

**“A PROSPECTIVE RANDOMIZED CONTROLLED STUDY
TO COMPARE APPLICATION OF BETAMETHASONE
GEL AND LIDOCAINE JELLY ON TRACHEAL
TUBE TO REDUCE POST OPERATIVE SORE THROAT,
COUGH AND HOARSENESS OF VOICE”**

201220015

*Submitted in Partial fulfilment of
Requirements for*

M.D.DEGREE EXAMINATION

BRANCH - X ANAESTHESIOLOGY

THE TAMILNADU DR. M.G.R MEDICAL UNIVERSITY

CHENNAI



INSTITUTE OF ANAESTHESIOLOGY AND CRITICAL CARE

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CHENNAI - 600003

APRIL - 2015

CERTIFICATE

This is to certify that the dissertation entitled “**A PROSPECTIVE RANDOMIZED CONTROLLED STUDY TO COMPARE APPLICATION OF BETAMETHASONE GEL AND LIDOCAINE JELLY ON TRACHEAL TUBE TO REDUCE POST OPERATIVE SORE THROAT, COUGH AND HOARSENESS OF VOICE**” is a bonafide work done by **Dr. STALIN.R**, Post Graduate Student, Institute of Anaesthesiology and Critical Care, Madras Medical College, Chennai-3, in partial fulfillment of the University Rules and Regulations for the award of MD Branch – X Anaesthesiology, under our guidance and supervision, during the academic year 2012 – 2015.

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ACKNOWLEDGEMENT

I am extremely thankful to **Dr.R.VIMALA, M.D.**, Dean, Madras Medical College & Rajiv Gandhi Govt General Hospital, for her permission to carry out this study.

I am immensely grateful to **Prof.Dr.B.KALA, M.D., D.A.**, Director and Professor, Institute of Anaesthesiology and Critical Care, for her concern and support in conducting this study.

I am extremely grateful and indebted to my guide **Prof.Dr.R.LAKSHMI, M.D., D.A.**, Professor of Anaesthesiology, Institute of Anaesthesiology and Critical Care, for her concern, inspiration, meticulous guidance, expert advice and constant encouragement in preparing this dissertation.

I am very grateful to express my sincere gratitude to the Professors, **Dr. ESTHER SUDHARSHINI RAJKUMAR, MD., DA,** **Dr.T.VENKATACHALAM MD., DA.,** **Dr.D.GANDHIMATHI., MD, DA.,** **Dr.SAMUEL PRABAKARAN, MD., DA,** and Institute of Anaesthesiology and Critical Care, for their constant motivation and valuable suggestions.

I am also thankful to my Assistant Professors **Dr.Suganthalakshmi, M.D.,** **Dr.Ganesh, M.D.,** and **Dr.Sivakanth, M.D.,** for their constant help and encouragement.

I am thankful to the Institutional Ethical Committee for their guidance and approval for this study.

I am thankful to all my colleagues and friends for their help and advice in carrying out this dissertation.

I am grateful to my family and friends for their moral support and encouragement.

Last but not the least, I thank all the patients for willingly submitting themselves for this study.

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LIST OF ABBREVIATIONS USED

ASA	-	American Society of Anaesthesiologists grading
ASTM	-	American Society for Testing and Materials
Cm	-	centimeter
ECG	-	Electrocardiogram
ETT	-	Endotracheal tube
G.A	-	General Anaesthesia
Hrs	-	Hours
ID	-	Internal Diameter
IV	-	Intravenous
Kg	-	Kilogram
mg	-	milligram
Min	-	Minutes
ml	-	Millilitre
N ₂ O	-	Nitrous oxide
PACU	-	Post Anaesthesia Care Unit
POSTCH	-	Post operative sore throat, cough and hoarseness
PVC	-	Poly Vinyl Chloride
SD	-	Standard Deviation

ABSTRACT

Back ground and objectives

Endotracheal intubation often gives way to airway mucosal traumatization resulting in post operative sore throat, cough and hoarseness of voice [POSTCH]. These are minor sequelae after extubation but very distressing to the patient. Many agents have been used on the endotracheal tube to reduce the occurrence of POSTCH with variable results. This randomized controlled study was conducted to compare the incidence of POSTCH with betamethasone gel and lidocaine jelly as a lubricant for tracheal tube insertion in patients undergoing general anesthesia.

Methods

This study was conducted on three hundred American Society of Anaesthesiologist [ASA] class I and II patients undergoing elective general, orthopaedic and ear a surgeries. They were divided equally into three groups. 100 patients [group-I], 100 patients [group II] and 100 control [group III]. The tracheal tubes for group I were lubricated with 0.05 % betamethasone gel, for group II lidocaine 2% jelly was used and for control

group III nothing was applied. A blinded anaesthesiologist interviewed all patients regarding POSTCH at 1,6,12 and 24 hours after surgery.

Results

The mean score for sore throat in group I was always lower than mean scores in group II and III at all the specified time intervals over the 24 hour evaluation period. The P value was < 0.05 over all the four evaluation periods and hence it was statistically significant. In addition, at 24 hours, the mean score was comparable between the groups II and III. As P value is > 0.05 , there was no statistically significant difference between group II and group III. The mean scores for cough was similar in group I and II at 1,6 and 24 hours. There was no statistically significant difference between group I and II since the P value is > 0.05 . The cough was less in group I and II when compared to group III at 1,6 and 24 hrs but at 12 hrs there was no statistically significant difference between all the three groups [P value > 0.05]. The mean scores for hoarseness in group I was always lower than mean scores in group II and III at all the specified time intervals over the 24 hour evaluation period. The P value was less than 0.05 over all the four evaluation periods and hence it was statistically significant.

Interpretation and conclusion

From the present study it can be concluded that betamethasone gel application on endotracheal tube significantly reduces post operative sore throat when compared to lidocaine jelly but the lidocaine jelly has got a comparable effect as betamethasone gel in reducing post operative cough and hoarseness of voice.

Key words

Endotracheal intubation, POSTCH, betamethasone, lidocaine.

INTRODUCTION

Endotracheal intubation is a routine part of delivering anaesthetic gases and vapours to the patients undergoing surgeries. It is not without risks. Sore throat is the most common complaint following intubation. Cough and hoarseness are other problems that follow intubation. Although these are minor sequelae, they are very distressing to the patients. The reported value for post operative sore throat and hoarseness of voice ranging from 24% to 90% even under good intubating conditions.¹²

Different factors were identified to correlate with occurrence of these complications, including irritation and inflammation of the airway, traumatization of airway mucosa, tracheal mucosal hypoperfusion induced by pressure, tracheal tube contact with vocal cords, size of endotracheal tube, cuff design, cuff pressure and lastly duration of surgery.^{4,12,19}

Various interventions have been introduced to reduce post operative throat complaints, such as use of smaller size endotracheal tubes, lower intra cuff pressure, application of topical lidocaine, post operative inhalation of steroids and use of steroid coated tubes. In addition to these, post operative IV administration of Dexamethasone has been confirmed to offer analgesic, anti-inflammatory effects and also an anti emetic action. Further more this

intervention reduced the occurrence of severity of sore throat and hoarseness in patients receiving general anaesthesia with tracheal intubation.^{4,12}

In previous studies, the anti inflammatory role of steroids has been clearly demonstrated. Therefore, the application of betamethasone gel on the endotracheal tube might reduce the severity of sore throat, cough and hoarseness. Also, the application of local anaesthetic jelly decreases potential damage to the mucosa of trachea has been proved. Since the local anaesthetic jelly acts as a lubricant, it suppresses bucking on the endotracheal tube.^{9,10} This study aimed to evaluate the incidence of post operative sore throat, cough and hoarseness when betamethasone gel and lidocaine jelly were applied to the endotracheal tube. Hence forth, this study was conducted to compare the incidence of post operative sore throat, cough and hoarseness following application of 0.05 % betamethasone gel against 2% lidocaine jelly and the control groups.

OBJECTIVES OF THE STUDY

To study the protective effects of betamethasone gel as lubricate on the tracheal tube in prevention of post operative sore throat, cough and hoarseness when compared to lidocaine jelly and without any application.

REVIEW OF LITERATURE

Sore throat is a common complaint following tracheal intubation. The other frequent complaints are cough and hoarseness of voice. It has been proposed that these effects are because of irritation and inflammation of the airway. In addition, it has been suggested that post operative sore throat may be caused by the activation of tracheal pain receptors and the rapidly adapting stretch receptor stimulation possibly could play a role in occurrence of post operative cough. Furthermore, coughing during emergence from general anaesthesia is a serious problem that can result in potentially dangerous complications such as hypertension, bleeding, cardiac arrhythmias, myocardial ischemia, myocardial infarction, increased intracranial pressure and intraocular pressure.

