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Regenerative efficacy of therapeutic quality platelet-rich plasma injections versus phonophoresis with kinesiotaping for the treatment of chronic plantar fasciitis: A prospective randomized pilot study

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Abstract:

BACKGROUND: Plantar fasciitis (PF) a common chronic musculoskeletal pain routinely diagnosed and treated in rehabilitation practices. When conservative management fails in this degenerative disease, local injections of corticosteroids, platelet rich plasma (PRP), botulinum toxin, extracorporeal shockwave therapy, surgical release are used. In our prospective randomized pilot study we compared the regenerative efficacy of Platelet Rich Plasma vs Kinesiotaping with phonophoresis who were resistant to conservative management of PF.

MATERIALS AND METHODS: Sixty-four chronic plantar fasciitis patients nonresponding to conservative management were evaluated for two interventions.36 patients received ultrasound guided 2.5 ml autologous platelet rich plasma (PRP) injection and 28 participant received phonophoresis and total10 Kinesiotaping on alternate days. 54 participants 33 in PRP intervention group and 21 in KT group were analyzed, by Numerical Rating Scale (NRS), plantar fascia thickness (ultrasound guided) and disability and activity limitation measured by foot function index in every two weeks up to 6 months.

RESULTS: Post intervention assessment at 2 weeks revealed improvement in pain relief was better in Kinesiotaping group (NRS-4.619) as compared to PRP group (NRS- 6.061). But evaluation at 12 and 24 weeks showed statistically significant improvement in NRS and Foot function index in PRP group than in Kinesiotaping. Similarly, at the end of 24-week improvement in foot function index (FFI) was more in PRP group ($P<0.0001$). At end of 12 and 24 weeks there was significant reduction in plantar fascia thickness in PRP group ($p<0.0001$) as compared to KT group ($p<0.05$).

CONCLUSION: Our study concluded that therapeutic quality autologous PRP injection ($1x10^6$ platelets/μl) has regenerative effect with long and better efficacy in pain management of chronic recalcitrant plantar fasciitis than Phonophoresis and Kinesiotaping.

Keywords:
Autologous platelet-rich plasma, chronic plantar fasciitis, kinesiotaping, phonophoresis

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Introduction

Plantar fasciitis (PF) or plantar heel pain is one of the common chronic musculoskeletal conditions due to overuse injury of plantar fascia routinely diagnosed and treated in rehabilitation practices. It is estimated that approximately 1 in 10 people with predominance of middle-aged

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obese female and young male athlete will develop PF during their lifetime.[1] Increased body mass index (BMI), calcaneal spur, pes planus, pes cavus, deficits in flexibility of the plantar flexors (reduced ankle dorsiflexion), weak intrinsic foot muscles, excessive pronation, and improper footwear are identified risk factors for the development of PF. There is also a weak association of PF with increasing age prolonged standing and decreased first metatarsophalangeal joint extension.[2-5]

The current literature has confirmed its degenerative rather than inflammatory pathology and coined the term plantar fasciosis instead of PF because of the histological evidence of chronic inflammatory changes without fibroblastic proliferation suggestive of degenerative changes. The diagnosis of PF is exclusively based on clinical history and physical examination;[6,7] it usually presents with severe sharp early morning first step inferior heel pain that improves with movements but aggravated by weight-bearing activities. PF is usually unilateral, but up to 30% of cases may have bilateral presentation. On physical examination, patients have local tenderness at medial calcaneal tuberosity, plantar flexors tightness, increased discomfort with passive dorsiflexion of great toe or standing on the tip of toe.[8-12] In majority, it is a self-limiting disease, but for frustrating pain, several conservative treatment options are available which include nonsteroidal anti-inflammatory drugs (NSAIDs), soft heel cups, eccentric plantar fascia stretching exercises, night splints, and orthotics to relieve pain. In patients who develop chronic intractable PF not responding to conservative means, local injections of corticosteroid (most favored), platelet-rich plasma (PRP) injection, botulinum toxin injection, and extracorporeal shockwave therapy are other nonsurgical means of treatment. Few clinical trials disputed the role of local corticosteroid injections because of its potential complications and high rate of relapse. Surgical options are rarely used nowadays.[13-19] PRP which contains a natural higher concentrate of various autologous growth factors thought to stimulate regeneration of tissue with low healing potential. Local injection of PRP is an emerging modality which has recently been used worldwide for the treatment of recalcitrant tendon and ligament pathologies as well as PF.[20,21]

Phonophoresis is the therapeutic ultrasound (USG) in which high-frequency mechanical wave causes vibration. This vibration cause the production of deep heat. This energy causes the production of deep heat, increased local blood flow, pain relief, and fibrosis termination. Mechanism of action of kinesiotaping is it controls or minimizes the pulling force of tendon or ligament which helps to minimize further injury so that the tissue repair can be facilitated. It is being widely used in patients with PF and showed pain relief with a better effect as compared to those treated with only a traditional physiotherapy program.[22]

Objective of our prospective randomized pilot study was to compare the clinical efficacy of PRP versus phonophoresis with kinesiotaping in chronic PF patients who are resistant to conservative management. Outcome was measured in terms of pain relief and improvement in disability and activity limitation (functional foot index).

Materials and Methods

This prospective randomized study was conducted in the Department of Physical Medicine and Rehabilitation (PMR) in collaboration with Department of Transfusion Medicine and Blood Bank and Radiology Department in a tertiary care teaching and research hospital from March 2016 to February 2017. Institutional research ethics committee approved the study protocol and study was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all the participants of the study.

The inclusion criteria of patients were (i) age between 18 and 75 years and heel pain was consistent with a diagnosis of PF and (ii) chronic recalcitrant PF for more than 3 months with failed conservative management.

Patients with heel pain were excluded from the study if they (i) had a history of arthritis, foot infection, bleeding disorders, and diabetes, (ii) if patient refused to come for follow-up visits, and (iii) had received recently corticosteroids, acetylsalicylic acid, or steroidal anti-inflammatory drugs and new orthotics.

In our study, we had screened 79 patients out of which 64 were enrolled for intervention. All of them were nonresponding cases of conservative management of PF. Participants were randomly allocated into two treatment arms by computer-generated simple random charts. They were randomly divided in two groups, PRP-group had 36 patients (24 females and12 males) assigned to receive two USG-guided PRP injection in 2 weeks' gap and KT-group had 28 patients (17 females and11 males) who gave consent for phonophoresis and total 10 kinesiotaping at gastrocnemius and plantar fascia muscle on alternate days.

Platelet-rich plasma preparation technique

For preparation of PRP, double spin method was selected and standardized and validated in 10 normal individuals in our transfusion medicine blood component laboratory. In PRP group patients, 8.5 ml venous blood sample was collected in a 10 ml ACD-A tubes (BD Vacutainer

REF 364606). After 20 min of resting period, sample was centrifuged first spin at 1500 rpm (200 rcf) for 12 min in a standard table top laboratory centrifuge Remi R-8C. After first soft spin, we had three layers, one half bottom layer of packed red blood cells, thin layer of buffy coat, and upper cloudy layer of plasma and platelets. The upper cloudy layer was gently transferred in a plain sterile BD tube from sterile micropipette inside a laminar flow hood. Then, plain tube containing 5 ml of plasma and platelets was again centrifuged in Eppendorf centrifuge (model 5702) at 3900 rpm (240 rcf) for 15 min. After second spin, the upper half of clear supernatants was transferred in separate tube gently and small pellets of platelets are suspended in a remaining amount of plasma. Final volume of 2.5 ml of concentrated PRP was obtained from each tube. The final product was left on platelet shaker for 1 h so that platelet microaggregates evenly dispersed in plasma at the time of issue. For the quality check of final product, complete blood count of whole blood and final PRP product was done on Sysmex XN-550 before issue. For sterility check of the product, 1 ml sample from supernatant was sent to microbiology laboratory for culture. We had followed the same technique in all cases, and the results were found reproducible. The platelet yield by this method ranges between 4.2 and 5.1 times of the baseline, and the platelet concentration ranges 1.08×10^6–1.3×10^6 platelets/μL. None of the culture report came positive. The white blood cell count in final product ranges from 0.2×10^3 to 0.8×10^3/mm^3. The shelf life of the product was 4 h from the time of collection.

