"COMPARATIVE EVALUATION OF AMBU AURA-I AND FASTRACHTM INTUBATING LARYNGEAL MASK AIRWAY FOR TRACHEAL INTUBATION: A RANDOMIZED CONTROLLED STUDY"

By

Dr. S M KUSHAL

DISSERTATION SUBMITTED TO SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, KOLAR, KARNATAKA

In partial fulfillment of the requirements for the degree of

DOCTOR OF MEDICINE

IN

ANAESTHESIOLOGY

Under the Guidance of

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"COMPARATIVE EVALUATION OF AMBU AURA-I AND FASTRACHTM INTUBATING LARYNGEAL MASK AIRWAY FOR TRACHEAL INTUBATION: A RANDOMIZED CONTROLLED STUDY"

ABSTRACT

Background: When it comes to airway management, supraglottic airway devices (SADs) are indispensable, particularly in situations when tracheal intubation is difficult or impossible.

Ambu Aura-i and Fastrach™ laryngeal mask airway (FT-LMA) are two well-known SADs that are intended to make tracheal intubation and ventilation easier.

The FT-LMA, while effective, has limitations such as its rigid airway tube and non-availability for pediatric use. The Ambu Aura-i, with its preformed curvature and availability in various sizes, offers a modern alternative with reported success in managing difficult airway. This study aims to comparatively evaluate these two devices in anticipated difficult airway management in adults.

Aim: "To compare the effectiveness of Fastrach™ LMA and Ambu Aura-i in tracheal intubation in adults with anticipated difficult airway management."

Materials and Methods: "This randomized, interventional, two-group, comparative prospective clinical study involved 50 adult patients undergoing scheduled surgeries requiring tracheal intubation under general anesthesia. Patients, aged 18 to 60 years, with

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Date: **Dr S M KUSHAL**

Place:

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ABBREVIATIONS

ASA: American Society of Anaesthesiologists

DAS: Difficult Airway Society

ETT: Endotracheal Tube

FT-LMA: Fastrach™ Laryngeal Mask Airway

ILMA: Intubating Laryngeal Mask Airway

LMA: Laryngeal Mask Airway

SAD: Supraglottic Airway Device

ABSTRACT

Background: Supraglottic airway devices (SADs) are critical in airway management, especially in scenarios where tracheal intubation is challenging or impossible. The Fastrach™-laryngeal mask airway (FT-LMA) and Ambu Aura-i are two prominent SADs designed to facilitate both ventilation and tracheal intubation. The FT-LMA, while effective, has limitations such as its rigid airway tube and non-availability for pediatric use. The Ambu Aura-i, with its preformed curvature and availability in various sizes, offers a modern alternative with reported success in difficult airway management. This study aims to comparatively evaluate these two devices in anticipated difficult airway management in adults.

Aim: To compare the effectiveness of Fastrach™ LMA and Ambu Aura-i in tracheal intubation in adults with anticipated difficult airway management.

Materials and Methods: This randomized, interventional, two-group, comparative prospective clinical study involved 50 adult patients undergoing scheduled surgeries requiring tracheal intubation under general anesthesia. Patients, aged 18 to 60 years, with ASA physical status I or II, were randomly assigned to two groups: Group A (Fastrach™ LMA) and Group B (Ambu Aura-i). Data on success rates, number of attempts, duration of successful attempts, and adverse events were recorded. Hemodynamic parameters were monitored throughout the procedure.

Results: Both groups showed comparable baseline characteristics including age, gender distribution, ASA grade, and physical parameters. There was no significant difference in heart rate, systolic and diastolic blood pressure, mean arterial pressure, or oxygen saturation between the groups. However, Group A (Fastrach™ LMA) required significantly shorter tracheal tube insertion time (16.1±2.0 sec vs. 19.1±1.9 sec; $p<0.05$) and fewer attempts for successful intubation compared to Group B (Ambu Aura-i). The incidence of blood on SAD and sore throat was higher in Group B but not statistically significant.

Conclusion: The Fastrach™ LMA demonstrated marginally superior performance over the Ambu Aura-i in terms of shorter tracheal tube insertion times and fewer attempts required for successful intubation. Both devices are effective in managing difficult airways, but the Fastrach™ LMA offers advantages in ease and efficiency, making it a potentially more effective option for critical scenarios requiring rapid and reliable tracheal intubation.

Keywords: Supraglottic airway device, Fastrach™ LMA, Ambu Aura-i, tracheal intubation, difficult airway management, anesthesia.

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INTRODUCTION

INTRODUCTION

The management of airways requires the use of supraglottic airway devices, or SADs.(1) In any situation where intubation cannot be done, the use of SADs in order to facilitate tracheal intubation is advised by several guidelines.(2, 3)

The FastrachTM-laryngeal mask airway (FT-LMA, Laryngeal Mask Company, Jersey, United kingdom) was designed to allow for both ventilating and the blind insertion of a tracheal tube into the trachea.(4,5)

Several successful intubations have been performed for both expected and unexpectedly difficult airways, and blind tracheal intubation is generally successful. Nonetheless, Fastrach-LMA has certain drawbacks, such as hardness of airway tube, which restricts its long-term usage. Also, the tracheal tube needed is a different and exorbitant. Furthermore, it is not present for pediatric age group.(6,7)

The Aura-i, a single-use intubating SAD from Ambu USA, is meant to be used for tracheal intubation as well as ventilation.(8,9) If a fiberscope is to be inserted during intubation, it features navigation markings, a biting block, and a 90° prepared curve. Eight distinct sizes are offered for the Aura-i to accommodate all age groups. There are reports of successful intubations with it, despite difficult airway clearance.(9–15)

The Ambu aura-I and FastrachTM Intubating Laryngeal Mask Airway (ILMA) represent innovative advancements in airway management, offering a reliable and efficient alternative for tracheal intubation. The AMBU Aura-I features a unique anatomically curved design and integrated suction capabilities, enhancing both ease of insertion and patient safety during airway management procedures. On the other hand, the FastrachTM

ILMA combines the benefits of a laryngeal mask airway with a guiding mechanism for tracheal tube placement, facilitating swift and accurate intubation even in challenging situations. These devices are particularly crucial in emergency scenarios or difficult airway situations where traditional intubation methods may be impractical or unsuccessful. Their significance lies in their ability to provide a secure airway and ensure optimal patient outcomes while minimizing the risk of complications associated with conventional intubation techniques.(16)

After extensive research on the literature, it is discovered that there is insufficient information available regarding the Ambu Aura-i tracheal intubation assessment. Thus, the objective of the present study is to compare adult Fastrach- LMA with Aura-i for tracheal intubation procedures.

AIMS & OBJECTIVES

AIMS & OBJECTIVES

Aim

Comparative evaluation of Ambu Aura-I and Fastrach^{TM} intubating laryngeal mask airway for tracheal intubation

Objectives:

Primary- To evaluate the effectiveness of intubation with Fastrach^{TM} LMA and Ambu aura-i in Anticipated Difficult Airway Management

Secondary- To evaluate the time taken and number of attempts for intubation with Fastrach^{TM} and Ambu Aura-i in Anticipated Difficult Airway Management.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

In 1983, in the London hospital Whitechapel, Dr Archie Brain invented the laryngeal mask airway, a breakthrough device in the concept of airway management under anaesthesia. When it came to managing the airway of anaesthetized patients, a laryngeal mask airway was first recommended as being preferable to a facemask. Hundreds of handcrafted prototypes were evaluated in the clinic by the inventor between 1981 and 1988, leading to the creation of at least 27 variants with potential therapeutic benefits, five of which are used in anaesthetic practice.(17,18) Soon after the laryngeal mask airway was introduced into clinical practice in 1988, it was shown to be a more effective breathing device than the facemask and to cause less activation of the cardiovascular system and defensive airway reflexes than the endotracheal tube. The laryngeal mask airway has been used in clinical practice for over 15 years. Over 150 million patients have benefited from its safe and successful usage, and its clinical uses have grown to include almost every anaesthesia subspecialty.(19)

Dr A.I.J. Brain created the laryngeal mask airway, a novel kind of device that maintains the airway under anaesthesia, in 1981. In 1983, he released his first report. This device proved helpful for patients who had difficult intubations and provided some of the benefits of endotracheal intubation. In 1988, the laryngeal mask was introduced to clinical practice. Since then, its application has grown quickly and is becoming increasingly established in the field of anaesthesia. Both spontaneous breathing and sporadic positive pressure ventilation were permitted under the LMA.(20)

Anatomy:

Upper airway consists of nose and nasal cavity, mouth and oral cavity, the pharynx, the larynx and trachea.(21)

Mouth and Oral cavity:

The mouth is divided by the teeth into the oral cavity proper and an outside vestibule. It extends from the lips to the oropharyngeal isthmus, which is located at the level of the palatoglossal folds. Mucus-secreting glands are housed inside the squamous epithelium that lines the mouth cavity. Its borders are the hard and soft palates superiorly, and the teeth and gums anterolaterally. The oropharyngeal isthmus is defined by the palatoglossal fold, sometimes referred to as the front pillar of the tonsil. It divides the tongue from the soft palate. Its front two thirds and posterior thirds are connected to the tongue.(22)

The tongue: The tongue sits on the floor of the mouth, almost filling it. It contains intrinsic and several extrinsic muscles connecting it to associated structures.(23) e.g.

Hyglossus: Connects to hyoid bone

Genioglossus: Connects to mandible

Palatoglossus: Connects to the soft palate

Styloglossus: Connects to styloid process of the skull base

The underside of the tongue is connected to the floor of the mouth by a mucous membrane fold known as the frenulum. The posterior third of the tongue originates from distinct embryological origins and is situated within the oropharynx.(22)

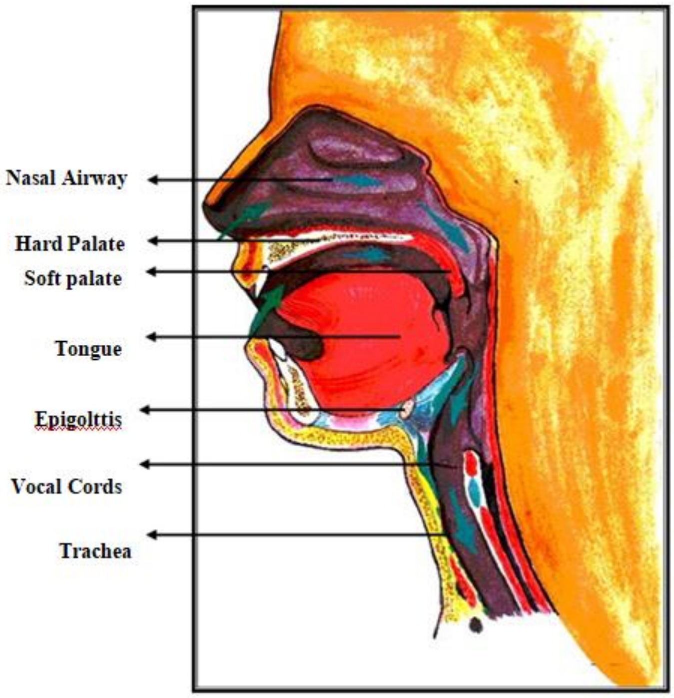

Figure 1: Normal upper airway

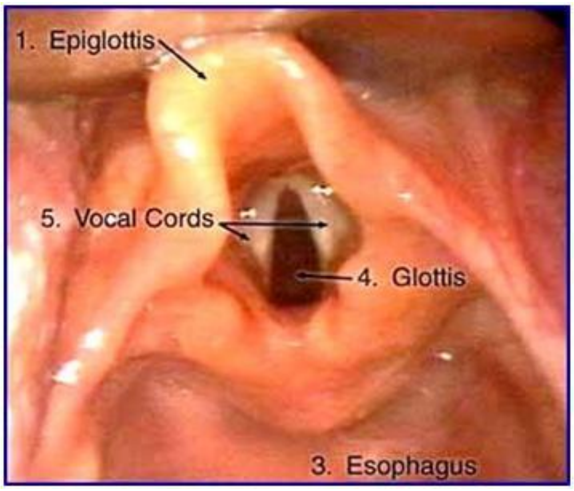

Figure 2: Vocal Cords

The soft palate comprises an aponeurotic sheath that houses multiple muscles inserted laterally. It forms a divide between the nasopharynx and oropharynx and joins 'anteriorly to the back of the hard palate. Its detached posterior border supports the midline uvula'.

The soft palate has ciliated columnar epithelium lining its top surface and squamous epithelium lining its lower surface.

Muscles acting on soft palate:

The tensor palati and levator palati muscles attach to the sides of the palate, causing it to rise and contract, respectively. The oropharyngeal aperture becomes constricted as a result of the palatoglossus muscle, which passes through the palatopharyngeal fold and towards the tongue.(22)

The pharyngeal constrictor muscle and the palatopharyngeus muscle are connected by the palatopharyngeal fold, referred to as the posterior pillar. Its action contributes to the constriction of the oropharyngeal aperture. The uvula is elevated by the musculus uvulae, an intrinsic muscle.

<u>Somatic innervation of oral cavity:</u>

The Vestibule:

Sensory: **Trigeminal (V2 and V3) via alveolar and labial branches.**

Motor: **Facial (VII).**

Hard Palate:

Taste: Facial (VII) via branches of V2.

Sensory: **Trigeminal (V2) via palatine and nasopalatine branches.**

Soft palate:

Motor: **Trigeminal (V3) to tensor levi palatini and via pharyngeal plexus (IX, X, XI) to rest of the muscles.**

Sensory: **Trigeminal (V2) via palatine branches to anterion region and Glossopharyngeal to posterior region.**

Taste: Facial (VII) via greater petrosal nerve.

Tongue:

Sensory: **Trigeminal (V3) via lingual nerve to anterior 2/3.**

Glossopharyngeal (IX) to posterior 1/3."

Motor: **Pharyngeal plexus (IX, X, XI) to palatoglossus. Hypoglossal nerve supplies all other muscles.**

Taste: Facial (VII) via chorda tympani to anterior 2/3.

Glossopharyngeal (IX) to posterior 1/3.

Blood supply and lymphatic drainage:

Arterial supply: Lingual, maxillary and facial branches of external carotid artery.

Drainage of blood is to the corresponding veins. Soft palate drains into the pharyngeal venous plexus.

Lymphatic drainage: Deep cervical lymph chain. Anterior tongue and floor of the mouth drain initially into sub mental and submandibular nodes.

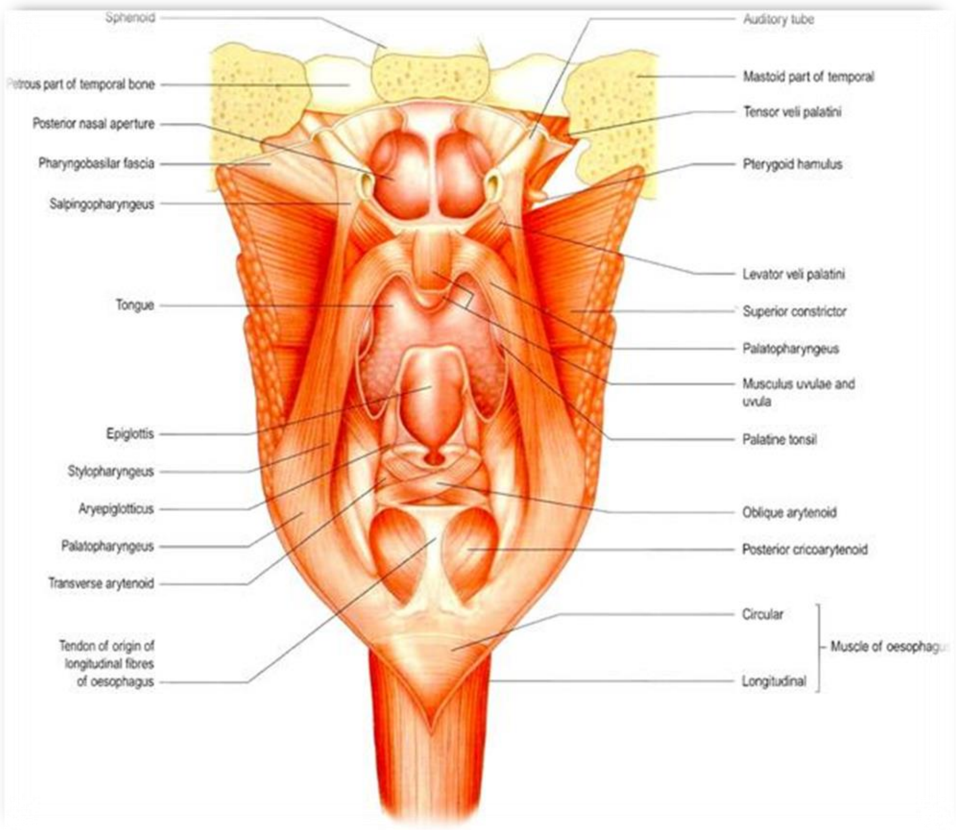

Figure 3: Schematic representation of Pharynx.

