

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

Interventional procedures guidance

Published: 23 March 2011

www.nice.org.uk/guidance/ipg382

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. However, 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.

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.

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 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 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'.

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 Efficacy

- 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% (3/12) and 48% (15/31) 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% (42/89) of patients were pain-free and 32% (28/89) 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% [19/89]).
- 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% (50/65) 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% (5/141) 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% (17/141) 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% (10/141) 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.

3 Further information

- 3.1 For related NICE guidance see our [website](#).

Information for patients

NICE has produced [information on this procedure for patients and carers](#) ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedure guidance](#) process.

We have produced a [summary of this guidance for patients and carers](#). Information about the evidence it is based on is also [available](#).

Changes since publication

2 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

Copyright

© National Institute for Health and Clinical Excellence 2011. All rights reserved. NICE copyright material can be downloaded for private research and study, and may be reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the written permission of NICE.

Contact NICE

National Institute for Health and Clinical Excellence
Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT

www.nice.org.uk

nice@nice.org.uk

0845 033 7780

Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).

Accreditation

