"COMPARISON OF LARYNGEAL MASK AIRWAY PROTECTOR AND INTUBATING LARYNGEAL MASK AIRWAY FOR EASE OF FIBEROPTIC GUIDED TRACHEAL INTUBATION IN ADULT PATIENTS- A ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL"

BY

REG NO: BA0122009

Dissertation

Submitted to the KLE Academy of Higher Education and Research, Belagavi, Karnataka
In Partial Fulfilment
of the Requirements for the Degree of

M. D.
In
ANAESTHESIOLOGY

DEPARTMENT OF ANAESTHESIOLOGY
JAWAHARLAL NEHRU MEDICAL COLLEGE,
BELAGAVI, KARNATAKA

SEPTEMBER/OCTOBER 2025

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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 LARYNGEAL MASK AIR WAY PROTECTOR AND INTUBATING LARYNGEAL MASK AIR WAY FOR EASE OF FIBEROPTIC GUIDED TRACHEAL INTUBATION IN ADULT PATIENTS : A ONE YEAR HOSPITAL BASED RANDOMISED CONTROL TRIAL",** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee.

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LIST OF ABBREVIATIONS

ASA	-	American society of Anaesthesiologists
ECG	-	Electro cardiogram
EtCO2	-	End tidal carbon dioxide
ETT	-	Endotracheal tube
FOB	-	Fibreoptic bronchoscope
GA	-	General anesthesia
ILMA	-	Intubating LMA
LMA	-	laryngeal mask airway
MRI	-	Magnetic resonance imaging
NIBP	-	Non Invasive blood pressure
NPO	-	Nil Per oral
PPV	-	Positive pressure ventilation
SAD	-	Supraglottic airway device
sILMA	-	Single use intubating laryngeal mask airway
SPO2	-	Saturation of peripheral oxygen

ABSTRACT

Title:

COMPARISON OF LARYNGEAL MASK AIRWAY PROTECTOR AND INTUBATING LARYNGEAL MASK AIRWAY FOR EASE OF FIBEROPTIC GUIDED TRACHEAL INTUBATION IN ADULT PATIENTS- A ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL.

Background:

Anesthesiologists play a critical role in ensuring optimal gas exchange. While advancements like video laryngoscopy and supraglottic airway devices (SADs) have improved airway management, challenges persist, particularly during emergence. The laryngeal mask airway (LMA), introduced by Archie Brain in 1988, revolutionized airway management, offering a less invasive alternative to endotracheal intubation. The intubating LMA (ILMA), designed for fiberoptic-guided tracheal intubation, enhances success in difficult airway scenarios. The LMA Protector™, a second-generation SAD, improves upon traditional designs by incorporating gastric drainage channels and facilitating fiberoptic intubation. This study compares the ILMA and LMA Protector in terms of insertion ease and efficacy as conduits for fiberoptic-guided intubation in adults undergoing general anesthesia.

Aims and Objectives:

The objectives of the study is to compare the ease of fiberoptic guided tracheal intubation through the LMA Protector and Intubating LMA and the grade of view of glottic aperture through LMA Protector and Intubating LMA with a flexible fibrescope

Methodology:

A randomized control trial at KLES Prabhakar Kore Hospital & Medical Research Centre included 68 ASA I and II patients, aged 18-60 years, undergoing elective surgeries under General Anaesthesia. Patients were divided into two groups of 34 each: Group P (LMA Protector) and Group I (Intubating LMA). Patients in Group P was intubated using LMA Protector while those in Group I were intubated using Intubating LMA with the help of fiberoptic guidance. The time taken for LMA insertion, grade of resistance during insertion, number of attempts at LMA insertion, time taken for tracheal intubation and number of attempts at intubation were noted. Additionally grade of glottic view was also assessed.

Results:

This study compares the ILMA (LMA-Fastrach™) and LMA Protector in airway management, showing both devices have high first-attempt success rates and similar ease of insertion ($p = 0.742$). The ILMA demonstrated faster placement (27.36 vs. 29.17 seconds; $p = 0.188$) and significantly shorter tracheal intubation time (58.60 vs. 64.18 seconds; $p < 0.001$). While overall success rates were comparable ($p = 0.555$), the ILMA showed a slight advantage in first-attempt intubation success. These findings suggest the ILMA is superior for rapid intubation, whereas the LMA Protector emphasizes airway sealing and protection.

Conclusion:

The search for an optimal supraglottic airway device (SAD) for fiberoptic-guided tracheal intubation continues with the evolution of second-generation devices. This study compares the ILMA, long considered the gold standard, with the LMA

Protector, which incorporates modern design enhancements. Both devices demonstrated high success rates, with the ILMA seating slightly faster and offering marginally better glottic visualization, though differences were not statistically significant. These findings reinforce the reliability of both devices, with operator expertise playing a crucial role in optimizing performance.

Keywords: LMA Protector, Intubating LMA, fiberoptic, General Anaesthesia, Glottic View.

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INTRODUCTION

The primary aim of an anesthesiologist is to ensure optimal gas exchange, a critical responsibility given that transient lapses in oxygenation can precipitate catastrophic hypoxic injury[1]. Although advancements in airway management and monitoring have attenuated intubation-related adverse events, challenges during emergence continue to be a predominant contributor to severe perioperative complications, with the failure to secure a difficult airway accounting for up to 30% of anesthesia-related mortalities[1].

Ensuring a patent and secure airway during surgical procedures is critical in safeguarding patient outcomes during the perioperative period[2]. Although the occurrence of difficult airway management in anesthesia is relatively infrequent, comprehensive preoperative assessment and the strategic use of advanced techniques such as video laryngoscopy, supraglottic airway devices (SADs), and fiberoptic-guided intubation play an essential role in mitigating risks associated with general anesthesia[3]. Practitioners employ a wide array of methods, ranging from conventional direct laryngoscopy to SADs, with individualized planning emphasized to ensure continuous oxygenation and ventilation[3,4].

The laryngeal mask airway (LMA), conceived by Archie Brain and initially implemented in clinical settings in 1988, represents a significant innovation in airway management[5]. Brain described the LMA as “an alternative to either the endotracheal tube (ETT) or the face mask with either spontaneous or positive-pressure ventilation (PPV),” highlighting its versatility[5]. Almost three decades hence, the laryngeal mask airway has evolved into a pivotal innovation in anesthesiology, currently representing the predominant airway management device employed for general anesthesia across numerous countries[6]. Its minimally invasive design features an inflatable mask that conforms to the supraglottic tissues, providing a reliable seal while reducing trauma compared to traditional intubation[6,7].

The intubating laryngeal mask airway (ILMA), introduced in 1997, represents a significant modification of the traditional LMA, specifically designed to enable fiberoptic-guided tracheal intubations[8]. Unlike the standard LMA, the ILMA is designed with a shorter, wider profile, permitting the passage of larger tracheal tubes (up to 8-mm internal diameter)[9]. Additionally, the incorporation of an epiglottic elevator and a rigid, anatomically curved stainless steel shaft improves alignment with the laryngeal inlet, optimizing intubation success in difficult airways[8,9]. Studies have demonstrated first-attempt success rates for blind intubation via ILMA ranging from 76% to 95%, with overall success rates reaching 99.7% when combined with fiberoptic guidance[10]. This positions the ILMA as particularly valuable in cannot-intubate scenarios and airway rescue situations[11].

Since the introduction of the classic LMA, substantial developments have occurred in supraglottic airway technology. Second-generation devices incorporate design improvements specifically addressing the limitations of their predecessors, particularly regarding aspiration risk and ventilation efficacy[12].

The LMA Protector™, one of the newer second-generation SADs, is engineered to reduce gastric aspiration risk through dual gastric drainage tubes and an enlarged inflatable cuff that ensures a robust supraglottic seal[13]. Clinical trials report high first-attempt insertion success rates, reliable sealing pressures, and compatibility with 7.5-mm tracheal tubes for fiberoptic-guided intubation[13]. Its rigid, curved structure aligns with the laryngeal inlet, minimizing manipulation during intubation, while integrated suction compatibility enhances its utility in managing secretions[13]. These features position the LMA Protector as a pivotal tool in both elective and emergency airway management[13].

Clinical algorithms for difficult airway management highlight the importance of having multiple strategies available, including both SAD options and fiberoptic intubation capabilities[14]. The availability of devices that can function both as effective ventilation tools and as reliable conduits for intubation represents a significant advancement in the difficult airway algorithm, potentially reducing the need for multiple device exchanges in critical situations[15].

This study aims to compare the Intubating LMA and the LMA Protector with respect to ease of device insertion and efficacy as conduits for fibreoptic-guided intubation in adult patients undergoing surgical procedures under general anesthesia.

AIMS AND OBJECTIVES

Primary Objective

"The primary objective of the study is to compare the ease of fiberoptic guided tracheal intubation through the LMA Protector and Intubating LMA."

Secondary Objective

"To evaluate the grade of view of glottic aperture through LMA Protector and Intubating LMA with a flexible fibrescope."

REVIEW OF LITERATURE

The laryngeal mask airway (LMA) revolutionized general anesthesia practice since its introduction by Dr. Archie Brain in 1981.[5] Originally designed to bridge the gap between face masks and endotracheal tubes, the LMA quickly transformed from an experimental device to a cornerstone of modern anesthetic technique.[16] Brain's initial clinical study in 1983 demonstrated successful use in 23 patients, highlighting its ease of insertion and minimal airway trauma.[17] Despite early skepticism regarding aspiration risk and ventilation adequacy, the landmark multicenter study by Verghese and Brimacombe in 1996, documenting over 11,000 LMA insertions with minimal complications, firmly established its safety profile in general anesthesia.[18] The device's evolution progressed rapidly with specialized variants like the ProSeal LMA (2000), featuring an esophageal drainage tube to reduce aspiration risk during general anesthesia,[19] and the single-use Supreme LMA (2007).[20] Initially limited to spontaneously breathing patients undergoing brief procedures, LMA applications expanded dramatically with Cook's 1996 research demonstrating successful use in prolonged surgeries[21] and Miller's pivotal 1997 paper showing safe positive pressure ventilation during general anesthesia.[22] The versatility of LMAs in pediatric anesthesia was confirmed by Bordet's 2002 study, which revealed superior outcomes compared to face masks.[1] The Fourth National Audit Project (2011) highlighted the crucial role of LMAs in difficult airway management during general anesthesia,[10] leading to their incorporation in anesthesia algorithms worldwide.[14] Simulation-based training has improved insertion success rates,[23] contributing to widespread adoption, with Woodall and Cook reporting in 2011 that supraglottic airways were used in approximately 56% of general anesthetics in the United Kingdom, often replacing endotracheal tubes.[24]

The use of the laryngeal mask airway (LMA) as a conduit for blind or fiberoptic-guided tracheal intubation has evolved significantly since its early applications in the 1990s. Initially explored as an alternative to direct laryngoscopy in difficult airways, blind tracheal intubation through the LMA was met with variable success. Early reports highlighted technical challenges, including malpositioning and low success rates, prompting the integration of fiberoptic guidance to enhance precision. Dimitriou and Voyagis demonstrated in 1996 that combining the LMA with a fiberoptic bronchoscope (FOB) improved visualization and successful tube placement, establishing fiberoptic-guided intubation as a more reliable method compared to blind techniques.[25] This approach became particularly valuable in anticipated difficult airways, where traditional methods failed. Subsequent advancements led to the development of specialized intubating LMAs, such as the LMA-Fastrach™ (ILMA), designed explicitly to facilitate tracheal intubation. Brain et al. reported a 96% success rate using the ILMA in 500 patients, underscoring its efficacy in both blind and fiberoptic-aided intubations.[26] Comparative studies, including a multicenter trial by Baskett et al., noted higher first-attempt success rates with the ILMA (95%) compared to conventional blind techniques (75%), reinforcing its role in emergency and elective settings.[27] Fiberoptic guidance further optimized outcomes, particularly in anatomically challenging cases, as evidenced by Ferson et al., who achieved a 98.4% success rate in 254 difficult airway patients using the ILMA with FOB assistance.[6] Despite these advancements, blind intubation via the LMA remains a critical skill in resource-limited scenarios, though its application is now largely supplanted by fiberoptic or video-assisted methods. Current guidelines endorse the LMA, particularly the ILMA, as a first-line rescue device in difficult airway algorithms, emphasizing its dual utility as a ventilatory conduit and intubation pathway.[28]

Kleine-Brueggeney et al. (2011) conducted a randomized controlled trial to compare the efficacy of fibreoptic-guided tracheal intubation with the i-gel and the single-use intubating laryngeal mask airway (sILMA) in 160 patients anticipated to have difficult airways.[28] Their study found that the i-gel had a first-attempt fibreoptic intubation success rate of 96%, which was slightly higher than the sILMA's 90%, although this was not statistically significant ($p = 0.21$). They noted that both devices were successful in facilitating fibreoptic intubation, although the i-gel provided a larger airway channel that facilitated scope navigation and tube placement. The researchers observed that the i-gel design facilitated intuitive insertion and facilitated fibreoptic access to the glottic opening, thereby decreasing total intubation time. While the sILMA had higher airway leak pressure, both devices had comparable results in glottic visualization and ease of intubation. The findings of this study showed that the i-gel is an acceptable alternative to the sILMA for fibreoptic-guided intubation, with both devices having high success rates and consistent conduit function. Notably, the streamlined design of the i-gel facilitated the passage of the endotracheal tube, indicating that its use may simplify procedural complexity during fibreoptic intubation.

According to Moore et al., their study compared the efficacy of the i-gel and the LMA-Fastrach as conduits in fibreoptic-guided tracheal intubation.[29] In this randomized study of 120 patients, the researchers reported that the first attempt success rate of fibreoptic-guided intubation was 100% for the i-gel and 95% for the LMA-Fastrach ($p = 0.12$). Their findings demonstrated that the i-gel facilitated significantly faster intubation with an average intubation time of 30 ± 11 seconds compared to 50 ± 21 seconds for the LMA-Fastrach ($p < 0.0001$). Regarding visualization, they found that 63.3% of i-gel insertions facilitated a grade 1 view (optimal visualization), compared to only 3.3% for the LMA-Fastrach ($p < 0.0001$). Conversely, they noted that the LMA-Fastrach was more likely to facilitate a grade 3 view (poor visualization) at 60.0%, compared to only 1.7% for the i-gel.

Samir and Sakr (2012) conducted a prospective randomized study to evaluate the efficacy of the Air-Q supraglottic airway as a conduit for fiberoptic intubation in patients undergoing cervical spine fixation.[30] They acknowledged that airway management in patients with limited cervical mobility presents significant challenges due to restricted neck movement and the risk of exacerbating spinal injuries. The researchers explained that the Air-Q, an intubating laryngeal airway device, was designed to facilitate blind and fiberoptic-assisted intubation while allowing adequate ventilation. In their study of sixty adult patients, they found that the Air-Q group had a higher first-attempt success rate (96.7%) compared to the direct fiberoptic intubation group. Additionally, the Air-Q also significantly reduced the time required for tracheal intubation (21.6 ± 5.7 seconds vs. 29.8 ± 6.2 seconds). Their observations showed that the fiberoptic view of the vocal cords was superior in the Air-Q group, facilitating easier and faster tube insertion. The researchers concluded that the Air-Q provides an effective conduit for fiberoptic intubation, improving visualization and reducing intubation time, making it particularly useful in patients with restricted neck mobility.

Sood et al. (2019) conducted a prospective randomized study comparing fiberoptic-guided tracheal intubation through the LMA Fastrach™ and the i-gel in adult patients undergoing general anesthesia.[31] The study aimed to evaluate differences in ease of insertion, time required for intubation, airway seal pressure, and success rates between the two devices. Their results demonstrated that tracheal intubation was successfully performed in both groups with no significant differences in the number of attempts. They reported that the LMA Fastrach™ group had a mean intubation time of 69.53 ± 5.09 seconds, while the i-gel group had a slightly longer intubation time of 72.33 ± 6.73 seconds. However, they found that the i-gel provided a better fiberoptic view in more patients (96.7%) compared to the LMA Fastrach™ (93.3%). The researchers concluded that both devices are effective for fiberoptic-guided intubation, with the i-gel offering a cost-effective and reliable alternative to the LMA Fastrach™.

Karim and Swanson (2011) conducted a randomized trial comparing the LMA Fastrach™ and Air-Q™ supraglottic airway devices as conduits for blind tracheal intubation.[32] The study aimed to assess whether the Air-Q™ could achieve non-inferior intubation success compared to the LMA Fastrach™. A total of 154 healthy adult patients undergoing elective surgery were randomly assigned to either the LMA Fastrach™ or Air-Q™ group. After supraglottic airway insertion, blind tracheal intubation was attempted. If two blind attempts failed, a third was performed using fiberoptic guidance. Primary outcomes included blind intubation success rates, fiberoptic-assisted intubation rates, and time to successful intubation and device removal. The LMA Fastrach™ achieved a 99% success rate (75/76) for blind intubation after two attempts, significantly higher than the 77% (60/78) success rate with the Air-Q™ ($p < 0.0001$). After a third fiberoptic-guided attempt, success rates were 100% for the LMA Fastrach™ and 95% for the Air-Q™. Notably, 31% of Air-Q™ cases required fiberoptic assistance compared to just 1% in the LMA Fastrach™ group. Median tracheal tube insertion times were 27 seconds for the LMA Fastrach™ and 35 seconds for the Air-Q™, with total intubation times being shorter for the LMA Fastrach™ (185 vs. 219 seconds). The study concluded that the LMA Fastrach™ is superior for blind intubation, offering higher success rates and faster intubation times.

The Air-Q™, while less effective for blind techniques, remains a useful option when fiberoptic equipment is available. The findings reinforce the LMA Fastrach™'s role as the gold standard for blind intubation, with the Air-Q™ serving as a backup device for fiberoptic-guided intubation.

Mishra et al. (2024) conducted a hospital-based observational study to evaluate the Ambu® Aura-i™, a second-generation supraglottic airway device, as a ventilatory device and conduit for fiberoptic-guided tracheal intubation in adult patients undergoing elective surgery.[33] The Aura-i™ features a wide airway channel designed to accommodate standard cuffed tracheal tubes and is compatible with MRI, making it versatile for both emergency and routine airway management. The study included 80 adult patients, stratified into two weight-based groups using size 3 or 4 Aura-i™ devices. After anesthesia induction with propofol and muscle relaxation with atracurium, the Aura-i™ was inserted using the standard midline technique. Fiberoptic bronchoscopy was performed to assess the glottic view and guide endotracheal tube placement. Key parameters recorded included insertion time, fiberoptic intubation time, glottic view grades, and device removal time. The results revealed that fiberoptic intubation was successful in all patients. The mean time for fiberoptic-guided intubation was 14.95 ± 1.85 seconds in group 1 and 14.15 ± 1.37 seconds in group 2. Insertion of the Aura-i™ was quick (13.53 ± 1.91 seconds and 13.98 ± 2.4 seconds, respectively). The study concluded that the Ambu® Aura-i™ is an effective, cost-efficient, and user-friendly supraglottic airway device for fiberoptic-guided intubation. Its broad size range, quick insertion time, and compatibility with MRI make it a valuable tool for both routine and emergency airway management.

Preece et al. (2018) conducted a randomized controlled trial comparing fiberoptic-guided tracheal intubation through the Ambu® AuraGain™ and the LMA Fastrach™ in 116 adult patients undergoing general anesthesia.[34] The AuraGain™, a second-generation supraglottic airway device, has a wide bore allowing for endotracheal tube insertion, while the LMA Fastrach™ is a well-established device designed for both blind and fiberoptic-assisted intubation. The study aimed to assess intubation success rates, glottic visualization, and time to intubation for both devices. Patients were randomly assigned to the AuraGain™ or LMA Fastrach™ group, and anesthesia was induced using propofol and muscle relaxants. After confirming ventilation through the supraglottic devices, fiberoptic bronchoscopes were used to guide tracheal tube placement. Key data recorded included fiberoptic view grades, time to successful intubation, and complication rates. The results showed that the AuraGain™ achieved better laryngeal alignment, with 29 of 59 patients having a Grade 4 view (vocal cords fully visible), compared to 20 of 54 patients with the LMA Fastrach™ ($p = 0.003$). Intubation was also faster with the AuraGain™. Both devices demonstrated similar success rates for tracheal intubation and comparable minor complication rates, such as sore throat and dysphonia. The study concluded that the Ambu® AuraGain™ is a reliable alternative to the LMA Fastrach™, offering better glottic visualization and faster fiberoptic intubation, supporting its use in difficult airway scenarios.

Moser et al. (2018) investigated fiberoptic intubation through two supraglottic airway devices — the Ambu® AuraGain™ and the i-gel™ — in severely obese patients.[35] Managing the airway in obese patients poses unique challenges due to limited neck mobility and higher rates of difficult intubation. This study aimed to compare the time taken for fiberoptic-guided tracheal intubation and the ease of device insertion between the two airway conduits. The prospective, randomized trial enrolled 44 obese patients (BMI >35 kg/m²) scheduled for elective shoulder, knee, or hip surgery. Participants were randomly assigned to either the AuraGain™ or i-gel™ group. Anesthesia was induced with fentanyl, propofol, and rocuronium, and the assigned supraglottic device was inserted. Ventilation was confirmed before performing fiberoptic-guided intubation through the device. The primary outcome was the time required for trans-device intubation, measured from the insertion of the bronchoscope until confirmation of tube placement. Secondary parameters included oropharyngeal leak pressure, number of intubation attempts, and postoperative airway morbidity. The mean intubation time was 55.7 ± 5.8 seconds for the AuraGain™ and 54.1 ± 8.5 seconds for the i-gel™ ($p = 0.474$), with no significant difference between the two groups. Both devices demonstrated high success rates for fiberoptic-guided intubation, with no failed attempts. Oropharyngeal leak pressures were also comparable, indicating effective airway seals. Postoperative airway morbidity, including sore throat or dysphonia, was minimal and similar across both groups. The authors concluded that both the AuraGain™ and i-gel™ are effective for fiberoptic-guided intubation in obese patients, offering quick and reliable airway management options.

In their comparative evaluation of supraglottic airways as conduits for fibreoptic-guided intubation, Mendonca et al.[36] directly contrasted the LMA Protector and i-gel devices, with particular emphasis on glottic visualization quality and overall intubation efficiency. Their investigation revealed that both devices facilitated excellent glottic views, with a grade 1 view (complete visualization of vocal cords) achieved in 77% of i-gel cases and 84% of LMA ProtectorTM cases. While this difference suggested a potential advantage for the LMA Protector, statistical analysis indicated that the variation was not significant, consistent with findings from Kleine-Brueggeney et al.[28] who similarly reported excellent visualization with both device types. Mendonca and colleagues documented nearly identical first-attempt intubation success rates (98%) for both devices, suggesting comparable clinical utility for this specific application. However, their detailed assessment noted that tracheal tube impingement – a technical complication that can delay successful intubation and potentially cause airway trauma – occurred less frequently with LMA Protector (27%) as compared to i-gel (41%). This difference in impingement rates might be attributed to variations in the internal channel design and exit angle at the laryngeal portion of each device, as proposed by Michalek and Donaldson[37] in their technical analysis of supraglottic airway architecture. Despite this variation, the overall comparable performance led Mendonca et al.[36] to conclude that both devices represent viable options for fibreoptic-guided intubation in appropriate clinical scenarios.

BASIC SCIENCES

Upper Airway Anatomy

Pharynx:

Functionally, the pharynx operates as a dual-purpose pathway, facilitating the passage of inspired air from the nasal cavity to the larynx and concurrently allowing the transit of ingested materials from the oral cavity to the esophagus. Anatomically, it is divided into three distinct regions: the nasopharynx, situated posterior to the nasal cavity and involved primarily in respiratory functions; the oropharynx, located posterior to the oral cavity and participating in both respiratory and digestive processes; and the laryngopharynx (or hypopharynx), which lies posterior to the larynx and directs both air towards the trachea and food towards the esophagus. Each region is structurally specialized to fulfill its respective physiological roles, ensuring the coordinated execution of breathing, swallowing, and airway protection mechanisms.[38]

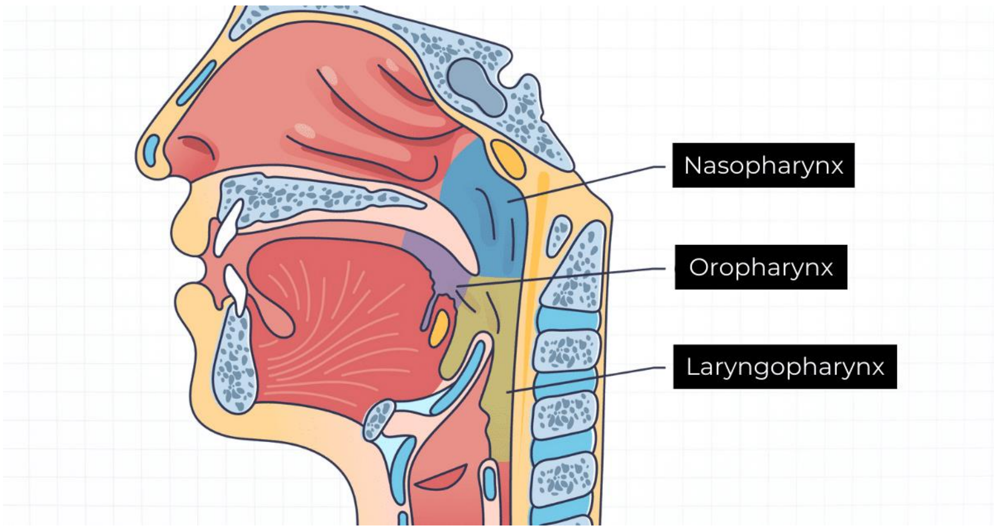


FIG 1: ANATOMY OF PHARYNX

Nasopharynx

The nasopharynx constitutes the uppermost section of the pharynx, situated behind the nasal cavity and superior to the soft palate. Its primary function is to serve as an airway passage, guiding the flow of air from the nasal cavity to the oropharynx. The nasopharyngeal lining is composed of ciliated pseudostratified columnar epithelium, which plays a crucial role in filtering and humidifying inhaled air. The rhythmic motion of the cilia propels mucus and entrapped particles toward the oropharynx, where they are swallowed, thus helping to maintain a clear respiratory tract and prevent the entry of pathogens.[39]

Several anatomical structures within the nasopharynx contribute to both respiratory efficiency and immune defense. The pharyngeal tonsils, commonly known as adenoids, are clusters of lymphoid tissue located along the roof and posterior wall of the nasopharynx. As part of the immune system, adenoids act as a first line of defense by capturing and neutralizing pathogens that enter through nasal inhalation. They are particularly active during childhood, and their enlargement can obstruct airflow, leading to breathing difficulties or recurrent infections.[39]

Another notable feature is the presence of the Eustachian tube openings, also referred to as the pharyngotympanic tubes. These tubes link the nasopharynx to the middle ear cavity and play a pivotal role in equalizing air pressure on both sides of the tympanic membrane (eardrum). This balance is vital for proper auditory function and prevents barotrauma, which may arise during activities like flying or diving. Additionally, the Eustachian tubes allow mucus drainage from the middle ear into the nasopharynx, reducing the risk of otitis media, or middle ear infections.

The nasopharynx's structural and functional attributes highlight its significance within the upper respiratory system. It not only prepares inhaled air by filtering, warming, and moisturizing it but also contributes to immune surveillance and auditory regulation. A thorough understanding of the nasopharynx's anatomy and physiology is crucial for medical professionals, especially those in otolaryngology and pulmonology, as it aids in diagnosing and managing conditions affecting the upper airway and related structures.[40]

Oropharynx

The oropharynx represents the central segment of the pharynx, spanning from the soft palate to the level of the hyoid bone. This region functions as a vital passageway for both respiratory and digestive processes, channeling air towards the larynx and trachea while simultaneously directing ingested food and liquids into the esophagus. Given its dual role, the oropharynx is structurally adapted to withstand mechanical stress. It is lined with stratified squamous epithelium, a more durable tissue type compared to the ciliated pseudostratified columnar epithelium found in the nasopharynx. This histological difference is critical, as the oropharynx must endure friction and abrasion from food passage in addition to air movement.

Structurally, the superior boundary of the oropharynx is defined by the soft palate, which elevates during swallowing to seal off the nasopharynx and prevent food or liquid from entering the nasal cavity. The anterior aspect of the oropharynx is demarcated by the oral cavity, with the isthmus of the fauces serving as a transitional zone between the two.

This area is bordered by the palatoglossal and palatopharyngeal arches, which house the palatine tonsils. These tonsils, located within the tonsillar fossae on either side of the oropharynx, are composed of lymphoid tissue and play a crucial role in immune defense by capturing and neutralizing pathogens introduced through the mouth and nose.[41]

Additional immune structures within the oropharynx include the lingual tonsils, situated at the base of the tongue. These, along with the palatine tonsils and other lymphoid tissues such as the pharyngeal tonsils (adenoids) in the nasopharynx, form Waldeyer's ring—a collective barrier that provides the first line of defense against airborne or ingested pathogens. Posteriorly, the oropharynx is bounded by the pharyngeal wall, which comprises multiple layers including mucosa, submucosa, pharyngeal musculature, and the pharyngobasilar fascia. The pharyngeal muscles, particularly the superior, middle, and inferior constrictors, function in a coordinated manner to facilitate the propulsion of the food bolus towards the esophagus during swallowing.

Beyond its role in digestion and immunity, the oropharynx is integral to respiration. During breathing, air flows through this region en route to the larynx and lower airways. The maintenance of an open oropharyngeal airway depends on the coordinated activity of several muscles, including those of the tongue and soft palate, which prevent airway collapse and obstruction. The oropharynx receives an extensive blood supply from branches of the external carotid artery, including the ascending pharyngeal artery, the tonsillar branch of the facial artery, and the lingual artery. Venous drainage occurs via the pharyngeal venous plexus, which empties into the internal jugular vein. Lymphatic drainage is primarily directed towards the deep cervical lymph nodes, which play a key role in immune surveillance and pathogen clearance.[42]

Laryngopharynx (Hypopharynx)

The laryngopharynx, also known as the hypopharynx, is the inferior segment of the pharynx. It extends from the hyoid bone to the lower border of the cricoid cartilage, where it continues as the esophagus. This anatomical region serves as a critical junction for the passage of both air and food, ensuring that air is directed to the larynx and trachea while food and liquids are guided into the esophagus. The laryngopharynx plays a vital role in the digestive and respiratory systems, and its structure is intricately designed to perform these functions efficiently.

Anatomical Boundaries

Superior Boundary: The laryngopharynx starts at the level of the hyoid bone, where it transitions from the oropharynx.

Inferior Boundary: It extends downward to the lower edge of the cricoid cartilage, where it merges with the esophagus.

Anterior Boundary: At the front, the laryngopharynx connects to the laryngeal inlet, leading into the larynx. The epiglottis, an important structure in this region, prevents food and liquids from entering the airway during swallowing.

Posterior Boundary: The back wall is supported by the prevertebral fascia and the muscles of the vertebral column.

Lateral Boundaries: The sides of the laryngopharynx consist of the pharyngeal constrictor muscles and lie adjacent to the thyroid cartilage.[43]

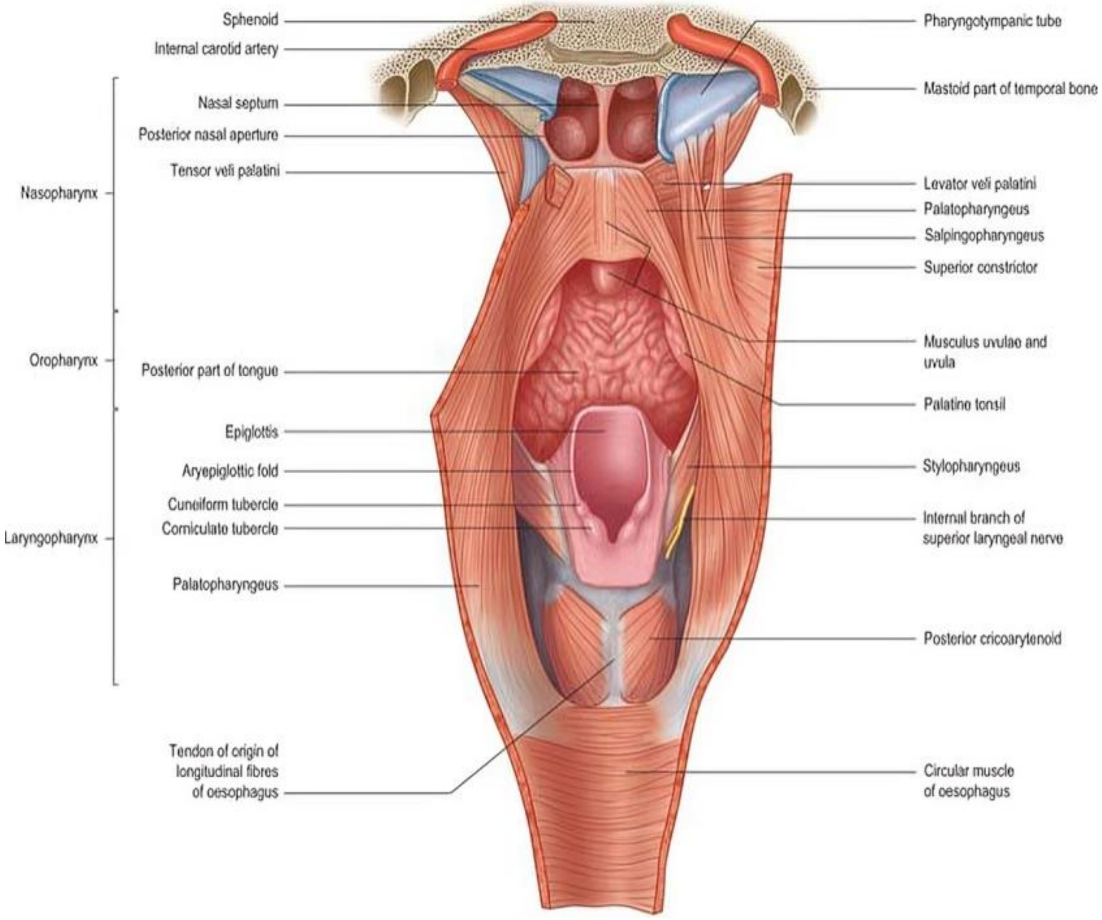


FIG 2: POSTERIOR OPENED VIEW OF PHARYNX

Lining and Mucosa

The laryngopharynx is lined with stratified squamous epithelium, which provides resistance to mechanical stress and abrasion from ingested materials. This epithelial layer also offers protection against pathogens and physical damage. The muscular structure of the laryngopharynx includes the inferior pharyngeal constrictor muscle, essential for swallowing. This muscle comprises two parts: (a) the thyropharyngeal part, originating from the oblique line of the thyroid cartilage and the lateral surface of the cricothyroid muscle; and (b) the cricopharyngeal part, arising from the lateral surface of the cricoid cartilage. The latter forms the cricopharyngeal muscle or upper esophageal sphincter (UES), crucial for preventing air entry into the esophagus during breathing and reflux of esophageal contents. During swallowing, these muscles contract sequentially to propel the food bolus into the esophagus while safeguarding the airway.[44]

Muscles Of Pharynx

The pharyngeal wall muscles consist of the superior, middle, and inferior constrictor muscles, with fibers running in a circular direction, and the stylopharyngeus and salpingopharyngeus muscles, with fibers running longitudinally. The three constrictor muscles encircle the pharyngeal wall, inserting into a fibrous raphe extending from the pharyngeal tubercle on the basilar part of the occipital bone to the esophagus. These muscles overlap, with the middle constrictor lying external to the lower part of the superior constrictor, and the inferior constrictor external to the lower part of the middle constrictor.

The lower portion of the inferior constrictor, originating from the cricoid cartilage, is called the cricopharyngeus muscle. Its fibers pass horizontally around the narrowest part of the pharynx, acting as a sphincter. Killian’s dehiscence refers to the area on the posterior pharyngeal wall between the upper propulsive part of the inferior constrictor and the lower sphincteric part of the cricopharyngeus.[45]

TABLE 1: MUSCLES OF PHARYNX

Muscle	Origin	Insertion	Nerve Supply	Action
Superior constrictor	Medial pterygoid plate, pterygoid hamulus, pterygomandibular ligament, mylohyoid line of mandible	Pharyngeal tubercle of occipital bone, raphe midline posteriorly	Pharyngeal plexus	Aids soft palate in closing off nasal pharynx, propels bolus downward
Middle constrictor	Lower part of stylohyoid ligament, lesser and greater cornu of hyoid bone	Pharyngeal raphe	Pharyngeal plexus	Propels bolus downward
Inferior constrictor	Lamina of thyroid cartilage, cricoid cartilage	Pharyngeal raphe	Pharyngeal plexus	Propels bolus downward
Cricopharyngeus	Lowest fibers of inferior constrictor muscle	Pharyngeal raphe	Pharyngeal plexus	Sphincter at lower end of pharynx
Stylopharyngeus	Styloid process of temporal bone	Posterior border of thyroid cartilage	Glossopharyngeal nerve	Elevates larynx during swallowing
Salpingopharyngeus	Auditory tube	Blends with palatopharyngeus	Pharyngeal plexus	Elevates pharynx
Palatopharyngeus	Palatine aponeurosis	Posterior border of thyroid cartilage	Pharyngeal plexus	Elevates wall of pharynx, pulls palatopharyngeal arch medially

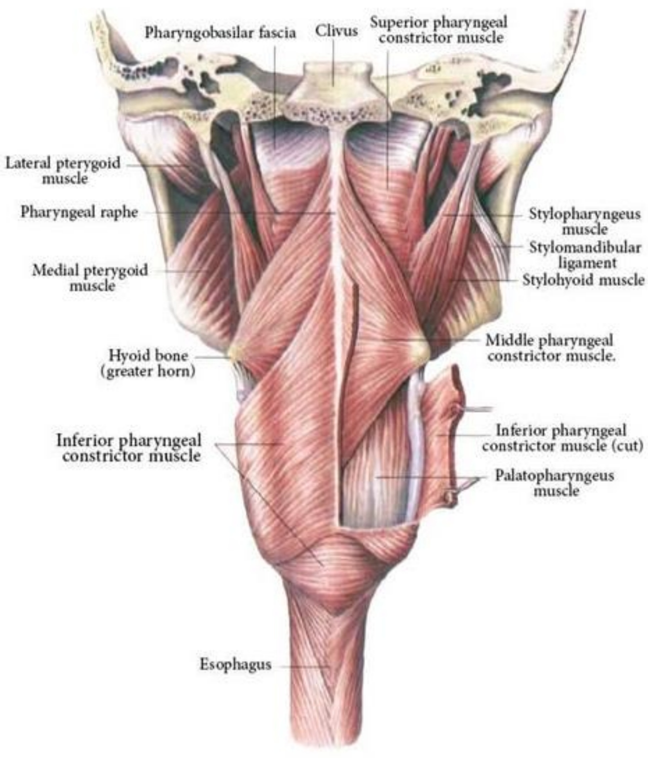


FIG 3: MUSCLES OF PHARYNX

Epiglottis

The epiglottis is a leaf-shaped flap of elastic cartilage located at the root of the tongue, anterior to the laryngeal inlet. It serves as a critical structure within the laryngopharynx, functioning as a switch between the trachea and the esophagus to direct food and air appropriately. During swallowing, the larynx elevates, and the epiglottis folds back to cover the glottis, preventing food and liquids from entering the airway. This protective reflex is vital for preventing aspiration and ensuring that swallowed substances are directed into the esophagus.

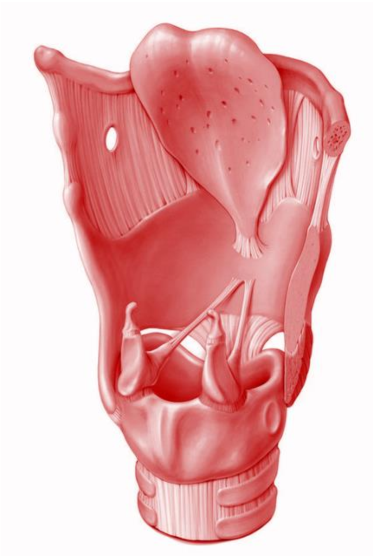


FIG 4: EPIGLOTTIS

Recesses

The piriform recesses (or fossae) are paired, anatomically distinct depressions positioned lateral to the laryngeal inlet. They are bordered medially by the aryepiglottic folds and laterally by the thyroid cartilage. The mucosal lining consists of non-keratinized stratified squamous epithelium. These recesses function as essential conduits that channel ingested material around the laryngeal orifice, ensuring that food and liquids are efficiently directed into the esophagus while bypassing the airway. Clinically, the piriform recesses are of particular interest because they are common sites for the impaction of foreign bodies, residual food particles, or secretions, which can precipitate dysphagia or aspiration..[46]

Innervation and Blood Supply

Sensory Nerve Supply of the Pharyngeal Mucous Membrane

- Nasal pharynx: The maxillary nerve (V2)
- Oral pharynx: The glossopharyngeal nerve
- Laryngeal pharynx (around the entrance into the larynx): The internal laryngeal branch of the vagus nerve

Blood Supply of the Pharynx

- Ascending pharyngeal, tonsillar branches of facial arteries, and branches of maxillary and lingual arteries

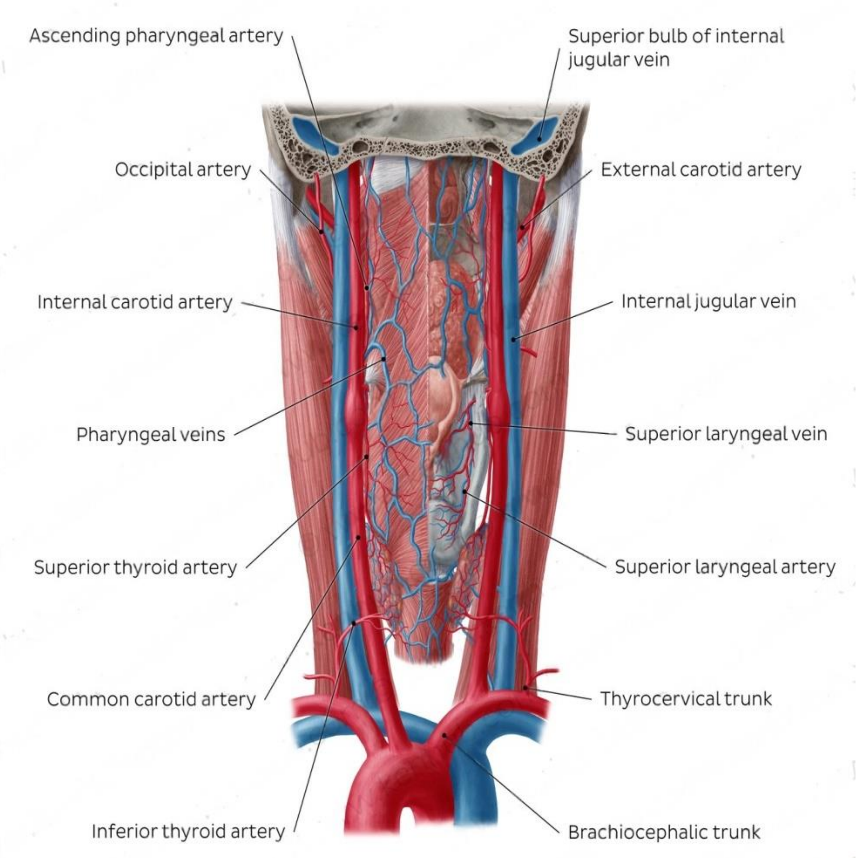


FIG 5: BLOOD SUPPLY OF PHARYNX

Laxynx

The larynx, also known as the voice box, is located in the anterior neck at the level of the C3-C6 vertebrae. It connects the pharynx to the trachea and performs several critical functions, including airway protection, phonation, respiration, and sphincteric function. This complex structure is composed of several cartilages, muscles, and ligaments, each contributing to its functionality.

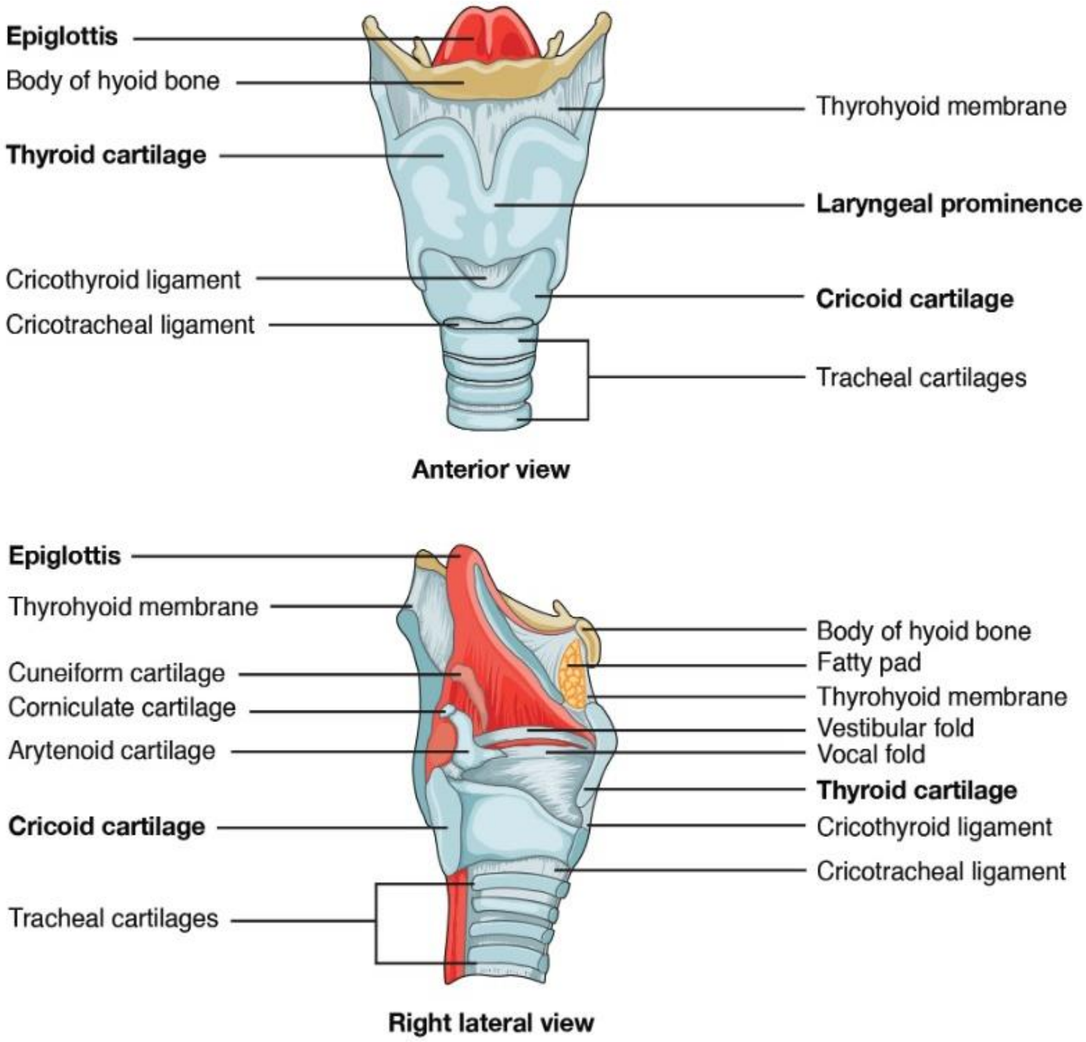


FIG 6: ANATOMY OF LARYNX

Functions of the Larynx

Airway Protection

The primary function of the larynx is to prevent aspiration of food and liquids into the lower respiratory tract. The epiglottis, a leaf-shaped flap of cartilage, plays a vital role in this protective function by covering the glottis during swallowing. This mechanism ensures that ingested materials are directed towards the esophagus rather than the trachea.

Phonation

The larynx houses the vocal cords (vocal folds), which are essential for sound production. The vibration of the vocal cords, modulated by the intrinsic laryngeal muscles, produces voice. The tension and length of the vocal cords can be adjusted to change the pitch and volume of the sound produced.

Respiration

The larynx allows the passage of air into the trachea and lungs. The glottis, the opening between the vocal cords, regulates airflow during breathing. The intrinsic muscles of the larynx adjust the size of the glottis to control the flow of air, facilitating both quiet breathing and forced respiration.

Sphincteric Function

The laryngeal muscles close the glottis during activities such as coughing, sneezing, and the Valsalva maneuver, which increases intra-abdominal pressure. This closure is essential for protecting the lower airways and for functions that require a build-up of thoracic pressure.

Anatomical Components of the Larynx

Cartilages

- **Thyroid Cartilage**: The largest laryngeal cartilage, known for its prominent anterior projection (Adam's apple). It consists of two laminae that meet in the midline anteriorly and form the laryngeal prominence.
- **Cricoid Cartilage**: The only complete ring of cartilage in the respiratory tract, providing structural support. It lies below the thyroid cartilage and above the trachea.
- **Arytenoid Cartilages**: Paired cartilages that sit on the superior border of the cricoid cartilage. They anchor the vocal cords and are pivotal in vocal cord movement.
- **Epiglottis**: A leaf-shaped cartilage that projects upwards behind the tongue and the hyoid bone. Its primary function is to cover the glottis during swallowing, preventing food from entering the larynx.

Muscles

Intrinsic Muscles

These muscles control the tension and position of the vocal cords and include:

- **Thyroarytenoid Muscles**: Adjust tension and length of the vocal cords.
- **Cricothyroid Muscles**: Tense the vocal cords by tilting the thyroid cartilage forward.
- **Posterior Cricoarytenoid Muscles**: Abduct (open) the vocal cords.
- **Lateral Cricoarytenoid Muscles**: Adduct (close) the vocal cords.
- **Transverse and Oblique Arytenoid Muscles**: Close the posterior part of the glottis.

Extrinsic Muscles

These muscles connect the larynx to surrounding structures and assist in its movement. They include:

- **Sternothyroid Muscles**: Depress the larynx.
- **Thyrohyoid Muscles**: Elevate the larynx.
- **Inferior Constrictor Muscles of the Pharynx**: Assist in swallowing.

Ligaments and Membranes

- **Thyrohyoid Membrane**: Connects the thyroid cartilage to the hyoid bone.
- **Cricotracheal Ligament**: Connects the cricoid cartilage to the first tracheal ring.
- **Hyoepiglottic Ligament**: Connects the epiglottis to the hyoid bone.
- **Quadrangular Membrane**: Forms the framework of the aryepiglottic folds and the vestibular folds (false vocal cords).
- **Cricovocal Ligament (Conus Elasticus)**: Forms the vocal ligaments (true vocal cords) and extends from the cricoid cartilage to the vocal processes of the arytenoids.

Vascular and Neural Supply

- **Blood Supply**: The larynx receives blood from the superior and inferior thyroid arteries. The superior thyroid artery arises from the external carotid artery, while the inferior thyroid artery originates from the thyrocervical trunk.
- **Venous Drainage**: The venous blood is drained via the superior and inferior thyroid veins, which empty into the internal jugular vein and the brachiocephalic veins, respectively.

- **Lymphatic Drainage**: Lymphatic vessels drain into the deep cervical lymph nodes. The vocal cords lack lymphatic drainage, acting as a barrier between the supraglottic and infraglottic regions.
- **Nerve Supply**: The larynx is innervated by branches of the vagus nerve:
  - **Superior Laryngeal Nerve**: Divides into the internal laryngeal nerve (sensory to the mucosa above the vocal cords) and the external laryngeal nerve (motor to the cricothyroid muscle).
  - **Recurrent Laryngeal Nerve**: Provides motor innervation to all intrinsic muscles of the larynx except the cricothyroid muscle, and sensory innervation below the vocal cords.

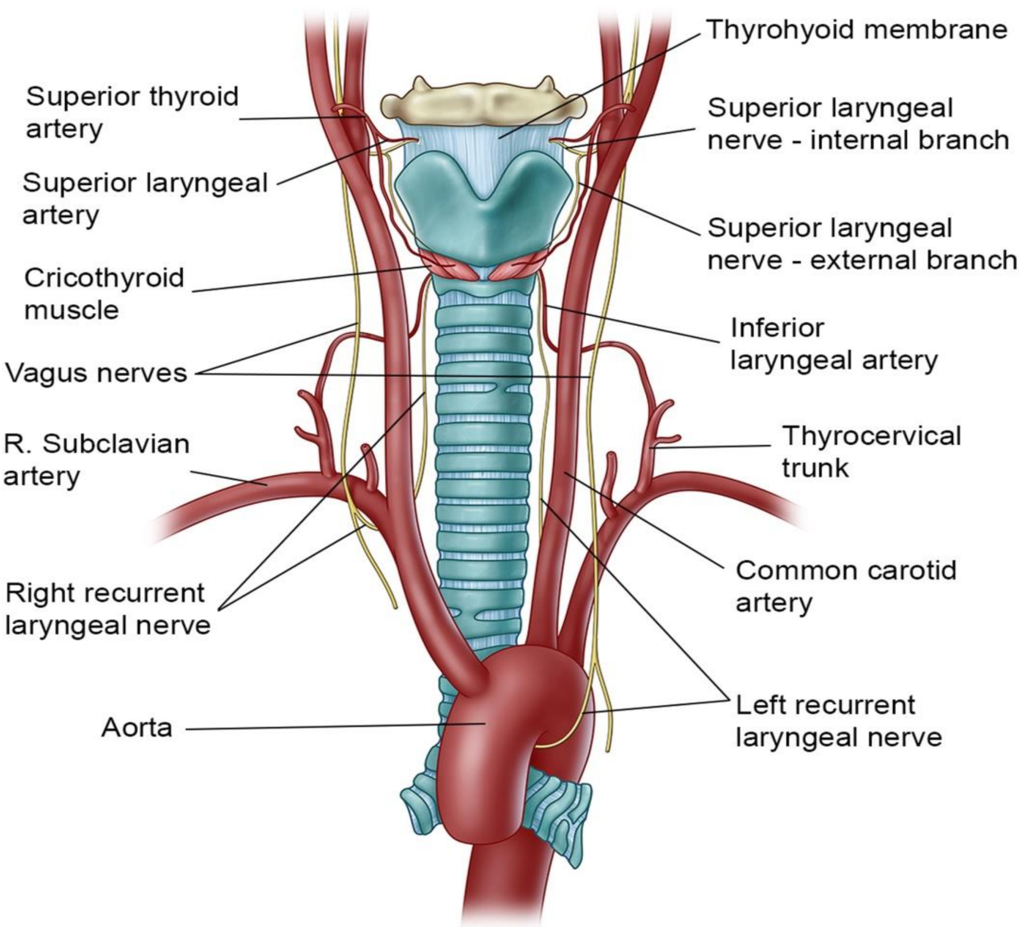


FIG 7: BLOOD SYPPLY OF LARYNX

Trachea

The trachea, commonly known as the windpipe, is a crucial component of the respiratory system. It is a tubular structure that extends from the larynx to the primary bronchi, playing a vital role in conducting air to the lungs. The trachea begins at the level of the sixth cervical vertebra and descends to the level of the fifth thoracic vertebra, where it bifurcates into the right and left main bronchi.

Structure

The trachea is approximately 10-12 cm in length and about 2 cm in diameter. It is composed of a series of 16-20 C-shaped cartilaginous rings that provide structural support and maintain airway patency. These rings are made of hyaline cartilage and are open posteriorly, allowing for flexibility and the passage of the esophagus behind it.

- Cartilaginous Rings: These rings are crucial for maintaining the shape and rigidity of the trachea, preventing collapse during inhalation. The open ends of the rings are connected by the trachealis muscle and fibroelastic tissue.
- Trachealis Muscle: The posterior part of the trachea is not supported by cartilage but by a membranous wall consisting of the trachealis muscle. This smooth muscle allows for flexibility and expansion of the trachea during swallowing and contributes to the regulation of airway diameter.
- Mucosal Lining: The inner lining of the trachea is composed of ciliated pseudostratified columnar epithelium. Interspersed among the epithelial cells are goblet cells that secrete mucus. This mucus traps dust, bacteria, and other foreign particles.[48]

Function

The trachea performs several critical functions in the respiratory system:

- Air Conduction: The primary function of the trachea is to conduct air from the larynx to the bronchi and subsequently to the lungs. This pathway is essential for efficient gas exchange.
- Structural Support: The C-shaped cartilaginous rings play a vital role in preventing the trachea from collapsing during the negative pressure phase of inhalation. This structural integrity is crucial for maintaining an open airway.
- Mucociliary Clearance: The mucosal lining of the trachea, with its ciliated epithelium and goblet cells, plays a significant role in trapping and expelling foreign particles. The coordinated movement of cilia propels mucus, along with trapped particles, upwards towards the pharynx, where it can be swallowed or expectorated.

Physiological Mechanisms

The trachea is involved in several physiological mechanisms that ensure the proper functioning of the respiratory system:

- Ciliary Action: The cilia in the tracheal lining beat in a coordinated manner, creating a mucus current that moves trapped particles upward toward the pharynx. This ciliary movement is essential for clearing the airway of debris and pathogens, thereby protecting the lower respiratory tract from infections and blockages.
- Trachealis Muscle Function: The trachealis muscle plays a crucial role in adjusting the diameter of the trachea. During quiet breathing, the muscle

remains relaxed, allowing the trachea to maintain its standard diameter. However, during activities such as coughing or sneezing, the trachealis muscle contracts, narrowing the tracheal lumen and increasing the velocity of expelled air. This mechanism facilitates the expulsion of irritants and foreign particles from the respiratory tract.

- Regulation of Airflow: The ability of the trachea to expand and contract helps in regulating airflow to the lungs. The flexibility provided by the trachealis muscle and the elasticity of the fibroelastic tissue ensures that the trachea can accommodate varying volumes of air during different phases of respiration.[49]

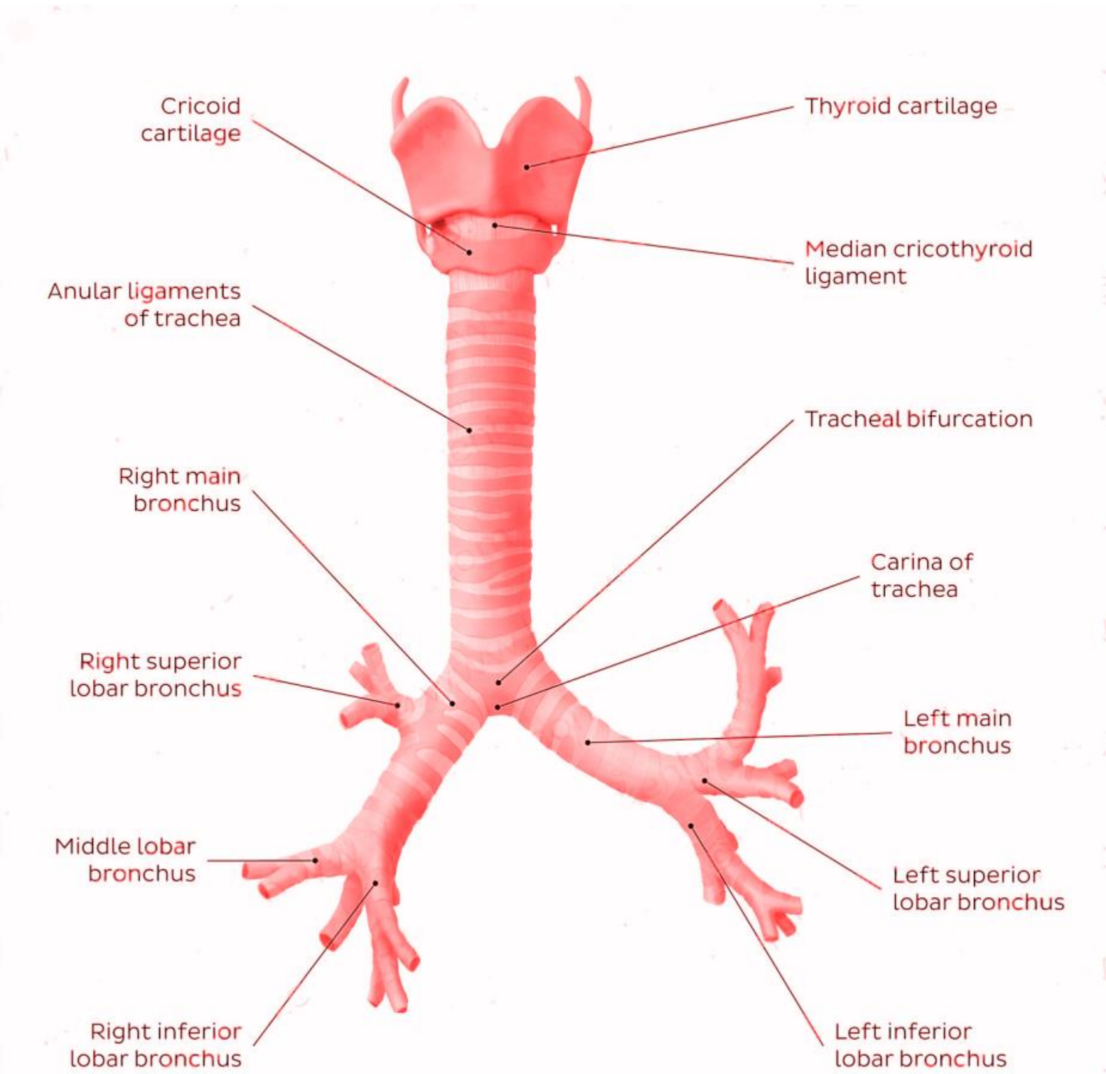


FIG 8: ANATOMY OF TRACHEA AND BRONCHI

<u>Structure of Intubating LMA (ILMA FASTRACH)</u>

The ILMA Fastrach is meticulously designed to address the limitations of classic laryngeal mask airways (LMAs) by incorporating features that facilitate intubation. Its key structural components include:

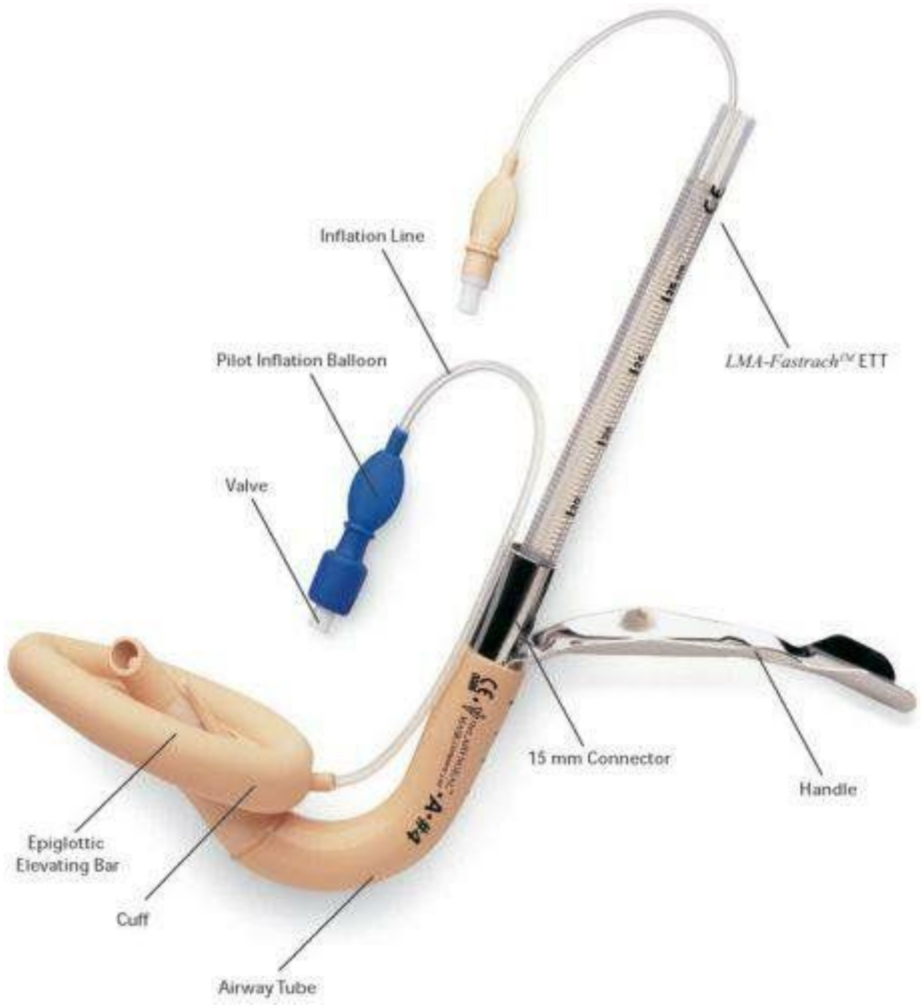


FIG 9: INTUBATING LMA

1. **Airway Tube:** The airway tube is a rigid, curved, and anatomically shaped shaft that mirrors the upper airway's natural curvature. Unlike the classic LMA, the rigid design allows better control and stability during insertion and intubation. The tube has a wide internal diameter (15 mm) to accommodate endotracheal tubes (ETTs) up to 8.0 mm in size.

2. **Mask Assembly (Cuff):** The mask consists of a silicone inflatable cuff designed to form a low-pressure seal around the laryngeal inlet. The mask's posterior aspect is reinforced with a rigid backplate that prevents airway obstruction due to epiglottic downfolding.

3. **Epiglottic Elevating Bar (Epiglottic Aperture Bar):** A crucial innovation, the epiglottic elevating bar is positioned at the distal end of the mask. It lifts the epiglottis during tube advancement, reducing the risk of airway obstruction.

4. **Handle:** A stainless steel handle is attached to the proximal end of the airway tube. The handle aids in controlling the device's insertion angle and facilitates alignment with the glottis opening, crucial for blind intubation. The handle also allows for single-handed operation, freeing the other hand to manage ventilation or stabilize the patient's head.

Mechanism of Insertion

Preparation begins with a thorough inspection of the device for structural integrity, ensuring the cuff is intact and free from leaks. A water-based lubricant is applied to the posterior surface of the cuff to facilitate smooth insertion and minimize mucosal trauma. The patient is positioned supine with the head in a neutral or slight "sniffing" position, optimizing the oropharyngeal axis for easier insertion. In cases where cervical spine movement is restricted or contraindicated, a neutral position is maintained to prevent exacerbation of spinal injuries. Adequate pre-oxygenation is administered to maintain oxygen saturation during the procedure, and anesthesia is typically induced using intravenous agents. Muscle relaxants may be employed to suppress airway reflexes and facilitate smoother insertion, with the choice of agents depending on the patient's medical history and the clinical scenario.

During insertion, the clinician holds the ILMA Fastrach by its rigid handle, positioning the mask aperture anteriorly. With the patient's mouth gently opened, the deflated mask is introduced into the oral cavity, following the natural curvature of the oropharynx. A single, smooth motion advances the device until resistance is felt, indicating proper seating over the laryngeal inlet. Care is taken to avoid folding or twisting of the cuff during this maneuver. Once positioned, the cuff is inflated with the recommended volume of air (usually 20–30 mL) to create a seal around the glottis, avoiding overinflation to prevent excessive pressure on surrounding tissues. The effectiveness of ventilation is assessed by observing bilateral chest rise, auscultating breath sounds over both lung fields, and utilizing capnography to monitor end-tidal CO_2 levels, providing real-time confirmation of airway patency and effective ventilation. For intubation, an appropriately sized, lubricated endotracheal tube (ETT) is inserted through the ILMA Fastrach. The device's guiding ramp and epiglottic elevating bar function synergistically to direct the tube tip toward the glottic opening, facilitating successful intubation. This can be performed blindly or under fiberoptic guidance, depending on the clinician's preference and the clinical scenario. After advancing the ETT, correct placement within the trachea is confirmed by auscultation of bilateral breath sounds, observation of chest movement, and verification of appropriate capnographic waveforms. Once tracheal intubation is confirmed, the ILMA Fastrach is prepared for removal. A stabilizing rod or "stabilizer" is inserted alongside the ETT to maintain its position during device withdrawal, preventing accidental extubation or displacement. With the stabilizer securing the ETT, the cuff of the ILMA Fastrach is deflated, and the device is gently withdrawn from the patient's mouth. Continuous monitoring of the ETT's position is essential during this process to ensure it remains correctly placed within the trachea. After removal, the ETT is secured in place, and ventilation is reassessed to confirm ongoing effective airway management, with continuous monitoring and appropriate ventilatory support maintained as per standard clinical protocols.

Structure of LMA Protector

1. **Airway Tube:**

The LMA Protector features dual reinforced airway tubes made from medical-grade silicone, ensuring flexibility without kinking. The dual-lumen design allows for simultaneous airway ventilation and gastric access, reducing the risk of regurgitation and aspiration. The tube ends in a 15 mm universal connector, compatible with standard breathing circuits and ventilators.

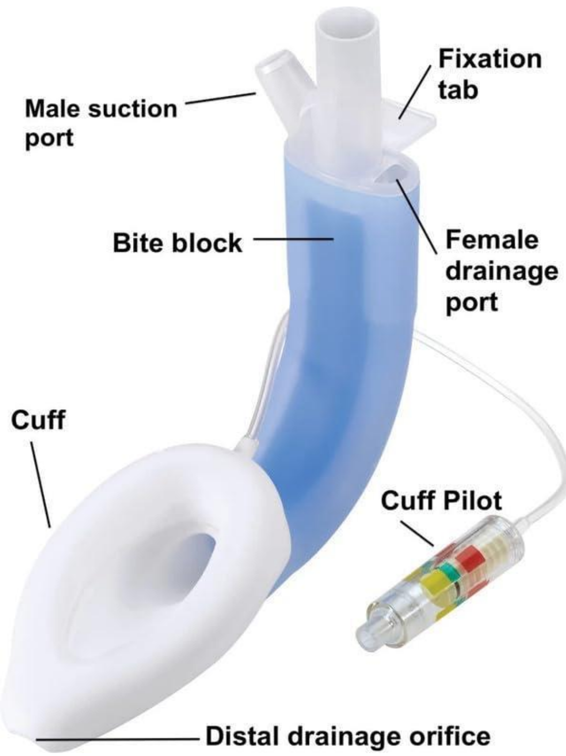


FIG 10: LMA PROTECTOR

2. Cuff and Mask Assembly:

The mask consists of an anatomically curved, silicone cuff designed to form an effective seal around the periglottic tissues with minimal mucosal trauma. The cuff's shape is intended to create a high seal pressure (>30 cmH_2O) without causing significant airway resistance or tissue damage. Pharyngeal and esophageal drainage ports within the mask help divert gastric contents away from the airway, enhancing patient safety.

