Section I: Guidelines

Evidence-Based Guidelines for Weaning and Discontinuing Ventilatory Support*

A Collective Task Force Facilitated by the American College of Chest Physicians; the American Association for Respiratory Care; and the American College of Critical Care Medicine

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The discontinuation or withdrawal process from mechanical ventilation is an important clinical issue.1,2 Patients are generally intubated and placed on mechanical ventilators when their own ventilatory and/or gas exchange capabilities are outstripped by the demands placed on them from a variety of diseases. Mechanical ventilation also is required when the respiratory drive is incapable of initiating ventilatory activity either because of disease processes or drugs. As the conditions that warranted placing the patient on the ventilator stabilize and begin to resolve, attention should be placed on removing the ventilator as quickly as possible. Although this process often is termed “ventilator weaning” (implying a gradual process), we prefer the more encompassing term “discontinuation.”

Unnecessary delays in this discontinuation process increase the complication rate for mechanical ventilation (e.g., pneumonia or airway trauma) as well as the cost. Aggressiveness in removing the ventilator, however, must be balanced against the possibility that premature discontinuation may occur. Premature discontinuation carries its own set of problems, including difficulty in reestablishing artificial airways and compromised gas exchange. It has been estimated that as much as 42% of the time that a medical patient spends on a mechanical ventilator is during the discontinuation process.3 This percentage is likely to be much higher in patients with more slowly resolving lung disease processes.

There are a number of important issues involved in the management of a mechanically ventilated patient whose disease process has begun to stabilize and/or reverse such that the discontinuation of mechanical ventilation be-

Abbreviations: AHCPR = Agency for Healthcare Policy and Research; ASV = adaptive support ventilation; CPAP = continuous positive airway pressure; FIO2 = fraction of inspired oxygen; HCP = health-care professional; IMV = intermittent mandatory ventilation; LOS = length of stay; LR = likelihood ratio; MMV = minimum minute ventilation; NPPV = noninvasive positive-pressure ventilation; NRCU = noninvasive respiratory-care unit; Pdi = transdiaphragmatic pressure; PEEP = positive end-expiratory pressure; PMV = prolonged mechanical ventilation; RWC = regional weaning center; SBT = spontaneous breathing trial;

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CHEST / 120 / 6 / DECEMBER, 2001 SUPPLEMENT 375S
comes a consideration. First, an understanding of all the reasons that a given patient required a mechanical ventilator is needed. Only with this understanding can medical management be optimized. Second, assessment techniques to identify patients who are capable of ventilator discontinuation need to be utilized. Ideal assessment techniques should be able to easily and safely distinguish which patients need prompt discontinuation and which need continued ventilatory support. Third, ventilator management strategies for stable/recovering patients who still require some level of ventilatory support need to be employed. These strategies need to minimize both complications and resource consumption. Fourth, extended management plans (including tracheotomy and long-term ventilator facilities) need to be considered for the long-term ventilator-dependent patient.

To address many of these issues, the Agency for Healthcare Policy and Research (AHCPR) charged the McMaster University Evidence Based Practice Center to perform a comprehensive evidence-based review of many of the issues involved in ventilator weaning/discontinuation. Led by Deborah Cook, MD, an exhaustive review of several thousand articles in the world literature resulted in a comprehensive assessment of the state of the literature in 1999. At the same time, the American College of Chest Physicians, the Society for Critical Care Medicine, and the American Association for Respiratory Care formed a task force to produce evidence-based clinical practice guidelines for managing the ventilator-dependent patient during the discontinuation process. The charge of this task force was to utilize the McMaster AHCPR report as well as their own literature review to address the following five issues: (1) the pathophysiology of ventilator dependence; (2) the criteria for identifying patients who are capable of ventilator discontinuation; (3) ventilator management strategies to maximize the discontinuation potential; (4) the role of tracheotomy; and (5) the role of long-term facilities. Review/writing teams were formed for each of these issues.

From these evidence-based reviews, a series of recommendations were developed by the task force, which are the basis of this report. Each recommendation is followed by a review of the supporting evidence, including an assessment of the strength of the evidence (Table 1). As there were many areas in which evidence was weak or absent, the expert opinion of the task force was relied on to “fill in the gaps.” Consensus was reached, first, by team discussions and, later, through the repeated cycling of the draft through all members of the task force.

Both the McMaster AHCPR group and the task force recognized the needs for the future. These include more randomized controlled trials to look at a number of issues. Among the more important questions that need answering are the following: (1) Which criteria are the best indicators of the reversal of respiratory failure in the screening process? (2) What factors are involved in ventilator dependence, and which measurement techniques are most useful in determining ultimate success in the discontinuation process? (3) In balancing discontinuation aggressiveness against the risks of premature discontinuation, what is a reasonable reintubation rate in patients who recently have been removed from ventilatory support? (4) What is the value of trying to reduce the levels of partial ventilator support in stable/recovering patients who have failed a discontinuation assessment? (5) What role do tracheotomies have in facilitating the discontinuation process? (6) What is the role of the long-term facility, and when should patients be transferred to such facilities?

**Pathophysiology of Ventilator Dependence**

**Introduction**

Patients require mechanical ventilatory support when the ventilatory and/or gas exchange capabilities of their respiratory system fail. This failure can be the result of processes both within the lung as well as in other organ systems, most notably the CNS and the cardiovascular system. Although patients may be dependent on ventilatory support for brief periods of anesthesia or neuromuscular blockade, the term “ventilator dependent” is usually reserved for patients with a need for mechanical ventilation beyond 24 h or by the fact that they have failed to respond during discontinuation attempts. Under these circumstances, the clinical focus should be not only on ventilator management but also should include a search for all of the possible reasons (especially potentially reversible ones) that may explain the ventilator dependency.

**Recommendation 1:** In patients requiring mechanical ventilation for > 24 h, a search for all the causes that may be contributing to ventilator dependence should be undertaken. This is particularly true in the patient who has failed attempts at withdrawing the mechanical ventilator. Reversing all possible ventilatory and nonventilatory issues should be an integral part of the ventilator discontinuation process.

**Evidence (Grade B)**

There are a number of specific reasons why patients may be ventilator-dependent (Table 2). Determining which factor or factors may be involved in a given patient requires both clinical awareness of these factors as well as focused clinical assessments. The search for the underlying causes for ventilator dependence may be especially important if previously unrecognized, but reversible, conditions are discovered.

### Table 1—Grades of Evidence

<table>
<thead>
<tr>
<th>Grades</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Scientific evidence provided by well-designed, well-conducted, controlled trials (randomized and nonrandomized) with statistically significant results that consistently support the guideline recommendation</td>
</tr>
<tr>
<td>B</td>
<td>Scientific evidence provided by observational studies or by controlled trials with less consistent results to support the guideline recommendation</td>
</tr>
<tr>
<td>C</td>
<td>Expert opinion supported the guideline recommendation, but scientific evidence either provided inconsistent results or was lacking</td>
</tr>
</tbody>
</table>
Neurologic Issues: The ventilatory pump controller in the brainstem is a rhythm and pattern generator, which receives feedback from cortical, chemoreceptive, and mechanoreceptive sensors. The failure of this controller can come from several factors.8–12 These factors can be either structural (e.g., brainstem strokes or central apneas) or metabolic (e.g., electrolyte disturbances or sedation/narcotic usage13,14). The failure of the peripheral nerves also can be the result of either structural factors15 or metabolic/drug factors.16,17 A unique neurologic dysfunction that also could cause ventilator dependence is obstructive sleep apnea, in which an artificial airway may be necessary to maintain airway patency.10,11

Respiratory System Muscle/Load Interactions: Often, patients who exhibit ventilator dependence do so because there appears to be a mismatch between the performance capacity of the ventilatory pump and the load placed on it (i.e., the capacity/load imbalance hypothesis).18–23 There is ample evidence that ventilatory pump performance may be impaired in ventilator-dependent patients because ventilatory muscles are weak. This may be a consequence of atrophy and remodeling from inactivity.2,24 It also may be a consequence of injury from overuse and of insults associated with critical illness neuropathy and myopathy.25–29 A number of drugs (e.g., neuromuscular blockers, aminoglycosides, and corticosteroids) also can contribute to myopathy,30–32 as can various metabolic derangements (see below). Finally, dynamic hyperinflation can put ventilatory muscles in a mechanically disadvantageous position.33 In a number of studies, patients who failed to respond to a withdrawal from mechanical ventilation tended to be weaker (i.e., they had a lower performance capacity) than those who succeeded,34–49 but, in general, the within-group variability in respiratory muscle strength was too large to justify general conclusions.

