment. Patients whose pain did not abate and who required further treatment were included in the study. One week later, we randomly divided patients into 2 groups using an online random number generator. Group 1 underwent dry needling, and group 2 underwent corticosteroid injection. All dry needling was performed by a single physiotherapist, and all corticosteroid injections were performed by the second author. Patients were assessed in the third week and sixth month by a single investigator using the foot function index. In terms of foot function index scores, dry needling caused significant decrease in the third week and also in the sixth month. However, although corticosteroid use led to a significant decrease at the third week, it lost efficacy in the sixth month ($p < .001$). In conclusion, dry needling seems to be a reliable procedure for treating PF, with better outcomes than corticosteroid injection.

Plantar fasciopathy (PF), a common disorder in our clinical practice, occurs in a range of patients, from athletes to those who have been working for a long time to sedentary individuals. PF has an adverse effect on activities of daily living and can result in pain, particularly in middle-aged and elderly patients (1–4).

PF has been treated with gastrocnemius and plantar fascia stretching exercises (4–6); local injections of corticosteroids (7), anesthetics, and botulinum toxin (8); extracorporeal shock wave therapy; ultrasound scanning; radiofrequency ablation (4,9); cryopreserved human amniotic membrane injection (10); taping; and endoscopic release (11,12). However, as yet, there is no consensus regarding the optimal treatment method (13–15).

We hypothesized that dry needling would be as effective as corticosteroid injections for treating PF while avoiding the potential adverse effects of corticosteroids. In this preliminary report, we aimed to introduce a minimally invasive but effective method of treating PF, using the relatively new dry needling method, and to compare the outcomes with those of corticosteroid treatment, which is a widely accepted treatment for PF.

Patients and Methods

After approval was obtained from the institutional review board (İstanbul Medeniyet University Göztepe Training and Research Hospital), patients diagnosed with PF were prescribed a 3-week nonoperative treatment regimen. In addition to using oral and topical antiinflammatory drugs (oral flurbiprofen 200 mg 1×1 + topical flurbiprofen 4×1), patients engaged in plantar fascia and gastrocnemius stretching exercises.

In the treatment of PF, dry needling had not yet been investigated, so the sample size calculation was determined on the basis of the preliminary study that we had done on patients in each group. Based on a .275 effect size, an α level of 0.05, and a β level of 20%, a study population of 98 patients was planned.

Inclusion criteria were as follows: patients between ages 18 and 80; pain at the plantar medial aspect of the heel for > 3 months, maximal tenderness on clinical examination

