

Non-invasive peripheral nerve neuromodulation in diabetic neuropathic pain: A randomised controlled trial

 Gevher Rabia Genç Perdecioğlu,¹  Gökhan Yıldız,¹  Mehlika Panpallı Ateş,²  Damla Yürük,¹  Taylan Akkaya¹

¹Department of Algology, Ministry of Health Ankara Etlik City Hospital, Ankara, Türkiye

²Department of Neurology, Ministry of Health Ankara Etlik City Hospital, Ankara, Türkiye

SUMMARY

Objectives: Diabetic neuropathic pain (DNP) is one of the most common and challenging complications of diabetes mellitus and often results in significant distress and impaired quality of life. Pulsed radiofrequency (pRF) treatment has gained traction in recent years as an effective intervention for the management of chronic pain. Therefore, non-invasive pRF (NipRF) has been introduced as an innovative treatment that promises to provide pain relief without invasiveness. In this study, we aimed to evaluate the efficacy of NipRF in the treatment of DNP.

Methods: This double-blind, randomized, controlled study included 64 patients with DNP and distal symmetric polyneuropathy refractory to multiple medical therapies, as confirmed by electroneuromyelography (ENMG). Participants were divided into two groups: one received NipRF treatment via a transcutaneous electrode (treatment group) and the other received a sham electrode (sham group) without radiofrequency. Pain levels were measured using the visual analog scale (VAS) and Self Leeds Assessment of Neuropathic Symptoms and Signs (S-LANSS) before treatment and at 4 and 12 weeks after treatment.

Results: The treatment group experienced significant reductions in the VAS and S-LANSS scores at 1 and 3 months post-treatment ($p < 0.001$). The sham group showed a moderate, but not statistically significant, decrease at week 4, with scores reverting to baseline by week 12.

Conclusion: NipRF therapy may be a good option for DNP management. Its non-invasiveness and low risk of adverse events make it a good alternative to interventional and drug therapies.

Keywords: Chronic pain; diabetes mellitus; diabetic neuropathies; neuralgia; polyneuropathies; pulsed radiofrequency treatment.

Introduction

Diabetic polyneuropathy is a prevalent complication of diabetes mellitus (DM) that affects up to 50% of patients. Distal symmetric polyneuropathy (DSPN) is the most common type of diabetic neuropathy (DN). DSPN is a debilitating condition that causes severe neuropathy and significantly diminishes quality of life. Treatment options for this condition primarily involve medical combination therapies. These include gabapentinoids, tricyclic antidepressants, serotonin-norepinephrine reuptake inhibitors, and lidocaine infusion combinations. However, in cases where there is resistance to treatment or the dose cannot

be further increased owing to side effects, interventional treatments are necessary. These advanced procedures include sympathetic blockade, botulinum toxin injection, spinal cord stimulation, and surgical decompression of the peripheral nerves. It is important to note that, while these interventions offer potential benefits, they also carry risks and have variable success rates.^[1]

Pulsed radiofrequency (pRF) is a nondestructive neuromodulation technique that reduces inflammation and pain. It is based on transferring waves from the current radiofrequency provider to tissues using a cannula or transcutaneous electrode

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Correspondence: Dr. Gevher Rabia Genç Perdecioğlu. Sağlık Bakanlığı, Ankara Etlik Şehir Hastanesi, Algoloji Kliniği, Ankara, Türkiye.

Phone: +90 - 533 - 200 91 84 **e-mail:** gevhgerenc@gmail.com



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(1-8 Hz, 10-30 ms, and 500 KHz). pRF elicits electric field effects, resulting in changes in the neural cellular substrates.^[2] Consequently, inflammatory cytokines are suppressed and endogenous opioids increase.^[3,4]

Non-invasive pRF (NipRF) treatment is the delivery of pulsed radiofrequency current to biological tissues using electrodes. The electrodes are placed over the skin on the area to be treated. A cable connects the electrodes to the current generator. After the device is set to the desired parameters, it is activated and RF current is transmitted through the electrodes to the skin. This current is transmitted from the skin to deeper tissues, just as in transcutaneous electrical nerve stimulation (TENS) devices. However, because RF current can penetrate deeper, its neural stimulation is higher than TENS current. This allows for more effective treatment. Neuromodulation with NipRF is a novel treatment for neuropathic pain caused by conditions such as carpal tunnel syndrome.^[5] And this is the first study to examine the use of NipRF in the treatment of DN, and there is currently no existing literature on this subject.

Our aim was to modulate and desensitize the PTN (posterior tibial nerve), the peripheral nerve that receives the sensation of the sole of the foot. Neuropathic complaints such as felting, numbness, and burning were perceived less by the patient. PTN's superficial course in the ankle would allow the pRF current delivered by transcutaneous electrode to reach the nerve easily. The primary objective of this study was to evaluate the improvement in pain severity in patients with DSPN using the visual analog scale (VAS) score, especially basal-12 week change; the secondary objectives were to evaluate the efficacy of NipRF treatment on neuropathic pain and to observe any adverse events related to the electrode pad.

Material and Methods

Ethics Approval and Registration

Approval from the Ethics Committee of the local hospital was obtained on 22.03.2021 (Decision no: 107/23). This study was registered at ClinicalTrials.gov (Register Number: NCT05480527). The first patient enrollment date was 01.06.2023. All patients were informed of the study, and written informed

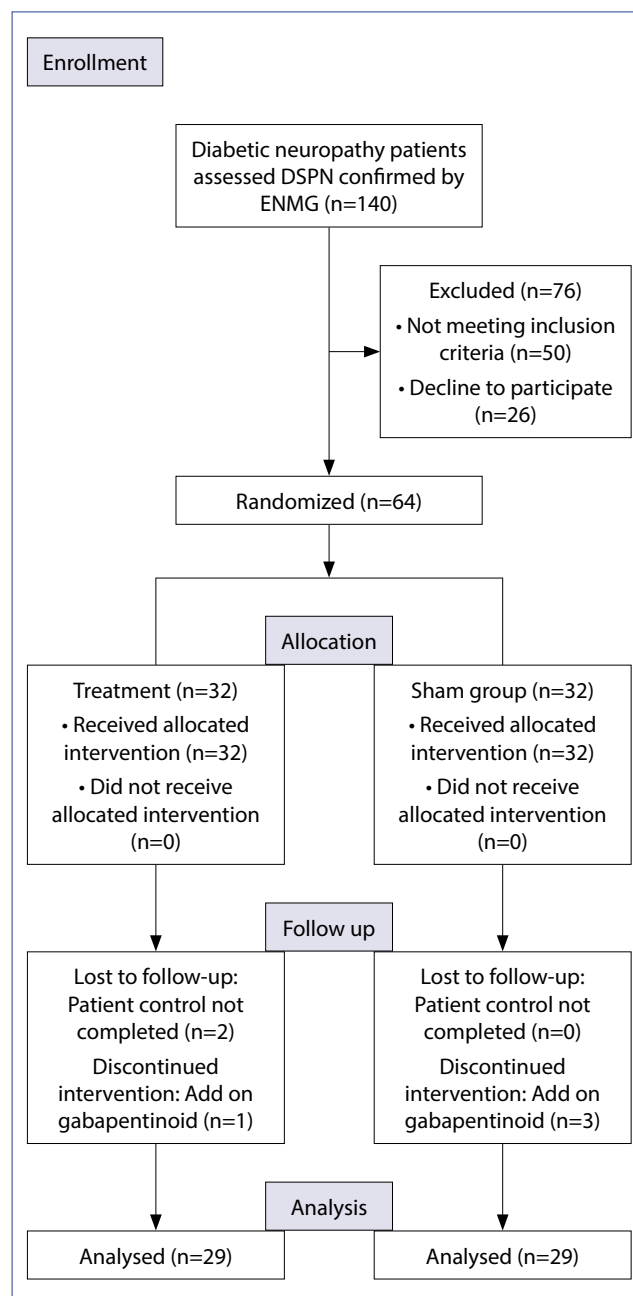


Figure 1. Flow chart diagram.

consent was obtained from all patients. The Declaration of Helsinki was followed in this study.

