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Criteria for Extubation and Tracheostomy Tube Removal for Patients With Ventilatory Failure*

A Different Approach to Weaning

John R. Bach, MD, FCCP; and Lou R. Saporito, RRT, BS

The purpose of this study was to prospectively compare parameters that might predict successful translaryngeal extubation and tracheostomy tube decannulation. Irrespective of ventilatory function, 62 extubation/decannulation attempts were made on 49 consecutive patients with primarily neuromuscular ventilatory insufficiency who satisfied criteria. Thirty-four patients required 24-h ventilatory support. Noninvasive intermittent positive pressure ventilation (IPPV) was substituted as needed for IPPV via translaryngeal or tracheostomy tubes. Successful decannulation was defined as extubation or decannulation and site closure with no consequent respiratory symptoms or blood gas deterioration for at least 2 weeks. Failure was defined by the appearance of respiratory distress and decreases in vital capacity and oxyhemoglobin saturation despite use of noninvasive IPPV and assisted coughing. The independent variables of age, extent of predecannulation ventilator use, vital capacity, and peak cough flows (PCF) were studied to determine their utility in predicting successful extubation and decannulation. Only the ability to generate PCF greater than 160 L/min predicted success, whereas inability to generate 160 L/min predicted the need to replace the tube. All 43 attempts on patients with PCF greater than 160 L/min succeeded; all 15 attempts on patients with PCF below 160 L/min failed; and of 4 patients with PCF of 160 L/min, 2 succeeded and 2 failed. We conclude that the ability to generate PCF of at least 160 L/min is necessary for the successful extubation or tracheostomy tube decannulation of patients with neuromuscular disease irrespective of ability to breathe.

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Key words: cough; exsufflation; mechanical ventilation; muscular dystrophy; poliomyelitis; respiratory paralysis; respiratory therapy

Abbreviations: ALS=amyotrophic lateral sclerosis; IPPV=intermittent positive pressure ventilation; MI-E=mechanical insufflation-exsufflation; PCF=peak cough flow; SaO₂=oxyhemoglobin saturation; SCI=spinal cord injured; VC=vital capacity; VFBT=ventilator-free breathing time

Although ventilator weaning parameters have been described and their relative importance has been debated, to our knowledge no criteria exist for tracheostomy tube removal. For patients with ventilatory insufficiency secondary to muscle paralysis or impaired chest wall mechanics, even for those with no measurable vital capacity (VC), alveolar ventilation can be maintained long term by noninvasive means.\(^1\)\(^2\) However, although we have succeeded in removing the tracheostomy tubes of many patients with negligible VC,\(^4\)\(^5\) because of inability to mobilize airway secretions, we have failed to decannulate some patients, some of whom no longer required ventilator use. Indeed, although they cause secretions and impair the ability to cough, translaryngeal and tracheostomy tubes are often retained by autonomously breathing individuals for the sole purpose of airway suctioning. We hypothesized that the ability to create expiratory airflow to clear secretions may be an important parameter for determining when it might be safe to extubate or decannulate patients, whether they require ventilatory assistance or not. The purpose of this study was to prospectively compare parameters that might predict successful extubation or tracheostomy tube removal. Tracheal extubation or decannulation, despite ventilator dependence, is part of a different approach to weaning patients primarily with ventilation impairment.

Materials and Methods

A ventilator unit accepted 49 consecutive patients primarily with neuromuscular ventilatory impairment with endotracheal or tr-
Table 1—Clinical Data at Tracheostomy Tube Decannulation for Patients With COPD

