THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Protocol Page

RANDOMIZED COMPARISON OF AMBU® AURAGAIN™ AND TELEFLEX® LMA PROTECTOR™ USING CLINICAL AND FIBEROPTIC ASSESSMENTS IN ELECTIVE PATIENTS
2017-0449

Core Protocol Information

Short Title	AMBU® AURAGAIN™ AND TELEFLEX® LMA PROTECTOR™ FIBEROPTIC ASSESMENTS IN ELECTIVE PATIENTS
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Full Title:	RANDOMIZED COMPARISON OF AMBU® AURAGAIN™ AND TELEFLEX® LMA PROTECTOR™ USING CLINICAL AND FIBEROPTIC ASSESSMENTS IN ELECTIVE PATIENTS
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Which Committee will review this protocol?

◉ The Clinical Research Committee - (CRC)

Protocol Body

1.0 Background

Since the introduction of the first laryngeal mask airway, the Classic LMA®, the use of supraglottic airway devices (SGADs) have experienced a remarkable evolution and are now routinely used in clinical anesthesia practice. One of the SGADs on the market is the LMA Protector™ (Teleflex Medical Europe Ltd., IDA Business and Technology Park, Dublin Road, Athlone, Co. Westmeath, Ireland), which is a single-use modification of the older, reusable LMA Proseal™ (Teleflex). The LMA Protector™ has a pre-curved, rigid airway tube similar to the Ambu AuraGain™ (Ambu A/S-Copenhagen, Demark). The concept of a curved airway tube is to imitate the airway anatomy during device placement, thus making insertion relatively easy and smooth. Like some of the newer SGADs, they have a built-in gastric drainage channel to facilitate efflux of gastric fluid and gas, and allows for the insertion of a gastric tube. These devices are referred to as second generation SGADs.

Due to the similarities between the AuraGain™ and the LMA Protector™, a randomized, prospective clinical study with a detailed evaluation of the performance of these two devices will be conducted. The AuraGain™ is Ambu's 3rd generation laryngeal mask, satisfying 3 fundamental airway management needs by integrating gastric access and intubation capability in an anatomically curved single-use device that facilitates rapid establishment of a safe airway. The LMA® Protector™ is a next-generation, single-use laryngeal mask with a dual gastric drainage channel and pharyngeal chamber designed specifically to channel high volume, high pressure gastric contents away from the airway. A clinical evaluation will be performed on elective patients with normal airway anatomy for device insertion, function as a ventilatory device and as an intubation conduit, functionality of the gastric drainage channel, oropharyngeal leak pressure (OLP). Also, a fiberoptic assessment, utilizing the Ambu® aScope™ 3 Slim, of the glottic view via the SGAD device and signs of airway morbidity will be investigated.

2.0 Objectives and Hypothesis

The purpose of this study is to estimate the ratio or difference in success rate of both the Ambu® AuraGain™ and Teleflex® LMA Protector™ during insertion and placement into an airway. Other findings include ease of supraglottic airway device (SGAD) insertion, anatomical fit of the SGAD (i.e. SGAD displacement, bloodstaining), rate of successful ventilation and intubation, functionality of gastric drainage channel (via orogastric tube insertion through each SGAD; to ensure easy insertion), oropharyngeal leak pressure (OLP; measured by a portable, handheld manometer), and postoperative complications in elective surgical patients who are not expected to have a difficult airway. Also, a fiberoptic assessment (with the Ambu® aScope™ 3 Slim) of the glottic view via the SGAD device and signs of airway morbidity will be investigated.

2.1 **Primary**: The ratio or difference in success rates of either the Ambu® AuraGain™ or Teleflex® LMA Protector™ during insertion and placement into an airway.
2.2 **Secondary**: Rate of successful ventilation and intubation (by utilizing the SGAD as an intubation conduit guided by the Ambu® aScope™ 3 Slim), ease of SGAD insertion (based on a numerical subjective rating scale), anatomical fit of SGAD (i.e. SGAD displacement, bloodstaining), OLP (measured by a portable, handheld manometer), functionality of gastric drainage channel which will be inserted through the appropriate channel of the SGAD, and postoperative complications
2.3 **Exploratory**: Fiberoptic assessment of the glottic view via the SGAD device and signs of airway morbidity

3.0 Device Description

The AuraGain™ is Ambu's 2nd generation laryngeal mask, which satisfies three fundamental airway management needs by integrating gastric access and intubation capability in an anatomically curved single-use device that facilitates rapid establishment of a safe airway. AuraGain™ is the only anatomically curved SGAD with integrated gastric access and intubation capability. The integrated gastric access channel is designed with a low friction inner surface to facilitate easy placement of a gastric tube. The AuraGain also provides intubation capabilities in case of an unexpected difficult airway, or a 'Cannot Intubate, Cannot mask Ventilate' (CICV) situation. The AuraGain™ can be used as a conduit for direct endotracheal intubation assisted by a flexible scope (such as the Ambu® aScope3).

