RAPID SHALLOW BREATHING INDEX AND WEANING OUTCOME IN CARDIOVASCULAR SURGERY PATIENTS REQUIRING MECHANICAL VENTILATION FOR 24 HOURS OR LONGER

A DISSERTATION

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To the Dean of the Graduate School:

I am submitting herewith a dissertation written by Dorothy M. Kite-Powell entitled "Rapid Shallow Breathing Index and Weaning Outcome in Cardiovascular Surgery Patients Requiring Mechanical Ventilation for 24 Hours or Longer." I have examined this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy with a major in Nursing.

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Finally, this dissertation is dedicated to the memory of my parents, Dorothy J. and Robert W. McCoy, who taught me that knowledge is power and the quest for it never stops.

ABSTRACT

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RAPID SHALLOW BREATHING INDEX AND WEANING OUTCOME IN CARDIOVASCULAR SURGERY PATIENTS REQUIRING MECHANICAL VENTILATION FOR 24 HOURS OR LONGER

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The purpose of this prospective descriptive study was to investigate the differences between the rapid shallow breathing index (RSBI) measured at 2 different time points for cardiovascular surgical patients who have a positive weaning outcome and those that do not. The study was conducted in a 52-bed cardiovascular recovery room (CVRR) in a tertiary care teaching institution located in the south central portion of the US. Twenty-nine consecutive patients undergoing cardiac surgery on cardiopulmonary bypass were enrolled. All measures of the RSBI were obtained with the Wright respirometer while the patient was breathing spontaneously. The first RSBI (RSBI1) was measured at 24 hours or when the patient was stable on mechanical ventilation per the study protocol. The second measure (RSBI2) was obtained at the beginning of the first weaning trial. Of the total sample (N = 29), 24 cases had a positive weaning outcome, defined as the ability to breathe spontaneously for 24 hours after weaning, compared to 5 cases that had a negative weaning outcome. Data were analyzed using two independent t-tests that compared mean differences of the

RSBI measures between the positive and negative weaning outcome groups. The assumption for homogeneity of variance was tested and found to be met prior to conducting the *t*=tests. There was a significant difference between the weaned and the non-weaned groups for the RSBI 1 (t=-6.414, df=27, p=0.000). RSBI means were significantly higher for the group with a negative weaning outcome. In addition, the RSBI at the time of weaning (RSBI 2) was statistically significant indicating that the mean RSBI scores were higher for the non-weaned group (t=-8.404, df=27, p= .000). The results of this study indicate that the RSBI may be useful in predicting weaning outcome in cardiovascular surgery patients.

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CHAPTER I

INTRODUCTION

Patients requiring critical care account for 4% of national health care expenditures which equals approximately $112 billion annually (Cooper, Walter, & Linde-Zwirble, 2004; Halpern, Pastores, & Greenstein, 2004). Much of the increased cost of intensive care unit (ICU) care can be attributed to the use of mechanical ventilation, a core technology used for treating critically ill patients. Approximately 33% to 41% of all patients admitted to ICU require mechanical ventilation (Dasta, McLaughlin, Moody, & Piech, 2005; Esteban et al., 2000). Recently published data indicates an overall increased incidence of 11% in use of mechanical ventilation during the period of 1996 to 2002 (Carson, Cox, Holmes, Howard, & Carey, 2006). During mechanical ventilation, almost 50% of a patient's total ventilation time may be spent in the process of weaning. In most patients, mechanical ventilatory support is discontinued when the underlying disease process is reversed. Generally, the majority of patients can be successfully liberated from mechanical ventilation in 3 days or less. However, for the more critically ill patient weaning may take weeks, even months. Therefore, it is crucial that weaning commences as soon as the patient's condition permits.

All patients undergoing open heart procedures on cardiopulmonary bypass utilize mechanical ventilation. In 2004, there were 90,000 valve replacements and 427,000 cardiac revascularization procedures performed in the United States (American Heart Association, 2007). In most of these patients, mechanical ventilation is discontinued in 6 to 8 hours after surgery. However, a significant number of patients continue to receive mechanical ventilation for a prolonged period following surgery. The incidence of ventilation greater than 24 hours is 5.5% after a first coronary artery bypass graft (CABG) surgery and 10.5% after reoperation (Yende & Wunderlink, 2002). This percentage translates into approximately 23,485 to 42,700 annually and does not include patients who require valve replacement.

Problem of Study

No one variable or group of variables can accurately predict weaning outcome in all patients. The categories of weaning variables include cardiopulmonary, individual and grouped patient characteristics, vital signs, and severity markers. The existing evidence spans over 40 years and remains inconclusive as to the most accurate weaning process or prognostic index. Reasons for the lack of definitive findings in prior research are related to inconsistent definition of weaning and the heterogeneity of patient groups studied. The Rapid Shallow Breathing Index (RSBI) represents a pulmonary predictor that may be useful in projecting weaning outcome. The purpose of this study was to evaluate the RSBI as an indicator of weaning readiness for patients undergoing cardiovascular surgery and placed on coronary bypass.

Rationale for the Study

Liberation from mechanical ventilation without complication is the goal of weaning. While mechanical ventilation is a vital piece of the treatment plan for critically ill patients, it is not without significant risks. Delays in withdrawing mechanical ventilation can result in ventilator-associated pneumonia (VAP), discomfort, and ventilator-induced lung injury (MacIntyre, 2004). VAP is defined as pneumonia occurring >48 hours after endotracheal intubation and initiation of mechanical ventilation (American Thoracic Society & Infectious Diseases Society of America, 2005). Mechanically ventilated patients have between a 10 to 21-fold higher pneumonia rate than non-ventilated ICU patients (Chastre & Fagon, 2006). The mortality rate for patients with VAP ranges from 24-50% and can be as high as 76% in specific settings or if high-risk pathogens are involved (Chastre & Fagon, 2006). The presence of VAP increases cost by as much as $40,000 per case (Rello et al., 2002).

Just as delays in weaning may lead to untoward patient outcomes, premature discontinuation of mechanical ventilation can contribute to failed extubation requiring reintubation. The risks of premature withdrawal include difficulty in re-establishing an artificial airway, ventilatory muscle fatigue, and compromised gas exchange (MacIntyre, 2004). Rates of reintubation at 48 hours range from 9.5% to 29.4% (Tobin & Laghi, 2006). The need for reintubation is an independent predictor of mortality, even after controlling for co-morbid conditions and severity (Epstein, Ciubotaru, & Wong, 1997). Mortality among patients requiring reintubation ranges from 10% to 40%. Clinicians must carefully weigh the value of removing the ventilator as soon as possible against the risks of premature withdrawal, as both actions may potentially lead to severe complications. However, if clinicians could precisely identify the exact point in time when weaning readiness occurs, these complications could be limited or even prevented.

In 1993, weaning from mechanical ventilation was identified as a high priority in critical care research by the American Association of Critical-Care Nurses (AACN) (Lindquist et al., 1993). AACN revised their research priorities in 1999 and made them much broader in scope (American Association of Critical Care Nurses, May 25, 2006). The current priorities that are specific to weaning from mechanical ventilation are (a) effective and appropriate use of technology to achieve optimal patient assessment, management, and/or outcomes; (b) processes and systems that foster the optimal contribution of critical care nurses; and (c) prevention and management of complications. Other organizations have identified weaning from mechanical ventilation as a high priority for nursing as well, including the American Thoracic Society (Larson et al., 2006).

Although weaning works best utilizing a multidisciplinary approach, the key facilitators of the process are the ICU nurses, as they are with the patient on a continuous basis. Past thinking indicated that the gestalt of an expert clinician was better at predicting weaning outcome than physiologic variables. Stroetz and Hubmayr (1995) determined this belief to be a fallacy. They asked the attending

ICU physicians of 31 patients undergoing mechanical ventilation which ones were likely to be successfully weaned that day. The physicians predicted that 22 would fail a weaning trial. However, of those 22 patients, 50% were actually successfully weaned. Clearly, the systematic use of reliable predictors is warranted and alerts physicians and nurses that some patients they deem not ready to wean are in fact candidates for the weaning process. Despite a plethora of research studies, clinicians still have difficulty in identifying the exact point in time that a patient exhibits weaning readiness.

Two major problems exist with weaning research and may potentially contribute to the inability to identify accurate predictors. The first is related to definitional confusion (Hanneman & Kite-Powell, 2004). Many researchers fail to differentiate between weaning and weaning outcome. Weaning in the strict literal sense is a gradual reduction in the level of ventilator support (Tobin & Juran, 2006). Weaning outcome includes complete weaning, with or without extubation, or incomplete weaning, where the patient requires long-term partial or full mechanical ventilatory support (Knebel et al., 1998). It is crucial to denote that extubation, which is removal of the artificial airway, is a completely separate outcome from weaning.

The second issue confounding weaning predictor research is patient population variability. Weaning commences when the underlying issue requiring mechanical ventilation is reversed. However, multiple factors may impede progression and it is unknown whether these factors vary from population to population. Research studies have tended to group patients by category rather than using pure patient population definitions. For example, any patient with a surgical diagnosis may be grouped as "surgical" rather than to use homogeneous populations such as cardiac bypass graft patients. Another example is the mixture of medical patient diagnoses, such as patients with pulmonary fibrosis versus patients with chronic obstructive pulmonary disease. Although both of these diagnoses are pulmonary related, the underlying pathology of restrictive versus obstructive disease is very different. Since predictor performance will vary with patient characteristics and pathologies, it is imperative that a well defined homogeneous population is used.

No single or multidimensional predictor of weaning outcome has emerged as superior across all patients. The Rapid Shallow Breathing Index (RSBI) is a pulmonary predictor studied over a span of 15 years. Despite variations in study designs, measurement issues, and population differences, the index remains a moderate predictor of weaning outcome as determined by a meta-analysis from which guidelines for weaning were developed. (Meade et al., 2000), Further study of this variable was warranted utilizing a more rigorous approach in design and measurement.

Conceptual Framework

This study used the Weaning Continuum Model as the guiding framework for ventilator weaning. The American Association of Critical Care Nurses' (AACN) Third National Study Group on Weaning from Mechanical Ventilation defined weaning as the process of assisting the patient to breathe spontaneously with or without an endotracheal tube (Knebel, Shekleton, Burns, Clochesy, & Hanneman, 1994). The study group developed the weaning concept (See Figure 1) to explain the weaning process and guide both weaning practice and research.

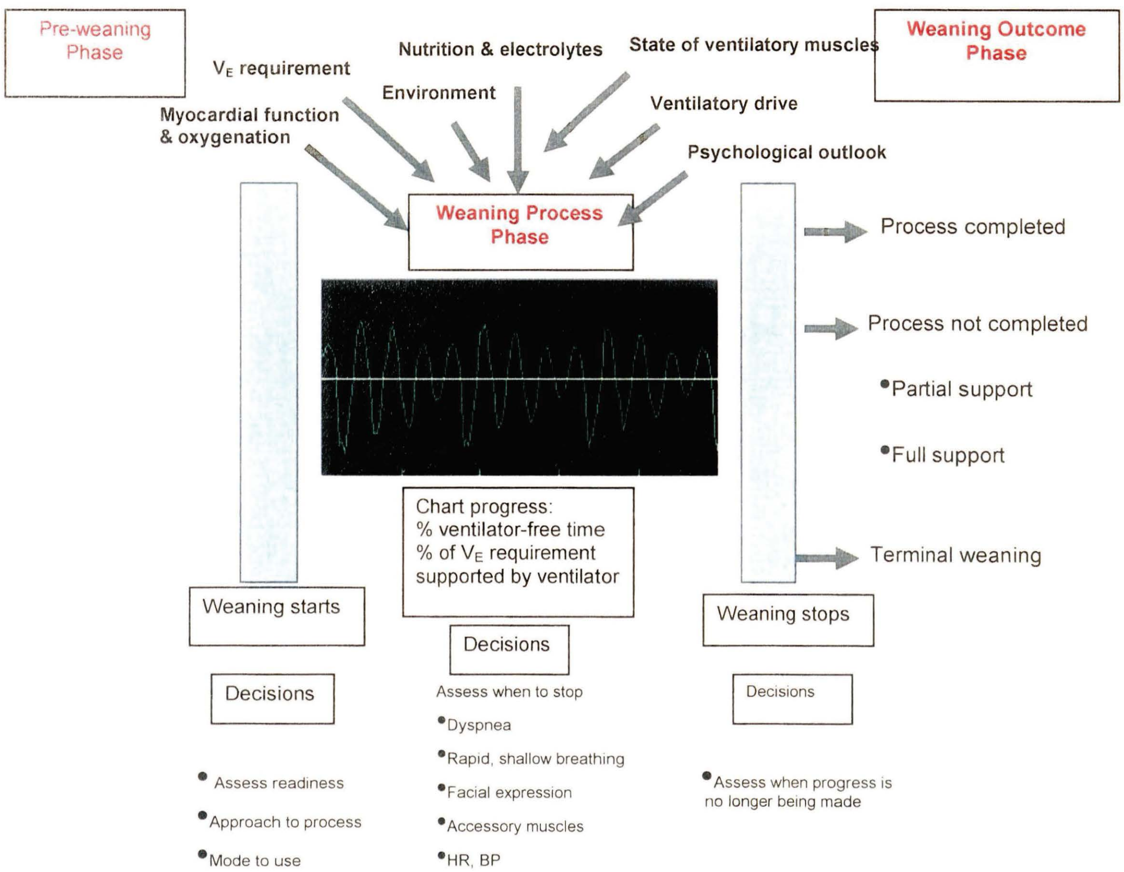

Figure 1. Weaning Concept

The weaning process is described as having peaks and valleys of progress before reaching the outcome. The Weaning Concept also described environmental factors, which relate to the environment of care and the use of a multidisciplinary approach to weaning, and also patient factors affecting weaning. The patient factors influencing weaning are myocardial function and oxygenation, ventilatory requirements in relation to capability, nutrition, electrolyte balance, the condition of the ventilatory muscles, ventilatory drive, and psychological status (Knebel et al., 1994). The Weaning Concept was refined and published as the Weaning Continuum Model (See Figure 2) (Knebel, Shekleton, Burns, Clochesy, & Hanneman, 1998). The phases of weaning were re-defined as stages with the addition of a readiness threshold. The three phases of weaning are defined as (a) pre-weaning phase, when active weaning cannot occur because the condition warranting mechanical ventilation has not resolved, and/or other complications are present; (b) weaning phase, when the patient's condition has stabilized and actual reduction of ventilatory support is achieved; and (c) weaning outcome phase. Two possible outcomes can occur: (a) process completed, with spontaneous breathing sustained for 24 – 48 hours; and (b) process not completed, as the patient needs partial or continued full support. The weaning readiness threshold is a point at the end of the preweaning stage where physiological stability has been achieved. If the patients' physiological status deteriorates below the readiness threshold, weaning stops and the preweaning stage is re-entered. When patients again achieve stability, they move into the weaning stage.