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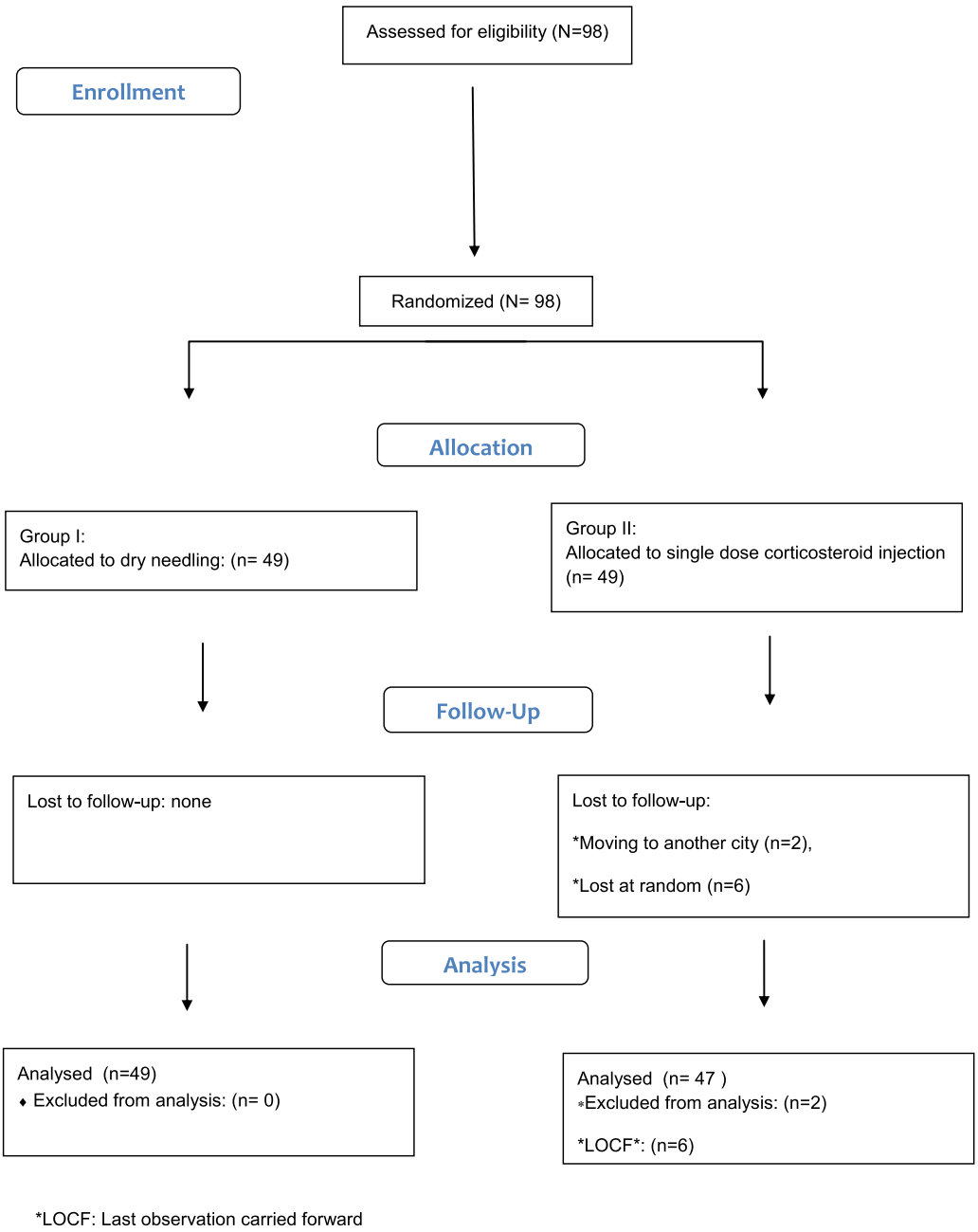

Fig. 1. Study flowchart.

over the medial tubercle of the calcaneus, pain with palpation of the proximal insertion of the plantar fascia, pain when first stepping onto the heel, and no previous other form of treatment (eg, insoles, pain medication) during the needling process.

Exclusion criteria were as follows: pregnancy; patients whose pain was abated >50% by first-line treatment; bilateral heel pain; treatment for PF in the past 3 months; allergies to drugs or metal; skin lesions that would prevent needling in the treatment area; foot/ankle trauma or surgery; chronic disease, such as diabetes mellitus, chronic renal failure, potential arthritis, rheumatoid arthritis, generalized polyarthritis seronegative arthropathy, neurologic impairments, tumors of the foot or ankle, extremity nerve entrapment or corticosteroid therapy; and cancer treatment.

An appointment was made for patients who had undergone 3 weeks of first-line treatment. Patients whose pain did not abate >50% according to the foot function index (FFI) pain subscale and required further treatment were included in the study after providing informed consent. One week later (after the effects of the flurbiprofen had worn off completely), we randomly divided patients into 2 groups using an online random number generator (16). The numbers, obtained from online software, were matched to the patients on the order of the application. Group 1 underwent dry needling, whereas group 2 underwent corticosteroid injection (Fig. 1). In this study, corticosteroid injection refers to a combination of methylprednisolone acetate (2 mL Depo Medrol, 40 mg/mL; Pfizer, Kırklareli, Turkey) and bupivacaine (1 mL marcaine, 0.5%; Zentiva, Kırklareli, Turkey). Additional local anesthetic was not used alone during either dry needling or corticosteroid injection.

In group 1, with the patient in the prone position, the skin was cleaned with povidone iodine, and 15 stainless steel needles (0.25 × 40 mm; Yao Tong®, Barcelona, Spain) were inserted into the plantar fascia origin at the calcaneus, which is considered the most painful area in PF (Fig. 2). Needles were directed through the skin and fascia (0.5 to 1.5 cm). They were applied with peppering, kept in place for 10 minutes, and rotated 3 to 4 times. This rotating procedure was repeated twice in each session. After removal of the needles, the insertion sites were compressed firmly to prevent excessive bleeding. Applications were repeated twice a week for 5 sessions. All interventions were performed by a single experienced physiotherapist (E.G.Y.). Patients were prohibited from taking any medications during the trial.

