

Vagus nerve stimulation for refractory epilepsy in children

1 Guidance

- 1.1 Current evidence on the safety and efficacy of vagus nerve stimulation for refractory epilepsy in children 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 The procedure should only be undertaken by specialist paediatric epilepsy teams.
- 1.3 Almost all the current evidence on the efficacy of the procedure relates to reducing seizure frequency only. However the effect on quality of life remains uncertain. Future audit and research should include quality of life measures. Patients, carers and children should be informed about the unpredictability of benefit. Use of the Institute's *Information for the Public* is recommended.

2 The procedure

2.1 Indications

- 2.1.1 Vagus nerve stimulation is indicated for use as an adjunctive therapy in reducing the frequency of seizures in patients who are refractory to anti-epileptic medication. This includes patients whose epileptic disorder is dominated by partial seizures (with or without secondary generalisation) or generalised seizures.

2.2 Outline of the procedure

- 2.2.1 A battery-powered pulse-generating device is implanted under the skin of the upper left chest. A wire is tunneled under the skin and connected to the left vagus nerve in the neck. The stimulation parameters (pulse width and frequency, current intensity, and on/off cycles) are programmed into the pulse generator via a programming wand. Patients or carers can give additional stimulation or temporarily inhibit stimulation. The battery lasts 8–10 years and can be replaced under local anaesthesia. A typical treatment regimen might comprise intermittent stimulation for 30 seconds every 5 minutes throughout the day and night.

2.3 Efficacy

- 2.3.1 In one study of 50 children aged 12 years and younger, 23 (46%) experienced a greater than 50% reduction in seizure frequency. In a study of 28 children aged 12 years and younger, a mean reduction of 62% in seizure frequency was reported at 1 year. There was some evidence to suggest that quality of life improved following the procedure. Comparisons are difficult to make between the studies because of variations in the patient populations, the methods of outcome assessment and the reporting of outcomes. For more details, refer to the Sources of evidence (see below).
- 2.3.2 The Specialist Advisors also noted that the procedure seemed to have some benefits in terms of mood and quality of life.

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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. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

2.4 Safety

- 2.4.1 The most commonly reported complications were hoarseness, sore throat and cough. In a case series of 125 children, 73 children (58%) experienced voice alteration and 48 children (38%) experienced coughing during stimulation. More serious adverse events included infection (requiring device removal) in 3% (3/100) to 6% (1/16) of patients, and breathing irregularities in 19% (3/16) of patients. For more details, refer to the Sources of evidence (see below).
- 2.4.2 The Specialist Advisors believed that this is a safe procedure with no major complications.

3 Further information

- 3.1.1 The Institute is in the process of developing a clinical guideline on epilepsy. The expected date of issue is June 2004.

Andrew Dillon
Chief Executive
March 2004

Information for the Public

The Institute has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available, in English and Welsh, from www.nice.org.uk/IPG050publicinfo.

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

Interventional procedure overview of vagus nerve stimulation for refractory epilepsy in children, October 2002.

Available from: www.nice.org.uk/IP122overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0493. *Information for the Public* can be obtained by quoting reference number N0494 for the English version and N0495 for a version in English and Welsh.

The distribution list for this guidance is available on the NICE website at URL www.nice.org.uk/IPG050distributionlist

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