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Platelet-Rich Plasma Has Better Long-Term Results Than Corticosteroids or Placebo for Chronic Plantar Fasciitis: Randomized Control Trial

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ABSTRACT

Plantar fasciitis is the most common cause of heel pain. Platelet-rich plasma (PRP) is a supersaturated concentration of autologous platelets that augments the natural healing response of fascia. Previous studies have shown the superiority of PRP over corticosteroids (CS) for chronic plantar fasciitis. The aim of this study was to compare the pain and functional outcomes of PRP with CS and placebo injections for the treatment of chronic plantar fasciitis. We conducted a 3-arm randomized controlled trial of 90 patients: PRP (n = 30 patients), CS (n = 30 patients), and placebo (n = 30 patients). The patients were followed at regular intervals until 18 months postinjection using validated instruments. The mean visual analog scale score showed significant improvement in all groups between baseline and 18-month follow-up (PRP: 8.2 vs 2.1; CS: 8.8 vs 3.6; placebo: 8.1 vs 5.4), with CS showing significantly better improvement than PRP in the short term, whereas longer-term PRP was significantly better than CS. The mean Roles and Maudley score showed significant improvement in all groups between baseline and 18-month follow-up (PRP: 1.7 vs 3.7; CS: 1.2 vs 3.1; placebo: 1.2 vs 2.0), with CS showing significantly better improvement than PRP in the short term, whereas longer-term PRP was significantly better than CS. The mean Short Form 12 score showed significant improvement in all groups between baseline and 18-month follow-up (PRP: 55.4 vs 80.2; CS: 56.2 vs 76.2; placebo: 54.1 vs 62.4). We found that all 3 groups showed significant improvement between baseline and end of the follow-up period with regard to pain, function, and general health. The CS arm showed better improvement in the short term, whereas the PRP arm showed better results in the long term. In contrast to previous studies, we found no significant drop-off effect of CS in the long term, which may be owing to background natural healing process of the disease. In summary, both PRP and CS are safe and effective treatment options for chronic plantar fasciitis, showing superior results to placebo treatment. The longer-term results and less reinjection and/or surgery rate of PRP makes it more attractive as an injection treatment option versus CS injection.

Plantar fasciitis is the most common cause of heel pain. The peak incidence of heel pain occurs between ages 40 and 60 years and particularly is a common problem in older athletes, military recruits, and laborers (1). Individual risk factors include obesity, decreased ankle dorsiflexion, and extensive work-related weightbearing (2,3). It has been estimated that the annual economic burden of disease ranges between $192 and $376 million (1). Although 90% of cases resolve with conservative treatment within a few weeks, there is no general consensus on the best treatment.

Although there is no clear consensus on the primary medical treatment of plantar fasciitis, it generally accepted that traditional treatment is successful in the majority of cases. In general, plantar fasciitis is a self-limiting disease. Conservative treatments, such as stretching, nonsteroidal anti-inflammatory drugs (NSAIDs), physical therapy, and night splints are regarded the mainstays of plantar fasciitis treatment and provide substantial relief to 80% of patients. Despite the ubiquitous use of these techniques, there have been very few randomized trials assessing their efficacy (4–6).

Steroid injection into the plantar fascia is an effective treatment of plantar fasciitis when conservative management is unsuccessful; however, the lack of an inflammatory process histologically in

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plantar fasciitis questions its mode of action. Critical reviews of cortisone injection therapy have yielded equivocal short-term findings and disappointing long-term results (7,8). Potentially disabling complications have also been reported, such as rupture of the plantar fascia. In adults, steroid injection has been associated with rupture of the plantar fascia in 2.4% to 10% (9) of patients, as well as attenuation of the plantar fat pad.

Platelets, otherwise known as thrombocytes, are derived from fragments of their precursor megakaryocytes found in bone marrow (10). Platelet-rich plasma (PRP) is a bioactive component of whole blood with platelet concentrations well above the baseline and containing high levels of various growth factors. The increases in concentration of multiple growth factors in platelets are responsible for the increased healing aspects of various tissues and actions such as cell proliferation, chemotaxis, cell differentiation, and angiogenesis (11). It is postulated that when injected into injured tissue, these platelet nests act as rally points for the modulation of collagen synthesis and tissue-healing—releasing cytokines and chemoattractants (12). Early-term pain relief is hypothesized to be owing to anti-inflammatory activity afforded by inhibition of COX-2 enzymes by the platelet released cytokines, whereas the longer-term effects are owing to augmentation of the natural healing response through cellular proliferation, neoangiogenesis, and increased type 1 collagen production. PRP has been shown to be helpful in treating chronic severe tendinopathies including Achilles tendinosis and has proven more effective and reliable than traditional cortisone injections in the treatment of lateral epicondylitis (12).

There have been a handful of studies examining the role of PRP in chronic plantar fasciitis (Table); all show good long-term results, although the short-term results appear to be better with corticosteroid (CS) injections. Further, CS injections show a definite drop-off effect in these studies after the short term. To our knowledge, there is no study in the Indian population and only 1 study comparing PRP with CS and placebo. The aim of our study was to compare PRP with CS and placebo for the treatment of chronic plantar fasciitis with regard to pain and function.

Patients and Materials

We conducted a 3-arm randomized controlled trial of 90 patients between January 2014 and July 2015. Ethics approval was obtained from the institutional ethics review committee (Padmashree Dr. D.Y. Patil Hospital and Research Centre, Navi Mumbai, India), and written valid informed consent was taken from all patients before participation in the study, for both the research investigation and the treatment. A total of 90 patients were randomized by computer (using GraphPad software for block randomization of patients; the fourth author [S.D.]) into 1 of 3 arms: PRP (n = 30), CS (n = 30), and placebo (n = 30). All patients were recruited from the orthopedic outpatient department at our institution (second author [A.D.]). The inclusion criteria were adults ≥18 years with diagnosis of chronic plantar fasciitis who had failed conservative treatment for ≤3 months. The exclusion criteria were prior injection to the same heel, prolonged (>12 months) history of narcotic dependence, prior surgery, prior history of arthritis, peripheral neuropathy or diabetes, and age <18 years. The PRP was prepared using a standard double centrifugation protocol by the central laboratory of our institute. The PRP group received 2 mL of PRP mixed with 1 mL of 1% lidocaine; the CS group received 2 mL of methylprednisolone acetonide (40 mg/mL) mixed with 1 mL of 1% lidocaine; and the placebo group received 2 mL of 0.9% normal saline mixed with 1 mL of 1% lidocaine. All injections were given by the corresponding author of the study (M.A.), who was blinded to the randomization process conducted by the fourth author (S.D.) under full aseptic precautions to the point of maximal tenderness in the heel using a multiple peppering technique (quadrant-based penetration from the plantar side with equal volume injections into each of the quadrants). All patients were blinded to which injection they were receiving, and a standardized postinjection protocol for all 3 arms was used including a 5-day course of an oral NSAID and analgesic (etoricoxib 60 mg twice daily and paracetamol 500 mg twice daily), with home bed rest for the first 24 hours followed by progressive weightbearing as tolerated and gentle stretching exercises for the plantar fascia and eccentric strengthening of the heel cord. All patients were followed at 1 week, 3 weeks, and 3, 6, 12, and 18 months using a self-developed item set for demographic data and validated tools to assess pain (visual analog scale [VAS]) (13), function (Roles and Maudsley [R&M] score) (14), and general health (Short Form 12 Health Survey [SF-12], Quality Metric Inc., Lincoln, RI) (15) (all follow-ups were done by the second and corresponding authors [A.D. and M.A.]). Statistical analysis (by the lead author [S.H.S.]) of the nonparametric data was done using SPSS version 16 software. We used the Mann-Whitney *U* test, and statistical significance was defined as a $p \leq .05$.

