NICE guidance

Sacral nerve stimulation for urge incontinence and urgency-frequency

Interventional procedures guidance
Published: 23 June 2004

www.nice.org.uk/guidance/ipg64

This guidance replaces IPG4.

1 Guidance

This document replaced previous guidance on sacral nerve stimulation for 'Urge incontinence' (NICE Interventional Procedures Guidance no. 4) after the Interventional Procedures Advisory Committee reconsidered the procedure based on the results of a systematic review commissioned by NICE.

1.1 Current evidence on the safety and efficacy of sacral nerve stimulation for urge incontinence and urgency-frequency 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 is important. The diagnosis should be defined as clearly

as possible and the procedure limited to patients who have not responded to conservative treatments such as lifestyle modifications, behavioural techniques and drug therapy. Patients should be selected on the basis of their response to peripheral nerve evaluation.

2 The procedure

2.1 Indications

2.1.1 Sacral nerve stimulation is used to treat the symptoms of an overactive bladder, including urinary urge incontinence and/or urgency frequency in patients who have failed or cannot tolerate conventional treatments.

2.1.2 In patients for whom conservative treatments have been unsuccessful, the standard alternatives include bladder reconstruction (such as augmentation and cystoplasty) and urinary diversion.

2.2 Outline of the procedure

2.2.1 Sacral nerve stimulation involves applying an electric current to one of the sacral nerves via an electrode placed through the corresponding sacral foramen. The electrode leads are attached to an implantable pulse generator, which stimulates nerves associated with the lower urinary tract.

2.3 Efficacy

2.3.1 This procedure was subject to a systematic review commissioned by the Institute in November 2003. Evidence from two randomised controlled trials (RCTs), including a total of 50 patients with urge incontinence, showed that complete continence (completely dry with no incontinent episodes) or improvement of more than 50% in incontinence symptoms was observed in 50% and 80% of patients, respectively, following the procedure. This compared with 5% of patients in the control groups, who were receiving conservative treatments while waiting for an implant. In the one RCT that reported on patients with urgency-frequency, an

improvement of more than 50% in incontinence symptoms was observed in 56% (14/25) of patients, compared with 4% (1/25) in the control group. More evidence is available for patients with urge incontinence than for those with urgency-frequency. For more details, refer to the Sources of evidence section.

2.3.2 The results of the case series studies included in the systematic review showed similar results, with complete continence and improvement in symptoms being reported in 39% (139/361) and 67% (338/501) of patients with urge incontinence, respectively, and 41% (22/54) and 65% (75/116) of patients with urgency-frequency, respectively. The benefits of sacral nerve stimulation were reported to persist for at least 3–5 years after implantation. For more details, refer to the Sources of evidence section.

2.4 Safety

2.4.1 In general, evidence on the safety of this procedure was not well reported. Most complications observed in the studies were the result of technical problems related to implantation of the device. The results of the systematic review showed that, overall, the re-operation rate for patients with implants was 33% (283/860). The most common reasons for surgical revision were to replace or reposition implants due to pain or infection at the implant site, or to adjust and modify the lead system to correct breakage or migration. For more details, refer to the Sources of evidence section.

2.4.2 Pain at the site of the pulse generator or at the site of stimulation was reported in 24% (162/663) of patients, sometimes requiring replacement and repositioning of the pulse generator. Other complications included lead-related problems such as migration (16%), wound problems (7%), adverse effects on bowel function (6%), and infection (5%). No cases of long-lasting neurological complications were identified. For more details, refer to the Sources of evidence section.

2.5 Other comments

2.5.1 There is a lack of long-term quality of life data.

2.5.2 There is limited evidence relating to the use of this procedure in older patients.

Andrew Dillon
Chief Executive
June 2004

3 Further information

Sources of evidence

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

'Brazzelli M, Murray A, Fraser C, Grant A. Systematic review of the efficacy and safety of sacral nerve stimulation for urinary urge incontinence and urgency-frequency. Aberdeen: Review Body for Interventional Procedures; 2003'. Commissioned by the National Institute for Clinical Excellence.

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 Other NICE recommendations on sacral nerve stimulation

Further recommendations have been made as part of the clinical guideline on lower urinary tract symptoms published in May 2010, as follows:

- Consider offering implanted sacral nerve stimulation to manage detrusor overactivity only to men whose symptoms have not responded to conservative management and drug treatments.

Clinical and cost-effectiveness evidence was reviewed in the development of this guideline which has led to this more specific recommendation. More information is available.

The IP guidance on sacral nerve stimulation for urge incontinence and urgency-frequency remains current, and should be read in conjunction with the clinical guideline.

5 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 updates and replaces NICE interventional procedure guidance 4.

We have produced a summary of this guidance for patients and carers. Information about the evidence it is based on is also available.

Changes since publication

27 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.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.