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ABSTRACT & COMMENTARY

Acute Respiratory Distress Syndrome Treatment Guidelines

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Dr. Walter reports no financial relationships relevant to this field of study.

SYNOPSIS: This article provides a collaborative, evidence-based guideline for mechanical ventilation in acute respiratory distress syndrome.

SOURCE: Fan E, Del Sorbo L, Goligher EC, et al. An official American Thoracic Society/European Society of Intensive Care Medicine/Society of Critical Care Medicine clinical practice guideline: Mechanical ventilation in adult patients with acute respiratory distress syndrome. *Am J Respir Crit Care Med* 2017;195:1253-1263.

Acute respiratory distress syndrome (ARDS) is a common cause of respiratory failure. Patients with ARDS frequently need respiratory support with mechanical ventilation. While it can be life-saving, mechanical ventilation itself can cause and exacerbate lung injury. Over the past 20 years, numerous ventilator management strategies have been evaluated in an attempt to determine how to best provide respiratory support while preventing or minimizing additional lung injury. Representatives from the American Thoracic Society, the European Society of Intensive Care Medicine, and the Society of Critical Care Medicine reviewed this literature and developed a clinical practice guideline with recommendations for ARDS treatment strategies. Recommendations were classified as either strong or conditional. The authors used the phrases "we recommend" when discussing strong recommendations and "we suggest" when discussing conditional recommendations. The authors reviewed six specific ARDS treatment strategies *(see Table 1)*.

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Table 1. Recommended Treatment Strategies for Acute Respiratory Distress Syndrome

Treatment Strategy	GRADE Recommendation	Author's Terminology
Low tidal volume ventilation	Strong recommendation for	Recommended
Prone positioning in severe acute respiratory distress syndrome	Strong recommendation for	Recommended
Higher positive end-expiratory pressure in moderate or severe acute respiratory distress syndrome	Conditional recommendation for	Suggested
Recruitment maneuvers	Conditional recommendation for	Suggested
High-frequency oscillatory ventilation	Strong recommendation against	Not recommended
Extracorporeal membrane oxygenation	Insufficient evidence	Insufficient evidence

The recommendation for low tidal volume (LTV) ventilation was based on nine randomized, controlled trials (RCTs) comparing LTV and traditional tidal volumes (mean tidal volume 6.8 ± 1.2 mL/kg predicted body weight (PBW) vs. 11.4 ± 1.1 mL/kg PBW, respectively). In the seven studies that compared LTV and traditional tidal volumes without any other interventions, such as high positive end-expiratory pressure (PEEP), there was no difference in mortality (relative risk [RR], 0.87; 95% confidence interval [CI], 0.70-1.080). However, a sensitivity analysis, including trials with LTV and protocolized PEEP, showed reduced mortality (RR, 0.80; 95% CI, 0.66-0.98). Furthermore, there was a significant inverse association between tidal volume gradient (difference in tidal volume between LTV and control groups) and mortality.

Among all ARDS patients, prone positioning was not associated with a reduction in mortality (RR, 0.84; 95% CI, 0.60-1.04). However, subgroup analyses in many studies and one RCT showed a significant reduction in mortality for patients placed in prone positioning for > 12 hours (RR, 0.74; 95% CI, 0.56-0.99) and patients with moderate or severe ARDS (RR, 0.74; 95% CI, 0.54-0.99). Thus, prone positioning for > 12 hours per day was recommended for patients with severe ARDS.

Higher PEEP and recruitment maneuvers were suggested rather than recommended. There was a recommendation against the use of high-frequency oscillatory ventilation based primarily on results from two RCTs that showed either no benefit or significant harm. Not enough data were available to make a recommendation for or against the use of extracorporeal membrane oxygenation. This guideline did not address the use of different modes of mechanical ventilation or neuromuscular blockade.

■ COMMENTARY

To best understand how to interpret this guideline, it is helpful to understand how it was developed. The authors used the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system. The GRADE system attempts to rate the quality of evidence across studies by both estimating a treatment effect (i.e., does the RR show benefit or harm) and assessing the confidence one can have in the treatment effect. Higher quality evidence allows for more confidence that the estimated treatment is true. Low-quality evidence may provide an estimated treatment effect but the confidence this treatment effect is true is

lower. The GRADE system also bases the strength of a recommendation not solely on the evidence but on four concepts: balance of desirable and undesirable effects, quality of the evidence, values and preferences, and resource implications.

