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NEUROPATHIC PAIN (A. ABD-ELSAYED, SECTION EDITOR)

A Systematic Review of Radiofrequency Treatment of the Ankle for the Management of Chronic Foot and Ankle Pain

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Abstract

Background Chronic pain of the lower extremity remains challenging to manage. Radiofrequency treatment applies heat to nerve fibers with the goal of mitigating chronic pain conditions. The clinical efficacy has not yet been adequately established for pathologies of the ankle and foot. In this review paper, we report the use and efficacy of radiofrequency treatment applied to foot and ankle pain.

Recent Findings PubMed and the Cochrane Controlled Trials Register were searched (final search 30 March 2018) using the MeSH terms "radiofrequency ablation," "neurolysis," "radiofrequency therapy," "pain syndrome," "analgesia," "plantar heel pain," "plantar fascitis," and "chronic pain" in the English literature. Of the 23 papers screened, 18 were further investigated for relevance. Our final search methodology yielded 15 studies that investigated the use of radiofrequency treatment at the ankle. Of these 15 studies, there were three randomized control trials, four prospective studies, three retrospective studies, and five case reports. The quality of selected publications was assessed using the Cochrane risk of bias instrument.

Summary The evidence from our studies suggests that radiofrequency treatment can be used safely for the management foot and ankle pain. The technique (continuous vs pulsatile), temperature, location of treatment, and duration of administration need more thorough evaluation. Randomized control trials are needed to establish the efficacy and safety profile of radiofrequency ablation and its long-term benefits in patients with chronic pain of the foot and ankle.

Conclusion The evidence from our studies suggests that radiofrequency treatment can be used safely for the management foot and ankle pain. The technique (continuous vs pulsatile), temperature, location of treatment, and duration of administration need more thorough evaluation. Randomized control trials are needed to establish the efficacy and safety profile of radiofrequency ablation and its long-term benefits in patients with chronic pain of the foot and ankle.

Keywords Foot pain · Ankle pain · Radiofrequency ablation · Analgesia

This article is part of the Topical Collection on *Neuropathic Pain*

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Introduction

Chronic plantar heel pain (CPHP) is a common complaint, often causing significant morbidity and disability. It has been estimated to account for 15% of all painful foot-related symptoms, affecting as many as two million American adults per year with a lifetime prevalence of 10% [1, 2]. Patients with CPHP demonstrate significantly lower quality of life, evidenced by lower physical activity and social capacity [3]. Though the etiology of CPHP is poorly understood, risk factors associated with the disorder include increased BMI, increased age, and decreased ankle mobility [4, 5]. The term CPHP is often used to generalize and describe a conforming host of conditions affecting the plantar heel [6]. Conditions such as neuritis, calcaneal periostitis, and subcalcaneal spur have been implicated in CPHP; however, plantar fasciitis is the most common cause, accounting for 80% of cases, and thus often used reciprocally to describe the condition [7, 8].

The plantar fascia is a collection of thick fibrous tissue that serves to support the arch of the foot. It originates at the medial calcaneal tubercle and fans distally to insert at each phalangeal base. Once thought to be inflammatory, pathology of the aponeurosis is thought to be related to cumulative mechanical stress; repetitive tensile forces lead to acute and chronic microtears causing pain [9]. As a condition of overuse, it is the third most common running-related injury, affecting 7.8% of runners [10]. This is further evidenced by histological tissue analysis, which points to microtears of the fascia with evidence of degenerative changes and angiofibroblastic hyperplasia [10].

The diagnosis of plantar fasciitis is largely clinical, based on physical exam and patient history. Patients with plantar fasciitis typically present with pain while walking and tenderness localized to the posterior sole of the foot. Typically, the pain is described as piercing and in many cases has persisted for many months to years [11]. Onset of heel pain caused by plantar fasciitis is reported to be gradual and greatest in intensity upon waking. The pain often improves with light activity, exacerbates with further ambulation, and ultimately becomes unbearable by the end of the day, limiting daily activity [12]. Moreover, one third of patients may present with bilateral symptoms [13]. In cases of recalcitrant plantar fasciitis, refractory to conservative management, radiographic imaging may aid in the diagnosis [14, 15].

Many nonsurgical therapeutic modalities are employed for the management of pain caused by plantar fasciitis including rest, physical therapy, NSAIDs, and corticosteroid injection. Though conservative management has been shown to be successful in as many as 80% of patients, there is little evidence demonstrating the long-term efficacy of any one therapy [16–18]. Furthermore, in a 5- to 15-year follow-up study of patients diagnosed with plantar fasciitis, only 54% were asymptomatic at the end of the study, demonstrating a mean duration of symptoms lasting 725 days. Moreover, 44% of patients reported continued pain after 15 years from their first onset of symptoms [19]. Those with elevated BMI, bilateral symptoms, or prolonged disease course are at a higher risk of developing pain refractory to conservative therapy, sometimes requiring surgical intervention [12]. Surgical release of the plantar fascia, however, is not always effective in alleviating the pain; in a study of 26 patients undergoing plantar fasciotomy, 29% reported persistent pain following the procedure [20]. Alternative treatments include the injection of platelet-rich plasma and shockwave therapy, though have demonstrated variable efficacy [21].

