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Clinical and imaging effects of corticosteroids and platelet-rich plasma for the treatment of chronic plantar fasciitis: A comparative non randomized prospective study

Adriana E. Jiménez-Pérez^{a,*}, Daniel Gonzalez-Arabio^b, Andrés Saldaña Diaz^b,
Jose A. Maderuelo^b, Luis R. Ramos-Pascua^b

^a Radiology Department Complejo, Asistencial Universitario de León, Gerencia Regional de Salud de Castilla y León (SACYL), Spain

^b Orthopedic surgery and traumatology service, Complejo Asistencial Universitario de León, Gerencia Regional de Salud de Castilla y León (SACYL), Spain

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ABSTRACT

The purpose is to compare the effectiveness and imaging changes (US and MRI) between PRP and corticoids injections for the treatment of chronic plantar fasciitis, using clinical results evaluated by the visual analogue scale (VAS), the AOFAS clinical rating system and the modified Roles and Maudsley score, and using imaging results (US and MRI). Our hypothesis is that PRP infiltrations are a more effective therapeutic method than infiltrations with corticosteroids. A single-centre, non randomized, prospective study of 40 consecutive patients (40 feet) with plantar fasciitis who had not responded to conservative treatment for at least 6 months was undertaken. The first 20 consecutive patients (group A) were treated with two local injections of 4 ml of a PRP concentrate. The second group of 20 patients (group B) were injected with 4 ml of 40 mg methylprednisolone. Clinical results were evaluated using a visual analogue scale (VAS), the AOFAS clinical rating system and the modified Roles and Maudsley score, with a mean follow-up of 33 months. Imaging results were evaluated by plantar US after 3 and 6 months, and MRI after 6 months. There were no complications arising from the treatment. In group A (PRP), the VAS changed from 8.25 to 1.85 and the AOFAS from 47.05 to 92.10. In group B (methylprednisolone), the VAS changed from 7.7 to 5.30 points and from 50.85 to 49.75 on the AOFAS. In the imaging tests, the thickness of the fascia in group A changed from 7.90 mm to 4.82 mm over 3 months following the injection, maintaining this thickness in the biannual controls. In group B the change was from 8.05 mm to 6.13 mm over 3 months, increasing to 6.9 mm after 6 months. The other inflammatory signs improved in all cases, especially in group A. The treatment of chronic plantar fasciitis by two injections of PRP is a safe, more efficient and long-lasting method than corticoid injections.

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1. Introduction

Chronic plantar fasciitis is the most common cause of heel pain, affecting people who do sports as well as inactive middle-aged individuals [1–3]. The condition is a degenerative pathology rather than an inflammatory process [4–7], and its diagnosis is based on the typical history and the presentation of localized tenderness in the medial calcaneal tubercle. Although the condition is self-limiting, and the majority of cases spontaneously resolve regardless of the type of intervention received, including placebo [8], the

symptomatology can be very limiting for the patient, and treatment may last for many months. Conservative methods are used in its initial management. In resistant plantar fasciitis, when changes in daily activities, shoe modification, ice packs, physiotherapy, plantar fascia-stretching exercises, taping, orthoses, extracorporeal shock-wave therapy (ESWT), and nonsteroidal anti-inflammatory drugs (NSAIDs) are not effective, local injection modalities can be tried. Other treatment options include surgical procedures, such as conventional fasciotomy or proximal medial gastrocnemius release [9].

Local injection of platelet-rich plasma (PRP), which is a natural concentrate of autologous growth factors [10], has been widely tested for treating muscle and tendon injuries for its possibilities for aiding the regeneration of tissue with low healing potential [4,11,12]. Its use has also recently been discussed for the treatment

* Corresponding author at: C/Cardenal Lorenzana 6, 5C, 24001, Leon, Spain.

E-mail addresses: etcaej00@estudiantes.unileon.es (A.E. Jiménez-Pérez), danielarabio@yahoo.es (D. Gonzalez-Arabio), ansaldiaz@gmail.com (A.S. Diaz), luisramospascua@gmail.com (L.R. Ramos-Pascua).

of plantar fasciitis [13], although there is considerable controversy about its benefits and advantages over other treatment methods [3]. Few randomized controlled trials have examined the role of PRP in the treatment of plantar fasciitis. Most of them have a follow-up of no longer than 6 months and do not address the changes in the images [1,5,6].

The purpose of this prospective comparative case series study was to compare the effectiveness and imaging changes (US and MRI) between PRP and corticoids injections for treatment of chronic plantar fasciitis. We think that the PRP injections is a more effective treatment with a demonstrable anatomical base.

2. Material and methods

A single-centre, non randomized, prospective study of 42 consecutive patients with plantar fasciitis who had not responded for at least 6 months to conservative treatment modalities (ice packs, stretching of the Achilles tendon, physiotherapy and NSAID medication) was performed in our institution between July 2011 and May 2015. The mean time of rehabilitation before the injection for all cases was 1.5 months (range, 1–3 months). A group of 20 consecutive patients (20 feet, group A) were treated by a local injection of 4 ml of a concentrate of platelet-rich plasma (PRP). A second group of 22 patients (22 feet, group B) were selected to inject with 2 ml of 40 mg methylprednisolone (Trigon Depot[®] 40 mg, Bristol-Myers Squibb S. A., Madrid, Spain). All patients received two injections into the plantar fascia between four and six weeks after clinical and imaging confirmation. Neither the patients nor the researchers were blinded to the agent used.

Inclusion criteria included patients with heel pain longer than six months diagnosed with plantar fasciitis (clinical and imaging (US and MRI) criteria), aged between 18 and 85 years, able to understand the treatment. Exclusion criteria included any previous injection treatment or surgery for heel pain, any wound or skin lesion on the plantar aspect of the foot; generalised inflammatory arthritis, systemic diseases, and other local pathologies for heel pain. One patient was excluded because he refused the injection, and another patient was lost to follow-up, both from group B. Forty patients constituted the final sample of the study.

All patients were recruited from two traumatology outpatient clinics and one rehabilitation clinic by two of the authors (AS, DGA) when they fulfilled the study's inclusion criteria, after informing the

responsible physicians of the existence of this ongoing study. All patients were subjected to simple radiography (AXIOM Aristos MX), MRI (Siemens AVANTO MRI Scanner, 1.5 Tesla) and an ultrasound scan (Philips IU22 scanner with a 17 MHz high-frequency flat sector transducer) before the first injection. All injections were performed by the senior author (AJ) on an outpatient basis. The baseline characteristics of each group, including age, gender, affected side, height, weight, body mass index, and duration of the foot pain, were recorded (Table 1). The Ethical Committee of our institution approved the study and informed consent was obtained from all patients.

2.1. Obtaining PRP

Using the method of Anitua [14], 20 cm³ of blood was drawn from the cubital vein and placed in four sterile test tubes with 3.8% sodium citrate as anticoagulant. Platelets were separated from the plasma by centrifugation at 1800 rpm for 8 min. The fraction nearest the surface (platelet-poor plasma, PPP) was removed with a sterile pipette; another pipette was used to extract the intermediate plasma fraction, which has the same platelet content as a sample of normal blood; a third pipette was used to select the concentrated platelet-rich plasma (PRP). Calcium chloride (10%) was added to this fraction 10 min before being used to activate and aggregate the platelets.

2.2. Injection technique

With the patient in a prone position and the ankle in a neutral position at 90°, the location of the swollen plantar fascia was confirmed by ultrasound. After pulverising the skin and the ultrasound transducer with chlorhexidine and without local anaesthetic, an 18G intramuscular needle was introduced decisively parallel to the transducer, penetrating the most swollen fascia and the adjacent tissues with 4 ml of PRP in group A, and with 2 cm³ of 40 mg methylprednisolone in group B. A new control ultrasound and a dressing was applied to the site of the injection.

