UNDERSTANDING ANESTHESIA PROVIDERS' KNOWLEDGE AND PRACTICE OF LUNG-PROTECTIVE POSITIVE END-EXPIRATORY PRESSURE IN OBESE PATIENTS UNDERGOING LAPAROSCOPIC SURGERY

by

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ABSTRACT

CAMERON MCCLANE. Understanding Anesthesia Providers' Knowledge and Practice of Lung-Protective Positive End-Expiratory Pressure in Obese Patients Undergoing Laparoscopic Surgery (Under the Direction of DR. STEPHANIE WOODS)

Problem Statement: Obese adults having laparoscopic surgery are at increased risk for postoperative pulmonary complications (PPCs) due to the alteration in pulmonary physiology caused by their body habitus, the use of Trendelenburg position, and the abdominal insufflation required for this surgical approach. Current literature recommends utilizing lung-protective ventilation (LPV) strategies to reduce the incidence of PPCs, but anesthesia provider implementation of LPV strategies is inconsistent. The purpose of this quality improvement project was to explore anesthesia providers' knowledge and utilization of lung-protective positive end-expiratory pressure (PEEP) strategies in obese patients undergoing laparoscopic surgery.

Methods: The project's descriptive design aimed to investigate anesthesia providers' knowledge and use of LPV PEEP strategies in obese patients (BMI > $30 kg/m^2$) undergoing laparoscopic surgery via an anonymous, quantitative electronic survey consisting of 24 Likert-scale questions. A convenience sampling of certified registered nurse anesthetists (CRNAs) and anesthesiologists (MDAs) was used. The survey was disseminated via e-mail and available by QR code. Data was stratified by role/education, age and years of experience to evaluate for trends.

Results: Fifty-two providers completed the survey. There were significant differences in likelihood to incorporate LPV PEEP strategies across groups.

Conclusions: Anesthesia provider utilization of LPV PEEP strategies was found to be inconsistent. Education regarding utilization of evidence-based LPV PEEP strategies in obese patients undergoing laparoscopic surgery is warranted.

Keywords: postoperative pulmonary complications, lung-protective ventilation, positive end-expiratory pressure

DEDICATION

This project is dedicated to all of the people who believed in me even when I did not believe in myself. To my husband- your love and support day in and day out the past 3 years means more than words could ever express. To my parents- thank you for encouraging me to challenge myself and to continue my educational journey even when it was tough. To my classmates- there is no other group of people I would have rather gone through these challenging years with. To my dog- thank you for your unconditional love on the best days and on the worst. Thank you for reminding me to smile and play. Most importantly, thank you to God for His provision and protection each and every day of this journey. May this project help us better care for one another.

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LIST OF ABBREVIATIONS

ACT	anesthesia care team
ANOVA	analysis of variance
ARDS	acute respiratory distress syndrome
ARM	alveolar recruitment maneuver
BMI	body mass index
CRNA	Certified Registered Nurse Anesthetist
ΔP	driving pressure
FiO_2	fraction of inspired oxygen
FRC	functional residual capacity
IRB	Institutional Review Board
LPV	lung-protective ventilation
MDA	physician anesthesiologist
PACU	post-anesthesia care unit
PaO2	partial arterial oxygen tension
PDSA	plan-do-study-act
PEEP	positive end-expiratory pressure
PFT	pulmonary function test
PPCs	postoperative pulmonary complications
RCT	randomized controlled trial
V-Q	ventilation-perfusion

SECTION I: INTRODUCTION

Background

The delivery of general anesthesia alters normal respiratory physiology. This is compounded by the respiratory alterations induced by both laparoscopic surgery and obesity, defined as a body mass index (BMI) greater than or equal to 30 kg/m^2. Anesthesia providers deliver mechanical ventilation to patients during surgery in hopes of maintaining respiratory homeostasis despite all of these alterations. The way in which this ventilation is delivered affects patient outcomes. The term “postoperative pulmonary complications” (PPCs) refers to a number of complications negatively affecting the respiratory system following surgery, such as atelectasis, pneumothorax, aspiration pneumonitis, pneumonia, pulmonary edema, exacerbation of pre-existing lung disease and many others (Miskovic & Lumb, 2017). PPCs can be caused by ventilator-induced lung injury, the mechanisms of which include barotrauma, volutrauma, and atelectrauma. Barotrauma results from excessive pressure, volutrauma results from excessive volume, and atelectrauma results from shear stress induced by cyclic recruitment and derecruitment of alveoli (Tsumara et al., 2017). The reported incidence of PPCs varies greatly, likely due to varied definitions. According to Miskovic and Lumb (2017), “incidence of PPCs in major surgery ranges from <1 to 23%” (p. 319). In their article referencing multiple studies, Tsumara et al., (2021) reported an incidence of PPCs of between 2-70%. PPCs increase morbidity, mortality and healthcare costs. Lung-protective ventilation (LPV) strategies are a proven method to reduce PPC incidence. More specifically, LPV “minimizes damage to pulmonary epithelial and vascular endothelial cells and their associated connective tissue” (Nieman et al., 2017, p. 1517). Evidence continues to grow in support of LPV strategies which include application of optimal PEEP among other strategies.

Use of optimal PEEP increases end-expiratory lung volumes by reducing small airway closure and atelectasis, which makes it an essential component of LPV. Optimal PEEP is particularly useful in obese patients undergoing laparoscopic surgery because these patients are at increased risk for atelectasis and reduced lung capacities, which both increase risk of PPCs. The PICO question "what are anesthesia providers' knowledge and utilization of lung-protective PEEP recommendations in obese (BMI>30) patients aged 18 and older undergoing laparoscopic surgeries?" seeks to explore barriers to the consistent use of one LPV strategy- the use of PEEP intraoperatively.

Purpose

The purpose of this quality improvement project was to understand anesthesia providers' knowledge and utilization of LPV strategies, specifically PEEP, in obese patients undergoing laparoscopic surgery.

Problem Statement

Anesthesia providers care for a variety of patient populations in many practice areas. The risk for PPCs varies among patient population and type of surgery. Having a BMI of 30 kg/m^2 or above poses increased risk for PPCs. Obesity reduces pulmonary compliance and increases airway resistance, leading to reduced lung capacities (Dixon & Peters, 2018). Atkinson et al. (2017) stated, "given the obesity pandemic, the number of laparoscopic bariatric surgeries has increased. Obesity is associated with respiratory comorbidities including restrictive lung disease, obstructive sleep apnea, and obesity hypoventilation syndrome"(p. 707). In fact, induction of general anesthesia in the obese patient reduces functional residual capacity (FRC) up to 50% compared with approximately 20% in the non-obese patient (Tsumura et al., 2021). This reduced FRC equates to a smaller oxygen reserve. Additionally, obesity increases the required work of breathing which subsequently increases myocardial oxygen consumption (Nagelhout & Elisha, 2018, p. 1001).

Intraoperative positioning is also an important risk factor for developing PPCs. Specifically, laparoscopic surgeries that require use of the Trendelenburg position shift abdominal contents cephalad, reducing pulmonary compliance and increasing peak airway pressures. The abdominal insufflation used for a laparoscopic approach further displaces the diaphragm cephalad and leads to even higher airway pressures, increased ventilation-perfusion (V-Q) mismatches, and further reduces pulmonary compliance (Atkinson et al., 2017). This laparoscopic approach has become increasingly common for abdominal and gynecologic procedures, making the risk for PPCs higher and the need for LPV greater. Because the obese patient undergoing laparoscopic surgery is highly vulnerable to PPCs, they have much to gain from diligent use of LPV.

LPV, initially shown to improve outcomes in acute respiratory distress syndrome (ARDS), "minimizes damage to pulmonary epithelial and vascular endothelial cells and their associated connective tissue" (Nieman et al., 2017, p. 1517). LPV strategies include low tidal volumes, optimal positive end-expiratory pressures (PEEPs), optimal inspiratory time, alveolar recruitment maneuvers (ARMs), and lowest possible fraction of inspired oxygen (FiO_2). Despite growing evidence, anesthesia providers do not consistently utilize LPV strategies. In one study, only 50% of surveyed providers used the recommended tidal volumes of 6-8 mL/kg and only 22.3% used optimal PEEP (Tretheway, et al., 2021). LPV strategies, including optimal PEEP, are important for reducing the occurrence of atelectasis, ventilator-induced lung injury and subsequent PPCs. The objective of this scholarly project was to understand anesthesia providers' knowledge and current use of PEEP as a LPV strategy in obese patients (BMI ≥ 30 kg/m2) undergoing laparoscopic procedures.

Clinical Question

What are anesthesia providers' knowledge and utilization of lung-protective PEEP recommendations in obese (BMI>30) patients aged 18 and older undergoing laparoscopic surgery?

SECTION II: LITERATURE REVIEW

Positive End-Expiratory Pressure (PEEP)

Atelectasis During Anesthesia. The goal of mechanical ventilation during anesthesia is to maintain sufficient oxygenation and ventilation despite the pulmonary changes induced by anesthetic agents and surgical factors. In order to achieve this strategies must be employed to limit atelectasis, as the shunting of pulmonary blood flow can lead to hypoxia and other dangerous sequelae. Use of PEEP in mechanically ventilated patients under anesthesia has been shown to be beneficial through its reduction of atelectasis and the resulting shunting of pulmonary blood flow.

Atelectasis is the de-recruitment of alveoli, meaning they are functionally unavailable to participate in gas exchange. This leads to reduced pulmonary compliance, meaning higher pressures are required to recruit these alveoli. The pressure that must be generated with each respiration to overcome the decreased respiratory elasticity and produce the desired tidal volume is referred to as the driving pressure (ΔP). The cyclic recruitment and derecruitment of alveoli during mechanical ventilation that occurs when ΔPs are elevated is an important risk factor for acute lung injury and increased PPCs (Young et al., 2019). Several retrospective studies suggest that ΔP impacts the occurrence of pulmonary complications more than any other ventilatory parameter (Park et al., 2019).

PEEP and Postoperative Pulmonary Complications. Driving pressure is the ventilator plateau pressure (the pressure at end-inspiration) minus the PEEP. Therefore, PEEP can often be manipulated to reduce ventilator ΔPs by preventing the de-recruitment of alveoli. Because PEEP can be used to reduce ΔP, optimizing PEEP therefore reduces the risk of PPCs by "improving perioperative oxygenation and respiratory mechanics, and reducing oxidative stress, inflammatory response, and lung injury" (Young et al., 2019). In one randomized controlled trial

(RCT), 24 healthy patients receiving general anesthesia were delivered a PEEP of 0, 7 or 9 cmH_2O. The group that received PEEP of 7 or 9 cmH_2O demonstrated reduced atelectasis at the end of surgery compared to the group who received zero PEEP (Ostberg et al., 2018).

Optimal PEEP Levels. The optimal level of PEEP should prevent cyclic de-recruitment and avoid overdistension of alveoli. Optimal PEEP is that which produces the lowest ventilator ΔP while maintaining the desired tidal volumes. The optimal level of PEEP varies greatly based on patient and surgical factors. In order to maintain an optimal PEEP level during times when lung compliance varies, such as during abdominal insufflation or Trendelenburg positioning, titration is required (Young et al., 2019). A meta-analysis that included eight studies with a total of 849 patients found that an individualized PEEP reduced the occurrence of PPCs more so than a fixed PEEP during one lung ventilation (Ostberg et al., 2021).

Illustrating the important concept that optimal PEEP levels vary, a study by Simon et al. (2021) demonstrated that the optimized PEEP levels in obese patients (BMI >/= 35 kg/m2) undergoing laparoscopic abdominal surgery ranged from 10-26 cmH_2O with a median level of 18cmH_2O. When using the optimal individualized PEEP level, as compared to a standard PEEP level of 5 cmH_2O, better oxygenation resulted as well as lower ΔPs which may reduce occurrences of PPCs.

In a double-blind RCT 292 patients undergoing one lung ventilation received either conventional protective ventilation with a standard PEEP level or ventilation with individualized PEEP selected based on the lowest possible ΔP. The primary outcome explored in this study was the occurrence of PPCs during the first 3 postoperative days. Over twelve percent of patients in the conventional protective ventilation group experienced PPCs while approximately five percent of patients in the individualized PEEP group experienced PPCs (Park et al., 2019).

As the evidence demonstrates, the optimal level of PEEP should be determined based on unique patient and surgical factors. Determination of the optimal level of PEEP may require titration anytime patient or surgical factors change. Use of optimal PEEP improves oxygenation, lowers ΔP and reduces PPCs.

Use of PEEP in Laparoscopic Procedures and Obesity. Laparoscopic procedures include intra-abdominal insufflation of gas (most commonly carbon dioxide) which reduces pulmonary compliance and increases pulmonary blood flow shunting. Optimal PEEP utilization is crucial in this context in order to counteract the effects of increased intra-abdominal pressures on the lungs and prevent the de-recruitment of alveoli. A RCT of 75 patients undergoing laparoscopic cholecystectomies demonstrated that a PEEP of 8 cmH_2O, compared with a PEEP of 0 cmH_2O or 5 cmH_2O, led to increased pulmonary compliance during surgery and better pulmonary function tests (PFTs) postoperatively (Arinalp et al., 2016).

