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A randomized controlled trail to evaluate the efficacy of autologous blood injection versus local corticosteroid injection in treatment of plantar fasciitis

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Abstract
Introduction: Plantar fasciitis is often associated with a heel spur (exostosis); however, many asymptomatic individuals have bony heel spurs, whereas many patients with plantar fasciitis do not have a spur
Methodology: The present study was conducted at District Hospital Gadag attached to Gadag Institute of Medical Sciences Gadag during the period of April 2015 to May2016. A total sample size of 60 cases divided into two groups.
Results: The mean VAS score at the beginning were comparable in both the groups (7.55 ± 1.40 vs 7.70 ± 1.14; p=0.810). At first week these scores reduced significantly in group B (4.27 ± 1.76) compared to group A (6.92 ± 2.04; $p<0.001$). Further, at fourth week the mean VAS scores in group A significantly reduced to 3.18 ± 2.38 and at 12 weeks and six months to 0.3 ± 1.37 ($p<0.001$)
Conclusion: Autologous blood provides intermediate and long term results in term of pain relief in compared to corticosteroid injection which gives short term relief.

Keywords: plantar fasciitis, autologous blood injection, local corticosteroid injection

Introduction
Plantar fasciitis is the most common cause of heel pain for which professional care is sought. It is an inflammation of the fascia of the plantar surface of the foot, usually at the calcaneal attachment [1]. It is the most common cause of heel pain presenting to the outpatient clinic [2]. Although thought of as an inflammatory process, plantar fasciitis is a disorder of degenerative changes in the fascia, and may be more accurately termed plantar fasciosis [3]. Plantar fasciitis is diagnosed on the basis of a history of pain on taking the first few steps in the morning, worsening pain with weight bearing, and pain and tenderness to palpation over the medial calcaneal tubercle [2, 6].
Various terms have been used to describe plantar fasciitis, including jogger's heel, tennis heel, policeman's heel, painful heel syndrome, heel spur syndrome, subcalcaneal pain, calcaneodynia, calcancal periostitis [2]. and even gonorrhoeal heel. Although a misnomer, this condition is sometimes referred to as heel spurs by the general public.
The typical presentation is sharp pain localized at the anterior aspect of the calcaneus. Plantar fasciitis is often associated with a heel spur (exostosis); however, many asymptomatic individuals have bony heel spurs, whereas many patients with plantar fasciitis do not have a spur [7].
Approximately 10% of the United States population experiences bouts of heel pain, which results in 1 million visits per year to medical professionals for treatment of plantar fasciitis [8]. the annual cost of treatments for plantar fasciitis, are estimated to be between $192 and $376 million dollars [9].
The etiology of this condition is multifactorial, and the condition can occur traumatically; however, most cases are from overuse stresses.
Plantar fasciitis can be a difficult problem to treat, with no panacea available. No evidence strongly supports the effectiveness of any treatment for plantar fasciitis [10, 11]. Fortunately, most patients with this condition eventually have satisfactory outcomes with nonsurgical treatment [12]. For patients who do not improve after initial treatment, corticosteroid injection or

dexamethasone (Decadron) iontophoresis may provide short-term benefit. However, these therapies do not improve long-term outcomes [11] and may cause plantar fascia rupture [13]. Recently an injection of autologous blood has been reported beneficial for both intermediate / long term outcome for treatment of plantar fasciitis and there was significant decrease in pain. Platelet derived growth factor induce fibroblastic mitosis. Transforming growth factor cause fibroblast to migrate and it has been found to cause angiogenesis. A specific humoral mediator may promote the healing cascade in the treatment of tendinosis as well. This growth factor triggers stem cell recruitment, increases local vascularity and directly stimulate the production of collagen of fascia [14].

However, so far, few studies have evaluated injection of autologous blood for plantar fasciitis. Several studies have been conducted in lateral epicondylitis as treatment modality and reported that, its application is minimally traumatic; it has a reduced risk for immune-mediated rejection, devoid of potential complications such as hypoglycaemia, skin atrophy, tendon tears associated with corticosteroid injection, simple to acquire and prepare, easy to carry out as outpatient procedure and inexpensive [15, 16].