Intervention 1: Platelet-rich plasma injection

PRP injection was executed by same PMR consultant in all patients, under fully aseptic conditions. The patient was placed in a prone comfortable position with his or her ankle in a neutral position, and linear array transducer (5–12 MHz) was kept longitudinal to his foot to measure proximal fascia thickness. USG-guided posterior tibial nerve block was given, with 2% lidocaine hydrochloride to minimize pain during PRP injection. Injections were made by 22-gauge 1½" needle, by palpating maximum tender point and plantar fascia enthesis was approached. 2.5 ml of PRP was injected near maximum fascial thickness using peppering technique (single skin entry with multiple penetrations of fascia) as given in previous studies.[23] Hemostat achieved with compression dressing and patient was monitored for next 2 h for any complications. Postinjection, patients were instructed to avoid long-distance walking, running, and high impact activity for 2 weeks. Patients were instructed to do gastro soleus and plantar fascia stretching exercise (3–4 times/day) and wearing of soft comfortable shoes. No NSAIDs, orthoses, and night splints were prescribed during follow-up period. The second injection of PRP was given after 2 weeks unlike 4 weeks as described in studies by Martinelli *et al*.[24] and O'Malley *et al*.,[25] they suggested minimum of two injections should be given. Postprocedure instructions were same as given after first injection.

Intervention 2: Phonophoresis and kinesiotaping

In this group of patients, we had used therapeutic USG (high-frequency mechanical waves) along with kinesiotaping. Phonophoresis was done by US (Chattanooga intelect mobile combo unit model-2778) with following parameters of continuous mode base frequency of 1 MHz, power 2 w/Cm^2 applied for 3 min after topical application of Voltaren gel (Diclofenac topical) on each region (calcaneus medial tuberosity and 2 cm distal to tuberosity), which was followed by the Kinesiotaping (Mueller Kinesiology) from 100% cotton, latex free, breathable elastic and flexible tape of 5 cm width and 0.5 mm thickness on gastrocnemius and planter fascia by same physiotherapist on alternate days. A total ten episodes were repeated in 20 days.

Taping of gastrocnemius

Patients were placed in a prone comfortable position with knee in extended and ankle (feet) in neutral position on the edge of the table. Two reference points for medial and lateral head of gastrocnemius muscle and for Achilles tendon at medial (MM) and lateral malleoli level were marked on posterior aspect of leg. "Y-shaped" tape was applied to the gastrocnemius muscle in the affected side[22] as shown in Figure 1.

Taping of plantar fascia

Similarly, for plantar fascia, patient in a prone position placed the knee at 90° of flexion and the ankle joints at a neutral position. The one reference point on the posterior margin of the calcaneal bone and four points on metatarsal joints of 1st–5th toes except 3rd were marked, and "palm shape" tape was applied to the plantar fascia as described by Tsai *et al*.[22] as shown in Figure 2.

Outcome assessment

The outcome analysis was done by a blinded observer, a senior resident in PMR Department. In both interventional Group 1 and 2, pain severity was assessed

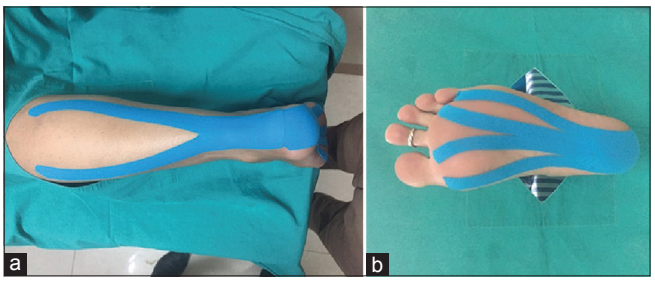

Figure 1: (a) Y-shaped kinesiotaping applied on the gastrocnemius muscle. (b) Palm shape kinesiotaping applied on planter fascia

by Numerical Rating Scale (NRS)[26] at 0, 2, 6, 12, and 24 weeks. Similarly, participant's disability and activity limitation were measured by foot function index (FFI),[27] and USG-guided proximal plantar fascia thickness at calcaneal attachment was also measured at 0, 6, 12, and 24 weeks. The primary end point was defined in our study as NRS score, FFI, and plantar fascia thickness at the end of 6 months of follow-up. Our hypothesis was that PRP has regenerative potential and it would be more helpful in the treatment of chronic recalcitrant PF than kinesiotaping with phonophoresis.

Statistical analysis

Results were calculated as mean and standard error of mean with *P* value. Statistical significance was calculated by one-way nonparametric analysis of variance ANOVA followed by the Tukey's *post hoc* multiple comparison tests to compare with baseline values of three end point measures: NRS score, FFI, and USG-guided proximal plantar fascia thickness within groups. $P < 0.05$ was considered statistically significant. Statistical analysis was performed using Prism 5.00 software (Graph Pad Software Inc., San Diego, California, USA).

