J Surg Med. 2021;5(11):1131-1134.
DOI: 10.28982/josam.1000962

Journal of Surgery and Medicine
e-ISSN=2602-2079

Effects of cranial nerve blockage in patients with chronic migraine resistant to first-line treatment

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Ethics Committee Approval
The study was approved by the local Ethics Committee of Derince Training and Research Hospital (no:2019/18).
All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

Conflict of Interest
No conflict of interest was declared by the authors.

Financial Disclosure
The authors declared that this study has received no financial support.

Published
2021 November 20

Abstract

Background/Aim: Migraine is a common, disabling neurological disorder and cranial nerve blocks (CNB) are used in the treatment of headaches. This study aimed to compare the effectiveness of a CNB with conventional medical treatment in patients with chronic migraine resistant to first-line treatment.
Methods: This retrospective cohort study included 102 patients with chronic migraine resistant to first-line treatment who were treated in our outpatient clinic. The patients were divided into two groups as those who underwent CNB (n=67) and the control group, who were only treated with conventional drugs (n=35). Bilateral CNB was performed on the patients at baseline and in the second week. The patients' Visual Analogue Scale (VAS) scores, number of days in pain, and the number of analgesics taken were recorded at baseline and the second month.
Results: The second-month VAS scores and the number of days in pain were significantly lower than baseline in both the CNB and control groups ($P<0.01$, and $P<0.05$, respectively). However, while the number of analgesics taken in the 2nd month was lower in the CNB group, it was similar in the control group. ($P<0.01$, $P=0.33$). No significant difference was found between the groups in terms of the number of days in pain in the second month ($P=0.09$). The second month's VAS scores and the number of analgesics taken were significantly lower in the CNB group compared to the control group ($P=0.01$, $P<0.01$).
Conclusion: Our findings indicated that the CNB was more effective than conventional treatment in patients with chronic migraine resistant to first-line treatment.

Keywords: Chronic migraine, Nerve block, Great occipital nerve, GON, SON

How to cite: Evcili G, Yabalak A. Effects of cranial nerve blockage in patients with chronic migraine resistant to first-line treatment. J Surg Med. 2021;5(11):1131-1134.

Introduction

Migraine is a quite common condition and causes workforce loss, which increases its cost to society. The prevalence of migraine in Europe and America is 17.6% in women and 5.7% in men [1]. In Turkey, the one-year prevalence of migraine is 16.4% [2]. Various medical treatment options, such as beta-blockers, calcium channel blockers, antiepileptic drugs, tricyclic antidepressants, selective serotonin reuptake inhibitors, and botulinum toxin are available to reduce the frequency of attacks in patients with migraine. Among these, Divalproex, topiramate, metoprolol, propranolol, and timolol are recommended as first-line treatments [3]. However, the long-term use of multiple drugs is required in resistant patients, most of which cannot receive regular medical treatment because of the limited effects and many intolerable side effects of these treatments. One study conducted with episodic migraine patients reported that only 28.3% of the patients were regularly using medical treatment [4].

For several decades, headaches were treated with cranial nerve blocks (CNB). The most common CNB for headache treatment is the great occipital nerve (GON) block, although peripheral nerve block applications, such as blocks of the lesser occipital nerve (LON) and the supraorbital (SON) or the supratrochlear (STN) branches of the trigeminal nerve, are also used [5]. Some publications report that the GON block is effective in cervicogenic, tension-type, and migraine headaches [6-10].

In this study, we aimed to evaluate the effectiveness of CNB in patients with chronic migraine unresponsive to first-line treatment.

Materials and methods

This retrospective study included 102 patients with chronic migraine who were admitted to Derince Training and Research Hospital between 2018-June 2019. The study was approved by the Health Sciences University Kocaeli Derince Training and Research Hospital Clinical Research Ethics Committee (13.06.2019 - no: 2019/18) and conducted per the Declaration of Helsinki. All participants were informed about the study and written informed consent was obtained from each participant. The diagnosis of chronic migraine was made according to the criteria of the International Headache Classification Committee (ICHD-3). Patients who had headaches for at least 15 days a month for the last 3 months, had 8 or more typical migraine attacks per month with or without aura for the last 3 months and who did not respond to the first-line treatment were included in the study. Patients with needle phobia, those who did not show up for the second injection two weeks later, and patients at risk of allergies were excluded from the study. Among the 118 migraine patients who underwent CNB in our clinic between 2018 and June 2019, 67 patients who met the inclusion criteria were included in the study group. Thirty-five patients who were followed up in our clinic with medical treatment and met the inclusion criteria were included as the control group. To avoid bias in patient selection, CNB was recommended to all patients, and patients who did not accept were followed up with medical treatment.

Bilateral GON, LON, and SON blocks were performed on the patients in the CNB group at the beginning and in the second week. The injection was administered after wiping the area with an antiseptic solution. The GON block was achieved by an injection of 1.5 ml 2% lidocaine, 2 cm lateral and 2 cm inferior to the occipital protuberance. The LON block was attained by an injection of 1.5 ml 2% lidocaine, 2/3 lateral to the line between the occipital protuberance and the mastoid. The SON block was administered from the medial to the outer part of the eyebrow, 2 cm from the frontal notch at the mid-pupillary level, in the supraorbital arch. All injections were made with a 27 G needle.

After the injection, the patients were followed up for ten minutes for early side effects. The same protocol was repeated two weeks later. The primary outcomes were a decrease in pain score and the days with pain in a month. The secondary outcome was the number of analgesics taken per month.

A Visual Analog Scale (VAS) score was used to assess the severity of pain. The number of days in pain and the number of analgesics taken in the last month were recorded. The patients' VAS scores, the number of days in pain, and the number of analgesics taken in the second month after the first injection were also recorded.

Statistical analysis

All data were analyzed using SPSS 21.0 (IBM Corp.; Armonk, NY, USA). All descriptive data were presented as mean (SD). Parametric tests were used for normally distributed data and nonparametric tests, for non-normally distributed data. A paired sample t-test was used in the analysis of dependent groups, while Student's t-test was used for parametric data in independent groups. The Mann-Whitney U test was used to evaluate non-parametric data. The Chi-square test was used to compare categorical variables. A *P*-value of <0.05 was considered statistically significant.

Results

In total, 102 patients were included in the study, with 67 patients in the CNB group, and 35 patients in the control group. The mean ages of the patients in the CNB and control groups were 41.2 (10.6) (range, 22–68) years and 39.1 (13.1) (range, 20–65) years, respectively. The CNB group included 61 female and 6 male patients, while the control group consisted of 30 female and 5 male patients.

In the CNB group, the mean VAS scores, number of analgesics taken last month, and the number of days in pain in the last month were 8.1 (0.7), 21.9 (9.6), and 23.4 (6.5), respectively. In the control group, the same values were 8.0 (0.8), 13.8 (2.5), and 16.0 (1.3), respectively. The two groups were similar in terms of age and gender distribution ($P=0.37$, and $P=0.41$, respectively).

The number of days in pain in the last month and the number of analgesics taken were significantly higher in the CNB group than in the control group ($P<0.01$ for all). No significant difference was found between the baseline VAS scores of the CNB and control groups ($P=0.05$). The baseline characteristics of the study and the control groups are shown in Table 1.

Table 1: Baseline characteristics of the study and control groups

	CNB group	Control group	*P*-value*
Age (years)	41.2 (10.6)	39.1 (13.1)	0.37
Gender (Female/Male)	61 / 6	30 / 5	0.41
VAS	8.1 (0.7)	8.0(0.8)	0.05
The number of days in pain (the last month)	23.4 (6.5)	16 (1.39)	<0.01
The number of analgesics taken (the last month)	21.9 (9.6)	13.8 (2.5)	<0.01

* Independent Samples T-test, VAS: Visual Analog Scale, CNB: Cranial Nerve Block

The second-month VAS scores, the number of days in pain, and the number of analgesics taken were significantly lower than those at baseline both in the CNB group (P<0.01 for all), and the control group (P<0.01, and P<0.02, respectively). However, no significant difference was detected between the number of analgesics taken in the control group (P=0.33) (Table 2).

Table 2: Comparison of the primary and secondary outcomes between the groups

	VAS	VAS (2nd month)	*P*-value*
CNB group	8.1 (0.7)	5.3 (2.4)	<0.01
Control group	8.0 (0.8)	6.5 (1.8)	<0.01
	The number of days in pain	The number of days in pain (2nd month)	
CNB group	23.4 (6.5)	9.2 (10.3)	<0.01
Control group	16 (1.3)	12.6 (8.8)	0.02
	The number of analgesics taken	The number of analgesics taken (2nd month)	
CNB group	21.9 (9.6)	6.7 (8.5)	<0.01
Control group	13.8 (2.5)	12.3 (9.0)	0.33

* Paired Samples T-test, VAS: Visual Analog Scale, CNB: Cranial Nerve Block

The number of days in pain in the second month was similar between the two groups (P=0.09). However, second-month VAS scores and the number of analgesics taken were significantly lower in the CNB group than in the control group (P=0.01 and <0.01, respectively) (Table 3).