Radiofrequency (RF) treatment is an effective therapy for various chronic pain conditions including radicular pain, sacroiliac joint pain, post-surgical pain, myofascial pain, and arthritic pain [22–24]. Using similar principles, plantar fasciitis has been treated with RF targeting peripheral nerves that innervate the heel. Innervation of the heel is primarily by the proximal tibial nerve, which gives rise to distal medial calcaneal branches and the sural nerve. As the etiology of CPHP is poorly understood, various peripheral nerves have been targeted via RF. The formation of calcaneal bone spurs has been associated with the development of plantar fasciitis, possibly leading to pain caused by entrapment of the first branch of the lateral planter nerve [25]. Degenerative changes of the subtalar joint may result in increased pressure on the medial calcaneal nerve branches leading to inflammation, neuritis, and neuroma formation [26, 27]. The posterior tibial nerve lies within the tarsal tunnel and is subject to compression and inflammation which has also been implicated as a cause for CPHP [28]. Both conventional (CRF) and pulsed radiofrequency therapy (PRF) have been utilized in these applications.

CRF works by applying an active electrode to heat-targeted neural tissue to temperatures of 60–80 °C. These high temperatures cause coagulative necrosis, collagen destruction, and axonal degeneration, thereby resulting in third- and fourth-degree peripheral nerve injury [29–31]. Pain relief is limited however by progressive axonal regeneration [29, 32]. In contrast to CRF, PRF delivers high-frequency current in a pulsed manner, allowing time between pulses for the dissipation of produced heat. As such, the electrode tip is kept at a maximum of 42 °C, which is below the temperature that produces nerve damage. Instead, though it is not yet clarified, it is thought that PRF employs a strong electromagnetic field to functionally change neuronal cells in small unmyelinated and lightly myelinated nerve fibers selectively [33, 34]. This in effect causes disruption of neuronal membranes, modulation of neuronal gene expression, and modulation of neuronal local cytokine release [31, 35–38]. Following treatment, immediate changes of endoneurial edema can be seen histologically and clinical pain relief may last several years [30, 39]. In either CRF or PRF, persistent pain can stem from failure to completely disrupt nociceptive sensation of the targeted nerve. Moreover, aberrant neuronal regeneration can lead to complications such as neuroma formation, reduced motor function, deafferentation pain syndrome, neuritis, and paresthesia [29].

The use of RF to target the peripheral nerves, innervating the ankle and foot, may be effective in the treatment of CPHP. Patients with recalcitrant plantar fasciitis, following failure of conservative therapy, may benefit most from RF. In this review, we highlight the use of RF in the treatment of chronic foot and heel pain and examine the efficacy of both CRF and PRF.

Materials and Methods

Systematic Literature Search

Authors searched Medline, PubMed, Cochrane Database of Systematic Reviews, PROSPERO, and Cochrane Central

Register of Controlled Trials for relevant publications. We also searched Google Scholar and the clinical trial registry (clinicaltrials.gov) for additional publications. This database search was completed on 30 March 2018. Our EMBASE and MEDLINE included both controlled terms (MeSH, EMBASE, Emtree, MEDLINE) and free text that included the following terms "radiofrequency ablation," "neurolysis," "radiofrequency therapy," "pain syndrome," "analgesia," "plantar heel pain," "plantar fascitis," and "chronic pain" in the English literature. Bibliographies of the published papers were screened for various chronic pain pathologies that received radiofrequency treatments of ankle and heel pathologies.

Inclusion and Exclusion Criteria

We included RCTs, open nonrandomized control studies, prospective studies, retrospective studies, case series, and case reports for this systematic review. We limited our search to publications of original studies that investigated the use of conventional or pulsed radiofrequency treatment in adult patients with chronic heel and ankle pain lasting for at least 1 month or patients with a diagnosis of plantar fasciitis or ankle pain. We excluded research that was only available in abstract or poster forms, encompassed animal studies, were non-English papers, employed non-radiofrequency treatment technology, and focused on treatment of the pediatric population.

Outcome

We included pain scores from studies that recorded visual analog scale (VAS: 0 to 100) or numerical rating scale (NRS: 0 to 10). In addition, we also recorded outcomes of validated instruments that evaluated functional or physical disability scores. We included documentation of the foot health status questionnaire (FHSQ-function and general foot health), quality of life (using SF-36), American Orthopedic Foot-Ankle Society (AOFAS) ankle-hind foot scale, and patient satisfaction. Adverse effects from RF treatments were also recorded.

Data Extraction

Our final evaluation included case reports, retrospective, prospective, and randomized controlled studies. The reference population, diagnostic group, and outcomes were extracted from these articles using a pre-specified standardized extraction form. The information extracted from each study include author's last name, publication year, study design, number of arms, sample size, treatment technique (pulse vs conventional), temperature range and duration, duration of pain relief, secondary outcomes, side effects, and conclusion. We also extracted the mean and standard deviations for the pain scores when reported. If pain scores were not reported, we included the paper for thorough analysis and additional discussion purposes.

Quality of Evidence

The quality of evidence was assessed using Oxford quality scoring system and GRADEpro risk of bias methodology [40, 41]. The Oxford quality of evidence was classified as either a "high-range quality score" or a "low-range quality score" [40]. The GRADEpro approach was used to assess for selection bias, performance bias, detection bias, attrition bias, and reporting bias for each outcome [41].

