Original Article

Comparison of High-intensity Laser Therapy with Extracorporeal Shock Wave Therapy in the Treatment of Patients with Plantar Fasciitis: A Double-blind Randomized Clinical Trial

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Abstract

Background: The most common cause of heel pain is plantar fasciitis (PF). Although conservative treatments relieve pain in more than 90% of patients, it may remain painful in some cases. This study aimed to compare High-intensity Laser Therapy (HILT) with Extracorporeal Shock Wave Therapy (ESWT) in patients with PF.

Methods: In this double-blinded randomized clinical trial (conducted in Yazd, Iran, from May 2020 to March 2021), patients were classified into two groups, including the ESWT and HILT, using online randomization. Nine sessions, three times a week for 3 weeks, were the treatment period in both groups. Visual Analogue Score (VAS), Heel Tenderness Index (HTI), and the SF36 questionnaire were compared and analyzed statistically at the beginning and 9 months after treatment.

Results: 38 patients (19 in each group) completed the study. Results showed that pain and patient satisfaction improved significantly 3 months after treatment. The VAS and HTI decreased 3 months after treatment in both groups, which was statistically significant (P<0.001). The SF36 score in both groups increased 3 months after treatment, and this increase was statistically significant (P<0.001). Although the two modalities were effective based on VAS, HTI, and SF36, a significant statistical difference was observed between them (P=0.03, P=0.006, P=0.002, respectively), and the HILT was more effective.

Conclusion: ESWT and HILT decrease pain and increase patient satisfaction in PF. Besides, both methods are non-invasive and safe. However, there is a significant difference between them, and HILT is more effective.

Trial registration number: IRCT20210913052465N1.

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Keywords ● Physical therapy modalities ● Laser therapy ● Fasciitis, plantar ● Conservative treatment ● Patient satisfaction

What's Known

- Shockwave, steroid injection, and surgery effectively reduce pain and inflammation in patients with plantar fasciitis.
- High-intensity laser therapy restores damaged tissues and eliminates painful irritations by stimulating collagen production, increasing blood flow, increasing vascular permeability, and having anti-inflammatory effects.

What's New

- Both extracorporeal shock wave therapy and high-intensity laser therapy are non-invasive, safe, and effective treatment methods for relieving heel pain. There were no significant differences when these two methods were compared. Laser therapy is preferred due to accessibility and less pain and cost.

Introduction

Repetitive microscopic ruptures in plantar fascia in the medial tubercle of calcaneus result in plantar fasciitis (PF).[1] PF causes chronic pain in the adult population[2, 3] and accounts for nearly

11%-15% of all foot symptoms.[4, 5] Although the suffix "itis" expresses an inflammatory mode, there is increasing evidence that shows this disorder is associated with degenerative changes, so better to be called as "fasciopathy" or fasciosis.[6]

The sex ratio of its occurrence is equal.[3] It is often seen in military personnel, sedentary persons, and athletes.[7] Work activities that need a long-standing position, poor biomechanics of the foot, inappropriate ankle dorsiflexion or excessive foot pronation, higher body mass index (BMI), and weakness of muscles are some of the risk factors.[8-11] Calcaneal spurs may be seen in 50% of radiographies, but the diagnosis is clinical and by ruling out other conditions.[12]

There are many treatment options to relieve symptoms, such as modification of daily or job activities, weight reduction, plantar fascia stretch, physiotherapy, ice massage, non-steroidal anti-inflammatory drugs in combination with other treatment modalities, such as shock wave therapy, local steroidal injection, and surgery.[13, 14]

Pain in almost 10% of PF patients cannot be relieved with conservative treatment.[4] Local corticosteroid injection is a low-cost, available, and effective method of treatment.[15] Extracorporeal shockwave therapy (ESWT), as a recent treatment modality, is a kind of short-duration pulse sound wave with a high-pressure amplitude that may cause an analgesic effect by destroying unmyelinated sensory fibers.[16] High-intensity laser therapy (HILT) is another recent method that can improve pain scores in affected patients.[17]

Clinical studies concluded that low-level laser therapy (LLLT) is an effective and promising treatment for chronic PF.[18, 19] In 2019, Wang and colleagues reviewed six studies in a meta-analysis and concluded that LLLT significantly decreases heel pain in patients with PF, and the efficacy of this treatment lasts for 3 months.[20]

Moreover, the effectiveness of different laser therapies in PF treatment has been evaluated in a clinical trial, and it is concluded that both HILT and LLLT improve the level of pain, function, and quality of life in people with PF. However, HILT has a more significant therapeutic effect than LLLT in PF.[17]

Yesil and colleagues conducted a placebo-controlled study to evaluate the efficacy of HILT on pain, foot function, quality of life, and plantar pressure in patients with plantar heel pain. The results of their study indicated improvement in all parameters in both groups except dynamic pedographic measurement. Additionally, results showed no superiority of HILT over the placebo.[21]

Thus, it can be concluded that there is not enough data on using these new modalities and their adverse effects. This study aimed to compare HILT with ESWT in treating patients with PF.

Patients and Methods

In this double-blinded randomized clinical trial, all patients who referred to the Physical Medicine and Rehabilitation Clinic of Sadoughi Hospital, Yazd, Iran, and diagnosed with PF (tenderness in the medial tubercle of calcaneus and heel pain in the first few steps in the morning, which gets worse with increased activity), from May 2020 to March 2021, were included. They were enrolled in this study if they met the inclusion criteria and gave their consent.

Inclusion criteria were age from 18 to 55 years old, diagnosis of PF confirmed by physical medicine and rehabilitation specialist and orthopedic surgeon, no response to conservative treatments such as ice, soft tissue massage, stretching, usage of insoles, and non-steroidal anti-inflammatory (NSAID) drugs after 6 weeks.

Exclusion criteria included having history of foot surgery in the last 6 months, history of corticosteroid injection in the last 6 months, history of surgery for lumbar disc herniation, diagnosis of rheumatologic disease (rheumatoid arthritis, diffuse idiopathic skeletal hyperostosis (DISH), systemic lupus erythematosus (SLE), gout, Sjogren disease, enthesopathy, and so on), history of heel pain due to trauma in the last 3 months, wounds, infections, and tumors in the treatment area, HILT or ESWT contraindications, no desire to participate in the study, use of any medications that interfere with the healing process or affect the pain, such as glucocorticoids and NSAID drugs.

In this research, considering the confidence level of 95% and the test power of 80% and according to the results of previous similar articles were followed,[22, 23] the standard deviation of the pain level is S=1.05. To achieve a significant difference of at least 0.95 in the average pain level in the intervention groups, 19 people were needed in each group. Considering a 25% drop, the number of 25 people for each group was required, using the below formula.

$$h = \frac{\left(Z\frac{\alpha}{2} + Z\beta\right)^2 \times 2S^2}{(\bar{x}_1 - \bar{x}_2)^2}$$

The study was approved by the Ethics Committee of Shahid Sadoughi University of Medical Sciences (IR.SSU.MEDICINE.REC.1399.017) and was also registered in the Iranian Registry of Clinical Trials (IRCT20210913052465N1). This study was

conducted in accordance with the principles of the Declaration of Helsinki and Iran's ethical codes of research, and before participating in the study, the objectives of the research, the entire process, and its benefits were explained to the participants. Additionally, written informed consent was obtained.

All patients who participated in this study were randomized to HILT or ESWT groups. A random sequence was created using online randomization on www.random.org/integres https://www.random.org/integers/, with a 1:1 allocation using random block sizes of four. Then, the participants were placed in two groups based on their envelopes and codes by the physical medicine and rehabilitation residents. Both the participants and the researcher were unaware of the type of intervention, and the intervention was performed on them by a physical medicine and rehabilitation resident.

