Pulsed Radiofrequency Therapy versus Greater Occipital Nerve Block in the Management of Refractory Cervicogenic Headache – A Pilot Study

Gabrhelík T.[1], Michálek P.[2,3], Adamus M.[1]

[1]Department of Anesthesiology and Intensive Care, Faculty of Medicine and Dentistry, Palacký University in Olomouc and University Hospital Olomouc, Olomouc, Czech Republic;

[2]Department of Anesthesiology and Intensive Care, First Faculty of Medicine, Charles University in Prague and General University Hospital in Prague, Prague, Czech Republic;

[3]Department of Anaesthetics, Antrim Area Hospital, Antrim, United Kingdom

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Abstract: The aim of this pilot study was to compare the efficacy of pulsed radiofrequency to the greater occipital nerve versus a greater occipital nerve block with a mixture of local anaesthetic and steroid in the management of refractory cervicogenic headache. We enrolled 30 patients suffering from refractory cervicogenic headache. Patients were randomly allocated into two groups of fifteen. A greater occipital nerve block with steroid was utilised in group A, while a pulsed radiofrequency treatment was employed in group B. Success of both procedures was evaluated by comparing pre and post intervention Visual Analogue Scale of pain, Medication Quantification Scale – III. and Global Perceived Effect at three and 9 months after the procedures. At three months post therapy a significant decrease in Visual Analogue Scale ($p<0.001$) was identified (3.2 points in group A, 3.3 points in group B respectively). In group B pain remained reduced even after 9 months ($p<0.001$) when compared to pre treatment scores. The consumption of analgesic medication was reduced significantly in both groups at three months ($p<0.001$)

Mailing Address: Tomáš Gabrhelík, MD., PhD., Department of Anesthesiology and Intensive Care, Faculty of Medicine and Dentistry, Palacký University in Olomouc and University Hospital Olomouc, I. P. Pavlova 6, 775 20 Olomouc, Czech Republic; Mobile Phone: +420 602 750 913; Fax: +420 585 852 524; e-mail: gabrhelikt@post.cz

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and 9 months ($p<0.01$), respectively. No serious complication was noted. Greater occipital nerve block is a safe, efficient technique in the management of cervicogenic headaches. Despite the lack of high quality scientific evidence (level III or IV) in the literature, we have extensive experience with steroid application and pulsed radiofrequency to the greater occipital nerve and report the beneficial results in our study.

Introduction

The symptom of headache is one of the most common causes of chronic pain, with an incidence of approximately 30% in the adult Czech population (Dočekal et al., 2006). Headache is commonly classified in accordance with the IHS classification published in 2004 (International Headache Society, 2004). There are several types of primary and secondary headaches. Cervicogenic headache is classified as a secondary headache. These are a heterogeneous group of headaches, which are described as unilateral, constant headache, spreading from the cervical spine and occiput to the frontotemporal area.

Cervicogenic headaches can have many causative factors and may be attributed to degenerative or postraumatic cervical spine pathology, cervical spine dysfunction, cervical muscle pathology or by a cytokine release (Martelletti and van Suijlekom, 2004).

The prevalence of this condition ranges between 0.7% and 13.8%. Headache caused by pathology within the cervical spine is one of the typical lifestyle diseases and is a very common syndrome presenting often to the pain clinic. Another cause of refractory headaches may be occipital neuralgia, which is described as an ipsilateral, paroxysmal, non-pulsatile, stabbing headache, caused by a greater or lesser occipital nerve irritation (Vanelderen et al., 2010a).

Tension cephalea can also be included into the category of cervicogenic headaches, although according to the IHS classification is ranked among the primary headaches.

There is no standard algorithm for the treatment of refractory cervicogenic headache. The first treatment step is often poly-pharmacotherapy using combinations of NSAIDs, paracetamol, tricyclic antidepressants, muscle relaxants, magnesium and opioids. Other potential methods of conservative treatment include physiotherapy, psychotherapy, autogenic training or acupuncture. If conservative methods fail or produce significant side effects, it may become necessary, dependent upon patient choice and consent, to consider the use of interventional methods. Minimally invasive procedures for treatment of refractory cervicogenic headache include regional anaesthesia techniques, pulsed radiofrequency or subcutaneous occipital nerve stimulation.

Material and Methods

This blind, randomized clinical pilot study included 33 patients with refractory cervicogenic headache previously treated by conservative measures who felt that

previous treatment methods had failed. Ethical approval was granted by The Ethical Committee of the Palacký University in Olomouc. Patients received an Information Sheet, approved by the ethics committee, before their procedure and consented to take part in the study following a rigorous process of informed consent.