Hence the present study was undertaken to evaluate the efficacy and role of autologous blood injection in plantar fasciitis by comparing with the local corticosteroid injection.

Methodology:

The present study was conducted at District Hospital Gadag attached to Gadag Institute of Medical Sciences Gadag during the period of April 2015 to May2016

Source of Data

Confirmed patients of plantar fasciitis attending to District Hospital Gadag

Sample Size

A total sample size of 60 cases divided into two groups.

Selection Criteria

Inclusion criteria

- Clinically confirmed cases of plantar fasciitis with a pain in the antero-medial border of calcaneum
- Either sex
- Age above 15 years

Exclusion criteria

- Patients receiving steroid injections within three months before blood injection.
- A history of substantial trauma.
- Previously treated by surgery for plantar fasciitis.
- Other causes of heel pain such as;
  - Calcaneal stress fracture
  - Retrocalcaneal bursitis
  - Peroneal, posterior tibial, Flexor hallucis longus tendonitis
  - Tarsal tunnel syndrome
  - Lumbar radiculopathy
- Other causes like
  - Rheumatoid arthritis
  - Ankylosing spondylitis
  - Reiters syndrome
  - Osteoarthritis

Randomization

Based on the computer generated randomization the selected patients were randomized into two groups namely;

- Group A (n=60) – Autologus blood injection group.
- Group B (n=60) – Corticosteroid injection group.

Informed Consent

Patients fulfilling the selection criteria were briefed about the nature of the study and a written informed consent was obtained from the selected patients.

Investigations

Investigations such as X-ray foot AP and lateral,

Random blood sugar, bleeding time and clotting time were done.

Data collection

After obtaining written informed consent from the selected patients, demographic data, chief complaints at presentation and history was taken and clinical examination was done for all patients and findings were recorded on predesigned and pretested proforma (Annexure II).

Outcome variables

Pain of the participants will be assessed by most widely used and accepted “visual analogue scale”. It consists of a 10 centimeter line marked at one end with “no pain” and at other end with “worst pain ever”. Participant is asked to indicate where on the line he or she rates the pain on the day of presentation, 1, 4, 12weeks and 6 month of follow-ups. Numerical valve is then given to it simply by measuring length between “no pain” to patients mark

Results

Procedure was done in 120 patients under the present study. Participants were clinically evaluated. A baseline VAS scores and Nirschl staging of the pain at heel region was recorded. Cases were treated with autologous blood injection and controls with local corticosteroid injection. After the procedure patients were asked to report immediately if any increase in pain was there and were asked to follow up at 1 week, 4 weeks, 12 weeks and 6 months interval after the intervention. Some patients were given just placebos like calcium tablets or B-complex capsules for one to three weeks.

Table 1: Sex distribution

Sex	Group A (n=60)		Group B (n=60)	
	Number	Percent	Number	Percent
Male	32	53.33	27	45.00
Female	28	46.67	33	55.00
Total	60	100.00	60	100.00

x^2_1=0.832 p=0.361

Out of the 120 participants, 59 were males and 61 were females. In autologous blood injection group 32 were males and 28 were females. In corticosteroid injection group 27 were males and 33 were females p=0.361 which is non-significant. Thus both the groups were comparable in terms of number of males and females in each group.

Table 2: Age distribution

Age group (Years)	Group A (n=60)		Group B (n=60)	
	Number	Percent	Number	Percent
< 30	6	10.00	9	15.00
30 to 45	39	65.00	30	50.00
46 to 60	9	15.00	20	33.33
> 60	6	10.00	1	1.67
Total	60	100.00	60	100.00

x^2_3=9.524 p=0.023

Most of the patients in group A (65%) and in group B (50%) were aged between 30 to 45 years

Table 3: Side

Side	Group A (n=60)		Group B (n=60)	
	Number	Percent	Number	Percent
Right	31	51.67	39	65.00
Left	29	48.33	21	35.00
Total	60	100.00	60	100.00

x^2_1=2.193 p=0.138

Out of the 120 participants, 70 participants had their right side elbow affected and 50 had their left side affected. p=0.138 which is not significant. Thus both the groups were comparable in terms of side of elbow involved.

Table 4: Duration

Duration	Group A (n=60)		Group B (n=60)	
	Number	Percent	Number	Percent
< 5	21	35.00	30	50.00
5 to 10	15	25.00	5	8.33
11 to 15	7	11.67	10	16.67
16 to 20	5	8.33	12	20.00
> 20	12	20.00	3	5.00
Total	60	100.00	60	100.00

x^2_4=15.406 p=0.004

The mean duration of the condition in all 120 patients suffering from plantar fasciitis was 9.75 weeks. The mean duration of the condition in autologous blood injection group was 10.88 weeks. The mean duration of the condition in corticosteroid injection group was 8.62 weeks. P Value= 0.121 which is not significant. Thus both the groups were comparable in terms of duration of the condition in each group.

Table 5. VAS scores

Duration	Pain	Group A (n=60)		Group B (n=60)	
		Number	Percent	Number	Percent
Beginning	Mild	0	0.00	0	0.00
	Moderate	17	28.33	9	15.00
	Severe	43	71.67	51	85.00
	Total	60	100.00	60	100.00
		x^2_1=1.162			p=0.204
First week	Mild	8	13.33	29	48.33
	Moderate	15	25.00	24	40.00
	Severe	37	61.67	7	11.67
	Total	60	271.67	60	285.00
		x^2_2=34.451			p<0.001
Fourth week	Mild	34	56.67	42	70.00
	Moderate	24	40.00	15	25.00
	Severe	2	3.33	3	5.00
	Total	60	433.33	60	396.67
		x^2_1=3.124			P=0.210
12 weeks	Mild	58	96.67	46	76.67
	Moderate	0	0.00	14	23.33
	Severe	2	3.33	0	0.00
	Total	60	536.67	60	501.67
		x^2_1=10.381			p=0.001
Six months	Mild	58	96.67	44	73.33
	Moderate	0	0.00	16	26.67
	Severe	2	3.33	0	0.00
	Total	60	640.00	60	601.67
		x^2_1=12.814			p=0.0003

This study, the mean VAS score at the beginning were comparable in both the groups (7.55 ± 1.40 vs 7.70 ± 1.14; p=0.810). At first week these scores reduced significantly in group B (4.27 ± 1.76) compared to group A (6.92 ± 2.04; p<0.001). Further, at fourth week the mean VAS scores in group A significantly reduced to 3.18 ± 2.38 and at 12 weeks and six months to 0.3 ± 1.37 (p<0.001).

Table 6: Mean Nirschal staging scores

Duration	Group A (n=60)		Group B (n=60)		'z' value	'p' value
	Mean	SD	Mean	SD		
Beginning	5.33	1.23	5.28	0.98	0.508	0.611
First week	4.97	1.55	2.92	1.29	6.361	<0.001
Fourth week	2.25	1.61	1.2	1.71	4.108	<0.001
12 weeks	0.28	0.94	1.13	1.5	4.003	<0.001
Six months	0.22	0.92	1.2	1.52	4.758	<0.001

At the beginning P value for Nirschal staging is 0.611 which are statistically not significant. Hence the outcome values before the injection are comparable.

At 1st week P value for Nirschal staging is p<0.001 which are statistically significant. Hence the decrease in pain at 1st week is statistically significant in corticosteroid injection group compared to autologous blood injection group.

At 4th week P value for Nirschal staging is p<0.001 Hence the decrease in pain at 4th week is statistically significant in corticosteroid injection group compared to autologous blood injection group.

At 12th week P value for Nirschal staging is p<0.001 which are statistically significant. Hence at 12th week the decrease in pain is statistically significant in autologous blood injection group compared to corticosteroid injection group

At 6 month P value for Nirschal staging is p<0.001 which are statistically significant. Hence at 6 month the decrease in pain is statistically significant in autologous blood injection group compared to corticosteroid injection group.

