Assessing Anesthesia Providers' Preferences and Perceptions of Adequacy of Endotracheal Tube Cuff Pressure Assessment Techniques: A Quality Improvement Project

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Abstract

This Doctor of Nursing Practice project assessed CRNA preferences and perceptions of adequacy regarding subjective versus objective methods to assess endotracheal tube cuff pressure. The ideal pressure within an endotracheal tube cuff is approximately 20-30 cm H_2O. Pressure from the cuff is transferred to the surrounding tracheal mucosa and both inadequate and excessive pressures can lead to medical complications. Subjective methods, such as pilot balloon palpation, minimal occlusive volume, leak test, and a set volume, are generally less accurate than objective measurement with a manometer for the achievement of appropriate endotracheal tube cuff pressure. Seven total CRNA participants at an outpatient surgical center were provided manometers and a brief informational video on cuff pressure and how to use the provided manometers. They reported using the manometers between zero and 20 times during the two-week intervention period. Survey results indicated most participants perceived both subjective and objective methods as adequate for obtaining appropriate endotracheal tube cuff pressure. Pre- and post-intervention survey results also indicated that most participants used solely subjective assessment methods prior to the intervention and will continue to do so after the two-week intervention period.

Keywords: CRNA, anesthesia, endotracheal tube cuff pressure, manometer

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Section I. Introduction

Background

Certified Registered Nurse Anesthetists (CRNAs) skillfully provide general anesthesia to induce complete unconsciousness in patients when such an anesthetic is indicated, either by procedure type or patient-specific factors. The goal is to safely deliver adequate analgesia, amnesia, and areflexia for successful surgical procedures. When CRNAs care for patients under general anesthesia, they are caring for patients when they are at their most vulnerable and incapable of communicating discomfort or pain. The CRNA must be extremely vigilant while caring for all patients, and they must minimize the risk of any anesthesia-related complications spanning the entire perioperative period. Though there are a multitude of elements to consider while providing safe and effective general anesthesia, establishing and maintaining a secure airway is of paramount importance and one of the CRNA's top priorities. An endotracheal tube (ETT) is often the device of choice for this task, but like many medical devices they do not come without risk and must be utilized correctly to minimize potential harm.

Mechanical ventilation during general anesthesia is one of the primary indications for the use of an ETT as it is a means of maintaining a patent airway (Turner et al., 2020). Endotracheal tubes are held in place within the trachea by a cuff that is inflated, typically with air, after insertion. The cuff should not be underinflated or overinflated as either condition may lead to complications. If underinflated, the cuff may not exert adequate pressure on the tracheal wall and could result in air leakage around the cuff, thus hindering mechanical ventilation and placing the patient at increased risk of aspiration. With overinflation, the cuff may exert too much pressure on the tracheal wall and cause a host of complications related to decreased perfusion to the

tracheal mucosa including “tracheal edema, tracheal ischemia, tracheal stenosis, tracheal rupture, sore throats, [or] recurrent laryngeal nerve palsy” (Turner et al., 2020, p. 203).

To avoid complications from underinflated or overinflated ETT cuffs, there is a recommended pressure range to which ETT cuffs should typically be inflated. Many sources within anesthesia literature agree that the ideal pressure range is between 20 and 30 centimeters of water (cm H_2O; Ashman, et al., 2017; Hedberg et al., 2015; Hockey, et al., 2016; Kumar et al., 2020; Mort & Keck Jr., 2018; Sanaie et al., 2019; Stevens et al., 2018; Turner et al., 2020). Despite many sources pointing to an ideal pressure range for ETT cuffs, there is not a standard of practice within the anesthesia community for how to inflate an ETT cuff and ensure appropriate pressure within the cuff. There are currently many techniques, both subjective and objective, that CRNAs and other anesthesia providers use to inflate and assess ETT cuff pressure. Understanding their perceptions of adequacy of these various methods may provide insight and help pave the way for future standardization of practice.

Organizational Needs Statement

This quality improvement project took place in an outpatient surgical center affiliated with a large tertiary hospital in a rural region of a southeastern state. Their mission and values show their determination to improve the health of those in their community by providing excellent care with an emphasis on safety. Much like any respectable health care organization, they strive to cause zero harm to their patients. Attaining zero harm is a continual process that can be pursued by following best practice and safety recommendations and having the ability to identify and prevent potential sources of harm.

At the time of this project, no policy existed at the surgical center that defined precisely how CRNAs should inflate or assess ETT cuffs. Accordingly, there was variation from provider

to provider and many times the methods used were solely subjective. Naturally, anesthesia providers do not want any patient harm to come from inappropriate ETT cuff pressure no matter which method is employed. CRNAs at the surgical center have at their disposal an objective measurement device, called a manometer, that can be used to accurately measure ETT cuff pressure, although its use was not widespread. This quality improvement project aimed to increase CRNA awareness of this device and understand CRNA preferences and perceptions of adequacy of ETT cuff pressure assessment techniques.

This quality improvement project has the potential to help the organization work toward several goals of Healthy People 2030 and the Institute for Healthcare Improvement (IHI) Triple Aim. One of the goals in Healthy People 2030 is to improve health care (Office of Disease Prevention and Health Promotion [ODPHP], n.d.-a), while another is to prevent injuries (ODPHP, n.d.-b). Endotracheal tubes are essential medical devices that can improve patient safety during general anesthesia, but they are inherently invasive. Any invasive medical device has the potential to cause harm or precipitate an adverse event, especially if used inappropriately. Increasing CRNA awareness of a more accurate and effective method for ETT cuff pressure measurement has the potential to help address both of these goals. At the same time, understanding CRNA perceptions regarding the adequacy of various ETT cuff pressure assessment techniques could help the organization determine if and what steps should be taken to champion these goals.

Quality improvement efforts such as these can create tremendous positive change within an organization. The IHI's Triple Aim (2020) is a framework that guides health care organizations towards improving health care delivery and health system performance. Two of the three aims are directly related to ETT cuff pressure. They include "improving the patient

experience of care (including quality and satisfaction) … and reducing the per capita cost of health care" (IHI, 2020, para. 1). Patients who undergo tracheal intubation during general anesthesia are more likely to view their anesthesia experience as satisfactory if they do not experience any post-anesthesia adverse effects. Inappropriate ETT cuff pressure during anesthesia has the potential to cause a variety of adverse effects, ranging from a mild sore throat to more severe complications such as aspiration pneumonia or tracheal injury (Turner et al., 2020, p. 203). By increasing CRNA awareness of a method that ensures appropriate ETT cuff pressure, adverse effects and complications could potentially be reduced. With fewer complications, health care costs would naturally decrease, as medical complications often require additional treatments or extended hospital stays.

This project also lends support to the Standards of Nurse Anesthesia Practice from the American Association of Nurse Anesthetists (AANA). Standard 1 entails protecting patients' rights and implores CRNAs to "respect the patient's autonomy, dignity, and privacy, and support the patient's needs and safety" (AANA, 2019, para. 5). Standard 6 pertains to equipment, calling for CRNAs to follow safety precautions relating to anesthesia equipment (AANA, 2019). ETTs are considered anesthesia equipment and using these devices properly by ensuring appropriate ETT cuff pressure falls into the realm of patient safety. Standard 12 involves the quality improvement process, calling on CRNAs to apply this process to improve anesthetic outcomes (AANA, 2019). As this project is one based on quality improvement, it directly relates to this standard.

Lastly, this project also embraces the Anesthesia Patient Safety Foundation's (APSF) mission and vision statements. Their mission is to improve patient safety during anesthesia care and their vision is that no harm comes to any patient because of anesthesia care (APSF, 2021).

Appropriate ETT cuff pressure not only improves safety but also reduces the risk of patient harm.

Problem Statement

CRNAs use a variety of subjective and objective methods to assess ETT cuff pressure. Endotracheal tube cuff pressures that are either too low or too high during general anesthesia are capable of causing complications for patients. There is currently a lack of understanding about CRNA preferences and perceptions of adequacy regarding both subjective and objective ETT cuff pressure assessment methods.

Purpose Statement

The purpose of this quality improvement project was to assess anesthesia providers' perceptions of perioperative usefulness of subjective tactile methods and the objective manometer method to assess occlusive volume in ETT cuffs.

Section II. Evidence

Literature Review

There is a substantial volume of literature addressing ETT cuff pressure. However, there is less literature regarding CRNA preferences for and perceptions of adequacy of the various subjective and objective methods used to assess pressure within ETT cuffs. Initial literature searches sought to identify articles pertaining to two contemporaneous concepts: "ETT cuff pressure" and "anesthesia." Keywords, PubMed Medical Subject Headings (MeSH), and Cumulative Index to Nursing and Allied Health Literature (CINAHL) Subject Headings were determined based on these overarching concepts (see Appendix A). These search terms, along with Boolean operators, search criteria, and quantity of results, including duplicates from multiple sources, are noted in Appendix B. The databases and search engines used included PubMed, CINAHL, East Carolina University (ECU) Libraries' OneSearch, ProQuest, and Google Scholar. Items identified through these searches were screened at title level followed by abstract level. Eight articles were identified as pertinent to this project. Information about each of these articles may be found within the literature matrix in Appendix C.

Current State of Knowledge

The research articles presented in Appendix C provided insight into the current state of knowledge concerning ETT cuff pressures and related issues pertinent to this project. Applying Melnyk and Fineout-Overholt's (2019) levels of evidence, levels I through IV were represented in these selected articles. Level I evidence includes systematic reviews or meta-analyses of randomized controlled trials and is regarded as the highest level of evidence. Level II evidence is obtained from randomized controlled trials, level III from non-randomized controlled trials, and level IV from cohort or case-control studies (Melnyk & Fineout-Overholt, 2019). A wide variety

of other source types was also reviewed and used to support this project. These additional sources included respected textbooks and references, websites of professional and governmental organizations, expert opinions, and related articles.

Currently, it is generally accepted that the optimal pressure range for an ETT cuff to avoid complications is between 20 and 30 cm H_2O (Ashman, et al., 2017; Hedberg et al., 2015; Hockey, et al., 2016; Kumar et al., 2020; Mort & Keck Jr., 2018; Sanaie et al., 2019; Stevens et al., 2018; Turner et al., 2020). At cuff pressures below 20 cm H_2O, aspiration around the cuff is possible and could lead to pneumonia (Kumar et al., 2020). When cuff pressure exceeds 34 cm H_2O, blood flow to the tracheal mucosa surrounding the ETT cuff may become compromised, and when cuff pressure exceeds 50 cm H_2O, complete obstruction of blood flow to the tissue may occur (Williams et al., 2019).

Obtaining an objective measurement of ETT cuff pressure with a manometer is regarded as the most accurate technique, and the gold standard, to ascertain the pressure within an ETT cuff (Kumar et al., 2020; Mort & Keck Jr., 2018). Despite this, CRNAs often use methods that are more subjective. Use of these subjective methods has frequently been shown to result in maintenance of ETT cuff pressures outside the optimal range, usually in excess of 30 cm H_2O (Ashman, et al., 2017; Hockey, et al., 2016; Kumar, et al., 2020; Stevens et al., 2018; Turner et al., 2020).

