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CT-guided infiltration of greater occipital nerve for refractory craniofacial pain syndromes other than occipital neuralgia

Short title:

Greater occipital nerve infiltration in cranio-facial pain syndromes

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Abstract

Purpose. The purpose of this study was to evaluate the effectiveness of computed tomography (CT)-guided infiltration of greater occipital nerve (GON) for the treatment of refractory craniofacial pain syndromes other than occipital neuralgia.

Materials and methods. Fifty-six patients suffering from refractory craniofacial pain syndromes were included between 2011 and 2017. There were 33 women and 23 men with a mean age of 50.7 years \pm 13.1 (SD) (range: 27 - 74 years). CT-guided infiltration was performed at the intermediate site of the GON with local anesthetics and cortivazol. Twenty-six (26/56; 46%) patients suffered from chronic migraine, 14 (14/56; 25%) from trigeminal neuralgia and 16 (16/56; 29%) from cluster headaches. Clinical success at 1, 3, and 6 months was defined by a decrease of at least 50% of pain as assessed using visual analog scale (VAS).

Results. Mean overall VAS score before infiltration was 8.7 ± 1.3 (SD) (range: 6 - 10). Mean overall VAS scores after infiltration were 2.3 ± 3 (SD) (range: 0 - 10) ($P < 0.01$) at one month, 3.5 ± 3.3 (SD) (range: 0-10) ($P < 0.01$) at three months and 7.6 ± 1.3 (SD) (range: 1 - 10) ($P < 0.01$) at six months. After infiltration, clinical success was achieved in 44 patients (44/56; 78.5%) at 1 month, 37 patients (37/56; 66%) at 3 months and 13 patients (13/56; 23%) at 6 months. Clinical success according to the clinical presentation were as follows: 88% (23/26) at one month, 73% (19/26) at 3 months, and 23% (6/26) at 6 months in patients with chronic migraine, 81% (13/16), 69% (11/16) and 31% (5/16) in those with cluster headaches and 57% (8/14), 50% (7/14) and 14% (2/14) in those with trigeminal neuralgia. No major complications due to CT-guided GON infiltration were reported in any patient.

Conclusion. CT-guided infiltration at the intermediate site of the GON appears as an effective treatment of craniofacial pain syndromes especially in patients with chronic migraine and those with cluster headaches.

Keywords: Greater occipital nerve, CT-guided intervention; Migraine, Cluster headache, Trigeminal neuralgia.

Abbreviations

CH: cluster headache

CT: computed tomography

GON: greater occipital nerve

SD: standard deviation

TCC: trigeminocervical complex

TN: trigeminal neuralgia

VAS: visual analog scale

Introduction

Headache is one of the most common forms of pain reported in up to 47% of patients [1, 2]. Among these headache syndromes, craniofacial pain syndromes represent a group of chronic diseases including chronic migraine, cluster headache (CH), and trigeminal neuralgia (TN) [3]. Chronic migraine is by far the most common with a global prevalence estimated of up to 11% [4]. According to the Global Burden of Disease Study [1], migraine has become the second largest cause of disability since 2016 with an estimated cost of 78 billion dollars in the USA [5]. CH and TN are more rare conditions but present very severe and debilitating symptoms which induces high functional disability of the population [6, 7]

These chronic conditions may induce important psychological and physical impacts possibly leading to many work stoppages [8]. Indeed, existing conservative management such as analgesics, non-steroid analgesics, corticosteroids, anticonvulsants, antidepressants are not always effective and may lead to drug overuse and adverse events including interactions and a tolerance phenomenon [3, 8, 9]. Therefore, more invasive managements such as nerve blocks, neurolysis, or surgical management have emerged in order to alleviate patients with specific refractory craniofacial pain syndromes [10-13]. More specifically, subcutaneous infiltration of the greater occipital nerve (GON) at the suboccipital emergence conveys satisfactory results in patients with craniofacial pain syndromes and is now being used to help selected patients for occipital nerve stimulation in specific indications [11, 14], based on the existence of the trigeminal cervical complex, which has been shown to be implicated in the pathophysiology of these cranio-facial pain syndromes via the communications between the deep cervical nuclei of the V1 nerve and the occipital nerve in the medulla [15-17]. Furthermore, studies have shown that the use of imaging guidance, especially CT guidance, provided longer efficacy in the treatment of occipital neuralgia [18]. However, to date, no studies have assessed the use of CT guidance to perform GON infiltration in other indications than GON neuralgia or cervicogenic headaches.

