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Clinical Efficacy of the Cocktail and 15% Hypertonic Dextrose Solution Injection for Plantar Fasciitis

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ABSTRACT

Background: Plantar fasciitis as a cause of heel pain results from the degeneration of the plantar fascia. Risk factors include obesity, shorting of the Achilles tendons, and letting weight-bearing activities continue for long periods. Diagnosis is done through physical examinations and ultrasonographic evaluations. Management options are non-surgical treatments like shockwave therapy, exercise-based adaptive changes, and tissue regenerative therapies like hypertonic dextrose stimulation. The aim of this study compare the clinical efficiency of cocktail therapy versus 15% hypertonic dextrose explanation injections for plantar fasciitis treatment.

Methods: This randomized clinical trial was conducted from November 2023 to October 2024 and included 41 participants aged 20-70 years, suffering from heel pain for >4 months. The pain was assessed using the visual analogue scale (VAS) and the American Orthopaedic Foot and Ankle Society (AOFAS) scales. Under ultrasound guidance, participants were assigned either cocktail (methylprednisolone, lignocaine) or hypertonic dextrose injection treatments, followed by pain and functional improvement assessment at 1-, 3-, and 6-months post-injection.

Results: Prolotherapy and cocktail treatments were compared in the study conducted for patients suffering from plantar fasciitis. Both groups have nearly the same demographics and baseline characteristics. Although both improved, the past six months had the cocktail group with more VAS and AOFAS. The ultrasound-guided injections assured the precise delivery of treatment, improving the efficacy by targeting the inflamed plantar fascia correctly.

Conclusion: This study concluded that both prolotherapy and cocktail treatments are effective for plantar fasciitis, with cocktail treatment yielding superior pain reduction and functional development. Ultrasound-guided injections confirmed accurate, targeted delivery.

Key-words: Plantar Fasciitis, Cocktail Therapy, Hypertonic Dextrose, Pain Reduction and functional Improvement

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INTRODUCTION

Plantar fasciitis is caused by degenerative irritation of the plantar fascia, located at the medial calcaneal tuberosity of the heel, and the structures surrounding the perifascia (Fig. 1). The fascia supports the arch and aids in shock absorption. Plantar fasciitis, the most prevalent cause of heel pain, impairs an adult's quality of life and makes walking difficult [1]. The incidence of plantar fascitis in runners ranges from 4.5% to 10% [2]. It occurs in 10.3% of the general population, and 84.1% of active working individuals of 25-65 years of age. The highest incidence is

seen in the general population aged 40-60 years. Although the etiology is unclear, the main mechanism of plantar fasciitis is due to plantar fascia degeneration. A meta-analysis stated that increased body-mass index, increased ankle dorsiflexion, and increased body mass are the risk factors [3]. The most common etiology of plantar fasciitis is: sudden weight gain, unaccustomed running, prolonged running, shoes with less cushioning effect, Achilles tightness in the tendon, and occupations with long-term weight bearing.

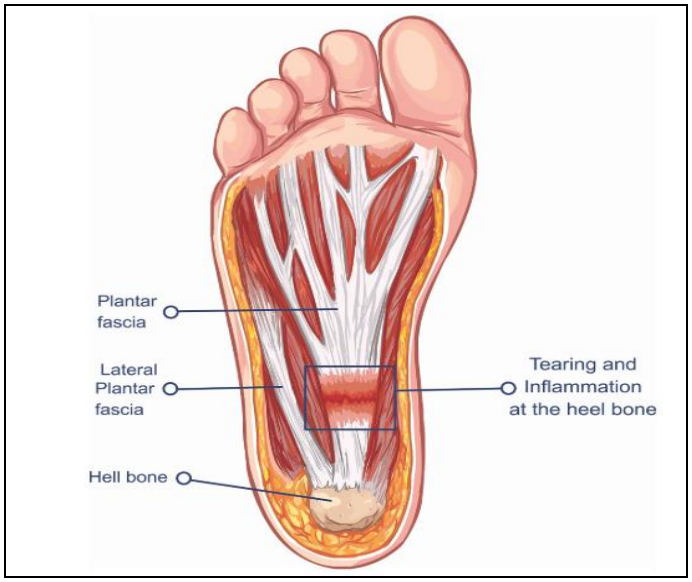

Fig. 1: Anatomy of Plantar fasciitis [Source: https://www.kardinyaphysiotherapy.com.au/injury-treatment/treating-plantar-fasciitis/]

Plantar fasciitis is diagnosed based on the physical examination and history of the patients. Ultrasonography is used for the diagnosis of plantar fasciitis and the evaluation of therapeutic outcomes. The non-surgical approach is the first line of treatment that includes modification of activity, injection therapy, and extracorporeal shockwave therapy where pain relief is seen in 70-80% of the population [1,2].

