NICE National Institute for Health and Care Excellence

NICE guidance

Deep brain stimulation for refractory chronic pain syndromes (excluding headache)

HealthTech 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.

Contents

This guidance replaces IPG382.

1 Recommendations

1.1 Current evidence on the safety of deep brain stimulation (DBS) for refractory chronic pain syndromes (excluding headache) shows that there are serious but well-known risks. There is evidence that the procedure is efficacious in some patients who are refractory to other forms of pain control. Therefore, this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 During the consent process patients should be informed that DBS may not control their chronic pain symptoms. They should be fully informed about the possible risks associated with this procedure including the small risk of death.

1.3 DBS should only be used in patients with refractory chronic pain syndromes that other treatments have failed to control. Patient selection should be carried out by a multidisciplinary team specialising in pain management.

2 The procedure

2.1 Indications and current treatments

2.1.1 Chronic refractory pain syndromes often have a complex natural history and unclear aetiology. Pain may be nociceptive, neuropathic or deafferentation or in some cases, of uncertain origin.

2.1.2 Treatment of chronic refractory pain usually includes physical, psychological and/or pharmacological treatments. Neurostimulation of the motor cortex, spinal or peripheral nerves have been introduced as treatment options for patients whose condition is unresponsive to other forms of treatment.

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 pain signals.

2.2.2 With the patient under local anaesthesia and/or intravenous sedation, or general anaesthesia, electrodes are inserted into the brain using magnetic resonance imaging and/or computed tomography. 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 non-randomised comparative study of 43 patients with post-stroke pain treated by DBS or motor cortex stimulation reported pain reduction greater than 60% in 25% (3 out of 12) and 48% (15 out of 31) of patients respectively (measured on a visual analogue scale [not described]; follow-up not stated).

2.3.2 A case series of 112 patients with chronic intractable deafferentation pain reported that 47% (42 out of 89) of patients were pain-free and 32% (28 out of 89) of patients were 'improved' at follow-ups ranging from 6 months to 6 years. The procedure was considered to have failed in the remaining patients (21% [19 out of 89]).

2.3.3 A case series of 122 patients reported treatment success (defined as the patient being able to control their pain using the device with or without medication) in 77% (50 out of 65) of patients with severe intractable pain of peripheral origin (follow-up not stated).

2.3.4 The Specialist Advisers listed key efficacy outcomes as a reduction in frequency and severity of pain, improvement in physical and mental function, improvement in quality of life, and reduction in medication requirements.

2.4 Safety

2.4.1 Intracranial haemorrhage was reported in 4% (5 out of 141) of patients (timing of events not stated) in a case series of 141 patients with nociceptive or deafferentation pain; 1 patient died and 4 patients had neurological deficits, of whom 2 recovered completely and 2 were left with significant deficits.

2.4.2 The case series of 122 patients reported 2 deaths: 1 due to massive cerebral oedema and haematoma in the basal ganglia and the other to coronary occlusion occurring 9 weeks after ventricular haemorrhage (a complication of the procedure).

2.4.3 The case series of 141 patients reported infection in 12% (17 out of 141) of

patients (23 cases). Of these, 12 cases occurred within 30 days of the procedure and 10 cases were reported after 30 days (1 case not described). One patient was successfully treated with antibiotics alone, 2 with antibiotics and debridement, and 11 with antibiotics and electrode removal (3 patients not described).

2.4.4 The case series of 122 patients reported ventriculitis in 1 patient, subgaleal infection in 4 patients and subdural empyema in 1 patient. The patient with ventriculitis and 3 of those with subgaleal infection were successfully treated with antibiotics, but the remaining 2 patients required removal of the DBS system.

2.4.5 The case series of 141 patients reported erosion of hardware in 7% (10 out of 141) of patients. Of these, 5 patients had the DBS system removed and 5 had successful re-implantation without the need for antibiotics. Electrode migration occurred only with early versions of the electrodes.

2.4.6 The Specialist Advisers listed anecdotal adverse events as suspected development of a new neuropathic pain condition after migration of the lead, mood change from aberrant stimulation, stimulation-induced reversible side effects such as dysarthria, and seizures. The Specialist Advisers considered theoretical adverse events to include cerebral infarction.

2.5 Other comments

2.5.1 The Committee noted that the available studies described heterogeneous treatment protocols and patient groups. In addition, most were published some years ago and DBS techniques have evolved. These factors made interpretation of the evidence difficult. The Committee considered that there was insufficient evidence to assess efficacy in different patient groups.

2.5.2 The Committee noted strongly positive commentaries from patients who had been treated by DBS; some described how even partial relief of their pain had resulted in significantly improved quality of life.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 382 has been migrated to HealthTech guidance 253. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.