



Subthalamotomy for Parkinson's disease

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg65

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 <u>Yellow Card Scheme</u>.

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 <u>assess and reduce the environmental</u> impact of implementing NICE recommendations wherever possible.

1 Guidance

- 1.1 Current evidence on the safety and efficacy of subthalamotomy for Parkinson's disease does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research.
 - Clinicians wishing to undertake subthalamotomy for Parkinson's disease should take the following actions.
 - Inform the clinical governance leads in their Trusts.
 - Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the <u>information for the public</u> is recommended.
 - Audit and review clinical outcomes of all patients having subthalamotomy for Parkinson's disease.
- Subthalamotomy for Parkinson's disease is a treatment option in the <u>PD Surg trial</u>, which is expected to complete randomisation in 2005/6. Clinicians are encouraged to consider randomising patients in the trial.
- Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE may review the procedure upon publication of further evidence.
- 1.4 It is recommended that patient selection should be made with the involvement of a multidisciplinary team, and that patients should be offered the procedure only when their disease has become refractory to best medical treatment.

2 The procedure

2.1 Indications

- 2.1.1 Parkinson's disease is a chronic disease of the brain characterised by gradually worsening tremor, muscle rigidity, and difficulties with starting and stopping movements. The condition is usually treated with drugs. Surgery may be considered for people who have responded poorly to drugs, who have severe side effects from medication or who have severe fluctuations in response to drugs (on–off syndrome).
- 2.1.2 Parkinson's disease affects about 0.5% of people aged 65 to 74 years and 1% to 2% of people aged 75 years and older. Experts believe that 1% to 10% of people with Parkinson's disease might be suitable for brain surgery.
- Surgery for Parkinson's disease is carried out on structures within the brain that are responsible for the modification of movements, such as the thalamus, the globus pallidus and the subthalamic nucleus. Surgery may be carried out on these structures in either or both hemispheres of the brain.
- 2.1.4 Surgical treatment aims to correct the imbalance created by diminished function of the substantia nigra, the underlying abnormality in Parkinson's disease. Surgery alters, either through destruction or electrical stimulation, the function of brain nuclei (such as the thalamus, globus pallidus or subthalamus) that interact functionally with the substantia nigra. Subthalamotomy is one form of surgery for Parkinson's disease.

2.2 Outline of the procedure

2.2.1 Subthalamotomy involves inserting very fine needles into the brain through small holes made in the skull, to destroy a part of the subthalamic nucleus using heat or radiofrequency. The exact points of needle insertion may be different in each patient. The procedure is usually carried out under local anaesthetic. Patients remain awake during the procedure so that the effects on movements can be monitored.

2.3 Efficacy

- 2.3.1 The evidence was limited to small case series, with only two case series assessing efficacy on a total of 32 patients. Both these studies suggested an improvement in motor skills as measured by the Unified Parkinson Disease Rating Scale (UPDRS) at 12 months' follow-up.
- 2.3.2 The specialist advisors commented that there were not enough data to assess the long-term benefits of subthalamotomy for Parkinson's disease, and that subthalamic electrical stimulation had become the preferred intervention.

2.4 Safety

- 2.4.1 Reported complications included persistent dyskinesia, deterioration in learning and retrieval, and deterioration in spatial working memory. In one study of 66 patients, signs of cerebellar dysfunction persisted in 41% of patients (27 of 66) 2 weeks after surgery.
- 2.4.2 The specialist advisors listed the potential complications as risk of stroke; hemiballismus; and disturbance of speech, swallowing or gait. One advisor was concerned about the irreversible nature of subthalamotomy and the potential need for repeated surgery.

2.5 Other comments

2.5.1 Current evidence relates to relatively young patients.

3 Further information

3.1 NICE has produced <u>interventional procedures guidance on deep brain stimulation</u> for Parkinson's disease. See also NICE's guideline on Parkinson's disease.

Information for patients

NICE has produced <u>information on this procedure for patients and carers</u>. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 Update information

Minor changes since publication

January 2012: Minor maintenance.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.