Study Title: A Randomized study to compare LMA® Gastro™, a dual channel supraglottic airway (SGA) device, to oxygenation with standard nasal cannula for endoscopic retrograde cholangiopancreatography (ERCP)

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Sponsor Name: Teleflex

SUMMARY TABLE

Title	**A Randomized study to compare LMA® Gastro™, a dual channel supraglottic airway (SGA) device, to oxygenation with standard nasal cannula for endoscopic retrograde cholangiopancreatography (ERCP)**
Study Size (# of patients)	64
Study Design	This is a prospective, controlled, randomized trial.
Primary Objective	To compare the incidence of desaturation (SpO_2 < 90%) between patients undergoing ERCP with LMA® Gastro™ vs standard nasal cannula.
Secondary Objectives	To evaluate the following: 1) The incidence of additional airway maneuvers (jaw thrust/chin lift/placement of oral airway or nasal trumpet/intubation) 2) Incidence of withdrawal of duodenoscope from airway to facilitate airway support 3) The incidence of adverse events 4) Times related to anesthesia and procedure (defined as "anesthesia start to anesthesia end" and "procedure start to procedure end" respectively. Also evaluate time from procedure end to anesthesia end) 5) To describe hemodynamics within the two groups (recorded blood pressures, heart rates, oxygen saturations, and end tidal CO_2) 6) To evaluate anesthesiologist placing the device (training video viewed, number of practice attempts, years of experience)

Inclusion Criteria	Adult patients (≥ 18 years old) undergoing ERCP
Exclusion Criteria	Patients with propofol allergy Patients at increased aspiration risk Patients with abnormal head/neck pathology making LMA® Gastro™ placement difficult Patients with surgical or radiation treatment to the head/neck making LMA® Gastro™ placement difficult Patient with known difficult airway requiring advanced intubation equipment (with the exception of the video-laryngoscope) in the past Esophagectomy patients Patients already intubated upon arrival to endoscopy suite Patients undergoing Endoscopic Ultrasound (EUS) Patients with BMI ≥ 35 kg/m^2 Non-index cases for this study
Study Procedures	
Pretreatment Evaluation	Eligible subjects will be identified from within the patient population of the study site. There will be no advertisements for study subjects.
On-Study Visits	**Intervention Group:** All patients in the LMA® Gastro™ group will be pre-oxygenated with 100% oxygen via face mask prior to induction of general anesthesia. Pre-oxygenation will be administered for 3 minutes of normal tidal volume breathing or for 8 deep breaths over one minute. Once pre-oxygenation is complete, patients will be induced with 0.5-1mg/kg lidocaine and 1-4 mg/kg propofol. Upon loss of the patient's lash reflex, the LMA® Gastro™ will be placed in the patient's oropharynx. The cuff should be inflated until the cuff pilot indicator line is within the green zone. Appropriate placement will be confirmed with end tidal CO_2 and adequate tidal volumes of at least 4-5 cc/kg. Following placement confirmation, sedation will be titrated to achieve deep to general anesthesia using a propofol infusion at 50-300 mcg/kg/min. Propofol may be supplemented with inhalational anesthetics or opioids at the discretion of the anesthesiologist. After securing the airway, the patient will be repositioned (if necessary) on the fluoroscopy table in the prone position with head facing to the right (although occasionally patient may be positioned in the left lateral decubitus or supine position) to facilitate the ERCP. Positioning is at the discretion of the gastroenterologist. After the patient is positioned, the anesthesiologist will again confirm that the LMA® Gastro™ is positioned properly before allowing the procedure