The nose, mouth, larynx, and oesophagus are joined by a smooth muscular tube known as the pharynx. It joins the oesophagus at the sixth cervical vertebra, after beginning at the base of the skull. The laryngopharynx, oropharynx, and nasopharynx are the three sections that make up the pharynx, which is situated right in front of the cervical spine and prevertebral fascia.

The nasopharynx, which is lined with ciliated columnar epithelium and connects to the oropharynx at the level of the soft palate, has an opening for the Eustachian tube in each of its lateral walls. The oropharynx, characterised by stratified squamous epithelium, readily gives way to the laryngopharynx at the level of the epiglottis.

Two lateral and a central glosso-epiglottic fold connect it to the front of the epiglottis, generating two pockets called the valecullae. Before elevating the epiglottis during a laryngoscopy, the laryngoscope's tip is positioned at these valecullae.(24,25)

The laryngopharynx spreads around the larynx in anterolateral direction, towards laminae of the thyroid cartilage. It is lined by stratified squamous epithelium.

The arrangement creates two longitudinal channels known as the pyriform fossae, which commonly serve as sites for foreign body impaction. A fibromuscular sheath, with a denser fibrous layer superiorly when muscle tissue is missing, sits beneath the pharyngeal mucosa. These are important muscles in the swallowing process. The pharynx is surrounded by the superior, middle, and inferior constrictor muscles, which overlap like a stack of paper cups. This fibromuscular tube is shaped by the stylopharyngeus, salpingopharyngeus, and palatopharyngeus muscles, which attaches into it.(24,25)

Nerve supply: The pharyngeal plexus supplies sensory, motor and autonomic nerves

Motor fibres pass through the Vagus nerve.

Taste perception originates from the posterior portion of the tongue and is mostly carried by sensory fibres in the glosopharyngeal nerve.

Blood supply and lymphatic drainage:

Arterial supply: Ascending pharyngeal, superior thyroid, lingwall facial and maxillary arteries (all branches of external carotid artery).

Venous drainage: Pharyngeal Plexus and thus to the internal jugular vein.

Lymphatic flow: Passes to retropharyngeal lymph nodes and to the deep cervical lymph node chain.

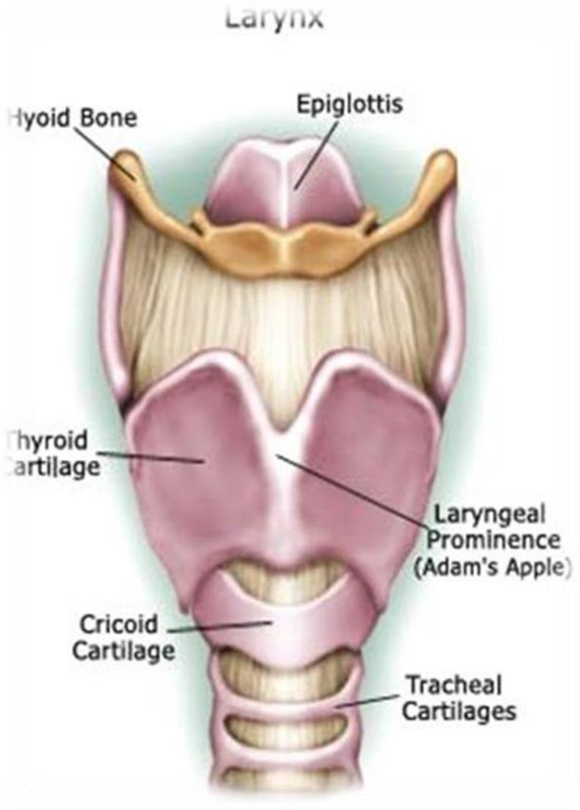

Figure 4: Structure of Larynx.

The pharynx and trachea are divided by the larynx. Its skeleton is composed of membranes, ligaments, and cartilage.

Stratified squamous epithelium lines the larynx, while ciliated columnar epithelium is present in the mucous membrane beneath the voice cords. The larynx in adult males is approximately 45 mm long and has an anteroposterior width of 35 mm; in adult females, the larynx is approximately 35 mm by 25 mm. The larynx is positioned in front of the third and sixth cervical vertebrae, anterior to the proximal oesophagus.(26)

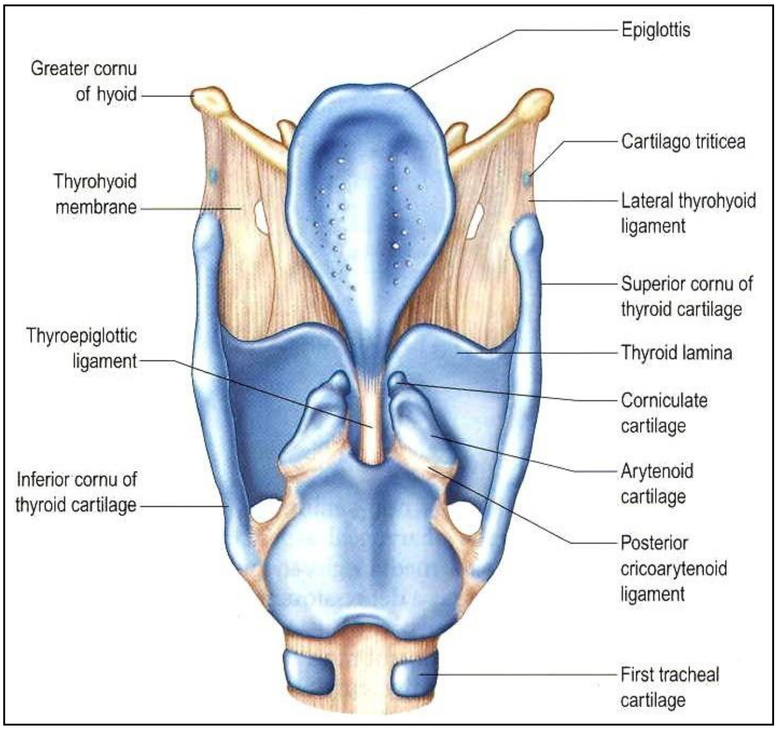

Figure 5: Posterior View of Larynx.

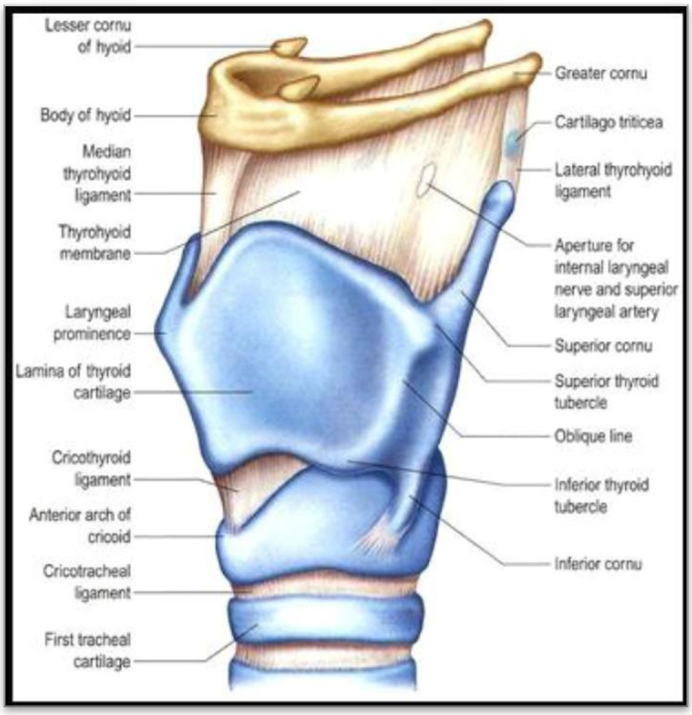

Figure 6: Lateral view of Larynx.

THE LARYNX

The larynx contains cartilages, ligaments and membranes and muscles.

Cartilages: Following are the cartilages present in the larynx:

Thyroid cartilage

Epiglottic cartilage

Cricoid cartilage.

Arytenoids cartilages (paired)

Cuneiform (paired)

Corniculate (paired)

Ligament and membranes:

Thyroid and hyoepiglottic ligaments: Connect with the hyoid bone.

Vestibular membrane (quadrate): Joins the thyroid, epiglottic and aryteniod cartilages.

Cricotracheal ligament: Joins with the trachea below

The cricothyroid membrane: Joins the cricoid and arytenoid cartilages to the thyroid cartilage. This is an important site access for securing and emergency airway (cricothyrotomy).(26)

Muscles: Muscles are extrinsic and intrinsic

Intrinsic muscles: The cricothyroid muscle functions to increase tension on the vocal cords by tilting the lamina of the cricoid and consequently moving the arytenoids posteriorly. The posterior cricoarytenoid muscle serves as the primary abductor of the vocal cords. The lateral cricoarytenoid muscle contributes to cord adduction through internal rotation. Acting as an adductor of the vocal cords, the interarytenoid muscle is the sole unpaired muscle in this group. The aryepiglottic muscle functions as a sphincter at the laryngeal inlet. The thyroarytenoid muscle is responsible for relaxing the vocal cords. Lastly, the thyroepiglottic muscle acts as a sphincter at the laryngeal inlet.(27)

Extrinsic muscles:

Thyrohyoid and sternohyoid muscles: Elevate and depress the larynx respectively

Inferior constructor muscle of pharynx

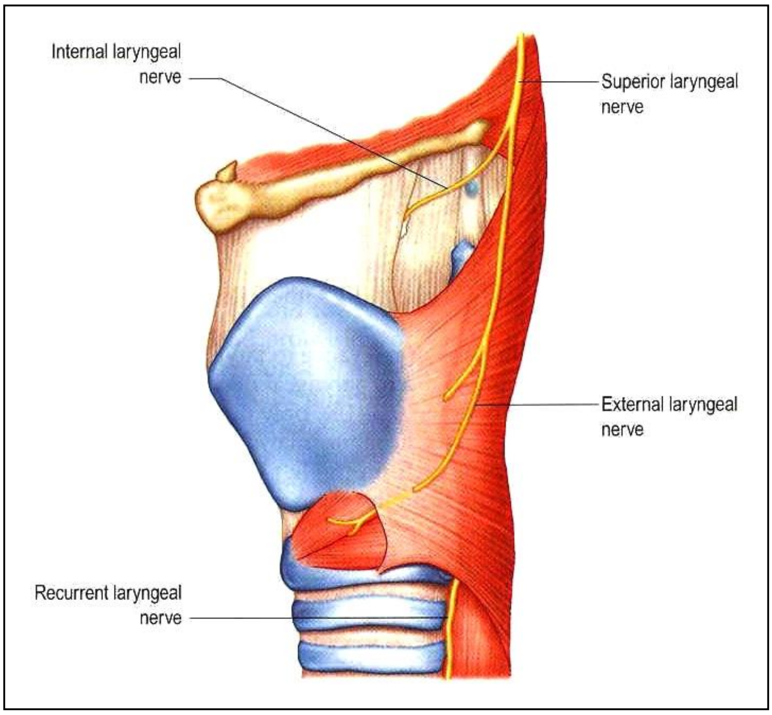

Figure 7: Somatic innervations of Larynx.

The sensory innervation of Larynx is provided by the vagus nerve (X). It sends impulses via the recurrent laryngeal nerve to the mucosa below the vocal cords and the internal laryngeal nerve to the mucosa above the vocal chords.

The accessory nerve (XI) controls motor function. With the exception of the cricothyroid muscle, which is under the control of the external laryngeal nerve to X, it unites with the vagus nerve (X) to transmit impulses to all intrinsic muscles via the recurrent laryngeal nerve.

Taste sensation is mediated by the vagus nerve (X), which transmits signals to the epiglottis and back to the tongue. The superior laryngeal artery, a branch of the superior thyroid artery, supplies the interior of the larynx, whereas the inferior laryngeal artery, a branch of the inferior thyroid division of the thyrocervical trunk, facilitates lymphatic drainage and blood flow to the larynx.(28)

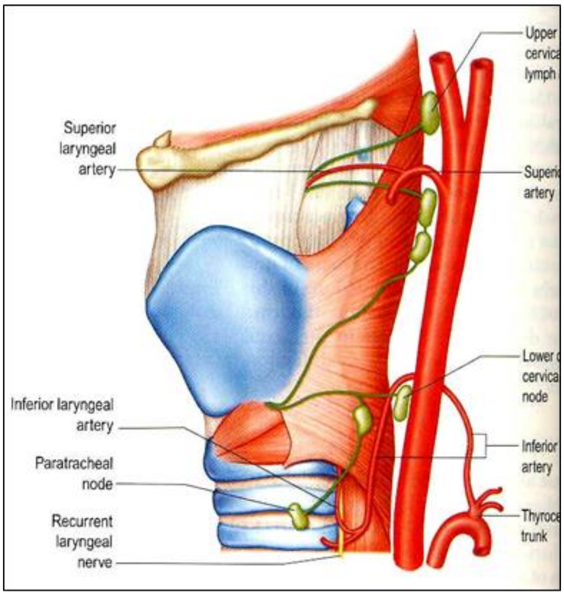

Figure 8: Blood supply and lymphatic drainage.

Venous drainage: Through the internal jugular and branchiocephalic veins, via the corresponding superior and inferior thyroid veins.

Lymphatic drainage: Deep cervical chain of lymph nodes. Vocal cords form a ’watershed’ from where channels pass up or down.

