

Vagus nerve stimulation for treatment-resistant depression

Interventional procedures guidance

Published: 16 December 2009

www.nice.org.uk/guidance/ipg330

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 and efficacy of vagus nerve stimulation (VNS)

for treatment-resistant depression is inadequate in quantity and quality.

Therefore this procedure should be used only with special arrangements for clinical governance, consent and audit or research. It should be used only in patients with treatment-resistant depression.

1.2 Clinicians wishing to undertake VNS for treatment-resistant depression should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients and/or their parents/carers understand the uncertainty about the procedure's safety and efficacy 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 VNS for treatment-resistant depression (see section 3.1).

1.3 Patient selection and management should be carried out by a multidisciplinary team including a psychiatrist and a surgeon (usually a neurosurgeon), with other relevant specialists (for example, a clinical psychologist and an appropriately trained technician).

1.4 NICE encourages further research into VNS for treatment-resistant depression. Research outcomes should include depression rating scales, objective measures of depressive symptoms and patient-reported quality of life. NICE may review the procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 Depression is characterised by low mood, loss of interest in and enjoyment of life, and a range of associated emotional, cognitive, physical and behavioural symptoms. People with severe depression may also develop psychotic symptoms (hallucinations and/or delusions). Depression is associated with risk of suicide. The more severe the episode of depression, the less likely it is that remission will occur spontaneously.

- 2.1.2 Conventional treatment for depression includes antidepressant medication or psychological therapies (including cognitive behavioural therapies) or a combination of both. Electroconvulsive therapy (ECT) may be used to treat depression that has proven resistant to other treatments.

2.2 Outline of the procedure

- 2.2.1 The aim of VNS for treatment-resistant depression is to improve mood regulation and reduce depression by stimulating the vagus nerve.
- 2.2.2 The procedure is carried out with the patient under general or local anaesthesia. An incision is made on the left side of the neck and the left vagus nerve is identified. A stimulator electrode is cuffed around the nerve and the leads of the stimulator electrode are tunnelled subcutaneously to the left chest wall and attached to a pulse generator unit, which is implanted into a subcutaneous pocket.
- 2.2.3 The vagus nerve is stimulated periodically (a short period of stimulation followed by a few minutes rest). The stimulation intensity and frequency can be programmed as required via an external (remote) electronic control. Patients may temporarily inhibit stimulation by activating a switch with a magnet.

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 Interpretation of the evidence was complicated by different publications reporting on the same patients but at different follow-up periods.
- 2.3.2 A systematic review of 18 studies (1 randomised controlled trial [RCT] and 17 case series) including 1251 VNS-treated patients with treatment-resistant depression (only defined in some of the studies) reported a satisfactory response (defined as a more than 50% reduction in baseline Hamilton Depression Rating Scale [HDRS] score). This ranged from 31% to 40% of patients in 'short-term' studies (up to 10-week follow-up) and from 27% to 58% of patients in 'long-term' studies (minimum 12-month follow-up). In the RCT

(112 VNS-treated and 110 sham therapy patients) no significant differences were reported in the change in HDRS scores between treatment groups (absolute figures and follow-up not stated). A case series of 74 patients with severe depression (more than 2 years or at least 4 depressive episodes) reported that mean HDRS scores improved significantly compared with baseline at 12-month follow-up ($p < 0.0001$; absolute figures not stated), and that 55% of patients had a response to VNS.

2.3.3 The Specialist Advisers listed key efficacy outcomes as depression scale scores, quality of life indicators, and a decrease in the use of adjunctive antidepressant medication or support services.

2.4 Safety

2.4.1 The systematic review reported serious or clinically important adverse events (not otherwise described) in 17% (10/59) of patients in 1 case series, including 2 patients with worsening depression. In 6 short-term studies in the systematic review, 2 patients discontinued VNS treatment because of adverse events (not otherwise described).

2.4.2 In the case series of 74 patients, 2 of 61 patients were reported to have committed suicide at 12-month follow-up. In the RCT included in the systematic review, 1 of 112 VNS-treated patients were reported to have committed suicide (time after treatment not stated).

2.4.3 In the case series of 74 patients, 1% of patients developed a manic episode and 1% had worsening depression at 3-month follow-up (absolute figures not stated). Hypomania or mania was reported after VNS treatment in 5 patients across 2 case series (including 317 VNS-treated patients) in the systematic review.

2.4.4 Dyspnoea was reported in 10% of patients in the case series of 74 patients at 3-month follow-up (absolute figures not stated).

2.4.5 Pain (not otherwise defined) was reported in 20% of patients at 3-month follow-up in the case series of 74 patients.

2.4.6 In the case series of 74 patients, cough and voice alteration was reported in 26%

and 63% of patients, respectively, at 3-month follow-up (absolute figures not stated).

- 2.4.7 The Specialist Advisers reported anecdotal adverse events including glottic spasm and hoarseness. They stated that theoretical adverse events include asystole, arrhythmias, cognitive disturbance, vocal cord paralysis, diarrhoea and local inflammation.

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).
- 3.2 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.

It has been incorporated into the [NICE pathway on depression](#), along with other related guidance and products.

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 since publication

5 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 2009. 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