Study Design and Participants

This study was designed as a single-blind, placebo-controlled, randomized clinical trial. The inclusion criteria were as follows: diagnosis of type 2 DM; complaint of neuropathic pain in the distal lower extremity for at least two years; diagnosis of DSPN confirmed by ENMG; failure or minimal response to medical therapy despite at least dual combination therapy and maximum tolerated doses; and a visual analog scale (VAS) score >5.

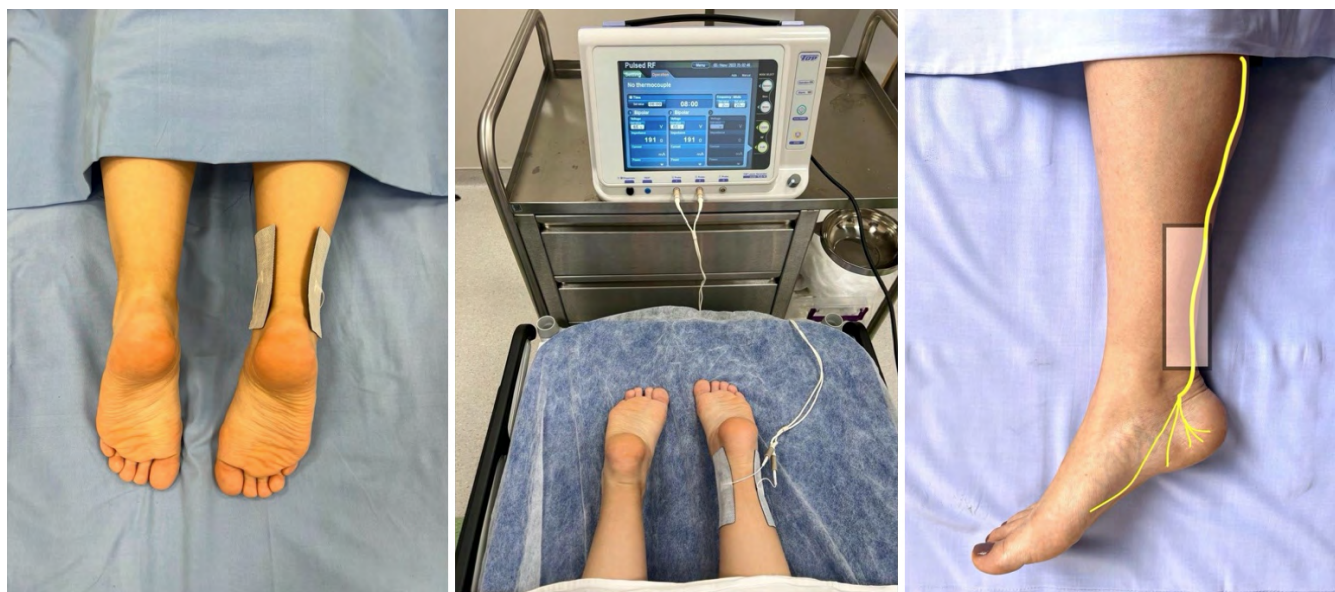


Figure 2. Electrode placement and RF transducer device.

The exclusion criteria were as follows: motor deficits in the lower extremities and diabetic scars; malignancy; pregnancy; B12-folic acid deficiency; presence of other causes of DSPN (chronic liver or kidney disease; chronic toxin exposure such as alcohol; presence of autoimmune diseases such as rheumatoid arthritis and lupus; drug use such as chemotherapy, amiodarone, and colchicine; infectious causes such as HIV, Hepatitis C; and hereditary diseases such as Charcot-Marie-Tooth and Familial Amyloidosis).

The study design is depicted in Figure 1.

Randomization and Blinding

In the current study, randomization of the participants was performed using a computerized method, maintaining a balanced 1:1 allocation ratio. An independent statistician who was not involved in the recruitment of participants generated a random allocation sequence. The sequence was obtained using a web-based platform. To maintain allocation concealment, sealed opaque envelopes containing allocation details were used. Participants were then assigned to their respective intervention groups by a different researcher, according to the established sequence. To eliminate assessment bias, blinding of the outcome assessor was strictly maintained throughout the duration of the study. Patients were informed that the discomfort could be caused by the pads and not by the

pRF current. Thus, it was ensured that the patients did not know whether symptoms such as redness or paresthesia were caused by the current or the pad. In addition, patients were treated separately, and we aimed to mask any symptoms, such as mild warming, burning, and redness, in the active electrode group. The investigators who assessed the patients at the three-month follow-up and those who analyzed the data were also blinded.

Intervention

Non-invasive Pulsed Radiofrequency Procedure

We used a transcutaneous electrode-compatible pRF generator (TOP Lesion Generator TLG-10 Sluiter Teixeira Pulse [STP], Equip Mediskey BV, the Netherlands) and 44×98 mm transcutaneous neurostimulation electrodes (Equip, FIAB SPA, Via P. Costoli, Italy). For each patient, the device was first applied to the right lower extremity, and then to the left lower extremity. One of the electrodes was placed on the posterior tibial nerve tract at the level of the medial malleolus, and the other on the opposite lateral malleolus. The RF transducer was operated in silent mode to prevent the patients from knowing whether the device was active or inactive. The electrodes were placed on both feet for 8 min each. The treatment group received a pRF (80 volts, 2 Hz, 20 ms). The sham group did not receive a pRF current. Each patient underwent two sessions with a one-week interval (The treatment was depicted in Fig. 2).

Table 1. Demographic data, between and within group analyses of VAS and S-LANSS scores

	Treatment Group			Sham Group			Test st.	p*
	Mean±SD	Median (min–max)	Mean rank	Mean±SD	Median (min–max)	Mean rank		
Age	58.9±8.4	59 (36–75)		57.9±8.2	60 (40–60)		0.439	0.662 ^a
Gender, n (%)					20 (69)			0.283 ^b
Female	15 (51.7)			9 (31)				
Male	14 (48.3)							
VAS								
Basal	8.3±1.2	8 (6–10)	2.84	7.5±1.8	8 (5–10)	2.00	1.712	0.078 ^c
Week 4	4.4±2.3	4 (0–10)	1.19	6.9±2.2	7 (2–10)	1.83	4.195	<0.001^c
Week 12	5.9±2	6 (2–10)	1.97	7.5±1.7	8 (5–10)	2.17	3.093	0.002^c
p**		<0.001			0.114			
S-LANSS								
Basal	16.4±4.2	16 (8–24)	2.72	18.6±7	19 (6–38)	2.10	1.712	0.087 ^c
Week 4	9.3±5.8	8 (0–24)	1.24	17.4±6.7	19 (6–30)	1.90	3.763	<0.001^c
Week 12	12.9±5.7	12 (2–25)	2.03	18.1±6.4	19 (6–30)	2.00	3.092	0.002^c
p**		<0.001			0.223			

p*: A Independent Samples t-Test; b: Chi-Square Fischer Exact Test; c: Mann-Whitney U-test. p**: Friedman test; SD Standard deviation; VAS Visual Analog Scale; S-LANSS: Self-Leeds Assessment of Neuropathic Symptoms and Signs Pain Score.

Assessment

All patients were assessed using the VAS and Self-Leeds Assessment of Neuropathic Symptoms and Signs (S-LANSS) scores before and at 1 and 3 months after treatment. The VAS is a psychometric response scale that is commonly used in pain assessment. It measures the intensity of the pain experienced by a patient on a continuum. The scale is typically a 10 cm line anchored by two descriptors representing the extremes of 'no pain' and 'worst imaginable pain.' Patients marked a point on the line corresponding to their pain level, which was then measured and recorded. The S-LANSS score is used to identify pain of predominantly neuropathic origin. It is based on patient self-reports and includes questions about pain quality and the presence of sensory abnormalities in the area of pain. S-LANSS assesses parameters such as pain location, pain characteristics (e.g., burning, tingling), autonomic changes (e.g., sweating, flushing), evoked pain (e.g., touch or pressure), and sensory dysfunction.^[6] The presence of these symptoms and signs contributes to a score that indicates a neuropathic component of pain above a certain threshold. Our primary objective was to determine the effect of treatment on pain intensity, specifically

using VAS scores from baseline to 12-week change. Our secondary objectives were to examine the effect of treatment on neuropathic pain using the S-LANSS score, and to reveal procedure-related adverse events.

