"COMPARISON OF I-GEL AIRWAY VS SLIPA 2G AIRWAY IN PAEDIATRIC PATIENTS UNDERGOING GENERAL ANAESTHESIA WITH CAUDAL EPIDURAL ANAESTHESIA- ONE YEAR RANDOMISED CLINICAL TRIAL."

By

REG NO. BA0121020

Dissertation

Submitted to

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In

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Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **" COMPARISON OF I-GEL AIRWAY VS SLIPA 2G AIRWAY IN PAEDIATRIC PATIENTS UNDERGOING GENERAL ANAESTHESIA WITH CAUDAL EPIDURAL ANAESTHESIA- ONE YEAR RANDOMISED CLINICAL TRIAL"** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee.

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ABBREVIATIONS

ASA	-	American Society of Anaesthesiologist
DBP	-	Diastolic blood pressure
ETCO2- end	-	Tidal carbon dioxide
HR	-	Heart rate
I-GEL	-	Intersurgical limited
Kg	-	Kilogram
LMA	-	laryngeal masked airway
LMA-P	-	laryngeal masked airway proseal
LMA-S	-	laryngeal masked airway supreme
LMA-U	-	laryngeal masked airway unique
min	-	Minute
ml	-	Milliliter
mm	-	Millimeter
NIBP	-	non-invasive blood pressure
OPS	-	Oropharyngeal seal pressure
SAD	-	Supraglottic airway devices
SBP	-	systolic blood pressure
SD	-	Standard deviation
SLIPA	-	Streamlined liner of the pharyngeal airway
SLIPA -2G	-	Streamlined liner of the pharyngeal airway second-generation
yrs	-	Years
Inj.	-	Injection
cm of H2O	-	Centimetre of water
Mm of hg	-	Millimetre of mercury

ABSTRACT

TITLE: "Comparison of I-GEL airway vs SLIPA 2G airway in paediatric patients undergoing general anaesthesia with caudal epidural anaesthesia- one year randomized clinical trial"

BACKGROUND AND AIMS:

Supraglottic airway devices (SGAs) are often utilized as a less invasive alternative in general anaesthesia. The use of Supraglottic airways has many advantages over endotracheal intubation like more haemodynamic stability, less incidence of increase in intracranial, and intraocular pressures and lesser incidence of postoperative hoarseness of voice, cough and sore throat.

Comparing the I-GEL and SLIPA-2G supraglottic airway devices in pediatric patients regarding ease of insertion, oropharyngeal seal pressure, and post-operative pharyngolaryngeal morbidity is a relevant pursuit, considering their advantages over traditional intubation methods.

The ease of insertion is critical in paediatrics due to anatomical variability. The I-GEL features a design that conforms anatomically, potentially facilitating smoother insertion.

Similarly, while specific pediatric data is limited, the SLIPA-2G incorporates advancements aimed at improving insertion ease. Oropharyngeal seal pressure is crucial for effective ventilation; the I-GEL's gel-like cuff aims for a superior seal, and the SLIPA-2G integrates design enhancements for optimal seal pressure.

Both devices aim to reduce post-operative complications such as sore throat and hoarseness, with existing literature indicating potential advantages for the I-GEL due to its design features. However, comparative studies directly comparing these devices in pediatric populations are lacking, underscoring the need for further research in this area.

METHODS

In our study involving 80 children aged one to twelve years undergoing elective procedures under general anesthesia with caudal epidural anesthesia, we compared the I-GEL and SLIPA-2G supraglottic airway devices. After obtaining parental consent and performing preoperative evaluations, children were pre-medicated to reduce separation stress and transferred to the operating room for standard monitoring. The study randomly assigned patients to Group A (I-GEL airway) or Group B (SLIPA-2G airway).

Both groups underwent standardized preoxygenation and anaesthesia induction without muscle relaxants. Ease of insertion, oropharyngeal seal pressure, and other parameters including heart rate, ECG, NIBP, and ETCO2 were recorded. After securing the airway device and confirming its effectiveness, anaesthesia was maintained with spontaneous breathing and assisted ventilation.

Post-procedure, patients underwent caudal epidural anaesthesia and were assessed for pharyngolaryngeal morbidity, specifically hoarseness of voice in the recovery period.

RESULTS

A comparison of oropharyngeal seal pressure between the I-GEL airway group and the SLIPA 2G airway group showed a significant difference. While the average seal pressure in the I-GEL airway group was recorded as 23.38 with a criterion deviation of 2.950, the average seal pressure in the SLIPA 2G airway group was higher at 27.68 with a standard deviation of 2.795. A p-value of 0.001 indicates a significant difference among the two groups.

In the I-GEL group, 1 individual (2.5%) experienced difficult insertion, 28 individuals (70.0%) found it easy, and 11 individuals (27.5%) found it very easy. Conversely, in the SLIPA 2G group, 3 individuals (7.5%) encountered difficult insertion, 31 individuals (77.5%) found it easy, and 6 individuals (15.0%) found it very easy. Overall, out of the total 80 participants, 4 (5.0%) experienced difficult insertions, 59 (73.8%) found insertion easy, and 17 (21.3%) found it very easy. Ease of insertion ratings are similarly high for both devices, suggesting that they are equally user-friendly for clinicians.

No post-operative pharyngolaryngeal morbidity was observed in patients from either the I-Gel airway group or the SLIPA-2G airway group.

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INTRODUCTION

Endotracheal intubation is widely recognized as the gold standard for securing the airway during general anaesthesia and ventilation. Nonetheless, supraglottic airway devices (SGAs) are often utilized as a less invasive alternative in such settings. [1] The use of Supraglottic airways has many advantages over endotracheal intubation like more haemodynamic stability, less incidence of increase in intracranial, and intraocular pressures and lesser incidence of postoperative hoarseness of voice, cough and sore throat. [2]

Supraglottic airway devices (SGAs) are classified into first and second-generation devices based on Tim Cook's classification. The Laryngeal Mask Airway (LMA) Classic is the most widely recognized supraglottic airway device. As a first-generation device, it has a low oropharyngeal sealing pressure, which can cause issues such as insufficient ventilation, gastric distension during positive pressure ventilation, and a higher risk of pulmonary aspiration. [3]

In contrast, second-generation supraglottic airway devices have an additional drainage channel for gastric contents, offering better protection against aspiration.

I-GEL (Intersurgical Ltd) is the second generation of supraglottic airway devices popular in pediatric anaesthesia. All devices are made of clear thermoplastic elastomer and use a non-inflatable cuff to provide perilaryngeal sealing. [4]

SLIPA-2G (Streamlined Pharyngeal Airway Liner) is a second-generation comparatively new supraglottic method made of soft plastic conforms perfectly to the throat tissues, providing better airway sealing. The presence of the double back flow protection i.e., the gastric drainage tube can be placed via the channel provided also the presence of the original reflux collection cavity can hold up to 20ml of liquid hence minimizing the risk of aspiration. [3]

Various studies in pediatric patients have shown that the I-GEL supraglottic airway works better in treatment than other secondary devices. This advantage is evident in terms of insertion time, effortlessness of insertion, and oropharyngeal leak pressure.

A literature search did not yield any studies comparing I-GEL airway with SLIPA-2G airway in paediatric patients undergoing general anaesthesia. Hence, we attempt to compare the two Supraglottic airways, I-GEL and SLIPA-2G.

OBJECTIVES

The aims and objectives of the present study are

- **PRIMARY OBJECTIVE-** To compare ease of insertion and oropharyngeal seal pressure in two second-generation supraglottic airway devices, I-GEL and SLIPA-2G.

- **SECONDARY OBJECTIVE-** To assess pharyngolaryngeal morbidity as hoarseness of voice in post anaesthesia care unit.

REVIEW OF LITERATURE

Supraglottic airway devices play a crucial role in anaesthetic care. However, much of the existing literature on these devices tends to focus on first-generation supraglottic airway devices. (9) This creates a gap in the literature regarding the assessment of second-generation supraglottic airway devices, such as the I-gel and SLIPA-2G. Therefore, we aim to address this gap by comparing these two second-generation devices.

In a preliminary study led by Ashish Kannaujia, I-gel was evaluated to assess ease of insertion, oropharyngeal sealing pressure, stability during head and neck movements. This study concluded that the I-GEL airway is easy to use. Easily inserted, quickly established and maintaining airway without general intervention. These findings show that the device is highly effective and useful, especially for elderly patients who undergo surgery lasting 30 to 60 minutes, where breathing is spontaneous. (4)

A study conducted by C. Hein, which evaluated the SLIPA (Streamlined Liner of Pharyngeal Airway) by initially testing the device on manikins and then on consenting patients, indicated that the SLIPA is user-friendly, requiring minimal practice to achieve proficiency, and offers satisfactory ventilation in the studied population. (11)

Ju-Hyun Lee's comparative study on airway devices in children, specifically I-GEL airway a second-generation airway device and classic laryngeal mask, showed that oropharyngeal leakage was high, and the success rate of I-GEL airway insertion was comparable to the classic laryngeal masked airway. However, studies have shown that I-gel tends to slip from the child's mouth. (12)

Rakhee Goyel evaluated the effectiveness of the second-generation supraglottic airway device I-gel in laparoscopic surgery in a prospective clinical study. The results of the study showed that I-gel provides adequate ventilation of the lungs in children who underwent these surgeries and did not experience any side effects. (13)

A review by Choi, GJ compared Streamlined liner of the pharyngeal airway (SLIPA) and laryngeal mask airways. The analysis showed that the two devices showed similar results. There was also no noteworthy difference between the two devices in terms of ease of insertion, oropharyngeal seal pressure, or the quality of the fiberoptic view of the larynx. It is worth noting, however, that blood stains on the device were more easily seen after using the SLIPA. The study also found that novice users were more likely to insert the SLIPA on the first try and were faster compared to the laryngeal mask airway. This observation suggests that SLIPA may be easier for novice users because it does not have a cuff for inflation and involves fewer steps. (14)

A study by Yun Mi Choi compared the effectiveness of Streamlined liner of the Pharyngeal Airway (SLIPA) and laryngeal mask airway Proseal during anaesthesia and concluded that SLIPA is a significant alternative to Proseal laryngeal mask airway liner. Studies have shown that SLIPA has comparable efficacy and complications to the Proseal laryngeal mask airway. Therefore, SLIPA may be considered the primary supraglottic generator for surgery under general anaesthesia if practitioners acquire the necessary skills to use it correctly. (3)

In a randomized trial led by Khaled EL-Radaideh, the effectiveness of a disposable Streamlined liner of the pharyngeal airway (SLIPA) was compared with a disposable I-GEL airway in adults with anaesthesia and paralysis. This study concluded that SLIPA placement was easier and faster than I-gel, although the rate of blood spotting on the device was higher. Additionally, SLIPA shows the superior oropharyngeal seal pressure. Both devices show similar features in terms of ventilation, oxygenation and hemodynamic stability. These findings suggest that non-inflatable supraglottic airway devices are both useful options. However, due to its rapid insertion and effective sealing, SLIPA is a good alternative to I-gel. (15)

A study by Ziae Totonchi compared laryngeal mask airway (LMA) placement with and without muscle relaxants in pediatric anaesthesia and concluded that the use of atracurium, a muscle relaxant, did not affect the ease of insertion of the laryngeal mask. Additionally, it appears that there is no protection against problems such as laryngospasm.. (16)

A comparative study conducted by Seok-Kyoung Oh evaluated the clinical outcomes of Streamlined liner of the pharyngeal airway (SLIPA) versus laryngeal mask airway (LMA) and found that SLIPA performed similarly to LMA in the context of placement by novice users using success rates, postoperative airway outcomes, and hemodynamic response. However, the insertion time on the first attempt and the overall successful insertion time were shorter with SLIPA compared with LMA. Therefore, SLIPA has become a useful alternative to LMA as the primary supraglottic airway device (SGA) by novice users. (17)

A randomized clinical trial conducted by Young Cheol Woo titled "Less peri-laryngeal gas leakage with Streamlined liner of the pharyngeal airway than with Laryngeal masked airway-ProSeal in paralyzed patients" found that both SLIPA and laryngeal mask airway-ProSeal were used in paralyzed patients undergoing laparoscopic surgery gynaecological surgery without major complications. However, SLIPA has the advantage of less peri laryngeal gas leakage compared to Laryngeal Mask Airway ProSeal, especially in situations where there are changes in head position and the peritoneal cavity insufflation. [(18)]

A comparative study led by Praveen Shiveshi investigated the efficacy of the Proseal laryngeal mask versus the I-GEL in children with controlled ventilation, where the I-GEL was determined to have an oropharyngeal seal pressure comparable to the Proseal laryngeal mask in children in. Studies also showed that the two devices had similar characteristics in terms of ease of insertion, number of attempts, and glottic fibre optic appearance. However, the insertion time of the I-GEL was shorter compared to the laryngeal masked airway proseal. [(19)]

BASIC SCIENCES

The respiratory tract, also known as the airway, is a complex system responsible for facilitating the exchange of gases between the body and the environment. It can be divided into two main regions: the upper airway and the lower airway. Each region consists of various structures with specific functions. [5]

- **Upper Airway**:
  - *Nasopharynx*: Extends from the nares to the posterior nasal cavity, separated from the oropharynx by the palate.
  - *Oropharynx*: Connects the nasopharynx to the hypopharynx, situated between the palate and the hyoid bone.
  - *Hypopharynx*: Connects the oropharynx to the oesophagus and larynx, located below the hyoid bone.
  - *Larynx*: Positioned between the pharynx and the trachea, containing cartilaginous structures and organs for speech production, such as the epiglottis and vocal folds.

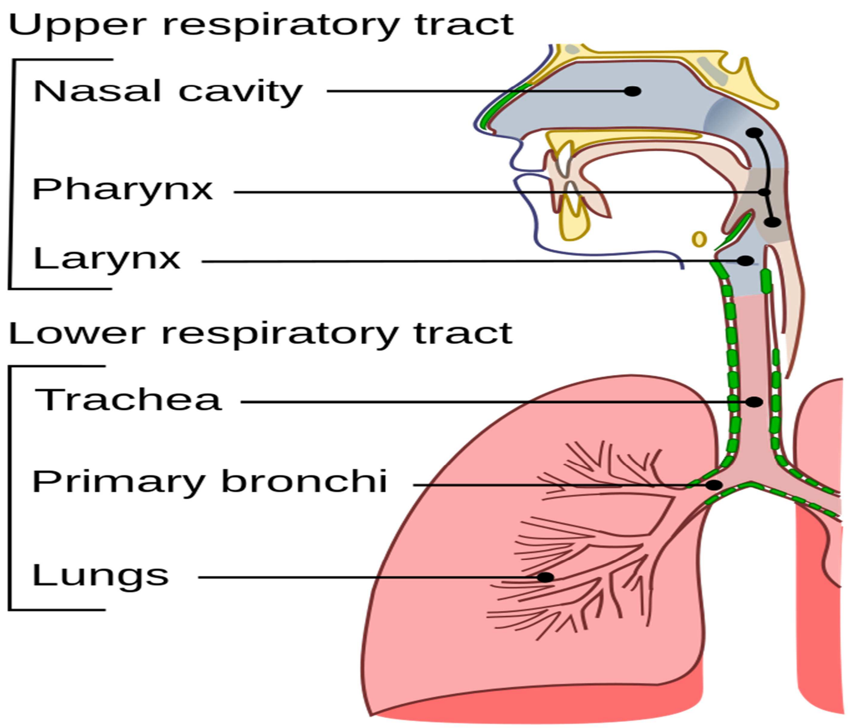


FIGURE 1: REGIONS OF RESPIRATORY TRACT

- **Lower Airway:**
  - *Trachea*: Tubular structure lined with ciliated pseudostratified columnar epithelium and supported by C-shaped rings of hyaline cartilage.
  - *Bronchi*:

Main Bronchi: Divided into left and right, supplying ventilation to each lung.

Lobar Bronchi: Supply individual lobes of the lung.

Segmental Bronchi: Supply bronchopulmonary segments.