<table>
<thead>
<tr>
<th>Age, yr</th>
<th>TIPPV,*</th>
<th>FEV₁, mL</th>
<th>FEV₁ FVC %</th>
<th>Unassisted PCF, L/min</th>
<th>aPCF†</th>
<th>S or F‡</th>
<th>h/‡</th>
<th>F/h‡</th>
<th>C**</th>
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<tbody>
<tr>
<td>72.0</td>
<td>7</td>
<td>870</td>
<td>75</td>
<td>120</td>
<td>300</td>
<td>S</td>
<td>24</td>
<td>12</td>
<td>24††</td>
</tr>
<tr>
<td>72.9</td>
<td>7</td>
<td>700</td>
<td>60</td>
<td>250</td>
<td>250</td>
<td>S</td>
<td>15</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>46.3</td>
<td>6</td>
<td>320</td>
<td>31</td>
<td>250</td>
<td>250</td>
<td>S</td>
<td>24</td>
<td>24</td>
<td>24††</td>
</tr>
<tr>
<td>73.5</td>
<td>6</td>
<td>730</td>
<td>61</td>
<td>&lt;50</td>
<td>&lt;50</td>
<td>F</td>
<td>24</td>
<td>2</td>
<td>24††</td>
</tr>
<tr>
<td>53.0</td>
<td>4</td>
<td>650</td>
<td>55</td>
<td>190</td>
<td>190</td>
<td>S</td>
<td>8</td>
<td>22</td>
<td>8</td>
</tr>
</tbody>
</table>

*Months of attempted weaning from tracheostomy IPPV (TIPPV) before decannulation.
†aPCF-assisted peak cough flows.
‡Decannulation succeeded (S) or failed (F).
§Hours per day of ventilatory support needed at decannulation.
††Months of noninvasive IPPV used following the decannulation attempt.
‡‡Hours per day of ventilatory assistance currently.
†††Hours per day of ventilatory assistance just prior to death.

The patients with chronic hypercapnia so it was not used for quantitative statistical analysis.

Peak cough flows (PCFs), both unassisted and assisted, were measured (Peak Flow Meter; HealthScan Inc; Cedar Grove, NJ). For assisted coughing, a maximum depth insufflation was held with a closed glottis (air stacking), and an abdominal thrust was applied at the instant of glottic opening to maximize PCF. The maximum observed flow in four to seven attempts was noted.

The protocol for the ventilator users can be summarized as follows: switching to portable volume ventilator use, usually on assist/control mode; weaning from oxygen administration (for the patients with neuromuscular disease) by maintaining adequate oxygenation with the use of ventilatory assistance and MI-E to clear secretions; switching to fenestrated cuffed tubes that could then be cuffed; then, once the patient was comfortable using mouthpiece and nasal IPPV as needed with the tube cuffed or a tracheostomy button in place, extubation or decannulation and use of assisted coughing, including MI-E as needed; and finally, weaning from ventilatory assistance by taking fewer and fewer assisted insufflations as tolerated while maintaining normal SaO2 and, for non-COPD patients, normal end-tidal PCO2.

The patients received IPPV via nasal interface or mouthpiece when awake and via nasal interface or lipseal during sleep, as they preferred. Oxygen supplementation was systematically avoided for all but the COPD patients. This optimized the use of oximetry as feedback as well as the use of noninvasive IPPV during sleep. The patients were instructed that desaturations either signaled the need to take assisted breaths to normalize alveolar ventilation or the need for manually or mechanically assisted coughs to clear airway secretions. All patients quickly mastered this concept.

MI-E was used at settings of +30 to +50 to −30 to −50 cm H2O. It was used via the endotracheal or tracheostomy tube with the cuff inflated. For buttoned or decannulated patients, MI-E was used via oral-nasal interfaces with abdominal thrusts delivered during the exsufflation phase. It was used whenever the patient felt the need to cough and especially when bronchial mucous plugging caused oxyhemoglobin desaturation. In this case, it was used until the VC and the SaO2 returned to preplug baselines and secretions were no longer being eliminated. A decrease in baseline SaO2 below 92% in a eucapnic patient with neuromuscular disease despite aggressive assisted coughing at least temporarily precluded further steps toward extubation and signaled the need for further diagnostic workup.

After weaning from supplemental oxygen, the tracheally intubated patients were extubated and directly placed on a regimen of noninvasive IPPV and continued to use MI-E as needed. Five of the 12 patients with neuromuscular disease had been trained in.
receiving IPPV noninvasively before being intubated so they were able to easily use noninvasive IPPV immediately following extubation. The other seven patients required a short training period in noninvasive IPPV during which time those with no VFBT often required “bagging.”

The 49 patients with neuromuscular disease who met the criteria were, therefore, extubated or decannulated irrespective of their ability to breathe autonomously. Successful decannulation was defined as extubation or tracheostomy tube removal and closure of the tracheostomy site with continued use of noninvasive IPPV and assisted coughing as needed, without respiratory distress or blood gas deterioration for at least 2 weeks. Failure was defined by the appearance of progressive oxyhemoglobin desaturation and respiratory distress within 3 days secondary to airway secretion retention that could be relieved only by replacing the tracheostomy tube and resuming MI-E or suctioning through it.

The duration and hours per day of use of invasive IPPV were noted at the time of extubation or tracheostomy tube removal. Univariate and multivariate analyses were performed correlating success and failure with age, VC, PCF, duration, and hours per day of ventilator use. Separate analyses were performed on the spinal cord injured (SCI) patients, the SCI patients not including the six who were ventilator weaned before the first decannulation attempt, the non-SCI patients with primarily ventilatory impairment, and on the whole group of patients with primarily ventilatory impairment. Since there were only five tracheostomized and two tracheally intubated COPD patients, their data were not included in the statistical analyses. Univariate and stepwise discriminate analyses that resulted in p values less than 0.05 were considered to significantly predict the success of the intervention.

**Results**

Forty-nine tracheostomy tube decannulation attempts were made on 37 patients with the following diagnoses: 22 with SCI; 15 with global alveolar hypoventilation, including 11 with progressive neuromuscular disease; 2 with Guillain-Barré syndrome; 1 with obesity hypoventilation syndrome; and 1 with partial lung resection and chronic alveolar hypoventilation. Initial decannulation attempts were successful for 25 patients, 12 initial attempts failed, and on subsequent attempts, 7 succeeded and 5 failed. At the time of the subsequent attempts, five of the seven patients who succeeded and two of the five who failed were already weaned from ventilator use.

Thirty-seven tracheostomy tube decannulation attempts were made on patients with neuromuscular disease who had not been weaned from ventilator use over a mean period of 9.4±13.1 months (range, 1 to 65 months); and following decannulation, 26 required noninvasive IPPV for a mean of 19.8±21.6 months (range, 0.2 to 70 months). Seventeen of these 26 patients still use noninvasive IPPV a mean of 16.8±8.0 h/d (range, 8 to 24 h/d). Seventeen successful transitions from tracheostomy to noninvasive IPPV were on long-term 24-h ventilator users (mean use, 19.5 months; maximum, 65 months) whose primary physicians had recommended maintaining indwelling tracheostomies.

Six decannulation attempts were made on SCI patients who had already been weaned from ventilatory support before the initial attempt; three succeeded and three failed. The three who succeeded had a mean age of 55.6±26.3 years, had been using IPPV via tracheostomy for 14.0±11.3 months before weaning, had VC of 1,470±304 mL, and assisted PCF of 477±258 L/min (range, 275 to 790 L/min). The three who failed had a mean age of 35.6±15.7 years, had been using IPPV via tracheostomy for 7.0±11.4 months before weaning, had VC of 1,200±414 mL, and assisted PCF of 85±58 L/min (range, 50 to 115 L/min). Only the difference in PCF was statistically significant at p<0.05. One patient in the latter group was recently successfully decannulated after 6 months of tracheal sounding had dilated the airway sufficiently to permit assisted PCF in excess of 300 L/min. Thus, 13 decannulation attempts in all were made on patients free of ventilator use; 6 who were ventilator weaned before the initial attempt and 7 who had become free of ventilator use despite initially failing to maintain decannulation.

The results of the univariate and stepwise discriminate analyses of the independent variables associated with success or failure of decannulation are listed in Table 2. Stepwise discriminate analysis indicated that only PCF predicted successful decannulation and did so independently of the other parameters. Univariate analyses confirmed the correlation between PCF and successful decannulation. In addition, univariate analysis indicated a significant correlation between longer use of predecannulation tracheostomy IPPV and successful decannulation for the SCI patients.

The results of the decannulation attempts on the five COPD patients are noted in Table 1. Four of the 5 patients succeeded in being maintained using noninvasive IPPV after extubation (Table 1). Two of these patients died after 6 and 12 months of 24-h noninvasive IPPV, respectively. The COPD patient who failed to respond to decannulation died while using tracheostomy IPPV several months after discharge from the unit.