Results

Demographic Data

There were 41 males (45.56%) and 49 females (54.44%) in the study. The mean age at the time of injection of the patients was 44.6 years (range 34 to 58). The mean duration of symptoms was 6.8 months (range 3.5 to 12), and the mean duration of unsuccessful conservative treatment was 4.2 months (range 3.0 to 6.1). There was no statistically significant difference between the subgroups with respect to age, gender, occupation, duration of symptoms, or duration of unsuccessful conservative treatment. All patients completed their follow-up visits, there were no drop-outs from the study, and no participant crossover occurred.

There were 38 right feet (42.22%) and 52 left feet (57.78%). A total of 10% of patients had hypertension, 14% had hyperlipidemia/hypercholesterolemia, and there were 19% alcoholics and 10% smokers. There was no statistically significant difference between the subgroups with respect to any comorbidities.

VAS Data

With respect to the VAS, all groups had significant improvement in scores between preinjection and 18-month follow-up (Fig. 1). There

Table
Summary of data from studies examining the role of platelet-rich plasma in treatment of plantar fasciitis

Study	Year	Groups	Tools	Conclusion
López-Gavito et al (20)	2011	PRP only	AOFAS VAS	Significant improvement in both scores; no complications
Martinelli et al (16)	2013	PRP only	R&M VAS	Significant improvement; no complications
Ragab and Othman (21)	2012	PRP only	VAS	Significant improvement; no complications
Akşahin et al (17)	2012	PRP vs CS	R&M VAS	Both effective; PRP safer
O'Malley et al (22)	2013	PRP only	AOFAS VAS SF-12	Adequate treatment; safe treatment option
Kalaci et al (18)	2009	PRP vs placebo vs CS	R&M VAS	CS better short-term, PRP better long-term, and both better than placebo; multiple peppering technique better than single injection
Kim and Lee (23)	2014	PRP vs CS	Foot Functional Index VAS	Both almost equal; PRP slightly better

Abbreviations: AOFAS, American Foot and Ankle Score; CS, corticosteroid; PRP, platelet-rich plasma; R&M, Roles and Maudsley score; SF-12, Short Form 12; VAS, visual analog scale.

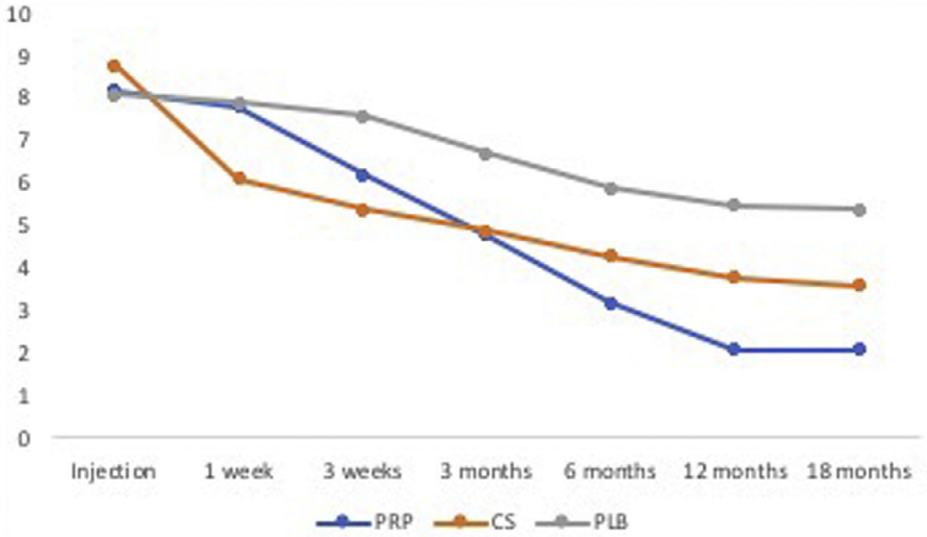

Fig. 1. Line graph depicting mean VAS scores for patients for PRP (n = 30), CS (n = 30), and PLB (n = 30) according to follow-up time. The x-axis denotes the follow-up time period and the y-axis the VAS score range. CS, corticosteroid; PLB, placebo; PRP, platelet-rich plasma; VAS, visual analog scale.

was no statistically significant difference between mean VAS scores for the PRP, CS, and placebo groups preinjection; however, both the PRP and CS groups had a significant improvement in VAS score versus the placebo group at the end of the follow-up period. All groups showed a trend toward improvement in VAS score over time, with CS demonstrating greatest improvement in first 3 weeks (area under the curve) and PRP demonstrating greatest improvement in the 3- to 18-month follow-up period (area under the curve).

