Case Report

Case report: Minimally invasive method to activate the expiratory muscles to restore cough

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Context: Spinal cord stimulation (SCS) via disc electrodes surgically placed via laminotomy incisions has been shown to restore an effective cough in subjects with spinal cord injury (SCI). The purpose of this study was to evaluate a new method of expiratory muscle activation utilizing spinal cord wire leads, which can be implanted with minimally invasive techniques.

Methods: In a subject with SCI, parallel wire leads with two electrode contacts were inserted percutaneously through a needle, advanced to the T9, T11 spinal levels and connected to an implanted radiofrequency receiver. Stimulus parameters were set at values resulting in near maximum airway pressure generation (Paw) (40V, 50Hz, 0.2ms). Paw was measured at functional residual capacity (FRC) and total lung capacity (TLC) as an index of expiratory muscle strength.

Results: Paw during spontaneous efforts was 20 cmH₂O (8.6% predicted). Bipolar (T9-T11) SCS resulted in Paw of 84 and 103 cmH₂O, at FRC and TLC respectively. Monopolar (T9 only) SCS resulted in Paw of 61 and 86 cmH₂O, at FRC and TLC respectively. This subject experienced much greater ease in raising secretions with use of SCS and no longer required other methods of secretion management.

Conclusion: SCS via wire leads, which can be implanted using minimally invasive techniques, may provide a new useful method to restore an effective cough and possibly reduce the morbidity and mortality associated with respiratory tract infections in patients with SCI.

Keywords: Spinal cord injury, Cough, Spinal cord stimulation, Rehabilitation

Introduction

Patients who lack an effective cough may experience significant physical discomfort including difficulty clearing secretions and the sensation of choking and, medical complications including a higher risk of aspiration and the development of respiratory tract infections.¹⁻⁷ In fact, respiratory infection is a major cause of death in this patient population.^{1,8-13} In a recent clinical trial, we demonstrated that lower thoracic spinal cord stimulation (SCS) with disc electrodes

resulted in the development of large positive airway pressures and peak expiratory airflow rates characteristic of a normal cough.¹⁴⁻¹⁶ Use of this technique improved secretion management, reduced the incidence of respiratory tract infections and significantly improved the quality of life in these subjects.¹⁷ While successful, this method requires an invasive procedure i.e. laminotomy incisions for placement of disc electrodes.

In animal studies, we have recently demonstrated that comparable positive airway pressures can also be achieved with wire electrodes positioned on the epidural dorsal surface of the spinal cord.¹⁸ The advantage of this type of electrode lies in the fact that they can be placed via minimally invasive techniques resulting in

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much smaller incisions, shorter surgical times, and lower overall risk.

In this report, we present the successful use of wire electrodes to restore an effective cough in a patient with spinal cord injury.

Methods

This investigation was approved by the Investigational Review Boards at MetroHealth Medical Center and the National Institute of Neurological Disorders and Stroke. Informed consent was obtained prior to enrollment in this study.

A 50-year-old male who suffered a cervical spinal cord injury (C4) secondary to a gunshot wound was in stable condition at the time of study (2 years post-injury). His height was 5'6", weight 195 lbs and BMI 31.2. He had no evidence of significant lung, cardiac or brain disease. He had no history of pulmonary emboli. He did not require ventilator support. He was

treated for pneumonia each year for the past 2 years. He was a life-long non-smoker. His vital capacity was 1.22 liters. He had evidence of significant paresis of his expiratory muscles as evidenced by a maximum expiratory pressure generation (20 cm H₂O, 8.6% predicted). He was being suctioned intermittently and using a Cough Assist device for management of airway secretions.

Surgical procedure

In the operating room at MetroHealth Medical Center, two wire leads were implanted in parallel in the midline on the epidural dorsal surface of the lower thoracic spinal cord (Fig. 1) utilizing standard surgical technique under general anesthesia. It should be noted that the wire leads were designed such that when the upper electrode was positioned in the region of the T9 spinal level, the more caudal electrode would be located in the vicinity of the T11 spinal level.

Figure 1 Experimental set-up.

