SCHOLARLY PROJECT: PERIOPERATIVE CARE OF OBSTRUCTIVE SLEEP APNEA AT AN AMBULATORY SURGERY CENTER

by

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ABSTRACT

VICTORIA ANNALEE VALENCIA CASALES. Scholarly Paper: Perioperative Care Of The OSA Patient At An Ambulatory Surgery Center.

(Under The Direction Of DR. STEPHANIE WOODS)

Obstructive Sleep Apnea (OSA) is the most common sleep-related breathing disorder in the United States. OSA affects 25 million adults nationally, with as many as 80% of patients potentially undiagnosed (Hines & Marschall, 2018). Timely identification with a blue wristband will increase the anesthesia providers' cognizance of OSA-related concerns for prolonged effects from anesthetic drugs, and heightened sensitivity to opioids in the post-operative period. This is a Quality Improvement (QI) project using a descriptive design to identify patients with suspected OSA on the Day of Surgery (DOS) and examine the clinical practice of providers' administration of benzodiazepines and opioids to this patient population. The PICOT question is: In patients who are greater than or equal to 18 years old scheduled for elective surgery at an ambulatory surgical center (P), how does the implementation of a blue wristband to identify patients with diagnosed or suspected OSA (STOP-Bang score >/=4) (I) compared to current practice (C) affect the perioperative management of OSA patients as defined as receiving benzodiazepines alone or in combination with opioids (O) within the intra-operative period (T)? The project's setting occurred at the One Day Surgery (ODS) Outpatient Center at Atrium Health. The sample for this project consisted of a total of 73 patients who either underwent elective non-cardiac surgery at CMC Atrium Health ODS from June 2022 through August 2022 or who underwent elective non-cardiac surgery from October 2022 through November 2022. The author collected data via chart review.

Inclusion criteria for Atrium Health ODS pre and post-implementation group were female and male adults older than or equal to 18 years old, scheduled for elective non-cardiac surgery, and have a STOP-Bang score >/=4. Exclusion criteria include patients younger than 18 years old, emergency surgery, Intensive Care Unit (ICU) admission, or specialized surgeries, including trauma, cardiovascular, neurological, and obstetric surgeries. To maintain the confidentiality of data, all patient data collection was de-identified, and management was completed via Excel sheets under password protection. This QI project noted a decrease in the administration of benzodiazepines by 10% in patients identified with a blue wristband, although not statistically significant.

ACKNOWLEDGMENTS

I cannot express enough gratitude and appreciation to my partner Niki Ushakumari for her continuous hard work on this project. This project's completion and full potential could not have been accomplished without her dedication. I greatly look up to her devotion and passion for this project and the practice of Nurse Anesthesia. Special thanks is due to Suzi Kuykendall, whose help allowed us to implement this project at Atrium Health. Dr. Ian Cohen was instrumental in the initial planning and aiding in directing our project with his knowledge of patients with Obstructive Sleep Apnea. Dr. Zhuo Job Chen for his expertise in statistics in assisting in running a statistical analysis with our data collection. I also acknowledge with much appreciation the crucial role of the pre-operative staff at ODS Atrium Health, who were the frontrunners for the implementation of this process. Lastly, I cannot express enough thanks to my committee for their continuous support and encouragement: Dr. Stephanie Woods, Dr. Lorraine Schoen, Dr. Sherry Bernardo, Dr. Katie Shue-McGuffin, and Dr. Mark DeHaven. I appreciate the endless support and opportunities provided to complete this project.

DEDICATION

Este proyecto está dedicado a las personas que más me han influenciado en mi vida, dándome los mejores consejos, guiándome, y haciéndome una persona de bien, con todo mi amor y afecto se los dedico a mis padres Claudia y Alfredo Valencia. Sin ellos, nunca hubiera podido encontrar la carrera a la que me quiero dedicar por el resto de mi vida. Nunca dudaron en apoyarme ciegamente en cualquier camino que hubiera tomado para mi vida profesional. Desde pequeña me han alentado a soñar grande y a poner todo mi esfuerzo y espíritu en mis metas personales y profesionales.

TABLE OF CONTENTS

LIST OF TABLES ix

LIST OF FIGURES x

LIST OF ABBREVIATIONS xi

CHAPTER 1: INTRODUCTION 1

Problem Statement 1

Purpose of Project 2

Clinical Question – PICOT 3

CHAPTER 2: LITERATURE REVIEW 3

Methods 3

Anesthetic Implications and Effects of Opioids/Sedatives 4

Associated Complications 7

STOP-Bang Questionnaire versus Polysomnography 9

Ambulatory Surgery 11

Perioperative Management of OSA Patients 13

Conceptual Framework/Theory 14

CHAPTER 3: METHODOLOGY 14

Project Design 14

Sample with Inclusion & Exclusion Criteria 15

Setting 16

Methods & Interventions 16

Tools & Measures 18

Project Implementation 19

CHAPTER 4: RESULTS 21

Data Analysis & Interpretation 21

CHAPTER 5: DISCUSSION 24

Discussion & Significance 24

Limitations 27

Recommendations 27

REFERENCES 30

APPENDIX A: University Of North Carolina Charlotte IRB Approval 36

APPENDIX B: Wake Forest Health Baptist IRB Approval 38

APPENDIX C: OSA In The Perioperative Period Assessment And Application Of Blue Wristband Protocol 40

APPENDIX D: OSA Assessment Of Risk And Treatment Diagram 43

APPENDIX E: Excel Worksheet Template 44

APPENDIX F: Gantt Chart 44

LIST OF TABLES

TABLE 1: Descriptive analysis and comparison between no wristband, wristband, and no wristband but monitored groups in the ODS.

LIST OF FIGURES

FIGURE 1: Flowchart of patient selection

LIST OF ABBREVIATIONS

AHI	Apnea-hypopnea index
ARDS	Acute Respiratory Distress Syndrome
APSF	Anesthesia Patient Safety Foundation
ASA	American Society of Anesthesiologists
ASC	Ambulatory Surgery Centers
ASPAN	American Society of Peri-Anesthesia Nurses
CDSR	Cochrane Database of Systematic Reviews
CPAP	Continuous Positive Airway Pressure
CRNA	Certified Registered Nurse Anesthetist
DMV	Difficult Mask Ventilation
DOS	Day of Surgery
DTI	Difficult Tracheal Intubations
EBP	Evidence-Based Practice
EMR	Electronic Medical Record
FFY	Federal Fiscal Year
ICU	Intensive Care Unit
IRB	Institutional Review Board
LOS	Length of Stay
MRN	Medical Record Number
NPV	Negative Predictive Value
NSAIDs	Non-Steroidal Anti-Inflammatory Drugs
ODS	One Day Surgery

OIRD	Opioid-Induced Respiratory Depression
OSA	Obstructive Sleep Apnea
PACU	Post-Anesthesia Care Unit
PDSA	Plan-Do-Study-Act
PSG	Polysomnography
PPV	Positive Predictive Value
QI	Quality Improvement
RDI	Respiratory Disturbance Index
REM	Rapid Eye Movement
SASM	Society of Anesthesia and Sleep Medicine

CHAPTER 1: INTRODUCTION

Obstructive Sleep Apnea (OSA) is the most common sleep-related breathing disorder in the United States. OSA affects 25 million adults nationally, with as many as 80% of patients potentially undiagnosed (Hines & Marschall, 2018). OSA is associated with an array of systemic diseases, such as congestive heart failure, diabetes, stroke, hypertension, and increased mortality. (Vasu, Grewal & Doghramji, 2012). In addition, this patient population is at higher risk for perioperative adverse events such as hypoxemia, respiratory failure, cardiovascular events, unplanned transfer to the Intensive Care Unit (ICU), and increased hospital length of stay (LOS). With an aging population and increasing rates of obesity, the number of patients presenting to surgery with undiagnosed OSA is only expected to grow (Chung et al., 2016). The increased duration of hospital stay and healthcare expenditures in OSA patients poses a tremendous economic burden (Nagappa et al., 2017). Identifying patients with suspected OSA throughout the perioperative process will improve the quality of care for these patients and ameliorate harmful financial and clinical complications.

Problem statement

Failure to communicate a patient's OSA status from the pre-optimization clinic to the pre-operative holding area, operating room, and post-anesthesia care unit (PACU) increases the risk of perioperative adverse events due to the potential administration of benzodiazepines and opioids. Although patients are screened for OSA using the STOP-Bang score weeks before surgery, this information is not easily accessible or communicated on the DOS. Identifying patients with suspected OSA with a blue wristband will alert staff about expected problems and their management.

The perioperative outcomes of patients with OSA directly impact all stakeholders, including patients, hospital administration, anesthesiologists, Certified Registered Nurse Anesthetists (CRNAs), and perioperative nursing staff. Patients benefit from proper OSA management since safety outcomes, and patient satisfaction rates will improve if their anesthetic is without complications. The economic burden of managing adverse events of patients with OSA will decrease due to proper identification and management of OSA patients and more efficient allocation of hospital resources. Lastly, anesthesiologists and CRNAs will be positively impacted by confidently providing patient care without substantial pulmonary instability. Significantly, no perioperative risks can be mitigated until the patient has been identified on the DOS. This is a problem since patients with OSA have a higher rate of postoperative complications and hypoxemia, a higher rate of postoperative pulmonary and cardiac complications, and a significantly higher LOS in the hospital compared to patients at low risk of OSA (Vasu et al., 2012).

Purpose of Project

Timely identification will increase the anesthesia providers' cognizance of OSA-related concerns for prolonged effects from anesthetic drugs, and heightened sensitivity to opioids in the postoperative period. Undiagnosed OSA can be detrimental to the surgical patient, and prompt identification is imperative. Patients with OSA may have cardiopulmonary consequences that could be aggravated in the perioperative setting due to the adverse effects of anesthetics agents and opioid medications on respiratory control and airway muscle tone in the upper pharynx-particularly during the early postoperative period (Vasu et al., 2010). Most patients with OSA are undiagnosed and, therefore, unaware of their OSA at the time of surgery. The American Society of Anesthesiologists (ASA), the Society of Anesthesia and Sleep Medicine (SASM), and the

American Society of Peri-Anesthesia Nurses (ASPAN) recommend standardized preoperative screening for OSA (Nagappa et al., 2018). Although Polysomnography (PSG) is considered the gold standard for diagnosing OSA, it can be time-consuming and expensive. The STOP-Bang is an easy and concise tool that has been validated in surgical patients and has a high sensitivity to identify most patients with this detrimental disease. While many studies suggest that suspected OSA patients should be identified on the DOS, more research is needed on the perioperative care of patients with suspected OSA.

Clinical Question - PICOT

There is strong evidence that patients with diagnosed or suspected sleep apnea require specialized care for elective surgery to decrease the risk of respiratory complications. This PICOT question was developed after the communication failure of suspected OSA patients was identified in the ODS center at a Level 1 trauma Urban hospital. Patients treated at the outpatient center have the same number of comorbidities as patients from the Level 1 Trauma hospital and are at equal risk of suffering adverse effects due to undiagnosed OSA. The PICOT question asks: In patients who are greater than or equal to 18 years old scheduled for elective surgery at an ambulatory surgical center (P), how does the implementation of a blue wristband to identify patients with diagnosed or suspected OSA (STOP-Bang score >/=4) (I) compared to current practice (C) affect the perioperative management of OSA patients as defined as receiving benzodiazepines alone or in combination with opioids (O) within the intra-operative period (T)?

CHAPTER 2: LITERATURE REVIEW

Methods

A literature review was conducted, and databases were searched, including PubMed, Cochrane Database of Systematic Reviews (CDSR), CINAHL complete, North Carolina AHEC

Digital Library, and Google Scholar, to examine evidence regarding perioperative care of OSA. The keywords used were ambulatory surgery, anesthesia, complications, anesthesia management, difficult airway, obstructive sleep apnea, opioids, polysomnography, and STOP-Bang. Inclusion criteria included a published date on or after 2008, full-text availability, English language, and peer-reviewed articles. Exclusion criteria were articles that did not involve humans or were not written in English.

Anesthetic Implications and Effects of Opioids/Sedatives

To understand why OSA patients are more susceptible to perioperative respiratory complications, it is essential to know the mechanisms of respiratory-related arousal response. OSA is associated with repeated episodes of partial or complete obstruction of the upper airway, with nocturnal breathing cessation and hypoxia. Typically, the pharynx muscles keep the upper airway open to allow air to flow into the lungs during inspiration. These muscles relax during sleep but typically remain open enough to permit adequate airflow. In patients with a narrow passage in the upper airway, relaxation of the pharyngeal muscles can cause complete collapse so that air cannot flow into the lungs. A common cause of narrowed airway is redundant soft tissue, such as inflamed tonsils or abundant parapharyngeal fat pads.

Usually, there is a protective respiratory-arousal response stimulated by hypercapnia, hypoxia, upper airway obstruction, and the work of breathing (Hines & Marschall, 2018). In patients with OSA, there is a reduced respiratory-related arousal response and instability of the ventilatory response to chemical stimuli. This can be especially concerning in surgical patients receiving anesthetics, sedatives, opioids, and neuromuscular blocking agents, which can all increase the risk of upper airway obstruction and respiratory depression. According to Vasu, Grewal & Doghramji (2012), general anesthetics have been shown to decrease upper airway

dilator muscle activity in a dose-dependent manner, increase upper airway collapsibility and decrease genioglossus muscle activity.

Additionally, opioids depress a patient's ventilatory response to obstruction and inhibit the normal arousal and awakening response to hypoxia and hypercapnia (Liao et al., 2009; Nagappa et al., 2017). In a study by Gupta et al. (2018), OSA was identified as an independent risk factor for Opioid-Induced Respiratory Depression (OIRD). OIRD is a current topic of importance in the anesthesia setting; in fact, The Anesthesia Patient Safety Foundation (APSF) made it a top priority in 2006 (Hines & Marschall, 2018). OIRD results from alveolar hypoventilation, central respiratory depression, decreased consciousness, and upper airway obstruction (Miller et al., 2011). A review performed by Nagappa et al. (2018) evaluated the incidence of postoperative OIRD and found that eighty-five percent of OIRD events occurred within the first 24 hours. The review also found that the odds of OIRD occurring were 1.4 times higher in OSA than in non-OSA patients (Nagappa et al., 2018). Similarly, in another retrospective study, OSA was present in 38% of the patients with OIRD, and 50% of patients who died as a result of OIRD had OSA (Ramachandran et al., 2011).

According to the SASM on Intraoperative Management of Adult Patients with Obstructive Sleep Apnea, the "presence of robust, high-quality scientific evidence to demonstrate the merit of heightened concern and guide safe opioid practice in this population is limited" (Memtsoudis et al., 2018, 127:973). Nevertheless, there is evidence that perioperative adverse events can be attributed to the administration of opioids to patients with OSA. SASM reviewed 17 observational studies examining the impact of systemic opioid use on OSA. Most studies found an association between opioid use and adverse perioperative outcomes in OSA, but it was not confirmed by all (Memtsoudis et al., 2018). Morwald et al. (2018) performed another

analysis on the impact of opioids administered to OSA patients and found increased rates of gastrointestinal complications, prolonged LOS, and increased hospital costs.

Concerning the use of opioids and benzodiazepines in this vulnerable population, there is also evidence of detrimental effects. For example, the combination of opioids and benzodiazepines has been explicitly shown to cause a substantial reduction in hypoxic ventilatory response (Vasu et al., 2012; Nagappa et al., 2017). Additionally, Nagappa et al. (2017) explained that benzodiazepines and narcotics could reduce the pharyngeal muscle tone, increasing upper airway collapsibility and worsening the existing OSA. Prolonged apnea can lead to respiratory arrest and sudden unexpected death.

Given the growing evidence regarding the perioperative side effects associated with the administration of opioids and benzodiazepines, practice guidelines are available to help guide an appropriate anesthetic technique in patients with OSA. The ASA recommends using regional analgesia, avoiding opioids in neuraxial anesthesia, avoiding basal infusions in a PCA, using a multimodal anesthetic technique including Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), and caution administering other sedatives (American Society of Anesthesiologists Task Force on Perioperative Management of Patients with Obstructive Sleep Apnea, 2014). Lastly, patients with OSA are highly vulnerable to the adverse effects of neuromuscular blocking drugs. The upper airway muscles are more sensitive to paralytic drugs than other muscles groups like the peripheral muscles or the diaphragm; therefore, the residual neuromuscular blockade can be particularly dangerous in patients with OSA (Liao et al., 2009).

In addition to airway collapsibility, patients with OSA are at increased risk of oxygen desaturation, difficult mask ventilation, and endotracheal intubation (Hines & Marschall, 2018). In a prospective cohort study by Mathangi, Matthews, and Mathangi (2018), 77% of patients

with OSA had Difficult Mask Ventilation (DMV), 20% had Difficult Tracheal Intubations (DTIs), and 33% had difficult direct laryngoscopy. In this study, the authors found that the STOP-Bang score was the most critical predictor of difficult mask ventilation. Individual risk factors for difficult intubations also correlate with OSA: obesity, narrow oropharynx, and crowded oral cavity. Interestingly, the specific fat distribution may be more critical in developing OSA versus overall BMI in patients with obesity. For example, fat deposits around the neck and pharyngeal structure contribute to the narrowing and collapsibility of the upper airway.

Associated Complications

It has been well established that patients with OSA have a higher prevalence of pre-existing comorbidities, including respiratory diseases such as asthma and chronic obstructive pulmonary disease, and systemic disorders like obesity, hypertension, gastroesophageal reflux disease, diabetes, and hypothyroidism (Hines & Marschall, 2018; Liao et al., 2009; Mathangi, Matthews & Mathangi, 2018). In addition, patients with OSA have a higher rate of postoperative complications and hypoxemia, postoperative pulmonary and cardiac complications, and a significantly longer LOS (Vasu et al., 2012). In a retrospective matched cohort study, the authors found that OSA patients had a 33% increased incidence of respiratory complications (Liao et al., 2009). A separate study by Kaw et al. (2012) revealed that patients with OSA had a higher rate of post-op hypoxemia, respiratory failure, and transfer to the ICU. Likewise, a case-control study by Memtsoudis et al. (2011) concluded that patients with OSA had a higher aspiration rate, acute respiratory distress syndrome (ARDS), and need for intubation. Interestingly, patients with OSA were found to be at increased risk of aspiration even during normal sleep, which may explain the increased need for postoperative intubation and ventilation among this group.

A significant limitation of many of these studies is the lack of documentation on the severity of OSA. The retrospective studies used patient data in which OSA was formally diagnosed using PSG. Many of the studies failed to capture patients who had high-risk or suspected OSA using the STOP-Bang score. In a study by Nagappa et al. (2017), STOP-Bang scores greater than three were used to delineate patients with OSA and without OSA. Undiagnosed OSA patients were found to have a 3-fold increased risk of cardiac complications before surgery. In addition, suspected OSA patients had more postoperative complications and increased hospital stays than formally diagnosed OSA patients on continous positive airway pressure (CPAP). A linear association was found between increasing postoperative complications and higher scores of STOP-Bang. The authors defined postoperative complications as cardiac arrhythmias, myocardial infarction, congestive cardiac failure, reintubations due to respiratory failure, hypoxia or pneumonia, laryngospasm, bronchospasm, prolonged mechanical ventilation, acute pulmonary edema, and ICU admissions (Nagappa et al., 2017). Post-op complications were nearly four times higher in high-risk OSA patients versus low-risk OSA patients, and the average hospital LOS was two days longer.

Early postoperative complications may be attributed to the adverse effects of drugs given during anesthesia; however, later complications are more likely related to postoperative rapid eye movement (REM) sleep rebound (Kaw et al., 2012). An essential link between REM sleep rebound and sympathetic tone may lead to an MI or unexplained postoperative death. According to Vasu, Grewal, and Doghramji (2012), surgical patients have highly fragmented sleep on postoperative nights 1 or 2, secondary to surgical stress, pain, and the use of anesthetic and pain meds. On recovery nights 3-5, there is a vast increase in the amount and density of REM sleep. Occurrences of sleep-disordered breathing and hypoxemia are much worse during REM sleep

due to decreased muscle tone and episodes of unstable breathing. Subsequently, OSA patients had higher apnea-hypopnea index (AHI) and oxygen desaturation index on the third postoperative night compared with preoperatively or on the first postoperative night (Kaw et al., 2012).

STOP-Bang Questionnaire versus Polysomnography

The gold standard for diagnosis of OSA is nocturnal PSG. This diagnostic procedure requires an evaluation at a sleep clinic followed by overnight monitoring in a sleep clinic or at home with a portable monitor (Carr et al., 2020). The respiratory disturbance index (RDI), or the AHI, determines disease severity. AHI is defined as the average number of abnormal breathing events per hour of sleep. The severity of OSA is graded according to the recorded abnormal breathing events per hour of sleep and classified as mild (AHI > 5 to < 15), moderate (AHI > 15 to < 30), or severe (AHI >30) (Nagappa et al., 2018). While PSG is considered to be the gold standard, it has limitations. A systematic review by Nagappa et al. (2015) revealed that PSG is time-consuming, labor-intensive, and costly. PSG requires the expertise of sleep medicine specialists, which may only be available at some hospitals. PSG is difficult to implement in the perioperative setting because it prolongs the process of surgery and contributes to overall increases in costs (Vasu, Grewal & Doghramji, 2012). An analysis determined that the cost-effectiveness of preoperative OSA screening depends on the time period. Perioperative screening with STOP-Bang followed by immediate confirmatory testing with PSG is cost-effective on the lifetime but not the perioperative horizon (Sankar et al., 2020).

A review of the literature shows a variety of questionnaires suitable for assessing the probability and severity of undiagnosed sleep apnea, including the STOP-Bang, Berlin questionnaire, Epworth Sleepiness Scale, and the NoSAS. These questionnaires are easy to use;

however, they have different sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) when used in various populations. Unfortunately, studies suggesting which questionnaire can be helpful in the general population are sparse (Malolpesza et al., 2021).

STOP-Bang is the most commonly used questionnaire in the perioperative setting and is highly sensitive for categorizing the severity of sleep apnea (American Society of Anesthesiologists Task Force on Perioperative Management of Patients with Obstructive Sleep Apnea, 2014). STOP-Bang is a self-reporting tool and is easy to use in this setting. It has been validated in surgical patients and has a high sensitivity to identify most patients with OSA, especially moderate and severe OSA (Vasu et al., 2010). STOP-Bang includes four subjective items (STOP: Snoring, Tiredness, Observed Apnea, and High Blood Pressure) and four demographic items (Bang: BMI, age, neck circumference, and gender) (Nagappa et al., 2015).

For each item, the clinician answers "yes/no" if it applies to the patient. For each question, answering "yes" scores one point, and a "no" response scores zero points. For the demographic items, one point is obtained for BMI > 35 kg/m², age > 50 years old, neck circumference in males ≥ 43 cm and females ≥ 41 cm, or male gender. The total score ranges from zero to eight points (Malolepsza et al., 2021). A systematic review titled, *Association of STOP-Bang Questionnaire as a Screening Tool for Sleep Apnea and Postoperative Complication*, indicates that a STOP-Bang score of three or greater has the best equilibrium between sensitivity and specificity: 84% for detecting any OSA (AHI> 5), 93% for detecting moderate to severe OSA (AHI > 15), and almost 100% for detecting severe OSA (AHI > 30) (Nagappa et al., 2017).

Unless specifically defined, the STOP-Bang score's standard cutoff for OSA diagnosis is greater than or equal to three (Nagappa et al.,2015). The STOP-Bang score can be used to detect moderate to severe OSA with a higher accuracy, which is why the author is choosing a cutoff score for this doctorate project of ≥ 4 (Naggappa et al., 2017).

The ASA, the SASM, and the ASPAN recommend standardized preoperative screening for OSA. Patients with high-risk OSA (STOP-Bang ≥ 3) were found to be associated with an increased risk of postoperative complications and prolonged LOS compared with low-risk OSA (STOP-Bang 0-2) (Nagappa et al., 2018). Another study of 746 patients screened with the STOP-Bang questionnaire and PSG concluded that increasing STOP-Bang scores resulted in increased predicted probability, odds ratio, and specificity for having mild, moderate, and severe OSA (Carr et al., 2020).

There are several studies in which the STOP-Bang questionnaire has been standardized as a perioperative screening tool. One study concluded that identifying early at-risk OSA patients increased from 23% (based on a medical diagnosis of OSA) to 54% with intermediate and high-risk OSA (Kertes, 2020). Similarly, another QI project concluded that the STOP-Bang questionnaire increased the identification of surgical patients at risk for OSA but did not affect PACU LOS or unanticipated admissions (Carr et al., 2020).

Ambulatory Surgery

Over the past several decades, the number of Ambulatory Surgery Centers (ASCs) has grown significantly and is not expected to slow down anytime soon. With the continuous implementation of surgical innovations and new anesthetic techniques, the number of surgeries that can be performed safely at ASCs has increased. In the United States, procedures at outpatient centers tripled between 1996 and 2006; at present, 64% of all elective surgeries are

performed in outpatient centers (Nagelhout & Elisha, 2018). Currently, patients treated in ASCs have the same prevalence for undiagnosed OSA as general noncardiac surgical patients and are at equal risk of suffering adverse perioperative complications.

As previously mentioned, patients with OSA have an increased length of ICU stay and a higher rate of postoperative complications. The scientific literature regarding the safety of ambulatory surgery in OSA patients is sparse and of limited quality (Nagappa et al., 2018). A systematic review evaluated the perioperative complications in OSA patients undergoing ambulatory surgery and found several studies that reported a higher incidence of postoperative hypoxemia in the OSA population. None of the studies had differences in the need for reintubation or ventilation assistance (Joshi et al., 2012). Likewise, a consensus by Raveendran and Chung (2014) concluded that patients with OSA may safely undergo ambulatory surgery if they are carefully selected and receive appropriate perioperative care.

Thorough preoperative evaluation of patients at ASCs should include the STOP-Bang tool to identify patients with undiagnosed OSA. A review regarding OSA patient management in the ambulatory setting evaluated the association of STOP-Bang with postoperative complications, favoring STOP-Bang as a perioperative risk stratification tool (Nagappa et al., 2017). These findings were also mirrored by a consensus statement on the preoperative selection of adults with OSA scheduled for ambulatory surgery, where they recommended using the STOP-Bang for preoperative OSA screening and considered the patient's comorbid conditions in the patient selection process (Joshi et al., 2012).

All the evidence regarding the care of the OSA patient in the ambulatory setting concludes that surgery can be performed safely with a thorough and careful anesthetic plan. A limitation is that only a few published studies evaluate any correlation between postoperative

complications and the OSA patient in ASCs. However, the studies published provided helpful information that can guide clinical practice (Joshi et al., 2012). As the number of outpatient surgeries continues to increase, more evidence will become available regarding the appropriate anesthetic care for the OSA patient.

Perioperative Management of OSA Patients

Preoperative evaluation of patients should include a thorough medical record review and a screening protocol such as the STOP-Bang tool to detect suspected OSA. Physical examination includes evaluating the patient's airway, nasopharyngeal characteristics, neck circumference, tonsil size, and tongue volume.

Intraoperative management of patients with OSA involves an individualized plan of anesthesia to minimize postoperative complications. This includes considerations of local anesthesia or peripheral nerve blocks, neuraxial anesthesia, general anesthesia with a secured airway, and verification of complete reversal of neuromuscular blockade. Airway management is of utmost importance, given the high risk of airway collapse. Memtsoudis et al. (2018) strongly recommended that regional anesthesia is preferred over general anesthesia in patients with OSA when applicable. Moreover, Nagappa et al. (2018), in an extensive population-based analysis of perioperative outcomes, explained that postoperative adverse effects were decreased in OSA patients after neuraxial anesthesia versus general anesthesia.

Postoperative management encompasses consideration of analgesia selection, oxygenation, patient positioning, and continuous pulse oximetry monitoring. Patients with OSA require a more extended period of monitored recovery time to lessen the chance of postoperative complications in the ambulatory setting (Avitsian & Galway, 2015). Raveendran & Chung (2014) indicated that patients with known or suspected OSA receiving general anesthesia should

have extended monitoring for an additional 60 minutes. CPAP or NIPPV should be continuously administered postoperatively to patients using these modalities preoperative unless contraindicated by the surgical procedure.

Conceptual Framework/Theory

The conceptual framework chosen for this QI project is the Plan-Do-Study-Act (PDSA). The PDSA cycle has become a widely adopted and practical approach to testing and learning about change on a small scale (Melnyk & Fineout-Overholt, 2019). Plan: The plan is to identify adult surgical patients with suspected OSA on the day of surgery using results from the STOP-Bang questionnaire completed in the pre-optimization clinic before surgery. Do: Implement the application of blue OSA wristbands in the preoperative area for patients with a STOP-Bang score >/= 4. Study: Compare the number of benzodiazepines and opioids administered to patients with suspected OSA before and after the implementation of this project. This outcome measure will reveal if there is a change in practice by CRNAs and perioperative nurses after patients with suspected OSA are identified. Act: Evaluate the effectiveness of the process for identifying patients. The need for educating CRNAs and perioperative nurses on the adverse effects of administering a combination of benzodiazepines and opioids to suspected OSA patients during the intra-operative period will be evaluated.

CHAPTER 3: METHODOLOGY

Project Design

This is a Quality Improvement (QI) project using a descriptive design to identify patients with suspected OSA on the DOS and examine the clinical practice of providers' administration of benzodiazepines and opioids to this patient population. The project will be conducted at an ASC in Charlotte, North Carolina, with Institutional Review Board (IRB) approval by both

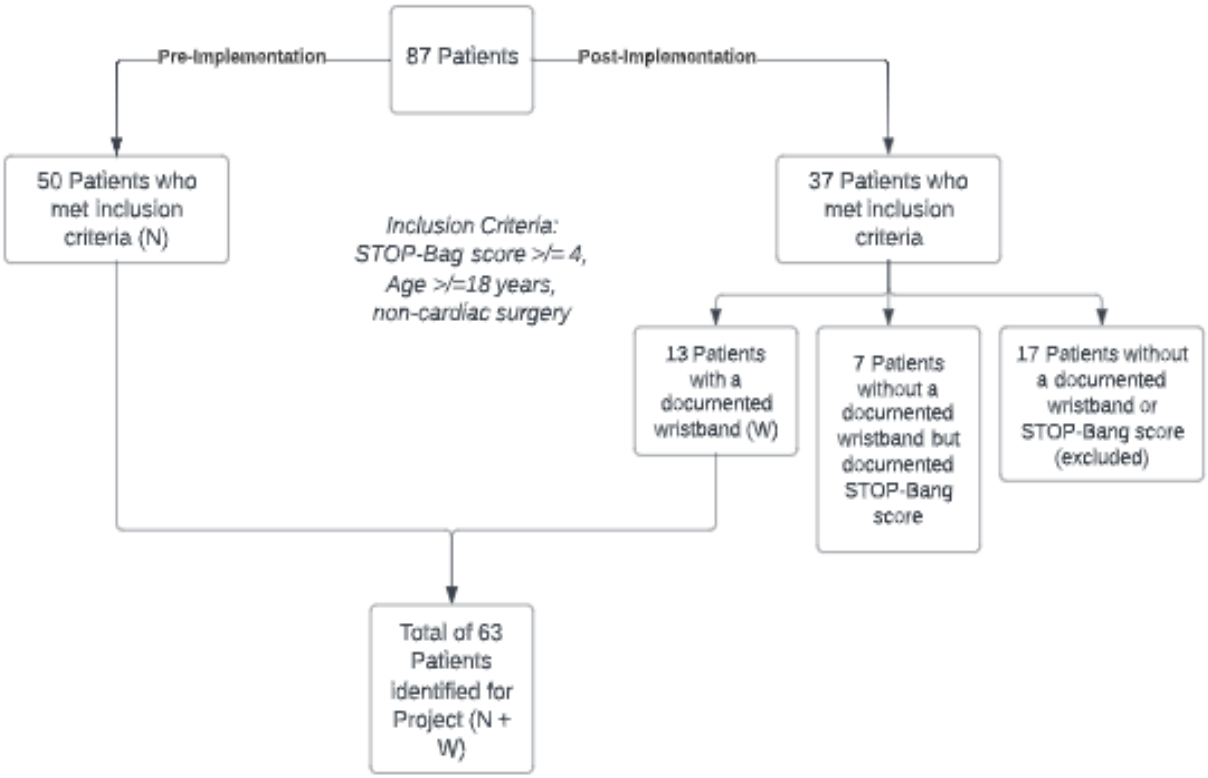
University of North Carolina Charlotte and Atrium Health Wake Forest Baptist. IRB approvals are depicted in Appendix A and Appendix B. The project PICOT question is: In patients who are greater than or equal to 18 years old scheduled for elective non-cardiac surgery at an ambulatory surgical center (P), how does the implementation of a blue wristband to identify patients with diagnosed or suspected OSA (STOP-Bang score >/=4) (I) compared to current practice (C) affect the perioperative management of OSA patients as defined as receiving benzodiazepines alone or in combination with opioids (O) within the intra-operative period (T)?

Sample with Inclusion & Exclusion Criteria

The sample for this project will consist of a total of 70 patients that have undergone elective surgery at Atrium Health ODS from June 2022 through August 2022 or who will undergo elective surgery from October 2022 through November 2022. Data will be collected via chart review. A convenience sample of the first 50 patients that meet the inclusion criteria for the pre-and post-implementation of the blue wristband intervention will be included.

Inclusion criteria for Atrium Health ODS pre and post-implementation group will be female and male adults older than or equal to 18 years old, scheduled for elective non-cardiac surgery, and have a STOP-Bang score >/=4. Exclusion criteria include patients younger than 18 years old, emergency surgery, ICU admission, or specialized surgeries, including trauma, cardiovascular, neurological, and obstetric surgeries.

Figure 1. Flowchart of patient selection



Setting

The setting of the project will take place at Atrium Health ODS Center. Based in Charlotte, North Carolina, Atrium Health is an integrated, nonprofit health system with more than 70,000 employees serving patients at 40 hospitals and over 1,400 care locations (Atrium Health, 2022). This project will focus on the location of Atrium Health ODS. Atrium Health ODS is a surgical clinic offering same-day surgical services and is made up of 11 ORs. For the federal fiscal year (FFY) 2018, CMC Main, combined with Atrium Health ODS, performed 32,066 cases with a total of 95,278 surgical hours. The total number of outpatient surgical cases for CMC Main and Atrium Health ODS for the same year was 16,412 (Atrium Health, 2019).

Methods & Interventions

There are three phases of implementation of the blue wristband intervention: (1) before implementation, (2) implementation, and (3) after implementation. All phases will be completed at CMC ODS. Phase one, pre-implementation, will consist of a retrospective chart review on patients with STOP-Bang scores >/= 4 who received benzodiazepines and narcotics during their intra-operative stay. Phase two, implementation, will consist of identifying patients in the pre-operative area who have a STOP-Bang score >/=4 and placing a blue wristband on their wrist. Appendix C contains the protocol explaining the use of the blue wristbands throughout the perioperative period, which was written to meet compliance with the Atrium Health Nursing Department and Safety Department. Appendix D explains the process and criteria for applying and removing the blue wristband. This phase will also include educating pre-operative nurses on finding the STOP-Bang score during chart review. In addition, the STOP-Bang score will be written on the hand-off communication tool in the pre-operative area to increase awareness among all providers who are in the direct care of these patients. Lastly, the STOP-Bang score will be verbalized during the safety huddle in the pre-operative area, ensuring that all staff is aware of the blue wristband prior to the CRNA and circulator bringing the patient back to the operating room.

Phase three, post-implementation, will consist of a chart review of patients with STOP-Bang scores >/= 4 who received benzodiazepines and narcotics alone or in combination after implementing the blue wristband identification tool for suspected OSA patients. A convenience sample of 70 patients that meet the inclusion and exclusion criteria will be selected for both the pre-and post-implementation groups at CMC ODS, for a total of 70 patients. A retrospective chart review of surgeries from June 2022 through August 2022 and October 2022 through November 2022 will be conducted at the clinical site. The Epic computer system will collect

initial data via chart review in September 2022, pre-implementation of the blue wristband intervention. During November 2022, following the blue wristband implementation, chart review data will be collected once again.

For each patient, a review of the anesthetic record will note the patient's age, sex, STOP-Bang total score, anesthesia date, length of the procedure in minutes, ASA score, type of anesthetic received, and if they received any benzodiazepines or narcotics alone or in combination during the intra-operative period. A data collection sheet of the variables of interest will be developed. Microsoft Excel will be used for data management and will be utilized to organize data collection findings from the patient's charts. Appendix E provides an example of the measurement collection tool that will be utilized for each location.

To maintain the confidentiality of data, all patient data collection will be de-identified, and management will be completed via Excel sheets under password protection. In this manner, patient data such as name identifiers and Medical Record Numbers (MRNs) will not be obtained when it is downloaded. To ensure accuracy in the data retrieved from patients' Electronic Medical Records (EMR), data collection will be performed solely by the investigator of the doctoral project and the clinical expert, Sherry Bernardo, DNP, MHA, CRNA. Appendix F references a Gantt Chart that extrapolates the timeline of this project. This doctoral project started in August 2021 and is projected to finish in December 2022.

Tools & Measures

The project will use statistical analysis to organize data and transform numbers into meaningful information that can be interpreted (Moran et al., 2019). Descriptive analysis will be completed on all data for both settings. Means, standard deviations, and frequencies of the independent variable (STOP-Bang >/= 4), the individual STOP-Bang items, and the dependent

variables (benzodiazepines and narcotics) will be analyzed. ANOVA *T*-test will be used to compare the pre-and post-blue wristband intervention groups on benzodiazepines and opioid administration during surgery. It will be noted whether the communication of the STOP-Bang score was documented in the handoff tool in the patient's chart.

Project Implementation

The implementation of this QI project needed facility-wide support from stakeholders, including hospital administrators, department leaders, CRNAs, anesthesiologists, and pre-operative RNs. Anticipated resources for this project include

- the cost of wristbands,
- the use of secure email for communication, and
- the use of Excel for confidential data collection by the project committee members.

Initial discussions for implementing the blue wristband included several meetings with the Perioperative Nursing Director of CMC ODS. Once the director approved the idea, the author took part in a second meeting with the Nursing Practice Council of Atrium Health in May 2022. Throughout the planning phase and preparation for rollout, the writer was able to educate the stakeholders in several ways. Education included face-to-face meetings to inform the pre-operative RNs, staff meetings for the anesthesia staff, and continuous communication via email for all stakeholders involved.

After the QI project obtained IRB approval from both UNCC (Appendix A) and Wake Forest Health Baptist (Appendix B) on September 2022, Atrium Health ordered the blue wristbands to identify these patients. To prepare for the initial blue wristband rollout set for October 12th, 2022, the diagram depicted in Appendix D was printed, laminated, and placed in pre-operative bays, pre-operative area, the OR, and PACU at the beginning of the month. Due to

unforeseen circumstances, the blue wristband shipment arrived after the initial rollout day and was postponed until October 17th, 2022. Once the wristbands arrived, they were placed in each pre-operative bay along with other wristbands used by the hospital so that pre-operative RNs have ease of accessibility to them. Four days after the initial rollout, the author visited ODS to meet with the pre-operative RNs and evaluated the efficiency and application of the blue wristband. The author took questions regarding needed improvement and gave further education to reiterate the wristband use. Evidence-Based Practice (EBP) Champions were identified at this facility and instrumental to the success of this project, given that pre-operative RNs played a crucial role in this QI project. The writer educated the EBP Champions to assist in identifying the STOP-Bang score in the patient's chart and documenting the wristband on the EMR.

At the same time that continuous education was given to the pre-operative nurses, additional education was given to the anesthesia staff, including CRNAs and anesthesiologists. This education included a brief PowerPoint at a Teams weekly morning meeting in which the author presented the process for implementation and recommendations for the project. In the presentation, the essayist conferred a summary of the literature review explaining the possible detrimental effects of the combination of benzodiazepines and opioid administration. Recommendations to avoid giving this combination of medications were provided for patients with a STOP-Bang score >/=4 and a blue wristband. Further communication included an email sent out multiple times to make the anesthesia providers aware of the rollout date. A week after implementation, the author attended an in-person staff meeting to provide further education and to answer any questions the anesthesia staff may have had about the new process.

Challenges to this project were thought to be a facility-wide transition from Cerner to EPIC Electronic Health Records in April 2022. As a result, the anticipated challenge would be

retrospective data collection. Since IRB approval took longer than expected, this was not an issue since all data was collected solely on EPIC. Despite stakeholders' support for the implementation of this project, there was a concern for buy-in from the manager at ODS and pre-operative RNs to help identify patients with STOP-Bang score >/= 4 and designate and chart the blue wristband in the EMR. To mitigate the buy-in concerns, the author visited ODS multiple times to converse with the management team and staff members regarding any feedback and further education on the wristband implementation process. Another challenge encountered throughout this QI project was the limited number of patients who arrived with a completed evaluation from the pre-optimization clinic and therefore missed the STOP-Bang score. Given the volume of patients, ODS cares for on a daily basis, asking pre-operative nurses to complete the STOP-Bang score was not feasible, and therefore fewer patients were identified.

CHAPTER 4: RESULTS

Data Analysis & Interpretation

The analysis included 70 patients that met the inclusion criteria. From the 70 patients, the first 50 include the sample for the pre-wristband implementation group and 20 for the post-implementation phase. For the post-implementation sample, 13 patients had a blue wristband documented on their EMR, and 7 patients did not have a blue wristband documented but had a STOP-Bang score charted by the pre-operative RN (see Figure 1). Given that the project aims to identify patients with a blue wristband, the main focus on analysis will be between the pre-implementation group (n=50) and the post-wristband implementation group (n=13) unless stated otherwise. Table 1 shows the descriptive analysis and comparison between pre-wristband and post-wristband groups at ODS.

Analysis of variance showed that there was no significant difference among the pre-wristband implementation group (n=50) and the post-wristband implementation group (n=13) in age (F=0.10, *p*=.755), ASA (F= 0.08, *p*= .783), STOP-Bang score (F=0.07, *p*=.795), or anesthesia time (F=3.20, *p*=0.79). BMI was higher in the post-wristband implementation group although not significant (F=6.07, *p*=.17). There was a lower percentage of female patients in the pre-wristband implementation group (x^2= 3.87, *p*=.049).

Logistic regression tested whether the pre-wristband implementation group differed from the post-wristband implementation group on the use of benzodiazepines, narcotics, or a combination of both. All the analyses controlled for gender as there was a significantly higher percentage of females in the post-wristband group. There was no significant difference between the pre and post-wristband groups in the use of benzodiazepine, *b*= -1.40, *p*=.123; narcotics *b*= -0.26, *p*= .829; or the combination of both, *b*= -1,.00, *p*= .254.

The last column on the right depicts a small post-implementation sample in which no wristband was recorded on the patient's EMR, but the pre-operative nurses completed a STOP-Bang score. Analysis of variance and logistic regression was tested between all three groups, and it is explained as follows.

Analysis of variance showed that there was no significant difference among the three groups in age ($F = 0.54$, $p = .585$), ASA ($F = 0.11$, $p = .894$), STOP-Bang score ($F = 0.82$, $p = .442$), BMI ($F = 2.98$, $p = .058$), anesthesia time ($F = 1.78$, $p = .177$). There was a lower percentage of female patients in the no wristband recorded post-implementation but monitored group ($\chi^2 = 7.12$, $p = .028$).

Logistic regression tested whether the pre-wristband implementation group differed from the other two groups on the use of benzodiazepine, narcotics, or a combination of both. All the analyses controlled for gender as it was significantly associated with the group.

There was no significant difference between the pre-wristband and post-wristband implementation groups in the use of benzodiazepine, b = -1.12, p = .184; narcotics, b = -0.26, p = .829; or the combination of both, b = -0.86, p = .305.

There was no significant difference between the post-wristband and no wristband recorded post-implementation but monitored groups in the use of narcotics, b = 15.91, p = .994, or the combination of both, b = -1.05, p = .299. The no wristband recorded post-implementation but monitored group had lower use of benzos than the pre-wristband implementation group, b = -1.98, p = .039. For this group, even if there was not a blue wristband recorded on the EMR, there is a notable decrease in the percentage of the combination of benzodiazepines and opioids administered to this patient indicating the likelihood of effective communication of the patient STOP-Bang score.

Table 1. Descriptive analysis and comparison between no wristband, wristband, and no wristband but monitored groups in the ODS.

ODS	Pre-Wristband Implementation (n = 50)	Post- Wristband Implementation (n = 13)	No Wristband recorded post-implementation but monitored (n = 7)
Age	60.32 ± 10.53	61.38 ± 12.43	55.71 ± 20.56
Gender (% of female)	n = 12, 24.0%	n = 7, 58.3%	n = 4, 57.1%
ASA	2.66 ± 0.52	2.62 ± 0.51	2.57 ± 0.53
STOP-Bang score	4.48 ± 0.67	4.54 ± 0.88	4.14 ± 0.38
BMI	30.96 ± 6.98	35.97 ± 4.31	33.27 ± 8.47
Anesthesia time	74.48 ± 55.96	45.54 ± 31.03	76.29 ± 29.65

Benzodiazepine	*n* = 43, 86.0%	*n* = 10, 76.9%	*n* = 4, 57.1%
Narcotics	*n* = 46, 92.0%	*n* = 12, 92.3%	*n* = 7, 100%
Benzos & Narcotics	*n* = 40, 80.0%	*n* = 10, 76.9%	*n* = 5, 71.4%

CHAPTER 5: DISCUSSION

Discussion & Significance

This QI project is the first to examine monitoring STOP-Bang scores, applying a blue wristband for scores >/=4 in the pre-operative area and provider behavior regarding the administration of benzodiazepines and opioids in patients with undiagnosed sleep apnea in an ambulatory surgery center in the perioperative period. The project aimed to identify patients with undiagnosed sleep apnea and look at the effects of current practice in administering benzodiazepines and opioids by identifying these patients with a blue wristband in the pre-operative area. OSA is associated with health consequences, including hypertension, congestive heart failure, stroke, and all-cause mortality (Vasu, Grewal & Doghramji, 2012). Currently, at Atrium Health and specifically ODS, there are no policies for managing patients with undiagnosed and diagnosed sleep apnea. With this project, the author provided recommendations for anesthesia providers regarding managing this patient population. Furthermore, the author identified a need for ODS since patients at high risk of OSA were not correctly identified and were at the same risk of postoperative adverse events compared to general noncardiac surgical patients from the administration of benzodiazepines and opioids.

The ASA guidelines regarding perioperative management for OSA recommend a careful preoperatively assessment to identify these patients (Gali et al., 2009). STOP-Bang is the most commonly used questionnaire in the perioperative setting and is highly sensitive for categorizing the severity of sleep apnea (American Society of Anesthesiologists Task Force on Perioperative Management of Patients with Obstructive Sleep Apnea, 2014). Using a blue wristband applied in

the pre-operative area identified patients with a STOP-Bang score >/=4 with a higher risk of postoperative complications, including hypoxemia and postoperative pulmonary and cardiac complications.

For the pre-implementation period, from July 2022 through September 2022, 80% of patients with a STOP-Bang score >/=4 received a combination of benzodiazepines and narcotics, while 86% received benzodiazepines. After implementing the blue wristband at ODS, this number decreased, with 76% of patients receiving a combination of benzodiazepines and narcotics and only 76% receiving benzodiazepines. Even though there was no statistically significant difference between the pre-and post-implementation groups regarding the use of benzodiazepines (p=.123) or the combination of both (p=.254), a lower percentage of medication administration was recorded alluding to provider awareness in medication administration. Moreover, STOP-Bang monitoring and blue-wristband application could add clinical value to the pre-operative assessment if it is effectively communicated. This is demonstrated in the “no wristband recorded post-implementation but monitored” group where there is a notable decrease in the amount of benzodiazepines given to these patients.

The author of this project attributed the different sample sizes to different factors. As previously mentioned, most patients with a recorded STOP-Bang score had an evaluation from the pre-optimization clinic. Pre-optimization before a major surgery has become increasingly popular over the last few years and aims to improve postoperative outcomes in OSA patients (Hughes et al., 2019). Given that ODS is an Ambulatory Surgical Center (ASC) and patients have fewer risk factors and not partaking in major surgery, only a select number of patients get flagged to attend the pre-optimization clinic at Atrium Health and therefore do not have a STOP-Bang score. Since the pre-operative RNs were not required to complete the STOP-Bang score

independently, this decreases the chances of patients getting flagged with undiagnosed OSA at ODS. This is further exemplified by noting the pre-and post-implementation sample data sets. The pre-implementation retrospective data utilized a review period of three months to obtain fifty patients with a STOP-Bang score recorded. In comparison, thirty-seven patients met the inclusion criteria, as exemplified in Figure 1, for the one-month post-implementation period, with thirteen having a blue wristband documented on the chart.

It is also important to note that out of those thirty-seven patients who met the inclusion criteria, seven had the STOP-Bang score completed by the pre-operative nurses instead of the pre-optimization clinic with no blue wristband recorded on the EMR. Given that the aim of this QI project did not include a STOP-Bang assessment completion by the pre-operative nurses, this was an unforeseen sample. For this sample, however, a blue wristband was not recorded on the EMR. This group, with a STOP-Bang score but no blue wristband recorded, received a lower amount of benzodiazepines (57%) compared to 71% received a combination of narcotics and benzodiazepines. Given that in order to place a blue wristband the patients needed a completed STOP-Bang score from the pre-optimization clinic, this results means that the pre-operative RNs were noting and communicating the STOP-Bang score but either not applying the blue wristband or not documenting it on the EMR.

Another reason the post-implementation group had a smaller sample size could be attributed to the lack of buy-in at ODS. Different factors can contribute to employee buy-in. These factors include employee engagement, trust, personal connection, and adequate time to engage in an initiative (French-Bravo & Crow, 2015). Employee trust was difficult since the author needed more time to engage with the ODS staff and establish a personal connection. Even though this author engaged with the pre-operative staff multiple times, face-to-face time was a

primary factor in the need for more buy-in. A systematic review regarding barriers to implementing shared decision-making in clinical practice by Légaré et al., 2008, found that time constraints remain the most often cited barrier across different organizational contexts.

Limitations

There were various limitations identified during this QI project. A significant limitation of the project consisted of time constraints to implement this project. Due to an extensive IRB approval process, the implementation of the blue wristbands in the perioperative period was delayed. Considerations for this project would be a better assessment of the project timeline.

The administration of benzodiazepines and opioids in the perioperative setting is up to the discretion of the anesthesia provider. Because of this, the author cannot restrict medication usage even when patients are identified with a blue wristband. CRNAs and anesthesia providers undergo rigorous training and are under the scope of practice to administer these medications without a doctor's orders. Further projects should focus on applying a blue wristband and aim to study the difference in any potential adverse complications or PACU LOS in patients receiving a combination of benzodiazepines and opioids.

Recommendations

This QI project demonstrated insight into anesthesia provider behavior in choosing medication administration in patients identified with a blue wristband. A recommendation would be to implement a hospital-wide policy regarding perioperative management recommendations for current and suspected OSA patients. Atrium Health does not have a current policy, including guidelines for practice in the ambulatory setting. A review by Nagappa et al., 2018 on best perioperative practice in managing ambulatory patients with obstructive sleep apnea found that scientific literature regarding the safety of ambulatory surgery in OSA patients is meager. The

ASA and SASM strongly recommend pre-operative screening for all patients at risk of undiagnosed OSA. Also, the SASM has recently introduced its guidelines on the intraoperative management of adults with OSA, which could benefit the application at ODS (Nagappa et al., 2018).

Various things can be done to apply this guideline smoothly at Atrium Health and get adequate buy-in. A recommendation would be to have continuous education outlining evidence-based practice guidelines. Yearly educational modules are mandatory for all staff involved in face-to-face patient care, and adding a module for managing the OSA patient would be valuable.

The inability to have a STOP-Bang score recorded on all patients at ODS did not permit more extensive inclusion criteria in the post-implementation group. If Atrium Health integrated the STOP-Bang score as the standard of care in the surgical patient, a larger sample could be utilized for the project. Furthermore, from those patients with a STOP-Bang score recorded, perioperative staff had low compliance that recorded the blue wristband on the EMR. Based on feedback from the staff, pre-operative RNs have consistently mentioned the STOP-Bang score in the safety huddle before proceeding to surgery. The QI author understands the need for further education and engagement to close the gap in the lack of the blue wristband chart in the EMR.

With ongoing technological advancements, EMRs have helped concise all patient information in one location. EMRs permit healthcare systems to add different patient warnings. These alerts serve as a second safety check, including medication administration with perilous adverse effects or alerting the healthcare provider of certain patient infections. In this manner, a recommendation would be to incorporate a warning for the anesthesia provider on EPIC when administering a combination of benzodiazepines and opioids to patients with a STOP-Bang score >/=4.

This QI project noted a decrease in the administration of benzodiazepines by 10% in patients identified with a blue wristband, although not statistically significant. Literature notes the array of postoperative complications when given a combination of benzodiazepines and opioids. The strength of this project was that this is the first project in the literature that incorporates a blue wristband to alert and understand behavior providers in the care of suspected OSA patients. Due to time constraints, this project had a small post-implementation group. It would be valuable to repeat it with a larger sample to get more meaningful data and understand if provider behavior changes when treating these patients.

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APPENDIX A: UNIVERSITY OF NORTH CAROLINA CHARLOTTE IRB APPROVAL

CHARLOTTE
RESEARCH AND ECONOMIC DEVELOPMENT

To:	Amber Ushakumari
	University of North Carolina at Charlotte
From:	Office of Research Protections and Integrity
Date:	26-Sep-2022
Expiration Date:	03-Aug-2023
RE:	Agreement to Rely on External IRB
Study #:	IRB-23-0096
External Organization:	Wake Forest School of Medicine
Study Title:	Perioperative Care of Obstructive Sleep Apnea

This confirms that an IRB Authorization Agreement with the organization identified above has been executed to rely on their IRB for continuing oversight of this study. This agreement specifies the roles and responsibilities of the respective entities.

Study Description:

Obstructive Sleep Apnea (OSA) is the most common sleep-related breathing disorder in the United States. OSA affects 25 million adults nationally with as many as 80% of patients potentially undiagnosed (Hines & Marschall, 2018). We aim to identify OSA patients with a blue wristband to increase the anesthesia providers' awareness of OSA-related concerns for potential airway manipulation, prolonged sedation from anesthetic agents, and increased sensitivity to opioids in the post-operative period. This is a Quality Improvement (QI) project using a descriptive design aimed at identifying patients with suspected OSA using a blue wristband on the Day of Surgery (DOS) and examining the clinical practice of providers' administration of benzodiazepines and opioids to this patient population. The PICOT question is: In patients who are greater than or equal to 18 years old scheduled for elective non-cardiac surgery at a level one trauma medical center (P) how does the implementation of a blue wristband to identify patients with diagnosed or suspected OSA (STOP-Bang score >/=4) (I) compared to current practice (C) affect the perioperative management of OSA patients as defined as receiving benzodiazepines alone or in combination with opioids (O) within the perioperative stay (pre-op, intra-op, PACU) (T)? The setting of the project will take place through Atrium Health. The sample for this project will consist of a total of 200 patients that have either undergone elective non-cardiac surgery at CMC Main or Atrium Health ODS during the month of July 2022, or who will undergo elective non-cardiac surgery during September 2022. Data will be collected via chart review.

It is your responsibility to:

1. Inform the UNC Charlotte IRB about any actions by the external IRB affecting their approval to conduct the study, including suspension or termination of approval.
2. Submit a modification to the UNC Charlotte IRB (via Niner Research) if/when new personnel are added to the study team or the study is modified in such a way that additional institutional approvals are required (e.g., radiation safety, biosafety).
3. Submit a copy of the external IRB approval letter and current approved consent document to the UNC Charlotte IRB (via Niner Research) when the study is renewed; you will continue to receive reminder notices from the UNC Charlotte IRB for renewal, and should provide the external approval and consent documents within 30 days of receipt.
4. Report all Unanticipated Problems protocol violations and unresolved subject complaints to the UNC Charlotte IRB *in addition to the external IRB*. You may submit a copy of the report you submitted to the external IRB; this should be done via the Adverse Event form in Niner Research.
5. Maintain compliance with all other UNC Charlotte policies (e.g., data security, conflict of interest).

APPENDIX B: WAKE FOREST HEALTH BAPTIST IRB APPROVAL

Office of Research
INSTITUTIONAL REVIEW BOARD

MEMORANDUM

To: Lorraine Schoen
Atrium/Carolinas Healthcare System

From: Brian Moore, Chair, Institutional Review Board

Date Approved: 8/4/2022

Subject: Expedited Review: IRB00086371
Perioperative Care of Obstructive Sleep Apnea

Amber N. Ushakumari and Victoria Valencia
University of North Carolina Charlotte/Atrium Health Nurse Anesthesia Program

Study Documents:
Protocol Version: Project Protocol: Perioperative Care of Obstructive Sleep Apnea

This research study qualifies for expedited review under the Federal Regulations [45CFR46.110]. These regulations allow an IRB to approve certain kinds of research involving no more than minimal risk to human subjects. The risks of harm anticipated in the proposed research are not greater than those ordinarily encountered by the general population in daily life or during the performance of routine physical, laboratory, or psychological exams or tests. [45CFR46.102(i)].

Upon review of the research, the IRB finds that this study is classified as Expedited Category 5.

This research meets the criteria for a waiver of consent entirely according to 45 CFR 46(d).

This research meets the criteria for a waiver of HIPAA authorization according to 45 CFR 164.512.

IRB approval is for a period of 12 months from 8/4/2022**.** Please notify the Office of Research when the project is complete.

The Wake Forest School of Medicine IRB is duly constituted, has written procedures for initial and continuing review of clinical trials; prepares written minutes of convened meetings, and retains records pertaining to the review and approval process; all in compliance with requirements of FDA regulations 21 CFR Parts 50 and 56, HHS regulations 45 CFR 46, and International Conference on Harmonisation (ICH) E6, Good Clinical Practice (GCP), as applicable. WFSM IRB is registered with OHRP/FDA; our

IRB registration numbers are IRB00000212, IRB00002432, IRB00002433, IRB00002434, IRB00008492, IRB00008493, IRB00008494, and IRB00008495.
WFSM IRB has been continually fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) since 2011.

APPENDIX C: OSA IN THE PERIOPERATIVE PERIOD ASSESSMENT AND APPLICATION OF BLUE WRISTBAND PROTOCOL

Atrium Health Carolinas Medical Center (CMC)
Sites: CMC Main and One Day Surgery (ODS)
Pilot Project Policy - Perioperative Care of Obstructive Sleep Apnea
UNC Charlotte; Atrium Health Nurse Anesthesia Program
Sep 4, 2022

TITLE: **Obstructive Sleep Apnea (OSA) in the Perioperative Period Assessment of Risk Protocol and Application of Blue Wristband**

PURPOSE: To improve patient safety and minimize respiratory complications in adult patients with possible obstructive sleep apnea during the perioperative period by identification with a blue wristband

APPLIES TO: Female and male adults who are greater than or equal to 18 years old scheduled for elective non cardiac surgery and have a STOP-Bang score >/=4.

DOES NOT APPLY TO: Patients younger than 18 years old, emergency surgery, ICU admission, or specialized surgeries including trauma, cardiovascular, neurological, and obstetric surgeries.

AUTHOR(S): Victoria Valencia SRNA and Amber Ushakumari SRNA

OBSTRUCTIVE SLEEP APNEA:

- OSA is characterized by periodic partial or complete obstruction of the upper airway
- Patients with OSA are more likely to experience postoperative pulmonary complications such as aspiration pneumonia, ARDS, and pulmonary embolism

POLICY STATEMENTS:

1) Patients who may have OSA will be identified by the anesthesia team in the pre-optimization clinic as early as possible in the admission process prior to planned surgery.
2) Patients will undergo a preoperative anesthesia evaluation and be screened for OSA using the STOP-Bang questionnaire by the Department of Anesthesia. *Patients with a STOP-Bang score greater than five will be flagged for a formal sleep evaluation prior to surgery.*
3) All efforts will be made by the interdisciplinary health care team (MDAs, CRNAs and RNs) to minimize co-administration of opioid analgesia and benzodiazepines in patients identified with possible or diagnosed OSA.

4) All members of the interdisciplinary health care team are responsible for ensuring best practices for patients with suspected or diagnosed OSA to reduce any complications due to the pathophysiology of sleep apnea.
5) For patients identified with possible OSA, a blue wristband will be applied to the patient's wrist in the pre-operative area. The wristband will remain on the patient until discharge from PACU in which the wristband will be removed.

PROCEDURE:

Preoperative Period:

1) All patients will be screened using the STOP-Bang questionnaire.
2) Pre-op nurses will apply a blue wristband to all patients with a STOP-Bang score >/= 4 as documented in EPIC.
    a) The blue wristband identifies those patients at risk for OSA to alert all members of the healthcare team and allow for proper management of the patient with respiratory distress/difficulty
3) Pre-op benzodiazepines will be avoided if possible.

Intraoperative Period:

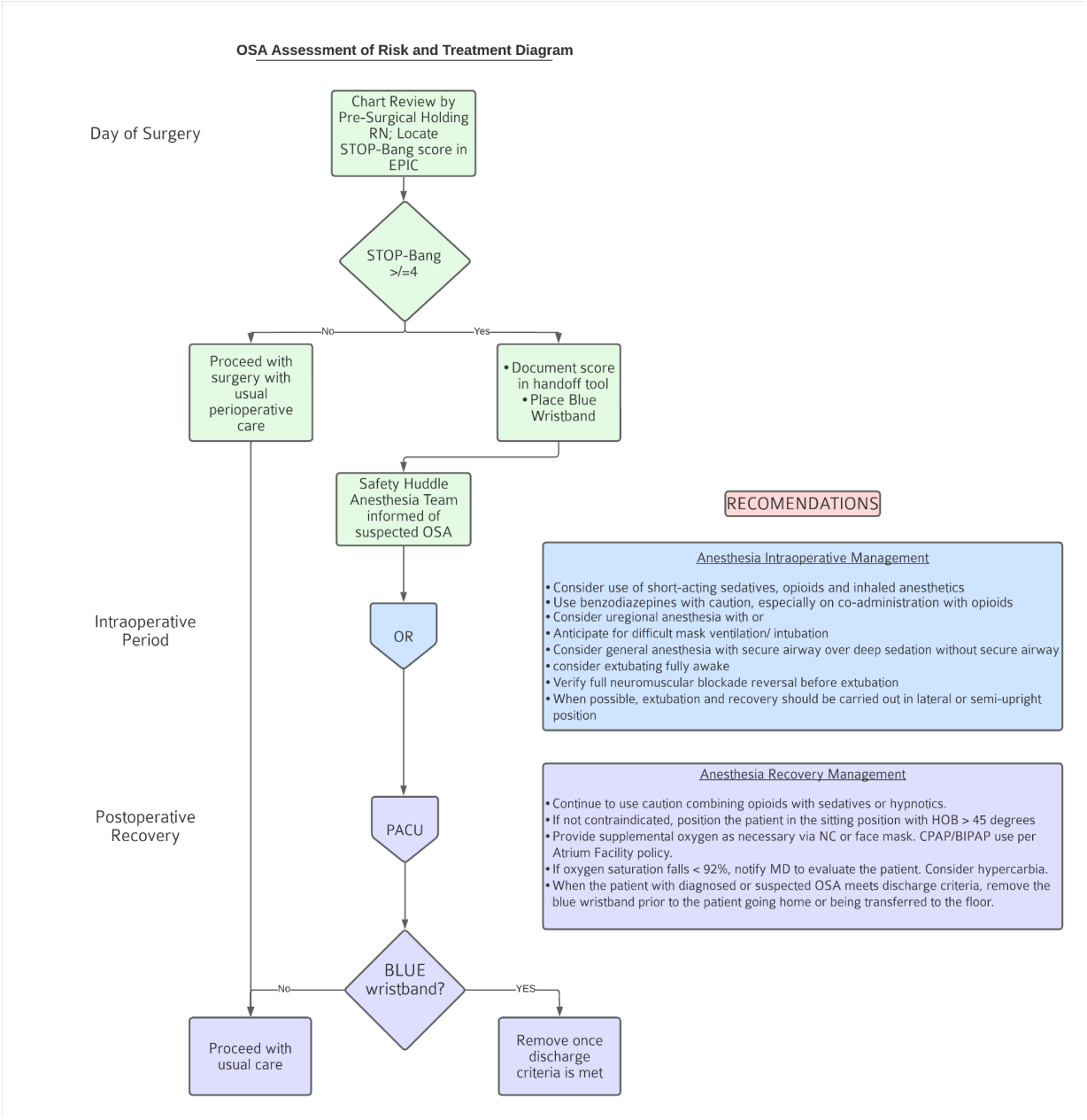
1) The anesthesia team will consider recommendations per the American Society of Anesthesiologists Guidelines on the Perioperative Care of Obstructive Sleep Apnea:
    a) Consider use of short-acting sedatives, opioids and inhaled anesthetics
    b) Use benzodiazepines with caution, especially on co-administration with opioids
    c) Consider use of regional anesthesia with or without moderate sedation for superficial procedures
    d) Anticipate for difficult mask ventilation and difficult intubation
    e) Consider general anesthesia with secure airway over deep sedation without secure airway
    f) Unless a contraindication, consider extubating fully awake
    g) Verify full neuromuscular blockade reversal before extubation
    h) When possible, extubation and recovery should be carried out in lateral or semi-upright position
2) The anesthesia team will consider using and prescribing (in the post-operative period) non-opioid analgesics such as non-steroidal anti-inflammatory drugs (NSAIDs) with OSA patients whenever possible.

Postoperative Period:

1) Continue to use caution combining opioids with sedatives or hypnotics.
2) If not contraindicated, position the patient in the sitting position with head of bed greater than 45 degrees (obstruction to breathing is worse when patients lie flat on their back).

3) Use standard airway maneuvers such as mandibular advancement and/or oral airways to maintain a patent airway.
4) Provide supplemental oxygen as necessary via nasal cannula or face mask. CPAP/BIPAP use per Atrium Facility policy.
5) If oxygen saturation falls below 92%, notify MD to evaluate the patient. Consider hypercarbia.
6) When the patient with diagnosed or suspected OSA meets discharge criteria, remove the blue wristband prior to the patient going home or being transferred to the floor.

APPENDIX D: OSA ASSESSMENT OF RISK AND TREATMENT DIAGRAM



APPENDIX E: EXCEL WORKSHEET TEMPLATE

The excel worksheet depicted below will be utilized to record the information from each column through the patient's electronic health record. For each patient, the following will be recorded: Anesthesia date, STOP-Bang Score, Age, Gender, Anesthesia length in minutes, benzodiazepine received Y/N, narcotic received Y/N, Benzodiazepines and narcotic combination received, ASA Score, Anesthesia type, and BMI.

CMC ODS

	A	B	C	D	E	F	G	H	I	J	K	L
1	#	Anesthesia date	STOP-Bang score	AGE	Gender	Anesthesia time (min)	Benzos Y/N	Narcotic Yes/No	Benzos/narc combo	ASA score	Anesthesia type	BMI
2												
3												
4												
5												
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APPENDIX F: GANTT CHART

The following Gantt Chart exemplifies the timeline for this doctoral project. Project conception and initiation included the Needs Assessment, Topic Approval, and CITI Training. Navigating through the project definition and planning phase including the Review of Literature and Mapping of the project was finished with Oral Defense scheduled for April 12, 2022. Project definition and planning ended with IRB applications to UNCC and Atrium Health Wake Forest Baptist completed on September 2022. Data collection and analysis are planned for October 2022, followed by Project Defense and submission of the Final Scholarly Paper on December 2022.

GANTT CHART

Smartsheet Tip

PROJECT NAME	PERIOPERATIVE CARE OF THE GSA PATIENT AT AN AMBULATORY SURGERY CENTER	INSTITUTION NAME	UNCC/ATRIUM HEALTH NAP
PRINCIPAL INVESTIGATOR	Stephanie Woods	DATE	November 22, 2022

WBS NUMBER	TASK TITLE	TASK OWNER	START DATE	DUE DATE	DURATION	PCT OF TASK COMPLETE
1	**Project Conception and Initiation**					
1.1	Needs Assessment	Victoria Valencia	8/1/21	10/22/21	81	100%
1.2	Topic Approval	Victoria Valencia	10/22/21	12/1/21	39	100%
1.3	CITI Training	Victoria Valencia	12/1/21	1/15/22	44	100%
2	**Project Definition and Planning**					
2.1	Review of Literature	Victoria Valencia	12/1/21	2/6/22	65	100%
2.2	Mapping Out the Project	Victoria Valencia	2/6/22	3/3/22	27	100%
2.3	Submit Draft of Section I and II of Project	Victoria Valencia	3/3/22	4/1/22	28	100%
2.4	Submit Oral Defense Powerpoints to Chair for Review	Victoria Valencia	4/1/22	4/7/22	6	100%
2.5	Proposal Defense	Victoria Valencia	4/7/22	4/12/22	5	100%
2.6	Final Paper Chapter 1-3 along with any Revisions	Victoria Valencia	10/22/21	4/21/22	179	100%
2.7	IRB Submission for Wake Health	Victoria Valencia	6/15/22	8/4/22	49	100%
2.8	IRB Submission for UNCC	Victoria Valencia	6/15/22	8/4/22	49	100%
2.7	IRB Submission Approval	Victoria Valencia	8/4/22	9/26/22	52	100%
3	**Project Conception and Initiation**					
3.1	Blue Wristband Approval	Victoria Valencia	9/15/21	9/15/22	360	100%
3.2	Blue Wristband Roll Out	Victoria Valencia	9/25/22	10/17/22	22	100%
3.2.1	Perioperative education to staff	Victoria Valencia	9/25/22	11/10/22	45	100%
3.3	Pre-Implementation Retrospective Chart Review	Victoria Valencia	9/9/22	9/23/22	14	100%
3.4	Post-Implementation Chart Review	Victoria Valencia	10/17/22	11/17/22	30	100%
4	**Project Performance / Monitoring**					
4.1	Submit Final Scholarly Paper Draft	Victoria Valencia	10/22/21	11/25/22	393	100%
4.2	Project Defense	Victoria Valencia	12/9/22	12/9/22	1	100%