The LMA® Protector™ is a next-generation, single-use laryngeal mask with a dual gastric drainage channel and pharyngeal chamber designed specifically to channel high volume, high pressure gastric contents away from the airway. The LMA® Protector™, with its 100% silicone cuff and airway tube, is designed to be gentle to one's airway anatomy. The elongated cuff integrates two technological advancements for facilitating esophageal seal and indicating cuff pressure levels. This enables clinicians to monitor pressure levels at a glance and adjust when necessary. The LMA® Protector™also allows for intubation with compatible sizes of endotracheal tubes to provide a safer and more effective option for airway replacement.

The Ambu® aScope™ 3 Slim is an ultra slim, single-use, flexible scope that once and for all solves the problem of accessibility, simplifies set-up procedures and eliminates the need for complex cleaning procedures thus releasing valuable resources for other procedures as an alternative to reusable scopes. The Ambu® aScope™ 3 Slim's distal end contains a camera with two LED light sources, a maneuverable tip with a bending angle of 130°/130°, as well as, suction and channel ports (including an ETT connection). When connected to the aView monitor, the Ambu® aScope™ 3 Slim provides high quality images of anatomical landmarks that are suitable for various airway procedures such as intubation, airway inspection, double lumen tube placement, bronchial blocker placement, and even Aintree catheter placement.

4.0 Patient Population

A total of 50 patients will be included in this study to be carried out at the Outpatient Surgical Center by the Department of Anesthesiology and Perioperative Medicine at MD Anderson Cancer Center in the Texas Medical Center, Houston. All patients will be adult surgical candidates, ASA I-III, Age >18 years, Mallampati I – III, BMI ≤ 30 kg/m^2. Patients will be excluded if they meet any of the listed following: ASA IV-V, Age < 18 years old (as the SGADs will not be supplied in pediatric sizes), require prone position for surgery, planned operating time > 4 hours, liquid only diet < 2 hours, are at high risk of regurgitation, exhibit signs of respiratory tract pathology, or have a sore throat preoperatively. In addition, patients with any of the following features

will also be excluded: Mallampati IV, upper lip bite not possible, inter-incisor distance < 2.5 cm, thyromental distance < 6 cm, limited neck movement, airway pathology/facial abnormality, diagnosed with dementia or exhibit any neurological mental disorders (handicaps) such as epilepsy, Alzheimer's disease, Parkinson's disease, etc.

Inclusion Criteria
Subjects enrolled in this study will meet the following inclusion criteria:

1) Age 18 years of age or older
2) Scheduled for an elective surgery requiring general anesthesia
3) Scheduled surgery < 4hrs
4) American Society of Anesthesiology (ASA) Physical Status I-III
5) BMI $\leq$ 30 kg/m^2
6) Mallampati I-III
7) Able to bite upper lip via Upper Lip Bite Test (ULBT)
8) Inter-incisor distance > 2.5cm
9) Thyromental distance > 6cm
10) Full range of motion in the neck
11) Has provided written informed consent

Exclusion Criteria
Subjects will not be enrolled in this study if they meet any of the following exclusion criteria:

1) Under the age of 18 years old
2) ASA IV-V
3) Require prone positioning for surgery
4) Scheduled surgery > 4hrs
5) Liquid only diet < 2hrs and/or solids < 8hrs
6) High risk of regurgitation
7) Exhibits signs of respiratory tract pathology (including a sore throat preoperatively)
8) Mallampati IV
9) Unable to bite upper lip via ULBT
10) Inter-incisor distance < 2.5cm
11) Thyromental distance < 6cm
12) Limited neck movement
13) Airway pathology/facial abnormality
14) Has been diagnosed with/exhibits any mental neurological disorder/disease/condition that would prevent participation in the study in the opinion of the investigator.

5.0 Randomization

CORe will be the designated software for the randomization of each intervening device (SGAD) arm. The treatment will be named 1 for Ambu® AuraGain™, 2 for Teleflex® LMA Protector™ for both parts of the study in the list. Block randomization is 25 blocks of size of 2.
The following demographic data and medical history will be collected on the case report form (CRF): Gender, age, height, weight, body mass index, fasting time, ASA class, Mallampati classification, thyromental distance, sternomental distance, interincisor distance, and ability to protrude lower jaw. Please refer to Appendix 'C'.

6.0 Subject Identification, Recruitment and Consent

Discussion of Subject Population
Patients that elect to have surgery typically require general anesthesia and tracheal intubation. Tracheal intubation is usually acheived, traditionally, by direct or indirect laryngoscopy, and is the preferred method when securing an airway. SGADs are the recommended alternative to laryngoscopy via laryngoscopes if failed or not possible, to aid in sufficient oxygenation and ventilation of patients according to difficult airway algorithms.Therefore, SGADs are constantly studied for significance and adequacy as a rescue device for emergent scenarios or when laryngoscopy fails.

Method Of Subject Identification And Recruitment
Eligible subjects will receive a detailed explanation of the study, its purpose, their role, and study procedures in relation to what's considered research and standard of care (SOC); as well as the potential risks, benefits and alternatives prior to study enrollment. 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 in accordance. The Principal Investigator (or delegate) 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.

Consent Process
Eligible subjects will receive a detailed explanation of the study, its purpose, their role, and study procedures in relation to what's considered research and standard of care (SOC); as well as the potential risks, benefits and alternatives prior to study enrollment. 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 in accordance. The Principal Investigator (or delegate) 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.

Subject participation in this investigation is voluntary. Written informed consent is required from all subjects prior to the subject's participation in the investigation. Also, an obtained permission of the faculty anesthesiologist, in charge of the patient's anesthesia care, must also be granted for subject participation. If the subject is illiterate or unable to adequately read the informed consent form, a witness' signature and a cross mark or a fingerprint of the subject is required. In accordance with FDA regulation 21 CFR Part 50, informed consent shall be obtained prior to any study procedure. The original of the signed consent

will be retained at the investigational site. A signed copy of the consent will be given to the subject. While not anticipated, Sponsor will report any failure to obtain subject consent to the IRB within 5 days of learning of such an event, as required by regulation.

Prior to participating in this investigation, the site will be required to have an IRB-approved Informed Consent Document. Any modifications to the consent must be approved by Sponsor and by the IRB of record. The Principal Investigator at each study site is responsible for obtaining and maintaining the approved informed consent and forwarding an IRB-stamped copy to Sponsor.

7.0 Criteria for Removal from the Study

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

Clinician decision that it is in the best interest of the subject to withdraw from the study

8.0 Study Intervention and Data Collection

This study involves the placement and usage of a laryngeal mask airway on a human subject for adequate airway management, oxygenation, and ventilation. The intervention directly related to this study is that of airway management, airway device/equipment, oxygen administration, mechanical ventilation, fiberoptic assistance, and tracheal intubation. The subject will have a surgical procedure that is incidental to his or her study participation, along with tracheal intubation. Besides the principal investigator and co-investigator, listed collaborators (anesthesiologists) will be involved in managing enrolled patient airways in accordance to the protocol. Randomization of the anesthesia practitioner is not necessary and will not occur. All patients will be recruited and enrolled based on the availability of the 8 study anesthesiologists during the study period.

Patient Preparation Procedures

Prior to the surgical procedure, patient demographics and airway assessment will be recorded, as well as the selected randomized SGAD that will be used to secure the airway. The patient will be monitored with 5-lead ECG, pulse oximetry, non-invasive blood pressure (BP) and end-expiratory gas analysis. Vital sign measurements will be taken and recorded at the following time points: Pre-oxygenation, pre-induction, post-induction, post-SGAD insertion, 10 minutes after SGAD insertion, on admission to the post anesthesia recovery unit (PACU), and every 30 minutes until discharge from PACU. The patient will be positioned supine on the operating table with the head resting on a foam cushion and/or pillows and blankets (if needed). The patient will be pre-oxygenated via full facemask for a minimum of 3 minutes. Prior to pre-oxygenation, the circle system will be filled with 100% oxygen. The flow of oxygen will be set at 10 liters to obtain the highest end tidal concentration of oxygen (EtO_2).

