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The Effect of Corticosteroid Local Injection Versus Platelet-Rich Plasma for the Treatment of Plantar Fasciitis in Obese Patients: A Single-Blind, Randomized Clinical Trial

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ABSTRACT

Chronic plantar heel pain (CPHP) is one of the most common painful and disabling foot conditions, for which various treatments have been proposed. We aimed to investigate the efficacy of local injection of platelet-rich plasma (PRP) compared with the conventional method of local corticosteroid injection in obese patients who were resistant to other nonsurgical treatments. In this single-blind, randomized clinical trial, 32 obese patients with chronic plantar heel pain were randomly allocated to 2 groups of 16 participants each. In 1 group, 40 mg of dimethylprednisolone was injected once into the painful heel, whereas the other group received 3 separate injections of PRP, with each injection administered 1 week apart. The groups were compared at baseline and at 24 weeks after the injection, or course of injections, was administered. Exposures, total morning pain, and foot function index were not statistically significantly different between the groups at baseline; however, at 24 weeks after the treatment, final pain and morning pain scores were statistically significantly ($p < .001$) better in the corticosteroid group, and the mean foot function index scores were 65.4 ± 3.2 and 58.3 ± 2.9 ($p < .001$) in patients treated with corticosteroid and PRP, respectively. In obese patients with plantar fasciitis, injection with corticosteroid was more effective than PRP at reducing pain and improving function.

Plantar fasciitis is a common disorder of the foot, but we believe that there is limited data available as to its precise etiology. Plantar fasciitis requires interventional treatment in 11% to 15% of cases. Acute and chronic inflammatory variations in the calcaneal attachment of the plantar fascia can occur as a result of activity or lifestyle, and biopsy samples from patients undergoing plantar fascia release surgery showed degenerative changes in the plantar fascia with and without fibroblastic proliferation as well as the presence of chronic inflammatory cells (1,2).

Obesity and being overweight have been shown to be associated with chronic plantar heel pain (CPHP) as a result of plantar fasciitis, and a body mass index (BMI) > 30 kg/m^2 increases the risk of developing plantar fasciitis (3). Local injection modalities are widely used in the treatment of resistant plantar fasciitis, in addition to other supportive and physical treatments. Corticosteroid injection, with or without local anesthetic, is the most common nonsurgical, pharmacologic treatment for plantar fasciitis, with the exception of oral nonsteroidal anti-inflammatory drug (NSAID) therapy (4). Platelet-rich plasma (PRP) is a natural concentrate rich in autologous growth factors that has been extensively used in various medical fields because of its ability to promote tissue regeneration, and local injection of PRP is an option for the treatment of plantar fasciitis (5,6). We undertook a randomized controlled clinical trial that aimed to compare the efficacy of local injection of PRP with corticosteroid injection in obese patients with plantar fasciitis resistant to other conservative treatments. We hypothesized that corticosteroid has a more effective role in reducing pain than other medical treatments in obese patients with plantar fasciitis.

Methods

Participants

In this single-blind, randomized clinical trial, were investigated patients with obesity and CPHP who were referred to the Orthopedic Clinic of Urmia University of Medical Sciences during the period from October 2015 through December 2017. Plantar fasciitis was diagnosed by a single orthopedist, based on a history of complaints of morning pain or pain after sitting (poststatic dyskinesia), intensified pain with walking or standing > 15 minutes, pain severity of > 4 on a visual analog scale (VAS) of 0 to 100 mm, and pain on deep palpation of the medial plantar tubercle of the calcaneus, without evidence of any other focal pathology or systemic disease thought to

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account for the heel pain. Patients with obesity and with unilateral or bilateral CPHP were considered to be potentially eligible for inclusion in the investigation. Conventional radiography was used for the determination of plantar heel spurs and to rule out bone tumor, fracture, ectopic calcification, or other conditions.

We considered patients with a BMI ≥ 30 kg/m^2 to have obesity, based on the following classification: underweight, ≤ 18.5 kg/m^2; normal weight, 18.5 to 24.9 kg/m^2; overweight, 24 to 29.9 kg/m^2; and obesity, ≥ 30 kg/m^2) (7).

The sample size was determined by using Minitab/13 (Minitab, State College, PA) and based on Martinelli et al (16). With 80% power and $d \leq .60$, a group size of 14 patients was considered adequate to identify a statistically significant difference at the 5% level, should one exist. To account for ~5% attrition, 16 patients were allocated to each treatment group. To be included in the study, a participant had to have a BMI ≥ 30 kg/m^2 and to have first been treated with other conservative methods, including physical therapy, consumption of NSAIDs, stretching of plantar muscles and the Achilles tendon, and use of silicone heel cushions, for a minimum of 2 months before their pain was considered recalcitrant. Patients were excluded if they were known to have a history of diabetes mellitus, rheumatoid arthritis, lupus erythematosus, gout, blood clotting disorder, congenital deformity of the foot or ankle, lumbosacral radiculitis, previous fracture or surgery in the affected foot or ankle, blood clotting disorder (including a platelet count < 100,000), allergy to local anesthetic, pregnancy, history of extracorporeal shock wave therapy to treat the affected heel, or previous plantar heel injection. Demographic data were recorded before any form of injection therapy, and BMI was determined by using the standard formula. After obtaining a participant's written consent, height, weight, and waist circumference were clinically examined before the treatment. The patients' heights were measured with the accuracy of 0.1 cm with use of a wall-mounted stature meter. The patients' weights were assessed by use of a Sega scale at the precision of 0.5 kg. Then, their BMIs were calculated. The patients' activity levels were evaluated based on their sports activity and walking (sports activities and walking > 30 minutes were considered high activity levels and ordinary daily tasks were considered a medium activity level).

Morning and daily pain of the patients was recorded before the injection, and the pain severities of the patients were evaluated 8, 12, and 24 weeks after the treatment. Methylprednisolone plus corticosteroid (40 mg) was used with 1 to 1.5 mL of lidocaine 1%. For injection, the origin of plantar fascia was approached from the medial side with use of a small needle (gauge 22); after touching the calcaneus bone in the plantar part, the injection was performed in the plantar fascia with maximum tenderness (4). Finally, the patients were followed (pain severity response and patient function) for at least 6 months.

The visual analog scale (VAS) was used to investigate pain severity. For this purpose, the patients scored their pain level from 1 to 100. According to Jensen et al (8), VAS values within the range of 0 to 4 mm are considered as no pain, whereas VAS values within the ranges of 4 to 44, 45 to 75, and 75 to 100 mm indicate mild, moderate, and severe pain, respectively. To evaluate the functional ability of the patients and their responses to treatment, we used the standard Foot Function Index (FFI) questionnaire. The FFI questionnaire is divided into 3 subcategories; pain, disability, and activity restriction. It consists of 23 items including 9 items for the pain subcategory, 9 items for the disability subcategory, and 5 items for the activity restriction subcategory. This questionnaire is used to closely investigate patients' response to treatment and was filled out 2 months after treatment (23). Decline in pain severity (based on VAS) by > 60% was considered as treatment success. Accordingly, a 50% reduction in FFI values was regarded as a proper clinical criterion for response to treatment (9). Symptom return and recurrence were determined within 6 months of follow-up. Patient activity level were determined by using the International Physical Activity Questionnaire–Short Form (IPAQ-SF) for use in young and middle-aged adults (15 to 69 years) (22).

Intervention Groups

For the patients who met the inclusion criteria, randomization was carried out by using a computer-generated random number list, alternatively allocating patients to one or the other treatment group. One group was treated with local injection of corticosteroid. In so doing, the skin was disinfected with alcohol before the injection, and preparations were made under aseptic conditions. Methylprednisolone corticosteroid (40 mg) was used with 1 to 1.5 mL of lidocaine 1% in a single dose. For injection, the origin of plantar fascia was approached from the medial side with a small needle (gauge 22). After touching the calcaneus bone in the plantar part, the injection was performed in the plantar fascia section with maximum tenderness (4). The second group received PRP injections. To prepare PRP, the ACP Double Syringe System (Arthrex, Naples, FL) was used. This system possesses an outer 10-mL syringe on which a 5-mL syringe is attached, which is accessible and replaceable. For PRP injection, 10 mL of autologous blood was drawn from the antecubital vein using the outer syringe and transferred to a centrifuge (Rotofix; Arthrex), where the blood samples were spun for 5 min at 1500 rpm. Using this system, the supernatant (PRP) is transferred from the 10-mL outer syringe to a 5-mL syringe under aseptic conditions. All the patients in the PRP group received 3 injections at the attachment of their plantar fascia to the medial tubercle of the calcaneus via a medial approach at the junction of the plantar and medial surfaces of the involved heel, once per week over a 3-week period. All of the injections were performed by the same orthopedist on an outpatient basis and each time under aseptic conditions. Before injection of the 3 mL of PRP, 2 mL of plain lidocaine 2% was injected into the subcutaneous tissue to locally anesthetize the planned injection site. After the first injection of PRP, the patients were allowed to walk but were advised to avoid strenuous weightbearing and sports activities, such as running or jumping, for a period of 4 weeks after the last injection.

