STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

Official title: The Use of a Second-Generation Laryngeal Mask Airway versus Endotracheal Tube

in Obese Patients

NCT number: NCT03748342

IRB approved date: 07-28-21

The Use of a Second-Generation Laryngeal Mask Airway versus Endotracheal Tube in Obese Patients

Principal Investigator: Tiffany Sun Moon, MD

Sponsor/Funding Source: UT Southwestern of Department of Anesthesiology and Pain Management

Version 3.1 06/21/2021

PROJECT SUMMARY

Introduction and Purpose:
The laryngeal mask airway (LMA) was invented in the 1980s and has been used in millions of patients worldwide. Since that time, the original prototype has been modified in several ways in order to improve the design of the LMA. "Second-generation" LMAs are those with a gastric channel, through which an orogastric tube can be inserted to decompress the stomach.

The LMA is associated with a decreased incidence of sore throat as well as a smoother emergence from general anesthesia compared to endotracheal tubes [1]. In randomized studies comparing second generation LMAs with endotracheal tubes, patients have been shown to have less pain and postoperative nausea and vomiting with LMAs [2].

In this prospective study, we plan to evaluate the use of a second-generation laryngeal mask airway (LMA) versus an endotracheal tube (ETT) in obese patients undergoing surgery. The second-generation LMAs offer additional benefits over traditional LMAs since they include a gastric channel through which an orogastric tube can be inserted to decompress the stomach. Modifications in the cuff have been shown to decrease the incidence of sore throat and achieve higher seal pressures [3, 4]. Some even include an integrated cuff pressure indicator, which allows the practitioner to assess inflation cuff pressures, therefore minimizing the incidence of over-inflation, which can cause mucosal ischemia and increase the incidence of sore throat [5].

Specific Aim 1:
To compare the use of a second-generation LMA versus endotracheal intubation with respect to the incidence of hypoxia in the immediate postoperative period.

Primary Hypothesis: Patients managed with the second-generation LMA will have a 50% decreased incidence of hypoxia compared with patients managed with an endotracheal tube.

Specific Aim 2:
To determine the alterations in hemodynamics with insertion and removal of the LMA versus an endotracheal tube.

Secondary Hypothesis: The LMA will cause less hemodynamic alterations for insertion and removal compared to an endotracheal tube.

Background:
The laryngeal mask airway (LMA) was invented in 1983 and has been in clinical use since 1988 with millions of uses worldwide [6]. It has a very good record of successful insertion and the learning curve for LMA insertion is not as steep as that for direct laryngoscopy and intubation [5]. In a series of almost 12,000 patients, LMA placement was successful in 99.8% of patients [7]. The LMA has a lower risk of airway complications since its placement does not necessitate laryngoscopy and its final position sits superior to the vocal cords and trachea, therefore causing less airway trauma [5]. The LMA was designed for either spontaneous or controlled positive pressure ventilation (PPV). In his first clinical series using the LMA, Dr. Brain described 16 cases of PPV in patients undergoing gynecologic surgery [6]. Use of the LMA in abdominal surgery, including laparoscopic gynecological surgery, has been documented in previous studies [8]. Newer, so called 'second-generation' LMAs have an additional gastric drainage tube, which allows passage of an orogastric tube to decompress the stomach. This separation of the alimentary and respiratory tracts is a significant advantage of second-generation LMAs. Additionally, higher airway pressures are afforded by these devices, which allow the provider to provide positive pressure ventilation without gastric insufflation. Therefore, these newer devices offer increased protection against aspiration when compared to first-generation LMAs. When second-generation LMAs are properly positioned, the risk of pulmonary aspiration is very low [9-11].

Insertion of an LMA is significantly less stimulating than insertion of an endotracheal tube (ETT), as direct laryngoscopy is not required for LMA insertion [12, 13]. Prior studies have shown that compared with ETT insertion, LMA insertion resulted in less hemodynamic and hormonal activation [14, 15]. The stress of surgery itself promotes platelet aggregation and thrombus formation, thus predisposing patients to ischemic events in the perioperative period [16]. Catecholamines increase heart rate and blood pressure and therefore increase myocardial oxygen consumption. By decreasing the stress response associated with airway manipulation, the LMA may be advantageous compared to the ETT, especially for patients with comorbidities (e.g., obesity) that may predispose them to cardiovascular complications.

LMA use results in less postoperative cough, laryngospasm, sore throat, hoarseness, and postoperative nausea and vomiting (PONV) compared to ETTs [2, 5, 8, 10, 17]. Additionally, use of a LMA compared to an ETT results in less postoperative hypoxemia and sore throat in the PACU [14]. Excessive intracuff pressures can lead to pharyngolaryngeal complications including sore throat, dysphagia, and dysphonia [18, 19]. The modifications to the cuff of second-generation LMAs can decrease the incidence of postoperative pharyngolaryngeal symptoms [20].