There was a statistically significant difference: between the PRP and CS groups at 1 week ($p = .04$), 6 months ($p = .05$), 12 months ($p = .01$), and 18 months ($p = .005$); between the PRP and placebo group at 3 months ($p = .05$), 6 months ($p = .01$), 12 months ($p < .001$), and 18 months ($p < .001$); and between the CS and placebo group at 3 weeks ($p = .02$), 3 months ($p = .05$), 12 months ($p = .05$), and 18 months ($p = .04$). At all other follow-up points, there was no statistically significant difference among the 3 subgroups with respect to the VAS.

R&M Score Data

With respect to the R&M score, all groups had significant improvement in scores between preinjection and 12-month follow-up (Fig. 2). There was no statistically significant difference between mean R&M scores for the PRP, CS, and placebo groups preinjection; however, both the PRP and CS groups had significant improvements in the R&M score versus the placebo group at the end of the follow-up period. All groups showed a trend toward improvement in the R&M score over time, with CS demonstrating the greatest improvement in first 3 weeks (area under the curve) and PRP demonstrating greatest improvement in the 3- to 18-month follow-up period (area under the curve).

There was a statistically significant difference between the PRP and CS group at 3 weeks ($p = .05$), 12 months ($p = .05$), and 18 months ($p = .05$); between the PRP and placebo group at 3 weeks ($p = .04$), 3 months ($p = .004$), 6 months ($p = .01$), 12 months ($p = .01$), and 18 months ($p = .01$); and between the CS and placebo group at 1 week ($p = .05$), 3 weeks ($p = .008$), 3 months ($p = .01$), 6 months ($p = .01$), 12 months ($p = .02$), and 18 months ($p = .02$). At all other follow-up points, there was no statistically significant difference among the 3 subgroups with respect to the R&M score.

SF-12 Health Survey Data

With respect to the SF-12 score, all groups had significant improvement in scores between preinjection and 18-month follow-up (Fig. 3). There was no statistically significant difference between mean SF-12 scores for the PRP, CS, and placebo groups preinjection; however, both the PRP and CS groups had a significant improvement in SF-12 score versus the placebo group at the end of the follow-up period. All groups showed a trend toward improvement in SF-12 score over time, with CS demonstrating more but not statistically significant improvement in first 3 weeks (area under the curve) and PRP demonstrating more but not statistically significant improvement in the 3- to 18-month follow-up period (area under the curve).

There was a statistically significant difference: between the PRP and CS group at 3 weeks ($p = .05$); between the PRP and placebo groups at 3 weeks ($p = .05$), 3 months ($p = .02$), 6 months ($p = .008$), 12 months ($p = .003$), and 18 months ($p = .002$); and between the CS and placebo group at 1 week ($p = .05$), 3 weeks ($p = .03$), 3 months ($p = .04$), 6 months ($p = .03$), 12 months ($p = .01$), and 18 months ($p = .01$). At all other follow-up points, there was no statistically significant difference among the 3 subgroups with respect to the SF-12 score.

Complications

No patients in any of the 3 arms suffered any complication (local or systemic) through the end of their follow-up. There was no crossover allowed in our study; however, 19 of the 30 patients (63%) in the placebo group had a CS or PRP injection at the completion of the study (≥18 months after the initial injection), 7 of the CS group (23%) and 5 of the PRP group (17%) required a repeat injection (≥18 months after the initial injection), and 3 of the CS group (10%) and 1 of the PRP group (3%) opted for surgery at the end of the study (≥18 months after the initial injection).

