Head & Face Medicine

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Effectiveness of combining greater occipital nerve block and pulsed radiofrequency treatment in patients with chronic migraine: a double-blind, randomized controlled trial

Tuba Tanyel Saraçoğlu[1*], Ayten Bılır[2] and Mehmet Sacit Güleç[2]

Abstract

Background Pulsed radiofrequency (PRF) treatment targeting the greater occipital nerve (GON) has shown efficacy in treating various conditions. This double-blind, randomized controlled study aimed to evaluate the effects of combining PRF therapy with GON block (GONB) therapy in patients with chronic migraine.

Methods The study consisted of two groups: GONB and GONB + PRF, each comprising 16 patients with chronic migraine. Using 0.5-Hz sensorial stimulation, a 5-cm-long radiofrequency needle was inserted under ultrasound guidance in both groups. Subsequently, all patients received a GONB by administering 2 mL of 0.25% bupivacaine. In the GONB + PRF group, patients underwent 4 min of PRF at 42℃, whereas the GONB group did not receive any PRF treatment. Follow-up examinations were performed at 1, 2, 3 and 6 months after the procedure to evaluate the frequency and severity of migraine attacks, number of headache days, and analgesic consumption.

Results In the GONB + PRF group, the visual analog scale (VAS) score, number of migraine attacks, number of headache days, and analgesic consumption were significantly lower compared to the GONB group ($P < 0.05$). Significant decreases (60%) in mean VAS scores, number of migraine attacks, number of headache days, and consumption of analgesic medications were observed in the GONB + PRF group at the 1-, 2-, 3-, and 6-month follow-ups compared with the pre-treatment period ($P < 0.05$).

Conclusions The combination of GONB and PRF presents a promising new treatment option for patients with chronic migraine. This approach has demonstrated efficacy in minimizing analgesic use, decreasing the frequency of migraine attacks, reducing the number of headache days and decreasing the severity of migraine attacks.

Trial Registration NCT05464212.

Keywords Migraine, Greater occipital nerve, Pulsed radiofrequency, Chronic migraine, Headache

*Correspondence:
Tuba Tanyel Saraçoğlu
tbtnyl@gmail.com
[1]Department of Pain Management, Başakşehir Çam and Sakura City Hospital, İstanbul, Turkey
[2]Depatment of Pain Management, Faculty of Medicine, Eskişehir Osmangazi University, Eskişehir, Turkey

Background

Migraine, a prevalent type of headache, profoundly impacts the quality of life of patients. Among neurological disorders, it stands as a leading cause of disability, particularly in women. Its repercussions extend beyond impairing daily functioning and quality of life, and it often results in a significant loss of productivity in the workforce [1].

The primary objectives of migraine management are to relieve pain and reduce the frequency of headaches. Chronic migraine (CM) affects 1–2% of the general population and approximately 8% of all patients with migraine. The annual conversion rate from episodic migraine (EM) to CM is approximately 3% [2, 3]. Despite its lower prevalence compared to EM, CM is associated with a substantially greater burden of headache-related disability, a more profound impact on negative social and occupational functioning, and a markedly reduced quality of life [4–6].

Individualized treatment options for patients with CM are needed to alleviate the substantial burden it imposes [7]. Treatment modalities for CM include oral medications, non-pharmacological interventions such as greater occipital nerve block (GONB), calcitonin gene-related peptide antagonists and antibodies, botulinum toxin A injections, and neuromodulation.

Peripheral nerve blocks with local anesthetics and/or corticosteroids have long been an established therapeutic approach in the management of various headache treatments. GONB stands as the most widely employed procedure for this purpose. However, due to a limited number of double-blind, randomized controlled trials, there is no standardized procedure for GONB. Additionally, the analgesic effects of GONB have been observed to range from days to weeks [8].

Pulsed radiofrequency (PRF) is a technique that alleviates pain by delivering electrical fields and heat bursts to targeted nerves or tissues without causing damage [9]. PRF treatment applied to the greater occipital nerve (GON) has shown efficacious in treating conditions such as occipital neuralgia, cervicogenic headache, and intracranial hypotension headache [10]. A retrospective study reported on the application of only PRF with the needle technique, whereas a prospective study investigated transcutaneous non-invasive PRF treatment in patients with CM [11–13]. However, to the best of our knowledge, there are no prospective randomized controlled studies evaluating the long-term effects of combined GONB and PRF treatment for CM.

The objective of this double-blind, randomized controlled study was to evaluate the effectiveness of combining ultrasound-guided (USG) GONB with PRF in patients with CM.

Methods

Study population

This prospective study was approved by the Institutional Review Board of Eskisehir Osmangazi University Faculty of Medicine (approval no.: 8058721-050.99-E.34888). Participants were provided with a clear explanation of the purpose of the study, its duration, their role, and the possible risks they might face when participating. Prior to randomization, written informed consent was obtained from all participants. The study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki as revised in 2000 (protocol number E.27336). Between April 2019 and April 2020, 63 patients with CM who presented to the Pain Management Clinic of Eskisehir Osmangazi University were evaluated sequentially. Among the 63 patients with CM, 51 met the inclusion criteria and were further evaluated, whereas five with fibromyalgia, eight with medication-overuse headache, one who had botulinum toxin A injection 2 months previously, and two who reported allergy to local anesthetic agents were excluded from the study (Fig. 1). The datasets generated during and/or analyzed during the current study are retrospectively registered in ClinicalTrials.gov (NCT05464212) (Date: July.19.2022).

The inclusion and exclusion criteria were as follows:

Inclusion criteria

- Age 18–65 years.
- Experienced CM, as defined according to the international classification of headache disorders-3 (ICHD-3), for at least 12 months [14].
- Maintenance of a headache diary for at least 4 weeks.
- Insufficient efficacy with adequate dosing and duration of medical treatment; intolerable side effects; contraindications precluding use.

Exclusion criteria

- Experience of medication-overuse headache.
- Presence of secondary headache conditions.
- Treatment with peripheral nerve blocks, trigger point injections, or botulinum toxin injections within the past 3 months.
- Known allergy to local anesthetics.
- Pregnancy or nursing.
- History of chronic medical conditions (e.g., cardiovascular, hepatic, renal, and endocrine conditions).
- History of other chronic pain syndromes (e.g., low back pain and fibromyalgia).
- Failure to fill in the headache diary for more than 6 non-consecutive days in a 4-week period.