Exclusion criteria included patients with bilateral migraine headache, cervical nerve root irritation or pain caused by spinal stenosis. All patients with a haemocoagulation disorders, local infection or those who refused to consent were also excluded. Another three patients were excluded during the trial, as they requested re-treatment for the occurrence of contralateral pain or other types of pain less than nine months after the initial procedure.

The final sample consisted of 30 patients who reported a positive effect following a diagnostic occipital nerve blockade with a local anaesthetic.

Fifteen patients underwent a blockade of the greater occipital nerve with administration of local anaesthetic and corticosteroids (group A), while another fifteen patients had a pulsed radiofrequency procedure to the greater occipital nerve (group B). Patients were not informed what type of treatment they had received (they lay in prone position and in both groups radiofrequency generator for neurostimulation was used). Pain scores were evaluated by monitoring pain intensity on an eleven point Visual Analogue Scale (VAS) of pain from 0–10. We compared the consumption of analgesic medication on a MQS – III. scale (Medication Quantification Scale – version III.) (Harden et al., 2005). This scale allows comparison of analgesic medication (non-opioid analgesics, opioids, antiepileptics and antidepressants). The drugs are ranked according to their analgesic potency and a daily dose, converted to a numeric value to allow statistical comparisons.

Patients evaluated the results of subjective satisfaction with treatment according to the seven-point GPE scale (Global Perceived Effect), where –3 points represent the greatest deterioration after treatment, 0 means no change, and +3 points mean greatest possible improvement. The subjective improvement of 50 percent or more was considered a success. All evaluated parameters were recorded before the procedures, and at 3 and 9 months after the treatment. We also monitored the patients for any complications associated with the treatment.

Both the utilised techniques in this study were performed according to the local protocol in the operating theatre. Patients were placed in the prone position with their heads in mild flexion. After marking the injection site 1 cm below the level of the superior nuchal line just medial to the palpable pulsation of the occipital artery, antiseptic preparation of the area was performed. A 20-G insulated radiofrequency needle with 5 mm active tip (TycoHealthcare, USA) was then inserted.

According to responses to neurostimulation of sensory nerve fibres at 50 Hz and voltage <0.5 V, re-direction of needle tip was performed. The course of the nerve is usually medial to the artery but may be located variably also lateral to the vessel. Following placement of the needle we applied 3 ml of mixture of 0.25%

bupivacaine with 10 mg of methylprednisolone to the patient in group A. Two cycles of pulsed radiofrequency treatment at a voltage 45 V for 120 s (Radionics RF Generator 3, Radionics Inc., USA) were performed in the group B without using bupivacaine or methylprednisolone. If the temperature of the active needle tip exceeded 42 °C, the voltage was reduced to 40–42 V. After the procedures, the patients' vital signs were monitored for 60 min at recovery area.

All patients were evaluated before discharge in a standard manner: pain intensity using VAS, overall neurological function and observation of the needle entry point for bleeding.

The patients received a contact telephone number for reporting potential complications of treatment.

Statistics

The data obtained in this pilot study were analyzed using statistical software package, Instat® (GraphPad, v. 3.10). Normality of data distribution was assessed by the statistical test according to Kolmogorov-Smirnov. For a comparison of demographic parameters, we used unpaired *t*-test. P-values <0.05 were considered significant.

The data were not normally distributed (apart from demographic data), therefore we used the non-parametric tests (Wilcoxon test for comparisons within the groups, Mann-Whitney U-test for inter-group comparison). Frequencies in the groups were compared using Fisher's exact test. According to the nature of the data results are expressed as frequency (or %), or as the average standard deviation and range, or as median and range.

Results

In total, 30 patients (13 men, 17 women) were included in the study during a four year period (from July 2006 to October 2009). Both groups did not differ significantly on noted baseline parameters – age, BMI, VAS and MQS levels before treatment (Table 1).