Discussion

The search for a uniformly successful treatment for plantar fasciitis remains an enigma. Although the majority of cases are self-limited, a consensus has yet to be reached on a reliable universal comprehensive

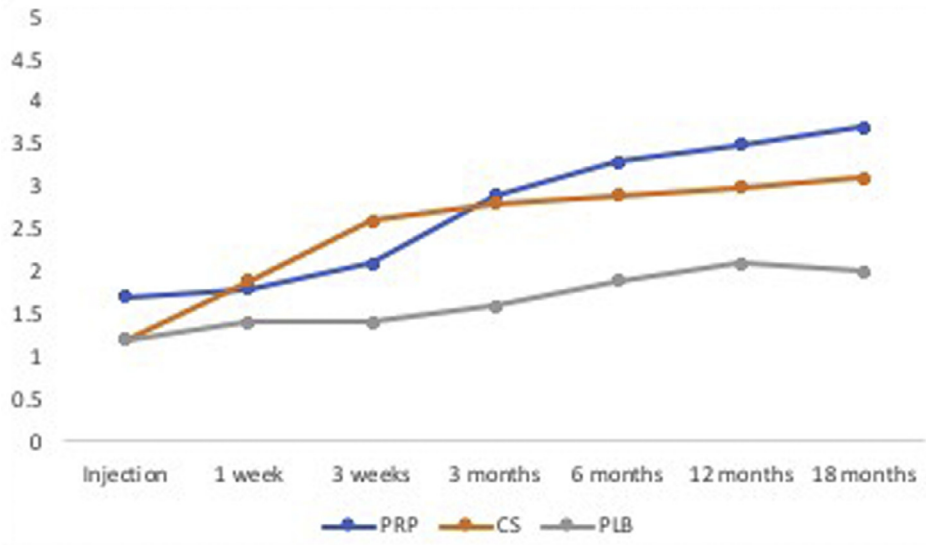

Fig. 2. Line graph depicting mean R&M scores for patients for PRP (n = 30), CS (n = 30), and PLB (n = 30) according to follow-up time. The x-axis denotes the follow-up time period and the y-axis the R&M score range. CS, corticosteroid; PLB, placebo; PRP, platelet-rich plasma; R&M, Roles and Maudley.

treatment strategy. Accordingly, most surgeons use various treatment regimens without a solid base of evidence. Despite myriad available treatments, there is a 10% failure rate. The introduction of PRP into the treatment paradigm as a modulator of angiogenesis and anabolic effects theoretically addresses the underlying pathophysiology of collagen matrix degeneration, angiofibroblastic hyperplasia, and intense vascularity seen in plantar fasciitis.

Our study of 90 patients, comparing 3 arms of PRP, CS, and placebo for chronic plantar fasciitis, is the second study worldwide to compare all 3 arms and the first Indian study to assess PRP as an injection treatment modality for chronic plantar fasciitis. We found no difference among the 3 arms with respect to age, gender, duration of symptoms, and duration of unsuccessful conservative treatment, which signifies that these factors were no confounding variables significant enough to create bias between the groups.

With respect to pain and function, we found that both PRP and CS significantly improved the VAS and R&M score versus placebo treatment in the short (<1 month) and long term (6 to 18 months). Additionally, CS has better pain relief and improved function in the short term (within the first month) versus PRP; however, PRP has better pain relief and improved function in the long term (at 6, 12, and 18 months) versus the CS group. Based on this, pain relief and improved function for both PRP and CS for chronic plantar fasciitis is better than for placebo, with CS offering better shorter-term pain relief and improved function for the first month, whereas PRP offers better longer-term pain relief and improved function at 6 to 18 months postinjection. These

