Occipital Nerve Stimulation for Non-Migrainous Chronic Headaches: A Systematic Review and Meta-analysis Protocol

Sylvine Carrondo Cottin PhD; Léo CANTIN MD; Michel Prudhomme MD, PhD
Centre de recherche du CHU de Québec-Université Laval, Axe Neurosciences, Québec, Canada
Département des Sciences neurologiques, CHU de Québec-Université Laval, Québec, Canada

Background

Description of the condition

Chronic headache, defined as headache on 15 or more days every month, affects 1.7% to 4% of the adults worldwide (1). Recognized as particularly debilitated, chronic headache patients are often resistant or intolerant to the available treatment managements (2).
Although, the most frequently studied, migraine is not the most common headache disorder (HD), as tension-type headache and medication-overuse headache represent more than a half of the prevalence of HD (3) and are considered to be at least as costly as migraine for health-care systems (4).

Description of the intervention

Occipital nerve stimulation (ONS) is a neurostimulation procedure aiming at subcutaneously implanting cylindrical or paddle leads over the occipital nerves in order to deliver electrical impulses in order to alleviate pain (5).

Why it is important to do this review?

A recently published guideline on ONS for chronic intractable migraine (6) recommends to use this procedure with 'special arrangements for clinical governance, concent, and audit or research'. Even if no such guidelines have been published for HD from other aetiology, and despite its 'off-label' status according to regulatory instances, ONS is becoming more and more used for treating various chronic HD.
Techniques and technology are rapidly evolving and it becomes necessary to conduct well-designed studies able to assess the efficacy and safety of such devices.

Methods

MEDLINE, Embase, and the Cochrane Library databases will be searched for eligible studies. ONS will be compared to sham stimulation or the best available treatment including injections, ablative techniques, and pharmacological or psychological interventions.
To determine the methodological quality of included studies, the risk of bias will be assessed independently by two reviewers using the Cochrane Collaboration toll for assessing the risk of bias (7).
Meta-analyses of risk ratios (for dichotomous outcomes) will be carried out using Mantel-Haenzel random-effect models. Pooled effect sizes and their 95% confidence limits will be reported. Means and mean differences (for continuous variables) will be analyzed using inverse variance method with random effects models.

Objective

The aim of this review is to evaluate the efficacy and safety of ONS with respect to the best available medical treatment or sham stimulation for patients suffering from HD excluding migraines.

Table1. Structured question.

Population	- adult patients with chronic headache
Intervention	- occipital nerve stimulation
Comparator	- any comparator
Primary outcome	- pain relief
Secondary outcome	- headache frequency, intensity and duration
	- functional status
	- quality of life
	- return to work
	- medication use
	- health-care utilization
	- complications
Study design	- all designs

Table 2. Study eligibility criteria.

Inclusion criteria	- randomized controlled trials
	- Chronic setting
	- At least 80% of patients suffering from chronic headache
	- At least 80% of adult patients (≥ 18 years old)
	- At least 80% of patients treated by occipital nerve stimulation
Exclusion criteria	- Sample of patients with migraine
	- Combination of ONS and other forms of nerve stimulation

Data items

Extracted data will include study characteristics, patients' characteristics; surgery procedure; and comparator.
The primary outcome will be the overall reduction of head pain severity. Rates of reduction in severity of head pain, headache frequency and duration, use of medication, impairment, quality of life, health-care utilization, and return to work will also be extracted as a secondary outcome.
For the safety profile we will consider the occurrence of surgery complications, hardware-related complications, and stimulation complications.

Conclusion

This systematic review will allow us to better assess the potential role of ONS for the treatment of patients with chronic headache excluding migraines that are refractory to less invasive therapies.
This review will also bring a clear evidence of ONS efficacy for the treatment of non-migraine headache disorders. From a clinical standpoint, this review will clarify the relevance of offering this expensive and invasive treatment.

Learning Objectives

This project will allow the knowledge synthesis regarding occipital nerve stimulation in adult patients with non-migrainous chronic headache. Considering the paucity of rigorous data on the efficacy of this neurostimulation-based therapy in this population, it is of major importance to assess current practices.

References

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