

Deep brain stimulation for tremor and dystonia (excluding Parkinson's disease)

1 Guidance

- 1.1 Current evidence on the safety and efficacy of deep brain stimulation for tremor and dystonia (excluding Parkinson's disease) appears adequate to support the use of this procedure, provided that the normal arrangements are in place for consent, audit and clinical governance.
- 1.2 Patient selection and management should be carried out in the context of a multidisciplinary team specialising in the long-term care of patients with movement disorders.

2 The procedure

2.1 Indications

- 2.1.1 Tremor and dystonia are symptoms arising from a number of different neurological diseases, including essential tremor, multiple sclerosis and primary generalised dystonia. Tremor and dystonia associated with Parkinson's disease are not covered by this guidance.
- 2.1.2 Tremor is an involuntary rhythmic repetitive movement, most frequently affecting the upper limbs. It can occur at rest or can be brought on (or exacerbated) by posture or intentional movement. Severe tremor can be disabling because it affects fine-movement coordination.
- 2.1.3 Dystonia is the simultaneous uncoordinated contraction of opposing antagonistic muscles. It may be limited to a particular group of muscles, or it may be generalised.
- 2.1.4 Tremor can be treated by rehabilitation and drug therapy, and early appropriate treatment may minimise functional disability. Anti-tremor drugs reduce the amplitude but not the frequency of tremor, and this does not always translate into functional improvement. Surgery, which often involves ablation of the thalamic nucleus, is usually reserved for patients with severe disabling tremor and functional disability that interferes with activities of daily living, and for tremor that is refractory to the highest tolerated doses of medication.

- 2.1.5 Dystonia can be treated conservatively or surgically. Currently available conservative management options for dystonia improve the symptoms but do not cure the underlying neurological disorder. The severity of dystonia may progress over time as part of the underlying neurological condition. Surgical options include thalamotomy and pallidotomy; however, benefits may not be maintained in the long term.

2.2 Outline of the procedure

- 2.2.1 Deep brain stimulation can be carried out on structures within the brain that are responsible for modifying movements, such as the thalamus, the globus pallidus and the subthalamic nucleus, which interact functionally with the substantia nigra (nigra). These structures are all bilateral, and surgery can be performed on one or both sides. The function of these brain nuclei is altered during deep brain stimulation through the application of an electrical current.
- 2.2.2 The procedure involves inserting fine needles into the brain through small holes in the skull under imaging guidance, to determine the exact position of the targeted nucleus, which may be different in each patient. One or more permanent electrodes are subsequently placed into this nucleus. Wires are tunnelled subcutaneously to the anterior chest wall, where they are connected to an implanted pulse generator. Local or general anaesthetic may be used in this procedure.
- 2.2.3 Further operations may be required for replacement of the pulse generator.

2.3 Efficacy

- 2.3.1 A case-control series found that, in up to 27 months' follow-up, total tremor score improved in 17 patients treated with deep brain stimulation, but there was no significant improvement in most other efficacy outcomes. A case series of 52 patients with essential tremor

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This guidance is written in the following context

This guidance represents the view of the Institute, which 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.

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This guidance is endorsed by NHS QIS for implementation by NHSScotland.

who underwent deep brain stimulation reported a significant improvement in activities of daily living at 3 months' follow-up, with scores improving from 17.8 points to 6.5 points ($p < 0.001$). Another case series of 19 patients found that deep brain stimulation produced an improvement in tremor score (Fahn–Tolosa–Marin scale) from 3.3 points at baseline to 0.8 points at 27 months' follow-up ($p < 0.005$).

- 2.3.2 A case series of 22 patients with dystonia who underwent deep brain stimulation reported that the total score on the Burke–Fahn–Marsden dystonia rating scale improved significantly from a mean of 46.3 points at baseline to 24.3 points at 3 months' follow-up. This improvement was maintained to 12 months' follow-up, with a score of 21.0 points ($p < 0.001$ for both comparisons with baseline). Similarly, global disability score improved from 11.6 points at baseline to 7.6 points at 3 months' follow-up and 6.5 points at 12 months' follow-up ($p < 0.001$).
- 2.3.3 Very few data are available on the use of deep brain stimulation for tremor in multiple sclerosis. Three case series reported significant improvements in tremor secondary to multiple sclerosis at 12–22 months; however, two of these studies found that improvements in tremor did not necessarily correlate with improvements in functional ability. For more details, refer to the 'Sources of evidence' section.
- 2.3.4 The Specialist Advisers noted that there are concerns about the long-term efficacy of the procedure, because tremor may become resistant to stimulation.

2.4 Safety

- 2.4.1 One case series reported that the pulse generator failed in 50% (6/12) of patients. Across three case series where it was reported as an outcome, displacement of the stimulating electrode occurred in 6% (1/18), 8% (1/12) and 15% (8/52) of patients. The incidence of lead fracture or failure in three studies was 4% (2/52), 5% (1/22) and 6% (1/18). These complications sometimes required further surgery.
- 2.4.2 One case series of 22 patients who underwent deep brain stimulation for dystonia reported transient oedema of the frontal lobe, cutaneous necrosis of the scalp, localised skin infection and haematoma near the neurostimulator, in one patient each. However, none of these events had

permanent sequelae. For more details, refer to the 'Sources of evidence' section.

- 2.4.3 The Specialist Advisers noted that adverse events relating to this procedure include infection, haemorrhage (possibly causing hemiparesis), hardware failure, dysarthria, speech disturbance, cerebral oedema and death. They also noted that theoretical complications include stroke, speech impairment, cognitive impairment, depression, suicide and risk of injury during subsequent magnetic resonance imaging.

2.5 Other comments

- 2.5.1 There are variations in the technique of deep brain stimulation. In addition, the procedure may be used concurrently or sequentially with other surgery or drug therapies. Different rehabilitation methods may also have an effect on outcome.
- 2.5.2 Further information on the long-term effects of this procedure in patients undergoing surgery at a young age would be useful.

3 Further information

- 3.1 The Institute has published interventional procedures guidance on deep brain stimulation for Parkinson's disease (www.nice.org.uk/IPG019) and a clinical guideline on Parkinson's disease (www.nice.org.uk/CG035).

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'Understanding NICE guidance'

NICE has produced information describing its guidance on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG188publicinfo

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document. 'Interventional procedure overview of deep brain stimulation for tremor and dystonia (excluding Parkinson's disease)', February 2006.

Available from: www.nice.org.uk/IP319overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1105. 'Understanding NICE guidance' can be obtained by quoting reference number N1106.

The distribution list for this guidance is available at www.nice.org.uk/IPG188distributionlist

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