The purpose of this study was to evaluate the effectiveness of CT-guided GON infiltration in the treatment of refractory craniofacial pain syndromes such as chronic migraine, CH and TN.

Materials and methods

Patients

Local institutional review board approval was obtained and informed consent was waived. The database of our institution was queried to retrieve all patients who had CT-guided GON infiltration between February 2011 and April 2017. The exclusion criteria were as follows: double site GON infiltration, other indications than chronic migraine, CH or TN, or incomplete data.

A total of 56 consecutive patients suffering from chronic craniofacial pain syndromes including chronic migraine, CH, and TN refractory to conventional specific oral treatments were ultimately included in this single-center retrospective study. There were 33 women and 23 men with a mean age of 50.7 years \pm 13.1 (SD) (range: 27 - 74 years). A flow chart of inclusion/exclusion of patients is given in Figure 1. Twenty-six patients suffered from chronic migraine, fourteen from TN, and sixteen from CH. All patients presented with at pain refractory to specific conservative medication for more than 3 months.

Clinical diagnosis was made by referring physicians (pain doctors, neurologists, neurosurgeons and general practitioners) or by interventional radiologist, based on the International Headache Society definitions of headache syndromes [3]. Data were collected from patient medical records, including patient demographics (age and sex) and clinical and pain management history. All of patients were followed-up at one month by the operating radiologist and at three and six months after GON infiltration by the referring physician.

Pain evaluation

Pain intensity was rated on a visual analog scale (VAS) score (from 0 to 10) before the procedure. The following data were also recorded prior to infiltration mean duration of pain, laterality of pain. Pain after the procedure was also assessed using VAS scores (from 0 to 10) at one, three, and six months. Clinical success was defined by a decrease of at least 50% of the VAS score after the procedure. Changes in oral medication were also noted after the procedure and were classified as: medication consumption discontinuation, increase or

identical to prior dosage. Details on the studied population and pain characteristics are summarized in Table 1.

Procedure details

All infiltrations of GON were performed by two interventional radiologists (B.K, 30 years of experience and A.K, 7 years of experience) under CT guidance on an outpatient basis. A 64-row multi-detector CT unit was used for the procedure (Somatom[®] Sensation 64, Siemens Healthineers) with the patients in prone position.

First, an unenhanced CT examination was obtained from C0 vertebra to C3 vertebra to determine targets and the safest needle pathway. The target was the fatty space between the posterior margin of the inferior obliquus capitis and semi spinalis capitis muscle at the C1-C2 vertebrae level (Figure 2A) as previously described [18]. Local anesthesia using 1% lidocaine hydrochloride was performed at the defined skin entry point. Needle insertion with a 22-Gauge needle (Chiba, Cook Medical) was performed under repetitive axial CT guidance until the needle tip was located at the defined target (Figure 2B). When the tip of the needle was located at the target, aspiration was maintained for 5 seconds before the injection. Then, a test injection with 1 ml of a mixture of fast- and slow- acting anesthetic (1/3 lidocaine hydrochloride + 2/3 ropivacain chlorhydrate 2mg/mL) and 5% iodinated contrast was done to confirm the correct position of the needle. Finally, a 4 mL of the same mixture was administered slowly (in order to obtain rapid onset of anesthesia with the lidocaine and longer duration with ropivacain), followed by a 1.5ml of cortivazol (ALTIM), Sanofi) (3.75 mg/1.5 mL). After the procedure, the patient was monitored for 30 minutes in a lying position.

Study endpoints and definitions

Technical success was defined when the needle tip was accurately positioned at the intermediate site in the fatty space between the obliquus capitis inferior and semi spinalis capitis muscle.

VAS scores were obtained for each group of patients (chronic migraine, CH, and TN) at different time points (before procedure, at one month and 3 months after procedure). The following adverse events were assessed: allergic reaction, pain flare after infiltration and duration of the flare.