Statistical Analysis

The Dersimonian and Laird random effects meta-analysis model was used because we expected heterogeneity due to the diverse populations, pain conditions, and treatment approach adopted in the included studies [42]. Heterogeneity was assessed with visual inspection of the forest plot and the Q test, and Higgins I^2 statistic was used to quantify it ($I^2 > 50\%$ indicates substantial heterogeneity). We estimated the pooled effect and the effect of the primary outcome was calculated with the corresponding 95% confidence intervals (CIs).

Results

Search Result

Our final search methodology yielded 15 studies that investigated the use of radiofrequency treatment at the ankle or foot [27, 28, 43–55]. The search and study selection flow chart is displayed in Fig. 1. We identified 23 publications after duplicates were removed. These studies were screened based on our inclusion and exclusion criteria. The details of the 15 studies are described in Table 1. These 15 studies were comprised of three RCTs, four prospective trials, three retrospective studies, and five case reports. The median age was 49.3 years with a range of 46.9 to 56 years. The studies were published from 2009 to 2016 with a follow-up time from 1 to 12 months.

Nerve Target

Five of the 15 publications included in this review had subjects with a diagnosis of chronic plantar heel pain [27, 44, 47, 50, 53]. An additional five publications included patients with a diagnosis of plantar fasciitis [43, 45–47, 55] and two studies with ankle pain [52, 54]. The medial calcaneal nerve was the mostly commonly targeted nerve. It was targeted for patients with plantar fasciitis/fasciosis [43, 45, 51], chronic heel pain

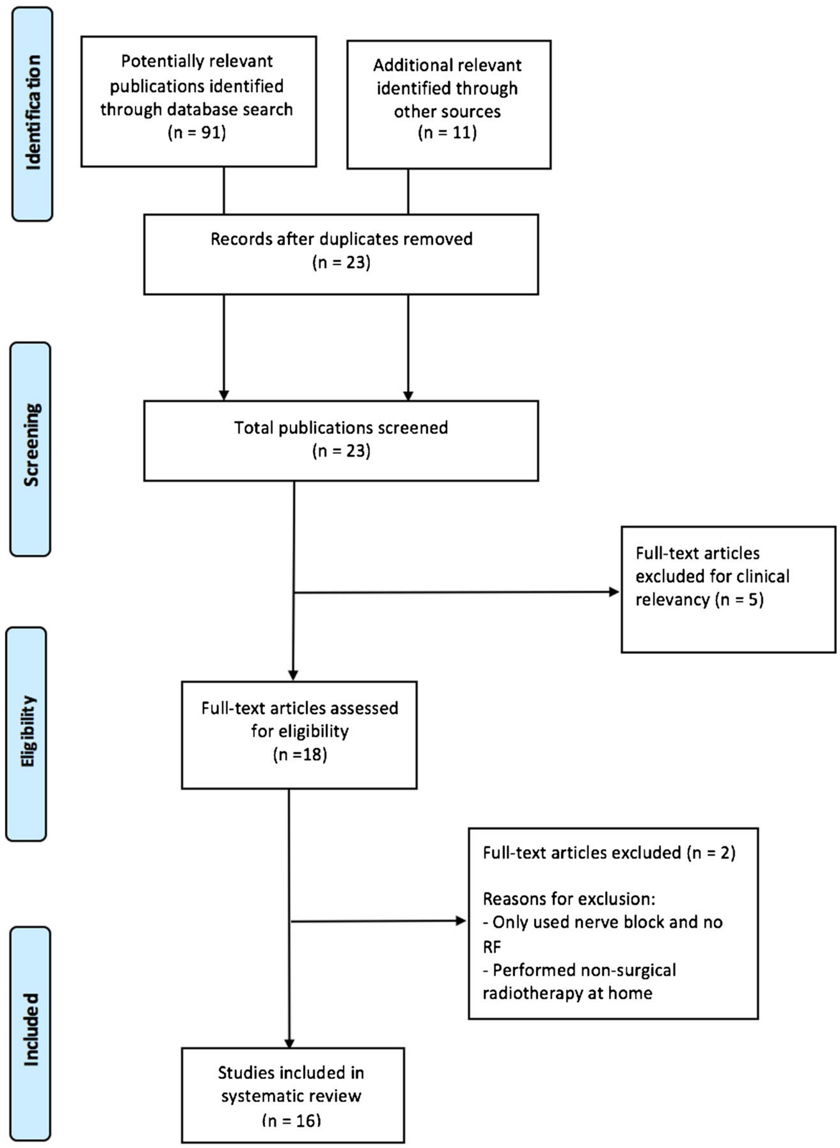

Fig. 1 Flowchart of articles selected for systematic review

[27, 44, 53], and medial neuritis [49]. The sural nerve was targeted in two case reports [52, 54].