2.3. Post-injection management

After each injection the patients were instructed not to put weight on their heel for two days and to avoid physical activity

Table 1

Characteristics of the patients in the two study groups: sex, age, gender, height, weight, BMI (BMI = body mass index), and clinical and imaging data, were recorded previous to the injection. (ST: soft tissues).

	Total (N = 40)	Group A (PRP) (N = 20)	Group B (corticosteroid) (N = 20)	p
Sex				
Male	11 (27.7%)	5 (25%)	6 (30%)	0.723
Female	29 (72.5%)	15 (75%)	14 (70%)	
Age, mean (sd), years				
Total	54.4 (10.0)	53.7 (9.8)	55.1 (10.4)	0.779
Male	54.4 (13.1)	52.9 (14.6)	55.6 (12.9)	
Female	54.4 (8.8)	54.0 (8.4)	54.8 (9.6)	
Height (cm)	168.3 (6.7)	167.2 (5.9)	169.4 (7.4)	0.369
Weight (kg)	69.9 (7.4)	70.4 (7.4)	69.6 (7.7)	0.659
BMI	24.7 (2.1)	25.2 (2.2)	24.2 (1.8)	0.134
Previous symptomatology				
VAS	7.98 (1.05)	8.25 (0.97)	7.70 (1.08)	0.149
AOFAS	50.9 (20.8)	47.1 (20.9)	54.7 (20.6)	0.314
Ultrasound findings				
Thickness	8.00 (1.52)	7.95 (1.67)	8.05 (1.40)	0.678
Abnormal echogenicity	40 (100%)	20 (100%)	20 (100%)	
Perifascial ST	40 (100%)	20 (100%)	20 (100%)	
MRI findings				
Thickness	8.00 (1.52)	7.95 (1.67)	8.05 (1.40)	0.678
Altered signal	40 (100%)	20 (100%)	20 (100%)	
Perifascial ST	40 (100%)	20 (100%)	20 (100%)	
Bone signal	29 (72.5%)	14 (70%)	15 (75%)	

involving impact for a month. They were recommended to wear sporting footwear during this time and were not allowed NSAIDs, rehabilitation treatment or the use of orthoses.

Patients were clinically assessed after 3, 6 and 12 months and at the end of the study, after a mean follow-up of 33 months after the final injection (range, 23–43 months) by two of the authors (AS, DG-A). The ultrasound scans were repeated after 3 and 6 months and one MRI after 6 months by the senior one of the authors (AJ). The imaging results were evaluated by a radiologist specializing in musculoskeletal pathology. The clinical evaluation at each review included the register of complications, the Visual Analogue Scale (VAS), used to measure the patient’s subjective assessment of their pain, in which 0 and 10 correspond respectively to the complete absence of pain and the worst pain imaginable. The AOFAS Ankle-Hindfoot Scale [15,16] and the modified criteria of Roles and Maudsley [17] were used to define the outcome of the procedure: excellent (no pain, patient satisfied with the treatment outcome and unlimited walking without pain), good (symptoms substantially decreased, patient satisfied with the treatment outcome, and ability to walk without pain for >1 h), acceptable (symptoms somewhat decreased, pain at a more tolerable level than before treatment, and patient slightly satisfied with the treatment outcome), or poor (symptoms identical or worse and patient not satisfied with the treatment outcome). Treatment was considered successful when the patient had a good or excellent score. Ultrasound evaluation included the measure of the thickness of the fascia (considering normal 4 mm, and measured in the place of greatest inflammation), and its echostructure, and the perifascial soft tissues changes. In MRI scan, the thickness and the signal of the fascia and adjacent soft tissues, and the bone signal of the fascial insertion in the calcaneus were evaluated.

2.4. Statistical analysis

Continuous and categorical variables were summarized as a mean ± SD and a frequency distribution, respectively. Differences in medians between treatment groups were examined with the Mann-Whitney U test, while differences in the proportions of categorical variable classes were analysed using the χ^2 test. We analysed the evolution of VAS and AOFAS Ankle-Hindfoot Scale, thickening of the fascia and the modified criteria of the Roles and Maudsley scores at follow-up with a repeated-measures generalized linear model (GLM) apply a Bonferroni correction for multiple testing. We used the Cochran tests to contrast the hypothesis of two or more related proportions. Analyses were carried out with

IBM SPSS Statistics for Windows, Version 23.0 (Armonk, NY: IBM Corp). Statistical significance was defined at the 5% ($p \leq 0.05$) level.

3. Results

The clinical and imaging data of the patients from the two study groups are summarised in Table 1. There was no significant difference between the groups with respect to epidemiological, imaging and clinical characteristics ($p = 0.05$).

In the group treated with PRP, thickening of the fascia before the injection was observed with ultrasound and MRI, with thicknesses between 6 and 11 mm (mean, 7.95 mm), and a brighter intrafascial signal of the calcaneus bone adjacent to the insertion of the plantar fascia in 14 (70%) patients, traducing bone inflammation and an increase in the signal of the inflammatory aspect in the whole group (100%). 14 (70%) patients showed fine linear collections of locoregional inflammatory liquid. Other observations were made that were not connected with plantar fasciitis, such as the presence of calcaneal spurs, Achilles tendinitis, tendinitis of the lateral peroneus, and arthrosis. All of them were considered incidental findings, and were not reasons for exclusion.

In the group treated with corticoids, the ultrasound and MRI revealed thickening of the fascia before the injection, with thicknesses between 7 and 11 mm (mean, 7.95 mm), with a diffuse diminution of the normal echogenicity of the fascia in all cases. The MRI also revealed an increase in the intrafascial signal in all cases before the injection. The ultrasound and MRI revealed an increase in the signal of the calcaneus adjacent to the calcaneal insertion of the plantar fascia in 15 (75%) patients, and increase in the signal of inflammatory appearance in all cases (100%) and, in 15 (75%) cases, fine linear collections of locoregional inflammatory liquid, before the injection.

3.1. Clinical results

Clinical results are summarized in Table 2. VAS in the PRP group decreased significantly from 8.25 before treatment to 1.85 at the last follow-up ($p = 0.0001$). VAS in the corticoid group decreased from 7.95 before treatment to 5.3 after 6 months follow-up, increasing to 6.05 after 12 months and 6.25 at the final follow-up. We found a statistically significant difference in VAS scores between groups at 6 months ($p < 0.0001$), 12 months ($p < 0.0001$) and at the final follow-up ($p < 0.0001$) with lower scores in PRP group. The AOFAS score, registered six months after treatment, and patient satisfaction according to the modified criteria of the Roles

Table 2

Comparative clinical results of patients from the two groups after 6 months, 12 months and at the end of follow-up.

	Previous value (N=20)	6 months (N=20)	12 months (N=20)	Last revision (N=20)
VAS (mean value)	$p = 0.149$ (intergroup)	$p < 0.001$ (intergroup)	$p < 0.001$ (intergroup)	$p < 0.0001$ (intergroup)
PRP	8.25	2 ($p = 0.0001$)	1.9 ($p = 0.0001$)	1.85 ($p = 0.0001$)
Corticoids	7.7	5.3	6.05	6.25
AOFAS	$p = 0.314$ (intergroup)	$p < 0.0001$ (intergroup)	–	–
PRP	47.05	92.1 ($p < 0.0001$)		
Corticoids	50.85	49.75 ($p = 0.478$)		
Roles & Maudsley (%)				
Excellent				
PRP		8 (40%)	10 (50%)	11 (55%)
Corticoids		0 (0%)	0 (0%)	0 (0%)
Good				
PRP		10 (50%)	8 (40%)	7 (35%)
Corticoids		3 (15%)	0 (0%)	0 (0%)
Acceptable				
PRP		1 (5%)	1 (5%)	1 (5%)
Corticoids		10 (50%)	11 (55%)	8 (40%)
Poor				
PRP		1 (5%)	1 (5%)	1 (5%)
Corticoids		7 (35%)	9 (45%)	12 (60%)

and Maudsley score, at six months and at the final follow up, were taken into consideration (Table 2). A worsening in the clinical results was found in the patients in group B by the end of follow-up. No complications attributable to PRP and corticosteroid injections were observed.

