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Phonophoresis Plus Topical Nitroglycerin or Hydrocortisone for the Management of Plantar Fasciitis, Which Topical Agent is Superior?

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Abstract

Background: Plantar fasciitis (PF) is the most common reason for inferior heel pain. Various approaches have been raised for the treatment of PF; however, none had substantial outcomes. The current study aims to assess and compare phonophoresis outcomes plus topical nitroglycerin versus phonophoresis plus topical hydrocortisone for PF management. **Materials and Methods:** The current study has been conducted on 65 patients with PF diagnosis, among whom underwent ten every-other-day sessions of treatment with phonophoresis plus 20 mg nitroglycerin (n=33) or 20mg hydrocortisone (n=32), respectively. The Modified Roles and Maudsley (RM) score and the visual analog scale (VAS) were compared between the two groups at baseline, three weeks, and two months after the interventions. Besides, the plantar fascia thickness was measured at baseline and two months after the intervention. **Results:** The baseline RM (P-value=0.067) and pain severity (P-value=0.057) was similar between the two groups, but other assessments revealed the superiority of phonophoresis plus topical nitroglycerin over topical hydrocortisone (P-value<0.05). The reduction in plantar fascia thickness was more in phonophoresis plus nitroglycerin-treated patients as compared to the latter group (P-value<0.001), but the requirement of additional doses of analgesia was remarkably more in hydrocortisone-treated patients (P-value<0.001). **Conclusion:** Based on the current study, phonophoresis plus topical nitroglycerin was superior to phonophoresis plus topical hydrocortisone in pain relief, improved quality of life, and decreased fascia thickness. However, further investigations are required to achieve the ultimate outcomes for a more extended period.
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Keywords: Plantar Fasciitis; Phonophoresis; Nitroglycerin; Hydrocortisone
Introduction

Introduction

Plantar fasciitis (PF), also known as painful heel syndrome, is the most common underlying reason for inferior heel pain refers to a physician [1].

PF is a degenerative syndrome resulting from repeated trauma to the site of fascia origin on the calcaneus [2]. Despite the word fasciitis that assumes inflammation in this syndrome, a degenerative process seems to play a crucial role in PF's pathogenesis [3].

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Although PF is more prevalent among the runners or military personnel; it can affect the general population regardless of age, gender, race, ethnicity, or even activity status; females in fifth-to-seventh decades of life, in particular. Plantar fasciitis is mostly unilateral; however, it may occur bilaterally in up to 30% of the patients [4].

The plantar fascia is responsible for providing support to the longitudinal arch; therefore, it acts as an absorber of dynamic shocks to the foot and even the entire leg [5].

Painful heel syndrome is substantially diagnosed based on clinical examinations and past medical history. Most of the patients represent pain when rising in the morning, and the anteromedial aspect of their calcaneus is painful. In contrast, pain due to stress fracture or nerve entrapment usually deteriorates by walking. The painful passive dorsiflexion or active plantar flexion is PF's other clinical manifestations [6].

Various approaches, including rest and avoidance of aggravating factors, anti-inflammatory agents, orthotics and arch support, splinting and walking casts, stretching and strengthening exercise, have been raised for the treatment [7-9], and eventually, surgical procedures if non-responded to the previous methods have been raised for the management of PF [10]; however, there is no successful unified treatment yet.

Phonophoresis is a high-frequency mechanical wave ultrasound leading to vibration and heat production in the tissues' depth [11]. The use of phonophoresis combined with topical analgesics/ anti-inflammatory agents gave good results; however, the data about the efficacy of phonophoresis for managing plantar fasciitis is limited [12].

Hydrocortisone is a corticosteroid with an anti-inflammatory characteristic that has been successfully topically used for varieties of musculoskeletal inflammatory conditions [13]. In addition, topical nitroglycerin has been introduced as a potential agent for treating tendinopathies [14]. Nevertheless, the information in this regard is limited and controversial, for plantar fasciitis in particular.

The current study is aimed to assess and compare the outcomes of phonophoresis plus topical nitroglycerin versus phonophoresis plus topical hydrocortisone.

Materials and Methods

Study Population

The current randomized clinical trial has been conducted on 65 patients diagnosed with plantar fasciitis referred to the outpatient Physical Medicine and Rehabilitation Clinic of Amin Hospital affiliated at Isfahan University of Medical Sciences from July 2019 to June 2020.

