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BEST PRACTICE POLICY RECOMMENDATION OF LARYNGEAL MASK AIRWAY MANOMETRY USAGE TO REDUCE INTRA-OPERATIVE COMPLICATIONS

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by

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ABSTRACT

Laryngeal mask airway (LMA) devices are a vital aspect of modern anesthesia practice. Unfortunately, even the simplest of airway management devices can lead to the development of negative pharyngeal-laryngeal patient consequences by over-inflation of the cuff on the LMA device. While these airway injuries are certainly harmful to the patient, they are preventable. With the utilization of manometry monitoring intra-operatively, the potential occurrences of these postoperative complications can be decreased, leading to better patient care and higher satisfaction for the healthcare facility and its stakeholders.

The current practice of measurement for LMA intra-cuff pressure intra-operatively is largely subjective, and there is still currently no standard in place for ideal monitoring of these intra-cuff pressures for safe usage. The purpose of this doctoral project was to further identify discrepancies among anesthesia providers to determine assessment methods among providers and the barriers to the implementation of manometry usage to providers in practice. The doctoral project utilized evidence identified in the review of the literature to develop a best practice policy to encourage increased manometry monitoring usage intra-operatively in order to reduce post-operative complications from increased LMA intra-cuff pressures to present to a clinical affiliate, which is a facility that offers clinical experience for student nurse anesthetists, lacking such a policy. An anonymous Qualtrics© survey was disseminated to Mississippi CRNAs concerning LMA intra-cuff assessment methods. The data was collected, and the survey was analyzed for common themes and differences. From this data and an extensive literature review, a best practice policy was created. An educational module

with the proposed best practice policy was also prepared and presented to the doctoral project committee for final suggestion on the effectiveness of the educational module if the doctoral project information was of high quality, and if the proposed best practice policy would benefit a clinical affiliate of The University of Southern Mississippi (USM).

ACKNOWLEDGMENTS

We would like to express sincere thanks to our committee chair, Dr. Mary Jane Collins for all her support and guidance. We would also like to express appreciation for the assistance of our committee member, Dr. Nina McLain. Finally, we would like to thank all the anesthesia providers who participated in our doctoral project's survey.

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LIST OF ABBREVIATIONS

AACN	American Association for Colleges of Nursing
CMS	Centers for Medicaid and Medicare Services
CRNA	Certified Registered Nurse Anesthetist
DNP	Doctor of Nursing Practice
ETT	Endotracheal Tube
IRB	Institutional Review Board
LMA	Laryngeal Mask Airway
SAD	Supraglottic Airway Device
USM	The University of Southern Mississippi

CHAPTER I - INTRODUCTION

Laryngeal mask airways (LMAs) can easily be misused in everyday anesthesia practice, despite their ease of handling. An LMA is a supraglottic airway device (SAD) that is commonly used when securing a patient's airway that requires a general anesthetic for surgical surgery. LMAs can be inserted into the posterior pharynx to allow for spontaneous ventilation and oxygenation. These airway devices can allow for the administration of inhalation anesthetic gases without the need for an endotracheal tube and can also be utilized in emergency airway algorithms or situations (Doyle, 2019). However, this type of anesthetic airway can generate a multitude of complications that result from an over-inflation of the LMA intra-cuff by producing excessive pressure on soft tissues, nerves, and other airway anatomy. Subjective assessments or units of measurement of intra-cuff pressures of the airway device have been determined to be inadequate to the actual intra-cuff pressures as these pressures are not routinely gauged and monitored in many healthcare institutions (Castro & Gopalan, 2016). Subjectivity can result in careless inflation or lack of adjusting the intra-cuff pressure after insertion leading to patient and hospital complications that can include but are not limited to sore throat, nerve damage, dysphagia, dysphonia, and swelling to the airway.

These human errors have been shown as the likely cause of these post-operative airway complications of elevated LMA intra-cuff pressure beyond those of the recommended ranges. With the practice and usage of manometry monitoring, anesthesia providers can measure intra-cuff pressures quickly and inexpensively. The manometry monitoring devices have been evidenced to decrease the occurrences of unfavorable pharyngeal-laryngeal consequences after LMA insertion and could notify the anesthesia

provider with a fast and precise reading of the intra-cuff pressure as to remain within the LMA to the recommended intra-cuff pressure ranges.

The intention of this doctoral project was to develop a best practice policy to implement the increased usage and education of intraoperative manometer equipment in anesthesia healthcare settings in which LMA devices are most utilized. Increasing evidence supports that monitoring and reducing intra-cuff pressures of LMAs can decrease pharyngeal-laryngeal complications with the usage of manometry monitoring. Manometry monitoring, combined with anesthesia provider education, may promote higher quality patient outcomes and increased satisfaction rates.

Background

The usage of manometry monitoring can assure that the LMA intra-cuff pressures do not exceed the maximum range for the patient. By utilizing this monitoring device in practice, the potential for patient post-operative complications can decrease leading to better patient care and higher satisfaction for the healthcare facility and its stakeholders. While many components may influence the increased occurrences of post-operative airway traumas to the patient, it is important to understand the role of the anesthesia provider in the potential complications. There has been a nonuniformity among anesthesia providers regarding manometry monitoring of intra-cuff pressures despite the most recent evidence-based research proving the benefit and success of lessening or diminishing patient complications (Castro & Gopalan, 2016).

To evolve and guide the current anesthesia practice, it is essential to determine what influences are impacting provider application concerning intra-cuff pressure in order that appropriate recommendations may be established to create a more consistent

environment with similar patient outcomes. Assessing the anesthesia providers' knowledge of the most current literature and training regarding the outcomes of improper inflation methods or over-expansion of the LMA cuff beyond 60 cm H_2O should be assessed to determine the potentiality of post-operative patient complications. Understanding the correlation can presumptively decrease these negative experiences for the patient and the financial ramifications for the healthcare institutions.

Statement of the Problem

The current practice for measurement of LMA intra-cuff pressure intra-operatively is largely subjective, potentially leading to negative consequences for patients and healthcare stakeholders. These repercussions could lead to an increased likelihood of patient injury that would negatively affect patient outcomes and could cause an increase in expenditures for patients and the facility. Based on evidenced-based best practice literature of LMA intra-cuff insufflation and data obtained from a survey sent to anesthesia professionals regarding LMA intra-cuff pressure monitoring, a policy was created and presented to anesthesia administration at a USM clinical affiliate lacking such a policy, which is to implement the increased usage and education of intra-operative manometer equipment in anesthesia healthcare settings in which LMA devices are most utilized.

Significance of the Project

Even though this airway device has been in anesthetic usage for many decades, there is still currently not a standard in place for ideal monitoring intra-operatively of intra-cuff pressures for safe usage in these supraglottic airway devices (Letvin et al., 2018). The two most common methods for assessing LMA intra-cuff pressures are using

tactile digital palpation of the balloon pilot of the airway device or utilizing manometry monitoring for direct measurements (Letvin et al., 2018). The overall goal of LMA intra-cuff pressure monitoring is to maintain the intra-cuff pressures in a range between 20 and 60 cm H_2O. Intra-cuff pressures exceeding 60 cm H_2O have been associated with numerous, avoidable, and costly complications to the patient and the healthcare stakeholders involved in the entire surgical experience.

Approximately 70% of LMA intra-cuffs are surpassing the maximum recommended pressure as current evidence-based studies have revealed that anesthesia providers are still routinely overinflating (Bick et al., 2014). This data might imply an unawareness of the anesthesia practitioner of actual and recommended LMA intra-cuff range pressures for the patient that this device could monitor. This data could also imply a lapse in the reassessment of the airway or an incompetent education concerning measuring equipment devices. Additional exploration and research regarding the diverse post-operative complications due to increased LMA intra-cuff pressures could generate best practice changes and policy development within an anesthesia department.

Available Knowledge

A thorough exploration of the foundational characteristics of the LMA device, insertion techniques, challenges arising to patients and stakeholders from complications, and the effectiveness of the use of manometry monitoring with the device in the operating room was conducted. Thorough informal discussions took place with clinical preceptors at USM clinical affiliates and a literature examination for current information regarding the subject was conducted. This comprehensive review of the literature was performed to

obtain the most recent and accurate information relating to the subjects under consideration.