Statistical Analyses

Sample calculation was performed by G*Power software. The effect size is 0.917, $\alpha=0.05$, and power ($1-\beta$)=0.95. For each group, 27 participants were identified. The four-week resting pain VAS score (mean and standard deviation values) of Taverner et al.^[7] was used for analysis.

All analyses were conducted using Jamovi Project (2022, Jamovi Version 2.3, Computer Software, <https://www.jamovi.org>). The findings of this study are expressed as frequencies and percentages. Normality analysis was performed using the Shapiro-Wilk test, skewness, kurtosis, and histograms. Normally distributed variables are presented as means and standard deviations (SD). Categorical variables were compared using the chi-squared test. Numerical dependent variables were compared between the groups using an independent

sample t-test. Repeated measures with normal distribution, such as VAS and S-LANSS scores, were analyzed using a two-way ANOVA. Statistical significance was set at $p < 0.05$.

Results

In total, 140 patients with DSPN were screened for eligibility. Sixty-four patients who met the inclusion criteria were included in this study. Since six patients were lost to follow-up, fifty-eight participants completed the 12 weeks of follow-up.

No significant differences in age, sex, or baseline scale scores were observed between groups.

The VAS and S-LANSS scores were compared between the groups. No differences were found in baseline measurements. However, at 4 and 12 weeks, the treatment group showed a significant improvement in both scale scores compared with the control group ($p < 0.001$, $p = 0.002$) (Table 1).

We analyzed changes in the VAS and S-LANSS scores of both groups over time. The treatment group showed a significant decrease in VAS and S-LANSS scores at 4 and 12 weeks compared with baseline ($p < 0.001$). The change in both scale scores was analyzed using Bonferroni correction. A significant difference was found in the VAS and S-LANSS scales measured at three different times in the treatment group (p values respectively; basal-4 week, 4-12 week, basal-12 weeks; VAS: $p < 0.001$, 0.009, 0.002; S-LANSS: $p < 0.001$, 0.008, 0.026) (Table 1, Fig. 3).

The sham group showed a moderate decrease in the VAS and S-LANSS scores at week 4, but this was not statistically significant. By week 12, both scores had returned to baseline values. No statistical difference was found between the VAS and S-LANSS scores measured at the three different time points in the sham group (Table 1, Fig. 3).

The number of patients with at least 50% reduction in pain was analyzed. This rate was 66% at four weeks and 22.2% at 12 weeks in the treatment group. In the sham group, 11.1% pain reduction was seen at week 4, while none at week 12. The treatment group showed mild hyperaemia in seven participants, but no serious adverse effects were observed.

