Ventilator Management of Patients with ARDS in Medical and Surgical ICUs

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A. Study Purpose and Rationale

This observational study is designed to assess how frequently patients with acute respiratory distress syndrome (ARDS) in the medical intensive care unit (MICU) and the surgical intensive care unit (SICU) are treated with an appropriately small volume of air with each breath given by a ventilator machine. All patients with ARDS have lung disease serious enough that they require treatment with a ventilator, and recent studies show decreased mortality in patients with ARDS who are administered smaller breaths than had typically been given in the past. It is unclear how consistently the recommendations are followed, particularly in the SICU, where ARDS is less commonly seen.

B. Study Design and Statistical Analysis

This is strictly an observational study comparing current practice in the MICU and the SICU; there is no proposed study intervention. ARDS is defined by strict criteria, one of which the ratio of oxygen in the bloodstream to oxygen given by the ventilator (P/F ratio). Virtually all patients who are on a ventilator for an acute respiratory illness have at least one arterial blood gas checked per day; by assessing the daily arterial blood gas and ventilator settings on all patient in the MICU and SICU, it will be possible to determine which patients have P/F ratios that qualify for ARDS. This method would not overlook any patients with ARDS, as they would all be expected to require ventilator management. Patients who qualify based on P/F ratio will be assessed for the other criteria for ARDS (bilateral lung infiltrates on chest x-ray, absence of left-sided heart failure), all of which is part of standard evaluation in the ICU. All patients who meet criteria for ARDS will be enrolled. The investigators will record the volume of air given with each breath on the ventilator (i.e, tidal volume), the plateau pressure detected by the ventilator, and the patient's height (which will be used to calculate predicted body weight, a more useful predictor of a person's lung volume than actual body weight). Assessment of tidal volume will be performed once per patient, within 24 hours of arrival to the ICU or within 24 hours of meeting criteria for ARDS in patients who develop ARDS while in the ICU.

The primary outcome of the trial will be a categorical assessment of the proportion of patients treated with the recommended tidal volume (<6.5 cc/kg of ideal body weight). The proportion of patients with tidal volume >8 cc/kg will also be assessed, as this cutoff is clearly demarcated as an excessively large tidal volume in ARDS (tidal volume between 6 and 8 cc/kg is above the recommended volume, but not clearly identified as inappropriate). Comparison will be made between the MICU and SICU. Given assumptions that 90% of patients in the MICU and 75% of patients in the SICU will meet treatment guidelines, each group would require 113 patients in order to detect a statistically significant difference with 80% power at $p<0.05$. However, adjustments will be made given the likely discrepancy in frequency of ARDS cases between the two ICUs; if there is a 3:1 predominance of ARDS in one ICU over the other, the number of patients required would be 209 and 70 in each ICU. Statistically significance of the differences between the two ICUs will be assessed using chi-square test.

Secondary outcomes will include mean tidal volume (a continuous measure to be compared between ICUs using t-test), and correlation of tidal volumes to plateau pressures. Secondary analysis will also be performed to determine if there is a difference in tidal volume settings between patients who present to the ICU with ARDS compared with patients who develop ARDS while in the ICU; again, chi-square test will be used to evaluate for statistically significant differences as with the primary outcome, and t-test will be used to identify differences between the mean tidal volume for the two groups.

C. Study Procedure

No procedures other than standard care as determined by ICU care providers, except for measurement of patient height in order to calculate predicated body weight.

D. Study Drugs

Not applicable.

E. Medical Device

Use of ventilators as dictated by ICU care providers; no intervention by investigators.

F. Study Questionnaires

None.

G. Study Subjects

As described above, this is an observational study of all patients with ARDS in the MICU and SICU. They will be evaluated based on information already available in the course of ICU care to determine which patients meet published ARDS criteria (P/F ratio <200, bilateral infiltrates on chest x-ray, acute onset of respiratory illness, and absence of evidence for left-sided heart failure).

H. Recruitment of Subjects

As this is an observational study, patients will not specifically be recruited.

I. Confidentiality of Study Data

All subjects will be provided a unique identifier code which will not include name, initials, medical record number, social security number, phone number, or address. Data will be stored securely, with access limited solely to investigators.

J. Potential Conflict of Interest

No potential financial or other benefit to any investigators involved in the study.

K. Location of the Study

The study will be performed only within the medical ICU and the surgical ICU at Columbia University Medical Center.

L. Potential Risks

There are no risks associated with the study itself.

M. Potential Benefits

The information obtained from this trial will provide information regarding whether or not treatment recommendations are being met, which will identify whether future interventions are necessary to safeguard that standards of care are met.

N. Alternative Therapies

All care is to be dictated by the ICU care providers; no intervention by investigators.

O. Compensation to Subjects

None.

P. Costs to Subjects

None.

Q. Minors as Research Subjects

All subjects will be 18 years of age or older.

R. Radiation or Radioactive Substances

There will be no patient exposure to radiation except as directed in the course of their standard care.