For example, the authors concluded there was only moderate quality of evidence for LTV ventilation (the primary analysis was not statistically significant). Therefore, the confidence that LTV ventilation is associated with lower mortality is not as high as it could be. If the quality of evidence was only moderate, then why was LTV ventilation given a strong recommendation? The authors evaluated other concepts and not just the evidence alone. The balance of desirable and undesirable effects seemed weighted for LTV ventilation. The point estimate of 0.87 suggests a 13% reduction in mortality and the CI suggests that the reduction in mortality could be as high as a 30% (albeit with the possibility of up to an 8% increase in mortality). Furthermore, the authors assessed there was moderate confidence that undesirable outcomes (adverse events due to LTV) are not severe and avoiding these outcomes is not highly valued, while the outcome of reduced mortality is highly desirable. The authors addressed the potential adverse outcomes of ventilator dysynchrony, patient discomfort, and potential need for increased sedation. To address this, they recommended an initial tidal volume of 6 mL/kg PBW, but if needed, LTV can be increased up to 8 mL/kg PBW, as carried out in the original landmark trial. Prone positioning was recommended based on moderate-high confidence in the moderate treatment effect on a highly desirable outcome (mortality). However, the strong recommendation for prone positioning was not unanimous. Dissenting committee members noted that undesirable effects of prone positioning can be severe and that the data were weighted heavily by a single trial. As opposed to the recommendation for prone positioning, recruitment maneuvers and higher PEEP only were suggested. This was primarily due to lower confidence of smaller treatment effects. With respect to recruitment maneuvers, there was some evidence of harm, so caution was suggested when recruitment maneuvers are used in patients with hypovolemia or shock.

This guideline helps synthesize decades of ARDS research in a systematic fashion and provide easy-to-interpret recommendations. These recommendations should not be considered all-encompassing, as all patients are unique. Recommendations will help guide clinicians, but the authors were right to note that clinicians should personalize decisions for all patients. This was noted to be most important for the conditional recommendations. ■

ABSTRACT & COMMENTARY

Early Lung Recruitment Reduces Pulmonary Complications

By Richard Kallet, MS, RRT, FCCM

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Mr. Kallet reports that he is a major stockholder in the Asthma & Allergy Prevention Company and receives grant/research support from Nihon-Kohden.

SYNOPSIS: In postoperative cardiac surgery patients with hypoxemia at admission to the ICU, the brief application of an intensive recruitment maneuver followed by lung-protective ventilation was associated with reduced occurrence and severity of pulmonary complications.

SOURCE: Costa Leme A, Hajjar LA, Volpe MS, et al. Effect of intensive vs. moderate alveolar recruitment strategies added to lung-protective ventilation on postoperative pulmonary complications. *JAMA* 2017;317:1422-1432.

In this single-center prospective trial, 320 patients undergoing elective cardiac surgery and who had hypoxemia upon ICU admission were randomized to receive either a moderate or intensive recruitment maneuver (RM). Then, they were managed with a tidal volume of 6 mL/kg and positive end-expiratory pressure (PEEP) of 8 cm H_2O. Hypoxemia was defined as an arterial oxygen tension-to-inspired oxygen fraction ratio (PaO_2/FiO_2) < 250 mmHg on PEEP > 5 cm H_2O. The age range studied was 18-80 years and excluded those with a history of chronic obstructive lung disease,

pulmonary hypertension, neuromuscular disease, or prior cardiac surgery.

The primary outcome was the incidence and intensity of pulmonary complications during hospitalization. The severity was quantified using an ordinal scale between 0-5, with scores > 3 signifying major pulmonary complications. Secondary outcomes included both ICU and hospital length of stay and hospital mortality.

In the moderate RM strategy group, continuous positive airway pressure (CPAP) of 20 cm H_2O was applied for 30 seconds for a total of three applications. The intensive RM consisted of applying PEEP of 30 cm H_2O with pressure control ventilation with a driving pressure of 15 cm H_2O (i.e., achieving a plateau pressure or Pplat of 45 cm H_2O) that was sustained for 60 seconds for a total of three applications.

All 320 patients completed the study, and there were no differences in baseline characteristics. Those who received an intensive RM exhibited higher PaO_2/FiO_2 and chest compliance with a lower driving pressure than those who received a moderate RM. Moreover, those treated with an intensive RM demonstrated both a lower incidence (15.3% vs. 26.4%) and severity (1.7 vs. 2.0) of postoperative complications compared to the moderate RM group (both of which were statistically significant).

Both ICU and hospital lengths of stay were significantly lower in those who received intensive vs. moderate RMs to treat postoperative hypoxemia (3.8 vs. 4.8 days and 10.9 vs. 12.4 days, respectively). In addition, the need for oxygen therapy, prolonged use of non-invasive ventilation, and reinstitution of mechanical ventilation all were significantly lower in those randomized to the intensive RM group. The incidence of postoperative pneumonia and septic shock was not different between treatment groups. Hospital mortality was not significantly different between treatment groups.

■ COMMENTARY

In 1992, an editorial by Lachmann proposed an open lung ventilation strategy for patients with acute respiratory distress syndrome (ARDS), which emphasized aggressive recruitment of collapsed lung followed by low-stretch tidal ventilation and minimizing shear injury by applying sufficient levels of PEEP.[1] Early studies on RM produced mixed results in terms of gas exchange and chest mechanics, explained by different approaches to RM as well as patient selection criteria.

Over the past two decades, investigators have produced more than 120 publications studying the nature and prevalence of shear-related lung injury in ARDS and its response to RMs and higher PEEP levels. It has become increasingly apparent that repetitive closure and reopening of peripheral airways (i.e., compliant collapse and formation/destruction of liquid bridges), along with de-recruitment/recruitment of alveoli, probably are a major source of ventilator-induced lung injury in severe ARDS. In turn, this may partly explain why mortality in severe ARDS remains stubbornly high (42-50%) despite great strides in reducing the effect of stretch-related injury.

Recently, a multicenter pilot study of 200 subjects compared lung-protective ventilation incorporating an RM (similar to that described above) along with a decremental PEEP trial to the ARDSNet low tidal volume protocol. The lung-protective approach that incorporated an RM showed significant improvement in oxygenation and lower elastic driving pressure over 72 hours of study. Although not significant, those randomized to the RM treatment group demonstrated a 14% lower hospital mortality rate and lower incidence of death attributed to progressive respiratory failure (12% vs. 33%).

Taken together, both studies are consistent with the conceptual approach first proposed by Lachmann. Both in ARDS and other conditions with similar mechanical derangements (i.e., severely reduced chest wall compliance), transient application of high plateau pressure is necessary to reopen collapsed lung tissue, along with sufficient PEEP to counteract superimposed compressive forces related to lung edema as well as reduced chest wall compliance. Emerging evidence over the past 15 years behooves us to re-examine the wisdom of adhering to the "least PEEP" philosophy that has guided clinical practice since the early 1980s. ■

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ABSTRACT & COMMENTARY

Prophylactic Steroids Prevent Reintubation in Patients at Risk for Post-extubation Stridor

By Samuel Nadler, MD, PhD

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Dr. Nadler reports no financial relationships relevant to this field of study.

SYNOPSIS: This meta-analysis demonstrated the administration of steroids between one to 24 hours prior to extubation reduced the risk of reintubation for patients at risk for post-extubation stridor.

SOURCE: Kuriyama A, Umakoshi N, Sun R. Prophylactic corticosteroids for prevention of postextubation stridor and reintubation in adults: A systematic review and meta-analysis. *Chest* 2017;151:1002-1010.

Post-extubation stridor is associated with prolonged length of stay in the ICU and duration of mechanical ventilation with associated costs, morbidity, and mortality.[1] Prevention strategies such as prophylactic steroids may reduce these harms, but not every intubated patient is at risk. Identification of patients who might benefit from prophylactic steroids would maximize benefit and limit harms from unnecessary steroid administration.

This meta-analysis and systematic review focused on the benefits of prophylactic steroids for patients at elevated risk for post-extubation stridor. The authors examined 11 randomized, controlled studies that contained 2,472 patients. Included were trials in medical, surgical, and mixed ICUs, with sample sizes ranging from 71-700 patients from multiple countries.

Overall, prophylactic steroids were associated with reduced risk of post-extubation respiratory failure (relative risk [RR], 0.43; 95% confidence interval [CI], 0.24-0.48). A subgroup analysis demonstrated that risk reduction is statistically significant only in patients identified as high risk prior to extubation.

