Using Manometers in Operating Rooms for Endotracheal Tube Cuff Pressure Measurements

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A DNP Project Manuscript
Submitted in Partial Fulfillment of the Requirements for the
Doctor of Nursing Practice Degree

School of Nursing, University of Maryland at Baltimore
May 2022

Abstract

Problem & Purpose: Postoperative sore throat represents a common adverse event following general endotracheal anesthesia. Anesthesia providers play an integral role in preventing postoperative sore throat by minimizing airway trauma, selecting appropriate size blades and endotracheal tubes, and maintaining optimal intracuff pressures at 20-30 cm H_2O using manometers. Cuff over-inflation leads to tracheal mucosa damage, while cuff under-inflation leads to micro-aspiration and tube migration. At a small Maryland community hospital, the incidence of postoperative sore throat was 38%. This quality improvement project aimed to implement the use of manometers in operating rooms for intraoperative endotracheal tube cuff pressure monitoring. **Methods:** The practice change involved anesthesia providers measuring and documenting endotracheal tube cuff pressures with manometers after intubation. Eligible patients included adults scheduled for elective surgery. Electronic chart audits were completed to track provider compliance and cuff pressures. Post-anesthesia care unit nurses monitored postoperative sore throat occurrence. Data collection was performed weekly and analyzed using descriptive statistics and run charts. **Results:** The sample included a total of 146 patients. Following implementation of manometers into operating rooms, median anesthesia provider compliance to endotracheal tube cuff pressure monitoring and optimal cuff pressures improved from 0% to 26% and 0% to 69% respectively. The average percentage of patients who denied POST symptoms in the recovery unit was 83%. **Conclusions:** Manometer utilization in operating rooms at this organization was feasible. Findings suggest that routine intraoperative measurements and maintenance of cuff pressures between 20-30 cm H_2O reduces postoperative sore throat occurrence in adults.

Postoperative sore throat (POST) represents the second most common adverse event following general endotracheal anesthesia, affecting up to 50% of adults (Borzoo & Grondin, 2018; Lee et al., 2017). Symptoms typically manifest as odynophagia, cough, or hoarseness, and subside within 48-72 hours (Koo et al., 2019; Liu et al., 2010). POST correlates to lower patient satisfaction scores, increased postoperative analgesic consumption, and prolonged recovery times (Chattopadhyay et al., 2017; Kalil et al., 2014).

Anesthesia providers play an essential role in preventing POST by gentle laryngoscopy, minimizing intubation attempts, selecting appropriate size blades and tubes, and maintaining optimal cuff pressures at 20-30 cm H_2O using manometers (Hockey et al., 2016; Pacheco-Lopez et al., 2014; Puthenveettil et al., 2018). Published evidence indicates manometers are the gold standard of practice for endotracheal tube (ETT) cuff pressure measurements. Only 10% of anesthesia providers monitor intraoperative cuff pressures (Turner et al., 2020). Key barriers noted in the literature include lack of provider knowledge on the effects of high cuff pressures, inability to access manometers, and device unfamiliarity (Abubaker et al., 2019; Turner et al., 2020).

At a small community hospital in Maryland, 38% of adult surgical patients reported POST. ETT cuff pressures were not routinely monitored by anesthesia providers (see Appendix A for current process map). The purpose of the project was to implement the use of manometers in operating rooms (ORs) for intraoperative ETT cuff pressure measurements. The anticipated outcome of the practice change was a reduction in POST rates. Furthermore, health disparities were addressed by providing the intervention to all adult surgical patients and allowing extra time to non-English speaking patients for the assessment of POST symptoms.

Literature Review

This evidence review synthesized evidence-based interventions anesthesia providers could implement in the OR to mitigate POST. The levels of evidence were evaluated using the hierarchy of I-VI in the John Hopkins Nursing Evidence Based Practice model. While the quality of studies was rated using the scale of A-D in the Newhouse model (see Tables 1 & 2). First, the review compared the different methods for ETT cuff pressure measurements. Next, the synthesis highlighted the optimal range for ETT cuff pressures in reducing POST risk. Lastly, the review concluded with strategies for improving anesthesia provider compliance to best practice guidelines regarding ETT cuff pressures.

Significant variation existed in ETT cuff pressure measurement technique. Anesthesia providers utilized qualitative or quantitative methods. A well-designed, level IA systematic review by Hockey et al. (2016) revealed that quantitative methods such as manometers were superior in terms of accuracy, maintaining optimal cuff pressures between 20-30 cm H_2O (1.61, 95% CI: 2.69 to 0.53, $p = 0.003$), and decreasing POST and silent aspiration events ($p < 0.003$). A level IVB cross-sectional study, by Rahmani et al. (2017) and level IVC quality improvement project by Selman et al. (2019) evaluated the estimation of cuff pressures by qualitative methods such as manual palpation of the pilot balloon, fixed-volume, and minimal leak test. Both studies found these techniques grossly under-estimated cuff pressures and required readjustments. The three studies differed in levels of evidence, design, methods, and sample size. Hockey et al. (2016) and Rahmani et al. (2017) selected anesthesia providers as the primary investigators, while Selman et al. (2019) selected respiratory therapists. The timing of cuff pressure measurement also diverged among studies. Hockey et al. (2016) and Rahmani et al. (2017) recorded cuff pressures after intubation in the OR, while Selman et al. (2019) noted cuff pressures every 12 hours in the intensive care unit. However, all three studies included adult patients and proposed manometers as the gold standard of practice for ETT cuff pressure measurements.

The literature differed in the optimal range for ETT cuff pressures. In three level IIB, randomized controlled trials by Koo et al. (2019), Liu et al. (2010), and Ansari et al. (2014), groups with manometer-guided intraoperative cuff pressure monitoring and adjustments to 20-30 cm H_2O experienced a lower incidence and severity of POST symptoms. Additionally, Liu et al. (2010) noted more tracheal injuries in the group without ETT cuff monitoring ($p = 0.043$). Studies varied in timeframes for symptom assessment, ranging from 1, 6, 24 and 48 hours, and surgical patient populations. However, all three studies were rated as high-quality evidence due to their design, randomization, blinding, large sample sizes, clearly defined data collection protocols, validated statistical instruments, and consistent results. All studies proposed that maintaining intraoperative ETT cuff pressures between 20-30 cm H_2O was safe for minimizing airway trauma and the risk of POST.

A quality improvement project by Turner et al. (2020) identified potential barriers as lack of provider awareness on the effects of high cuff pressures, inability to access manometers, and device unfamiliarity. A multifaceted approach of education and manometers in ORs effectively improved anesthesia provider knowledge, compliance, and frequency of cuff pressures within the safe range of 20-30 cm H_2O ($p < 0.001$). Although, the study was graded as level IVC evidence, internal validity was strengthened by an adequately powered sample size, a single provider performing and evaluating interventions, validated statistical instruments, and consistent findings. In conclusion, the evidence review supported the practice change of manometers in ORs for measuring and maintaining intraoperative cuff pressures at 20-30 cm H_2O. Manometers produced accurate cuff pressure readings, thereby minimizing airway trauma, and reducing the risk of POST among adult surgical patients.

Theoretical Framework

The Theory of Unpleasant Symptoms (TOUS) assisted in understanding the practice problem of POST. Symptom experience was described in terms of clinical symptoms, influencing factors, and performance (Blakeman, 2019) (Refer to Figure 1). POST represented a frequent complication following surgery with general endotracheal anesthesia. Symptoms manifested as odynophagia, cough, or hoarseness and were distressing and anxiety-provoking for patients. The TOUS offered a holistic description for POST, specifically highlighting multiple factors contributing to its development and the potential impact on activities of daily living and comfort. Ultimately, by selecting the TOUS, initiatives were tailored towards mitigating POST among adult surgical patients. Subsequently, these initiatives improved patient satisfaction scores, shortened discharge times, and reduced postoperative analgesic consumption (Chattopadhyay et al., 2017).

Helfrich's Framework for Complex Innovations (2007) was selected for developing the quality improvement project. The framework highlighted the importance of management support, resources, change champions, innovation-values fit, and implementation climate for successful practice change implementation (Refer to Figure 2). The intervention was routine measurement of intraoperative ETT cuff pressures by anesthesia providers using manometers. This was supported by management as their resources and values aligned with the goals of the project. Endorsement was obtained from the chief anesthesiologist, chief nurse anesthetist and nursing manager. Change champions were selected from anesthesia and perioperative nursing teams. The combination of high rates of POST among adult surgical patients and providers who were invested in improving patient outcomes led this project to be a priority. With all elements in support of the project, implementation was effective.

Methods

The setting of the quality improvement (QI) project was a small community hospital with 10 ORs. Approximately 200 elective surgeries were performed monthly with general anesthesia requiring tracheal intubation. Prior to implementation, anesthesia providers utilized subjective methods like manual palpation of the pilot balloon or a fixed volume of air for ETT cuff pressure measurements. Often, intraoperative cuff pressures were not routinely monitored.

For the QI project, a team of stakeholders including the Chief Nurse Anesthetist, Anesthesiology Department Chairman, Perioperative Services Nursing Manager and change champions from anesthesia and post-anesthesia care unit (PACU) nursing staff, was mobilized to develop an evidence-based intervention targeting the organization's high POST rates. Commitment from anesthesia and nursing departments was obtained to establish the practice changes of anesthesia providers measuring ETT cuff pressures after intubation with manometers and PACU nurses assessing for POST symptoms. The implementation team consisted of 13 full-time anesthesia providers and 15 PACU nurses.

Prior to implementation, education sessions were provided to the anesthesia providers and PACU nurses. Completion of training was confirmed by sign-in sheets (Appendix B). Anesthesia staff received instruction on the correct technique for manometers, optimal range for cuff pressures at 20-30 cm H_2O, and documentation (Appendix C). PACU nursing staff received instruction on POST symptoms and documentation (Appendix D). Clinical aids and manometers were placed into ORs at this institution (Appendix E). OR case postings were used to identify eligible patients, resulting in a sample of 146 patients. The intervention was provided to all patients 18 years of age or older and scheduled for elective surgery with general endotracheal anesthesia. Exclusion criteria included pediatrics, parturients, laryngeal mask airway, tracheostomy, or double lumen ETT placement, difficult airways, severe gastroesophageal reflux disease, a positive COVID-19 status, American Society of Anesthesiologists Class ≥ 4 or E, and/or cases scheduled with sedation or regional anesthesia.

Data collection occurred over 15 weeks. Analysis was performed using descriptive statistics and run charts. Actions were taken by the project lead to maintain privacy and confidentiality of participants including adherence to Health Insurance Portability and Accountability Act protocols, data collection within ORs and PACU, data de-identification using a code key, transcription onto an Excel management spreadsheet, and storage on an internal password protected computer. At the project's completion, all data and collection tools were destroyed.

The QI project had several structure, process, and outcome measures. First, structure measures consisted of anesthesia and nursing staff education and availability of manometers and clinical aids in ORs. These measures were evaluated by sign-in sheets and daily checklists (Appendix F), and consistently met 100%. Implementation strategies involved communication with leadership to coordinate education during optimal times, and distribution of supplemental handouts (Appendix G). Second, process measures included staff compliance to practice changes and frequency of optimal cuff pressure readings. Outcome measures involved the absence of POST symptoms in the recovery unit. Both measures were tracked by electronic and paper chart audits (Appendix H). Implementation tactics involved clinical aids, written reminders, reinforcement by change champions, and communication with stakeholders via emails on weekly data and project updates (Appendices E, I, J). The most effective strategy for optimizing provider compliance rates was post-it note reminders on OR computers, as evidenced by a 11.5% increase from weeks 3 to 4. The least effective strategy was dissemination of project updates over donuts and coffee, as demonstrated by a marginal 5% increase from weeks 8 and 9. Unfortunately, not all full-time staff were available. Moreover, Joint Commission visits, COVID-19, and weekly variation in full-time and per-diem anesthesia staff represented unanticipated factors hindering 100% provider compliance rates.

Results

The implementation of manometers into ORs for measuring and maintaining ETT cuff pressures between 20-30 cm H_2O was successful in collaboration with stakeholders and change champions. Preceding the practice change, education sessions were provided to full-time anesthesia and perioperative nursing staff. Both sessions had 100% attendance. Thirteen anesthesia providers (5 anesthesiologists, 8 certified registered nurse anesthetists) were trained on the correct manometer technique, optimal range for cuff pressures, and documentation. Fifteen PACU nurses were educated on the symptoms of POST and documentation.

The total sample size was 146 patients. A positive relationship was found among provider compliance with manometers, optimal ETT cuff pressures, and the absence of POST symptoms. Figure 3 demonstrates that provider compliance with manometers for intraoperative ETT cuff pressure monitoring improved from a baseline of 0% to 26%. The highest compliance rate was noted during week 4 at 38%. This coincided with the placement of written reminders into ORs. Written reminders represented the most effective implementation strategy, as evidenced by the 11.5% increase between weeks 3 and 4. As shown in Figure 4, ETT cuff pressure readings between 20-30 cm H_2O increased from a baseline of 0% to 69%. Lastly, Figure 5 revealed the overall incidence of POST was 17%. This translated to an improvement from a baseline of 62%

to 83% adult surgical patients denying POST symptoms in the recovery unit after manometer use. During week 2, the POST rate of 66% was considered an outlier and related to a small sample size. Overall, all three charts contained runs of six to nine points, indicating adequate variability due to random causes. No shifts or trends were observed.

During implementation, a major barrier identified was weekly variability of providers. With staffing shortages, per-diem staff were on site. However, education sessions had only been coordinated during monthly meetings with full-time staff. An unexpected facilitator was the consistent rotation of anesthesia students to the site. Students encouraged the adherence of the practice change among providers.

Discussion

This quality improvement project provided initial support regarding the feasibility of manometers in ORs. The average incidence of POST reported in adult surgical patients after general endotracheal anesthesia is 50-60% (El-Boghdadhly et al., 2016). At this organization, the implementation of manometers in ORs resulted in a 21% reduction in POST rates. These results were consistent with the evidence-based literature. Randomized controlled trials by Koo et al. (2019), Liu et al. (2010), and Ansari et al. (2014) also presented lower POST rates and pain scores in intervention groups with intraoperative manometer-guided ETT cuff pressure measurements.

Education on the correct technique and optimal cuff pressure range coupled with clinical aids augmented the application and anesthesia providers' comfort level with manometers in daily practice. This was exemplified by a 69% increase in cuff pressure readings that fell between 20-30 cm H_2O. The quality improvement project by Turner et al. (2020) demonstrated the success of a multifaceted approach. Provider compliance with routine intraoperative ETT cuff pressure monitoring, knowledge base, frequency of optimal cuff pressures, and documentation all significantly improved.

Although, various implementation strategies were employed, the goal of 100% anesthesia provider compliance was difficult to achieve. It was lower than expected due to the COVID-19 pandemic, limited supply of manometers, and Joint Commission mock site visits. The site had a total of seven manometers for 10 ORs. Therefore, manometers were designated to rooms scheduled with the highest number of cases with general endotracheal anesthesia. In addition, the organization had Joint Commission site visits, which prompted the removal of clinical aids and written reminders from ORs. Feedback from anesthesia providers revealed that adherence with intraoperative manometers would have appreciably improved with manometers and consistent reminders in each OR. Change champions and weekly communication among leadership, perioperative nursing, and anesthesia staff were efforts to minimize limitations. However, lessons were learned on the critical role of timing. In the setting of no pandemic or regulatory agency visits, a more accurate glimpse into the effects of provider compliance with manometry on POST rates may have been observed.

Conclusions

Overall, the implementation of manometers in ORs to monitor and adjust ETT cuff pressures was a feasible intervention at this organization and resulted in decreased POST rates among adult surgical patients. Intraoperative manometer use limits cuff pressures, minimizing laryngeal trauma. Manometry should be continued and extrapolated to all elective general surgeries. It is superior to subjective methods such as manual palpation of the pilot balloon, fixed-volume technique, and minimal leak test. It offers several benefits to patients and organizations. Preventing POST results in higher patient satisfaction scores and experience, as well as costs saved by shorter recovery times and lower analgesic consumption.

To promote spread and sustainability of the practice change, support from anesthesia leadership should be ongoing, education sessions to providers should be offered annually, documentation of cuff pressure should become mandatory in the electronic health record, and manometers should be purchased and placed into all ORs. Anesthesia providers were able to document ETT cuff pressures in the EHR, which was a major strength in the study. However, documentation was not mandatory. Future projects could focus on collaboration with IT to develop practice alerts and mandatory documentation of cuff pressures. The convenience of manometers in each room and mandatory documentation would prompt providers to perform routine intraoperative cuff pressure measurements and adjustments. Moreover, any future quality improvement projects at this organization on manometers and POST, should examine additional intraoperative factors that this project did not consider or control in the criteria such as intubation technique, cuff lubrication, and use of topical local anesthetics or corticosteroids. Lastly, manometers can be applied in the same manner to laryngeal mask airways for monitoring and preventing cuff overinflation.

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Table 1

Evidence Review Table

Citation: Hockey, C.A., Van Zundert, A.J., & Paratz, J.D. (2016). Does objective measurement of tracheal tube cuff pressures minimize adverse effects and maintain accurate cuff pressures? A systematic review and meta-analysis. *Anaesthesia Intensive Care, 44*(5), 560-570. https://doi.org/10.1177/0310057X1604400503					**Level**: I (Melnyk & Fineout-Overholt, 2019)
Purpose/ Hypothesis	**Design**	**Sample**	**Intervention**	**Outcomes**	**Results**
"The purpose of this systematic review was to examine whether the adjustment of endotracheal tube (ETT) cuff pressures guided by objective measurement, as compared with subjective measurement or observation of the pressure value alone, was able to prevent patient-related adverse effects in mechanically ventilated patients with an artificial airway. Secondarily, the review compared the ability of the two forms of measurements to	Systematic review (SR) with meta-analysis	**Search Strategy:** A search was conducted using the databases: PubMed, Web of Science, Embase, CINAHL, and Science Direct. Articles were searched with the following keywords: "cuff pressure," "cuff volume," "mechanical ventilation," and "measurement." 525 studies were initially identified and screened based on inclusion and exclusion criteria. Two reviewers independently rated the studies' quality using a standardized protocol (Physiotherapy Evidence Database/PEDro scale). Reasons for inclusion and exclusion were documented. **Eligible Studies:** Systematic reviews, randomized controlled trials (RCTs), and pseudo-randomized controlled	**Control:** Controls varied between studies included in the SR; (subjective measurement methods for ETT cuff pressures included manual pilot balloon palpation, auscultation, and/or measuring but not adjusting cuff pressures). **Intervention:** Interventions in SR were consistently objective measurements of ETT cuff pressures in the form of manometers, with continuous or intermittent frequency of monitoring. **Protocol:** Not applicable to SR critique	**Dependent Variable:** Researchers selected articles with a primary outcome of patient-related adverse effects such as sore throat, hoarseness, cough, and bleeding of tracheal mucosa at various timepoints post-operatively (2,6, 24 hours). The secondary outcome was frequency of ETT cuff pressures within the recommended safe or optimal range (25-30 cm H_2O). **Measures:** Questionnaires, numeric rating scales, observations, and examination of tracheal mucosa by fiberoptic bronchoscopy	**Level of Measurement:** The meta-analysis of studies was performed using the fixed and random effects models to pool risk ratios. Researchers applied descriptive statistics when meta-analysis was not feasible. **Outcome Data Retrieval:** Researchers pooled data from all 9 articles. **Analysis:** The meta-analysis found ETT cuff pressures adjusted by objective methods had benefit in preventing adverse patient events after surgery, specifically cough at 2 hours (OR 0.42, CI 95%: 0.23 to 0.79, p = 0.007), hoarseness at 24 hours (OR 0.49, CI 95%: 0.31 to 0.76, p < 0.002), sore throat (OR 0.73, CI 95%: 0.54 to 0.97, p <0.03), and tracheal lesions and silent aspiration (p = 0.001) Additionally, six of nine studies recorded the difference in ETT cuff pressures between groups, displaying significantly lower and safer mean pressures in the intervention group (Hedges' *g*

maintain accurate cuff pressures.”		trials comparing subjective to objective methods for ETT cuff pressure measurements. Populations in studies included adults with artificial airways in intensive care units or operating rooms. **Excluded studies**: 1) irrelevant to purpose of SR, 2) studies with lack of randomization and weak design, 3) language other than English, 4) full text unavailable, 5) articles with publication dates older than 1970, 6) pediatric and animal subjects **Included studies:** 9 studies (7 RCTs and 2 pseudo-randomized controlled trials with a total of 1,007 participants, across five countries: United States, China, Korea, Thailand, Saudi Arabia, and all trials focused on comparing objective to subjective methods for ETT cuff pressure measurement **PRISMA**: Included, provided description of decision-making criteria for retaining/omitting studies from the SR			1.61, CI 95%: 2.69 to 0.53, p = 0.003). **Conclusions:** The review provided evidence that ETT cuff pressure adjustment guided by objective measurement, as compared to subjective measurement or observation of pressure alone can prevent adverse patient events, while maintaining accurate and optimal cuff pressures. **SR Bias Risk:** Based on the PEDro scale, the SR with meta-analysis had low bias risk. The PEDro scale is a reliable and validated instrument for appraising the quality of RCTs. The tool consists of 11 principles: specification of eligibility criteria, random allocation, concealed allocation, baseline similarity, therapist blinding, assessor blinding, measure of key outcomes for >85% of subjects, intention to treat, between-group statistical comparison and point measures, and measures of variability. Studies are graded on a 0–10-point scale. A cumulative score of 6 or greater indicates RCTs of moderate-high quality. Flaws in lower-scoring studies primarily included lack of therapist or assessor blinding.

		Power analysis: Not applicable to SR critique **Group Homogeneity:** Studies were different in setting, patient age, indications for artificial airway, type of airway device used, and intubation times. No I^2 statistic was reported.			
Citation: Koo, C.H., Sohn, H.M., Choi, E.S., Choi, J.Y., Oh, A.Y., Jeon, Y.T. & Ryu, J.H. (2019). The effect of adjustment of endotracheal tube cuff pressure during scarless remote access endoscopic and robotic thyroidectomy on laryngopharyngeal complications: Prospective randomized and controlled trial. *Journal of Clinical Medicine, 8*(11), 1787. https://doi.org/10.3390/jcm8111787					**Level**: II (Melnyk & Fineout-Overholt, 2019)
Purpose/ Hypothesis	**Design**	**Sample**	**Intervention**	**Outcomes**	**Results**
"The purpose of this study was to evaluate the effect of intraoperative adjustment of endotracheal tube cuff pressures during scarless remote access endoscopic and robotic thyroidectomy (SERT) on the incidence of laryngopharyngeal complications, including post-operative sore throat (POST), hoarseness, dysphagia and cough."	Experimental Prospective, single-blind randomized controlled trial **Location**: Single center; university hospital in Seoul, South Korea Anesthesiologist in charge of allocation or primary investigator (PI) was not blinded to group allocation.	**Sampling Technique:** Convenience **Eligible Participants:** 104; Adult patients (19-70 yrs. old), American Society of Anesthesiologists (ASA) I-II status, and scheduled for elective SERTs **Excluded Participants**: 0; Pre-operative sore throat, hoarseness or dysphagia, obesity ((body mass index (BMI) > 30 kg/m^2)), upper respiratory tract symptoms within two weeks of surgery, anticipated difficult airway, previous surgeries of oral cavity or pharynx, thyroid cancer with goiter	**Control:** Cuff pressures were set to 25cm H_2O with a manometer initially after intubation. Cuff pressures were then monitored and only adjusted if pressures reached < 25 or > 50 cm H_2O during surgery. **Intervention:** Cuff pressures were set to 25cm H_2O with a manometer initially after intubation. Cuff pressures were then monitored and continuously adjusted to maintain pressures at 25 cm H_2O during surgery. **Treatment fidelity:** Both groups received same anesthetic plan:	**Dependent Variable:** Incidence and severity of laryngopharyngeal symptoms at 1, 6, 24, and 48 hours after surgery **Laryngopharyngeal symptoms** **POST:** defined as pain at larynx or pharynx **Dysphagia:** defined as difficulty with swallowing **Hoarseness:** defined as a harsh or strained voice **Cough:** defined as a sudden reflux that forces air out of the throat **POST Severity** **None:** Patient reports no sore throat **Mild:** Patient reports sore throat with swallowing **Moderate:** Patient reports sore throat during rest and with swallowing	**Statistical Procedures(s) and Results:** Descriptive and inferential analysis were performed. P values of <0.05 were considered statistically significant. Chi-Square test: There was a significant difference in the outcomes of incidence and degree of POST between the two groups (p = 0.035), especially pronounced at 6 and 24 hours postoperatively. The incidence of POST was lower in patients who received continuous ETT cuff pressure monitoring and adjustments compared to those that received it only as needed (53.3% vs. 74.5%). ANOVA: Endotracheal tube cuff pressures fluctuated drastically during

		or metastasis, asthma, gastroesophageal reflux **# Accepted**: 104 adult patients undergoing elective SERT Computer randomization assigned subjects into either the control or intervention group. **# Control:** 52 patients; 3/52 excluded from final analysis **# Intervention**: 52 patients; 6/52 excluded from final analysis Patients were excluded from final analysis due to conversion from SERT to open surgery. **Power analysis:** 86 subjects required to meet β = 80%, α = 0.05 and moderate effect size. Power analysis met, minimizing risk for Type II error. **Group Homogeneity**: Intervention and control groups were similar in age, gender, BMI, ASA status, airway exam, anesthesia type, and surgery	Total intravenous anesthesia (TIVA) using propofol and remifentanil infusions. One anesthesiologist performed intubations using direct laryngoscopy with MAC blades and NIM-EMG reinforced ETTs and assessed cuff pressures using manometers. The anesthesiologist followed up with patients in PACU using questionnaires to gauge the incidence of POST, hoarseness, dysphagia, and cough at 1, 6, 24 and 48 hours. Anesthesiologists were briefed by PI on study protocols. Training on manometers was not provided.	**Severe:** Patient reports sore throat is unbearable, requiring analgesics **Measures:** The dependent variables were measured by numeric rating scales (0-100; 0 = no pain, 100 = most severe pain) for laryngopharyngeal symptoms and degree of POST by severity scale. Additionally, observations of symptoms were recorded by anesthesiologists.	anesthesia ($p < 0.05$). The mean cuff pressures of the intervention group were lower compared to the control group during surgery (25.0 vs. 28.3 cmH_2O, $p < 0.001$).
Citation: Ansari, L., Bohluli, B., Mahaseni, H., Valaei, N., Sadr-Eshkevari, P. & Rashad, A. (2014). The effect of endotracheal tube cuff pressure control on post-extubation sore throat pain in orthognathic surgeries: A randomized double-blinded control clinical trial. *British Journal of Oral and Maxillofacial Surgery, 52*, 140-143. http://dx.doi.org/10.1016/j.bjoms.2013.10.005					**Level**: II (Melnyk & Fineout-Overholt, 2019)

Purpose/ Hypothesis	Design	Sample	Intervention	Outcomes	Results
"The purpose of this study was to determine whether there was a difference in the incidence of throat pain after extubation in patients with uncontrolled and controlled endotracheal tube cuff pressures using mechanical adjustment."	Experimental Prospective, double-blind randomized controlled trial **Location**: Single center; university hospital in Tehran, Iran	**Sampling Technique:** Convenience **Eligible Participants:** 60; Adult patients (>18 yrs. old), ASA I-II status, and scheduled for elective maxillofacial surgeries **Excluded Participants**: 17; Anticipated difficult airway, previous tracheal injury or discomfort, procedure and intubation duration > 4 hours, and injections for severe postoperative pain **# Accepted**: 43 adult patients undergoing elective maxillofacial surgeries Computer randomization assigned subjects into either the control or intervention group. **# Control:** 23 patients **# Intervention**: 20 patients **Power analysis:** 40 subjects required to meet $\beta = 90\%$, $\alpha = 0.05$ and moderate effect size. Power analysis met, minimizing risk for Type II error.	**Control:** Cuff pressures were adjusted using manual palpation of pilot balloon and/or minimal leak technique. **Intervention:** Cuff pressures were measured and adjusted using a manometer initially after intubation and hourly. Cuff pressures were then maintained at 20-30 cm H_2O during surgery. **Treatment fidelity:** Both groups received same anesthetic plan: Total intravenous anesthesia (TIVA) using propofol and remifentanil infusions. Anesthesiologists performed intubations using direct laryngoscopy with nasal RAE ETTs. Standardized ETT sizing was used: 7.0 mm for females and 7.5mm for males. Oral and maxillofacial residents followed-up with patients in PACU using questionnaires to evaluate incidence of POST,	**Dependent Variable:** Incidence of throat pain at 1, 6, and 24 hours after surgery **Throat pain:** defined as discomfort reported at larynx or pharynx **Measures:** The dependent variable was measured by numeric rating scales (visual analog scale: 0-10; 0 = no pain, 10 = maximum pain). Additionally, observations of symptoms were recorded by residents in the PACU.	Descriptive analysis was performed. P values of <0.05 were considered statistically significant. **Statistical Procedures(s) and Results:** Mann-Whitney U test: There was a significant difference in reported throat pain scores between the intervention and control groups ($p = 0.002$), at 1 and 6 hours postoperatively. Subjects with ETT cuff pressure monitoring using manometers reported overall lower scores compared to those with monitoring by manual palpation or minimal leak test technique (3.1-3.9/10 vs. 4.5-5.3/10 respectively).

		Group Homogeneity: Intervention and control groups were similar in age, gender, BMI, ASA status, airway exam, anesthesia type, surgery, duration of intubation	hoarseness, dysphagia, and cough at 1, 6, and 24 hours. Anesthesiologists and residents were briefed by PI on study protocols. Training on manometers was not provided.		
Citation: Liu, J., Zhang, X., Gong, W., Li, S., Wang, F., Fu, S., Zhang, M., & Hang, Y. (2010). Correlations between controlled endotracheal tube cuff pressure and postprocedural complications: A multicenter study. *Anesthesia and Analgesia, 111*(5), 1133-1137. https://doi.org/10.1213/ANE0b013e3181f2ecc7					**Level**: II (Melnyk & Fineout-Overholt, 2019)
Purpose/ Hypothesis	**Design**	**Sample**	**Intervention**	**Outcomes**	**Results**
"The purpose of this landmark study was to investigate the short-term impact of measuring and controlling endotracheal tube cuff pressures on tracheal intubation-related respiratory complications (e.g., cough, sore throat, hoarseness and blood-streaked expectoration)."	Experimental Prospective, double-blind randomized controlled trial **Location**: Multi-center; Four tertiary care hospitals in Shanghai, China Anesthesiologist in charge of allocation/PI was not blinded to group allocation.	**Sampling Technique:** Convenience **Eligible Participants:** 509; Adult patients (>18 yrs. old), ASA I-II status, and scheduled for elective surgeries **Excluded Participants**: 0; Anticipated difficult airway, pre-operative cough or sore throat, double-lumen endotracheal intubations, and oral and laryngopharyngeal surgery **# Accepted**: 509 adult patients undergoing elective surgeries Randomization via sealed envelopes assigned subjects into either the control or intervention group. **# Control:** 273 patients	**Control:** ETT cuff was inflated using manual palpation of pilot balloon by anesthesiologist. PI did not make any adjustments to cuff pressure. Cuff pressure was recorded after inflation. **Intervention:** ETT cuff was inflated using manual palpation of pilot balloon by anesthesiologist. PI then adjusted cuff pressure using manometer to 15-25 cm H_2O. Cuff pressures were recorded after inflation and adjustment. Following extubation, 20 patients from each group with duration of intubation lasting 120-180 minutes were randomly selected and examined by fiberoptic bronchoscopy to identify	**Dependent Variables:** Incidence of post-operative sore throat, cough, hoarseness, and blood-streaked expectorant at 24 hours after extubation Degree of tracheal mucosal injury after extubation **POST:** defined as pain at larynx or pharynx **Hoarseness:** defined as a harsh or strained voice **Cough:** defined as a sudden reflux that forces air out of the throat **Blood-streaked expectorant**: defined as secretions with visible amounts of blood **Tracheal Mucosal Injury** **Mild:** Sporadic spots of congestion visualized on fiberoptic bronchoscopy, associated with no patient reports of POST.	Descriptive analysis was performed. P values of <0.05 were considered statistically significant. **Statistical Procedures(s) and Results:** Chi-square test: There was a significant difference in the outcomes of sore throat, hoarseness, and blood-streaked expectoration at 24 hours post-extubation between the intervention and control groups ($p = 0.03$), at 44% vs. 34%, 11% vs. 3%, and 11% vs. 4% respectively. The incidence of sore throat increased significantly in both groups with endotracheal intubation, longer than 3 hours ($p = 0.005$). Tracheal mucosal injuries were observed in both groups. However, subjects with ETT cuff pressure monitoring and

		# Intervention: 236 patients **Power analysis:** Not mentioned. Potential risk for type II error. **Group Homogeneity**: Intervention and control groups were similar in age, gender, BMI, ASA status, anesthesia type, duration of intubation and surgery	the degree of tracheal mucosa injury. **Treatment fidelity:** Both groups received same anesthetic plan: Propofol infusion and Inhalational agent (Sevoflurane or Isoflurane) Anesthesiologists performed intubations using direct laryngoscopy with ETTs. Standardized ETT sizing was used: 7.0-7.5 mm for females and 7.5-8.0 mm for males. A physician resident followed-up with patients in PACU using questionnaires to assess incidence of POST, hoarseness, dysphagia, and cough at 1, 6, and 24 hours. Anesthesiologists, residents, and fiberoptic bronchoscopists were briefed by PI on study protocols. Training on manual palpation of pilot balloon or manometers was not provided.	**Moderate:** Local patchy congestion visualized on fiberoptic bronchoscopy, associated with patient reports of POST **Severe degree:** Patchy hemorrhagic ulceration visualized on fiberoptic bronchoscopy, associated with patient reports of POST and blood-streaked secretions **Measures:** The dependent variables were measured by questionnaires for laryngopharyngeal symptoms. Additionally, observations of symptoms were recorded by residents in the PACU. The degree of tracheal mucosal injury was confirmed on exam using fiberoptic bronchoscopy.	adjustment by manometers had less severe images on fiberoptic bronchoscopy than those with no adjustment (p = 0.043). Local patchy congestion of the tracheal mucosa was seen in 9/20 patients (45%) in the control group vs. 5/20 patients (25%) in the intervention group.
Citation: Turner, M.A., Feeney, M. & Deeds, J.L. (2020). Improving endotracheal cuff inflation pressures: An evidence-based project in a military medical center. *AANA Journal, 88*(3), 203-208. https://www.aana.com/docs/default-source/aana-journal-web-documents-1/improving-endotracheal-cuff-inflation-pressures-an-evidence-based-project-in-a-military-medical-center-aana-journal-june-2020.pdf					**Level**: IV (Melnyk & Fineout-Overholt, 2019)
Purpose/ Hypothesis	**Design**	**Sample**	**Intervention**	**Outcomes**	**Results**

"The aim of this evidence-based practice project was to remove any barriers to the routine use of cuff manometry, resulting in regular measurements and documentation of endotracheal tube (ETT) cuff pressures within acceptable evidence-based limits."	Experimental, Pretest-Posttest Design Evidence-based quality improvement (QI) project **Location**: Single center; military hospital in San Antonio, Texas No blinding done	**Sampling Technique:** Convenience **Eligible Participants:** 46; Providers in anesthesia department **Excluded Participants**: 0; No exclusion criteria mentioned **# Accepted**: 46 anesthesia providers; 5 anesthesiologists (MDAs), 35 nurse anesthetists (CRNAs), 6 nursing anesthesia students (SRNAs) No randomization of subjects performed. **# Control:** 46 anesthesia providers; 16/46 excluded from final analysis **# Intervention**: 46 anesthesia providers; 15/46 excluded from final analysis Participants were excluded from final analysis due to not completing pre- and/ or post-intervention questionnaires. **Power analysis:**	**Control:** Baseline ETT cuff pressure monitoring practice and knowledge of anesthesia providers **Intervention:** Staff education provided on best practices for ETT cuff pressure monitoring and complications of cuff under- and over-inflation, training on manometer technique, visual aids reflecting safe and appropriate cuff pressures (20-30 cm H_2O) in ORs, reminders in chart to document cuff pressures, and placement of manometers in all ORs. **Treatment fidelity:** Evidence-based QI project had 3 phases. **Phase 1: Pre-implementation** Anesthesia providers completed questionnaires on current practice modalities and knowledge of best practices to assess ETT cuff pressures. PI performed random ETT cuff pressure checks using manometer on 40 patients undergoing elective surgery with general anesthesia. **Phase 2: Intervention**	**Dependent Variable:** Primary: Incidence of safe ETT cuff pressures (20-30 cm H2O), pre- and post- intervention Secondary: Frequency of anesthesia providers who monitored ETT cuff pressures using manometers at the start and hourly during surgery, pre- and post-intervention Frequency of anesthesia providers who used manometers over manual palpation of pilot balloon or minimal leak technique, pre- and post-intervention Anesthesia providers' knowledge of appropriate ETT cuff pressure range, pre- and post-intervention Compliance of anesthesia providers in documenting ETT cuff pressures, pre- and post-intervention **Measures:** The primary dependent variable was measured by ETT cuff pressure checks using manometers by the PI. The secondary dependent variables were measured using staff questionnaires and chart audits by the PI.	Descriptive analysis was performed. P values of <0.05 were considered statistically significant. **Statistical Procedures(s) and Results:** Chi-square test: All of the primary and secondary outcomes improved significantly after the intervention. Safe ETT cuff pressures (20-30 cm H2O) increased from 27.5% to 62.5% (p < 0.0032). The incidence of unsafe ETT pressures (>30 cm H_2O) was 4.4 times more likely prior to the intervention (OR = 4.394; CI 95%: 1.709 to 11.29). The percentage of providers who used manometers over manual palpation or auscultation to determine ETT cuff pressures increased from 10% to 94% (p <0.001). The percentage of anesthesia providers who monitored ETT cuff pressures at the start and hourly during cases increased from 11% to 53% (p = 0.0007). Anesthesia providers' knowledge of accurate ETT cuff pressures increased from 35% to 87% (p < 0.001) Lastly, provider documentation of ETT cuff pressures improved from 19% to a 75%, based on chart audits.

		80 subjects required to meet β = 80%, α = 0.05 and moderate effect size. This was determined as sample size of patients and cuff pressures required to demonstrate practice change among anesthesia providers related to intervention. Power analysis met, minimizing risk for Type II error. **Group Homogeneity**: Intervention and control groups were the same, as this was a pre-test and post-test design. However, anesthesia providers varied in years of clinical experience and certifications.	PI provided staff education and training sessions on manometers. Availability of manometers in all ORs, visual aids on anesthesia machines displaying recommended ETT cuff pressures, and charting reminders were added as supplemental tools to improve provider compliance of routine ETT cuff pressure monitoring. **Phase 3: Post-implementation** Stage occurred 30-60 days after implementation. Questionnaires were distributed and completed by anesthesia providers. PI performed ETT cuff pressure checks again using manometer on second set of 40 patients undergoing surgery with general anesthesia. The PI conducted chart audits to determine whether cuff pressures were documented. One anesthesiologist/PI conducted intervention		
Citation: Selman, Y., Arciniegas, R., Sabra, J.M., Ferreira, T.D., & Arnold, D.J. (2019). Accuracy of the Minimal Leak Test for Endotracheal Cuff Pressure Monitoring. *The Larynoscope,130.* 1646-1650. http://doi.org/10.1002/lary.28328					**Level**: IV (Melnyk & Fineout-Overholt, 2019)
Purpose/ Hypothesis	**Design**	**Sample**	**Intervention**	**Outcomes**	**Results**

