Marian University

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Doctor of Nursing Practice

Intraoperative Cuff Pressure Monitoring of Airway Devices:

An Evidence-Based Educational Intervention

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Abstract

Background and Review of Literature: Subjective methods for assessing airway device cuff pressures (CP) remain in use to determine correct inflation, despite evidence indicating inadequate sensitivity for identifying under and overinflation. Inadequate CP can cause tissue ischemia, mucosal ulcers, stenosis, and aspiration. Recommendations for endotracheal tubes (ETT) CP are 20 to 30 cmH_2O and $\leq$ 60 cmH_2O for supraglottic airway (SGA) devices. Currently, there are no guidelines for intraoperative monitoring of airway devices. Manometers are the most accurate and accepted method for assessing CP; however, they are underutilized intraoperatively.

Purpose: The project goal was to promote CP assessment intraoperatively with manometry and create a practice guideline for measuring and monitoring CP.

Methods: A literature review was performed to evaluate recent evidence on CP assessment for airway devices to develop practice guidelines for intraoperative monitoring of CP. A group of 23 licensed anesthesia providers participated in the project. Pre-and post-surveys were utilized. Evaluation of current knowledge, methodology, rating of importance, and willingness to adopt manometry for CP intraoperative monitoring was obtained. Education on CP monitoring was discussed with participants, followed by post-survey. Pre-survey was used to evaluate participants' current methods for ETT and SGA CP assessment. During routine intubation, participants were asked to inflate an airway device using their preferred technique to determine adequate CP. Readings for CP were measured using a manometer device approved by the Food and Drug Administration (FDA). Data for their corresponding CP reading was shared with participants, and educational information reflecting current evidence for CP monitoring. Post-

survey was then performed to evaluate the participants' willingness to adapt CP assessment with manometry into their practice.

Conclusion: Intraoperative CP was predominantly performed with subjective techniques. Anesthesia providers expressed a willingness to assess CP with manometry, posing education as a possible foundational step for future implemention of CP monitoring in the operating room (OR). Lack of guidelines for CP monitoring intraoperatively and variability in monitoring CP due to subjective assessment methods emphasized the need for standardization and the increased availability of manometry devices for intraoperative use.

Keywords: Endotracheal cuff pressure, supraglottic airway manometer, tracheal injury, anesthesia, pharyngolaryngeal complications, and laryngeal mask airway.

Introduction

There are no current guidelines for intraoperative monitoring of CP for airway management devices in the United States. Excess cuff inflation and underinflation for ETT and SGA devices potentially cause adverse clinical outcomes (Hyzy, 2020; Patel, Brain, Bick, & Bailes, 2014). A previous survey evaluating monitoring of cuff pressures across 131 accredited anesthesiology residency programs reported techniques for the assessment of CP for airway devices were performed by non-manometer methods, which have been shown as unreliable in determining adequate CP (Conlin, Walker, Shelley, & Diu, 2011). The use of recent evidence and practitioner input to address cuff inflation and monitoring for ETT and SGA intraoperatively offers an opportunity to improve anesthesia practice and avoid adverse clinical outcomes.

Background

The management of cuffed ETT and SGA is routine practice for anesthesia providers. Optimal CP airway devices are essential to reduce complications associated with overinflation; complications include tissue ischemia, nerve injury, sore throats, mucosal ulcers, and tracheal tissue stenosis (Hyzy, 2020; Patel et al., 2014). Researchers' recommendations vary for appropriate CP. The consensus recommendations suggest pressures between 20 to 30 cmH_2O for ETT, utilizing the lowest CP to allow adequate mechanical ventilation without gas leaks (Jaber et al., 2007; Liu et al., 2010; Rello et al., 1996). The recommended CP for SGA devices is ≤ 60 cmH_2O (El-Boghdadly, Bailey, & Wiles, 2016). Manometers are the most reliable method for assessing CP (Letvin et al., 2018); however, other methods, such as the pilot balloon palpation, remain widely used by anesthesia providers despite evidence supporting lack of sensitivity in estimating adequate cuff inflation (Chan, Wong, & Cherng, 2009; Galinski et al., 2006; Liu et al., 2010; Parwani, Hoffman, Russel, Preblick, & Hahn, 2007).

Studies evaluating anesthesia providers' use of manometer devices have highlighted some of the barriers to implementing manometer devices intraoperatively. For example, after the Canadian Anesthesiologists' Society placed manometer devices for CP as a piece of immediately available monitoring equipment in their practice guidelines, an anesthesia department in an academic center in Canada obtained the devices and performed a quality audit to evaluated their use (Miao, Jee, & Pysyk, 2018). Two manometer devices were made available for 17 operating rooms, followed by an evaluation on the frequency of manometer use for the 66 anesthesia providers in the facility via a survey (Miao et al., 2018). The results indicated anesthesia providers relied mostly on estimation methods to assess CP, with 76% of providers reporting using the available manometers less than once a month (Miao et al., 2018). The results also

showed that only 52% of the participants were aware that manometers were available at their facility, but 88% of participants reported willingness to use the device if readily available in the OR (Miao et al., 2018). The availability of manometer devices in a healthcare facility is an obvious barrier to implementing their use. In this facility, manometers were available in a designated area for anesthesia providers. However, they were underutilized due to access limitations and lack of staff engagement.

Problem Statement

Under and overinflation of CP for ETT and SGA can lead to tracheal injury, increasing the risk for patient complications (Hyzy, 2020; Patel et al., 2014). Although some variability exists in research results concerning the appropriate CP for airway devices to avoid patient injury, the consensus is to utilize the lowest pressure for adequate mechanical ventilation without gas leakage. This lowest adequate pressure is obtained at CP of 20 to 30 cmH_2O for ETT (Jaber et al., 2007; Liu et al., 2010; Rello et al., 1996) and $\leq$ 60 cmH_2O for SGA (El-Boghdadly et al., 2016). Manometers are accepted in practice for the assessment of CP airway devices (Letvin et al., 2018); however, low accuracy estimation techniques are predominant used intraoperatively (Chan et al., 2009; Galinski et al., 2006; Liu et al., 2010; Parwani et al., 2007). This project aimed to provide practice guideline education for CP monitoring intraoperatively and to promote best evidence practice for intraoperative assessment.

Organizational Analysis of Project Site

Evaluation of two organizations' required practices and policies was performed for a rural hospital and the anesthesia managing group in central Indiana. There was no explicit policy found for intraoperative monitoring for ETT and SGA in either organization. An assessment for

manometer availability within the hospital and anesthesia group was performed. The equipment availability evaluation indicated that manometers were not supplied to anesthesia providers by the hospital or the anesthesia group. Manometer devices had limited availability in the hospital's critical-care unit for use with patients requiring extended respiratory support. The lack of a policy for intraoperative monitoring of airway devices among the anesthesia and healthcare facility offered an opportunity to institute practice guidelines for improving patient care in the OR.

Review of the Literature

In the review, the following search terms were used: endotracheal cuff pressure, supraglottic airway manometer, tracheal injury, anesthesia, pharyngolaryngeal complications, and laryngeal mask airway. A comprehensive search included the following electronic databases: PubMed, Web of Science, Embase, Google Scholar, CINAHL, Medline, and ScienceDirect. The search yielded 278 articles between 2014 to 2020. The exclusion of 263 articles was made during abstract review because these studies did not meet the inclusion criteria or file duplicate material. Inclusion criteria were peer-reviewed, randomized controlled trials, and clinical relevance. Three landmark studies published before 2014 were also included.

Anesthesia providers frequently utilize airway devices to deliver oxygen, inhalation anesthetics, adequate ventilation, and airway protection during surgical procedures. Monitoring of CP using manometers in acute care settings has been adopted to avoid iatrogenic complications related to ETT use; however, monitoring of CP intraoperatively has not received the same degree of attention (Mendelsohn, Mukdad, & Dhillon, 2018). Intraoperative adoption

varies among facilities and providers, indicating the need for protocols and set guidelines (Hockey, Van-Zundert & Paratz, 2016).

Adequate CP for Airway Devices

Results in the literature vary on the appropriate use of CP for airway devices. Researchers and practitioners have a general agreement for a need to reduce the potential for iatrogenic complications; the lowest pressure should be used for adequate mechanical ventilation without gas leakage. The typical target range is CP of 20 to 30 cmH_2O for ETT (Jaber et al., 2007; Liu et al., 2010; Rello et al., 1996) and ≤ 60 cmH_2O for SGA (El-Boghdadly et al., 2016).

Techniques Utilized for the Evaluation of CP

Several estimation techniques are utilized for the assessment of CP. The focus of this review was four methods frequently discussed in the literature: pilot balloon, air return, minimum air leak, and minimum volume.

The pilot balloon method, or finger-pressure method, consists of utilizing finger palpation of the pilot balloon to make a subjective assessment of the compliance pressure of the cuff against the trachea (Hensel et al., 2016; Pisano, Verniero, Galdieri, & Corcione, 2019; Tsaousi, Oloktsidou, Tsiaousi, Gkinas, & Vasilakos, 2014). The effectiveness of this technique has been explored in multiple clinical studies. Pisano et al. (2019) evaluated the palpation technique and potential for improvement utilizing a pilot balloon with larger radius. In the study, 62 anesthesia providers were asked to estimate CP when inflated to 88 mmHg, and 40 mmHg into a simulated trachea by feeling both a common and a modified large pilot balloon. The cuffs inflated to 88 mmHg were recognized by 35% of participants on a common pilot balloon, and 87% of participants after palpation of the large modified pilot balloon (Pisano et al., 2019). The cuffs

inflated to 40 mmHg were recognized by 32% of participants after palpation of the modified pilot balloon (Pisano et al., 2019). The study concluded that increasing the radius of the pilot ballon aid identification of CP when inflated to 88 mmHg, but offered no benefit when inflated to 44 mmHg. Its worth noting the lowest CP evaluated in the study is almost double the recommended pressure for ETT, supporting the low sensitivity of pilot ballon palapation for the assessment of CP. Tsaousi et al. (2014), evaluated accuracy of the pilot balloon, air return, minimum air leak, and minimum volume for the assessment of CP. In the study each technique was evaluated by dividing 84 participants undergoing surgical intervention into four groups. The results evaluating the pilot ballon method indicated greater variability on CP measurements with the pilot ballon method, with half the samples outside the recommended range (Tsaousi et al., 2014). Hensel et al., 2016, evaluated the effectivesness of the pilot balloon method to determine adequate CP on SGA. In the study, the median CP in 90 surgical cases were pilot ballon palpation was used to controlled CP was 130 cmH_2O (Hensel et al., 2016). Pillot ballon papation yield low reliability for the assessment of CP, and its routine use is not recommended (Hensel et al., 2016; Pisano et al., 2019, Tsaousi et al., 2014).

The minimum volume and the minimum air leak techniques involved direct auscultation over the trachea while slowly inflating the ETT cuff until the air leak is eliminated. A small, subtle leak should remain in the minimum air leak technique (Hensel et al., 2016; Pisano et al., 2019, Tsaousi et al., 2014). Both techniques rated poor attainment of the safe ranges for adequate CP, yielding safe CP in less than half of the cases, with underinflation representing the majority of out of range readings (Hensel et al., 2016; Pisano et al., 2019, Tsaousi et al., 2014).

