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I, Heidi Marie Stewart,
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It is entitled:

"Calculation of Initial Tidal Volume Settings for Acute Respiratory Distress Syndrome Patients in One Southern Ohio Hospital's Critical Care Units"

Approved by:

Susan McCall
Thomas Bury
Christine Colella

Calculation of initial tidal volume settings for acute respiratory distress syndrome patients in one southern Ohio hospital's critical care units

Abstract

Acute Respiratory Distress Syndrome (ARDS) is characterized by bilateral pulmonary infiltrates, stiff lungs, and hypoxemia, without evidence of cardiac disease. ARDS has a high mortality of around 40-50 % (Slutsky, 2002). With the creation of the National Institutes of Health ARDS network in 1994, knowledge about ARDS pathophysiology and treatment has advanced tremendously (Martin, 2002). Several independent studies have shown improved prognosis of patients with Acute (Adult) Respiratory Distress Syndrome (ARDS) requiring mechanical ventilation using a tidal volume based on six milliters per kilogram (6mL/kg) of patient body weight, as opposed to the conventional tidal volume based on 12 milliters per kilogram (12mL/kg) (Amato et al., 1995: The Acute Respiratory Distress Syndrome Network, 2000). At the 98th International Conference of the American Thoracic Society a protocol based on clinical data was presented stating using lower tidal volumes is the only strategy proven to improve survival in Acute Lung Injury (ALI)/ARDS patients (Martin, 2002). The purpose of this study is to answer the following questions: (1) Do mechanically ventilated patients with ARDS in one southern Ohio hospital's critical care units receive the initial conventional tidal volumes based on the ARDS Network recommendation of 6mL/kg; and, (2) Is there a significant difference between the actual mL/kg used and the ARDS Network recommendation of 6mL/kg to calculate tidal volumes. The descriptive study used a retrospective chart review of patients diagnosed with ARDS and admitted to intensive care units between May 2002 and May 2003. The results indicated that the

majority of patients did not receive the recommended tidal volume. Those patients who did receive the recommended tidal volume had a mortality rate of zero versus a mortality rate of 61% for those patients who did not receive the ARDS Network recommended tidal volume based on 6mL/kg.

CALCULATION OF INITIAL TIDAL VOLUME SETTINGS FOR ACUTE RESPIRATORY DISTRESS SYNDROME PATIENTS IN ONE SOUTHERN OHIO HOSPITAL'S CRITICAL CARE UNITS

A thesis submitted to the

Division of Graduate Research and Advanced Studies

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by

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Life's little endeavors help us to grow stronger and wiser, after this little endeavor, within myself, I should be one of the strongest and wisest people. I know I certainly could not have accomplished this by myself. With special thanks, love, and appreciation to all the wee bairns in my family for being self-sufficient, independent, and caring in times of chaos and insanity. This time has also made you grow stronger and wiser. Ed, there are not enough words to say thank-you and how I cannot wait for the next journey.

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Chapter I

Introduction to the Problem

Patients with Acute Respiratory Distress Syndrome (ARDS) have poor prognosis for recovery with a 40-50% mortality rate (Slutsky, 2002). The estimated financial burden of ARDS is approximately five billion dollars annually in the United States (Martin, 2001). At this time, there is no specific treatment for ARDS, only supportive care. In 1994, the American–European Consensus Conference (AECC) established four criteria for ARDS: acute onset, bilateral infiltrates on frontal chest radiograph, hypoxemia [Arterial Partial Pressure of Oxygen (PaO2)/ Oxygenation Concentration (FiO2) ratio, less than 200 millimeters of mercury (mmHg)], and no evidence of left atrial hypertension (no congestive heart failure or pulmonary wedge pressure less than or equal to 18 mmHg) (Martin, 2002). The physiological changes present in patients with ARDS result in a clinical presentation of profound hypoxia, increased airflow resistance, decreased lung compliance, interstitial and alveolar edema, alveolar collapse, and increased work of breathing. These changes lead to respiratory failure and the need to support pulmonary function with mechanical ventilation.

Mechanical ventilation of the patient with pulmonary compromise is well recognized. It allows support of the patient's respiratory function while treating the underlying condition by providing a reliable oxygen source, decreasing the work of breathing, decreasing transthoracic pressures, and increases recruitment of unventilated alveoli. Traditional mechanical ventilation management uses 10-15 milliliter per kilogram (mL/kg) of predicted body weight (PBW) to determine tidal volume. This traditional calculation of tidal volume results in higher rates of barotraumas, longer

ventilator dependent days, and increased mortality. Thus, efforts are being made to optimize ventilation strategies in patients with ARDS (Efferen, 2002: Villagra et al., 2002). Traditional ventilator management in ARDS worsens lung injury in patients with ARDS by one the following two mechanisms: either over distention of the alveoli or repetitive recruitment and derecruitment of alveoli cause sheer stress injury from the repetitive opening and closing of alveoli (MacIntyre, 2003: Sharam, 2003). The lung then produces low ventilation/perfusion (V/Q) lung units and shunts, which lead to profound hypoxemia and less compliant lungs. Lungs that are repeatedly over-distended lose their elasticity (MacIntyre, 2003).