Ventilatory muscle fatigue also could contribute to poor muscle performance. However, the role of fatigue in ventilator dependence is not well-understood, and the studies performed to date21,26,50–54 have failed to delineate the sensitivity and specificity of specific fatigue tests in ventilator-dependent patients. Ventilatory support reduction-related changes in transdiaphragmatic pressure (Pdi), respiratory rate, and thoracoabdominal dysynchrony are clearly not specific manifestations of respiratory muscle fatigue.55–60 The most promising diagnostic test of diaphragm contractility to date is the Pdi measurement during twitch stimulation of the phrenic nerves.21,61 However, too few patients have been studied with this technique to draw any meaningful conclusions about the prevalence of diaphragm fatigue that is attributable to ventilator dependence.

The load on the ventilatory muscles is a function of ventilation demands and respiratory system mechanics (i.e., primarily compliance and resistance). Normal minute ventilation during spontaneous breathing is generally < 10 L/min, normal respiratory system compliance (i.e., tidal volume/static inflation pressure) is generally > 50 to 100 mL/cm H2O, and normal airway resistance (i.e., peak static inflation pressure/constant inspiratory flow) is generally < 5 to 15 cm H2O/L/s. Ventilation demands can increase as a consequence of increased oxygen demands in patients with sepsis or increased dead space in patients with obstructive diseases. Compliance worsening can be a consequence of lung edema, infection, inflammation, or fibrosis, and of chest wall abnormalities such as edema or surgical dressings. Resistance worsening can be a consequence of bronchoconstriction and airway inflammation. Additional load also can be imposed by narrow endotracheal tubes and by insensitive or poorly responsive ventilator demand valves.

The load imposed by ventilation demands interacting with respiratory system mechanics can be expressed as respiratory work, the pressure-time integral, or the change in metabolism (i.e., the oxygen cost attributable to breathing). Many studies10,35,62–66 show that patients who are ventilator-dependent tend to have larger respiratory muscle loads than do patients who can be withdrawn from mechanical ventilation. In patients with airways obstruction, the load imposed by dynamic hyperinflation has received particular attention as an important contributor to ventilator dependence.23,31,65,67–71 As is true for measures of ventilatory pump capacity, however, most investigators report a considerable overlap in load parameters between patients with different discontinuation outcomes.

Patients who go on to fail to respond to ventilator withdrawal attempts because of a capacity/load imbalance tend to display rapid, shallow breathing patterns.2,72,73 This pattern is advantageous from an energetics perspective, but it is also associated with increased dead space and wasted ventilation, and hence with impaired CO2 elimination. Chemoreceptive and mechanoreceptive feedback into the neural control of breathing is not well-understood, and thus it is difficult to distinguish whether this breathing pattern is a consequence of a reduced respiratory drive per se or an inability of ventilatory muscles to respond to an appropriately increased neural stimulus.59,62,65,71,72

Table 2—Causes of Ventilator Dependency

<table>
<thead>
<tr>
<th>Causes</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>Neurologic controller</td>
<td>Central drive; peripheral nerves</td>
</tr>
<tr>
<td>Respiratory system</td>
<td>Mechanical loads: respiratory system mechanics; imposed loading</td>
</tr>
<tr>
<td>Ventilatory muscle properties: inherent strength/endurance; metabolic state/</td>
<td></td>
</tr>
<tr>
<td>nutrients/oxygen delivery and</td>
<td>extraction</td>
</tr>
<tr>
<td>Gas exchange properties: vascular properties and ventilation/perfusion matching</td>
<td></td>
</tr>
<tr>
<td>Cardiovascular system</td>
<td>Cardiac tolerance of ventilatory muscle work; peripheral oxygen demands</td>
</tr>
<tr>
<td>Psychological issues</td>
<td></td>
</tr>
</tbody>
</table>
spontaneous also have been shown to deteriorate under conditions of semistarvation. In contrast, overfeeding also can impair the ventilator withdrawal process by leading to excess CO₂ production, which can further increase the ventilation loads on ventilatory muscles. Studies have suggested that proper nutritional support can increase the likelihood of the success of ventilator withdrawal. A number of electrolyte imbalances also can impair ventilatory muscle function. Phosphate deficiency has been associated with respiratory muscle weakness and ventilator withdrawal failure. A study demonstrating improved Pdi values with the repletion of serum phosphorus levels in patients receiving mechanical ventilation, however, did not specifically address the issue of ventilator withdrawal. Magnesium deficiency also has been reported to be associated with muscle weakness, although the relationship to ventilator dependence has not been specifically addressed. Finally, bicarbonate excretion from inappropriate overventilation (often occurring in COPD patients with chronic baseline hypercapnia) can impair ventilator withdrawal efforts as the patient has a diminished capacity to compensate for hypercapnia. Severe hypothyroidism and myxedema directly impair diaphragmatic function and blunt ventilatory responses to hypercapnia and hypoxia. Other hormonal factors that are important for optimal muscle function include insulin/glucagon and adrenal corticosteroids.

As in other organs, adequate oxygen delivery and oxygen uptake by the ventilatory muscles is necessary for proper muscle function. Impaired oxygen delivery can be a consequence either of inadequate oxygen content or of inadequate cardiac output. Impaired oxygen uptake occurs most commonly during systemic inflammatory syndromes such as sepsis.

Gas Exchange Factors: Gas exchange abnormalities can develop during ventilatory support reductions for several reasons. Various lung diseases produce ventilation-perfusion imbalances and shunts. Ventilator dependence thus may be a consequence of a need for high levels of expiratory pressure and/or the fraction of inspired oxygen (FiO₂) to maintain an adequate oxygen content. A patient with hypoxemia also can develop a fall in mixed venous Po₂ levels from the cardiovascular factors described below.

Cardiovascular Factors: Several groups of investigators have drawn attention to cardiovascular responses in ventilator-dependent patients and have emphasized the potential for ventilatory support reductions to induce ischemia or heart failure in susceptible patients with limited cardiac reserve. Putative mechanisms include the following: (1) increased metabolic demands, and hence circulatory demands, that are associated with the transition from mechanical ventilation to spontaneous breathing in patients with limited cardiac reserve; (2) increases in venous return as the contracting diaphragm displaces blood from the abdomen to the thorax; and (3) the increased left ventricular afterload that is imposed by negative pleural pressure swings. Lemaire and colleagues demonstrated left ventricular dysfunction (i.e., the pulmonary capillary wedge pressure increased from 8 to 25 mm Hg) during failed ventilator withdrawal attempts in 15 patients with COPD. Following diuresis, 9 of these 15 patients were successfully withdrawn from the ventilator.

Psychological Factors: Psychological factors may be among the most important nonrespiratory factors leading to ventilator dependence. Fear of the loss of an apparent life support system as well as social/familial/economic issues all may play a role. Stress can be minimized by frequent communication among the staff, the patient, and the patient’s family. Environmental stimulation using television, radio, or books also appears to improve psychological functioning. Ambulation using a portable ventilator (or bagging) has been shown to benefit attitudes and outlooks in long-term ventilator-dependent patients. Sleep deprivation may cause impairment of the respiratory control system, although this may be related to accompanying factors rather than to sleep deprivation per se. Finally, biofeedback may be helpful in decreasing the weaning time in patients who are having difficulty withdrawing from ventilator support.

Criteria to Assess Ventilator Dependence

Introduction

The process of discontinuing mechanical ventilatory support begins with a recognition of adequate recovery from acute respiratory failure. Thereafter, careful clinical assessments are required to determine the patient’s readiness for subsequent discontinuation of ventilatory support and, ultimately, extubation. To facilitate this process, investigators have focused on identifying objective criteria to determine the answers to the following questions: When can efforts to discontinue ventilation be initiated? What assessment strategies will best identify the patient who is ready for ventilator discontinuation? When should extubation be carried out, and how can extubation outcome best be predicted?

Evidence to answer these questions comes largely from observational studies in which a certain parameter (or set of parameters) is compared in a group of patients who either successfully or unsuccessfully have been removed from the ventilator. The general goal of these studies is to find “predictors” of outcome. Evaluating the results from these types of studies can be difficult for several reasons.

First, the “aggressiveness” of the clinician/investigator’s weaning and discontinuation philosophy needs to be understood, as it will affect the performance of a given predictor. A very aggressive clinical philosophy will maximize the number of patients withdrawn from ventilatory support but could also result in a number of premature discontinuations with a subsequent need for reintubations and/or reinstitution of support. In contrast, a less aggressive clinical philosophy will minimize premature discontinuations but could also unnecessarily prolong ventilatory support in other patients. Unfortunately, there are no good data to help clinicians to determine the best balance between premature and delayed discontinuations in evaluating a given discontinuation strategy. Clearly, extubation...
failure should be avoided whenever possible because the need for reintubation carries an 8-fold higher odds ratio for nosocomial pneumonia⁹⁹ and a 6-fold to 12-fold increased mortality risk.⁹⁰–⁹⁶ In contrast, the maintenance of unnecessary ventilator support carries its own burden of patient risk for infection and other complications.⁰⁴,⁰⁵ Reported reintubation rates range from 4 to 23% for different ICU populations⁰⁰,⁰¹,⁰³,⁰⁴,⁰⁶–¹¹⁰ and may be as high as 33% in patients with mental status changes and neurologic impairment.⁰³ Although the optimal rate of reintubation is not known, it would seem likely to rest between 5% and 15%.

Second, a number of methodological problems exist with most of these observational studies. For instance, patients are recruited into these studies because investigators believe that there is some reasonable chance of supporting patients in these observational studies. For instance, between 5% and 15%.

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Second, a number of methodological problems exist with most of these observational studies. For instance, patients are recruited into these studies because investigators believe that there is some reasonable chance of success for ventilator discontinuation. These “entry” criteria often include some form of clinical judgment or intuition, making results from one study difficult to compare to another. In addition, clinician/investigators deciding to proceed with ventilator discontinuation/extubation often have not been blinded to the parameters being analyzed as possible predictors. Indeed, the parameter being analyzed may often enter into the clinical decision on whether either to continue or to discontinue ventilatory support. Other methodological problems with these observational studies include different measurement techniques of a given parameter from study to study, large coefficients of variation with repeated measurements or techniques of a given parameter from study to study, large changes in probability. ¹¹⁵

Finally, because some investigators report data as continuous values (eg, means) rather than providing defined threshold values, combining studies using meta-analytic techniques often cannot be done.

Recommendation 2: Patients receiving mechanical ventilation for respiratory failure should undergo a formal assessment of discontinuation potential if the following criteria are satisfied:

1. Evidence for some reversal of the underlying cause for respiratory failure;
2. Adequate oxygenation (eg, $Pao_2/Fio_2$ ratio > 150 to 200; requiring positive end-expiratory pressure [PEEP] ≤ 5 to 8 cm H₂O; $Fio_2$ ≤ 0.4 to 0.5); and pH (eg, ≥ 7.25);
3. Hemodynamic stability, as defined by the absence of active myocardial ischemia and the absence of clinically significant hypotension (ie, a condition requiring no vasopressor therapy or therapy with only low-dose vasopressors such as dopamine or dobutamine, < 5 µg/kg/min); and
4. The capability to initiate an inspiratory effort.

The decision to use these criteria must be individualized. Some patients not satisfying all of the above criteria (eg, patients with chronic hypoxemia values below the thresholds cited) may be ready for attempts at the discontinuation of mechanical ventilation.

Rationale and Evidence (Grade B)

While some investigators argue that the process of discontinuation starts as soon as the patient is intubated, it would seem reasonable that an appropriate level of ventilatory support should be maintained until the underlying cause of acute respiratory failure and any complicating issues have shown some sign of reversal. Indeed, patients with unresolving respiratory failure who require high levels of ventilatory support are probably at high risk for respiratory muscle fatigue (and the consequent prolongation of the need for mechanical ventilation) if aggressive reductions in support are undertaken.⁵⁰,⁵²,¹¹⁶–¹¹⁸

The criteria used by clinicians to define disease “reversal,” however, have been neither defined nor prospectively evaluated in a randomized controlled trial. Rather, various combinations of subjective assessment and objective criteria (eg, usually gas exchange improvement, mental status improvement, neuromuscular function assessments, and radiographic signs) that may serve as surrogate markers of recovery have been employed (Table 3).⁰¹–⁰³,¹⁰⁷–¹⁰⁹,¹¹⁹,¹²⁰

CHEST / 120 / 6 / DECEMBER, 2001 SUPPLEMENT 3795
Table 3—Criteria Used in Weaning/Discontinuation Studies101–103,107–109,119,120 To Determine Whether Patients Receiving High Levels of Ventilatory Support Can Be Considered for Discontinuation (ie, Entered Into the Trials)*

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Description</th>
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<tbody>
<tr>
<td>Objective measurements</td>
<td>Adequate oxygenation (eg, Po2 ≥ 60 mm Hg on Fio2 ≤ 0.4; PEEP ≤ 5–10 cm H2O; Po2/Fio2 ≥ 150–300); Stable cardiovascular system (eg, HR ≤ 140; stable BP; no (or minimal) pressors) Afefrile (temperature &lt; 38°C) No significant respiratory acidosis Adequate hemoglobin (eg, Hgb ≥ 8–10 g/dL) Adequate mentation (eg, arousable, GCS ≥ 13, no continuous sedative infusions) Stable metabolic status (eg, acceptable electrolytes)</td>
</tr>
<tr>
<td>Subjective clinical assessments</td>
<td>Resolution of disease acute phase; physician believes discontinuation possible; adequate cough</td>
</tr>
</tbody>
</table>

*Hgb = hemoglobin; HR = heart rate; GCS = Glasgow coma scale.

It should be noted, however, that some patients who have not ever met one or more of these criteria still have been shown to be capable of eventual liberation from the ventilator.104

These “clinical assessments” of the status of the patient’s respiratory failure, however, are not enough to make decisions on the discontinuation of support. For example, one survey121 of intensivists using clinical judgment to assess the potential for discontinuation found a sensitivity of only 35% (6 of 17 patients who were successfully discontinued were identified) and a specificity of 79% (11 of 14 patients who failed discontinuation were identified). Moreover, in two large trials,107,109 despite the presence of apparent disease stability/reversal, prior to performing a screening SBT the managing clinicians did not recognize that discontinuation was feasible in almost two thirds of the subjects. Thus, the conclusion is that some evidence of “clinical” stability/reversal is a key first step in assessing for discontinuation potential but that more focused assessments are needed before deciding to continue or discontinue ventilatory support.

Recommendation 3: Formal discontinuation assessments for patients receiving mechanical ventilation for respiratory failure should be performed during spontaneous breathing rather than while the patient is still receiving substantial ventilatory support. An initial brief period of spontaneous breathing can be used to assess the capability of continuing onto a formal SBT. The criteria with which to assess patient tolerance during SBTs are the respiratory pattern, the adequacy of gas exchange, hemodynamic stability, and subjective comfort. The tolerance of SBTs lasting 30 to 120 min should prompt consideration for permanent ventilator discontinuation.

Rationale and Evidence (Grade A)

Because clinical impression is so inaccurate in determining whether or not a patient meeting the criteria listed in Table 3 will successfully discontinue ventilator support, a more focused assessment of discontinuation potential is necessary. These assessments can be performed either during spontaneous breathing or while the patient is still receiving substantial ventilatory support. These assessments can be used not only to drive decisions on weaning and discontinuation (ie, functioning as predictors) but also to offer insight into mechanisms of discontinuation failures.

The McMaster AHICPR report4 found evidence in the literature supporting a possible role for 66 specific measurements as predictors. Some of these (eg, the negative effects of the duration of mechanical ventilation and the length of/difficulty of surgery4,122–124) were derived from general clinical observations, but most were from studies on focused assessments of the patient’s respiratory system. From these, the McMaster AHICPR group identified eight parameters that had consistently significant LRs to predict successful ventilator discontinuation in several studies. Some of these measurements are made while the patient is still receiving ventilatory support; others require an assessment during a brief period of spontaneous breathing. These parameters, their threshold values, and the range of reported LRs are given in Table 4. It should be noted that despite the statistical significance of these parameters, the generally low LRs indicate that the clinical applicability of these parameters alone to individual patients is low.

Although assessments that are performed while a patient is receiving substantial ventilatory support or during a brief period of spontaneous breathing (Table 3, 4) can yield important information about discontinuation potential, assessments that are performed during a formal, carefully monitored SBT appear to provide the most useful information to guide clinical decision making regarding discontinuation. Indeed, because of the efficacy and safety of a properly monitored SBT (see below), the assessments in Table 4 that are performed to predict SBT outcome are generally unnecessary.