Pilot balloon palpation is one of the subjective methods commonly used by CRNAs to assess ETT cuff pressure. Although not a study among CRNAs, Giusti et al. (2017) found that experienced providers were grossly unable to accurately approximate the pressure within an ETT cuff when using pilot balloon palpation. Researchers have noted that this method leads to overinflation of the ETT cuff 30-98% of the time (Kumar, et al., 2020). A study by Ganason et

al. (2019) looked at the incidence of post-operative sore throat and hoarseness, two adverse effects that can be associated with overinflated ETT cuffs (> 30 cm H_2O). One study group had their ETT cuff pressure adjusted to 25 cm H_2O immediately after tracheal intubation and the other study group had their ETT cuff pressure guided solely by pilot balloon palpation. Sore throat and hoarseness were roughly twice as likely in the pilot balloon palpation group. This suggests that pilot balloon palpation alone is less reliable than an objective measurement at producing acceptable ETT cuff pressures and that overinflated ETT cuffs may cause adverse effects for patients.

Another frequently used technique uses either a 5 mL or 10 mL syringe to inject a set volume of air followed by subjective adjustments guided by pilot balloon palpation. Williams et al. (2019) noted that providers are highly likely to overinflate the ETT cuff when using the more commonly employed 10 mL syringe and a subjective method, such as pilot balloon palpation. They found that the average ETT cuff pressure with this combined method was 68.8 cm H_2O. Even when a 5 mL syringe was used instead of a 10 mL syringe, the average cuff pressure was 55.8 cm H_2O.

An additional subjective method for assessing ETT cuff pressure is the minimal leak test. This is when air is incrementally injected into the ETT cuff until audible air leakage around the cuff is eliminated during ventilation. Selman et al. (2020) found that when using this method, providers inflated ETT cuffs to pressures outside the range of 20 to 30 cm H_2O 24% of the time. This technique may be more appropriate, however, than injecting a set volume of air if trying to attain ETT cuff pressures within the target range. Sanaie et al. (2019) found that ETT cuffs inflated with 10 mL of air had a mean cuff pressure of 46.07 cm H_2O, compared to a mean of 33.72 cm H_2O in the minimal leak test group. The minimal leak test was also more reliable than

using 10 mL of air to produce ETT cuff pressures between 20 and 30 cm H_2O, at 78.2% and 56.4% respectively.

A systematic review and meta-analysis by Hockey et al. (2017) looked at multiple studies to determine which type of method, either subjective or objective, was best at preventing adverse effects from cuff pressures outside the recommended range of 20 to 30 cm H_2O. Their findings coincided with the general themes found in the previously mentioned articles: that using objective measurements to guide cuff pressure management is more reliable than subjective measurements at maintaining optimal cuff pressures and can decrease the rate of adverse effects.

Current Approaches to Solving Population Problem

While many hospitals have guidelines and protocols for managing ETT cuff pressure with objective measurement devices in intensive care settings, there does not seem to be the same precedent set forth within anesthesia settings. One reason for this may be that, on average, endotracheal tubes are in place for a much shorter duration of time when used for general anesthesia. However, this does not mean that monitoring ETT cuff pressure during general anesthesia is unimportant, as complications from underinflated or overinflated ETT cuffs are still possible even during shorter periods of tracheal intubation (Ganason et al., 2019; Mort & Keck Jr., 2018; Kumar et al., 2020).

No studies identified during review of current literature related to this project examined CRNA preferences for, and perceptions of adequacy of, subjective versus objective methods of assessing ETT cuff pressure. Literature pertaining to such subject matter could provide insight as to why CRNAs often use subjective methods to inflate ETT cuffs and manage cuff pressure over objective methods. The literature reflects a general view that objective methods may be superior to subjective, and several identified studies evaluated interventions intended to increase

anesthesia provider use of objective methods to guide ETT cuff pressure management (Ashman et al., 2017; Stevens et al., 2018; Turner et al., 2020).

A study by Ashman et al. (2017) assessed if educating anesthesia providers about ETT cuff pressure had any impact on average ETT cuff pressures and the frequency of ETT cuff pressure measurement. The anesthesia provider participants were informed that reduced rates of postoperative pharyngeal complications are seen when ETT cuff pressures are maintained between 20 and 30 cm H_2O during general anesthesia. They were also warned of the inaccuracies of pilot balloon palpation. The researchers subsequently placed physical reference cards noting the recommended cuff pressure range in all operating rooms and added a place within the electronic anesthesia record for recording a measured cuff pressure in cm H_2O. Their interventions increased provider monitoring and adjustment of cuff pressures intraoperatively and also decreased the mean intraoperative cuff pressures as compared to the pre-intervention period.

Stevens et al. (2018) and Turner et al. (2020) conducted quality improvement studies with similar focuses. They both concentrated on educating staff about manometer usage and optimal ETT cuff pressure. They both provided easily accessible manometers in each operating room and posted prominent signs near the anesthesia workstations reminding providers to check the cuff pressure. Compared to pre-intervention, Stevens et al. (2018) found that median cuff pressure dropped from 38.5 cm H_2O to 30 cm H_2O, with twice as many cuff pressures within the range of 20 to 30 cm H_2O after the intervention period. Turner et al. (2020) found that cuff pressures were 4.4 times more likely to be within the recommended range after the intervention period and that provider use of manometers to determine cuff pressure improved from 10% pre-intervention to 94% post-intervention.

Evidence to Support the Intervention

There are multiple examples in the literature suggesting that safe inflation pressures of ETT cuffs are most reliably attained with a manometer and that anesthesia provider education on manometers and ETT cuff pressure can increase manometer use (Ashman et al., 2017; Stevens et al., 2018; Turner et al., 2020). This supports the intervention of providing each CRNA participant with a manometer and a short informational video that discusses subjective versus objective ETT cuff pressure measurement, appropriate manometer use, and the recommended ETT cuff pressure range of 20 to 30 cm H_2O. Since CRNA preferences and perceptions regarding the adequacy of subjective and objective methods for ETT cuff pressure management are not well understood, survey questions were asked to glean more information and hopefully provide insight into the methods used by the CRNAs at the surgical center both before and after the intervention.

Evidence-Based Practice Framework

The Iowa Model-Revised is a framework for employing evidence-based practice that is very applicable to this quality improvement project. The Iowa Model-Revised is a derivative of the original Iowa Model after a "re-evaluation, revision, and validation of the model" by the Iowa Model Collaborative in 2017 (p. 175). The first steps of the Iowa Model-Revised are to identify an opportunity or triggering issue that warrants attention and to determine the question to be answered (Iowa Model Collaborative, 2017). In this project, there is an opportunity to improve current practice at the surgical center since subjective methods are still used more often by CRNAs than objective methods when it comes to ETT cuff inflation and pressure management. This opportunity warrants attention because adverse events are less likely to occur if ETT cuff pressures are maintained within the optimal range of 20 to 30 cm H_2O. There is also

an opportunity to better understand CRNA preferences and perceptions of adequacy of subjective versus objective methods for assessing ETT cuff pressure since accessible data on this topic was not apparent during the literature search for this project. The questions to be answered are: 1. How to best facilitate provider use and knowledge of objective methods? 2. How to assess CRNA preferences and perceptions regarding subjective and objective assessment of ETT cuff pressure?

Next, the model (Iowa Model Collaborative, 2017) directs one to determine if there is adequate evidence in the literature to answer the question or if research needs to be conducted. There is adequate and convincing evidence in the Ashman et al. (2017), Stevens et al. (2018), and Turner et al. (2020) studies that a brief educational presentation and readily available manometers will likely increase CRNA utilization of objective methods for ETT cuff pressure management. Since adequate evidence is available, the model next states to develop and test out a plan for change (Iowa Model Collaborative, 2017). This is where the intervention phase of the project takes place. If the intervention appears to be successful, then the change must be incorporated into and maintained in practice (Iowa Model Collaborative, 2017). The scope of this project allows for recommendations and encouragement, but it will be up to the organization to pursue any formal practice changes.

Ethical Consideration & Protection of Human Subjects

This quality improvement project was deemed as exempt from full review through a process created in conjunction with the ECU and medical center Institutional Review Board and the partnering organization (see Appendix D). The researcher completed the basic courses of the Collaborative Institutional Training Initiative (CITI) Program's (2017) Biomedical Responsible Conduct of Research Course and Group 1 All Biomedical Investigators and Key Personnel

Course. Participation by the surgical center CRNAs was completely voluntary throughout the entire duration of the project. There was no more than minimal risk to participants, confidentiality was maintained, and no identifying information was gathered during data collection. Delivery of the informational video and surveys was virtual, which reduced time and access demands on participants and reduced health risks related to non-essential person-to-person contact during the ongoing viral COVID-19 pandemic.

Accepted practice at the project facility already allowed for provider discretion regarding which method they utilized when inflating ETT cuffs and assessing cuff pressure. This included manometers, which prior to this project were already available to the CRNAs at the surgical center. The intervention, which included administering surveys and distributing an informational video on evidence-based practices, is also typical and expected within a health care organization. No patient data was collected, and no personal information was gathered from the participating CRNAs other than name and email address as surveys and the video were accessed using anonymous Qualtrics links.

Section III. Project Design

Project Site and Population

Description of the Setting

This project took place at an outpatient surgical center affiliated with a large tertiary hospital located in the southeastern United States. The surgical center is situated in a town of almost 100,000 residents although many of the surrounding counties are quite rural. The facility provides surgical services to patients from all over the state, a majority of whom are able to return home the same day. In 2018, almost 12,000 surgeries were performed at the facility. The surgical center consistently scores highly on measures of patient satisfaction, health care performance, and quality.

The surgical center performs procedures Monday through Friday and has ten operating rooms, each one starting procedures around 7:30 a.m. and ending around 3:00 p.m. Operating room turn-around time and time from patient in the room to procedure start is fast-paced. While this is very quick and efficient, it does not leave much time for staff to participate in ancillary quality improvement initiatives such as this project. While there is a considerable volume of cases at the surgical center, not all cases require endotracheal tubes, meaning the purpose of this project is inapplicable at the facility roughly half of the time.

Description of the Population

The CRNAs who work at the surgical center were the target population for this project. They are not employed by the surgical center itself, but rather a private anesthesia organization that is contracted to provide anesthesia services to the surgical center and the hospital with which it is affiliated, as well as other facilities across the state. Seven CRNAs were full-time at the surgical center at the time of this project, with all having multiple years of experience as CRNAs

(T. Chabo, personal communication, August 11, 2020). The surgical center CRNAs have had a relationship with the ECU Nurse Anesthesia Program for many years as they routinely precept ECU's Nurse Anesthesia students. They were recruited to participate by a CRNA faculty member of the program. This relationship facilitated CRNA participation but still some of the CRNAs were less willing to readily participate in this project than others.

Project Team

The project team consisted of a Doctor of Nursing Practice (DNP) student in the ECU Nurse Anesthesia Program and CRNA faculty from the program including the ECU Nurse Anesthesia Program Director and a faculty member who served as the site coordinator and project chair. In addition, the project was supported by a non-CRNA faculty member who served as the project facilitator. The chief CRNA at the surgical center also supported the project. Initial project development, including design and creation of the surveys and video, was conducted in conjunction with several other doctoral students in the ECU Nurse Anesthesia Program. Implementation, data collection, and data analysis, however, were conducted individually by the writer of this paper.

Project Goals and Outcome Measures

Description of the Methods and Measurement

This project utilized a pre- and post-intervention survey design to evaluate CRNA preferences regarding subjective versus objective methods of ETT cuff pressure assessment. CRNA perceptions of adequacy of these two types of methods both before and after viewing an informational video were also evaluated. The video addressed the recommended ETT cuff pressure range of 20 to 30 cm H_2O, differences between subjective and objective methods for assessing ETT cuff pressure, and effective use of a manometer.

This project was conducted as a partial, single-cycle Plan-Do-Study-Act (IHI, 2017) process, applying the plan, do, and study portions. The 'plan' portion consisted of literature searches, developing the project and intervention, and recruiting participants. Literature searches have been described previously. The project intervention, consisting of pre- and post-surveys and a brief informational video, may be found in Appendices E and F, respectively. Participants were recruited by a clinical CRNA faculty member who had an existing relationship with the surgical center CRNAs. The faculty member gathered the names and email addresses of the seven full-time surgical center CRNAs, all of whom agreed to receive information about the project, and subsequently provided these to the DNP student.

The 'do' portion consisted of implementing the intervention. This entailed distribution of the pre- and post-surveys and the informational video to potential participants. In April 2021, potential participants were provided with anonymous Qualtrics hyperlinks via email to the pre-survey and informational video, with instructions to complete the pre-survey prior to viewing the video (see Appendix G). After viewing the video, participants had two weeks to utilize a manometer and incorporate the information from the video into their practice at their discretion. Manometers were made readily available in the anesthesia supply room, tacked to the bulletin board next to the CRNA room assignments. A reminder email about the pre-survey, video, and ongoing implementation period was sent during the implementation period (see Appendix H). The DNP student was in a clinical rotation at the surgical center during the first week of the implementation period and was available to answer any questions pertaining to the project. After two weeks from the initial email, an email was sent with an anonymous Qualtrics hyperlink to the post-intervention survey as well as a final reminder about the pre-survey and video with the appropriate hyperlinks (see Appendix I). An email expressing thanks was sent following

satisfactory completion of data collection (see Appendix J).

To satisfy the 'study' portion of the Plan-Do-Study-Act cycle (IHI, 2017), an analysis of both pre-intervention and post-intervention survey results was conducted and is described in Section IV of this paper. Survey questions were formulated to gather data on the nominal, ordinal, and ratio levels. Analysis was performed to assess if the informational video and two-week intervention period had an effect on CRNA preferences and perceptions of adequacy of subjective versus objective methods for ETT cuff pressure management.

Discussion of the Data Collection Process

Surveys and the informational video were distributed by email as Qualtrics hyperlinks. These links were accessible via computer or mobile platforms and provided anonymity during survey completion and video viewing. Qualtrics software tracked survey results. Several questions appeared on both pre- and post-intervention surveys to allow for comparison and assessment of change. Surveys consisted primarily of Likert-type questions but also contained several free response questions and one with a dichotomous answer choice.

Implementation Plan

All full-time CRNAs at the surgical center were informed of the opportunity to participate in this quality improvement initiative by the clinical CRNA faculty member supporting this project. Unless they expressly stated they did not want to participate, the CRNAs were informed that their email addresses would be provided to the DNP Project Student and that they would receive emails regarding participation. Their email addresses were used for survey and video distribution purposes only. Qualtrics was used provide a link to the informational video and to track survey results anonymously. A detailed description of the survey questions, video transcript, and emails sent to participants can be found in Appendices E-J.

Timeline

Formulation of this project began in the academic semester of fall 2020. This included initial literature searches, meetings with project team members, development of purpose and problem statements, drafting portions of this paper, verifying exemption from full institutional review board (IRB) review, and finalizing pre- and post-survey questions. Subsequent semesters included producing the informational video, recruiting CRNA participants from the surgical center, and distributing emails containing the pre-survey, informational video, post-survey, and reminders, followed by data collection and data analysis. A detailed timeline can be found in Appendix K.

Section IV. Results and Findings

Results

Both pre- and post-intervention survey results were collected over a total period of approximately two and a half weeks. Of seven participants recruited for the project, the pre-intervention survey had five respondents and the post-intervention survey had seven respondents. In the pre-intervention survey, all participants reported using one or more subjective methods in their current practice to obtain adequate ETT cuff pressure, including minimal occlusive pressure, pilot balloon palpation, and audible air leak while none reported utilizing an objective measurement (i.e., a manometer). Both pre- and post-intervention opinions of adequacy of subjective and objective methods to obtain appropriate ETT cuff pressure were evaluated. All but one of the seven post-intervention survey respondents reported utilizing a manometer at least once during the intervention period. Most reported using a manometer less than five times, but one participant stated they used it 10 times and another reported using it 20 times. At the end of the intervention period, post-survey data showed that most participants intended to utilize a manometer less than 25% of the time in their future practice. Regardless of these findings, the intervention experience exposed each participant to an objective method for measuring ETT cuff pressure. This led to six out of the seven participants utilizing and becoming acquainted with a manometer over the two-week period. This introduction to manometers may have value in and of itself.

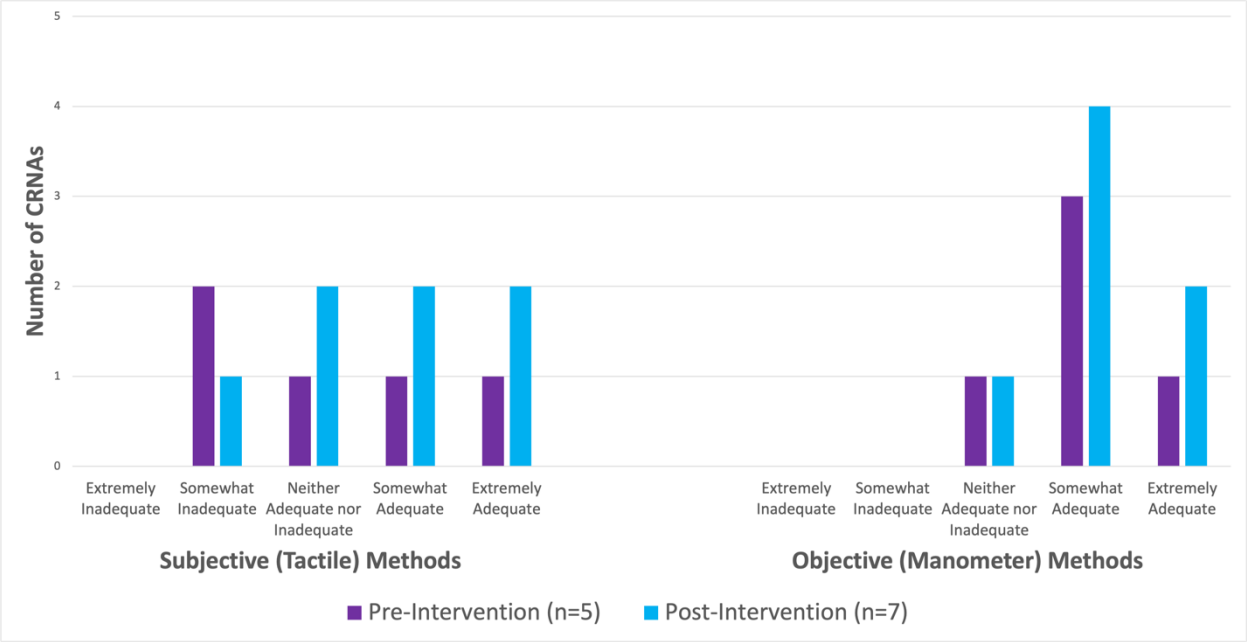
Analysis

Participants were asked about their opinions of the adequacy of subjective and objective methods to obtain appropriate ETT cuff pressure both before and after the intervention period. Survey results displayed in Figure 1 show participants found the adequacy of subjective methods

about the same both pre- and post-intervention. At pre-intervention, all respondents reported using *solely* subjective methods around half the time or greater, whereas post-intervention several respondents reported that they utilized or intended to utilize *solely* subjective methods either never or sometimes. This shows that, post-intervention, some of the surveyed CRNAs reported that they intend to utilize an objective measurement (i.e., manometer) to obtain appropriate ETT cuff pressure at least some of the time in their future practice. Of the seven post-intervention respondents, three responded that they would utilize a manometer at least some of the time (see Figure 2). Despite some participants' intentions to occasionally utilize a manometer in future practice, pre- and post-intervention opinions of the adequacy of objective measurement to obtain appropriate ETT cuff pressure remained relatively stable. Similarly, pre- and post-intervention opinions regarding subjective assessment varied minimally (see Figure 1).

