

Efficacy and Safety of Triamcinolone Acetate Injection in Plantar Fasciitis: A Prospective Interventional Study**Raghu N.¹, V. Karthik², Jayanth G.S.³, Deepak P.⁴, Nalini G. K.⁵, Manjula M.J.⁶, Anusha J.⁷, Neelamma Patil⁸**¹Assistant Professor, Department of Pharmacology, Sri Siddhartha Institute of Medical Science, T. Begur, Nelamangala Tq., Bangalore, India²Assistant Professor, Department of Pharmacology, Chandramma Dayanand Sagar Institute of Medical Education and Research (CDSIMER), Harohalli, Ramanagara, India³Associate Professor, Department of Pharmacology, Sri Siddhartha Institute of Medical Science, T. Begur, Nelamangala Tq., Bangalore, India⁴Associate Professor, Department of Pharmacology, Hassan Institute of Medical Sciences, Hassan, Karnataka, India⁵Professor, Department of Pharmacology, Shri Atal Bihari Vajpayee Medical College and Research Institute, Bengaluru, Karnataka, India⁶Assistant Professor, Department of Pharmacology, Rajarajeshwari Medical College and Hospital, Bengaluru, Karnataka, India⁷Assistant Professor, Department of Pharmacology, Sri Venkateshwarra Medical College, Hospital and Research Centre, Puducherry, India⁸Assistant Professor, Department of Pharmacology, Karwar Institute of Medical Sciences, Karwar, Karnataka, India

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Conflict of interest: Nil

Abstract**Introduction:** Plantar fasciitis is a common cause of heel pain that can significantly interfere with daily activities when symptoms persist despite conservative treatment. Corticosteroid injections are widely used for rapid pain relief, although concerns regarding their safety and effectiveness remain. This study evaluated the efficacy and safety of local Triamcinolone acetate injection in patients with plantar fasciitis.**Materials and Methods:** A prospective, open-label interventional study was conducted in the Department of Orthopaedics, HIMS Teaching Hospital, Hassan, from December 2018 to January 2020. Sixty patients aged 20–60 years with plantar fasciitis, persistent heel pain for more than three months, and baseline VAS pain score ≥ 4 were included. Patients received 1 mL (40 mg) Triamcinolone acetate injection at the most tender point of the heel, with a second dose administered at three weeks when adequate pain relief was not achieved. Pain intensity was assessed using the Visual Analog Scale and Wong-Baker Faces Pain Rating Scale at baseline, three weeks, and six weeks. Safety was assessed by recording treatment-related adverse effects. Statistical analysis was performed using SPSS 15.0, with $p < 0.05$ considered statistically significant.**Results:** Among the 60 patients, 33 (55%) were males and 27 (45%) were females. The mean baseline VAS score was 8.45 ± 0.79 , which decreased to 3.65 ± 1.96 at three weeks and 1.05 ± 2.17 at six weeks ($p < 0.001$). The mean percentage improvement in VAS score was 57.41% at three weeks and 88.33% at six weeks. At six weeks, 45 (75%) patients reported no pain, 10 (16.7%) had mild pain, 3 (5%) had moderate pain, and 2 (3.3%) had severe pain. No significant treatment-related adverse effects were reported.**Conclusion:** Local Triamcinolone acetate injection produced significant and progressive reduction in pain among patients with plantar fasciitis over six weeks and was well tolerated. The findings suggest that Triamcinolone acetate injection may be an effective and safe option for short-term symptomatic management of plantar fasciitis.**Keywords:** Plantar fasciitis; Triamcinolone acetate; Corticosteroid injection; Heel pain; Visual Analog Scale.**DOI:** 10.25258/ijcpr.18.10.65This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.

Introduction

Plantar fasciitis is a prevalent cause of heel discomfort, with approximately 90% of cases resolving within ten months without medical intervention. However, around 10% of individuals may experience persistent symptoms, particularly middle-aged, overweight women, and young male athletes.[1] While not all cases require medical attention, severe pain that interferes with daily activities may prompt patients to seek assistance from family physicians or foot specialists. Various intrinsic factors such as obesity, flat feet, high arches, and a shortened Achilles tendon, as well as extrinsic factors like walking on hard surfaces or inadequate footwear, contribute to the development of plantar fasciitis. Individuals with occupations requiring prolonged standing or walking are particularly susceptible.[2]

Corticosteroid injections have been a standard treatment for plantar heel pain since the 1950s, commonly administered by orthopedic surgeons and rheumatologists due to their affordability, simplicity, and rapid pain relief.[6] However, concerns regarding potential complications associated with this treatment modality exist, prompting a need for evidence-based recommendations on the use of Triamcinolone acetate injections in plantar fasciitis patients. [2,4]

Methodology

Source of Data: The study was conducted from December 2018 to January 2020 in patients attending the Department of Orthopaedics in HIMS Teaching Hospital, Hassan. The study was approved by the ethics committee of Hassan Institute of Medical Sciences, Hassan.

Method of Collection of Data: Patients who were diagnosed to have Plantar fasciitis at the Orthopaedic outpatient department at HIMS teaching hospital, Hassan, and who satisfied the following inclusion and exclusion criteria, were included in the study.

Inclusion Criteria

1. The patients diagnosed as plantar fasciitis
2. Aged between 20- 60 years
3. Patient who gave informed consent

Exclusion Criteria

1. Age < 20 years and >60 years
2. Not giving Informed consent
3. Patients who are with history of diabetes, diabetic foot, previous Calcaneus fracture, rheumatoid arthritis, gout and also has treatment history with some injection treatment were excluded from study.

Study Type: Prospective interventional study.

Study Design

Masking: Open Label study.

Primary Purpose: Treatment.

End point classification: Safety/Efficacy study.

The research conducted was a prospective interventional study, initiated following approval from the Institutional Ethics Panel. It involved 60 patients aged 20 to 60 years experiencing heel pain persisting for more than three months, unrelieved by conservative measures such as analgesics, exercises, or splinting, or presenting with morning heel pain upon first step, with a Visual Analog Scale (VAS) pain score ≥ 4 and a Wong-Baker faces pain rating scale > 4 . The clinical severity of plantar fasciitis was categorized as no pain, mild, moderate, severe, or worst possible based on VAS and Wong-Baker faces pain rating scale assessments. Patients received a 1 ml (40 mg) Triamcinolone injection at the tenderest point on the heel upon diagnosis, with a second dose administered on the third week if pain relief was not achieved. VAS pain score and Wong-Baker faces pain rating scale were recorded before and after injection administration, with the mean reduction in pain score documented at three and six weeks post-treatment. The degree of pain was assessed using the Pain Assessment Scale (Visual Pain Score Analog Scale/Wong-Baker Faces Pain Rating Scale) before and after three weeks and six weeks following treatment completion. The study was observational, and the downregulation of pain degree was evaluated using appropriate methods.

Primary Outcome Measures: Pain intensity score was measured on day 1 before starting the treatment and then at 3rd week and 6th week after starting the treatment.

Pain relief (relative to the amount of pain before enrolment) was assessed based on the reduction in pain intensity score at the end of this study.

Secondary Outcome Measures: Safety was assessed on the number of patients who has experiencing side effects during and after the treatment.

Statistical Analysis: All data collected was recorded in a data recording sheet. The primary analysis focused on patients assigned to treatment with the study drugs. Statistical analysis was conducted for both primary and secondary outcome variables. Descriptive statistical analysis was performed, presenting results for continuous measurements as Mean $\pm$ SD and results for categorical measurements as Number (%). Significance was evaluated with a significance level set at $p < 0.05$. The difference in pain reduction

was assessed using the Chi-square test for qualitative data. Statistical software, specifically SPSS 15.0, was utilized for data analysis. Microsoft Word and Excel were employed to generate graphs, tables, and other necessary visual aids.

Sample Size Calculation (G* Power 3.1.92): The sample size was calculated in consultation with a biostatistician using G* Power 3.1.92 software.