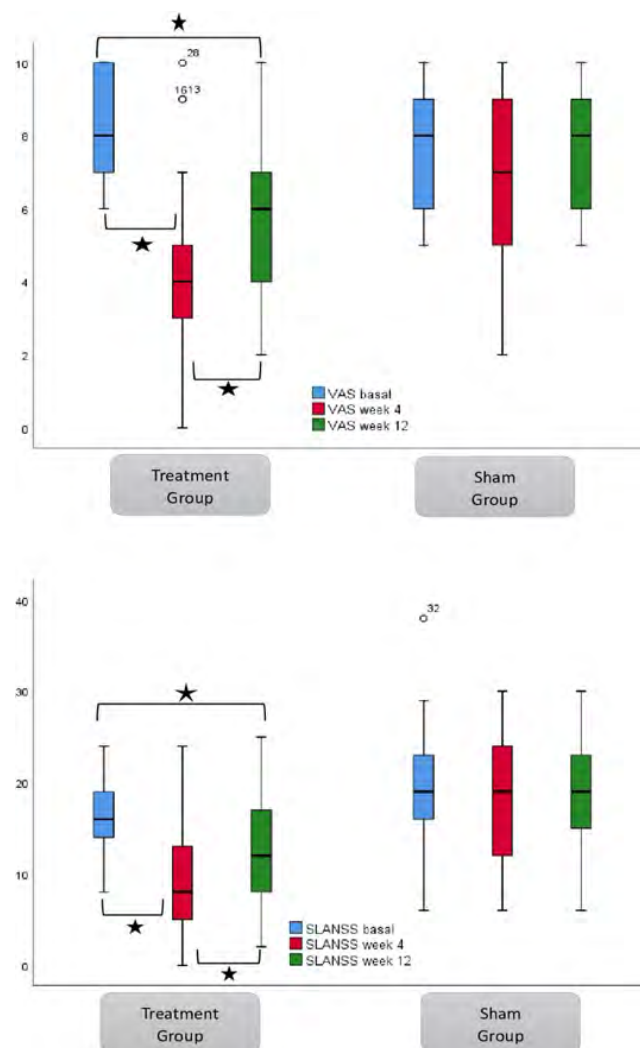


Figure 3. VAS and S-LANSS changes in Treatment and Sham groups.

Black Star: $p < 0.005$ between two time points. x-axis: shows measurement times. Blue: basal, Red: 4th week, Green: 12th week. y-axis: scale scores. Upper graphic: VAS score, lower graphic: S-LANSS score.

Discussion

NipRF treatment provided effective analgesia for neuropathic pain, with significant improvements in S-LANSS and VAS scores compared to the sham group at weeks 4 and 12 in our study. In addition, while providing this improvement, transient minimal side effects were observed that did not require treatment.

PTN is the main nerve that provides sensations to the heel and sole of the foot. PTN divides into the medial plantar, lateral plantar, and medial calcaneal nerves, and the branches provide sensory innervation to the entire sole and heel area, except for the lateral heel.^[8] Therefore, PTN blockade or pRF therapy has been used to treat a variety of conditions such as calcane-

al spur and plantar fasciitis, which cause pain in the sole and heel.^[9,10] To our knowledge, pRF via cannula or transcutaneous electrodes on the PTN has never been studied for the treatment of diabetic neuropathic pain (DNP). This is the first study to evaluate NipRF therapy for the treatment of diabetic neuropathic pain.

In the non-drug treatment of DNP, methods such as transcutaneous electrical nerve stimulation (TENS) therapies, sympathetic blockade, botulinum toxin, and surgical decompression are used. Pain symptoms are improved by surgical decompression of the peripheral nerves in the treatment of DNP.^[1] Dellon et al.^[11] followed 628 patients with DM who underwent medial and lateral plantar nerve decompression with PTN branches for 3.5 years; a significant decrease in VAS scores was observed over this period.

Electrotherapy methods applied in the form of low- and high-frequency TENS have been reported by the authors as effective methods for the treatment of DNP.^[12,13] The effects of TENS are explained by gate control theory and endorphin release, which are partially similar to pRF.^[14]

NipRF (500 kHz) is an electrical stimulation therapy that is capable of reaching deeper tissues than TENS (150 kHz). Consequently, it has greater neuromodulation ability.^[15,16] The system is based on the principle of transmitting pRF current generated from a transducer to biological tissues through electrodes attached to the skin with a cable connection.

Our aim was to reduce neuropathic plantar pain by modulating the PTN, which provides sensory innervation to this region, with NipRF. pRF is usually applied with a needle electrode close to the nerve, but this requires ultrasound visualization and is an invasive and painful process. The administration method is irrelevant, whether transcutaneous electrode or needle, in neuropathic pain, pRF, which has a complex mechanism of action, exerts its effects via biological pathways. The modification mechanisms of pRF in nociceptive signalling have been included, and occur through various mechanisms, such as neurotransmitters, ion channels, postsynaptic receptors, immune activity, microglial markers, inflammatory cytokines, and intracellular proteins. These microstructural

changes in the peripheral nerve result in a prolonged depression of C-fiber-associated spinal sensitivity, consequently blocking the pain signal from the peripheral nerve to the central nervous system (Fig. 4).^[3]