3. Integrated Gastric Access Channel:

A major innovation is the gastrointestinal (GI) access channel that permits the passage of a nasogastric tube (up to 18 Fr) for active suctioning of gastric contents.This feature helps mitigate aspiration risks, a crucial advantage over earlier LMAs.

4. Cuff Pressure Indicator:

The LMA Protector includes an integrated cuff pressure indicator for real-time monitoring of intracuff pressure.This design helps prevent overinflation, reducing the risk of mucosal ischemia — an area of growing interest in airway research.

5. Endoscopic Compatibility:

The LMA Protector is optimized for fiberoptic-guided intubation and endoscopic airway management.The airway tube's wider internal diameter allows smooth passage of endotracheal tubes (ETT) up to 7.5 mm, enabling a seamless transition to a definitive airway.

Mechanism of Insertion of LMA Protector

Prior to insertion, the device undergoes a thorough inspection to ensure structural integrity, with the cuff fully deflated to facilitate smooth placement. A water-based lubricant is applied to the posterior surface of the mask and airway tube to reduce mucosal trauma during insertion. The patient is pre-oxygenated to maintain adequate oxygen saturation, and anesthesia is typically induced to suppress airway reflexes and promote patient comfort.

For insertion, the patient's head is positioned in a neutral or slight "sniffing" position to align the oropharyngeal axis, facilitating easier insertion. The LMA Protector is inserted using a midline approach, with the deflated mask's tip pressed against the hard palate and advanced along the natural curve of the airway until resistance is felt at the upper esophageal sphincter, indicating proper placement. Once positioned, the cuff is inflated with the recommended air volume (typically 20–30 mL) to create a seal around the laryngeal inlet. The integrated cuff pressure indicator allows real-time adjustments to maintain optimal seal pressures, minimizing both air leaks and mucosal compression. After cuff inflation, the airway tube permits immediate ventilation using a self-inflating bag or mechanical ventilator. The LMA Protector's dual-lumen design includes a gastrointestinal access channel, allowing for the placement of a nasogastric tube to actively suction stomach contents, thereby reducing the risk of aspiration. Additionally, the LMA Protector supports fiberoptic-guided intubation, with epiglottic aperture bars maintaining airway patency during endotracheal tube (ETT) passage.

MATERIALS AND METHODS

Materials and Methods

The present study is titled **" COMPARISON OF LARYNGEAL MASK AIRWAY PROTECTOR AND INTUBATING LARYNGEAL MASK AIRWAY FOR EASE OF FIBEROPTIC GUIDED TRACHEAL INTUBATION IN ADULT PATIENTS- A ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL"**

Source of Data

"The study involved patients aged 20 years to 60 years of either gender, belonging to ASA grades I, II, and III, who underwent elective surgery under general anaesthesia at KLE's Dr Prabhakar Kore Charitable Hospital and Medical Research Centre, Nehru Nagar, Belagavi."

Study Design

"Randomised Clinical Trial."

Study Period

"The study was conducted over a period of one year."

Sample Size

"Sample size formula: Sample size formula for a two-proportion z-test:

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 (p_1 q_1 + p_2 q_2)}{(p_1 - p_2)^2}$$

$Z_{1-\alpha/2}$: Z-score corresponding to the desired confidence level.

$Z_{1-\beta}$: Z-score corresponding to the desired power of the test.

p_1 and p_2 : Expected proportions in the two groups.

$q_1 = 1 - p_1$ and $q_2 = 1 - p_2$."

Total sample size was obtained after taking the exposure of the glottis with respect to the glottic aperture of the LMA as the parameter for the study with reference to "Metterlein T, Dintenfelder A, Plank C, Graf B, Roth G. A comparison of various supraglottic airway devices for fiberoptical guided tracheal intubation. *Braz J Anesthesiol*. 2017;67(2):166-171. doi:10.1016/j.bjane.2015.09.007"

"Here,

p_1= 97%

p_2= 72.8%

$Z_{1-\alpha/2}$= 1.96

$Z_{1-\beta}$= 0.85

The sample size obtained after substituting the above values is 34 in each group, giving a total sample size of 68."

Randomisation Technique

" Computer generated randomised table."

Inclusion Criteria

- ASA status I, II, III
- Patients between 20-60 years
- Patients undergoing elective surgery under general anaesthesia
- Patients willing to give consent.

Exclusion Criteria

- Patients undergoing emergency surgeries.
- Patients not willing to give consent.
- Patients with pharyngeal pathology.
- Patients having anatomical deformity of mouth, pharynx and larynx.
- Patients with high risk for aspiration.
- Patients with high airway resistance (severe obesity).
- Pregnant patients.

Study Protocol

"A one year hospital-based randomised clinical trial was followed."

Data Collection Procedure

"Data collection commenced after the approval of the synopsis by institutional ethics committee and obtainng CTRI. After meeting the inclusion and exclusion criteria and obtaining informed consent, patients will be randomly assigned to two groups, Group I and Group P, using a computer-generated randomization table. Intubating LMA was used for patients in Group I and LMA protector was used for patients in Group P.

Informed written consent was obtained from patients during pre-anesthetic check-ups, and routine investigations were conducted one day prior to surgery. The study participants were kept NPO for 8 hours prior to the surgery.

After the patients were shifted to the preoperative area on the day of surgery, the NPO status of the patients was confirmed. A wide bore peripheral IV cannula was secured and Ringer's lactate was started as maintenance fluid.

After shifting the patients into the operating room, standard monitors- Spo_2, NIBP and ECG were connected and baseline measurements were taken. It was ensured that two sizes of the LMA, size 3 and size 4, allotted to the patient and a flexible fibrescope were available and kept ready in the operating room.

Patients were pre-oxygenated with 100% O_2 for 3 minutes and were premedicated with Glycopyrrolate 0.005mg/kg, Midazolam 0.05mg/kg and Fentanyl 2mcg/kg. Propofol 2mg/kg was used for induction of general anaesthesia. After confirming the ability to ventilate with bag-mask by looking for bilateral chest rise and capnography reading, Atracurium 0.5mg/kg was used for neuromuscular blockade. Patients were then ventilated manually by bag-mask for 3 mins.

For patients in Group I, Intubating LMA was inserted and for patients in Group P, LMA Protector was inserted. Both the LMAs were inserted using the manufacturer's guidelines.The cuff of the LMA was then inflated and air entry confirmed using bilateral chest rise and square-wave in capnography. Absence of an audible leak was confirmed.

Time taken for LMA insertion was noted (measured from the time of insertion of LMA into the oral cavity till the appearance of capnography trace). The resistance to LMA insertion was graded by the examiner using a subjective score (1: mild resistance, 2: moderate resistance, 3: severe resistance, 4: failure). The number of attempts at LMA insertion was was also noted.

Insertion of LMA was considered failure on absence of end-tidal capnography trace or if bilateral air entry was absent. A maximum of two attempts at LMA insertion was performed. If both attempts at insertion failed, tracheal intubation was performed using direct laryngoscopy.

After confirming successful LMA placement, a flexible fibrescope loaded with a reinforced tracheal tube of 7.0 mm internal diameter was introduced into the lumen of the LMA. The fibrescope was advanced into the tracheal. The view of the glottic aperture was then graded using a scoring system developed by Brimacombe and Berry (vocal cords fully visible: 1; vocal cords partially visible or arytenoids cartilages visible: 2; epiglottis visible: 3; no laryngeal structures visible: 4).

The fibrescope was advanced till the carina was visualised and the endotracheal tube was passed into the trachea and the cuff was inflated. Position of the endotracheal tube was then confirmed by square-wave capnography trace and bilateral equal air entry on auscultation.

The time taken to view carina (measured from the time of insertion of fibrescope into the lumen of LMA till carina is visualised) and time taken for intubation (measured from the time of insertion of fibrescope into the lumen of LMA till the appearance of capnography trace) were noted. Number of attempts at intubation was also noted. Tracheal intubation was considered a failure if the procedure took more than 120 seconds or if the SpO_2 fell to 94%.

Two attempts at tracheal intubation were allowed. If the second attempt fails, LMA was removed and patient was intubated using direct laryngoscopy.

After successful intubation the cuff of the LMA was deflated and the LMA was removed with the help of a stabilising stylet."

RESULTS

The present study titled " COMPARISON OF LARYNGEAL MASK AIRWAY PROTECTOR AND INTUBATING LARYNGEAL MASK AIRWAY FOR EASE OF FIBEROPTIC GUIDED TRACHEAL INTUBATION IN ADULT PATIENTS- A ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL." the patients were ramdomised into two groups:

Group I : Intubating LMA group

Group P: LMA Protector group

Table 4.1. Age Distribution of Respondents by Group

Age (years)	Group I	Group P	Total
20 – 30	8	14	22
31 – 40	8	10	18
41 – 50	10	8	18
51 – 60	8	2	10
Total	**34**	**34**	**68**

Chi-square (χ^2) = 5.681, p = 0.128

Interpretation:

The age distribution between Group I and Group P was not statistically significant (p = 0.128). The majority of participants fell within the 20–30 and 31–40 age ranges in both groups. This indicates that age was relatively evenly distributed and unlikely to influence the observed airway management outcomes. Since age can affect airway anatomy and intubation success, confirming no significant difference allows for a clearer comparison of device performance

Graph 4.1. ***Bar Chart of Age Distribution by Group***

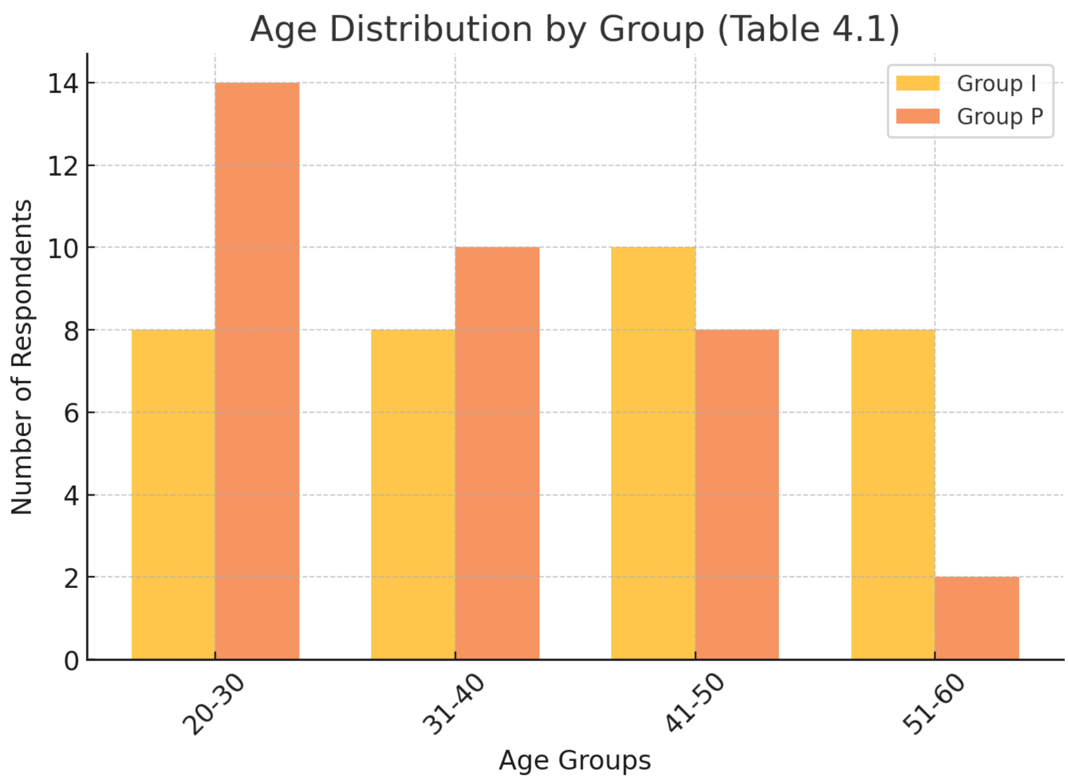


Table 4.2. Sex Distribution of Respondents by Group

Sex	Group I	Group P	Total
Female	22	13	35
Male	12	21	33
Total	**34**	**34**	**68**

Chi-square (χ^2) = 4.769, p = 0.029

Interpretation:

Group I had more females (22) compared to Group P (13), while Group P had more males (21) compared to Group I (12).

Graph 4.2. ***Bar Chart of Sex Distribution by Group***

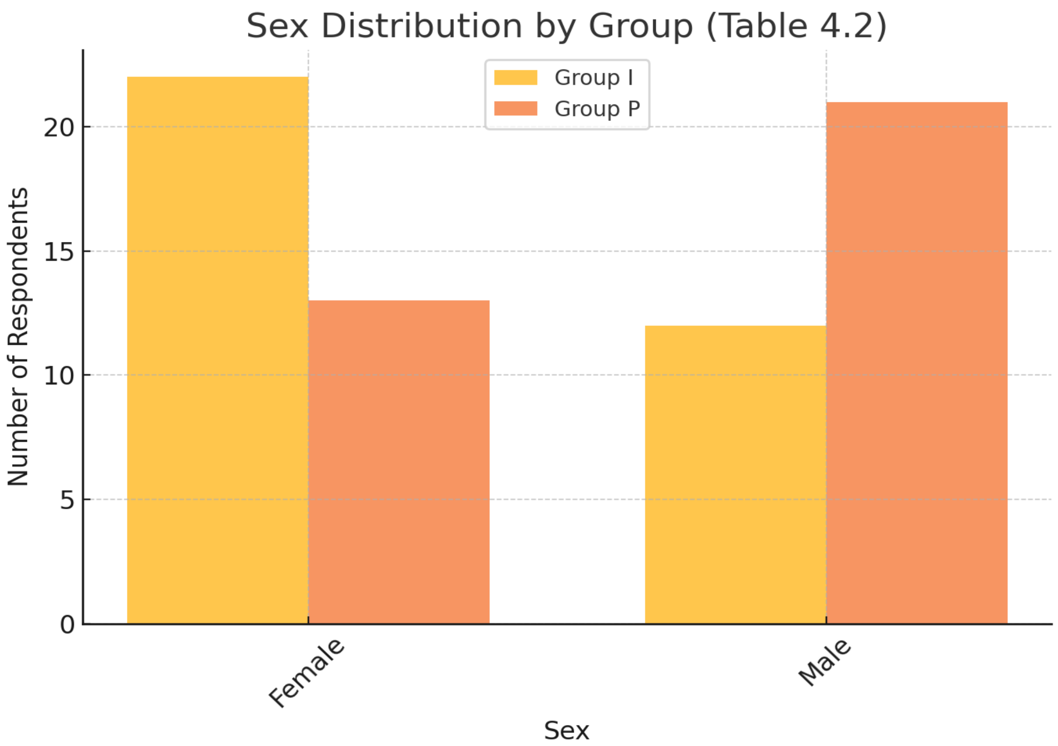


Table 4.3. Descriptive Statistics for Weight (kg) by Group

Group	N	Mean	Std. Deviation	p-value
I	34	60.82	6.137	0.050
P	34	65.06	7.463	

Interpretation:

Group P had a higher mean weight (65.06 kg) compared to Group I (60.82 kg), with a borderline significance (p = 0.050). Although weight can influence airway patency and the ease of SAD insertion, the small difference observed here is unlikely to have had a meaningful clinical impact.

Graph 4.3. ***Comparison of Mean Weight (kg) by Group***

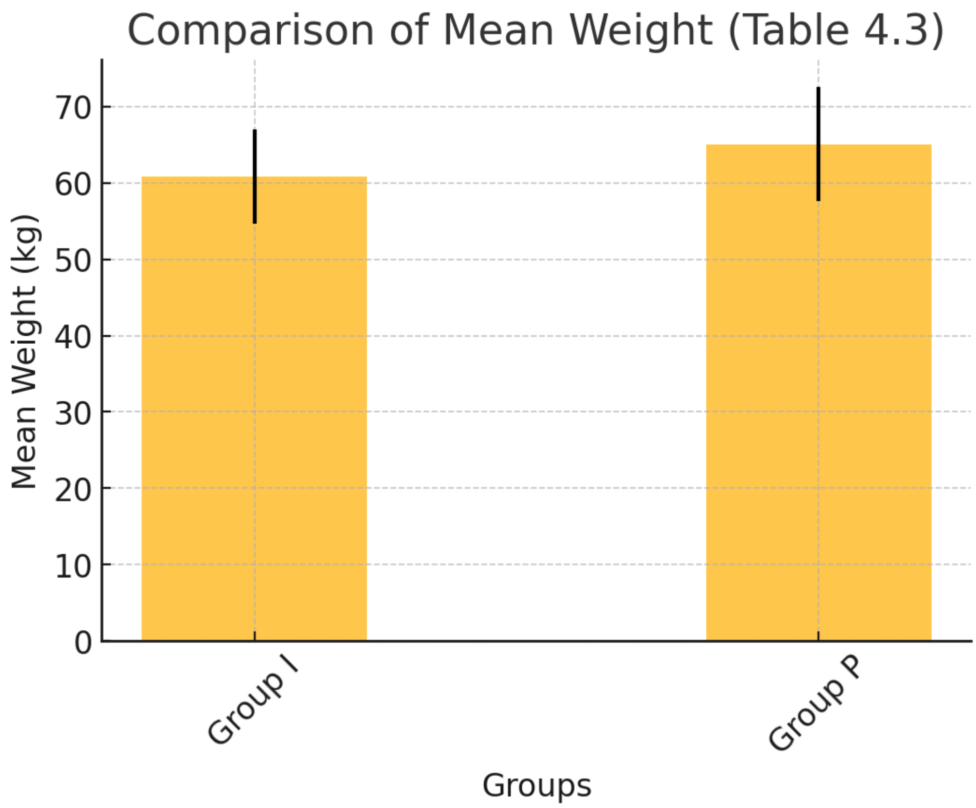


Table 4.4. ASA Grading of Respondents by Group

ASA Grade	Group I	Group P	Total
1	19	23	42
2	14	11	25
3	1	0	1
Total	**34**	**34**	**68**

Chi-square (χ^2) = 1.741, p = 0.419

Interpretation:

There was no significant difference in ASA grading between Group I and Group P (p = 0.419). Most participants were ASA Grade 1 or 2, with only one participant in Group I classified as Grade 3. This similarity in ASA grades ensures that baseline health status was comparable between groups, minimizing confounding effects and reinforcing that the observed airway outcomes were likely due to device performance rather than patient condition.