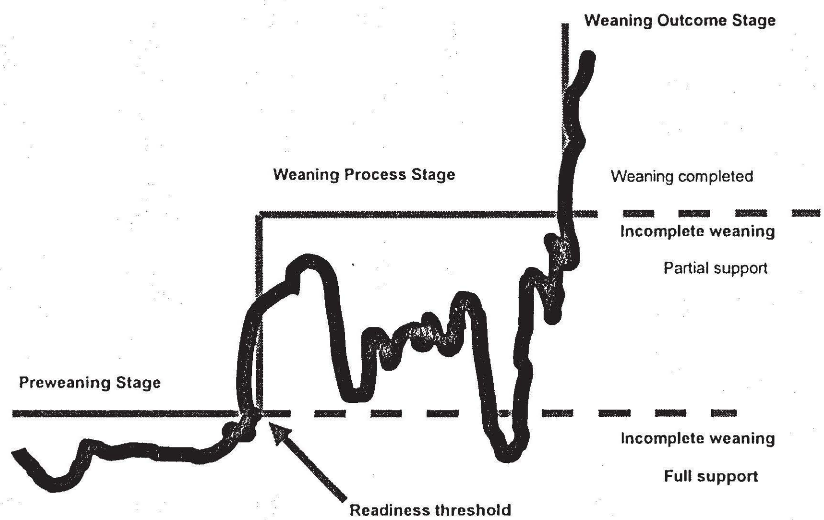

Figure 2. Weaning Continuum Model

To date only two studies (Curley & Fackler, 1998; Burns, Ryan, & Burns, 2000) and one unpublished dissertation (Mylott, 1999) were located that have tested the Weaning Continuum Model. The population in the study by Curley and Fackler (1998) was comprised of pediatric patients with acute respiratory distress syndrome requiring long-term mechanical ventilation. The findings of the study identified three major patterns of weaning: (a) sprint pattern, which involved 1 day of weaning; (b) consistent pattern, which involved 3 days of progressive weaning and constant forward momentum; and (c) inconsistent pattern, which was consistent with the peaks and valleys of the Model. The premise behind the inconsistent group is that progress starts at a more dependent level and slowly progresses toward a less dependent level over time. The findings of the inconsistent pattern were congruent with the assumptions of the Weaning Continuum Model. Curley and Fackler found no significant differences among groups in terms of acuity, demographics, lung function, ventilatory or weaning mode. However, they did determine that patients who experienced more days of ventilation before the start of weaning and who had a higher oxygenation index (Fio_2 /mean airway pressure/100) during the weaning process were most likely to have an inconsistent weaning pattern. A limitation of the study was the retrospective design. The patient population in this study consisted of children which makes it difficult to compare results to adults, as age specific considerations of function and physiology in the developing respiratory system have to be taken into account (Rimensberger & Hammer, 2006).

Burns et al. (2000) studied adult medical patients requiring long-term mechanical ventilation, defined as ≥ 72 hours. The study was part of a larger research project designed to test an outcomes management approach to weaning using an outcomes manager and a detailed clinical pathway. The convenience sample consisted of a total of 97 patients and 839 patient days. The study hypothesis proposed that clinical tools designed to quantify severity of illness could identify the distinct stages of weaning defined by the Weaning Continuum Model. Four clinical tools were utilized: (a) Acute Physiologic and Chronic Health Evaluation III score (APACHE III): a prognostic system designed to associate the acute changes in a patient's physiologic state with risk of death. The system has two major components: the APACHE III score and the predictive equations that compare a patient to an extensive database. Only the score was used in the study; (b) Therapeutic Intervention Scoring System (TISS): a classification system for critically ill patients. TISS assigns points to interventions based on an increasing level of complexity of interventions and support; (c) Burns Wean Assessment Program (BWAP): a computer application designed to help clinicians assess, evaluate, and track factors important to weaning. This tool is the only one specifically designed for weaning; and (d) Work Index (WI): an integrated index of strength, endurance, and gas exchange. Thresholds of the WI have been < 4 (successful wean) and > 4 (unsuccessful wean).

The researchers added another stage to the Weaning Continuum Model, the Acute Stage (Burns et al., 2000). The Acute Stage was part of the clinical pathway used in the larger study. The researchers proposed that addition of this stage could help define the interval that separates short-term from long-term ventilation. The addition of this stage merely divided the Pre-Wean Stage of the model and could have potentially confounded results, due to the fact that a greater number of scores were obtained for each index in the early stages of the patient's illness compared to the latter stages. Although the study validated the

Pre-Wean and Wean stages of the model with the distinct scores of APACHE III, the TISS, and the BWAP tools, no specific cut point by stage was determined. The study failed to distinguish between the Wean and Outcome stage. Possible explanation would be that weaning outcome is not a stage, but the end point of the weaning process. This study is critical to weaning literature and to testing the Weaning Continuum Model. Future studies that test the stages of weaning in different populations using stage specific scores in combination with other data may enable true prediction of outcomes.

The dissertation completed by Mylott (1999) was based on the previous work by Curley and Fackler (1998) and used the sprint, consistent, and inconsistent patterns to describe the weaning process. Mylott studied 66 patients who had an acute myocardial infarction (AMI). For the majority of these patients weaning was brief and progressive. Twelve patients demonstrated an inconsistent weaning pattern. This pattern is congruent with the Weaning Continuum Model in that there are identifiable peaks and valleys. However, for the AMI patients, the pattern demonstrated a downward slope of the baseline until the day of extubation when it peaks. This outcome was inconsistent with the Model and findings by Curley and Fackler (1998). Possible explanation was that the AMI patients had essentially healthy lungs and needed mechanical ventilation for cardiovascular failure. Once the heart recovered, weaning was an expeditious process.

Assumptions

The Weaning Continuum Model is constructed around the assumption that weaning is a variable process where progress may be gained and then lost when patient complications occur, only to resume forward momentum as conditions stabilize. The model is divided into three distinct stages which denote completion of one stage before progression to another. In the model, there is a point identified where weaning readiness occurs. This point is measured by pulmonary, physiologic, and psychological variables. The RSBI is a pulmonary predictor that can define weaning readiness in patients requiring coronary bypass graft surgery and/or surgery involving one or more of the cardiac valves.

Research Question

The research question addressed by this study was

Is the Rapid Shallow Breathing Index measured at 24 hours and at the time of the first weaning trial for post-cardiovascular surgery patients requiring ≥ 24 hours of mechanical ventilation different for those who wean and those who do not?

Definition of Terms

The terms utilized in this study were defined as follows:

1. Adult patient: a patient 19 years or more of age undergoing cardiovascular surgery at a large tertiary teaching facility.
2. Cardiovascular surgery: can be either coronary artery bypass graft (CABG) or replacement of one or more of the cardiac valves, or a combination of both. All patients in this study will be placed on a coronary perfusion bypass

machine that circulates the blood through the body while new vessels are grafted into the heart and/or one or more of the cardiac valves are replaced.

3. Mechanical ventilation: A therapy whereby breathing is supplemented or replaced with a continuous flow of pressurized gas delivered through an artificial airway.
4. Rapid Shallow Breathing Index (RSBI): RSBI is a ratio of respiratory frequency (*f*) to tidal volume (V_t) which quantifies the extent of rapid shallow breathing, a finding in patients who failed weaning in some studies and case reports (Tobin et al., 1986). Frequency of respirations (*f*): the number of spontaneous (unsupported by mechanical ventilation) breaths that a patient takes in one minute. Tidal volume (V_t): the amount of air exhaled with each breath, as measured by the Wright respirometer (Mark 20 Model, Ferraris Respiratory, Hertford, England, SG13 7NW).
5. Weaning outcome: two possible outcomes occurred: (a) process completed, with spontaneous breathing sustained for 24 hours; (b) process not completed, as the patient needed partial or continued support.

Limitations

The generalizability of this study was limited by several factors that must be considered when interpreting findings. While the sample in this study is one of convenience, it was also consecutive. Using consecutive sampling minimized volunteerism and other selection biases by consecutively selecting every accessible person who met entry criteria (Hulley, Newman, & Cummings, 2007). However, the results can still only be generalized to cardiac surgery patients in similar institutions. Secondly, the RSBI is already used by some practitioners as a weaning predictor. Although the results obtained for the study purposes with the Wright respirometer was not shared with clinicians, the measurement obtained via the ventilator was available and could have influenced weaning decisions. The third limitation is that weaning techniques vary from practitioner to practitioner and could have impacted the outcome. All patients in the cardiovascular recovery room are placed on the same standard weaning protocol which limited some but not all of this effect.

Summary

Mechanical ventilation is a life-saving technology provided to critically ill patients when they experience either acute or chronic respiratory failure for a variety of reasons. Both weaning too early and delays in weaning impose complications that are associated with increased morbidity and mortality. With the incidence of mechanical ventilation on a consistent upward trajectory, it is imperative that clinicians be able to identify the exact point a patient can be liberated from mechanical ventilation. Despite abundant weaning research, no descriptor or test has emerged as superior in ability to predict weaning readiness in all patients. The RSBI is a pulmonary predictor that has been studied more frequently than most over a span of 17 years. Further research using consistent and accurate definitions and measurement in specific patient populations was needed.

CHAPTER II

REVIEW OF LITERATURE

The institution of mechanical ventilation for respiratory failure of multiple etiologies has increased over the past three decades (Cox, Carson, Govert, Chelluri, & Sanders, 2007). Technological advancements have resulted in computerized ventilators with ability to automatically synchronize mechanical and patient efforts. Despite the clinical support provided by technology, mechanical ventilation remains one of the most challenging treatment modalities in modern critical care medicine. Mechanical ventilation is a life-saving treatment, but it is not without potential risks and complications. Therefore, clinicians must continuously monitor and assess patient readiness to wean. Weaning is the process of withdrawing ventilatory support until a patient is able to breathe spontaneously. Even though the science of mechanical ventilation has evolved tremendously, practitioners still have difficulty identifying the point at which weaning readiness occurs. Many physiological and demographic variables have been tested both individually and as complex predictor systems of weaning readiness. Despite these studies, no single or modeled predictor group has emerged as superior.

The search for evidence of weaning predictors, and then specific to the Rapid Shallow Breathing Index (RSBI), included computer based searches for systematic reviews, evidence-based guidelines, individual studies, and unpublished dissertation abstracts. MEDLINE, CINAHL, the Cochrane Controlled Trials Registry, the Cochrane Data Base of Systematic Reviews, and the evidenced based databases, and Dissertation Abstracts were the primary bibliographic databases utilized. Reference lists from seminal studies were hand searched. Because the Agency for Healthcare Research and Quality (AHRQ) recently published the results of a comprehensive and systematic evidence report of mechanical ventilation weaning (Cook et al., 2000), individual studies, with the exception of those incorporating the RSBI, were limited to subsequently published randomized and controlled clinical trials with adults, published in English from 1999 to 2007. Exclusions were studies of patients with primary neurological injuries or pathology, patients with transplants, and burn victims, as each of these requires specialized knowledge and will not be included in the proposed study. The search terms used were mechanical ventilation, ventilator weaning, clinical protocols, prediction, population forecasts, and planning techniques. This chapter presents a literature overview of ventilator weaning, predictors of weaning outcome, weaning in cardiovascular surgery patients, and the review of literature for the RSBI.

Overview of Ventilator Weaning

Approximately 33 - 41% of critically ill patients in the United States and Canada receive mechanical ventilation daily (Esteban et al., 2000), which translates to nearly 273,000 individuals annually. The incidence of mechanical ventilation has increased by as much as 11% in 2006, which would make the annual number of patients requiring mechanical ventilation 303,030 (Cox et al., 2007). Mechanical ventilation is required to treat impending or existing respiratory failure. Other indications may include decreased ventilatory drive secondary to anesthesia or drug overdose, for therapeutic hyperventilation in the presence of increased intracranial pressure, or reduced oxygen delivery from cardiopulmonary causes (Hanneman & Kite-Powell, 2004). As conditions that warrant the need for mechanical ventilation resolve, the goal of care shifts toward liberating the patient from the ventilator. It is estimated that 40% of the time a patient receives mechanical ventilation is spent in the process of weaning (Salipante, 2002).

Weaning refers to withdrawing the patient from mechanical ventilatory support in a staged manner (Pierce, 1995). Weaning outcome is defined as the ability to breathe spontaneously for 24 hours with or without an artificial airway (Burns et al., 1995). Patients requiring mechanical ventilation for only a short time and having no specific underlying pulmonary dysfunction generally may be weaned rapidly, and without untoward effects. The majority of patients fall into this category and are weaned in ≤ to 72 hours. For the other more critically ill patient, weaning may take weeks, even months.

Prolonged mechanical ventilation has been defined as > 3 days (Burns, Clochesy, Hanneman, Ingersoll, Knebel, & Shekleton, 1995) and even > 21 days (Cox et al., 2007). Nearly 10% and up to 34% of patients ventilated for greater than 2 days require prolonged mechanical ventilation, accounting for 30,303 to 103,030 patients in the US annually (Cox et al., 2007). Several complications are associated with prolonged mechanical ventilation, including increased risk for ventilator-associated pneumonia, lung injury, morbidity, and mortality (Meade, Guyett, Cook et al., 2001). Prolonged mechanical ventilation translates into increased resource consumption in terms of ICU days, nursing staff, respiratory therapy, and equipment for healthcare institutions and payers. Because of the risk of complications and high costs associated with mechanical ventilation, weaning patients from mechanical ventilation should occur as rapidly and as safely as possible. However, weaning too rapidly can lead to respiratory muscle fatigue (Tobin & Jubran, 2006) and cardiovascular instability (Lemaire, 1988). Weaning too soon may result in premature extubation, leading to reintubation which carries a higher risk for nosocomial pneumonia (Torres et al., 1992) and increased risk of mortality (Epstein, Ciubotaru, & Wong, 1997). Both ends of the spectrum pose untoward outcomes for these patients (too early versus late weaning). Therefore, determining the most accurate predictor of weaning readiness will potentially prevent premature withdrawal of mechanical ventilation and untoward outcomes for patients.

Predictors of Weaning Outcome

No one variable or group of variables can accurately predict ability to wean in all patients (MacIntyre et al., 2001; Hanneman & Kite-Powell, 2004). The predictors of weaning that clinicians currently use, and that investigators have studied include an assortment of (a) demographic characteristics such as age, diagnosis, and gender; (b) vital signs and hemodynamic variables; (c) lung mechanics and gas exchange; and (d) severity of illness measures (Table 1). These variables have been tested individually and as complex systems. No one factor has emerged as superior across all patient populations.

The lack of accurate predictors may partially be explained by definitional confusion among studies. Investigators of weaning predictor studies often confuse weaning and extubation outcomes. The goal of weaning is spontaneous ventilation, with or without an artificial airway. Confusion regarding outcome is related to the fact that, in many patients, the endotracheal tube is in place only for mechanical ventilatory support. Therefore, when the patient is capable of total spontaneous ventilation, the endotracheal tube should be removed. However, patients with the inability to effectively clear their airways may require the tube to remain in, even with total spontaneous ventilation. However, the rationale for this is not failure to wean but to maintain a protected airway.

Key predictors statistically linked to increased mechanical ventilation time and weaning outcome are gender, age, and severity of illness. Table 1 is a review of some of the pertinent studies that pertain to weaning predictors. Research data has varied in terms of the influence of gender on weaning outcome and extubation. Bezanson, Deaton, Craver, Jones, Guyton, and Weintraub (2001) determined that female gender was significantly linked to increased time to extubation, odds ratio 1.48; $p = 0\ .005$, while Kollef, O'Brien, and Silver (1997) determined that the duration of mechanical ventilation and ICU stay was only moderately significantly higher when compared to males, $p = 0.056$. In other studies (Epstein & Vuong, 1999) female gender was not a significant predictor of weaning outcome. Authors have proposed that this may be due to researchers not controlling for broad enough co-morbid factors, such as HIV disease, or linking gender to age. Other explanations that have been offered for the possible difference in mortality between genders include referral bias, gender-based differences in physiology, hormonal or immunologic distinctions, and possibly treatment biases (Epstein & Vuong, 1999). According to Bezanson et al. (2001) age and female gender are both independent predictors of increased mechanical ventilation time in cardiovascular surgery patients. However, those variables did not enter into the final multiple regression model in the same study. The significant factors in the model were renal insufficiency, peripheral vascular disease, non-elective cardiovascular surgery, congestive heart failure (CHF), and re-operation. In reference to increased age as an independent predictor of increased mechanical ventilation time, a specific age or range has not been determined. In another large study (Reddy, Grayson, Griffiths, Pullen, & Rashid, 2007), differing ages were linked to increased mechanical ventilation support in cardiovascular surgery patients: age 65 to 75, odds ratio 0.7831, $p < 0.001$;, age 75 to 80, odds ratio 1.5605, $p < 0.001$; and age greater than 80, odds ratio 1.7115, $p < 0.001$). Ely, Wheeler, Thompson, Anckiwicz, Steinberg, and Bernard (2002) had similar findings: age greater than

70 was statistically related to increased mechanical ventilation time and increased ICU days, $p < 0.001$. The findings of these studies indicate that older age may be a predictor of increased mechanical ventilation time, but did not determine a specific age across studies. Lack of clear age related information makes it difficult for bedside clinicians to use this information in strategically planning optimal weaning. Although increased age is associated with increased ventilation time, age alone has not been shown to be an independent predictor of weaning outcome.

Reddy et al. (2007) developed and tested a predictive scoring system for increased mechanical ventilation time in cardiovascular surgery patients. The independent risk factors that were predictive of prolonged mechanical ventilation time in this study and statistical notations are listed in Table 1 in conjunction with other significant references. Factors that are associated with increased mechanical ventilation time and mortality for these patients and others with mixed medical and surgical diagnoses are a combination of co-morbid conditions and pathologies (Bezanson et al., 2001; Estaban et al., 2002; Reddy et al., 2007; Seneff, Zimmerman, Kraus, Wagner, & Draper, 1996). Predictors of increased mortality for ventilated patients include a diagnosis of chronic obstructive pulmonary disease (COPD), and Acute Respiratory Distress Syndrome (ARDS), and ventilator strategies that fail to decrease a plateau pressure < 35 cm H_2O, an indication of decreased lung elasticity and worsening ARDS. Specific pathologies increasing mechanical ventilation time are pneumonia, pulmonary embolism, ARDS, sepsis, neuromuscular disease, non-operative head trauma, and multiple trauma. Post-operative categories increasing mechanical ventilation time are intracranial hemorrhage, dissecting ruptured aorta, gastrointestinal (GI) obstruction, cholelithiasis, head trauma, and multiple trauma. For patients undergoing cardiac surgery, independent predictors of increased mechanical ventilation include renal insufficiency, peripheral vascular disease, and congestive heart failure. Clearly, research findings vary across studies and fail to identify consistent patient characteristics, disease entities, and ages that are associated with increased mechanical ventilation time. The commonality associated appears to be acuity.

The major pulmonary predictors of weaning readiness and outcome that have been studied and demonstrated statistical significance are respiratory rate (RR), respiratory rate > 30 breaths/minute, minute ventilation (V_E), tidal volume (V_T), V_E/V_T, RSBI, and negative inspiratory force (NIF), and maximum inspiratory pressure (P_I max) (Meade, Guyatt, Griffith et al., 2001). These predictors have been tested under varying conditions and in various patient populations. None have been determined to be superior. However, for trials of unassisted breathing, the most promising predictors are RR, RSBI, a product of RSBI and occlusion pressure < 450 cm H_2O breaths/liter/minute, and P_I max (Meade, Guyatt, Cook, et al., 2001). Therefore, further study of the RSBI was undertaken.

Table 1

Variables Influencing Mechanical Ventilation Time and Weaning

Source	Purpose	Results
Bezanson, Deaton, Craver, Jones, Guyton, & Weintraub, 2001 *N* = 919 CABG patients ≥ 65 years	Examine specific variables increasing mechanical ventilation time (MVT)	Independent predictors: Age $p < 0.001$ Female $p = 0.005$ Logistic regression model: Renal insufficiency $p = 0.01$ Peripheral Vascular Disease (PVD) $p = 0.01$ Non-elective surgery $p = 0.006$ CHF $p = 0.001$ Reoperation $p < 0.001$
Chatila, Jacob, Guaglionone, & Manthous, 1996 *N* = 100 Medical/Cardiac ICU patients	Compared the RSBI, NIF, Spontaneous V_T as predictors of weaning outcome defined as extubation	RSBI at 30 minutes for patients that were extubated was lower (0.92 $\pm$ 0.3) compared to those that were not extubated (132 $\pm$ 57.4) $p < 0.05$ RSBI performed better than the other indices
Ely, Wheeler, Thompson, Anckiwicz, Steinberg, & Bernard, 2002 *N* = 902 Medical/Surgical patients	To examine age as an independent risk factor in recovery and ICU discharge for patients with acute lung injury	Patients >70, MV = 19 days Patients $\leq$ 70, MV = 10 days $P = 0.001$ Patients > 70, ICU days = 21 Patients $\leq$ 70, ICU days = 16 $P = 0.004$
Epstein, S. & Vuong, V., 2002 *N* = 588 Medical patients	Determine if there are gender-based differences in outcomes in mechanically ventilated medical patients	Findings did not support gender difference with MV. Mechanically ventilated females had a higher mortality rate than men ($p > 0.2$);

Table 1 (Continued)

Variables Influencing Mechanical Ventilation Time and Weaning

Source	Purpose	Results
Yang, K. & Tobin, M. 1991 *N* = 100 Medical/Surgical patients	Compare 2 new pulmonary weaning indices, CROP (integrates thoracic compliance, respiratory rate, arterial oxygenation, and P_1max) and RSBI with traditional indices of minute ventilation (V_E), respiratory frequency, tidal volume, tidal volume/patient's weight, maximal inspiratory pressure, dynamic compliance, static compliance, and the $PaO_2/P_A O_2$.	Sensitivity was highest for the P_1max (1.00), followed by the RSBI (0.97). Specificity was highest for the RSBI (0.64) and lowest for the P_1max (0.11). The area under the Receiver Operating Curve for the RSBI (0.89) was larger than under the curves for the CROP (0.78, $p < 0.05$), P_1max (0.61, $p < 0.001$, and V_E (0.40, $p < 0.001$). This indicates that the RSBI was the best predictor of weaning and accounted for the greatest variation.
Hanneman, S., 1994 *N* = 162 Cardiovascular Surgery patients	Determine the contributions of pulmonary mechanics, gas exchange and hemodynamics on weaning success or failure	Success: Failure: *N* = 134 *N* = 28 *p* MVpH 7.41 7.35 < 0.001 MVMAP 93 79 < 0.001 VC/KG 14.2 11.0 = 0.001 SVTpH 7.37 7.43 < 0.001 The predictor set of variables were pH during SVT (spontaneous ventilation trial), MAP & pH during MV. Diagnostic accuracy was 0.93.
Krieger, Ershowsky, Becker, & Gazeroglu, 1989 *N* = 269 Medical/Surgical patients	Determine if RR (spontaneous), V_t, MV, MIP, pH, $Paco_2$, Pao_2, and Pao_2/Fio_2 predict ability to discontinue MV in patients ≥ 70.	MIP for unsuccessfully weaned group (-32 $\pm$ 14 cm H_2O) was lower than successfully weaned group (38 ± 14), $p < 0.02$. All parameters had only marginal diagnostic accuracy (58% to 86%)

Table 1 (Continued 2)