Since all of the 13 translaryngeal extubation attempts on ventilator users with neuromuscular disease succeeded, no statistical comparisons could be made. These patients had the following diagnoses: SCI, five; progressive neuromuscular disease, five; postpoliomyelitis, one; and obesity hypoventilation syndrome, one patient who was weaned and extubated on two separate occasions. Immediately prior to extubation, these patients had a mean age of 37.3±18.4 years (range, 16.7 to 72.5 years), had been using IPPV via translaryngeal tubes for a mean of 18.2±9.9 days (range, 2 to 32 days), and for a mean of 23.5±1.7 h/d (range, 18 to 24 h/d), and had mean VCs of 575±213 mL (range, 200 to 1,020 mL). Immediately following extubation, their assisted PCFs were 235±62 L/min (range, 197 to 436 L/min). Following extubation, 4 of the 5 SCI patients
were weaned from ventilator use in less than 1 week. The remaining patients have continued to require noninvasive IPPV for a mean of 15.2±8.6 months (range, 2 to 30 months), initially for 24 h/d, and now for 11.6±7.0 h/d. All continue to use at least nocturnal noninvasive IPPV and 2 continue to require noninvasive IPPV 24 h/d.

Recently, 2 additional extubation attempts were made on 2 autonomously breathing patients with advanced lung disease who, following extubation, could not generate 2 L/min of PCF. Both failed.

The fact that the extent of need for ventilatory support was not important for successful extubation or decannulation was emphasized by the fact that the patients who failed to maintain decannulation required fewer hours of ventilator use than those who were successfully decannulated (Table 2). Likewise, all but 1 of the extubated patients required 24-h ventilatory support at the time of successful extubation. In addition, in terms of autonomous breathing ability, 26 of the successfully extubated or decannulated patients had 30 or fewer minutes of VFBT and 33 required 24-h ventilatory support, 4 could breathe adequately when sitting but required nocturnal ventilator use, 6 required between 10 and 20 h of daytime use, and 6 were not using a ventilator at the time of the attempts. In the failed group, only 2 had 30 or fewer minutes of VFBT, 4 required 24-h support, 3 required nocturnal assistance, 5 required between 10 and 20 h of aid, and 6 were not using ventilators.

For the patients who succeeded in maintaining decannulation, precipitous decreases in VC and $\text{SaO}_2$ signaled bronchial mucous plugging; however, VC returned to baseline and $\text{SaO}_2$ normalized as the plugs were eliminated by manually and mechanically assisted coughing. For those who failed, however, plug-related oxyhemoglobin desaturations could not be promptly reversed and baseline $\text{SaO}_2$ decreased until the tube was replaced. All of the failures occurred and the tracheostomy tubes had to be replaced within 2 to 48 h of decannulation.

Of the 18 failed decannulation attempts on 14 patients in all, only 7 patients were not subsequently decannulated and were discharged from the hospital with tracheostomy tubes. Those who initially failed underwent fiberoptic laryngoscopy and several subsequently underwent surgery to relieve obstructing lesions in the upper airway. All patients were treated

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**Table 2—Statistical Comparisons of Dependent Variables Associated With Tracheostomy Tube Decannulation**

<table>
<thead>
<tr>
<th></th>
<th>Succeeded</th>
<th>Failed</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, yr</strong></td>
<td>37.2±20.9</td>
<td>34.1±18.4</td>
</tr>
<tr>
<td><strong>TIPPV</strong></td>
<td>9.7±11.0</td>
<td>3.8±3.4</td>
</tr>
<tr>
<td><strong>VC, mL</strong></td>
<td>1045±707</td>
<td>1053±467</td>
</tr>
<tr>
<td><strong>Hours/day</strong></td>
<td>12.8±10.7</td>
<td>8.7±10.4</td>
</tr>
<tr>
<td><strong>Assisted PCF, L/min</strong></td>
<td>278±157</td>
<td>101±40</td>
</tr>
</tbody>
</table>

For the SCI individuals:

<table>
<thead>
<tr>
<th></th>
<th>19</th>
<th>12</th>
</tr>
</thead>
</table>

For the SCI individuals (not including the 6 patients who were already weaned from ventilator use at the initial attempt):

<table>
<thead>
<tr>
<th></th>
<th>16</th>
<th>9</th>
</tr>
</thead>
</table>

For all patients with primarily ventilatory impairment:

<table>
<thead>
<tr>
<th></th>
<th>32</th>
<th>17</th>
</tr>
</thead>
</table>

For the whole patient group except for those with SCI:

<table>
<thead>
<tr>
<th></th>
<th>13</th>
<th>5</th>
</tr>
</thead>
</table>

*The five patients with COPD were excluded from these analyses.

†Duration of use of tracheostomy IPPV before the decannulation attempt.

‡Hours per day of ventilator use.

§Assisted PCFs following decannulation.

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by air stacking to ever-greater maximum insufflations to increase PCF until adequate to permit decannulation.\textsuperscript{8}

Five successfully decannulated patients who had had indwelling tracheostomy tubes for 4 to 28 months had previously been hospitalized for tube-associated complications. Since the successfully extubated or decannulated patients no longer underwent tracheal suctioning, at least 6 patients who had been hospitalized for ventilatory support for 2 to 5 months and could not be discharged home using tracheostomy IPPV were successfully discharged home in 1 week or less after decannulation. The decannulation process, including training in noninvasive IPPV and assisted coughing and tracheostomy site closure, took 3 to 9 days except for 1 patient with a partial lung resection and Milroy's disease for whom it took 12 days, and for the COPD patients who required more than 2 weeks because of persistent airway secretions and late site closures.

Of the four patients with neuromuscular disease who died, one died from sepsis related to a renal stone, one patient who failed decannulation continued to receive tracheostomy IPPV and died from pneumonia several months after the attempted decannulation, and two died when they were left without personal care assistance and lost their IPPV interfaces. Neither of the latter two patients had VFBT using respiratory muscles but 1 of the 2 could have used glossopharyngeal breathing for up to 8 h before succumbing to fatigue. Except for 2 of the 3 noninvasive IPPV users who died, none of the successfully extubated or decannulated non-COPD patients have required reintubation despite having had subsequent upper respiratory tract infections that necessitated 24-h noninvasive IPPV and aggressive assisted coughing.

**DISCUSSION**

A normal cough requires a precough inspiration or insufflation to about 85 to 90\% of total lung capacity.\textsuperscript{9} Glottic closure follows for about 0.2 s and sufficient intrathoracic pressures are obtained to generate peak transient expiratory flows or PCFs upon glottic opening that are normally 360 to 1000 L/min.\textsuperscript{7,10} Total expiratory volume during normal coughing is about 2.3± 0.5 L.\textsuperscript{9}

For patients with paralytic conditions, PCFs are reduced by the inability to adequately inflate the lungs (reduced VC), abdominal (expiratory) muscle weakness, and often the inability to adequately adduct the vocal cords and close the glottis to retain a deep breath before generating the cough. In addition, bronchospasm or any conditions that result in irreversible upper or lower airway obstruction also reduce PCF.

It has been shown that for patients with paralytic conditions, PCF can be significantly increased by providing maximal insufflations; also, flows can be further increased by appropriately timing an abdominal thrust to glottic opening (manually assisted coughing).\textsuperscript{5} A manual resuscitator or portable ventilator can be used to deliver the deep insufflations. Concomitant weakness of oropharyngeal or glottic muscles, however, can diminish the ability of patients with little VC to air stack insufflations delivered to them, or to hold deep insufflations for effective assisted coughing. Likewise, any conditions that interfere with the application of effective abdominal thrusts such as thoracic cage deformities, scoliosis, abdominal distention, a full stomach, and weight extremes will also diminish assisted PCF.