Briefly, the subject was placed in the prone posture and under fluoroscopic guidance, the L1-L2 interspace was identified. One and one-half vertebral levels caudal and lateral to the midline, a size 14 gauge Tuohy needle was inserted gradually until the tip of the needle entered the L1-L2 spinal level. After rotating the needle so that the beveled edge faced cephalad, the needle stylet was removed. The guide wire was inserted through the needle and advanced 1–3 cm past the needle tip. After removing the guide wire, the lead was inserted through the needle and the superior electrode contact was positioned at the T9 level just left of the midline. The second lead was then advanced through a second needle at an equal distance to the right of the midline and also advanced to the T9 level. The needles were then removed. The leads were secured with #3–0 Prolene to the skin after looping them. A separate ground electrode was implanted in the back musculature. The subject was then positioned in the supine position and a 4 cm skin incision was made over the lower rib cage to make a subcutaneous pocket (8 cm x 5 cm) just above the costal margin. A modified implantable radiofrequency receiver (8×5×0.7 cm; 20 g) (Finetech Medical Ltd., Welwyn Garden City, Herfordshire, UK) was placed in the pocket. The electrode wires were tunneled subcutaneously and connected to the receiver. During electrical stimulation applied in the operating room, contraction of the abdominal muscles was confirmed by visual inspection and palpation of the chest wall. The subject was discharged the following day. There were no post-operative complications such as infection or bleeding.

Electrical stimulation system

Stimulation was applied by activating a small portable external transmitter (10×6.5×2.5 cm) connected to a rubberized antenna, which was secured to the skin with tape directly over the implanted receiver (Fig. 1). The transmitter, powered by a rechargeable battery, delivers a radiofrequency signal to the implanted receiver, which is converted to an electrical signal that is transmitted to the electrodes. The stimulator provides a biphasic stimulus over a wide range of stimulus amplitudes (10–40 V), stimulus frequencies (2–53 Hz) and pulse width (0–0.72 ms). Stimulus on-time and off-time could be adjusted between 0.2 and 50 s. Several settings could also be programmed into the system to allow for different intensities and durations of stimulation, or multiple stimulus trains applied at different intervals. In all, 9 different settings could be applied. The system was designed to provide monopolar stimulation at the T9 spinal level or bipolar stimulation at the T9/T11 levels.

Muscle reconditioning

Prior to use of the stimulation system, 3 weeks was allowed to elapse to provide time for regression of edema and hemorrhage at the electrode and receiver sites and healing of all wounds. It was assumed that the expiratory muscles were significantly atrophied secondary to disuse and would require a period of repeated muscle stimulation to restore strength. After an initial evaluation session, the subject was instructed to apply stimulation every 30 s for 5–10 min, 2 or 3 times/day, in the home. Stimulus parameters were set at values resulting in maximal positive airway pressure generation since maximum muscle force generation for short periods results in the greatest increases in muscles strength. The subject was also instructed to use the device for evacuation of secretions or airway clearance, as needed.

During the conditioning period, the subject learned to coordinate contraction of his expiratory muscles with the other components of the cough reflex. The device was activated by a relative who depressed a button on the external transmitter.

Measurements

Expiratory airflow and airway pressure generation was monitored using a BIOPAC Data Acquisition and Analysis System with AcqKnowledge software, MP150 system with TSD 160C pressure transducer and TSD117 pneumotach airflow transducer interfaces with the DA 100C transducer amplifiers (Biopac Systems Inc., 42 Aero Camino, CA, USA). Measurements were made with use of a tight fitting full face mask or through the tracheostomy tube, when present. A small degree of air leakage was unavoidable via the tracheostomy tube which may have underestimated pressure and airflow measurements. In the seated posture, pressure measurements were made under conditions of airway occlusion at FRC and TLC. After peak airway pressure was achieved during SCS, the occlusion was released to assess peak expiratory airflow rate. Oxygen saturation was monitored with a pulse oximeter (Nellcor N-200; Hayward, CA). During the period of stimulation, the subject was instructed to relax completely. In instances of patient effort, evidence of glottic closure or obvious mask leakage, data was discarded.

During the initial phase of stimulation, blood pressure, pulse rate and oxygen saturation were closely monitored. If significant blood pressure changes (> 20 mm Hg systolic or > 15 mm Hg diastolic) or if absolute systolic blood pressure exceeded 150 mm Hg systolic or 95 mm Hg diastolic, stimulation was withheld until

values returned to baseline or below 140 mm Hg systolic and 90 mm Hg diastolic. Stimulation was then applied at less frequent intervals.