Variables Influencing Mechanical Ventilation Time and Weaning

Source	Purpose	Results
Kollef, O'Brien, & Silver, 1997 *N* = 357 Medical/Surgical patients	To determine the importance of gender on outcome of MV	Controlling for baseline demographics, illness severity, reason for MV and number of dysfunctional organs, hospital mortality rate greater for women ($p = 0.016$). Duration of MV and ICU length of stay was marginally lower for females ($p = 0.056$)
Lemaire, et al., 1988 *N* = 15 COPD patients	determine the hemodynamic effects of rapid weaning and 10 minutes of spontaneous breathing with O_2	All outcomes significant, $p < 0.001$ • Cardiac index increased from 3.2 ± 0.9 to 4.3 ± 1.3 • BP increased from 77± 12 to 90 ± 11 mm Hg • HR increased from 97± 12 to 112 ± 16 BPM • PCWP increased from 8± 5 to 25 ± 13 mm Hg
Reddy, Grayson, Griffiths, Pullan, & Rashid (2007) *N* = 12,662 Cardiovascular Surgical patients Data were randomly split into a development data set (*n* = 6000) and a validation set (*n* = 6662).	Develop a multivariate risk prediction model after adult cardiac surgery.	Independent variables identified with prolonged ventilation: Age 65 to 75 years ($p < 0.001$); Age 75 – 80 years ($p < 0.001$);Age > 80 years ($p < 0.001$); Forced expiratory volume less than 70% of predicted ($p = 0.013$);Current smoker ($p = 0.001$); Serum creatinine increased ($p < 0.001$;) Peripheral Vascular Disease ($p < 0.001$); EF < 30% ($p < 0.001$); MI < 90 days ($p < 0.001$); Prior cardiac surgery ($p < 0.001$); Urgent surgery (p= 0.004); Emergent surgery ($p = 0.005$); Mitral valve surgery ($p < 0.001$;) Aortic surgery ($p < 0.001$); Use of cardiopulmonary bypass ($p = 0.025$);

Table 1 (Continued 3)

Variables Influencing Mechanical Ventilation Time and Weaning

Source	Purpose	Results
Seneff, Zimmerman, Kraus, Wagner, & Draper, 1996 *N* = 5,915 Medical/Surgical	To determine patient and disease variables that significantly influenced MV days.	Average duration of MV = 2.6-7.9 days. Most variation is accounted for by differences in patient characteristics. ($R^2 = 0.60$) Significant Diagnoses ($p = 0.001$): Pneumonia, pulmonary embolism, ARDS, other respiratory disease, sepsis, neuromuscular disease, non- operative head trauma, multiple trauma. Significant post-operative diagnoses: ($p = 0.001$): Intracranial hemorrhage, dissecting ruptured aorta, GI obstruction, cholelithiasis, head trauma, multiple trauma

Note. MVT = mechanical ventilation time; PVD = peripheral vascular disease; CHF = congestive heart failure; NIF = negative inspiratory forces; Vt = tidal volume; CROP = compliance, respiratory rate, arterial oxygenation, and P_1 Max (maximal inspiratory pressure); PaO_2/PAO_2 = the ratio of alveolar to arterial oxygenation; $PaCO_2$ = arterial carbon dioxide; MAP = mean arterial pressure; SVT = spontaneous breathing trial; VC = vital capacity; KG = kilograms; RR = respiratory rate; FiO_2 = fraction of inspired oxygen; BP = blood pressure; HR = heart rate; PCWP = pulmonary capillary wedge pressure; ARDS = acute respiratory distress syndrome.

Weaning in Cardiovascular Surgery Patients

The majority of cardiovascular surgery patients are weaned from mechanical ventilation and extubated within 6- 8 hours after surgery (Meade, Guyatt, Butler et al., 2001; Yende & Wunderlink, 2002). Weaning following cardiovascular surgery can be expedited if the anesthesia during surgery is modified, in particular a reduction in the dose of fentanyl and benzodiazepines or the substitution of fentanyl for propofol (Meade, Guyatt, Butler, et al., 2001). Patient criteria increasing mechanical ventilation time for these patients has been identified in the literature: (a) increased age; (b) gender (female, although inconsistently); (c) New York Heart Association class 4 heart failure; (d) COPD and other respiratory disease; (e) peripheral vascular disease; (f) increased serum creatinine, indicating renal failure; (g) MI < 90 days; (h) ejection fraction less than 30 %; (i) previous cardiac surgery; (j) emergent surgery; and (k) cardiogenic shock; (Bezanson, Deaton, Craver, Jones, Guyton, & Weintraub, 2001; Reddy, Grayson, Griffiths, Pullan, & Rashid, 2007). Regardless of the patient characteristics that lead to prolonged mechanical ventilation, once the patient goes past 24 hours, mechanical ventilation support and testing for weaning is the same as for other patients. Therefore, the same weaning predictors will apply to this patient population.

Review of the Rapid Shallow Breathing Index

Although potential predictors have been studied in all of the categories listed above, the majority of studies have been aimed at predictors associated with ventilatory requirement and drive, state of the ventilatory muscles, and oxygenation. Until approximately 1990 to 1991 clinicians used a variety of single weaning predictors such as vital capacity, maximum inspiratory pressure, and minute ventilation. Use of these factors was supported by research. However, each one assessed a single factor specific to the ventilatory system. Over time in repeated studies, researchers determined these variables had poor predictive value.

The RSBI was developed by Yang and Tobin (1991). The RSBI is a ratio of respiratory frequency (*f*) to tidal volume (V_t) which quantifies the extent of rapid shallow breathing, a finding in patients who fail weaning in some studies and case reports (Tobin et al., 1986). The precise pathophysiologic basis of an elevated RSBI is unknown, but the premise is that it reflects an imbalance between respiratory neuromuscular reserve and respiratory demands. What the researchers observed was an increase in respiratory rate and a decrease in $V_{t,}$ which indicated a mismatch between ventilatory capacity and load. Yang and Tobin (1991) compared the RSBI to traditional indexes with regard to accuracy and found it to be superior. In the second phase of the study, they tested the predictive accuracy prospectively in a convenience sample of 64 adult medical patients whose physicians considered ready to undergo weaning. The primary physicians were blinded to the RSBI. Progression to liberation was the sole responsibility of the primary physician based on usual criteria. Results of the study were very promising. Sensitivity of the RSBI was 0.97, specificity was 0.64, positive predictive value was 0.78, and negative predictive value was 0.95. These results were significantly higher than those of other predictors (minute ventilation, respiratory frequency, tidal volume, tidal volume/patient's weight, maximal inspiratory pressure, dynamic compliance, static compliance, and

PaO_2/PAO_2). The significant threshold value of the RSBI was established at less than or equal to 100 breaths/liter/minute for successful liberation from mechanical ventilation, defined in this study as extubation. The study was rigorous, especially since the physicians were blinded to the predictors. True blinded research regarding predictors of weaning is difficult to do since the physicians want to use the criteria in determining weaning readiness.

Other researchers began to study the RSBI. Gandia and Blanco (1992) tested the diagnostic accuracy of the RSBI compared to the inspiratory occlusion pressure at 0.1 second to maximum inspiratory pressure ratio (P01/MIP), and the inspiratory effort quotient. The sample consisted of 30 diverse patients with medical diagnoses. The dependent variable was again defined as extubation. If the patient was not able to be extubated, the outcome was considered a failure. Extubation with reintubation within 48 hours of extubation was also considered failure. All of the indexes showed good predictability. In this study, sensitivity of the RSBI was 0.83, specificity of 0.82, and a diagnostic accuracy of 0.82.

In contrast, in a study of 52 medical patients, Lee, Hui, Chan, Tan, and Lim (1994) did not find the RSBI to be an accurate predictive tool. However, in previous studies, the measurements of tidal volume and frequency were taken with the patient off the ventilator, spontaneously breathing, with tidal volume measured via a hand-held spirometer. In this study, measures of frequency and tidal volume were taken with the patient on the ventilator with either pressure support or continuous positive airway pressure (CPAP). Expiratory volume was measured by averaging 10 readings from the ventilator. Methodology of measurements in this study makes comparison quite difficult. From a clinical perspective, measurement of the RSBI is much easier with the patient on the ventilator. The study would have been more rigorous if the measurement was taken with respirations unassisted.

Shikora, Benotti, and Johannigman (1994) prospectively compared the RSBI to a new index, the Oxygen Cost of Breathing (OCOB), in 28 patients studied in a hospital in the northeastern United States. The OCOB is calculated from the difference in oxygen consumption between spontaneous breathing and mechanical ventilation calculated from measurements obtained by indirect calorimetry. Results for the RSBI were poor, with sensitivity 40% and specificity 52%. The RSBI measurements were again taken with the patient on mechanical ventilation in varying modes of support. These patients were also given morphine sulfate and/or diazepam as "light sedation" during weaning, a practice not generally supported for weaning patients. The doses and frequency of the medications were not specified. The methodology of measurement with the patient on mechanical ventilation and the use of sedation during weaning may have influenced study results.

In 1995, Epstein published a rigorous prospective study of 94 patients with mixed medical and surgical diagnoses. Epstein's premise was that the RSBI was a strong predictor of the inability to wean based on primary pulmonary etiologies. The defined categories for the etiology of extubation failure were (a) original respiratory process; (b) congestive heart failure (CHF); (c) new pneumonia; (d) new or worsening lobar atelectasis; (d) new aspiration; (e) upper airway obstruction; and (f) new aspiration plus encephalopathy (Epstein, 1995). Extubation failure was defined as the need for reintubation within 72 hours of extubation. The RSBI was measured in the same manner as the original study, with the patient off the ventilator and spontaneously breathing. The findings of this study supported Yang and Tobin's (1991) study. The RSBI ≤ 100 had a positive predictive value (0.83) for extubation success. The results also demonstrated that the RSBI of > 100 accurately identifies patients in whom an underlying respiratory process decreases the capacity of the respiratory muscle pump, leading to weaning failure. Of the total ten patients extubated with RSBI scores > 100, 4 required reintubation, all due to underlying respiratory processes. Eighty-four patients extubated had RSBI scores ≤ 100. Of this group, there were 14 patients requiring reintubation. Thirteen of the fourteen patients required reintubation secondary to congestive heart failure, upper airway obstruction, aspiration, encephalopathy, or the development of a new pulmonary issue. This means that these patients had another identified pathologic process distinct from or in addition to an underlying respiratory process. One third of the extubation failures in the entire group were attributed to CHF. This outcome is consistent with the findings of Lemaire (1988) who demonstrated that patients with COPD and cardiovascular disease frequently fail weaning secondary to exacerbation of acute left ventricular dysfunction. The study by Epstein (1995) confirmed the high positive predictive value of the RSBI < 100. The false positive results of 20% are best explained by extubation failure caused by processes for which the RSBI is "physiologically or temporally unlikely to predict success or failure" (Epstein, 1995, p. 545).

Findings from Chatila, Jacob, Guaglionone, and Monthous (1996) were similar to the original findings (Yang & Tobin, 1991). The patient population consisted of 100 medical patients. The study compared four commonly used parameters to assess weaning outcome: The spontaneous RSBI and NIF, and V_E at the onset of weaning, and the RSBI again after 30 to 60 minutes of weaning. Weaning decisions were made by the patients' primary physicians independent of the study. The RSBI measured at the onset of weaning had a sensitivity of 0.89, specificity of 0.41, positive predictive value of 0.72, and negative predictive value of 0.68. However, the RSBI measured after 30 to 60 minutes of weaning had a sensitivity of 0.98, specificity of 0.59, positive predictive value of 0.83, and negative predictive value of 0.94. Accuracies for the V_E were much lower than the RSBI. Discrepancy in the performance of the RSBI could possibly relate to timing of the measurement. Since the RSBI relates to pulmonary muscle fatigue, measurements taken early in the process would not be reflective of fatigue. Perhaps the most accurate RSBI would be taken further into the weaning process.

Jacob, Chatila, and Manthous (1997) tested the RSBI in 183 surgical patients requiring mechanical ventilation greater than 12 hours. They compared the V_E, NIF, and RSBI. The RSBI was measured off the ventilator during spontaneous breathing. The dependent variable was weaning outcome, defined as successful if unassisted breathing for 24 hours or more occurred, irrespective of endotracheal tube presence. The sensitivity and specificity for the predictors were: initial RSBI 0.97, 0.33; RSBI at 30 minutes 0.96, 0.31; V_E 0.76, 0.40; NIF 0.96, 0.07. The RSBI measured at 30 to 60 minutes after the onset of weaning correlated with the initial measurement of the RSBI and did not add significant predictive information. This finding was different from the study by Chatila el al., as they had determined that the RSBI measured at 30 to 60 minutes into weaning was superior to the measurement obtained at the beginning of the weaning trial. Possible explanation could potentially lie in the difference in patient populations, surgical cases versus medical, as the original study by Yang and Tobin (1991) was designed for medical patients who required longer mechanical ventilation time. Generally, surgical patients wean more quickly than medical patients. Conclusions of the study were that the RSBI was more highly predictive of weaning outcome than the NIF and V_E. The principal weakness of the RSBI is false-positive results, meaning that there are patients with an RSBI ≤ 100 who fail weaning.

In 1997, Krieger and colleagues (Krieger, Isber, Breitenbucher, Throop, & Ershowsky) designed a study to test the effectiveness of serial measurements of the RSBI. The study was based on one published in 1992 (Breitenbucher, Ershowsky, & Krieger) in which the researchers determined that a RSBI ≤ 130 accurately predicted weaning success in patients 70 years old and older with medical diagnoses. The diagnostic accuracy of the RSBI increased from 0.82 at the beginning of the trial to 0.92 after 3 hours. The results demonstrated that serial measurements of the RSBI could improve the accuracy of predicting weaning success in medical patients. One of the primary conclusions was the original RSBI index of 100 (Yang & Tobin, 1991) may not be accurate for mechanically ventilated patients that are ≥ 70.