The following databases were searched and utilized: CINAHL, EBSCOhost, MEDLINE, and Google Scholar. Key search-words included: supraglottic airway, laryngeal mask airway, LMA, laryngeal mask airway complications, manometer, and intra-cuff monitoring. The initial search yielded 309 articles between the years 2008 and 2019. Numerous studies were examined and reviewed for relevance and accuracy. 17 articles and references were obtained and recorded in a literature matrix to include in this project (Appendix B). The data was thoroughly reviewed and developed into a policy recommendation for measuring LMA intra-cuff pressures with manometry monitoring.

LMA

Dr. Archibald Brain invented the LMA in 1981 as a method to ventilate the lungs without having to hold a facemask over the patient's face during a surgical procedure (Barash et al., 2017). This airway device reduced provider fatigue and consequently led to an increase in patient ventilation and oxygenation. These devices also sealed the larynx and kept the airway clear of secretions. Though the LMA was being used in practice in the United Kingdom, the Food and Drug Administration did not approve usage in the United States until 1991 (Barash et al., 2017).

There are several circumstances for selecting an LMA in practice. These circumstances include utilizing the device after a failed intubation with an endotracheal tube (ETT), facilitation of a bougie or ETT into the trachea, or allowance of spontaneous ventilation to patients of low-risk regurgitation while still allowing anesthetic gasses to pass through the device (Nickson, 2019). Evidence has indicated that this airway device

is accompanied by less pharyngeal-laryngeal complications to the patient versus an endotracheal tube and often allows for a smoother emergence (Barash et al., 2017).

There are a variety of designs and abilities of the LMA devices. A seminal reference has found that the most well-known and frequently used LMA model is constructed of a rubber shaft that opens at the distal end of the device into an oval-shaped inflatable mask that is designed to fit inside a patient's hypopharynx to create a seal (Dorsch & Dorsch, 2008). The mask has a smooth upper surface for the prevention of pharyngeal secretions that potentially enters the patient's larynx. The shaft and the mask of the LMA device are fused, forming a 30-degree angle. There are slots at the connection of the shaft and mask that inhibit the patient's epiglottis from obstructing the device's opening (Griner, 1996). A self-sealing pilot balloon and pilot tube are attached to the proximal end of the mask for inflation of the device.

LMA Size

The current recommendations for choosing the correct LMA size are based upon the weight in kilograms of the patient. The appropriate sizing for LMAs is presented in Table 1. As patients may be of a certain weight range but have other factors influencing LMA selection, it is essential to provide the availability of other sizes for insertion before anesthesia induction. A standardized LMA size should not be chosen based on gender. Current literature has suggested that smaller, incorrectly fitting devices can decrease the likelihood of obtaining a proper seal in the pharynx and may result in an anesthetic gas leak during positive pressure ventilation (Dorsch & Dorsch, 2008). In contrast, an LMA that is too large for the patient will not accurately seat in the hypopharynx and increase

the incidences of pharyngeal-laryngeal trauma such as mucosal ischemia or temporary lingual, hypoglossal, or recurrent laryngeal nerve paralysis.

Table 1

LMA Size

LMA Size	Patient Selection Guidelines	Maximum Cuff Inflation Volume (mL)
1	up to 5 kg	4
1.5	5-10 kg	7
2	10-20 kg	10
2.5	20-30 kg	14
3	30-50 kg	20
4	50-70 kg	30
5	70-100 kg	40
6	>100 kg	50

Note. (Evans, 2010).

Insertion Techniques

There are numerous and opposing methods of inserting an LMA device, all of which can seal the hypopharynx. Insertion methods are largely based on the provider's preference. However, a few of these approaches can lead to device malposition and airway obstruction or over-expansion of the inflatable mask causing pharyngeal-laryngeal trauma. These methods were examined, including the current insertion recommendations.

As with any procedure, a patient assessment must be completed prior to anesthesia to determine any contraindications for utilizing the LMA device, an overall airway assessment must be performed, and the correct size of the LMA must be chosen. The standard and most common technique for insertion begins with placing the patient in sniffing position with the head extended and flexion of the neck. Butterworth, Mackey, and Wasnick (2013) recommend that the LMA cuff be fully deflated with a non-

anesthetic lubricant applied to the posterior side of the cuff. The leading edge of the cuff should be without wrinkles and facing away from the mask aperture. The anesthesia provider then guides the cuff along the hard palate and down the patient's hypopharynx until increased resistance is felt (Butterworth et al., 2013). The LMA cuff should then be inflated with an amount of air appropriate to the size inserted to achieve an effective seal.

An alternative method of insertion includes rotating a partially or fully inflated LMA cuff in a 180-degree technique. The same method is utilized as above with the only variation being a rotation occurring within the oropharynx and then advancing the device into the hypopharynx (Nagelhout & Plaus, 2014). Literature has stated that this manner of insertion with a fully inflated LMA cuff has a lower incidence of patient complaints of dysphagia and expectorant blood in the pharynx (Middleton, 2009). This reduction in dysphagia and expectorant blood in the pharynx suggests a lower incidence of pharyngeal-laryngeal trauma.

A final insertion technique has also been found to have a decreased percentage of dysphagia among patients. This method involves inserting the LMA device midline into the oropharynx, rotating 90-degrees counter-clockwise until resistance is met, and then rotating the device 90-degrees back into midline position into the hypopharynx (El-Boghdadly et al., 2016). No research evidence was recorded concerning patient complications with this insertion method.

Cuff Pressures

SADs require the insertion of air into the pilot balloon to inflate the device's intra-cuff. Once inflated, these intra-cuffs create a seal in the hypopharynx to allow for optimal ventilation for spontaneous ventilation during a surgical procedure. Current literature has

stated that over-inflation of LMA intra-cuffs can exert unintended pressure on pharyngeal-laryngeal structures leading towards complications and/or trauma such as postoperative sore throat, hoarseness, blood-streaked expectorant, among others (Ashman et al., 2017). It is recommended that LMA intra-cuff pressures not exceed 60 cm H_2O (44 mm Hg). LMA intra-cuff pressures inflated at the recommended ranges reduce the incidence of the above complications (Ashman et al., 2017).

Despite LMA manufacturers' endorsements of maximum air volume that can be injected into a cuff, various research has disputed these recommendations. Research has found that the maximum volume of air inserted does not correspond with the appropriate LMA intra-cuff ranges due to the injected pressure from the anesthesia provider, because this maximum volume more than doubles the recommended 60 cm H_2O of pressure (Bick et al., 2014). Additionally, some anesthesia providers will palpate the pilot balloon pressure with his or her fingers once air is injected, using a subjective measurement system for the intra-cuff pressures (Ashman et al., 2017). This estimation method has been shown to be an ineffective approach regardless of the provider's number of years in practice or experience which has the increasing likelihood of pharyngeal-laryngeal post-operative trauma to the patient (Ashman et al., 2017). The routine usage of manometers for monitoring pressures has been proven to accurately calculate and maintain LMA intra-cuff pressures at the recommended ranges to assist in reducing these patient complications (Ashman et al., 2017).

Manometers

A manometer is a small device that quickly measures SAD intra-cuff pressures in patients which could potentially further reduce the risk of increased intra-cuff pressure

effects of dysphonia, dysphagia, mucosal ischemia, or nerve damage (Bick et al., 2014). The manometer connects to the end of the LMA pilot balloon to measure the intra-cuff pressure. These devices are an effective means to examine LMA intra-cuff pressures to prevent them from exceeding 60 cm H_2O.

The devices range in cost from $200 to $500 each and can last for a considerable number of years while being reliable, accurate, and easy to use with minimal maintenance required (Ashman et al., 2017). However, there is currently no standard of how or when to check intra-cuff pressures as intra-cuff pressures can change due to patient positioning, duration of the procedure, or a change in airway anatomy such as with swelling (LeCroy, 2014). Continuous manometry monitoring is recommended as these devices not only monitor intra-cuff pressures but also adjust the volume of air in the cuff automatically, ensuring the precision of measurements and success of patient safety (LeCroy, 2014).

In a randomized research study, patients who received LMAs for surgery were grouped and compared. The first group was assessed utilizing digital palpation of the pilot balloon for intra-cuff pressure measurement versus the second group whose LMAs were monitored with continuous manometry for pressure measurement (Hensel et al., 2016). In the palpation group, 37% of patients experienced post-operative pharyngeal-laryngeal complications compared to only 12% of the trial population in the continuous manometry group (Hensel et al., 2016). This study demonstrated that digital palpation yielded inaccurate LMA intra-cuff pressure measurements and was associated with an increased incidence of post-operative pharyngeal-laryngeal complications, though without increased severity or duration (Hensel et al., 2016). The manometry group also

reported higher patient satisfaction scores, stating that they would repeat their surgical operative experience with an LMA.

This study was one of many that suggested that utilizing a manometer routinely to monitor and calibrate LMA intra-cuff pressures to the appropriate pressure ranges to administer better care for surgical patients. Another study presented that half of the participating anesthesia providers (49.4%) had never been trained in the usage of manometry and 10.3% of the providers were unaware of how to use the device (Hensel et al., 2016). This study identifies an inadequacy in anesthesia education and training that needs to be acknowledged for safer patient care when utilizing LMAs.

Patient Complications

As there is no standard of practice for LMA intra-cuff monitoring, a potential of physical postoperative complications for the patient can occur. These complications can range from a sore throat, hoarseness, sore neck, dysphagia, venous neck congestion, arytenoid cartilage dislocation, lingual nerve damage, jaw tenderness, and mucosal ulceration and bleeding (Ashman et al., 2017). To put this in perspective, at 30 cm H2O of intra-cuff pressure, mucosal, and soft tissue perfusion can become reduced in patients (Castro & Gopalan, 2016). Beyond physical damage to the patient, over-inflation of the LMA intra-cuff may also result in impairment of the airway seal, as the LMA cuff should conform to the patient's laryngeal tissue rather than the soft tissue conforming to the LMA cuff to seal properly in the airway. Ventilation can still be achieved through an improper seal; however, it involves the risk of aspiration of secretions, blood, or regurgitant into the airway (Bick et al., 2014). Pulmonary morbidity will vary with the type and amount of aspirate. Effects from these aspirations range from but are not limited

to: cough, laryngeal spams, tracheal irritation, pulmonary edema, airway obstruction, fibrinous changes, chemical pneumonitis, hypoxemia, atelectasis, epithelial degeneration, and possible acute respiratory distress syndrome (Barash et al., 2017).

Increased Cost to Stakeholders

Along with the patient's potential physical complications to the excessive inflation to the LMA intra-cuff, the healthcare facility stakeholders may also accrue increased expenses as a direct result of these complications. These physical complexities can result in the patient remaining in an extended hospital course from the surgical and airway injury. The negative pharyngeal-laryngeal symptoms will possibly need to be diminished by an increased quantity or dosages of post-operative medications to additionally comfort the patient. Possible loss of working hours to the patient or caregivers of the patient may occur due to these longer hospital course stays and post-operative recovery time. Furthermore, supplemental surgery may become needed to repair potential trauma of the soft tissues in the patient's airway continually decreasing the overall patient satisfaction rates with the surgical team and treatment plans (Ashman et al., 2017). Satisfaction rates can highly impact hospital perceptions and values. Though these consequences of patient airway incidences from LMA intra-cuff pressures may be rare occurrences, even negligible injuries such as a postoperative sore throat can have considerable costs to stakeholders and may increase these expenses to the facility in the future. A simple sore throat could have a major impact on the hospital's patient satisfaction score, which can have a negative impact on hospital reimbursement and reputation within the community.

According to Falco, Rutledge, and Elisha (2017), Centers for Medicaid and Medicare Services (CMS) utilize a standardized patient satisfaction criterion for policy and guideline purposes. CMS utilizes results from patient surveys and hospital readmissions to regulate incentive payments to healthcare facilities. These payments potentially imply that the patients' survey responses may be calculated to influence future anesthetic reimbursements (Falco et al., 2017). Furthermore, anesthesia providers and healthcare establishments increase the threat of litigation related to injuries the patient sustains during the perioperative period as well as a damaged reputation the facility incurs which may reduce future funding and revenue (Ashman et al., 2017). It is already understood that patients' perspectives of the healthcare providers and the relationships before, during, and after his or her surgical procedures play a major role in decisions to pursue litigation should any incidents occur during the procedure (Falco et al., 2017).

Policy in Healthcare

Bick et al. (2014) have claimed that the LMA has quickly become the preferential airway device by many anesthesia providers for a predominance of many general anesthetic surgeries. The most recent evidence-based literature has indicated that while older data may show that at least 35% of general anesthesia is performed with supraglottic airway devices, such as the LMA, more current data has implied that an LMA is used in approximately 56% of general anesthesia cases (Barash et al., 2017). Considering the increased utilization of the LMA and the potential negative outcomes associated with the airway intra-cuff over-inflation, it may be appropriate to incorporate evidence-based policies and applicable guidelines into healthcare facilities where these anesthetic airways are most utilized.

Healthcare policies are intended to guide actions and provide clear instructions to achieve suggested outcomes to potentially result in a higher quality of care to patients. These policies can establish a point of educational reference and be modified as new evidence-based knowledge is identified. They are also a means of accordance with current clinical practice to facilitate a decreased occurrence of patient complications that may arise.

Barash et al. (2017) has claimed that institutional policies and healthcare guidelines are an indispensable organizational component that is oftentimes overlooked (Barash et al., 2017). These guidelines are a necessity for each anesthesia department and facility with consideration to locations and anesthesia specialty. All procedural anesthesia environments should have a policy manual concerning that particular location component containing references and evidence-based recommendations pertaining to responses for particular adverse airway circumstances (Barash et al., 2017). Some anesthesia facilities fail to have such a comprehensive policy manual detailing a plan of action in such situations to which an increase of patient incidences can potentially occur.

Conclusion

Pre-operatively, patients are educated and consented on the risks and benefits pertaining to anesthesia before surgery, which includes airway complications from inserted anesthesia devices. These incidences and complications, however, can potentially be reduced or nullified through manometry monitoring and education when utilized correctly by anesthesia providers. With this information, an evidence-based best practice policy based on the usage of a manometer has the potential to minimize the severity of increased LMA intra-cuff pressures.

Rationale

As a manner of guiding appropriate care and to decrease these complications, a best practice policy was developed based upon an evidence-based standard of care across healthcare establishments. Creating this new best practice policy is an integral approach to protect a point of care in the operating room for anesthesia providers who are caring for patients with particular airway devices. Policies and procedures are more than generalized guidelines as these are a set of expectations and proper techniques of performing duties and most importantly, these are a means of helping to promote consistencies in clinical anesthesia practices to reduce incidences to keep patients safe perioperatively (Irving, 2014).

This best practice policy has the potential to assist the healthcare establishments to manage and reduce patient risks from post-operative airway injuries due to excessive LMA intra-cuff pressures. If a patient lawsuit due to an anesthesia incident were to occur, policies and procedures could potentially minimize liability to the facility and the provider if proper education and processes were in place. These policies in place further have the potential to motivate the providers to learn and follow the most evidence-based literature for LMA insertion and maintenance by increasing and utilizing continuous manometry throughout the surgery (Irving, 2014).

Framework Theory

A seminal study by Donabedian (2005) created a framework of structure, process, and outcomes which was utilized for understanding the principle of this research and used as a model for surveying anesthesia professionals as an approach for evaluating quality patient care. This framework theory recognizes that structure information affects

process measures, which in turn affect outcome developments. To further define the theory, the structure information is the input for the research.

For the best practice policy proposal, this information is the responses obtained from the survey of anesthesia professionals. These responses include the current practices and knowledge regarding LMA intra-cuff pressure monitoring. The process measures are an essential quality improvement tool as it describes whether or not anesthesia providers have implemented the proposed policy for LMA manometry monitoring. These measures are a means of potential clinical practice change and positive patient outcomes. The outcome developments reflect the impact on the postoperative patient complications from the LMA intra-cuff pressures and demonstrate how a manometry device would improve and reduce negative consequences for patients and healthcare stakeholders. The theory as a whole works as a guide for quality improvement performance to better care for patients and lead to a sustained performance change (Donabedian, 2005).