Table 1 – Demographic parameters

	Group A	Group B	p
n	15	15	
Gender (M/F)	7/8	6/9	0.571
Age (years)	45.90 (12.8) [22–73]	43.60 (9.2) [28–65]	0.682
BMI kg/m^2	27.61 (3.10) [23.60–32.80]	27.14 (3.15) [20.4–32.4]	0.437
VAS before treatment	5.50 (1.13) [4–7]	5.90 (1.2) [4–8]	0.874
MQS before treatment	8.88 (2.98) [4.8–14.8]	9.05 (2.93) [4.6–13.6]	

Data is expressed as median or plain numbers, (SD), range [minimal–maximal]
BMI – body mass index; VAS – Visual Analogue Scale; MQS – Medication Quantification Scale

Median VAS before treatment was 5.5 in group A, while in group B it was 5.9. A significant decrease in VAS score – 2.3 in group A and 2.6 for group B ($p<0.001$) – was noted at three months. At 9 months, the median VAS was 4.3 in group A ($p<0.05$) and 3.1 in group B ($p<0.001$). In comparison to the VAS before treatment a significant decrease in median VAS after 9 months was still present in group B, while in group A the results were not statistically significant.

When comparing the VAS score at 9 months post treatment with the results at three months there was deterioration in pain score in a number of the patients in both groups (Table 2).

Before treatment, the median index MQS – III. was 9.2 in both groups. Three months after treatment the median index decreased significantly to 4.8 in group A, and to 3.2 in group B respectively ($p<0.001$).

Table 2 – VAS at 3 and 9 months after the procedures, compared to the baseline

	VAS 0	VAS 3	VAS 9
Group A	5.5 [4–7]	2.3 [0–6]***	4.3 [2–6]*
Group B	5.9 [4–8]	2.6 [0–5]***	3.1 [2–5]***

Data is expressed as median, range [minimal–maximal]; ***p<0.001 vs. VAS 0; *p<0.05 vs. VAS 0
VAS – Visual Analogue Scale; VAS 0 – VAS before treatment; VAS 3 – VAS 3 months after treatment; VAS 9 – VAS 9 months after treatment

Table 3 – MQS at 3 and 9 months after the procedures, compared to the baseline

	MQS 0	MQS 3	MQS 9
Group A	9.2 [4.8–14.8]	4.8 [0–12.8]***	6.8 [0–14.8]**
Group B	9.2 [4.6–13.6]	3.2 [0–11.4]***	6.8 [0–11.4]**

Data is expressed as median, range [minimal–maximal]; ***p<0.001 vs. MQS 0; **p<0.01 vs. MQS 0
MQS – Medication Quantification Scale; MQS 0 – MQS before treatment; MQS 3 – MQS 3 months after treatment; MQS 9 – MQS 9 months after treatment

Table 4 – Subjective improvement after treatment by at least 50% (GPE, Global Perceived Effect)

	GPE		p
	at 3 months	at 9 months	
Group A	10/15 (67%)	5/15 (33%)	0.143
Group B	11/15 (73%)	9/15 (60%)	0.700
p	1.000	0.272	

Data is expressed as total numbers of patients (%); GPE – Global Perceived Effect

This decrease from baseline persisted to a lesser extent, also after 9 months. The median index was 6.8 in both groups ($p<0.01$). Consumption of analgesics in both groups at 9 months after procedures slightly rose when compared with the results at three months (Table 3).

Subjective improvement after treatment by at least 50% (GPE) was reported at three months in 10 patients in group A (67%) and in 11 patients in group B (73%).

There was 5 satisfied patients in group A (53%) at 9 months, while in group B it was 9 patients (60%), which made a statistically significant difference (Table 4).

We did not experience any serious complications related to the treatment. Three patients (10%) reported pain at the injection site for longer than 1 day.

Discussion

Refractory cervicogenic headache is one of the most common types of headaches. If conservative methods fail (pharmacotherapy, physiotherapy, acupuncture, etc.), pain physicians should consider the inclusion of interventional therapy in the treatment algorithm. Methods of regional or local anaesthesia injections include trigger point blocks, nerve root injections, peripheral nerve blocks or facet blocks depending on the underlying causes of pain.

Injections of local anaesthetic into trigger points or peripheral nerve blocks are used commonly and are associated with low risk of complications.

Greater occipital nerve block is most frequent peripheral nerve block used for the management of cervicogenic headache (Ashkenazi and Levin, 2007), although the positive effect of the blockade of other peripheral nerves (lesser occipital nerve, supraorbital nerve, auricular nerves) or facet joints have been described (Levin, 2010). Greater occipital nerve blockade has also been used for the treatment of transformed migraine. The authors reported in the group of 37 patients significant short-term relief from headaches, but there were no difference between using a local anaesthetic with or without steroids (Ashkenazi et al., 2008).

