2018

Assessing Baseline and Post-Discharge Risk Factors in Subjects with and without Sleep Apnea Undergoing Endoscopy with Deep Sedation

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A dissertation submitted in partial fulfillment of the requirements for the degree of

Doctor of Philosophy at Virginia Commonwealth University.

by

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December, 2018

DEDICATION

This dissertation is dedicated to my parents who have inspired and helped me in all things. Thank you for encouraging me throughout every step of this journey to never give up.

ACKNOWLEDGMENTS

The culmination of this work would not have been possible without the financial support of an American Association of Nurse Anesthetists (AANA) Foundation Grant, and generous scholarships from Virginia Commonwealth University (VCU) School of Allied Health Professions.

I am indeed grateful to all of those who have provided guidance on this journey especially my teachers and administrative staff of VCU's School of Allied Health Professions Doctoral Program (Drs Paula Kupstas, George Cavanos, Ernie Steidle, Henry Carreta, James Cotter and Diane Dodd-McCue, as well as Jeff Lodge, Jerry Clarke and our "Den mother" Monica White.

I am particularly proud of the distinguished individuals that served on my committee. I would especially like to thank my advisor Dr. Chuck Biddle for expertly guiding and keeping me on task throughout this entire research project. Dr. Carey, it was a pleasure to have the opportunity to be mentored by you again. Special thanks to Dean Drain, Drs. Corey Davis and Lemont Kier who made time to ensure my passage across the finish line.

Special appreciation to my statistic consultants Dr. Brad Verhulst and Dillon Dzikowicz. Your input was immeasurable and priceless. Thanks also for essential formatting and editing assistance from Statistics Solutions.

To my endearing project participants, volunteer research assistants (Noemi Meneses CRNA and Michael Tarrau CRNA to be) family members (brothers in law, sisters, Marchelle, cousins, niece (Keava my oral defense coach), nephew (Myles my PowerPoint consultant) to colleagues, friends at work, school (my cohort who kept me sane), and church (Pierre Thompson, Drs Roberts et.al) who helped in innumerable ways while cheering me on: a heartfelt thank you.

Thanks to my two wonderful sons, Derrick and Jonathan Hall who have made significant sacrifices as I pursued these educational goals. You have both provided unending inspiration. I look forward to spending more life with you.

Finally, I would like to thank my parents, Meremoth and Beatrice Weir who have always supported, prayed for and believed in me. Thank you for your unwavering support and example of excellence in service, scholarship and life-long learning.

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ABSTRACT

ASSESSING BASELINE AND POST-DISCHARGE RISK FACTORS IN SUBJECTS WITH AND WITHOUT SLEEP APNEA UNDERGOING ENDOSCOPY WITH DEEP SEDATION

Background: Outpatient procedures encompass over 60% of all surgeries in the United States, and the prevalence of obstructive sleep apnea (OSA) remains high among adult surgical ambulatory patients. Ambulatory surgery poses problems for patients with OSA because narcotics and anesthetics used during surgery can complicate the negative effects of OSA, leading to cardiac events, brain hypoxia, and even death. This study was designed to evaluate the prevalence of cardiopulmonary risk factors among post endoscopic patients with diagnosed and undiagnosed sleep apnea. Methods: The study involved a prospective, descriptive cross-sectional design and incorporated a pre-test or post-test data collection approach, using Actigraphy, pulse oximetry and 24-hour ECG monitoring via Bluetooth technology to monitor outpatients undergoing endoscopy with deep Propofol sedation. Patients were recruited pre-procedure to obtain a resting baseline ECG, and pre-procedure values were then monitored post procedure continuously for 24 hours. A p-value less than 0.05 was considered to be statistically significant. A target sample included 50 adult outpatients from a Florida suburban endoscopy center. Results: Pulse oximetry and Actigraph scores revealed no difference based on OSA. The ANOVA for oxygen desaturation events and sleep quality indices reflected no differences across groups. Sleep quality had no measurable influence on adverse events and was similar across groups; participants diagnosed with OSA slept longer than those in the untreated or no OSA group. Regressions for sleep quality indices reflected no differences among groups. Conclusions: There remains a lack of literature on cardiopulmonary and ECG indicators of cardiac risks in patients with OSA in the 24 hours following discharge from ambulatory surgery. This

dissertation characterized the ECG at baseline and post-discharge among post-endoscopy outpatients with OSA and without OSA. Further research is recommended.

Chapter 1: The Problem

Introduction

Background of the Problem

Sleep disordered breathing refers to the entire spectrum of sleep-related breathing abnormalities including upper airway resistance syndrome with and without snoring, central sleep apnea, and obstructive sleep apnea (OSA; Garcha, Aboussouan, & Minai, 2013). OSA is a sleep disorder that involves intermittent or complete obstruction of the airway during sleep (Garcha et al., 2013). OSA is associated with several negative consequences including cardiovascular disorders, neurocognitive dysfunctions, and metabolic dysfunction, and exists in an estimated 3 to 7.5% of the population of the United States (Mador, 2013). The prevalence of OSA is increasing in the general population and remains high among adult surgical patients, including patients of ambulatory surgery (Joshi, Ankichetty, Gan, & Chun, 2012; Mador, 2013; Singh, Liao, & Kobah, 2013). Benumof (2016) urged anesthetists to effect immediate change by addressing OSA in surgical patients because of the high risk of adverse outcomes and death. The current study represents an answer to that call and was designed to examine the clinical and ECG risk factors of cardiac risks in OSA patients in the 24 hours immediately following discharge from ambulatory surgery.

Ambulatory surgery refers to any surgical procedure that allows the patient to go home the same day (Hall, Schwartzman, Zhang, & Liu, 2017). The number of ambulatory surgeries

performed nationwide in hospital outpatient departments or freestanding ambulatory centers has grown exponentially from 3.7 million to over 48 million in the period spanning 1981 to 2010 (Hall et al., 2017). Outpatient procedures encompassed over 60% of all surgeries in the United States in 2011, as compared to 19% in 1981(American Hospital Association, 2014).

Ambulatory surgery can pose serious problems for patients with OSA because sedatives and anesthesia used during surgery may complicate and compound the negative effects of OSA, leading to cardiac events, brain hypoxia, and even death (Joshi et al., 2012; Mador, 2013). The possibility of these adverse events poses unique risks to ambulatory surgery patients because post-operative patients are released into settings lacking skilled nursing care (Kent, Metzner, & Bollag, 2014). Although studies focused on post-operative recovery of outpatients with OSA in hospital settings are beginning to emerge, few researchers have monitored and studied the post-operative recovery of outpatients with OSA in patients' homes (cf. Biddle et al., 2016). There is still scarce information on the negative consequences for ambulatory surgery patients at home in the immediate post-operative period and particularly for those patients with undiagnosed moderate to severe OSA.

Statement of the Problem

There are an increasing number of ambulatory surgeries, such as endoscopic procedures, as well as an increasing number of patients with OSA undergoing surgery in ambulatory settings (Hall et al., 2017; Joshi et al., 2012). Information on the negative consequences for ambulatory surgery patients and particularly those with OSA shortly after being discharged from ambulatory surgery was scarce. It is important that patients who have diabetes, hypertension, coronary artery disease, or pulmonary disease be adequately assessed and prepared based on the needs of their

conditions before surgery. The current study helped identify whether selected patients with OSA risk factors require special care prior to and after their procedures.

Purpose of the Study

The purpose of this study was to assess the prevalence of patient risk factors for cardiopulmonary adverse events in a diverse range of patients presenting for outpatient endoscopy under deep propofol sedation, and to determine the relative risk of adverse cardiopulmonary events occurring in the first 24-hours post-procedure following deep propofol sedation for endoscopy in patients with or without OSA. The proposed study was designed to evaluate the prevalence of cardiopulmonary risk factors among post endoscopic patients with diagnosed and undiagnosed sleep apnea. In doing so, the study made a meaningful contribution to the literature regarding the outcomes and management of patients with undiagnosed and untreated OSA in the Ambulatory Surgery Center (ASC) environment. It further helped to define the associated risks and inform decisions outlining care for ASC patients. For instance, diagnosing sleep apnea and prescribing continuous positive airway pressure (CPAP) therapy, prior to surgery, significantly reduced postoperative cardiovascular complications, specifically cardiac arrest and shock, by more than half (Mutter, Chateau, & Moffatt, 2014). This study provided additional data for future projects on ensuring preoperative preparedness and postoperative monitoring, while triggering identification and risk amelioration in this burgeoning population of patients.

Rationale and Theoretical Framework

According to the Centers for Disease Control and Prevention, the rate of sleep disorders has reached epidemic proportions, affecting 1 in 3 American adults (Liu et al., 2014). Sleep disorders and OSA are associated with adverse events ranging from loss of productivity to

increased risk of cardiopulmonary illness and related death (Gami et al., 2013). The National Center on Sleep Disorders Research, a subsidiary of the National Heart, Lung, and Blood Institute within the National Institutes of Health, was established in 1993 to address this serious public health concern. The most current NIH Sleep Disorders Research Plan was released in 2011, with the overall goal of better understanding sleep disorders and circadian biology to develop therapies that will make a significant impact on this serious public health epidemic (National Center on Sleep Disorders Research, 2011). With OSA in epidemic proportions, greater research is needed on OSA among ambulatory surgery patients released from clinical settings within 24-hours post-procedure.

Almost two decades since the U.S. Institute of Medicine report, *To Err Is Human* (1999), most errors in patient care are still caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them. As many as 25% of patients undergoing surgery have OSA, but few hospitals or ASCs have policies that address the risks of this condition during the perioperative period, and fewer follow recommended consensus statements (Joshi et al., 2012). How patients with OSA are identified, determined suitable for ambulatory surgery, and discharged after ambulatory surgery represents a trajectory of problems inherent within the system that can lead to potential patient harm (Joshi et al., 2012). Not considering the needs of patients with OSA in ASC settings and the possible associated cardiac sequelae represents a latent risk factor that can be mitigated by information generated by this study.

Reason (2000) studied error management in clinical settings and developed the Swiss Cheese Model (SCM) that holds that most errors or accidents are caused not so much by inevitable human mistakes, but rather by an organization's incomplete layers of error protection that allow errors to pass through unchecked on their way to causing harm. These layers of

protection are like slices of Swiss cheese with gaps that may allow errors to pass through unchecked on their way to causing harm. Holes in the SCM represent gaps in organizational defenses. However, unlike holes in real Swiss cheese, these holes are dynamic. They open, close, and change location over time. Holes in these layers of protection happen for two reasons: active failures and latent conditions (Reason, 2000).

Active failures involve problematic acts committed by those in direct contact with patients or the system, and they take several forms (e.g., lapses, slips, mistakes, and procedural violations; Reason, 2000). Latent conditions refer to inevitable problems inherent within the system that arise from the decisions of procedure architects, upper level management, and designers (Reason, 2000). Holes in any one layer of protection may lead to errors that usually do not result in negative outcomes. Latent conditions may allow holes to align to permit a trajectory of accident opportunity, potentially bringing hazard or harm to the patient or system. The trajectory path will show that errors result from holes in multiple layers of safeguards (Reason, 2000).

This study is innovative because, to date, no researchers have reported both the clinical (e.g., actigraphy, pulse oximetry, anthropometric parameters, etc.) and electrocardiographic (ECG) indicators of cardiac risks that occur in this group of patients, particularly in the 24 hours immediately following discharge from ambulatory surgery (Rotenberg, 2013). Amidst this dearth of scientific evidence, organizations concerned with patient safety, such as the American Society of Anesthesiologists, have recommended that patients with OSA be observed for extended periods of time and routinely receive CPAP (Joshi et al., 2012). Lack of clinical and ECG indicators of cardiac risks in patients with OSA in the 24 hours immediately following discharge from ambulatory surgery may represent a gap in healthcare that may lead to adverse patient

outcomes. An innovative approach is necessary to report the clinical and ECG risk factors of cardiac risks that occur in OSA patients in the 24 hours immediately following discharge from ambulatory surgery.

Some institutions require that certain populations of patients with OSA who have received particular narcotics be held overnight and not undergo surgery in ASCs (Rotenberg, 2013). Healthcare providers are rightfully concerned about the increased risk of adverse events for OSA patients. Holding patients overnight may prove to be unnecessary and is inconsistently practiced (Memtsoudis & Stundner, 2014). The current study was designed to examine the clinical and ECG risk factors of cardiac risks in OSA patients in the 24 hours immediately following discharge from ambulatory surgery.

Design and Methods

Within this study, the researcher assessed the relationship between cardiac risk factors and OSA 24 hours before and after sedation. Data was collected before and after the treatment was administered. The study utilized a pre/post-procedure, prospective, descriptive cross-sectional design. The primary goal of this study was to assess the baseline and post-discharge clinical and ECG risk factors of cardiac risk among post-endoscopy outpatients during the 24 hours before and following discharge from the ASC. The participants received deep Propofol sedation during their procedure. This study aimed to determine whether participants with undiagnosed or untreated OSA have a higher risk of potentially fatal cardiac or respiratory events compared to patients using appropriate treatment for OSA (i.e., dental appliance, CPAP, and patients who do not have OSA.

Research Questions

The following research questions guide the study: RQ1: What is the prevalence of known ECG characteristics for cardiac events among pre-endoscopic patients with high and normal STOP-bang scores on resting 12-lead ECGs clinical (pulse oximetry and actigraph derived sleep quality scores) and ECG characteristics of cardiopulmonary risk in post-endoscopy outpatients with undiagnosed or untreated OSA, post-endoscopy outpatients receiving treatment for OSA, and post-endoscopy patients without OSA?

