NICE National Institute for Health and Care Excellence

NICE guidance

Occipital nerve stimulation for intractable chronic migraine

HealthTech guidance
Published: 26 April 2013

www.nice.org.uk/guidance/htg310

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.

Contents

This guidance replaces IPG452.

1 Recommendations

1.1 The evidence on occipital nerve stimulation (ONS) for intractable chronic migraine shows some efficacy in the short term, but there is very little evidence about long-term outcomes. With regard to safety, there is a risk of complications, needing further surgery. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

1.2 Clinicians wishing to undertake ONS for intractable chronic migraine should take the following actions:

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy, and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.

1.3 Selection of patients for treatment using ONS for intractable chronic migraine should be done by a multidisciplinary team, including specialists in headache, pain management and neurosurgery.

1.4 Clinicians should enter details about all patients undergoing ONS for intractable chronic migraine onto the UK Neuromodulation Register when access to that database is available. They should audit and review clinical outcomes locally and should document and consider their relationship to patient characteristics.

1.5 NICE encourages publication of further information from comparative studies and from collaborative data collection to guide future use of this procedure and to provide patients with the best possible advice. Publications should include full details of any complications, and of adjunctive or subsequent treatments. Outcomes should include measures of pain, function and quality of life, particularly in the long term.

1.6 NICE may review the procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 Migraine is a severe headache, often accompanied by sensitivity to light and sound. It may be preceded by an aura, consisting of perception of an unusual light, an unpleasant smell or, occasionally, confusing thoughts or experiences. The International Classification of Headache Disorders provides a classification of migraine types.

2.1.2 Current treatment for patients with migraine aims to prevent or stop episodes with drugs such as painkillers, anti-emetics and triptans (as recommended in NICE's guideline on headaches in over 12s). If these fail, invasive treatments such as nerve blocks, botulinum toxin type A (see NICE's technology appraisal guidance on botulinum toxin type A for the prevention of headaches in adults with chronic migraine) or acupuncture are sometimes used.

2.2 Outline of the procedure

2.2.1 Occipital nerve stimulation (ONS) for intractable chronic migraine is usually done in 2 stages, although a single-stage procedure is sometimes used. In the first, trial stage, using local anaesthesia and usually with fluoroscopic guidance, electrodes are passed through a subcutaneous tunnel and placed over the occipital nerve(s) around the level of C1. Correct placement of electrodes is verified by intraoperative stimulation and patient feedback before they are sutured to subcutaneous tissue. A lead is tunnelled under the skin from the electrode to an exit site in the posterior cervical region, where it is connected by an external extension lead to a hand-held neurostimulator.

2.2.2 The second stage is carried out if the trial is successful. With the patient under general anaesthesia, an implantable neurostimulator is secured in a subcutaneous pocket, usually in the infraclavicular region or the abdominal wall. A lead is tunnelled from the electrode to the implantable neurostimulator. The

patient uses a remote control to stimulate the occipital nerves when needed.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the systematic review and its addendum.

2.3.1 A randomised controlled trial (RCT) of 157 patients compared ONS (active stimulation, n=105) against sham stimulation (n=52). It reported a statistically significantly greater decrease in the 'Migraine disability assessment score' (MIDAS), which takes into account headache days and their impact on the patient's life (maximum score 200), at 12-week follow-up for the ONS group than for the sham stimulation group (64.6 and 20.4 reduction respectively, p=0.001).

2.3.2 An RCT of 67 patients comparing ONS (n=33) against sham stimulation (n=17) or medical management (n=17) reported a responder rate (defined as a reduction in headache days per month of 50% or more, or a 3-point or greater reduction in average overall pain intensity compared with baseline at 3 months) of 39% (11 out of 28) in the ONS group, 6% (1 out of 16) in the sham stimulation group and 0% (0 out of 17) in the medication group (p value not reported).

2.3.3 A case series of 25 patients reported that headache frequency per 90 days reduced from 75.56 (standard deviation [SD] 26.81) before implantation to 37.45 (SD 7.49) over a mean follow-up of 18 months (p<0.001).

2.3.4 The RCT of 157 patients reported no significant difference between the groups in the proportion of patients whose pain reduced by 50% or more (measured on a visual analogue scale; 17% for ONS and 14% for sham stimulation, p=0.55) at 12-week follow-up.

2.3.5 The case series of 25 patients reported a significant reduction in headache severity (0 to 10 scale) from a baseline of 9.32 (SD 1.28) to 5.72 (SD 3.31) over a mean follow-up of 18 months (p<0.001).

2.3.6 The Specialist Advisers listed key efficacy outcomes as a reduction in migraine or

headache days, headache severity, frequency and duration, disability score (measured by MIDAS), medication use and improvements in quality of life (SF-36).

2.4 Safety

2.4.1 Infections at the implant site were reported in 14% (7 out of 51) of patients in the RCT of 67 patients at 3-month follow-up. Infection was reported in 4% (4 out of 105) of patients in the ONS group and 6% (3 out of 52) of patients in the sham stimulation group in the RCT of 157 patients at 12-week follow-up (no further details available).

2.4.2 Skin erosion was reported in 4% (4 out of 105) of patients in the ONS group and 4% (2 out of 52) of patients in the sham stimulation group in the RCT of 157 patients at 12-week follow-up.

2.4.3 Lead migration or dislodgement was reported in 10% (5 out of 52) of patients in the sham stimulation group and 14% (15 out of 105) of patients in the ONS group in the RCT of 157 patients after 3 months; and in 24% (12 out of 51) of patients in the RCT of 67 patients at 3-month follow-up. Lead migration was reported in 36% (9 out of 25) of patients in the case series of 25 patients at mean 18-month follow-up.

2.4.4 Problems with ineffective device programming and ineffective leads were reported in 12% (6 out of 51) and 4% (2 out of 51) of patients respectively, in the RCT of 67 patients at 3-month follow-up.

2.4.5 Persistent pain or numbness at the implant site was reported in 13% (14 out of 105) of patients in the ONS group and 17% (9 out of 52) of patients in the sham stimulation group in the RCT of 157 patients at 12-week follow-up. Loss of motor or musculoskeletal control was reported in 1% (1 out of 105) of patients in the ONS group in the same RCT (timing not reported).

2.4.6 Unintended stimulation effect (no further details available) was reported in 6% (6 out of 105) of patients in the ONS group and 2% (1 out of 52) of patients in the sham stimulation group in the RCT of 157 patients.

2.4.7 In addition to the above, the Specialist Advisers listed haemorrhage, nerve damage and lead fracture as theoretical adverse events.

2.5 Other comments

2.5.1 The Committee recognised that patients being considered for ONS for intractable chronic migraine commonly have very distressing and long-term symptoms that other methods of treatment have failed to control.

2.5.2 The Committee recognised that research in this area is difficult because there is uncertainty about the percentage level of relief that should be considered significant and it is difficult to achieve blinding in trials, and because of the complex and heterogeneous nature of chronic migraine. Currently, there are not enough good-quality comparative studies to be able confidently to evaluate the procedure's efficacy. This underpins the recommendations in section 1.

2.5.3 The Committee recognised that techniques and technology are evolving and, implicitly, this may produce better results.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 452 has been migrated to HealthTech guidance 310. The recommendations and accompanying content remain unchanged.

ISBN 978-1-4731-8851-8

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.