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Comparative Study of Platelet-Rich Plasma and Steroid Injection for the Treatment of Plantar Fascitis

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Abstract: ***Background: Plantar fascitis (PF) is the most common cause of heel pain. Platelet-rich plasma (PRP) has been recently used as an alternative therapy for plantar fasciitis (PF) to reduce heel pain and improve functional restoration. The aim of this study was to compare the short term results of platelet-rich plasma (PRP) and steroid injections in patients diagnosed with chronic plantar fasciitis. Materials & Methods: In this study, 50 patients with unilateral chronic plantar fasciitis were randomized into two groups, the PRP group(n=25), and the steroid group(n=25) by selecting a sealed envelope. In the PRP group (n=25), PRP taken from the patients blood was activated using calcium chloride and injected in a single dose. In the steroid group (n=25), a single dose methylprednisolone with local anesthetic injection was given. Patients who had been diagnosed with plantar fasciitis, monitored for a minimum of 3 months and showed no benefit from conservative treatment starting with stretching exercises and NSAIDs were included in the study. The patients were followed regularly, initially at two week intervals till 6weeks and then at 3, 6, and 12 months after the procedure. Pain intensity and functional outcomes were measured using Visual Analogue Scale (VAS), Ankle-Hind foot Scale (AHFS), and Roles-Maudsley Subjective Pain Scale (RMSPS). Results: Both groups were similar in terms of age, gender, side and baseline VAS & AHFS scores. In both the groups, mean VAS scores and the mean AHFS scores improved significantly at the end of one year over the baseline values. Similarly, in both the groups, functional status improved significantly over a period of one year with 70% patients in the steroid group and 94% in the PRP group achieving excellent functional status. The PRP group had significantly higher mean VAS, AHFS and RMSPS scores at 1 year follow-up than the steroid group (p<0.001). Conclusion: We conclude that local infiltration of platelet rich plasma is safe, convenient, superior and more effective treatment compared to local infiltration of steroids in chronic plantar fasciitis.***

Keywords: Plantar fasciitis; Platelet Rich Plasma; Steroid; Unilateral; Chronic

1. Introduction

Plantar fasciitis is an inflammation of the plantar fascia at the bottom of foot which is most common cause of plantar heel pain. Pain is intensified by prolonged weight bearing, obesity, and gradually increased activity [1, 2, 3]. PF can occurs at all ages, the highest risk of occurrence of PF is 40 to 60 years of age, with no significant sex bias [4, 5]. Although, thought of as an inflammatory process, plantar fasciitis is a disorder of degenerative changes in the fascia, and may be more accurately termed as Plantar Fasciosis [6] .Pain is generally localized in the medial calcaneal tubercle. In the acute phase, the pain is sharp and typically on the first step of the day or after a period of rest. In the chronic phase, pain is continuous and of a duller nature. The inflammation is never acute and in chronic cases, in fact, there is a loss of inflammatory response and a scar formation. A heel spur is a calcium deposit that is a growth of bone which can develop on the bottom of the heel bone where the muscles of the foot connect to the bone. One out of 10 people has heel spurs, but only 1 out of 20 people (5%) with heel spur has foot pain [7,8]. The diagnosis of PF is mainly based on the patient's history and clinical examination and further investigation is rarely needed. Treatment options include rest, NSAIDs, night splints, foot orthosis, stretching protocols, corticosteriod injection ESWT (Extra Corporeal Shock Wave Therapy and even surgical treatment [9,10,11].Most cases of plantar fasciitis resolve with time and conservative methods of treatment .Usually for the first few weeks people are advised to rest, change their activities, take pain medications, and stretch. If this is not sufficient, physiotherapy, orthotics, splinting, or steroid injections may be the options. However, patient may require multiple steriod injections, which may be associated with potential complications, including plantar fascia rupture and fat pad atrophy [12, 13].PRP applied to the wound area accelerates the physiological healing process, provides support for the connection of cells, reduces pain and has antinflammatory and antibacterial effects. A local injection of platelet rich plasma (PRP) is an emerging therapy for ligament pathologies and recalcitrant tendons, including PF. PRP is prepared from autologous whole blood that contains an increased concentration of autologous platelets. Degranulation of the alpha granules in platelets releases many different growth factors which initiate body's natural healing response.