Results

A total of 79 participants screened for eligibility out of which 64 were qualified according to our set inclusion and exclusion criteria. Thirty-six enrolled in PRP and 28 were given consent for kinesiotaping and phonophoresis intervention. At the end of study, we analyzed data of 54 participants: 33 in PRP intervention group and 21 in KT group because they had completed our structured follow-up program for 24 weeks. Three patients from intervention 1 group and 7 patients of intervention 2 group were either had withdrawn their consent to participate in the middle of study or lost to follow-up. Baseline characteristic of patients in two intervention groups is summarized in Table 1. The mean age, sex, and BMI of patients in PRP group and KT group was 47.5 and 46.3 years, 64% females and 62% females, and 30.9 kg/m^2 and 31.5 kg/m^2. Mean NRS score, FFI, and plantar fascia thickness in PRP group were 8.030, 114.7, and 5.042 mm, respectively, whereas in KT group, it was 7.571, 108.6, and 4.810 mm, respectively. There were no statistically significant differences at the time of recruitment of patients in two groups. After 2 weeks of intervention, evaluation of NRS score in both groups showed significant improvement in pain relief but the KT group (4.619 ± 0.3344, $P < 0.0001$) showed greater improvement in pain relief than PRP group (6.061 ± 0.1843, $P < 0.0001$). Again at the end of 6 weeks, pain decreased significantly in PRP group ($P < 0.001$) compared to KT group ($P < 0.01$). The PRP group continued to show greater improvement in pain relief throughout the study duration, i.e., 24 weeks whereas KT group showed no improvement in pain relief beyond 12 weeks.

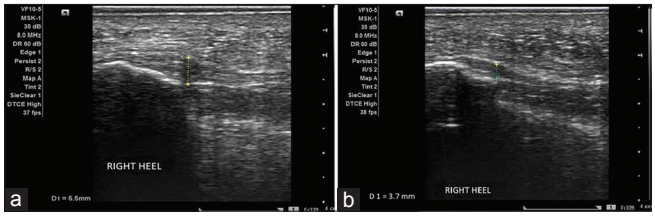

Figure 2: (a) Preplatelet-rich plasma injection ultrasound-guided right heel plantar fascia thickness (5.5 mm). (b) Postplatelet-rich plasma injection ultrasound-guided right heel plantar fascia thickness (3.7 mm)

Table 1: Baseline values of two intervention groups

Variables	PRP group (*n*=33)	KT group (*n*=21)
Age (years)	47.5 (9.31)	46.3 (7.16)
Male	12	8
Female	21	13
Right foot	20	15
Left foot	13	6
BMI (kg/m^2)	30.9 (3.90)	31.5 (3.7)
Duration of symptoms (months)	5 (3.1)	5 (3.3)
Pain score NRS at base line	8.030 (0.1713)	7.571 (0.2447)
FFI at base line	114.7 (2.4590)	108.6 (3.658)
Plantar fascia thickness (mm) at base line	5.042 (0.0979)	4.810 (0.149)

FFI=Foot function index, NRS=Numerical Rating Scale , PRP=Platelet-rich plasma, BMI=Body mass index

Similarly, FFI was evaluated at 6 weeks after PRP injection and phonophoresis with kinesiotaping and results of respective groups showed statistically significant improvement in PRP group as compared to KT group. At the end of 12-week, improvement in foot function and disability was more in PRP group ($P < 0.0001$) while there was no statistically significant improvement in KT group. The PRP group continued to show greater improvement in foot function and disability (FFI index) throughout the 24-week follow-up duration of trial. In USG evaluation of plantar fascia thickness in PRP and KT group mean, values were 5.042 and 4.810 mm preprocedure, respectively. At the end of 6 weeks, there was no significant reduction in both groups. At the end of 12 weeks, PRP group showed significant reduction in plantar fascia thickness ($P < 0.001$) as compared to KT group [Figure 2a and b]. At the end of 24 weeks, PRP group continued to show greater reduction in plantar fascia thickness ($P < 0.0001$), whereas reduction in KT group was statistically insignificant. Table 2 summarizes the results.