Level of Evidence Classification

The overall level of evidence was determined as low with only three small RCTs included [28, 43, 47]. All three studies were blinded with one crossover trial [43]. We calculated Jadad scores for the RCTs [40]. We designated a 2/5 for the study by Ye et al. [47], 4/5 for the study by Wu et al. [28], and 4/5 for the study by Landsman et al. [43] (Table 2). The Ye et al. study had the lowest Jadad score because of inadequate blinding and lack of data due to patient dropout. We identified four prospective studies [45, 50, 53, 55], three retrospective studies [27, 44, 49], and five case reports [46, 48, 51, 52, 54]. The number of subjects in the individual case reports varied from one to six patients (Table 1).

Outcome

Pain outcomes were reported as VAS or NRS by most of the publications included in this review. Simultaneously, we attempted to gather all related data on functional outcome measures but the data was sparse. The foot health status questionnaire (FHSQ-function and general foot health) and quality of life (using SF-36) were reported in one study [47] and the AOFAS ankle-hind foot scale was reported in three studies [28, 50, 55]. Patient satisfaction outcome was reported in two studies [45, 55].

Outcomes for Continuous Radiofrequency Treatments

A total of eight publications (one RCT, four prospective studies, and three retrospective studies) performed a continuous radiofrequency treatment at 80 to 90 °C. The continuous

Table 1 Characteristics of studies included in systematic review

Author	Clinical diagnosis	Study size	Average age	Percent male	Study design	Ablation technique	Ablated nerve	Lower extremity region
Ye et al. [47]	Plantar heel pain	100 (50 UG-PRF, 50 sham)	50.4	62	RCT	Pulsed at 42 °C for 5 min at one or multiple trigger points vs sham (probe applied with no energy)	Not specified	Heel
Wu et al. [28]	Recalcitrant plantar fasciitis	36 pts., 20 ft per group	47.1	47.5	RCT	Pulsed for 120 s at 2 Hz with 30 ms pulse width at 42 °C vs lidocaine injection	Posterior tibial nerve	Heel
Landsman et al. [43]	Plantar fasciosis	17 (8 RFNA, 9 sham)	N/A	N/A	Randomized double-blinded crossover trial	Continuous 90 °C for 60 s vs sham (probe applied with no energy)	Sensory nerves at the medial aspect of calcaneus	Heel
Arslan et al. [53]	Chronic plantar heel pain	41 ft, 37 pts.	50.7	18.9	Single-arm prospective study	Continuous 90 °C for 90 s (1–3 sites per foot)	First branch of lateral plantar nerve and/or medial calcaneal nerve	Heel
Erken et al. [50]	Plantar heel pain	35 ft, 29 pts.	48.1	73.7	Single-arm prospective study	Continuous 90 °C for 75 s	Inferior calcaneal nerve (i.e. FBLPN)	Heel
Osman et al. [45]	Chronic refractory plantar fasciitis pain	40 ft, 20 pts.	56	25	Prospective non-randomized comparative study	Continuous 90 s at 80 °C vs pulsed for 6 min at 42 °C	Medial calcaneal nerve	Heel
Wu et al. [55]	Recalcitrant plantar fasciitis	30 pts.	46.9	20	Single-arm prospective study	Continuous 120 s at 80 °C	Not Specified (but probe placed into plantar fascia near calcaneal tuberosity)	Heel
Cione et al. [49]	Medial calcaneal neuritis	90 ft, 75 pts.	55	66.7	Retrospective study	Continuous 86 °C for 90 s (average 6 sites per foot)	Medial calcaneal nerve	Heel
Liden et al. [44]	Plantar heel pain	31 ft, 22 pts.	N/A	N/A	Retrospective study	Continuous 90 °C for 90 s	Medial calcaneal nerve	Heel
Cozzarelli et al. [27]	Chronic neurogenic heel pain	89 at 5 years, 84 at 10 years, 82 at 12 years	42	45.3	Retrospective study	Continuous 90 °C for 90 s (average 5 sites per foot)	Medial calcaneal nerve	Heel
Chae et al. [48]	Mechanical allodynia	2	35.5	50	Case report	Pulsed for 120 s at 45 V and kept under 42 °C, repeated × 3	Superficial peroneal nerve	Foot and ankle
Todorov [52]	Ankle pain	1	39	0	Case report	Pulsed for 240 s at 45 V and kept under 42 °C	Sural nerve	Ankle
Pelloso et al. [54]	Ankle pain	1	60	0	Case report	Pulsed for 140 s at 45 V up to 42 °C, 2 sessions	Sural nerve	Ankle
Michel [46]	Recalcitrant plantar fasciitis	6 pts., 8 ft	55.2	83.3	Case reports	Pulsed; carrier frequency of 27.12 MHz, delivered twice daily 8–12 h apart for 30 min each time, for 3–3.5 months	Not specified	Heel
Thapa et al. [51]*	Plantar fasciitis	2	33.5	50	Case reports	Pulsed for 2 min at 42.5 °C, 3 times	Medial calcaneal nerve	Heel

Table 1 (continued)

