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ORIGINAL ARTICLE

Could pulsed radiofrequency stimulation of the proximal greater occipital nerve be a treatment option for refractory chronic migraine patients?

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ABSTRACT

Objectives: This study aimed to demonstrate the change in pain intensity, frequency of attacks, and life quality before and after treatment in patients with chronic migraine who underwent greater occipital nerve (GON) pulsed radiofrequency (PRF).

Patients and methods: This prospective, cross-sectional study was conducted with 30 patients (1 male, 29 females; mean age: 43.7±9.8 years; range, 26 to 64 years) with chronic migraine diagnosed according to the beta version of the third edition of the International Classification of Headache Disorders. Patients who did not respond to conventional treatments were enrolled in the study. The PRF procedure on the proximal GON at the C2 vertebra level was performed under the guidance of ultrasound at 5 Hz and 5 msec pulsed width for 360 sec at 45 V. The Visual Analog Scale (VAS), pain frequency (per week), analgesic consumption frequency (per week), and the SF-12 (12-item Short-Form Health Survey) were used to compare pain intensity and quality of life (QoL) before and three months after treatment.

Results: There was significant decrease in pain frequency (5.5 to 2.0), analgesic consumption frequency (7.0 to 2.0), and VAS scores (9.0 to 7.0) three months after the intervention compared to baseline ($p<0.001$). At the end of the first month, 17 patients reported more than 50% reduction in pain. In this study, a prominent improvement was observed in mental and physical components of QoL scores, indicating that disability rates of chronic migraine patients decreased with PRF compared to pretreatment.

Conclusion: According to the results, PRF can be considered an effective treatment option in patients with refractory chronic migraine.

Keywords: Chronic migraine, drug resistant, greater occipital nerve, pulse radiofrequency, quality of life, refractory headache.

Chronic migraine patients experience persistent and incapacitating symptoms, often showing resistance to standard and conservative treatments.[1-4] According to the International Headache Society, chronic migraine is defined as experiencing a headache on 15 or more days per month for over three months annually, with the characteristics of migraine with or without aura on a minimum of eight days within a month.[5] It is noteworthy to mention that the incidence of chronic migraine among the general population is estimated to be between 2 and 8%, indicating that approximately 14% of all individuals experience migraine.[3,4] Furthermore it impacts both the productivity and output of individuals' work, leading to a considerable economic burden. As a result, these individuals face substantial challenges, leading to impaired social functioning and diminished quality of life (QoL). Approximately 2 to 8% of patients experience chronic migraine, a severe form of the condition that does not respond to medications and necessitates alternative treatment approaches.[1,2] Despite the approval of several treatments for chronic migraine, there remains a significant number of patients

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who continue to suffer from this condition. There remains a need for exploring alternative treatment options.[6] In the past five years, there have been significant advancements in treatments available for patients suffering from this condition. It is crucial for healthcare professionals to stay informed about therapeutic options for chronic migraine.[1]

Numerous studies have shown that pulsed radiofrequency (PRF) treatment effectively relieves neuralgia and joint pain that do not respond to conventional therapies.[7,8] Ultrasound-guided PRF therapy to the greater occipital nerve (GON) is employed for various refractory headache conditions, making it a versatile therapeutic option. The primary indications for PRF include migraine, cervicogenic headaches, occipital neuralgia, and intracranial hypotension.[9-13] While numerous studies focus on GON block in existing literature, there is a scarcity of research addressing the utilization of GON radiofrequency therapy for migraine treatment.[13-16] Hence, this study aimed to evaluate the effect of PRF treatment on pain and QoL in patients diagnosed with chronic migraine who did not respond to standard and conservative treatments.

PATIENTS AND METHODS

This prospective, cross-sectional study was conducted at the Hatay Training and Research Hospital between June 2022 and December 2022. Thirty-six patients who were admitted to the neurology clinic with the diagnosis of chronic migraine according to the beta version of the third edition of the International Classification of Headache Disorders were evaluated.[5] Three patients did not accept interventional treatment, two patients had uncontrolled hypertension, and one had bleeding disorder; these six patients were excluded from the study. The remaining 30 patients (1 male, 29 females; mean age: 43.7±9.8 years; range, 26 to 64 years) were included in the study and scheduled for interventional therapy, following the standard therapeutic protocol for headache management. All patients were on prophylaxis and used triptans for rescue treatment. Exclusion criteria were <18 years of age, pregnancy/lactation, a cardiac pacemaker, previous therapy with PRF at the same area, severe psychiatric diseases, and coagulation disorders. A written informed consent was obtained from each patient. The study protocol was approved by the Mustafa Kemal University Faculty of Medicine Ethics Committee (date: 24.10.2022, no: 2022/94). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Visual Analog Scale (VAS) and the 12-item Short-Form Health Survey (SF-12) forms were filled out by all patients before treatment and three months after treatment. The patients were asked how much they benefited from the treatment in the first month after the treatment. Patients reporting more than a 50% decrease in headache intensity were considered responders. Sociodemographic characteristics, such as age, sex, and education, headache characteristics, frequency of headaches, number of years with migraine, the prophylaxis treatment, and the number of daily analgesics were recorded.

Headache severity was recorded using VAS. All patients were informed about the scale numbered from 0 (no pain) to 10 (worst pain) and were asked to indicate pain severity with VAS in the headache diary.

The SF-12 is a self-reported QoL measure assessing the impact of health on an individual's everyday life. It is the shorter form of the SF-36 (36-item Short-Form Health Survey) and evaluates physical and mental domains. This scoring algorithm, developed by Ware et al.,[17] consists of 12 questions with binary and Likert-type answer options. Of these, six are related to physical health, and five are related to mental health. A final question combines both physical and mental health dimensions. Answers from the 12 questions are then grouped into the following eight functional health subdomains: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. Four items in the SF-12, namely general health, body pain, mental health, and vitality, are reverse scored.[17,18]

For all patients, the diagnosis of chronic intractable migraine was made by a neurologist. All PRF procedures were performed by an algologist. The aseptic technique was applied during the PRF procedure. The patient was maintained in the prone position. At the level of the C2 vertebra, the procedure was performed accompanied by ultrasonographic imaging using a linear probe (6-12 MHz Toshiba Aplio 500 Ultrasound Device; Toshiba Medical Systems Co., Otawara, Japan). The probe was slid down to find the bifid spinous process of the C2 vertebra and subsequently moved laterally to identify the obliquus capitis inferior muscle of the neck. The GON was found superficial to the obliquus capitis inferior muscle

at this level. Doppler ultrasonography was used to avoid vascular injury. After identifying the GON, the catheter needle (22-gauge, 5.5-cm active lead curved-tip electrode) was inserted with an in-plane technique from the lateral to the medial side. Under ultrasound guidance, the radiofrequency needle was placed close to the unilateral GON. A sensory stimulation test was performed using an radiofrequency generator (NeuroTherm NT1100; St. Jude Medical Inc., St. Paul, MN, USA), and the patient reported dysesthesia and a tingling sensation at the occipital area with less than 0.2V. The PRF treatment was administered at 5 Hz and 5 msec pulsed width for 360 sec at 45 V under the constraint that the temperature of the electrode tips did not exceed 42°C.

Statistical analysis

Data were analyzed using IBM SPSS version 25.0 software (IBM Corp., Armonk, NY, USA). Normal distribution was evaluated through the Shapiro-Wilk normality test for every variable involved in the analysis. Most of the variables were not normally distributed; hence, the Wilcoxon signed-rank test was used to compare the differences between baseline and after the procedure. Since a nonparametric approach was adopted, the first quartiles, medians, and the third quartiles were reported. Effect size (r) was also calculated. Effect sizes that were <30 in the absolute value indicated a small effect, those between 30 and 50 in the absolute value indicated a medium effect, and those >50 in the absolute value indicated a large effect. A p-value <0.05 was considered statistically significant.

A post hoc power analysis was conducted using the G*Power version 3.1 software (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany) with a sample size of 30. Effect sizes in the study ranged from 0.45 to -0.72, with an alpha level set at 0.05. The results showed that the power for the study outcomes ranged from 0.64 to 0.96.

RESULTS

Demographic data are shown in Table 1. Seventeen patients reported over 50% pain relief one month after the GON PRF treatment. All patients used at least two prophylactic drugs, and eight patients used three or more prophylactic drugs. Duloxetine (n=16), topiramate (n=10), valproic acid

TABLE 1
Demographic characteristics (n=30)

Variables	n	%	Mean±SD	Min-Max
Age (year)			43.7±9.8	26-64
Sex				
Male	1	3.33		
Female	29	96.6		
Number of years with migraine			15.1±8.4	2-30
Education			6.4±3.8	0-16

SD: Standard deviation.

TABLE 2
Drugs used for prophylaxis

Drugs	n	%
Duloxetine	16	53.3
Topiramate	10	33.33
Valproic acid	2	6.66
SSRIs	4	13.33
Amytriptiline	6	20
Venlafaxine	3	10
Beta blockers	8	26.66
Calcium channel blockers	4	13.33

SSRIs: Selective serotonin reuptake inhibitors.

