NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Neurostimulation of lumbar muscles for refractory non-specific chronic low back pain

Low back pain of unknown cause (non-specific) can be long term (chronic) and difficult to treat (refractory). In this procedure, a cut is made on the lower back and a small battery-powered device (neurostimulator) is placed under the skin. Two wires are placed on the nerves that control the muscles either side of the spine (lumbar muscles) and connected to the neurostimulator. After the procedure, the patient uses a remote control to stimulate the nerves using low-voltage electricity. This is usually done twice a day for about 30 minutes. The aim is to stimulate the lumbar muscles and reduce pain.

NICE is looking at neurostimulation of lumbar muscles for refractory non-specific chronic low back pain.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 07 April 2022

Target date for publication of guidance: August 2022

1 Draft recommendations

1.1 Evidence on the safety of neurostimulation of lumbar muscles for refractory non-specific chronic low back pain shows well-recognised complications. Evidence on its efficacy is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.

1.2 Clinicians wanting to do neurostimulation of lumbar muscles for refractory non-specific chronic low back pain should:

- Inform the clinical governance leads in their healthcare organisation.
- Give people (and their families and carers as appropriate) clear written information to support shared decision making, including NICE's information for the public.

- Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
- Enter details about everyone having neurostimulation of lumbar muscles for refractory non-specific chronic low back pain onto the National Neuromodulation Registry and review local clinical outcomes.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
- Regularly review data on outcomes and safety for this procedure.

1.4 Patient selection should be done by a multidisciplinary team with experience in pain management and neuromodulation stimulation procedures.

1.5 Further research should include suitably powered randomised controlled trials comparing the procedure with sham and current best practice with appropriate duration. It should report details of patient selection and long-term outcomes.

2 The condition, current treatments and procedure

The condition

2.1 Non-specific severe long-term chronic refractory low back pain can present in various ways including as neuropathic pain (associated with damage to nervous system) or nociceptive pain (associated with physical damage to joints, muscles, and ligaments). In some people, it is associated with dysfunction of the lumbar multifidus (large muscles that support the lower back) and arthrogenic muscle inhibition.

Current treatments

2.2 Treatments for low back pain are described in NICE's guideline on low back pain and sciatica in over 16s: assessment and management. Conservative pain management includes pharmacological treatments (such as oral non-steroidal anti-inflammatory drugs, and weak opioids with or without paracetamol) and non-interventional treatments (such as self-management advice and education, exercise, manual therapies, and combined physical and psychological therapy). People with severe chronic low back pain that is refractory to conservative treatments may be offered interventional procedures (such as radiofrequency denervation and epidural injections) or surgery (such as spinal fusion procedures).

The procedure

2.3 The procedure is done under general anaesthesia, or local anaesthesia with sedation. A pulse generator (neurostimulator) is implanted in a pocket created under the skin of the upper buttock. Under fluoroscopic guidance through a midline approach, 2 stimulating leads are inserted. The distal end of each lead has

stimulation electrodes. They are positioned next to the spinal column, near the medial branch of the L2 motor nerve supply (dorsal ramus nerve) to the multifidus muscles and secured in place. The leads are tunnelled internally, then the proximal ends are connected to the pulse generator and the position is checked radiographically.

2.4 Fourteen days after the implantation procedure, the patient can start to use the device to manage their pain. While lying prone, they use a handheld wireless remote control to deliver stimulation to the nerve supply of the multifidus muscles, which causes them to contract. This is usually done twice a day for about 30 minutes each time. The pulse generator can be programmed to deliver stimulation between any pair of electrodes on each lead if needed.

2.5 The aim of neurostimulation is to help the body regain multifidus neuromuscular control by 'activating' the lumbar muscles and stabilising the spinal column, reducing chronic pain. The procedure is reversible.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 6 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial (described in 2 publications) 1 case series (described in 2 publications) and another 2 case series. It is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: patient-reported outcome measures including reduction in back pain, improved quality of life and improved activities of daily living.

3.3 The professional experts and the committee considered the key safety outcomes to be: lead fracture, lead migration, infection, pain, pulse generator failure and need for early removal.

3.4 Twenty-two commentaries from patients who have had this procedure were discussed by the committee.

Committee comments

3.5 The committee was informed that there have been changes in the leads used in the device and in the surgical technique used to implant them, which have reduced the risk of lead fractures.

3.6 The devices are not MRI compatible, but research is ongoing to make them safe in some scanners (MRI conditional).

3.7 The committee noted that majority of the research is in younger patients with a body mass index below 35.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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