3.2. Imaging results

Ultrasound controls were performed before treatment and three and six months after injection, and MRI was also performed before treatment and six months after the injection. The thickness of the plantar fascia after treatment with PRP (Fig. 1) was reduced to 4.82 mm, with a mean reduction of more than 3 mm. The fascia maintained near-normal measures in the subsequent control ultrasound scans. In the group treated with corticosteroids (Fig. 2) the thickness of the plantar fascia fell to 6.13 mm, although in the biannual control it had risen to 6.9 mm. Likewise, an improvement was found in the rest of the inflammatory changes found in the ultrasound scan associated with the plantar fascia (Table 3). The MRI findings 6 months after treatment, were similar to those obtained with the ultrasound scan, with a better anti-inflammatory response in the PRP group (Table 4).

4. Discussion

Plantar fasciitis (PF) is a painful inflammatory process, generally located at the origin of the plantar fascia on the calcaneus [1,18–22]. Management of chronic plantar fasciitis (CPF) is often difficult and frustrating. Around 80–90% of patients improve to achieve satisfaction within nine months of the onset of symptoms, but nearly 10% of patients are unresponsive to conservative methods.

Numerous treatments have been advocated for the management of CPF [23–26].

When conservative management fails, surgical options must be considered. The techniques available are open plantar fasciotomy and minimally invasive procedures: endoscopic plantar fasciotomy [23], percutaneous cryosurgery [25], radiofrequency nerve ablation [26], ablation therapy with Topaz, etc. Monteagudo et al. [27], in a retrospective study, compared 30 patients who underwent partial proximal fasciotomy with 30 patients who underwent isolated proximal medial gastrocnemius release, this being the second option to show better results. Open surgery has risks and approximately 25% of patients will still experience heel pain after surgery. Excessive release of the plantar fascia may lead to flat-foot complications. Nerve entrapment can occur, as well as pain along the scar [1,28]. Contompasis [29] made a 3-year retrospective study of 126 operations for plantar fasciitis. Plantar fascial release provided satisfactory relief in 36% of cases. A combination of fascial release and spur resection produced complete resolution of pain in 44.3% patients. Pain was improved in a further 45.2% of them, and 10.5% experienced no relief.

The treatment of plantar fasciitis with corticosteroid injections has been widely studied. These have yielded generally efficient results but only in the short term and they indicate the possibility of local complications, like rupture of the plantar fascia [30–32]. However, there are relatively few publications referring to the use of PRP in the treatment of PF. Eppley et al. [33] draws attention to the wide variety of clinical applications that have been reported for PRP, although many reports are anecdotal and few include controls enabling the role to be determined definitively.

Although the benefits of PRP and the means of achieving them are controversial [34–38], it can be a treatment option for many