TABLE 3
Comparisons between baseline and after the procedure regarding clinical scores

	Baseline		Post procedure 3th month		Change from baseline				
	Median	1st-3rd quartile	Median	1st-3rd quartile	Median	1st-3rd quartile	z	*p*	r
Attack frequency (per week)	5.5	4.0-7.0	2.0	1.0-3.5	–3.0	–4.0 - –1.0	–3.93	<0.001***	–0.72
Frequency of analgesic use (per week)	7.0	3.8-7.0	2.0	0.8-4.8	–3.0	–6.0-0.0	–3.69	<0.001***	–0.67
Visual Analog Scale	9.0	8.0-10.0	7.0	6.0-9.3	–1.0	–4.0-0.0	–3.65	<0.001***	–0.67
Physical component summary	34.1	29.7-38.3	40.6	36.0-45.4	6.3	1.2-10.4	3.51	<0.001***	0.64
Mental component summary	39.2	34.5-43.2	42.0	39.5-47.2	4.5	1.4-10.9	2.46	0.014*	0.45

* p<0.05; ** p<0.01; *** p<0.001.

(n=2), selective serotonin reuptake inhibitors (n=4), amitriptyline (n=6), venlafaxine (n=3), beta-blockers (n=8), and calcium channel blockers (n=4) were the medications used (Table 2). All patients had migraine without aura.

The results of the Wilcoxon signed-rank tests and effect size analyses conducted to evaluate the differences in patients' clinical scores in the baseline and after the procedure are listed in Table 3. A statistically significant decrease in VAS scores (p<0.001), pain frequency per week (p<0.001), and frequency of analgesic use per week (p<0.001) was demonstrated. Based on the effect size, the procedure had a large effect on VAS scores (r=–0.67), pain frequency per week (r=–0.72), and analgesic consumption frequency per week (r=–0.67). Focusing on the SF-12 component scores, a significant increase was observed between baseline and after the procedure in physical component summary (p<0.001) and mental component summary (p=0.014) scores. Based on the effect size, the procedure had a large effect on physical component summary scores (r=0.64) and a medium effect on mental component summary scores (r=0.45). The SF-12 component median scores at the baseline and after the procedure are shown in Figure 1.

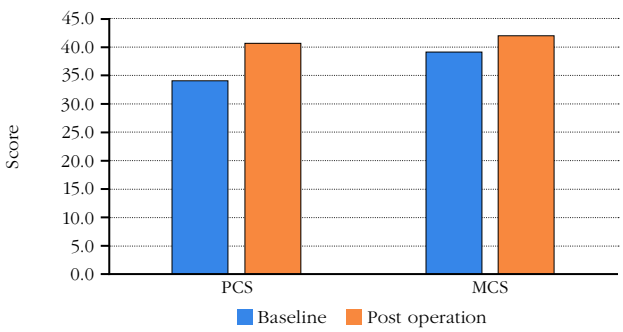

Figure 1. The SF-12 component median scores at the baseline and after the procedure.

PCS: Physical Component Summary (p<0.001) and MCS: Mental Component Summary (p<0.014); SF-12: 12-item Short-Form Health Survey.

DISCUSSION

This study demonstrated the beneficial response of PRF stimulation on the GON in the management of refractory chronic migraine. As mentioned in the results; headache intensity, pain frequency, and analgesic consumption frequency per week showed a statistically significant decrease. Furthermore, life quality scores were improved compared to pretreatment.

Refractory chronic migraine affects approximately 1% of the population worldwide[19] and is unresponsive to standard therapies, significantly impacting daily activities and diminishing the overall QoL. Consequently, the treatment of refractory migraine continues to pose a significant clinical challenge.[20] While pharmacological approaches can help many patients and currently are the cornerstone of headache management, those who still endure persistent or severe headaches might discover considerable advantages from a spectrum of more invasive interventions designed to specifically block the transmission of pain signals from the affected nerves.[21,22] For example, several interventional treatments have come into focus as alternatives for managing refractory headaches during the past few decades. These therapies encompass a variety of procedures including botulinum toxin A, injections, local occipital nerve anesthetic and corticosteroid infiltration, subcutaneous stimulation of the occipital nerve, PRF treatment

of the occipital nerve, sphenopalatine ganglion block, deep brain stimulation, radiofrequency ablation, and dorsal root surgery targeting nucleus caudalis.[23,24]