Repeat measurements were made during out-patient visits every 4–5 weeks during the first 6 months, then at 3 month intervals for 6 months, and then at 6 month intervals. The inspiratory capacity was assessed at each out-patient visit as an index of resting lung volume.

Results

During the course of the reconditioning period, peak expiratory airflow rate and maximum expiratory pressure gradually increased and plateaued after 6–8 weeks. The effects of SCS following the reconditioning period are displayed graphically in Fig. 2. During monopolar stimulation (40V, 50Hz, 0.2ms, 0.6s) at the T9 level, maximum peak expiratory airflow rates and maximum airway pressure generation were 2.8 l/s and 61 cmH₂O and 7.5 l/s and 93 cmH₂O and at FRC and TLC, respectively. During bi-polar stimulation at the T9-T11 level, these same parameters were 4.2 l/s and 84 cmH₂O, and 7.1 l/s and 103 cmH₂O, respectively.

This subject became aware of much greater ease in raising secretions. He no longer required suctioning nor use any other means of secretion management. Importantly, he also experienced less fear associated with eating and the potential risk of aspiration.

Blood pressure increased and pulse rate decreased following the initial application of SCS to as high as 175 mmHg, and as low as 55 beats/min, respectively.

However with repeated application of stimulation over the course of the subsequent 9 weeks, these hemodynamic changes gradually abated and eventually disappeared. This subject did not experience any physical discomfort associated with SCS. Other than obvious contraction of the expiratory muscles, there was no other detectable movement. There was no evidence of bowel leakage.

Discussion

This report represents the first successful use of a minimally invasive method to apply spinal cord stimulation (SCS) to the lower thoracic spinal cord to restore an effective cough. Both peak airflow rates and airway pressure generation with use of wire electrodes were in the same range as that achieved with disc electrodes. Moreover, the patient achieved the same subjective improvement in secretion management, as observed utilizing disc electrodes.¹⁷

Compared to the use of disc electrodes, the surgical time for electrode placement was reduced by ~60%. In addition, there was minimal blood loss and recovery time appeared much shorter. The only significant side effect, which was also observed with disc electrodes in about 30% of subjects, was the temporary development of autonomic dysreflexia, which was not symptomatic. As in our previous study, this resolved completely over 5–6 weeks.¹⁷

In our previous study using disc electrodes, we found that stimulation of any 2 of 3 electrode placements (T9, T11 and L1) resulted in maximum activation of the

Figure 2 Representative tracings of expiratory airflow (A) and airway pressure (B) in one patient during spontaneous cough and bipolar and monopolar SCS (40V, 50Hz, 0.2ms) at functional residual capacity (FRC - middle panel) and total lung capacity (TLC - right panel).

expiratory muscles, as determined by airway pressure generation.^{14,15} Since stimulation at the L1 site often resulted in some leg movement, stimulation was generally limited to the T9 and T11 levels.¹⁷ For this reason, the wire leads used in this study were designed to activate the motor roots and spinal cord at these same spinal levels. Moreover, since the distance between the two spinal levels was similar in each individual in our prior study, the location of each electrode on the wire leads was designed to match this distance.

In a recent cost analysis of the cough system using disc electrodes, we found that the break-even point was achieved within the first year due to the reduction in overall costs of respiratory care.¹⁹ Since placement of wire electrodes can be placed utilizing less surgical time and on an out-patient basis, cost savings with this method could exceed \$10,000 resulting in a break-even point well within the first year of use.

It is important to mention that the technique of wire electrode placement, as applied in this report, is virtually identical to the common, world-wide use of wire electrodes for pain control which has been performed for several decades. The only significant difference between the technique of SCS to restore cough and that for pain control are the much higher stimulus requirements to activate the motor roots innervating the expiratory muscles and spinal cord pathways.²⁰ Consequently, this method can be applied by physicians versed in this technique, without any further special training.

In summary, this report indicates that an effective cough system can be implemented using a commonly performed minimally invasive technique which should improve both physician and patient acceptance of this method. It is conceivable that restoration of an effective cough by this method and positively impact both the morbidity and mortality in the spinal cord injured population.

Disclaimer statements

Contributors None.

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Conflicts of interest Dr. DiMarco holds two United States Patents for technology related to the content of this paper: Method and Apparatus for Electrical Activation of the Expiratory Muscles to Restore Cough (5,999,855); Bipolar Spinal Cord Stimulation to Activate the Expiratory Muscles to Restore Cough (8,751,004).

Ethics approval None.

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