The benefits of PEEP are greatest when the level is individualized to the patient and the surgical circumstances. In a RCT of 51 elderly patients undergoing laparoscopic procedures, one group was delivered dynamic, individualized PEEP levels that were titrated hourly to those which produced the lowest ΔP while still preserving the desired tidal volume. The other two groups were delivered either constant PEEP of 6 cmH_2O or zero PEEP. The postoperative atelectasis on ultrasound at the end of surgery and 15 minutes into their post-anesthesia care unit (PACU) admission was compared between groups. The group that received dynamic, individualized PEEP levels titrated to the lowest ΔP and highest static lung compliance level demonstrated significantly lower levels of atelectasis postoperatively (Xu et al., 2009).

The benefits of optimal PEEP are likely even greater in obese patients, particularly those undergoing laparoscopic surgery. This is demonstrated by a RCT of 66 obese patients (BMI 30-50 kg/m2) that revealed improved postoperative oxygenation, reduced postoperative atelectasis and fewer PPCs in those that received PEEP of 10 cmH_2O in comparison to those that received PEEP of 0 cmH_2O or 5 cmH_2O (Talab et al., 2009). Further emphasizing the benefit of individualized PEEP, a RCT of 40 adults with BMIs > 35 kg/m^2 undergoing laparoscopic bariatric surgery compared application of a standard PEEP of 4 cmH_2O with an individualized stepwise PEEP titration based on lung ultrasound. Partial arterial oxygen tension (PaO2) was higher both intraoperatively and postoperatively in the individualized PEEP group. Additionally, this group also had no PPCs whereas the control group (standard PEEP of 4 cmH_2O) experienced 5 PPC occurrences in the first 24 hours (Elshazly et al., 2021).

The use of an appropriate level of PEEP is an important consideration during mechanical ventilation for general anesthesia as it improves intraoperative oxygenation and ventilation in addition to reducing the occurrence of PPCs. The importance of PEEP is even greater in obese patients, those undergoing laparoscopic surgery, or both. This is because the application of PEEP counteracts the reduced lung capacities caused by obesity as well as the surgical environment typically required for a laparoscopic approach, including Trendelenburg positioning and insufflation of gas into the abdomen. This reduces the level of V-Q mismatching and thus less hypoxia and hypercarbia.

Summary of Findings

The literature demonstrates a clear benefit in mechanically ventilated patients undergoing general anesthesia who receive application of optimal PEEP. Obese patients undergoing laparoscopic surgery encounter multiple risk factors that predispose them to PPCs. Patients who receive optimal PEEP have a reliably lower incidence of PPCs than those who do not.

Although the evidence supporting the use of optimal PEEP as an LPV strategy is abundant, utilization varies among anesthesia providers. Studies have shown that anesthesia providers' utilization of lung protective strategies is insufficient, especially in the obese population (Tretheway, et al., 2021). It is recommended that anesthesia providers consistently implement LPV strategies to mitigate PPCs, facilitate optimal respiratory mechanics, and reduce morbidity and mortality, especially in the obese population undergoing laparoscopic surgery.

Conceptual Framework

This quality improvement project's framework followed the Plan-Do-Study-Act (PDSA) method. For this project, the "plan" was to complete an in-depth review of the literature surrounding the identified clinical problem and PEEP as a LPV strategy. A validated survey was created to assess current knowledge and practice habits regarding the use of PEEP as a LPV strategy among anesthesia providers. The survey was distributed to the identified anesthesia providers, making up the "do" component of this method.

The "study" component included analyzing survey responses and identifying trends surrounding the knowledge and use of PEEP as a LPV strategy amongst those who completed the survey. Areas for improvement were identified by comparing survey responses with evidence-based practice guidelines. The "act" component was completed via presentation of the survey findings and discussion of the identified areas where responses deviated from practice recommendations in the evidence.

SECTION III: METHODOLOGY

Project Design

This quality improvement project's methodology utilized a descriptive design. The project aimed to investigate anesthesia providers' knowledge and use of lung protective ventilation (LPV) strategies in obese patients (BMI > 30kg/m^2) via a survey. Relationships between variables were not addressed, and participants were not assigned to groups. This quality improvement project occurred as part of a larger quality improvement project containing three distinct components: PEEP as a LPV strategy, ARMs as a LPV strategy (Paluba, 2023), and tidal volume delivery as a LPV strategy (McConnell, 2023).

Sample

The population for this quality improvement project consisted of certified registered nurse anesthetists (CRNAs) and physician anesthesiologists (MDAs) at the designated facility. At the time of survey dissemination, there were 259 CRNAs and 62 MDAs practicing at the designated facility. The survey was sent to all of them. The sample was chosen by convenience. Exclusion criteria was not being a CRNA or MDA or not working at this facility.

CRNAs have completed their undergraduate studies with a Bachelor of Science in Nursing, which is then followed by at least one year of critical care/intensive care unit experience prior to entering a nurse anesthesia program. CRNAs have acquired a doctoral or master's degree in nurse anesthesia practice. MDAs have completed four years of medical school, four years of residency, and possibly one to two years of specialized fellowship training.

The operating rooms at this large urban trauma center function in a team approach following the Anesthesia Care Team (ACT) model. In the ACT Model, MDAs are responsible for up to four simultaneously functioning operating rooms with care managed by CRNAs, who are present throughout the entire anesthetic. The MDAs, who are present on the induction and emergence of anesthesia, may also perform specialized skills including insertion of central venous catheters and performance of regional anesthesia for multimodal analgesia. The MDAs visit the patient prior to the surgery to perform and document a thorough preoperative assessment. The CRNAs are responsible for one patient per case, allowing them to provide vigilant care and safe passage for patients undergoing anesthesia. The CRNAs also perform a preoperative assessment and tailor a patient-specific anesthetic plan in collaboration with the MDA and surgeon.

Setting

This quality improvement project took place at a large urban teaching hospital. This institution serves as the city's only Level 1 trauma center and transplant center for heart, kidney, liver, and pancreas transplants. The hospital has 874 beds and provides residency training to more than 200 physicians in 15 specialties. This facility is equipped to serve many medically complex patients. There are 45 operating rooms at this facility, not including obstetric operating rooms and procedural areas. Approximately 150 to 200 surgical cases are performed each day. Around 60 to 70 CRNAs are staffed each day, along with about 15 to 20 MDAs.

Data Collection

The method of data collection was a quantitative electronic survey (Appendix A) sent to anesthesia providers (CRNAs and MDAs) practicing at the previously described facility. The survey was conducted via the SurveyMonkey platform. It was delivered to anesthesia providers via their hospital email addresses as well as made available via QR code. QR codes were placed in break rooms and work rooms. Participants were able to complete the survey on their mobile devices. The survey consisted of 24 Likert scale questions that aimed to elicit anesthesia providers' knowledge and utilization of evidence-based recommendations for LPV strategies. Eight of the 24 questions were specific to PEEP as a LPV strategy. Survey questions along with the selected Likert scale were reviewed by CRNA faculty and clinical experts prior to dissemination to establish reliability and validity. Responses were anonymous with only basic demographic data collected, including age, professional title, location of practice, educational background, and years of experience in anesthesia. Survey participants indicated the range that their age and years of experience fell into in order to avoid jeopardizing confidentiality in any way. Taking into consideration the survey fidelity and design of the study, the project addressed possible setbacks and challenges in implementation at the outset in order to ensure consistency throughout the study’s course (Bellg et al., 2004, pg 446). The project’s intent was to understand anesthesia providers’ knowledge and use of PEEP as a LPV strategy in obese patients undergoing laparoscopic surgery.

Timeline

The project proposal was defended on April 18th, 2023. Institutional Review Boards (IRB) approval from the Wake Forest School of Medicine and University of North Carolina at Charlotte were obtained the Summer of 2023. The survey was disseminated and data collection began on August 1st, 2023. A reminder e-mail was sent week 2 and week 3. The survey concluded on August 28th, 2023 meaning it remained open for approximately 4 weeks. There were 52 total responses and each survey was completed entirely without any missing data. Data analysis and final results including discussions, limitations, implications and recommendations were completed by the beginning of November 2023. Project defense occurred December 1st, 2023. Dissemination of project findings continued through spring of 2024.

Needed Support/ Challenges

Because the project's data collection occurred in the form of a survey, success relied upon the participation of CRNAs and MDAs at the clinical site. The project team worked to gain buy-in from anesthesia department leaders and staff by maintaining an open-line of communication with them regarding the purpose and needs of the project. Support from anesthesia department leaders was heavily relied upon. Permission was gained to advertise the survey in anesthesia break rooms and operating rooms in order to promote participation. Finally the survey was made accessible via both cell phone and computer. Computers in anesthesia break rooms and operating rooms were another valuable resource in encouraging survey participation.

There were many challenges that threatened survey participation. One is the pace of the operating room and the brevity of breaks taken by anesthesia providers. There is often little down-time between cases, and providers are under pressure to get back to work quickly. It is also impossible to know where providers take their breaks. To address these challenges, the project team promoted the survey in the most common break areas and in the operating rooms. The survey was kept brief and simple. Another challenge that the project team continually assessed for was the possibility of technical issues with the electronic survey, though no issue was ever found or reported.

Data Analysis and Evaluation

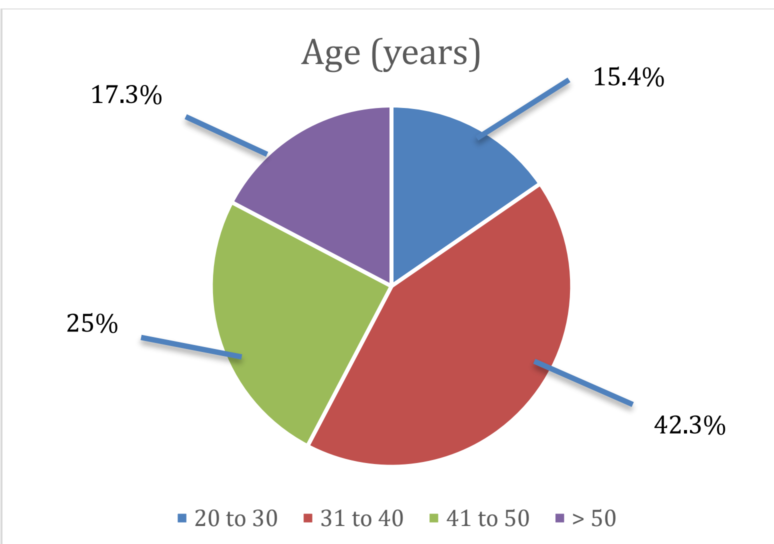
Basic data analysis was performed via the SurveyMonkey platform. The results were also exported to Microsoft Excel for more advanced analysis, including calculation of the mean response to each survey item. The SurveyMonkey responses and Microsoft Excel data was password-protected and only accessible to the project committee. The results were analyzed to assess trends in anesthesia providers' knowledge and use of PEEP as a LPV strategy and how these responses compare to evidence-based recommendations. Data was stratified for each subgroup, allowing for evaluation of patterns in clinical practice and schools of thought by demographic data. The groups' responses were compared using analysis of variance (ANOVA).

By using Likert scale style questions, data could be distorted by multiple types of respondent bias. Central tendency bias, which describes the idea that people have a tendency to rate items toward the middle of the scale, may have affected survey results. Acquiescence bias, which describes the idea that people tend to agree with provided statements whether or not it truly reflects their own actions or views, could also have affected survey results. A third type of bias that may have affected survey results is social desirability bias, describing the idea that people wish to portray themselves or their affiliations in a positive light (*Analyzing Likert Scale/Type Data*, 2013). In an effort to combat potential bias, survey items were written as neutrally as possible to avoid leading the participant to the correct response. Additionally, survey items did not reveal information that would influence answers to the following questions. The investigator monitored survey item response rates for trends of bias.

SECTION IV: PROJECT FINDINGS

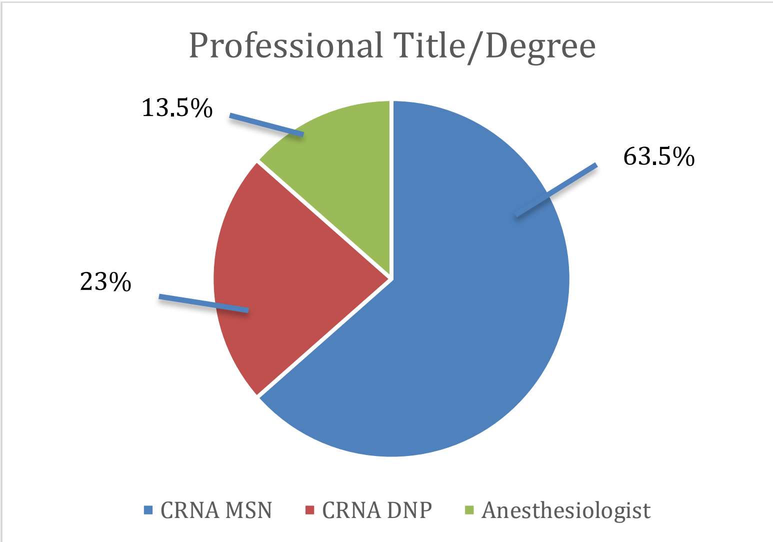
Sample Characteristics

Fifty-two anesthesia providers completed the survey out of the total 321 anesthesia providers to which it was sent. This yielded a response rate of approximately 16%. Figure 1 displays the age distribution of survey participants. The most frequent age of participants was between 31-40 years. Figure 2 displays the frequency of professional title/degree distribution of survey participants and shows that the majority of the participants were CRNA MSN. Figure 3 displays the frequency distribution of the years of experience of survey participants. The majority of the participants had 6 to 10 years' experience.



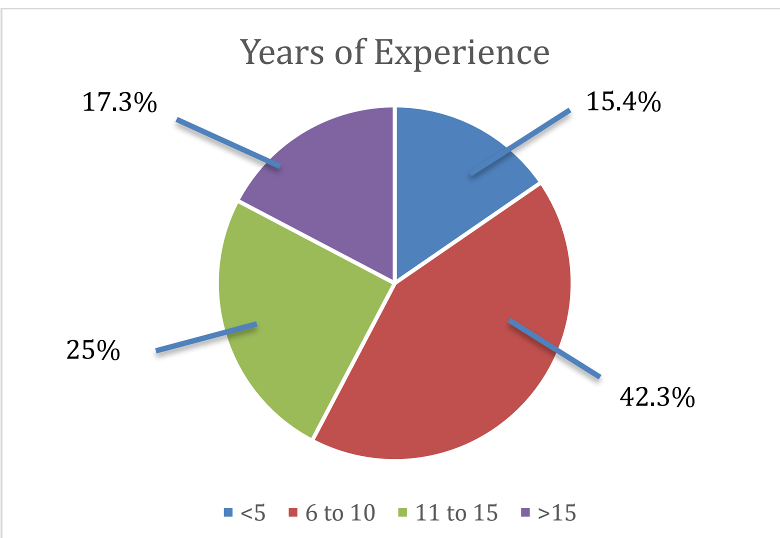
Age (years)	Survey Responses
20-30	8
31-40	22
41-50	13
>50	9

Figure 1: Ages of Survey Participants (in years)



Title/Degree	Survey Responses
Anesthesiologist	7
CRNA DNP	12
CRNA MSN	33

Figure 2: Professional Title/Degree of Survey Participants



Experience (years)	Survey Responses
< 5	8
6-10	22
11-15	13
>15	9

Figure 3: Years of Experience of Survey Participants

Survey Results

Table 1: Lung Protective Ventilation Survey… Positive End-Expiratory Pressure (PEEP) Results

Survey Item	LPV-Compliant Answer	Average Likert-Scale Score M(df)
How likely are you to set PEEP between **5-9 cmH2O** for most obese adult patients undergoing laparoscopic surgery? **	0	3.94 (1.47)
During any part of the procedure, how likely are you to increase PEEP to **10 cmH2O or above** in an obese patient undergoing laparoscopic surgery?	5	2.77 (1.49)
How likely are you to keep PEEP the same throughout a case so long as the patient is oxygenating and ventilating adequately? **	0	3.73 (0.91)
How likely are you to routinely increase PEEP upon abdominal insufflation in an obese patient?	5	2.71 (1.29)
How likely are you to routinely increase PEEP upon placing an obese patient in the Trendelenburg position?	5	3.04 (1.33)
How likely are you to <u>increase</u> PEEP if you notice elevated plateau pressures in an obese patient undergoing laparoscopic surgery?	5	2.38 (1.16)
How likely are you to titrate PEEP based on driving pressure (plateau pressure minus PEEP) throughout laparoscopic surgery on an obese adult?	5	2.83 (1.23)
After insufflation and Trendelenburg positioning have been achieved, how likely are you to titrate PEEP at regular time intervals throughout the maintenance phase of the case?	5	2.33 (1.02)
How likely are you to incorporate lung protective ventilation strategies as part of your anesthetic plan in obese patients?	5	4.21 (0.91)

*standard deviation in parenthesis
**reverse-scored survey item: lower score indicates higher compliance with LPV strategies

Item 1 of the survey inquired about the likelihood of a provider to set PEEP between 5-9 cmH20 for most obese adults undergoing laparoscopic surgery. The overall likelihood was scored a 3.94 on the Likert scale indicating an approximate average response of “very likely.” However, this item was reverse scored meaning that a higher score indicates lower compliance with the literature’s recommendations. The literature indicates that optimal PEEP levels for obese adults undergoing laparoscopic surgery are very often significantly higher than those presented in this survey item (Talab et al., 2009). Simon et al., (2021) found that the average range of optimal PEEP in a study of obese patients undergoing laparoscopic surgery was 10-26 cmH_2O. PEEP should be individualized to each and every patient.

Item 2 inquired about the likelihood of a provider to increase PEEP above 10 cmH20 during any part of a laparoscopic procedure for an obese adult. The overall likelihood was scored a 2.77 on the Likert scale indicating an approximate average response of “likely.” This indicates some level of compliance with the lung-protective recommendation of increasing PEEP based on BMI along with surgical factors like Trendelenburg positioning and abdominal insufflation, often requiring a PEEP > 10 cmH20 in order to be considered optimal (Talab et al., 2009).

Item 3 surveys the likelihood of a provider to keep PEEP the same throughout a case if the patient is oxygenating and ventilating adequately. The overall likelihood was scored a 3.73 on the Likert scale indicating an approximate average response of “very likely.” This survey item was reversed scored meaning that a higher score indicates a lower compliance with the literature’s recommendation. The response to this item reveals the unlikelihood of providers to titrate the level of PEEP throughout the case in order to find the dynamic, optimal level which is highly recommended in the literature (Young et al., 2019; Xu et al., 2009). The optimal level of

PEEP that contributes to the reduction of PPCs is based on achieving the lowest possible ΔP and not simply adequate oxygenation and ventilation.

Item 4 surveys the likelihood of a provider to routinely increase PEEP upon abdominal insufflation in an obese patient. This is a highly recommended practice for LPV in effort to prevent the de-recruitment of alveoli that occurs due to increased abdominal pressures (Arinalp et al., 2016). The overall likelihood was scored a 2.71 on the Likert scale indicating an approximate average response of “likely.” This indicates moderate compliance with the recommendation.

Similar to item 4, item 5 surveys the likelihood of a provider to routinely increase PEEP upon Trendelenburg positioning in an obese patient, another LPV strategy recommended for maintaining pulmonary compliance and lung capacities (Arinalp et al., 2016). The overall likelihood was scored a 3.04 on the Likert scale indicating an approximate average response of “likely.” This indicates moderate compliance with the recommendation.

Item 6 surveys the likelihood of a provider to increase PEEP when plateau pressures become elevated in an obese patient undergoing laparoscopic surgery. This is a recommended LPV strategy in effort to decrease ΔP and thus reduce PPCs (Xu et al., 2009). The average response was a 2.38 on the Likert scale, indicating an approximate average response of “unlikely.” This indicates a level of non-compliance with the literature’s recommendation.

Item 7 asks about the likelihood of a provider to titrate PEEP based on ΔP throughout laparoscopic surgery on an obese adult. As previously noted, this is a key concept in LPV outlined in the literature as high ΔPs have been linked to greater incidences of PPCs (Park et al., 2019; Xu et al., 2009). PEEP titration has the ability to decrease ΔP in many cases. The average response was a 2.83 on the Likert scale, representing an approximate average response just below “likely.” This indicates moderate compliance with the recommendation, certainly presenting room for improvement with this key LPV strategy.

Item 8 asks about the provider’s likelihood to titrate PEEP at regular time intervals throughout the maintenance phase of the case. This item surveys providers’ likelihood of finding the optimal level of PEEP at different points in the case since it is a dynamic level, an important strategy for preventing PPCs (Xu et al., 2009; Young et al., 2019). The average response was a 2.33 on the Likert scale, indicating an approximate average response of “unlikely.” This indicates a level of non-compliance with the literature’s recommendation.

Finally, item 9 asks about the provider’s overall likelihood to incorporate LPV strategies as part of their anesthetic plan in obese patients undergoing laparoscopic surgery. The average response was a 4.21 on the Likert scale, indicating an approximate average response of “very likely.” Though this is a promising response as it indicates buy-in regarding the overall concept of LPV, survey results collectively reveal a lack of compliance with the recommended lung-protective PEEP strategies.

Appendices B, C and D show ANOVA results for role, years of experience, and age, respectively. ANOVA tests were performed to compare means between groups. There was a significant difference on overall likelihood to incorporate LPV strategies across roles, $F = 4.67$, $p = .014$. CRNA DNP respondents indicated that they were more likely to incorporate LPV strategies than CRNA MSN respondents did. There was a greater likelihood of CRNA DNP respondents over CRNA MSN ($p = .051$) respondents to titrate PEEP based on ΔP throughout laparoscopic surgery on an obese adult which is the LPV recommendation. The likelihood of respondents with 6-10 years of experience to keep PEEP the same if oxygenation and ventilation was adequate (not lung-protective) was nearing significance ($p = .061$) compared to those with greater than 15 years of experience who would be less likely to keep PEEP the same. The literature recommends regular titrations throughout the case in order to maintain an optimal level of PEEP. There were no significant differences in lung-protective PEEP strategies related to age of participant.

In summary, out of the 9 survey items, 7 were scored in a way that represents “less than likely” to be compliant with the literature’s recommendations for lung-protective PEEP strategies. Survey item 5 and survey item 9 responses were noted to be the most compliant, with item 5 being just slightly above “likely” to be compliant. Generally, respondents agreed that they would likely choose a level of PEEP that is often too low for the population at hand. They were likely to keep PEEP the same throughout the maintenance phase of the case rather than implementing regular titrations in order to find optimal PEEP. Importantly, they indicated being fairly unlikely to adjust PEEP based on plateau pressures and ΔPs, both of which make up the foundation of LPV PEEP strategies.

SECTION V: DISCUSSION

Implications for Practice

The survey results revealed significant implications for practice in regard to LPV strategies, specifically those related to PEEP. Survey participants indicated they were generally in favor of implementing LPV strategies in this patient population, particularly CRNA DNP participants. However, survey results reveal that education regarding how these lung-protective PEEP strategies should be implemented in this patient population is necessary. CRNA MSN respondents indicated that they were the least likely of the 3 job roles to implement LPV strategies. Because the CRNA DNP degree is newer than the CRNA MSN degree, CRNA MSN participants might have been out of school longer as a whole. This is likely to impact their perspective and knowledge on LPV strategies as it is a fairly recent practice change that continues to develop in recent literature.

PEEP is just one component of LPV. As explained by McConnell (2023), utilization of tidal volumes between 6-8 mL/kg of ideal body weight is an important method of preventing PPCs in the obese patient undergoing laparoscopic surgery. Another crucial element of LPV is utilization of ARMs as explained by Paluba (2023). ARMs work in tandem with PEEP in preventing atelectasis and its negative sequelae, particularly in the vulnerable population that this project explores. Though each component is uniquely important, they elicit the greatest benefit when used in conjunction with one another.

Strengths

The setting and sample of the surveyed population were both strengths of the project. The survey was disseminated to approximately 321 anesthesia providers from various backgrounds. The providers that completed the survey varied greatly in both age and years of experience.

Additionally, surveys were completed by anesthesia providers with various educational backgrounds and degrees. The surveyed facility frequently performs laparoscopic surgeries on obese adults, making the anesthesia providers intimately familiar with the population described in the survey.

The structure of the survey was advantageous, particularly the use of the Likert-scale for survey responses. This allowed for a range of provider perspectives to be captured through their responses. The survey was kept relatively brief at 24 questions in total, allowing it to be completed quickly during a provider's break or in between cases.

Another advantage was the accessibility of the survey and the multiple ways it was advertised to the anesthesia department. Survey dissemination occurred in various methods, including by e-mail using the hospital Listserv and by QR codes placed strategically throughout break rooms and operating rooms. The survey was easily accessible by both cell phone or computer and no account or log-in was required to take it. Multiple reminder e-mails were sent out and the survey remained open for several weeks. Prior to survey dissemination, the project team introduced the project and its importance at a facility meeting with all anesthesia providers. Lastly, the surveyed facility is one where the project directors regularly attend clinical rotations which allowed for verbal promotion of survey participation.

Limitations

An important limitation of the project is the relevance to other healthcare facilities or anesthesia groups. Use of lung-protective PEEP strategies in obese patients undergoing laparoscopic surgery is universally important. However, the knowledge and utilization of these strategies among anesthesia providers at other locations should be examined.

The usefulness of project findings are limited by the overall participation rate of approximately 16% , which was certainly lower than the initial participation goal. This limits the ability of the data to accurately represent the entire groups' practices and perspectives.

An important limitation of the project was that the survey relied on participants to honestly and accurately report their usual practices surrounding application of PEEP. Self-report presents an opportunity for some level of bias to occur.

Recommendations

There are several recommendations evident upon conclusion of this project. First, project findings along with education surrounding LPV strategies should be shared with anesthesia providers both at the facility where the project was conducted as well as at other facilities. Importantly, the surveyed facility currently lacks specific guidelines surrounding how to implement lung-protective PEEP strategies in this patient population. Along with education, providing guidelines to clinicians would likely improve compliance with LPV techniques. Guidelines should include recommended initial PEEP settings based on patient BMI, methods for determining the optimal PEEP level based on ΔP, and reminders about when to adjust PEEP throughout the procedure. These guidelines could also be made into a cognitive aid placed in operating rooms that commonly perform laparoscopic surgeries. An additional strategy that could be implemented in effort to improve clinician compliance with LPV strategies is adding reminders in the intraoperative electronic health record to be triggered when patient or surgical factors are met that call for manipulation of ventilator settings (i.e. increased BMI, laparoscopic procedures, Trendelenburg positioning, abdominal insufflation).

The project's survey did not differentiate between provider knowledge of proper use of LPV strategies and their likelihood to employ these strategies if they are aware. For example, a survey response that does not indicate proper compliance with LPV strategies does not clarify whether this is due to a knowledge gap or reluctance to employ the strategy for an alternative reason. Provider knowledge of LPV strategies versus their actual implementation of the recommended practices is an important distinction that the survey questions did not explore. A future project that differentiates between the two would be beneficial in its ability to provide more targeted education in hopes of increasing adherence to the literature's recommendations. Additionally, a project gathering objective data regarding PEEP utilization that does not rely on self-report would be beneficial for analyzing actual practice patterns.

As previously mentioned, this project occurred as part of a larger quality improvement project containing three distinct LPV components: PEEP, ARMs and tidal volume delivery. The project did not explore other important LPV components such as use of lowest possible FiO_2, which would be useful to examine in the future. Going forward, new evidence will continue to develop and practice patterns will continue to change. It will be important for future projects to evaluate the most effective ways of improving compliance with evidence-based practice.

Conclusion

The surveyed anesthesia providers reported a high likelihood of utilizing LPV strategies in obese patients undergoing laparoscopic surgery. However, responses to individual survey questions indicated an overall lack of compliance with lung-protective PEEP strategies. Findings varied based on education/job role and years of experience with no significant differences based on provider age. Nonetheless, compliance lacked across all demographic groups. Education of anesthesia providers regarding implementation of lung-protective PEEP strategies in obese patients undergoing laparoscopic surgery is indicated.

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APPENDIX A: LUNG PROTECTIVE VENTILATION SURVEY

1. How likely are you to set PEEP between **5-9 cmH2O** for most obese adult patients undergoing laparoscopic surgery?
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

2. Your patient presents for a roux-en-y procedure. He is male, **5 foot 9 inches (175 cm)** tall, and weighs **200 kg**. How likely would you be to use an initial tidal volume of **450 mL**?
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

3. Your obese patient presents for a laparoscopic total hysterectomy for uterine fibroids. Her **BMI is 37 kg/m**^{2}. How likely are you to administer a post-induction alveolar recruitment maneuver while still in the supine position?
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

4. During any part of the procedure, how likely are you to increase PEEP to **10 cmH2O or above** in an obese patient undergoing laparoscopic surgery?
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

5. How likely are you to use an initial tidal volume of greater than 8 mL/kg of ideal body weight/predicted body weight for an obese patient?
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

6. Your patient (**BMI 40 kg/m**^{2}) is about to undergo laparoscopic pelvic surgery. After being positioned into steep Trendelenberg their oxygen saturation is 99% with stable hemodynamics. How likely are you to administer a post-induction alveolar recruitment maneuver?
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

7. How likely are you to keep PEEP the same throughout a case so long as the patient is oxygenating and ventilating adequately?
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

8. Your patient presents for a roux-en-y procedure. He is male, **5 foot 9 inches (175 cm)** tall, and weighs **70 kg**. How likely would you be to use an initial tidal volume of **450 mL**:
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

9. Your patient (**BMI is 37 kg/m**^{2}) is undergoing a laparoscopic total hysterectomy for uterine fibroids. During the maintenance phase of anesthesia in this hemodynamically stable patient, how likely are you to administer an alveolar recruitment maneuver while in Trendelenberg?
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

10. How likely are you to routinely increase PEEP upon abdominal insufflation in an obese patient?
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

11. Your patient presents for a roux-en-y procedure. He is male, **5 foot 9 inches (175 cm)** tall, and weighs **70 kg**. How likely would you be to use an initial tidal volume of **700 mL**?
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

12. How likely are you to administer an alveolar recruitment maneuver every 30 minutes throughout the surgical procedure?
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

13. How likely are you to routinely increase PEEP upon placing an obese patient in the Trendelenburg position?
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

14. Your patient presents for a roux-en-y procedure. He is male, **5 foot 9 inches (175 cm)** tall, and weighs **200 kg**. How likely would you be to use an initial tidal volume of **700 mL**?
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

15. How likely are you to incorporate alveolar recruitment maneuvers as a routine part of your anesthetic plan?
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

16. How likely are you to increase PEEP if you notice elevated plateau pressures in an obese patient undergoing laparoscopic surgery?
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

17. I was taught in my anesthesia training to deliver tidal volumes of 6-8 mL/kg of ideal or predicted body weight.
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

18. How likely are you to administer an alveolar recruitment maneuver to your patient to improve oxygen saturation prior to adjusting the fraction of inspired oxygen (FiO_2)?
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

19. How likely are you to titrate PEEP based on driving pressure (plateau pressure minus PEEP) throughout laparoscopic surgery on an obese adult?
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

20. How likely are you to consider the BMI of the patient when setting tidal volume for general anesthesia?
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

21. How likely are you to administer an alveolar recruitment maneuver to decrease the driving pressure on your obese, hemodynamically stable patient in a steep Trendelenberg position undergoing laparoscopic surgery?
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

22. After insufflation and Trendelenburg positioning have been achieved, how likely are you to titrate PEEP at regular time intervals throughout the maintenance phase of the case?
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

23. Setting tidal volumes based on ideal body weight in obese patients may contribute to the development of atelectasis.
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

24. How likely are you to incorporate lung protective ventilation strategies as part of your anesthetic plan in obese patients?
Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely likely

APPENDIX B: TABLE 2. SURVEY SCORES ACROSS PROFESSIONAL TITLE/DEGREE.

Role	Anesthesiologist (*n* =7)	CRNA DNP (*n* = 12)	CRNA MSN (*n* = 33)	*p*-value
1. Set PEEP	3.43 (2.07)	3.83 (1.53)	4.09 (1.33)	.544
2. Increase PEEP	2.71 (1.11)	2.83 (1.85)	2.76 (1.46)	.984
3. Keep same	3.86 (0.90)	4.17 (0.94)	3.55 (0.87)	.118
4. Insufflation	2.86 (1.35)	3.00 (1.60)	2.58 (1.17)	.599
5. Trendelenburg	2.86 (1.35)	3.08 (1.56)	3.06 (1.27)	.929
6. Plateau	2.14 (0.69)	2.42 (1.38)	2.42 (1.17)	.843
7. Titrate	3.29 (1.38)	3.42 (1.24)	2.52 (1.12)	.051
8. Maintenance	2.86 (1.07)	2.50 (0.90)	2.15 (1.03)	.205
9. Incorporate	4.57 (0.79)	4.75 (0.62)	3.94 (0.93)	.014

Note. *p*-values were based on ANOVA testing differences across the role groups. In the cells were mean (standard deviation).

APPENDIX C: TABLE 3. SURVEY SCORES ACROSS YEARS OF EXPERIENCE GROUPS.

Years of experience	0-5 (*n* = 8)	6-10 (*n* = 22)	10-15 (*n* = 13)	> 15 (*n* = 9)	*p*-value
1. Set PEEP	3.89 (1.45)	4.75 (0.50)	4.62 (0.52)	3.38 (1.89)	.187
2. Increase PEEP	3.04 (1.65)	2.75 (2.06)	2.38 (1.41)	2.46 (0.97)	.588
3. Keep same	3.70 (0.91)	4.50 (0.58)	4.12 (0.99)	3.31 (0.75)	.061
4. Insufflation	2.78 (1.34)	2.75 (2.22)	2.62 (1.41)	2.62 (0.87)	.982
5. Trendelenburg	3.30 (1.41)	3.25 (1.71)	2.50 (1.41)	2.77 (0.93)	.406
6. Plateau	2.19 (1.14)	3.00 (1.41)	2.00 (1.07)	2.85 (1.07)	.181
7. Titrate	2.70 (1.35)	2.75 (1.71)	2.62 (1.06)	3.23 (0.93)	.607
8. Maintenance	2.41 (0.93)	1.25 (1.26)	2.00 (0.76)	2.69 (1.11)	.065
9. Incorporate	4.30 (0.91)	4.50 (0.58)	4.12 (0.99)	4.00 (1.00)	.718

Note. *p*-values were based on ANOVA testing differences across the experience groups. In the cells were mean (standard deviation).

APPENDIX D: TABLE 4. SURVEY SCORES ACROSS AGE GROUPS.

Age	20-30 (*n* = 8)	31-40 (*n* = 22)	41-50 (*n* = 13)	> 50 (*n* = 9)	*p*-value
1. Set PEEP	4.00 (1.69)	4.14 (1.36)	3.54 (1.51)	4.00 (1.66)	.721
2. Increase PEEP	3.00 (1.31)	3.00 (1.69)	2.54 (1.51)	2.33 (1.12)	.627
3. Keep same	4.25 (0.71)	3.77 (1.02)	3.54 (0.78)	3.44 (0.88)	.252
4. Insufflation	2.50 (1.07)	2.95 (1.36)	2.38 (1.56)	2.78 (0.83)	.615
5. Trendelenburg	2.88 (1.13)	3.50 (1.30)	2.46 (1.61)	2.89 (0.78)	.147
6. Plateau	1.88 (1.13)	2.55 (1.10)	2.00 (1.15)	3.00 (1.12)	.111
7. Titrate	2.88 (1.64)	2.64 (1.18)	2.69 (1.18)	3.44 (1.01)	.408
8. Maintenance	2.12 (0.64)	2.23 (0.97)	2.38 (1.19)	2.67 (1.22)	.682
9. Incorporate	4.12 (0.99)	4.36 (0.90)	4.00 (0.91)	4.22 (0.97)	.723

Note. *p*-values were based on ANOVA testing differences across the age groups. In the cells were mean (standard deviation).

APPENDIX E: IRB APPROVAL LETTER WAKE FOREST

Office of Research

INSTITUTIONAL REVIEW BOARD

WAKE FOREST UNIVERSITY HEALTH SCIENCES

MEMORANDUM

To: Karen Lucisano
Clinical and Translational Science Institute {CTSI}

From: Jeannie Sekits, Senior Protocol Analyst
Institutional Review Board

Date: 7/19/2023

Subject: Exempt Protocol: IRB00098451
Understanding Anesthesia Providers' Utilization of Lung Protective Ventilation Strategies in Obese Patients Undergoing Laparoscopic Surgery

No protected health information will be used or disclosed in this research proposal; therefore the requirement for individual Authorization does not apply.

null (Category null).

Note that only the Wake Forest University School of Medicine IRB can make the determination for its investigators that a research study is exempt. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt. Each project requires a separate review and approval or exemption. The Board must be informed of any changes to this project, so that the Board can determine whether it continues to meet the requirements for exemption.

Medical Center Boulevard, Winston-Salem, NC 27157-1023 (336) 716-4542 / fax (336) 716-4480

Association for the Accreditation of Human Research Protection Programs, Inc.

Full Accreditation

APPENDIX F: IRB APPROVAL LETTER UNCC

CHARLOTTE
DIVISION OF RESEARCH

To:	Cameron McClane University of North Carolina at Charlotte
From:	Office of Research Protections and Integrity
Approval Date:	25-Jul-2023
RE:	Notice of Determination of Exemption
Exemption Category:	2
Study #:	IRB-24-0045
Study Title:	Understanding Anesthesia Providers' Utilization of Lung Protective Ventilation Strategies in Obese Patients Undergoing Laparoscopic Surgery

This submission has been reviewed by the Office of Research Protections and Integrity (ORPI) and was determined to meet the Exempt category cited above under 45 CFR 46.104(d). This determination has no expiration or end date and is not subject to an annual continuing review. However, you are required to obtain approval for all changes to any aspect of this study before they can be implemented and to comply with the Investigator Responsibilities detailed below.

Your approved consent forms (if applicable) and other documents are available online at Submission Page.

Investigator's Responsibilities:

1. Amendments **must** be submitted for review and the amendment approved before implementing the amendment. This includes changes to study procedures, study materials, personnel, etc.
2. Researchers must adhere to all site-specific requirements mandated by the study site (e.g., face mask, access requirements and/or restrictions, etc.).
3. Data security procedures must follow procedures as described in the protocol and in accordance with OneIT Guidelines for Data Handling.
4.Promptly notify the IRB office (uncc-irb@charlotte.edu) of any adverse events or unanticipated risks to participants or others.
5.Five years (5) following this approval/determination, you must complete the Admin-Check In form via Niner Research to provide a study status update.
6.Be aware that this study is included in the Office of Research Protections and Integrity (ORPI) Post-Approval Monitoring program and may be selected for post-review monitoring at some point in the future.

7. Reply to the ORPI post-review monitoring and administrative check-ins that will be conducted periodically to update ORPI as to the status of the study.
8. Complete the Closure eform via Niner Research once the study is complete.

Please be aware that approval may still be required from other relevant authorities or "gatekeepers" (e.g., school principals, facility directors, custodians of records).