Statistical analysis

Statistical calculations were performed with Systat software version 12.0 (Systat Software Inc., Chicago, IL, USA). Continuous variables were expressed as means \pm standard deviations and ranges. Categorical variables were expressed as raw numbers, proportions and percentages. Shapiro-Wilk test was used to determine whether continuous variables were normally distributed. As the null hypothesis was systemically rejected, Wilcoxon signed rank test was used for comparison. Categorical variables were compared using Fisher exact test. VAS scores were analyzed with a repeated-measure ANOVA (analysis of variance) using the type of patients as the group factor and time point as a within-subjects factor. Duration of pain prior to the procedure as well as pre-infiltration VAS score were analyzed according to clinical success at 1 month, 3 months, and 6 months, using Mann-Whitney U test. A *P* value < 0.05 was considered to indicate significant differences.

Results

Patients characteristics

Patients demographic data and pain characteristics are shown in Table 1. All patients underwent a single ipsilateral infiltration at the intermediate site: right sided infiltration in 28 patients, and left sided infiltration in the other 28 patients.

CT-guided infiltration

Technical success rate was 100%. The mean procedure time of the procedure was 21.5 ± 4.8 (SD) min (range: 13 - 30 min). No major adverse events were reported. The tolerance for the procedure was excellent and the following minor adverse events were found in 7 patients (7/56, 12.5 %): three patients (3/56; 5.4%) reported transient procedure-related pain, one patient (1/56; 1.8%) presented with persisting pain lasting one week after the procedure, one patient (1/56; 1.8%) had a pain flare for one week after the procedure, the remaining one patient (1/56; 1.8%) had transient 2 day allergic reaction (*i.e.*, facial erythema). None of these side effects required specific monitoring or hospitalization.

Pain Evaluation

Mean duration of the pain before the procedure was 14.4 ± 13.2 (SD) years (range: 0.7 - 60 years) with a mean overall VAS score of 8.7 ± 1.3 (SD) (range: 5 - 10). Clinical success

was achieved in 44 patients (44/56, 78.5%) at one month, in 37 (37/56, 66%) at three months and in 13 (13/56, 23%) at 6 months with the following mean VAS scores: 2.3 ± 3 (SD) (range: 0 - 10) ($P < 0.01$) at one month, 3.5 ± 3.3 (SD) (range: 0 - 10) ($P < 0.01$) at three months and 7.6 ± 1.3 (SD) (range: 1 - 10) ($P < 0.01$) at six months. No associations were found when comparing clinical success with either duration of pain prior to the procedure or pre-infiltration VAS score. Based on the statement of the 56 treated patients, 21 patients (21/56, 37.5%) were able to stop their medication after the procedure, 25 patients (25/56, 44.6%) continued their drug consumption without changes in dose, and 10 patients (10/56, 17.9%) decreased the dose of the drug. No significant associations were found between clinical efficacy and drug consumption.

Details regarding clinical success as assessed with the VAS score are given in Table 2. In the chronic migraine group, clinical success was achieved in 23 patients (23/26, 88%) at one month, in 19 patients (19/26, 73%) at three months and in 6 patients (6/26, 23%) at 6 months. The mean VAS score before the procedure was 8.2 ± 1.4 (SD) (range: 7 - 10). It dropped to 1.18 ± 2.4 (SD) (range: 0 - 10) ($P = 0.001$) at one-month, to 3 ± 3.0 (SD) (range: 0 - 10) ($P < 0.001$) at three months and was 7.23 ± 3.4 (SD) (range: 1 - 10) ($P < 0.001$) at six months.

In the 16 patients suffering from CH, clinical success was achieved in 13 patients (13/16, 81%) at one month, in 11 patients (11/16, 69%) at three months and in 5 patients (5/16, 31%) at 6 months. The mean VAS score before the procedure was 9.6 ± 0.8 (SD) (range: 8 - 10). VAS score dropped to 2.13 ± 3.4 (SD) (range: 0 - 10) ($P < 0.005$) at one month, to 3.6 ± 4.0 (SD) (range: 0 - 10) ($P = 0.005$) at three months and was 8.06 ± 4.5 (SD) (range: 2 - 10) ($P < 0.001$) at six months.

In the 14 patients suffering from TN, clinical success was achieved in 8 patients (8/14, 57%) at one month, in 7 patients (7 /14, 50%) at three months and 2 patients (2/14, 14%) at 6 months. The mean VAS score before the procedure was 8.5 ± 1.2 (SD) (range: 7 - 10). It dropped to 3.5 ± 3.4 (SD) (range: 0 - 10) ($P = 0.002$) at one month, to 4.3 ± 3.0 (SD) (range: 0 - 10) ($P < 0.001$) at three months and was 7.85 ± 3.5 (SD) (range: 2 - 10) ($P < 0.001$) at six months.

When comparing the clinical success among the three groups of patients, no differences were found among the groups. Although we found an overall decrease in VAS scores [$F(2,106) = 102.53$, Huynh–Feldt $\epsilon = 1$; $P < 0.0001$], these effects were similar across the groups and we did not obtain significant interactions between the time and the group ($P =$

0.373) nor a significant main effect for the group factor ($P = 0.142$). VAS scores before the procedure and at one, three and six months after the infiltration in each subgroup are illustrated in Figure 3. No differences in recurrence rate at 6 months were observed between the three groups,

Discussion

Peripheral nerve blocks have been performed in headache treatment for a long time [19-27] with interesting results. However, to our knowledge, no previous studies have assessed the usefulness of GON infiltration at this intermediate C2 site in cranio-facial pain syndromes other than occipital neuralgia. The presented results show that this technique may be of interest for these refractory patients as overall clinical success was observed in 78.5% of patients at one month, 66% at three months and decreased to 23% at six months. When assessing efficacy rates depending on the type of craniofacial pain, the results of our study show that there was no significant difference in the subgroup analysis although previous reports have shown higher efficacy in patients with chronic migraine and those with CH [19-27].

Chronic migraine is a common headache condition as it has been reported in up to 11% [4] of the population. Although the implication on the GON in the pathophysiology of migraine remains unclear, a recent randomized, double-blind, placebo-controlled study conducted in 84 patients suffering from primary migraine reported higher efficacy rates of repetitive GON blockade compared with placebo [24]. Several other studies have reported the usefulness of GON blocks in chronic migraine, with conflicting results [19, 21, 22]. In each study, the study period or efficacy appeared to be less than those reported in the present study. Indeed, we report clinical success in 88%, 73% and 23 % respectively at one, three months, and six months in patients suffering from chronic migraine.

CH, which is also known as trigeminal autonomic cephalalgia, is a very rare but very severe and debilitating primary headache with a very typical presentation, reported in up to 12% of the population [4]. Ambrosi et al. have reported an efficacy rate of 65% at 4 weeks and significantly fewer attacks in the first 15 days after GON infiltration compared with placebo [20]. Here again, our results seem to provide better and longer lasting pain relief, as clinical success was achieved in 81%, 69% and 31% of patients with CH at respectively 1, 3 and 6 months.

The higher efficacy rates reported in both patients with CH and those with chronic

migraine may be explained by the GON infiltration technique used in our study. Indeed, in most studies, the injection was performed at the GON superficial emergence based on external anatomical landmarks [28, 29]. The infiltration site used in our study has been previously described [18, 30]. It is an intermediate site between the deep and superficial emergence of the GON. It corresponds to the fatty space between on the inside the posterior face of the inferior obliquus capitis and on the outside semi spinalis muscle at the C1-C2 vertebrae. CT guidance provides technical precision, allowing the needle to be placed in the correct target area. However, it has also been reported that ultrasound may also be used [31].

Our results in the TN group are encouraging, clinical success was achieved in 57 % at one month, 50% at 3 months and 26 % at 6 months. The literature is poor on GON infiltration in the treatment of TN. Only Weatherall et al. studied GON infiltration in a 69-year-old patient with a left TN (territory of V2) [27]. At 8 weeks, only a pain sensation in the left cheek persisted, but the response was considered positive. Our procedure could represent an alternative to the more invasive treatments currently proposed such as percutaneous alcohol neurolysis of the sphenopalatine ganglion [32] or trigeminal ganglion radiofrequency thermocoagulation [33], which have been described with encouraging results, but also present a more invasive approach with possible serious adverse events [34]. Our results show a relatively high rate of recurring pain at six months, and particularly in patients with TN. In patients with recurring pain, repeat infiltration may be performed as the procedure is well tolerated [35]. In 80% of the included patients, a second infiltration was performed to obtain longer lasting results similar to previous studies [25, 27, 34].

Several hypotheses can explain the effectiveness of the infiltration in cranio-facial pain syndromes. Studies have shown the existence of a convergence in the dorsal neuron horns of the spinal cord at the level of C2, receiving nociceptive information from the GON and branch of the cervical nuclei of the fifth cranial nerve, called the trigeminal-cervical complex [15-17]. During pain attacks, the convergence neuron receives nociceptive information through the C fibers of both nerves, which is necessary for the pain message to be transmitted. Therefore, a steroid GON infiltration causes a nerve impulse reduction of GON C fibers and as a result the convergence neuron will lack complete pain information, resulting in a blockade of the pain message. The other two hypotheses that could explain the efficacy of steroid infiltration are either the systemic effect of steroids in which the added value of an infiltration can be discussed [28, 36, 37] and the placebo effect. The use of corticosteroids has been studied with different types of steroids and it is not proven that particle or non-particle

steroids may influence the outcome of GON injections. Therefore, although cortivazol, which is no longer commercially available was used for this study, the influence of the type of steroids on the results may be discussed but has not been studied to date. However, in our experience, and since 2018, we have been using other particulate steroids, such as bethamethasone (0.75mg, 1 mL) or triamcinolone (40 mg, 1mL) with similar outcomes. The complications of particulate steroids in this specific anatomical location is not an issue, as the injection site is far from any hazardous structures [38, 39].

Our study has some limitations due to a retrospective design. Moreover, our subgroups were not homogeneous with more subjects into CH subgroup and chronic migraine subgroup as compared to TN subgroup and with a higher initial pain intensity in CH subgroup. Although statistical analysis excluded an influence of drug consumption on efficacy rates, an effect of drug use cannot entirely be excluded as all patients presented with severe, refractory chronic diseases with medical treatments that may have influenced the effectiveness of the procedure. Finally, assessment of efficacy was made on VAS score alone, and no quality of life score were available for analysis.

In conclusion, CT-guided infiltration of the GON at the intermediate site appears as an effective method in the management of refractory craniofacial pain syndromes other than occipital neuralgia. This procedure should represent an alternative treatment in patients wishing to avoid drug overuse especially as it can be repeated. CT-guidance provides a safe means of precise positioning of the needle tip at the accurate target. Further controlled randomized studies should be performed to confirm our results.

Authors' contributions

All authors attest that they meet the current International Committee of Medical Journal Editors (ICMJE) criteria for Authorship.