The air-return technique consists of overinflation of the ETT cuff, followed by air return to the syringe (Hensel et al., 2016; Pisano et al., 2019; Tsaousi et al., 2014). This technique has been compared with other estimation techniques in randomized clinical trials, yielding CP within the recommended range close to 70% of the time, with underinflation representing out of range readings (Fred et al., 2017; Tsaousi et al., 2014). When compared to other estimation methods for the assessment of ETT CP, the air-return technique is considered to be the most reliable in the absence of a manometer device (Fred et al., 2017; Hensel et al., 2016; Pisano et al., 2019; Tsaousi et al., 2014).

Considerations of CP Overinflation and Underinflation

A randomized, prospective, and observational study was aimed to evaluate ETT CP and postprocedural complications related to intubation in 509 subjects from four tertiary facilities in Shanghai, China (Liu et al., 2010). In the study, 273 participants were placed into a control group where ETT CP was determined by pilot balloon palpation; the remaining 236 participants were assigned to a group where assessment for CP was made with a manometer (Liu et al., 2010). The control group results indicated that post-extubating, 44% experienced coughing, and 11% blood streak expectoration. In the study group, 34% of the subjects experienced coughing and 4% blood streak expectoration (Liu et al., 2010). The researchers also randomly selected 20 subjects whose duration of endotracheal intubation was longer than 180 minutes to examine the tracheal mucosa via fiberoptic bronchoscopy. Injury occurred to the tracheal mucosa in both groups, with more severity present in the control group along with hemorrhagic ulcerations (Liu et al., 2010).

The results suggested that unwanted side effects and injury to the tracheal mucosa associated with excessive ETT CP can be reduced using manometers.

The assessment of CP for SGA devices has also been evaluated. A double-blind, randomized trial involving 203 subjects evaluated the occurrence of sore throat, dysphasia, and dysphonia in patients where SGA was used and monitored with a manometer (Seet et al., 2010). A classic laryngeal mask airway (LMA) was used with a target CP of 60 cmH_2O for a control group (Seet et al., 2010). The results showed a significantly lower frequency of complications ($p < .001$) in pharyngeal and laryngeal complications in the group where CP adjustment was made with manometer (13.4%) versus the control group (45.6%), translating into a relative risk reduction of 70.6%. Notably, the initial CP achieved by anesthesia providers for both groups using their routine method of inflation resulted in almost double the recommended pressure to avoid injury (Seet et al., 2010). Although the study was not aimed at assessing anesthesia providers' methods of CP inflation, the practitioners utilized typical techniques; the results support other studies focused on the challenges in achieving adequate CP without manometers.

Frequency of Monitoring

Practitioners' frequency recommendations for monitoring the CP of airway devices using manometers vary. Most of these results were found in studies performed in acute settings where extended ventilation was required. Nseir et al. (2015) performed a comprehensive meta-analysis of three prospective clinical trials to examine the effects of continuous monitoring for CP in preventing ventilator-associated pneumonia (VAP). Findings from 543 subjects were included in the study, and results showed a lower incidence of VAP among subjects where continuous monitoring was utilized versus manometer use during routing care (13.6% vs. 25.7%); however,

data for mechanical ventilation, treatment, and mortality lacked statistical significance (Nseir et al., 2015). The findings suggested potential benefits for reducing VAP for patients requiring extended mechanical ventilation. Further research is warranted concerning the application of continuous monitoring for CP intraoperatively to assess the benefits.

In a recent study, Letvin et al. (2018) evaluated the influence of CP monitoring frequency on patients requiring mechanical ventilation in a critical care unit. The 305 patients were in two conditions: a group that received monitoring every eight hours, and a second group monitored only after intubation, audible leak, loss of tidal volumes, patient adjustment, and manipulation of an endotracheal tube (Letvin et al. 2018). The study indicated that for both groups, ventilator-associated events, VAP, length of hospital stay, witness aspiration, and 100-day mortality yield no significant differences (Letvin et al., 2018). Findings from the study suggested that frequency for endotracheal tube CP monitoring using a manometer is likely safe when performed after intubation, patient repositioning, manipulation of an endotracheal tube, and loss of tidal volumes or presence of air leaks.

Nitrous Oxide (N_2O) can also influence CP. The rate of N_2O diffusion into airway devices cuff is influenced by the partial pressure gradient of N_2O, the cuff, the area of the cuff that is exposed to N_2O, time, and the thickness of the cuff (Hockey et al., 2016; Nakamura, Fujiwara, Tsukamoto, Sakamoto, Yokoyama, 2013; Park, Kim, & In, 2017). In evaluations of CP during the administration of N_2O in concentrations of 50% and 70%, CP increases within minutes of N_2O application. The CP rise variance is influenced by airway device cuff materials and time (Nakamura et al., 2013; Park et al., 2017; Hockey et al., 2016). Due to the variability of CP's

increase during N_2O administration, recommendations include frequent or continuous CP monitoring when N_2O is used in the intraoperative setting.

Evidence-Based Practice: CP assessment

The information from the literature review was made available to the participants and guidelines for the assessment of ETT and SGA intraoperatively (Appendix A).

Theoretical Framework

The framework utilized for this project was the Johns Hopkins nursing evidence-based practice (JHNEBP) model (Appendix B). The JHNEBP model includes a problem-solving approach to clinical decision-making with the goal of implementing the best research evidence into clinical practice (Dang & Dearholt, 2017). The JHNEBP model uses a three-step process, practice question, evidence, and translation (Dang & Dearholt, 2017).

In this process, the practice question consists of seven substeps: recruit interprofessional team, define the problem, develop and refine the practice question, identify stakeholders, determine responsibility for project leadership, and schedule team meetings (Dang & Dearholt, 2017). The following step, evidence, is composed of five substeps: searching for evidence, appraising the level and quality of the evidence, summarize the individual evidence, synthesize overall strength and quality of evidence, and develop recommendations based on the evidence (Dang & Dearholt, 2017).

The last step is translation, consisting of eight substeps: determine fit, feasibility, appropriateness of recommendation(s), create an action plan, secure support and resources to implement the action plan, implement the action plan, evaluate outcomes, report outcomes to stakeholders, identify next steps, and terminating with finding dissemination (Dang & Dearholt,

2017). All these steps are organized and assigned with tentative due dates and timeframes. The JHNEBP model also provides tools to aid with question development, implementing and tracking the action plan and the active dissemination of the evidence-based practice (EBP) findings.

Goals, Objectives, and Expected Outcomes

The goal of this project was to facilitate a practice guideline for intra-cuff pressure monitoring in the operative setting and promote CP assessment for airway devices in an anesthesia team in central Indiana. Assessments of intra-cuff pressures for airway devices encompassed measurement and monitoring. The goals are to be evaluated using pre- and post-surveys. The pre-survey was used to evaluate current practice and knowledge regarding CP for ETT and SGA. Their corresponding CP readings were provided along with information from a literature review on methodologies for CP monitoring. Participants completed a post-survey to evaluate the effectiveness of the educational intervention and participants' willingness to adapt CP monitoring with manometry into their practice. As a result, the willingness to adopt manometry for CP monitoring and increase awareness on manometry was expected.

Project Design

A literature review was performed, and a practice guideline for intraoperative monitoring of airway devices was created. Participants were provided with educational information from the literature review on the assessment of ETT and SGA CP, followed by evaluating CP after routine intubation. Anesthesia providers were asked to inflate the cuff of an airway device using their preferred technique. CP was then evaluated by the primary investigator using a manometer device approved by the FDA. Data for their corresponding CP reading was then shared with participants. Surveys were used to evaluate anesthesia providers' methods for evaluating ETT

and SGA CP and assessing their willingness to adopt manometry to assess CP after the educational intervention.

Project Site and Population

The population for this project consisted of 23 anesthesia providers in charge of delivering anesthesia services in a rural hospital in central Indiana. The providers are physicians and nursing professionals with specialized training in anesthesia care. The inclusion criteria included anesthesia providers willing to participate in the study.

Some of the barriers in this project are associated with developing and adopting a new practice habit. Also, anesthesia organizations' lack of practice guidelines can hinder adoption by anesthesia providers and healthcare organizations.

Methods

A group of 23 licensed anesthesia providers was recruited to participate in the quality improvement project. No personal identifying information about the patients or participants was obtained. As mentioned previously, the JHNEBP model was used as a theoretical framework for developing this project. After recruitment, participants were asked pre-survey questions to rank the level of importance for CP monitoring, willingness to utilize a manometer device, and current knowledge of methods used to assess airway devices CP. Anesthesia providers gave permission to obtained CP readings using an FDA approved manometer after routine intubation. Adjustments to the CP readings were also performed when warranted. Corresponding CP readings were shared with participants, along with evidence from the literature review concerning CP monitoring. Participants then completed a post-survey to evaluate the

intervention's effectiveness and their willingness to adapt CP monitoring with manometry into their practice.

Measurement Instruments

Pre-intervention and post-intervention surveys were utilized to measure the outcomes of the project (Appendix C). The surveys were aimed to evaluate knowledge, technique, and degree of importance placed on CP monitoring by participants.

A manometer device was also utilized to obtained objective CP readings after cuff inflation by participants. The manometer device utilized was the Posey Cufflator. The device is FDA approved and is used to measure and regulate CP for air-filled airway devices (US Food & Drug Administration, 2020). The manufacturer's instructions for the manometer usage were followed (Appendix D). The principle investigator collected all samples.

Ethical Considerations and Protection of Human Subjects

Approval from the Institutional Review Board at Marian University was obtained (protocol #B20.159, Appendix F) before initiating the DNP Project. The privacy of the participants in this study was protected, and all information collected will remain confidential. Assurance of confidentiality was provided, and a consent form was offered to participants. No identifiable information was collected or disseminated in the study. Data were collected and accessible to the faculty mentor and principal investigator. The principle investigator will store data and keep it for three years, after which it will be destroyed using the University's confidential recycling carts.

Data Collection Procedures

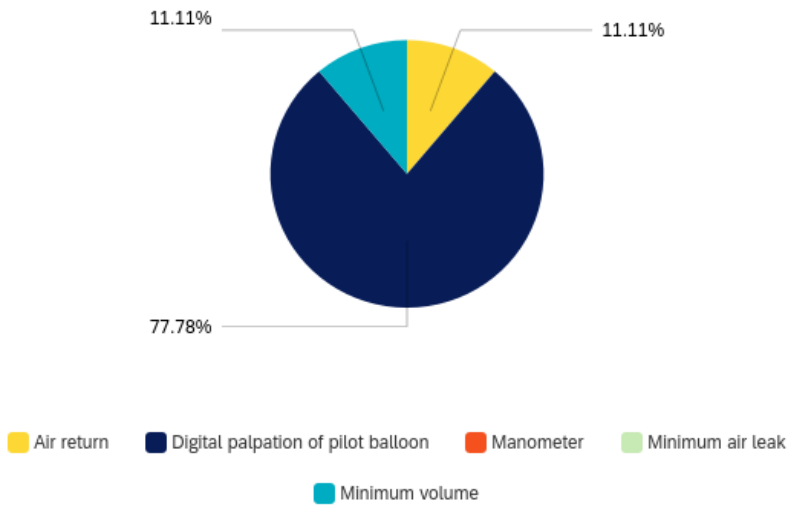
The steps implemented in the project were divided into three stages: pre-intervention, intervention, and post-intervention. Pre-intervention included data collection of CP and pre-survey. The intervention stage consisted of sharing corresponding CP data with anesthesia providers and educational information reflecting current evidence for CP monitoring. Post-intervention was focused on collecting the data from the post-survey.

Data Analysis

Descriptive statistics were used to represent the findings from the surveys. Graphical illustrations were also utilized to represent the data. Manometry CP readings were classified as within range (20 to 30 cmH_2O), out of range low (<20 cmH_2O), and out of range high (≥30 cmH_2O). A chi-square test was performed comparing willingness to adopt manometry and level of importance attributed to CP monitoring before and after the intervention.

Results

Twenty-three anesthesia providers were recruited. Two providers chose not to participate in the study, and incomplete data from three participants were excluded. Eighteen measurements



of ETT CP were collected in the pre-implementation and post-implementation stages. 94.44%

(17) of the readings for ETT CP were in out of range high, and 5.6% (1) were out of range low. To determine adequate CP, 77.8% (14) of providers reported using digital palpation of a pilot balloon, followed by 11.1% (2) using the air return, and 11.1% (2) the minimum volume technique (Fig. 1.).

Figure 1.

When participants were asked to select the adequate CP for ETT, 100% (18) of providers selected the correct CP. When participants were asked the adequate CP for SGA, 94.44% (17) of providers selected the adequate CP. The majority of participants considered cuff pressure monitoring in anesthesia as somewhat important 61.11% (11), followed by 27.78% (5) considering it neutral, and 11.11% (2) important (Fig. 2.). None of the participants reported access to a manometer device to measure CP for airway devices directly. When participants were asked if they would utilize a manometer in their practice if provided with the device, 61.1% (11) reported wiliness.

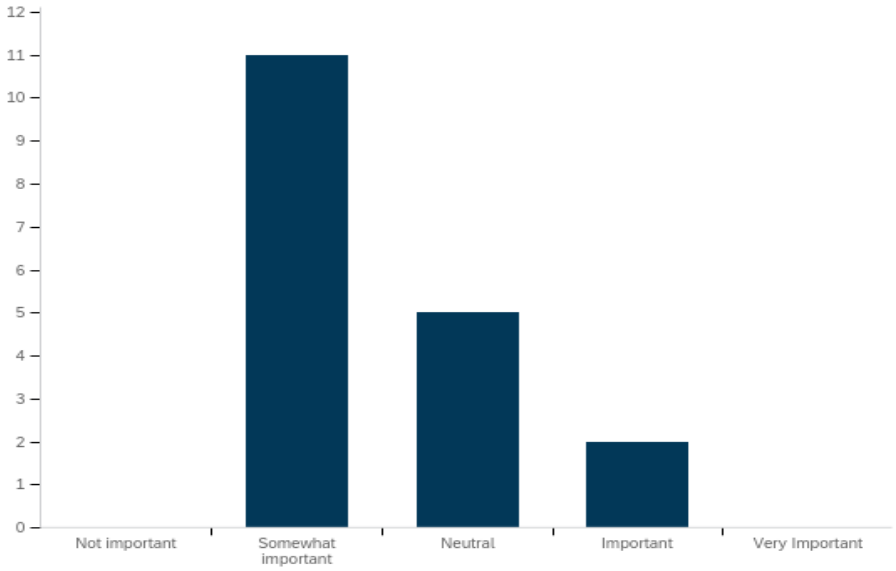


Figure 2.

In the post-implementation phase, 100% (18) of participants identify digital palpation of a pilot balloon as a method lacking accuracy for the monitoring CPs. All 18 participants selected the correct CP for ETT and SGA. The majority of participants considered CP monitoring in anesthesia as important 88.89% (16), followed by 5.6% (1) considering it neutral and 5.56% (1) very important (Fig. 3.). After the intervention, 94.4% of participants reported willingness to utilize a manometer in their practice if provided with the device.

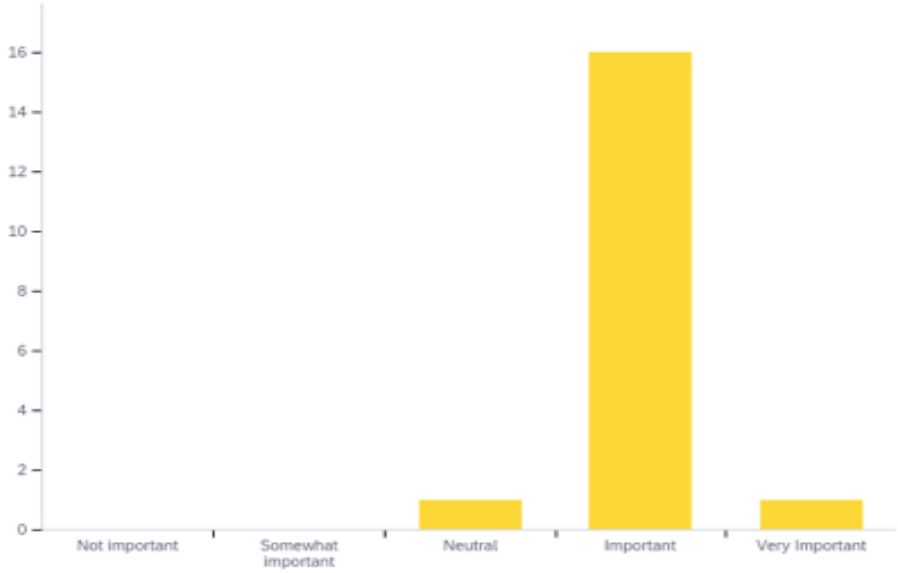


Figure 3.

Discussion

The anesthesia providers' rating of importance for assessing CP in the OR were higher after the educational intervention and EBP guidance. After the educational intervention, 88.89% (16) participants considered CP monitoring as important, followed by 5.6% (1) participants considering it neutral, and 5.56% (1) very important. Contrasting to data obtained during post-implementation, where 11.11% (2) rated monitoring of CP as important, 61.11% (11) somewhat important, and 27.78% (5) neutral. When contrasting how providers rated the importance of CP

monitoring, an improvement of significance was identified ($p < .001$), with a median score of 4 and SD of 0.3.

Knowledge regarding adequate CP was identified by the great majority of participants on both stages of implementation. With adequate identification for CP for ETT and SGA devices on the pre-implementation stage 100% (18) and 94.44% (17), respectively, and on the post-implementation, 100% (18) of participants selected the correct CP for ETT and SGA.

A project aim was to increase awareness of the assessment of CP for airway devices intraoperatively and provide EBP guidelines for the assessment of CP for airway devices intraoperatively. Anesthesia providers routinely utilize airway devices; inadequate CP for ETT and SGA devices can cause iatrogenic complications that could lead to patient harm. A range of 20 to 30 cmH_2O has been deemed adequate for ETT (Hockey et al., 2016) and less than or equal to 60 cmH_2O for SGA (El-Boghdadly et al., 2016).

The routine evaluation of CP with objective devices such as manometers has been recommended to prevent adverse effects; unfortunately, adoption varies among facilities and providers with literature indicating the need for protocols and guidelines (Hockey et al., 2016). Intraoperative adoption of manometer usage in anesthesia has been slow, with subjective techniques predominantly used in the intraoperative setting (Chan et al., 2009; Galinski et al., 2006; Liu et al., 2010; Parwani et al., 2007). Accessibility of manometers was identified in previous studies assessing the frequency of use by anesthesia providers (Miao et al., 2018). Facilitating access to manometers can potentially help increase intraoperative use. Efforts to improve CP monitoring by anesthesia providers using devices that can deliver accurate and objective measures could improve clinical practice and patient outcomes.

The small sample size and methodology were considered a limitation of the project. A larger sample could have ensured a representative distribution and gather data with significant relationships. The short time frame of the project restricted further data collection, limiting future inferences on effectiveness.

Conclusion

Anesthesia providers routinely utilize airway devices. Inadequate CP for ETT and SGA devices can cause iatrogenic complications that can potentially lead to patient harm. A range of 20 to 30 cmH_2O has been deemed adequate for ETT (Hockey et al., 2016) and less than or equal to 60 cmH_2O for SGA (El-Boghdadly et al., 2016).

The routine evaluation of CP with objective devices such as manometers is recommended in the literature to prevent adverse effects; unfortunately, adoption varies among facilities and providers, with current literature indicating the need for protocols and set guidelines (Hockey et al., 2016). The project identified a low rating of importance towards CP monitoring and subjective techniques as the primary assessment methods. Post-intervention, anesthesia providers expressed willingness to assess CP with manometry in their practice, posing education as a possible foundational step for implementing CP monitoring in the OR. Lack of guidelines for CP intraoperative monitoring and CP variability from subjective assessment methods emphasize the need for standardization and increase manometry accessibility intraoperatively. Efforts to improve CP monitoring by anesthesia providers using devices that can deliver accurate and objective measures can improve clinical practice and patient outcomes. The following steps would include the implementation of manometry for intraoperative use by anesthesia providers. Future studies implementing or seeking to improve compliance of CP monitoring for airways

devices with manometry can give further insights into the effectiveness of the educational intervention as a practice modifier. Additionally, studies evaluating patient outcomes after implementing the practice guideline can provide further insights into the impact of standardized methods for evaluating CP intraoperatively.

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Appendix A: Cuff Pressure Monitoring Guide

Guideline for Intraoperative Measurement of Endotracheal, and Supraglottic Airway Cuff Pressures

Purpose To standardize measurement of pressure being exerted upon the tracheal wall and oropharyngeal structures by the cuff of airway devices in the intraoperative setting.

Scope Anesthesia providers evaluates the cuff pressure of airway devices for patients in the intraoperative setting during mechanical ventilation to reduce the potential of injury to the tracheal wall and oropharyngeal structures.
Anesthesia providers

Indication For intraoperative monitoring and measurement of endotracheal and supraglottic airway devices cuff pressures

Goal Prevent damage to the tracheal wall and oropharyngeal structures by maintaining pressures for endotracheal cuff between 20-30 cm H20 and ≤ 60 cmH_2O for supraglottic airway devices.

Equipment Devices intended to measure and regulate the intra-cuff pressure of Endotracheal tubes, supraglottic airways.

Guideline Cuff pressures should be inflated for endotracheal cuff between 20-30 cmH20 and ≤ 60 cmH_2O for supraglottic airway devices.

Assessment of cuff pressures should be performed after intubation, patient repositioning, manipulation of airway device, and with loss of tidal volumes or presence of air leaks.

Manufacture instructions from manometer device should be used to adjust pressures. Decontamination for devices should be made using manufactures recommendations before and after use.

In the absence of a manometry device, air-return technique should be used for cuff inflation of airway devices. Assessment with a manometer device should be made as soon as possible.

During administration of N2O, cuff pressures should be monitored continuously or frequently.

Appendix B: Theoretical framework model

Johns Hopkins Nursing Evidence-Based Practice

Appendix A
PET Management Guide

PRACTICE QUESTION

Step 1: Recruit interprofessional team
Step 2: Define the problem
Step 3: Develop and refine the EBP question
Step 4: Identify stakeholders
Step 5: Determine responsibility for project leadership
Step 6: Schedule team meetings

EVIDENCE

Step 7: Conduct internal and external search for evidence
Step 8: Appraise the level and quality of each piece of evidence
Step 9: Summarize the individual evidence
Step 10: Synthesize overall strength and quality of evidence
Step 11: Develop recommendations for change based on evidence synthesis
- Strong, compelling evidence, consistent results
- Good evidence, consistent results
- Good evidence, conflicting results
- Insufficient or absent evidence

TRANSLATION

Step 12: Determine fit, feasibility, and appropriateness of recommendation(s) for translation path
Step 13: Create action plan
Step 14: Secure support and resources to implement action plan
Step 15: Implement action plan
Step 16: Evaluate outcomes
Step 17: Report outcomes to stakeholders
Step 18: Identify next steps
Step 19: Disseminate findings