Table 3: Comparison of the CNB and control group 2nd month data

2nd-month data	CNB group	Control group	*P*-value*
VAS	5.3 (2.4)	6.5 (1.8)	0.01
The number of days in pain	9.2 (10.3)	12.6 (8,8)	0.09
The number of analgesics taken	6.7 (8.5)	12.3 (9.0)	<0.01

* Independent Samples T-test, VAS: Visual Analog Scale, CNB: Cranial Nerve Block

Discussion

Our study shows that the CNB was more effective than conventional treatments in patients with chronic migraine unresponsive to first-line treatment. Conflicting results were published regarding the efficacy of CNBs in the treatment of migraine, but most of these studies deemed CNBs as effective as migraine treatments. The treatment protocol and the local agents used for injection vary between the studies, and additional steroid injections were used in some. No consensus has been reached on whether CNB should be performed bilaterally or unilaterally. Differences in terms of the choice of nerve for the block and the frequency of administration also exist [8, 11-14].

Caputi et al. [11] reported that repeated GON and SON blocks with bupivacaine injection reduced the frequency of migraine attacks, the duration of pain, and the pain intensity in 85% of patients for 6 months. Repeated injections (5 to 10 injections) were also significantly more effective for reduction in pain severity and frequency, even in patients who did not benefit from the first injection. In our study, a significant reduction was also achieved in the frequency and severity of pain, although only two injections were administered to the patients.

A study that evaluated GON blocks with weekly bupivacaine injections for one month as a migraine treatment reported statistically significant decreases in the patients' MIDAS and VAS scores and the number of attacks [14]. Gul et al. [12] compared a bupivacaine injection group and a placebo-controlled group and reported significant decreases in the VAS scores and the number of days in pain in the last month in both groups in the first month, but only in the treatment group in the second and third months, and they deemed GON blocks as effective. Inan et al. [13] found that the VAS score, number of days in pain in the last month, and the pain duration in chronic migraine sufferers were significantly lower in patients who underwent GON blocks with bupivacaine injection compared to the placebo group. Another study comparing two groups who received only a GON block or a GON block and medical treatment showed decreases in the intensity and duration of pain in both groups in the third month, but no significant difference in the frequency of pain and the duration of the attack between the two groups. The authors emphasized that the GON block alone is effective without medical therapy [8]. In our study, while the number of analgesics taken in the CNB group was higher at the beginning, it was lower in the second month. Although there was no difference between the VAS scores, it was lower in the CNB group in the second month, and while the number of days in pain in the CNB group was higher, there was no difference between the two groups in the second month. These findings can be interpreted in two different ways as the number of days in pain and the number of analgesics taken were higher in the study group at the beginning, and the numerical decrease after the treatment was higher, or that there was a greater decrease due to CNB effectiveness.

A comparison of two groups that were administered a GON block with a mixture of lidocaine and bupivacaine and additionally injected with triamcinolone revealed no difference in terms of efficacy in the group that was given additional steroids [15]. Some publications in the literature report that the use of steroids in addition to local anesthetics does not have any additional benefit; however, other cases have shown a significant benefit after a block with a steroid injection alone [16]. We did not give steroid injections in addition to lidocaine injections because no consensus exists regarding this issue.

A comparison of unilateral and bilateral GON blocks revealed no significant difference, but the study emphasized that the unilateral GON block is also an effective treatment [17]. In our study, we administered the block bilaterally and found the treatment effective.

No significant side effects were reported due to nerve block treatments. Local pain at the injection site, nausea, dizziness, and presyncope attack were rarely observed [12]. We recommend monitoring the patient for 30 minutes after the injection. In our study, no side effects were seen.

In some studies, nerve blocks were generally performed with bupivacaine, lidocaine, or both. The doses also differed, but an injection of 1.5 ml of 0.5% bupivacaine has been effective in previous studies [12, 13, 18]. The GON block was also effective in a study that used a 1 ml injection of 2% lidocaine [19]. The studies that used 80 mg prednisolone and 20 mg triamcinolone in addition to a local anesthetic injection reported that steroid injections did not contribute to the efficacy [15]. In our study, we used 1.5 ml of 2% lidocaine for all injections.

A review of the literature reveals studies in which a single injection was performed, as well as studies in which repeated injections were performed [8, 13, 14, 17-21]. A study reported that patients who did not respond after a single injection would subsequently respond to treatment after repeated GON blocks [22]. In our study, although we applied only two repeated injections, we found the treatment effective. Increasing the number of repeated injections may further increase the effectiveness.

The advantage of our study is that, in addition to the GON block, concurrent SON and LON blocks were also performed, and the number of patients included in the study was relatively high compared to other studies in the literature.

Limitations

The main limitations of our study are its retrospective nature, that the number of patients in the control group was smaller than that in the study group, and the short follow-up period.

Conclusion

Our results show that the CNB was more effective than conventional treatment in patients with chronic migraine who do not respond to first-line treatment. CNB is a cheap, easy-to-apply, and effective treatment for chronic migraine patients. Therefore, we think that it should be used more frequently in daily practice. Randomized controlled studies should be conducted to compare patients who receive a GON block alone and those who receive GON, SON, and LON blocks performed together as cranial nerve blocks.

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