

POST-OPERATIVE VENTILATION PATTERNS AND
THE EFFECTS OF NON-INVASIVE POSITIVE PRESSURE THERAPY
ON VENTILATORY CHANGES AS MEASURED BY A
NON-INVASIVE IMPEDANCE DEVICE
IN PATIENTS WITH OBSTRUCTIVE SLEEP APNEA

by

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Patients undergoing general anesthesia who have or are suspected of obstructive sleep apnea (OSA) may be at increased risk for ventilatory complications, including respiratory depression, airway obstructions, and apnea events. The increased prevalence of OSA in the surgical population has led clinicians and researchers to explore strategies to screen for OSA and employ best management practices to minimize perioperative respiratory events. Standardized monitors in the postoperative anesthesia care unit (PACU) may have limited utility in this patient population to readily detect real or potential airway complications. The purposes of this prospective observational study were: to further explore the relationship of OSA risk to perioperative events in participants undergoing laparoscopic gastric bypass surgery (GBS); explore the utility of using an innovate respiratory volume monitor (RVM, ExSpirom™, Waltham, MA, USA) to identify reduced ventilatory function before standard postoperative monitors alert nurses of hypoventilation or apnea events; measure the ventilatory changes when noninvasive positive pressure therapy (NPPV) was applied in the PACU using the RVM. A prospective convenience sample of 50 adult participants with 25 assigned as “mild OSA” (M-OA) and 25 in the “moderate/severe OSA” (S-OA) were selected and observed in the PACU

to explore the research questions. Findings included no differences perioperative outcomes with the exception of longer PACU stay mean times for the M-OSA, despite S-OSA group being older, having larger neck circumferences, and receiving more opioids in the PACU. The RVM identified respiratory depression events earlier and more often than decreases in pulse oximetry. Thirteen participants who received NPPV and had no significant change in minute ventilation (MV) during use, however a mean decrease of 25% in tidal volume (TV) was measured from mask removal time to five-minute post removal period. This supports the effects of NPPV on maintaining MV when measured by RVM. Findings of the study help support the need to further explore the utility of using RVM to measure ventilatory function, guide therapies, and incorporate RVM into practice settings where patient populations are at risk for respiratory complications. The use of postoperative NPPV therapy needs further exploration in randomized studies to identify optimal NPPV type, pressure settings, and duration of use to help improve ventilatory function in patients known to or suspected of having OSA.

(Key Words: Obstructive Sleep Apnea, OSA, Postoperative Ventilation Monitoring)

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CHAPTER 1: STATEMENT OF THE PROBLEM

Introduction

Approximately 2-4% of the U.S. population is diagnosed with obstructive sleep apnea (OSA). Twenty to thirty percent of surgical candidates, and upward of 90% of bariatric surgical patients (Finkel et al., 2009) have OSA but are undiagnosed prior to surgery. This population is at risk for inadequate ventilation and hypoxia (Liao, Yegneswaran, Vairavanathan, Zilberman, & Chung, 2009; Mador et al., 2013), requiring interventions to improve respiratory function (Kaw, Pasupuleti, Walker, Ramaswamy, & Folvary-Schafer, 2012). Diagnosing the etiology of altered ventilatory patterns in patients with known or suspected OSA can be difficult, and lead anesthesia providers to initiate interventions when respiratory depression occurs that may not result in expected outcomes. Perioperative airway management requires accurate identification of ventilatory problems and subsequent implementation of appropriate interventions. In patients with OSA, this may be even more essential.

Postoperative hypoventilation and apneic events can delay recovery, increase risks for perioperative morbidity and mortality, and add tens of thousands of dollars of additional expense to patients and healthcare systems (Kapur, 2010; Shin, Zaremba, Devine, Nikolov, Kurth, & Eikermann, 2016). Researchers conducted meta-analyses and found that patients with OSA have increased odds of respiratory failures, cardiovascular events, oxygen desaturations, ICU admissions, and increased lengths of hospital stay (Kaw et al., 2012; Hai et al., 2014). These events may be avoided with appropriate screening, perioperative monitoring, and timely assessments and interventions made by perioperative healthcare providers (Gammon & Ricker, 2012).

Gupta, Parvizi, Hanssen, and Gay (2001) explored perioperative complications associated with patients who have of OSA. In their retrospective case-controlled analysis of 202 patients undergoing orthopedic surgery they reported that patients with OSA had a two-fold risk of experiencing adverse perioperative events. Serious complications occurred in 24% of patients with OSA vs. 9% of the control group. Continuous positive airway pressure (CPAP) therapy applied prophylactically eliminated airway complications during the first postoperative night.

Opperer et al. (2016) conducted a systematic review of 61 studies concerning OSA positive or suspected patients who had ≥ 1 adverse postoperative outcome after anesthesia. The analysis included 413,304 OSA positive patients and 8,556,270 in control groups. They reported that patients with OSA have a higher incidence of adverse cardiopulmonary events (Gupta et al., 2001; Mokhlesi, Hovda, Vekhter, Arora, Chung, & Meltzer, 2013), re-intubation (Memtsoudis, Liu, Ma, Chiu, Walz, Gaber-Baylis, & Mazumdar, 2011), hypoxemia, and increased length of hospital stay (Kaw et al., 2012). Liao et al. (2009) reported in a retrospective cohort study (240 matched pairs) that overall postoperative complications associated with patients who had OSA was 48% compared to 28% in control group. Patients with OSA required longer oxygen therapy (23% OSA vs. 15% non-OSA), additional monitoring (13% OSA vs. 6% non-OSA) and had higher rates of ICU admissions (40% OSA vs. 28% non-OSA). They further reported that patients with OSA who were non-compliant with CPAP exhibited the “highest incidence of postoperative complications” (p. 823), with oxygen desaturations most commonly noted. Since most of these were retrospective studies, the authors concluded that randomized prospective control studies are needed. They suggested exploring the relationship of OSA severity with perioperative outcomes, including the effects of CPAP therapy, and monitoring strategies to improve patient outcomes.

In 2005, the American Society of Anesthesiologists (ASA) established a task force in order to study the prevalence of OSA and suggest best perioperative management strategies. They published preliminary guidelines (Gross et al., 2006) on perioperative screening and general management of patients with OSA in the perioperative setting. Updates (Gross et al. 2014) addressed collaboration with surgeons, recommendations for sleep study referrals, and strategies to optimize perioperative ventilation in patients with OSA. Recommendations also included strategies for patient positioning (upright vs. supine), reducing opioid use, and utilizing regional anesthesia techniques when feasible. Despite the general recommendations, no formal practice standards were adopted. Instead, broad guidelines for patients with OSA undergoing surgical procedures were provided, allowing practitioners and health care systems to customize individual patient management. They too advocated for prospective randomized control trials to explore perioperative implications of OSA and to standardize practice guidelines for anesthesia providers (Stewart, 2013).

There are several aims in this dissertation research. One aim is to explore relationships between OSA severity and postoperative ventilation patterns (minute ventilation and perioperative vital signs). A second aim is to document direct effects of postoperative non-invasive positive pressure ventilation (NPPV) in this group. A third aim is to provide additional insight into standardized screening of patients with OSA, the measures used to detect apnea and hypoventilation events, and the processes used in managing these patients in the perioperative setting.

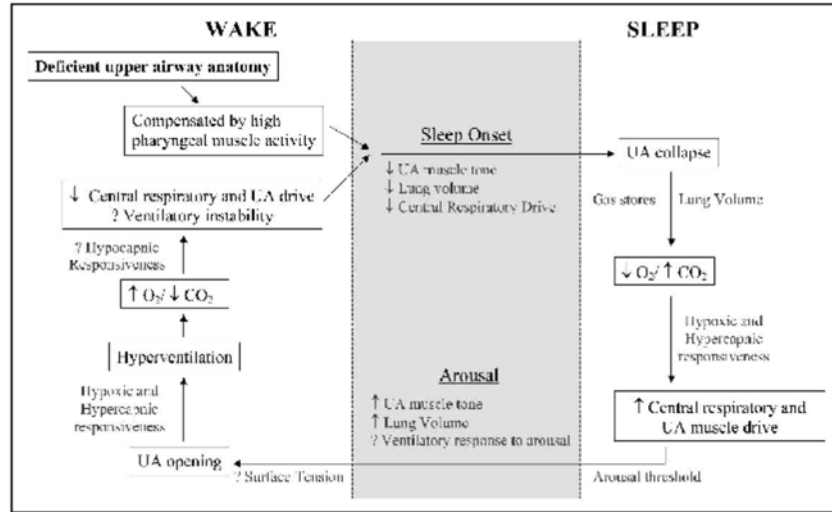
Background and Significance of Obstructive Sleep Apnea

The Physiology of Obstructive Sleep Apnea

Patients with a diagnosis of OSA have altered airflow patterns during sleep that lead to reductions in pharyngeal muscular tone, specifically the genioglossus dilator muscle that is associated with a reduction or cessation in airflow to the lungs. The changes to airflow can be demonstrated in Pouseille's law, where flow is proportional of the radius to the fourth power and inversely proportional the length of the lumen (Susarla, Thomas, Abramson, & Kaban, 2010). This means that decreasing the radius of a lumen, such as the trachea by half will decrease the flow 16-fold. Upper airway pharyngeal dilating tone decreases in patients with OSA, leading to narrowed and/or an obstructed airways. Because of narrower hypopharyngeal structures, patients with OSA are predisposed to obstructive airflow patterns under normal circumstances. And the risk for obstruction is compounded in the perioperative setting due to the effects of medications, anesthesia, and alterations in sleep structure after surgery.

The time spent in OSA breathing patterns include hypopnea or apneic events, defined as periods of reduced (<50% airflow) or absent (>90% reduction) airflow for >10 seconds when simultaneous chest/abdominal exertions are noted (Cropsey, & McEvoy, 2017; Moos, Prash, Cantral, Huls, & Cuddeford, 2005). Unlike central sleep apnea where a cessation of airflow accompanies no skeletal/diaphragm exertion, the diaphragm, and chest attempts to move against closed glottic structures. Ultimately, the individual gasps for air, often awakening momentarily, increasing the percentage of fragmented sleep. Figure 1 (Jordan, White, & Fogel, 2003) depicts a physiological model of an OSA sleep pattern with plausible pathophysiological factors.

Figure 1: Model of OSA sleep cycle. Model moves in a clockwise direction. UA: Upper Airway (Jordan, White, & Fogel, 2003).



Note: Figure 1 from “Recent advances in understanding the pathogenesis of OSA,” by A.S. Jordan, D.P. White, and R.B. Fogel, 2003, *Current Opinion in Pulmonary Medicine, Volume 9*, p. 460. Copyright [2003] by Lippincott Williams & Wilkins (Wolters Kluwer Health Inc.). Reprinted with permission.

Sleep patterns in those with OSA become fragmented from repeated awakenings caused by reduced or obstructed airflow. Remodeling of the airway and reduced quality of sleep increases daytime somnolence, affecting activity levels and cognitive function. These alterations can hinder diet and exercise patterns, increase body weight, and add stress to other physiological systems. Rapid eye movement (REM) sleep percentages increase with escalating periods of obstructive airflow and fragmented sleep.

Over time, alterations in airflow increase circulating carbon dioxide levels (CO₂), vascular tone, and sympathetic catecholamine levels, and lead to right-sided heart strain. Changes in electrical conduction pathways can occur because of the cardiovascular strain and lead to increased risk for uncontrolled hypertension (Marcus, Potheneni, Marcus, & Bisognano, 2014) and/or atrial fibrillation (Lin et al., 2015; Sidhu & Tang, 2017). Physiological changes then reduce the central nervous system's sensitivity to circulating CO₂, making the person less arousable, which can decrease their daytime energy levels, ability to concentrate, or stay awake

(Jordan, McSharry, & Malhotra, 2014). These changes in sleep patterns are associated with increased risk for airway decompensation and adverse airway events in the perioperative setting (Paje & Kremer, 2006).

Co-Morbidities associated with OSA

OSA can be independent of other disease processes, but typically coincides with other health issues (e.g., diabetes, hypertension, arrhythmias, stroke, obesity, and higher BMI scores) (Dempsey, Veasey, Morgan, & O'Donnell, 2010). The long-term physiological effects described by Grippi et al. (2015) include changes in neurocognitive function, increased cardiovascular strain, hypercoagulability, endocrine dysregulation, additional oxidative stress, increased inflammation, and endothelial dysfunction. The compounded effects of co-morbidities lead to an increased risk of perioperative morbidity and mortality and worsening OSA (Chung et al., 2016).

Individuals who have OSA but are undiagnosed, may have additional perioperative complications. It has been demonstrated that undiagnosed patients are at increased risk for cardiovascular complications (Liao et al., 2009). Mutter, Chateau, Moffatt, Ramsey, Roos, and Kryger, (2014) compared postoperative outcomes in undiagnosed and diagnosed OSA patients to low-risk/non-OSA groups, measuring longitudinal data for 21 years. They documented an increased risk of pulmonary complications in all OSA groups compared to controls (OR 2.08, [CI 1.35 to 2.19]). The incidence increased as the severity of OSA worsened. Patients with undiagnosed OSA had higher incidence of cardiovascular complications and shock (OR 2.20 [CI 1.16 to 4.17]) compared to matched controls. They reported that the use of CPAP therapy reduced these risks. These researchers advocated for prospective/randomized studies to evaluate the efficacy of CPAP in both subgroups. Preoperative polysomnography (PSG) is the gold

standard for diagnosing OSA. PSG is not performed on all surgical patients, increasing the risk of missing the identification of OSA on patients scheduled for surgery and anesthesia.

OSA Screening Tools

The gold standard for diagnosing and classifying the severity of OSA is through a PSG study performed in a sleep study lab (Jordan et al., 2014). In these studies, electroencephalography, electrocardiography (ECG) electrodes, airflow sensors, and chest impedance devices are attached to patients. A technician monitors and records respiratory changes in airflow patterns, chest movement, and depth of sleep. Altered airflow patterns, typically seen during REM sleep, are recorded during the PSG study. A diagnosis of OSA is confirmed when periods of hypoventilation (>30-50% airflow reduction) or apneustic (>90% airflow reduction for >10 seconds) breathing patterns are identified, measured, and averaged (Abrishami, Khajehdehi, & Chung, 2010; Boese, Ransom, Roadfuss, Todd, & McGuire, 2014; Chung, Liao, Yegneswaran, Shapiro, & Kang, 2014). The average number of these events per hour of sleep determines the apneustic/hypopnea index (AHI). A higher AHI correlates with more severe OSA.

A diagnosis of mild OSA is defined to include 5 to <15 AHI events/hour, moderate, 15-30 events/hour, or severe, >30 events/hour (Chung, Yang, Brown & Liao, 2014; Chung et al., 2016). Sleep efficiency is determined to be normal if there is >80% of total sleep to REM sleep (sleep efficiency = (total sleep time – REM)/total sleep) x 100). After a positive OSA diagnosis, individuals with moderate and severe OSA are often offered treatment. Typically this involves fitting them with a nasal or full-face mask that provides NPPV through continuous or bi-level positive airway pressure (CPAP and BiPAP respectively). The goal is to assist in maintaining a patent hypopharynx and improve airflow during sleep. A second sleep test is then conducted to

properly fit the mask and adjust pressure settings to open the closed airway, attenuate obstructive airflow, and reduce AHI severity.

The PSG is effective in diagnosing OSA, however it is time-consuming and expensive. Therefore, many patients who present for surgery may actually have OSA, without a formal diagnosis. Gross et al. (2014) suggests preoperative screening is essential to identifying potential issues in surgical candidates, and identifying those who may benefit from preoperative sleep studies. In patients who are suspected of having OSA without the benefit of a formal diagnosis, screening questionnaires may be useful (Abrishami et al., 2010). These tools if utilized preoperatively, may alert anesthesia providers of likelihood of OSA so they can anticipate associated complications during surgery

The STOP-Bang questionnaire (SBQ) (Appendix C) is an eight-item questionnaire where having >3 positive answers may indicate an undiagnosed OSA airway pattern. There is a positive correlation between the number of questions answered positively and the severity of the OSA (Seet & Chung, 2010). Researchers using the tool in the peri-anesthetic setting have demonstrated mixed results. Since it has been demonstrated to be useful in categorizing risk for OSA, it will be used in this research study. To improve uniformity in categorizing OSA risk, the STOP-Bang questionnaire will be administered in the perioperative setting.

OSA in the Perioperative Setting

Patients with OSA may have higher pre-existing CO₂ levels, increasing their sensitivity to medications commonly administered in the perioperative setting, elevating their risk of apnea and other adverse respiratory events (Liao et al., 2009). Opioids, benzodiazepines, and other common perioperative medications administered for anxiety and pain management attenuate the central nervous system's (CNS) response to circulating CO₂. Recumbent positioning can further

exacerbate the problem of reduced and obstructed airflow (Jordan et al., 2014). By nature of the obstructive process, there is a need for nurses to detect changes in ventilatory status and intervene promptly. If unrecognized, patients with OSA pose a higher risk of decompensating, requiring emergency interventions to support ventilation.

The anatomic and physiological changes to airway structures and respiratory patterns associated with OSA should be of concern for nurses and anesthesia providers who care for these patients, especially in the perioperative setting (Gammon & Ricker, 2012). Patients who undergo monitored anesthesia care sedation, regional, or general anesthesia receive anxiolytics, potent opioid narcotics, antihistamines, and other anesthetic adjuncts. The CNS changes associated with these medications can increase respiratory depression severity, reduce CNS stimulation to the genioglossus dilator muscles, and alter REM sleep patterns (Chung, et. al., 2014).

In the operating room, anesthesia providers use pulse oximetry, which measures hemoglobin saturation of oxygen (SpO₂), capnography, mechanical ventilation, and occasionally arterial blood gas analyses to guide ventilation and oxygenation status (Allan Klock, Anderson, & Hernandez, 2017). Anesthesia providers use these monitors help in identifying obstructed airflow patterns to make appropriate interventions, improving ventilatory and oxygenation patterns. Upon entry to the postoperative anesthesia care units (PACU), qualified registered nurses typically receive reports regarding the anesthetic and intraoperative events (Robins & Dai, 2015) and begin assessing patients. Monitors for ECG, blood pressure, and oxygenation status are reapplied, and vital signs are examined. Without specific monitors to help guide clinical decisions, inaccurate assessments and treatments can be administered. Capnography and

mechanical ventilation are not routinely used in the PACU setting making early detection of an impaired airway more difficult.

Postoperative Management Standards for OSA Patients

After surgery, patients undergo recovery in a designated PACU where nurses monitor and identify changes in patients' status, follow written postoperative orders, and make decisions to notify anesthesia providers to make interventions (Whitaker et al., 2013). Routine monitoring of airway and ventilatory status, pain level, hemodynamics, and hydration may be insufficient when patients with OSA arrive in PACUs after receiving anesthesia. Society of Anesthesia and Sleep Medicine has recently published (Chung et al., 2016) and updated practice recommendations for screening and management of patients with OSA. Additional guidelines have been published including checklists specifically for anesthesia providers and perioperative nurses to assess and manage outcomes (Butterworth, Mackey, & Wasnick, 2013; Gammon & Ricker, 2012).

Standard monitors include pulse oximetry, ECG, and noninvasive or arterial blood pressure monitors (NIBP or ABP respectively). Anesthesia providers and PACU registered nurses (RNs) use data from these monitors coupled with assessment skills to evaluate patient's physiological status, level of arousal, and severity of pain. Before moving from the PACU to a less intensely monitored area, patients must meet discharge readiness criteria. PACU nurses follow standardized checklists approved for their postoperative setting. The Modified Aldrete Scoring Tool (Appendix D) is a common instrument used to evaluate discharge readiness; patients must meet a score of >9/10 (Hadzic et al., 2005). The tool measures a patient's "activity, respiration, circulation, consciousness, and oxygen saturation" (Butterworth, Mackey, & Wasnick, 2013), deriving a 0, 1, or 2 rating for each parameter with a composite score totaling

up to 10. Additional criteria for discharge may require a set time in PACU to be met (typically 45 minutes after a general anesthetic) depending on the procedure and type of anesthetic administered.

Monitors and the OSA Patient

Difficulties can arise when patients are admitted to the PACU with co-morbidities such as OSA, that challenge the nurse's ability to make accurate and timely clinical decisions (Moos et al., 2005). Selection and use of appropriate monitors support a nurse's ability to recognize changes, deter complications, and reduce morbidity (Tweddell, Ghanayem, & Hoffman, 2014). Current respiratory monitoring devices used in PACUs lack a high degree of sensitivity and may underestimate patients' ventilatory status even when applied appropriately.

Traditional monitoring techniques are prone to sampling error and are indirect or delayed measurements of ventilation status. New instruments that are statistically and clinically valid and reliable are needed to detect hypoventilation events (Voscopoulos, Brayanov, Ladd, Lalli, Panasyuk, & Freeman, 2013).

ExSpirom™ Monitor and OSA

The ExSpirom™ is a FDA approved respiratory ventilation monitor (RVM) that measures chest movement through variations in impedance and continuously identifies respiratory patterns (Voscopoulos et al, 2013; Schumann et al., 2016). Respiratory rate (RR) and tidal volume (TV) are measured, and minute ventilation (MV) is calculated. The RVM has the potential to identify inadequate ventilatory patterns in patients, thus alerting healthcare providers to make timely interventions that may reduce the incidence of postoperative complications. Use of the RVM in the perioperative setting has been limited, but promising. Previous studies using the RVM have measured postoperative hypoventilation and apneic events in morbidly obese patients (Schumann

et al., 2016), the effects of opioids on ventilation in patients after orthopedic surgery (Fleming et al., 2015), and ventilatory changes in patients who have received intravenous sedation (Holley, MacNabb, Georgiadis, Minasyan, Shukla, & Mathews, 2016).