  - *Bronchioles*:

Conducting Bronchioles: Conduct airflow without containing mucous glands.

Terminal Bronchioles: Last division without respiratory surfaces.

Respiratory Bronchioles: Contain occasional alveoli and surfactant-producing cells.

- <u>*Alveolar Region*</u>:

Alveoli: Lined with pneumocytes and Clara cells, containing surfactant-producing type II pneumocytes. Responsible for gas exchange with capillaries.

Alveolar Ducts: Tubular portions with respiratory surfaces, giving rise to alveolar sacs.

Alveolar Sacs: Blind-ended spaces connected by pores, forming clusters for gas exchange and the air-blood barrier. [6]

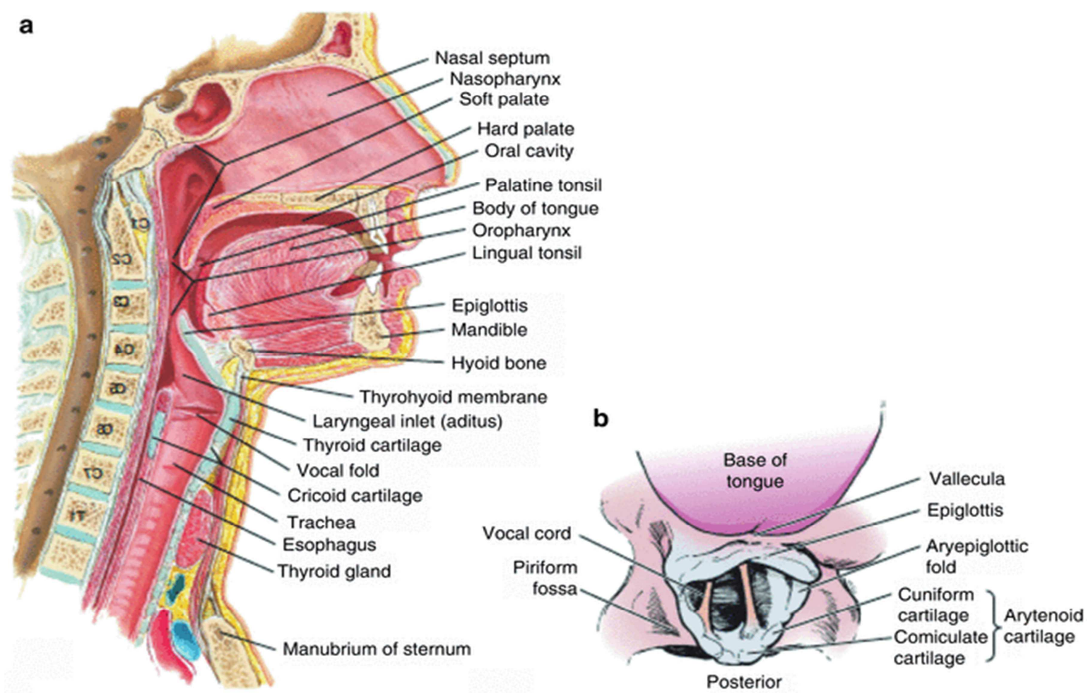


FIGURE 2: ANATOMY OF AIRWAY

FUNCTION

Airways play a crucial role in facilitating the exchange of gases between the external environment and the respiratory surfaces where gas exchange occurs.

1. **Moisture Barrier:** The mucous lining of the airways acts as a moisture barrier, preventing excessive loss of moisture during ventilation. It increases the humidity of the air in the upper airway, helping to keep the respiratory surfaces moist and facilitating efficient gas exchange.

2. **Temperature Barrier:** The airways help maintain the body's internal temperature by warming the air as it enters the respiratory system. Structures such as nasal turbinates and increased vasculature contribute to heating the air to match body temperature, reducing thermal stress on the respiratory surfaces.

3. **Barrier to Infection:** The lining of the airways contains a rich lymphatic system, including mucosa-associated lymphoid tissue (MALT), which plays a crucial role in immune defence. MALT helps prevent early access of invading pathogens by mounting immune responses against them. Additionally, macrophages patrol the respiratory surfaces, phagocytosing and eliminating pathogens, thus contributing to the airway's defence mechanisms. The "air-blood barrier" formed by the alveoli and pulmonary capillaries also serves as a barrier to prevent pathogens and foreign particles from entering the bloodstream.

EMBRYOLOGY

The upper airways develop from the pharyngeal arches as part of the embryological development of the head and neck structures.

1. **Formation of the Pharyngeal Arches (Weeks 4-5):** The development of the upper airway begins with the formation of pharyngeal arches, which are bulges of tissue that form in the early embryo. These arches contribute to the development of various structures in the head and neck region, including parts of the upper airway.

2. **Laryngotracheal Groove (Week 4):** Around week four of embryonic development, a groove called the laryngotracheal groove appears in the ventral wall of the foregut. This groove extends caudally from the developing pharynx and serves as the precursor to the larynx and trachea.

3. **Laryngotracheal Diverticulum (Week 4-5):** The laryngotracheal groove deepens and forms a tubular structure called the laryngotracheal diverticulum. This diverticulum eventually separates from the foregut by the formation of the tracheoesophageal folds, which divide the foregut into the respiratory primordium (future trachea and lungs) and the oesophagus.

4. **Development of Larynx and Trachea (Week 4-5):** The larynx and trachea develop from the laryngotracheal diverticulum. The larynx houses the vocal cords and is essential for phonation, while the trachea serves as the main airway leading to the lungs.

5. **Differentiation of Laryngeal Structures (Weeks 5-8):** The laryngeal cartilages and musculature develop from the fourth and sixth pharyngeal arches. The glottic opening, which connects the larynx to the trachea, forms during this period as well.

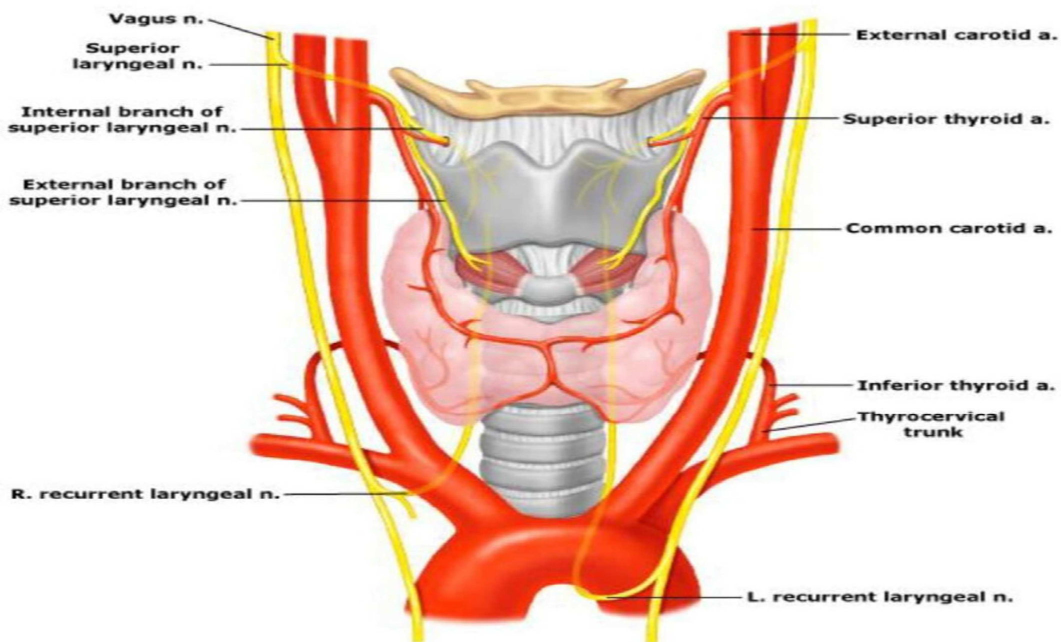
6. **Branching of Respiratory Tree (Weeks 5-16):** The laryngotracheal diverticulum continues to branch and bud, forming the bronchi and branching bronchioles. This branching pattern creates the intricate network of airways that conduct air into the lungs.

7. **Maturation of Respiratory Surfaces (Week 16 Onward):** From 16 weeks onward, the respiratory surfaces within the lungs begin to form. Alveolar sacs start to develop, and pneumocyte (lung cell) differentiation leads to the formation of the respiratory membrane, which facilitates gas exchange.

8. **Alveolar Formation (Continues Postnatally):** Although the basic structure of the lungs is present at birth, the formation of alveoli and the maturation of the respiratory membrane continue after birth. Alveolar formation persists until around the age of eight, contributing to the increase in lung surface area and gas exchange efficiency. [(6)]

BLOOD SUPPLY AND LYMPHATICS

- The external carotid artery provides blood to the upper airway through various branches, including the facial artery and its tonsillar branch, which supply the naso and oropharynx. Venous drainage occurs via the pharyngeal plexus into the internal jugular vein. Additionally, lymphatic drainage occurs through several lymphatic plexuses surrounding the internal jugular vessels, helping to maintain fluid balance and immune function in the region. This vascular and lymphatic network plays a crucial role in supporting the physiological functions of the upper airways and pharynx.



FIGIURE 3: BLOOD SUPPLY AND NERVE SUPPLY OF THE UPPER AIRWAY

- The lower airways receive blood flow from two sources: the pulmonary circulation and the bronchial circulation.

Pulmonary Circulation: Oxygen-depleted blood from the heart is pumped into the lungs via the pulmonary arteries. Within the lungs, these arteries follow a branching pattern similar to that of the airways, ensuring that each region of the lungs receives blood for oxygenation. After oxygenation in the pulmonary capillaries, the oxygen-rich blood returns to the heart through the pulmonary veins, eventually reaching the left atrium. This oxygenated blood is then pumped out to the body via the systemic circulation.

Bronchial Circulation: In addition to the pulmonary circulation, the lower airways also receive blood supply from the bronchial arteries, which arise independently from the systemic circulation. The two left bronchial arteries typically emerge directly from the thoracic aorta, while the right bronchial artery may arise from one of the superior posterior intercostal arteries or share a common trunk with the left bronchial artery. These bronchial arteries provide oxygenated blood specifically to the tissues of the airway structures themselves. They extend as far as the end of the conducting airways, where they anastomose (connect) with the pulmonary circulation. This ensures that the tissues of the lower airways receive adequate oxygen and nutrients for their metabolic needs.

The bronchial veins indeed primarily drain blood from the trachea and bronchi near the lung hilum. These veins typically accompany the bronchial arteries and drain into the systemic venous system.

On the right side, bronchial veins often drain into the azygos vein, while on the left side, they may drain into the accessory hemiazygos vein or intercostal vessels.

The pulmonary veins, primarily drain the more distal regions of the lungs, where gas exchange occurs in the alveoli.

These veins carry oxygen-rich blood back to the heart, specifically to the left atrium.

While a small amount of deoxygenated blood from the bronchial circulation may mix with the oxygenated blood in the pulmonary veins, this mixing typically has minimal impact on the overall oxygen saturation of the blood returning to the heart.

LYMPHATIC DRAINAGE

Lymphatic Drainage Pathway:

- Lymphatic drainage of the lower airways occurs primarily through the deep lymphatic plexuses of the pulmonary lymphatic plexuses.
- These lymphatic vessels drain into the superior and inferior tracheobronchial lymph nodes bilaterally.
- From the tracheobronchial lymph nodes, lymph flows into the right and left lymphatic ducts.

Right and Left Lymphatic Ducts:

- The right lymphatic duct drains lymph from the right side of the body above the diaphragm.
- The thoracic duct (on the left side) drains lymph from the rest of the body.
- These ducts typically connect directly to the venous angles, allowing lymph to re-enter the bloodstream.

Thoracic Duct Convergence:

- On the left side, the thoracic duct may converge with the left duct draining from the tracheobronchial lymph nodes before reaching the venous angles.
- This convergence ensures that lymph from the lower airways, among other structures, ultimately returns to the bloodstream for recirculation.

Paratracheal Lymph Nodes:

- Paratracheal lymph nodes directly drain lymph from the trachea.
- Lymph from these nodes flows into the right and left lymphatic ducts, contributing to the overall lymphatic drainage of the lower airways.

NERVE SUPPLY

- Innervation of the pharynx is via cranial nerves VII, IX, X, and XII. The larynx is supplied by the vagus (cranial nerve X) by the superior laryngeal branch directly and the clinically important recurrent laryngeal branch.
- The lower airways receive parasympathetic fibres from the vagus, some of which are afferent sensory nerves that transmit cough sensations from specialized J receptors in the mucosa as well as stretch receptors from the bronchial muscles and inter-alveolar connective tissues. The efferent fibres of the vagus cause broncho-constriction and secretion from the glandular tissues in the airways. The efferent sympathetic fibres cause bronchodilation by inhibiting the activity of the smooth muscles of the airways. [(6)]

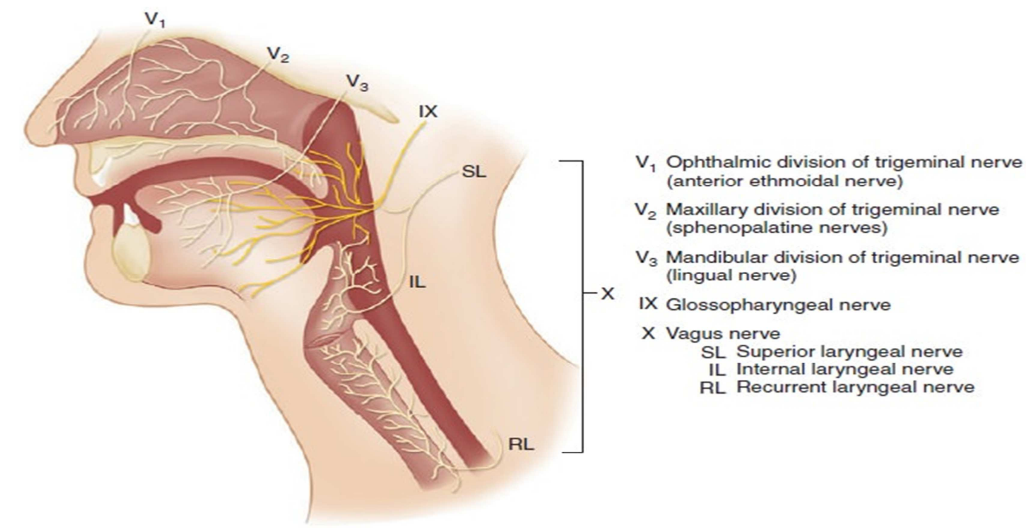


FIGURE 4: NERVE SUPPLY OF UPPER AIRWAY

PEDIATRIC AIRWAY

The upper airway is composed of three segments:

1. Supraglottic Segment:
    - This segment is the most poorly supported portion of the upper airway.
    - It primarily consists of the pharynx, which serves as a passageway for both air and food.
    - The supraglottic segment includes structures such as the nasopharynx, oropharynx, and laryngopharynx.
    - It plays a vital role in airway patency and protection, especially during swallowing and breathing.

2. Glottic (Laryngeal) Segment:

    - The glottic segment encompasses the area around the vocal cords, the subglottic region below the vocal cords, and the cervical trachea.
    - It is a critical site for airway control and phonation in both adults and children.
    - Proper function of the glottic segment is essential for maintaining airway patency and preventing obstruction.

3. Intrathoracic Segment:

    - The intrathoracic segment includes the thoracic trachea and bronchi, extending from the lower part of the cervical trachea into the chest cavity.
    - This segment serves as the conduit for air passage into the lungs, where gas exchange occurs.
    - It is essential for delivering oxygen to the body and removing carbon dioxide, thus supporting respiratory function.

Several developmental characteristics distinguish the paediatric airway from the adult airway:

- **Smaller Diameter and Shorter Length:**

The paediatric airway is smaller in diameter and shorter in length compared to the adult airway. This difference in size can affect airflow dynamics and resistance.

- **Relatively Larger Tongue:**

In young children, the tongue occupies proportionally more space in the oropharynx compared to adults. This relative enlargement of the tongue can contribute to airway obstruction, especially during sedation or anaesthesia.

- **Anteriorly Positioned Larynx:**

The larynx in infants and young children is located more anteriorly in the neck compared to adults. This anatomical difference can affect airway access and visualization during medical procedures, such as intubation.

- **Longer, Floppy, and Narrow Epiglottis:**

The epiglottis in infants and young children is relatively long, floppy, and narrow. This morphology can make it more prone to collapse over the glottis during breathing or swallowing, potentially leading to airway obstruction.

- **Narrowest Portion of Airway Below the Glottis:**

In children younger than 10 years of age, the narrowest portion of the airway is below the level of the glottis, specifically at the level of the cricoid cartilage. This anatomical characteristic has implications for airway management and the choice of equipment during interventions such as intubation. [7]

SUPRAGLOTTIC AIRWAY DEVICES

Supraglottic airways (SGAs) are a category of airway devices that can be inserted into the pharynx to facilitate ventilation, oxygenation, and the delivery of anaesthetic gases, all without the necessity of endotracheal intubation. Dr. Charlie

Brain first invented the inflatable cuffed laryngeal mask in the early 1980s and, since then, many relatively new SADs have been described. In anaesthesia, these devices serve multiple purposes, including as the primary method for airway management, as a backup option for ventilation when facemask ventilation proves challenging, and as a means for facilitating endotracheal intubation. (8)

Supraglottic airway devices (SADs) are tools engineered to ensure unobstructed ventilation by keeping the upper airway clear. These devices are alternatively referred to as supraglottic airways, as well as extraglottic or periglottic airway devices.

Supraglottic airway devices (SADs) can be grouped according to two primary criteria.

The first is the presence or absence of an inflatable cuff. Devices without cuffs may reduce the risk of complications related to cuff inflation but could lead to increased chances of leaks and malfunction.

Another commonly used classification system distinguishes between first-generation and second-generation SADs. First-generation devices are basic airway tubes lacking specific design elements aimed at preventing the aspiration of gastric contents. Conversely, second-generation SADs incorporate specific features designed to enhance positive-pressure ventilation (PPV) and decrease the risk of aspiration. (9)

I-GEL airway

The I-GEL, developed by Intersurgical Ltd in Wokingham, U.K., is an advanced supraglottic airway device characterized by its unique design and materials. Crafted from thermoplastic elastomer, its non-inflatable mask offers a soft, gel-like texture and transparency for improved patient comfort and visibility during use. Specifically engineered to fit the peri laryngeal framework snugly, the mask's tip positions itself at the opening of the oesophagus, effectively isolating the oropharynx from the laryngeal inlet. [9]

The outer shape of the cuff is meticulously designed to maintain blood flow to critical laryngeal and peri-laryngeal structures, thus minimizing the risk of neurovascular compression trauma.

Additionally, the device incorporates a buccal cavity stabilizer that adapts to the patient's oropharyngeal curvature, preventing rotation and potential malpositioning. This stabilizer serves as a housing for both the airway tubing and a separate gastric channel. The tubing section, firmer than the softer gastric channel, allows for easy insertion by gripping the proximal end against the hard palate, eliminating the need to insert fingers into the patient's mouth. Its smooth surface enables seamless posterior movement along the hard palate, pharynx, and hypopharynx. [10]

An integral bite block, featuring a horizontally placed black line as a depth insertion guide, enhances user confidence during placement. Moreover, the device incorporates a dedicated channel for gastric tube drainage, facilitating suction, leak detection, and gastric tube insertion. Finally, an epiglottic blocker effectively prevents the epiglottis from folding downwards, ensuring unobstructed airflow through the device's distal opening. [4]

FIGURE 5: Components of I-GEL supraglottic airway device

FIGURE 6: I-GEL Supraglottic airway device sizes 1,1.5,2,2.5

TABLE 1: RECOMMENDED SIZE OF I-GEL ACCORDING TO ACTUAL BODY WEIGHT

i-gel size	Patient size	Patient weight guidance (kg)
1	Neonate	2-5
1.5	Infant	5-12
2	Small paediatric	10-25
2.5	Large paediatric	25-35
3	Small adult	30-60
4	Medium adult	50-90
5	Large adult+	90+

SLIPA-2G Airway

The Streamlined Liner of the Pharynx Airway second-generation airway (SLIPA 2G), categorized as a second-generation SAD, offers potential advantages over its first-generation counterparts. These advantages derive from its design features, notably its generous chamber capacity of 50mL, which may reduce the risk of aspiration even in cases of regurgitation, and its ability to establish a more effective seal around the peri laryngeal area. Notably, the SLIPA 2G does away with the need for a cuff, eliminating the necessity for cuff inflation and pressure regulation.

Crafted from a thermoplastic material blend comprising polyethene and vinyl acetate, the SLIPA was purposefully crafted to enhance post-insertion sealing efficacy. Its stiffness diminishes at body temperature, allowing it to conform more effectively to the contours of the perilaryngeal structure. [3]

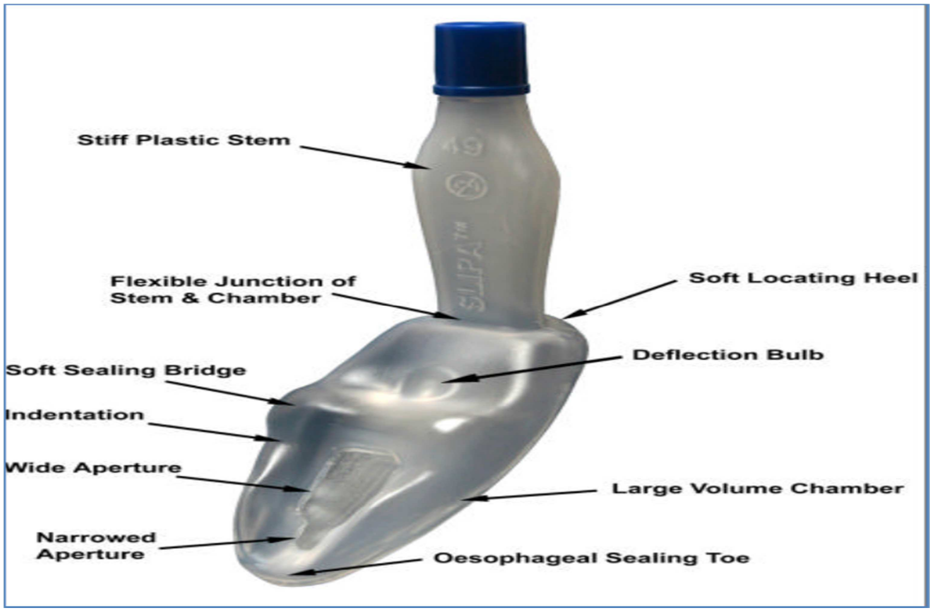


FIGURE 7: Parts of SLIPA-2G airway

TABLE 2: SIZES OF SLIPA WITH CORRESPONDING LMA SIZES ACCORDING TO ACTUAL BODY WEIGHT OF THE PATIENT

SLIPA SIZES	LMA SIZES	PATIENT WEIGHT (KG)
35-37#	1-2.0	2-10
38-41#	2	10-20
41-45#	2.5	20-30
47#	3	30-40
48#	3-4	40-50
51#	4	60-70
53#	5	70-80
55#	5	90-110

FIGURE 8: Different sizes of SLIPA-2G

MATERIALS AND METHOD

The study, titled **"Comparison of I-GEL Airway vs SLIPA 2G Airway in Paediatric Patients Undergoing General Anaesthesia with Caudal Epidural Anaesthesia - A One-Year Randomized Clinical Trial,"** The study involved children aged 1-12 years, encompassing both genders, and classified as ASA grade I and II. It was conducted from September 2022 to August 2023, with a focus on patients undergoing elective surgeries while positioned supine and receiving a combination of general anaesthesia and caudal epidural anaesthesia at KLE’s Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi -10.

Type of study:

Randomised clinical trial

The inclusion criteria were as follows:

- Classified as ASA physical status I and II.
- Age group 1 to 12 years old.
- Undergoing surgeries, such as hernia repair, circumcision, hypospadias repair and brief procedures like cystoscopy, with general anaesthesia supplemented by caudal epidural anaesthesia.
- Willing to provide informed consent for participation in the study.

The Exclusion criteria were as follows:

- Expected duration of the operation exceeding 4 hours
- Aspiration risk
- Known airway difficulties
- Congenital malformations of the respiratory tract
- Cervical spine disorders
- Preoperative sore throat or significant upper respiratory tract infection (URTI)

Sample size:

The total sample size was 80.

Calculation of sample size:

The formula for calculating the least sample size based on two proportions is

$$n = \frac{(z_\alpha + z_\beta)^2 \bar{p}(1-\bar{p})}{d^2}$$

where p_1 and p_2 are the proportions of the two groups being compared.

$$p = \frac{p_1 + p_2}{2} \text{ and } d = p_1 - p_2$$

z_α is associated with the level of implication and z_β is associated with the power of the test. For 5% level of the significance z_α = 1.96 and z_β = 0.84 for 80% power of the test. (2)

The parameter considered in the calculation is overall success rates in the two groups.

With proportion of success, p_1 = 81% and p_2 = 100% the sample size obtained is 40.

There would be two groups with size of 40.

Methodology

Our study enrolled 80 children aged one to twelve years who were planned for elective procedures under general anaesthesia with caudal epidural anaesthesia following approval from the institutional review board.

Once the patient met the inclusion norms and we received parental consent, preoperative evaluation was performed the day before surgery. Advise patients to observe appropriate fasting time before surgery.

On the day of the surgery, the nil per mouth status was confirmed and an intra-venous cannula was secured on the forearm.

To reduce parental separation stress, children were pre-medicated with 0.004 mg/kilograms body weight glycopyrrolate and 1.5 mg/kilograms body weight ketamine. During premedication, the patient is transferred to the operating room where standard monitoring is performed, including ECG, spo2, and a non-invasive blood pressure (NIBP) cuff.

The patients were divided into 2 groups-

Group A - The I-GEL airway

Group B - The SLIPA-2G airway

Patients in both groups underwent preoxygenation lasting 3 minutes, using a closed paediatric circle using appropriate flow with the head resting on a head ring. The patient was induced intravenously with 0.05 mg/kilograms body weight midazolam and 2 mcg/kilograms body weight fentanyl, followed by additional doses of isoflurane. After reaching a sufficient depth of anaesthesia, the airways of patients in Group A were secured with an I-GEL airway, and patients in Group B were secured with a SLIPA-2G airway of the appropriate sizes. Both devices were fixed by taping the airway over the chin. No muscle relaxants were given. Patients were maintained on spontaneous breathing with assisted ventilation to maintain normocapnia.

The following parameters were recorded for both Group A and Group B.

Heart rate, ECG, NIBP and end-tidal CO2 (ETCO2)

Ease of insertion Assess ease of insertion by taking into account respiratory movements such as neck flexion, head extension, chin thrust, or deep breathing required for insertion. Insertion difficulty is measured as very easy, easy, and difficult as follows

- Very easy: Insertion without the need for any manipulation.
- Easy: Only one manipulation is necessary.
- Difficult: Encountering resistance during insertion, requiring more than one manoeuvre or attempt.

Up to three insertion attempts were permitted before considering insertion as unsuccessful. If neither the I-GEL airway nor the SLIPA-2G airway could establish a satisfactory airway within these attempts, conventional endotracheal intubation was performed. The effectiveness of the airway was determined by the presence of normal thoraco-abdominal movement and the absence of any leaks.

After securing the supraglottic airway device patient was put under apnea using propofol 1mg/kg iv to measure oropharyngeal seal pressure.

Oropharyngeal seal pressure (OSP) Airway efficiency was determined by permanently closing the airway valve at a constant rate of 3 liters per minute. Record the pressure at which gas leak occurs, at the mouth by an audible leak or by detection of an audible noise by using a stethoscope placed just lateral to the thyroid cartilage. At the end of the surgical procedure, anaesthesia was discontinued, and the device was removed. Blood staining of the device and tongue, lip, dental trauma, and sore throat were recorded.

After placement of the supraglottic ventilator and evaluation of the above parameters, all patients were placed in the left lateral decubitus position and strict aseptic precautions were followed, including painting and draping. Locate the superior iliac spine and palpate the sacral angle. A 23-gauge hypodermic needle is then inserted into the sacral hiatus at an approximately 45-degree angle until a distinct "pop" is felt as it pierces the sacrococcygeal ligament to identify the caudal epidural space. Turn the needle on the skin so that it is parallel to the sacrum and enters the canal. A "whoosh" test is performed to confirm the location of the needle, followed by tests to ensure there is no blood or cerebrospinal fluid. Then, 1 ml/kg local anaesthetic 0.25% bupivacaine was injected into the caudal epidural space.

Following the procedure, the supraglottic airway device was removed after thorough oral suctioning, ensuring the maintenance of a clear airway without the need for any support. Subsequently, the patient was transferred to the recovery area.

Pharyngolaryngeal morbidity was evaluated by assessing for hoarseness of voice in the post-anaesthesia care unit one hour after the procedure.

The comparative parameters were tabulated as follows:

TABLE 3: Intra Operative Vital Parameters

VITAL PARAMETERS	***BASELINE***	***AT1 MIN***	***AT 2 MIN***	***AT 3 MIN***	***AT 4 MIN***	***AT 5 MIN***
HR						
NIBP						
ETCO2						
Pulse oximetry						

TABLE 4: Comparative parameters

PARAMETERS	***I-GEL AIRWAY***	***SLIPA-2G AIRWAY***
Ease of insertion		
Airway sealing pressure		
Complication (in any)		

Pharyngolaryngeal morbidity in post-op care unit after 1 hour.

Statistical analysis

This study was designed to equate two groups. The mean and standard deviation of the mean of the variable will be calculated. Continuous variables will be compared between groups using appropriate statistical methods (e.g., unpaired Student's t-test). Assessment of two mean differences within groups will be made using Student's t-Test. Associations between outcomes and clinical and demographic characteristics will be evaluated using the chi-square test or Fisher test. Different variables will be represented by medians and different measures will be used to compare them. Plots can be used for visual representation purposes.

RESULTS

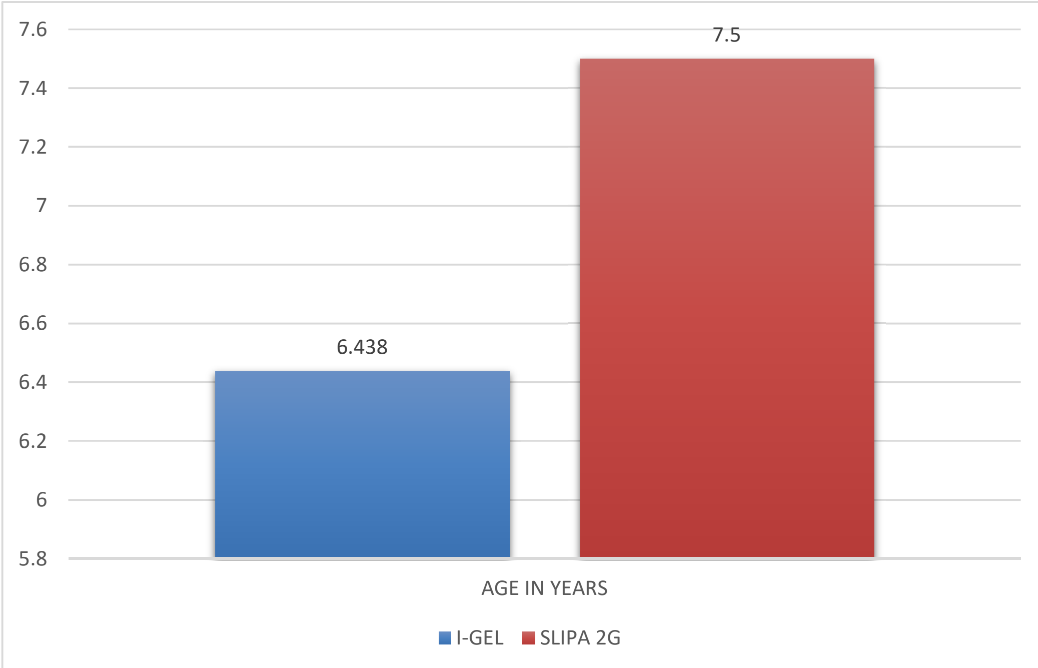
The present study titled "Comparison of I-GEL airway vs SLIPA 2G airway in paediatric patients undergoing general anaesthesia with caudal epidural anaesthesia- one year randomised clinical trial" showed the following results

The results were assessed, analysed and tabulated as follows:

TABLE 5: AGE DISTRIBUTION

Variable	I-GEL		SLIPA 2G		P value
	Mean	SD	Mean	SD	
AGE	6.438	3.6005	7.500	3.0551	0.159

Data represent a comparison of the mean age of subjects in the I-GEL airway group and the SLIPA 2G airway group. In the I-GEL airway group, the average age was 6,438 years and the standard deviation was 3.6005, and in the SLIPA 2G airway group, the avergae age was 7,500 years and the standard deviation was 3.0551. The corresponding p-value for this comparison is 0.159.

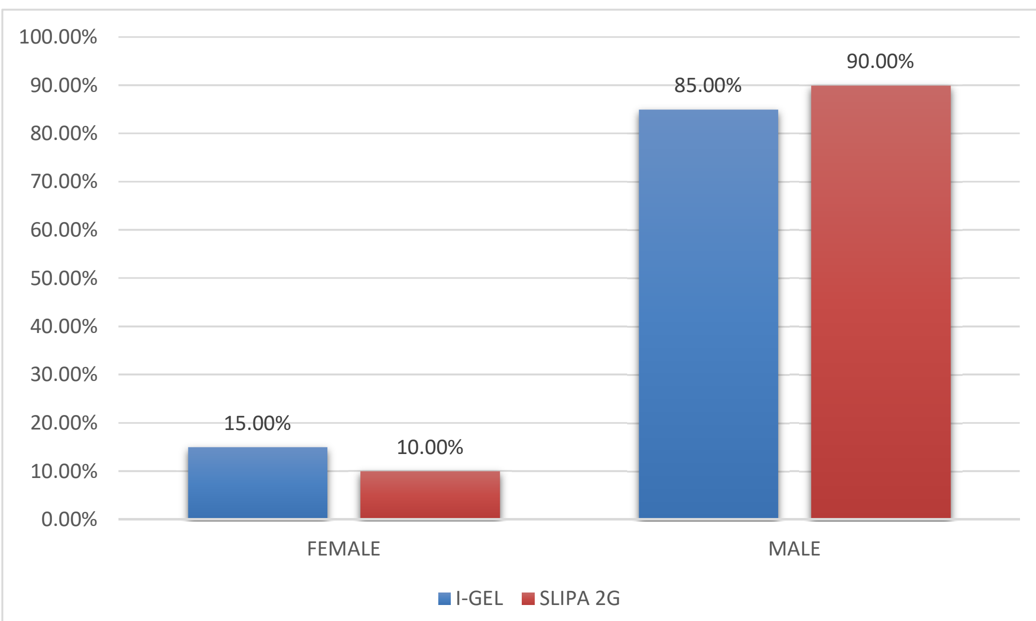


GRAPH 1: AGE DISTRIBUTION IN TWO GROUPS

The mean age of subjects in the I-GEL airway group (6.438 years) does not exhibit a significant difference from the mean age of subjects in the SLIPA 2G airway group (7.500 years), given the obtained p-value of 0.159. Consequently, age does not appear to be a confounding factor in comparing other variables between these two groups. This outcome enables a more straightforward interpretation of other variables such as oropharyngeal seal pressure, ease of insertion, complications, and post-operative pharyngolaryngeal morbidity.

TABLE 6: GENDER DISTRIBUTION

			GROUP		Total
			I-GEL	SLIPA 2G	
GENDER	FEMALE	Count	6	4	10
		%	15.0%	10.0%	12.5%
	MALE	Count	34	36	70
		%	85.0%	90.0%	87.5%
Total		Count	40	40	80
		%	100.0%	100.0%	100.0%



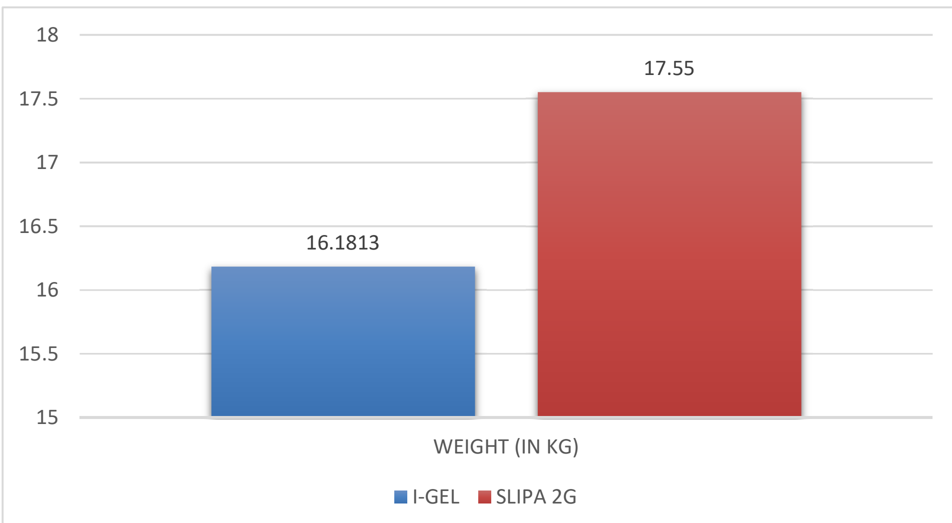
GRAPH 2: GENDER DISTRIBUTION

In the tabulated data, the distribution of gender across the I-GEL airway and SLIPA 2G airway groups is presented. Within the I-GEL airway group, there are 6 female participants, accounting for 15.0% of the group, and 34 male participants, making up 85.0% of the group. Similarly, in the SLIPA 2G airway group, there are 4 female members, representing 10.0% of the group, and 36 male members, comprising 90.0% of the group. Overall, out of the total 80 participants, 10 (12.5%) are female and 70 (87.5%) are male.

TABLE 7: WEIGHT DISTRIBUTION

Variable	I-GEL		SLIPA 2G		P value
	Mean	SD	Mean	SD	
WEIGHT	16.1813	5.32844	17.5500	4.40105	0.214

The data compares the mean weights of subjects in the I-GEL airway and SLIPA 2G airway groups. In the I-GEL set, the mean weight is recorded as 16.1813 kg, with a standard deviation of 5.32844, while in the SLIPA 2G airway group, the mean weight is 17.5500 kg, with a standard deviation of 4.40105.



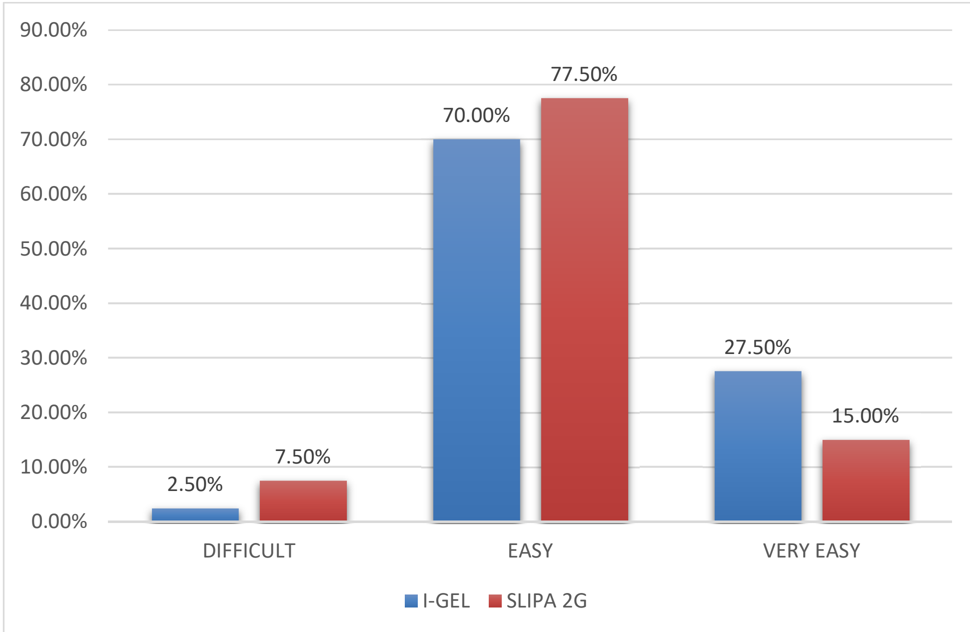
GRAPH 3 : WEIGHT DISTRIBUTION

The mean weight of subjects in the I-GEL airway group (16.1813 kg) does not exhibit a significant difference from the mean weight of subjects in the SLIPA 2G airway group (17.5500 kg), given the obtained p-value of 0.214. Consequently, weight does not appear to be a confounding factor in comparing other variables between these two groups.

TABLE 8 : EASE OF INSERTION

			GROUP		Total
			I-GEL	SLIPA 2G	
EASE OF INSERTION	DIFFICULT	Count	1	3	4
		%	2.5%	7.5%	5.0%
	EASY	Count	28	31	59
		%	70.0%	77.5%	73.8%
	VERY EASY	Count	11	6	17
		%	27.5%	15.0%	21.3%
Total		Count	40	40	80
		%	100.0%	100.0%	100.0%

For the I-GEL airway group, 1 individual (2.5%) found the insertion difficult, 28 individuals (70.0%) found it easy, and 11 individuals (27.5%) found it very easy. For the SLIPA 2G airway group, 3 individuals (7.5%) found the insertion difficult, 31 individuals (77.5%) found it easy, and 6 individuals (15.0%) found it very easy. Overall, the total counts were 4 (5.0%) for difficult insertions, 59 (73.8%) for easy insertions, and 17 (21.3%) for very easy insertions, out of a total of 80 participants, with each group having 40 participants.



GRAPH 4: EASE OF INSERTION

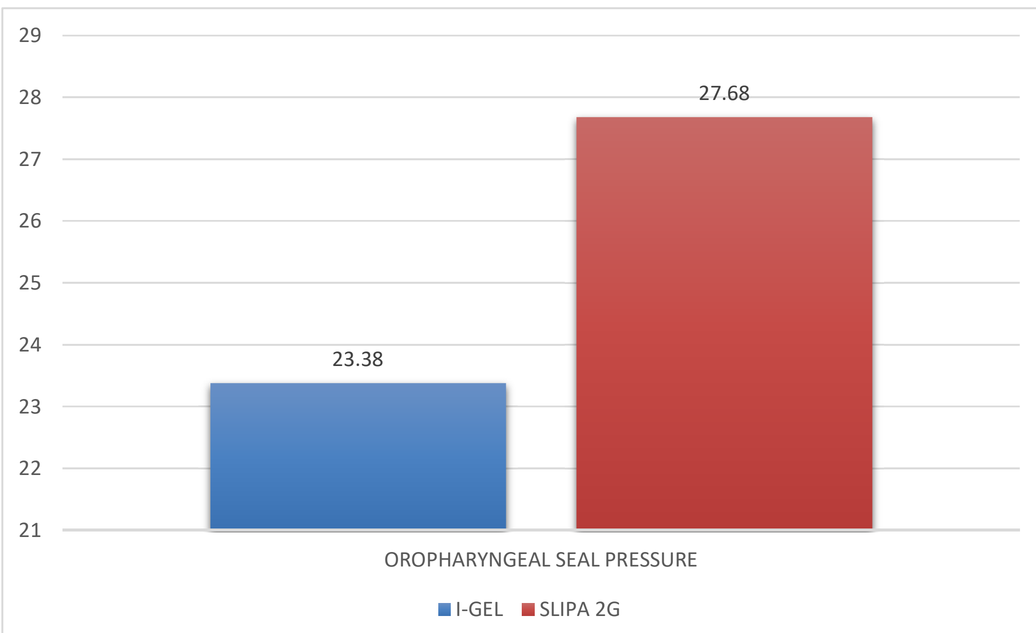
Chi-square test was performed to evaluate whether there was a significant difference in easy access distribution between the I-GEL airway group and the SLIPA 2G airway group. Therefore, the difference in ease of access between the I-GEL airway group and the SLIPA 2G airway group was not significant.

TABLE 9: OROPHARYNGEAL SEAL PRESSURE

T-Test

Variable	I-GEL		SLIPA 2G		P value
	Mean	SD	Mean	SD	
OROPHARYNGEAL SEAL PRESSURE	23.38	2.950	27.68	2.795	0.001

The data compares the oropharyngeal seal pressure between the I-GEL airway and SLIPA 2G airway groups. The I-GEL airway group has a average seal pressure of 23.38 with a standard divergence of 2.950, while the SLIPA 2G group has a mean seal pressure of 27.68 with a standard deviation of 2.795.

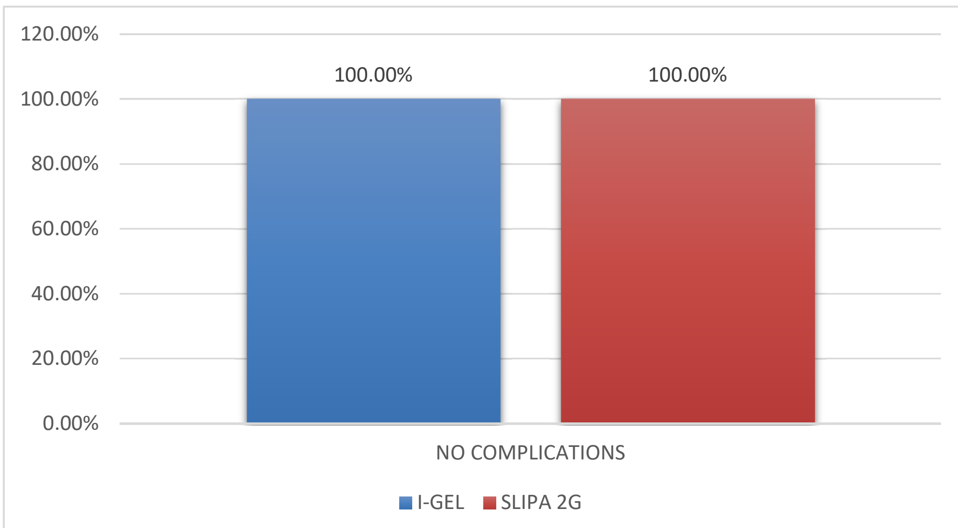


GRAPH 5: OROPHARYNGEAL SEAL PRESSURE

This result strongly suggests that the SLIPA 2G airway group achieves a higher oropharyngeal seal pressure compared to the I-GEL airway group.