"The purpose of this evidence-based practice project was to determine the accuracy of the minimum leak test as a surrogate for target endotracheal cuff pressure of 20-30 cm H_2O in intubated patients."	Prospective, Longitudinal Design Evidence-based quality improvement (QI) project **Location**: Single center; Medical ICU and University hospital in Miami, Florida No blinding done	**Sampling Technique:** Convenience **Eligible Participants:** 122; Adult patients (>18 yrs. old), recent tracheal intubation **Excluded Participants**: 0; <18 years old, DNR/DNI status **# Accepted**: 122 adults patients intubated No randomization of subjects performed **# Control:** 122 patients **# Intervention**: 122 patients **Power analysis:** Not mentioned. Potential risk for type II error. **Group Homogeneity**: Intervention and control groups were the same, as this was a prospective, longitudinal design.	**Control:** Baseline ETT cuff pressure monitoring practice **Intervention:** Respiratory therapists inflated ETT cuff pressures using the minimal leak test technique once every 12-hour shift for a maximum of 6 days. Cuff pressures were then measured with a manometer, recorded, and adjusted to 20-30 cm H_2O. **Treatment fidelity:** Respiratory therapists were briefed by PI on study protocols. Training on minimal leak test technique and manometers was provided.	**Dependent Variable:** Readjustment rates per procedure and patient (# of times ETT cuff pressure measurements were outside of 20-30 cm H2O and required adjustment by manometer) **Measure:** The dependent variables were measured by ETT cuff pressure checks using manometers by respiratory therapists.	Descriptive analysis was performed. P values of <0.05 were considered statistically significant. **Statistical Procedures(s) and Results:** Chi-square test: Of the 722 minimal leak test techniques performed by respiratory therapists, 24% resulted in ETT cuff pressures outside the optimal range of 20-30 cm H_2O and required readjustment via manometers. Specifically, 66% of cuffs (113) were overinflated, while 34% (57) were underinflated. There was no correlation between age, ETT size, or duration of intubation for cuff pressure readjustment rates. Logistic Generalized Mixed Effects Model: The likelihood of a patient requiring one or more cuff pressure readjustments during their intubation course was 54.9% (CI 95%: 52.9% to 57.2%).
Citation: Rahmani, F., Soleimanpour, H., Zeynali, A., Mahmoodpoor, A., Nia, K.S., Panahi, J.R., Sanaie, S., Soleimanpour, M., & Esfanjani, R.M., (2017). Comparison of tracheal tube cuff pressure with two techniques: fixed volume versus pilot balloon palpation. *Journal of Cardiovascular Thoracic Research, 9*(4), 196-199. http://doi.org/10.15171/jcvtr.2017.34					**Level**: IV (Melnyk & Fineout-Overholt, 2019)
Purpose/ Hypothesis	**Design**	**Sample**	**Intervention**	**Outcomes**	**Results**

"The aim of this present study was to compare endotracheal cuff pressures by the pilot balloon and fixed volume methods using a manometer."	Prospective, randomized, cross-sectional study **Location**: Single center; Emergency department and hospital in Iran Critical care provider in charge of allocation or primary investigator (PI) was not blinded to group allocation	**Sampling Technique:** Convenience **Eligible Participants:** 194; Adult patients (>18 yrs. old), requiring tracheal intubation **Excluded Participants**: 0; laryngeal stenosis, tracheal bleeding, and patient or family's refusal to participate in study **# Accepted**: 194 adult patients undergoing intubation Computer randomization assigned subjects into either the control group or intervention group **# Control**: 97 patients **# Intervention**: 97 patients **Power analysis:** 94 subjects required to meet $\beta = 80\%$, $\alpha = 0.05$ and moderate effect size. Power analysis met, minimizing risk for Type II error. **Group Homogeneity**: Intervention and control groups were similar	**Control:** ETT cuff inflated using manual palpation of pilot balloon by critical care provider. PI measured cuff pressure using manometer and adjusted to 20-30 cm H_2O. **Intervention:** ETT cuff inflated using fixed volume (10 cc syringe of air) by critical care provider. PI measured cuff pressure using manometer and adjusted to 20-30 cm H_2O. Initial cuff pressures were recorded after inflation and adjustments. **Treatment fidelity:** Both groups received same anesthetic plan: One critical care provider performed intubations using rapid-sequence induction and direct laryngoscopy with ETTs. Standardized ETT sizing was used: 7.5 mm for females and 8.0 mm for males.	**Dependent Variables:** ETT cuff pressures (cm H_2O) Percentage of ETT cuff pressures outside of safe range (20-30 cm H_2O) The dependent variables were measured using manometers and recorded on a checklist.	Descriptive analysis was performed. P values of <0.05 were considered statistically significant. **Statistical Procedures(s) and Results:** Chi-square test: There was a significant difference in the outcomes of ETT cuff pressures between the control and intervention groups ($p < 0.001$). The average cuff pressures in the manual palpation of the pilot balloon technique were 118.15 +/- 22.15 cm H_2O and 44.96 +/- 21.77 cm H_2O in the fixed-volume group. In the manual palpation of the pilot balloon group, 100% of cuff pressures were outside the safe range, while only 57% were in the fixed volume group. Both techniques provide inaccurate cuff pressure measurements during intubation.

		in age, gender, height, weight, BMI, hemodynamics			

Note. Melnyk, B.M. & Fineout-Overholt, E. (2019). *Evidence-based practice in nursing & healthcare: A guide to best practice* (4th ed.). Wolters Kluwer.

Table 2

Evidence Synthesis Table

PICOT Question: Does intraoperative measurement and adjustment of endotracheal tube cuff pressures guided by manometers reduce the incidence and severity of post-operative sore throat (POST) among adult surgical patients while in the post-anesthesia care unit, compared to no monitoring or subjective monitoring methods (e.g., manual palpation of pilot balloon, minimal leak test, fixed-volume)?			
Level of Evidence	**# of Studies**	**Summary of Findings**	**Overall Quality** (Newhouse, 2006)
I	**1**	Hockey et al. (2016) found that the adjustment of endotracheal tube cuff pressures guided by objective measurement methods such as manometers, compared to subjective methods such as manual palpation of the pilot balloon and minimal leak test technique, were superior in maintaining accurate and optimal cuff pressures (20-30 cm H_2O) (Hedges' *g* 1.61, 95% CI: 2.69 to 0.53, $p = 0.003$), as well as reducing the incidence of adverse events (e.g. POST, cough, hoarseness, tracheal lesions, silent aspiration) within 24 hours after surgery ($p < 0.03$).	The study receives a quality rating of an B. Internal validity was fortified by the characteristics of a systematic with meta-analysis design, large sample size involving 1,007 participants across five different countries, multiple database search, clearly defined data collection protocols and outcomes, validated statistical and bias risk assessment tools, and consistent results. One limitation of this study was heterogeneity, as the study population was diverse and included adult patients intubated in intensive care units, medical wards, and operating rooms. Heterogeneity has the potential to mask the ability in determining whether findings are truly related to the intervention or to sample variation. Heterogeneity may also limit generalizability of findings. Furthermore, authors suggest that future trials should be performed to determine a standardized cuff pressure range and frequency of measurements.
II	**3**	Koo et al. (2019) and Liu et al. (2010) investigated the incidence and severity of respiratory symptoms within 24-48 hours after surgery. Koo et al. (2019) assessed for the symptoms of sore throat, cough, hoarseness, dysphagia, and blood-streaked expectorant in adult patients undergoing elective SERTs. Liu et al. (2010) examined not only those symptoms, but also the degree of tracheal mucosal injury in adult patients undergoing various types of elective procedures. Both studies found a significant difference in the outcomes of sore throat, hoarseness, and blood-streaked expectoration between intervention and control groups ($p = 0.03$). Patients who had intraoperative ETT cuff pressure measurements and adjustments	Both studies receive a quality rating of a B. Internal validity was strengthened by the traits of a single-blinded, prospective randomized controlled study design, use of a single experienced anesthesia provider performing the interventions, moderate to large sample sizes, clearly defined protocols, and outcomes, validated statistical instruments, and consistent results.

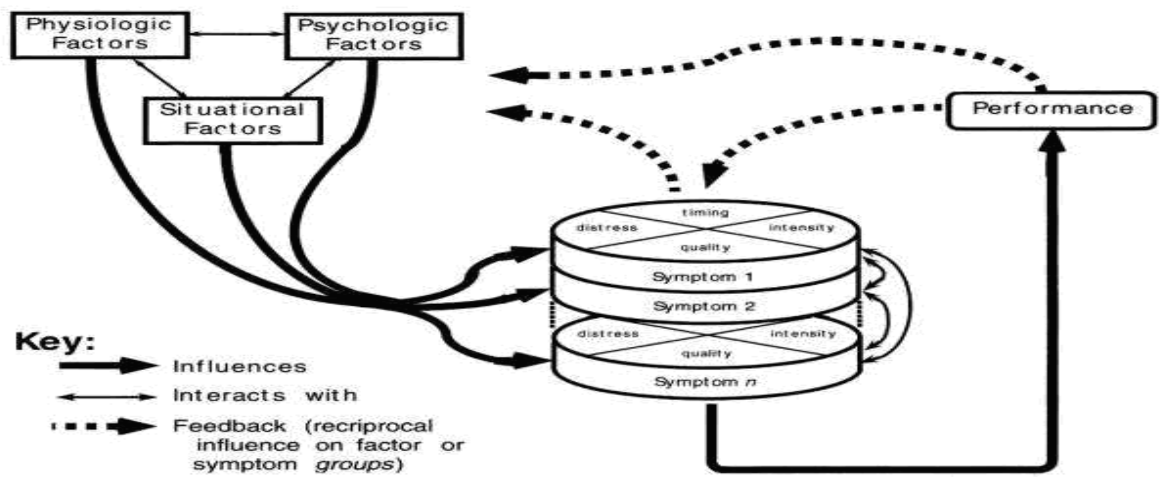
		using manometers reported lower incidence and severity of symptoms. Liu et al. (2010) additionally noted the presence of tracheal mucosal injuries in both groups, however the control group, without ETT cuff pressure monitoring or adjustment, had more severe images with local congestion and patchy hemorrhagic ulceration ($p = 0.043$). Ansari et al. (2014) exclusively investigated the incidence of postoperative throat pain at 1, 6, 24 hours in adult patients undergoing elective thyroidectomies. A significant difference was noted in the throat pain rates and scores between intervention and control groups ($p = 0.02$). Patients with intraoperative endotracheal tube cuff pressure monitoring using manometers reported lower pain scores than those monitored by manual palpation or minimal leak test technique (3.9/10 vs. 5.3/10 and 3.1/10 vs. 4.5/10).	Liu et al. (2010) did not mention a power analysis; however, the study utilized a large sample across four tertiary care hospitals. Koo et al. (2019) had stringent enrollment criteria and concentrated on adult patients receiving elective minimally invasive thyroidectomies, which may have controlled for confounding variables, while concurrently decreasing external validity. Additionally, the inability to blind the PI or outcome assessors in both studies presented the potential risk for performance and detection biases. The study receives a quality rating of a B. Internal validity was reinforced by the elements of a double-blinded, prospective randomized controlled study design, adequately powered sample size, clearly defined protocols, and outcomes, validated statistical instruments and consistent results. Ansari et al. (2014) had rigorous enrollment criteria and focused solely on adult patients receiving maxillofacial surgeries, which may have controlled for confounding variables, while simultaneously reducing external validity.
IV	**3**	Turner et al. (2020) found that a multifaceted intervention involving staff education on the best practices for ETT cuff pressure monitoring, training on manometer technique, placement of posters stating recommended cuff pressure range (20-30 cm H_2O) and manometers in all operating rooms, and electronic health record reminders to chart cuff pressures, all effectively increased provider knowledge and improved compliance to routine intraoperative ETT cuff pressure monitoring and documentation. Subsequently, these actions maintained safe and optimal ETT cuff pressures and reduced the risk for POST and silent aspiration events. Rahmani et al. (2017) and Selman et al. (2019) investigated the accuracy of subjective methods for measuring and maintaining endotracheal tube cuff pressures within the optimal range of 20-30 cm H_2O. Rahmani et al. (2017) evaluated cuff pressure measurements using the manual palpation of the pilot balloon and fixed-volume techniques among adult patients intubated in the emergency department. The manual palpation group had higher average cuff pressures than the fixed-volume (118.15 +/- 22.15 cm H2O and	The study receives a quality rating of C. Although, internal validity was increased with one anesthesiologist performing the intervention and evaluating the outcomes, an adequately powered sample size, the use of validated statistical instruments, and consistent findings, there were some flaws noted. There was no randomization or controls applied. The study was a quality improvement project with a pre-test post-test design. Additionally, recommendations were aimed at future research. The study receives a quality rating of B. Internal validity was fortified by the elements of a prospective and randomized study design, use of a single critical care provider performing the interventions and evaluating the outcomes, adequately powered sample size, clearly defined protocols, validated statistical instruments, and consistent results.

		44.96 +/- 21.77 cm H2O) (p<0.001) and 57% or more pressures were outside of the safe range. Selman et al. (2019) assessed cuff pressure measurements using the minimal leak test technique and the rate of readjustments among adult patients intubated in the medical intensive care unit. Both studies revealed gross over- and underestimations in cuff pressure measurements and proposed manometry as the most accurate method. Selman et al. (2019) additionally reported the likelihood that a patient required one or more cuff pressure readjustments over their intubation course as 52.4% (95% CI, 52.9, 57.2).	The study receives a quality rating of C. Although, internal validity was increased with the use of a single provider evaluating the outcomes, use of validated statistical instruments, and consistent findings, there were some flaws noted. There was no randomization or controls applied. The study was a quality improvement project with a longitudinal design. Additionally, recommendations were directed at future research. Additionally, the inability to blind the PI or outcome assessor in both studies presented the potential risk for performance and detection biases.

Note. Newhouse, R.P. (2006). Examining the support for evidence-based nursing practice. *The Journal of Nursing Administration, 36*(7/8), 337-340.

Figure 1

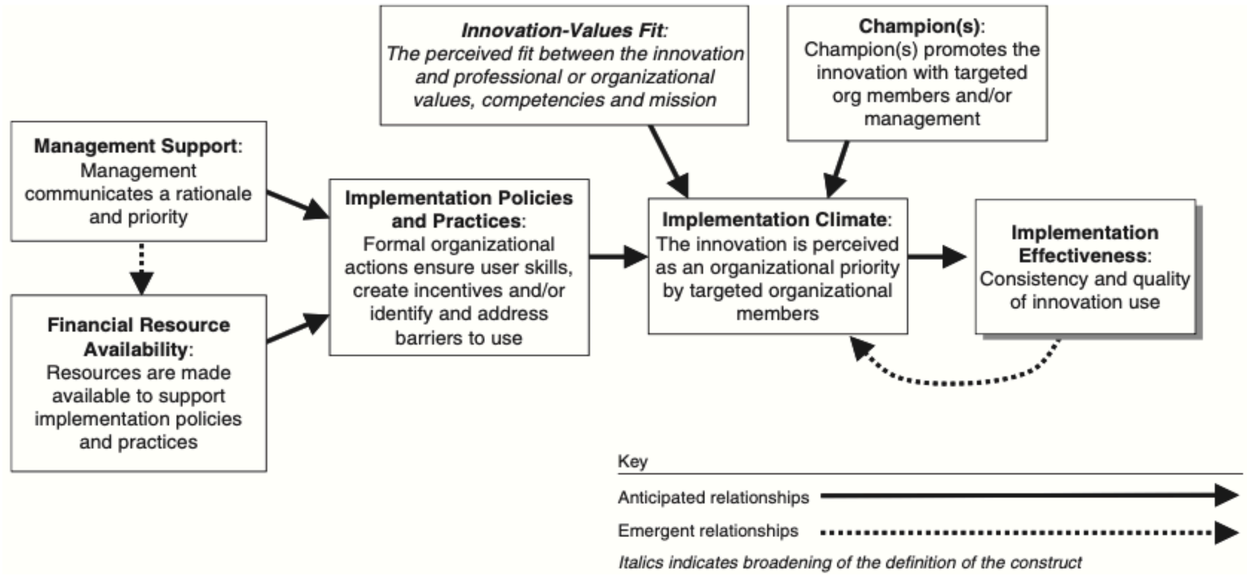
The Theory of Unpleasant Symptoms Pathway



Note. From "An Integrative Review of the Theory of Unpleasant Symptoms," by J.R. Blakeman, 2019, *Journal of Advanced Nursing, 75*(5), pp. 946-961 (https://doi.org/10.1111/jan.13906).

Figure 2

Conceptual Framework of Complex Innovations Pathway



Note. From "Determinants for Implementation Effectiveness: Adapting a Framework for Complex Innovations," by C. D. Helfrich, B. J. Weiner, M. M. McKinney, and L. Minasian, 2007, *Medical Care Research and Review, 64*(3), pp. 279-303 (https://doi.org/10.1177/1077558707299887).

Figure 3

Anesthesia Provider Compliance to Manometer-Guided Endotracheal Tube Cuff Pressure Measurements Run Chart