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Conflict of interest

The authors have no conflict of interest to report in relation with this article

Local IRB was obtained

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Figure legends

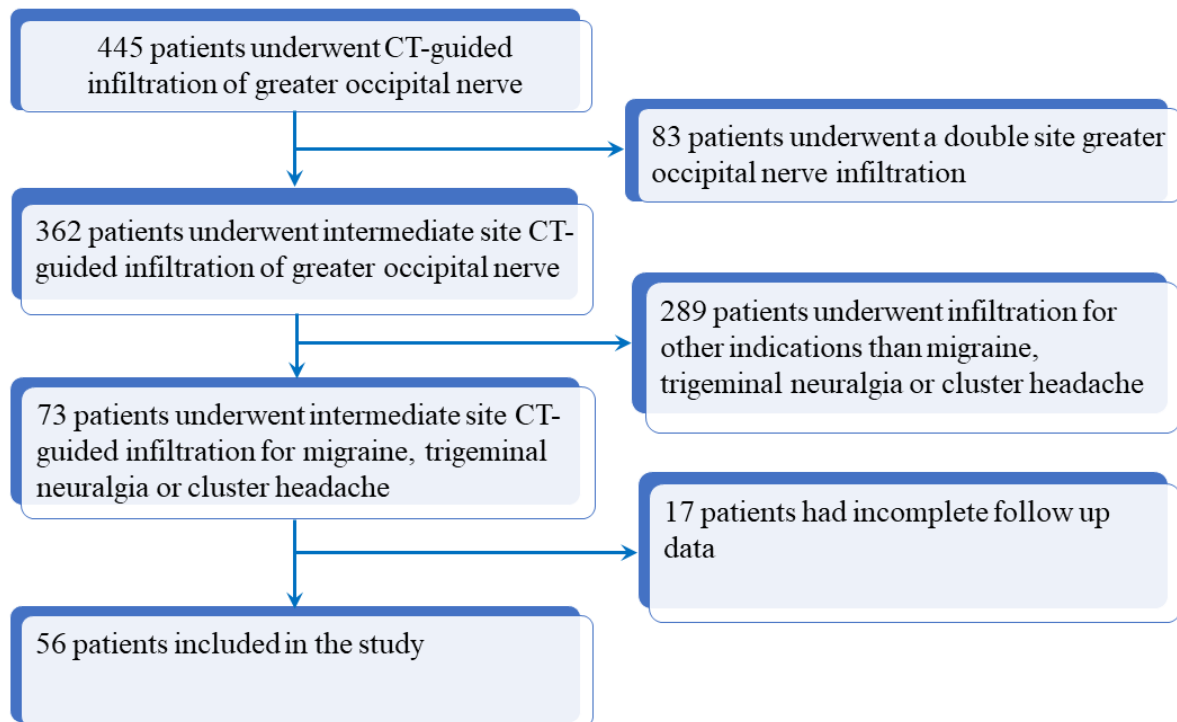
Figure 1. Study flow chart.

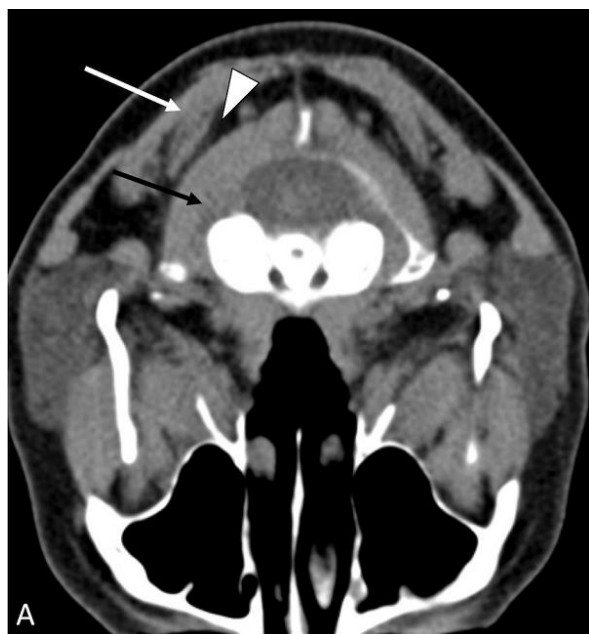
Figure 2: A 46-year-old man with cluster headache who underwent computed-tomography (T)-guided infiltration of the greater occipital nerve at the intermediate site. A - Unenhanced CT image in the axial plane shows the intermediate site (arrowhead) between the inferior obliquus capitis (black arrow) and the semi spinalis capitis (white arrow) muscles. B- Axial unenhanced CT image shows the needle tip in correct position in the target site with accurate diffusion of iodinated contrast material in the fatty space. Arrowhead indicates fatty space; black arrow indicates inferior obliquus capitis muscle; white arrow indicates semi spinalis capitis muscle.