In 2006, Kuo and colleagues (Kuo, Wu, Lu, Chen, Kuo, & Yang) published a study measuring the predictive accuracy of the RSBI at initiation (RSBI 1) and termination (RSBI 2) of a spontaneous breathing trial. Weaning outcome was defined as positive if the patient maintained spontaneous respirations for 48 hours after extubation. Three outcomes could occur: successful weaning, trial failure, and extubation failure. Successful weaning outcome occurred in 106 patients, while 66 patients had a negative outcome. Of the patients with weaning failure, RSBI 2 was superior to RSBI1 ($p < 0.001$). RSBI 2 was significantly higher in patients with extubation failure (95.9 ± 20.6) and trial failure (98.0 ± 50.0) than patients with weaning success (64.6 ± 26.3). Using a threshold value of 105, the sensitivity, specificity, diagnostic accuracy, and likelihood ratio for weaning success were 0.91, 0.25, 0.85, and 1.38 for RSBI 2. Specificity of 0.25 was significantly lower than in previously cited studies.

In 2000, Cook et al. published an inclusive, scientific review of the research literature on weaning from mechanical ventilation. This scientific review was based upon a meta-analysis funded by the Agency for Healthcare Quality and Research (AHRQ). Findings of this review were incorporated into guidelines by a group of expert clinicians (MacIntyre et al., 2001). These guidelines significantly changed the way weaning was initiated and profoundly influenced clinical practice. Although the published results did not convey evidence of strong weaning predictors, they did demonstrate that the rapid, shallow breathing index (RSBI) was the most frequently studied predictor. From the meta-analysis, the pooled likelihood ratio (95% confidence interval) for a RSBI threshold of 100 was 1.66 (1.08, 2.55) for a positive test and 0.11 (0.03, 0.37) for a negative test (Cook et al., 2000). The principal weakness of the RSBI is false-positive results, meaning that some patients who have an RSBI > 100 will actually have a successful weaning outcome. Again, these findings may be attributed to broad patient populations and inconsistencies in timing and method of measurement.

The review of the evidence also determined that the maximal inspiratory pressure and the compliance, rate, oxygenation, and pressure (CROP) index were more powerful predictors of readiness to wean than the RSBI. However, those indices have been studied on a limited basis and are also much more difficult to perform, which makes application at the bedside extremely difficult. The consensus of the guidelines was that poor predictor performance may be due to the fact that the results are taken into account by clinicians when they test the patient for weaning readiness.

Summary

Multiple factors to predict weaning outcome have been studied extensively in varied patient populations. Despite these studies, no effective predictor of weaning outcome exists. Inaccurate and inconsistent definitions of weaning outcome and variation in patient populations may account for some of the poor performance of weaning predictors. A good portion of the research studies had very small sample sizes, which can confound meaningful results. Inconsistencies in measurement methods also make comparisons difficult.

The RSBI is a pulmonary predictor studied over a span of 18 years. Despite variations in study designs, measurement issues, and population variations, the tool remains a moderate predictor of weaning outcome across studies. If research methodology and measurements were consistent and rigorous in a distinct patient population, would the degree of accuracy increase? Since the numbers of patients requiring mechanical ventilation are increasing, the search for accurate, reliable, and easily obtained predictors of weaning continues. Clinicians need accurate indices to determine the point in time when the patient is ready to begin weaning from mechanical ventilation to prevent complications and improve patient outcomes.

CHAPTER III

PROCEDURE FOR THE COLLECTION AND TREATMENT OF DATA

This prospective study was designed to determine if there was a difference between rapid shallow breathing index (RSBI) measures taken at 24 hours and at the start of weaning for post-cardiovascular surgery patients requiring ≥ 24 hours of mechanical ventilation among those patients who weaned and those who did not. The use of the RSBI was explored without deliberate manipulation with measurements taken at two key points during the weaning process. This chapter includes the information on the study setting, subjects, instruments, data collection, and analysis plan.

Setting

This study was conducted in a 52-bed cardiovascular recovery room (CVRR) in a tertiary care teaching institution located in the south central portion of the US. The institution is an international referral center known for cardiovascular procedures and research. In 2006, there were 1,227 patients who had open heart revascularization, cardiac valve, or combined revascularization and valve procedures. This patient group utilized 2,737 ventilator days with a mean of 2.23, standard deviation 2.9153. Of this group, 584 patients required mechanical ventilation > 24 hours, mean ventilator days were 3.28 with a standard deviation of 3.7986.

Population and Sample

The target population for this study was adult cardiovascular surgery patients who were mechanically ventilated for a period of 24 hours or greater. The convenience sample consisted of consecutively enrolled adult patients age 19 years or older who underwent the aforementioned cardiovascular surgery requiring placement on coronary perfusion bypass. For the majority of these types of patients, weaning commenced when the patient was stable, which was generally within 6 to 8 hours after surgery. Such patients were not part of this study. This study focused on cardiovascular surgery patients who required mechanical ventilation greater than 24 hours. Weaning progressed in a staged manner as per the standard weaning protocol or as determined by the physicians.

Prior to the study sample size assessment indicated a total of 87 patients were needed. Sample size determination was taken from Cohen (1988, p. 258) and was based on a power of 0.80, a medium effect of 0.30, and alpha of 0.05. For the combined likelihood ratios of the RSBI, sensitivity is 0.90, and specificity is 0.40. However, since the RSBI has not been tested specifically in the cardiovascular surgery population, a medium effect was chosen for the proposed study. The combined sensitivity and specificity levels used for the sample size determination were selected based on the ranges in the most rigorous studies involving the RSBI (Cook et al., 2000). Sensitivity ranged from 0.88 to 0.98, with

7 out of 8 studies at 0.90 or greater. Specificity ranged from 0.22 to 0.73. Because of subject availability, thirty participants composed the final sample.

Protection of Human Subjects

The study was approved by the Institutional Review Board for the institution where the study was conducted (Appendix A) and the Institutional Review Board for Texas Woman's University (Appendix B). Informed consent was waived since the RSBI is already part of weaning data gathered in the institution. Data collection forms (Appendix C) had no individual identifying information on them and were kept in a locked file in the researcher's office. The forms will be retained for a period of two years after the completion of the study, per direction of the institutional guidelines for the conduct of research. After two years, all forms will be destroyed.

Instruments

The RSBI was measured with a Wright Mark 20 respirometer. The Wright respirometer has a variability of +/- 2% with a gas flow of 16 liters/minute (LPM) or less, to +10% with a gas flow of 60 LPM (Ferraris Respiratory, 2004). Although the RSBI could be measured directly via the Evita 2 Dura ventilator, the variability is +/- 8%, much higher than the Wright respirometer. The measurement on the ventilator is done with the addition of added positive pressure, which alters the characteristics of the measurement of the RSBI (El-Khatib, Jamaleddine, Khoury, & Obeid, 2002). El-Khatib et al. (2002) studied 33 coronary artery bypass graft patients ready for extubation. Prior to extubation attempts, each of the 33 patients underwent three experimental conditions. During condition 1, patients received continuous positive airway pressure (CPAP) of 5 cm H_2O with an FIO_2 of 40%. During condition 2, patients received CPAP of 5 cm H_2O with an FIO_2 of 21%. During condition 3, patients were disconnected from ventilatory support for exactly 1 minute, during which they spontaneously breathed room air. No pressure support or flow-by was applied during any of the conditions. The measurement of the RSBI was not taken with a Wright respirometer but with a computerized pulmonary mechanics monitoring system (CO_2SMO Plus! Novametrix Medical System). The average RSBI was significantly smaller during conditions 1 and 2. The use of 5 cm H_2O CPAP significantly decreased (49%) RSBI (El-Khatib et al., 2002). In contrast, changes in FIO_2 had no significant change on RSBI determination. Although the measurement with the patient on the ventilator is much easier to perform, the impact on measurement accuracy made it necessary to use the Wright respirometer, the method used during the original study (Yang & Tobin, 1991). The measurement with the Wright respirometer was taken with the patient off assisted ventilation and was therefore a more accurate representation of the patient's own breathing pattern. Research studies (Lee et al., 1994; Shikora et al., 1994) where the RSBI was not measured using the Wright respirometer have impacted the ability to make measurement comparisons between studies.

The accuracy of the Wright respirometer derives from repeating the characteristics of the variation of calibration factor with continuous flow. This process requires that at 16.00 LPM the volume must be within ± 2%, while at 60.00 LPM it must be within +5% to + 10% of absolute. This shift means that with a true flow of 60 LPM, the Wright would measure 66 given the maximum error. Instruments are calibrated by the manufacturer at sea level at 20 degrees Celsius (°C). For each increase of 3 °C above 20 °C for ambient air, 1% is added to the registered volume. The temperature of the CVRR is set between 20 °C and 21.11 °C. Therefore, no additional increase in volume is necessary. The volume range on the Wright is 0 – 100 L. The large outer scale covers 100 L subdivided to 1 L and marked every 10 L. The mini-scale covers 1 L and is further sub-divided into 0.05 L graduations and marked every 0.1 L.

The second instrument used in this study was a data collection tool (Appendix C) developed by the investigator. This form was used to record demographic data, the RSBI scores, and weaning outcome. Collection of demographic variables was essential to describe the sample and determine the population for generalization of the findings (Burns & Groves, 2001). Demographic variables were selected by the researcher on the basis of experience and previous research. Basic demographic data regarding age, gender, and ethnicity were collected. In addition, other patient characteristics have been linked to increased mechanical ventilation time in coronary artery bypass graft (CABG) or cardiac valve replacement surgery. The presence or absence of these characteristics was collected on the data tool including: (A) Ejection Fraction (EF) < 30%; (B) Hypertension; (C) Peripheral Vascular Disease; (D) Chronic Obstructive Pulmonary Disease (COPD); (E) Previous Cardiac Surgery; (F) Pre-operative mechanical ventilation; (G) Myocardial Infarction (MI) < 90 days; (H) Smoker; (I) Urgent Surgery; and (J) Emergent Surgery (Reddy, Grayson, Griffiths, Pullan, & Rashid, 2007).

Data Collection

All data were collected by the Principal Investigator (PI). The measurements of the RSBI were taken and recorded as described below. Prior to commencement of the study, the PI was trained to accurately measure RSBI using the Wright respirometer. The senior researcher performed a demonstration of the measurement of her own minute ventilation and rate, using the Wright respirometer. She then worked with the PI to calculate RSBI (f/V_t) (frequency of respirations/tidal volume). These steps were repeated until 100% agreement in the reading was consistently obtained. During data collection, the PI had the senior Respiratory Therapists check the Wright for agreement with the reading of the minute ventilation for every measure obtained.

The PI received a daily schedule of all patients undergoing cardiovascular surgery. Each patient's medical record was checked post-operatively to determine if study requirements were met. If so, then the patient was followed by the PI daily to monitor for stabilization and progression to weaning. The PI kept a log of all patients meeting inclusion criteria.

The PI also received a daily list of all patients who were concurrently undergoing mechanical ventilation in the institution. Use of this list ensured that patients were followed and assessed for weaning, even if patients transferred out of the CVRR to another intensive care unit (ICU). Signs were posted in the CVRR and all of the ICUs, with the exception of the transplant ICU, announcing the study with the PI's name and pager number. Whenever a patient was enrolled in the study, an explanation was given to the bedside RN along with the PI's business card, so that the researcher was paged when the patient was either stable on predetermined ventilator settings or was to start a weaning trial. Although all of these measures were taken to assure that the staff contacted the PI, the staff did not do so on a regular basis. The PI made multiple follow-up visits to the CVRR during day and night hours to monitor the patients for stabilization and weaning readiness. This methodology more adequately ensured that patients were not missed.

Weaning the patient from mechanical ventilation began when clinicians determined the patient was ready. Generally weaning commenced per the standard CVRR weaning protocol for the majority of the patients. The first measure of the RSBI for the study was taken after 24 hours of mechanical ventilation when the patient was stable, per the RSBI protocol (Appendix D). The patient had to be stable on synchronized intermittent mandatory ventilation (SIMV) or assist control (AC) mode with a rate ≤ 10, $FiO_2 \leq 0.60$, positive end expiratory pressure (PEEP) ≤ 5 cm. The second measure was taken at the start of the first weaning trial that was undertaken after the patient had been mechanically ventilated for greater than 24 hours.

Prior to the procedure the Wright was turned on. The patient was disconnected from the ventilator and the Wright respirometer was attached to the end of the patient's endotracheal tube using a filter and the adapter. The Wright was held in the palm of one hand. The measurement was recorded over 1 minute.