Figure 1

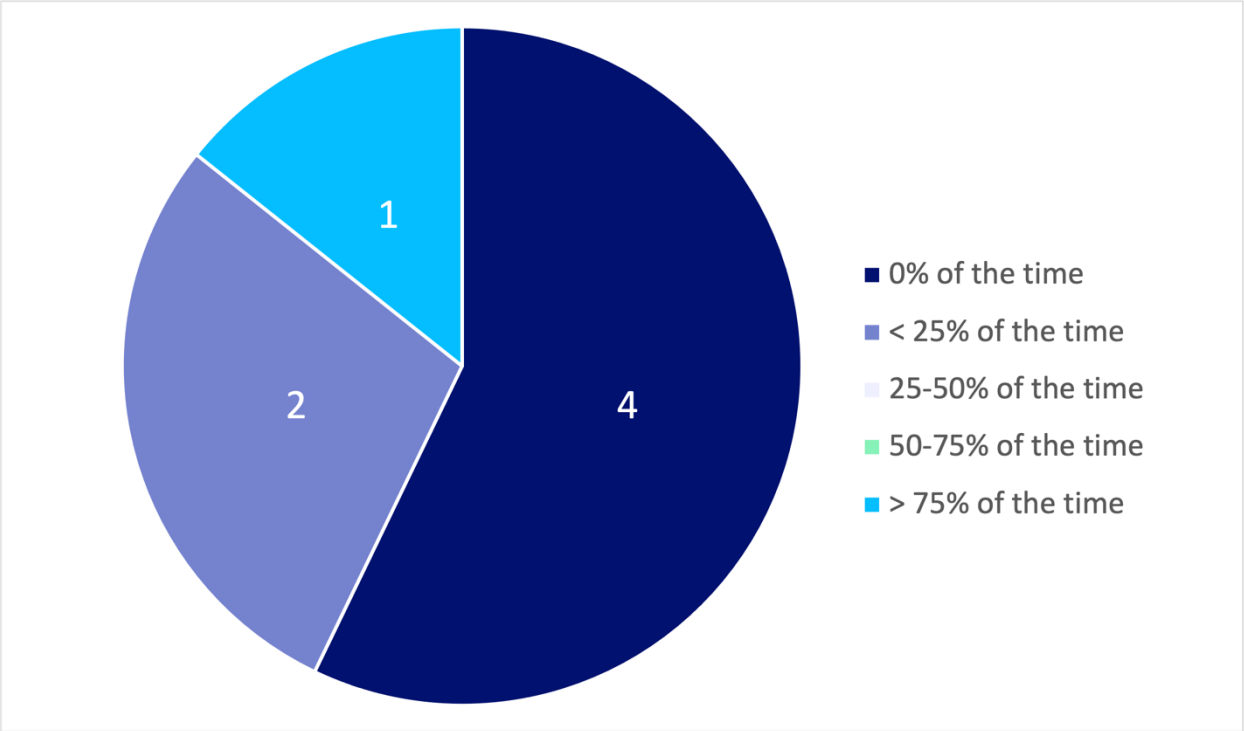
CRNA Opinions on Adequacy of Methods for Obtaining Appropriate ETT Cuff Pressure



Note. Pre-intervention n = 5. Post-intervention n = 7. Since the post-intervention survey included two more respondents than the pre-intervention survey, results may inaccurately reflect changes in opinions.

Figure 2

Post-Intervention Frequency that CRNAs Intend to Utilize a Manometer in their Practice



Note. Post-intervention n = 7.

With a small sample size and unequal pre- and post-intervention participant numbers, it is difficult to make any inferences about whether the intervention had any bearing on CRNA preferences or perceptions regarding subjective or objective methods. The survey results indicate that both before and after the intervention, some of the CRNAs found subjective methods adequate while others found them inadequate. In contrast, none of the CRNAs reported objective measurement with a manometer being inadequate before or after the intervention. At worst, some of them believed objective measurement was "neither adequate nor inadequate."

The final question of the post-intervention survey queried if participants thought utilization of an objective manometer would be beneficial in certain types of surgical cases. Six

of the seven respondents answered this dichotomous yes/no question with half responding “yes” and half responding “no.” The three respondents selecting “yes” were then provided a text box within the electronic survey for suggesting types of cases for which they believed a manometer would be beneficial. One of the participants noted pediatric cases and two of them noted patient history of tracheal stenosis as situations when a manometer could be advantageous; all three noted that a longer intubation time could be an occasion when objective measurement with a manometer could be beneficial.

Section V. Interpretation and Implications

Cost Benefit Analysis

The cost of this project was minimal. All CRNA participants were able to access emails and information pertaining to the project as well as complete online surveys during their normal working hours, either from a computer or their personal mobile device. Manometers were supplied to each participant for convenience during the intervention period as these devices were not currently an item kept in inventory at the surgical center at the time of this project. However, these devices were readily available at the surgical center's affiliated hospital where the CRNAs are also credentialed to practice. As employees of the anesthesia group that provides anesthesia at both locations, the CRNA participants of this project had the ability to use these devices at the hospital and incorporate them into their practice.

The manometers cost $17 each and are not items patients are charged for if one is used during their care. These manometers are multi-use: the manufacturer states each one is designed to provide approximately 100 pressure measurements (Hospitech Respiration, Ltd, 2015). This amounts to roughly $0.17 per measurement and depending on how many times a manometer is used during an individual case it could cost as little as $0.17 per patient to ensure appropriate ETT cuff pressure. This cost is extremely negligible considering the potential cost of medical services that may be necessary if a complication from inappropriate ETT cuff pressure were to occur. Patients who experience complications related to inappropriate ETT cuff pressure may require additional tests, procedures, or hospital days to effectively treat the complication. These costs may be exorbitant. For example, the average cost of a 3-day hospital stay is $30,000 (U.S. Centers for Medicare & Medicaid Services, n.d.). Many surgical procedures requiring endotracheal intubation are performed on an outpatient basis. A complication associated with

inappropriate ETT cuff pressure that results in a 3-day hospital admission with additional tests and procedures would no doubt increase health care costs. These monetary costs do not include the potentially detrimental personal costs to patients that may be associated with a medical complication such as decreased or altered physical function, a loss of working days, or depression. By incorporating manometers into practice there could theoretically be fewer medical complications and increased patient satisfaction. The health system would likely spend less health care dollars even if just one patient out of many is prevented from suffering a complication related to ETT cuff pressure.

Resource Management

The partnering organization could promote the use of manometers without additional effort in their daily processes. The chief CRNA at the surgical center was a proponent of manometers during the project period and has multiple modes of communication with the CRNA staff. Simple education and information about manometers through emails, flyers, posters, staff meetings, or reminder cards in the operating rooms could increase awareness of the measurement tool and may encourage its use. Manometers could be made readily available to each CRNA by stocking them in the supply room or by keeping one in the top drawer of each anesthesia machine. Manometers are currently only stocked in the main hospital, not within the surgical center, which could present a potential hurdle to maintaining a supply of manometers at the surgical center.

Implications of Findings

Although this project was conducted on a small scale, the findings suggest that a larger scale assessment of CRNA perceptions of adequacy of subjective versus objective methods for obtaining appropriate ETT cuff pressure and implementation of manometers may have

meaningful implications for future practice. None of the seven CRNA participants in this project had ready access to a manometer prior to the intervention. With project implementation, however, each one of them received easy access to a manometer as well as information on appropriate ETT cuff pressure and manometer operation. Receiving this information and a manometer created the potential for changes to occur in their practice.

The Iowa Model-Revised is a framework that helps guide evidence-based practice (Iowa Model Collaborative, 2017). This quality improvement project applied the foundational steps of the framework successfully, regardless of its small sample size. This project was able to identify an opportunity that warranted attention, determine a question to be answered, and evaluate evidence found in existing literature. The next step in the model states that a plan for change to be developed and tested; if it's successful, the change should be incorporated into and maintained in practice. If it is unsuccessful at creating appropriate change, alternatives should be considered and the plan for change should be redesigned. The intervention created for this project principally assessed the potential for practice change, and the findings suggest that the potential is there.

The results of this project gained insight into CRNA preferences and perceptions of adequacy of subjective versus objective methods for assessing ETT cuff pressure. Since there is adequate existing research that supports manometer utilization to obtain appropriate ETT cuff pressure (Ashman et al., 2017; Stevens et al., 2018; Turner et al., 2020), a practice change may be warranted. Further development, revision, and testing of a plan for sustainable practice change is the next step toward incorporating more evidence-based practice into ETT cuff pressure management at the surgical center.

Implications for Patients

Patients are the ones who stand to gain the most benefit from this project. The APSF's mission is to improve patient safety; accordingly, their vision is that no patient harm occurs because of anesthesia care (APSF, 2021). Manometers are objective devices that give an actual measurement of ETT cuff pressure and since ideal ETT cuff pressure is generally believed to be 20 to 30 cm H_2O (Ashman, et al., 2017; Hedberg et al., 2015; Hockey, et al., 2016; Kumar et al., 2020; Mort & Keck Jr., 2018; Sanaie et al., 2019; Stevens et al., 2018; Turner et al., 2020), one can deduce that manometers are an effective way to obtain an appropriate ETT cuff pressure. The informational video provided to CRNA participants in this project contained information on the appropriate ETT cuff pressure range, complications that can arise from inappropriate ETT cuff pressures, and how to use a manometer. This information can help guide safer practice and hopefully reduce the risk of complications for patients.

Implications for Nursing Practice

The AANA's 12th Standard of Nurse Anesthesia Practice calls on nurse anesthetists to employ the quality improvement process to improve anesthetic outcomes (AANA, 2019). Initiatives that support increased utilization of manometers would fall under this standard. Since around half of the CRNA participants in this project endorsed that they would not be using a manometer in their future practice, the organization may need to devise further quality improvement initiatives if they wish to pursue this avenue. One way they could accomplish this is by placing small, laminated cards on every anesthesia machine that remind staff of the appropriate ETT cuff pressure range and encourage the use of a manometer. Variations of this process were a success in studies by Ashman et al. (2017), Stevens et al. (2018), and Turner et al. (2020). Having manometers at each anesthesia station may reduce the time and effort required to

find and incorporate the device into practice. This process may increase manometer utilization and help CRNAs strive toward continual quality improvement.

Impact for Healthcare System

The overall resources needed to maintain a quality improvement initiative such as encouraging manometer utilization would be nominal but the opportunities to prevent patient harm could be substantial. Thus, the impact on the health care system would be subtle but powerful. A reality in health care is that financial implications are often a huge consideration. One of the IHI's three aims in their Triple Aim is to "reduc[e] the per capita cost of health care" (IHI, 2020, para. 1) and fewer medical complications means less cost.

Sustainability

The incorporation of manometers into CRNA practice at the surgical center could certainly be sustainable with some effort within the organization. The biggest potential barriers are buy-in from the CRNAs to increase their use of manometers and the actual manometer supply. The CRNA participants each received a manometer during this project that can be used to obtain approximately 100 pressure measurements. (Hospitech Respiration, Ltd, 2015). After that, new manometers would need to be supplied. Although manometers are readily available at the main hospital with which the surgical center is affiliated, a supply chain adjustment would need to be made to have manometers stocked regularly at the surgical center.

In terms of CRNA buy-in, a point-person would likely need to be selected to provide continued encouragement of manometer use. This could include personal communication, emails, and/or information posted near work areas and on the anesthesia machines. Additional steps to increase manometer utilization may include adding a location on the anesthesia record

where an ETT cuff pressure measurement could be documented and/or by incorporating manometer use into a new protocol.

Dissemination Plan

This DNP project was shared and made public via multiple avenues. This paper itself was posted in East Carolina University's institutional repository, The ScholarShip, which makes it discoverable by the general public. A poster was created and presented to members of the ECU nurse anesthesia community, and those from the partnering organization, including the CRNA participants, were invited to attend as well.

Section VI. Conclusion

Limitations

While this project was successful overall in its process and execution, there were several limitations identified during planning, implementation, and evaluation of this project. First, it was known ahead of time that the sample size would be small. There were seven total CRNAs who were full-time surgical center anesthesia providers that were potential participants in this project. Five of them responded to the pre-intervention survey while all seven responded to the post-intervention survey. Another limitation is that participants were only encouraged to watch the informational video but the CRNAs were never asked in a survey if they did, in fact, watch it. The Qualtrics video link recorded only three views, although it is unclear what constituted a view: did the link just need to be opened or did the video need to be watched in its entirety? This, in conjunction with the two additional post-intervention survey responses, could undermine the results from this project as it made it difficult to compare results in a meaningful way from before and after the two-week intervention period.

Additionally, the actual survey questions themselves were reflected upon during data analysis. Several of the questions could have been stronger. The parenthesized word “tactile” in questions pertaining to subjective assessment techniques could have been misleading to participants as subjective techniques do not necessarily require palpation. Question 3 and 4 in the post-survey (see Appendix E) could have been improved as well. Question 3 should have specified a timeline (prior to the intervention, during the two-week intervention period, etc.) or could have been eliminated. Question 4 was more pertinent to evaluation of the intervention. However, the word “solely” that appeared in several pre- and post-intervention survey questions, including post-survey question 4, implies “only,” and that could have caused some ambiguity in

the question as the response choices were on a Likert-type scale. Afterthought also suggested that another valuable question could have been asked – one that directly asked participants if they perceived a difference in the adequacy and/or accuracy of subjective versus objective methods, and if so, which one they found superior.

Recommendations for Others

There are several recommendations that could improve this project's effectiveness if it were to be recreated by others. First, a larger sample size would help to more broadly understand CRNA perceptions regarding ETT cuff pressure assessment and management techniques. This could include project implementation at several surgical centers or practice settings. Survey questions could be modified to increase clarity, as mentioned previously, to strengthen their ability to assess what is intended to be assessed. If the goal is to incorporate manometers into evidence-based practice, a more structured approach to the intervention would be recommended. This could include an organized viewing of the instructional video, such as at a staff meeting, and more formal encouragement of manometer utilization. Ways to encourage manometer use might include emails to staff, flyers, posters, and reminders affixed to each anesthesia machine. Tracking of manometer use, by self-report or documentation in the anesthesia record, could also increase usage rates.

Recommendations for Further Study

Anesthesia care is continually evolving, and room should always be made for further study when it comes to research and evidence-based practice. With the evidence currently available, it is reasonable that manometer use for ETT cuff pressure assessment could be instituted as a standard of practice. However, further research studies should be conducted to assess which types of cases and situations see a clear benefit from manometer utilization in terms

of costs. This includes both reduced financial burdens and decreased incidences of ETT cuff pressure-related morbidity and mortality. Results from these additional studies would need to be widely disseminated. This could help improve buy-in from accrediting bodies, stakeholders, and nurse anesthesia providers.

Nonetheless, quality improvement initiatives could increase manometer usage in the meantime. Offering a brief educational in-service on ETT cuff pressure and manometers would be a simple place to start. Providing manometers and familiarizing staff with how to properly use the devices would also be a key aspect of a quality improvement initiative. A plan for a go-live or rollout event should then be devised that would effectively encourage increased manometer usage. With a little effort and education, manometers may help decrease perioperative complications caused by inappropriate ETT cuff pressure.

Key realizations made throughout this quality improvement project include a need for further evaluation of CRNA perceptions on ETT cuff pressure assessment methods, and the development of a process to increase objective measurement of ETT cuff pressure at surgical centers. Providing ETT cuff pressure measurement devices, such as manometers, and encouraging their use may improve patient outcomes and reduce real and potential patient complications.

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randomized evaluation with variable syringe size (Spair-Tire) study. *The Clinical Respiratory Journal, 13*(1), 66-69. https://doi.org/10.1111/crj.12984

Appendix A

Keywords, PubMed MeSH, and CINAHL Subject Headings Used for Literature Searches

	Concept	
	Anesthesia	Endotracheal tube cuff pressure
Keywords	Anesthesia General anesthesia Intraoperative Surgery	Endotracheal tube cuff pressure Endotracheal tube intracuff pressure Monitoring Manometer
PubMed MeSH	Anesthesia Anesthesia, general Monitoring, intraoperative Intraoperative care Surgical procedures, operative	Intubation, intratracheal Anesthesia, endotracheal Pressure
CINAHL Subject Headings	Anesthesia Anesthesia, general	Endotracheal tubes Pressure (physiology)

Note. Keywords, PubMed MeSH terms, and CINAHL subject headings used to conduct literature searches in CINAHL, East Carolina University Libraries' OneSearch, Google Scholar, ProQuest, and PubMed. Boolean operators were used in different combinations to yield search results.

Appendix B

Search Strategy

Search date	Database or search engine	Search strategy	Limits applied	Number of results	Number kept
9/11/2020	PubMed	(anesthesia OR (anesthesia, general) OR (monitoring, intraoperative) OR (intraoperative care) OR (surgical procedures, operative)) AND (((intubation, intratracheal) OR (anesthesia, endotracheal)) AND pressure AND cuff)	Last 5 years (2015-2020) English Full text	138	3
9/11/2020	CINAHL	(anesthesia OR (anesthesia, general)) AND ((endotracheal tubes) AND (pressure (physiology)) AND cuff)	English Pub. in 2016-2020 Full text	45	0
9/11/2020	ECU Libraries' OneSearch	(anesthesia) AND (endotracheal tube cuff pressure) AND (education) AND (manometer)	Last 5 years (2015-2020) Journal article	50	3
9/11/2020	ProQuest	(anesthesia) AND (endotracheal tube cuff pressure) AND (education) AND (manometer)	Last 5 years (2015-2020) Peer reviewed Scholarly journal	44	2
9/11/2020	Google Scholar	(anesthesia) AND (endotracheal tube cuff pressure) AND (education) AND (manometer)	Since 2016 (to 2020) Reviewed first 5 pages	631	6
10/27/2020	Google Scholar	(endotracheal tube cuff pressure) AND (monitoring)	Since 2016 (to 2020) Reviewed first 5 pages	18,300	4

Appendix C

Literature Matrix

Authors	Year Published	Article Title and Journal	Level of Evidence*	Brief Description of Article
Ashman, R. E. Appel, S. J. Barba, A. J.	2017	Effectiveness of interventions to increase provider monitoring of endotracheal tube and laryngeal mask airway cuff pressures *AANA Journal*	Level III	This study determined if an intervention including education, reference cards, and a highly visible place in the electronic anesthesia record for cuff pressure documentation would increase the number of times that anesthesia providers monitor ETT cuff pressures and thus decrease the frequency of high intraoperative cuff pressures. The interventions increased provider monitoring and adjustment of ETT cuff pressures intraoperatively as well as decreased the mean of cuff pressures intraoperatively.
Giusti, G. D. Rogari, C. Gili, A. Nisi, F.	2017	Cuff pressure monitoring by manual palpation in intubated patients: How accurate is it? A manikin simulation study *Australian Critical Care*	Level II	This study determined how accurate providers are when assessing ETT cuff pressure by palpation of the pilot balloon. Only 32.4% of participants correctly estimated the range either within, below, or above the target range 20-30 cm H_2O, of ETT cuff pressures. 10.3% of the participants correctly detected cuffs within the target range, 11.8% detected cuffs below the range, and 10.3% detected cuffs the above the range. 68% of the time participants were unable to correctly estimate the cuff pressure by palpation. Providers who had experience in emergency courses (equivalent to ACLS or PALS) were more likely to correctly identify cuff pressure below, within, or above the target range by palpation than nurses who had not (Cramer's V = 0.501).

Hockey, C. A. van Zundert, A. A. J. Paratz, J. D.	2016	Does objective measurement of tracheal tube cuff pressures minimise adverse effects and maintain accurate cuff pressures? A systematic review and meta-analysis *Anaesthesia and Intensive Care*	Level I	This study determined if adjustment of cuff pressure guided by objective or subjective measurements, or observation of pressure value alone, is best at preventing adverse effects from ETT cuff pressure outside of the recommended range of 20-30 cm H_2O. Using objective measurements to assess ETT cuff pressure was more reliable than subjective measures at maintaining accurate cuff pressures and better prevented post-extubation airway complications and adverse effects.
Kumar, C. M. Seet, E. Van Zundert, T. C. R. V.	2020	Measuring endotracheal tube intracuff pressure: No room for complacency *Journal of Clinical Monitoring and Computing*	Level II-IV**	This article reviewed some of the current evidence regarding appropriate ETT cuff pressure, the complications that can arise from inappropriate cuff pressure, and the methods most commonly utilized to inflate ETT cuffs and assess cuff pressure. They concluded that cuff pressures not within 20-30 cm H_2O can lead to complications and that the best way to ensure appropriate cuff pressure is to use an objective measuring device such as a manometer.
Sanaie, S. Rahmani, F. Chokhachian, S. et al.	2019	Comparison of tracheal tube cuff pressure with two technique: Fixed volume and minimal leak test techniques *Journal of Cardiovascular and Thoracic Research*	Level II	The study compared using a fixed volume of air (10 ml) versus the minimal leak test to inflate ETT cuffs. The goal was to find out which technique of inflating ETT cuffs led to cuff pressures closest to the recommended range of 20-30 cm H_2O. Cuff pressure means were significantly higher in the fixed volume group than in the minimal leak test group. Cuff pressures were within the range of 20-30 cm H_2O after initial inflation 78.2% of the time in the minimum leak test group and 56.4% of the time in the fixed volume group.
Stevens, G. J. Warfel, J. W. Aden, J. K., Blackwell, S. D.	2018	Intraoperative endotracheal cuff pressure study: How education and availability of manometers help guide safer pressures *Military Medicine*	Level IV	The study was conducted to determine if an intervention of ETT cuff pressure education and easy access to manometers in operating rooms would lead to a higher rate of ETT cuff pressures within the recommended range of 20-30 cm H_2O. The researchers found that mean cuff pressures dropped from 48.92 cm H_2O before to 41.96 cm H_2O after the intervention. The median dropped from 38.5 cm H_2O to 30 cm H_2O.

Turner, M. Feeney, M. Deeds, J. L.	2020	Improving endotracheal cuff inflation pressures: An evidence-based project in a military medical center *AANA Journal*	Level IV	This evidence-based project was conducted to improve the rate of intraoperative ETT cuff pressures within the range of 20-30 cm H_2O. ETT cuff pressures outside of the range were 4.4 times less frequent after their intervention of provider education, accessible manometers and reminder signs at each anesthesia station, and a variable for charting ETT cuff pressure added to the electronic anesthesia record. The rate at which anesthesia providers checked endotracheal tube cuff pressure after intubation rose from 11% to 53% and their knowledge about accurate cuff pressures increased from 35% to 87%.
Williams, W. W. Artime, C. A. Mancillas, O. L. et al.	2019	Subglottic perioperative airway—tube inflation via randomized evaluation with variable syringe size (Spair-Tire) study *The Clinical Respiratory Journal*	Level II	This study evaluated the inflation of ETT cuffs with a 10 ml versus a 5 ml syringe. The researchers wanted to determine if one syringe or the other would lead to more ETT cuff pressures within a range of 22-32 cm H_2O. Cuff pressures from the 5 ml syringe group averaged 55.8 cm H_2O while the 10 ml syringe group yielded average cuff pressures of 68.8 cm H_2O. The rate that cuffs were inflated within the 22-32 cm H_2O range was 6.78% for the 10 ml syringe and 10.53% for the 5 ml syringe. Neither syringe produced reliable cuff pressures within the 22-32 cm H_2O range, but the 5 ml syringe was statistically significant over the 10 ml syringe ($P = 0.01$) for yielding lower average cuff pressures (55.8 cm H_2O versus 68.8 cm H_2O).

