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ABSTRACT

RESEARCH SUBJECT: Mechanical Ventilation and Weaning Protocols

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Mechanical ventilation refers to the use of life support technology to perform the work of breathing for patients who are unable to do so adequately. Over 80% of critical care patients are ventilated at some point during their hospitalization. The use of prolonged intubation is associated with nosocomial pneumonia, cardiac associated morbidity and even death. The discontinuation of mechanical ventilation prematurely may result in re-intubation which is associated with similar complications as prolonged ventilation. Optimally weaning a patient from mechanical ventilation is an important role in the management of critically ill patients. This is a replication of McLean, Jenson, Schroeder, Gibney, and Skodt (2006) study. The purpose of this study is to compare the efficacy and efficiency of nurse directed weaning protocols to wean patients from mechanical ventilation against traditional physician directed weaning. Development of standardized weaning protocols provides an evidence-based method for nursing practice and care of patients receiving ventilator support. Standardized weaning protocols can reduce the length of duration of mechanical ventilation and its associated complications.
Chapter I

Introduction

Today’s health care system is more advanced than ever before with many patients requiring specialized care. Great strides in medical technology have allowed physicians and nurses to be able to treat the patient with more sophisticated specialized equipment. With great advancements in medical technology, there have come increased costs of health care. According to the Center for Medicare and Medicaid Services (CMS), the National Health Expenditure Fact Sheet, Americans spent $2.5 trillion on health care in 2009. CMS reported that Medicare spent $502.3 billion and Medicaid spent $373.9 billion in 2009. CMS (2009) went on to state that a single day in an Intensive Care Unit (ICU) is approximately $2500 for the room alone, with no specialized medical equipment or treatments included. The costs can rise to $3000 to $5000 per day per patient when more complex medical equipment and treatments is required. The challenge is in discovering ways to lower the overall health care cost while at the same time retaining the integrity of patient care which is invaluable.

The mechanical ventilator is a life-saving advancement in medical technology that has enhanced health care, but has also greatly increased costs. Mechanical ventilators use positive pressure to mechanically assist or replace spontaneous respirations. Mechanical
ventilation is a life-saving measure for critically ill patients, but it is also associated with severe complications. Complications include ventilator associated pneumonia, prolonged duration of mechanical ventilation, vocal cord trauma, prolonged hospitalization, and poor patient outcomes. It is estimated that 80% of all patients who receive medical treatment in an ICU require the use of mechanical ventilation (McLean, Jensen, Schroeder, Gibney, & Skjodt, 2006).

Removal of an endotracheal tube is an important decision that the health care team must make. Even when the decision to remove the endotracheal tube was made by a physician or a nurse using an established protocol, any failure to remain off of the mechanical ventilator can cause detrimental patient outcomes. Inability to wean or remove patients from mechanical ventilation means a longer duration in the ICU with specialized care that involves close, frequent monitoring. It is estimated that for approximately 40% of the time any patient spends on mechanical ventilation that they are undergoing weaning trials to come off of the medical device (Blackwood, Wilson-Barnett & Trinder, 2007). Traditionally, weaning from mechanical ventilation is controlled by a physician.

Physicians typically use their experience and observations to create weaning parameters for the nurses and patients. Mechanical ventilator weaning protocols are designed to be used by either nursing or respiratory therapy in place of physician directed orders. These protocols work best when all health care team members (nursing, respiratory therapy and medical staff) work as a collaborative group that benefits the patient.
Mechanical ventilator weaning protocols are designed to enable the nurse and/or respiratory therapist to have more autonomy when working with physicians and patients and to assist the patient to be removed from mechanical ventilation. Mechanical ventilator weaning protocols have a halt or a stop built into their design for any change in patient condition and have been clinically shown to help the health care team wean the patient from mechanical ventilation in a safe and quick manner, ultimately decreasing the duration of mechanical ventilation and the length of hospitalization.

Background and Significance

The history of modern medical research can be traced back to the Roman physician Galen (US National Library of Medicine, 2009). The US National Library of Medicine (2009) stated that it was Galen who first described of mechanical ventilation by writing: “If you take a dead animal and blow air through its larynx with a tube, you will fill its bronchi and watch its lungs attain the greatest distention” (http://www.nlm.nih.gov/hmd/greek/greek_galen.html). But it wasn’t until 1908 when American George Poe built on Galen’s idea of ventilation. Absolute Astronomy (2011) stated that it was Poe who was the first to build a respirator that seemed “to bring dogs back to life” (http://www.absoluteastronomy.com/topics/George_Poe).

The Smithsonian National Museum of American History (2011) notes that it was “in 1927, when the first device best known as the “iron lung”, was invented by two Harvard medical researchers Philip Drinker and Louis Agassiz Shaw. It was nicknamed the “iron lung” because of its use of an iron box and two vacuums” (http://americanhistory.si.edu/polio/howpolio/ironlung.htm). This first negative pressure
device was used widely in the polio epidemic in the 1940s. Byrd, Kosseifi, and Roy (2010) noted that it was during “World War II when the military sought a way to supply oxygen for the fighter pilots in high altitudes that the modern positive-pressure devices” were developed (from http://emedicine.medscape.com/article/304068-overview). The Smithsonian National Museum of American History (2011) stated “that as the Polio Epidemic of the 1950s grew in Scandinavia and the United States the use of what was to become the modern positive pressure mechanical ventilator grew” (http://americanhistory.si.edu/polio/howpolio/ironlung.htm).

Byrd et al. (2010) noted that mechanical ventilators “began to grow in popularity and use” (from http://emedicine.medscape.com/article/304068-overview). With continued advancements in medical technology, greater innovations came to mechanical ventilator development and design. These machines became more widely known and “used to treat severe lung injury such as acute respiratory distress syndrome, asthma, pneumonia, hypoxemia and cardiac/pulmonary arrest” (Byrd et al., 2010, http://emedicine.medscape.com/article/304068-overview). Mechanical ventilation has now become an established and successful way to treat many severe lung injuries. Unlike those first machines, patients now have the ability to move from their hospital room. The development of portable mechanical ventilators now allows a patient to move throughout the hospital and receive therapy. These new “mechanical ventilator devices are portable and can be set up in patients’ homes for long term use” (Fludger & Klein, 2008, p. 199).

The increased employment of mechanical ventilators gave rise to new complications from the use of the devices and the inability to remove the patient from it.
Byrd et al. (2010) state that “from prolonged duration of mechanical ventilation, prolonged hospitalization, nosocomial infections to increasing the mortality of patients” (http://emedicine.medscape.com/article/304068-overview) receiving treatment in the ICU. All of these complications affect health care costs associated with mechanical ventilator use. With the growth of mechanical ventilator use there has also became a need for specialized health care as well. That need for specialized health care has brought growing health care costs.

Weaning is the process of re-training patients to breathe on their own without the use of mechanical ventilation by decreasing the amount of support that they receive from the medical device. Alia and Esteban (2006) noted that “patients need a progressive withdrawal from mechanical ventilation” (p. 72). Traditionally, physicians were responsible for weaning parameters to help a patient’s successful removal from mechanical ventilation therapy. In the early 1990s, a new trend began to emerge. Protocols were developed to assist the bedside nurse and/or respiratory therapist to begin the weaning process. These weaning protocols allowed the nurse/respiratory therapist to begin assessing the patient based on their hemodynamic presentation for weaning before the physicians made rounds. It is important to note that failure of successful removal “still occurs in approximately 20% of all patient extubations whether it is physician directed or from weaning protocols” (Mokhlesi et al., 2007, p. 1710).

Evidence from clinical trials suggests that mechanical ventilator weaning protocols are able to reduce “total duration of mechanical ventilation, weaning duration and length of stay in the ICU” (Blackwood et al., 2011, p. 7237) while improving overall
patient outcomes. Patients depend on their nurses to help them overcome and see them through their illness. By using weaning protocols, nurses have more autonomy and more responsibility to patients and their overall health.

**Problem Statement**

Mechanical ventilators are often associated with difficulty to wean, increased hospitalization and increased health care costs. Mechanical ventilator weaning protocols are an analytical tool used to enhance the nurses ability to help the patient adapt to their environment and improve their health.

**Purpose**

The purpose of this study is to determine if the use of a mechanical ventilator weaning protocol improves patient outcomes while decreasing the duration of mechanical ventilation and length of stay while in the Intensive Care Unit (ICU). This study is a replication of McLean, Jenison, Schroeder, Gibney, and Skodt’s (2006) study.

**Research Questions**

1. Do mechanical ventilator weaning protocols decrease the duration of mechanical ventilation?
2. Do mechanical ventilator weaning protocols decrease the length of stay of a patient in the Intensive Care Unit?
3. Are patient outcomes improved with the use of mechanical ventilator weaning protocols?
Theoretical Framework

The Roy Adaptation Model for Nursing has established concepts that relate strongly to mechanical ventilator weaning protocols and determining the most effective means to wean a patient from mechanical ventilation. Roy’s Adaptation Model includes nursing, health, adaptation, and environment with the key component being nursing care. Tomey and Alligood (2006) noted that the practice of nursing “relates the processes that people positively affect their health status” while the goal of nursing is to “promote the adaptation and contribute to the health and quality of life” (p. 362). Tomey and Alligood defined health as a progression “of being and becoming an integrated and whole person” (p. 362). Health can easily be defined as having the ability to cope with stress and disease in a competent manner because health ensues when humans were able to adapt continuously to our environment. Environment is defined by Roy as stated in Tomey and Alligood (2006) as everything that “surround[s] and affect[s] the development…of a person” (p. 362). Tomey and Alligood (2006) noted that it was “the changing environment that stimulates a person to make an adaptive change” (p. 362). Adaptation was the merging of human and environment. Roy believed that humans were “inseparable from their environment” (Tomey & Alligood, p. 361).

Mechanical ventilator weaning protocols have a teaching/learning strategy for physicians and nurses in their daily patient care assessments and their ability to think critically, as well as for the patient who is receiving treatment from mechanical ventilation. Roy’s Adaptation Model used the person as the adaptive system as it is the person who possesses the ability to adapt to their environment and their surroundings.
Mechanical ventilator weaning protocols allowed the nurse to integrate Roy’s Adaptation Model into their practice. This study proposes to determine whether the use of a mechanical ventilator weaning protocols improves patient outcomes while decreasing the duration of mechanical ventilation and length of stay while in the ICU.

**Definition of Terms**

*Conceptual Definitions*

1. Intensive Care Units/Critical Care Units: Clinical areas that are for patients being treated for a critical illness. These areas include the cardiovascular, medical, surgical, neurological and trauma Intensive Care Units.

2. Adaptation: Process by which a “person uses conscious awareness to choice to merge themselves with their environment” (Tomey & Alligood, 2006, p. 361).

3. Mechanical Ventilator: A medical device that is used to assist or replace spontaneous respirations

*Operational Definitions*

1. Mechanical ventilator weaning protocols: A set of routine orders, previously approved by hospital policy-makers, used to assess and wean patients from mechanical ventilation therapy.

2. Acute Physiology and Chronic Health Evaluation II (APACHE II) score: A score used to classify and estimate mortality rates for ICU patients.

3. Successful Extubation: Ability to remain off of mechanical ventilation for a period of greater than 48 hours.
4. Unsuccessful Extubation: Need for re-intubation with the use of mechanical ventilator therapy within 48 hours of extubation.

Limitations

This study does have limitations. This study was performed at one hospital in two critical care units in a metropolitan city. Study limitations include limited method trials as nurses were aware of which patients were receiving weaning protocols and which patients were under physician directed weaning orders resulting in biased estimate of treatment effect.

Assumptions

The following assumptions were made in this study:

- Nurses understood complications of mechanical ventilator therapy
- Nurses wanted to have the autonomy of performing weaning assessments
- Physicians were accepting of a nurse directed weaning protocol

Summary

Mechanical ventilation refers to the use of specialized medical life support technology that was able to assist or replace spontaneous respirations for those patients that were unable to do so on their own. Mechanical ventilation therapy has become integral to the treatment of severe lung injury. The prolonged use of mechanical ventilators is associated with many complications including nosocomial infections, cardiac associated morbidity and even death. The discontinuation of mechanical ventilation prematurely may result in re-intubation which is associated with similar complications as prolonged ventilation. Weaning from mechanical ventilation was
considered by some to be an art and a science. Mechanical ventilator weaning protocols were designed to improve the efficacy of patient care by following a consensus not an individual’s judgment. Optimally weaning a patient from mechanical ventilation thus minimizing the duration of mechanical ventilation without the risk of re-intubation and preventing major complications is an important role in the management of the critically ill patient.
Chapter II

Review of Literature

Introduction

Mechanical ventilation is required in over 80% of critically ill adults receiving treatment in ICU. Mechanical ventilation is a life-saving measure for patients but is associated with severe complications. Prolonged duration of mechanical ventilation can cause complications such as inability to wean, tracheostomy placement and ventilator associated pneumonia as well as increased health care costs to the patient and the health care facility. Weaning protocols were initially designed in the early 1990s as a way to assist physicians in their ability to extubate the patients safely and quickly. As weaning protocols become more popular in use, it is important to reassess their value to health care and satisfactory patient outcomes. The ability to reduce the duration of mechanical ventilation and length of stay would result in improved patient’s health and reduced health care costs.

Purpose

The purpose of this study was to determine whether the use of a mechanical ventilator weaning protocol improves patient outcomes while decreasing the duration of mechanical ventilation and length of stay while in the Intensive Care Unit (ICU). This is a replication of McLean et al.’s (2006) study.
Organization of Literature

The literature review to support this study was divided into three sections: (a) complications; (b) nursing education; and (c) patient and family education. This chapter concludes with a summary.

Theoretical Framework

McLean et al. (2006) did not elect to use a decision making theory in the study. This replication study used an organizing framework based on Roy’s Adaptation Model for Nursing. Sister Callista Roy developed the Roy Adaptation Model in 1970 (Tomey and Alligood, 2006).

The Roy Adaptation Model for Nursing has concepts that relate strongly to this study which include nursing, health, adaptation, and environment. Nursing was important in Roy’s Adaptation Model. Tomey and Alligood (2006) noted that defined nursing as “relates the processes that people positively affect their health status” (p. 362) while the goal of nursing is to “promote the adaptation and contribute to the health and quality of life” (p. 362). Tomey and Alligood (2006) defined health as a progression “of being and becoming an integrated and whole person” (p. 362). Health can easily be defined as having the ability to cope with stress and disease in a competent manner because health ensues when humans were able to adapt continuously to the environment. Environment was defined by Roy as stated in Tomey and Alligood (2006) as everything that “surround[s] and affect[s] the development…of a person” (p. 362). Tomey and Alligood noted that it was “the changing environment that stimulates a person to make an adaptive change” (p. 362). Adaptation is the merging of human and environment. Roy
believed that humans are “inseparable from their environment” (Tomey and Alligood, p. 361).

Roy’s Adaptation Model consists of three levels of adaptation: integrated, compensatory and compromised. The integrated level of adaptation allows a harmony between stress and function in the human need. The compensatory level of adaptation was when a strong stressor enters into the human need that cannot be adequately adjusted for. The compromised level of adaptation was when a stressor enters the human function that is unable to be adjusted for within the prior two levels.

Applying the use of Roy’s Adaptation Model to the use of weaning protocols for mechanical ventilation therapy works well as the physicians and nurses are experiencing a learning curve in their caretaking by using weaning protocols. The patients that were receiving therapy from mechanical ventilators are also learning. Roy’s Adaptation Model used the person as the adaptive system as it is people who possess the ability to adapt to their environment and their surroundings. This study proposed to determine whether the use of mechanical ventilator weaning protocols improves patient outcomes in the ICU.

Complications

Many patients who receive treatment in an ICU were treated with mechanical ventilation therapy during their critical illness. It is estimated that over 80% of patients who were treated in an ICU received therapy from mechanical ventilation. Mechanical ventilator therapy is costly to maintain as a life-saving treatment for patients. However, patients who receive treatment from mechanical ventilators are also faced with unique
complications that can hinder their medical treatment. Complications can include ventilator associated pneumonia (VAP) as well as unplanned extubations.

The incidence of nosocomial infections is an important safety issue that hospitals must face on a daily basis. One of the leading types of nosocomial infections found in patients receiving mechanical ventilation in an Intensive Care Unit is VAP. The Centers for Disease Control and Prevention (CDC) has established what is known as the “ventilator-bundle’ for best practice as a guideline to help reduce and prevent VAP.

Tolentino-DelosReyes, Ruppert, and Shiao (2007) conducted a study to assess nurses’ knowledge of VAP bundles and the prevention of VAP when working with mechanically ventilated patients.

The setting was a large hospital in a medical center in a major metropolitan city. Twenty-eight nurses from the hospital coronary care unit (CCU) and 33 nurses from the hospital surgical intensive care unit (SICU) participated in the study. Ninety-nine patients from both the SICU and the CCU were observed for the care that they received by the nurses (Tolentino-DelosReyes et al., 2007).

Nurses were asked if they would like to participate in the study. Nurses were then given a 10-item exam that included questions regarding the nurses’ knowledge of best practice guidelines, organisms that can cause VAP, hand washing techniques, head of bed (HOB) positioning with the use of enteral feedings, diagnosis of pneumonia and definition of VAP. After the 10-item exam, the staff nurses were given 30-minute educational seminars on how to prevent VAP from occurring through use of the Centers for Disease Control (CDC) guidelines. Demographic data was gathered on participating
nurses that included age range, educational level as well as years of experience. The staff nurses were then given the 10-item exam again after formal educational sessions to see if any knowledge of VAP had occurred (Tolentino-DelosReyes et al., 2007).

Nurses were observed during shift reports for practice care standards. These standards were if the nurses addressed patients’ HOB angle, hand washing practices, use of artificial nails, and nail polish as well as the number of rings worn by the nursing staff. Nursing documentation was assessed for HOB elevation, frequency of oral care and assessment of nasogastric tube placement. After the educational sessions, an increase in hand washing was noted amongst the nurses. The very few nurses that wore artificial nails before the sessions continued to do so after the educational sessions. An evaluation of the documentation of the nurses showed an increase in the HOB angle, performance of oral care and assessment of residuals noted from nasogastric tube feedings (Tolentino-DelosReyes et al., 2007).

Findings from this study show that educational sessions have a great impact on nursing care. Nurses knowledge of VAP bundles increased from ($p$<.001 to $p$<.05) after having 20-minute educational sessions. Nurses’ knowledge of hand washing was not increased from the sessions as nurses scored 98% to 100% both in pre- and post-educational sessions. The HOB angle had a dramatic change post-educational sessions as nurses knowledge was shown to increase from 44% pre-educational session to 74% post-educational session ($p$<.001). Nursing compliance with hand washing before contact with a patient increased from 11% pre-educational session to 45% post-education session. Nursing also showed strong evidence of oral care therapy as the frequency of oral care
increased from 16% to 35% (p=.009) post-educational session. Residuals from nasogastric feedings was also shown to be assessed more often going from 3% to 18% after post-educational session (Tolentino-DelosReyes et al., 2007).

Tolentino-DelosReyes et al. (2007) showed findings that support evidence-based practices should be used as driving forces in nursing education and practices. Education has a strong impact on standard of care as well as beneficial to overall patient outcomes.

Many patients who were receiving mechanical ventilation are also receiving some form of continuous sedation. A continuous infusion of sedation was considered to have greater benefits for maintaining sedation but is considered to prolong mechanical ventilation and hospitalization. Sedation vacations were considered influential to decreasing mechanical ventilation durations and hospital stay length. Anifantaki, et al. (2009) conducted a study to assess effect of daily interruption of sedation medications had on nursing implemented weaning protocols compared to those who did not have a sedation vacation.

In this study, the setting was an adult medical-surgical ICU. The patients were split into two groups. Forty-nine of the patients received sedation vacations with nurse implemented weaning protocols and 48 patients received nurse implemented weaning protocols with no change in sedation management. Patients were considered eligible for admission into the study after they had received 48-hours of mechanical ventilation therapy. Patients were excluded if they were pregnant, were transferred to ICU after cardiac arrest or if sedation therapy was initiated at another medical facility.
Demographic data gathered on the patients included: age, gender and admission diagnosis (Anifantaki, et al., 2009).

Anifantaki et al. (2009) recorded the following variables each day on every patient: (a) number of sedation interruption attempts; (b) total doses of sedatives and analgesics; (c) duration of sedatives as infusions (in hours); (d) Ramsey score; (e) duration of mechanical ventilation (in hours); (f) death in ICU; and (g) transfer to another department. Associations between variables were examined using Fisher’s exact test as appropriate. Differences in variables were examined using the Kaplan-Meier curves as appropriate.

Anifantaki et al. (2009) found no differences in results based upon age and gender as well as both groups had similar admission diagnoses. The number of days patients received mechanical ventilation with 8.7 vs. 7.7 days (p=0.7) was similar as was length of ICU stay 14 days vs. 12 days (p=0.5) for the intervention group vs. the control group. There was also no difference in rate of mortality (p=0.2). Anifantaki et al. also noted that there was no significant difference in the doses of analgesics and sedatives between the two groups at 13 hours vs. 10 hours (p<0.001).

Findings from this study showed that giving patients a sedation vacation did not affect their weaning from mechanical ventilation nor did it increase the length of stay in the ICU or length of duration of mechanical ventilation. Anifantaki et al. (2009) found that nurse implemented weaning protocols were an effective way to wean a patient with no direct correlation with halting of sedation medication. Anifantaki et al. did note that
there were variations among sedation practices and that a team approach when weaning
with the use of sedation should be considered (Anifantaki, et al., 2009).

Unplanned extubations were an unfortunate occurrence that can be a life-
threatening situation whether the result of a deliberate act or not. Impacts from
unplanned extubations can be effect the on length of ICU stay, length of hospitalization,
length of mechanical ventilation, and ultimately mortality. Weaning protocols can be
used to promptly and successfully extubate a patient from mechanical ventilation.

The setting for this study was an adult medical ICU in a large urban teaching
hospital in the Midwest. The study used a sample size of 156 patients from September 1,
2007 to September 1, 2008. All adult patients that were admitted to the medical ICU,
who were ventilated and receiving treatment from the medical ICU physician service
were admitted to the study. Demographic data gathered on the patients included age,
number of intubated days, diagnosis, medical history, Glasgow Coma score, Riker scores,
arterial blood gases, pain score, ventilator settings, and total length of stay (Jarachovic,

Jarachovic, Mason, Kerber, and McNett (2011) assessed whether or not protocols
for pain, sedation and weaning were ordered and used by nursing staff. The protocols
were assessed on whether they decreased the number of patients experiencing an
unplanned extubation. The researchers used a yes/no checklist to indicate whether or not
the protocol was used. If the protocol was used then researchers assessed the degree of
compliance with the protocol and documented compliance as yes/no or moderate. The
researchers stated that if the protocol was ordered and was closely followed by nursing
staff, then compliance was marked as a “yes”. Jarachovic et al. also noted that if a protocol had been ordered but was not followed then compliance was documented as a “no”. If a protocol was ordered but only some components were followed then they documented a “moderate” on their graphic compliance sheet. Each protocol use for pain, sedation and weaning from mechanical ventilation was assessed by the researchers for degree of compliance.

Jarachovic et al. (2011) found that the majority of patients with an unplanned extubation were male (72.4%). Jarachovic et al. also noted that patients who were cared for with the weaning protocols in place were less likely to have an unplanned extubation than those patients who were not on a weaning protocol for mechanical ventilation. The researchers further discovered that once a medical practitioner ordered the weaning protocols, nursing staff were very compliant in following the protocol. Jarachovic et al. in addition also noted that having pain and sedation protocols in place did not affect unplanned extubations. The researchers discovered that 83% of unplanned extubations were from patients who had no weaning protocol in place thus the use of weaning protocols was supported by the findings.

This study showed that the use of weaning protocols were highly regarded and complied with by nursing staff with nursing compliant 96% of the time. Physicians were willing to order the use of mechanical ventilator protocols and nursing staff was willing to follow them. Jarachovic et al. (2011) noted that having mechanical ventilator weaning protocols that were designed by the medical staff, respiratory therapists and nursing staff gave validity to the protocols from the collaborative team. The researchers state that
quality improvement initiatives should be addressed in the future to explore the
effectiveness of protocol-driven extubations.

Removal of an endotracheal tube is an important decision that the health care
team must make. Whether the decision to remove the endotracheal tube was made by a
physician or a nurse using a protocol failure to remain off of the mechanical ventilator
can cause detrimental patient outcomes. A patient spends about 40% of the time on
mechanical ventilation undergoing the weaning process. Yet, a failed extubation still
occurs in up to 20% of patients. The purpose of this study was to develop a computerized
protocol for weaning from mechanical ventilation to improve patient outcomes
(Lellouche, Mancebo, Jolliet, Roeseler, Schortgen, Dojat, Cabello, Bouadma, Rodriguez,
Maggiore, Reynaert, Mersmann, and Brochard, 2006).

The settings used for this study were five medical-surgical ICUs at five large
university hospitals. A total of 1014 patients were evaluated for inclusion in the study. A
total of 866 patients were deemed ineligible for participation in the study due to: (a)
mechanical ventilation for less than 24 hours; (b) death; and/or (c) self extubation had
occurred. The remaining 144 patients were included in the study and were separated into
two groups. The first group of 74 patients was weaned using the computerized protocol
with the other 70 patients weaned from mechanical ventilation in the manner that
facilities existing protocol (Lellouche et al., 2006).

Lellouche et al. (2006) indicated that proportions were compared using the \(X^2\) test
or the Fischer exact test. Lellouche et al. also used the Mann-Whitney U test to analyze
duration of mechanical ventilation and length of stay. The authors also noted that $p$ values smaller than 0.05 were considered to be significant.

Lellouche et al. (2006) found that the computerized weaning protocol was able to reduce the weaning time of patients from 4.0 to 2.0 ($p=0.02$). The authors also noted that the duration of mechanical ventilation was decreased from 9 days to 6.5 days ($p=0.03$) as well as the length of stay in the ICU was decreased from 15.5 days to 12 days ($p=0.02$). The mortality of patients was shown to have no change based upon computer driven weaning (21.6% vs. 22.9%, $p=1.0$). The researchers noted that complications from mechanical ventilation remained but that the computerized driven group had 30% less complications than the other group. The authors also noted that the total amount of days spent on mechanical ventilation by the computerized driven group was 293 days compared to the existing method weaning group which logged 392 days.

Findings from this study demonstrated that computerized weaning protocols are an effective tool that can aid the medical staff in weaning a patient from mechanical ventilation. Safe and effective removal from mechanical ventilation is associated with better patient outcomes including decreased risk of ventilator-associated pneumonia and decreased mortality and morbidity rates (Lellouche et al., 2006).

*Nursing Education*

Mechanical ventilation is a common form of treatment that is used in the ICU. The majority of patients receiving treatment inside of an ICU will spend some of their time receiving mechanical ventilation. Weaning protocols are designed for use by either respiratory care practitioners or the bedside staff nurse. Having one protocol in place that
can be used by both the respiratory care practitioners and the staff nurses can improve patient care for those patients that are on mechanical ventilation. Marelich et al. (2000) conducted a study to assess the use of a single mechanical ventilator protocol used by nurses and respiratory care practitioners.

The setting was a large urban hospital in a university medical center in a major metropolitan city in California. Three hundred and thirty five consecutive patients participated in the study. All patients were seen in the trauma and medical ICUs and were randomly assigned to either the physician order for weaning control group or the mechanical ventilator weaning protocol group. Only patients pregnant, less than 18 years of age, prisoners or mentally disabled were excluded. The only demographic data that was collected on the patients were age and sex. Marelich et al. (2000) developed an inclusion criterion of: (a) lack of failure of ventilator discontinuation within the past 24 hours; (b) minute volume ≤15 L/min (≤200mL/kg/min); (c) static compliance ≥25 mL/cm H₂O; and (d) PaO₂/fraction of inspired oxygen (FiO₂) ≥ 200.

Patients in the mechanical ventilator weaning protocol group were screened twice daily for spontaneous breathing trials (SBT). Specific criteria for passing the screening included: (a) Glasgow coma score of ≥10 or a tracheostomy; (b) mean arterial pressure of ≥ 60 without any vasopressor agents (the authors noted that dopamine ≤5mcg/kg/min was allowed); and (c) an adequate cough. Patients who passed the SBT screening were then eligible for a 30-minute SBT. If the patients were deemed to have had a successful SBT, the physician in charge of the patient was then asked permission to extubate. Physician approval was not needed in order to initiate the SBT only extubation. Failure of SBT was
defined as having an oxygen saturation level less than 92%, respiratory rate greater than 30 breaths per minute or having respiratory distress. If the patient did fail the SBT, the patient was then placed back onto their prior ventilator settings and rescreened in six hours. Marelich et al. (2000) noted that in the physician control group a physician’s order was required for all ventilator changes and weaning parameters.

Marelich et al. (2000) used a Wilcoxon rank sum statistic or $X^2$ to examine the univariate relationship between the groups and their outcomes. Kaplan-Meier survival curves were used for each group. Cox proportional hazards analysis was also used to compare time to each end point. Marelich et al. expected to have an 80% power to detect a 1.5-day difference between the groups with respect to time to extubation. It was also estimated by Marelich et al. to have a 1.5% change in frequency rate of VAP.

Marelich et al. (2000) found no significant differences in age or sex of the patients during SBT for success or failure. It was discovered that the duration of mechanical ventilation was 232 hours in the physician control group compared to 78 hours in the mechanical ventilator weaning protocol group ($p=0.0003$). The researchers noted that there was a significant reduction with the use of weaning protocols in the medical ICU. The trauma ICU had a decrease in the duration of mechanical ventilation of 52 hours in the physician control group compared to 33 hours in the ventilator protocol group ($p=0.067$).

Findings from this study show that weaning protocols can reduce costs and improve quality of patient care. Marelich et al. (2000) noted that no additional staff was needed to perform the weaning protocol than what was already being utilized in the
MICU. A limitation to the study noted by Marelich et al. is that physician cooperation is vital to the success of mechanical ventilator weaning protocols.

Despite growing research showing the benefits of using weaning protocols for mechanical ventilated patients their usage is still uncommon. The majority of patients undergoing weaning were doing so under direct physician order. Weaning protocols were designed for use by either the respiratory care practitioners or the bedside staff nurse. It is important to understand the opinions of the ICU physicians on their beliefs of mechanical ventilation weaning protocols. Blackwood, Wilson-Barnett, and Trinder (2004) conducted a study to assess the views of ICU physicians’ use of mechanical ventilation weaning protocols by staff nurses.

The setting was two-ICUs within two large university hospitals. Eleven physicians consented for the interviews on their opinions of weaning protocols. The physicians underwent 20-45 minute structured interviews. Blackwood et al. (2004) used audiotapes to assure consistency and accurate reporting of data.

The physicians were asked seven questions: (a) what information do you use to decide that a patient is ready for weaning; (b) can you describe your preferred method of weaning; (c) how do you perceive the nurse’s role in weaning; (d) what information do you use to decide that a patient is ready for extubation; (e) what do you feel is the most important issue related to weaning patients from mechanical ventilation; (f) what are your perceptions about the use of protocols in weaning; and (g) are there any other issues about weaning that we haven’t discussed and you’d like to tell me about? All interviews with the physicians were transcribed verbatim for accuracy (Blackwood et al., 2004).
The physicians believed that weaning patients from mechanical ventilation was an art and a science. They felt that nursing relied on objective parameters for weaning decisions. The physicians also stated their belief that having nursing staff perform mechanical ventilator weaning by use of protocols crossed a professional boundary. The physicians stated that the role of nursing was to complement the medical staff and not to perform their own practice. Two of the eleven physicians stated that if the nurse who was performing the weaning by use of a protocol was an experienced nurse who had undergone an educational seminar with them then they would have been more comfortable in having the nurse oversee mechanical ventilator weaning. The physicians did not state what they considered to be experienced (Blackwood et al., 2004).

Findings from this study showed that physicians believe that nurses need specific education in regards to weaning protocols. Physicians also believed that weaning should be performed by a team approach involving physicians, nurses and respiratory therapists. Physicians also believed that due to high nurse turnover rates that any weaning performed by a nurse should be overseen by a designated experienced nurse. Blackwood et al. (2004) showed that for any weaning protocol to be embraced, the ICU physicians needed to be supportive of the process.

Weaning protocols for patients who were mechanically ventilated started to develop and become popular in the early 1990s. Although many of the protocols look strictly at SBTs and patients hemodynamics there are other protocols that look more closely at elements of care. The Burns Wean Assessment Program (BWAP) was one of those protocols. BWAP is an in-depth analysis of weaning parameters with a systematic
approach and assessment to improve clinical outcomes. The purpose of this study was to determine a relationship between BWAP assessment protocol and extubation outcomes. Burns et al. (2010) used a descriptive design study with approval from the hospital's institutional review board.

The setting was an adult medical-surgical intensive care unit (ICU), a surgical neuro-trauma ICU, a cardiac ICU, and a cardiothoracic ICU. A total of 1889 patients were receiving mechanical ventilation for more than 72 hours and therefore eligible for weaning parameter analysis using the BWAP protocol. Unsuccessful weaning was defined as re-intubation within 24 hours of extubation. Demographic data obtained on the patients included sex (58% male, 42% female); age (all patients were between 43 to 69 years of age); length of ICU stay as well as length of mechanical ventilation (Burns et al., 2010).

Burns et al. (2010) designed a weaning protocol assessment checklist consisting of 26 questions. The first twelve questions addressed general assessment questions and included vital signs, lab values, nutrition assessment, pain control, anxiety, bowel assessment, body strength, and improvement of chest x-ray. The remaining fourteen questions were based upon respiratory assessment and involved work of breathing, airway clearance, respiratory strength, and respiratory endurance along with arterial blood gas analysis. Any response marked by a "yes" was then tallied and the total divided by 26 for a final BWAP score.

Burns et al. (2010) found that patients who scored a 50 or above were significantly more likely to successfully be weaned (p<.001) and extubated 96% of the
time. The patients who received a score of less than 50 were still able to be weaned and extubated but only 74% of the time. In evaluating the demographic data obtained from the patients, it was noted that with increasing age there was a direct correlation with a lower BWAP score and increased rate of unsuccessful weaning. No differences were noted in sex, length of ICU stay or length of mechanical ventilation.

Findings from this study showed that using the BWAP can increase successful weaning of patients from mechanical ventilation as 88% of the patients were successfully weaned (p=.002) and 12% were unsuccessful. The BWAP also showed that although sex (p=.005) and length of stay may affect hospital outcomes they have no bearing on weaning from mechanical ventilation. Age was shown to be a contributing factor for increasing difficulty to successfully wean from mechanical ventilation as age increases. BWAP is shown to be a successful weaning protocol that can be used successfully to wean and extubate patients from mechanical ventilation (Burns et al., 2010).

Many patients who undergo care in an ICU receive treatment from a mechanical ventilator. Although, mechanical ventilator therapy is costly to maintain it is a life-saving treatment. It can be difficult to wean patients from mechanical ventilator therapy and time consuming to the patient, their family and the health care team. Strategies that can improve weaning and ultimately decrease the patients’ length of stay were valuable to the patient, the family and the health care team. Grap et al. (2003) noted that "41% of time required for mechanical ventilation is spent on weaning patients from treatment" (p. 454). A collaborative effort from all members of the health care team during weaning can produce not only a satisfactory approach by all health care professionals involved but
also positive outcomes by the patient. The purpose of this study was to assess the development and implementation of a weaning protocol through the use of a collaborative approach.

The setting used for this study was an adult medical respiratory ICU in a large urban academic medical center in Virginia. The study does not state how many patients were examined for the research. A weaning protocol was developed by the health care collaborative team consisting of the medical ICU nurse practitioner, medical director, medical ICU nurse practice committee, and the respiratory therapy staff.

Grap et al. (2003) assessed the development process, implementation and outcome of weaning protocols on mechanically ventilated patients. The collaboratively developed weaning protocol consisted of an initial assessment of the patients’ hemodynamic stability, use of vasopressors, FiO2 ratio, PEEP setting and Richmond Agitation-Sedation Scale (RASS) score. The RASS score is a 10-point scale score from +4 (combative) through 0 (calm and alert) to -5 (unarousable) used to assess patient responsiveness. The RASS has a validity \( r=0.97 \) in comparison to the Ramsey sedation score \( r= -0.85 \) and the Sedation Agitation Scale \( r=0.86 \). This assessment was used to direct the staff as to whether the patient was appropriate to begin weaning per protocol. If the patient passed the initial step of the protocol directed assessment then step two was initiated. This step was a Rapid Shallow Breathing Index (RSBI). RSBI is a calculation of the patients’ ratio of respiratory rate frequency to ventilation during a one minute trial. An RSBI is used to assess a patient’s readiness for weaning. If the patient passed the RSBI as directed by the protocol with having a score of 125 or less then the medical staff
was to move onto the Spontaneous Breathing Trial (SBT) as directed by the protocol. Termination of the SBT was also accounted for in the weaning protocol.

Grap et al. (2003) noted that the protocol was highly effective and showed that the duration of mechanical ventilation can be successfully reduced. On average, the days of mechanical ventilation were reduced from 7 days to 5.5 days ($p=.02$). The number of hours spent on mechanical ventilation was also reduced from 20.95 hours to 16.7 hours ($p=.02$). It was discovered that nurses felt a greater responsibility for patient care. Nurses were shown through the use of education to have gained experience and positive contributions to patient care through the use of weaning protocols.

Grap et al. (2003) noted that extensive education was spent in teaching the weaning protocol to the respiratory therapists, nurses and physicians. Initially, each daily assessment for every mechanically ventilated patient in the MICU was performed by a respiratory therapist or the bedside nurse at 8am but was later changed to 6am due to the amount of tasks already scheduled at the later hour. The authors’ also noted that wording was changed after the initial months of the protocol to enhance clarity of the steps based on staff comments. The researchers also noted that as time progressed the physicians became more receptive as the nurses and respiratory therapists became more comfortable with the protocol. It was discovered that with the time change of initiation of the protocol, an SBT was well under way when the physicians made rounds. Grap et al. noted that respiratory therapists were the most compliant of the medical staff with the protocol and initially found that nursing staff were not as compliant or involved with the protocol.
Findings from this study showed that the education of all health care team members was imperative to the proper use and support of weaning protocols. Continuing education about mechanical ventilator weaning and the use of weaning protocols was found to have a positive ability to sustain the weaning protocol process with new respiratory therapists, new nurses and new interns/residents as well as experienced staff. Benefits of using mechanical ventilator weaning protocols were shown to have positive effects on patient outcomes.

While on mechanical ventilation, most patients receive some form of sedation and or analgesic therapy. Communication hindered when a patient is receiving therapy from mechanical ventilators and can be difficult for medical staff to properly medicate the patient. Treating a patient prophylactically for pain and discomfort can be beneficial but it can also cause an increase in length of treatment due to an over use of sedatives and analgesic agents that hinder proper assessment. Jakob et al. (2007) assessed the use and development of protocols for sedation and analgesia in conjunction with weaning from mechanical ventilation.

The setting used for this study was a medical-surgical adult ICU within a university hospital. A total of 300 patients with 100 patient groupings were assessed for weaning abilities. The patients were separated into three groups with the patients being separated randomly with consecutive admissions to the unit. Adjustments to the assessments and protocols were undertaken with each group based upon the prior group of patients from a retrospective analysis (Jakob et al., 2007).
The initial 100 patients were assessed on protocols developed based upon current literature and what were believed to be good indicators. Through interactive communication with physicians and bedside nurses adjustments were made to the protocols and then reassessed for satisfaction after 6-months of use. Data was assessed using the Kruskal-Wallis test and differences variables by the $X^2$ test. Statistical significance was not considered at $p \leq .05$ (Jakob et al., 2007).

Jakob et al. (2007) noted the use of sedation and analgesia protocols were able to decrease the use of morphine by $>85\%$ ($p=.001$), midazolam ($p=.050$) and other sedatives ($p<.001$) whereas the use of propofol ($p=.052$) and fentanyl ($p=.001$) increased in use. The ICU was able to save over $700,000$ in the first year of implementation of sedative and analgesic protocols. The hours of ventilation were decreased from 18 hours to 12 hours ($p=.046$). Mortality rates of patients receiving care in the ICU has been able to be decreased as mortality rates decreased from 19% to 7% ($p=.020$). In the ensuing 27 months of implementation of protocols for sedation and analgesia on mechanically ventilated patients mortality was reduced by more than 50%.

Findings from this study showed that the development and use of protocols for sedation and analgesic therapy are beneficial to the patient. The effectiveness of these protocols was shown through the decrease in the length of duration of mechanical ventilation as well as the decrease in mortality of the ICU patient.

Mechanical ventilation has been shown through many studies to have complex and sometimes deadly complications. Prolonged intubation by mechanical ventilation was shown to cause increases in mortality and morbidity. Specialized care and
monitoring was required for the patient receiving care from mechanical ventilation. The ability to wean a patient from mechanical ventilation was commonly based upon a physician’s judgment and experience. An emerging way to wean a patient from mechanical ventilator use is for nurses to use a hospital approved weaning protocols. The purpose of this study was to assess the ICU nurses perception, satisfaction, knowledge and usefulness of weaning protocols (Blackwood & Wilson-Barnett, 2007).

The settings used for this study were three ICUs at three university hospitals. Blackwood and Wilson-Barnett (2007) noted that the study was done in two sections. Both sections of the study were reassessed after 9-months. All three ICUs were assessed in section one of the study by the use of physician directed weaning. After the initial 9-month period, only two of the three ICUs then used the weaning protocol to allow for non-randomization and to allow for any changes in nursing practice. Student nurses and nurses who were on probation were excluded from participation in the study.

Blackwood and Wilson-Barnett (2007) gave formal and informal teaching sessions to all the nurses in all three ICUs. These formal and informal teaching sessions were designed to engage and educate the nurses on the mechanical ventilator weaning protocols. The nurses’ views and prior knowledge were integrated into the sessions. Once the initial formal educational sessions were completed, then the weaning protocols were enacted. Blackwood and Wilson-Barnett noted that the bedside nurses assessed patients’ ability to wean every AM with a predesigned weaning protocol screen. Nurses assessed the readiness of every patient receiving mechanical ventilation by: (a) respiratory rate <30bpm; (b) PaO2/FiO2 ratio >20; (c) systolic blood pressure >90 but
<180; (d) temperature <38.4° C; (e) pH >7.3, hemoglobin ≥7.0; (f) PEEP ≤ 5cmH₂O and (g) tidal volume >5. If upon assessment the patients met the criteria for weaning, then the weaning protocol was initiated.

Blackwood and Wilson-Barnett (2007) noted a seven item questionnaire was given to all nurses at the end of the study. The questionnaire was a mixture of open- and closed-ended questions. The closed-ended questions were coded. Independent t-tests and ANOVA were used for differences between groups; the dependent t-test was used for differences within the groups. The open-ended questions were assessed for content. Blackwood and Wilson-Barnett noted that there was a 93% response rate from nurses. The authors found that nurses were more aware of the weaning plans \( p=0.02 \) and had more knowledge of weaning \( p=0.02 \) in the group that was using weaning protocols. Those groups were also more satisfied with communication \( p<0.00 \) and collaboration with the multi-disciplinary team \( p<0.00 \).

Findings from this study showed that nurses felt more knowledgeable and satisfied with communication when there were protocols in place for weaning from mechanical ventilation. Protocols were shown to help newer nurses gain a better understanding of the critical care process and treatment while allowing experienced nurses more autonomy in judgment. Mechanical ventilator weaning protocols can decrease the duration of mechanical ventilation and increase nursing satisfaction which promotes a positive atmosphere in the ICU.
Patient and Family Education

Mechanical ventilation restricts communication of patients and their family as well as medical staff. Patients and families both have a need to understand and communicate with each other and the medical staff while receiving mechanical ventilator therapy. Patients believe that having their family present during weaning is important. Happ et al. (2007) conducted a study to assess the communication and interaction processes during weaning from mechanical ventilation between patients, their families and the health care team.

The setting was an urban, tertiary care medical ICU and step-down medical intensive care unit. Thirty patients with variations in age, gender, ethnicity, primary diagnosis and ability to wean were considered for inclusion. Thirty-one family members agreed to participate in interviews (Happ et al., 2007).

Direct observation of patients and their family members were conducted by a researcher. Families were observed for: (a) speech; (b) touch; (c) physical stance; (d) proximity to patient; (e) movement in the room; and (f) attention to the medical equipment being used was documented by either dictation or handwritten notes. Family members also underwent a 30 to 90 minute interview to assess their understanding of mechanical ventilation, weaning and their role at the bedside of the patient. Patients were given a 10 to 40 minute interview about their family members and what they believed to be helpful from their families during their time on mechanical ventilation. Medical staff was also interviewed about their opinions regarding family members being at bedside during the weaning process (Happ et al., 2007).
Happ et al. (2007) showed that family members were present at the bedside for some of the time (46%) during the weaning process. The results showed family member’s interacted with their loved ones through holding hands, stroking their hair or extremities, hugging, kissing, foot massage, adjusting their loved ones position and talking to their loved ones. Touch by family members seemed to be more beneficial to the family members than to the patient as noted by the observers. Talking seemed to be stressful to the family members but calming to the patients to hear their voices. Clinicians, who oversaw direct observation found that while having family present was calming and helpful to the patient, it was at times a hindrance to medical care. The researchers noted that the duration of mechanical ventilation was longer when family was present (p<.0001).

Findings from this study show that with proper coaching and guidance from nursing staff having family members at the bedside can be helpful to patients during weaning trials. A family-centered ICU benefits all parties: the patients, their families and the nursing staff of the ICU. Patients feel safe when they have their families near them and the families feel as if they are helping with their care (Happ et al., 2007).

Mechanical ventilation was a successful and established method of supporting the lungs during a critical illness. Increasing research indicated that mechanical ventilator weaning protocols can be used to successfully wean and extubate patients from mechanical ventilation with improved outcomes. There was evidence that indicated a shorter duration of mechanical ventilation with the use of weaning protocols. The purpose of this study was to evaluate a weaning protocols and effect on mechanical
ventilation duration and outcomes of patients from the ICU. Blackwood, Wilson-Barnett, Patterson, Trinder, and Lavery (2006) used a non-randomized trial with an intervention group and a non-intervention group.

The settings used for this study were two adult ICUs at two university-affiliated teaching hospitals. A total of 1745 patients were evaluated on both units. The study was separated into two parts for evaluation of weaning protocols and duration of mechanical ventilation. One assessment occurred before weaning protocols were implemented and the other after weaning protocols was implemented. All patients who were receiving mechanical ventilation and were over 18 years of age were considered eligible for the study. Demographic data obtained included age, gender, body mass index, diagnosis, admission Acute Physiological and Chronic Health Evaluation (APACHE) II score and mode of mechanical ventilation before the start of the weaning protocols (Blackwood, Wilson-Barnett, Patterson, Trinder, and Lavery, 2006).

Blackwood et al. (2006) used the Chi-squared test where appropriate with the qualitative variables. Chi-square tests are a valid and common way to test what is observed by researchers with what is expected to be found. Blackwood et al. used the Chi-square to analyze data observed in relation to duration of mechanical ventilation and the duration of stay in the ICU. APACHE II scores were also calculated on every patient who was a part of the study. APACHE II scores provides a severity of disease scoring system that is used with ICU patients with the higher the score indicating a more severe disease and a higher mortality rate.
Blackwood et al. (2006) found that in the control group where no weaning protocols were used to wean patients there were no significant differences noted in duration of mechanical ventilation or patient outcomes in either facility. After the introduction of weaning protocols to the intervention group, decreases were noted in duration of mechanical ventilation (33.3% or $p=0.001$); length of intubation ($p<0.001$) and length of ICU stay ($p<0.001$) while overall patient outcomes were improved. APACHE II scores were not considered to be relevant statistically after initiation of the study ($p=0.11$ to $p=0.06$).

Findings from this study showed that there was benefit from the use of weaning protocols with decreases evident in the duration of mechanical ventilation of duration of stay in the ICU. The study pointed out that in Phase I when no weaning protocol was used that there was no encouragement from nursing staff to initiate weaning unless directed to do so by the physicians in charge. Blackwood et al. (2006) noted that nurses are proactive in care of patients and any weaning protocol needs to have the support of nursing staff to be successful.

**Summary**

Mechanical ventilation is a complex life-saving form of treatment that requires specialized care. It can be costly to patients, their families and the health care team. Successful weaning from mechanical ventilation is associated with better patient outcomes and decreased overall costs of care. The implementation of weaning protocols can have a beneficial effect on the medical staff as well as the patients. Weaning protocols allow nurses to have a larger sense of direct involvement in patient care. These
protocols can be beneficial to new nurses who are still learning patient judgment and care as well as allowing experienced nurses to have more autonomy and feel as if they are contributing to the overall best practice patient care. Physicians need to be involved and allowed to have a voice in the conception and direction of any weaning protocol that is developed and integrated into daily care.

These types of studies are important to nursing. Nurses are understanding of the needs of the patients and how they are responding to treatments. Development of mechanical ventilator weaning protocols provides a uniform method of practice and offer great support to newer nurses. The literature review showed that the use of protocols reduce the length of duration of mechanical ventilation and its associated complications (Blackwood and Wilson-Barnett, 2007).

The literature review showed that weaning protocols worked best with a collaborative approach with physicians, nurses and respiratory therapists working together as a team. This was shown to have a better outcome as all members of the health care team felt a connection to the overall progress of the patient (Grapp et al, 2003)

The literature review also showed that patients and families want to participate in the care of the patient. The families want to know that they are helping the health care team to provide better outcomes for their loved ones. Taking time to educate the family and the patient on what to expect can help the patients and families feel safe and cared for during their stressful time (Happ et al., 2007, p. 55).
Chapter III

Methodology

Introduction

An important safety concern that the health care team of any critical care unit must address is the safe removal of a mechanical ventilator from a patient. Premature removal of the mechanical ventilator is associated with several risk factors including re-intubation. Prolonged intubation is associated with severe complications from ventilator associated pneumonia to death. The slow process of discontinuing the mechanical ventilator is known as weaning. Traditionally, the removal process of a mechanical ventilator is performed by a physician. Research has found that mechanical ventilator weaning protocols that are performed by a nurse and/or respiratory therapist decreases the duration of mechanical ventilation, length of hospitalization and mortality rates while providing positive patient outcomes. Nurses are the ambassadors of patient care due to the amount of time and care that nurses spend with patients on a daily basis. This study is a replication of the study conducted by McLean et al. (2006) to determine whether the use of a mechanical ventilator weaning protocol improves patient outcomes while decreasing the duration of mechanical ventilation and length of stay while in the Intensive Care Unit (ICU). This chapter presents the research questions, population, sample, setting, procedures and methodology utilized in this study.
Research Questions

1. Do mechanical ventilator weaning protocols decrease the duration of mechanical ventilation?

2. Do mechanical ventilator weaning protocols decrease the length of stay of a patient in the Intensive Care Unit?

3. Are patient outcomes improved with the use of mechanical ventilator weaning protocols?

Population, Sample and Setting

This study will be conducted at a hospital in the South Central portion of the United States of America. The population for this study will be drawn from the hospitals Cardiovascular Recovery Unit (CVRU) and the Intensive Care Unit (ICU). The sample will consist of approximately 71 nurses from the CVRU and ICU nursing units as well as 457 patients that agreed to participate.

Protection of Human Subjects

Prior to the initiation of this study, permission will be obtained from the Institutional Review Board of Ball State University and the Review Board of the participating hospital. Ethical standards will be maintained with the protection of human rights throughout this process.

Participant in the study will voluntary and have no relation to employment. Informed consent will be obtained and all participant data will be coded to assure confidentiality of participants. Additional explanations will be given in regards to no harm or potential risk of harm will be done, inherent provisions for confidentiality and
privacy will be maintained and the ability to withdraw from the study at any time. Fair and unbiased treatment as well as privacy and confidentiality of all subjects will be maintained at all times.

**Procedures**

Once approval is obtained from Ball State University’s Institutional Review Board, the participating hospital will be contacted and the proposed study will be explained. Once approval is received, then the researcher will meet with each of the nursing administrators, managers, clinical nurse specialists, nurse educators as well as the hospital ICU intensivists and pulmonologists for the critical care units. All pertinent information related to the study will be discussed and any questions proposed by participating hospital will be addressed fully and to the satisfactory of participating hospital.

All potential nurse participants will receive written and verbal explanation of the study during staff meetings, posted flyers and hospital emails. All nurses who are willing to voluntarily participate in the study will be asked to attend an educational seminar on the mechanical ventilator weaning protocol and how to use it. Several seminars will be set up so that all nurses willing to participate have ample opportunity to attend a session. During the educational seminars, a researcher will discuss the nurses’ role and responsibility, what will be expected of them should they participate as well as answer any questions that the participating staff members may have. The roles and responsibilities of fellow medical colleagues as well as patients and their families will also be discussed. Before the start of the weaning protocol study, a survey will be
conducted by Key Survey, which is an independent survey company that will assure anonymity and confidentiality of the responses for all participants. The survey will be given out during the educational seminars and will consist of 10 questions regarding patient safety, understanding of mechanical ventilator weaning protocols and demographic data of the nurses. Data from the study will be maintained at an off-site secure storage terminal for a minimum of 2-years. All electronic data will be destroyed at that time by magnetic degaussing, a technique that alters the way data align in the magnetic storage field and renders the previous data unrecoverable and impossible to reconstruct.

Once the study is active, a researcher will be present during the assessment and spontaneous breathing trial portions of the weaning protocols for the first week to answer any questions that the nurse participants or families have. After the first week of protocol initiation, a researcher will always be available by phone for any questions as well as periodically assess the patients’ inclusion or exclusion from the study. Periodically throughout the six-month study period, a researcher will gather all data and begin the evaluation process. A researcher will present and update the nurses and physicians approximately every 100 patients with findings of the protocol.

Once results are obtained and reviewed, the researcher will meet with the nurse educators of the critical care units to discuss the results. The researcher will then design an educational program for use on the hospital education website for dissemination of results. A meeting will then be scheduled with the hospital ICU intensivists and pulmonologists to discuss the findings of the study. At the end of the survey, the original
A 10-item survey will then be sent to all nursing participants to re-assess the understanding and knowledge of patient safety and the weaning process.

**Design**

This study will utilize a prospective comparative design with before and after implementing the mechanical ventilator weaning protocol. Demographic data of age, sex, smoking history and admission diagnosis will also be gathered.

**Instrumentation**

A chart review will be performed on every study subject to gather demographic data which will include: age, sex, smoking history and admission diagnosis. A data collection flow sheet will be used by the researcher to collect all weaning protocol information on all patients. The data collection flow sheet will consist of: (a) what is the critical care day; (b) what is the mechanical ventilation day; (c) did the patient meet weaning criteria; (c-1) if no then what was the reason weaning criteria was not meet; (d) did the patient pass an SBT; (d-1) if SBT was not passed what occurred; (e) was the patient extubated; and (f) when did the patient leave ICU. The data collection flow sheet will be compiled and coded while being maintained on an encrypted computer by the researcher.

**Intended Method for Data Analysis**

Data analysis will be performed by descriptive statistics. Comparison of scores from before and after implementation of mechanical ventilator weaning protocols will be done using the $t$-test. The level of significance will be $p \leq .05$. All survey responses from the participating nurses will be categorized and summarized.
Summary

This study replicates McLean et al.’s (2006) study and will seek to determine whether the use of a mechanical ventilator weaning protocol improves patient outcomes while decreasing the duration of mechanical ventilation and length of stay while in the Intensive Care Unit (ICU). This study is a descriptive comparison study design with additional anecdotal data. Data will be collected from 71 nurses and 457 patients. The findings generated from this study will expand the information regarding the use of mechanical ventilator weaning protocols and enhance the knowledge and assessment skills of staff nurses.
References