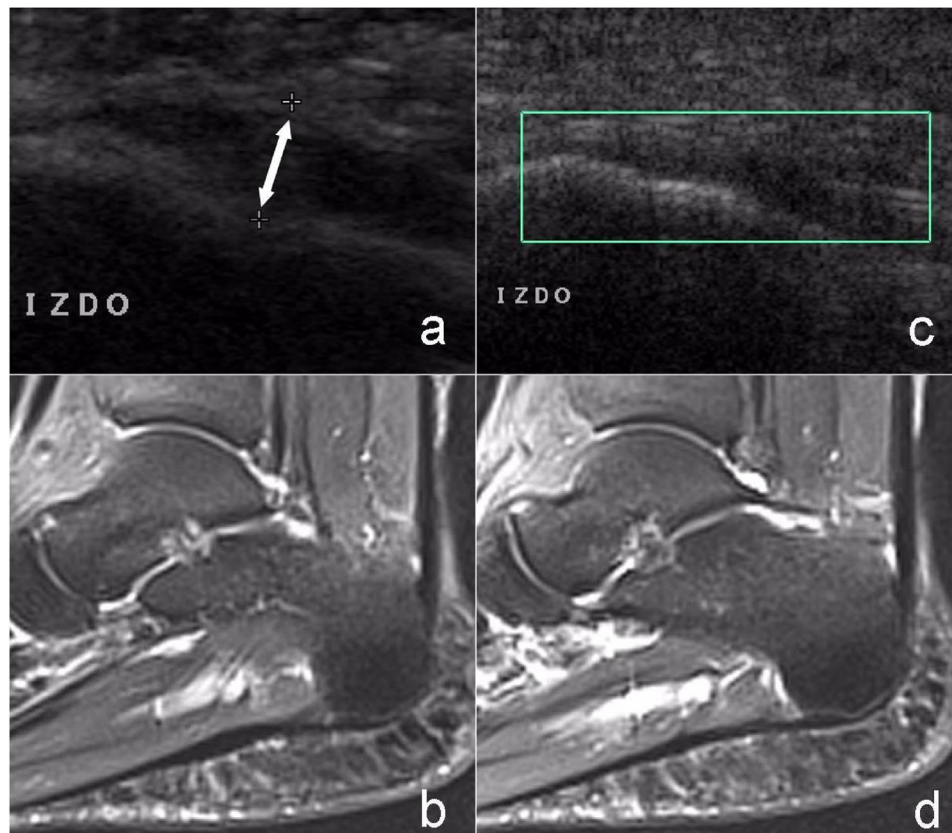


Fig. 1. Case treated with PRP. US sagittal and MRI sagittal BLADE view before treatment (a, b). US control after 3 months (c) and sagittal BLADE MRI after 6 months (d) shows significant fascial narrowing and a less increased signal of perifascial soft tissues.

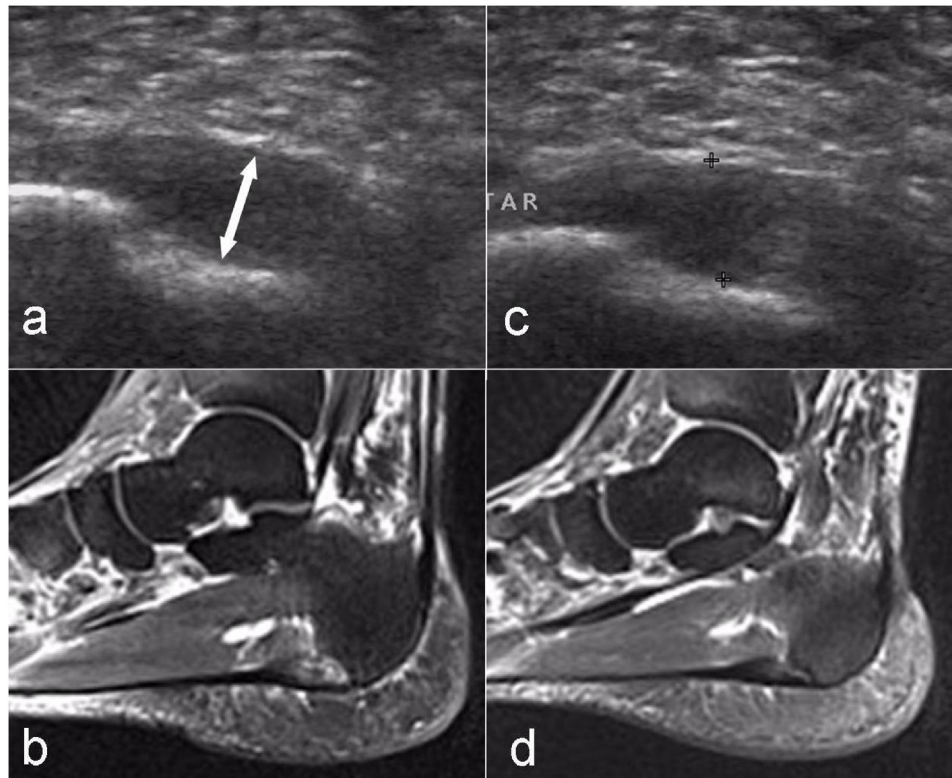


Fig. 2. Case treated with corticosteroids. US sagittal and MRI sagittal BLADE view before treatment (a, b). US control after 3 months (c) and sagittal BLADE MRI after 6 months (d) shows fascia of 6.6 and 9.0 mm thickness, respectively. The bone oedema is also apparent with the MRI scan.

Table 3

Imaging results: US maximum thickness, adjacent soft tissue (ST) echogenicity, collections and tissues hyperemia.

	Group A (PRP) (N = 20)				Group B (corticoids) (N = 20)				Group A vs Group B
	Pre	3 months	6 months	p	Pre	3 months	6 months	p	p
Thickness of fascia (ultrasound)	7.95 (1.67)	4.83 (1.04)	4.82 (0.78)	<0.001	8.05 (1.40)	6.28 (1.52)	6.85 (1.69)	<0.001	<0.001
Echogenicity of fascia, n (%)									
Hypo	20 (100)	4 (20%)	1 (5%)	<0.001	20 (100%)	20 (100%)	17 (85%)	0.050	<0.001
Normal	0 (0%)	16 (80%)	19 (95%)		0 (0%)	0 (0%)	3 (15%)		
ST oedema									
Yes	20 (100%)	1 (5%)	0 (0%)	<0.001	20 (100%)	15 (75%)	17 (85%)	0.042	<0.001
No	0 (0%)	19 (95%)	20 (100%)		0 (0%)	5 (25%)	3 (15%)		
ST collections									
Yes	14 (70%)	1 (5%)	1 (5%)	<0.001	15 (75%)	15 (75%)	15 (75%)	1.000	0.001
No	6 (30%)	19 (95%)	19 (95%)		5 (25%)	5 (25%)	5 (25%)		
Doppler hyperaemia									
Yes	16 (80%)	0 (0%)	0 (0%)	<0.001	17 (85%)	14 (70%)	13 (65%)	0.368	<0.001
No	4 (20%)	20 (100%)	20 (100%)		3 (15%)	6 (30%)	7 (135)		

foot and ankle pathologies, including tendinopathy, ligamentous injury (plantar fasciitis, lateral ankle), augmentation of bone, tendon rupture repair, cartilage injury, sesamoiditis, and chronic wounds [4]. Essentially PRP is used to increase the concentration of platelets to an injured site and to release the bioactive proteins and growth factors to initiate and accelerate tissue repair and regeneration. In chronic injuries that have failed to respond to conservative therapies, the inflammatory phase has ceased, so the application of PRP produces two beneficial results. First, the act of applying PRP through injection stimulates the tissue and restarts the inflammatory process, making the chronic injury an acute injury once again. Second, the addition of autologous concentrations of platelets theoretically augments the healing process [30,36–48].

Barrett and Erredge [44] used ultrasound of the fascia before and after treatment and a patient pain scale to determine the

efficacy of PRP. Nine subjects were weight bearing in a walking boot for 2 days and then in regular footwear with limited activity, and restricted from using anti-inflammatories of other modalities. They found that six of the nine subjects achieved complete resolution of symptoms after 2 months. After 1 year, seven of the subjects had no symptoms. The authors showed that ultrasound measurements of the thickness of the plantar fascia were reduced between pre-injection and post-injection, as we describe in our study. It is unclear how long the patients had their symptoms before treatment.