The Trachea

The trachea is positioned along the midline, measures roughly 10-12 cm in length, though this dimension may expand by 3-5 cm while profound inspiration.(29) With an adult's internal diameter of around 2.5 cm, the cricotracheal ligament, which connects to the cricoid ring, supports it from above. The fibrous membrane encircling the trachea is joined by this ligament at the level of the sixth cervical vertebra.(30)

Below, the trachea divides at the carina into the right and left main bronchi, a junction typically found at the fourth to fifth thoracic vertebrae (T4-T5), coinciding with the sternal angle (angle of Louis). The 16–20 C-shaped cartilaginous rings that support the tracheal structure are connected by the smooth trachealis muscle. The ends of the rings are situated at the back. This configuration gives a flattened form the back of the trachea. When the trachealis muscle contracts, the lumen narrows, protecting against severe distension brought on by elevated intraluminal pressure, as when a cough occurs.(30)

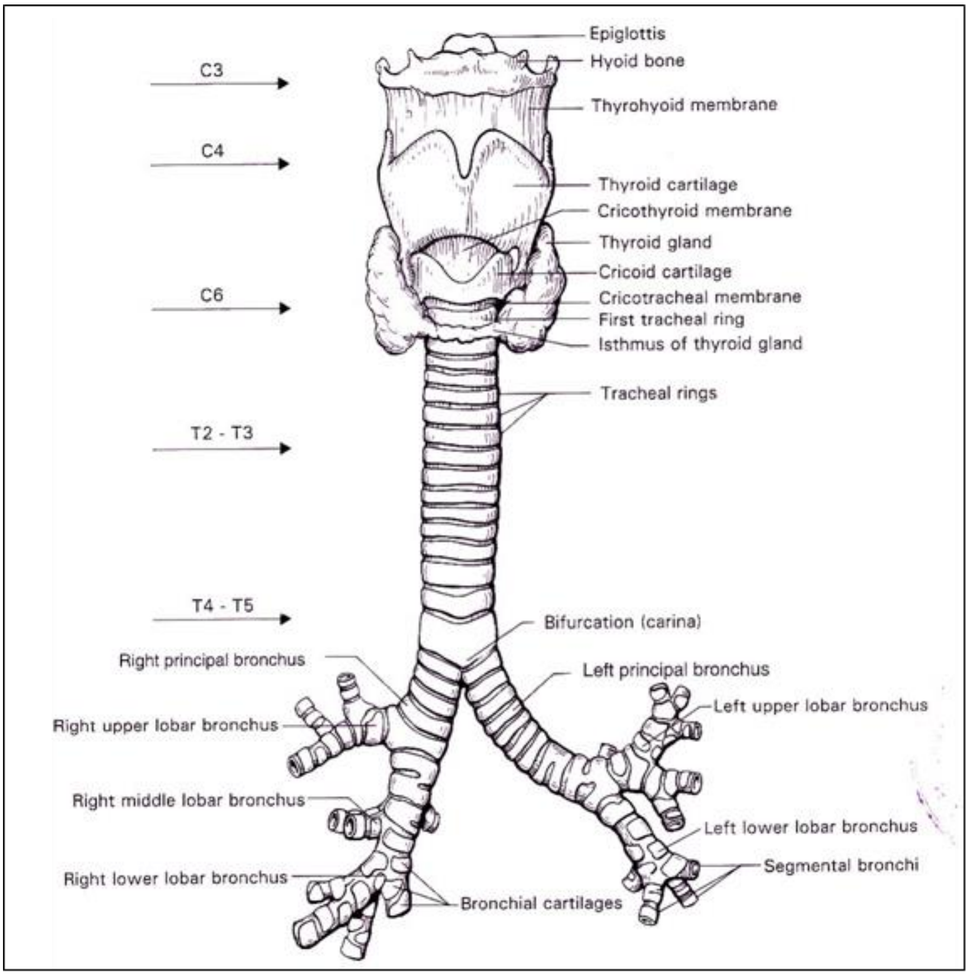

Figure 9: Schematic diagram of trachea.

Nerve supply:

Autonomic nerve supply to trachea and bronchi→ vagus nerve via its recurrent laryngeal branch and from sympathetic chain (originating from T2- T5).

Lymphatic drainage: Deep cervical nodes, pre and paratracheal and tracheobroncheal lymph nodes.

Blood supply: Arterial supply: Is through bronchial artery (branch of descending aorta) and Inferior thyroid artery.

Venous drainage: Is through tracheal veins, or through bronchial veins. Tracheal veins drain into Inferior thyroid venous plexus or directly into brachiocephalic vein. Whereas the bronchial veins drains into left bronchial vein and the right bronchial veins. The left bronchial vein further drains into left superior hemiazygous vein, whereas right bronchial vein further drains into azygous vein.(31)

Ambu Aura-i(32,33)

The Ambu Aura-i is a type of disposable laryngeal mask airway (LMA) device used in anesthesia and emergency medicine for airway management. Here are some scientific details about it:

Material Composition: Typically, the Ambu Aura-i is made of strong, flexible thermoplastic elastomer of medical grade.

This material is biocompatible and hypoallergenic, ensuring patient safety.

Anatomical Design: In order to create a seal against the perilaryngeal tissues, the Aura-i is made to fit the anatomy of the pharyngeal and laryngeal structures.

Its cuff is shaped to fit the hypopharyngeal space, minimizing leakage and facilitating ventilation.

Inflation System: The device features an inflation system for the cuff, usually utilizing a pilot balloon and valve mechanism. This makes it possible to inflate the cuff easily and precisely, creating a tight seal inside the pharynx.

Figure 10: Ambu Aura-i

Integrated Bite Block: Many Aura-i models have an integrated bite block to keep patients from biting down on the device and reduce the risk of airway obstruction or device damage.(34–36)

Gastric Access: Some versions of the Aura-i have a gastric access port, permitting a gastric tube to pass beside the apparatus. This can be useful for decompression of the stomach or administration of medications.

Size Range: The Aura-i comes in various sizes to accommodate different patient anatomies, ranging from pediatric to adult sizes.

Use in Ventilation: Once inserted, the Aura-i provides a conduit for positive pressure ventilation, delivering oxygen-enriched air or anesthesia gases to the patient's lungs. Its design minimizes airway resistance and facilitates efficient gas exchange.

Disposable Nature: Being a disposable device, the Aura-i is intended for single-patient use to prevent cross-contamination and ensure hygiene standards.

Clinical Applications: Typically, the ‘Ambu Aura-i is utilized in settings where endotracheal intubation may not be feasible or appropriate, such as in pre-hospital care, emergency departments, and during certain surgical’ procedures.(37,38)

Research and Validation: The design and efficacy of the Aura-i have been validated through clinical studies and trials, assessing factors such as ease of insertion, airway seal, and patient outcomes.

Overall, the Ambu Aura-i represents advancement in airway management technology, offering a reliable and user-friendly alternative to traditional methods of securing the airway during anesthesia and emergency interventions.

Fastrach™ ILMA(39,40)

One specialized medical equipment used particularly for difficult airway management and to facilitate tracheal intubation in patients receiving anaesthesia is the FastrachTM intubating Laryngeal Mask Airway (ILMA).

Here are some scientific details about it:

Anatomy and Design: The Fastrach™ ILMA is made up of an inflatable cuff attached to a curved tube, like an ordinary laryngeal mask airway (LMA). However, it has a unique anatomical curvature and integrated guiding channels specifically designed to aid in the endotracheal tube's (ETT) successful transit past the glottis and into the trachea.

Material Composition: The device is typically made of medical-grade silicone rubber or other biocompatible materials. These materials are flexible yet sturdy, allowing for effective airway management while minimizing the risk of tissue damage or irritation.

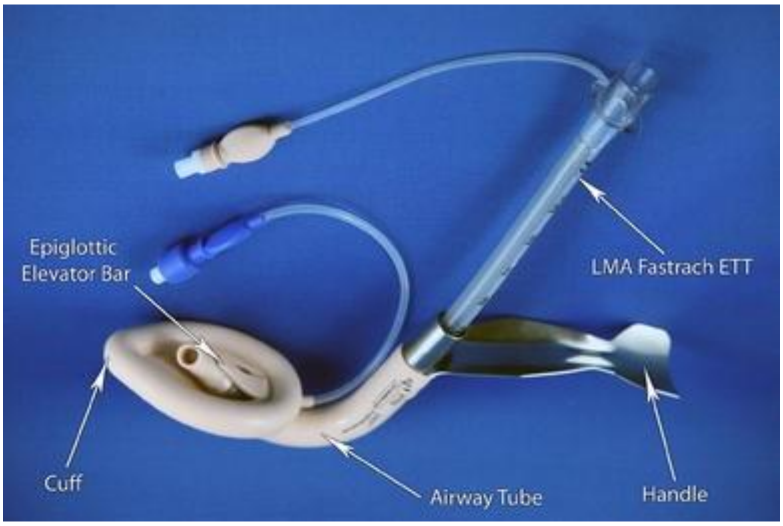

Figure 11: Fastrach™ ILMA

Integral Features: The Fastrach™ ILMA includes several integral features to aid in intubation, such as:

- Guiding Channels: These are incorporated into the structure of the device to guide the ETT toward the glottic opening, optimizing the success rate of intubation.

- Rotatable Connector: Some models feature a rotatable connector that allows for greater flexibility and maneuverability during intubation, enhancing the clinician's control over the procedure.

- Inflatable Cuff: Like standard LMAs, the Fastrach™ ILMA has an inflatable cuff that seals around the laryngeal inlet, preventing leakage of ventilation gases and minimizing the risk of aspiration.(41)

Size Range: The Fastrach™ ILMA comes in various sizes to accommodate different patient anatomies, ranging from pediatric to adult sizes. Proper sizing is crucial for achieving an effective seal and optimizing intubation success.

Intubation Technique: The technique for intubating with the Fastrach™ ILMA typically involves passing the ETT after inserting the device into the patient's airway through the guiding channels under direct visualization using a fiberoptic bronchoscope or other visualization device. This method allows for precise placement of the ETT into the trachea while minimizing trauma to surrounding tissues.

Clinical Applications: The Fastrach™ ILMA is commonly used in settings where difficult airway management is anticipated, such as in patients with anatomical abnormalities, limited mouth opening, or cervical spine instability. It is particularly useful in emergency situations where rapid and secure airway access is essential.(42,43)

Validation and Research: The efficacy and safety of the Fastrach™ ILMA have been demonstrated in numerous clinical studies and trials, confirming its utility as a valuable tool for airway management in challenging clinical scenarios.

All things considered, the FastrachTM ILMA is a significant development in airway management technology, providing physicians with a dependable and efficient technique to establish airway securing and to make tracheal intubation easier for patients whose airways are difficult.

Numerous articles about intubating laryngeal mask airway for tracheal intubation with the Ambu Aura-i and FastrachTM

Kundra P et al. (2005) describe the Ambu Aura-i (Aura-i, Ambu USA) as a single-use Supraglottic airway device in their case study. It serves as a channel for tracheal intubation and is utilized for ventilation, much like the FT-LMA.

In vitro measurements of forces on distal objects offer valuable guidance for selecting appropriate tracheal tubes. However, during intubation via an intubating laryngeal mask airway (ILMA), it's crucial to avoid excessive pressures if the tracheal tube encounters resistance. Instead of forcing the tube, adjustments should focus on aligning the ILMA properly with the glottis. Trauma incidence can be significantly reduced by gently performing blind tracheal intubation. While fiberoptic laryngoscopy is the preferred method for difficult airways, its availability may not be guaranteed at all times. In such cases, alternative methods should be encouraged. Less costly alternatives have demonstrated efficacy in challenging situations, with satisfactory success rates, offering viable options when fiberoptic endoscopes are unavailable.(8)

According to study conducted by Karim YM et al., (2011) to evaluate laryngeal markings airway during tracheal intubation and Air QTM. In the trial, patients in the LMA Fastrach group comprised 99%, while 77% of patients were in the Air-Q group were able to successfully complete blind intubation after two tries ($p<0.0001$ and a 95% confidence interval for the difference). For the third try, fiberoptic intubation was helpful. After three tries, 95% in the Air-Q group and 100% in the LMA Fastrach group were successful. These results suggest that the Air-Q is inferior to the single-use LMA Fastrach in terms of aiding blind tracheal intubation.(11)

According to study conducted by Kavitha J et al., (2011) to evaluate upper airway morbidity and hemodynamic parameters on LMA. When it comes to tracheal intubation, direct laryngoscopy (DLS) is a quicker method than intubating laryngeal mask airway (ILMA).

When it comes to lowering hemodynamic responses, ILMA is equal to DLS in this regard. Using ILMA for intubation has a success rate comparable to DLS. Furthermore, there are similarities in mean oxygen saturation levels and upper airway morbidity between the two groups. (14)

According to study conducted by Jagannathan N et al., (2012)to evaluate the Ambu Aura and air-Q laryngeal airway intubation comparison. The efficiency of the Ambu Aura-i and air-Q devices in enabling tracheal intubation using fiberoptic guidance was compared in the study. All patients had successful device implantation, tracheal intubation, and removal following intubation. When comparing the two devices' times for a successful tracheal intubation, there was no appreciable difference. There were no significant differences in the fiberoptic grade of view across the devices, and the time to intubation did not correlate with the laryngeal view's fiberoptic grade in either group. Overall leak pressures for the Aura-i and air-Q devices were comparable, with the exception of the 5–10 kg weight group, where the leak pressures in air-Q was higher.

The size 1.5 Aura-i required the tracheal tube's pilot balloon to be removed in order to make device removal after intubation easier, but other than that, there was little difference in the amount of time needed to remove the device between the two. To sum up, fiberoptic-guided tracheal intubation was successfully aided by both the Ambu Aura-i and air-Q devices. However, the smaller proximal airway tube of the size 1.5 Aura-i should be considered if cuffed tracheal tubes are to be used. (7)

According to Anand L. et al., (2019) The FastrachTM Laryngeal Mask Company, Henley-on-Thames, United Kingdom, intubating laryngeal mask airway (ILMA) is newly designed equipment that serves as an operative ventilator and intubation guide in both aberrant and normal airways. With more features than standard laryngeal mask airway, its purpose is to aid tracheal intubation (LMA). Anatomically curved and rigid airway tube, integrated guiding handle, epiglottis elevating bar, and guiding ramp that treats the tube anteriorly as it exits the mask hole are the primary parts of the ILMA.

The LMA has been included into problematic airway design, representing a significant breakthrough in airway control. When treating individuals who have difficult intubation, the ILMA has proven to be effective.(1)

According to study conducted by Salahu D et al., (2022) to assess the hemodynamic alterations brought on by tracheal intubation using direct laryngoscopy and intubating LMA. The groups who received Direct Laryngoscopy (DL) and Intubating Laryngeal Mask Airway (ILMA) had comparable baseline hemodynamic characteristics.

The average heart rate ranged from 97.88 to 107.47 in the DL group and 104.98 to 115.28 in the ILMA category, with no discernible variations. Changes in mean arterial pressure (MAP) were also not significant. However, there was a noticeable variation in the length of intubation between the DL group (mean of 19.93 ± 6.17 seconds) and the ILMA group (mean of 46.54 ± 11.63 seconds). In conclusion, hemodynamic responses did not differ significantly between ILMA and DL during endotracheal intubation with propofol, fentanyl, and suxamethonium. But when compared to the DL group, the ILMA group's intubation times were noticeably longer. (15)

In a research that was randomized by Mishra N et al., (2020) to assess the ILMA Fastrach™ and Ambu Aura-i, both groups' anthropometric and airway metrics were comparable. The success rate of insertion for both devices was 100%. In group 1, the mean insertion time was 20.53±1.91 seconds, while in group-2, it was 13.98±2.4 seconds (P <0.001). The glottic view's fiberoptic evaluation demonstrated grade 1 in 80% of patients in group-1 (ILMA group) and 92% in group-2 (Ambu Aura-i) (P=0.54). For fiberoptic-guided intubation, there was no appreciable difference in the intubation timings between the Ambu Aura-i and the FastrachTM Intubating Laryngeal Mask Airway (ILMA). Intubation duration was somewhat faster on average for Group 2 at 14.15±1.37 seconds (P>0.001) than Group 1 i.e., 14.95±1.85 seconds. When it came to first-attempt intubation, both groups showed similar success rates: 75% of Group 1 and 87.5% of Group-2 were able to insert the device successfully on the first try (P=0.33). Comparable removal times were also observed for the device: Group 1 averaged 11.87±1.265 seconds, whereas Group 2 averaged 11.25±1.58 seconds (P=0.054). Overall, Ambu Aura-i considerably outperformed the ILMA, taking a little less time for insertion to be successful, suggesting that it may be a more efficient(44)

According to study conducted by Zhi J et al., (2023) to evaluate children's laryngeal mask airway Ambu Aura-I and SaCoVLM, the Ambu Aura-i and SaCoVLM groups did not significantly vary in the amount of time needed for a successful endotracheal intubation. Unlike the Ambu Aura-i group, the SaCoVLM group's removal time was longer. The SaCoVLM group had a greater incidence of blood staining (16.7%) and a greater initial airway leak pressure compared to the Ambu Aura-i cohort. Overall, there was little variation in performance among the SaCoVLM and the Ambu Aura-i mask. However, the SaCoVLM shown benefits in lowering device demand when compared without using a flexible intubation scope, to guide intubation.(45)

Based on the research that was done by Solarajan S et al., (2023) to evaluate the LMA Fastrach and blockbuster as crucial instruments. In the current study, the majority of patients from groups B (95%) and F (82.5%) said that inserting LMA was easy. Group F experienced 7 (17.5%) instances of requiring two attempts during LMA insertion, whereas Group B had only 1 (2.5%) such occurrence. All groups found ETT intubation to be of similar ease. Moreover, there was no discernible variation in the ease of ETT intubation between groups B and F. On the other hand, group F's 8 patients (20%) required two tries at a somewhat higher rate than group B's 2 patients (5%). Group F experienced more cases of sore throats and blood stains than Group B following the operation. In summary, compared to the Fastrach LMA, the Blockbuster LMA showed a greater first success rate for SAD insertion and ETT intubation.

During intubation, the total success rate of both devices was 100%. Furthermore, the Blockbuster LMA was not associated with as many post-operative complications.(46)

MATERIALS &
METHODS

MATERIAL & METHOD

Adult patients with an anticipated difficult intubation undergoing scheduled surgery who required tracheal intubation with general anaesthesia were prospectively included in the study after informed consent taken

Study Design: A Randomized interventional two group comparative prospective clinical study

Sample Size: 50 (25 in each group)

50 (25 in each group)

Formula

Sample size estimation with two means page no 10

$$N = \frac{(r+1)(Z\,\alpha/2 + Z\,1-\beta)2\sigma 2}{rd2}$$

Where,

Zα is normal deviate at a level of significance (Zα is 1.96 for 5% level of significance and 2.58 for 1% level of significance)

Z 1-ß is the normal deviate at 1-8% power with ß5 of Type II error (0.84 at 80% power and 1.28 at 90% statistical power)

R=n1n2 is the ratio of sample size required for 2 groups, generally it is one for keeping equal sample size for 2 groups.

d and σ are pooled standard deviation and difference of mean of two groups.

Duration of study: 18 months

Study Participants: This study was conducted on patients posted for procedures under General Anaesthesia with Anticipated Difficult Airway Management at R L Jalappa Hospital and Research Centre, Tamaka, Kolar.

Sampling Method: Computer generated random sequence of numbers and concealed by closed envelope technique

Inclusion Criteria

- Age 18 to 60 years
- ASA 1 and 2

Exclusion Criteria

- Younger than 18 years old
- American Society of Anaesthesiologists physical status IV or V
- Diagnosed with respiratory tract pathology or coagulation disorders requiring a nasal route for tracheal intubation
- Those at risk of regurgitation–aspiration (previous upper gastrointestinal tract surgery, known hiatus hernia, oesophageal reflux, peptic ulceration, or not fasted).

Methodology

1. Detailed history of the patient
2. Complete physical examination was done.
3. Routine investigations were checked.
4. Intravenous line was secured and IV fluids will be connected.

5. Patients were divided into two groups randomly.

Group A: Pre-emptive multimodal group with anticipated difficult intubation were intubated with Fastrach^{TM} Laryngeal Mask Airway.

Group B: Pre-emptive multimodal group with anticipated difficult intubation were intubated with Ambu Aura-i Laryngeal Mask Airway.

Using a data collection form, concerned anesthesiologist and an assistant recorded the following information: the number of total attempts, the time taken for the successful attempt (the time interval between the insertion of the device and the confirmation of end-tidal carbon dioxide), the technique's success or failure, and the anaesthetic doses used.

Measurements of hemodynamics were made all along the process. Unfavorable incidents that occurred during tracheal intubation were noted. These included bronchospasm, soft tissue damage with hemorrhage, and oxygen desaturation (saturation of 90%).

Parameters to be observed

- Heart rate
- Mean arterial pressure
- Oxygen Saturation
- Time taken for intubation
- Number of attempts for intubation

STATISTICAL ANALYSIS

Excel sheets with data were filled in, and SPSS v23.0 running on Windows 10 was used for analysis. The mean, standard deviation, frequency, and percentage of the data were summarised. Tables, figures, and bar diagrams were used to illustrate the summarised data. The average difference between follow-up data using a paired t-test and continuous data compared using an unpaired t-test. The chi-square test was used to compare the category data. A p-value of less than 0.05 was considered statistically significant for all purposes of statistics.

RESULTS

RESULTS

In present study total of 50 patients fulfilling inclusion criteria are included with mean age of 40.31±12.1yrs. They were divided into two groups according to the study procedure as

Group A: Pre-emptive multimodal group with anticipated difficult intubation were intubated with Fastrach™ Laryngeal Mask Airway.

Group B: Pre-emptive multimodal group with anticipated difficult intubation were intubated with Ambu Aura-i Laryngeal Mask Airway.

Table 1: Comparison of mean age between the groups

	Group A		Group B		p-value
	Mean	SD	Mean	SD	
Age	41.5	12.3	39.0	12.2	0.447

There is no significant difference in mean age of the patients between the groups.

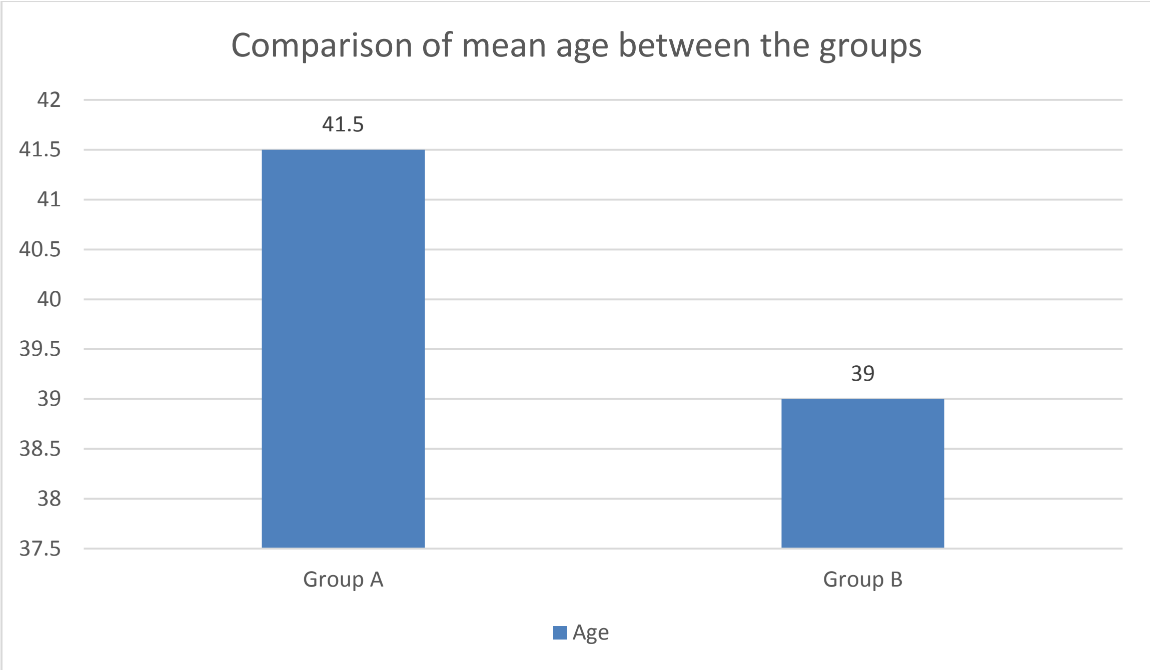

Figure 12: Comparison of mean age between the groups

Table 2: Distribution of gender and ASA grade between the groups

		Group A		Group B		Chi-square
		Count	N %	Count	N %	(p-value)
Gender	Female	14	56.0%	18	72.0%	1.38 (0.23)
	Male	11	44.0%	7	28.0%	
ASA	1.0	13	52.0%	15	60.0%	0.32 (0.529)
	2.0	12	48.0%	10	40.0%	

Among included patients, there is no significant difference in the gender distribution between the groups, however there is overall female preponderance in the present study. The ASA grade was also comparable between the groups.

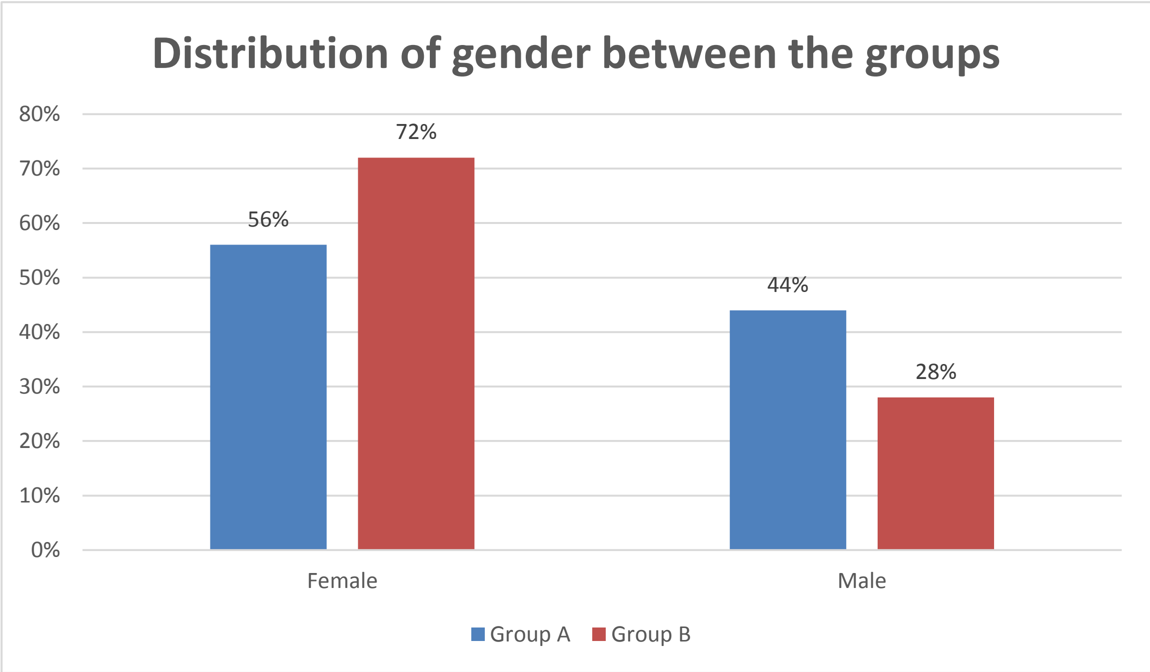

Figure 13: Distribution of gender between the groups

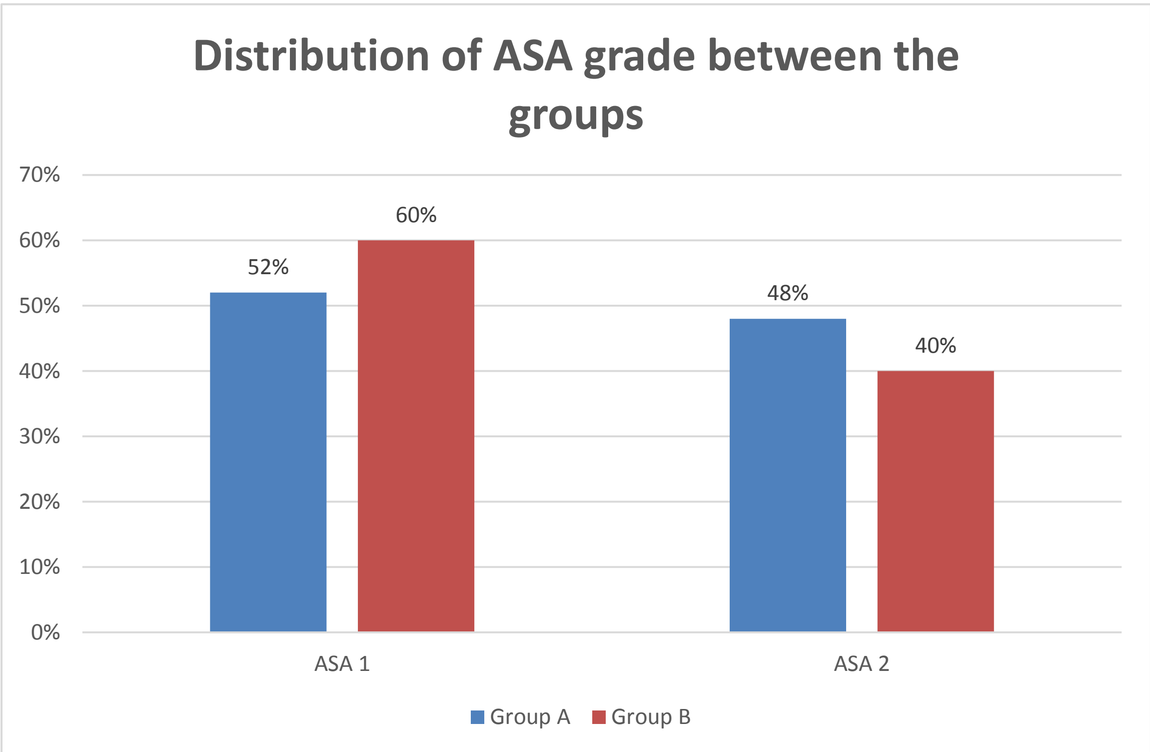

Figure 14: Distribution of ASA grade between the groups

Table 3: Comparison of mean weight, height and BMI between the groups

	Group A		Group B		p-value
	Mean	SD	Mean	SD	
Weight (kg)	67.4	8.7	71.0	6.9	0.116
Height (cms)	162.7	6.6	162.0	5.5	0.658
BMI(kg/m^2)	25.7	4.4	27.2	3.5	0.191

Among the patients, the physical characters such as weight, height and BMI were comparable between the groups.

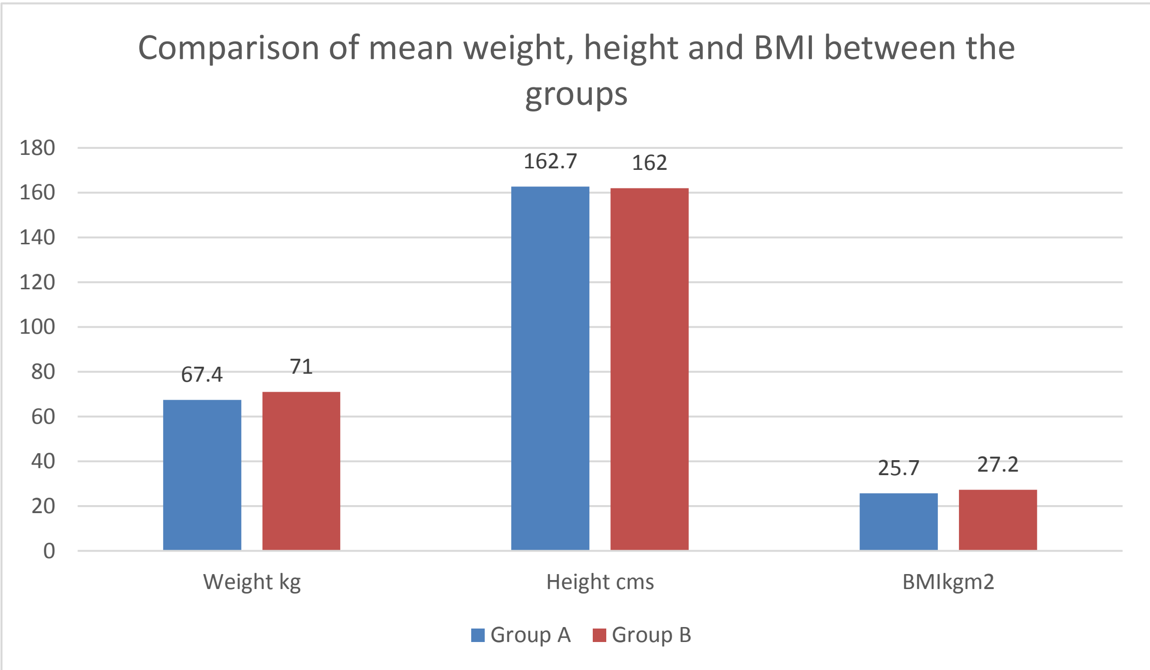

Figure 15: Comparison of mean weight, height and BMI between the groups

Table 4: Comparison of the mean heart rate between the groups

Heart rate	Group A		Group B		p-value
	Mean	SD	Mean	SD	
Pre-Intubation	83.0	9.5	82.4	8.1	0.83
1min Post-Intubation	87.0	9.8	88.6	9.1	0.55
3min Post-Intubation	82.1	6.2	86.6	7.3	0.02*
5min Post-Intubation	81.2	6.5	81.0	6.5	0.93
10min Post-Intubation	82.1	6.1	81.5	8.0	0.78

The heart rate was comparable between the groups at the preintubation period. Post intubation there is significant lower mean heart rate in group A patients at 3min. however other period of time it was comparable with no significant difference noted.

