Technoleg Iechyd Cymru
Health Technology Wales

HEALTH TECHNOLOGY WALES (HTW) GUIDANCE 013 (November 2019)

Occipital nerve stimulation for treating medically refractory chronic cluster headache

HTW Guidance: Occipital nerve stimulation shows promise for treating medically refractory chronic cluster headache, but the evidence is insufficient to support routine adoption.

There is uncertainty about the therapeutic impact of occipital nerve stimulation from the non-comparative evidence available and the economic consequences are difficult to estimate. Further research is recommended to determine the impact of occipital nerve stimulation on the frequency and severity of cluster headache attacks, quality of life and cost implications.

Why did Health Technology Wales (HTW) appraise this topic?

Chronic cluster headache is a rare form of headache disorder that gives rise to severe and sometimes intractable symptoms. The headache attacks are managed with a range of different drugs. A small proportion (between 5% and 20%) of people with chronic cluster headache are refractory to drug treatment and these people continue to experience daily or almost-daily headache attacks. The implantation of a device to stimulate the occipital nerves has been proposed as a means of modulating the frequency and severity of cluster headache attacks that do not respond well to drug treatment.

This topic was suggested through the Welsh Health Specialised Services Committee (WHSSC). Current access to occipital nerve stimulation for eligible Welsh patients is through individual patient funding requests and referral to NHS England.

The status of HTW guidance is that NHS Wales should adopt this guidance or justify why it has not been followed. HTW will evaluate the impact of its guidance.

Summary of the evidence

Six case series reported an overall reduction in cluster headache attack frequency, and four studies showed that between 52.9% and 90% of participants had a greater than 50% reduction in attack frequency. However, these studies are limited by the number of participants (between 8 and 51), the lack of a comparator, and the outcomes and methods of analyses varied across the studies.

No studies evaluating the cost-effectiveness of occipital nerve stimulation were identified. Two studies estimated costs or cost savings associated with the use of occipital nerve stimulation, but these were non-comparative.

HTW did an analysis to estimate the cost-utility of occipital nerve stimulation as compared to standard care. The results were heavily influenced by assumptions around quality of life and triptan use over time. If it was assumed that clinical effectiveness and triptan use was maintained over time (up to 5 years), occipital nerve stimulation was found to be equally effective or more effective while also cost saving in all scenarios. If it assumed that quality of life returns to baseline at three years after implantation, occipital nerve stimulation is found to be more effective than standard care but not cost-effective (ICER £100,142 per QALY gained). However, if it is assumed that quality of life benefit is maintained over time, occipital nerve stimulation is found to be more effective than standard care and cost effective (ICER £7,556 per QALY gained).

For the detailed review of evidence on occipital nerve stimulation for chronic cluster headache, see Evidence Appraisal Report 013 (EAR013).

Appraisal Panel considerations

- The Panel were informed by the clinical expert that chronic cluster headache is a condition that is associated with substantial morbidity and that headache attacks can be excruciating and intractable. In those patients that are refractory to medical treatment, alternative treatment options are limited but include transcutaneous vagal nerve stimulation (gammaCore), percutaneous nerve stimulation and deep brain stimulation.
- The Panel noted that there are no randomised or sham control studies available that have investigated the effect of occipital nerve stimulation on cluster headache frequency and severity. While observational case series have described a reduction in symptoms with occipital nerve stimulation, the Panel concluded that in view of the very variable natural history of this condition, these studies do not allow for definitive conclusions to be drawn about the clinical effectiveness of occipital nerve stimulation.
- The Panel noted that occipital nerve stimulation is an invasive procedure involving the use of an implantable device and that the case series have reported the occurrence of a variety of adverse events. The Panel considered that it is particularly important, therefore, to be confident about any clinical benefits before recommending adoption of this technology.
- The Panel noted that that there is one randomised control trial in progress that was due to complete in March 2019 and that results from this study may provide more evidence to inform the clinical effectiveness of occipital nerve stimulation. Data from this study is currently unavailable and therefore could not be considered further in the course this appraisal.
- Overall, the Panel concluded that there is currently insufficient evidence of clinical effectiveness to be able to support adoption, but considered that the symptom improvements reported in the observational studies reflected promise. The Panel recommend that further research be undertaken to explore the potential clinical and cost benefits of occipital nerve

stimulation. The expert informed the Panel that sham control studies with low frequency occipital nerve stimulation have been difficult to do as patients are aware of the paraesthesia when the device is switched on. However, there are high-frequency stimulation devices that are not associated with paraesthesia so sham controlled studies are possible. The Panel recommended that such studies be done to define the impact of occipital nerve stimulation on the frequency and severity of headache attacks as well as quality of life in patients with medically refractory chronic cluster headache. Such studies should include documentation of triptan usage before and after occipital nerve stimulation treatment and determine the long-term sustainability and cost effectiveness of treatment.

- In considering the cost implications of occipital nerve stimulation, the Panel noted that a sustained improvement in quality of life and reduction in triptan medication use were key to demonstrating the cost-effectiveness of occipital nerve stimulation. Since there is no evidence to support these, the Panel concluded that the case for cost effectiveness could not currently be proven.
- While the Panel concluded that the current evidence does not support routine adoption of occipital nerve stimulation for the treatment of medically refractory chronic cluster headache, it supports the continuation of a process of individual patient funding for occipital nerve stimulation. The Panel would encourage the collection of real-world data from people who are funded to receive this treatment to provide contextual Welsh evidence to inform any future evaluation of occipital nerve stimulation.

Responsibilities for consideration of this Guidance

Health Technology Wales (HTW) was established by Ministerial recommendation[1,2] to support a strategic, national approach to the identification, appraisal and adoption of non-medicine health technologies into health and care settings. The HTW Appraisal Panel comprises senior representation from all Welsh boards with delegated authority to produce guidance 'from NHS Wales, for NHS Wales'. The status of HTW guidance is 'adopt or justify'. There is an expectation from Welsh Government that HTW guidance is implemented with adoption regularly audited by HTW.[3]

The guidance in this document is intended to assist Welsh care system decision makers to make evidence-informed decisions when determining the place of health technologies and thereby improve the quality of care services.

The content of this HTW guidance was based upon the evidence and factors available at the time of publication. An international evidence base was reviewed and external topic experts and HTW committee members consulted to contextualise available evidence to Wales. Readers are asked to consider the generalisability of the evidence reviewed to NHS Wales and that new trials and technologies may have emerged since first publication and the evidence presented may no longer be current. It is acknowledged that evidence constitutes only one of the sources needed for decision making and planning.

This guidance does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgment in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

No part of this guidance may be used without the whole of the guidance being quoted in full. This guidance represents the view of HTW at the date noted. HTW guidance is not routinely updated. It may, however, be considered for review if requested by stakeholders, based upon the availability of new published evidence which is likely to materially change the guidance given.

Standard operating procedures outlining HTWs evidence review methods and framework for producing its guidance are available from the HTW website.

Acknowledgements. HTW would like to thank the individuals and organisations who provided comments on the draft Evidence Appraisal Report or HTW guidance.

Declarations of interest were sought from all reviewers. All contributions from reviewers were considered by HTWs Assessment Group. However, reviewers had no role in authorship or editorial control and the views expressed are those of Health Technology Wales.

Chair, Health Technology Wales Appraisal Panel

1. National Assembly for Wales, Health and Social Care Committee. Access to medical technologies in Wales. December 2014.
2. Response to Recommendations from the Health & Social Care Committee: Inquiry into Access to Medical Technologies in Wales. February 2015.
3. Gething, V. Letter to all Health Board Chairs re Funding for Sacral Nerve Stimulation in Wales. VG_01655_17. September 2017.