Graph 4.4. ***Bar Chart of ASA Grading by Group***

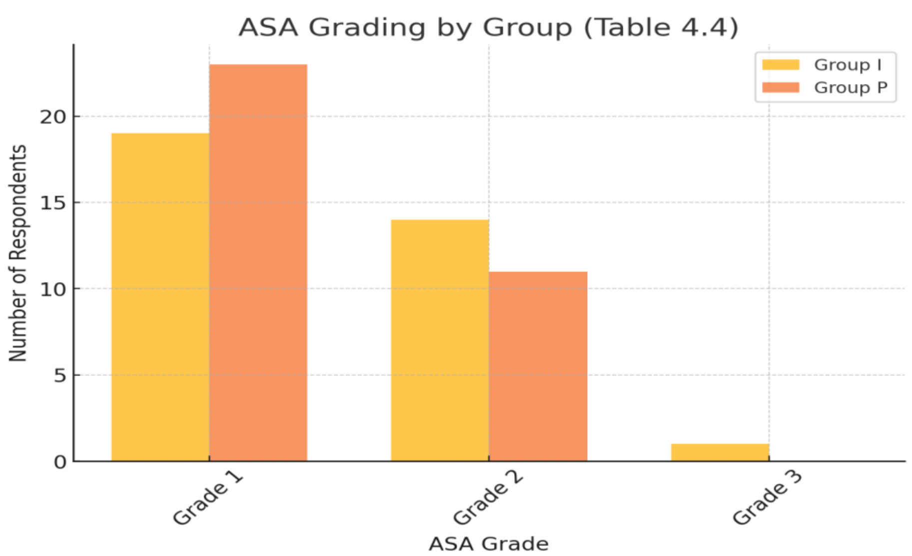


Table 4.5. LMA Size Distribution by Group

LMA Size	Group I	Group P	Total
3	27	22	49
4	7	12	19
Total	**34**	**34**	**68**

Chi-square (χ^2) = 1.826, p = 0.177

Interpretation:

LMA size 3 was the most frequently used size in both groups (Group I: 27/34, Group P: 22/34). The distribution difference was not statistically significant (p = 0.177). The similar use of LMA sizes further standardizes the comparison, allowing for a more direct evaluation of insertion times and success rates without the added variability of differently sized devices.

Graph 4.5. ***Bar Chart of LMA Size by Group***

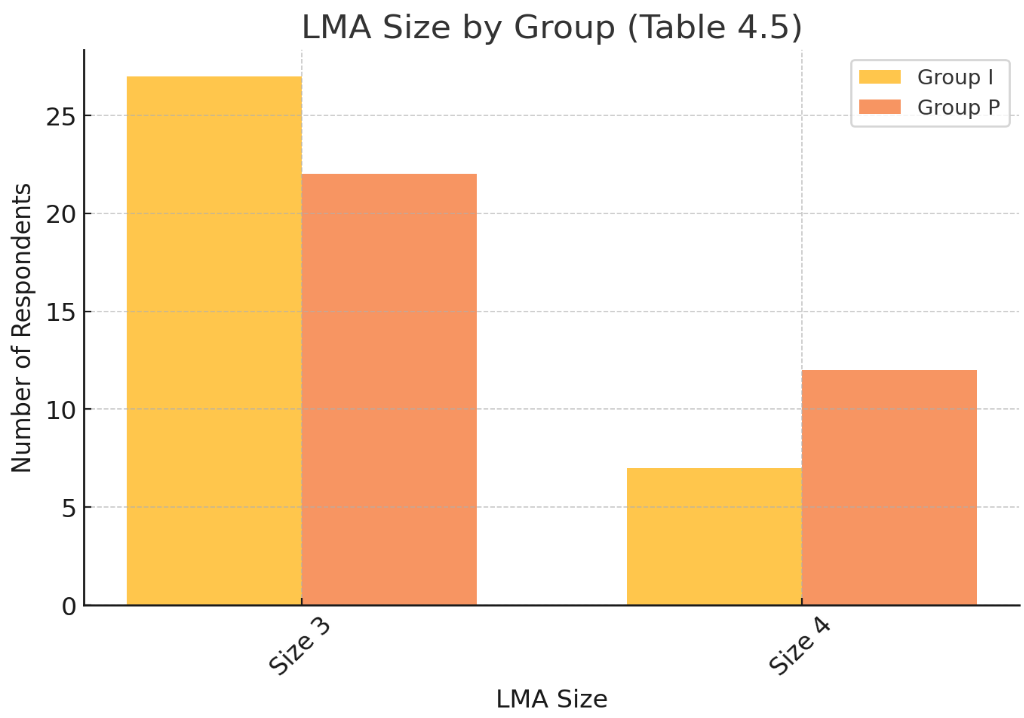


Table 4.6. Time Taken for LMA Insertion (seconds)

Group	N	Mean	Std. Deviation	p-value
I	34	27.362	2.7355	0.188
P	34	29.174	2.0255	

Interpretation:

The mean LMA insertion time was slightly longer in Group P (29.17 s) compared to Group I (27.36 s), but this difference was not statistically significant (p = 0.188). Clinically, this suggests both devices allowed for similarly efficient insertion processes. The slight delay observed in Group P may reflect minor differences in device design or user familiarity, but the lack of statistical significance means these differences are likely not impactful in practice.

Graph 4.6. ***Comparison of Time for LMA Insertion by Group***

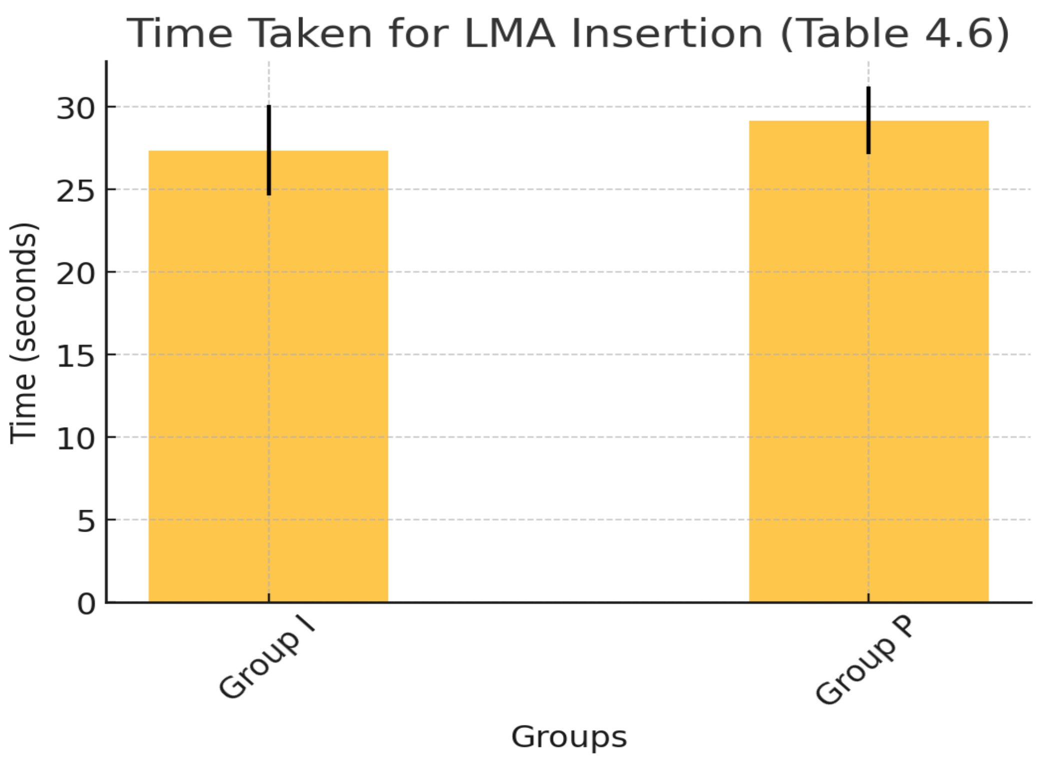


Table 4.7. Number of Attempts at LMA Insertion by Group

Number of Attempts	Group I	Group P	Total
1	31	30	61
2	3	4	7
Total	**34**	**34**	**68**

Chi-square (χ^2) = 0.159, p = 0.690

Interpretation:

Most participants achieved successful LMA insertion on the first attempt, with 31/34 in Group I and 30/34 in Group P succeeding on their initial try. The difference was not statistically significant (p = 0.690). This high first-attempt success rate highlights the user-friendliness and reliability of both devices. The small number of second attempts (3 in Group I and 4 in Group P) suggests that both devices perform consistently well.

Graph 4.7. ***Bar Chart of Number of LMA Insertion Attempts by Group***

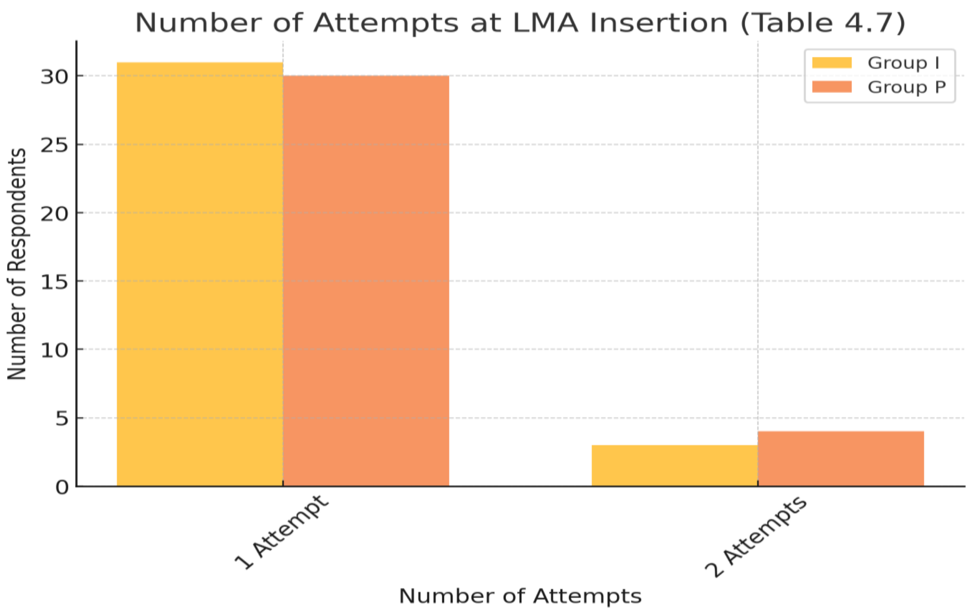


Table 4.8. Grade of Resistance During LMA Insertion by Group

Grade of Resistance	Group I	Group P	Total
1	20	17	37
2	12	14	26
3	2	3	5
Total	**34**	**34**	**68**

Chi-square (χ^2) = 0.597, p = 0.742

Interpretation:

Grade 1 resistance (minimal resistance) was most common in both groups (Group I: 20/34, Group P: 17/34), with no significant difference observed (p = 0.742). The similar resistance profiles imply that both devices provide comparable ease of insertion.

Graph 4.8. ***Bar Chart of Grade of Resistance During LMA Insertion***

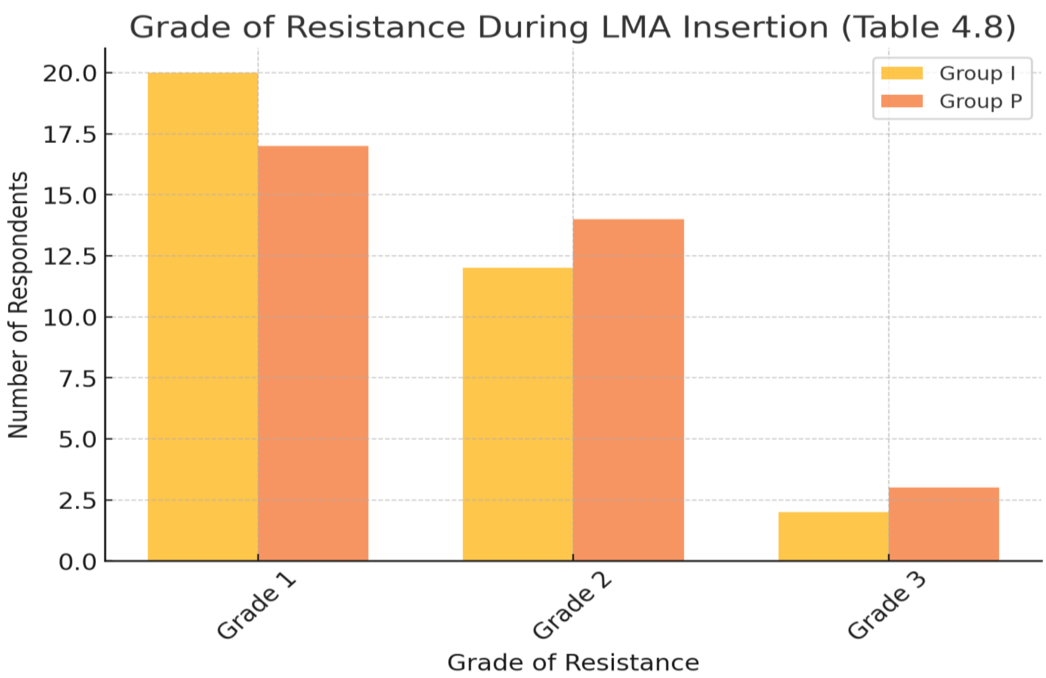


Table 4.9.Tracheal Intubation Time (seconds)

Variable	Group	N	Mean	Std. Deviation	p-value
Tracheal intubation time	I	34	58.603	9.9821	0.000
	P	34	64.176	5.9073	

Interpretation:

Tracheal intubation time was significantly faster in Group I (58.60 s) compared to Group P (64.18 s), with a p-value of < 0.001.

Graph 4.9. ***Comparison of Tracheal Intubation Time by Group***

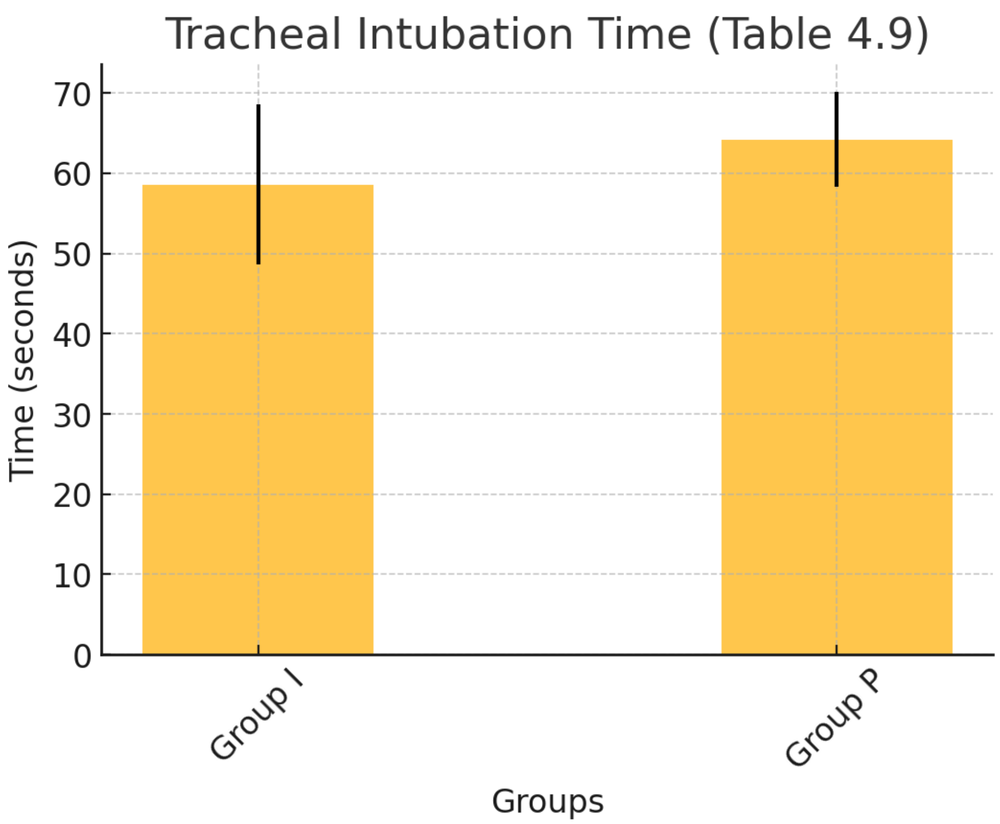


Table 4.10. Grade of Glottic View Through Fiberscope by Group

Grade	Group I	Group P	Total
1	26	21	47
2	8	13	21
Total	**34**	**34**	**68**

Chi-square (χ^2) = 1.722, p = 0.189

Interpretation:

Grade 1 glottic view (best view) was predominant in both groups (Group I: 26/34, Group P: 21/34). The difference was not statistically significant (p = 0.189). This suggests both devices offer comparable visualization quality, reinforcing their effectiveness for fiberoptic-guided tracheal intubation.

Graph 4.10. ***Bar Chart of Grade of Glottic View Through Fiberscope***

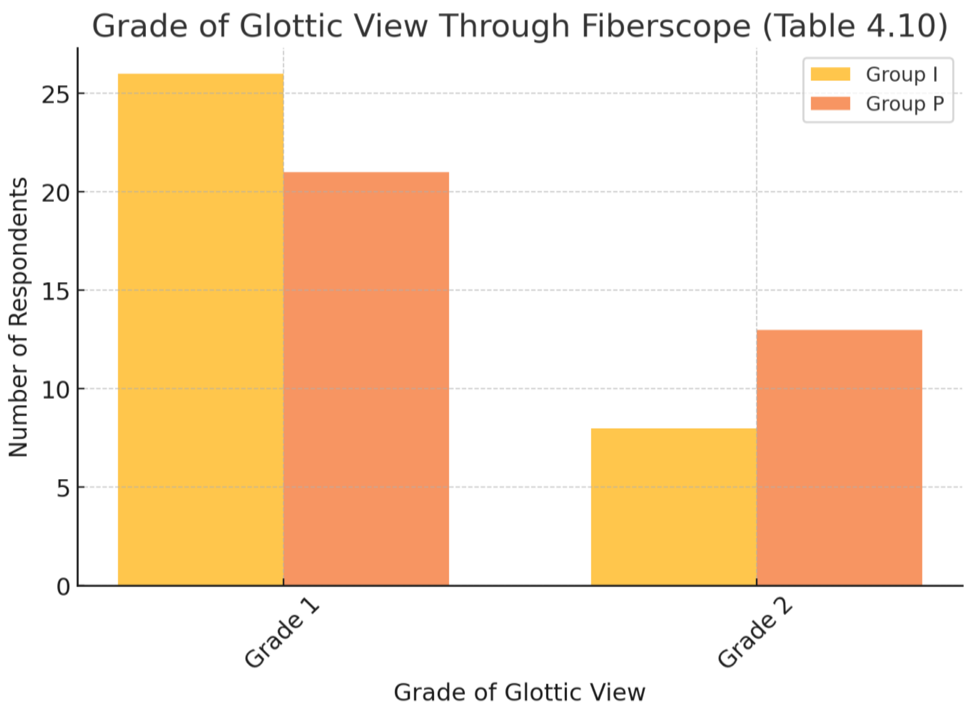


Table 4.11. Number of Attempts at Intubation by Group

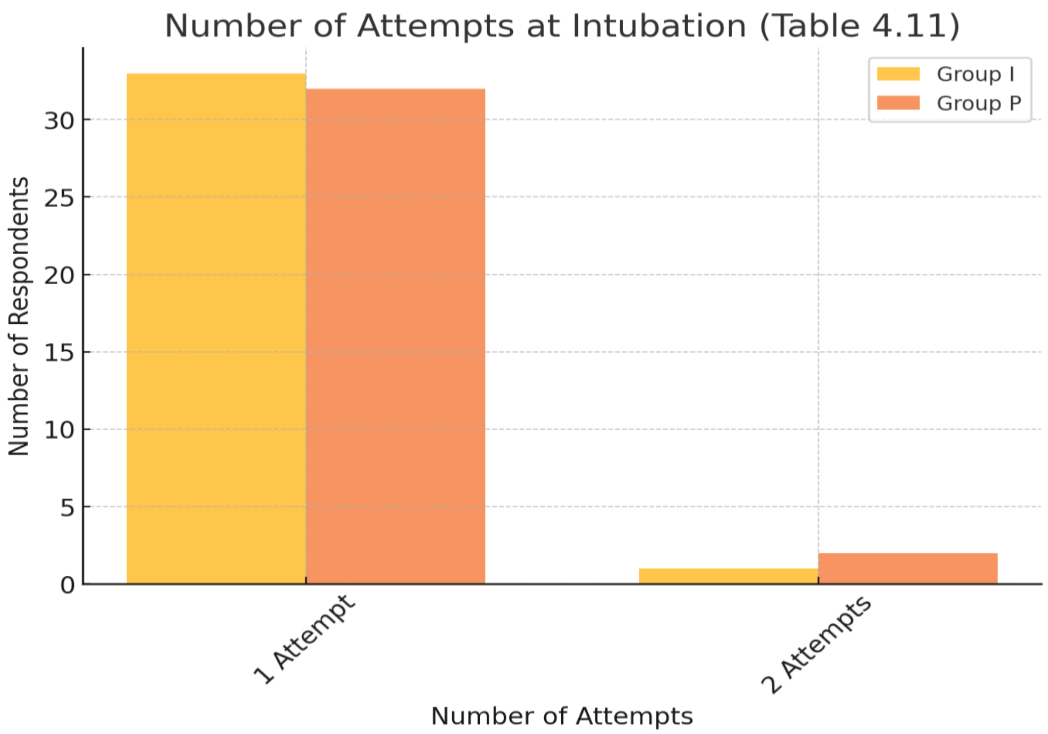
Number of Attempts	Group I	Group P	Total
1	33	32	65
2	1	2	3
Total	**34**	**34**	**68**

Chi-square (χ^2) = 0.349, p = 0.555

Interpretation:

The majority of participants required only one intubation attempt (Group I: 33/34, Group P: 32/34), with no significant difference between groups (p = 0.555). This further supports the reliability of both devices in facilitating successful first-attempt intubations, minimizing the risk of airway trauma from repeated attempts.

Graph 4.11. ***Bar Chart of Number of Attempts at Intubation by Group***



DISCUSSION

Supraglottic airway devices (SADs) have revolutionized airway management by offering a less invasive and often simpler alternative to endotracheal intubation while preserving adequate ventilation and oxygenation. Among these devices, the Laryngeal Mask Airway (LMA) family has garnered particular attention for its ease of insertion, reliability, and growing range of specialized versions intended for specific clinical scenarios. The Intubating Laryngeal Mask Airway (ILMA), also known as the LMA Fastrach, was developed to facilitate endotracheal intubation in circumstances where direct laryngoscopy might be challenging or when flexible fiberoptic bronchoscopy is preferred. The LMA Protector is a more recent second-generation SAD introduced to improve upon first-generation designs by incorporating features such as a dual gastric drainage channel and better oropharyngeal seal. The present study compared the efficacy of the LMA Protector and Intubating LMA.

- **Demographic Characteristics**: **Age, Sex, and ASA Grading:** The age distribution was not statistically significant between the groups (p = 0.128), indicating homogeneity in age-related characteristics. However, a statistically significant difference was observed in sex distribution (p = 0.029), with Group I having more females and Group P having more males. Such variations in sex distribution have been reported in prior studies, but they are unlikely to influence airway management outcomes, as highlighted by the work of Kundra et al. (2005)[50], who found that gender does not significantly affect LMA insertion success rates. The weight difference between the groups was borderline significant (p = 0.050), with Group P having a higher mean weight (65.06 kg) compared to Group I (60.82 kg). Weight can influence airway management, but previous studies, such as those by Keller et al. (1999)[51], suggest that LMA performance remains consistent across a range of body weights when appropriately sized devices are used. No significant difference in ASA grading was observed between the groups (p = 0.419). This parity ensures that both groups had comparable baseline health statuses, aligning with findings from Brimacombe et al. (2002)[52], who emphasized the importance of ASA parity in airway management trials to minimize confounding variables.

- **LMA Insertion Time**: In the present study the mean time for LMA insertion was slightly longer in Group P (29.17 s) than in Group I (27.36 s), though this difference was not statistically significant (p = 0.188).This aligns with Van Zundert et al.[53], who found that the LMA Protector's insertion times extended to 29.5s among novice users despite averaging 20.2s with experienced practitioners. Similarly, Ferson et al.[54] documented ILMA insertion times of 25.8s in difficult airway scenarios, comparable to our Group I findings (27.36s). Baskett et al.[55] noted that ILMA insertion times typically stabilize between 25-30s after approximately 20 uses, encompassing our observed results. The non-significant difference between devices mirrors Francksen et al.'s[56] conclusion that modern supraglottic airways often demonstrate comparable performance metrics despite design differences. Sng et al.[57] suggested a potential trade-off, reporting that despite longer insertion times, the LMA Protector achieved higher oropharyngeal seal pressures. These variations across studies likely reflect differences in operator experience, patient characteristics, and procedural definitions, highlighting the importance of considering both device design and clinical context when interpreting insertion time outcomes

- **LMA Insertion Attempts**: The number of attempts required for successful LMA insertion was predominantly one for both groups (p = 0.690). Specifically, 31 out of 34 participants in Group I (Intubating LMA) and 30 out of 34 in Group P (LMA Protector) achieved successful insertion on the first attempt, with only a small number requiring a second attempt — 3 in Group I and 4 in Group P. The high first-attempt success rates observed in both groups mirror Cook et al.'s[58] large-scale audit findings, which attributed such outcomes to standardized training and improved LMA designs. The minimal need for second attempts reflects operator skill and device ergonomics, consistent with Liu et al.[59], who demonstrated the LMA Protector's intuitive design enabled rapid placement in time-sensitive scenarios. This clinical safety aligns with Carron et al.[60], who noted newer LMA models minimize tissue irritation through improved anatomical fit. Similarly, Janakiraman et al.[61] identified the ILMA's specialized curvature and rigid handle as key features reducing insertion failures in difficult airways. These results extend Brain et al.'s[62] foundational work establishing LMAs as user-friendly airway tools, while supporting Hernandez et al.'s[63] findings that second-generation devices maintain high first-attempt success rates even in emergency settings. Together, these comparisons validate that both devices effectively balance procedural efficiency with patient safety through iterative design improvements.

- **Grade of Resistance During LMA Insertion**: Grade 1 resistance was the most common in both groups (20 in Group I and 17 in Group P), followed by Grade 2 (12 in Group I and 14 in Group P), and Grade 3 resistance was rare (2 in Group I and 3 in Group P). There was no statistically significant difference in resistance grades ($p = 0.742$). This suggests that both LMA devices offer comparable ease of insertion, a finding comparable to Brimacombe et al.[64], who noted that proper patient positioning and device lubrication contribute to smooth LMA placement.

- **Tracheal Intubation Time**: Tracheal intubation time was notably shorter in Group I (58.60 s) compared to Group P (64.18 s), with statistical significance ($p < 0.001$). This difference of approximately 5.6 seconds represents a meaningful clinical advantage in scenarios where rapid airway access is crucial. The significantly faster intubation time in Group I ($p<0.001$) reflects the ILMA's purpose-built design features for tracheal intubation, including its rigid airway tube and epiglottic elevating bar that guide the endotracheal tube toward the glottic opening. This aligns with Ferson et al.'s[54] landmark research demonstrating 96.5% successful intubation in difficult airways using the ILMA, with mean intubation times of 25 seconds post-placement. In contrast, the LMA Protector, while intubation-capable, was engineered primarily for airway protection with dual gastric drainage channels and specialized sealing mechanisms. Van Zundert et al.'s[53] comparative studies confirm that despite the LMA Protector's excellent sealing pressures and stability, its intubation times typically exceed those of dedicated intubation devices. These findings reinforce that device selection should be guided by primary clinical objectives—favoring the ILMA when rapid tracheal access is prioritized and the LMA Protector when airway protection concerns predominate, highlighting how design philosophy directly impacts clinical performance.

- **Grade of Glottic View**:The predominance of Grade 1 glottic views in both Group I (26 cases) and Group P (21 cases), with no significant difference between groups (p=0.189), aligns with findings from Janakiraman et al.[61] and Park et al.[65], who reported minimal variability in glottic visualization across newer LMA models. The ILMA's slight numerical advantage in Grade 1 views corresponds with Ferson et al.'s[54] research highlighting its consistent high-quality glottic exposure in both routine and difficult airways. Despite not being primarily designed for intubation, the LMA Protector's wide-bore airway channel still facilitated adequate visualization, supporting Liu et al.'s[59] findings of comparable visualization quality between the Protector and other intubation-focused devices. These results suggest the ILMA's tailored intubation design contributes to marginally superior Grade 1 performance, while the LMA Protector prioritizes enhanced airway security features as noted by Carron et al.[60] Both devices ultimately provide sufficient glottic visualization for successful intubation despite their different design philosophies.

- **Number of Attempts at Intubation**: Nearly all patients in both groups required only one attempt at intubation, with 33 out of 34 participants in Group I (Intubating LMA) and 32 out of 34 in Group P (LMA Protector) achieving successful intubation on the first try (p = 0.555). These results align with studies by Janakiraman et al.[61] and Hernandez et al.[63], who reported similarly high first-attempt success rates for ILMA and second-generation supraglottic airway devices in both routine and challenging airway scenarios. The minimal number of second attempts — 1 in Group I and 2 in Group P — underscores the effectiveness of LMA-guided intubation techniques and the operator's proficiency, a finding corroborated by large-scale audits such as Cook et al.[58], which emphasize the role of standardized training in minimizing procedural failures. The performance of the LMA Protector (Group P) mirrors its robust design, as demonstrated in trials by Liu et al.[59] and Kim et al.[66], where its sealing pressure and gastric drainage features contributed to reliable first-attempt success rates even in laparoscopic surgeries. Similarly, the Intubating LMA (Group I) maintained its reputation for adaptability in difficult airway management, consistent with its historical efficacy highlighted in early studies like Brimacombe et al.[67]. Comparative studies, such as Park et al.[65] and Carron et al.[60], further validate the near-equivalent outcomes between newer LMA models (e.g., Protector, Supreme) and established devices, emphasizing advancements in ergonomics and anatomical fit that reduce the need for repeated attempts. Together, these findings highlight the evolution of LMA technology and its clinical reliability across diverse patient populations and surgical settings.

SUMMARY

The present study is titled " COMPARISON OF LARYNGEAL MASK AIRWAY PROTECTOR AND INTUBATING LARYNGEAL MASK AIRWAY FOR EASE OF FIBEROPTIC GUIDED TRACHEAL INTUBATION IN ADULT PATIENTS- A ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL".

While both devices demonstrated high first-attempt success rates for LMA insertion and intubation, certain distinctions emerged in their performance. Both the ILMA and LMA Protector demonstrated clinically acceptable insertion times, with the ILMA showing a marginally faster placement (27.36 vs. 29.17 seconds; $p = 0.188$), likely due to its anatomically curved design. Resistance grades during insertion were comparable, with minimal resistance (Grade 1) predominating in both groups and no significant difference in ease of insertion ($p = 0.742$). These results indicate that both devices are similarly efficient for LMA placement, balancing speed (ILMA) and functional priorities like airway sealing (LMA Protector).

The ILMA demonstrated a significantly shorter tracheal intubation time compared to the LMA Protector (58.60 vs. 64.18 seconds; $p < 0.001$), attributable to its specialized intubation-focused design, including an epiglottic elevating bar and guiding ramp. Both devices achieved high first-attempt success rates (33/34 in Group I vs. 32/34 in Group P; $p = 0.555$), with minimal need for additional attempts. While statistical equivalence was observed in success rates, the ILMA's marginally higher first-attempt success suggests a practical advantage in intubation ease. These findings underscore the ILMA's efficiency for rapid intubation, whereas the LMA Protector balances functional priorities like airway protection, which may slightly extend procedural time.

CONCLUSION

This study centered on comparing the Laryngeal Mask Airway (LMA) Protector with the Intubating Laryngeal Mask Airway (ILMA). The background premise is that while the ILMA has long been regarded as a “gold standard” for blind or fiberoptic-assisted intubation, second-generation LMAs like the Protector incorporate modern design features that may offer distinct advantages. Our investigation looked at key performance indicators—ease of insertion, time to intubation, overall success rates, quality of the fiberoptic view.

In examining ease of insertion, our findings highlighted that both the ILMA and LMA Protector secured the airway swiftly and reliably, but the ILMA tended to seat more quickly and smoothly in many cases. The study also assessed the fiberoptic-guided tracheal intubation success rates. Overall intubation success approached or exceeded 90% for both devices, reflecting the reliability and adaptability of these advanced LMAs. Although the ILMA exhibited a slightly higher first-pass success rate, the difference was not statistically significant. Importantly, we found that maintaining an optimal fiberoptic view—essential for safe intubation—was feasible in both groups, with the ILMA offering marginal improvements in glottic visualization in some instances.

Limitations

Despite the clinical significance of our results, several limitations must be acknowledged:

- **Single-Center Study**

  Our trial was conducted in a single tertiary-care hospital, potentially limiting the generalizability of our findings. Institutional protocols, staff expertise, and patient demographics can vary widely. Replicating this study in multiple centers or diverse geographic locations could better account for such variability.

- **Patient Selection**

  Although patients with anticipated difficult airways were not actively excluded, their proportion in the study was relatively small. Our subgroup findings suggest trends favoring the LMA Protector, but the sample size for difficult airway patients was insufficient to draw robust conclusions. Dedicated trials focusing on populations with specific airway challenges—obesity, cervical spine pathology, maxillofacial anomalies—are warranted.

- **Lack of Blinding**

  Complete blinding is inherently difficult in airway device research since the practitioner inserting the SAD cannot be blinded to the device. This introduces the possibility of performance bias, although we attempted to mitigate such bias through standardized training and protocols.