With the inception of the ARDS network, the knowledge about ARDS pathophysiology and treatment has advanced tremendously (Martin, 2002). Several independent studies have shown improved prognosis of patients with ARDS requiring mechanical ventilation using a lower tidal volume based on 6mL/kg of patient predicted body weight, as opposed to the traditional tidal volume of 12mL/kg (Amato et al., 1995: The Acute Respiratory Distress Syndrome Network, 2000). The standards, as recommended from the results of current research, are that patients' with ARDS outcomes are improved and mortality decreased by 20% when using lower tidal volumes of 6ml/kg (Johannigman et al., 2003). Therefore, the ARDS network strongly supports the use of lower tidal volumes when managing patients with ARDS on mechanical ventilation pending additional research to guide further treatment.

It should be noted, that the traditional tidal volume of 10-12mL/kg for mechanical ventilation continues to be the recommended treatment protocol for those patients without ARDS. Those patients with ARDS that receive 6 mL/kg and present with a

declining clinical picture must be evaluated and treated to prevent further trauma or harm. The ARDS Network strategy suggests further evaluation of the inspiratory plateau pressure, patients' breathing pattern, arterial oxygenation, and inspiratory to expiratory ratio. The goal treatment of a patient with ARDS is to provide supportive care, including optimizing a PaO_2 between 55-80 millimeters of mercury (mm) while concurrently searching for and treating the underlying causes of the pulmonary failure(ARDSNet, 2002).

Purpose f the Study

The purpose of this study is to determine if mechanically ventilated patients diagnosed with ARDS in one southern Ohio hospital's critical care units receive the initial tidal volumes based on the ARDS Network recommendations of 6 mL/kg.

Review of the Literature

The development of effective treatments, both supportive and curative is essential to improve the outcomes of ARDS patients. To this end, the ARDS Network has been instrumental in the development of knowledge and protocols for treatment of this costly condition. In order to optimize research and disseminate information for the treatment of ARDS the National Heart, Lung, and Blood Institute, National Institutes of Health created a network to carry out multi centered clinical trails of therapeutic therapies for ARDS (Martin, 2002.) The Network for ARDS research is comprised of nineteen clinical centers, which include 44 university or university affiliated hospitals that conduct research to improve therapies for patients with Acute Lung Injury (ALI) and ARDS. Each center has a Principal Investigator that is a member of the Network wide steering committee, which evaluates the current research trials and brainstorms about further

research. The Network also has a Clinical Coordinating Center, which is responsible for a centralized data management system, data analysis, and coordination of the Networks functions (ARDSNet, 2002).

The ARDS Network 6mL/kg tidal volume ventilation strategy is a result of the ARDS Network research.

Amato and colleagues conducted a three year randomized controlled study of 28 patients (Amato et al., 1995) that examined the effects of lower tidal volumes and the outcomes of patients with ARDS. The researchers conducted a trial that used a traditional tidal volume of 12 mL/kg of predicated body weight, volume-assisted/controlled delivery system of ventilation, and minimum Positive End Expiration Pressure (PEEP), which was guided by FiO_2, hemodynamics, and normal PaO_2 levels. The researchers used a new approach (NA) of a lower tidal volume equal to 6 milliliters per kilogram (Vt = 6mL/kg), levels of PEEP above the lower inflection point of the respiratory system pressure-volume curve, which intended to maintain patency and reduce cyclic opening and closing of injured alveoli (Amato et al.). The investigators found a small trend in reduction in mortality, avoidance of alveolar collapse, improved pulmonary compliance, avoidance of high distending pressures, and marked improvement in the lung function in the experimental group.

In an extension study, Amato and colleagues conducted a prospective trial with an additional 25 patients with the continued goal to minimize ARDS complications from ventilator settings and to decrease mortality (Amato et al., 1998). The patients were randomly assigned to one of two groups, the traditional or the protective ventilation (low tidal volume) treatments. The traditional treatment patients strategy was to maintain the

lowest PEEP for acceptable oxygenation, Vt =12 mL/kg, and normal arterial carbon dioxide levels (35-38 mm Hg). Protective ventilation involved end-expiration pressures above the lower inflection point on the static pressure-volume curve, Vt = 6mL/kg, driving pressures of less than 20 centimeters (cm) of water above the PEEP value, permissive hypercapnia, and preferential use of pressure ventilatory modes (Amato et al., 1998). Amato et al. again found a beneficial effect in patient outcomes. After 28 days, 11 of 29 patients in the lower tidal volume group had a 38 percent mortality rate In comparison to, the traditional ventilation group, with 17 of the 24 patients having a 71 percent mortality rate (Amato, p.347)

The study was stopped after 25 additional patients were enrolled because of the significant survival difference between the groups. Significantly, more patients were successfully weaned from mechanical ventilation in the experimental group than the traditional ventilation group, 66 % vs. 29% (Amato et al.). A limitation of the study was that the authors recognized their inability to do a blinded study, although the use of strict algorithms minimized this limitation.