	to begin. During the procedure, the patient may receive positive pressure ventilation keeping airway pressures ≤20 mmHg or the patient may maintain spontaneous ventilation with or without ventilator support, as long as adequate minute ventilation (≥5 L/min) and appropriate end tidal CO_2 (< 45 mmHg) is maintained. A duodenoscope will be lubricated with KY jelly by the gastroenterologist and inserted into the LMA® Gastro™. Should the LMA® Gastro™ impede completion of the procedure, the anesthesiologist will remove the LMA® Gastro™ and either proceed with a native airway or place an endotracheal tube. This decision will be at the discretion of the anesthesiologist. **Standard Care Group:** Patients will be positioned on the fluoroscopy table in the prone position with head facing to the right (although occasionally patient may be positioned in the left lateral decubitus or supine position) to facilitate the ERCP. Positioning is at the discretion of the gastroenterologist. After the patient is positioned, the anesthesiologist will apply standard nasal cannula at 2-3 L/minute. Patients will be induced with 0.5-1 mg/kg lidocaine and 0.5 - 1 mg/kg of propofol and will be started on a propofol drip at 50-200 mcg/kg/min. The drip will be titrated to achieve a deep to general level of sedation as defined by the American Society of Anesthesiologists (ASA) Continuum of Depth of Sedation Scale. Each incidence of desaturation < 90% will be noted, as well as the length of each desaturation. The anesthesia provider may utilize nasal trumpets if needed to improve saturations. The decision to intubate should the patient experience recurrent or prolong desaturations is at the discretion of the anesthesiologist and gastroenterologist.
Follow-up Visits	None
End of Study Visit	None
Brief Analysis Plan	We will summarize continuous demographics and clinical variables, such as age and anesthesia time, using means, standard deviations, medians and ranges. Categorical demographic variables and clinical variables, such as gender, incidence of additional airway maneuvers, incidence of adverse events and incidence of withdrawal of duodenoscope from airway to facilitate airway support, will be summarized through frequencies and percentages. Fisher's exact test

	will be used to compare the percentage of patients with desaturations (SpO_2< 90%) between LMA Gastro and standard nasal cannula groups, as well as patient reported sore throat in recovery and other categorical variables of interest. Wilcoxon-rank sum test will be used to compare continuous outcomes between study arms. Logistic regression model may be fitted to assess the effect of important covariates on the primary endpoint.

1. OBJECTIVES

Primary Objective: To compare the incidence of desaturation (SpO_2 < 90%) between patients undergoing ERCP with LMA® Gastro™ vs standard nasal cannula

Secondary Objectives:

1) To evaluate the incidence of additional airway maneuvers (jaw thrust/chin lift/placement of oral airway or/nasal trumpet/intubation)
2) To evaluate the incidence of withdrawal of duodenoscope from the airway to facilitate airway support
3) To evaluate the incidence of adverse events
4) To evaluate times related to anesthesia and procedure (defined as "anesthesia start to anesthesia end" and "procedure start to procedure end" respectively. Also evaluate time from procedure end to anesthesia end)
5) To describe hemodynamics within the two groups (recorded blood pressures, heart rates, oxygen saturations, and end tidal CO_2)
6) To evaluate anesthesiologist placing the device (training video viewed, number of practice attempts, years of experience)

2. BACKGROUND

There is ongoing debate within the anesthesia and gastroenterology community concerning the best way to manage the anesthetic for patients undergoing ERCP. Traditionally, anesthesiologists have intubated these patients. However, many ERCP patients are now receiving propofol sedation with a native airway. It has been demonstrated that moderate propofol sedation frequently progresses to deep anesthesia which is a risk for airway and cardiopulmonary complications.(Bhananker et al., 2006; Metzner, Posner, Lam, & Domino, 2011; Patel et al., 2005; Perbtani et al., 2016; Sudheer, Logan, Ateleanu, & Hall, 2006) This type of anesthetic requires constant vigilance on the part of the anesthesia provider and, at times, frequent interventions (chin lift/jaw thrusts or placement of an oral airway or nasal trumpet). Furthermore, 28-38% of patients experience oxygen desaturations of < 90% and a small percentage (0.2%) experience aspiration pneumonia which may lead to significant morbidity and mortality.(Klare et al., 2016; Yang, Farooq, Zwilling, Patel, & Siddiqui, 2016)

Management of a native airway for overweight individuals or for longer procedures is particularly challenging.(Cote et al., 2010; Vargo, 2014) The alternative to propofol sedation with a native airway