A prospective randomised study by Lee and Ahmad [45] compared autologous blood injection with corticosteroid injection. Although intralesional autologous blood significantly decreased pain levels and increased tenderness thresholds over the six-month follow-up period, corticosteroid was considered superior in terms of speed and, probably, extent of improvement. The authors

Table 4
MRI measurements before treatment and in the 6 month control in both groups. Maximum thickness, increased signal or inflammation of the soft tissue (ST), calcaneus oedema and perifascial collections were assessed.

	Group A (PRP) (N = 20)			Group B (corticoids) (N = 20)			Group A vs Group B
	Pre	6 months	p	Pre	6 months	p	p
Thickness of fascia (MRI)	7.95 (1.67)	4.82 (0.78)	<0.001	8.05 (1.40)	6.85 (1.69)	0.001	<0.001
MRI signal							
Augmented	20 (100%)	0 (0%)	<0.001	20 (100%)	20 (100%)	–	<0.001
Normal	0 (0%)	20 (100%)		0 (0%)	0 (0%)		
ST MRI							
Augmented	20 (100%)	0 (0%)	<0.001	20 (100%)	20 (100%)	–	<0.001
Normal	0 (0%)	20 (100%)		0 (0%)	0 (0%)		
Bone oedema MRI							
Yes	14 (70%)	3 (15%)	0.001	15 (75%)	14 (70%)	1.000	<0.001
No	6 (30%)	17 (85%)		5 (25%)	6 (30%)		
Perifascial collections							
Yes	14 (70%)	0 (0%)	<0.001	15 (75%)	20 (100%)	0.063	<0.001
No	6 (30%)	20 (100%)		5 (25%)	0 (0%)		

suggested that administration of intralesional autologous blood injection could be used for patients in whom first-line non-invasive treatment fails to decrease pain levels and when corticosteroid injection fails or is contraindicated. Their results were similar to ours, although our longer follow-up period allows us to demonstrate the effectiveness of PRP over time.

Monto [30] states that PRP was more effective and durable than corticosteroids for the treatment of chronic recalcitrant cases of plantar fasciitis in a prospective randomized study of 40 patients, with unilateral chronic plantar fasciitis that did not respond to a minimum of 4 months conservative treatment, treated with either a single ultrasound guided injection of 3 cc PRP or 40 mg DepoMedrol cortisone.

In our study, the clinical results of the PRP injection were better over time than those obtained with corticoids, these results having their consequences for the ultrasound and MRI studies. The thickness of the fascia and all the local inflammatory signs were significantly reduced. However, the study had some limitations. First, it was neither a blinded nor a randomised study. And second, the method of production and the protocol of the injections, which were not standardised and may not have been ideal. In this respect, several systems are commercially available that allow efficient preparation for outpatient use [1,4,44]. Although procedures have a small chance of rejection because the material is produced from the patient's own blood, disagreement persists regarding the optimal quantity of platelets and growth factors required for muscle and tendon healing. For the same reason, it may not be possible to generalise our results to all systems, although we attempted to reproduce the technique of Anitua and Sánchez, which has proved to be effective [14,50,51]. Overall, with a longer follow-up time than most other studies we believe that our study has sufficient validity to accept its results [52–54].

At last, the material used in the group treated with PRP, following Anitua's indications, is less than 35 euros, except for the centrifuge, whose cost is high, but since there is one available in our hospital, the process was not expensive. In the group treated with corticosteroids, the costs are approximately 30 euros, without the need to use a centrifuge.

However, despite our appreciation of the limitations of our investigation, we believe that the results of this study could be useful in the future development of prospective cohort studies and randomized controlled trials that focus on the effectiveness of local infiltrations of PRP in the treatment of chronic plantar fasciitis resistant to conservative treatments.

In conclusion, two injections of PRP in the treatment of chronic plantar fasciitis is a safe and more effective and long-lasting method than that of corticoid injections, producing a significant clinical improvement that endures for at least 33 months, with a

mean reduction of more than 3 mm in the thickness of the plantar fascia as measured by ultrasound and MRI.

Conflict of interest

The authors declare that they have no conflict of interest.

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