The positive effect of occipital nerve blockade in the treatment of migraine, tension cephalea and cervicogenic headache is often explained as a consequence of the connection of the upper cervical and trigeminal sensory nerves at the level of the caudal nucleus of the trigeminal nerve. The exact mechanism is unknown (Saracco et al., 2010). The cause of headache can be a nerve entrapment between the trapezius muscle, obliquus capitis inferior muscle, or semispinalis capitis muscle. This cause should be treated effectively with a physiotherapy, since the nerve compression is caused by a local congestion and swelling of these muscles.

Currently, some authors advise performing greater occipital nerve block using ultrasound guidance to target the nerve between the obliquus capitis inferior and semispinalis capitis muscles. This approach provides precise localisation of the nerve in the case of the variable anatomy. Ultrasound guidance was not used in our study as it was not part of our local protocol when this study was approved by our ethics committee.

Pulsed radiofrequency (RF) is an option for the treatment of neuropathic pain related to peripheral nerves (greater occipital nerve) or cervical nerve roots. Pulsed RF offers temporary neuromodulation of pain transmission with minimal side effects and without damaging sensitive components or mixed motor nerves. Pulsed RF of the greater occipital nerve was first described in 2006 (Navani et al., 2006).

Haspeslagh et al. (2006) compared pain relief following greater occipital nerve block and cervical facet RF denervation in a group of 30 patients and found no difference in VAS, GPE, or quality of life at 48 weeks after the procedures.

Vanelderen et al. (2010b) described the positive effect of pulsed RF to the greater occipital nerve on a sample of 19 patients in a prospective observational study. 6 months after the treatment, the mean VAS decreased by 3.6, MQS by 8 points and 52.6% of patients expressed subjective satisfaction with the procedures, according to Likert scale. No complications were observed.

There have been two review articles related to the interventional treatment of cervicogenic headaches recently published. First article showed that according to the studies published, the greater occipital nerve blockade with an application of a local anaesthetic with steroids is strongly supported according to the principles evidence-based medicine (EBM) and the recommended level of evidence is 1B + (van Suijlekom et al., 2010). The level of evidence for effectiveness of the RF thermolesion of the medial branch of C2 and C3 was described as 2B +/–. The authors did not find enough studies related to the pulsed RF to the dorsal root ganglia of C2 and C3 to allow assessment of the strength of evidence (only studies level III and IV).

Vanelderen et al. (2010a) published a review study which evaluated the efficacy of various interventional methods used in the treatment of occipital neuralgia. Greater occipital nerve blocks with a mixture of local anaesthetics and steroids, and subcutaneous peripheral stimulation received the recommendation 2C +, while application of botulinum toxin A to the occipital nerves was evaluated as Level 2C +/–. Pulsed RF treatment to the occipital nerves received recommendation at the Level 2C +, indicating a lack of power of published studies, but always with a positive clinical effect. Pulsed RF to the nerve roots of C2 and C3 could not prove any evidence. Both review articles have highlighted the poor quality of published studies, mainly due to differences in inclusion and exclusion criteria, short term follow-ups and non-standardized algorithms of treatment.

RF treatment of painful conditions has been used in the Czech Republic since 2003 (Gabrhelík and Michálek, 2004).

Our pilot randomized single-blinded study demonstrated that the effect of pulsed RF is comparable with greater occipital nerve blockade using a mixture of local anaesthetic and steroids in the treatment of cervicogenic headaches. Three months after the intervention there was a significant decrease in pain and analgesic consumption in both groups. At 9 months the beneficial effect of intervention

seemed to reduce, this trend was more pronounced in group A. Similar results were also recorded in overall patient satisfaction (GPE). In contrast, the analgesic consumption was comparable in both groups even after 9 months.

The main limitation of this study is a small sample size; however it has been designed as a pilot study to inform the development of a larger trial which should provide more robust results. It will be necessary to randomize a larger number of patients to both groups and the results of a study comparing the effect of pulsed RF with the effect of pharmacological blockade of the greater occipital nerve in the treatment of refractory headache. It is our intention to include a control group in the larger study comparing both treatment techniques with the effect of application of saline as a placebo.

Conclusion

Greater occipital nerve blockade with a mixture of local anaesthetic and steroid and pulsed radiofrequency to the greater occipital nerve are both effective intervention techniques in the treatment of refractory cervicogenic headaches. These techniques are safe and often can reduce the analgesic treatment. In case of pain re-appearance these techniques are easily repeatable.

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