In concept, the SBT should be expected to perform well, as it is the most direct way to assess a patient’s performance without ventilatory support. Indeed, the evidence for this concept is quite strong. As can be seen in Table 5, multiple studies have found that patients tolerant of SBTs that are 30 to 120 min in length were found to have successful discontinuations at least 77% of the time.

Because the 12 to 42% of patients in the Table 5 studies failing the SBTs were not systematically removed from ventilatory support, the ability of a failed SBT to predict the need for ventilator dependence (ie, negative predictive
value) cannot be formally assessed. Indeed, it is conceivable that iatrogenic factors such as endotracheal tube discomfort or continuous positive airway pressure (CPAP) demand-valve insensitivity/unresponsiveness, rather than true ventilator dependence, caused the failure of the SBT in at least some of these patients. Thus, it is unclear how many patients who are unable to tolerate an SBT would still be able to tolerate long-term ventilator discontinuation. Although the number is likely to be small, it is probably not zero, and this needs to be considered when dealing with patients who repeatedly fail an SBT.

The criteria used to define SBT “tolerance” are often integrated indexes, since, as noted above, single parameters alone perform so poorly. These integrated indexes usually include several physiologic parameters as well as clinical judgment, incorporating such difficult-to-quantify factors as “anxiety,” “discomfort,” and “clinical appearance.” The criteria that have been used in several large trials are given in Table 6.

A potential concern about the SBT is safety. Although unnecessary prolongation of a failing SBT conceivably could precipitate muscle fatigue, hemodynamic instability, discomfort, or worsened gas exchange, there are no data showing that SBTs contribute to any adverse outcomes if terminated promptly when failure is recognized. Indeed, in a cohort of > 1,000 patients in whom SBTs were routinely administered and properly monitored as part of a protocol, only one adverse event was thought to be even possibly associated with the SBT.

There is evidence that the detrimental effects of ventilatory muscle overload, if it is going to occur, often occur early in the SBT. Thus, the initial few minutes of an SBT should be monitored closely before a decision is made to continue (this is often referred to as the “screening” phase of an SBT). Thereafter, the patient should continue the trial for at least 30 min but for not > 120 min to assure maximal sensitivity and safety. It also appears that whether the SBT is performed with low levels of CPAP (e.g., 5 cm H₂O), low levels of pressure support (e.g., 5 to 7 cm H₂O), or simply as “T-piece” breathing has little effect on outcome.

Recommendation 4: The removal of the artificial airway from a patient who has successfully been discon...

Table 5—Frequency of Tolerating an SBT in Selected Patients and Rate of Permanent Ventilator Discontinuation Following a Successful SBT

<table>
<thead>
<tr>
<th>Study</th>
<th>Pts Receiving SBT</th>
<th>Pts Tolerating SBT</th>
<th>Pts Discontinuing Ventilation</th>
<th>Pts Having Ventilation Reinstated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Esteban et al</td>
<td>546</td>
<td>416 (76)</td>
<td>372</td>
<td>58 (16)</td>
</tr>
<tr>
<td>Ely et al</td>
<td>113</td>
<td>88 (78)</td>
<td>65</td>
<td>5 (4)</td>
</tr>
<tr>
<td>Dojat et al</td>
<td>98</td>
<td>22 (58)</td>
<td>22</td>
<td>5 (23)</td>
</tr>
<tr>
<td>Esteban et al</td>
<td>246</td>
<td>192 (78)</td>
<td>192</td>
<td>36 (19)</td>
</tr>
<tr>
<td>Esteban et al</td>
<td>270†</td>
<td>237 (89)</td>
<td>32 (14)</td>
<td>29 (13)</td>
</tr>
</tbody>
</table>

*Values given as No. (%). Pts = patients.  
†30-min SBT.  
‡120-min SBT.
tined from ventilatory support should be based on assessments of airway patency and the ability of the patient to protect the airway.

Rationale and Evidence (Grade C)

Exubation failure can occur for reasons distinct from those that cause discontinuation failure. Examples include upper airway obstruction or the inability to protect the airway and to clear secretions. The risk of postextubation upper airway obstruction increases with the duration of mechanical ventilation, female gender, trauma, and repeated or traumatic intubation.\(^{106}\) The detection of an air leak during mechanical ventilation when the endotracheal tube balloon is deflated can be used to assess the patency of the upper airway (cuff leak test).\(^{134}\) In a study of medical patients,\(^ {135}\) a cuff leak of < 110 mL (ie, average of three values on six consecutive breaths) measured during assist control ventilation within 24 h of extubation identified patients at high risk for postextubation stridor. Although others have not confirmed the utility of the cuff leak test for predicting postextubation stridor,\(^ {136}\) many patients who develop this can be treated with steroids and/or epinephrine (and possibly with noninvasive ventilation and/or heliox) and do not necessarily need to be reintubated. Steroids and/or epinephrine also could be used 24 h prior to extubation in patients with low cuff leak values. It is also important to note that a low value for cuff leak may actually be due to encrusted secretions around the tube rather than to a narrowed upper airway. Despite this, reintubation equipment (including tracheostomy equipment) should be readily available when extubating patients with low cuff leak values.

The capacity to protect the airway and to expel secretions with an effective cough would seem to be vital for extubation success, although specific data supporting this concept are few. Successful extubations have been reported\(^ {137}\) in a select group of brain-injured, comatose patients who were judged to be capable of protecting their airways. However, it is difficult to extrapolate this experience to more typical ICU patients, and many would argue that some capability of the patient to interact with the care team should be present before the removal of an artificial airway. Airway assessments generally include noting the quality of cough with airway suctioning, the absence of “excessive” secretions, or the frequency of airway suctioning (eg, every 2 h or more).\(^ {34,108,138}\) Coplin et al\(^ {137}\) devised an “airway care score,” which semiquantitatively assesses cough, gag, suctioning frequency, and sputum quantity, viscosity, and character, that predicted extubation outcomes. Peak cough flows of > 160 L/min predict successful translaryngeal extubation or tracheostomy tube decannulation in neuromuscular or spinal cord-injured patients.\(^ {139}\)

MANAGING THE PATIENT WHO HAS FAILED AN SBT

Introduction

The failure of a patient to complete an SBT raises two important questions. First, what caused the SBT failure, and are there readily reversible factors that can be corrected? Second, how should subsequent ventilatory support be managed? Specifically, should an SBT be tried again? If so, when? What form of ventilatory support should be provided between SBTs, and should support be at a constant high level or should efforts be made to routinely reduce the level of support gradually (ie, to wean support)?

Evaluating evidence addressing mechanical ventilatory support strategies is particularly problematic. This is because trials comparing two or more approaches to ventilator management compare not only the modes of ventilation but also how those modes are used. Ideally, trial design should be such that management philosophies and the aggressiveness of support reduction are similar in each strategy being evaluated. Unfortunately, this is often not the case, as investigator experience with one approach has a tendency to result in more favorable “rules” of support reduction for that approach compared to others.

Recommendation 5: Patients receiving mechanical ventilation for respiratory failure who fail an SBT should have the cause for the failed SBT determined. Once reversible causes for failure are corrected, and if the patient still meets the criteria listed in Table 3, subsequent SBTs should be performed every 24 h.

Table 6—Criteria Used in Several Large Trials\(^ {101,102,105,106,110,119,120}\) To Define Tolerance of an SBT\(^ *\)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective measurements indicating tolerance/success</td>
<td>Gas exchange acceptability ((\text{SpO}_2 \geq 85%); (\text{PaO}_2 \geq 50-60) mm Hg; (\text{pH} \geq 7.32); increase in (\text{PaCO}_2 \leq 10) mm Hg); Hemodynamic stability (HR &lt; 120-140 beats/min; HR not changed &gt; 20%; systolic BP &lt; 180–200 and &gt; 90 mm Hg; BP not changed &gt; 20%, no pressors required)</td>
</tr>
<tr>
<td>Subjective clinical assessments indicating intolerance/failure</td>
<td>Change in mental status (eg, somnolence, coma, agitation, anxiety); Onset or worsening of discomfort; Diaphoresis; Signs of increased work of breathing (use of accessory respiratory muscles, and thoracoabdominal paradox)</td>
</tr>
</tbody>
</table>

\(^*\)HR = heart rate; \(\text{SpO}_2 = \) hemoglobin oxygen saturation. See Table 4 for abbreviations not used in the text.
Rationale and Evidence (Grade A)

Although failed SBTs are often a reflection of persistent respiratory system abnormalities, a failed SBT should prompt a search for other causes or complicating factors (see the “Pathophysiology of Ventilator Dependence” section). Specific issues include the adequacy of pain control, the appropriateness of sedation, fluid status, bronchodilator needs, the control of myocardial ischemia, and the presence of other disease processes that either can be readily addressed or else can be considered when deciding to proceed further with ventilator discontinuation attempts.

Assuming that medical management is optimized and that the patient who has failed an SBT still meets the criteria listed in Table 3, the following two questions involving subsequent SBTs arise: First, should SBTs be attempted again or should another approach to ventilator withdrawal be attempted? Second, if an SBT is attempted again, when should that be?

There are some data on which to base an answer to the first question. The one large randomized trial that compared routine SBTs to two other weaning strategies that did not include SBTs provides compelling evidence that SBTs administered at least once daily shorten the discontinuation period compared to strategies that do not include daily SBTs. In addition, two studies showing the success of protocol-driven ventilator discontinuation strategies over “usual care” both included daily SBTs. The subsequent use of routine SBTs in this patient population thus seems appropriate.

There are several lines of evidence that support waiting 24 h before attempting an SBT again in these patients. First, except in patients recovering from anesthesia, muscle relaxants, and sedatives, respiratory system abnormalities rarely recover over a short period of hours, and thus frequent SBTs over a day may not be expected to be helpful. Supporting this are data from Jubran and Tobin showing that failed SBTs often are due to persistent respiratory system mechanical abnormalities that are unlikely to reverse rapidly. Second, there are data suggesting that a failed SBT may result in some degree of respiratory muscle fatigue. If so, studies conducted in healthy subjects suggest that recovery may not be complete for anywhere from several hours to > 24 h. Third, the trial by Esteban et al specifically addressed this issue and provided strong evidence that twice-daily SBTs offer no advantage over a single SBT and, thus, would serve only to consume unnecessary clinical resources.

Recommendation 6: Patients receiving mechanical ventilation for respiratory failure who fail an SBT should receive a stable, nonfatiguing, comfortable form of ventilatory support.

Rationale and Evidence (Grade B)

There are a number of ventilator modes that can provide substantial ventilatory support as well as the means to reduce partial ventilatory support in patients who have failed an SBT (Table 7). A key question, however, is whether attempts at gradually lowering the level of support (weaning) offer advantages over a more stable, unchanging level of support between SBTs. The arguments for using gradual reductions are (1) that muscle conditioning might occur if ventilatory loads are placed on the patient’s muscles and (2) that the transition to extubation or to an SBT might be easier from a low level of support than from a high level of support. Data supporting either of these claims, however, are few. However, maintaining a stable level of support between SBTs reduces the risk of precipitating ventilatory muscle overload from overly aggressive support reduction. It also offers a significant resource consumption advantage in that it requires far less practitioner time. The study by Esteban et al partially addressed this issue in that it compared daily SBTs (and a stable level of support in those patients who failed) to two other approaches using gradual reductions in support (ie, weaning with pressure support or intermittent mandatory ventilation [IMV]) and demonstrated that the daily SBT with stable support between tests permitted the most rapid discontinuation. What has not been addressed, however, is whether gradual support reductions coupled with daily SBTs offer any advantages.

<table>
<thead>
<tr>
<th>Mode</th>
<th>Patient Work Adjusted By</th>
</tr>
</thead>
<tbody>
<tr>
<td>SIMV</td>
<td>No. of machine breaths supplied (ie, the fewer the No. of machine breaths, the more spontaneous breaths are required)</td>
</tr>
<tr>
<td>PSV</td>
<td>Level of inspiratory pressure assistance with spontaneous efforts</td>
</tr>
<tr>
<td>SIMV + PSV</td>
<td>Combining the adjustments of SIMV and PSV</td>
</tr>
<tr>
<td>VS</td>
<td>PSV with a “guaranteed” minimal tidal volume (PSV level adjusts automatically according to clinician tidal volume setting)</td>
</tr>
<tr>
<td>VAPS(PA)</td>
<td>PSV with “guaranteed” minimal Vt (additional flow is supplied at end inspiration if necessary to provide clinician Vt setting)</td>
</tr>
<tr>
<td>MMV</td>
<td>SIMV with a “guaranteed” Vn (machine breath rate automatically adjusts according to clinician Vn setting)</td>
</tr>
<tr>
<td>APRV</td>
<td>Pressure difference between inflation and release (ie, the less the pressure difference, the more spontaneous breaths are required)</td>
</tr>
</tbody>
</table>

*SIMV = synchronized intermittent mandatory ventilation; PSV = pressure support ventilation; VS = volume support; VAPS(PA) = volume assured pressure support (pressure augmentation); MMV = mandatory minute ventilation; APRV = airway pressure release ventilation. See Table 4 for abbreviations not used in the text.
The McMaster AHCPR report identified three other randomized trials that compared gradual reduction strategies using different modes but not routine daily SBTs. The study by Brochard et al was the most similar in design to the study by Esteban et al that was noted before, and it included a pressure-support group and an IMV group. A third group received gradually increasing fixed periods of spontaneous breathing that were designed only to provide brief periods of work and not specifically to test for discontinuation (ie, they were not routine daily SBTs, as defined above). The results showed that their use of gradually lengthening spontaneous breathing periods was inferior to other strategies and, like the Esteban trial, the pressure support strategy was easier to reduce than the IMV strategy. The other two randomized trials that were identified by the McMaster AHCPR report were much smaller than those by Esteban et al and Brochard et al, and both suggested that pressure support was easier to reduce than IMV alone. Because none of these studies offer evidence that gradual support strategies are superior to stable support strategies between SBTs, the clinical focus for the 24 h after a failed SBT should be on maintaining adequate muscle unloading, optimizing comfort (and thus sedation needs), and avoiding complications, rather than aggressive ventilatory support reduction.

Ventilator modes and settings can affect these goals. Assisted modes of ventilation (as opposed to machine-controlled modes) are generally preferable in this setting because they allow patient muscle activity and some patient control over the ventilatory pattern. Although good clinical supporting data are lacking, these features may help to avoid muscle disuse atrophy and may reduce sedation needs in these types of patients. With assisted modes, sensitive/responsive ventilator-triggering systems, applied PEEP in the presence of a triggering threshold load from auto-PEEP, flow patterns matched to patient demand, and appropriate ventilator cycling to avoid air trapping are all important to consider in achieving patient comfort and minimizing imposed loads.

In recent years, several ventilator support modes (volume support, adaptive support ventilation [ASV], minimum minute ventilation [MMV], and a knowledge-based system for adjusting pressure support) have been developed in an attempt to “automatically” wean patients by feedback from one or more ventilator-measured parameters. MMV set at either 75% of measured minute ventilation or set to a CO2 target, and a knowledge-based system for adjusting pressure support, all have been shown to be capable of automatically reducing support safely in selected populations. However, none of these systems has been compared to the daily SBT approach described above. Moreover, the premises underlying some of these feedback features (eg, that an ideal volume can be set for volume support or that an ideal ventilatory pattern based on respiratory system mechanics can be set for ASV) may be flawed, especially in sick patients. Indeed, potentially flawed feedback logic may, in fact, delay support reduction. Further work is clearly needed to establish the role (if any) of these automated approaches.

There has been increasing interest in the use of noninvasive positive-pressure ventilation (NPPV) in recent years. Although NPPV has been used primarily as a method to avoid intubation, it has also been used as a technique to facilitate the discontinuation of invasive ventilatory support. Data from the pooling of results of two prospective, randomized, controlled trials in patients with chronic respiratory disease suggest the need for reductions in the durations of mechanical ventilation, ICU stay, mortality, and the incidence of nosocomial pneumonia with postextubation support provided by NPPV. Appropriate patient selection and the feasibility of the widespread application of these findings remains to be determined.

**Recommendation 7: Anesthesia/sedation strategies and ventilator management aimed at early extubation should be used in postsurgical patients.**

**Rationale and Evidence (Grade A)**

The postsurgical patient poses unique problems for ventilator discontinuation. In these patients, depressed respiratory drive and pain issues are the major reasons for ventilator dependence. Optimal sedation management, pain management, and ventilator strategies offer opportunities to shorten the duration of mechanical ventilation.

The McMaster AHCPR report identified five randomized controlled trials in postsurgical patients that demonstrated that a lower anesthetic/sedation regimen permitted earlier extubation. The pooled results showed a mean effect of 7 h. Similar effects were found using these approaches in other postsurgical populations. Ventilator modes that guarantee a certain breath rate and minute ventilation (ie, assist control modes, IMV, and MMV) are important in patients with unreliable respiratory drives. However, frequent assessments and support reductions are necessary since recovery in these patients usually occurs over only a few hours. Aggressive support reduction strategies have been shown to lead to earlier discontinuations of ventilation. Conceptually, the immediate postoperative patient might be ideally suited for simple automatic feedback modes that provide a backup form of support (eg, MMV or ASV). Data showing improved outcomes or lower costs with these automated approaches, however, are lacking.

**Recommendation 8: Weaning/discontinuation protocols that are designed for nonphysician health-care professionals (HCPs) should be developed and implemented by ICUs. Protocols aimed at optimizing sedation also should be developed and implemented.**

**Rationale and Evidence (Grade A)**

There is clear evidence that nonphysician HCPs (eg, respiratory therapists and nurses) can execute protocols that enhance clinical outcomes and reduce costs for critically ill patients. In recent years, three randomized controlled trials incorporating 1,042 patients also have demonstrated that outcomes for mechanically ventilated patients who were managed using HCP-driven protocols...
were improved over those of control patients managed with standard care. Specifically, Ely et al. published the results of a two-step protocol driven by HCPs using a daily screening procedure followed by an SBT in those who met the screening criteria. The discontinuation of mechanical ventilation then was recommended for patients tolerating the SBT. Although the 151 patients managed with the protocol had a higher severity of illness than the 149 control subjects, they were removed from the ventilator 1.5 days earlier (with 2 days less weaning), had 50% fewer complications related to the ventilator, and had mean ICU costs of care that were lower by > $5,000 per patient. In a slightly larger trial with a more diverse patient population, Kollef et al. used three different HCP-driven protocols and showed that the mean duration of mechanical ventilation could be reduced by 30 h. Finally, Marelich et al. showed that the duration of mechanical ventilatory support could be reduced almost 50% using nurse-driven and therapist-driven protocols (p = 0.0001).

The reproducibility of benefit for using various protocols in different ICUs and institutions suggests that it is the use of a standardized approach to management rather than any specific modality of ventilator support that improves outcomes. Indeed, when other key features in the management of mechanically ventilated patients, such as sedation and analgesia, are also subjected to protocols, further reductions in the time spent receiving mechanical ventilation can be achieved. For example, in a randomized controlled trial of a nursing-implemented sedation protocol for 321 patients receiving mechanical ventilation, the use of the protocol was associated with a 50% reduction in the duration of mechanical ventilation, and 2-day and 3-day reductions in the median ICU and lengths of hospital stay, respectively (all p values < 0.01). More recently, Kress et al. published the results of a randomized controlled trial of 128 patients showing that a daily spontaneous awakening trial was associated with 2 days fewer spent receiving mechanical ventilation (p = 0.004) and a 3-day shorter ICU stay (p = 0.02).

The data do not support endorsing any one ventilator discontinuation protocol, and the choice of a specific protocol is best left to the individual institution. In designing these protocols, consideration should be given to other recommendations in this document as well as to the specific patient populations. For instance, medical patients with severe lung injury might benefit from one type of management strategy (see recommendations 2 to 5), whereas surgical patients recovering from anesthesia might benefit from another strategy (see recommendation 7). In the context of emerging data about the benefits of NPPV and the substantial roles of HCPs in providing this treatment, there should be efforts made to develop HCP-driven protocols for this modality.

While each institution must customize the protocols to local practice, there are important general concepts that may ease the process of implementation and enhance success.

First, protocols should not be used to replace clinical judgment, but rather to complement it. Protocols are meant as guides and can serve as the general default management decision unless the managing clinician can justify a departure from the protocol. Any such departure should be carefully assessed and used to guide possible future modifications of the protocol.

Second, protocols should not be viewed as static constructs, but rather as dynamic tools that are in evolution, which can be modified to accommodate new data and/or clinical practice patterns. More studies regarding the impact of protocol-based ventilator management are needed for specific patient populations (eg, neurosurgical patients and trauma patients), in specific organizational structures (eg, open vs closed units and teaching vs community hospitals), and using computer-assisted decision making.

Third, institutions must be prepared to commit the necessary resources to develop and implement protocols. For instance, the effective implementation of protocols requires adequate staffing, as it has been shown that if staffing is reduced below certain thresholds, clinical outcomes may be jeopardized. Indeed, in the specific context of the discontinuation of mechanical ventilation, reductions in nurse/patient ratios have been associated with a prolonged duration of mechanical ventilation.

ROLE OF TRACHEOTOMY IN VENTILATOR-DEPENDENT PATIENTS

Introduction

Tracheotomy is commonly performed for critically ill, ventilator-dependent patients to provide long-term airway access. The benefits commonly ascribed to tracheotomy, compared to prolonged translaryngeal intubation, include improved patient comfort, more effective airway suctioning, decreased airway resistance, enhanced patient mobility, increased opportunities for articulated speech, ability to eat orally, and a more secure airway. Conceptually, these advantages might result in fewer ventilator complications (eg, ventilator-associated pneumonia), accelerated weaning from mechanical ventilation, and the ability to transfer ventilator-dependent patients from the ICU. Concern, however, exists about the risks associated with the procedure and the costs involved.

The impact of tracheotomy on the duration of mechanical ventilation and on ICU outcomes in general has been examined by several different study designs, none of them ideal. Most studies are retrospective, although a few prospective studies have been performed. A serious problem is that many studies assigned patients to treatment groups on the basis of physician practice patterns rather than random assignment. Those studies that used random assignment frequently used quasi-randomization methods (eg, every other patient, every other day, hospital record number, or odd-even days). Studies have compared patients undergoing tracheotomy vs those not undergoing tracheotomy, and patients undergoing early tracheotomy vs those undergoing late tracheotomy. The definition of early vs late tracheotomy varies between studies. “Early” may be defined as a period as short as 2 days after the start of mechanical ventilation to as late as 10 days after the start.
Patient populations included in studies also vary widely between investigations and include general surgical and medical patients in some studies and specific patient groups (e.g., trauma patients or head-injured patients) in other studies. Most studies have design flaws in the collection and analysis of data, foremost of which is the absence of blinding. The absence of blinding is especially important considering that no study has used explicit, systematic protocols for weaning to control for any effects of tracheotomy on altering the approaches of clinicians to weaning. Finally, an outcome such as transfer to a non-ICU setting may depend on local resources, such as the availability of a non-ICU ventilator service.

Because there is such a surprisingly small amount of quality data regarding the relative impact of tracheotomy in terms of patient outcome relative to prolonged translaryngeal intubation, past recommendations for timing the procedure to achieve these benefits have been based on expert consensus.

**Recommendation 9:** Tracheotomy should be considered after an initial period of stabilization on the ventilator when it becomes apparent that the patient will require prolonged ventilator assistance. Tracheotomy should be performed when the patient appears likely to gain one or more of the benefits ascribed to the procedure. Patients who may derive particular benefit from early tracheotomy are the following:

- Those requiring high levels of sedation to tolerate translaryngeal tubes;
- Those with marginal respiratory mechanics (often manifested as tachypnea) in whom a tracheostomy tube having lower resistance might reduce the risk of muscle overload;
- Those who may derive psychological benefit from the ability to eat orally, communicate by articulated speech, and experience enhanced mobility; and
- Those in whom enhanced mobility may assist physical therapy efforts.

**Rationale and Evidence (Grade B)**

While carrying some risks, tracheotomies in ventilator-dependent patients are generally safe. The problems associated with tracheotomy include perioperative complications related to the surgery, long-term airway injury, and the cost of the procedure.

Patient series reported during the early 1990s suggested that tracheotomy had a high risk of perioperative and long-term airway complications, such as tracheal stenosis. More recent studies, however, have established that standard surgical tracheotomy can be performed with an acceptably low risk of perioperative complications. Regarding long-term risks, analyses of longitudinal studies suggest that the risk of tracheal stenosis after tracheotomy is not clearly higher than the risks of subglottic stenosis from prolonged translaryngeal intubation. Also, the nonrandomized studies commonly reported in the literature bias results toward greater long-term airway injury in patients undergoing tracheotomy because the procedure was performed after a prolonged period of translaryngeal intubation, which may prime the airway for damage from a subsequent tracheotomy. Finally, the cost of tracheotomy can be lowered if it is performed in the ICU rather than in an operating room, either by the standard surgical or percutaneous dilational technique. Even when tracheotomy is performed in an operating room, the cost may be balanced by cost savings if a ventilator-dependent patient can be moved from an ICU setting after the placement of a tracheostomy. The actual cost benefits of tracheotomy, however, have not been established because no rigorous cost-effectiveness analyses have been performed.

Given the above conditions, it seems reasonable to conclude that none of the potential problems with tracheotomy is of sufficient magnitude to make tracheotomy any less clinically acceptable compared with other procedures that are commonly performed in critically ill patients.

Potentially, the most important beneficial outcome from a tracheotomy would be to facilitate the discontinuation of mechanical ventilatory support. Supporting evidence comes both from observations on “intermediate” end points (e.g., comfort and mobility, decreased airway resistance, and a lower incidence of ventilator-associated pneumonia) as well as ICU outcome studies examining the duration of mechanical ventilation, ICU length of stay (LOS), and mortality. This evidence is reviewed below.

**Improved Patient Comfort:** No prospective outcome studies in general populations of ventilator-dependent patients using validated measurement tools have established that tracheotomy results in greater patient comfort or mobility, compared with prolonged translaryngeal intubation. Indeed, to our knowledge, only one study has attempted to document this by reporting that interviewed ICU caregivers believed ventilated patients were more comfortable after tracheotomy. Despite this lack of data, the general clinical consensus is that patients supported with long-term mechanical ventilation have less facial discomfort when nasotracheal or orotracheal endotracheal tubes are removed and a tracheotomy is performed. Furthermore, patient well-being is thought to be promoted by a tracheotomy through its effects on assisting articulated speech, oral nutrition, and mobility, which may promote the discontinuation of sedatives and analgesics. The maintenance of continuous sedation has been associated with the prolongation of mechanical ventilation, but the effects of tracheotomy on sedation usage have not been studied specifically.

**Decreasing Airway Resistance:** Although the small radius of curvature of tracheostomy tubes increases turbulent airflow and airway resistance, the short length of tracheostomy tubes results in an overall lowering of airway resistance (and thus reduced patient muscle loading) when compared to standard endotracheal tubes in both laboratory and clinical settings. While the development of secretions will increase resistance in both tracheostomy and endotracheal tubes, easier suctioning and removable inner cannulas may reduce this effect in tracheostomy tubes. The existing data thus indicate that airway resistance and muscle loading may decrease in some patients after the performance of tracheotomy, but the
clinical impact of this improvement in pulmonary mechanics on weaning has not been established. Conceivably, patients with borderline pulmonary mechanics may benefit from a tracheotomy because of decreased airway resistance, which becomes more clinically important with high respiratory rates.

Impact of Tracheotomy on Ventilator-Associated Pneumonia: Early tracheotomy and, alternatively, the avoidance of tracheotomy by maintaining a translaryngeal endotracheal tube in place both have been proposed as strategies to promote the successful discontinuation of mechanical ventilation by avoiding ventilator-associated pneumonia. Few data support the conclusion, however, that the timing of tracheotomy alters the risk of pneumonia. Three prospective studies have evaluated the relative risk of pneumonia in patients randomized to early vs late tracheotomy.198–200 These studies examined 289 patients and found a relative risk for pneumonia (early tracheotomy group vs late tracheotomy group) of only 0.88 (95% interval, 0.70 to 1.10). Considerable methodological flaws in these studies, however, do not allow firm conclusions to be drawn regarding the effects of tracheotomy on pneumonia risk. Presently, no data support the competing contentions that early tracheotomy either decreases or increases the risk of ventilator-associated pneumonia.

Outcome Studies: the Impact of Tracheotomy on Duration of Mechanical Ventilation: The results of a number of studies examining ICU outcome (ie, ventilator days, ICU LOS, mortality) have been reported and are summarized in Table 8.198–204 Several of these studies were appraised in a systematic review.205 The authors of this review concluded that insufficient evidence existed to support the contention that the timing of tracheotomy alters the duration of mechanical ventilation in critically ill patients. Also, the review identified multiple flaws in the available studies. There appears to be a clinical impression that the timing of tracheotomy promotes the discontinuation of mechanical ventilation in some ventilator-dependent patients, but not all. However, the quality of existing studies does little to support this clinical impression. In the future, because of the difficulty in blinding caregivers to the presence or absence of tracheotomy, studies should use explicit weaning protocols to control for different levels of approaches toward weaning that the presence of a tracheotomy may invoke. Studies also could be improved by more rigorous patient inclusion and exclusion criteria, better accounting for dropouts, the use of conventional randomization methods, multicenter designs to allow sufficient sample sizes to determine the interaction of underlying conditions, and multivariate analysis techniques. Cost-effectiveness analysis also would assist the determination of the value of tracheotomy for weaning.

Table 8—The Impact of Tracheotomy on Mechanical Ventilation Outcome

<table>
<thead>
<tr>
<th>Reference</th>
<th>Patient Types/No.</th>
<th>Design</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesnik et al198</td>
<td>Trauma/101</td>
<td>Randomized early (6 d) vs late (21 d) tracheotomy</td>
<td>Ventilator days shorter with earlier tracheotomy</td>
</tr>
<tr>
<td>Blot et al199</td>
<td>Neutropenic/53</td>
<td>Retrospective early (2 d) vs late (&gt; 7 d) tracheotomy or no tracheotomy</td>
<td>LOS longer in patients undergoing early tracheotomy</td>
</tr>
<tr>
<td>Koh et al200</td>
<td>Neurosurgical/49</td>
<td>Retrospective elective (9 d) vs failed extubation tracheotomy</td>
<td>LOS shorter in elective tracheotomy</td>
</tr>
<tr>
<td>Dunham and LaMonica200</td>
<td>Trauma/74</td>
<td>Prospective early (4 d) vs late (14 d) or no tracheotomy</td>
<td>No effect</td>
</tr>
<tr>
<td>El-Naggar et al201</td>
<td>General acute respiratory failure/52</td>
<td>Prospective (3 d) vs delayed (&gt; 10 d) tracheotomy</td>
<td>More patients weaned in delayed tracheotomy</td>
</tr>
<tr>
<td>Rodriguez et al202</td>
<td>Trauma/106</td>
<td>Randomized early (≤ 7 d) vs late (&gt; 7 d) tracheotomy</td>
<td>LOS shorter in patients undergoing early tracheotomy but those weaned before late tracheotomy were not considered</td>
</tr>
<tr>
<td>Sugerman et al203</td>
<td>Trauma/126</td>
<td>Randomized early (3–5 d) vs late (10–21 d) tracheotomy</td>
<td>No effect</td>
</tr>
</tbody>
</table>

THE ROLE OF LONG-TERM FACILITIES

Introduction

The patient who remains ventilator-dependent despite maximal medical/surgical therapy and aggressive attempts to remove ventilator support is becoming an increasing challenge for critical-care practitioners. In two studies,206,207 up to 20% of medical ICU patients met the 21-day Health Care Financing Administration definition of prolonged mechanical ventilation (PMV).208 Better treatment and technology, no doubt, are playing a major role in the conversion of patients who would have died a decade ago into patients who survive today, but who have substantial remaining respiratory dysfunction. Prior to the 1980s, these patients simply remained in ICUs and were managed using acute-care principles. The only other option was permanent ventilatory support in either the patient’s home or in a nursing home. Financial pressures, coupled with the concept that the aggressive ICU mindset might not be optimal for the more slowly recovering patient, have led to the creation of weaning facilities (both free-standing facilities and units within hospitals) that are potentially more cost-effective and better suited to meet the needs of these patients. A body
of literature now is emerging that suggests that many patients who previously would have been deemed “unweanable” may achieve ventilator independence in such facilities.

**Recommendation 10:** Unless there is evidence for clearly irreversible disease (eg, high spinal cord injury or advanced amyotrophic lateral sclerosis), a patient requiring prolonged mechanical ventilatory support for respiratory failure should not be considered permanently ventilator-dependent until 3 months of weaning attempts have failed.

**Rationale and Evidence (Grade B)**

A critical clinical issue is determining whether a patient requiring PMV has any hope of ventilator discontinuation or whether he/she is to have lifelong ventilator dependence. Patients in the former category clearly need at least several months of attempts at ventilator discontinuation to be pursued, whereas patients in the latter category are only being subjected to unnecessary episodes of worsening respiratory failure with such attempts. These latter patients, instead, need to have the clinical focus changed to establish a lifelong support program.