TABLE 10: COMPLICATIONS

			GROUP		Total
			I-GEL	SLIPA 2G	
COMPLICATIONS	NO COMPLICATIONS	Count	40	40	80
		%	100.0%	100.0%	100.0%
Total		Count	40	40	80
		%	100.0%	100.0%	100.0%

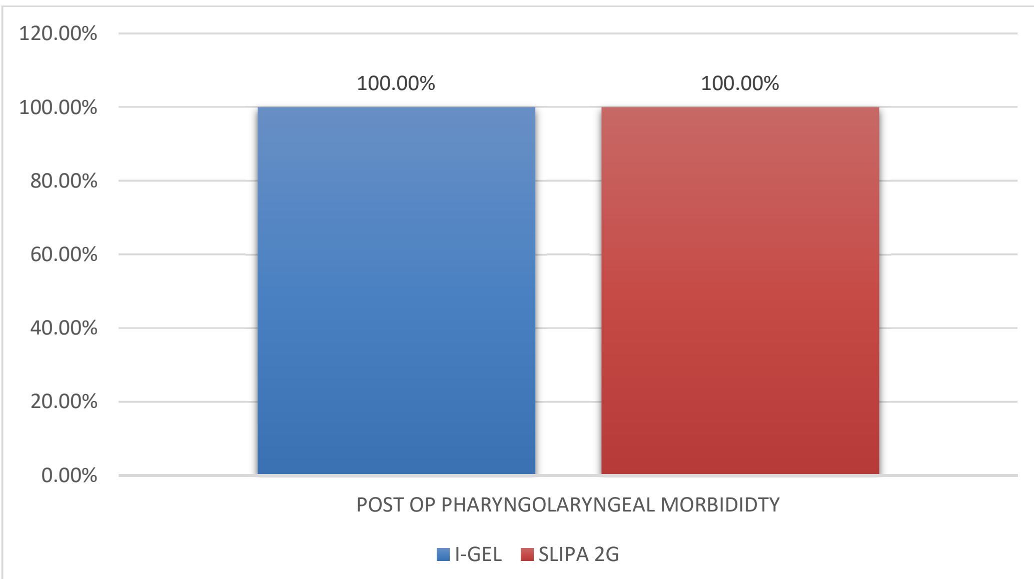


GRAPH 6 : COMPLICATIONS

The data provided shows the incidence of complications in the I-GEL airway and SLIPA 2G airway groups, revealing that both groups reported no complications. Specifically, all 40 participants in each group experienced no adverse effects, resulting in a total of 80 participants (100%) without complications. This lack of variability indicates that both devices are equally safe regarding the complications monitored in this study. Given that no complications were reported for either device, it suggests that both I-GEL airway and SLIPA 2G airway are highly safe.

TABLE 11: POST OP PHARYNGOLARYNGEAL MORBIDITY

			GROUP		Total
			I-GEL	SLIPA 2G	
POST OP PHARYNGOLARYNGEAL MORBIDIDTY	NO	Count	40	40	80
		%	100.0%	100.0%	100.0%
Total		Count	40	40	80
		%	100.0%	100.0%	100.0%

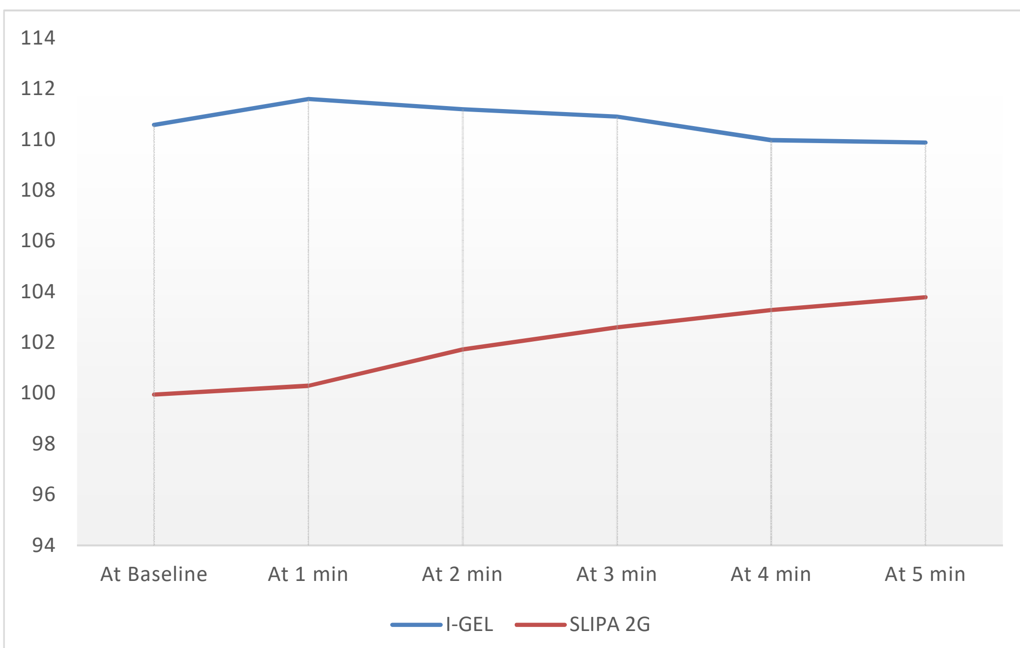


GRAPH 7: PHARYNGOLARYNGEAL MORBIDITY

The data shows that both the I-GEL airway and SLIPA 2G airway groups reported no cases of post-operative pharyngolaryngeal morbidity. All 40 participants in each group experienced no morbidity, resulting in a total of 80 participants (100%) without this complication. This uniformity indicates that both devices are equally effective in preventing post-operative pharyngolaryngeal morbidity. Therefore, other factors, such as ease of insertion or oropharyngeal seal pressure, should guide the choice between I-GEL airway and SLIPA-2G airway devices.

TABLE 12 : HEART RATE

Time	I-GEL		SLIPA 2G		P value
	Mean	SD	Mean	SD	
At B	110.58	12.681	99.95	7.317	.001
At 1 min	111.60	12.770	100.30	7.412	.001
At 2 min	111.20	11.787	101.73	7.383	.001
At 3 min	110.90	11.767	102.60	7.228	.001
At 4 min	109.98	11.457	103.28	7.310	.003
At 5 min	109.88	11.447	103.78	6.720	.005



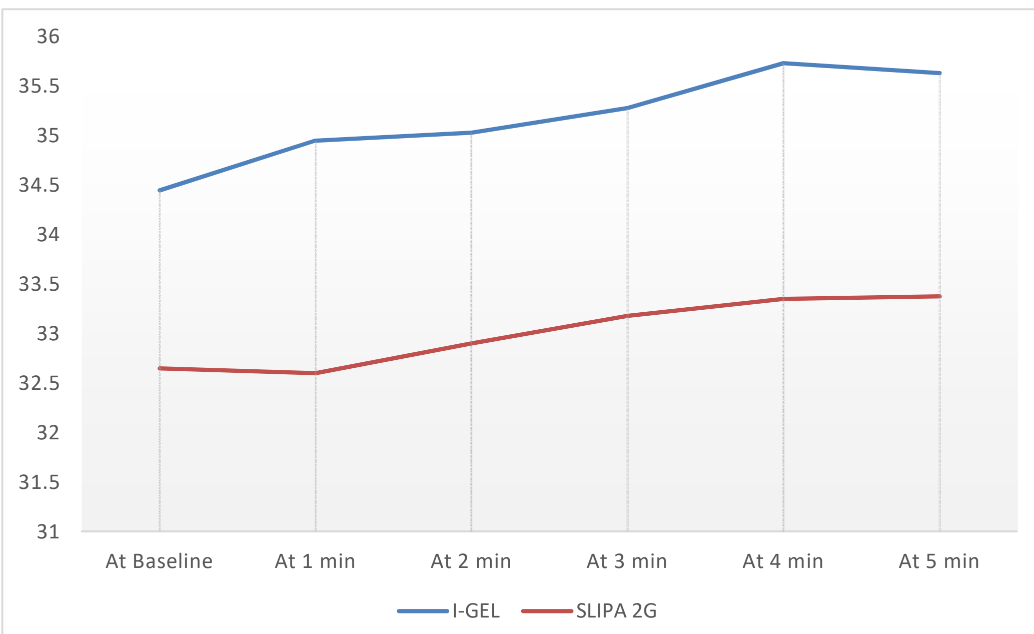
GRAPH 8 : HEART RATE

The table presents the heart rate data at different time points for both the I-GEL airway and SLIPA 2G airway groups, along with the associated p-values. At baseline, the mean heart rate for the I-GEL airway group is 110.58 (SD = 12.681), while for the SLIPA 2G airway group, it is 99.95 (SD = 7.317). At 1 minute, the mean heart rates are 111.60 (SD = 12.770) for the I-GEL airway group and 100.30 (SD = 7.412) for the SLIPA 2G airway group.

This pattern continues at 2 minutes (I-GEL: 111.20, SD = 11.787; SLIPA 2G: 101.73, SD = 7.383; p = 0.001), 3 minutes (I-GEL: 110.90, SD = 11.767; SLIPA 2G: 102.60, SD = 7.228; p = 0.001), 4 minutes (I-GEL: 109.98, SD = 11.457; SLIPA 2G: 103.28, SD = 7.310; p = 0.003), and 5 minutes (I-GEL: 109.88, SD = 11.447; SLIPA 2G: 103.78, SD = 6.720; p = 0.005). These results consistently show significant differences in heart rates between the two groups across all measured time points.

TABLE 13:ETCO2

Time	I-GEL		SLIPA 2G		P value
	Mean	SD	Mean	SD	
At B	34.45	2.900	32.65	3.150	.010
At 1 min	34.95	3.202	32.60	2.977	.001
At 2 min	35.03	2.991	32.90	2.781	.002
At 3 min	35.28	2.418	33.18	2.735	.001
At 4 min	35.73	2.481	33.35	2.627	.001
At 5 min	35.63	2.705	33.38	2.628	.001



GRAPH 9: ETCO2

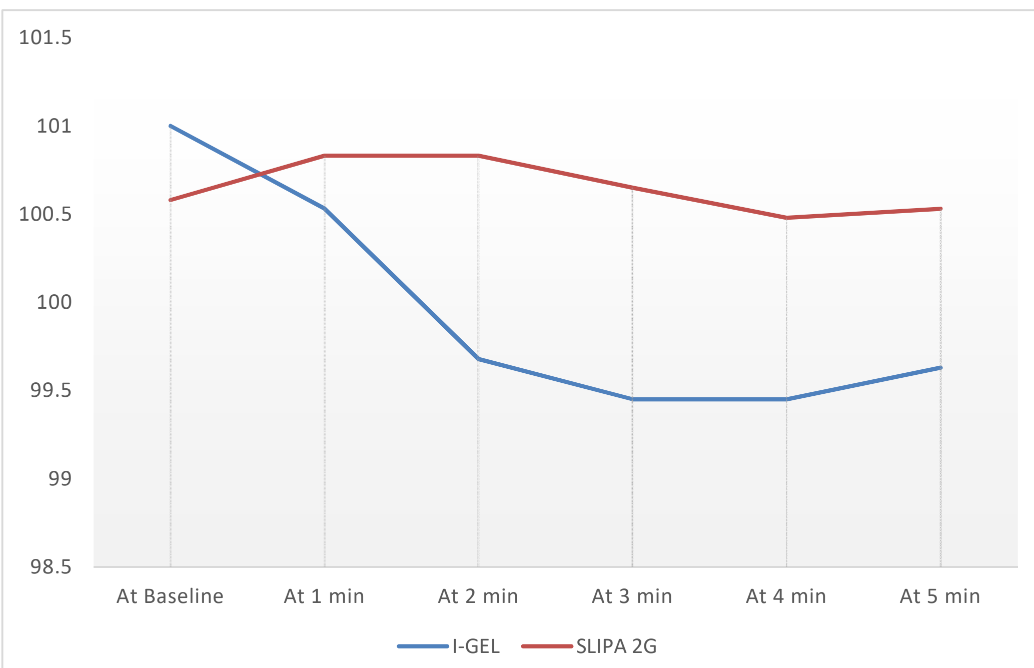
The table presents the end-tidal carbon dioxide (ETCO2) levels at various time points for the I-GEL airway and SLIPA 2G airway groups, along with the associated p-values. At baseline, the mean ETCO2 for the I-GEL airway group is 34.45 (SD = 2.900), while for the SLIPA 2G airway group, it is 32.65 (SD = 3.150).

At 1 minute, the mean ETCO2 levels are 34.95 (SD = 3.202) for the I-GEL airway group and 32.60 (SD = 2.977) for the SLIPA 2G airway group. This pattern of significant differences continues at 2 minutes (I-GEL: 35.03, SD = 2.991; SLIPA 2G: 32.90, SD = 2.781; p = 0.002), 3 minutes (I-GEL: 35.28, SD = 2.418; SLIPA 2G: 33.18, SD = 2.735; p = 0.001), 4 minutes (I-GEL: 35.73, SD = 2.481; SLIPA 2G: 33.35, SD = 2.627; p = 0.001), and 5 minutes (I-GEL: 35.63, SD = 2.705; SLIPA 2G: 33.38, SD = 2.628; p = 0.001).

These results consistently show significant differences in ETCO2 levels between the two groups across all measured time points.

TABLE 14: Systolic blood pressure

Time	I-GEL		SLIPA 2G		P value
	Mean	SD	Mean	SD	
At B	101.00	6.401	100.58	5.519	.751
At 1 min	100.53	5.974	100.83	5.764	.820
At 2 min	99.68	5.230	100.83	5.710	.350
At 3 min	99.45	5.449	100.65	5.489	.329
At 4 min	99.45	4.925	100.48	5.301	.373
At 5 min	99.63	4.694	100.53	5.306	.424



GRAPH 10:SBP

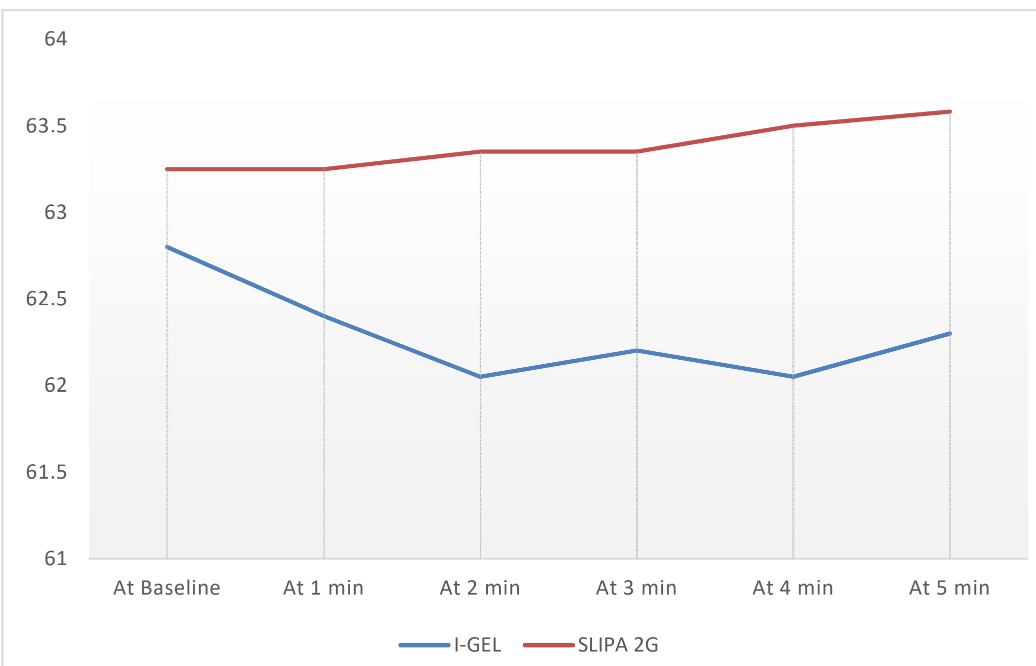
The table outlines the systolic blood pressure (SBP) measurements at various time points for the I-GEL airway and SLIPA 2G airway groups, along with the corresponding p-values. At baseline, the mean SBP for the I-GEL airway group is 101.00 (SD = 6.401), while for the SLIPA 2G airway group, it is 100.58 (SD = 5.519).

At 1 minute, the mean SBP levels are 100.53 (SD = 5.974) for the I-GEL airway group and 100.83 (SD = 5.764) for the SLIPA 2G airway group. This pattern of non-significant differences continues at 2 minutes (I-GEL: 99.68, SD = 5.230; SLIPA 2G: 100.83, SD = 5.710; p = 0.350), 3 minutes (I-GEL: 99.45, SD = 5.449; SLIPA 2G: 100.65, SD = 5.489; p = 0.329), 4 minutes (I-GEL: 99.45, SD = 4.925; SLIPA 2G: 100.48, SD = 5.301; p = 0.373), and 5 minutes (I-GEL: 99.63, SD = 4.694; SLIPA 2G: 100.53, SD = 5.306; p = 0.424).