Author	Duration of pain relief	Secondary outcome	Side effect	Conclusion
	20 and 17.9 compared to sham at 3 months and 6months VAS-"first-step" pain decreased significantly by 26.1 and 14.3 compared to sham at 3 months and 6 months FHSQ-foot function and FHSQ-general foot health were increased more by UG-PRF vs sham at 3 months and 6 months	SF-36 physical component score in sham was 10.8 and 10.4 lower than UG-PRF at 3 months and 6 months	3/50 (6%) in UG-PRF group had pain and IE. 2/50 (4%) in sham group had similar reactions.	UG-PRF reduces pain intensity and increased foot health and function in comparison to sham treatment for plantar heel pain.
Wu et al. [28]	First-step pain (VAS) in PRF group decreased significantly from 6.38 ± 1.87 pre-op at the 1, 4, 8, and 12 weeks follow-ups. First-step pain (VAS) in the control group decreased significantly from 6.24 ± 1.81 pre-op at 1 week but was back to baseline at 4, 8, and 12 weeks follow-ups.	Overall pain (VAS) in PRF group decreased significantly from 6.03 ± 1.82 pre-op at the 1, 4, 8, and 12 weeks follow-ups. First-step pain (VAS) in the control group decreased significantly from 6.06 ± 1.79 pre-op at 1 week but was back to baseline at 4, 8, and 12 weeks follow-ups. AOFAS ankle-hind foot scores decreased significantly in PRF group at 1, 4, 8, and 12 weeks while this effect was not observed in the control group.	None	UG-PRF stimulation of PTN is effective for recalcitrant PF. More clinical trials with more cases and longer follow-up periods are needed.
Landsman et al. [43]	In the treatment group at 4 weeks, there was a significant reduction in average pain (4.06 ± 2.1) and peak pain (5.33 ± 4.31). This was not seen in the sham group.	In the treatment group at 16 weeks (which includes cross-overs), there was a significant reduction in first-step pain (7.71 ± 2), average pain (6.57 ± 1.33), and peak pain (8.29 ± 1.52). This was not seen in the sham group	Ecchymosis at injection site and vasovagal response during injections.	RFNA is efficacious in treating plantar fasciosis.
Arslan et al. [53]	Mean VAS before RFNA was 91.6 ± .8, then significant reduction to 11.1 ± 1.9 at 1 month, 13.3 ± 2.3 at 6 months, and 14.2 ± 3 at 12 months	88% rated treatment as very successful or successful (vs fair or poor) 12 months after RFNA.	1/37 reported neuralgia, 2/37 reported stiffness at medial heel.	Diagnostic nerve blocks should be used prior to RFNA. Chronic heel pain from FBLPN and MCN can be successfully treated with RFNA.
Erken et al. [50]	Mean VAS before RNA was 9.2 ± 0.8, then significant reduction to 1.2 ± 1.3 at 1 month, 1.5 ± 1.7 at 1 year, and 1.5 ± 1.6 at 2 years.	85.7% rated their treatment as very successful or successful. AOFAS score for 26 ft, 20 patients were 66.9 ± 8.1 pre-op, then significant increase to 95.2 ± 6.1 at 1 month, 93 ± 7.5 at 1 year, and 93.3 ± 7.9 at 2 years	1/35 ft developed hematoma, 2/35 developed neuropathic pain, and 3/35 developed transient discomfort.	RFNA is an effective treatment for chronic heel pain that does not respond to other conservative measures. US can be used to locate plantar fascial attachments and the targeted nerve.
Osman et al. [45]	NVRS upon waking for the pulsed group dropped from 8.7 ± .14 pre-op to 2.8 ± .3 at 1 week and 2.05 ± 0.35 at 24 weeks. For continuous group, dropped from 8.7 ± .16 pre-op to 6.15 ± 0.33 at 1 week to 1.9 ± 0.28 at 24 weeks. PRF superiority was maintained at 1 week and 3 weeks, but they were equal at 6, 12, and 24 weeks.	Satisfaction was higher for pulsed group at 1 and 3 weeks. Satisfaction for pulsed and continuous was equal at 6, 12, and 24 weeks	None	PRF and TRF are safe and effective treatments for chronic plantar fasciitis pain. PRF may have a faster onset of analgesia compared to TRF.
Wu et al. [55]	Mean pre-op VAS was 8.5 ± 1, then significant reduction to 1.4 ± 1.3 at 12 months. Mean pre-op AOFAS score was 42.4 ± 6.9, then significant increase to 92.3 ± 9.1 at 12 months.	The decrease in VAS and increase in AOFAS scores were not different between obese and non-obese groups at 6 months. The non-obese group had pain reduction sooner than the obese group (1 month vs 3 months). 24/30	None	US-guided RTL for recalcitrant plantar fasciitis is a satisfactory treatment alternative to more invasive procedures. Obesity is associated with later improvement in pain and return to function post-RT, but obesity does not affect outcome after 6 months.