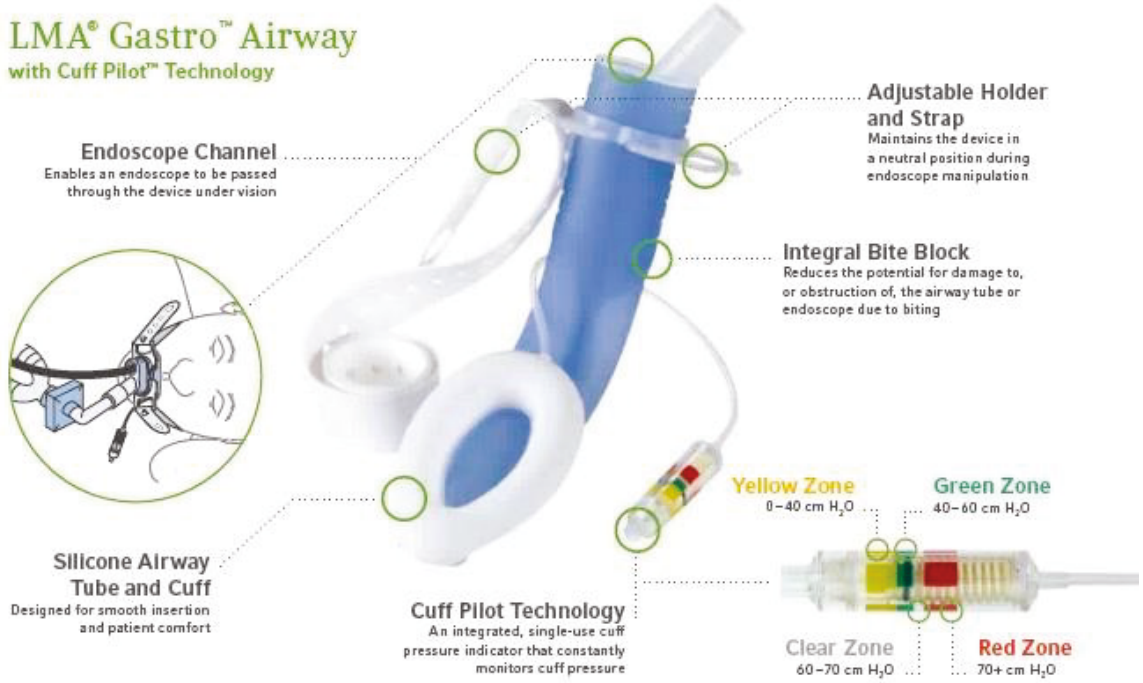
is endotracheal intubation (which is more invasive for the patient, increases anesthesia time, and is not without its own risks, such as prolonged muscle paralysis and dental damage). Osborn et al. demonstrated that it was feasible to perform ERCP with a laryngeal mask airway by displacing the LMA tube to the lower left side of the mouth.(Osborn, Cohen, Soper, & Roth, 2002) LMAs are generally placed easily by trained practitioners, with a maximum of 3 attempts allowable, as described by the Difficult Airway Society.(Frerk et al., 2015)

The LMA® Gastro™ represents a novel device with the ability to facilitate direct endoscopic access via the integrated endoscopic channel. The safety of the LMA® Gastro™ for esophagogastroduodenoscopy and ERCP has been demonstrated(Skinner, 10/24/2016), (Hagan, 2020). We propose a randomized control trial of the LMA® Gastro™ versus standard nasal cannula to elucidate the true oxygenation benefits of this device.

3. Background Device Information

The LMA® Gastro™ has separate gastric and airway access. The LMA® Gastro™Airway with Cuff Pilot™ Technology from Teleflex is the only supraglottic airway (SGA) specifically designed to give clinicians control of the patients' airway while facilitating direct endoscopic access via the integrated endoscopic channel. With the LMA® Gastro™ in place, clinicians can monitor end tidal CO_2 for patient safety. The LMA® Gastro™Airway is indicated for airway management in adult patients.

The LMA® Gastro™Airway is a single-use laryngeal mask with a di(2-ethylhexyl)phthalate (DEHP)-free silicone cuff and airway tube. The silicone cuff is soft and flexible. It conforms to patient anatomy to create an effective oropharyngeal seal. The LMA® Gastro™Airway also features Cuff Pilot Technology – an integrated, cuff pressure indicator that constantly monitors cuff pressure detecting changes resulting from fluctuations in temperature, nitrous oxide levels and movements within the airway. It provides at-a-glance feedback, highlighting changes that could affect patient safety so that adjustments can be made when necessary.



4. Study Design

This is a prospective, controlled, randomized trial.

5. Discussion of Study Population

5.1 Study Characteristics

a) **Number of Subjects:** This study will enroll 56 evaluable (defined as in Section 12.2) patients. We anticipate a screen failure rate of 30-50% and an attrition of consent rate of 10%. We will keep enrolling patients until we have 56 evaluable patients. Factoring the attrition rate of 10%, we will need to enroll 64 patients to ensure that we have 56 evaluable patients.

5.2 Inclusion and Exclusion Criteria

a) Inclusion Criteria

- Adult patients (≥ 18 years old) undergoing ERCP.

b) Exclusion Criteria

- Patients with propofol allergy
- Patients at increased aspiration risk
- Patients with abnormal head/neck pathology preventing LMA® Gastro™ placement
- Patients with surgical or radiation treatment to the head/neck making LMA® Gastro™ placement difficult
- Patient with known difficult airway requiring advanced intubation equipment (with the

exception of the video-laryngoscope) in the past
- Esophagectomy patients
- Patients already intubated upon arrival to endoscopy suite
- Patients undergoing Endoscopic Ultrasound (EUS)
- Patients with BMI ≥ 35 kg/m^2
- Patients with hypoxemia (SpO_2 <94% on room air or on home oxygen)
- American Society of Anesthesiology (ASA) Physical Status IV-V
- Cognitively impaired adults, pregnant women, students, and employees
- Non-readers/Non-English speakers

6. Subject Identification, Recruitment and Consent

6.1 Method of Subject Identification and Recruitment

Eligible subjects will be identified from within the patient population of the study site by members of the research team. Advertisements for study subjects are not anticipated.

6.2 Consent Process

Subjects deemed eligible to participate in the study will be explained in detail the purpose, nature and procedures of the study, as well as the potential risks, benefits and alternatives. They will be given a consent form to read and if they so choose, to discuss with friends, family, and other clinicians. They will be invited to ask questions and, after all questions are answered to their satisfaction, invited to sign the consent form. The Principal Investigator or another member of the research team will participate in the consenting process to ensure the subject has full understanding of the procedure and risks. No study-specific procedure will be performed before the consent form is signed.

All consents will be signed electronically within the medical record on a MD Anderson password protected computer.

6.3 Costs to the Subject

None

6.4 Payment for Participation

There will be no payments for participation in the study.

6.5 Return of Individual Research Results

Individual research results will not be provided back to the subject.

7. Methods and Study Procedures

7.1 Pretreatment Evaluation

The PI/Co-PI/research coordinator of the study will evaluate the inclusion/exclusion criteria. Patients will be approached while in the preoperative area to discuss participation in the study. The PI/Co-PI/research coordinator will ensure that patients are properly informed about the study. All study related data will only be collected after the PI or Co-PI approves patient enrollment in the study and the patient has signed the consent.

7.2 Procedure

Intervention Group: Standard ASA monitors will be applied to all patients. Patients in the LMA® Gastro™ group will be pre-oxygenated with 100% oxygen via full face mask in the supine position prior to induction of general anesthesia. Pre-oxygenation will be administered for 3 minutes of normal tidal volume breathing or for 8 deep breaths over one minute, or until end expiratory oxygen reaches 90%.

Prior to patient induction, the appropriate size LMA® Gastro™ will be chosen based upon manufacturer recommendations and anesthesia assessment. The inside of the LMA will be sprayed with silkospray. The LMA® Gastro™ will be fully deflated and the posterior aspect will be lubricated with KY jelly as per manufacturer instructions prior to insertion.

Once pre-oxygenation is complete, patients will be induced with 0.5-1 mg/kg lidocaine and 1-4 mg/kg propofol. Upon loss of the patients lash reflex, the LMA® Gastro™ will be placed in the patient's oropharynx. The anesthesiologist may attempt placement for a maximum of 3 attempts. The cuff should be inflated until the cuff pilot indicator line is within the green zone. Appropriate placement will be confirmed with end tidal CO_2 and adequate tidal volumes of at least 4-5 cc/kg. Following placement confirmation, sedation will be titrated to achieve deep to general anesthesia using a propofol infusion at 50-300 mcg/kg/min. Insufficient sedation with propofol may be supplemented with inhalational anesthetics, opioids, and/or benzodiazepines.

After securing the airway, the patient will be positioned on the fluoroscopy table in the prone position with head facing to the right (although occasionally patient may be positioned in the left lateral decubitus or supine position) to facilitate the ERCP. Positioning is at the discretion of the gastroenterologist. After the patient is positioned, the anesthesiologist will again confirm that the LMA® Gastro™ is positioned properly before allowing the procedure to begin. During the procedure, the patient may receive positive pressure ventilation keeping airway pressures $\leq$20 mmHg or the patient may maintain spontaneous ventilation with or without ventilator support, as long as adequate minute ventilation (≥5 L/min) and appropriate end tidal CO_2 (< 45 mmHg) is maintained.

A duodenoscope will be lubricated with KY Jelly by the gastroenterologist and inserted into the LMA® Gastro™. Should the LMA® Gastro™ impede completion of the procedure, the anesthesiologist will remove the LMA® Gastro™ and either proceed with a native

airway or place an endotracheal tube. This decision will be at the discretion of the anesthesiologist. A research assistant will note the frequency of additional airway maneuvers such as chin lift and jaw thrust.

Standard of Care: Upon arrival to the procedure room, standard ASA monitors will be applied to all patients. Patients will be positioned on the fluoroscopy table in the prone position with head facing to the right (although occasionally patient may be positioned in the left lateral decubitus or supine position) to facilitate the ERCP. Positioning is at the discretion of the gastroenterologist. After the patient is positioned, the anesthesiologist will apply standard nasal cannula at 2-3 L/minute. A bite block will be placed in the patients mouth prior to or simultaneous to beginning sedation.

Patients will be induced with 0.5-1 mg/kg lidocaine and 0.5 - 1 mg/kg of propofol and will be started on a propofol drip at 50-200 mcg/kg/min. The drip will be titrated to achieve a deep to general level of sedation as defined by the American Society of Anesthesiologists (ASA) Continuum of Depth of Sedation Scale. A duodenoscope will be lubricated with KY Jelly by the gastroenterologist and inserted into the LMA® Gastro™. The decision to intubate should the patient experience recurrent (>2 desaturations < 90%) or prolonged desaturations (desaturation <90% for longer than 1 minute) is at the discretion of the anesthesiologist and gastroenterologist. Insufficient sedation with propofol may be supplemented with opioids or benzodiazepines. A research assistant will note the frequency of additional airway maneuvers such as chin lift and jaw thrust.

7.3 Data Collected from EMR

- Demographics (e.g. BMI, age, gender)
- Comorbidities
- Indication for procedure
- Dosing of medications
- Information regarding anesthetic management
- Information about the ERCP procedure
- Patient vital signs
- Ventilation/Respiratory data
- Anesthesiologist identifier (training video viewed, number of practice attempts, years of experience)
- Anesthesia times (anesthesia start to anesthesia end and procedure end to anesthesia end)
- Procedure times (procedure start to procedure end)

7.3 Additional Data Collected by Research Coordinator

- Incidence of desaturation to a SpO_2 < 90% (See Appendix 2)
- Amount of time spent with oxygen saturation < 90% (See Appendix 2)

- The incidence of additional airway maneuvers (jaw thrust/chin lift/placement of oral airway or nasal trumpet/intubation) (See Appendix 2)
- The incidence of withdrawal of duodenoscope from the airway to facilitate airway support (See Appendix 2)
- Adverse events (See Appendix 2)

8. Subject Withdrawals

Subjects may be withdrawn from the study for the following reasons:

1). Subject non-compliance with study procedures
2). Unacceptable adverse events (safety or tolerability)
3). The subject may withdraw from the study at any time and for any reason
4). Clinician decision that it is in the best interest of the subject to withdraw from the study

9. Safety and Reportable Events

9.1 Adverse Event Definition

An adverse event is any symptom, sign, illness, or experience which develops or worsens during the course of the study, whether or not the event is considered related to investigational product. This includes a change in a subject's condition or laboratory results, which has or could have a deleterious effect on the subject's health or well-being. An Adverse Event that is related to the investigational device may be referred to as an Adverse Device Effect (ADE).