The widely used injection therapy for plantar fasciitis is corticosteroids, to provide rapid pain relief in the heel due to the anti-inflammatory effects. The results of a Cochrane review stated that there is only short-term relief with the use of corticosteroid injections in addition to numerous reports of severe complications (soft tissue infection, flare at the site of injection, and rupture of plantar fascia) [4]. They also accuse complications like infection, decrease in strength of ligaments and tendons, and rupture in plantar fasciitis. Therefore, injections with long-term outcomes have been explored targeting degenerated plantar fasciitis. The use of a "cocktail" injection, which is a combination of injections, is one promising therapeutic strategy. This usually comprises topical anesthetics to relieve pain, corticosteroids to reduce inflammation, and other substances that could aid in the healing process. Dextrose prolotherapy helps heal connective tissue damage by injecting a hypertonic dextrose solution into the local lesion [5].

Prolotherapy is a regenerative injection which does not contain biological agents, unlike PRP. There is a remarkable outcome seen when prolotherapy is used for degenerative musculoskeletal diseases. The most used prolotherapy is hypertonic dextrose, preparation is easy, cost-effective, and safe. The goal of dextrose prolotherapy, a form of regenerative injectable therapy, is to strengthen and restore soft tissues. The dextrose solution does not contain any biological agents like platelet-rich plasma, but still, it helps in the recovery of soft tissue. The mechanism of dextrose is not known, but it is proven to cause localized trauma at the site of injection and also initiate an inflammatory process that reactivates soft tissue healing [5]. When dextrose is injected into the cells, it causes cell destruction resulting in increased platelet-derived growth factors, epithelial growth factors, connective tissue growth factors, and complex proteins that cause the regenerative process. Animal studies stated that there is proliferation of connective tissue at the site injected with dextrose [6]. Topol et al., in their study, observed that there is a re-growth of knee cartilage and decreased pain after injection of dextrose via arthroscopy in severe knee osteoarthritis patients [7].

MATERIALS AND METHODS

This is a prospective controlled and randomised clinical study which was conducted from November 2023 to October 2024 among 41 participants. After taking content from each participant, this was conducted based on the approval of the hospital's ethical committee. Before conducting this study, this study was screened 200 participants with complaints of foot pain. This study excluded 120 participants who did not meet our inclusion criteria, and 19 were excluded because they were lost in follow-up. Out of 200 participants, 41 included in this study met the inclusion criteria.

Inclusion Criteria

- This study included participants in the age group 20 to 70 years.
- This study included males and females.
- Participants who had heel pain for > 4 months
- Participants who were able to walk.

Exclusion Criteria

- This study excluded those participants who had a history of plantar fasciitis.
- This study excluded those who had foot deformation
- It also excluded those participants who had allergies to local anaesthesia and pregnancy, fracture, and tumour foot.

Pre-Injection Assessment- Pre-injection pain severity was assessed using a VAS, and AOFAS evaluated pain severity and functional operation.

VAS score Activity- The VAS is a linear line with no pain on the left and the worst on the right. There are 4 groups: no pain, mild 1 to 3, occasional work pain, moderate 4-6 pain throughout work and severe 7-10 pain that stops work but resumes after rest.

AOFAS clinical rating scale- AOFAS is a clinical rating scale comprising subjective and objective clinical criteria inside a numerical rating system. The AOFAS grading scale spans from 0 to 100, where a higher score signifies reduced disability. This score evaluates pain, function, and alignment without radiological considerations. The AOFAS clinical rating scale provides the significant advantage of being suitable for a diverse range of foot and ankle problems.