Discussion

In this study slight male preponderance was seen in both the groups (53.33% and 55%) with male female ratio of 1.14:1 in group A and 1:1.22 in group B. However this difference was statistically not significant (p=0.361). Most of the patients in group a (65%) and in group B (50%) were aged between 30 to 45 years. The mean in group A was 41.80 ± 10.96 years and in group B the mean age was 40.68 ± 10.47 years suggesting both the groups were comparable with respect to age (p=0.568).

In the present study, most of the patients in group A and group B presented with right foot involvement (51.67% and 65.00% respectively; p=0.138). In group A, among 35% and in group B among 50% of patients duration of symptoms was within five weeks (p=0.004). The mean duration in group A was 10.88 compared to 8.62 weeks in group B (p=0.121). At the beginning of treatment severe pain was recorded among 71.67% in group A and 85% in group B. However this difference was statistically not significant. Hence, all the demographic and clinical variables were comparable in both the groups.

In this study at the first week of treatment, in group a 61.67% patients were still having sever grade of pain but in group B only 11.67% patients having pain. P value for VAS Score is p<0.001 which are statistically significant. Hence the decrease in pain at 1st week is statistically significant in corticosteroid injection group compared to autologous blood injection group.

In the present study during the first week follow up significantly less number of patients had mild (13.33%), moderate (25%) and severe (61.67%) compared to group B (48.33%, 40% and 11.67% respectively) (p<0.001). Though at fourth week follow up most of the patients (70%) reported mild pain in group B compared to group C this difference was

statistically not significant (p=0.210). At 12 weeks and six months follow up almost all the patients (96.67%) reported mild pain in group A compared 76.67% at 12 week follow up and 73.33% patients at six months follow up reported mild pain (p<0.001) suggesting overall better pain control in group A at first week, 12 weeks and six months follow up period.

In this study, the mean VAS score at the beginning were comparable in both the groups (7.55 ± 1.40 vs 7.70 ± 1.14; p=0.810). At first week these scores reduced significantly in group B (4.27 ± 1.76) compared to group A (6.92 ± 2.04; p<0.001). Further, at fourth week the mean VAS scores in group A significantly reduced to 3.18 ± 2.38 and at 12 weeks and six months to 0.3 ± 1.37 (p<0.001) suggesting significantly less pain in group A compared to group B. Similar trend of reduction among patients in groups A was observed with Nirschal staging scores (p<0.001).

In the present study, 6.6% patients had local skin atrophy in group B whereas no patient in group B had this problem (p=0.118) However, no statistically significant difference was observed between the groups.

In the present study patients recurrence was not observed in patients with group A whereas 16.67% patients reported recurrences between four to six months follow up suggesting significantly less recurrence rates with the treatment of autologus blood injection (p=0.003).

At six months of follow up, significantly more number of patients (91.67%) patients in group A were completely relieved of pain whereas more than half (51.67%) patients in group B were not relieved of pain (p=<0.001)

There is limited data showing comparison between autologous blood injection and corticosteroid injection. A prospective, randomized, controlled, observer-blinded study[113] was done over a period of 6 months in Kuala Lumpur, Malaysia. Sixty-four patients were randomly allocated to either the autologous blood or corticosteroid treatment group. All patients were assessed for the worst pain daily on visual analogue scale (VAS) and tenderness threshold (TT) at the plantar fascia origin using a pressure algometer before treatment, and at 6 weeks, 3 months, and 6 months after treatment. A p value of 0.05 was considered significant. Data were complete for 61 patients. The reduction in VAS and increase in TT for both groups was significant over time (p<0.0001). At 6 weeks and 3 months, the corticosteroid group had significantly lower VAS than the autologous blood group (p<0.011 and p<0.005, respectively), but the difference was not significant at 6 months. The corticosteroid group had significantly higher TT than the autologous blood group at 6 weeks, 3 months and 6 months (p<0.003, p<0.003, p<0.008, respectively).

The limitation of the study was lack of comparison with other studies as there is minimal availability of the similar trials.

Conclusion

Based on the results of our present study it may be concluded that, autologus blood injection significantly reduced the pain based on VAS and Nirschal staging without complications there by lowering the recurrence rate upto six months in patients with plantar fascitiis. It also provided complete relief of pain for the period of six months without any complication. Autologous blood is simple to acquire and prepare, easy to carry out.

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