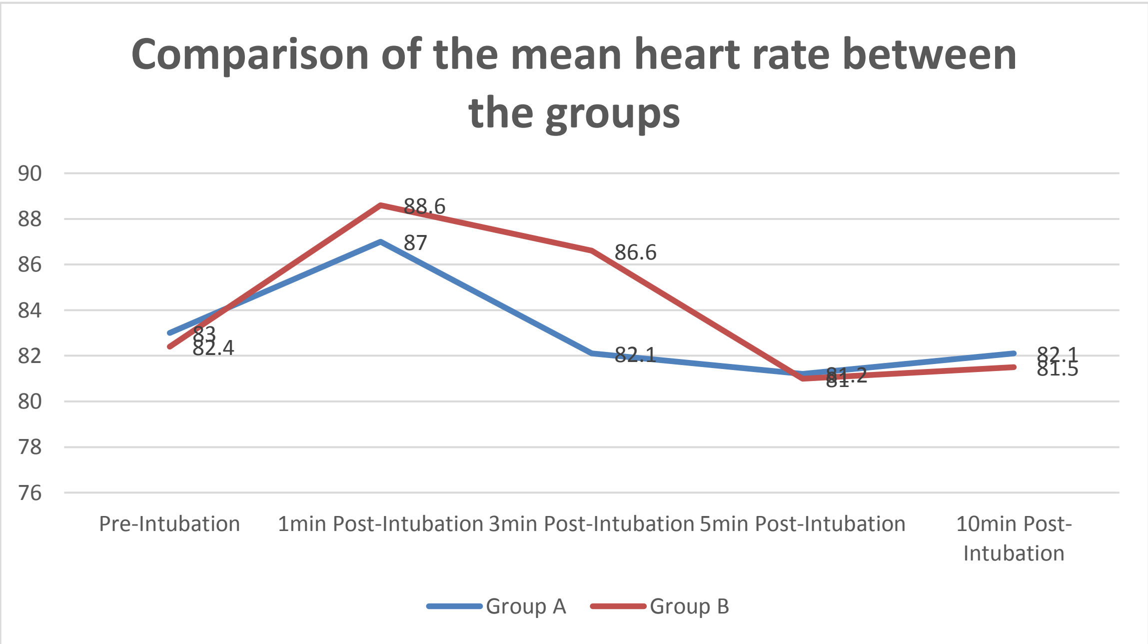

Figure 16: Comparison of the mean heart rate between the groups

Table 5: Comparison of mean systolic blood pressure between the groups

Systolic blood pressure	Group A		Group B		p-value
	Mean	SD	Mean	SD	
Pre-Intubation	120.1	9.1	119.0	7.9	0.63
1min Post-Intubation	116.9	8.1	119.0	8.0	0.34
3min Post-Intubation	115.9	6.1	115.2	7.3	0.37
5min Post-Intubation	115.0	6.2	115.8	6.0	0.36
10min Post-Intubation	116.3	6.7	114.5	5.5	0.704

On assessment of the systolic blood pressure, there is no significant difference in the mean SBP between the groups.

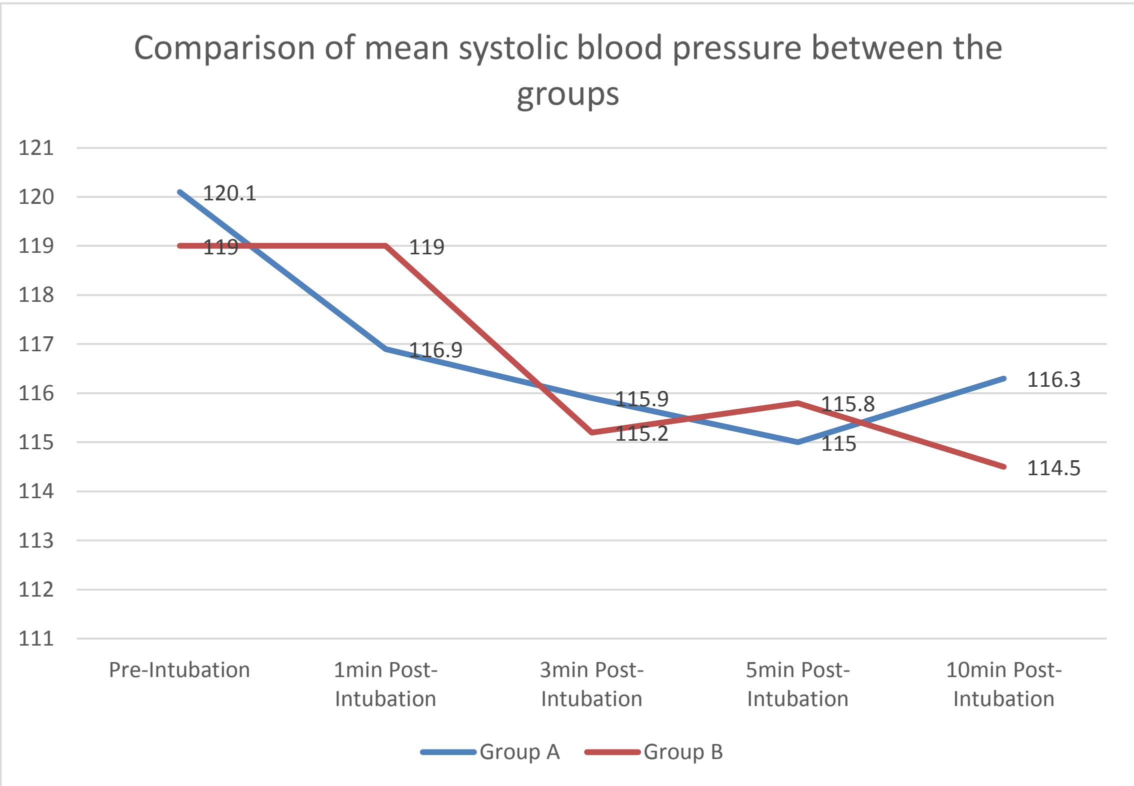

Figure 17: Comparison of mean systolic blood pressure between the groups

Table 6: Comparison of mean diastolic blood pressure between the groups

Diastolic blood pressure	Group A		Group B		p-value
	Mean	SD	Mean	SD	
Pre-Intubation	78.9	8.2	76.7	7.8	0.83
1min Post-Intubation	74.3	7.8	75.2	7.7	0.73
3min Post-Intubation	75.6	8.2	74.5	7.5	0.63
5min Post-Intubation	74.1	7.1	75.0	7.7	0.60
10min Post-Intubation	74.0	7.8	72.9	7.3	0.67

On assessment of diastolic blood pressure at pre and post intubation period, there is no significant difference in DBP between the groups.

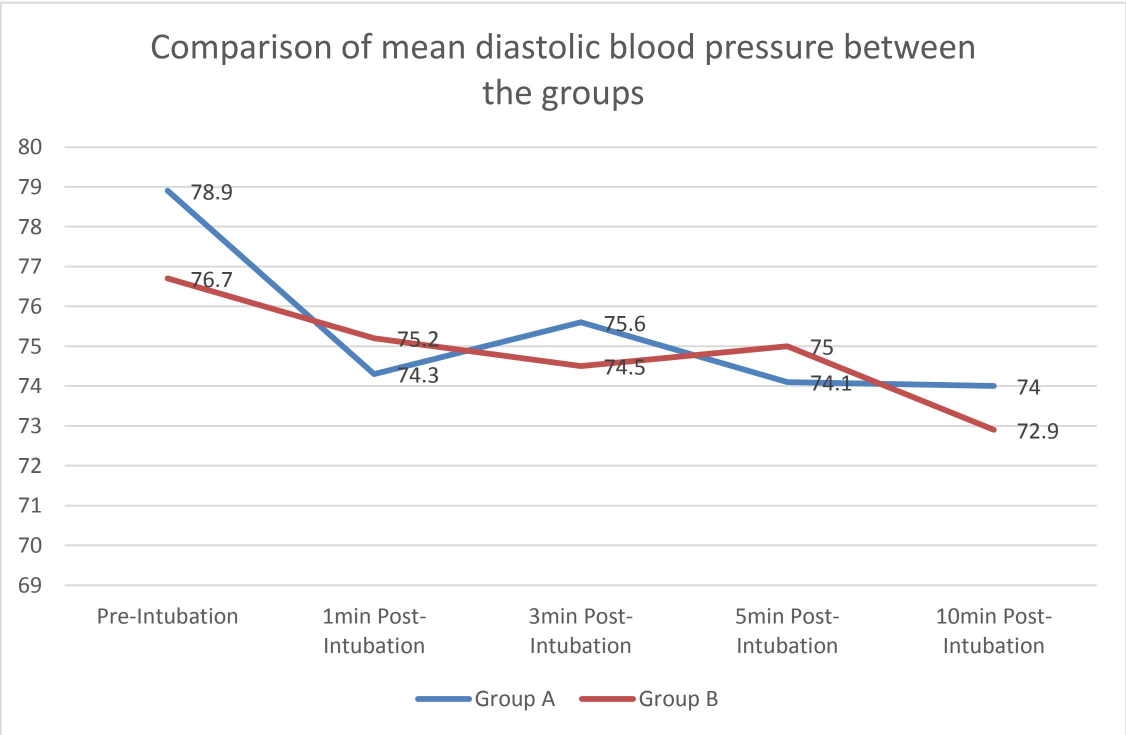

Figure 18: Comparison of mean diastolic blood pressure between the groups

Table 7: Comparison of the mean arterial pressure between the groups

Mean Arterial Pressure	Group A		Group B		p-value
	Mean	SD	Mean	SD	
Pre-Intubation	92.4	7.9	90.4	7.1	0.67
1min Post-Intubation	89.8	7.0	90.2	6.7	0.59
3min Post-Intubation	89.5	6.6	88.5	6.6	0.31
5min Post-Intubation	88.1	5.9	89.0	6.2	0.629
10min Post-Intubation	88.5	6.5	86.4	5.9	0.231

On assessment of the mean arterial pressure at pre and post intubation period, there is no significant difference in MAP between the groups.

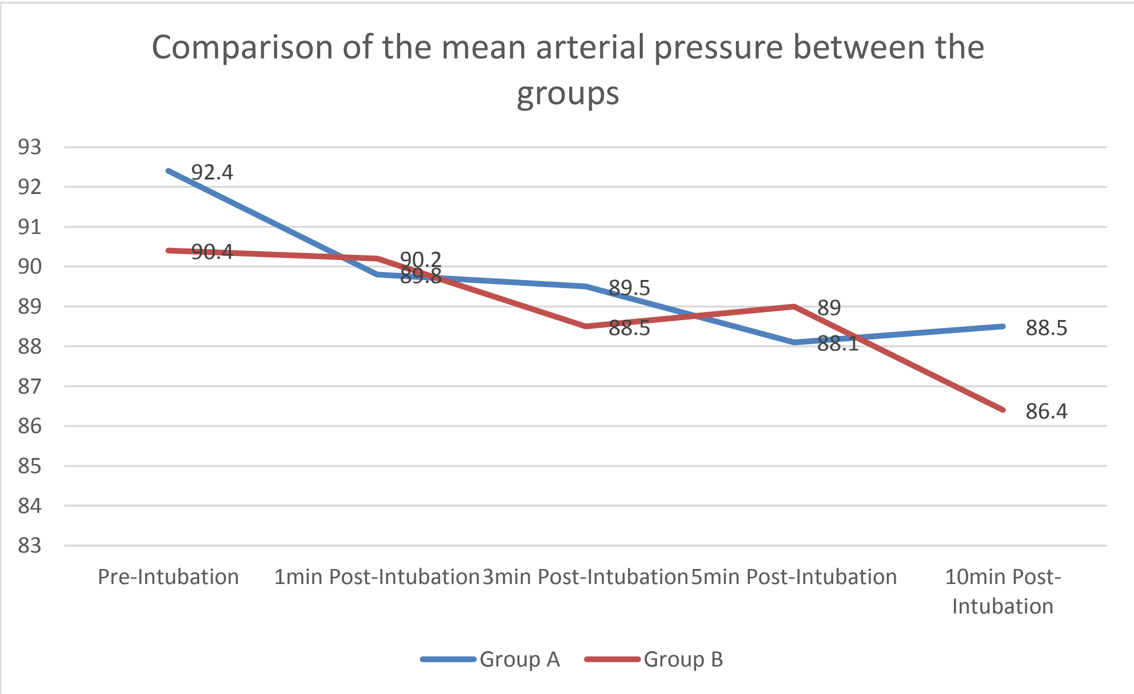

Figure 19: Comparison of the mean arterial pressure between the groups

Table 8: Comparison of the oxygen saturation between the groups

SpO2	Group A		Group B		p-value
	Mean	SD	Mean	SD	
Pre-Intubation	97.0	.9	97.2	.9	0.418
1min Post-Intubation	100.0	.0	100.0	.0	-
3min Post-Intubation	100.0	.0	100.0	.0	-
5min Post-Intubation	100.0	.0	100.0	.0	-
10min Post-Intubation	100.0	.0	100.0	.0	-

On assessment of the oxygen saturation between the groups, there is no significant difference noted between them.