2. Materials & Method

A total of 50 patients with unilateral chronic plantar fasciitis who presented to us at Bone and Joint Hospital Srinagar Kashmir, between April 2015 and May 2016 were enrolled in this randomized controlled comparative study. An informed consent was taken from each case to participate in the study. All patients had plantar fasciitis for more than 6 months. All patients had undergone at least 3 months of conservative treatment, including ice packs, plantar fascia stretching exercises, footwear modification like micro-cellular rubber sandals and shoes, silicone insoles, silicone heel-cups, and ultrasound therapy to the heel and night splints. Despite the conservative treatment, all patients had inadequate pain relief or functional outcome and were still experiencing severe pain or limitation of activity. Diagnosis was mainly on clinical grounds i.e. on palpation there was

mild to severe tenderness on medial calcaneal tubercle and sometimes on lateral aspect of heel. Radiographs were examined to rule out other heel pathologies.

Exclusion criteria included age less than 18 years, bilateral cases, patients with history of corticosteroid injection in last 3 months; generalised inflammatory arthritis, including ankylosing spondylitis; Reiter syndrome, rheumatoid arthritis or psoriatic arthritis; any wound or skin lesion at the plantar aspect of the foot, pregnancy, diabeties mellitus, severe infection, known malignancy, bleeding disorder, previous surgery, nerve related symptoms such as radiculopathy, tarsal tunnel syndrome or tarsi sinus syndrome and osteoarthritis of foot and ankle. The ethics committee of our institution approved this study. All of the included patients were informed regarding their condition. Likewise, the purpose of the study was explained to them, and all agreed to participate by signing an informed consent form. Patients were assigned to one of the two groups (Steriod and PRP group) in a randomized manner by selecting a sealed envelope. Steriod group was treated with Inj. Depo-Medrol® (Methyl prednisolone acetate I.P.) 40mg × 1 ml and 1 ml lidocaine, and PRP group was treated with 2.5 ml of Platelet Rich Plasma once only. A total of 30 cc peripheral blood was taken from the antecubital region and mixed with 3.2% sodi- um citrate. Samples were centrifuged at 1800 rpm for 8 minutes at room temperature. From the 3.5 ml PRP obtained, 1 ml was sent to the laboratory for bacteriological testing and platelet count. After activation, 2.5 ml of PRP containing 5.5% calcium chloride ($CaCl_2$) (50 µl of $CaCl_2$ in 1 ml of PRP) was administered to the foot from the medial side to maximal tenderness area with palpation under sterile conditions. The peppering injection technique was used in both groups and the fascia was injected in 4 to 5 different locations.

NSAIDs were prescribed for no more than two days after injection for initial pain relief, and ice packs were allowed for post injection pain. Patients were instructed to remain non-weight bearing for 48 hrs. Patients were instructed on gentle stretching exercises before standing from prolonged rest i.e. plantar fascia stretching exercises, toe-walking & bottle roller exercises. They were started on eccentric home exercises and allowed to return to normal activities as tolerated and without support. Patients were given a home eccentric exercise and stretching program and were not permitted to use nonsteroidal medications during the first 2 weeks after treatment except for initial two days.

All the patients were evaluated for pain relief and functional status at 2 weeks, 4 weeks, 6 weeks, 3 months, 6 months and 1 year on the basis of Ankle-Hind Foot Scale (AHFS) and Visual Analogue Scale (VAS) with zero indicating no pain and ten the worst pain imaginable. AHFS evaluation covered pain, function, maximum walking distance, walking surfaces, gait abnormality, sagittal motion, hindfoot motion, alignment, and ankle-hindfoot stability. Furthermore, Roles and Maudsley Subjective Pain Scale (RMSPS) was 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 >one hour), 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). Additionally, a clinical history and examination was conducted to asses for local and systemic complications such as infection, unremitting pain etc. Patients were questioned with regard to side effects if any, and subjective satisfaction.

3. Results

A total of 50 patients diagnosed with unilateral chronic plantar fasciitis were included in this study. Steriod group comprised of 25 patients who had received steroid infiltration and PRP comprised of 25 patients who had received platelet rich plasma infiltration. The mean duration of symptoms from the time of onset of symptoms to the time of enrollment in the study was 7.8 months (range: 6.3–9.5 months).The right foot was the most frequently affected foot (62%) and females constituted 64% of all patients. Both groups were similar in terms of age, gender, side involvement and baseline VAS and AHFS scores **(Table1).**

