NICE guidance

Peripheral nerve-field stimulation for chronic low back pain

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg451

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 Current evidence on the efficacy of peripheral nerve-field stimulation (PNFS) for chronic low back pain is limited in both quantity and quality, and duration of follow-up is limited. Evidence on safety is also limited and there is a risk of complications from any implanted device. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake PNFS for chronic low back pain should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.

1.3 Patient selection for treatment using PNFS for chronic low back pain should be done by a multidisciplinary team, including specialists in pain management and neurosurgery.

1.4 Clinicians should enter details about all patients undergoing PNFS for chronic low back pain onto the UK Neuromodulation Register when it is available. They should audit and review clinical outcomes locally.

1.5 NICE encourages collaborative data collection and publication of comparative studies on PNFS for chronic low back pain. Outcomes should include measures of

pain, function and quality of life, particularly in the long term. Full details of any complications and adjunctive or subsequent treatments should be recorded.

2 The procedure

2.1 Indications and current treatments

2.1.1 Chronic low back pain is a common condition with a number of contributing and/or causative factors. In some people the pain can resolve spontaneously.

2.1.2 Conservative treatments include advice and education, posture and exercise training, manual therapies, analgesics, non-steroidal anti-inflammatory drugs and acupuncture. For patients with severe chronic low back pain that is refractory to conservative interventions, surgery such as spinal fusion or insertion of prosthetic intervertebral discs may be done.

2.2 Outline of the procedure

2.2.1 PNFS for chronic low back pain is less invasive than spinal cord stimulation or spinal fusion and offers a reversible method of pain control for those with severe refractory pain. The procedure is usually done in 2 stages. First, electrodes are implanted and connected to a neurostimulator. If this produces benefit over a trial of several days then the patient receives a fully implanted system, at a second operation.

2.2.2 The procedure is done using local anaesthesia. One or more lead(s) are introduced percutaneously into the subcutaneous tissues of the lower back. Depending on the patient's pain pattern, areas of pain and anticipated changes in the patient's condition, it may be appropriate to implant several leads. Implanting several leads may provide greater flexibility for covering the patient's pain pattern with paraesthesia. Intra-operative stimulation is used to verify that the electrodes have been correctly placed. The lead(s) are tunnelled under the skin to a distant exit site and connected by an external extension lead to a hand-held

neurostimulator. The patient is able to change the stimulation settings within limits set by the clinician.

2.2.3 The second stage is carried out if the trial is successful. Local anaesthesia is used (sometimes with sedation). A subcutaneous pouch is formed for the implantable neurostimulator, which is connected to the already implanted trial electrodes. The patient has a hand-held remote control that permits stimulation within set parameters. The system can be removed if desired.

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 case series of 100 patients reported a significant reduction in pain scores (in 44 patients who received treatment at the lumbosacral region) (measured on a visual analogue scale [VAS]; 0 to 10; higher score indicating greater pain) from 7.0 to 3.7 at a mean follow-up of 7 months ($p<0.001$).

2.3.2 A case series of 18 patients reported that all patients had greater than 50% reduction in pain (measured on a VAS; 0 to 10; higher score indicating greater pain) at 12 months, from a baseline pain score of 7.4.

2.3.3 A case series of 13 patients reported a reduction in pain (measured on a VAS; 0 to 10; higher score indicating greater pain) from a mean score of 7.4 (standard deviation [SD] 1.2) before PNFS to a mean score of 3.9 (SD 1.7) at a mean follow-up of 7 months ($p<0.05$). Pain relief was rated by the patients as excellent (improvement of 75% or more) in 15% (2 of 13) of patients, good (improvement 50% to 74%) in 38% (5 of 13), fair (improvement 25% to 49%) in 38% (5 of 13), and poor (improvement less than 24%) in 8% (1 of 13) of patients.

2.3.4 A case series of 119 patients with mixed types of pain (including 37 with failed back surgery syndrome [FBSS] and 29 with low back pain) reported a reduction in mean pain intensity score (measured on a numerical rating scale; lower score

indicating less pain). The scores improved from 8.0 (SD 1.4) before the procedure to 3.3 (SD 2.1) in the FBSS group ($p<0.0001$) (3 months after implantation) and from 8.3 (SD 0.9) before the procedure to 4.2 (SD 2.2) in the low back pain group ($p<0.0001$) (3 months after implantation).

2.3.5 The case series of 18 patients reported that 89% (16 of 18) of patients had reduced or stopped opioid analgesic use at 12-month follow-up. The case series of 13 patients reported that 54% (7 of 13) of patients reported a reduction in analgesic use (exact timing of reporting unclear).

2.3.6 The case series of 13 patients reported that 69% (9 of 13) of patients were 'satisfied' or 'very satisfied' with treatment (exact timing of reporting unclear).

2.3.7 The specialist advisers listed key efficacy outcomes as pain reduction measured on a VAS; improvement in function as measured by the Oswestry Disability Index; improvement in quality of life as measured on the EQ-5D; reduction in concomitant medication for pain relief including neuropathic agents, opioids and non-steroidal anti-inflammatory drugs; and early mobilisation and rehabilitation.

2.4 Safety

2.4.1 Postoperative infection requiring removal of the stimulation system was reported in 1 patient in the case series of 18 patients (timing unclear). The stimulation system was later re-implanted.

2.4.2 Electrode migration requiring repositioning was reported in 1 patient in a case series of 10 patients (3 weeks after implantation).

2.4.3 Device reprogramming was needed in 67% (12 of 18) of patients within the first 6 weeks (no further details provided) and additional education about device recharging was needed in 17% (3 of 18) of patients in the case series of 18 patients.

2.4.4 In addition to the above, the specialist advisers listed lead fracture and postoperative bleeding as anecdotal adverse events. They listed theoretical adverse events as skin erosion, visceral damage (very rare, but not impossible,

particularly in very thin patients) and haematoma.

2.5 Other comments

2.5.1 The committee recognised that patients being considered for PNFS for chronic low back pain commonly have very distressing and chronic symptoms, which other methods of treatment may have failed to control effectively, and who might otherwise need spinal cord stimulation.

2.5.2 The committee recognised research in this area is difficult because of the complex and heterogeneous nature of chronic low back pain. Currently there are not enough good-quality comparative studies to be able to confidently evaluate the procedure's efficacy. This underpinned the recommendations in section 1.

3 Further information

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.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation