INSTRUCTIONS:

Protocol Title	Comparison of Ambu Auragain and I-Gel Supraglottic Airways in adult patients at an Ambulatory Surgery Center
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PROTOCOL COVER PAGE

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	2 2/12/2020	HRPP Scientific Assessment added to cover page and combined consent/HIPPA form clarified in section 5.4	No
2	3 6/3/2020	Addition of e-consent process	No
3	4 3/8/2021	LMA cuff inflation adjustment	No

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ABBREVIATIONS/DEFINITIONS

- LMA: laryngeal mask airway
- OLP: oropharyngeal leak pressure

1.0 Objectives

1.1 Purpose: The purpose of this study is to determine if an I-gel LMA has a higher oropharyngeal leak pressure compared to an Ambu Auragain in adult patients in an ambulatory surgery center.

2.0 Background

2.1 Significance of Research Question/Purpose: This study will help to determine if the use of I-gel LMA has a clinical advantage over the Ambu Auragain LMA.

2.2 Preliminary Data: Existing Literature: A previous study in pediatric patients demonstrated that I-gel has a higher OLP compared to Ambu auragain. A study performed in adult patients undergoing laparoscopic surgery demonstrated no significant difference between the two LMAs OLP. No studies have compared the two in a multispecialty ambulatory surgery center in patients undergoing general non laparoscopic surgery.

3.0 Study Endpoints/Events/Outcomes

3.1 Primary Endpoint/Event/Outcome: OLP immediately after placement

3.2 Secondary Endpoint(s)/Event(s)/Outcome(s): Time to placement, insertion attempts, first attempt success rate, ease of insertion, number of mid case adjustments, sore throat upon discharge from recovery room and at 24 hours after surgery analyzed using NRS 0-10 scale, and blood staining of LMA.

4.0 Study Intervention(s)/Investigational Agent(s)

4.1 Description: Patients who are scheduled for elective ambulatory surgery under general anesthesia will be randomized to one of two groups. Group 1 will receive an I-gel LMA and group 2 will receive an Ambu Auragain LMA.

4.2 Drug/Device Handling: The I-gel and Ambu auragain will be stocked in the anesthesia carts as they currently are.

4.3 Biosafety: N/A

4.4 Stem Cells: N/A

5.0 Procedures Involved

5.1 Study Design: This is a level I randomized prospective outcomes study comparing two groups of patients. All patients scheduled for general anesthesia at the M Health Ambulatory Surgery Center who are appropriate for an LMA will be approached for the study. Once enrolled patients will be randomized 1:1 between the groups based on a randomization schedule generated before study initiation using permuted

block randomization with blocks of sizes 2, 4, and 6 used in equal proportion (i.e., 1:1:1) to ensure approximate balance at any point in the study between the two groups. Patients in group 1 will receive an I-gel LMA. Those in group 2 will receive an Ambu Auragain LMA. A standard anesthetic induction will take place using propofol, lidocaine, dexamethasone, and ondansetron. The LMA will be placed by an experienced anesthesia provider. Once absence of lid reflex is confirmed, the LMA will be placed according to instructions from the LMA such that the patient is supine with head in sniffing position. A water-based lubricant will be used on the LMA to ease insertion. The ambu auragain will be inflated to a pressure of 60cmH20. Muscle relaxant will not be used in any patient and maintenance of anesthesia will be with propofol infusion. A research assistant or another anesthesia provider will be in the room to capture all data points. OLP will be measured immediately after insertion. This will be accomplished by closing the expiratory valve while keeping fresh gas flow at 3 liters/minute until equilibrium is reached.