The Ethics Committee of Isfahan University of Medical Sciences approved the study's proposal by the code number IR.MUI.MED.REC.1398.154. Besides, this study has been registered in the Iranian Registry of Clinical Trials (IRCT) based on the code number. (IRCT20190824044598N2) Then, the study protocols and each protocol's advantages were explained to the patients, they were reassured about their personal information confidentiality, and written consent was obtained. Eighteen-to-sixty-five-year-old patients diagnosed with plantar fasciitis due to the clinical presentations who could represent their pain severity according to VAS and RM were included. The diagnosis of plantar fasciitis was made clinically according to the history and physical examination findings of point tenderness at or near the medial calcaneal insertion of the plantar fascia.

Diabetes mellitus, peripheral neuropathy, vasculitis and vasculopathy, any pathology in ankle/foot (instability, arthritis, malignancy, acute infection, and skin disorders), pregnancy or lactation, coronary artery disease, hypertension, renal diseases and anemia, atrophy/ scar or skin ulcers at the site of intervention were accounted as the unmet criteria.

The exclusion criteria consisted of inappropriate cooperation in the intervention sessions (absence in ≥2 sessions of intervention), the exacerbation of the symptoms during the interventions represented by the patients, and the concurrent use of other medications affecting pain such as local injections or oral analgesics.

The study population was enrolled in the study through convenience sampling, and then they were randomly allocated to each of the intervention groups using Random Allocation soft-

ware (Graph-Pad software, Inc., California, USA). Therefore, each patient was provided with a particular number by the software allocated him/her to the phonophoresis plus topical hydrocortisone intervention or phonophoresis plus topical nitroglycerin intervention.
The patients and the physician who performed phonophoresis were unaware of the type of utilized topical agent; therefore, the study has been designed double blindly.

Interventions
Celecoxib 200 mg once a day for fifteen days, as well as plantar fasciitis adjuvant therapy, including stretching of the calf muscle and plantar fascia, toes passive dorsiflexion, intrinsic foot muscle strengthening, and shoe modification (soft medial longitudinal arch support or silicon heel pad if needed) were ordered for all of the patients. Besides, they were prohibited from the performance of heavy physical activities and the use of other analgesics (other non-steroid anti-inflammatory drugs (NSAIDS) than celecoxib in particular). They were also recommended to use acetaminophen for pain control if needed and record the administered dosage in the study checklist.
The patients were asked to scrub the heel skin before each phonophoresis session to remove calluses and dead cells.
The patients under topical nitroglycerin medication were treated with 1 gr nitroglycerin 2% ointment (containing 20 mg nitroglycerin), and the latter group was treated with 2 gr hydrocortisone 1% ointment (containing 20 mg hydrocortisone) topically at the site of the plantar fascia, within 20 minutes prior to phonophoresis performance. Then, the pulsatile ultrasound (2:1) with the frequency of 0.8 MHz and intensity of 1.5 W/CM for 10 minutes was dynamically administered for the patients in 10 every other day sessions [15].

Follow-up
The patients were visited at baseline and by the end of each session of the intervention to present their pain intensity or any complication related to the interventions. By the end of the interventions, they were re-visited within the next three weeks and then within two months.
The patients filled the assessment instruments at baseline, by the end of the intervention, within three weeks and finally, after two months following the end of the interventions.

1.Means of Assessment

1.1.Pain Severity
The Visual Analogue Scale (VAS), a ten-score scale ranging from zero to 10 as the least to the most severe pain, was administered to evaluate the intensity of the pain sensation by the patients. The pain severity was evaluated at baseline, by the end of the last intervention session, within three weeks and two months after the end of the interventions.

1.2.Modified Roles and the Maudsley Score
The Modified Roles and Maudsley (RM) score is a means to assess the usual daily activities-related pain in which the scores from the least to the most represent the excellent, good, acceptable, and poor quality of life, respectively [1].