Unanticipated Adverse Device Effect (UADE): Any device related adverse event, the nature or severity of which is not consistent with or listed in the applicable product information (e.g., instructions for use, subject informed consent document, subject information brochure [if applicable], promotional literature) or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects. These are dichotomous outcomes.

Expected Adverse Events
Abrasion to lips, tongue, or oral mucosa
Conversion to endotracheal intubation or native airway
Small amount of blood tinged sputum
Sore throat

9.2 Serious Adverse Event

A serious adverse event is defined as any adverse medical experience that results in any of the following outcomes:

- Death
- Is life-threatening

- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect
- Requires medical or surgical intervention to prevent permanent impairment or damage

9.3 Recording Adverse Events

The site study staff will assess adverse events by recording all voluntary complaints of the subject and by assessment of clinical and laboratory features.

All adverse events, whether observed by the investigator, elicited from or volunteered by the subject, should be documented. Each adverse event will include a brief description of the experience, the date of onset, the date of resolution, the duration and type of experience, the severity, the relationship to investigational product (i.e. the device), contributing factors, and any action taken with respect to the study device.

9.4 Responsibilities for Reporting Serious Adverse Events

The Investigator should record all serious adverse experiences that occur during the study period in the appropriate source documents and/or AE log as applicable. The study period for reporting serious adverse events (e.g. from the time of signing consent to final study visit) should be indicated, who needs to be notified and the time frame for notification. If there are any specific reporting forms to be completed, this should be indicated here. The Investigator will comply with regulations and IRB policy regarding the reporting of adverse events.

10. Risk/Benefit Assessment

10.1 Potential Risks

- Minor trauma to the lips of oropharynx
- Difficulty ventilating through the LMA® Gastro™
- Possibility that device will need to be removed prior to procedure completion, necessitating intubation

10.2 Protection Against Risks

- Appropriate patient selection, avoiding patients with oropharyngeal abnormalities

10.3 Potential Benefits to Subjects

- More secure airway with reduced risk of respiratory compromise and aspiration than treatment with a native airway
- Less likely to have a sore throat than with endotracheal intubation

10.4 Alternatives to Participation

- Management of the airway with an endotracheal tube or with a native airway at the discretion of the anesthesiologist

11. Confidentiality of Data and Information Storage

All study participants will be assigned a study number. The PI will maintain the key to the study number and medical record number in a password locked MD Anderson computer. Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Patient data will be entered into a password protected electronic spreadsheet and online database (i.e. REDCap). Only the investigators, who have been invited to participate in the study and who are registered with the IRB, as well as have documented completion of all IRB and HIPAA regulations will have access to patient data, but not the medical record key.

Electronic records will be stored for 5 years after study conclusion on the institution's password protected computer, after which time they will be deleted. If there is a breach in confidentiality or violation of IRB and HIPAA regulations, the IRB will be notified in a timely manner (within 7 days) and appropriate actions taken thereafter. All data used in the analysis and reporting of this investigation will be de-identified. Any photography shall be done in a discrete manner. Should images run the risk of enabling patient identification, identifying characteristics will be obscured electronically prior to publication.

In order to ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA), all subjects enrolled in the study will be required to provide authorization to disclose Protected Health Information (PHI). This authorization will be included in the informed consent document as required by the IRB. In all study reports and in any resulting publications, subjects will not be referred to by their initials and/or study identification number.

12. SAMPLE SIZE DETERMINATION AND DATA ANALYSIS

12.1 Randomization

Once patients meet all inclusion criteria, they will be randomized to receive either LMA® Gastro™ or standard nasal cannula with a 1:1 allocation ratio. CORe at MDACC will be used for randomization. Subjects will be randomized on the day of the scheduled procedure. Patients will be blinded as to their study group.
Once the patient is consented, a research coordinator will register the patient in CORe. A randomization number will be generated, and study anesthesiologist will be notified.

12.2 Sample Size Determination

The primary objective of the study is to determine if the LMA Gastro group will have a significantly smaller percentage of patients with incidence of desaturations less than 90% when compared to patients on the standard nasal cannula. The primary endpoint,

incidence of desaturations (SpO_2 < 90%), is defined as at any time under sedation during procedure a patient has experienced at least one episode of desaturations (SpO_2 < 90%). We assumed the incidence of desaturation (SpO_2 < 90%) to be 5% or less in the LMA® Gastro™ group(Hagan, 2020). If the incidence of desaturation (SpO_2 < 90%) is 38% in the standard nasal cannula group(Klare et al., 2016), then we require 28 patients per group (a total of 56 patients) in order to provide approximately 81% power to detect the difference in incidence of hypoxemia (SpO_2≤90%) using Fisher's exact test with a two-sided type I error rate of 0.05 (nQuery Advisor 7.0).

Previous studies had a patient attrition rate of 10% after consent.(Hagan, 2020) Therefore we will enroll 64 patients (32 in each study arm) to ensure sufficient evaluable participants. Evaluable patient is defined as a patient who has the assessment for the primary endpoint.

Table 1. Sample size justification for the comparison of two proportions

Two group Fisher's Exact test of equal proportions (equal n's)	
Test significance level, alpha	0.05
1 or 2 sided test?	2
Group 1 proportion	38%
Group 2 proportion	5%
Power (%)	81%
n per group	28

12.3 Planned Statistical Analysis

We will summarize continuous demographics and clinical variables, such as age and anesthesia time, using means, standard deviations, medians and ranges. Categorical demographic variables and clinical variables, such as gender, incidence of additional airway maneuvers, incidence of adverse events and incidence of withdrawal of duodenoscope from airway to facilitate airway support, will be summarized through frequencies and percentages. Fisher's exact test will be used to compare the percentage of patients with desaturations (SpO_2 < 90%) between LMA Gastro and standard nasal cannula groups, as well as patient reported sore throat in recovery and other categorical variables of interest. Wilcoxon-rank sum test will be used to compare continuous outcomes between study arms. Logistic regression model may be fitted to assess the effect of important covariates on the primary endpoint.

13. Data Monitoring

a. Data and Safety Monitoring

Training of Clinical Site Personnel

The PI will conduct a training session with all anesthesia collaborators. The anesthesia collaborators will view a video demonstrating placement of the LMA® Gastro™ and will practice LMA® Gastro™ placement on a mannequin 10 times prior to being cleared to begin the study.

b. Data Collection and Management

All study data will either be collected on a paper case report form (CRF) (which will be entered in a computer database) or will be extracted directly from the EMR to the REDCap database. Each subject will be assigned a random number code and the key linking the code and the subject identifier will be stored on an MD Anderson password protected computer. All changes to the CRF will follow Good Clinical Practice guidelines. The Research Manager is responsible for auditing the consistency of the data transcribed from the paper CRF to the computer. A protocol violation log will be maintained and all protocol violations will be reported to the IRB.

Members of the research team are responsible for transferring the information to the appropriate CRFs. The PI is responsible for ensuring the forms are accurately completed at the time of, or as soon as possible after, the subject procedure or the availability of test results. The PI is required to sign the CRF on the appropriate page(s) to verify that she has reviewed the recorded data. Upon PI approval, CRFs will be entered into the password protected REDCap database for analysis.

Additional clinical monitoring by the sponsor will be at the sponsor's discretion.

14. References

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14. Appendix 0

14.1 Calendar of Events
14.2 RCF for Intraprocedural events

Appendix 1: Calendar of Events

Visit Window	Screening	Intra-op	Post-op
Subject Recruitment	x		
Enrollment/Pt education	x		
Medical Record Documentation	x	x	x
CRF completion		x	x

Appendix 2: RCF for Intraprocedural and Postprocedural Events

1) Incidence of desaturation to a SpO_2 < 90% in patients undergoing ERCP with LMA® Gastro™ vs standard nasal cannula
2) Amount of time spent with oxygen saturation < 90% in patients undergoing ERCP with LMA® Gastro™ vs standard nasal cannula

3) The incidence of additional airway maneuvers (jaw thrust/chin lift/placement of oral airway or nasal trumpet/intubation)
4) The incidence of withdrawal of duodenoscope from the airway to facilitate airway support
5) Adverse events