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Using an evidence-based protocol to guide rehabilitation and weaning of ventilator-dependent cervical spinal cord injury patients

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Abstract—An evidence-based clinical protocol was developed to improve ventilatory muscle strength and endurance of ventilator-dependent cervical spinal cord injury (SCI) patients. The goal was to help these patients discontinue mechanical ventilation. The protocol, based on findings from other studies in the literature, consisted of pretraining optimization, as well as progressive resistance and endurance training. Following the protocol, mean maximal inspiratory pressure for low tetraplegic patients improved 75 percent, mean maximal expiratory pressure improved 71 percent, mean vital capacity increased 59 percent, mean on-vent endurance time increased 91.6 percent, and mean off-vent breathing time increased 76.7 percent. Both high and low tetraplegic patients achieved gains in inspiratory and expiratory muscle strength, vital capacity, on-vent endurance, and off-vent breathing times. High tetraplegic patients improved their ability to spontaneously ventilate for short periods in case of accidental disconnection from the ventilator, while low tetraplegic patients were able to discontinue mechanical ventilation, which was the desired clinical outcome for this preliminary study.

Key words: endurance, evidence-based, mechanical ventilation, protocol resistance, tetraplegia.

INTRODUCTION

In the two years preceding the implementation of a protocol-driven program designed to rehabilitate and wean ventilator-dependent cervical spinal cord injury (SCI) patients, the number of patients weaned from mechanical ventilation at James A. Haley Veterans Hospital in Tampa, Florida, was 20 percent. With the opening of a new SCI Center at our hospital, the Department of Respiratory Care and Diagnostic Services collaborated with the Spinal Cord Injury/Disorder Service to design an evidence-based program for rehabilitating and weaning this population of patients. Aggressive clinical management of pulmonary complications has substantially increased the

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Abbreviations: CPAP = continuous positive airway pressure, ERST = expiratory resistance strength training, $ETCO_2$ = end-tidal carbon dioxide, FiO_2 = fractional inspired oxygen concentration, GIN = gas injection nebulizer, IRST = inspiratory resistance strength training, LOV = length of ventilation, MDI = metered-dose inhaler, PEEP = positive end-expiratory pressure, PSV = pressure support ventilation, RCTs = randomized controlled trials, REP = resistance and endurance protocol, RR = respiratory rate, RV = residual volume, SCI = spinal cord injury, SIMV = synchronized intermittent mandatory ventilation, SpO_2 = pulse oximetry, SVN = small volume nebulizer, TGI = tracheal gas insufflation, TLC = total lung capacity, VC = vital capacity, Vt = tidal volume.

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survival of ventilator-dependent cervical SCI patients. Consequently, comprehensive efforts should be made to rehabilitate and wean these patients as soon as they are clinically stable, since morbidity and mortality are strongly associated with dependence on mechanical ventilation. The survival rate for ventilator-dependent SCI patients is approximately 33 percent; for those who are able to discontinue mechanical ventilation, it is approximately 84 percent [1]. Resistance training has been found to strengthen ventilatory muscles and improve ventilatory endurance in SCI patients, thereby improving prospects for discontinuing mechanical ventilation. Although strength and endurance are closely related, ventilatory muscles respond differently to resistance training to enhance strength and endurance training to improve stamina [2]. Resistance training is characterized by high-intensity muscular contractions with few repetitions, while endurance training involves low-intensity contractions over an extended period of time. The time required to achieve ventilator independence may vary from weeks to years [3].

Gross and colleagues were the first to demonstrate the effect of training the ventilatory muscles of tetraplegic patients [4]. Their studies exposed a predisposition among tetraplegics to develop inspiratory muscle fatigue due to reduced ventilatory muscle strength and endurance. Inspiratory muscle training significantly increases strength and endurance in these patients [5]. In one randomized controlled trial, patients with levels of injury ranging from C4 to C7 performed resistance strength training with fixed resistance devices and demonstrated significant improvements in maximal inspiratory pressure, maximal expiratory pressure, and perceived difficulty of spontaneous ventilation [6]. Rutchik and coworkers noted decreased restrictive ventilatory impairment in subjects with complete or incomplete cervical SCI through the use of inspiratory muscle training [7]. Others have reported enhanced endurance capacity and increased aerobic exercise performance after training of ventilatory muscles [8]. Improvements in pulmonary function, attributable to training, were greatest in the first 6 months following SCI.

These findings emphasize the importance of intervening with ventilatory muscle resistance and endurance training during the acute stage of cervical SCI. The use of a protocol, in particular an evidence-based resistance and endurance protocol (REP), may accelerate weaning of cervical SCI patients from mechanical ventilation by improving the efficiency and effectiveness of the weaning process. This pilot study represents a preliminary attempt to implement an evidence-based REP designed to help patients discontinue mechanical ventilation.

METHODS

Subjects

We studied ventilator-dependent male patients (n = 7) aged 45 to 68 years with cervical SCI levels ranging from C2 to C7. Two patients had high tetraplegia (injury level cephalad to C4) and five patients had low tetraplegia (injury level C4 or caudal). All had neurologically incomplete spinal cord injuries, as defined by the international standards for Neurological Classification of Spinal Cord Injury. Patients underwent rehabilitation and endurance training for periods from 1 to 15 months. All patients had an 8.0 mm cuffed trach tube (Portex REF 503080) and were ventilated with Puritan Bennett 760 or Versa Med I-Vent mechanical ventilators. During periods of rest and sleep, all were ventilated on assist/control mode to preclude the need for spontaneous ventilation. Descriptive characteristics of the patients are shown in **Table 1**.

The patients' readiness for resistance and endurance training was determined by an interdisciplinary team: an SCI physician, SCI respiratory therapist, and SCI nurse, in consultation with an SCI pharmacist, pulmonologist, and other SCI specialists. Initiation and continuation of the REP was dependent on unremarkable findings for

Table 1.
Descriptive characteristics of patients.

Patient	Age	Level of SCI	SCI	Months on Vent Before Protocol
High Tetraplegic Patients				
1	44	C2	Trauma	36
2	66	C2	Trauma	18
Low Tetraplegic Patients				
3	67	C5–7	Trauma	24
4	54	C5	Trauma	6
5	56	C4	Trauma	6
6	68	C7	Trauma	4
7	68	C5	Trauma	9

SCI = spinal cord injury

each of the following: chest radiograph, heart rate, blood pressure, tracheal secretions, white blood cell count, hematocrit, albumin, pre-albumin, and body temperature. In addition, all patients had a minimum spontaneous vital capacity (VC) of 200 cc.

Designing an Evidence-Based REP

We conducted a literature search for relevant abstracts before designing the REP. Abstracts were identified through the systematic use of MeSH descriptors with such databases as MEDLINE® and Ovid® [9]. Full-length papers containing relevant findings were screened by two independent reviewers according to a list of criteria for ranking scientific strength. Few studies involving SCI patients are randomized controlled trials (RCTs). Therefore, findings from non-RCTs were also used [2]. Analysis of literature revealed that pretraining optimization and resistance and endurance training were essential components of any regimen designed to rehabilitate and wean ventilator-dependent cervical SCI patients. Therefore, we performed multiple literature searches to identify evidence-based protocols consisting of separate resistance and endurance sessions. We were unable to locate evidence-based REPs for rehabilitating and weaning [10,11] ventilator-dependent cervical SCI patients. Therefore, our clinical team developed and implemented one such protocol. All respiratory care interventions included in the REP were standard procedures that represent community practice and therefore did not require review by an Institutional Review Board. Our objective was to include as many procedures as possible, whose effectiveness had been demonstrated through randomized controlled trials, in designing a protocol to standardize the rehabilitation and weaning process, thereby improving the prospect for discontinuing mechanical ventilation. The protocol used was as follows:

- Pretraining Optimization
  - Position
  - Suction
  - Aerosolize
  - Hyperinflate
- Inspiratory/Expiratory Resistance Training
  - Inspiratory/expiratory trainer
  - Cuff deflated and red cap on trach tube
- On-Vent Endurance Training
  - Synchronized intermittent mandatory ventilation (SIMV) rate of 1–2
  - Pressure support ventilation (PSV) to maintain ~400 cc
  - Progress to off-vent training when patient maintains a tidal volume (Vt) = 400 ml on continuous positive airway pressure (CPAP) 5 PSV 5 for 2 continuous hours per day for 1 week
- Off-Vent Endurance Training
  - Gas injection nebulizer (GIN) wye-piece as tolerated
  - Tracheal gas insufflation (TGI) device as tolerated
  - Red cap to trach tube as tolerated
  - Tracheal decannulation unless contraindicated

Pretraining Optimization

Trendelenberg Positioning

The first component of the protocol was daily pretraining optimization: placing the patient in the Trendelenberg position, suctioning the trachea, aerosolizing bronchodilators, and hyperinflating the lungs to increase chest compliance and reverse atelectasis. Following pretraining optimization, inner cannulas were removed from the trach tubes.

Prior to placement in Trendelenberg, patients were placed in a supine position, shifted to the head of the bed, and centered. Before training, their arms and legs were arranged in stable, comfortable positions. Patients usually started an endurance training session sitting in Fowler’s standard training position at approximately 45°. Multipurpose boots and/or arm splints were used when needed to further stabilize body position.

After confirming stable hemodynamics, patients were placed in shallow Trendelenberg (15°) for 15 to 20 min [12]. In this position, lungs migrate cephalad, increasing transpulmonary pressures at the bases, where atelectasis predominates. Patients were maintained on mechanical ventilation while in this position to further distend the basilar alveoli and chest wall. Suctioning was performed in Trendelenberg to remove any secretions moving cephalad from the lung bases. At the end of treatment, the trach tube cuff was deflated and the patient suctioned before returning to Fowler’s standard training position to prevent secretions from moving caudally.