1.3.*Measurement of Plantar Fascia Thickness*
Besides, the thickness of plantar fascia was measured at baseline and within two months after the end of the interventions using ultrasonography (Alpinion E-CUBE 9, Republic of Korea) using a 5-13 MHz probe. Therefore, the patients lay prone with their feet hanging free over the end of the examination table (knee in full extension and ankles in 90° dorsiflexion). With a perpendicular approach, the plantar fascia thickness was measured at a standard reference point where the plantar fascia crosses the anterior aspect of the calcaneus's inferior border. The Plantar fascia thickness was measured twice to prevent the transducer obliquity error, and the average thickness was recorded.

Statistical Analysis
The obtained data were entered into the Statistical Package for Social Sciences (SPSS) version 25 (IBM, Armonk, USA). The descriptive data were presented in mean, standard deviation, absolute numbers, and percentages. For analytics, independent T-test, paired T-test, Chi-square test, Fisher's exact test, Freidman test, and Mann-Whitney test were used. Bonferroni test was administered as a post hoc test to assess the significance of differences between the different measured times of the study.

The P-value of less than 0.05 was determined as the two-sided level of significance.

Results

The current study has been conducted on 65 patients diagnosed with plantar fasciitis, among which 32 patients were allocated to the phonophoresis plus hydrocortisone intervention and 33 ones to the phonophoresis plus nitroglycerin intervention. Two patients in the first group, including one due to other analgesics administration and one due to absence in ≥2 sessions of the intervention, were withdrawn from the study. Three patients of the second group left the study because of the absence in ≥2 sessions of intervention (Figure-1).

The two assessed groups were similar in terms of age (P-value=0.89), gender distribution (P-value=0.65) and BMI (P-value=0.3). The detailed demographic characteristics of the studied population are demonstrated in Table-1.