A three-year multi-centered study conducted in 1996-1999 enrolled 861 patients and randomized them into two ventilator tidal volume groups. The traditional ventilator tidal volume group was given the initial tidal volume (Vt) of 12mL/kg and an airway plateau pressure measured after a 0.5 second pause at end of expiration of </=50 cm of H_2O. The experimental ventilator tidal volume group was given the lower initial Vt of 6mL/kg and an airway plateau pressure of </=30 cm of H_2O (Martin, 2001). This trial was stopped after the enrollment of 861 patients, at which time the lower tidal volume group had a reduced mortality of 24%, increased organ failure free days, and increases in

the number of days without a ventilator (The Acute Respiratory Distress Syndrome Network, 2000: Efferen, 2002). This Acute Respiratory Distress Syndrome Network trial was the first successful large, clinical trial that investigated ventilation strategies in ARDS (Medscape Clinical Updates, 2002).

At the 98th International Conference of the American Thoracic Society in May of 2002, Bernard, reported low tidal volume ventilation as the only strategy proven to improve survival in ALI/ARDS patients (Martin, 2002). Mild hypercapnia and respiratory acidosis did occur, but were considered of no clinical significance to patients with ARDS. The best evidence based recommendation for patients with ARDS is implementation of the ARDS Network protocol, which includes using a tidal volume of 6mL/kg of predicted body weight (Hall, 2002). This recommendation is from the National Heart, Lung, and Blood Institute, National Institutes of Health and the ARDS Network based on the previously mentioned research studies. This protocol is one recommendation for the treatment of ARDS. In addition to these recommendations, there are further resources, which have protective modalities.

The use of PEEP has been investigated in the treatment of ARDS. PEEP increases the pulmonary functional residual capacity, improves V/Q matching, increases PaO_2 and decreases the requirement for high fractions of inspired oxygen (Siegel, 2003). The ARDS Network protocol contains PEEP in relationship to FiO_2 with the goal to maintain the $PaO_{2\ mm}$ Hg or $SpO_{2\ of}$ 88-95% (ARDSNet, 2002). Ideal levels of PEEP for patients with ARDS are unknown. Providers must evaluate individual patients to optimize outcomes in relationship to levels of PEEP. Currently there are various applications of PEEP to patients with ARDS. The following is a list of some applications of PEEP:

- Pressure-Volume (P-V) Curve - Patients with ARDS have a prolonged initial inflation response, this increase in pulmonary pressures show only a small increase in volumes. With much higher inflation pressures, there is a risk of baraotrauma and alveolar changes. These changes are counterproductive for patient with ARDS lung function. An increased pressure which improves compliance, minimizes cyclic alveoli recruitment and derecruitment, improves hemoglobin saturation, and decreases oxygen requirements is the goal for this PEEP application. This point on the P-V curve is called the lower inflection point or Pflex. The limitations with using Pflex as sole criteria for optimizing PEEP levels are because pulmonary tissue with ARDS does not respond as an entire unit to mechanical ventilation and segmental derecruitment occurred over a range of pressures, which was not foreseen by the Pflex approach. In addition, Pflex cannot be determined in some patients (Siegel, 2003).
- Stepwise application of PEEP based on a calculation, which includes respiratory system compliance, tidal volumes and plateau pressures. This is a progressive increase in PEEP to optimize the application of PEEP and oxygenation (Seigel, 2003).
- Increased PEEP to maximize oxygen delivery based on a calculation, which includes cardiac output, hemoglobin concentration, arterial hemoglobin oxygen saturation, and partial pressure oxygen. Application of PEEP and oxygen delivery is dependent on the hemoglobin concentration; the optimal level of PEEP may be less than the amount that achieves the highest arterial hemoglobin saturation (Seigel, 2003).

- PEEP at the lowest level to keep FiO_2 less tan 60 % and an adequate arterial PO_2. Patient goal to minimize lung injury in addition to ARDS treatment.
- PEEP at least 16 cm H_2O and 6mL/kg tidal volume.

These PEEP methods are some of the additional recommendations for the treatment of ARDS.

There is a gap in the current literature on using a low tidal volume for ventilation support of patients because there are only a few studies that have been accomplished to date and only one of those was a large study. Dr. Andrew Bersten suggested at the 8th World Congress of Intensive and Critical Care Medicine that these trials if repeated may have negative results. He discussed two potential problems with meta-analysis data from all the randomized low tidal volume trials to date: there was a small early PEEP difference between the traditional tidal volume group and the lower strategy group and only 16% of eligible patients were enrolled in the trial, questioning its generalizability. There is no further discussion about the eligibility criteria for the patients in these multiple trials. (Slutsky, 2002).

Follow up studies by Stewart et al. (1998) and Brochard, Roudot-Thoraval, and Roupie (1998) failed to support Amato et al.'s findings. Stewart et al (1998) stated that after enrolling 120 patients into a two armed study, the strategy of mechanical ventilation which limits peak inspiratory pressures and tidal volumes of 8mL.kg or less does not appear to reduce mortality and may increase morbidity. The Brochard et al. (1998) study enrolled 15 patients to assess if low tidal volumes 6mL/kg, or a reduction in end-inspiratory plateau pressures was responsible for alveolar recruitment. The results were when Plateau pressures were kept less than 30 cm H_2O, Vt = 6 mL/kg, and a increased

PEEP may recruit more alveoli and provide better oxygenation compared to the traditional Vt and PEEP. The authors felt that the results might not be applicable to all patients with ARDS with large nonrecruitable alveoli and high airway pressures (Brochard, p. 92). Nevertheless, the ARDS Network recommendation remains to use the lower tidal volume of 6mL/kg because of the overwhelming evidence by the ARDS network trial (Hall, 2002). While the evidence and recommendations for lower tidal volumes are the standard of practice now, research continues to find more effective treatments to reduce complications, morbidity and mortality. Initial lower tidal volumes of 6mL/kg of Predicated Body Weight are implemented as the standard for the management of ARDS patients. The lower tidal volumes reduce barotraumas, decreases ventilator dependency days, and decreases mortality.

