

Sacral nerve stimulation for faecal incontinence

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg99

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 [Yellow Card Scheme](#).

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 assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG5.

1 Guidance

- 1.1 Current evidence on the safety and efficacy of sacral nerve stimulation for faecal incontinence 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 performed in specialist units by clinicians with a particular interest in the assessment and treatment of faecal incontinence.

2 The procedure

2.1 Indications

- 2.1.1 Faecal incontinence occurs when a person loses control of their bowel and is unable to retain faeces in the rectum. Faecal incontinence may result from dysfunction of the anal sphincter, which may be due to sphincter damage, spinal injury or a neurological disorder.
- 2.1.2 Faecal incontinence is associated with a high level of physical and social disability.
- 2.1.3 Typically, first-line treatment for faecal incontinence is conservative, such as anti-diarrhoeal medication and pelvic floor muscle training (including biofeedback

therapy). In patients for whom conservative treatments have been unsuccessful, surgical alternatives include tightening the sphincter (overlapping sphincteroplasty), creating a new sphincter from the patient's own muscle (for example, dynamic graciloplasty) or implanting an artificial sphincter. Some patients may require colostomy. Sacral nerve stimulation is a surgical treatment option for patients with faecal incontinence.

2.2 Outline of the procedure

- 2.2.1 In patients with a weak but structurally intact sphincter, it may be possible to alter sphincter and bowel behaviour using the surrounding nerves and muscles. It involves applying an electric current to one of the sacral nerves via an electrode placed through the corresponding sacral foramen. Commonly, the procedure is tested in each patient over a 2- to 3-week period, with a temporary percutaneous peripheral nerve electrode attached to an external stimulator. If significant benefit is achieved, then the permanent implantable pulse generator can be implanted.

2.3 Efficacy

- 2.3.1 This procedure was subject to a systematic review commissioned by the Institute. The systematic review included six case series studies reporting on 266 patients in total. In patients who had permanent implants, complete continence was achieved in 41% to 75% (19 out of 46 to 12 out of 16) of patients, whereas 75% to 100% (3 out of 4 to 16 out of 16) of patients experienced a decrease of 50% or more in the number of incontinence episodes. There was also evidence to suggest an improvement in the ability to defer defecation after permanent implantation. Patients also reported improvements in both disease-specific and general quality-of-life scores after the procedure. For more details, see the [systematic review of the efficacy and safety of sacral nerve stimulation for faecal incontinence](#).

2.4 Safety

- 2.4.1 Complications were reported both during the test peripheral nerve evaluation phase and after implantation. Evidence from the systematic review indicated that of the 266 patients receiving test evaluation, 4% (10 out of 266) experienced an adverse event. Fifty-six per cent (149 out of 266) went on to receive permanent implantation. Of the patients who had permanent implants, 13% (19 out of 149) reported adverse events. These included three patients who developed infections requiring device removal, seven patients who had lead migration requiring either relocation (five cases) or removal of the device, and six patients who experienced pain after implantation.
- 2.4.2 Implantation techniques have been modified in recent years, with a view to reducing the occurrence of complications.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [systematic review of the efficacy and safety of sacral nerve stimulation for faecal incontinence](#).

Information for patients

NICE has produced [information for the public on this procedure](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).