Cocktail injection- A 3 ml cocktail injection of 1 ml (40 mg) of methylprednisolone suspension, 1 ml of distilled water, and 1 ml of 2% plain lignocaine was administered under ultrasound guidance.

Dextrose injection- 4ml 15% hypertonic dextrose injection, consisting of 1.2ml 50% hypertonic dextrose mixed with 1.8 ml distilled water and 1ml 2% lignocaine (plain), was injected under USG supervision.

Technique- The USG-guided injection was inclined to the foot being relaxed outside the table. Sterile 72% V/v alcohol + 1% isopropyl alcohol solution was used to prepare and cover the injection site. A 6-15 MHz high-frequency linear array ultrasound probe was utilized and scanned along the longitudinal axis of the heel. Scanning shows the calcaneum, plantar fascia, thickness, and change in inechogenicity and perifascial oedema. The fascia was scanned before the medial heel injection was delivered out-of-plane. Mark the sole's fascia's maximal tenderness and the needle entrance location from the malleolus' posterior border to 1 finger width proximal to the sole. After injection, patients were told to apply an ice pack and avoid hard activity for 5 days. In addition, mild non-steroidal anti-inflammatory medicines (paracetamol 500 mg twice daily) were administered as needed. Post-injection follow-up occurred at one month, three months, and six months. The level of pain was assessed using a visual analogue scale. The degree of pain and its effect on functional status were evaluated using the AOFAS scale.

Statistical Analysis- SSPS version 23.0 was utilized for statistics following gathering data. The following tests were employed to compare means and standard deviations. The demographic variable and comparison group data were tested using chi-square. An independent student t-test was conducted between the two comparison groups. The p-value was computed for all variables, indicating <.001 for significant results and >.05 for inconsequential results.

RESULTS

Table 1 shows the demographic information about the participants, which compares the treated versus the control groups against each other in the prolotherapy cases versus cocktail cases. The gender distribution showed a slightly higher proportion of females in each group, that is, the prolotherapy group, 10 females and 8 males, and the control group, 16 females and 7 males (p=0.854), thus found not to be statistically significant. Also, no significant differences existed between the two groups in the affected foot - such as the right, left, or bilateral distributions. In the prolotherapy group, 6 participants had the right foot affected, 4 had the left, and 8 had bilateral afflictions, whereas in the control group, those numbers were 5, 5, and 13, respectively (p=0.794). These results show that there are balanced demographic characteristics across both groups.

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Table 1: Demographic details of participants

Variables		Treating group (prolotherapy)	Control group (cocktail)	p-value
Gender	Male Female	8 10	7 16	0.854
Affected foot	Right Left Bilateral	6 4 8	5 5 13	0.794

The baseline characteristics of participants in the treating group (prolotherapy) and the control group (cocktail) are summarized in Table 2. Mean age was slightly higher in prolotherapy compared with control; in years, it is 43.69±9.70 (28-62) against 39.29±8.70 (range 26-52), but the difference was statistically insignificant (p=0.479). Also, the mean plantar fascia thickness was slightly lesser in the prolotherapy group than in the mean control group (4.49mm±1.10; range 2.59-6.88 mm against 4.90mm±1.49; range 2.3-8 mm). However, there was no significant difference (p=0.369). Thus, in terms of mean BMI, both groups had comparable (26.49±2.61 vs. 26.70±2.69; p=0.890), suggesting that the groups did well in matching the parameters of BMI. It demonstrates that both groups have comparable baseline variables.

Table 2: Baseline Characteristics of Participants

Variable		Treating group (prolotherapy)	Control group (cocktail)	p-value
Age	Mean Range	43.69±9.70 28 to 62	39.29±8.70 26 to 52	0.479
Plantar fascia thickness	Mean Range	4.49mm±1.10 2.59 to 6.88 mm	4.90mm±1.49 23 to 8 mm	0.369
Body mass Index	Mean Range	26.49±2.61 22.79 to 29.69	26.70±2.69 23 to 29	0.890

The performance of the treatment group (prolotherapy) and control group (cocktail) concerning VAS and AOFAS scores is shown in Table 3. For VAS, the groups did not differ significantly before treatment (5.06±0.24 vs 5.13±0.34; p=0.435), but both groups improved substantially in the 1st, 3rd, and 6th month, and the control group showed more significant reductions (p<0.001). Similarly, for AOFAS, there was no significant pre-treatment difference (66.94±4.02 vs. 67.26±5.11; p=0.826). However, in the 1st, 3rd, and 6th months, the control group significantly improved their functional scores compared to the treating group (p<0.001). These outcomes indicate that while both groups improve over time, the cocktail treatment group shows more significant pain reduction and better functional outcomes.