Note. * Levels of Evidence from *Evidence-based practice in nursing & healthcare: A guide to best practice* (4th ed.) by B. M. Melnyk and E. Fineout-Overholt. Copyright 2019 by Wolters Kluwer Health. ** Multiple sources were reviewed and discussed in the article, which was not, itself, a comprehensive systematic review or meta-analysis (Level I Evidence).

Appendix D

Exemption from Full IRB Review

Click "download PDF" to save a copy of this page for your records.
Note: The IRB Office does not maintain copies of your responses.

Below is a summary of your responses

Download PDF

Quality Improvement/Program Evaluation Self-Certification Tool

Purpose:
Projects that do not meet the federal definition of human research pursuant to 45 CFR 46 do not require IRB review. This tool was developed to assist in the determination of when a project falls outside of the IRB's purview.

Instructions:
Please complete the requested project information, as this document may be used for documentation that IRB review is not required. Select the appropriate answers to each question in the order they appear below. Additional questions may appear based on your answers. If you do not receive a STOP HERE message, the form may be printed as certification that the project is "not research", and does not require IRB review. The IRB will not review your responses as part of the self-certification process. For projects being done at Vidant Health, site support will be required. Please email [redacted] to obtain site support from [redacted]

Name of Project Leader:

Hannah Travlos, SRNA & Maura McAuliffe, CRNA, PhD (Project Chair)

Project Title:

Assessing anesthesia providers' perceptions of adequacy of endotracheal tube cuff occlusion assessment techniques

Brief description of Project/Goals:

The purpose of this quality improvement project is to assess anesthesia providers' perceptions of perioperative usefulness of subjective assessment (tactile) and objective assessment (manometer) of occlusive volume for endotracheal tube cuffs. Process:. Anesthesia providers at Vidant SurgiCenter will be asked several questions (through Qualtrics) about their perceptions of adequacy of currently used subjective and objective methods of assessing perioperative minimum occlusive volume for ETT cuffs . A video reviewing several currently accepted methods of both subjective and objective assessment for determining adequate ETT cuff volumes will then be made available. Providers will be asked to record their preferred (subjective/objective) assessment practice for two weeks. Upon completion of the two-week period they will be asked to complete a questionnaire about their perceptions of the usefulness of the subjective (tactile) and objective (manometer) assessments. Qualtrics survey software will be used to deliver the intervention link and gather participant perceptions of acceptability and adequacy of THE INTERVENTION prior to and post implementation of the project. No patient information will be recorded or maintained during this project.

Will the project involve testing an experimental drug, device (including medical software or assays), or biologic?

- ○ Yes
- ● No

Has the project received funding (e.g. federal, industry) to be conducted as a human subject research study?

- ○ Yes
- ● No

Is this a multi-site project (e.g. there is a coordinating or lead center, more than one site participating, and/or a study-wide protocol)?

- ○ Yes
- ● No

Is this a systematic investigation designed with the intent to contribute to generalizable knowledge (e.g. testing a hypothesis; randomization of subjects; comparison of case vs. control; observational research; comparative effectiveness research; or comparable criteria in alternative research paradigms)?

- ○ Yes
- ● No

Will the results of the project be published, presented or disseminated outside of the institution or program conducting it?

- (●) Yes
- ( ) No

Would the project occur regardless of whether individuals conducting it may benefit professionally from it?

- (●) Yes
- ( ) No

Does the project involve "no more than minimal risk" procedures (meaning the probability and magnitude of harm or discomfort anticipated are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests)?

- (●) Yes
- ( ) No

Is the project intended to improve or evaluate the practice or process within a particular institution or a specific program, and falls under well-accepted care practices/guidelines?

- (●) Yes
- ( ) No

Based on your responses, the project appears to constitute QI and/or Program Evaluation and IRB review is not required because, in accordance with federal regulations, your project does not constitute research as defined under 45 CFR 46.102(d). If the project results are disseminated, they should be characterized as QI and/or Program Evaluation findings. Finally, if the project changes in any way that might affect the intent or design, please complete this self-certification again to ensure that IRB review is still not required. Click the button below to view a printable version of this form to save with your files, as it serves as documentation that IRB review is not required for this project. 11/14/2020

Center for Research & Grants

[redacted]

Quality Assurance/Quality Improvement Project vs. Human Research Study (Requiring IRB approval) Determination Form

This worksheet is a guide to help the submitter to determine if a project or study is a quality assurance/quality improvement (QA/QI) project or research study and is involving human subjects or their individually identifiable information and requires IRB approval as defined by the Health and Human Services (HHS) or Food and Drug Administration (FDA). Once completed, please email the form to the Vidant Health Center for Research and Grants [redacted] CRG) CRG.Quality@[redacted] A CRG team member will contact you with the results of their review and may request additional information to assist with their determination. The determination will be made in conjunction with the UMCIRB office.

Please contact the [redacted] CRG with any questions at [redacted] or CRG.Quality@[redacted]

For more guidance about whether the activity meets the definition of Human Subjects Research see https://rede.ecu.edu/umcirb/irb-faqs/definitions/ or https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c1

Project Title: Assessing anesthesia providers' perceptions of adequacy of endotracheal tube cuff occlusion assessment techniques		
Funding Source: None		
Project Leader Name: Hannah Travlos/Travis Chabo	☐ Ed.D. ☐ J.D. ☐ M.D. ☐ Ph.D. ☐ Pharm.D. ☒ R.N. ☐ Other(specify):	
Job Title: ECU SRNA/ECU CRNA Faculty	**Phone:** [redacted]	**Email:** chabot14@ecu.edu
	Primary Contact (if different from Project Leader): student	
	Phone: [redacted]	**Email:** travlosh10@students.ecu.edu

Key Personnel/ Project Team members:

Name and Degree:	Department: (Affiliation if other than Vidant)	Email:
Hannah Travlos, SRNA	ECU Nurse Anesthesia Program	travlosh10@students.ecu.edu
Travis Chabo, PhD, CRNA	ECU Nurse Anesthesia Program	chabot14@ecu.edu
Maura McAuliffe, PhD, CRNA	ECU Nurse Anesthesia Program	mcauliffem@ecu.edu

QI/QA Assessment Checklist:

Consideration	Question	Yes	No
PURPOSE	Is the PRIMARY purpose of the project/study to: • IMPROVE care right now for the next patient? OR • IMPROVE operations outcomes, efficiency, cost, patient/staff satisfaction, etc.?	☑	☐
RATIONALE 1	The project/study falls under well-accepted care practices/guidelines or is there sufficient evidence for this mode or approach to support implementing this activity or to create practice change, based on: • literature • consensus statements, or consensus among clinician team	☑	☐
RATIONALE 2	The project/study would be carried out even if there was no possibility of publication in a journal or presentation at an academic meeting. (**Please note that answering "Yes" to this statement does not preclude publication of a quality activity.)	☑	☐
METHODS 1	Are the proposed methods flexible and customizable, and do they incorporate rapid evaluation, feedback and incremental changes?	☑	☐
METHODS 2	Are patients/subjects randomized into different intervention groups in order to enhance confidence in differences that might be obscured by nonrandom selection? (Control group, Randomization, Fixed protocol Methods)	☐	☑
METHODS 3	Will there be delayed or ineffective feedback of data from monitoring the implementation of changes? (For example to avoid biasing the interpretation of data)	☐	☑
METHODS 4	Is the Protocol fixed with fixed goal, methodology, population, and time period?	☐	☑
RISK	The project/study involves no more than minimal risk procedures meaning the probability and magnitude of harm or discomfort anticipated are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.	☑	☐
PARTICIPANTS	Will the project/study only involve patients/subjects who are ordinarily seen, cared for, or work in the setting where the activity will take place?	☑	☐
FUNDING	Is the project/study funded by any of the following? • An outside organization with an interest in the results • A manufacturer with an interest in the outcome of the project relevant to its products • A non-profit foundation that typically funds research, or by internal research accounts	☐	☑

If all of the check marks are inside the shaded gray boxes, then the project/study is very likely QI and not human subject research. Projects that are not human subject research do not need review by the IRB.

rev. 12.2020

In order to assess whether your project meets the definition of human subject research requiring IRB review or may qualify as a quality improvement/assurance activity, please provide the following information:

1. **Project or Study Summary:**
   As a separate attachment, please provide a **summary of the purpose and procedures** as well address all of the following:
   a) The project question/hypothesis.
   b) The project design.
   c) Any interaction or intervention with humans.
   d) A description of the methods that will be used and if they are standard or untested.
   e) Specify where the data will come from and your methods for obtaining this data -please specify who/where (i.e. CRG will provide you with the data, or someone from a specific department will provide you with the data, or you will pull it yourself).
   f) Specify what data will be used and any dates associated with when that data was originally collected (i.e Patient Name, Diagnosis, Age, Sex), *If applicable, please attach your data collection sheet.*
   g) Where will the data (paper and electronic) for your project be stored? Please specify how it will be secured to protect privacy and maintain confidentiality. For paper data, please provide physical location such as building name and room number and that it will be kept behind double lock and key. For electronic data, please provide the file path and folder name network drive where data will be stored and specify that it is secure/encrypted/password protected. If using other storage location, please provide specific details.
   h) Please specify how long data will be stored after the study is complete? (Keep in mind that data collected/generated during the course of the project that includes protected health information (PHI) should have identifiers removed at the earliest opportunity.)
   i) Please specify how the collected data will be used (internal/external reports, publishing, posters, etc.).

   Please attach a summary and/or any other additional documentation describing your project

2. **If the Primary purpose of your project/study is for QA/QI, have you obtained approval from the operational leader within your department or health system:**
   ☒ **Yes** [Please specify here whom and obtain their signature in the signature section below] [redacted]
   ☐ **No** [Contact the appropriate operational leader for approval.]

Please note:

- By submitting your proposed project/study for QA/QI determination you are certifying that if the project/study is established to qualify as QA/QI project, you and your Department would be comfortable with the following statement in any publications regarding this project: "This project was reviewed and determined to qualify as quality improvement by the [redacted] Center for Research and Grants."
- If you are submitting a Poster to Media Services for printing, you will need to also submit this Quality Improvement Worksheet or proof of your IRB Application and IRB Approval.
- If the [redacted] CRG determines the activity is not human subject research, then any presentation, publication, etc. should not refer to the activity as "human subject research," "exempt research," or "expedited research."
- If you would like the [redacted] CRG to verify that a project/study is not human subject research, please provide this form completed with the summary of your activity and any additional information to the [redacted] CRG at CRG.Quality@[redacted] and the following will be completed and returned to you for your records.

NHSR vs. HSR Determination:

☒ **Not Human Subject Research:** The [redacted] CRG has determined that based on the description of the project/study, approval by the IRB is not necessary. Any changes or modifications to this project may be discussed with the [redacted] CRG at that time to ensure those changes do not elevate the project to human research that would need IRB approval.

☐ **Human Subject Research:** This project/study requires review by the IRB prior to initiation. An application in the electronic IRB submission system should be submitted.

Approval Signatures:

Department (Site) Manager: [redacted] **Date:** 2/24/2021

VH CRG Reviewer: [redacted] **Date:** _____

UMCIRB Office Staff Reviewer: [redacted] **Date:** 3-10-21

Appendix E

Pre- and Post-Intervention Survey Questions

Pre-Survey Questions

1. **In your current practice, which method(s) do you prefer for obtaining adequate ETT cuff pressure? (select all that apply)**

   Minimal occlusive volume
   Pilot balloon palpation
   Manometer
   Audible air leak
   Set volume
   Other: (include text box)

2. **In your opinion, is subjective assessment (tactile) adequate for obtaining appropriate ETT cuff pressure?**

   Not at all adequate / slightly adequate / moderately adequate / very adequate / extremely adequate

3. **How often in your practice do you solely utilize subjective assessment (tactile) to obtain appropriate ETT cuff pressure?**

   Never / rarely / sometimes / often / always

4. **In your opinion, is objective measurement (manometer) adequate for obtaining appropriate ETT cuff pressure?**

   Not at all adequate / slightly adequate / moderately adequate / very adequate / extremely adequate

5. **How often in your practice do you utilize an objective measurement (manometer) for obtaining appropriate ETT cuff pressure?**

   0% of the time / <25% of the time / 25-50% of the time / 50-75% of the time / >75% of the time

Post-Survey Questions

1. **While participating in this quality improvement project, approximately how many times did you use the manometer over the last two weeks?**

   (text box)

2. **In your opinion, is subjective assessment (tactile) adequate for obtaining appropriate ETT cuff pressure?**

   Not at all adequate / slightly adequate / moderately adequate / very adequate / extremely adequate

3. **How often in your practice do you solely utilize subjective assessment (tactile) to obtain appropriate ETT cuff pressure?**

   Never / rarely / sometimes / often / always

4. **In your future practice, how often do you think you will choose to solely utilize subjective assessment (tactile) for obtaining appropriate ETT cuff pressure?**

   Never / rarely / sometimes / often / always

5. **In your opinion, is objective measurement (manometer) adequate for obtaining appropriate ETT cuff pressure?**

   Not at all adequate / slightly adequate / moderately adequate / very adequate / extremely adequate

6. **In your future practice, how often do you think you will utilize an objective measurement (manometer) for obtaining appropriate ETT cuff pressure?**

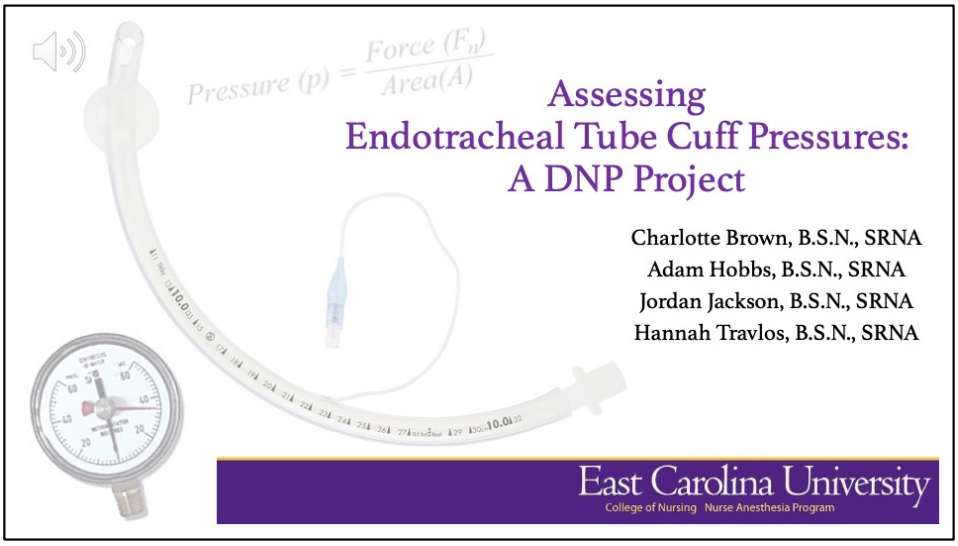
   0% of the time / <25% of the time / 25-50% of the time / 50-75% of the time / >75% of the time

7. **Are there certain types of cases in which you think utilization of an objective manometer would be beneficial?**

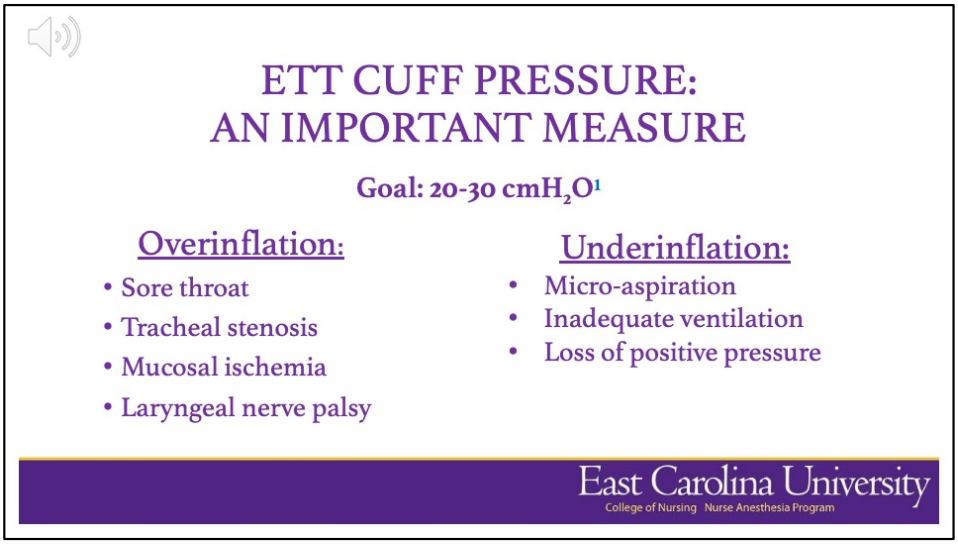
   Yes / No
   If yes, which types of cases? (text box)

Appendix F

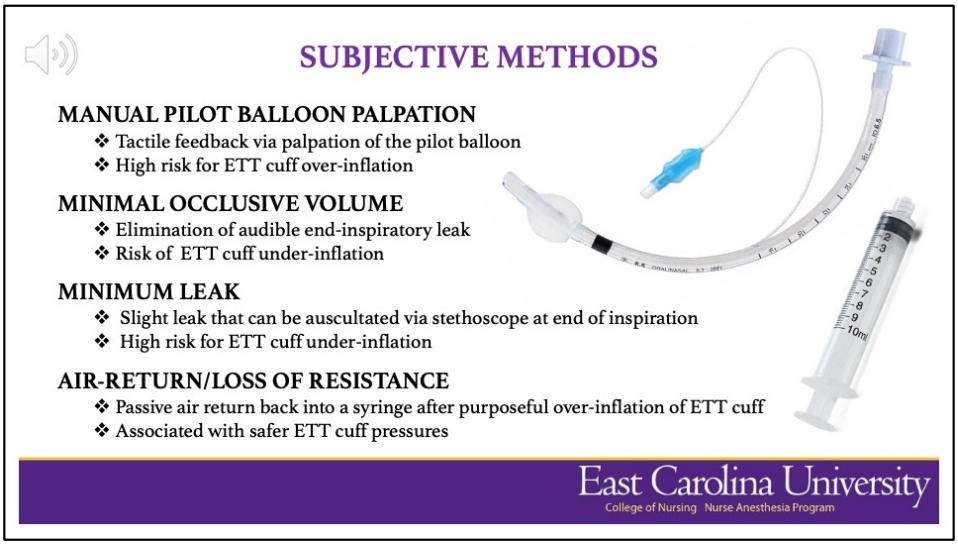
Transcript of Informational Video



Thank you for your participation in this quality improvement project titled: Assessing Endotracheal Tube Cuff Pressures: A DNP Project. Endotracheal tube, or ET tube, cuff pressure monitoring is an important patient safety measure that can be performed via a variety of methods. The goal of this presentation is to highlight the available methods of ET tube cuff pressure monitoring and to share current literature findings regarding this element of patient care within the perioperative period.

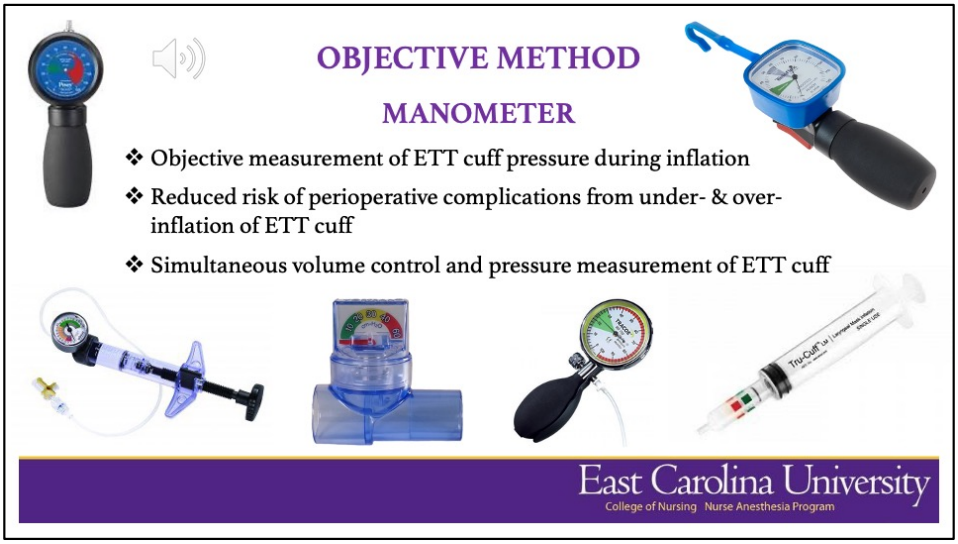


Appropriate cuff inflation decreases the risk of adverse effects that are associated with over- and under-inflated ET tube cuffs. Current research supports a cuff pressure between 20 and 30 cm H2O. Pressures outside of this range may lead to complications such as sore throat, tracheal stenosis, mucosal ischemia, laryngeal nerve palsy, micro aspiration, inadequate ventilation, and/or loss of positive pressure.



Common subjective ET tube cuff pressure assessment methods include manual pilot balloon palpation, minimal occlusive volume technique, minimum leak technique, and air-return/loss of resistance technique.

Researchers have identified an increased likelihood of ET tube cuff over- or under-inflation with these techniques. Furthermore, researchers have found no correlation between anesthesia provider experience and the ability to achieve safe ET tube cuff pressures via palpation.



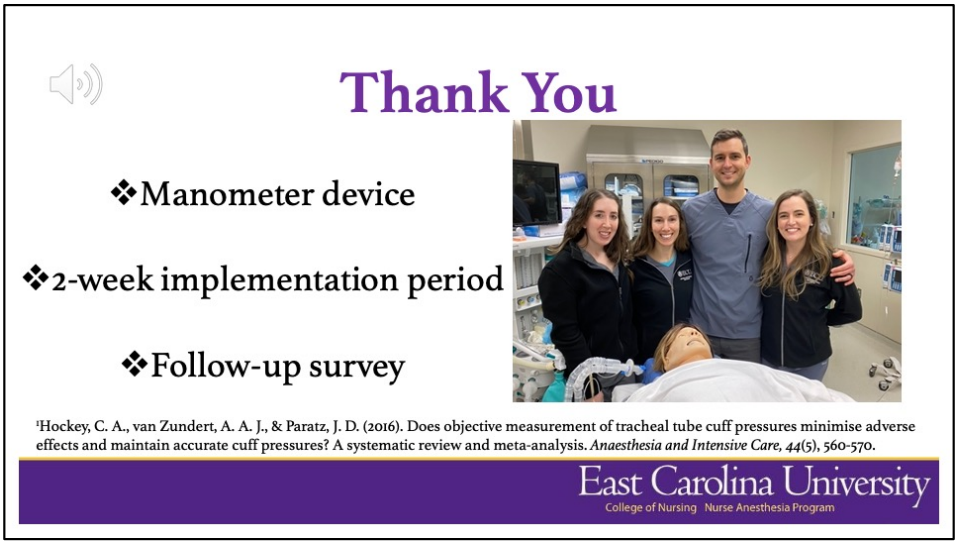
Objective measurement of ET tube cuff pressure has been suggested by researchers as having increased accuracy, ensuring safer ET tube cuff pressures for patients in the perioperative period. The manometer device allows for numerical measurement of the ET tube cuff pressure during simultaneous inflation or deflation of the ET tube cuff.

Recorded video showing proper use of manometer on mannikin

This is the AG Cuffill device (video showing device and steps of proper use)

Per the manufacturer's recommendations:

- Turn the device ON by pressing the yellow button. The device is ready for use when the digital readings reads "zero".
- For Cuff inflation/deflation: connect the device to the pilot balloon with the plunger pulled back about 3ML. The plunger should be pushed or pulled until the required cuff pressure is shown.
- For continued measurement the cuff pressure: connect the device to the pilot balloon when desired, with the plunger pushed to distal end of the syringe throughout measurement. A digital reading will be displayed. Adjust the plunger as needed to obtain the desired cuff pressure.



We would like to thank you for taking the time to watch this informational video about ET tube cuff pressure management.

- A **manometer device**, as seen in this presentation, will be available to you for use with your future surgical patients.
- During the following **2-week implementation period** of this project, your use of this manometer device, while not mandatory, is encouraged.
- You will receive a **follow-up survey** via email upon completion of the implementation period. The purpose of this post-survey is to gain a better understanding of anesthesia provider preferences regarding ET tube cuff pressure measurement methods.

Thank you again for participating in our quality improvement project!

Appendix G

Pre-Survey and Video Email to Participants

Dear SurgiCenter CRNAs,

Thank you for considering participating in a quality improvement project titled "Assessing Anesthesia Provider's Perceptions of Adequacy of Endotracheal Tube Cuff Pressure Assessment Techniques." The purpose of this project is to assess anesthesia providers' perceptions of perioperative usefulness of subjective assessment (tactile) and objective assessment (manometer) of occlusive volume for endotracheal tube cuffs at [redacted]

Participation is voluntary and will involve completing a short pre-intervention questionnaire, viewing a brief video, utilizing a manometer device in your CRNA practice for two weeks at your discretion, and completing a short post-intervention questionnaire when the two-week implementation period is over.

Each questionnaire and the video should take less than 2-4 minutes to complete and is provided via email using Qualtrics® survey software. The use of a manometer falls within currently accepted practice in your work area. Your participation is voluntary and confidential. We will share the results of this QI study with you upon completion.

First, complete the pre-intervention questionnaire here.
Followed by viewing the informational video.
Manometers are available on the bulletin board in the supply room.

Again, thank you for your participation in our quality improvement project. I will be at SurgiCenter May 3-6 if you have any questions but you may also reach out to me or Travis Chabo by email.

Sincerely,

Hannah Travlos at travlosh10@students.ecu.edu
Travis Chabo (project chair) at chabot14@ecu.edu

Appendix H

Pre-Survey and Video Reminder Email to Participants

Hello SurgiCenter CRNAs,

I just wanted to send a quick reminder about the ongoing DNP Project on ETT cuff pressure assessment (original email below). If you've already filled out the pre-survey and viewed the video, thank you! If you haven't had a chance to yet, it's not too late and would be very helpful and much appreciated. There are also manometers tacked to the bulletin board if you haven't already received one - you may use these at your discretion. After the end of next week, I will begin sending out the post-surveys.

Links:
Pre-survey
Video

Please let me know if you have any questions and thank you again for your participation.

Sincerely,

Hannah Travlos, SRNA
ECU Nurse Anesthesia Program
Class of 2022

Appendix I

Post-Survey Email to Participants

Dear SurgiCenter CRNAs,

Thank you to everyone who has already completed my pre-survey and viewed the video! It's now time to complete the brief post-survey (link below).

If you have not filled out a pre-survey, I would really and truly appreciate your participation (it's just surveys and a video!) as I'm shy of my goal by just one person 🙂 The link to the survey is here, and you can follow it up by watching the video here). Manometers are available for your use if you would like them, but their use is not mandatory for participation in this project.

If you've already completed the first survey, here is the link to the post-survey. It should take less than 2 minutes.

If anyone has questions or issues with the links, please let me know. Again, thank you to everyone for your help and for being excellent preceptors. I look forward to coming back to the SurgiCenter soon.

Sincerely,
Hannah Travlos, SRNA
ECU Nurse Anesthesia Program
Class of 2022

Appendix J

Thank You Email to Participants

SurgiCenter CRNAs,

I just wanted to say thank you so much to everyone for helping me out with my DNP Project! I have collected all the data that I need to proceed with data analysis and will then be finishing my paper. Once it's complete you all will be able to read it if you'd like. And if you liked the manometer and found it useful, you can get roughly 100 uses out of it. When you first turn it on, the number that flashes on the digital display before it shows "0" (manometer is zeroed) is the number of times you have left to use it.

Thanks again, see everyone next time I'm at the SurgiCenter!

Take care,
Hannah Travlos, SRNA
ECU Nurse Anesthesia Program
Class of 2022

Appendix K

Project Timeline

August 2020	• Beginning of DNP I academic course
August 11, 2020	• Meeting #1 with DNP project team
September 11, 2020	• Initial literature search (see Appendix A and B)
September 22, 2020	• Meeting #2 with DNP project team
September 27, 2020	• Literature matrix created (see Appendix C)
October 27, 2020	• Subsequent literature search (see Appendix B)
November 5, 2020	• Meeting #3 with DNP project team
November 11, 2020	• Meeting #4 with DNP project team o Finalization of pre- and post-intervention survey questions
November 14, 2020	• IRB exemption from ECU (see Appendix D)
November 28, 2020	• Last draft submission of DNP paper sections I-III for fall 2020 semester
January 19, 2021	• Beginning of DNP II academic course
January 26, 2021	• Meeting #5 with DNP project team o Finalization of transcript for informational video (see Appendix F) o Finalization of email script to participants (see Appendix G)
February 9, 2021	• Meeting #6 with DNP project team
February 19, 2021	• Informational video created (see Appendix F)
March 12, 2021	• IRB exemption from partnering organization (see Appendix D)
March 28, 2021	• Pre- and post-surveys created in Qualtrics
April 6, 2021	• Draft submission of DNP paper sections I-III for spring 2021 semester
April 2021	• Participants recruited for DNP project by DNP project chair
April 26-29, 2021	• DNP project student present at surgical center for clinical rotation
April 28, 2021	• Participant email addresses supplied to DNP project student by DNP project chair
April 29, 2021	• Manometers tacked to bulletin board in surgical center anesthesia supply room next to CRNA room assignments
April 30, 2021	• Informational video embedded into Qualtrics • Email sent to CRNAs with pre-survey and informational video hyperlinks to Qualtrics (see Appendix G)

April 30 – May 14, 2021	• Two-week project implementation period
May 3-6, 2021	• DNP project student present at surgical center for clinical rotation
May 4, 2021	• Reminder email sent to CRNAs with pre-survey and informational video hyperlinks to Qualtrics (see Appendix H)
May 7, 2021	• Meeting with DNP project facilitator to review draft of DNP paper sections I-III
May 16, 2021	• Email sent to CRNAs with post-survey hyperlink to Qualtrics (see Appendix I)
May 22, 2021	• Thank you email sent to CRNAs regarding participation in DNP project (see Appendix J)
May 17, 2021	• Beginning of DNP III academic course
May 23, 2021	• First submission of DNP paper sections I-III for DNP III academic course
June 16, 2021	• Draft data analysis and visualizations created using Microsoft Excel
June 17, 2021	• Meeting #6 with DNP project team and ECU nurse anesthesia DNP class ○ Review of draft visualizations created by all ECU nurse anesthesia DNP class members
June 20, 2021	• Initial data analysis and visualizations created using Microsoft Excel
June 27, 2021	• Revised data analysis and visualizations created using Microsoft Excel
July 11, 2021	• Revised submission of DNP paper sections I-III and draft submission of sections IV-VI for DNP III academic course
August 8, 2021	• Revised submission of DNP paper sections I-VI for DNP III academic course
August 23, 2021	• Beginning of DNP IV academic course
August 25, 2021	• Meeting with DNP project chair to review DNP project chair edits to DNP paper sections I-VI
September 12, 2021	• Revised submission of DNP paper sections I-VI
October 9, 2021	• Revised submission of DNP paper sections I-VI
October 17, 2021	• Draft submission of DNP project poster
November 4, 2021	• Revised submission of DNP project poster and DNP paper sections I-VI
November 16, 2021	• DNP project poster presentation at ECU College of Nursing
December 2021	• Final versions of DNP paper and DNP project poster uploaded to ECU's institutional repository, the ScholarShip