
**"AWAKE EXTUBATION RESPONSE: COMPARISON OF SUPERIOR
LARYNGEAL NERVE BLOCK AND IN LINE NEBULISATION WITH
LIGNOCAINE- A RANDOMISED CONTROLLED STUDY"**

By

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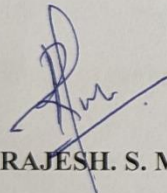
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
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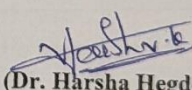
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LIST OF ABBREVIATIONS USED

SLN	-	Superior laryngeal Nerve
ASA	-	American Society of Anaesthesiology
SLNB	-	Superior laryngeal Nerve Block
HR	-	Heart rate
SBP	-	Systolic blood pressure
DBP	-	Diastolic blood pressure
MAP	-	Mean arterial pressure
mg	-	milligrams
ECG	-	Electrocardiograph
ETT	-	Endotracheal Tube
dl	-	Decilitre
IV	-	Intravenous
MHz	-	MegaHertz

min	-	Minute
kg	-	kilogram
mcg/ μ g	-	microgram
TM	-	Thyrohyoid membrane
US	-	Ultrasound
USG	-	Ultrasonograph
CTM	-	Cricothyroid membrane
Group B	-	Group with Superior Laryngeal Nerve Block
Group N	-	Group with nebulisation
ETCO ₂	-	end-tidal carbon dioxide

ABSTRACT

Introduction

Extubation is the critical phase of anaesthetic management that can trigger significant stress responses in the form of hemodynamic fluctuations. These responses are mediated by the stimulation of the larynx and trachea, leading to sympathetic nervous system activation. Effective management of extubation stress is crucial for patient safety and comfort. This study aims to compare the efficacy of superior laryngeal nerve block versus in-line nebulization with lignocaine in mitigating extubation responses in surgical patients.

Objectives

Primary objective of the study is to compare the hemodynamic stress response post-extubation in the form of HR, SBP, DBP and MAP and secondary objective is to grade the severity of post-operative cough and postoperative sore throat at different time interval post-extubation between the group receiving superior laryngeal nerve block and in line nebulisation with lignocaine.

Materials and Methods

This randomized controlled trial was conducted in the Department of Anaesthesiology, Jawaharlal Nehru Medical College, KAHER, Belagavi, from June 2022 to May 2023. A total of 100 patients meeting the inclusion criteria were enrolled and randomized into two groups (Group N: superior laryngeal nerve block, Group B: in-line nebulization with lignocaine) using a computer-generated randomization table. Hemodynamic parameters, cough severity, and sore throat incidence were measured at various intervals post-extubation. Data analysis was performed using SPSS 22.0 and R environment ver.3.2.2.

Results

Demographic data showed no significant differences between the groups. Heart rate changes were not significant at any time point post-extubation. Systolic, diastolic, and mean arterial pressures were significantly lower in Group B compared to Group N at pre-extubation, 1, 5, and 10 minutes post-extubation. Group B also exhibited significantly lower cough severity and incidence of sore throat immediately and 10 minutes post-extubation.

Conclusion

In-line nebulization with lignocaine is more effective than superior laryngeal nerve block in controlling hemodynamic responses, reducing cough severity, and minimizing sore throat post-extubation. This method provides better management of extubation-related complications, suggesting a preferable approach for patient care in the perioperative setting.

CONTENTS

SL. NO.	TOPIC	PAGE NO.
1.	INTRODUCTION	
2.	OBJECTIVES	
3.	REVIEW OF LITERATURE	
4.	BASIC SCIENCES	
5.	METHODOLOGY	
6.	RESULTS	
7.	DISCUSSION	
8.	CONCLUSION	
9.	SUMMARY	
10.	BIBLIOGRAPHY	
11.	ANNEXURE I – CONSENT FORM	
12.	ANNEXURE II – PROFORMA	
14.	ANNEXURE III – PHOTOGRAPHS	
15	ANNEXURE IV- MASTER CHART	
16	ANNEXURE V- KEY TO MASTER CHART	

LIST OF TABLES

TABLE NO.	DESCRIPTION	PAGE NO.
1	Age distribution	
2	Gender distribution	
3	ASA distribution	
4	Type of surgery distribution	
5	Heart rate(bpm)- Comparison in two groups of patients studied prospectively	
6	Systolic blood pressure- Comparison in two groups of patients studied prospectively	
7	Diastolic blood pressure- Comparison in two groups of patients studied prospectively	
8	Mean arterial pressure- Comparison in two groups of patients studied prospectively	
9	Severity of Cough- Comparison in two groups of patients studied prospectively	
10	Post-operative sore throat- Comparison in two groups of patients studied prospectively	
11	Remarks- Comparison in two groups of patients studied prospectively	

LIST OF GRAPHS

GRAPH NO.	DESCRIPTION	PAGE NO.
1	Age distribution (years)	
2	Gender distribution	
3	ASA distribution	
4	Type of Surgery	
5A	Analysis of Heart rate with time interval	
5B	Analysis of Heart rate with time interval	
6A	Analysis of Systolic blood pressure with time interval	
6B	Analysis of Systolic blood pressure with time interval	
7A	Analysis of Diastolic blood pressure with time interval	

7B	Analysis of Diastolic blood pressure with time interval	
8A	Analysis of Mean arterial pressure with time interval	
8B	Analysis of Mean arterial pressure with time interval	
9 A-E	Grades of severity of cough post-extubation at different intervals	
10 A-E	Grades of severity of postoperative sore throat at different	
11	Distribution based on surgical procedures	

LIST OF FIGURES

FIGURE NO.	DESCRIPTION	PAGE NO.
1	Anatomy of Laryngeal Nerve supply A-P view	
2	Anatomy of Laryngeal Nerve supply Lateral view	
3	Diagrammatic representation of Voltage gated Sodium channel	
4	Principle and functioning of Ultrasonography	
5	Linear array probe	
6	Sono-anatomy of superior Laryngeal Nerve Block	

LIST OF PHOTOGRAPHS

FIGURE NO.	DESCRIPTION	PAGE NO.
1	2% LIGNOCAINE	
2	2% LIGNOCAINE, 100ml NS used for dilution and 5cc syringe	
3	USG image showing hyoid bone and greater cornua of hyoid	
4	Patient receiving superior laryngeal nerve block	
5	4% LIGNOCAINE	
6	4% LIGNOCAINE, 5cc syringe, In line nebulizer	
7	In line nebulizer attached to inspiratory limb of ventilator	
8	Patient receiving In-line nebulisation	

INTRODUCTION

A crucial stage in general anaesthesia is tracheal extubation. Significant physiological reactions are triggered by this process, including sympathetic discharge, which results in hemodynamic abnormalities like hypertension, tachycardia, and arrhythmias. These changes, albeit brief and erratic, increase the dangers for people who already have a medical history of hypertension or heart failure. Handling these difficulties is crucial to guarantee patient safety and maximize results. ⁽¹⁾⁽²⁾

Successful extubation indicates good breathing and the patient's ability to tolerate removal of the endotracheal tube. "Successful extubation" goes beyond this limitation and includes the absence of physiological consequences that could lead to adverse outcomes. This difference is important, especially because previous studies on successful extubation technique have focused mainly on critically ill patients receiving prolonged ventilation. ⁽¹⁰⁾

Sympathetic responses involve polysynaptic pathways in which the glossopharyngeal nerve and vagus nerve create afferent arcs through the brain and spinal cord to the sympathetic nervous system. This leads to stimulation of adrenergic mediators such as norepinephrine and epinephrine, resulting in increased heart rate and blood pressure. Parasympathetic reflexes are monosynaptic.

In order to combat these undesirable hemodynamic responses after extubation and provide smooth extubation, non-pharmacological methods as extubation under deeper plane of anaesthesia, exchange of ETT with placement of LMA, "No touch" extubation and pharmacological methods such as use of fentanyl,

preservative free lignocaine, beta-blockers like esmolol and labetalol, nitroglycerine, propofol, dexmedetomidine and remifentanyl has been extensively studied. ⁽⁷⁾⁽⁸⁾⁽⁹⁾

Superior laryngeal Nerve block (SLNB) is now commonly used for intubation and bronchoscopic maneuvers. ⁽⁶⁾ According to recent studies exploring SLNB as an option for prevention of postoperative sore throat, have concluded that SLNB could control the erratic hemodynamic changes and shorten the duration of extubation. ⁽³⁾

In-line nebulisation with local anaesthetics is another option to alleviate extubation stressor response. Nebulisation with Ropivacaine and Lignocaine are found to be useful during intubation, but there is a lack of information about nebulisation of local anaesthetics just before extubation. ⁽³⁾⁽⁴⁾⁽⁵⁾

The percentage of patients who experience postoperative sore throat, cough, and hoarseness varies greatly, from 6.6% to 91%. Apart from the property of maintaining the hemodynamic homeostasis during extubation, pre-extubation nebulisation and superior laryngeal nerve block can reduce the incidence of sore throat postoperatively. ⁽⁴⁾⁽⁵⁾

Hence in our study we compared the efficiency of Superior laryngeal Nerve block and in-line nebulisation of lignocaine for hemodynamic stress response, post-operative sore throat and cough.

OBJECTIVES

- **Primary objective** is to compare hemodynamic changes during extubation between the following groups: -
 - Superior laryngeal nerve block
 - In-line lignocaine nebulisation
- **Secondary objective** is to compare the severity of cough and post-operative sore throat between the above-mentioned groups.

REVIEW OF LITERATURE

Tracheal extubation stands as a pivotal phase in the continuum of general anesthesia, marking the transition from controlled sedation to the emergence of consciousness. This process initiates a cascade of physiological responses, prominently characterized by sympathetic discharge, which precipitates hemodynamic fluctuations, notably hypertension, tachycardia, and arrhythmias. While transient and unpredictable in nature, these alterations pose heightened risks, particularly for individuals with preexisting medical conditions such as hypertension or heart failure. Managing these complexities with precision and diligence is imperative to ensure patient safety and optimize clinical outcomes, underscoring the paramount importance of vigilant peri-extubation care. ⁽¹⁾⁽²⁾

In the study by Kashinath K. Jadhav et al., it has been concluded that Superior laryngeal nerve block with in-line lignocaine nebulization for awake extubation is effective in curbing the hemodynamic and respiratory responses of extubation. Moreover, no severe complications due to extubation were observed. It was found that there was significant reduction in systolic blood pressure at 5th minute and 10th minute after extubation which is supposed to be the crucial time for heightened stressor response, while significant heart rate reduction was found at 10th minute. Though combining both techniques have all the advantages mentioned above, they have serious disadvantages of aspiration risk if the patient is not on adequate nil per oral before surgery and cough reflex is completely abolished. The study stated that 57.1% of patients scored 3 on Modified Ramsay scoring scale (which means patients were drowsy but awake on arousal). ⁽³⁾

Mathur et al. concluded that Superior Laryngeal Nerve (SLN) Block exhibits superior hemodynamic stability, ease of intubation, and postoperative patient satisfaction compared to the group receiving lignocaine nebulization during awake intubation. However, there were no significant differences observed in postoperative sore throat and cough between the two groups. ⁽²³⁾

Zhipeng et al. suggested that SLN block outperforms nebulization with lignocaine and buprenorphine suspension in reducing postoperative sore throat and mean arterial pressure (MAP), although the reduction in MAP was not statistically significant, there was a noticeable decrease. This intervention was administered prior to the commencement of the procedure. ⁽²⁰⁾

In controlled trials conducted by Ahmed et al. and Bao et al., SLN block was compared with a control group, where the intervention was administered before the initiation of the procedure. The studies concluded that patients receiving SLN block experienced significantly alleviated intubation stressor responses compared to the control group. ⁽⁴⁾⁽⁶⁾

In the trial comparing ultrasound guided airway block and nebulisation with lignocaine for awake fiberoptic intubation in case of difficult airway, where primary objective was to assess the time taken for intubation while secondary objective assessed the hemodynamic responses which was not statistically significant within the two group. ⁽³¹⁾

Randomised control trail that determined the efficiency of lignocaine nebulisation for alleviating intubation stressor response amongst pregnant patient with pre-eclampsia undergoing general anaesthesia for Caesarean section, systolic blood pressures were significantly lower at time interval of

1st, 3rd, 5th and 10th minute after intubation while the heart being significant at 1st and 3rd minute when compared with the control group, the sample size of this study being 101 with 50 and 51 in each group. ⁽³⁰⁾

In a study conducted by Gaidhankar et al., medications were administered 15 minutes before the conclusion of the surgery. Inhalational agents and nitrous oxide were gradually tapered off, and upon the adequate return of spontaneous respiratory efforts, patients in Group D received a dose of Dexmedetomidine at 0.5 µg/kg, while those in Group L received intravenous lignocaine at a dose of 1.5 mg/kg. Dexmedetomidine exhibited superiority over lignocaine in terms of hemodynamic stability following extubation. However, it induced significant sedation in patients ⁽¹⁾

Luthra et al. recommended administering dexmedetomidine at 0.5 µg/kg diluted to 10 ml before initiating the infusion, over a 10-minute period at the commencement of dural closure. Infusion rates of 0.2 and 0.4 mcg/kg were initiated at 4 ml/hour. Although there were no significant differences in hemodynamic parameters between the two groups, emergence from anesthesia was delayed in the 0.4 mcg/kg group ⁽²⁾

Amutharani et al. concluded that dexmedetomidine, when compared to fentanyl, resulted in a significant reduction in both systolic and diastolic pressures. However, patients in the dexmedetomidine group experienced profound bradycardia. Sedation scores did not significantly differ between the two groups ⁽¹⁸⁾

Zhao et al. proposed continuous infusion of Remifentanil at different doses along with a single dose of parecoxib until extubation criteria were met. The study revealed that increased Remifentanil doses led to delayed emergence, respiratory depression, and reduced postoperative cough. The study population underwent total intravenous anesthesia using a combination of propofol and remifentanil ⁽¹⁹⁾

In a comparative study by Nagrale MH et al., it was observed that while lignocaine, propofol, or esmolol improved the quality of extubation, propofol and esmolol were most effective in controlling stressor responses. Propofol induced significant sedation compared to other drugs, while esmolol emerged as an ideal choice ⁽⁷⁾

Another multi-drug comparative study, which included lignocaine, labetalol, and fentanyl, found that heart stability was significant with fentanyl and lignocaine. However, fentanyl induced significantly higher sedation scores, making labetalol a preferable option ⁽⁸⁾

Chungsamarnyart et al. concluded that a combination of propofol and ketamine reduced the incidence of postoperative cough and laryngospasm more effectively than propofol alone ⁽⁹⁾

In three separate studies, different doses and methods of administering nitroglycerin were evaluated for their effectiveness in attenuating the pressor response during intubation. The first study by Indira Kumari et al. in 2016 involved 90 ASA I and II patients undergoing surgeries under general

anesthesia. Patients were randomized into three groups: Group C (control), Group N1 (1 puff of NTG spray), and Group N2 (2 puffs of NTG spray) administered one minute before intubation. Both doses of nitroglycerin effectively attenuated the pressor response in normotensive patients.

The second study by Mona Panchal and Upasana Bhatia compared two doses of intranasal nitroglycerin spray (400 mcg and 800 mcg) administered two minutes before laryngoscopy and intubation in 50 ASA I and II patients. The study found that 400 mcg effectively attenuated the pressor response, while 800 mcg did not provide additional benefit. In the third study by V. Madhuri Gopal in 2017, 60 ASA I and II patients received either oropharyngeal lignocaine spray or oral nitroglycerin spray before induction. Nitroglycerin spray was found to be superior in attenuating the pressor response compared to lignocaine spray during laryngoscopy and intubation. [\(26\)\(27\)](#)

In Safavi, Honarmand, and Azavi's 2011 study, 120 patients undergoing elective cesarean section were divided into three groups: Nitroglycerin infusion (Group NTG), Sublingual Nifedipine (Group NIF), and Intravenous Hydralazine (Group H). The study concluded that Nitroglycerin infusion was most effective in attenuating the pressor response to tracheal intubation in severe preeclampsia. [\(25\)](#)

In studies where local anesthetics were administered via intramuscular injection and nebulization, effective reduction in hemodynamic stressor responses and postoperative cough was observed. Gao et al. found no significant difference between lignocaine and ropivacaine at the time of intubation. Both lignocaine and ropivacaine demonstrated efficacy in halting neural conduction and inhibiting airway reflexes triggered by contact with an endotracheal tube. Given that the discrepancy primarily lies in the duration

of topical anesthesia induced by each agent (approximately 45–60 minutes for lignocaine and over 2 hours for ropivacaine), there was no discernible difference between the two local anesthetic groups at the time of intubation, which typically occurred within 20 minutes of nebulization administration. Thangavelu et al. reported similar findings, although mean arterial pressure (MAP) and heart rate (HR) values during intubation were lower in the lignocaine group compared to the saline group, achieving only partial statistical significance with $P = 0.062$ and $P = 0.060$, respectively. Conversely, ropivacaine effectively attenuated the intubation response compared to saline ($P < 0.05$). There was no significant disparity between lignocaine and ropivacaine concerning intubation responses ($P = 0.998$ and $P = 0.986$ for HR and MAP, respectively). [\(5\)\(24\)](#)

In our study, we compared the effectiveness of ultrasound-guided superior laryngeal nerve block with lignocaine nebulization for managing extubation stress response, avoiding other drugs due to their potential for causing significant hemodynamic changes and cost considerations.

BASIC SCIENCE

ANATOMY

LARYNX NERVE SUPPLY

Motor and sensory innervation of larynx are from the two branches of vagal nerve- the superior laryngeal nerve and recurrent laryngeal nerve ⁽¹⁶⁾⁽¹⁷⁾

SUPERIOR LARYNGEAL NERVE

Superior laryngeal nerve originates from the inferior vagal ganglion, runs along the medial side of internal carotid and divides into internal and external branch at the level of superior horn of hyoid bone bilaterally.

- The external branch or external laryngeal nerve runs down the lateral wall of larynx, providing innervation to and penetrating the inferior constrictor of pharynx. Its pathway culminates by supplying the cricoid muscle
- Internal branch or internal laryngeal nerve, follows an anteroinferior course penetrating the thyrohyoid membrane. Primarily a sensory nerve fanning out its fibers throughout the laryngeal cavity till level above the vocal cord ⁽¹⁶⁾⁽¹⁷⁾

RECURRENT LARYNGEAL NERVE

The left recurrent laryngeal nerve originates within the thorax, while its counterpart, the right recurrent laryngeal nerve, arises in the root of the neck. Typically, both nerves ascend through the neck, following a path nestled between the esophagus and trachea. Upon reaching the larynx, they traverse beneath the margin of the inferior constrictor muscle. Along their journey, these nerves may adopt various routes relative to the lateral ligament of the thyroid gland. This ligament, which connects the thyroid gland to the trachea and lower

portion of the cricoid cartilage on each side, may see the nerves pass medial to, lateral to, or even through it

Sensory component is supplied to area below the vocal cord, while motor component innervates all intrinsic muscles of larynx except for cricothyroid (16)(17)

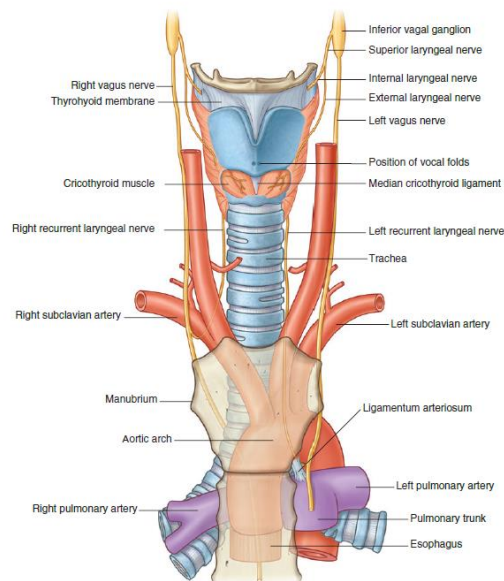


FIGURE 1: Anatomy of Laryngeal Nerve supply A-P view

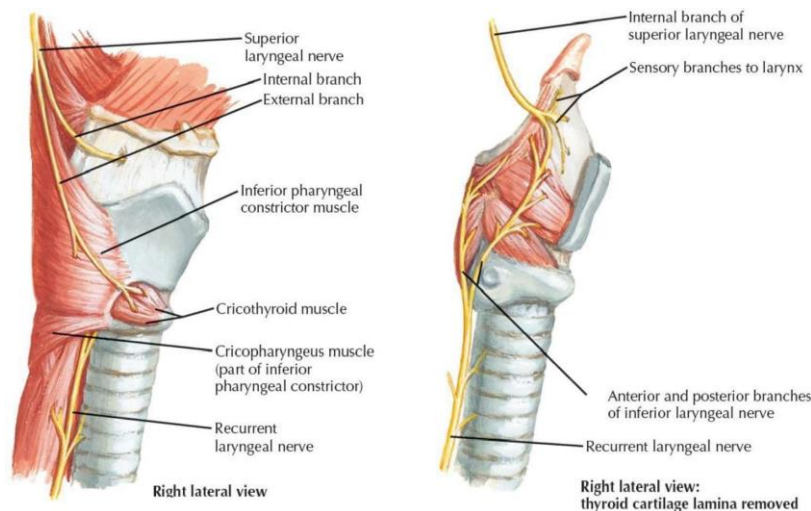


FIGURE 2: Anatomy of Laryngeal Nerve supply Lateral view

LOCAL ANAESTHETICS

Local anaesthetics encompass a diverse group of compounds that function by blocking voltage-gated sodium channels (VGSCs). Structurally, they share common features, including a hydrophobic aromatic group, an amide group, and an intermediary chain connecting them. This structural composition grants the molecule both hydrophobic and hydrophilic properties. ⁽¹⁴⁾

Classification of local anaesthetics often revolves around whether they are ester-linked or amide-linked, based on the type of intermediary chain. Additionally, they are further categorized into short-acting (e.g., chlorprocaine), intermediate-acting (e.g., mepivacaine, lidocaine), and long-acting (e.g., bupivacaine, ropivacaine) compounds. ⁽¹⁴⁾⁽¹⁵⁾

Metabolism of ester-linked local anaesthetics primarily occurs via plasma cholinesterases and tissue esterases, while amide-linked counterparts are predominantly metabolized in the liver through the mixed-function oxidase system. These compounds possess distinct physicochemical properties that dictate their mode of action, including the pKa value, lipophilicity, protein binding, and intrinsic vasoactivity. In the bloodstream, local anaesthetics bind to albumin and alpha-1-acidic glycoprotein (AAG), with the latter being an acute phase protein whose synthesis increases postoperatively and after trauma. This increase in AAG levels leads to decreased levels of free local anaesthetic, thereby mitigating systemic toxicity. ⁽¹⁴⁾⁽¹⁵⁾

Commonly used local anaesthetics typically follow the classic hydrophilic pathway, reaching the local anaesthetic binding site from the cytoplasmic compartment. However, some may also act via the lipid membrane (the “hydrophobic pathway”) or gain entry through large-pore channels (the “alternative hydrophilic pathway”). ⁽¹⁵⁾

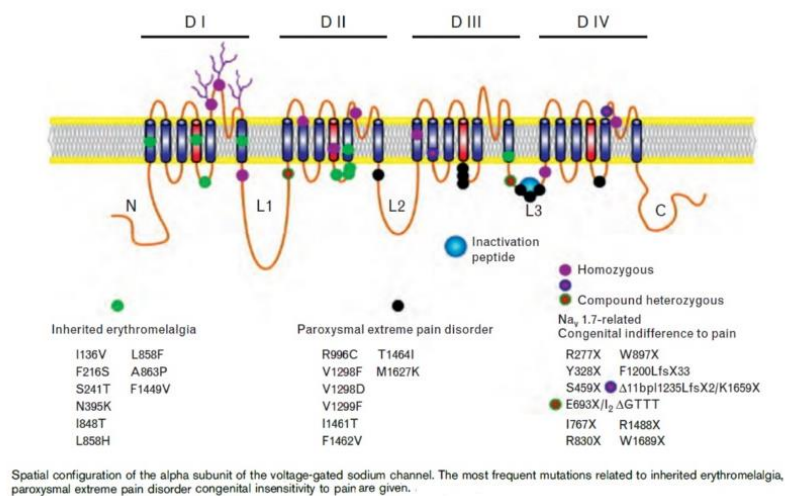


FIGURE 3: Diagrammatic representation of Voltage gated Sodium channel

LIGNOCAINE

Lignocaine, an intermediate-acting local anesthetic, is classified as an amide-linked compound. Being achiral, it possesses a singular molecular configuration.

Lignocaine binds to specific sites in voltage-gated sodium channel. They block sodium current causing a reduction in excitability of neuronal, cardiac or central nervous system tissue. There is intermission of nerve impulse transmission in the sodium ion passage through ion selective sodium channel in nerve membrane, due to which there is slow rate of depolarisation such that threshold potential is not reached and thus action potential is not achieved ⁽¹⁴⁾

This amide local anaesthetic has a rapid onset of action due to its high lipid solubility characteristics that hastens the process of drug getting diffused faster through the nerve sheath and get to the site of action. Duration of action solely depends on the protein binding ability; lignocaine has a duration of action of 60-120 minutes after infiltration ⁽²⁸⁾

Lignocaine being a weak alkaline amide with a pK value of 7.9 (just above normal physiological pH 7.4) action during acidosis environment as in case of sepsis is reduced. pH reflects the amount of ionised and unionised form of drug available at the action site. Intrinsic vasodilatory activity will also influence the potency and duration of action of drug [\(28\)](#)[\(29\)](#)

The principal metabolic pathway of lignocaine is oxidative dealkylation in liver to monoethylglycinexylidide followed by hydrolysis to metabolites of xylidide, the precursor having a property of protecting from cardiac dysrhythmias. 75% of the xylidides are excreted as urine. In case of hepatic disease half-life of drug might increase by five folds, hence caution to be taken during such condition [\(29\)](#)

Notably, it exhibits a significant anti-inflammatory effect by modulating various stages of the inflammatory process, including leucocyte adhesion, shape alteration, trans-endothelial migration, phagocytosis, and the release of inflammatory mediators. In vivo studies have demonstrated lignocaine's efficacy in attenuating inflammatory conditions such as reperfusion injuries in vital organs like the heart, lungs, and brain, as well as injuries induced by endotoxins or hyperoxia in the lungs.

ULTRASONOGRAPHY

Ultrasonography operates by emitting high-frequency ultrasound waves, which subsequently bounce off tissues within the body, generating echoes. Among the primary modalities of ultrasonic imaging, B-mode (brightness mode) stands as the foundation. B-mode imaging furnishes physicians with a two-dimensional portrayal of anatomical structures, showcasing various grayscale changes. Regions containing fluid appear dark or hypoechoic due to their adeptness in transmitting ultrasound waves. Conversely, dense structures like bone reflect the

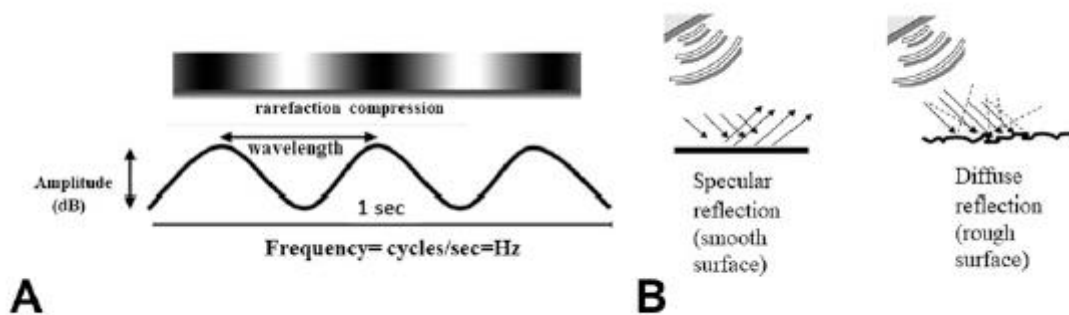


FIGURE 4: Principle and functioning of Ultrasonography

majority of the waves, resulting in a bright or hyperechoic image, often accompanied by pronounced acoustic shadowing. By manipulating the position of the ultrasound probe, physicians can elucidate anatomical details and detect pathological findings by generating 1 mm-thin images in each plane. It serves as a valuable and indispensable diagnostic tool, offering physicians immediate, high-resolution insights into internal organs and pathology. ⁽¹¹⁾⁽¹²⁾

Ultrasound waves in the frequency range of around 2 to 15 megahertz have a wide range of diagnostic and treatment purpose in the field of medicine. The ultrasonography works on the principle of Piezoelectric effect. This effect converts mechanical / kinetic energy into electrical energy by deformation of crystals. Piezoelectric effect can also be reversed i.e., by electrical energy the crystals can be oscillated to form ultrasound waves (mechanical energy). ⁽¹²⁾⁽¹³⁾

TRANSDUCER:

This is the hand-held part of the ultrasound machine. It has the function of inter-converting the energies (electrical and mechanical) based on piezoelectric effect. They contain lead zirconate titanate crystals commonly.

It comprises 5 major components:

- Crystals: possessing piezoelectric property. Can be arranged in either linear or curvilinear manner.
- Electrodes: positive and ground. For electrical connection
- Damping block: to dampen stray sound waves.
- Matching layer: For proper transmission of sound waves to one or multiple tissues.
- Housing.

They produce the ultrasound waves in either linear(sequential) arrays or phased array. In our study we have used linear probe for superior laryngeal nerve block.

[\(13\)](#)

Linear Transducer:

- The piezoelectric crystals – Linearly arranged
- Produce rectangular ultrasound beam
- Used for superficial imaging.

- Footprint – wide with frequency of 2.5 – 12MHz at the centre in 2D imaging probe and frequency 7.5 – 12 MHz at the centre in 3D imaging probe.
- Applications of linear probe in anaesthesia:
 - Airway assessment
 - Visualisation of superficial structures like Brachial plexus
 - Vascular access
 - Vascular examination
 - Ultrasonic velocity change imaging. ([12](#))



FIGURE 5: Linear array probe

The structures to be identified are: -

- Hyoid bone
- Thyroid cartilage
- Thyrohyoid membrane
- Superior laryngeal artery
- Superior laryngeal nerve

Place the transducer probe in the sagittal plane to locate the greater cornu of the hyoid bone, then rotate it transversely to pinpoint the superior lateral aspect of the thyrohyoid membrane. Rotate the medial aspect of the probe cephalad to visualize the superior laryngeal nerve, which lies superficial to the thyrohyoid membrane. The internal branch of the superior laryngeal nerve runs alongside the superior laryngeal artery, just below the greater cornu of the hyoid bone. An alternative method involves identifying the hyperechoic hyoid bone in the midline and then visualizing the greater cornu and internal branch of the nerve by moving the probe laterally. Using an in-plane technique, insert a needle perpendicular to the skin just below the greater cornu of the hyoid bone and inject 1–2 mL of local anesthetic after ensuring negative aspiration.

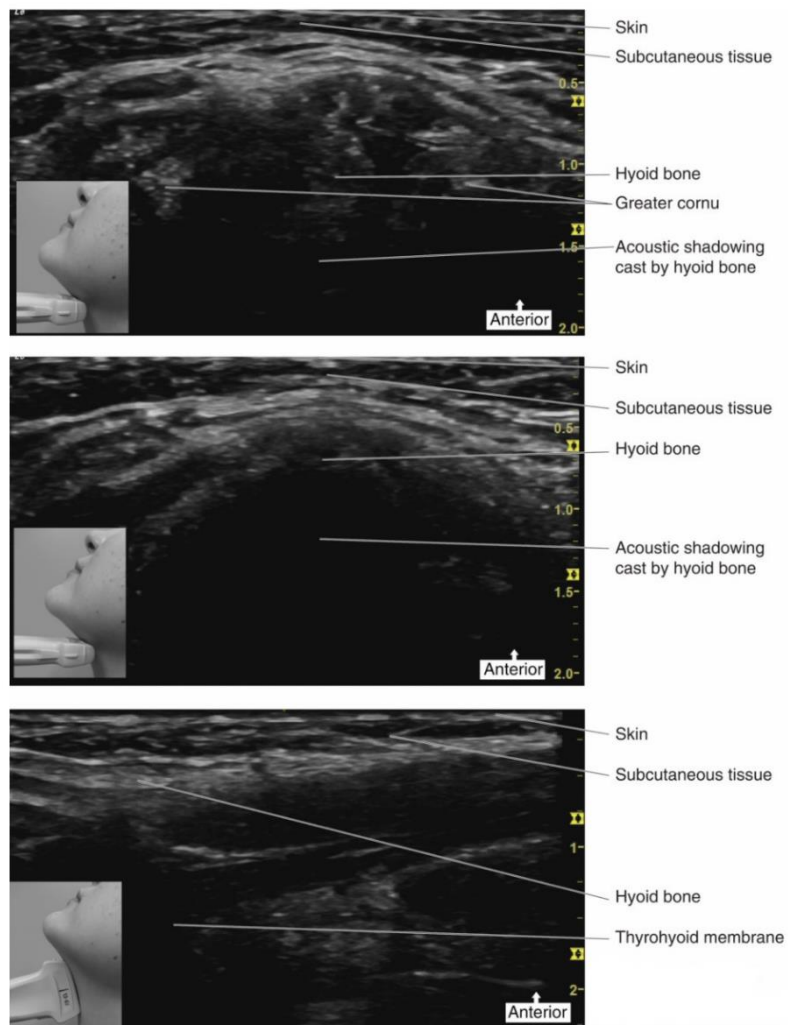


FIGURE 6: Sono-anatomy of superior Laryngeal Nerve Block

MATERIAL AND METHOD

STUDY DESIGN:

A One Year Hospital Based Randomized Control Trail

STUDY PERIOD:

One year (June 2022 – May 2023)

PLACE:

“Department of Anesthesiology, KLE’S Dr. Prabhakar Kore Hospital and Medical Research Centre, KAHER, Belagavi”.

SOURCE OF DATA:

Patients between age group of 18-60, ASA-I and II posted for elective surgery under general anaesthesia at KLE’S Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi -10.

SAMPLE SIZE:

A total of 100 patients (50 in each group who receive nebulization with lignocaine and superior laryngeal nerve block)

SAMPLING PROCEDURE:

The minimum sample size formula based on mean and standard deviation is

$$n = \frac{(z_{\alpha} + z_{\beta})^2 (s_1^2 + s_2^2)}{(\bar{X}_1 - \bar{X}_2)^2}$$

Where z_{α} is linked with the level of significance and z_{β} is linked with the power of the test. For 5% level of the significance $z_{\alpha} = 1.96$ and $z_{\beta} = 0.84$ for 80% power of the test.

Ref: Bao Y, Xiong J, Wang H, Zhang Y, Zhong Q, Wang G. Ultrasound-Guided Block of the Internal Branch of the Superior Laryngeal Nerve Reduces Postoperative Sore Throat Caused by Suspension Laryngoscopic Surgery: A Prospective Randomized Trial. *Front Surg.* 2022 Feb 15;9

The parameter considered in the calculation is HR at 5 minutes.

\bar{X}_1 is the mean of the first group (98.6) and \bar{X}_2 is the mean of the second group (90.0).

s_1 is the standard deviation of the first group (14.7) and s_2 is the standard deviation of the second group (12.3).

With these values the sample size obtained is 39.

To get confirmative results the sample size will be increased to 50

There will be two groups with 50 cases in each group.

SAMPLING TECHNIQUE:

Randomization was done by using www.randomizer.org which uses “Math.random” method within the JavaScript programming language as core method for generating its random number.

INCLUSION CRITERIA:

- Age 18-60years
- ASA Grade I and II
- Duration of surgery less than 3 hours

EXCLUSION CRITERIA:

- Emergency Surgeries
- Difficult Airway
- Head and Neck Surgeries
- Cervical spine abnormalities
- Airway anomalies

- Patient with risk for aspiration

ETHICAL CLEARANCE:

The approval by the institutional Ethical and Research Committee, Jawaharlal Nehru Medical College, Belagavi, was taken before starting the study.

INFORMED CONSENT:

All the patients who fulfilled the selection criteria were explained about the nature of the study and intervention being done. A written informed consent was obtained from all patients before enrolment in their vernacular language.

METHOD OF DATA COLLECTION:

After obtaining clearance & informed consent, the randomized controlled trial was carried out on patients posted for elective surgery under general anaesthesia, of the age group between 18 & 60 years, of either gender, with ASA I and II.

The day before surgery, after thorough pre-operative assessment patients were advised to be in overnight fasting and oral clear fluids were allowed till 6 hours prior to surgery. On the day of the procedure in the pre-op room, the nil per

mouth status was confirmed, vital parameters (pulse oximeter, NIBP & ECG) were measured and intravenous cannula was secured on the upper limb.

All patients were administered with aspiration prophylaxis, intravenous Pantoprazole 40 mg and intravenous Metoclopramide 10 mg as premedication. Baseline blood pressure and heart rate were noted as pre-operative readings.

After shifting the patient to operation theatre, standard monitoring was performed by continuously recording noninvasive blood pressure, electrocardiogram, saturation level, and end-tidal carbon dioxide (ETCO₂) level. In all patients, pre-medication with intravenous Glycopyrrolate 0.005 mg/kg, Midazolam 0.05 mg/kg, Fentanyl 2 µg/kg was administered, and general anesthesia was induced with intravenous Propofol 2 mg/kg along with Succinylcholine 2 mg/kg to facilitate tracheal intubation. Anesthesia was maintained with oxygen, nitrous oxide (with the ratio of 50:50), isoflurane (0.6%-1.0%), and Atracurium 0.5 mg/kg with positive pressure ventilation. Analgesia was provided in all patients with intravenous Paracetamol 15 mg/kg.

Patients were divided into two groups based on the randomization technique mentioned above:

- Group B – USG guided bilateral Superior Laryngeal Nerve block of the internal branch was performed.
- Group N – In-line nebulization with Lignocaine.

Towards the end of surgery, when skin closure began, the patients under Group N, underwent In-line nebulization with 5 ml of lignocaine 4%. After the reversal of neuromuscular blockade, and once all the extubation criteria was met patient being fully awake, extubation was performed following proper suctioning of the oropharynx

In Group B, patients underwent Bilateral Superior Laryngeal nerve block on each side under ultrasound guidance, with 2 ml of 1% Lignocaine injected on each side. After the reversal of neuromuscular blockade, and once all the extubation criteria was met patient being fully awake, extubation was performed following proper suctioning of the oropharynx

The hemodynamic parameters such as heart rate and blood pressure (systolic blood pressure, diastolic blood pressure and mean arterial blood pressure) were noted at intervals of pre-extubation, 1st minute, 5th minute and 10th minute. Post-extubation patient was assessed for postoperative sore throat and cough at immediately, 10th minute, 1st hour, 6th hour and 24th hour after extubation

STATISTICAL ANALYSIS:

In this study, both descriptive and inferential statistical analyses were conducted. Continuous data are shown as Mean \pm SD (Min-Max), while categorical data are presented as Number (%). Statistical significance was evaluated at the 5% level. The following assumptions were made:

- 1) Dependent variables are normally distributed
- 2) Samples drawn from the population are random, and
- 3) Cases within the samples are independent

The Student's t-test (two-tailed, independent) was employed to determine the significance of study parameters on a continuous scale between two groups (inter-group analysis). Levene's test for homogeneity of variance was conducted to evaluate the consistency of variance. The t-test, a statistical method used to compare the means of two groups, is commonly applied in hypothesis testing. It helps determine whether a process or treatment has a significant effect on the population or if there is a difference between two groups. The null hypothesis (H_0) posits that the true difference between the group means is zero, while the alternative hypothesis (H_a) suggests that the true difference is not zero.

The Chi-square test or Fisher Exact test was utilized to determine the significance of study parameters on a categorical scale between two or more groups, suitable for non-parametric qualitative data analysis. The Fisher Exact test was specifically employed when sample sizes were very small.

Significant figures

+ Suggestive significance (P value: $0.05 < P < 0.10$)

* Moderately significant (P value: $0.01 < P \leq 0.05$)

** Strongly significant (P value : $P \leq 0.01$)

Statistical software: The Statistical software namely SPSS 22.0, and R environment ver.3.2.2 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

RESULTS

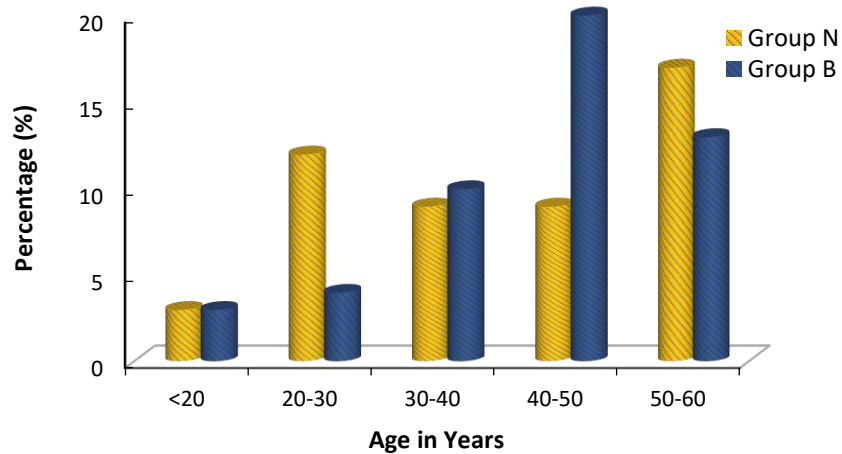
This study titled “Awake Extubation Response: Comparison of Superior Laryngeal Nerve Block and In Line Nebulisation with Lignocaine- A Randomised Controlled Trial” was conducted in the Department of Anaesthesiology, Jawaharlal Nehru Medical College, KAHER, Belagavi from June 2022 to May 2023. 100 patients were enrolled in the study after having met inclusion criteria. Written informed consent in the vernacular language was taken from the patients. Patients were randomized into two groups consisting of 50 patients in each group using computer generated randomization table.

The data was tabulated on Microsoft Excel which was represented as Mean and Standard for all sets of data. Students’ “t” test has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameter. “Chi-square/ Fisher Exact test” has been used to find the significance of study parameters on categorical scale between two or more groups. Software: The statistical software namely “SPSS 22.0, and R environment ver.3.2.2” was used for data analysis and graphs and tables were generated using Microsoft Excel and Word.

Table 1: Age in Years- Frequency distribution in two groups of patients studied

Age in years	Group N	Group B	Total
<20	3	3	6(6%)
20-30	12	4	16(16%)
30-40	9	10	19(19%)
40-50	9	20	29(29%)
50-60	17	13	30(30%)
Total	50	50	100(100%)

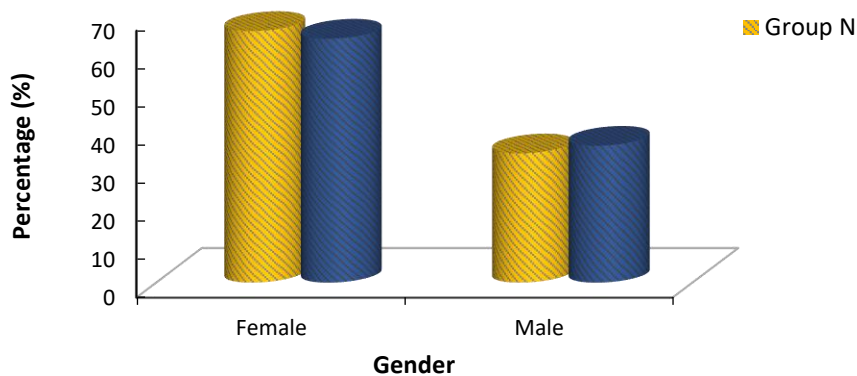
Samples are age matched with $P=0.5$, student t test



GRAPH 1: Age distribution ($P=0.5$, student t test)

Table 2: Gender- Frequency distribution in two groups of patients studied

Gender	Group N	Group B	Total
Female	39(78%)	29(58%)	68(68%)
Male	11(22%)	21(42%)	32(32%)
Total	50(100%)	50(100%)	100(100%)

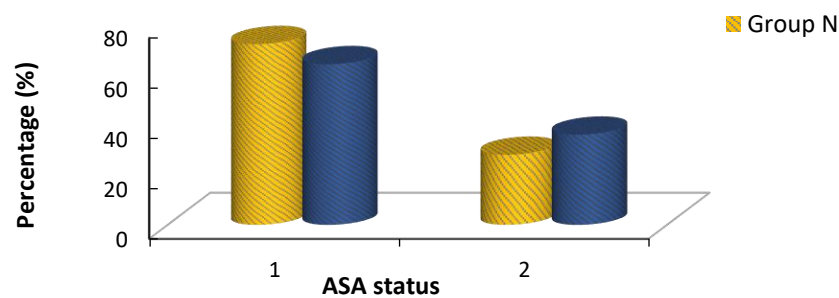


GRAPH 2: Gender distribution (P=0.501, Insignificant, Chi-Square Test)

Table 3: ASA status- Frequency distribution in two groups of patients studied

ASA status	Group N	Group B	Total
1	36(72%)	32(64%)	68(68%)
2	14(28%)	18(36%)	32(32%)
Total	50(100%)	50(100%)	100(100%)

P=0.521, Not Significant, Chi-Square Test

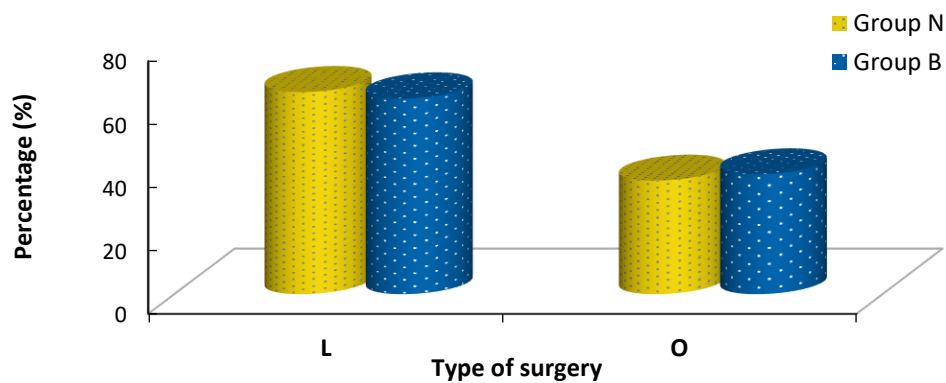


GRAPH 3: ASA distribution (P=0.521, Not Significant, Chi-Square Test)

Table 4: Type of surgery

Type of surgery	Group N	Group B	Total
L	32(64%)	31(62%)	63(63%)
O	18(36%)	19(38%)	37(37%)
Total	50(100%)	50(100%)	100(100%)

P=1.000, Not Significant, Chi-Square Test

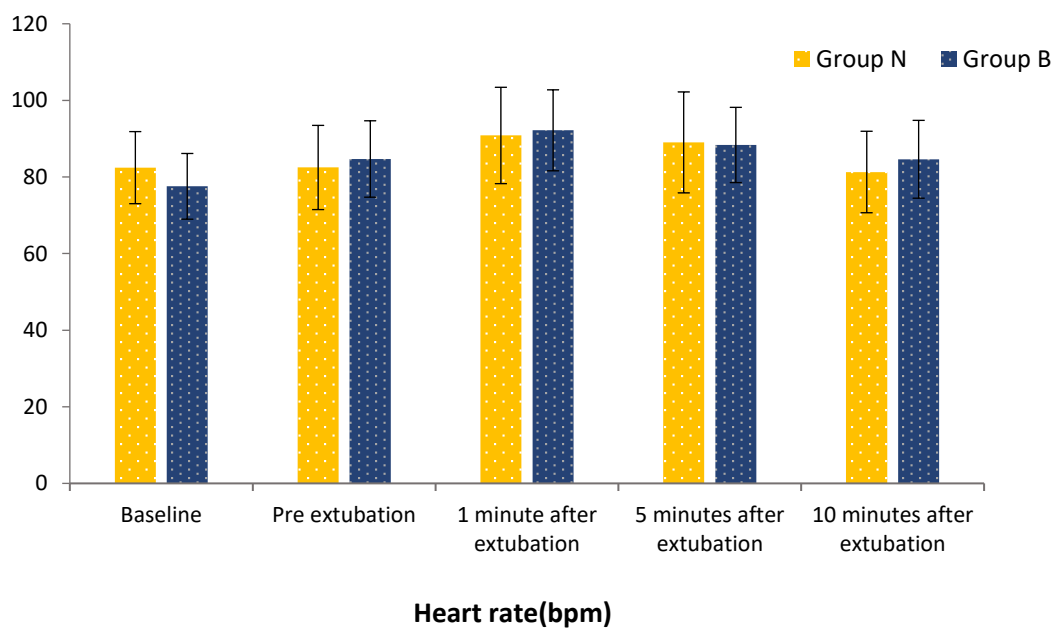


GRAPH 4: Type of surgery (P=1.000, Not Significant, Chi-Square Test)

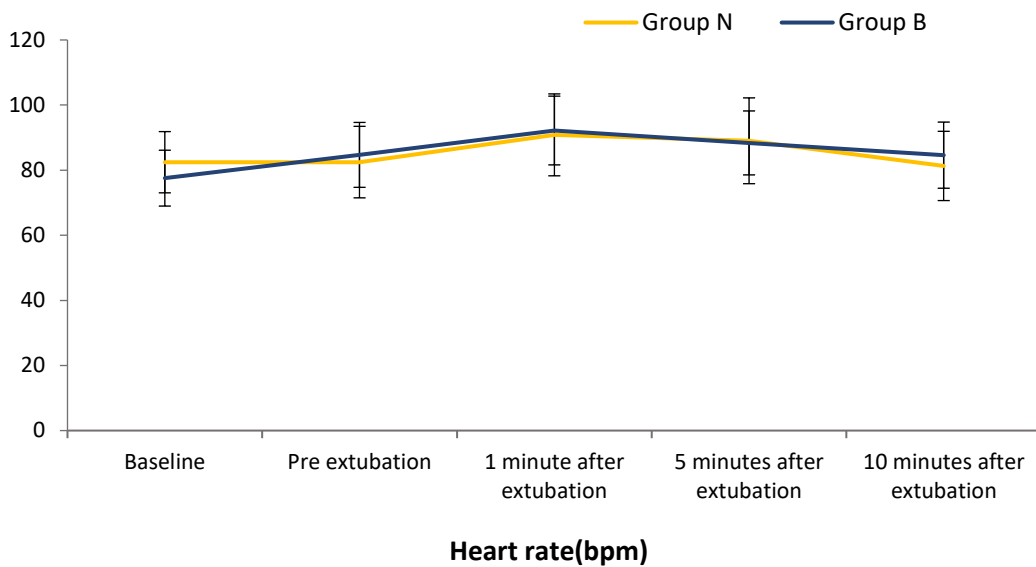
Demographic data were similar between the two groups, there no significant difference with respect to age, gender, type of surgery, ASA status and type of surgery.

Table 5: Heart rate(bpm)- Comparison in two groups of patients studied prospectively

Heart rate(bpm)	Group N (Mean±SD)	Group B (Mean±SD)	Total (Mean±SD)	P Value
Baseline	82.44±11.8	77.56±10.34	80±11.31	0.030*
Pre extubation	82.48±13.04	84.7±13.66	83.59±13.33	0.408
1 minute after extubation	90.84±16.7	92.18±14.45	91.51±15.55	0.669
5 minutes after extubation	89.02±14.78	88.36±13.05	88.69±13.88	0.813
10 minutes after extubation	81.3±10.24	84.62±11.11	82.96±10.76	0.124



GRAPH 5A: Analysis of Heart rate with time interval



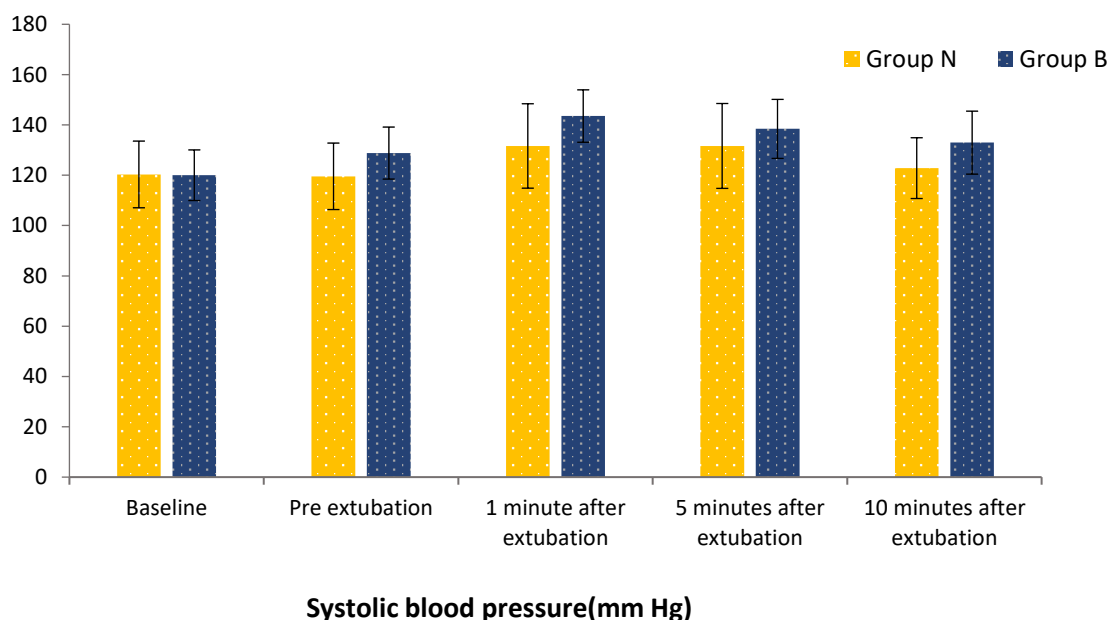
GRAPH 5B: Analysis of Heart rate with time interval

Mean values of heart rate were not significant during any time interval as shown in the above table. On comparing the heart rate between the two groups following inference were made.

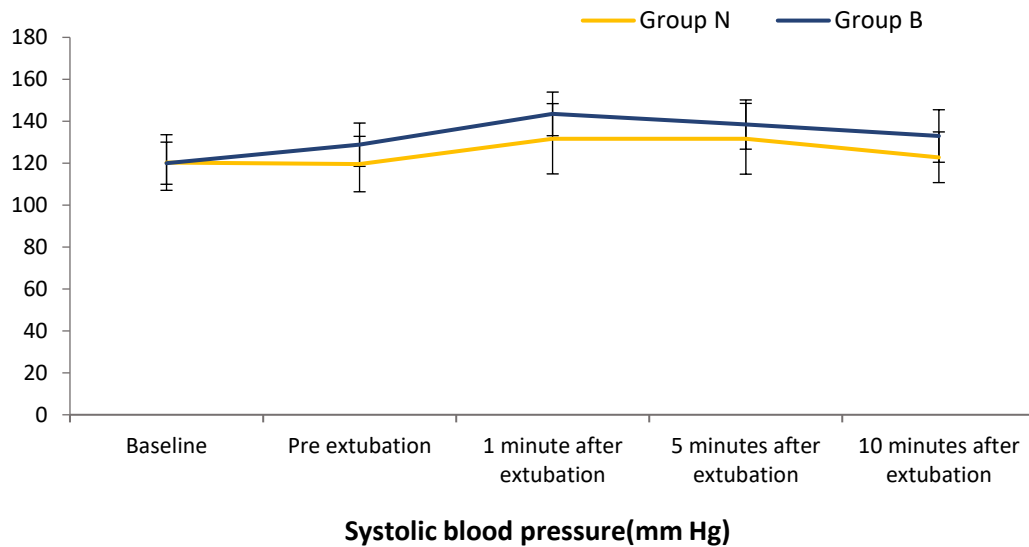
- Pre-extubation heart rate in Group N (82.48 ± 13.04) and Group B (84.7 ± 13.66) were insignificant with $p=0.408$
- After 1 minute of extubation in Group N was 90.84 ± 16.7 and Group B was 92.18 ± 14.45 with $p=0.669$
- 5th minute after extubation in Group N was 89.02 ± 14.78 and Group B was 88.36 ± 13.05 with $p=0.813$
- 10th minute after extubation in Group N was 81.3 ± 10.24 and Group B 84.62 ± 11.11 was with $p=0.124$

Table 6: Systolic blood pressure- Comparison in two groups of patients studied prospectively

Systolic blood pressure (mm Hg)	Group N (Mean±SD)	Group B (Mean±SD)	Total (Mean±SD)	P Value
Baseline	120.32±13.26	120±10.05	120.16±11.71	0.892
Pre extubation	119.58±13.22	128.82±10.34	124.2±12.69	<0.001**
1 minute after extubation	131.64±16.77	143.52±10.41	137.58±15.12	<0.001**
5 minutes after extubation	131.64±16.87	138.42±11.73	135.03±14.85	0.022*
10 minutes after extubation	122.82±12.08	132.96±12.52	127.89±13.26	<0.001**



GRAPH 6A: Analysis of Systolic blood pressure with time interval

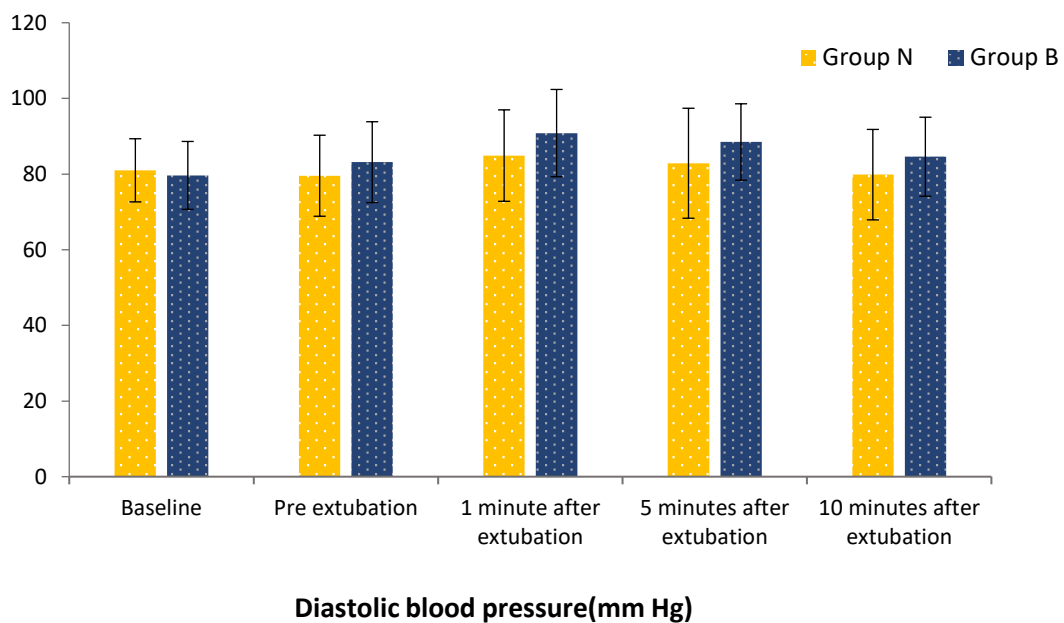


GRAPH 6B: Analysis of Systolic blood pressure with time interval

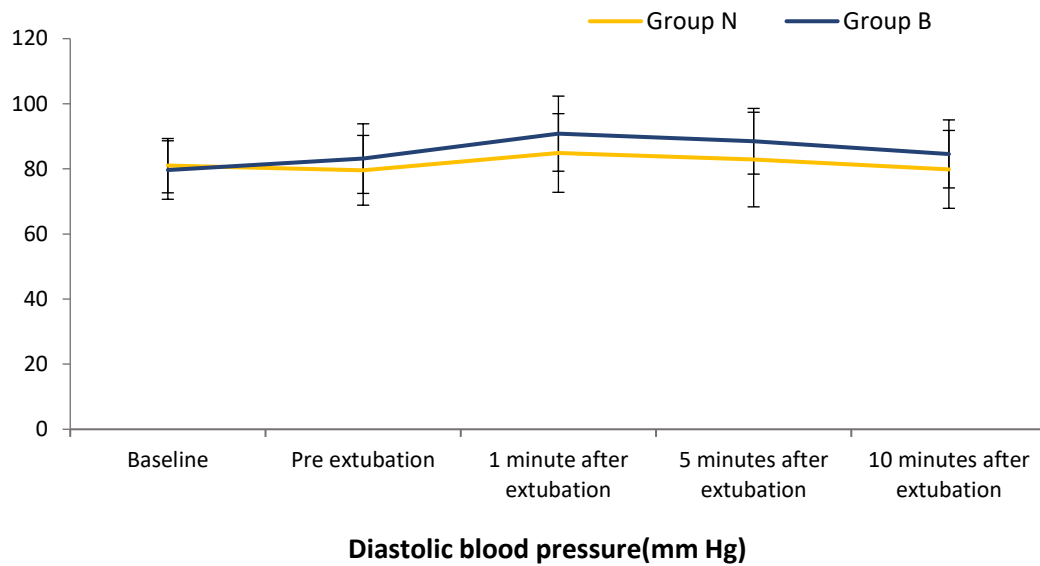
- Comparing the systolic blood pressure between the Group N and Group B baseline was insignificant with Group N (120.32 ± 13.26) and Group B (120 ± 10.05) ($p=0.892$)
- While values were significantly lower in Group N when compared with Group B during
 - Pre-extubation Group N (119.58 ± 13.22) and Group B (128.82 ± 10.34) with $p < 0.001^{**}$
 - 1st minute after extubation Group N (131.64 ± 16.77) and Group B (143.52 ± 10.41) with $p < 0.001^{**}$
 - 5th minute after extubation Group N (131.64 ± 16.87) and Group B (138.42 ± 11.73) with $p < 0.022^*$
 - 10th minute after extubation Group N (122.82 ± 12.08) and Group B (132.96 ± 12.52) with $p < 0.001^{**}$

Table 7: Diastolic blood pressure- Comparison in two groups of patients studied prospectively

Diastolic blood pressure (mm Hg)	Group N (Mean±SD)	Group B (Mean±SD)	Total (Mean±SD)	P Value
Baseline	80.98±8.35	79.64±8.98	80.31±8.65	0.441
Pre extubation	79.56±10.71	83.14±10.69	81.35±10.8	0.098+
1 minute after extubation	84.88±12.08	90.82±11.54	87.85±12.13	0.014*
5 minutes after extubation	82.86±14.54	88.48±10.09	85.67±12.77	0.027*
10 minutes after extubation	79.84±11.96	84.58±10.45	82.21±11.42	0.037*



GRAPH 7A: Analysis of Diastolic blood pressure with time interval

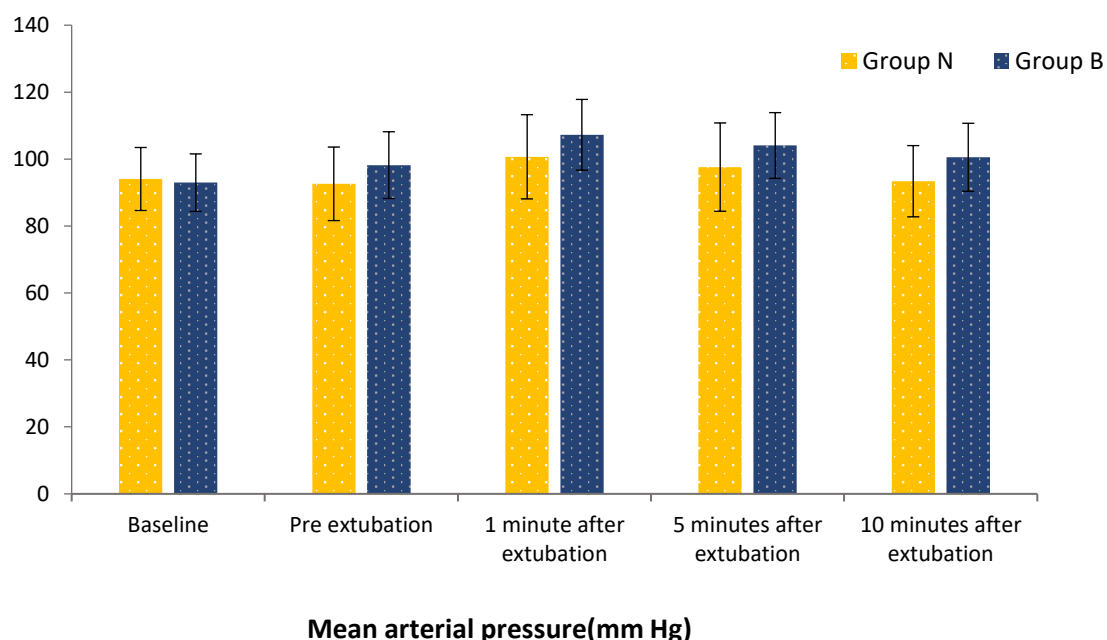


GRAPH 7B: Analysis of Diastolic blood pressure with time interval

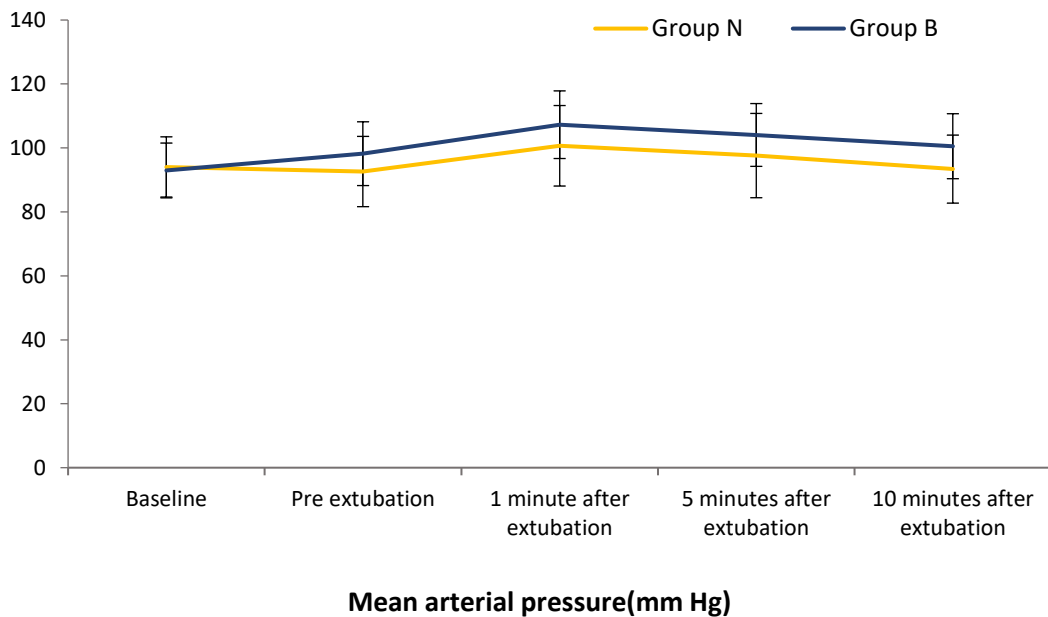
- In case of diastolic blood pressure between the Group N and Group B baseline with Group N (80.98 ± 8.35) and Group B (79.64 ± 8.98) ($p=0.441$)
- Pre-extubation Group N (79.56 ± 10.71) and Group B (83.14 ± 10.69) were insignificant
- While values were significantly lower in Group N during 1st minute after extubation (84.88 ± 12.08) when compared with Group B during 1st minute after extubation (90.82 ± 11.54) with p value 0.014*
- 5th minute after extubation Group N (82.86 ± 14.54) and Group B (88.48 ± 10.09) with $p < 0.027^*$
- 10th minute after extubation Group N (79.84 ± 11.96) and Group B (84.58 ± 10.45) with $p < 0.037^*$

Table 8: Mean arterial pressure- Comparison in two groups of patients studied prospectively

Mean arterial pressure (mm Hg)	Group N (Mean±SD)	Group B (Mean±SD)	Total (Mean±SD)	P Value
Baseline	94.06±9.41	92.96±8.58	93.51±8.98	0.543
Pre extubation	92.62±10.99	98.2±9.97	95.41±10.81	0.009**
1 minute after extubation	100.68±12.58	107.26±10.57	103.97±12.02	0.006**
5 minutes after extubation	97.61±13.18	104.06±9.82	100.87±11.99	0.007**
10 minutes after extubation	93.39±10.64	100.54±10.16	97±10.95	<0.001**



GRAPH 8A: Analysis of Mean arterial pressure with time interval



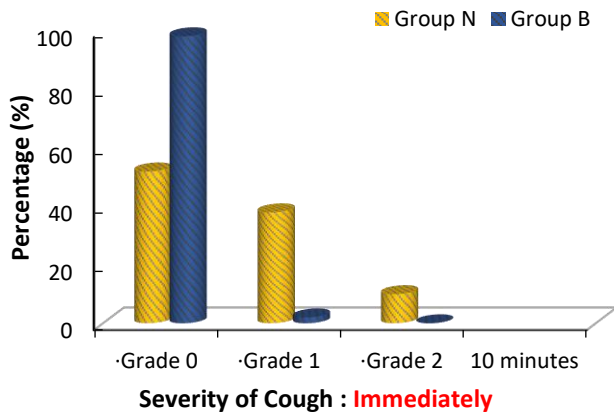
GRAPH 8B: Analysis of Mean arterial pressure with time interval

- Comparing Mean arterial pressure Group N and Group B baseline was insignificant with Group N (94.06 ± 9.41) and Group B (92.96 ± 8.58) ($p=0.543$)
- While values were significantly lower in Group N during pre-extubation (92.62 ± 10.99) when compared with Group B (98.2 ± 9.97) with $p > 0.009^{**}$
- 1st minute after extubation Group N (100.68 ± 12.58) and Group B (107.06 ± 10.57) with $p < 0.006^{**}$
- 5th minute after extubation Group N (97.61 ± 13.18) and Group B (104.06 ± 9.82) with $p < 0.007^{**}$
- 10th minute after extubation Group N (93.39 ± 10.64) and Group B (100.54 ± 10.16) with $p < 0.001^{**}$

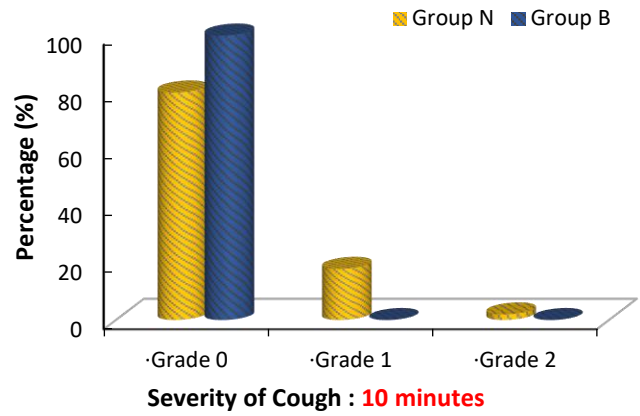
Table 9: Severity of Cough- Comparison in two groups of patients studied prospectively

Severity of Cough	Group N	Group B	Total	P Value
Immediately				
• Grade 0	26(52%)	49(98%)	75(75%)	<0.001**
• Grade 1	19(38%)	1(2%)	20(20%)	
• Grade 2	5(10%)	0(0%)	5(5%)	
10 minutes				
• Grade 0	40(80%)	50(100%)	90(90%)	<0.001**
• Grade 1	9(18%)	0(0%)	9(9%)	
• Grade 2	1(2%)	0(0%)	1(1%)	
1hour				
• Grade 0	49(98%)	50(100%)	99(99%)	1.000
• Grade 1	1(2%)	0(0%)	1(1%)	
• Grade 2	0(0%)	0(0%)	0(0%)	
6 hours				
• Grade 0	50(100%)	50(100%)	100(100%)	1.000
• Grade 1	0(0%)	0(0%)	0(0%)	
• Grade 2	0(0%)	0(0%)	0(0%)	
24hours				
• Grade 0	50(100%)	50(100%)	100(100%)	1.000
• Grade 1	0(0%)	0(0%)	0(0%)	
• Grade 2	0(0%)	0(0%)	0(0%)	
Total	50(100%)	50(100%)	100(100%)	

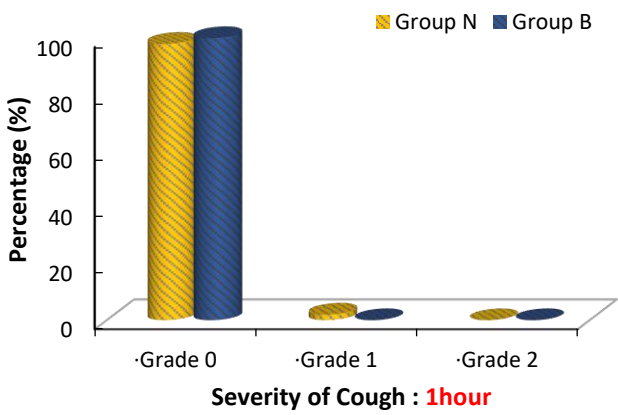
Chi-Square Test/Fisher Exact Test



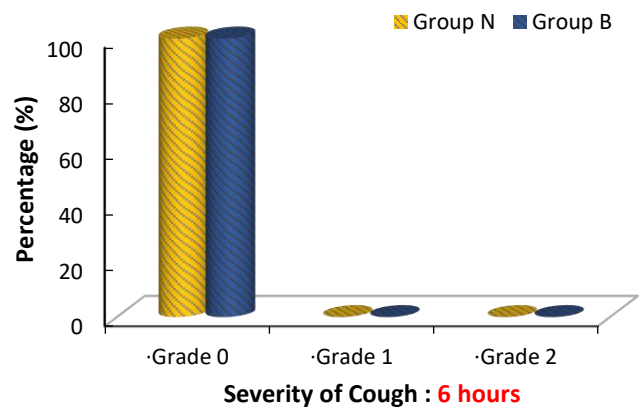
A



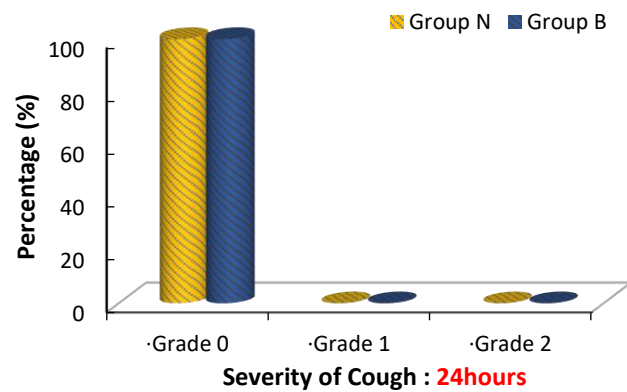
B



C



D



E

GRAPH 9 A-E: Grades of severity of cough postextubation at different intervals

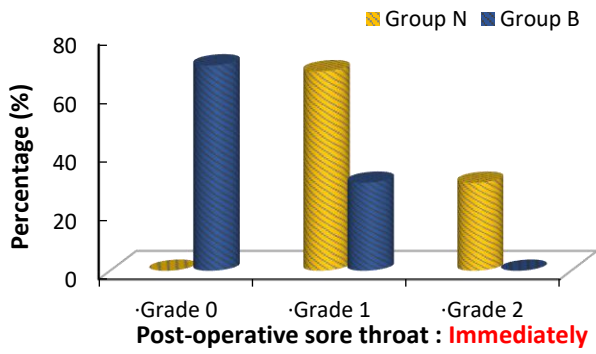
- Immediate post-extubation

- In Group N 52% of patients had no cough, 38% had grade 1 cough and 10% had grade 2 cough.
- Whereas in Group B 98% had no cough and 2% had grade 1 cough
- 10th Minute after extubation
 - In Group N 80% of patients had no cough, 18% had grade 1 cough and 2% had grade 2 cough.
 - In Group B all patients were recorded with no cough
- 1st hour after extubation
 - In Group N 98% of patients had no cough and 2% had grade 1 cough
 - In Group B all patients were recorded with no cough
- During 6th hour and 24th hour after extubation patients from both the groups recorded no cough
- The difference between the groups were significant at intervals of immediately and 10th minute post-extubation with $p < 0.001^{**}$

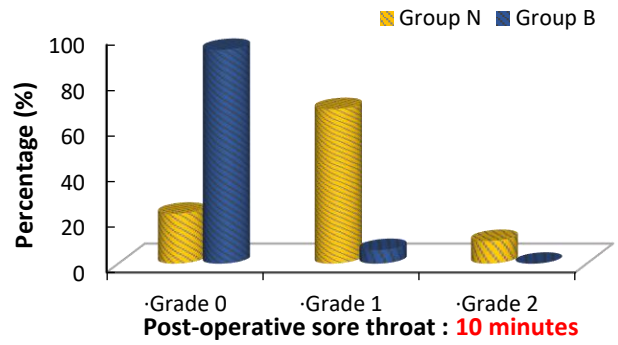
Table 10: Post-operative sore throat- Comparison in two groups of patients studied prospectively

Post-operative sore throat	Group N	Group B	Total	P Value
Immediately				
• Grade 0	0(0%)	35(70%)	35(70%)	<0.001**
• Grade 1	34(68%)	15(30%)	49(49%)	
• Grade 2	15(30%)	0(0%)	15(15%)	
10 minutes				
• Grade 0	11(22%)	47(94%)	58(58%)	<0.001**
• Grade 1	34(68%)	3(6%)	37(37%)	
• Grade 2	5(10%)	0(0%)	5(5%)	
1hour				
• Grade 0	30(60%)	50(100%)	80(80%)	<0.001**
• Grade 1	19(38%)	0(0%)	19(19%)	
• Grade 2	1(2%)	0(0%)	1(1%)	
6 hours				
• Grade 0	49(98%)	50(100%)	99(99%)	1.000
• Grade 1	1(2%)	0(0%)	1(1%)	
• Grade 2	0(0%)	0(0%)	0(0%)	
24hours				
• Grade 0	50(100%)	50(100%)	100(100%)	1.000
• Grade 1	0(0%)	0(0%)	0(0%)	
• Grade 2	0(0%)	0(0%)	0(0%)	
Total	50(100%)	50(100%)	100(100%)	

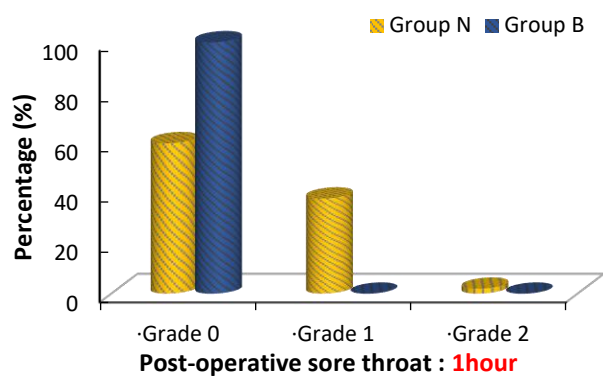
Chi-Square Test/Fisher Exact Test



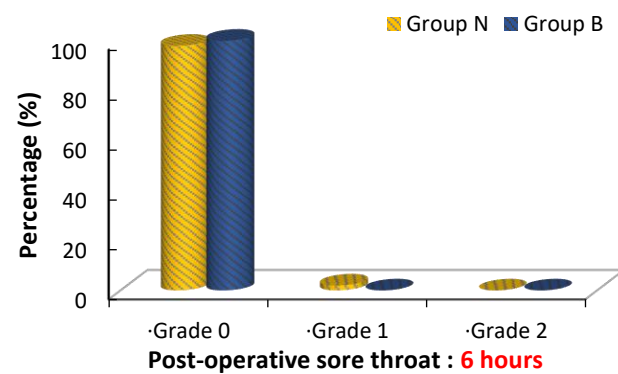
A



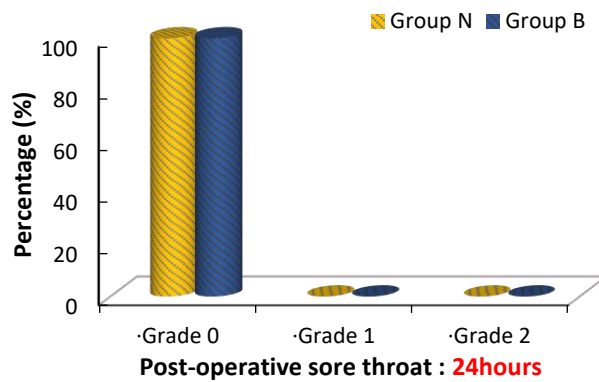
B



C



D



E

GRAPH 10 A-E: Grades of severity of postoperative sore throat at different intervals

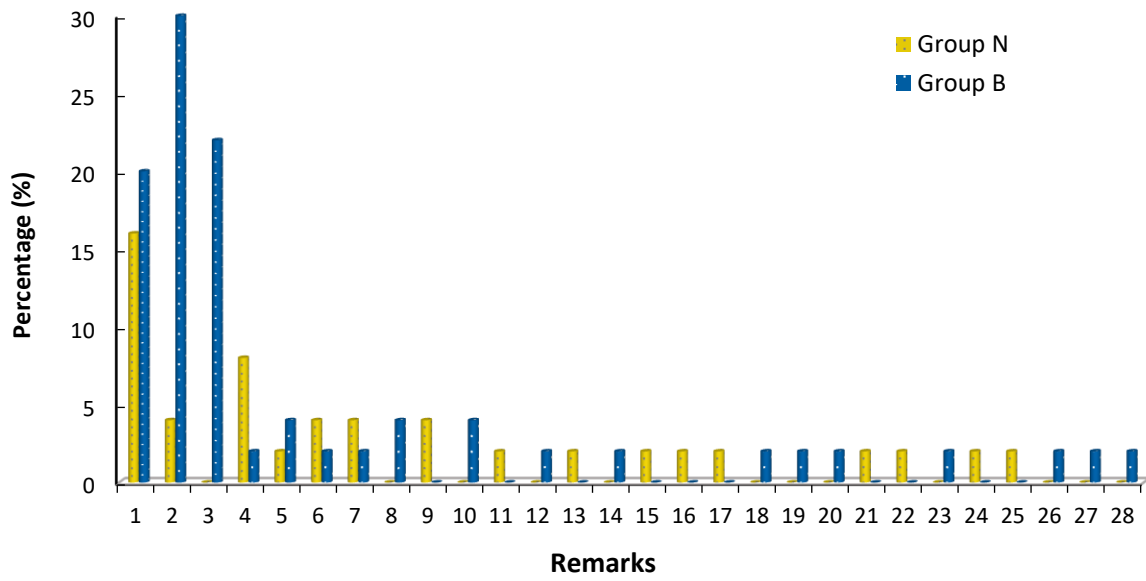
- Immediate post-extubation
 - In Group N 68% of patients were grade 1, 30% were grade 2 and 2% were grade 3 of sore throat
 - Whereas in Group B grade 0 was recorded in 70% and grade 1 was in 30% for sore throat
- 10th Minute after extubation
 - In Group N 22% of patients had no sore throat, 68% had grade 1 sore throat and 10% had grade 2 sore throat.
 - In Group B 94% of patients had no sore throat and 6% had grade 1 sore throat.
- 1st hour after extubation
 - In Group N 60% of patients had no sore throat, 38% had grade 1 and 2% had grade 2 sore throat
 - In Group B all patients were recorded with no sore throat
- 6th hour after extubation
 - In Group N 98% of patients had no sore throat and 2% had grade 1 sore throat
 - In Group B all patients were recorded with no sore throat
- During 24th hour after extubation patients from both the groups recorded no sore throat

- The difference between the groups were significant at intervals of immediately, 10th minute and 1st hour post-extubation with $p < 0.001^{**}$

Table 11: Remarks- Comparison in two groups of patients studied prospectively

Remarks	Group N	Group B	Total
EXCISION OF SWELLING (LIPOMA/SEBACEOUS CYST/LYMPH NODE)	8(16%)	10(20%)	18(18%)
DIAGNOSTIC LAPROSCOPY	2(4%)	15(30%)	17(17%)
LAPROSCPIC CHOLECYSTECTOMY	0(0%)	11(22%)	11(11%)
EXPLORATORY LAPROTOMY	4(8%)	1(2%)	5(5%)
BREAST LUMP	1(2%)	2(4%)	3(3%)
FIBROADENOMA	2(4%)	1(2%)	3(3%)
UMBILICAL HERNIA	2(4%)	1(2%)	3(3%)
HERNIS REPAIR	0(0%)	2(4%)	2(2%)
PAIN IN ABDOMEN	2(4%)	0(0%)	2(2%)
SEBACEOUS CYST ON BACK	0(0%)	2(4%)	2(2%)
ACROMIO-CLAVICULAR JOINT DISLOCATION	1(2%)	0(0%)	1(1%)
CARCINOMA ANAL CANAL	0(0%)	1(2%)	1(1%)
HYSTERECTOMY	1(2%)	0(0%)	1(1%)
DUCT ECTASIA	0(0%)	1(2%)	1(1%)
LEFT ADNEXAL CYST	1(2%)	0(0%)	1(1%)
LUMPECTOMY	1(2%)	0(0%)	1(1%)
MULTIPLE LIPOMA	1(2%)	0(0%)	1(1%)

PANCREATIC PSUEDOCYST WITH CHRONIC CALCIFIED PANCREATITIS	0(0%)	1(2%)	1(1%)
PAROTID SWELLING	0(0%)	1(2%)	1(1%)
BREAST FOLLICULLITIS	0(0%)	1(2%)	1(1%)
CARCINOMA BREAST	1(2%)	0(0%)	1(1%)
MODIFIED RADCAL MASTECTOMY	1(2%)	0(0%)	1(1%)
RIGHT DUCTAL CARCINOMA OF BREAST	0(0%)	1(2%)	1(1%)
RIGHT SUPRASPINATUS TEAR	1(2%)	0(0%)	1(1%)
ARTHROSCOPY	1(2%)	0(0%)	1(1%)
RUPTURED APPENDICITIS LAPROSCOPY	0(0%)	1(2%)	1(1%)
PARAUMBILICAL HERNIA	0(0%)	1(2%)	1(1%)
SWELLING OVER RIGHT SHOULDER	0(0%)	1(2%)	1(1%)
Total	50(100%)	50(100%)	100(100%)



GRAPH 11: Distribution based on surgical procedures

The above table and graph show the distribution of cases between the two groups

DISCUSSION

This study demonstrates the efficiency of superior laryngeal nerve block and in-line nebulisation with lignocaine to ameliorate the stress response and incidence of post-operative cough and sore throat

Tracheal extubation is a critical phase in general anesthesia, often provoking significant physiological responses, such as sympathetic discharge, leading to hemodynamic issues like hypertension, tachycardia, and arrhythmias. ⁽¹⁾

In our study with parallelly distributed demography among the study groups, we had inferred comparing systolic, diastolic, and mean arterial pressures between Group N and Group B, baseline values were insignificant: systolic (Group N: 120.32 ± 13.26 , Group B: 120 ± 10.05 , $p=0.892$), diastolic (Group N: 80.98 ± 8.35 , Group B: 79.64 ± 8.98 , $p=0.441$), and mean arterial pressure (Group N: 94.06 ± 9.41 , Group B: 92.96 ± 8.58 , $p=0.543$).

However, during pre-extubation and at 1, 5, and 10 minutes post-extubation, Group N showed significantly lower values compared to Group B:

- systolic (pre-extubation: 119.58 ± 13.22 vs. 128.82 ± 10.34 ; 1st minute: 131.64 ± 16.77 vs. 143.52 ± 10.41 ; 5th minute: 131.64 ± 16.87 vs. 138.42 ± 11.73 ; 10th minute: 122.82 ± 12.08 vs. 132.96 ± 12.52),

- diastolic (1st minute: 84.88 ± 12.08 vs. 90.82 ± 11.54 ; 5th minute: 82.86 ± 14.54 vs. 88.48 ± 10.09 ; 10th minute: 79.84 ± 11.96 vs. 84.58 ± 10.45), and
- mean arterial pressure (pre-extubation: 92.62 ± 10.99 vs. 98.2 ± 9.97 ; 1st minute: 100.68 ± 12.58 vs. 107.26 ± 10.57 ; 5th minute: 97.61 ± 13.18 vs. 104.06 ± 9.82 ; 10th minute: 93.39 ± 10.64 vs. 100.54 ± 10.16).

Though the difference in SBP, DBP and MAP of blood pressure were $\leq 20\%$ between the two groups, there was significant varying degree exhibited across different points of time, in case of

- systolic blood pressures during pre-extubation, Group B showed a 7.73% higher systolic pressure compared to Group N, followed by a further 9.02% increase one minute after extubation. However, at 5 minutes post-extubation, the percentage difference reduced to 5.15%, then slightly increased again to 8.26% by the 10-minute mark.
- In case of diastolic pressures that demonstrated pre-extubation, Group B had a 4.31% higher diastolic pressure compared to Group N, which escalated to 6.54% one minute after extubation. Subsequently, at 5 minutes post-extubation, the percentage difference remained relatively high at 6.35%, before slightly decreasing to 5.60% by the 10-minute mark.

