



ORIGINAL RESEARCH

# Ultrasound-Guided Pulsed Radiofrequency Stimulation of Posterior Tibial Nerve: A Potential Novel Intervention for Recalcitrant Plantar Fasciitis

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## Abstract

**Objective:** To evaluate the therapeutic benefit of ultrasound-guided pulsed radiofrequency (PRF) stimulation at the posterior tibial nerve (PTN) in patients with recalcitrant plantar fasciitis (PF).

**Design:** A prospective, randomized, double-blinded, placebo-controlled trial (12-wk follow-up).

**Setting:** Outpatient local medical center settings.

**Participants:** Patients (N=36) with recalcitrant PF underwent randomization, and all were included in the final data analysis.

**Interventions:** Patients in the PRF group were treated with 1 dose of ultrasound-guided PRF stimulation at the PTN, and those in the control group received 1 dose of 2% lidocaine, 0.5mL, injected at the PTN under ultrasound guidance.

**Main Outcome Measures:** The visual analog scale (first-step and overall pain), American Orthopedic Foot-Ankle Society (AOFAS) ankle-hindfoot scale, and ultrasonographic thickness of the plantar fascia were evaluated at 1, 4, 8, and 12 weeks after treatment.

**Results:** Thirty-six patients (20 feet per group) completed the study. The PRF group had a significantly larger improvement in first-step pain, overall pain, and AOFAS score (all  $P<.001$ ), as well as plantar fascia thickness ( $P<.05$ ), compared with those of the control group at all observed time points.

**Conclusions:** This study shows that ultrasound-guided PRF stimulation at the PTN is effective for treating recalcitrant PF. This simple, reproducible method could be a novel strategy for managing recalcitrant PF.

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Plantar fasciitis (PF) is a widespread primary origin of heel pain. The prevalence ranges from 3.6% to 7% in the general population and up to 8% in running-related injuries.<sup>1</sup> The typical symptoms of PF include pain at the medial plantar heel, particularly during the initial few steps out of bed, with progressive relief with ambulation. Moreover, the heel pain sometimes worsens with prolonged standing or resting.<sup>2</sup>

Although approximately 90% of patients with PF respond satisfactorily to conservative therapy (ie, treatment with rest, stretching, analgesic agents, physical therapy, arch support, night splints, shoe modifications, or steroid injections) within 10 to 15 months,<sup>3,4</sup> the remaining 10% of patients may need invasive or surgical intervention.<sup>5,6</sup> Extracorporeal shock wave therapy (ESWT) and platelet-rich plasma may be other therapeutic options for recalcitrant PF, but have variable success rates.<sup>7</sup> Invasive strategies, including calcaneal spur excision and fasciotomy, are not always successful (success rate between 50% and 95%), and the risk of complications and long (4–8 months) recovery periods limit their clinical value.<sup>8,9</sup> Therefore, it is important to identify a novel presurgical intervention for recalcitrant PF.

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Pulsed radiofrequency (PRF) is designed to create bursts of heat through the delivery of an electrical field. The short bursts allow for the alleviation of pain in neural tissue, while allowing the tissue to maintain a temperature below 42°C, preventing the nerve damage associated with conventional radiofrequency.<sup>10</sup> Many studies<sup>11,12</sup> have confirmed the effectiveness of PRF for multiple pain conditions. Recent studies have successfully applied ultrasound-guided PRF stimulation to the medial nerve (carpal tunnel syndrome),<sup>13</sup> suprascapular nerve (adhesive capsulitis),<sup>14</sup> interscalene brachial plexus (neoplastic plexopathic pain),<sup>15</sup> intercostal nerve,<sup>16</sup> trigeminal nerve (trigeminal neuralgia),<sup>17</sup> and sciatic nerve (chronic knee pain).<sup>18</sup> The ultrasound-guided technique offers improved quality of regional nerve blocks and limits neural trauma.<sup>19</sup> Moreover, ultrasound is radiation-free, more affordable, and more expedient than the computerized tomography and fluoroscopy that are conventionally performed for PRF guidance.

Some studies<sup>2,20-23</sup> have observed beneficial long-term effects of radiofrequency neural ablation (RFNA) of the medial calcaneal nerve (MCN) (a branch of the posterior tibial nerve [PTN] with sensory innervations at the posterior heel) in patients with chronic PF or neurogenic heel pain. Unfortunately, these studies did not include control groups and, because of the dependence of the procedure on fluoroscopic guidance, the procedures are inconvenient for clinical practice. The first report of PRF for neural ablation in patients with PF was reported by Thapa and Ahuja<sup>24</sup> in 2014. They performed the first successful PRF stimulation at the MCN with the assistance of transcutaneous nerve stimulation in 3 patients with PF. Furthermore, Chon et al<sup>25</sup> first used ultrasound-guided PRF stimulation of the PTN to treat 2 patients with recurrent tarsal tunnel syndrome. We hypothesized that ultrasound-guided PRF stimulation of the PTN might be effective and more convenient for recalcitrant PF than conventional RFNA.