Tracheal Suction

We cannot overstate the importance of suctioning secretions from the airways of a marginally ventilating patient about to experience an increased work of breathing due to training [13]. Cervical SCI patients, especially in the acute phase of their injury, produce large amounts of tracheal secretions due to parasympathetic predominance following cervical cord injury [14]. Even though patients were suctioned at the beginning of a resistance and endurance training session, patients engaged in prolonged on-vent endurance training or off-vent breathing frequently needed additional suctioning. Some required periodic lavage with saline (2–3 cc) in spite of adequate humidification of inspired gases and optimal systemic hydration. When lavaging was necessary, the procedure was carried out in Trendelenberg to prevent washing tracheal secretions into the lungs. Increased peak inspiratory pressures, excessive coughing, decreased oxygen saturation (SpO_2) or increased end-tidal carbon dioxide ($ETCO_2$) measurements were deemed possible indications for additional suctioning.

Bronchodilator Aerosolization

The need for adequate bronchodilation in mechanically ventilated patients has been established. Optimal bronchodilator dosing strategies specifically for ventilator-dependent cervical SCI patients have not been well defined. As with increased secretions, pronounced bronchoconstriction in SCI patients may be due to parasympathetic predominance following cervical cord injury [15]. A significantly higher incidence of airway responsiveness has been reported in SCI patients than in patients without SCI [16]. Reducing airway resistance is paramount in patients with limited ventilatory reserve and increased work of breathing associated with training. Although a number of studies have reported that metered-dose inhalers (MDIs) are equally effective as small volume nebulizers (SVNs) in mechanically ventilated patients [17,18], it is not known whether this also applies to ventilator-dependent cervical SCI patients.

Based on findings advocating the use of ipratropium bromide and albuterol sulfate in chronic obstructive pulmonary disease patients, both bronchodilators were simultaneously used in this REP unless contraindicated. Combination therapy with ipratropium bromide and albuterol sulfate has been found to induce bronchodilation in large and small airways, respectively [19]. Long-term use of aerosolized antimuscarinic and *ß* agonist medications is well tolerated [20]. Furthermore, in combination therapy, tolerance to a *ß* agonist is far less likely, and overall clinical efficacy is improved [21]. Bronchodilators were aerosolized via an SVN [17] placed proximal to the outlet filter on the ventilator to improve delivery of aerosol to the lungs [22].

Studies at our SCI Center suggest that bronchodilation is maintained for a longer period of time when albuterol sulfate (0.083%) and ipratropium bromide (0.02%) unit doses are delivered via SVN, instead of via MDI. Most patients in this study maintained mean decreases in airway resistance of 15 to 20 percent throughout the training sessions. This was determined by periodic measurements of airway resistance, performed with the ventilator's software. SCI patients in the acute phase of their injury appear to exhibit airway resistance that is refractory to conventional doses (2–4 actuations) administered via MDIs. The larger quantity of medication from SVNs, along with steps taken to augment deposition of particles in the airways, may be largely responsible for the sustained decreases in airway resistance.

Flow rate to the SVN was set at 8 L/min [23] to generate optimally sized particles that enhance airway deposition. Flow rate on the ventilator was set at 30 L/min [24] for the duration of the treatment to decrease inertial impaction of nebulized particles within the conducting airways. Normal saline diluent (2 cc) was added to the SVN to augment the amount of drug aerosolized and therefore deposited on the smooth muscle of the airways [25]. Compared to MDIs, SVNs deliver a greater dose of medication to the lower respiratory tract [26], where atelectasis and mucus plugging predominate [27]. Positioning patients in shallow Trendelenberg and performing tracheal suctioning very likely improve delivery of aerosolized drug to the atelectasis-prone basilar regions of the lungs.

Transient Hyperinflation of the Lungs

While in Trendelenberg, the patient's set Vt (10–15 cc/kg) was increased by 200 cc and set ventilatory rate was decreased by 2 breaths per minute to provide the lungs and chest wall with a transient stretch without changing minute volume appreciably. Ventilator-dependent patients with chronic cervical SCI typically exhibit restriction of the chest wall due to spastic intercostal muscles. The use of larger than normal Vt in this patient population reportedly increases compliance of the chest wall, thus making it easier for them to spontaneously ventilate during endurance sessions. It is unclear whether transient hyperinflation of the lung as used in this study (1) resulted in a decreased work of breathing or (2) can be considered equivalent to the use of sustained, above-normal (20 cc/kg) Vt advocated by Peterson [28].

Removal of Trach Tube Inner Cannula

All patients had 8.0 mm cuffed trach tubes with disposable inner cannulas. After pretraining optimization, inner cannulas were removed to reduce resistance of the artificial airway during on-vent and off-vent endurance training [29].

Inspiratory and Expiratory Resistance Strength Training

After completing pretraining optimization, patients rested for 10 min in the standard training position. A respiratory therapist reviewed the steps of the inspiratory and expiratory resistance strength training with patients before the session began. A bedside protocol form provided instructions for each maneuver and served as a data collection tool. (See the **Appendix**, which appears in the on-line version only). Patients about to undergo inspiratory resistance strength training (IRST) had their trach tube cuffs deflated and were removed from the ventilator. A red decannulation cap (Portex REF 519000) was placed on the trach tube, and nose clips were applied. IRST consisted of a specified number of inspiratory maneuvers through a fixed resistance device. A Resistex PEP therapy trainer (Mercury Medical) was modified to enable inspiration through one of four orifices. Although the device is intended for use during expiration, the modification reversed a one-way valve, enabling the trainer to serve as an inspiratory resistor. The largest orifice (size 4) offered the least resistance during inspiration; the smallest (size 1) offered the most resistance.

Patients were encouraged to progress from the least resistant orifice to most resistant as quickly as possible. A cufflator pressure manometer (Posey REF 8199) was connected to the inspiratory resistor to measure negative deflections during inspiration. Patients inhaled to total lung capacity (TLC). Improvement of inspiratory capacity is known to occur when inspiratory muscles are trained near TLC [7]. Patients performed a set of 10 inspiratory maneuvers, each lasting at least 2 s, followed by a 1 min rest period on the ventilator. Patients performed four sets, once a day in the morning. When patients were able to perform at least 30 inspiratory maneuvers at a stable maximal inspiratory pressure, the resistance was increased by decreasing the size of the orifice on the Resistex. A patient's best inspiratory effort was recorded as the PImax for that shift on the bedside protocol form.

After completing IRST, patients rested for 10 min in the standard training position. Expiratory resistance strength training (ERST) consisted of a specified number of expiratory maneuvers using the Resistex. Patients were coached to exhale to residual volume (RV). Improvement of expiratory capacity occurs when expiratory muscles are trained near RV [7]. Patients performed a set of 10 expiratory maneuvers, each lasting at least 2 s, followed by a 1 min rest period on the ventilator. Patients performed four sets, once a day in the morning. When patients were able to perform at least 30 expiratory maneuvers at a stable maximal expiratory pressure, the resistance was increased by decreasing the size of the orifice on the Resistex. A patient's best expiratory effort was recorded as the PEmax for that shift on the bedside protocol form.

Endurance Training

After completing IRST and ERST, patients were allowed to rest for 10 min in the standard training position. A respiratory therapist reviewed the steps of the endurance training with patients before the session began. Endurance training consisted of low-intensity muscular contractions on-vent and, if possible, off-vent. SpO_2 and/or $ETCO_2$ measurements were used to monitor patients performing endurance training.

On-Vent Endurance Training

After resistance training, patients were returned to the ventilator for on-vent endurance training, which consisted of SIMV of 1 to 2 breaths per minute, positive end-expiratory pressure (PEEP) of 5 cm H_2O, and PSV of 5 to 10 cm H_2O. Patients spontaneously ventilated at a rate that was comfortable and generally maintained a minimum Vt of 400 cc. Patients were able to see changes in their SpO_2 and $ETCO_2$ values by viewing bedside monitors. The visual biofeedback was used in coaching patients to maintain an appropriate respiratory rate (RR) and Vt. Decreased SpO_2 or increased $ETCO_2$ that could not be reversed by a patient's effort was usually resolved by tracheal suctioning, aerosolization of bronchodilators, and resting on assist/control mode for 10 min. Patients who experienced a second episode of decreased SpO_2 or increased $ETCO_2$ were returned to assist/control mode for 24 hours before attempting another endurance session. If patients do not rest sufficiently before the next weaning trial, structural injury to the ventilatory muscles can occur, thereby hindering the prospects for discontinuing mechanical ventilation [26]. Attempts were made to progressively lengthen endurance times while simultaneously decreasing levels of PSV to 5 cm H_2O. To progress to off-vent breathing, patients were required to maintain a Vt of at least 400 cc on PSV 5 and CPAP 5 for 2 continuous hours per day for 1 week, without decreased SpO_2 or increased $ETCO_2$. Most on-vent endurance training was carried out without an increased fractional inspired oxygen concentration (FiO_2), unless changes in heart rate or SpO_2 warranted supplementation. Patients requiring 40 percent FiO_2 or more were not promoted to off-vent endurance. If suctioning was required, the patient was returned to assist/control mode for the duration of the procedure, after which training resumed. Patients' responses to the effects of exercise were meticulously monitored. To continue training, patients were required to remain within normal ranges for each of the following: SpO_2 (92–100%), $ETCO_2$ (baseline ±5), heart rate (<120 bpm), blood pressure (<140 mmHg), RR (<30 bpm), and Vt ~400 cc. Ventilator settings for patients are shown in **Table 2**.

Off-Vent Breathing Time (Ventilator-Free Breathing)

Esteban et al. reported that T-piece trials are associated with a shorter median weaning time when compared with PSV [30]. It is yet to be determined whether T-piece trials produce shorter weaning times when the population under study is ventilator-dependent cervical SCI patients. In the current study, patients who were removed from mechanical ventilation were placed on a modified T-piece setup, consisting of a wye connector, a GIN at 21 percent, and a CPAP valve at 5 cm H_2O. The trach tube cuff was intermittently deflated as tolerated so that patients could practice speaking and coughing. Although the reasons are not entirely clear, the wye connector appeared to facilitate spontaneous ventilation more than a conventional T-piece (Briggs adapter), especially when coupled directly to a patient's trach tube without a swivel adapter.

In some instances, patients were placed on a tracheal gas insufflation (TGI) device in order to provide a more gradual transition from the wye connector to the red trach tube cap [31]. This device was developed at our institution and works by delivering air or O_2 through a trach tube into the trachea. The displacement of CO_2 from the lungs lessens a patient's work of breathing. Patients are able to draw as much additional atmospheric gas as desired through two one-way valves. Placement of the device at the trachea rather than at the mouth decreases the anatomical deadspace and the work of breathing, thus enabling patients to spontaneously ventilate for longer periods than might otherwise be possible. The decision to employ TGI was based on successful completion of training on a GIN and CPAP. If a patient experienced increased respiratory rate, shortness of breath, increased heart rate, decreased SpO_2, increased $ETCO_2$, etc., after having his trach tube capped, we inferred that there was a need for assistance at an intermediate step between the GIN and the cap, and TGI was used. To empirically determine readiness for wearing the cap full-time, we periodically placed a red trach tube cap on a patient who had tolerated TGI for several days without sequelae.

Table 2.
Ventilator settings for patients.

Patient	Level of SCI	Settings Vt/Set Rate/FiO_2/PEEP	On-Vent Endurance Settings PSV/CPAP	Pretraining Mean Pressure-Supported Vt (cc)	Posttraining Mean Pressure-Supported Vt (cc)
High Tetraplegic Patients					
1	C2	1000/09/21/05	5/5	110	400
2	C2	1000/12/21/05	5/5	120	400
Low Tetraplegic Patients					
3	C5–7	1000/12/21/05	5/5	275	350
4	C5	800/12/21/05	5/5	250	450
5	C4	800/10/21/05	5/5	310	450
6	C7	1000/12/21/05	5/5	320	450
7	C5	800/10/21/05	5/5	350	420

SCI = spinal cord injury
Vt = tidal volume
FiO_2 = fractional inspired oxygen concentration
PEEP = positive end-expiratory pressure
PSV = pressure support ventilation
CPAP = continuous positive airway pressure
Note: All rates are on assist/control mode.

Patients eventually progressed to a red trach tube cap full-time, thus enabling spontaneous ventilation to occur via the upper airways. TGI appeared to be of greater assistance to low tetraplegic patients than to high tetraplegic patients. Unassisted ventilation via the upper airways represented an additional increase in the work of breathing. Most patients received supplemental O_2 (up to 2 L/min) via nasal cannula at first, and later progressed to room air. Patients were coached in using visual biofeedback from SpO_2 and $ETCO_2$ bedside monitors to maintain appropriate RR and Vt. Patients were returned to assist/control mode for overnight rest. The amount of time on nocturnal ventilation was progressively decreased as tolerated, until mechanical ventilation could be discontinued.

DATA ANALYSIS

PImax, PEmax, VC, on-vent endurance duration, and off-vent breathing time were expressed pre- and post-REP as mean ± standard deviation and as percentage changes. Comparisons were made using the paired t-test. Statistical analysis was done with commercially available software (Primer of Bio-Statistics: The Program, version 4.0, McGraw-Hill, New York). Differences were considered significant if $p < 0.05$.

RESULTS

Improvements in Inspiratory Muscle Strength

Patients ($n = 2$) with high tetraplegia improved their PImax pre- and post-REP an average of –9.5 cm H_2O ($p = 0.16$). Patients ($n = 5$) with low tetraplegia significantly improved their PImax pre- and post-REP by an average of –18 cm H_2O ($p = 0.001$). Improvements in PImax for low tetraplegic patients were significantly greater than improvements for high tetraplegic patients. Inspiratory strength measurements are shown in **Table 3**.

Improvements in Expiratory Muscle Strength

Patients ($n = 2$) with high tetraplegia increased their PEmax pre- and post-REP by an average of 7 cm H_2O ($p = 0.21$). Patients ($n = 5$) with low tetraplegia significantly increased their PEmax pre- and post-REP by an average of 21.6 cm H_2O ($p = 0.003$). Improvements in PEmax for low tetraplegic patients were significantly greater than improvements for high tetraplegic patients. Expiratory strength measurements also are shown in **Table 3**.

Improvements in Vital Capacity

Patients ($n = 2$) with high tetraplegia increased their VC pre- and post-REP by an average of 240 cc ($p = 0.21$). Patients ($n = 5$) with low tetraplegia significantly increased their VC pre- and post-REP by an average of 340 cc ($p = 0.003$). Improvements in VC for low tetraplegic patients were significantly greater than improvements for high tetraplegic patients. Vital capacity measurements are included in **Table 3**.

Improvements in On-Vent Endurance

On-vent endurance times and neurological level of injury were inversely related. High tetraplegic patients ($n = 2$) were able to ventilate on PSV 5 and CPAP 5 for an average of 67.5 min before experiencing decreased RR (>30 bpm), Vt (<400 cc), and SpO_2 (<92%), and/or increased $ETCO_2$ (>35). The small number of patients in this category adversely affected on-vent endurance times reported for high tetraplegic patients. The average value reported for these patients reflects their best achievements, which were attained late in the rehabilitation process. In comparison with low tetraplegic patients, high tetraplegic patients were much more likely to require unscheduled rest periods during on-vent endurance sessions, as well as more frequent tracheal suctioning. They appeared to be significantly more dependent on daily pretraining optimization to help them achieve their on-vent goals.

Low tetraplegic patients ($n = 5$) who ventilated on PSV 5 and CPAP 5 for a minimum of 120 min without increased RR, decreased VT and SpO_2, and/or increased $ETCO_2$, were transitioned to off-vent endurance sessions. The relative amounts of time spent each day in on-vent and off-vent endurance training varied from patient to patient. Some patients made the transition from on-vent to off-vent endurance progressively, while others seemed to require a return to on-vent endurance training after an extended period of off-vent endurance training. On-vent endurance measurements are shown in **Table 4**.

Improvements in Off-Vent Breathing

High tetraplegic patients ($n = 2$) were able to ventilate off-vent for an average of 61 min before experiencing increased RR (>30 bpm), decreased Vt (<400 cc) and SpO_2 (<92%), and/or increased $ETCO_2$ (>35). The small number of patients in this category adversely affected

Table 3.
Strength measurements.

Patient	Level of SCI	PImax Pre/Post REP (cm H_2O)	% change	PEmax Pre/Post REP (cm H_2O)	% change	VC Pre/Post REP (cc)	% change	Months of Training
High Tetraplegic Patients								
1	C2	–3/–15	80	5/10	50	120/350	66	12
2	C2	–3/–10	70	5/15	66	150/400	62	15
Mean	—	–3/–12.5	75	5/12.5	58	135/375	64	—
SD ±	—	0/3.5	—	0/3.5	—	21.2/35.4	—	—
p	—	0.16	—	0.21	—	0.27	—	—
Low Tetraplegic Patients								
3	C5–7	–5/–20	75	5/15	66	200/450	56	2*
4	C5	–5/–20	75	10/30	66	150/500	70	1†
5	C4	–5/–25	80	7/30	77	170/500	66	2*
6	C7	–10/–35	71	10/40	75	200/650	69	1*
7	C5	–15/–30	50	10/35	71	300/450	33	1*
Mean	—	–8/–26	75	8.4/30	71	170/510	59	—
SD ±	—	4.5/6.5	—	2.3/9.4	—	98/82	—	—
p	—	0.001	—	0.003	—	0.011	—	—
All Patients								
Mean	—	–6.6/–22	72	7.4/25	57	—	51	—
SD ±	—	4.4/8.6	—	2.5/12	—	—	—	—
p	—	0.001	—	0.002	—	0.001	—	—

SCI = spinal cord injury
PImax = maximal inspiratory pressure
REP = resistance and endurance protocol
PEmax = maximal expiratory pressure
VC = vital capacity
*Patient weaned from ventilator
†Patient expired

off-vent endurance times reported for high tetraplegic patients. The average value reported for these patients reflects their best achievements, which were attained late in the rehabilitation process. The considerable difference in off-vent breathing times between the two high tetraplegia patients in the current study is thought to be the result of a younger, more determined patient achieving better outcomes.

High tetraplegics were compared with high tetraplegics and low tetraplegics with low tetraplegics. Both (2/2, 100%) high tetraplegics improved their ability to ventilate off-vent, albeit for only a few minutes, in case of accidental disconnection from the mechanical ventilator. Similarly, 4/5 (one expired) low tetraplegic patients completed their prescribed training. Of these, 4/4 (100%) were weaned from mechanical ventilation. Both high tetraplegic patients and the low tetraplegic patient who expired were present when the protocol was first implemented; the remaining four in the study arrived shortly after implementing the protocol. Mean length of ventilation (LOV) before the protocol-driven program began was 27 months for high tetraplegics and 10 months for low tetraplegics. Off-vent breathing measurements are shown in **Table 4**.