In group 2, all corticosteroid injections (single-dose application) were performed by the second author (B.A.) with a 25-gauge needle, with the patient in the prone position. When the hallux was extended, the plantar fascia became prominent. A longitidunal line was drawn from the medial malleolus toward the plantomedial aspect of the foot, cutting

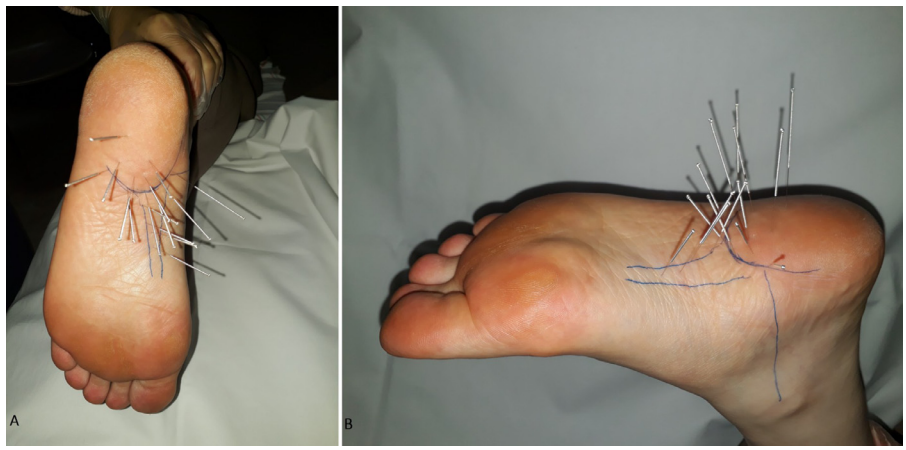

Fig. 2. After the most painful areas were marked at the heel, dry needling was performed with the patient in the prone position.

off this plantar fascia. The needle was inserted at this point through the skin, fascia, and finally the periosteum. Peppering was also done during the injection, and corticosteroid was injected between the fascia and periosteum. After needling, patients were allowed to apply ice to the heel to reduce pain and the risk of bleeding.

Patients were assessed at 3 weeks and 6 months after the interventions by a single investigator (E.U.) using the criteria described previously in a single-blind manner. The FFI score was used for clinical evaluations (17). The FFI measures pain, disability, and activity limitation. A total foot function score is derived by calculating the average of the 3 subscale scores. Missing data at the last control was handled by the carrying forward of the last observation (LOCF) method (18).

Statistical analyses were performed with SPSS version 21.0 (SPSS, Chicago, IL). In all analyses, $p < .05$ indicated statistical significance. The data were compared within and between the 2 groups. The Kolmogorov-Smirnov test was used for assessing normality of the distribution. Normally distributed data were analyzed by paired samples *t* testing and independent samples *t* testing. Dependent variables that were not distributed normally were analyzed by the Wilcoxon signed-rank test, whereas independent variables were analyzed by the Mann-Whitney *U* test.

Results

Although the initial plan called for 98 patients, the final study population consisted of 96 patients because 2 of the patients moved to another city and an additional 6 patients were unable to give a last control visit (Fig. 1). Two (2%) patients were excluded from the analysis, whereas data from 6 (6.1%) patients were handled by the LOCF method.

There were no differences between groups in terms of sex, age, or FFI score before treatment. The mean age of the patients was 49.6 ± 11.7 (range 30 to 73) years in group 1 and 49.9 ± 12.3 (range 26 to 71) years in group 2, and 66% of the patients were female. The average follow-up duration was 6.3 (range 6 to 7.3) months. The average follow-up duration of the patients, whose outcomes were carried forward, was 3.6 (range 3 to 4) months.

FFI scores were analyzed statistically to explore pain, disability, and activity limitation. Paired samples *t* tests were used to analyze the efficacy of the treatment regimens at 3 weeks and 6 months within each group. Significant differences between the 2 groups were detected at both 3 weeks and 6 months. In terms of all subscales, the corticosteroid injection group showed a loss of efficacy at 6 months, which was significant ($p < .001$; Tables 1 and 2). However, in the dry needling group, there were no significant differences in results between the third week and sixth month. The corticosteroid group showed significant loss of efficacy between the third week and sixth month. The findings were the same for pain, disability, and activity limitation scores (Tables 1 and 2). Moreover, when the third week and sixth month total FFI scores were calculated, the outcomes in the dry needling group were better than in the corticosteroid group in the sixth month ($p < .001$; Tables 1 and 2).