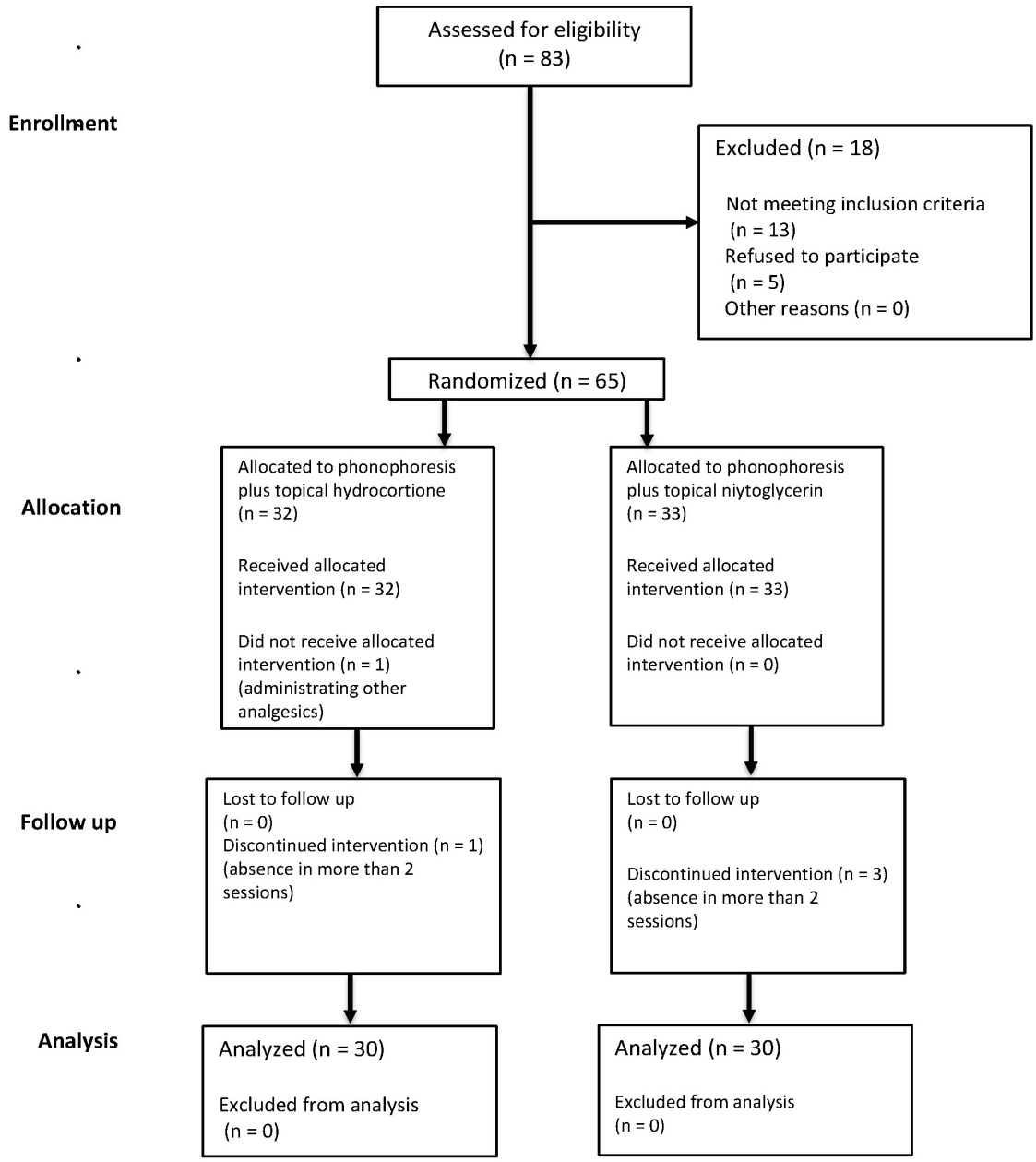

Figure 1. The Consort Diagram of the Studied Population

The pain severity was evaluated based on VAS, in which the two groups were similar at baseline (P-value=0.057). The comparison of the two groups revealed significantly fewer VAS scores at the end, within three and two months after the interventions in phonophoresis with nitroglycerin group (P-value<0.001). Bonferroni test showed that the pain score at the last session of phonophoresis plus hydrocortisone and within three weeks after the end of the intervention was statistically less than the baseline (P-value<0.001), while it was remarkably more within two months after the intervention than the assessments done at the end of the intervention (P-value=0.006) and within three weeks (P-value=0.001). Further assessments about the latter group showed fewer pain scores at the end of the intervention, within three weeks and two months than the baseline (P-value<0.001, Table-2).Evaluation of quality of life distribution based on RM revealed an insignificant difference between the groups at baseline (P-value=0.067); besides, the comparison of the groups showed remarkable better outcomes in the group treated with phonophoresis plus nitroglycerin than the other one in the RM assessments at the end of the interventions (P-value=0.002), within three weeks (P-value=0.008) and two months after the intervention (P-value=0.001, Table-3).As demonstrated in Table-4, the plantar fascia thickness measurements showed a significant reduction in both groups regardless of the intervention type. Nevertheless, the plantar fascia thickness reduction was more prominent among those treated with topical nitroglycerin accompanying with phonophoresis (-0.75±0.27) as compared to the latter group (-0.51±0.18) (P-value<0.001, Figure-2).

The requirement of additional doses of analgesia was remarkably higher among the patients treated with phonophoresis plus hydrocortisone (3759.78±766.69 mg) as compared to those treated with phonophoresis and nitroglycerin (2069.38±998.88 mg, P-value<0.001).

Erythema or pain at the intervention site was represented neither by topical nitroglycerin-treated patients nor those treated with topical hydrocortisone. Headache, as one of the most common adverse effects of nitroglycerin use, was not notified by any of the patients in this group.

Table 1. Demographic Characteristics of the Studied Group

	+Hydrocortisone	+Nitroglycerin	P-value
Age, mean±standard deviation	41.66±7.07	41.90±6.65	0.89
Female: male, n (%)	18 (60): 12 (40)	18 (60): 12 (40)	1*
Body mass index, mean±standard deviation	23.85±2.09	23.26±2.05	0.30**

* Chi-square test
** Independent T-test

Table 2. The Comparison of Pain Severity Alterations between the Studied Groups

Variables	Baseline	End of the interventions	After 3 weeks	After 2 months	Mean differences	P-value*
	mean±standard deviation					
+Hydrocortisone	8.96±0.76	3.48±1.72	3.86±1.55	5.29±1.14	-3.66±0.222	<0.001
+Nitroglycerin	8.50±0.91	1.31±0.93	1.56±0.87	1.91±0.81	-6.59±0.173	<0.001
P-value**	0.057	<0.001	<0.001	<0.001	<0.001	

* Freidman
** Mann-Whitney

Table 3. The Comparison of Modified Roles and the Maudsley Score between the Studied Groups