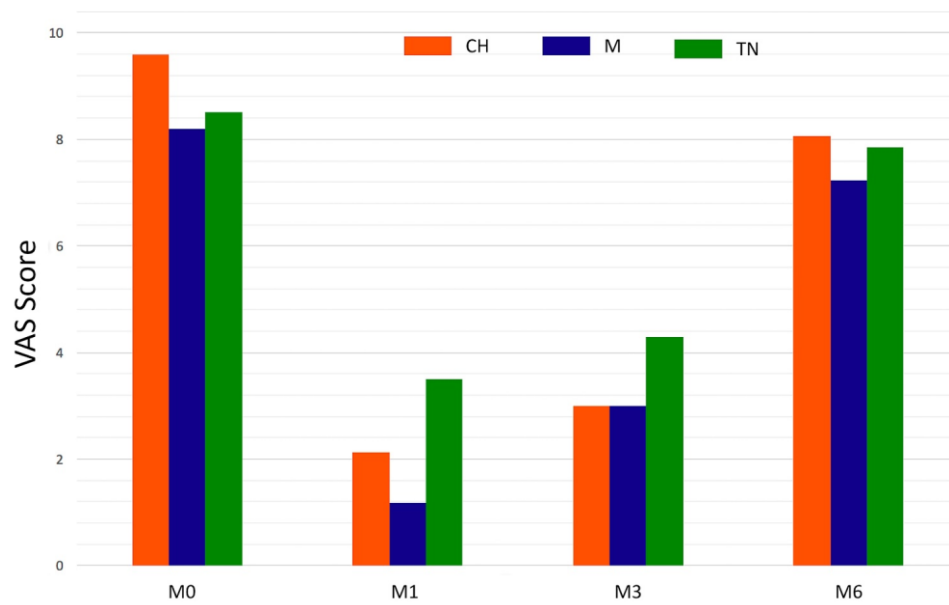
Figure 3. Graph shows visual analysis scale (VAS) scores before (M0), at one (M1), three (M3) and six months (M6) after the infiltration in each sub-group of patients according to the indication. CH indicates cluster headache; M indicates chronic migraine and TN indicates trigeminal neuralgia.

Table 1. Demographic data and pain characteristics of the study population.

Table 2. Details concerning clinical success and VAS scores during the follow up period.







Variables

Demographic data	
<i>Age (years)</i>	50.7 ± 13.1 [27 - 74]
<i>Female</i>	33 (33/56; 59%)
<i>Male</i>	23 (23/56; 41%)
Pain syndromes	
<i>Cluster headache</i>	16 (16/56; 29%)
<i>Chronic migraine</i>	26 (26/56; 46%)
<i>Trigeminal neuralgia</i>	14 (14/56; 25%)
Laterality of pain	
<i>Right</i>	28 (28/56; 50%)
<i>Left</i>	28 (28/56; 50%)
Mean VAS prior procedure (1 – 10)	
<i>Whole cohort</i>	8.7 ± 1.3 [5 - 10]
<i>Cluster headache</i>	9.6 ± 0.8 [8 - 10]
<i>Chronic migraine</i>	8.2 ± 1.4 [7 - 10]
<i>Trigeminal neuralgia</i>	8.5 ± 1.2 [7 - 10]
Mean pain duration prior to procedure (years)	14.5 ± 14.6 [0.7 - 60]

Quantitative variables are expressed as means ± standard deviations; numbers in brackets are ranges. Qualitative variables are expressed as raw numbers; numbers in parentheses are proportions followed by percentages.

	One month		Three months		Six months	
	Clinical Success	VAS	Clinical Success	VAS	Clinical Success	VAS
Whole study population	44 (44/56; 78.5%)	2.3 ± 3 [0 - 10]	37 (37/56; 66%)	3.5 ± 3.3 [0 - 10]	13 (13/56; 23%)	7.6 ± 1.3 [1 - 10]
Chronic migraine	23 (23/26; 88%)	1,18 ± 2.4 [0 - 10]	19 (19/26; 73%)	3.0 ± 3.0 [0 - 10]	6 (6/26; 23%)	7.23 ± 3.4 [1 - 10])
Cluster headache	13 (13/16; 81%)	2.13 ± 3.4 [0 - 10]	11 (11/16; 69%)	3.6 ± 4.0 [0 - 10]	5 (5/16; 31%)	8.06 ± 4.5 [2 - 10]
Trigeminal neuralgia	8 (8/14; 57%)	3.5 ± 3.4 [0 - 10]	7 (7/14; 50%)	4.3 ± 3.0 [0 - 10]	2 (2/14; 14%)	7.85 ± 3.5 [2 - 10]

Quantitative variables are expressed as means ± standard deviations; numbers in brackets are ranges. Qualitative variables are expressed as raw numbers; numbers in parentheses are proportions followed by percentages.

VAS = visual analogic scale