NipRF is a relatively new treatment method with limited experience. Favorable results in different anatomical locations and pain syndromes have been reported for NipRF treatment. In a double-blind placebo study, Taverner et al.^[17] showed a statistically significant decrease in VAS scores in the active treatment group with NipRF treatment for knee pain. In a retrospective study published by Taverner et al.^[18] in 2013, NipRF treatment for shoulder pain showed a significant reduction in 10 of 15 painful shoulders lasting longer than three months. In another double-blind, placebo-controlled study by Taverner et al.^[7] evaluating the efficacy of TPRF for shoulder pain, the active electrode group showed improvement at 12 weeks. In a report of 4 cases by Stall, headache frequency decreased in 3 patients with TPRF applied from the occipital region.^[19] A prospective, double-blind, placebo-controlled study by Lin et al.^[16] compared NipRF with TENS for shoulder pain. Treatment in the NipRF group was found to be significantly more effective and comfortable than in the TENS group at weeks 4 and 12. Ilfeld reported two case series using a portable ambulatory pRF device to treat post-amputation residual limb and postoperative pain after amputation. Continuous pRF current was delivered for 30 days, and pain was reduced to the point where opioids were no longer required.^[20,21]

In our study, we found that the treatment group experienced a 47% improvement in VAS scores at week 4 and a 29% improvement at week 12. The corresponding rates for S-LANSS scores were 43% and 21%, respectively. Previous studies on NipRF have shown successful results in the treatment of chronic migraine and carpal tunnel syndrome. One of these studies compared the effectiveness of two sessions of NipRF applied to the median nerve trajectory with wrist splint therapy in patients with carpal tunnel syndrome. Although there was no significant difference in the Boston Carpal Tunnel Syndrome Questionnaire scores between the groups, a 43% improvement was observed at week 4 and a 28% improvement at week 12 in the NipRF group.^[5] In another study, the results of two sessions of NipRF treatment applied to