In this study, the most common adverse effects of dry needling were pain (38%) at the needling site and subcutaneous bleeding (12%). Those were the unwanted affects of needling during the process and did not last very long. Thus, none of the patients had to terminate the procedure because of these complications. No complications occurred in the corticosteroid group during the trial.

Table 1
Before and after-treatment values of foot function index scores

	Pretreatment Mean ± SD	*p* Value	3 Weeks Mean ± SD	*p* Value	6 Months Mean ± SD	*p* Value
FFI pain score		.128*		.020*		.006†
Group 1 (n = 49)	72.6 ± 12.3		27.7 ± 9.82		29.7 ± 10.3	
Group 2 (n = 47)	70.4 ± 9.8		33.6 ± 10.6		50.5 ± 12.3	
FFI disability score		.730*		.493†		< .001†
Group 1 (n = 49)	63.2 ± 7.9		28.3 ± 8.9		28.8 ± 8.8	
Group 2 (n = 47)	60.3 ± 8.5		28.4 ± 11.6		43.1 ± 11.1	
FFI activity limitation score		.275*		.824*		< .001*
Group 1 (n = 49)	32.8 ± 7.9		12.7 ± 5.8		12.6 ± 5.5	
Group 2 (n = 47)	32.1 ± 6.0		12.9 ± 6.7		22 ± 8.8	
FFI total score		.006†		.631†		< .001†
Group 1 (n = 49)	56.2 ± 8.2		22.9 ± 7.4		23.7 ± 7.4	
Group 2 (n = 47)	54.3 ± 5.8		25 ± 8.7		38.5 ± 9.3	

Abbreviation: FFI, foot function index; SD, standard deviation.
* Mann-Whitney *U* test.
† Independent samples *t* test.

Table 2
Before- and after-treatment values of foot function index scores

	Mean ± SD	*p* Value
FFI pain score		
Group 1 (n = 49)		
Pretreatment to third week*	72.6 ± 12.3 to 27.7 ± 9.82	<.001
Pretreatment to sixth month*	72.6 ± 12.3 to 29.7 ± 10.3	<.001
Third week to sixth month†	27.7 ± 9.82 to 29.7 ± 10.3	.100
Group 2 (n = 47)		
Pretreatment to third week*	70.4 ± 9.8 to 33.6 ± 10.6	<.001
Pretreatment to sixth month*	70.4 ± 9.8 to 50.5 ± 12.3	<.001
Third week to sixth month†	33.6 ± 10.6 to 50.5 ± 12.3	<.001
FFI disability score		
Group 1 (n = 49)		
Pretreatment to third week*	63.2 ± 7.9 to 28.3 ± 8.9	<.001
Pretreatment to sixth month*	63.2 ± 7.9 to 28.8 ± 8.8	<.001
Third week to sixth month†	28.3 ± 8.9 to 28.8 ± 8.8	.376
Group 2 (n = 47)		
Pretreatment to third week	60.3 ± 8.5 to 28.4 ± 11.6	<.001
Pretreatment to sixth month	60.3 ± 8.5 to 43.1 ± 11.1	.001
Third week to sixth month†	28.4 ± 11.6 to 43.1 ± 11.1	<.001
FFI activity limitation score		
Group 1 (n = 49)		
Pretreatment to 3rd week*	32.8 ± 7.9 to 12.7 ± 5.8	<.001
Pretreatment to 6th month*	32.8 ± 7.9 to 12.6 ± 5.5	<.001
Third week to 6th month*	12.7 ± 5.8 to 12.6 ± 5.5	.104
Group 2 (n = 47)		
Pretreatment to third week*	32.1 ± 6.0 to 12.9 ± 6.72	<.001
Pretreatment to sixth month*	32.1 ± 6.0 to 22 ± 8.8	<.001
Third week to sixth month*	12.9 ± 6.7 to 22 ± 8.8	<.001
FFI total score		
Group 1 (n = 49)		
Pretreatment to third week†	56.2 ± 8.2 to 22.9 ± 7.4	<.001
Pretreatment to sixth month†	56.2 ± 8.2 to 23.7 ± 7.4	<.001
Third week to sixth month†	22.9 ± 7.4 to 23.7 ± 7.4	.108
Group 2 (n = 47)		
Pretreatment to third week†	54.3 ± 5.8 to 25 ± 8.7	<.001
Pretreatment to sixth month†	54.3 ± 5.8 to 38.5 ± 9.3	<.001
Third week to sixth month†	25 ± 8.7 to 38.5 ± 9.3	<.001

Abbreviation: FFI, foot function index; SD, standard deviation.
* Wilcoxon signed-rank test.
† Paired samples *t* test.

Discussion

This is the first prospective randomized controlled study comparing dry needling and corticosteroid injection for the treatment of PF. There have been some previous reports on this topic, but studies have been limited by small sample sizes and lack of a control group (19,20).

The use of the FFI score is a validated and useful method for evaluating PF (17,21), because this score measures pain, disability, and activity limitation. In this study, both the dry needling and corticosteroid groups showed efficacy at the 3-week and 6-month follow-up visit. In terms of all subscales, the corticosteroid injection group showed loss of efficacy at the sixth month, which was significant ($p < .001$; Tables 1 and 2). However, when the FFI total score was calculated, it was found that dry needling offers comparable outcomes at the third week and better outcomes at 6 months (Tables 1 and 2).

Although corticosteroid injection has antiinflammatory effects on tissues, dry needling can reduce pain by affecting substance P, β-endorphin (22), and local blood flow levels (23). Thus, it is reported that dry needling is effective against tendinitis (24). Eftekharsadat et al (13) performed remote needling (to the gastrocnemius muscle) for PF and reported positive effects of treatment. In this study, we compared dry needling with single-dose corticosteroid injection, which is a widely accepted treatment for PF (25). We hypothesized that dry needling would be effective and avoid the side effects of corticosteroid injection (eg, plantar fascia rupture, local infection, and fat pad atrophy) (7,26,27).

In a clinical consensus statement, Schneider et al (25) postulated that dry needling in the treatment of PF can lead to uncertain outcomes. Minimal side effects of dry needling have been reported in the literature (13). During the procedure, pain at the needling site and subcutaneous bleeding were the most common adverse effects encountered in the present study. However, none of the patients had to terminate the procedure because of these complications. Therefore, dry needling seems to be a safe procedure.

This study indicates that dry needling promotes adequate and longer-lasting recovery than corticosteroid injection. Although there was no significant difference between the third week and the sixth month in group 1 ($p = .108$), a significant loss of efficacy was depicted in group 2 between the third week and the sixth month ($p < .001$) (Tables 1 and 2).

The strengths of this study include its prospective and randomized design and its adequate study power. In addition, all needling procedures were performed by the same investigators in both groups. Another strength is the single-blind nature of the third-week and sixth-month evaluations. However, a limitation of the study is the comparison of a single-dose corticosteroid application versus multiple dry needling applications, which may lead to misinterpretation. Although the needles (25 gauge vs 0.25 mm) and the philosophy are totally different from each other, the efficacy of different needling methods were compared in this study. Another limitation is the LOCF method, which was used for handling missing data from 6 patients (12.2%). Although it may impart a bias, we believed that this method would be less problematic than simply omitting the data (18).

This study should lead physicians to consider needling. If both types of injection are effective, this raises the question of whether the key point in treating PF is peppering into the fascia or the induction of microbleeding. Lemont et al (27) also postulate that PF does not contain inflamation. Perhaps that is why dry needling is more effective than corticosteroids. Additionally, dry needling avoids the complications of corticosteroid injection. However, unlike a single-dose corticosteroid injection, repeated applications of dry needling are needed to obtain an effective outcome. The fact that dry needling is time consuming and costly may be included as other drawbacks of the application, because a 5-session application requires a considerable amount of time and cost. Nevertheless, to avoid adverse effects of corticosteroids, dry needling may be a treatment option.

Although some authors advocate that PF is a self-limiting disease, it can be refractory in some cases. Therefore, dry needling may be considered an alternative method in refractory cases. In these cases, a profit-and-loss account should be made. Given its promising results, dry needling may improve clinical outcomes of patients with other types of tendinopathy.

In conclusion, in terms of the FFI score, dry needling seems to be a reliable procedure for treating PF. It is found that outcomes of dry needling are more effective than corticosteroid injection in the sixth month of follow-up. Although multiple sessions are required (unlike with corticosteroid injection), dry needling may be as useful as corticosteroid injection because it seems to have greater physiological compatibility than corticosteroid injection.

Supplementary Materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1053/j.jfas.2018.08.058.

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