Patients who are managed with LMAs require less muscle relaxants than patients managed with ETTs. Upper airway muscles are very sensitive to the effects of residual neuromuscular blockade, increasing the risk of microaspiration, hypoxia, and pharyngeal dysfunction postoperatively [21, 22]. Being able to decrease the amount of neuromuscular blockade necessary could therefore result in less postoperative respiratory adverse events, especially in patients intolerant of residual neuromuscular blockade such as those who are obese. Previous studies have used the LMA for successful ventilation of obese patients [23-25].

In a recent Cochrane review of LMAs vs ETTs in obese patients, the authors concluded that there was a significant improvement in oxygenation during and after surgery, including better pulmonary performance of the second-generation LMA. They also reported less postoperative coughing, suggesting a better recovery for patients [26]. Another prospective study evaluating the use of LMA vs. ETT in moderately obese patients undergoing peripheral surgeries concluded that the LMA group had better early postoperative lung function and pulse oximetry saturation compared with the ETT group [27].

Compared to airway management with an ETT, the use of LMAs resulted in a shorter PACU stay and a faster discharge home [14]. In a hospital such as Parkland with a busy surgical service and limited resources, the associated cost savings could be significant [28].

There has been inconclusive evidence of whether obese patients have higher gastric volumes compared to lean patients but recent articles report that there does not seem to be a link between obesity and delayed gastric emptying [29-32]. Gastric ultrasound is a noninvasive tool to examine stomach contents at the bedside and is feasible in lean and severely obese patients [33, 34]. The antrum is highly amenable to ultrasound imaging and accurately reflects the content of the entire stomach [35]. A volume of < 1.5mL/kg suggests low gastric volumes and a low risk of aspiration [36].

Concise Summary of Project:
This prospective, randomized, comparative study is intended to enroll a total of 150 obese patients with a BMI >30 kg/m^2 undergoing surgery at Parkland Hospital. There will also be a second site (MD Anderson) that will enroll an additional 150 obese patients. The efficacy and performance of the second-generation LMA will be compared to endotracheal intubation. A standardized anesthetic protocol that is usual and customary for the type of operation the patient is having will be provided to the anesthesia teams of enrolled subjects. The remainder of the anesthetic care of the subject will not deviate from the standard of care.

Study Procedures:
Screening and Informed Consent
A member of the research team will use a screening form to look for surgical patients that meet all the inclusion and exclusion criteria. He/she will approach potential subjects in the preoperative area and the study will be explained in detail in a private room. Patients will be informed that they will receive no compensation for participating in the study and there will be no adverse consequences if they choose not to participate. If the subjects agree to participate, informed written consent will be obtained prior to any study procedures and this document will be sent to pmhresearchparticipants@phhs.org, for inclusion in the patient's medical record, per Parkland regulations. The study duration will be from the beginning of anesthesia care to 2 hours after the patient's surgery ends.

Anesthetic Protocol
The anesthesia team that will be caring for the subject during surgery will be given the protocol for the study, which standardizes the general anesthetic technique.

Subject Group Assignment:
A randomization schedule will be created by a member of the research team that is not involved in clinical care (i.e., statistician). Subjects will be randomized to receive either a standard endotracheal tube or a second-generation LMA. The ETT size will be selected based on gender- 7.0 for women and 8.0 for men. LMA sizing will be according to manufacturer guidelines.

In the preoperative holding area, a gastric ultrasound will be performed to rule out the presence of significant gastric contents. This will be done with a curved array low-frequency transducer on the current ultrasound machine that is already available in the preop area. No visible contents in the gastric antrum in either the supine or right lateral decubitus (Grade 0) provides unequivocal diagnosis of an empty stomach. A threshold of 1.5 mL/kg will be the upper limit of acceptable gastric volume. Any patients who has more than this volume will not undergo any further study procedures.

Once the patient is in the operating room, they will be positioned on the operating room table and standard ASA monitors will be applied. All patients will undergo a standard anesthetic induction. Patients who are randomized to endotracheal intubation will also have a neuromuscular blocking agent (i.e., rocuronium) administered to facilitate intubation.

Preparation of the endotracheal tube will consist of ensuring that the cuff holds air as well as inserting a stylet into the endotracheal tube. Preparation of the LMA will consist of ensuring that the cuff holds air, and then withdrawing all the air in preparation for insertion, per manufacturer guidelines. A water-soluble lubricant will be applied to the dorsal surface of the LMA to assist with insertion, which is

standard practice.