General anesthesia will be induced via traditional methods as requested by the anesthesiologist. Appropriate doses of propofol, fentanyl, and rocuronium will be administered as recommended by the anesthesiologist's discretion. A mixture of sevoflurane or desflurane will be utilized for maintenance of anesthesia. Vital signs will be recorded throughout. Lungs will be mechanically ventilated with a semi-closed circle system to maintain an end-tidal CO_2 near 35mmHg. Once there are no twitches on the train of four (ToF) twitch monitor, following rocuronium administration, insertion of the randomized SGAD will then be performed. The size of the SGAD device used will be based on the manufacturers' recommendations or by clinical evaluation of the patient the anesthesiologist.

SGAD Preparation Materials

The following materials will be ready on a preparation table before the anesthesia procedure is commenced: tablecloth, water-soluble lubricant, correct size of SGAD and one size bigger and one size smaller, 20 & 50 ml syringes, pressure gauge, silk tape for fixation of the SGAD, 16 Fr. gastric tube (max. size gastric tube recommended by the manufacturer – is listed in the CRF), 5 gauze wipes, and a timer.

aScope Preparation Procedures

Prior to its use, the Ambu aScope3 Slim, and compatible Ambu aScope monitor, will be inspected for: visual harm to the scope, mechanical performance by tip manipulation, in which the distal end should be bent to a maximum in both directions while the scope is held in a straight position (The bending degree should be at least 110°), and aScope3 to aScope monitor connection. The quality of the monitors' standard installation should be evaluated. If the picture is not acceptable from the beginning, the quality will be adjusted via the contrast button and light button. When the picture quality is evaluated, the aScope3 Slim will be placed 1 cm from black letters placed on a white background to secure picture quality. When preparing the aScope3 Slim, the insertion cord should be well lubricated. When the aScope3 Slim has fulfilled the functional criteria, it should be placed on the preparation table and turned off. If flaws or errors are detected with the aScope3 Slim or the aScope monitor, either should be replaced and a new aScope3 evaluation will be performed with the new device. An alcohol wipe shall be used to thoroughly clean the lens if the image is not clear. Antifog should not be used for cleaning the aScope™ 3 Slim lens.

1. Insertion of the SGAD

The patient will be placed in the sniffing position to optimize the oropharyngeal angle. The SGAD will be lubricated on the posterior surface of the cuff prior to insertion. Timing will begin when the tip of the cuff of the device touches the patient's lips. During insertion, the tip of the cuff will be pressed upwards against the hard palate and the cuff will be flattened against it. Jaw lift technique will be used on all patients. A jaw lift is performed by using the index finger and thumb of the non-dominant hand to lift the chin while the device is passed along the hard palate with the dominant hand. Additional maneuvers performed to optimize positioning or ventilation, such as adjusting head/neck position, additional jaw lift, adjusting depth of insertion, lateral insertion technique, or changing size of the SGAD. For the SGAD to be considered as placed correctly, the teeth of the patient should be between the teeth-marks indicated on the proximal end of the airway tube designed as a bite absorption area. The appearance of the first square end tidal carbon dioxide trace will indicate establishment of effective ventilation, and T1 (watch 1) will be stopped. Once successful placement has been confirmed, the cuff of SGAD will be inflated with air to attain an intra-cuff pressure of 60 cm H2O, measured with a handheld aneroid manometer (pressure gauge). The volume of air will be recorded. The SGAD will be taped to the participant's cheek with adhesive tape.

Unsuccessful appearance of CO2 curve suggests incomplete placement of the SGAD, and the device will be removed completely and another insertion attempt should be performed while the recording of time continues. An insertion attempt is defined as, when the SGAD touches the patient's lips. Only three attempts shall be made for proper device placement. The first two attempts will be made by either attending anesthesiologists or certified registered nurse anesthetists (CRNA) and the final attempt by the attending anesthesiologist. In case of failure of both SGAD and bag-mask ventilation, the airway will be secured according to the discretion of the attending anesthesiologist.

2. Fiberoptic Evaluation of the SGADs Anatomical Position
Once ventilation is achieved, the laryngeal view will be determined, thus illustrating the anatomical positioning of the device. The investigation will be performed with the aid of the flexible scope, the Ambu aScope3 Slim, which will be introduced into the airway tube and guided through the SGAD until it is possible to view the vocal cords. Description of the maximal optical view will be measured by the Percentage Of Glottic Opening (POGO).1 The POGO score and any presence of blood will be recorded.

If the epiglottis is down-folded obscuring the optical view, a jaw lift will be performed and another POGO score will be obtained. In case of secretions or blood, the channel of the aScope3 Slim will be used for removing the debris. If this fails, the aScope3 Slim will be withdrawn and a suction catheter will be used, and the lens of the aScope3 Slim will be cleaned using an alcohol wipe, before a new attempt is commenced.

3. Investigation of the Functionality of the Gastric Drainage Channel of the SGADs
A size 16 Fr. gastric tube will be pre-lubricated with a water-soluble lubricant and will be passed through the gastric drainage channel, of either SGAD, until depth mark of 40-50 cm. The female gastric drainage channel will be used on the Protector. Confirmation of gastric tube placement will be obtained by aspiration of 2 ml of gastric content and/or auscultation of inflated air at the epigastrium.

An insertion attempt is defined as when the tip of the gastric tube touches the proximal channel. Insertion failure is defined as inability to pass a gastric tube until appropriate depth mark, lack of confirmation of correct placement by auscultation, and inability to evacuate any gastric content.

Additionally, the ease of insertion of gastric tube, number of insertion attempts, volume of air evacuated, volume of gastric content, and fluid observed in gastric drainage channel will be recorded.

4. Measurement of Oropharyngeal Leak Pressure (OLP)
The measurement of OLP will be performed, with an Ambu cuff pressure gauge, prior to surgical incision and at the end of surgery; this measurement will be performed by closing the adjustable pressure-limiting valve, with a fresh gas flow of 3 L/min, and noting the airway pressure at equilibrium. The maximum pressure allowed is 40 cmH2O. The epigastrium will not be auscultated when measuring leak pressure with the purpose of detecting any possible air entrainment into the stomach intraoperatively. Moreover, OLP and any audible leak into the stomach or over the mouth will also be recorded.

5. Use of SGAD as an Intubation Conduit

1) Intubation Procedure
An intubation procedure will be performed by placement of an ETT over the Ambu aScope3 Slim. A standard use Parker Flex Tip™ ETT of maximum recommended size will be used depending on SGAD size for both female and male patients. ETTs of 6.0, 7.0, and 8.0 mm will be paired with the AuraGain, sizes 3, 4, and 5 respectively. An ETT of 6.0 mm will be paired with the LMA Protector size 3, and ETTs of 7.0 and 8.0 mm will be paired with the LMA Protector, sizes 4 and 5 respectively.
The airway tube of the SGAD will be lubricated and the aScope3 Slim will be passed through the airway tube until carina is visualized. Once the aScope3 Slim is at the carina, the ETT will be passed down the insertion cord of the aScope3 Slim and correct placement of the ETT will be verified. Once the ETT is placed correctly, the cuff of the ETT will be inflated and the aScope3 Slim will be removed.

An intubation attempt will be defined as from when the tip of the ETT is touching the SGAD connector and advanced through the SGAD. If an unsuccessful attempt occurs, and the ETT is withdrawn from the SGAD, the next attempt will be considered a new attempt. No more than 3 intubation attempts shall be made for proper ETT placement. If unsuccessful after 3 attempts with at least 2 different size SGAD devices used, standard tracheal intubation will be performed.

Intubation time will be measured from when the tip of the aScope3 Slim is touching the SGAD connector until endoscopic confirmation of correct ETT placement. End-tidal capnography will be used to confirm successful intubation. In addition, size of SGAD, size of ETT, and number of intubation attempts will also be recorded. Qualitative assessment of ease of intubation, and will be based on an analog scale from 1-4: 1: Easy 2: Resistance 3: Difficult 4: Unsuccessful.

9.0 Risks and Benefits

Risks
In general, subjects will be a part of a study that may potentially affect how anesthetic providers practice and manage difficult airway patients. As a specific benefit, subjects will be intubated using a new video laryngeal mask airway. Risks are similar to a regular laryngeal mask airway, including but not limited to, device malfunction and airway adverse events.