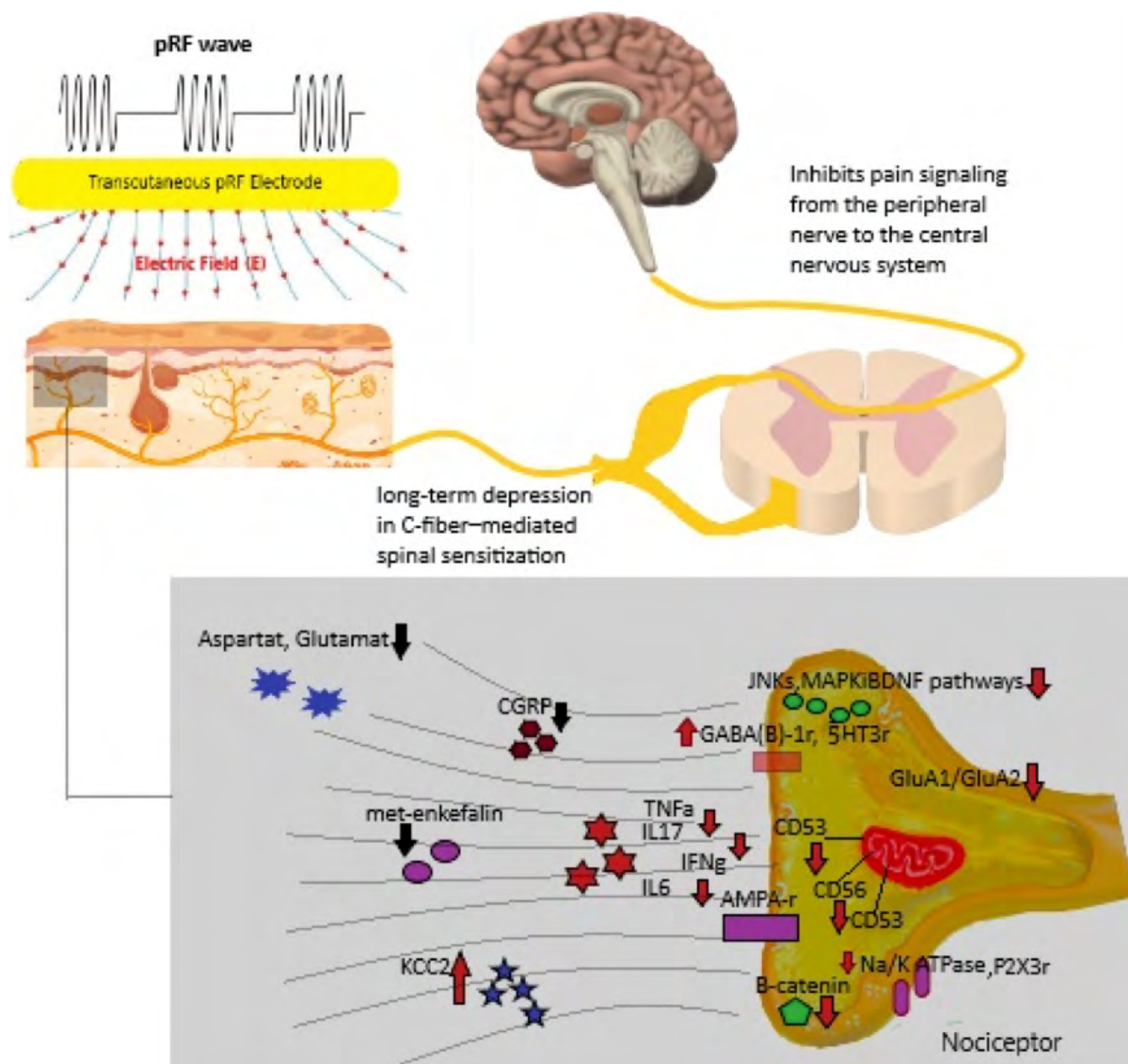


Figure 4. Cellular and molecular mechanisms of action of pulsed radiofrequency.

the greater occipital nerve trace in chronic migraine were compared with those of a control group with greater occipital nerve blockade. After four weeks of follow-up, there was no significant difference in the VAS scores between the two groups. However, the NipRF group showed a 32% improvement at week 4.^[22] When examining the results of these studies, similar effectiveness rates were observed.

No serious adverse events were reported. Seven patients experienced mild redness and burning that resolved without treatment. No serious adverse events related to electrode-mediated NipRFs have been reported in previous studies.

Unlike conventional RF, which heats up to 70-80°C, pRF does not cause thermocoagulation and is considered safe. Although it is thought to act by neuromodulation without causing destruction of nerve tissue, Erdine, Podhajsky, and Cahana have shown that a pRF current applied at 42-43 degrees causes significant destruction of the cellular structure of the dorsal root ganglion, sciatic nerve, and thalamic neurons.^[23-25] In this respect, transcutaneous application of pRF via electrodes appears to be safer than cannula-mediated application. However, further studies are required to compare cannula-mediated and transcutaneous electrode-mediated pRF treatments and to draw definitive conclusions.

Limitations

Our study has several limitations. First, the treatment period was limited to 2 sessions. Second, the follow-up period was limited to 12 weeks. Third, although the method used to calculate the sample size of the study was NipRF treatment with sham and active electrodes, the patient group studied was shoulder pain.

Conclusion

In this study, with two sessions of NipRF treatment, we observed sustained improvement in diabetic neuropathic pain complaints for 12 weeks. pRF via transcutaneous electrodes offers non-invasive and easy-to-use, effective pain control without serious side effects. More frequent use may provide greater and longer-lasting pain relief; however, further studies are needed to confirm this.

Ethics Committee Approval: The University of Health Sciences Dışkapı Yıldırım Beyazıt Training and Research Hospital Ethics Committee granted approval for this study (date: 22.03.2021, number: 107/23).

Informed Consent: Written informed consents were obtained from patients who participated in this study.

Conflict of Interest: The authors declare that there is no conflict of interest.

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