5.2 Study Procedures: Patients will be approached on the day of surgery about participating in the trial. This will be done as soon as they arrive at the ASC to allow adequate time for them to review the study procedures and consent forms. All questions will be answered and patients will be ensured that they have adequate time to review and understand all study procedures. Patients undergoing all surgical procedures with general anesthesia appropriate for an LMA will be eligible to participate. Once enrolled patients will be randomized to one of two groups. Patients in group 1 will receive an I-gel LMA. Those in group 2 will receive an Ambu Auragain LMA. A standard anesthetic induction will take place using propofol, lidocaine, dexamethasone, and ondansetron. The LMA will be placed by an experienced anesthesia provider. Once absence of lid reflex is confirmed, the LMA will be placed according to instructions from the LMA such that the patient is supine with head in sniffing position. A water-based lubricant will be used on the LMA to ease insertion. The ambu auragain will be inflated to a pressure of 60cmH20. Muscle relaxant will not be used in any patient and maintenance of anesthesia will be with propofol infusion. A research assistant or another anesthesia provider will be in the room to capture all data points. OLP will be measured immediately after insertion. This will be accomplished by closing the expiratory valve while keeping fresh gas flow at 3 liters/minute until equilibrium is reached. Once in the recovery room the patient will be asked about a sore throat immediately prior to discharge. Patient will also be called 24 hours after surgery to evaluate sore throat analyzed using NRS 0-10 scale.

Baseline demographics such as surgical procedure, intraoperative opioids, surgical procedure length, BMI, weight, age, and sex will be recorded.

5.3 Study Duration: Once ready to discharge from PACU the patient will end study participation with one follow up call on the day after surgery. The study should take 1 month to enroll and another 2 months for study analysis.

5.4 Individually Identifiable Health Information: This study does involve PHI, please see combined consent/HIPAA form.

5.5 Use of radiation*:* N/A

5.6 Use of Center for Magnetic Resonance Research*:* N/A

6.0 Data and Specimen Banking

6.1 Storage and Access: All study data will be stored on excel spreadsheets stored in Box. Only the PI and members of the research team will have access to the data.

6.2 Data: The data from this study will be collected both from Epic and directly from the patient. The data collected includes: demographic data, age, weight, ASA class, duration of surgery, length of stay in recovery room both phase 1 and 2, time to place LMA, number of attempts, ease of LMA insertion, blood staining, sore throat prior to discharge and at 24 hours post surgically, and any adverse events.

7.0 Sharing of Results with Participants

7.1 Study results will not be shared with participants. De-identified study data may be shared with the peer-reviewed journal.

8.0 Study Population

8.1 Inclusion Criteria: Adult patients aged 18-80 undergoing outpatient ambulatory surgery under general anesthesia that is amenable to LMA.

8.2 Exclusion Criteria: Patients under the age of 18, non-English speaking patients, patients with abnormal airway anatomy

8.3 Screening: Patients will be screened by looking at the surgical schedule. They will be contacted by the research team ahead of time and have the study introduced on the morning of surgery. They will have adequate time to evaluate the study and read through the consent and ask questions.

9.0 Vulnerable Populations

9.1 Vulnerable Populations:

Population / Group	
Children	Excluded from Participation

Pregnant women/fetuses/neonates	Excluded from Participation
Prisoners	Excluded from Participation
Adults lacking capacity to consent and/or adults with diminished capacity to consent, including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders	Excluded from Participation
Non-English speakers	Excluded from Participation
Those unable to read (illiterate)	Excluded from Participation
Employees of the researcher	Excluded from Participation
Students of the researcher	Excluded from Participation
Undervalued or disenfranchised social group	Excluded from Participation
Active members of the military (service members), DoD personnel (including civilian employees)	Excluded from Participation
Individual or group that is approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc.	Excluded from Participation
Individual or group that is disadvantaged in the distribution of social goods and services such as income, housing, or healthcare.	Excluded from Participation
Individual or group with a serious health condition for which there are no satisfactory standard treatments.	Excluded from Participation
Individual or group with a fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior).	Excluded from Participation
Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence	Excluded from Participation

consent to research or decision to continue in research.	

9.2 Additional safeguards: N/A

10.0 Local Number of Participants

10.1 Local Number of Participants to be Consented: 165

11.0 Local Recruitment Methods

11.1 Recruitment Process: Patients will be recruited from the group of adult patients undergoing surgery at the University of Minnesota Ambulatory Surgery Center. On the day of surgery as soon as they are checked in, patients will be informed of a research opportunity by a member of the clinical care staff, including the check-in staff, nursing staff, or member of the anesthesiology team, and asked if they are interested in talking with a member of the research team. A research team member will then explain the study and present the consent form. All patients will have sufficient time to review the consent and ask questions and go over the potential risks of the study with the research team as they arrive several hours prior to the procedure. If they decide to participate they will be consented and given a copy of the consent form for their records.

11.2 Identification of Potential Participants: Patients will be identified by members of the research team by evaluating the surgical schedule. Patients who have opted out of research will not be approached. Patients who agree to participate will sign a consent and HIPAA authorization form.

11.3 Recruitment Materials: N/A

11.4 Payment: No payment will be provided to patients.

12.0 Withdrawal of Participants

12.1 Withdrawal Circumstances: Subjects who have consented and for some reason choose not to participate will be withdrawn and a notation will be made in the study records and these people will be considered screen failures. The surgeon may choose to withdraw the patient from the study prior to surgery for any medical reason or if they suffer a major life-threatening adverse event.

12.2 Withdrawal Procedures: If the patient is withdrawn from study prior to the procedure, they will be noted in study records as screen failures. If they undergo the procedure and they decide they no longer want to be a part of the study or withdrawn by the physician, they will be withdrawn and no further data will be collected. This will also be noted in the study documentation.

12.3 Termination Procedures: If the study is terminated for any reason, or there are more than 5% major adverse events the data that is already collected will be stored in a secure location only accessible to research personnel on this study. No further data will be collected if the study is terminated.

13.0 Risks to Participants

13.1 Foreseeable Risks: This study has the following risks: None as both are FDA approved LMA devices and routinely used in clinical practice.

13.2 Reproduction Risks: N/A

13.3 Risks to Others: N/A

14.0 Potential Benefits to Participants

14.1 Potential Benefits: None.

15.0 Statistical Considerations

15.1 Data Analysis Plan: We plan to collect our data using excel which will be maintained in the box. When the study is completed and ready for statistical analysis the data will be shared with our staff statistician.

15.2 Power Analysis: Previous studies on OLP have shown that there was a mean difference between i-gel and AuraGain in OLP immediately after insertion in pediatrics of -5.9 cmH_2O (95% CI: -8.5 to -3.3) [Mihara EJA 2019 with estimated SD of 4.00 for AuraGel and 8.20 for i-gel] or an estimated mean difference of -1.8 cmH_2O (95% CI: -3.6 to 0.01) [Sabuncu SMJ 2018 with estimate SD of 3.56 for AuraGel and 4.20 for i-gel]. The table below shows the total sample size needed based upon the reported standard deviations from each study to detect a difference of at least 3 cmH_2O in OLP between AuraGel and i-gel:

Power	AuraGel SD	i-gel SD	Total Sample Size
80%	3.56	4.20	56
	4.00	8.20	148
90%	3.56	4.20	74
	4.00	8.20	198

15.3 Statistical Analysis: This study data will be de-identified and shared with our staff biostatistician to be analyzed. The statistician will be provided the protocol so they are able to analyze for primary and secondary objectives.

Continuous data will be summarized with mean (standard deviation) or median (interquartile range) and categorical data will be summarize by

count (percent). Normality will be evaluated with both the Shapiro-Wilk test and graphical evaluation. Univariate comparisons between groups will use t-tests or Mann-Whitney U-tests, as appropriate for normality, to compare continuous variables and chi-squared or Fisher's exact tests to compare categorical variables between groups. Linear regression models will be explored to adjust for variables that are imbalanced after randomization or other covariates that may be clinically relevant.

15.4 Data Integrity: All patients will be assigned a unique patient identifier. The data that will be sent to the statistician will be de-identified.

16.0 Confidentiality

16.1 Data Security: All paper documents and consent forms will be stored in a locked cabinet in the anesthesia research office in B573 Mayo. All study data will be stored electronically in Box and only the PI and members of the research team will have access to the data.

17.0 Provisions to Monitor the Data to Ensure the Safety of Participants

17.1 Data Integrity Monitoring: The PI, co-investigators, and research assistants will all have access to the study data stored in the University's Box storage system. All the research assistants have experience collecting study information. The PI of the study will periodically review the study data to ensure accuracy and completeness of study data.

17.2 Data Safety Monitoring: The Department of Anesthesiology has established a Data and Safety Monitoring Committee consisting of several staff anesthesiologists which include persons who are board certified as pain specialists. Data will be transmitted in box to persons on the board on a monthly basis for review. If there are patterns of adverse events, the board will meet as needed and provide recommendations.

All safety data will be collected on a case report form and transferred into an excel spread sheet that will be stored in box.

The data will be reviewed on a regular basis (weekly) by the PI and research staff. If there are consistent complications noted a meeting will be convened by the DSMB for recommendations.

The statistician uses R or SAS for analysis of safety data to determine whether harm is occurring. Most likely a regression analysis will be performed to see which event is most likely the contributor for the complications. Also, a chi-square analysis may be performed; all dependent on data variability.

18.0 Provisions to Protect the Privacy Interests of Participants

18.1 Protecting Privacy: Patients will be asked if this is a good time to answer questions. All patients will have the right to refuse to answer questions when asked. All data will stored using a unique study identifier.

18.2 Access to Participants*:* All patients will be required to sign a consent that states their privacy of the data being collected. In addition, they are required to sign a HIPAA consent that further describes the data being collected. They will be informed that data is stored and reviewed in box which is HIPAA compliant and that only study personnel have access.

19.0 Compensation for Research-Related Injury

19.1 Compensation for Research-Related Injury: In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment, and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to the patient and/or insurance company.

19.2 Contract Language: N/A

20.0 Consent Process

20.1 Consent Process (when consent will be obtained): Patients will be identified in the pre-operative time period by the research team on the day of surgery. As soon as they enter the pre-operative room, an anesthesiologist will mention the study and ask permission for a research team member to discuss it further if they are interested. If an anesthesiologist is not available when they are roomed, check-in or nursing staff will mention the study and ask the patient if a research member can discuss it with them further. If they are interested they will meet a research member and be presented with a combined Health and Insurance Portability and Accountability Act (HIPAA) and study consent form. The patient will review the forms with the surgeon, research staff, or anesthesiologist, with the REDCap e-consent process being preferentially used. They will be reminded that participation is completely voluntary, and that they may stop participation at any time without question or penalty. The research team will answer any questions that they may have about the study. If the patient decides to participate, they will be asked to sign the consent and HIPAA form. One copy will be saved for study records, and the subject will be provided with a copy of the forms for their own records.

20.2 Waiver or Alteration of Consent Process (when consent will not be obtained): N/A

20.3 Waiver of Written/Signed Documentation of Consent (when written/signed consent will not be obtained): N/A

20.4 Non-English Speaking Participants: N/A

20.5 Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age): N/A

20.6 Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent: N/A

20.7 Adults Unable to Consent:

- Permission: N/A
- Assent: N/A
- Dissent: N/A

21.0 Setting

21.1 Research Sites: Patients will be consented and care will take place at the M Health ASC.

21.2 International Research: N/A

22.0 Multi-Site Research

- N/A

23.0 Resources Available

23.1 Resources Available: Research assistants are available to aid in consent and data acquisition. All research assistants will be familiar with the study protocol and have experience working with similar studies.

We plan to enroll 148 patients and consent 165, assuming around 10% drop out. This center performs approximately 100 surgical procedures weekly.

We plan to conduct this study over 4 weeks. Enrollment and data collection will be completed at this time. Statistical Analysis will take approximately one month to complete.

All procedures will be performed in the clinical facilities at the MHealth Clinics and Surgery Center. Data storage and analysis will be done using desktop equipment which is available at the Research Office B573 Mayo.

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to the patient and/or insurance company. All study personnel will be adequately trained by the Principle Investigator on the study protocol and study conduct. A log will be maintained to track which personnel are trained. A delegation of authority log will also be maintained to track which personnel are responsible for specific duties.

24.0 References

1. Mihara T et al. Comparison of the clinical performance of i-gel and Ambu Auragain in children. Eur J Anaesthesiol 2019;36:411-417

2. Sabuncu U et al. Auragain and i-Gel laryngeal masks in general anesthesia for laparoscopic cholecystectomy. Saudi Med J. 2018;39:1082-1089