Table 1: Comparison of the patients' characteristics at baseline

	Steroid Group (n=25)		PRP Group (n=25)		P Value
	n	Mean ± SD	n	Mean ± SD	
Age (year)	20-58	43.16 ± 5.18	22-56	41.28 ± 6.42	> 0.05
Male/Female	10/15		8/17		> 0.05
Affected Heel (Right/Left)	14/11		17/8		> 0.05
VAS		7.22 ± 1.12		7.86 ± 1.04	> 0.05
AHFS		60.76 ± 8.34		58.92 ± 6.54	> 0.05

In the Steroid group, mean VAS score was 7.22 ± 1.12 (range: 6.2–8.6). at the baseline and 1.48 ± 4.24 (range: 1.1–2.8) at 1 year follow-up (Table 2). Means AHFS score was 60.76 ± 8.34 (range: 40–88)at the baseline and 94.63 ± 6.84 (range: 84–98) at 1 year follow-up (Table 2). The differences between pretreatment and follow-up scores were statistically significant**.**

In the PRP group, mean VAS score was 7.86 ± 1.04 (range: 6.4–8.8) at the baseline and 0.64 ± 0.36 (range: 0.24–1.6) at 1 year follow-up (Table 2). Means AHFS score was 58.92 ± 6.54 at the baseline and 98.08 ± 6.48 at 1 year follow-up (Table 2). The differences between pretreatment and at 1 year follow-up scores were statistically significant.

Results in Steroid group revealed greatest improvement in pain and functional status in first 4 weeks and further improvement up to 6 weeks which remained fairly constant up to 1 year. PRP group revealed improvement in pain and functional status after 4 to 6 weeks and further improvement seen up to 3 months which was constantly improving up to 1 year (Table 2).

From the average pre-treatment score of 60.76 ± 8.34, the AHFS score of Steroid group increased to a mean of 94.06 ± 6.88 (range: 86–98) at 6 weeks follow-up, a mean of 96.54 ± 6.33 at 3 months follow-up (range: 86–98), and declined to the mean of 92.62 ± 7.48 at 6 months follow-up (range:

82–96), and further declined to a mean of 84.63 ± 6.84 (range: 72–94) at 12 months follow-up. In PRP group, the average pretreatment AHFS score of 58.92 ± 6.54 increased to 92.73 ± 6.54 at 6 weeks, and further improved to a mean of 94.56 ± 6.38 at 3 months, 96.88 ± 2.54 at 6 months, with a final improved score of 98.08 ± 6.48 at 12 months. PRP group had significantly higher mean AHFS Score at final follow-up than the steroid group ($p<0.001$).

Table 2: Comparison of VAS and AHFS scores of the groups according to follow-up period.

	Steroid Group (n=25)	PRP Group (n=25)	P Value
	Mean ± SD	Mean ± SD	
VAS			
Baseline	7.22 ± 1.12	7.86 ± 1.04	> 0.05
6 th week	1.22 ± 1.48	3.64 ± 0.92	< 0.05
3 rd month	0.96 ± 1.42	0.64 ± 0.82	> 0.05
6 th month	1. 22 ± 1.96	0.32 ± 0.46	< 0.05
1 year	1.48 ± 4.24	0.64 ± 0.36	< 0.05
AHFS			
Baseline	60.76 ± 8.34	58.92 ± 6.54	> 0.05
6 th week	94.06 ± 6.88	92.73 ± 6.54	< 0.05
3 rd month	96.54 ± 6.33	94.56 ± 6.38	> 0.05
6 th month	92.62± 7.48	96.88 ± 2.54	< 0.05
1 year	84.63 ± 6.84	98.08 ± 6.48	< 0.05

VAS: Visual Analogue Scale; AHFS: Ankle Hind Foot Scale

At baseline in Steroid group, 16% patients had Poor, 66% had Fair and 18% had Good functional status and at 1 year follow-up 8% had Fair, 24% patients had good and 70% patients had excellent functional status (Table 3). In PRP group, 18% patients had Poor, 68% had Fair and 14% had Good functional status and at 1 year follow up 6% patients had good and 94% patients had excellent functional status **(Table 3).** The PRP group had significantly higher mean RMSPS scores at 1 year follow-up than the steroid group. ($p<0.001$)

Table 3: Comparisons of RMSPS score of the groups at baseline and 1 year

	Steroid Group (n=25)				PRP Group (n=25)				Chi Square	p
	Poor	Fair	Good	Excellent	Poor	Fair	Good	Excellent		
Baseline	16%	66%	18%		18%	68%	14%		- 0.14	>0.05
1 year		8%	24% -	70% -			6%	94%	6.42	<0.05

None of the patients in any of the groups suffered any complications (local or systemic) till the end of their follow up. However, In Steroid group, 3 out of 25 (12%) patients had recurrence of pain at 4 to 6 weeks, whereas in PRP group , none of the patients had recurrence of the symptoms except 1 who had mild pain till the end of the follow-up. In Steroid group, all but 2 (8%) patients benefitted noting marked reduction in first-step pain, post-rest pain, and improved ability to stand and walk at the final follow up.