The GON serves as the primary sensory nerve for the occipital area of the skull, originating from the second cervical root. By examining the convergence in the trigeminal nucleus within the upper cervical segments, it is evident that inhibiting the transmission of nociceptive information from the GON can be an effective approach to controlling migraine-induced headaches.[15,16] The PRF protocol, which does not generate excessive heat that could cause structural damage, was introduced by Sluijter et al.[25] The proposed mechanism of PRF is based on the idea that its electrical field can modify pain signals. Also Hagiwara et al.[26] reported that PRF has the potential to modulate neuropathic pain by enhancing the descending noradrenergic and serotonergic pain inhibitory pathways. Their findings further revealed that PRF was capable of suppressing the excitation of nociceptive C-fibers, providing an alternative approach to manage pain. Erdine et al.[27] discovered that PRF had a disruptive impact on the smaller sensory nociceptive axons (C fibers and A-delta fibers), sparing the larger non pain related sensory fibers such as A-beta fibers. Furthermore, Cho et al.[28] observed a decrease in microglial activity in the spinal dorsal horn following PRF treatment on the dorsal root ganglion. As microglia are responsible for releasing pain-signaling cytokines and chemokines, the authors proposed that this downregulation could effectively inhibit the transmission of pain signals.[28] In our study, after the application of PRF on the GON, medication overuse, pain intensity, and pain frequency decreased for at least three months. Furthermore, no postprocedural side effects were observed.

There are limited studies on PRF in migraine patients. In a study including 81 patients diagnosed with migraine and occipital neuralgia, a local anesthetic and GON PRF were administered to one group (n=42), and local anesthetics and steroids were administered to the other group (n=39).[11] Pulsed radiofrequency offered significantly better pain relief than steroids throughout the study; however, the benefits diminished between six weeks and three months. In a study of patients with chronic headache who underwent PRF on the C2 dorsal root ganglion, a significant decrease was observed in pain scores at the six-month follow-up.[30] In two case reports of patients with a diagnosis of resistant migraine undergoing GON PRF, a significant reduction in pain was detected for three months.[20] In two other headache studies performed, a significant decrease in pain scores was found in the follow-up of resistant cervicogenic headache and occipital neuralgia treated with PRF.[11,30]

Chronic migraine is frequently associated with various psychiatric comorbidities, which can negatively impact both disability and treatment outcomes. These psychiatric problems are mainly anxiety, depression, and sleep disturbance, and these issues adversely affect the treatment of the disease and the QoL.[31] Psychiatric conditions and migraine may influence each other via common pathophysiological mechanisms. Central sensitization and dysregulation of the hypothalamic-pituitary-adrenal axis, central monoaminergic disturbances, and dopaminergic polymorphisms have been implicated in both psychiatric comorbidities and migraine.[32] Güner and Eyigor[33] showed that GON PRF applied to refractory chronic migraine patients was an effective and safe treatment option; it also improved symptoms of depression, sleep disturbance, and disability, thereby enhancing QoL. Perdecioğlu et al.[34] compared GON PRF and GON block under ultrasound guidance in chronic migraine patients. Visual Analog Scale scores and headache frequency decreased significantly after treatment in both groups, but no superiority was found between the groups in terms of effectiveness. According to our study, patients undergoing PRF stimulation on the GON treatment ensures a significant reduction in pain intensity and frequency, leading to notable improvements in both physical function and mental health. This improvement is believed to result from the underlying pathophysiological mechanisms.[35]

Limitations of the current study include its uncontrolled design and small number of patients. Additionally, mental status was evaluated only with the SF-12, and the presence of depression and anxiety was not screened. Despite these limitations, as shown in our findings, PRF treatment on the GON showed the potential to decrease the frequency of monthly headache episodes and ameliorate the intensity of pain experienced during each episode. Moreover, it was shown that decreased pain affected both physical and psychological status positively. This is important for maintaining independence, social relationships, and avoiding financial burden.[35]

In conclusion, the utilization of PRF as an interventional neuromodulatory treatment for

chronic migraine holds great appeal due to its minimally invasive percutaneous technique with little to no neurodestruction and favorable side effect profile. Furthermore, PRF offers a potentially safe and noninvasive therapeutic option. By targeting the occipital nerves, PRF effectively reduces pain intensity, attack frequency, and disability, leading to improved overall QoL for chronic migraine patients. Further research with larger controlled studies is warranted to confirm and expand on these findings.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Idea/concept, design, analysis and/or interpretation, literature review, writing the article: D.Y.D.; Control/supervision, materials: F.E.; Datacollection and/or processing, critical review, references and fundings: D.Y.D., F.E.

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