Data from a number of centers caring for the patient requiring long-term mechanical ventilation offer insight into this question. In the Barlow Regional Weaning Center experience,206–210 patients with prolonged ventilator dependence following acute cardiorespiratory failure were still undergoing ventilator discontinuation up to 3 months (and, on occasion, 6 months) postintubation. Other studies211,212 suggest similar results in postsurgical and medical populations. Data from these studies on the time that patients spend, on average, dependent on ventilator support in the ICU (36 days), and during subsequent weaning in the post-ICU setting (31 days), suggest a time frame for the reasonable continuance of ventilator discontinuation attempts. Thus, the weight of evidence is that several months of attempts at ventilator discontinuation are required before most patients who are receiving mechanical ventilation for acute respiratory failure can be declared to be permanently ventilator-dependent.

**Recommendation 11:** Critical-care practitioners should familiarize themselves with facilities in their communities, or units in hospitals they staff, that specialize in managing patients who require prolonged dependence on mechanical ventilation. Such familiarization should include reviewing published peer-reviewed data from those units, if available. When medically stable for transfer, patients who have failed ventilator discontinuation attempts in the ICU should be transferred to those facilities that have demonstrated success and safety in accomplishing ventilator discontinuation.

**Rationale and Evidence (Grade C)**

There are > 30 studies on post-ICU weaning from PMV. Most of these studies are observational, a reflection of the inherent logistical difficulties in designing randomized controlled trials in such a heterogeneous population that is being treated in such diverse settings. Table 9 summarizes the studies that report outcomes in > 100 patients in which PMV is defined as > 21 days of ventilator dependency. Most of these studies208,211–219 support the conclusion that ICU patients receiving PMV can be discontinued effectively and safely from ventilation when they are transferred to units dedicated to that activity. Efficacy is suggested in the fact that the data in Table 9

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**Table 9—Comparison of Observational Studies, Each With > 100 Patients Transferred for Weaning From PMV (> 21 Prior ICU Ventilator Days)**

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</thead>
<tbody>
<tr>
<td><strong>Type of unit</strong></td>
<td>NRCU</td>
<td>NRCU</td>
<td>WRC</td>
<td>WRC</td>
<td>WRC</td>
<td>WRC</td>
<td>NRCU</td>
<td>NRCU</td>
<td>NRCU</td>
</tr>
<tr>
<td><strong>Patients, No.</strong></td>
<td>171</td>
<td>224</td>
<td>388</td>
<td>113</td>
<td>278</td>
<td>1,123</td>
<td>133</td>
<td>212</td>
<td>420</td>
</tr>
<tr>
<td><strong>Age, yr†</strong></td>
<td>67</td>
<td>72</td>
<td>65</td>
<td>67</td>
<td>69</td>
<td>71</td>
<td>68</td>
<td>67</td>
<td></td>
</tr>
<tr>
<td><strong>Gender, % women‡</strong></td>
<td>54</td>
<td>47</td>
<td>53</td>
<td>56</td>
<td>53</td>
<td>57</td>
<td>52</td>
<td>55</td>
<td>53‡</td>
</tr>
<tr>
<td><strong>Diagnoses precipitating ventilator dependency</strong></td>
<td>COPD</td>
<td>Medical &gt;</td>
<td>Medical &gt;</td>
<td>Medical =</td>
<td>Medical &gt;</td>
<td>Medical &gt;</td>
<td>Medical =</td>
<td>Medical &gt;</td>
<td>Surgical &gt;</td>
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<tr>
<td></td>
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<td>surgical</td>
<td>surgical</td>
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<td>surgical</td>
<td>surgical</td>
<td>surgical</td>
<td>medical</td>
</tr>
<tr>
<td><strong>ICU days receiving ventilation†</strong></td>
<td>55</td>
<td>23</td>
<td>42</td>
<td>44</td>
<td>25</td>
<td>25†</td>
<td>37‡</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Days to weaning in ICU†</strong></td>
<td>39</td>
<td>43</td>
<td>43</td>
<td>43</td>
<td>39</td>
<td>39</td>
<td>13†</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td><strong>% weaned‡</strong></td>
<td>34</td>
<td>51</td>
<td>51</td>
<td>47</td>
<td>38</td>
<td>38</td>
<td>60</td>
<td>60</td>
<td></td>
</tr>
<tr>
<td><strong>% survival to discharge¶</strong></td>
<td>60</td>
<td>50</td>
<td>66</td>
<td>61</td>
<td>53</td>
<td>71</td>
<td>50</td>
<td>82</td>
<td>94</td>
</tr>
<tr>
<td><strong>% survival 12 mo after discontinue ventilator</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

*Adapted from Scheinhorn et al214
†Mean value.
‡Median value.
§Data from an earlier report on the same cohort of patients211
¶Authors’ data were recalculated so that “% weaned” signifies No. of patients weaned/No. of patients who were admitted to the hospital ventilator-dependent.
¶Value attained 4 years after hospital discharge.
encompass 3,062 post-ICU patients and show that 1,588 patients (52%) successfully discontinued mechanical ventilation. Safety is suggested in that a 69% overall survival-to-discharge rate in this “chronically critically ill” cohort seems quite reasonable.

The facilities generating the data of Table 9 are of two basic types. (1) Most facilities, but not all, are licensed as long-term acute-care hospitals, which are required by the Health Care Financing Administration to maintain a mean LOS of >25 days. These facilities are most often free-standing hospitals, which may have their own ICUs. Called “regional weaning centers” (RWCS) in Table 9, they serve several to many hospitals in their geographic area. (2) Step-down units or noninvasive respiratory-care units (NRCUs) have no specific LOS requirement. These units usually reside within a host hospital and primarily serve that hospital. While both settings have acute-care staffing, but not critical-care (ICU) staffing, they are often dissimilar in hospital admission and discharge criteria, treatment capability, and the availability of specialty/subspecialty consultation services and procedures offered on site, all of which may have a significant effect on the outcome of care. Both of these types of facilities are characterized by less intensive staffing and less costly monitoring equipment, and, therefore, they generate less cost per patient than do ICUs.219,220

Recommendation 12: Weaning strategies in the PMV patient should be slow-paced and should include gradually lengthening self-breathing trials.

Rationale and Evidence (Grade C)

Despite differences in patient population and physical facilities, the available information on strategies for the discontinuation of PMV in the studies listed in Table 9 has a number of similarities (Table 10). Daily SBTs initially are uncommon since patients have already established themselves as very unlikely to “turn around” in 24 h. Instead, ventilator support is gradually reduced, using common modes of partial support (Table 7). Usually at the point of approximately half-support, patients are switched to the SBT approach described above, which is often employed along with self-breathing trials of increasing duration. Since most patients are tracheotomized, tracheal collars are used, instead of the familiar T-piece in the ICU, to supply oxygen and humidity. During these procedures, it is important for the staff to remain patient. Psychological support and careful avoidance of unnecessary muscle over-load is important for these types of patients.

Long-term facilities may be a particularly useful place to implement protocols such as those described earlier in the “Managing the Patient Who Has Failed an SBT” section (recommendation 8).221–223 Skilled nonphysician personnel (e.g., registered nurses and registered respiratory therapists) are generally present in these units continually and, thus, are in a position to constantly interact with the patient and to make ventilator adjustments as appropriate. Of interest, after the implementation of a therapist-implemented protocol for weaning, the time to wean in an RWC, with its predominantly “medical” population, declined from a median of 29 days to < 17 days over a 2-year period of protocol use.223

### Table 10—Post-ICU Weaning Strategies*

<table>
<thead>
<tr>
<th>Study</th>
<th>Strategies To Decrease Ventilator Support To Increase SBTs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gracey et al220†</td>
<td>IMV/PSV</td>
</tr>
<tr>
<td>Scheinorn et al209</td>
<td>IMV/PSV</td>
</tr>
<tr>
<td>Bagley and Cooney217</td>
<td>VTM</td>
</tr>
<tr>
<td>Peterson et al215†</td>
<td>AC or PSV</td>
</tr>
<tr>
<td>Clark and Theis216</td>
<td>PSV</td>
</tr>
<tr>
<td>Latriano et al214†</td>
<td>IMV/PSV</td>
</tr>
</tbody>
</table>

*AC = Assist-control; PSV = pressure support ventilation; TTO = transtracheal oxygen; TP = T-piece; VTM = Venti-Trach mask (tracheal collar).
†Data from personal communication.

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