While Schumann et al. (2016) used the RVM to monitor obese patients for occurrences of postoperative hypoventilation and apnea, they did not explore the relationship to pulse oximetry data, nor measure the ventilatory changes when respiratory interventions (including NPPV) were used postoperatively. ExSpiron™ technology may give clinicians an additional layer of information beyond oximetry and capnography (Voscopoulos et al., 2013). These relationships have not been explored. Because research is lacking these areas, the ExSpiron™ will be used in this research study to monitor postoperative ventilatory patterns in the OSA surgical population. The PI will use data obtained from the RVM to: 1.) Record ventilatory changes and correlate those changes to coinciding pulse oximetry data. 2.) Measure changes in ventilation when NPPV is used or discontinued. 3.) Explore the relationship between screened OSA severity and occurrences of respiratory depression in the PACU. 4.) Explore relationships between patients who have a formal diagnosis of OSA to those who do not, including the occurrence of respiratory depression in the PACU.

The Role of Postoperative CPAP Therapy

The primary therapy after diagnosis of moderate and severe OSA is application of a NPPV. Typically this is a CPAP or Bi-level auto-titrated positive pressure (BiPAP) mask (Antonescu-Turcu & Parthasarathy, 2010; Brousseau, Dobson, & Milne, 2014). At the institution where this study will be taking place, patients who use a NPPV (CPAP/BiPAP) mask at home are instructed to bring their mask and machine to the hospital on the day of surgery. The mask may be used postoperatively to assist in ventilation, especially in the patient's room while

they are sleeping. Kohler, Smith, Tippett, and Stradling (2010) noted from prior studies that home CPAP use for just 3.5-4 hours nightly improves subjective sleepiness and attenuates cardiovascular effects of OSA. Patients with OSA who wear a NPPV mask at least 4 hours night are considered to be compliant with using the therapy. Because of the airway changes associated with OSA and the compounding effects perioperative medications may have on the airway, a NPPV device should be available for every patient with OSA.

Postoperative application of NPPV as a respiratory intervention is typically initiated after other interventions (positioning, oxygen therapy, and physical/verbal stimuli) are used to maintain oxygenation and ventilation. A clinical limitation of NPPV use is the nurses' inexperience with mask application. This may result in inappropriate application and ineffectiveness. A lack of standardized orders (Gross et al., 2014) for timing and duration of NPPV, and patient unfamiliarity with the treatment may also limit the benefits of this therapy. Patients with OSA who are not diagnosed preoperatively may resist postoperative application due to discomfort (Paje & Kremer, 2006) and irritation. Therefore, preoperative screening and patient and healthcare provider education are required (Porhomayon, Zadeii, Nader, Bancroft, & Yarahamadi, 2013) if this treatment is to be successful.

Statement of the Problems

Noninvasive measurements of postoperative ventilatory values of patients with OSA have been limited. Thus, the ability of a PACU nurse to make judicious clinical decisions regarding a patient's status is confined to clinical experience, knowledge, and the use of current monitoring instruments.

There are numerous ways to measure perioperative oxygenation and ventilation status. Pulse oximetry is an indirect measurement of ventilation status, and SpO₂ recordings can be

misleading when supplemental oxygen is used (Fu, Downs, Schweiger, Miguel, & Smith, 2004; Sivilotti, Messenger, van Vlymen, Dungey, & Murray, 2010). Arterial blood gas (ABG) provides an accurate assessment of ventilation, oxygenation, and metabolic demands, but is invasive, costly, and requires an arterial blood sample to run the analyses (Allan Klock et al., 2017). Capnography in the extubated patient provides excellent respiratory rate information (Gaucher, Frasca, Mimosz, & Debaene, 2012), but actual exhaled CO₂ partial pressures are prone to sampling error, especially with high supplemental oxygen flow rates, making it difficult to interpret values when devices are not placed in a closed system (e.g., endotracheal intubation).

To help overcome these measurement limitations of postoperative ventilatory status, a non-invasive impedance device, the ExSpirom™ Respiratory Volume Monitor (RVM) will be included with the existing monitors. The instrument measures tidal volumes and respiratory patterns, and calculates minute ventilation (Voscopoulos et al. 2013; Voscopoulos, MacNabb, Freeman, Galvagno, Ladd, & George, 2014). The monitor provides measurements of MV independent of supplemental oxygenation, use of facemasks, or peripheral tissue perfusion issues that can compromise other instruments/measurements.

Schumann et al. (2016) assessed the accuracy of the RVM in obese surgical patients. They synchronized the RVM intraoperatively and found the RVM to be very accurate. It had only a 0.13L/min measurement error and correlation of $r = 0.89$ against the ventilator data. The RVM can deliver continuous data on postoperative ventilation status providing feedback to the practitioner and the capability of alerting healthcare providers when inadequate ventilation is detected. Default limits are set to notify providers when MV volumes fall below 40 percent of the patients predicted MV ($P_{Pred} 40\%$). The monitor has been successfully used in the

perioperative setting assessing postoperative respiratory depression in an obese surgical population (Schumann et al., 2016).

Current postoperative monitors for assessing patients recovering from anesthesia provide beneficial information but have limitations. In the postoperative patient with OSA, standardized monitoring and assessment techniques may be insufficient identifying early changes in ventilation status before respiratory decompensation occurs. Finally, there is a gap in the literature regarding ventilatory responses (MV, TV) associated with NPPV application in the PACU setting. Having real-time feedback on ventilatory changes including the effects of NPPV in the PACU may increase our understanding of the benefits of NPPV devices in patients with obstructive airflow patterns. Recognition of ineffective ventilation before it becomes severely limited may lead to timely interventions to help increase gas exchange and attenuate the negative effects of obstructive airflow. Through implementing NPPV or other interventions, OSA patients may have improved ventilation and oxygenation, be more alert, and have reduced recovery times.

Conceptual Framework

The conceptual framework for respiratory ventilation patterns in OSA patients was depicted in figure 1 (Jordan et al., 2003). Grippi et al. (2015) noted the effects of sustained OSA ventilation patterns on various physiological processes. This physiological cycle is important to identify in any patient undergoing surgery. For those predisposed to obstructive airflow patterns (older, obese, male gender, larger neck circumferences) more sensitive instruments may be needed to determine when there is a reduction or cessation in airflow. A model noting the identification and attenuation of obstructed airflow is proposed (figure 2). As nurses are alerted to ventilatory alterations (signal from RVM) and nursing interventions (position changes,

verbal/tactile stimuli, NPPV therapy) are initiated, the airway can reestablish patency allowing for gas exchange. The net effects in the PACU setting include reduced CO₂ retention, a more awake/alert patient that can participate in their recovery process, and are ready for discharge earlier. If hypoventilatory states are missed, or not detected, worsening of ventilation may ensue requiring more invasive interventions and may lead to worse outcomes. The purpose for this study is to determine if obstructed airflow patterns correlate with OSA severity, and if these alterations are identified with the RVM before other standard monitors detect hypoventilation/obstructed respiratory patterns. The effects of CPAP therapy as an intervention will be measured directly with the ExSpirom™ monitor to demonstrate the reversal of impeded airflow with positive airway pressure.

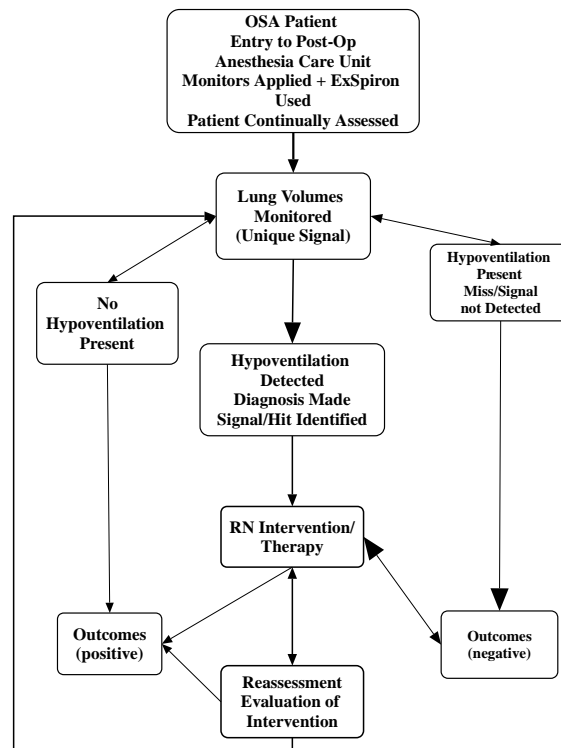


Figure 2: A conceptual model depicting identification of postoperative ventilatory changes. Large arrow depicting worsening outcomes from missed signal.

The central purpose is the appropriate identification of obstructed airflow patterns as demonstrated by hypoventilation or apneic breathing. As hypoventilation or obstructed patterns are identified and interventions are performed (CPAP application), the patient's CO₂ levels can be reduced. PaO₂ can increase and the airway becomes more open. This will improve ventilation and thereby gas exchange. The overall effect is improved level of alertness and overall minute ventilation, reduced PACU stay, and improved patient outcomes. If hypoventilation detection is missed or delayed, it is hypothesized that worsening airflow/obstructive patterns will ensue, increasing the patient's CO₂ levels and reducing oxygen to the tissues. The overall effects lead to delayed recovery, more aggressive interventions to regain a patent airway, and potential worsening patient outcomes.

The proposed research is intended to increase understanding of clinical data an RVM provides. By measuring minute ventilation, alterations in minute ventilation may be detected earlier than with standard monitoring devices to improve outcomes. Additionally, data will be correlated with OSA severity when NPPV is used in the postoperative setting.

Research Questions

Three research questions will guide the research study to address knowledge gaps regarding the effects of OSA on post-surgical patients and the role of NPPV application on their minute ventilation. The proposed study design will be a prospective observational correlational study of patients with known or suspected OSA, recovering gastric bypass surgery (GBS) (Roux en-Y or gastric sleeve) in the PACU of a major medical center in the eastern United States. The researcher will address the following questions:

1. Is there a difference in pulse oximetry recordings, respiratory rates, minute ventilation (MV) patterns, and PACU length of stay between OSA severity groups (mild vs.

moderate/severe), OSA history groups (previously diagnosed vs. no formal diagnosis), or NPPV use groups (NPPV vs. non-NPPV) as measured by the STOP-Bang and preoperative evaluation questionnaires?

2. What is the association of pulse oximetry recordings to respiratory parameters (TV, RR, MV) measured by the RVM?
 - a. Which monitor identifies changes in respiratory parameters earlier (SpO₂ recording 90-92% (moderate hypoxemia) lasting ≥ 1 minute while on oxygen at 2-4 liters/minute or a drop in a SpO₂ recording $\geq 4\%$ from baseline lasting ≥ 1 minute when no supplemental oxygen is used vs. RVM recording of a MV $<_{\text{pred}} 40\%$ (moderate hypoventilation)), and is the detection time difference significant?
 - b. When the RVM detects hypoventilation (MV $<_{\text{pred}} 40\%$) or apnea events (no detected RR > 10 seconds), are there associated changes in pulse oximetry (SpO₂ $< 92\%$ when on oxygen 2-4 liters/min or drop in SpO₂ $\geq 4\%$ from the preoperative SpO₂ lasting ≥ 1 minute when no supplemental oxygen is used)?
3. How does NPPV application affect MV (TV and RR)?
 - a. When NPPV is applied or removed, what are the MV volumes at 1, 5, and 15 minutes of use and/or removal, and is the volume change significant?
 - b. Is there a significant difference in the number of respiratory events (any recorded MV $<_{\text{pred}} 40\%$ value; any SpO₂ recording $< 92\%$ lasting ≥ 1 minute while on oxygen at 2-4 liters/minute, or any drop in SpO₂ $\geq 4\%$ from the preoperative SpO₂ recording lasting ≥ 1 minute when no supplemental oxygen is used) between participants who receive NPPV and those who do not during PACU recovery?

Significance

Future management of OSA requires additional research to identify specific outcomes of interventions provided in the perioperative setting. Gaps in research include: 1.) Determining best methods for assessing for changes in ventilatory patterns in patients suspected of or diagnosed with OSA. 2.) Understanding and/or anticipating patient variability and response to interventions and medications. 3) Identifying and developing specific practice standards for screening, monitoring, and managing patients with OSA. It is intended that this dissertation will demonstrate that an alternative method for monitoring ventilatory status in the PACU setting is effective for patients that are at a higher risk for postoperative ventilatory disturbances and that NPPV responsiveness may be measured directly to help guide additional postoperative therapies.

Five chapters compose this dissertation. Chapter 1 is the introduction and overview of OSA significance and perioperative management, theoretical framework of OSA ventilation patterns, and plans to explore research gaps of knowledge. Chapter 2 is the literature review of OSA severity and screening tools, current postoperative monitoring methods for ventilation patterns, and use of positive pressure airway devices as a supportive therapy. Chapter 3 describes the research methodology and proposed study. Chapter 4 is the results and data summaries, analyses, and interpretation of data. Chapter 5 is the concluding remarks and recommendations for solutions and additional research.

Definitions

Obstructive sleep apnea (OSA) is the physiological effect of reduced or obstructed airflow from collapsed posterior pharyngeal structures when simultaneous chest/abdominal exertions are noted (Cropsey & McEvoy, 2017; Moos et al., 2005). Symptomology may include snoring, gasping, nocturnal awakenings and disrupted sleep, increasing daytime sleepiness, weight gain, and a lack of energy. Physiological characteristics associated with increased OSA risk include

hypertension, male gender, and large neck circumference. Obstructive breathing patterns are measured and reported as an AHI index determining the events per hour, and correlating those to severity of OSA (Chung et al., 2016). Subjective assessments of severity will be scored using the STOP-Bang questionnaire with 1-3 yes questions categorized as mild, and >4 yes questions categorized as moderate/severe OSA (Seet & Chung, 2010; Schumann et al., 2016).

Hypopnea and apnea is a reduction (>50%) or cessation (>90%) of airflow in during sleep from the closure of the posterior pharyngeal dilator muscles despite the musculoskeletal effort of the diaphragm or chest wall. OSA is defined by "an apnea-hypopnea index (AHI) of 5 or greater" (Chung et al., 2014, p. 287).

Apneustic-hypopnea index (AHI) is the score given after a polysomnography sleep study calculated by measuring and averaging the hourly apneustic and hypopnea events per hour of sleep. There is a negative correlation: A higher AHI score correlates with a worsening OSA severity. AHI scores will be collected from the participant's electronic health record when applicable.

Non-invasive positive pressure ventilation (NPPV) can include any device applied to the mouth and/or nose to provide continuous or intermittent positive airway pressure to aid in dilating the hypopharyngeal structures and/or support ventilation. Devices include continuous positive airway pressure (CPAP) masks and intermittent positive pressure masks, typically bi-level positive pressure (BiPAP) masks or nasal prongs (Masa et al., 2015). Pressure settings will be collected from all participants who use CPAP/BiPAP at home.

Bi-level positive pressure (BiPAP) is a type of noninvasive ventilation device used to both stent open an obstructed airway and provide positive pressure to improve ventilation by increasing tidal volume. Settings are in cm H₂O and are adjustable. The higher pressure assists in

ventilation while the lower is set to stent the airway open. Both pressures are used in tandem to increase the depth of ventilation and open obstructive airways.

Continuous positive airway pressure (CPAP) is an airway device used to stent open an obstructed airway to reduce the collapsibility of the pharyngeal structures. CPAP devices include home or hospital designated devices. In the perioperative setting a disposable CPAP device is available (Boussignac CPAP) that provides CPAP at 5cm H₂O or 10 cm H₂O when corresponding oxygen flows are at 15 or 25 liters/minute.

NPPV compliance is the adherence of the participant to wearing a home pressure support mask to attenuate obstructive airflow patterns while asleep. Compliance will be noted “yes” if the participant is consistently wearing the mask >4 hours/night for three weeks prior to surgery.

NPPV application is the time and duration of NPPV use during the postoperative recovery period. The initiation, duration, and completion times of NPPV use will be extracted from the participant’s document flow sheet.

Minute ventilation (MV) is volume of gas exchanged through breathing in and out per minute time. MV is calculated using the following formula: (MV= respiratory rate x tidal volume), and reported in liters/minute. MV will be calculated by the ExSpironTM RVM from the continuous data collected of respiratory rates (RR) and tidal volumes (TV) calibrated against the anesthesia ventilator.

Mean minute ventilation is the average MV recorded during the PACU admission obtained from the RVM and matched to the patient record. Mean minute ventilation from the RVM monitor will be recorded at one and five minute intervals to calculate overall mean MV.

Hypoventilation is described as any period of inadequate gas exchange causing retention of CO₂. Common causes are respiratory depression from opioids, residual anesthetics or hypnotic agents,

airway obstructions or blockages, or any airway edema developing insufficient gas exchange (Allan Klock et al. 2017). Hypoventilation will be recorded when any minute ventilation data point measured is less than 40% of the predicted MV volume ($_{pred}40\%$) calculated from the participants gender, height, and weight (Voscopoulos et al., 2014).

Respiratory Events are observed or recorded adverse changes in MV or oxygenation during the PACU recovery period. A respiratory event will include any recorded MV $<_{pred}40\%$ value, any SpO₂ recording $<92\%$ lasting >1 minute while on oxygen at 2-4 liters/minute, or any drop in SpO₂ $\geq 4\%$ from the preoperative SpO₂ value lasting ≥ 1 minute when no supplemental oxygen is used.

PACU Time is overall time required for the patient to stabilize and meet discharge criteria set for patients in the PACU setting. This includes, having regular breathing patterns, stable hemodynamic readings, tolerable pain levels, and being able to protect their airway from obstruction and aspiration. PACU time is measured in minutes. It starts at PACU admission and ends when the patient has a Modified Aldrete Score $\geq 9/10$. PACU RNs record these time events in the documentation flow sheet (Hadzic et al., 2005).

CHAPTER 2: REVIEW OF THE LITERATURE

Much has been published in health professional journals about the impact of OSA on quality of life, healthcare management, as well as strategies to identify and manage patients with this diagnosis. Different expert professional organizations have conducted literature reviews to better understand screening, monitoring, and management strategies to reduce negative outcomes of patients with OSA in the perioperative setting. Research has demonstrated higher costs both in dollars and time, as well as increases in perioperative morbidity and mortality. However, there remains a lack of standardized approaches to screening, managing, and monitoring OSA in the perioperative setting. General guidelines have been suggested but practitioners and health systems remain responsible for individual acceptance and implementation of treatment strategies.

The purpose of this literature review is first, to review polysomnography as an OSA evaluation standard. Second, to evaluate the STOP-Bang questionnaire (SBQ) as an assessment tool for identifying OSA risk severity, and its potential usefulness in this research study.

The third objective is to review typical monitors used to monitor patients with OSA in the PACU. This will be followed by a review of a new machine called the ExSpiron™. It is an innovative impedance respiratory volume monitor (RVM) that directly measures respiratory rates and calculates ventilation patterns.

The final aspect of this review of literature is to examine the role of non-invasive positive pressure ventilation (NPPV) and its effects on postoperative ventilation. Several types of NPPV are available for use by patients in the home setting. These include CPAP and BiPAP full-face and nasal prong masks. NPPV is often used as an intervention for those diagnosed with moderate or severe OSA determined by PSG. It seems appropriate that healthcare providers would understand the function and use of NPPV in order to determine when the therapy is

working effectively. The use of postoperative NPPV therapy will be reviewed to identify the possible benefits of this therapy. The analysis of the literature will conclude with thoughts regarding the three focused areas and their relationship to the research proposal questions and design.

Preoperative Screening for OSA

OSA Screening

Literature suggests the importance of identification of OSA through screening tools. The "gold standard" is a polysomnography (PSG) sleep study that provides an apneustic/hypopnea index (AHI) (Abrishami, et al., 2010; Boese, et al., 2014; Chung et al., 2014). The averaged events per hour of sleep determine the AHI, with higher averaged events indicating greater OSA severity. An AHI ≥ 5 is a diagnostic result of the PSG for OSA. Screening for severity is determined as mild, moderate, or severe with corresponding averaged AHIs of 5-15, 15-30, >30 events/hour (Chung et al., 2016) confirmed by a sleep medicine physician. AHI score is often correlated with results from OSA questionnaires when available.

Individuals with moderate and severe OSA are often treated with NPPV. This requires proper fitting of a nasal or a full-face mask (CPAP or BiPAP) to assist in maintaining a patent hypopharynx, improving airflow during sleep. A second sleep test is then conducted to fit-test the mask and adjust pressure settings to open the closed airway, attenuate obstructive airflow, and improve sleep. The test, performed in an overnight sleep lab or with a home portable unit is the standard measurement tool for determining OSA severity. Limitations of PSG sleep studies include cost, time commitment, and participants willing to attend sleep studies and be compliant with wearing the NPPV device.

For those not participating in a sleep study, several types of screening questionnaires are available for diagnosing OSA severity (Chiu, et al., 2016; Chung et al., 2008; Dimitrov, & Macavei, 2016; Finkel et al., 2009; Wolfe, Pomerantz, Miller, Weiss-Coleman, & Solomonides, 2016), and identifying patients with potential airway problems (Abrishami et al., 2010; Chung, et al., 2014; Seet & Chung, 2010). The questionnaires assign risk of OSA and/or OSA severity based on responses and clinical measures obtained from participants. The results if utilized during preoperative evaluation may alert anesthesia providers of potential complications prior to surgery. Despite the usefulness and ease of the screening tools, no national standard for adopting or implementing them exist, leaving institutions to decide their best practice strategies. Additionally, screening tools available have variable degrees of sensitivity and specificity for predicting OSA (Chiu et al., 2016; Dimitrov, & Macavei, 2016). Most however have been validated against formal PSG. The STOP-Bang questionnaire (SBQ) has demonstrated an increased level of sensitivity in predicting moderate to severe OSA, when compared to the STOP, Berlin Questionnaire (BQ), and Epworth Sleepiness Scales (ESS) (Chui et al., 2016).

The STOP-Bang Questionnaire

The SBQ is one of the most commonly used preoperative screening tools for predicting OSA (Appendix C) (Seet & Chung, 2010). The eight-item instrument was developed by Chung et al. (2008) and based on similar questions to the BQ. The four initial questions comprised the STOP portion of the questionnaire. All questions accompany yes/no responses; with patients responding to ≥ 2 STOP questions with a “yes” are suggestive of having moderate OSA severity.

The tool was validated using patients from preoperative clinics in two metropolitan hospitals. A total of 2721 participants completed the STOP and BQ screening questionnaires for factor analysis of the 14 screened items. Researchers noted four factors comprised >95% of the

eigenvalues, having a loading factor greater than 0.3 (Chung et al., 2008). Pilot test results identified 27.5% of patients (679 of 2,467) as being at “high risk” of having OSA. Participants underwent PSG studies to validate the STOP questionnaire, with 177 (pilot and validation study) participants completing the STOP questionnaire and PSG study. Researchers used $AHI \geq 5$ as an OSA diagnosis and found 122 patients with OSA: 52 (29.4%) mild, 31(17.5%) moderate, and 39 (22.0 %) severe. Predictive parameters demonstrated the STOP score as having a sensitivity of 66%, specificity 60%, Positive Predictive Value (PPV) of 78% and Negative Predictive Value (NPV) of 44%. Sensitivity and NPV increased with comparative OSA severity screened with overnight PSG.

During a secondary analysis of individual parameters among different patient populations, Chung et al. (2008) noted four factors increased the predictive ability of the tool to detect moderate and severe OSA. These four additional factors included a BMI $>35\text{kg/m}^2$, age >50 years, male gender, and a neck circumference $> 40\text{cm}$. Four questions were added to the STOP tool to form the STOP-Bang questionnaire. Researchers then adopted the STOP-Bang screening questionnaire to increase tool’s sensitivity in predicting moderate to severe OSA risk.

Clinical benefits of this tool are ease of use, minimal time to complete the questionnaire, having only eight yes/no questions, and one measurement to be accomplished (Chung et al. 2008; Chung et al., 2012). Limitations include the importance of the participant and/or family members to understand and answer questions. Dimitrov and Macavei (2016) suggested that participants answering or having ≥ 3 “yes” responses to the STOP-Bang questionnaire may indicate an underlying undiagnosed OSA airway pattern. Suggestive OSA severity increases as more questions are answered "yes", increasing the sensitivity for predicting mild, moderate, or severe OSA.

STOP-Bang Utility

Additional research has been conducted to further validate the utility of the SBQ. Researchers have used the SBQ to screen for OSA severity, compare results against PSG and/or other questionnaires, and correlate screened risk to perioperative outcomes. The SBQ has been used in research, including patient populations undergoing CABG vs. abdominal (Nunes, Danzi-Soares, Genta, Drager, Cesar, & Lorenzi-Filho, 2016), gynecologic oncology (Bamgbade, Khaw, Sawati, & Holland, 2016), emergency (Chudeau et al., 2016), and bariatric surgeries (Proczko, et al., 2014; Schumann et al., 2016). Systematic reviews (Dimitrov & Macavei, 2016; Nagappa et al., 2015) and a meta-analysis (Chiu et al., 2016) have further validated the benefits of using the SBQ in screening patients for OSA severity.

Dimitrov and Macavei's (2016) review included 12 studies with varying sample sizes (n= 61-5342). Studies (10 case-cohort, 2 case-control, 7 retrospective, 5-prospective) categorized OSA risk high vs. low as a SBQ of ≥ 3 or ≤ 3 respectively. A SBQ ≥ 3 was associated with longer lengths of PACU stay, larger neck circumferences, difficulties with ventilation and/or intubations, and a higher likelihood of patients experiencing postoperative hypoxemia events (9% vs. 3%, $p = 0.012$). Nagappa et al. (2015) reviewed 17 studies (n= 9206) using SBQ. These studies correlated PSG with AHI ≥ 5 or respiratory desaturation index (RDI) ≥ 5 . Researchers noted their review was limited. Most of the studies involved only sleep labs and few surgical populations were included. Overall pooled SBQ sensitivity was 94% in sleep labs and 91% in surgical populations when SBQ of ≥ 3 was used as cut-off criteria. Researchers identified three additional factors important to identify with patients at risk of OSA when the SBQ is ≥ 2 . These included a "yes" response to questions: male gender, BMI $>35\text{kg/m}^2$, and neck circumference $>40\text{cm}$. For patients who have only a few "yes" responses to the SBQ, a serum bicarbonate level $>28\text{ mmol/dl}$ may indicate a high OSA risk.

Fernandez-Bustamante et al. (2017) retrospectively reviewed perioperative adverse respiratory events when screened by the SBQ. They found those who were not previously identified but screened and/or suggestive of being OSA positive (5.3%) had similar rates of adverse respiratory events (AREs) as those previously diagnosed (11.9%). However, they required additional respiratory interventions, hospital resources, an increased length of hospital stay, and had higher all-cause 30-day mortality. Researchers suggested participants may benefit from additional medical care and focused strategies to monitor and prevent AREs.

Xara, Mendonca, Pereira, Santos, and Abelha (2015) performed a matched-pairs study to identify AREs after general anesthesia in patients who had SBQ >3 vs. <3. Fifty-nine matched pairs were observed. The high-risk OSA group had larger BMIs, more gastric bypass procedures, higher incidences of co-morbidities, and significantly more AREs in PACU (39% vs. 9%, $p=0.001$). Of note, more patients designated as “high-risk” had difficulties breathing deeply, and increased mild to moderate hypoxia incidents. Researchers used moderate and severe hypoxemia cut-off values of SpO₂ readings (93%-90% or <90% on 3 liters of nasal cannula O₂ respectively) to correlate AREs with OSA severity.

Gokay, Tastan, and Orhan (2016) prospectively compared the BQ to SBQ for evaluating potential respiratory complications. Researchers used oxygen desaturations as one of the respiratory complications for comparison. Oxygen desaturations were defined as period of SpO₂ 90-95% for >1minute or <90% for >1 minute when O₂ nasal cannula flow was at 4 liters/minute. Sample size (n=126) included adults ≥ 18 years old with ASA physical class I-II undergoing cholecystectomy surgery. Researchers noted that the SBQ tool identified more female patients with high-risk OSA than the BQ. There was a relationship demonstrated between SBQ and the incidence of smoking, alcohol consumption, higher BMI scores, age, and male gender. In

contrast, BMI and age were associated factors with high OSA risk when the BQ was used. Study limitations included small sample size, a single institution study site, and inconsistent monitoring of respiratory complications after PACU discharge. Study strengths included participants undergoing the same surgical procedure and having the same evaluator in the PACU to identify respiratory complications. Authors suggested using the SBQ as the first-line screening tool for OSA risk assessment.

Chiu et al's. (2016) meta-analysis (108 studies) of the SBQ, STOP, BQ, and ESS screening instruments reported favorable results for the SBQ. All studies compared questionnaire risk assignment against PSG or RDI's. Despite high heterogeneity between the studies, there was low publication bias (using Deek's funnel plots). Studies were from several countries, and included sleep labs, surgical patients, and other populations. A random effects model was used to estimate sensitivity, specificity and diagnostic odds ratios. Overall the SBQ outperformed the other three instruments in detecting mild, moderate, and severe OSA with respective pooled sensitivities of 88%, 89%, 93%, with relatedly high response rates. Researchers noted limitations of the analysis related to low specificity values, possibly limiting the feasibility of the instruments use and increasing the risk of higher false positives, over treatment, and wasting resources/personnel.

STOP-Bang Limitations

A few studies have demonstrated that other instruments outperform the SBQ (Deflandre, et al., 2017), or were unable to correlate postoperative complications with OSA risk (Bamgbade et al., 2016). Deflandre et al. (2017) compared a new instrument (OSA-50) measuring only anthropometric data metrics, reducing subjectivity of answers to the SBQ and other developed instruments. There findings are promising but need additional research and validation.

Schumann and colleagues (2016) prospectively screened bariatric patients undergoing gastric bypass or abdominal surgery. OSA risk scores were assigned and validated against PSG when available. Participants (n =56) screened and assigned OSA risk groups (mild, moderate, or severe), had no significant difference in occurrence for postoperative apnea (POA) or postoperative respiratory depression (PORD) events. Overall, respective POA and PORD events were found to occur in 31% and 16.3% of participants in the PACU. A PORD event was noted when a measured minute ventilation rate fell below 40% of the predicted minute ventilation ($<_{pred}40\%$) value for at least 5 minutes. A POA event was defined as no detectable breaths noted by the respiratory volume monitor (RVM) for > 10 seconds. POA was determined to be positive when >5 apneic events/hour occurred during the PACU period. Researchers did not report the total number of POA or PORD events per patient/OSA group nor correlate pulse oximetry to the RVM event data. This suggests additional research opportunities are available. A better understanding of data healthcare providers receive from postoperative monitors to evaluate potential or real AREs should be explored, including which device can consistently alert providers to changes in ventilatory patterns.

STOP-Bang Questionnaire and Research Implications

The study findings by Schumann et al. (2016) may help elucidate the limitations of the SBQ in associating perioperative risks with the bariatric surgical population and possible confines of current PACU monitors. Despite any validated tool used to predict OSA severity, confounding effects of general anesthesia, sedatives, and opioids also exist. A screening tool can assign or predict risk but may not necessarily determine perioperative outcomes. Additional research is needed in bariatric and other surgical populations to further correlate OSA risk to postoperative AREs.

Researchers (Subramani, Singh, Wong, Kushida, Malhorta, & Chung, 2017) noted that individual OSA phenotypes may exist, including *low arousing* and *high arousing* threshold phenotypes that may benefit from sedatives (*low arousing*) or be at higher risk of AREs when opioids are administered (*high arousing*). Variable responses to changes in CO₂ when perioperative medications are administered may be seen (Lam, Kunder, Wong, Doufas, & Chung, 2016). Further research is needed to gain additional information into OSA variations as they relate to risk assessment and perioperative complications.

Most SBQ studies reviewed did not involve both screening/validation of the SBQ and correlating assigned risk to clinical outcomes. Researchers either validated the SBQ against PSG alone or in conjunction with other screening tools, or used the SBQ to assign OSA risk groups and correlate groups to perioperative events. Since the SBQ has been validated against PSG in many studies over the past 12 years, additional validation against PSG may not be warranted. However, Dimitrov and Macavei (2016) suggested additional research is needed in different surgical populations and surgical procedures (e.g. bariatric, cardiovascular, orthopedic, and general surgeries). Additional research in this area would be beneficial to stratify patient populations requiring more sensitive strategies to identify and prevent AREs. Despite classifying OSA severity and validating against a PSG, there are variations in individual responses to general anesthetics, opioids, and sedatives in the perioperative setting.

This review supports the utility of the SBQ in the research design. Participants' SBQ scores will be compared to postoperative respiratory ventilatory patterns as recorded by the RVM as was done in Schumann and colleagues (2016) study. Additionally, the RVM data will be compared to SpO₂ recordings in the PACU to correlate AREs against RVM data.

Postoperative Monitoring Methods for Ventilation Patterns

Patients with OSA can be more difficult to assess postoperatively with respect to their ventilation and oxygenation. Application of oxygen may mislead providers into a false sense of safety (Sivilotti, et al., 2010). Relying on and using the appropriate monitor or combination of monitors is needed to attenuate potential complications. Patients with OSA, like all patients, recover from the effects of intravenous and/or inhalational anesthetics in the PACU (Whitaker et al., 2013). But with OSA, trapping of gases (CO₂, inhaled anesthetics) from recurrent airway obstructions has the potential to occur more often. The obstructed airway coupled with increased CNS sensitivity to opioids and sedatives (Lam et al., 2016) may reduce the drive to ventilate, and compromise responsiveness. Subsequently, ensuing acidosis, somnolence, or ultimately an acute respiratory event can occur. Emergency interventions will need to be initiated to stimulate the patient's ventilatory drive, reverse sedative and opioid effects, and reestablish a patent airway.

Monitors used to assess changes in hemodynamic status are utilized perioperatively to improve patient outcomes, reducing morbidity and mortality. Monitors and tools specifically for assessing/measuring postoperative ventilation and oxygenation will be reviewed. The understanding and appropriate application of these devices aid in alerting healthcare providers to identify ventilatory changes and attenuate AREs.

Current Monitoring Devices

Because OSA patients are at a higher risk for respiratory depression, including periods of postoperative hypoventilation and apnea, higher levels of vigilance by PACU nurses are needed. First and foremost, clinical judgment and immediate observation of the patient by trained personnel should never be replaced by technology. Second, monitors to identify changes in ventilatory patterns should be utilized to attenuate respiratory complications. The tools used to

assess and monitor for variability are only as good as the observers understanding and appropriate use of them. Monitors and instruments have been developed to guide clinical decisions, provide imminent alarms of changes in physiological status, and provide data to confirm and analyze interventions (Applegate et al., 2016; Tweddell et al., 2014).

Typical monitors to assess patient's respiratory function in the PACU are pulse oximetry and capnography/end-tidal carbon dioxide (PETCO₂). An invasive assessment of ventilation and oxygenation includes arterial blood gas (ABG) analyses, and other blood analyses can assist in quantifying respiratory and metabolic changes related to ventilation and oxygenation. A novel noninvasive technique has been developed to calculate minute ventilation through chest wall impedance (Voscopoulos et al., 2013) and may provide additional information to help assess for ventilatory changes and responses to therapies.

Pulse Oximetry

Pulse oximetry (SpO₂) has been utilized for decades in perioperative, in-patient, and clinic settings. This monitor is the primary method of monitoring oxygenation, hypoxia, and pulse rate of patients in operating rooms and critical care units. The probe is disposable or reusable and non-invasive. The device indirectly measures hemoglobin saturation by passing two wavelengths of light (660 and 940 nm) through capillary tissue. Two common types of probes use light emitting diodes or reflective oximetry. They and can be applied over various sites, including the nose, ears, fingers, temporal forehead, and feet (Hess & Kacmarek, 2012).

Infrared and near infrared wavelengths used in pulse oximetry can produce misleading information. The technology is dependent on blood flow through capillary beds, hemoglobin concentration, skin pigmentation, temperature, and movement (Tweddell et al., 2014).

Historically, failure rate is below 5% (Freund et al., 1991), and increases above this level when a

patient's perfusion is compromised. This can occur more frequently in elderly, those with ASA status ≥ 3 , during prolonged surgical procedures, and after ingestion or inhalation of substances that compete with oxygen loading onto the hemoglobin.

Inaccurate placement of probes or movement can increase pulse oximetry false-alarm rates and may increase alarm burden and missed alarm events (Voepel-Lewis et al., 2013). The addition of oxygen via mask or nasal cannula can overestimate perceived respiratory function and is not correlated with end-tidal CO₂ levels (Sivilotti et al., 2010). Comorbidities such as OSA may lead to false interpretations of oxygenation and ventilation. Because of these limitations, indirect and incomplete analysis of pulse oximetry can occur, misleading providers to make inappropriate clinical decisions. Additional monitoring devices if implemented in the perioperative setting could potentially increase the ability of providers to identify subtle changes in ventilation.

Capnography

Capnography, or end-tidal CO₂ analysis, provides an additional monitor for ventilation assessment and layer of sensitivity in the perioperative setting. Clinical application of the device assists in identifying airway obstruction, esophageal intubation, and hypo/hyperventilatory states. Capnography sensitivity is increased when in-line measuring is performed, typically concurrent with endotracheal intubation (Sivilotti et al., 2010). A sample of ventilated gases is obtained through a collection line and analyzed by software spectrometry computing the fraction of expired CO₂. The data output produces a waveform (capnography) and numerical output in millimeters of mercury (mmHg) called capnometry. Capnography waveform moves along the x-axis on the screen for analysis. The waveform elevates from the baseline x-axis with expiration of mixed and dead space gases to a plateau phase representing expiration of alveolar gases to a

turn toward baseline when inspiration is initiated. An elevated baseline could represent rebreathing or exhausted CO₂ absorbent, and an upstroke of the plateau waveform may represent an obstructive airway pattern (Hess & Kacmarek, 2012).

Capnography and associated capnometry is closely equivalent to partial pressure of arterial carbon dioxide (PaCO₂) levels in healthy adults, but may be misleading or erroneous during ventilation/perfusion (V-Q) mismatches, hypotension, and inadequate ventilation of the lungs (e.g. OSA ventilation patterns after extubation) occurs. The result is an increased PaCO₂ to partial pressure of expired end-tidal carbon dioxide (PETCO₂) gradient greater than 3-5mmHg (Hess & Kacmarek, 2012).

Several other physiological changes in the cardiovascular system can alter capnography waveform output and thus affect the interpretation of results. These include metabolic changes, dysrhythmias, pulmonary vascular congestion, hypotension/hypovolemic states, pulmonary secretions, alveoli-capillary membrane changes, and obstructive or restrictive respiratory disease states. Despite potential errors from these influences, capnography is a standard monitor used in the perioperative environment. Anesthesia providers routinely use capnography during general anesthesia and intravenous sedation cases (Sivilotti et al., 2010). Capnography is also utilized in the PACU setting (Kasuya, Akca, Sessler, Ozaki, & Komatsu, 2009) when warranted.

Capnography analyses have been utilized in the postoperative setting when patients are admitted with endotracheal or laryngeal mask airway devices in place. PETCO₂ sampling is obtained in an in-line fashion and numerical and/or waveform recordings can be measured and evaluated. The added benefit of this monitor is it displays a respiratory waveform and rate providing a relatively consistent indication of ventilation status, even with variable oxygen flow

(Kasuya et al., 2009). Despite possible ventilation-to-perfusion (V-Q) mismatch, capnography and PETCO₂ monitoring provides additional information that may increase patient safety.

Anesthesia providers infrequently use capnography in the PACU as most patients are extubated prior to admission and direct measurement of expired gases is not possible. Products have now been designed to provide CO₂ analysis when patients have an oxygen facemask or nasal cannula. Within these devices, multi-sampling, and micro-stream CO₂ sampling ports are included to increase accuracy of waveform analysis (Hess & Kacmarek, 2012).

Postoperative capnography monitoring may be limited or inadequate in patients with OSA. There is an increased ventilation-to-perfusion (V-Q) mismatch as obesity and OSA worsens, and narrowing of small airspaces in the recumbent position becomes more profound. Pulmonary changes increase air trapping and airway collapse, and may lead providers to underestimate PaCO₂ approximations based on observed PETCO₂ output. Additionally, masks and cannulas can become clogged with condensation or secretions resulting in inaccurate readings. Home or hospital NPPV masks can irritate patients, and may not be applied appropriately when used (Hess & Kacmarek, 2012). Kasuya et al. (2009) suggested patients who are obese and diagnosed OSA positive, should receive postoperative ventilation monitoring using capnography that includes an oral sampling port to reduce the PaCO₂-PETCO₂ gradient.

ABG Analysis

ABG analysis is considered a “gold standard” test, and provides clinicians with accurate measurements of patient’s oxygenation and ventilation status. A patient’s CO₂, acidosis, bicarbonate, and oxygenation levels can be measured. This measurement tool is used for intraoperative management and assessment of ventilation and perfusion changes in

cardiothoracic and other surgical procedures where anesthesia providers are concerned about V-Q changes, large blood losses, and changes in tissue perfusion and oxygenation.

Postoperatively, ABG analysis can be used to quantify the severity of hypoxemia, hypoventilation, and V-Q mismatch to help clinicians determine a course of action (Maddox, Oglesby, Williams, Fields, & Danello, 2008). However, ABG analysis comes with a cost, both monetarily (as an additional invasive procedure requiring an arterial sampling) and as a use of time and additional resources to process the sample. It does not provide immediate assessment of the patient's status but does deliver a direct evaluation of invasive and noninvasive interventions implemented to improve oxygenation, ventilation, and perfusion.

ABG analysis as an initial intervention to guide therapy may not be warranted. See, Phua, and Mukhopadhyay, (2009) found no clinically significant differences in ABG analysis after extubation in the ICU to help predict those who would require reinstitution of respiratory support measures. Bingol, Pihtili, Cagatay, Okumus, and Kiyani (2015) found no added benefit of ABG interpretation when screening for the severity of Obesity Hypoventilation Syndrome in patients with OSA. Instead, the authors found serum bicarbonate ≥ 27 mmol/L with a SpO₂ <80% as predictive screening factors. Perioperative ABG analysis is useful when available but should be reserved as a secondary tool and to corroborate output of less invasive monitors.

ECG Respiratory Monitoring

Respiratory impedance analysis is not new technology. In the perioperative setting, the application of special ECG electrodes that have capabilities to interpret changes in chest wall movement can compute and display a respiratory waveform. Special monitors can be set to notify healthcare providers of apneic periods, or where no chest movement is detected (Helfenbein, Firoozabadi, Chien, Carlson, & Babaeizadeh, 2014). A benefit of ECGs with

respiratory impedance monitoring is its portability for use in remote locations. ECG impedance monitors are incapable of quantifying the depth and volume of respirations. Electrodes may become dislodged, inappropriately placed, limiting its usefulness. Patients with OSA commonly have higher BMIs increasing the likelihood of altered lead placement limiting the accuracy of identifying changes in chest wall movement.

Respiratory Minute Ventilation Monitor

Improving upon the ECG respiratory impedance concept, an innovative instrument has been developed. The ExSpirom™ is a FDA approved respiratory volume monitor (RVM) developed by Respiratory Motion Inc. (located in Watham, CT). The RVM continuously measures tidal volume and respiratory rates, and calculates a minute ventilation value. The monitor records the data and provides immediate numerical feedback of patients' ventilatory status and plots respiratory patterns on a bedside monitor. The device may provide an additional layer of safety in identifying changes in ventilatory patterns, allowing anesthesia providers and PACU nurses to attenuate AREs before they occur. The RVM may be beneficial in monitoring patients with a variety of pulmonary co-morbidities.

Special electrodes are placed on the patient's skin and are connected to a strip that attaches to the RVM. The electrodes are adjustable and can accommodate variable chest girths, reducing measurement error in patients with higher BMIs. This is an advantage over earlier ECG impedance devices as described above. Proper electrode placement for the device is the mid-axillary line at the level of the xyphoid and along the sternum forming an L-shape. The RVM has been tested in a variety of clinical settings against calibrated spirometry systems monitoring both passive and obstructive respiratory patterns (Voscopoulos et al., 2013).

Once connected to the patient, the RVM is calibrated against a measured ventilation value, obtained from either a mechanical ventilator or an oral spirometer with concurrent nasal obstruction (Voscopoulos et al., 2013). Calibration coefficients for each patient are stored in the monitoring device itself. This is advantageous as electrodes can become damaged or require temporary removal. The RVM has the capability of being zeroed to a patient's baseline ventilation rate or calibrated as described above and measured against a known algorithm for height, gender, and age. The non-calibration feature is helpful when a patient undergoes sedation or neuraxial anesthesia and a spirometer not available.

Williams, George, Harvey, and Freeman (2016) compared the RVM against capnography and found while both respiratory rate patterns correlated, the RVM detected changes in ventilation patterns earlier than capnography. Ventilation patterns provided by the RVM give more accurate assessment of patients' ventilatory status and can be used in the extubated patient when spirometry cannot be obtained.

ExSpirom™ technology apprises healthcare providers with an additional layer of information beyond pulse oximetry and capnography. Point of care information about interventions affecting minute ventilation, tidal volume, and respiratory rates can be measured. In patients with OSA, researchers (Schumann et al., 2016) found no difference between respiratory rate recording and manual counting, and that BMI had no significant effect on the accuracy of MV and TV ($P > 0.6$) measurements. Obstructive breathing patterns were detected with this technology and were confirmed against a closed-cell spirometer. The RVM measured artifact "to be in the range of anatomic dead space" providing clinicians with an early warning of respiratory obstruction (Voscopoulos et al., 2013, p.7).

Recent clinical applications of the RVM include measuring and quantifying ventilatory changes during surgical procedures where hypnotics and opioids are administered. Effects of medications were quantified and subsequent doses adjusted (Ebert, Middleton, & Makhija, 2015). The RVM has also been used to measure changes in ventilation in the PACU after opioid administration (Voscopoulos et al., 2014). This has important clinical implications as those who develop a reduced MV (below a set threshold) or an obstruction after opioid administration can be identified. Appropriate interventions can then be initiated to improve their ventilatory states. The goal is to identify and reduce postoperative respiratory events before PACU discharge.

Patients with co-morbidities including OSA, require closer monitoring for changes in ventilation. Earlier detection of ventilatory changes using the RVM may be possible to decrease the incidence of perioperative AREs. The RVM could be used in conjunction with other standard monitors, and help provide an immediate assessment of alterations in respiratory rate and depth. The RVM can inform anesthesia providers about subtle changes in ventilation patterns. Providers can then use the data to initiate interventions to reverse respiratory depression and obstruction. Clinical applications in other populations have demonstrated its usefulness (Ebert et al., 2015; Holley et al., 2016).

Few potential limitations may preclude the use of the RVM. These include occlusive dressings over monitoring sites, and rare allergic reactions to the electrode adhesive. Fortunately electrodes do not irritate the skin, can be removed, and reapplied (Voscopoulos et al., 2013) when needed. The monitor is portable and can be transported with the patient to various settings increasing the usefulness for continuously monitoring patients' ventilatory patterns.

Instruments to Guide Practice

Advances in technology of monitors have allowed clinicians to assimilate information and make more informed decisions to guide patient care. In the PACU setting, there are a variety of constraints and pressures affecting patient outcomes. Patient co-morbidities, staffing workload/assignments, clinical experience, and case types all have their toll (Whitaker et al., 2013; Street et al., 2015) on providing quality and safe care. The goal of identifying and using effective monitors is to determine when, how long, and for what purposes are they applied and used (Tweddell et al., 2014). After a review of articles regarding perioperative monitors, specifically for examining respiratory status and for patients with OSA, no clear recommendations were found. The ASA and other perioperative professional organizations (Chung et al., 2016) have provided data about the severity of OSA and perioperative strategies to screen, manage, and monitor events. Without specific clinical guidelines, institutions are left to formulate their own protocols.

Monitoring acute respiratory changes in a deteriorating patient with co-morbidities is essential. Basic monitors should include ECG, non-invasive blood pressure, and pulse oximetry. Trained nurses and anesthesia providers should not be substituted for any monitor and all personnel must be oriented to and trained to manage patient changes and make timely interventions. The ExSpiron™ could be used on patients prone to respiratory events where increased vigilance in monitoring is needed, especially patients with OSA or obstructive airway patterns.

OSA and Newer Monitoring Devices

The development of innovative monitors and advanced measuring techniques within the last several decades (Sivarajan & Bohn, 2011) has increased patient safety and improved

perioperative outcomes (Tweddell et al., 2014). The increased incidence and impact of OSA in the surgical setting (Moos et al., 2005; Schumann, Brayanov, Gupta, & Bonney, 2015) necessitates nurses and anesthesia providers to apply current technology with the goal of reducing morbidity and unintentional harm. Including the ExSpirom™ as an additional monitor for postoperative nurses may allow for early detection of ventilatory changes and reduce potential errors in assessing patients' respiratory status.

The ExSpirom™ provides clinicians in the perioperative setting an opportunity to measure and assess both respiratory rate and depth. This RVM monitor provides an added level of information that is independent of the application oxygen. Pulse oximetry is limited in detecting hypoventilation when supplemental oxygen is used, and cannot be used as a measure of ventilatory status when oxygen is needed. Capnography is dependent upon continuous airway sampling. The reliability of this can be compromised by obstruction of sampling lines, rapid shallow breathing, and alterations in patient positioning. The RVM does not have the limitations that pulse oximetry and capnography have. When added to basic monitoring techniques, RVM has the ability to detect subtle ventilatory changes in a decompensating patient with or without OSA. This may allow nurses and anesthesia providers to make timely interventions to preclude re-intubation, respiratory failure, and unanticipated admission to an ICU. The RVM should be evaluated in other settings and more fully with patients diagnosed with and without OSA to gain additional insight into further applications. Additional benefits may include determining the effectiveness and change in ventilation when NPPV (CPAP/BiPAP) support is applied and ventilatory changes when opioids are administered to patients susceptible to AREs.

NPPV in the Postoperative Setting

NPPV therapy after OSA diagnosis for moderate and severe OSA is the application of a CPAP mask or BiPAP mask (Antonescu-Turcu & Parthasarathy, 2010; Brousseau et al., 2014). Patients with OSA and using home CPAP/BiPAP are instructed to bring it on the day of surgery. Kohler et al. (2010) noted from prior studies that when patients use CPAP at least 3.5-4 hours nightly, subjective sleepiness and cardiovascular effects of OSA improve.

Postoperative NPPV application is usually secondary to other interventions (positioning, oxygen therapy, and physical/verbal stimuli) used to maintain oxygenation and ventilation. Other clinical limitations to NPPV effectiveness are a lack of standardized orders for timing and duration of application. Additionally, patients with OSA who are not comfortable with NPPV or are undiagnosed formally may resist postoperative application due to discomfort (Paje & Kremer, 2006) and irritation. Therefore preoperative screening and patient and provider education is needed (Porhomayon, et al., 2013) if postoperative NPPV is to be a successful intervention.

NPPV Literature Findings

Research articles were reviewed regarding the use of NPPV (CPAP or BiPAP) in the postoperative setting for patients with OSA. Eleven articles were identified. Unique articles, including five retrospective studies, four randomized control studies, and two clinical case reports were reviewed. The results of research findings were limited, but promising (Del Campo Matias et al., 2008; Liao et al., 2013; Liao et al., 2009; Meng, 2010; Porhomayon et al., 2013; Shearer, Magee, Lacasia, Raw, & Kerrigan, 2013). The review was conducted to investigate NPPV use in patients with OSA and postoperative outcome measures used to reduce morbidity and mortality.

Prospective Research Findings

Gaszynski, Tokarz, Piotrowski, & Machala (2007) performed a small randomized prospective study (n=19) assigning morbidly obese patients for elective gastric bypass surgery to receive CPAP or nasal cannula postoperatively. They found that CPAP application resulted in more alert and better-oxygenated patients compared to the control group, with the control group experiencing more oxygen desaturations, and increased work of breathing. ABG samples were obtained at four time intervals for comparison. Patients who received CPAP had no complications related to the positive pressure therapy. Limitations of the research included small sample size, and the fact that CPAP users were allowed to remove their mask up to 30 minutes for discomfort.

Laio, et al., (2013) conducted a prospective randomized trial (n =100) of patients with SBQ ≥ 3 with a history of OSA who did not use CPAP at home. Participants with PSG AHI ≥ 15 were randomized into control and CPAP groups. Automated positive airway pressure (APAP) devices were initiated for overnight use two to three days preoperatively and postoperatively for five nights. Researchers found APAP improved the quality of sleep. APAP users reduced their AHI rates from a mean of 30 down to 3 events/hour ($p = 0.001$), while the control group had no improvement in AHI scores ($p = 0.302$) or desaturation indexes on postoperative day 3. This is significant as the percentage of REM hours can increase postoperatively as sleep interruptions and hours of fragmented sleep increase. APAP users reduced their AHI at postoperative day 3 indicating a possible benefit of consistent use pre- and post-operative NPPV therapy.

Nigelin et al. (2009) prospectively demonstrated the effects of CPAP application using the Boussignac CPAP (BCPAP) mask postoperatively in laparoscopic gastric bypass patients (n = 40). The controls group received six-liters/minute nasal cannula oxygen and intervention group had the BCPAP mask applied upon extubation. Oxygen flow at 25 liters/min was used to

approximate 10cm H₂O CPAP pressure. BCPAP therapy was paused after one hour to perform spirometry testing. BCPAP was then restarted and continued for the remainder of PACU stay and continued on the postoperative night. A generalized linear model was used for direct comparisons and τ -tests at the time point measurements. Baseline spirometry values were comparable. After the first postoperative hour there were significant differences between groups in their spirometry results. The BCPAP group had clinically and statistically sustained preservation of preoperative respiratory function. They also reported that patients with BCPAP application were more alert and had improved FEV1/FVC average scores compared the control group.

A prospective Canadian study involved bariatric surgical patients >18 to 75 years of age, ASA class I-II (n = 81). Researchers reported that ABG analyses postoperatively were improved with BCPAP use compared to patients with venturi mask application (Wong et al., 2011). They also noted improved pulmonary function values and lower titrated oxygen rates in the BCPAP without any patient intolerances facemask application. Pulse oximetry saturations were maintained at $\geq 92\%$. Strengths of the study included blinding of groups to anesthesia providers, and standardized intraoperative anesthetic management. To increase participants' compliance with the intervention, preoperative education was conducted regarding mask application, including potential face and airway irritation from masks and oxygen therapies. Their study limitations included a relatively small sample size and single site study. Researchers suggested additional studies are needed, including applying BCPAP therapy to various surgical patient populations.

CPAP Study Implications

In this review of the literature, relatively few prospective studies involving NPPV application in the PACU setting were found. None assessed actual minute ventilation or changes in ventilatory patterns as NPPV was applied and/or discontinued. Researchers provided suggestions for future research that included performing additional prospective randomized control studies with larger populations, involving multiple case types, and obtaining direct measurements of CPAP on minute ventilation during its use. Chung, Nagappa, Singh, and Mokhlesi's (2016) review of the literature on CPAP use, reconfirmed previous findings. Some of their suggestions included identifying better assessment tools and strategies for identifying patients with OSA before they experience respiratory depression, and to conduct studies regarding postoperative monitoring procedures.

NPPV (CPAP and BiPAP) application will be observed in the postoperative setting. Participant's minute ventilation and oxygen saturations will be measured continuously to identify changes in ventilatory status when this intervention is initiated or discontinued. Previous research suggests that ventilatory patterns should improve when NPPV is administered, but the discrete changes (percent change, and absolute volumes) have not been studied to date.

Summary

Findings in the literature support the research questions. OSA severity can be screened and categorized as mild, moderate, or severe as measured by the SBQ. The tool has been widely used and is simple to complete in the preoperative setting. Many studies used a cut off score of 3-4 to differentiate between moderate and high risk OSA severity (Dimitrov & Macavei, 2016; Schumann et al., 2016). This will facilitate in comparing groups to perioperative outcomes, particularly ventilatory patterns including TV, MV, and POA/PORD events. Standard monitors

will be used and recorded on all patients, as is hospital protocol. These include ECG, pulse oximetry, and non-invasive blood pressure to assess for changes in cardiopulmonary status and alterations in ventilation and oxygenation. Desaturation indexes can be identified as a $\geq 4\%$ decrease in baseline oxygenation or $SpO_2 \leq 90$ or 92% (Fernandez-Bustamante et al., 2017; Xara et al., 2015). The RVM monitor will be used to compare TV, MV, and POA/PORD events (Schumann et al., 2016) to pulse oximetry readings and changes associated with use of NPPV, as this has not yet been observed.

Studies have demonstrated patients benefit from NPPV application (Gaszynski, et al, 2007; Liao et al., 2013; Nigelan, et al., 2009; & Wong et al., 2011). Some associated improvements include improved oxygenation and ventilation, reduced AHI indexes over time, and reduced oxygen desaturation events. While spirometry has been used to measure changes pulmonary function, the test requires patient cooperation, and may be diminished when opioids and other medications are administered. To increase the understanding of the direct effects of NPPV therapy on patient's ventilatory patterns, the RVM will be used postoperatively, as it has the ability to continuously measure tidal volumes and respiratory rates, and calculate minute ventilation (Voscopoulos et al, 2013; Voscopoulos et al., 2104). The machine will be calibrated to the anesthesia ventilator and be used throughout the PACU period. The goal is to identify ventilatory changes when any type of NPPV therapy is initiated or discontinued to further understand the benefits of this intervention.

The review of the research identified the potential benefits of implementing a standardized tool to identify and assign potential risk in many populations. But assignment of risk does not always correlate with actual patient outcomes. Innovative instruments such as the RVM may provide additional objective data about OSA patients' ventilatory patterns that may be

associated with administration of perioperative medications and NPPV therapy. Limitations of this review include the paucity of current prospective studies of NPPV application in the immediate postoperative setting, and the benefits of RVM monitoring in other surgical populations.

CHAPTER 3: RESEARCH DESIGN

Background/Significance

The review of the literature supports further inquiry into postoperative ventilation monitoring for obstructive sleep apnea (OSA) patients and understanding the direct effects of NPPV (CPAP or BiPAP) therapy. The purposes of this study were to:

1. Determine the differences in postoperative ventilation patterns of participants screened and categorized by the STOP-Bang Questionnaire (SBQ) as “mild” or “moderate/severe” risk for obstructive sleep apnea (OSA).
2. Determine the correlation of hypoventilation events or apnea events measured by the respiratory volume monitor (RVM) versus continuous pulse oximetry recordings (SpO₂).
3. Examine the effects of NPPV (CPAP/BiPAP) application on ventilation status.

Using this modality to monitor ventilation, it was theorized that postoperative hypoventilation, respiratory depression, and apnea events would be identified earlier than with the use of other standard PACU monitors. This study assessed the effectiveness of the RVM to detect and measure ventilatory changes in participants with OSA undergoing bariatric gastric bypass surgery. Participants undergoing gastric bypass surgery (GBS) diagnosed or suspected of being OSA positive were used to explore the research questions. The RVM was used to correlate OSA severity risk (from SBQ) to ventilatory changes, pulse oximetry output, and to identify changes in ventilatory patterns as NPPV (CPAP/BiPAP) therapy was administered and discontinued.

Research Questions

1. Is there a difference in pulse oximetry recordings, respiratory rates, minute ventilation (MV) patterns, and PACU length of stay between OSA severity groups (mild vs.

moderate/severe), OSA history groups (previously diagnosed vs. no formal diagnosis), or NPPV use groups (NPPV vs. non-NPPV) as measured by the STOP-Bang and preoperative evaluation questionnaires?

2. What is the association of pulse oximetry recordings to respiratory parameters (TV, RR, MV) measured by the RVM?
 - a. Which monitor identifies changes in respiratory parameters earlier (SpO₂ recording 90-92% (moderate hypoxemia) lasting ≥ 1 minute while on oxygen at 2-4 liters/minute or a drop in a SpO₂ recording $\geq 4\%$ from baseline lasting ≥ 1 minute when no supplemental oxygen is used vs. RVM recording of a MV $<_{\text{pred}}40\%$ (moderate hypoventilation)), and is the detection time difference significant?
 - b. When the RVM detects hypoventilation (MV $<_{\text{pred}}40\%$) or apnea events (no detected RR > 10 seconds), are there associated changes in pulse oximetry (SpO₂ $< 92\%$ when on oxygen 2-4 liters/min or drop in SpO₂ $\geq 4\%$ from the preoperative SpO₂ lasting ≥ 1 minute when no supplemental oxygen is used)?
3. How does NPPV application affect MV (TV and RR)?
 - a. When NPPV is applied or removed, what are the MV volumes at 1, 5, and 15 minutes of use and/or removal, and is the volume change significant?
 - b. Is there a significant difference in the number of respiratory events (any recorded MV $<_{\text{pred}}40\%$ value; any SpO₂ recording $< 92\%$ lasting ≥ 1 minute while on oxygen at 2-4 liters/minute, or any drop in SpO₂ $\geq 4\%$ from the preoperative SpO₂ recording lasting ≥ 1 minute when no supplemental oxygen is used) between participants who receive NPPV and those who do not during PACU recovery?

A prospective observational study was conducted to explore the relationship between

OSA severities in participants recovering from laparoscopic gastric bypass surgery (GBS) in the PACU to select postoperative outcomes. Specifically, the relationships between TV, RR, & MV calculated from the ExSpiromTM respiratory ventilation monitor (RVM), time to discharge from the PACU, and the effects of NPPV in the PACU were explored.

This study sought to identify relationships between OSA screened severity and recorded variables detecting hypoventilation in the PACU (pulse oximetry and minute ventilation data). The effects of NPPV therapy on minute ventilation were measured using an innovative respiratory volume monitor (RVM) as a method for identifying and improving ventilatory outcomes. The study used a consecutive convenience sample of participants consented for RY or GS surgery.

Population and Sample

In estimating sample size, one aspect of the study was determining the feasibility (Leon, Davis, & Kraemer, 2011) of the RVM instrument for measuring MV changes when CPAP was used. Schumann et al. (2016) explored the relationship between OSA severity and postoperative respiratory depression (PORD) and postoperative apnea (POA) events. Sample size for their study was 80 participants divided into mild (n =12), intermediate (n =25), and high (n = 43) OSA risk. They found no “statistically significant differences” (p. 297) among groups regarding frequency of PORD and POA events. Despite these findings, PORD and POA events occurred in all groups (8-40%). Their study provides a basis for further inquiry. What was not addressed was the correlation of arterial blood gases or SpO₂ analyses when these respiratory events occurred. In this research the sample participants were divided into mild vs. moderate/severe OSA groups to explore the relationships among the data.

Leon et al. (2019) noted that the nature of pilot studies should not be used to estimate

population effect size, instead a “clinically meaningful effect” (p. 5) should be sought. In estimating pilot study sample size, Hertzog (2008) suggests a population sample of 40 to 50 for two groups is sufficient to perform independent τ -test with a probability of detection of differences 0.80, and an $\alpha = 0.05$ between groups. A minimum sample of 50 participants were sought for this study ($n= 25$ in each group). It was estimated that six to eight laparoscopic gastric bypass cases were scheduled weekly at the data collection site.

Inclusion criteria: Male and female English-speaking surgical candidates ≥ 18 years of age scheduled for general anesthesia for GBS (Gastric Sleeve (GS) or Roux en-Y (RY)) surgery, having a BMI of ≥ 35 , answering “yes” to at least one STOP-Bang question (Appendix C), and willing to consent and participate.

Exclusion criteria: Participants who were not extubated after surgery, unable to give informed consent, and/or unwilling to be monitored with the ExSpiron™ RVM machine.

Participant recruitment was continued until at least 25 participants’ data was collected in each OSA severity group (mild and moderate/severe with SBQ ≤ 3 or ≥ 4 respectively). Dichotomous classification for OSA severity was based on previous literature findings (Chudeau et al., 2016; Dimitrov & Macavei, 2016; & Nagappa et al., 2015) where there was a consistent higher sensitivity for OSA related complications with higher SBQ scores. Schumann et al. (2016) used similar cut-off points for grouping OSA risk. A SBQ cut off score of 3 to differentiate mild from moderate/severe OSA risk was used for group selection.

Participant selection was used to assist in controlling for confounding variables and improve homogeneity during data analyses. All participants had surgery performed by the same surgical group in the same facility, and recovered from general anesthesia in the same PACU. The ExSpiron™ RVM was previously used in an orthopedic surgical population with patients

over 65 years of age undergoing total joint replacement to monitor for postoperative respiratory depression. There were six RVM monitors available, which made it feasible to use the equipment, and required no modification for applying it to the research population.

Participant Recruitment

Potential participants from a bariatric surgical clinic of two surgeons who performed their surgeries at the same large hospital in southeastern United States were recruited. Participants underwent gastric bypass surgery from a single practice and were recruited for the study to reduce confounding variables, increase homogeneity of sampling, and provide a sample where results were used as a cause for further inference. The nurse manager at the surgeons' office was asked to give those scheduled for GBS a brochure describing the research study (Appendix E). The brochure included a brief explanation of the research purposes and to alert participants that the PI would meet and talk with them about the study on the morning of their scheduled surgery.

Informed Consent

The PI met all potential participants in the preoperative area and fully explain the research study. Participants were given a copy of the informed consent and HIPPA privacy authorization to read and sign (Appendix F) after inclusion criteria was confirmed. Participants were given an opportunity to ask questions and then sign consent for the study including a HIPPA form for privacy per IRB policy. Preoperative questions were asked using the SBQ and "OSA and Bariatric Preoperative Data Sheet" (Appendix G). Participants received a duplicate signed consent and HIPPA form. Copies of participants' consents and HIPPA forms were uploaded into their electronic record per IRB policy. Paper documents and consents were filed and kept in locked cabinet in ECU College of Nursing Office 3110.

Data Collection

After obtaining consent, the PI completed the preoperative assessment and obtained physiological and demographic data on participants. Additional baseline data and preoperative information was extracted from the EHR and placed into REDCap (Appendix G) on the day of surgery. Preoperative information included preoperative medications, age, weight, height, and co-morbid conditions (e.g. cardiopulmonary issues, endocrine disorders, BMI, and OSA history), and diagnosis of OSA. All participants were assigned an identification number at time of inclusion to match additional data collection sheets.

Perioperative data was collected after surgery from the EHR record and during the participant's PACU recovery period. Information collected (Appendix H) included: Perioperative times; post extubation support of the airway; intraoperative opioid(s) type(s) and doses administered; neuromuscular, opioid, and benzodiazepine antagonist medication type(s) used; and opioid(s) type(s), dosage(s), and times administered in the PACU. Additional perioperative data collected at PACU discharge time included the time in minutes when the patient met PACU discharge criteria.

Postoperatively, the PI observed and recorded pulse oximetry and RVM data, and NPPV use times and settings on the "OSA and Bariatric Sx Postoperative Event & Vital Signs Log" (Appendix I). This allowed the PI to measure changes in MV when NPPV was applied or removed, and record respiratory events and related MV and pulse oximetry output.

All collected data was stored in REDCap, an IRB approved storage site that performs encryption and de-identification of stored data. A laptop was used to input data, capturing SpO₂ and RVM recordings as NPPV is used in the PACU. Paper forms were printed and used as a back-up data collection method (Appendices G, H, & I) if there were issues with entering data electronically. Copies of consents were uploaded and stored per IRB policy. All paperwork

was stored in a locked box at the PI's office when not being used. After completion of the study, all paper versions of identifiable PHI was secured and stored in a locked cabinet until forms are able to be shredded/destroyed per IRB policy. PHI is kept on file in REDCap for future questions or issues related to this study or for additional research. A de-identified data set was extracted and used for data analyses and reporting of findings.

Setting

Study location was the perioperative surgical department at large medical center in the eastern United States. The study was conducted during participants' preoperative admission, surgery, and PACU recovery periods. Prior to study initiation, PACU RNs and nurse managers, and anesthesia providers received information on the study design and purpose. A study summary sheet (Appendix J) was distributed to PACU staff and anesthesiologists.

Study Procedure

Preoperative Setting

On admission to the preoperative area, participants were interviewed, and informed consent was obtained. Each participant was assigned a number for matching data in the REDCap system. The following information will be asked by the PI and collected at time of consent and entered into REDCap (Appendix G):

1. Height, weight, BMI calculations.
2. STOP-Bang Score. Participants were screened and categorized as low or moderate/severe OSA via the SBQ assessment score, 1-3, or ≥ 4 "yes" answers respectively.
3. Diagnosis of sleep apnea and AHI scores.
4. NPPV type and settings if used at home.

5. Physical and medication histories including co-morbidities (hypertension, diabetes, asthma, orthopnea, dyspnea on exertion, or chronic obstructive pulmonary disease).

Intraoperative Setting

The anesthesia provider transported participants to the OR for their scheduled surgery and continued with standard anesthesia induction and intubation. Surgical preparation of the participant and surgery proceeded in a standard manner. Before extubation in the operating room, electrodes were placed on the participant's chest for calibration of the RVM. The PI entered the participant's height, weight, age, and gender into the RVM machine before calibration. Electrodes were connected to the RVM machine and a calibration of the RVM to the ventilator occurred. This configured the calibrated MV thresholds for postoperative monitoring. If there was an error in the calibration or unusual reading or error entering the data on the RVM, the machine was recalibrated to the ventilator. The RVM continuously measured ventilation patterns and alarmed when minute ventilation fell below 40% of the participants predicted MV values ($_{pred}40\%$) calibrated to the participant's gender, height, and weight (Schumann, et al., 2016) calculated within the RVM software.

PACU Setting

Upon entry to the PACU the participant was attached to the standard PACU monitors and anesthesia personnel completed their transfer report. RNs performed their standard assessment and interventions for all patients in the PACU. The PI verified that the pulse oximetry was on and that NIBP monitors were set at 5-minute intervals. Typically, NIBP monitors are set at 15-minute intervals. Increasing the frequency helped correlate standard vital sign data (HR, blood pressure, pulse oximetry) to RVM data (RR, TV, MV).

The times on the RVM were noted and matched to the PACU monitor for future data analyses. During a previous pilot study conducted by the PI, retrospective analysis determined that the RVM internal clock times were up to 13% different from actual times. This led to a decision to match the times on the RVM with PACU monitors. The following data was obtained during PACU recovery and placed into the REDCap data storage system:

1. Pulse oximetry, heart rate, and blood pressure recordings upon admission and at 5-minute intervals (admission, 5, 10, 15, 20...to 45 minutes) of PACU time, and when SpO₂ is noted be $\leq 90\%$.
2. RVM data (MV, TV, RR) recorded upon admission and at 5-minute intervals of PACU time, and when RVM notes $MV <_{\text{pred}} 40\%$ of their calculated baseline MV.
3. Oxygen flow rates and devices used for delivery.
4. Times of NPPV application, discontinuation, and oxygen flow rates if Boussignac CPAP is used, or pressure settings of other NPPV devices.
5. Respiratory parameters (TV, RR, SpO₂, and MV values) with NPPV application after 1, 5, and 15 minutes of use and after 1, 5, and 15 minutes of discontinuing NPPV therapy.

Upon completion of PACU recovery, RVM electrodes were removed from participants' chest. Sites were observed for redness or rash and monitor were cleaned. Participants were transferred to their designated stepdown unit at the discretion of PACU nurse.

Data Collection After PACU Discharge

Participant's data recorded in the RVM was extracted using a designated thumb drive. This assisted in post-hoc comparison of PORD and POA frequencies between OSA risk and NPPV therapy groups. Vital sign spreadsheets were reviewed to identify any missing variables for analyses. The PI obtained the time patients were ready for PACU discharge. PACU nurses

determined readiness for discharge by using the Modified Aldrete scoring instrument (Appendix D). The five-item instrument has each criterion rated on a 0-2 scale, assessing activity, respiration, circulation, consciousness, and oxygen saturation. A minimum aggregate score of 9/10 was required to meet postoperative discharge criteria (Mayers, Haas, & Convery, 2012). The times were matched to the RVM output for analysis of the number of hypoventilation and apnea events during PACU recovery. MV data was extracted and uploaded into REDCap. The following data was be collected after PACU recovery:

1. Time in minutes from PACU admission to completing discharge criteria.
2. Continuous RVM data output including TV, RR, and MV values for post-hoc analyses comparing ventilatory output to OSA severity, and NPPV application/no application groups.
3. Perioperative narcotic types, dosages and PACU administration times, intraoperative reversal agents, NPPV use times, and duration of anesthesia (Appendices H, I).

Instruments

Perioperative instruments used included the Modified Aldrete scoring instrument, the RVM monitors with associated disposable electrodes, the SBQ, standard vital sign monitors, and nursing PACU flow sheets recorded in the patient's EHR. The RVM recorded tidal volumes and respiratory rates, calculating MV rates continuously in real-time. The RVM recorded and stored participant's data within the monitor's software and was extracted, matched, and coded with the EHR data in REDCap. Participant's EHR data and RVM output was uploaded into REDCap for storage, de-identification, and analyses. Original paper data was available for use as a backup in case the REDCap site was offline. The paper consents and thumb drive with RVM data was secured in a locked cabinet in a secure office (3110) at the ECU College of Nursing.

Data Analysis and Statistics

Statistical analyses was completed utilizing the Statistical Package for the Social Sciences (SPSS), version 24. An initial analysis of all data points were reviewed and coded for appropriate statistical use. The sample size of at least 50 patients (25 per group) was used to approximate clinically significant differences between group outcomes.

Research Question 1: *Is there a difference in pulse oximetry recordings, respiratory rates, minute ventilation (MV) patterns, and PACU length of stay between OSA severity groups (mild vs. moderate/severe), OSA history groups (previously diagnosed vs. no formal diagnosis), or NPPV use groups (NPPV vs. non-NPPV) as measured by the STOP-Bang and preoperative evaluation questionnaires?*

Descriptive statistics for demographic and anthropometric measures (means, percentages, and standard deviations) were presented. A series of independent-samples t-tests was used to compare demographic, perioperative clinical variables, and perioperative ventilatory outcomes between OSA severity groups (mild vs. moderate/severe). Independent-samples t-tests were also used to compare perioperative ventilatory outcomes between OSA history groups (previously diagnosed vs. no formal diagnosis) and NPPV use groups (NPPV vs. no PPV).

Research Question 2: *What is the association of pulse oximetry recordings to respiratory parameters (TV, RR, MV) measured by the RVM?*

- a. *Which monitor identifies changes in respiratory parameters earlier (SpO₂ recording 90-92% (moderate hypoxemia) lasting ≥ 1 minute while on oxygen at 2-4 liters/minute or a drop in a SpO₂ recording $\geq 4\%$ from baseline lasting ≥ 1 minute when no supplemental oxygen is used vs. RVM recording of a MV <*

pred40% (moderate hypoventilation)), and is the detection time difference significant?

- b. *When the RVM detects hypoventilation ($MV <_{pred40\%}$) or apnea events (no detected $RR > 10$ seconds), are there associated changes in pulse oximetry ($SpO_2 < 92\%$ when on oxygen 2-4 liters/min or drop in $SpO_2 \geq 4\%$ from the preoperative SpO_2 lasting ≥ 1 minute when no supplemental oxygen is used)?*

The prevalence of low minute ventilation, normal minute ventilation, low hypoxemia, and high hypoxemia events will be assessed to determine if there is enough expected counts to permit a chi-square test for independence. If the expected counts are too small, descriptive frequencies will be used to identify the number of events in each category.

Research Question 3: *How does NPPV application affect MV (TV and RR)?*

- a. *When NPPV is applied or removed, what are the MV volumes at 1, 5, and 15 minutes of use and/or removal, and is the volume change significant?*
- b. *Is there a significant difference in the number of respiratory events (any recorded $MV <_{pred40\%}$ value; any SpO_2 recording $< 92\%$ lasting ≥ 1 minute while on oxygen at 2-4 liters/minute, or any drop in $SpO_2 \geq 4\%$ from the preoperative SpO_2 recording lasting ≥ 1 minute when no supplemental oxygen is used) between participants who receive NPPV and those who do not during PACU recovery?*

Paired-sample t-tests were used to compare MV, TV, and RR values at 1, 5, and 15 minutes to baseline after the application and removal of the NPPV device. Paired-sample t-tests were also used to compare percent change in MV at 1, 5, and 15 minutes with NPPV on and at NPPV removed. Independent-sample t-tests were used to compare demographic,

perioperative clinical variables, and perioperative ventilatory outcomes and events between participants who received NPPV and those not receiving NPPV during their PACU recovery.

Study Limitations and Potential Difficulties

Limitations to the study regarding sampling included having participants undergo gastric bypass procedures at a single facility, with a diagnosis of or a suspected OSA history. The sample may have not been representative and generalizable to other surgical patient populations with OSA. However, homogeneity was sought to limit confounding variables, to determine if significant ventilation differences and outcomes exist between groups, and explore the feasibility of the RVM for postoperative monitoring and future prospective research.

Other potential limitations included delays in participant recruitment with variable surgical case volumes. The PI minimized this by regularly reviewing the operating room's daily schedule, providing brochures in the surgeons' office, and contacting participants in the preoperative surgical unit after they were seen by the preoperative RN. Measurement and data collection issues may have related to removal of electrodes as well as potential monitor failures and calibration issues. The PI ensured vital sign monitors were in place and recording upon PACU entry, and electrodes were replaced as needed in the event of dislocation/breakage. RVM monitors were plugged into wall outlets to reduce the likelihood of power failure. This allowed the RVM to continually record ventilatory data throughout the PACU stay allowing the researcher to correlate this information to participants' pulse oximetry. The PI remained at the bedside collecting data and monitoring the patient's progression throughout the PACU stay to ensure accuracy of data collection.

CHAPTER 4: RESULTS

A prospective observational study was performed at a major medical center in the Southeastern United States. The purpose was to examine the effects of obstructive sleep apnea (OSA) severity on ventilation changes and the results of non-invasive positive pressure ventilation use in the Postoperative Anesthesia Care Unit (PACU).

From June 29th, 2018 through October 30th, 2018 a consecutive convenience sample of prospective surgical participants undergoing gastric bypass (gastric sleeve, Roux en-Y anastomosis) surgery were interviewed. A total of 68 participants were contacted to participate immediately prior to surgery in the preoperative area. Of these, 67 agreed to participate. The data from 17 participants were excluded for the following reasons: monitor/calibration issues ($n = 8$) primarily from not having time to adequately establish a baseline minute ventilation value; excessive patient movement/monitoring issues observed ($n = 5$); unavailability of the researcher during the entire data collection process ($n = 3$); and one participant's ventilation data not recorded in the respiratory volume monitor (RVM). The final sample included 50 participants with 25 in each assigned OSA risk group.

Sample Description

Forty-four participants (88%) underwent gastric sleeve surgery compared to six for Roux en-Y anastomosis. They included a majority of females 39 (78%), White/Caucasian (61%) with an average age of 47 years and a BMI 44.2 (37.9-58.1). Sixty-four percent had a neck circumference greater than 40cm (see Table 1).

Sixteen (32%) subjects reported a physician diagnosis of OSA. Of these 16 subjects, 15 had received a non-invasive positive pressure ventilation (NPPV) mask. Twelve stated they were compliant at home with wearing their mask greater than four hours per night. Home

pressure setting ranged from 5cm H₂O to 17cm H₂O with a mean pressure of 11.6 cm H₂O.

Participants had a variety of chronic health conditions including hypertension (52%), diabetes (32%), asthma (36%), with 24% reporting dyspnea with activities.

Individual STOP-Bang Questionnaires with eight item “yes or no” (SBQ) responses were consistent with other health-risk findings in addition to having an inclusion criteria of a BMI >35kg/m². The most common measured risk factor was large neck circumference (64%), and the most common self-report responses were diagnosis of hypertension and someone reported them snoring (50%), and age greater than 50 years (42%). The least noted SBQ response was report that someone observed the participant stopping breathing (2%). Participants’ collective mean SBQ score was 3.7, and ranged from 1-7. Each participant was assigned OSA group based on his or her aggregate SBQ score. Those with a score ≤ 3 designated as “mild OSA risk” and participants scoring 4 to 8 as “moderate/severe OSA risk” (see Tables 2 & 3).

Table 1*Demographic Characteristics of Participants (n = 50)*

Characteristic	<i>n</i>	%
Age at time of study (years)		
23-40	15	30
41-50	14	28
51-60	18	36
61-71	3	6
Gender		
Female	39	78
Male	11	22
Race		
Black/African American	18	36
White/Caucasian	32	64
Surgery Type		
Gastric Sleeve Resection	44	88
Roux en-Y Anastomosis	6	12
OSA Risk Group		
Mild	25	50
Moderate/Severe	25	50

Table 2*Physiological History of Participants (n = 50)*

Interview Question ("Yes" Responses)	n	%
Preoperative Health History		
Do you Have any Health Issues	44	88
High Blood Pressure	26	52
Atrial Fibrillation	1	2
Diabetes	16	32
Asthma	18	36
COPD	0	0
Orthopnea	11	22
Dyspnea/SOB with Activities	12	24
Home O ₂ Use	1	2
Formal Diagnosis of OSA	16	32
Home NPPV Mask	15	30
STOP-BANG Questions		
Snore at Night	25	50
Tired During the Daytime	20	40
Has Anyone Observed You Stop Breathing	1	2
High Blood Pressure	25	50
BMI >35	50	100
Age >50 Years	21	42
Neck Circumference >40cm	32	64
Male Gender	11	22

Table 3*Physiological Measurements (n = 50)*

Measurement	<i>M</i>	<i>SD</i>
Height (cm)	165.83	0.09
Weight (kg)	121.71	17.34
BSA	2.25	0.20
BMI	44.21	5.11
Neck Circumference (cm)	43.32	4.96
STOP-BANG total Score	3.70	1.68
Preoperative Laboratory Values		
Serum Sodium Bicarbonate (mg/dl)	25.26	2.63
Preoperative Serum Hemoglobin (mg/dl)	13.24	1.08
Ventilation Parameters		
Predicted Minute Ventilation	8.12	1.10
40% Predicted Minute Ventilation Calculated	3.23	0.44
Home Mask Pressure Setting (cm H ₂ O)	11.6	3.35

Analyses Related to Research Questions

Research Question 1

Is there a difference in pulse oximetry recordings, respiratory rates, minute ventilation (MV) patterns, and PACU length of stay between OSA severity groups (mild vs. moderate/severe), OSA history groups (previously diagnosed vs. no formal diagnosis), or NPPV use groups (NPPV vs. non-NPPV) as measured by the STOP-Bang and preoperative evaluation questionnaires?

Research Question 1 Analyses

There were 25 subjects in the mild and 25 subjects in the moderate/severe group. OSA severity group (mild vs. moderate/severe) clinical measures and postoperative outcomes were compared for differences (Table 4) using independent samples t-tests. Participants in the

moderate/severe OSA group were significantly older and had larger neck circumferences. The magnitudes of these differences were large respective to their effect sizes (eta squared = 0.26 & 0.29). Statistical differences in mean PACU length of stay were noted between mild and moderate/severe OSA groups with longer PACU recovery times in the mild group ($p = .04$). The magnitude this difference was moderate (eta squared = .086). The mild OSA group received significantly more postoperative pain medication measured as mean morphine equivalents than those with moderate/severe OSA risk with a moderate effect size (eta squared = 0.083) (see Table 4).

Table 4

Perioperative Measurements Between OSA Assigned Groups

Outcome	Mild (<i>n</i> = 25)		Moderate/Severe (<i>n</i> = 25)		<i>t</i>	<i>p</i>	<i>eta</i> ²
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>			
Age	41.32	9.05	52.76	10.37	-4.16	<.001	.26
BMI	44.97	5.36	43.45	4.84	1.05	.30	.022
Neck Circumference	40.68	3.14	45.97	5.08	-4.43	<.001	.29
Surgery Duration	41.80	9.98	43.84	13.42	-.61	.55	.019
Surgical Morphine equivalents.	14.93	6.28	12.29	5.56	1.58	.12	.049
PACU Length (min)	78.12	25.86	63.84	21.56	2.12	.04	.086
PACU Morphine Equivalents	8.14	5.72	12.13	7.68	-2.09	.04	.083
Admission SpO ₂	96.0	3.55	96.7	2.97	-.74	.47	.011

Postoperative ventilatory outcomes were continually monitored with pulse oximetry and respiratory rate recorded at five-minute intervals and continuous ventilation data (tidal volumes,

respiratory rates and calculated minute ventilations) retrieved from the ExSpirom™ (RVM) machines. The mean postoperative outcomes were obtained for the first 45 minutes of recovery. Apnea events, and the percentage of time participants had low minute ventilation readings were counted from the continuous RVM data. No significant differences were found between OSA severity groups (see Table 5).

Table 5

Postoperative Ventilatory Outcomes Between OSA Assigned Groups

Outcome	Mild (<i>n</i> = 25)		Moderate/Severe (<i>n</i> = 25)		<i>t</i>	<i>p</i>	<i>eta</i> ²
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>			
Pulse Oximetry	96.7	2.50	96.8	2.13	-.141	.89	.000
Respiratory Rates	17.04	4.71	15.94	2.98	.986	.33	.020
Minute Ventilation	5.56	2.16	5.95	1.66	-.706	.48	.010
RVM Minute Ventilation Output*	5.96	2.62	6.42	2.25	-.67	.50	.009
Desaturation Events	.48	1.05	.64	1.08	-.533	.60	.006
Low MV Events	2.80	3.18	3.64	4.17	-.801	.43	.013
Apnea Events	.68	3.40	.20	.58	.696	.49	.010
Percent Low MV first 45 minutes	18.85	28.91	12.26	12.97	1.039	.31	.022

*ExSpirom™ RVM 1-Minute Data Recordings Averaged

To further explore the first research question the series of independent-samples t-tests were repeated between formal OSA diagnosis groups (Table 6), and home NPPV mask wearers (Table 7). The purpose was to determine if there was a difference in pulse oximetry recordings, respiratory rates, minute ventilation (MV) patterns, and PACU length of stay between groups. There were no statistical differences in outcomes between those formally or not pre-diagnosed

with OSA. Sixteen participants with a previous OSA diagnosis, 15 were given home NPPV masks (continuous or automated positive airway pressure masks), but three were non-compliant in wearing the mask on a regular basis (>4hrs average use/night) (Table 7). No ventilatory differences or PACU length of stay were found between NPPV mask user/non-user groups.

Table 6

Postoperative Outcomes Between Formal OSA Diagnosis Groups

Outcome	No OSA Hx (<i>n</i> = 34)		Positive OSA Hx (<i>n</i> = 16)		<i>t</i>	<i>p</i>	<i>eta</i> ²
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>			
Pulse Oximetry	96.9	2.55	96.35	1.66	.82	.42	.014
Respiratory Rates	16.49	4.00	16.49	3.94	.005	.99	.000
Minute Ventilation	5.65	1.95	5.98	1.89	-.573	.57	.007
RVM Minute Ventilation Output*	6.06	2.39	6.48	2.57	-.566	.57	.007
PACU Length (min)	69.15	26.53	74.88	20.28	-.763	.45	.012

*ExSpiron™ RVM 1-Minute Data Recordings Averaged

Table 7

Postoperative Outcomes Between Non-NPPV Users and NPPV-Complaint Users

Outcome	No NPPV Use (<i>n</i> = 38)		NPPV Use >4hrs (<i>n</i> = 12)		<i>t</i>	<i>p</i>	<i>eta</i> ²
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>			
Pulse Oximetry	96.8	2.44	96.5	1.85	.336	.74	.002
Respiratory Rates	16.49	4.07	16.48	3.67	.009	.99	.000
Minute Ventilation	5.69	1.96	5.96	1.85	-.423	.67	.004
RVM Minute Ventilation Output*	6.1	2.32	6.6	2.80	-.671	.51	.009
PACU Length (min)	70.6	25.76	72.1	21.72	-.176	.86	.000

*ExSpiron™ RVM 1-Minute Data Recordings Averaged

Research Question 2

What is the association of pulse oximetry recordings to respiratory parameters (TV, RR, MV) measured by the RVM?

- a. Which monitor identifies changes in respiratory parameters earlier (SpO₂ recording 90-92% (moderate hypoxemia) lasting ≥ 1 minute while on oxygen at 2-4 liters/minute or a drop in a SpO₂ recording $\geq 4\%$ from baseline lasting ≥ 1 minute when no supplemental oxygen is used vs. RVM recording of a MV $<_{\text{pred}}40\%$ (moderate hypoventilation), and is the detection time difference significant?
- b. When the RVM detects hypoventilation (MV $<_{\text{pred}}40\%$) or apnea events (no detected RR > 10 seconds), are there associated changes in pulse oximetry (SpO₂ $< 92\%$ when on oxygen 2-4 liters/min or drop in SpO₂ $\geq 4\%$ from the preoperative SpO₂ lasting ≥ 1 minute when no supplemental oxygen is used)?

Research Question 2 Analyses

Participants were monitored for low minute ventilation events (MV $<_{\text{pred}}40\%$) and mild and moderate hypoxemia as measured by pulse oximetry. A total of 178 respiratory events occurred. Of these respiratory events, 166 were low minute ventilation. There were a total of 28 mild or moderate hypoxemic events. Of these, 16 occurred when low minute ventilation was also detected and 12 occurred when there was a normal minute ventilation.

The 12 hypoxemia events when normal minute ventilation occurred were explored in more detail. Of these eight events, five participants were not receiving supplemental oxygen. Three participants had previous intermittent low MV periods of less than one-minute duration thus not causing the RVM to alarm. Others were moving in bed or at the bedside ($n = 1$) or received intravenous opioids or sedatives ($n = 2$). One of the eight participants was using their home CPAP without supplemental oxygen. Chronic health conditions of the eight participants

using oxygen included hypertension ($n = 3$), asthma ($n = 3$), and dyspnea on exertion ($n = 2$), with four reporting using CPAP at home. Of the four participants receiving supplemental oxygen, they had either previous low MV events or received opioids, reducing their MV but not less than the $MV_{pred}40\%$. Of all total 28 hypoxemia events very few were noted to be one minute or longer in duration and did not meet the study’s definition of moderate hypoxemia.

The 178 low MV incidents were investigated to determine the effects of NPPV and supplemental oxygen therapies on event duration. Independent samples t-tests explored the differences in mean duration of hypoventilation events. Overall, oxygen therapy did not change the duration of the hypoventilation event, however NPPV mask application reduced mean duration time by nearly one minute (see Table 8). Only four subjects experienced apnea events (AE). All but one AE had a correlating SpO_2 value $\geq 94\%$. One participant had 17 AE, but had no desaturation events. The other participants ($n = 3$) received an opioid prior to all but one of their apnea events.

Table 8

Effect of NPPV on Duration of Low MV Events’ Duration

	No NPPV ($n = 139$)		NPPV ($n = 39$)		<i>df</i>	<i>t</i>	<i>p</i>	<i>eta</i> ²
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>				
Event Duration in Minutes	2.89	4.51	1.92	1.79	176	2.02	.045	.023

Research Question 3

How does NPPV application affect MV (TV and RR)?

- a. When NPPV is applied or removed, what are the MV volumes at 1, 5, and 15 minutes of use and/or removal, and is the volume change significant?

- b. Is there a significant difference in the number of respiratory events (any recorded $MV <_{pred} 40\%$ value; any SpO_2 recording $< 92\%$ lasting ≥ 1 minute while on oxygen at 2-4 liters/minute, or any drop in $SpO_2 \geq 4\%$ from the preoperative SpO_2 recording lasting ≥ 1 minute when no supplemental oxygen is used) between participants who receive NPPV and those who do not during PACU recovery?

Research Question 3 Analyses

Fifteen participants received postoperative non-invasive positive pressure (NPPV) support. Data was analyzed for 13 participants. Two subjects were excluded because one received Boussignac CPAP (BCPAP) less than 15 minutes and the other's home CPAP was not discontinued in the PACU. Of the 13 participants, their average age was 55 years, with a BMI mean of 42.5. Eight received a BCPAP and eight were females with a mean duration of NPPV use of 34.9 minutes. Of the BCPAP users, 75% of the masks were applied when the participant was in the operating room prior to transport to PACU. Overall mean start time of NPPV therapy was 12 minutes after PACU admission.

Multiple paired-samples t-tests were conducted to compare baseline respiratory rates, minute ventilation mean scores, and TV and MV percent changes from baseline during and after NPPV use (Tables 9 & 10). Baseline measurements were obtained from values recorded at the time of NPPV application with designated paired-samples t-tests at measured intervals (1, 5, and 15 minutes after application, at removal, and 1, 5, and 15 minutes after removal). Predicted MV 100% values were used as a physiological measurement based on predicted BSA and gender. Percent change from baseline and percent of the predicted MV 100% were measured. Tidal volume measurements were compared against a percentage change from baseline and a

percentage of their predicted TV (based on predicted body weight*5ml/kg). Mean changes from baseline MV values were used to compare repeated measures during application and removal.

When NPPV was applied, percent of predicted TV and MV improved with highest percent change at time of mask removal. There was a significant difference between mean baseline percent of predicted MV scores and percent of predicted MV at time of NPPV removal (see Table 9). Following NPPV removal percent scores decreased. Similarly, mean TV measurements improved between baseline and at the time of discontinuation and TV decreased after NPPV removal. A paired-samples t-test of MV percent change from baseline to NPPV removal was statistically significant (see Table 10). A paired-samples t-test was performed between TV predicted mean values when NPPV was off for 1-minute and the NPPV was off for 5-minutes. Participants' predicted tidal volume percentage mean scores were reduced 25%, which was clinically and statistically significant ($p = .027$, 2-tailed). A paired-samples t-test was performed substantiate the decline in TV in milliliters (ml) change and found it to be reduced from a mean of 473ml to 354ml ($p = .029$, two-tailed). No other repeated measures were found to be significant.

Table 9

Paired-samples t-tests of Ventilation Measures With Application and Removal of NPPV Against Values at Baseline NPPV Application

Time Event	Ventilation Measures (<i>n</i> = 13)					
	Respiratory Rates		Percent of Predicted TV		Percent of Predicted MV 100%	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Baseline	16.47	5.12	124.8	59.13	70.36	36.69
NPPV on 1 Min	15.09	2.79	134.9	60.70	71.92	36.38
NPPV on 5 Min	16.22	4.55	132.8	58.95	74.12	35.46
NPPV on 15 Min	16.43	5.25	125.1	62.84	69.96	36.75
NPPV Removal	16.89	3.81	154.9	70.49	91.50*	35.88
NPPV Off 1 Min	14.66	3.18	159.6	72.86	81.39	33.27
NPPV Off 5 Min	18.08	4.31	119.0	68.88	72.17	39.63
NPPV Off 15 Min	16.89	4.17	137.3	65.37	78.36	33.52

* significantly different from baseline measure $p < .05$ (2-tailed).

Table 10

Paired-samples t-tests of Percent Change in MV from Baseline MV Value

Time Event	Minute Ventilation Measure (<i>n</i> = 13)			
	<i>M</i>	<i>SD</i>	<i>t</i>	<i>p</i>
Baseline	5.84	3.46		
NPPV on 1 Minute	5.95	3.33	-.167	.87
NPPV on 5 Minutes	6.04	2.81	-.391	.70
NPPV on 15 Minutes	5.65	2.79	.292	.78
NPPV Removal	7.45*	3.17	-2.14	.05
NPPV Off 1 Minute	6.56	2.53	-.997	.34
NPPV Off 5 Minutes	5.89	3.31	-.052	.96
NPPV Off 15 Minutes	6.29	2.61	-.617	.55

* significantly different from baseline measure $p < .05$ (2-tailed).

Postoperative outcomes were compared to determine a difference in postoperative respiratory events between participants who received postoperative NPPV therapy and those that did not ($n = 35$). Independent-samples t-tests were first conducted to determine differences in perioperative measurements, opioid doses, and duration of their surgical procedures (Table 15). Participants who received postoperative NPPV were statistically older ($M = 54.73$) than those who did not ($M = 43.74$) with a large effect size (eta squared = .205). They also had larger neck circumferences ($p = .015$) with a moderate to large effect size (eta squared = .117). There were no other statistical differences in means analyzed, including height, weight, and perioperative opioid morphine equivalents.

Table 11

Perioperative Measurements Between Post-Extubation NPPV Application and Non-Application Groups

Outcome	No Application ($n = 35$)		NPPV Use ($n = 15$)		t	p	eta^2
	M	SD	M	SD			
Age	43.74	10.06	54.73	10.26	-3.519	.001	.205
BMI	44.79	5.52	42.84	3.81	1.245	.22	.031
Neck Circumference	42.23	4.55	45.89	5.08	-2.516	.015	.117
Surgery Type	1.11	.32	1.13	.35	-.186	.85	.001
Surgery Duration	40.51	8.22	48.20	16.58	-1.708	.11	.057
Surgical Morphine equivalents.	13.59	5.55	13.67	7.22	-.043	.97	.000
PACU Length (min)	70.32	24.66	72.53	25.41	-.289	.77	.002
PACU Morphine Equivalents	10.17	6.44	10.04	8.41	.057	.16	.000

Finally, independent-samples t-tests were conducted resulting in no significant differences in low MV or desaturation events, mean apnea events, or mean lengths of PACU stay (Table 16). Of the participants that received NPPV, not all were diagnosed with OSA ($n = 10$) or were in the moderate/severe OSA group ($n = 12$). Some received the Boussignac NPPV mask after extubation ($n = 6$) in the operating room. NPPV application was at the discretion of the nurse anesthetist or PACU nurse with most participants not receiving NPPV (home mask or BCPAP) until after a period of recovery time in the PACU. Application times ranges from 5 minutes before PACU arrival to 65 minutes after admission ($M = 12.3$ minutes). Mean respiratory events, particularly low MV events were more frequent with postoperative NPPV and were approaching significance. However, mean lengths of low MV events were significantly shorter when NPPV was used (Table 12). Postoperative NPPV use participants were statistically older and had larger necks, suggesting the therapy improved their ventilatory outcomes.

Table 12

Postoperative Respiratory Outcomes Between Post-Extubation NPPV Application and Non-Application Groups

Outcome	No Application ($n = 35$)		NIPPV Use ($n = 15$)		t	p	eta^2
	M	SD	M	SD			
Pulse Oximetry	96.6	2.40	97.1	2.06	-.753	.46	.011
Total Respiratory Events	2.94	3.14	4.93	4.42	-1.81	.08	.064
Low MV Events	2.63	3.097	4.60	4.64	-1.77	.08	.061
Desaturations	.51	1.011	.67	1.18	-.465	.64	.004
Apnea Events	.03	.169	1.40	4.37	-1.215	.25	.029
PACU Length (min)	70.3	24.66	72.5	25.41	-.289	.77	.002

CHAPTER 5: DISCUSSION

Introduction

In this prospective observational research dissertation the effects of obstructive sleep apnea (OSA) severity risk on postoperative ventilatory patterns was documented. The performance of an impedance device that identifies ventilatory events and respiratory depression was compared to “standard” monitors used in a PACU setting; and the effects of postoperative non-invasive positive pressure ventilation (NPPV) therapy examined. By using a non-invasive respiratory volume monitor (RVM) to directly measure respiratory rates (RR) and tidal volumes (TV), participant’s minute ventilation (MV) was continuously calculated and displayed for analyses. Fifty participants assigned to one of two OSA risk groups were observed in the PACU setting after receiving general anesthesia to explore the research questions introduced in Chapter One. A discussion of the findings, as well as study assumptions, study strengths and limitations, with related future implications for practice and research will be discussed.

Summary of Findings

Finding One

In this dissertation study no statistical difference was found in respiratory events between OSA severity (mild vs. moderate/severe), diagnosis of OSA (previously vs. no formal diagnosis), or NPPV use (NPPV vs. non-NPPV). Moderate/severe OSA (S-OSA) participants were statistically older and had larger neck circumferences than the mild-risk OSA (M-OSA) group participants. An anecdotal finding was the M-OSA group received less postoperative opioid morphine equivalents, and had a longer mean PACU stay compared to the S-OSA group. This may suggest there are underlying physiological factors not accounted/screened for in this study. Variations in pain management strategies and opioid administration techniques were not

considered. Regardless of other factors, the results of STOP-Bang Questionnaire (SBQ) and subsequent assignment of groups by the researcher did not correlate with any differences in postoperative ventilation events or outcomes between OSA-assigned groups.

This finding may be of importance clinically as practitioners are faced with choosing preoperative screening questionnaires or questions to help identify potential and real issues during perioperative periods. The SBQ has been used on a variety of patient populations (Nunes et al., 2016; Bamgbade et al., 2016; Proczko et al., 2014; Schumann et al., 2016) and tested against polysomnography (Chung, Yang, & Liao, 2013; Nagappa et al., 2015). Nevertheless, limitations exist with respect to its' ability to predict perioperative OSA-related events as seen in this study. The SBQ was originally designed for risk-stratification for presence of OSA, not for the purpose of identifying patients "at risk" for postoperative respiratory depression. So, not surprisingly, this study did not find a correlation between positive STOP-Bang severity and episodes of postoperative respiratory depression.

Many factors could affect the likelihood of patients experiencing a respiratory event. Some of these include administration of perioperative opioids incomplete/partial reversal of neuromuscular blockade, severity of OSA, duration of surgery, and facial or airway edema. Other physiological differences not measured (e.g. genetics and/or sensitivity to opioids and other medications) may also affect changes in perioperative ventilatory patterns (Lam et al., 2016; Subramani et al., 2017).

In this study the SBQ was used to categorize participants into two risk groups. Of the eight item responses the questions with the highest frequency of "yes" responses were BMI $>35\text{kg/m}^2$, positive history of snoring, age >50 years, neck circumference $>40\text{cm}$, and subjective response of daytime tiredness. Other questionnaires may be more objective and useful in

categorizing OSA risk (Deflandre et al., 2017). The SBQ is used to assign OSA risk into one of three groups (low, intermediate, or high). However, Chung et al. (2013, p. 2056) determined that individuals with a SBQ score of ≥ 4 , as having a “high sensitivity” for severe OSA. For this study, participants were grouped into M-OSA and S-OSA risk groups with respective SBQ totals ≤ 3 or ≥ 4 .

Schumann and colleagues (2016) similarly reported no differences between assigned OSA risk groups and postoperative respiratory depression or apnea events. However, Fernandez-Bustamante et al. (2017) reported that participants screened positive for OSA but without a formal diagnosis of OSA had similar postoperative respiratory events, but longer length of admission and required more respiratory interventions than those presenting with a formal OSA diagnosis. These findings were similar with Xara and colleagues (2015) who found that a SBQ > 3 (reported as “high risk”) had more adverse respiratory events, and hypoxia incidents than the low risk group (SBQ < 3). In this study, the PI included only obese participants undergoing bariatric surgery. This may have influenced the postoperative outcomes, as BMIs were similar between sub-groups. Results may not be reflective of other populations receiving different surgical procedures. M-OSA and S-OSA participant assignments for this study helped support the importance of screening for but not relying upon a questionnaire’s results to predict postoperative outcomes. More research is needed into applying the SBQ to different surgical populations.

Study outcomes were similar to Schumann and colleagues (2016), where no group differences in postoperative respiratory depression or apnea events were seen between assigned groups. Therefore, larger sample sizes and diverse surgical populations may demonstrate differences in respiratory outcomes. A “universal approach” to monitor for and manage apnea

and respiratory depression may be more realistic for any patient screened or perceived to be “at risk” for sleep apnea. Considering each patient as having an equal potential for airway complications may be more prudent. Instead of focusing on the assignment of “potential risk” preoperatively, more robust methods for monitoring and assessing for ventilatory changes may be more practical.

Finding Two

The RVM outperformed traditional pulse oximetry monitoring to alert the researcher when the patient experienced a reduction in their minute ventilation, particularly after parenteral opioid administrations. There was a negative correlation to RVM notification of hypoventilation and reductions in pulse oximetry. This finding may suggest a change is needed in how practitioners monitor for and identify real or potential ventilatory depression. Only 12 desaturation events (6.7%) were noted without an accompanying decrease in minute ventilation. Most of the desaturation events were less than one minute in duration, as the nurse was alerted by the alarm or the saturation increased above the alarm threshold. Many desaturation events were preceded by previous decreases in MV at or below the $p_{red}40\%$ threshold, or were noted when the participant was observed moving in bed. The utility of the RVM to identify hypoventilatory states was similar to previous research measuring ventilatory patterns during moderate sedation procedures (Ebert et al., 2015) and effects of opioid administration on postoperative ventilatory patterns (Voscopoulos et al., 2014)

RVM results support previous findings in the literature: Ventilation and oxygenation are related but not the same, especially when supplemental oxygen is used (Sivilotti et al., 2010). Supplemental oxygen therapy may mask apnea and hypoventilation events (Gross et al., 2014), increasing circulating CO₂ (Mehta et al., 2013). In examining ventilatory patterns when oxygen

therapy was off, pulse oximetry was five-times more likely to display a desaturation event than when supplemental oxygen was in use. This finding suggests the possible benefits of weaning off oxygen therapy as soon as it is safe and reasonable so changes in pulse oximetry can more closely correlate with potential or real hypoventilation events. In this study, the RVM was superior in detecting compromised ventilation prior to hypoxemic events. Most participants were receiving supplemental oxygen, which supports previous finding and provides a basis for further inquiry into the ability of the RVM to be used in other patient populations to monitor for changes in ventilatory patterns instead of observing changes on pulse oximetry alone.

Finding Three

The NPPV masks used in this study were the participants home CPAP ($n = 6$) and the Boussignac CPAP (BCPAP) ($n = 9$) with one participant's data in each group not used for analyses. The BCPAP was often applied earlier than home-NPPV devices. Application times were at the discretion of the anesthesia provider or RN, and usually occurred before transport to or upon arrival in the PACU.

Somewhat surprisingly, low MV events were more frequent with patients who had postoperative NPPV therapy initiated. However, there is no way to determine the frequency of low MW events these patients might have had, if preventative NPPV had not been established, but it likely would have been a larger number. Overall, NPPV therapy was applied to participants who were older and had larger necks. Both of these factors have been associated with depressed postoperative ventilatory patterns, suggesting their baseline risk for obstructive events may have been elevated. Having objective data that identifies those patients who are experiencing postoperative decrements in MV would inform patient care decisions in real time. When participants were receiving NPPV the duration of the respiratory depression event was

statistically shorter in duration. The application of NPPV may have reduced more severe effects of post-operative obstructive ventilation breathing patterns.

These findings support previous literature on the mechanism of NPPV to improve ventilation. As the airways are opened and supported with positive pressure, respiratory function can be preserved (Nigelin et al., 2009), reducing AHI severity over time (Laio et al., 2013), and increase participants' level of alertness, reducing REM sleep percentages. This results in a more awake and better ventilating patient in the PACU, potentially reducing airway events and length of stay. Brousseau et al. (2014) suggested proactive postoperative use of CPAP is an area where improvement could be made to reduce length of stay and improve respiratory function. BiPAP was not used in this study and is a limitation of the findings. The clinical application of the device needs further research as it both opens the closed glottis structures and provides positive support to increase tidal volumes.

The RVM was able to provide digital output on changes to ventilatory parameters (RR, TV, and MV) and the effects of the NPPV mask before application, during use, and after removal. Timed interval measurements of vital signs and ventilatory parameters were obtained when the participant was quietly breathing, not talking, or being stimulated. Overall, no statistically significant changes in mean MV values or percentage change from baseline occurred except at the time of NPPV removal vs. baseline status. CPAP and BCPAP physiologically provide constant pressure support to open airways and maintain patency, thereby maintaining TV but they do not provide positive pressure support during inspiration. So, BiPAP application would be needed to determine that effect on ventilation.

Finding Four

A 25% reduction in mean TV was noted after NPPV mask removal for participants ($n = 13$) who received NPPV therapy for at least 15 minutes and had their mask discontinued in the PACU. This difference was measured comparing ventilation parameters at one and five-minute post-NPPV removal. This suggests NPPV application maintains TV and thereby MV values when in use. Participants in this study had a reduction in mean volumes >115 ml. This only affected MV by 11% as respiratory rates likely attenuated the drop in TV by increasing 23% (mean increase in RR 15 to 18), maintaining MV. This has potential clinical implications. First, low MV may not be detected by RR monitors commonly used in PACUs since increased RR may not trigger alarm thresholds. Second, if patients are unable to increase their RR in response to the lowering TV because of physiologic or iatrogenic (opioid administration) compromises, the MV decreases associated with removal of NIPPV could be higher. If an average TV of 500ml were to decrease by 25%, it would equate to about 125ml. Since physiological dead space is about 150ml on average size patients, this decrease of 125ml is equivalent of the entire volume that does not participate in gas exchange. This level of reduction in gas exchange may increase risk for atelectasis, delay elimination of residual inhaled anesthetics, and result in worsening of respiratory depression.

No prior studies were found where researchers used direct methods to observe changes in TV or MV while NPPV was used. Researchers in prior studies relied upon invasive (Gaszynski et al., 2007; Wong et al., 2011) or indirect measurements (Nigelin et al., 2009) to determine effectiveness of NPPV therapy. The effects of NPPV on ventilatory function were measured by removing the NPPV, then having the participant perform pulmonary function tests.

In the current study, participant compliance with NPPV therapy was similar to previous literature findings. Consistently providing preoperative patient education about the importance

of proper NPPV use and potential benefits of wearing the mask may result in more compliant participants (Wong et al., 2011). It is well known that when patients are instructed preoperatively about the use of NPPV they tend to be more compliant with keeping it on in the PACU.

Study Limitations

This prospective observational study used a single convenience sample of relatively small size ($n = 50$) in absence of a priori power analysis. By design, there was limited time for monitoring vital signs and respiratory parameters (45 minutes) in the PACU for participants. End-tidal CO₂ was not utilized for comparative analyses, and application of oxygen was not randomized or applied similarly among participants. Several factors increased homogeneity of the sample (BMIs, surgical durations, and type). These factors increased the internal validity of the study, but may have limited generalizability of findings to other patients and surgical types. The single setting also limits generalizability of findings. However, the research purposes were not only to observe ventilatory outcomes based on assigned OSA risk, but also to determine the feasibility of using a new innovative technology (RVM) in PACUs that might potentially alert providers earlier of changes in ventilatory patterns.

A major limitation of the study was small sample size in the NPPV group. Only 15 participants received NPPV therapy and data from only 13 was used for paired-samples analyses of therapy effects. The information provided insights about the effects of therapy, but due to the small sample size, differences in outcomes between BCPAP vs. home CPAP could not be determined. The fact that no participants received BiPAP therapy, and flow rates may have been inadequate with those who received BCPAP therapy were additional study limitations. Participants who reported using CPAP at home used a mean pressure support setting of 12cm

H₂O. Practitioners often chose oxygen flow settings at 15-liters/min when using BCPAP, which is not equivalent to 12cm H₂O of support. This lower support flow setting may have diminished the intended effects of BCPAP.

While important discoveries were made, the effects of NPPV therapy on ventilatory patterns were only measured for 15 minutes after application and removal. It may be useful to measure ventilatory parameters for longer periods after removal of NPPV masks. The only significant change in MV was seen between baseline MV values and MV upon mask removal. It is possible that longer-term benefits of NPPV therapy exist. In this study data was collected for the first 45 minutes of PACU stay.

Finally, while PACU nurses were unable to see the RVM screen, the RVM did sound an alarm when low MV events occurred. The researcher remained at the bedside to pause the alarms, record data, and make observations of initiated interventions. These factors may have led nurses to alter their routine cares, as an additional clinician was present. Additionally, a Hawthorne effect cannot be excluded. Nurses may have been more attentive than usual to the patient and may have caused increase in stimulation to the patient, reducing the actual effects/time percentage of low minute ventilation or desaturation events.

Study Strengths

All consents were obtained and questionnaires conducted by the researcher who also was present during the postoperative period. This provided consistency in data collection.

Calibration of the RVM machine to the ventilator was performed in all but one instance by the researcher. This increased validity and reliability of data as electrodes were placed in the correct sites. If calibration efforts were not deemed accurate, recalibration attempts were made. Data was excluded in 19% of participants relating to calibration issues, poor waveforms, or

inconsistent readings ($n = 13$). This extended the data collection phase of the study, but increased reliability of results.

Vital signs and respiratory patterns were observed and measured by the researcher in a prospective manner. The researcher controlled the data entry and recording of ventilatory output. Since impedance devices (RVM) also assess movement (repositioning, talking, shivering, etc.), the researcher obtained values only when patients were resting quietly which facilitated error reduction in ventilatory values and provided more consistent data. Data was entered directly into REDCap software system with back-up paper forms available when needed. This facilitated timely and accurate record keeping.

Another strength of the study was consistent researcher presence; ventilatory patterns were directly observed, increasing the validity of the findings. In most instances (98%) the researcher escorted the participant with the anesthetist to the PACU, recording RVM data as needed and ensured PACU monitors were set at 5-minute intervals. Having the researcher present allowed RVM output to be matched to the timing of interventions and correlated with vital signs. All these processes in the research design ensured minimal error, making comparisons of data possible.

Finally, effects of NPPV therapy were measured in a unique way. Using a noninvasive impedance device to measure the effects of NPPV therapy has not been reported in the literature and its use in the postoperative setting allowed detection of discreet changes in post-operative TV, RR, and MV. The data were calculated and recorded during NPPV application and removal. All data recorded with participants quietly breathing which allowed more accurate assessments by eliminating the influence of secondary interventions (mask removal, spirometry studies, etc.).

Recommendations for Research

This dissertation revealed possibilities for additional research to more fully understand the effects of NPPV therapy, the use of the ExSpiron™ respiratory volume monitor in measuring changes in ventilation, and the effects of opioids, neuromuscular blocking antagonists, and other medications have on ventilation. Additional research is needed to explore what NPPV types, durations of application, and pressure settings best improve oxygenation and ventilation in patients with known or suspected OSA.

The results of this research have provided insights for future studies that can be implemented. This prospective observational study did not control for many potentially confounding variables. For instance, only 30% of the participants received postoperative NPPV therapy and initiation was at the discretion of the PACU RN or anesthetist. The sample size was too small to determine how types of NPPV masks (BCPAP vs. home CPAP vs. BiPAP) affected outcome variables. Prospective RCTs would help explore effects of different types of NPPV therapy as well as gain insight into the optimal duration of NPPV use.

Future research about effects of extended NPPV application as measured by the RVM would be beneficial. This study measured ventilatory changes up to 15-minutes post-NPPV removal. Additional measurements of ventilatory patterns after PACU discharge may provide additional information about NPPV therapy on patients with a diagnosis of OSA. Larger prospective RCTs with a variety of patient populations (general surgery, thoracic, laparoscopic vs. open, etc.) are needed as most research to-date have relatively small sample sizes and/or are retrospective in nature.

The ExSpiron™ RVM has been used to measure ventilatory states in a number of patient populations (Voscopoulos, et al. 2013). These studies included monitoring for postoperative opioid respiratory depression (Voscopoulos et al., 2014), and the effects of sedation medications

during anesthetic cases (Ebert et al., 2015). Additional perioperative insights can be sought using this technology to measure the effects of interventions aimed to improve patients' respiratory status. This could include the difference in ventilation when CPAP vs. BiPAP therapy is used, home CPAP vs. hospital NPPV therapy, and the perioperative effects of using NPPV therapy upon admission to the PACU vs. as a rescue therapy. Findings may eventually be used to develop practice standards with a goal of reducing potential complications for those known or suspected of having OSA.

Finally, the RVM can be used to measure ventilatory parameters and the effects of various medications. For instance, participants received sugammadex or neostigmine for non-depolarizing neuromuscular blocking antagonism. Selection of specific drugs and dosages were at the discretion of the anesthesiologists. As each mechanism of action is different, it would be beneficial to further understand the perioperative and clinical effects of reversal technique in this patient population. Performing research where participants randomized into neostigmine or sugammadex medication-groups and measuring ventilatory parameters in the PACU with the RVM may help clinicians make informed clinical decisions about selection of neuromuscular reversal agents. Similar studies could include observing the effects of opioids and other sedative medications or multimodal approaches for analgesia.

Implications for Practice

The results of this research have led to additional insights for evolving clinical practice. Four main implications for clinical practice were found in the study. This includes insights into screening for OSA, monitoring for respiratory depression, titration and removal of oxygen, and a more proactive approach to using NPPV to maintain ventilation throughout the PACU stay. A review of these implications is as follows.

Use of the STOP-Bang Questionnaire

There may be mixed usefulness of using STOP-Bang Questionnaire (SBQ) to assign OSA risk, as assignment of that risk does not predict risk of adverse postoperative respiratory events. It may be important to identify those at-risk of adverse postoperative respiratory events by reviewing other objective measures (Deflandre et al., 2017). The SBQ is a quick screening tool for identifying OSA. If certain responses are noted positive: Age >50 years, neck circumference >40cm, male gender, or history of snoring or airway obstruction; or an aggregate score ≥ 3 is determined, the patient is presumed to have OSA. Strategies can be employed to reduce potential postoperative ventilatory complications.

The results of the SBQ or other preoperative screening tools should be placed on the patients chart for all practitioners to see. In this study no numerical values of preoperative SBQ scores were noted. The SBQ or similar questionnaires can be easily administered in the preoperative clinic, allowing a follow-up consultation to be arranged as needed.

Strategies used to reduce postoperative respiratory depression should be implemented (multimodal pain management, regional anesthetic techniques, supportive airway devices, etc.) with patients suspected of having any potential for OSA. Additionally, as general guidelines exist for screening and management of OSA (Gross et al., 2014), those with any risk may benefit from improved monitoring strategies. The RVM may be used for this problem as the ventilatory changes can be continuously monitored in the PACU. As previously mentioned, this takes a more universal approach to monitoring for respiratory depression, potentially reducing and/or eliminating postoperative airway events.

Proactive Use of Postoperative NPPV Therapy

The American Society of Anesthesiologists appointed a task force to review relevant literature and establish general guidelines for perioperative management of patients with OSA

(Gross et al., 2006; Gross et al., 2014). They developed and updated general management guidelines that include: establishing screening protocols, assuring physical examinations, and assigning patient's risk level and including postoperative designation (in-patient vs. outpatient). Guidelines promote the advising of patients to be compliant with home CPAP and to bring their devices with them the day of surgery. Guidelines also encourage placing patients in the non-supine position and using regional anesthesia for pain relief when possible. There was a lack of sufficient literature to support recommendations about use of opioids and oxygen use post-operatively. Continuous monitoring such as pulse oximetry was advocated as "effective in detecting hypoxemic events" (Gross et al., 2014, p. 273). However with the use of oxygen, hypoventilation or apnea events may be prolonged or missed. These basic guidelines for practice need to be understood and implemented consistently.

Additional modifications of these guidelines may be appropriate based upon individual patient risk, surgical type and duration. Some modifications might include having all OSA positive patients bring and use their home NPPV mask on admission to PACU as needed instead of waiting until they are discharged to step down units. Earlier use of NPPV appears to attenuate the effects of OSA and potentially reduce longer-term ventilatory complications.

NPPV therapy (BCPAP or other CPAP devices) could be initiated upon arrival in PACUs for those known to be at any risk for OSA. Finally, using monitors to measure ventilatory function could improve care. The RVM has been demonstrated in various populations to detect hypoventilation states (Ebert et al., 2015; Holley et al., 2016; Voscopoulos et al., 2014). The device can be used to detect respiratory depression and monitor for the effects of opioids and other medications that affect postoperative ventilatory patterns.

Standardized Use of RVM Monitor For At-Risk Populations

As there is a percentage of the surgical population with undiagnosed OSA (Finkel, et al., 2009) or the potential for OSA-related breathing problems, it may be prudent to see all patients as having an equal risk for airway obstruction. Implementing a standardized method of measuring ventilatory function may mitigate potential and actual airway events. The RVM is a noninvasive machine that measures changes in RR and TV to continuously calculate MV and can be used in the PACU setting to identify states of hypoventilation, effects of opioids or other medications, and changes in ventilatory patterns after interventions.

Practitioners should reduce/limit opioids in patients with known OSA and observe them more closely after each medication administration. By adjusting RVM alarms for RR and TV changes to identify low TV/RR in addition to a decline in MV, respiratory depression may be identified earlier. RVM alarms can be changed to notify a drop in MV at the $MV <_{pred}60\%$ instead of the preset $MV <_{pred}40\%$ or a decrease in RR at 12 vs. 10 breaths/min. This information may be used to adjust opioid administration, change analgesic types, including dosages and frequencies, and measure the effects of interventions aimed to improve ventilatory parameters.

The RVM can be implemented and used as a standard monitor in the PACU and inpatient settings. Newer software also aids in performing a universal calibration (Respiratory Motion Inc., 2017) to minimize time in setting up the device when needed. The monitor can display numerical data and graph trends to ease understanding of information, guide therapies and interventions. This is important for several reasons. First, individual responses to general anesthesia, medications, and interventions are present. Second, pulse oximetry has limitations in alerting RNs for hypoventilation, especially if supplemental oxygen is used. Finally, the RVM

provides direct, non-invasive feedback on interventions and therapies given, presenting continuous information to guide interventions in real-time.

Strategies for Earlier Identification of Hypoventilation

In this study, the RVM was found to have superior ability to detect states of hypoventilation over standard pulse oximetry readings. Only when oxygen therapy was discontinued did pulse oximetry begin to reflect ventilatory declines. Two implications are suggested from these findings. First, the RVM is a potentially important adjunct to standard monitors to measure RR, TV, and MV to alert PACU RNs and anesthesia providers of changes in patients' ventilatory status. The information can be used to adjust medications as stated previously as well as the monitor effects of interventions on ventilatory status.

Second, oxygen is a medication and its effects can be therapeutic as well as deleterious. One practice aim should be to minimize and ultimately wean oxygen flows off as soon as patients can maintain satisfactory oxygen saturation without supplemental oxygen. In this study, a significant negative association between “desaturation events to oxygen use” was demonstrated: Desaturation events matched hypoventilation events 46.8% of the time when no oxygen was used vs. 8.9% when supplemental oxygen was used. This may indicate that supplemental oxygen confounds or clouds real or potential hypoventilation/apnea states. Although no re-intubations or transfers to the ICU occurred, some participants who required NPPV therapy had delayed PACU discharges, and experienced periods of hypoventilation unknown to the RN. It seems prudent to reduce and discontinue oxygen therapy as soon as it is no longer indicated when devices that directly measure ventilatory function are not used. Pulse oximetry changes would then be better at alerting nurses of low oxygen saturations reflecting ventilatory depression.

Proactive use of NPPV Therapy

Despite a low number of total NPPV applications in this study, benefits of maintaining MV were noted. The benefit of improving MV was not statistically significant during the initial 15-minute application period. This implies that the effect takes longer than 15 minutes of therapy to achieve desired MV. Thus it may be prudent to apply NPPV immediately after extubation until the patient fully participates in their care and is without symptoms of respiratory depression.

If providers choose to use the BCPAP, flow rates of 25 liters/min will approximate 10cm H₂O. Instead of using high flow of oxygen, air can be used in the PACU as an alternative source to supply the mask pressure. This would decrease unnecessary use of oxygen and increase the effectiveness of using O₂ saturation as an indicator of respiratory depression. The use of patient's home CPAP can be initiated earlier as well, but may need coordination with respiratory therapy if additional oxygen is needed as it must be entrained into the supply line. Previous researchers have noted the benefit of immediate NPPV therapy after extubation (Laio et al., 2013; Gaszynski et al., 2007). It may be prudent to apply home or hospital-provided NPPV on arrival to the PACU after initial assessment by the RN is completed.

Implications for Nursing Education

The use of new technology requires training practitioners associated with its use. Nurses use assessment skills, standard monitors, and patients' responses to therapies to guide cares. Various monitors are used based upon patient's physical status and the types of surgical procedures performed. Providing instruction about the differences between ventilation and oxygenation as well as how to use data from RVMs will be required. While use of pulse oximetry can improve understanding of ventilatory status when oxygen is not used, most patients

are transferred to PACU with supplemental oxygen. Finally, pulse oximetry readings can be obscured by changes in patient's positioning, and temperature (Voepel-Lewis et al., 2013).

End-tidal CO₂ (capnography) monitoring is also beneficial in the PACU to observe patient's respiratory patterns but capnography also has limitations. Respiratory volumes are not calculated and higher oxygen flow rates can washout the sampling stream. If capnography is used, multi-port sampling lines are suggested (Hess & Kaczmarek, 2012) to reduce sampling error. For these reasons, nurses should not rely upon capnography alone to estimate ventilatory function. At-risk OSA patients may benefit from using capnography in addition to the RVM technology with a RN that understands how to use the data these devices provide.

Conclusions

This dissertation study explored the relationship of OSA severity on ventilatory outcomes after general anesthesia as well as the effects of non-invasive positive pressure ventilation in the PACU using an innovative non-invasive but direct-measuring respiratory volume monitor (RVM). The RVM was able to identify apnea and hypoventilation events in most cases before any decrease in pulse oximetry was observed. This supports an indication that this innovative technology should be studied further for implementation into clinical practice.

The processes of conducting this study have provided several insights for future research and practice. Some of the assumptions were confirmed during the data collection and statistical analyses of the findings. This included further support that pulse oximetry is a tool for measuring blood oxygenation saturation as a proxy measure for adequacy of patient ventilation. It has limited value when used to identify hypoventilation events in OSA patients, especially when supplemental oxygen is in use. Additionally, patients with or suspected of having OSA are at risk for postoperative ventilatory impairments including airway obstructions, desaturations,

and periods of hypoventilation that may lead to additional complications in the perioperative setting.

The frequencies of respiratory events were not significantly different between OSA assigned groups. This finding suggested that all patients should be managed in similar ways for identifying and reducing respiratory events. However, sample size for this study was relatively small and homogenous as it related to participant's BMI, surgical type and duration, and postoperative outcomes. Additional studies with larger and various populations, BMIs, and procedures are needed to increase the external validity and generalizability of these findings.

Routine postoperative monitors (pulse oximetry, and ECG respiratory leads) provided limited and indirect information about patients' ventilatory status when potential or real events occurred. PACU RNs are faced with a variety of challenges that compete for their attention. While collecting data, the researcher observed patients being admitted, stabilized, and discharged in a cyclical fashion. Often, after the RN gave opioids and other medications, or assessed the participant, they turned their attention to charting or to the care of other patients. The monitors that RNs used to alert them to changes in participant's ventilatory status were pulse oximetry, heart rate, and ECG respiratory leads. None of these monitors were able to calculate minute ventilation. If the RN was not directly viewing the patient, hypoventilation and obstructive states could and often did go unnoticed. This provided additional support for using RVM technology to continuously monitor and measure ventilatory states and alert clinicians to changes in ventilatory function, especially when their attention is on care of other patients.

The RVM alarms alert clinicians of hypoventilatory or apneic states and increase awareness of changes in patient's ventilatory status and provide digital feedback of ventilatory patterns from interventions initiated. This includes identification of hypoventilation patterns and

effects of interventions aimed to improve respiratory function in spontaneously breathing patients. The technologically advanced (RVM) monitor was used to compare ventilatory outcomes between OSA groups, and the effects of NPPV therapy on ventilation. To date, the RVM has not been incorporated for use in the perioperative setting for all patient populations. Data from the RVM alerted the principle investigator to apnea and hypoventilation in most cases before any decrease in pulse oximetry was seen. This supports the indication that this innovative technology should be studied further for adoption into clinical practice.

Effects of NPPV therapy on ventilation were observed and recorded for 15 participants. Despite the low number for statistical analysis ($n = 13$), insights were gained into the effects of both BCPAP and home CPAP application in the PACU. Future RCTs using this RVM technology to measure ventilatory states for different NPPV interventions have the potential to provide researchers with additional insights into best-practice strategies. Longer application times and data collection periods are needed to further explore NPPV benefits in the perioperative setting. Additionally, using the RVM with various surgical populations and settings would increase the generalizability of the findings. By performing additional research in these areas, insights into best practice strategies may be formed and provide a basis for universal approach to managing any “at risk” patient for OSA.

Finally, if insights gained from this study go unnoticed, or future research does not advance from these findings, anesthesia providers and PACU RNs may be providing care in an ineffective/reactive manner. It is essential that proactive methods for identifying and managing ventilation issues for OSA at-risk patients be implemented. Patients with co-existing diseases (including OSA) require additional attention from perioperative team members. Management strategies to mitigate potential and real problems during a patient’s perioperative stay need to be

in place and used. Future research is needed to develop efficient ways to identify which preoperative questions and patient characteristics may identify an OSA patient. On the other hand, it may be more efficient to see all patients as “at risk” and use RVM technology on everyone preemptively. Practice standards and clear plans for approaching the care and management of postoperative pain, hydration, oxygenation, and ventilation states in the perioperative period need to be continually modified to fit this unique patient population.

As suggested earlier, the use of NPPV during the PACU recovery period needs additional research to gain insights for practice standards to mitigate airway events in the OSA surgical population. By incorporating findings of this study, hypoventilation states may be identified more readily and proactive measures may be initiated earlier to reduce airway events and support ventilation. Additional research, including larger RCTs with various surgical populations should be implemented to support the findings of this dissertation study. Overall, findings gleaned from this dissertation may provide a path into future endeavors for improving healthcare management and delivery for the OSA patient during their perioperative experience.

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APPENDIX A: IRB APPROVAL LETTER



EAST CAROLINA UNIVERSITY
University & Medical Center Institutional Review Board
4N-64 Brody Medical Sciences Building· Mail Stop 682
600 Moye Boulevard · Greenville, NC 27834
Office **252-744-2914** · Fax **252-744-2284**
www.ecu.edu/ORIC/irb

Notification of Initial Approval: Expedited

From: Biomedical IRB
To: [Travis Chabo](#)
CC: [Ann Schreier](#)
Date: 6/21/2018
Re: [UMCIRB 17-000398](#)
Ventilatory changes and The Effects of NPPV therapy in Patients with OSA after Gastric Bypass Surgery

I am pleased to inform you that your Expedited Application was approved. Approval of the study and any consent form(s) is for the period of 6/20/2018 to 6/19/2019. The research study is eligible for review under expedited category #1,4,5,7. The Chairperson (or designee) deemed this study no more than minimal risk.

Changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. The investigator must submit a continuing review/closure application to the UMCIRB prior to the date of study expiration. The Investigator must adhere to all reporting requirements for this study.

Approved consent documents with the IRB approval date stamped on the document should be used to consent participants (consent documents with the IRB approval date stamp are found under the Documents tab in the study workspace).

The approval includes the following items:

Name	Description
Chabo IRB Dissertation Proposal	Study Protocol or Grant Application
Clinic Brochure	Recruitment Documents/Scripts
Informed Consent for Participating in Study	Consent Forms
IRB Research Protocol	Study Protocol or Grant Application
OSA and Bariatric Surgery Preoperative Data Sheet	Surveys and Questionnaires
Research Data Collection Sheets	Data Collection Sheet
STOP-Bang Questionnaire License Agreement	Surveys and Questionnaires
UMCIRB HIPAA Consent Form	HIPAA Authorization

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

APPENDIX B: ATTENDING PHYSICIAN SIGNATURE FORM



ATTENDING PHYSICIAN SIGNATURE FORM

Protocol Title: Postoperative Ventilation Patterns and the Effects of Non-invasive Positive Pressure Therapy on Ventilatory Changes as Measured by a Non-invasive Impedance Device in Patients with Obstructive Sleep Apnea

Principal Investigator Name: Travis L. Chabo MSN, CRNA PhD(c)

The following physicians acknowledge their willingness to participate in the above named research study, have read the protocol describing the study, and agree to allow their patients to participate.

Willie A. Coy *William Cheyne* *5/17/18*
Signature Print Date

W. May *Wade Nazari* *5-21-18*
Signature Print Date

APPENDIX C: STOP-BANG QUESTIONNAIRE

STOP-Bang Questionnaire

1. **Snoring:** Do you snore loudly (loud enough to be heard through closed doors)?
Yes No
2. **Tired:** Do you often feel tired, fatigued, or sleepy during daytime?
Yes No
3. **Observed:** Has anyone observed you stop breathing during your sleep?
Yes No
4. **Blood Pressure:** Do you have or are you being treated for high blood pressure?
Yes No
5. **BMI:** BMI more than 35 kg/m²?
Yes No
6. **Age:** Age over 50 years old?
Yes No
7. **Neck circumference:** Neck circumference greater than 40 cm?
Yes No
8. **Gender:** Male?
Yes No

(Chung et al., 2008)

APPENDIX D: MODIFIED ALDRETE SCORING SYSTEM FOR PACU DISCHARGE

Modified Aldrete Scoring System For PACU Discharge

Criteria	Patient status	Score
Activity	Able to move four extremities voluntarily on command	2
	Able to move two extremities on command	1
	Unable to move	0
Respiration	Able to deep breath and cough freely	2
	Dyspnea or limited breathing	1
	Apneic	0
Circulation	BP and HR \pm 20% of preanesthetic level	2
	BP and HR \pm 20% to 50% of preanesthetic level	1
	BP and HR \pm 50% of preanesthetic level	0
Consciousness	Fully awake (able to answer questions)	2
	Arousable on calling (arousable <i>only</i> to calling)	1
	Unresponsive	0
Oxygenation	Able to maintain O ₂ saturation >92% on room air	2
	Needs O ₂ inhalation to maintain saturation >92%	1
	O ₂ saturation <90% even with O ₂ supplement	0

Score of $\geq 9/10$ is needed to meet phase 1 discharge criteria



You are Invited to Participate in a Research Study

Purpose: To understand the effects of surgery and general anesthesia on breathing patterns of people with known or suspected obstructive sleep apnea. Results of the study may help improve patient outcomes and identify additional ways to monitor patients safely.

Who can participate? Individuals undergoing gastric bypass (Gastric Sleeve or Roux-en Y) surgery.

What you need to do? Briefly discuss your sleep and health history before surgery. After surgery your breathing patterns will be monitored with a portable monitor attached to you by electrodes and calibrated during surgery.

Where will it take place? In the surgical area and recovery room at the hospital the day of your surgery.

How long will it take? 10-15 minutes for questions and minimal time for placing electrodes. Monitoring will be performed in addition to standard monitors used in the recovery room.

You will be contacted in person the morning of your surgery to discuss the study in more detail. **If interested or have questions prior to your surgery date, please call Travis Chabo, MSN, CRNA, PhD Candidate at 252-744-6401.**

APPENDIX F: INFORMED CONSENT AND HIPPA FORMS



Informed Consent to Participate in Research
Information to consider before taking part in research that has no more than minimal risk.

Title of Research Study: Post-Operative Ventilation Patterns and The Effects of Non-Invasive Positive Pressure Therapy on Ventilatory Changes as Measured by a Non-Invasive Impedance Device in Patients with Obstructive Sleep Apnea

Principal Investigator: Travis L. Chabo, MSN, CRNA, PhD Candidate (Person in Charge of this Study)

Institution, Department or Division: East Carolina University, College of Nursing
Address: 3110 Health Science Building, Greenville NC, 27858
Telephone #: 252-744-6401

Participant Full Name: _____ **Date of Birth:** _____
Please PRINT clearly

Researchers at East Carolina University (ECU) and Vidant Medical Center study issues related to society, health problems, environmental problems, behavior problems and the human condition. To do this, we need the help of volunteers who are willing to take part in research.

Why am I being invited to take part in this research?

The purpose of this research is to...

- 1. Study the effects of surgery and general anesthesia on breathing patterns of people with known or suspected obstructive sleep apnea (OSA) in a recovery room setting.**
- 2. Use a monitor that measures breathing patterns to detect inadequate ventilation (breathing patterns) and relate it to obstructive sleep apnea severity.**
- 3. Determine if the use of FDA approved ventilation monitor (ExSpirom™) alerts nurses sooner than pulse oximetry changes when inadequate breathing is detected.**
- 4. Measure the changes in breathing before and after nurses and doctors assist patients to through interventions that support ventilation.**

You are being invited to take part in this research because the surgery you are having is performed under general anesthesia and in a population that are at a higher risk for postoperative breathing difficulties. People undergoing bariatric surgery are at an increased risk of being diagnosed or suspected of having obstructive sleep apnea (OSA).

The decision to take part in this research is yours to make. By doing this research, we hope to learn if you have a potential risk for ventilation problems after surgery, and if the results of your participation can help improve patient outcomes by measuring breathing patterns in a different way. If you volunteer to take part in this research, you will be one of about 50 people to do so.

Are there reasons I should not take part in this research?

I understand I should not volunteer for this study if I am, under 18 years of age, unable to give consent, or unwilling to wear electrodes that monitor chest movement during and after surgery, or have a severe allergy to adhesives (blisters/rash, etc.).

What other choices do I have if I do not take part in this research?

You can choose not to participate. You will receive the same standards of care regardless of your decision.

Where is the research going to take place and how long will it last?

The research will be conducted at Vidant Medical Center in the pre-operative holding area, the operating room, and in the recovery room (PACU). You will come in for surgery as regularly scheduled. You will receive final instructions and a copy of this consent the day of surgery. The total amount of time you will be asked to volunteer for this study is less than 1(one) hour.

What will I be asked to do?

You will meet with the principal investigator to discuss the research study and give consent to participate. The principal investigator will ask you questions to obtain your health history and conduct a sleep apnea questionnaire before surgery. The “STOP-Bang Questionnaire” is an 8 (eight) question survey that asks about your sleeping and breathing patterns. You will be asked other necessary questions that relate to your health and medical history; this should take less than 15 (fifteen) minutes to complete. By giving consent you allow the principle investigator to discuss your health care with your physician and review your medical records to gain additional information regarding your health history, to include but not limited to your height, weight, gender, medication history, previous sleep study information, and surgical information (medications, airway interventions, and length of surgery).

During your surgery, you will have 3 electrodes that similar to a heart monitor stickers placed on your chest and side. The electrodes will be attached to the respiratory monitor (ExSpirom™) and your breathing patterns measured from the monitor will be calibrated (compared to the anesthesia ventilator) before you awaken from anesthesia. The monitor will be with you in the recovery room. You will receive the same cares that all patients undergo after general anesthesia. Cares may include additional medication for pain relief, repositioning in bed, supplemental oxygen by nose, mouth, or mask, and/or breathing support from a positive pressure mask (CPAP or BiPAP) to support your breathing. After your recovery period the electrodes will be removed and you will be moved to an in-patient recovery room and receive standard postoperative cares.

The respiratory monitor readings will be compared to your other vital signs during your recovery to help answer the research purposes. The principal investigator will perform no additional tests. No audio or videotapes will be used during the research study. All paper documents will be transferred into an electronic database and/or stored in a locked cabinet behind a locked door in the principal investigators office. All protected health information (PHI) will be secured for future contact/follow-up, or for future research. After which time all PHI will be destroyed per the institutional review board policy.

What might I experience if I take part in the research?

We don't know of any risks (the chance of harm) associated with this research. Any risks that may occur with this research are no more than what you would experience in everyday life. We don't know if you will benefit from taking part in this study. There may not be any personal benefit to you but the information gained by doing this research may help others in the future.

Will I be paid for taking part in this research?

We will not be able to pay you for the time you volunteer while being in this study.

Will it cost me to take part in this research?

It will not cost you any money to be part of the research.

Who will know that I took part in this research and learn personal information about me?

ECU and the people and organizations listed below may know that you took part in this research and may see information about you that is normally kept private. With your permission, these people may use your private information to do this research:

- Any agency of the federal, state, or local government that regulates human research. This includes the Department of Health and Human Services (DHHS), the North Carolina Department of Health, and the Office for Human Research Protections.
- The University & Medical Center Institutional Review Board (UMCIRB) and its staff have responsibility for overseeing your welfare during this research and may need to see research records that identify you.
- People designated by **Vidant Medical Center and Southern Surgical Associates**
- If you are a patient at ECU or Vidant, a copy of the first page of this form will be placed in your medical records.

How will you keep the information you collect about me secure? How long will you keep it?

The Principal Investigator will have access to your electronic health record (EHR) to obtain pertinent health information used to measure and relate postoperative and operating room outcomes. Information will be stored on a secure and encrypted server approved by the IRB, ECU, and Vidant Medical Center. Your protected health information (PHI) (name, date of birth, address, phone number, medical record number (MRN) will be used to collect data. A copy of your consent and PHI will be stored in a lock box and on an encrypted server per the UMCIRB policy for six (6) years after study completion and reporting of research

findings. After which, your PHI will be erased/destroyed. Unidentifiable data may/will be used as a basis for additional research studies. You may be contacted within the three (3) year period for additional information or opportunities to participate in further research related to this study.

What if I decide I don't want to continue in this research?

You can stop at any time after it has already started. There will be no consequences if you stop and you will not be criticized. You will not lose any benefits that you normally receive.

Who should I contact if I have questions?

The people conducting this study will be able to answer any questions concerning this research, now or in the future. You may contact the Principal Investigator at 252-744-6401 (weekdays, 8:00 am-5:00 pm).

If you have questions about your rights as someone taking part in research, you may call the Office of Research Integrity & Compliance (ORIC) at phone number 252-744-2914 (days, 8:00 am-5:00 pm). If you would like to report a complaint or concern about this research study, you may call the Director of the ORIC, at 252-744-1971 and the Vidant Medical Center Risk Management Office at 252-847-5246.

I have decided I want to take part in this research. What should I do now?

The person obtaining informed consent will ask you to read the following and if you agree, you should sign this form:

- I have read (or had read to me) all of the above information.
- I have had an opportunity to ask questions about things in this research I did not understand and have received satisfactory answers.
- I know that I can stop taking part in this study at any time.
- By signing this informed consent form, I am not giving up any of my rights.
- I have been given a copy of this consent document, and it is mine to keep.

Participant's Name (PRINT)

Signature

Date

Principal Investigator: I have conducted the initial informed consent process. I have orally reviewed the contents of the consent document with the person who has signed above, and answered all of the person's questions about the research.

Principal Investigator (PRINT)

Signature

Date

UMCIRB HIPAA Privacy Authorization

East Carolina University (ECU)/Vidant Medical Center (VMC): Research Participant Authorization to Use and Disclose Protected Health Information for Research

For use only with the research consent form for UMCIRB#: 17-000398

Principal Investigator: Travis L. Chabo, MSN, CRNA, PhD Candidate

Title: Postoperative Ventilation Patterns and the Effects of Non-invasive Positive Pressure Therapy on Ventilatory Changes as Measured by a Non-invasive Impedance Device in Patients with Obstructive Sleep Apnea

Location where research will be conducted

The members of the research team will conduct the research study at:

East Carolina University (ECU) VMC ECU & VMC Other

When taking part in research, protected health information (PHI) is collected, used, and shared with others who are involved in the research. Federal laws require that researchers and health care providers protect your PHI. Also, federal laws require that we get your permission to use collected PHI for the research. This permission is called authorization.

In order to complete the research project in which you have decided to take part, the research team needs to collect and use some of your PHI as described below.

What types of protected health information (PHI) about me will be used or disclosed?

(Select all that apply.)

ECU Health Care Component:

- ECU Physicians
- School of Dental Medicine
- Speech, Language, and Hearing Clinic
- Human Performance Lab
- Physical Therapy
- Student Health
- Other ECU Health Entity

(please list): ECU College of Nursing

Vidant Health Entity:

- Entire Vidant Health system
 - Vidant Medical Center
 - Other Vidant Health Entity
- (please list):

Type of ECU Records:

- Medical/clinic records
- Billing records
- Lab, Pathology and/or Radiology results

- Mental Health records
- PHI previously collected for research
- Records generated during this study
- Other:

Type of Vidant Records:

- Medical/clinic records
- Billing records
- Lab, Pathology and/or Radiology results
- Mental Health records
- PHI previously collected for research
- Records generated during this study
- Other: Southern Surgical Associates

Who will use or disclose my PHI?

- Principal Investigator
- Other members of the research team
- Other providers involved in your care during research procedures, outpatient/inpatient stays during which research is being performed, or physician office visits during which research is being performed.

Who will receive my PHI?

- Sponsor or other funding source to provide oversight for entire research project
- Research investigators to conduct and oversee the research project
- Principle Investigator and research team members to participate in the various research activities
- FDA or other regulatory agencies to provide regulatory oversight
- UMCIRB to provide continuing review of the research project
- Institutional officials in connection with duties for monitoring research activity
- Other providers involved in your care during research procedures, outpatient/inpatient stays during which research is being performed, or physician office visits during which research is being performed.
- Researchers at other sites—List sites:
- Data and Safety Monitoring Board and its staff
- Contract Research Organization and its staff
- Other

We will share only the PHI listed above with the individuals/agencies listed above. If we need to share other PHI or if we need to send PHI to other individuals/agencies not listed above, we will ask for your permission in writing again

How my PHI may be released to others:

ECU and VMC are required under law to protect your PHI. However, those individuals or agencies who receive your PHI may not be required by the Federal privacy laws to protect it and may share your PHI with others without your permission, if permitted by the laws governing them.

What if I do not sign this form?

You will not be eligible to participate in this study if you do not sign this Authorization form.

How may I revoke (take back) my authorization?

You have the right to stop sharing your PHI. To revoke (or take back) your authorization, you must give the Principal Investigator your request to revoke (or take back) your authorization in writing. If you request that we stop collecting your PHI for the study, you may be removed from the study. If you are removed from the study, it will not affect your ability to receive standard medical care or affect payment, health plan enrollment or benefit eligibility. PHI collected for the research study prior to revoking (or taking back) your Authorization will continue to be used for the purposes of the research

study. Also, the FDA (if involved with your study) can look at your PHI related to the study even if you withdraw this authorization.

Restrictions on access to my PHI:

You will not be able to see your PHI in your medical record related to this study until the study is complete. If it is necessary for your care, your PHI will be provided to you or your physician.

How long may the PHI about me be used or disclosed for this study?

Research information continues to be looked at after the study is finished so it is difficult to say when use of your PHI will stop. There is not an expiration date for this authorization to use and disclose your PHI for this study.

If you have questions about the sharing of PHI related to this research study, call the principal investigator Travis L. Chabo at phone number 252-744-6401. Also, you may telephone the University and Medical Center Institutional Review Board at 252-744-2914. In addition, if you have concerns about confidentiality and privacy rights, you may phone the Privacy Officer at Vidant Medical Center at 252-847-3310 or the Privacy Officer at East Carolina University at 252-744-5200.

Authorization

To authorize the use and disclosure of your PHI for this study in the way that has been described in this form, please sign below and date when you signed this form. A signed copy of this Authorization will be given to you for your records.

Name of Participant or Authorized Representative (print)	Signature	Date
---	------------------	-------------

If an Authorized Representative has signed on behalf of a Participant please print on the line above the authority of the Legal Representative to do so (*such as parent, court-appointed guardian, or power of attorney*).

Person Obtaining Authorization	Signature	Date
---------------------------------------	------------------	-------------

APPENDIX G: OSA AND BARIATRIC SURGERY PREOPERATIVE DATA SHEET

OSA And Bariatric Surgery Preoperative Data Sheet

Name: _____ Surgery Date: _____ ID#: _____

Surgery Type: (GS): _____ (RY): _____

Participant Demographics

Age (years): _____ Gender (M): _____ (F): _____ Height (cm): _____ Weight (kg): _____ BMI: _____

Ethnicity (check one):

Hispanic or Latino: _____ Not Hispanic or Latino: _____ Unknown: _____

Race (check one):

American Indian/Alaskan Native: _____ Asian: _____ Hawaiian/Pacific Islander: _____

Black or African American: _____ White/Caucasian: _____ Hispanic/Latino: _____

Other: _____

Health History (check if yes)

Hypertension: _____

COPD: _____

Atrial Fibrillation: _____

Orthopnea (>1 pillow at night): _____

Diabetes Mellitus: _____

Dyspnea on Exertion: _____

Asthma: _____

Home Oxygen use: _____

Labs

Serum Bicarbonate (mEq/L): _____

Hemoglobin (g/dL): _____

ID#: _____

STOP-Bang Questionnaire (Chung et al., 2008) (Check of yes)

1. Snoring: Do you snore loudly (loud enough to be heard through closed doors)? _____
2. Tired: Do you often feel tired, fatigued, or sleepy during daytime? _____
3. Observed: Has anyone observed you stop breathing during your sleep? _____
4. Blood Pressure: Do you have or are you being treated for high BP? _____
5. BMI: BMI more than 35 kg/m²? _____
6. Age: Age over 50 years old? _____
7. Neck circumference: Neck circumference greater than 40 cm? _____
8. Gender: Male? _____

Obstructive Sleep Apnea History

STOP-Bang Score (#): _____

AHI Score (#): _____

Neck Circumference (cm): _____

Epworth Sleepiness Score (#): _____

Formal OSA History (check if yes): _____

NPPV Type (check one)

BiPAP: _____ CPAP: _____

Home NPPV Use greater than 4hrs/night (check if yes): _____

Home NPPV Pressure Setting (cm H₂O)

CPAP: _____ BiPAP: _____/_____

Assigned OSA Group Based on STOP-Bang Score (Mild, 1-3; Moderate/Severe, 4-8)

(1-Mild, 2-Moderate/Severe): _____

APPENDIX H: OSA AND BARIATRIC SX PERIOPERATIVE DATA SHEET

OSA and Bariatric Sx Perioperative Data Sheet

Name: _____

Sx Date: _____

ID: _____

Perioperative Times

Surgery Start	
Surgery Finish	
Total Anesthesia Time	
PACU Admission Time	
PACU Discharge Time	
Total PACU Minutes	

Post Extuabtion Support

Y/N

Nasal Cannula	
Oxygen Flow (liters/min)	
Oropharyngreal Airway	
Nasopharyngea Airway	
Face Mask Oxygen flow	
Boussignac CPAP	

Intraoperative Medications

Medication	Y/N	Total in OR
Midazolam (mg)		
Fentanyl (mcg)		
Sufenta (mcg)		
Remifentanil (mcg)		
Morphine (mg)		
Dilaudid (mg)		
Ketamine (mg)		
Demerol (mg)		

PACU Opioid Medications

Medication	Dose	Time

Intraoperative Neuromuscular Blocking Antagonists, Opioid Antagonist, and Benzodiazepine Antagonist Given (Check if Yes)

Neostigmine
 Suggamadex

Naloxone
 Romazicon

APPENDIX I: POSTOPERATIVE EVENT AND VITAL SIGNS LOG

OSA and Bariatric Sx Postoperative Event & Vital Signs Log

Name: _____ Date: _____ RVM Used: _____

Vital Signs

Time	Vital Sign ✓	MV	SPO2	HR	RR	Tidal V.	NIBP
	Admission						
	5 minutes						
	10 minutes						
	15 minutes						
	20 minutes						
	25 minutes						
	30 minutes						
	35 minutes						
	40 minutes						
	45 minutes						

CPAP Therapy Log

Time	CPAP	MV	SPO2	HR	RR	Tidal V.	NIBP
	ON						
	1 min use						
	5 min use						
	15 min use						
	Off						
	Off 1 min						
	Off 5 min						
	Off 15 min						

Ventilation Status Log

Time	Respiratory Event	MV	RR	SPO2	O2 Flow	O2 source

Notes: "Respiratory Event" includes MV reading <pred40% rate (Low MV), SpO2 Alarm 90-93% (mild desat) <90% (severe desat) and O2 intervention (CPAP on/off; O2 Change/on/off)



Postoperative OSA Research Study Summary

Purpose: To observe the effects of surgery and general anesthesia on postoperative ventilatory patterns of known or suspected OSA patients after gastric bypass surgery using non-invasive impedance technology.

Participants: Individual patients of Southern Surgical Physicians undergoing gastric bypass (Gastric Sleeve or Roux-en Y) surgery.

Process:

1. Participants will be screened and consented prior to surgery.
2. At the completion of the participant's surgery, but before extubation, the ExSpiron™ monitor and disposable padset will be applied to the participant. The monitor will be calibrated to the anesthesia ventilator prior to extubation.
3. The monitor will be transported with the participant to the PACU and used to continuously monitor ventilatory patterns.
4. The PI will record ventilatory patterns and vitals signs for analyses as well as timing, duration, and effects of NPPV therapy when used during the PACU period.

How can you help? **Anesthesia providers** please assist in calibration of the ExSpiron™ in the OR to the ventilator and take the machine connected to the patient to the PACU. No changes to the anesthetic plan are needed. **PACU RNs** continue providing standard nursing cares, please keep electrodes on during the PACU period for data collection.

If you have any questions regarding the research study please see the PI: Travis Chabo, MSN, CRNA, PhD Candidate or call 740-202-0187.

Thank you!

