NICE guidance

Deep brain stimulation for refractory epilepsy

Interventional procedures guidance
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nice.org.uk/guidance/ipg416

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 The evidence on the efficacy of deep brain stimulation (DBS) for refractory epilepsy is limited in both quantity and quality. 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 refractory epilepsy 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 safety and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended.
- Audit and review clinical outcomes of all patients having DBS for refractory epilepsy (see section 3.1).

1.3 Patient selection, treatment and follow-up should be carried out by a multidisciplinary team specialising in the management of difficult epilepsy, including a neurologist, a neurophysiologist, a neuroradiologist and a functional neurosurgeon.

1.4 Further research should describe patient selection and define clearly the target area of the brain. Outcomes should include measures of seizure frequency, functional ability, social inclusion and quality of life.

2 The procedure

2.1 Indications and current treatments

2.1.1 Epilepsy is characterised by recurrent seizures unprovoked by any immediately identifiable cause.

2.1.2 Treatment mainly comprises anti-epileptic drugs to prevent seizure recurrence. However, some patients have epilepsy that is inadequately controlled by medical treatment. These patients experience frequent seizure activity and are at risk of status epilepticus and also sudden death in epilepsy (SUDEP).

2.1.3 If medical therapy fails to achieve adequate control, surgery to resect or disconnect parts of the brain or vagus nerve stimulation may be considered.

2.2 Outline of the procedure

2.2.1 DBS is used for selected patients with medically refractory epilepsy for whom surgical resection is considered unsuitable. It involves electrical stimulation of specific sites within the brain (such as the anterior nucleus of the thalamus), which may suppress abnormal electrical activity associated with seizures.

2.2.2 DBS for refractory epilepsy is carried out with the patient under local or general anaesthesia. One or more permanent electrodes are inserted into the brain using imaging guidance.

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 randomised controlled trial (RCT) of 109 patients with DBS treated by either 'on' or 'off' (control) stimulation reported that at the end of a 3-month blinded phase there was a 29% greater reduction in seizure frequency among the 54 patients with 'on' stimulation compared with the 55 patients with 'off' stimulation ($p = 0.002$). After the blinded phase, all patients received stimulation; seizure frequency decreased by a median of 56% from baseline at 2-year follow-up (n = 81).

2.3.2 Following the use of stimulation in all patients after the 3-month blinded phase in the RCT of 109 patients, Quality of Life in Epilepsy scores improved significantly at 13- and 25-month follow-up (n = 102 and 98, respectively; $p < 0.001$ at both time intervals).

2.3.3 The Specialist Advisers listed key efficacy outcomes as reduction in seizure frequency and medication use, and improvement in quality of life.

2.4 Safety

2.4.1 Subdural haemorrhage during the DBS implantation procedure was reported in 1 patient in a case series of 17 patients. Open cranial surgery was required; the patient was reported as hemiparetic and obtunded 1 week after the event.

2.4.2 The RCT of 109 patients reported that 5% (5/109) of patients had asymptomatic haemorrhages detected incidentally by neuroimaging.

2.4.3 The RCT of 109 patients reported that 13% (14/109) of patients developed implant site infections and were treated with antibiotics; 9 patients had additional removal of hardware (not otherwise described).

2.4.4 The RCT of 109 patients reported depression in 15% (8/54) of patients treated by DBS compared with 2% (1/55) of control patients during the blinded phase ($p = 0.016$). Symptoms in 4 of the 8 patients in the DBS group resolved within a mean follow-up of 76 days.

2.4.5 The RCT of 109 patients reported memory impairment during the 3-month blinded phase in 13% (7/54) and 2% (1/55) in the DBS and the control group patients, respectively ($p = 0.032$). This was not judged to be serious in any of the patients and resolved within 12–476 days.

2.4.6 The RCT of 109 patients reported a total of 5 deaths during a mean follow-up of 3 years: 1 patient died before electrode implantation because of probable SUDEP; 2 further patients died from SUDEP (1 during the unblinded phase and the other during subsequent follow-up); 1 patient drowned; and 1 committed suicide during the follow-up phase. None of the deaths were judged to be device-related.

2.4.7 The Specialist Advisers listed adverse events (reported in the literature or known from experience) as stroke, neurological deficit, and breakage and displacement of leads.

2.5 Other comments

2.5.1 The Committee recognised the disability and distress that refractory epilepsy can cause and noted that patients may die from a variety of causes. Any

treatment that is shown to reduce seizure frequency, SUDEP risk, need for medication and concomitant side effects to an extent which improves the lives of patients and their carers would be a welcome addition to the options for management.

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 audit support (which is for use at local discretion), which will be available when the guidance is published.

3.2 For related NICE guidance see the NICE 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.

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 procedures guidance process.

We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Changes after publication
May 2012: minor maintenance

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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.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation