"TO COMPARE LEAK VOLUME WITH AND WITHOUT THE APPLICATION OF POSITIVE END-EXPIRATORY PRESSURE WITH I-GEL BASED GENERAL ANAESTHESIA IN PEDIATRIC PATIENTS - A ONE YEAR RANDOMISED CONTROL TRIAL"

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With reference to the above, we wish to inform you that your proposed research project titled **"TO COMPARE THE LEAK VOLUME WITH AND WITHOUT THE APPLICATION OF POSITIVE END- EXPIRATORY PRESSURE WITH I-GEL BASED GENERAL ANAESTHESIA IN PEDIATRIC PATIENTS : A RANDOMISED CONTROL TRIAL"**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee.

(Dr. Smita Sonoli)
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ABBREVIATIONS

GA - general anaesthesia
ETT - endotracheal tube
VAP - ventilator- associated pneumonia
PEEP - peak end expiratory pressure
VILI - ventilator induced lung injury
SAD - supraglottic airway device
LMA - laryngeal mask airway
PIP - peak inspiratory pressure
EtCO2 - end tidal carbon dioxide
O2 - oxygen
CO2 - carbon dioxide
PaCO2 - arterial partial pressure of carbon dioxide
PaO2 - arterial partial pressure of oxygen
TV - tidal volume
PCV - pressure controlled ventilation
VCV - volume controlled ventilation
P/V - pressure volume
CT - computer tomography
HR - heart rate
BP - blood pressure
ARDS - acute respiratory distress syndrome
PPV - positive pressure ventilation
FRC - functional residual capacity
IV - intravenous
OR - operating room
NIBP - non invasive blood pressure
ECG - electrocardiogram
SpO2 - oxygen saturation
SD - standard deviation
OR - operating room

ABSTRACT

Title:

To compare leak volume with and without the application of positive end-expiratory pressure with I-gel based general anaesthesia in pediatric patients. A one year randomised control trial.

Background:

General anesthesia (GA) is an essential component of pediatric surgical procedures, ensuring unconsciousness, analgesia, and muscle relaxation. The use of supraglottic airway devices, such as the I-gel, has gained attention due to their ability to maintain airway patency with minimal complications. Positive end-expiratory pressure (PEEP) is widely used in adult patients to improve oxygenation and reduce airway collapse, but its benefits in pediatric patients undergoing I-gel-based GA remain unclear. This study aims to compare the effects of applying PEEP on airway leak volume and leak fraction in pediatric patients.

Aims and Objectives:

This study aims to compare leak volume, leak fraction, end-tidal CO_2, and peak inspiratory pressure in pediatric patients undergoing I-gel-based general anesthesia with and without 5 cm H_2O of PEEP to assess its impact on ventilation efficiency and airway leaks.

Methodology:

A randomized controlled trial was conducted on 70 pediatric patients (ages 2-12 years) undergoing elective surgery under GA. Patients were divided into two groups: Group A (I-gel with PEEP of 5 cm H_2O) and Group B (I-gel without PEEP). Standard anesthetic protocols were followed, including premedication, induction, and maintenance of anesthesia. Leak volume, leak fraction, peak inspiratory pressure, and

$EtCO_2$ levels were assessed at 5, 30, and 60 minutes. Statistical analysis was performed using SPSS 22, employing Student's t-test, ANOVA, and Chi-square tests where appropriate.

Results:

The mean age of patients in Group A was 7.23 ± 4.00 years, while in Group B, it was 8.28 ± 3.78 years (p = 0.129). The mean leak fraction at different time intervals was statistically significant within Group A but not within Group B or between groups. Leak volume showed statistical significance within both groups, but intergroup differences were only significant at the 30-minute mark. Peak inspiratory volume was significantly higher in Group A compared to Group B across all time intervals. No significant differences were found for inspiratory or expiratory volumes. No complications, including airway trauma, regurgitation, or aspiration, were reported.

Conclusion:

The use of PEEP with I-gel in pediatric anesthesia demonstrated slight improvements in leak fraction and leak volume, but statistical significance between groups was limited. Given the observed trends, further large-scale, multi-center studies with standardized protocols are recommended to better define the role of PEEP in optimizing ventilation strategies for pediatric patients.

Keywords:

I-gel, PEEP, pediatric, general anaesthesia, leak voume, leak fraction

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INTRODUCTION

General anaesthesia (GA) is one of the common anaesthetic techniques used for surgical procedures. Anaesthesia, Analgesia, and Amnesia - an anaesthetist's cardinal rule.

GA allows for controlled airway management and ventilation, ensuring adequate oxygenation and reducing the risk of aspiration. This makes it particularly useful in long and complex surgical procedures where patient immobility is essential. Furthermore, GA is highly adaptable, making it suitable for a wide range of surgical interventions, including emergency cases.

Despite these advantages, GA also has several disadvantages. Patients may experience postoperative side effects like nausea, vomiting, sore throat, or shivering. More serious risks include blood pressure fluctuations, arrhythmias, and respiratory depression. Recovery is typically longer than with regional anesthesia. GA also requires specialized equipment and skilled anesthesiologists, with potential complications such as airway obstruction, aspiration, and rare but severe reactions like malignant hyperthermia.

The use of an endotracheal tube (ETT) during GA, while essential for maintaining airway patency, can also introduce risks. Intubation can cause airway trauma, including vocal cord injury, tracheal damage, and laryngeal edema.

Improper positioning of the ETT can lead to aspiration, causing pneumonia. Difficult intubation increases the risk of hypoxia, while complications like laryngospasm or bronchospasm, especially in children, make ventilation challenging. Accidental extubation or tube displacement can result in airway obstruction or inadequate ventilation. Repetitive expansion and contraction of alveoli while under general anaesthesia, contributes to ventilator-induced lung injury (VILI). Studies have shown

that anesthesia can cause atelectasis, particularly in the dependent lung regions, which can compromise gas exchange. Prolonged intubation may cause ventilator-associated pneumonia (VAP), tracheal stenosis, atelectasis, V/Q mismatch, and postoperative hypoxia, all of which highlight the respiratory risks of extended ETT use in GA.[5,7]

PEEP (peak end expiratory pressure) is frequently utilized during general anesthesia to enhance breathing and oxygenation. PEEP is the amount of pressure that is kept in the lungs above atmospheric pressure at the conclusion of expiration.[2,3]

During general anesthesia, the application of PEEP has been found to prevent atelectasis formation and is a fundamental component of protective ventilation strategies. Limiting tidal volumes to 6-8 ml/kg has been universally adopted as a standard practice in operating rooms to minimize lung injury. The application of PEEP improves gas exchange, enhances oxygenation, and reduces the risk of ventilator-induced lung injury by preventing cyclic alveolar collapse and reopening.[1,4]

In recent years, I-gel has garnered considerable attention within the medical fraternity, especially in the area of anaesthesiology.[1] I-gel is a cutting-edge, secondgeneration SAD that's being used to manage airway promptly and swiftly during anaesthesia and resuscitation. I-gel is composed of a medical-grade thermoplastic elastomer, it can create an anatomical, non-inflated seal around the pharyngeal, laryngeal, and perilaryngeal structures, which is in contrast to conventional airway devices that depend on inflatable cuffs. This unique feature minimizes the risk of compression trauma, which is a common issue associated with inflatable cuffed devices.[5,7]

There has been extensive research which has demonstrated the advantages Igel poses in adults. Studies have proven its low complication rate and effectiveness in maintaining a seal even when airway pressures are high. The I-gel has been widely accepted in adult anesthesia practice due to its ease of use, ability to reduce airway trauma, and overall effectiveness in securing the airway.

However, despite its proven benefits in mechanical ventilation, PEEP is not commonly used in patients undergoing general anesthesia, particularly with a supraglottic airway device (SAD).[2]

Although there is substantial evidence supporting the use of I-gel and PEEP in adult patients, the lack of pediatric-specific studies limits the generalizability of these findings to children. Pediatric patients have unique airway and lung mechanics that necessitate dedicated research to determine the safety and effectiveness of I-gel, particularly when used in conjunction with PEEP.

While the I-gel shows promise in pediatric anesthesia, its effectiveness and safety in children require further research due to anatomical and physiological differences from adults. The traditional laryngeal mask airway (LMA) has been commonly used in children but has limitations, including airway leakage, upper airway obstruction, and the risk of gastric distension.[8,14]

In light of these factors, our study intended to evaluate the reliability and performance of I-gel in pediatric patients, by comparing leak volume, leak fraction, EtCO2, and peak inspiratory pressure, with and without the application PEEP as divided in two cohorts. This study seeks to offer meaningful insights capable of enhancing clinical practices and optimize airway management techniques for children receiving general anesthesia.[5]

AIMS AND OBJECTIVES

Primary Objective:

To compare leak volume & leak fraction,

Secondary Objective:

To compare EtCO2 & peak inspiratory pressure, in pediatric patients receiving I-gel based general anaesthesia with and without the application of 5cm of H_2O of peak end expiratory pressure.

REVIEW OF LITERATURE

The Review of Literature for this study focuses on the effect of Positive End-Expiratory Pressure (PEEP) on leak volume during supraglottic airway device, I-gel, based general anesthesia in pediatric patients.

Several studies have explored the efficacy of I-gel, a SAD, in providing a secure airway and minimal complications. However, airway leaks remain a concern, particularly in pediatric anesthesia, due to differences in airway anatomy and compliance.

Existing research highlights that PEEP may help reduce airway leaks by improving lung compliance and maintaining positive airway pressure, potentially leading to better ventilation efficiency. Studies comparing ventilation with and without PEEP suggest that applying PEEP may reduce leak volume and improve oxygenation, though the optimal level of PEEP remains debated.

A 2018 study by Kamhawy et al.[1] evaluated the use of the I-gel in 42 pediatric patients, with half receiving a PEEP of 5 cm H2O. The results showed no clinically significant differences in leak volume or leak fraction between the two groups. However, the PEEP group demonstrated significantly improved ventilation, including reduced end-tidal CO2 (EtCO2), higher peak inspiratory pressures (PIP), and increased inspiratory and expiratory tidal volumes, along with lower partial pressure of carbon dioxide (PaCO2). These findings suggest that the I-gel, particularly with PEEP, can optimize ventilation in pediatric patients, improving gas exchange and ventilation efficiency without compromising airway seal. Further research is needed to explore long-term outcomes and comparisons with other airway devices.

Mascha *et al.'s*[2] 2020 study sought to determine how physiological levels of PEEP affected gastric air insufflation and breathing parameters in children undergoing general anesthesia who were on pressure controlled ventilation (PCV) with an LMA. Excluding respiratory rate (no significant difference) and EtCO2 (significant drop), all metrics increased significantly with increasing PEEP. Their research suggested that oxygenation with PEEP of 5 cm H_2O may be more lung protective in pediatrics using the SupremeTM LMA, even if stomach air insufflation increased with increasing PEEP.

Research performed by Pablo *et al.*[3] in 2018 analyzed respiratory mechanics in anesthetized healthy children and, found that applying PEEP of 5 cmH_2O positions the respiratory system more favorably on the pressure-volume (P/V) curve. This optimal positioning suggests improved lung compliance and ventilation efficiency. Understanding lung mechanics in greater detail can potentially lead to modifications in traditional ventilatory strategies, thereby reducing the risk of mechanical ventilation-associated lung injury and improving overall respiratory outcomes in pediatric anesthesia.

In their case series, Serafini *et al.*[4] examined the pulmonary morphology of children who had received general anesthesia for either cranial or abdomen CT scans. After ventilation with PEEP of 5 cmH2O, all of the observed densities that were present in the gravity dependent areas of lungs in the patients disappeared without influencing HR, BP, hemoglobin concentration, or EtCO2. The study concluded that denitrogenation and an O2 reabsorption mechanism cannot account for the onset of atelectasis in youngsters. A PEEP of 5 cmH2O can both recruit every alveolar unit that is accessible and cause atelectasis to go away in dependent lung regions.

According to a 2014 study by Vargas *et al*.[5], PEEP helps individuals with ARDS avoid cyclic opening and collapsing of their alveoli, but it may also be involved in general anesthesia. There are two aspects to their review. The first one pertains to disease mechanics and their effects of PEEP on cerebral perfusion pressure, hemodynamic pressure, and thoracic pressure. Information aswell as supporting data regarding PEEP's application in critical care and general anesthesia are compiled in the second section. According to research by Neumann *et al*. and Tusman *et al.*[29] in 2017, varying PEEP levels and tidal volumes were linked to a decrease in postoperative atelectasis without affecting oxygenation.

One crucial aspect of supraglottic airway devices is oropharyngeal leak (or seal) pressure. It assesses how beneficial they are at providing intermittent positive pressure ventilation while under anesthesia. In a 2014 study, Smith *et al*.[7] compared the pediatric I-gel and other SAD of comparable size in 14 randomized controlled trials. I-gel often offers a greater oropharyngeal leak pressure and seems to be comparable to other SAD used in children. Since there is no cuff to inflate, I-gel has proved to be easier to install than LMA Classic or LMA ProSeal. When larger airway leak pressures are beneficial, such as in obese youngsters or patients undergoing lap surgeries, i-gel should be taken into consideration. Since high inspiratory pressure is necessary during positive pressure ventilation because of decreased lung compliance and higher airway resistance, it is advantageous to employ a supraglottic airway device with a high oropharyngeal leak pressure in newborns.

According to a 2014 study by Park et al.[6], the i-gel offers adequate airway sealing; nevertheless, when PIP surpasses i-gel's airway seal pressure without a gastric tube, stomach insufflation may occur. In contrast to VCV, PCV offers lower

PIP, and low PIP may lessen likelihood of abdominal distension in children receiving PPV.

Their work was meant to evaluate PIP, oropharyngeal leak pressure, and abdominal inflation during VCV or PCV in youth undergoing I-gel based GA without a ryle's tube in place.[6]

In a 1999 case series, Serafini et al.[4] came to the conclusion that denitrogenation and an O2 reabsorption mechanism could not account for the onset of atelectasis in infants. On the other hand, a PEEP of 5 cmH2O can both recruit every alveolar unit that is accessible and cause atelectasis to go away in dependent lung areas. This discrepancy between the child's and adult's experiences may be due to unique lung physiologies. While the inner elastic return of the lungs is similar in children and adolescents[7], the outward rebound of the chest wall is less. This lowers the functional residual capacity (FRC), and the lower definitive value of subatmospheric intrathoracic pressure increases risk of airway collapse, and alveolar deflation.

Acosta et al.[9] 2020 study investigated the use of positive end-expiratory pressure (PEEP) to treat anesthesia-induced atelectasis in pediatric patients, demonstrating that even a brief increase in PEEP at a constant driving pressure can effectively open and maintain the lungs. This brief PEEP application significantly improved lung mechanics, enhanced ventilation, and prevented atelectasis, which is particularly concerning in pediatric patients due to their smaller, more compliant lungs. The study showed that PEEP, a simple and feasible intervention, could prevent alveolar collapse and improve oxygenation during anesthesia, reducing the risk of hypoxia and postoperative complications. These findings suggest that PEEP could be an effective strategy in pediatric anesthesia to maintain lung function and improve

patient outcomes, providing a safe and efficient approach for managing respiratory challenges in young patients.

However, a 2011 study by Humphrey *et al.*[28] found that although PEEP prevents atelectasis, it did not enhance ventilation inhomogeneity when used during mechanical ventilation. The dependent lung received preferential ventilation before to induction, whereas the nondependent lung received better ventilation following induction when PEEP was used.

BASIC SCIENCES

Upper Airway Anatomy

Pharynx

The pharynx is a muscular, funnel-shaped tube that serves as a critical structure in both the respiratory and digestive systems. Extending from the base of the skull to the level of the sixth cervical vertebra, where it continues as the Esophagus, the pharynx functions as a shared pathway for both air and food. Anatomically, the pharynx is divided into three distinct regions: the nasopharynx, oropharynx, and laryngopharynx, each serving specialized roles.[30]

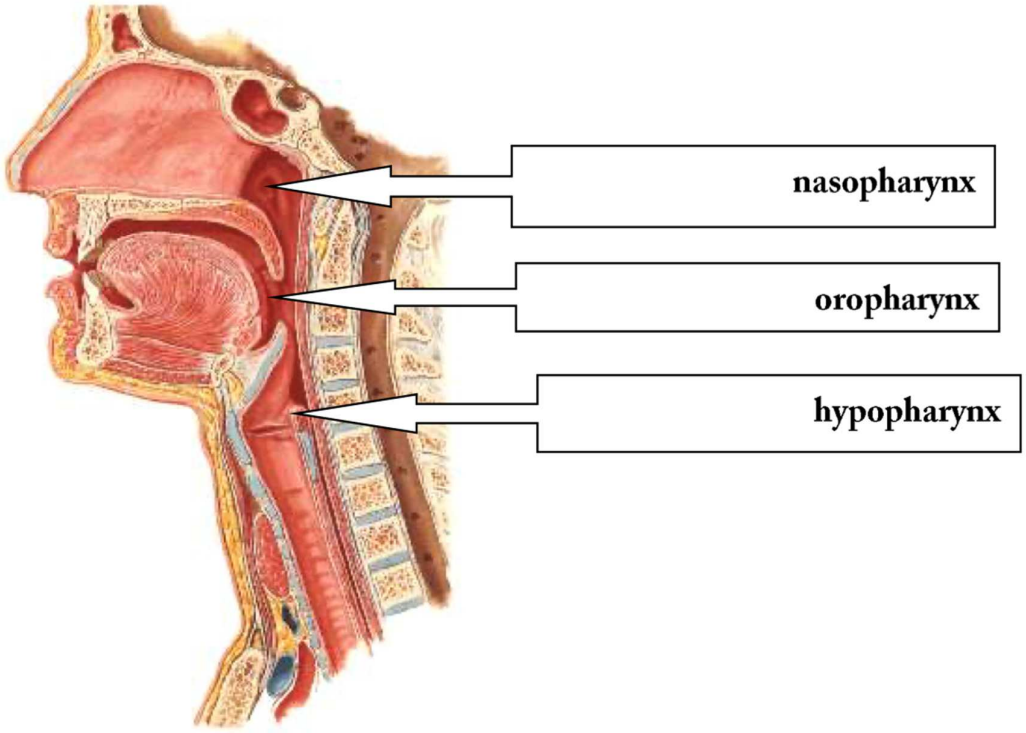


Figure 1: Anatomy of Pharynx.

Nasopharynx

The nasopharynx is the superior portion of the pharynx, located posterior to the nasal cavity and above the soft palate. This region functions primarily as a conduit for air, ensuring that it passes seamlessly from the nasal cavity to the oropharynx. The nasopharynx is lined with a ciliated pseudostratified columnar epithelium, which is essential for the filtration and humidification of inhaled air. The cilia beat rhythmically to transport mucus and trapped particles towards the oropharynx, where they can be swallowed, thereby keeping the respiratory tract clear of debris and pathogens. Within the nasopharynx, several anatomical structures play vital roles in maintaining respiratory function and overall health. The pharyngeal tonsils, commonly referred to as adenoids, are masses of lymphoid tissue situated in the roof and posterior wall of the nasopharynx. These adenoids are part of the immune system, providing a first line of defence by trapping and destroying pathogens that enter the body through the nasal passages. During childhood, the adenoids are particularly active and can sometimes become enlarged, potentially obstructing airflow and leading to breathing difficulties or recurrent infections.[31]

Another significant feature of the nasopharynx is the presence of the openings of the Eustachian tubes, also known as the pharyngotympanic tubes. These tubes connect the nasopharynx to the middle ear cavity, playing a crucial role in equalizing air pressure on either side of the tympanic membrane (eardrum). This pressure equalization is essential for proper hearing and prevention of barotrauma, which can occur during activities such as flying or diving. The Eustachian tubes also facilitate the drainage of mucus from the middle ear into the nasopharynx, thereby helping to prevent middle ear infections (otitis media). The structural and functional characteristics of the nasopharynx make it a critical component of the upper

respiratory system. It ensures that inhaled air is properly conditioned and free of harmful particles before it progresses to the lower respiratory tract. Furthermore, its role in immune defence and pressure regulation underscores its importance in maintaining overall respiratory health. Understanding the detailed anatomy and physiology of the nasopharynx is essential for medical professionals, particularly those specializing in otolaryngology and respiratory medicine, as it informs the diagnosis and treatment of various conditions affecting the upper airway.[32]

Oropharynx

The oropharynx is the middle portion of the pharynx, extending from the soft palate to the level of the hyoid bone. This anatomical region serves as a crucial conduit for both air and food, directing air to the larynx and trachea while guiding food and liquids to the esophagus. The oropharynx plays a significant role in the respiratory and digestive systems, and its anatomical features and structures are essential for various physiological functions. The oropharynx is lined with a stratified squamous epithelium, which is more resilient to mechanical stress and abrasion than the ciliated pseudostratified columnar epithelium found in the nasopharynx. This adaptation is crucial because the oropharynx handles the passage of food and liquids, which can cause more wear and tear compared to air alone. The oropharynx begins at the level of the soft palate and extends inferiorly to the level of the hyoid bone, which is located in the anterior neck just above the larynx.

The soft palate forms the superior boundary of the oropharynx. During swallowing, the soft palate elevates to close off the nasopharynx, preventing food and liquids from entering the nasal cavity. This action is coordinated with the movements of other muscles in the pharynx and larynx to ensure that swallowed material is directed properly into the Esophagus. The anterior boundary of the oropharynx is

formed by the oral cavity, with the isthmus of the fauces acting as the transitional area between the oral cavity and the oropharynx. This region includes the palatoglossal arches (anterior pillars) and the palatopharyngeal arches (posterior pillars). The palatine tonsils are situated between these arches, occupying the tonsillar fossae on either side of the oropharynx. The palatine tonsils are large masses of lymphoid tissue that play a vital role in the immune response by trapping and neutralizing pathogens that enter through the mouth and nose.[33]

The lateral walls of the oropharynx contain additional lymphoid tissue known as the lingual tonsils, located at the base of the tongue. These tonsils, along with the palatine tonsils and other lymphoid tissues in the region (including the adenoids in the nasopharynx), form Waldeyer's ring, a ring of lymphoid tissue that serves as a first line of defence against ingested or inhaled pathogens. The posterior boundary of the oropharynx is formed by the pharyngeal wall, which is composed of several layers, including the mucosa, submucosa, pharyngeal muscles, and the pharyngobasilar fascia. The pharyngeal muscles, including the superior, middle, and inferior constrictor muscles, play a key role in swallowing by contracting sequentially to propel the bolus of food downward into the esophagus.

In addition to its roles in the immune response and swallowing, the oropharynx also participates in respiration. During breathing, air passes through the oropharynx on its way to the larynx and trachea. The patency of the oropharyngeal airway is maintained by the coordinated actions of various muscles, including the muscles of the tongue and the soft palate, which prevent airway collapse and obstruction. The oropharynx is richly supplied with blood from branches of the external carotid artery, including the ascending pharyngeal artery, the facial artery (via the tonsillar branch), and the lingual artery. Venous drainage is provided by the

pharyngeal venous plexus, which drains into the internal jugular vein. Lymphatic drainage from the oropharynx primarily involves the deep cervical lymph nodes, which play a key role in the immune response and the clearance of pathogens.[34]

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 superior boundary of the laryngopharynx is at the level of the hyoid bone, where it transitions from the oropharynx.

Inferior Boundary: The inferior boundary is at the lower border of the cricoid cartilage, marking the beginning of the esophagus.

Anterior Boundary: Anteriorly, the laryngopharynx is continuous with the laryngeal inlet, which leads to the larynx. The epiglottis, a crucial structure within the laryngopharynx, is located here.

Posterior Boundary: The posterior wall of the laryngopharynx is formed by the prevertebral fascia and muscles of the vertebral column.

Lateral Boundaries: The lateral walls are composed of the pharyngeal constrictor muscles and are adjacent to the thyroid cartilage.[35]

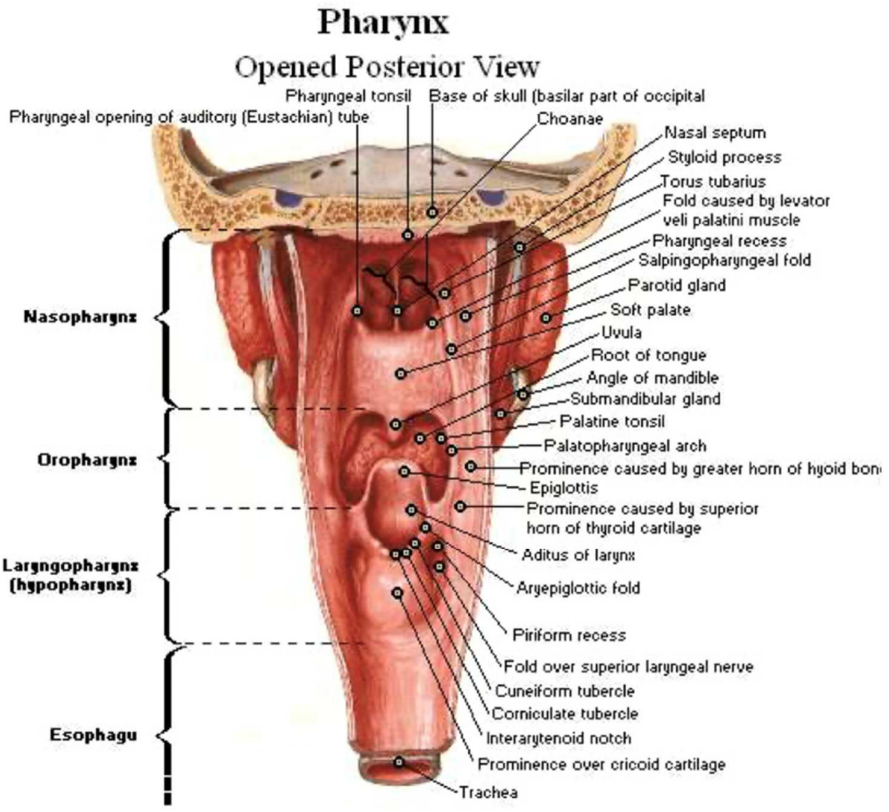


Figure 2: Opened Posterior View of Pharynx

Lining and Mucosa

The laryngopharynx is lined with stratified squamous epithelium, which provides resistance to the mechanical stress and abrasion caused by the passage of food and liquids. This epithelium also offers some protection against pathogens and physical damage. The muscular structure of the laryngopharynx is composed of the inferior pharyngeal constrictor muscle, which plays a key role in the swallowing mechanism. This muscle has two parts. (a) Thyropharyngeal part arises from the oblique line of the thyroid cartilage and the lateral surface of the cricothyroid muscle. (b) Cricopharyngeal part arises from the lateral surface of the cricoid cartilage. This part forms the cricopharyngeal muscle or upper esophageal sphincter (UES), which is essential in preventing air from entering the esophagus during respiration and

preventing reflux of esophageal contents. During swallowing, these muscles contract sequentially to propel the bolus of food downward into the esophagus while protecting the airway.[36]

Muscles of Pharynx

The muscles in the wall of the pharynx consist of the superior, middle, and inferior constrictor muscles, whose fibers run in a somewhat circular direction, and the stylopharyngeus and salpingopharyngeus muscles, whose fibers run in a somewhat longitudinal direction. The three constrictor muscles extend around the pharyngeal wall to be inserted into a fibrous band or raphe that extends from the pharyngeal tubercle on the basilar part of the occipital bone of the skull down to the esophagus. The three constrictor muscles overlap each other so that the middle constrictor lies on the outside of the lower part of the superior constrictor and the inferior constrictor lies outside the lower part of the middle constrictor.

The lower part of the inferior constrictor, which arises from the cricoid cartilage, is called the cricopharyngeus muscle. The fibers of the cricopharyngeus pass horizontally around the lowest and narrowest part of the pharynx and act as a sphincter. Killian's dehiscence is the area on the posterior pharyngeal wall between the upper propulsive part of the inferior constrictor and the lower sphincteric part, the cricopharyngeus.[37]

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

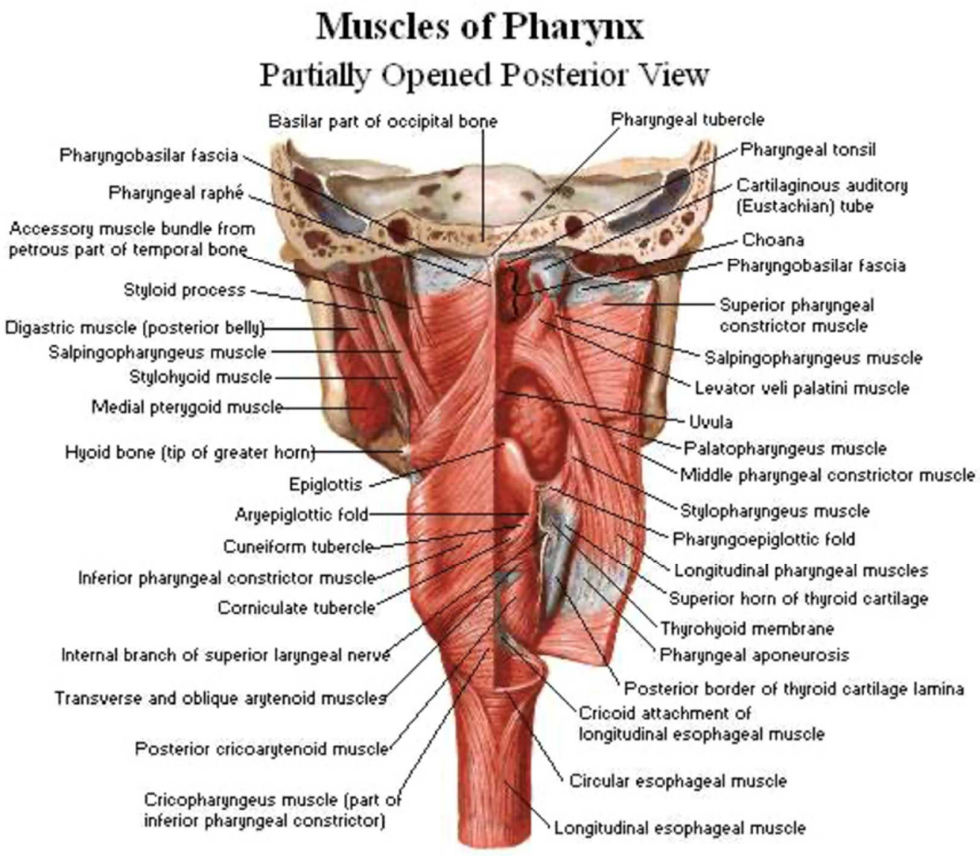


Figure 3: Muscles of Pharynx

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.

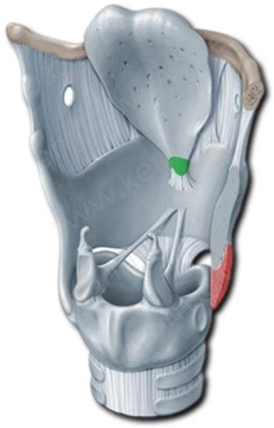


Figure 4: Epiglottis

Recesses

Two important anatomical features of the laryngopharynx are the piriform recesses (or fossae). These are depressions located on either side of the laryngeal inlet. They serve as pathways that guide food and liquids around the laryngeal opening and into the esophagus. The piriform recesses are clinically significant because they are common sites where foreign bodies can become lodged, leading to dysphagia or aspiration.[38]

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

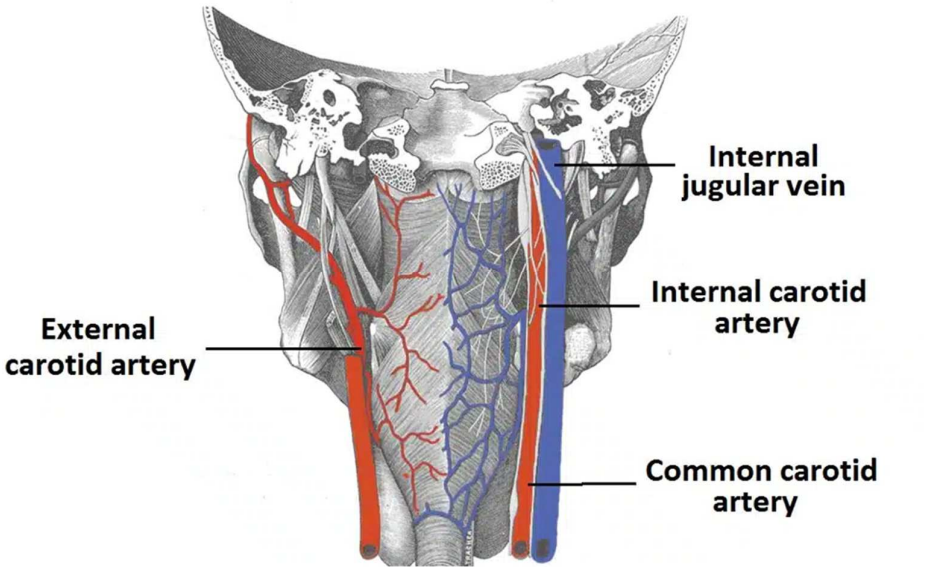


Figure 5: Blood Supply of Pharynx

Lymph Drainage of the Pharynx

- Directly into the deep cervical lymph nodes or indirectly via the retropharyngeal or paratracheal nodes into the deep cervical nodes

Waldeyer's Ring of Lymphoid Tissue

The lymphoid tissue that surrounds the opening into the respiratory and digestive systems forms a ring. The lateral part of the ring is formed by the palatine tonsils and tubal tonsils (lymphoid tissue around the opening of the auditory tube in the lateral wall of the nasopharynx). The pharyngeal tonsil in the roof of the nasopharynx forms the upper part, and the lingual tonsil on the posterior third of the tongue forms the lower part.[39]

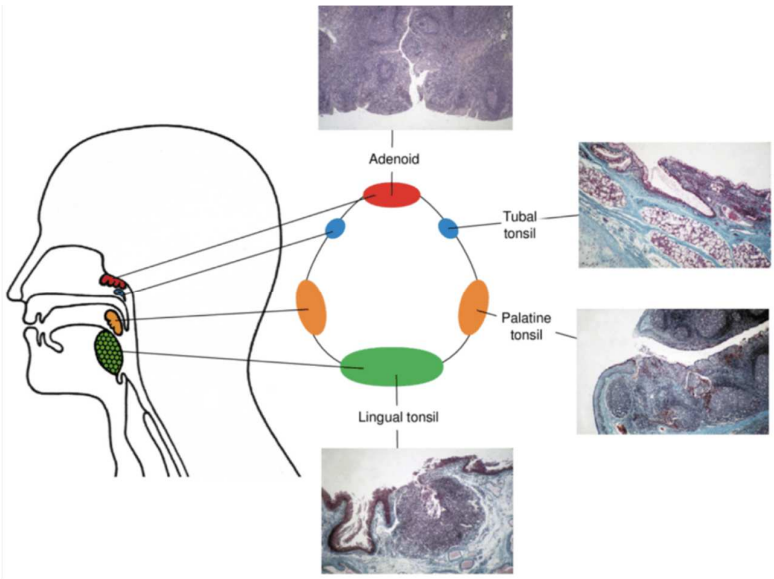


Figure 6: Waldeyer's Ring.

Larynx

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.

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.

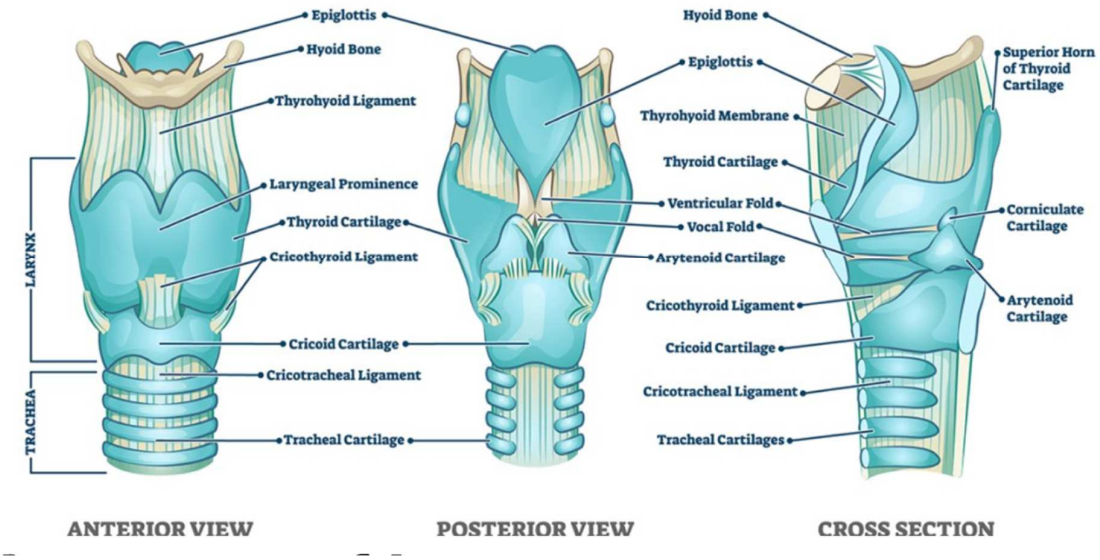


Figure 7: Anatomical Components of Larynx

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.[40]

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.[41]

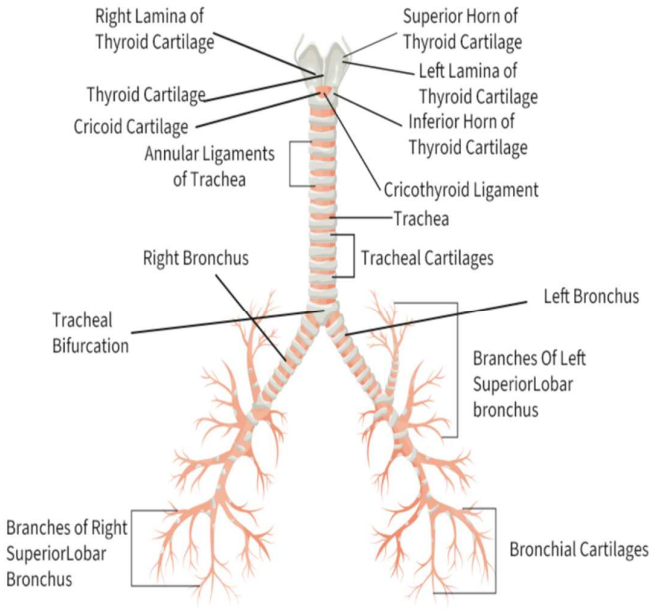


Figure 8: Anatomy of Trachea, Bronchi and Bronchioles.

PEDIATRIC AIRWAY

The airway extends from the external nares to the junction of the larynx with the trachea. It includes the nose, the paranasal sinuses, the pharynx and the larynx. Functions of the airway include phonation, olfaction, digestion, humidification and warming of inspired air. The pediatric airway differs from the adult airway particularly in infancy, with differences becoming much less marked as the child grows older.

Anatomy

The skull develops from a membranous and cartilaginous neurocranium. The membranous neurocranium gives rise to the flat bones of the skull (the cranial vault) and the cartilaginous neurocranium (chondrocranium) forms the skull base. The shaping of the skull base is a dynamic process involving reciprocal influences between the cranial base, the pharynx, the face and the palate. In the fetus, the rapid

growth of the brain leads to a predominance of neural influences; whilst in the neonate and young child, nasal influences play a major role. Later, because of changing nutri- tional requirements and the development of speech, the pharynx also influences the development of the skull base. Children have a proportionally larger head and occiput relative to body size. This causes neck flexion, leading to potential airway obstruction when lying supine.

Nose

The nose originates in the cranial ectoderm and is composed of the external nose and the nasal cavity. The external nose is made up of the nasal bones, the nasal part of the frontal bones and the frontal processes of the maxillae. The nasal cavity is subdi- vided by the nasal septum into two separate com- partments that open to the exterior via the nares and into the nasopharynx via the choanae or posterior

nasal apertures. Immediately within the nares lies the vestibule, which contains an area of arterial anastomosis known as Little's area. Epistaxis commonly occurs from this zone. The sensory innervation of the nasal mucosa is via the maxillary division of the trigeminal nerve.

During development, the nasal cavities extend under the influence of the posteriorly directed fusion of the palatal processes. These changes cause the membrane that separates the palatal processes from the oral cavity to become progressively thinner and eventually rupture to form the choanae or posterior nasal apertures. Failure of this membrane to rupture results in choanal atresia. In a child, the nose is soft and distensible, with relatively more mucosa and lymphoid tissue than in the adult. Deviation of the nasal septum occurs in all ages of children and may be the result of nasal injury or irregular development of the nasomaxillary complex. Racial differences in the dimensions of the nasal cavity have also been described.

Each side of the nose has a roof, a floor, a medial wall and a lateral wall. The roof slopes upwards and backwards to form the bridge of the nose, with the floor being concave from side to side. The medial wall is the nasal septum and the lateral wall has a bony framework which includes three scroll-like conchae or turbinate bones. The major nasal air passage lies beneath the inferior turbinate, and during nasal intubation the endotracheal tube should be encouraged to follow this route by passing it directly backwards along the floor of the nose. The posterior end of the inferior turbinate may occasion- ally be hypertrophied, resulting in resistance to the passage of the tube.

Nasal breathing increases the resistance to air- flow. In children, the smaller nasal apertures are easily obstructed by secretions, edema or blood. As infants are obligate nasal breathers, such conditions may increase the work of breathing, and similarly contribute to difficulties with management of the airway under general anesthesia.

Pharynx

The pharynx forms the common upper pathway of the respiratory and alimentary tracts. It is in free communication with the nasal cavity, the mouth and the larynx, forming the nasopharynx, oropharynx and laryngopharynx, respectively.

Nasopharynx

The nasopharynx lies behind the nasal cavity and above the soft palate. It communicates with the oropharynx via the pharyngeal isthmus, which becomes closed off during the act of swallowing. Its sensory innervation is derived from the trigem- inal nerve and the glossopharyngeal nerve. During development, the depth of the nasopharynx increases as a result of remodelling of the palate as well as changes

in angulation of the skull base, eventually producing an enlarged nasal airway in the adult. The pharyngeal opening of the pharyngotympanic (Eustachian) tube lies on the lateral wall of the nasopharynx. The nasopharyngeal tonsils (adenoids) lie on the roof and posterior wall of the nasopharynx in children. Although these atrophy with age, enlargement in early childhood may obstruct breathing through the nose. Nasopharyngeal tonsils may also become dislodged during instrumentation of the nose.

Oropharynx

The oropharynx extends from the soft palate to the tip of the epiglottis. It is attached anteriorly to the base of the tongue via the glossoepiglottic folds. Between these folds lie the valleculae. The sensory innervation of the oropharynx is derived from the glossopharyngeal nerve and the superior laryngeal branch of the vagus nerve, which transmits afferent impulses from the base of the tongue and the valleculae. The reflex circulatory responses to direct laryngoscopy and tracheal intubation result largely from stimulation of the pharyngeal wall by the laryngoscope blade. A smaller additional response is produced by the passage of an endotracheal tube through the vocal cords.

At the entrance to the oropharynx is a collection of lymphoid tissue known as Waldeyer's ring. This consists of the lingual tonsil at the base of the tongue and bilateral palatine tonsils. The nasopharyngeal and tubal tonsils also form part of this ring. Inflammation of these lymphoid tissues may obstruct breathing efforts in conscious patients and may make laryngoscopy difficult because of an increase in size of the tissue or associated masseter spasm. Gender and ethnic variations in the dimensions of the oropharynx have been demonstrated, together with a relationship

between oropharyngeal dimensions and sleep disordered breathing. Tonsillar asymmetry has been reported to occur in the absence of pathology in some children.

The relatively large tongue decreases the size of the oral cavity in children and more easily obstructs the airway. Decreased muscle tone also contributes to passive obstruction of the airway by the tongue. In infants lying supine, the tongue tends to flatten out against the soft palate in inspiration and may remain in the same position for the passive expiration through the nose. Extension of the head at the atlantooccipital joint, with anterior displacement of the cervical spine, may result in improved hypopharyngeal airway patency but does not necessarily change the position of the tongue.

Laryngopharynx

The laryngopharynx extends from the tip of the epiglottis to the lower border of the cricoid cartilage. The larynx bulges back into the center of the laryngopharynx, leaving a recess on either side, known as the piriform fossa. This is a common site for impaction of swallowed sharp foreign bodies.

Larynx

The larynx is situated between the pharynx and trachea, extending from the base of the tongue to the cricoid cartilage. It is the organ of phonation and protects the tracheobronchial tree during swallowing and coughing. The development of the respiratory system begins at approximately 3 weeks of gestational age, with the formation of the laryngotracheal tube from the ventral wall of the foregut. A definite larynx can usually be identified by 41 days gestation. The cricoid and thyroid cartilages begin chondrification at about 7 weeks of gestation. The primitive glottis is formed at 10 weeks gestation when the true vocal cords split. Failure of this pro- cess results in a congenital laryngeal web, or in some cases, congenital atresia of the

larynx. Incomplete division of the embryonic foregut into the anteriorly positioned trachea and the posteriorly positioned esophagus results in tracheo-oesophageal fistula.

The larynx consists of the thyroid cartilage, the cricoid cartilage, the paired arytenoids and the epiglottis, together with the small corniculate and cuneiform cartilages. These form a framework of articulating cartilages linked together by ligaments, which move in relation to each other by the action of the laryngeal muscles. The largest of these cartilages is the thyroid cartilage, which is open posteriorly and forms the laryngeal prominence (Adam's apple) anteriorly. Beneath the thyroid cartilage is the cricoid cartilage, in the shape of a signet ring with the widest portion lying posteriorly. This is the only complete cartilage ring found in the respiratory tract. At birth, the lower border of the cricoid cartilage lies opposite the lower border of the fourth cervical vertebra. At 6 years of age it is at the level of the fifth cervical vertebra and in the adult it lies at the level of the sixth cervical vertebra. Because of the small size of the cricoid cartilage in children, and the fact that it is a complete ring, the presence of mucosal edema at this site will severely compromise the airway. Young children are also at risk of acquired subglottic stenosis when exposed to prolonged or repeated tracheal intubation.

The paired arytenoid cartilages articulate at the posterosuperior aspect of the cricoid cartilage. Each arytenoid has an anterior process, the vocal process, to which the vocal ligament is attached. At the apex of each arytenoid lies a triangular corniculate cartilage, attached by a perichondrium. The vestibular folds, or false cords, are created by the mucosa that covers the thyroarytenoid muscles. The true vocal cords are the vocal folds covered by mucosa. Reflex adduction of the true and false cords is known as laryngospasm and may result from local stimulation of the

larynx, or from surgical stimulation in the absence of adequate anesthesia. The cricothyroid membrane is a tough, elastic connective tissue sheet that spans the joint between the inferior process of the thyroid cartilage and the cricoid cartilage. Puncture or incision of this membrane allows the creation of a surgical airway when acute airway obstruction occurs at or above the larynx.

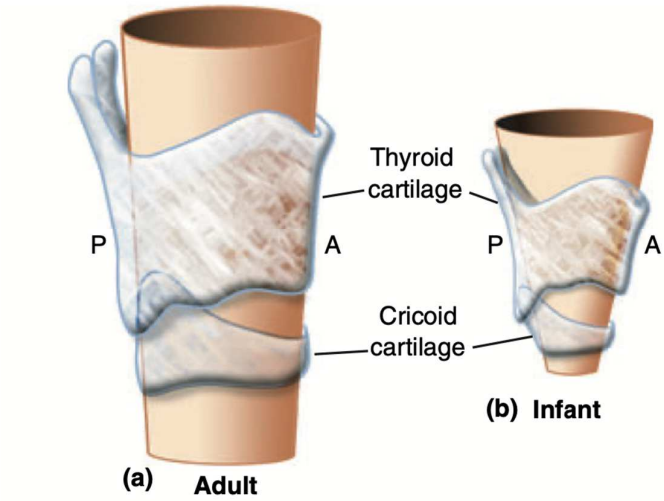


Figure 9: Configuration of larynx in adult and infant

The epiglottis is a leaf-shaped structure attached to the posterior border of the thyroid cartilage by the thyroepiglottic ligament. In the adult, the epiglottis is broad, with its axis parallel to that of the trachea. The epiglottis in the infant is narrower, softer and more horizontally positioned than in the adult. The straight laryngoscope blade facilitates lifting of the epiglottis and is therefore useful during tracheal intubation in younger children. At laryngoscopy, the epiglottis in the neonate appears more deeply furrowed at its free end, and in some babies, it has a V-shaped appearance. By the age of 4 or 5 years, the epiglottis is usually firm enough to allow

visualization of the vocal cords using a curved laryngoscope blade. The cuneiform cartilages lie anterior to the corniculate cartilages, in the aryepiglottic folds.

The more superior location of the larynx in children may create difficulty in visualizing laryngeal structures because of the more acute angulation between the base of the tongue and the laryngeal opening. During laryngoscopy, a neck or shoulder roll will relieve the hyperflexion of the infant's neck caused by the relatively large occiput.

The nerve supply to the larynx is from the vagus nerve, via its superior and recurrent laryngeal branches. The superior laryngeal nerve gives rise to an internal laryngeal branch which runs beneath the mucosa of the piriform fossa. In this position, it is easily blocked by the topical application of a local anesthetic agent to provide anesthesia for laryngoscopy and bronchoscopy. The laryngeal inlet and the inferior surface of the epiglottis are innervated by the vagus nerve. When the epiglottis is lifted with a straight laryngoscope blade, bradycardia and hypotension may occur as a result of a vagal reflex. When a curved blade is used, the tip is placed in the angle between the epiglottis and the base of the tongue. This theoretically reduces the risk of brady- cardia because the superior surface of the epiglottis and the valleculae are innervated by the glossopharyngeal nerve. Damage to the recurrent laryngeal nerve results in paralysis of the corresponding vocal cord, causing it to lie motionless in the midline and at a lower level than the opposite side. Bilateral paralysis results in complete loss of vocal power. The two paralyzed cords may then flap together to cause a valve-like obstruction during inspiration, producing dyspnea and inspiratory stidor.

The pediatric airway is highly compliant and the cartilaginous support is less developed than in the adult airway. This leads to increased susceptibility to dynamic airway collapse in the presence of airway obstruction. Studies have demonstrated that air- way obstruction during general anesthesia is related to a reduction in laryngeal muscle tone. Loss of muscle tone in the pharynx leads to airway obstruction at the level of the soft palate and epiglottis. Laryngomalacia is a congenital abnormality of the larynx and results from the laryngeal structures being more pliable and less rigid than in the adult.[42]

SUPRAGLOTIC AIRWAY DEVICES (SAD)

Supraglottic airways (SGAs) are a category of airway devices that can be inserted into the pharynx to facilitate ventilation, oxygenation, and the delivery of anaesthetic gases, all without the necessity of endotracheal intubation. Dr. Charlie Brain first invented the inflatable cuffed laryngeal mask in the early 1980s and, since then, many relatively new SADs have been described. In anaesthesia, these devices serve multiple purposes, including as the primary method for airway management, as a backup option for ventilation when facemask ventilation proves challenging, and as a means for facilitating endotracheal intubation. to enhance positive-pressure ventilation (PPV) and decrease the risk of aspiration.

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

SADs can be grouped according to two primary criteria. The first is the presence or absence of an inflatable cuff. Devices without cuffs may reduce the risk of complications related to cuff inflation but could lead to increased chances of leaks and malfunction. Another commonly used classification system distinguishes between first- generation and second-generation SADs. First-generation devices are basic airway tubes lacking specific design elements aimed at preventing the aspiration of gastric contents. Conversely, second-generation SADs incorporate specific features designed.[43]

STRUCTURE OF I-GEL

The I-GEL, developed by Intersurgical Ltd in Wokingham, U.K., is an advanced supraglottic airway device characterized by its unique design and materials. I-Gel is a supraglottic airway device designed to provide a secure and effective means of airway management in anesthesia and emergency situations. Its design eliminates the need for an inflatable cuff, relying instead on its anatomical shape and soft gel-like material to achieve an effective seal.

Non-Inflatable Cuff

The cuff is made of a soft, gel-like thermoplastic elastomer, which is designed to conform to the anatomy of the pharynx and larynx. This material provides a secure seal without the need for inflation. The cuff is anatomically shaped to fit the contours of the perilaryngeal structures, creating a snug fit around the glottis opening.

Airway Tube

The airway tube is wide and rigid enough to prevent kinking, ensuring a clear passage for ventilation. The dimensions of the tube vary according to the size of the I-Gel, which is available in different sizes to accommodate patients from neonates to large adults. The epiglottic rest is a small, raised ridge at the proximal end of the I-Gel

that helps to lift the epiglottis away from the glottis, ensuring that the airway remains open.

Integral Bite Block

An integral bite block is incorporated into the airway tube to prevent occlusion of the airway by the patient's teeth. This feature ensures continuous airflow even if the patient bites down on the device.

Gastric Channel

The I-Gel includes a gastric channel that runs parallel to the airway tube. This channel allows for the insertion of a gastric tube, providing a means to decompress the stomach and reduce the risk of aspiration. The gastric channel facilitates the venting of gas and drainage of gastric contents, enhancing patient safety during anesthesia.

Proximal End

The proximal end of the I-Gel is equipped with a standard 15mm connector that allows it to be attached to various breathing systems and ventilation devices. The connector is color-coded to indicate the size of the I-Gel, making it easy to identify and select the appropriate device for each patient.

Distal Tip

The distal tip is rounded and soft to minimize the risk of trauma during insertion. It is designed to sit just above the esophageal opening, helping to direct air into the trachea while reducing the risk of aspiration. The drain tube provides an additional channel for fluid drainage, further reducing the risk of aspiration and ensuring that the airway remains clear.[44]

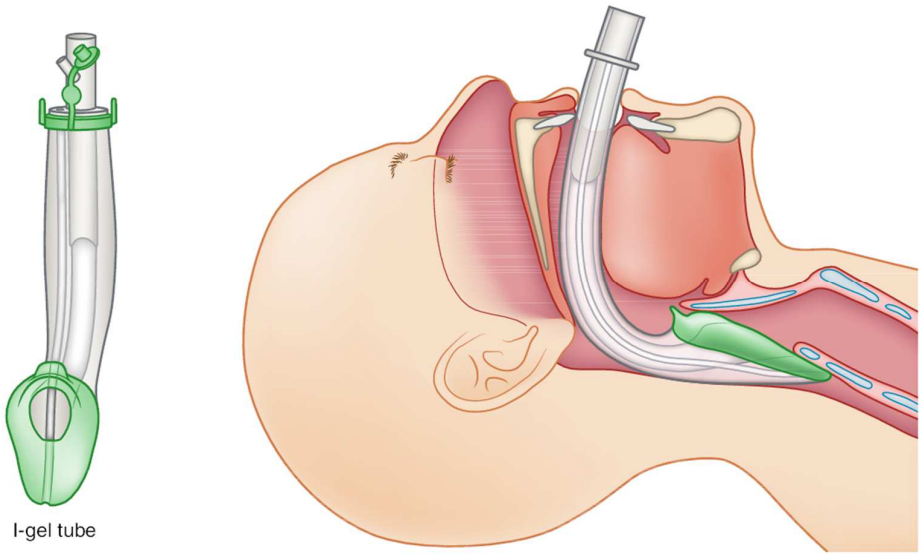


Figure 10: - I- Gel and its insertion

Mechanism of I-Gel Insertion

The I-Gel is anatomically designed to fit snugly over the laryngeal inlet, creating an effective seal without the need for an inflatable cuff. Its key features that enable this conformation include;

Non-Inflatable Cuff:

Made of a soft, gel-like thermoplastic elastomer, the cuff conforms to the perilaryngeal structures, including the base of the tongue, the piriform fossae, and the arytenoids. The gel material adapts to the anatomical contours, providing a seal that minimizes air leakage and reduces the risk of trauma.

Epiglottic Rest

Positioned at the proximal end of the I-Gel, the epiglottic rest helps lift the epiglottis away from the glottis, ensuring that the airway remains open and unobstructed.

Gastric Channel

The integrated gastric channel runs parallel to the airway tube, allowing for the insertion of a gastric tube to decompress the stomach and reduce the risk of aspiration. The I-Gel's design allows it to fit securely around the laryngeal inlet, with the distal tip sitting just above the esophageal opening. This positioning ensures that air is directed into the trachea while minimizing the risk of regurgitation and aspiration.

A thorough pre-insertion assessment is essential to identify potential difficulties in airway management. This includes checking for anatomical variations, obstructions, or conditions that may affect the insertion of the I-Gel. Proper preparation involves selecting the appropriate size of I-Gel based on the patient's weight and lubricating the back, sides, and front of the cuff to facilitate smooth insertion. During insertion, the patient's head should be positioned in a sniffing position (neck flexed, head extended) to align the oral, pharyngeal, and laryngeal axes. The I-Gel should be held at the proximal end, ensuring the distal tip is oriented correctly, and gently inserted into the mouth, following the curvature of the airway until resistance is felt, indicating proper seating over the laryngeal inlet. Verification of correct placement includes assessing bilateral chest rise, auscultating for breath sounds, and using capnography to ensure effective ventilation. Securing the I-Gel in place prevents displacement during the procedure. Continuous post-insertion monitoring is crucial to detect signs of airway obstruction, inadequate ventilation, or device displacement, and to ensure the gastric channel remains patent if used.[51]

I-gel is available in seven sizes, with three adult and four pediatric sizes in range, ideal for use with patient weights between 2-90+ kgs.[45]

Figure 11: - I-gel of different sizes

Size Recommendation	Weight Range
Size 5	90+ kg
Size 4	50-90 kg
Size 3	30-60 kg
Size 2.5	25-35 kg
Size 2.0	10-25 kg
Size 1.5	5-12 kg
Size 1.0	2-5 kg

POSITIVE END EXPIRATORY PRESSURE

Positive end-expiratory pressure (PEEP) has been used during mechanical ventilation for decades, and it was first described by Ashbaugh and colleagues when they noted the benefits of PEEP in patients with acute respiratory distress syndrome (ARDS)

PEEP ensures that the pressure in the alveoli is higher than atmospheric pressure, and this creates a positive baseline pressure. PEEP can be further defined as extrinsic or intrinsic. This review will focus on extrinsic PEEP, which is a ventilator setting that is controlled by the operator. Intrinsic PEEP, or auto-PEEP, is most commonly associated with inadequate expiratory times, collapse of small airways, or increased airway resistance. This may be due to a small endotracheal tube, bronchospasm, or accumulation of secretions

Functional residual capacity (FRC) is the volume of air remaining in the lungs after a normal expiration and is an important oxygen reserve that allows for continued gas exchange. Reduced FRC results in less alveolar tension pulling airways open, and subsequently, airway narrowing or collapse and increased airway resistance. FRC is decreased by many factors important to mechanically ventilated patients including lung compliance, patient position, and anesthesia/drugs. Mechanically ventilated patients with pulmonary disease, including ARDS, will have decreased lung compliance which contributes to a decrease in FRC. Additionally, mechanically ventilated patients are maintained in a supine position which

also decrease FRC. Finally, anesthetic drugs and sedatives decrease the tone of respiratory muscles, further contributing to a decrease in FRC.

The primary goals of PEEP are to restore FRC through: (1) recruitment of alveoli, which decreases intrapulmonary shunting, and (2) prevention of alveolar collapse, which may occur due to surfactant impairment, increased lung weight, and chest wall recoil. Clinically, the goal is to improve arterial oxygenation. When PEEP is applied, the end expiratory lung volume (EELV) increases, which is predominately due to the recruitment of collapsed alveoli. An increased EELV leads to decreased lung strain and improved compliance, ultimately contributing to a decrease in DP.

Through these mechanisms, PEEP improves arterial oxygenation and may reduce the risk of ventilator-induced lung injury (VILI) by reducing atelectrauma resulting from the cyclic opening and closing of alveoli, preventing alveolar flooding, and reducing lung heterogeneity. Alveolar recruitment also reduces lung strain and improves lung compliance in both humans and dogs. In a study of healthy, mechanically ventilated dogs, the addition of 5mmHg PEEP improved compliance and decreased DP. In addition, PEEP reduced global and regional dynamic lung strain, but it also increased static strain. Dynamic lung strain has been shown to be more injurious than static lung strain, so the addition of PEEP may be considered beneficial based on research.[46]

MATERIALS AND METHODS

The present study titled "**To compare leak volume with and without the application of positive end- expiratory pressure with I-gel based general anaesthesia in pediatric patients - a one year randomised control trial"** was conducted at KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nahar, Belagavi.

Type of study: One year randomized control trial.

Duration of study and study population: After having met the inclusion and exclusion criteria, and informed consent obtained, pediatric patients aged two to twelve years of either gender, belonging to ASA grade I or II, scheduled for surgery under GA between March 2023 and February 2024 at KLE's Dr. Prabhakar Kore Hospital and Medical Research

Centre, Nehru Nagar, Belagavi. (Data Collection-12 Months)

Sampling technique: A one year randomized control trial. Unbiased distribution was achieved by computer generated randomized chart.

Inclusion Criteria

- Age : 2-12 years
- ASA - I ,II
- Elective surgeries

Exclusion Criteria

- Airway deformities
- Risk of aspiration
- Preoperative sore throat or URTI

Sample Size Calculation

The minimum sample size formula based on two proportions is

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

p where p1 and 2 are the proportions of the

two groups

p=p1+p2 and d=p1−p2

zα is linked with the level of significance and zβ is linked with the power of the test. For 5% level of the significance zα = 1.96 and zβ = 0.84 for 80% power of the test. Ref: “A comparison of supraglottic airway I-gel vs classic laryngeal mask airway in small children by author Ju-Hyun Lee.”

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

With proportion of success, p1 = 81% and P2 = 100% the sample size obtained was 32.

Sample size was calculated with 95% confidence interval, with 90% power.

For more definitive outcomes, the sample size was raised to 35

Hence, resulted in two cohorts with total size of 70.

METHODOLOGY

After obtaining institutional ethical committee clearance, and registration in Clinical Trials Registry of India (CTRI/2024/07/070072), children aged between 2 and 12 who were posted for elective procedures done under general anesthesia were included in the study with their informed consent.

After having met the inclusion and exclusion criteria, a thorough pre anaesthetic evaluation was done on the day before surgery and patients were advised for adequate hours of nil per mouth as per the ASA guidelines.

After confirming nil-by-mouth status, children were premedicated with Inj. Glycopyrolate 0.004mg/kg body weight & Inj. Ketamine 5 mg/kg body weight IM to overcome parental separation anxiety.

Patients were then shifted inside the operating room, intravenous access was secured, and standard monitoring devices were attached, which included NIBP, HR, ECG, and SpO^2.

Pre- oxygenation for 3 mins was done with paediatric closed circuit using appropriate flow with head resting on a head ring. Anaesthesia was induced with Inj. Propofol 2mg/kg body weight & Inj. Fentanyl 2mcg/kg body weight IV, with Isoflurane in incremental doses.

After obtaining adequate depth of anaesthesia, I-gel of appropriate size as per manufacturer recommendation was inserted, fixed and connected to pressure controlled mode (PCV mode).

The patients were then divided into two groups—

Group A: PEEP of 5cm of H2O applied to PCV,

Group B: no PEEP was applied to PCV

The patients were monitored throughout the procedure.

The following parameters were assessed

1. Inspiratory tidal volume
2. Expiratory tidal volume
3. Leak volume
4. Leak fraction
5. End tidal CO2
6. Peak inspiratory pressure

During different time intervals, leak in both cohorts was observed by calculating leak volume, and from the measured inspiratory and expiratory volumes, leak fraction was calculated. Leak volume is defined as the difference between inspiratory and expiratory tidal volumes, and leak fraction is calculated by dividing the leak volume by total inspiratory tidal volume. EtCO2 and peak inspiratory pressure were also noted.

Vitals were noted and recorded.

At the end of the procedure, I-gel was removed after adequate verbal response, and patients were shifted to recovery for post-op monitoring.

Data analysis table:

		With PEEP	Without PEEP
Inspiratory tidal volume (ml)	**5 min**		
	30 min		
	1 h		
Expiratory tidal volume (ml)	**5 min**		
	30 min		
	1 h		
Leak volume	**5 min**		
	30 min		
	1 h		
Leak fraction	**5 min**		
	30 min		
	1 h		
End tidal CO2 (mmHg)	**5 min**		
	30 min		
	1 h		
Peak inspiratory pressure (PIP) cm H2O	**5 min**		
	30 min		
	1 h		

Statistical analysis:

This study was focused on comparison of two groups. For the continuous quantitative variables, mean and standard deviation were calculated. The inter group sequential variables were compared using suitable tools of statistics like unpaired student's t test. Two quantitative variables, within a group, were compared using student's paired t test.

The categorical data were expressed in terms of rates, ratios and percentages. The association between the outcome, clinical and demographic characteristics were tested using Chi-square test or Fisher's exact test.

Discrete variables were represented by median.

Nonparametric tests were used for correlating discrete variables.

Appropriate graphs were used to depict the comparison.

For all the tests the value of p less than 5% (0.05) was considered significant.

RESULTS

This study entitled “to compare leak volume with and without the application of positive end- expiratory pressure with I-gel based general anaesthesia in pediatric patients” was conducted in KLE’s Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, India. Patients were divided into two groups, and all data was collected & entered into Microsoft excel sheet according to their parameters in their respective groups. Tabulation of the results as per the respective parameters/variables of the study was statistically analysed using SPSS 22.

The autonomous Student "t" test was used to evaluate the mean values of the two cohorts as an intergroup comparison. Comparison of mean values at more than two repeated intervals was analyzed using repeated ANOVA test.

TABLE 1: MEAN AGE OF STUDY SUBJECTS IN EITHER GROUPS

MEAN AGE	**Group A (n = 35)**	**Group B (n = 35)**	**P - VALUE**
MEAN ± S.D	7.23 ± 4.00	8.28 ± 3.78	**0.129834**

The t-value is -1.13667. The p-value is .129834. The result is not significant at p < .05.

The Mean ± S.D age of study subjects in Group A & B was 7.23 ± 4.0 & 8.28 ± 3.78 years respectively, which was found to be statistically significant. (p<0.05)

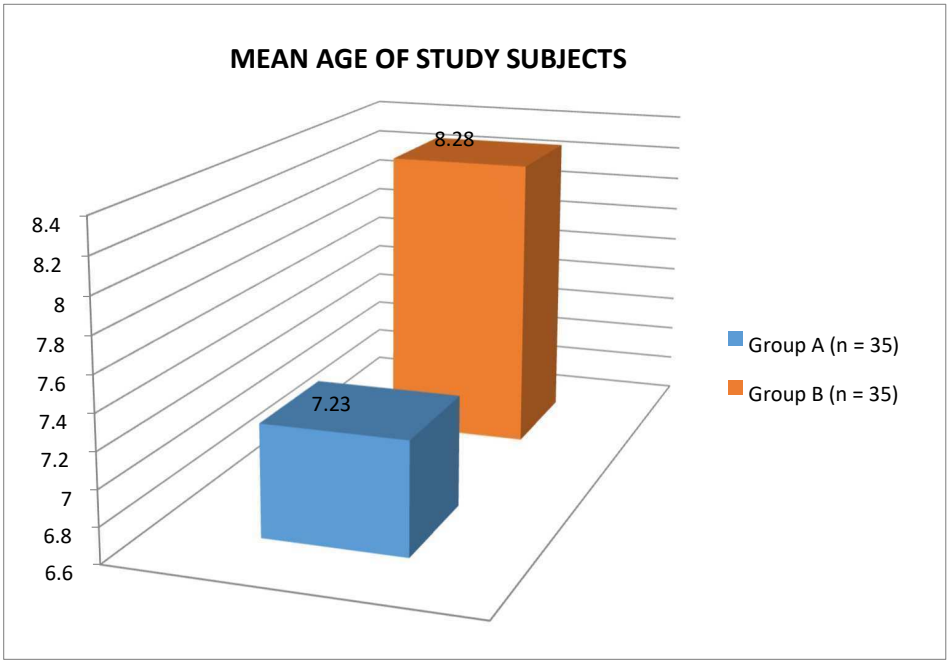


TABLE 2: INSPIRATORY VOLUME

TIME INTERVALS	Group A (n = 35)	Group B (n = 35)	P - VALUE
5 MINS	162.8 ± 86.20	160.57 ± 84.57	**0.456692**
30 MINS	162.91 ± 86.08	160.45 ± 84.53	**0.452225**
60 MINS	162.89 ± 86.09	160.54 ± 84.56	**0.454448**
P - VALUE	**0.511**	**0.373224**	

Significant if $p < .05$

The mean inspiratory volume in group A at 5, 30 & 60 mins time interval was

162.8, 162.91 & 162.89, which was statistically insignificant. ($p<0.05$)

The mean inspiratory volume in group B at 5, 30 & 60 mins time interval was 160.57, 160.45 & 160.54, which was statistically insignificant. ($p<0.05$)

The mean inspiratory volume in between group A & B at 5, 30 & 60 mins time interval was always found to be statistically insignificant. ($p<0.05$)

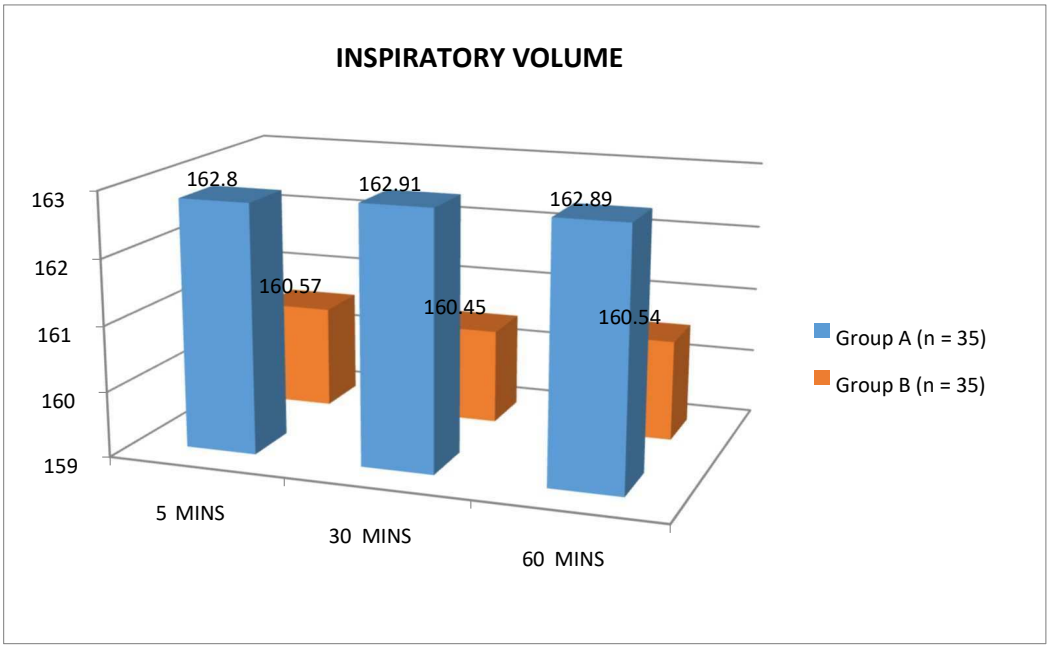


TABLE 3: EXPIRATORY VOLUME

TIME INTERVALS	Group A (n = 35)	Group B (n = 35)	P - VALUE
5 MINS	166.63 ± 85.76	164.74 ± 83.92	**0.463098**
30 MINS	167.28 ± 85.99	164.63 ± 85.04	**0.448482**
60 MINS	166.86 ± 85.86	162.23 ± 85.91	**0.411155**
P - VALUE	**0.855258**	**0.114459**	

Significant if $p < .05$

The mean expiratory volume in group A at 5, 30 & 60 mins time interval was 166.63, 167.28 & 166.86, which was statistically insignificant. ($p<0.05$).

The mean expiratory volume in group B at 5, 30 & 60 mins time interval was 164.74, 164.43 & 162.23, which was statistically insignificant. ($p<0.05$)

The mean expiratory volume in between group A & B at 5, 30 & 60 mins time interval was statistically insignificant. ($p<0.05$)

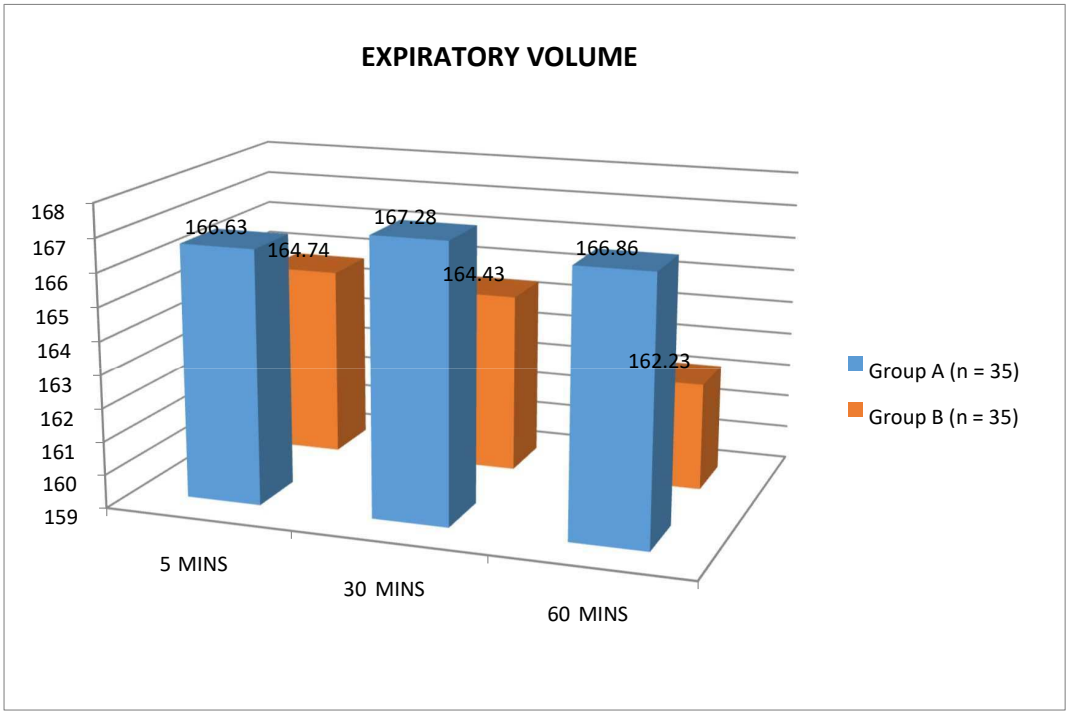


TABLE 4: LEAK VOLUME

TIME INTERVALS	Group A (n = 35)	Group B (n = 35)	P - VALUE
5 MINS	4.97 ± 4.51	5.17 ± 4.44	**0.426***
30 MINS	4.97 ± 4.51	7.14 ± 5.98	**0.045***
60 MINS	8.09 ± 6.03	7.57 ± 5.17	**0.351**
P - VALUE	**0.000106***	**0.040181***	

Significant if $p < .05$

The leak volumes at different time intervals were compared with the baseline of values within the groups.

The mean leak volume in group A at 5, 30 & 60 mins time interval was 4.97, 4.97 & 8.09, which was scientifically relevant. ($p<0.05$)

The mean leak volume in group B at 5, 30 & 60 mins time interval was 5.17, 7.14 & 7.57, which was clinically meaningful. ($p<0.05$)

The mean leak volume in between group A & B at 30 mins time interval was found to be statistically significant; however in between the groups at 5 & 60 mins time interval it was found to be statistically insignificant. ($p<0.05$)

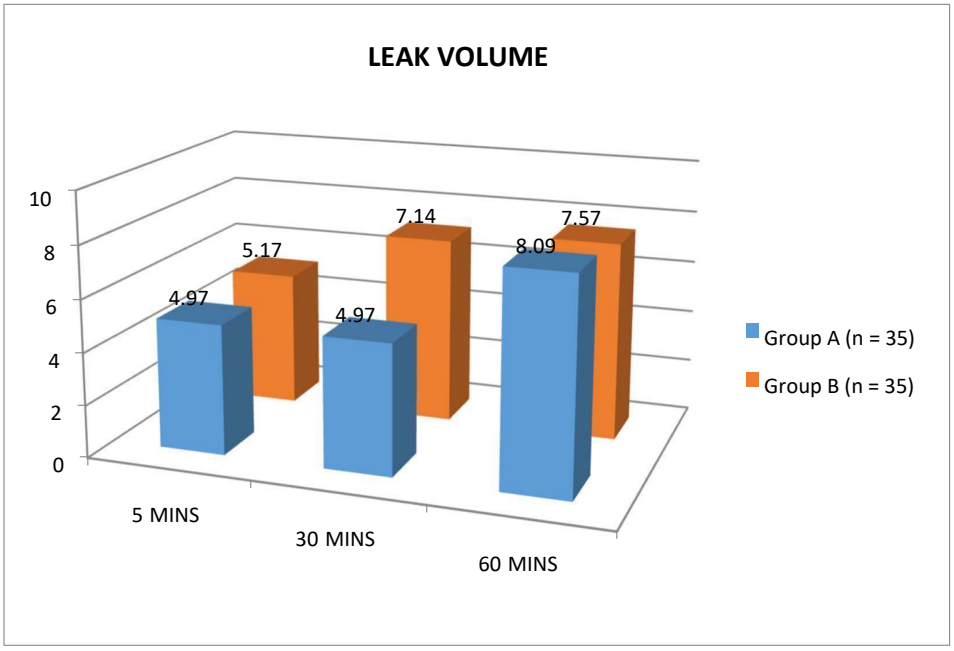


TABLE 5: LEAK FRACTION

TIME INTERVALS	Group A (n = 35)	Group B (n = 35)	P - VALUE
5 MINS	0.03 ± 0.03	0.042 ± 0.0471	**0.1211**
30 MINS	0.04 ± 0.03	0.0482 ± 0.0415	**0.37404**
60 MINS	0.05 ± 0.03	0.0509 ± 0.0416	**0.26432**
P - VALUE	**0.01536***	**0.67951**	

Significant if p < .05

The mean leak fraction in group A at 5, 30 & 60 mins time interval was 0.03, 0.04 & 0.05, which was found to be clinically relevant. ($p<0.05$)

Similarly, a comparative analysis with respect to the mean fraction in group B at 5, 30 & 60 mins time interval was found to be 0.042, 0.0482 & 0.0509, which was statistically valid. ($p<0.05$)

The mean fraction in between group A & B at 5, 30 & 60 mins time interval was found to be always statistically insignificant. ($p<0.05$)

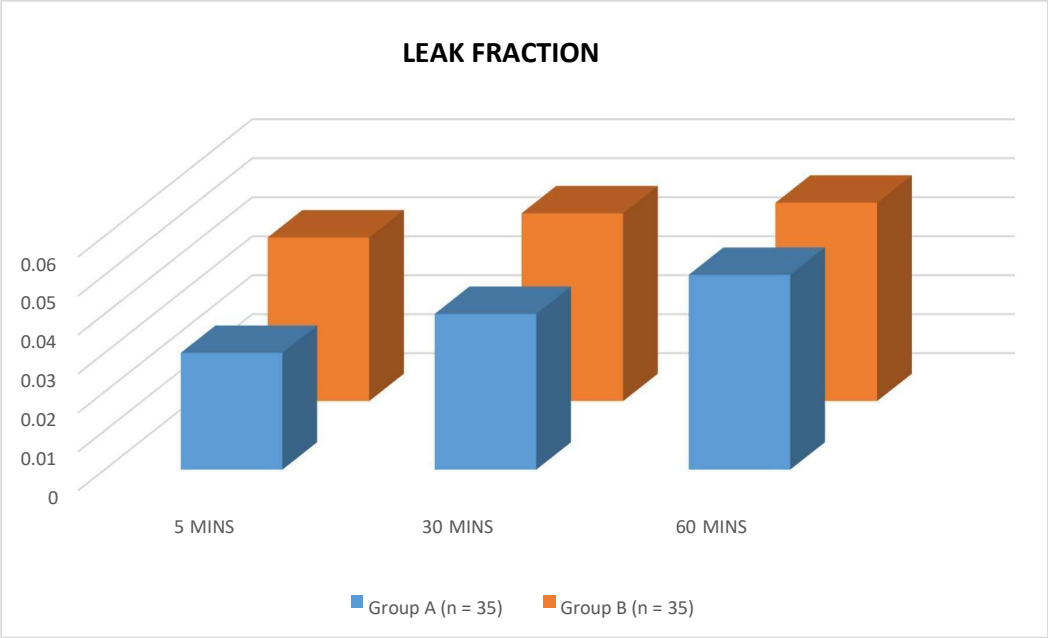


TABLE 6: PEAK INSPIRATORY PRESSURE

TIME INTERVALS	Group A (n = 35)	Group B (n = 35)	P - VALUE
5 MINS	15.03 ± 2.05	13.37 ± 1.82	**0.00032**
30 MINS	15.20 ± 1.92	13.03 ± 2.23	**0.000022**
60 MINS	15.66 ± 1.90	13.0 ± 2.14	**<0.00001**
P - VALUE	**0.001093***	**0.19651**	

The mean peak inspiratory pressure in between group A & B at 5, 30 & 60 mins time interval was statistically significant. The mean peak inspiratory volume in group A at 5, 30 & 60 mins time interval was statistically significant.

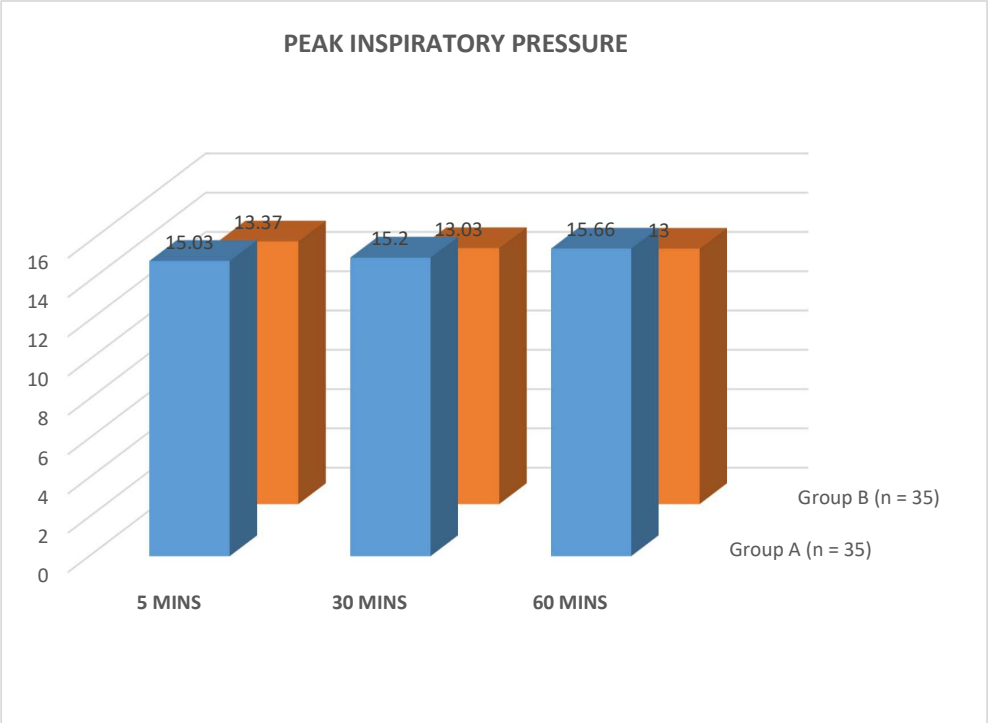
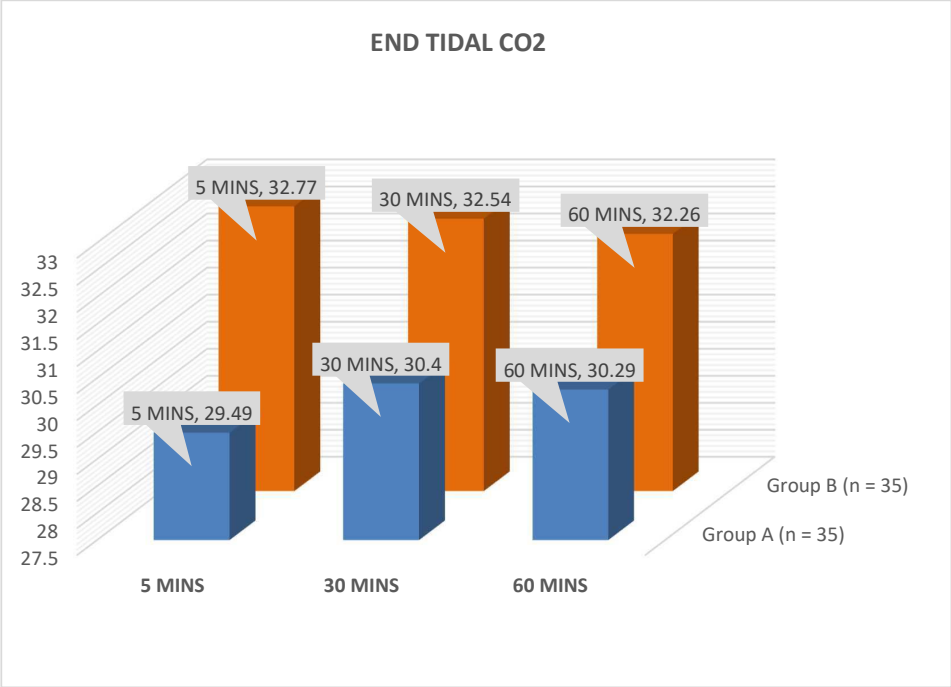


TABLE 7: END TIDAL CO2

TIME INTERVALS	Group A (n = 35)	Group B (n = 35)	P - VALUE
5 MINS	29.49 ± 4.88	32.77 ± 4.36	**0.02059**
30 MINS	30.4 ± 3.99	32.54 ± 3.64	**0.01095**
60 MINS	30.29 ± 4.04	32.26 ± 3.98	**0.02179**
P - VALUE	**0.03301**	**0.5085**	

The mean end tidal pressure in between group A & B at 5, 30 & 60 mins time interval was statistically significant. The mean end tidal pressure in group A at 5, 30 & 60 mins time interval was statistically significant.


END TIDAL CO2
5 MINS, 32.77
30 MINS, 32.54
60 MINS, 32.26
5 MINS, 29.49
30 MINS, 30.4
60 MINS, 30.29
33
32.5
32
31.5
31
30.5
30
29.5
29
28.5
28
27.5
5 MINS
30 MINS
60 MINS
Group B (n = 35)
Group A (n = 35)

DISCUSSION

Over the years, there is an abundance of research which is primarily focused on improving patient care during surgeries. The use of anesthesia remains the foremost phase of any surgical procedure, wherein anesthetic techniques are constantly improvised whilst reducing complications by means of conservative as well as non-conservative approaches.

SAD may soon take the place of tracheal tubes in pediatric GA, according to these advancements in research. SAD are recommended due to their low airway leak pressure [p-leak] and stomach inflation. To address this issue, it has been proposed to combine barometric controlled breathing with tidal volumes of 6–8 ml/kilogram.[1,11] The I-gel (Intersurgical Ltd.) is a disposable, single-use supraglottic airway device that has gained popularity in recent years.[1,8] Unlike traditional laryngeal cuffs, it is non-inflatable and made of thermoplastic rubber.[10,12]

Its symmetrical, broad, elliptical shape with a laterally flattened stem facilitates easier insertion and better stabilization during anesthesia.[8] These features are particularly beneficial for pediatric patients. The I-gel supports both positive pressure ventilation and spontaneous breathing.[1]

The application of I-gel overcomes known drawbacks of the standard LMA, which include upper airway obstruction, airway leakage, and gastric distension, which limit its usefulness in juvenile age range.[1]

Tidal volumes and positive end expiratory pressure (PEEP) help prevent the common problems of atelectasis brought on by airway closure. One of the main causes of ventilator-induced lung damage (VILI) during anesthesia has been identified as the cyclic opening and caving in of alveoli.[3] After general anesthesia,

tracheal intubation with appropriate TV and PEEP is frequently used in children to avoid alveolar and airway collapse.[1,13]

For lung recruitment and improving functional residual capacity, PEEP combined with controlled breathing has been suggested. This includes using an endotracheal tube or PLMA to rectify the ventilation/perfusion mismatch.[1]

With the exception of size 1 (without a ryles tube), studies assessing I-gels of different pediatric sizes have shown that they are an effective airway device with few complications, a high success rate, and ease of insertion.[12, 16] Size one I-gel has just made available for usage and is recommended for small babies as well as neonates weighing between two and five kilograms.[12] The intention of this research was to assess the patient risk and efficacy of I-gel in pediatric patients both while incorporating and disregarding PEEP of physiological pressure.

In our study, the Mean ± S.D age of the study subjects in Group A & B was found to be 7.23 ± 4.0 & 8.28 ± 3.78 years respectively, which was found to be statistically insignificant. ($p<0.05$) We found a very slight difference in the mean age of patients; with a slightly lesser age recorded in group A patients (approx. 1 year less).

In a similar study, carried out by Kamhawy G et al.,[1] they reported the mean age of the PEEP group study subjects as 9.76, whereas it was 9.86 amongst the non PEEP group of subjects.

The age of the patient plays a pivotal role in deciding the size of the tube required, in order to decide a correct I-gel size which has minimal leakage and discomfort to the patient, while avoiding/reducing the risk of any complications.

It is important to consider the fact that the airway passage amongst pediatric patients is comparatively small than in adults, thus requiring more attention in choosing the perfect size, even though i-gel has thermoplastic properties which helps to adapt well to the airway passage.

Without the need for a inflating cuff, I-gel is built to fit the architecture of hypopharyngeal and perilaryngeal regions; however, no adjustments were made to accommodate young patients.[1,13]

Young kids and infants are more likely to experience respiratory failure following anaesthesia due to a variety of age-related respiratory physiology characteristics. These characteristics include the size and collapsibility of the upper and lower airways, a reduced effectiveness of the pulmonary architecture, a smaller epithelial surface that can undergo gas exchange, a change in the balance between chest wall and lung compliance, and a lack of maturity of respiratory control along with certain protective responses (in the youngest children).[10]

Respiratory adverse events are a leading source of mortality and morbidity in pediatric anesthesia, accounting for up to 20% of all anesthetics.[17,18] Respiratory difficulties account for over three-quarters of critical events, and pulmonary complications, particularly laryngospasm, are directly linked to one-fourth of all anesthesia-related heart failure in young children.[10]

PEEP has been used primarily to bring in/stabilize lung unit to improve patient oxygenation.[1] According to imaging studies, PEEP prevents the development of atelectasis in dependent areas, whereas GA causes it.

Despite the widespread recognition and use of protective ventilation during GA to limit TV (6–8 ml/kg) in the OR , PEEP is still not frequently applied for subjects undergoing general anesthesia with LMA.[4]

The mean inspiratory volume in group A at 5, 30 & 60 mins time interval was 162.8, 162.91 & 162.89, whereas in group B at 5, 30 & 60 mins time interval it was 160.57, 160.45 & 160.54. Further, the mean inspiratory volume in between group A & B at 5, 30 & 60 mins time interval was also found to be statistically insignificant. ($p<0.05$). Thereby, we never recorded any significant changes across the various time intervals in within or across the groups.

In the study by Kamhawy G et al.,[1] the mean inspiratory volume at time interval of 5, 30 & 60 mins time interval was 294, 292.62 & 296.81 amongst PEEP patients, whereas in non-PEEP patients it was 253.29, 255.29 & 296.81; with either groups showing any significance; however it was significant between the groups at all time intervals.

The mean expiratory volume in group A at 5, 30 & 60 mins time interval was

166.63, 167.28 & 166.86, whereas in group B at 5, 30 & 60 mins time interval was 164.74, 164.43 & 162.23. Also, the mean expiratory volume in between group A & B at 5, 30 & 60 mins time interval always remained statistically insignificant. ($p<0.05$); similar to that observed across the mean expiratory volume.

In the study by Kamhawy G et al.,[1] the mean expiratory volume at time interval of 5, 30 & 60 mins time interval was 289.24, 287.29 & 293.09 amongst PEEP patients, whereas in non-PEEP patients it was 249.57, 249.62 & 251.48; with either groups showing any significance; however it was significant between the groups at all time intervals.

Tidal breathing, V/Q matching, and respiratory drive can all be hampered by anesthesia. Understanding the pulmonary mechanics and how it changes during anesthesia in children of different ages may help to prevent, identify, and predict any decline that could lead to respiratory failure.[10]

An important determinant of the effectiveness of SAD is leak pressure. Particular therapeutic circumstances, such as obesity as well as restrictive lung disease, can benefit from higher leak pressures.[1]

We recorded the mean leak volume in group A at 5, 30 & 60 mins time interval to be 4.97, 4.97 & 8.09, which was significant statistically. ($p<0.05$). Herein, we found an exponential increase in the leak volume after a period of 60 mins; which had remained the same at the 5 & 30 mins interval.

A similar analysis within group B showed that the mean leak volume at 5, 30 & 60 mins time interval was 5.17, 7.14 & 7.57, which was also clinically relevant. ($p<0.05$). Herein, we discovered a constant increase in mean leak volume at 30 mins time interval in comparison to the 5 min interval, which further increased at 60 mins time interval.

A comparative intergroup-analysis showed that the mean leak volume in between group A & B at only 30 mins time interval was statistically significant; whereas it remained statistically insignificant in between the groups at 5 & 60 mins of time interval. ($p<0.05$)

The mean leak volume at 30 mins in group A & B was found to be 4.97 & 7.14, which cannot be clearly understood as the difference remains high. However, it reflects the effectiveness of normal PEEP pressure in counteracting such changes

In the study by Kamhawy G et al.,[1] the leak volume at time interval of 5, 30 &

60 mins time interval was 4.76, 5.33 & 4.76 amongst PEEP patients, whereas in nonPEEP patients it was 4.09, 6.0 & 5.76; with either groups showing any significance

Nevertheless, Goyal et al.,[23] proved the efficacy of I-gel versus PLMA with respect to the leak pressure, with I-gel being proven to be more efficacious in paediatrics airway passage.

Supraglottic airway devices could be used as substitutes for endotracheal tubes following general anesthesia in children. In terms of speed as well as feasibility, I-gel insertion outperformed the ProSeal laryngeal mask airway (PLMA) as well as the traditional LMA. SAD exhibit low airway leak pressure (p-leak), posing a danger of stomach inflation. Guidelines propose using PPV with TV of 6–8 ml/kg.[1]

Due to lack of an inflatable cuff, I-gel may experience higher leaks compared to alternative supraglottic airway devices throughout positive pressure breathing.[24] Using PEEP with regulated breathing has been recommended for lung recruiting, enhancing functional residual capacity, along with correcting ventilation/perfusion mismatch using endotracheal tube/PLMA.[1]

On assessment of other objectives, a constant increase in the mean leak fraction levels was observed in group A. At time interval of 5, 30 & 60 mins time interval, the mean leak fraction was recorded to be 0.03, 0.04 & 0.05, which was clinically relevant. ($p<0.05$)

However, a comparative analysis with respect to the mean fraction in group B at 5, 30 & 60 mins time interval was 0.042, 0.0482 & 0.0509, which was mathematically not relevant. ($p<0.05$) Herein, the increase in mean leak fraction was found to be lesser at each time interval in comparison to that observed amongst group A patients.

Further, an intergroup analysis of the mean fraction in between group A & B at 5, 30 & 60 mins time interval was found to be always statistically insignificant. ($p<0.05$)

The values observed in our study were similar to the study by Kamhawy G et al.,[1] who observed the mean leak fraction at the time interval of 5, 30 & 60 mins to be 0.015, 0.018 & 0.16 amongst PEEP patients, whereas in non-PEEP patients it was 0.024, 0.023 & 0.022; with either groups showing any statistical significance

In a separate study, Uppal et al.[19] examined the use of I-gel in comparison to a cuffed tracheal tube during PCV while applying three distinct pressures (15, 20, and 25 cm H2O). The tracheal tube and I-gel users did not, however, vary discernably in terms of leak fractions at 15 and 20 H2O pressure. The variation in the leak fraction at 25 cm H2O was statistically significant.

The mean peak inspiratory pressure in the PEEP group at 5, 30 & 60 mins time interval was found to be 15.03, 15.20 and 15.66, whereas in non-PEEP group it was 13.37, 13.03 & 13.0; with statistically significance in group A only. The mean peak inspiratory pressure in PEEP vs NON-PEEP group at 5, 30 & 60 mins time interval was always statistically significant.

Kamhawy G et al.,[1] also reported statistical significance against the groups at all-time intervals as in PEEP group it remained at 16 & in non-PEEP group it remained at 13.71 across all time intervals; however it was insignificant within their non-PEEP group across the respective time intervals.

When respiratory pressure surpasses atmospheric pressure at the conclusion of passive expiration, it is referred to as positive end expiratory pressure, or PEEP.

The mean end tidal CO2 in the PEEP group at 5, 30 & 60 mins time interval was found to be 29.49, 30.4 and 30.29, which is statistically significant, whereas in non-PEEP group it was 32.77, 32.54 & 32.26; which is not statistically significant. The mean end tidal CO2 in PEEP vs NON-PEEP group at 5, 30 & 60 mins time interval was statistically significant.

Almost similar results were observed by Kamhawy G et al.,[1] with 35.62, 36.14 & 35.95 readings at 5, 30 & 30 mins time interval; wherein there was statistical significance against the groups at all-time intervals, however it was insignificant within their non-PEEP group across the respective time intervals.

In the research by Kamhawy G et al.,[1] the mean peak inspiratory pressure at time interval of 5, 30 & 60 mins time interval remained 16 amongst PEEP patients, whereas in non-PEEP patients remained at 13.71; with either groups showing any significance, however it was reportedly highly significant between the groups at all time intervals.

We never discovered any issues in either group during our investigation. Additionally, Sebastian RG et al.[25] found no hemodynamic effect from I-gel insertion in their trial, suggesting that I-gel use causes little respiratory irritation.

Similar findings were reported by Kim et al.,[20] wherein there were no local common complications like severe sore throat, soft tissue injury or any damage to tooth. Also there was no gastric insufflation, regurgitation, or any aspiration.[26] However, Fukuhara A et al.[27] described a brief episode of apnea following I-gel insertion, along with a rare instance of size 2 I-gel accidentally slipping after I-gel was successfully inserted. The literature research revealed no notable adverse effects though, such as trauma, laryngospasm, or bronchospasm.[1]

Our study showed statistical significance in terms of leak fraction and leak volume in group A (with PEEP), however in group B (without PEEP) patients; statistical significance was observed only in leak volume and not in leak fraction.

LIMITATIONS

The present study had the following limitations:

1. Smaller sample size
2. Single centre based study
3. Non randomised sample

FUTURE SCOPE

We recommend a large sample, multi-centric, randomized, multi-observer standardized study to overcome the limitations of our study.

CONCLUSION

We found the use of PEEP at physiological pressure to be slightly better than that observed in non-PEEP patients using I-gel, with the most important parameters being leak fraction & leak volume. We found limited statistical significance within & between the groups, therefore to limit/reduce the bias caused by other confounding factors we advocate large, multi-centric, standardized protocol studies amongst pediatric patients to obtain a more comprehensive understanding of the significance of PEEP & their most ideal levels, in order to achieve a favorable prognostic outcome.

SUMMARY

- Study consisted of 35 pediatric patients each in I-gel with PEEP & I-gel without PEEP group
- In both the groups, the mean age of the subjects were almost similar, with a slightly less age reported amongst peer group subjects
- For inspiratory volume, there was no statistical significance; neither within the group nor between the groups.
- For expiratory volume, there was no statistical significance; neither within the group nor between the groups.
- The mean leak volume at different time intervals within group A & B was found to be statistically significant. An inter-group comparison at 30 mins time interval, however there was no statistical significance at 5 & 60 mins time interval. Herein, there was a significant difference between the groups only at 30 mins time interval, suggestive of a more definitive superiority of use of PEEP.
- The mean leak fraction at different time intervals within group A was found to be statistically significant, however there was no statistical significance within group B and in intergroup comparison (A vs B) at different time intervals
- In terms of peak inspiratory pressure, statistical significance was observed within group A & in intergroup comparison between PEEP vs non-PEEP patients at all time intervals, with the exception of those within group B at different time intervals
- The end tidal CO2 in group A was found to be statistically significant, in intergroup comparison between PEEP vs non-PEEP patients at all time intervals, with the exception of those within group B at different time intervals.

- There were no complications reported in either of the group at any stage with the use of I-gel or with the use/non-use of PEEP.

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ANNEXURE 1- INFORMED CONSENT FORM

KAHERs JNMC, BELAGAVI

"To compare leak volume with and without the application of positive end-expiratory pressure with I-gel based general anaesthesia in pediatric patients: A Randomised Control Trial "

Name of Student/Principal Investigator:

Name of Guide/Co Investigators:

Objective: To compare the effect of leak volume with and without the application of PEEP pressure with I-gel based general anaesthesia in pediatric patients.

Introduction: Positive end expiratory pressure has been demonstrated to decrease ventilator induced lung injury in patients under mechanical ventilation, increase functional residual capacity, and improve ventilation/perfusion mismatch. This study is designed to assess the effectiveness and safety of applying PEEP pressure in the presence of an LMA, ie, I-gel in children. Although there are significant advances in literature in regards to advantages of PEEP pressure, the significant anatomical and physiological differences in children prove those results not completely applicable to the paediatric age group [1]

Explanation of procedure: On the day of the surgery the nil per mouth status will be confirmed and intra venous cannula will be secured on the forearm. Children will be premedicated with Inj. glycopyrrolate 0.004mg/kg body weight and Inj. ketamine 1.5mg/kg body weight iv to overcome parental separation anxiety and patient will be shifted to operation theatre, standard monitors will be attached which include ECG, SpO2 and NIBP cuff. patient will be pre oxygenated for 3 minutes with pediatric

closed circuit using appropriate flow with head resting on a head ring. Patient induced with Inj midazolam 0.05 mg/kg body weight and Fentanyl 2 mcg/kg body weight iv, isoflurane in incremental doses. After achieving adequate depth of anaesthesia, airway of patients in group A will be secured with I-gel and PEEP pressure in the range of 0-5 cm of H2O will be applied, and in group B just I-gel will be inserted. The device will be fixed by taping the tube over the chin. No muscle relaxants were given. Patients will be maintained on spontaneous breathing with assisted ventilation to maintain normocapnia.