In this study, all patients for whom greater than 160 L/min of PCF could be achieved were successfully extubated or decannulated, whereas no patients with PCFs under 160 L/min were successfully extubated or decannulated. When assisted coughing is not adequate because of inability to hold a deep breath, diaphragm asymmetries, weight extremes, or abdominal distention, MI-E can be particularly useful. For example, one 45.4-year-old SCI ventilator user's assisted PCF varied from 120 to 170 L/min depending on the extent of his abdominal distention. He relied heavily on MI-E when he was very distended. Manually assisted coughing also requires a cooperative patient, good coordination between the patient and caregiver, and adequate physical effort and often frequent application. MI-E can be simpler and easier.

A mechanical insufflator-exsufflator can provide 600 L/min of expiratory flow directly to the airway. We found MI-E to be very important for eliminating airway secretions and permitting safe extubation for all but the COPD patients. For the 3 patients with neuromuscular disease who were permanently decannulated with PCFs of 160 to 175 L/min, glottic patency and control permitted all 3 to rely heavily on the application of MI-E to facilitate secretion elimination. The increases in VC and SaO\textsubscript{2} noted following mucus extrusion by MI-E applied via the upper airway,\textsuperscript{11} as well as that seen when MI-E was used via transtracheal or tracheostomy tubes, demonstrated its efficacy and eliminated any further need for tracheal suctioning.

MI-E is often ineffective via the upper airway when there is poor glottic stability during exsufflation such as for many patients with bulbar-onset amyotrophic lateral sclerosis (ALS) or for small children who cannot cooperate. It can also be ineffective when there is irreversible upper or lower airway obstruction. Upper airway obstruction is often due to inability to fully abduct the vocal cords or to subglottic stenosis. In COPD, PCFs are diminished and neither manually nor mechanically assisted coughing is usually helpful.

In a recent study of 50 ALS ventilator users,\textsuperscript{12} the 27 who succeeded in using long-term 24-h ventilatory
support by noninvasive means (without a tracheostomy tube) had assisted PCFs greater than 180 L/min (mean, 275±65 L/min). The 23 who could not be treated by noninvasive means of ventilatory support had assisted PCFs of 150±80 L/min. This was true despite the fact that the latter group had higher mean VC (934 vs 580 mL). The severe reduction in PCFs, however, pointed to the more severe glottic impairment in these patients with higher VC. Therefore, the ability to generate greater than 180 L/min of PCF was more important than the ability to breathe in, permitting the long-term management of ALS ventilatory insufficiency without a tracheostomy tube.

Similarly, in this study, the ability to generate at least 160 L/min of PCF, whether unassisted or manually assisted, was found to be more important to predict successful extubation or decannulation and conversion from tracheostomy to noninvasive IPPV than VFBT, VC, age, or pulmonary function in general. This is not surprising since most patients with progressive neuromuscular disorders remain free of ventilator use, often despite chronic lung underventilation, until an intercurrent upper respiratory tract infection and the inability to clear airway secretions triggers acute respiratory failure. Few of these patients attain 160 L/min PCF because few are trained in air stacking and in assisted coughing methods.13

We conclude that the assisted PCF but not age, VFBT, duration or extent of ventilator need, or VC significantly predict the ability to safely extubate or decannulate patients with neuromuscular conditions irrespective of extent of ventilatory insufficiency. Preliminary data suggest that this parameter may also be useful for predicting successful extubation or decannulation of patients with COPD. A weaning approach emphasizing noninvasive monitoring and use of noninvasive inspiratory and expiratory muscle aids can eliminate the need for indwelling tracheostomy tubes and tracheal suctioning for appropriate neuromuscular ventilator users. This is important because, besides significantly reducing cost,14 59 recently surveyed ventilator users who were converted from tracheostomy to predominantly noninvasive IPPV for long-term ventilatory support preferred it for safety, convenience, comfort, speech, swallowing, sleep, and appearance.15 Even patients converted from noninvasive methods to tracheostomy IPPV overwhelmingly preferred the former. There is also evidence that noninvasively supported 24-h ventilator users with functional bulbar musculature have significantly fewer respiratory complications than tracheostomy supported patients.16 Thus, a strategy of weaning from oxygen, extubation, or decannulation, then weaning from noninvasive IPPV as tolerated, is possible for patients with primarily ventilatory impairment when PCFs greater than 160 L/min can be generated; and this approach has many potential advantages over conventional weaning methods for these patients.

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