NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine

Migraines are moderate to severe headaches, usually felt as a throbbing pain at the front or on one side of the head. There can also be symptoms like feeling or being sick, and sensitivity to light. A migraine may last for several hours or days. In this procedure, a small device is positioned on the forehead with an adhesive electrode. When it is activated, it sends small electrical currents through the skin (transcutaneous) to stimulate the nerves that bring sensation to the upper eyelids, forehead and scalp (supraorbital nerves). The aim is to relieve pain and reduce the number of migraine attacks. Stimulation is applied daily for about 20 minutes to prevent migraine or 1 to 2 hours as needed to treat an acute migraine attack.

NICE is looking at transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine. This is a review of NICE's interventional procedures guidance on transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

Issue date: June 2022

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 30 June 2022

Target date for publication of guidance: October 2022

Issue date: June 2022

1 Draft recommendations

1.1 Evidence on the safety of transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine is adequate and raises no major safety concerns. For efficacy:

- Evidence for treating an acute migraine attack is adequate, but the evidence for treating subsequent attacks is limited in quality and quantity. So, for treating acute migraine, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page
- Evidence for preventing migraine is inadequate in quality. So, for preventing migraine, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.

1.2 Clinicians wanting to do transcutaneous electrical stimulation of the supraorbital nerve for acute treatment of migraine should:

- Inform the clinical governance leads in their healthcare organisation.
- Give people and their families and carers clear written information to support shared decision making, including NICE's information for the public.
- Ensure that people and their families and carers understand the procedure's safety and efficacy, and any uncertainties about these.
- Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
- Regularly review data on outcomes and safety for this procedure.

1.4 Patient selection should usually be done by clinicians in specialist headache clinics.

1.5 NICE encourages further research on transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine. Studies should describe clearly whether the procedure is used for treatment or prevention. They should include details of patient selection, and the intensity, duration and frequency of use. Outcome measures should include the number and severity of migraine episodes, quality of life in the short and long term, any changes in medication and management of subsequent attacks. The development of any complications after starting treatment should be documented.

2 The condition, current treatments and procedure

The condition

2.1 Migraines are moderate to severe headaches that may last for hours, days or longer. They are often accompanied by nausea, photophobia, phonophobia and the perception of unpleasant odours. In some people, they may be accompanied by an aura, characterised by the focal neurological symptoms that usually precede or sometimes accompany the headache. The International Headache Society's international classification of headache disorders classifies migraine types.

Current treatments

2.2 The usual treatment options for migraines are medical therapies, either to stop or prevent attacks (see NICE's guideline on headaches in over 12s). For acute migraine attacks, these include analgesics, triptans and antiemetics. Treatments to stop or reduce the frequency of migraine attacks include beta blockers, calcium-channel blockers, tricyclic

antidepressants, antiepileptics and calcitonin gene-related peptide inhibitors.

2.3 Invasive treatments are reserved for people with distressing symptoms that are refractory to medical therapy. These include nerve blocks, botulinum toxin (see NICE's technology appraisal guidance on botulinum toxin type A for the prevention of headaches in adults with chronic migraine), acupuncture and interventional procedures (see NICE's interventional procedures guidance on occipital nerve stimulation, transcutaneous stimulation of the cervical branch of the vagus nerve or transcranial magnetic stimulation).

The procedure

2.4 Transcutaneous electrical stimulation of the supraorbital nerve uses small electrical currents to stimulate the supraorbital nerves (branches of the ophthalmic nerve, the first division of the trigeminal nerve) through the skin overlying the nerves. It is also called external trigeminal nerve stimulation or eTNS. The aim is to relieve headache and, when used regularly, to reduce the severity and the frequency of migraine attacks.

2.5 People with migraine administer the therapy themselves using a small battery-operated device. For example, 1 device consists of a headband with a central button connected to a self-adhesive electrode patch. This is applied to the forehead above the eyebrows. When the device is activated, small electrical impulses stimulate the supraorbital nerves (branches of the ophthalmic nerve, the first division of the trigeminal nerve). The intensity of the electrical pulses increases periodically and can be self-adjusted. Stimulation is applied daily for about 1 to 2 hours during an acute migraine attack, and for 20 minutes for prevention between attacks.

Issue date: June 2022

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 14 sources, which was discussed by the committee. The evidence included 2 randomised controlled trial, 3 case series, and 1 observational survey for acute treatment of migraine. It included 4 randomised controlled trials, 2 case series,1 observational survey and 1 Food and Drug Administration Manufacturer and User Facility Device Experience database adverse event report for prevention. It is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: reduced frequency, duration and severity of migraine episodes, reduced medication use and improved quality of life.

3.3 The professional experts and the committee considered the key safety outcomes to be: pain, weakness, poststimulation headaches and worsening of migraine.

3.4 Twelve commentaries from people who have had this procedure and a submission from a patient organisation were discussed by the committee.

Committee comments

3.5 The committee noted that migraine is often a chronic condition with a detrimental effect on quality of life. It recognised that, for some people, there is a lack of effective prevention and treatment options.

3.6 The committee noted that many people having this procedure continued to take medications to treat or prevent migraine.

3.7 The committee was pleased to receive patient commentary and a submission from a patient organisation for this procedure. It noted that several people reported a negative experience of the procedure, including unpleasant side effects.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
June 2022

ISBN:

Issue date: June 2022