- Meanwhile, mean arterial pressures showed consistent increments between Group B and Group N across the time points. Pre-extubation, there was a 6.03% difference between the two groups, which slightly increased to 6.53% one minute after extubation. At 5 minutes post-extubation, the percentage difference remained stable at 6.62%, then slightly heightened to 7.65% by the 10-minute mark. These fluctuations in systolic, diastolic, and mean arterial pressures reflect the dynamic physiological responses between the two groups during and after extubation.

On comparing the heart rate variability between the groups between Group B and Group N revealed subtle differences in their values at different time points following extubation. Pre-extubation, Group B exhibited a slightly higher value, with a percentage difference of 2.69%. One minute after extubation, this difference reduced to 1.47%, indicating a closer alignment between the two groups. At 5 minutes post-extubation, Group N showed a slightly higher value, albeit with a minimal percentage difference of 0.74%.

However, at the 10-minute mark, Group B displayed a more pronounced difference of 4.09%, suggesting a divergence in responses between the two groups over time but these differences were not statistically significant.

In case of post-operative cough and sore throat assessment the difference between the two groups were significant during the intervals of immediately and 10th minute after extubation for post-operative cough and intervals of immediately, 10th minute and 1st hour after extubation for post-operative sore throat but the action mitigating the undesired effect was high, which was equivalent to the findings by Bao et al. and Nabil et al., [\(4\)\(5\)\(30\)](#)

The data from our study were synonymous to finding by Jadhav et al., but the difference was that they had combined the two interventions (USG guided superior laryngeal nerve block and in-line nebulisation with lignocaine) one group and compared with control (nil intervention). [\(3\)](#) Our study was focused on determine the individual effect of these intervention.

Our study outcomes echoed those of trials employing vasodilator drugs like labetalol, [\(8\)](#) nifedipine, esmolol, [\(7\)](#) and nitroglycerine, [\(25\)](#) alongside sedative agents such as dexmedetomidine, clonidine, [\(35\)](#) and propofol, [\(7\)](#) as well as analgesics like remifentanil [\(19\)](#) and fentanyl [\(18\)](#). These findings collectively demonstrate the efficacy of these interventions in managing the stressor response during extubation. Though these drugs were parallel in containing the stressor responses they either had side effects such as sedation or did not address the problem of postoperative sore throat and analgesia.

On contrary to our study there was an unparallel inference made by Zhipeng et al., where they have concluded superior laryngeal nerve block was superior in maintaining hemodynamic stressor than nebulisation with lignocaine. ⁽²⁰⁾

The larynx, rich in sensory nerves, triggers reflexes upon mechanical stimulation. Endotracheal intubation and extubation that requires manipulation of laryngeal mucosa may cause transient yet potentially dangerous hemodynamic reactions, especially in patients with cardiovascular or cerebrovascular conditions. ⁽³²⁾ Blocking the nerve impulse transmission using local anaesthetics can mitigate hemodynamic responses and catecholamine release during direct laryngoscopy. ⁽³⁴⁾ Additionally, superior laryngeal nerve blocks are effective in treating neurogenic cough, highlighting the nerve's key role in laryngeal sensory innervation. ⁽³³⁾ Paltura et al. showed that aerosolized lidocaine can inhibit the sympathetic reflex and block the superior laryngeal nerve, thereby effectively improving hemodynamics. ⁽³⁵⁾

Limitations of our study includes, firstly even though the superior laryngeal nerve block being safe, just anaesthetising the supraglottic area there can risk of aspiration and it is mandatory to pre-medicate patients with anti-emetics and strict nil by mouth period of 8 hours pre-operatively and 2 hours post-operatively for the effect of drug to come down and excludes patients with risk

of aspiration. Secondly the concentration and volume of drug administered to the patients were fixed rather than being tailored for individual patients. Thirdly the comparison was not done with a control group. Fourthly further evaluation with patients under ASA grade III and IV were not assessed, were in the need for controlling stressor response is mandate.

CONCLUSION

Our study was conducted to identify efficiency of USG guided Superior laryngeal nerve block and in-line nebulization with Lignocaine for extubation stressor response, post-operative sore throat and cough. We concluded that

1. Hemodynamic stability (SBP,DBP and MAP) during extubation was significantly better in case of patients who received in-line nebulization with lignocaine than USG guided superior laryngeal nerve block
2. Post-operative sore throat and cough curbing efficiency was equal in both patients who received in-line nebulization with lignocaine and USG guided superior laryngeal nerve block

SUMMARY

The present study entitled **“AWAKE EXTUBATION RESPONSE: COMPARISON OF SUPERIOR LARYNGEAL NERVE BLOCK AND IN LINE NEBULISATION WITH LIGNOCAINE- A RANDOMISED CONTROLLED STUDY.”**

After obtaining clearance from hospital’s ethical committee, 100 patients of ASA I and II between age group 18-60 years were randomized to two groups having 50 patients in each Group.

Group N- Patients underwent In-line nebulization with 5 ml of lignocaine 4%.

Group B- Patients underwent ultrasonography guided superior laryngeal nerve block with 2 ml of 1% Lignocaine injected on each side

General anaesthesia was induced as per standard technique. Patients in each group were intervened with the procedure during the skin closure. HR, SBP, DBP and MAP were recorded in both the groups at intervals of pre-extubation, 1st minute, 5th minute and 10th minute. Patients were extubated once criteria for extubation were achieved. Post-extubation patient was assessed for postoperative cough and sore throat at immediately, 10th minute, 1st hour, 6th hour and 24th hour after extubation. The demographics were identical in both the groups.

We observed that SBP, DBP and MAP significantly reduced in Group N on comparison with Group B, while blood pressure parameters were $\leq 20\%$ in both the groups. There were no significant changes observed between the groups in case of HR. In terms of post-operative cough and sore throat both groups were comparable and efficient.

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CONSENT STATEMENT

I am making a voluntary decision to participate in the study “COMPARING EFFECT OF SUPERIOR LARYNGEAL NERVE BLOCK AND IN-LINE LIGNOCAINE NEBULISATION ON AWAKE EXTUBATION RESPONSE- A RANDOMISED CONTROLLED TRIAL”. My signature below indicates that I have decided to participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity to ask questions and that they have been answered to my satisfaction.

Name of the participant:

Signature or left thumb
impression of the participant

Name of the witness:

Signature or left thumb
impression of the witness

Name of the investigator

Signature of the investigator

PROFORMA

“AWAKE EXTUBATION RESPONSE: COMPARISON OF SUPERIOR LARYNGEAL NERVE BLOCK AND IN LINE NEBULISATION WITH LIGNOCAINE- A RANDOMISED CONTROLLED STUDY”

Group allotted :

Name :

Age:

Gender:

Weight:

Height :

Date of Examination:

Address:

Occupation :

Pre examination evaluation

Past History

- HTN DM IHD
Thyroid Disorder Respiratory Disorders
Others (Specify)
- H/o previous surgery/(s) where airway difficulty will be encountered.
Yes No

General physical examination

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

Musculoskeletal disorders:

Teeth :

Jaw movements:

Airway assessment:

Spine:

Investigations

Hb%:

Platelet Count :

TLC:

INR:

FBS:

Systemic examination:

CNS:

RS:

CVS:

GIT:

Preoperative physical status

American society of anesthesiologist

I II

Diagnosis:

Proposed surgery:

Monitors attached:

Pulse oximetry:

NIBP:

1. Hemodynamic Changes

Hemodynamic Parameters	Pre-extubation recordings	1 Min after extubation T1	5 Min after extubation T2	10 Min after extubation T3
SBP (mmHg)				
DBP (mmHg)				
MAP (mmHg)				
HR				

2. Post-operative sore throat and Severity of Cough

Time	Immediately	10mins	1hour	6 hours	24 hours
Post-operative sore throat					
Severity of Cough					

Signature of Guide

Signature of Consultant

Signature of Witness

SUPERIOR LARYNGEAL NERVE BLOCK

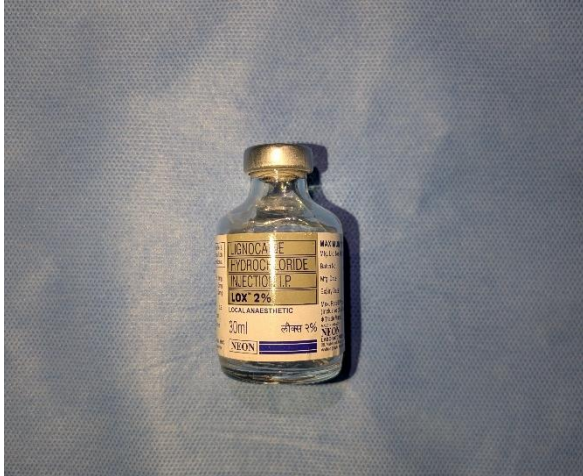


PHOTO 1: 2% LIGNOCAINE

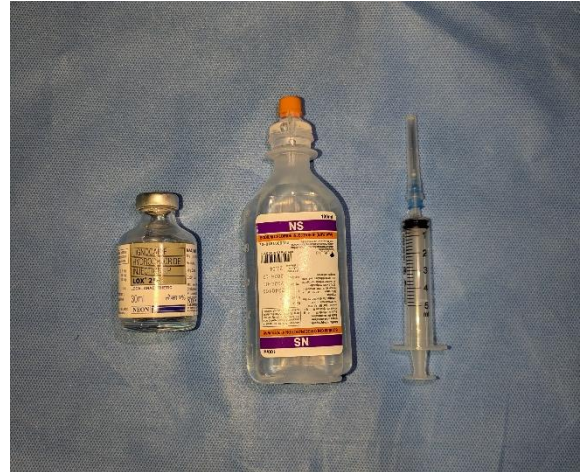


PHOTO 2: 2% LIGNOCAINE, 100ML NS USED FOR DILUTION, 5CCC SYRINGE



PHOTO 3: USG IMAGE SHOWING HYOID BONE AND GREATER CORNUA OF HYOID



PHOTO 4: PATIENT RECEIVING SUPERIOR LARYNGEAL NERVE BLOCK

IN LINE NEBULISATION

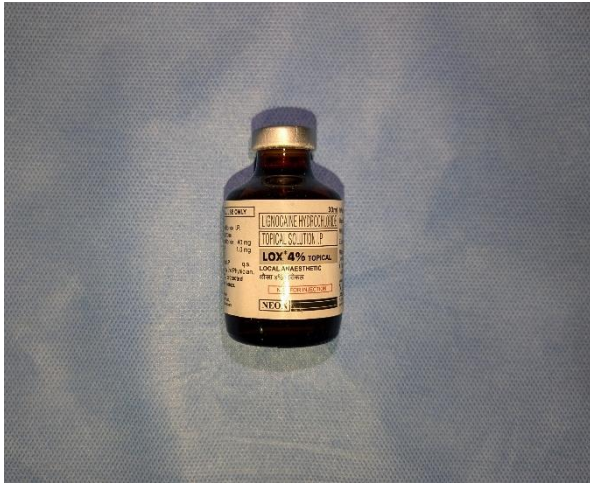


PHOTO 5: 4% LIGNOCAINE



PHOTO 6: 4% LIGNOCAINE, 5CC SYRINGE, IN LINE NEBULISER

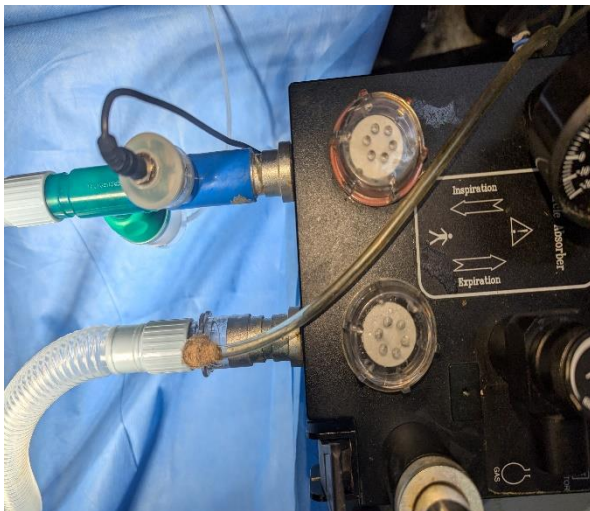


PHOTO 7: IN LINE NEBULISER ATTACHED TO INSPIRATORY LIMB OF VENTILATOR



PHOTO 8: PATIENT RECEIVING IN LINE NEBULISATION

***All values of systolic blood pressure, diastolic blood pressure and mean arterial pressure in millimeters of mercury (mmHg)*

***All values of heart rate are beats per minute (/bpm)*

L- Laproscopic surgery

O- Open type surgery

F- Female

M- Male

MPG- Mallampati Grading