These results consistently show no differences in SBP levels between the two across all measured time points.

TABLE 15:Diastolic blood pressure

Time	I-GEL		SLIPA 2G		P value
	Mean	SD	Mean	SD	
At B	62.80	4.339	63.25	4.430	.648
At 1 min	62.40	3.901	63.25	4.430	.365
At 2 min	62.05	3.665	63.35	4.377	.154
At 3 min	62.20	3.618	63.35	4.377	.204
At 4 min	62.05	3.580	63.50	4.362	.108
At 5 min	62.30	3.777	63.58	4.385	.167



GRAPH 10: DBP

The table presents the diastolic blood pressure (DBP) measurements at various time points for the I-GEL airway and SLIPA 2G airway groups, along with the corresponding p-values. At baseline, the mean DBP for the I-GEL airway group is 62.80 (SD = 4.339), while for the SLIPA 2G airway group, it is 63.25 (SD = 4.430).

At 1 minute, the mean DBP levels are 62.40 (SD = 3.901) for the I-GEL airway group and 63.25 (SD = 4.430) for the SLIPA 2G airway group. This pattern continues at 2 minutes (I-GEL: 62.05, SD = 3.665; SLIPA 2G: 63.35, SD = 4.377; p = 0.154), 3 minutes (I-GEL: 62.20, SD = 3.618; SLIPA 2G: 63.35, SD = 4.377; p = 0.204), 4 minutes (I-GEL: 62.05, SD = 3.580; SLIPA 2G: 63.50, SD = 4.362; p = 0.108), and 5 minutes (I-GEL: 62.30, SD = 3.777; SLIPA 2G: 63.58, SD = 4.385; p = 0.167).

These results show no differences in DBP levels between the two across all measured time points.

TABLE 16: PULSE OXIMETRY

Time	I-GEL		SLIPA 2G		P value
	Mean	SD	Mean	SD	
At B	99.85	.427	99.43	.549	.001
At 1 min	99.78	.480	99.45	.552	.006
At 2 min	99.75	.543	99.83	.385	.478
At 3 min	99.88	.404	99.98	.158	.149
At 4 min	99.95	.221	100.00	.000	.156
At 5 min	99.98	.158	99.98	.158	1.000

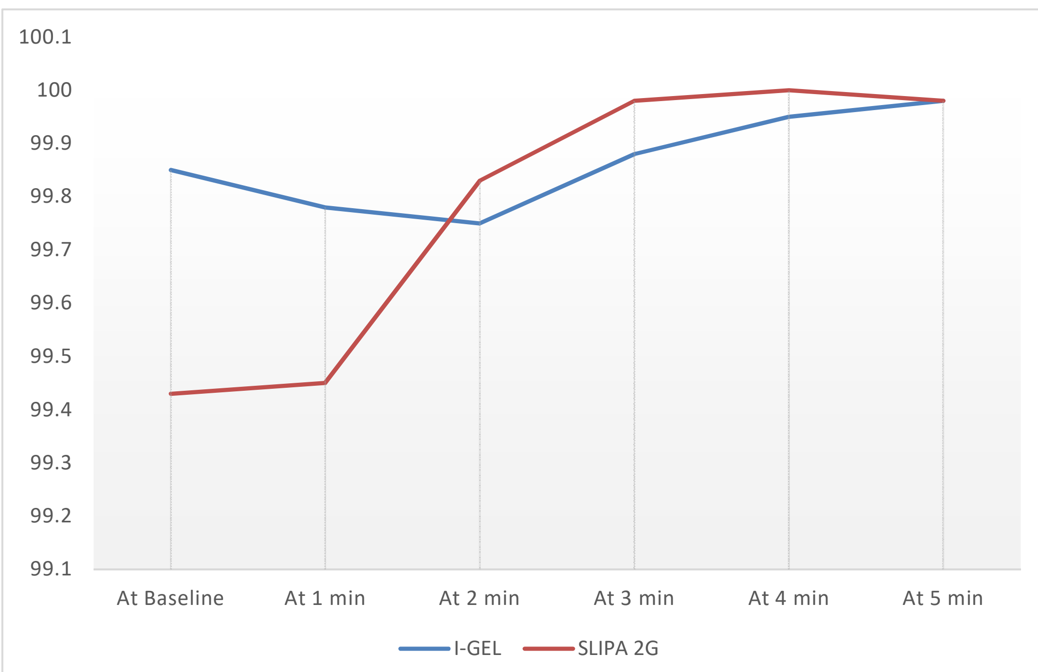


TABLE 12: PULSE OXIMETRY

The data displays pulse oximetry (SpO2) readings at various time points for the I-GEL airway and SLIPA 2G airway groups, along with the corresponding p-values. At baseline, the mean SpO2 for the I-GEL airway group is 99.85% (SD = 0.427), compared to 99.43% (SD = 0.549) for the SLIPA 2G airway group. At 1 minute, the mean SpO2 levels are 99.78% (SD = 0.480) for the I-GEL airway group and 99.45% (SD = 0.552) for the SLIPA 2G group. However, at 2 minutes, the mean SpO2 for the I-GEL group is 99.75% (SD = 0.543) and 99.83% (SD = 0.385) for the SLIPA 2G group. Similarly, at 3 minutes, the mean SpO2 levels are 99.88% (SD = 0.404) for the I-GEL group and 99.98% (SD = 0.158) for the SLIPA 2G group. At 4 minutes, the mean SpO2 for the I-GEL group is 99.95% (SD = 0.221) and 100.00% (SD = 0.000) for the SLIPA 2G group. By 5 minutes, both groups have identical mean SpO2 levels of 99.98% (SD = 0.158). Overall, significant differences in SpO2 are observed at baseline and at 1 minute, but not at later time points.

DISCUSSION

Innovations in medical technology over the earlier three decades have led to the elaboration of various supraglottic devices and the expansion of airway management. One of these devices is the I-GEL Airway, a supraglottic airway whose benefits are widely recognized, especially for pediatric patients. Its use in children has shown good results in both routine and difficult airway management. The advantages of the I-GEL airway in terms of ease of insertion, and minimal risk of tissue compression make it the first-choice in pediatric anaesthesia management. It has established a safety and efficacy profile that establishes its status as a reliable tool for the management of children in routine clinical practice. [10]

The I-GEL airway's paediatric version retains the adult model's benefits, offering a suitable option for younger patients. It includes a channel for gastric catheter placement, enhancing its versatility, although this feature is absent in the smallest size. The device's design simplifies airway management, potentially reducing the incidence of complications associated with traditional cuffed supraglottic airways. [13]

The SLIPA 2G is a supraglottic airway device designed to provide an effective and secure airway during anaesthesia and emergencies. The SLIPA 2G airway represents a significant advancement in supraglottic airway technology, offering improved performance and safety compared to traditional devices. Its streamlined design and compatibility with different patient populations make it a valuable addition to modern airway management protocols. [11]

The comparison between the I-GEL airway and SLIPA 2G airway devices reveals several important findings pertinent to their clinical use.

Our study encompassed a total of 40 subjects. In the I-GEL airway group, the mean age was recorded as 6.438 years, with a standard deviation of 3.6005, while in the SLIPA 2G airway group, the average age was 7.500 years. The mean weight of subjects in the I-GEL airway group was 16.1813 kg, and in the SLIPA 2G airway group, it was 17.5500 kg. Analysis revealed no significant differences in the mean ages or weights of patients. These findings suggest that demographic factors such as age and weight do not influence the comparative assessment of the devices.

Comparison of various physiological parameters at different time points between the I-GEL airway group and the SLIPA 2G airway group during the heart rate, end-tidal carbon dioxide (ETCO2) level, systolic blood pressure (SBP), diastolic blood pressure study; blood pressure (DBP) and pulse blood oxygen saturation (SpO2) readings. Overall, while significant differences were observed in heart rate and ETCO2 levels at certain time points, no noteworthy differences were detected in SBP, DBP, and SpO2 readings between the I-GEL airway and SLIPA 2G airway groups, indicating similar physiological responses and clinical outcomes between the two airway management devices throughout the study.

In the I-GEL group, 1 individual (2.5%) experienced difficult insertion, 28 individuals (70.0%) found it easy, and 11 individuals (27.5%) found it very easy. Conversely, in the SLIPA 2G group, 3 individuals (7.5%) encountered difficult insertion, 31 individuals (77.5%) found it easy, and 6 individuals (15.0%) found it very easy. Overall, out of the total 80 participants, 4 (5.0%) experienced difficult insertions, 59 (73.8%) found insertion easy, and 17 (21.3%) found it very easy. Ease of insertion ratings are similarly high for both devices, suggesting that they are equally user-friendly for clinicians.

The findings from the studies by R. Nirupa and Young Cheol Woo, MD, complement the results of our study, reinforcing the notion of consistently high ease of insertion across different supraglottic airway devices. In R. Nirupa's randomized trial, both the I-Gel airway and Proseal Laryngeal masked airway exhibited comparable ease of insertion in paediatric patients, indicating their equal efficacy in airway management for children. [(20)] Similarly, research by Young Cheol Woo, MD, reported positive results for the SLIPA airway and the Proseal laryngeal mask airway, with a success rate of 92% and 94%, respectively, and 98% and 100% after one or two attempts, highlights the ease of insertion of these devices. [(21)] Together, these findings support our study's conclusion that ease of insertion is equivalent between the I-Gel airway and the SLIPA-2G airway.

Significantly, no post-operative pharyngolaryngeal morbidity was observed in patients from either the I-Gel airway group or the SLIPA-2G airway group.

The randomized controlled trial by L’Hermite et al. focused on supraglottic devices in adults and aimed to evaluate the occurrence of sore throat. Of the 436 patients evaluated, 104 (23.9%) reported sore throat 24 hours after surgery. Interestingly, the study found no noteworthy difference in the incidence of sore throat between the 2 groups (P = 0.34), indicating that the post-operative sore throat level was similar despite the use of different supraglottic devices. However, at 24 hours postoperatively, dysphagia with significantly more fluid was observed with Laryngeal Mask Airway Supreme (12.1%) compared to Laryngeal Mask Airway Unique (5.3%) and I-gel (2.9%) (P = 0.0065). [(22)]These results highlight the need to consider not only sore throat but also other postoperative complications such as dysphagia when choosing an adult supraglottic airway device for treatment.

In a comparative study by Ankur Dhanda, the I-GEL airway supraglottic airway device was evaluated with an endotracheal tube for pressure-controlled ventilation during everyday surgical procedures. This study found that postoperative hoarseness was more common in the endotracheal intubation group, and 7 patients (23.33%) experienced this problem in the I-GEL airway group, although it was painless (p=0.002). [(23)]

In a network analysis by T. Mihara et al, clinical characteristics of various supraglottic devices (SADs) in children were compared with data from a randomized trial. This study included 16 different types of SAD: Laryngeal Masking Airway - Classic, Laryngeal Masking Airway - proseal, Laryngeal Masking Airway - Supreme, Laryngeal Masking Airway - Flexible, Laryngeal Masking Airway - Unique, I -GEL Airway, Laryngeal Tube, Soft -QTM, Self-Pressure Air-QTM, Cobra Perilaryngeal Airway, Aerodynamic Pharyngeal Airway Lining (SLIPA), PRO-Breathe, Ambu Aura-i, Ambu AuraOnce and Ambu AuraGain. Among these devices, the I-GEL airway stands out because it reduces the risk of blood spots by 0.46 (95% confidence interval) (0.22-0.90) compared to the laryngeal mask. This finding suggests that I-GEL airways are less invasive to the airways, making them a better choice for paediatric anaesthesia. [(24)]

In our study, a notable difference is observed in oropharyngeal seal pressure, with the SLIPA 2G airway demonstrating a significantly higher mean pressure than the I-GEL airway. This implies a superior seal with SLIPA 2G airway, potentially enhancing its effectiveness in maintaining airway patency.

A comparison of oropharyngeal seal pressure between the I-GEL airway group and the SLIPA 2G airway group showed a significant difference. While the average seal pressure in the I-GEL airway group was recorded as 23.38 with a criterion deviation of 2.950, the average seal pressure in the SLIPA 2G airway group was higher at 27.68 with a standard deviation of 2.795. A p-value of 0.001 indicates a significant difference among the two groups. These findings suggest that although both the I-GEL airway and the SLIPA 2G airway are effective and safe, their choice may be influenced by specific needs, such as the need for attachment.

Acharya R. et al. When comparing the I-GEL second generation airway with the ProSeal laryngeal mask, results are similar. Oropharyngeal closure pressure was 26.23 ± 2.3 cm H2O for the I-GEL airway group and 21.3 ± 1.75 cm H2O for the ProSeal laryngeal mask airway group. (25)

In an experiment led by Srinath Damodaran, the oropharyngeal seal pressure of three different supraglottic airway devices (air-Q, I-GEL airway, and laryngeal mask airway Supreme) was compared. Mean oropharyngeal closure pressure was 26.1 ± 4.9 cm H2O for Air-Q, 23.8 ± 5.4 cm H2O for I-GEL airway, and 24.8 ± 4.8 cm H2O for laryngeal mask, with no significant There was no difference. These findings suggest that all three devices provide similar oropharyngeal seal pressures during anaesthesia in adults and that they are equally effective in preventing airway obstruction. (26)

The study by Markus Lange, MD, et al., indicates that the airway sealing pressure was comparable between the Streamlined Pharynx Airway Liner and the conventional Laryngeal Mask Airway, as demonstrated by maximum pressures of 24 ± 6 mm H2O and 24 ± 4 mm H2O, respectively. (27)

Similarly, a study by Zhu Wenxiu et al compared children streamlined pharyngeal airway lining (SLIPA) and laryngeal mask airway-Unique, and found that the leak pressure of SLIPA was consistent with the characteristic of laryngeal mask airway. Specifically, the mean air pressure for SLIPA was 25 cm H2O (interquartile range: 22 to 30) and for nasal masks was 21 cm H2O (interquartile range: 19 to 26) – Unique. Additionally, the mean flow pressure for SLIPA was 25.3 ± 4.6 cm H2O, while the mean flow pressure for the laryngeal mask airway-Unique was 22.6 ± 4.8 cm H2O.(28) These findings are consistent with other studies showing the effectiveness of SLIPA as respiratory control in paediatric patients.

The SLIPA 2G airway is designed with anatomical contours that closely mimic the peri-laryngeal framework, ensuring a precise fit and compatibility with the natural anatomy of the upper airway. This feature enhances its effectiveness in creating a secure seal and maintaining airway patency during ventilation. These characteristics make the SLIPA 2G airway a valuable option for airway management, particularly in situations where maintaining effective ventilation is paramount.

LIMITATIONS

Our study did not examine how intermittent positive pressure ventilation affects the functioning of the I-GEL airway and SLIPA-2G airway devices. Additionally, we did not evaluate the airway status of the patients included in our study.

CONCLUSION

The SLIPA 2G airway and I-GEL airway have demonstrated comparable ease of insertion in both groups. However, the SLIPA airway provides superior oropharyngeal sealing pressure compared to the I-GEL airway. Notably, neither the SLIPA 2G nor I-GEL airway exhibited any post-operative pharyngolaryngeal morbidity. Overall, both the SLIPA and I-GEL airways are viable options for secure airway management in the paediatric population.

SUMMARY

The current study titled "Compairison of I-GEL airway vs SLIPA 2G airway in paediatric patients undergoing general anaesthesia with caudal epidural anaesthesia- one year randomised clinical trail ", was conducted among 80 ASA I and II patients aged between 1 to 12 years scheduled for elective surgeries under general anaesthesia and caudal epidural anaesthesia as per the inclusion and exclusion criteria. The patients were divided into two groups and the airways of patients in group A were secured with I-GEL airway and those of group B with SLIPA 2G airway. Comparitive parameters were ease of insertion, oropharyngeal seal pressure and post operative pharyngolaryngeal morbidity.