Appendix C: Surveys

Pre-Survey

1. How do you assess adequate cuff pressure intraoperatively most frequently?
    a. Air return
    b. Digital palpation of pilot balloon
    c. Manometer
    d. Minimum air leak
    e. Minimum volume
2. What is the recommended cuff pressure range for endotracheal tubes?
    a. 20 to 30 cmH_2O
    b. > 20 cmH_2O
    c. > 30 cmH_2O
    d. < 20 cmH_2O
3. What is the recommended cuff pressure range for supraglottic airway devices?
    a. 20 to 30 cmH_2O
    b. ≤ 60 cmH_2O
    c. > 50 cmH_2O
    d. < 70 cmH_2O
4. How important do you consider cuff pressure monitoring for airway devices in anesthesia?
    a. Not important
    b. Somewhat important
    c. Neutral
    d. Important
    e. Very Important
5. Do you have access to a manometer to measure cuff pressure for airway devices directly?
    a. Yes
    b. No
6. If provided with a manometer device would you be willing to adopted into your practice?
    a. Yes
    b. No

Post-Survey

1. Is digital palpation of pilot balloon and accurate method to determine cuff pressure monitoring?
    a. Yes
    b. No
2. Select the adequate cuff pressure for an endotracheal device?
    a. 19 cmH_2O
    b. 22 cmH_2O
    c. 40 cmH_2O
    d. 60 cmH_2O
3. Select the adequate cuff pressure for a supraglottic airway device?
    a. 55 cmH_2O
    b. 68 cmH_2O
    c. 71 cmH_2O
    d. 78 cmH_2O
4. How important do you consider cuff pressure monitoring for airway devices in anesthesia?
    a. Not important
    b. Somewhat important
    c. Neutral
    d. Important

    e. Very Important
5. If provided with a manometer device would you be willing to adopted into your practice?
    a. Yes
    b. No

Appendix D: Manometer Application Instructions

Posey® Cufflator™ Application Instructions

Posey®

DESCRIPTION OF PRODUCT: Respiratory therapy – Endotracheal tube inflator and manometer

Rx ONLY

Instructions for Use

1. The Posey Cufflator should only be used on tracheal tubes with high-volume, low-pressure cuffs. NOTE: The Posey Cufflator is designed only for use with air-filled cuffs. Use with saline-filled cuffs will cause damage to the unit and void the product warranty.
2. Before use, the control inflator needs to be checked as follows:
   a. Close connecting piece with the finger (Fig. 1).
   b. Inflate with inflation bulb to 120 cm H_2O; value must be constant for 2-3 seconds. If the pressure drops, the device needs repair by the Posey Company.
   c. Inspect the unit and check the cuff for leaks prior to use. Prior to intubation or extubation, withdraw all the air from the cuff with a syringe and close the inflation line.

Fig. 1

3. To properly seal:
   a. Connect the patient to the ventilator.
   b. Connect the Posey Cufflator to the cuff inflation line, and inflate the cuff to a pressure in the range of 60-90 cm H_2O. This will ensure that the cuff is in close contact with the tracheal wall.
   c. Immediately release air by pressing the red release button (Fig. 2) until the lowest safe cuff pressure level is reached.
   d. Intra-cuff pressure should be maintained at a minimum of 20-25 cm H_2O to reduce the occurrence of microaspiration[1] and a maximum of 34 cm H_2O to decrease the incidence of mucosal ischemia and subsequent stenosis.[2]

Fig. 2

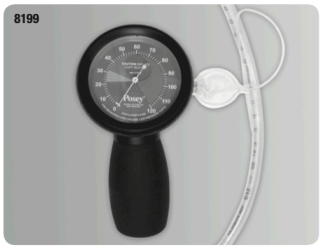
4. The extension tube may be used if constant monitoring of intra-cuff pressure is desired. Connect the extension tube to the cuff inflation line and to the Posey Cufflator. Use the hook on the back of the Posey Cufflator to hang it on the headboard of the bed. The Posey Cufflator will now monitor the intra-cuff pressure continuously and can be inflated or deflated as required.
5. The accuracy of the Posey Cufflator may be verified by connecting it to a mercury sphygmomanometer. Note: The Posey Cufflator is calibrated in cm of water pressure (H_2O). The conversion rate is 1 mm of mercury (Hg) equals 1.36 cm water (H_2O). For example, the Posey Cufflator will read 20 cm H_2O when the mercury sphygmomanometer reads 14.7 mmHg.
6. The accuracy of measurements is ± 2 cm H_2O for the entire range.

⚠WARNING Do not use with saline.

⚠WARNING If the Posey Cufflator is used out of calibration, it may lead to incorrect readings.

[1] Elpern EH. Pulmonary aspiration in hospitalized adults. *Nutr Clin Pract.* 1997;12(1):5-13.
[2] Hill BB, Zweng TN, Maley RH et. al. Percutaneous dilational tracheostomy: report of 356 cases. *J Trauma.* 1996;40:238-245.
For additional information see Stauffer, J.L. Complications of endotracheal intubation and tracheotomy. *Respir Care.* 1999;44(7):828-844.

8199



Cufflator

REF **8199** Cufflator, complete with extension tube

Cleaning Instructions

Wipe the surface thoroughly with an alcohol-based disinfectant. Do not submerge the Posey Cufflator, and do not autoclave. The Posey Cufflator face should be cleaned with a glass cleaner only.

Storage

- This device is designed for use in normal indoor environments.
- This device may be stored in ambient warehouse temperatures at normal humidity levels. Avoid excess moisture or high humidity that may damage product materials.

Disposal

⚠WARNING Dispose of per facility policy for BIOHAZARDOUS material. Be sure to follow all laws that apply.

Service/Repair

The Posey Cufflator should be calibrated annually. If measurements fall outside of the range, or if the Cufflator needle does not indicate a reading of zero when nothing is connected, or if the unit is ever dropped, calibration is recommended.

Cufflator Warranty (Limited)

Posey warrants to the original purchaser that the Posey Cufflator is free of defects in materials and workmanship for a period of one (1) year from date of first use. If the product is found to be defective in workmanship or materials, Posey will repair or replace it with an equivalent product at no charge, other than certain transportation charges. This warranty does not cover damage caused by accident, water immersion, misuse, abuse, improper care, alteration or exposure to heat. This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

⚠WARNING Never open the Posey Cufflator body. If the Posey Cufflator body is opened, any damages that result will not be covered under warranty.

Obtaining Warranty Service

Service under this warranty is available by contacting the Posey Customer Service hotline (1.800.447.6739 or 1.626.443.3143) for a return authorization, and by sending the product to Posey in clean condition, freight pre-paid, and with a dated proof of purchase.

⚠WARNING The Posey Cufflator is a mechanical device. It may fail to work if subjected to severe shock, such as being dropped or immersed in liquid. To reduce the risk of an inaccurate reading (either high or low), inspect the Posey Cufflator each time before putting into use. Do not use if the needle is not on zero when not connected.

⚠CAUTION Federal law (USA) restricts this device to sale by or on order of a physician.

Posey Company • 5635 Peck Road, Arcadia, CA 91006-0020 USA
Phone: 1.800.447.6739 • 1.626.443.3143 • Fax: 1.800.767.3933 • www.posey.com

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Johns Hopkins Nursing Evidence-Based Practice

Appendix A

PET Management Guide

Initial EBP Question: Can education and increasing accessibility to manometers for anesthesia providers help improve the usage of manometers for airway devices cuff pressures intraoperatively?

EBP Team Leader(s): A. Osorio

EBP Team Members: Dr. Stelflug

Activities	Start Date	Days Required	End Date	Person Assigned	Milestone	Comment/ Resources Required
PRACTICE QUESTION:						
Step 1: Recruit interprofessional team	9/1	# days	date	Dr. Hitt, Dr. Steflug	milestone	Pending community partner
Step 2: Define the problem	9/1	90	11/30	N/A	milestone	comments
Step 3: Develop and refine the EBP question	9/1	60	10/31	N/A	milestone	comments
Step 4: Identify stakeholders	9/1	90	10/31	name	Completed	Students of nurse anesthesia and anesthesia providers have been indentified as stakeholders for this project.
Step 5: Determine responsibility for project leadership	9/1	30	10/1	A. Osorio	Completed	comments
Step 6: Schedule team meetings	9/1	# days	date	A. Osorio	Completed	No scheduled mettings will be set at this time. Communication will be maintained via email based on project progression.
EVIDENCE:						
Step 7: Conduct internal and external search for evidence	9/1	30	10/1	A. Osorio	Completed	comments
Step 8: Appraise the level and quality of each piece of evidence	9/1	60	10/30	A. Osorio	Completed	comments
Step 9: Summarize the individual evidence	9/1	60	10/30	A. Osorio	Completed	comments
Step 10: Synthesize overall strength + quality of evidence	9/1	60	10/30	A. Osorio	Completed	comments
Step 11: Develop recommendations for change based on evidence synthesis: • Strong, compelling evidence, consistent results • Good evidence, consistent results • Good evidence, conflicting results • Insufficient or absent evidence	10/30	30	11/30	A. Osorio	Pending	comments
TRANSLATION:						
Step 12: Determine fit, feasibility, and appropriateness of recommendation(s) for translation path	10/30	60	12/30	A. Osorio	Pending	comments
Step 13: Create action plan	10/30	60	12/30	A. Osorio	Pending	comments
Step 14: Secure support and resources to implement action plan	10/30	90	1/31	A. Osorio	Pending	comments
Step 15: Implement action plan	1/31	90	5/1	A. Osorio	Pending	comments
Step 16: Evaluate outcomes	5/1	30	5/31	A. Osorio	Pending	comments
Step 17: Report outcomes to stakeholders	5/31	30	6/30	A. Osorio	Pending	
Step 18: Identify next steps.	5/31	30	6/30	A. Osorio	Pending	comments
Step 19: Disseminate findings.	6/30	120	10/30	A. Osorio	Pending	comments

Appendix F: IRB approval

MARIAN UNIVERSITY
Indianapolis ®

Institutional Review Board

DATE:	04-16-2020
TO:	Alvaro Andres Osorio
FROM:	Institutional Review Board
RE:	IRB #B20.159
TITLE:	Improving manometer usage intraoperatively by increasing accessibility and education.
SUBMISSION TYPE:	New Project
ACTION:	Determination of Non-Exempt Status (Expedited Review)
DECISION DATE:	04-16-2020

The Institutional Review Board at Marian University has reviewed your protocol and has determined the procedures you have proposed are appropriate and approved under the federal regulations. As such, there will be no further review of your protocol and you are cleared to proceed with your project. Your protocol will remain on file with the Marian University IRB as a matter of record.

It is the responsibility of the PI (and, if applicable, the faculty supervisor) to inform the IRB if the procedures presented in this protocol are to be modified or if problems related to human research participants arise in connection with this project. Any procedural modifications must be evaluated by the IRB before being implemented, as some modifications may change the review status of this project. Please contact me if you are unsure whether your proposed modification requires review. Proposed modifications should be addressed in writing to the IRB. IRB approved protocols are administratively closed after one year. Should you need to extend, you must submit a renewal for approval at least one month before the one year date. The IRB will send you an annual report document in which you may request the protocol remain open. **Please reference the above IRB protocol number in any communication to the IRB regarding this project.**

[IRB Chair Name]