As with use of all medical devices, complications may occur. Recognized risks associated with the use of the study intervention include, but are not limited to, the following:

- Allergic reactions: although the materials being used are hypoallergenic and the risk is small, there remains a risk for an allergic reaction that may result in hives, swelling, or anaphylaxis.
- Oropharyngeal injury: although the both LMAs were designed for supraglottic placement, some bleeding/bloodstaining may occur upon placement
- Oropharyngeal pressure: over inflation of the both LMAs can occur that can cause an increase in pressure

Risk Minimization
- To minimize the risk of allergic reactions, both Auragain and LMA Protector have undergone and successfully passed biocompatibility testing.
- To minimize the risk of an oropharyngeal injury, it is recommended that all clinicians be properly trained on how to use the both LMAs and be familiar with the Instructions For Use (IFU).
- To minimize the risk of increased pressure, it is recommended that all clinicians be properly trained on how to both LMAs and the recommended inflation pressure. There will also be a recording of the both LMA cuffs when inflated measured by the OPL testing, to aid in adequate cuff inflation.

Potential Benefits to Subject
- Improved oxygen delivery, administration, and oxygenation
- Potentially able to reduce post-op respiratory complications

Alternatives to Participation
The alternative for not participating in this study would result in not using either SGAD for tracheal intubation. Therefore, a traditional alternative (the standard of care) such as a laryngoscope would be utilized for tracheal intubation.

10.0 Statistical Methods

Descriptive statistics such as the mean (standard deviation) or median (range) will be used to summarize continuous variables as appropriate. Frequencies and percentages will be used to summarize categorical variables, such as success rates. Independent samples t-tests or Wilcoxon rank-sum tests (if more appropriate) will be used to compare differences in continuous variables between study arms. Fisher's exact test or Chi Square test will be used to compare categorical variables between study arms. Correlations and regression will be used to estimate associations of interest, primarily for exploratory analyses and further hypothesis generation.

11.0 Sample Size

The AMBU® AURAGAIN™ and TELEFLEX® LMA PROTECTOR™ are FDA approved SGADs that can be used for ventilation, and as a conduit for intubation. For patients in the general hospital setting, each device has exhibited a relatively high success rate of at least 90% as a ventilatory device.[3,4] Success is defined as the insertion and placement of a SGAD on the first attempt. Success rates will be computed as proportions for each study arm. Taking the ratio of the success rates for each study arm will derive the relative risk. A two-sided 95% confidence interval will have the following lower and upper limits: (0.945, 1.255) assuming a relative risk of 1.089 (ie. success rate for study arm 1 = 0.90 and success rate for study arm 2 = 0.98) and 25 patients in each treatment arm.

12.0 Ethics

Institutional Review Board (IRB)
Prior to participating in this investigation, the site will be required to obtain approval from its governing IRB. The Principal Investigator is responsible for obtaining and maintaining IRB approval to participate in this investigation. Prior to subject enrollment, a signed copy of the IRB approval letter addressed to the Investigator certifying study approval must be submitted to the Sponsor. The IRB for this study is the local IRB at the University of Texas MD Anderson Cancer Center in Houston, TX (IRB00000308, IRB00003763, IRB00004604 or IRB00008445).

The Investigator will report to the Sponsor immediately if, for any reason, the approval to conduct the investigation is withdrawn. This report will include a complete description of the reason(s) for which approval was withdrawn.

Subject Data Confidentiality
All information recorded on the anesthetic records will be kept strictly confidential and all data will be kept in a data logbook locked in the office of the principal investigator. We will record patients only by study code number.
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 the file and password. No identifiable data will be collected. Electronic records will be stored for five years after study conclusion on the agreed upon investigator's laptop 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.

Sponsor will consider all information and data sent to Sponsor concerning a subject or their participation in this investigation as confidential. Only authorized Sponsor personnel will have access to these confidential files and have the right to inspect and copy all of the records pertinent to this study for data verification. This may include medical information gathered prior to the onset of the study. All data used in the analysis and reporting of this investigation will be conducted without identifiable reference to specific subject name. The site will maintain a list matching each subject's name with the study identification.

Data collected and stored by Sponsor will be free of identifying information such as subject name and medical record numbers. Any photos taken during the study will make every effort not to include subject faces or other identifying marks such as scars or tattoos.

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.

13.0 Reporting Requirements

Adverse Events

For study conduct purposes, adverse events will be categorized at the investigative site into two groups: Serious Adverse Events, and Non-Serious Adverse Events. The Investigator as either related to the device or its deployment, or not related to the device or its deployment will assess the causal relationship of each adverse event. Each Adverse Event assessed as being related to the device or its deployment will also be assessed by the Investigator as being anticipated or unanticipated.

Adverse Events Definitions
Adverse Event (AE): An Adverse Event is any undesirable clinical event occurring to the subject during clinical study, whether or not it is considered related to the 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).

An adverse event does not include:

- Medical or surgical procedures; the condition that leads to the procedure is not an adverse event
- Pre-existing disease, conditions, or laboratory abnormalities present at the start of the study that do not worsen in frequency or intensity
- Situations where an untoward medical occurrence has not occurred (e.g., hospitalizations for cosmetic or elective surgery or social/convenience admissions)
- Expected post-operative course

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.

Reporting of Adverse Events
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., drug or device), contributing factors, and any action taken with respect to the study drug/device.
Investigators and research coordinators will be instructed that all AE and corresponding relevant information should be recorded on the Adverse Event Form. In addition, the clinical site will be responsible for notifying Sponsor within 24 hours of any UADE. All relevant information regarding an UADE should be recorded on the Adverse Event Form and reported to Sponsor via Fax within 24 hours of the event. In addition to the event form, copies of adverse device effect related source documents should be forwarded to the Sponsor.
The Principal Investigator is responsible for reporting AEs to the IRB of record in accordance with IRB procedures. The Sponsor is responsible for informing the appropriate regulatory authorities and other Investigators of any UADEs that have occurred.

Responsibilities for Reporting Serious Adverse Events
The Principal Investigator will record all serious adverse experiences that occur during the study period in the appropriate source documents and/or AE log as applicable.

14.0 Data Monitoring Plan

Training of Clinical Site Personnel
The training of clinical site personnel will be the responsibility of the Sponsor. To ensure uniform data collection and protocol compliance, personnel from Sponsor will review the investigational plan, techniques for the identification of eligible subjects, instructions on data collection, methods for soliciting data from alternate sources, and schedules for follow-up, as necessary, with the research coordinator.

Data Reporting
All data will be recorded on the site's standard source documentation. The Investigator or designee is responsible for transferring the information to the appropriate Case Report Forms (CRFs) supplied by the Sponsor. The Investigator 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 Investigator is required to sign the CRF on the appropriate page(s) to verify that he/she has reviewed the recorded data.

Data Review
The Sponsor will review all deidentified CRFs for completeness and clarity upon receipt. Missing or unclear data will be requested as necessary throughout the study. The Sponsor will request further documentation such as physician procedure notes when UADEs and/or malfunctions are observed and reported.

The Sponsor will provide clinical monitoring including comparison of CRFs to source documentation for accuracy and appropriateness, review of/for adverse events, prompt evaluation of UADE, and site compliance. To this end, the Principal Investigator will permit inspection of the study files and subject CRFs by Sponsor representatives and/or responsible government agencies.

Prior to initiation of the study, sites will be trained on the clinical protocol, accepted clinical practices and Federal regulations pertaining to clinical research. Study sites will receive interim monitoring, as needed, and a final visit prior to study closure.

15.0 Deviation and Compliance

Compliance
It is expected that sites (Investigators, study coordinators, ancillary site personnel, and study subjects) will be compliant with the study protocol. Should it be determined that the site is non-compliant, reasonable efforts will be made to secure compliance.

These efforts/actions shall be documented in writing and maintained within the study administration file at the Sponsor’s location.

Should the site continue to remain non-compliant, the study Sponsor may restrict device availability and/or notify the governing IRB. Should efforts to bring the site into compliance fail, the site may be suspended from study participation until the noncompliance is resolved. Federal regulations require the Sponsor to report non-compliances in the study to the appropriate regulatory authorities. Therefore, in the event of an Investigator or site suspension, the governing IRB and other appropriate regulatory authorities shall be notified.

Protocol Deviations
Protocol Deviations (PDs) will be documented on a Protocol Deviation Case Report Form. PDs are reportable to the institution's governing IRB and regulatory agencies during the annual reporting process, unless otherwise directed by the individual governing IRB requirements or as the specific circumstance dictates.

Every attempt shall be made to adhere to the study protocol. However, should an Investigator be required to deviate from the protocol to protect the life or physical well-being of a study subject in an emergent circumstance, such notice shall be given to the study Sponsor as soon as possible, but no more than 5 working days from the date the event occurred. With the exception of an emergent circumstance, prior approval from Sponsor and the appropriate regulatory authorities is required for any change in, or deviation from, the study protocol as such changes may affect the soundness of the investigation or the rights, safety, and welfare of study subjects.