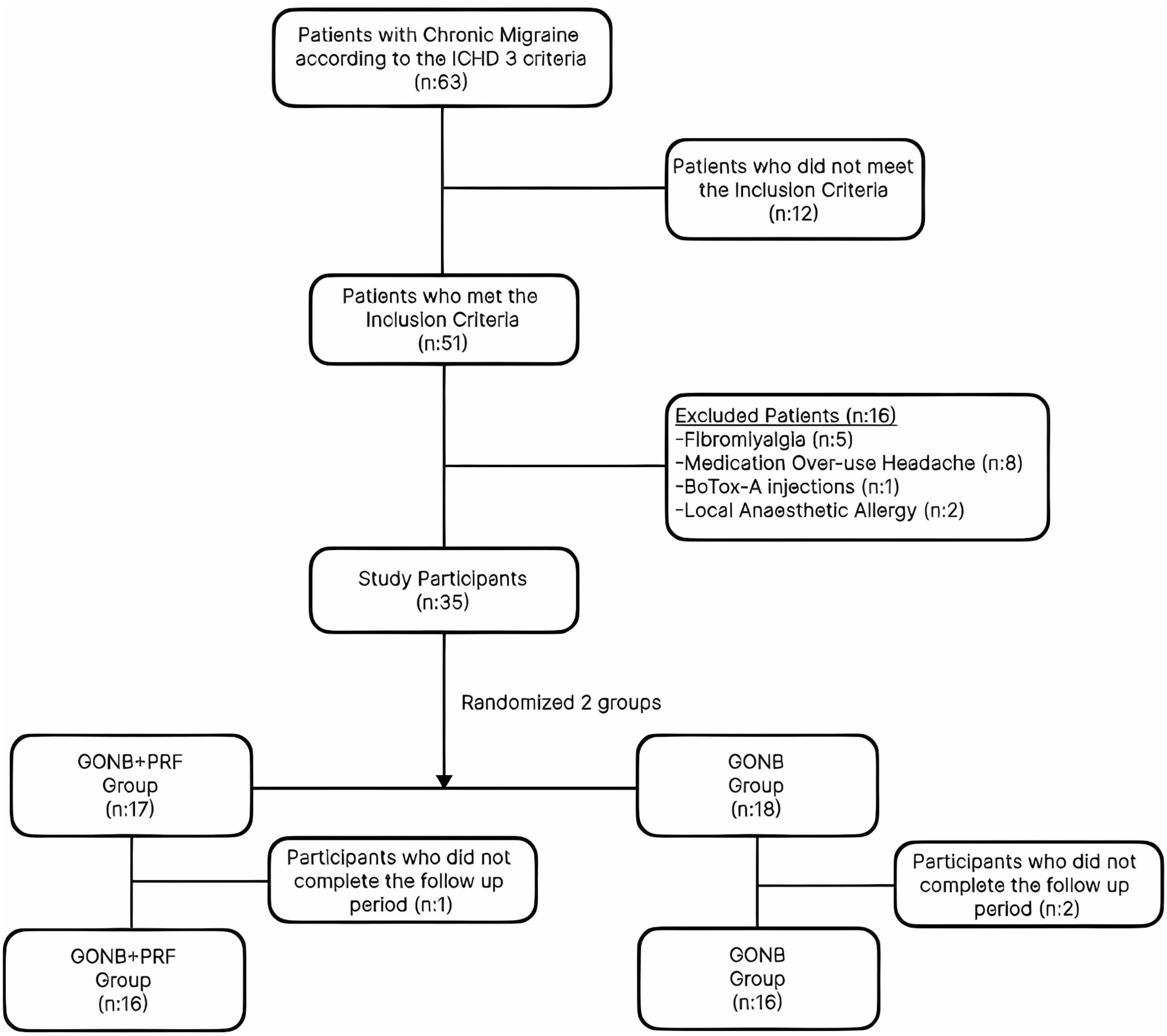

Fig. 1 Consolidated flowchart illustrating patient screening, eligibility assessment, and the final composition of the study sample. ICHD, International Classification of Headache Disorders; GONB, greater occipital nerve block; PRF, pulsed radiofrequency

Randomization and blindness

Patients were selected through randomization performed using a computer random number generator. An independent researcher, blinded to the patients' treatment assignments, conducted evaluations before treatment initiation and throughout the study period. Additionally, another blinded researcher also evaluated the procedures.

Visual analog scale

A visual analog scale (VAS) ranging from 0 (no pain) to 10 (intense pain) was used to assess pain intensity.

Headache diary

Clinical data were collected through a self-report headache diary. All participants were given a headache diary and were instructed to record the frequency of migraine attacks, number of headache days, pain intensity, and analgesic consumption. Patients were asked to maintain this information in a diary for 4 weeks before inclusion in the study. Drugs used for the treatment of migraine attacks were noted. Patients who could not maintain a diary were not included in the study.

Intervention

In the operating room, electrocardiography, non-invasive blood pressure, and percutaneous oxygen saturation were routinely monitored in all patients. Patients were first placed in the prone position. Studies have shown that there is no difference in the effect of migraine treatment between using distal GONB and GONB performed at the C2 vertebral level [15]. Distal GONB was preferred in our study. USG distal GONB was performed to accurately locate the nerve and artery in all patients.

All procedures were performed bilaterally by the same blinded investigator, using a hockey-stick probe. The ultrasound probe was located at the medial one-third of the superior nuchal line between the occipital tubercle and mastoid process, under sterile conditions (Fig. 2). A 5 cm-long radiofrequency (RF) needle with a 0.5-cm active tip was advanced under ultrasound guidance in both the GONB+PRF and GONB groups. Needle placement was verified using Doppler imaging of the occipital artery (Fig. 3). Finally, a 0.3–0.5-Hz sensory stimulus was administered, the paresthesia sensation in the patient's occipital nerve dermatome was assessed, and a location verification was performed.

The GONB was administered to all patients by injecting 2 mL of 0.25% bupivacaine through a PRF needle. Following the GONB, PRF neuromodulation was applied at 42℃ for 4 min in the GONB+PRF group. To maintain blinding, in the GONB group, the PRF generator was set to run for 4 min and a sham administration was performed. The same clinic nurse operated the device in both groups and either provided or did not provide PRF to the patients based on the randomization protocol.

Follow-up

Patients were followed up at 1, 2, 3, and 6 months after the procedure. The severity and number of migraine attacks, number of headache days, and analgesic drugs administered were recorded. Although the treatments for migraine attacks remained unchanged for the patients, their frequency of use was noted. The name of the procedure performed on the patient was not included in the follow-up files. Data were unblinded after the study period, and information on the procedures performed were added to the patients' files.

Statistical analysis

Sample size estimation was performed using G*power version 3.1 (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany). According to a similarly designed previous study, using 3-month control mean VAS scores (group 1: 6.3±1.9, group 2: 8.6±0.8), the required number of patients was calculated as at least 12 patients in each group for an α of 0.05 and a power of 0.95 [16]. SPSS Statistics for Windows (version 22.0; IBM, Armonk, NY) was used for statistical analysis. Descriptive statistics (mean, standard deviation, frequency, and percentage) were employed to assess demographic and clinical characteristics. It was determined that the variables were normally distributed. This determination was made by dividing the interquartile range by the standard deviation, yielding a value between 1 and 3, and calculating the skewness and kurtosis values.

The mean values of the GONB and GONB+PRF groups were compared using an independent sample *t*-test. A comparison of the values recorded in the GONB+PRF group before and after treatment was performed using repeated measures analysis of variance. For variance analysis, Greenhouse–Geisser F-statistics were used in cases where the sphericity assumption was not met. *P*-values < 0.05 were considered statistically significant.

Results

A total of 35 patients with CM were enrolled in the study. After randomization, 17 and 18 patients were allocated to the GONB+PRF and GONB groups, respectively. Three patients, one from the GONB+PRF group and two from the GONB group, were lost to follow-up. Thus, a total of 16 patients in each group were included in the final analyses (Fig. 1).

Demographic data

The mean age of the patients in the GONB group (n=16) was 37.56±9.67 years. Three of the patients were male, and 13 were female. In the GONB+PRF group, the mean age was 35.88±9 years, comprising two males and 14 female patients. No significant differences in demographic data were observed between the two groups.

Primary outcome

VAS score

There were no significant differences between the pre-treatment VAS scores of the GONB and GONB+PRF groups (P=0.711); however, the mean VAS scores at 1 (P=0.011), 2 (P=0.024), 3 (P=0.004), and 6 months (P=0.002) after treatment were significantly reduced in the GONB+PRF group compared to the GONB group (Table 1).

In the GONB+PRF group, significantly decreased VAS scores were observed at 1 (P<0.001), 2 (P<0.001), 3 (P<0.001), and 6 months (P<0.001) post-treatment, compared with the pre-treatment VAS scores (P<0.001). At the final follow-up (at 6 months), we observed an approximately 60% decrease in the mean VAS scores compared with the pre-treatment VAS score in the GONB+PRF group (Table 2).

Secondary outcomes

Number of migraine attacks per month

There was no significant difference in the pre-treatment number of migraine attacks between the GONB and GONB+PRF groups (P=0.718). However, the mean number of migraine attacks at 1 (P<0.001), 2 (P<0.001), 3 (P<0.001), and 6 months (P<0.001) after treatment were significantly reduced in the GONB+PRF group

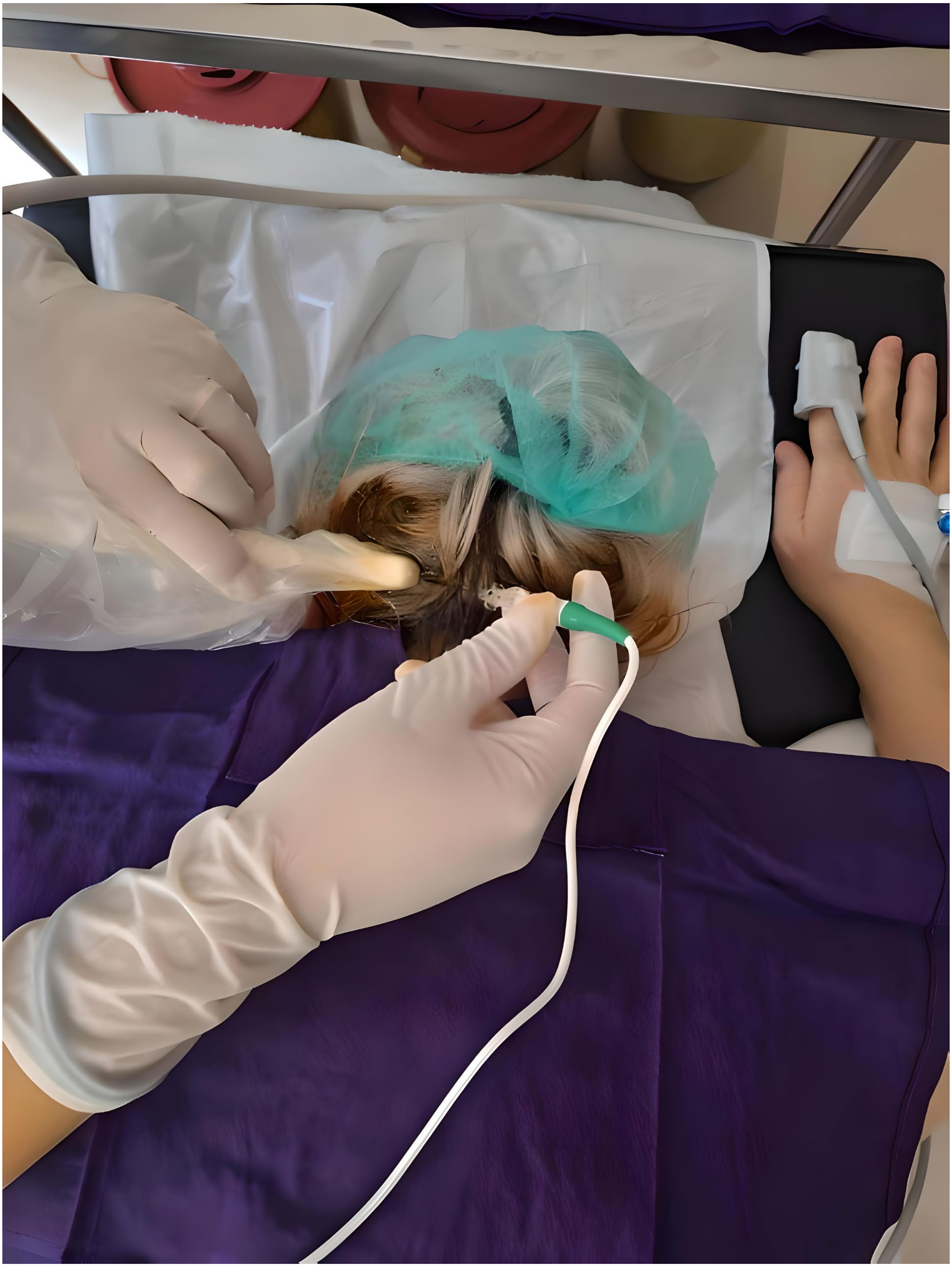

Fig. 2 Optimal positioning of the ultrasound probe for precise needle guidance during the greater occipital nerve block (GONB) procedure