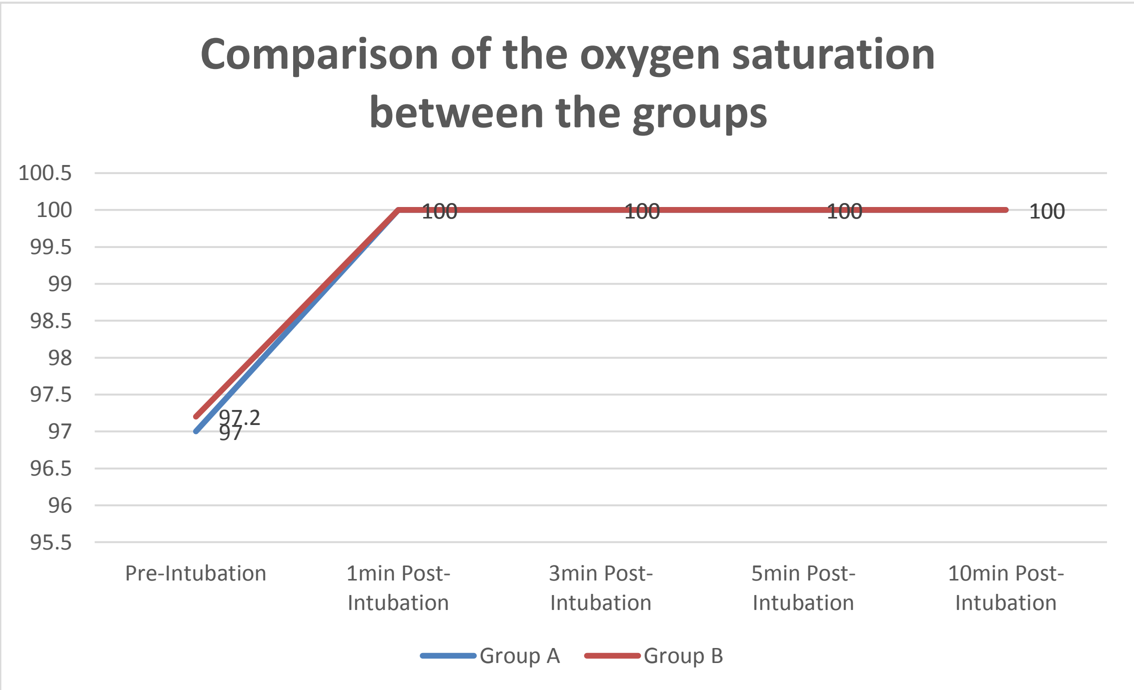

Figure 20: Comparison of the oxygen saturation between the groups

Table 9: Comparison of the SAD insertion time and tracheal tube insertion time between the groups

	Group A		Group B		p-value
	Mean	SD	Mean	SD	
SAD Insertion Time Sec	22.4	4.3	22.3	3.0	0.90
Tracheal Tube Insertion time sec	16.1	2.0	19.1	1.9	0.01*

On assessment of the SAD insertion time between the groups, the mean time required is comparable with no significant difference noted.

Similarly, on assessment of the tracheal tube insertion time, there is significant short time required in group A (16.1±2.0sec) patients compared to group B (19.1±1.9sec). ($p<0.05$)

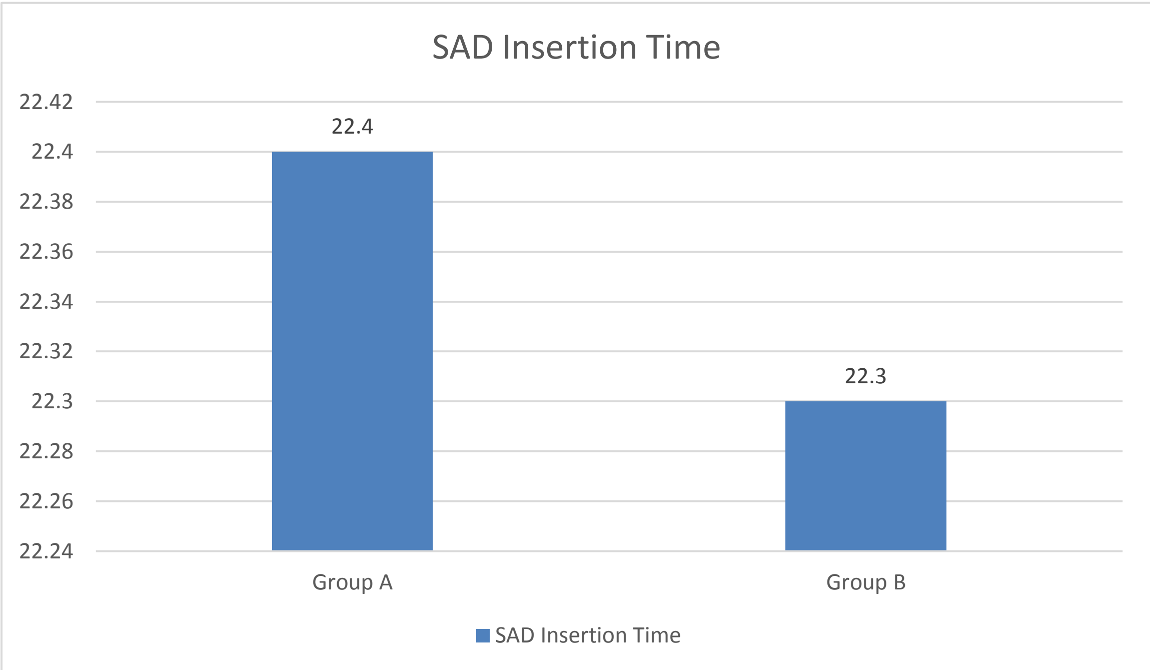

Figure 21: Comparison of the SAD insertion time between the groups

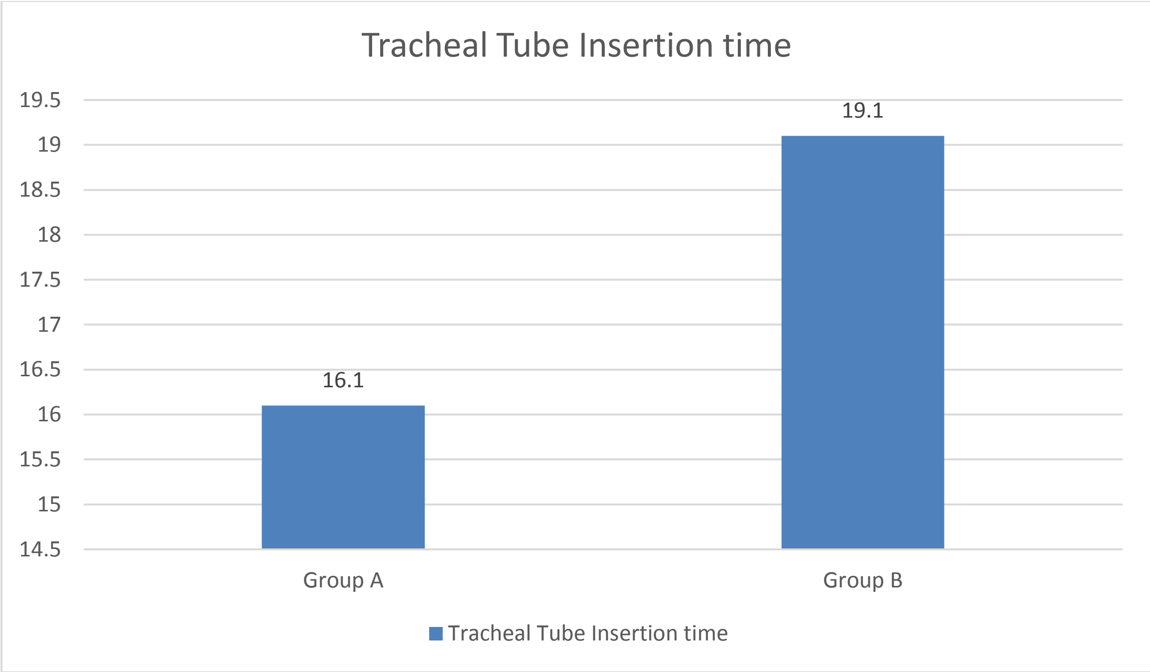

Figure 22: Comparison of tracheal tube insertion time between the groups

Table 10: Comparison of number of attempts for SAD insertion and tracheal tube insertion between the groups

		Group A		Group B		Chi-square (p-value)
		Count	N %	Count	N %	
Attempts of SAD Insertion	1st	23	92.0%	21	84.0%	0.758 (0.38)
	2nd	2	8.0%	4	16.0%	
Attempts of Tracheal Tube Insertion	1st	23	92.0%	21	84.0%	0.758 (0.384)
	2nd	2	8.0%	4	16.0%	

On comparison of the number of attempts required for SAD insertion and tracheal tube insertion between the groups, the results were statistically comparable. However, there is higher incidence of 2nd attempt to insert the SAD and Tracheal tube in group B (16%) compared to group A (8%).($p>0.05$)

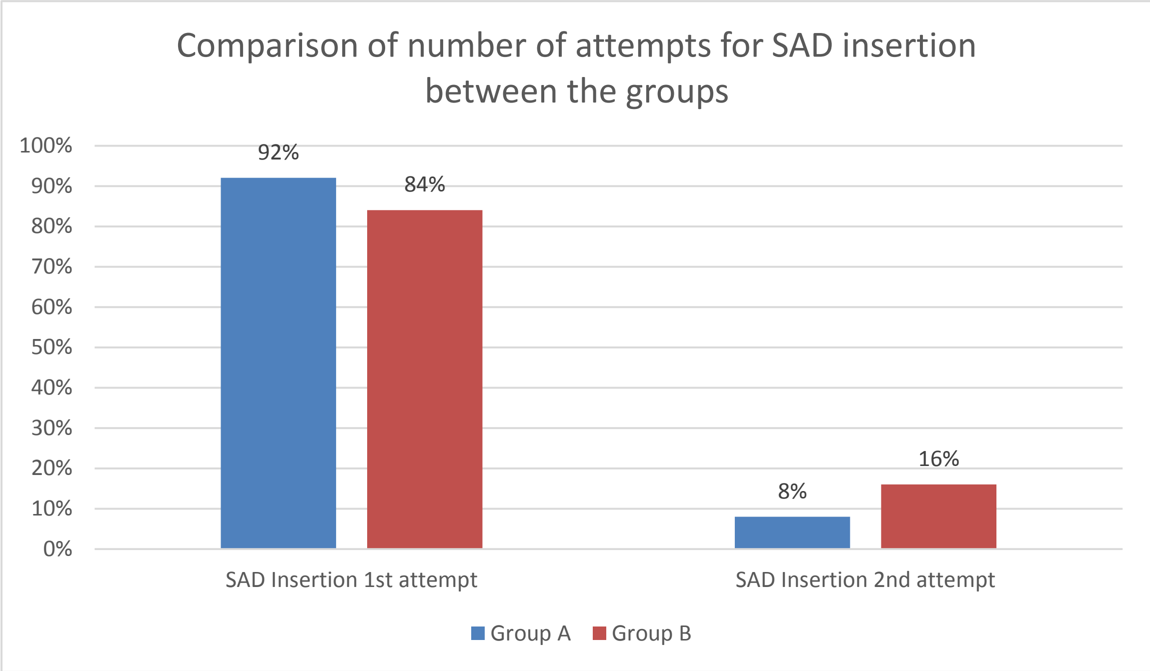

Figure 23: Comparison of number of attempts for SAD insertion between the groups

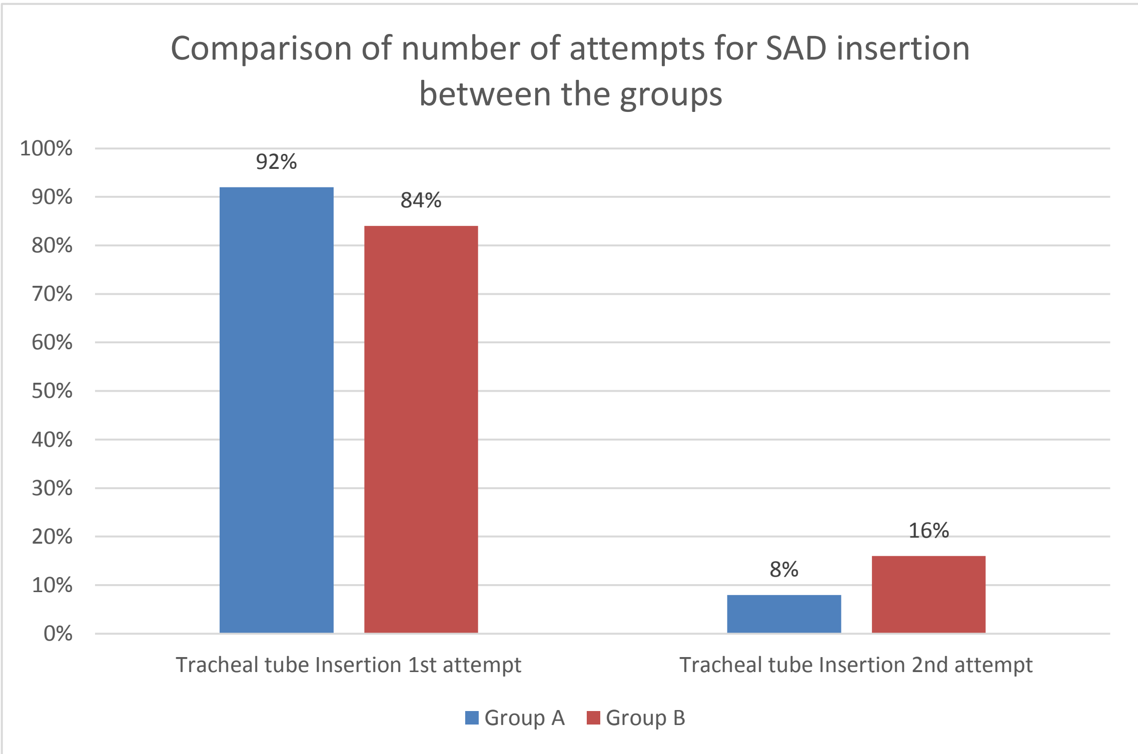

Figure 24: Comparison of number of attempts for SAD insertion between the groups

Table 11: Comparison of the blood on SAD and sore throat between the groups

		Group A		Group B		Chi-square
		Count	N %	Count	N %	(p-value)
Blood on SAD	Absent	24	96.0%	22	88.0%	1.08 (0.29)
	Present	1	4.0%	3	12.0%	
Sorethroat	Absent	23	92.0%	22	88.0%	0.22 (0.637)
	Present	2	8.0%	3	12.0%	

On assessment of the complications, there is no significant difference in the presence of blood on SAD and sore throat reported between the groups. However, there is higher incidence of blood on SAD and sore throat among the patients of group B (12% & 12% respectively) compared to patients in group A (4% & 8% respectively).

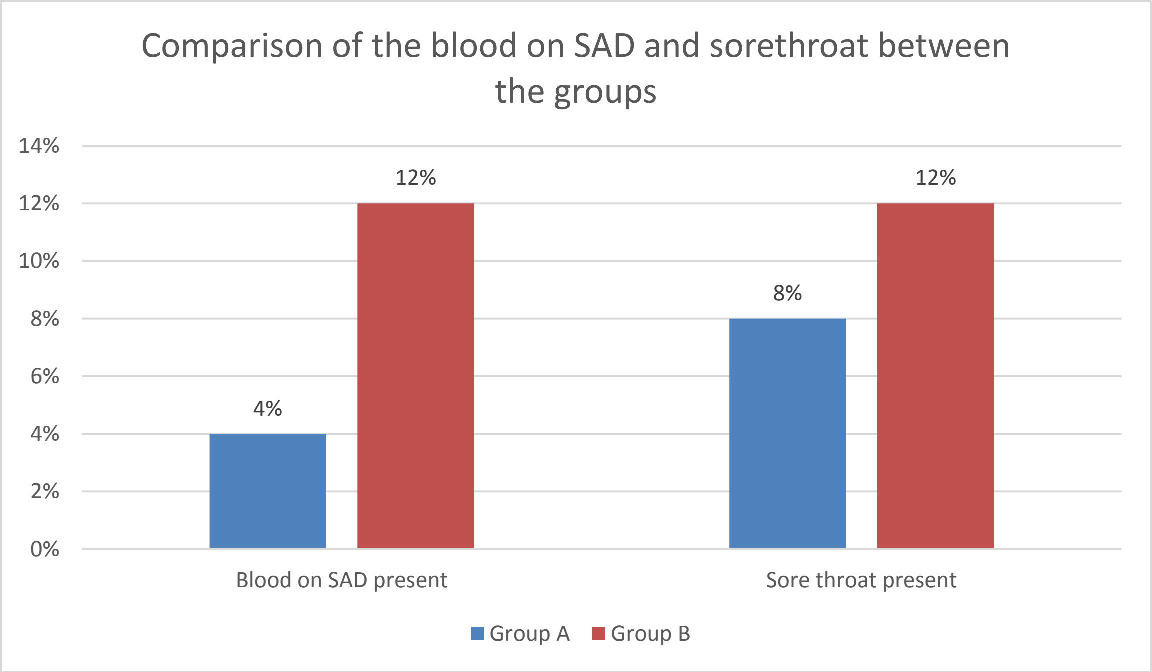

Figure 25: Comparison of the blood on SAD and sore throat between the groups

DISCUSSION

DISCUSSION

When conventional intubation techniques are impractical or ineffective, use of supraglottic airway devices (SADs) has become a crucial part of managing difficult airways. The Ambu Aura-i and the FastrachTM Intubating Laryngeal Mask Airway (ILMA) are two of the most widely used of these devices because of their ability to operate as both ventilation and tracheal intubation conduits. With its prepared curvature and inbuilt navigation markers, the Ambu Aura-i is a single-use gadget that may be used by patients of various ages.

Conversely, the Fastrach™ ILMA, designed for both ventilation and blind intubation, is noted for its guiding mechanism that facilitates accurate tracheal tube placement. Despite the advancements each device offers, comparative data on their performance in anticipated difficult airway scenarios remain sparse. The objective of this conversation is to assess the Ambu Aura-i and FastrachTM ILMA critically in terms of efficacy, efficiency, and safety. Specific topics of discussion include success rates for intubations, ease of insertion, time efficiency, and related issues. Through this comparative analysis, we aim to provide insights that can guide the selection of the most appropriate SAD for managing challenging airway conditions.

The findings from this study, which compared the effectiveness of the Ambu Aura-i and Fastrach™ Intubating Laryngeal Mask Airways (LMA) in tracheal intubation among 25 patients, offer valuable insights into their clinical performance. Both devices were evaluated in patients with anticipated difficult airways, split up into two groups: Group A, intubated using Fastrach™ LMA, and Group B, intubated using Ambu Aura-i LMA.

Age, gender, and physical parameters like height, weight, and BMI were comparable among both the groups' demographics, and no discernible variations were found.

The mean age of the patients in the groups was similar in the current study. Marginal female preponderance is noted in study by Mishra et al. also the physical character between the group were comparable.(44)

Except for a lower mean heart rate in Group A three minutes after intubation, hemodynamic parameters such as heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) did not significantly differ between the groups during the pre- and post-intubation periods. Throughout the process, there was no significant difference in the oxygen saturation levels.

In similar to present study Salahu D et al., found hemodynamic responses did not differ significantly between ILMA and DL during endotracheal intubation with propofol, fentanyl, and suxamethonium. However, the ILMA group experienced significantly longer intubation times compared to the DL group. (15)

In similar to present study Mishra et al., also revealed similar blood pressure, MAP, oxygen saturation, and mean heart rate among the groups. (44) In another study by Anand L et al., also found female preponderance in both group and mean age of patients comparable between both the groups. Also, the ASA grade and physical attributes like height, weight, and BMI were similar between the groups. (1) Hemodynamically both the Aura-I airway and FT-LMA were comparable between the group during pre and post intubation in study done by Anand L et al.(1)

The study found that while the time required for supraglottic airway device (SAD) insertion was similar in both groups, Group A had a significantly shorter tracheal tube insertion time (16.1±2.0 seconds) compared to Group B (19.1±1.9 seconds) ($p<0.05$). Additionally, Group B required more second attempts for both SAD and tracheal tube insertion (16%) compared to Group A (8%). Despite this, the difference was not statistically significant. Complication rates, including presence of blood on SAD and reports of sore throat, were slightly higher in Group B. However, these variations fell short of statistical significance.

According to the current research Anand L et al., documented higher number of attempts for SAD and tracheal tube insertion in Aura I airway tube (group 2) compared to the patients in FT-LMA (group 1) group. Also there is higher incidence of the sore throat among group 2 patients compared to group 1. But in their study, it was not statistically significant.(1)

According to the research conducted by Solarajan S et al., the majority of patients from groups B (95%) and F (82.5%) reported that inserting LMA was easy.

In comparing the performance of the Fastrach™ LMA (Group F) and the Blockbuster LMA (Group B), significant differences were observed in several key areas. For LMA insertion, 7 patients in Group F (17.5%) required two attempts, whereas only 1 patient in Group B (2.5%) needed a second attempt. This suggests a higher initial success rate with the Blockbuster LMA. Both groups exhibited similar ease in endotracheal tube (ETT) intubation overall; however, Group F had a slightly higher incidence of requiring two attempts for ETT placement, affecting 8 patients (20%) compared to just 2 patients (5%) in Group B. Post-operatively, Group F also demonstrated a higher occurrence of complications, specifically sore throats and blood stains, when compared to Group B.

In conclusion, the Blockbuster LMA showed superior performance in terms of initial success rates for both LMA insertion and ETT intubation, along with fewer post-operative complications, while both devices achieved a 100% success rate for overall intubation.(46)

In study by Zhi J et al., the time needed for Ambu Aura-I to be inserted was not significantly different from that of other groups. They documented lower blood staining in Ambu Aura I group compared to the SaCoVLM group. (45) In study by Mishra N et al., the number of attempts to intubate using ILMA/Ambu Aura-i did not significantly differ from one another. In their study Ambu Aura-i demonstrated superior performance over ILMA, less time is needed for a successful insertion, making it a potentially better independent ventilatory device.(44)

In line with findings, Karim YM et al., recorded that the LMA Fastrach group had a 100% success rate for successful intubation after three tries, whereas the Air-Q group had a 95% success rate. These findings imply that when it comes to facilitating blind tracheal intubation, the single-use LMA Fastrach outperforms the Air-Q.(11)

Study found that the “Fastrach™ Intubating Laryngeal Mask Airway (LMA) outperformed the Ambu Aura-i LMA”, particularly with shorter tracheal tube insertion times and fewer insertion attempts. Although both devices effectively managed difficult airways, the Fastrach™ LMA provided advantages in ease and efficiency, making it a potentially better choice for situations requiring quick and reliable tracheal intubation.

SUMMARY

SUMMARY

A total of 25 patients, whose mean age is 40.31±12.1 years, who meet the inclusion criteria are included in the current study.

The study process resulted in their division into two groups, as

Group A: Pre-emptive multimodal group with anticipated difficult intubation were intubated with FastrachTM Laryngeal Mask Airway.

Group B: Pre-emptive multimodal group with anticipated difficult intubation were intubated with Ambu Aura-i Laryngeal Mask Airway.

The mean age of the patients in the two groups does not significantly differ from one another.

Although there is an overall female majority in current study, there is no discernible difference in the gender distribution across the groups among the enrolled patients.

The ASA grade was also comparable between the groups.

Among the patients, the physical characters such as weight, height and BMI were comparable between the two groups.

At preintubation stage, the heart rates of the groups were similar.

Post intubation there is significant lower mean heart rate in group A patients at 3min. however other period of time it was comparable with no significant difference noted.

When systolic blood pressure is measured, there is no discernible difference in the mean SBP of two groups.

When diastolic blood pressure is measured before and after intubation, there is no discernible variation in DBP across the groups.

There is no discernible variation in the groups' mean arterial pressure (MAP) when comparing the measurements taken before and after intubation.

There is no discernible variation between the groups when it comes to the oxygen saturation measurements.

When comparing the mean amount of time needed for SAD insertion among the groups, no discernible differences were found.

Similarly, on assessment of the tracheal tube insertion time, there is significant short time required in group A (16.1±2.0sec) patients compared to group B (19.1±1.9sec). ($p<0.05$)

The findings were statistically equal when comparing the number of attempts needed for SAD insertion and tracheal tube insertion within the group. In contrast to group A (8%), group B has a greater incidence of second attempts to insert the SAD and Tracheal tube (16%).($p>0.05$)

The presence of blood on SAD and sore throats reported by the groups do not significantly differ when it comes to the complications. Patients belonging to group B, however, have a higher incidence of blood on SAD and sore throat (12% and 12%, respectively) than patients belonging to group A (4% and 8%, respectively).

CONCLUSION

CONCLUSION

In conclusion, the Fastrach™ LMA demonstrated a marginally superior performance over the Ambu Aura-i LMA, particularly in terms of shorter tracheal tube insertion times and fewer attempts required for successful insertion. Both devices are effective for managing difficult airways, but there could be some benefits to using FastrachTM LMA in terms of usability and effectiveness. This study supports the use of Fastrach™ LMA as a potentially more effective option in scenarios where rapid and reliable tracheal intubation is critical.

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ANNEXURE

ANNEXURE

PROFORMA

“Comparative evaluation of Ambu Aura-i and Fastrach^{TM} intubating laryngeal mask airwayfor tracheal intubation: A randomized controlled study”

Investigators: Dr Ravi M / Dr S M Kushal

1. **Name of the patient:**
2. **Age/Sex:**
3. **IP No. :**
4. **Ward:**
5. **ASA grade:**

- **General physical examination:**

Pallor/icterus/cyanosis/clubbing/lymphadenopathy/edema:

Height:

Weight:

Pulse rate:

BP:

SpO2:

- **Systemic examination:**

RS -

CVS -

CNS -

P/A -

- **Investigations :**

Blood group: RBS:

Hb: Blood Urea:

WBC: Sr.Creatinine:

Platelets: Sodium:

ECG:

Diagnosis:

- **Group A:** Pre-emptive multimodal group with anticipated difficult intubation will be intubated withFastrach^{TM} Laryngeal Mask Airway.

- **Group B**: Pre-emptive multimodal group with anticipated difficult intubation will be intubated withAmbu Aura-i Laryngeal Mask Airway.

Baseline vitals: HR: BP: MAP: SpO2:

Monitoring:-

TIME	Group- A	Group-B	Heart rate	Blood pressure	MAP	SP02
Pre-intubation						
1min post intubation						
3min post intubation						
5min post intubation						
10 min post intubation						

PARAMETERS	GROUP A (Fastrach)	GROUP B (Ambu Aura i)
SAD Insertion Time 1st/2nd attempt		
SAD Insertion Time		
Tracheal tube Insertion attempts,		
1st attempt		
2nd attempt		
3rd attempt(fibre optic)		
Failure		
Tracheal Tube Insertion time(sec),		
1st attempt		
2nd attempt		
3rd attempt (Fibreoptic guided)		
SAD Removal time (After intubation)		
Blood on SAD		
Sore throat, number		

PATIENT INFORMATION SHEET

STUDY: "Comparative evaluation of Ambu Aura-i and Fastrach^{TM} intubating laryngeal maskairway for tracheal intubation: A randomized controlled study"

Investigators: Dr S M Kushal / Dr Ravi M

Study location: R L Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College,Tamaka, Kolar.

Details -

Please read the information and discuss with your family members. You can ask any question regarding the study. If you agree to participate in the study we will collect information. Relevant history will be taken. This information collected will be used only for dissertation and publication. All LMA insertion has been performed by trained anaesthesiologist who has experience in LMA insertion.

All information collected from you will be kept confidential and will not be disclosed to any outsider. Your identity will not be revealed. There is no compulsion to agree to this study. The care you will get will not change if you don't wish to participate. You are required to sign/ provide thumb impression only if you voluntarily agree to participate in this study.

For further information contact

Dr. S M Kushal

Post graduate

Dept of Anaesthesia,

SDUMC Kolar

Mobile no: 7760505880

INFORMED CONSENT FORM

Comparative evaluation of Ambu Aura-i and Fastrach™ intubating laryngeal mask airway for tracheal intubation: A randomized controlled study

Date:

I,____________________, aged_________, after being explained in my own vernacular language about the purpose of the study and the risks and complications of the procedure, hereby give my valid written informed consent without any force or prejudice for using Laryngeal mask Airway. The nature and risks involved have been explained to me to my satisfaction. I have been explained in detail about the study being conducted. I have read the patient information sheet and I have had the opportunity to ask any question. Any question that I have asked, have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research. I hereby give consent to provide my history, undergo physical examination, undergo the procedure, undergo investigations and provide its results and documents etc to the doctor / institute etc. For academic and scientific purpose the operation / procedure, etc. may be video graphed or photographed. All the data may be published or used for any academic purpose. I will not hold the doctors / institute etc. responsible for any untoward consequences during the procedure / study.

A copy of this Informed Consent Form and Patient Information Sheet has been provided to the participant.

____

(Signature & Name of Patient / patient Attendant)

Witness 1:

Witness 2:

____

(Signature & Name of Research person /doctor)

ಮಾಹಿತಿ ಮತ್ತು ಒಪ್ಪಿಗೆ ನಮೂನೆ

"ಶ್ವಾಸನಾಳದ ಒಳಹರಿವುಗಾಗಿ ಅಂಬು ಔರಾ–ಐ ಮತ್ತು ಫಾಸ್ಟ್ರಾಚ್ ಟಿಒ ಇಂಟ್ಯೂಬೇಟಿಂಗ್ ಲಾರಿಂಜಿಯಲ್ ಮಾಸ್ಕ್ ವಾಯುಮಾರ್ಗದ ತುಲನಾತ್ಮಕ ಮೌಲ್ಯಮಾಪನ: ಯಾದೃಚ್ಛಿಕ ನಿಯಂತ್ರಿತ ಪ್ರಯೋಗ"

ದಿನಾಂಕ:

ನಾನು, ____ , ನನ್ನ ಸ್ವಂತ ಸ್ಥಳೀಯ ಭಾಷೆಯಲ್ಲಿ ಅಧ್ಯಯನದ ಉದ್ದೇಶ ಮತ್ತು ಕಾರ್ಯವಿಧಾನದ ಅಪಾಯಗಳು ಮತ್ತು ತೊಡಕುಗಳ ಬಗ್ಗೆ ವಿವರಿಸಿದ ನಂತರ, ಲಾರಿಂಜಿಯಲ್ ಮಾಸ್ಕ್ ಏರ್ವೇ ಅನ್ನು ಬಳಸಲು ಯಾವುದೇ ಬಲ ಅಥವಾ ಪೂರ್ವಾಗ್ರಹವಿಲ್ಲದೆ ನನ್ನ ಮಾನ್ಯ ಲಿಖಿತ ತಿಳುವಳಿಕೆಯನ್ನು ನೀಡುತ್ತೇನೆ. ಒಳಗೊಂಡಿರುವ ಸ್ವಭಾವ ಮತ್ತು ಅಪಾಯಗಳನ್ನು ನನಗೆ ತೃಪ್ತಿಪಡಿಸಲು ವಿವರಿಸಲಾಗಿದೆ. ನಡೆಸುತ್ತಿರುವ ಅಧ್ಯಯನದ ಬಗ್ಗೆ ನನಗೆ ವಿವರವಾಗಿ ವಿವರಿಸಲಾಗಿದೆ. ನಾನು ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆಯನ್ನು ಓದಿದ್ದೇನೆ ಮತ್ತು ಯಾವುದೇ ಪ್ರಶ್ನೆಯನ್ನು ಕೇಳಲು ನನಗೆ ಅವಕಾಶವಿದೆ. ನಾನು ಕೇಳಿದ ಯಾವುದೇ ಪ್ರಶ್ನೆಗೆ ನನ್ನ ತೃಪ್ತಿಗೆ ಉತ್ತರಿಸಲಾಗಿದೆ. ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವವರಾಗಿ ಭಾಗವಹಿಸಲು ನಾನು ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಸಮ್ಮತಿಸುತ್ತೇನೆ. ನನ್ನ ಇತಿಹಾಸವನ್ನು ಒದಗಿಸಲು, ದೈಹಿಕ ಪರೀಕ್ಷೆಗೆ ಒಳಗಾಗಲು, ಕಾರ್ಯವಿಧಾನಕ್ಕೆ ಒಳಗಾಗಲು, ತನಿಖೆಗೆ ಒಳಗಾಗಲು ಮತ್ತು ಅದರ ಫಲಿತಾಂಶಗಳು ಮತ್ತು ದಾಖಲೆಗಳನ್ನು ಇತ್ಯಾದಿಗಳನ್ನು ವೈದ್ಯರು / ಸಂಸ್ಥೆ ಇತ್ಯಾದಿಗಳಿಗೆ ಒದಗಿಸಲು ನಾನು ಈ ಮೂಲಕ ಒಪ್ಪಿಗೆ ನೀಡುತ್ತೇನೆ. ಶೈಕ್ಷಣಿಕ ಮತ್ತು ವೈಜ್ಞಾನಿಕ ಉದ್ದೇಶಕ್ಕಾಗಿ ಕಾರ್ಯಾಚರಣೆ / ಕಾರ್ಯವಿಧಾನ, ಇತ್ಯಾದಿಗಳನ್ನು ವೀಡಿಯೊ ಗ್ರಾಫ್ ಅಥವಾ ಛಾಯಾಚಿತ್ರ ಮಾಡಬಹುದು . ಎಲ್ಲಾ ಡೇಟಾವನ್ನು ಪ್ರಕಟಿಸಬಹುದು ಅಥವಾ ಯಾವುದೇ ಶೈಕ್ಷಣಿಕ ಉದ್ದೇಶಕ್ಕಾಗಿ ಬಳಸಬಹುದು. ಕಾರ್ಯವಿಧಾನ / ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಯಾವುದೇ ಅಹಿತಕರ ಪರಿಣಾಮಗಳಿಗೆ ನಾನು ವೈದ್ಯರು / ಸಂಸ್ಥೆ ಇತ್ಯಾದಿಗಳನ್ನು ಹೊಣೆಗಾರರನ್ನಾಗಿ ಮಾಡುವುದಿಲ್ಲ.