In the I-GEL group, 1 individual (2.5%) experienced difficult insertion, 28 individuals (70.0%) found it easy, and 11 individuals (27.5%) found it very easy. Conversely, in the SLIPA 2G group, 3 individuals (7.5%) encountered difficult insertion, 31 individuals (77.5%) found it easy, and 6 individuals (15.0%) found it very easy. Overall, out of the total 80 participants, 4 (5.0%) experienced difficult insertions, 59 (73.8%) found insertion easy, and 17 (21.3%) found it very easy. Ease of insertion ratings are similarly high for both devices, suggesting that they are equally user-friendly for clinicians.

A comparison of oropharyngeal seal pressure between the I-GEL airway group and the SLIPA 2G airway group showed a significant difference. While the average seal pressure in the I-GEL airway group was recorded as 23.38 with a criterion deviation of 2.950, the average seal pressure in the SLIPA 2G airway group was higher at 27.68 with a standard deviation of 2.795. A p-value of 0.001 indicates a significant difference among the two groups.

No post-operative pharyngolaryngeal morbidity was observed in patients from either the I-Gel airway group or the SLIPA-2G airway group.

To summarise both I GEL airway and SLIPA 2G airway exhibited similar ease of insertion, but SLIPA 2G airway showed superior oropharyngeal seal pressure and no pharyngolaryngeal morbidity was observed in both the devices.

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ANNEXURE I

INFORMED CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mr. /Mrs. /Miss. _____________________________ we are requesting you to enroll you in the study titled "Comparison of I-GEL airway vs SLIPA 2G airway in paediatric patients undergoing general anaesthesia with caudal epidural anaesthesia-one year randomized clinical trial" conducted by REG NO. BA0121020 Post Graduate in M.D. Anesthesiology under the guidance of Dr. ________________ Department of Anesthesiology, J.N. Medical College, Belagavi under KAHER, Belagavi. Respected Sir/Madam, we request you to participate in our study as you are eligible for it. During the study, you will be asked some questions regarding your medical history and you are supposed to answer to the best of your knowledge.

Your participation in this research is voluntary. Your decision whether or not to participate in the study will not affect your relationship with J.N. Medical College.

If you decide to participate you are free to withdraw at any time.

Purpose of the study: The purpose of this research is to compare I-GEL airway vs SLIPA 2G airway in paediatric patients undergoing general anaesthesia with caudal epidural anaesthesia.

Procedure Involved: If you agree to enroll in my study, you will be asked a brief present and past history along with a clinical examination to evaluate if you can participate in the study as per inclusion and exclusion criteria.

On the day of the surgery, the nil per mouth status will be confirmed and intra venous cannula will be secured on the forearm. Children will be premedicated with Inj. glycopyrrolate 0.004mg/kg body weight and Inj. ketamine 1.5mg/kg body weight iv to overcome parental separation anxiety and the patient will be shifted to operation theatre, standard monitors will be attached which include ECG, SpO2 and NIBP cuff. the patient will be pre-oxygenated for 3 minutes with a paediatric closed circuit using appropriate flow with head resting on a head ring. Patient induced with Inj midazolam 0.05 mg/kg body weight and Fentanyl 2 mcg/kg body weight iv, isoflurane in incremental doses and inj propofol 1mg/kg iv. After achieving adequate depth of anaesthesia, airways of patients in group A will be secured with I-gel and in group B with SLIPA-2G airways of appropriate sizes. Both devices will be fixed by taping the tube over the chin. No muscle relaxants were given. Patients will be maintained on spontaneous breathing with assisted ventilation to maintain normocapnia.

Voluntary Participation/Withdrawal:

Taking part in the study is voluntary. You may choose not to enrol yourself in this study. Your decision will not change any health care services offered to you or your ward at K.L.E. S Hospital & MRC.

Risks:

There is no risk involved.

Benefits:

Privacy and Confidentiality:

The only people to know that you are as research subject are you and members of the research team. No information provided by you during the research will be disclosed to other without your written permission except:

1. In emergency to protect your rights and welfare.

2. If required by law.

Authorization to Publish Results:

When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with your identity remaining confidential.

Financial Incentives for participation:

No financial incentives are being offered to enrolled patients. It is purely being done with the idea of research and all the cost of the study will be borne by the investigator.

Compensation:

In the event of injury related to the study, treatment will be made available through KLES Hospital and MRC, Belagavi. There is no compensation or payment for such medical treatment by law. If you get injured you may contact REG NO. BA0121020 at Department of Anesthesiology, J.N. Medical College.

Questions:

In case you have any questions related to the study, in future or in case of study-related injury or illness, you can contact REG NO.BA0121020, Department of Anesthesiology, J.N. Medical College, Belagavi. Dr. _______________ Professor and HOD, Dept. Of Anesthesiology, J.N. Medical College.

If you have any queries about your rights as a study subject, you may call Dr. Harsha Hegde, Chairperson, JNMC, IEC & Scientist D, ICMR, National Institute of Traditional Medicine, Belagavi. Ph No: 9480422500

INFORMED CONSENT FOR PARTICIPATION IN RESEARCH TRIAL

"Comparison of I-GEL airway vs SLIPA 2G airway in paediatric patients undergoing general anaesthesia with caudal epidural anaesthesia- one year randomized clinical trial". Mr./Ms./Mrs. ______________________________ voluntarily agree for the participation of as a subject of study. By signing this consent form I am not giving up any of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read for me in vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name : ____________________

Signature or the Left Thumb Print of Subject/Guardian: ___________________

Date:

Witness Name: ____________________ Signature: _______________

Investigators Name: __________________ Signature: _______________

Date:

Place : _______________

ANNEXURE II

PROFORMA

"COMPARSION OF I-GEL AIRWAY VS SLIPA 2G AIRWAY IN PAEDIATRIC PATIENTS UNDERGOING GENERAL ANAESTHESIA WITH CAUDAL EPIDURAL ANAESTHESIA- ONE YEAR RANDOMISED CLINICAL TRIAL AT DR. PRABHAKAR KORE CHARITABLE HOSPITAL, BELAGAVI"

Explanation of procedure: On the day of the surgery the nil per mouth status will be confirmed and intra venous cannula will be secured on the forearm. Children will be premedicated with Inj. glycopyrrolate 0.004mg/kg body weight and Inj. ketamine 1.5mg/kg body weight iv to overcome parental separation anxiety and patient will be shifted to operation theatre, standard monitors will be attached which include ECG, SpO_2 and NIBP cuff. patient will be pre oxygenated for 3 minutes with peadiatric closed circuit using appropriate flow with head resting on a head ring. Patient induced with Inj midazolam 0.05 mg/kg body weight and Fentanyl 2 mcg/kg body weight iv, isoflurane in incremental doses and inj propofol 1mg/kg iv. After achieving adequate depth of anaesthesia, airway of patients in group A will be secured with I-gel and in group B with SLIPA-2G airway of appropriate sizes. Both devices will be fixed by taping the tube over the chin. No muscle relaxants were given. Patients will be maintained on spontaneous breathing with assisted ventilation to maintain normocapnia.

Group allotted :

Name : Age :

Gender : Weight :

Height : Date of Examination :

Address : Occupation :

Pre examination evaluation

Past History

- Congenital disorders ☐ ICU admission ☐ URTI ☐ `
- H/o previous surgery/(s) where airway difficulty will be encountered. ☐

  Yes ☐ No ☐

General physical examination

Weight (Kg)	:	Temperature (^{0}F)	:	Pallor	:
Cyanosis	:	Pedal edema	:	Clubbing	:
PR	:	BP	:	RR	:

Musculoskeletal disorders:

Teeth: Jaw movements:

Airway assessment : Spine:

Investigations

Hb%: Platelet Count :

TLC: INR:

FBS:

Systemic examination:

CNS: RS:

CVS: GIT:

Preoperative physical status American society of anesthesiologist I ☐ II ☐

Diagnosis:

Proposed surgery:

Monitors attached:

Pulse oximetry: NIBP:

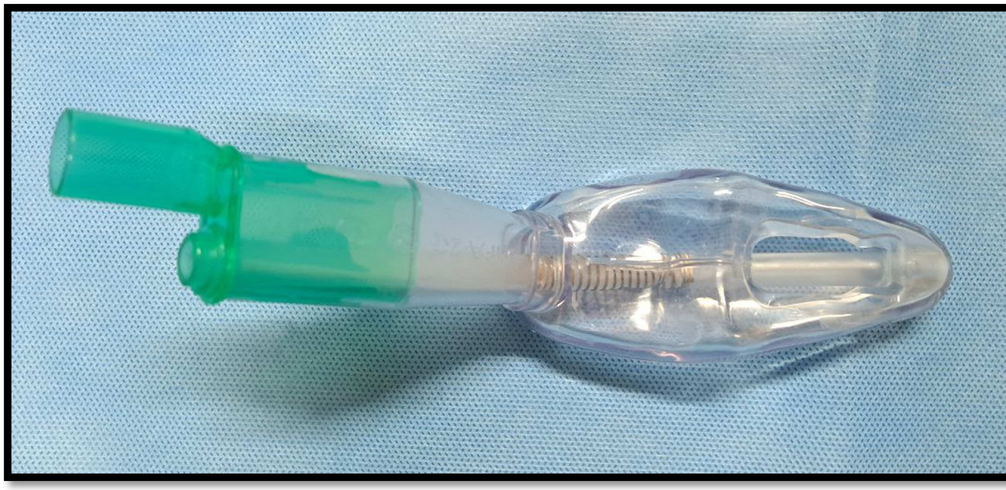
ECG:

VITAL PARAMETERS	***BASELINE***	***AT1 MIN***	***AT 2 MIN***	***AT 3 MIN***	***AT 4 MIN***	***AT 5 MIN***
Heart rate						
NIBP						
ETCO2						
Pulse oximerty						

PARAMETERS	***I-GEL AIRWAY***	***SLIPA-2G AIRWAY***
Ease of insertion		
Airway sealing pressure		
Complication(in any)		

ANNEXURE – IV - PHOTOGRAPHS

PHTOGRAPH 1: SLIPA 2G airway size #39



PHOTOGRAPH 2: SLIPA 2G airway size #47

PHOTGRAPH 3: I-GEL airway size 11/2

PHOTGRAPH 4: I-GEL airway size 11/2

ANNEXURE IV- MASTER CHART

SNO.1	GENDER	GROUP	BASELINE HR	HR 1MIN	HR 2 MIN	HR 3MIN	HR 4 MIN	HR 5MIN	ETCO2 BASELINE	1 MIN	2 MIN	3MIN	4 MIN	5MIN	SBP BASELINE		1 MIN	2 MIN	3 MIN	4 MIN	5 MIN	DBP BASELINE	1 MIN	2 MIN	3 MIN	4 MIN	5 MIN	PULSE OXIMETRY BASELINE	1MIN	2 MIN	3 MIN	4 MIN	5 MIN	EASE OF INSERTION	OROPHARYNGEAL SEAL PRESSURE	COMPLICATIONS	POST OP PHARYNGOLARYNGEAL MORBIDIDTY	AGE(IN YEARS)	WEIGHT (IN KG)	I-GEL SIZE
1	MALE	A	110	110	110	120	108	108		38	35	33	33	33		110	100	100	100	100	100	60	60	60	60	60	60	100	100	100	100	100	100	EASY	22cm of H2O	NO COMPLICATIONS	NO	4	15	2
2	MALE	A	120	120	110	110	106	108	34	35	35	36	38	38		110	110	100	100	100	100	60	60	60	60	60	60	100	100	100	100	100	100	EASY	25cm of H2O	NO COMPLICATIONS	NO	10	18	2.5
3	MALE	A	120	120	110	110	106	108	34	35	35	35	36	38		90	90	98	90	98	98	60	60	60	60	60	70	100	100	100	100	100	100	EASY	25cm of H2O	NO COMPLICATIONS	NO	11	19	2.5
4	MALE	A	120	115	116	112	110	110	34	40	40	38	38	40		110	110	90	90	90	98	60	60	60	60	60	60	100	100	100	100	100	100	VERY EASY	20cm of H2O	NO COMPLICATIONS	NO	5	16.9	2
5	MALE	A	104	102	108	110	110	110	35	35	35	33	35	35		110	110	108	108	108	108	60	60	60	62	62	62	98	98	98	100	100	100	EASY	25cm of H2O	NO COMPLICATIONS	NO	8	21	2
6	MALE	A	100	110	108	108	106	106	40	44	44	42	40	40		98	98	98	98	98	98	70	66	66	62	62	62	100	100	100	100	100	100	EASY	22cm of H2O	NO COMPLICATIONS	NO	4	17.3	2
7	MALE	A	90	96	96	98	98	98	30	30	30	33	33	33		110	100	100	100	100	100	70	70	70	70	70	70	100	100	100	99	99	99	VERY EASY	25cm of H2O	NO COMPLICATIONS	NO	11	13	1.5
8	MALE	A	110	110	110	100	100	100	30	30	33	33	33	33		110	110	110	110	111	111	70	70	70	70	70	70	100	100	100	100	100	100	VERY EASY	21cm of H2O	NO COMPLICATIONS	NO	4.5	14	1.5
9	MALE	A	98	98	98	99	99	99	35	35	35	35	35	35		100	110	110	110	110	110	70	70	70	70	70	70	100	100	100	100	100	100	VERY EASY	20cm of H2O	NO COMPLICATIONS	NO	2	11.6	1.5
10	MALE	A	100	100	110	110	110	110	33	33	33	35	35	35		100	100	100	100	100	100	70	70	70	70	70	70	100	100	100	100	100	100	EASY	22cm of H2O	NO COMPLICATIONS	NO	4	13	1.5
11	MALE	A	100	110	110	110	110	110	30	30	30	33	33	33		110	100	100	100	100	100	70	70	70	70	70	70	100	100	100	100	100	100	EASY	25cm of H2O	NO COMPLICATIONS	NO	10	20	2.5
12	MALE	A	130	130	120	120	120	120	33	34	34	34	34	34		100	99	99	98	98	98	60	60	60	60	60	60	100	100	100	100	100	100	EASY	21cm of H2O	NO COMPLICATIONS	NO	4	12	2
13	MALE	A	98	98	99	99	100	100	30	34	34	34	34	34		100	100	100	100	100	100	60	60	60	60	60	60	100	100	100	100	100	100	EASY	28cm of H20	NO COMPLICATIONS	NO	6	15	2.5
14	FEMALE	A	120	120	120	115	118	118	34	34	34	34	35	35		98	98	98	98	99	98	62	62	62	62	60	60	100	100	100	100	100	100	EASY	20cm of H2O	NO COMPLICATIONS	NO	3	14	2
15	MALE	A	110	110	110	100	100	100	34	34	34	35	35	35		100	100	100	100	100	100	60	60	60	60	60	60	100	100	100	100	100	100	EASY	25cm of H2O	NO COMPLICATIONS	NO	10	12	2
16	MALE	A	99	98	99	99	99	100	34	34	34	35	35	35		110	100	100	100	100	100	70	66	62	62	62	62	100	100	100	100	100	100	EASY	28cm of H20	NO COMPLICATIONS	NO	12	18	2.5