The following was the procedure for measuring minute ventilation: With the unit on, the reset control was released while the inspiratory phase was in progress. As the instrument registers flow in only in one direction, the next expiration was registered. Measurement was taken over one minute. Frequency of respirations (f) was counted during this interval with a stopwatch. After one minute, the on/off control was depressed to retain the V_t measurements. This procedure was repeated 3 times to obtain an average and to decrease the chance of error. For each 1 minute measurement, the average V_t was calculated by dividing the minute ventilation by f. Then, f was divided by the average V_t to obtain the RSBI. The RSBI was expressed as a whole number, e.g., 100.

After the measurements were taken, the Wright was disconnected and the patient was placed back on mechanical ventilation at the same settings they were previously using. This process was the same for either RSBI 1 or RSBI 2. The calculations were recorded on the data collection form. If this was the first RSBI measure, then the patient was continuously followed until the first weaning trial, when the second measure could be obtained. After the second measurement was obtained, the patient was followed by the PI for 24 hours to determine the outcome. Weaning outcome was then recorded by the PI on the data collection sheet.

Pilot Study

A prospective observational pilot study was completed to determine the feasibility of a larger study designed to test the diagnostic accuracy of the RSBI in predicting weaning outcome in post-operative cardiovascular surgery patients. The setting for this study was a 52-bed cardiovascular recovery room in an 888 bed hospital in a large metropolitan medical center located in the south central region of the United States. Consecutive sampling was used for simplicity and the ability to yield estimates that are more precise than those produced by simple random sampling (Pedhazur & Schmelkin, 1991). Thirteen cases made up the sample. Inclusion criteria included any patient who had CABG, cardiac valve surgery, CABG with cardiac valve surgery, or CABG surgery without cardiopulmonary bypass. For the pilot study, measurements of the RSBI were obtained from the Evita 2 dura Ventilator (Drager Medical, Inc.). Accuracy of the RSBI measured on the ventilator is ± 8% (SE) for the tidal volume and ± 1 breath per minute for frequency (Drager Medical, Inc., April, 2001). Measurement of the RSBI was obtained with the patient on mechanical ventilation and CPAP at multiple time points.

All data were collected and recorded by the Principal Investigator on a data sheet. When the patient's condition was stabilized and pre-determined criteria met, the patient was placed on a weaning trial. Weaning from mechanical ventilation for post-operative cardiovascular patients was guided by an established protocol (Appendix E). When the patient progressed to Stage 3, the first measure of the RSBI was taken via the Evita 2 dura Intensive Care Ventilator (Drager Medical™). The measure could only be obtained once the patient is on Continuous Positive Airway Pressure (CPAP) and off Synchronized Intermittent Mandatory Ventilation (SIMV). The second measure was taken at the end of Stage 3. A final measurement was taken at the end of the weaning trial, which for most patients (12 out of 13) ended in extubation.

The study consisted of 13 cardiovascular surgery patients. The mean age for the group of patients was 56.46 (SD = 14.768), with 10 patients age < 70 years and 3 patients age ≥ 70 years. Female patients comprised 46.2 % of the sample and male patients made up the other 53.8%. Eight (61.5%) patients were Caucasian, one (7.7%) was black, and four (30.8%) were Hispanic. Six patients (46.2%) had coronary artery bypasses, five (38.5%) had valve replacements, and 1 (7.7%) had a coronary artery bypass off the pump.

The mean RSBI for measure 1 was 42.0 (*SD*=18.3), for the second measure the mean was 43.38 (*SD*=17.8), and for the third measure 43.69 (*SD*=18.1). Because all measures of the RSBI were less than 100 for all patients, a Chi-Square analysis was unable to be run to test the hypotheses. However, when the mean RSBI data are graphed by patient, patient number 13 was different from the others (Figure 3). This patient had the highest mean RSBI and was the only one who did not wean from mechanical ventilation. The RSBI measurements were taken on mechanical ventilation with the addition of CPAP, which will artificially deflate the number. Even though a statistical analysis was unable to be completed, the RSBI data was compelling clinically.

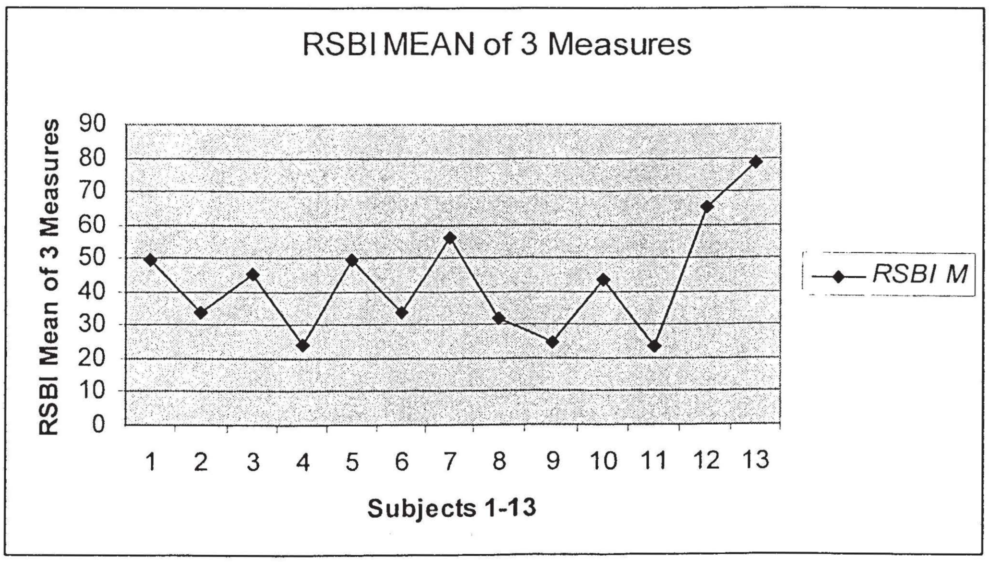

Figure 3. RSBI *M* data graphed by patient

Difficulty with analysis may be attributed to the extremely small sample size. Additionally, all cardiovascular surgery patients were included without regard to the length of time needed to wean. Consequently, most patients readily weaned and had low RSBI measurements. To make the current study more rigorous, several actions were taken. The measurement of the RSBI was taken with a Wright respirometer, the method used by the original researchers (Yang &

Tobin, 1991). The standard error is lower, ± 2%, with the Wright versus ± 8% with the Evita 2 Dura Ventilator. The inclusion criteria for the larger study were modified to only include patients who required mechanical ventilation for ≥ 24 hours, rather than all patients who met the cardiac surgery qualification. Also, only patients who required cardiovascular surgery on bypass were enrolled, eliminating patients that had the surgery off bypass. Another adjustment made in the larger study was timing of the RSBI measures. The first measure was obtained after the patient was stable on mechanical ventilation for 24 hours, prior to any decision to wean had been made. This measurement contrasted with the pilot study where first measurement of the RSBI was taken when the patient was approximately 30 minutes into weaning.

Treatment of Data

For the larger study, analysis of the demographic data was completed with descriptive statistics of frequencies and percentages for nominal level information and means and standard deviations for interval/ratio data. These were calculated using SPSS 12.0© (SPSS Inc., Chicago, Il), as were other statistical tests for this study. Two independent *t*-tests were used to test for significant difference of the means comparing the first and second RSBI measures of patients who weaned to those who did not. This test is appropriate for research questions comparing means of independent groups. The assumptions for this test are that the measure is continuous and is normally distributed, the groups are independent of each other, and the groups have equal variance (Munro, 2005). This test is considered to be robust even if all assumptions are not met (Munro, 2005).

CHAPTER IV

ANALYSIS OF DATA

The purpose of this prospective descriptive study was to investigate the differences between the rapid shallow breathing index (RSBI) measured at 2 different time points for cardiovascular surgical patients who have a positive weaning outcome and those that do not. The patient population consisted of all adults age ≥ 19 who required mechanical ventilation ≥ 24 hours after surgery. The study was conducted at a tertiary care international cardiovascular teaching hospital. This facility performs more than 2500 open heart procedures annually. Data collection occurred between February 7, 2008, through April 30, 2008. The RSBI was measured with the Wright respirometer, the instrument that was used in the original Yang and Tobin (1991) study. Two measures of the RSBI were completed, the first taken at 24 hours or longer of mechanical ventilation when the patient was stable and the second at the start of the first weaning trial. A positive weaning outcome was defined as the ability to sustain spontaneous ventilation for 24 hours; a negative weaning outcome was defined as an incomplete process, as the patient required full or partial mechanical ventilation support. Once the second RSBI measure was taken, the patient was followed for 24 hours to determine if weaning outcome was positive or negative. This chapter includes a description of the sample and reports the study findings.

Description of the Sample

The initial sample was comprised of 30 patients with 24 patients (80%) having a positive weaning outcome and 6 patients (20%) who did not. However, one patient did not have the second measure of the RSBI. This patient had a post-operative stroke and was never stable enough to be off the ventilator for the second measure to be completed. Therefore, this patient was not included in the statistical analysis. The sample contained almost an equal number of males (*n*= 15) and females (*n*= 14) (Table 2). The positive weaning outcome group was divided evenly in terms of gender. However, the negative weaning outcome group had more males (*n* = 3) versus females (*n* = 2). Ages for the total group ranged from 39 to 87 years, with a mean age of 69 (*SD* = 11.71; *Mdn* = 71). In the group weaned from mechanical ventilation, ages ranged from 39 to 87 years with a mean age of 67.3 (*SD* = 12.52; *Mdn* = 68.5). In the group who did not wean ages ranged from 71 to 78 with a mean age of 74.5 (*SD* = 2.35; *Mdn* = 74).

The total patient group was well diversified in terms of race having almost equal numbers of white and black participants (Table 2). Hispanics were the third most represented group. Overall, race did not vary substantially between the positive and negative weaning groups. The only difference was that the single Asian patient had a positive weaning outcome and the single American Indian patient had a negative weaning outcome.

Table 2

Gender, Race, and Type of Surgery for Weaned and Non-weaned Groups and Total Sample

	Weaned Group *f* (%) *n* = 24	Non-weaned Group *f* (%) *n* = 5	Total Sample *f* (%) *N* = 29
Gender			
Male	12 (50.0)	3 (60.0)	15 (51.7)
Female	12 (50.0)	2 (40.0)	14 (48.3)
Race			
White	9 (37.5)	2 (40.0)	11 (37.9)
Black	8 (33.3)	2 (40.0)	10 (34.5)
Hispanic	4 (16.7)	0 (0.0)	4 (13.9)
Asian	1 (4.2)	0 (0.0)	1 (3.4)
American Indian	0 (0.0)	1 (20.0)	1 (3.4)
Other	2 (8.3)	0 (0.0)	2 (6.9)
Type of Surgery			
CABG	14 (58.3)	1 (20.0)	15 (51.7)
Valve	7 (29.2)	1 (20.0)	8 (27.6)
Combination	3 (12.5)	3 (60.0)	6 (20.7)

The majority of the group underwent coronary artery bypass graft (CABG) (*n* =15, 51.7%) while 8 patients (27.6%) had a cardiac valve replacement, with the remaining 6 patients (20.7%) having a combination CABG and valve procedure. Type of surgical procedure differed between the positive weaning outcome group, compared to the negative weaning outcome group. For the positive weaning outcome group, 14 (58%) underwent CABG. In the negative weaning outcome group the majority of the patients (60%) had a combination procedure. Previous research has demonstrated that reoperation is associated with increased mechanical ventilation time (Bezanson et al., 2001; Reddy et al., 2007) but there are no studies indicating that combination procedures affect mechanical ventilation time.

The most prevalent diagnostic characteristic of the group was hypertension with 28 (96.6%) patients falling into this group (Table 3).

Table 3

Diagnostic and Co-morbid Categories for Groups with Positive and Negative Weaning Outcomes and Total Group

Variable	Positive Weaning Outcome *f* (%) *n* = 24	Negative Weaning Outcome *f* (%) *n* = 5	Total Sample *f* (%) *N* = 29
Hypertension	22 (91.7)	5 (100.0)	28 (96.6)
Peripheral Vascular Disease	10 (41.7)	3 (60.0)	13 (46.6)
Current Smoker	10 (41.7)	3 (60.0)	13 (46.6)
Myocardial Infarction < 90 days	8 (33.3)	2 (40.0)	10 (34.5)
Ejection Fraction < 30%	6 (25%)	0 (0.0)	6 (20.7)
Chronic Obstructive Pulmonary Disease	5 (20.8)	1 (20.0)	6 (20.7)
Previous Open Heart Surgery	3 (12.5)	2 (40.0)	5 (17.2)
Urgent pre-op status	4 (16.7)	0 (00.0)	4 (13.8)
Emergent pre-op status	1 (4.2)	2 (40.0)	3 (10.3)
Pre-operative Mechanical Ventilation	0 (0.0)	1 (20.0)	1 (3.4)

Although only 6 (20.7%) patients were diagnosed with COPD, 13 (44.8%) were current smokers. There were interesting differences in the demographic and co-morbid categories between the positive wean and negative weaning groups. While 25% of the positive weaning group had an ejection fraction of EF < 30%, none of the negative weaning outcome group did. This finding is in direct contrast to other studies that have determined that an ejection fraction ≤ 30% increases mechanical ventilation time in these patients (Bezanson et al., 2001; Reddy et al., 2007). Two patients (40%) from the non-weaning group had emergent surgery compared to only 1 (4%) from the weaned group, a finding consistent with previous research (Bezanson et al., 2001; Reddy et al., 2007).