Group A received stretching exercises, insoles (if needed), and ESWT, and Group B received stretching exercises, insoles (if needed), and HILT. Medication modalities and adverse effects were described for all patients in the treatment process. Since these services are not covered by insurance, the used equipment was donated, and HILT and ESWT were performed by residents. Therefore, free services were provided to avoid imposing costs on patients. Exercises included towel stretching, plantar fascia stretching, standing calf stretching, and towel pickup, performed three times a day for 2 weeks.

ESWT therapy was done using a Master plus MP100 Shock wave device (STORZ MEDICAL, Switzerland) in the low energy mode.

The first step was done by an R15 transmitter, Bar 2-3, Pulse 3000, and 12 MHZ frequency. The second was done using a D20-S transmitter, Bar 1.8-3, Pulse 3000, and 15 MHZ frequency.

HILT was performed using an Nd: YAG Laser Source GaIA'S (GIGAA LASER, VELASII-30B, United Kingdom) 980±10 nm device.

The device was applied to the plantar fascia area with a voltage of 30 W, a dosage of 8 J/cm^2, and a spot beam diameter area of 10 cm^2.

In both groups, the patient was in a prone position, and treatment was applied to the plantar fascia. Patients' feet were examined and scanned at first, and an insole was administered if needed (such as in patients with *pes planus* or *pes cavus* or other structural disorders in the feet).

In both groups, the treatment period was nine sessions, three times a week, for 3 weeks. Patients were asked to complete the SF-36 questionnaire before the start of treatment and 3 months after the end of treatment. The 36-question quality of life questionnaire (SF-36) has 36 questions and consists of eight subscales including physical function and role disturbance due to physical health. Pain and general health are categorized as physical health and role disturbance due to emotional health, energy/fatigue, emotional well-being, and social functioning are categorized as physical and mental health. Each item is scored from 0 to 100. Scores that are closer to 100, represent a higher quality of life.

The validity and reliability of the Persian version of this questionnaire have been investigated and confirmed in the Montazeri and colleagues' study. They evaluated the reliability of this scale with "internal consistency" and their results showed that except for the Vitality scale (α=0.65), other scales have minimum standard reliability coefficients (0.77 to 0.9).[24] In the current study, nine experts evaluated and confirmed the validity of this scale, with the following results: CVI=0.87 and CVR=0.90.

Visual Analogue Scale (VAS) and Heel Tenderness Index (HTI) were evaluated at the start of treatment and after three months. VAS is one of the scales used for pain rating and is scaled from 0 to 10, where 0 means no pain, and 10 is the most severe pain the patient has experienced. Depending on the amount of pain in the last 48 hours, the person marks it. (0-1: no pain, 2-3: mild pain, 4-5: severe pain, 6-7: very bad pain, 8-9: maximum pain, 10 unbearable pain).[25] HTI is scaled between 0 and 3 when touching the heel (0: no pain, 1: only causes pain, 2: pain with the whine, 3: pain with the whine and withdrawal).

Statistical Analysis

Data analysis was done using SPSS version 22.0 (SPSS, Chicago, IL). The primary characteristics of the patients were reported for quantitative variables as (mean±SD or median [first quartile-third quartile] and for qualitative variables as frequency (percentage). Data distribution was checked using the Shapiro-Wilk test. Paired *t* test was used for the paired comparison of VAS, HTI, SF36, and physical and mental health scores at different times in each group. To compare the effectiveness of two different modalities on pain, an analysis of covariance was used. The homogeneity of variable variances was confirmed using Leven's Test (P>0.05). The significance level of the test was considered to be 5%.