4. Discussion

Plantar fascitis is an inflammatory response to micro tears which form as a result of mechanical loading. In fact, histology of chronic cases with PF has shown no signs of inflammatory cell invasion into the affected area. The normal fascia tissue is replaced by an angiofibroblastic hyperplastic tissue which spreads itself throughout the surrounding tissue creating a self-perpetuating cycle of degeneration. Despite the myriad of available treatments, a 10% failure rate persists. Shockwave treatment, Botulinum toxin-A injection, radiofrequency ablation, and surgical procedures have each provided some measure of success but also carry measurable risk for complication and failure. The therapeutic use of PRP is an autologous biotechnology that relies on the local delivery of a various growth factors and cytokines with the aim of enhancing tissue healing. This randomized study was designed to compare the use of platelet rich plasma with steroid in patients with plantar fasciitis. In both, steroid and PRP groups, there were significantly great improvement in VAS and AHFS score. However, PRP group has shown significant pain relief and functional status than the steroid group. This was similar with the results of Ferhat SAY et al. [14] Nicolo Martinelli et al. [15] in his study of platelet rich plasma reported excellent in 9 (64.3%), good in 2 (14.3%), fair in 2 (14.3%) and poor in 1 (7.1%) patient whereas we found 96.67% patients with excellent functional status at 1 year follow-up period. Steroid injections are a popular method of treating the condition but Crawford et al. [16] concluded that steroid injections provide short term relief. In our study, we found a positive effect on pain and functional scores in the steroid group which can be explained by the anti-inflammatory effect. However, treatment with corticosteroids has a high frequency of relapse and recurrence, probably because intra facial injection may lead to permanent adverse changes within the structure of the fascia and because patients tend to overuse the foot after injection as a result of direct pain relief [17]. Additionally and more seriously is that repeated corticosteroids injections could predispose to rupture of the plantar fascia [18] , fat pad atrophy, abscess [19], and osteomyelitis [20] .Fascial rupture and fat pad atrophy are particularly serious complications because they can lead to intractable complications. Fascial rupture interrupts the intrinsic windlass mechanism of the foot and can promote further inflammation in the surrounding tissue, thus promoting pain. In addition, plantar fat pad atrophy diminishes subcalcaneal cushioning, leading the plantar fascia to further insult and hence more pain. Platelet rich plasma was first used by Ferrari et al in 1987 in heart surgery to prevent excessive blood transfusion. The introduction of PRP into the treatment paradigm as a modulator of angiogenesis and anabolic effects appears to address the pathophysiology of collagen matrix degradation and chaotic vascularity seen in plantar fasciitis [21]. By combining eccentric exercise and cyclic plantar fascia–specific stretching with PRP injection, enhanced and accelerated healing with excellent long-term results can be achieved in refractory cases [22] . Platelet-rich plasma stimulates the proliferation of various cell types in cells and tissue [23]. Within the alpha granules of platelets, growth factors such as platelet-derived growth factor, transforming growth factor, vascular endothelial growth factor and insulin-like growth factor, and proteins such as fibrin,

fibronectin, vitronectin, and thrombospondin are found in PRP. These growth factors play a function in soft tissue healing [24]. With its growth factors, PRP stimulates the local stem cells and activates the repair cells in the circulation and bone marrow. Excessive inflammation inhibits apoptosis and metalloproteinase activity[25]. Moreover, in tendon recovery, PRP increases tenocyte proliferation in the injured area by providing revascularization by means of the included growth factors and is effective in increasing collagen expression in the tenocytes [26]. None of the patients of our study in both groups suffered any complications (local or systemic) till the end of their follow up. However, small sample size and short term follow up remains the limitation of this study.

5. Conclusion

The application of PRP appears to be more effective than steroid injection in terms of pain and functional results in the treatment of chronic plantar fasciitis and is not associated with any major complications. Use of PRP in the treatment of severe chronic plantar fasciitis may be considered as an alternative to surgical care for use in severe refractory cases of plantar fasciitis where symptoms have persisted longer than 6 months despite prolonged conservative treatment

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