

Sacral nerve stimulation for urge incontinence and urgency- frequency

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg64

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 IPG4.

1 Guidance

- 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 2 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 1 RCT that reported on patients with urgency-frequency, an improvement of more than 50% in incontinence symptoms was observed in 56% of patients (14 of 25), compared with 4% (1 of 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](#).
- 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 of 361) and 67% (338 of 501) of patients with urge incontinence, respectively, and 41% (22 of 54) and 65% (75 of 116) of patients with urgency-frequency, respectively. The benefits of sacral nerve stimulation were reported to persist for at least 3 to 5 years after implantation. For more details, refer to the sources of evidence.

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 of 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.
- 2.4.2 Pain at the site of the pulse generator or at the site of stimulation was reported in 24% (162 of 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.

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.

3 Further information

- 3.1.1 Further recommendations have been made as part of [NICE's guideline on lower urinary tract symptoms in men](#) (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."

Sources of evidence

The evidence considered by the interventional procedures advisory committee is described in the [systematic review](#).

Information for patients

NICE has produced [information on this procedure for patients and carers](#). 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 [Healthcare Improvement Scotland](#).