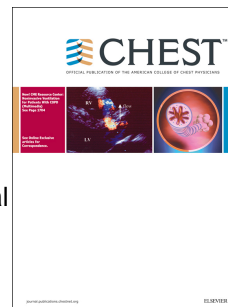


# Accepted Manuscript



Liberation from Mechanical Ventilation in Critically Ill Adults: Executive Summary of an Official American College of Chest Physicians / American Thoracic Society Clinical Practice Guideline

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**ABSTRACT**

Background: This clinical practice guideline addresses six questions related to liberation from mechanical ventilation in critically ill adults. It is the result of a collaborative effort between the American Thoracic Society (ATS) and American College of Chest Physicians (CHEST).

Methods: A multi-disciplinary panel posed six clinical questions in a Population, Intervention, Comparator and Outcomes (PICO) format. A comprehensive literature search and evidence synthesis was performed for each question, which included appraising the quality of evidence using the GRADE (Grading of Recommendations, Assessment, Development and Evaluation) approach. The Evidence-to-Decision Framework was applied to each question, requiring the panel to evaluate and weigh the: importance of the problem, confidence in the evidence, certainty about how much the public value the main outcomes, magnitude and balance of desirable and undesirable outcomes, resources and costs associated with the intervention, impact on health disparities, and acceptability and feasibility of the intervention.

Results: Evidence-based recommendations were formulated and graded, initially by subcommittees and then modified following full panel discussions. The recommendations were confirmed by confidential electronic voting; approval required that at least 80% of the panel members agree with the recommendation.

Conclusion: The panel provides recommendations regarding liberation from mechanical ventilation. The details regarding the evidence and rationale for each recommendation are presented in the American Journal of Respiratory and Critical Care Medicine and CHEST.

ACCEPTED MANUSCRIPT

## **INTRODUCTION**

Mechanical ventilation is essential for many critically ill adults; however, it also is associated with numerous complications and patient discomfort. In an effort to facilitate liberation from mechanical ventilation the American Thoracic Society (ATS) and American College of Chest Physicians (CHEST) collaboratively developed evidence-based recommendations that address common clinical questions. The goal of the guidelines is to help clinicians safely and effectively liberate patients from mechanical ventilation and improve outcomes among critically ill patients.

Guidelines cannot take into account all of the often compelling unique individual clinical circumstances. Clinicians are not expected to adhere to these recommendations blindly or universally. However, these unbiased, evidence-based guidelines may provide support to clinicians who manage these vulnerable patients and have questioned the efficacy of selected methods for ventilator liberation.

## **METHODS**

Six co-chairs were appointed, three each by the American Thoracic Society (ATS) and CHEST leadership, and reviewed for credentials and possible conflicts of interest. The six co-chairs (ATS: TDG, PEM, JDT and CHEST: JPK, DRO, GAS) suggested panelists to the ATS and CHEST staff, who invited, reviewed for potential conflicts of interest, then finally approved them. The final panel consisted of the six co-chairs, eight pulmonary/critical care physicians, four critical care physicians, one critical nurse, one physical therapist, and one critical care pharmacist. There were also two

methodologists, one of whom is also a critical care physician. The panelists were divided among six topic groups as content experts for their particular area of expertise.

The six co-chairs proposed six clinical questions, which were vetted and confirmed by the panel. Outcomes for each question were weighted following an approach outlined by the Grading Recommendations, Assessment, Development and Evaluation (GRADE) Working Group. After comprehensive evidence synthesis of published manuscripts, the panel used the GRADE approach to assess the overall certainty of the evidence for each question's associated outcomes. The Evidence-to-Decision framework facilitated panel deliberation and recommendation development. Each recommendation was considered strong or conditional (Table 1) and required at least 80% panel consensus for approval. Any recommendation not meeting this threshold was revised based on panel feedback and resubmitted for vote.

## **RESULTS**

ATS and CHEST elected to share publication of the guideline, which consists of six questions and the related evidence syntheses and recommendations (Table 2). After appropriate review by ATS and CHEST leadership, the guidelines are published as three manuscripts; an executive summary and two manuscripts that address three questions each. The panel made recommendations but did not support specific protocols for any of the six questions. One of two manuscripts is

published in CHEST (1) and the other in the American Journal of Respiratory and Critical Care Medicine (2). Both are accompanied by this executive summary.

***Question #1: In acutely hospitalized patients ventilated more than 24 hours, should the spontaneous breathing trial (SBT) be conducted with or without inspiratory pressure augmentation?***

The evidence suggested that conducting the SBT with pressure augmentation was more likely to be successful; produced a higher rate of extubation success; and was associated with a trend towards lower ICU mortality than SBTs performed without pressure augmentation.

#### **CHEST/ATS Recommendation**

For acutely hospitalized patients ventilated more than 24 hours, we suggest that the initial SBT be conducted with inspiratory pressure augmentation (5-8 cm H<sub>2</sub>O) rather than without (T-piece or CPAP). (Conditional recommendation, Moderate quality evidence)

*Remarks:* This recommendation relates to how to conduct the initial SBT, but does not inform how to ventilate prolonged weaning patients between SBTs.



**Values and Preferences**

This recommendation places a high value on reducing the duration of mechanical ventilation and maximizing the probability of extubation success.

***Question #2: In acutely hospitalized patients ventilated for more than 24 hours, do protocols attempting to minimize sedation compared to approaches that do not attempt to minimize sedation impact duration of ventilation, duration of ICU stay, and short-term mortality (60 days)?***

The evidence showed a trend towards a shorter duration of mechanical ventilation, a shorter ICU length of stay, and a trend towards lower short-term mortality in the protocolized sedation group.

**CHEST/ATS recommendation**

For acutely hospitalized patients ventilated for more than 24 hours, we suggest protocols attempting to minimize sedation. (Conditional recommendation, Low quality evidence).

*Remarks*

There is insufficient evidence to recommend any protocol over another.

**Values and preferences**

This recommendation places a high value on reducing mechanical ventilation duration, ICU length of stay, and short-term survival, and views the burden of protocolized sedation as very low.

***Question 3: In high-risk patients receiving mechanical ventilation for more than 24 hours who have passed a spontaneous breathing trial (SBT), does extubation to preventive non-invasive ventilation compared to no non-invasive ventilation have a favorable effect on duration of ventilation, ventilator-free days, extubation success (liberation > 48 hours), duration of intensive care unit (ICU) stay, short-term mortality (60 days), or long-term mortality?***

In studies of preventive NIV, there was heterogeneity in defining the high-risk patient. Risk factors included older age, comorbidities such as chronic obstructive pulmonary disease or congestive heart failure, and hypercapnia during the SBT. The evidence synthesis indicated that preventive NIV was superior to no preventive NIV with regards to extubation success; ICU length of stay; and both short- and long-term mortality.

#### **CHEST/ATS recommendation**

For patients at high risk for extubation failure who have been receiving mechanical ventilation for more than 24 hours, and who have passed a spontaneous breathing trial, we recommend extubation to preventative NIV (Strong recommendation, moderate quality evidence).

*Remarks*

Patients at high risk for failure of extubation may include those patients with hypercapnia, COPD, CHF, or other serious co-morbidities. Physicians may choose to avoid extubation to NIV in selected patients for patient-specific factors including but not limited to the inability to receive ventilation through a mask or similar interface. Physicians who choose to use NIV should apply such treatment immediately after extubation to realize the outcome benefits.

**Values and preferences**

This recommendation places a high value on early extubation and a lesser value on the burdens related to institution and maintenance of preventive NIV.

***Question #4: Should acutely hospitalized adults who have been mechanically ventilated for >24 hours be subjected to protocolized rehabilitation directed toward early mobilization or no protocolized attempts at early mobilization?***

The evidence synthesis demonstrated that patients who received an intervention directed toward early mobilization had a shorter duration of mechanical ventilation and were more likely to be able to walk at hospital discharge. There were no differences in mortality, ICU length of stay, ability to walk at ICU discharge, six minute walk distance, or ventilator-free days. Low rates of serious adverse events, including arrhythmias, have been reported.

**ATS/CHEST recommendation**

For acutely hospitalized adults who have been mechanically ventilated for >24 hours, we suggest protocolized rehabilitation directed toward early mobilization (Conditional recommendation, low quality evidence).

### **Remarks**

There is insufficient evidence to recommend any rehabilitation protocol over another.

### **Values and preferences**

This recommendation places a high value on reducing the duration of mechanical ventilation and maintenance of ambulation, and a lower value on cost and resource utilization.

***Question #5: Should acutely hospitalized adults who have been mechanically ventilated for >24 hours be managed with a ventilator liberation protocol or no protocol?***

The guideline panel defined a “ventilator liberation protocol” as protocol-guided efforts to identify a patient’s readiness for liberation (i.e., extubation) from invasive mechanical ventilation. The evidence demonstrated that patients managed with a ventilator liberation protocol spent fewer hours on mechanical ventilation than did patients managed without a protocol. Additionally, management with a ventilator liberation protocol led to being discharged from the ICU earlier than management

without a protocol. However, ventilator liberation protocols had no significant effect on mortality or reintubation rates. Adverse events were rarely reported. Subgroup analyses found that, compared to management without a ventilator liberation protocol, personnel-driven and computer-driven protocols had similar effects.

### **ATS/CHEST recommendation**

We suggest managing acutely hospitalized adults who have been mechanically ventilated for >24 hours with a ventilator liberation protocol (Conditional recommendation, low quality evidence).

### **Remarks**

The ventilator liberation protocol may be either personnel-driven or computer-driven.

