NICE guidance

Percutaneous electrical nerve stimulation for refractory neuropathic pain

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg450

1 Guidance

1.1 Current evidence on the safety of percutaneous electrical nerve stimulation (PENS) for refractory neuropathic pain raises no major safety concerns and there is evidence of efficacy in the short term. Therefore this procedure may be used with normal arrangements for clinical governance, consent and audit.

1.2 Patient selection and treatment using PENS for refractory neuropathic pain should be carried out by teams specialising in pain management.

1.3 NICE encourages further research into PENS for refractory neuropathic pain, particularly to provide more information about selection criteria and long-term outcomes, with clear documentation of the indications for treatment.

2 The procedure

2.1 Indications and current treatments

2.1.1 Neuropathic pain means pain arising from dysfunction of sensory nerves and pathways in the nervous system. It may occur in a heterogeneous group of disorders: examples include painful diabetic neuropathy, post-herpetic neuralgia and trigeminal neuralgia. People with neuropathic pain may experience altered pain sensation, areas of numbness or burning, and continuous or intermittent evoked or spontaneous pain. Neuropathic pain is an unpleasant sensory and emotional experience that can have a significant impact on a person's quality of life.

2.1.2 A range of different drugs are used to manage neuropathic pain, including antidepressants, anti-epileptic (anticonvulsant) drugs, opioids, and topical treatments such as capsaicin and lidocaine (see Neuropathic pain: the pharmacological management of neuropathic pain in adults in non-specialist settings [NICE clinical guideline 96]). Neuropathic pain is often difficult to treat, because it can be refractory to many medications and/or because of the adverse effects associated with some medications.

2.2 Outline of the procedure

2.2.1 In PENS, 1 or more individual nerves or dermatomes are stimulated using needle probes. A single probe with a grounding pad or pairs of fine-gauge needles are inserted into soft tissue near the targeted nerves or into the affected dermatomes. The needles are connected to a low-voltage pulse generator and an electrical current is then applied. This may generate a sensation of paraesthesia and muscle contraction. The duration of treatment varies but each session of stimulation typically lasts between 15 and 60 minutes.

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 systematic review.

2.3 Efficacy

2.3.1 A crossover randomised controlled trial (RCT) of 64 patients comparing PENS against sham PENS or transcutaneous electrical nerve stimulation (TENS) in patients with pain from sciatica reported a significant reduction in pain after the last treatment session (measured on a visual analogue scale [VAS]; 0–10 from best to worse) compared with baseline in both PENS (from 7.2 to 4.1, $p<0.05$) and TENS (from 7.0 to 5.4, $p<0.05$) groups, but not in the sham-PENS group (from 6.6 to 6.1, p=not significant). The reduction in the PENS group was significantly greater than the reductions in the TENS and sham-PENS groups ($p<0.01$).

2.3.2 A crossover RCT of 50 patients with diabetic neuropathic pain in the legs comparing PENS with sham PENS reported a significantly greater reduction in pain (measured on a VAS; 0–10 from best to worse) in the PENS group (from 6.2 to 2.6) compared with the sham-PENS group (from 5.2 to 4.8) after the last treatment session ($p<0.05$).

2.3.3 The RCT of 64 patients reported a significant improvement after the last treatment session from baseline in physical activity (measured on a VAS; 0–10 from best to worse) in both the PENS group (from 6.4 to 4.0, $p<0.05$) and the TENS group (from 5.8 to 4.5, $p<0.05$) but not in the sham-PENS group (from 6.0 to 5.5, p=not significant). The improvement in the PENS group was significantly greater than in the TENS and sham-PENS groups ($p<0.01$).

2.3.4 The RCT of 50 patients reported baseline physical and mental component SF-36 scores of 31.2 and 41 respectively (mean scores taken 24 hours before the first treatment session). These scores increased to 36.8 ($p<0.01$) and 43.9 ($p<0.01$) respectively for the PENS group; and to 32.4 ($p<0.05$) and 42 ($p<0.05$) respectively for the sham-PENS group (these were mean scores taken 36 hours after the last treatment

session). Improvement was significantly greater for the PENS group ($p<0.05$). In both RCTs of 64 and 50 patients, the post-intervention scores for PENS groups were still below the normal population score of 50.

2.3.5 The RCT of 64 patients reported a 50% reduction over 3 weeks in daily analgesic use with PENS treatment compared with TENS (29%) and sham PENS (8%) (level of significance not reported).

2.3.6 The RCT of 64 patients reported a significant improvement from baseline in quality of sleep after the last treatment session (measured on a VAS; 0–10 from best to worse) in both the PENS group (from 5.5 to 3.1, $p<0.05$) and the TENS group (from 5.0 to 4.0, $p<0.05$) but not in the sham-PENS group (from 5.2 to 4.9, p=not significant). The improvement in the PENS group was significantly greater than the reductions in the TENS and sham-PENS groups ($p<0.01$). The RCT of 64 patients reported that most patients (73%) rated PENS as the most desirable treatment, compared with TENS (21%) and sham PENS (6%).

2.3.7 The Specialist Advisers listed key efficacy outcomes as reduction in pain (alleviation of localised neuropathic pain, relief of allodynia and hyperpathia, reduction in the frequency of sharp shooting pains, reduction in the burning sensation) and its associated functional and emotional improvements.

2.4 Safety

2.4.1 The RCT of 64 patients did not report safety findings.

2.4.2 The RCT of 50 patients and an RCT of 31 patients stated that no adverse events were reported.

2.4.3 The Specialist Advisers listed exacerbation of pain, bruising and bleeding as anecdotal adverse events. They listed theoretical adverse events as vascular damage; damage to local nerves with sequelae, depending on which nerve was damaged; pneumothorax; possible interaction with a cardiac pacemaker if used above the waistline; possible epileptogenic effect if used near the head; possible effects if used in pregnancy;

dislodgement (with loss of effect); unpleasant paraesthesias; and local bruising or haematoma.

2.5 Other comments

2.5.1 The Committee noted that clinical response to treatment with PENS may differ according to the indication treated.

2.5.2 The Committee recognised that the numbers of patients in the RCTs were relatively small, but the evidence of efficacy in relieving pain was consistent. No major safety concerns were raised by the trials or the Specialist Advisors, or in the Committee's judgement of likely risks. Patients being considered for this procedure are often distressed by chronic pain that has been refractory to other treatments. The Committee therefore considered that the balance of benefits and risks justified a recommendation for use of this procedure with normal arrangements for clinical governance, consent and audit, in the context of patient selection by teams specialising in pain management.

3 Further information

3.1 For related NICE guidance see the NICE website.

Information for patients

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

About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and

Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedures guidance process.

We have produced a summary of this guidance for patients and carers.

Yourresponsibility
This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their 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.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation