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Predicting the Risk of Obstructive Sleep Apnea and Difficult Endotracheal Intubation in a Surgical Population in a Rural Community Hospital Setting

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REVIEW, APPROVAL AND ACCEPTANCE

The document mentioned above has been reviewed and accepted by the student's advisor, on behalf of the advisory committee, and by the Assistant Dean for MSN and DNP Studies, on behalf of the program; we verify that this is the final, approved version of the student's DNP Project including all changes required by the advisory committee. The undersigned agree to abide by the statements above.

Craig S. Atkins, Student

Dr. Carolyn Williams, Advisor

Final DNP Project Report

Predicting the Risk of Obstructive Sleep Apnea and Difficult Endotracheal Intubation in a
Surgical Population in a Rural Community Hospital Setting

Craig S. Atkins APRN, CRNA, MS

University of Kentucky

College of Nursing

Summer 2013

Carolyn Williams PhD, RN - Committee Chair

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Dedication

This project is dedicated to my spouse of twenty five years, Juliana M. Atkins. Without her support, encouragement and writing help, none of this would be accomplished. This is dedicated to my children, Christopher, Benjamin, Hannah and Daniel Atkins. This is also dedicated as a memorial to my deceased parents, Clyde and Zoe Atkins, who always believed in me and encouraged me. And, lastly to all my colleagues and mentors through the years of practice who helped make this possible.

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Table of Contents

Acknowledgements..... iii

Introduction/DNP Capstone Overview 1

Manuscript 1 The Nurse Anesthetist Role in Facilitating Patient Flow through the Operative
Process Using the Lean Model 3

Manuscript 2 Inter-rater Reliability of Modified Mallampati: Registered Nurse versus Certified
Registered Nurse Anesthetist..... 35

Manuscript 3 Predicting the incidence of Difficult Intubation from Obstructive Sleep Apnea
Screening in a Rural Kentucky Population..... 53

Capstone Report Conclusions 91

Capstone Report References 26

Introduction/ DNP Capstone Overview

Obstructive Sleep Apnea (OSA) is a growing worldwide problem, especially in the United States given the rise in obesity. These patients present at the hospital for surgical procedures at a higher rate than is their prevalence in the general population. It has been reported in the medical literature that OSA is associated with difficult mask ventilation, difficult endotracheal intubation and a higher than normal incidence of post-operative respiratory complications. It is imperative that the anesthesia provider be prepared to safely accomplish their anesthetic and recovery.

Preparing for the OSA patient should begin prior to the day of surgery. Patients with OSA have numerous comorbidities. Their associated medical problems need to be managed in an optimum fashion to limit the risk of perioperative complications. The pre-anesthesia/operative clinic is an ideal place for early assessment and management of the OSA patient. During the clinic visit the OSA patient can be medically optimized, laboratory work ordered, consults scheduled (as needed) and an overall physical assessment performed. This should include evaluating the patient's airway to identify those patients who may present as a potentially difficult endotracheal intubation. Preparing the patient pre-operatively can improve the pre-, peri, and post-operative management of OSA patients.

The first manuscript addresses the topic of managing the patient to optimize their experience in the operative theatre, to include pre, peri and post-anesthesia. The second manuscript evaluates the role registered nurses play in the preoperative clinic in performing airway evaluations using the Modified Mallampati exam. The third manuscript attempts to

identify the incidence of OSA in the rural Kentucky population and how pre-operative OSA screening can help in identifying those patients which may be difficult to intubate.

Manuscript 1 The Nurse Anesthetist Role in Facilitating Patient Flow through the Operative Process Using the Lean Mode

This paper addresses the role of the nurse anesthetist in expediting patient movement through the surgical process. The Lean model presents a framework to streamline the operative process using manufacturing techniques to minimize delays and cancellations. There are three components to the surgical process, the pre- peri and postoperative phases. The pre-operative phase is where the patient is assessed to evaluate their readiness for surgery. The peri-operative phase is where the anesthetic is administered and the post-operative phase occurs once the patient begins to recover from the anesthetic.

In the pre-operative phase their medical conditions can be optimized, laboratory work obtained and consults ordered. This should include airway assessment to evaluate the patient for the potential of a difficult intubation. After the pre-operative clinic visit an anesthesia plan can be developed to improve the patient's experience and minimize their risk of anesthetic complications during the peri and post-operative phase. This paper identified that the pre-operative phase is where most optimization of patient care can take place. Identifying and managing OSA patients begins with a pre-operative anesthesia clinic visit.

The Nurse Anesthetist Role in Facilitating Patient Flow through the Operative Process Using the

Lean Model

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Abstract

Purpose: The purpose of this paper is to provide a theoretical framework with practical application for facilitating patient flow through the operative process using the Lean philosophy to minimized delays and cancellations.

Theoretical orientation: Efficient, quality patient care has always been the hallmark of Nurse Anesthetist practice. Lean healthcare introduces continuous quality improvement (CQI) processes used in Lean manufacturing to the healthcare system. The principal aspect of Lean healthcare is the concept of a value stream where work is standardized, work flow is streamlined and waste is eliminated, thus creating value.

Nature of Review: In the surgical suite waits, delays and cancellation are endemic. Lean healthcare views these as waste in the system. They must be eliminated to provide value to the patient, who is the ultimate customer. Managing the flow of the patient successfully through this process will increase the quality of patient care (“value”), increase patient and provider satisfaction, increase operating room efficiency and reduce cost. Nurse Anesthetists are uniquely positioned in the operative arena to accomplish this. The greatest opportunity to reduce delays and cancellations is seen with smoothing the inter-daily workload. Successful interventions to accomplish this include: 1) maximizing the preoperative anesthesia assessment, 2) standardizing and streamlining work during the perioperative phase to minimize turn over time, and 3) adequate staffing levels to optimize postoperatively care.

Keywords: nurse anesthesia, preoperative, perioperative, lean, patient flow

Introduction

Waits, delays and cancellations are a source of chronic frustration for patients, surgeons and anesthesia providers within the preoperative, perioperative and postoperative processes. These problems are endemic to the operating room and are in direct opposition to the Institute of Medicine's (IOM) "core need of health care": safe, effective, patient-centered, timely, efficient and equitable.¹ According to Lean technology and processes, waiting, delays and cancellations are examples of waste, which decrease "value" to the patient and need to be eliminated.²

Therefore, these problems should lend themselves to the solutions that Lean continuous quality improvement (CQI) has to offer by standardizing and streamlining work and eliminating waste.

Since 1990 all Certified Registered Nurse Anesthetists (CRNA) are educated at the Master's Degree or higher. Currently 16 CRNA educational programs offer Doctoral level degrees.³ By 2025 all CRNA's will enter the workforce with Doctoral degrees.⁴ Often the CRNA(s) is (are) the highest trained nurse(s) at their facility. This educational expertise can translate into expert power with leadership potential within organizations.⁵ This role is consistent with the second "Essential of Doctoral Education for Advance Practice Nurses."⁶ Therefore as "nursing leaders and experts", Nurse Anesthetists are uniquely placed in the operative process to use their DNP education to facilitate this change and to accomplish IOM's "aims" in the operating room.

There are ways the preoperative, perioperative and postoperative processes can be streamlined to minimize delays and reduce cancellations. It begins in the preoperative period. The purpose of this paper is to provide a theoretical framework with practical application for facilitating patient flow through the operative process using the Lean CQI philosophy to reduce perioperative delays and cancellations.

A literature search was performed, limited to the last ten years (2002-2012), using the Cochrane database, Trip database, PubMed, Medline, and Cinahl. Keywords, terms and phrases included *lean process and sigma six, modified by healthcare, surgery, anesthesia, operating room, patient flow, surgical delays and cancellation: and preoperative and pre-anesthesia*, modified with *evaluation, assessment and clinic*. All “English” articles retrieved, on the subject matter were read. Retrieved articles were reviewed and those with relevant subject matter had their reference list reviewed for additional reference sources. Twenty four articles were retrieved that were related to use of the Lean/TPS model in the operative period. Initial overall results yielded 506 articles and only 124 involved anesthesia. Final results yielded 45 articles related to patient flow process improvements that were congruent with the lean concepts of standardization, eliminating waste and streamlining work flow. Dexter and Watchel have written over 50 articles in the area of operating room (OR) efficiency and the anesthesia providers role in OR management. While Dexter and Watchel’s articles are not written from a “Lean” perspective, they are congruent with the concepts. They appear to be the primary researchers in the field.⁷⁻¹⁸ Only two systematic reviews were retrieved and no randomized controlled trials.^{19,20} Eight prospective and retrospective case-control and observational studies were identified.^{7,9,12-15,21-24} Most of the information in the literature was at the level of personal opinion/preference or directed at overall hospital patient flow.

Review of the Literature

Lean Concepts

The Lean manufacturing or production model is based on the philosophy of the Toyota Production System (TPS). While the Lean philosophy was first used in the automotive industry, it has been applied to other industries with great success. It was first identified as Lean in 1988

by Michael Krafcik.²⁵ Over the last decade it has been increasingly adopted in the healthcare community.²⁶⁻²⁸ The key concepts in Lean/TPS need to be identified in order to understand how it applies to patient flow through the operative arena.

Lean manufacturing attempts to create a product with the most value for the customer. This is accomplished by creating the best product available at the right price. Lean CQI works to eliminate waste in the manufacturing process so all manufacturing steps create “value” for the customer. “Value” is defined as anything for which the customer would pay, i.e. higher quality product.²⁹ By removing waste, costs are reduced and value created for the consumer and profit for the corporation. This creates the ideal paradigm for industry, a high quality product with maximum “value” at a profit to the company and a product the consumer wants. This “value” product is the goal of healthcare, where “value” is “quality patient care”.¹

Lean uses the “Servant Leadership” model for its managers.²⁹ In this model the manager is responsible to ensure that each employee is achieving their maximum potential.³⁰ Employee suggestions for improving flow and minimizing waste are encouraged and sought. This process engages the employees and facilitates their “buy in”, which is needed for success. This is a bottom up versus a top down approach to management.

The Toyota Production System is often depicted as a house with a foundation of standardization, and a roof (kaizan) supported by two pillars, Jit and Jidoka. (Figure 1) Kaizen is interpreted to mean good (Zen) change (Kai) or continuous quality improvement. Jit means “Just in time.” Jidoka is “the ability to stop a process at the point of time and location when a problem occurs.”² According to the Lean philosophy, continuous quality improvement is built upon a foundation of

standardized work and supported by two pillars of 1) on time delivery of the product to the customer and 2) the ability to stop the process and fix it should an error occur.

Within the Lean concepts, waste (muda) is defined as anything that does not add value to the process.(Figure 2) Lean identifies seven wastes. They are overproduction, waiting, conveyance, over-processing, inventory, motion and correction, i.e. repairing defects.²⁹ These seven items need to be eliminated to create the ultimate value for the customer. Additional Lean concepts are overburden (muri) and unevenness (mura). These are inefficiencies that require adjusting to maximize the flow to meet the desired needs as opposed to a “prearranged production schedule.”²⁷

The value stream, an aspect of the Jidoka phase, is where waste (muda), overburden (muri) and unevenness (mura) are minimized. It is developed by mapping the flow across all aspects of the company’s relevant departments. By removing muda, muri and mura at each step in the stream, value is added to the product. Any process that does not add value to the end product is eliminated. The flow is smoothed and anticipating areas of waste and bottlenecks are eliminated to maximized production. The value stream is mapped across the the individual departments, which are called silos in Lean. The value stream flow occurs through these silos. During this stream, if a problem develops the production is stopped at any point and the problem fixed before the finished product gets to the customer. Most problems with flow occur upon entry or exit from the silos. The goal is a quality product with value. According to Lean, nothing could be worse than sending a defective product to the customer.²⁹

The Lean CQI process requires 1) standardizing the work so that it is easily repeatable by all workers, 2) a continuous work flow based on the client needs, and 3) the ability to stop the

process when an error occurs and correct it as needed.² Ultimately, this requires a method to evaluate changes and see if they are effective, hence the Plan-Do-Check-Act (PDCA) method used by Lean.^{28,29} The standard is put in place, it is implemented, evaluated and changed as needed to improve quality.(Figure 3) The CQI process in conjunction with the servant leadership management model encourage all employees and stakeholders to suggest, implement and evaluate ideas to improve quality, not just the managers.²⁹ This process is very similar to the Plan-Do-Study-Act (PDSA) method of quality improvement.³¹ Overall, Lean is a quality improvement process involving the whole team.

Lean in HealthCare

There are many areas for application of this thought process in the healthcare industry and the OR. In Lean healthcare the ultimate customer is the patient.²⁸ Providing the best patient experience is a continuous quality improvement process involving the whole team. As an example, Davis used the Lean concepts to reduce patient travel time to the operating room by approximately 25 percent.³² Also, Lean concepts were used at the University of Iowa to streamline the surgical process of esophagectomy. This resulted in a reduced overall cost, a decreased length of stay and a lessened anastomosis leak rate.³³ These two examples demonstrate the potential effectiveness of the Lean processes in the operating theatre.

Recently, Virginia Mason Medical Center adopted the lean philosophy.²⁸ This was a “culture change” for them but, it has been “very positive”. They call their process the “Virginia Mason Production System”. Their culture changed from expert driven to process driven, from internal focus to customer focused and instead of functioning silos, they developed multidisciplinary teams. This was radical thinking for their culture. Ideally, using Lean processes is an

institutional, cultural changing event, just as Virginia Mason and others have accomplished.^{27,34-}

³⁶ Lean technology and processes can help focus on streamlining the process. ³⁷

Understanding Patient Flow

Unfortunately in the operative arena, waits, delays and cancellations are a plague to the flow process. These situations are a source of patient to provider and provider to provider angst.

Theoretically, if patient flow can be facilitated to minimize delays and cancellations, better patient care can be delivered.¹⁴ An overall understanding of patient flow can help achieve this.

According to Harden and Resar (2004), flow through the hospital is best viewed as “an interdependent system rather than individual departments.”³⁸ According to the Institute of Healthcare Improvement, the three critical care areas, emergency room(ER), intensive care unit(ICU) and operating room(OR), are fraught with the largest number of flow problems.³⁹ The tremendous variation in flow is often assumed to be the result of unpredictable emergency situations or conditions that arise. However this is not necessarily the case. This uncontrollable variability is the result of a patient’s disease process or when they present to the hospital. It is referred to as *natural or random variation*. This variability cannot be eliminated but needs to be “managed”. However the real culprit, which is amenable to reduction, appears to be the other variation, *artificial or non-random variation*. This is the variation introduced into the system by a provider’s preferences or beliefs.^{38,39 40} An example of non-random variation would be excessive surgical cases on one day of the week. McManus et al. (2003) identified that the variation in elective surgery case load is the best prognosticator of intensive care unit diversions. Even though the emergency room had more admission requests to the ICU, the variation in the

elective surgery schedule had the most impact on the ICU.⁴⁰ Therefore, effective management of the OR schedule can minimize delays and cancellations.

According to the Institute of Healthcare Improvements white paper, Optimizing Patient Flow,³⁹ there are three steps a hospital can take to improve patient flow, “evaluate flow, measure and understand flow and test changes to improve flow.” To evaluate flow two questions should be asked: 1) “Do you park more than 2 percent of your admissions?” And 2) “Do you have a midnight census of 90 percent of your bed capacity?” If you answered yes to these two questions you probably have a flow problem. To measure and evaluate flow requires determining certain metrics such as volume, census and occupancy/utilization rates. These rates can be used to determine inter and intra-daily variation. The variation within the day and between the days has different solutions. Lastly, any instituted changes need to be tested. Often changes can be made within the hospital but, some will require support from those outside, especially smoothing the surgical schedule to reduce inter-daily variation.^{38,39} Not only will this improve patient satisfaction but employee satisfaction. According to Litvak et al. (2005) managing flow can reduce stress and lead to a safer work environment.⁴¹

Nurse Anesthetist as OR Nursing Leaders

Nurse anesthetist’s are uniquely positioned to exert their leadership capabilities given their academic and practice expertise. Yukl states that, “most definitions (of leadership) share the assumption that it involves an influence process concerned with facilitating the performance of a collective task.”⁵ He also defines power as “the absolute capacity of an individual agent to influence the behavior or attitudes of one or more designated target persons at a given point in time.” As of 1990 all CRNA’s are Master’s prepared. By 2025 all CRNA’s will be graduating

with a Doctorate degree. As a rule no group of nurses providing direct patient care within a hospital are as highly trained as are CRNAs. Leadership training in quality improvement is one aspect of DNP education.⁶ Additionally, CRNA's as nurses come from an intensive care unit background and most have years of experience in other nursing areas. Currently, CMS requires hospitals to govern all nurse anesthetists within the medical staff rules. This nationally recognized credentialing requirement by CMS gives additional support as to the government's view of CRNA's as expert and leaders.⁴²

Exerting leadership requires accepting the role and using the position of leadership to improve the patient care process. Using Lean concepts can facilitate a safe and efficient patient care environment. Nurse Anesthetist have, and can use "lean" concepts to guide and optimize patient care, especially patient flow through the operative event and thereby providing value for the patient.^{35,36} These concepts are consistent with the role of the nurse anesthetist as a leader in the operating theatre, if they chose to accept this role. By accepting the leadership role and using lean principles Nurse Anesthetists can be a force for quality improvement change in the operative theatre.

Preoperative Assessment

Quality improvement within the operative sphere from a Lean perspective begins in the initial silo of preoperative assessment (Figure 4). The preoperative assessment phase is one of the most important areas of patient care. It is the starting point in the anesthesia process for Nurse Anesthetist as identified by the AANA Standard 1.⁴³ A well performed assessment can reduce anxiety⁴⁴, increase patient satisfaction⁴⁵ and expedite the perioperative process²¹. However, if an assessment is performed poorly or improperly it may lead to delays and cancellations. This can

result in patient dissatisfaction as well as patient harm and even litigation.⁴⁶ The preoperative assessment area is an entry point where the anesthetist can begin to influence the flow of patient care.

The preoperative assessment phase begins once the surgeon/physician schedules the operative case. The purpose of the preoperative assessment phase is to ensure that the patient is in the optimal condition for the scheduled surgery. This includes obtaining a thorough history and physical. These two pieces of information allow the practitioner the opportunity to build their anesthesia plan, give additional patient instructions and order indicated medical consults and laboratory tests. Any necessary consults and tests should be scheduled appropriately to ensure that the information is available prior to the day of surgery. Additionally, the patient's questions and concerns about the anesthesia/surgery are addressed and preoperative instructions are given such as NPO and arrival times. From a Lean perspective the preoperative clinic is the proper place to begin to address muda expressly as well as, muri and mura.

The preoperative assessment phase looks differently from institution to institution. Some institutions have elaborate pre-anesthesia clinics staffed by nurse practitioners, residents and anesthesiologist, others have a physician, a nurse practitioner or a nurse anesthetist.⁴⁷ Some have register nurses who are specifically trained to obtain the anesthesia history and order indicated consults and laboratory test.^{45,47} Each entity seeks to retrieve and dispense similar information to and from the patient in their own way to ensure adequate patient preparation.

Managing flow is not just about accomplishing the goals of a given silo. There are two aspects of this process, one is vertical retrieving the right information and the other is horizontal, conveying the information and plan to the next silo, the perioperative anesthesia provider (Figure

4). This interphase aspect is often where delays and cancellations occur.² If the right information is not obtained in a timely manner the process cannot precede and the case may be delayed or cancelled (muda).

The preoperative clinic has demonstrated viability in reducing delays and cancellations (muda).^{21,48,49} Anesthesia provider guided clinics where the anesthesia department determines the required testing and consults have been shown to be the most efficient and better than the alternatives in reducing costs.^{21,23,50} Numerous evidence based guidelines are available to standardize preoperative testing.^{51 52-54} From a lean value stream perspective, the goal of these guidelines is to manage the *natural variations* of care by standardizing the preoperative process. This consists of removing waste (muda) unnecessary medical testing, overburden (muri) over testing, and unevenness (mura) with different testing paradigms for similar patients. Every patient does not need every possible medical test prior to surgery. Depending upon the patient and surgery, some examinations are indicated and others are not. Pairing the right patient with the right medical assessment will help eliminate waste. The end result is a cost-effective, high quality, efficient, patient satisfying experience. An example of such a guideline is found in the Cochrane Collaboration, “Routine Preoperative Medical Testing for Cataract Surgery.”²⁰ This systematic review demonstrates that routine preoperative testing for the cataract surgery patient is unnecessary given the dynamics of that surgery. Routine testing does not improve the quality of the care provided and substantially increases the cost.²⁰

The dilemma is when and whom to see in the preoperative clinic. Pollard and Olson prospectively studied 529 surgical outpatients and found no difference in the cancellation rate for those seen earlier than 24 hours and those seen within 24 hours prior to surgery.²² Ferschl, et al. in their retrospective chart review demonstrated reduced OR delays and cancellations, among

American Society of Anesthesiologist (ASA) 3 and 4 classes (Figure 5), who were seen in the preoperatively clinic prior to surgery.²¹ Correll, et al. prospectively studied 5083 preoperative clinic patients of which 115 had new problems identified, primarily cardiac and pulmonary.⁴⁹ This “new problem” subgroup represented those with the “highest probability” for delay (10.7%) and/or cancellation (6.8%). However, these only characterized 2.26% of the preoperative patients. Phone histories have come into vogue. The phone history is conducted a few days prior to the scheduled surgery with the final anesthesia assessment conducted on the day of surgery, especially for outpatient surgery.⁴⁷ McKinstry et al. (2010) identified that telephone consults were shorter, presented fewer problems and gathered less information.⁵⁵ While physician and patient satisfaction was high, they concluded that phone consults may not be best suited for acute management as often information regarding serious illness is missed. Regardless of the timing, Bader, Sweitzer and Kumar (2009) emphasized the importance of standardization of the preoperative assessment at each of their respective facilities.⁴⁷ This was similar to the findings of Cima et al. (2011).²³ They standardized the preoperative process and improved OR on time starts.²³ These recommendations are consistent with the Lean/TPS concepts.

Wachtel and Dexter (2007) developed a methodology to determine arrival times and preoperative fasting times based on historical surgical data.¹⁷ Using a statistical model they demonstrated that ASA based NPO and arrival times could be adjusted, beyond the NPO after midnight guideline. Based on earliest possible time for surgery, NPO and arrival time were adjusted without a negative impact to the patient, excluding the first case of the day start. For “to follow” case starts the earliest start time can be calculated and the arrival time and fasting times can be derived, six hours for solid and two hours for clear liquids.

Perioperative

According to Lean thinking the entry into and the exit from the silo is where delays can be expected.² In the perioperative phase this is identified in typical anesthesia terms as induction and emergence. This is where to look for flow problems. However, depending upon the anesthesia provider delays generated during maintenance may influence emergence. Lean has been used most successfully in managing operating room throughput.^{23,24,32}

The handoff from the preoperative to the perioperative phase begins before the first case of the day. This is where an initial deficit in the preoperative preparation will appear and delays or cancellations begin to appear. With the estimated OR cost of \$10-20 per minute, empty ORs are expensive therefore, tardy cases have received a lot of attention.^{47,56} Tardy first case starts are a source of consternation and perceived OR cost increases.^{7,11} Significant OR resources are focused on improving first starts.⁹ Nevertheless, according to Dexter, “The advantage of focusing on first-case starts is principally an economic one, but rarely is the focus important economically.”⁸ Dexter and Epstein (2009) have provided a detailed economic analysis of the economic impact of first case tardiness.⁷ Each minute of reduced tardiness increased staffed time by 1.1 minute. They developed a table to calculate the estimated savings by improving tardiness. Using this tool can help providers evaluate the significance of the problem. Wachtel and Dexter (2010) showed that regardless of whether the first case started on time it had minimal impact on the next case starting on time as 67% of the scheduled cases end before their anticipated time. Their solution to improving tardiness involved producing a new schedule after the first case starts to recalculate start times of follow on cases or schedule a gap between cases.¹¹ However, Wong et al. (2010) documented a delayed start of subsequent cases if the first case was tardy.⁵⁷

The other issue of delays is not just late starts, but the time between starts or turn over time (TOT). Harders et al. (2006) sought to improve TOT in the operating room by minimizing non operative time (NOT).⁵⁸ They accomplished this by “minimizing non operative tasks in the OR, effecting parallel performance of activities and reducing nonclinical disruptions.” However, this all began in the preoperative assessment phase. They streamlined their preoperative phase transition. A couple of examples of this include: eliminating the interview by the circulation nurse as the preoperative nurse has already done this, (muda, waste), scheduling a mandatory pre-anesthesia assessment (standardizing work) and having the surgeon’s office obtain the signed informed consent (muda). The use of electronic medical records (EMC) was identified as an additional change in the redesign. By eliminating waste and standardization they were able to demonstrate over a 3 month period a significant reduction in TOT, NOT and anesthesia related time. Upon emergence they had one provider take the patient to the post anesthesia care unit (PACU) while the other assessed the next patient. However, the question becomes did they save enough time to add another case to the schedule and increase their overall efficiency? Their success was related to a redesign of the flow and getting everyone on board.

Cima et al. (2011), used lean concepts within three surgical specialties to increase “OR efficiency and financial performance” at the Mayo Clinic.²³ This was the result of value stream mapping, engaging staff and leadership support and reducing redundant infrastructure. Variation in emergency surgery was reduced. The pre-operative process was streamlined and OR NOT time was reduced. They concluded that, “the performance gains were substantial, sustainable, positive financially, and transferrable to other specialties.”

Induction, maintenance and emergence are the three areas where flow can be impacted by the nurse anesthetist. Standardization and streamlining of work during these processes can help

reduce delays.^{23,24,32,35,36} Wong et al. (2010) documented perioperative delays in more than half their patients. Delays were the most common form of error with equipment malfunctions being the most common source.⁵⁷ Routine pre-anesthesia machine checks are one way the anesthetist can minimize this issue. Some advocate bringing intubated patients routinely in the PACU as a means to improve TOT. However, if staffing is insufficient in the PACU, this can create a bottleneck. This is similar to parking patients in the hall in the ER. Adjusting flow in one area without anticipating the resulting imbalance will not necessarily solve the flow problem.³⁸

Approaching NOT from a different perspective, financial incentives were awarded to practitioners of an urban academic medical center in an effort to improve NOT. The incentives were based on peer to peer performance.⁵⁹ They evaluated first case tardiness and TOT over a six month period and both decreased over the timeframe with financial incentives. Conversely, these results are in contrast to the findings of Masursky et al. (2009), where financial incentives to academic anesthesiologist to work late did not influence TOT.¹⁵ However, the National Health Service in Great Britain is starting to apply some pay for performance to increase system productivity.⁶⁰

Post-operative

The post-operative phase is the most difficult to impact. Smoothing of the surgical schedule can minimize transportation delays to open rooms or the ICU.³⁸ However, this requires coordination between the operating room scheduling office and the operating surgeons.^{39 16} It is hard to determine prior to the scheduled caseload how many patients will need admission to the floor or ICU. If the Post Anesthesia Care Unit (PACU) gets full, patients will need to be recovered in the OR. This is an expensive, time consuming endeavor. It ties up the anesthesia personnel who

could be better used elsewhere. Dexter et al. (2006) have provided guidelines for PACU staffing based on patient flow.¹⁶ Their recommendations include adjusting staffing ratios based on monthly surgical historical data, adjusting PACU staff the day before and day of surgery, re-sequencing the surgical schedule and reducing the patient time in PACU. Bypassing the PACU with certain prescribed patients is often accomplished in facilities and reduces overall patient demand.

Discussion

Given the inherent variability of the operative process waits, delays and cancellations are inevitable. The Lean model offers some theoretical basis for improving patient flow. Changes in flow can be evaluated via PDCA which is similar to the PDSA approach to quality improvement. Patient flow through the OR needs to be managed to minimize delays and cancellations. Dealing with the artificial variation in flow, flow variation introduced by organizations and providers outside the operative theatre, is the key issue. Artificial or non-random variation in flow introduces uncontrollable flow situations into the environment. Managing artificial flow requires more planning and coordination than natural flow. It is difficult to enlist the cooperation of organizations and providers outside the operating room to help manage the flow within the operative theatre. Soliciting their “buy-in” is important in improving flow.

Nurse anesthetists are recognized as experts in anesthesia and can be leaders in the operating room. They are in a unique position to exert influence and power over how the operating room situation evolves. Their academic, professional and practical expertise affords them expert power and a unique perspective on delivering patient care. Their influence should be used to optimize patient flow through the operating environment. Understanding the concepts of Lean can help

improve the work environment by standardizing procedures, eliminating waste and streamlining the overall surgical experience. Training the CRNA in Lean procedures can help them identify areas where improvement can be made and how to make them. They can then provide more “value” to the patient and the organization.

The preoperative phase provided the most promise for improving flow by minimizing delays and cancellations and is where most of the published work has already been done. Standardizing work task, eliminating waste and smoothing workload are facilitated through the preoperative process. Ensuring a thorough preoperative history and physical with related consults and laboratory tests prior to patient arrival seems the best route to assure the smoothest flow. The potential for delays and cancellations appears in those patients who present with new or undiagnosed problems. Additionally, there are numerous guidelines available to standardize the process and smooth the flow (Standardization). Adjusting arrival times and NPO status based on historical data can eliminate some wait time and improve patient satisfaction (Eliminating waste, Smoothing workload). Nevertheless, compliance is always an issue with NPO status.

Anesthesia provider directed ordering of preoperative testing and consults is the most effective and cost efficient (Eliminating waste). The job is to ensure that on the day of surgery, the anesthesia provider is confident in the preoperative assessment and testing, and will proceed with the case. Regardless of the best job done some will feel the assessment was inadequate (Smoothing workflow).

Unfortunately an inordinate amount of resources and time have been spent trying to reduce first case tardiness (Eliminating waste, smoothing flow). The perception is that improving on-time-first-case-starts, will facilitate a more efficient daily schedule. This may not be the case and may be more related to provider satisfaction as opposed to efficiency, much as moving longer

scheduled cases to other ORs. Dexter and Epstein provided a table to calculate the economic impact of the delays and evaluate whether there is sufficient revenue to be recouped pursuing the issue.¹⁰ The differences between Dexter and Wong on first case tardiness and follow on case tardiness are confounding. They may be related to different organizational culture or national health system.

Pay for performance has been shown to be successful in motivating providers to be more active in minimizing NOT and TOT (Eliminating waste). As an aside, Harders et al. (2006) identified that all hourly OR employees need some incentive to be more productive other than the usual reward of more work, if you are going to get their “buy in” with flow improvements. Moving cases between ORs that take more than 2 hours will not improve OR efficiency as there are typically not enough cases to move in an 8-10 hour day.⁵⁸ The concept of moving cases from one OR to another may expedite that particular case but not necessarily improve OR efficiency.⁶¹ Many facilities focus on minimizing TOT (Eliminating waste). Unfortunately, unless sufficient time is saved to schedule an additional case or bring an overtime period scheduled case into the regular time period and prevent overtime, OR efficiency is not necessarily improved. However, this does not take into account intrinsic surgeon and OR personnel satisfaction with getting cases done ahead of schedule. Harders et al. (2006) identified electronic medical records (EMR) as a source of standardization and smoothing workflow.⁵⁸ The verdict is still out on EMR, but the future will tell us as to how much standardization and eliminating waste it can save as we move toward this in the OR.

The postoperative phase poses the biggest challenge in improving flow. The availability of inpatient beds is often not controlled by the anesthesia provider. Areas outside the OR are difficult to influence. The strongest recommendation is smoothing the work flow through the

OR, but again this is often difficult to achieve as coordination is required with extra facility providers (Smoothing work flow). Most recommendations regarding controlling flow through the PACU center around PACU staffing. Flexible PACU staffing arranged the day before or of surgery can minimize the delays in and out of the unit (Eliminating waste).

Summary

The Lean model is a viable theoretical framework which has been documented to facilitate patient flow through the operative process. Nurse anesthetists can use Lean concepts to improve the surgical work environment. Ideally, Lean transformation is a hospital wide phenomenon. Nevertheless, standardizing work task, eliminating waste and smoothing the work load are “value” adding activities that can and should occur in the surgical suite. However, accomplishing these tasks requires coordination amongst all intra and extra facility stakeholders. Nurse anesthetist as leaders with expert power should and can facilitate this process. Training CRNA’s to use the “Lean Model” would afford them tools to implement quality improvement changes.

Most studies are directed at the pre and perioperative phases, ensuring adequate medical preparation and specifically eliminating first case tardiness. The preoperative clinic seems to offer the most assistance in minimizing delays and cancellations. The elimination of first case tardiness may not be the most financially rewarding aspect of streamlining the operative process, but may offer intrinsic satisfaction rewards to patient, staff and surgeon.

Additional research should address which ASA classifications of patients need to be seen in the preoperative clinic, if not all. These clinics, depending on staffing model, can generate substantial expenses.⁴⁷ Research appraising the cost effectiveness of various pre-anesthesia clinic

staffing models is needed. The effectiveness of phone histories in preoperative assessment needs further research. More research is needed to evaluate flow through the post-operative area. The reasons for provider satisfaction for non-proven methods to affect TOT and NOT, need to be explored. The overall effectiveness of Lean processes within the operating theatre needs further research. Lastly, financial incentives to improve productivity should be explored.

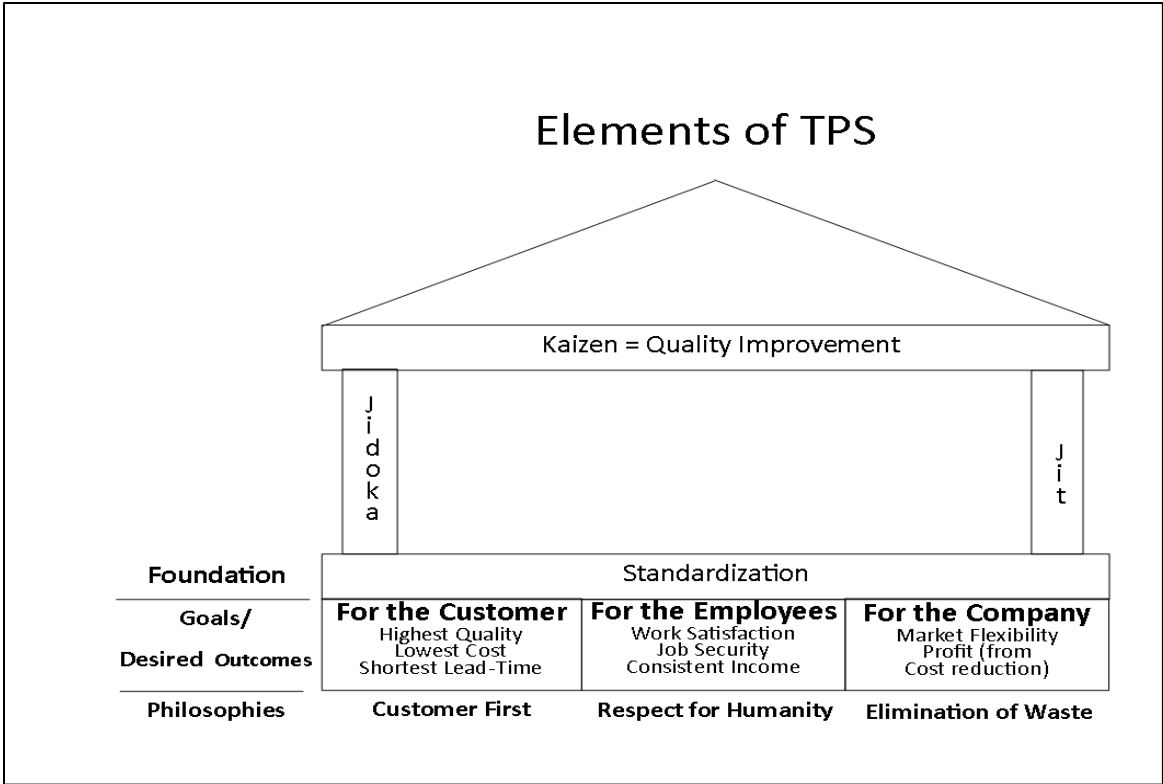


Figure 1

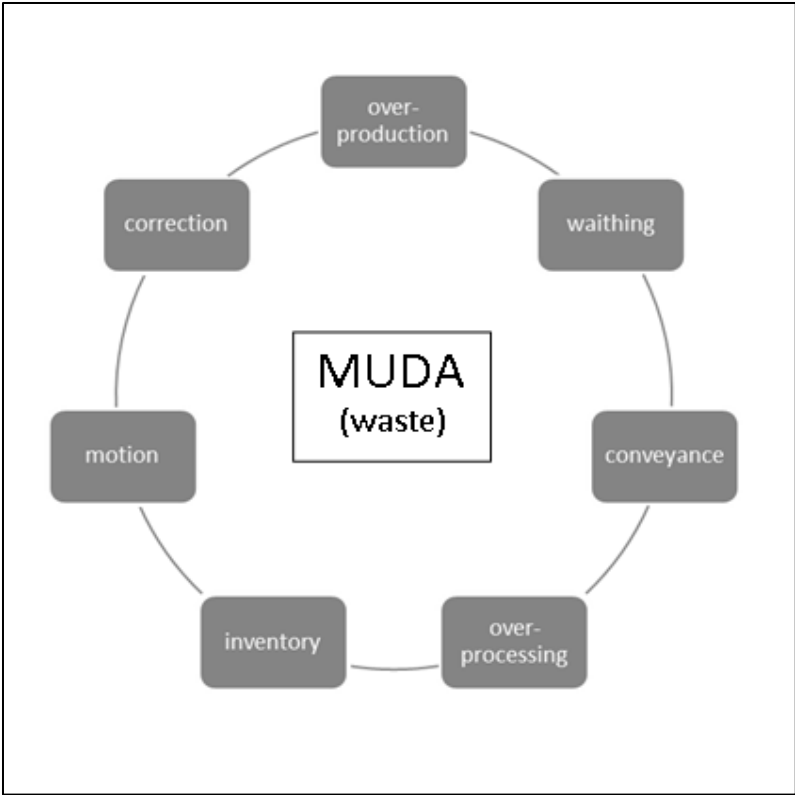


Figure 2

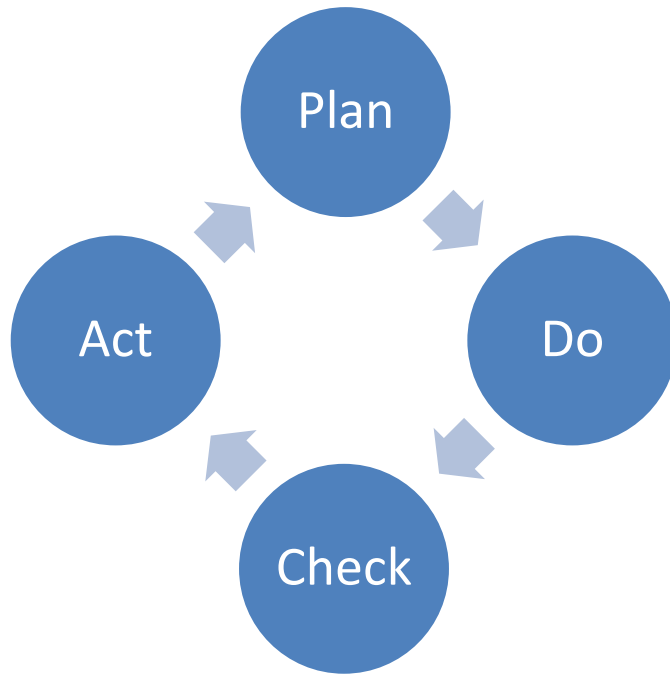


Figure 3

Lean Value Stream Flow

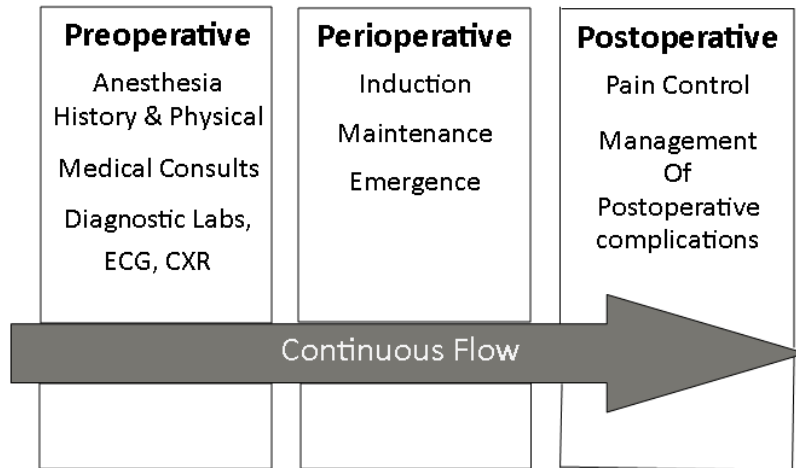


Figure 4

ASA Physical Status Class*	Preoperative Health Status	Comments
ASA Class 1	Normal Healthy Patient	No organic or physiologic diseases with good exercise tolerance, excludes the extremes of ages <2 or >80
ASA Class 2	Patient with mild systemic disease	No functional limitations. One mild disease, that affects one body organ and is well controlled, i.e. smoking, hypertension, diabetes, or chronic obstructive pulmonary disease (COPD)
ASA Class 3	Patient with severe systemic disease	Functional limitation by a disease of one body or organ system. No apparent immediate threat of death. i.e. congestive heart failure (CHF), stable angina, uncontrolled hypertension, Chronic renal failure (CRF).
ASA Class 4	Patient with a severe systemic disease that is a constant threat to life.	At least one severe disease that is poorly controlled or at end stage with the possible risk of death, unstable angina, poorly controlled COPD, symptomatic CHF or liver failure.
ASA Class 5	Severely ill patient who is not expected to survive the surgery	Not expected to survive without surgery for greater than 24 hours. Immediate risk of death.
ASA Class 6	Brain dead patient	

* ASA Physical Status from the American Society of Anesthesiologist

Figure 5

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Manuscript 2 Inter-rater Reliability of Modified Mallampati: Registered Nurse versus Certified Registered Nurse Anesthetist

The pre-operative anesthesia clinic visit is an integral part of surgical process. There are a variety of staffing styles of pre-operative anesthesia clinic to include, physician, resident, nurse anesthetist and registered nurse. Each seeks to elicit similar information from the patient and transfer that information to the anesthesia provider on the day of surgery to optimize the patient's surgical and anesthetic experience.

Identifying those patients who may be difficult to intubate is crucial to managing their anesthetic safely. Airway assessment of the patient to evaluate the potential degree of difficulty which may be encountered during attempted endotracheal intubation is one component of the pre-operative anesthesia clinic visit. Obstructive Sleep Apnea patients are thought to be difficult to intubate. This paper attempts to address the role the registered nurse can play in airway assessment. Can the registered nurse be trained in airway assessment and help identify those potentially difficult to intubate patients? As the Institute of Medicine report suggests, can the registered nurse be used to their optimal skill?

Inter-rater Reliability of Modified Mallampati: Registered Nurse versus Certified Registered

Nurse Anesthetist

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Abstract

Registered nurses routinely obtain medical histories and the physical status of patients scheduled for surgery in the pre-anesthesia clinic. They obtain vital information to prepare the patients for surgery and help ensure each patient has a safe anesthetic. Often these nurses are not trained in airway assessment. The question arises: “Can the pre-anesthesia clinic nurse be trained to reliably identify those patients? The Modified Mallampati (MM) exam was chosen as the test parameter.

This is a prospective study of 216 consenting adults scheduled for elective surgery at a rural Kentucky hospital. The pre-anesthesia nurses were trained in the process of the MM airway screening. They performed a MM screening on elective surgical patients and recorded their findings. Those patients were later re-evaluated, the day of surgery by a Nurse Anesthetist who was blinded to the nurse’s assessment and the assessments compared.

The inter-rater reliability of the MM screening between the pre-anesthesia clinic nurse and nurse anesthetist was poor, $k = 0.167$. The four categories of the MM were compressed into two categories $MM > 3$ or $MM < 3$. This produced fair inter-rater agreement, $k = 0.276$. However, the pre-anesthesia nurses demonstrated a higher sensitivity in predicting those patients that were difficult to intubate ($MM >$) than the Nurse Anesthetist. Nurses in the pre-anesthesia clinic can be trained for airway assessment. However, the MM demonstrated poor as a standalone predictor of difficult airway ($p < 0.625$).

Keywords: Mallampati, Endotracheal intubation, Nurse Anesthetist, Pre-Anesthesia Clinic, Inter-rater reliability

Inter-rater Reliability of the Modified Mallampati: Registered Nurse versus Certified Registered Nurse Anesthetist

Introduction

Airway assessment is a learned art for the anesthesia provider. Anticipating how difficult a patient may be to ventilate or intubate is crucial to the anesthetist's success in the operative theatre. Identifying the potential for difficult intubation early in the operative process allows for planning on how to conduct the anesthesia safely for the patient. Ideally, this should occur in the pre-anesthesia clinic visit before the day of surgery.

A critical component to the pre-anesthesia screening is an assessment of the patients' airway to prevent an unanticipated difficult intubation on the day of surgery. Identifying a patient with the potential of a difficult intubation requires training and skill on the part of the healthcare practitioner who is conducting the exam. This screening is often accomplished alone or with other professionals.¹ The screener needs to be able to identify the physical characteristics associated with difficult intubation. One longstanding component of airway assessment is the Modified Mallampati (MM) exam.² While airway assessment may be routine practice for anesthesia providers, many pre-anesthesia clinics are staffed by registered nurses and not anesthesia providers. According to the Institute of Medicine, health care savings and improved patient care can be accomplished by allowing registered nurses to practice to the fullest extent of their licenses.³ The question arises, "Can early identification of potentially difficult intubation/airways be accomplished by training the pre-anesthesia clinic nurses in airway assessment?" This study addresses inter-rater reliability of the (MM) exam as an approach to airway assessment by assessing the congruence in scores on the MM between the nurses in the pre-anesthesia clinic and the anesthesia provider on the day of surgery.

Methods and Materials

This is a prospective study evaluating the inter-rater reliability of the MM assessment score. This study compared the ability of the registered nurses in the preoperative anesthesia clinic after formal training in the MM evaluation to provide an accurate MM assessment when compared to certified registered nurse anesthetists. The CRNAs were blinded to the MM scores of the RNs. This study received approval from the University of Kentucky Institutional Review Board. All subjects provided informed consent. Study subjects were English speaking patients scheduled for elective surgery, greater than the age of 18 and seen in the preoperative anesthesia clinic prior to the day of scheduled surgery. Informed consent was obtained at that time. All participants involved in obtaining informed consent completed the Collaborative Institutional Training Initiative (CITI).

The preoperative anesthesia clinic nurses were trained by the Principal Investigator (PI), a certified registered nurse anesthetist (CRNA), in the MM evaluation. The categories of the MM were defined as follows: Class 1- able to visualize hard palate, soft palate, uvula, tonsils, and pillars, Class 2- able to visualize hard palate, soft palate, uvula, upper poles of tonsils and pillars, Class 3 –able to visualize hard palate and soft palate only, possible slight uvula, Class 4 – able to visualize hard palate only.

The education for the registered nurses working the pre-anesthesia clinic included: instructional photographs and diagrams of the oropharynx, discussion of how to perform the evaluation, demonstration by the PI of the evaluation and repeat demonstrations by the nurses collecting the data to ensure their ability to replicate the evaluation. After obtaining informed consent from the subject, the evaluation was performed by the pre-anesthesia clinic nurse and this information was recorded on the study form (Attachment 1). The following data were

recorded on the study form: STOP-BANG (SB) questionnaire, Epworth Sleepiness Scale (ESS) and MM score. This form was then returned to the author. The subjects were then re-evaluated by the anesthetizing CRNA immediately prior to surgery as is standard procedure for this facility. On a separate form and without the knowledge of the pre-anesthesia RN's evaluation, the anesthetist recorded their MM assessment, difficult ventilation score and Carmack-Lehane (CL) airway assessment if indicated. These data were returned to the PI (Attachments 2 and 3). If an incomplete CRNA patient assessment form was returned, the PI attempted to complete it by retrieving the missing information from the electronic anesthesia record. Two pre-anesthesia nurses and eight CRNAs participated in the study. The pre-anesthesia clinic nurses had 10 or more years of experience at their current position. Each CRNA had a minimum of 7 years of experience and at least 2000 endotracheal intubations. The anesthetizing CRNA was blinded to the preoperative nurse's evaluation. A crosswalk table was developed to store study data and personal information separately.

Results

Informed consent was obtained and data collected prospectively on 222 of 1648 patients scheduled for surgery over a 5 month period. Six patients did not have their surgery after completing the pre-anesthesia data collection and 18 subjects had incomplete MM data. These cases were removed from the data set (n=198). The males were older, taller, and weighted more than the females, but had a lower body mass index, BMI. More females than males consented to participate in the study (Table 1). Twelve of 57 patients who were intubated were identified as difficult intubations. This represents a difficult intubation rate of 21.1 percent among those intubated.

Inter-Rater Reliability

Statistical analysis of the data set was performed to include the kappa coefficient for inter-rater reliability. The four MM categories were compared between providers for inter-rater reliability. When comparing the four MM categories amongst the providers inter-rater reliability was very weak with a $k=0.167$. The pre-anesthesia clinic nurses scored more patients as MM class 4 than the anesthesia providers, 32 versus 2 (Table 2).

Threshold parameters of “difficult to intubate” were established as an MM greater than or equal to 3 and not difficult to intubate as less than 3 were established (Table 3). This allowed the data to be compressed into two categories, 1 and 2 and 3 and 4. Class 1 and 2 represented study subjects without potentially difficult airways, while classes 3 and 4 represented those with potentially difficult airways. The two class analysis demonstrated better (fair) inter-rater reliability^{4,5} ($k=0.276$). Categorizing the data in this fashion allowed for analysis to see if the pre-anesthesia clinic nurses could identify those with probable or not probable difficult laryngoscopy and endotracheal intubation. This analysis was similar to that of Hilditch et al.⁶

Predicting Difficult Intubations

Twelve of the 57 (21.1%) patients requiring intubation were identified as difficult intubations as defined by the study criteria of having a Carmack-Lehane score greater than or equal to 3. Only 2 (16.7%) of these patients were identified as MM class 3 or greater by the CRNA’s (CRNA MM). However, 6 of the 12 (50%) patients were identified by the pre-anesthesia clinic nurse (RN MM) as having a MM score consistent with difficult intubation. Both the CRNA $MM \geq 3$ and RN $MM \geq 3$ demonstrated good specificity (Specificity = 84.40% for the CRNA’s and 71.10% for the nurse) for predicting difficult intubation, but the sensitivity data varied considerably between the two groups (16.70% for the CRNA’s and 50% for the nurse)(Table 4). Of these 12 “difficult to intubate” patients only 1 required an alternate means

to intubation, i.e. “Glidescope” fiber optic, or otherwise awake intubation. There were no “failure to intubate” patients. The difficult to intubate percentage of this study was higher than the findings of Crosby, et al,⁷ or Djabatay and Barclay,⁸ of an average difficult airway/intubation rate of 1.5 to 8 and 0.4 to 1 percent respectively.

Discussion

The purpose of the pre-anesthesia clinic is to evaluate and prepare patients for surgery. Ideally, those patients with medical problems that could complicate the anesthetic are identified. This information is passed on to the provider responsible for anesthetizing the patient for planning purposes, to include potentially difficult intubations. The ultimate decision on how to proceed will rest with the anesthetist providing the anesthetic. The anesthetist on the day of surgery will determine the best course of action, alone or in consultation with a supervisor or another colleague. The decision to secure the airway by a method other than direct laryngoscopy will be determined on the day of surgery, not in the clinic. The purpose of the pre-anesthesia clinic is not to dictate what anesthetic should be administered, but to give reliable information so the best decisions can be made on the day of surgery.

The MM exam was chosen for inter-rater reliability as it has been historically associated with difficult intubation. It has been thought easy to use and teach.² Recently, a MM score greater than 3 has been linked with obstructive sleep apnea (OSA).⁹⁻¹²

The higher sensitivity of the RN MM ≥ 3 as compared to the CRNA MM ≥ 3 for predicting difficult intubation was an interesting finding. This suggests that the pre-anesthesia nurses were much better than the CRNA’s at predicting those “difficult to intubate” patients using the MM exam. On the other hand the CRNA MM ≥ 3 demonstrated a higher specificity than the RN MM ≥ 3 . These findings show that in this study the CRNAs were better than the RNs

at using the MM in determining those patients that would not be difficult to intubate. Together, this was a surprising finding. A larger study with more “difficult to intubate” patients might clarify this issue.

Two studies comparing the inter-reliability of the MM were available for review. Only one evaluated the inter-rater reliability between a nurse and an anesthesia provider.⁶ Hilditch et al compared the “inter-observer reliability between a nurse and an anesthetist to predict difficult intubation.”⁶ They compared five airway assessment tests, mouth opening, thyro-mental distance, atlantal-occipital movement, upper-lip bite test and MM view. The comparison of all 4 MM classifications between the nurse and anesthesia provider resulted in fair agreement^{4,5} ($k = 0.38$). However, when two “threshold parameters” were compressed into two categories, 1 and 2, and 3 and 4, $k = 0.56$ and showed moderate agreement. Using two categories for all the parameters they found that “most of the tests had either good or very good reliability” to predict difficult intubation, except the Mallampati. It could be argued that the MM has more inherent variability secondary to its lack of objective measurability when compared to other airway assessment tools, such as thyro-mental distance and inter-incisor measurements. The question arises: “Should the MM exam be used as a standalone airway assessment tool to predict difficult intubation?”

Rosenstock et al compared the inter-rater agreement on the Mallampati exam between two anesthesiology resident and two staff anesthesiologists.¹³ In this study 136 patients, 120 with a normal airway and 16 with a known history of difficult intubation were evaluated. Four observers assessed each patient for the original Mallampati exam with 3 other categories, inter-incisor gap, upper lip bite, and thyro-mental distance. Evaluators were blinded to prior evaluator’s assessments. Rosenstock et al found higher inter-observer reliability, $k=0.41-1$, than

Hilditch et al.⁶ Possibly, the tight control of the evaluation process by Rosenstock et al improved their inter-rater reliability. This control consisted of limiting the study to the original number of Mallampati classes (3 vs. 4 in MM), and using a small number of evaluators with repeat evaluations of study subjects, thus increasing the inter-rater reliability.

This study produced results similar to that of Hilditch et al. There was slight inter-rater reliability when comparing the 4 classes of MM between nurse and nurse anesthetist. While inter-rater reliability amongst all 4 MM classes is important, it is a means to the end not the end itself in airway assessment. The ultimate goal of airway assessment is to identify those patients at risk for potentially difficult intubation ($MM \geq 3$). To this end the study demonstrated that when predicting those patients who were anticipated to have difficult intubations ($MM \geq 3$), there was fair agreement between the nurse and CRNA. The pre-anesthesia nurses demonstrated a higher sensitivity in predicting those patients who were difficult to intubate. However, both provider's evaluations (CRNA MM and RN MM) demonstrated similar specificities for predicting those patients that were not difficult to intubate.

The role of the pre-anesthesia clinic is to prepare patients for surgery and inform anesthesia providers of the potential risk to their patients. The pre-anesthesia clinic nurse is an important component in the process. Using these providers to the fullest extent of their training is one of IOM's goals to improve health care and reduce cost. This study supports training registered nurses in the pre-anesthesia clinic to help identify those patients with potentially difficult intubation. This is especially true given the fact that the MM is a more subjective test than other screening tools. Those facilities using pre-anesthesia nurses instead of anesthesia providers to staff their clinics may benefit from training their nurses to perform airway

assessment in addition to the routine medical history and testing to help identify those patients at risk for difficult laryngoscopy and intubation.

This work has several limitations. First, the demographics of the study population (rural Kentucky) may not represent those populations in other areas (rural or urban USA), particularly given the higher incidence of difficult intubation. Second, the prospective nature of this study limited the number of subjects. Had the study been conducted retrospectively all patients presenting during the 5 month study period would have been candidates. This larger data pool would have yielded more stable information. Third, examining the data at midpoint could have allowed the author and nurse trainer to conduct “re-training”, if the “over rating” by the pre-anesthesia clinic nurse was evident at that point. Fourth, rater bias from the previous training of the CRNAs cannot be discounted. While the CRNAs were instructed to complete the forms in the same manner as the pre-anesthesia clinic nurse, rater bias may have been introduced as the anesthesia providers had prior training regarding MM scoring during their professional training. This prior training may have influenced their assessments. More extensive training of the pre-anesthesia nurse and CRNA’s may have improved the overall inter-rater reliability. Also, inter-rater reliability testing within each group may have improved overall inter-rater reliability. Poor inter-rater reliability within each group could have been discussed and reassessed. Last, if using the original MM with 3 instead of 4 classes was used, a higher inter-rater reliability may have been achieved.

In summary, inter-rater reliability of the MM scoring for the 4 classes between pre-anesthesia clinic nurse and nurse anesthetist was slight ($k=0.167$). Evaluations based on a threshold parameter demonstrated fair association between nurses and nurse anesthetists identifying the patients with probable difficult and non-difficult intubation ($k=0.276$). . This is

especially true given the fact that the sensitivity data showed that the pre-anesthesia nurses identified more of the difficult to intubate patients than the CRNAs via the MM exam. The later finding supports the concept that pre-anesthesia clinic nurses can be trained in evaluating airway assessment with the MM. Nevertheless, the MM scoring alone cannot be recommended as a standalone airway assessment tool for predicting difficult laryngoscopy/airway.

The data analysis for this paper was generated using SAS software, Version 9.3 of the SAS System for Windows. Copyright © 2102 SAS Institute Inc. SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc., Cary, NC, USA.

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Tables

Table 1 Mean \pm SD of Age, Height, Weight, and BMI by gender.

Gender	Number	Age	Height	Weight	BMI
Male	45	56.64 \pm 2.40	70.42 \pm 0.49	212.84 \pm 6.13	30.82 \pm 1.04
Female	171	48.57 \pm 1.28	64.06 \pm 0.21	189.25 \pm 4.34	32.52 \pm 0.72

Table 2 Distribution of Patients by Modified Mallampati Class and Provider Group

MM score	Pre-Anesthesia Nurse	CRNA
Class 1	64	77
Class 2	62	78
Class 3	56	41
Class 4	32	2

Kappa 0.167

Table 3 Distribution of Patients by Modified Mallampati Scores by Provider Group

		CRNA MM		Total
		1, 2	3, 4	
RN MM	1, 2	101	14	115
	3, 4	50	31	81
Total		151	45	196

Kappa 0.276

Table 4 Sensitivity and Specificity of Using the Modified Mallampati for Predicting Difficult Intubation by Provider Group

	Sensitivity (%)	Specificity (%)
RN MM \geq 3	50.00	71.10
CRNA MM \geq 3	16.70	84.40

Attachment 1

Pre-Operative OSA Screening Tool

Patient ID Number: _____

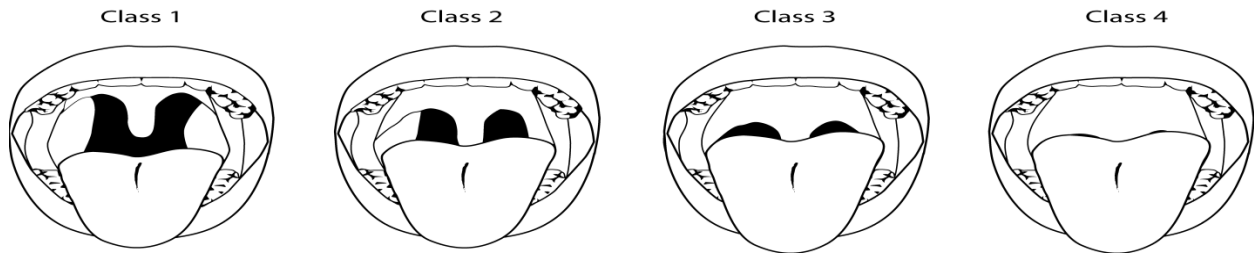
This questionnaire is a screening tool used to identify if a patient at increased risk for sleep apnea. Please answer either yes or no if it applies to you.

- | | | |
|---|-----|----|
| (S) Do you <u>snore</u> loudly enough to hear through a closed door? | Yes | No |
| (T) Do you often feel <u>tired</u> , fatigued or sleepy during the daytime? | Yes | No |
| (O) Has anyone observed you stop breathing during sleep? | Yes | No |
| (P) Have or are you being treated for high blood pressure? | Yes | No |
| (B) BMI greater than 35? | Yes | No |
| (A) Age greater than 50 years? | Yes | No |
| (N) Neck circumference greater than 17 inches or 40 cm? | Yes | No |
| (G) Gender male? | Yes | No |

How **likely** are you to **doze off or fall asleep** in the following situations? Even if you have not done some of these things recently, try to answer on how these activities may affect you. Use the following scale to choose the most appropriate response for each situation: (Choose only one response for each question)

Response Score: Never doze 0, Slight chance of dozing 1, Moderate chance of dozing 2, High chance of dosing 3.

- | | |
|---|-------|
| 1. Sitting and reading | _____ |
| 2. Watching television | _____ |
| 3. sitting, inactive in a public place (e.g., a theatre or a meeting) | _____ |
| 4. as a passenger in a car for an hour without a break | _____ |
| 5. Lying down to rest in the afternoon when circumstances permit | _____ |
| 6. Sitting and talking to someone | _____ |
| 7. Sitting quietly after a lunch without alcohol | _____ |
| 8. in a car, while stopped for a few minutes in traffic | _____ |
| Total | _____ |

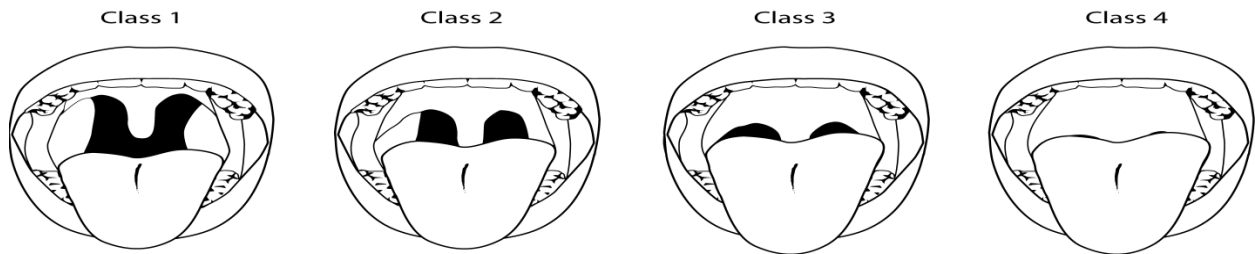


Attachment 2

Intraoperative/Anesthesia Data Collection Tool

Patient ID _____

Mallampati



Cormack-Lehane



Difficult Ventilation Score

0 1 2 3 4

Attachment 3

Modified MMScore

The Modified MMScore is based on the visualized structures of the posterior pharynx to include uvula, faucial pillars, and soft palate. Criteria include:

1. Able to visualize full uvula, soft palate and faucial pillars.
2. Able to visualize partial soft palate and faucial pillars, uvula masked by base of tongue.
3. Able to visualize soft palate only.
4. Unable to visualize any posterior pharynx structures, tongue only.

Difficult Mask Ventilation Score

0. Mask ventilation, did not attempt
1. Easy mask ventilation
2. Mask ventilation with oral airway device
3. Difficult mask ventilation, unstable or requiring 2 persons
4. Unable/impossible mask ventilation.

Cormack-Lehane Difficult Intubation Score

1. Able to visualize entire larynx, arytenoids, chords, true and false, epiglottis superior to chords.
2. Chords partially obstructed from view with epiglottis, arytenoids visible.
3. Epiglottis visible only.
4. Soft palate visible only.

Manuscript 3 Predicting the incidence of Difficult Intubation from Obstructive Sleep Apnea Screening in a Rural Kentucky Population

Obstructive sleep apnea (OSA) is a growing worldwide problem, given the endemic issue of obesity. Patients with OSA present to the operative theatre at a higher rate than is their prevalence in the general population. Patients with OSA are at risk for difficult mask ventilation, endotracheal intubation and post-operative respiratory complication. It is important to identify these patients early and to help ensure a safe, peri-operative experience.

Several screening tools are available to help identify those patients at risk for OSA and difficult intubation. The STOP-BANG, Epworth Sleepiness Scale and Modified Mallampati were chosen as screening tools for this paper. This paper has three objectives: to identify the potential risk of OSA in this rural Kentucky population, attempt to identify difficult intubation in this population with the screening tools and identify difficult mask ventilation.

Predicting the incidence of Difficult Intubation from Obstructive Sleep Apnea Screening in a
Rural Kentucky Population
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Abstract

Background: In the United States 3-5 percent of the adult population has Obstructive Sleep Apnea (OSA). A disproportionate share of OSA patients present for elective surgery. These patients are at increased risk for various perioperative respiratory complications to include difficult intubation. STOPBANG, Epworth and Modified Mallampati screening are associated with OSA and can help identifying those patients at risk for difficult intubation.

Methods: After receiving informed consent, 216 elective surgery patients were screened preoperatively for OSA and difficult intubation (DI) with the STOPBANG (SB) questionnaire, Epworth Sleepiness scale (ESS) and Modified Mallampati (MM) score. On the day of surgery the anesthetist performed a MM screening, a Cormack-Lehane (CL) Difficult Intubation score and the Han Difficult Mask Ventilation (DMV) score. Sensitivity, Specificity, and correlation were determined for each variable in relation to DI.

Results: Difficult intubation was identified in 21.1% and undiagnosed OSA in 47.4% of the surgical population. An $ESS \geq 9$ was associated with difficult intubation. There was no statistical association between SB, RN MM, CRNA MM, DI and SB, ESS and MM with DI. STOPBANG and ESS had the highest sensitivities for predicting DI and CRNA MM the least. Difficult mask ventilation was statistically associated with a positive SB screening ($p=0.011$).

Conclusions: Rural Kentucky has a higher than national average of difficult intubation and OSA. The STOPBANG and Modified Mallampati screening scores do not appear to be independent or collective predictors of DI while the ESS does predict DI.

Keywords: Obstructive Sleep Apnea, STOPBANG, Difficult Intubation, Difficult Ventilation, Mallampati

Predicting the incidence of Difficult Intubation from Obstructive Sleep Apnea Screening in a Rural Kentucky Population

Introduction

Background and Significance.

Sleep apnea is a growing, worldwide health care problem.^{1,2} It is the most common form of sleep-disordered breathing (SDB) in the adult population. It is estimated that 3-5 percent of the adult population has obstructive sleep apnea (OSA).³⁻⁶ In spite of the high prevalence of OSA, it often remains undiagnosed. Young et al in 1997 found that 82 percent of the men and 93 percent of the women with moderate to severe OSA in the US are undiagnosed.⁷ Current estimates place the prevalence of undiagnosed OSA at 75 percent.⁵

Obstructive sleep apnea syndrome is a cycle of sleep, apnea and arousal (Figure 1). Obstructive Sleep Apneas is defined as a cessation of breathing for 10 or more seconds during sleep despite respiratory effort. This is secondary to upper airway closure/collapse.^{8,9} Collapse of the upper airway results in decreased (hypopnea) or obstructed (apnea) airflow.¹⁰ The airway collapse is the result of a “complex interaction of pharyngeal anatomical compromise with state-dependent upper airway dilator muscle dysfunction.”¹¹ This lack of ventilation produces hypoxemia and hypercarbia which stimulate further respiratory effort. Hypoventilation/apnea continues until the upper airway reopens. Typically, airway patency is restored with arousal from sleep.¹²⁻¹⁴ The “awakening” is thought to be caused by the changes in the respiratory effort and blood gases.¹⁵ The return of airway patency is followed by a period of hyperventilation and re-

oxygenation as the blood gases attempt to normalize.¹⁵ This is followed by the patient returning to sleep, ready to reproduce another cycle of OSA.¹⁰

The disruption of the sleep cycle by OSA is accompanied by concomitant hypoxia and hypercarbia. The respiratory variations produce blood pressure, serum electrolyte and acid-base disturbances. These changes stimulate atherosclerosis, hypertension, stroke and cardiovascular disease in general.^{3,16,17} The lack of sleep promotes sleep fragmentation and deprivation which results in daytime sleepiness, fatigue, and neurocognitive dysfunction.^{10,18-20} The incidence of OSA increases with age and is more common in males than females, 2-3:1.⁷ Obstructive sleep apnea is closely associated with obesity and smoking.^{3,21} Obstructive sleep apnea is connected with other co-morbidities: diabetes, metabolic syndrome, and hypothyroidism.^{17,22-25} Additionally, moderate to severe and untreated OSA has been identified as risk factors for all-cause mortality.^{5,26,27} As a public health issue, patients with OSA have been shown to be at an increased risk for motor vehicle accidents.²⁸ Numerous health and social consequences are associated with OSA.

Endotracheal intubation is often required for general anesthesia and is a prerequisite skill for nurse anesthetists. The failure to intubate a patient who requires ventilator support can produce a life-threatening event. In the surgical patient, prevention begins with effective preoperative screening.²⁹ Standard pre-anesthesia assessment tools for airway evaluation include: the Modified Mallampati (MM) score, upper lip bite test, thyromental distance, inter incisor distance and atlantal-occipital extension test.³⁰⁻³² In the preoperative arena each patient should be screened and evaluated for their perceived difficulty of intubation.

Difficult intubation is hard to quantify, as it is not solely dependent upon the patient but varies with provider experience and skill. Crosby et al found an incidence of difficult intubation and quantified the risk of difficult intubation from 1.5-8 percent.³³ Among “skilled” providers Djabatey and Barclay found that the incidence of difficult intubation in the obstetrical population to be 1:100-128.³⁴

Obstructive sleep apnea is associated with an increased difficulty with endotracheal intubation, difficult mask ventilation and other perioperative respiratory complications.^{2,35-37 38-45} Chung et al found a strong association between OSA and difficult intubation.⁴⁰ They recommended that if a patient is found to be difficult to intubate, they are to be referred to a sleep study lab for OSA evaluation. Recently, difficult/impossible mask ventilation has been associated with difficult intubation and OSA.^{4,46,47} Gali et al,⁴¹ Kaw et al,^{48,49} and Memtsoudis et al,⁵⁰ documented post-operative respiratory complications associated with OSA.

More frequently than expected, undiagnosed OSA patients present to the operating room for surgical procedures.^{51,52} Identifying the risk to these patients preoperatively and optimizing their perioperative care should help minimize their complications.^{2,51} To this extent, the American Society of Anesthesiologist (ASA) and the American Society of Ambulatory Surgery (ASAS) recommend preoperative OSA screening for all patients requiring anesthesia services and scheduled for surgery.^{53,54} The ASA did not recommend using a screening tool as no tool had been validated in 2006. Since that time several OSA screening tools have been validated. Chung et al validated the STOP-BANG as screening tool for OSA.⁶ In 2012 the ASAS recommended use of the STOP-BANG Questionnaire as a screening tool based on their systematic review of the literature.⁵³

If OSA is associated with an increased difficulty in intubation and mask ventilate, then pre-operatively OSA screening could help identify those patients. The question arises; “Can screening for OSA predict difficult intubation and or mask ventilation? And if so can combining more than one OSA screening tool such as the Epworth and Mallampati with the STOP-BANG improve the overall ability to correctly predict difficult intubation? This information is important as anesthesia providers need to identify those patients at risk for difficult intubation, difficult mask ventilation and OSA. As the United States population continues to age and become more obese, this information will become increasingly relevant, particularly in Kentucky where the there is an extraordinary prevalence of risk factors for OSA and difficult intubation.

Study Objectives:

1. To identify the risk of undiagnosed OSA in a rural Kentucky surgical population based on a positive screening with the STOP-BANG questionnaire ($SB \geq 3$).
2. To compare the ability of the STOP-BANG, the Epworth Sleepiness Scale and the Modified Mallampati screening tools independently and as a group to predict the incidence of difficult intubation in a surgical population requiring general anesthesia and intubation in rural Kentucky community hospital.
3. To determine if the difficult ventilation score is associated with difficult intubation and/ or a positive SB screening.

Definitions of Variables. (Established threshold parameters were consistent with the current literature recommendations)

Obstructive Sleep Apnea (OSA). Obstructive sleep apnea (OSA), the most common Sleep Disordered Breathing (SDB) condition, is characterized by the repetitive collapse or partial collapse of the pharyngeal airway during sleep and the need to arouse to resume ventilation.⁵⁵ Formal diagnosis of OSA is accomplished with a polysomnogram, i.e. sleep study. The polysomnogram quantifies the severity of the sleep-disorder breathing with the apnea-hypopnea index (AHI).¹ The patient's OSA diagnosis is classified with AHI score as none 0-4, mild 5-14, moderate 15-29, and severe greater than 30. Patients with diagnosed with OSA (AHI \geq 5) are at significant risk for perioperative complications.^{38,41,43} Once diagnosed, the constant positive airway pressure (CPAP) machine is often prescribed to those patients with moderate to severe sleep apnea (\geq AHI 15).^{2 56} The regular use of CPAP can reduce the cardiorespiratory effects and excessive daytime sleepiness of OSA.^{11,56}

STOPBANG (SB) Questionnaire. The STOPBANG questionnaire is an eight question self-administered OSA screening tool for sleep apnea. A SB score of 3 or more is associated with the risk of OSA (Figure 2). Subjects with STOPBANG scores greater than or equal to 3 were considered a positive screen for sleep apnea.

Preoperative screening for OSA can be easily accomplished using one of the available questionnaires.^{54,57} These include the Berlin, American Society of Anesthesiologist, STOP, STOPBANG and Epworth Sleepiness Scale.⁵⁸ Of those, the STOPBANG has shown reliable specificity (39-43 percent) and the highest sensitivity (93-100 percent) for detecting OSA.^{6,59-61} Chung et al demonstrated that STOP-BANG scores greater than 3 on the scale of 8 have an 83.6 percent chance to be associated with mild OSA.⁶²

Epworth Sleepiness Scale (ESS). The Epworth Sleepiness Scale is a nine question self-administered screening tool used to evaluate the daytime sleepiness of patients and predict the risk of OSA. Each question is given a score of 0-3 and the score totaled. Total scores greater than nine are associated with OSA (Figure 3).⁶³ Subjects with an ESS score greater than or equal to 9 were considered a positive screen for excessive daytime sleepiness and OSA. The Mallampati score and ESS have been shown to significantly correlate with OSA.^{58,63-65}

Modified Mallampati (MM). The Modified Mallampati is a screening tool used by health care professionals, especially anesthesia providers, to predict the degree of difficulty of intubation that may be encountered during direct laryngoscopy. The MM score is a ranking of the patient's posterior pharyngeal anatomy based on the visualized structures to include uvula, faucial pillars, and soft palate. This evaluation is accomplished by having the subject open their mouth as wide as possible and stick out their tongue. The assessor looks at the posterior pharynx and rates it on a scale of one to four, with one being the most visible and four being the least visible anatomy (Figure 4).

A Modified Mallampati score greater than or equal to three is considered consistent with potentially a difficult intubation. Those patients so identified may require some form of an alternate intubation method other than direct laryngoscopy such as with a "Glidescope" or even an awake fiber optic intubation. Nuckton et al identified the Mallampati score as an "independent predictor of both the presence and severity of obstructive sleep apnea."⁶⁵

Cormack-Lehane (CL) Difficult Intubation Score. The Cormack-Lehane Difficult Intubation score was defined by Cormack and Lehane.⁶⁶ They delineated difficult intubation as a class 3-4 on their scale of 1-4 on initial direct laryngoscopy assessment (Figure 5).⁶⁶ Cormack and Lehane classified scores greater than or equal to 3 to be consistent with difficult intubations.

Han Difficult Mask Ventilation Score (DMV). The Han Difficult Mask Ventilation Score is a screening tool developed by Han, et al.⁶⁷ It ranks difficult mask ventilation on a scale 0-4, easy to impossible. It is used to describe the means and the ability of a health care provider to mask ventilate patients post-induction during anesthesia (Figure 6). A difficult ventilation score greater than or equal to 3 was considered significant.

Body Mass Index (BMI). The Body Mass Index is a formula used to define a person's body fat. A normal BMI is defined as 18.5-24.9, overweight is defined as 25-29.9 and obese is defined as a BMI greater than 30.

Setting.

The study was conducted at a community hospital serving a suburban and rural population in Kentucky. The hospital agreed to provide the necessary resources for the study to include clinic space, personnel and forms. The existing pre-anesthesia clinic space, nursing staff and anesthesia personnel were involved in the study. The pre-anesthesia clinic was staffed by two registered nurses with greater than 10 years of experience in performing preoperative assessments. All anesthesia providers were Certified Registered Nurse Anesthetists (CRNA) with more than 7 years of experience in performing general anesthesia with endotracheal intubation. Forms included printed copies of the data collection and screening tools.

All Personally Identifiable Information (PII) and Personal Health Information (PHI) data was kept in separate files with crosswalk tables. All collection devices were behind firewalls and password protected under the control of Principal Investigator (PI) at all times. All data was encrypted upon entry and stored on a jump drive. When not in use the jump drive was in a locked and secured drawer. Incomplete data was abstracted from the electronic patient record when

possible. Each patient was assigned a unique study identification number. A master crosswalk table with patient medical record number and correlating study number was maintained by PI.

Methods.

Study Design:

The study involved the voluntary, non-randomized, prospective collection of data on English speaking patients, of at least eighteen years of age, scheduled for surgery or an endoscopic procedure for a 5 month period beginning May 15, 2012 who agreed to participate. Informed consent was obtained from all participants. All Health Insurance Portability and Accountability Act (HIPAA) protocols were followed. The research protocol received Institutional Review Board (IRB) approval from the University of Kentucky with the consent from the study hospital prior to implementation. There was no payment for participation, nor any incentives.

Participants were recruited and screened by the pre-anesthesia nurses in the preoperative anesthesia clinic of the hospital. Each subject was seen prior to surgery in the pre-anesthesia clinic where a history and physical was conducted as well as relevant lab test ordered. The pre-anesthesia nurses completed the SB questionnaire, ESS and the MM score for each patient.

Evidence based protocols in the medical literature for managing OSA patients were not found. According to Auckley and Bolden evidence based protocols for OSA do not exist and all current protocols are expert driven.⁵¹ The subsequent recommendations for managing OSA patients were gathered from consensus models and followed during the study.^{54,68-70} All consenting elective surgical patients were screened for OSA. After OSA screening, the patients were classified into 3 categories, no risk ($SB < 3$) or at risk ($SB \geq 3$) or known OSA. Those patients

with no risk proceed to surgery without further follow-up. Those patients identified as at risk for OSA and undiagnosed had their chart labeled as at risk for OSA to alert the staff. They were referred to the sleep lab for formal diagnosis.² If the surgery could wait, then a sleep study was performed prior to surgery. (None of the patients so identified afforded themselves of this opportunity.) If the surgery could not wait, then the suspect OSA patient would be identified and managed according to the hospital's OSA protocol.^{41,54} Those patients with a formal diagnosis of OSA and using a Continuous Positive Airway Pressure (CPAP) machine were instructed to bring their CPAP machine with them to the hospital. The CPAP machine was made available for patient use in the peri-anesthesia period.

On the day of surgery, the CRNA assigned to administer the anesthetic on the study subject evaluated the patient for difficult ventilation and intubation using the MM, CL and DMV assessment tools. These findings were recorded. The CRNA was blinded to the MM score given to the patient by the pre-anesthesia nurses. The scores were documented on the study form immediately after they were performed. The author/PI collected and stored the study forms. Those study forms submitted by the assigned CRNA with a missing MM score had that information retrieved by the author from the electronic anesthesia record, if available.

The collected information was entered into a specifically designed Microsoft Accesstm database. It was then transferred into an excel spreadsheet and subsequently into SAS v9.3 for data analysis. The two sample t-test was used to compare population means (male vs female, OSA vs non-OSA) and determine if there was a statistical difference for the quantitative data. Thresholds for positive results were established for the following variables: SB greater than or equal to 3, ESS greater than or equal to 9, MM (RN and CRNA), greater than or equal to 3 and DMV greater than or equal to 3. Chi-square or Fischer's Exact Test was used to determine the

significance among the frequency data, SB, ESS, MM (RN and CRNA), and DMV. Sensitivity, Specificity, and correlation (Pearson's or Spearman's as indicated) were determined for SB, ESS, MM, and DMV.

Study Results

Description of Sample

Informed consent was obtained and data collected prospectively on 222 of 1648 patients scheduled for surgery over a 5 month period. Six patients did not have their surgery after completing the pre-anesthesia data collection (n=216). An additional 18 subjects had incomplete CRNA MM data which was irretrievable from the stored electronic anesthesia record. Those patients with missing CRNA MM scores were removed for that portion of the study (n=198).

Of this sample 71 subjects had attempted mask ventilation and 62 were intubated. Twenty three of the subjects who had mask ventilation attempted did not have DMV scores recorded. Five of the subjects requiring intubation did not have CL scores documented. None of this data were retrievable from the electronic anesthesia record. Those patients with missing DMV and CL scores were removed for that portion of the study (DMV n=48, CL n=57).

The study population (n=216) consisted of 20.8 percent males and 79.2 percent females. The two sample t-test was used to compare age, height, weight and BMI means by gender. The males were older ($p<0.05$), taller ($p<0.001$), and weighted more than the females ($p<0.01$), but body mass index (BMI) was not significantly different ($p=0.259$). The means for all men and women by height, weight and BMI can be found in the totals in Tables 1 and 2.

Within the study set there were 175 (81%) study subjects without a formal diagnosis of OSA and 41 (19%) patients with a prior diagnosis of OSA by a physician with a formal

polysomnogram. Demographics and data analysis was performed on these two subsets of subjects conjointly and independently. The two sample t-test was used to determine if there was a statistically significant difference between the mean age, height, weight and BMI of the diagnosed (n=41; m=13, f=28) and undiagnosed (n=175; m=32, f=143) OSA groups and by gender. Significant differences were noted. The OSA group was older (p=0.003), weighed more (p<0.001) and had a higher BMI (p<0.001). The data in Table 1 show that the males diagnosed with OSA weighed significantly more than their undiagnosed counterparts (p<0.001). As seen in Table 2 the females with diagnosed OSA were older (p=0.003), weighed more (p<0.001), and had a higher BMI (p<0.001) than the females undiagnosed with OSA.

Risk of Undiagnosed OSA

Positive STOP-BANG screening (SB \geq 3) identified probable OSA in 56.5 percent of the patients presenting to the hospital for surgery (Table 3). Of those patients diagnosed with OSA 39 of the 41 screened positive for OSA with the STOPBANG (p<0.001). Within the study population 41 subjects were formally diagnosed with OSA with a polysomnogram while 175 subjects were not. As seen in Table 4 of the 175 subjects not diagnosed with OSA, 83 screened positive for OSA based on their SB score (SB \geq 3). This represents a potential of 47.4 percent of undiagnosed OSA within the study population. Within this subset were 25 males (30.12%) and 58 females (69.88%). (Table 5) While there were more females than males in this subset, the incidence of males screening positive over females was significant (p<0.001). The potential incidence of undiagnosed OSA by gender was 78.13 percent for the males and 40.56 percent for the females.

Predicting Difficult Intubation by SB, ESS or MM

Intubation was performed on 62 of the 216 patients. Five subjects did not have the Cormak-Lehane score documented. Difficult intubation was identified in 12 of 57 subjects by CL criteria ($CL \geq 3$). One subject required an alternate form of intubation, i.e. Glidescope™, fiberoptic scope or awake intubation. There were no “failure to intubate” subjects. This represents a difficult intubation rate of 21.1 percent.

A positive STOPBANG ($SB \geq 3$) score was identified in 25 of the 57 subjects requiring intubation. Of these 25 subjects 8 were identified as “difficult to intubate” with $CL \geq 3$. The STOP-BANG questionnaire with a positive SB screening demonstrated moderate sensitivity and specificity for predicting difficult intubation, 66.7 and 60 percent respectively. (Table 6). The STOP-BANG scores ≥ 3 as demonstrated in Table 7 identified a significant positive correlation with $ESS \geq 9$, $RN\ MM \geq 3$, and $DMV \geq 3$. The STOP-BANG scores ≥ 3 were not correlation with $CL \geq 3$ or $CRNA\ MM \geq 3$.

The Epworth Sleepiness Scale with a positive screening ($ESS \geq 9$) identified 59 of the 215 (27.31%) patients as potential OSA. A positive ESS screening was identified in 14 of the 57 requiring intubation. Of the 14 ($ESS \geq 9$) requiring intubation 6 were identified as “difficult to intubate”. The $ESS \geq 9$ had a moderate sensitivity (50.00%) for predicting difficult intubation ($CL \geq 3$) and a high specificity (81.10%). As seen in Table 6 $ESS \geq 9$ was significantly associated with difficult intubation ($p=0.021$).

The Modified Mallampati score was recorded separately for patients in the study by the preoperative nurse (RN MM) ($n=214$) and the CRNA’s (CRNA MM) ($n=198$). The pre-operative nurses identified 88 of 214 subjects as having a MM greater than or equal to 3 score while the CRNA’s identified 41 of 198. The preoperative nurses identified 6 of 12 difficult to intubate

patients with a MM greater than or equal to 3.(Table 8) The CRNA's scored 2 of the 12 subjects who were difficult to intubate with a MM greater than or equal to 3. (Table 9) The preoperative nurse's MM ≥ 3 had a higher sensitivity than the CRNA's (50.00 vs. 16.70%) but a lower specificity (71.10 vs. 84.40%) for predicting difficult intubation. As seen on table 6 the CRNA MM ≥ 3 had the least agreement for predicting difficult intubation of all screening tools.

Predicting Difficult Intubation by Combining OSA Screening Test.

The OSA screening tool results were combined to see if any two tests could produce better sensitivity and/or specificity for predicting difficult intubation than either test individually. When combining the scores, ESS ≥ 9 or RN MM ≥ 3 had the highest sensitivity (100%) but 0 percent specificity (Table 10). The SB ≥ 3 or RN MM ≥ 3 had the second highest sensitivity (80%). The other combinations produced lower sensitivities that varied from 60 to 78 percent, and 0.00 percent specificity.

The Association between Difficult Mask Ventilation and STOP-BANG Screening and between Difficult Mask Ventilation and Difficult Intubation.

A Difficult Mask Ventilation score (DMV ≥ 3) was identified in 10 of 48 subjects who had mask ventilation attempted (20.8%). The study identified that 4 of the 11 difficult to intubate patients (CL ≥ 3) required some form of airway device or other assistance to maintain or attain adequate mask ventilation (DMV ≥ 3). The data showed that the STOP-BANG equal to or greater than 3 had a 90 percent sensitivity and 55.3 percent specificity in predicting difficult mask ventilation and that difficult mask ventilation (CL ≥ 3) demonstrated a sensitivity of only 36.4 percent and a specificity of 86.2 percent in predicting difficult intubation. The low sensitivities

indicates that the majority of those who were difficult to intubate were missed by the test for difficult mask ventilation.

Discussion.

Risk of Undiagnosed OSA

The study demonstrated a high risk within the elective surgical population in rural Kentucky of undiagnosed OSA (47.4%) as documented by a positive SB screening and a significant prevalence of diagnosed OSA (19.4%). The risk of undiagnosed OSA was not as high as the estimates of Young et al⁵ but the prevalence of diagnosed OSA was much higher than the estimated 3-5 percent.³⁻⁵ Overall, there were 122 patients out of 216 who screened positive for OSA (56.4%). The study appears to identify a high degree of potentially undiagnosed OSA within the adult population of rural Kentucky. Also, it supports the premise that patients with OSA present more frequently for elective surgery than is their prevalence in the general population.

The incidence of potential and diagnosed OSA in this study is significantly higher than the incidence in previous studies. When compared to the data reported by Stierer et al,⁷¹ this study found 9.9 times the incidence of potentially undiagnosed OSA (47.4% vs. 4.8%) and 4.3 times the incidence of diagnosed OSA (19.0% vs. 4.3%). Additionally, this study's population had 3.80 times the incidence of OSA as reported by Young et al.⁵ The substantial differences may be the result of the study's more diverse surgical procedure mix, a higher patient acuity level based on the ASA classification (III-IV) and OSA comorbidities, obesity, smoking, diabetes, and cardiovascular disease. Kentucky has a higher prevalence of the associated

comorbidities of OSA than Maryland or Wisconsin where the above identified studies took place.⁷²⁻⁷⁵

Farney et al⁶¹ and Chung et al,⁶² examined SB scores and their predictability for identifying patients with OSA. Both found as the SB score increased, so did the propensity of moderate to severe OSA. Farney et al found that a SB score greater than or equal to 3 had an 85.1 percent probability of having some form of OSA, mild to severe.⁶¹ This is consistent with the findings of Chung et al⁶ of an 83.6 percent of mild to severe OSA with a STOPBANG score greater than or equal to 3. Also, Chung et al⁶² found that for those patients with a SB greater than or equal to 3 compared to a SB less than 3 had an odds ratio (OR) of 3.01-3.56 to have OSA versus a SB less than 3. These two authors have validated the ability of the SB to predict OSA.

Predicting Difficult Intubation by SB, ESS or MM

This study found 8 of 12 (66.7%) patients who were difficult to intubate had a positive OSA screen (SB \geq 3) to include the 2 with known OSA. While OSA as defined by SB \geq 3 was not statistically associated with DI, OSA as defined as ESS \geq 9 was associated with difficult intubation ($\chi^2=5.309$, $p=0.021$). Obstructive sleep apnea (SB \geq 3) was correlated with the RN MM \geq 3, but not the CRNA MM \geq 3 ($p>0.001$). This study appears to support the findings of Hiremath et al³⁵ and Chung et al⁴⁰ that difficult intubation is associated with OSA. Hiremath et al³⁵ and Chung et al⁴⁰ examined subjects with known difficult intubation and evaluated them for OSA. Hiremath et al³⁵ performed a case control study on 15 subjects with known difficult airways and 15 controls to compare the incidence of OSA. They found that 53 percent of the subjects with difficult intubation had OSA. The difficult intubation group had a significantly higher AHI (28.4 ± 31.7) consistent with moderate to severe OSA ($p=0.02$). Hiremath et al³⁵

also found “Both difficult intubation and OSA were associated ($P < 0.05$) with a greater Mallampati score.” Chung et al⁴⁰ found that 66 percent of their difficult intubation patients had OSA confirming that finding of Hiremath et al.³⁵ This study could not confirm the findings of Hiremath et al³⁵ and Chung et al⁴⁰ regarding the association of $MM \geq 3$ with difficult intubation.

Several authors have identified an association between OSA and difficult intubation.^{35,36,40,46,76} This study identified a 32 percent rate for difficult intubation among the subjects screening positive with STOP-BANG (8 of 25) and a 42.86 percent rate for those screening positive with ESS (6 of 14). A 16.67 percent rate of difficult intubation was noted in the subgroup with known OSA (2 of 9). These rates of difficult intubation, while limited by being based on only a screening test, are quite similar to what Corso et al³⁶ and Lee et al⁷⁶ reported in their retrospective reviews. Corso et al³⁶ identified that 24 percent of their ENT patients who had OSA were difficult to intubate as opposed to just 3 percent of those patients without OSA. They concluded that OSA is associated with an increased risk of difficult intubation. Lee et al⁷⁶ found a similar difficult intubation rate of 20 percent for those patients with OSA when compared to Corso et al.³⁶

This study found the Modified Mallampati (≥ 3) to be more accurate in predicting difficult intubation in the hands of the pre-anesthesia nurses (sensitivity of 50%; specificity of 71%) as opposed to those of the CRNAs (sensitivity of 16.7%; specificity of 84.4%). Nevertheless, neither test alone was a very good predictor since so many who experienced difficult intubation were not identified by either test. This confirms the work of previous authors. Lundstrom et al⁷⁷ in their meta-analysis that found the MM exam to be unreliable as a standalone evaluation to predict difficult intubation, confirming the work done by Lee et al (2006).⁷⁸ The analyses which

looked at the possibility of improving the prediction of difficult intubation by combining two screening test showed a considerable improvement in sensitivity, that is identifying those who would have difficult intubation, but with a sacrifice in specificity and generating false positives.

The Association between Difficult Mask Ventilation and STOP-BANG and between Difficult Mask Ventilation and Difficult Intubation

This study found a correlation between OSA ($SB \geq 3$) and $DMV \geq 3$ ($p < 0.01$) but not $DMV \geq 3$ and $DI (CL \geq 3)$. Kheterpal et al prospectively recorded the Han DMV scores and difficult intubation scores of 22,600 patients.⁴⁶ They found OSA and a MM of 3 to 4 to be independent predictors of a grade 3 DMV. Additionally, they confirmed that OSA and a MM score of 3 to 4 to be consistent with difficult intubation. In 2009 Kheterpal et al. in a follow on study of 50,000 subjects established the findings that patients with OSA and a MM score greater than or equal to 3 were at increased risk for being difficult to intubate.⁷⁹ Plunket et al⁴⁷ evaluated 10 known DMV ($DMV \geq 3$) patients with polysomnography to confirm whether or not they had OSA. They identified that 8 of 10 subjects had confirmed OSA and 1 subject had sleep disordered breathing. This present study supports the findings of Kheterpal et al⁴⁶, Kheterpal et al⁷⁹ and Plunket et al⁴⁷ regarding the association of DMV and OSA.

This work has several limitations. The first is related to the study demographics. The study size is limited ($n=216$). A larger study population would increase the power of the study. The demographics of the study population (rural Kentucky) may not represent those populations in other areas (rural or urban USA). More females consented to the study and the data may not represent the true gender demographics. Secondly, there is some evidence of a selection factor in who participated. Two patients refused to participate as they were over-the-road truck drivers

and “felt” they had OSA. Current state law prohibits over-the-road truck drivers who have OSA from participating in this occupation. Therefore, they refused to participate, being concerned that they might be identified as having OSA. The prospective nature of this study limited the number of subjects. Had this study been conducted retrospectively, all patients presenting during the 5 month study period would have been candidates. This larger data pool would have yielded more accurate demographic information. Thirdly, the PI was unable to get any of the subjects screening positive for OSA to consent to have a polysomnogram and possibly confirm OSA. Fourthly, inter-rater reliability between the pre-anesthesia nurses and CRNAs was fair.⁸⁰

There are several avenues for further work. A larger study examining the demographics of diagnosed and undiagnosed OSA in the rural health community is warranted. Further study should include evaluating the association of OSA, DMV ESS, and difficult intubation to include perioperative outcomes. Finally, evidenced based protocols for managing the patient who screens positive for OSA and OSA patients after they present for surgery need to be given more attention.

Conclusion

The risk of undiagnosed OSA as identified by a positive SB screening in this rural Kentucky elective surgical population is 47.4 percent. The incidence of diagnosed OSA (19.0%) and DI (21.1%) is higher in this population than others. Patients with undiagnosed OSA present to the surgical arena at a disproportionate rate than is their prevalence in the general population. The Epworth Sleepiness Scale with a score greater than or equal to 9 was statistically associated with difficult intubation. The SB and MM screening tools were not strong predictors of difficult intubation in this population. However, when they were combined, they were more successful in

identifying cases but with a loss in specificity and, thus creating false positives. It should be noted that $SB \geq 3$ and $ESS \geq 9$ had a higher sensitivity than $RN\ MM \geq 3$ or $CRNA\ MM \geq 3$ in predicting $DI\ (CL \geq 3)$.

In this study 56.4 percent of the surgical population screened positive for OSA (to include those with know OSA). Rural Kentucky has a higher than the expected incidence of OSA. It is imperative for anesthetists with similar populations at high risk for OSA to anticipate a high volume of OSA patients. They present to the surgery department more frequently than is their prevalence in the general population. Pre -anesthesia screening for OSA can be recommended based on these findings. This should include training registered nurses who work in this area to screen for potential airway problem.⁸⁰ Patients presenting with OSA for surgery are at increased risk for perioperative respiratory complications. Identifying these OSA patients and implementing some formalized plan to manage their care is indicated.

Given the association reported in the literature between difficult ventilation and OSA, it would seem prudent that the anesthetist attempt to ventilate OSA patients prior to intubation and evaluate the degree of difficult mask ventilation. If the patient proves difficult to ventilate or requires a second person to help ensure ventilation, then a difficult endotracheal intubation can be anticipate.

The data analysis for this paper was generated using SAS software, Version 9.3 of the SAS System for Windows. Copyright © 2102 SAS Institute Inc. SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc., Cary, NC, USA.

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Tables

Table 1 Means of Males Age, Height, Weight and BMI by OSA diagnosis

Male	Number	Age	Height	Weight	BMI
Total	45 (20.8%)	56.64 ± 2.40	70.42 ± 0.49	212.84 ± 6.13	30.82 ± 1.04
(+OSA)	13	57.62 ± 4.54	70.92 ± 1.07	242.39 ± 12.33*	33.85 ± 1.45
(-OSA)	32	56.25 ± 2.86	70.22 ± 0.54	200.84 ± 5.92	29.59 ± 1.29

* (p<0.001)

Table 2 Means of Female Age, Height, Weight and BMI by OSA diagnosis

Female	Number	Age	Height	Weight	BMI
Total	171 (79.2%)	48.57 ± 1.28	64.06 ± 0.21	189.25 ± 4.34	32.52 ± 0.72
(+OSA)	28	57.18 ± 2.86**	63.61 ± 0.42	226.36 ± 8.10*	39.68 ± 1.46*
(-OSA)	143	46.89 ± 1.38	64.17 ± 0.23	181.99 ± 4.72	31.12 ± 0.76

* (p<0.001)

** (p<0.003)

Table 3 Frequency and Percentage of Study STOP-BANG Screening

	Frequency	Percentage
STOPBANG <3 (Negative)	94	43.5
STOPBANG ≥ 3 (Positive)	122	56.5
Total	216	100

Table 4 Frequency and Percentage of STOP-BANG Screening of undiagnosed OSA

	Frequency	Percentage
STOPBANG <3 (Negative)	92	52.6
STOPBANG ≥ 3 (Positive)	83	47.4
	175	100

Table 5 Frequency of STOP-BANG screening positive or negative for OSA by Gender

Gender	Negative (SB<3)	Positive (SB≥3)	Total (% Screening Positive)
Male	7	25* (30.12%)	32 (78.13%)
Female	85	58 (69.88%)	143 (40.56%)
Total	92	83 (100%)	175

*(p<0.001)

Table 6 Sensitivity, Specificity, and p value of OSA Screening Tools for Predicting Difficult Intubation

	Sensitivity (%)	Specificity (%)	P value
SB \geq 3	66.70	60.00	p =0.1169
ESS \geq 9	50.00	81.80	p = 0.0241*
RN MM\geq 3	50.00	71.10	p = 0.1680
CRNA MM \geq 3	16.70	84.40	p = 0.6306
DMV \geq 3	36.40	86.20	p = 0.1170

* Significant p value

k= 0.276 for RN MM \geq 3 and CRNA MM \geq 3

Table 7 Distribution of Difficult Ventilation by STOP-BANG < 3 or \geq 3

	Difficult Ventilation	Not Difficult Ventilation	Total
STOPBANG 3 or more	9*	21	30
STOPBANG 2 or less	1	17	18
Total	10	38	48

Sensitivity 90%; Specificity 55.3%, p=0.011

Table 8 Distribution of RN Modified Mallampati Score by Difficulty of Intubation

	Difficult Intubation	Not Difficult Intubation	Total
RN MM 3 or more	6	13	19
RN MM 2 or less	6	32	38
Total	12	45	57

Sensitivity 50%; Specificity 71.1%

Table 9 Distribution of CRNA Modified Mallampati Score by Difficulty of Intubation

	Difficult Intubation	Not Difficult Intubation	Total
CRNA MM 3 or more	2	7	9

CRNA MM 2 or less	10	38	48
Total	12	45	57

Sensitivity 16.7%; Specificity 84.4%

Table 10 Sensitivity and Specificity of Pairwise Predictability of OSA Screening Tools

Pairwise Tools	Sensitivity	Specificity
SB\geq3 or ESS\geq9	60	0
SB\geq3 or CRNA MM\geq3	78	0
SB\geq3 or RN MM\geq3	80	0
ESS\geq9 or CRNA MM\geq3	71.4	0
ESS\geq9 or RN MM\geq3	100	0
CRNA MM\geq3 or RN MM\geq3	71.4	0

Figures

Figure 1 Cycle of Sleep Apnea

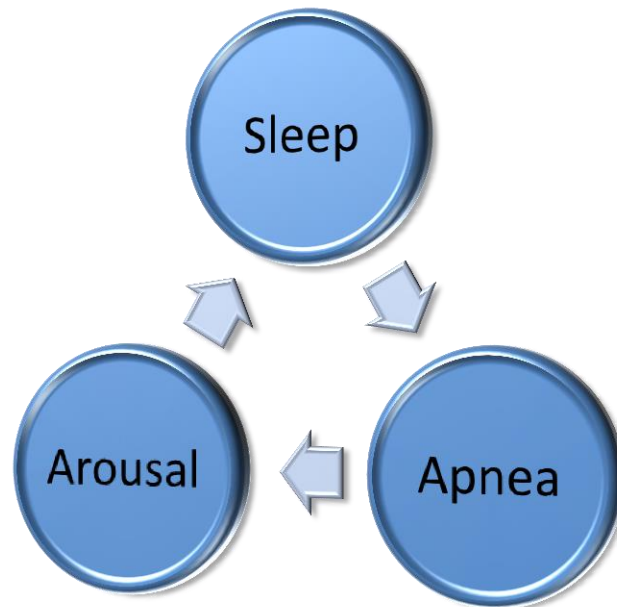


Figure 2 STOPBANG Questionnaire

STOPBANG Questionnaire

Answer **Yes** or **No** to the following questions

- (S) Do you snore loudly enough to hear through a closed door?
- (T) Do you often feel tired, fatigued or sleepy during the daytime?
- (O) Has anyone observed you stop breathing during sleep?
- (P) Have or are you being treated for high blood pressure?
- (B) BMI greater than 35?
- (A) Age greater than 50 years?
- (N) Neck circumference greater than 17 inches or 40 cm?
- (G) Gender male?

Figure 3 Epworth Sleepiness Scale

Epworth Sleepiness Scale

How likely are you to doze off or fall asleep in the following situations? Even if you have not done some of these things recently, try to answer on how these activities may affect you. Use the following scale to choose the most appropriate response for each situation: (Choose only one response for each question)

Never doze	0
Slight chance of dozing	1
Moderate chance of Dozing	2
High Chance of Dosing	3

1. Sitting and reading
2. Watching television
3. Sitting, inactive in a public place (e.g., a theatre or a meeting),
4. As a passenger in a car for an hour without a break,
5. Lying down to rest in the afternoon when circumstances permit,
6. Sitting and talking to someone,
7. Sitting quietly after a lunch without alcohol,
8. In a car, while stopped for a few minutes in traffic,

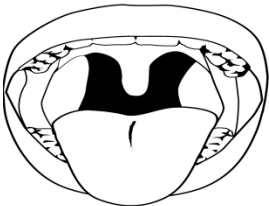
Figure 4 Modified Mallampati Score

Modified Mallampati Score

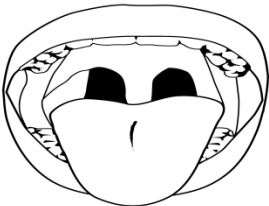
The Mallampati score is based on the visualized structures of the posterior pharynx to include uvula, faucial pillars, and soft palate. Criteria include:

1. Able to visualize full uvula, soft palate and faucial pillars.
2. Able to visualize partial soft palate and faucial pillars, uvula masked by base of tongue.
3. Able to visualize soft palate only.
4. Unable to visualize any posterior pharynx structures, tongue only.

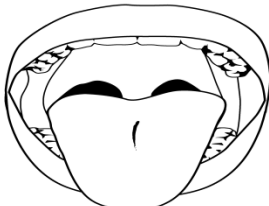
Class 1



Class 2



Class 3



Class 4

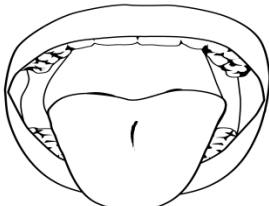


Figure 5 Han Difficult Mask Ventilation Score





Difficult Mask Ventilation Score

0. Mask ventilation, did not attempt
1. Easy mask ventilation
2. Mask ventilation with oral airway device
3. Difficult mask ventilation, unstable or requiring 2 persons
4. Unable/impossible mask ventilation.

Figure 6 Cormack-Lehane Difficult Intubation Score

Cormack-Lehane Difficult Intubation Score

1. Able to visualize entire larynx, arytenoids, chords, true and false, epiglottis superior to chords.
2. Chords partially obstructed from view with epiglottis, arytenoids visible.
3. Epiglottis visible only.
4. Soft palate visible only.

Grade 1	Grade 2	Grade 3	Grade 4
			

Capstone Report Conclusions

Obstructive Sleep Apnea is a growing worldwide healthcare problem. In this study 56.4 percent of the surgical population screened positive for OSA (to include those with know OSA). Rural Kentucky has a higher than the expected incidence of OSA. It is imperative for anesthetists with similar populations at high risk for OSA to anticipate a high volume of OSA patients. They present to the surgery department more frequently than is their prevalence in the general population. Pre -anesthesia screening for OSA can be recommended based on these findings. This should include training registered nurses who work in this area to screen for potential airway problem. Patients presenting with OSA for surgery are at increased risk for perioperative respiratory complications. Identifying these OSA patients and implementing some formalized plan to manage their care is indicated.

The Lean model is a viable theoretical framework which has been documented to facilitate patient flow though the operative process. Nurse anesthetists can use Lean concepts to improve the surgical work environment. Standardizing work task, eliminating waste and smoothing the work load are “value” adding activities that can and should occur in the surgical suite. However, accomplishing these tasks requires coordination amongst all intra and extra facility stakeholders. Nurse anesthetist as leaders with expert power should and can facilitate this process. Training CRNA’s to use the “Lean Model” would afford them tools to implement quality improvement changes. The preoperative clinic seems to offer the most assistance in minimizing delays and cancellations. The elimination of first case tardiness may not be the most financially rewarding aspect of streamlining the operative process, but may offer intrinsic satisfaction rewards to patient, staff and surgeon

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