### **Values and preferences**

This recommendation places a high value on reducing the duration of mechanical ventilation and ICU length of stay and a lower value on resource utilization.

***Question #6: Should a cuff leak test (CLT) be performed prior to extubation of mechanically ventilated adults? Should systemic steroids be administered to adults who fail a CLT prior to extubation?***

The evidence suggested that patients with an absent or insufficient cuff leak are at increased risk of post-extubation stridor (PES) and unsuccessful extubation. Very low quality evidence also suggested that the use of a CLT to guide management may decrease the reintubation and PES rate, and delay extubation (due to high false positive rate). It has no effect on the duration of mechanical ventilation when considering the additional days associated with reintubation. Moderate quality evidence suggested that administration of systemic steroids to patients failing a CLT may reduce both the reintubation and PES rates. Patients passing a CLT have a low risk of reintubation and PES, although these risks are also low among patients extubated without having a CLT performed.

#### **ATS/CHEST recommendations**

1. We suggest performing a CLT in mechanically ventilated adults who meet extubation criteria and are deemed high risk for PES (Conditional recommendation, very low certainty in the evidence).
2. For adults who have failed a cuff leak test but are otherwise ready for extubation, we suggest administering systemic steroids at least 4 hours before extubation (Conditional recommendation, moderate quality evidence).

#### **Remarks**

Risk factors for PES include: traumatic intubation, intubation > 6 days, large endotracheal tube, female sex, and reintubation after unplanned extubation. A

repeat cuff leak test is not required following the administration of systemic steroids.

### **Values and preferences**

These recommendations place a high value on avoiding reintubation and delayed extubation and a lower value on PES, the burdens related to implementing the cuff leak test, and the side effects of steroid use.

### **SUMMARY**

The recommendations in these guidelines are the result of our expert panel's interpretation of the existing evidence and how it may be applied in clinical practice. Only one recommendation, extubation to preventive non-invasive mechanical ventilation in high risk patients, is strongly suggested. All others are considered conditional recommendations and include: conducting spontaneous breathing trials with inspiratory pressure augmentation, using protocols to minimize sedation, using protocolized physical therapy directed toward early mobilization, using ventilator liberation protocols, performing a CLT in mechanically ventilated patients who meet extubation criteria and are deemed high risk for post-extubation stridor, and administering systemic steroids at least 4 hours prior to extubation in patients who fail a CLT.

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**Table 1**

<b>Implications for:</b>	<b>Strong recommendation</b>	<b>Conditional recommendation</b>
<b>Patients</b>	Most individuals in this situation would want the recommended course of action, and only a small proportion would not.	The majority of individuals in this situation would want the suggested course of action, but many would not.
<b>Clinicians</b>	Most individuals should receive the intervention. Adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator. Formal decision aids are not likely to be needed to help individuals make decisions consistent with their values and preferences.	Recognize that different choices will be appropriate for individual patients and that you must help each patient arrive at a management decision consistent with his or her values and preferences. Decision aids may be useful in helping individuals to make decisions consistent with their values and preferences.
<b>Policy makers</b>	The recommendation can be adopted as policy in most situations.	Policy making will require substantial debate and involvement of various stakeholders.

**Table 2**

<b>RECOMMENDATION</b>	<b>STRENGTH OF RECOMMENDATION</b>	<b>QUALITY OF EVIDENCE</b>
1. For acutely hospitalized patients ventilated more than 24 hours, we suggest that the initial SBT be conducted with inspiratory pressure augmentation (5-8 cm H <sub>2</sub> O) rather than without (T-piece or CPAP).	Conditional	Moderate certainty in the evidence
2. For acutely hospitalized patients ventilated for more than 24 hours, we suggest protocols attempting to minimize sedation.	Conditional	Low certainty in the evidence
3. For patients at high risk for extubation failure who have been receiving mechanical ventilation for more than 24 hours, and who have passed a spontaneous breathing trial, we recommend extubation to preventive NIV.	Strong	Moderate certainty in the evidence
4. For acutely hospitalized patients who have been mechanically ventilated for >24 hours, we suggest protocolized physical therapy directed toward early mobilization.	Conditional	Low certainty in the evidence
5. We suggest managing acutely hospitalized patients who have been mechanically ventilated for >24 hours with a ventilator liberation protocol.	Conditional	Low certainty in the evidence
6a. We suggest performing cuff leak test in mechanically ventilated patients who meet extubation criteria and deemed high risk for PES.	Conditional	Very low certainty in the evidence

6b. For adults who have failed a cuff leak test but are otherwise ready for extubation, we suggest administering systemic steroids at least 4 hours before extubation. A repeat cuff leak test is not required.

Conditional

Moderate  
certainty in the  
evidence

*\* More detailed discussions of questions 1-3 appear in CHEST (1) and of questions 4-6 appear in American Journal of Respiratory and Critical Care Medicine (2)*