NICE guidance

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

Interventional procedures guidance
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nice.org.uk/guidance/ipg594

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. However, 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.

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.

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.

This guidance replaces IPG307.

1 Recommendations

1.1 Current evidence on intramuscular diaphragm stimulation for ventilator-dependent chronic respiratory failure caused by high spinal cord injuries shows that there are serious but well-recognised safety concerns. Evidence on efficacy is limited in quantity and quality. Therefore, this procedure should only be used in the context of research.

1.2 Further research should give details of patient selection, patient-reported outcomes and long-term effects including survival and quality of life. NICE may update the guidance on publication of further evidence.

2 Indications and current treatments

2.1 Spinal cord injuries can damage the nerves that control breathing and cause respiratory failure.

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

3 The procedure

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

3.2 The procedure is done laparoscopically with the patient under general anaesthesia. A special probe is used to identify areas of the diaphragm where minimal electrical stimulation causes maximal diaphragm contraction (known as the 'motor points'). 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 carried out 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.

4 Efficacy

This section describes efficacy outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

4.1 In a systematic review of 148 patients with traumatic high cervical spinal injuries and ventilator-dependent respiratory failure (from 12 studies), intramuscular diaphragm stimulation systems were implanted successfully in all patients except 1. This was because of a false positive preoperative phrenic nerve conduction test in this patient.

4.2 In the systematic review of 148 patients, the mean delay in inserting diaphragm pacing wires ranged from 40 days to 9.7 years. In 1 study in the systematic review (Posluszny 2014) in which devices were implanted early at a mean of 40 days, the highest percentage of patients fully weaned from a ventilator (73% [16/22]) was reported at a mean of 10 days.

4.3 In the systematic review of 148 patients, half of the patients (range 40% to 72%) could be weaned from ventilators after the procedure and most could use the diaphragm stimulator instead of the ventilator for several hours per day. The largest study (Onders 2009; 50 patients) reported that more than 50% were using diaphragm pacing 24 hours per day and up to 96% were able to use pacing for 4 hours continuously. Other studies also described similar rates.

4.4 The specialist advisers listed key efficacy outcomes as reduction in dependency on external mechanical ventilation, survival and quality of life.

5 Safety

This section describes safety outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

5.1 Capnothorax was reported in 42% (21/50) of patients with spinal cord injuries in a case series of 88 patients included in a systematic review of 148 patients. Capnothorax was managed successfully with simple aspiration, drainage or observation.

5.2 Asymptomatic pneumothorax (which was treated by chest tube drainage) was reported in 1 patient in a case series of 6 patients with spinal cord injuries included in the systematic review of 148 patients.

5.3 Superficial wound infection along tunnelled wires (which resolved with oral antibiotics, shortening and terminating electrodes) was reported postoperatively in 1 patient with spinal cord injuries in the case series of 88 patients included in the systematic review. Delayed wound infection at the superficial wire connection site was reported in 1 patient in the case series of 6 patients included in the systematic review.

5.4 The diaphragm pacing stimulator interacting with a pre-existing cardiac pacemaker was reported in 1 patient in a case series of 20 patients included in the systematic review.

5.5 Right shoulder pain during maximum stimulation of a single electrode (which was relieved by reducing the current) was reported in 1 patient in the case series of 6 patients included in the systematic review.

5.6 Fever symptoms redeveloped in 1 patient (which were common before injury but absent during mechanical ventilation) in the case series of 6 patients included in the systematic review.

5.7 Intermittent aspiration of food was reported in 1 patient in the case series of 6 patients included in the systematic review. This was thought to be related to the large negative airway pressure generated during contraction of the

diaphragm. It was stopped by using a 1-way valve, designed for patients with a tracheostomy tube, during meals.

5.8 Progressive pacing failure was reported in 1 quadriplegic patient who was successfully weaned off mechanical ventilation with an intra-diaphragm phrenic stimulator. After a year hypoventilation developed without obvious cause. The patient had gained a massive amount of weight as a result of endocrine disorders. Pacing failure was because of excessive chest wall and abdominal weight preventing diaphragm contractions to adequately inflate the rib cage.

5.9 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers listed the following anecdotal adverse event: excess mortality. They considered that the following were theoretical adverse events: decompensated respiratory failure and breathlessness related to diaphragm pacing.

6 Further information

6.1 For related NICE guidance, see the NICE website.

6.2 Patient commentary was sought but none was received.

Information for patients

NICE has produced information on this procedure for patients and carers (information for the public). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation