

# Extracorporeal shock wave therapy of gastroc-soleus trigger points in patients with plantar fasciitis: A randomized, placebo-controlled trial

Alireza Moghtaderi, Saeid Khosrawi, Farnaz Dehghan

Department of Physical Medicine and Rehabilitation, Isfahan University of Medical Sciences, Isfahan, Iran

## Abstract

**Background:** Plantar fasciitis is the most common cause of heel pain. Extracorporeal shock wave therapy (ESWT) is an alternative treatment for refractory cases of plantar fasciitis. Studies also demonstrated that ESWT may be an appropriate treatment for myofascial trigger points. This study was designed to evaluate its effectiveness by comparing the ESWT of *Gastrocnemius/Soleus* (gastroc-soleus) trigger points and heel region with the ESWT of the heel region alone.

**Materials and Methods:** The study was carried out among 40 patients with a clinical diagnosis of plantar fasciitis, divided randomly to case (n = 20) and control (n = 20) groups. The case group received ESWT for the heel region and for the gastroc-soleus trigger points. The control group received ESWT just for the heel region. The protocol was the same in both groups and they were treated for three sessions every week. The pain score (100 mm visual analog score [VAS]) and the modified Roles and Maudsley score was evaluated before the first session and eight weeks after the last session.

**Results:** Eight weeks after the last session, although the mean VAS had decreased significantly in both groups, this decrement was more significant in the case group. ( $P = 0.04$ ). According to the modified Roles and Maudsley score, there was a significant improvement in both the case ( $P < 0.001$ ) and control ( $P = 0.01$ ) groups, eight weeks after treatment, but there were significantly better results in the case group.

**Conclusion:** The combination of ESWT for both plantar fasciitis and gastroc-soleus trigger points in treating patients with plantar fasciitis is more effective than utilizing it solely for plantar fasciitis.

**Key Words:** Extracorporeal shock wave therapy, plantar fasciitis, trigger points

## Address for correspondence:

Dr. Saeid Khosrawi, Department of Physical Medicine and Rehabilitation, Faculty of Medicine, Isfahan University of Medical Sciences, Sofeh St., Isfahan, Iran.  
E-mail: [khosrawi@med.mui.ac.ir](mailto:khosrawi@med.mui.ac.ir)

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## INTRODUCTION

Plantar fasciitis is the most common cause of inferior heel pain, and may account for up to 15% of all foot symptoms requiring professional care among adults. Plantar fasciitis affects women slightly more often than men.<sup>[1]</sup> The incidence peaks between the ages of 40 and 60 years.<sup>[2]</sup> Increased bodyweight and work on

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hard surfaces are the risk factors.<sup>[3-5]</sup> Reduced range of ankle dorsiflexion is associated with plantar fasciitis,<sup>[3]</sup> as are calf and hamstring tightness.<sup>[6]</sup>

A great variety of therapies have been reported for the treatment of plantar fasciitis, including local steroid injections, platelet-rich plasma, intralesional botulinum toxin A (BTX-A), extracorporeal shock wave therapy, and a combination of all of these treatments with stretching exercises of the gastrocnemius and soleus muscles, or the plantar fascia.<sup>[7-14]</sup> Additionally, the effectiveness of trigger point needling in relieving plantar heel pain has been shown in some studies.<sup>[15-17]</sup> Some studies have also demonstrated that ESWT may be an appropriate treatment for myofascial trigger points.<sup>[18,19]</sup>

As there is a lack of studies evaluating the effectiveness of ESWT of the gastroc-soleus trigger points in the treatment of plantar fasciitis, we designed this study to evaluate its effectiveness by comparing ESWT of the gastroc-soleus trigger points and heel region with the ESWT of the heel region alone.