Table 1 (continued)

Author	Duration of pain relief	Secondary outcome	Side effect	Conclusion
		(80%) rated satisfaction as "good to excellent" at 12 months.		
Cione et al. [49]	Median VAS reduction from 9/10 pre-op to 1/10 post-op, at a median follow-up of 18 months. Overall, a 79.7% reduction in pain was observed in 93.3% of patients.	None	5/75 patients experienced recurrent plantar heel pain that was not worse than their pre-op pain.	RTL is effective in treating patients with recalcitrant neurogenic plantar heel pain. It is a safe and minimally invasive alternative to surgery.
Liden et al. [44]	VAS before RFA was 8.12 ± 1.61, then 3.26 ± 1.97 at 1 week, and 1.46 ± 1.76 at 1 month. Mean follow-up was 8.1 months, and 1 month results persisted for up to a year.	92% rated outcome as completely successful or very successful (vs moderately, marginally, or not successful). 1/22 rated outcome as not successful.	1/22 had bruising at the injection site, 1/22 had peroneal tendonitis, 1/22 had lateral calf pain, 1/22 had the sensation of walking on a wad of tissue, 1/22 had persistent poststatic dyskinesia	RFA is an excellent treatment of recalcitrant plantar fasciopathy, especially as an alternative to open surgery.
Cozzarelli et al. [27]	For 5-year group, pre-op VAS was 7.2 and at 5 years, it was 0. For 10- and 12-year groups, pre-op VAS was 7.1, and at 10 and 12 years, it was 0. 79/89 (89%) at 5 years were pain free. 75/84 (89%) at 10 years were pain free. 73/82 (89%) at 12 years were pain free.	None	At 5, 10, and 12 years, 100% of the patients said they would do the procedure again.	RFNA is fast and easy with almost no recovery and low morbidity. RFNA may eliminate the need for open surgery for chronic neurogenic heal pain.
Chae et al. [48]	Case 1: pre-op VAS was 7–8/10 and decreased to 2–3/10 at 2 weeks, then 5–6/10 at 4 months. Case 2: pre-op VAS was 7–8/10 and decreased to 3–4/10 at 2 weeks, then 3–4/10 at 3 months, then pain gradually returned.	None	None	PRF on the SPN can successfully treat patients with CRPS of the foot and ankle.
Todorov [52]	Pre-op pain was 3/10 when non-weight bearing and 7/10 weight bearing. Pain was 0/10 with and without weight bearing directly post-op and at 5 months follow-up.	None		First report of RFA of sural nerve to successfully treat neuropathic pain of the lateral ankle.
Pelloso et al. [54]	80% pain improvement.	None	None	PRF of sural nerve is an option to control chronic lateral ankle pain.
Michel [46]	6/6 patients reported pre-treatment VAS was 10/10 for first-step in morning pain and first-step after rest pain. After treatment, 4/6 patients reported 0/10 pain. The 2 patients with bilateral PF reported scores of 2/10.	None	None	PRFE therapy assists in the treatment of recalcitrant plantar fasciitis. Further study is warranted.
Thapa et al. [51]*	1 patient had VNRS 5/10 pre-op and was reduced to 0/10 on prolonged walking after PRF. Another patient had VNRS 5/10 pre-op and was reduced to 3/10 on prolonged walking.	None	None	Combined MCN block with PRF can successfully treat PF.

*NB: there were actually three cases presented but the third case report did not utilize RF

Table 2 Quality assessment of randomized controlled trials investigating the role of radiofrequency ablation in patients with ankle or heel pain

Questions	Grading		
	Ye et al.	Wu et al.	Landsman et al.
1. Study described as random?	1	1	1
2. Randomization described and appropriate?	1	1	1
3. Study described as double-blind?	0	1	1
4. Method of double blinding described?	0	0	1
5. Dropouts and withdrawals described?	− 1	1	− 1
Total	2	4	4

treatment duration varied from 60 to 120 s. Two retrospective studies targeted five [27] and six [49] sites per foot on average, while a prospective study targeted three sites per foot [53].

Analgesia

All eight publications that used CRF reported a significant reduction in ankle or foot pain with follow-up periods ranging from 1 to 24 months [43–45, 49, 50, 53, 55] (Table 1). A single retrospective study went as far back as 12 years for additional follow-up [27]. The only RCT that used CRF reported lower pain scores in the treatment group compared to sham at 4 weeks [43]. In addition, a non-randomized prospective study compared CRF with PRF and demonstrated PRF to be superior at 1 week and 3 weeks, but equally efficacious at 6, 12, and 24 weeks [45].

Adverse Effects

Skin findings were noted after CRF treatment. Landsman et al. reported ecchymosis at the needle insertion site [43]. One patient from Erken's study developed hematoma and one patient sustained bruising at the needle insertion site in the study by Liden et al. [44, 50]. Pain was also a common side effect. In the study by Arslan, one patient reported to have neuralgia and two patients reported stiffness at the medial heel [53]. In another study by Erken et al., two patients developed neuropathic pain and three patients developed transient discomfort [50]. Cione et al. also reported that five patients experienced recurrent plantar heel pain but this pain was not worse than preoperative pain [49]. Similarly, one patient from Liden et al. reported to have lateral calf pain [44]. None of the studies reported major complications.

Outcomes for Pulsed Radiofrequency Treatment

Analgesia

All seven publications that used PRF reported significant reduction in ankle or foot pain with follow-up periods ranging from 1 to 6 months (Table 1) [28, 46–48, 51, 52, 54]. One of the two RCTs that used PRF reported lower pain scores in the treatment group compared to sham at 3 and 6 months. The second RCT reported a significant reduction in pain that was sustained for 12 weeks [28]. The remaining six studies were case reports [46, 48, 51, 52, 54].

Adverse Effects

Neurological side effects were noted in the RCT conducted by Ye et al. [47]. Three of the patients in the PRF group complained of pain and sweating. However, this reaction was similarly found in the control group. No additional adverse events were reported in the additional studies that investigated the use of PRF.