High-risk patients demonstrated a reduced risk of events (RR, 0.34; 95% CI, 0.24-0.48), while unselected patients did not (RR, 0.62; 95% CI, 0.24-1.61). Similarly, the risk of reintubation was reduced with steroid administration in high-risk patients (RR, 0.35; 95% CI, 0.20-0.64), but not in unselected patients (RR, 0.53; 95% CI, 0.15-1.89). This finding was robust, with sensitivity analyses showing consistent effect sizes and precision. The number needed to treat to prevent post-extubation events and airway obstruction was five and 16, respectively.

■ COMMENTARY

This study is an update of previous analyses of the use of steroids to prevent post-extubation stridor. It further helps specify which patients are at risk and demonstrates that various steroid regimens are effective. Cuff leak testing identified high-risk patients. Several criteria were used, including cuff leak volume < 24-25% of tidal volume or total cuff leak volume < 110 mL.

Effective steroid regimens included 40 mg IV methylprednisolone every six hours for four doses prior to extubation, dexamethasone 5 mg IV every six hours for four doses prior to extubation, and methylprednisolone 40 mg one time four hours before extubation. The effects seemed greatest in individuals intubated for shorter periods, but this finding remains controversial.

The positive predictive value of a negative cuff leak test for post-extubation stridor is poor.[2] However, this meta-analysis indicated that prophylactic steroids in selected patients would reduce reintubation and other airway events.

The decision to treat is based on risk vs. benefits. Of the trials included in this study, only half reported on adverse effects, but no gastrointestinal bleeding events were reported and only one patient receiving steroids became infected.

There does not appear to be significant harms associated with such short-term steroid use.

Thus, a short course of steroids to prevent post-extubation stridor and the need for reintubation seems reasonable and evidence-based in high-risk patients. ■

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ABSTRACT & COMMENTARY

Assessing Serial Ventilator Settings May Help Reduce Duration of Antibiotic Courses for Suspected Ventilator-associated Pneumonia

By Betty Tran, MD, MSc

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Dr. Tran reports no financial relationships relevant to this field of study.

SYNOPSIS: In mechanically ventilated patients with stable ventilator settings for at least three days, very short courses of antibiotics (< 3 days) for suspected ventilator-associated pneumonia were associated with similar outcomes when compared to longer courses (> 3 days).

SOURCE: Klompas M, Li L, Menchaca JT, et al. Ultra-short-course antibiotics for patients with suspected ventilator-associated pneumonia but minimal and stable ventilator settings. *Clin Infect Dis* 2017;64:870-876.

Given the difficulty in diagnosing ventilator-associated pneumonia (VAP) in the ICU with certainty, many patients who are prescribed antibiotics for suspected VAP do not actually have it.[1] Instead of focusing on ways to limit initiation of antibiotics, which is impractical in the setting of non-specific symptoms in critically ill patients, early discontinuation of antibiotics when no longer needed is a more pragmatic approach. Currently, there are few objective strategies that can inform clinical judgment as to when antibiotics can be discontinued without adverse consequences.

In this single-center, retrospective database study between 2006 and 2014, Klompas et al compared outcomes among patients started on empiric antibiotics for suspected VAP with minimal and stable ventilator settings (positive end-expiratory pressure or PEEP < 5 and fraction of inspired oxygen or FiO_2 < 40%) who were treated for < 3 days vs. > 3 days. Patients were defined as suspected of having VAP if they exhibited an endotracheal aspirate (ETA) or bronchoalveolar lavage (BAL) on or after day three of mechanical ventilation with initiation of one or more new antibiotics within two days of the culture order date (excluding the first two days of mechanical ventilation). Outcomes assessed included time to extubation alive, ventilator death, time to hospital discharge alive, and hospital death.

Three sensitivity analyses using propensity score matching were performed, including a subset of patients with ICD-9 pneumonia codes entered on or after ventilator day three and within two days of respiratory culture and antibiotic start dates and a subset of patients with > 25 neutrophils per low power field on ETA or BAL Gram stain and positive culture.

Of the 30,336 mechanical ventilation episodes identified, 1,290 patients were suspected of having VAP and had minimal ventilator settings that were stable for at least three days. Of these, 259 were prescribed antibiotics for one to three days, while 1,031 were prescribed > 3 days of antibiotics. Patients prescribed shorter courses of antibiotics tended to be older, more likely be in the medical ICU, exhibit a history of renal failure, and demonstrate higher predicted risk of hospital death on the first day of mechanical ventilation.

Patients in this short-course group were given a

median of two days of antibiotics (interquartile range [IQR], 1-3 days) compared to nine days (IQR, 6-12 days) in the long-course group. Subsequent propensity matching eliminated all measured differences between the two groups.

After adjustment for potential confounders, there were no significant differences between the two groups with regard to time to extubation alive, ventilator death, time to hospital discharge alive, or hospital death. In fact, point estimates favored patients treated with shorter courses of antibiotics (i.e., hazard ratios were > 1 for time to extubation alive and time to hospital discharge alive and < 1 for ventilator and hospital death). Similar findings were observed in all three sensitivity analyses.

■ COMMENTARY

Antibiotic stewardship is an important goal in the ICU, with hopes of improving patient outcomes, reducing microbial resistance, and decreasing the spread of multidrug-resistant organisms.[2] However, the predilection to overprescribe antibiotics in the ICU, especially when it comes to predicting VAP, mainly has to do with its nonspecific features, including fever, leukocytosis, increased secretions, and radiographic infiltrates. Once antibiotics are started, even if a pathogenic organism ultimately is not identified, the tendency is to complete a full seven-day course based on Infectious Diseases Society of America/American Thoracic Society guidelines.[3]

This study raises an interesting question that merits further confirmation in a larger, preferably randomized, controlled trial. It suggests that for patients with suspected VAP, in a subset that have minimal and stable ventilator settings, the cessation of antibiotics after one to three days was not associated with any difference in important outcomes. It is highly possible that this subgroup of patients does not have VAP to begin with. Indeed, a decline in oxygenation, as evidenced by an increase in FiO_2 by 20 points or PEEP by 3 cm H_2O, is an early requisite in an algorithm proposed for the surveillance of ventilator-associated events, the last tier of which includes possible and probable VAP.[4] Alternatively, this group of patients may have mild pneumonia that can be managed effectively with ultra-short courses of antibiotics.

The appeal of using daily ventilator settings as a screening tool to complement clinical judgment in early antibiotic discontinuation is that it is objective, simple, fast, and inexpensive as opposed to other measurements such as procalcitonin testing and the Clinical Pulmonary Infection Score, which are either costly, not widely available (or take time for results to return), and/or are more complicated to calculate or interpret. If these results are confirmed, serial ventilator setting surveillance could be a useful criterion in identifying a group of patients in whom antibiotics can be discontinued earlier. ■

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CME/CE QUESTIONS

1. **Which of the following is true with respect to the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system:**
   a. The quality of evidence across studies is rated rather than rating the quality of individual studies.
   b. The quality of evidence is determined by estimating a treatment effect.
   c. The quality of evidence is determined by assessing the confidence one can have in the treatment effect.
   d. The quality of evidence is determined by not only the evidence but also a consideration of the balance of desirable and undesirable effects, the quality of the evidence, values and preferences, and resource implications.
   e. All of the above

2. **Which of the following statements is *false* regarding the study by Leme et al?**
   a. The incidence and severity of pulmonary complications was lower in the intensive recruitment maneuver (RM) group.
   b. The study authors recruited postoperative cardiac surgery patients who developed acute respiratory distress syndrome.
   c. Both ICU and hospital length of stay were significantly lower in those who received intensive vs. moderate RMs.
   d. The intensive RM applied pressure control ventilation with a driving pressure of 15 cm H_2O above a positive end-expiratory pressure (PEEP) of 30 cm H_2O.
   e. The moderate RM applied 20 cm H_2O of continuous positive airway pressure for 30 seconds and was repeated three times.

3. **Prophylactic corticosteroids were shown to be beneficial in prevention of post-extubation stridor in:**
   a. all patients.
   b. high-risk patients determined by cuff leak test.
   c. patients with prolonged intubations.
   d. low-risk patients determined by cuff leak test.
   e. patients intubated in the field.

4. **In the study by Klompas et al, which of the following is true regarding the use of ultra-short courses of antibiotics in patients with suspected ventilator-associated pneumonia when compared to longer courses?**
   a. There was no difference in time to extubation alive.
   b. It was studied in patients who have been on stable ventilator settings for at least three days.
   c. There was no difference in time to hospital discharge alive.
   d. It was studied in patients with PEEP < 5 cm H_2O and FiO_2 < 40%.
   e. All of the above