Considering an alpha error of 5%, Effect size d_z of 0.48 and power of study $(1-\beta)$ 95% and Degree of freedom (df) 58, sample size estimated was minimum 59.

t tests - Means: Difference between two dependent means (matched pairs)

Analysis: A priori: Compute required sample size

Input:	Tail(s)	=	Two
	Effect size d_z	=	0.48
	α err prob	=	0.05
	Power ($1-\beta$ err prob)	=	0.95
Output:	Noncentrality parameter δ	=	3.6869500
	Critical t	=	2.0017175
	df	=	58
	Minimum sample size	=	59
	Actual power	=	0.9520712

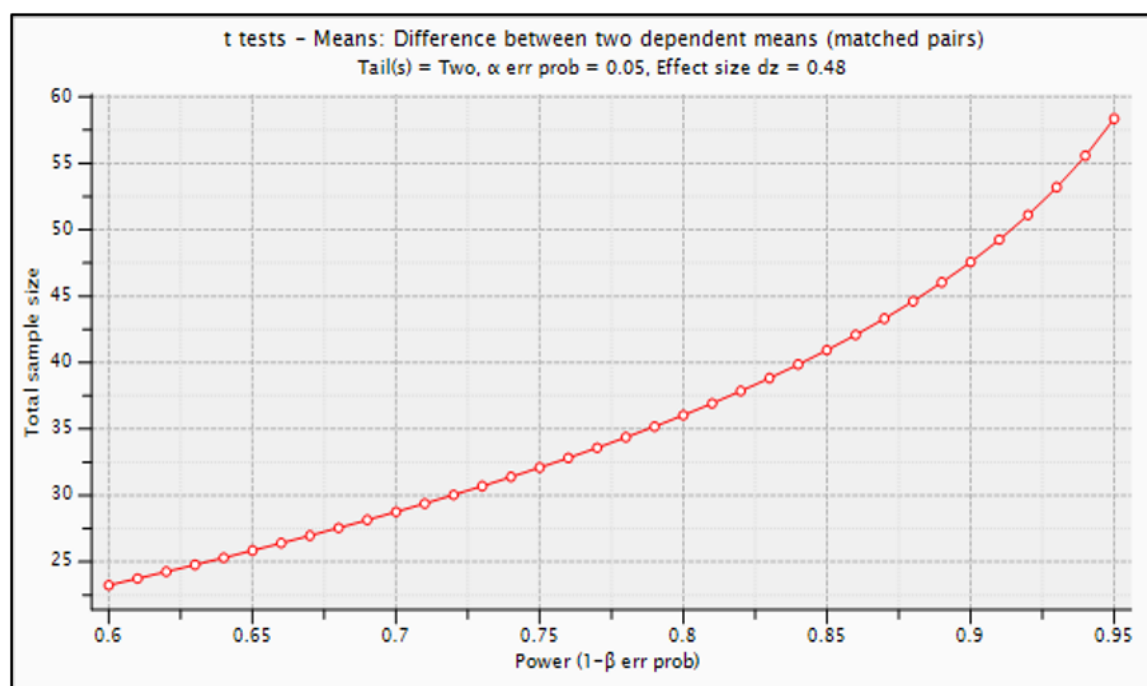


Figure 1:

Results

Demography

Table 1: Demographic data

Gender	Number	Percentage
Male	33	55
Female	27	45
Total	60	100

Total number of patients included were 60 in which 33(55%) were males and 27(45%) were females. Among 60 patients minimum age was 25 years and maximum age was 58 years.

Table 2: Frequency of the side of foot among patients

Sides	Number	Percentage
Right foot	29	48.3
Left foot	31	51.7
Total	60	100

Among the 60 patients, the right foot was affected in 29 patients (48.3%) and left foot was affected in 31 patients (51.7%).

Table 3: Predisposing factors

Predisposing factor	Number	Percentage
Walking on hard surface	59	98.3
No	1	1.7
Total	60	100

The predisposing factor most strongly associated with Plantar fasciitis was walking on hard surfaces, with 59 patients (98.3%) reporting this behavior. Only one patient had no predisposing factors, indicating a high prevalence of Plantar fasciitis among those who walk on hard surfaces (Table 3 and Figure 14). Specifically, 59 patients (98%) had a history of walking on hard surfaces, while only one patient did not report any predisposing factors. Among the 60 patients included in the study, there were no dropouts. Pain relief was assessed using the Visual Analog Scale (VAS) and Wong-Baker Faces Pain Rating Scale. The baseline mean score for patients was 8.45 with a standard deviation of 0.79. After receiving Triamcinolone acetate injection at the tenderest site on the heel upon palpation and assessment at 3 weeks, the mean

VAS score and Wong-Baker Faces pain rating scale were 3.65 and 1.96 standard deviation, respectively.

After 6 weeks, following the second dose of injection for patients whose pain was not relieved, the mean scores were 1.05 and 2.17 standard deviation, respectively. These results indicate a significant improvement in the VAS score/Wong-Baker Faces pain rating scale, with a p-value < 0.001 (Table 4), as depicted in Figure 2.

Pain Assessment: The pain assessment is done by using validated pain assessment tools. The tools are frequently used as standardized scales like : Visual Analog Scales (VAS) and Wong Bakers Faces Pain Rating Scale.

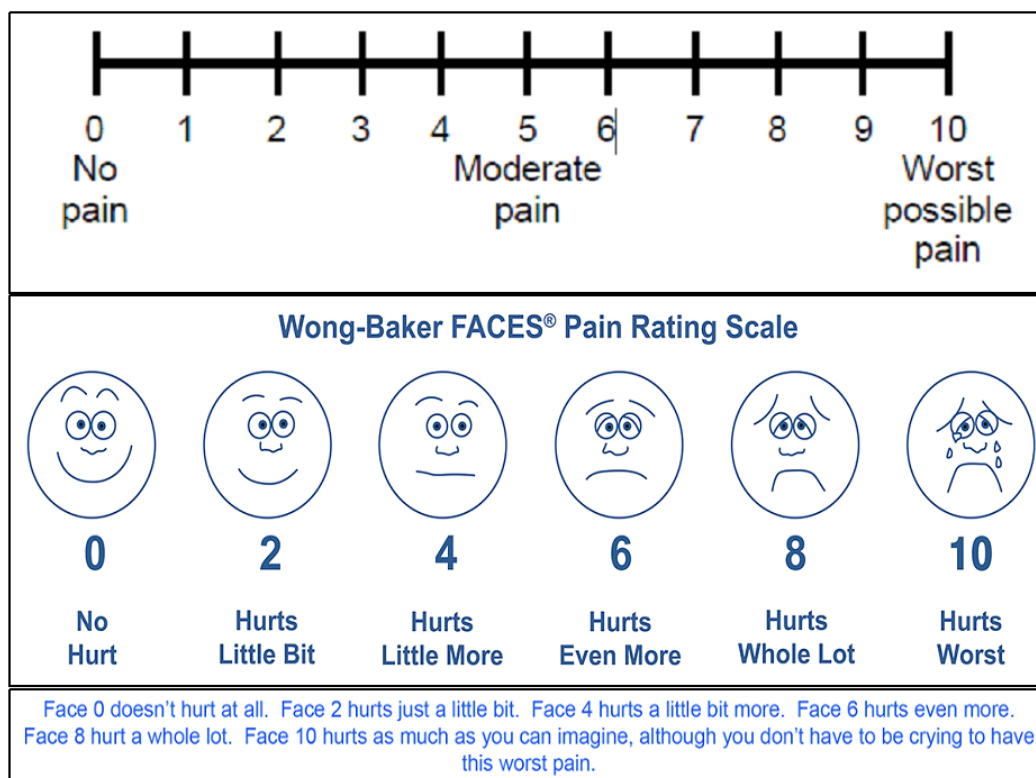
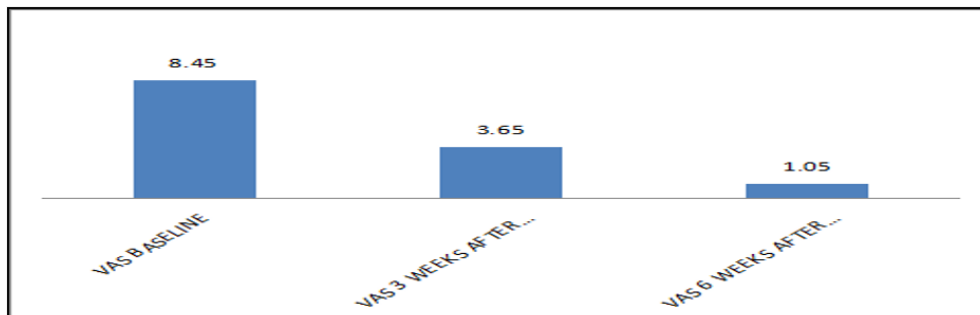
**Figure 2: Visual Analog Pain Scale**

Table 4: Mean VAS scores at Baseline, 3rd week and 6th week

Descriptive statistics					
	N	Minimum	Maximum	Mean	Standard Deviation
VAS Baseline	60	6.00	9.00	8.4500	0.79030
VAS after inj Triamcnenolone 3 weeks	60	0.00	9.00	3.6500	1.96430
VAS after inj Triamcnenolone 6 weeks	60	0.00	9.00	1.0500	2.17400

**Figure 3:**

Measuring of mean pain score

Table 5: Comparison of VAS mean scores

Paired t-test					
		Mean	N	Standard Deviation	P
1	VAS	8.4500	60	0.79030	<0.001
	VAS after inj Triamcinolone 3 weeks	3.6500	60	1.96430	
2	VAS	8.4500	60	0.79030	<0.001
	VAS after inj Triamcinolone 6 weeks	1.0500	60	2.17400	
3	VAS after inj Triamcinolone 3 weeks	3.6500	60	1.96430	<0.001
	VAS after inj Triamcinolone 6 weeks	1.0500	60	2.17400	

According to the paired t-test (Table 5), there was a significant change and a p-value < 0.001 when comparing the baseline VAS score/Wong-Baker Faces pain rating scale with the scores after injection at 3 weeks.

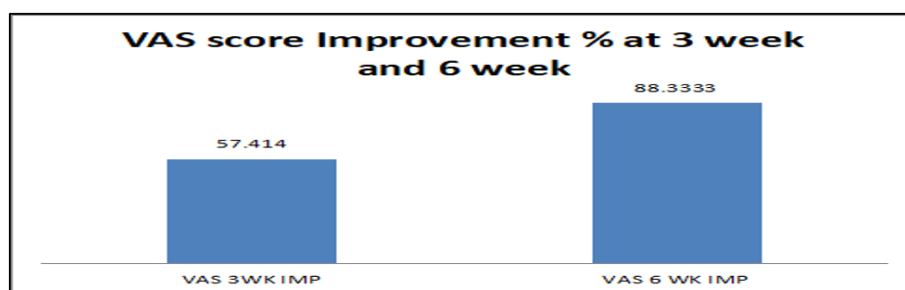
Similarly, when comparing the baseline scores with those after two doses of injections at 6 weeks, there was also a significant improvement with a p-value

< 0.001. Moreover, when comparing the VAS scores between only 3 weeks and 6 weeks after two doses of injections, there was again significant improvement with a p-value < 0.001.

These findings suggest that Triamcinolone acetate injection resulted in substantial relief from plantar fasciitis pain, as evidenced by the significant improvements in pain scores over time.

Table 6: Percentage of Improvement in VAS score

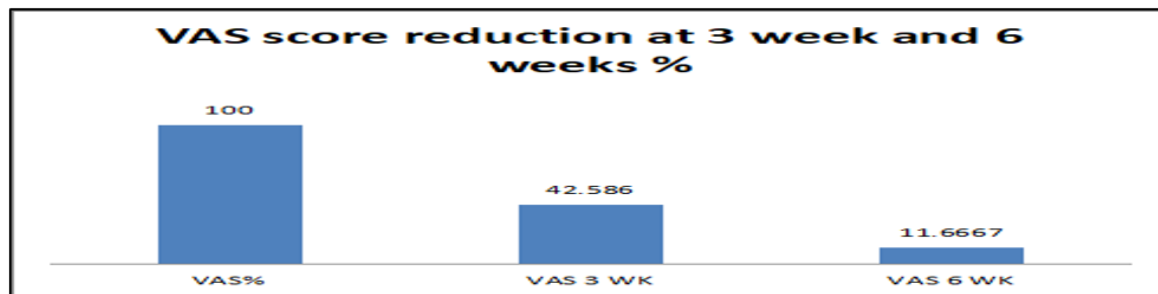
VAS IMP%	N	Minimum	Maximum	Mean	Standard Deviation
VAS 3 WK IMP	60	0.00	100.00	57.4140	21.28720
VAS 6 WK IMP	60	0.00	100.00	88.3333	24.15554

**Figure 4:**

Percentage of improvement of VAS score: Percentage of VAS Score/Wong-Bakers faces pain rating scale out of 60 subjects pain has improved to 57.4% in 3rd week after Injection Triamcinolone acetate and further it improved to 88.33% from the base line after second dose of Injection Triamcinolone acetate.

Table 7: Percentage of reduction in VAS score

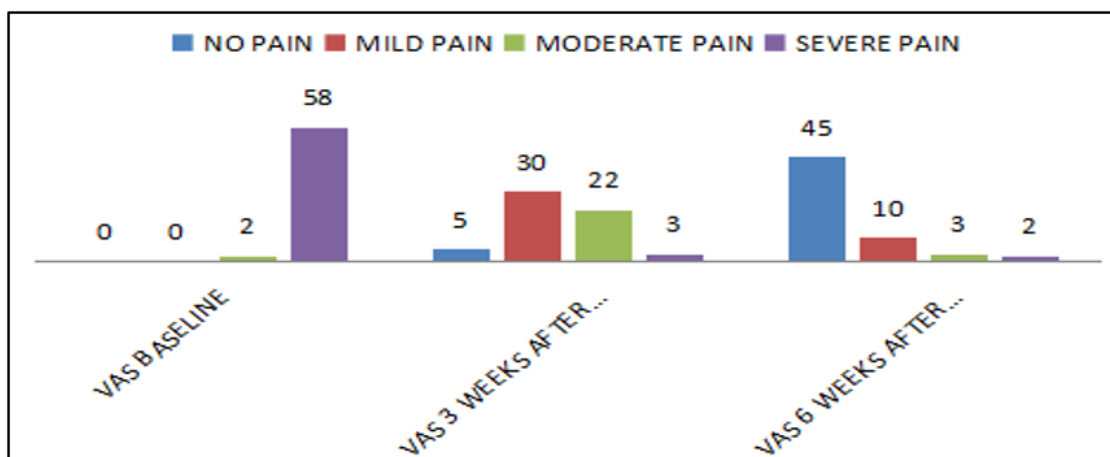
VAS score reduction%	N	Minimum	Maximum	Mean	Std. Deviation
VAS%	60	100.00	100.00	100.0000	.00000
VAS 3 WK	60	0.00	100.00	42.5860	21.28720
VAS 6 WK	60	0.00	100.00	11.6667	24.15554

**Figure 5:**

Percentage of reduction of VAS score: The percentage of pain reduction by 3 weeks after injection Triamcinolone acetate was 42.58% and after second dose was 11.66% by 6th week.

Table 8: Comparison of reduction in Pain

	PAIN				Significance
		VAS	VAS 3 weeks	VAS 6 weeks	
No pain	Count	0	5	45	p<0.001
	%	0.0%	8.3%	75.0%	
Mild pain	Count	0	30	10	
	%	0.0%	50.0%	16.7%	
Moderate pain	Count	2	22	3	
	%	3.3%	36.7%	5.0%	
Severe pain	Count	58	3	2	
	%	96.7%	5.0%	3.3%	
Total	Count	60	60	60	
	%	100.0%	100.0%	100.0%	

**Figure 6:**

Pain scale with time: When comparing the improvement in pain among patients with baseline VAS scores/Wong-Baker Faces pain rating scale, out of 60 patients:

- Initially, 58 patients (96.7%) reported severe pain, while 2 patients (3.3%) reported moderate pain.
- After receiving Triamcinolone acetate injection, the distribution of pain severity after 3 weeks changed significantly:
 - 3 patients (5%) reported severe pain.
 - 22 patients (36.7%) reported moderate pain.
 - 30 patients (50%) reported mild pain.
 - 5 patients (8.3%) reported no pain according to the VAS score.

- At 6 weeks following the second dose of injection, the distribution of pain severity further improved:
 1. 45 patients (75%) reported no pain.
 2. 10 patients (16.7%) reported mild pain.
 3. 3 patients (5%) reported moderate pain.
 4. 2 patients (3.3%) reported severe pain according to the VAS score/Wong-Baker Faces pain rating scale.

This improvement in pain severity distribution is statistically significant and indicates the effectiveness of Triamcinolone acetate injection in alleviating plantar fasciitis pain over time.

Discussion

The aim of our study was to assess the effectiveness and safety of Triamcinolone acetate injection in patients suffering from plantar fasciitis.

Our study involved 60 patients diagnosed with plantar fasciitis who experienced severe pain. These patients received two doses of Triamcinolone acetate injection. By the end of the 6-week treatment period, 45 patients reported no pain, which was a statistically significant outcome with a p-value <0.001. Importantly, no adverse effects were reported during the course of treatment.

Patients were thoroughly informed about the treatment approach and were given the opportunity to express their preferences. Interestingly, all patients opted to follow the prescribed medication regimen, prioritizing pain relief. Concerns about the burden of medication were not raised by any participant.

However, when asked about their treatment preferences, 48 patients (80%) preferred injections to quickly alleviate pain, while only 12 patients (20%) preferred oral analgesics due to a fear of injections. These findings underscore the effectiveness of Triamcinolone acetate injection in reducing pain associated with plantar fasciitis and highlight the importance of patients' attitudes and adherence to treatment instructions.

In our study, out of 60 subjects, 58 (96.7%) initially reported severe pain, while 2 (3.3%) reported moderate pain. After receiving Triamcinolone acetate injection, the distribution of pain intensity changed significantly:

At 3 weeks post-treatment, 5 (8.3%) patients reported no pain, 30 (50%) reported mild pain, 22 (36.7%) reported moderate pain, and 3 (5%) reported severe pain.

By 6 weeks, 45 (75%) patients reported no pain, 10 (16.7%) reported mild pain, 3 (5%) reported moderate pain, and 2 (3.3%) reported severe pain,

indicating no relief from pain even after receiving two doses of Triamcinolone acetate injection.

These results highlight the variable responses to treatment and suggest that while the majority of patients experienced significant pain relief, a small proportion did not respond adequately even after two doses of the injection. It underscores the need for further research to understand factors influencing treatment response in such cases.

In a study conducted by Aydiner Kalaci, MD et al., 100 patients were divided into four groups, each consisting of 25 patients. The first group received a local injection of 2ml of autologous blood, the second group received a local injection of 2ml lidocaine with peppering, the third group received 2ml of Triamcinolone acetate as a local injection, and the fourth group received a local injection of 2ml of Triamcinolone acetate with peppering. Pain scores were measured using the VAS scale at the 3rd week and 6 months after the local injection. [3]

The study concluded that corticosteroid injections combined with peppering resulted in successful outcomes in 22 out of 25 patients, compared to 20 out of 25 patients who received corticosteroids without peppering, showing significant clinical improvement 6 months after treatment. Similarly, in our study, we are treating patients with a local injection of Triamcinolone acetate at the tenderest point and using the VAS scale to measure the improvement in pain. In another study conducted by Ryan et al., involving 56 participants, 28 patients underwent daily physiotherapist-taught exercises over a 12-week period, while 28 patients received local corticosteroid injections. The first group showed significant improvement during the six-week and 12-week follow-up compared to baseline, but the improvement was not significantly better than the second group, i.e., the corticosteroid injection group. Pain was measured using the VAS scale, similar to our study, where we are using local corticosteroid injection and following up at the 3rd and 6th weeks, measured by VAS score. [10]

Similarly to our study, Yucel et al. conducted a study involving 44 patients who were randomized into two groups. In one group, consisting of 22 patients, corticosteroid injections were administered, while in the other group, also comprising 22 patients, pre-fabricated full-length silicone insoles were provided. Pain assessment was conducted using the VAS scale after one month, followed by a follow-up assessment.

The results showed that the corticosteroid injection group reported significantly better pain relief compared to the group who wore pre-fabricated full-length silicone insoles daily for one month. This suggests that corticosteroid injections may be more effective in alleviating pain associated with

plantar fasciitis compared to the use of silicone insoles.[11]

In a study conducted by Crawford et al., a four-arm study examined the efficacy of corticosteroid injections, local anesthesia, and tibial nerve block. Improvements in mean pain scores were reported for all groups. At the one-month follow-up compared to baseline, the corticosteroid injection groups showed significantly better results compared to the other non-steroid groups. This suggests that corticosteroid injections may be more effective in reducing pain associated with plantar fasciitis compared to other non-steroid treatments such as local anesthesia and tibial nerve block.[12]

Most studies investigating the use of corticosteroid injections for plantar fasciitis have utilized palpation-guided techniques, as seen in studies by references [10, 12, 13]. However, two studies, focused primarily on ultrasound-guided corticosteroid injections.[11,14]

In contrast, a study by Ball et al. included both techniques - palpation and ultrasound-guided corticosteroid injections - for comparison. Interestingly, this study found no significant differences in heel pain reduction between the ultrasound-guided and palpation-guided corticosteroid injection groups.[15]

Thus, the approach utilized in our study, which employs palpation-guided corticosteroid injections, aligns with the predominant method used in previous research on this topic.

In a recent meta-analysis conducted by Li et al.,[16] comprising five randomized controlled trials (RCTs) with 149 patients, heel pain measured with the VAS scale was not significantly different between the ultrasound-guided and palpation-guided corticosteroid injection groups. This suggests that both techniques yield comparable results in terms of pain reduction.

Additionally, a study by Tze Gin Lee et al. in 2014 demonstrated that out of 61 patients divided into two groups (Group A and Group B), patients in Group A who received corticosteroid injections showed quicker and possibly greater improvement in plantar fasciitis compared to those in Group B who received intralesional autologous blood injection. This indicates that corticosteroid injections are more effective than autologous blood injections in terms of speed and extent of improvement. Similarly, in our study, we are using corticosteroid injections, which have been shown to be effective. The effectiveness of corticosteroid injections may be influenced by genetic and pharmaceutical factors that alter drug bioavailability.[17]

In our study, Triamcinolone acetate injections were found to be highly effective. At 6 weeks after receiving two doses of injection, the majority of patients reported no pain (75%), with 16.7% reporting mild pain, 5% reporting moderate pain, and 3.3% reporting severe pain according to the VAS score/Wong Baker Faces pain rating scale. This improvement was statistically significant, with pain intensity decreasing significantly from baseline to the 3rd and 6th week intervals. Triamcinolone acetate injections were well tolerated by patients, with only mild pain reported, managed with oral analgesics. Importantly, no complications such as skin hypopigmentation, hematoma, infection, plantar fascia rupture, or other adverse effects were observed during the study.[3,18]

Overall, Triamcinolone acetate injections proved to be highly effective and safe for the treatment of plantar fasciitis in our study.

Conclusion

The primary objective of our study was to alleviate the pain associated with plantar fasciitis, which was successfully achieved through the administration of Triamcinolone acetate injections. All patients exhibited a positive response to the injections, with significant reductions in pain scores observed at both the 3rd and 6th-week follow-up assessments. This consistent improvement in pain scores throughout the study duration underscores the efficacy of Triamcinolone acetate in managing plantar fasciitis pain. The administration of Triamcinolone acetate injections enabled patients to resume their daily activities with greater ease, highlighting the substantial impact of this treatment on their quality of life.

Importantly, no significant adverse events related to Triamcinolone acetate injections were reported during the study period. This suggests that Triamcinolone acetate is not only effective but also well-tolerated in patients with plantar fasciitis pain. In conclusion, Triamcinolone acetate injections represent a safe and effective treatment option for reducing pain associated with plantar fasciitis, allowing patients to maintain their daily lifestyle activities with improved comfort and mobility.

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