NICE guidance

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

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg792

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 Recommendations

1.1 Use phrenic nerve pacing as an option to treat ventilator-dependent high cervical spinal cord injury 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 spinal cord injury 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 that controls the diaphragm (the main muscle used in breathing) and cause chronic respiratory insufficiency. Some people with high cervical SCIs cannot breathe 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 phrenic nerve function.

The procedure

2.3 This procedure involves directly stimulating the phrenic nerve 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 phrenic nerves and functioning diaphragm muscles.

2.4 The procedure is usually done using a thoracic approach (often using a thoracoscopic technique; thoracotomy is rarely used) and under general anaesthesia. Once the phrenic nerve 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 phrenic nerve 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.

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.

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

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.