NICE guidance

Percutaneous tibial nerve stimulation for faecal incontinence

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.

1 Guidance

1.1 The evidence on percutaneous tibial nerve stimulation (PTNS) for faecal incontinence raises no major safety concerns. There is evidence of efficacy in the short term in a limited number of patients. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake PTNS for faecal incontinence should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients and their carers understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having PTNS for faecal incontinence (see section 3.1).

1.3 This procedure should only be carried out in units specialising in the assessment and treatment of faecal incontinence, as one of a range of treatment options.

1.4 The Committee was advised that further research is in progress. Future research should clearly define the patient groups being treated and should explicitly address treatment schedules. Studies should report long-term outcomes and requirements for retreatment. NICE may review this guidance on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 Faecal incontinence occurs when a person loses the ability to control their anal sphincter and bowel movements, resulting in leakage of faeces. Causes include neurological disease and perineal injury during vaginal delivery (a relatively common cause in women).

2.1.2 First-line treatment is conservative, with measures such as dietary management or antidiarrhoeal medication. If these are not successful, pelvic floor muscle or anal sphincter training (sometimes including biofeedback therapy) may be used.

2.1.3 If conservative treatments have been unsuccessful, surgical options include sphincter repair, sacral nerve stimulation, stimulated graciloplasty (creation of a new sphincter from other suitable muscles), anorectal or transabdominal implantation of an artificial anal sphincter, or permanent colostomy.

2.2 Outline of the procedure

2.2.1 The aim of percutaneous tibial nerve stimulation (PTNS) is to achieve a neuromodulatory effect similar to that of sacral nerve stimulation through a less invasive route, but its exact mechanism of action is unclear.

2.2.2 A fine gauge needle is inserted percutaneously, just above and medial to the ankle, next to the posterior tibial nerve, and a surface electrode is placed near the arch of the foot. The needle and electrode are connected to a low-voltage stimulator. Stimulation of the posterior tibial nerve produces a motor (plantar flexion or fanning of the toes) and/or 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. Treatment may be repeated if required.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and 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.

2.3.1 A non-randomised comparative study of 52 patients treated by PTNS or sham reported that 53% (17 out of 32) had 'good' results, 31% (10 out of 32) had 'fair' results and 16% (5 out of 32) had 'poor' results after treatment with PTNS. No clinical improvement was reported in the 20 patients treated with sham. Clinical improvement was measured using a score ranging from 0 to 20, with 0 being perfect continence. Patients in the 'good' group had a reduction in mean score from 17.4 to 1.7 ($p<0.001$), the 'fair' group had a reduction from mean 18.2 to 8.5 ($p<0.05$) and the 'poor' group had a reduction from mean 18.6 to 14.8 (significance not stated).

2.3.2 The non-randomised comparative study of 52 patients reported that of those patients with any improvement in scores after PTNS, 30% (8 out of 27) had a recurrence of symptoms during a mean follow-up of 22.3 months (3 and 5 patients were originally considered to have 'good' and 'fair' results respectively). Six patients had further treatment but 2 refused treatment.

2.3.3 The Specialist Advisers listed key efficacy outcomes as sustained improvement in continence (including where top-up therapy is required) measured as a reduction in weekly faecal incontinence episodes and quality of life.

2.4 Safety

2.4.1 The case series of 22 patients reported gastrodynia (stomach ache) that lasted for several hours in 2 patients, occurring 2 to 3 hours after treatment sessions, and leg numbness that lasted for 2 hours in 1 patient in the first treatment session only (none required medical intervention).

2.4.2 Transient discomfort or throbbing pain at the insertion site, redness or inflammation at or around the needle insertion site, and transient toe numbness were all reported in a case series of 30 patients (number of cases not reported).

2.4.3 A case series of 13 patients reported that 1 patient stopped treatment after 7 weeks because of a swollen and painful leg (no further details).

2.4.4 The Specialist Advisers listed anecdotal adverse events as haematoma and nerve injury.

2.5 Other comments

2.5.1 The Committee considered that PTNS could offer a simple and relatively non-invasive procedure for relieving faecal incontinence that could have a significant impact on quality of life, if further research supports its efficacy and helps to define the patients for whom it is most likely to be effective.

2.5.2 The Committee noted that the published studies included patients with a variety of different conditions and that not all patients had serious disability as a result of their symptoms. It also noted, however, that current research is addressing these issues.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

Sources of evidence

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

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.