

Fall 12-11-2015

In the Surgical Patient Requiring Neuromuscular Blockade, Is There an Increased Incidence of Postoperative Adverse Respiratory Events with Rocuronium or Vecuronium?

Martha Claudine Boos
University of Southern Mississippi

Follow this and additional works at: https://aquila.usm.edu/dnp_capstone

 Part of the [Perioperative, Operating Room and Surgical Nursing Commons](#)

Recommended Citation

Boos, Martha Claudine, "In the Surgical Patient Requiring Neuromuscular Blockade, Is There an Increased Incidence of Postoperative Adverse Respiratory Events with Rocuronium or Vecuronium?" (2015). *Doctoral Projects*. 8.
https://aquila.usm.edu/dnp_capstone/8

This Doctoral Nursing Capstone Project is brought to you for free and open access by The Aquila Digital Community. It has been accepted for inclusion in Doctoral Projects by an authorized administrator of The Aquila Digital Community. For more information, please contact Joshua.Cromwell@usm.edu.

The University of Southern Mississippi

IN THE SURGICAL PATIENT REQUIRING NEUROMUSCULAR BLOCKADE, IS
THERE AN INCREASED INCIDENCE OF POSTOPERATIVE ADVERSE
RESPIRATORY EVENTS WITH ROCURONIUM OR VECURONIUM?

by

Martha Claudine Boos

Abstract of a Capstone Project
Submitted to the Graduate School
of the University of Southern Mississippi
in Partial Fulfillment of the Requirements
for the Degree of Doctor of Nursing Practice

December 2015

ABSTRACT

IN THE SURGICAL PATIENT REQUIRING NEUROMUSCULAR BLOCKADE, IS THERE AN INCREASED INCIDENCE OF POSTOPERATIVE ADVERSE RESPIRATORY EVENTS WITH ROCURONIUM OR VECURONIUM?

by Martha Claudine Boos

December 2015

It is estimated that up to 45% of surgical patients will have postoperative residual neuromuscular blockade (NMB) upon arrival to the postanesthesia care unit (PACU), and incomplete recovery can impair upper airway function and contribute to adverse respiratory events (Nagelhout & Plaus, 2014). This retrospective cohort study examined whether there was an increased incidence of postoperative adverse respiratory events with the neuromuscular blocking agents Rocuronium or Vecuronium. Inclusion criteria included any surgical patient aged 18-65, receiving NMB agents Rocuronium or Vecuronium during the procedure. Exclusion criteria included any surgical patient aged 18-65 with ASA classification > 4 , any emergent cases, any patient with documented neuromuscular disorder or history of prolonged intubation, and patients arriving intubated preoperatively. A Pearson Chi-Square test statistic was used to evaluate whether the patients receiving Rocuronium experienced a greater increase in post-operative adverse respiratory events compared with the patients whom received Vecuronium.

COPYRIGHT BY
MARTHA CLAUDINE BOOS
2015

IN THE SURGICAL PATIENT REQUIRING NEUROMUSCULAR BLOCKADE, IS
THERE AN INCREASED INCIDENCE OF POSTOPERATIVE ADVERSE
RESPIRATORY EVENTS WITH ROCURONIUM OR VECURONIUM?

by

Martha Claudine Boos

A Capstone Project
Submitted to the Graduate School
and the Department of Advanced Practice
at the University of Southern Mississippi
in Partial Fulfillment of the Requirements
for the Degree of Doctor of Nursing Practice

Approved:

Dr. Vickie L. Stuart, Committee Chair
Assistant Professor, Advanced Practice

Dr. Michong K. Rayborn, Committee Member
Assistant Professor, Advanced Practice

Dr. Joe Campbell, Committee Member
Professor, University of Mississippi Medical Center

Dr. Karen S. Coats
Dean of Graduate School

December 2015

DEDICATION

I would like to take the opportunity to thank my husband, my children, my parents, and my friends whom have supported me throughout the process of obtaining my Doctor of Nursing Practice degree. Thank you for your love and, especially for your patience.

In addition, I would like to dedicate this work to my Lord and Savior through whom all things are possible.

ACKNOWLEDGMENTS

I would like to offer a special thanks to Dr. Vickie Stuart, my committee chair, and to my other committee members, Dr. Joe Campbell and Dr. Michong Rayborn, for their support and guidance throughout this capstone project.

I would also like to thank Dr. James T. Johnson, Director and Research Consultant at The University of Southern Mississippi, and Dr. Hwanseok Choi, Assistant Professor, Department of Public Health at The University of Southern Mississippi, for their assistance in compiling the statistical data.

TABLE OF CONTENTS

ABSTRACT	ii
DEDICATION	iii
ACKNOWLEDGMENTS	iv
LIST OF TABLES	vii
LIST OF ABBREVIATIONS.....	viii
CHAPTER	
I. INTRODUCTION	1
Statement of the Problem	
Conceptual and Theoretical Framework	
Needs Assessment	
Significance and Implications	
Review of Literature	
II. METHODOLOGY	20
Setting	
Target Outcome	
Barriers	
Populations	
Sampling	
Research Strategies	
Methods	
Measurement Method	
III. ANALYSIS OF DATA	29
Statistical Analysis	
Presentation of Findings	
White Paper Change Proposal	
IV. SUMMARY	40
Summary of Findings	
Recommendations	
Conclusion	

APPENDICES	42
REFERENCES	45

LISTS OF TABLES

Table

1.	Demographic Characteristics of All Patients.....	31
2.	Demographic Characteristics of Those Whom Experienced Adverse Event	32
3.	Adverse Event and Paralytic Crosstabulation.....	34
4.	Pearson Chi-Square test table for Adverse Event and Paralytic	35
5.	Reversal and Adverse Event Crosstabulation	36
6.	Pearson Chi-Square test table for Reversal and Adverse Event	37
7.	TOF and Adverse Event Crosstabulation	38
8.	Pearson Chi-Square test table for TOF and Adverse Event.....	38

LIST OF ABBREVIATIONS

<i>AAAA</i>	American Academy of Anesthesiologist Assistant
<i>AANA</i>	American Association of Nurse Anesthetists
<i>AHRQ</i>	Agency for Healthcare Research and Quality
<i>ASA</i>	American Society of Anesthesiologists
<i>BMI</i>	Body Mass Index
<i>CDC</i>	Centers of Disease Control
<i>COPD</i>	Chronic Obstructive Pulmonary Disease
<i>CRNA</i>	Certified Registered Nurse of Anesthesia
<i>DNP</i>	Doctor of Nurse Practice
<i>EPIC</i>	Electronic Patient Integrated Care
<i>ICU</i>	Intensive Care Unit
<i>NMB</i>	Neuromuscular blockade
<i>OR</i>	Operating Room
<i>PACU</i>	Postanesthesia Care Unit
<i>SPSS</i>	Statistical Package for the Social Sciences
<i>TOF</i>	Train-of-four

CHAPTER I

INTRODUCTION

Statement of the Problem

General anesthesia is the act of rendering a patient unconscious and unresponsive to painful stimuli, and in some general anesthesia cases, the usage of a NMB is also required. Their action is to block acetylcholine from activating nicotinic receptors on skeletal muscles, and acetylcholine is the neurotransmitter responsible for muscle contraction (Guyton & Hall, 2011). Therefore, NMB agents produce muscle relaxation that facilitate tracheal intubation and optimize the surgical field. However, with the use of these agents, residual neuromuscular blockade can occur which can impair upper airway function contributing to adverse respiratory events in the postanesthesia care unit (PACU). Given that postoperative NMB is a potentially preventable incident, it is important to find ways to prevent this patient safety problem from occurring.

Clinical Question

In the surgical patient requiring neuromuscular blockage, is there an increased incidence of adverse respiratory events with the usage of the intermediate acting agent Rocuronium or Vecuronium? Confounding variables such as length of procedure, age, gender, comorbidities, dosages of neuromuscular blocking agent administered, train-of-four (TOF) testing,

inhalation agent utilized, and if a reversal agent was administered, were examined.

Problem Statement

Each year approximately 74 million individuals will undergo surgery, and of these, approximately 60% will receive general anesthesia and some form of a neuromuscular blockade agent (Advisory Board Company, 2014; CDC, 2014). It is estimated that up to 45% of patients will have postoperative residual neuromuscular blockade upon arrival to the postanesthesia care unit (Nagelhout & Plaus, 2014). This incomplete recovery of neuromuscular function can impair upper airway function and contribute to adverse respiratory events. In the United States, up to 3% of these patients with residual neuromuscular blockade will experience clinically evident events such as serious respiratory complications, and these events are associated with increase in morbidity and mortality (Nagelhout, 2013). Furthermore, according to the Agency for Healthcare Research and Quality (AHRQ), these adverse events and other adverse medical events cost the United States in excess of 19.5 billion dollars annually (AHRQ, 2011).

Purpose of the Project

The purpose of this capstone project was to determine if surgical patients receiving Rocuronium or Vecuronium are at a greater risk of experiencing an adverse respiratory event. Variables, such as length of procedure, age, gender, comorbidities, dosages of neuromuscular blocking agent administered, train-of-

four (TOF) testing, and if a reversal agent was administered, were all addressed. Results were disseminated, and a white paper change proposal was shared with the identified key stakeholders in an effort to reduce future incidence of adverse respiratory events associated with residual neuromuscular blockade in the postoperative patient.

Conceptual and Theoretical Framework

Integrating nursing theory into practice provides the foundation for which nurses pursue understanding of patients and their health concerns. Therefore, the purpose of nursing theories is to guide the care and improve patient outcomes. In exploring the many nursing theories that could apply to this capstone project, the Neuman's systems model theory was identified. The Neuman's systems theory is a systems-based guide that focuses on person, environment, health, and nursing (Whetsell, Gonzalez, & Moreno-Fergusson, 2011). The theory involves patient processes and outcomes, and is based on the client's perception, reaction, and resolution to stress. The three main concepts of Neuman's systems theory include stress, homeostasis, and patient perception. The theory is based on wholism, with a focus on stress and systematic feedback loops, and takes into account all the variables that can affect a patient's response to stress (Neuman, 1995). Furthermore, "Neuman considered all variables affecting a client's response to environmental stressors and explains that knowing something about one part of a

system enables us to know something about another part” (Whetsell et al., 2011, p. 431).

The Neuman’s model focused on three types of prevention that help promote wellness. The three types of prevention include primary, secondary, and tertiary. According to Zaccagnini and White (2014), primary prevention involves identifying stressors before the patient encounters the stressor; secondary prevention involves assisting the patient to overcome the stressor once it has occurred; and tertiary prevention involves focusing on maintaining wellness after the patient has encountered a stressor. Lastly, the Neuman’s systems theory envelops a total person approach by evaluating the environment and understanding how the environment affects the patient.

In the field of anesthesia, the Neuman’s systems theory can be applied in several aspects of nursing care. The bulk of interventions carried out by the anesthesia providers are aimed at decreasing physical and emotional stress. As stated before, the Neuman’s theory focuses on stress and the variables that affect the client’s response to that stress. Therefore, in performing a pre-anesthetic evaluation, factors that can influence the perceptions of the client can be identified. These factors, or variables, can be taken into account while developing an anesthetic plan for that patient. Striving to maintain the normal line of defense by blocking those identified stressors can help the anesthesia provider maintain a homeostatic environment for the patient. From the initial preoperative evaluation,

through the administration of agents such as anxiolytics, vagolytics, and anesthetics, to the postoperative examination, these actions can be performed in an attempt to maintain homeostasis (Martin, 1996). All of these actions or interventions are aspects of applying Neuman's systems theory into the advanced nursing practice of anesthesia.

The area of interest for this study involved comparing the incidence of postoperative adverse respiratory events in patients receiving Rocuronium versus Vecuronium for neuromuscular blockage during surgery. Adverse respiratory events can include hypoxia, delayed extubation, or a patient requiring reintubation after a surgical procedure. For this capstone, a retrospective analysis was performed. Variables such as gender, age, American Society of Anesthesiologists (ASA) classification, type of surgery, length of surgery, number of doses of each medication (total dose administered), reversal (full, partial, or none), train-of-four documentation, temperature, body mass index (BMI), comorbidities, reintubation rate percentage for each NMB agent, length in PACU, inhalation agent used, and disposition (discharged home, transferred to ICU, expired) were identified and analyzed to consider their affects upon systems. Furthermore, this capstone utilized the Neuman's theory by evaluating the anesthetic process and outcomes of the patients included within the analysis of data.

Needs Assessment

Thousands of surgeries are performed every day in the U.S., with the majority of these being done as ambulatory procedures. Advances in medical technology and improvements in anesthesia now allow patients to regain consciousness quicker and return home faster without complications. While most patients will not experience an adverse event, a few will experience complications.

Several preexisting factors are known to increase the risk of postoperative pulmonary complications associated with residual neuromuscular blockade. These factors include renal impairment, liver impairment, preexisting lung disease such as chronic obstructive pulmonary disease, asthma, or emphysema, poor health, obesity, and smoking (Yoder & Sharma, 2011). Fluid and electrolyte imbalances, hypothermia, drug interactions, neurological and muscular diseases, and genetics may affect the patients' ability to overcome the effects of residual muscular paralysis (Wilson, Collins, & Rowan, 2012). Other factors include advanced age and male gender. Abdominal or orthopedic surgeries and the length of the surgery have been shown to increase the risk of residual paralysis. Finally, the anesthetic variables that potentiate adverse effects include the usage of neuromuscular blockage agents, opioids, and general anesthesia (Murphy et al., 2008).

The patient with the greatest risk of an adverse respiratory event associated with residual neuromuscular blockade would include those with a history of Chronic Obstructive Pulmonary Disease (COPD) and smoking. COPD is the third leading cause of death in the United States, and 90% of the diagnoses cases are individuals over the age of forty-five (American Lung Association, 2011). Therefore, this disease can pose a major risk for those undergoing any procedure, especially one requiring general anesthesia.

Obesity and a history of apnea are also syndemically associated. Increased fat deposition in the pharynx can cause compression and obstruction to the airway tract. Therefore, if residual paralysis is allowed to occur, this can potentially increase the risk of the patient requiring reintubation due to airway obstruction. Finally, renal and liver impairment can prolong the effects of neuromuscular blockade. The kidneys and/or the liver metabolize all anesthetic, analgesic, opioid, and muscle relaxant drugs. Therefore, if a patient has liver or renal disease, this can and will prolong the effects of all medications (Morgan, Mikhail, & Murray, 2007). In reviewing the factors that increase the risk of residual neuromuscular blockade, all are noted components associated with the majority of patients whom receive care at the facility of choice.

Determining which nondepolarizing agent has a higher incidence of residual neuromuscular blockade resulting in adverse respiratory events will be a great strength and benefit to the identified key stakeholders at the hospital.

However, one weakness of the project could involve anesthesia providers feeling threatened by the review of patient data in regards to the anesthesia technique utilized and outcome results. The opportunity of completing the outcome analysis of the capstone will reveal and answer the question if Rocuronium is associated with an increase in adverse respiratory events in surgical patients requiring neuromuscular blockade during surgery. Thus results will determine possible change in practice. A threat to the project may involve the data revealing that no significant difference in outcomes with the usage of Rocuronium over Vecuronium, but that the incidence may be related to other variables not within the provider's control.

Significance and Implications

The significance of this capstone was to determine if there is an increased incidence of adverse respiratory events with Rocuronium versus Vecuronium. If there is an increased incidence of adverse respiratory events with Rocuronium over Vecuronium, then those results will be disseminated to the anesthesia department in a white paper proposal with the aim to improve future surgical outcomes. In addition, each variable was evaluated in an effort to determine if practice changes should occur to improve the possibility of an adverse event. As stated before, according to the Agency for Healthcare Research & Quality, these adverse events and other adverse medical events cost the United States in excess of 19.5 billion dollars annually (AHRQ, 2011). Furthermore, according to Zhang

et al. (2009), these adverse events can extend OR time contributing to high cost utilization.

If this capstone demonstrates to provide statistically significant information, a pilot study could be performed. The recommendations made with the white paper proposal could be tested to verify feasibility and accuracy of the proposed changes. According to Gearing, Mian, Barber, and Ickowicz (2006), a pilot study is basically a small version of a proposed research plan that can offer researchers valuable information. If that data suggests that Rocuronium has a greater incidence of adverse respiratory events, this information could guide the anesthesia provider in the future in an effort to improve patient outcomes.

Review of Literature

Each year approximately 70 million individuals will undergo surgery, and of these, approximately 60% will receive general anesthesia and some form of a neuromuscular blockade agent (Advisory Board Company, 2014; CDC, 2014). In fact, it is estimated that approximately 45% of postoperative patients will have residual neuromuscular blockade upon arrival to the recovery room (Nagelhout & Plaus, 2014). However, approximately 90% of United States anesthesia providers and 80% of European anesthesia providers say they have never encountered this issue (Murphy, 2012). It is believed this discrepancy is due to the providers not recognizing the signs and symptoms of residual paralysis, and choosing to relate the adverse events to obesity or some other probable comorbidity issue. In

addition, 6 out of every 10 surgeries will be performed as a same-day operative procedure, and one may think there are minimal risks associated with such procedures. However, approximately 100,000 individuals will experience adverse respiratory events related to residual neuromuscular blockade (Marcus, 2012).

General anesthesia is the act of producing unconsciousness and unresponsiveness to all painful stimuli, and in some general anesthesia cases, the usage of a muscle relaxant or neuromuscular blockade agent is also required (Lehne, 2004). Nondepolarizing neuromuscular blocking agents are used to prevent undesired patient movement during some surgical procedures. Their action is to block acetylcholine, which is responsible for muscle contraction, from activating nicotinic receptors on skeletal muscles (Guyton & Hall, 2011). NMB produces muscle relaxation to assist the surgeon in procedures that require complete relaxation such as in abdominal cases. However, with the use of these agents, risks are involved if not monitored closely by the anesthesia provider. Lastly, as stated before, several adverse effects are associated with the use of neuromuscular blockade agents such as respiratory depression, aspiration, airway obstruction, and muscle weakness (Wilson et al., 2012).

Residual neuromuscular blockade is not a new phenomenon. In fact, over 60 years ago, Dr. Henry Knowles Beecher and Dr. Donald Todd published a study in the *Annals of Surgery* regarding this issue. Their study involved ten hospitals and 599,548 anesthetic procedures administered between 1948 and 1952 (Beecher

& Todd, 1954). According to their study, patients administered a neuromuscular blockade agent had a six-fold increase in mortality than patients not administered a neuromuscular blockade agent (Beecher & Todd, 1954). Most of the causes of death were related to patient disease process, surgical management, anesthetic management, and adverse respiratory events. In the 1970s, studies were performed by Viby-Mogensen, and they concluded approximately 42% of patients had residual paralysis upon arrival to the recovery unit (Murphy, 2012). In the 1980s, studies concluded 21% to 36% had residual from the neuromuscular blockade agent, and in the mid 2000s, several compiled studies revealed residual in as high as 65% of the patients (Murphy, 2012). Many studies over the last 20 years have involved healthy subjects whom volunteered to undergo procedures with neuromuscular blockage agents. The end results concluded that there were two main adverse events associated with residual neuromuscular blockade. Those adverse events included airway obstruction and extreme muscle weakness. With this investigation, it also concluded that 33% reported upper airway obstruction, and over half complained of the impaired ability to swallow (Murphy, 2012). However, the relevant question is whether the problem exists in anesthesia today?

Currently, as many as 100,000 patients experience some form of an adverse respiratory event after surgery linked to residual neuromuscular blockade agents. This accounts annually for approximately 0.8% of the patients, with 0.1% of the patients requiring reintubation due to the residual respiratory paralysis

(Marcus, 2012). Recently, in a study conducted by Murphy and colleagues, data were collected over a one-year period on 7,459 patients whom received general anesthesia. Of those, approximately 0.8% demonstrated residual neuromuscular blockade and suffered a critical respiratory event (Murphy et al., 2008). The study suggested that incomplete recovery from neuromuscular blockade is an important contributing factor in postoperative adverse respiratory events.

Potential Legal Implications of an Adverse Event

According to the Agency for Healthcare Research and Quality (AHRQ), these adverse events and other adverse medical events cost the United States in excess of 19.5 billion dollars a year (AHRQ, 2011). However, this is not just an U.S. issue, it occurs globally. In fact, to help decrease the incidence, the Association of Anaesthetists of Great Britain and Ireland require nerve stimulators be available whenever a neuromuscular blockade agent is administered during surgery and must be available in the recovery unit (Marcus, 2012). One study conducted in the Netherlands involved approximately 870,000 patients. The investigation determined that poor management of neuromuscular blockade agents was the most significant factor for death or coma. The study also concluded that usage of reversal agents reduced the mortality rates by 90%, compared to not using reversal agents. Lastly, a study conducted in South Africa involving over 240,000 patients concluded that respiratory failure related to residual paralysis was the second leading cause of death attributed to anesthesia,

following hypovolemia which was the leading cause of death (Murphy, 2012). As one can conclude, this is a global issue that requires further investigation and review of standards.

A literature review conducted by MacRae (2007) involving 7,117 closed anesthesia claims revealed lack of vigilance is believed to be the leading cause of all adverse events. In fact, despite the fact that airway management is considered the anesthesia provider's area of expertise, difficulty in managing the airway is the leading cause of morbidity and mortality for anesthesia. According to MacRae (2007), results from the closed claims studies in anesthesia revealed that approximately 45% of the cases were related to respiratory events, 31-32 % to death or brain damage, 25% to a cardiovascular event, and approximately 21% to nerve injury. Anesthesia providers must be aware that the median cost of a malpractice suit is approximately \$300,000 (Bishop, Ryan, & Cassalino, 2011). Therefore, it is important to identify and examine preventive measures that could decrease this incidence.

Current Recommended Prevention Measures

There are several recommended measures all anesthesia providers can perform to potentially decrease the incidence of residual neuromuscular blockade. On December of 2012, the Anesthesia Patient Safety Foundation (APSF) sponsored a panel titled, "Residual Muscle Relaxant Induced Weakness in the Postoperative Period: Is It a Patient Safety Issue?" According to Morell (2013),

the panel of experts agreed that routine monitoring of neuromuscular blockade should be performed routinely and a train-of-four (TOF) ratio of >0.9 is an appropriate goal. The panel of experts concluded that lesser TOF ratios could increase the potential for adverse events, both short-term and long-term (Morell, 2013). According to Stoelting (2014), following the APSF meeting, a survey was conducted using random sampling of 25% of the active members (21,482), and resulted with 90% of respondents agreeing that there is a need for routine intraoperative monitoring of neuromuscular blockade. Furthermore, the survey results also overwhelmingly recommended the APSF should encourage the American Society of Anesthesiologists (ASA), American Association of Nurse Anesthetists (AANA), and American Academy of Anesthesiologist Assistant (AAAA) to adopt monitoring neuromuscular function as part of their standards of care.

According to Foster and Callahan (2011), “standards are rules or minimum requirements that describe specific responsibilities and principles of patient care and define the expectations against which professional performance can be measured” (p. 157). Since that time, the AANA, ASA, and AAA have adopted such a standard or recommendation. According to the AANA Standards for Nurse Anesthesia Practice (2013), “when neuromuscular blocking agents are administered, monitor neuromuscular response to assess depth of blockade and degree of recovery” (p. 2). Therefore, to adequately monitor the depth of

blockade and degree of recovery, the anesthesia provider must utilize certain techniques such as physical assessment and the use of a peripheral nerve stimulator.

The peripheral nerve stimulator is a device that verifies the TOF responses. The TOF is a series of four minimal shocks that are applied to a peripheral nerve such as the facial nerve. The anesthesia provider will count the number of twitches elicited from the 4 shocks. If 4 twitches are observed, this could indicate that approximately 0-75% of the receptors are still blocked. Three twitches indicate approximately 75% are blocked. Two twitches could mean approximately 80% are blocked, and no twitches would indicate 100% blockage (Saenz, 2011).

The percentage of blockage is directly related to the amount of muscle relaxant or paralysis (Nagelhout & Plaus, 2014). The anesthesia provider will observe for a fade. A fade is a decreasing in amplitude noted with the twitches, and this result is directly related to the amount of paralysis present from the neuromuscular agent. Therefore, as a primary prevention, the anesthesia provider should utilize the TOF when monitoring the patient to determine readiness for extubation at the end of the procedure. However, not all anesthesia providers utilize the TOF monitoring device. In fact, it is estimated only 22% of the practitioners in the U.S., and only 70% of the European anesthesia providers report using this TOF device (Donati, 2010).

Another recommended prevention measure is routine pharmacologic reversal of a nondepolarizing neuromuscular blockade (Miller & Ward, 2010). After an extensive review, Miller and Ward (2010) stated their opinion as, “these databases and our own review of many cases of adverse outcomes has led to the conclusion that reversal of NMB with neostigmine should be routine. Conversely, there should be written documentation as to why neostigmine was unnecessary” (p. 2). According to the Neostigmine package insert, Neostigmine inhibits the hydrolysis of acetylcholine by directly competing with acetylcholine for cholinergic receptor sites, has a half life of 24 – 113 minutes, should be administered slowly over at least one minute, and takes a minimum of 10 minutes to achieve a TOF of 90% reversal (Eclat Pharmaceuticals, 2014). As acetylcholine levels build, a return of muscle contraction begins thereby reversing the effects of the NMB. According to Nagelhout (2013), the recommended protocol is to have a minimum of 2 twitches from a TOF when neostigmine is administered. Lastly, according to Eclat Pharmaceuticals (2014), since Neostigmine has a direct postsynaptic cholinergic effect, these effects can be managed by administration of glycopyrrolate or atropine in a separate syringe prior to Neostigmine administration.

One retrospective cohort study concluded that patients whom received a reversal agent were associated with a reduction of elapse operating room (OR) or PACU time (Zhang, et al., 2009). The retrospective study involved reviewing

9670 elective surgeries performed under general anesthesia and using one or more neuromuscular blocking agents. The study concluded that utilizing a reversal agent may lead to more efficient OR resources since the reversal agent was shown to reduce OR time 12 to 46 minutes in the majority of the surgical cases (Zhang et al., 2009). Brull, Kopman, and Naguib (2013), reported successful antagonism is enhanced when the antagonist such as neostigmine is administered 15 to 20 minutes before tracheal extubation and when there is a TOF of 4 twitches. However, routine reversal is not a common practice. In fact, only 34% of clinicians in the United States and 18% of anesthesia providers from Europe report routine usage (Nagelhout, 2013). In a survey conducted involving 108 clinical anesthesiologists, the decision to reverse a neuromuscular blocking agent was based on the pharmacological knowledge of the medication and on personal judgment of patient breathing (Videira & Vieira, 2011). According to Videira and Vieira (2011), “clinicians judge themselves as better skilled at avoiding residual block than they do their colleagues, making them overconfident in their capacity to estimate the duration of action of intermediate-acting NMBD” (p. 1192).

Comparison of Rocuronium and Vecuronium

Rocuronium and Vecuronium are two nondepolarizing relaxants with similar efficacy. Rocuronium is usually the drug of choice on induction and is widely used when succinylcholine, a depolarizing relaxant, is contraindicated. Rocuronium has a faster onset of 45 to 90 seconds, duration of 30 to 60 minutes,

undergoes both hepatic and renal elimination, and has an elimination half-life of 60 to 120 minutes (Nagelhout & Plaus, 2014). In comparison, Vecuronium is also an intermediate acting nondepolarizing agent with an onset of 3.1 minutes, duration of 30 to 45 minutes, undergoes hepatic and renal elimination, and has an elimination half-life of 51 to 91 minutes (Nagelhout & Plaus, 2014). In addition, reversal of the effects of these nondepolarizing relaxants requires time or the usage of an anticholinesterase agent.

Several studies have evaluated the incidence and duration of postoperative residual neuromuscular blockade between Vecuronium, Rocuronium, and other non-depolarizing muscle relaxants. One such study conducted by Khan, Divatia, and Sareen (2006), concluded that residual neuromuscular blockade was significantly higher with Rocuronium at 37% compared to 17% with Vecuronium. In another study involving 60 patients, 20 received Rocuronium, 20 received Vecuronium, and the other 20 received Cisatracurium. The results concluded that intubation times were shorter in those receiving Rocuronium, recovery time was faster with Cisatracurium, and TOF was significantly longer with Rocuronium (Sagir et al., 2013). Several studies revealed patients could experience residual paralysis for several hours after neuromuscular blockade administration.

One such study involved 526 patients whom received a single intubating dose of Rocuronium, Vecuronium, or Atracurium and did not receive a reversal agent. The TOF ratio was measured upon admission into the PACU, and the

study concluded that residual paralysis is common even more than 2 hours after administration of an intubating dose of an intermediate acting muscle relaxant (Debaenne, Plaud, Dilly, & Donati, 2003). In a case report involving an 84 year-old female undergoing elective hysterectomy and receiving a one-time intubating dose of Rocuronium, the study revealed that it might take more than 3.5 hours before it is possible to antagonize a block (Claudius, Karacan, & Viby-Mogensen, 2007). Therefore, one may conclude from these studies, when deciding which intermediate-acting non-depolarizing muscle relaxant to utilize, Vecuronium may be the more reliable choice. However, further studies may be beneficial.

CHAPTER II

METHODOLOGY

The purpose of this capstone project was to determine if surgical patients receiving Rocuronium or Vecuronium are at a greater risk of experiencing an adverse respiratory event. The methodology of this capstone will follow this order: 1) Setting, 2) Target Outcomes, 3) Barriers, 4) Populations, 5) Sampling, 6) Research Strategies, 7) Methods, and 8) Measurement Methods.

Setting

The capstone setting for this retrospective analysis took place at a level II regional trauma center located in Hattiesburg, Mississippi. It is a 512-bed facility offering services to the surrounding 19 counties, performing over 7000 inpatient and 9900 outpatient procedures each year (Forrest General Hospital, 2014). In 2013, the hospital successfully installed the Electronic Patient Integrated Care (EPIC) system. Therefore, this hospital provided an excellent setting to perform the retrospective analysis.

Target Outcome

The desired goal for this capstone was to determine if surgical patients requiring neuromuscular blocking agents are at a greater risk of experiencing an adverse respiratory event with the intermediate acting agents Rocuronium or Vecuronium. The desired outcome of the project was to develop a practice change policy based upon the results in an effort to improve patient safety. The

results of the retrospective review were shared with the identified key stakeholders in an effort to further reduce future incidence of adverse respiratory events associated with residual neuromuscular blockade in the postoperative patient.

Barriers

Some barriers this project encountered included time constraints, a limited number of providers whom utilize Vecuronium as the neuromuscular blocking agent of choice upon induction of anesthesia, the inability to discover an existing data abstraction tool specific to this capstone project, and the limited number of cases in which anesthesia providers re-dose paralytics.

Populations

A total of 50 subjects, 25 in each group, whom received either Rocuronium or Vecuronium, were chosen for the retrospective analysis. The inclusion population included any surgical patient ages 18-65 whom either received an intubating dose or where re-dosed with the NMB agents Rocuronium or Vecuronium during the procedure. Exclusion criteria included any surgical patient ages 18-65 with ASA classification > 4 , any emergent cases, any patient whom only received a defacilitating dose of Rocuronium or Vecuronium, any patient with documented neuromuscular disorder or history of prolonged intubation, and patients arriving intubated preoperatively.

Sampling

Since every retrospective chart review requires a statistical power analysis, one was completed to determine the appropriate sample size. In addition, convenience sampling, which is the most common method, was utilized. With convenience sampling, the subjects included in the study are used because they “happened to be in the right place at the right time” (Grove, Burns, & Gray, 2013, p. 363). Of course, with this sampling, the researcher continued to enter subjects into the study until the desired sample size was obtained.

To prevent bias during sampling and collection of data, the investigator employed a specific procedure of review. First, each time the investigator audited charts, a different month of surgical cases were reviewed. Upon entering the health record for the first case, the gender was obtained and then the age. If the patient was under the age of 18 or over the age of 65, the audit ceased. Next, the ASA was viewed. If the ASA was greater than 4 or classified as an emergent case, the audit ceased. If criteria were found appropriate, comorbidities, the inhalation agent used, temperature, and BMI were recorded. Then the paralytic agent was reviewed. If the patient was not intubated with the paralytic Rocuronium or Vecuronium, or was not re-dosed with one of these agents, the audit of this chart ceased. If criteria were found appropriate to this point, the total doses of Rocuronium or Vecuronium, reversal, TOF, and all other variables found on the data abstraction tool were recorded. Next, the investigator reviewed the

first vital signs recorded in the PACU area after surgery. If an adverse respiratory event was noted, the data received a yes in the adverse event category. If not, a no was recorded. Data were collected until minimum of 25 charts were audited of patients whom had received Rocuronium and 25 whom had received Vecuronium. Lastly, to prevent bias, the investigator only included the data of the first 25 whom received Rocuronium regardless of the outcomes, and the first 25 of those whom received Vecuronium, regardless of if an adverse event occurred.

Research Strategies

To explore the capstone question in the surgical patient requiring neuromuscular blockade, is there an increased incidence of postoperative adverse respiratory events with Rocuronium or Vecuronium a retrospective cohort study was completed. A retrospective cohort study is a study in which the researcher identifies a group of people (Rocuronium versus Vecuronium recipients) who have experienced a particular event (adverse respiratory event). Therefore, a retrospective analysis of de-identified electronic health record data was performed. Inclusion criteria included all surgical patients whom received NMB of Rocuronium or Vecuronium during the procedure. Exclusion criteria included any surgical patient with ASA classification > 4 , any emergent cases, any patient with documented neuromuscular disorder or history or prolonged intubation, and patients arriving to OR previously intubated.

The study involved the collection of existing data from the electronic medical record, and not any experimental procedures. Confidentiality of records was maintained throughout the collection of data from the electronic health record. The investigator in such a manner recorded all information that subjects cannot be identified, directly or indirectly.

After data was analyzed, results were shared with key identified stakeholders, and a white paper proposal was formulated. According to the AANA (2014), a white paper is “complete descriptions of a particular concept, position or solution to a problem, from overview to detailed facts, created to promote professionalism and advocacy. Intended to guide decision-makers on policy development” (p. 2). Therefore, as stated before, a white paper proposal was formulated after all data was collected and reported in a manner in which the subject were not and could not be identified.

Methods

After obtaining approval from the institutional review board (IRB) at the university and the clinical site, the retrospective analysis began. A retrospective analysis of de-identified electronic health record data was performed using a medical record abstraction form. According to Banks (1998), a well-designed data abstraction tool is designed to promote accuracy of data transcription, limit the likelihood of missing data, and is designed to promote accurate data entry into the computerized database for analysis. This investigator developed a data

abstraction tool that included the variables of gender, age, ASA classification, type of surgery, length of surgery, number of doses of each paralytic (total dose administered), reversal (full, partial, or none), inhalation agent used during procedure, TOF documentation, TOF documentation when reversed, temperature, BMI, comorbidities, time of last dose of paralytic to reversal, time of last dose/reversal to extubation time, narcotic used, dose of narcotic, and if adverse event experienced.

Inclusion criteria included any surgical patients aged 18-65 receiving NMB of Rocuronium or Vecuronium during the procedure. Exclusion criteria included any surgical patient with ASA classification > 4 , any emergent cases, any patient with documented neuromuscular disorder or history or prolonged intubation, and patients arriving intubated preoperatively. A Pearson's Chi-Square Test was used to evaluate whether the patients receiving Rocuronium experience a greater increase in post-operative adverse respiratory events compared with the patients whom received Vecuronium.

Confidentiality of records was maintained throughout the collection of data from the electronic health record, and the investigator recorded all data in such a manner that subjects cannot be identified directly or indirectly. After data was analyzed, a white paper proposal was formulated, and results were shared with key identified stakeholders.

Measurement Method

The measurement methodology for this capstone involved performing a retrospective chart review analysis from computerized healthcare information at the clinical site. According to Groves and colleagues (2013), data collected from stored electronic healthcare information is considered secondary data, and these databases provide large amounts of information relevant for research. In addition, according to Gearing and colleagues (2006), data should be extracted effectively and systematically. To begin, a literature review was performed to identify the variables that could potentiate the problem of residual neuromuscular blockade. After all variables were identified, a data extraction instrument was created (See Appendix C).

According to Gearing et al. (2006), data collection should be organized to follow the flow of the health care record. Each variable needs a simple and definite response section, where the information can be captured. Internal validity and reproducibility of any retrospective study is greatly enhanced if the data is standardized (Jansen et al., 2005). Lastly, according to Allison et al. (2000), paper or an electronic document can be the data abstraction instrument.

To begin, the anesthesia record was reviewed to determine the flow of data in regards to the variables identified. Second, permission from the clinical site was obtained to perform the retrospective analysis of the health records. It was determined a paper document would be created and utilized during the chart

reviews, and the information would be collected in such a manner that no subjects could be identified. The abstractor guaranteed in writing to destroy the paper document after all information had been analyzed. As stated before, each variable needs a simple and definite response. The data extraction instrument was created with the following legend: gender coded as M for male, F for female; age coded with numeric number; ASA classification coded as I, II, III, or IV; comorbidities coded R for respiratory issue, C for cardiac, N for neurological, H for hepatic, G for gastrointestinal, R for renal, E for endocrine, O for other; inhalation agent coded as S for sevoflurane, D for desflurane, I for isoflurane; temperature coded with numerical number in Celsius; BMI coded with numerical number; paralytic used coded as R for Rocuronium, V for Vecuronium; total dose of paralytic coded in numerical number as dose in milligrams; reversal agent coded T for total, P for partial dose, N for no reversal agent used; time of last dose to reversal coded in numerical number in minutes; time of last dose/reversal dose to extubation coded in numerical number in minutes; TOF documentation coded as Y for yes, N for no; TOF documentation when reversed coded as numerical number; type of procedure coded as A for abdominal, E for extrathoracic, O for orthopedic, H for head; P for perineal, I for intrathoracic, N for neuroskeletal, S for spine, V for vascular; length of surgery coded in numerical number in minutes; narcotic coded F for fentanyl, M for morphine, D for dilaudid, P for precedex; narcotic dosage

coded as numerical number in milligrams; and adverse event coded as Y for yes or N for no.

CHAPTER III

ANALYSIS OF DATA

The purpose of this capstone project was to perform a retrospective cohort analysis utilizing a well-developed data abstraction tool to determine if surgical patients requiring NMB were at greater risk of experiencing an adverse respiratory event with Rocuronium or Vecuronium. The analysis of data is organized as follows: 1) Statistical Analysis, 2) Presentation of Findings, and 3) White Paper Change Proposal.

Statistical Analysis

After data was extracted into categorical variables, a Pearson's chi-square test using Statistical Package for the Social Sciences (SPSS) for association was performed. With the chi-square test, it is utilized to determine if a relationship exists between two categorical variables. According to Daniel (2009), the chi-square distribution is the most frequently used statistical tool for analysis of frequency or count data. Furthermore, a hypothesis and null hypothesis was developed. The hypothesis for the capstone was: there is an increased incidence of adverse respiratory events with Rocuronium versus Vecuronium? The null hypothesis was: there is not a significant increase incidence of adverse respiratory events with Rocuronium over Vecuronium? Lastly, the level of significance was computed. According to Daniel (2009), "the level of significance α is a probability and, in fact, is the probability of rejecting a true null hypothesis" (p.

220). As known in statistics, an alpha of 0.05 is the maximum level in scientific research. Therefore, this capstone analyzed the data at the significance level of 0.05.

Presentation of Findings

The retrospective analysis was conducted at a level II regional trauma center located in Hattiesburg, Mississippi over a four-month period. All surgical patients who underwent general anesthesia and received either Rocuronium or Vecuronium during the procedure were reviewed. A convenience sample of 50 subjects, 25 whom received Rocuronium and 25 whom received Vecuronium, were chosen for the project. Inclusion criteria included any surgical patient ages 18-65 whom received the NMB agents Rocuronium or Vecuronium during the procedure. Exclusion criteria included any surgical patient ages 18-65 with an ASA classification > 4 , any emergent cases, any patient with documented neuromuscular disorder or history of prolonged intubation, and patients arriving intubated preoperatively.

The retrospective analysis of de-identified electronic health record data was performed using a paper medical record abstraction form. Demographic characteristics of all patients were collected, and can be reviewed on Table 1. Confidentiality of the information was maintained throughout the collection of data, and the investigator recorded all data in such a manner that subjects cannot

be identified directly or indirectly. The abstractor, as guaranteed in writing to IRB, destroyed the paper document after all information was analyzed.

Table 1

Demographic Characteristics of All Patients

Characteristic	Number	Percentage
Gender		
Male	24	48
Female	26	52
Age (y)		
Mean	52.5	
Range	18 – 65	
Mean length surgery (min)	126	
Body mass index (kg/m ²)		
Mean	27.9	
Range	19.5 – 46.6	
ASA category		
I	4	8
II	17	34
III	26	52
IV	3	6
Type of surgery		
Abdominal	33	66
Orthopedic	5	10

Table 1 (continued).

Characteristic	Number	Percentage
Neurosurgery	3	6
Extrathoracic	2	4
Thyroid	3	6
Spine	3	6
Intrathoracic	1	2

Only 7 of the sample of patients experienced an adverse respiratory event. Two of the patients were males, 5 were females, averaged 43 years of age (range, 27 to 65), and average BMI was 30.9 (range, 19.5 to 39 kg/m²), placing all but one patient into the overweight or obese categories. Demographic characteristics of these patients can be viewed in Table 2.

Table 2

Demographic Characteristics of Those Whom Experienced Adverse Event

Gender	ASA	Paralytic	Age	Inhalation Agent	BMI	Surgery	Length of Surgery (minutes)
Female	III	V	57	S	36.9	A	117

Table 2 (continued).

Gender	ASA	Paralytic	Age	Inhalation Agent	BMI	Surgery	Length of Surgery (minutes)
Female	IV	V	65	S	19.5	A	153
Male	III	R	24	D	25.9	O	67
Female	II	R	27	D	35.3	A	182
Female	IV	R	62	S	32	N	84
Male	III	R	60	S	28	A	112
Female	III	R	44	S	39	T	141

Note. R = Rocuronium; V = Vecuronium; D = Desflurane; S = Sevoflurane; A = Abdominal; N = Neurosurgery; T = Thyroid; O = Orthopedic; BMI – Body Mass Index

A Pearson chi-square test of independence was performed to examine the relationship between the paralytic used and if an adverse respiratory event occurred. Of the patients whom receive the NMB agent Rocuronium, 80% did not experience an adverse respiratory event such as $SpO_2 < 90\%$, arrived to PACU intubated, or had to be re-intubated in PACU, and 20% did experience an event (Table 3). Of the patients whom received the NMB agent Vecuronium, 92% did not experience an adverse respiratory event and 8% did experience an event.

Although the differences in percentages appears large, the relationship, as seen in Table 4, between these variables were found to be insignificant, ($N=50$, $df=1$) = 1.495, $p = 0.221$.

Table 3

Adverse Event and Paralytic Crosstabulation

			Paralytic		Total
			R	V	
Adverse Event	N	Count	20	23	43
		% within paralytic	80.0%	92.0%	86.0%
	Y	Count	5	2	7
		% within paralytic	20.0%	8.0%	14.0%
Total		Count	25	25	50
		% within paralytic	100.0%	100.0%	100.0%

Note. R = Rocuronium; V = Vecuronium; N = No; Y = Yes.

Table 4

Pearson's Chi-Square test table for Adverse Event and Paralytic

	Value	df	Asymptotic Sig. (2-sided)
Pearson Chi-Square	1.498 ^a	1	.221
Continuity Correction ^b	.664	1	.415

Note. df = Degree of freedom; a = 2 cells (50%) have expected count less than 5; b = Computed only for a 2 x 2 table.

Although the project did not provide a statistically significant relationship between adverse respiratory events and the usage of Rocuronium or Vecuronium, some serendipitous findings were noted. One serendipitous finding throughout this project was the significant relationship found between the variables of adverse events and the usage of NMB reversal agent (Table 5).

Table 5

Reversal and Adverse Event Crosstabulation

Reversal		Adverse Event		Total
		N	Y	
None	Count	8	5	13
	% within	18.6%	71.4%	26.0%
Partial	Count	15	1	16
	% within	34.9%	14.3%	32.0%
Complete	Count	20	1	21
	% within	46.5%	14.3%	42.0%
Totals	Count	43	7	50
	% within	100.0%	100.0%	100.0%

Note. N = No; Y = yes.

A Pearson's chi-square test revealed ($N=50$, $df=1$) = 8.747, $p = 0.013$ (Table 6). Of the 7 patients whom experienced an adverse respiratory event postoperatively, 5 did not receive a NMB reversal agent, 1 received a partial dosage, and 1 received a total reversal dose. However, it was of interest that the patient whom received total reversal, that patient had been re-dosed 16 minutes prior with Vecuronium. As literature states, Vecuronium has a half-life of 51 to

91 minutes and duration of 30 to 45 minutes. Therefore, it is probable the reversal dose may have potentiated the NMB thus leading to the adverse respiratory event.

Table 6

Pearson Chi-Square test table for Reversal and Adverse Event

	Value	df	Asymptotic Sig. (2-sided)
Pearson Chi-Square	8.747 ^a	2	.013
Likelihood Ratio	7.651	2	.022
Number of Valid Cases	50		

Note. df = Degree of Freedom; Sig = Significance; a = 3 cells (50%) have expected count less than 5. The minimum expected count is 1.82.

Another serendipitous finding was that 100% of the patients whom experienced an adverse respiratory event had not received TOF evaluation during nor prior to extubation. Table 7 compares the variables of measuring TOF to adverse events. Although this finding had a p value of .075 and is therefore considered insignificant, it is hypothesized that a larger data sampling may allow the variable to become statistically significant (Table 8).

Table 7

TOF and Adverse Event Crosstabulation

TOF		Adverse Event		Total
		N	Y	
TOF	N Count	29	7	36
	% within	67.4%	100.0%	72.0%
	Y Count	14	0	14
	% within	32.6%	0.0%	28.0%

Note. N = no; Y = yes.

Table 8

Pearson's Chi-Square test table for TOF and Adverse Event

	Value	df	Asymptotic Sig. (2-sided)
Pearson Chi-Square	3.165 ^a	1	.075
Likelihood Ratio			.025

Note. df = Degree of Freedom; Sig = Significance; a = 1 cells (25.0%) have expected count less than 5. The minimum expected count is 1.96.

White Paper Change Proposal

The desired goal for this capstone project was to determine if surgical patients requiring NMB agents were at greater risk of experiencing an adverse respiratory event with the intermediate acting agents Rocuronium or Vecuronium. The desired outcome was to develop a white paper practice change proposal based upon the results in an effort to improve patient safety. According to the AANA (2014), a white paper is “complete descriptions of a particular concept, position or solution to a problem, from overview to detailed facts, created to promote professionalism and advocacy. Intended to guide decision-makers on policy development” (AANA, 2014, p. 1). Although no statistically significant relationship was found between the variables of adverse events and the paralytics Rocuronium or Vecuronium, unanticipated findings did occur. The serendipitous results regarding the variable of the usage of a reversal agent and possibly usage of TOF monitoring did provide positive findings for areas of improvement. The results of this capstone was shared with identified key stakeholders at the hospital in which the retrospective analysis occurred in an effort to further reduce future incidence of adverse respiratory events associated with residual neuromuscular blockade in the postoperative patient.

CHAPTER IV

SUMMARY

The purpose of this capstone project was to perform a retrospective cohort analysis utilizing a well-developed data abstraction tool to determine if surgical patients requiring NMB were at greater risk of experiencing an adverse respiratory event with Rocuronium or Vecuronium. This chapter is organized as follows: 1) Summary of Findings, 2) Recommendations, and 3) Conclusions.

Summary of Findings

The major finding of the project included there is no statistically significant relationship between increased incidences of postoperative adverse respiratory events with the usage of Rocuronium over Vecuronium. However, the project did provide a statistically significant relationship between adverse relationships and patients not being fully reversed from the NMB agent. This finding correlates with the recommendation that routine pharmacologic reversal of a nondepolarizing NMB should occur. Furthermore, the project determined that TOF monitoring is only occurring 28.0% of the time even though this is considered an AANA Standard. According to the AANA Standards for Nurse Anesthesia Practice (2013), the standard is as follows: “when neuromuscular blocking agents are administered, monitor neuromuscular response to assess depth of blockade and degree of recovery” (p. 2). Therefore, to adequately monitor the

depth of blockade and degree of recovery, the anesthesia provider should utilize certain techniques such as physical assessment and TOF monitoring.

Recommendations

Given the relatively small sample size and short duration of the retrospective analysis, it is recommended the proposed changes made with the white paper proposal be tested to verify feasibility and accuracy of the proposed changes. Each variable previously reviewed could be reevaluated in an effort to determine if practice changes have decrease the incidence of adverse respiratory events associated with residual NMB.

Conclusion

The findings of this retrospective analysis may not have proven the hypothesis that Rocuronium is associated with increased risks of postoperative adverse respiratory events. However, this capstone was instrumental in providing a statistically significant relationship between the usage of reversal agents and the incidence of adverse respiratory events. Residual neuromuscular blockade is not a new phenomenon. It is hopeful that this capstone has provided the key stakeholders current evidence-based knowledge regarding the neuromuscular blocking agents Rocuronium and Vecuronium, the recommended practice of reversal, and the knowledge that TOF monitoring is now considered an AANA and ASA standard of care.

APPENDIX A

FORREST GENERAL IRB APPROVAL LETTER

APPROVAL OF RESEARCH

August 6, 2014

M. Claudine Boos
47420 Westmoreland Road
Franklinton, LA 70438

Dear Ms. Boos:

On August 6, 2014 the IRB reviewed the following protocol:

Type of Review:	<i>Exemption Category 4</i>
Project Title:	<i>Capstone Project – In the surgical patient requiring neuromuscular blockade, is there an increased incidence of postoperative adverse respiratory events with Rocuronium versus Vecuronium?</i>
Principle Investigator:	<i>M. Claudine Boos (USM CRNA Student)</i>
IRB ID:	<i>14-006</i>
Funding Agency:	<i>N/A</i>
Documents Reviewed:	<ul style="list-style-type: none"> ▪ IRB Application ▪ Protocol ▪ HIPAA IRB Waiver of Authorization ▪ CITI Training Certificate ▪ FGH Non-Employee Confidentiality Agreement

The Forrest General Hospital IRB has determined this project is EXEMPT FROM IRB REVIEW according to federal regulations. Please notify the IRB in writing when your study is complete.

Please note that any changes to the study as approved must be promptly reported and approved. Contact Michele Stanley at 601-288-4324, if you have any questions or require further information.

Sincerely,

Lewis E. Hatten, M.D.
Chairman, Institutional Review Board
P.O. Box 16389 • Hattiesburg, MS 39404-6389
6051 Highway 49 • Hattiesburg, MS 39401-7201
601-288-7000 • forrestgeneral.com

APPENDIX B

UNIVERSITY OF SOUTHERN MISSISSIPPI IRB APPROVAL LETTER

**INSTITUTIONAL REVIEW BOARD**

118 College Drive #5147 | Hattiesburg, MS 39406-0001
 Phone: 601.266.5997 | Fax: 601.266.4377 | www.usm.edu/research/institutional.review.board

NOTICE OF COMMITTEE ACTION

The project has been reviewed by The University of Southern Mississippi Institutional Review Board in accordance with Federal Drug Administration regulations (21 CFR 26, 111), Department of Health and Human Services (45 CFR Part 46), and university guidelines to ensure adherence to the following criteria:

- The risks to subjects are minimized.
- The risks to subjects are reasonable in relation to the anticipated benefits.
- The selection of subjects is equitable.
- Informed consent is adequate and appropriately documented.
- Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the subjects.
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of all data.
- Appropriate additional safeguards have been included to protect vulnerable subjects.
- Any unanticipated, serious, or continuing problems encountered regarding risks to subjects must be reported immediately, but not later than 10 days following the event. This should be reported to the IRB Office via the "Adverse Effect Report Form".
- If approved, the maximum period of approval is limited to twelve months.
 Projects that exceed this period must submit an application for renewal or continuation.

PROTOCOL NUMBER: 15012802

PROJECT TITLE: In the Surgical Patient Requiring Neuromuscular Blockade, is there an Increased Incidence of Postoperative Adverse Respiratory Events with Rocuronium or Vecuronium?

PROJECT TYPE: New Project

RESEARCHER(S): Martha Claudine Boos

COLLEGE/DIVISION: College of Nursing

DEPARTMENT: Advanced Practice Department

FUNDING AGENCY/SPONSOR: N/A

IRB COMMITTEE ACTION: Exempt Review Approval

PERIOD OF APPROVAL: 01/29/2015 to 01/28/2016

Lawrence A. Hosman, Ph.D.

Institutional Review Board

APPENDIX C

DATA COLLECTION TOOL

Adverse Event
Narcotic Dose
Narcotic
Surgery Length
Surgery
TOF when reversed
TOF
Time last does/reversal to extubation
Time Last dose of reversal
Reversal
Paralytic total dose
Paralytic Agent
BMI
Temperature
Inhalation Agent
Comorbidities
ASA
Age
Gender

Legend

Gender

Age

ASA

Comorbidities

Inhalation agent

Temperature

BMI

Paralytic agent

Total dose of paralytic

Reversal Agent

Time last dose of reversal

Time last dose/reversal to extubation

TOF

Type of procedure

Length of surgery

Narcotic

Narcotic dose

Adverse event

M = male; F = female

Numerical number expressed in years

I, II, III, IV

R = respiratory; C = cardiac; N = neurological;

H = hepatic; G = gastric;

R = renal; E = endocrine; O = other

S = Sevoflurane; D = Desflurane; I = Isoflurane

Numerical number in Celsius

Numerical number

R = Rocuronium; V = Vecuronium

Numerical number expressed in milligrams

T = total; P = partial; N = no reversal used

Numerical number in minutes

Numerical number in minutes

Numerical number

A = abdominal; E = extrathoracic; O =

orthopedic; H = head; P = perinal; I =

intrathoracic; N = neuroskeletal; S = spine; V =

vascular

Numerical number in minutes

F = fentanyl

Numerical number in micrograms

Y = yes; N = no

REFERENCES

- Advisory Board Company. (2014). *Ambulatory surgery centers may soon outnumber hospitals*. Retrieved from <http://www.advisory.com/daily-briefing/2013/01/31/ambulatory-surgery-centers-may-soon-outnumber-hospitals>
- Agency for Healthcare Research and Quality. (2011). *National healthcare quality report, 2011*. Retrieved from <http://www.ahrq.gov/research/findings/nhqrdr/nhqr11/chap3.html>
- Allison, J. J., Wall, T. C., Spettell, C. M., Calhoun, J., Fargason, C. A., Kobylinski, R. W., Farmer, R., & Kiefe, C. (2000). The art and science of chart review. *Journal of Quality Improvement*, 26(3), 115-136. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/10709146>
- American Association of Nurse Anesthetists. (2014). *AANA document definitions*. Retrieved from <http://www.aana.com/resources2/professionalpractice/Documents/PPM%20Document%20Definitions.pdf>
- American Association of Nurse Anesthetists. (2013). *Scope and standards for Nurse anesthesia practice*. Retrieved from <http://www.aana.com/resources2/professionalpractice/Pages/Standards-for-Nurse-Anesthesia-Practice.aspx>
- American Lung Association. (2011). *Chronic obstructive pulmonary disease (COPD) fact sheet*. Retrieved from <http://www.lung.org/lung-disease/>

[copd/resources/facts-figures/COPD-Fact-Sheet.html](http://www.copd/resources/facts-figures/COPD-Fact-Sheet.html)

- Banks, N. (1998). Designing medical record abstraction forms. *International Journal of Qualitative Health Care*, 10(2), 163-167. Retrieved from <http://www.intqhc.oxfordjournals.org/content/10/2/163.long>
- Beecher, H. K., & Todd, D. P. (1954). A study of the deaths associated with anesthesia and surgery. *Annals of Surgery*, 140(1), 1-34.
- Bishop, T. F., Ryan, A. M., & Casalino, L. P. (2011). Paid malpractice claims for adverse events in inpatient and outpatient settings. *JAMA*, 305(23), 2427-2431.
- Brull, S. J., Kopman, A. F., & Naguib, M. (2013). Management principles to reduce the risk of residual neuromuscular blockade. *Current Anesthesiology Reports*, 3, 130-138.
- Centers of Disease Control and Prevention. (2014). *Inpatient surgery*. Retrieved from <http://www.cdc.gov/nchs/fastats/inpatient-surgery.htm>
- Chism, L. A. (2013). *The doctor of nursing practice: A guidebook for role development and professional issues* (2nd ed.). Burlington, MA: Jones & Bartlett Learning.
- Claudius, C., Karacan, H., & Morgensen, J. (2007). Prolonged residual paralysis after a single intubating dose of Rocuronium. *British Journal of Anaesthesia*, 99(4), 514-547.
- Daniel, W. W. (2009). *Biostatistics: A foundation for analysis in the health*

sciences. (9th ed.). Hoboken, NJ: Wiley.

Debaenne, B., Plaud, B., Dilly, M. P., & Donati, F. (2003). Residual paralysis in the PACU after a single intubating dose of nondepolarizing muscle relaxant with an intermediate duration of action. *Anesthesiology*, 98(5), 1042-1048.

Donati, F. (2010). Neuromuscular monitoring: What evidence do we need to be convinced? *International Anesthesia Research Society*, 111(11), 6-8.

Forrest General Hospital. (2014). *Welcome to Forrest General Hospital*.

Retrieved from <http://www.forrestgeneral.com>

Foster, S. D., & Callahan, M. F. (2011). *A professional study and resource guide for the CRNA* (2nd ed.). Park Ridge, IL: American Association of Nurse Anesthetists.

Gearing, R. E., Mian, I. A., Barber, J., & Ickowicz, A. (2006). A methodology for conducting retrospective chart review research in child and adolescent psychiatry. *Journal of the Canadian Academy of Child and Adolescent Psychiatry*, 15(3), 126-134.

Grove, S. K., Burns, N., & Gray, J. R. (2013). *The practice of nursing research: Appraisal, synthesis, and generation of evidence* (7th ed.). St. Louis, MO: Elsevier.

Guyton, A. C., & Hall, J. E. (2011). *Guyton and Hall textbook of medical physiology* (12th ed.). Philadelphia, PA: Saunders.

- Jansen, A. C. M., van Aalst-Cohen, E. S., Hutten, B. A., Buller, H. R., Kastelein, J. J. P., & Prins, M. H. (2005). Guidelines were developed for data collection from medical records for use in retrospective analyses. *Journal of Clinical Epidemiology*, 58, 268-274.
- Khan, S., Divatia, J. V., & Sareen, R. (2006). Comparison of residual neuromuscular blockade between two intermediate acting nondepolarizing neuromuscular blocking agents – Rocuronium and Vecuronium. *Indian Journal of Anaesthesia*, 50(2), 115-117.
- Lehne, R. A. (2004). *Pharmacology for nursing care* (5th ed.). St. Louis, MO: Saunders.
- MacRae, M. (2007). Closed claim studies in anesthesia: A literature review and implications for practice. *AANA Journal*, 75(4), 267-275.
- Marcus, A. (2012). Residual paralysis: The problem that won't go away. *Clinical Anesthesiology Issue*, 38(7), 3-9.
- Martin, S. A. (1996). Applying nursing theory to the practice of nurse anesthesia. *Journal of American Association of Nurse Anesthesia*, 64(4), 369-372.
Retrieved from http://www.aana.com/newsandjournal/Documents/applying_0906_p369.pdf
- Miller, R. D., & Ward, T. A. (2010). Monitoring and pharmacologic reversal of a nondepolarizing neuromuscular blockade should be routine. *Anesthesia-Analgesia*, 111(1), 3-5.

- Morgan, G. E., Mikhail, M. S., & Murray, M. J. (2007). *Lange clinical anesthesia* (3rd ed.). New York, NY: McGraw-Hill.
- Morrell, R. C. (2013). *Panel on monitoring neuromuscular blockade at 2012 New York PGA Meeting, sponsored by APSF*. Retrieved from http://www.apsf.org/newsletters/html/2013/spring/03_NMBpanel.htm
- Murphy, G. S. (2012). Residual neuromuscular blockage: An important patient safety issue. *American Association of Nurse Anesthetists*, 80(6), 4-10.
- Murphy, G. S., Szokol, J. W., Marymont, J. H., Greenberg, S. B., Avram, M. J., & Vender, J. S. (2008). Residual neuromuscular blockade and critical respiratory events in the postanesthesia care unit. *Anesthesia-Analgesia*, 107(1), 130-137.
- Nagelhout, J. J. (2013). Reversal of neuromuscular blocking agents: Current practice. *American Association of Nurse Anesthetists Journal*, 81(6), 8-11.
- Nagelhout, J. J., & Plaus, K. L. (2014). *Nurse anesthesia* (5th ed.). St. Louis, MO: Elsevier.
- Neuman, B. (1995). *The Neuman systems model* (3rd ed.). Norwalk, CT: Appleton & Lange.
- Sagir, O., Noyan, F. Y., Koroglu, A., Cicek, M., & Toprak, H. I. (2013). Comparison between the effects of Rocuronium, Vecuronium, and Cisatracurium using train-of-four and clinical tests in elderly patients. *Iranian Society of Regional Anesthesia and Pain Medicine (ISPAPM)*, 2

(4), 142-149.

Saenz, A. D. (2011). *Peripheral nerve stimulator – train of four monitoring*.

Retrieved from <http://emedicine.medscape.com/article/2009530-overview#al>

Stoelting, R. K. (2014). Ninety percent of respondents agree on need for routine intraop monitoring of NMB. *Journal of the Anesthesia Patient Safety Foundation*, 28(3), 71-72.

Videria, R. L., & Vieira, J. E. (2011). What rules of thumb do clinicians use to decide whether to antagonize nondepolarizing neuromuscular blocking drugs? *Anesthesia & Analgesia*, 113(5), 1192-1196.

Whetsell, M. V., Gonzalez, Y. M., & Moreno-Fergusson, M. E. (2011). In Butts, J. B., & Rich, K. L. (Eds.), *Philosophies and theories for advanced nursing practice* (pp. 413-444) Sudberry, MA: Jones & Bartlett Learning.

Wilson, J., Collins, A. S., & Rowan, B. O. (2012). Residual neuromuscular blockade in critical care. *Critical Care Nurse*, 32(3), e1-e9.

Yoder, M. A., & Sharma, S. (2011). Perioperative pulmonary management.

Retrieved from <http://emedicine.medscape.com/article/284983-overview>

Zaccagnini, M. E., & White, K. W. (2014). *The doctor of nursing practice essentials: A new model for advanced practice nursing* (2nd ed.).

Burlington, MA: Jones & Bartlett Learning.

Zhang, B., Hepner, D. L., Tran, M. H., Friedman, M., Korn, J. R., & Menzin, J.

(2009). Neuromuscular blockade, reversal agent use, and operating room time: retrospective analysis of US inpatient surgeries. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/19257799>