Table 3: Comparison Between Treating and Control Group

	Treating group (prolotherapy) Mean±SD	Control group (Cocktail) Mean±SD	p-value	t-value
VAS –pretreatment 1st month	5.06±0.24 4.54±0.71	5.13±0.34 1.65±0.49	0.435 <0.001	-0.788 15.588

3rd month 6th month	3.94±0.64 5.00±0.34	1.91±0.29 2.35±0.71	<0.001 <0.001	13.612 14.477
AOFAS – pretreatment 1st Month 3rd month 6th month	66.94±4.02 71.94±5.46 76.78±4.12 67.22±4.19	67.26±5.11 93.17±3.33 90.43±2.86 86.39±4.20	.826 <0.001 <0.001 <.001	-0.215 -15.381 -12.518 -14.518

Fig. 2 shows the clinical method used to administer injection treatments for plantar fasciitis, the importance of the exact marking of the injection site on the plantar surface and the use of ultrasound control to confirm the accurate delivery of the therapeutic solution. The ultrasound imaging shows the plantar fascia thickness, a vital metric for measuring the severity of the illness and monitoring treatment growth. By visualizing the fascia and supervising the needle placement, this method enhances the efficacy of the administered cocktail and 15% hypertonic dextrose solution, ensuring targeted relief for the inflamed fascia.

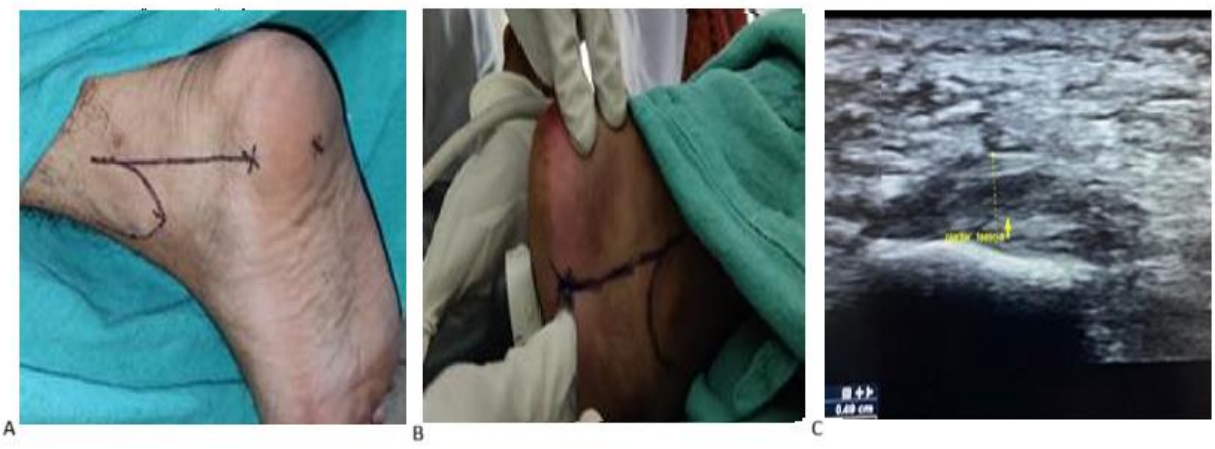

Fig. 2: Marking of injection site and ultrasound-guided injection and plantar fascia thickness.

DISCUSSION

A study evaluated the efficiency of dextrose prolotherapy in comparison with the control group for treatment Ing chronic resistant plantar fasciitis. The visual analogue scale was used to measure the intensity of pain, disability and pain was measured with the foot function index. Plantar fascia thickness was measured with ultrasonography. They concluded that dextrose prolotherapy showed an efficacy of up to 15 weeks and stated that it can be used as an alternative therapeutic option [8].

