



## Review

# Intramuscular diaphragmatic stimulation for patients with traumatic high cervical injuries and ventilator dependent respiratory failure: A systematic review of safety and effectiveness



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## ABSTRACT

**Background:** Intramuscular diaphragmatic stimulation using an abdominal laparoscopic approach has been proposed as a safer alternative to traditional phrenic nerve stimulation. It has also been suggested that early implementation of diaphragmatic pacing may prevent diaphragm atrophy and lead to earlier ventilator independence. The aim of this study was therefore to systematically review the safety and effectiveness of intramuscular diaphragmatic stimulators in the treatment of patients with traumatic high cervical injuries resulting in long-term ventilator dependence, with particular emphasis on the affect of timing of insertion of such stimulators.

**Methods:** The Cochrane database and PubMed were searched between January 2000 and June 2015. Reference lists of selected papers were also reviewed. The inclusion criteria used to select from the pool of eligible studies were: (1) reported on adult patients with traumatic high cervical injury, who were ventilator-dependant, (2) patients underwent intramuscular diaphragmatic stimulation, and (3) commented on safety and/or effectiveness.

**Results:** 12 articles were included in the review. Reported safety issues post insertion of intramuscular electrodes included pneumothorax, infection, and interaction with pre-existing cardiac pacemaker. Only one procedural failure was reported. The percentage of patients reported as independent of ventilatory support post procedure ranged between 40% and 72.2%. The mean delay of insertion ranged from 40 days to 9.7 years; of note the study with the average shortest delay in insertion reported the greatest percentage of fully weaned patients.

**Conclusions:** Although evidence for intramuscular diaphragmatic stimulation in patients with high cervical injuries and ventilator dependent respiratory failure is currently limited, the technique appears to be safe and effective. Earlier implantation of such devices does not appear to be associated with greater surgical risk, and may be more effective. Further high quality studies are warranted to investigate the impact of delay of insertion on ventilator weaning.

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## Introduction

Spinal cord injury is a serious condition primarily affecting young adults resulting in significant disability or death. Worldwide, the prevalence of spinal cord injury is estimated to be between 3.6 and 195.4 per million [1]. The majority of such cases are traumatic in nature with road traffic accidents, falls, and recreational activities being the most common mechanism of injury.

Approximately 20% of spinal cord injuries occur between the levels of C1 and C4. Patients with such injuries are at high risk of respiratory complications, and invariably require mechanical ventilation at hospital discharge [2]. The mainstay of treatment for patients with ventilator-dependant spinal cord injury is positive pressure mechanical ventilation. Due to the nature of these ventilator devices, the ability to cough is impaired, increasing the risk of respiratory tract infections. Although regular suction of secretions helps avoid these complications, this can be intrusive and disruptive for patients. Therefore, ventilated patients have increased mortality and decreased independence compared to patients with similar injuries who are not ventilated [3].

In selected patients with ventilator-dependent spinal cord injury, phrenic nerve stimulation, also known as diaphragmatic pacing, is an alternative to standard mechanical ventilation. Regular electrical pulses applied directly to the nerve via implanted phrenic nerve stimulators cause contraction of the diaphragm, resulting in the intake of air.

Each phrenic nerve is formed by the cervical rootlets from the C3 to C5 spinal cord segments. For successful diaphragmatic pacing, it is imperative that the phrenic motor neurons are viable. Patients with mid cervical injuries often have damaged phrenic motor neurons. However, in patients with upper cervical spinal cord injuries, the somatic neuromuscular and mechanical function of the respiratory apparatus below the level of injury usually remain intact and are amenable to electrical stimulation to restore function [4]. Therefore patients with injuries cephalad to the C3–C5 spinal cord segments are ideal candidates.

Diaphragmatic pacing offers the ability to limit some of the changes in respiratory physiology seen in chronic spinal cord injury. Over time, ventilator-dependent spinal cord injury can result in a decrease in total lung capacity. There exists an inverse relationship between forced vital capacity and higher levels of injury [5]. Although it has been thought that the loss of gas containing alveoli causes the changes in pressure volume curves, one study suggested that lung distensibility is related to changes in elasticity of lung tissue [6].

Early phrenic nerve stimulators all used electrodes placed in direct contact with the phrenic nerve through an open cervical or thoracic approach. These implant procedures are invasive, requiring mobilisation of nerves that may result in their injury [7]. Recently, intramuscular diaphragmatic stimulation using an

abdominal laparoscopic approach has been proposed instead, in an effort to reduce the risk of phrenic nerve injury.

The timing of diaphragmatic pacing is contentious. Typically, implantation is avoided in the acute setting due to safety concerns associated with surgery in unstable patients. However, animal studies suggest that a significant amount of phrenic motor neurones are lost during the first 24 h post-injury, resulting in persistent phrenic nerve axonal degenerations and denervation at the diaphragm neuromuscular junction [8]. Provided the phrenic motor neurons are viable, the clinical corollary is that early surgery may be more effective.

The aim of this study was to systematically review the safety and effectiveness of intramuscular diaphragmatic stimulators in the treatment of patients with traumatic high cervical injuries resulting in long-term ventilator dependence. Particular emphasis was placed on the timing of insertion of such stimulators.

## Methods

The review protocol was registered on the PROSPERO international prospective register of systematic reviews. The Preferred Reporting Items For Systematic Reviews and Meta-Analyses (PRISMA) Statement was used in the preparation of this manuscript.

### Search methods

The Cochrane database and PubMed was searched between January 2000 and June 2015. The search terms used were: (diaphragm OR diaphragmatic) AND (pacing OR stimulation) AND (spinal OR spine OR quadriplegia OR tetraplegia). An English language restriction was applied. Reference lists of selected papers were also reviewed to identify additional eligible manuscripts.

### Study selection

Two authors (BG and HJM) independently identified articles using the above criteria and reviewed all titles and abstracts. Discrepancies were resolved by discussion with the senior author (MK). The inclusion criteria used to select from the pool of eligible studies were: (1) reported on adult patients with traumatic high cervical injury, who were ventilator-dependant, (2) patients underwent intramuscular diaphragmatic stimulation, and (3) commented on safety and/or effectiveness. In the event that duplication of data was observed, larger and more recent studies were preferentially considered.

### Data extraction

The following data were extracted from the selected studies: (1) study design, (2) study group, (3) delay of insertion, (4) key safety findings, (5) key efficacy findings, and (6) follow up.

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