The purpose of this study was to assess the therapeutic benefit of ultrasound-guided PRF stimulation at the PTN in patients with recalcitrant PF.

## Methods

### Study design

This prospective, randomized, double-blinded, placebo-controlled study was conducted at a single medical center from September 2014 to July 2016. It was reviewed and approved by the institutional review board of the Tri-Service General Hospital (no. 1-102-05-095), and all enrolled subjects gave their written, fully informed consent for this study. This trial was registered with [ClinicalTrials.gov](https://clinicaltrials.gov) (registration no.: NCT02242513). Forty-five patients with diagnosed recalcitrant PF were screened for eligibility; of these, 36 patients were enrolled in this study. Patients were block-randomized with a 1:1 ratio into PRF and control

groups by an independent researcher using computer-generated randomized study numbers.<sup>a</sup>

The participants in the PRF group received 1 dose of ultrasound-guided PRF stimulation at the PTN. The patients in the control group received 1 dose of ultrasound-guided lidocaine at the PTN. All participants were instructed to refrain from any additional treatments for PF discomfort, including analgesic agents, physical therapy, local injections, ESWT, platelet-rich plasma, or surgery throughout the follow-up period; patients were required to disclose the use of any of these therapies.

### Inclusion and exclusion criteria

The inclusion criteria were as follows: active PF for  $\geq 6$  months with tenderness at the origin of the plantar fascia on the calcaneal tuberosity<sup>2</sup>; plantar fascia thickness of  $>4$ mm, measured by ultrasonography<sup>26,b</sup>; and lack of relief with conservative therapy (ie, rest, orthoses, stretching, strengthening exercises, analgesic agents, steroid injections, or ESWT). The exclusion criteria were as follows: inflammatory arthritis, neurologic defects of the foot, leg length discrepancies, coagulopathy, infection, cancer, peripheral vascular disease, pregnancy, previous surgery on the plantar fascia or heel, previous platelet-rich plasma injection, and previous ESWT or local steroid injections within 3 months of the study.

### Ultrasound-guided PRF stimulation and lidocaine injection of PTN

The same physician performed the ultrasound-guided PRF stimulation or lidocaine injection of the PTN. Patients lay in the prone position with slight ankle eversion. Musculoskeletal ultrasonography<sup>b</sup> was used for guidance (fig 1A). The high-frequency linear probe was placed just posterior to the medial malleolus. The PTN, vein, and artery were identified, and a 54-mm radiofrequency probe with a 4-mm active tip was inserted in-plane near the PTN (fig 1B). When the needle tip was clearly visualized, the PRF stimulation was applied for 120 seconds at 2Hz, with a 30-millisecond pulse width at 42°C.<sup>13,14</sup> In the control group, the same ultrasound-guided technique was performed, and 0.5mL of 2% lidocaine was injected around the PTN. To facilitate true blinding of the study, several procedures were taken during treatment including not using sensory or motor testing before PRF stimulation, turning off the sound of the radiofrequency generator, covering the patient's head, and increasing the volume of music in the room. All patients were observed for 30 minutes after the injection and were discharged with no significant complications (eg, pain, bleeding, weakness) except for some numbness of the plantar area in the control group.

### Outcome measurements

The same physiatrist, who was blinded to the randomization and treatment procedures, carried out all outcome measurements. Outcome measurements were performed before PRF stimulation and 1, 4, 8, and 12 weeks after stimulation.

#### Primary outcome: first-step pain

First-step pain was defined as the average intensity of heel pain when getting up in the morning over the previous week.<sup>27</sup> Pain severity was measured by the visual analog scale, where 10 points indicated extremely severe pain and 0 points indicated no pain.<sup>28</sup>

#### List of abbreviations:

|       |                                            |
|-------|--------------------------------------------|
| AOFAS | American Orthopedic Foot and Ankle Society |
| ESWT  | extracorporeal shock wave therapy          |
| MCN   | medial calcaneal nerve                     |
| PF    | plantar fasciitis                          |
| PRF   | pulsed radiofrequency                      |
| PTN   | posterior tibial nerve                     |
| RFNA  | radiofrequency neural ablation             |

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