Imaging Approach for Positioning RF Cannulas

The use of fluoroscopy or ultrasound as a guide for placement of RF cannulas was used in seven studies [27, 28, 47–50, 55]. Five studies used patient feedback of sensory stimulation as a guide [43–45, 52–54]. Fluoroscopy was employed by two studies that used CRF [27, 49]. Three studies that used an ultrasonographic approach used a PRF technique.

Use of Prognostic Nerve Blocks

Prognostic nerve blocks with local anesthetic were used in six studies [45, 48, 52–54]. Two studies used lidocaine with volumes varying from 1 to 2 ml [45, 53]. Osman et al. used 2 ml of 2% lidocaine but the concentration used by Arslan et al. was unknown. Two studies used bupivacaine for a diagnostic block [52, 54]. Pelloso et al. used 4 ml of 0.25% bupivacaine while Todorov used a mixture of 5 ml 0.25% bupivacaine and 20 mg triamcinolone. The use of 0.5 ml 2% lidocaine and 0.5 ml 2% ropivacaine (20 mg methylprednisone) was used by Thapa et al. [51]. Nine studies did not provide information about the use of prognostic blocks [27, 28, 43, 44, 46, 47, 49, 50, 55].

Author, Year	RF Group Mean Pain Score	SD	Total	Placebo Group Mean Pain Score	SD	Total	Weighted Mean Difference D+L, Random, 95% CI	Weight
Wu YT, 2016	2.39	1.16	18	5.87	1.69	18	-3.48 (-4.43, -2.53)	79.40
Landsman, 2013	3.19	2.10	9	6.64	1.81	8	-3.45 (-5.31, -1.59)	20.60
Total (95% CI)			**27**			**26**	**-3.47 (-4.32, -2.63)**	**100.00**

Heterogeneity: $Tau^2=0.00$, $Chi^2=0.00$, df=1 (P=0.978): $I^2=0.0\%$
Test of Overall effect: Z =8.07, P<0.0001

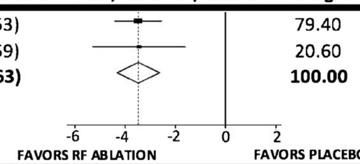

Fig. 2 Forest plot of the effects of RF ablation on 1 month overall mean pain score

Discussion

The data from this evidence-based narrative review of 15 publications on CRF and PRF treatment at the ankle suggests that these procedures can relieve chronic pain of the ankle or foot at 1 to 24 months follow-up. There was limited evidence to support improvement of function; however, no study reported any major complications. Despite these positive results, there are several concerns regarding the quality, procedural approach, image guidance, and interpretation of outcomes in these publications.

Quality of Evidence

The quality of evidence for this narrative review was considered low. This review had three RCTs which studied a small population size [28, 43, 47]. The quality was further impacted as one of the studies did not reveal any description of dropout or withdrawal [43] and another failed to address the method of blinding [47]. Only two of the studies had an acceptable protocol for randomization and blinding [28, 43]. Nonblinded and nonrandomized studies were ranked low for quality due to bias and inability to control for placebo effects on outcome measures [56]. In addition, the small number of patients in each individual study makes it difficult to detect other effects that may result from the use of RF treatments.

Pulsed vs Continuous Radiofrequency Treatment Approach

The use of both PRF and CRF has been reported to be used for chronic ankle and foot pain. The argument favoring PRF over CRF is that PRF does not lead to presumed extensive nerve injury compared to CRF. CRF, performed at high temperature, on the other hand, has been implicated in neuroma formation in patients with neuropathic pain. In this review, we report two RCTs that used PRF to treat ankle and foot pain. Although randomized, one of these studies was methodologically flawed as it failed to specify the targeted nerves [47]. Hence, it was not clear if treatment was performed on either motor or sensory nerves. This study also failed to perform a diagnostic block, further confounding the category of nerve that was targeted. The study by Wu et al. also used PRF with similar methodological flaws. The authors did not use a diagnostic block though the tibial nerve was identified as a target via ultrasound [28]. The only RCT that used CRF was performed by Landsman et al. In this study, the authors targeted sensory nerves at the medial aspects of the calcaneus though no diagnostic block was used. This study however used sensory feedback from patients as a tool to identify the sensory nerves. Despite the lack of identification of sensory nerves by most RCTs in this review, all three studies reported a reduction in pain scores. The use of PRF vs CRF technique remains controversial as there still remains no clinical study that compares efficacy in the treatment of ankle or foot pain.

Pain Scores and Function

The pain scores after RF treatment were pooled from the RCTs included in this narrative review. Only two of the three studies reported pain scores that could be analyzed. The overall VAS pain score and the VAS pain score upon first step, at the end of the first month, were pooled (Figs. 2 and 3). The forest plot for overall pain score at the end of the first month suggests a significant reduction in pain in the RF treatment group compared to the control group (Fig. 2). This result was similar for the pain score upon first step at the end of the first month; the RF treatment group had a significant pain reduction upon first step compared to control. Although the confidence intervals for both outcomes were quite narrow, there is still a low level of confidence in this meta-analysis. This is true because we performed analysis on only two studies, which increases the risk of random error and leads to a misleading conclusion [57]. Regarding function, four publications in this review reported improvement with RF treatments [28, 47, 50, 55]. The study by Ye et al. showed improvement with FHSQ-foot function and FHSQ-general foot health at 3 months and 6 months. A similar functional improvement in AOFAS scores was also noted in three other studies [28, 50, 55].