Findings

The research question addressed by this study was:

Is the Rapid Shallow Breathing Index measured at 24 hours and at the time of the first weaning trial for post-cardiovascular surgery patients requiring ≥ 24 hours of mechanical ventilation different for those who wean and those who do not? The sample consisted of 29 patients who were mechanically ventilated for > 24 hours. The first measure of the RSBI was taken at 24 hours or when the patient was stable on mechanical ventilation per the study protocol (Appendix D). The second measure of the RSBI was taken at the beginning of the first weaning trial.

Data were analyzed using two independent *t*-tests that compared mean differences of the RSBI measures between the positive weaning and negative weaning outcome groups. The individual average minute ventilation measurements and respiratory rates used for calculation of RSBI 1 and RSBI 2 are listed in Appendix F. Group means, medians, and standard deviations are reported in Table 4.

Table 4

RSBI Means, Medians, and Standard Deviations for Groups with Positive and Negative Weaning Outcome

	Positive Weaning Outcome (n = 24)		Negative Weaning Outcome (n = 5)		Statistical Test
	M (*SD*)	*Mdn*	*M* (*SD*)	*Mdn*	*t*-test
RSBI 1	60.29 (21.74)	57.0	133.00 (29.50)	140.0	t=-6.414 df=27 p=0.000
RSBI 2	55.21 (18.06)	51.5	138.80 (29.79)	142.0	t=-8.404 df=27 p=0.000

To determine if the RSBI measured at 24 hours of mechanical ventilation was different for those who had a positive versus negative weaning outcome, an independent *t*-test was conducted. A nonsignificant Levene test indicated the assumption of homogeneity of variance was met. There was a significant difference between the weaned and the non-weaned groups. RSBI 1 means were significantly higher for the group with a negative weaning outcome. The effect size for this test was large at 2.465.

To determine if the RSBI measured at the time of the first weaning attempt (RSBI 2) was different for the weaned versus the non-weaned group, a second independent *t*-test was conducted. The assumption of homogeneity of variance was met. There was a significant difference between the weaned and the non-weaned groups. RSBI scores for the non-weaned group were significantly higher when compared to the group experiencing positive weaning outcomes. Again, the effect size was large at 2.806. Patients with a positive weaning outcome experienced a decrease in RSBI level between measure 1 and 2, while patients with a negative weaning outcome demonstrated and increased RSBI level between measures 1 and 2.

Summary

The total sample consisted of 29 subjects who met the inclusion criteria for this study. Of that sample, 24 cases had a positive weaning outcome, defined as the ability to breathe spontaneously for 24 hours after weaning, compared to 5 cases that had a negative weaning outcome. The RSBI 1 measured at 24 hours or when the patient was stable on mechanical ventilation per the study protocol was statistically significant between the positive and negative weaning outcome groups. The RSBI 2 measured at the time of weaning was statistically significant indicating that the mean RSBI scores were higher for the non-weaned group.

CHAPTER V

SUMMARY OF THE STUDY

The purpose of this study was to determine if there was a difference in RSBI measured at two different points in cardiovascular surgery patients requiring mechanical ventilation for 24 hours or longer. A prospective, descriptive design was used to compare RSBI measurements made at 24-hours of mechanical ventilation and at time of first weaning attempt for patients who successfully weaned and those who did not. Demographic information related to gender, age, race, type of surgical procedure, history of previous cardiac surgery, presence of preoperative mechanical ventilation, history of myocardial infarction, smoking history, presence of a clinical status that was either urgent or emergent, ejection fraction, diagnoses of hypertension, peripheral vascular disease, and chronic obstructive pulmonary disease (COPD) was gathered. Two *t*-tests were calculated to compare RSBI means between the weaned and non-weaned groups. This chapter contains a summary of the study, a discussion of the findings, conclusions and implications, and recommendations for further study.

Summary

Twenty-nine postoperative cardiovascular surgery patients were enrolled in this study; 15 underwent CABG, 8 patients had cardiac valve replacement, and 7 patients had combination CABG and valve procedure. All of the patients required mechanical ventilation for ≥ 24 hours. All study participants had an RSBI measured at 24-hours or when they were first stable on mechanical ventilation and a 2nd RSBI measurement at the onset of the first weaning trial. Twenty-four study participants experienced a positive weaning outcome while five did not. Independent *t*-tests were conducted to assess differences between the weaned and non-weaned groups. The RSBI measurements taken at 24-hours or when patients were first stable were significantly lower for the group who successfully weaned when compared to those who did not wean. The second measure of RSBI also indicated that patients who weaned had significantly lower RSBI score than those who were unable to wean.

Discussion of Findings

Findings of this study indicate that there is a significant difference in RSBI between patients with positive and negative weaning outcomes. For the first measure of RSBI at 24 hours (RSBI 1), all but one value (RSBI = 109) was less 100 for the group who weaned. For the nonweaning group – only one value (RSBI = 82) was below 100. At the time of the second measure (RSBI 2) all RSBI values for the weaned group were less than 100 and all values for the nonweaned group were greater than 100 .

At both measures of RSBI – the means for the weaned group were significantly less than 100 (RSBI 1 M=60.29 and RSBI 2 M=55.21) while the means for the nonweaned group were significantly greater than 100 (RSBI 1 M=133.0 and RSBI 2 M=138.0). The nonweaned group had higher RSBI levels than those of the weaning group. It is important to note that the established threshold of 100 appears consistent with similar studies (Yang & Tobin, 1991; Epstein, 1995; Jacob et al. 1997; Kau et al., 2006).

The Weaning Continuum Model (Knebel et al., 1998) served as the guiding framework for this study. The model depicts a weaning readiness threshold in front of a weaning trajectory with peaks and valleys where gains and losses are made. Data were not collected to determine if the trajectory of the Weaning Continuum Model fit the trajectory of the patients in the present study. Because the model was not developed for patients who wean quickly, it does appear to have limited usefulness for the majority of patients undergoing cardiovascular surgery as they wean within hours.

Past research studies involving the RSBI have differed greatly as to the exact timing of the measurement. Some studies indicate that the most consistent, accurate performance of the index occurs when it is taken at the beginning of the weaning trial (Epstein, 1995; Gandia & Blanco, 1992; Jacob et al., 1997; Yang & Tobin, 1991). However, other researchers have determined that when the measurement is taken further into the weaning trial, it is more accurate (Chatila et al., 1996; Krieger et al., 1997; Kuo et al., 2006). As there was minimal difference between RSBI 1 and RSBI 2 in the present study, implications in terms of measurement timing cannot be generalized, although the findings appear to be consistent with measuring the RSBI early in the weaning trial.

Advanced age is a variable associated with prolonged mechanical ventilation (Bezanson et al., 2001; Ely et al., 2002; Krieger et al., 1997; Reddy et al., 2007). In the current study, the mean age was higher for the failed weaning group ($M = 74.5$) compared to the positive outcome group ($M = 67.63$). Although in the present study age was not controlled for or part of the research question, it remains interesting that the current demographic data are consistent with past findings.

Previous studies have identified that re-operation and increased cardiopulmonary bypass time are associated with increased mechanical ventilation time and delayed extubation (Bezanson et al., 2001; Nozawa, Azeka, Feltrim, & Auler, 2005; Reddy et al., 2007). Increased severity of illness as evidenced by increased numbers of co-morbid factors or the presence of pre-surgical mechanical ventilation (Reddy et al., 2007) has been associated with increased mechanical ventilation and delayed extubation in cardiac surgical patients. In the present study, the only patient in the entire group who had pre-operative mechanical ventilation in place was part of the non-weaning group. Also in the present study, 60% of the non-weaning group had combination procedures, valve and CABG, while only 12.5% of the weaning group did. Both of these factors are consistent with prior research findings.

Conclusions

The use of the RSBI as a predictor of weaning outcome in post-operative cardiovascular surgery patients is validated by this study. The conclusions include:

1. RSBI scores are a positive means to predict weaning outcome among cardiovascular surgery patients requiring greater than 24 hours of mechanical ventilation.
2. High RSBI scores are an indicator of potentially unsuccessful weaning outcomes in cardiovascular surgery patients that require greater than 24 hours of mechanical ventilation.

Implications

The implications suggested by this study include the following:

1. Considering the increased resource utilization for prolonged mechanical ventilation, the RSBI should be incorporated as one of the predictors for weaning outcome into standard weaning protocols for cardiovascular surgery patients requiring mechanical ventilation ≥ 24 hours.
2. The established RSBI threshold of 100 may be appropriate for cardiovascular surgery patients requiring mechanical ventilation for ≥ 24 hours.

Recommendations for Further Study

The following recommendations are made for further research:

1. Replicate this study in the same institution with a larger population over time while controlling for age, severity of illness, and type of surgery.
2. Future studies should track the time intervals between measures of RSBI.
3. Future studies should track the outcomes of the non-weaning group from failure of the first weaning trial to initiation of the second weaning trial.
4. Future studies should exclude patients that are on mechanical ventilation prior to surgery.
5. Future studies should address variables such as age, disease severity, hemodynamic instability and anxiety.
6. Conduct a study to compare the RSBI measured with the Wright respirometer to the RSBI measured on the ventilator.
7. Test the RSBI threshold of 100 in cardiovascular surgery patients requiring mechanical ventilation for $\geq$ 24 hours.

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Appendix A

Institutional Review Board Approval

St. Luke's Episcopal Hospital

Institutional Review Board
Mail Code 3-288
832-355-3347

January 8, 2008

Dorothy Kite-Powell, RN, MSN, CNS
Texas Woman's University
Nelda C. Stark College of Nursing
6700 Fannin
Houston, TX 77030

Project #2857
"Rapid Shallow Breathing Index and Weaning Outcome in Cardiovascular Surgery Patients Requiring Mechanical Ventilation for 24 Hours or Longer"

Dear Ms. Kite-Powell:

This letter will inform you that, under the expedited review process of the St. Luke's Episcopal Hospital Institutional Review Board, your IRB Waiver of Authorization for the above referenced study was approved (pending the February 20, 2008 meeting of the committee) of the above referenced study.

This letter will serve as verification that the St. Luke's Episcopal Hospital Institutional Review Board operates in accordance with all applicable laws, regulations and guidelines for clinical trials and under Federal Wide Assurance No. FWA00002312 issued April 8, 2002. We maintain compliance with the FDA Code of Federal Regulations, International Conference of Harmonization (ICH) and Good Clinical Practice (GCP) guidelines. Continued review will be required as follows:

a. Annually
b. Prior to any change in protocol
c. Promptly after unanticipated problems (adverse events)
d. After any other unusual occurrence

The method of review will be by written summary.

Sincerely,

Frank A. Redmond, M.D., Ph.D.
Chair
Institutional Review Board

FAR/are

Appendix B

Institutional Review Board Approval

Texas Woman's University

TEXAS WOMAN'S UNIVERSITY
DENTON DALLAS HOUSTON

Office of Research
6700 Fannin Street
Houston, TX 77030-2343
713-794-2480 Fax 713-794-2488

February 4, 2008

Ms. Dorothy Kite-Powell
College of Nursing - Anne Young, Faculty Advisor
6700 Fannin Street
Houston, TX 77030

Dear Ms. Kite-Powell:

Re: *"Rapid shallow breathing index and weaning outcome in cardiovascular surgery patietns requiring mechanical ventilation for 24 hours or longer"*

The above referenced study has been reviewed by the TWU Institutional Review Board (IRB) and was determined to be exempt from further review.

Any changes in the study must receive review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and significant information that may impact a research participant's safety or willingness to continue in your study.

Sincerely,

William P. Hanten

Dr. William P. Hanten, Chair
Institutional Review Board - Houston

Appendix C

RSBI Data Tracking Tool

RSBI Data Tool

Demographics

Gender: ____ Male ____ Female

Race: ____ Hispanic ____ African American ____ Asian ____ White

____ American Indian

____ Native Hawaiian or other Pacific Islander

Age: _____

Surgical procedure & date: ______________________________

Date & time of MV start: ______________________________

Co morbid Conditions	Yes	No
EF ≤ 30%		
Hypertension		
Peripheral Vascular Disease		
COPD		
Previous Cardiac Surgery		
Pre-Operative Mechanical Ventilation		
MI < 90 days		
Smoker		
Urgent Preoperative Clinical Status		
Emergent Preoperative Clinical Status		

RSBI Measurement # 1

Minute Ventilation	**MV # 1**	**MV # 2**	**MV # 3**
Respiratory Rate	**RR # 1**	**RR # 2**	**RR # 3**

RSBI # 1 calculation (by PI only): ______________________

RSBI Measurement # 2

Minute Ventilation	MV # 1	MV # 2	MV # 3
Respiratory Rate	RR # 1	RR # 2	RR # 3

RSBI # 2 calculation (by PI only): ______________________________

Weaning outcome: ______Positive ________ Negative

Appendix D

RSBI Measurement Protocol

RSBI Measurement Protocol

Patient eligibility criteria:

- Ventilator settings must be SIMV or AC mode with rate ≤ 10, $FiO_2 \leq 0.60$, PEEP ≤ 5 cm.
- If the patient's blood pressure, heart rate, or respiratory rate increase or decrease 10% above baseline, then the measurement is immediately stopped and the patient placed back on mechanical ventilation. This will be documented on the data collection tool.

