

Percutaneous posterior tibial nerve stimulation for overactive bladder syndrome

Interventional procedures guidance

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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 should be read in conjunction with CG171.

1 Guidance

- 1.1 Current evidence on percutaneous posterior tibial nerve stimulation (PTNS) for overactive bladder (OAB) syndrome shows that it is efficacious in reducing symptoms in the short and medium term. There are no major safety concerns. Therefore, the procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Overactive bladder syndrome is defined as urinary urgency, with or without urge incontinence, usually with frequency and nocturia. In most cases, the cause of the overactive bladder is unknown. In some cases, it is associated with neurological conditions such as multiple sclerosis or Parkinson's disease.
- 2.1.2 First-line treatments for overactive bladder (OAB) include bladder training, pelvic floor muscle training and anticholinergic drugs. Botulinum toxin injection and sacral nerve stimulation may be used in patients for whom conservative treatments have been unsuccessful. More extensive surgical options for treating OAB include bladder reconstruction (such as augmentation cystoplasty) and

urinary diversion.

2.2 Outline of the procedure

- 2.2.1 The exact mechanism of action of posterior tibial nerve stimulation (PTNS) on the bladder is unclear, but it is thought to be mediated by retrograde stimulation of the sacral nerve plexus (neuromodulation). The posterior tibial nerve contains mixed sensory motor nerve fibres that originate from the same spinal segments as the nerves to the bladder and pelvic floor.
- 2.2.2 A fine-gauge needle is inserted percutaneously just above the ankle, next to the tibial nerve, and a surface electrode is placed on the foot. The needle and electrode are connected to a low-voltage stimulator. Stimulation of the posterior tibial nerve produces a typical motor (plantar flexion or fanning of the toes) and sensory (tingling in the ankle, foot or toes) response. Initial treatment usually consists of 12 outpatient sessions lasting 30 minutes each, typically a week apart. Further sessions are generally needed for longer-term relief.

2.3 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 [overview](#).

- 2.3.1 A randomised controlled trial (RCT) of 220 patients treated by PTNS or sham reported a moderate or marked improvement in overall bladder symptoms in 55% (60 of 110) and 21% (23 of 110) of patients respectively at 13-week follow-up ($p < 0.001$).
- 2.3.2 An RCT of 100 patients treated by PTNS or medication reported that 80% (35 of 44) and 55% (23 of 42) of patients respectively considered themselves to be cured or improved after 12 weeks of therapy ($p = 0.01$).
- 2.3.3 A case series of 90 patients reported a subjective response of 64% (58 of 90),

defined as a patient request for continuous chronic treatment to maintain the response, and an objective response of 57% (34 of 60), defined as a reduction of 50% or more in urinary leakage episodes per 24 hours, at 12-week follow-up.

- 2.3.4 The RCT of 100 patients treated by PTNS or medication reported a significant improvement in quality-of-life scores in both groups, 12 weeks after treatment.
- 2.3.5 In a case series of 35 patients, the proportion of patients who were symptom-free decreased from 54% (19 of 35) immediately after treatment to 23% (8 of 35) at 1-year follow-up. In a case series of 33 patients who responded to an initial 12 sessions of PTNS and were offered additional treatment sessions at varying intervals for a further 9 months, 94% (30 of 32) of patients considered themselves to be cured or improved at 6 months and 96% (24 of 25) at 12-month follow-up.
- 2.3.6 The specialist advisers commented that long-term efficacy has not been established and listed key efficacy outcomes as reduced episodes of urgency and urge incontinence, reduced daily pad usage, and improvements in quality of life and bladder capacity.

2.4 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 [overview](#).

- 2.4.1 In the RCT of 100 patients treated by PTNS or medication, at least 1 'moderate adverse event' considered to be related to the treatment was reported in 16% (8 of 49) and 14% (7 of 49) of patients respectively at 12-week follow-up. In the PTNS group, there was 1 report each of generalised swelling (not otherwise described), worsening of incontinence, headache, haematuria, inability to tolerate stimulation, leg cramps, intermittent foot or toe pain and vasovagal response to needle placement within the 12-week follow-up period.
- 2.4.2 The RCT of 220 patients treated by PTNS or sham reported 7 treatment-related adverse events among the 110 patients treated by PTNS. These were bleeding or

discomfort at the needle site (4% [5 of 110]), and 1 case each of ankle bruising and tingling in the leg.

- 2.4.3 The specialist advisers listed adverse events reported in the literature as minor bleeding, pain and infection at the needle site.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

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. A large print version is also available.

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Endorsing organisation

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