DNP Essentials

The requirements for the Doctor of Nursing Practice (DNP) project for the USM College of Nursing and Health Professions include meeting the American Association for Colleges of Nursing (AACN) DNP Essentials (Nurse Anesthesia Program [NAP], 2019). There are eight essential components that must be fully present and met for the objectives of this project. Essentials I, II, V, VI, and VIII were met in detail, though all DNP Essentials were fulfilled for the completion of this project and are outlined in Appendix A (American Association of Colleges of Nursing [AACN], 2006).

Essential I: Scientific Underpinnings for Practice. For the purpose of this doctoral project, this Essential is achieved by the identification of support for the use of

manometry monitoring to assess laryngeal mask airway intra-cuff pressures in order to avoid various pharyngeal-laryngeal complications and negative associations to the stakeholders due to over-inflation of the intra-cuff. With an anesthesia providers' foundation of knowledge of the LMA and the maximum pressures allowed to the device, many of these complications could be decreased or avoided to the patient. This doctoral project provides a basic foundation of information to the provider and an educational module regarding LMA intra-cuff pressure as a second deliverable to increase understanding of manometry monitoring and outcomes.

Essential II: Organizational and Systems Leadership for Quality Improvement and Systems Thinking. Within this element, there is interaction with the head of the anesthesia department, educators of the hospital, hospital administration, anesthesia providers, and a panel of experts to implement an educational module and the policy proposal. Every one of these stakeholders has a vital role in the implementation of evidence-based practice and policy change for the increased understanding and insight for manometry monitoring with LMA usage.

Essential V: Health Care Policy for Advocacy in Health Care. This doctoral project advocates for the implementation of a new evidence-based best practice policy that will improve patient outcomes for patients who receive a laryngeal mask airway for general anesthesia. This new best practice policy will implement the increased usage of manometry monitoring to decrease negative outcomes to the patient and the stakeholders involved. These negative outcomes include physical and monetary costs to stakeholders.

Essential VI: Interprofessional Collaboration for Improving Patient and Population Health Outcomes. This project will improve patient outcomes by

implementing a best practice policy that will require collaboration from the head of the anesthesia department, hospital educators, hospital administrators, anesthesia providers, and a panel of experts. The collaboration of these stakeholders is critical for decision-making and practice change occurring for the increased awareness and usage of manometry monitoring with LMAs during general anesthesia.

Essential VIII: Advanced Nursing Practice. For this principle, current literature has been reviewed, evidence analyzed, data presented, and professionals in collaboration in order to form a best practice policy for implementation. This best practice policy will be presented to a USM clinical affiliate to better increase patient outcomes and satisfaction when LMAs are utilized.

Specific Aims

The current practice for measurement of LMA intra-cuff pressure intra-operatively is largely subjective, possibly leading to negative consequences for patients and healthcare stakeholders. The potential negative consequences may include post-operative patient complications and increased cost to healthcare stakeholders. Based on evidence-based, peer-reviewed literature of LMA intra-cuff insufflation and data obtained from a survey of anesthesia providers, a policy was created and presented to anesthesia administration at a USM clinical affiliate lacking such a policy.

Summary

The current practice for measurement of LMA cuff pressure intra-operatively is largely subjective, potentially leading to negative consequences for patients and healthcare stakeholders. The potential negative consequences may include patient complications and increased cost to stakeholders. There is an increasing importance

placed on evidence-based practice and policies in healthcare and many researchers have called for intra-cuff manometry to become routine practice in the surgical setting. Instead, there seems to be a great discrepancy in clinical practice among providers. The evidence-based policy development for LMA intra-cuff pressure measurement in surgery should advantage patients to receive quality care and has the potential to decrease post-operative pharyngeal-laryngeal complications.

CHAPTER II – METHODOLOGY

Introduction

The purpose of this doctoral project was to develop a best practice policy to implement the increased usage and education of intraoperative manometer equipment in anesthesia healthcare settings in which LMA devices are most utilized. Increasing evidence supports that monitoring and reducing intra-cuff pressures from LMAs can decrease pharyngeal-laryngeal complications with the usage of manometry monitoring. Manometry monitoring, combined with anesthesia provider education, may promote higher quality patient outcomes and increased satisfaction rates.

Context

The investigation was among Certified Registered Nurse Anesthetists (CRNAs) who practice anesthesia in Mississippi at USM clinical affiliates. CRNAs at these sites use LMAs on a regular basis in a variety of facilities, hospital-based operating rooms, ambulatory surgery centers, and specialty hospital locations outside of the operating room. Historically, these clinical sites have demonstrated a culture that is accommodative to the implementation of evidence-based practice, making it appropriate for the proposed intervention.

Study for Intervention

This project was submitted to The University of Southern Mississippi's Institutional Review Board (IRB) for approval as well as the clinical affiliate's facility where the project was conducted in survey form, for implementation and approval. The following components of the project's proposed concerns were addressed and discussed. These concerns include current provider knowledge of evidence regarding LMAs and

post-operative airway complications, provider barriers to the usage of LMA manometry monitoring, facility practices of measuring intra-cuff pressures, and a policy presented to the facility's anesthesia providers of the benefits that could potentially arise from the recommendations. After completing clinical rotations at various surgical facilities in Mississippi, no distinct policy was found at clinical affiliate hospitals for which LMA manometry monitoring was solely utilized for measuring intra-cuff pressures on patients to prevent postoperative complications and challenges that could be negatively affect stakeholders.

A best practice policy recommendation was developed stating the intention of this project, which was assist the healthcare facility to manage and mitigate patient risks from pharyngeal-laryngeal post-operative traumas due to high LMA intra-cuff pressures. After this policy was submitted for approval by the DNP committee faculty, a review of literature and survey tool was sent electronically to the DNP committee and subsequently to participating CRNAs, who routinely use LMAs at USM clinical affiliate sites, for data collection. This survey tool, as shown in Appendix E, was utilized to collect feedback on the current LMA intra-cuff pressure measurement methods, the usefulness of the project information, potential adoption of the policy into the clinical affiliate site facility. Feedback from this survey tool was combined with current evidence-based practice from peer-reviewed literature to create the policy recommendation, an educational module from the data collected and evidence-based available knowledge, and the development of an executive summary. The executive summary, policy recommendation, and educational module were then presented to the facility's anesthesia department to share the policy

recommendation regarding the increased usage of manometry when using an LMA on patients within the facility.

The CRNAs were invited by email to participate in the project's survey with no repercussions for refusal. An abridged version of the report of findings and proposed policy recommendations, along with the review of literature were attached to the email to be accessible for reference. The correspondence was contained in a link for a Qualtrics© survey to complete the survey tool. Feedback and information gathered from this survey were anonymous and the CRNAs remained unidentifiable throughout the project's evaluation period.

Intervention

The email invitation and survey tool sent to the participating CRNAs was an essential aspect in the project in order to gather feedback for the creation of the best practice policy proposal which was used to assist the healthcare facility to manage and mitigate patient risks from pharyngeal-laryngeal post-operative traumas due to high LMA intra-cuff pressures. This data collected provided an informal assessment of the current practice of LMA cuff pressure measurement by CRNAs and barriers to manometer usage. The survey tool specifically asked for the most frequently used techniques providers were personally using to measure LMA intra-cuff pressure intra-operatively and the reasoning behind this technique. This data collected assessed the degree of evidenced-based care in current practice regarding LMA usage and assisted in promoting consistencies in clinical practices to keep patients safe perioperatively. Another aspect of this survey was to examine if the CRNA provider did not use an LMA intra-cuff manometry device, what barriers were preventing this method. Evaluating the barriers of equipment availability,

provider knowledge background, and surgical procedure length were taken into consideration when inquiring about this aspect, as the current practice for measurement of LMA intra-cuff pressure intra-operatively is largely subjective. There is still currently no accepted standard of practice or policies in place for optimal monitoring of intra-cuff pressures for safe usage in these supraglottic airway devices for patients, and it is sometimes provider-preference at certain facilities (Letvin et al., 2018).

Steps

1. A survey tool and an email invitation template were created. The email invitation is shown in Appendix D. The Qualtrics© survey is shown in Appendix E.
2. The project was proposed and approved by the DNP project's committee for approval.
3. After approval from the DNP project chairs, an application for approval was submitted to the IRB through The University of Southern Mississippi. The IRB approval letter is shown in Appendix G.
4. The IRB was then be submitted to the USM clinical facility for review.
5. An email invitation with the anonymous survey attachment was sent to 30 CRNAs from USM clinical affiliate sites. The survey invitation is shown in Appendix D.
6. Data received from the submitted surveys were collected and arranged into a table for analysis (Table 2).
7. A report of findings and a clinical policy recommendation (Appendix C) will be developed based on available knowledge. The participating CRNAs, who

were invited through email, was allowed to provide feedback via an anonymous Qualtrics© survey (Appendix E), which was used to alter the policy recommendation.

8. Feedback data from the CRNAs were analyzed for common themes. Any necessary adjustments of the policy were made, based upon evidence and advisements.
9. An educational module was designed from available knowledge provided and data collected from the anonymous surveys returned.
10. After approval from the DNP committee, the executive summary, policy recommendation, education module, report of findings, and literature review were presented to the USM clinical affiliate site.
11. Dissemination of information was at the USM graduate scholarship day in September of 2020.
12. All data collected from the information gathered from the Qualtrics© survey was permanently deleted from personal electronic computer devices following the dissemination of the study. Written notes will be shredded appropriately.

Analysis

Both qualitative and qualitative data were collected from the surveys delivered to the CRNAs and recommendations were collected for the prospective best practice policy proposal. The data was compiled into table form (see Table 2) to display responses from the panel for the proposed policy. The survey represented the quantitative aspect of this DNP project. Anesthesia provider methods were measured with the inquiry of personal LMA practices of cuff measurement, barriers of LMA manometry device usage, and

techniques of reassessment of intra-cuff pressures. The authors of this project used qualitative feedback from the DNP committee to adjust this best practice policy proposal. The feedback from the DNP committee was obtained through review comments and edit suggestions. This information was taken into consideration for the final policy to deliver to the DNP committee.

Ethical Considerations

The ethical considerations of the best practice policy proposal for this doctoral project were the possibility of providing two different levels of care. The two levels included a: anesthesia providers adhering to the research and information recommended by this policy and utilizing manometers when using LMAs in practice or b: omission of the identified benefits and consequences to the patient and stakeholders regarding manometry in LMA usage. Negligence of providing research-based care despite adequate information available to the anesthesia providers would be an ethical consideration. There were no conflicts of interest with this policy proposal.

Summary

As many USM clinical affiliates lack a policy regarding the usage of LMA manometry monitoring for patients with post-operative pharyngeal-laryngeal complications, a best-practice policy recommendation was created to potentially reduce the incidence of these negative consequences. The available knowledge determined that these repercussions could lead to an increased likelihood of patient injury that would negatively affect patient outcomes and could cause an increase in expenditures for patients and the facility. The available knowledge additionally assisted in showing that the benefit of incorporating an LMA manometer device in the surgical setting is an

essential way to protect a point of care in the operating room for anesthesia providers who are caring for patients receiving general anesthesia.

To aid in creating a policy recommendation, data was collected via a Qualtrics© survey from 30 CRNAs at USM clinical affiliate sites. The CRNAs were asked for the most frequently used techniques individual providers are personally using to measure LMA intra-cuff pressure intra-operatively and the reasoning behind this technique. The survey was used to assess what barriers were preventing the CRNA from utilizing an LMA intra-cuff manometer intra-operatively. Data was then produced into table form (see Table 2). An educational module was designed from available knowledge provided and data collected from the anonymous surveys returned. A report of findings and a best practice policy recommendation (Appendix C) were created from the available knowledge and presented to the DNP committee of this project. After critiques and advisements were gathered from the committee regarding the policy proposal, the policy and educational module were then presented to the clinical affiliate site to administer to the anesthesia department at the facility via email.

CHAPTER III - RESULTS

Introduction

The current practice for measurement of LMA intra-cuff pressure intra-operatively is largely subjective, potentially leading to negative consequences for patients and healthcare stakeholders. These repercussions could lead to an increased likelihood of patient injury that would negatively affect patient outcomes and could cause an increase of expenditures for patients and the facility. Based on evidenced-based best practice literature of LMA intra-cuff insufflation and responses to a survey by anesthesia providers regarding LMA intra-cuff pressure monitoring, a best practice policy and an educational module were created and presented to anesthesia administration at a USM clinical affiliate lacking such a policy and educational module, to implement the increased usage and education of intra-operative manometry monitoring equipment in anesthesia healthcare settings in which LMA devices are most utilized.

Survey Results

Twenty-one of 30 anesthesia professionals who received the anonymous email survey responded to the survey. Of the twenty-one that responded, 100% consented to the survey and answered the questions that followed regarding LMA intra-cuff pressure monitoring, which were formatted as select-all-that-apply questions with multiple choices available, including an option for *other*. This *other* option allowed the survey participant to elaborate in a text box on any answer that was not listed as an option.

When asked which techniques the respondents most frequently use to assess LMA intra-cuff pressure intra-operatively, 76.2% selected pilot balloon palpation, 47.6% selected minimal occlusive volume test, 23.8% selected injection of set volume of air,

23.8% selected checks for outward movement of LMA, 14.3% selected " minimal leak test", 4.8% selected minimal occlusive pressure test, and no respondents selected use of cuff manometer or other as techniques for assessing LMA intra-cuff pressure intra-operatively. When asked for what reasons the respondents check LMA intra-cuff pressures intra-operatively, 76.2% selected audible cuff leak, 42.9% selected change in ventilation parameters, 42.9% selected routinely reassess, 38.1% selected long procedure, 38.1% selected change in patient position, 19% selected aspiration risk, 14.3% stated use of N2O, 4.8% selected pediatric patient, and 4.8% selected other with if a leak is questionable. When asked for the reasons for not using manometry monitoring to measure LMA intra-cuff pressures, 66.7% selected unavailability of manometer, 33.3% selected trust own method, 23.8% selected lack of knowledge on use of manometer, 23.8% selected did not know cuff manometers could be used with an LMA, 23.8% said too time-consuming, 9.5% selected do not feel postoperative complications are significant enough, 4.8% selected consider the duration of surgery too short, 4.8% selected N/A, I do utilize a manometer to measure LMA cuff pressures, and no respondents selected do not consider it a best practice or other.

Table 2

Survey Responses

The most frequently used technique(s) for intraoperative assessment of LMA intra-cuff pressure	
Pilot balloon palpation	76.20%
Minimal occlusive volume test	47.60%
Injection of set volume of air	23.80%
Checks for outward movement of LMA	23.80%
Minimal leak test	14.30%
Minimal occlusive pressure test	4.80%
Use of cuff manometer	0%
Other	0%
Reason(s) for intraoperative assessment of LMA intra-cuff pressure	
Audible cuff leak	76.20%
Change in ventilation parameters	42.90%
Routine re-assessment	42.90%
Long procedure	38.10%
Change in patient position	38.10%
Aspiration risk	19%
Use of N2O	14.30%
Pediatric patient	4.80%
Other	4.80%
Reason(s) for not routinely using a manometer for assessment of LMA intra-cuff pressure	
Unavailability of manometer	66.70%
Trust own method	33.30%
Lack of knowledge on the use of a manometer	23.80%
Did not know manometers could be used for LMA cuff pressure	23.80%
Too time-consuming	23.80%
Do not feel postoperative complications are significant enough	9.50%
Consider the duration of surgery too short	4.80%
N/A, I do use a manometer for assessment of LMA cuff pressure	4.80%
Do not consider it best practice	0%
Other	0%

Intervention Results

The policy for manometry monitoring usage for monitoring LMA intra-cuff pressures intra-operatively was submitted to the DNP committee for review. Qualitative

feedback was gathered from the committee regarding the appropriateness of doctoral-level work, the adherence of the policy to evidence-based literature, the practicality of the proposal for clinical practice, and the usefulness of the policy. No suggestions for edit were received and the policy was approved without revision.

The evidence based LMA educational module was submitted to the DNP committee for review and approval. Qualitative feedback was sought regarding the appropriateness of doctoral-level work, the adherence of the educational module to evidence-based literature, and the clinical practicality and usefulness for CRNA adult learners. No suggestions for edit were received and the module was approved without revision.

Summary

The results of the survey supported the information in the literature that the project's problem statement was founded upon. The results of the survey indicated that subjective techniques for assessing LMA intra-cuff pressure were predominant, that there was a lack of uniformity among providers in the chosen technique, and there existed a knowledge deficit with regards to manometry monitoring usage for LMA intra-cuff pressure assessment as well as the consequences for not having an objective measurement technique. The project interventions, consisting of the proposed policy and educational module, sought to address the prevalence of subjective assessment techniques, the lack of uniformity of such techniques, as well as the knowledge deficit found in the literature and confirmed by the professional survey, thereby avoiding the negative consequences for stakeholders that might otherwise occur.

CHAPTER IV – DISCUSSION

Report of Findings

Background

Certain laryngeal mask airway (LMA) post-operative complications are largely preventable in anesthesia practice. The cuffs on these devices are primarily provider preference when inflating the cuff and measuring the pressure once inflated. However, this type of anesthetic airway can develop numerous complications as a result of the over-inflation of the LMA device. Subjective measurements of intra-cuff pressures of the LMA have been shown to inadequately compare to actual pressure ranges as these pressures are not routinely calculated and monitored in many healthcare facilities (Castro & Gopalan, 2016). This discrepancy can result in careless inflation or lack of adjusting the intra-cuff pressure after insertion leading to patient and hospital complications that can include but are not limited to sore throat, nerve damage, dysphagia, dysphonia, and swelling to the airway.

Anesthesia providers can measure intra-cuff pressures with a quick and inexpensive device utilizing the practice of manometry monitoring. By utilizing this device in practice, the potential for patient post-operative complications can decrease leading to better patient care and higher satisfaction for the healthcare facility and its stakeholders. The increasing evidence promotes higher quality patient outcomes and increased satisfaction rates. The intention of this DNP project was to examine the best practice for decreasing patient post-operative airway complications when utilizing LMAs in surgical settings and develop a policy recommendation based upon these findings.

Available Knowledge

Recent literature indicates that many components may influence the increased occurrences of post-operative airway traumas to the patient following LMA insertion, though it is important to understand the role of the anesthesia provider in the potential complications. The current practice for measurement of LMA cuff pressure intra-operatively is largely subjective, potentially leading to negative consequences for patients and healthcare stakeholders. The two most common methods for assessing intra-cuff pressures are using tactile digital palpation of the balloon pilot of the LMA device and utilizing manometry for direct measurements (Letvin et al., 2018). The estimation method with digital palpation has been shown to be an ineffective approach regardless of the provider's number of years in practice or experience which has the increasing likelihood of pharyngo-laryngeal post-operative trauma to the patient versus a calculated manometer device (Ashman et al., 2017).

The overall goal of LMA intra-cuff pressure monitoring is to maintain the cuff pressures in a range between 20 and 60 cm H_2O (Letvin et al., 2018). Intra-cuff pressures extending beyond 60 cm H_2O have been associated with numerous, avoidable, and costly complications to the patient and the healthcare stakeholders involved in the entire surgical experience. Evidence has revealed that approximately 70% of LMA cuffs exceed the maximum intra-cuff pressure (Bick et al., 2014). Though this airway device has been in use for several decades, there is still currently no accepted standard of practice or policies in place for optimal monitoring of intra-cuff pressures for safe usage in these supraglottic airway devices for patients in many healthcare settings (Letvin et al., 2018).

Recommendations

As supported by the available knowledge, LMA manometry is a more objective method for measuring and monitoring intra-cuff pressure ranges during general anesthesia. This approach has the potential to increase the safety and quality of care and decrease patient airway complications when utilizing LMA devices. The increased safety and quality, as well as the decreased airway complications, will not only benefit patients, but all stakeholders involved.

Interpretation

The results of the survey indicated the predominance of subjective measurement techniques for assessing LMA intra-cuff pressure, non-uniformity in assessment techniques among providers, and a knowledge deficit regarding manometry monitoring usage and the consequences to stakeholders of not using an objective measurement technique. These findings were anticipated by the current literature regarding LMA intra-cuff pressure assessment and supported the specific aim and rationale for the best practice policy proposal. The aim and rationale were to implement evidence-based care by making best practices found in the literature the expectation for practice as well as the consistent way that anesthesia professionals perform duties in the operating room.

A strength of the survey was the relevance for the region in which the policy was proposed. The policy was proposed to a USM clinical affiliates in Mississippi, which is where the survey respondents were concentrated. This indicated that there may have been a cultural barrier to manometer use or a lack of availability in the region.

The survey results supported the disconnect discussed in the literature between best practice guidelines and deviations from these best practices found in actual practice.

Though LMAs have been in surgical use for several decades, there is still currently no accepted standard of practice or policies in place for optimal monitoring of intra-cuff pressures (Letvin et al., 2018). Recent literature has indicated that anesthesia providers are still routinely overinflating LMA cuffs and up to 70% may exceed maximum pressure (Bick et al., 2014). Subjective measurements of intra-cuff pressures have been shown to inadequately compare to actual pressures as these are not routinely calculated and monitored in many healthcare institutions (Castro & Gopalan, 2016). The survey results also indicated that this discrepancy may be partly due to a knowledge deficit regarding best practices, as well as a lack of access to the means to implement these best practices. According to one study, half of the participating anesthesia providers (49.4%) had never been trained in the usage of manometry and 10.3% of the providers were unaware how to use the device (Hensel et al., 2016). The two most common methods for assessing intra-cuff pressures are using tactile digital palpation of the pilot balloon of the LMA device and utilizing manometry for direct measurements (Letvin et al., 2018). The results of the survey accounted for these facts by indicating that digital palpation of the pilot balloon was the most widely used technique, while it also indicated that though manometers were not available to the respondents, they lacked knowledge regarding manometer use for LMA cuff pressure assessment in general.

Given that the survey findings were consistent with the current literature regarding LMA intra-cuff pressure assessment techniques as well as provider knowledge regarding these techniques, the consequences of over-inflation of LMA intra-cuffs should be assumed to persist. The patients incur the immediate perceived costs. These complications can range from a sore throat, hoarseness, sore neck, dysphagia, venous

neck congestion, arytenoid cartilage dislocation, lingual nerve damage, jaw tenderness, and mucosal ulceration and bleeding (Ashman et al., 2017). However, these costs are not limited to the patients, and will also be borne by the patient's caregivers, the facility, and the anesthesia providers. Physical complications may result in longer hospital stays for surgical patients, additional or higher doses of post-operative medications to alleviate negative pharyngeal-laryngeal symptoms, possible loss of work for the patient or caregivers of the patient due to longer hospital stays or recovery time, possible additional surgery for repair of the potential damage to the pharynx, sequelae related to the morbidity in the patient's future, and overall decreased patient satisfaction of the entire surgical ordeal (Ashman et al., 2017). Anesthesia students are not exempt from these consequences either. A lack of policy and education regarding the assessment of LMA intra-cuff pressures perpetuates these practices throughout the profession by students being educated and trained by professionals in the clinical environment who aren't implementing best practices. The framework theory by Donabedian (2005) that was utilized for the project allowed the use of the survey responses to serve as structure information to inform the framework's process measures, which assessed whether or not the standards in the policy proposal had been implemented and what the outcome developments could potentially be if the proposed policy was adopted.

Despite the current literature and the findings of the survey regarding current LMA intra-cuff pressure assessment techniques and barriers to knowledge, the survey also indicated a lack of access to manometry, which serves as a barrier to implementing the proposed policy. A further area of inquiry that would be beneficial in providing a more complete understanding of the divide between the current literature and current

practice could be a cost-benefit analysis of manometry. While the current literature affirms the importance of manometry for best practices and the cost of manometers for clinical use are easily obtainable, the costs to patients, caregivers, anesthesia professionals, healthcare facilities, and other stakeholders are less straightforward and obtainable. A focused study in this area may bring to light further explanations for the divide between evidence-based and actual practice, as well as provide a resource to facilities looking for more information to make policy decisions.

Limitations

Limitations of the survey tool used included a small sample size, which precludes statistical significance, and the length of the survey. While the survey was concentrated in the same region of the facility receiving the policy proposal, it was a small sample and did not necessarily represent the facility. The length of the survey was chosen to overcome barriers to compliance. Lowering the time cost of completing the survey was intended to incentivize a greater response from those who received the survey. Surveys have limitations as a method of obtaining data. Aside from the possibility of respondents answering dishonestly, surveys may also be difficult to interpret or understand. For example, in question two of the survey, it was indicated that manometers were not used by any respondents, while in question four it was indicated that one of the respondents did use a manometer device in practice.

Summary

The discrepancy between best practices for LMA intra-cuff pressure monitoring in the literature and what is found in practice can be explained by a lack of means to implement best practices from the lack of availability of manometers, a lack of policy

with expectations of utilizing best practices, or a lack of education on the deficiency of subjective assessments of LMA intra-cuff pressures and the consequences of these deficiencies. To help resolve these issues, this project sought to propose a best practice policy for a standard procedure for assessing LMA intra-cuff pressures intra-operatively and to supplement this policy with an educational module for anesthesia providers. The educational module may also be of use to professionals outside of the anesthesia department, as LMAs may also be utilized after a failed intubation with an endotracheal tube to allow ventilation or to facilitate alternative means of obtaining a secure airway (Nickson, 2019). Additional healthcare providers who are not anesthesiologists and paramedics may benefit from this educational module as well. The educational module may also be useful for educational facilities for teaching and simulation purposes.

Negative outcomes from not adopting the proposed policy and educational module may be continued discrepancy between best practices as found in the literature and clinical practice at the USM clinical affiliate site. This outcome could have detrimental consequences to the patient, the patient's caregivers, the anesthesia providers, and the facility. Further research that could be beneficial to this subject could be a cost-benefit analysis of manometer purchases or a study to measure actual LMA intra-cuff pressures in practice at this facility or others do determine if a lack of manometry does correlate with over-inflated LMA intra-cuff pressures.

APPENDIX A Doctor of Nursing Practice Essentials

DNP Essential	Clinical Implications
I: Scientific Underpinnings for Practice	Identification of support for the use of manometers to assess laryngeal mask airway cuff pressures in order to avoid various complications associated with over-inflation of the cuff.
II: Organizational and Systems Leadership for Quality Improvement and Systems Thinking	Interaction with the head of the anesthesia department, educators, hospital administration, anesthesia providers, and a panel of experts to implement education and policy proposal.
III: Clinical Scholarship and Analytical Methods for Evidence-Based Practice	Literature was reviewed, analyzed, and synthesized to construct a policy proposal that would be evidence-based.
IV: Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Healthcare	Research technology was used to gather and assess literature to support the use of manometry to improve patient outcomes. An educational module was also constructed to facilitate the acquirement of relevant knowledge for providers.
V: Health Care Policy for Advocacy in Health Care	This project advocates for the implementation of a new evidence-based policy that will improve patient outcomes for patients who receive a laryngeal mask airway for general anesthesia.
VI: Interprofessional Collaboration for Improving Patient and Population Health Outcomes	This project will improve patient outcomes by implementing a policy that will require collaboration from the head of the anesthesia department, educators, hospital administrators, anesthesia providers, and a panel of experts.
VII: Clinical Prevention and Population Health for Improving the Nation's Health	This project utilizes research to form a policy that will ensure that evidence-based practice is utilized in the clinical setting to improve patient outcomes.
VIII: Advanced Nursing Practice	Current literature is reviewed, the evidence is analyzed, data is presented, and professionals collaborate in order to form a policy for implementation.

APPENDIX B Literature Matrix

Date of Publication	Author(s)	Type of Evidence	Summary and Conclusion
2017	Ashman, Appel & Barba	Research Article	Some anesthesia providers will palpate the pilot balloon for a subjective cuff pressure despite this being an unreliable method compared to manometer use. A manometer's cost is $200 to $500 with minimal maintenance. Using a subjective technique to assess the cuff pressure may result in complications for the patient, decreased satisfaction, and a damaged reputation for the provider.
2017	Barash, Cullen, Stoelting, Cahalan, Stock, Ortega, Sharar & Holt	Book Chapter	Laryngeal mask airways have less pharyngolaryngeal complications that endotracheal tubes and may allow for a smoother emergence.
2014	Bick, Bailes, Patel & Brain	Review Article	The laryngeal mask airway has become the most popular airway for general anesthesia. Most LMA cuff pressures exceed the maximum recommended which may lead to adverse consequences. The LMA cuff should conform to the tissue rather than the tissue conforming to the cuff. Using a manometer to check the cuff pressure may help avoid some adverse consequences associated with cuff over-inflation.
2016	Castro & Gopolan	Research Article	There is a lack of uniformity in laryngeal mask airway cuff measurement techniques and inflation pressures. Subjective assessments of cuff pressures are inadequately comparable to actual pressures. If the pressure exceeds 30 cm H2O, mucosal perfusion may be hindered.
2008	Dorsch & Dorsch	Book Chapter	The most widely used laryngeal mask airway consists of a rubber shaft and

			an oval-shaped inflatable mask that creates a seal in the hypopharynx. A device that is too small may not seal properly, allowing a leak during positive pressure ventilation.
2018	Letvin, Kremer, Silver, Samih, Reed-Watts & Kollef	Research Article	There is still no current standard of practice for assessing laryngeal mask airway intracuff pressures. The two most common methods for assessing cuff pressures are digital palpation and manometry.
2018	Falco, Rutledge & Elisha	Review Article	Centers for Medicaid and Medicare use standardized metrics to assess patient satisfaction. Patient decisions regarding pursuit of litigation depend on their perception of providers and their relationship with them before, during, and after their procedure.

APPENDIX C Policy Recommendation

1. Rationale or background to policy: To help reduce the incidence of perioperative complications associated with over-inflation of laryngeal mask airway (LMA) cuffs such as pharyngeal-laryngeal trauma. Available knowledge shows that LMA intra-cuff pressure should not exceed 60 cm H2O and that subjective measurement techniques, such as digital palpation of the cuff balloon, are unreliable regardless of provider experience. Current literature supports the use of manometry to quickly and accurately assesses LMA intra-cuff pressures to avoid the complications associated with the over-inflation of LMA cuffs.
2. Policy: All anesthesia providers using a laryngeal mask airway (LMA) to provide a general anesthetic will utilize a manometer to assess the intra-cuff pressure to ensure that the pressure remains below 60 cm H2O during the intraoperative period.
3. Procedure:
    1. All anesthesia providers will assess the candidacy of their patients for the utilization of a laryngeal mask airway (LMA) to administer a general anesthetic by referencing the appropriate indications and contraindications for LMA use.
    2. The LMA will be inserted using an appropriate technique if its use is not contraindicated for the patient's anesthetic.
    3. Following insertion and proper seating of the LMA, the intra-cuff pressure will be promptly assessed using a manometer to ensure that the pressure does not exceed 60 cm H2O and adjusted accordingly.

4. The LMA intra-cuff pressure should be re-assessed in the intraoperative period anytime that the cuff pressure is adjusted or the LMA moves or requires readjustment.

APPENDIX D Anesthesia Provider Survey Email Invitation

Dear CRNA,

We are conducting research pertaining to cuff pressure measurements for Laryngeal Mask Airways (LMAs). We are inviting you to participate because you frequently utilize LMAs in clinical practice.

Participation in this research includes answering an electronic survey about methods that you currently use to measure cuff pressures in LMAs. If you agree to complete this voluntary anonymous questionnaire, it will take approximately 5 minutes. Participation is voluntary; there will be no repercussions for non-participation.

Informed consent is required and is included in the survey. This project and the informed consent form have been reviewed by the Institutional Review Board, which ensures that research projects involving human subjects follow federal regulations. Refer to the informed consent for participant assurance information.

If you have any questions, please contact us using the information provided below.

Thanks in advance for your time and cooperation!

Tyler Armstrong & Catherine Crabtree

APPENDIX E Qualtrics© Survey

Intraoperative Measurement Technique for Laryngeal Mask Airway Cuff Pressure

1. Please refer to the informed consent attachment in the introduction email.

   Yes (I consent)
   No (I do not consent)

2. Which of the following techniques do you most frequently use to assess LMA cuff pressure, intraoperatively? SELECT ALL THAT APPLY.

   Pilot balloon palpation
   Minimal leak test (inflating the cuff and then removing air until the leak is auscultated)
   Minimal occlusive volume test (inflating the cuff until the leak is no longer auscultated)
   Minimal occlusive pressure test
   Injection of set volume of air
   Checking for outward movement of LMA
   Cuff manometer
   Other technique(s)

3. What are the reasons that you assess LMA cuff pressure intraoperatively? SELECT ALL THAT APPLY.

   Audible cuff leak
   Change in ventilation parameters
   Use of nitrous oxide
   Long procedures
   Change in patient position
   Routinely re-assess
   Aspiration risk
   Pediatric patients
   Other reasons

4. If you do not use a cuff manometer, for LMA cuff measurement, what are the reasons that you do not routinely use a cuff manometer to measure LMA cuff pressures? SELECT ALL THAT APPLY.

   Unavailability of the manometer
   Consider the duration of surgeries too short
   Lack of knowledge on the use of manometers
   Did not know that cuff manometers could be used with and LMA
   Too time-consuming

Trust own method
Do not feel postoperative complications are significant enough
Did not consider it best practice
Other reasons
N/A, I do utilize a manometer to measure cuff pressures

APPENDIX F Executive Summary

Executive Summary of a Policy Recommendation for the Increased Usage of LMA Manometry

Tyler Armstrong and Catherine Crabtree

The University of Southern Mississippi

The authors of this doctoral project evaluated the collective research and developed an evidence-based clinical policy recommendation on the most appropriate implementation for the increased usage and education of intraoperative manometer equipment in anesthesia healthcare settings in which LMA devices are most utilized. Presented is the executive summary of the full report "Best Practice Policy Recommendation of Laryngeal Mask Airway Manometry Usage to Reduce Intra-Operative Complications of Intra-cuff Pressures," which will be printed and presented at The University of Southern Mississippi College of Nursing in September 2020.

This policy recommendation regarding the increased usage of laryngeal mask airway manometry in clinical settings is provided to encourage standardization of anesthesia practice and decrease the potential pharyngo-laryngeal patient complications to better ensure patient safety. The purpose of this project was to examine and analyze evidence-based research along with gathering qualitative data from current anesthesia providers to develop a best practice policy based upon these findings.

The current policy recommendation is evidence-based and should be integrated into clinical practice with the anesthesia provider's professional judgment and the individual patient's needs.

APPENDIX G IRB Approval Letter

Office *of*
Research Integrity

THE UNIVERSITY OF SOUTHERN MISSISSIPPI

118 COLLEGE DRIVE #5125 • HATTIESBURG, MS | 601.266.6576 | USM.EDU/ORI

NOTICE OF INSTITUTIONAL REVIEW BOARD ACTION

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

- The risks to subjects are minimized and reasonable in relation to the anticipated benefits.
- The selection of subjects is equitable.
- Informed consent is adequate and appropriately documented.
- Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the subjects.
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of all data.
- Appropriate additional safeguards have been included to protect vulnerable subjects.
- Any unanticipated, serious, or continuing problems encountered involving risks to subjects must be reported immediately. Problems should be reported to ORI via the Incident template on Cayuse IRB.
- The period of approval is twelve months. An application for renewal must be submitted for projects exceeding twelve months.
- FACE-TO-FACE DATA COLLECTION WILL NOT COMMENCE UNTIL USM'S IRB MODIFIES THE DIRECTIVE TO HALT NON-ESSENTIAL (NO DIRECT BENEFIT TO PARTICIPANTS) RESEARCH.

PROTOCOL NUMBER: IRB-20-177
PROJECT TITLE: Best Practice Policy Recommendation of Laryngeal Mask Airway Manometry Usage to Reduce Intra-Operative Complications of Intracuff Pressures
SCHOOL/PROGRAM: School of LANP, Leadership & Advanced Nursing
RESEARCHER(S): Catherine Crabtree, Tyler Armstrong, Mary Jane Collins

IRB COMMITTEE ACTION: Approved
CATEGORY: Expedited
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

PERIOD OF APPROVAL: May 14, 2020

Donald Sacco Jr.

Donald Sacco, Ph.D.
Institutional Review Board Chairperson

APPENDIX H Educational Module to Anesthesia Providers

INTRAOPERATIVE MEASUREMENT FOR LARYNGEAL MASK AIRWAY CUFF PRESSURES

Though laryngeal mask airways (LMAs) have been in surgical use for several decades, there is still currently no accepted standard of practice or policies in place for optimal monitoring of intra-cuff pressures for safe usage in these supraglottic airway devices for patients (Letvin et al., 2018). Subjective measurements of intra-cuff pressures have been shown to inadequately compare to actual LMA intra-cuff pressures as these are not routinely calculated and monitored in practice and are resulting in human error (Castro & Gopalan, 2016).

Despite LMA manufacturers' endorsements of maximum air volume that can be injected into a cuff, various research has disputed these recommendations. Research has found that the maximum volume of air inserted does not correspond with the appropriate LMA intra-cuff ranges due to the injected pressure from the anesthesia provider, because this maximum volume more than doubles the recommended 60 cm H_2O of pressure (Bick et al., 2014).

Intra-cuff pressures can be measured by anesthesia providers with a quick and inexpensive device utilizing the practice of manometry monitoring. The manometer fits on the end of the LMA airway device in the pilot balloon to read the pressure number.

The overall goal of LMA intra-cuff pressure monitoring is to maintain the cuff pressures in a range between 20 and 60 cm H_2O.

Potential complications: sore throat, hoarseness, sore neck, dysphagia, venous neck congestion, arytenoid cartilage dislocation, lingual nerve damage, jaw tenderness, and mucosal ulceration and bleeding. Physical complications may result in longer hospital stays for surgical patients, additional or higher doses of post-operative medications to alleviate negative pharyngo-laryngeal symptoms, possible loss of work for the patient or caregivers of the patient due to longer hospital stays or recovery time, possible additional surgery for repair of the potential damage to the pharynx, sequelae related to the morbidity in the patient's future, and overall decreased patient satisfaction of the entire surgical ordeal (Ashman et al., 2017).

QUESTIONS:

1. Approximately what percentage of general anesthesia cases is the LMA utilized in?

Current data has implied that an LMA is used in approximately 56% of general anesthesia cases (Barash et al., 2017, p. 775). As a result of the increased usage of the laryngeal mask airway and the impact associated with the possible device misuse related to over inflated intra-cuffs, it may be appropriate to include evidence-based practices into surgical policy manuals in healthcare facilities where these devices are most employed.

2. How can LMA intra-cuff pressures change intraoperatively?

Cuff pressures can change due to patient positioning, duration of procedure, a change in airway anatomy, and usage of nitrous oxide. Continuous manometry Continuous manometry is recommended as these not only monitor intra-cuff pressures, but also adjusts volume of air in the cuff automatically ensuring the precision of measurements and success of patient safety (LeCroy, 2014).

3. What is the number one reason for not utilizing an LMA manometer in practice? "Trust own method." One of the most common methods for assessing intra-cuff pressures is using tactile digital palpation of the balloon pilot of the LMA device. This estimation method with digital palpation has been shown to be an ineffective approach regardless of the provider's number of years in practice or experience which has the increasing likelihood of pharyngo-laryngeal post-operative trauma to the patient versus a calculated manometer device (Ashman et al., 2017).

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