NICE guidance

Deep brain stimulation for intractable trigeminal autonomic cephalalgias

Interventional procedures guidance
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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.

1 Guidance

1.1 Current evidence on the efficacy of deep brain stimulation (DBS) for intractable trigeminal autonomic cephalalgias (TACs) is limited and inconsistent, and the evidence on safety shows that there are serious but well-known side effects. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake DBS for intractable TACs should take the following actions:

- Inform the clinical governance leads in their Trusts.
- Ensure that patients and their carers understand the uncertainty about the procedure's efficacy. They should be specifically informed that DBS may not control their headache symptoms and they should be fully informed about the possible risks associated with the procedure, including the small risk of death. Clinicians should provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having DBS for intractable TACs (see section 3.1).

1.3 Patient selection for DBS for intractable TACs should be carried out by a multidisciplinary team specialising in pain management.

1.4 Further research studies should clearly define patient selection and report the intensity and duration of stimulation, medication use and quality of life, in addition to documenting the effects on headache symptoms as clearly as possible.

2 The procedure

2.1 Indications and current treatments

2.1.1 Trigeminal autonomic cephalalgias (TACs; for example, cluster headaches) are characterised by relatively short-lasting but severe pain attacks associated with autonomic manifestations such as sweating, flushing, and ipsilateral rhinorrhoea.

2.1.2 The first-line treatment for TACs is usually medical therapy, carried out with the aim of either preventing or limiting the duration of episodes. Surgery to interrupt the trigeminal sensory or autonomic pathways is sometimes used, but this has a risk of serious complications including diplopia and corneal ulcers.

2.2 Outline of the procedure

2.2.1 Deep brain stimulation (DBS) involves stereotactic targeting of specific anatomical sites within the brain (such as the sensory thalamus or periaqueductal grey matter) to modulate the central processing of the pain signals.

2.2.2 DBS for intractable TACs is usually carried out with the patient under local anaesthesia and/or intravenous sedation. Electrodes are inserted into the brain using MRI and/or CT. A test stimulation (or macrostimulation) is used to check for side effects. Postoperative scans may be used to assess the position of the electrodes and to identify complications such as local haemorrhage.

2.2.3 Following satisfactory electrode testing, a pulse generator is implanted under the chest wall and connected by tunnelled wires to the electrodes. The generator usually remains switched 'on'.

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 overview.

2.3.1 A crossover randomised controlled trial (RCT) of 12 patients with refractory chronic cluster headache (CH) reported that there was no significant difference between the 'on' and 'off' periods in either the 'on–off' group or the 'off–on' group for a number of outcomes including frequency of attacks, pain intensity and patient satisfaction.

2.3.2 During a 10-month open phase of the RCT of 12 patients, when all patients received DBS, the mean weekly attack frequency decreased by 48% from baseline (from a median of 14 to 8 attacks per week; p=0.08).

2.3.3 A case series of 20 patients reported that all 16 patients treated for refractory chronic CH had relief from pain at a mean follow-up of 23 months. Time to response occurred at a mean of 42 days (range 1 to 86 days) with mean 71% of pain-free days.

2.3.4 The RCT of 12 patients reported reduced Hospital Anxiety and Depression Scale scores (7 anxiety items and 7 depression items with scores greater than 7 indicating anxiety and depression, respectively) in the open phase only. Median anxiety scores decreased from 13 to 7.5 (p=0.008) and median depression scores decreased from 10 to 4.5 (p=0.052).

2.3.5 The Specialist Advisers listed key efficacy outcomes as improvement in the number of headaches, severity and duration of attacks, and quality of life, measured by headache scoring systems.

2.4 Safety

2.4.1 In a case series of 6 patients with unilateral refractory chronic CH, 1 patient died 3 days after the procedure from an intracerebral haemorrhage which developed along the lead tract a few hours after the procedure.

2.4.2 The RCT of 12 patients reported subcutaneous infection 3 weeks after surgery in 1 patient, and the case series of 21 patients reported 1 occurrence of deep infection. Both resolved after hardware removal and antibiotic treatment.

2.4.3 In the RCT of 12 patients, 1 patient developed transient loss of consciousness

with hemiparesis shortly after test stimulation and subsequent severe micturition syncopes associated with a decrease in blood pressure in the standing position (not otherwise described).

2.4.4 The case series of 6 patients reported that all patients had diplopia and dizziness if high levels of electrical stimulation were used (above 1.5 V). One patient became tachypnoeic and tachycardic but symptoms resolved after the recording electrode was removed.

2.4.5 The Specialist Advisers listed anecdotal adverse events as stroke, seizures and lead migration.

2.5 Other comments

2.5.1 The Committee found interpretation of the evidence difficult: the single RCT dealt only with a subgroup of patients.

2.5.2 The Committee noted patient commentary, which reported improvements in quality of life, even if pain was relieved only partially, and noted that some patients were no longer suicidal after treatment.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.