Discussion

There is no standard of care management for chronic recalcitrant PF which is nonresponsive to conservative

Table 2: Mean standard error values of numerical rating score, foot function index, and plantar fascia thickness of two groups

Outcome measures	PRP group					Tapping group				
	Pretreatment	2 weeks	6 weeks	12 weeks	24 weeks	Pretreatment	2 weeks	6 weeks	12 weeks	24 weeks
NRS	8.030±0.1713	6.061±0.1843***	4.030±0.1475***	2.394±0.1226***	2.000±0.1306***	7.571±0.2447	4.619±0.3344***	6.333±0.2702*	7.222±0.2365	7.722±0.1948
FFI	114.7±2.459	Not followed up	71.70±3.317***	53.27±2.383 ***	39.94±1.769***	108.6±3.658	Not followed up	94.19±3.438*	98.00±3.086	101.1±3.313
Plantar fascia thickness	5.042±0.09790	Not followed up	4.906±0.09711	4.482±0.09832**	4.226±0.08583***	4.810±0.1496	Not followed up	4.738±0.1556	4.531±0.09297	4.519±0.09047

*$P<0.5$, **$P<0.01$, ***$P<0.0001$. FFI=Foot function index, NRS=Numerical Rating Score, PRP=Platelet-rich plasma

treatment. Many researchers believe, since PF is a degenerative disease, regenerative potential of PRP could help. Our study was a single-blind prospective randomized clinical trial to compare the efficacy of autologous PRP and phonophoresis with kinesiotaping in recalcitrant chronic PF. We followed the patients for 6 months after intervention and improvement in pain scoring; FFI and plantar fascia thickness at the end of 6 months was our primary end point. We found that both PRP and phonophoresis with kinesiotaping can give early relief in pain and improve disability but the effect of PRP injection is more persistent whereas the effect of KT is transitory. Earlier observational studies and few randomized clinical trials concluded that PRP is an effective therapy in chronic cases but still there is controversy due to lack of Level 1 evidence. Kumar *et al*.,[28] Wilson *et al*.,[29] Martinelli *et al*.,[24] and Ragab and Othman[30] strongly favors the use of PRP in chronic PF but these were an observational study with few number of patients and no control group. First time, Akşahin *et al*.[19] compared PRP injection with corticosteroids prospectively in 60 chronic PF; they concluded that PRP is as effective as corticosteroid injection but they followed patients only for 6 months. After this, Monto[21] in his single-blinded, prospective, randomized, longitudinal case series of 40 patients concluded that PRP injection is more efficacious and long lasting than cortisone injection in the long-term management of severe chronic PF. One trial by Shetty *et al*.[31] also compared PRP with cortisone but they found no difference in the two. The drawback of this study is short follow-up of only 3 months. Peerbooms *et al*.[32] designed a multicenter randomized controlled trial but the results were not published. The most recent study by Mahindra *et al*.[33] found that PRP and cortisone are better than placebo, but at 3 months of follow-up, PRP injection was significantly better than corticosteroid injection. In our study, we had not used any expensive automated system with costly disposable kits. From simple laboratory centrifuge, we had prepared therapeutic quality pure PRP (P-PRP), i.e., 4–5-fold increase in baseline platelet values as recommended for PRP injections and poor leukocyte contamination because therapeutic benefit depends on concentration of growth factors which is directly related to platelet counts in each dose. Our product was P-PRP as described in study of Dohan Ehrenfest *et al*.[34] Majority of previous studies used single PRP injection, but in the current study, two injections of PRP 2 weeks apart showed improvement throughout 24 weeks. No other study before ours has compared PRP with kinesiotaping; our results clearly indicates that in chronic cases, it is better to pick PRP injections therapy rather than steroids or any other conservative means because it has no complications or any other conservative means. USG-guided and peppering technique is advocated in previous studies

and we also used the same and found good results in our study. An important issue in PRP therapy is that there are no clearly defined indications. When, how, and how much are not yet answered. Researchers used different protocols and gave variable results. It is now mandatory that quality control of PRP for regenerative medicine should be clearly defined by regulatory bodies in blood banking. Our study can add some evidence in the existing literature of evidence-based medicine. The major limitations of our study were small sample size which increases the risk of type 2 error, short-term follow–up, and it was a single-blinded study.

Conclusion

This study concluded that autologous PRP injection of high platelet counts is more efficacious as compared to phonophoresis with kinesiotaping which gives temporary benefit in PF. Effects of PRP are long lasting and no adverse effects were reported. Physicians should consider well-standardized therapeutic quality PRP injections early in their management protocol of chronic PF rather than other conservative means and compromising the quality of life of patients. Therapeutic quality PRP can be prepared in simple laboratory centrifuge without investing in costly equipment and consumables. Double-blind randomized clinical trial of large sample size is seriously required to generate Level 1 evidence.

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Conflicts of interest
There are no conflicts of interest.

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