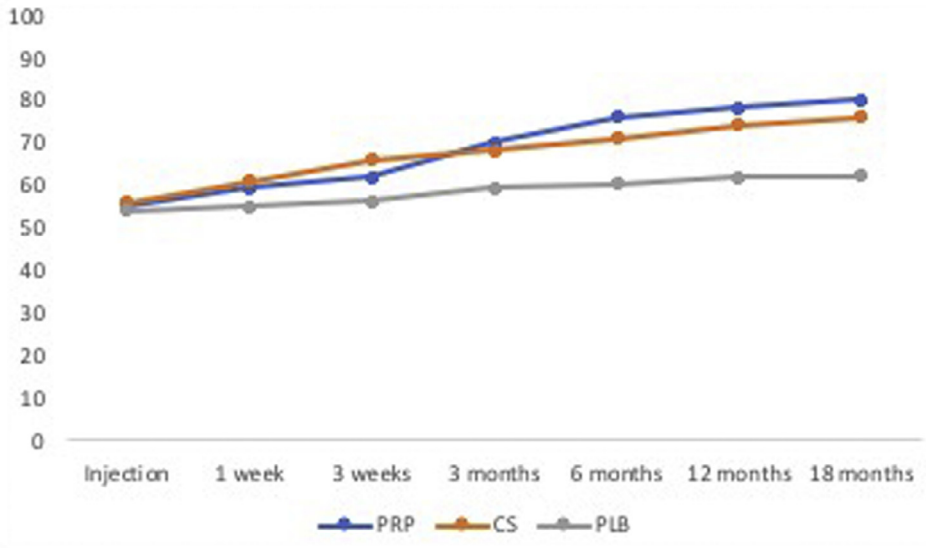

Fig. 3. Line graph depicting mean SF-12 scores for patients for PRP (n = 30), CS (n = 30), and PLB (n = 30) according to follow-up time. The x-axis denotes the follow-up time period and the y-axis the SF-12 score range. CS, corticosteroid; PLB, placebo; PRP, platelet-rich plasma; SF-12, Short Form 12; VAS, visual analog scale.

findings have been supported by previous studies (16–18); however, in contrast to them, we also found that the much-touted drop-off effect of CS (7,8) after the first month of treatment is not seen; they consistently offer better pain relief and improved function than placebo, albeit less so than PRP. The improvement in the placebo group over the study period is explained by the self-limiting nature of the disease process.

With respect to general health, both PRP and CS improved the SF-12 score versus placebo treatment in the short and long term. Additionally, CS were better than PRP for the first month, but thereafter there were no differences between these 2 subgroups. Our findings are consistent with previous studies that found general health improvement with either PRP or CS (16,19), a subjective assessment of patient well-being. Thus, general health improvement is achieved faster with CS, but either PRP- or CS-receiving patients have better general health than placebo patients.

With respect to complications, we found no serious ones (local or systemic) in our study with either CS or PRP. Repeat injections were required for 1.4 more patients in the CS group than in the PRP group; however, with both groups combined, the reinjection rate was 20%, meaning that roughly 2 in 10 patients require a repeat injection with either CS or PRP. Almost triple the number of patients in the CS group went on to have plantar release surgery; the rate of surgery postinjection of either PRP of CS was 7%.

One of the limitations of our study was the self-bias of measuring our own results and the institutional bias of producing PRP; that said, blinding was done at as many levels as possible to reduce the bias. Further, the use of a standard regimen of 5 days of oral NSAID therapy may affect outcome; however, because this along with lidocaine was used in all 3 arms, including the placebo arm, the effect is negated. An interesting avenue of further pharmacological research would be in vitro studies of the effect of steroid and PRP mixture on tendon healing before any attempt at clinical trial. The combination of the short-term effect of asteroid with the long-term effect of PRP is certainly interesting; however, its pharmacological viability is yet to be elucidated.

In our prospective comparative study of 90 patients of chronic plantar fasciitis treated with either PRP, CS, or placebo injection, our results showed that both CS and PRP are superior to placebo in the short and long term with respect to pain and function and general health. CS appeared better in the short term; however, results were less superior than PRP in the long term. Additionally, we found no significant drop-off effect of CS in the long term. Further, we found that the complication rate in both groups was negligible; however, more patients on CS require either repeat injection or plantar release surgery compared with PRP.

In conclusion, both PRP and CS are safe and effective treatment options for chronic plantar fasciitis. The longer-term results and lower reinjection and/or surgery rate of PRP make it more attractive as an injection treatment option versus CS injection.

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