NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Intramuscular diaphragm stimulation for ventilator-dependent chronic respiratory failure from high spinal cord injuries

Some people with high spinal cord injuries cannot breathe on their own (chronic respiratory failure) because the main muscle used for breathing (diaphragm) is paralysed. So, they need a mechanical ventilator to help them breathe. In this procedure, which involves keyhole abdominal surgery, electrodes are implanted into the diaphragm (intramuscular). Wires from the electrodes run under the skin and come out from the chest. They are connected to an external battery-operated electrical stimulation system which causes the diaphragm to contract as in normal breathing. The aim of the procedure is to stimulate and possibly strengthen the diaphragm, enabling people to breathe without a ventilator for periods of time and to improve their quality of life.

This is a review of NICE's interventional procedures guidance on intramuscular diaphragm stimulation for ventilator-dependent chronic respiratory failure caused by high spinal cord injuries.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts 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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.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:

Issue date: January 2023

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 1 February 2023

Target date for publication of guidance: May 2023

1 Draft recommendations

1.1 Intramuscular diaphragm stimulation for ventilator-dependent chronic respiratory failure from high spinal cord injuries 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 intramuscular diaphragm stimulation for ventilator-dependent chronic respiratory failure from high spinal cord injuries should:

- Inform the clinical governance leads in their healthcare organisation.
- Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Take account of NICE's guidance on shared decision making, and NICE's information for the public.
- 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).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

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 managing high spinal cord injury and in managing home ventilation.

1.5 The procedure should only be done by surgeons with experience and training in this procedure.

1.6 Report any problems with a medical device using the Medicines and Healthcare products Regulatory Agency's Yellow Card Scheme.

1.7 Further research should preferably be randomised controlled trials or observational data from registries or other sources of real world evidence.

Why the committee made these recommendations

The evidence for this procedure is limited because there is a lack of long-term data and no high-quality clinical trials. But the evidence does suggest that this procedure may improve quality of life and enable people to have some ventilator-free time each day. The evidence on safety includes reports of electrode insertion site infection and pneumonia, but it is not certain if pneumonia is directly caused by the procedure. More research will offer more evidence on safety and long-term outcomes.

High spinal cord injury is severely disabling. For people who are dependent on mechanical ventilation, this procedure offers one of few options that could enable them to have ventilator-free time. So, this procedure is recommended but only with special arrangements.

2 The condition, current treatments and procedure

The condition

2.1 High spinal cord injuries can damage the nerves that control breathing and cause chronic respiratory failure.

Current treatments

2.2 Current standard care for managing chronic respiratory failure in patients with high spinal cord injuries includes non-invasive forms of ventilation support (such as bi-level positive airway pressure). In advanced stages of respiratory failure, mechanical ventilation is done through a permanent tracheostomy. Phrenic nerve pacing is an alternative treatment for patients who have intact phrenic nerves (the nerves that contract the diaphragm). The diaphragm is stimulated to contract by electrodes placed on the phrenic nerve in the neck or thorax.

The procedure

2.3 The aim of intramuscular diaphragm stimulation is to make the diaphragm contract, enabling a full or partial weaning from mechanical ventilation. This procedure needs intact phrenic nerve function. It avoids the need to access the phrenic nerve through the neck or thorax, as well as reducing the risk of phrenic nerve damage.

2.4 The procedure is done laparoscopically with the patient under general anaesthesia. Areas of the diaphragm where minimal electrical stimulation causes maximal diaphragm contraction (known as the 'motor points') are mapped. Two intramuscular electrodes are implanted on the abdominal surface of each hemi-diaphragm at the motor points. The electrode leads are tunnelled subcutaneously to an exit site in the chest where they are

connected to an external battery-powered pulse generator. A reference electrode (anode) is also implanted and the leads tunnelled with the other electrodes. Intraoperative stimulation and voltage calibration tests are done to confirm adequate contraction of the diaphragm. After implantation the patient has a diaphragm conditioning programme, which involves progressive use of the system for increasing periods of time with gradual weaning from the ventilator.

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 prospective single-arm trial and meta-analysis of 5 studies, 3 retrospective case series, 1 systematic review and 1 case report. 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: improved quality of life and number of ventilator-free hours.

3.3 The professional experts and the committee considered the key safety outcomes to be: pain, pneumonia, electrode insertion site infection, electrode breakage, device failure and survival.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The committee noted that the procedure can interfere with cardiac pacemakers.

3.6 The committee was informed that the device currently used for this procedure is not MRI compatible.

3.7 The committee noted that this procedure is likely to be suitable for only a small number of people.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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