NICE guidance

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

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg740

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG559.

1 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:

- The evidence for treating an acute migraine attack is adequate but, 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.
- The 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 procedures 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 (including clinical nurse specialists) with expertise in managing migraine.

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, to either 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 and 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.

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.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation