

**“A STUDY ON EFFECTIVENESS AMONGST INRACUFF
PRESERVATIVE FREE LIGNOCAINE, ALKALINISED PRESERVATIVE
FREE LIGNOCAINE AND KETAMINE IN ABATEMENT OF
POST OPERATIVE SORE THROAT. ONE YEAR HOSPITAL BASED
RANDOMISED CONTROLLED TRIAL”**

By

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Dissertation

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ENDORSEMENT

This is to certify that the dissertation entitled “**A STUDY ON EFFECTIVENESS AMONGST INRACUFF PRESERVATIVE FREE LIGNOCAINE, ALKALINISED PRESERVATIVE FREE LIGNOCAINE AND KETAMINE IN ABATEMENT OF POST OPERATIVE SORE THROAT. ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL**” is a bonafide research work done by **REG NO. BA0119002**, Department of Anaesthesiology, Jawaharlal Nehru Medical College, Nehru Nagar, Belagavi – 590 010.

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LIST OF ABBREVIATIONS USED

ASA	-	American Society of Anaesthesiologists
BMI	-	Body Mass Index
BP	-	Blood Pressure
HR/PR	-	Heart Rate/ Pulse Rate
cm	-	Centimetre
mm	-	Millimetre
ID	-	Internal diameter
CNS	-	Central nervous system
CVS	-	Cardiovascular system
ETT	-	Endotracheal tube
GIT	-	Gastrointestinal tract
Kg	-	Kilogram
mg	-	Miligram
mcg	-	Microgram
MPG	-	Mallampatti grading
RR	-	Respiratory rate
RS	-	Respiratory system
O ₂	-	Oxygen
N ₂ O	-	Nitrous Oxide
NAHCO ₃	-	Sodium Bicarbonate
Inj	-	Injection
Gp/G	-	Group
S.D	-	Standard Deviation
POST	-	Post operative sore throat
PONV	-	Post operative nausea and vomiting
PVC	-	Poly vinyl chloride
URTI	-	Upper Respiratory Tract Infections
COPD	-	Chronic Obstructive pulmonary disease
OT	-	Operation theatre
Mins	-	Minutes
Hrs	-	Hours
MAP	-	Mean Arterial Pressure

ABSTRACT

TITLE: “A study on effectiveness amongst intracuff preservative free lignocaine, alkalinised preservative free lignocaine and ketamine in abatement of post operative sore throat: A one year hospital based randomised controlled trial.”

INTRODUCTION: Endotracheal intubation is a standard airway management used to achieve and maintain a definitive airway in patients undergoing general anaesthesia(GA) surgery. Endotracheal tube cuff pressure causes increased airway secretions, mucosal irritation, and post-operative sore throat [POST]. Enhanced postoperative outcomes are now possible following recent breakthroughs in anaesthesia. This study is undertaken to evaluate efficacy of preservative free lignocaine, preservative free alkalinised lignocaine and ketamine in minimising POST.

AIM: To evaluate the 3 drugs in preventing incidence and severity of sore throat post operatively, voice hoarseness ,cough and to evaluate hemodynamics at extubation.

METHODS: Total of 132 patients of ASA (I,II);18-60yrs of age, undergoing GA surgery,were enrolled after obtaining written informed agreement. They were randomly allocated in to three groups of 44 each. Gp A- Intracuff solution of preservative free lignocaine, Gp B- Intracuff solution of preservative free alkalinised lignocaine and Gp C- Intracuff solution of ketamine. Patients were evaluated post operatively for prevalence and severity of sore throat,cough, voice hoarsenss for 24hrs at regular time interval. Analysis of data done using ANOVA, chisquare test.

RESULTS: Overall POST incidence in all three groups 52.6%, highest in lignocaine group(75%) and least in ketamine group(22%), being significant. Maximum severity(Grade 2) of POST was seen with lignocaine group 61.4% followed by preservative free alkalinised lignocaine, least in ketamine group (p value <0.001)

CONCLUSION: In conclusion to our study, we noted that prevalence and severity of POST, cough, voice hoarseness, PONV was significantly reduced in ketamine group followed by preservative free alkalinised lignocaine group when compared to lignocaine group.

KEYWORDS: Post operative sore throat, ketamine, lignocaine, alkalinised lignocaine, intracuff

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INTRODUCTION

Endotracheal intubation is a standard procedure followed as an airway management in order to secure and maintain a definitive airway in patients undergoing surgery under general anaesthesia.

Most commonly achieved through single lumen orotracheal tube. Endotracheal tube is a common source of pain and discomfort. This discomfort and pain is due to tracheal tube cuff pressure causing increased airway secretions, mucosal inflammation and post operative sore throat [POST].

The prevalence of POST is 21-65% ^[1, 2]

The stimulation of tracheal pain receptors causes sore throat post surgical procedure. A range of methods both pharmacological and non-pharmacological have been used to prevent or reduce incidence of sore throat post surgical procedure. Prophylactically anti-inflammatory drugs, opioids, steroids, or local anesthetics have been used for the same. Studies have shown that POST is attenuated pharmacologically by lubricating endotracheal tube [ETT] with lignocaine jelly or by spraying topical lignocaine to airway. Inflation of ETT cuff with lignocaine alone ^[3] or with sodium bicarbonate. ^[4] Non-pharmacologically, POST has been reduced by using supraglottic airway devices, gentle manipulation of airway and suctioning.

Using of lignocaine instead of air in filling the cuff of endotracheal tube has been studied during general anaesthesia. When lignocaine is injected, it spreads through the semipermeable membrane in the poly vinyl chloride [PVC] tube in a dose time dependent fashion. By blocking the activation of tracheal pain receptors, it increases airway tolerance to endotracheal tube, which may reduce cough and sore throat.

Sodium bicarbonate enhances lignocaine diffusion over the semipermeable barrier by increasing its alkalinity, resulting in longer anaesthetic duration and efficacy.

Ketamine's anti-inflammatory and antinociception properties, as well as the presence of NMDA receptors in the peripherally, aid in the tolerance of endotracheal tubes, cough, and sore throat.

In studies, intracuff lignocaine and ketamine were found to be beneficial in reducing post-operative sore throat. Few studies, however, have examined the effectiveness of preservative-free lignocaine, alkalized preservative-free lignocaine, and ketamine in decreasing occurrence & severity of POST. As a result, we're doing this research to see how successful these medications are at minimising POST.

OBJECTIVES OF STUDY

PRIMARY OBJECTIVE:

To compare effectiveness of intracuff preservative free lignocaine, alkalized preservative free lignocaine and ketamine in preventing incidence and severity of sore throat post operatively, voice hoarseness and cough.

SECONDARY OBJECTIVE:

- To compare effectiveness of intracuff preservative free lignocaine ,alkalized preservative free lignocaine and ketamine in preventing incidence and severity of post operative nausea,vomiting, dysphagia
- To evaluate hemodynamics during extubation.

REVIEW OF LITERATURE

Hippocrates (460-380 BC)⁽⁷⁾ described tracheal intubation in humans for breathing support in Greece. Dr. Charles Kite, a surgeon, developed the first ETT in 1778, and reported inserting a catheter into the nares or mouth of drowning victims to resuscitate them^(7,8).

William Macewan, a Scottish surgeon, was the first to employ elective oral intubation in the year 1880.⁽⁹⁾ O'Dwyer (1887) developed a series of metal tubes that he implanted in the larynx of diphtheritic croup patients, eliminating the necessity for tracheostomy⁽⁹⁾. Eisenmenger (1893) was the first to describe the use of a cuffed ETT, as well as the concept of a pilot balloon to measure intracuff pressure (reintroduced in 1939 by Langton Hewer)^(9,10).

Janeway (1913)⁽¹⁰⁾ described their laryngoscopy experiences, setting the path for the invention and widespread use of flexible rubber tubes. They utilised insufflation, an anaesthetic procedure in which gas was blasted into the lungs through a tiny tube and exhaled gas flowed around the exterior of the tube.

Rowbotham and Magill (1926)^(9,10) were constructed after realising that the insufflation technique of anaesthesia did not prevent aspiration, bigger rubber tubes were developed to allow bidirectional gas passage through the tube. These tubes were sealed with pharyngeal sponges and hand-sewn gauze pull threads to help with removal.

The cuff which is inflatable was reintroduced to Magill's rubber tube by Guedel (1928) and Waters (1931)⁽¹¹⁾. Rubber glove fingers and rubber condoms were used to make their initial cuffs. The cuffs were made to sit half above and half below the glottis; 3 to 4 inches long. They then developed cuffs made of rubber dental dams that were 1.5 inches long and sat behind the vocal cords.

In the 1960s, rubber was phased out of ETT in favour of plastic. The late 1960s saw the introduction of high-volume, low-pressure cuffs.

The expandable cuff was restored to Magill's rubber tube (1931) by Guedel (1928) and Waters (1929)⁽¹¹⁾. Their first cuffs were constructed of condoms and rubber glove fingers. . These 3 to 4 inch long cuffs were designed to sit half above and half below the glottis. They created 1.5-inch-long rubber dental dam restraints that rested behind the vocal cords.

In the 1960s, rubber was phased out of ETT in favour of plastic. The late 1960 saw introduction of HVLP (high-volume, low-pressure)cuffs.

Manufacturers developed a PVC-cuffed HVLP ETT in the 1970, now become the industry standard.

Despite the fact that HPLV cuffs are still accessible, they are not widely used. Red rubber tubes were manufactured of thick , low compliance rubber. These cuffs required a lot of strain to distend and had a little volume.⁽¹²⁾ Rather than adapting to the contour of the trachea, these cuffs inflate in a circular shape. These cuffs feature a low residual volume and a tiny diameter at rest. It makes a small area of contact with tracheal membrane causes trachea to stretch and deform in to circular shape.⁽¹²⁾ Relative overinflation was required to achieve adequate contact with the tracheal wall and an acceptable seal, resulting in high pressure within cuff being transmisioned.

HPLV cuffs caused tracheal injury, particularly during extended intubations. There were reports of tracheal rupture, stenosis, tracheo-esophageal fistula, and tracheal dilatation. The difficulties were caused by the pressure that built up inside the HPLV cuff. The HPLV is less compliant, causing the trachea to deform. The pressure within this sort of cuff is unrelated to the pressure on the lateral wall. The initial pressure required to expand the less compliant cuff material is the reason for this. This resulted in a rise in mucosal pressure to critical levels, which could result in mucosal ischemia, tracheal scarring, and tracheal stenosis if left untreated. These cuffs offer superior protection against aspiration, improved visibility during intubation, and a reduced incidence of sore throat than low-pressure cuffs.

As the pressure of intracuff closely resembles tracheal wall pressure, the pressure imposed on the tracheal mucosa can be measured and controlled. Hence, there are fewer cuff-related problems associated with prolonged intubation. These cuffs also have a few drawbacks. As cuff can block tip and larynx vision, it may be more difficult to implant. Even after a good seal, multiple microfolds remains intracuff, forming microchannels that run the length of the cuff. These channels have the potential to produce pneumonia associated with the use of a ventilator. The HVLP cuff causes more postoperative sore throat than the HPLV cuff, but the tracheal seal at lower pressures minimises future issues from tracheal damage.

After general anaesthesia, postoperative sore throat (POST) is a well-known mild consequence. Although the symptoms disappear on their own without therapy, preventive intervention is nevertheless indicated to improve the quality of post-anesthesia care by reducing the frequency and severity of the symptoms. POST refers to a group of signs and

symptoms that include laryngitis, tracheitis, hoarseness, cough, and dysphagia. A difficult intubation, it is indicated, does not significantly enhance the risk of POST. Younger patients, gynaecological surgery, a large tracheal tube, cuff design, intracuff pressure, and a throat pack have all been linked to a higher risk of POST.

Everyday intubation for normal surgical operations might create pathological changes that may give an organic basis for patients' postoperative throat discomfort, which is less known. POST may be caused by a lack of airway humidity, trauma during airway insertion, suctioning, high anaesthetic air flow rates, and surgical manipulation of the airway and associated tissue. Neuropraxia of the recurrent laryngeal nerve due to high intracuff pressure and nerve demyelination due to gas sterilisation of the tubes are two possible explanations.⁽¹³⁾ POST can be reduced employing a multi-modal approach that includes both non-pharmacological and pharmaceutical therapies, according to research. Some risk factors, including as sex, operation duration, nasogastric tube use, and surgical positioning, are beyond of the anaesthesia provider's control. The identification of factors linked to a higher risk of POST, on the other hand, will allow anaesthesia providers to avoid combinations of controllable factors, lowering the incidence of POST and improving patient anaesthetic outcomes.

The use of a smaller endotracheal tube has regularly been found to lower the risk of POST without causing issues with the patient's ventilation. Many studies show that women should use a 7.5 millimetre endotracheal tube and men should use an 8.5 millimetre endotracheal tube. POST can be reduced by determining and maintaining a minimum pressure of <20 mm Hg (millimetres mercury) for an efficient cuff seal ,during positive pressure ventilation, as well as minimising cautious oropharyngeal suctioning. Various pharmacological treatments, including as lignocaine, steroids, and ketamine, have been used to lower the occurrence and intensity of POST with varied degrees of success.

Huang et al. ⁽¹⁴⁾ observed in 1998 that alkalizing lidocaine can increase in vitro diffusion by tens of times across the endotracheal tube cuff. The approach would be more effective if lidocaine was alkalized and surgery was performed for a long time. Warming the lidocaine solution can promote diffusion through the cuff membrane, therefore using a heated breathing circuit may have an added effect.

Seventy five ASA (I, II) patients were studied by Estebe JP, Dollo G et al⁽⁴⁾ in 2002 who underwent surgery in GA. They were separated into three groups of 25, Intracuff air, 40mg lidocaine and intracuff alkalized lidocaine were used. 24hrs post extubation, incidence of POST was found to be lesser in group alkalized lignocaine. Cough, hoarseness, and diminished hemodynamic effects were all discovered to be similar.

Navarro et al⁽¹⁵⁾ investigated effects of intracuff alkalized 2 percent lidocaine on emerging cough, sore throat, and hoarseness in smokers in 2012. Saline or lignocaine with NaHCO_3 were used to inflate ETT cuff. Lignocaine was superior to saline in the cuff. In PACU, lignocaine group had a significantly reduced incidence of POST. The incidence was comparable after 24 hours. Lignocaine levels in the blood were measured and did not change appreciably during the course of the trial.

Fai Lam, Yu-Cih Lin, and colleagues⁽¹⁶⁾ conducted a meta-analysis in 2015 that looked at nineteen trials involving 1566 patients and found that incidence of late and early phase of POST, coughing, agitation, hoarseness, and dysphonia were significantly lower in the lignocaine. POST severity and the emerging phenomenon was also much reduced.

PapuNath et al⁽¹⁷⁾ undertook a prospective double-blind randomised controlled experiment in 2016 to check if alkalized lignocaine may lessen incidence of cough post extubation in 120 min procedure. Patients were divided into 2 groups: one which was pre-filled with alkalized lignocaine (8.4%) or with normal saline 90 mins prior procedure. Prior intubation, the cuffs were promptly emptied. Following intubation, 2 mL of

lignocaine 2% or 2 mL of NS were injected. Additional 8.4% sodium bicarbonate or normal saline was injected into the cuff. Patient was kept in deeper plane of anaesthesia. Extubation cough was found to be 12 % alkalised lignocaine as compared to NS (22%). The researchers discovered that alkalised lidocaine in the ETT cuff decreased GA emergence cough after procedures lasting an average of little less than 1 hour.

In 2017, Prerana P Shroff et al⁽¹⁷⁾ conducted a 3 month prospective RCT to assess the efficacy of various media for tracheal tube cuff inflation. Using the sealed envelope approach, patients were subdivided equally into 3 groups (air, isotonic saline, and alkalised lignocaine as ETT cuff media). ETT cuff volume, pressure, intubation duration, withdrawn volume from cuff, and complications such as tube intolerance, coughing on the tube, restlessness, hoarseness, laryngospasm, POST and breathlessness, were investigated. Pressure in intracuff was more in group air at all intervals after intubation, with statistical significance at 5 minutes, half hour, a complete hour, and just prior extubation. Volume of air in group air increased soon before extubation, but the volume in the other groups decreased. Alkalised lignocaine group had highest tube tolerance, and least hoarseness & POST. Hence, alkalised lignocaine and saline were better than air as ETT cuff media.

Sixty surgical patients receiving elective abdomen and lower limb procedures were involved in a study conducted by Rajan S, Malayil GJ et al in 2017⁽¹⁸⁾. Patients of each of 4 groups were nebulised with ketamine (20mg), magnesium sulphate 250mg, 500mg and normal saline 15mins prior to surgery. Incidence and severity of POST was noted in 24hrs. In study groups, the incidence and severity of POST, cough and hoarseness were less than control at all times.

In a study conducted in 2017 by Rashmi N R, Shashidhar G S, Balabhaskar S, and Kiranchand N⁽⁵⁾ In this research, 100 patients from 18 to 50 years with normal ASA status (I,II) for elective surgery under GA were considered, divided into 4 group: air, lignocaine 2%, alkalinised lignocaine (with 7.5% sodium bicarbonate) and ketamine (20mg) ,with 25 in each group. Various parameters such as sore throat, hemodynamics at extubation, hoarseness, and dysphagia were measured. Results showed that ketamine used as intracuff media was better than other 3 groups for above parameters”.

Budhania L S, Chamala V, Rao M et al⁽¹⁹⁾ observed that when 104 patients were randomised into one of four groups I.e, air, anaesthetic gases , saline or lignocaine 2% as ETT cuff media,it was noted that there was no difference in extubation cough response. But it was also noted that ETT cuff deflation happened more with liquid media than gaseous media. All groups had similar rates of painful throat at 2 hours and at 18 & 24 hrs, voice hoarsenss, and dysphagia.

In a 2018 study by Nath P, Williams S, et al⁽²⁰⁾ 213 patients up to ASA III were included.ETT cuff were inflated with either 2ml of 2% lignocaine or 8cc of 8.4% NAHCO_3 or 10cc of normal saline. Rate of extubation cough in NAHCO_3 was 12%, which was lower than the 22% in lignocaine group.

Endotracheal intubation has been linked to morbidities such as sore throat, voice hoarseness, cough, and postoperative nausea and vomiting in all of these trials. As a result, the goal of this research is to see how effective these drugs are at minimising the occurrence of certain morbidities.

BASIC SCIENCES

ANATOMY OF THE AIRWAY

PHARYNX

The pharynx is a wide muscular tube that forms the common upper pathway of the respiratory and alimentary tracts. Anteriorly, it is in free communication with the nasal cavity, the mouth and the larynx, which conveniently divide it into three parts, termed the nasopharynx, oropharynx and laryngopharynx, respectively. ^(21,22)

Nasopharynx:

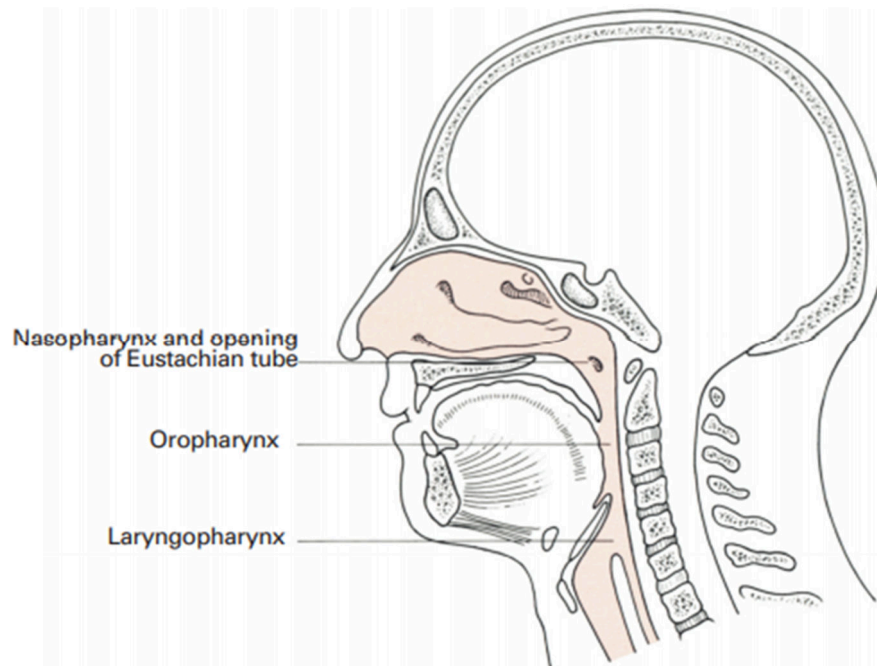


Figure 1: Anatomy of nasopharynx

- The nasopharynx lies behind the nasal cavity and the soft palate. It communicates with the oropharynx through the pharyngeal isthmus. Eustachian tube, adenoids, Fossa of Rosenmuller are the important structures present in nasopharynx. ^(21,22)

- Extension:
 - Superior: Base of the skull.
 - Inferior: Soft palate's superior surface.
 - It allows free passage for respiration.
 - On each side the eustachian tube opens.

Oropharynx:

- The extension of oropharynx is from uvula to hyoid bone.
- The palatoglossal arch (that passes through the oropharyngeal isthmus) delineates the mouth and the oropharynx.
- Lateral wall: Palatopharyngeal arch and palatine tonsil

Laryngopharynx:

- It forms the posterior part of the pharynx in its entire length.
- Extension: superior – epiglottis (superior border), inferior – cricoid cartilage.
- Borders:
 - Superior: Lateral glosso-epiglottic folds - Delineates oro-pharynx and laryngo-pharynx
 - Inferior: continuous with oesophagus.
- On either side of the inlet of larynx lies the pyriform fossa. Its boundaries include:
 - Medial: Aryepiglottic fold.
 - Lateral: Thyroid cartilage and thyrohyoid membrane.

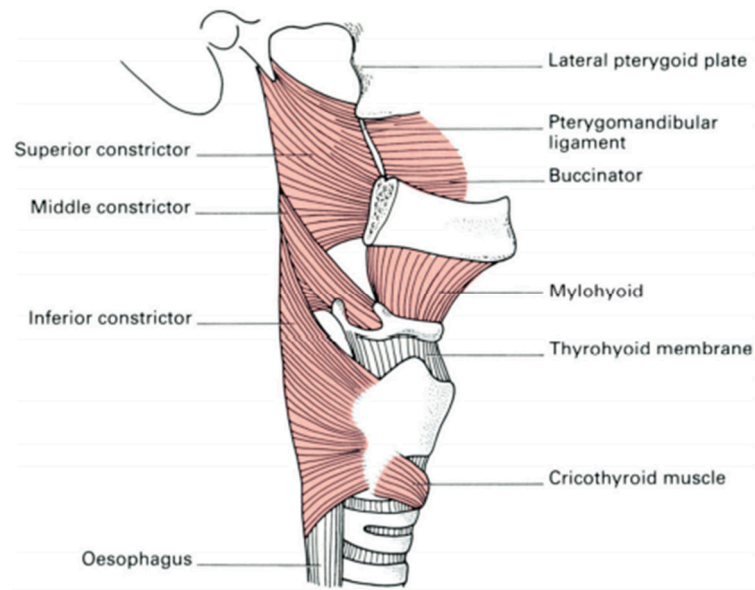


Figure 2: The constrictor muscles of pharynx

- Muscles of the pharynx:
 - Constrictors:
 - Superior,
 - Middle,
 - Inferior.
- Longitudinal muscle coat:
 - The Palato-pharyngeus muscle,
 - The Stylopharyngeus muscle, and
 - The Salphingo-pharyngeus muscle.

- Nerve supply of pharynx:
 - Motor: Glossopharyngeal nerve, cranial part of accessory nerve.
 - Sensory: General sensation is carried by the pharyngeal branches of glossopharyngeal nerve and palatine branches of maxillary nerve.
 - Taste: The lesser petrosal nerve to the pterygopalatine ganglion (also has secretomotor innervations to the pharyngeal mucosa).

- Arterial supply:

The arterial supply is provided by the lingual, facial and maxillary arteries.

Ascending pharyngeal as well as the superior thyroid artery also provides arterial supply.

- Venous drainage:

- Venous drainage is by both the pterygoid and the pharyngeal plexus which further drains into the internal jugular vein.

- Lymphatic drainage:

- Retropharyngeal lymph nodes
- Upper deep cervical lymph nodes.

LARYNX^(21,22)

By evolution, larynx served as a protector of upper airway from aspiration, later developed into an organ of phonation. It lies against the cervical vertebrae C4-6.

Various cartilages, ligaments and muscles together form the structure of larynx.

Cartilages: Thyroid, epiglottis, cricoid, arytenoid, corniculate and cuneiform.

Ligaments: Thyrohyoid, cricothyroid, cricotracheal, hyoepiglottic membrane.

Muscles: Extrinsic- Sternothyroid, thyrohyoid, inferior constrictor.

Intrinsic- Posterior cricothyroid, lateral cricothyroid, interarytenoid, thyroarytenoid, vocalis and cricothyroid.

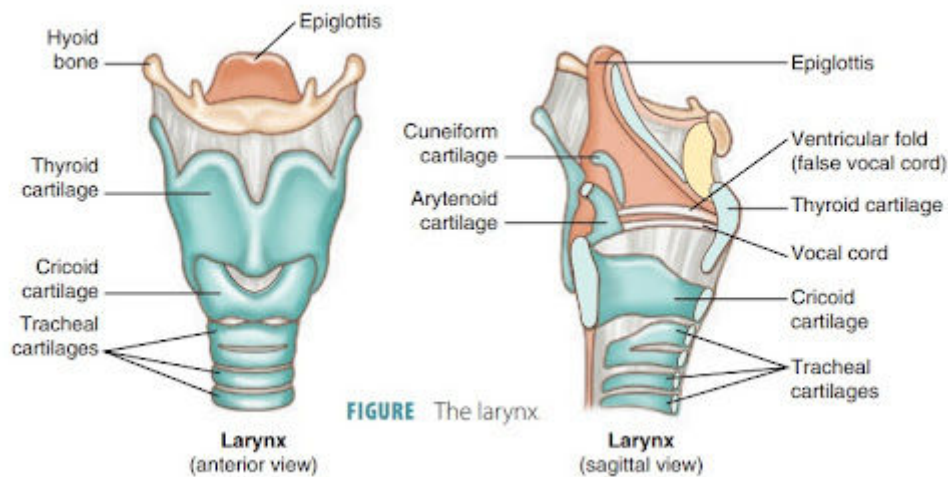


Figure 3: Cartilages of the larynx: anterior and sagittal views.

THYROID: Largest laryngeal cartilage and shaped like a shield with two laminae joining inferiorly in midline to form a prominence commonly known as the Adam's apple which is more prominent in males. The laminae have each one superior and one inferior horn for articulation with other cartilages.

CRICOID: The only cartilage which forms a full circle within the trachea, shaped like a signet ring. Lying against C6 vertebra, it forms an arch anteriorly and widens posteriorly as a lamina. Cricoid articulates superiorly with inferior horn of thyroid and arytenoid.

EPIGLOTTIS: Shaped like a leaf, it is linked to the thyroid through the thyro-epiglottic ligament. The mucous membrane of upper part continues with that of the tongue and oropharynx forming the median and lateral glosso-epiglottic folds respectively between which lie the valleculae, a dangerous site for sharp objects like fish bones to get impacted. The hyo-epiglottic ligament links the lower part to the hyoid bone. Neonates have floppy epiglottis to protect the airway while suckling.

ARYTENOID: They are a paired pyramid shaped cartilages lying on the posterior aspect of cricoid. They each have a lateral process for muscular attachment and anterior process for the vocal ligament to attach to in its posterior aspect.

CUNEIFORM (Wrisberg cartilages): These are paired cartilages present on either side of aryepiglottic fold, supporting the vocal folds and epiglottis in its lateral aspect.

CORNICULATE (Cartilage of Santorini): They are small, nodule-like, paired cartilages each lying on the apex of an arytenoid.

EXTRINSIC LIGAMENTS: Attach larynx to hyoid or trachea.

- a. Thyrohyoid: Between upper part of thyroid to posterior aspect of hyoid.
- b. Cricotracheal: Between cricoid and first ring of trachea.
- c. Hyoepiglottic: Between upper aspect of hyoid and epiglottis.

INTRINSIC LIGAMENTS: Connections within the larynx.

- a. Cricothyroid membrane: Shaped like a pyramid, its apex lies on the thyroid cartilage and base lies on the cricoid in its superior border.
- b. Cricocorniculate: Between cricoid and corniculates.
- c. Thyroepiglottic: Between thyroid and epiglottis.
- d. Thyroarytenoid: Between the arytenoid and middle portion of thyroid. The ligament is subdivided into superior and inferior ligaments in relation to vocal cords.
- e. Arytenoidepiglotic: Between arytenoids and epiglottis.

MUSCLES OF LARYNX: They have three functions which include closing the airway passage while swallowing, opening the inlet during respiration and aiding in phonation.

- a. Abductors: Posterior cricoarytenoids.
- b. Adductors: Lateral cricoarytenoids, interarytenoid.
- c. Tensor: Cricothyroid.
- d. Relaxor: Thyroarytenoid.
- e. Fine adjustment: Vocales

LARYNGEAL CAVITY

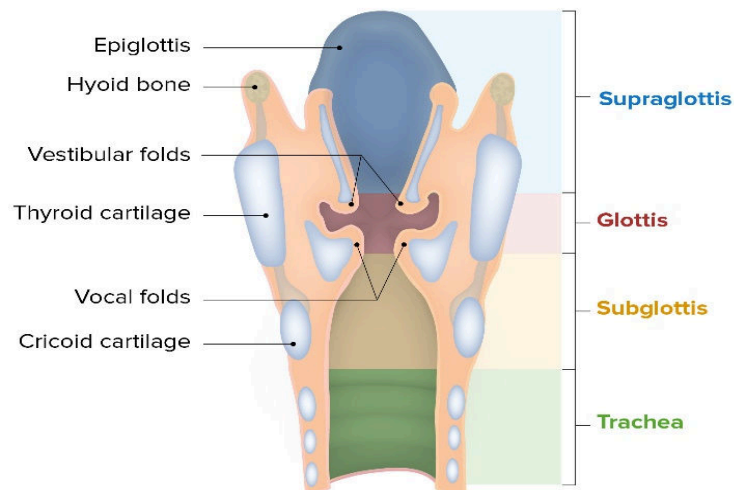


Figure 4: Boundaries of the laryngeal cavity.

Extends from the inlet of larynx to the lower part of cricoid. It is shaped as an inverted pyramid, with its oval base facing the tongue, apex into the trachea, two lateral parts and one posterior part. The lateral aspects consist of superior thyroid, middle cricothyroid and inferior cricoid parts. The posterior part of the cavity is a part of the anterior aspect of pharynx, consisting of two vertical recesses called pyriform sinuses. The middle portion of laryngeal cavity, called glottis, divides the cavity into supraglottic, glottic and infraglottic regions. The glottic space is comprised of vocal cords, glottis and ventricles of larynx. The vocal cords are four in number, two lying superiorly and two inferiorly. They

attach to thyroid anteriorly and arytenoid posteriorly. The superiorly lying cords are relatively thin and devoid of muscles hence referred to as false vocal cords while the inferior folds comprise of muscles which aid in adduction, hence referred to as true vocal cords. Ventricles of larynx (Morgagni sinus) are present between the false and true vocal cords. (21,22)

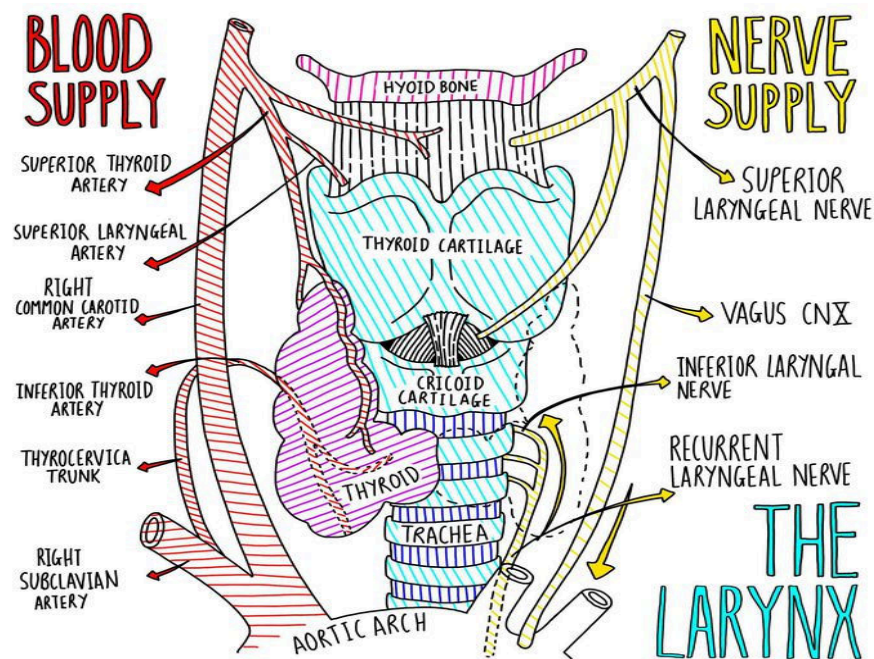


Figure 5: Blood supply and Nerve supply of the larynx.

The external carotid artery gives the superior thyroid artery and the thyrocervical trunk gives the inferior thyroid artery. These two arteries give superior and inferior laryngeal branches and superior thyroid gives cricothyroid branch. From epiglottis to superior vocal cords, the superior laryngeal artery supplies while for inferior vocal cords and below, the supply is inferior laryngeal artery.

The veins accompany the arteries and hence named after the same. They eventually drain into subclavian and internal jugular veins via inferior and superior thyroid veins.

LYMPHATIC DRAINAGE

Two groups of lymphatics namely supraglottic and infraglottic are present. The denser supraglottic and subglottic lymphatics drain ultimately into deep cervical nodes. The vocal cords do not have lymphatic drainage.

NERVE SUPPLY

- a. Superior Laryngeal Nerve (SLN): It is a branch of tenth cranial nerve Vagus from its inferior ganglion. It divides into internal and external laryngeal nerves beneath the hyoid. While the external branch innervates cricothyroid, the internal branch runs caudally along the thyrohyoid membrane supplying the mucosa of laryngeal inlet.
- b. Inferior Laryngeal Nerve or Recurrent Laryngeal Nerve (RLN): It supplies all the intrinsic muscles excluding cricothyroid. The left RLN takes origin from vagus in the thorax, loops around aortic arch and then runs cranial to the trachea and finally enters larynx. The right RLN originates at neck base, loops around the right subclavian artery and then runs cranial to trachea finally entering the larynx.

SORE THROAT

Sore throat pain is commonly reported following ETT. Although the underlying mechanisms promoting throat pain following ETT placement are yet to be described, there is evidence that neutrophils may trigger nociception. Previously it was shown that depletion of neutrophils can prevent the induction of hyperalgesia. The trachea is highly innervated with a subepithelial network of peripheral nerves that express transient receptor potential vanilloid calcium ion channels (TRPVs), which are well-established pain receptors. It was observed that neutrophilia was significantly greater in patients who reported sore throat when compared to patients without sore throat. Neutrophils of sore throat patients also constitutively produced higher levels of ROS. Several studies have shown that ROS directly promotes hyperalgesia in both acute and inflammatory settings. In addition, tracheal lavage fluid of sore throat patients induced the release of HNE (human neutrophil elastase), a mediator of neuropathic pain. Recent work has revealed that neutrophil elastase generates pain through the activation of protease-activated TRPV4 receptors on nociceptive neurons. Finally, it was observed higher levels of IL-1 β and TNF- α gene transcription in sore throat TLF-treated neutrophils, and similar secretion of these cytokines, IL-1 β and TNF- α , increases the sensitivity of nociceptors by promoting TRPV1 activation. Data show that TLF from sore throat patients induce neutrophils to release significantly higher amounts of proinflammatory mediators known to trigger peripheral nerve pain. ⁽²³⁾

ENDOTRACHEAL TUBES

These are the tubes through which the anaesthetic gases or vapours along with breathing gases are conveyed to and from trachea

An endotracheal tube has two ends. The distal end which is bevelled is called patient end and proximal end which is vertically cut is called the machine end

Some endotracheal tube have a side hole just above and opposite the bevel called murphy eye. It helps ventilation to occur if the bevel is occluded by secretions, blood or the tracheal wall. In some endotracheal tubes there is a radio opaque marker at the tip or along the length of tube to detect the position of tube after intubation. ^(24,25)

Various substances like natural rubber, synthetic rubber, silicon rubber, nylon, Teflon, polyethylene, polyvinyl chloride (PVC) are used for manufacturing endotracheal tubes. Of these PVC are most widely used.

To meet the standards of American Society for Testing and Materials (ASTM), materials must pass a United States Pharmacopeia (USP) implantation test.

The distal end lies in the mid to lower part of trachea, whereas the proximal end lies outside the mouth or nose where it is connected to the anaesthesia circuit or other device. Tracheal tubes used in adult patients have a cuff near the distal end that is inflated to provide a seal against the tracheal wall to protect the lungs from pulmonary aspiration and to ensure that the tidal volume delivered ventilates the lungs, rather than escapes into the upper airway. Cuffs are normally inflated with air and have an inflation tube with a pilot balloon that indicates cuff inflation.

Use of small tracheal tubes reduces the incidence of sore throat and hoarseness of voice. Small tracheal tubes may cause less tissue pressure in larynx. Cuff inflation achieves a seal between the tracheal tube and the wall of the trachea.

ventilation and the lungs should be protected from aspiration. The tracheal tube must be long enough for the cuff to lie 2 cm beyond the vocal cords. ^(24,25)

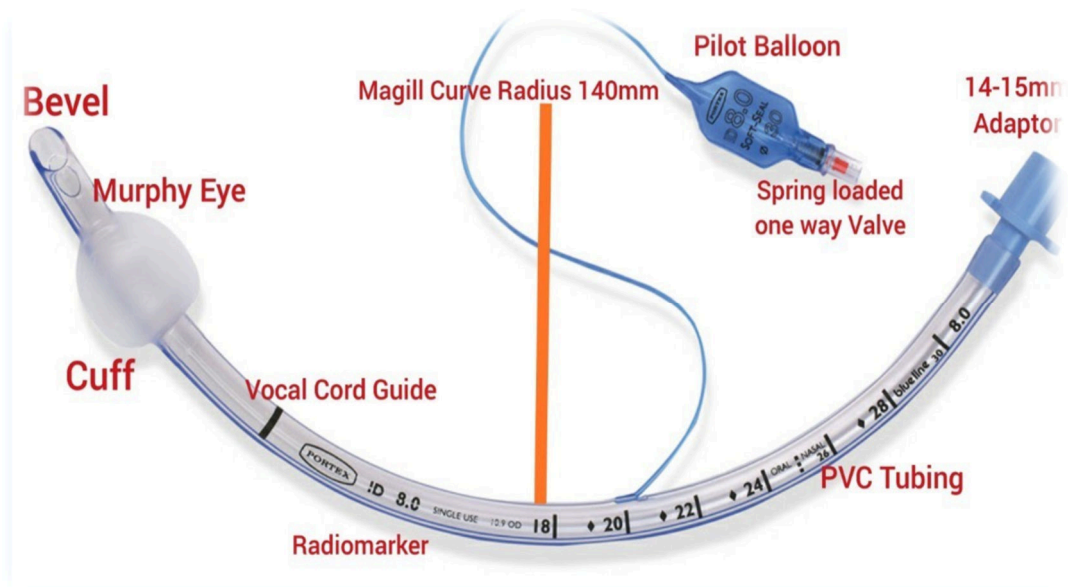


Figure 6: Endotracheal tube with parts

LIGNOCAINE

Lignocaine is a tertiary amine which is an amide derivative of diethylaminacetic acid with the longest pedigree and the most widely used local anaesthetic in clinical medicine. It is effective in suppressing re-entry cardiac arrhythmias such as premature ventricular contractions and ventricular tachycardia. It has a pKa of 7.6. It is a standard antiarrhythmic agent when given intravenously. Initial dose is 1-1.5 mg/kg iv can be repeated at 0.5-0.75 mg/kg iv every 5-10 min upto maximum cumulative dose of 3mg/kg. Infusion dose is 1-4mg/min (30-50mcg/kg/min)^(26,27)

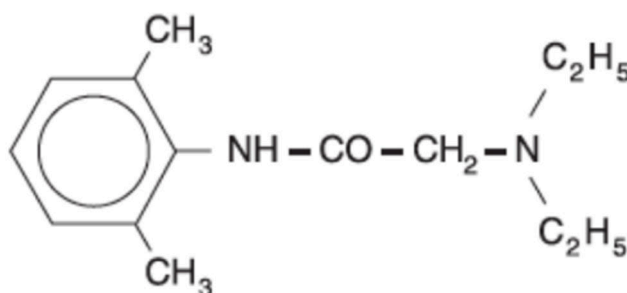


Figure 7: Structure of Lignocaine

It is available in the following forms:

Preservative-free solutions:

1. 2% solution for intravenous use, as an antiarrhythmic agent or to blunt responses to endotracheal intubation;
2. 5%, 'heavy' solution for intrathecal use. It is made hyperbaric by the addition of 7.5% dextrose.

With preservative (methyl paraben):

1. 1%, 2% solutions for use as local anaesthetic – intradermal, subcutaneous injections, epidural anaesthesia and nerve blocks.
2. 2% viscous solution for gargling, 2% jelly for mucosal analgesia
3. 2% lignocaine with adrenaline (5µg/ml) for local infiltration. This can also be used for peripheral nerve blocks.
4. 4% solution for mucosal analgesia.
5. 4% (provides 4mg/spray) and 10% (provides 10mg/spray) lignocaine spray.

Pharmacokinetics:

Due to high first pass metabolism in liver, it is orally inactive. When given iv bolus, action lasts only for 10–20 min because of rapid redistribution. Lidocaine is metabolized in the liver by N-dealkylation, with subsequent hydrolysis to monoethylglycine and xylidide. Monoethylglycine is further hydrolysed, whilst xylidide undergoes hydroxylation to 4-hydroxy-2,6-xylidine which is the main metabolite and excreted in the urine. Metabolites of lidocaine may lower the fit threshold, thereby potentiating seizure activity, whilst others have some antiarrhythmic properties. ^(26,27)

The $t_{1/2}$ of early distribution phase is 8 min and of elimination phase is nearly 2 hours. Its $t_{1/2}$ is prolonged in Congestive Heart Failure(CHF) due to decrease in volume of distribution and hepatic blood flow.

Mechanism of action:

Diffusion of the uncharged base form through neural sheaths and the axonal membrane to the internal surface of cell membrane of Sodium (Na^+) channels. There they combine with hydrogen ions to form a cationic species which enters the internal opening of the Na^+ channel and combines with a receptor. This produces blockade of the Na^+ channel, thereby decreasing Na^+ conductance which delays the rate of spontaneous phase 4 depolarization by preventing or diminishing the gradual decrease in potassium ion permeability that normally occurs during this phase.

Lidocaine is a blocker of inactivated Na^+ channels more than that of open state. As such, it is relatively selective for partially depolarized cells and those with longer Action potential duration. While normal ventricular and conducting fibres are minimally affected, depolarized/damaged fibres are significantly depressed. Brevity of atrial action potential and lack of lidocaine effect on channel recovery might explain its lack of efficacy in atrial arrhythmias. ^(26,27)

It has minimal effect on normal ECG- QT interval may decrease. It causes little depression of cardiac contractility or arterial BP. There are no significant autonomic actions: all cardiac effects are direct actions.

The most prominent cardiac action of lidocaine is suppression of automaticity in ectopic foci. Enhanced phase-4 depolarization in partially depolarized or stretched PFs, and after-depolarizations are antagonized, but SA node automaticity is not depressed.

Adverse effects:

Dose related neurological effects are drowsiness, nausea, paraesthesia, blurred vision, disorientation, nystagmus, twitching and seizures. When the plasma concentration remains less than 5 mg/mL there is no cardiovascular effect. Seizures occur at plasma concentrations of 5 to 10 mg/mL. CNS depression, apnea, and cardiac arrest occur when plasma concentrations are greater than 10 mg/mL. The convulsive threshold for lidocaine is decreased during arterial hypoxemia, hyperkalemia, or acidosis, emphasizing the importance of monitoring these parameters during continuous infusion of lidocaine to patients for suppression of ventricular arrhythmias. The dose required to produce cardiovascular toxicity is said to be approximately 7 times higher than that required to produce central nervous system toxicity. ^(26,27)

ALKALINISED LIGNOCAINE

Alkalinized lidocaine in the endotracheal tube (ETT) cuff decreases the incidence of cough and throat pain on emergence after surgery lasting more than 2 hours. However, alkalinized lidocaine needs 60–120 minutes to cross the ETT cuff membrane; therefore, its usefulness in shorter duration surgery is unknown.

During general anesthesia using nitrous oxide the cuff pressure increases as the temperature of the cuff rises and nitrous oxide diffuses into it more rapidly .

This overinflation of the ETT cuff has been associated with damage to pharyngeal mucosa and recurrent laryngeal nerve palsy. These complications can be prevented by filling the ETT cuffs with lignocaine.⁽²⁸⁾

Alkalinization of lignocaine shortens the onset of a neural blockade, enhances the depth of blockade and increases the spread of the blockade. The pH of commercial preparation of local anesthetics range from 3.9 to 6.5.

Alkalinization increases the percentage of local anaesthetic existing in the lipid soluble form that is available to diffuse lipid cellular barriers.

Lidocaine when used as endotracheal tube (ETT) cuff inflation media reduces the postintubation related sore throat and cough. A lower incidence of endotracheal tube discomfort and sore throat after 24 hours and lower systolic arterial pressure at the time of extubation has also been observed when lignocaine is used as the cuff inflation media . Tracheostomized patients, who have to keep the tube for a long time and whose discomfort seems to come mainly from the inflated cuff, can benefit from intracuff lidocaine. Pressures in cuffs filled with lignocaine were significantly lower than in cuffs filled air.

For patients with high peak inflation pressure, an injection of a large volume of lignocaine into the cuff is needed because the minimum occlusive pressure increases linearly with peak inflation pressure . It should be ascertained, not to use more than the maximum allowable dose. ⁽²⁸⁾

In addition, intracuff lidocaine does not increase the cuff volume during the maintenance of general anesthesia with nitrous oxide. It would be more effective for certain kinds of surgery like neuro or craniofacial surgery because this type of surgery usually takes long time, and the pilot balloon port cannot be accessible for the cuff pressure adjustment without interrupting the surgical procedure.

KETAMINE**HISTORY**

Victor Maddox of Detroit synthesized phencyclidine and it was introduced into clinical use by Greifenstein and Johnstone in 1958. Ketamine was synthesized in 1962 by Stevens and was first used in humans in 1965 by Corsen and Domino.

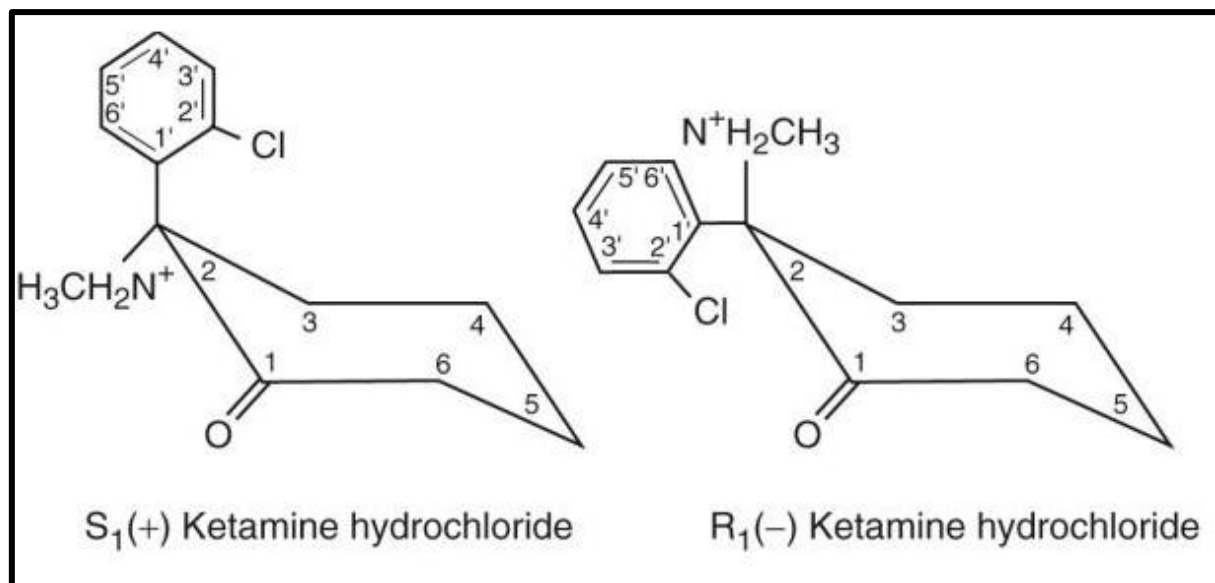


Figure 8: Stereoisomers of ketamine

PHYSICOCHEMICAL CHARACTERISTICS

Ketamine is 2-(2-chlorophenyl)-2-methylamino-cyclohexanone hydrochloride. The molecular weight is 238 kD. It is partially water soluble and forms a white crystalline salt with a pKa of 7.5. It is prepared in a slightly acidic pH of 3.5-5.5 and is available in 1%, 5% and 10% solutions containing the preservative benzathonium chloride. Ketamine has a chiral center at the carbon-2 atom of its cyclohexanone ring and therefore it exists as the optical stereoisomers S(+) and R(-)ketamine. Ketamine was previously only available as a racemic mixture but now comes in its two stereoisomer varieties. S(+)ketamine binds NMDA receptors with an affinity that is four times greater than that of R(-)ketamine. While the duration of S(+)ketamine is shorter than that of

R(-)ketamine, S(+)-ketamine has been shown to have an analgesic potency twice as great as the racemic mixture and four times as great as R(-)ketamine. ^(29,30)

PHARMACOKINETICS

The extreme lipid solubility of ketamine ensures its rapid transfer across the Blood - brain barrier. Peak plasma concentration occurs within 1 minute after IV administration and 5 minutes after IM injection. Not significantly bound to plasma proteins.

Distribution half life – 11 to 16 minutes.

Elimination half life – 2 to 3 hours.

Large volume of distribution – 3 L / kg.

Total body clearance – 1.4 L / min.

Alterations in hepatic blood flow influences ketamine clearance rate.

Metabolism is by the hepatic microsomal enzymes cytochrome P – 450 . Major pathway is N- demethylation to form nor – ketamine (20-30% activity) which is then hydroxylated to form hydroxy norketamine. These products are conjugated to water soluble glucuronide derivatives and are excreted in the urine. Chronic administration of ketamine can stimulate the enzymes responsible for its metabolism (enzyme induction) and explain the observation of tolerance and dependence. ^(29,30)

MECHANISM OF ACTION

Ketamine interacts with the following receptors.

A) N-methyl D- Aspartate receptor antagonism :

Non-competitive antagonist of the NMDA – receptor calcium pore. It also binds to the phencyclidine binding receptor site causing inhibition of the NMDA receptor activity (S(+)-isomer more affinity)

B) Opioid receptors :

Ketamine may be an antagonist at mu receptors and an agonist at kappa receptors.

C) Mono aminergic receptors :

Antinociceptive actions may involve descending inhibitory monoaminergic pain pathways.

D) Muscarinic receptors :

Ketamine produces an antagonistic effect at these receptors. Anticholinergic symptoms are common.

E) Voltage sensitive calcium channels

PHARMACODYNAMICS

Effect on the Central nervous system :

a) Dissociative anaesthesia : A cataleptic state, with profound analgesia, the eyes remain open with a slow nystagmic gaze. Noncommunicative, though wakefulness appears to be present. Corneal, cough and swallowing reflexes are present but not protective. Varying degrees of hypertonus and purposeless movements can occur. The patient is amnesic. In the thalamo neocortical projection systems, ketamine produces a functional disorganization of pathways and dissociation between the thalamocortical and limbic system. Plasma levels for anaesthesia are 0.6 to 2 mcg / ml in adults and 0.8 to 4 mcg / ml in children. Duration of action is 10 to 15 minutes and full orientation occurs in 15 to 30 minutes.

b) Ketamine produces an increase in the cerebral blood flow and cerebral metabolic oxygen requirement. With increase in cerebral blood flow and generalized increase in the sympathetic nervous system response, there is an increase in the intra cranial pressure. Cerebrovascular response to carbon-di-oxide appears to be preserved with ketamine. Prior administration of thiopental, diazepam or midazolam can blunt the

ketamine induced increase in cerebral blood flow and cerebral metabolic oxygen requirement.

c) Due to its excitatory central nervous system effects, the drug produces theta – wave activity as well as petitmal seizure like activity in hippocampus. Theta activity signals analgesic activity. Onset of delta activity coincides with the loss of consciousness. Ketamine does not alter the seizure threshold in epileptic patients but it can produce a myoclonic and seizure like activity without cortical epileptic activity.

d) Emergence reaction: Vivid dreaming, extracorporeal experiences (sense of floating) and illusions, may progress to delirium associated with excitement, confusion, euphoria and fear. This occurs in the first hour of emergence and usually abates within 1 to several hours. Emergence delirium occurs secondary to ketamine induced depression of the inferior colliculus and medial geniculate nucleus leading to misinterpretation of auditory and visual stimuli. The loss of skin and musculo skeletal sensation results in decreased ability to perceive gravity producing a sensation of bodily detachment (floating in space). Incidence 10 to 30 %. Prevention – benzodiazepines especially midazolam is more effective; can be given 5 minutes before induction. Inclusion of thiopental or inhalation can decrease the incidence. Premedication with atropine or droperidol may increase the incidence of emergence delirium. ^(29,30)

Effect on the Respiratory system :

Ventilatory response to carbon-di-oxide is maintained; transient decrease in minute ventilation (1-3 min) can occur after a bolus dose; apnoea can occur after rapid IV or along with an opioid. Respiratory depression can occur with the use of sedative and anaesthetic drugs. In children, it can cause respiratory depression. Bronchodilator activity is used to treat bronchospasm and status asthmaticus. Mechanisms include

increased circulatory catecholamine concentrations, inhibition of catecholamine uptake, voltage sensitive calcium channel block and inhibition of post synaptic nicotinic or muscarinic receptors.

Effect on the Cardio vascular system :

Sympathetic and pulmonary arterial blood pressure, heart rate, cardiac output and myocardial oxygen requirements are increased after IV ketamine. Ketamine has a direct myocardial depressant effect (negative inotropic) getting unmasked when the compensatory sympathetic nervous system activity is exhausted or following depletion of endogenous catecholamine stores. Enhances the dysrhythmogenicity of epinephrine. Mechanisms causing stimulation of sympathetic nervous system include: direct central nervous system stimulation and increased outflow, depression of baroreceptor reflex via N-methyl D-aspartate receptor, inhibition of norepinephrine uptake into post ganglionic sympathetic nerve endings and associated increase of plasma catecholamines. Methods used to block ketamine induced sympathetic stimulation are use of alpha and beta adrenergic antagonist, vasodilators, clonidine, prior administration of benzodiazepines, inhalational anaesthetics, barbiturates, and droperidol. ^(29,30)

USES

I. INDUCTION AND MAINTENANCE :

Intramuscular induction in children and mentally retarded patients, for burn dressing changes, wound debridements and skin grafting procedures. Induction agent of choice in patients with reactive airway disease or bronchospasm or asthma. Its use as cardiac stimulant is advantageous in trauma victims with acute hypovolemia provided there is sufficient sympathetic reserve. Patients with septic shock also benefit from ketamine. Ketamine anaesthesia is used for cardiac tamponade, constrictive Pericarditis &

congenital heart disease with right to left shunt. In patients with malignant hyperthermia and anterior mediastinal mass, ketamine use maintains spontaneous ventilation (inhalation contraindicated). Diazepam 0.5mg/kg IV and ketamine 0.5 mg/kg IV followed by a continuous infusion of ketamine 15 to 30 µg/kg/min can be used in patients with coronary artery disease. Low dose ketamine can be used as an analgesic following thoracic surgery.

Induction : 0.5 – 2 mg/kg IV 4 - 6 mg/kg IM

Maintenance : 0.5 – 1 mg/kg IV 30 – 90 µg/kg/min IV

II. SEDATION :

Ketamine sedation is used for paediatric procedures like cardiac catheterization, radiation therapy, dressing changes and dental work.

0.2 - 0.8 mg/kg IV

2 - 4 mg/kg IM Ketamine

0.5mg/kg IV combined with diazepam 0.15mg/kg IV is better accepted for supplementation of regional anaesthesia. ^(29,30)

III. NEURAXIAL ANALGESIA :

Extra dural (30mg) and intrathecal (5mg) administration produces variable and brief analgesia.

Adverse Effects

Increased Blood Pressure, tachycardia, tonic & clonic muscle movements, tremors and vocalization, emergence reaction, visual hallucination, vivid dreams or illusions. Less frequently bradycardia, hypotension, respiratory depression, apnoea, vomiting, cardiac arrhythmias, laryngospasms and airway obstructions occur. Rarely double vision, loss of appetite, nystagmus, skin rash (red skin) etc are noted.

METHODOLOGY

Source of Data: KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi.

Patients of age 18-60 years; ASA status of I & II, either gender who underwent elective surgical procedures required general anaesthesia with single lumen oro tracheal intubation from January 2020 to December 2020.

METHOD OF COLLECTION OF DATA:

- a) **Study design:** A one-year hospital based randomized controlled study.
- b) **Sample size:** Total sample size -132 adult patients subdivided into 3 groups of 44 each.
- c) **Sample size calculation:**

The formula for calculating the minimal sample size based on prevalence

$$n = \frac{z_{\alpha}^2 P(1-P)}{d^2} \text{ where } P \text{ is the percentage of prevalence;}$$

The significance level is related to z_{α} .

For a level of significance of 5%, $z_{\alpha} = 1.96$

With a type I error rate α of less than 0.05,

The percentage probable difference in prevalence is denoted by d .

Ref: The prevalence of sore throat after surgery is 32 percent in the intracuff lignocaine group⁽⁵⁾

As a result of $P = 32\%$ and $d = 25\%$ of P , the sample size was 131.

The sample size was expanded to 132 in order to have three groups of similar size, each with 44 participants.

d) Place:

KLES Dr. Prabhakar Kore Hospital and Medical Research Center, Jawaharlal Nehru Medical College, Belagavi.

e) Selection Criteria:

Inclusion Criteria:

- Patients who gave consent, underwent elective surgical procedures under general anaesthesia with single lumen ETT ,age of 18-60 years.
- ASA status I & II.
- Mallampatti Grade [MPG] grade I,II
- Duration of surgery 30mins- 120mins

[Female- Poly vinyl chloride cuffed ETT 7.5mm ID. Male- Poly vinyl chloride cuffed endotracheal tube size 8.5mm internal diameter.]

Exclusion Criteria :

- Patient with *URTI*
- Patient consuming steroids
- History of asthma, COPD
- Multiple intubation attempts
- Laparoscopic surgery

f) Sampling procedure:

A one year randomized control trial. Randomization was achieved by computer generated randomization chart.

g) Methodology:

The Department research committee gave their approval and the Institutional ethical board gave its support for the study. Before enrolling, written informed agreement was obtained from 132 patients who were over the age of 18 and under the age of 60, belonged to the ASA I and II, and were scheduled for elective surgical operations requiring general anaesthesia with ETT.

After obtaining consent and completing inclusion & exclusion criteria, patients were randomly subjected to one in 3 groups using a *computer-generated randomization* table.

Gp A: Intracuff preservative free lignocaine 2% (2ml) with normal saline (5ml)

Gp B: Intracuff preservative free lignocaine 2% (2ml) with 7.5% sodium bicarbonate(5ml)

Gp C: Intracuff Ketamine 20mg (2ml) with normal saline (5ml)

A detailed pre anaesthetic assessment were done on day prior to procedure with necessary investigations and also receive 0.25mg alprazolam (benzodiazepine) and 150mg ranitidine (H2 blocker) orally day prior to procedure.

Intravenous access was obtained with 18G or 20G on the day of surgery. Iv fluids (Ringer lactate/ Normal saline) was started. Standard monitoring devices was attached before induction of anaesthesia, including NIBP, ECG, and pulse oximeter.

Patient received Inj ondansetron 4mg and Inj Ranitidine 50mg after shifting to OT complex

For three minutes, patients were preoxygenated with 100 percent FiO₂. “Injections of Glycopyrrolate 0.005 mg/kg, Midazolam 0.05 mg/kg, and Fentanyl 2 mcg/kg” were used to premedicate the patients.

“Injections of thiopentone (5 mg/kg) & Succinylcholine (2 mg/kg)” were used to induce the patients. After the onset of neuromuscular blockade laryngoscopy was done and endotracheal intubation is done with *cuffed PVC ETT size: 7.5mm ID* for women and *8.5mm ID* for men.

Then after confirming bilateral equal air entry, cuff of endotracheal tube was filled with
Gp A: Intracuff preservative free lignocaine 2% (2ml) with normal saline (5ml)

Gp B: Intracuff preservative free lignocaine 2% (2ml) with 7.5% sodium bicarbonate(5ml)

Gp C: Intracuff Ketamine 20mg (2ml) with normal saline (5ml)

Correct inflation volume was confirmed by auscultation for air leak over trachea.

ET tube was secured with tapes at appropriate length and mechanically ventilated.

Monitoring of pulse oximeter, NIBP, electrocardiography and capnography after intubation was done

Patients were maintained with oxygen, nitrous oxide Isoflurane. Inj. vecuronium in loading dose of 0.1 mg/kg and top up 1/4th of loading dose is given.

At the end of the procedure of duration 60mins- 120 mins, patients were reversed using injections Glycopyrrolate 0.005mg/kg & Neostigmine 0.05mg/kg and then the patients were extubated.

Post extubation, heart rate, NIBP, saturation was monitored at intervals of 1 min, 5 min and in the recovery at 10 min.

Hoarseness, dysphagia, cough, post operative sore throat, post operative nausea and vomiting incidence and severity were noted at extubation and followed up for 24 hours at regular interval of 6 hours.

Severity of sore throat post surgery, hoarseness, cough were graded according to the following, (based on Laryngo pharyngeal morbidity score; LPM score)⁽⁶⁾ :

Postoperative sore throat⁽⁶⁾

0 No sore throat at any time since the operation

1 Minimal patient answered in the affirmative when asked about sore throat

2 Moderate for patient complained of sore throat on his/her own

3 Severe for patient is in obvious distress

Postoperative cough⁽⁶⁾

0 no cough at any time since the operation

1 minimal cough/ scratchy throat

2 moderate cough present but present throughout

3 severe cough with signs of infection

Postoperative hoarseness⁽⁶⁾

0 No complaint of hoarseness at any time since the operation

1 Minimal - Minimal change in quality of speech. Patient answers in the affirmative only when enquired about.

2 Moderate - Moderate change in quality of speech of which the patient complains on his/her own

3 Severe - Gross change in the quality of voice perceived by the observer

Dysphagia⁽⁶⁾

0 None

1 Minimal

2 Moderate

3 Severe and cannot eat

Post operative nausea and vomiting⁽⁶⁾

0 None

1 Minimal (1 episode)

2 Moderate(2-3 episodes)

3 Severe (4 or more episodes)

Data obtained were entered in proforma, tabulated and analysed.

Statistical Analysis

Study focused on three-group comparison. Mean and standard deviation was determined for continuous quantitative data. Intergroup continuous variables was compared using appropriate statistical procedures such as one-way ANOVA. For pair - wise comparison, an unpaired student's t test was utilised. To compare two quantitative variables within a group, the students paired t-test was utilised.

The median was used to represent discrete variables. The comparison was depicted using appropriate graphs.

Rates, ratios, and percentages were used to express categorical data. Associations amongst results, clinical, and demographic features were studied using Chi-square-test or Fisher's-exact-test.

All tests considered substantial if the *p-value* was less than 5% (0.05).

RESULTS

The purpose of study was to *compare efficacy* of intracuff preservative free lignocaine, alkalized preservative free lignocaine and ketamine in preventing incidence and severity of *sore throat postoperatively, cough and voice hoarseness*.

This was a 1 year hospital based study ,conducted in the Department of Anaesthesiology, KLES Dr.Prabhakar Kore Hospital and Medical Research Center,Belgavi between January 2020 to December 2020 .

The study results are tabulated, analyzed, observations and results are discussed below.

One hundred thirty two patients between 18-60 years of both sexes belonging to ASA class I and II scheduled to undergo various elective surgeries under *GA* were included in present study and were classified in to 3 groups:

Group A – Intracuff preservative free lignocaine

Group B- Intracuff alkalised preservative free lignocaine

Group C- Intracuff ketamine

Table 1: Gender distribution

Gender	Gp-A	Percentage%	Gp-B	Percentage%	Gp-C	Percentage%
Male	27	61	32	72	25	56
Female	17	39	12	28	19	44
Total:	44.0	100.0	44.0	100.0	44.0	100.0
p Value	0.2789					

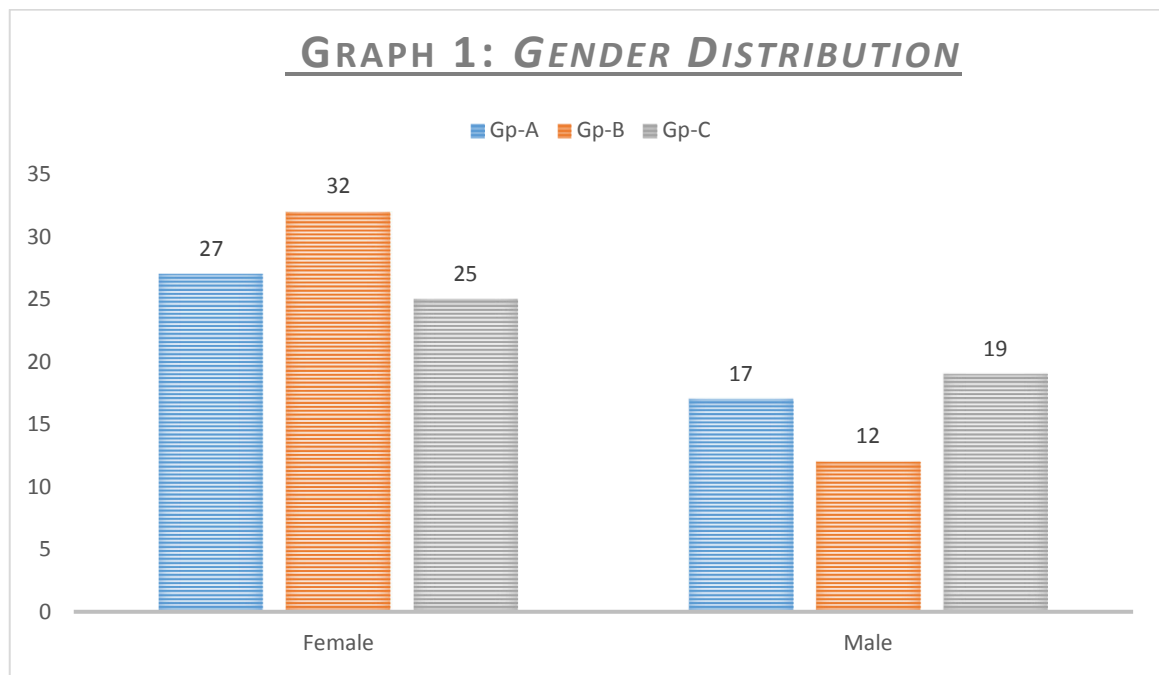


Table 1 and Graph 1 represents the gender distribution of patients. In group A, 61 % were females and 39% males. In group B, 72% were females and 28% males. In group C, 56 % were males and 44% females. The gender distribution was not statistically significant (p value 0.2789). Hence all 3 groups were comparable.

Table 2: Age Distribution

Age	Gp-A	Gp-B	Gp-C
Mean	39.16	39.39	42.48
SD	13.41	13.87	21.70
p value	0.5852		

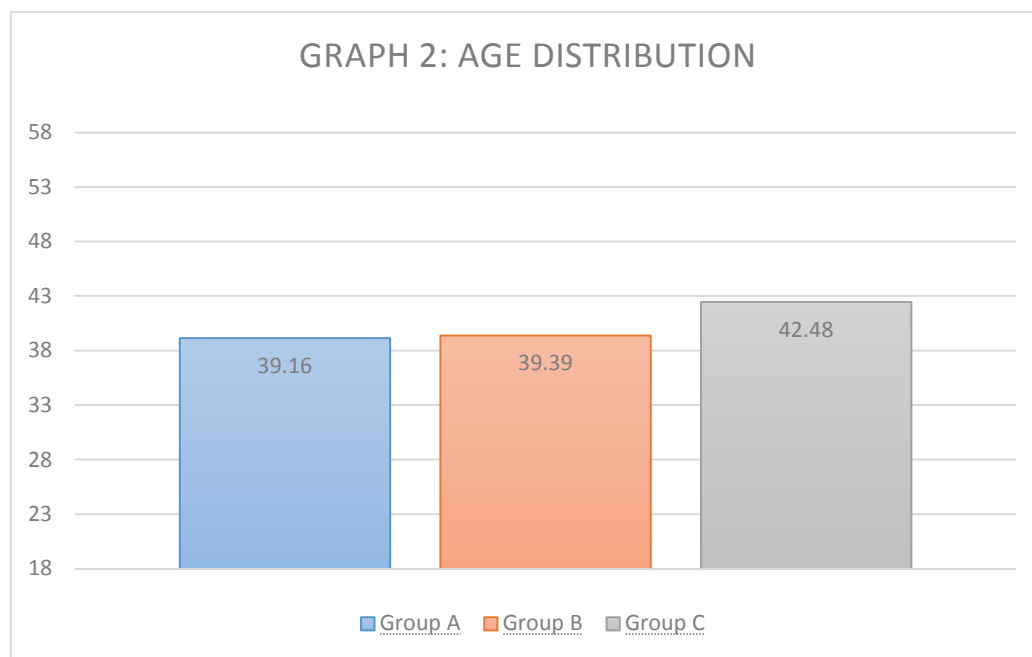
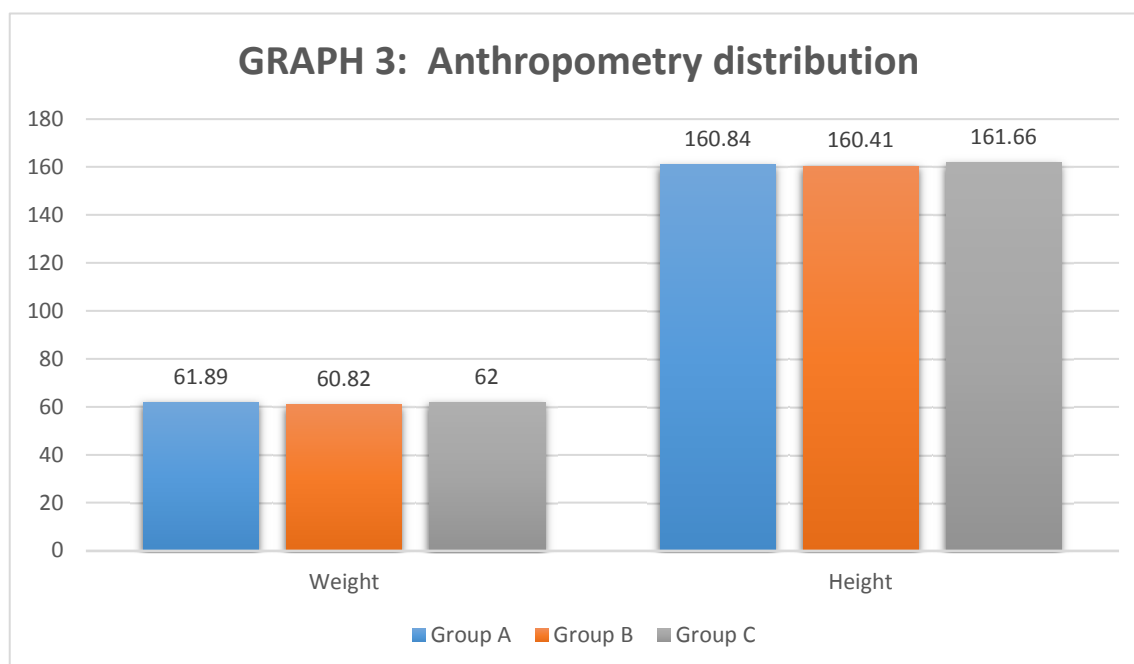


Table 2 and Graph 2 shows the age distribution of patients studied. Patients were above 18 years and up to 60 years old. In group A, the average age of the patients was 39.16 ± 13.41 , in group B 39.39 ± 13.87 and in group C 42.48 ± 21.70 which are comparable with a p Value of 0.5852.

Table 3: Anthropometry Distribution

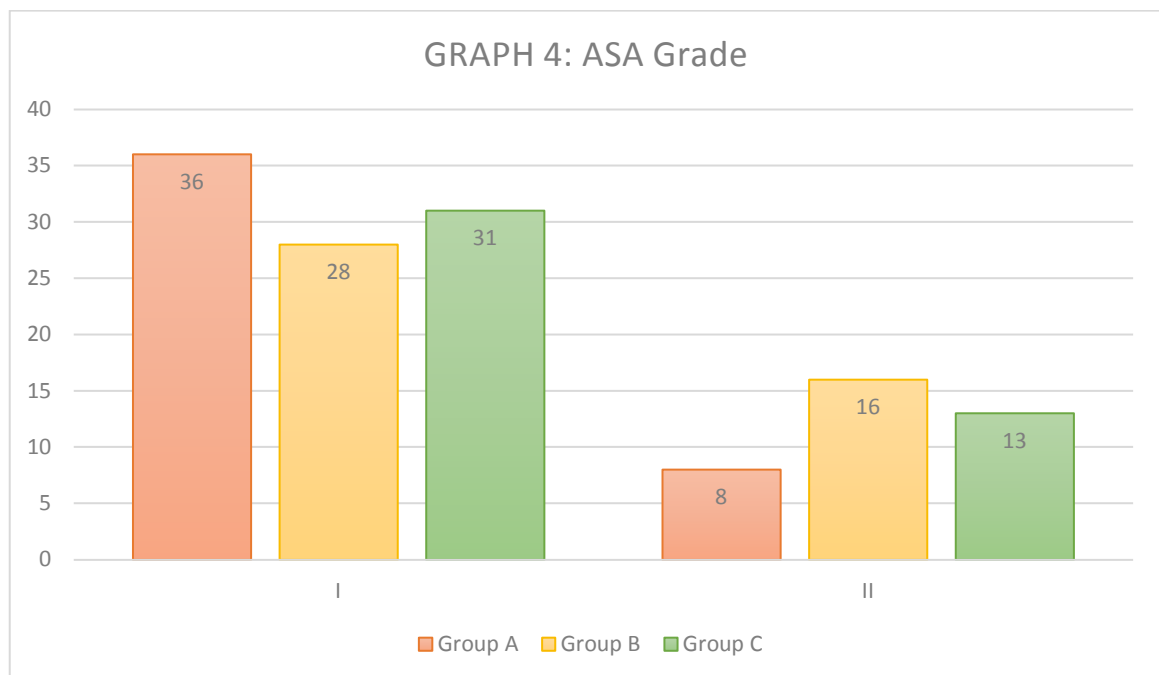
Variables	Gp-A		Gp-B		Gp-C		p Value
	MEAN.	S.D.	MEAN.	S.D.	MEAN.	S.D.	
Weight(kgs)	61.89	8.67	60.82	8.45	62.00	6.92	0.7498
Height.	160.84	7.61	160.41	7.75	161.66	7.92	0.7455



In this study, no statistical difference were observed amongst Group A, B and C with regards to mean weight (61.89 ± 8.67 ; 60.82 ± 8.45 kg and 62.00 ± 6.92 respectively; $p=0.7498$)and mean height(160.84 ± 7.61 ; 160.41 ± 7.75 and 161.66 ± 7.92 cm respectively; $p=0.7455$) as shown in table and graph 3.

Table 4: ASA Grade

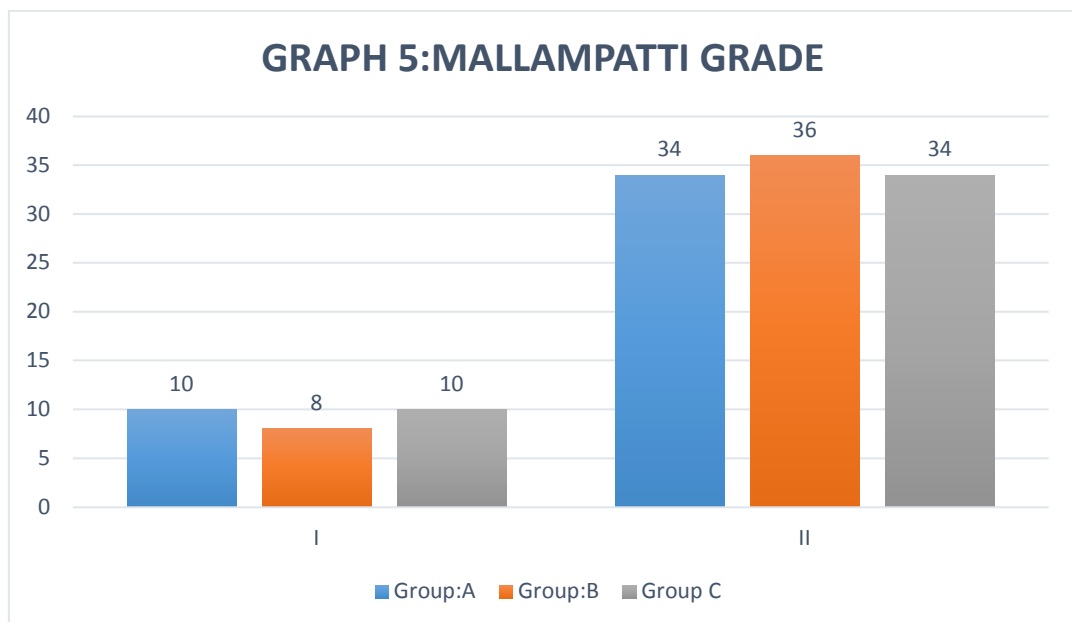
ASA Grade	Gp-A	Percentage%	Gp-B	Percentage %	Gp-C	Percentage %
I	36	81.8	28	63.7	31	70.5
II	8	18.2	16	36.4	13	29.5
Total:	44.0	100.0	44.0	100.0	44.0	100.0
p Value	0.055					



In this study, A, B and C group have 81.8, 63.7 and 70.5 percent respectively of participants belonging to ASA I and 18.2, 36.4 and 29.5 percent participants belonging to ASA II and here the three groups are comparable with each other (p value 0.055) as shown in table 4 and graph 4.

Table 5: Mallampatti Grading for ease of intubation

MPG	Gp-A	Percentage %	Gp-B	Percentage %	Gp-C	Percentage %
I	10	22.7	8	18.2	10	22.7
II	34	77.3	36	81.8	34	77.3
Total:	44.0	100.0	44.0	100.0	44.0	100.0
p Value	0.597					



In group A and C, 10 (22.7%) and 34(77.3%) patients had Mallampatti grade I and II respectively. In group B, 8 (18.2%) and 36(81.8%) had Mallampatti grade I and II respectively. Distribution of patients according to Mallampatti grade in two groups were statistically similar (p value=0.597) as shown in table 5 and graph 5.

Table 6: Volume of drug inflated into and deflated from cuff

	Gp-A	Gp-B	Gp-C
Mean Volume inflated(mL)	4.79	4.93	4.92
Min Vol inflated	4mL	4mL	4mL
Max Vol inflated	6mL	5.5mL	5.5mL
SD	0.49	0.39	0.49
p value	0.283		
Mean Volume deflated(mL)	4.07	4.11	4.14
Min vol deflated	3.4mL	3.5mL	3.5mL
Max vol deflated	5mL	4.6mL	4.8mL
SD	0.45	0.33	0.39
p value	0.731		

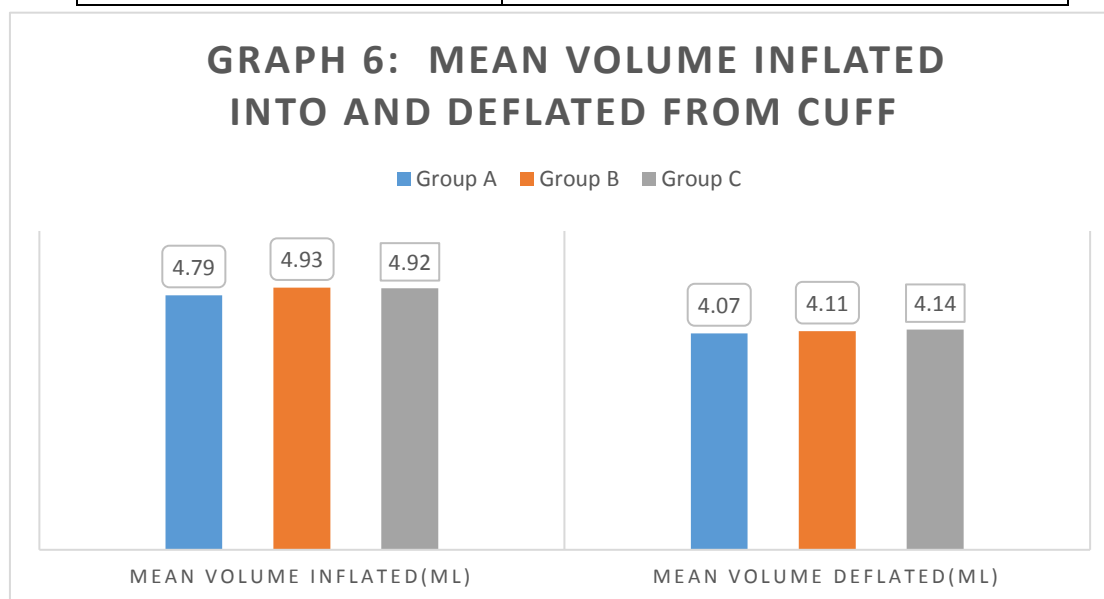


Table 6 and graph 6 represents the volume of drug inflated in to and deflated from the cuff in Group A, B and C. The minimum volume inflated from cuff in all three groups is 4mL and maximum volume inflated in Group A is 6mL, in group B and C maximum volume inflated is 5.5mL. Minimum volume deflated from cuff in Group A is 3.4mL, Group B and C is 3.5mL. Maximum volume deflated from cuff in Group A is 5mL, Group B is 4.6mL, Group C is 4.8mL. Hence the volume inflated into (*p Value* :0.283) and deflated from (*p Value*: 0.731) the cuff are statistically similar. In all 3 groups around 0.5ml -1mL of drug has been diffused in the semipermeable membrane of the cuff.

Table 7: Mean duration(mins) of surgical procedure

	Gp-A	Gp-B	Gp-C
Mean duration(mins)	102.27	98.52	101.59
p value	0.8177		

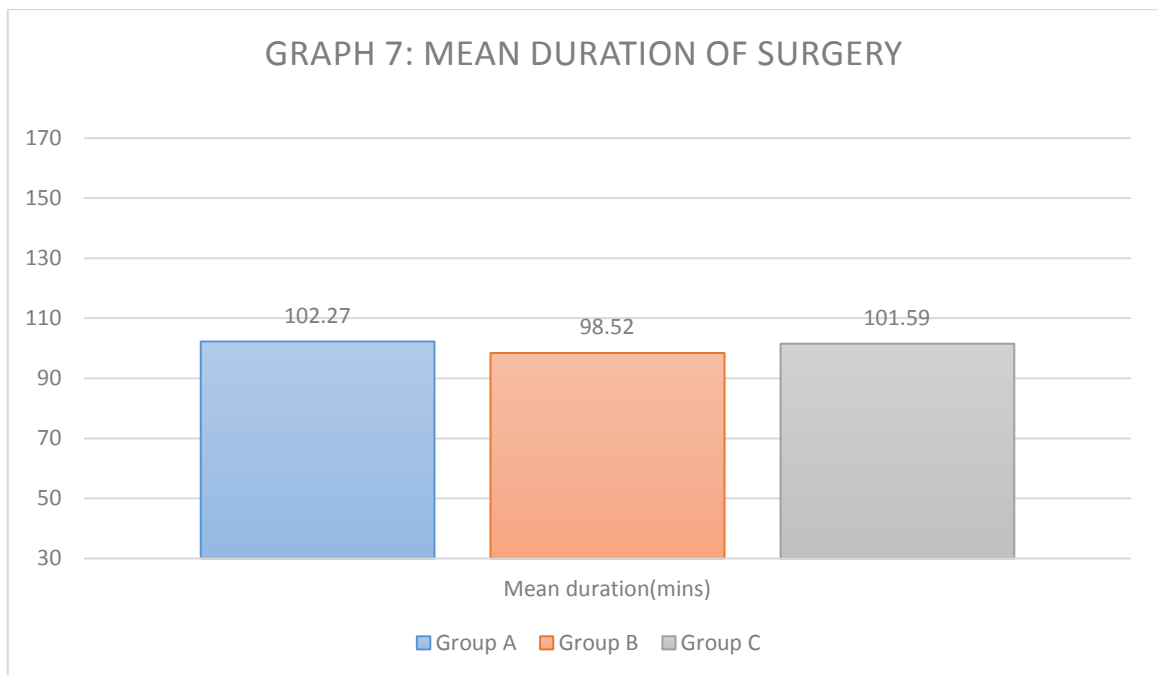
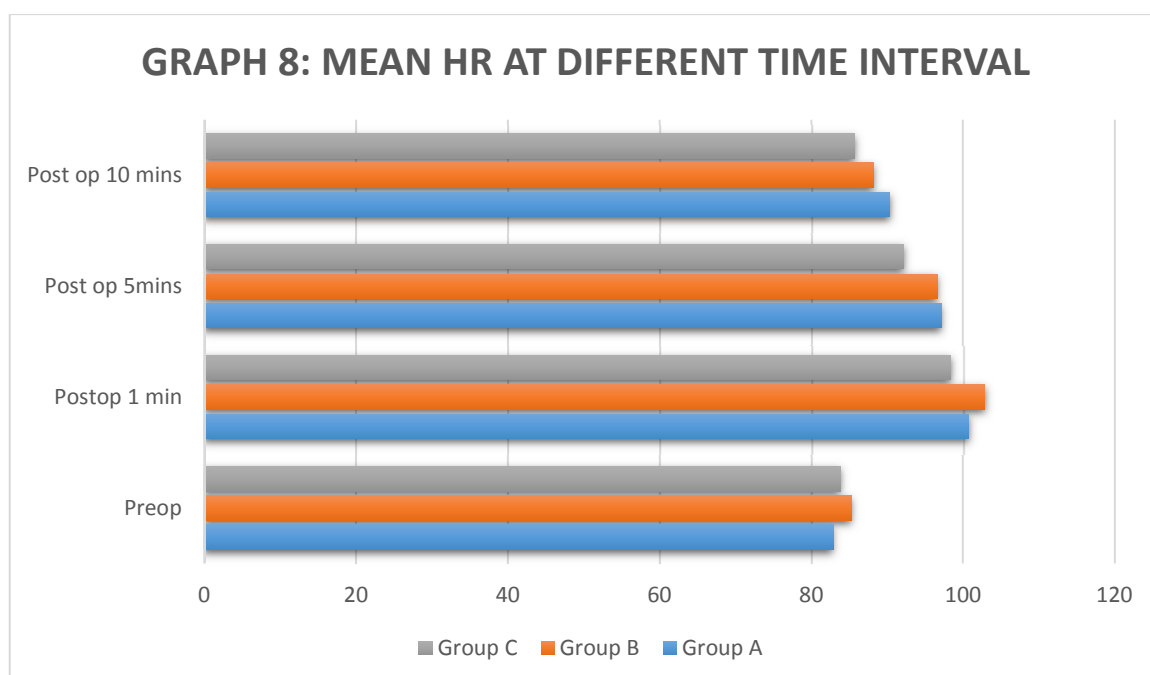


Table 7 and graph 7 shows mean duration (mins) of surgical procedure. Here all three groups have comparable with each other. Mean duration of surgery ranged from 98.52-102.27 mins.

Table 8: Comparison of Mean HR at different time interval in different group

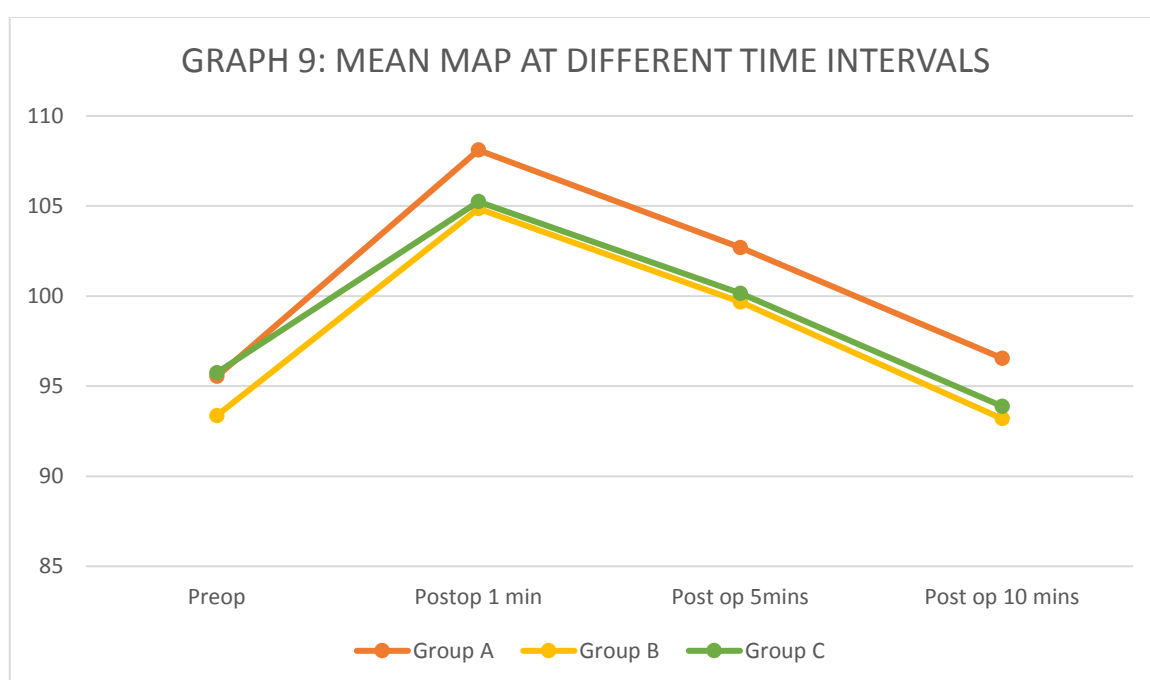
HR(bpm)	Gp-A		Gp-B		Gp-C		p Value
	MeanHR	S.D	MeanHR	S.D	MeanHR	S.D	
Preop	82.86	11.31	85.30	12.06	83.82	11.62	0.5841
Postop 1 min	100.73	17.05	102.86	5.15	98.36	9.50	0.198
Post op 5mins	97.07	9.33	96.59	5.29	92.16	8.60	0.007*
Post op 10 mins	90.30	9.25	88.18	5.24	85.70	7.21	0.021*



In this study, mean HR in all three groups are comparable in preoperative period and in immediate post operative period at 1 min. Mean HR is significantly reduced in Group C in postoperative period at 5 mins (92.16 ± 8.60) and 10 mins (85.70 ± 7.21) while compared to group B (p Value: 0.007) and group A (p Value: 0.021).

Table 9: Comparison of Mean MAP at different time interval in different group

MAP	Gp-A		Gp-B		Gp-C		p value
	MeanMAP	S.D	MeanMAP	S.D	MeanMAP	S.D	
Preop	95.55	7.41	93.36	8.53	95.75	8.24	0.3103
Postop 1 min	108.11	5.57	104.86	6.89	105.25	5.82	0.027*
Post op 5mins	102.70	5.01	99.68	7.13	100.16	5.58	0.0417*
Post op 10 mins	96.55	6.51	93.20	5.97	93.89	6.70	0.038*

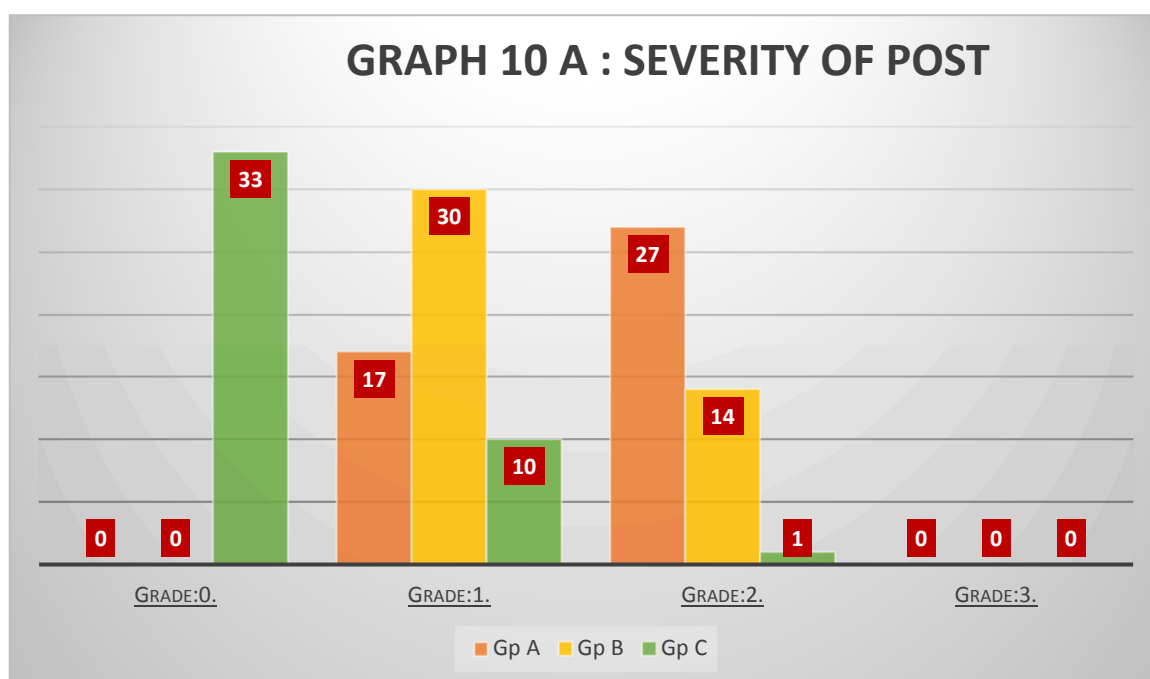


As seen on the above table 9 and graph 9, mean MAP preoperatively were comparable in all the three groups. Postoperatively, at 1 min, 5 min and 10 min interval mean MAP were reduced in Group C (p value-0.02, 0.03, 0.04 respectively) while compared to group B and A.

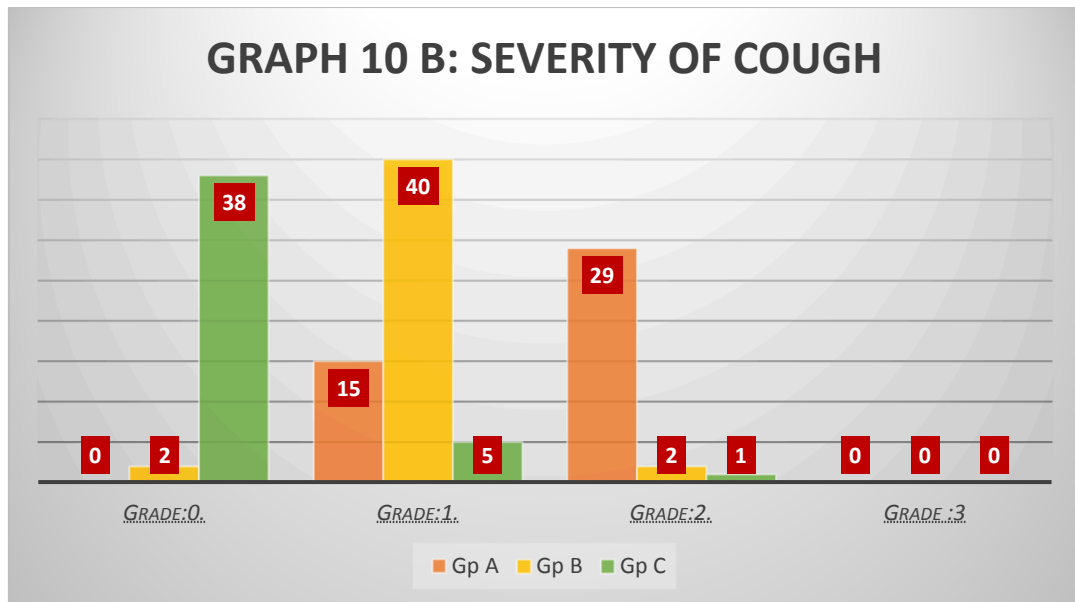
Table 10: Severity of POST, Cough, Hoarseness of voice and PONV in 1st hr

(Gp- Group)

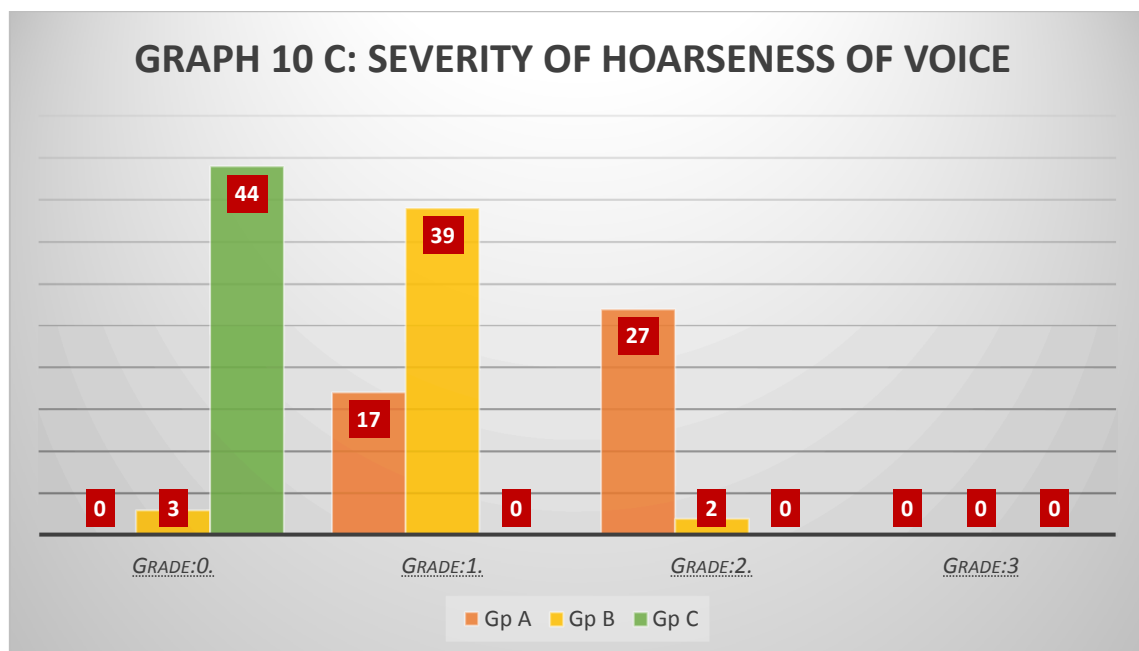
	POST			Cough			Hoarseness			PONV		
	Gp- A	Gp- B	Gp- C	Gp- A	Gp- B	Gp- C	Gp- A	Gp- B	Gp- C	Gp- A	Gp- B	Gp- C
Grade 0	0	0	33	0	2	38	0	3	44	31	38	44
Grade 1	17	30	10	15	40	5	17	39	0	12	6	0
Grade 2	27	14	1	29	2	1	27	2	0	1	0	0
Grade 3	0	0	0	0	0	0	0	0	0	0	0	0
p value	<0.001			<0.001			<0.001			0.0027		



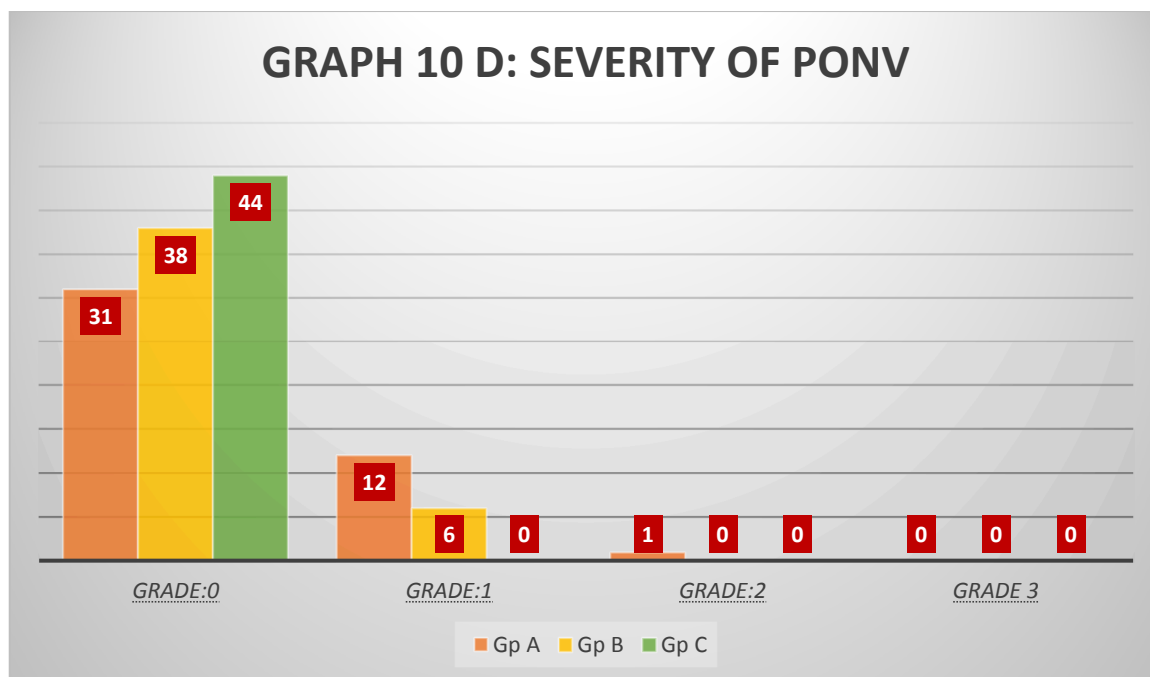
Severity of POST in group A, B and C is represented in table 10 and graph 10 A. In group C maximum patients (33) have grade 0 severity. In group B, maximum patients (30) have grade 1 severity. In group A, maximum patients (27) have grade 2 severity. Grade 3 severity is absent in all three groups. (p value< 0.001)



Severity of Cough in group A, B and C is represented in table 10 and graph 10 B. In group C maximum patients (38) have grade 0 severity. In group B, maximum patients (40) have grade 1 severity. In group A, maximum patients (29) have grade 2 severity. Grade 3 severity is absent in all three groups. (p value< 0.001)



Severity of Hoarseness of voice in group A, B and C is represented in table 10 and graph 10 C. In group C, all patients (44) have grade 0 severity. In group B, maximum patients (39) have grade 1 severity. In group A, maximum patients (27) have grade 2 severity. Grade 3 severity is absent in all three groups. (p value< 0.001)



Severity of PONV in group A, B and C is represented in table 10 and graph 10 D. In group C, all patients (44) have grade 0 severity. In group B, maximum patients (38) have grade 0 severity. In group A, maximum patients (12) have grade 1 severity. Grade 3 severity is absent in all three groups. (p value 0.0027)

Table 11 : Presence of POST, Cough , Voice hoarseness and Postoperative nausea and vomiting (PONV) at different time intervals

(Gp- group)

	POST			Cough			Hoarseness			PONV		
	Gp- A	Gp- B	Gp- C	Gp- A	Gp- B	Gp- C	Gp -A	Gp- B	Gp- C	Gp- A	Gp- B	Gp- C
6hr	44	43	12	44	44	6	42	43	0	17	5	3
p value	<0.001			<0.001			<0.001			<0.001		
12hr	42	25	1	42	43	1	36	27	0	12	5	1
p value	<0.001			<0.001			<0.001			<0.001		
24hr	33	4	0	32	11	0	22	5	0	0	0	0
p value	<0.001			<0.001			<0.001			0.79		

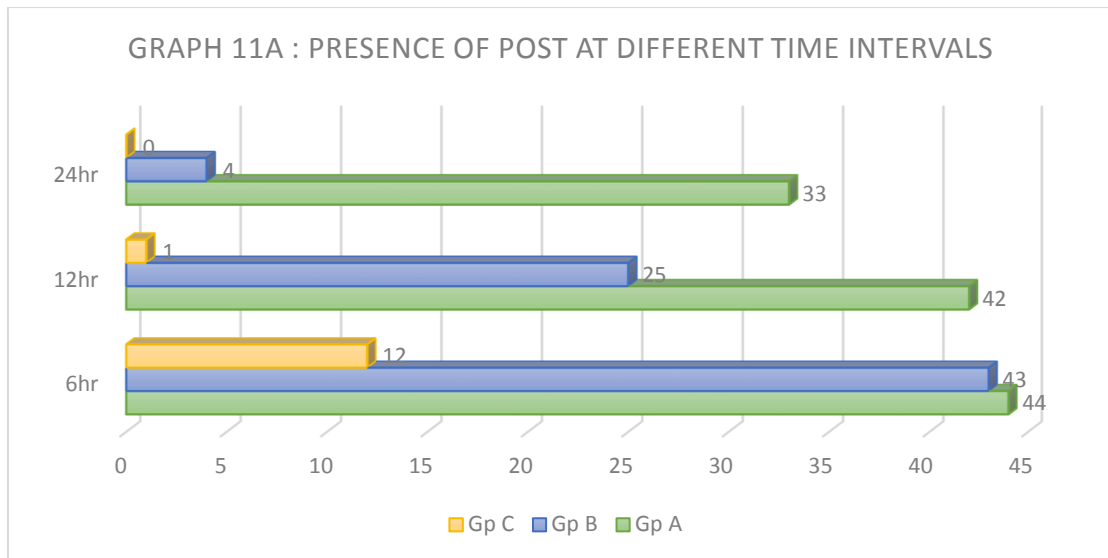


Table 11 and Graph 11A represents the presence of POST (post-operative sore throat) at 6 hr , 12hr and 24hrs in group *A*, *B* & *C*. In group *A* & *B* POST are comparable at 6hr and 12hr , but group *C* POST is significantly reduced (p value < 0.001). At 24hrs, POST is maximum only in group:*A*; & significantly reduced in groups:*B* & *C* (p value < 0.001)

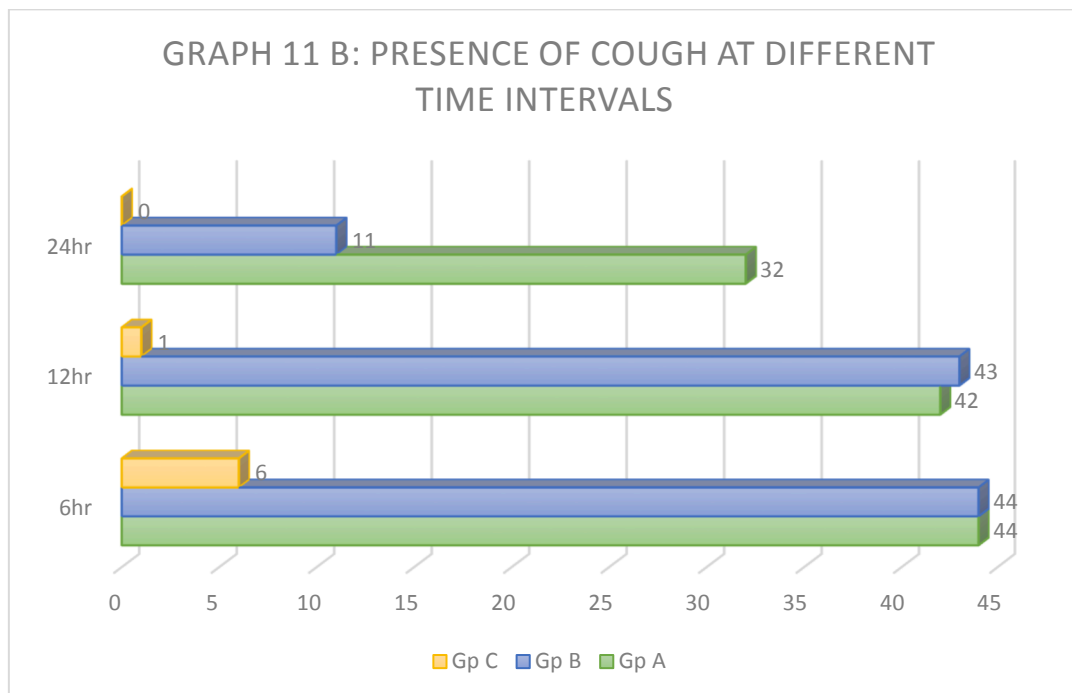


Table 11 and Graph 11B represents the presence of cough at 6hr, 12hr and 24hrs in group *A*, *B* & *C*. In group *A* and *B* cough is comparable at 6hr and 12hr , but group *C* cough is significantly reduced (p value < 0.001). At 24hrs, cough is maximum only in group:*A*; and significantly reduced in groups:*B* & *C* (p value < 0.001)

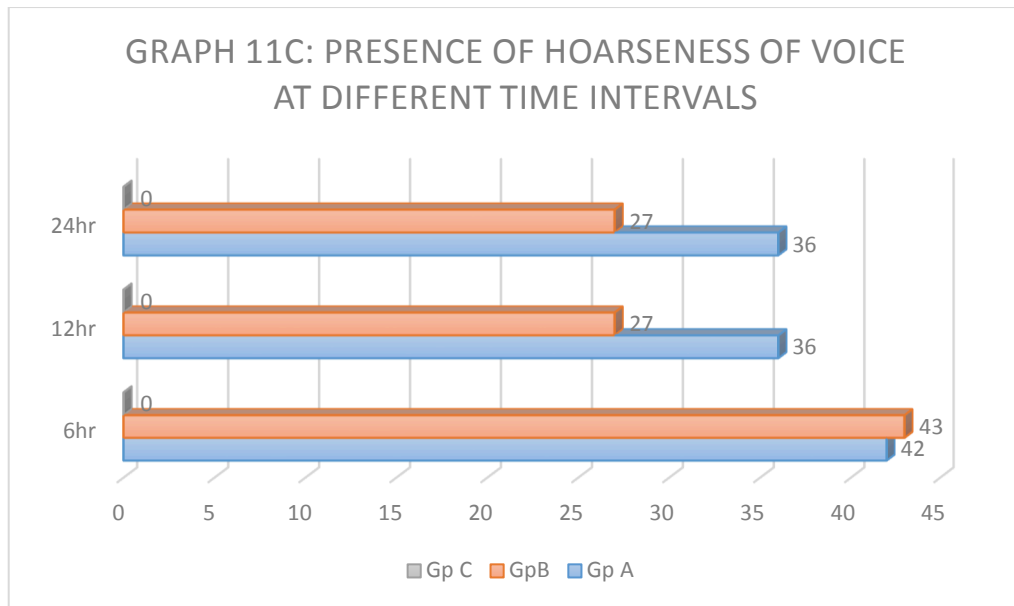


Table 11 and Graph 11C represents the presence of hoarseness of voice at 6hr, 12hr and 24hrs in group A, B & C. In group A and B hoarseness of voice is comparable at 6hr, but in group C hoarseness of voice is significantly reduced (p value < 0.001). At 12 hr and 24hrs, hoarseness of voice is maximum only in group A, reduced in group B & C (p value <0.001)

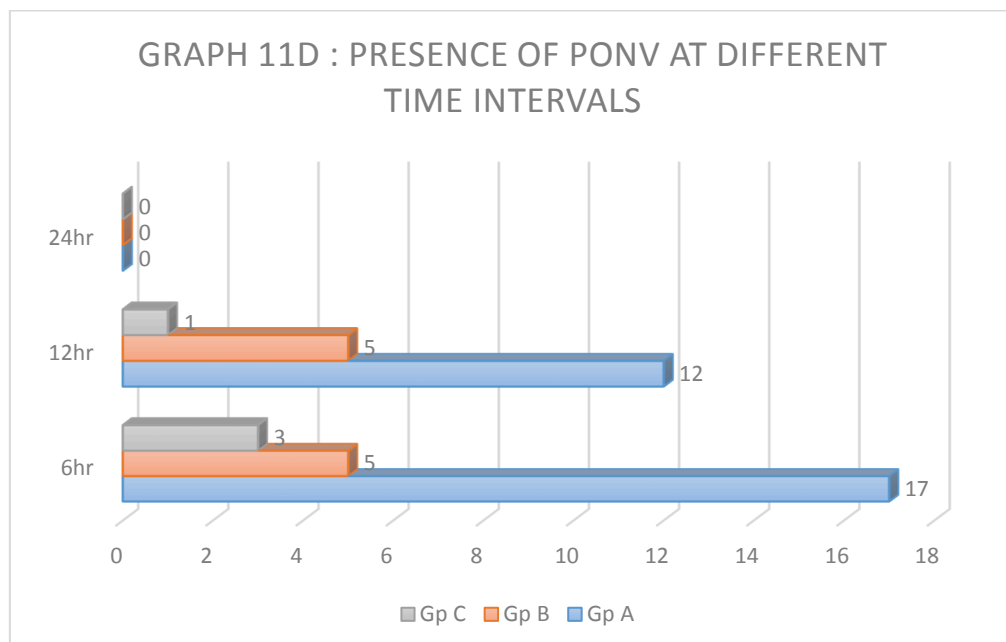


Table 11 and Graph 11D represents the presence of PONV (post-operative nausea and vomiting) at 6hr, 12hr and 24hr in group A, B&C. At 6hr and 12hr, presence of PONV is maximum in group:A; in comparison to group: B&C (p Value <0.001). At 24hr, all three groups are comparable- with absence of PONV.

DISCUSSION

In current anaesthetic practise, many surgeries under general anaesthesia are now performed with endotracheal intubation. After endotracheal intubation, POST is a well-known consequence⁽¹³⁾. However, the discomfort caused by a sore throat makes it one of the most unfavourable surgical side effects⁽³¹⁾.

POST (Post-operative sore throat) is a term that refers to a wide range of symptoms such as laryngitis, tracheitis, hoarseness, cough, or dysphagia that occur following intubation⁽³²⁾.

Patient sex, age, endotracheal tube size, cuff design, and intra cuff pressure have all been reported as contributing factors to sore throat after surgery⁽¹³⁾.

The identification of factors linked to the occurrence and severity of POST will assist anaesthesiologists to minimise these risk factors, reducing the occurrence and severity of POST and improving post-surgery outcomes. POST has been reduced using a multi-modal approach.

Non-pharmacological and pharmacological therapies are included. Non-pharmacological measures to reduce the incidence of POST include the use of smaller endotracheal tubes, careful airway manipulation, intubation after complete cord relaxation, gentle oral suctioning, minimising intra-cuff pressure, and extubation after complete deflation of the endotracheal tube's cuff.⁽³³⁾

Bethamethasone inhalation, IV preservative-free lignocaine, lubricating the tube with lignocaine jelly, gargling with lignocaine, and other pharmacological therapies are available^(33,34). However, all of these approaches have flaws and haven't been wholly successful in reducing the occurrence and POST severity.

Our study was designed to compare the effectiveness of intracuff preservative free lignocaine, alkalinised preservative free lignocaine and ketamine in abatement of post operative sore throat.

Many of the risk factors for POST, cough, and hoarseness were eliminated to avoid bias and minimise the influence of confounding factors as much as possible.; which were controlled in this study by inclusion criteria, exclusion criteria, and equivalent use of anaesthetic agents.

The sample distribution was comparable across all three groups in terms of gender, age, ASA physical status, Mallampatti grading, kind of surgical treatment, and duration of surgical procedure, making it more standardised.

As Stout D M et al (1987)⁽³⁵⁾ found that larger tubes cause more post-operative sore throat than smaller tubes, we used 8.5mm ID portex endotracheal tubes for men and 7.5mm ID portex endotracheal tubes for women in all three groups in our research.

The likelihood of soreness of throat increases as the surgery duration progresses. As a result, the duration of the process was determined in our research. In all three groups, the duration was standardised. The average length of the surgical operation was 98.52-102.27 minutes in all three groups. Our analysis eliminated any patient whose operation lasted less than half an hour but more than three hours.

When used as a cuff inflation medium, lidocaine may protect the tracheal mucosa by acting as a continuous topical anaesthetic and preventing nitrous oxide from diffusing into the cuff, lowering the incidence and severity of post-operative sorethroat cough and hoarseness^(36,37,38).

Alkalinization of lidocaine with sodium bicarbonate raises the pH of the solution to 7.43, which speeds up the diffusion of lidocaine through the cuff and its anaesthetic impact on the mucosa^(33,39,40,41). This alkalinization creates a hydrophobic base that allows the nonionised form to diffuse more readily through the polyvinylchloride wall of the cuff than lignocaine^(33,39,40,41).

Ketamine is an NMDA antagonist, and NMDA receptors can also be present in peripheral nerves^(42,43,44). By lowering NF κ B activity, TNF- (tumour necrosis factor) production, expression of inducible nitric oxide synthase serum C-reactive protein, IL-6, and IL-10, NMDA receptor antagonists are involved in the antinociception and anti-inflammatory cascade.^(42,43,44).

Due to stimulation of pain receptors in the throat mucosa owing to endotracheal tube adhesion, the incidence of postoperative sore throat is 21-65 percent after endotracheal intubation⁽³⁾.

In our study, the overall occurrence of POST was 52.6 percent in all three groups, with the highest incidence in the group using preservative free lignocaine (75 percent) as intracuff inflation media and the lowest incidence in the group using ketamine (22%), and the incidence in the alkalinised preservative free lignocaine group being 61 percent.

In a research by Soares SM et al⁽⁴⁵⁾., the incidence of sore throat was 11 times greater in the air (22%) and 5 times higher in the saline (10%) groups when compared to alkalinised lignocaine (2%) group, with the decrease being greatest with 1% lignocaine.

Similarly, Jaichandran W et al. ⁽⁴⁶⁾discovered that using 2 percent alkalinised lignocaine instead of air for cuff inflation reduced POST incidence by 5 times after 1 hour of extubation. In a different study, Ahuja V, Mitra S, and Sarna R⁽⁴⁷⁾ found that the Ketamine group had 17 (34 percent) patients complaining postoperative sore throat

compared to the Alkalinized lignocaine group, which had 28 (56 percent) patients complaining of it, with a $p=0.043$.⁽⁴⁷⁾

The POST intensity in ketamine group was considerably reduced than in the lignocaine group one hour after extubation in our study. (p value < 0.001).

In our study, POST is equivalent in the lignocaine and alkalinised lignocaine groups at 6hr and 12hr, whereas POST is significantly reduced in the ketamine group (p Value < 0.001). Only lignocaine group has the highest POST at 24 hours, whereas the other two groups have much lower POST. (p Value < 0.001).

In our study, the ketamine group had the most participants (33) who did not have POST. Maximum patients (30) in the alkalinised lignocaine group experienced mild POST. The majority of individuals (27) in the lignocaine group reported moderate POST.

Cambay et al. (2008)⁽³¹⁾ found that the incidence of mild, moderate, and severe POST in the ketamine gargle group was 25%, 10%, and 0%, respectively, compared to 57 percent, 17 percent, and 0% in the control group, with the difference being statistically significant (p value < 0.01). In our study, ketamine group had maximum patients with no sore throat and a few of them had mild sore throat.

Mechanical or chemical variables acting on sensory receptors along the respiratory mucosa cause cough, which has a postoperative incidence of 40-90 percent.

When the ETT cuff was inflated with lignocaine, air, or saline, Fagan C et al. examined the incidence of cough after extubation. They discovered that the lignocaine group had the lowest incidence of cough, at 16 percent, as compared to the air and saline groups, which had 38 percent and 44 percent, respectively.

The severity of cough in the ketamine group was considerably reduced than in the lignocaine group one hour after extubation (p value<0.001).

Cough is equivalent in the lignocaine and alkalinised lignocaine groups at 6 and 12 hours, however cough is significantly reduced in ketamine group (p Value< 0.001). Only the lignocaine group has the most cough after 24 hours, whereas the other two groups have dramatically reduced cough.

With a p-value of 0.04, Jolly S et al.⁽⁴⁸⁾ found that hoarseness of voice was limited in the alkalinised lignocaine group (6%) compared to saline (19%) and plain lignocaine (11%) at 24 hours post-extubation.

Hoarseness of voice in the lignocaine and alkalinised lignocaine groups is equivalent at 6 hours, however it is dramatically reduced in the ketamine group (p value <0.001). At 12 and 24 hours, only the lignocaine group had the most hoarseness of voice, whereas the other two groups had the least (p value <0.001).

The maximum volume deflated from the cuff in our trial was 5mL in the lignocaine group, 4.6mL in the alkalinised lignocaine group, and 4.8mL in the ketamine group.

As a result, the volume deflated from the cuff is statistically similar in all three groups, indicating that about 0.5mL-1mL of medication has diffused through the semipermeable membrane of the cuff.

Due to diffusion through the cuff, the deflating volume of liquid media would be smaller than the inflating volume when evaluating deflating volume of intracuff media at the moment of extubation. Because of the absorption of N₂O into the cuff, removed volume in the air group would be greater than inflating.⁽⁴⁹⁾

In a past study, the effects of alkalinised 2 percent lidocaine on cardiovascular alterations after extubation were not seen. Researchers discovered that intacuff alkalinised lidocaine decreases heart rate and blood pressure much more than air or saline after extubation in adults.

In our research, the preoperative HR of all three groups was comparable. When compared to alkalinised lignocaine group (p Value 0.007) and lignocaine group (p Value 0.007), mean HR in the ketamine group is considerably lower in the postoperative period at 5 minutes (92.16 ± 8.60) and 10 minutes (85.70 ± 7.21) (p value 0.021).

Preoperative mean MAP was comparable in all three groups in our investigation. When compared to alkalinised lignocaine and lignocaine group, mean MAP was reduced in the ketamine group at 1 minute, 5 minute, and 10 minute intervals (p value-0.02, 0.03, 0.04 correspondingly).

Due to insufficient uniform questioning strategies, the prevalence of postoperative sore throat differed among different investigators in different studies. Direct inquiry by Harding et colleagues (1987)⁽⁵⁰⁾ revealed a greater prevalence of sore throat. In order to determine the incidence of post-operative sore throat, nausea and vomiting, hoarseness, dysphagia, and cough, we utilised a direct way of asking.

The intracuff solution utilised in our study was chosen by randomization, which is a major strength. The name of the intracuff solution used for inflating the endotracheal tube was not indicated in the anaesthesia chart or on the proforma in order to eliminate bias on the part of the anaesthesiologist assessing the morbidities.

Coughing or buckling on the endotracheal tube have been linked to an increased risk of POST. On the other hand, none of our patients coughed or buckled while on the

tube. All of the patients recovered quickly and were extubated after the cuff was completely deflated.

POST is more likely when a throat pack is placed around the endotracheal tube. Throat packs, on the other hand, were not used in any of the patients in our study.

The effects of preservative-free lignocaine, alkalized lignocaine, and ketamine as cuff inflation media which when were compared in a study, was observed that utilising ketamine as the cuff inflation medium resulted in a considerable reduction in occurrence of POST after emergence from GA (p Value < 0.0001). In addition, compared with the other 2 groups, the incidence of various ETT insertion negative effects such as cough post operatively, voice hoarseness, and PONV was lower when preservative free lignocaine and alkalised preservative free lignocaine as the cuff inflation media.

We reported post-intubation morbidities in connection to endotracheal tube intacuff inflation in this study. Other factors that contribute to these morbidities include endotracheal tube cuff pressure and trauma during intubation. These aspects, however, were not taken into account in our research. This can be stated as one of the limitation in our study.

If these characteristics were factored into the study's approach, a more accurate comparison of various intracuff treatments may have been done in terms of lowering post-intubation morbidity.

SUMMARY

A study was conducted to compare effectiveness of preservative free lignocaine, alkalinised preservative free lignocaine and ketamine in abatement of sore throat ,voice hoarseness and cough postoperatively. Patients of age 18-60 years; ASA status of I & II, either gender who underwent non elective surgical procedures requiring GA with single lumen oro tracheal intubation were considered in the study.

After obtaining consent and completing inclusion & exclusion criteria, patients were randomly subjected to one in 3 groups using a computer-generated randomization table.

Gp A: Intracuff preservative free lignocaine 2% (2ml) with normal saline (5ml)

Gp B: Intracuff preservative free lignocaine 2% (2ml) with 7.5% sodium bicarbonate(5ml)

Gp C: Intracuff Ketamine 20mg (2ml) with normal saline (5ml).

Technique, endotracheal; tube size and drugs for procedure were kept standardized in the 3 groups.

In post operative period direct questions were asked to patients with regarding to severity and prevalence of POST, PONV, cough and voice hoarseness

Observations showed that age, sex distribution, preoperative vitals ,procedure vitals and volume of cuff inflated and deflated were comparable between 3 groups.

Presence of POST was maximum in preservative free lignocaine group compared to others. Severity of POST was also maximum (grade 2) in same group, observed more commonly within 6hrs post procedure. Preservative free alkalinised lignocaine group saw the presence of POST within 6 hrs of procedure but the intensity of POST was much lesser. Ketamine group saw the maximum reduction in POST in terms of severity and incidence. Same results were seen with regards to voice hoarseness and cough.

With regards to stability of hemodynamics post extubation it was noted that better stability (HR, mean MAP) was provided by ketamine group post extubation followed by preservative free alkalinised lignocaine group.

CONCLUSION

In conclusion to our study, we noted that prevalence and severity of POST, cough, voice hoarseness, PONV was significantly reduced in ketamine and preservative free alkalised lignocaine group when compared to lignocaine group. Both the groups even provided better hemodynamic stability. However ketamine used as intracuff media was more effective than preservative free alkalised lignocaine. Hence contributing to better patient satisfaction and smoother recovery.

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ANNEXURE I – CONSENT FORM

INFORMED CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mr./Mrs. _____ we are requesting you to enroll your ward in study titled **“A STUDY ON EFFECTIVENESS AMONGST INRACUFF PRESERVATIVE FREE LIGNOCAINE, ALKALINISED PRESERVATIVE FREE LIGNOCAINEAND KETAMINE IN ABATEMENT OF POST OPERATIVE SORE THROAT.ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL”**

conducted by Post-Graduate in M.D. Anaesthesiology Department of Anaesthesiology, J.N. Medical College, Belagavi under KLE University, Belagavi.

Respected Sir/Madam We request you allow your ward to participate in our study as he/she is eligible for participating in the study. During the study you will be asked some questions regarding the present complaints that your ward is having.

Your participation in this research is voluntary. Your decision whether or not to participate in the study will not affect your relationship with J.N. Medical College. If you decide to participate you are free to withdraw at any time.

Purpose of the study:

To assess and compare effectiveness of intracuff preservative free lignocaine ,alkalinized preservative free lignocaine and ketamine in preventing incidence and severity of post operative sore throat, cough, hoarseness of voice,post-operative nausea,vomiting and dysphagia.

Procedure involved:

If you agree to enroll in my study, I will ask your present past and family history. Then you will be clinically examined in detail .You will be allotted into one of the three groups randomly using computer generated software.

Group A: Intracuff preservative free lignocaine 2% (2ml) with normal saline (5ml)

Group B:Intracuff preservative free lignocaine 2% (2ml) with 7.5% sodium bicarbonate(5ml)

Group C: Intracuff Ketamine 20mg (2ml) with normal saline (5ml)

There will be possibility in reduction in incidence and prevalence of post- operative sore throat

Voluntary Participation/Withdrawal:

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

Alternatives: Even if you decline the participation in the study, you will get the routine line of management.

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

1. In emergency to protect your rights and welfare.
2. If required by law.

Authorization to Publish Results:

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

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

Compensation: In the event of injury related to the study, treatment will be made available through KLES Hospital and MRC, Belagavi. There is no compensation or payment for such medical treatment by law.

CONSENT FOR PARTICIPATION IN RESEARCH TRIAL

“A STUDY ON EFFECTIVENESS AMONGST INRACUFF PRESERVATIVE FREE LIGNOCAINE, ALKALINISED PRESERVATIVE FREE LIGNOCAINE AND KETAMINE IN ABATEMENT OF POST OPERATIVE SORE THROAT. ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL”

I, Mr./Mrs. _____ voluntarily agree for the participation of my ward as a subject of study. By signing this consent form, I am not giving up any of my legal rights, I may withdraw my ward from the study anytime. I am signing the consent form after having read or been read for me in vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name: _____

Guardian Name: _____

Signature or the Left Thumb Print

of Guardian: _____

Date:

Witness Name: _____ Signature: _____

Investigators Name: _____ Signature: _____

Date: _____ Place : _____

ANNEXURE II – PROFORMA

“A STUDY ON EFFECTIVENESS AMONGST INTRACUFF PRESERVATIVE FREE LIGNOCAINE, ALKALINISED PRESERVATIVE FREE LIGNOCAINE AND KETAMINE IN ABATEMENT OF POST OPERATIVE SORE THROAT: A ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL.”

Patients Name	:	I.P No.	:	
Age	:	Weight	:	
Height	:	Gender	:	
Date of operation	:	Occupation	:	
Address	:	Anaesthesiologist:		

Chief complaints :

HOPI:

Past History

- HTN / DM/ IHD / Arrhythmia / LVH / Valvular heart disease/ COPD/ Asthma
- H/o steroid usage
- H/o URTI
- H/o uncontrolled hypertension/diabetes mellitus
- H/o previous surgery/(s) where airway difficulty was encountered.

Family History :

General physical examination:

Weight (Kg)	:	Temperature (°F)	:	Pallor	:
Cyanosis	:	Pedal oedema	:	Clubbing	:

Baseline Vitals:

Parameter	Measurement
Systolic BP	
Diastolic BP	
Heart rate	
MAP	

Systemic examination:

RS : CNS :
CVS : GIT :

Airway Assessment –

Spine-

Investigations

Hb% : Platelets :
Random sugar(RBS) : Serum creatinine: ECG
: CXR :

Diagnosis:

Proposed surgery:

Duration of surgery:

Preoperative physical status ASA Grade I II III IV V

Endotracheal tube size:

Volume inflated	Volume deflated

Parameter	After intubation	After extubation 1 min	After extubation 5 mins	In recovery (at 10 mins)
Systolic BP				
Diastolic BP				
Heart rate				
MAP				

Parameter	1 hour post extubation	6 hours post extubation	24 hours post extubation
Cough			
Dysphonia			
Sore throat			
Post operative nausea and vomiting			



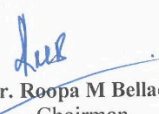
	Absent	Present		
		Mild	Moderate	Severe
Post operative sore throat				
Post operative nausea and vomiting				
Hoarseness				
Cough				
Dysphagia				

SIGNATURE OF THE WITNESS - _____

SIGNATURE OF THE PRINCIPAL INVESTIGATOR - _____

SIGNATURE OF THE ANAESTHESIOLOGIST - _____

ANNEXURE III – ETHICAL CLEARANCE LETTER

	K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH (Deemed - to- be- University)	
	Accredited 'A' Grade by NAAC (2 nd Cycle)	Placed in Category 'A' by MHRD (GoI)
JAWAHARLAL NEHRU MEDICAL COLLEGE, NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)		
Website: http://www.jnmc.edu E-Mail : dome@jnmc.edu	Phone: (+ 91-(0)831 Office : 2472550 Principal: 2471701 Fax No. +91 (0)831 – 2470759	
Ref: MDC/DOME/ 181		Date: 24/12/2019
<p>To,</p> <p>BA0119002 PG student in Anaesthesiology, J.N.Medical College, BELAGAVI.</p>		
<p>Sub: Institutional Ethical Clearance for the study.</p>		
<p>With reference to the above, we wish to inform you that your proposed research project titled “A STUDY OF EFFECTIVENESS AMONGST INTRACUFF PRESERVATIVE FREE LIGNOCAINE, ALKALINIZED PRESERVATIVE FREE LIGNOCAINE AND KETAMINE IN ABATEMENT OF POST OPERATIVE SORE THROAT: A ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL ”, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.</p>		
 (Dr. Anita Dalal) Member Secretary JNMC Institutional Ethics Committee on Human Subjects Research, J.N.Medical College, Belagavi.		 (Dr. Roopa M Bellad) Chairman, JNMC Institutional Ethics Committee on Human Subjects Research, J.N.Medical College, Belagavi.

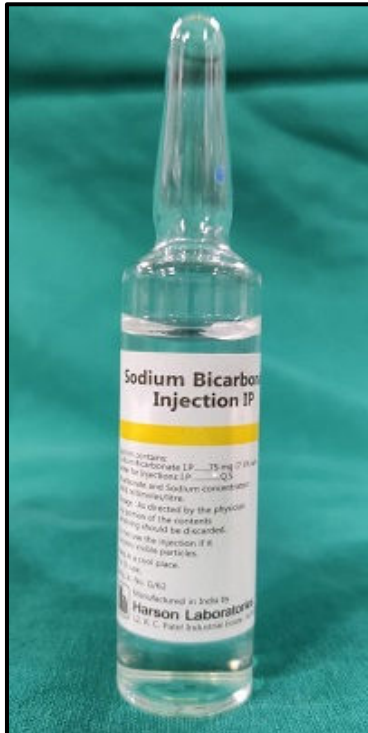
ANNEXURE IV: PHOTOGRAPHS



Photograph 1:
Endotracheal tube(ETT) with
inflated intracuff solution
media



Photograph 2:
The ETT cuff is being
inflated with the solution
post intubation



Photograph 3:
Sodium bicarbonate
7.5%



Photograph 4:
Normal saline

Drugs used as cuff inflation media



Photograph 5 :
Preservative free
lignocaine



Photograph 6:
Ketamine (20mg)

Drugs used as cuff inflation media



Photograph 7: Anaesthesia workstation and monitor

ANNEXURE – V - KEY TO MASTERCHART

ASA	-	American society of Anaesthesiologist
MAP	-	Mean Arterial Pressure
POST	-	Post operative sore throat
PONV	-	Post operative nausea and vomiting
ETT	-	Endotracheal tube
MAP	-	Mean Arterial Pressure
HR	-	Heart Rate
SBP	-	Systolic Blood Pressure
DBP	-	Diastolic Blood Pressure
M	-	Male
F	-	Female
Cm	-	Centimeter
Kg	-	Kilogram
MPG	-	Mallampati Grade

ANNEXURE - VI MASTER CHART

Lignocaine																																														
Sl.No	Age(yrs)	Sex(F/M)	Ip No	Height(cms)	Weight(kgs)	ASA(I/II)	MPG(I/II)	Procedure duration(mins)	ETT(7.5/8.5)	Vol inflated(ml)	Vol deflated(ml)	Preop Vitals				Post op vitals at 1min				Post op vitals at 5mins				Post Op vitals at 10mins				Cough		Dysphonia		Sore throat		PONV		POST	PONV	Hoarseness	Cough	Dysphagia						
												HR(bp)	SBP(mmHg)	DBP(mmHg)	MAP	HR	SBP	DBP	MAP	HR	SBP	DBP	MAP	HR	SBP	DBP	MAP	Extubation	Extubation	Extubation	Extubation	Extubation	24hr post	1hr post	6hr post	24hr post	1hr post	6hr post	24hr post	A/M/MO/S	A/M/MO/S	A/M/MO/S	A/M/MO/S	A/M/MO/S		
1	46	F	995629	152	56	II	II	150	8	5	4	70	136	84	101	80	162	92	115	76	156	84	108	72	148	78	101	Y	Y	Y	N	N	N	Y	Y	Y	Y	N	N	N	MO	A	MO	MO	A	
2	59	F	996973	148	55	I	I	100	8	4	4	70	120	68	85	104	144	88	107	100	136	84	101	88	130	78	88	Y	Y	N	Y	N	N	Y	Y	N	N	N	N	N	N	MO	A	MO	M	A
3	23	F	997248	152	45	I	II	120	8	4	3	74	118	70	86	82	122	78	93	80	116	72	87	74	108	68	81	Y	N	N	Y	N	N	Y	N	N	N	N	N	M	A	M	M	A		
4	34	M	997326	168	78	I	II	140	9	5	4	84	132	70	91	112	148	94	98	109	140	94	109	101	130	86	80	Y	N	N	Y	N	N	Y	Y	Y	N	N	N	MO	A	M	M	A		
5	58	M	1000781	178	80	II	II	60	9	4	4	80	156	90	112	94	138	94	112	94	138	94	106	86	136	88	104	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	N	MO	M	MO	NO	M		
6	20	M	1002020	166	50	I	II	120	9	5	5	60	120	78	92	74	134	90	105	66	124	86	99	60	116	78	91	Y	Y	N	Y	Y	N	Y	Y	N	N	N	MO	A	M	MO	A			
7	42	F	1006380	154	58	I	I	90	8	4	4	72	110	70	85	100	152	90	111	90	140	80	100	76	134	78	97	Y	Y	N	N	N	Y	Y	N	Y	N	N	M	A	M	M	A			
8	30	F	1011662	148	44	I	II	120	8	4	4	86	130	84	99	110	138	106	117	96	134	96	109	84	126	88	101	Y	Y	Y	Y	Y	N	Y	Y	Y	N	N	N	MO	A	MO	MO	A		
9	54	F	1012723	156	72	I	II	120	8	5	4	90	128	86	100	10	138	84	102	94	130	80	97	84	124	82	96	Y	Y	Y	Y	N	N	Y	Y	Y	N	N	N	MO	A	MO	MO	A		
10	56	M	1012814	170	55	I	I	120	9	5	4	70	120	68	85	104	142	88	106	100	136	84	101	88	130	78	95	Y	Y	Y	Y	Y	N	Y	Y	Y	N	N	N	MO	A	M	M	A		
11	55	M	1013630	152	60	II	II	90	8	5	4	65	160	80	107	100	118	98	125	100	160	90	113	96	156	88	111	Y	Y	Y	Y	Y	N	Y	Y	Y	N	N	N	M	A	M	M	A		
12	20	M	1013123	166	58	I	II	150	9	5	4	86	150	80	103	100	166	96	114	94	156	80	105	90	150	78	102	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	MO	A	M	MO	A			
13	25	F	1014349	155	65	I	II	60	8	5	4	70	124	78	93	120	140	90	107	110	136	84	101	94	122	74	90	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	MO	A	MO	MO	A		
14	38	F	1015216	162	60	I	II	160	8	5	4	70	126	82	97	104	128	86	100	100	126	82	97	86	122	78	93	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	MO	A	MO	MO	A			
15	60	M	1014229	166	70	I	II	150	9	6	5	80	116	78	91	116	132	100	111	108	126	90	102	100	118	86	97	Y	Y	Y	Y	Y	N	Y	Y	Y	N	N	N	MO	A	M	M	A		
16	44	F	1015438	162	65	I	I	40	8	5	4	90	114	72	86	100	144	96	112	90	136	90	105	86	124	80	95	Y	Y	Y	Y	N	N	Y	Y	Y	N	N	N	M	A	M	M	A		
17	30	M	1015506	158	52	I	I	60	9	6	5	90	130	90	103	120	138	100	113	110	128	90	103	104	120	70	87	Y	Y	Y	Y	N	N	Y	Y	Y	N	N	N	MO	A	M	M	A		
18	38	F	1015773	150	45	I	II	40	8	5	4	84	114	82	93	110	134	92	106	96	126	90	102	84	116	80	92	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	MO	A	M	MO	A		
19	19	M	1015673	168	65	I	II	90	9	5	4	84	128	84	99	100	132	98	109	92	128	92	104	86	122	84	98	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	MO	M	MO	MO	M		
20	48	F	1017028	158	60	II	II	120	8	5	4	96	128	90	103	110	140	100	113	102	128	90	103	90	118	86	97	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	MO	A	MO	MO	A		
21	34	M	1016272	170	70	I	II	90	9	5	4	90	126	84	98	106	132	94	107	100	128	86	100	94	118	84	95	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	N	N	MO	A	M	M	A	
22	38	F	1017626	156	60	I	II	60	8	4	4	84	110	76	90	98	136	82	100	90	124	84	97	82	116	78	91	Y	Y	Y	Y	Y	N	Y	Y	Y	N	N	N	MO	A	M	M	A		
23	57	F	1019679	155	70	I	II	150	8	5	4	86	134	90	105	100	144	96	112	94	140	88	105	90	134	80	98	Y	Y	N	Y	Y	N	Y	Y	N	N	N	N	N	MO	A	M	M	A	
24	18	M	1021349	168	65	I	II	90	9	5	4	90	128	76	93	114	128	96	107	108	124	90	101	100	116	80	100	Y	Y	N	Y	Y	N	Y	Y	N	N	N	N	N	MO	A	M	M	A	
25	37	M	1021456	168	70	I	I	150	9	5	5	##	136	90	105	106	136	98	111	100	128	88	101	94	128	84	99	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	MO	A	MO	MO	A			
26	28	F	1021826	164	60	I	II	120	8	5	5	96	116	78	91	100	122	94	103	96	118	86	97	90	110	78	89	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	MO	A	MO	MO	A			
27	30	M	1021823	168	68	I	II	120	9	6	5	##	118	90	99	106	130	100	110	104	120	96	104	100	118	90	103	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	MO	A	MO	MO	A			
28	34	M	1021480	168	60	I	II	150	9	5	5	96	116	84	95	108	128	96	107	104	126	94	105	100	120	86	97	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	MO	A	MO	MO	A			
29	31	F	1023439	145	55	I	II	60	8	4	4	84	126	80	95	108	130	98	109	104	126	94	105	100	116	90	99	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	MO	A	MO	MO	A			
30	44	F	1015459	158	76	I	I	100	8	5	4	66	108	76	87	118	116	100	105	110	110	98	102	100	100	80	87	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	MO	A	MO	MO	A			
31	58	F	1023253	155	58	I	I	90	8	5	4	90	128	84	99	110	138	100	113	106	136	96	109	100	130	90	103	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	MO	M	MO	MO	A			
32	37	F	1023617	154	70	I	I	90	8	6	5	80	134	82	99	110	140	96	111	108	134	94	107	104	128	86	100	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	MO	M	MO	MO	A			
33	25	F	1023940	169	65	I	I	60	8	5	4	90	126	94	105	96	138	98	111	88	136	94	108	86	134	92	106	Y	Y	Y	Y	Y	Y	Y	Y	N	N	S	M	MO	MO	A				
34	18	F	1024041	166	60	I	II	100	8	5	4	84	118	86	97	102	124	88	100	98	116	80	92	90	114	78	90	Y	Y	Y	Y	Y	N	Y	Y	N	N	N	MO	A	MO	MO	A			
35	56	M	1025779	169	65	II	II	150	9	5	4	92	116	84	95	108	128	96	107	104	126	94	105	100	120	80	97	Y	Y	N	Y	Y	N	Y	N	N	MO	M	M	M	A					
36	55	F	1024902	160	72	II	II	100	8	5	4	76	144	80	101	90	154	92	113	90	148	90	109	86	144	86	105	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	MO	M	MO	MO	M			
37	34	F	1025343	160	65	II	II	120	8	5	4	96	126	88	101	104	128	88	101	100	124	78	93	94	118	78	91	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	MO	M	MO	MO	M			
38	40	M	1029594	172	75	I	II	100	9	5	4	66	122	84	97	98	136	90	105	90	120	86	101	84	128	84	99	Y	Y	N	Y	Y	N	Y	Y	N	Y	N	N	MO	MO	MO	M	M		
39	58	M	1029945	170	62	II	II	100	9	6	5	73	140	90	107	96	154	94	111	90	146	90	109	88	144	88	107	Y	Y	N	Y	Y	N	Y	Y	N	Y	N	N	MO	M	MO	MO			

Alkalinised Lignocaine

Sl.No	Age(yrs)	Sex(F/M)	Ip No	Height(cms)	Weight (kgs)	ASA(I/II)	MPG (I/II)	ETT(7.5/8.5)	Vol inflated(mL)	Vol deflated (mL)	Procedure duration(mins)	Preop Vitals				Post op vitals at 1hr				Post op vitals at 5hr				Post Op vitals at 10hr				Cough			Dysponia			Sore throat			PONV			POST	PONV	Hoarseness	Cough	Dysphagia		
												HR(bpm)	SBP(mmHg)	DBP(mmHg)	MAP	HR	SBP	DBP	MAP	HR	SBP	DBP	MAP	HR	SBP	DBP	MAP	1hr post ex	6hr post ex	24hrs post	1hr post ex	6hr post ex	24hr post ex	1hr post ex	6hr post ex	24hr post ex	A/M/MO/S	A/M/MO/S	A/M/MO/S						A/M/MO/S	A/M/MO/S
1	45	F	1010602	154	60	II	II	7.5	4.5	4	150	72	124	86	96	94	138	84	101	90	130	80	97	82	128	76	93	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	N	N	M	A	A	A	A
2	29	M	1011462	170	64	I	I	8.5	4.2	3.6	60	90	116	80	92	98	130	86	101	86	124	78	93	78	110	78	89	Y	Y	N	N	N	N	Y	Y	N	N	N	N	N	M	A	M	A	A	
3	26	F	1014502	155	45	I	I	7.5	4	3.5	45	80	110	70	83	100	130	92	105	96	126	90	102	84	116	80	92	Y	Y	Y	Y	Y	N	Y	Y	N	N	N	N	N	M	A	M	M	A	
4	38	F	1015209	160	65	II	II	7.5	5	3.5	120	80	126	84	98	110	140	90	107	104	132	88	103	90	124	80	95	Y	Y	Y	Y	Y	N	Y	Y	N	N	N	N	N	MO	A	A	M	A	
5	23	F	1015146	154	55	I	II	7.5	4.5	4	120	66	130	90	103	110	136	94	108	106	128	90	103	90	118	84	95	Y	Y	N	Y	N	N	Y	Y	N	N	N	N	N	M	A	M	M	A	
6	35	F	1016155	155	58	I	II	7.5	4.5	4	60	80	124	86	99	110	150	100	118	104	142	90	107	90	130	84	99	Y	Y	Y	Y	Y	N	Y	N	N	N	N	N	N	M	A	M	M	A	
7	19	F	1016208	160	55	II	II	7.5	5	4	60	76	110	74	86	106	130	100	110	100	128	98	108	90	118	90	99	Y	Y	Y	Y	Y	N	Y	N	N	N	N	N	MO	A	M	M	A		
8	60	M	1015986	166	65	I	II	8.5	5.5	4.5	140	74	140	90	107	100	156	96	116	94	150	90	110	88	140	86	104	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	M	M	M	M	A	
9	31	M	1015981	174	58	I	II	8.5	5	4	100	80	136	84	101	110	154	104	121	104	146	98	114	80	126	84	98	Y	Y	N	Y	N	N	Y	Y	N	Y	N	N	MO	M	MO	M	A		
10	59	F	1017362	154	45	I	II	7.5	5	4.5	120	92	126	84	98	104	136	98	111	90	128	96	107	80	120	84	96	Y	Y	N	Y	Y	N	Y	Y	N	N	N	N	M	A	M	M	A		
11	45	F	1017455	150	60	I	II	7.5	4.5	4	120	90	128	86	100	100	128	96	107	90	120	94	103	84	116	80	92	Y	Y	N	Y	N	N	Y	N	N	N	N	N	M	A	A	M	A		
12	18	F	1016525	160	58	I	II	7.5	5	4.5	90	80	116	74	88	104	128	94	105	96	126	84	98	90	120	80	93	Y	Y	N	Y	N	N	Y	N	N	N	N	N	M	A	M	M	A		
13	18	F	1017112	150	54	I	II	7.5	4.5	4	90	90	128	84	99	104	132	94	107	96	126	84	98	90	116	80	92	Y	Y	N	Y	N	N	N	N	N	N	N	MO	A	M	M	A			
14	39	F	1017544	170	68	I	I	7.5	4	3.5	100	90	106	72	83	98	128	90	103	90	124	86	99	84	112	74	87	Y	Y	Y	Y	Y	N	Y	N	N	N	N	N	M	A	M	M	A		
15	60	F	1019285	155	55	II	II	7.5	5	4	100	70	130	80	97	104	138	90	106	98	130	88	102	86	128	78	95	Y	Y	N	Y	Y	Y	Y	Y	N	N	N	N	M	A	M	M	A		
16	55	F	1018944	160	75	I	II	7.5	5	4	100	70	128	88	101	98	134	92	106	96	128	88	101	90	118	78	91	Y	Y	N	Y	N	N	Y	Y	N	N	N	N	M	A	M	M	A		
17	60	F	1019690	158	55	II	II	7.5	4.5	4	100	60	146	90	109	106	156	96	116	100	150	90	110	90	140	86	104	Y	Y	N	Y	N	N	Y	N	N	N	N	N	M	A	M	M	A		
18	25	M	1019776	160	58	I	II	8.5	5	4	100	84	100	76	84	90	116	84	95	86	108	76	88	78	104	80	88	Y	Y	N	Y	N	N	Y	N	N	Y	N	N	M	A	M	M	A		
19	34	F	1059483	152	75	I	II	7.5	5	4.5	100	84	122	82	95	104	130	90	103	100	128	88	101	90	126	80	95	Y	Y	N	Y	N	N	Y	Y	N	N	N	N	M	A	M	M	A		
20	32	F	1019348	158	58	I	II	7.5	5	3.5	70	90	116	86	96	98	124	86	99	94	114	82	95	86	110	74	86	Y	Y	Y	Y	Y	N	Y	Y	N	Y	N	N	MO	M	M	M	A		
21	60	F	1014533	147	64	II	II	7.5	5	4	100	70	110	80	90	92	130	90	103	88	124	86	99	80	112	78	89	Y	Y	N	Y	Y	N	Y	N	N	Y	N	N	M	M	M	M	A		
22	35	F	1020283	152	65	I	II	7.5	4.5	4	60	75	106	68	81	100	124	88	107	102	120	88	99	94	104	80	88	Y	Y	N	Y	Y	N	Y	N	N	N	N	N	M	A	M	M	A		
23	45	M	1020515	155	68	II	II	8.5	4.5	3.6	90	100	116	86	96	100	128	90	103	96	124	86	99	94	112	74	87	Y	Y	N	Y	N	N	Y	N	N	N	N	N	M	A	M	M	A		
24	25	M	1020612	172	76	I	II	8.5	5	4.5	120	78	130	84	99	108	138	96	110	100	134	90	105	92	126	86	99	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	MO	A	M	M	A		
25	35	M	1020872	170	66	I	II	8.5	5	4.5	120	110	118	86	97	110	122	82	96	100	118	78	91	90	112	76	88	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	MO	A	MO	MO	A		
26	25	M	1021296	170	60	I	II	8.5	5.5	4.5	60	96	110	74	86	100	130	84	99	96	122	90	101	86	116	84	95	Y	Y	Y	Y	Y	N	Y	Y	N	N	N	N	MO	A	M	M	A		
27	19	M	1021987	165	65	I	II	8.5	5.5	4.5	100	100	110	70	83	104	114	78	90	96	100	70	80	88	96	76	83	Y	Y	N	Y	Y	N	Y	N	N	N	N	M	A	M	M	A			
28	34	M	1021825	176	56	I	II	8.5	5.5	4.6	100	96	118	84	95	100	122	90	101	96	118	84	95	90	110	78	89	Y	Y	Y	Y	N	N	Y	N	N	N	N	N	M	A	M	M	A		
29	55	M	1022258	170	70	II	II	8.5	5	4.5	100	100	104	64	77	100	124	80	95	90	116	76	89	84	110	70	83	Y	Y	N	Y	Y	N	Y	Y	N	N	N	N	MO	A	M	M	A		
30	26	F	1023148	162	58	I	II	7.5	5	4	100	100	100	60	73	104	120	88	99	96	110	78	89	90	100	70	83	Y	Y	N	Y	Y	N	Y	Y	N	N	N	N	MO	A	M	M	A		
31	43	F	1015524	166	56	I	II	7.5	5	4	100	106	100	78	85	106	114	86	95	100	110	82	91	92	106	78	87	Y	Y	N	Y	Y	N	Y	Y	N	N	N	N	M	A	M	M	A		
32	43	F	1015303	158	75	II	I	7.5	5	4.5	120	80	130	90	103	100	130	98	109	90	126	90	102	80	116	88	97	Y	Y	N	Y	Y	N	Y	N	N	N	N	N	MO	A	M	M	A		
33	53	F	1023485	160	66	II	II	7.5	5	4	40	86	110	74	86	100	124	90	101	94	120	80	96	80	116	80	92	Y	Y	N	Y	Y	N	Y	Y	N	N	N	N	M	A	M	M	A		
34	51	F	1023691	162	64	II	I	7.5	5.5	4.5	120	96	144	88	107	110	150	96	114	104	148	94	112	98	140	90	107	Y	Y	N	Y	Y	N	Y	N	N	N	N	M	A	M	MO	A			
35	28	F	1024116	168	58	I	I	8.5	5	4	150	106	100	70	80	110	108	86	93	104	104	82	89	90	100	78	85	Y	N	N	Y	Y	N	Y	N	N	N	N	N	M	A	M	M	A		
36	53	F	1024057	160	65	I	I	7.5	5.5	4.5	120	84	128	90	100	100	132	88	103	94	126	86	99	90	120	78	92	Y	Y	N	Y	Y	N	Y	Y	N	N	N	N	M	A	M	M	A		
37	47	F	1026403	152	46	I	II	7.5	4.5	4	100	70	116	84	95	100	132	88	101	96	128	84	99	94	124	78	93	Y	Y	N	Y	N	N	Y	N	N	N	N	N	M	A	M	M	A		
38	40	F	1025195	150	60	II	II	7.5	5	4	120	96	118	80	93	106	126	98	107	100	120	90	100	90	114	82	93	Y	Y	N	Y	N	N	Y	YN	Y	N	N	N	MO	M	M	M	A		
39	60	M	1029693	180	80	II	II	8.5	5.5	4.5	100	76	140	80	100	104	136	82	100	100	134	80	98	96																						

