**Expansible Muscle Training in Spinal Cord Injury: A Randomized Controlled Trial**

**Elliot J. Roth, MD, Katherine W. Stenson, MD, Scott Powley, MD, Jeffrey Oken, MD, Scott Primack, DO, Steven B. Nussbaum, MD, Michael Berkowitz, MD**


**Objective:** To assess the effectiveness of expiratory muscle training on the pulmonary function of spinal cord injured patients.

**Design:** Randomized controlled trial.

**Setting:** Acute inpatient rehabilitation hospital.

**Participants:** Patients (N = 29, 22 men and 7 women) with recent traumatic, motor complete, spinal cord injury (SCI) at or above level T1 consecutively admitted to an SCI rehabilitation service. Subjects were randomized to either resistance training (n = 16) or sham training (n = 13).

**Interventions:** The subjects completed either sham training or expiratory muscle resistive training with maximal expiratory force using a small handheld device, which is a tube with an aperture at the distal end, for 10 repetitions twice a day 5 days a week for a total of 6 weeks.

**Main Outcome Measures:** Pulmonary function tests were measured before and after the training program and included forced vital capacity (FVC); forced expiratory volume in 1 second (FEV1); maximum expiratory pressure (MEP), which is often referred to as forced expiratory pressure; maximum inspiratory pressure (MIP), which is often referred to as negative inspiratory force; inspiratory capacity (IC); expiratory reserve volume (ERV); total lung capacity (TLC); functional residual capacity (FRC); and residual volume (RV).

**Results:** FVC, FEV1, and ERV improved in both groups. Although exit values of MEP were improved in both groups compared with entry values, this increase was statistically significant only in the resistance training group. No significant improvements occurred in IC, TLC, FRC, or RV from entry to exit. MIP improved in both groups, but this increase was statistically significant only in the resistance training group. There was also a significant between-group difference in MEP exit values (98cmH2O for the resistance training group and 59cmH2O for the sham training group, t = 3.45, P = .002). Multivariate analyses failed to reveal significant effects of treatment for any of the pulmonary function tests.

**Conclusions:** The resistance training group had significantly greater exit MEP values than the sham training group in univariate analysis only. However, improvements in pulmonary function were noted in both the resistance training and sham training groups. Although multivariate analysis failed to reveal a significant difference between groups, these findings offer some indication that expiratory training may benefit people with SCI.

**Key Words:** Breathing exercises; Exhalation; Rehabilitation; Spinal cord injuries. © 2010 by the American Congress of Rehabilitation Medicine

**RESPIRATORY COMPLICATIONS** are major sources of morbidity and mortality in both the acute and chronic phases of SCI.1-6 In patients with tetraplegia, weakness of the accessory muscles of breathing along with decreased lung and chest wall compliance severely decrease respiratory efficiency. Weak inspiratory muscles impair the ability of the patient with tetraplegia to take a deep breath, causing atelectasis and a higher risk of developing pneumonia.2 Weakness of expiratory muscles impairs the ability of the patient with tetraplegia to cough and successfully clear respiratory secretions.2 This also predisposes patients with tetraplegia to developing atelectasis, pneumonia, and ultimately an increased risk of early mortality.1 The degree of expiratory muscle weakness can be assessed by using spirometry. MEP has been used in studies to show force-generating capacity for cough.8

Recent large cross-sectional studies evaluating pulmonary function in SCI have shown that FVC and FEV1, as measures of maximum inspiration, decrease linearly with higher levels of SCI (ie, FVC and FEV1 are virtually normal in low-level paraplegia, decrease with higher SCI levels, and are worst with high cervical tetraplegia).1,8,9 PEFR, which is thought to be indicative of cough strength, has also been shown to decrease with higher SCI levels.10 The PEFR has been found to be more dramatically reduced at higher levels of injury than FVC or FEV1. This may indicate that the impairment of effective cough and expiration contributes to the development of respiratory complications.1,10,11 A number of studies1-12-14 have evaluated the potential benefits of respiratory muscle training in patients with SCI.

**List of Abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>ERV</td>
<td>Expiratory reserve volume</td>
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<tr>
<td>FEV1</td>
<td>Forced expiratory volume in 1 second</td>
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<tr>
<td>FVC</td>
<td>Forced vital capacity</td>
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<td>MEP</td>
<td>Maximum expiratory pressure</td>
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<tr>
<td>PEFR</td>
<td>Peak expiratory flow rate</td>
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<td>SCI</td>
<td>Spinal cord injury</td>
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Most of these have been focused on resistive inspiratory muscle training. Although fewer studies have evaluated expiratory muscle training, the results tend to show more improvements in ventilatory measures for resistive expiratory training. Furthermore, strengthening muscles of expiration may help to improve the strength of cough in patients with tetraplegia.

Gounden et al12 showed significant improvements in expiratory mouth pressure and vital capacity in an experimental group of patients with tetraplegia undergoing progressive respiratory resistive loading on accessory muscles of expiration. Estenne et al16 showed both significantly improved pectoral muscle strength and decreased residual volume in patients with tetraplegia undergoing expiratory muscle training compared with controls.

A recent systematic review14 of resistive muscle training studies in the literature failed to reveal consistent, statistically significant benefits for inspiratory muscle training despite the larger number of studies available for review. The potential role of resistive expiratory muscle training deserves further study.

It has been posited that improved expiratory muscle strength after expiratory muscle training may be associated with improved cough and clearance of secretions. The decreased end-expiratory lung volume resulting from a stronger exhalation also increases vital capacity.10 As such, it would be valuable to measure pulmonary function tests after targeted expiratory muscle training, including measurements of residual lung volume and the standard measurements of FEV1 and FVC.6 There are several methods of assisting patients with tetraplegia with cough, but most are highly dependent on the motivation of a caregiver, such as manual cough assist, which is contraindicated in SCI patients with inferior vena cava filters.2 Patients with SCI also might be dependent on costly equipment, such as in/exsufflation. Some interventions are invasive, such as functional electrical stimulation.3 Given the role of ineffective cough in increasing the risk of pneumonia and early death after high SCI, it is important to find optimal means to increase the efficacy of cough. Targeted resistance training of expiratory muscles offers a relatively easy and inexpensive method to enhance cough. We hypothesize that (1) a simple expiratory muscle training program will improve the pulmonary function of patients with recent onset of tetraplegia and (2) resistance training will do so to a greater degree than the sham training performed by the control group.

METHODS

Patients admitted to the SCI unit of a freestanding inpatient rehabilitation hospital were invited to participate in the study if the SCI had occurred within the previous 6 months, was motor complete, and was at or above level T1. Exclusion criteria included age 16 or younger, open tracheostomies, active pneumonia at the time of testing, or unresolved chest injuries. Subjects were randomized into either the experimental (resistance training) group or the control (sham training) group at the time of enrollment based on the medical record number.

The initial evaluation consisted of a comprehensive medical history, including age, sex, race, marital status, education, employment, smoking history, etiology and level of injury, presence of spine fracture, spine surgery, and the presence of a tracheostomy. Each subject underwent a thorough neurologic assessment by 1 of 3 trained examiners, and a determination of the level of spinal cord injury was made according to the American Spinal Injury Association Impairment Scale.

Each subject underwent baseline pulmonary function testing within 5 days of neurologic examination. Three trials were performed with the maximum result of the 3 attempts recorded.

Pulmonary function testing was performed in the seated position by using the Cybermedics Pulmonary Function Testing Machine.4 Testing included FVC, FEV1, inspiratory capacity, ERV, total lung capacity, functional residual capacity, and residual volume. MEP, which is often referred to as forced expiratory pressure, and maximum inspiratory pressure, which is often referred to as negative inspiratory force, were measured by the Boehringer High Pressure Inspiratory Force Meter Model 4101 (fig 1). Pulmonary function testing was repeated at the end of the training period.

The technicians and those reading the pulmonary function tests were blinded to the group assignment of each subject. The study was approved by an internal institutional review board, and each subject gave informed consent before enrollment in the study.

At the initiation of the respiratory muscle training, each subject was instructed on the proper use of the breathing device, the Boehringer High Pressure Inspiratory Force Meter Model 4101 (see fig 1). The device is a small, handheld plastic tube through which the subjects exhale against a pressure gauge. The experimental or resistance training group used a closed-end device, creating high-pressure resistance to expiration. The only outlet for the expired air was through a small (≤0.5cm) aperture connected to the pressure gauge. The control or sham training group used a device with an open gauge without added respiratory resistance. Each subject performed 10 repetitions (duration of about 3–5min) with the assigned device, as tolerated, twice a day 5 days a week for 6 weeks. The subjects were instructed to breathe as quickly and as hard as possible without rest between repetitions. Every expiratory muscle training session was supervised by a trained research physician.

Age and education levels were compared between the sham and resistance training groups by using the Student t test. Differences in distributions between the 2 training groups were assessed for sex, race, marital status, employment status, etiology and level of injury, presence of spine fracture, spine surgery, history of smoking, and tracheostomy use using 2 chi-square analyses. Differences between entry and exit values for pulmonary function test results were determined by using the Student t test. Exit pulmonary function test values were compared between the sham and resistance training groups using the Student t test. Multivariate analysis of repeated measures data was performed by using PROC GLM in SAS 9.3. The changes between the results of the pre- and posttests were modeled to detect the difference between resistance training and sham training. A significance level of .05 was used.
RESULTS

Fifty-two consecutive subjects admitted to the inpatient SCI service of an academic freestanding acute rehabilitation hospital were initially enrolled in the study and randomized either to the experimental (resistance training) group or the control (sham training) group. Twenty-nine subjects were randomized to the resistance training group, and 23 subjects were randomized to the sham training group. A total of 23 subjects withdrew from the study after enrollment and initial pulmonary function testing; 13 of those who withdrew had been randomized to the resistance training group, and 10 had been randomized to the sham training group. All study withdrawals were initiated by the subjects. The major reason for withdrawal from the study was the onset of medical complications.

Study subjects included 29 subjects with acute SCI between the ages 16 and 60 who were admitted to the inpatient SCI service. The trial was conducted on the 16 subjects who completed the resistance training protocol and the 13 subjects who completed the sham training protocol.

As noted in table 1, there were no significant differences between the resistance training group and the sham training group with respect to age, sex, race, marital status, education, employment, smoking history, etiology and level of injury, presence of spine fracture and surgery, and presence of a tracheostomy. All subjects sustained traumatic injuries between levels C4 and T1 with no significant differences between training groups with regard to levels.

The resistance training group underwent a mean ± SD of 48.1±14.1 training sessions, and the sham training group underwent a mean ± SD of 48.7±14.7 training sessions. A comparison of pulmonary function testing results at baseline and the conclusion of expiratory muscle training revealed that 6 weeks of training with the handheld device twice per day improved a few key markers of general respiratory and expiratory function. A multivariate analysis failed to reveal significant effects of treatment for any of the pulmonary function tests (ie, there were no differences between the resistance training and sham training groups for any of the tests [F=1.59, P=0.22]).

Table 2 shows that there were improvements in many pulmonary function test results in both training groups in univariate analysis only. In the resistance training group, significant improvements were noted in FVC, FEV1, ERV, maximum inspiratory pressure, and MEP. Sham training resulted in improvements in FVC, FEV1, and ERV. Exit values were significantly greater for the resistance training group compared with the sham training group only for MEP but only in univariate analysis. Exit values for the sham training group were significantly greater than for the resistance training group only for the total lung capacity.

DISCUSSION

This study was conducted to determine if expiratory function, as evidenced by formal pulmonary function testing, improves with the use of a simple handheld expiratory resistance training device. Given the adverse impact of ineffective cough on the respiratory health of patients with SCI, the role of expiratory muscle function in developing effective cough, and the relative dearth of information on the effectiveness of expiratory muscle training, this study could provide useful information regarding the value of a simple intervention.

The results showed improvements in both groups, most favorably in FVC, FEV1, and ERV. The increase in vital capacity has been shown in previous studies and has been thought to be linked to decreased end-expiratory lung volume from stronger exhalation. The improvements in FEV1 and ERV indicate that the study subjects improved in parameters specific to the function of exhalation. ERV, which is forced expiration at end volumes, requires an active engagement of muscles of expiration, which would imply a beneficial training effect. The fact that both groups showed improvement in the same measures of pulmonary function shows that resistive expiratory training at any level may have some beneficial effects on the ventilatory function of patients with tetraplegia. Strengthening the chest wall muscles to any degree may enhance their capability and result in improved respiratory function.
Table 2: Pulmonary Function Test Results for Resistance Training and Sham Training Groups at Study Entry and Exit

<table>
<thead>
<tr>
<th>PFT</th>
<th>Resistance Training</th>
<th>Sham Training</th>
<th>Difference at Exit for Resistance vs Sham Training Groups</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Entry</td>
<td>Exit</td>
<td>Change</td>
</tr>
<tr>
<td>FVC (L)</td>
<td>1.90</td>
<td>2.18</td>
<td>0.28</td>
</tr>
<tr>
<td>FEV1 (L)</td>
<td>1.74</td>
<td>2.00</td>
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<tr>
<td>ERV (L)</td>
<td>0.31</td>
<td>0.45</td>
<td>0.14</td>
</tr>
<tr>
<td>MIP (cmH2O)</td>
<td>-47.00</td>
<td>-71.00</td>
<td>-24.00</td>
</tr>
<tr>
<td>MEP (cmH2O)</td>
<td>63.00</td>
<td>59.00</td>
<td>4.00</td>
</tr>
<tr>
<td>IC (L)</td>
<td>1.59</td>
<td>1.60</td>
<td>0.01</td>
</tr>
<tr>
<td>TLC (L)</td>
<td>4.17</td>
<td>4.13</td>
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</tr>
<tr>
<td>FRC (L)</td>
<td>2.56</td>
<td>2.49</td>
<td>-0.07</td>
</tr>
<tr>
<td>RV (L)</td>
<td>2.25</td>
<td>2.04</td>
<td>-0.21</td>
</tr>
</tbody>
</table>

Abbreviations: FRC, functional residual capacity; IC, inspiratory capacity; MIP, maximum inspiratory pressure; PFT, pulmonary function test; RV, residual volume; TLC, total lung capacity.

The significant difference in exit values for MEP between the resistance training and sham training groups (98cmH2O for the resistance training group and 59cmH2O for the sham training group) is important to note. Expiratory resistance training caused a 56% increase in MEP, whereas sham training caused only a 16% increase. This is not surprising because the training was specifically directed toward improving expiratory pressure and, in fact, even used the same device to perform both training and measuring. This finding provides excellent evidence for the “specificity of training.” However, the following implications of this study’s findings are significant: simple expiratory muscle training performed by forced exhalation through a tube with resistance has the potential to increase expiratory muscle function in patients with acute spinal cord injury. By extrapolation, this may have the potential to increase the strength and effectiveness of voluntary independent cough, decrease the amount of retained secretions, and thereby reduce the occurrence of pneumonias and other causes of respiratory morbidity. The failure of multivariate analysis to reveal significant differences between training groups indicates that many other factors may influence the potential to improve expiratory function. Nonetheless, the sizable difference in MEP, both between groups and between entry and exit, offers some indication that expiratory training may benefit people with SCI.

Causes and implications of the other significant between-group finding (ie, the difference between groups for exit total lung capacity values) are unclear. In this case, the sham training group results are significantly greater than the resistance training group results. This finding may support the concept that ventilatory training to any degree may yield some benefit to patients with high-level SCI.

Study Limitations

Limitations of this study include the relatively small number of subjects and insufficient power to show between-group significant differences of the intervention. This limitation is reflected in the lack of significance in the multivariate analysis. The sizable number of subjects who withdrew from the trial may introduce a bias into the study. This is a difficulty inherent in research of patients with new SCIs. Another important limitation was that the study was conducted during the acute phase of SCI, which means that some of the improvement may have resulted from the natural recovery of ventilatory muscle function. As such, it may have been helpful to have a group that had zero training. Furthermore, PEFR is thought to be the best measure of the strength of cough. It would have been helpful to have studied this measure. In addition, it would have been interesting to have follow-up testing at least 1 month after training to determine whether these benefits persist.

The results of this study may have implications for clinical practice in treating patients with SCI. The systematic repeated use of a simple expiratory muscle training device may improve respiratory function in patients with tetraplegia. This may reduce respiratory morbidity and improve outcomes.

CONCLUSIONS

Repeated expiratory resistance breathing exercises using a simple handheld breathing training device have the potential to improve maximal expiratory pressure and other measures of ventilatory function in people with tetraplegia. Sham training, which used a substantially lower level of resistance, also resulted in some improvements in pulmonary function test results for people with high-level SCI, indicating a role for ventilatory function to any degree. However, for maximal expiratory pressure, the measure on which the training was focused and the measure that is thought to play a substantial role in determining the strength of cough and the clearance of secretions, the results of high resistance training were substantially greater than they were for sham training. Expiratory resistance training has the potential to reduce respiratory morbidity.

References


Suppliers
a. Cybermedics Inc, 1341 Cannon St, Louisville, CO 80027.
b. Boehringer Labs Inc, PO Box 870, Norristown, PA 19404.
c. SAS Institute Inc, 100 SAS Campus Dr, Cary, NC 27513-2414.