

NICE interventional procedures consultation document, March 2024

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Phrenic nerve pacing for ventilator- dependent high cervical spinal cord injury

A high cervical spinal cord injury (SCI) is an injury in the upper neck between the first and fourth cervical vertebrae (C1 to C4). The phrenic nerve controls the diaphragm, which is the main muscle used for breathing. High cervical SCI can affect the phrenic nerve and some people cannot breathe on their own and need a mechanical ventilator to help them breathe.

In this procedure, an electrode is implanted around the phrenic nerve in the lower neck or chest. The electrode is connected to a receiver that is usually placed in the chest wall. An external transmitter then sends radiofrequency signals to the receiver, causing the electrode to stimulate (pacing) the phrenic nerve. The pacing makes the diaphragm contract. The aim is to help people breathe normally and to have some time without a ventilator, potentially improving their quality of life.

NICE is looking at phrenic nerve pacing for ventilator-dependent high cervical spinal cord injury.

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This document contains the [draft guidance for consultation](#).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 The draft guidance may change after this consultation.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:

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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 23 April 2024

Target date for publication of guidance: August 2024

1 Draft recommendations

- 1.1 Use phrenic nerve pacing as an option to treat ventilator-dependent high cervical spinal cord injury (SCI) with standard arrangements in place for clinical governance, consent and audit.
- 1.2 For auditing the outcomes of this 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).
- 1.3 Patient selection should be done by a multidisciplinary team experienced in managing the condition in specialist centres.
- 1.4 This procedure should only be done in specialist centres by clinicians with specific training and experience in the procedure.

Why the committee made these recommendations

The evidence for this procedure shows benefits, such as increased ventilator-free time, reduced respiratory infections and living longer. People with high cervical SCI have multiple comorbidities and their quality of life is often limited. This procedure only treats 1 part of a very complex condition, so the benefits of the procedure are limited. The evidence does not raise any major safety concerns. So, phrenic nerve pacing is recommended.

2 The condition, current treatments and procedure

The condition

- 2.1 A high cervical spinal cord injury (SCI) is an injury in the upper neck between the first and fourth cervical vertebrae (C1 to C4). SCIs can damage the phrenic nerve (PN) that controls the diaphragm (the main muscle used in breathing) and cause chronic respiratory insufficiency. Some people with high cervical SCIs cannot breathe

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on their own, so they need a mechanical ventilator to help them breathe.

Current treatments

2.2 Standard care for managing respiratory insufficiency caused by SCIs includes non-invasive ventilation (such as bi-level positive airway pressure) and invasive mechanical ventilation (such as intubation or tracheostomy). An alternative to ventilatory support is intramuscular diaphragm stimulation for people with intact PN function.

The procedure

2.3 This procedure involves directly stimulating the PN so that it sends a signal to the diaphragm to contract, which produces the inhalation phase of breathing. It aims to provide ventilatory support for people with intact PNs and functioning diaphragm muscles.

2.4 This procedure is usually done using a thoracic approach (either an open thoracostomy or thoracoscopic technique) and under general anaesthesia. Once the PN is identified and tested, an electrode is placed around the nerve in the chest, and then stabilised. The electrode is connected to a subcutaneous receiver, usually placed in the chest wall. An external transmitter (powered by batteries) then sends radiofrequency signals to the device through an antenna which is worn over the receiver. The receiver translates radio waves into stimulating electrical pulses that are delivered to the PN by the electrode, to achieve diaphragm contraction and support breathing. The device is tested during and after the surgery to ensure that it is working. This procedure is usually done bilaterally but can also be done unilaterally. A cervical approach can also be used and is done under general or local anaesthesia.

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- 2.5 After the procedure, the person follows 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 5 sources, which was discussed by the committee. The evidence included 4 non-randomised comparative studies and 1 analysis of the Avery Biomedical Devices database. 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: ventilator-free hours per day, tracheostomy decannulation, survival, respiratory infections, hospital admissions and quality of life.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: device failure, revision surgery, phrenic nerve palsy and infections.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 This procedure can be done using a cervical or thoracic approach, and is usually done bilaterally.

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- 3.6 Most evidence was for traumatic high cervical spinal cord injury (SCI), but this procedure also has a role in SCI caused by non-traumatic conditions.

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Chair, interventional procedures advisory committee

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