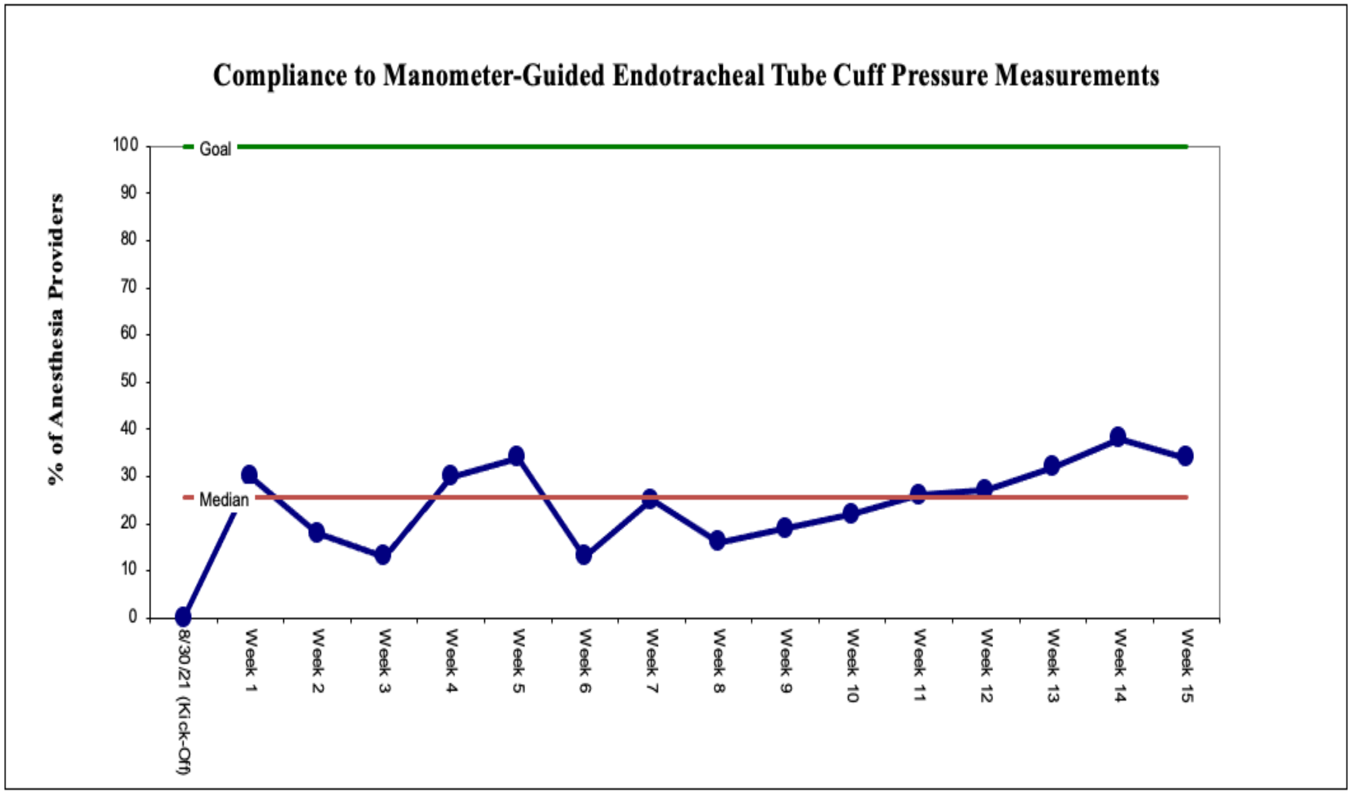


Figure 4

Endotracheal Tube Cuff Pressures in Safe Range (20-30 cm H_2O) Run Chart

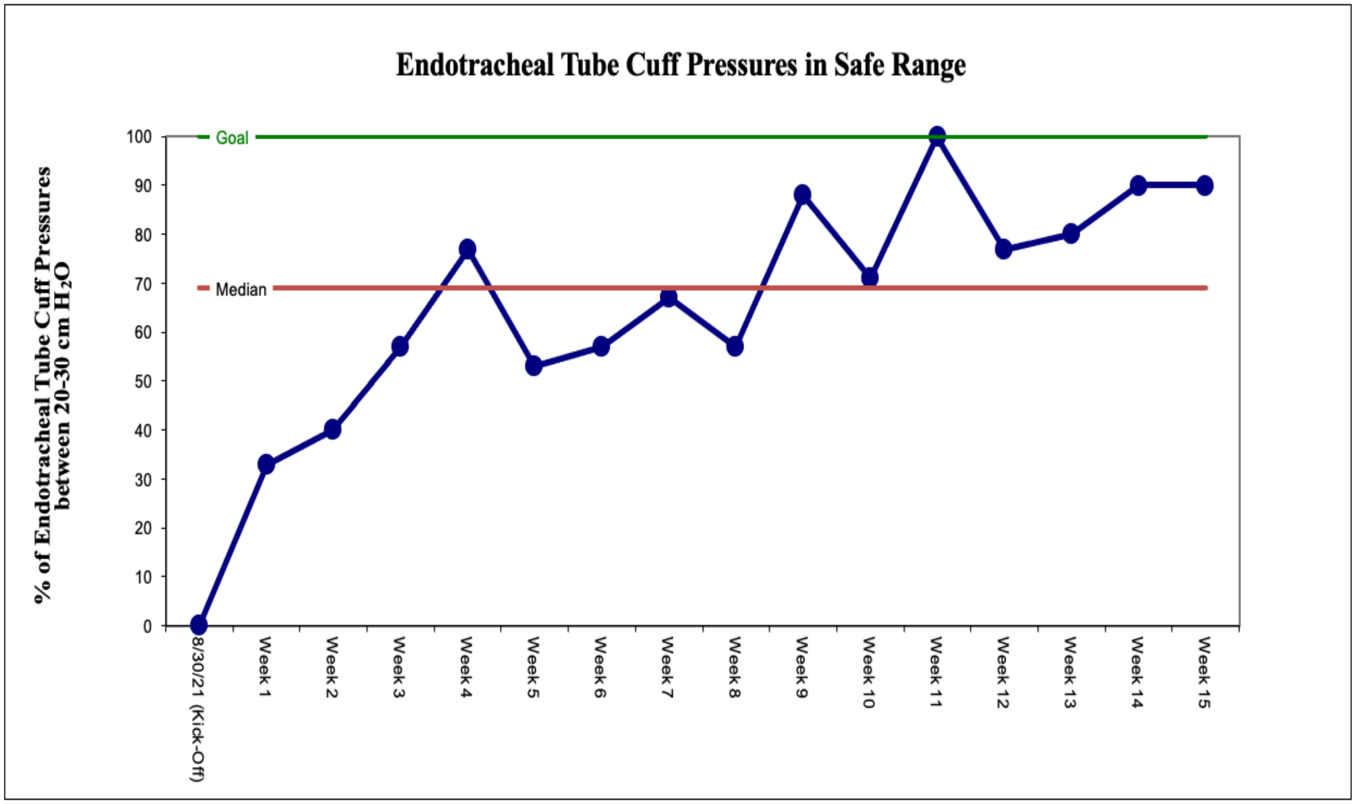
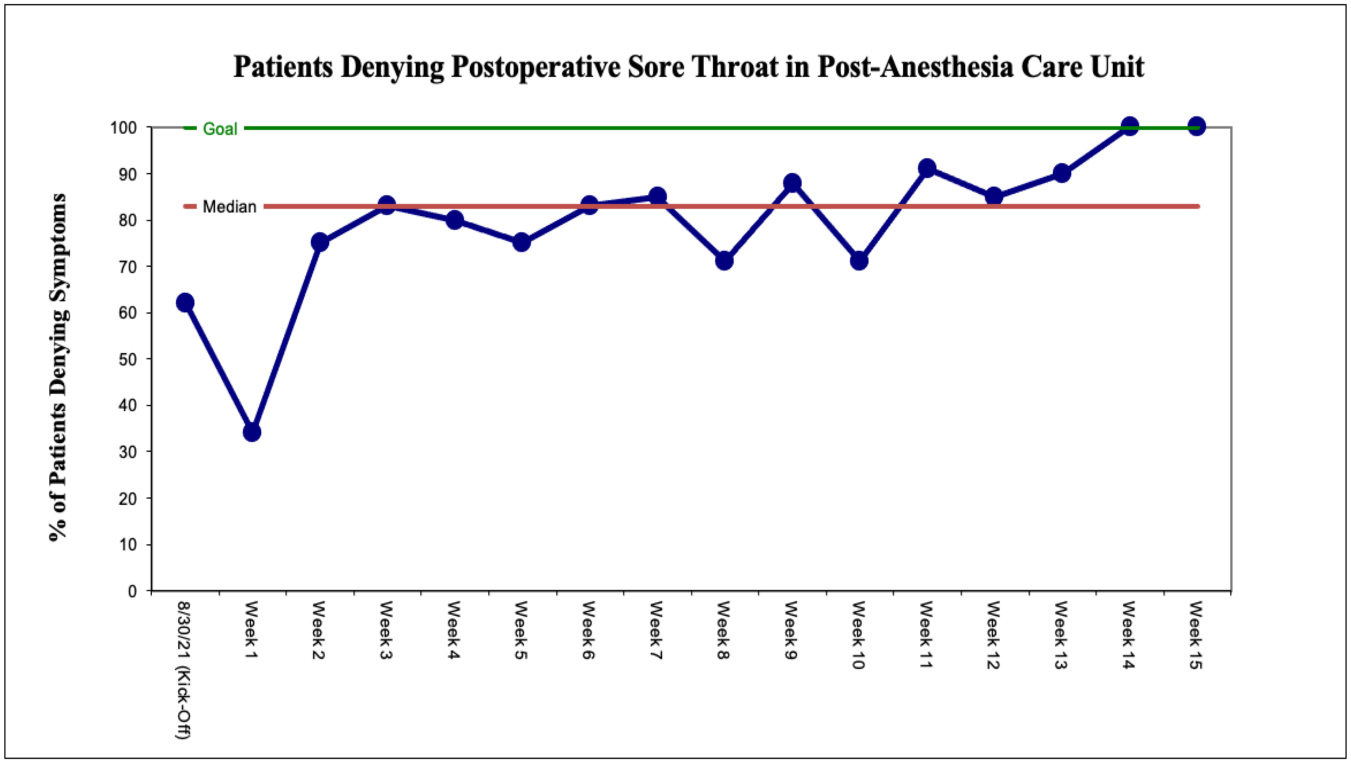


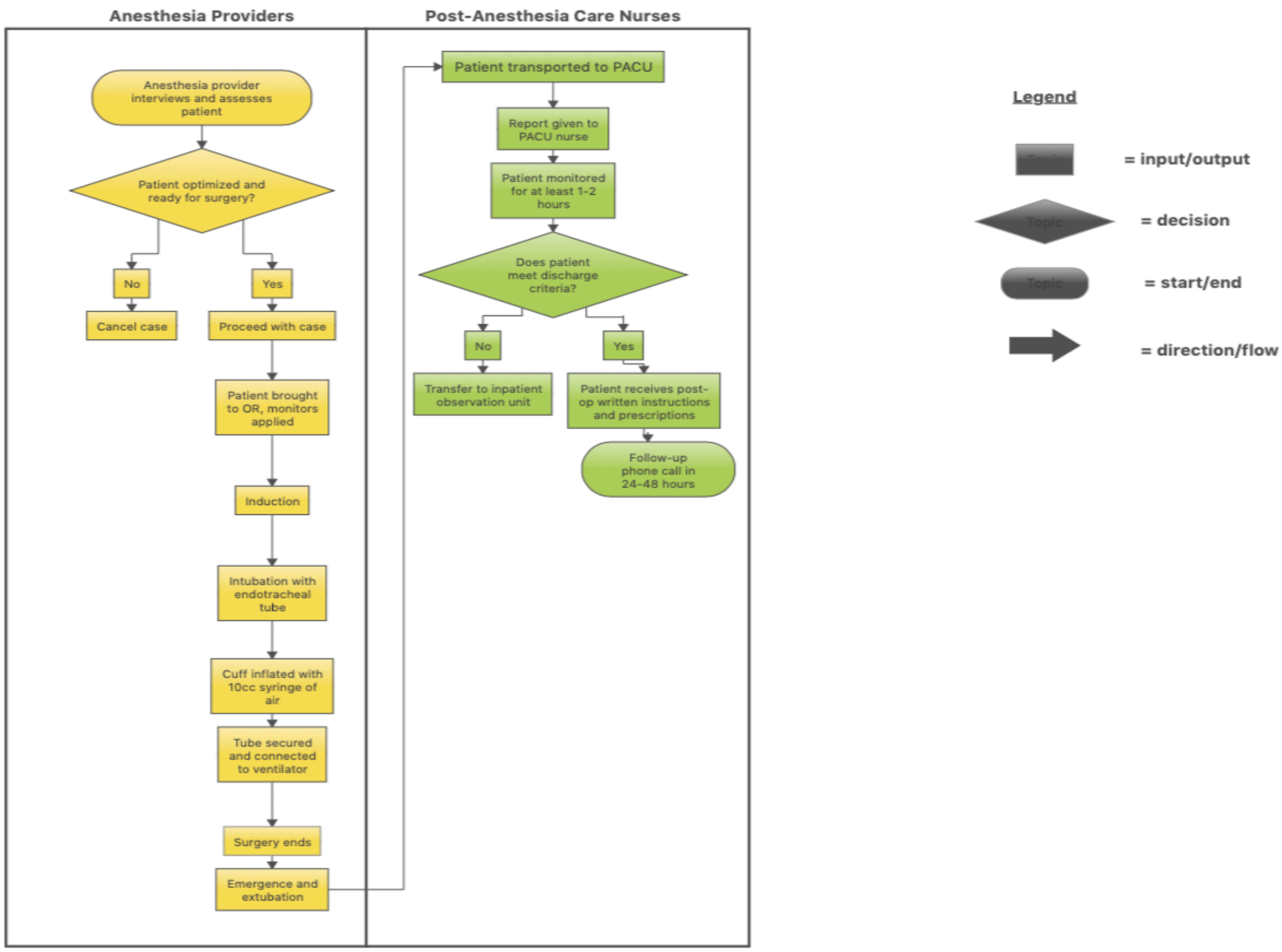
Figure 5

Incidence of Patients Denying Postoperative Sore Throat in Post-Anesthesia Care Unit Run Chart



Appendix A

Flow Map of Current Process



Appendix B

Education Session Sign-In Sheets

Date: _______________

# of Attendees	Print Name	Signature
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		

Figure B1. Anesthesia Providers Sign-In Sheet for Endotracheal Tube Cuff Pressures and Manometers Education

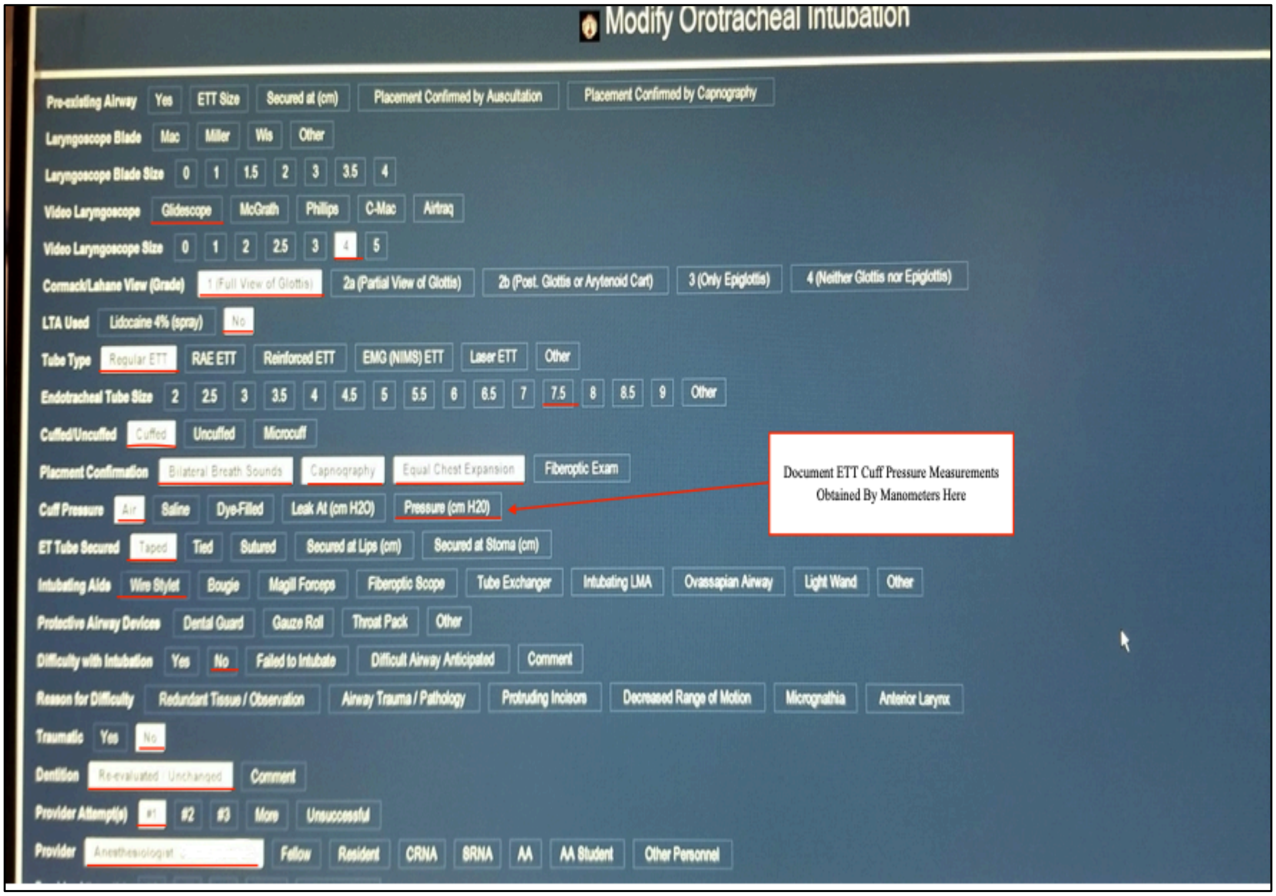
Date: _______________

# of Attendees	Print Name	Signature
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		

Figure B2. Perioperative Nursing Staff Sign-In Sheet for Postoperative Sore Throat Education

Appendix C

Documentation for Anesthesia Providers



Appendix C. Intraoperative Endotracheal Tube Cuff Pressure Measurements in Cerner

Appendix D

Documentation for PACU Nurses

THIS PATIENT HAD HIS/HER ETT CUFF PRESSURE MEASURED WITH A MANOMETER.

Place Label Here

OR: ______

☐ Main OR
☐ Ambulatory Surgery Center

Date: ___________________

Intraoperative Cuff Pressure = _________ cm H_2O

Presence of postoperative sore throat? *(please circle one)* Yes or No

Appendix D. Postoperative Sore Throat Incidence Form

Appendix E

Clinical Visual Aids

UNSAFE PRESSURES = <20 or >30 cm H_2O

MEASURE
Cuff pressures **ONCE** after intubation

DOCUMENT
in Surginet and POST Paper Form

SAFE PRESSURES = 20-25 cm H_2O

REMEMBER THE STOPLIGHT FOR ETT CUFF PRESSURES!

Figure E1. Stoplight Image for Endotracheal Tube Cuff Pressure Ranges

Steps:

1) Always check manometer prior to use
   a. Close connection piece with finger
   b. Inflate to 120 cm H_2O to ensure pressure holds for 2-3 seconds
   c. If manometer doesn't hold pressure, do not use it
2) After placing patient on ventilator, connect Posey Cufflator to pilot balloon via Luer connector
3) Document the cuff pressure displayed
4) For adjustments
   a. Inflate cuff to 60-90 cm H_2O
   b. Immediately release air by pressing red release button until lowest safe pressure level is reached
   c. **Optimal ETT intracuff** pressures**: 20-25 cm H_2O**

Figure E2. Manometer Technique Quick-Step Guide

Appendix F

Operating Room Checklist

Operating Room: _____

IS ROOM STOCKED WITH…

☐ A Manometer?

☐ Clinical aids?

- Posey Manometer quick-step guide
- Stoplight image reflecting safe range for endotracheal tube cuff pressures and frequency of measurements

☐ POST Incidence tracking forms?

Appendix G

Supplemental Handout

Post-Operative Sore Throat (POST)	
	
Incidence	Affects up to 50% adults undergoing elective surgery
Causes	Swelling and trauma of laryngopharyngeal tissues related to intubation, orogastric or nasogastric tube placement, and/or aggressive suctioning
Risk Factors	○ Airway devices (LMAs, ETTs) ○ ETT size, design and **intracuff pressures (>30 cm H_2O)** ○ Duration of anesthesia ○ Surgical position ○ Gender (Female) ○ Age ○ Concurrent use of nasogastric or orogastric tubes ○ Intubation technique and multiple attempts ○ Aggressive suctioning
Symptoms	○ Hoarseness to Aphonia ○ Throat Pain ○ Difficulty Swallowing ○ Cough
Duration	24-72 hours post-op
Treatment	Vocal rest, IV Fluids, Lozenges, NSAIDs

Appendix G. Postoperative Sore Throat Reference Guide

Appendix H

Chart Audit Form for Anesthesia Provider and PACU Nurse Compliance

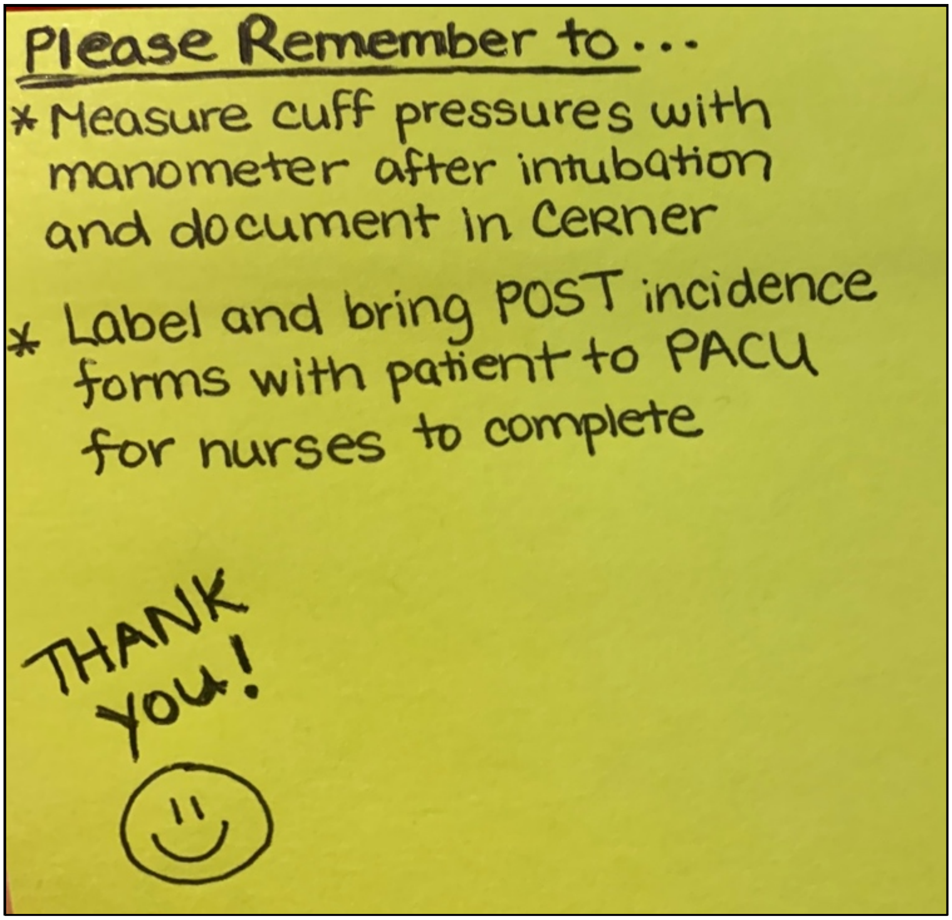
	De-Identified Patient	**Scheduled for general endotracheal anesthesia?**	**Manometer used to measure ETT cuff pressures?** ***If not, feedback will be provided**	**Cuff pressure (cm H_2O)**	**Cuff pressure within safe and optimal range? (20-30 cm H_2O)** ***If not, provide indication for cuff pressure out of range (>30 cm H_2O)**	**Anesthesia Provider compliant with documentation?**	**Presence of POST?**	**PACU RN compliant with documentation?**
Week 1								

Note: Coding Key for Patient De-identification

Patient Code	**Medical Record Number**
001	
002	

Appendix I

Post-It Note Reminder on Operating Room Computers



Appendix J

Weekly Email Template to Stakeholders

Good morning.
Here is an update with the data I collected from week #___.

- This past week, the total number of patients that received ETTs was ____.
- The number of ETTs in rooms with manometers was ____.
- ___ out of ___ patients with ETTs (%) had cuff pressures measured with manometers
- __ out of __ patients (%) had cuff pressures that fell within the safe range (20-25 cm H2O)
- __ out of __ patients (%) reported POST while in the PACU

I'd like to give shoutouts to the following anesthesia providers with the highest compliance rates: _________.

As a reminder, our project's goals are:

- 100% anesthesia provider compliance to measuring intraoperative endotracheal tube cuff pressures with manometers and documenting
- 100% endotracheal tube cuff pressures within the safe range (20-25 cm H2O)
- 100% of patients denying POST while in PACU

Thank you.