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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 22 July 2021
Target date for publication of guidance: November 2021

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 inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.

1.2 Patient selection should be done by a multidisciplinary team including a neurosurgeon, a specialist in pain management, a pain nurse and a clinical psychologist.

1.3 Further research should be randomised controlled trials comparing the procedure with current best practice. It should report details of patient selection and long-term outcomes.
2 The condition, current treatments and procedure

The condition

2.1 Non-specific chronic low back pain (NSCLBP) 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). It can be exacerbated by movements. In some people the pain can resolve spontaneously. NSCLBP is a common condition with several recognisable contributing or causative factors. These include functional instability of the spine caused by 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). Patients 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 subcutaneous pocket created in the lower back. Under fluoroscopic guidance either through a lateral or a midline approach, 2 stimulating leads are inserted. The distal end of each lead has 2 stimulating 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 tunneled 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.

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 3 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial and 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, 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, infection, pain, pulse generator failure and need for early explantation.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 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 considered incompatible with MRI, although research into that is ongoing.

3.7 There has been a well-conducted randomised controlled trial comparing the procedure against low-level sham stimulation, which did not show efficacy for the primary endpoint. But the patient selection for the trial was highly selective and not typical of patients with this condition, because it included young patients with a low BMI.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
June 2021

ISBN: