

## Mechanical Insufflation-Exsufflation for Airway Mucus Clearance

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**Cough is an important component of airway clearance, particularly in individuals with intrinsic pulmonary disease, weakness of respiratory muscles, or central nervous system disease that impairs breathing. The use of assisted cough to enhance airway clearance in individuals with neuromuscular disease is essential to produce and maintain peak cough flow above a minimum and thereby avoid retained secretions that cause infection, inflammation, and respiratory failure. Periodic insufflation of the lung above a reduced vital capacity is also important, to maintain range of motion of the thoracic cage and avoid progressive respiratory disability. Mechanical insufflation-exsufflation is a therapy in which the device (the CoughAssist In-Exsufflator is the only currently marketed insufflation-exsufflation device) gradually inflates the lungs (insufflation), followed by an immediate and abrupt change to negative pressure, which produces a rapid exhalation (exsufflation), which simulates a cough and thus moves secretions cephalad. Mechanical insufflation-exsufflation is used with patients with neuromuscular disease and muscle weakness due to central nervous system injury. Insufflation-exsufflation decreases episodes of respiratory failure, particularly during upper-respiratory-tract infection, and provides greater success in weaning from mechanical ventilation than do conventional methods. Alternatives to insufflation-exsufflation that can produce sufficient peak cough flow for airway clearance include (1) insufflation to maximum insufflation capacity (via breath-stacking with a bag and mask, a volume ventilator, or glossopharyngeal breathing) followed by a spontaneous cough, and (2) manually assisted cough with an abdominal thrust. The effectiveness of insufflation-exsufflation in patients with obstructive lung disease, such as chronic obstructive pulmonary disease or asthma, and in pediatric patients, is less clear.**

*Key words: insufflation-exsufflation, neuromuscular disease, chronic obstructive pulmonary disease, COPD, peak cough flow, maximum insufflation capacity.* [Respir Care 2007;52(10):1296–1305. © 2007 Daedalus Enterprises]

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## Introduction

Cough is an important mechanism to clear excess secretions and foreign matter from the airway, particularly in individuals with intrinsic airway disease and those with respiratory muscle weakness. Cough is a complex reflex that begins with rapidly adapting irritant receptors, which are found in greatest concentration in the posterior tracheal wall, carina, and bifurcations of large airways, less in distal smaller airways, and none beyond the respiratory bronchioles.<sup>1,2</sup> The irritant receptors consist of both mechanical and chemical receptors that respond to a wide range of stimulating foreign material and secretions.<sup>3</sup> Vagal afferents seem to play the most important role in transmitting sensorineural airway stimulation to the diffusely located cough center in the medulla.<sup>4</sup> The reflex arc is completed by efferents that emanate from the ventral respiratory group (nucleus retroambiguus and nucleus ambiguus), which send motor neurons to the inspiratory and expiratory respiratory muscles, the larynx, and the bronchial tree.<sup>5</sup> The phrenic and spinal motor nerves transmit efferent impulses to the respiratory musculature and recurrent laryngeal branches of the vagus nerve to the larynx. Disruptions of this reflex arc peripherally through afferent nerve disruption or intrinsic muscle disease, or centrally through central nervous system disease, may lead to ineffective cough.

Cough efficiency relies not only on intact medullary physiology and respiratory musculature but also on intrinsic airway conditions, including quantity and quality of secretions, an intact respiratory epithelium, and adequate airway caliber. Patients with inspiratory and expiratory muscle weakness and low lung volume have difficulty clearing increased secretions associated with viral upper-respiratory-tract infection. During 13 episodes of upper-respiratory-tract infection in 10 patients with various types of neuromuscular disease, vital capacity (VC), maximum inspiratory pressure, and peak expiratory pressure fell an average of 13%, 25%, and 29%, respectively, during the first 24–36 hours of illness.<sup>6</sup> In addition, 5 episodes of substantial hypercapnia occurred in 4 patients.

## Cough and Airway Clearance

Other factors that directly affect cough efficiency and, consequently, secretion clearance include mucus viscoelasticity and mucus depth. Mucus with higher elasticity clears less well via cough, but better via ciliary activity, whereas more viscous mucus clears more easily via cough. Also, increased mucus depth favors clearance via cough and decreases mucociliary clearance.<sup>7</sup> Acute and chronic inflammation may also disrupt ciliary function through direct damage to the respiratory epithelium.<sup>8</sup>

In conditions where mucociliary clearance is disrupted but cough is intact, such as cystic fibrosis, airway therapy

is directed at hydrating secretions (hypertonic saline, mannitol), mucolysis (dornase alfa), reducing inflammatory cells or cytokines (antibiotics, immunomodulators such as macrolides, ibuprofen), maximizing airway caliber, and transferring airway secretions from the peripheral airways to the central airways, where they can be coughed up and expectorated.<sup>9–11</sup> There are multiple airway clearance techniques designed to do that.<sup>12–16</sup>

What happens when the cough reflex arc is not intact, with or without abnormal secretions? This occurs with bulbar and respiratory muscle dysfunction, which leads to retained secretions, atelectasis, infection, and, eventually, irreversible airway and parenchymal lung damage.<sup>17–19</sup> Individuals with cervical spinal cord injury or with intrinsic expiratory muscle paresis or paralysis generate lower intrathoracic expiratory pressure (range 8–36 cm H<sub>2</sub>O) than do normal individuals, who can generate pressure of > 100 cm H<sub>2</sub>O. The lower expiratory pressure lowers the cough efficiency.<sup>20,21</sup> Inspiratory muscle weakness also lowers cough efficiency by reducing the inspiratory volume, which reduces the optimum respiratory muscle length-tension relationships and the elastic recoil of the respiratory system.<sup>22</sup> This reduces peak cough flow, which is dependent on volume, airway caliber, compliance of the respiratory tract, and inspiratory and expiratory muscle strength.

Peak cough flow is measured with a peak flow meter or a pneumotachometer. The patient is asked to inspire to total lung capacity and then forcibly expire, through either a face mask or a mouthpiece attached to the peak flow device. Although the peak flow meter is generally sufficient for serial clinical evaluation, the pneumotachometer can capture transient flow spikes produced during the peak cough expiratory maneuver.<sup>23</sup> Thus, a peak flow meter may underestimate peak cough flow, although for practical clinical use this may be relatively unimportant.

Normal individuals may produce a peak cough flow as great as 720 L/min (occasionally higher in healthy individuals).<sup>24</sup> The minimum effective peak cough flow was inferred from patients who were being weaned from mechanical ventilation; successful extubation requires at least 160 L/min (2.7 L/s).<sup>25,26</sup> Bach et al<sup>27</sup> found that a peak cough flow of at least 270 L/min (4.5 L/s) is necessary to avoid respiratory failure in patients with Duchenne muscular dystrophy during periods of upper-respiratory-tract infection with increased secretions. In individuals unable to achieve and maintain cough flow sufficient to remove these increased secretions, assisted cough can reduce morbidity and mortality.

## Mechanical Insufflation-Exsufflation

Mechanical insufflation-exsufflation (in-exsufflation) consists of insufflation of the lungs with positive pressure,

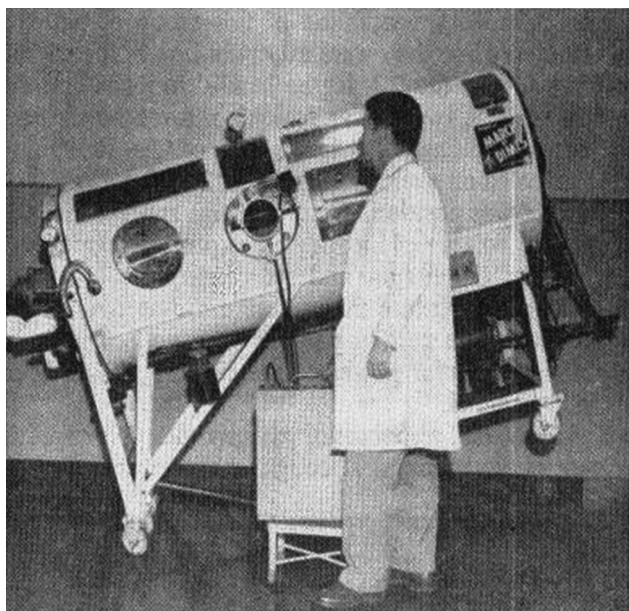


Fig. 1. Negative-pressure tank respirator adapted for use as an exsufflator (see text). (From Reference 30, with permission.)

followed by an active negative-pressure exsufflation that creates a peak and sustained flow high enough to provide adequate shear and velocity to loosen and move secretions toward the mouth for suctioning or expectoration. In-exsufflation is not new. Reports of its effectiveness on the removal of radiopaque material from the airways of anesthetized dogs appeared in the early 1950s.<sup>28,29</sup> Clinical use of in-exsufflation also appeared at that time. Barach et al<sup>30</sup> used a tank respirator setup, with the patient's head outside the tank and with the patient at a 20° head-down angle. A vacuum cleaner blower produced an intratank pressure of about  $-54$  cm H<sub>2</sub>O (Fig. 1). An approximately 13-cm valve rapidly (0.06 s) opened and allowed intratank pressure to return to atmospheric, effecting a rapid exhalation (exsufflation). With this method they attained maximum expiratory flows of about 60% of those attained with a vigorous cough in normal subjects, and 145% of the patient's own baseline without in-exsufflation. They also noted that applying a pressure of  $-20$  cm H<sub>2</sub>O via mask or in the dome of the respirator during the release of the intratank pressure increased the effectiveness of exsufflation.

The first commercially available device to provide insufflation combined with active exsufflation appears to have been the Cof-Flator (OEM, Norwalk, Connecticut), introduced in 1952. The use of tank respirators as insufflation devices had generally relied on negative pressure for insufflation and an enhanced passive exsufflation from the rapid drop to atmospheric pressure. The Cof-Flator applied both the positive and negative pressure via the mask, which created cough flow sufficient to expel



Fig. 2. The CoughAssist In-Exsufflator. (Courtesy of Respironics, Murrysville, Pennsylvania.)

secretions. Clinical trials and case reports from patients with poliomyelitis, asthma, emphysema, and bronchiectasis showed that Cof-Flator benefited the treatment of atelectasis, hypoxemia, and dyspnea.<sup>31</sup> However, with the extensive use of mechanical ventilation with tracheostomy and tracheal suctioning in the 1960s, reports of in-exsufflation use all but disappeared until its reemergence as an adjunct to noninvasive ventilation in the late 1980s and early 1990s.<sup>32</sup>

### The CoughAssist In-Exsufflator

The CoughAssist In-Exsufflator came on the market in 1993 as a method to augment airway clearance, particularly for individuals with respiratory muscle weakness (Fig. 2). It was originally manufactured and marketed by JH Emerson, Cambridge, Massachusetts, which was later bought by Respironics, Murrysville, Pennsylvania. The device uses a 2-stage centrifugal blower that gradually applies positive pressure to the airway, and then rapidly shifts to negative pressure that produces a high expiratory flow from the lungs, which simulates a cough. A peak expiratory flow of 6–11 L/s can be achieved.<sup>33</sup> The device can deliver in-exsufflation via a mask or a tracheostomy tube (Fig. 3). The positive insufflation and negative exsufflation pressures, duration, and inspiratory flow rate are preset, and the device is operated in either a manual or automatic mode, depending on the model. One treatment consists of 3–5 cycles of in-exsufflation (with or without an abdominal thrust during exsufflation) followed by about 30 seconds of rest (Fig. 4).<sup>34</sup> This is repeated several times or until secretions have been sufficiently expelled. The



Fig. 3. The CoughAssist In-Exsufflator used with a tracheostomy. (Courtesy of Respirationics, Murrysville, Pennsylvania.)



Fig. 4. The CoughAssist In-Exsufflator used with a mask and manual cough assist (abdominal thrust). (Courtesy of the Ottawa Hospital Rehabilitation Centre. From Reference 34, with permission.)

CoughAssist In-Exsufflator can be titrated to maximum insufflation with patient comfort, observation of chest-wall excursion, and auscultation of adequate air entry. However, Bach indicates, in referring to the need for adequate insufflation and exsufflation pressures, that “comfortable is irrelevant for efficacy during respiratory tract infections, when airways actually need to be cleared.”<sup>35</sup>

Although the present review focuses primarily on the importance of the exsufflation phase for airway secretion clearance, the insufflation phase is also important in patients with respiratory muscle weakness. Patients with neuromuscular disease have reduced VC and tidal volume, and, consequently, reduced cough flow because of denervation or deterioration of inspiratory and expiratory musculature.<sup>36</sup> Without the normal variation in tidal volume, intermittent deep breaths, and sighs, patients with neuromuscular disease have little regular chest expansion, so

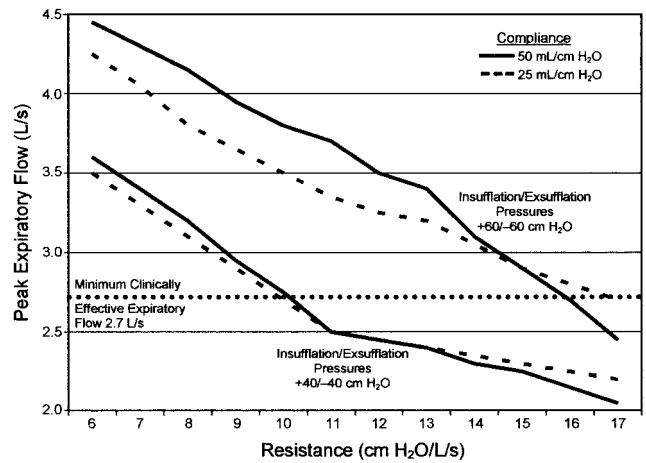


Fig. 5. Relationship between peak expiratory flow and airway resistance with 2 different insufflation-exsufflation pressures (the upper 2 curves represent +40/-40 cm H<sub>2</sub>O, the lower 2 curves represent +60/-60 cm H<sub>2</sub>O) and 2 levels of compliance (25 mL/cm H<sub>2</sub>O and 50 mL/cm H<sub>2</sub>O) in an artificial lung model (see text). (Data from Reference 41.)

they develop atelectasis and pneumonia, which often leads to respiratory failure that requires ventilatory support.<sup>27</sup> The lack of regular chest expansion, similar to decreased range of motion without regular limb exercise, can lead to permanent disability, in the form of decreasing chest-wall compliance due to thoracic muscle contracture and fibrosis, and reduced lung compliance due to microatelectasis.<sup>37-39</sup> To maintain chest-wall range of motion and lung expansion, periodic lung insufflation is desirable and necessary.

**Mechanics**

The mechanics of the CoughAssist In-Exsufflator have been studied in an artificial lung model.<sup>40,41</sup> At a static compliance of 50 mL/cm H<sub>2</sub>O, a resistance of 6 cm H<sub>2</sub>O/L/s, and the preset insufflation and exsufflation pressures, the insufflation-exsufflation times were altered to determine their effects on peak inspiratory and expiratory flows and volumes. The generated inspiratory pressures were also measured to assess the consistency of the manufacturer’s machine settings. The preset insufflation and exsufflation pressures correlated highly with the generated insufflation pressures, volumes, exsufflation volumes, and exsufflation flows. In the model, a minimum clinically effective expiratory flow of 2.7 L/s required preset insufflation and exsufflation pressures of +30/-30 cm H<sub>2</sub>O, regardless of cycle time.

Altering the airway resistance from 6 cm H<sub>2</sub>O/L/s to 17 cm H<sub>2</sub>O/L/s and compliance from 50 mL/cm H<sub>2</sub>O to 25 mL/cm H<sub>2</sub>O, as might be found in airway obstruction with secretions, microatelectasis, and chest deformity or

Table 1. Hospitalization Rate Among Protocol Versus Nonprotocol, Pre-Ventilator-Use, High-Risk Patients

	Nonprotocol* (n = 17)	Protocol* (n = 24)	P
Hospitalizations/patient	2.4 ± 1.8	0.5 ± 1.0	< 0.005
Hospitalizations/y/patient	2.3 ± 4.8	0.2 ± 0.5	< 0.005
Hospitalizations avoided*/patient	NA	1.8 ± 1.7	NA
Hospitalizations avoided/y/patient	NA	0.8 ± 1.0	NA
Hospitalization days/patient	35.4 ± 66.3	3.6 ± 8.7	< 0.005
Hospitalizations days/y/patient	21.4 ± 37.8	1.8 ± 5.2	< 0.005
Years	3.6 ± 2.7	3.1 ± 3.2	2.1

\* Values are mean ± SD.

† Acute episodes of respiratory distress relieved with 24 hours of protocol-driven therapy (see text).

NA = not applicable

(Data from Reference 27.)

restriction due to scoliosis or obesity, also changed the in-exsufflation mechanics. For given insufflation and exsufflation pressures, peak expiratory flow decreased with increasing resistance, in a fairly linear fashion (Fig. 5). At higher insufflation and exsufflation pressures, decreasing the compliance decreased the flow. Most clinical studies have found insufflation and exsufflation pressures of +40/–40 cm H<sub>2</sub>O to be optimal in adults, but higher pressures (up to +60/–60 cm H<sub>2</sub>O) may be needed in patients with conditions that lead to increased airway resistance or decreased lung compliance. Titration of in-exsufflation in infants should take into account their greater chest-wall compliance and higher peripheral airway resistance.<sup>42</sup>

## Clinical Studies

### Neuromuscular Disease

The CoughAssist In-Exsufflator has been used and studied in various neuromuscular diseases, including post-polio myelitis paresis and paralysis, Duchenne muscular dystrophy, amyotrophic lateral sclerosis (ALS), spinal muscular atrophy types 1 and 2, spinal cord injury, myopathies, myasthenia gravis, and nonspecific neuromuscular disease. The device has been used for both airway clearance and to wean patients from mechanical ventilation and tracheostomy. Many of the clinical variables in its use derive from observational studies, anecdotal information, and retrospective studies. Establishing the minimum peak cough flow for successful weaning from mechanical ventilation or to avoid hospitalization and/or intubation during infection is made even more complicated by the progressive nature of many of the conditions studied. However, multiple studies have been undertaken to try to establish these variables.

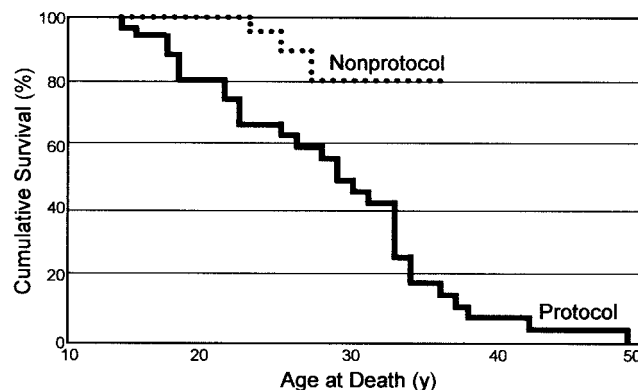


Fig. 6. Kaplan-Meier curve of survival among subjects with Duchenne muscular dystrophy. The protocol subjects were treated with an oximetry-driven protocol that included noninvasive positive-pressure ventilation and insufflation-exsufflation. (Data from Reference 43.)

In Duchenne muscular dystrophy, Bach et al<sup>27</sup> used the CoughAssist In-Exsufflator in a protocol to help avoid respiratory failure during upper-respiratory-tract infection. Patients with VC of < 1 L and maximum assisted peak cough flow of < 4.5 L/s were provided noninvasive positive-pressure ventilation (NPPV) (via nasal or oral interface) and in-exsufflation. They were also taught breath-stacking, trained in manually assisted cough and in-exsufflation, and prescribed oximeters. When short of breath, ill with upper-respiratory-tract infection, or fatigued, they monitored their blood oxygen saturation via pulse oximetry ( $S_{pO_2}$ ). When  $S_{pO_2}$  dropped below 95%, the patients used NPPV, manual assisted cough, and in-exsufflation as needed to maintain normal  $S_{pO_2}$ . When compared to patients who did not use the specific protocol over about a 3-year period, the protocol subjects had significantly fewer hospitalizations (Table 1). In addition, patients treated with the oximetry-driven protocol, NPPV, and in-exsufflation had longer survival (Fig. 6) and avoided tracheostomy.<sup>43</sup>

Patients can use the In-Exsufflator when unable to use alternative methods of airway clearance, such as breath-stacking and manually assisted cough, because of age, lack of cooperation, or poor bulbar function. Bach et al<sup>44</sup> showed that in children with spinal muscular atrophy type 1, ventilated for episodes of acute respiratory failure, re-intubation during the same hospitalization could be considerably reduced with the In-Exsufflator. A protocol that used in-exsufflation via the endotracheal tube plus an abdominal thrust was used to wean and extubate children to nasal NPPV without supplemental oxygen. Extubation with the protocol was attempted when no supplemental oxygen was needed to maintain  $S_{pO_2} > 94\%$ , the patient was afebrile, chest radiographs had cleared, and there was a reduction in need for airway suctioning. Eleven patients underwent 48 intubations, most often due to an upper-respiratory-tract

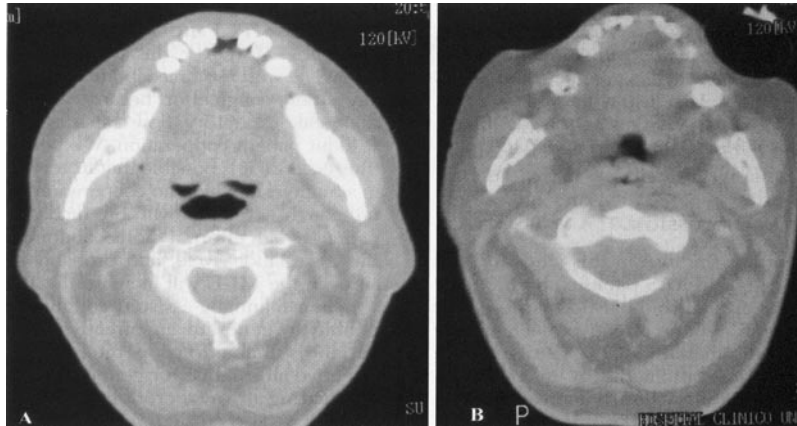


Fig. 7. Computed tomogram of the oropharynx in a patient with bulbar amyotrophic lateral sclerosis and a peak cough flow of  $< 2.7$  L/s (see text). A: Baseline. B: Pharyngeal collapse during exsufflation. (From Reference 46, with permission.)

infection. The protocol therapy was used 28 times and nonprotocol (conventional) extubation was done 20 times. There were 5 extubation failures (defined as need for re-intubation during the same hospitalization) in the protocol group and 18 in the nonprotocol group. Bach et al<sup>45</sup> also demonstrated that children with spinal muscular atrophy type 1 managed with noninvasive high-span (ie, large difference) positive inspiratory pressure plus positive expiratory pressure and in-exsufflation can have prolonged survival, without need for tracheostomy and with a hospitalization rate similar to those with tracheostomy and mechanical ventilation.

Most patients with ALS who have at least some intact bulbar function can attain adequate peak cough flow with in-exsufflation for effective airway clearance. The exception is with severe loss of pharyngeal and laryngeal muscle function, where the upper airway collapses during inspiration and expiration.<sup>35</sup> Sancho et al<sup>46</sup> found that some patients with bulbar dysfunction and peak cough flow  $< 2.7$  L/s and inability to increase their maximum insufflation capacity (the maximum volume that can be held in the lungs with a closed glottis) above forced vital capacity will produce greater peak cough flow with the In-Exsufflator than with manually assisted spontaneous cough. However, in their series, 4 patients with bulbar dysfunction and maximum insufflation capacity  $> 1$  L had in-exsufflation-generated peak cough flow  $< 2.7$  L/s, which indicates upper-airway collapse during exsufflation (Fig. 7).

Mustfa et al<sup>47</sup> found that exsufflation with negative pressure augmented peak cough flow in both bulbar and non-bulbar patients with ALS, but insufflation in addition to exsufflation augmented flow only in those patients with VC  $< 50\%$  of predicted. It is likely that patients with milder disease and greater VC have retained adequate chest-wall and lung recoil to provide for increases in peak cough flow with exsufflation alone, and insufflation may not provide additional benefit, although this may not hold true

during upper-respiratory-tract infection. The in-exsufflation pressures in that study were the “maximally tolerated” pressures, which makes it difficult to compare the study to other studies.

Miske et al<sup>48</sup> retrospectively determined the safety, effectiveness, and tolerance of in-exsufflation in pediatric patients with various neuromuscular diseases. The median age at the beginning of in-exsufflation use was 11.3 years, and the median use period was 13.4 months (range 0.5–45.5 months). The insufflation and exsufflation pressures used were independent of diagnosis and age (median  $+30/-30$  cm H<sub>2</sub>O, insufflation range 15–40 cm H<sub>2</sub>O, exsufflation range  $-20$  to  $-50$  cm H<sub>2</sub>O). Of 62 patients treated with in-exsufflation, 8 used no form of mechanical ventilation, 25 received NPPV, and 29 had ventilation via tracheostomy. There were no episodes of pneumothorax, hemoptysis, or symptomatic gastroesophageal reflux during in-exsufflation. Four patients (6%) showed improvement in chronic atelectasis after in-exsufflation (Fig. 8) and 5 patients (8%) were noted by their families to experience fewer pneumonias than prior to starting in-exsufflation. Miske et al<sup>48</sup> stated that, over the relatively short observation period, the benefit of in-exsufflation in reducing acute lower-respiratory-tract infections could not be determined.

As stated above, many of the studies of in-exsufflation in neuromuscular disease have been retrospective and involved diseases of a variably progressive nature, which makes it difficult to control for variables such as quality of home care. Patients with C1–C7 spinal cord injuries participated in a prospective study of airway clearance with in-exsufflation. Patients with tracheostomy and hypersecretion received either manual respiratory kinesitherapy (postural drainage, underwater positive expiratory pressure, assisted cough, manual bag-valve-mask ventilation, and endoscopic bronchoaspiration [the control group]) or manual respiratory kinesitherapy followed by in-exsuffla-

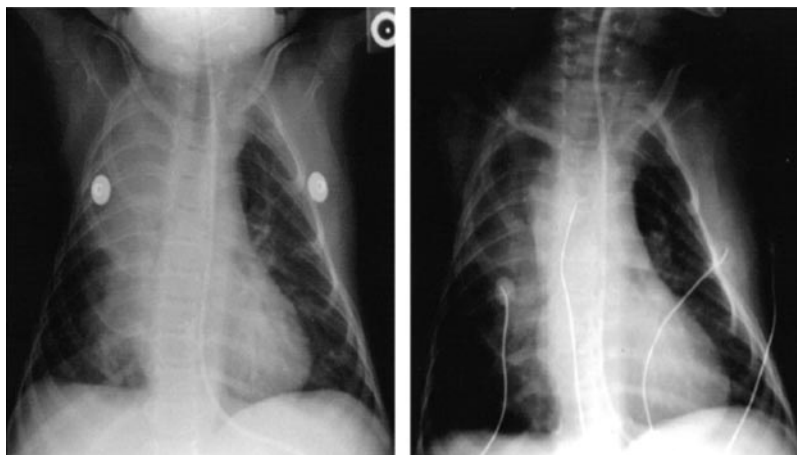


Fig. 8. Resolution of atelectasis in a child with neuromuscular disease after use of insufflation-exsufflation (see text). (From Reference 48, with permission.)

tion (pressure range 15–45 cm H<sub>2</sub>O). Although the exact patient numbers were not included in the article, the groups were well matched. They received 10 treatments each. Only the in-exsufflation group had significant increases in forced expiratory volume in the first second (FEV<sub>1</sub>), forced vital capacity, and peak expiratory flow. There were no reported complications with in-exsufflation therapy.<sup>49</sup>

### Obstructive Lung Disease

The usefulness of in-exsufflation in obstructive lung disease with increased and/or abnormal airway secretions is generally unknown, and there have been few comparisons to more traditional airway clearance methods. Barach and Beck<sup>31</sup> used in-exsufflation in 76 patients with “bronchopulmonary disease,” including asthma, emphysema, and bronchiectasis. They reported marked improvement in dyspnea in 65 patients immediately following in-exsufflation. They also found radiographic improvement in atelectasis in selected patients. When using in-exsufflation with bronchodilator aerosols they found average VC increases of 15% in 12 patients with bronchial asthma, 42% in 34 patients with emphysema, 39% in 10 patients with bronchiectasis, and 25% in patients with neuromuscular disease. This exceeded the VC improvements with bronchodilator alone, but it is unclear whether the improvements were due to better distribution of aerosol during the insufflation phase (and, thus, better, relief of bronchoconstriction), lung recruitment, a reduction of obstructing airway secretions, or all of the above. Importantly, Barach and Beck reported no significant complications in their studies.

Trials of the CoughAssist In-Exsufflator in patients with chronic obstructive pulmonary disease (COPD) have had mixed results. Winck et al<sup>50</sup> compared the use of in-exsufflation in patients with neuromuscular disease to those with severe COPD at insufflation and exsufflation pres-

ures of +20/–20 cm H<sub>2</sub>O, +30/–30 cm H<sub>2</sub>O, and +40/–40 cm H<sub>2</sub>O, with an insufflation time of 3 s and an exsufflation time of 4 s. They measured breathing patterns (with respiratory impedance plethysmography), Borg dyspnea score, peak cough flow, and S<sub>pO<sub>2</sub></sub> before and after in-exsufflation treatments. In the patients with COPD, their dyspnea and S<sub>pO<sub>2</sub></sub> values improved significantly after in-exsufflation at +40/–40 cm H<sub>2</sub>O, without change in breathing pattern that would suggest increased inspiratory or expiratory flow limitation, although, importantly, peak cough flow did not improve.

In another study, patients with COPD underwent manual insufflation, with an insufflation pressure of 20 cm H<sub>2</sub>O, and a manually assisted cough maneuver.<sup>23</sup> Compared to normals and patients with neuromuscular disease, the patients with COPD had lower peak cough flow and expiratory volume. Sivasothy et al suggested that premature peripheral airway closure, exacerbation of hyperinflation with insufflation, or induced bronchoconstriction might have contributed to the reduced cough flows and volumes in the patients with COPD.<sup>23</sup>

### Complications of In-exsufflation

As with any mechanical positive-pressure device, potential complications of in-exsufflation include abdominal distention, aggravation of gastroesophageal reflux, hemoptysis, chest and abdominal discomfort, acute cardiovascular effects, and pneumothorax. However, rarely have these been noted in the literature. Physiological effects on the cardiovascular system were studied early in the development of in-exsufflation. Peripheral venous pressure is increased about one third more than during normal coughing, and blood pressure increases slightly (mean 8 mm Hg in systole and 4 mm Hg in diastole).<sup>51</sup> Pulse can increase or decrease with in-exsufflation, and severe bradyarrhyth-

mias have been seen in patients with high spinal cord injury, and premature ventricular contractions occurred in an adolescent with Duchenne muscular dystrophy.<sup>48,51</sup>

Barach and colleagues<sup>30</sup> reported no adverse effects, including air leaks, in over 2,000 uses of in-exsufflation, except for a transient sensation of “suffocation” in a patient with emphysema, which was relieved after expectoration of large amounts of sputum. Bach<sup>51</sup> noted no episodes of pneumothorax, aspiration of gastric contents, or hemoptysis in over 650 patient-years and hundreds of applications of in-exsufflation in ventilated patients with neuromuscular disease. He also indicated that reducing the insufflation pressure to achieve an inspired volume below the inspiratory reserve volume can avoid the infrequently encountered gastric and abdominal distention. There have been no reported important complications from in-exsufflation in pediatric patients with various types of neuromuscular disease.<sup>48</sup> Prudent measures to avoid complications from in-exsufflation include short rest breaks between applications of in-exsufflation, to avoid hyperventilation, administering in-exsufflation before meals or feedings, vigorous medical treatment of gastroesophageal reflux, and adequate treatment of airway inflammation.

#### Alternatives to In-exsufflation

In-exsufflation may not be necessary for many patients with neuromuscular disease or patients with spinal cord injury but whose bulbar function is intact and in whom peak cough flow can be increased to attain the minimum effective flow (about 4.5–6 L/s) during upper-respiratory-tract infection.

The maximum insufflation capacity is the volume of air that can be held in the lung with the glottis closed.<sup>41</sup> Maintaining chest range of motion and assisting patients in clearing airway secretions by achieving maximum insufflation capacity and therefore maximum peak cough flow can be accomplished with self-administered, manual, or mechanical means. Maximum insufflation capacity is achieved in many patients by breath-stacking, with repetitive insufflations from a bag and mask, or a volume ventilator. It can also be achieved through the self-administered technique glossopharyngeal breathing (sometimes called “frog breathing”),<sup>33,50</sup> which involves the elevation and pump-like action of the tongue, pharyngeal muscles, and glottis to enter successive gulps or boluses of air into the lungs to achieve maximum insufflation capacity. Patients with intact bulbar function can also learn this technique, which allows for voluntary ventilator-free periods, emergency use in the event of ventilator failure, and for assisted cough.<sup>37,52</sup> The glossopharyngeal breathing maximum single-breath capacity can exceed VC by up to 5 times, and patients with little measurable VC can achieve glossopharyngeal breathing maximum single breaths of

> 3 L.<sup>53,54</sup> With insufflation via glossopharyngeal breathing, cough flows were significantly higher than with a maximum inspiration without glossopharyngeal breathing, and peak cough flow can be comparable to that attained with mechanical insufflation.<sup>52,55</sup>

Manually assisted cough, with an abdominal thrust timed to a spontaneous cough after maximum insufflation with bag and mask, mechanical insufflation, or glossopharyngeal breathing is important in augmenting airway clearance, by augmenting peak cough flow.<sup>56</sup> Bach<sup>57</sup> compared unassisted cough to insufflation (with bag and mask or glossopharyngeal breathing) followed by spontaneous cough, to insufflation followed by a cough assisted with an abdominal thrust, in 21 patients with neuromuscular disease. Those who used breath-stacking alone averaged a peak cough flow of  $3.37 \pm 1.07$  L/s versus  $4.27 \pm 1.29$  L/s in those who received added abdominal thrust, compared to their average unassisted peak cough flow of  $1.81 \pm 1.03$  L/s. Few reports have discussed the complications of abdominal thrusts, but theoretical considerations include abdominal organ injury, gastroesophageal reflux, and discomfort. In addition, if there is substantial chest-wall deformity, such as in scoliosis, the maximum insufflation capacity may be compromised and abdominal thrust ineffective.<sup>51,58</sup>

#### Future Directions

Considerations for future studies of in-exsufflation include:

- There has been no systematic study of the device with prior use of bronchodilators, such as long-acting or short-acting  $\beta$  agonists or anticholinergic agents. Patients with underlying airway inflammation and hyperresponsiveness may have airway compromise from bronchoconstriction, which may affect mucociliary clearance. Optimizing airway caliber with anti-inflammatory agents and bronchodilators prior to in-exsufflation could enhance its effectiveness.
- The pediatric studies of in-exsufflation have mostly been limited to patients with spinal muscular atrophy type 1 and Duchenne muscular dystrophy, or included in adult series. Systematic study of children with central nervous system injury or inherited developmental disabilities, with or without tracheostomy, would help determine the potential uses of in-exsufflation.
- The CoughAssist In-Exsufflator has been compared to the intrapulmonary percussive ventilator in limited studies. The intrapulmonary percussive ventilator has shown some success in effecting secretion removal and relief of atelectasis in children and adults with neuromuscular disease.<sup>59,60</sup> High-frequency chest-wall oscillation with



a chest-percussion vest has shown mixed results in reducing decline in VC and altering morbidity and mortality in patents with ALS.<sup>61,62</sup> Comparing the CoughAssist In-Exsufflator to other airway clearance techniques in adults and children with neuromuscular disease would be useful.

- The flow rates that cause sufficient shear and velocity to expel airway secretions are generally unknown with in-exsufflation, so they are inferred from studies of weaning from mechanical ventilation, anecdote, or human and animal studies that used bronchography. And these flow rates may not be applicable to young children or to those with obstructive lung disease. Airway clearance studies with radioaerosols may be useful to determine effective flow rates for mucus clearance in various age groups and disease states.
- Is there a role for in-exsufflation in obstructive lung disease when respiratory muscle weakness or lung disease becomes severe enough to decrease spontaneous cough?
- Should we use in-exsufflation acutely during upper-respiratory-tract-infection-associated respiratory compromise, or on a regular daily basis, with augmentation, during infections?

### Summary

Impaired cough leads to retained secretions, chronic inflammation and infection, increased airway resistance, decreased pulmonary compliance, and respiratory failure, particularly in individuals with neuromuscular weakness. Assisting individuals to clear secretions with multiple strategies, while maintaining chest mobility, is important. The CoughAssist In-Exsufflator has proven to be a useful adjunct for airway clearance in patients with neuromuscular disease and traumatic central nervous system injury; however, further investigation of its use in pediatrics and obstructive lung disease is needed.

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## Discussion

**MacIntyre:** One of the areas where this device intrigues me is in the immediate post-extubation phase. Fifteen to 20 percent of patients require re-intubation, at least in the adult ICUs [intensive care units], and many of those are because patients just can't seem to cough and clear secretions. They're just too drugged with sedatives and the like, and they need a couple of days of assistance with their cough. Would this be a legitimate application? And if so, has it been studied?

**Homnick:** It has been studied to wean patients and prevent re-intubation in neuromuscular disease and is effective. I think the important thing is that these are patients on mechanical ventilation, correct? So that you're probably providing intermittent positive expiratory pressure.

**MacIntyre:** I'm speaking about recently extubated patients. You've taken the tube out, and now you're getting worried, because they're still a little sleepy, and they're not getting the stuff up, and you can hear them kind of gurgling away, and you just say, "If Mr Smith or Mrs Jones would just cough, I'll bet we can keep him or her off the ventilator."

**Homnick:** I think that would be an effective use of the device.

**MacIntyre:** But it hasn't been studied?

**Homnick:** I think it has been studied. I couldn't point you to papers, though.

**Haas:** Just a comment on the observation that patients only use in-exsufflation as needed. I know of at least one report that suggests that if patients don't stay in practice, when they really need therapy then they aren't as effective at using the device.<sup>1</sup>

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**Homnick:** There are a couple of issues with that. I think it's not only effectiveness, but also because patients with neuromuscular disease tend to develop chest restriction, and with time they get degenerative changes in the intercostals, particularly, and restrictive chest. That periodic insufflation is very good for them. It's like exercising any other muscle to avoid contractures. With muscle disease or motor neuron disease it's important to continue to exercise and stretch those muscles, and that's true with the respiratory musculature, as well. So the periodic insufflation makes a lot of sense, rather than using it only intermittently—unless you're using something else as an insufflation device—bag and mask or the patient can take an adequate breath. Sighs are very important, as we know, in part to exercise the chest wall and maintain respiratory musculature in good condition. I would advocate, and we do have our patients using it on a regular basis, whether they're using it twice a day, every day, and then they're augmenting their use during respiratory-tract infection.

**Rubin:** Didn't Carolyn Beardsmore, about 18 years ago, do studies looking at peak cough flow in children who were both healthy and had neuromuscular disease?<sup>1,2</sup> I seem to recall.

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**Schechter:** I just want to comment on some of John Bach's studies.<sup>1</sup> John Bach is this fantastic clinician, and I

think, actually, his papers are all about quality improvement. He's got a proactive, protocolized approach to care of patients with neuromuscular disease, and probably has really superior outcomes, although it's hard to know without registry-type data. It's hard to say that his work demonstrates specifically the role of the In-Exsufflator. His success is really due to the combination of interventions that he applies to patients systematically, proactively, and with very high expectations, which is very similar to some of the things that we see utilized in quality-improvement activities in cystic fibrosis.

1. Bach JR. Update and perspective on non-invasive respiratory muscle aids. Part 2: the expiratory aids. *Chest* 1994;105(5):1538-1544.

**Homnick:** I agree with you completely. I think he treats CoughAssist as an adjunct therapy to everything else he does. I think it's very admirable. And he will tell you that you do not need CoughAssist if you have adequate peak cough flow by other means, realizing that it isn't necessarily good for everyone. But the ultimate that I can see is to avoid hospitalization, to avoid intubation, mechanical ventilation, to maintain patients at home on noninvasive positive-pressure ventilation, and this is the quality-of-life issue that he seems to be most concerned with. And avoid tracheostomy, yes.

**Fink:** Though there's few data on secretions with COPD, it appeared, in at least one study to be tolerated well.<sup>1</sup> I'm old enough that I remember when the Bird respirator came out with the NEEP [negative end-expiratory pressure] attachment. And our patients with floppy airways seemed to be having rather precipitous changes in their status with it, and they pulled it off the market pretty quick. I'd be surprised, because generally the NEEP levels were probably 5 or 10 cm H<sub>2</sub>O of the lowest negative end-expiratory

pressure. Even with the translation from 60 cm H<sub>2</sub>O at the airway, which is of course where NEEP was measured, it seems like we're doing a lot more stress to floppy airways, and if the EPP [equal pressure point] data are right, it sounds like we'd be getting some pretty early closures toward the airway.

1. Sivasothy P, Brown L, Smith IE, Shneerson JM. Effect of manually assisted cough and mechanical insufflation on cough flow of normal subjects, patients with chronic obstructive pulmonary disease (COPD), and patients with respiratory muscle weakness. *Thorax* 2001;56(6):438-444.

**Homnick:** I think there's probably no better way to drive your EPP into the periphery than to apply negative pressure to an airway. Into an unstable airway, anyway, is to drop that below atmospheric, and that's what this device does, which makes it logical then in many patients with obstructive disease; they probably would not be able to tolerate it.

**Hess:** We've had the discussion back home about whether we should use the In-Exsufflator in patients with obstructive lung disease. Someone always points out that if the patient were to cough, forcibly, the transairway pressure would be much greater than what you can get with the In-Exsufflator, is it not?

**Homnick:** COPD patients can generate more than 100 cm H<sub>2</sub>O pressure when they cough.

**Hess:** Which is much more than what you would generate with the negative intraluminal pressure with the In-Exsufflator.

**Fink:** I don't disagree with that. I just think that it's interesting that this is well tolerated. It would be nice to see it examined a little bit better to see if there's a role.

**Homnick:** I think with obstructive diseases such as COPD it would be very selective. Those patients with a considerable emphysematous component—I don't know too much about COPD, I'll admit it—but who don't have very well supported airways probably are those who are not going to benefit from negative pressure in the airway.

**Fink:** From Neil's previous comment, the post-extubation patient who might benefit the most from this are in that period of, "Gee, if they could only cough and clear their airways." These are often COPD patients.

**Homnick:** But we don't have any data on that, at least not here.

**Penn:\*** A further question came to mind when you were talking on outcome measures. I think Neil raised a question earlier on about not being sure about the good outcome measures, and I know it's a topic tomorrow, but, coming from a pharmaceutical background, FEV<sub>1</sub> always comes into my mind because it seems to be the standard. You managed to present a lot of data on these devices without—I don't think you used that once—but you referred quite often to S<sub>pO<sub>2</sub></sub>. And I just ask for your comment on the S<sub>pO<sub>2</sub></sub> as a measure of the lung's performance and how relevant that would be to other areas such as COPD.

**Homnick:** I think it is a reflection of the insufflation of the device, that if you have areas that are under-ventilated, under-oxygenated, if you can insufflate those areas and get better gas mixing, you will increase your saturations. It's not necessarily an effect of mechanical insufflation-exsufflation, but more an effect of lung recruitment that occurs during insufflation. I think that's why it's been used in these studies. FEV<sub>1</sub> has not been used. There is some association of FEV<sub>1</sub> with peak cough flow; with peak cough flow it seems to be the better prognostic indicator for when patients do need CoughAssist. So, FEV<sub>1</sub> has not been used very much.

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