The variables included in the study for Research Question 1 were clinical (pulse oximetry and actigraph derived sleep quality scores) and ECG risk factors of cardiac risk. The researcher conducted descriptive statistics to address Research Question 1. Descriptive statistics were used to represent the prevalence of clinical (pulse oximetry and actigraph derived sleep quality scores), ECG risk factors and participant group: post-endoscopy outpatients with undiagnosed or untreated OSA, post-endoscopy outpatients receiving treatment for OSA, and post-endoscopy patients without OSA.

RQ2: Among post-endoscopic patients receiving propofol, using a rhythm event recorder (BodyGuardian Heart) are there statistically significant differences in the frequency of oxygen desaturation events and tachy-brady-arrhythmias over 24 hours between outpatients with undiagnosed or untreated OSA, and post-endoscopy patients with and without a medical diagnosis of OSA?

The researcher conducted analyses of variance (ANOVA) tests for Research Question 2. For Research Question 2, the dependent variables are ECG and pulse oximetry. These dependent variables were compared among three groups of participants: post-endoscopy outpatients with

undiagnosed or untreated OSA, post-endoscopy outpatients with a medical diagnosis of OSA who are using CPAP, and post-endoscopy patients without OSA.

RQ3: Among pre-endoscopic patients receiving propofol, using a resting 12-lead ECG, are there statistically significant differences in the duration of resting heart rate, QRS duration, QTC duration and ST segment deviation between outpatients with undiagnosed or untreated OSA, and post-endoscopy patients with and without a medical diagnosis of OSA?

For Research Questions 3, the researcher conducted binary logistic regression to assess the amount of explained variance between sleep efficiency and cardiac adverse outcomes. Cardiac adverse outcomes were defined as the presence of bradycardia and tachycardia. The variables of interest for Research Question 3 are sleep quality and number of adverse events.

RQ4: Does sleep quality influence pulse oximetry readings? The variables of interest for Research Question 4 are sleep quality and pulse oximetry readings this relationship was assessed using regression analyses.

Clinical factors were operationalized as observations related to anthropomorphic measurements, oximetry results, and sleep during the data collection process. Cardiopulmonary risk factors comprised the 11 outcomes related to healthy cardiac function. An adverse event was defined as any negative medical occurrence following the use of Propofol sedation, regardless of its explicit connection to Propofol. Examples of adverse events would be decreased respiratory effort that resulted in sustained oxygen desaturations below 90% on room air or aggravation of or new onset arrhythmias. If the adverse event was deemed acutely detrimental, the participant was instructed to follow-up with their primary care physician. If the adverse event was not considered detrimental, no follow up steps were recommended. Sleep quality was operationalized as the sleep efficiency score from actigraphy.

The findings from the first research question addressed the dearth of literature related to the prevalence of clinical and ECG risk factors of cardiac risk in this burgeoning population of patients. Findings from the second research question provided information related to whether outpatients with undiagnosed OSA who receive sedation are subject to increased cardiac risk as determined by the presence of tachy-brady arrhythmias obtained from cardiac monitoring. The remaining questions regarding sleep quality were addressed by data retrieved from the actigraph watch and analyzed with the accompanying Action4 software package. Table 1 lists cardiopulmonary risk factors comprised the 11 outcomes related to healthy cardiac function.

Table 1: *Cardiopulmonary Risk Factors*

Variable	Definition	Variable Type	Cutoff for Cardiac Events	Clinical Significance
HR	Mean R-R interval of all QRS complexes during the duration of the recording	Continuous	> 75 beats per minute (Jouven et al.)	Poor sympathetic tone
QRS duration	Mean QRS onset to offset duration of all leads on the standard 10-s ECG	Continuous	>120 ms (Goldberger et al.)	Abnormal conduction/myocardial damage
QT_c Interval	Mean QRS onset to T offset interval of all leads on the standard 10-s ECG corrected for HR using Bazett formula	Continuous	> 470 ms (women) or >450 ms (men) (Straus et al.)	Abnormal global repolarization
LVH	The presence of this pattern on the standard 10-s ECG using Cornell voltage criteria	Continuous	>20 mm (women) or > 23 mm (Priori et al.)	Myocardial strain
LBBB	The presence of this pattern on the standard 10-s ECG using AHA criteria	Dichotomous	Present (Surawicz et al.)	Abnormal conduction/myocardial damage
fQRS	RSR morphology > 2 R' or notching in the nadir of S wave with a narrow QRS (<120ms) or > 2 R' or notching in the nadir of S wave with a widened QRS	Dichotomous	Present (Das et al.)	Myocardial scarring
ST event	The presence of at least 1 episode of ST depression of >0.5 mm in leads V2-V3 or > 1 mm in all other leads in > or = 2 contiguous leads for at least 5 min at any time	Dichotomous	Present (Holmvang et al.)	Transient myocardial ischemia
PVC	The presence of frequent premature ventricular contractions at rate of > or = 10 per hour for the duration of Holter recording.	Dichotomous	Present (Goldberger et al.)	Vulnerability to fatal arrhythmia
NSVT	At least 1 episode of > or = 3 consecutive ventricular beats at a rate of > 120 beats per minute	Dichotomous	Present (Goldberger et al.)	Vulnerability to fatal arrhythmia
Hypoxia	Pulse oximeter reading < or = 90 percent	Dichotomous	Present (Cintra et al.)	Vulnerability to fatal arrhythmia
OSA Sleep Efficiency	The intermittent cessation of breathing Ratio of total time spent asleep in a night compared to total time spent in bed.	Continuous Continuous	STOP-BANG > 3 > **85%**	Vulnerability to arrhythmia Vulnerability to arrhythmia

Note. Abbreviations: fQRS, fragmented QRS complex; HRV, HR variability; LBBB, Left bundle branch block; LVH, left ventricular hypertrophy; PVC, premature ventricular contraction; QTc, corrected QT interval, OSA; obstructive sleep apnea.

Importance of the Study

Despite the numerous advancements in our understanding of the pathogenesis and clinical consequences of this disorder, a majority of those affected remain undiagnosed (Peppard, Young, & Barnet, 2013). The continued prevalence of OSA combined with obesity trends and hypertension puts the population at serious risk of mortality and morbidity. The lack of information on the clinical and ECG risk factors of cardiac risks that occur in OSA patients within the 24 hours immediately following discharge from ambulatory surgery may represent a structural shortcoming in healthcare leading to adverse patient outcomes (Reason, 2000).

As is reflective of the dearth in epidemiological sleep studies, recent evaluations of the risks associated with undiagnosed moderate to severe OSA in surgical populations needs to be determined, but previous estimates show that OSA is more prevalent among surgical patients than in the general population (Singh et al., 2013). Further, there is a higher rate of perioperative complications in those with OSA compared to those without OSA (Peppard et al., 2013). ASCs offer patients the convenience of having surgical procedures performed outside of main hospital settings. The increased demand for these services, and the fact that over 10 million gastrointestinal (GI) endoscopic procedures are performed each year in the United States, suggests that hospitals and health care facilities must proactively manage the safety and economic implications of OSA patients (Joseph et al., 2016).

Adverse in-hospital events for all ASC patients are less than 1%, with major morbidity occurring with a frequency of approximately 0.1% (Kent et al., 2014). There is a void in the literature regarding the consequences for OSA patients in the first 24 hours at home after discharge from the ASC. The long-term adverse effects of OSA on health outcomes are well documented, while effects in the perioperative arena have only recently been systematically

assessed (Kaw, Pasupuleti, Walker, Ramaswamy, & Foldvary-Schafer, 2012; Mutter, Chateau, & Moffatt, 2014; Peppard et al., 2013). To date there are no published studies that have included systematic, in-home cardiopulmonary monitoring (e.g., Actigraphy, electrocardiogram, pulse oximetry) of patients after discharge from ASCs.

The present study involves an innovative approach, and patients were monitored for 24 hours in their homes before their procedure and following ASC discharge. The Cardiac monitor was worn optimally overnight post procedure for up to 24 hours, as it is clinically important to evaluate at least 24 hours of cardiac monitor data because there is greater risk for adverse events in the first 24 hours (Zimetbaum & Goldman, 2010). The prevalence of OSA among candidates for elective endoscopies and colonoscopies is estimated to be greater than 40% largely due to the high rate of coexisting diseases such as obesity, hypertension, pulmonary disorders, and diabetes, as well as a high number of patients over the age of 50 years (Boese, Ransom, Roadfuss, Todd, & McGuire, 2014).

Assumptions

The main assumption of this study was that ambulatory surgery patients, particularly those with undiagnosed sleep apnea, are especially vulnerable to cardiopulmonary peril once released from the immediate postoperative period in the post-anesthesia care unit (PACU) to their homes.

Limitations

This convenience sample itself was a limitation because it was not as representative as a random sample. Even though this study was limited to a convenience sample of endoscopy patients, it may still be representative of ambulatory surgery outpatients since endoscopy patients represent the largest proportion of ambulatory surgeries. Because of requirements and procedures

specific to other types of ambulatory procedures, results may not generalize well to patients undergoing ambulatory surgeries other than endoscopies. Additionally, another limitation to generalizability is that propofol is not standard for all ambulatory procedures, and the effects of other anesthesia on OSA patient's post-procedure may differ from those of propofol.

Scope and Delimitations

This study was designed to measure the relationship between cardiac risk and OSA 24 hours pre- and 24 hours post-sedation, with data being collected before and after the treatment is administered, using a pre/post-test, cross-sectional design. This study focused on the description of cardiopulmonary risks that may be encountered in ambulatory endoscopy patients, as monitored by pulse oximetry, cardiac monitor and actigraph. While some findings may be useful in the care of other categories of ambulatory patients, this study was not designed to examine the cardiopulmonary risks that may be observed in other outpatient populations such as other popular categories of ambulatory surgery, including orthopedic surgery and eye surgery.

Summary

OSA is a public health crisis and an acknowledged epidemic. The burgeoning obesity epidemic with the accompanying demand for cost-effective, efficient, and safe ambulatory surgeries demand that health care professionals and anesthetists take responsibility for the safety of patients beyond the procedure room and PACU.

Chapter 2 includes a review of the current literature related to obstructive sleep apnea in general and in the ambulatory patient population in particular. Chapter 3 includes the methodological procedures used to answer the research hypotheses. Chapter 4 consist of data analysis derived from the pulse oximeter, cardiac monitor, and actigraph watch. Chapter 5

provides a summary of findings, conclusions based on the findings, and end with recommendations for implementation of safety initiatives and suggestions for further research.

Chapter 2: Review of the Literature

Not much is known about what happens to ambulatory surgery patients on discharge. There may be significant changes in the cardiopulmonary status of ASC patients that are unknown and go undetected or untreated. The establishment of an "Obstructive Sleep Apnea Death and Near Miss Registry" by the Society of Anesthesia and Sleep Medicine and the Anesthesia Closed Claims Project is a step towards addressing these concerns (Biddle et al., 2016). The objectives of the "Obstructive Sleep Apnea Death and Near Miss Registry" are to help determine the level of monitoring at the time of death or near-miss and describe why the adverse event happened to provide understanding of how best to study the phenomena (Biddle et al., 2016). What occurs during the first 24 to 48 hours subsequent to same-day ASC surgery? This literature review aims to show the inherent gaps as well as identify what may be known about ambulatory surgery patients with OSA after they are released to their homes. The goal is to show the need for a study intended to answer questions aimed at improving patient safety and minimizing risks and adverse outcomes in the postoperative period.

In this chapter sleep apnea is defined before introducing the magnitude of the patient safety problem of OSA in the general population and the impact this phenomenon has on cardiopulmonary postoperative risks in the general surgical population. The chapter focuses on these same risks as it affects the ambulatory surgery patient population. The chapter ends with a summary.

Obstructive Sleep Apnea and the Surgical Patient

ASCs offer patients the convenience of having surgeries and procedures performed safely outside a hospital setting. Endoscopic procedures are the largest driver of ASC growth accounting for 32% of Medicare payments (Koenig, Doherty, Dreyfus, & Xanthopaulos, 2009). In spite of the increase in number of ambulatory cases, adverse events are less than 1% and major morbidity occurs with a frequency of approximately 0.1% (Kent et al., 2014). Notwithstanding, as more Americans living with OSA receive ambulatory surgery, the likelihood of increased postoperative morbidity and mortality is real.

OSA is one of several comorbidities that affect and is more prevalent in the surgery population, which is more than the general population and puts patients at increased risk for cardiopulmonary, neurocognitive, psychiatric, and gastrointestinal disorders, postoperative complications, morbidity, and mortality (Ambrosii, Sandru, & Belii, 2016; Chiang et al., 2017; Nagappa et al., 2017). The outpatient surgery population is particularly vulnerable, because patients arrive with undiagnosed OSA and go home unmonitored after the immediate postoperative/recovery period. In fact, a recent retrospective study showed that outpatients who were determined to have OSA during their preoperative visit had more respiratory complications than patients with known OSA (Fernandez-Bustamante et al., 2017). Fernandez-Bustamante et al. (2017) did not address cardiovascular complications in their study. An estimated 26% (25 million) of Americans between the ages of 30 and 70 have sleep apnea (Peppard et al., 2013). The incidence of undiagnosed OSA in patients undergoing endoscopy procedures is 40 to 43% (Boese et al., 2014).

Patients with hypertension have a higher rate of screening positively for OSA (70%) than those without hypertension (20%; Ge et al.,2013). Severe untreated OSA has been associated

with increased all-cause and cardiovascular mortality (Fu et al., 2017; Wang et al., 2013). OSA continues to be a common medical condition (Peppard et al., 2013) and is an important risk factor for SCD (Gami et al., 2013). Nocturnal hypoxemia is an important pathophysiological feature of OSA and strongly predicted SCD independently of well-established risk factors (Gami et al., 2013). In a meta-analysis, Iftikhar, Valentine, and Bittencourt (2014) found a favorable reduction of blood pressure with implementation of CPAP treatment in patients with recalcitrant hypertension and sleep apnea. In another published study, Cintra, Leite, and Storti (2014) found that nocturnal cardiac arrhythmias occurred in 92% of patients with severe sleep apnea compared to 53% of people without sleep apnea. The prevalence of circadian rhythm disturbance also increased with the severity of sleep apnea (Cintra et al., 2014).

The obesity epidemic and its associated co-morbidities, of which OSA is one, is likely to result in an increased number of patients who arrive in outpatient centers for screening and diagnostic endoscopies. Screening referrals will increase even more, particularly since OSA patients are known to be at increased risk for cancers, including colorectal cancers (Fang, Miao, Chen, Sithole, & Chung, 2015; Lee et al., 2017). So far, adverse events are rare (Rutter et al., 2012; Stock et al., 2013), but as patients with multiple co-morbidities and more procedures continue to be performed at ambulatory centers, this may change.

Sleep Apnea: Definition and Identification

OSA is the most common sleep disorder (Garcha et al., 2013). OSA is characterized by frequent partial or complete collapse of the upper airway during sleep. This leads to decreased blood oxygen levels (desaturation), increased respiratory effort, arousal, and sleep disruption. Patients will typically present with witnessed apneic periods, loud snoring, and excessive daytime somnolence. Hyper-somnolence resulting from fragmented sleep can increase

probability of motor vehicle and other accidents, as well as decreased quality of life (Garcha et al., 2013).

The Apnea-Hypopnea Index (AHI) is the measure used to delineate the severity of OSA. Sleep apnea is rated as mild, moderate, or severe (Joshi et al. 2012). Mild is an AHI of -5 to 15 events per hour of sleep; moderate is -15 to 30 events per hour; severe is more than 30 events per hour of sleep (Joshi et al., 2012). Polysomnography is still considered the reference standard for diagnosing OSA. It is both time-consuming and expensive and must be performed in a sleep laboratory. In the pre-operative setting, the Society for Ambulatory Anesthesia Consensus recommended that the STOP-Bang Questionnaire be used as a screening tool to detect OSA based on its high sensitivity and construct validity. (Joshi et al., 2012).

OSA is prevalent, though exact numbers are unknown, and is estimated to affect 10% to 17% of the U.S. population and as many as 49% in those of advanced ages (Peppard et al., 2013). That estimate is based on greater than or equal to 15 events/hour AHI. At greater than or equal to 5 events/hour AHI the overall population prevalence ranged from 9% to 38%. Among the elderly, prevalence was as high as 90% for men and 78% for women. Exact prevalence is undetermined partly because of variable criteria used to define disease, such as the number of apneic episodes per hour, or whether there are accompanying specific signs or symptoms (Senaratha et al., 2016; Young, Peppard, & Gottlieb, 2002).

Sleep Apnea and Cardiopulmonary Risk in the Surgical Population

OSA is associated with adverse physiological consequences, including cardiovascular disease, hypertension, cognitive impairment, and metabolic abnormalities, such as type 2 diabetes; OSA is also associated with increased risk for postoperative cardiac and pulmonary complications (Garvey, Pengo, Drakatos, & Kent, 2015). Several comorbidities that are

frequently present in OSA patients reportedly result in higher mortality risks (Chiang et al., 2017). Chiang et al. (2017) identified ten comorbidities that negatively impacted mortality of OSA patients. The top two were hypertension and chronic obstructive pulmonary disease, reflective of the negative impact OSA can have on cardiac and pulmonary physiology.

Nagappa et al. (2017a) completed the first meta-regression analysis comparing the incidence of postoperative complications among surgical patients at high risk for OSA (HR-OSA) versus those at low risk for OSA. From their systematic review they found a prevalence of 33.3% HR-OSA in the surgical population. After non-cardiac surgical procedures, adverse cardiopulmonary events were two to three times higher in OSA versus non-OSA patients, and in patients with HR-OSA cardiopulmonary risk was as much as four times higher. There was also an accompanying two-day increase in length of hospital stay. The authors felt that their analysis supports the use of the STOP-Bang questionnaire as a perioperative risk stratification tool to identify HR-OSA patients.

The strong association between arterial hypertension and OSA has been extensively described, studied, and established (Mohsenin, 2014; Parati, Ochoa, Bilo, & Al, 2014). Hypertension is common among OSA patients (35 to 80% affected) and appears to be directly affected by OSA severity. Conversely, among hypertensive patients the percentages affected by OSA range from approximately 40 to 50% (Parati et al., 2013). Moderate to severe OSA (AHI 15 to greater than 30 events per hour) is associated with a greater overall risk for cardiovascular diseases. These cardiovascular diseases include hypertension, coronary artery disease, stroke, congestive heart failure, and atrial fibrillation (Wang et al., 2013).

Sleep Apnea and Cardiopulmonary Risk in the Outpatient Surgery Population

OSA is particularly prevalent in the outpatient surgery population with as many as one fourth of patients undergoing elective surgery affected (Wolfe, Pomerantz, Miller, Weiss-Coleman, & Solomonides, 2016). GI endoscopies are known to be the most frequently preformed outpatient procedure, and patients who need gastrointestinal endoscopies also commonly have OSA (Chien et al., 2015).

While it is known that OSA negatively impacts postoperative outcomes, there are very few published studies that bear this out. Memtsoudis and Stundner (2014) analyzed data on over 500,000 hip and knee arthroplasty patients from over 400 institutions. These authors found that OSA was associated with a 47% increased risk of postoperative major morbidity and increased utilization of resources and length of stay (LOS). More recently, Ambrosii, Sandru, and Belii (2016) conducted a prospective descriptive study in Romania that enrolled 400 patients and reported that patients with OSA had 87.3% of postoperative complications and adverse events compared to 12.6% for those without OSA. Additionally, a retrospective cohort analysis of 418 patients who had undergone outpatient colonoscopy was done to assess the association of BMI and cardiopulmonary adverse events for ambulatory colonoscopy (Patel, Romain, Sanchez, Fisher, & Schulteis, 2017). This study was important because it showed OSA to be an independent risk factor for CAEs, independent of BMI and type or degree of sedation.

Obstructive Sleep Apnea and Patient Safety

Reason (2000) studied error management in clinical settings. The SCM was developed from Reason's studies and that holds that most errors or accidents are caused not so much by unavoidable human error, but rather by an organization's inadequate layers of error protection that allow errors to pass through unchecked on their way to causing harm. These layers of

protection are like slices of Swiss cheese with gaps that may allow errors to pass through unchecked on their way to causing harm.

The holes in the SCM represent deficiencies in organizational defenses. Unlike holes in real Swiss cheese, these holes are dynamic. They open, close, and change location over time. Holes in these layers of protection happen for two reasons: active failures and latent conditions. Latent conditions may allow holes to align and permit a trajectory of accident opportunity bringing hazard or harm to the patient or system. The trajectory path ultimately shows that errors result from holes in multiple layers of safeguards.

As many as 25% of patients undergoing surgery have OSA, but few hospitals or ASCs have policies that address the risks of this condition during the perioperative period, and fewer follow recommended consensus statements (Joshi et al., 2012). How patients with OSA are identified, determined suitable for ambulatory surgery, and discharged after ambulatory surgery represents a trajectory of problems inherent within the system that bring harm to patients. Not considering the needs of patients with OSA in ASC settings and the possible associated cardiac sequelae represents a latent risk factor that was mitigated by information generated by this study.

The study is innovative not only because of the use of three wearable body sensors, one of which utilizes Bluetooth technology and near real-time monitoring, but because to date, none have reported the clinical and ECG risk factors of cardiac risks that occur in this group of patients, particularly in the 24 hours immediately following discharge from ambulatory surgery (Rotenberg, 2013). Amidst this dearth of scientific evidence, organizations concerned with patient safety such as the American Society of Anesthesiologists, have recommended that patients with OSA be observed for extended periods of time and routinely receive CPAP; Joshi et al., (2012). Some institutions require that certain populations of patients with OSA who have

received particular narcotics be held overnight and not undergo surgery in ASCs (Rotenberg, 2013). Health care providers are rightfully concerned about the increased risk of adverse events for OSA patients. These measures may prove to be unnecessary and are inconsistently practiced (Memtsoudis & Stundner, 2014). More studies are needed to better identify patients who are at risk and apply evidence-based interventions that will significantly improve and impact outcomes and influence appropriate protocols to properly and efficiently manage these patients.

Summary

Based on the review of the literature, there has not been a study that has quantified both the cardiac and pulmonary risk factors that either ambulatory surgical patients or ambulatory patients undergoing endoscopies may be susceptible to in the immediate postoperative period (24 hours post procedure). The study was, therefore, designed to examine the prevalence of patient and procedural risk factors for adverse cardiopulmonary events in patients presenting for outpatient endoscopy under deep Propofol sedation and to determine the relative risk of adverse cardiopulmonary events occurring in the first 24 hours at home in patients with and without OSA. The following chapter sets forth the methodology of the study.

Chapter 3: Methodology

Research Design

The study utilized a prospective, descriptive cross-sectional design and incorporated a pre-test/post-test data collection approach. There was no manipulation of the independent variable, operationalized as the presence or absence of OSA. This was coded as '0' indicating absence of OSA and '1' presence of OSA. Presence of OSA was assessed based upon a STOP-BANG (Snoring, Tired, Observed, Pressure, Body Mass Index, Age >50, Neck Size, Gender = male) score greater than 3. The STOP-BANG is widely recognized as a reliable and valid inventory for OSA and is widely used in both clinical research and clinical practice domains (Cowan et al., 2014). The study had components of both a descriptive and a non-randomized pre- and post-test design.

This study is objective and quantitative because the data yielded quantifiable answers to closed-ended research questions. The equipment used to gather the data provided numerical data only. Regression analyses, *t*-test analyses, and ANOVAs were the primary statistical methods used.

This is a descriptive study because it aims to discover what are the cardiopulmonary risks of outpatients with and without sleep apnea. It is also cross-sectional because it examined the relationship between OSA, ambulatory surgery, and cardiopulmonary risk factors as delineated in Table 1 (page 9).

Selection of Subjects

The target population for the study consisted of outpatients scheduled for endoscopy, recruited through the selected facility. Approximately 25,000 patients receive endoscopies at the facility on a yearly basis, so enrollment of patients in using the facility was more efficient than most other centers. The researcher recruited a convenience sample of participants to address the research questions related to the prevalence of clinical and ECG cardiac risk factors of cardiac risk in post-endoscopy outpatients with and without OSA. A convenience sampling approach was appropriate because the researcher maintains a relationship with the doctors and staff of the facility, and the researcher recruited participants who were easily accessible via the facility (Acharya, Prakash, Saxena, & Nigam, 2013). A convenience sampling approach is best suited for the study because it would be difficult to include a randomized sample of participants from the target population (Etikan, Musa, & Alkassim, 2016).

Eligible participants were at least 18 years of age or older and scheduled to receive sedation for endoscopy at the certified and credentialed endoscopy center. Participants were able to independently review and complete the informed consent to participate in the study. Eligible participants were fluent in either English or Spanish.

The final target sample was comprised of 50 adults scheduled to receive sedation for endoscopic procedures at the ASC site. The center provides screening, detection, and polyp removal for approximately 80 patients on a daily basis. Consequently, there was an adequate flow of subjects for study inclusion. Subjects were approached during pre-procedure office visits with their gastroenterologist. During the patients' visits to the office, the principal investigator (PI) discussed the study protocol with the patient and determined if he or she would be interested

in consenting to participation in the study. The PI informed patients of the purpose of the study and of the follow-up requirement in case of a concerning adverse event.

Eligible subjects were recruited from the endoscopy schedule 30 days prior to the procedure up to two days preceding the procedure. The pre-anesthesia assessment was completed, updated, or revised on the day of the procedure, as is standard and mandated anesthesia practice. The ASC serves a diverse population and ensured an ethnically and culturally diverse patient pool for recruitment. Because Holter monitors and pulse oximeters must be returned and disinfected prior to use on subsequent subjects, the return of equipment limited the speed of recruitment. Given the anticipated three-day turnaround time for equipment, subjects generally received monitors on Mondays and Thursdays. The budget for the project included rental of 6 BodyGuardian cardiac monitors, 10 pulse oximeters, and rental of 10 MicroMotionlogger Actigraph watches. Figure 1 illustrates the schedule of activities for the study.

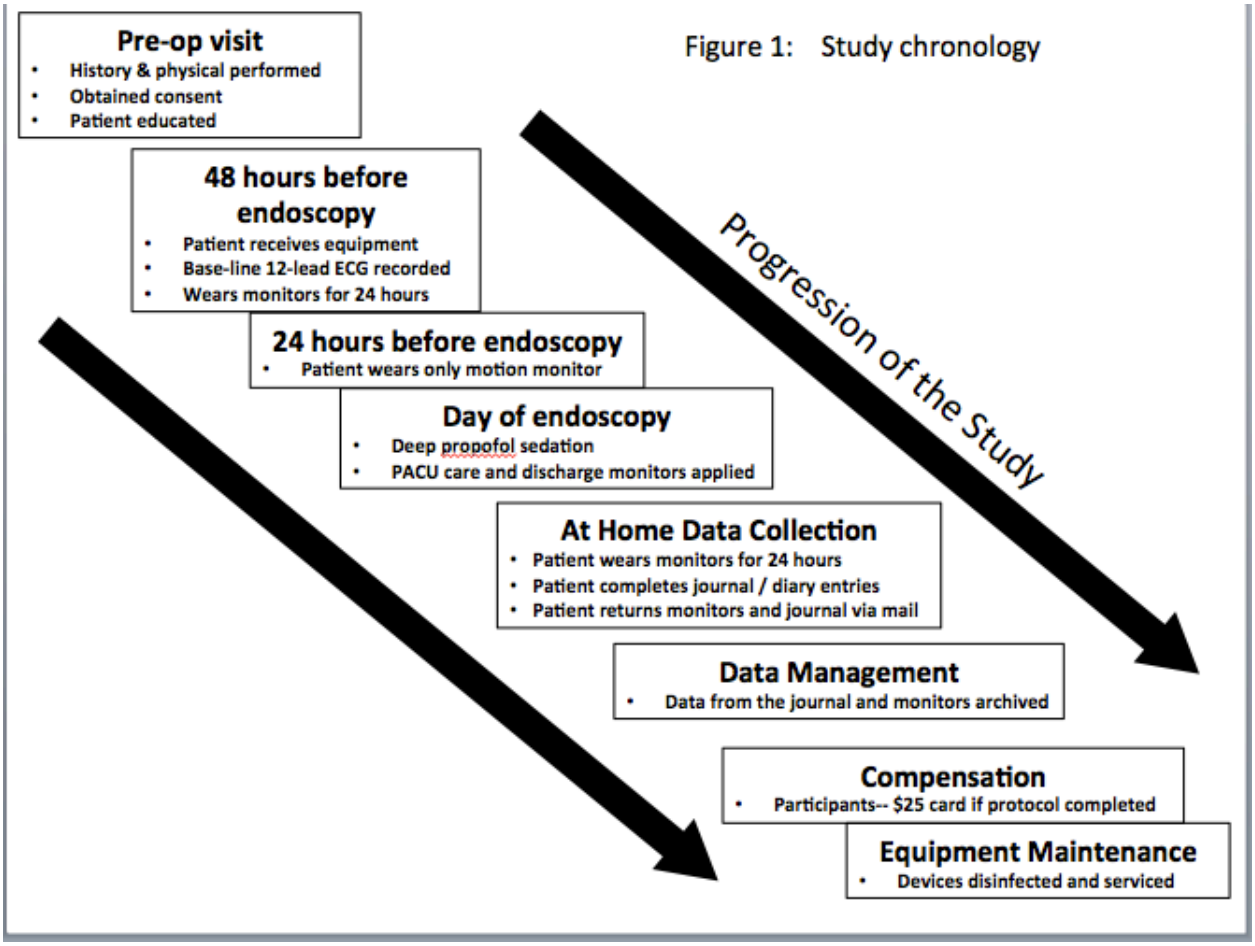

Figure 1. Study chronology

Study participants were assigned to one of three groups based on their STOP-BANG scores and presence or absence of previous diagnosis of sleep apnea as follows: probability of moderate to severe OSA (previously undiagnosed and untreated or diagnosed with treatment) or low-risk OSA (no OSA) groups based on their STOP-BANG scores. A STOP-BANG score greater than or equal to 3 is considered moderate to high risk for OSA (Table 2).

Table 2: *STOP-BANG Grouping*

Group	Score	Diagnosis
1	<3	Low risk or no OSA
2	≥3	Moderate to severe OSA (previously undiagnosed and untreated)
3	≥3	Moderate to severe OSA (diagnosed with treatment)

Recruitment continued until 51subjects proceeded through enrollment and data collection. One subject was removed because of incomplete data for a final count of 50 subjects. Enrollment took place over a 4-month period. Power analyses were conducted for the regression analysis using the number of times that an individual's SpO2 level dropped below 90 (red) and the duration of time that an individual spent with an SpO2 level below 90 (blue) on the STOP-BANG measure. There are 11 dependent variables; of these 11 variables, two variables have prototypical large and small expected effect sizes. The other 9 dependent variables fell somewhere between these two extremes. The power of the STOP-BANG procedure to predict number of significant SpO2 events is much larger than the power of the STOP-Bang procedure to predict the duration of time spent in an event. Specifically, approximately 50 patients are required to achieve 80% power to detect significant increases in the number of events associated with higher STOP-Bang measures, while approximately 150 patients are required to achieve

80% power to detect significant increases in the duration of such events. The strength of the associations was based upon preliminary analyses from another project (Biddle et al., 2016). As the current power analyses are *a priori*, it is possible that the associations observed are slightly larger or smaller. To account for this, the shaded areas of Figure 2 show the power for a 20% larger or smaller effect size.

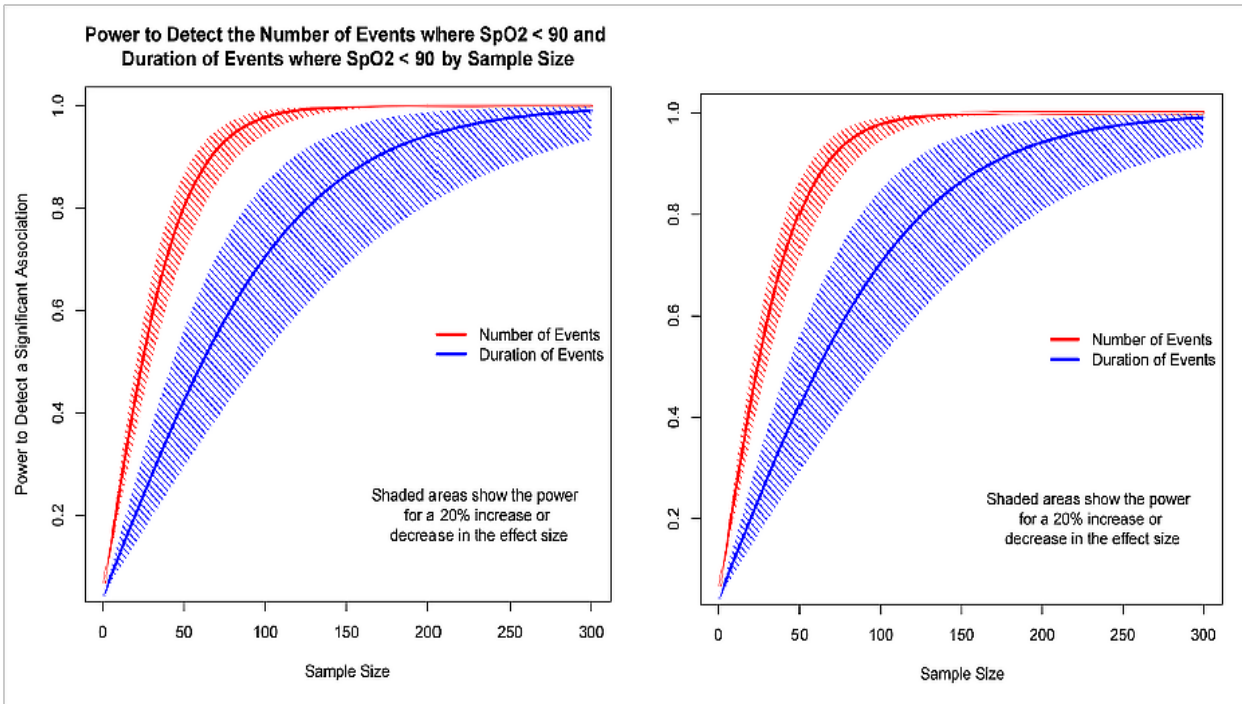

Figure 2. Power analysis for detection of number of events.

Instrumentation

The STOP-BANG Questionnaire, a validated and reliable predictor of obstructive events was used to classify subjects according to OSA risk (Cote et al., 2010; Cowan et al., 2014). For surgical patients, the STOP-BANG Questionnaire is recommended for OSA screening because of its ease of use and high degree of sensitivity. It is not feasible to have all patients undergo a

sleep study preoperatively. Screening questionnaires can successfully identify at-risk patients and allow the anesthesia provider to establish an early plan of care targeted at minimizing intraoperative/postoperative complications.

The Respironics Nonin WristOx 3150 from Nonin Medical, Inc. Plymouth, MN is an U.S. Food and Drug Administration-approved pulse oximeter, designed to be worn comfortably on the patient's wrist. It is well suited for in-home use and measures heart rate as well as arterial oxygen saturation (SpO2). The device is activated when the soft probe is capped over a fingertip. Sensitivity and negative likelihood ratio are reported at 100% and 0%, and specificity is of 100%. NONIN(R) Wrist Ox(R) 3100, 2005; Society of Anesthesia and Sleep Medicine. The accuracy of the device is reported to be 70% to 100% SpO2 within +/- 2% *SD* and +3% for pulse rate, with a bias of +0.03 and precision of +/- 2.08 *SD*. The accompanying software (nVision) was used for analysis of the retrieved data.

The 9 high-risk ECG parameters can be seen in Table 1 (page 9). This table was created based on a review of the literature to determine the appropriate ECG parameters used to assess cardiac risk (Carey & Thevenin, 2009). These ECG parameters were derived from parameters obtained using both a 12-lead ECG monitor before the procedure and the BodyGuardian cardiac monitor for continued monitoring after the procedure. The BodyGuardian by Preventice (Minneapolis, MN) is an FDA cleared device that is worn on the chest with the aid of bandage patch. This cardiac monitor uses Bluetooth technology to deliver biometric data (i.e., ECG, heart rate, activity level, and body position) securely to a smartphone which delivers the information to the cloud in real time using the Sprint network while meeting Health Insurance Portability and Accountability Act standards.

The Micro-Motionlogger is an Actigraph watch validated against polysomnography approved by the FDA for clinical research and use (Rupp & Balkin, 2011). The device has a tri-axial digital micro-electromechanical system-based accelerometer that senses and measures gravitational changes. Utilization of tri-axial dimensions result in increased reliability and less variability between devices. The device is water-resistant, so it can be worn continuously for all types of activities. The accompanying Action4 software sports up to 28 parameters from the micro-motionlogger watch. This data provided information on sleep and non-parametric circadian rhythm parameters.

Field Procedures

Participants were required to sign an IRB-approved informed consent form prior to participation in the study. Documentation of the consent process was required including documentation that follow-up requirements were reviewed with each patient. Within the 30 days prior to the procedure, the investigator provided participants with written materials outlining the study's purpose, expected participation, duration, foreseeable risks, discomforts or inconvenience, benefits of the research to society and the participant, and contact information for the person to contact regarding questions or in the event of a research-related injury or emergency. Pictures and written instructions for application and care of the monitors were also provided to participants.

The investigator ensured that participants had sufficient time to review the material and ask questions before completing the informed consent. Participants were informed that their participation was voluntary and that refusal to participate would not result in any negative consequences or loss of benefits to which they are entitled. The informed consent also included a

statement regarding the participants' right to confidentiality and right to withdraw from the study at any time without any consequences.

Data Collection and Recording

Subjects were initially recruited during the office visit with the GI physician, Advanced Registered Nurse Practitioner, or Physician Assistant. They were screened for inclusion pending their expressed interest in participating in the study. Once the schedule was confirmed, which generally occurred three days prior to the procedure, subjects who met inclusion criteria were asked to return to the office to sign informed consent for the study. Following the consent process, participants picked up the MotionWatch-8, pulse oximetry, completed the pre-operative anesthesia assessment including the STOP-BANG, and had a baseline 12-lead ECG recording then or on the day of the procedure. The subjects also had the option of having the information packet (including the informed consent) sent electronically to allow enough time for review of the documents and to ask questions. The pre-anesthesia assessment on pick up day included the STOP-BANG Questionnaire for all the research participants. Enrolled participants were prepped for the procedure per the facility standard. On day 1, participants began wearing the Actigraphy watch which was to be worn continuously for a 3-day period. The Pulse Oximeter was worn during hours of sleep on the first night of the study as well as the 24-hour period after receiving anesthesia for the endoscopy (night three).

Subjects were re-assessed by the anesthesia team on the day of the procedure. The cardiac monitor was worn during the 24-hour period immediately after discharge from the recovery room on day three. On the fourth day all three monitors were either returned to the GI doctor's office or pick up was arranged. Data was retrieved from the returned monitors once they

were returned. Monitors were cleaned, and batteries replaced if necessary. Monitors were then ready for assignment to subsequent participants.

The subjects were continuously monitored by a CRNA while receiving Propofol sedation during the endoscopy and up until transfer to the PACU. The patients were fitted with the cardiac monitor by a research team member when fully awake and deemed fit for discharge. The PI was available at all times for any concerns or questions participants had. All participants received a $25 gift card when the monitors were returned.

Data Processing and Analysis

Preliminary Data Management. IBM SPSS version 24 was used for data management and analysis. The dataset was screened for outliers prior to data analysis. Standardized values were calculated for each continuous variable. Standardized values represent each data point's distance from the sample mean (Tabachnick & Fidell, 2013). Standardized values greater than 3.29 units from the sample mean were considered evidence of an outlying value (Stevens, 2009). Outliers, defined as greater than three standard deviations from the mean, were removed from the dataset so the data would not be skewed.

Research Questions and Hypotheses. RQ1: What is the prevalence of known ECG characteristics for cardiac events among pre-endoscopic patients with high and normal STOP-bang scores on resting 12-lead ECGs clinical (pulse oximetry and actigraph derived sleep quality scores) and ECG characteristics of cardiopulmonary risk in post-endoscopy outpatients with undiagnosed or untreated OSA, post-endoscopy outpatients receiving treatment for OSA, and post-endoscopy patients without OSA?

RQ2: Among post-endoscopic patients receiving propofol, using a rhythm event recorder (BodyGuardian Heart) are there statistically significant differences in the frequency of oxygen

desaturation events and tachy-brady-arrhythmias over 24 hours between outpatients with undiagnosed or untreated OSA, and post-endoscopy patients with and without a medical diagnosis of OSA?

RQ3: Among pre-endoscopic patients receiving propofol, using a resting 12-lead ECG, are there statistically significant differences in the duration of resting heart rate, QRS duration, QTC duration and ST segment deviation between patients with low and high STOP BANG?

RQ4: Does sleep quality influence pulse oximetry readings? The variables included in the study for Research Question 1 are clinical (pulse oximetry and Actigraph derived sleep quality scores) and ECG risk factors of cardiac risk (Table 1). For Research Question 2, the dependent variables are ECG and pulse oximetry. These dependent variables were compared among three groups of participants: post-endoscopy outpatients with undiagnosed or untreated OSA, post-endoscopy outpatients receiving treatment for OSA, and post-endoscopy patients without OSA. The predictor variables for Research Question 3 are the comorbidities participants experience: diabetes, hypertension, obesity, OSA. The criterion variable is the number of adverse events participants experienced during the study. For Research Questions 4, the variables of interest are sleep quality, number of adverse events, and pulse oximetry readings.

Statistical Analyses

Descriptive Statistics. The researcher conducted descriptive statistics to address Research Question 1. Descriptive statistics to represent the prevalence of clinical (pulse oximetry and actigraph derived sleep quality scores), ECG risk factors and participant group: post-endoscopy outpatients with undiagnosed or untreated OSA, post-endoscopy outpatients receiving treatment for OSA, and post-endoscopy patients without OSA. Frequencies and percentages

were calculated for any categorical variables in the dataset (Howell, 2013). Means and standard deviations were calculated for any continuous variables in the dataset (Howell).

Analysis of Variance (ANOVA). The researcher conducted ANOVAs for Research Question 2 and 3. ANOVAs are the appropriate analysis to conduct when the researcher intends to assess mean differences between more than two groups (Field, 2013). The independent variables for the analyses are patient group (operationalized as post-endoscopy outpatients with undiagnosed or untreated OSA, post-endoscopy outpatients receiving treatment for OSA, and post-endoscopy patients without OSA) and sleep quality, operationalized as sleep efficiency measure from the Actigraph watch. The ANOVA allowed the researcher to assess statistically significant differences in the dependent variable by the groups corresponding to each independent variable (Pallant, 2013). A Tukey post hoc analysis was conducted to determine where the statistically significant differences lie between groups (Pagano, 2010). An *a priori* alpha level has been set at .05.

Multiple Linear Regressions. For Research Question 4 the researcher conducted a multiple linear regression. Multiple linear regressions are appropriate for analysis of the predictive relationship between a set of predictor variables and a criterion variable (Pagano, 2010). The researcher conducted multiple linear regressions to assess the predictive relationships between comorbidities and the number of adverse events participants experience. The researcher reported the F statistic and p value to indicate the statistical significance of the overall regression model (Pallant, 2013). The R^2 was reported to represent the amount of variation in the criterion variable that can be attributed to the predictor variables (Field, 2013). An *a priori* alpha level has been set at .05.

Limitations

The results must be viewed with respect to the study's limitations. The study was conducted with patients receiving Propofol sedation for outpatient endoscopies. While surveillance occurred both 24 hours before and after the procedure, it is ideal to monitor for an additional 24hr period of time. These results cannot be translated to the general surgical population or all outpatients.

Summary

The methodology as set forth in this quantitative longitudinal pre/post study, utilizing four instruments (STOP-bang questionnaire, Pulse oximeter, Actigraph watch, cardiac monitor); aims to describe, identify and quantify cardiopulmonary risk factors for outpatients in the 24 hours post endoscopy. The following chapter summarizes and present the collected data, statistical treatment and analysis of the data.

Chapter 4: Findings

The purpose of this study was to assess the prevalence of patient risk factors for cardiopulmonary adverse events in a diverse range of patients presenting for outpatient endoscopy under deep propofol sedation, and to determine the relative risk of adverse cardiopulmonary events occurring in the first 24-hours post-procedure following deep propofol sedation for endoscopy in patients with or without OSA

Over 4 months, 51 outpatients were recruited and consented to participate in this research study. One was removed because of incomplete data set for a final count of 50 subjects. Most outpatients in the sample were women (n = 35, 70%) and most had colonoscopy procedures (n = 44, 86%). Thirty eight percent of the participants had a STOP-BANG score greater than three and were therefore categorized as likely to have sleep apnea. Nine participants (18%) had a medical diagnosis of OSA, seven (14%) of whom had a medical diagnosis of OSA and used home CPAP. Fifteen participants were hypertensive (30%; Table 3).

Table 3: Sample Characteristics, N = 50

Characteristic	*N*	*%*
Female	35	70
Colonoscopy	44	86.3
STOP-Bang Score ≥3	19	38
Medical Diagnosis of Sleep Apnea	9	18
Home CPAP	7	14
Hypertensive (120/80 mmHg)	15	30

Table 4 presents frequencies and percentages for the number of participants presenting with sleep apnea according to their STOP-Bang scores. Scores lower than 3 on the STOP-Bang questionnaire are considered evidence that the participant is unlikely to have sleep apnea, while scores greater than or equal to 3 are likely indicative of sleep apnea. Participants with low risk of sleep apnea represented most of the sample (n = 31, 62%).

Table 4: *Frequencies and Percentages for Participants without Sleep Apnea (STOP-Bang ,3) and with Sleep Apnea (STOP-Bang ≥ 3), N = 50*

	N	*%*
No	31	62
Yes	19	38

Table 5 presents frequencies and percentages for the number of participants who reported a medical diagnosis of sleep apnea. The majority of participants indicated that they did not have a medical diagnosis (n = 41, 82%).

Table 5: *Frequencies and Percentages for Participants Reporting a Medical Diagnosis of Sleep Apnea, N = 50*

	N	*%*
No	41	82
Yes	9	18

Table 6 presents frequencies and percentages for participants exhibiting a fragmented QRS (fQRS) morphology and abnormality (notching and fragmentation) of QRS. A fQRS morphology was indicated by less than 2 R' or notching in the nadir of the S wave with QRS less

than 120 or 2 R' or notching in the nadir with wide QRS (Virk Hassan, Farooq, Ghani, & Arora, 2016). The majority of the sample data indicated no fQRS morphology (n = 44, 88%). Most participants did not exhibit QRS abnormality (n = 32, 64%).

Table 6 *Frequencies and Percentages for Participants Exhibiting fQRS Morphology and Exhibiting QRS Abnormality, N = 50*

	N	*%*
fQRS Abnormality		
No	44	88
Yes	6	12
QRS Abnormality		
No	32	64
Yes	18	36

Table 7 presents frequencies and percentages for presence of Premature Ventricular Contractions (PVCs) in participants. Almost all participants (n = 48, 96%) did not exhibit PVC.

Table 7: *Frequencies and Percentages for Presence of PVC in Participants, N = 50*

	N	*%*
No	48	96
Yes	2	4

Table 8 presents frequencies and percentages for the presence of a depression or elevation of 1.00 mm in any of the leads. Most participants did not exhibit a depression or elevation of 1.00 mm in any of the leads (n = 40, 80%).

Table 8: *Frequencies and Percentages for Participants Exhibiting Depression or Elevation of 1.00 mm in Leads*

	N	*%*
No	40	80
Yes	10	20

Table 9 presents descriptive statistics for participants' age, STOP-Bang Score, and heart rate measures. The average of participants was 54.48 (*SD* = 12.34). STOP-Bang scores ranged from zero to six with an average of 2.24 (*SD* = 1.42). The average heart rate for participants was 72.16 (*SD* = 11.32) and the average QRS duration was 86.66 (*SD* = 17.22). Finally, the mean QTc interval was 431.10 (*SD* = 30.40) and the mean ST segment in V1 was 139.40 (*SD* = 41.82).

Table 9: *Descriptive Statistics for Participants' Age STOP-Bang Score, and Heart Rate Measures*

	Minimum	Maximum	M	SD
Age	30	83	54.48	12.34
STOP-BANG Score	0	6	2.24	1.42
Heart Rate- mean R-R intervals for all QRS complexes during the duration of the recordings	50	102	72.16	11.32
QRS duration- mean QRS duration on standard 12 lead ECG	45	145	86.66	17.22
QTc interval per Bazett- Mean QRS onset to T offset interval of all leads	363	537	431.10	30.40
ST segment in V4	80	320	139.40	41.82

Pre-Procedure 12-Lead ECG Analysis

RQ1: Among pre-endoscopic patients receiving propofol, using a resting 12-lead ECG, what were the baseline ECG risk factors for cardiovascular events present in the recording? All subjects were in the cardiac rhythm of normal sinus. The most prevalent ECG risk factor of cardiac events were notched QRS complexes which is a marker for ventricular scarring (Virk Hassan, Farooq, Ghani, & Arora, 2016). Nearly a quarter (*n* = 10, 20%) had ST segment deviation on the pre-procedure 12-lead ECG indicating possible myocardial ischemic or reduced coronary perfusion (Carey, 2016). Table 10 presents frequencies and percentages for aberrant ECG characteristics.

Table 10: *Aberrant ECG Characteristics*

	N	*%*
Premature Ventricular Contraction (PVC)	2	4
Left Ventricular Hypertrophy (LVH)	4	8
Notched QRS complex	18	36
Fragmented QRS (fQRS)	6	12
ST segment event	10	20

Table 11 shows that the resting heart rates were normal and neither bradycardic or tachycardic. On average the other measures of duration, QRSd and QTc were normal as well as the magnitude of the ST segment.

Table 11: *Normal ECG Characteristics*

	M	*SD*
Resting Heart Rate (beats per minute)	72	11
QRS Duration (milliseconds)	87	17
QTc duration (milliseconds)	431	30
ST segment deviation (millimeters)	139	42

Post-Procedure Event Recorder Analysis

Regarding the rhythm event recorder worn for 24 hours, the mean heart rate was 78.14 (*SD* = 11.05). Mean tachycardic, or fast, heart rate maximum was 114, with a mean of 91.35 (*SD* = 37.19). The mean bradycardic, or low, heart rate ranged from 50 to 78, with a mean of 38.33 (*SD* = 27.62). Table 12 presents 24-hour heart rate information for participants.

Table 12: 24-*hour Mean Heart Rate Data for Participants*

	Minimum	Maximum	Mean	SD
Overall heart rate	58	103	78.14	11.05
Tachycardic heart rate	99	114	91.35	37.19
Bradycardic heart rate	50	78	38.33	27.62

RQ2: Among post-endoscopic patients receiving propofol, using an event recorder, are there statistically significant differences in the frequency of tachy- and brady- arrhythmias over 24 hours between outpatients with no diagnosis of OSA and a STOP-BANG score less than 3, outpatients with untreated OSA, and outpatients with a medical diagnosis?

A one-way ANOVA was conducted between three groups of participants: participants with no diagnosis of OSA and a STOP-BANG score less than 3 (Group 1); participants with untreated OSA (Group 2); and participants with a medical diagnosis (Group 3). The frequency of tachy-arrhythmias and brady-arrhythmias among those three groups was compared. Tables 13 and 14 present descriptive statistics for the three groups of participants.

Table 13: *Descriptive Statistics for Participants with No OSA, Untreated OSA, and a Medical Diagnosis of OSA, Tachycardia*

					Std.	95% C.I. for *M*			
	Group	*N*	*M*	*SD*	Error	Lower	Upper	Min	Max
Mean Tachy HR	1	28	99.50	28.32	5.35	88.52	110.48	0	114
	2	13	79.31	46.06	12.78	51.47	107.14	0	111
	3	9	81.89	46.53	15.51	46.12	117.66	0	110
	Total	50	91.08	37.52	5.31	80.42	101.74	0	114
% of time Tachy over 24 hours	1	28	11.25	13.30	2.51	6.09	16.41	0	50
	2	13	11.15	18.54	5.14	-.05	22.36	0	50
	3	9	6.78	7.00	2.33	1.40	12.16	0	20
	Total	50	10.42	13.88	1.96	6.48	14.36	0	50
Length of longest uninterrupted Tachy episode in Minutes	1	28	27.399	43.49	8.22	10.53	44.25	.00	209.59
	2	13	30.10	60.82	16.87	-6.65	66.85	.00	194.43
	3	9	22.47	29.86	9.95	-0.48	45.43	.00	84.48
	Total	50	27.21	45.83	6.48	14.19	40.23	.00	209.59

Table 14: *Descriptive Statistics for Participants with No OSA, Untreated OSA, and a Medical Diagnosis of OSA, Bradycardia*

	Group	*N*	*M*	*SD*	Std. Error	95% C.I. for *M* Lower	Upper	Min	Max
Mean Brady HR	1	28	37.61	28.87	5.46	26.41	48.80	0	78
	2	13	34.08	28.15	7.81	17.07	51.09	0	58
	3	9	44.67	25.42	8.47	25.13	64.21	0	61
	Total	50	37.96	27.77	3.93	30.07	45.85	0	78
% of time Brady over 24 hours	1	28	5.97	9.16	1.73	2.41	9.52	0	35
	2	13	14.62	21.26	5.90	1.77	27.46	0	56
	3	9	10.00	15.92	5.31	-2.24	22.24	0	48
	Total	50	8.94	14.56	2.06	4.80	13.08	0	56
Length of longest uninterrupted brady event in Minutes	1	28	11.97	19.75	3.73	4.31	19.63	.00	71.20
	2	13	14.55	19.72	5.47	2.63	26.46	.00	58.17
	3	9	13.57	19.65	6.55	-1.54	28.67	.00	51.09
	Total	50	12.93	19.35	2.74	7.43	18.43	.00	71.20

The results of the ANOVAs comparing the frequencies of tachy- and brady-arrhythmias between the three groups were not statistically significant (Table 15). These findings indicate that the frequencies of tachy-and brady-arrhythmias were similar across the three groups of participants. Because there were no statistically significant findings no post hoc testing was conducted.

Table 15: *Results of the ANOVAs Comparing Frequencies of Tachy- and Brady-arrhythmias Between the Three Groups of Participants*

		Sum of Squares	df	Mean Square	*F*	*p*
Mean Tachy HR	Between	4547.02	2	2273.51	1.66	.201
	Within	64432.66	47	1370.91		
	Total	68979.68	49			
% of time Tachy over 24 hours	Between	145.68	2	72.84	0.37	.694
	Within	9292.50	47	197.71		
	Total	9438.18	49			
Length of longest uninterrupted Tachy episode in Minutes	Between	311.26	2	155.63	0.07	.931
	Within	102587.60	47	2182.72		
	Total	102898.86	49			
Mean Brady HR	Between	604.32	2	302.16	0.38	.685
	Within	37177.60	47	791.01		
	Total	37781.92	49			
% of time Brady over 24 hours	Between	676.30	2	338.15	1.64	.206
	Within	9717.25	47	206.75		
	Total	10393.56	49			
Length of longest uninterrupted brady event in Minutes	Between	63.35	2	31.68	0.08	.922
	Within	18284.16	47	389.03		
	Total	18347.51	49			

RQ3: Among pre-endoscopic patients receiving propofol, using a resting 12-lead ECG, are there statistically significant differences in the duration of resting heart rate, QRS duration, QTC duration and ST segment deviation between patients with low and high STOP BANG?

Table 16 presents mean differences and *p*-values for comparison of ECG measures for high and low STOP-Bang groups. The t-test showed that across all ECG measures there were no statistically significant differences in mean ECG measure values across the two groups. All the *p*-values exceeded .05, therefore the researcher failed to reject the null hypothesis.

Table 16: *Comparison of Means between Patients with High and Low STOP-BANG (Low < 3, High ≥ 3)*

ECG Measure	Mean Difference	*p*-value
Resting HR (beats per minute)	2.7	0.415
QRS duration (milliseconds)	-4.7	0.353
QTc (milliseconds)	0.925	0.918
ST segment (millimeters)	14.3	0.244

RQ4: Does sleep quality influence pulse oximetry readings? Table 17 presents the results of the regression analyses conducted to assess the relationship between sleep quality and pulse oximetry readings. Statistical significance was found across several of the variables; however, the predictors accounted for minimal variation in the criterion variables.

Table 17: *Results of the Regressions for Duration and SEFF*

Variables	df1	df2	*F*	*p*	R^2
Duration					
D0.sleeptime ~ duration.2	1	32	4.92	0.03	0.11
Dn1.spo2_90 ~ duration.3	1	31	4.90	0.03	0.11
AVEn1_spo290 ~ duration.3	1	31	6.78	0.01	0.15
AVEd0_spo290 ~ duration.3	1	32	4.96	0.03	0.11
AVEd1_spo290 ~ duration.3	1	12	5.42	0.04	0.25
SEFF					
D0.sleeptime ~ seff.2	1	32	10.02	0.00	0.21
D1.sleeptime ~ seff.2	1	12	8.52	0.01	0.37
seff.3 ~ ASA Class	1	48	5.18	0.03	0.08
dn2.spo2_90 ~ seff.3	1	25	4.33	0.05	0.11
AVEn2_spo290 ~ seff.3	1	25	5.39	0.03	0.14

Chapter 5: Discussion

OSA is a disorder characterized by the intermittent cessation of breathing for at least 10 seconds while the affected person sleeps (Garcha et al., 2013). OSA is a prevalent public health concern affecting approximately 22 million Americans (Parati et al., 2014). The present study is important because it is estimated that 80% of the population with OSA is undiagnosed, and many patients with OSA remain undiagnosed at the time of surgery (Parati et al., 2014). Singh et al. (2013) reported that surgeons and anesthetists failed to identify up to 58% of surgical patients who had OSA as confirmed by polysomnography. OSA increases the mortality and morbidity of patients requiring general anesthesia, sedation, or intravenous opioids, increasing their risk for perioperative complications as much as four times that of patients without OSA (Kaw et al., 2012).

The purpose of this quantitative cross sectional pre/post study was to evaluate the prevalence of cardiopulmonary risk factors among post-endoscopic patients with diagnosed and undiagnosed sleep apnea in the 24-hour period after surgery. This chapter includes a discussion of the results obtained from the cardiac, pulse oximetry, and Actigraphy devices worn by participants. The chapter also includes a discussion of the implications of the results for perioperative teams in positively impacting outpatient safety during the perioperative period. The chapter concludes with a discussion of implications for practice, recommendations for future research, and a summary.

The research questions were: RQ1: What is the prevalence of known ECG characteristics for cardiac events among pre-endoscopic patients with high and normal STOP-bang scores on resting 12-lead ECGs, clinical (pulse oximetry and Actigraphy derived sleep quality scores) and ECG characteristics of cardiopulmonary risk in post-endoscopy outpatients with undiagnosed or untreated OSA, post-endoscopy outpatients receiving treatment for OSA, and post-endoscopy patients without OSA?

Notched QRS complexes are a marker for ventricular scarring (Virk Hassan, Farooq, Ghani, & Arora, 2016) and were the most prevalent ECG risk factor of cardiac events. Additionally, 20% (n=10) had ST segment deviation on the pre-procedure 12-lead ECG indicating possible myocardial ischemic or reduced coronary perfusion (Carey, 2016)Table 9. Pulse oximetry and actigraph derived sleep quality scores revealed no difference based on OSA.

RQ2: Among post-endoscopic patients receiving propofol, using a rhythm event recorder (BodyGuardian Heart) are there statistically significant differences in the frequency of oxygen desaturation events and tachy-brady-arrhythmias over 24 hours between outpatients with undiagnosed or untreated OSA, and post-endoscopy patients with and without a medical diagnosis of OSA?

ANOVA results comparing the frequencies of tachy- and brady-arrhythmias between the three groups were not statistically significant (Table 11). Lack of significance means that frequencies of tachy-and brady-arrhythmias were similar across the three groups of participants. The ANOVA for oxygen desaturation events and sleep quality indices similarly reflected no differences across the three groups.

RQ3: Among pre-endoscopic patients receiving propofol, using a resting 12-lead ECG, are there statistically significant differences in the duration of resting heart rate, QRS duration,

QTC duration and ST segment deviation between patients with low and high STOP BANG? The *t*-test for sleep quality indices reflected no differences between low and high STOP-bang groups. The presence or absence of OSA had no effect across groups on desaturation events or frequency of tachy-brady arrhythmias. Sleep quality also had no measurable influence on adverse events and was similar across all three groups, although participants diagnosed with OSA slept significantly longer than those in the untreated or no OSA group.

RQ4: Does sleep quality influence pulse oximetry readings? The regressions for sleep quality indices similarly reflected no differences between the three groups.

Conclusions

The study described the prevalence of known ECG characteristics for cardiac events among pre-endoscopic patients with high and normal STOP-bang scores on resting 12-lead ECGs, clinical (pulse oximetry and actigraph derived sleep quality scores) and ECG characteristics of cardiopulmonary risk in post-endoscopy outpatients with undiagnosed or untreated OSA, post-endoscopy outpatients receiving treatment for OSA, and post-endoscopy patients without OSA. The statistical level of significance expected for adverse events (oxygen desaturation and tachy-brady-arrhythmias) occurring in either of the groups in the 24 hours after the procedure was not achieved. Notwithstanding, there was an interesting incidental finding. Approximately one quarter up to a third of the participants had ECG markers on their baseline 12-lead that indicated decreased coronary perfusion, myocardial ischemia, or possible ventricular scarring. This is an unexpectedly interesting finding and latent hazard, given that no participants reported any previous significant cardiac event, nor did having these markers result in acute adverse events for the participants. In this sample, 20% of subjects (who would have otherwise been unidentified) without a medical diagnosis of OSA were identified as having undiagnosed

OSA based on STOP-bang scores. Pre-operative under diagnosis of OSA by anesthetists and surgeons represents one-way patients are exposed to avoidable risks.

While the results yielded no significant findings, several points are apparent. The importance of the preoperative anesthesia evaluation as a first line of defense against latent opportunities for hazard to become harm must be reiterated. In the Singh et al. (2013) study, almost 40% of patients with OSA confirmed by PSG only had one or two principal symptoms of OSA. At minimum, a proven screening tool like STOP-bang should be included as a requisite part of a thorough preoperative assessment.

In addition to the STOP-bang survey, the opportunity exists to use inexpensive readily available tools such as ECG to minimize risk and optimize results for outpatients during the vulnerable perioperative period. One-third of the subjects in this study had ECG high-risk markers that indicated possible myocardial scarring or compromised coronary perfusion. Biteker, Duman, and Tekkesin (2011) studied the predictive value of the preoperative ECG for perioperative cardiovascular outcomes in patients undergoing noncardiac, nonvascular surgery. Based on their findings, Biteker et al. (2011) recommended that prolonged QTc be viewed as an independent marker for preoperative cardiovascular outcome after noncardiac, nonvascular surgery.

While there was no significant instances of tachycardia or bradycardia post-procedure, the findings of these ECG markers highlight the role an individualized and complete preoperative assessment, that includes an ECG, can make towards thoughtful perioperative management and positive postoperative outcomes. The 12-lead ECG is inexpensive, convenient, and accessible to most outpatients. Although a pre-op ECG is not a current requirement for asymptomatic patients undergoing low-cardiac-risk surgery, individual patient factors such as an

above average BMI, having at least one risk factor for coronary artery disease, and consideration of OSA risk (assessed by STOP-BANG) should allow the ECG to be considered as part of an anesthesia pre-operative assessment.

There was an instance where a participant with the medical diagnosis of OSA had a STOP Bang score of less than 3. The patient attributed consistent use of CPAP in improving blood glucose levels to where the patient was no longer diabetic or obese.

Limitations

This is the first study to monitor patients in their homes with cardiac, actigraphy, and pulse oximetry. It was a challenge ensuring compliance with all three devices. The patients were required to wear three separate monitors. A heart monitor on the chest with an accompanying phone, an actigraphy watch on one wrist, and during sleep a pulse oximeter on the other wrist. One patient woke to find that all three monitors had been removed during sleep. Another patient went swimming in the watch and decided not to share that it quit working until the day of the procedure. Such issues with devices may have affected study results and partially explain findings of non-significance. The Bodyguardian with Bluetooth real-life monitoring was easiest to track, as the PI could check or allow notification in real time if the device was not being worn.

The sample size of 50 was the minimum needed to achieve 80% power to detect significant increases in the number of events associated with higher STOP-Bang measures. A larger, stratified sample of 150 or more may have improved statistical power. Examination of a power analysis graph indicated that increasing the number of participants did not greatly increase the statistical power of the analysis. The increase in statistical power from increasing the sample size did not justify the resource constraint (e.g., securing additional monitoring devices for additional participants) that would result from recruiting more participants. The researcher opted

to use a sample of 50 participants. The participants were only receiving propofol for endoscopy procedures. While this may be a strength in the uniformity of the drug received, the results may not generalize well to all outpatients who may receive general anesthesia or other classes of drugs (i.e., opioids, benzodiazepines, etc.) for other types of outpatient procedures. This study only included patients receiving sedation for endoscopy procedures that did not require post-operative pain management and cannot be generalized to patients receiving general anesthesia who may require post-operative pain management and control.

Implications for Practice

Propofol anesthesia has taken the dread out of screening colonoscopies, resulting in an easier sale on the part of gastroenterologists encouraging patients to get screening colonoscopies. Anesthetists are often not included in the pre-operative evaluation of patients. This task is usually the job of the primary attending physician or specialist to whom the patient has been referred. Typically, anesthetists review the medical information on the day of the procedure, immediately preceding the patient's entrance to the procedure room. On occasion, potential patient safety aberrancies are caught at the last moment and procedures are cancelled resulting in loss of time and revenue. The pressure is sometimes placed on the anesthetist to "just do the case" since, as evidenced by this study, patients often proceed through anesthetics without incident. The onus is on the anesthetist to place patient safety first. During the procedure, it may be noted that the patient may have OSA symptoms (i.e., an obstructed airway necessitating additional airway maneuvers) while under anesthesia. This is an opportunity for anesthetists to address the public health dilemma of undiagnosed OSA and help direct patients to appropriate resources for OSA screening. Pre-op clinics are not a reimbursable expense for insurance

purposes, but the payoff in perioperative patient safety and potential savings on public health costs would be well worth it.

Outpatients go home unmonitored. This may not be considered serious after procedures that do not require pain medication during recovery, but for outpatient procedures such as bariatric and orthopedic surgery that may require pain control at home this becomes life threatening. Pain control at home combined with the current opioid crisis lends itself to yet another latent and potentially deadly hazard. The importance of recognizing OSA, signs of opioid abuse, and the utilization of anesthetic modalities that minimize and or eliminate narcotic use and overuse should be encouraged in a multidisciplinary approach. Patients identified as having OSA by STOP-bang should be referred for a sleep study to ensure pulmonary optimization before and after surgery. Noncompliant OSA patients who do not use CPAP should be counseled on the importance of using their equipment. Case in point was one patient in the study who converted to atrial fibrillation in the early morning after the procedure. The patient had fallen asleep without wearing CPAP. After a call from the company, the patient replaced the CPAP and spontaneously reverted to sinus rhythm.

Similarly, patients with high-risk ECG markers signaling coronary perfusion issues or arrhythmia triggers may have their treatment customized to better ensure their safety during and after the procedure. Telemonitoring at home also could be made available when pertinent. The obligation should be on the perioperative team to ensure that during perioperative screening patients have the relevant equipment and that safety measures are anticipated and implemented.

There is an opportunity for anesthetists to be important not only at the head of the OR table as clinicians, but as leaders in patient safety initiatives affecting public health, such as the opioid crisis and OSA, and even smoking cessation. Anesthetists should embrace the role of

patient safety advocate beyond the OR. Patients should be educated on the life-threatening physiological and quality of life consequences of not using CPAP when indicated.

Recommendations for Future Research

This the first and only in-home study of utilizing three devices before and after surgical procedures. A pre- and post-test design was chosen for this longitudinal study to improve on a previous post-test study by Biddle et al. (2016) involving pulse oximetry monitoring of outpatients after orthopedic surgery. A convenience sample was used for this study for ease of recruitment and particularly because RQ1 was designed to identify the prevalence of known high-risk markers ECG characteristics in the outpatient endoscopy population. A Quota sampling technique would be helpful in future studies to hone in on the undiagnosed (high STOP-BANG score) OSA population. Further research might also include outpatient surgery populations that require general anesthesia and post-operative pain control.

Future studies might use an integrated Bluetooth monitor with integrated features to help facilitate patient compliance. Spence, Han, Morrison, and Couture (2018) completed an in home prospective observational study of patients undergoing total joint arthroplasty. The researchers started out with one sleep monitor and switched to another sleep monitor mid study mainly because of patient complaints of how uncomfortable the first device was to wear. The Watch-PAT200 (Itamar Medical Ltd, Caesarea, Israel) the researchers eventually used to complete their study, is an FDA approved device that incorporates both pulse oximeter and Actigraph capabilities and could have reduced the device number to two versus three thereby helping enhance patient compliance.

Conclusion

No differences were found between patients with and without OSA 24-hours post-procedure following deep propofol sedation for endoscopy. The findings suggest that Propofol sedation may be safe for patients with OSA. Additionally, preoperative screening or post-operative follow-up may not be necessary for Propofol sedation in patients with OSA, which can help to reduce healthcare costs. There were exactly enough patients to satisfy the power analysis with a sample size of 50, which was the minimum number needed to achieve 80% power to detect significant increases in the number of events associated with higher STOP-Bang measures. Findings should be interpreted with this limitation in mind, and replication of the study with a larger and stratified sample size is recommended.

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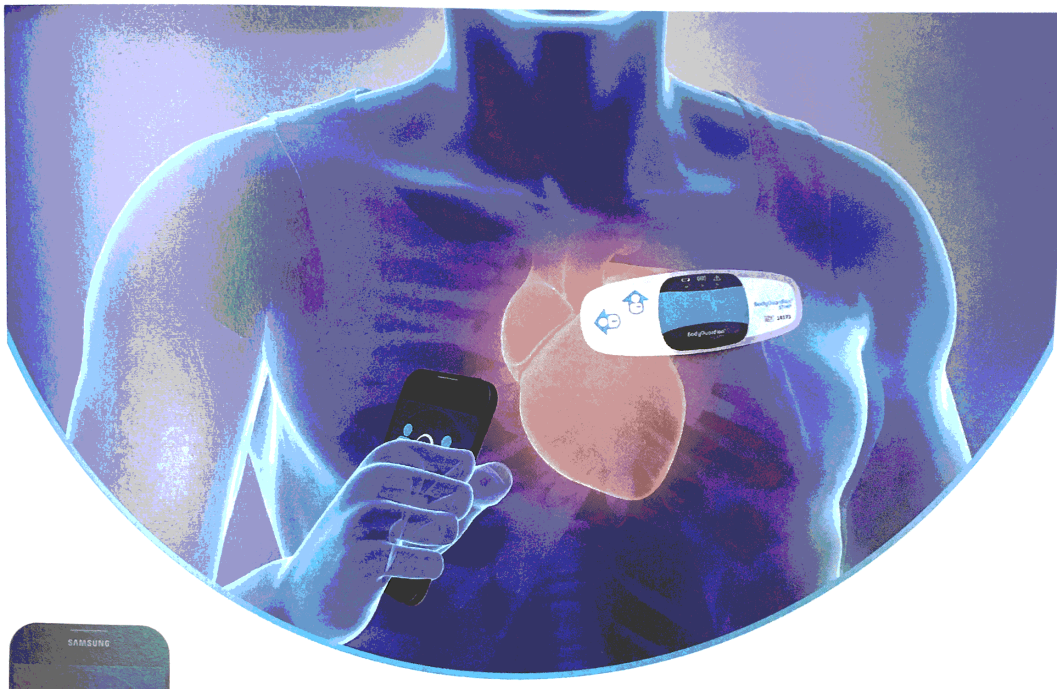
Appendix A

Preventic SOLUTIONS

BodyGuardian® HEART



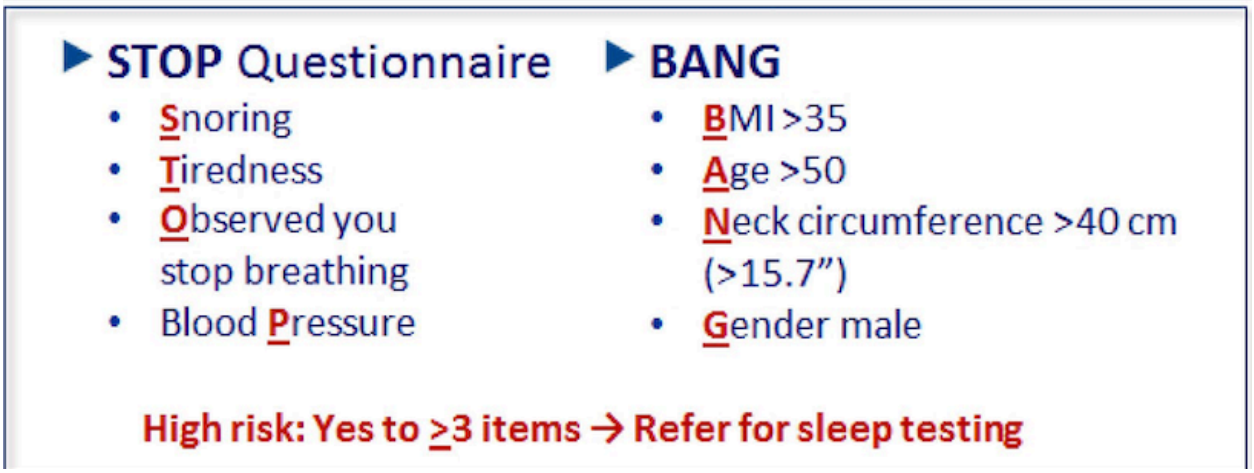
ADHERES to the skin
LISTENS to the beat
FOLLOWS the heart

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.
BodyGuardian® Heart Remote Monitoring System is a registered trademark of Preventice Technologies, Inc.

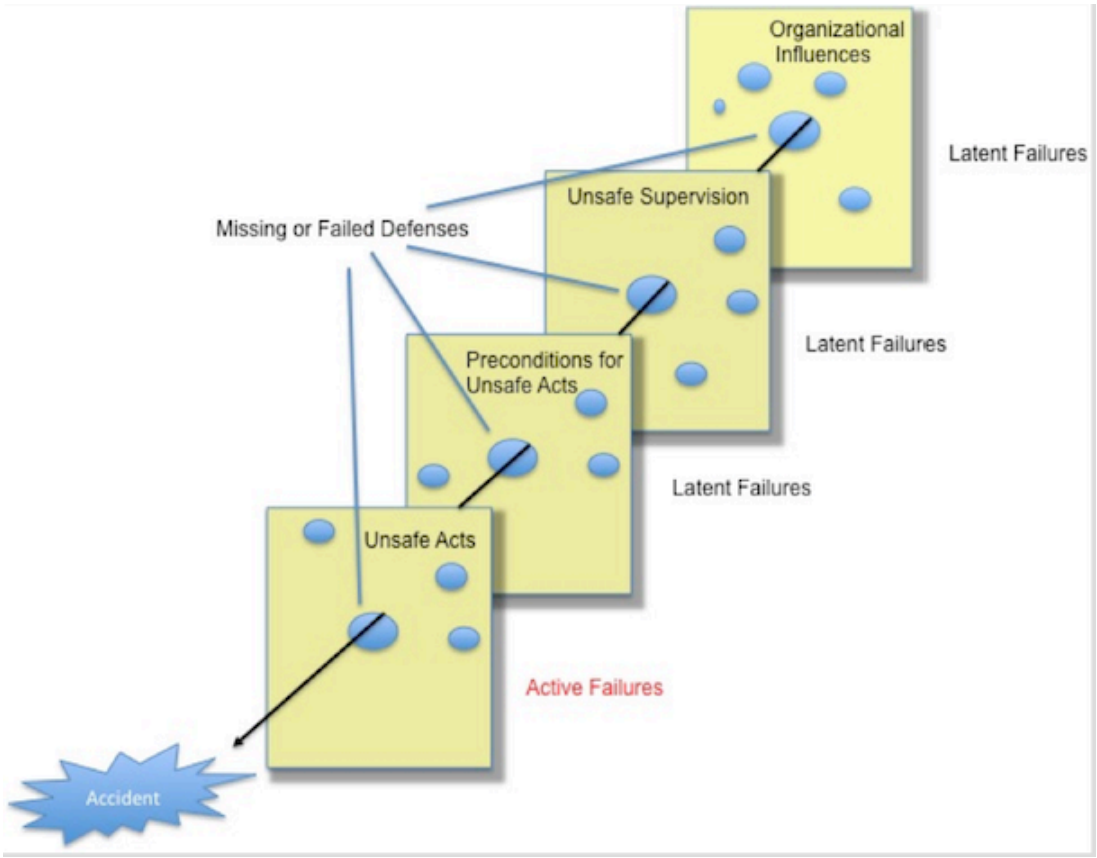
Depiction of pulse oximeter

Depiction of micromotionlogger watch

Appendix B



Stop-Bang Questionaire



Depiction of Reason's Swiss Cheese Model

Appendix C

Spanish Informed Consent

Información relacionada con temas de la investigación y formulario de consentimiento

Título: Evaluación de de la base de referencia y los factores de riesgo después de la descarga en sujetos con y sin apnea del sueño que se someten a endoscopia con sedación profunda.
NÚMERO DEL PROTOCOLO DE VCU IRB: HM20008241

Patrocinador: *AANA Foundation (Fundación de AANA)*

Si existe información en este formulario de consentimiento que no está claro, puede pedirle al personal del estudio que le explique cualquier información que no entienda completamente. Puede discutir esto con su familia o amigos hoy, pero necesitamos que firme su formulario de consentimiento hoy para matricularse.

PROPÓSITO DEL ESTUDIO
El propósito de este estudio es comparar los cambios en el estado de los sujetos con y sin apnea del sueño, antes y después de la sedación.

DESCRIPCIÓN DEL ESTUDIO Y SU PARTICIPACIÓN
Si decide participar en este estudio de investigación, se le pedirá que firme este formulario de consentimiento después de haber respondido a todas sus preguntas y entender lo que le sucederá.

Se someterá a un examen físico y un cuestionario antes de la cirugía que todos los pacientes deben someterse antes de la cirugía. Le preguntaremos acerca de sus antecedentes médicos y quirúrgicos, medicamentos, alergias, revise su expediente médico completo. Esta información rutinaria también se utilizará en el estudio. Además de esta información rutinaria, también se le harán preguntas para completar el cuestionario de STOP-BANG (para determinar la probabilidad de tener la apnea del sueño) y un electrocardiograma de 12 plomos (ECG) también se realizará en la mañana del procedimiento. Ambos se suman a su preparación preoperatoria habitual y son necesarios para las actividades de investigación.

Si acepta este estudio, le pediremos que use un monitor cardíaco que es un tipo de electrocardiograma ambulatorio (ECG). Este dispositivo registrará la actividad eléctrica de su corazón continuamente mientras se está moviendo durante sus actividades habituales y durante el sueño. Se adjuntará con pequeñas almohadillas o parches (electrodos) pegados en el pecho (ver demostración adjunta) después de su procedimiento. También llevarás un reloj de movimiento (como Fitbit) y un monitor de oxígeno (mide el porcentaje de oxígeno en la sangre) antes y después del procedimiento. El monitor de oxígeno sólo se llevará en la muñeca y el dedo (vea la demostración adjunta) siempre que descansa o duerme.

En el segundo día, devolverá el monitor del corazón, el reloj de movimiento y el monitor de oxígeno al equipo de investigación en el sobre de franqueo pagado que se proporciona. Estará en un grupo de cerca de 100 otros pacientes de cirugía y su información permanecerá confidencial. Usará el reloj del movimiento y el oxímetro del pulso por 3 días y el monitor del corazón por 1 día. Su compromiso de tiempo total será de 4 días.

RIESGOS Y MOLESTIAS

Hay un riesgo de malestar menor cuando se usan los monitores, especialmente el monitor de oxígeno. Para asegurar la comodidad, ajuste la correa de velcro de modo que no esté demasiado apretada.

Puede usarlo en cualquiera de las muñecas. También, utilice la punta de prueba plástica suave del dedo en cualquier dedo que sienta es más cómodo. La cinta adhesiva que se usa para fijar los electrodos del monitor cardíaco debe ser removida cuidadosamente para evitar la irritación de la piel. Vamos a hacer preguntas para completar el cuestionario STOP-Bang y hacer un ECG de 12 plomos. Ambas actividades relacionadas con la investigación no supondrán ningún riesgo adicional para y pueden proporcionar información adicional importante y útil a los médicos que proveen su cuidado.

Existe también un riesgo potencial de pérdida de confidencialidad. Este riesgo se minimizará al almacenar su información de manera segura y de acuerdo con todas las reglas de la HIPAA y la confidencialidad de la investigación.

USO Y DIVULGACIÓN DE INFORMACIÓN PROTEGIDA DE SALUD

Autoridad para Solicitar Información Protegida de Salud

Las siguientes personas y / o grupos pueden solicitar mi información protegida de salud:

- Investigador Principal e Investigación
- Personal del Patrocinio del Estudio
- Colaboradores de Investigación
- Juntas Institucionales de Evaluación
- Juntas de supervisión de seguridad de datos
- Agencias de Gobierno / de Salud
- Otros según lo requerido por la ley

Autoridad para Divulgar Información Protegida de Salud
El *Baptist Health System* (BHS) puede divulgar la información indicada en este formulario de autorización de mi antecedente médico para proporcionar esta información a:

- Proveedores de atención médica de BHS
- Proveedores de atención médica de VCUHS
- Coordinadores de datos
- Juntas de supervisión de seguridad de datos
- Otros según lo requerido por la ley
- Investigador principal y personal de investigación
- Colaboradores de Investigación
- Juntas Institucionales de Evaluación
- Agencias de Gobierno / de Salud
- Patrocinador del Estudio

Una vez que su información de salud ha sido divulgada a alguien fuera de este estudio, la información ya no puede ser protegida bajo esta autorización.

Tipo de información que se puede divulgar
Los siguientes tipos de información se pueden ser utilizados para la realización de esta investigación:

- Antecedente de salud completo
- Historia y examen físico
- Informes de consulta
- Resultados de las pruebas de laboratorio
- Informes de las radiografías
- Información del abuso de drogas o alcohol

Caducidad de esta autorización

- Esta autorización expirará cuando se cierre el estudio de investigación o no sea

necesario revisar, analizar y considerar los datos generados por el proyecto de investigación, lo que sea posterior.

Derecho a revocar la autorización y la Re-divulgación

Puede cambiar de opinión y revocar (retirar) el derecho de usar su información protegida de salud en cualquier momento. Aunque revoque esta Autorización, todavía los investigadores pueden usar o divulgar su información de salud que ya han recopilado para este estudio. Si revoca esta Autorización, ya no podrá participar en el estudio de investigación. Para revocar esta Autorización, debe escribir al Investigador Principal.

BENEFICIOS PARA Y OTROS

No puede recibir ningún beneficio directo de este estudio. Su participación puede ayudar a su equipo de atención médica para identificar a los pacientes en riesgo de eventos futuros cardiopulmonares después de la cirugía.

COSTOS

No hay costos por su participación en este estudio, excepto por su tiempo para recuperar y usar los monitores antes y después del procedimiento.

PAGO PARA LA PARTICIPACIÓN

Recibirá una tarjeta de regalo Visa de $25. Para recibir esta tarjeta de regalo, tiene que llevar los monitores el día antes y después del período de 24 horas después del procedimiento. Debe enviar por correo los monitores al equipo de investigación en el sobre que se proporciona. Después de que el equipo de investigación reciba sus monitores, le enviaremos la tarjeta de regalo a su dirección que nos proporcione.

ALTERNATIVOS

Tiene la opción de no participar en este estudio.

CONFIDENCIALIDAD

Su información potencialmente identificable consistirá en sus antecedentes médicos, examen físico y medidas de monitoreo. Los datos se están recopilando sólo con fines de investigación.

Sus datos serán identificados por un código numérico, no por nombres, y serán archivados en un programa informático protegido por contraseña. Toda la información

personal se guardará en archivos protegidos por contraseña y estos archivos se eliminarán al final del estudio. El acceso a todos los datos estará limitado al personal del estudio.

Lo que encontramos en este estudio puede ser presentado en reuniones o publicado en artículos, pero su nombre no se usará en estas presentaciones o artículos.

PARTICIPACIÓN VOLUNTARIA Y RETIRO

No tiene que participar en este estudio. Si decide participar, puede detenerse en cualquier momento sin ninguna penalización. También puede optar por no contestar preguntas particulares que se hacen en el estudio.

Su participación en este estudio se puede ser detenida en cualquier momento por el personal del estudio o el patrocinador sin su consentimiento. Las razones podrían incluir:

- el personal del estudio piensa que puede ser necesario para su salud o seguridad;
- no cumplió con las instrucciones del estudio.
- el patrocinador ha detenido el estudio;
- o motivos administrativos exigen su retiro.

Si deja el estudio antes de la visita final programada, devuelva los 3 monitores en el sobre proporcionado. No recibirá el pago por la participación si no completa completamente el monitoreo durante las 24 horas completas después de la cirugía.

CUESTIONES

Si tiene alguna pregunta, queja o inquietud con respecto a su participación en esta investigación, comuníquese con:

Mercedes Weir, CRNA, MSN: Investigadora asociada
Galloway Endoscopy Center
7500 SW 87th Ave

Miami, FL 33173
Móvil: (786) 999-9000
Correo electrónico: weirm@vcu.edu

Chuck Biddle, CRNA, PhD: Investigador Principal
Virginia Commonwealth University
School of Allied Health Professions
P.O Box 980226

Richmond, VA 23298-0226
Teléfono: (804) 828-9808
Correo electrónico: nrsa@vcu.edu

La investigadora asociada anteriormente mencionada es la mejor persona para ponerse en contacto con respecto a preguntas relacionadas con su participación en este estudio.

Si tiene alguna pregunta en cuanto a sus derechos, no dude en ponerse en contacto con:

Oficina de la Investigación
Virginia Commonwealth University
800 East Leigh Street, Suite 3000
P.O. Box 980568
Richmond, VA 23298
Teléfono: (804) 827-2157

Póngase en contacto con este número para preguntas generales, preocupaciones o quejas relacionadas con la investigación. También puede llamar a este número si no puede comunicarse con el equipo de investigación o si desea hablar con otra persona. También se puede encontrar información general en cuanto a la participación en los estudios de investigación en http://www.research.vcu.edu/irb/volunteers.htm.

CONSENTIMIENTO

Se me ha dado la oportunidad de leer este formulario de consentimiento. Entiendo la información relacionada con este estudio. Las preguntas que quería hacer con respecto al estudio se han sido contestadas. Mi firma significa que estoy dispuesto a participar en este estudio. Recibiré una copia del formulario de consentimiento una vez que haya aceptado participar.

Nombre impreso del participante Firma del participante Fecha

Nombre de la persona que realiza la discusión de consentimiento informado. (Impreso)

Firma de la persona que realiza el consentimiento informado. Fecha
Discusión

Investigador Principal Firma (Si es diferente del anterior) Fecha

Appendix D

Research Subject Information and Consent Form (English)

Title: Assessing Baseline and Post-Discharge Risk Factors in Subjects with and without Sleep Apnea Undergoing Endoscopy with Deep Sedation.

VCU IRB PROTOCOL NUMBER: HM20008241

Sponsor: *AANA Foundation*

If any information contained in this consent form is not clear, please ask the study staff to explain any information that you do not fully understand. You may discuss this with your family or friends today, but we need your signed consent today to enroll.

PURPOSE OF THE STUDY

The purpose of this study seeks to compare changes in status of subjects with and without sleep apnea, before and after sedation.

DESCRIPTION OF THE STUDY AND YOUR INVOLVEMENT

If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered and understand what will happen to you.

You will undergo a pre-surgery physical and questionnaire that all patients have before surgery. We will ask about your medical and surgical history, medicines, allergies, review your full medical record. This routine information will also be used in the study. In addition to this routine information, you will also be asked questions in order to complete the STOP-BANG questionnaire (helps determine likelihood of you having sleep apnea) and a 12-lead electrocardiogram (ECG) will also be done on the morning of the procedure. Both of these are in addition to your usual pre-operative preparation and are a necessary part of the research activities.

If you consent to this study, we will ask you to wear a Heart monitor which is a type of ambulatory electrocardiogram (ECG). This device will record your heart's electrical activity continuously while you move around doing your usual activities and during sleep. It will be attached with small pads or patches (electrodes) taped to your chest (see attached demonstration) after your procedure. You will also wear a Motion watch (like a Fitbit) and an oxygen monitor (measures the percentage of oxygen in your blood) before and after your procedure. The oxygen monitor will only be worn on your wrist and finger (see attached demonstration) whenever you rest or sleep.

On the second day, you will return the heart monitor, motion watch. and oxygen monitor to the research team in the postage-paid envelope provided. You will be in a group of about 100 other surgery patients and your information will remain confidential. You will wear the motion watch and pulse oximeter for 3 days and the Heart monitor for 1 day. Your total time commitment will be 4 days.

RISKS AND DISCOMFORTS

There is a risk of minor discomfort when wearing the monitors, particularly the oxygen monitor. To ensure comfort, adjust the Velcro strap so that it is not too tight.

You may wear it on either wrist. Also, wear the soft plastic finger probe on whichever finger you feel is more comfortable. The adhesive tape used to attach the electrodes of the heart monitor must be removed carefully to avoid skin irritation. We will ask questions to complete the STOP-BANG questionnaire and do a 12 lead ECG Both of these research related activities will pose no additional risk to you and may provide additional important and useful information to clinicians who provide your care.

There is also a potential risk for loss of confidentiality. This risk will be minimized by storing your information as securely and in keeping with all HIPAA and research confidentiality rules.

USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

Authority to Request Protected Health Information

The following people and/or groups may request my protected health information:

- Principal Investigator and Research Staff
- Research Collaborators
- Data Safety Monitoring Boards
- Others as Required by Law
- Study Sponsor
- Institutional Review Boards
- Government/Health Agencies

Authority to Release Protected Health Information

The Baptist Health System (BHS) may release the information identified in this authorization form from my medical records and provide this information to:

- Health Care Providers at BHS
- Health Care Providers at VCUHS
- Data Coordinators
- Data Safety Monitoring Boards
- Others as Required by Law
- Principal Investigator and Research Staff
- Research Collaborators
- Institutional Review Boards
- Government/Health Agencies
- Study Sponsor

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

Type of Information that may be Released

The following types of information may be used for the conduct of this research:

- Complete health record
- History and physical exam
- Consultation reports
- Laboratory test results
- X-ray reports
- Information about drug or alcohol abuse

Expiration of This Authorization

- This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

Right to Revoke Authorization and Re-disclosure

You may change your mind and revoke (take back) the right to use your protected health information at any time. Even if you revoke this Authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator.

BENEFITS TO YOU AND OTHERS

You may not receive any direct benefit in this study. Your participation might help your health care team identify future patients at risk for cardiopulmonary events after surgery.

COSTS

There are no costs for your participation in this study except for your time to retrieve and wear the monitors before and after your procedure.

PAYMENT FOR PARTICIPATION

You will receive a $25 Visa gift card. In order to receive this gift card, you need to wear the monitors the day before and after the 24-hour period after your procedure. You must mail the monitors to the research team in the provided envelope. After the research team receives your monitors we will mail the gift card to your address you provide to us.

ALTERNATIVES

You have the option to not participate in this study.

CONFIDENTIALITY

Potentially identifiable information about you will consist of your medical history, physical, and monitor measurements. Data is being collected only for research purposes.
Your data will be identified by a number code, not names, and stored in a password protected computer program. All personal identifying information will be kept in password-protected files and these files will be deleted at the end of the study. Access to all data will be limited to study personnel.

What we find from this study may be presented at meetings or published in papers, but your name will not ever be used in these presentations or papers.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

You do not have to participate in this study. If you choose to participate, you may stop at any time without any penalty. You may also choose not to answer particular questions that are asked in the study.

Your participation in this study may be stopped at any time by the study staff or the sponsor without your consent. The reasons might include:

- the study staff thinks it necessary for your health or safety;
- you have not followed study instructions;
- the sponsor has stopped the study;
- or administrative reasons require your withdrawal.

If you leave the study before the final regularly scheduled visit, return the 3 monitors in the provided envelope. You will not receive payment for participation if you do not fully complete monitoring for the full 24 hours after surgery.

QUESTIONS

If you have any questions, complaints, or concerns about your participation in this research, contact:

Mercedes Weir, CRNA, MSN: Co-Investigator
Galloway Endoscopy Center
7500 SW 87th Ave
Miami, FL 33173
Cell: (786) 999-9000
Email: weirm@vcu.edu

Chuck Biddle, CRNA, PhD: Principal Investigator
Virginia Commonwealth University
School of Allied Health Professions
P.O Box 980226
Richmond, VA 23298-0226
Phone: (804) 828-9808
Email: nrsa@vcu.edu

The co-investigator named above is the best person to call for questions about your participation in this study.

If you have any general questions about your rights as a participant in this or any other research, you may contact:

Office of Research
Virginia Commonwealth University
800 East Leigh Street, Suite 3000

P.O. Box 980568
Richmond, VA 23298
Telephone: (804) 827-2157

Contact this number for general questions, concerns or complaints about research. You may also call this number if you cannot reach the research team or if you wish to talk with someone else. General information about participation in research studies can also be found at http://www.research.vcu.edu/irb/volunteers.htm.

CONSENT

I have been given the chance to read this consent form. I understand the information about this study. Questions that I wanted to ask about the study have been answered. My signature says that I am willing to participate in this study. I will receive a copy of the consent form once I have agreed to participate.

Participant name printed	Participant signature	Date

Name of Person Conducting Informed Consent Discussion (Printed)

Signature of Person Conducting Informed Consent Discussion	Date

Principal Investigator Signature (if different from above)	Date

Vita

Mercedes Ermita Weir was born on September 7, 1967, in Buff Bay, Portland, Jamaica, West Indies. She is a naturalized citizen of the United States of America. She graduated from Kingsway High School in Kingston, Jamaica in 1983. She received her Diploma in Nursing from Kingston School of Nursing in Kingston, Jamaica in 1988 and her Bachelor's in Nursing from Southern Adventist University, Chattanooga, Tennessee in 1994. After 10 years of Oncology and Critical Care Clinical experience she attended the State University of New York at Buffalo (SUNY Buffalo) and completed her Masters of Science in Nursing with a concentration in Nurse Anesthesia. In 2013 she was accepted as a doctoral candidate at Virginia Commonwealth University. She currently continues her clinical practice as Certified Registered Nurse Anesthetist (CRNA) in various Locums assignments across the United States.