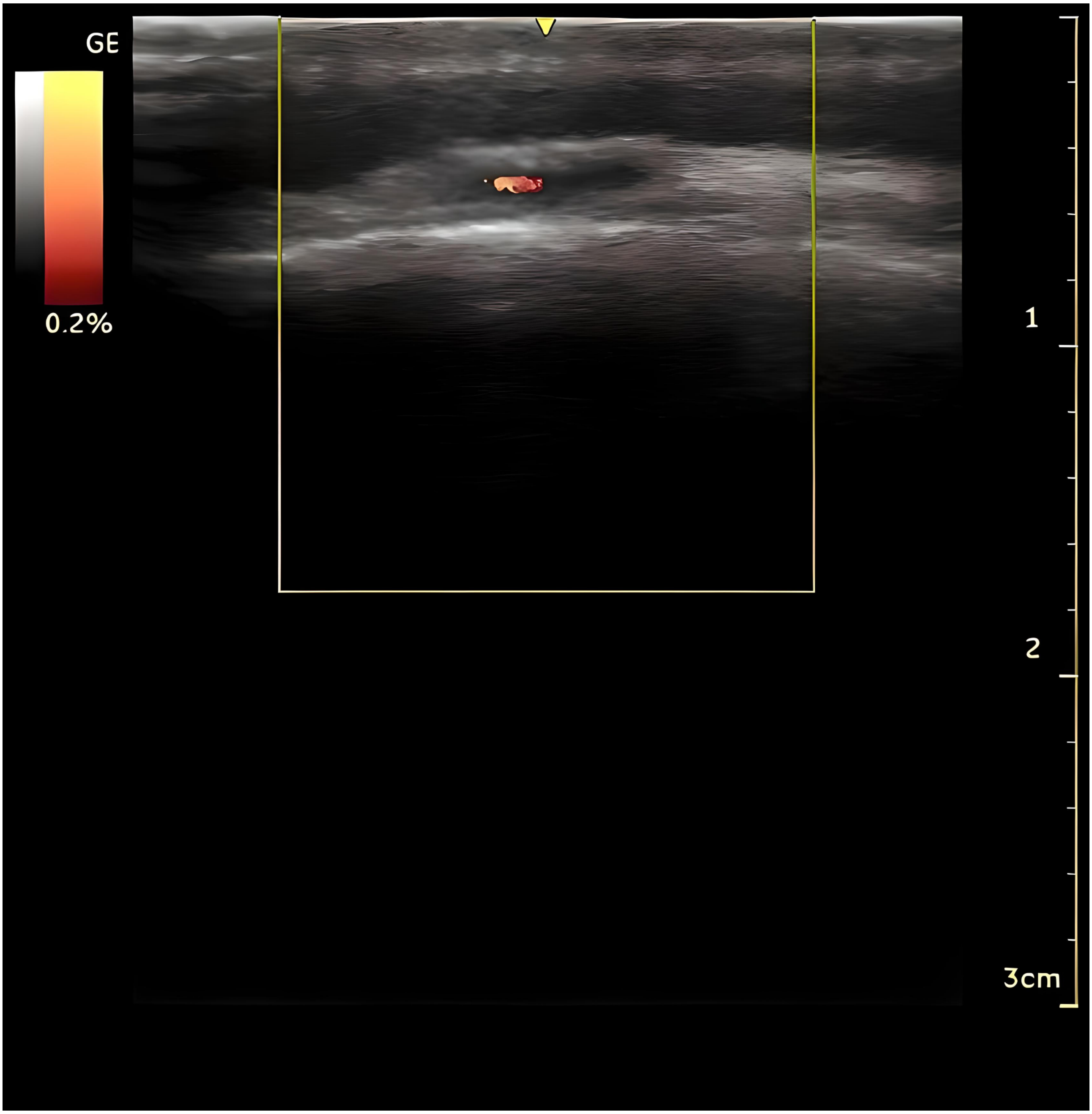

Fig. 3 Ultrasound visualization of the occipital artery and greater occipital nerve, guiding accurate needle placement during the greater occipital nerve block (GONB) procedure

compared to the GONB group (Table 1). Furthermore, there was a significant decrease in the mean number of migraine attacks experienced by patients in the GONB+PRF group at the 1-, 2-, 3-, and 6-month follow-ups compared with the pre-treatment period ($P<0.001$). This change accounted for an approximately 80% decrease in the mean number of migraine attacks experienced at 6 months after treatment compared to before treatment (Table 2).

Analgesic consumption per month

There was no significant difference between the pre-treatment mean number of analgesics consumed per month by patients in the GONB and GONB+PRF groups ($P=0.685$); however, the mean number of analgesics consumed at 1 ($P<0.001$), 2 ($P<0.001$), 3 ($P<0.001$), and 6 months ($P<0.001$) after treatment were significantly reduced in the GONB+PRF group compared to the GONB group (Table 1). In the GONB+PRF group, a significant decrease in the mean number of analgesics

Table 1 Comparison of the mean VAS scores, MNMA, MAC, and MNHD between the GONB and GONB + PRF groups

	Timepoint	GONB	GONB + PRF	*P* value
VAS	Baseline	8.75 ± 1.13	8.63 ± 0.719	0.711
	1st month	5.75 ± 2.41	3.7 ± 1.89	0.011*
	2nd month	5.94 ± 3.65	3.31 ± 2.41	0.024*
	3rd month	6.19 ± 3.45	2.75 ± 2.81	0.004*
	6th month	6.81 ± 2.81	3.5 ± 2.85	0.002*
MNMA	Baseline	9.4 ± 1.5	9.6 ± 1.4	0.718
	1st month	5.7 ± 2.2	1.94 ± 1	< 0.001*
	2nd month	7.31 ± 1.8	1.31 ± 0.95	< 0.001*
	3rd month	7.31 ± 1.9	1.06 ± 0.93	< 0.001*
	6th month	8 ± 1.83	1.56 ± 1.1	< 0.001*
MAC	Baseline	10.25 ± 2.3	9.95 ± 2.02	0.711
	1st month	5.2 ± 1.88	1.9 ± 1.5	0.011*
	2nd month	6.9 ± 2.3	1.2 ± 1	0.024*
	3rd month	7.06 ± 2.2	1.06 ± 0.93	0.004*
	6th month	7.44 ± 2.6	1.63 ± 1.2	0.002*
MNHD	Baseline	16.3 ± 1.62	16.56 ± 1.4	0.645
	1st month	10.3 ± 2.06	3.06 ± 1.29	< 0.001*
	2nd month	14.9 ± 1.2	3 ± 1.15	< 0.001*
	3rd month	15.8 ± 1.28	3.25 ± 1.24	< 0.001*
	6th month	16 ± 1.46	3.44 ± 1.26	< 0.001*

*$P < 0.05$ (95% confidence intervals)

GONB, greater occipital nerve block; GONB + PRF, greater occipital nerve block combined with pulsed radiofrequency; VAS, visual analog scale; MNMA, mean number of migraine attacks; MAC, mean analgesic consumption; MNHD, mean number of headache days

Table 2 Comparison of the mean VAS scores, MNMA, MAC, and MNHD in the GONB + PRF group at the 1-, 2-, 3-, and 6-month follow-up assessments

	Timepoint		Mean difference	*P* value
VAS	Baseline (8.63)	1st month (3.69)	4.94*	< 0.001[b]
	Baseline (8.63)	2nd month (3.31)	5.313*	< 0.001[b]
	Baseline (8.63)	3rd month (2.75)	5.875*	< 0.001[b]
	Baseline (8.63)	6th month (3.50)	5.125*	< 0.001[b]
MNMA	Baseline (9.6)	1st month (1.94)	7.63*	< 0.001[b]
	Baseline (9.6)	2nd month (1.31)	8.25*	< 0.001[b]
	Baseline (9.6)	3rd month (1.06)	8.5*	< 0.001[b]
	Baseline (9.6)	6th month (1.56)	8*	< 0.001[b]
MAC	Baseline (9.95)	1st month (1.9)	8.05*	< 0.001[b]
	Baseline (9.95)	2nd month (1.2)	8.75*	< 0.001[b]
	Baseline (9.95)	3rd month (1.06)	8.9*	< 0.001[b]
	Baseline (9.95)	6th month(1.63)	8,32*	< 0.001[b]
MNHD	Baseline (16.56)	1st month (3.06)	13.5*	< 0.001[b]
	Baseline (16.56)	2nd month (3)	13.56*	< 0.001[b]
	Baseline (16.56)	3rd month (3.25)	13.3*	< 0.001[b]
	Baseline (16.56)	6th month (3.44)	13.12*	< 0.001[b]

*The mean difference is significant at the 0.05 level.

[b]Adjustment for multiple comparisons: Bonferroni.

*$P < 0.05$ (95% confidence intervals).

GONB + PRF, greater occipital nerve block combined with pulsed radiofrequency; VAS, visual analog scale; MNMA, mean number of migraine attacks; MAC, mean analgesic consumption; MNHD, mean number of headache days.

consumed was observed at the 1-, 2-, 3-, and 6-month follow-ups compared to baseline ($P<0.001$). This change accounted for an approximately 80% reduction in the mean number of analgesics consumed at 6 months after treatment compared with that before treatment (Table 2).

Number of headache days per month

There was no significant difference between the mean number of headache days reported by patients in the GONB and GONB+PRF groups at pre-treatment ($P=0.645$); however, the mean number of headache days at 1 ($P<0.001$), 2 ($P<0.001$), 3 ($P<0.001$), and 6 months ($P<0.001$) after treatment were significantly reduced in the GONB+PRF group compared to the GONB group (Table 1). In the GONB+PRF group, a significant decrease was observed in the mean number of headache days at the 1-, 2-, 3-, and 6-month follow-ups compared with those reported at baseline ($P<0.001$). This decrease accounted for an approximately 85% decrease in the mean number of headache days at 6 months post-treatment compared to that reported pre-treatment (Table 2).

Discussion

At the end of our study, patients with CM reported a significant decrease in pain intensity, analgesic consumption, number of headache days, and number of migraine attacks following GONB+PRF treatment compared with those undergoing GONB treatment. To the best of our knowledge, this is the first prospective double-blind, randomized controlled study with a long follow-up period to evaluate the effectiveness of combining GONB and PRF in patients with CM.

The existing literature exploring the application of PRF to the GON in patients with migraines is limited [10]. In this prospective, double-blind study, we investigated the effectiveness of combining PRF and GONB and discovered that the combination was more efficacious than GONB alone in the treatment of CM.

Occipital and multiple cranial nerve blocks have been shown to effectively prevent CM [17, 18]. It has been reported that GONB with a local anesthetic may be beneficial in patients with migraine who are unresponsive to oral treatment or who do not prefer prophylactic medications. Additionally, the side effects of prophylactic migraine treatments limit the use of these drugs. Even a single GONB treatment session might be effective in some patients [19, 20]. In a previous review, Inan et al. reported that repetitive peripheral nerve blocks provide long-term migraine relief for most patients with CM [21]. Despite the extensive history of using peripheral nerve blocks in the management of headache disorder, standardized techniques, local anesthetic types, dosages, or intervention frequencies for patients with migraine are lacking. Furthermore, there is limited evidence regarding the long-term efficacy of a single GONB session for the treatment of migraine. In a randomized, double-blinded clinical trial, Palamar et al. compared the effectiveness of an USG GONB using bupivacaine versus placebo in facilitating clinical improvement in patients with refractory migraine without aura [19]. They observed a decrease in headache intensity in the first month following the injection, suggesting that USG should be used to increase the effectiveness of the injection. However, the short follow-up duration is a limitation of their study. In a study by Kashipazia et al., researchers compared GONB with triamcinolone versus lidocaine [20]. They reported reduced pain severity, migraine frequency, and analgesic consumption up to 2 months after the GONB. Alternatively, Güner et al. assessed the efficacy of PRF for patients with CM and found improvements that persisted for 3 months post-treatment [13]. Unlike in our study, Güner et al. did not use GONB.

Perdecioglu et al. conducted a clinical trial wherein one group underwent non-invasive PRF application (transcutaneously applied PRF with pad adhesion), while the other received GONB therapy. When the two groups were compared after 4 weeks, they found greater decreases in the 1-month VAS scores in the GONB group, although the difference was not significant [12]. This may be because the GON is impervious to blockage through transcutaneous applications, thereby precluding the opportunity for combined therapeutic approaches. Furthermore, the efficacy between needle-based and non-invasive techniques may vary.