Withdrawal from participation in the study: Participation in this study is 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/will not have nor get any benefits by participating in this study. The data gathered will help the 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 from identifying 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.

Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purposes and or presented to scientific groups.

However, your identity will never be revealed.

Questions:

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 allow my son/daughter to participate in the study "**To compare the leak volume with and without the application of positive end- expiratory pressure with I-gel based general anaesthesia in pediatric patients: A 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

"To compare leak volume with and without the application of positive end expiratory pressure with I-gel based general anaesthesia in pediatric patients: A Randomised Control Trial"

Explanation of procedure:

After having met the inclusion criteria and obtaining written informed consent from the parents, a thorough pre anaesthetic evaluation will be done on the day before surgery and patient will be advised for adequate hours of nil per mouth.

After confirming nil-by-mouth status, intravenous access will be secured. Children will be premedicated with Inj. Glycopyrolate 0.004mg/kg body weight and Inj.

Ketamine 1.5mg/kg body weight IV to overcome parental separation anxiety.

Patient then will be shifted inside the operating room and standard monitoring devices would be attached including non- invasive arterial blood pressure, heart rate, ECG, and oxygen saturation. Pre- oxygenation for 3 mins will be done with paediatric closed circuit using appropriate flow with head resting on a head ring. Patient induced with Inj. Propofol 2mg/kg body weight and Inj. Fentanyl 2mcg/kg body weight IV, Isoflurane in incremental doses. After obtaining adequate depth of anaesthesia, I-gel of appropriate size as per manufacturer recommendation will be inserted and fixed and put under pressure controlled mode (PCV mode). Following this, the patients will be divided into two groups— Group A where PEEP of 5cm of H2O will be added to pressure controlled ventilation (PCV) and Group B where no PEEP will be applied. Assessment of leak in both groups will be done by recording leak volumes. Leak volume is recorded as the difference between inspiratory and expiratory tidal volumes. EtCO2 and peak inspiratory pressure are also noted as the secondary

objective. The patients were monitored throughout the procedure. Vitals were noted and recorded. Patients shifted to recovery.

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

Pre examination evaluation

Past History

- Congenital disorders ☐ ICU admission ☐ URTI ☐ `

• H/o previous surgery/(s) where airway difficulty will be encountered. Yes ☐ No ☐

General physical examination

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

Musculoskeletal examination:

Teeth: Jaw movements:

Airway assessment : Spine:

Investigations

Hb%: Platelet Count :

TLC: INR:

FBS:

Systemic examination:

CNS: RS:

CVS: GIT:

Preoperative physical status American society of anesthesiologist I II

Diagnosis: ☐ ☐

Proposed surgery:

Monitors attached:

Pulse oximetry: NIBP:

ECG:

		With PEEP	Without PEEP
Inspiratory tidal volume (ml)	**5 min**		
	30 min		
	1 h		
Expiratory tidal volume (ml)	**5 min**		
	30 min		
	1 h		
Leak volume	**5 min**		
	30 min		
	1 h		
Leak fraction	**5 min**		
	30 min		
	1 h		
End tidal CO2 (mmHg)	**5 min**		
	30 min		
	1 h		
Peak inspiratory pressure (PIP) cm H2O	**5 min**		
	30 min		
	1 h		

Name and Signature of Investigator:

Name and Signature of Anesthesiologist:

Name and Signature of Witness:

ANNEXURE 3: PHOTOGRAPHS

PHOTO 1: PATIENT UNDERGOING GENERAL ANAESTHESIA WITH SECURE I-GEL PLACEMENT

PHOTO 2: GROUP SPECIFIC VITALS MONITORING

PHOTO 3: PERIOPERATIVE VITAL SIGNS MONITORING ALONGSIDE I-GEL BASED VENTILATION

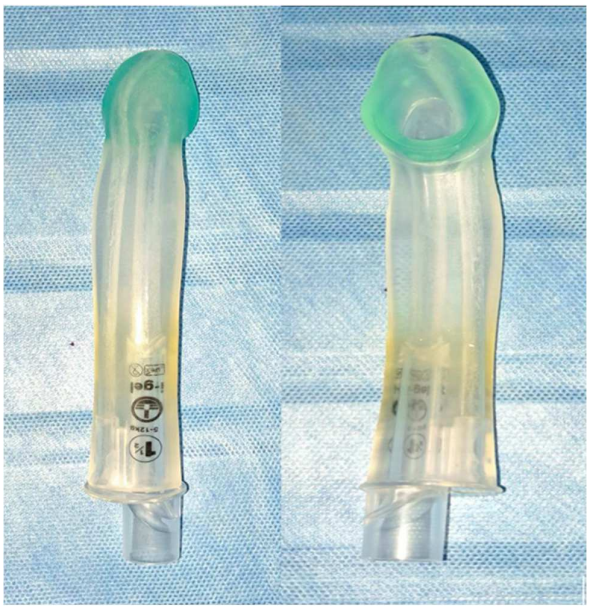

PHOTO 4: I-GEL SIZE 1[1/]

						END TIDAL ETCO2 (mmHg)		PEAK INSPIRATORY PRESSURE(cm H20)			INSPIRATORY TIDAL VOLUME			EXPIRATORY TIDAL VOLUME			LEAK VOLUME			LEAK FRACTION		
					5 min	30min	60 min	5 min	30 min	60 min	5 min	30 min	60 min	5 min	30 min	60 min	5 min	30 min	60 min	5 min	30 min	60 min
S. NO	IP #	AGE/GEN	Group A/B	PEEP																		
1	10017196	13/M	A	5	26	28	27	15	16	16	350	350	350	334	343	336	16	7	14	0.04	0.02	0.04
2	10110742	4/M	A	5	30	33	34	16	17	18	80	80	80	86	76	74	6	4	6	0.07	0.05	0.07
3	10014943	4/M	A	5	34	33	34	13	14	15	110	110	110	112	113	114	2	3	4	0.01	0.02	0.03
4	10110760	2/M	A	5	36	35	36	15	17	15	120	120	120	121	116	115	1	4	5	0	0.03	0.04
5	10014596	8/M	A	5	28	30	30	12	12	13	160	160	160	156	160	149	4	0	11	0.02	0	0.06
6	10110446	4/F	A	5	39	35	37	13	12	13	40	40	40	42	39	37	2	1	3	0.05	0.02	0.07
7	10031191	3/M	A	5	31	32	33	14	13	14	90	90	90	91	82	78	1	8	12	0.01	0.08	0.13
8	10014716	2/M	A	5	21	24	22	11	12	15	79	80	82	86	85	83	7	5	1	0.08	0.06	0.14
9	10027433	4/M	A	5	30	34	34	11	12	11	100	100	100	112	115	112	12	15	12	0.12	0.15	0.12
10	10110638	6/F	A	5	28	27	28	11	12	13	170	170	170	176	166	164	6	4	6	0.03	0.02	0.03
11	10124179	13/M	A	5	27	34	32	15	14	14	340	340	340	340	342	345	0	2	5	0	0.005	0.01
12	10121427	4/M	A	5	26	26	25	18	17	18	90	90	90	90	94	96	0	4	6	0	0.04	0.06
13	10124148	2/M	A	5	30	30	29	14	15	14	80	82	80	80	90	84	0	8	0	0	0.09	0
14	10124050	8M	A	5	22	24	25	18	17	18	150	150	150	154	156	155	4	6	5	0.02	0.04	0.03
15	10124158	3/F	A	5	26	27	30	16	15	16	100	100	100	101	101	114	1	1	4	0.01	0.01	0.04
16	10124164	4/M	A	5	29	29	28	18	18	18	79	80	80	80	86	88	1	6	8	0.01	0.07	0.07
17	10123995	8/F	A	5	28	28	29	15	14	15	150	150	150	154	157	154	4	7	4	0.02	0.04	0.04
18	10123257	11/F	A	5	24	29	29	16	16	16	260	260	260	264	267	280	4	7	20	0.01	0.02	0.07
19	10123422	12/F	A	5	38	34	32	17	18	17	200	200	200	220	221	218	20	21	18	0.1	0.1	0.09
20	10123407	12/M	A	5	39	39	38	16	15	16	170	170	170	174	176	174	4	6	4	0.02	0.02	0.02

21	10122500	5/M	A	5	36	36	35	17	16	18	140	140	140	146	145	145	6	5	5	0.04	0.03	0.03
22	10121365	12/F	A	5	34	35	32	15	16	15	170	170	170	174	180	184	4	10	14	0.02	0.05	0.08
23	10122590	6/F	A	5	26	27	27	14	15	15	190	190	190	194	200	210	4	10	20	0.02	0.05	0.1
24	10122817	6/M	A	5	25	26	27	16	16	17	160	158	159	164	162	165	4	4	6	0.02	0.02	0.03
25	10122813	8/F	A	5	34	32	33	15	14	14	140	142	140	150	155	153	10	13	13	0.07	0.09	0.09
26	10122580	13/M	A	5	35	36	38	14	13	15	160	160	160	165	167	170	5	7	10	0.03	0.04	0.06
27	10122701	15/F	A	5	24	27	27	17	18	18	350	350	350	355	357	370	5	7	20	0.01	0.02	0.05
28	10122851	16/M	A	5	26	30	26	16	16	17	390	390	390	400	388	370	10	2	20	0.02	0.005	0.05
29	10122456	5/F	A	5	28	29	29	15	16	17	160	160	160	170	168	165	10	8	5	0.06	0.05	0.03
30	10118193	9/F	A	5	35	36	30	16	17	18	240	240	240	245	250	242	5	10	2	0.02	0.04	0.008
31	10120992	7/M	A	5	26	27	29	18	18	18	190	190	190	190	186	188	0	4	2	0	0.02	0.01
32	10122197	3/M	A	5	25	26	25	16	16	16	80	80	80	85	87	88	5	7	8	0.06	0.08	0.1
33	10121823	8/M	A	5	33	33	35	11	13	12	160	160	160	160	164	165	0	4	5	0	0.02	0.03
34	10121823	8/M	A	5	26	27	27	16	16	16	170	170	170	176	177	170	6	7	0	0.03	0.04	0
35	10120678	5/F	A	5	27	26	28	16	16	17	80	80	80	85	84	85	5	4	5	0.06	0.05	0.06
36	10016013	3/F	B	0	42	36	34	18	19	19	70	70	70	88	63	70	18	7	0	0.25	0.1	0
37	10016789	2/F	B	0	31	32	33	11	12	11	110	110	110	115	114	109	5	4	1	0.04	0.03	0
38	10014716	2/M	B	0	29	27	28	11	10	9	100	100	100	101	102	104	1	2	4	0.01	0.01	0.04
39	10014659	9/M	B	0	35	36	35	15	14	16	240	240	240	236	240	230	4	0	10	0.01	0	0.04
40	10083169	6/M	B	0	38	32	28	11	11	11	190	186	189	193	184	185	3	2	4	0.01	0.01	0.02
41	10013771	11/M	B	0	29	30	28	15	16	12	180	180	180	186	190	193	6	10	13	0.03	0.05	0.07
42	10083184	2/M	B	0	37	34	39	12	12	12	100	100	100	92	97	90	8	3	10	0.08	0.03	0.1
43	10121758	8/M	B	0	36	34	34	11	14	13	200	200	200	201	210	214	1	10	14	0.005	0.05	0.07
44	10121266	5/F	B	0	38	38	27	14	14	13	100	100	100	105	109	104	5	9	4	0.05	0.09	0.04
45	10120621	13/M	B	0	29	29	29	11	10	11	160	160	160	155	156	160	5	6	0	0.03	0.03	0
46	10120883	10/F	B	0	34	35	35	12	14	14	130	130	130	133	134	133	3	4	3	0.02	0.03	0.02
47	10120035	9/M	B	0	28	29	29	13	13	13	100	100	100	110	115	116	10	15	16	0.1	0.15	0.16
48	10119980	8/F	B	0	26	27	26	14	13	14	90	90	90	96	87	85	6	3	5	0.06	0.03	0.05
49	10120822	13/F	B	0	25	26	27	15	15	14	300	300	300	310	322	311	10	22	11	0.03	0.07	0.03

50	10120621	13/M	B	0	38	36	38	13	12	11	340	340	340	345	333	324	4	7	16	0.01	0.02	0.04
51	10120775	4/F	B	0	33	32	33	14	12	11	110	110	110	113	116	100	3	6	10	0.02	0.05	0.09
52	10118897	8/M	B	0	36	35	34	13	12	11	130	130	130	134	136	134	4	6	4	0.03	0.04	0.03
53	10120547	11/F	B	0	29	29	30	10	9	10	110	110	110	112	120	116	2	10	6	0.01	0.09	0.05
54	10119000	14/M	B	0	34	36	37	11	10	10	150	150	150	155	154	148	5	4	2	0.03	0.02	0.01
55	10099807	4/F	B	0	36	37	36	12	12	12	70	70	70	76	68	68	6	2	2	0.08	0.02	0.02
56	10101216	10/M	B	0	38	38	38	16	15	15	110	110	110	120	130	125	10	20	15	0.09	0.18	0.13
57	10101213	10/M	B	0	37	38	37	14	13	15	200	200	200	220	224	214	20	24	14	0.1	0.12	0.07
58	10101007	10/F	B	0	29	29	30	13	13	14	200	200	200	200	213	216	0	13	16	0	0.06	0.08
59	10100974	10/F	B	0	35	34	33	12	11	12	150	150	150	156	157	143	6	7	7	0.04	0.04	0.04
60	10100866	14/F	B	0	33	32	33	13	13	13	400	400	400	402	400	416	2	0	16	0.005	0	0.04
61	10100946	11/F	B	0	38	38	38	14	14	15	300	300	300	300	302	297	0	2	3	0	0.006	0.01
62	10100344	3/M	B	0	33	34	33	13	11	10	60	60	60	65	54	51	5	4	9	0.08	0.06	0.15
63	10100711	11/M	B	0	29	29	28	14	14	14	130	130	130	132	135	125	2	5	5	0.01	0.03	0.03
64	10110733	11/F	B	0	25	29	28	16	16	15	120	120	120	126	114	110	6	6	10	0.05	0.05	0.08
65	10111068	7/M	B	0	26	27	26	15	10	14	190	190	190	198	200	201	8	10	11	0.04	0.05	0.05
66	10107514	11/M	B	0	33	34	38	13	13	13	260	260	260	260	265	259	0	5	1	0	0.01	0.003
67	10111318	12/M	B	0	31	30	31	16	18	16	270	270	270	270	256	266	0	14	4	0	0.05	0
68	10109653	2/M	B	0	34	34	35	15	15	15	60	60	60	64	65	65	4	5	5	0.06	0.08	0.08
69	10110273	8/M	B	0	29	29	29	14	14	15	100	100	100	103	98	96	3	2	4	0.03	0.02	0.04
70	10208861	5/M	B	0	34	34	32	14	12	12	90	90	90	94	99	100	6	1	10	0.06	0.01	0.1