A systematic review investigated the effect of dextrose compared to placebo or other nonsurgical treatment for treating pain in chronic plantar fasciitis patients. Due to the substantial risk of bias in almost all of the included studies and the lack of long-term follow-ups in several trials, more high-standard research is required to determine the long-term effects of DPT vs. placebo/other non-surgical therapy [9].

A study evaluated the effect of the cocktail group and patients treated with 15% hypertonic dextrose for chronic plantar fasciitis. The prolotherapy group (15% hypertonic dextrose solution was administered) and cocktail group (1ml 40mg of local methylprednisolone combined with 1ml 2% lignocaine and 1ml distilled water). They concluded that the cocktail group showed favorable outcomes in terms of VAS and American orthopedics foot and ankle score (AOFAS) in comparison to dextrose prolotherapy [10].

A study evaluated the efficiency of prolotherapy for the treatment of chronic plantar fasciitis. Three times every 21 days, the prolotherapy group received an injection with ultrasound guided into the plantar fascia at up to 5 locations. For 3 months, the control group were instructed to perform stretches for the Achilles tendon and plantar fascia three times each week. They stated that prolotherapy is an effective alternative treatment option for the treatment of chronic plantar fasciitis [11].

Dextrose prolotherapy is widely used for the treatment of numerous musculoskeletal disorders, it is considered as a regenerative therapy. A study evaluated the safety and efficacy of dextrose in treating plantar fasciitis. The study concluded that dextrose was an effective and safe therapeutic option for plantar fasciitis and showed long-term benefits. These effects were in comparison to PRP or extracorporeal shock wave therapy [12].

Dextrose prolotherapy's effectiveness and safety in chronic plantar fasciitis treatment were examined in a study. It is an effective treatment for the reduction of pain, decreasing the fascial thickness, and improving the foot's functional score in a limited time. Further studies with a large population are needed for the identification of optimal treatment regimens [13].

A study assessed the effect of radial extracorporal shock wave therapy (ESWT) with dextrose prolotherapy in treating chronic plantar fasciitis. They showed that in the intergroup comparison except for the FAAM subscale that is favorable with the ESWT group, other outcomes were not significant in the groups. Dextrose prolotherapy showed significant efficacy to radial ESWT for reduction of pain, thickness of plantar fascia, and limitation of daily functional activities with plantar fasciitis. No adverse effects were observed among the group [14].

A prominent cause of persistent heel discomfort is chronic plantar fasciitis (PF), which has a variety of traditional treatment options. A randomized control trial was conducted to evaluate the efficiency of ultrasound-guided injection of dextrose with corticosteroid for chronic plantar fasciitis. Both the treatment methods were found to be effective. When compared with dextrose prolotherapy corticosteroid injection showed superior treatment outcomes early after injection and after 12 weeks of treatment [15].

One of the main reasons for heel pain is plantar fasciitis. There are numerous significant therapy approaches. A study sought to assess the clinical outcomes of injectable therapies for prolotherapy and corticosteroids. When treating plantar fasciitis, prolotherapy and corticosteroid injections yield notable functional results in the near term. Injections of corticosteroids produce better clinical healing than prolotherapy [16].

CONCLUSIONS

This study concluded that it compared the prolotherapy and cocktail treatments for plantar fasciitis. This study found that both treatments were significantly effective in VAS and AOFAS over time. However, patients treated with the cocktail showed superior results to those treated with prolotherapy in pain reduction and functional improvement at every follow-up time point. Ultrasound-guided injections ensured accuracy in the targeted delivery of the inflamed plantar fascia. Thus, it is recommended that although both methods are beneficial, cocktail therapy may carry additional clinical efficacy in improving symptoms of plantar fasciitis.

CONTRIBUTION OF AUTHORS

Research concept- Md Salman Khan, Jagmohan Singh Dhakar

Research design- Md Salman Khan, Jagmohan Singh Dhakar

Supervision- Md Salman Khan, Vikas Dwivedi

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Critical review- Md Salman Khan, Vikas Dwivedi

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Final approval- Md Salman Khan, Vikas Dwivedi

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