For pain control in the PRP group, celecoxib 200 mg was used every 12 hours for 3 days after an injection. Ice packs were also used for up to 10 to 12 minutes, to control the postinjection pain at the site of administration in the PRP group. A silicone heel cushion pad was also used in the postinjection period in both groups.

This study was recorded as the residential thesis with code of 94-01-32-1907 in Urmia University of Medical Sciences. A written consent form was obtained from the patients, and they were informed that participation in the study was completely voluntary. This study was conducted with the approval of the Ethics Committee of Urmia University of Medical Sciences, Urmia, Iran.

Statistical Analysis

Descriptive statistics including mean ± standard deviation (SD), frequency counts, and percentages were used. To compare the qualitative variables between the 2 treatment groups, χ^2 or Fisher exact tests were used. Quantitative variables were compared using independent Student's t tests. To compare pain severity variations between the 2 groups, repeated-measures analysis of variance was used. Statistical analyses were performed using SPSS version 20, and a value of $p \leq .05$ (5% level) was considered statistically significant.

Results

A total of 40 patients with obesity and CPHP were considered for inclusion in the investigation. Eight (20%) of these patients were excluded because they did not meet the inclusion criteria: 3 (7.5%) had received previous corticosteroid injection and 5 (12.5%) had diabetes. The remaining 32 (80%) patients were randomly divided into the 2 treatment groups using the computer-generated random number list. One (6.25% of the group, 3.1% of those treated) patient from the PRP group was excluded as a result of being lost to follow-up (Fig. 1). Therefore, 31 (96.9%) of those treated were included in the analyses.

Table 1 presents the demographic data of the patients and shows that the 2 groups were homogeneous in this regard. In the corticosteroid-treated group, 11 patients received bilateral injection. In the PRP-treated group, 9 patients received bilateral injection. As seen in Table 2, morning and total pain severities of the patients showed no significant differences before the injections. However, a significant difference was detected 24 weeks posttreatment in regard to the severity of initial morning pain ($p < .001$). As Figs. 2 and 3 indicate, reduction in pain significantly differed throughout the study, such that corticosteroid-treated patients exhibited greater improvement in their pain severity. No severe pain was recorded in any of the patients at final follow-up. Mild pain was recorded in 9 (56.2%) corticosteroid-treated patients, whereas 4 (26.6%) PRP-treated patients reported mild pain. Moderate pain was reported in 4 (25%) and 9 (60%) patients in the corticosteroid- and PRP-treated groups, respectively. The mean FFI of the patients treated with corticosteroid injection also showed significantly greater improvement in regard to pain, disability, and activity limitation compared with those injected with PRP.

Discussion

In this clinical trial, we compared the responses of patients with obesity and CPHP with plantar fasciitis who were treated via local injection of methylprednisolone or PRP. Pain reduction and functional improvement were better in the corticosteroid-treated group compared with the PRP-treated group at 6 months after the course of injection therapy. Various studies have mentioned the correlation between increased BMI and CPHP as a result of plantar fasciitis; studies among typical, nonathletic individuals also suggest a strong correlation between increased BMI and CPHP (10,11). However, there is a scarcity of studies on the relationship between obesity and response to treatment.

In a study by Valizadeh et al (3), high BMI was reported as a strong risk factor for the recurrence of CPHP. There are also reports on the correlation between BMI and morning pain severity. And it has been