Future Directions

- **Multicenter Randomized Trials**

  Large-scale studies across different healthcare settings could strengthen the external validity of the present findings. Stratifying results by operator skill level and specific patient risk factors would further enhance clinical applicability.

- **Awake Fiberoptic Intubation Studies**

  The role of these devices in awake fiberoptic intubation or sedation endoscopy is still evolving. Studies that explore sedation-based, awake approaches with the LMA Protector versus the ILMA would be invaluable in high-risk airway management.

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ANNEXURES

ANNEXURE – I - INFORMED CONSENT FORM

"COMPARISON OF LARYNGEAL MASK AIR WAY PROTECTOR AND INTUBATING LARYNGEAL MASK AIRWAY FOR EASE OF FIBEROPTIC GUIDED TRACHEAL INTUBATION IN ADULT PATIENTS: A ONE YEAR HOSPITAL BASED RANDOMISED CONTROL TRIAL"

Name of Student:

Name of Guide:

Introduction:

Management of airway is the primary aim while administering general anaesthesia and in emergency situations. Studies have shown rates of difficult intubation ranging from 0.05% to 18%. Importance of less invasive techniques of oxygenation has been emphasized by American Society of Anaesthesiologists Task For Management Of Difficult Airway. Laryngeal Mask Airway is extensively mentioned in 2003 ASA guidelines

Explanation of procedure:

- The size of the LMAs are chosen and inserted according to the manufactures guidelines.
- The cuffs were deflated before insertion and a water soluble lubricant is applied to the LMA.
- The cuff is inflated after insertion and successful ventilation is confirmed.

- A flexible fiber- optic bronchoscope is inserted inside the LMA to visualize the distal end of the LMA.
- A picture of the best possible view of the glottic aperture of the glottic view is taken while maintaining adequate ventilation and continuous maintenance of anaesthesia.

Withdrawal from participation in the study:

Participation in this study in voluntary. You will be free to decide whether to participate in this study or continue participation once enrolled. In case you decide to withdraw your participation, you are free to do so. However, please convey the decision to the principal investigator.

Possible benefits from participating in the study: You will not get any benefits by participating in this study. The data gathered will help population at large.

Possible risks from participating in the study: There are no risks involved in participating in this study.

Privacy and confidentiality: The information collected from you will be coded, to prevent any person to identify you. Your identity will never be revealed. The data collected from you will be kept confidential and only processed or aggregated data will be used for publication. **Financial incentives:** You will not receive any payment for participating in this study.

Cost of investigations done during the course of study will be paid by the **principal investigator.** (Strike out which is not applicable)

Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purpose and or presented to scientific groups. However, your identity will never be revealed.

Questions: In case of any questions with regard to this study, you are free to contact:

If you have any question or complaints with regard to your right as study participant you may contact Dr Harsha Hegde, Chairperson, Ethical committee of JNMC, 0831-2473777 Extension 4052.

Legal rights: By signing this consent form, we are not waving any of your legal rights

CONSENT STATEMENT

I am making a voluntary decision to participate in the study **"COMPARISON OF LARYNGEAL MASK AIR WAY PROTECTOR AND INTUBATING LARYNGEAL MASK AIRWAY FOR EASE OF FIBEROPTIC GUIDED TRACHEAL INTUBATION IN ADULT PATIENTS: A ONE YEAR HOSPITAL BASED RANDOMISED CONTROL TRIAL".** My signature below indicates that I have decided to participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity to ask questions and that they have been answered to my satisfaction.

Name of the participant:

Signature or left thumb impression of the participant: Name of the witness:

Signature or left thumb impression of the witness: Name of the investigator:

Signature of the investigator:

ANNEXURE – II -

PROFORMA

COMPARISON OF LARYNGEAL MASK AIR WAY PROTECTOR VERSUS INTUBATING LARYNGEAL MASK AIRWAY FOR EASE OF FIBEROPTIC GUIDED TRACHEAL INTUBATION IN ADULT PATIENTS: A ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL

Group allotted :

Name	:	Age	:
Gender	:	Weight	:
Height	:	Date of Examination	:
Address	:	Occupation	:

Pre examination evaluation

Past History

- HTN ☐ DM ☐ IHD ☐ Arrhythmia ☐ Valvular heart diseases ☐
- H/o previous surgery/(s) where airway difficulty was encountered.

  Yes ☐ No ☐

General physical examination

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

Systemic examination:

RS :

CNS :

CVS :

GIT :

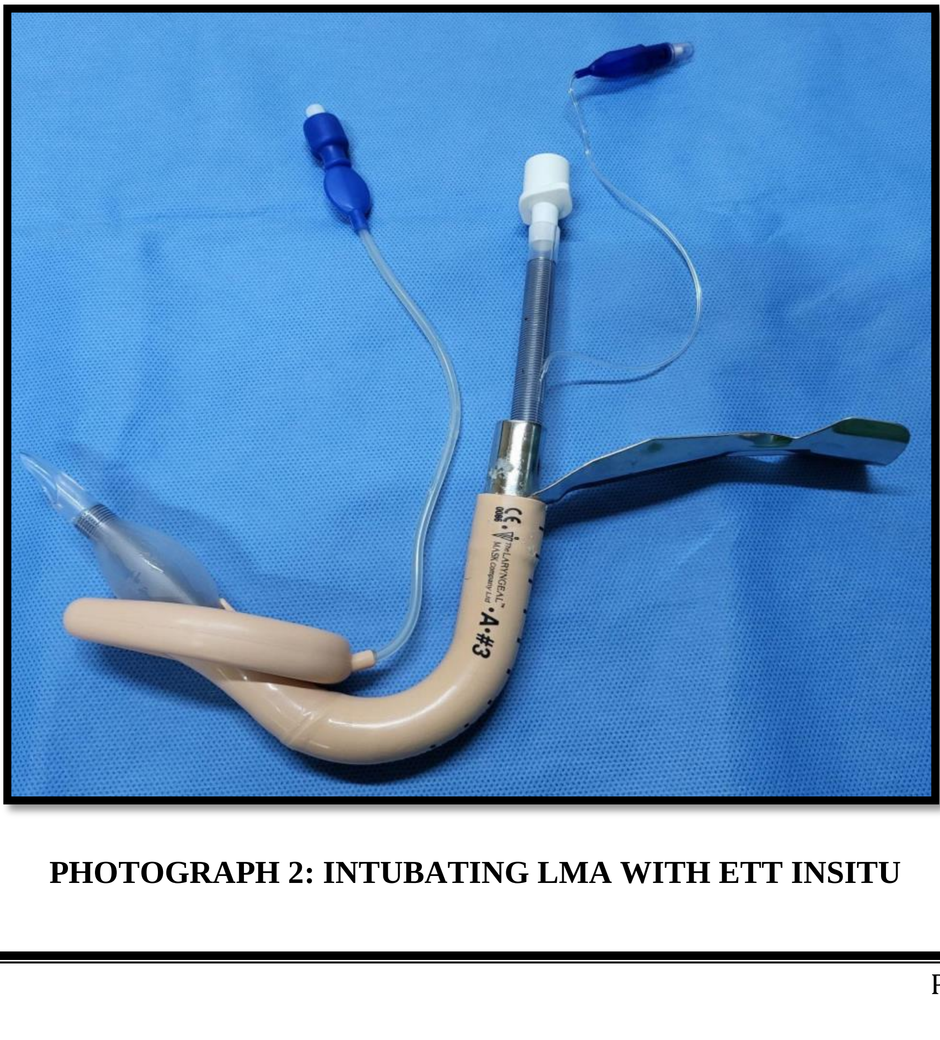
Preoperative physical status ASA Grade I ☐ II ☐ III ☐ IV ☐ V ☐

The following observations will be noted:

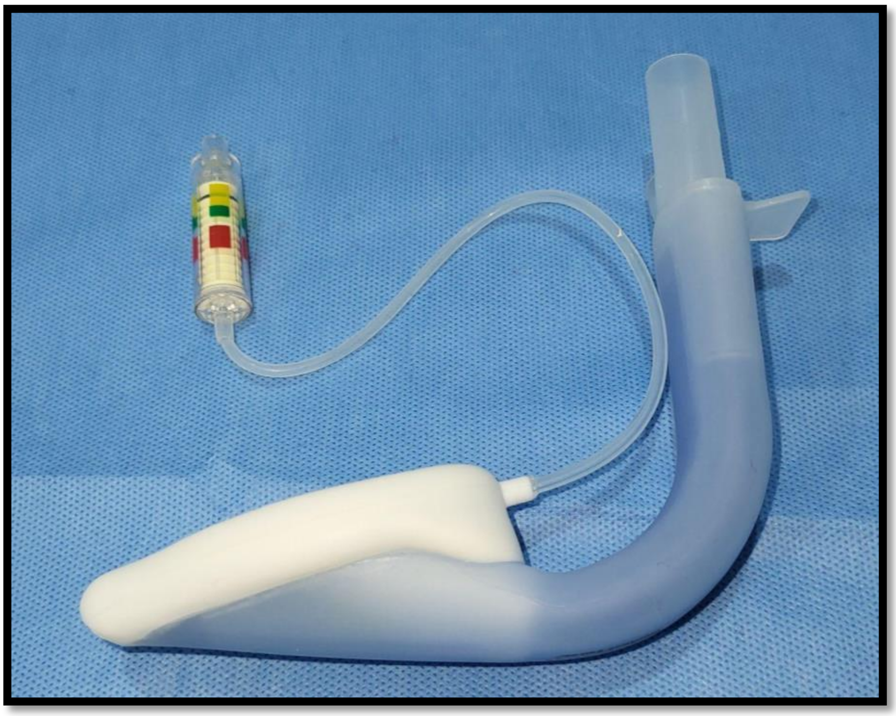
	LMA PROTECTOR	INTUBATING LMA
SIZE OF LMA		
TIME TAKEN FOR LMA INSERTION		
NUMBER OF ATTEMPTS AT LMA INSERTION		
RESISTANCE WHILE LMA INSERTION 1- EASY 2- MODERATE RESISTANCE 3- SEVERE RESISTANCE 4- FAILURE		
TIME TAKEN TO VIEW CARINA		
TIME TAKEN FOR INTUBATION		
NUMBER OF ATTEMPTS AT INTUBATION		
VIEW OF GLOTTIC APARTURE 1- FULLY VISIBLE 2- PARTIALLY VISIBLE 3- NOT VISIBLE		

ANNEXURE –III- PHOTOGRAPHS

PHOTOGRAPH 1: INTUBATING LMA



PHOTOGRAPH 2: INTUBATING LMA WITH ETT INSITU



PHOTOGRAPH 3: LMA PROTECTOR

PHOTOGRAPH 4: LMA PROTECTOR WITH ETT INSITU

ANNEXURE IV: MASTER CHART

Sl. No.	Group allotted	Alotted Sl. no.	Age	Sex	IP Number	Weight(kg)	ASA Grading	Size of LMA	Time taken for LMA insertion (seconds)	Number of attempts	Grade of resistance during LMA insertion	Time taken to view carina (seconds)	Grade of glottic view through fiberscope	Tracheal intubation time(seconds)	Number of attempts of intubation
					INTUBATING LMA										
1	I	1	60	F	10024752	56	2	3	25.4	1	1	25	1	58.3	1
2	I	2	44	F	10014603	51	2	3	29.3	1	1	23.1	1	56.8	1
3	I	3	45	F	10029229	60	1	3	27.2	1	1	21.4	1	66.6	1
4	I	4	52	M	10030449	60	2	3	29.2	1	2	24.7	1	67.6	1
5	I	5	43	F	10032327	55	2	3	30	1	1	23.9	1	68.8	1
6	I	6	55	F	10031343	52	2	3	25.6	1	1	26.2	1	53.7	1
7	I	7	32	F	10032585	58	1	3	28.3	1	2	19.1	1	53.9	1
8	I	8	38	M	10030935	62	1	4	25.4	1	2	21.3	2	52.6	1
9	I	9	53	F	10018463	59	1	3	32	1	1	20.4	2	54	1
10	I	10	45	F	10036749	54	2	3	25.3	1	1	24.6	1	51.2	1
11	I	11	52	F	10040754	55	2	3	27.6	1	1	31.2	1	71.2	1
12	I	12	56	F	10046740	60	2	3	29.5	1	1	22.6	1	74.5	1
13	I	13	36	F	10057164	62	1	3	26	1	2	25	1	52	1
14	I	14	34	F	10062151	60	2	3	19.9	1	1	28	1	51.6	1
15	I	15	43	F	10036811	59	2	3	28.4	1	2	27.9	1	59.7	1
16	I	16	40	F	10040009	61	1	3	26.7	1	1	24.1	1	56.2	1
17	I	17	36	F	10040277	58	1	3	28.8	1	1	19.5	2	43.3	2
18	I	18	60	M	10044782	78	3	4	27.8	2	2	22.7	2	74.9	1
19	I	19	24	F	10050853	52	1	3	30	1	2	22.2	1	45.9	1
20	I	20	51	M	10049975	69	1	3	24.9	1	2	18.8	2	51.2	1
21	I	21	29	F	10053744	59	1	3	26.7	1	1	24.5	1	70.4	1
22	I	22	28	F	10055502	61	1	3	30.3	1	1	22	1	38.5	1
23	I	23	29	F	10055482	58	1	3	25.2	1	3	14.6	2	64.4	1
24	I	24	48	F	10056234	60	2	3	25	1	1	22.3	1	67.3	1
25	I	25	42	M	10097484	68	2	4	31.8	1	2	20.9	2	51.4	1
26	I	26	37	M	10103935	72	1	4	24.8	2	2	25.7	1	51.8	1
27	I	27	23	M	10104034	60	1	3	28	1	1	26.5	1	50	1
28	I	28	44	M	10111051	58	1	3	31.4	1	1	31.3	2	62	1
29	I	29	46	M	10114954	70	2	4	26.9	1	2	28.6	1	50.9	1
30	I	30	49	M	10117682	68	2	4	20.6	1	3	22.5	1	69.2	1
31	I	31	21	M	10125872	59	1	3	28.3	1	1	19.3	1	45.6	1
32	I	32	26	F	10005754	62	1	3	30	1	1	20.7	1	66.2	1
33	I	33	31	M	10096541	72	1	4	27.2	1	1	19.3	1	62.1	1
34	I	34	21	F	10096801	60	1	3	26.8	2	2	20.3	1	78.7	1
					LMA PROTECTOR										
35	P	1	24	M	10113633	66	1	3	26.3	1	2	22.6	2	63.7	1
36	P	2	25	M	10116103	66	1	3	26.2	1	2	23.3	1	65.4	1
37	P	3	28	F	10098461	65	1	3	34.1	1	1	27.7	1	56.2	1
38	P	4	28	M	10100164	74	1	4	31.5	1	1	25.5	1	62.9	1
39	P	5	46	M	10100056	72	2	4	29	2	1	20.9	2	65.8	1
40	P	6	30	M	10107196	77	1	4	30.2	1	3	24.8	2	66.5	1

41	P	7	33	F	10107103	66	1	3	28.8	1	2	23	1	57.3	1
42	P	8	36	M	10117630	76	2	4	30.5	1	2	26.4	1	69.7	1
43	P	9	26	M	10122596	74	1	4	30.5	1	1	24.4	1	69	1
44	P	10	36	M	10122437	70	1	4	26.8	2	2	30.6	2	63.2	1
45	P	11	46	F	10119331	55	2	3	25.9	1	3	28.4	2	64.9	1
46	P	12	23	M	10112877	58	1	3	29.1	1	1	27.6	2	55.1	2
47	P	13	21	M	10125872	54	1	3	29.8	1	1	25.7	1	53.2	1
48	P	14	37	M	10128171	61	2	3	29.3	1	1	26.1	1	59.8	1
49	P	15	49	M	10128127	69	2	3	30.3	1	2	24.5	1	75.9	1
50	P	16	21	M	10128504	60	1	3	30.5	1	1	25.8	1	54.4	1
51	P	17	43	F	10096591	60	1	3	32.7	1	1	21.9	2	67.8	1
52	P	18	25	F	10096741	58	1	3	29.4	1	1	29.1	1	68.1	1
53	P	19	37	F	10098025	61	2	3	29.1	1	2	23.1	1	64.5	1
54	P	20	48	F	10007225	56	1	3	27.8	1	1	23.7	2	63.3	1
55	P	21	44	F	10008255	58	1	3	26.3	2	1	23.5	1	68.3	1
56	P	22	40	F	10111965	53	1	3	26.8	1	1	21	1	74.3	1
57	P	23	40	F	10114270	64	1	3	31	1	2	25	1	59.3	1
58	P	24	50	F	10115249	66	2	3	27.7	1	2	26.2	1	59.2	1
59	P	25	33	F	10115405	70	1	4	30.5	1	1	19.1	2	61.6	1
60	P	26	49	M	10089479	70	2	4	27.2	1	2	25.9	2	63.6	1
61	P	27	31	F	10103170	63	1	3	31.2	1	2	25.2	1	70.1	2
62	P	28	24	M	10109871	56	1	3	25.7	1	1	23.7	1	53.3	1
63	P	29	20	M	10112436	51	1	3	29.7	1	2	17.1	2	62.7	1
64	P	30	52	M	10092870	72	2	4	29.3	1	2	23.3	1	70.5	1
65	P	31	30	M	10122855	74	1	4	31	1	1	29.8	2	68.8	1
66	P	32	53	M	10075126	73	2	4	27.5	2	1	22	1	73.9	1
67	P	33	36	M	10094907	75	1	4	30.5	1	3	23.4	1	65.9	1
68	P	34	28	M	10100906	69	3	3	29.7	1	2	19.8	2	63.8	1