Following induction of anesthesia, if a patient is randomized to the ETT group, the anesthesia provider will perform a direct laryngoscopy and insert an endotracheal tube. The time that the face mask is taken off the patient's face will be recorded as the 'start time' for laryngoscopy, and the 'end time' will be when the positive $ETCO_2$ tracing appears. For patients randomized to the LMA group, the anesthesia provider will be asked to insert the LMA in the patient's posterior oropharynx until resistance is encountered. It will then be secured with a piece of tape, per manufacturer guidelines. Then the cuff will then be inflated. The time that the face mask is taken off the patient's face will be recorded as the 'start time' for LMA placement, and the 'end time' will be when the positive $ETCO_2$ tracing appears. A fiberoptic bronchoscope will be inserted through the lumen of the LMA to ensure that its placement is correct (i.e., just proximal to the glottic inlet). Correct placement of the LMA will also be tested with the gel displacement test [37, 38]. This test will be performed by placing 5 mL of water-soluble gel over the male drainage tube while occluding the female draining lumen and looking for its ejection during manual ventilation. A 'negative' test (gel does not move) indicates that there is no air leak from the airway port to the gastric port, and the LMA is correctly positioned. A 'positive' test (gel is displaced during ventilation) indicates that there is an air leak into the gastric port, and the LMA needs to be repositioned. Following confirmation of adequate ventilation, an orogastric tube will be inserted through the gastric channel of the LMA. Correct gastric tube placement will be confirmed by aspiration of gastric contents (amount will be recorded) or by auscultation during insufflation of 30 mL of air into the gastric tube.

Successful LMA and ETT placement will be defined as chest rise during ventilation, a square capnography waveform, bilateral breath sounds, and no air leakage. A maximum of three tries will be allowed for subjects in the LMA group. If the LMA is not properly placed after 3 attempts, the anesthesia provider will be asked to intubate the patient with an endotracheal tube and a 'LMA failure' will be noted. Details regarding ETT placement including Cormack-Lehane grade, number of attempts, number of operations, and use of any adjunct airway devices will be recorded.

Following confirmation of LMA or ETT placement, the patient will be ventilated using volume control ventilation with an inspiratory:expiratory ratio of 1:2, tidal volume of 6-8 mL/kg of ideal body weight (IBW) and a rate of 8-12, titrated to keep the $ETCO_2$ between 35-45 mmHg, and fresh gas flow rate of 2 L/min. Patients who are breathing spontaneously will be managed with pressure support ventilation (PSVPro). Immediately after confirmation of LMA or ETT placement, the patient will be placed on 1-2% sevoflurane in 50% oxygen.

Additional information collected will include:

- Aspiration at induction
- Amount and description of gastric fluid aspiration through orogastric tube suction (either through LMA or ETT)
- Evidence of gastric content after airway device removal
- Intraoperative medications
- Medications given in PACU
- Aldrete scores in PACU
- Hypoxic episodes in PACU

Vital signs including SpO_2, heart rate (HR), blood pressure (BP) will be recorded at the following times:

- Baseline in operating room prior to induction
- At induction (Ti)
- Immediately after placement of LMA/ETT
- Three minutes following placement of LMA/ETT
- Five minutes following placement of LMA/ETT
- Ten minutes following placement of LMA/ETT
- Just prior to removal of LMA/ETT
- Immediately after removal of LMA/ETT

- Three minutes following removal of LMA/ETT
- Five minutes following removal of LMA/ETT
- Ten minutes following removal of LMA/ETT

A blinded research assistant will perform all postoperative assessments. All patients will go to the post anesthesia care unit (PACU) after surgery, unless an intraoperative complication necessitates that the patient go to the intensive care unit (ICU), at which time they would no longer be a part of the study. As patient-reported outcomes have become increasingly important for hospitals, treatments that have the potential to increase patient satisfaction are being studied closely. The postoperative quality recovery scale (PQRS) is a tool that assesses recovery over time and compares them to baseline values. Some of the advantages of the PQRS are that it is validated, takes less than 5 minutes to administer, has a low patient refusal rate, and is acceptable to patients across a wide range of ages. The PQRS will be administered at baseline in the preoperative area, and after PACU arrival at 15 minutes and again at 45 minutes and 80 minutes (Appendix 1). The time when the patient arrives to the PACU, is ready for discharge from the PACU (modified Aldrete score ≥9) and actual discharge from the PACU will be recorded.

After the first ten patients have been enrolled, the PI and the research team will review the cases to make any adjustments to the protocol to better facilitate data collection for the remaining study participants.

Data Sources
Protected health information including name, medical record number, and date of birth will be recorded and stored securely in a password-protected, secured Excel database. De-identified data will be entered in RedCap data management system.

Parameters:
1. Protected health information (PHI): name, medical record number, date of birth, phone number
2. Demographic information (age, weight, height, BMI, gender), medical and surgical history, ASA)
3. Intraoperative parameters
    - Baseline vital signs upon arrival to operating room
    - Time of induction
    - Intraoperative vitals (systolic, diastolic, and mean blood pressures, heart rate)
    - ECG rhythm
    - Laryngoscopy details (Cormack Lehane view, blade used)
4. Adverse event monitoring
    - LMA unable to be inserted after 3 attempts
    - Patient unable to be intubated (e.g., difficult airway)
    - Prolonged hypoxia (> 1 min at <92%) from anesthesia start to anesthesia stop
    - Respiratory adverse event including bronchospasm, laryngospasm aspiration, reintubation
    - Prolonged PACU stay (> 2 hours)
    - Unplanned hospital admission

Criteria for Inclusion of Subjects:
- 18-80 years old
- Obese BMI $\geq$ 30 kg/m^2
- Scheduled for a non-emergent surgery that requires general anesthesia (e.g., orthopedic, breast, urological, colorectal, ENT, vascular, general surgery)
- Willing and able to consent in English or Spanish
- No current history of advanced pulmonary or cardiac disease

Criteria for Exclusion of Subjects:

- Age less than 18 or older than 80
- BMI >50 or < 30 kg/m^2
- Patient does not speak English or Spanish
- Expected surgical duration longer than 4 hours
- Planned postoperative ICU admission
- Patient refusal
- Monitored anesthesia care (MAC) or regional anesthesia without general anesthesia
- Pregnant or nursing women
- "Stat" (emergent) cases
- Known or suspected difficult airway
- Appearance of residual gastric volume >1.5 mL/kg on preoperative gastric ultrasound
- Full stomach/significant aspiration risk (gastroparesis, emergency surgery, untreated moderate to severe gastroesophageal reflux disease, hiatal hernia)
- No history of gastric surgery
- Surgery in position other than supine (e.g., Trendelenburg)
- Laparoscopic surgery

Sources of Research Material:
- Identifying patient information including name, medical record number, and birth date
- Medical history
- Surgical history
- Weight and height
- Laboratory studies
- Vital signs
- Intraoperative anesthetic record

Recruitment Methods and Consenting Process:
A member of the research team will approach subjects who meet all inclusion and exclusion criteria on the day of surgery in a private room. All study procedures will be explained to the patient in layman's terms. If the subject agrees to participate, he or she will sign the consent form and HIPAA Authorization Form prior to any study procedures.

Potential Risks:
There is some risk to subjects by participating in this study. The anesthetic management of subjects will not differ from the standard care. Patients will be randomized to be intubated with an endotracheal tube or have an LMA inserted as part of the airway management for their surgery. There is a very small risk of aspiration anytime a patient undergoes general anesthesia. A LMA is not considered a 'secured airway' because there is no cuff in the patient's trachea. Therefore, there is a risk of aspiration with a LMA. However, the overall incidence of aspiration with general anesthesia is very low (approximately 1 in 5000 general anesthetics) and no studies have been powered to look directly at aspiration. From existing studies, the LMA groups did not have a higher incidence of aspiration compared with the ETT groups [5, 39, 40]. One caveat is that patients at risk for aspiration have been excluded from these studies, which will also be done for this study. Currently there is no evidence to suggest that the use of a LMA (especially a second generation LMA) in appropriately selected patients increases the risk of aspiration compared with ETT [27].

<u>Study Procedure/Intervention</u>
The table below will be included in the consent form and lists the risks of ETT vs LMA placement.

Risks of Endotracheal Tube (ETT)

	Frequent 30% of subjects	**Occasional 15% of subjects**	**Rare Less than 1% of subjects**

Serious		Incorrect placement Difficult intubation	Tracheal perforation Aspiration Tracheal stenosis
Less Serious	Sympathetic surge (increased heart rate and blood pressure)	Trauma to vocal cords, trachea, soft tissues Bronchospasm (lower airway obstruction) Laryngospasm (upper airway obstruction) Dental damage	
Minor	Sore throat Cough	Minor bleeding Laryngeal edema (swelling of the throat) Lip damage Dysphonia (hoarseness) Dysphagia (difficulty swallowing)	

Risks of Laryngeal Mask Airway

	Frequent 30% of subjects	**Occasional 15% of subjects**	**Rare Less than 1% of subjects**
Serious		Difficult placement	Aspiration
Less Serious	Sympathetic surge (increased heart rate and blood pressure)	Bronchospasm (lower airway obstruction) Laryngospasm (upper airway obstruction) Local tissue injury	Dental damage
Minor	Sore throat Cough	Minor bleeding Laryngeal edema (swelling of the throat) Lip damage Dysphonia (hoarseness) Dysphagia (difficulty swallowing)	

Psychological Stress

There is minimal risk for psychological stress to the patient as a result of participation in this study. Subjects may refuse to answer any of the questions, or take a break or stop participation in the study at any time.

Subject Safety and Data Monitoring

Study oversight will include a Data Safety and Monitoring Board (DSMB). The DSMB will be chaired by a faculty member that is not the PI and will include specialists from different specialties including anesthesiology, critical care medicine, and surgery. The DSMB will meet quarterly as needed to review all patient enrollments. If necessary the DSMB will meet more often to review specific study subjects, unanticipated events, protocol violations, and adverse events. All study subjects will be reviewed by

the DSMB for any study-related adverse outcomes. A written record of all meetings will be kept. The IRB will be notified in writing of any adverse study-related outcomes.

Procedures to Maintain Confidentiality:
A non-identifiable code will be assigned to the data collection sheet so that there is not a direct link to specific names. Patient IDs will be standardized in chronological order as patient 1, patient 2, etc. A key to the coding system will be maintained in a locked storage cabinet with limited access until all the data is collected and analyzed. Access to study data will be restricted to authorized study personnel only. Following the completion of the analysis and the project, the key to the coding system or subject identifiers themselves will be destroyed by shredding the documents so that there is no direct or indirect link to subject identifiers and information.

All data from the study will be kept on encrypted computers belonging to the University, which are stored in secured areas. All electronic study data will be password protected and passwords will be changed on a regular basis. Patient data will be analyzed without patient identifiers by assigning study ID subject numbers that are de-linked from patient identifiers. Signed consent forms, HIPAA forms, and study questionnaires will remain in a locked cabinet in the PI's office.

Potential Benefits:
Previous studies have shown that appropriately selected patients who undergo surgery with a LMA (compared to an ETT) have less pulmonary physiological derangement in the postoperative period, as well as less pain and postoperative nausea and vomiting. Patients who are randomized to the LMA group may benefit from this. However, the study is not intended to directly benefit patients in either group (LMA vs. ETT).

Data Sharing
Data will be shared via RedCap; UT Southwestern PI will have access to the MD Anderson deidentified RedCap database and download an Excel data file. UT Southwestern will receive the deidentified data.

UT Southwestern team who have access to MD Anderson Center RedCap will download the deidentified data. RedCap (https://redcap.mdanderson.org) is hosted on a secure server by MD Anderson Cancer Center's Department of Oncology Care & Research Information Systems. RedCap has undergone an annual Governance Risk & Compliance Assessment (since May 2014) by MD Anderson's Information Security Office and found to be compliant with HIPAA, Texas Administrative Coes 202-203, University of Texas Policy 165, federal regulations outlined in 21CFR Part 11, and UTMDACC Institutional Policy #ADM0335.

Those having access to the data include the study's PI and research team personnel of both study sites. Users are authenticated against MDACC's Active Directory system. External collaborators are given access to the database once approved by the PI, with their access expiring in 6 months, but renewable in 6 month increments at the request of the PI. The application is accessed through Secure Socket Layer (SSL).

Statistics:
The study is powered to detect a change in the incidence of sore throat post-operatively between subjects in the ETT and LMA groups. Assuming a 20% rate of incidence of sore throat in the ETT group, the study is powered to detect a 50% reduction in the incidence rate to 10% (risk ratio = 1/2) in the LMA group. With these assumptions, the study will need a total of 116 patients to have 80% power (two-sided chi-square test with type I error rate = 0.05). To account for patient dropout, a total of 150 patients will be enrolled. The continuous data will be summarized as mean and standard deviation or median and inter-quartile range, as appropriate while categorical data will be summarized as frequency and percentages. The incidence rates of sore throat in the two groups will be compared

using a chi-square test or Fisher's exact test. Statistical significance is set at p=0.05. All analyses will be done using SAS 9.3 (SAS Inc., Cary, NC).

References:

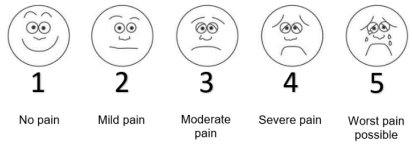
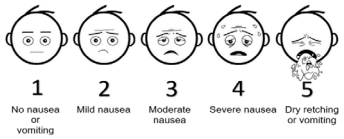
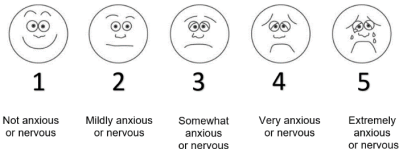
1. Smith I, White PF: **Use of the laryngeal mask airway as an alternative to a face mask during outpatient arthroscopy**. *Anesthesiology* 1992, **77**(5):850-855.
2. Hohlrieder M, Brimacombe J, von Goedecke A, Keller C: **Postoperative nausea, vomiting, airway morbidity, and analgesic requirements are lower for the ProSeal laryngeal mask airway than the tracheal tube in females undergoing breast and gynaecological surgery**. *Br J Anaesth* 2007, **99**(4):576-580.
3. William A, Chambers NA, Erb TO, von Ungern-Sternberg BS: **Incidence of sore throat in children following use of flexible laryngeal mask airways - impact of an introducer device**. *Paediatr Anaesth* 2010, **20**(9):839-843.
4. Jagannathan N, Sohn LE, Sawardekar A, Chang E, Langen KE, Anderson K: **A randomised trial comparing the laryngeal mask airway Supreme with the laryngeal mask airway Unique in children**. *Anaesthesia* 2012, **67**(2):139-144.
5. Yu SH, Beirne OR: **Laryngeal mask airways have a lower risk of airway complications compared with endotracheal intubation: a systematic review**. *J Oral Maxillofac Surg* 2010, **68**(10):2359-2376.
6. Brain AI: **The laryngeal mask--a new concept in airway management**. *Br J Anaesth* 1983, **55**(8):801-805.
7. Verghese C, Brimacombe JR: **Survey of laryngeal mask airway usage in 11,910 patients: safety and efficacy for conventional and nonconventional usage**. *Anesth Analg* 1996, **82**(1):129-133.
8. Maltby JR, Beriault MT, Watson NC, Liepert DJ, Fick GH: **LMA-Classic and LMA-ProSeal are effective alternatives to endotracheal intubation for gynecologic laparoscopy**. *Can J Anaesth* 2003, **50**(1):71-77.
9. Cook TM, Lee G, Nolan JP: **The ProSeal laryngeal mask airway: a review of the literature**. *Can J Anaesth* 2005, **52**(7):739-760.
10. Goldmann K, Hechtfischer C, Malik A, Kussin A, Freisburger C: **Use of ProSeal laryngeal mask airway in 2114 adult patients: a prospective study**. *Anesth Analg* 2008, **107**(6):1856-1861.
11. Latorre F, Eberle B, Weiler N, Mienert R, Stanek A, Goedecke R, Heinrichs W: **Laryngeal mask airway position and the risk of gastric insufflation**. *Anesth Analg* 1998, **86**(4):867-871.
12. Akbar AN, Muzi M, Lopatka CW, Ebert TJ: **Neurocirculatory responses to intubation with either an endotracheal tube or laryngeal mask airway in humans**. *J Clin Anesth* 1996, **8**(3):194-197.
13. Oczenski W, Krenn H, Dahaba AA, Binder M, El-Schahawi-Kienzl I, Jellinek H, Schwarz S, Fitzgerald RD: **Hemodynamic and catecholamine stress responses to insertion of the Combitube, laryngeal mask airway or tracheal intubation**. *Anesth Analg* 1999, **88**(6):1389-1394.
14. Carron M, Veronese S, Gomiero W, Foletto M, Nitti D, Ori C, Freo U: **Hemodynamic and hormonal stress responses to endotracheal tube and ProSeal Laryngeal Mask Airway for laparoscopic gastric banding**. *Anesthesiology* 2012, **117**(2):309-320.
15. Timmermann A: **[Modern airway management--current concepts for more patient safety]**. *Anasthesiol Intensivmed Notfallmed Schmerzther* 2009, **44**(4):246-255; quiz 256.
16. Warltier DC, Pagel PS, Kersten JR: **Approaches to the prevention of perioperative myocardial ischemia**. *Anesthesiology* 2000, **92**(1):253-259.
17. Maltby JR, Beriault MT, Watson NC, Liepert D, Fick GH: **The LMA-ProSeal is an effective alternative to tracheal intubation for laparoscopic cholecystectomy**. *Can J Anaesth* 2002, **49**(8):857-862.
18. Chantzara G, Stroumpoulis K, Alexandrou N, Kokkinos L, Iacovidou N, Xanthos T: **Influence of LMA cuff pressure on the incidence of pharyngolaryngeal adverse effects and evaluation of the use of manometry during different ventilation modes: a randomized clinical trial**. *Minerva Anestesiol* 2014, **80**(5):547-555.

19. Seet E, Yousaf F, Gupta S, Subramanyam R, Wong DT, Chung F: **Use of manometry for laryngeal mask airway reduces postoperative pharyngolaryngeal adverse events: a prospective, randomized trial**. *Anesthesiology* 2010, **112**(3):652-657.
20. Wong DT, Tam AD, Mehta V, Raveendran R, Riad W, Chung FF: **New supraglottic airway with built-in pressure indicator decreases postoperative pharyngolaryngeal symptoms: a randomized controlled trial**. *Can J Anaesth* 2013, **60**(12):1197-1203.
21. Murphy GS, Szokol JW, Marymont JH, Greenberg SB, Avram MJ, Vender JS: **Residual neuromuscular blockade and critical respiratory events in the postanesthesia care unit**. *Anesth Analg* 2008, **107**(1):130-137.
22. Brull SJ, Kopman AF: **Current Status of Neuromuscular Reversal and Monitoring: Challenges and Opportunities**. *Anesthesiology* 2017, **126**(1):173-190.
23. Combes X, Sauvat S, Leroux B, Dumerat M, Sherrer E, Motamed C, Brain A, D'Honneur G: **Intubating laryngeal mask airway in morbidly obese and lean patients: a comparative study**. *Anesthesiology* 2005, **102**(6):1106-1109; discussion 1105A.
24. Keller C, Brimacombe J, Kleinsasser A, Brimacombe L: **The Laryngeal Mask Airway ProSeal(TM) as a temporary ventilatory device in grossly and morbidly obese patients before laryngoscope-guided tracheal intubation**. *Anesth Analg* 2002, **94**(3):737-740; table of contents.
25. Frappier J, Guenoun T, Journois D, Philippe H, Aka E, Cadi P, Silleran-Chassany J, Safran D: **Airway management using the intubating laryngeal mask airway for the morbidly obese patient**. *Anesth Analg* 2003, **96**(5):1510-1515, table of contents.
26. Nicholson A, Cook TM, Smith AF, Lewis SR, Reed SS: **Supraglottic airway devices versus tracheal intubation for airway management during general anaesthesia in obese patients**. *Cochrane Database Syst Rev* 2013(9):CD010105.
27. Zoremba M, Aust H, Eberhart L, Braunecker S, Wulf H: **Comparison between intubation and the laryngeal mask airway in moderately obese adults**. *Acta Anaesthesiol Scand* 2009, **53**(4):436-442.
28. Ang WW, Sabharwal S, Johannsson H, Bhattacharya R, Gupte CM: **The cost of trauma operating theatre inefficiency**. *Ann Med Surg (Lond)* 2016, **7**:24-29.
29. Buchholz V, Berkenstadt H, Goitein D, Dickman R, Bernstine H, Rubin M: **Gastric emptying is not prolonged in obese patients**. *Surg Obes Relat Dis* 2013, **9**(5):714-717.
30. Bluemel S, Menne D, Milos G, Goetze O, Fried M, Schwizer W, Fox M, Steingoetter A: **Relationship of body weight with gastrointestinal motor and sensory function: studies in anorexia nervosa and obesity**. *BMC Gastroenterol* 2017, **17**(1):4.
31. Hellmig S, Von Schoning F, Gadow C, Katsoulis S, Hedderich J, Folsch UR, Stuber E: **Gastric emptying time of fluids and solids in healthy subjects determined by 13C breath tests: influence of age, sex and body mass index**. *J Gastroenterol Hepatol* 2006, **21**(12):1832-1838.
32. Juvin P, Fevre G, Merouche M, Vallot T, Desmonts JM: **Gastric residue is not more copious in obese patients**. *Anesth Analg* 2001, **93**(6):1621-1622, table of contents.
33. Van de Putte P, Perlas A: **Gastric sonography in the severely obese surgical patient: a feasibility study**. *Anesth Analg* 2014, **119**(5):1105-1110.
34. Kruisselbrink R, Arzola C, Jackson T, Okrainec A, Chan V, Perlas A: **Ultrasound assessment of gastric volume in severely obese individuals: a validation study**. *Br J Anaesth* 2017, **118**(1):77-82.
35. Van de Putte P, Perlas A: **Ultrasound assessment of gastric content and volume**. *Br J Anaesth* 2014, **113**(1):12-22.
36. Perlas A, Arzola C, Van de Putte P: **Point-of-care gastric ultrasound and aspiration risk assessment: a narrative review**. *Can J Anaesth* 2018, **65**(4):437-448.
37. Timmermann A, Cremer S, Eich C, Kazmaier S, Brauer A, Graf BM, Russo SG: **Prospective clinical and fiberoptic evaluation of the Supreme laryngeal mask airway**. *Anesthesiology* 2009, **110**(2):262-265.
38. Brimacombe J, Keller C: **Prime the ProSeal drain tube with lube from a tube!** *Can J Anaesth* 2005, **52**(3):338-339.

39. van Esch BF, Stegeman I, Smit AL: **Comparison of laryngeal mask airway vs tracheal intubation: a systematic review on airway complications**. *J Clin Anesth* 2017, **36**:142-150.
40. Park SK, Ko G, Choi GJ, Ahn EJ, Kang H: **Comparison between supraglottic airway devices and endotracheal tubes in patients undergoing laparoscopic surgery: A systematic review and meta-analysis**. *Medicine (Baltimore)* 2016, **95**(33):e4598.

Appendix 1: Postoperative Quality Recovery Scale evaluation at baseline, T15, T45, T80

Demographic and Preoperative Data[a]	
Age	yrs
Gender	Male or Female
ASA Status	1 2 3 4
Weight	kg
Height	in
BMI	kg/m^2
Education	Highest level finished:
Alcohol consumption	units/wk
Smoking status	Never, used to but quit, current smoker
Employment	Unemployed Employed and plan to return Employed but plan not to return Occupation: Approximate hrs/wk:
Inpatient	Yes or No
Surgical procedure	
Physiological Factors[a,d]	
P1 Blood Pressure Please record the patient's blood pressure	/ 3= SBP 90-140; 2= SBP 70-89 or 141-180; 1= SBP <70 or >180
P2 Heart Rate Please record the patient's heart rate	3= 45-100; 2= 35-44 or 101-139; 1= <35 or >140
P3 Temperature Please record the patient's temperature	*Method 1. Sublingual 2. Tympanic 3. Esophageal* 3= 36-37.6; 2= 35-35.9 or 37.7-38.9; 1= <35 or >39
P4 Respiration Please record the patient's respiratory rate	/breaths per minute
P5 Oxygen use to maintain SpO_2 Please record oxygen requirement	3= Oxygen administered by protocol or not required 2= Any SpO_2 <95% requiring oxygen as an intervention 1= Any SpO_2 <90% requiring oxygen as an intervention
P6 Airway Please record the number corresponding to the assessment	3= Self-maintenance of airway 2= Maintenance of airway with support (describe) 1= Device *in situ*
P7 Agitation Please record the number corresponding to the assessment	3= Shows no signs of agitation 2= Patient shows occasional agitation 1= Patient shows severe agitation
P8 Alertness Please record the number corresponding to the actual assessment	5=Awake, following commands 4=Responds to name spoken in normal tone 3=Responds only after name is spoken loudly and repeatedly or both 2=Responds only after mild prodding/ shaking 1=Does not respond to mild prodding/shaking

P9 What is the level of your strength now? Please record the number corresponding to the actual assessment	3= No weakness 2= A little weak 1= Very weak
Nociceptive Factors[a,b,c,e,f]	
N1 I am going to show you a series of faces and I would like you to indicate which face, number or description most accurately describes your level of pain at the moment.	
N2 I am going to show you a series of faces and I would like you to indicate which face, number, or description most accurately describes your level of feeling nauseous or vomiting at the moment.	
N3 Sore throat Please record the number corresponding to the actual assessment	0= No sore throat 1= Mild sore throat (complains of sore throat only on asking) 2= Moderate sore throat (complains of sore throat on his/her own) 3= Severe sore throat (change of voice or hoarseness, associated with throat pain)
N4 Hoarseness Please record the number corresponding to the actual assessment	0= No hoarseness 1= Hoarseness at the time of interview, but noted only the patient 2= Hoarseness that is readily apparent, but mild 3=Hoarseness that is readily apparent and severe or aphonia
Emotional Factors[a,b]	
E1 I am going to show you a series of faces and I would like you to indicate which face, number, or description accurately describes to what extent you feel sad, low, or depressed at the moment.	
E2 I am going to show you a series of faces and I would like you to indicate which face, number, or description accurately describes to what extent you feel anxious or nervous at the moment.	
*E3 What is the overall level of satisfaction with your immediate postoperative recovery (from the time surgery ended until now)- *T80 assessment only*	1-100 scale 100 = “completely satisifed” 90 = “mostly satisfied” 80 = “moderately satisfied” 70 = “minimally satisfied” < 70 = “not satisfied” and write reason here_____

a. Patient questionnaire adapted from Royse et al. 2010 and Amorim et al. 2014
b. Pain, depression, and anxiety scales are modified from Wong and Baker 1988
c. Nausea scale is modified from Baxter et al. 2011
d. Alertness scale adapted from Doufas et al. 2001
e. Sore throat scale adapted from Chattopadhyay 2017
f. Hoarseness scale adapted from Park 2010