“A PROSPECTIVE RANDOMIZED CONTROL STUDY ON INTRACUFF ALKALIZED LIGNOCAINE REDUCES SEDATIVE/ANALGESIC REQUIREMENTS FOR MECHANICALLY VENTILATED PATIENTS IN A TERTIARY CARE HOSPITAL”

Dissertation submitted to

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

In partial fulfillment for the award of the degree of

DOCTOR OF MEDICINE

IN

ANAESTHESIOLOGY

BRANCH X

INSTITUTE OF ANAESTHESIOLOGY AND CRITICAL CARE

MADRAS MEDICAL COLLEGE

CHENNAI- 600003

APRIL 2016

CERTIFICATE

This is to certify that the dissertation entitled, **"A PROSPECTIVE RANDOMIZED CONTROL STUDY ON INTRACUFF ALKALIZED LIGNOCAINE REDUCES SEDATIVE/ANALGESIC REQUIREMENTS FOR MECHANICALLY VENTILATED PATIENTS IN A TERTIARY CARE HOSPITAL",** submitted by **Dr. SARAVANAN.K**, in partial fulfilment for the award of the degree of Doctor of Medicine in Anaesthesiology by the Tamil Nadu Dr. M.G.R. Medical University, Chennai., is a bonafide record of the work done by him in the INSTITUTE OF ANAESTHESIOLOGY AND CRITICAL CARE, Madras Medical College and government hospital, during the academic year 2013-2016.

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DECLARATION

I hereby, solemnly declare that this dissertation entitled **"A PROSPECTIVE RANDOMIZED CONTROL STUDY ON INTRACUFF ALKALIZED LIGNOCAINE REDUCES SEDATIVE/ ANALGESIC REQUIREMENTS FOR MECHANICALLY VENTILATED PATIENTS IN A TERTIARY CARE HOSPITAL"** is a bonafide record of the work done by me in the Institute of Anaesthesiology and Critical Care, Madras Medical College and Government General Hospital, Chennai, during the period 2013 – 2016 under the guidance of **DR. B.KALA M.D., D.A., director and** Professor of anaesthesiology, Institute of Anaesthesiology and Critical Care, Madras Medical College, Chennai – 3 and submitted to **The Tamil Nadu Dr. M.G.R. Medical University, Guindy, Chennai – 32**, in partial fulfilment for the requirements for the award of the degree of M.D. Anaesthesiology (Branch X), examinations to be held on April 2016.

I have not submitted this dissertation previously to any university for the award of degree or diploma.

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Date:

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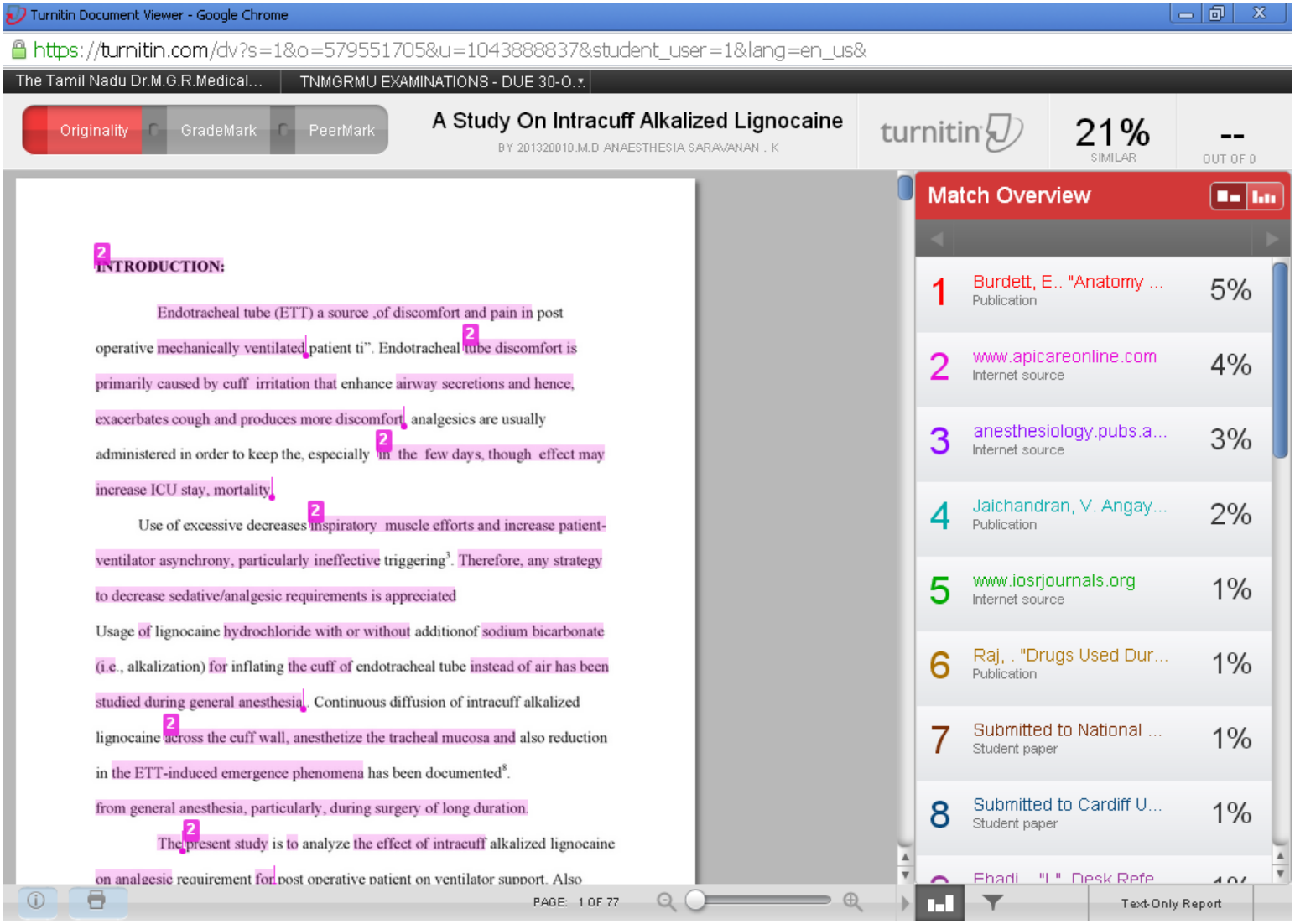
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Use of excessive decreases inspiratory muscle efforts and increase patient-ventilator asynchrony, particularly ineffective triggering[3]. Therefore, any strategy to decrease sedative/analgesic requirements is appreciated
Usage of lignocaine hydrochloride with or without additionof sodium bicarbonate (i.e., alkalization) for inflating the cuff of endotracheal tube instead of air has been studied during general anesthesia. Continuous diffusion of intracuff alkalized lignocaine across the cuff wall, anesthetize the tracheal mucosa and also reduction in the ETT-induced emergence phenomena has been documented[8].
from general anesthesia, particularly, during surgery of long duration.
The present study is to analyze the effect of intracuff alkalized lignocaine on analgesic requirement for post operative patient on ventilator support. Also
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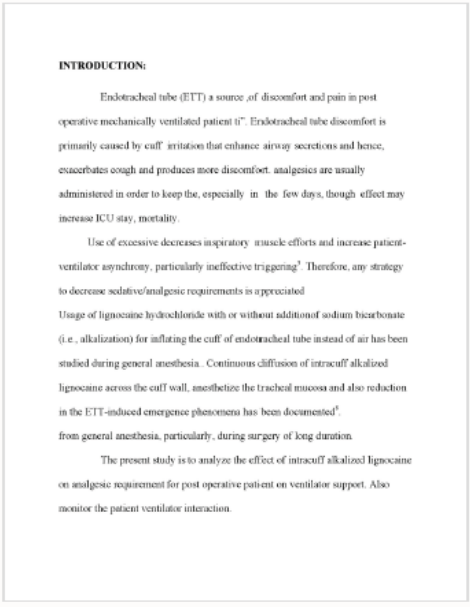

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“A PROSPECTIVE RANDOMIZED CONTROL STUDY ON INTRACUFF ALKALIZED LIGNOCAINE REDUCES SEDATIVE/ANALGESIC REQUIREMENTS FOR MECHANICALLY VENTILATED PATIENTS IN A TERTIARY CARE HOSPITAL”

ABSTRACT

OBJECTIVES:

This study is to investigate the effect of intracuff alkalised Lignocaine in reducing the requirement of analgesia in post-operative patients requiring ventilator support and also to analyse patient-ventilator interaction.

MATERIALS AND METHODS:

This prospective randomised control study was conducted at the Institute of Anaesthesiology, Madras Medical College, Chennai. The study population included fifty patients. Patients were randomly assigned into two groups Group A and Group B.

Group A (Intervention group) were administered intracuff alkalised Lignocaine (4% Lignocaine + 8.4% Sodium bicarbonate). Group B (Control group) were administered intracuff normal saline. All fifty patients were given Fentanyl infusion in a dose of 75µg/hr. The total requirement of fentanyl (25µg) bolus dose, when the patients Behavioural pain Scale was ≥5 was calculated during the first 24 hours.

RESULTS:

The requirement of Fentanyl bolus dose in patients with intracuff Lignocaine was less than that of the control group who were administered intracuff normal saline. The frequency of cough and ineffective trigger was lower in patients with intracuff alkalised Lignocaine compared to patients with intracuff normal saline.

CONCLUSION:

This study has documented significant reduction in the requirement of analgesia in patients with intrauff alkalised Lignocaine and also decreased frequency of ineffective trigger which implies better endotracheal tube tolerance and patient compliance.

KEY WORDS:

Endotracheal tube cuff tolerance, intracuff alkalised Lignocaine, Fentanyl bolus.

INTRODUCTION

Endotracheal tube (ETT) is a source of discomfort and pain in post operative mechanically ventilated intensive care unit (ICU) patient who have to keep the ETT for a long time. Endotracheal tube discomfort is primarily caused by cuff irritation that enhance airway secretions and hence, exacerbates cough and produces more discomfort. Sedatives and analgesics are usually administered in order to keep the patients in comfortable state, especially in the first few Postoperative days

Usage of Lignocaine hydrochloride with or without addition of sodium bicarbonate (i.e., alkalization) for inflating the cuff of endotracheal tube instead of air has been studied during general anesthesia.. Continuous diffusion of intracuff alkalized Lignocaine across the cuff wall, anesthetize the tracheal mucosa and also reduction in the ETT-induced emergence phenomena has been documented[8].

The present study is to analyze the effect of intracuff instillation of alkalized Lignocaine instead of air on analgesic requirement for post operative patient on ventilator support. Also monitor the patient ventilator interaction.

AIMS & OBJECTIVES:

1. To investigate the effect of intracuff alkalized Lignocaine on analgesic requirement for post-operative patients on ventilator.
2. To monitor the patient-ventilator interaction following the administration of intracuff Lignocaine.

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HISTORY OF LIGNOCAINE

Lignocaine was discovered from systematic investigations at the Institute of Chemistry at Stockholm University (StockholmsHo¨gskola), Stockholm. When in early 1930s, Hans von Euler-Chelpin, Ph.D. (1873–1964, Nobel Prize winner in 1929 for studies on the fermentation of alcohols), investigated chemical relationship and inheritance of genes and enzymes purely on chemical terms.

He was analyzing chemical differences between normal barley and some chlorophyll-defective mutants which were resistant to certain pests. These mutants were obtained from the famous Swedish plant and geneticist, H. Nilsson-Ehle,Ph.D. VonEuler-Chelpin et al. isolated an alkaloid, an indole, that they named gramine after the Latin name of the grass family Gramineae.

In von Euler-Chelpin's laboratory, Holger Erdtman, was given the task to synthesize a compound, (2-dimethylaminomethylindole) which was quiet different from Gramine, but it was an isomer, called isogramine. He tested the substance on his tongue, which he found anesthetized. This property was not present in Gramine.

Erdtman, along with a young chemistry student, Nils Lo¨fgren prepared several analogs, for the synthesis of isogramine, (dimethyl amino acetotoluidide).

Pharmaceutical tests of these compounds were performed in von Euler-Chelpin's laboratory with the assistance of his son, Ulf von Euler.The compounds were unable to compete with procaine, and the investigations were discontinued[16].

After some years, Lofgren continued the interrupted work. In 1943, Lofgren gave a compound to his assistant, Bengt Lundqvist who, in self-experiments, found that the compound to be active and also had a longer duration of action than procaine. It was originally labeled LL30 after the initials of the two main coworkers. It differed from one of the compounds prepared by Erdtman and Lofgren only by the addition of an extra methyl group in the 6^{th} position of the benzene ring[19].

Torsten Gordth started the official clinical trials of LL30 way back in 1944. It was tested on his students and patients..Leonard Goldberg, performed the initial pharmacological and toxicity work. LL30 was tested for 3 years before its use was sufficiently convinced. Toxicity test was compared with procaine[10,11].

LL30 was first given to produce intra cutaneous wheals and then subcutaneously. The analgesia was tested with the point of a needle. TorstenGordh's wife, Ulla Gordh, at that time a medical student was given eight different solutions with their identities concealed. She raised wheals by injecting them from eight different glass syringes. To indicate which injection was which, she made circles at the injection site and numbered it. It was observed that some of the marks quickly disappeared, within 15 minutes or so. But one injected site from one particular syringe, showed much larger anaesthetised area. This was the one that turned out to be Xylocaine. It started working quickly and lasted for a longer duration. And additionally had low toxicity.

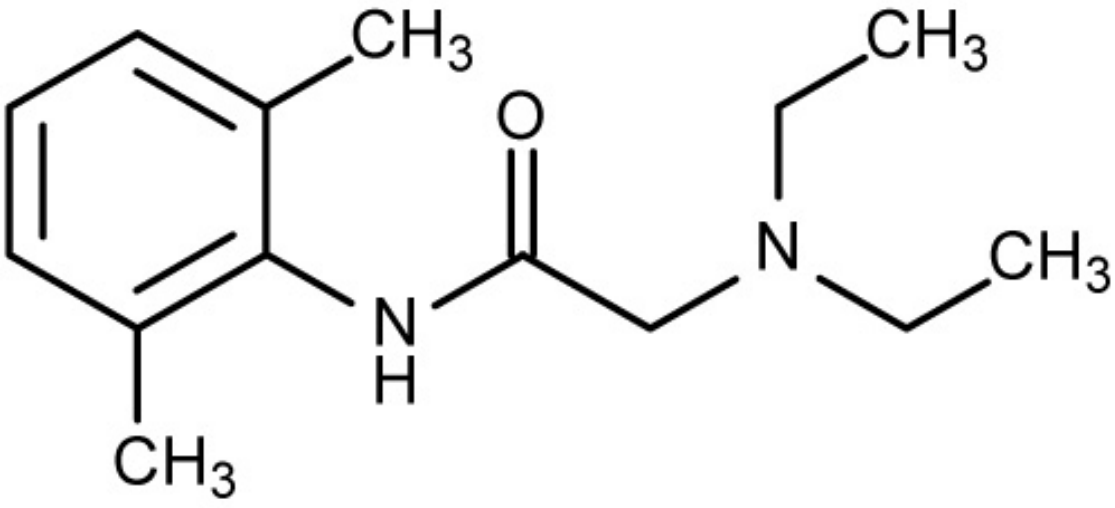
The Karolinska Institute conducted surgical clinic for military at the time of war. So Xylocaine was tested on the volunteers. Its effects lasted longer than Procaine. 175 subcutaneous skin wheal tests were performed in volunteers. The concentrations of Lignocaine varied from 0.1 to 2%, with and without the addition of adrenaline,1:100,000. The mean duration of effect of 25 tests per concentration was reported. It was compared with the effect of procaine. Seventy-five intracutaneous wheal tests were also performed. After these initial tests, clinical applications were started.

A full anesthetic effect was usually seen after 2 min. Xylocaine was tested in 100 patients for pain treatment, with infiltration, extradural analgesia, and blocks of the sympathetic system, in which a long lasting alleviation of pain was obtained. This effect was not be obtained by any other usual local anesthetics. Lignocaine was also attempted for spinal anesthesia in a 2% solution.

PHARMACOLOGY OF LIGNOCAINE AND FENTANYL

Lignocaine

Chemistry :[13,32]



Chemically Lignocaine is Diethyl amino 2, 6 acet-oxylidide $C_{14}H_{22}N_2O$

The molecular weight of the base is 234 and of hydrochloride salt is 270

Lignocaine produces faster, more intense, longer-lasting, and more extensive anaesthesia compared to an equal concentration of procaine. Lignocaine is used as an alternative choice for individuals sensitive to ester-type local anesthetics.

Physical property of Lignocaine:[32]

- It is a very stable compound, not decomposed by boiling, acid or alkalies withstanding, repeated autoclaving.
- It is colourless , crystalline solid that is readily soluble in water. The hydrochloride salt of Lignocaine in water has PH 6.5.
- The pKa of Lignocaine is 7.72.At the normal PH 7.4 approximately 65% of lognocaine exists in the charge cationic form,where 35% exists in un changed base form
- Lignocaine has moderate potency, Rapid onset and moderate duration of action, with good penetrative power and rapid onset of action. It is effective by all routes of administration.
- Adrenaline prolongs the action of Lignocaine and also reduces the rate of it's systemic absorption.

Preparation of Lignocaine:

1. Topical forms:

   Topical spray : 4% and 10% solution

   Gel 2% and 2.5%

2. Parentral form:

0.5%,1%,2% and 4% as Lignocaine hydrochloride. Lignocaine is also available along with adrenaline 1 in 1,00,000 and 1 in 2,00,000 concentrations

Pharmacokinetics:[32]

- At the plasma concentration of 2µg/ml approximately 65% bound with plasma proteins. The hepatic excretion ratio is 65.70% and plasma half life is 1.6 hours.
- The volume of distribution of Lignocaine is 1.3 liter/hour.
- The liver microsomal enzymes and oxydase ,amylases metabolizes it.
- The main pathway in man appears to be by oxydative – de alkylation of monoethyl glycine xylidide to 2,6 xylidine. 2,6 xylidne is hydrolysed to 4 hyroxy 2,6 xylidine.
- The metabolites are excreted through kidney.
- Lignocaine is de-alkylated in the liver by CYPs to monoethylglycinexylidide and glycine xylidide, which can be metabolized further to monoethylglycine and xylidide. Both monoethylglycinexylidide and glycine xylidide retain local

anesthetic activity. In humans, approximately 75% of the xylidide is excreted in the urine as the further metabolite 4-hydroxy-2, 6-dimethylaniline (Arthur, 1987).

Pharmacodynamics:

Local effects:

- Lignocaine blocks the conduction impulses in the nerve fibres at the site of the injection by blocking sodium channels.
- Sensory motor fibres are inherently equally sensitive to Lignocaine.
- Smaller fibres and long myalinated fibres are blocked more easily than un myalinated fibres .
- Autonomic fibres are more susceptible than somatic fibre

Additions of vasoconstrictors eg Adrenaline(1 in 50,000 to 1 in 2,00,000)

- Prolongs the duration of action of Lignocaine by decreasing the rate of removal from the local site of injection site into the general circulation.
- Reduces the systemic toxicity by decreasing the rate of absorption and keeping the plasma concentration lower.

- It is very effective surface anesthaetic .it gets rapidly absorbed from the mucosal surface.
- The peak blood concentration achieved with in 4 to 5 minutes after instillation.

SYSTEMIC EFFECTS

Cardiovascular effects:

- Heart : Lignocaine is the class1 b anti arrhythmic drug. It suppress the automatic ectopic foci by antagonizing the phase 4 depolarisation in the Purkinji fibres. It does not depress the SA node automaticity
- The rate of phase 0 depolarization not decreased except in the presence of hyperkalemia. Lignocaine markedly decrease the action potential duration and effective refractory period in the Purkinji fibres and ventricular muscles. But conduction velocity is not decreased. At therapeutic plasma concentration of 3-5µg/ml , it causes little depression in the cardiac contractility
- Lignocaine is widely used for ventricular arrhythmias in a dose of 1-2 mg/kg bolus intravenously followed by 2-4 mg/min infusion.

Vascular smooth musles:

- Lignocaine exists a two isomers and ability to provide vasoconstriction appear rested in one of these isomers. Hence Lignocaine produces vasoconstriction in low dose and vaso dilation in high dose.
- At the dose >75mg/kg/min with plasma concentration > 20µg/min Lignocaine can cause asystole and cardiovascular collapse.

Central nervous system:

- It readily crosses blood brain barrior causing CNS stimulation followed by depression with higher doses.
- The severity of CNS effects correlate with plasma concentration
- CNS is more susceptible to the toxic effect than CVS
- Objective sings of CNS is excitatory in nature many cause shivering , muscular twitching and convulsions . It is due to blockade of inhibitory pathways at limbic or higher centre in cerebral cortex.
- It has been shown to posses' analgesic property when given intravenously.
- Reduction of MAC of inhalational anesthatic agent is used as an index of its central analgesic property.

Neuro muscular junction:

- It can affect the transmission at the neuro muscular junction and hence potentiate the effect of depolarizing and non depolarizing mucle relaxant.

Dosage :

- The safe dose limit for Lignocaine has been much disputed. The factors governing the dosage are weight of the patients and different absorption rate from various sites of the injection.
- The maximum safe dose is 3 – 5 mg/kg without epinephrine , 7 mg/kg with epinephrine.
- Concentration of 0.25% - 0.5 % Lignocaine is used for infiltration.
- A concentration of 1.5 to 2% solution of Lignocaine is used for epidural anangesia
- A concentration of 4% Lignocaine is used for spraying.
- A concentration of 2 % Lignocaine is used in topical application.

Clinical uses of Lignocaine:

- A Lignocaine transdermal patch (LIDODERM) is used for relief of pain associated with post herpetic neuralgia. An oral patch (DENTIPATCH) is also available for application to accessible

mucous membranes of the mouth prior to superficial dental procedures.

- The combination of Lignocaine (2.5%) and prilocaine (2.5%) in an occlusive dressing (EMLA) is used as an anaesthetic agent prior to venipuncture, skin graft harvesting, and infiltration of anaesthetics into genitalia.
- Lignocaine in combination with tetracaine (PLIAGLIS) in a formulation that generates a "peel" has been approved for topical local analgesia for usage prior to superficial dermatological procedures such as filler injections and laser-based treatments.
- Lignocaine in combination with tetracaine is marketed in a formulation that generates heat upon exposure to air (SYNERA), which is presently used before to venous access and superficial dermatological procedures like excision, electrodessication, and shave biopsy of skin lesions. The mild warming is intended to increase skin temperature by up to 5°C for the purpose of enhancing distribution of local anaesthetic into the skin.

Other Uses of Lignocaine:

- Used in the treatment of Cardiac dysarrythmias, Ventricular fibrillation.

- A 5% ointment and 2% jelly are used for surface application and for lubrication of endotracheal tube and and oscopy instruments.
- When given topically on cornea, it causes mydriasis, vasoconstriction and cycloplegia.
- Used in the management of neonatal convulsions,
- For treatment of chronic pain syndrome in adults.
- It also posses anti-inflammatory, anti-thrombotic activity.

Adverse effects:

- Systemic reaction to Lignocaine primarily involve the CNS and CVS.
- The CNS is more susceptible to action of Lignocaine.
- Sudden cardiac arrest ,coma, cardio-respiratorye collapse may occur.
- Metabolism of Lignocaine may give rise to the formation of methaemoglobin ,the average peak concentration being 0.8%, ensuing 4-6 hours after injection. Cyanosis is rare.
- Lignocaine is reported to trigger malignant hyperthermia
- Neurological damage can occur leading to Cauda equine Syndrom.
- High plasma levels can cause bradycardia and hypotenion
- Increase in dose leads to drowsiness, tinnitus, dysgeusia, dizziness, and twitching

- Clinically significant cardiovascular depression invariably occurs at serum Lignocaine levels that produce marked CNS effects. The metabolites monoethyl glycinexylidide and glycine xylidide may contribute to some of these side effects.
- The other adverse effects of Lignocaine which are seen with increasing dose include drowsiness, tinnitus, dysgeusia, dizziness, and twitching. With the increases in dose, seizures, coma, and respiratory depression and arrest will be produced.
- Clinically significant cardiovascular depression invariably occurs at serum Lignocaine levels that produce marked CNS effects. The metabolites monoethylglycinexylidide and glycine xylidide may contribute to some of these side effects.

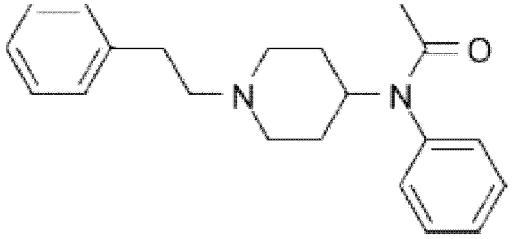
Pharmocology of Fentanyl:[13,32]

Fentanyl is a synthetic opioid which is lipophilic in nature. It acts as a μ receptor agonist and has rapid onset of action which lasts for a moderate period of time.

Chemistry:

It is a phenylpiperidine derivative.

The chemical name is N-{1-Phenethyl-4-piperidyl}propionanilide citrate.



$C_{22}H_{28}N_2OC_6H_8O_7$

Molecular weight is 528.5 Daltons

pKa is 8.43

The solubility of Fentanyl in alcohol is 1 in 140 and in water 1 in 40.

Octornal/water partition co efficient of Fentanyl is 955

Pharmacokinetics[32]:

- A three compartmental model is typically used to describe plasma Fentanyl concentration delay.
- The lung exert a significant first pass effect and transiently take up approximately 75% injected dose of Fentanyl. Fentanyl's

volume of distribution is high(3-6 $l.kg^{-1}$) and clearance also high (10-20ml/kg/min).

- Approximately 80% of Fentanyl is bound to plasma proteins, and significant amount (40%) is taken up by red blood cells. As the pKa of Fentanyl is high(8.4) at physiological PH, it exists mostly in the ionized form (>90).
- Fentanyl is the highly lipid soluble, a finding that explains in parts its large volume of distribution, The tissue/blood partition co efficient of Fentanyl is found to be 2-30 fold higher than those of aFentanyl. Fentanyl is distributed so widely in the body must finaly return to the body to get metabolized in the liver.
- Fentanyl is relatively long acting in large part because of its wide spread distribution in the body tissues. Fentayl is metabolized in the liver by N-dealkylation and hydroxylation. Fentanyl also have high hepatic clearance and high hepatic excretion ratio.
- The primary metabolite is nor Fentanyl which is detectable in the urine at least for 48 hours after intra venous Fentanyl administration .But activity of Fentanyl metabolites is unclear, but it thought to be minimal. A minimal amount of Fentanyl is excreted unchanged form in the urine.

Pharmacodynamis:

- Fentanyl is the μ agonist.It has more rapid onset and shorter duration of action than morphine.
- The greater potency and more rapid onset of the action reflect the greater lipid solubility of Fentanyl compared with the morphine.
- Fentanyl produces the dose related analgesia. Small doses 0.5-3.0μgs/kg may be used as supplement in spontaneously breathing anaesthetized patient. The dose of 5.0μgs/kg will suppress the somatic and autonomic response to surgical stimulation in ventilated patients.
- Fentanyl is potent respiratory depressant and reduces the brain stem respiratory centre responsiveness to carbon dioxide and peripheral chemoreceptor input during hypoxemia.
- Fentanyl exert minimal effect on circulation. There is vagaly mediated brady cardia and slight fall in the systemic vascular resistance.
- Skeletal muscle rigidity (woody chest) and clonic movement can hinder mechanical ventilation. The effect is reversed by the naloxone and overcome by the neuro muscular blocking drugs. Rigidity may also occur during emergence from anaesthesia.

- ❖ Fentanyl causes nausea and vomiting due to the stimulation of chemo receptor trigger zone. Fentanyl cause cough , papillary muscles constriction and itching of the nose.
- ❖ Fentanyl has been known to increase the inra cranial pressure in patient with severe head injury.Fentanyl also significantly decreases cerebral perfusion pressure.

Alkalized Lignocaine:

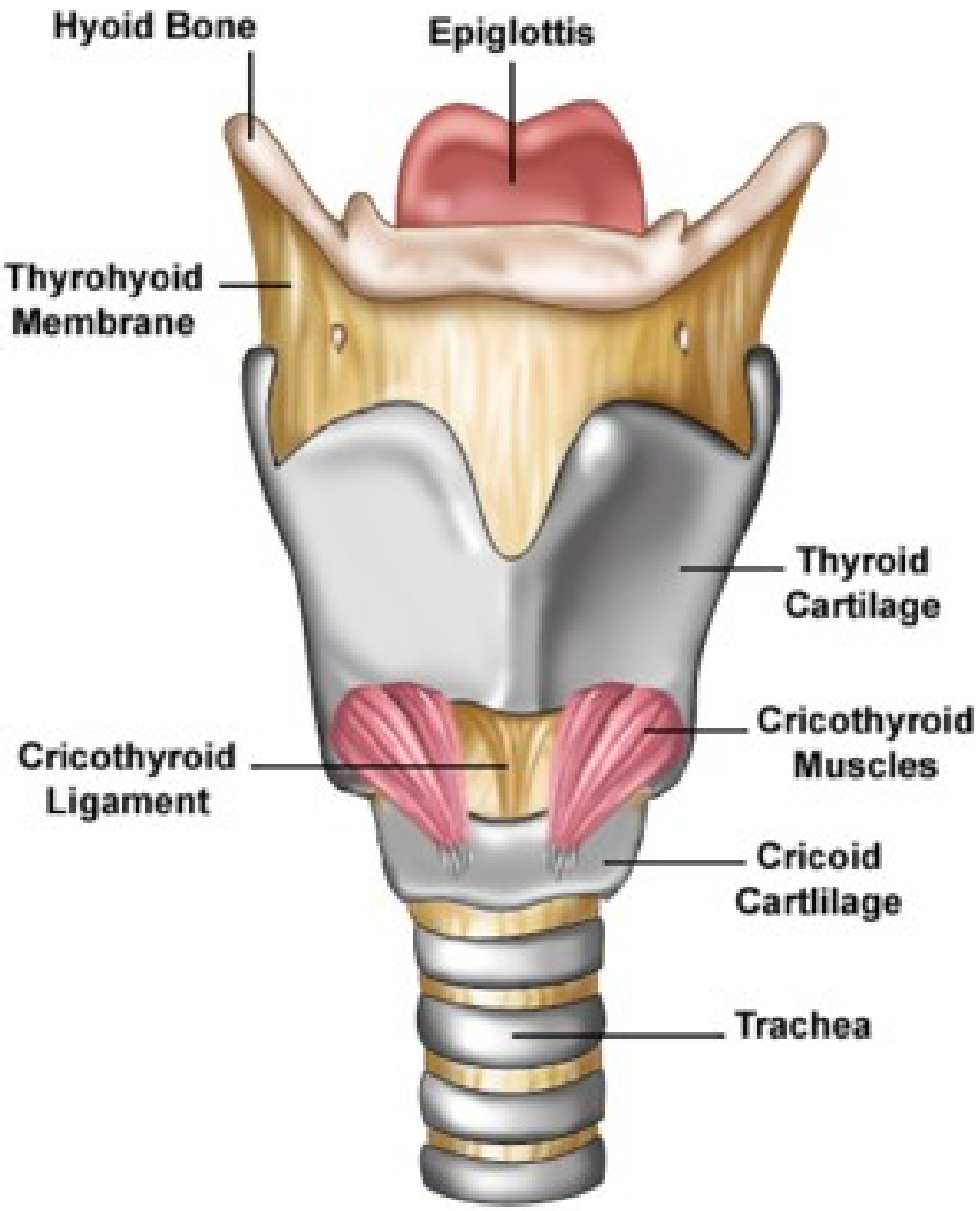
Alkalized Lignocaine is a mixture of Lignocaine 2% (Xylocaine) and sodium bicarbonate ($NaHCO_3$) 8.4% at a ratio of 1:1 ml. Increasing the PH of the solution predictably increase the percentage of non-ionized fraction of the drug. Addition of the bicarbonate causes 63 fold increase in the diffusion of Lignocaine across the ETT cuff.

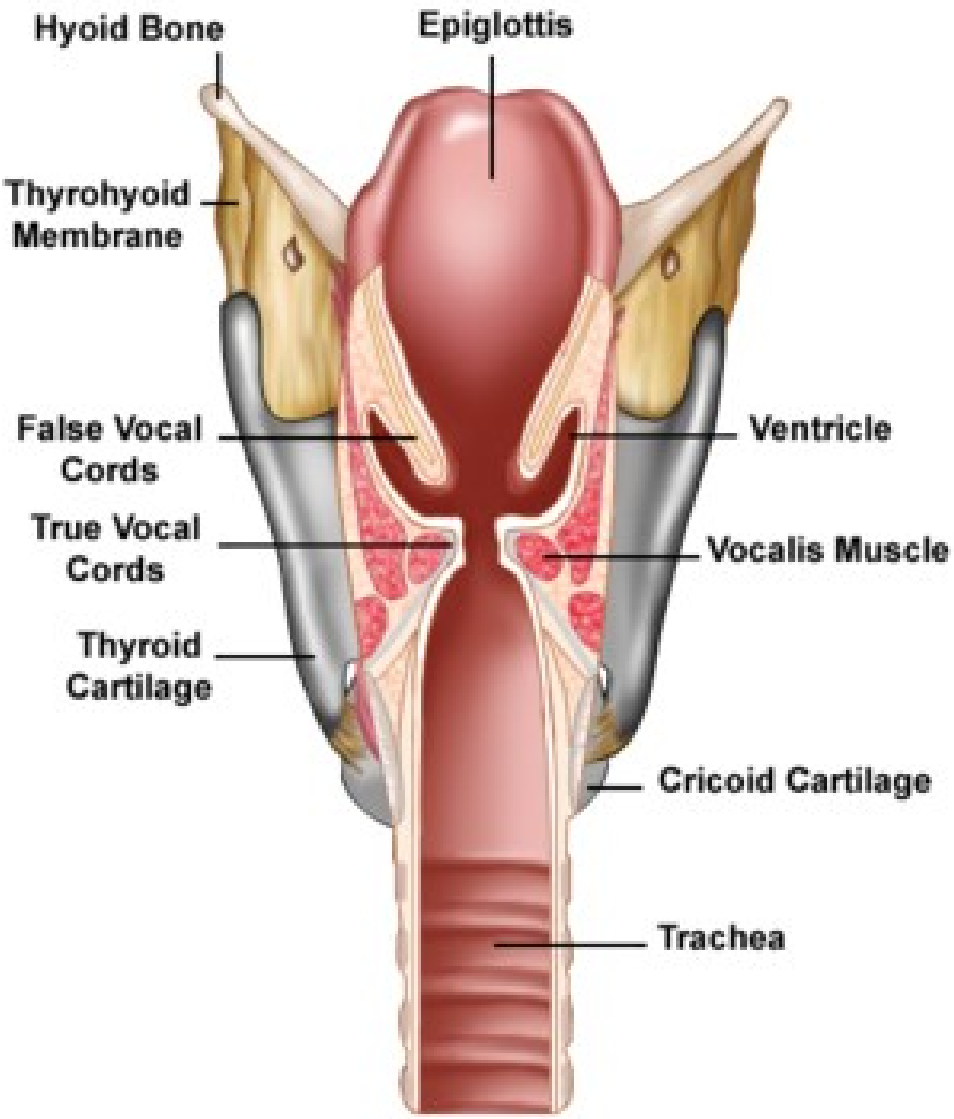
Diffusion of Lignocaine across the ETT cuff may enable the cuff to serve as reservoir of local anesthetics and subsequent anaesthesia of underlying local mucosa, by blocking cough receptors or rapidly adopting stretch receptors.

ANATOMY OF LARYNX[29]

- The larynx is the organ of phonation; it also assists in coughing and straining, and closes the respiratory system during swallowing, preventing aspiration.
- It develops from the fourth and sixth bronchial arches. At the level of C3toC6, it is smaller and slightly higher in adult females than in adult males.
- There are nine cartilages in the larynx, but the hyoid is the only bone. The U-shaped hyoid bone suspends the rest of the larynx. It does not directly articulate with any other bone; instead, it connects to the styloid process of the temporal bones by the stylohyoid ligament, and to the thyroid cartilage by the thyrohyoid membrane and muscle.
- The hyoid has a body, and greater and lesser horns, or cornua. The laryngeal cartilages consist of the solitary thyroid, cricoid and epiglottis, and pairs of arytenoids, corniculates and cuneiforms. They are connected by joints and ligaments, which are known as folds when covered by mucous membrane.
- The leaf-shaped epiglottis is situated between the superior laryngeal inlet and the base of the tongue. It is connected to the hyoid bone by the hyo-epiglottic ligament. Between the epiglottis and the base of the tongue is a pouch-like fold called the vallecula. It is into this that the

tip of the correctly placed laryngoscope is inserted during direct laryngoscopy in adults.

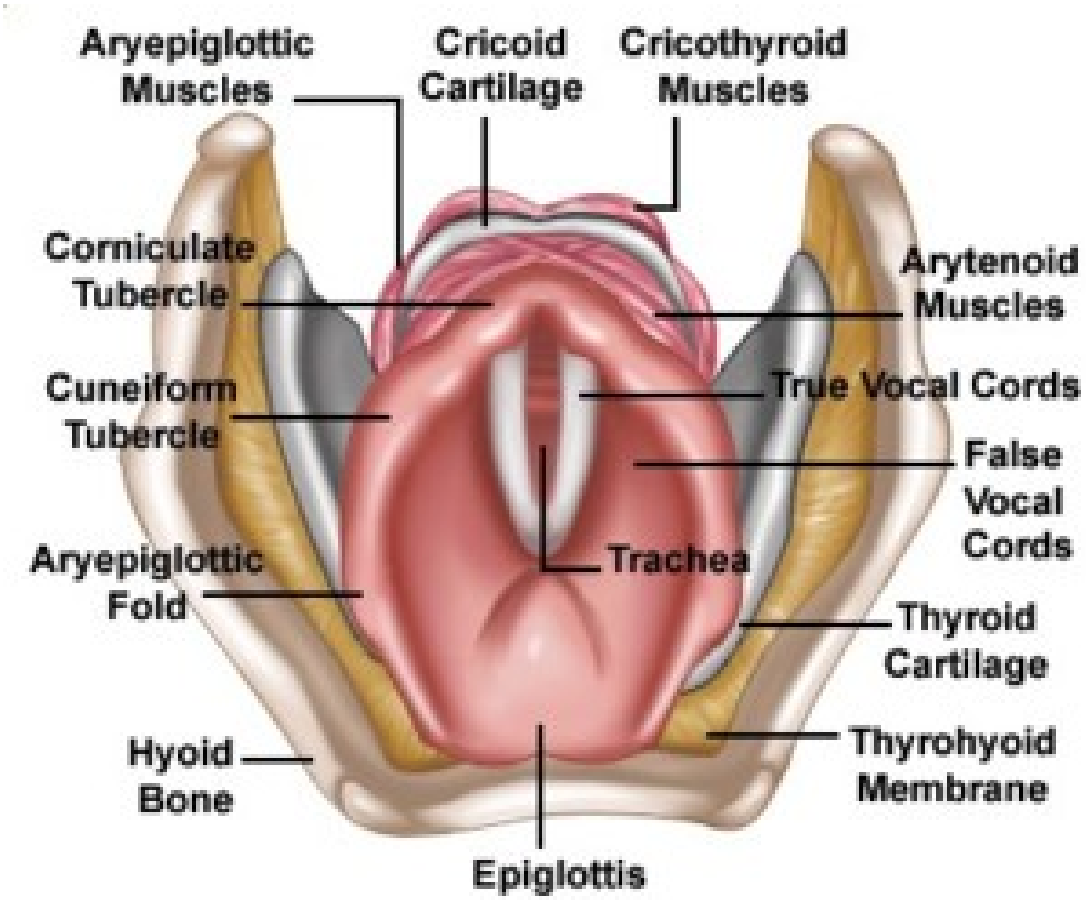




- The shield-like thyroid cartilage is formed from the fusion of two quadratic laminae. The angle of fusion is more acute in the male (90) than in the female (120), which causes the vocal cords to be longer in the male, accounting for the deeper voice and the greater laryngeal prominence (Adam's apple) in men.
- The superior cornu of the thyroid cartilage is attached to the lateral thyrohyoid ligament, and the inferior cornu articulates with the

cricoid cartilage at the cricothyroid joint. It is the articulation at this joint that maintains the tension with varying length of the vocal cords. The cricoid cartilage is shaped like a signet ring at the base of the larynx. Since it is relatively strong, and is the only complete ring of cartilage in the airway, it is here that Sellick's manoeuvre is performed to prevent regurgitation during rapid-sequence induction. Its anterior component connects to the thyroid by the cricothyroid membrane, an avascular structure.

- The arytenoid cartilages are in the posterior part of the larynx, and are shaped like three-sided pyramids. They articulate with the cricoid cartilage and control the tension of the vocal cords .
- The arytenoid cartilages connect with the epiglottis via the aryepiglottic folds. The cuneiform and corniculate cartilages are embedded in the aryepiglottic folds between the epiglottis and arytenoids. They reinforce the folds and may assist in movement of the arytenoids. The cuneiforms are cylindrical and are anterolateral to the triangular corniculates. They can be seen as raised areas in the folds during laryngoscopy .

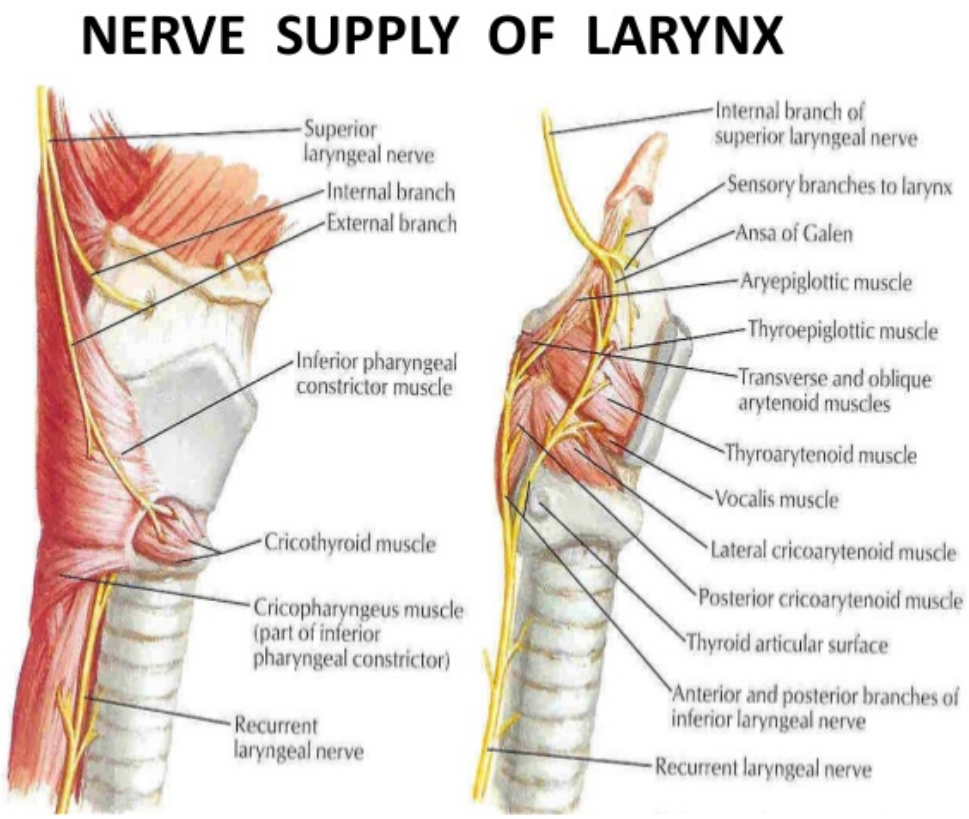


- Vocal cords The vocal cords are made from the free upper edges of the cricothyroid membrane (conus elasticus) where it thickens to become the cricovocal ligament and is covered with mucosa. The mucosa is pearly white and has no submucosa; thus, it cannot become oedematous. Posteriorly, it is attached to the vocal process of the arytenoid cartilage, which forms the posterior 40% of the cords. The cricothyroid membrane is attached circumferentially around the inside of the ring of the cricoid cartilage, and has a free upper inner

margin which is attached anteriorly to the back of the thyroid via a membrane called Broyle's ligament cartilage, and posteriorly to the arytenoids. It is this free margin which forms the cords themselves.

- **Muscles:** The muscles can be divided into intrinsic and extrinsic muscles.
- The extrinsic muscles can be further divided into suprahyoid muscles (stylohyoid, geniohyoid, mylohyoid, thyrohyoid digastric and stylopharyngeus), which can elevate the larynx, and infrahyoid muscles (omohyoid, sternothyroid, sternohyoid and thyrohyoid), which lower the larynx and to a minor degree alter the laryngeal shape.
- The intrinsic muscles control the vocal cords . All intrinsic muscles of the larynx are supplied by the recurrent laryngeal nerve except for the cricothyroid, which is supplied by the external branch of the superior laryngeal nerve.
- The cricothyroid is the only muscle that tightens the cord and it is supplied by the external branch of the superior laryngeal nerve is an intrinsic muscle of the larynx, but lies outside the larynx.
- **Nerve supply[29]:** Nerves supplying the intrinsic muscles and sensation to the larynx originate from the vagus, via the superior and recurrent laryngeal nerves. The superior laryngeal nerve separates from the vagus just outside the jugular foramen, at the inferior vagus

ganglion. At the level of the hyoid, it subdivides into internal and external branches. The internal branch passes through the thyrohyoid membrane and provides sensory innervation up to the vocal cords; the external branch supplies the cricothyroid muscle. The recurrent laryngeal nerve branches from the vagus in the thorax and loops around the arch of the aorta on the left and the subclavian artery on the right before travelling back up between the oesophagus and the trachea to supply all the intrinsic muscles of the larynx except the cricothyroid and sensation to the larynx below the vocal cords.



- **The blood supply :** blood supply derived from the external carotid, which gives off the superior and inferior thyroid arteries, which themselves give off the superior and inferior laryngeal arteries. The subclavian artery also supplies the larynx.
- **The trachea :** The trachea is an elastic structure which stretches on inspiration. It is formed by C-shaped cartilaginous incomplete rings, with the defect posteriorly, joined together by the trachealis muscle and is supplied by the inferior thyroid artery and veins and the bronchial arteries. Nerve supply is from the vagus and recurrent laryngeal nerves for pain and secreto-motor functions, and from the sympathetic nerves to blood vessels and smooth muscle.

Relations:

- Anterior: inferior thyroid veins, anterior jugular arch, inferior mesenteric artery, thymus, sternum, sternohyoid, sternothyroid, left brachiocephalic veins.
- Posterior: oesophagus, recurrent laryngeal nerves.
- Lateral: carotid sheath, lateral lobes of the thyroid to the sixth ring.

Cricothyrotomy and tracheostomy

- A cricothyrotomy is made by making a slit or small hole anteriorly in the relatively avascular cricothyroid membrane. A formal tracheostomy is made in the second or third tracheal ring by cutting a hole, often after dividing the thyroid isthmus if done surgically. The inferior thyroid veins and brachiocephalic vessels can get in the way and make this difficult.
- **Bronchi :** The right and left main bronchi differ from each other in the following ways: right: wider, shorter, more vertical, 2e3 cm long left: narrower, longer, more horizontal, 5 cm long.

This is the basis for two clinical points:

1. Inhaled foreign bodies are more likely to enter the right main bronchus.
2. The correct placement of a double-lumen tracheal tube is more likely to be successful if the bronchial part is inserted into the left main bronchus rather than the right.

- The bronchi are supplied by the bronchial arteries from the aorta, and drained by the azygos vein on the right and the hemiazygos vein on the left. There is also some drainage via the bronchial and pulmonary veins, which contributes to physiological shunt. Nerve supply is autonomic from the pulmonary plexus at the hilum. The parasympathetic supply vasodilates, bronchoconstricts, increases secretions and is responsible for sensation. The sympathetic supply vasoconstricts, bronchodilates via b2- receptors, and suppresses secretions via a-receptors.

ENDOTRACHEAL TUBE

In 1926 anaesthesiologist author Guedel experimented with rubber tube item, including, dental dams, glows to construct the first endotracheal tube cuff. Guedel found that a supra glottic cuff position allowed gas to pass upward easily, It was found that, endotraceal cuff at the level of vocal cords could not be inflated properly, and hence placing the ETT cuff in the distal tracheal area could allow the secretions along the side of the tube

After several experiments Guedel found that the proper positioning of the cuff would-be just below the vocal cord.

Cuff system, design and materials:

The American society for testing and materials (ASTM) specifies the requirements for the ideal design of endotracheal tube and cuff [5]. As per the ASTM standard, the maximum distance from the tip of the endotrachel tube to end of the cuff, which varies with sizes of different tube size. End point of the cuff should not impinge the Murphy's eye, and it should not herniate over the tube tip. It should be inflated symmetrically around the tube.

The functions of cuff is to ensure the proper sealing of ETT between the patient trachea. The cuff should completely seal the trachea

and prevent the oropharyngeal secretions entering the trachea, and also to avoid the leakage of air around the tube. The cuff pressure should be such that, it would allow adequate perfusion of tracheal mucosa[22]. In sufficient inflation of cuff will result in entry of oropharyngeal secretion into the trachea and lungs leading to aspiration and many nosocomial pulmonary infections[25,30].

LOW AND HIGH PRESSURE CUFF:

Intra cuff pressure:

Cuff Pressure	Cm H2O	mmHg
Ideal pressure	20-30	15-22
High pressure	>40	30
Low pressure	<20	18

Cuff pressure monitor

Two types of cuff are available

1. High pressure and low volume cuff
2. High volume and low pressure cuff

High pressure low volume tube (HPLV):

In 1960, the endotracheal tube used were made of red rubber and was known as was high pressure low volume tube (HPLV). ETT used currently are made of Polyvinyl chloride (PVC) and polyurethane.

HPLV required high intracuff pressure for covering the trachea and also to overcome the reduced compliance of the cuff. The cuff makes contact with small area of tracheal mucosa and renders it circular in shape.

Disadvantages of HPLV tube:

1. Prolonged contact with tracheal mucosa leads to ischemic necrosis of the tracheal mucosa.
2. It may also inflate in a non-circular form and cause injury to the trachea.

Advantages of HPLV tube:

1. Its reusability,
2. Inexpensive,
3. Lower incidence of sore throat,
4. Better protection against aspiration,
5. Since the cuff deflates and remains close to the ETT, they can easily visualise during intubation.

High Volume low Pressure cuff (HVLP):

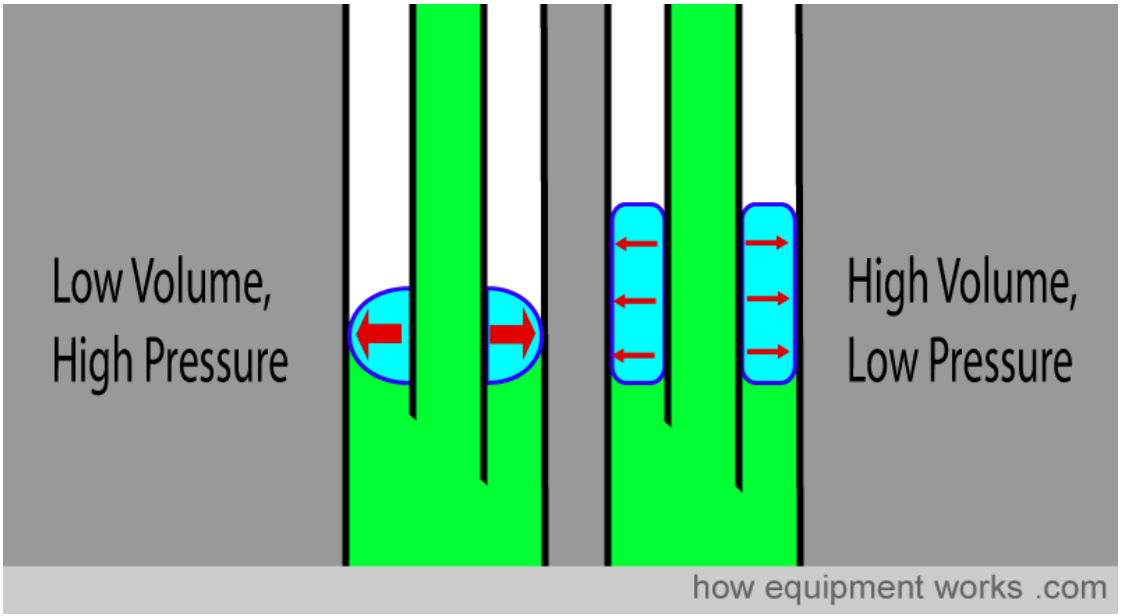
In HVLP cuff has thin compliant wall that adapts to irregular contour of tracheal walls.

Advantage:

The intracuff pressure correlates closely to the tracheal mucosal pressure.

Disadvantage:

It can cause tracheal injury , if the cuff pressure is maintained on the steeper side of the pressure-volume- curve.


Low Volume,
High Pressure
High Volume,
Low Pressure
how equipment works .com

REVIEW OF LITERATURE

- Malick et al[20] (1996;77:731–4.) in their study had documented 35% reduction in analgesic requirement, when alkalised Lignocaine was used to inflate the ETT cuff.
- Navarrro et al[23], (1997, 9:394–97). in their study documented that, there was a reduction in the frequency of sore throat and hoarseness in the patients who received intracuff Lignocaine than the patients who were given intracuff air and saline at the time of discharge from PACU.
- Haung et al [16](1998; 36:81-86.)in their study they concluded that buffering with or without warming but not just warming alone produced rapid diffusion from the cuffs.
- Haung et al [15] (1999; 46:1: 82-86) had also determined the time interval at which minimum concentration of Lignocaine blocking the Rapidly Adapting Stretch Receptors (RAR) by diffusion across the cuff wall. It was determined that buffered Lignocaine exerted RAR blocking effect within 120-180 minutes after its administration[8,9].
- Sidou et al [26] (1999, 67:49-52). in their study, they compared the effects of Lignocaine, air, and saline and they have reported a

significant reduction in post-operative sore throat and cough in patients who were administered Lignocaine than the other patients.

- Hirota et al [15] (2000;47:412–4). in their study they reported that inflation of the tracheostomy tube cuff with 4% Lignocaine remarkably reduced tube discomfort in patients who underwent tracheostomy following oral cancer resection. This was evaluated using visual analogue scale.
- Dollo et al [6]. (2001; 13:319-23) in their study they conducted in vitro study on diffusion of Lignocaine across the cuff and measured it using spectrometer. In his study Dolloett al used low volume, high pressureETT cuff with varying volumes of Lignocaine 2% (1-2ml) along with 8.4% of sodium bicarbonate (8-9ml). It was observed that 50% of Lignocaine diffused in 3 hours.
- Estebe et al [7](2004: 92:361-66) in their study they used high volume low pressure ETT with fixed dose of 2ml of 2% Lignocaine with varying volumes of 8.4% sodium bicarbonate (8-15ml) in which the 50% Lignocaine was released in 5 hours. This was found to be lower than that of Dollo et al study.
- Singh et al [28](2007;23: 163–7.) in their study they reported that the use of saline or 2% of Lignocaine without akalisation as liquid media for inflating ETT cuff decreased post-extubation reaction

- Jaichandran et al [31](2008; 52 (5); 536-540.) The study was to determine the optimal PH at which maximum diffusion of Lignocaine occurs across the ETT cuff. And they were concluded Lignocaine buffered at PH 7.4 as the optimal PH, for maximum diffusion across the ETT cuff and to block the cough receptors in the tracheal mucosa
- Ahmed Sobhy,[1] (2014 ; 451-455) did a study in 64 patients who required ventilator support for more than 48 hours. They documented that inflation of ETT cuff with Lignocaine reduced the requirement of propofol and Fentanyl by 30% than the control group

MATERIALS AND METHODOLOGY

The study protocol was approved, before the commencement of the study by the Institutional Ethics Committee, Madras Medical College, RGGGH, Chennai. Informed consent was obtained from all the patients included in the study.

Study Design & Duration:

This study is a Prospective randomized control study for a duration of three months.

Sample Size Calculation

Sample size was determined based on

Study: Intracuff alkalized lidocaine reduces sedative/ analgesic requirements for mechanically ventilated patients

Authored by: Ahmed Sobhy Basuni et al in Saudi Journal of Anesthesia Vol. 8, Issue 4, October-December 2014

In this study there was a significant reduction (about 30%) in the requirements for propofol and Fentanyl inpatients who received intracuff alkalinized lidocaine; $P < 0.001$.

Description:

- The confidence level is estimated at 95%
- with a z value of 1.96
- the confidence interval or margin of error is estimated at +/-15
- Assuming that 80 percent of the sample will have the specified attribute p% =30 and q%=70

$$n = p\% \times q\% \times [z/e\%]^2$$

$$n = 30 \times 70 \times [1.96/15]^2$$

$$n = 35.85$$

Therefore 36 is the minimum sample size required for the study.

In our study 50 subjects were chosen (n=25 in ETT Cuff + Alkalised Lignocaine Group and n=25 in ETT Cuff + Normal Saline Group)

Study Population:

Fifty patients were included in this study. Twenty five were intervention group and twenty five were control group.

Inclusion Criteria:

1. Patients of age 18 years and above
2. Patients with body mass index (BMI) ,< 35 kg/ m2were included in the study,
3. American Society of Anaesthesiology physical status: I, II, III.
4. Patients posted for both elective and emergency surgery were included.

Exclusion Criteria:

1. Post cardiac arrest patients,
2. Patients with ventilation through tracheostomy,
3. Pregnant women,
4. History of seizures and other neurological deficit.

Methodology:

Patients were randomly assigned into two groups.

- ❖ Group A (Intervention group)
- ❖ Group B (Control group).
- ❖ Fifty patients included in the study were segregated into two group with twenty five patients in each group.
- ❖ Patients in group A (Intervention group) were administered 2% Lignocaine with 8.4% sodium bicarbonate (Alkalised Lignocaine)

at a ratio of 1:1ml to inflate the ETT cuff before connecting to the ventilator to maintain a intra cuff pressure of 20-25mmHg

- Patients in group B (Control group) were administered normal saline to inflate the ETT cuff who were also connected to the ventilator.
- Endotracheal tube with 7-7.5 mm inner diameter were used for women and those with 7.5-8mm inner diameter were used for men.

Both the group of patients were connected to ventilator on Synchronized Intermittent Mandatory ventilation (SIMV). The ventilator settings were adjusted to obtain a tidal volume of 6-8ml/kg and delivered with inspiratory flow rate of ≥60 l/min. Positive End Expiratory Pressure (PEEP) was fixed to maintain PaO_2>90mmHg with FiO_2 <0.6.

Fentanyl infusion of 75µg/hr was given to the patients as post-operative analgesic to maintain a score of <5 on the Behavioral Pain Scale (BPS). The level of analgesia was monitored hourly using Behavioral Pain Scale.

If the score was ≥ 5, (outside the target level) the patients were administered Fentanyl bolus 25µg and were monitored.

For each patient, in both the groups, the control (Group A) and intervention (Group B), the number of bolus dose of Fentanyl required for first 24 hours was recorded and this was compared between both the groups.

Behavioral Pain Scale (BPS):[24]

Item	Description	Score
Fascial Expression	Relaxed	1
	Partially tightened (e.g., brow lowering)	2
	Fully tightened (e.g., eyelid closing)	3
	Grimacing	4
Upper Limb movements	No movements	1
	Partially bent	2
	Fully bent with finger flexion	3
	Permenently retracted	4
Compliance with mechanical ventilation	Tolerating movement	1
	Coughing but tolerating ventilation for most of the time	2
	Fighting ventilator	3
	Unable to control ventilation	4

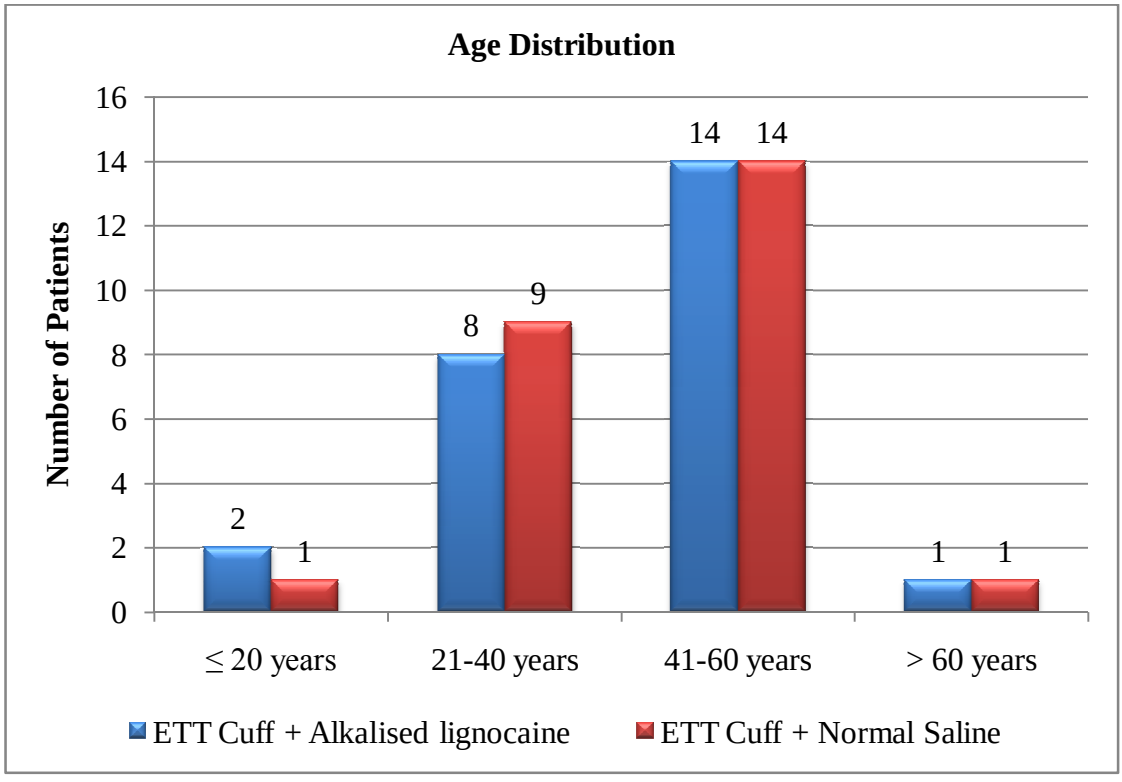
Behavioral Pain Scale (BPS):[24]

Score	Interpretation
3	No pain
12	Maximum pain

RESULTS

This study is a prospective randomized control study conducted at the Institute of anaesthesiology and critical care, Madras Medical College, Chennai. The study population included fifty postoperative patient who required ventilator support.

The patients were randomly assigned to two group. Group A (Intervention group) comprising of 25 patients ,received inracuff alkalized Lignocaine and Group B(Control group) comprising of 25 patients received inracuff normal saline.

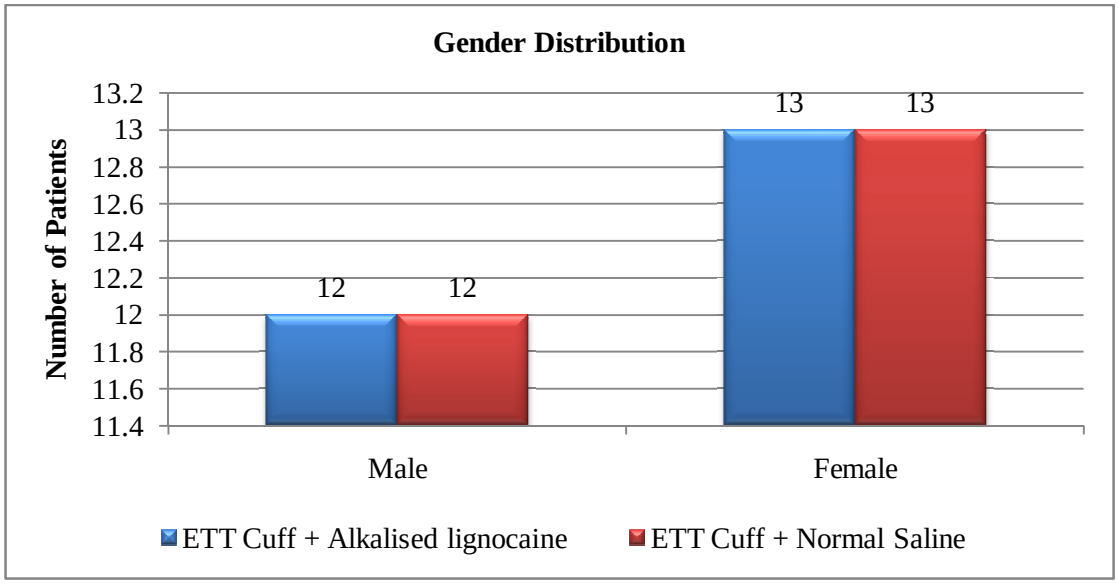


Age Distribution	ETT Cuff + Alkalised Lignocaine	Percentage	ETT Cuff + Normal Saline	Percentage
≤ 20 years	2	8.00	1	4.00
21-40 years	8	32.00	9	36.00
41-60 years	14	56.00	14	56.00
> 60 years	1	4.00	1	4.00
Total	25	100	25	100

Age Distribution	ETT Cuff + Alkalised Lignocaine	ETT Cuff + Normal Saline
N	25	25
Mean	44.88	45.32
SD	13.39	12.52
P value Unpaired t Test		0.9049

Majority of the ETT Cuff + Alkalised Lignocaine group patients belonged to the 41-60 years age class interval (n=14, 56%) with a mean age of 44.88 years. In the ETT Cuff + Normal Saline group patients, majority belonged to the same age class interval (n=14, 56%) with a mean age of 45.32 years. The association between the intervention groups and age distribution is considered to be not statistically significant since p > 0.05 as per unpaired t test.

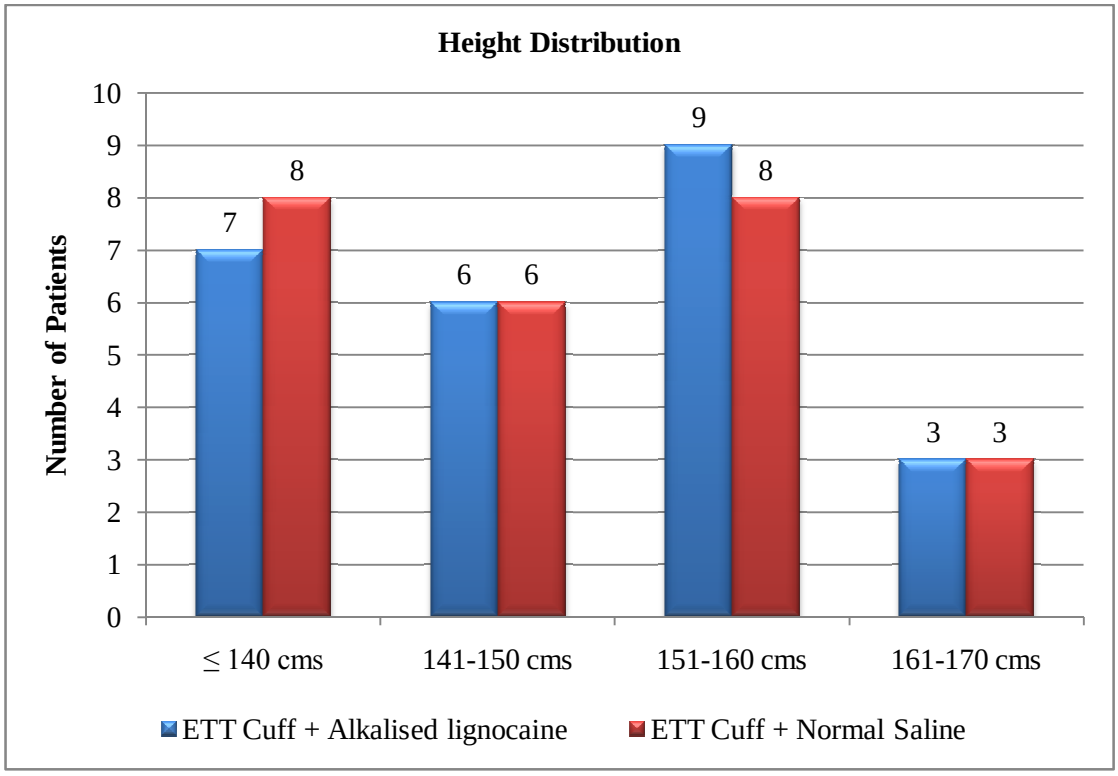
Gender Distribution



Gender Distribution	ETT Cuff + Alkalised Lignocaine	Percentage	ETT Cuff + Normal Saline	Percentage
Male	12	48.00	12	48.00
Female	13	52.00	13	52.00
Total	25	100	25	100
P value Fishers Exact Test			1.0000	

Majority of the ETT Cuff + Alkalised Lignocaine group patients belonged to the female gender class interval (n=13, 52%). In the ETT Cuff + Normal Saline group patients, majority belonged to the same gender class interval (n=13, 52%). The association between the intervention groups and gender distribution is considered to be not statistically significant since $p > 0.05$ as per chi squared test

Height Distribution

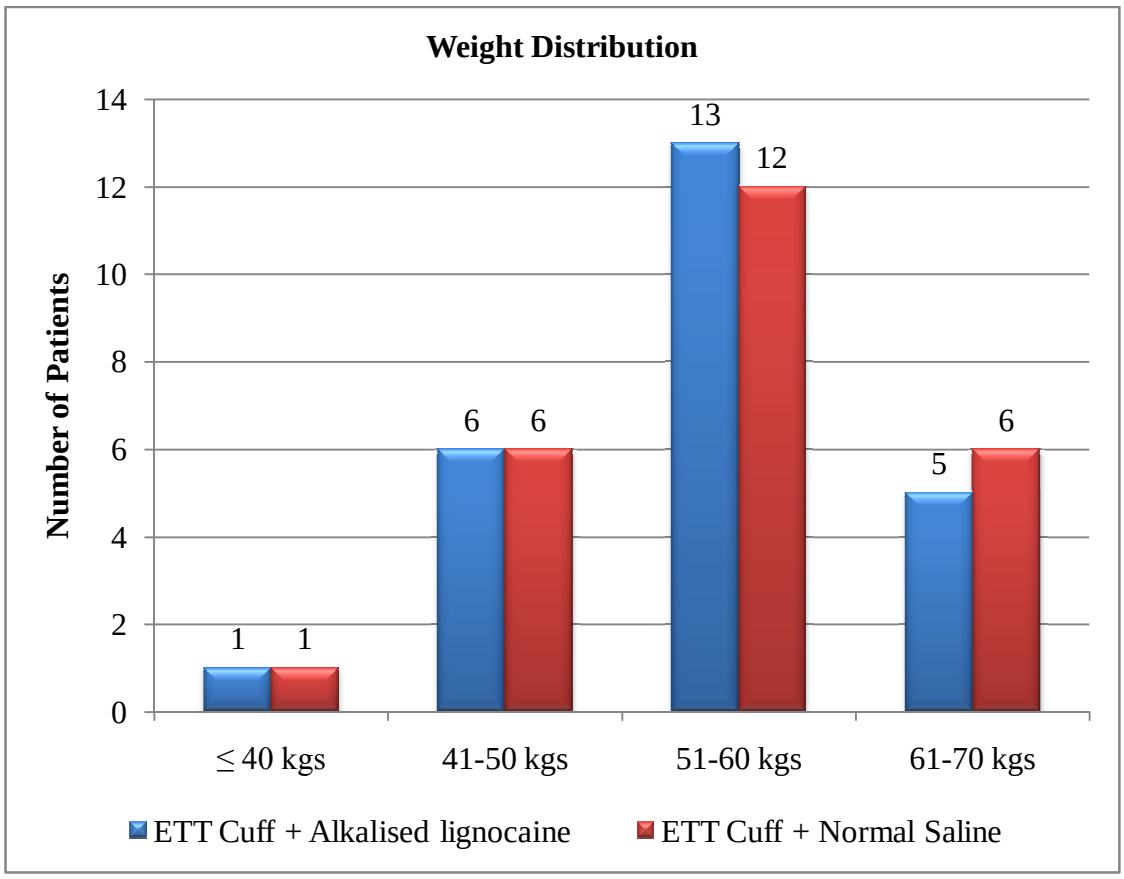


Height Distribution	ETT Cuff + Alkalised Lignocaine	Percentage	ETT Cuff + Normal Saline	Percentage
≤ 140 cms	7	28.00	8	32.00
141-150 cms	6	24.00	6	24.00
151-160 cms	9	36.00	8	32.00
161-170 cms	3	12.00	3	12.00
Total	25	100	25	100

Height Distribution	ETT Cuff + Alkalised Lignocaine	ETT Cuff + Normal Saline
N	25	25
Mean	148.80	148.00
SD	10.48	10.87
P value Unpaired t Test		0.7922

Majority of the ETT Cuff + Alkalised Lignocaine group patients belonged to the 151-160 cms height class interval (n=9, 36%) with a mean height of 148.80 cms. In the ETT Cuff + Normal Saline group patients, majority belonged to the same height class interval (n=8, 32%) with a mean height of 148 cms. The association between the intervention groups and height distribution is considered to be not statistically significant since $p > 0.05$ as per unpaired t test.

Weight Distribution

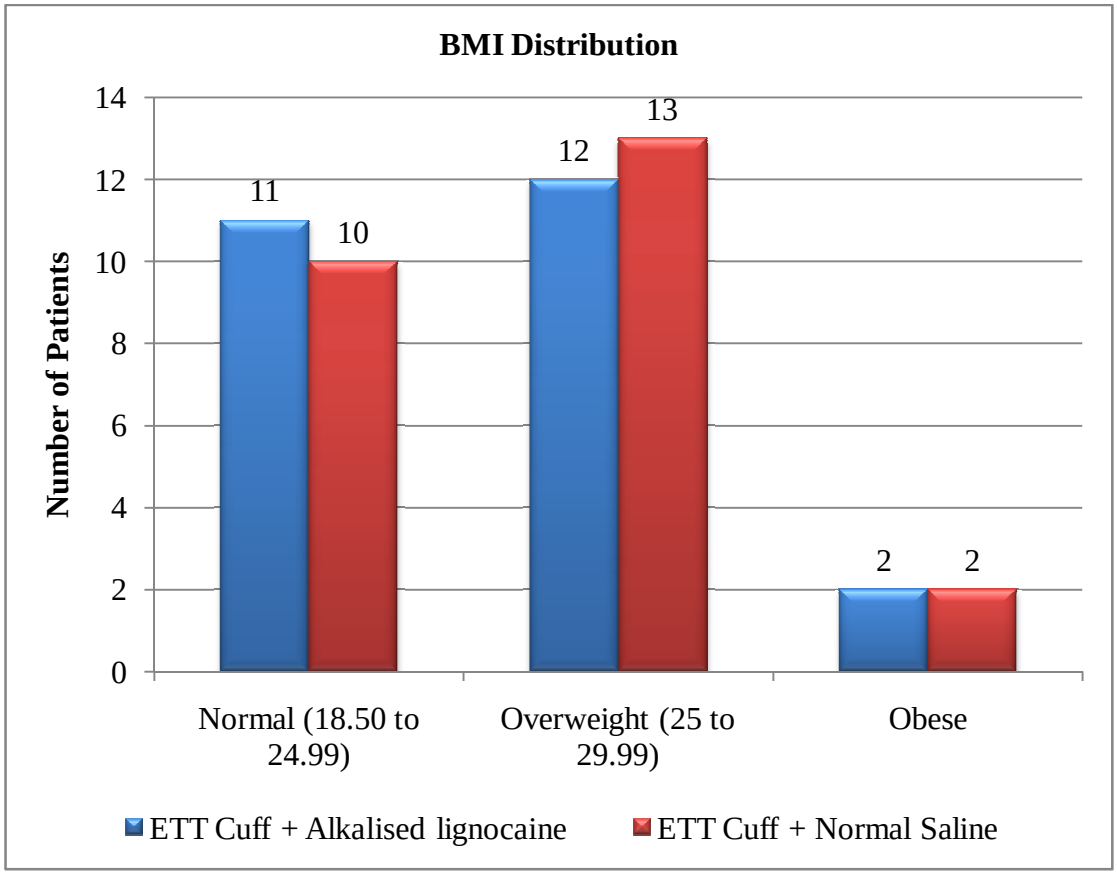


Weight Distribution	ETT Cuff + Alkalised Lignocaine	Percentage	ETT Cuff + Normal Saline	Percentage
≤ 40 kgs	1	4.00	1	4.00
41-50 kgs	6	24.00	6	24.00
51-60 kgs	13	52.00	12	48.00
61-70 kgs	5	20.00	6	24.00
Total	25	100	25	100

Weight Distribution	ETT Cuff + Alkalised Lignocaine	ETT Cuff + Normal Saline
N	25	25
Mean	55.08	55.48
SD	7.27	7.70
P value Unpaired t Test		0.8511

Majority of the ETT Cuff + Alkalised Lignocaine group patients belonged to the 51-60 kgs weight class interval (n=13, 52%) with a mean weight of 55.08 kgs. In the ETT Cuff + Normal Saline group patients, majority belonged to the same weight class interval (n=12, 48%) with a mean weight of 55.48 kgs. The association between the intervention groups and weight distribution is considered to be not statistically significant since $p > 0.05$ as per unpaired t test.

BMI Distribution

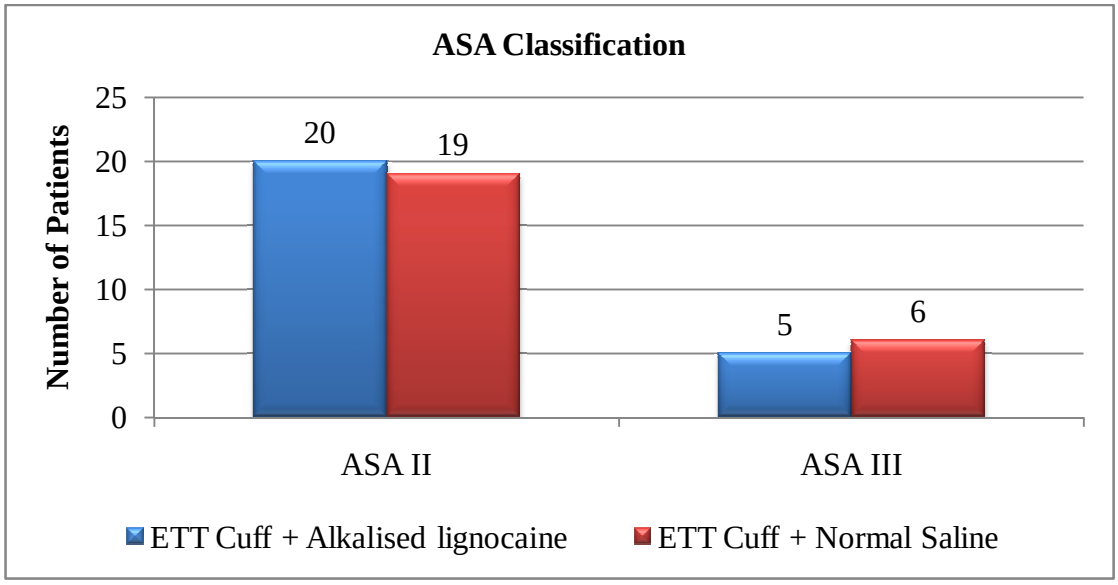


BMI Distribution	ETT Cuff + Alkalised Lignocaine	Percentage	ETT Cuff + Normal Saline	Percentage
Underweight (≤ 18.49)	0	0.00	0	0.00
Normal (18.50 to 24.99)	11	44.00	10	40.00
Overweight (25 to 29.99)	12	48.00	13	52.00
Obese	2	8.00	2	8.00
Total	25	100	25	100

BMI Distribution	ETT Cuff + Alkalised Lignocaine	ETT Cuff + Normal Saline
N	25	25
Mean	25.00	25.08
SD	2.84	2.84
P value Unpaired t Test		0.9212

Majority of the ETT Cuff + Alkalised Lignocaine group patients belonged to the overweight BMI class interval (n=12, 48%) with a mean BMI of 25.00. In the ETT Cuff + Normal Saline group patients, majority belonged to the same BMI class interval (n=13, 52%) with a mean BMI of 25.08. The association between the intervention groups and BMI distribution is considered to be not statistically significant since $p > 0.05$ as per unpaired t test.

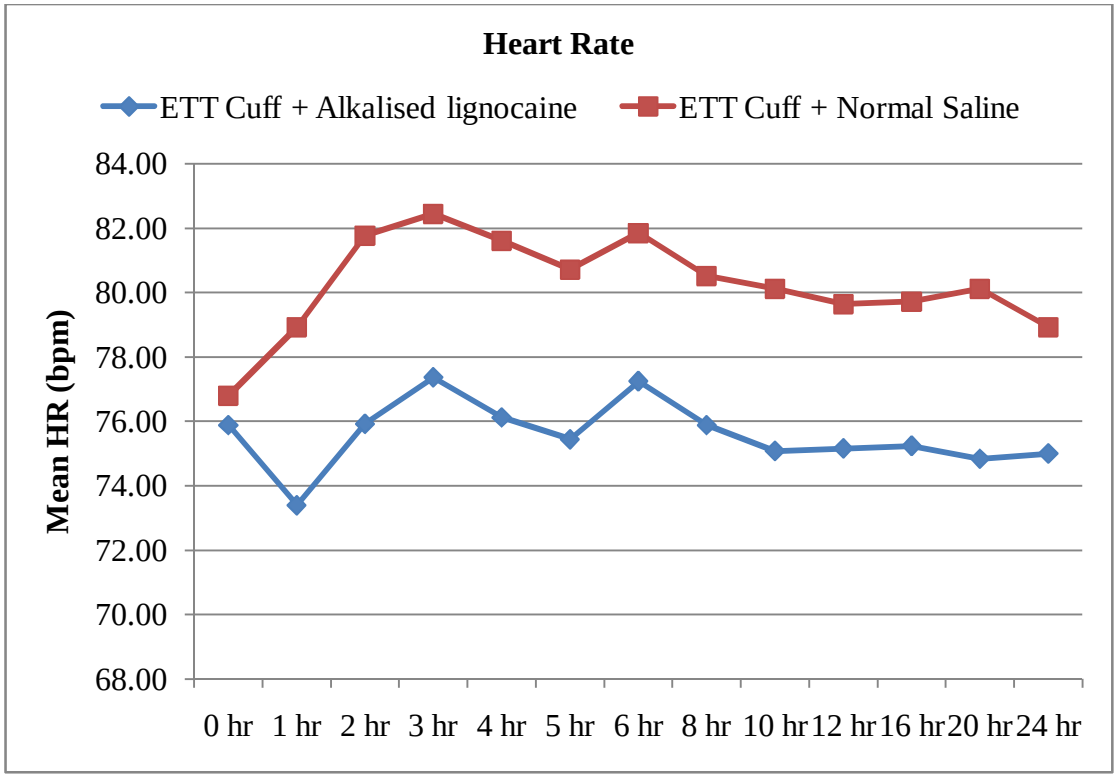
ASA Classification



ASA Classification	ETT Cuff + Alkalised Lignocaine	Percent age	ETT Cuff + Normal Saline	Percent age
ASA II	20	80.00	19	76.00
ASA III	5	20.00	6	24.00
Total	25	100	25	100
P value Fishers Exact Test			0.7481	

Majority of the ETT Cuff + Alkalised Lignocaine group patients belonged to the ASA II class interval (n=20, 80%). In the ETT Cuff + Normal Saline group patients, majority belonged to the same ASA class interval (n=19, 76%). The association between the intervention groups and ASA classification is considered to be not statistically significant since $p > 0.05$ as per chi squared test

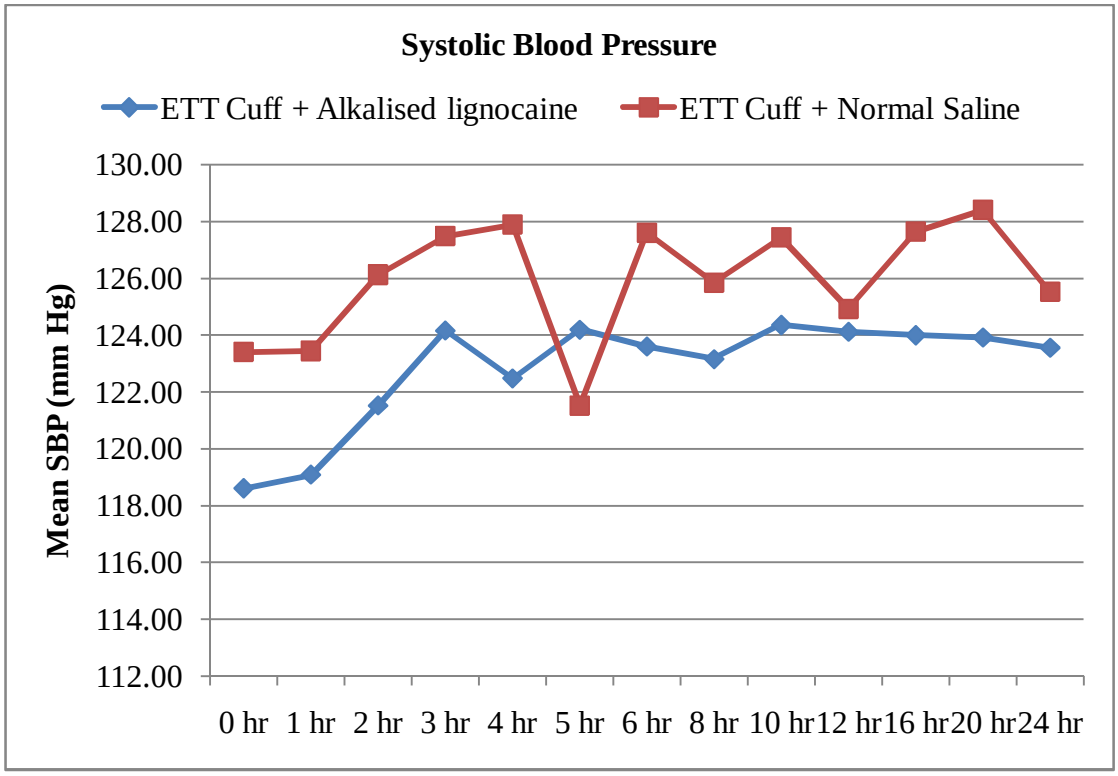
Heart Rate



Heart Rate	ETT Cuff + Alkalised Lignocaine			ETT Cuff + Normal Saline			P value Unpaired t Test
	N	Mean	SD	N	Mean	SD	
0 hr	25	75.88	8.66	25	76.80	10.58	0.7381
1 hr	25	73.40	7.08	25	78.92	9.54	0.0248
2 hr	25	75.92	7.80	25	81.76	8.87	0.0171
3 hr	25	77.36	8.18	25	82.44	9.12	0.0436
4 hr	25	76.12	7.81	25	81.60	8.32	0.0203
5 hr	25	75.44	8.32	25	80.72	7.76	0.0246
6 hr	25	77.24	7.50	25	81.84	6.52	0.0250
8 hr	25	75.88	7.93	25	80.52	7.93	0.0439
10 hr	25	75.08	7.94	25	80.12	6.65	0.0189
12 hr	25	75.16	6.86	25	79.64	6.67	0.0234
16 hr	25	75.24	8.01	25	79.72	6.39	0.0340
20 hr	25	74.84	6.71	25	80.12	7.53	0.0119
24 hr	25	75.00	5.92	25	78.92	6.85	0.0354

In patients belonging to ETT Cuff + Alkalised Lignocaine group, the mean heart rate measurement was 75.76 bpm. In ETT Cuff + Normal Saline group, the mean heart rate measurement is 80.53 bpm. The decreased mean heart rate measurement in ETT Cuff + Alkalised Lignocaine group compared to the ETT Cuff + Normal Saline group is statistically significant as the p value is < 0.05 as per unpaired t- test indicating a true difference among study groups.

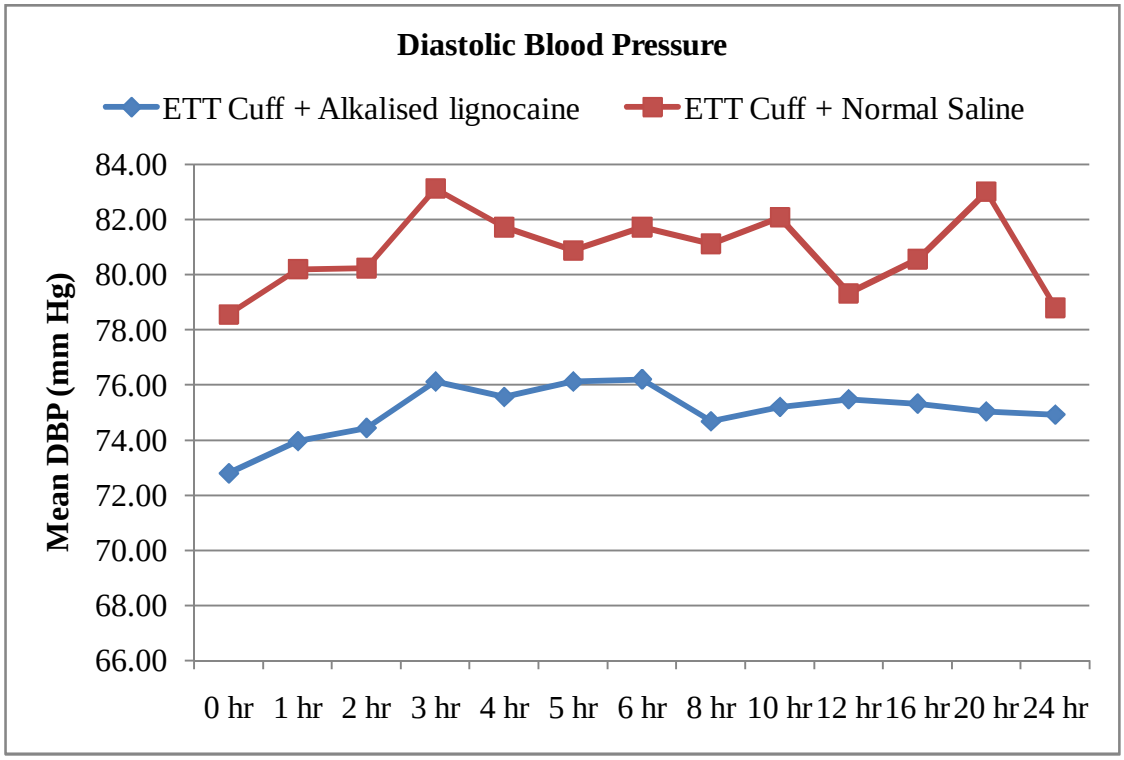
Systolic Blood Pressure



Systolic Blood Pressure	ETT Cuff + Alkalised Lignocaine			ETT Cuff + Normal Saline			P value Unpaired t Test
	N	Mean	SD	N	Mean	SD	
0 hr	25	118.60	13.92	25	123.40	12.41	0.2044
1 hr	25	119.08	12.70	25	123.44	12.65	0.2299
2 hr	25	121.52	13.21	25	126.12	13.36	0.2269
3 hr	25	124.16	11.96	25	127.48	11.26	0.3172
4 hr	25	122.48	11.25	25	127.88	9.49	0.0530
5 hr	25	124.20	9.70	25	121.52	24.73	0.6174
6 hr	25	123.60	9.30	25	127.60	9.83	0.1459
8 hr	25	123.16	9.91	25	125.84	10.55	0.3591
10 hr	25	124.36	8.63	25	127.44	9.19	0.2278
12 hr	25	124.12	9.20	25	124.92	9.47	0.7633
16 hr	25	124.00	7.31	25	127.64	9.41	0.1336
20 hr	25	123.92	7.99	25	128.40	8.44	0.0599
24 hr	25	123.56	7.79	25	125.52	5.94	0.3226

In patients belonging to ETT Cuff + Alkalised Lignocaine group, the mean systolic blood pressure measurement was 123.18 mm Hg. In ETT Cuff + Normal Saline group, the mean systolic blood pressure measurement is 126.15 mm Hg. The increased mean systolic blood pressure measurement in ETT Cuff + Alkalised Lignocaine group compared to the ETT Cuff + Normal Saline group is statistically significant as the p value is < 0.05 as per unpaired t- test.

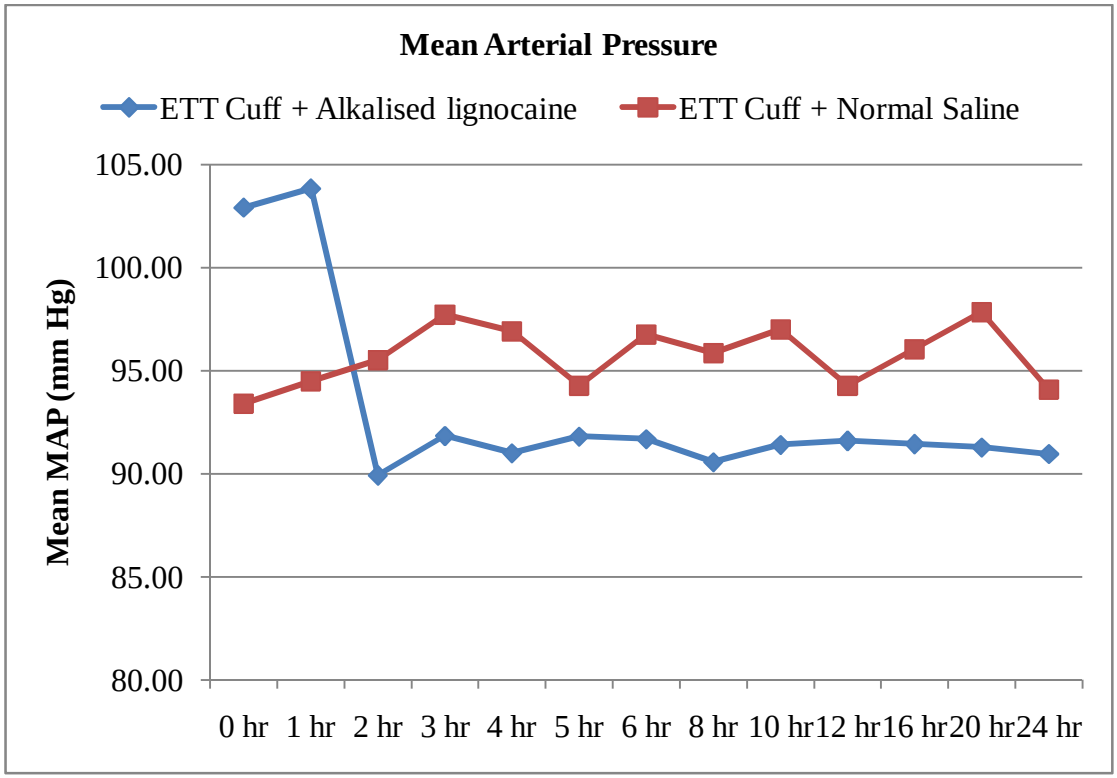
Diastolic Blood Pressure



Diastolic Blood Pressure	ETT Cuff + Alkalised Lignocaine			ETT Cuff + Normal Saline			P value Unpaired t Test
	N	Mean	SD	N	Mean	SD	
0 hr	25	72.80	7.46	25	78.56	8.01	0.0114
1 hr	25	73.96	6.12	25	80.20	7.62	0.0025
2 hr	25	74.44	6.44	25	80.24	8.62	0.0099
3 hr	25	76.12	6.13	25	83.12	7.89	0.0010
4 hr	25	75.56	7.07	25	81.72	5.31	0.0011
5 hr	25	76.12	7.30	25	80.88	5.64	0.0132
6 hr	25	76.20	5.95	25	81.72	6.45	0.0028
8 hr	25	74.68	6.85	25	81.12	5.33	0.0006
10 hr	25	75.20	6.95	25	82.08	6.18	0.0006
12 hr	25	75.48	7.95	25	79.32	6.12	0.0621
16 hr	25	75.32	7.05	25	80.56	5.61	0.0056
20 hr	25	75.04	7.01	25	83.00	5.28	0.0000
24 hr	25	74.92	7.04	25	78.80	4.37	0.0242

In patients belonging to ETT Cuff + Alkalised Lignocaine group, the mean diastolic blood pressure measurement was 75.25 mm Hg. In ETT Cuff + Normal Saline group, the mean diastolic blood pressure measurement is 81.06 mm Hg. The decreased mean diastolic blood pressure measurement in ETT Cuff + Alkalised Lignocaine group compared to the ETT Cuff + Normal Saline group is statistically significant as the p value is < 0.05 as per unpaired t- test indicating a true difference among study groups.

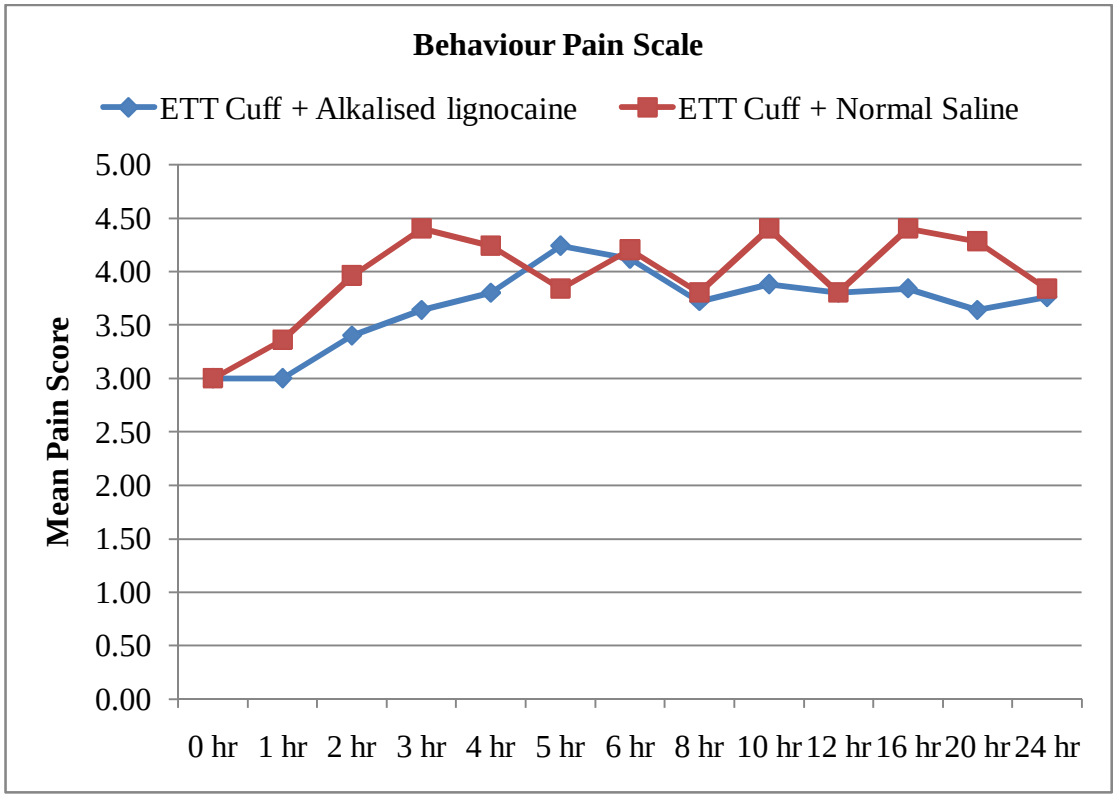
Mean Arterial Pressure



Mean Arterial Pressure	ETT Cuff + Alkalised Lignocaine			ETT Cuff + Normal Saline			P value Unpaired t Test
	N	Mean	SD	N	Mean	SD	
0 hr	25	102.92	11.62	25	93.40	8.75	0.0021
1 hr	25	103.84	10.20	25	94.48	8.66	0.0010
2 hr	25	89.92	8.24	25	95.52	9.45	0.0303
3 hr	25	91.84	7.72	25	97.72	8.06	0.0113
4 hr	25	91.00	8.21	25	96.92	5.70	0.0050
5 hr	25	91.80	7.41	25	94.28	9.25	0.3011
6 hr	25	91.68	6.30	25	96.76	5.66	0.0043
8 hr	25	90.56	7.11	25	95.84	6.19	0.0074
10 hr	25	91.40	6.72	25	97.00	6.03	0.0032
12 hr	25	91.60	7.76	25	94.28	5.80	0.1734
16 hr	25	91.44	6.21	25	96.04	5.46	0.0077
20 hr	25	91.28	6.49	25	97.84	5.16	0.0003
24 hr	25	90.96	6.05	25	94.08	3.03	0.0271

In patients belonging to ETT Cuff + Alkalised Lignocaine group, the mean arterial pressure measurement was 92.28 mm Hg. In ETT Cuff + Normal Saline group, the mean arterial pressure measurement is 95.90 mm Hg. The decreased mean arterial pressure measurement in ETT Cuff + Alkalised Lignocaine group compared to the ETT Cuff + Normal Saline group is statistically significant as the p value is < 0.05 as per unpaired t- test indicating a true difference among study groups.

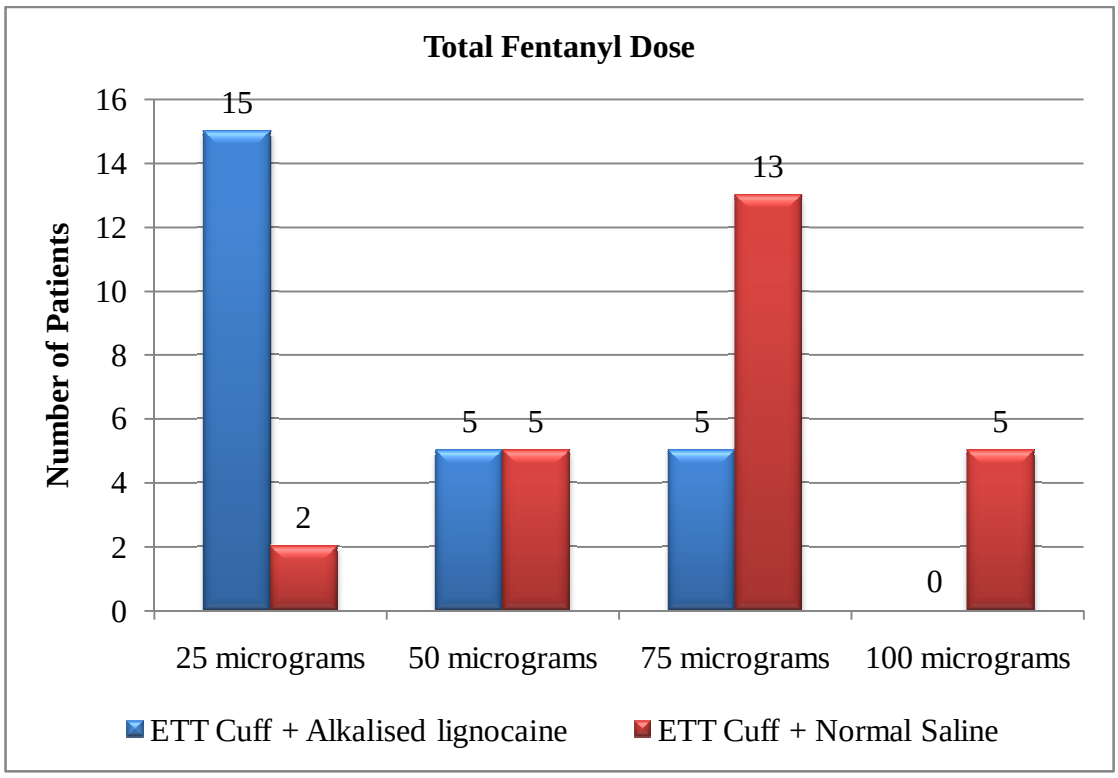
Behaviour Pain Scale



Behaviour Pain Scale	ETT Cuff + Alkalised Lignocaine			ETT Cuff + Normal Saline			P value Unpaired t Test
	N	Mean	SD	N	Mean	SD	
0 hr	25	3.00	0.00	25	3.00	0.00	1.0000
1 hr	25	3.00	0.00	25	3.36	0.49	0.0012
2 hr	25	3.40	0.65	25	3.96	0.54	0.0017
3 hr	25	3.64	0.64	25	4.40	0.82	0.0006
4 hr	25	3.80	0.41	25	4.24	0.97	0.0445
5 hr	25	4.24	0.72	25	3.84	0.85	0.0797
6 hr	25	4.12	0.78	25	4.20	0.82	0.7249
8 hr	25	3.72	0.84	25	3.80	0.76	0.7266
10 hr	25	3.88	0.93	25	4.40	0.96	0.0570
12 hr	25	3.80	1.08	25	3.80	0.91	1.0000
16 hr	25	3.84	1.03	25	4.40	1.00	0.0567
20 hr	25	3.64	0.64	25	4.28	0.89	0.0055
24 hr	25	3.76	0.44	25	3.84	0.37	0.4897

In patients belonging to ETT Cuff + Alkalised Lignocaine group, the mean behaviour pain scale measurement was 3.46 points. In ETT Cuff + Normal Saline group, the mean behaviour pain scale measurement is 3.99 points. The decreased mean behaviour pain scale measurement in ETT Cuff + Alkalised Lignocaine group compared to the ETT Cuff + Normal Saline group is statistically significant between 1-4 hours, 10^{th} hours and 16 to 20hrs as the p value is < 0.05 as per unpaired t- test indicating a true difference among study groups.

Total Fentanyl Dose

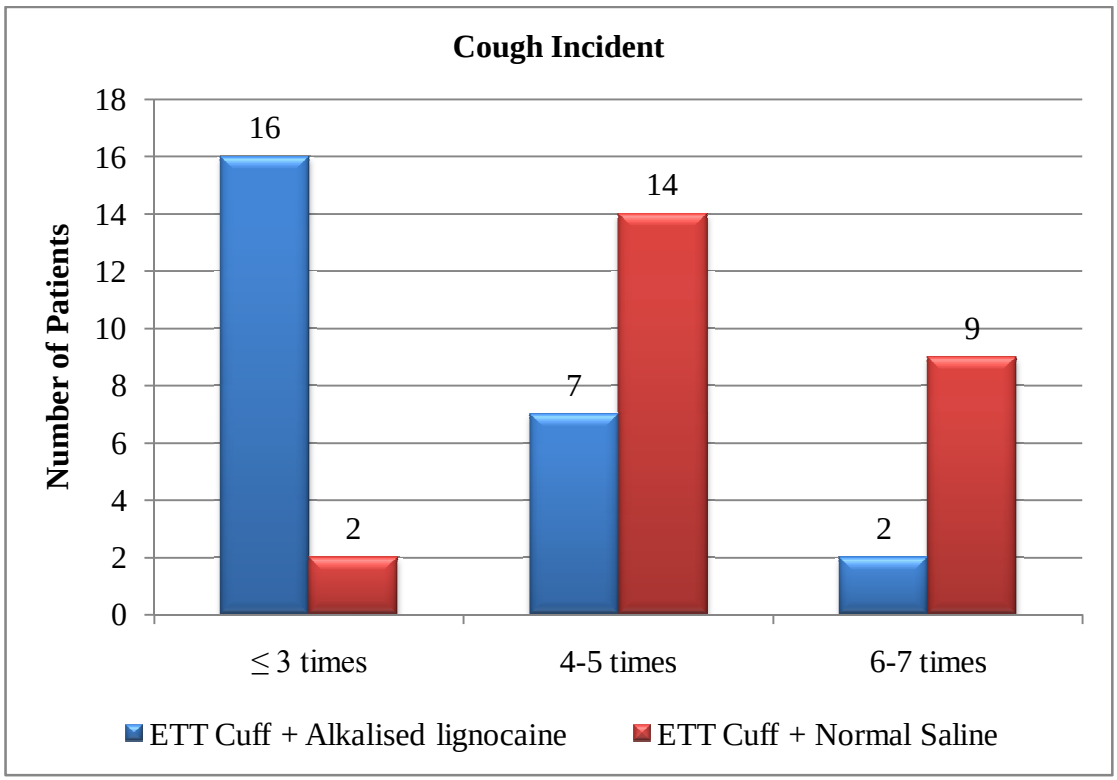


Total Fentanyl Dose	ETT Cuff + Alkalised Lignocaine	Percentage	ETT Cuff + Normal Saline	Percentage
25 micrograms	15	60.00	2	8.00
50 micrograms	5	20.00	5	20.00
75 micrograms	5	20.00	13	52.00
100 micrograms	0	0.00	5	20.00
Total	25	100	25	100

Total Fentanyl Dose	ETT Cuff + Alkalised Lignocaine	ETT Cuff + Normal Saline
N	25	25
Mean	40.00	71.00
SD	20.41	21.26
P value Unpaired t Test		0.0000

In patients belonging to ETT Cuff + Alkalised Lignocaine group, the mean total Fentanyl dose was 40 micrograms. In ETT Cuff + Normal Saline group, the mean total Fentanyl dose is 71 micrograms. The decreased mean total Fentanyl dose in ETT Cuff + Alkalised Lignocaine group compared to the ETT Cuff + Normal Saline group is statistically significant as the p value is < 0.05 as per unpaired t- test indicating a true difference among study groups.

Cough Incident

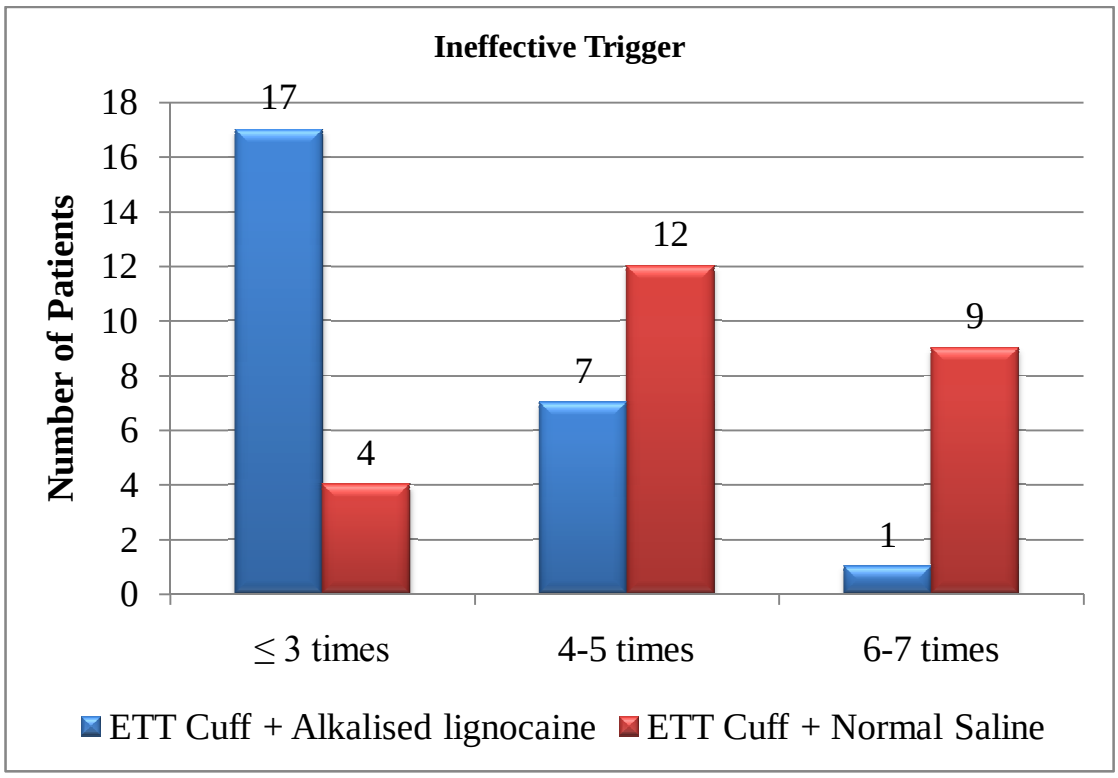


Cough Incident	ETT Cuff + Alkalised Lignocaine	Percentage	ETT Cuff + Normal Saline	Percentage
≤ 3 times	16	64.00	2	8.00
4-5 times	7	28.00	14	56.00
6-7 times	2	8.00	9	36.00
Total	25	100	25	100

Cough Incident	ETT Cuff + Alkalised Lignocaine	ETT Cuff + Normal Saline
N	25	25
Mean	3.32	5.04
SD	1.22	1.31
P value Unpaired t Test		0.0000

In patients belonging to ETT Cuff + Alkalised Lignocaine group, the mean cough incident measurement was 3.32 times. In ETT Cuff + Normal Saline group, the mean cough incident measurement is 5.04 times. The decreased mean cough incident measurement in ETT Cuff + Alkalised Lignocaine group compared to the ETT Cuff + Normal Saline group is statistically significant as the p value is < 0.05 as per unpaired t-test indicating a true difference among study groups.

Ineffective Trigger



Ineffective Trigger	ETT Cuff + Alkalised Lignocaine	Percentage	ETT Cuff + Normal Saline	Percentage
≤ 3 times	17	68.00	4	16.00
4-5 times	7	28.00	12	48.00
6-7 times	1	4.00	9	36.00
Total	25	100	25	100

Ineffective Trigger	ETT Cuff + Alkalised Lignocaine	ETT Cuff + Normal Saline
N	25	25
Mean	3.12	4.96
SD	1.30	1.34
P value Unpaired t Test		0.0000

In patients belonging to ETT Cuff + Alkalised Lignocaine group, the mean ineffective trigger measurement was 3.12 times. In ETT Cuff + Normal Saline group, the mean ineffective trigger measurement is 4.96 times. The decreased mean ineffective trigger measurement in ETT Cuff + Alkalised Lignocaine group compared to the ETT Cuff + Normal Saline group is statistically significant as the p value is < 0.05 as per unpaired t- test indicating a true difference among study groups.

DISCUSSION

This study is a prospective randomized control study conducted at the Institute of Anesthesiology and critical care, Madras Medical College, Chennai.

The study populations included fifty (n=50) postoperative patients who required ventilator support. The patients were randomly segregated into two groups.

Group A (Intervention group - n=25 patients) were administered intracuff alkalized Lignocaine

Group B (Control group – n=25 patients) were administered intracuff Normal Saline.

All the 50 (n=50) patients were given intra venous Fentanyl infusion in the dose of 75µgs/hour to achieve a score below 5. The levels of analgesia was monitored hourly for 24 hours using behavioral pain scale (BPS) . If the BPS score was ≥ 5, the patients were administered Fentanyl 25µg as as a bolus dose. The total bolus dose of Fentanyl required for 24 hours in each group was calculated.

The mean heart rate measurement was meaningfully less in ETT Cuff + Alkalised Lignocaine group compared to the ETT Cuff + Normal Saline group by 4.97 bpm. This significant difference of 6% decrease in

mean heart rate measurement in ETT Cuff + Alkalised Lignocaine group compared to the ETT Cuff + Normal Saline group is true and has not occurred by chance.

In this study mean heart rate measurement was significantly and consistently lower in ETT Cuff + Alkalised Lignocaine group compared to the ETT Cuff + Normal Saline group.

The mean diastolic blood pressure measurement was meaningfully less in ETT Cuff + Alkalised Lignocaine group compared to the ETT Cuff + Normal Saline group by 5.81 mm Hg. This significant difference of 7% decrease in mean diastolic blood pressure measurement in ETT Cuff + Alkalised Lignocaine group compared to the ETT Cuff + Normal Saline group is true and has not occurred by chance. In this study mean diastolic blood pressure measurement was consistently lower in ETT Cuff + Alkalised Lignocaine group compared to the ETT Cuff + Normal Saline group.

The mean arterial pressure measurement was meaningfully less in ETT Cuff + Alkalised Lignocaine group compared to the ETT Cuff + Normal Saline group by 3.62 mm Hg. This significant difference of 4% decrease in mean arterial pressure measurement in ETT Cuff + Alkalised Lignocaine group compared to the ETT Cuff + Normal Saline group is true and has not occurred by chance. In this study mean arterial pressure

measurement was significantly lower in ETT Cuff + Alkalised Lignocaine group compared to the ETT Cuff + Normal Saline group.

The mean behaviour pain scale measurement was meaningfully less in ETT Cuff + Alkalised Lignocaine group compared to the ETT Cuff + Normal Saline group by 0.53 points. This significant difference of 13% decrease in mean behaviour pain scale measurement in ETT Cuff + Alkalised Lignocaine group compared to the ETT Cuff + Normal Saline group is true and has not occurred by chance. In this study mean behaviour pain scale measurement was significantly and consistently lower in ETT Cuff + Alkalised Lignocaine group compared to the ETT Cuff + Normal Saline group.

The mean total Fentanyl dose was remarkably less in ETT Cuff + Alkalised Lignocaine group compared to the ETT Cuff + Normal Saline group by 31 micrograms. This significant difference of 40% decrease in mean total Fentanyl dose in ETT Cuff + Alkalised Lignocaine group compared to the ETT Cuff + Normal Saline group is true and has not occurred by chance.

In this study mean total Fentanyl dose was significantly lower in ETT Cuff + Alkalised Lignocaine group compared to the ETT Cuff + Normal Saline group.

Out of the 25 patients (n=25) in the Group A (Intervention group) 15 patients required 25µg of Fentanyl, 5 patients required 50µg and another 5 patients required 75µg of Fentanyl.

In the Group B (n=25) (Control group) 2 patients required 25µg of Fentanyl, 5 patients needed 50µg of Fentanyl and 13 required 75µg and 5 were given 100 µg of Fentanyl.

This study had documented 40% reduction in the Fentayl requirement during the first 24 hours in patients with intracuff alkalized Lignocaine .

Malik et al has reported 35% reduction in Fentanyl requirement in patients with intracuff alkalized Lignocaine[20]. Ahmed Sobhy had also documented 30% reduction in Fentanyl and propofol requirement in patients with intracuff Lignocaine[1].

The results of this study were comparable to the results of above quoted studies.

In this study 2% Lignocaine and 8.4% of sodium bicarbonate was used in the rartio of 1:1ml. Various studies have shown that variation in the concentration of sodium bicarbonate injected into the cuff had no effect on the diffusion of Lignocaine.

Lignocaine is known to be absorbed rapidly from tracheo brocheal mucosa. However for systemic Lignocaine to be effective in reduceing

ETT discomfort a very high plasma concentration of Lignocaine is required (IV Lignocaine 2mg/kg give plasma Lignocaine level >3µg/ml). than that attained in case of Lignocaine diffusion with 8.4% sodium bicorbanate(<0.08µg/ml) suggesting that improved ETT tolerance after intracuff alkalized Lignocaine is local rather than a systemic effect.

The present study had also documented significant reduction in the incidence of cough and restlessness in the the intervention group than the control group.

In the present study, the frequency of ineffective trigger was found to be lower in patients who received intracuff alkalized Lignocaine than the control group. This is attributed to the increased ETT tolerance and patient comfort associated with intracuff alkalized Lignocaine.

Ineffective trigger occurs when patients effort fails to reduce airway pressure below ventilator trigger sensitivity. However ineffective trigger occurs particularly due to improper ventilator settings (inappropriate trigger sensitivity) or abnormal pulmonary mechanics [2,3,4]. Also sedatives and analgesics have shown to depress the inspiratory drive and decreases the inspiratory muscle effort and thereby increasing ineffective trigger[12,33].

Sign et al had reported that use of saline or 2 % Lignocaine without alkalization as liquid media for inflating ETT cuff reduced post-extubation reaction[28].

In case of cuff rupture Lignocaine and sodium bicarbonate mixture could be irritative. However in vitro and vivo study showed no cuff obstruction or rupture. Similarly this study had no events of cuff rupture or obstruction[,9,27,34].

Some incidents of cuff rupture have been reported when Lignocaine was used as lubricant or for local anaesthesia[35].

SUMMARY

- This study is a prospective randomized control study conducted at the Institute of Anaesthesiology and critical care, Madras Medical College, Chennai.
- Study population included fifty post operative patients assigned into two groups (A and B)
- Group A (Intervention group) were administered intracuff alkalized Lignocaine
- Group B (Control group) were administered intracuff normal saline
- Fentanyl IV infusion in a dose of 75 µg was administered to all the fifty patients to achive a BPS of < 5. The effect of analgesia was monitored using Behavioural Pain Scale (BPS)[24] .
- Whenever the score was ≥ 5, patients were administered Fentanyl 25 µg IV as a bolus dose.
- The mean heart rate measurement in ETT Cuff + Alkalised Lignocaine group is less when compared to the ETT Cuff + Normal Saline group, which is statistically significant.
- The mean systolic blood pressure measurement in ETT Cuff + Alkalised Lignocaine group is less when compared to the ETT Cuff + Normal Saline group, which is statistically significant

- The mean diastolic blood pressure measurement in ETT Cuff + Alkalised Lignocaine group is less when compared to the ETT Cuff + Normal Saline group, which is statistically significant
- The mean arterial pressure measurement in ETT Cuff + Alkalised Lignocaine group is less when compared to the ETT Cuff + Normal Saline group, which is statistically significant.
- The mean behaviour pain scale measurement in ETT Cuff + Alkalised Lignocaine group is less when compared to the ETT Cuff + Normal Saline group, which is statistically significant.
- The mean total Fentanyl dose in ETT Cuff + Alkalised Lignocaine group is less when compared to the ETT Cuff + Normal Saline group, which is statistically significant
- The mean cough incident measurement in ETT Cuff + Alkalised Lignocaine group is less when compared to the ETT Cuff + Normal Saline group which is statistically significant
- The mean ineffective trigger measurement in ETT Cuff + Alkalised Lignocaine group is less when compared to the ETT Cuff + Normal Saline group which is statistically significant

CONCLUSION

From this study, It is conclude that the use of intracuff alkalized Lignocaine results in a significant decrease in the sedative/ analgesic requirement and frequency of ineffective trigger when compared to the use of intracuff saline and hence have better ET tube tolerance and improves patients compliance.

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PROFORMA

DATE: ROLL NO:

NAME:

AGE: SEX: IP NO:

DIAGNOSIS:

SURGICAL PROCEDURE DONE:

Ht: CVS:

Wt: RS:

AIRWAY: MMS - IID - -

PRE OP ASSESSMENT:

HISTORY: Any Co-morbid illness
H/O Documented Difficult Airway
H/O previous surgeries

INTRAOP EVENTS:

MEASURES OF STUDY OUTCOME:
GROUP A (INTRACUFF WITH ALKALIZED LIGNOCAINE)
FENTANYL INFUSION 100µg/hr

	1hr	2hr	3hr	4hr	5hr	6hr	8hr	10hr	12hr	16hr	20hr	24h
HR:												
SBP:												
DBP:												
MAP:												
BPS:												

COUGH INCIDENCE:
INEFFECTIVE TRIGGER:
TOTAL FENTANYL

GROUP B (INTRACUFF WITH NORMAL SALINE)
FENTANYL INFUSION 100µg/hr :

	1hr	2hr	3hr	4hr	5hr	6hr	8hr	10hr	12hr	16hr	20hr	24h
HR:												
SBP:												
DBP:												
MAP:												
BPS:												

COUGH INCIDENCE:
INEFFECTIVE TRIGGER:
TOTAL FENTANYL

INFORMATION TO PARTICIPENTS

Investigator: Dr SARAVANAN K

Name of the Participant:

Title: "A STUDY ON INTRACUFF ALKALIZED LIGNOCAINE REDUCES ANALGESIC/SEDATIVE REQUIREMENT FOR MECHANICALLY VENTILATED PATIENTS IN A TERTIARY CARE HOSPITAL"

You are invited to take part in this research study. We have got approval from the IEC. Your are asked to participate because you satisfy the eligibility criteria. We want to compare and study the safety and efficacy of Intracuff alkalized Lignocaine reduces analgesic/sedative requirement for mechanically ventilated patients

What is the Purpose of the Research:

1. **To investigate the effect of intracuff alkalized Lignocaine on sedative/analgesic requirements for mechanically ventilated patients.**
2. **To know its consequence on patient – ventilator interaction**

The Study Design:

All the patients in the study will be divided into two groups.

Group A – ETT cuff inflated with alkalized Lignocaine

Group B - ETT cuff inflated with normal saline

In mechanically ventilated patient

Benefits

ETT tolerance and reduses the requirements of analgesic/sedatives.

This intervention has been shown to be well tolerated as shown by previous studies.And if you do not want to participate you will have alternative of setting the standard treatment and your safety is our prime concern.

Time :

Date :

Place :

Signature / Thumb Impression of Patient

Patient Name:

Signature of the Investigator : _____

Name of the Investigator : _____

PATIENT CONSENT FORM

Study Title: **"A PROSPECTIVE RANDOMIZED STUDY ON INTRACUFF ALKALIZED LIGNOCAINE REDUCES ANALGESIC/SEDATIVE REQUIREMENT FOR MECHANICALLY VENTILATED PATIENTS IN A TERTIARY CARE HOSPITAL"**

Study Center: INSTITUTE OF ANAESTHESIOLOGY AND CRITICAL CARE RAJIV GANDHI GOVT. GENERAL HOSPITAL, MADRAS MEDICAL COLLEGE, CHENNAI-0 3.

Participant name: Age: Sex: I.P.No:

I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask the question and all my questions and doubts have been answered to my satisfaction.

I have been explained about the pitfall in the procedure. I have been explained about the safety,advantage and disadvantage of the technique.

I understand that my participation in the study is voluntary and that I am free to withdraw at anytime without giving any reason.

I understand that investigator, regulatory authorities and the ethics committee will not need my permission to look at my health records both in respect to current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from the study.

Time:

Date: Signature / thumb impression of patient

Place: Patient name:

Signature of the investigator:

Name of the investigator:

ஆராய்ச்சி ஒப்புதல் படிவம்

ஆராய்ச்சியின் தலைப்பு

மூன்றாம் நிலை மருத்துவமனையில் செயற்கை சுவாசக் கருவியில் பொருத்தப்பட்டிருக்கும் நோயாளிகளின் செயற்கை சுவாசக் குழாயின் சுற்று பட்டையில் அல்கலைசைடு லிக்னோகேன் செலுத்துவதால் மயக்கமருந்து மற்றும் வலி நிவராணி தேவையளவு குறைவதை கண்டறிவதற்கான ஆய்வு.

பங்கு பெறுபவரின் பெயர் :

பங்கு பெறுபவரின் எண் :

பங்கு பெறுபவர் இதனை (✓) குறிக்கவும்

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும். அதற்கான தகுந்த விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டது.

நான் இவ்வாய்வில் தன்னிச்சையாகத்தான் பங்கேற்கிறேன். எந்த காரணத்தினாலோ எந்த கட்டத்திலும் எந்த சட்ட சிக்கலுக்கு உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகி கொள்ளலாம் என்றும் அறிந்து கொண்டேன்.

இந்த ஆய்வு சம்மந்தமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும் போதும். இந்த ஆய்வில் பங்கு பெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன்.

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக் கொள்ளவும். அதை பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கிறேன்.

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக் கொள்கிறேன். எனக்கு கொடுக்கப்பட்ட அறிவுரைகளின் படி நடந்து கொள்வதுடன் இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்று உறுதியளிக்கிறேன்.

பங்கேற்பவரின் பெற்றோர்/ உறவினர் கையொப்பம் ..... இடம்..... தேதி.....

கட்டைவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம்.....

ஆய்வாளரின் கையொப்பம் ..... இடம்..... தேதி.....

ஆய்வாளரின் பெயர்.....

ஆராய்ச்சி தகவல் தாள்

ஆராய்ச்சி தலைப்பு : மூன்றாம் நிலை மருத்துவமனையில் செயற்கை சுவாசக் கருவியில் பொருத்தப்பட்டிருக்கும் நோயாளிகளின் செயற்கை சுவாசக் குழாயின் சுற்று பட்டையில் அல்கலைசைடு லிக்னோகேன் செலுத்துவதால் மயக்கமருந்து மற்றும் வலி நிவராணி தேவையளவு குறைவதை கண்டறிவதற்கான ஆய்வு.

ஆராயச்சியாளர் பெயர் : மரு.கி.சரவணன்

பங்கேற்பாளர் பெயர் :

செயற்கை சுவாசக் கருவிகள் பொருத்தப்பட்டிருக்கும் நோயளிகளின் சுவாசக் குழாயின் சுற்றுப்பட்டையில் மயக்கமருந்து மற்றும் வலி நிவராணி தேவையளவு குறைவதை கண்டறிதல்.

செயற்கை சுவாசக் கருவிகளால் நோயளிகளுக்கு ஏற்படும் விளைவுகளை ஆராய்தல்.

ஆய்வு முறை :

குழு 1

செயற்கை சுவாசக் குழாயின் சுற்றுப்பட்டையில் அல்கலைஸ்டு லிக்னோகேன் செலுத்துதல்

குழு 2

செயற்கை சுவாசக் குழாயின் சுற்றுப்பட்டையில் நார்மல் சலைன் செலுத்துதல்

நன்மைகள்

வலி நிவராணிகள் மற்றும் மயக்க மருந்துகளின் தேவை குறைகிறது.

இந்த முறையான ஆய்வு ஏற்கனவே பல இடங்களின் நடத்தப்பட்டு உள்ளது. மேலும் இதன் பாதுகாப்பு உறுதிசெய்யப்பட்டுள்ளது. நீங்கள் இந்த ஆய்வில் பங்கு கொள்ள விரும்பவில்லை என்றால் எப்போதும் உபயோகப்படுத்தப்படும் மருந்தே கொடுக்கப்படும். உங்கள் பாதுகாப்பே எங்கள் முக்கிய நோக்கமாகும்.

இந்த ஆய்வு சம்பந்தமான எல்லா புள்ளி விவரங்கள் மற்றும் நோயாளிகளின் விவரங்கள் ரகசியமாக வைக்கப்படும். இந்த ஆய்வு சம்பந்தப்பட்ட எல்லா பரிசோதனைகள், மருந்துகள் மற்றும் மருத்துவ சேவைகள் அனைத்தும் நோயாளிகளுக்கு இலவசமாக வழங்கப்படும்.

ஆய்வாளரின் பெயர் பங்கு பெறுபவரின் பெற்றோர் / உறவினர் பெயர்

ஆய்வாளரி கையொப்பம் பங்கு பெறுபவரின் பெற்றோர் / உறவினர் கையொப்பம்

நாள் :

இடம் :

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI-3

EC Reg No.ECR/270/Inst./TN/2013
Telephone No. 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr.K.Saravanan
Postgraduate M.D.(Anaesthesiology)
Madras Medical College
Chennai 600 003

Dear Dr.K.Saravanan,

The Institutional Ethics Committee has considered your request and approved your study titled **"Intracuff alkalized lignocaine reduces sedative/analgesic requirements for mechanically ventilated patients in tertiary care hospital" No.01082015.**

The following members of Ethics Committee were present in the meeting held on 04.08.2015 conducted at Madras Medical College, Chennai-3.

1.	Prof.C.Rajendran, M.D.,	: Chairperson
2.	Prof.R.Vimala, M.D., Dean, MMC, Ch-3	: Deputy Chairperson
3.	Prof.Sudha Seshayyan, M.D., Vice-Principal, MMC, Ch-3	: Member Secretary
4.	Prof.B.Vasanthi, M.D., Professor Pharmacology, MMC	: Member
5.	Prof.A.Rajendran, M.S., Professor, Inst.of Surgery, MMC	: Member
6.	Prof.Saraswathy, M.D., Director, Inst. Of Pathology, MMC	: Member
7.	Prof.Srinivasagalu, Director, Inst.of Inter Med. MMC	: Member
8.	Tmt. J.Rajalakshmi, J.A.O. MMC, Ch-3	: Lay Person
9.	Thiru S.Govindasamy, B.A., B.L.,	: Lawyer
10.	Tmt.Arnold Saulina, M.A., MSW.,	: Social Scientist

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary, Ethics Committee

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003

Group A:ETT CUFF FILLED WITH ALKALIZED LOGNOCAINE

							HEART RATE																SYSTOLIC BLOOD PRESSURE													
S.NO	NAME	AGE	SEX	IP.NO	DIAGNOSIS	SURGERY	HT	WT	BMI	ASA	0HR	1HR	2HR	3HR	4HR	5HR	6HR	8HR	10HR	12HR	16HR	20HR	24HR	0HR	1hr	2HR	3HR	4HR	5HR	6HR	8HR	10HR	12HR	16HR	20HR	24HR
1	govindammal	57	F	76793	ca mandible	hemi mandibulectomy	135	60	32	III	85	88	86	85	90	83	79	84	88	74	76	74	75	122	121	126	128	130	126	124	126	136	126	129	125	123
2	sengammal	40	F	79338	ca OG junction	total gastrectomy	140	48	24	II	65	73	74	79	73	76	79	74	80	73	75	76	78	116	115	113	119	123	125	126	121	120	138	121	125	126
3	rajakumar	50	M	74175	ca tongue	hemi glossectomy	135	45	25	III	88	88	83	85	88	94	75	76	79	78	75	76	77	126	126	121	126	130	126	120	119	134	126	126	129	126
4	Anbalagan	46	M	74593	cholilithiasis	cholecystectomy	160	62	24	II	65	68	74	72	76	74	80	72	79	72	75	74	76	109	106	118	113	105	126	126	115	116	109	113	126	126
5	Murugan	67	M	69175	chronic calcified pancriatitis	frey's procedure	165	68	25	II	92	90	88	92	102	92	88	87	84	85	83	86	88	116	115	116	113	126	129	115	113	124	112	109	124	121
6	Nirmala	51	F	73558	fibroadenoma left breast	excision	145	50	24	II	74	73	76	78	84	82	86	89	80	81	90	84	82	123	125	129	126	129	116	120	124	126	122	130	126	121
7	Rajakumari	32	F	64422	odantogenic myxoma	excision	130	45	26	II	92	95	90	105	88	86	82	83	84	88	89	94	86	132	134	130	140	131	136	126	121	129	134	126	121	126
8	jayaraman	25	M	64488	lumbar scoliosis	deformity correction	158	50	20	II	72	74	79	85	80	78	76	72	80	71	76	70	73	116	115	118	126	124	129	116	113	120	116	126	116	115
9	Nithya	20	F	71914	maxillary retroganthism	B/L sagittal split osteotomy	155	54	22	II	74	72	76	82	72	70	79	78	84	82	80	86	80	123	124	124	129	125	126	121	126	130	124	128	132	126
10	Devika	15	F	69923	fracture Rt mandible	ORIF	145	44	21	II	64	70	72	78	90	88	80	85	86	89	78	78	74	116	115	113	116	126	126	121	126	130	124	128	132	126
11	Remesh	45	M	64589	stricture esophagus	coloplasty	167	68	24	II	96	99	98	94	90	91	94	88	86	86	92	90	88	98	99	100	110	94	98	102	96	99	101	112	106	105
12	Sriniasan	60	M	66714	ca r buccal mucosa	WLE and manibulectomy	158	58	23	III	77	74	75	75	80	73	88	78	75	77	70	75	71	101	103	106	105	109	110	115	109	109	126	119	112	115
13	Gopalan	55	M	68189	periampulary ca	whipples procedure	156	60	25	III	66	68	64	70	75	71	74	75	78	80	87	84	85	126	122	134	138	130	126	124	134	121	129	130	136	135
14	Sujatha	32	F	62689	lefort 2 fracture	ORIF	155	54	22	II	66	69	68	70	68	77	69	66	70	74	78	71	74	99	102	105	113	104	115	103	115	120	119	112	116	126
15	kannan	38	M	54568	fracture Rt mandible	ORIF	145	52	25	II	88	84	90	82	86	89	84	88	92	82	81	86	80	138	134	140	139	136	135	130	135	134	139	136	129	130
16	Meenakkshi	52	F	74891	periampulary ca	whipples procedure	138	58	30	II	65	66	68	72	74	76	79	88	78	86	82	90	82	141	145	146	138	134	141	138	139	130	139	136	140	143
17	Kumarevel	58	M	74886	ca buccal mucosa	WLE and manibulectomy	162	66	25	II	74	72	76	88	70	72	78	71	74	86	72	71	74	102	113	114	124	120	115	126	121	124	129	120	121	123
18	Krishnamoorthy	56	M	54362	chronic calcified pancriatitis	frey's procedure	158	66	26	II	88	84	86	89	90	92	96	96	90	84	82	85	80	109	103	104	103	110	115	120	125	121	121	119	118	113
19	Rani	40	F	67115	incisional hernia	mesh repair	145	62	29	II	74	76	79	84	78	76	79	74	88	89	82	80	84	132	124	129	130	126	121	129	126	131	136	134	126	123
20	Megala	35	F	78112	ca tongue	hemi glossectomy	152	58	25	II	75	74	76	80	78	74	76	78	70	71	73	79	70	141	142	144	146	139	136	139	136	129	124	128	132	134
21	kannayan	36	M	82115	ca nasal cavity	WLE and sentinal nodal biopsy	142	52	26	III	88	84	90	82	86	85	88	89	78	74	76	80	78	124	129	130	129	126	130	134	136	129	122	125	129	121
22	Saroja	48	F	58188	ca maxilla	maxillectomy and ffp	142	58	29	III	66	64	68	88	89	90	92	88	80	84	89	80	81	94	99	102	105	108	112	126	120	119	126	124	113	115
23	Kalaivani	46	F	66713	fracture left mandible	ORIF	146	54	25	II	88	90	92	99	84	83	86	88	82	85	84	88	88	130	125	124	136	121	124	121	129	134	121	119	115	118
24	govindhan	60	M	74183	odantogenic myxoma	excision	136	40	22	II	64	62	70	68	78	74	79	68	64	65	68	62	60	129	126	139	126	132	134	139	134	129	124	126	124	123
25	Maheswari	58	F	78164	fibroadenoma left breast	excision	140	55	28	II	74	76	75	79	71	72	80	78	74	75	80	84	89	102	115	113	126	124	128	129	120	115	116	124	125	129

DIASTOLIC BLOOD PRESSURE													MEAN ARTERIAL PRESSURE												BEHAVIOUR PAIN SCALE															
0HR	1HR	2HR	3HR	4HR	5HR	6HR	8HR	10HR	12HR	16HR	20HR	24HR	0HR	1HR	2HR	3HR	4HR	5HR	6HR	8HR	10HR	12HR	16HR	20HR	24HR	0HR	1HR	2HR	3HR	4HR	5HR	6HR	8HR	10HR	12HR	16HR	20HR	24HR	T0TAL FENTANYL	COUGH INCIDENT	INEFFECTIVE TRIGGER	
74	70	74	80	90	70	84	74	88	74	74	70	84	106	104	90	96	104	88	97	90	104	92	92	88	97	3	3	3	3	4	4	4	4	5	3	4	4	4	25	3	3	
65	64	69	68	74	72	78	74	72	84	68	69	70	99	98	84	85	90	89	94	89	88	102	86	88	88	3	3	3	3	4	4	4	4	4	6	3	4	4	25	4	3	
74	71	74	78	89	74	76	78	64	82	74	71	79	108	107	90	94	102	90	90	90	87	96	91	90	95	3	3	3	3	4	4	4	4	5	3	3	3	4	25	3	4	
68	69	70	74	69	68	79	64	68	63	69	69	70	93	93	86	87	81	87	94	81	84	78	84	88	88	3	3	4	4	4	4	5	3	3	3	4	5	3	50	2	3	
72	76	68	70	72	84	72	74	80	78	74	84	70	100	102	84	84	90	99	86	87	95	90	86	97	87	3	3	3	3	3	4	4	4	5	3	4	5	3	50	2	3	
70	74	72	74	84	82	79	74	70	76	88	80	74	105	108	91	90	99	93	92	90	86	91	102	96	90	3	3	3	3	4	4	4	4	4	4	5	3	4	25	3	2	
82	85	80	89	81	84	79	79	80	88	82	80	86	115	117	96	106	98	101	94	93	96	103	96	94	99	3	3	3	4	4	6	3	3	4	5	3	4	4	50	4	3	
68	69	70	72	70	74	68	69	76	69	64	69	64	100	100	86	90	88	92	84	83	90	84	85	85	81	3	3	3	4	4	5	3	3	6	3	5	3	4	75	5	4	
69	68	69	74	72	70	69	68	70	62	68	72	70	105	105	87	92	90	88	86	87	90	82	88	92	88	3	3	3	4	4	4	4	4	5	3	3	4	4	25	3	2	
69	70	71	74	76	80	74	75	73	74	69	68	64	100	100	85	88	92	95	90	92	92	90	88	89	85	3	3	3	4	4	6	3	3	4	5	3	3	3	50	4	3	
64	69	68	70	63	65	70	70	69	64	68	63	70	86	89	78	82	72	76	80	78	79	76	82	77	82	3	3	3	4	4	4	5	3	3	3	4	4	4	25	3	2	
69	70	69	68	72	69	70	68	69	76	70	71	69	90	92	81	80	84	82	85	82	82	92	86	85	84	3	3	3	3	3	3	4	4	4	6	4	4	4	25	2	1	
74	78	82	80	84	86	80	89	82	84	80	88	80	108	108	99	99	99	99	95	104	95	99	97	104	98	3	3	3	3	4	4	4	6	3	3	3	4	4	25	3	2	
64	72	74	78	69	75	69	68	70	72	76	70	71	87	92	84	89	80	88	80	84	86	88	88	85	89	3	3	3	4	4	5	4	4	5	3	3	3	4	50	2	3	
84	80	79	85	74	76	82	80	81	79	88	80	81	120	116	99	103	95	96	98	98	99	99	104	96	97	3	3	4	4	4	5	3	3	3	4	4	4	4	25	2	2	
88	84	85	89	80	90	86	85	88	90	80	86	80	123	124	105	105	98	107	103	103	102	106	98	104	101	3	3	3	3	4	5	3	3	4	6	3	3	4	25	3	2	
69	70	74	78	72	74	79	72	76	78	70	72	80	91	98	87	94	88	88	95	88	92	95	86	88	94	3	3	4	5	3	4	6	3	3	5	3	3	4	75	4	5	
64	68	62	69	64	63	70	72	71	70	75	70	76	94	90	76	80	79	80	86	90	88	87	90	86	88	3	3	3	4	4	4	4	5	3	3	3	4	4	25	2	4	
84	82	79	76	80	81	78	84	80	82	83	84	86	116	110	96	94	95	94	95	98	97	100	100	98	98	3	3	3	4	4	4	4	5	3	3	4	4	4	25	3	2	
84	85	89	86	83	88	90	84	82	86	89	84	80	122	123	107	106	102	104	106	101	98	99	102	100	98	3	3	5	3	3	4	5	3	3	4	6	3	3	75	6	5	
74	78	76	70	73	78	70	79	72	69	75	70	76	107	112	94	90	90	95	90	98	91	86	92	90	91	3	3	4	4	4	4	4	5	3	3	3	4	4	25	3	2	
63	68	70	74	68	69	74	63	68	64	70	69	63	83	88	80	84	80	83	90	82	85	85	88	83	80	3	3	4	5	3	3	5	3	4	4	6	3	3	75	5	6	
84	80	85	79	74	80	81	83	88	80	82	84	86	114	110	98	98	90	94	94	98	103	94	94	94	96	3	3	3	3	4	4	4	4	5	3	3	3	3	25	2	2	
74	78	79	74	78	81	70	69	74	72	77	76	74	110	110	99	90	96	98	93	90	92	90	93	92	90	3	3	5	3	4	4	5	3	3	4	6	3	4	75	6	5	
70	71	73	74	78	70	78	72	69	71	70	77	70	91	100	86	90	93	89	95	88	84	86	88	93	90	3	3	4	4	4	4	5	3	3	3	4	4	4	25	4	5	

Group B: ETT CUFF FILLED WITH NORMAL SALINE											HEART RATE															SYSTOLIC BLOOD PRESSURE											
S.NO	NAME	AGE	SEX	IP.NO	DIAGNOSIS	SURGERY	HT	WT	BMI	ASA	0HR	1HR	2HR	3HR	4HR	5HR	6HR	8HR	10HR	12HR	16HR	20HR	24HR	0HR	1hr	2HR	3HR	4HR	5HR	6HR	8HR	10HR	12HR	16HR	20HR	24HR
1	ramkumar	45	M	64581	fracture left mandible	ORIF	167	68	24	II	84	82	86	88	90	82	86	86	90	84	89	90	84	126	121	121	128	134	126	124	129	130	128	126	130	120
2	Sriniasan	60	M	66754	ca buccal mucosa	WLE and manibulectomy	158	58	23	III	76	74	73	80	83	75	76	78	74	76	82	79	72	102	105	110	112	110	116	115	113	116	119	130	119	116
3	gopinath	55	M	66881	ca ilio caecal junction	laprotoy	156	60	25	II	68	69	70	76	64	68	73	69	65	68	77	70	74	132	130	131	138	129	126	134	129	132	130	136	126	122
4	sujitha	32	F	62555	odantogenic myxoma	excision	155	54	22	II	82	86	82	88	79	80	81	88	79	72	76	79	70	126	129	123	130	126	135	136	134	129	126	130	134	130
5	mariyadass	38	M	54824	# LT maxilla	ORIF	145	52	25	II	72	73	72	70	73	76	80	75	70	72	76	72	70	119	116	115	120	121	126	128	120	125	126	120	126	129
6	manimegalai	57	F	76333	ca mandible	hemi mandibulectomy	135	60	32	II	64	65	67	67	78	63	68	69	73	69	74	86	70	129	138	139	136	140	13	136	135	142	136	132	139	132
7	raammayi	40	F	79653	ca OG junction	total gastrectomy	140	48	24	III	74	76	78	84	72	71	78	70	73	77	85	72	73	102	105	116	130	115	116	124	108	109	105	126	122	124
8	mahendiran	50	M	74135	ca tongue	hemi glossectomy	135	45	25	III	94	92	98	96	102	86	89	89	94	82	88	90	84	126	121	126	123	130	120	121	136	138	130	139	136	130
9	rajamurali	46	M	74445	cholilithiasis	cholecystectomy	160	62	24	II	88	90	94	86	93	80	84	88	98	85	83	90	82	116	126	129	116	130	126	114	115	130	115	116	130	126
10	perumal	67	M	69452	peri ampulary ca	whipples procedure	165	68	25	III	76	78	74	82	77	70	78	86	70	72	89	80	86	132	130	131	140	142	138	131	140	120	121	130	131	134
11	meena	52	F	65248	chondrosarcoma rt manidible	WLE and manibulectomy	138	58	30	II	67	74	78	69	69	65	73	69	78	74	80	75	82	135	130	138	126	129	126	130	132	139	126	139	124	121
12	kulandaivel	58	M	74886	ccpancriatitis	freys procedure	162	66	25	II	88	89	88	92	84	83	92	86	88	95	84	86	86	126	121	128	134	126	129	134	121	126	130	126	119	124
13	krishnan	56	M	56542	poly trauma	ORIF RT rt UL and femour n tibia	158	66	26	II	77	76	79	80	89	74	78	78	83	70	75	70	73	99	98	102	105	126	120	121	119	130	115	128	129	130
14	meriyamma	40	F	65252	incisional hernia	mesh repair	145	62	29	II	66	68	67	70	71	78	69	64	68	64	61	69	68	130	131	136	126	129	134	138	132	130	140	125	130	126
15	sangeetha	35	F	74542	fracture Rt mandible	ORIF	152	58	25	II	88	89	94	82	86	90	81	88	76	72	78	84	70	129	130	131	134	119	118	129	130	129	120	121	136	120
16	karuppannan	36	M	80981	ca stomach	partial gastrectomy	142	52	26	III	93	89	88	91	94	102	90	88	92	86	84	87	87	142	140	148	132	126	134	120	130	126	126	121	140	125
17	Saroja	48	F	65821	lefort 1 fracture	ORIF	142	58	29	II	80	86	86	90	84	83	89	80	88	80	79	86	84	133	130	126	130	129	121	138	116	124	115	116	120	121
18	lakshmi	46	F	66969	lumbar disc disease	posterir stabilisation	146	54	25	II	76	74	78	79	86	72	74	82	83	88	90	86	82	139	135	140	138	140	131	140	139	132	126	140	138	130
19	govindhan	60	M	85647	# lt ramus of mandible	ORIF	136	40	22	II	70	72	74	76	73	85	73	74	88	74	70	79	72	115	116	115	118	126	129	130	131	136	129	126	130	116
20	meenammal	58	F	88585	cholelithiasis	lap and open cholecystectomy	140	55	28	II	69	68	70	88	74	76	80	72	71	76	89	82	84	128	121	129	130	136	131	135	128	124	130	135	128	130
21	neelamegam	51	F	79658	ca OG junction	total gastrectomy	145	50	24	II	80	86	84	82	88	82	89	88	96	82	86	84	82	119	115	120	121	126	120	116	115	129	117	126	109	126
22	Rajakumari	32	F	56541	fracture left mandible	ORIF	130	45	26	II	70	74	76	79	80	81	85	86	81	89	89	84	82	130	145	149	150	142	139	140	139	140	142	146	139	136
23	jayaraman	25	M	25653	peri ampulary ca	whipples procedure	158	50	20	III	80	78	79	80	85	76	74	78	79	85	78	72	70	98	99	94	102	105	96	99	98	102	105	100	110	112
24	Nithya	20	F	71546	stricture esophagus	coloplasty	155	54	22	II	70	74	78	80	72	73	84	79	70	79	72	80	75	116	115	116	126	121	120	125	128	120	130	131	136	128
25	devikala	26	F	65567	b/l peri odantal cyst	excision	145	44	21	II	65	66	65	69	68	74	68	68	70	78	69	69	73	136	139	140	142	140	148	132	129	128	136	126	129	130

DIASTOLIC BLOOD PRESSURE													MEAN ARTERIAL PRESSURE													BEHAVIOUR PAIN SCALE															
0HR	1HR	2HR	3HR	4HR	5HR	6HR	8HR	10HR	12HR	16HR	20HR	24HR	0HR	1HR	2HR	3HR	4HR	5HR	6HR	8HR	10HR	12HR	16HR	20HR	24HR	0HR	1HR	2HR	3HR	4HR	5HR	6HR	8HR	10HR	12HR	16HR	20HR	24HR	T0TAL FENTANYL	COUGH INCIDENT	INEFFECTIVE TRIGGER	
84	82	86	80	89	81	84	79	86	88	80	88	85	98	95	98	96	104	96	97	96	100	101	95	102	96	3	3	4	4	5	3	4	4	6	3	4	5	3	75	6	5	
74	78	76	79	80	74	75	74	72	70	80	74	76	83	87	87	90	90	88	88	87	86	86	96	89	89	3	3	3	4	5	3	4	4	4	4	6	4	4	50	4	2	
84	89	86	89	80	82	90	84	80	79	86	84	80	100	102	101	105	96	96	104	99	97	96	102	98	94	3	3	4	5	4	4	5	3	4	4	6	4	4	75	6	5	
74	76	70	84	79	72	78	84	70	71	74	86	74	91	94	88	99	95	93	97	100	89	89	92	102	92	3	4	4	6	3	4	4	5	3	4	4	5	4	75	4	6	
69	64	72	71	76	74	84	80	79	81	82	84	80	86	81	86	87	91	91	98	93	94	96	94	98	96	3	3	3	4	4	4	5	3	3	3	4	4	4	25	2	3	
84	82	89	86	90	83	82	84	88	84	80	88	82	99	100	106	102	106	60	100	101	106	101	97	105	98	3	3	4	4	6	3	4	4	5	3	4	6	4	75	6	5	
74	68	69	72	68	74	78	80	74	75	84	78	79	84	80	85	91	84	88	93	89	86	85	98	92	94	3	3	4	5	3	3	5	3	4	4	6	3	3	75	7	5	
71	74	78	80	84	82	80	84	86	80	79	85	72	89	90	94	94	99	95	93	101	103	96	99	102	91	3	3	4	4	6	3	3	4	5	3	4	6	4	75	6	5	
69	79	84	80	78	80	81	85	88	74	70	85	74	85	95	99	92	95	95	92	95	102	88	85	100	91	3	4	5	4	5	3	4	4	6	4	4	5	4	100	5	5	
84	88	84	92	84	85	80	87	80	81	89	84	80	100	102	100	108	103	102	97	105	93	94	102	100	98	3	4	4	6	3	4	4	5	3	3	5	3	4	75	5	6	
92	88	84	92	84	85	80	87	80	81	89	84	80	106	102	102	103	99	98	96	102	100	96	106	97	93	3	4	5	3	3	4	5	3	5	4	6	3	4	100	6	4	
74	80	85	88	74	76	79	70	71	81	82	84	86	91	93	99	103	91	94	97	87	89	97	96	96	98	3	4	4	6	4	4	5	3	4	5	3	4	4	75	6	5	
64	68	62	69	76	69	64	72	84	69	68	72	68	76	78	75	81	92	86	83	87	99	84	88	91	88	3	4	4	4	6	3	4	4	5	3	5	4	4	75	5	6	
84	86	89	90	84	86	84	89	90	78	79	87	80	99	101	105	102	99	102	102	103	103	98	94	101	95	3	3	3	4	4	5	3	3	4	4	4	4	4	25	4	4	
78	84	89	80	82	80	81	86	84	80	74	82	80	95	99	103	98	94	92	97	100	99	93	90	100	93	3	4	5	3	4	5	4	6	3	3	4	5	4	100	5	7	
92	90	98	102	89	90	99	80	94	89	88	96	80	108	106	115	112	101	104	106	96	104	101	99	110	95	3	3	4	4	4	5	4	4	6	3	3	4	4	50	5	6	
88	89	80	84	90	88	74	79	78	80	84	82	86	103	102	95	99	103	99	95	91	93	92	95	94	98	3	4	4	5	3	3	5	4	5	3	3	5	4	100	7	5	
84	82	79	80	82	88	81	88	88	78	79	80	81	102	100	99	99	101	102	100	105	102	94	99	99	97	3	3	4	4	5	3	3	4	4	4	5	4	4	50	4	3	
71	74	79	70	78	84	80	74	88	74	80	84	80	86	88	91	86	94	99	96	93	104	92	95	99	92	3	3	4	4	4	6	3	4	5	3	4	5	3	75	5	7	
81	84	78	88	80	81	86	81	79	74	84	80	81	96	96	95	102	98	98	102	96	94	92	101	96	97	3	3	4	5	4	4	5	4	4	4	6	4	4	75	5	5	
71	78	74	80	84	80	79	74	88	70	74	78	72	87	90	89	93	98	93	91	88	102	85	91	88	90	3	3	4	4	5	4	4	4	6	3	4	4	4	50	4	5	
84	88	80	90	84	85	92	88	80	82	89	80	78	99	107	103	110	103	103	108	105	100	102	108	96	97	3	4	4	5	4	4	6	3	4	4	5	3	4	75	7	6	
74	76	79	78	80	81	84	80	81	89	82	88	81	82	84	84	86	88	86	89	86	88	94	88	95	91	3	3	4	4	5	3	4	4	4	6	4	5	4	75	5	6	
70	69	64	84	80	74	84	81	80	86	80	88	80	85	84	81	98	94	89	98	96	94	100	97	104	96	3	3	4	5	3	4	5	3	4	6	4	5	3	100	5	6	
90	89	92	90	88	88	84	78	84	89	78	74	75	105	106	108	107	105	108	100	95	98	105	94	92	93	3	3	3	4	4	5	3	3	4	5	3	3	4	50	2	2	