Response to Ablative Treatments: Role of Diagnostic Blocks

The etiology of the pain pathophysiology that arises from the ankle and foot remains complex at best. Before every RF ablative procedure, it seems logical to perform a diagnostic

Author, Year	RF Group Mean Pain Score	SD	Total	Placebo Group Mean Pain Score	SD	Total	Weighted Mean Difference D+L, Random, 95% CI	Weight
Wu YT, 2016	2.74	1.32	18	6.07	1.81	18	-3.33 (-4.37, -2.30)	89.40
Landsman, 2013	3.63	3.90	9	7.00	2.30	8	-3.37 (-6.38, -0.36)	10.60
Total (95% CI)			**27**			**26**	**-3.33 (-4.31, -2.36)**	**100.00**

Heterogeneity: Tau²=0.00, Chi² =0.00, df=1 (P=0.980): I²=0.0%
Test of Overall effect: Z =6.68, P<0.0001

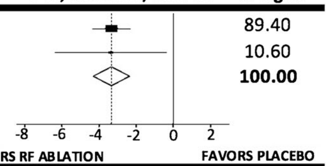

Fig. 3 Forest plot of the effects of RF ablation on 1 month mean pain score at first step

nerve block with local anesthetic to determine the likelihood of success and demonstrate temporary pain relief prior to nerve denervation. Only six [45, 48, 51–54] of the 15 studies used a prognostic nerve block prior to RF treatment. Studies by Chae et al., Todorov et al., and Pelloso et al. used relatively large volumes of local anesthetics (greater than 2 ml) though this has been shown to undermine the specificity and prognostic value of diagnostic blocks [58]. In addition, PRF studies that used large volumes have demonstrated poor treatment outcomes [58].

Controversy still exists in the pain community regarding the use of prognostic nerve blocks at the site of pain generators [59]. When a similar question regarding the use of diagnostic blocks in ankle and foot pain is brought up, there are no robust randomized control trials that discuss the roles of low-volume prognostic blocks targeting specific nerves of the foot or ankle to further predict the success of RF treatment. In our review, patients with heel pain received low-volume diagnostic blocks (1 ml lidocaine) at the first branch of the lateral plantar and medial calcaneal nerves with an 88% response rate 12 months after CRF treatment considered to be successful [53]. Another study by Osman et al. looked at low-volume diagnostic block (2 ml of 2% lidocaine) at the medial calcaneal nerve for patients treated with PRF [45]. This study reported patient satisfaction for the pulsed group at weeks 1 and 3; however, similar satisfaction for both PRF and CRF was observed at weeks 6, 12, and 24. Better designed studies are needed to further elucidate the implications of diagnostic block use in ankle, foot, and heel pain.

Adverse Effects

Overall, there were no reported major complications with the use of either PRF or CRF; however, more minor side effects were noted with CRF compared to PRF. Three studies identified skin changes after CRF [43, 44, 50]. One of the studies reported sustained bruising [43] while the other reported hematoma [50] and ecchymosis at the needle insertion site [44]. Pain was also reported in four studies that used CRF [44, 49, 50, 53]. In contrast, few adverse events were reported with the use of PRF. In the study by Ye et al., only three of the patients treated with PRF complained of pain and sweating. This reaction however was similar in the control group [47]. No additional side effects or adverse events were reported in the other studies that investigated the use of PRF.

Limitations

Despite the positive reports from the individual studies in this narrative review, there are several limitations. First, narrative reviews by definition tend to be subjective and the data analysis is not robust enough to draw very strong and meaningful conclusions. In addition, the studies in this review were very heterogeneous for clinical diagnosis, RF technique, RF location, and the use of multiple time points to assess different analgesic and functional outcomes. We caution our readers to be careful with drawing conclusions from this review because of the difficulty in evaluating the relationship between the small size studies and their respective outcomes. The largest single study in this review contained 100 patients [47] with the majority of other studies containing less than 45 patients [28, 43, 45, 50, 53, 55]. Only three publications were RCTs, albeit small [28, 43, 47], and the remainder prospective, retrospective, case series, and case reports.

Conclusions

Despite these aforementioned limitations, the evidence in our study suggests that radiofrequency treatment at the ankle can be used for the treatment of chronic ankle and foot pain with little to no complication. The technique (continuous vs pulsatile), temperature, treatment location, and duration of procedural technique need more thorough evaluation. Randomized control trials are needed to establish the efficacy and safety profile of radiofrequency treatment at the ankle and its long-term benefits in patients with chronic pain of the ankle and foot.

Compliance with Ethical Standards

Conflict of Interest Vwaire Orhurhu, Ivan Urits, Sebastian Orman, Omar Viswanath, and Alaa Abd-Elsayed declare no conflict of interest. Dr. Abd-Elsayed is a consultant for Innocoll, Ultimaxx Health, SpineLoop, Medtronic, Halyard, and Axsome.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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• Of importance
•• Of major importance

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