Research Questions

The following research questions are addressed in this study:

1. Do mechanically ventilated patients with ARDS in one southern Ohio hospital's critical care units receive initial tidal volumes based on the ARDS Network recommendations of 6mL/kg
2. Is there a significant difference between the actual mL/kg used to calculate tidal volumes and the ARDS Network recommendations of 6mL/kg to calculate tidal volumes?

Conceptual Definitions

Arterial Hemoglobin Saturation (SaO2): The measure of the amount of oxygen bound to hemoglobin.

Arterial Partial Pressure of Oxygen (PaO2): Partial pressure of oxygen dissolved in arterial blood.

Hypercapnia: Increased amounts of carbon dioxide in the blood.

Positive End Expiration Pressure (PEEP): Positive pressure applied at the end of expiration of ventilator breaths.

Predicted Body Weight (PBW): Calculated for males as 50 + 2.3 [height (inches) -60] or 50 + 0.91 [height (cm) – 152.4], and for females as 45.5 + 2.3 [height (inches) -60] or 45.5 + 0.91 [height (cm) -152.4]

Oxygen Concentration (FiO2): Fraction of inspired oxygen delivered to patient on ventilator, may be set between 21% and 100%: usually adjusted to maintain PaO2 level greater than 60 mm Hg or SaO2 level greater than 90%.

Tidal volume: The volume of air exhaled after a normal resting inhalation

Volume controlled ventilation: A ventilator setting that delivers a preset rate and tidal volume, regardless of patient's inspiratory efforts.

Volutrauma, (formerly known as barotrauma): Overdistention of the alveoli that cause rupture and air leakage into the pulmonary interstitial space.

CHAPTER II

Methods

Design of Study

A survey design with a retrospective chart review was used in this study.

Setting and Subjects

This research study was conducted in a large medical center in Cincinnati, OH. This medical center has 48 beds in medical, cardiovascular surgical and surgical intensive care units. Approximately 10- 30 patients with ARDS patients are seen annually in this medical center. In this study, charts of patients diagnosed with ARDS who received mechanical ventilation over a 12-month period from May 2002 to May 2003 were reviewed. Patients were included if they had either a primary or secondary diagnosis of ARDS and if they were 18 years of age or older. Patients were excluded from the study if they had any of the following conditions:

- Pregnancy
- Increased intracranial pressure (> 15 mm Hg)
- Previous neuromuscular disease which would impair spontaneous breathing
- Sickle cell disease
- Chronic respiratory disease: asthma, COPD
- Emphysema
- Tuberculosis
- Cystic fibrosis
- Lung transplant
- Myocardial infarction

- Terminal illness with less than six-month prognosis.

Instrument

The data collection tool was developed by the researcher to record patient information from the medical chart. Information about the subjects' admission was obtained and ARDS subjects' inpatient charts were used to collect treatment data (Appendix B). Demographic information about the subjects included age, gender, race, and assigned hospital unit, either a medical or a surgical unit. The admitting and secondary diagnoses were obtained to determine the subjects' eligibility into the study by the inclusion and exclusion criteria. The subjects' actual body weight at the time of the ARDS diagnosis was obtained. In addition, their height was documented to be used in the calculations for determining the subjects predicted body weight. Tidal volumes were obtained at the initiation of the ARDS diagnosis, and then at the first hour and the second hour. These three tidal volumes were recorded to determine if adjustments were made to the ventilator settings at the beginning of the ARDS diagnosis. The ARDS Network protocol suggests tidal volume adjustments in the first few hours based on the patient's tolerance of the lower tidal volume settings and clinical outcomes (ARDSNet, 2002). The provider data was used to indicate who determines the tidal volume settings. This data could provide insight into potential education opportunities. Finally, the patients' disposition was obtained to evaluate statistically the death rate and recovery rate of the subjects in the study. There is no reliability or validity data on this instrument.

Procedures

After Institutional Review Board approval, a HIPPA waiver, and hospital approval, the investigator collected data from charts of discharged ICU patients who had

been diagnosed with ARDS, who received mechanical ventilation between May 2002 and May 2003, and who met the inclusion and exclusion criteria. The investigator contacted the hospital and asked to see the charts of patients with the relevant diagnosis in the relevant time period. The investigator collected the data in the hospital records room under the supervision of hospital personnel.

Protection of Subjects

Institutional Review Board (IRB) approval was obtained prior to the start of the study (Appendix A). Confidentiality was maintained by numbering the data collection tool and not using personal identifying information (e.g., name, date of birth, address, or social security number). There were no known risks associated with the study. Statistical data and data collection tools were kept in locked file cabinet during the collection period and available only to the investigator.