	Baseline	End of the interventions	After 3 weeks	After 2 months
Phonophoresis with Hydrocortisone Number (%)				
Excellent quality of life	0 (0)	10 (33.3)	7 (23.3)	5 (16.6)
Good quality of life	0 (0)	16 (53.3)	19 (63.3)	17 (56.6)
Acceptable quality of life	14 (46.6)	2 (6.6)	2 (6.6)	6 (20)
Poor quality of life	16 (53.3)	0 (0)	0 (0)	0 (0)
Phonophoresis with Nitroglycerin Number (%)				
Excellent quality of life	0 (0)	23 (76.6)	18 (60)	15 (50)
Good quality of life	0 (0)	5 (16.6)	10 (33.3)	13 (43.3)
Acceptable quality of life	21 (70)	0 (0)	0 (0)	0 (0)
Poor quality of life	9 (30)	0 (0)	0 (0)	0 (0)
Missing	0	2 (6.6)	2 (6.6)	2 (6.6)
P-value	0.067*	0.002**	0.008**	0.001**

* Chi-square test
** Fisher's exact test

Table 4. The Comparison of Plantar Fascia Thickness between the Studied Groups

Variables	Baseline	After 2 months	mean difference	P-value
	mean±standard deviation			
+Hydrocortisone	5.13±0.47	4.61±0.43	-0.51±0.18	<0.001
+Nitroglycerin	5.15±0.55	4.40±0.40	-0.75±0.27	<0.001
P-value	0.87	0.071	0.001	

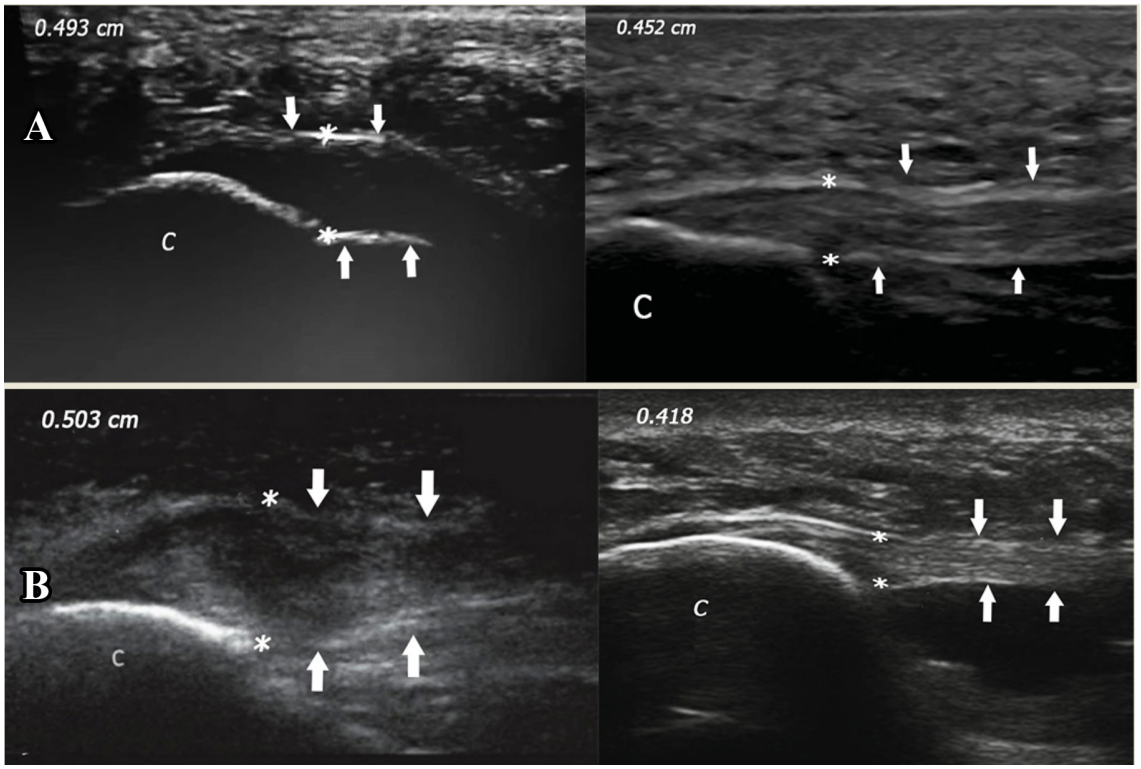

Figure 2. The changes in plantar fascia thickness; **A:** before phonophoresis with topical hydrocortisone (0.493 cm) and after the intervention (0.452 cm); **B:** before phonophoresis with topical nitroglycerin (0.503 cm) and after the intervention (0.418 cm)

Discussion

The current study evaluated the efficacy of phonophoresis in combination with either topical hydrocortisone or topical nitroglycerin on plantar fasciitis management. We observed topical nitroglycerin's superiority over hydrocortisone in pain control, the satisfaction of quality of life, reduction in fascia thickness, and fewer doses of additional analgesia requirement. A remarkable point found in our study was the unsteady quality of life found by the use of both agents; therefore, further interventions or more extended periods of phonophoresis are required to preserve the rehabilitated condition.

Plantar fasciitis is a common painful syndrome leading to significant disability in numerous cases worldwide. This condition leads to several referrals to the physicians and chronically administering analgesics agents and struggle with analgesic-related adverse effects. Nevertheless, despite all of the efforts made to treat PF, the best minimally invasive approach with the ultimate response remained unknown [7].

Phonophoresis is a therapeutic ultrasonographic approach that induces vibration in the affected tissues by producing high-frequency mechanical waves. This modality leads to heat production in the tissues' depth, improvement in the local blood flow, pain relief, regeneration of the injured tissues, and prevention from fibrosis formation [16].

In addition to the mentioned mechanism, Cardoso and colleagues performed an animal study in which they found that phonophoresis has anti-inflammatory and analgesic capacity by inhibition of cyclooxygenase-2 (COX-2) expression and transforming necrotizing factor-alpha (TNF-α) production [17]. Other than for plantar fasciitis, this approach has been successfully used for numerous musculoskeletal conditions [18-20]. Similar to our study, studies in the literature have shown reinforcement of phonophoresis efficacy when combined with topical anti-inflammatory agents such as topical ibuprofen [21], piroxicam [22], and triamcinolone [23].

Topical nitroglycerin is an agent that leads to an increase in the local levels of nitric oxide (NO) within the nearby tissue. In turn, NO causes an increase in the local blood flow, promotion of collagen synthesis, and host defense [24]. Data in the literature favor topical nitroglycerin in acute injuries, but the outcomes are controversial regarding chronic musculoskeletal conditions [14].

We found significant pain relief within two months after the end of the phonophoresis plus topical nitroglycerin compared to the baseline; however, the pain score deteriorated by comparing the last assessment with the end of the interventions or even within three weeks following the intervention. Like our study, most of the studies have represented excellent short-term outcomes and good-to-fair ones in mid-to-long-term follow-ups. Besides, minimal negligible adverse events are one of the advantages of topical nitroglycerin [25].

The current study results showed significant pain relief and improvement in the quality of life among those treated with hydrocortisone, as well; however, the pain relief was notably time-limited. Nevertheless, the outcomes of hydrocortisone use were generally acceptable. Our results were similar to the other studies in the literature regarding topical corticosteroid use for chronic tendinopathies, enthesitis, or epicondylitis, alone or in combination with phonophoresis [26-28]. However, in vitro and in vivo investigations of drug-related complications have revealed a significant local reduction in cell viability, cell proliferation, and collagen synthesis, as well as an increase in collagen disorganization and necrosis [29].

In summary, in the current study, we investigated the efficacy of phonophoresis plus either hydrocortisone or nitroglycerin to manage plantar fasciitis and found acceptable outcomes by both the interventions; however topical nitroglycerin was remarkably superior to the latter one. Our findings were consistent with the literature findings regarding the use of phonophoresis for musculoskeletal conditions and the efficacy and safety of topical nitroglycerin; however, more detailed information is required to achieve the ultimate outcomes for a more extended period.

Conclusion

Based on the current study, phonophoresis plus topical nitroglycerin was superior to phonophoresis plus topical hydrocortisone in pain

relief and its perseverance, improvement in the quality of life, and decreased fascia thickness. However, further investigations are required to achieve the ultimate outcomes for a more extended period.

Conflict of interest

The authors of this study declared no conflict of interest.

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