

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

### Interventional procedure consultation document

# Sacral nerve stimulation for idiopathic chronic non-obstructive urinary retention

Urinary retention is the inability to empty the bladder. It most often happens because of some kind of physical obstruction such as an enlarged prostate, but sometimes it occurs without any obstruction. Sacral nerve stimulation is done by implanting a small device just beneath the skin, usually in the upper buttock. This sends electrical impulses to nerves in the lower back, with the aim of helping the person gain control of their bladder function.

The National Institute for Health and Care Excellence (NICE) is examining sacral nerve stimulation for idiopathic chronic non-obstructive urinary retention and will publish guidance on its safety and efficacy to the NHS. NICE's Interventional Procedures Advisory Committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The Advisory Committee has made provisional recommendations about sacral nerve stimulation for idiopathic chronic non-obstructive urinary retention.

This document summarises the procedure and sets out the provisional recommendations made by the Advisory Committee. It has been prepared for public consultation. The Advisory Committee particularly welcomes:

- comments on the provisional recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

**Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.**

The process that NICE will follow after the consultation period ends is as follows.

- The Advisory Committee will meet again to consider the original evidence and its provisional recommendations in the light of the comments received during consultation.

- The Advisory Committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#), which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 23 July 2015

Target date for publication of guidance: 25 November 2015

## **1 Provisional recommendations**

- 1.1 Current evidence on the safety and efficacy of sacral nerve stimulation for idiopathic chronic non-obstructive urinary retention is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.
- 1.2 Patient selection and treatment should be done in specialist units by clinical teams who are experienced in the assessment,

treatment and long-term care of patients with bladder dysfunction, and in the use of sacral nerve stimulation.

- 1.3 NICE encourages audit and reporting of long-term safety outcomes.

## **2 Indications and current treatments**

2.1 Non-obstructive urinary retention is the inability to empty the bladder with no physical obstruction to the urine flow. It can occur as a result of neurological disorders, such as multiple sclerosis or spinal cord disease, or it can be idiopathic. In younger women, it may be caused by Fowler's syndrome, which is a rare disorder in which the urethral sphincter fails to relax to allow urine to be passed normally. This guidance covers idiopathic chronic non-obstructive urinary retention only (including Fowler's syndrome). Chronic non-obstructive urinary retention can cause complications such as recurrent urinary tract infections and chronic kidney disease.

2.2 Initial management in men is usually with drug therapy, such as alpha blockers, and urethral dilatation; whereas in women it is usually urethral dilatation only. The efficacy of both these options is limited and most patients need to do clean intermittent self-catheterisation or have an indwelling catheter. If these measures are unacceptable to the patient or do not work well enough, then surgical urinary diversion procedures may be considered. Sacral nerve stimulation has been introduced as an alternative option for patients with non-obstructive urinary retention.

### **3 The procedure**

- 3.1 Sacral nerve stimulation for idiopathic chronic non-obstructive urinary retention involves applying an electric current to one of the sacral nerves by an electrode placed through the corresponding sacral foramen. It aims to restore the ability to empty the bladder voluntarily and to remove the need for catheterisation.
- 3.2 Sacral nerve stimulation involves an evaluation phase to help the patient and physician decide if long-term therapy will be beneficial and also to assess the integrity of the sacral nerves and identify the optimal lead location. Two main techniques are used for this evaluation, both of which are initiated by an implantation procedure done using fluoroscopic guidance, with the patient under general or local anaesthesia. The conventional technique involves percutaneously placing a temporary lead, with a unipolar electrode, alongside a sacral nerve (usually S3) and taping it to the skin surface. A newer 2-stage technique involves implanting a permanent tined lead, with a quadripolar electrode, on the sacral nerve through the third sacral foramen. When the lead is correctly positioned, an extension cable is tunnelled to the proposed site for the neurostimulator, usually in the upper buttock. The lead is then tunnelled to the other buttock to provide a remote exit site through the skin.
- 3.3 In both techniques, the leads are attached to a small, external neurostimulator and the level of stimulation is adjusted to achieve normal voiding of urine while avoiding discomfort for the patient. The length of the evaluation phase varies but is generally around 3–7 days with the temporary lead method and approximately 2–4 weeks if a permanent lead is used.

- 3.4 When the evaluation phase is complete, the sacral nerve neurostimulator is implanted, usually with the patient under general anaesthesia. The neurostimulator is inserted into a subcutaneous pocket through a small incision in the upper buttock. If a permanent lead was used in the evaluation phase, it is connected to the neurostimulator. If a temporary lead was used, it is replaced by a permanent lead placed in approximately the same position and connected to the neurostimulator. The electrical current, generated by the neurostimulator and delivered by the lead, modifies sacral nerve activity. The patient can control the neurostimulator with a hand-held programmer, increasing or decreasing the level of stimulation or turning it on and off.

## 4 Efficacy

This section describes efficacy 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 [interventional procedure overview](#).

- 4.1 A systematic review of 14 articles reported post-void residual volume from 7 of the articles (n=478). The mean difference in post-void volume decreased by 236 ml (95% confidence interval [CI] 219 to 253,  $p < 0.0001$ ,  $I^2 = 83%$ ) after sacral nerve stimulation. A randomised controlled trial of 51 patients treated by sacral nerve stimulation or standard medical treatment, which was also included in the systematic review, reported that the mean catheter volume per catheterisation decreased from 339 ml to 49 ml at 6-month follow-up in the treatment group and from 350 ml to 319 ml in the control group ( $p < 0.0001$  comparing the mean differences).

- 4.2 The systematic review of 14 articles reported voided volume from 7 of the articles (n=478). The mean voided volume increased by 344 ml (95% CI 322 to 365,  $p < 0.0001$ ,  $I^2 = 97\%$ ) after sacral nerve stimulation. The randomised controlled trial of 51 patients reported that the mean total voided volume per day increased from 722 ml to 1808 ml at 6-month follow-up in the treatment group and decreased from 560 ml to 488 ml in the control group ( $p < 0.0001$  comparing the mean differences).
- 4.3 The randomised controlled trial of 51 patients reported that the mean number of catheterisations per day decreased from 5.7 to 1.4 at 6-month follow-up in the treatment group and from 4.0 to 3.9 in the control group ( $p < 0.0001$  comparing the mean differences). At 18-month follow-up 58% (14/24) of patients treated by sacral nerve stimulation did not need catheterisation. A case series of 60 patients reported that 72% (43/60) of patients were voiding spontaneously and 50% (30/60) of patients no longer needed to use catheterisation after a mean follow-up of 4 years. A case series of 40 patients reported that the mean number of catheterisations per day decreased from 4.3 to 1.0 after a mean follow-up of 41 months ( $p < 0.001$ ) and 55% (11/20) of patients with complete retention were able to stop catheterisation completely.
- 4.4 The case series of 40 patients reported that 69% (20/29) of patients with complete retention and 73% (8/11) of patients with incomplete retention had a successful response to sacral nerve stimulation (defined by a reduction in the number of daily catheterisations by 50% and a decrease in the mean post-void residual urine volume by 50%). A case series of 93 patients with idiopathic urinary retention reported a success rate of 73%; the cure rate (100%

success) was 63% for patients with Fowler's syndrome and 54% for patients with non-Fowler's idiopathic urinary retention.

- 4.5 The specialist advisers listed key efficacy outcomes as ability to void spontaneously, lower residual volume, reduced need for intermittent catheterisation, a 50% reduction in catheter volume per catheterisation, patient perception of cure or improvement, perception of improved flow rate, frequency of urination or nocturia, pain relief, urodynamic measurements, pad tests or number of leaks per day (if overflow incontinence is present), quality of life, general health status, psychosocial measures, impact of self-catheterisation or incontinence.

## 5 Safety

This section describes 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 [interventional procedure overview](#).

- 5.1 The neurostimulator device was removed in 14% (4/28) of patients in a case series of 40 patients: 2 because of infection, 1 because of pain and 1 because of the need for MRI. In the same study, neurostimulator revision was necessary in 21% (6/28) of patients because of battery expiry or device malfunction in 4 patients and infection in 2 patients. Device removal because of infection was reported in 2% (2/93) of patients in a case series of 93 patients. There were 63 surgical revisions in a case series of 60 patients during a total of 2878 months of sacral nerve stimulation. Device removal was reported in 4% of patients (actual numbers not reported) treated by sacral nerve stimulation at 18-month follow-up in a randomised controlled trial of 51 patients.

- 5.2 Infection was reported in 4% of patients in a systematic review of 14 articles, including a total of 1239 patients (actual numbers not reported). Infection was reported in 2% (2/93) of patients in the case series of 93 patients: both were successfully treated with antibiotics.
- 5.3 Lead migration was reported in 5% of patients in the systematic review of 14 articles, including a total of 1239 patients (actual numbers not reported). Lead migration was reported in 28% (17/60) of patients in the case series of 60 patients, 15 of whom were in the group of 30 patients who had a 1-stage procedure for implanting the neurostimulator.
- 5.4 Pain at the implant site, pain at the lead site and new pain (unspecified) were reported in 10% (128/1239), 2% and 4% of patients respectively, in the systematic review of 14 articles, including a total of 1239 patients. Pain at the implant site was reported in 32% (19/60) of patients in the case series of 60 patients. Leg pain, pelvic pain and urethral pain were reported in 30% (18/60), 3% (2/60) and 3% (2/60) of patients respectively, in the same study.
- 5.5 Sensation of electric shock was reported in 2% of patients in the systematic review of 14 articles, including a total of 1239 patients (actual numbers not reported).
- 5.6 Wound seroma was reported in 1 patient in the case series of 93 patients.
- 5.7 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events



(events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers listed the following anecdotal adverse events: change in bowel function, and decubitus ulceration. They did not describe any theoretical adverse events additional to those reported above.

## **6 Committee comments**

- 6.1 This guidance covers idiopathic chronic non-obstructive urinary retention and not retention caused by neurological diseases such as multiple sclerosis or spinal cord injury. The Committee was advised that studies are in progress on sacral nerve stimulation for treating chronic non-obstructive urinary retention caused by neurological diseases, and NICE may produce guidance when the results have been published.
- 6.2 The Committee noted that there has been a move from use of a 1-stage to a 2-stage technique for the evaluation phase of the procedure and were advised that the latter is associated with better outcomes.
- 6.3 The Committee noted that patient commentaries reported consistent benefits from the procedure and described substantial improvements in quality of life.

## **7 Further information**

- 7.1 For related NICE guidance, see the [NICE website](#).

Bruce Campbell

Chairman, Interventional Procedures Advisory Committee

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