17	MALE	A	98	98	98	99	99	99	30	30	33	33	33	33		100	100	100	100	100	100	60	60	60	60	60	60	99	99	99	100	100	100	VERY EASY	25cm of H_2O	NO COMPLICATIONS	NO	9	12.5	1.5
18	MALE	A	100	99	99	99	110	110	34	34	34	35	35	35		100	100	100	100	100	100	60	60	60	60	60	60	100	100	100	100	100	100	EASY	25cm of H_2O	NO COMPLICATIONS	NO	10	21.5	2.5
19	MALE	A	98	98	98	99	99	99	35	35	35	35	35	35		110	110	110	110	110	110	60	60	60	60	60	60	100	100	100	100	100	100	EASY	22cm of H_2O	NO COMPLICATIONS	NO	5	13	1.5
20	MALE	A	130	130	130	130	133	133	38	38	38	38	40	40		90	90	90	90	92	92	60	60	60	66	66	66	100	100	100	100	100	100	EASY	25cm of H_2O	NO COMPLICATIONS	NO	9	23.2	2.5
21	FEMALE	A	110	110	110	110	110	110	34	34	34	35	35	35		98	98	98	98	98	98	70	70	66	62	62	62	100	100	100	100	100	100	EASY	18cm of H_2O	NO COMPLICATIONS	NO	2	8.75	1.5
22	MALE	A	140	140	140	140	138	138	35	35	35	35	35	35		98	98	98	98	98	98	60	60	60	60	60	60	100	100	100	100	100	100	EASY	22cm of H_2O	NO COMPLICATIONS	NO	9	22	2.5
23	MALE	A	130	130	130	130	130	128	33	33	33	33	35	35		98	98	98	98	98	98	66	66	60	60	60	60	100	100	100	100	100	100	DIFFICULT	18cm of H_2O	NO COMPLICATIONS	NO	1	9	1.5
24	MALE	A	120	140	138	138	133	133	38	38	38	40	40	40		100	100	100	100	99	99	60	60	60	60	60	60	100	100	100	100	100	100	VERY EASY	25cm of H_2O	NO COMPLICATIONS	NO	4	14.2	2
25	FEMALE	A	120	120	120	118	118	118	35	35	35	35	38	38		98	98	99	99	99	99	70	60	60	66	62	62	100	100	99	99	99	100	EASY	21cm of H_2O	NO COMPLICATIONS	NO	3	9.5	1.5
26	FEMALE	A	88	88	90	92	92	92	40	40	40	38	38	40		110	110	110	110	100	100	70	70	70	70	70	70	100	100	100	100	100	100	EASY	20cm of H_2O	NO COMPLICATIONS	NO	1	8.2	1
27	MALE	A	120	120	118	118	118	118	35	35	35	35	38	38		110	Apr-00	100	100	100	100	60	60	60	60	60	60	100	100	100	100	100	100	EASY	28cm of H_2O	NO COMPLICATIONS	NO	15	30	2.5
28	MALE	A	130	130	130	130	128	128	38	38	38	38	40	30		90	90	90	90	90	90	60	60	60	60	60	60	99	99	98	98	100	100	VERY EASY	25cm of H_2O	NO COMPLICATIONS	NO	6	14.8	1.5
29	MALE	A	120	120	120	120	118	118	35	35	35	38	38	38		99	99	98	98	98	98	62	62	62	62	62	62	99	99	99	100	100	100	VERY EASY	20cm of H_2O	NO COMPLICATIONS	NO	2	12.1	1.5
30	FEMALE	A	120	120	120	120	120	120	35	35	35	35	35	35		100	100	100	100	100	100	60	60	60	60	60	60	100	100	100	100	100	100	VERY EASY	20cm of H_2O	NO COMPLICATIONS	NO	2	10	1.5
31	MALE	A	120	118	118	118	118	120	40	40	40	38	38	38		98	98	98	98	98	98	60	60	60	60	60	60	100	100	100	100	100	100	VERY EASY	20cm of H_2O	NO COMPLICATIONS	NO	2	11.5	1.5
32	MALE	A	110	110	110	110	100	100	34	34	34	35	35	35		100	100	100	100	100	100	60	60	60	60	60	60	100	100	100	100	100	100	EASY	25cm of H_2O	NO COMPLICATIONS	NO	4	11.7	1.5
33	MALE	A	98	98	99	99	99	99	30	30	30	33	33	33		98	98	98	98	98	98	60	60	60	60	60	60	100	99	99	100	100	100	EASY	28cm of H_2O	NO COMPLICATIONS	NO	6	18	2
34	FEMALE	A	110	110	110	110	110	100	35	35	35	35	35	35		100	100	100	100	99	99	60	60	60	60	60	60	100	99	99	99	100	100	EASY	25cm of H_2O	NO COMPLICATIONS	NO	10	22	2.5
35	MALE	A	100	100	110	110	110	110	40	40	40	40	39	39		90	90	90	90	90	90	60	60	60	60	60	60	100	100	100	100	100	100	EASY	25cm of H_2O	NO COMPLICATIONS	NO	4	13	1.5
36	MALE	A	110	110	110	110	100	100	30	30	30	30	30	30		100	110	110	110	110	110	60	60	60	60	60	60	100	100	100	100	100	100	EASY	30cm of H_2O	NO COMPLICATIONS	NO	10	25	2.5
37	MALE	A	92	98	98	98	98	99	33	33	33	33	34	34		100	100	100	100	100	100	60	60	60	60	60	60	99	99	99	100	100	100	EASY	25cm of H_2O	NO COMPLICATIONS	NO	7	25	2.5
38	MALE	A	100	100	100	100	100	100	35	35	35	35	35	35		98	98	98	98	98	98	60	60	60	60	60	60	100	99	100	100	100	100	EASY	22cm of H_2O	NO COMPLICATIONS	NO	9	22	2
39	MALE	A	110	110	100	100	100	100	33	33	33	33	33	33		90	92	92	92	92	92	60	62	62	62	62	62	100	100	100	100	100	100	VERY EASY	22cm of H_2O	NO COMPLICATIONS	NO	8	15.2	2
40	MALE	A	120	120	118	118	118	118	38	38	38	38	40	40		99	99	99	99	99	99	62	62	62	62	62	62	100	100	100	100	100	100	EASY	25cm of H_2O	NO COMPLICATIONS	NO	11	25.3	2.5

SNO.1	GENDER	GROUP	BASELINE HR	HR 1MIN	HR 2 MIN	HR 3MIN	HR 4 MIN	HR 5MIN	ETCO2	1 MIN	2 MIN	3MIN	4 MIN	5MIN	SBP BASELINE	1 MIN	2 MIN	3 MIN	4 MIN	5 MIN	DBP BASELINE	1 MIN	2 MIN	3 MIN	4 MIN	5 MIN	PULSE OXIMETRY BASELINE	1MIN	2 MIN	3 MIN	4 MIN	5 MIN	**EASE OF INSERTION**	**OROPHARYNGEAL SEAL PRESSURE**	**COMPLICATIONS**	**POST OP PHARYNGOLARYNGEAL MORBIDITY**	**AGE IN YEARS**	**WEIGHT(IN KG)**	**SLIPA-2G SIZE**
1	MALE	B	110	110	110	110	112	112	34	34	34	34	35	35	100	100	100	100	100	100	60	60	60	60	60	60	100	100	100	100	100	100	VERY EASY	30cm of H2O	NO COMPLICATIONS	NO	3	13.5	39
2	FEMALE	B	106	110	110	108	108	108	44	42	42	42	42	42	98	98	98	98	98	98	60	60	60	60	60	60	99	99	99	100	100	100	EASY	30cm of H2O	NO COMPLICATIONS	NO	4	14	37
3	MALE	B	98	98	98	98	99	99	32	32	32	33	33	33	100	100	100	100	100	100	60	60	60	60	60	60	100	100	100	100	100	100	EASY	30cm of H2O	NO COMPLICATIONS	NO	12	20	39
4	MALE	B	98	98	98	99	99	99	35	35	35	34	34	34	100	100	100	100	100	100	60	60	60	60	60	60	99	99	99	100	100	100	VERY EASY	28cm of H2O	NO COMPLICATIONS	NO	12	15	39
5	FEMALE	B	100	100	100	110	110	110	33	33	33	34	34	34	110	110	110	111	111	111	60	60	60	60	60	60	99	99	100	100	100	100	EASY	25cm of H2O	NO COMPLICATIONS	NO	12	16	39
6	MALE	B	100	100	110	110	110	110	35	35	35	35	35	35	98	98	98	98	98	98	60	60	60	60	60	66							EASY	25cm of H2O	NO COMPLICATIONS	NO	15	20	39
7	MALE	B	90	96	96	98	98	98	30	30	30	30	30	30	100	100	100	100	99	99	62	62	62	62	62	66	100	100	100	100	100	100	EASY	28cm of H2O	NO COMPLICATIONS	NO	4	15	39
8	MALE	B	106	106	108	108	110	110	32	32	32	32	33	33	110	111	110	110	111	111	70	70	70	70	70	70	99	99	100	100	100	100	VERY EASY	30cm of H2O	NO COMPLICATIONS	NO	9	10	37
9	MALE	B	98	98	98	99	99	99	33	33	33	33	34	34	100	110	110	110	110	110	70	70	70	70	70	70	100	100	100	100	100	100	EASY	28cm of H2O	NO COMPLICATIONS	NO	12	20	39
10	MALE	B	100	100	110	110	110	110	30	30	30	30	30	30	110	110	110	110	110	110	66	66	66	62	62	62	100	100	100	100	100	100	VERY EASY	25cm of H2O	NO COMPLICATIONS	NO	10	15	45
11	MALE	B	88	88	90	90	90	99	32	32	32	32	32	32	100	100	100	100	100	102	70	70	70	70	70	70	100	100	100	100	100	100	EASY	20cm of H2O	NO COMPLICATIONS	NO	3	13	39
12	MALE	B	100	100	110	110	110	110	33	33	33	34	34	34	100	99	99	98	98	98	60	60	60	60	60	60	100	99	100	100	100	99	EASY	25cm of H2O	NO COMPLICATIONS	NO	4	12	39
13	MALE	B	92	92	92	96	96	96	30	30	30	30	30	30	100	100	100	100	100	100	70	70	70	70	70	70	98	98	99	99	100	100	EASY	30cm of H2O	NO COMPLICATIONS	NO	8	22	39
14	MALE	B	98	98	99	99	100	100	34	34	35	35	35	35	100	100	100	100	100	100	70	70	70	70	70	70	99	99	100	100	100	100	EASY	25cm of H2O	NO COMPLICATIONS	NO	5	16	39
15	MALE	B	88	88	88	90	90	90	30	30	30	33	33	33	98	98	98	98	98	98	60	60	60	60	60	60	100	100	100	100	100	100	EASY	25cm of H2O	NO COMPLICATIONS	NO	10	20	45
16	MALE	B	98	98	99	99	99	100	30	30	30	30	30	30	110	110	110	110	100	100	70	70	70	70	70	70	100	100	100	100	100	100	EASY	28cm of H2O	NO COMPLICATIONS	NO	6	16	39
17	FEMALE	B	100	99	99	99	100	102	33	33	33	33	33	33	98	98	98	98	99	99	60	60	60	60	60	60	100	100	100	100	100	100	EASY	25cm of H2O	NO COMPLICATIONS	NO	3	11.5	37

18	MALE	B	99	99	99	99	99	100	30	30	30	30	30	30	100	100	100	100	100	100	60	60	60	60	60	60	99	100	100	100	100	100	EASY	25cm of H2O	NO COMPLICATIONS	NO	8	13	37
19	MALE	B	88	88	90	90	99	99	28	28	28	30	30	30	100	100	100	100	100	100	70	70	70	70	70	70	99	99	99	100	100	100	DIFFICULT	25cm of H2O	NO COMPLICATIONS	NO	11	20	45
20	MALE	B	98	100	100	110	110	110	33	33	33	33	33	33	98	98	99	99	99	99	60	60	62	62	62	62	99	99	99	100	100	100	EASY	25cm of H2O	NO COMPLICATIONS	NO	7	14	37
21	MALE	B	96	96	98	98	98	98	28	28	30	30	30	30	110	110	110	110	110	110	70	70	70	70	70	70	99	99	100	100	100	100	EASY	30cm of H2O	NO COMPLICATIONS	NO	7	12	37
22	MALE	B	92	92	100	110	110	110	28	28	33	33	33	34	100	100	100	100	100	100	60	60	60	60	60	60	100	100	100	100	100	100	EASY	25cm of H2O	NO COMPLICATIONS	NO	9	20	45
23	MALE	B	98	98	99	99	100	100	35	35	35	35	35	35	98	98	98	98	98	98	60	60	60	60	60	60	99	99	100	100	100	100	EASY	30cm of H2O	NO COMPLICATIONS	NO	10	15	39
24	MALE	B	100	100	100	99	99	99	30	30	30	30	30	30	100	100	100	99	99	99	70	70	70	70	70	70	99	99	100	100	100	100	DIFFICULT	28cm of H2O	NO COMPLICATIONS	NO	8	19	45
25	MALE	B	88	88	90	90	90	96	35	35	35	35	35	35	100	100	100	1001	100	100	60	60	60	60	60	60	100	100	100	100	100	100	EASY	28cm of H2O	NO COMPLICATIONS	NO	8	22	39
26	MALE	B	99	99	100	102	102	102	33	33	33	33	33	33	90	90	90	90	90	90	60	60	60	60	60	60	99	99	100	100	100	100	EASY	25cm of H2O	NO COMPLICATIONS	NO	4	13	37
27	MALE	B	98	98	98	100	100	100	32	32	32	35	35	35	98	98	98	98	99	99	66	66	66	66	66	60	100	100	100	100	100	100	EASY	30cm of H2O	NO COMPLICATIONS	NO	6	18	39
28	MALE	B	110	110	110	102	102	102	28	28	30	30	33	33	110	110	110	102	102	102	60	60	60	60	60	60	100	100	100	100	100	100	EASY	33cm of H20	NO COMPLICATIONS	NO	7	20	45
29	FEMALE	B	112	115	120	120	120	120	30	30	30	30	30	30	110	110	110	110	110	110	62	62	62	66	66	60	100	100	100	100	100	100	EASY	30cm of H2O	NO COMPLICATIONS	NO	5	16	37
30	MALE	B	98	98	98	100	100	100	35	35	35	35	33	33	90	90	90	90	90	90	60	60	60	60	60	60	100	100	100	100	100	100	EASY	28cm of H2O	NO COMPLICATIONS	NO	9	18	37
31	MALE	B	110	110	110	112	112	112	30	30	30	30	32	32	92	92	92	92	92	92	60	60	60	60	60	60	100	100	100	100	100	100	DIFFICULT	28cm of H2O	NO COMPLICATIONS	NO	3	12	37
32	MALE	B	110	110	110	110	116	116	35	35	35	35	35	35	100	100	100	100	100	100	60	60	60	62	62	66	99	99	99	100	100	100	EASY	33cm of H20	NO COMPLICATIONS	NO	10	25	45
33	MALE	B	99	99	100	100	100	100	34	34	34	34	33	33	98	98	98	98	99	99	62	62	62	60	66	66	99	99	100	100	100	100	EASY	25cm of H2O	NO COMPLICATIONS	NO	8	26	45
34	MALE	B	110	110	110	110	116	116	34	34	35	35	35	35	110	110	110	110	110	110	70	70	70	70	70	70	99	99	100	100	100	100	EASY	28cm of H2O	NO COMPLICATIONS	NO	5	22	45
35	MALE	B	120	120	115	115	112	112	35	35	35	35	35	35	100	100	100	100	100	100	60	60	60	60	60	61	99	99	100	100	100	100	VERY EASY	30cm of H2O	NO COMPLICATIONS	NO	11	29	45
36	MALE	B	99	99	100	100	100	100	40	40	40	41	41	41	100	100	100	100	100	100	60	60	60	60	60	60	99	99	100	100	100	100	EASY	28cm of H2O	NO COMPLICATIONS	NO	5	15	39
37	MALE	B	98	98	99	99	99	99	33	33	33	33	35	35	98	98	98	98	98	98	60	60	62	62	62	62	100	100	100	100	100	100	VERY EASY	25cm of H2O	NO COMPLICATIONS	NO	8	21	39
38	MALE	B	98	98	99	99	100	100	33	33	34	34	34	34	90	90	90	92	92	92	60	60	60	60	60	60	99	99	100	100	100	100	EASY	28cm of H2O	NO COMPLICATIONS	NO	8	23	45
39	MALE	B	98	98	99	99	99	100	32	32	32	32	33	33	100	100	100	100	100	100	70	70	70	70	70	70	99	99	100	100	100	100	EASY	30cm of H2O	NO COMPLICATIONS	NO	5	18	39
40	MALE	B	110	110	110	108	108	108	35	35	35	35	34	34	99	99	99	99	99	99	62	62	62	62	62	62	99	99	99	100	100	100	EASY	33cm of H20	NO COMPLICATIONS	NO	6	22	45