A previous study reported a significant reduction in the frequency of attacks in the RF group in the initial month of the trial. This trial involved repeating the block four times for both groups, administering steroids to one group, and using pulsed radiofrequency in the other group during the final session. However, no significant differences between the groups were observed in other aspects [11]. Conversely, in our study, the procedure was not repeated, and the patient underwent invasive intervention only once. Additionally, we observed a sustained effect for 6 months in the GONB+PRF group.

In our study, when GONB and PRF were combined, there was a significant reduction in the mean VAS score from the first month onwards, as well as a decrease in the mean number of analgesics consumed and the frequency of migraine attacks, when compared to those in the GONB group.

Additionally, no complications were observed in our study. USG and PRF needles with neurostimulatory properties seem to be more reliable in confirming the location of the occipital nerve and nerve blocks, which reduces the risks associated with intra-arterial injection. Another advantage is that a single session of the application is convenient for patients and physicians.

Our results showed that the combination of USG PRF and GONB is an effective treatment for patients with CM and showed that the combined treatment prolongs the effect of GONB. The mean VAS score, analgesic consumption, and number of migraine attacks were significantly lower in the GONB+PRF group than in the GONB group at all follow-up assessments. In addition, this study showed that PRF treatment following the blockade resulted in at least a 60% reduction in the mean VAS score, analgesic consumption, and number of migraine attacks compared with those at baseline, which persisted for 6 months. Therefore, the benefits of combining GONB and PRF include satisfactory analgesia, reduced analgesic consumption, reduced migraine attacks, and reduced headache days, with effects lasting at least 6 months.

PRF was first applied to dorsal root ganglia for the treatment of chronic lumbosacral pain and found to be effective [22]. Afterwards, it was shown to be an effective method in chronic pain such as trigeminal neuralgia, occipital neuralgia, neuropathic pain, and shoulder and knee pain [23].

PRF has been shown to cause changes at the molecular level and changes in neural activity, as well as long-term depression of pain transmission in the mechanism of action [24]. Similar to our results, in a study conducted for chronic cervical radicular pain, combined treatment was found to be more effective than both selective nerve root block alone and PRF treatment alone in reducing pain [25]. The combined effect we have shown in our study may be due to the long-term depression of pain transmission in addition to the modulation of the excitability of second-order neurons receiving input from trigeminal and cervical afferents provided by GONB [26].

This GONB procedure, which can be relatively painful and uncomfortable for patients, can be combined with PRF to prevent unnecessary discomfort and inconvenience for both patients and clinicians.

Additionally, GONB may cause complications such as nerve and vascular injury, infection and inflammation, and block procedures may necessitate repeated administration during routine follow-up to sustain the desired therapeutic effect. However, in our study, we saw that when combined with PRF, the effects lasted for a long time without the need for repetition.

This study is not without limitations. Notably, it focused solely on the clinical effects of combining GONB with PRF in patients with CM. Factors such as quality of life, disability, and headache impact were not assessed. The inclusion of such assessments could have provided further insights into the experiences of patients suffering from CM.

In conclusion, our findings provide evidence that combining GONB with PRF leads to a reduction in VAS scores, number of migraine attacks, and analgesic use for up to 6 months. Moreover, GONB+PRF was more effective than GONB alone. Furthermore, PRF may be preferred in combination with GONB therapy as a safe and effective method for managing CM. Future studies should evaluate the role of this treatment in improving the quality of life and psychological state of patients with CM.

Abbreviations

CM	chronic migraine
EM	episodic migraine
GON	greater occipital nerve
GONB	greater occipital nerve block
ICHD	International Classification of Headache Disorders
PRF	pulsed radiofrequency
USG	ultrasound-guided
VAS	visual analog scale

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Author contributions
TTS: Role in the procedures, analyzing data, writing manuscript; AB: Role in the evaluate the patients in outpatient clinic, drafting the manuscript for intellectual content; MSG: Role in designing and conceptualizing study, analyzing and interpreting of the data, revising the manuscript for intellectual content; All authors reviewed the manuscript.Additionally, the radiofrequency device was used by the clinical nurse TO in all cases.

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Data availability
The datasets generated during and/or analyzed during the current study are available in ClinicalTrials.gov (NCT05464212).

Declarations

Ethics approval and consent to participate
This prospective study was approved by the Institutional Review Board of Eskisehir Osmangazi University Faculty of Medicine (approval no.: 8058721-050.99-E.34888). All participants gave informed consent.

Consent for publication
All participants gave informed consent.

Competing interests
The authors declare no competing interests.

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