16.0 Investigator Responsibilities

Investigators are responsible for ensuring the investigation is conducted in accordance with the study protocol and applicable Federal regulations (21 CFR, Part 812, Subpart E). Investigators are also responsible for:

- Obtaining IRB approval for study conduct and re-approval as applicable (if more than one Investigator is participating in the study at a site, the Principal Investigator shall be responsible for the IRB approval and re-approvals)
- Obtaining informed consent of study subjects prior to enrollment into the clinical study
- Protecting the subject rights, safety, and welfare
- Maintenance of subject records and confidentiality
- Record retention as defined in Federal regulations 21 CFR, Part 812.140 (a), (d), and (e)
- Management of investigation and study related activities according to the Clinical Investigator Agreement and the Study Research Agreement
- Submission of site-specific study closure report to governing IRB within 3 months of notification from study Sponsor (if more than one Investigator is conducting the study, the Primary Investigator is responsible for submission of the study closure report)
- Return of any unused investigational product to the study Sponsor upon request or at the conclusion of the clinical study

In addition:

- An Investigator shall report to the Sponsor, within 5 working days, a withdrawal of approval by the reviewing IRB of the Investigator's part of an investigation
- If an Investigator uses a device without obtaining informed consent, the Investigator shall report such use to the Sponsor and the reviewing IRB within 5 working days after the use occurs
- An Investigator shall, upon request by a reviewing IRB or regulatory agency official, provide accurate, complete, and current information about any aspect of the investigation

17.0 Sponsor Responsibilities

The study Sponsor is responsible for ensuring the study is conducted in accordance with the study protocol and applicable federal regulations (21 CFR, Part 812, Subpart C). Further, the study Sponsor is responsible for the following:

- Selecting qualified Investigators and providing Investigators with appropriate information for study conduct
- Ensuring review and approval process for governing IRB is obtained
- Training all clinical investigators in the study on how to properly use both Ambu Auragain and Teleflex LMA Protector
- Appropriate monitoring of the clinical study
- Prompt notification to the appropriate regulatory and all Investigators of UADE
- Record maintenance and retention per Federal regulations (21 CFR, Part 812.140 (b), (d), and (e)
- Submission of final study closure report that details cumulative study experience to the appropriate regulatory authorities, governing IRBs, and Investigators within 6 months of completing the clinical investigation in addition to fulfilling annual reporting requirements

In addition:

- A Sponsor who conducts an evaluation of an UADE shall report the results of such evaluation to all reviewing IRBs and participating Investigators within 10 working days after the Sponsor first receives notice of the effect. Thereafter the Sponsor shall submit such additional reports concerning the effect as an IRB request
- A Sponsor shall notify all reviewing IRBs and participating Investigators of any withdrawal of approval of an investigation or a part of an investigation by a reviewing IRB within 5 working days after receipt of the withdrawal of approval
- At regular intervals, and at least yearly, a Sponsor shall submit progress reports to all reviewing IRBs. In the case of a significant risk device, a Sponsor shall also submit progress reports to the regulatory authority
- A Sponsor shall notify all reviewing IRBs of any request that an Investigator return, repair, or otherwise dispose of any units of a device. Such notice shall occur within 30 working days after the request is made and shall state why the request was made
- In the case of a significant risk device, the Sponsor shall notify the IRB within 30 working days of the completion or termination of the investigation and shall submit a final report to all reviewing IRBs and participating Investigators within 6 months after completion or termination. In the case of a device that is not a significant risk device, the Sponsor shall submit a final report to all reviewing IRB's within 6 months after termination or completion

- A Sponsor shall submit to the IRB a copy of any report by an Investigator of use of a device without obtaining informed consent, within 5 working days of receipt of notice of such use
- If an IRB determines that a device is a significant risk device, and the Sponsor had proposed that the IRB consider the device not to be a significant risk device, the Sponsor shall submit to the appropriate regulatory agency a report of the IRB's determination within 5 working days after the Sponsor first learns of the IRB's determination
- A Sponsor shall, upon request by a reviewing IRB, provide accurate, complete, and current information about any aspect of the investigation

18.0 Timeline for Research

The timeline to completion of this study will be 6-12 months following IRB approval.

19.0 References

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