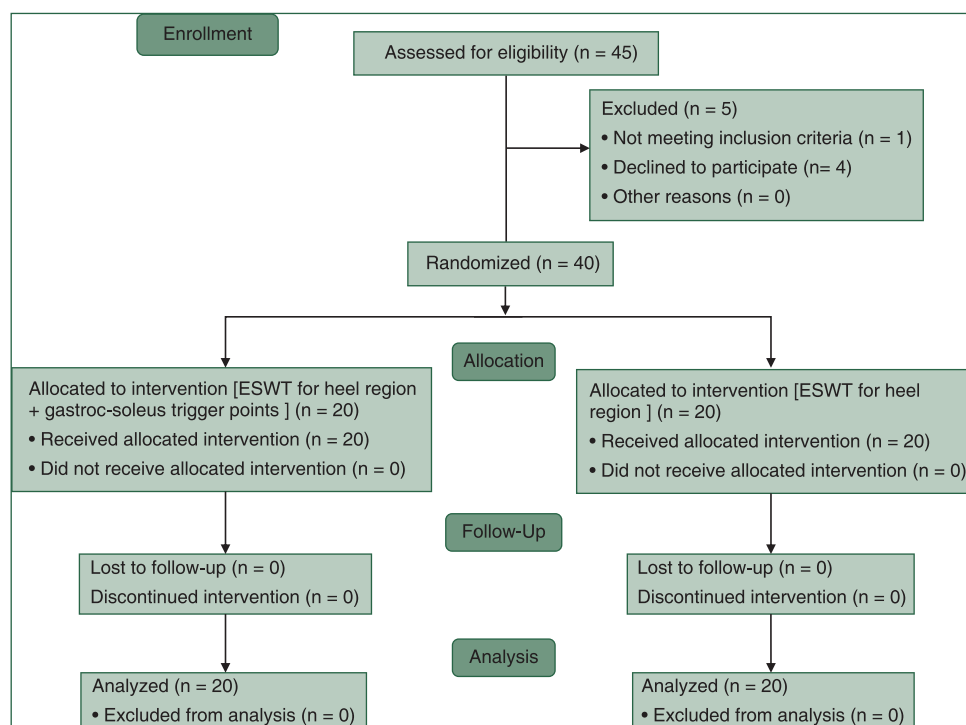
## MATERIALS AND METHODS

This study is a randomized, placebo-controlled trial, which was carried out from March 2012 to November 2012, among 40 patients, with a clinical diagnosis of plantar fasciitis, referred to the Outpatient Clinics of Kashani University Hospital, Isfahan, Iran [Figure 1]. The patients who met the following inclusion criteria

were included into the study: (1) Patients who had heel pain felt it localized to the site of the insertion of the plantar fascia and intrinsic muscles on the medial calcaneal tuberosity on the anterior-medial aspect of the heel for at least six months. (2) Patients who had at least one gastroc-soleus trigger point concomitantly. (3) Patients who did not respond to conservative treatments for at least three months. (4) Patients who were between 20 and 60 years of age, and had signed the informed consent form.

Exclusion criteria of the study were: (1) Dysfunction of the knee or ankle, local arthritis, generalized polyarthritis, rheumatoid arthritis, ankylosing spondylitis, and Reiter syndrome. (2) Neurologic abnormalities. (3) Bleeding tendency (hereditary or acquired). (4) Nerve entrapment syndromes such as the tarsal tunnel syndrome. (5) Previous operation on the heel. (6) Pregnancy. (7) Evidences of infection in the lower limbs. (8) Medical history of tumor. (9) Patients who had received local corticosteroid injection within 12 weeks.

The patients were divided randomly into case (n = 20) and control (n = 20) groups. The case group received extracorporeal shock wave therapy (ESWT) (3000 shock waves/session of 0.2 mJ/mm<sup>2</sup>) for the heel region and (400 shock waves/session of 0.2 mJ/mm<sup>2</sup> per each trigger point) for the gastroc-soleus trigger points. The control group received ESWT (3000 shock waves/session of 0.2 mJ/mm<sup>2</sup>) for just the heel region. The



**Figure 1:** CONSORT 2010 Flow Diagram of randomized clinical trial: number of participants screened, randomized, and retained and analyses

protocol was the same in both groups and they were treated for three sessions every week. The Duolith SD1 shock wave machine was used and shock waves were applied to the site of maximum local tenderness.

The pain score (100 mm visual analog score [VAS]) and the modified Roles and Maudsley score were evaluated before the first session and eight weeks after the last session. The modified Roles and Maudsley score was a patient-administered scoring system (see table A on [bmj.com](http://bmj.com)).<sup>[20]</sup>

The article has been submitted and registered in [www.clinicaltrials.gov](http://www.clinicaltrials.gov) as RCT number: NCT01786057.

### Statistical analysis

Statistical analyses were performed using the statistical package for social sciences (SPSS) statistical package version 13.0 (SPSS Inc., Chicago, IL, USA). Independent sample t-test or Mann–Whitney U-test, paired t-test or Repeated Measure ANOVA test, and the Chi Chi-square test were used to assess the differences between stages, as appropriate. A *P*-value less than 0.05 was considered significant.

### RESULTS

Among 45 patients who had plantar fasciitis, five patients did not pass the screening protocol because they refused treatment (four patients), or were withdrawn because of violation of the selection criteria at entry (one patient).

A total number of 40 patients were investigated after taking anamnesis and a thorough physical examination. In case group there were seven males (35%) and 13 females (65%) and the control group had six males (30%) and 14 females (70%). According to gender there was no significant difference between the two groups.

The results showed that the mean VAS scores did not differ significantly before treatment between the case and control groups (*P* < 0.001). Eight weeks after the last session, the mean VAS was significantly lower in the case group (*P* < 0.05). Although the mean VAS had decreased significantly in both groups, this decrement was more significant in the case group. (*P* = 0.04) [Table 1].

According to the modified Roles and Maudsley score, there was no significant difference between the baseline scores of the two groups (*P* = 0.86). The results revealed that there was a significant improvement in both groups eight weeks after the last session, but the Wilcoxon test showed significantly better results in the case group [Table 2].

Power analysis demonstrated that a sample size of 20 plantar fasciitis groups would be necessary to show that ESWT for both the gastro-soleus trigger points and the heel region was more accurate than ESWT for the heel region solely. ( $\alpha = 0.05$ ;  $\beta = 0.80$ ). Here, the power of the test means the probability of rejecting the null hypothesis, given that the alternative hypothesis is true. The result is a decision regarding the sample size at a given  $\alpha$  level (0.05) and statistical power (0.80).

### DISCUSSION

As we have described, in recent years, several treatment options, including dry needling, injection of therapeutic medications (local anesthetics, steroids, botulinum toxin A), and ESWT have been studied for plantar fasciitis treatment.<sup>[7-17]</sup> The local steroid injection is an alternative treatment, which is commonly used for refractory plantar fasciitis. It has been shown that it may cause plantar fascia rupture, fat pad atrophy, lateral plantar nerve injury secondary to injection, and calcaneal osteomyelitis.<sup>[21,22]</sup> During the past decade, ESWT has been used increasingly worldwide, and based on some well-controlled trials, it has been recently approved by the food and drug administration (FDA) for treatment of plantar fasciitis in the United States of America.<sup>[23]</sup>

It is a relatively safe procedure and can be considered before any surgical treatment. It may be preferable to try it before a local steroid injection.<sup>[24]</sup> Its proposed mechanism is cavitation of the deep tissue, which causes

**Table 1: Comparison of the visual analog scale scores before and after treatment within the case and control groups**

Time	Case Mean+/-SD	Control Mean+/-SD
Before treatment	7+/-1.3	6.6+/-1.4
Eight weeks after treatment	3+/-0.9	4+/-1.1
<i>P</i> -value	< 0.001	0.02

SD: Standard deviation

**Table 2: Comparison of results of modified Roles and Maudsley score before and eight weeks after treatment in the case and control groups**

Score	Time	Group	
		Case	Control
Excellent	Baseline	1	1
	Eight weeks after treatment	6	3
Good	Baseline	4	5
	Eight weeks after treatment	10	9
Acceptable	Baseline	10	9
	Eight weeks after treatment	2	5
Poor	Baseline	5	5
	Eight weeks after treatment	2	3
<i>P</i> value		< 0.001	0.01

micro rupture of capillaries, leakage of the chemical mediators, and promotion of neovascularization of the damaged tissue.<sup>[25]</sup> A study demonstrated that ESWT contributes to healing and pain reduction in plantar fasciitis, and ultrasound imaging is able to depict the morphological changes related to plantar fasciitis as a result of this therapy.<sup>[26]</sup>

A quasi-experimental trial using 1% lidocaine injections for the myofascial trigger points, has found a reduction in pain, when combined with physical therapy.<sup>[19]</sup> Two trials have investigated the effectiveness of trigger point needling in relieving plantar heel pain.<sup>[15,16]</sup> Another study shows that trigger point dry needling by improving the severity of heel pain, can be used as a good alternative option before proceeding to more invasive therapies of plantar fasciitis, despite the insignificant effect on the range of motion of the ankle joint.<sup>[17]</sup>

In this study we compared the effectiveness of ESWT for both the heel region and gastro-soleus trigger points with ESWT just for the heel region. As the results showed, although both VAS and the modified Roles and Maudsley score had improved in both groups, the results were significantly better in the case group compared to the control group. This difference could be due to the fact that the myofascial trigger points of the calf muscles played an important role in pain perception and functional impairment of patients with plantar fasciitis. The improvement in both groups was consistent with the other studies that examined the effectiveness of ESWT in plantar fasciitis.

Indeed, as we performed this study to evaluate the effectiveness of ESWT for gastro-soleus trigger points in plantar fasciitis, we did not compare the different methods for applying that (e.g., radial vs. focus). Further studies are recommended to find out the mechanisms of action of ESWT on gastro-soleus trigger points during the treatment of plantar fasciitis, along with comparing the different methods, to find the best method and dosage.

On the basis of our findings, in summary, it can be stated that a combination of ESWT for both plantar fasciitis and gastro-soleus trigger points in treating patients with plantar fasciitis is more effective than utilizing it solely for plantar fasciitis.

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