Results

Patient Characteristics

Fifty patients with PF participated in this

randomized clinical trial (RCT). 25 patients received ESWT, and 25 others received HILT. Three patients from the HILT group and three patients from the ESWT group were excluded from the study due to discontinued treatment sessions. Additionally, one patient from the ESWT group was excluded from the study due to bruising. In the continuation of the study process, two patients from the ESWT group and one patient from the HILT group were excluded from the study due to corticosteroid injection, and two patients were lost to follow-up. Finally, 19 people in each group successfully completed the RCT. The flowchart of the study is presented in figure 1.

The results of the present study showed that the majority of participants (71.1%) were men. There is no significant difference between the average age (P=0.77), BMI (P=0.63), and sex (P=0.57) in the ESWT and HILT groups. The frequency distribution of gender was the same in the two treatment groups. Demographic data and measurement results of the patients are presented in table 1.

According to table 2, a one-way ANCOVA was used to compare the effectiveness of two modalities based on VAS, HTI, SF36, and mental and physical health scores. The homogeneity of the variable variances was confirmed using Leven's Test (P>0.05). The results of the test by adjusting the effect of before-treatment scores showed that there was a significant difference in the mean of VAS between these two groups, so that the patients of the HILT group reported less pain (P=0.03). In addition, the HTI mean scores in the ESWT group were significantly less than in the HILT group (P=0.006). Moreover, SF36 and physical health and mental health scores were significantly higher in the HILT group than in the ESWT group (P=0.002, P<0.001, and P=0.008, respectively).

Furthermore, the results of the paired *t* test showed that the decrease of VAS and HTI and the increase of SF 36, physical health, and mental health scores, three months after the treatment compared to before the treatment in each group, was statistically significant.

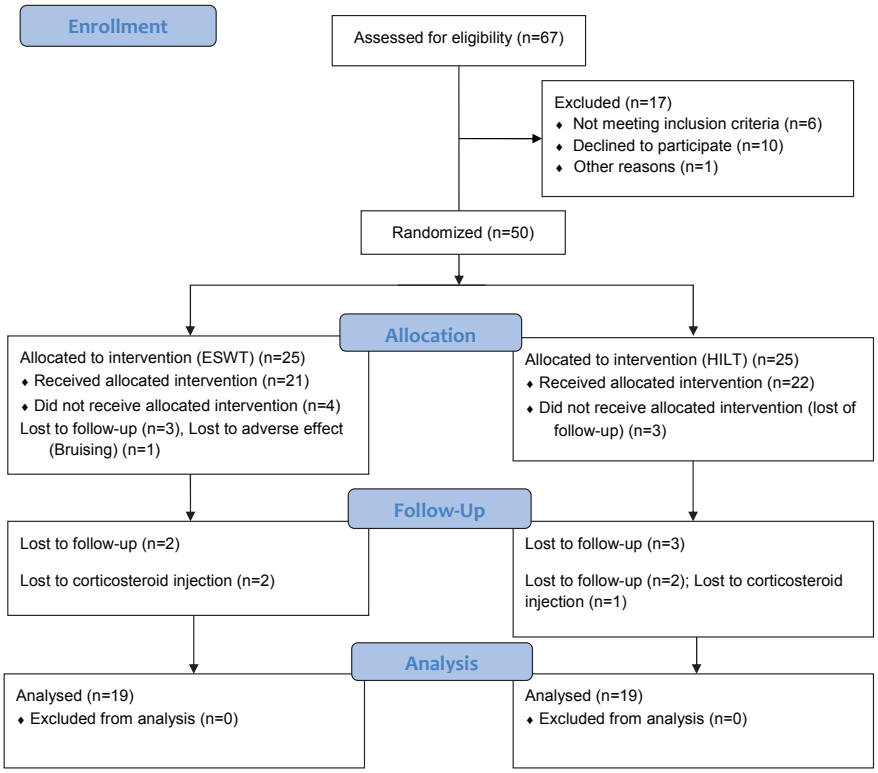

Figure 1: This figure represents the CONSORT flow diagram of the study.

Table 1: Patient demographic information

Variables		Total	ESWT	Laser	P value
Sex	Male	27(71.1)	16 (84.2%)	11 (57.9%)	0.57
	Female	11(28.9)	3 (15.8%)	8 (42.1 %)	
Age		44.65±8.20	45.05±6.85	44.26±9.53	0.77
BMI		27.2±3.51	26.92±3.11	27.47±3.94	0.63

Independent samples *t* test was used. P<0.05 was considered significant. ESWT: Extracorporeal shock wave therapy; BMI: Body mass index

Table 2: Comparison of the HTI, VAS, SF36, and physical and mental health scores within and between the two groups

Variables		ESWT Group Mean±SD	HILT Group Mean±SD	P value Between two Groups
VAS Scores	Before Treatment	7.68±1.53	7.36±1.77	0.03**
	After 3 months	1.68±1.63	1.67±0.99	
In each group at different intervals	P value	<0.001*	<0.001*	
HTI Scores	Before Treatment	2.68±0.95	2.84±0.83	0.006**
	After 3 months	0.42±0.50	0.53±0.69	
In each group at different intervals	P value	<0.001*	<0.001*	
SF36 Scores	Before Treatment	51.42±20.63	59.36±20.51	0.002**
	After 3 months	66.05±14.49	71.52±14.25	
In each group at different intervals	P value	<0.001*	<0.001*	
Physical Health Scores	Before Treatment	48.73±20.70	57.63±18.84	<0.001**
	After 3 months	64.21±14.17	69.58±12.83	
In each group at different intervals	P value	<0.001*	<0.001*	
Mental Health Scores	Before Treatment	56.42±21.91	61.16±22.32	0.008**
	After 3 months	66.79±17.87	71.42±16.69	
In each group at different intervals	P value	<0.001*	<0.001*	

*Paired *t* test was used for comparing variable scores in each group at different intervals, **One-way ANCOVA and Leven's Test were used for comparing variable scores between the two groups. P<0.05 was considered significant. SF36: 36-item short form survey; HTI: Heel tenderness index; VAS: Visual analogue scale; ESWT: Extracorporeal shock wave therapy; HILT: High-intensity laser therapy

Discussion

In this randomized study, we compared two different PF therapies. After the intervention, the score of pain considering the VAS decreased after 3 months in both ESWT and HILT groups, which was statistically significant. Comparing these modalities showed that HILT is more effective.

Similarly, both treatment groups showed a significant decline in HTI scores 3 months after treatment. However, the difference between the ESWT and HILT groups was significant, and the ESWT was more effective.

SF36 and physical and mental health scores improved significantly 3 months after treatment in both ESWT and HILT groups. However, the difference between these two groups was statistically significant, and the HILT was more effective.

Our results were consistent with previous similar studies, which suggest both ESWT and HILT modalities have benefits in reducing pain caused by PF. Similar to our results, a significant improvement in VAS scores was seen at 12 and 24 weeks following ESWT, in the studies by Gollwitzer and colleagues[26] and Dastgir,[27] respectively. VAS score decreased and heel pain improved by 60% in a study by Aqil and others,[28] who compared ESWT with a placebo.

Two other research teams, Kudo and colleagues[29] and Malay and others,[30] also found statistically better outcomes in patients treated with ESWT than those treated with a placebo, whereas Buchbinder and others[10] and Haake and colleagues[31] did not find a significant difference between ESWT and placebo.

Moreover, ESWT was introduced as a safe and effective method for treating chronic pain,[28] which is similar to our findings. Cosentino and colleagues evaluated the ESWT method in patients with heel pain and found a statistically meaningful decrease in VAS scores. They claimed that ESWT is effective in relieving pain, inflammation, and edema.[32] Again in another similar study, ESWT was recommended as a non-invasive method in the treatment approach before surgery.[33]

In contrast to our study, Rompe and colleagues treated their patients with stretching or low-energy shock wave therapy and reported a better mean change in foot function index cumulative score and more patient satisfaction in the stretching group.[34] Again in a study by Speed and others, shock wave therapy was ineffective compared to a placebo in a group of adults with PF.[35]

The differences between studies on ESWT efficacy in patients with PF may be multifactorial, including different study populations, using various machines or methods, and variations in treatment parameters such as intensity, focus target, and focal energy of shock waves. Additionally, using different outcome measuring

scales may cause bias in the comparison between various studies. There is no consensus on the best dosage and other treatment parameters of ESWT for PF.

Guimaraes and others conducted a systematic review and compared LLLT to ESWT in the treatment of patients with PF. They concluded that LLLT may improve pain in the short term and can be considered a component of PF patients' care. However, this superiority is not clear compared to ESWT.[36]

Koz and colleagues compared the efficacies of ESWT and LLLT in the treatment of PF patients. The results of this study indicated a significant reduction in pain, and an improvement in functional status, and daily life activities for both treatments. It also showed that the use of LLLT is more effective than ESWT in reducing pain.[37] Tkocz and others investigated the effect of HILT versus a placebo-controlled group on the management of painful heel spurs and PF. They found no statistically significant differences between the two groups. They concluded that HILT does not appear to be more effective in managing pain in patients with heel spurs and PF than standard conservative methods of physical therapy.[38]

According to Yesil and others, no difference between HILT and placebo was found in terms of pain, quality of life, and functionality in the management of painful calcaneal spur. However, they found a significant difference in favor of HILT in dynamic pedographic measurements.[21]

A systematic review by Ezzati and others suggested that it cannot yet be concluded that HILT is an effective non-invasive treatment for managing musculoskeletal pain. However, this treatment may have benefits in some conditions. As a result, to determine the effect of HILT on pain reduction, long-term and randomized controlled trials with appropriate methodological designs are needed.[39]

Dovile and colleagues conducted a randomized participant-blind controlled trial study and compared the HILT with LLLT in the management of PF. Their results showed that there is no statistically significant difference between the two groups according to VAS, pressure algometry, and sonography measurements. Although the reduction of plantar fascia thickness 3 weeks from baseline was statistically significant in the HILT group, and this reduction in HILT may be faster than LLLT, there was no statistically significant difference between the two groups.[40]

Ordahan and colleagues investigated the effect of HILT versus LLLT in the management of PF. They concluded that all evaluated parameters, including VAS and HTI scores, and FAOS showed significant improvements after 3 weeks of treatment in both groups. The improvement of all parameters in the HILT group was more significant than in the LLLT group.[17]

Although many studies show the efficacy of low-intensity laser therapy (LILT) in PF, few investigations have examined the effect of HILT in PF treatment. LILT and HILT are the two most commonly used laser methods in musculoskeletal disorders.

One of the limitations of the present study is the lack of long-term follow-up results. However, we believe that our study is valuable because it is one of the first studies in the literature to compare ESWT and HILT in patients with PF.

Another limitation of our study was the minimum number of treatment sessions due to specific conditions caused by the COVID-19 pandemic. To strengthen the findings of the research, more studies are suggested to be done with further treatment sessions, larger sample sizes, and a higher number of investigation groups, including control groups with placebo, to make a better comparison of the treatment methods.

Conclusion

As seen in our study, both ESWT and HILT treatment methods are non-invasive, safe, and effective therapies in relieving heel pain based on different pain scales and patient satisfaction questionnaires. However, HILT is preferred because it is more effective in the improvement of pain (based on VAS) and quality of life and is also more accessible with less pain and cost.

Authors' Contribution

M.ZB: Study conception, study design, data acquisition, data analysis, and interpretation, drafting the manuscript; MR.VN: Study conception, study design, revising the manuscript critically; A. Kh A: Study conception, study design, data acquisition, revising the manuscript critically; All authors have read and approved the final manuscript and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Conflict of Interest: None declared.

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