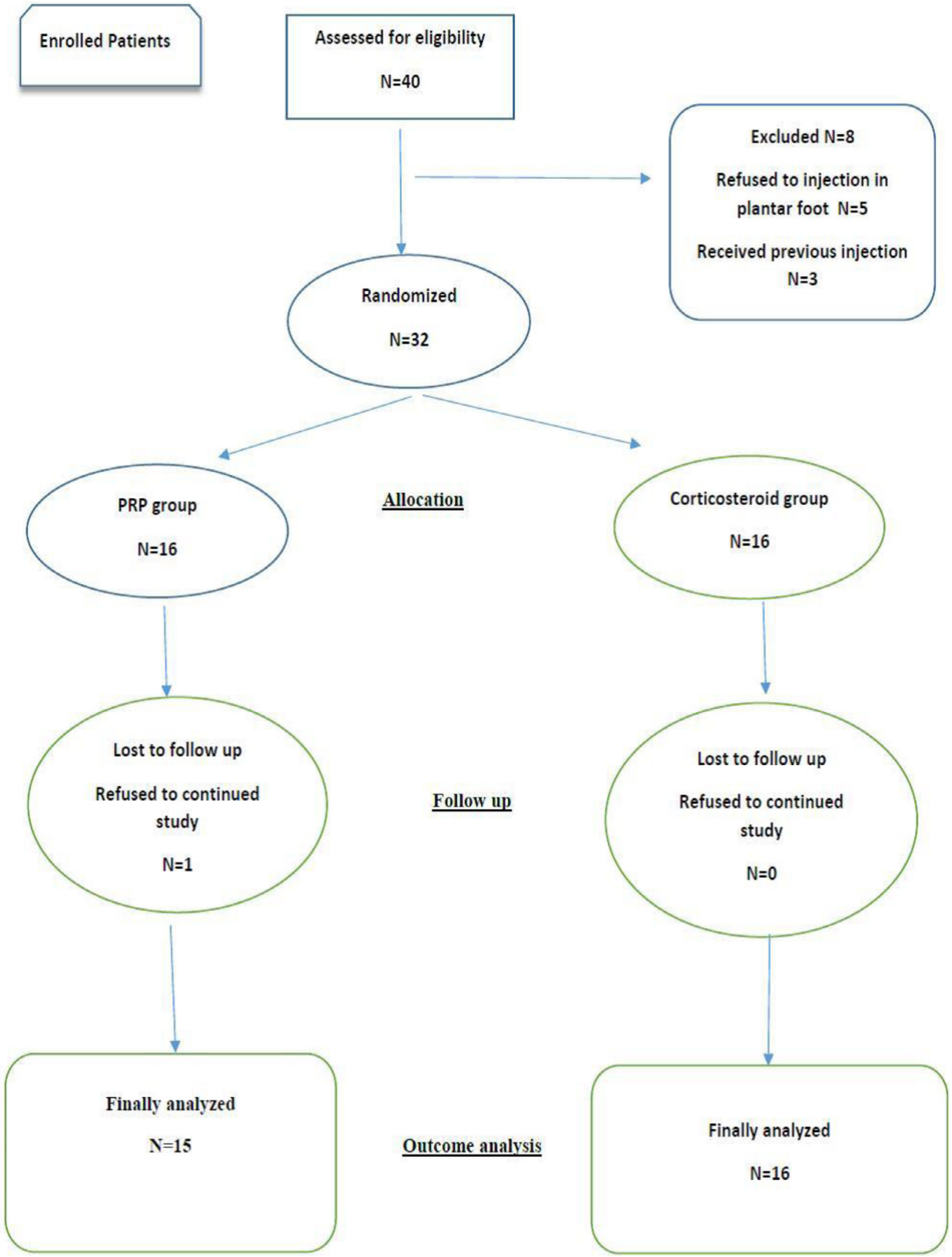

Fig. 1. Flowchart of the study protocol.

Table 1
Demographic data of the patients and homogeneity of groups

Variable	Corticosteroid-Treated Group (n = 16)	PRP-T Group (n = 15)	*p* Value
Age, mean ± SD y	31.7 ± 7.5	33.6 ± 8.5	.5
BMI, mean ± SD kg/m^2	32.4 ± 2.1	33.9 ± 3.3	.1
Sex (female/male), n	15/1	14/1	.7
Bilateral, n (%)	9 (56.3)	11 (73.3)	.1
Unilateral, n (%)	7 (43.8)	4 (26.7)	
Sedentary, n (%)	15 (73.8)	11 (73.3)	.2
Moderately active, n (%)	1 (6.3)	4 (26.7)	
Presence of heel spur on calcaneal radiography, n (%)	11 (68.1)	10 (66.7)	.6

BMI, body mass index; PRP, platelet-rich plasma; SD, standard deviation.

shown that corticosteroid has the same efficacy in reducing symptoms and controlling pain in patients with obesity as it does in patients with ideal weight and that corticosteroid injection in the plantar fascia is an effective treatment for patients in cases where conservative treatments fail (9,12–14).

Steroids are defined as modifiers of the ultrasonographic appearance of the plantar fascia through reduction in the thickness of the plantar fascia and decrease in the emergence of hypoechoic tissues. Corticosteroids also cause improvement in clinical symptoms associated with plantar fasciitis (12). Some authors, however, concluded that steroid injection could provide only short-term improvements (15), whereas others reported long-term positive effects of local steroid injection in patients with plantar fasciitis (6,12). Proter and Shadbolt (13) reported satisfactory outcomes at 12-month follow-up. In the study by Martinelli et al (16), PRP treatment resulted in effective pain reduction in patients with normal weight. Therefore, PRP was reported as a safe and highly efficacious treatment. It seems that plantar fasciitis treatment outcomes are multifactorial, and disease duration, patient activities, comorbid diseases, and obesity can influence the treatment outcomes.

A 2007 study by Irving et al (10), in Australia, addressed the relationship between BMI and CPHP. The BMI of patients with CPHP was significantly high. Based on logistic multivariate analysis, high BMI was the most important factor in CPHP and it was described as a major risk factor for plantar fasciitis (10). Chattereton et al (17), in a study of 9334 patients with CPHP, showed that BMI posed a relative risk of 1.5 for plantar fasciitis, and it was the main predisposing risk factor. In regard to bilateral cases, a strong correlation was observed between BMI and CPHP with a relative risk of 5.7 (17).

PRP is a filtered and centrifuged thick concentrate of platelets derived from autologous blood plasma. It contains high concentrations of growth factors such as platelet-derived growth factor, epidermal growth factor, vascular endothelial growth factor, and transforming growth factor-β (18). PRP injection in damaged tissue could be effective

Table 2
Comparison of clinical characteristics between the 2 groups after treatment

Variable, mean ± SD	Corticosteroid-Treated Group (n = 16)	PRP-Treated Group (n = 15)	*p* Value
VAS score pretreatment	93.3 ± 7.2	95.6 ± 5.1	.4
VAS score at 24 weeks	38.8 ± 7.8	58 ± 6.4	.001*
Morning VAS score pretreatment	91 ± 8.2	92.2 ± 5.5	.1
Morning VAS score at 24 weeks	44.3 ± 6.3	54.4 ± 5.7	.001*
FFI pain	43.4 ± 10.6	52.4 ± 11.6	.02*
FFI disability	38.4 ± 11.4	48.2 ± 12.7	.01*
FFI activity limitation	41.4 ± 15.5	46.4 ± 10.4	.01*

FFI, Foot Function Index; PRP, platelet-rich plasma; SD, standard deviation; VAS, visual analog scale.
* Statistically significant difference.

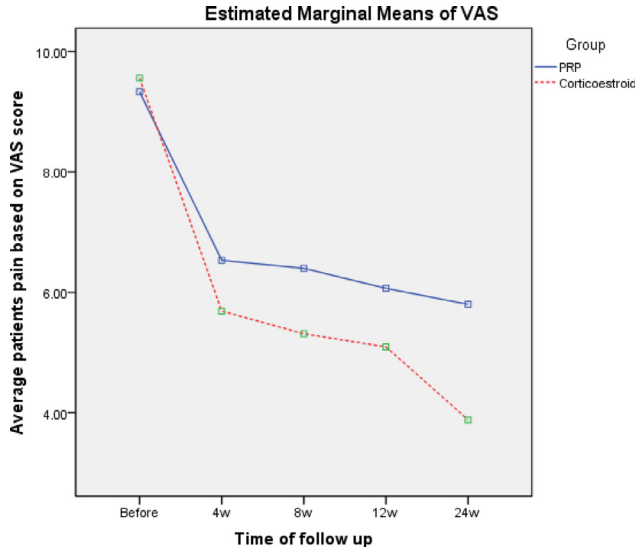

Fig. 2. Pain severity variation by time in during follow-up of the platelet-rich plasma– and corticosteroid-treated groups.

in the improvement of cases of chronic tendon recovery (6). Promising outcomes have been reported for the application of PRP in the treatment of cutaneous ulcers, damaged ligaments, cartilage injuries, muscle damage, and bone defects. In the case of chronic injuries, PRP reinitiates the inflammatory process, which is commonly stalled in cases where conservative treatments have failed. The secondary effect of PRP in chronic injuries theoretically lies in the implementation of recovery caused by the addition of autologous platelets (19).

A limited number of studies have compared the outcomes of steroid and PRP injections in chronic tendon disorders or plantar fasciitis (4,19,20). In a recent study by Peerbooms et al (6), a positive effect was observed with PRP injection in the origin of common extension of external epicondylitis. This study was the first to compare corticosteroid injection with PRP administration to treat external epicondylitis in patients in whom nonsurgical treatment had failed. These results showed that PRP injection can reduce pain and improve function better than corticosteroid treatment (6,19,20).

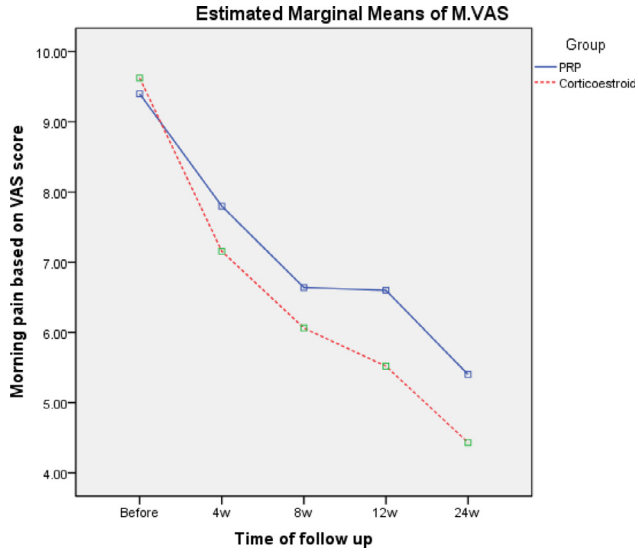

Fig. 3. Morning pain severity variation by time during follow-up of the platelet-rich plasma– and corticosteroid-treated groups.

Barrett and Erredge (5) published a study on PRP injection for the treatment of plantar fasciitis. They proposed that plantar fasciitis is not an inflammatory condition but rather a degenerative condition of the fascia (5). It was hypothesized that PRP injection, referred to as plantar fasciorrhaphy, could result in improvement in symptomatic and treatment-resistant plantar fasciitis. Complete recovery was observed in 6 of 9 investigated cases, and 1 of the patients improved after the second injection. After 1 year, 77.9% of the patients were symptom free. Lee and Ahmad (20) compared steroid and PRP injections for plantar fasciitis treatment in a randomized controlled study. They concluded that PRP injection was effective in reducing the pain and tenderness of CPHP; however, corticosteroid was preferred in terms of the speed and degree of recovery.

In patients with obesity, PRP treatment does not seem to be as effective as corticosteroid treatment. A meta-analysis by McMillan et al (21) showed a strong correlation between CPHP and increased thickness of the plantar fascia (> 2.1 mm). Patients with CPHP also exhibited higher rates of radiographic evidence of calcaneal spur formation (21). This increase in thickness has a significant relationship with BMI in such a way that thicknesses > 4 mm were reported for patients with BMI > 30 kg/m^2. Therefore, increased weight correlated with increased plantar fascia thickness. One of the reasons for the high prevalence of CPHP is increased thickness of the plantar fascia, thought to be the result of weight gain (21), which can explain the association of corticosteroid injection in obesity with resolving symptoms.

We realize that the clinical trial that we undertook is not without shortcomings. For example, our focus was on comparing outcomes after 2 different injection therapies, and the treatments were likely influenced by concomitant use of oral NSAID medication and other adjunct therapies. The precise degree to which such treatments were administered or their precise influence on the results was not ascertained. Moreover, we did not make any attempt to identify the prevalence or association of a plantar calcaneal spur with any of the outcomes of interest. Further, some of the participants in the study had bilateral plantar heel pain, which could have influenced our analyses because of the dependence of outcomes of interest that were linked by patient. Because of this, we made no attempt to distinguish between results in one foot versus the other in such patients; instead, we chose to focus on patient-level, rather than foot-level, outcomes, an approach that we thought would be more meaningful overall.

In addition, the 3 weekly PRP injections were carried out during a 3-week period compared with a single injection of corticosteroid administered during 1 visit, and this could have influenced our findings, although it was generalizable in that the usual administration of the 2 injectable preparations used in this study were given in the usual fashion. Also, we did not use any data in the final analysis from the 1 patient in the PRP group who was lost to follow-up.

In conclusion, based on the results of our randomized, controlled clinical trial, a single injection of corticosteroid appears to be more effective than a series of 3 PRP injections for the treatment of CPHP caused by plantar fasciitis in patients with obesity, in regard to improvements in functional performance and reduction of plantar heel pain. Understanding that 1 clinical trial does not provide enough evidence to alter therapy, we believe that the results of this investigation could be used in the development of future clinical trials that focus on the nonsurgical treatment of plantar fasciitis.

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