CONCLUSIONS

The use of evidence-based clinical protocols to guide resistance and endurance training of ventilator-dependent cervical SCI patients represents an important step in standardizing rehabilitation and weaning interventions for this functionally diverse neurological population. The protocol implemented for this pilot study was constructed

Table 4.
Endurance measurements.

Patient	Level of SCI	On-Vent Endurance Pre/Post REP (min/day)	% change	Off-Vent Breathing Pre/Post REP (min/day)	% change	Months of Training
High Tetraplegic Patients						
1	C2	10/45	78	5/120	96	12
2	C2	10/90	89	0.5/2	75	15
Mean	—	10/67.5	83.5	2.5/61	85.5	—
SD ±	—	0/31.8	—	3.5/83	—	—
p	—	0.24	—	0.49	—	—
Low Tetraplegic Patients						
3	C5–7	5/120	95.8	10/10*	0	2†
4	C5	10/120	91.6	10/300†	96.7	1*
5	C4	10/120	91.6	15/300†	95.0	2†
6	C7	10/120	91.6	10/300†	96.7	1†
7	C5	15/120	87.5	15/300†	95.0	1†
Mean	—	10/120	91.6	12/242	76.7	—
SD ±	—	3.5/0	—	2.7/130	—	—
p	—	0.001	—	0.016	—	—
All Patients						
Mean	—	10/105	90.4	9.3/190	95.1	—
SD ±	—	2.9/29	—	5.3/142	—	—
p	—	0.0001	—	0.013	—	—

SCI = spinal cord injury
REP = resistance and endurance protocol
*Patient expired.
†Patient weaned from ventilator.

after a systematic examination of relevant scientific literature. Several studies have shown that the use of protocols results in improved patient care outcomes [32,33]. Using evidence-based techniques to develop protocols may further improve their clinical efficiency and effectiveness.

Ongoing studies at our SCI Center reveal that preparation of chest wall, lungs, and airways through pretraining optimization enables ventilator-dependent SCI patients to perform resistance and endurance training for extended periods of time. Positioning patients in shallow Trendelenberg while on the ventilator resulted in increased compliance of the chest wall and lung. This was determined by periodic compliance measurements, taken with the ventilator's software. Cameron was the first to report a 6 percent increase in VC when tetraplegics were placed in a 15°, head-down position [34]. Short-term improvements in chest wall and lung compliance in our patients may have played an important role in improving performance of ventilatory muscles during resistance and endurance training. Increased work of breathing in tetraplegic patients has been attributed to restriction of the chest wall secondary to spasticity of intercostal muscles [35]. Progressive atelectasis and/or consolidation commonly encountered in the lungs of these patients similarly manifests as restricted pulmonary tissue, further adding to the ventilatory workload. Improved airway resistance and chest wall/lung compliance would be expected to decrease the work of breathing during bouts of resistance and/or endurance training. Patients who were positioned in Trendelenberg, suctioned, bronchodilated, and hyperinflated before training appeared to tolerate endurance training for extended periods. These findings should be considered preliminary because of the small number of patients in the current study.

In this study, patients with high tetraplegia experienced modest improvements in PImax, PEmax, and VC. Depending on the level and completeness of injury, patients may exhibit control of trapezius and sternocleidomastoid muscles for inspiration and the medial aspect of pectoralis major for expiration. Inadequacy of the inspiratory muscles leads to ineffective inspiration and an ineffective hold phase of the cough reflex. Studies have recently highlighted problems in measuring PImax and PEmax when using a flange mouthpiece rather than a tube mouthpiece [36]. During a strength test, high tetraplegic patients may use buccal musculature instead of ventilatory muscles, thus confounding strength measurements. While Resistex measurements for this study were conducted using flange mouthpieces, we believe careful coaching, monitoring, and multiple measurements produced valid strength measurements.

High tetraplegic patients experienced modest improvements in on-vent endurance and meager off-vent breathing times. However, they were able to exercise on and off the ventilator to some extent thus presumably forestalling atrophy of available ventilatory muscles. Among the most important reasons for patients with high tetraplegia attempting to improve endurance of their ventilatory muscles with exercise is the need to spontaneously ventilate in case of accidental disconnection from the ventilator. Justification for attempting to aggressively rehabilitate and wean high tetraplegic patients originally came from studies performed by Wicks and Menter [4], who reported successfully weaning 28 percent of patients with C2 injuries, and 51 percent with C3 injuries.

In contrast to patients with high tetraplegia, those with low tetraplegia exhibited significant improvements in PImax, PEmax, and VC. These improvements in ventilatory muscle strength may have played an important role in preparing patients to undertake endurance training. We have observed that patients who receive resistance training immediately before their endurance sessions, as directed by the REP, typically turn in longer endurance times. Among low tetraplegic patients, resistance training appeared to be of greatest clinical benefit to patients with C4 or C5 injuries. Most low tetraplegia patients required 1 or 2 months of training before mechanical ventilation could be discontinued. In most cases that was followed by an additional 1 or 2 months of daily optimization, in which patients were placed in Trendelenberg, suctioned, bronchodilated, and hyperinflated using either a ventilator or an AMBU bag. Steps were taken to augment chest wall/lung compliance and reduce airway resistance to help patients spontaneously ventilate, while minimizing increased metabolic demands associated with work required to expand atelectatic lung tissue or airways narrowed by secretions and/or bronchoconstriction. Patients occasionally required short-term mechanical ventilation due to ventilatory failure, refractory desaturations, or systemic problems such as sepsis. When well enough to leave the SCI vent unit, patients were transitioned to a step-down area. If patients experienced problems maintaining lung expansion or mobilizing secretions, an evidence-based lung expansion protocol was instituted.

All the low tetraplegic patients in this pilot study, except for one who expired, achieved discontinuation from mechanical ventilation using an evidence-based resistance and endurance protocol. Neither of the high tetraplegic patients achieved discontinuation from mechanical ventilation, although it may be said that their dependence on mechanical ventilation was lessened and the strength of available ventilatory muscles was improved. We conceptually separated high tetraplegics from low tetraplegics to draw attention to the fact that, while resistance and endurance training is indicated for both types of patients, the expected outcomes are quite different.

Two years before implementing the protocol program the weaning rate was 20 percent. When compared with the 100 percent weaning rate of the 24 months after implementing the protocol program, it is apparent that patient care outcomes have improved. Although limited by the small number of patients studied, our findings suggest that low tetraplegic patients were helped considerably more than high tetraplegic patients when discontinuation from mechanical ventilation was the desired clinical outcome. In the future, evidence-based protocols may need to address the needs of high tetraplegic patients much more specifically. The role that pharmacologic agents such as oxandrolone [37] and theophylline [38,39] may play in improving muscle strength and ventilatory drive as part of an evidence-based REP for high tetraplegic patients should be investigated. We are looking forward to the day when all ventilator-dependent SCI patients can achieve discontinuation from mechanical ventilation, regardless of level of injury.

Appendix-Bedside Resistance and Endurance Protocol (REP) Form

Patient Name:	**SS#:**
Ordered by Dr:	Date:

Preparation BEFORE Performing Resistance and Endurance Training Below

1. Place in shallow (15 degrees) Trendelenberg	2. Increase VT by 200 cc and decrease RR by 2	3. Suction	4. Give unit dose Atrovent & Albuterol via power neb	5. Wait 15 minutes for lung recruitment	6. Decrease VT by 200 cc and increase RR by 2

Inspiratory / Expiratory Resistance Training

1. Prepare inspiratory / expiratory trainer	2. Place Ventilator in standby	3. Remove Pt from vent	4. Attach red cap to trach & nose clip to nose
5. Have pt perform a deep breaths to TLC with pause followed by exhalations to RV with pause	6. TARGET: Pt should perform 10 maneuvers then rest on vent for 1-minute . Repeat 4 times.		
7. Return Pt. to vent	8. Record the patient's best inspiratory and expiratory efforts below .		

40																												
30																												
20																												
10																												
Pmax	**I**	**E**	**I**	**E**	**I**	**E**	**I**	**E**	**I**	**E**	**I**	**E**	**I**	**E**	**I**	**E**	**I**	**E**	**I**	**E**	**I**	**E**	**I**	**E**	**I**	**E**	**I**	**E**

On-Vent Endurance Training

1. Elevate head 30°	2. Attach Pulse Ox clip	3. Place on **SIMV-2**	4. Place on **PSV to maintain VT ~ 400 cc**	5. Have patient ventilate for one hour ON-VENT	6. Rest 15 minutes on A/C
7. TARGET: Pt should perform on-vent endurance as tolerated.	8. Terminate weaning if called off floor.	9. Record patient's best effort and duration below			

Normal Values

SpO2: 92-100%	**ETCO2: Baseline $\pm$ 5**	**HR < 120**	**RR < 30**	**VT: ~ 400cc**

PSV														
Pre SpO2														
Post SpO2														
Pre ETCO2														
Post ETCO2														
Pre HR														
Post HR														
Pre RR														
Post RR														
Pre VT														
Post VT														
Minutes														

Off-Vent Endurance Training

1. Attach aerosol GIN wye-piece or TGI device for off-vent endurance training	2. Return to A/C any time normal values are not maintained	
3. TARGET: Pt should perform off-vent endurance as tolerated.	4. Terminate weaning if called off floor.	5. Record patient's best effort and duration below

Normal Values

SpO2: 92-100%	**ETCO2: Baseline $\pm$ 5**	**HR < 120**	**RR < 30**	**VT: ~ 400cc**

Minutes														

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