ಭಾಗವಹಿಸುವವರಿಗೆ ಈ ತಿಳುವಳಿಕೆಯುಳ್ಳ ಒಪ್ಪಿಗೆ ನಮೂನೆ ಮತ್ತು ರೋಗಿಗಳ ಮಾಹಿತಿ ಹಾಳೆಯ ಪ್ರತಿಯನ್ನು ಒದಗಿಸಲಾಗಿದೆ.

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(ರೋಗಿ / ರೋಗಿಯ ಪರಿಚಾರಕರ ಸಹಿ ಮತ್ತು ಹೆಸರು)

ಸಾಕ್ಷಿ 1:

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ಸಾಕ್ಷಿ 2:

(ಸಂಶೋಧನಾ ವ್ಯಕ್ತಿ/ವೈದ್ಯರ ಸಹಿ ಮತ್ತು ಹೆಸರು

MASTER CHART

MASTERCHART

Group A Fastrach LMA

Group B Ambu aura-i LMA

SL No.	Group	UHID Number	Age	Gender	ASA	Weight (kg)	Height (cms)	BMI (kg/m2)	HR_Pre Intubation	HR_1 min Post Intubation	HR_3 min Post Intubation	HR_5 min Post Intubation	HR_10 min Post Intubation	SBP (mmhg)Pre Intubation	DBP (mmhg)Pre Intubation	MAP (mmhg)Pre Intubation	SBP (mmhg)1 min Post Intubation	DBP (mmhg)1 min Post Intubation	MAP (mmhg)1 min Post Intubation
1	A	226557	47	F	1	68	154	28.6	88	94	86	80	76	121	88	99	110	70	83
2	A	209490	50	F	1	59	165	21.6	73	78	78	84	90	116	74	88	122	63	82
3	A	211569	40	F	1	54	167	19.3	96	88	84	91	83	134	89	104	114	68	83
4	A	231381	52	F	2	82	157	33.2	79	71	83	87	89	105	78	87	117	75	89
5	A	224426	52	M	1	71	170	24.5	85	102	79	83	88	140	92	108	121	75	90
6	A	240173	38	F	1	59	165	21.6	87	95	91	84	86	110	70	83	110	66	80
7	A	240938	32	M	2	74	152	32	98	87	85	91	87	124	86	98	109	77	87
8	A	224941	23	F	2	58	162	22.1	69	78	75	82	83	112	78	89	129	77	94
9	A	241349	65	M	2	57	172	19.2	84	91	79	90	87	122	63	82	124	87	99
10	A	244005	49	M	1	66	160	25.8	92	89	82	80	76	136	94	108	127	82	97
11	A	239338	30	M	1	58	157	23.5	81	78	83	69	73	118	82	94	112	74	86

12	A	247171	46	F	2	69	151	30.3	70	85	83	87	83	110	66	80	117	75	89
13	A	247482	26	F	2	71	162	27	69	76	74	75	89	121	75	90	102	66	97
14	A	250615	50	M	2	83	170	28.7	70	72	82	70	90	124	87	99	116	74	88
15	A	255743	27	F	2	68	167	24.4	78	99	90	81	83	109	77	87	120	84	96
16	A	242298	36	F	1	53	175	17.3	94	100	89	78	75	130	74	92	112	78	89
17	A	258174	28	M	1	69	160	26.9	97	105	94	72	88	114	68	83	109	70	83
18	A	261972	49	M	2	70	165	25.7	73	82	79	84	74	129	77	94	127	82	97
19	A	251784	63	F	1	82	154	34.6	79	94	84	72	67	118	82	94	121	88	99
20	A	265143	38	F	2	59	154	24.9	85	79	72	78	79	120	84	96	121	75	90
21	A	261972	49	F	1	73	165	26.8	86	74	71	80	83	127	82	97	102	66	97
22	A	262189	55	M	2	70	164	26	94	98	88	79	82	124	87	99	114	68	83
23	A	210888	26	F	2	63	170	21.8	79	84	73	91	79	112	74	86	110	66	80
24	A	264538	23	M	1	77	163	30	74	92	89	85	80	117	75	89	134	89	104
25	A	278395	43	M	1	72	167	25.8	94	83	79	77	82	110	70	83	122	63	82
26	B	226857	49	F	1	72	158	28.9	73	89	86	87	82	118	82	94	122	63	82
27	B	228651	29	F	2	83	162	31.6	95	99	89	79	85	110	66	80	129	77	94
28	B	227864	49	M	1	73	165	26.8	83	84	76	89	79	112	78	89	124	87	99
29	B	168872	58	F	1	79	169	27.6	75	88	78	92	99	112	74	86	121	75	90
30	B	233664	21	F	1	71	158	28.4	91	105	97	83	82	114	68	83	130	74	92
31	B	235211	33	F	2	69	170	23.8	80	97	83	74	79	116	74	88	110	70	83
32	B	237991	35	F	2	80	159	31.6	73	85	95	71	72	130	74	92	114	68	83
33	B	239583	32	F	1	59	164	21.9	91	90	92	84	91	117	75	89	122	63	82
34	B	233428	27	F	2	69	169	24.1	70	82	84	89	87	129	77	94	118	82	94
35	B	238350	58	M	1	72	170	24.9	69	89	70	74	83	109	77	87	121	75	90
36	B	247861	22	M	1	80	154	33.7	70	83	93	80	77	136	94	108	121	88	99
37	B	247482	26	F	1	74	152	32	75	74	86	71	96	130	74	92	112	74	86
38	B	248137	58	M	2	69	161	26.6	89	99	79	93	82	124	87	99	102	66	97
39	B	247140	22	F	2	68	167	24.4	93	88	84	90	71	110	66	80	120	84	96
40	B	256671	53	M	1	75	157	30.4	86	76	90	80	69	118	82	94	114	68	83

41	B	255497	31	M	2	59	162	22.5	80	78	96	81	70	122	63	82	129	77	94
42	B	261054	37	F	1	71	167	25.5	79	92	83	79	88	112	74	86	121	75	90
43	B	261972	49	F	2	64	159	25.3	82	90	95	73	90	121	88	99	109	77	87
44	B	224942	57	F	2	73	161	28.2	94	89	91	79	81	117	75	89	134	89	104
45	B	259461	45	F	1	59	160	23	83	79	79	78	79	114	68	83	110	66	80
46	B	273125	28	F	2	72	156	29.6	86	74	83	82	74	121	75	90	112	78	89
47	B	269497	39	F	1	81	165	29.7	83	86	80	85	82	134	89	104	124	86	98
48	B	218323	36	F	1	73	152	31.6	91	105	99	79	80	112	74	86	129	77	94
49	B	276140	40	F	1	59	167	21.1	79	89	89	82	71	112	78	89	110	66	80
50	B	244344	41	M	1	70	165	25.7	91	104	89	72	89	124	86	98	116	74	88

SL No.	Group	SBP (mmhg) 3 min Post Intubation	DBP (mmhg) 3 min Post Intubation	MAP (mmhg) 3 min Post Intubation	SBP (mmhg)5 min Post Intubation	DBP (mmhg)5 min Post Intubation	MAP (mmhg)5 min Post Intubation	SBP (mmhg)10 min Post Intubation	DBP (mmhg)10 min Post Intubation	MAP (mmhg)10 min Post Intubation	SpO2_Pre Intubation	SpO2_1 min Post Intubation	SpO2_3 min Post Intubation	SpO2_5 min Post Intubation	SpO2_10 min Post Intubation	SAD Insertion 1st/2nd attempt	SAD Insertion Time (Sec)	Tracheal Tube Insertion attempt, 1st /2nd	Tracheal Tube Insertion time(sec),	SAD Removal time (After intubation)	Blood on SAD	Sore throat
1	A	112	78	89	114	68	83	118	82	94	98	100	100	100	100	1st	20	1st	14	22	Absent	Absent
2	A	122	63	82	112	74	86	129	77	94	96	100	100	100	100	1st	18	1st	15	23	Absent	Absent
3	A	124	86	98	110	70	83	122	63	82	96	100	100	100	100	1st	17	1st	13	20	Absent	Absent
4	A	118	82	94	112	78	89	121	88	99	97	100	100	100	100	1st	19	1st	17	24	Absent	Absent
5	A	112	74	86	117	75	89	110	66	80	96	100	100	100	100	1st	25	1st	15	19	Absent	**Present**
6	A	120	84	96	110	66	80	122	63	82	97	100	100	100	100	1st	28	1st	17	18	Absent	Absent
7	A	116	74	88	124	87	99	110	70	83	98	100	100	100	100	1st	26	1st	12	20	Absent	Absent
8	A	102	66	97	111	83	92	109	70	83	96	100	100	100	100	1st	20	**2nd**	18	21	Absent	Absent
9	A	114	68	83	109	77	87	116	74	88	97	100	100	100	100	**2nd**	29	1st	16	22	**Present**	Absent
10	A	109	70	83	110	66	80	12	75	90	96	100	100	100	100	1st	28	1st	17	19	Absen	Absen

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11	A	121	88	99	110	70	83	102	66	97	98	100	100	100	100	1st	18	1st	15	25	Absent	Absent
12	A	114	68	83	122	63	82	117	75	89	96	100	100	100	100	1st	17	1st	19	28	Absent	Absent
13	A	117	75	89	129	77	94	127	82	97	98	100	100	100	100	1st	19	1st	15	19	Absent	Absent
14	A	124	86	98	102	66	97	110	70	83	98	100	100	100	100	1st	20	1st	17	28	Absent	Absent
15	A	122	63	82	112	78	89	109	77	87	97	100	100	100	100	1st	26	1st	15	18	Absent	Absent
16	A	118	82	94	121	75	90	110	66	80	96	100	100	100	100	**2nd**	28	1st	16	16	Absent	Absent
17	A	110	66	80	121	88	99	118	82	94	98	100	100	100	100	1st	19	1st	18	19	Absent	Absent
18	A	109	77	87	112	74	86	121	75	90	98	100	100	100	100	1st	17	1st	14	20	Absent	Absent
19	A	124	87	99	117	75	89	122	63	82	97	100	100	100	100	1st	20	1st	19	24	Absent	Absent
20	A	111	83	92	112	78	89	114	68	83	97	100	100	100	100	1st	26	1st	17	21	Absent	Absent
21	A	109	70	83	124	86	98	110	70	83	98	100	100	100	100	1st	25	1st	13	21	Absent	Absent
22	A	110	70	83	122	63	82	124	87	99	98	100	100	100	100	1st	24	1st	17	23	Absent	Absent
23	A	124	87	99	116	74	88	112	74	86	96	100	100	100	100	1st	28	**2nd**	16	19	Absent	Absent
24	A	121	75	90	117	75	89	121	88	99	96	100	100	100	100	1st	18	1st	18	25	Absent	**Present**
25	A	114	68	83	110	66	80	112	78	89	97	100	100	100	100	1st	25	1st	19	23	Absent	Absent
26	B	114	68	83	112	78	89	11	70	83	96	100	100	100	100	1st	23	1st	19		Absen	Absen

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27	B	134	89	104	114	68	83	110	66	80	98	100	100	100	100	1st	25	1st	18		Absent	Absent
28	B	122	63	82	110	66	80	121	88	99	98	100	100	100	100	1st	19	1st	16		Absent	Absent
29	B	109	77	87	110	70	83	122	63	82	97	100	100	100	100	1st	21	**2nd**	19		**Present**	**Present**
30	B	110	70	83	118	82	94	109	77	87	96	100	100	100	100	**2nd**	26	1st	20		Absent	Absent
31	B	124	86	98	116	74	88	114	68	83	98	100	100	100	100	1st	24	1st	22		Absent	Absent
32	B	102	66	97	111	83	92	109	70	83	98	100	100	100	100	1st	22	1st	19		Absent	Absent
33	B	112	78	89	114	68	83	124	87	99	97	100	100	100	100	1st	25	**2nd**	18		**Present**	Absent
34	B	120	84	96	124	87	99	110	66	80	97	100	100	100	100	**2nd**	21	1st	20		Absent	Absent
35	B	127	82	97	109	70	83	112	74	86	98	100	100	100	100	1st	18	1st	17		Absent	Absent
36	B	110	70	83	121	75	90	109	70	83	98	100	100	100	100	1st	20	1st	21		Absent	Absent
37	B	110	66	80	117	75	89	118	82	94	98	100	100	100	100	1st	25	1st	18		Absent	Absent
38	B	114	68	83	122	63	82	110	70	83	96	100	100	100	100	1st	28	1st	16		Absent	**Present**
39	B	111	83	92	112	74	86	110	70	83	98	100	100	100	100	1st	24	1st	18		Absent	Absent
40	B	117	75	89	109	77	87	122	63	82	98	100	100	100	100	**2nd**	21	**2nd**	19		Absent	Absent
41	B	122	63	82	124	86	98	109	77	87	97	100	100	100	100	1st	18	1st	20		Absent	Absent
42	B	116	74	88	102	66	97	11	74	88	96	100	100	100	100	1st	17	1st	17		Absen	Absen

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43	B	109	70	83	110	70	83	122	63	82	96	100	100	100	100	1st	27	1st	20		Absent	Absent
44	B	124	87	99	120	84	96	117	75	89	98	100	100	100	100	1st	24	1st	21		**Present**	Absent
45	B	110	70	83	118	82	94	112	78	89	98	100	100	100	100	1st	19	1st	18		Absent	Absent
46	B	112	74	86	127	82	97	121	75	90	97	100	100	100	100	1st	20	**2nd**	18		Absent	Absent
47	B	109	77	87	121	88	99	124	87	99	96	100	100	100	100	**2nd**	22	1st	18		Absent	Absent
48	B	121	75	90	122	63	82	110	66	80	96	100	100	100	100	1st	19	1st	22		Absent	**Present**
49	B	112	78	89	117	75	89	110	70	83	98	100	100	100	100	1st	25	1st	20		Absent	Absent
50	B	110	70	83	114	68	83	112	74	86	97	100	100	100	100	1st	24	1st	24		Absent	Absent