Data Analysis

All measures of weight were converted to kilograms. All measures of height were converted to inches. The predicted body weight (PBW) was calculated using the following formulas: Male = 50 + 2.3 [height (inches) - 60] and Female = 45.5 + 2.3 [height (inches) - 60], (ARDSNet, 2003, p. 1). Predicted body weight was used to determine whether 6mL/kg or 12mL/kg was used to calculate tidal volume. Descriptive statistics appropriate to level of measurement were used to describe demographic characteristics of the sample and patient outcomes. Two-tailed t-tests were used to determine statistical differences between recommended tidal volume and actual tidal volume. For all analyses, statistical significance was determined using an alpha of .05.

CHAPTER III

Results

Sample

A total of 17 subjects met the inclusion and exclusion criteria for the study. There were slightly more males (n = 10) than females (n = 7). Sixteen subjects were white (94%) and one subject was African-American (6%). Subjects' ages ranged from 28 to 84, with a mean age of 61.1 years and a median age of 63.7 years. Predicted body weight of the sample ranged from 50.1 kg to 82.20 kg (four cases were missing height data, so PBW could not be calculated), with mean of 65.96 kg (SD = 10.05 kg). Actual body weight of sample ranged from 51.0 kg to 141.00 kg, with mean of 88.30 kg (SD = 26.28 kg). Initial recorded tidal volumes for these patients ranged from 500 to 1,100, (mean = 713.53, SD = 128.16). Eight patients in this sample died prior to discharge, one patient was discharged home, and eight patients were discharged to an extended care facility. All surviving patients had been successfully weaned before discharge.

Analysis of the Data

Research Question 1: Do mechanically ventilated patients with ARDS in one southern Ohio hospital's critical care units receive initial tidal volumes based on the ARDS Network recommendation of 6mL/kg? This question was answered by comparing each patient's recorded tidal volumes with tidal volumes calculated using their actual and predicted body weight multiplied by 6mL/kg. Four patients received tidal volumes approximating 6mL/kg when calculated using their actual body weight; no patients received tidal volumes approximating 6mL/kg when calculated using predicted body weight.

Research Question 2: Is there a significant difference between the actual mL/kg used to calculate initial tidal volumes and the ARDS Network recommendation of 6mL/kg to calculate tidal volumes? This question was answered by using each patient's actual and predicted body weight and initial tidal volume to calculate the actual mL/kg tidal volume amount based on (1) actual weight and (2) predicted body weight. The mean mL/kg tidal volume based on patients' actual weight was 8.6 mL/kg (SD = 2.29 mL/kg). The mean mL/kg tidal volume based on patients' predicted body weight was11.3 mL/kg (SD = 2.22mL/kg).

These means were compared to 6mL/kg in two-tailed t-tests. The tidal volume used with patients in these intensive care units, whether based on actual or predicted body weight, differed significantly from the ARDS Network recommendation of 6mL/kg; $t(16) = 4.7$, $p < .001$ and $t(12) = 8.6$, $p < .001$, respectively, for actual and predicted body weight. Therefore, in this sample, the lower tidal volume of 6 mL/kg was not used to determine tidal volume, either using actual body weight or predicted body weight. No significant differences were found in type of unit (see Table 1).

Table 1: Comparison of mean tidal volumes based on actual body weight (ABW) and predicted body weight (PBW) with tidal volume based on ARDS Network tidal volume based on 6mL.kg.

UNIT	Mean Tidal volume based on ABW	Statistic	Mean Tidal Volume based on PBW	Statistic
Medical	7.81 (2.10)	$t(10) = 2.9, p > .05$	10.40 (0.95)	$t(6) = 12.2, p > .001$
Surgical	10.08 (2.01)	$t(5) = 5.0, p = .004$	12.35 (2.88)	$t(5) = 5.4, p = .003$

Standard deviation (SD) in parentheses

Although, overall, tidal volume was not found to be based on 6mL/kg, four patients did have tidal volumes consistent with this ARDS Network recommendation. These four patients were all discharged to an extended care facility, none died, whereas eight of the 13 patients whose tidal volumes were not consistent with the ARDS Network did not survive the hospitalization.

CHAPTER IV:

Discussion

Application of Findings to Practice

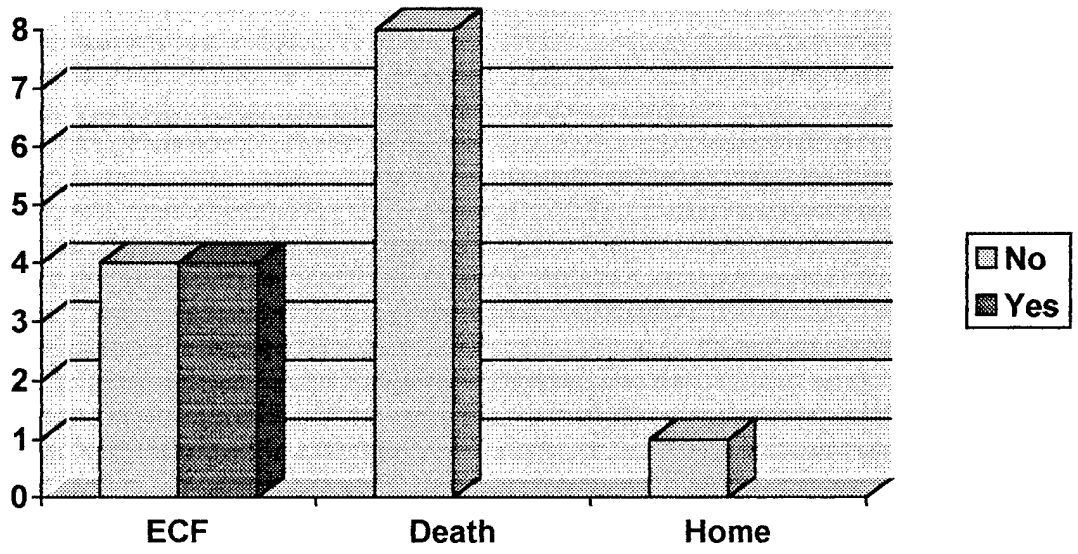
Patients with ARDS receiving mechanical ventilation have had poor outcomes with a high mortality of 40-50%, partially related to the trauma to lung tissue caused by the mechanical ventilation (Slutsky, 2002). The physiological changes present in patients with ARDS result in a clinical presentation of profound hypoxia, increased airflow resistance, decreased lung compliance, interstitial and alveolar edema, alveolar collapse, and increased work of breathing. These changes lead to respiratory failure and the need to support pulmonary function with mechanical ventilation. With the inception of the ARDS Network by the National Heart, Lung, and Blood Institutes of Health in 1994, the goal has been to improve ARDS patients' outcomes. The ARDS Network has implemented multi-centered network comprised of nineteen clinical centers including 44 hospitals. The ARDS Network conducts clinical trials to study the effectiveness of treatment strategies for ARDS patients both supportive and curative. Currently, the ARDS Network recommendations based on clinical data is that lower tidal volumes of 6 mL/kg is the only proven strategy to improve the outcomes of patients with ARDS, decreasing mortality by 20% (ARDSNet, 2003) (Johanningman, 2003).

From the results of this study, it can be determined that in one southern Ohio hospital's critical care units the patients with ARDS that are mechanically ventilated are not receiving the recommended ARDS Network protocol of 6mL/kg for initial tidal volumes using PBW. To determine the initial tidal volume for the 17 subjects the mL/kg tidal volume was calculated based on the recorded tidal volumes and the patient's actual

body weight. There was a statistically significant difference between the initial tidal volume used in this institution and in the recommended tidal volume of 6mL/kg. Nevertheless, it should be noted that four of the 17 subjects did have tidal volumes consistent with the recommended 6mL/kg of PBW. Of those four subjects, all were discharged to an extended care facility with no ventilatory support. The study results indicate that despite the protocol's recommendation to adjust the tidal volumes based on the patient's response and clinical findings (ARDSNet, 2003), only two of the 17 patients had the tidal volume adjusted during hospitalization. The first patient's initial tidal volume was 4.8mL/kg based on ABW, which was increased to 6.3mL/kg based clinical findings. While this patient's PBW could not be calculated due to missing height data, this patient's tidal volumes were within the recommended protocol using the ABW and the subject was discharged to an extended care facility. The second subject who had a tidal volume adjustment had an initial tidal volume of 7.3mL/kg based on ABW, which was increased to 8.0mL/kg. If the tidal volumes for this subject had been based on the PBW (as recommended), the initial tidal volume would have been 10.3 mL/kg, and the increased tidal volume would have been 11.5 mL/kg, thus, not meeting the ARDS Network protocol recommendations.

When the 17 patients' initial tidal volume at the diagnosis of ARDS and the PBW were calculated for the initial tidal volume of thirteen subjects, with the available PBWs the Mean was 11.06 mL/kg (SD = 1.86). This is an approximate increase of 85 % from the recommended protocol of 6 mL/kg. The initial tidal volumes of the remaining four patients based on their PBW were not calculated due to missing height data.

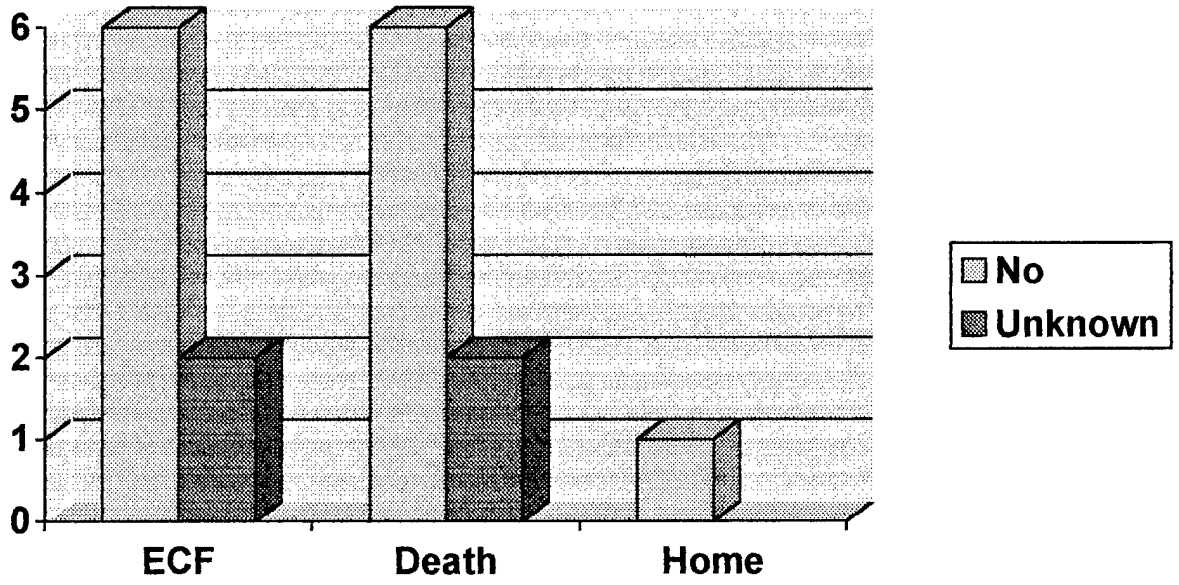
Figure 1: Outcomes of patients using tidal volumes based on actual body weight



Note. No = not following recommendation of 6mL/kg; yes = following recommendation of 6 mL/kg; ECF = Extended Care Facility.

Figure 1 illustrates that when comparing outcomes using the protocol of 6mL/kg based on the patients' ABW, only four subjects had tidal volumes of 6mL/kg or below. Those four subjects all were discharged to an extended care facility (ECF). Of the remaining thirteen subjects, eight died, four were discharged to an ECF, and one was discharged to home. Thus, the mortality rate of patients with initial tidal volumes inconsistent with the ARDS Network recommendation was 61.5%, whereas the mortality rate of patients with initial tidal volumes consistent with the ARDS Network recommendation of 6 mL/kg was 0%.

Figure 2 depicts the outcomes of patients when tidal volume was based on predicted body weight. The 13 patients whose height data was available did not meet the ARDS Network recommendation of tidal volumes of 6mL/kg calculated with predicted body weight. Four patients did not have height data available on their chart.



Note. No = not following recommendation of 6mL/kg; unknown = not determinable; ECF = Extended Care Facility.

The findings of this study indicate that in one southern Ohio hospital's critical care units the recommended ARDS Network protocol of an initial tidal volume of 6 mL/kg based on predicted body weight not being used. Examining the tidal volumes and actual body weight, it is clear that the more traditional tidal volume determination of 10-15 mL/kg was followed. The outcome of this study supports previous research suggesting that using a tidal volume greater than 6mL/kg increases the mortality rate of patients diagnosed with ARDS receiving mechanical ventilation.

CHAPTER V: SUMMARY

Summarization of Research

The purpose of this study was to determine if the ARDS Network protocol recommended initial tidal volume of 6 mL/kg based on predicted body weight was being used with patients diagnosed with ARDS in one southern Ohio hospital's critical care units.

The subjects included 17 adults who had either a primary or a secondary diagnosis of ARDS and were receiving mechanical ventilation. Data was obtained with a retrospective chart review of all the patients diagnosed with ARDS treated in the hospital's critical care units during a 12-month period, May 2002 to May 2003. Data collected included gender, age, race, height, actual body weight, initial tidal volume at the diagnosis of ARDS, tidal volumes at the first and second hours of ventilation following the ARDS diagnosis, the type of provider selecting the ventilator settings, and the subject's disposition (either to home, an extended care facility or death).

The financial cost and loss of human life for patients' diagnosed with ARDS has placed a large responsibility upon the health care provider to improve these patients' outcomes. The current recommendation by the ARDS network to limit tidal volumes to 6mL/kg is the only evidence-based strategy to decrease mortality and improve outcomes (Martin, 2002).The ARDS Network protocol of calculating initial tidal volumes based on 6 mL/kg of predicted body weight is one of several recommendations for the treatment of ARDS. In one southern Ohio hospital, this protocol had not been used in the treatment of patients with ARDS seen in the critical care units for the 12-month period of this study. The information obtained from this study revealed that of the 17 patients, 13 had

documented heights that would have allowed the calculation of PBW. Predicted Body Weight is the recommended weight when calculating tidal volumes for patients with ARDS receiving mechanical ventilation. Of those 13 patients with a PBW available, none had an initial tidal volume consistent with the ARDS Network recommendation. The mortality rate in this sample of 13 patients was 47.1%. However, the sample of four patients who had tidal volumes consistent with the ARDS Network recommendation experienced no deaths.

Scope and Limitations

The small sample size, the homogeneity of the sample, and the limited geographical representation are all serious limitations to this study. In addition, the small sample size did not allow the examination of the effects of other factors, such as admitting diagnoses, complications during hospitalization, age, sex, and other ventilatory strategies on patient outcomes.

Recommendations for further study

To determine if following the ARDS Network recommendations does affect patient outcomes in this geographical area, a much larger study should be done. A prospective study could help determine when changes occur in protocols or allow the investigator to determine if other factors are affecting the decision to use the ARDS Network recommendations. It is important to determine the effect of other ventilatory strategies on patients' short and long-term outcomes. In order to acquire a more accurate picture of the implementation of the ARDS network protocol in southern Ohio hospitals, hospitals should include those facilities with different levels of care from the Level I trauma centers to the outlying community hospitals.

Further studies may consist of continuing with a more comprehensive evaluation of the implementation of the ARDS network protocol. This could include evaluating the mode of ventilation provided, assessment of inspiratory plateau pressures, arterial oxygenation rates, inspiration to expiration ratios, and subjects' ability to be weaned from ventilatory support. Current clinical ARDS trials are evaluating the ability to use recruitment maneuvers to maintain the patency of alveoli. An additional study could include the use and evaluation of recruitment of alveoli maneuvers, evaluation of alternative applications of PEEP, and the subjects' outcomes.

Significance to nursing

This study has significance to nursing in the need for further research in the study of patients with ARDS. Implementation of the 6mL/kg tidal volume ventilation strategy has been proven to reduce mortality and improve patient outcomes. The ARDS Network protocol treatment information needs to be disseminated to health care providers in the form of formalized education plans, informal bedside staff teaching, and policy formulation in collaboration with the pulmonary service, policy implementation, and discussion at local and regional professional meetings about the need for further research in the treatment of patients with ARDS.

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APPENDIX A

INSTITUTIONAL REVIEW BOARD NOTIFICATION FORM

SUB-INVESTIGATOR(S):

UNIVERSITY OF CINCINNATI MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD

PRINCIPAL INVESTIGATC)R: Heidi Stewart

xxx *APPROVED - Initial-X- Full Board _ Expedited x
Informed Consent Requirement Waived

PROTOCOL: 03-4-4-3

"Calculation of Initial Tidal Volume Settings for Acute Respiratory Distress Syndrome Patients in Two Southern Ohio Critical Care Units"

In the event that an investigational study involves a drug, the principal investigator or his/her agent, must contact the Investigational Drug Service Pharmacy at the site/location where the study is being performed.
(The Health Alliance Pharmacy at University Hospital, 584-1766, can also assist if the location is off-site.)

2. You are required to immediately report to the Institutional Review Board: 1) any death/serious adverse event, or 2) any non-serious event which is both related to the study and is unexpected.

3. The period of approval of this research project is stated above. A progress report form must be filed with the Institutional Review Board on at least an annual basis, and sometimes more frequently at the discretion of the Board. If the progress report is not returned by the specified date, your department head will be notified.

4. There may be no change or addition to the project, or changes of the investigators involved, without prior approval of the IRB.

5. If this protocol has not been initiated within two years of this date, you will be required to resubmit the study for reconsideration by the Institutional Review Board. However, this regulation is not intended to negate the requirement that a progress report be filed with the IRB office on at least an annual basis.

6. Notification of approval by the Institutional Review Board does not necessarily indicate approval by other committees of the Medical Center with the exception of Radiation Safety.

7. You are required to modify this study, subject to IRS approval, if subsequent information regarding any drug, device or procedure utilized in the study is received from the manufacturer or any other reliable source that could reasonably increase or after potential harm to subjects. The informed -consent statement must be modified to include this new information or an addendum must be prepared as a means to assure subject notification. In cases where the subject has completed the study, the modification or addendum is only necessary if the additional information received could impact the subjects in the future.

Sponsor:

DATE:April 14, 2003

The approval for this research activity expires on: April 14, 2004

titutiona.I Review Board

FWA - **3152**

*The attached consent has been approved by the IRB. Please copy this ICS document and use for all subjects entered into the study

APPENDIX B

DATA COLLECTION TOOL

APPENDIX B

ARDS Data Collection Tool: Completed by Principle Investigator

Hospital 1 2

ICU A B

Subject Number _____

1. Age:_____

2. Female O

Male O

3. Latino O

African American O

Asian O

White O

Pacific Islander O

American Indian O

Other O

4. Admitting Diagnosis: _____

5. Additional Diagnosis:

Trauma O

Pneumonia O

Sepsis O

Other:_____

6. Body weight used to determine initial Tidal volume settings on Ventilator:

_____ Kilograms O Pounds O

7. Patient's actual body weight: _____ Kilograms O Pounds O

8. Patient's height in inches/cm: _____

9. Type of Ventilator used: _____

10. Type of initial ventilator settings used

Pressure Controlled	O
High Frequency Ventilation	O
Pressure Support Ventilation	O
SIMV	O
CMV	O
Intermittent Mandatory Ventilation	O
Independent Lung Ventilation	O
Assist Control Volume/Pressure	O

11. Initial ratio of inspiration to expiration settings

1:1	O
1:2	O
1.5:1	O
2:1	O
4:1	O

Other: _____

12. Initial tidal Volume _____

13. Tidal Volume at second hour of ventilation _____

14. Tidal Volume at third hour of ventilation? _____

15. Who determines the initial tidal volume ventilator settings for ARDS patients?

Physician, specialist	O
Physician, non-specialist	O
CNS	O
Nurse Practitioner	O
Respiratory Therapist	O

16. Patient's disposition

Death O At what number hospital day_____

Discharged to extended care facility/rehab O On a ventilator Yes O No O

Discharged to home O On a ventilator Yes O No O