Assemble supplies:

- Gloves
- Wright Mark 20 Respirometer (Ferraris Respiratory Europe, Hertford, UK)
    - Make sure protective casing is on Wright
- Patient filter
- Adaptor
- Data Collection Form
- Towel or chux
- Stopwatch or watch with a second hand

Procedure: Minute ventilation and spontaneous respiratory rate will be measured 3 times under the same conditions as outlined bellow. The RSBI will be calculated using the average of the 3 minute ventilations and the 3 respiratory rates. Calculation will only be performed by the PI.

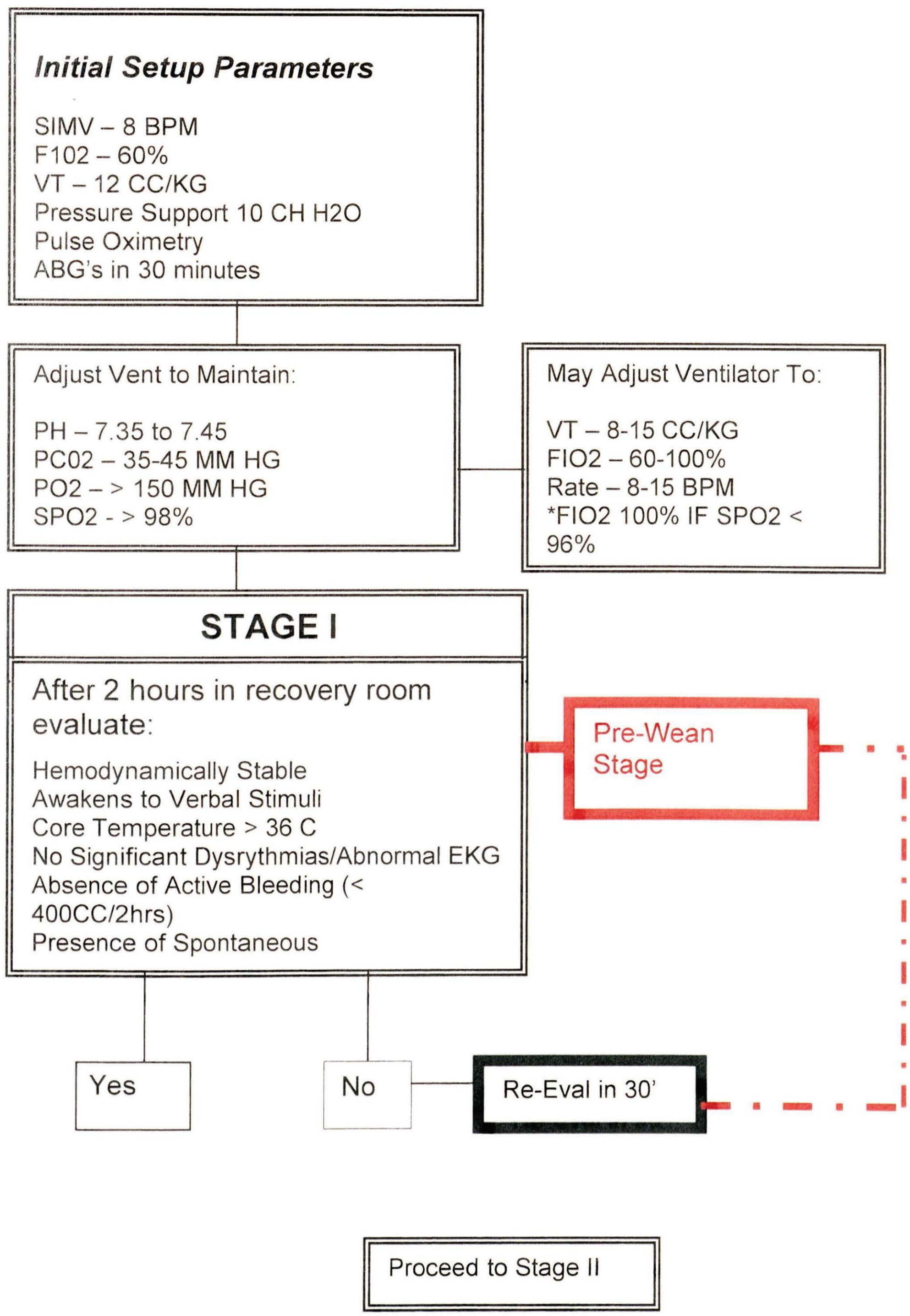
- Identify patient via two methods
- Wash hands
- Don non-sterile gloves
- Explain procedure to patient whether conscious or not
- Place towel or chux on patient's chest
- Connect filter to exhalation port of Wright Respirometer
- Connect adaptor to patient port of Wright Respirometer
- Disconnect patient from ventilator
- Connect endotracheal tube (ET) to patient port of Wright Respirometer
- Wait 1 minute and turn Wright on
- Start stopwatch
- Count respirations for 1 minute
- After 1 minute, turn Wright off
- Disconnect patient from Wright and place back on ventilator on previous settings for 5 minutes

- Record minute ventilation and respiratory rate on data collection form
- Depress reset button on Wright
- After patient has been back on mechanical ventilation for 5 minutes, disconnect from ventilator and connect to Wright Respirometer
- Perform second measurement as outlined above
- Disconnect patient from Wright and reconnect to ventilator
- Record minute ventilation and respiratory rate on data collection form
- After patient on mechanical ventilation for 5 minutes, disconnect and perform last measurement as outlined above
- Record minute ventilation and respiratory rate on data collection form

Appendix E

Weaning Protocol for the CVRR

Weaning Protocol for the CVRR



Weaning Protocol for the CVRR

Stages II, III, & IV

STAGE II

Weaning Stage

Decrease IMV to 4 BPM
Add 5 CM PEEP

After 1 hour evaluate:

Adequate SPO2 (See Stage II)
Stable Hemodynamics (See Stage I)

YES

NO — Notify CV Anesthesia

Good Mechanics: VT 5-7 CC/KG, RR < 25

NIF > 25 CM H20, VC 12-15 CC/KG
(PT. Off PS for Mechanics Only

STAGE III

Place Patient on CPAP 5 CM + 10 PS
FIO2 60%
ABG's in 30 minutes

ABG's Adequate (as above)

Good Mechanics: VT 5-7 CC/KG, RR < 25
NIF > 25 CM H2O, VC 12-15 CC/KG
(Pt. Off PS for Mechanics Only)
Patient awake and alert
Stage Criteria Met

YES
Proceed to Stage IV

No
Notify CV Anesthesia — Place Patient on IMV 4, FIO2 60%, VT 10-12 CC/KG

STAGE IV

Notify MD and Extubate Patient
Place on 50% Ventimask
ABG's in 30 minutes
If PO2 > 100 after ABG,
Place on NC 4LPM

Weaning Outcome Stage:
If patient remains free of mechanical ventilation for 24 hours, this is a positive outcome. If not, this is a negative outcome.

Appendix F

Means and Standard Deviations for Minute Ventilation and Respiratory Rates

Used to Assess Rapid Shallow Breathing Index (RSBI)

Means, Standard Deviations, and Coefficients of Variance for Tidal Volume and Respiratory Rates Used to Assess Rapid Shallow Breathing Index (RSBI) (*N*=29)

* Denotes Failed Weaning

	RSBI 1		RSBI 2	
Subject	Tidal Volume *M (SD) [Cv]*	Respiratory Rate *M (SD) [Cv]*	Tidal Volume *M (SD) [Cv]*	Respiratory Rate *M (SD) [Cv]*
1	0.17 (0.014) [8.24%]*	23.67 (2.08) [8.79%]	0.17 (0.019) [11.18%] *	25.67 (1.53) [5.96%]
2	0.24 (0.009) [3.75%]*	19.33 (1.16) [6.00%]	0.22 (0.001) [0.45%] *	24.67 (1.16)[4.70%]
3	0.55 (0.145) [26.36%]	24.00 (2.65) [11.04%]	0.36 (0.035) [9.72%]	27.00 (1.00) [3.70%]
4	0.64 (0.021) [3.28%]	16.67 (1.16) [6.96%]	0.71 (0.025) [3.52%]	18.33 (0.58) [3.16%]
5	0.55 (0.145) [26.36%]	24.00 (2.65) [11.04%]	0.56 (0.056) [10.00%]	33.33 (2.31) [6.93%]
6	0.16 (0.007) [4.38%]	22.33 (2.52) [11.29%]	0.13 (0.014) [10.77%]	21.67 (0.58) [2.68%]
7	0.40 (0.042) [10.50%]	19.33 (1.53) [7.92%]	0.43 (0.017) [3.95%]	21.00 (1.00) [4.76%]
8	0.23 (0.004) [1.74%]	18.33 (0.58) [3.16%]	0.36 (0.039) [10.83%]	18.33 (0.58) [3.16%]
9	0.18 (0.004) [2.22%]*	25.33 (1.16) [4.58%]	0.22 (0.016) [7.27%] *	23.33 (1.16) [4.97%]
10	0.27 (0.005) [1.85%]	21.33 (1.16) [5.44%]	0.25 (0.009) [3.60%]	17.67 (0.58) [3.28%]
11	0.38 (0.014) [3.68%]	19.33 (1.16) [6.00%]	0.37 (0.004) [1.08%]	17.33 (1.16) [6.70%]
12	0.49 (0.005) [1.48%]	21.33 (1.16) [5.44%]	0.46 (0.016) [3.48%]	19.00 (1.73) [9.11%]
13	0.30 (0.018) [6.00%]	24.67 (1.16) [4.702%]	0.33 (0.004) [1.2121%]	21.67 (0.58) [2.677%]
14	0.60 (0.010) [1.667%]	20.67 (1.16) [5.612%]	0.50 (0.014) [2.800%]	21.00 (1.00) [4.761%]
15	0.27 (0.004) [1.481%]	22.33 (1.53) [6.852%]	0.29 (0.004) [1.379%]	20.33 (0.58) [2.852%]
16	0.38 (0.003) [0.789%]	16.67 (1.16) [6.959%]	0.37 (0.008) [2.162%]	15.33 (1.16) [7.567%]

Subject	RSBI 1 Tidal Volume *M (SD) [Cv]*	RSBI1 Respiratory Rate *M (SD) [Cv]*	RSBI 2 Tidal Volume *M (SD) [Cv]*	RSBI 2 Respiratory Rate *M (SD) [Cv]*
17	0.47 (0.014) [2.979%]	21.67 (2.08) [9.599%]	0.48 (0.021) [4.375%]	18.33 (0.58) [3.164%]
18	0.22 (0.006) [2.727%]	24.00 (0.00) [0.00%]	0.24 (0.003) [1.250%]	22.67 (1.16) [5.117%]
19	0.33 (0.023) [6.969%]	22.00 (1.00) [4.545%]	0.43 (0.002) [0.4651%]	23.33 (2.31) [9.901%]
20	0.43 (0.018) [4.186%]	17.33 (1.16) [6.695%]	0.52 (0.006) [1.153%]	18.00 (0.00) [0.00%]
21	0.24 (0.007) [2.917%]	21.00 (1.00) [4.761%]	0.27 (0.004) [1.481%]	20.67 (0.58) [4.702%]
22	0.31 (0.009) [2.903%]	19.33 (1.16) [6.001%]	0.34 (0.002) [0.5882%]	20.67 (1.16) [5.612%]
23	0.67 (0.036) [5.373%]	18.33 (0.58) [3.164%]	0.69 (0.004) [0.5797%]	18.33 (0.58) [3.164%]
24	0.23 (0.013) [5.652%]	20.67 (2.31) [11.176%]	0.23 (0.012) [5.217%]	22.67 (1.16) [5.117%]
25	0.16 (0.004) [2.50%] *	23.00 (1.00) [1.328%]	0.15 (0.012) [8.000%] *	23.33 (2.31) [9.901%]
26	0.15 (0.005) [3.333%] *	23.67 (2.52) [10.646%]	0.12 (0.006) [5.000%*]	18.00 (0.00) [0.00%]
27	0.42 (0.007) [1.667%]	21.33 (0.58) [2.719%]	0.43 (0.008) [1.860%]	20.67 (0.58) [4.702%]
28	0.26 (0.004) [1.538%]	16.67 (0.58) [3.479%]	0.32 (0.008) [2.500%]	20.67 (1.16) [5.612%]
29	0.43 (0.022) [5.116%]	23.33 (1.16) [4.972%]	0.41 (0.003) [0.7317%]	18.33 (0.58) [3.164%]

* Denotes failed weaning