Many different studies have been conducted to evaluate the role of different methods in preventing these adverse effects on emergence from general anaesthesia. Betamethasone and lidocaine are commonly studied drugs and different routes of application of lidocaine have been tried. In preventing endotracheal tube induced emergence.

Soltani and Agadha voudi et al (2002)¹⁷ conducted a study to evaluate the effectiveness of various ways of lidocaine application in reducing post operative sore throat and cough. Two Hundred and Four ASA-PS 1 and

2 patients undergoing cataract surgery were selected and randomly divided into six groups. Group 1- 10% LIDOCAINE was sprayed on the distal end of the tube and its cuff, Group 2-10 % lidocaine was sprayed on the laryngeal structures before intubation, Group 3-distal end of the endo tracheal tube was lubricated with 2 % lidocaine jelly, Group 4-1.5 mg/kg IV lidocaine administration at the end of surgery. Group 5-tracheal tube cuffs were prefilled with 2 % lidocaine and Group 6-control group. Patients with chronic cough and sore throat, anticipated difficult intubation, and asthma were excluded from the study. Induction of anaesthesia was performed with Alfentanil 10 mcg/kg Thiopentone Sodium 5 mg /kg and succinyl choline 1.5 mg /kg IV to facilitate tracheal intubation. Male patients were intubated with 8 size tracheal tubes and for female 7 size, low pressure high volume cuffed tubes. Maintenance of anaesthesia was performed with 50% oxygen, 50 % N₂O and Halothane 1%. After extubation, patients were evaluated for post operative sore throat and cough at 1 and 24 hours after surgery.

The authors from this study concluded that the most effective methods to decrease post operative sore throat and cough were intra cuff lidocaine and IV Lidocaine. Lubrication with 2 % lidocaine jelly was associated with highest frequency of cough and sore throat which was greater than that in control group.

Kori K et al (2002) conducted a study to evaluate the severity of post operative sore throat and hoarseness after tracheal intubation. Sixty patients of ASA-PS 1 and 2 status undergoing elective surgery with intubation under general anaesthesia. They were divided into three groups : Group 1 Lidocaine 4 % was sprayed into the trachea, Group 2- 2 %lidocaine jelly applied over tracheal tube and Group 3 control. Evaluation of post operative sore throat was done by using Visual Analog Scale[VAS] at the end of surgery and the next day.

The author concluded that Lidocaine jelly lubrication to the tracheal tube increases the severity of sore throat. Lidocaine sprayed to the trachea did not reduce post operative sore throat.

Asif Kazemi et al (2007)³ conducted a study to evaluate the effectiveness of betamethasone gel in reducing sorethroat cough and hoarseness after laryngo tracheal intubation. One Hundred ASA-PS 1 and 2 patients aged between 16 to 50 years undergoing elective surgery under general anaesthesia. At entry to the operation theatre, patients were randomly divided into two equal groups : group A and group B. All patients were premedicated with 0.2 mg/kg orally. Induction of anaesthesia was performed with 0.2 mg/kg Morphine IV and 5 mg/kg of pentothal sodium and 0.6 mg/kg of Atracurium for muscle relaxation. high volume low pressure cuffed tube of size 7 to 8 mm ID was selected and lubricated with 3 ml of 0.05%

betamethasone [group A] or KY jelly in control[group B].Three minutes after injection of Atracurium intubation was done by an expert anaesthesiologist. Anaesthesia was maintained with 50 % oxygen and 50 % N2O and Halothane. At the end of surgery the trachea was extubated when the patient was fully awake.

Assesment of sore throat, cough and hoarseness at 1,24 hrs after surgery in PACU using grading system.

In this study, the authors recommended lubrication of all parts of tracheal tube that is in contact with posterior pharynx, larynx and trachea with betamethasone gel in order to reduce cough, hoarseness and sore throat.

PA Sumathi et al (2008)¹⁹ conducted a study to evaluate the incidence of post operative sore throat, cough and hoarseness of voice by applying betamethasone gel and lidocaine jelly over tracheal tube in intubated patient using general anaesthesia. One Hundred and fifty American Society of Anaesthesiologist [ASA-PS] class 1 and 2 patients of either sex, aged between 18 to 60 yrs undergoing elective surgery under general anaesthesia with oro tracheal intubation.

Patients undergoing surgeries of the oral cavity and pharynx, anticipated difficult airway, more than two attempts at intubation, any surgery lasts greater than 240 mins, use of nasogastric tube, throat packs, upper

respiratory tract infection and patients on steroid therapy were excluded from the study.

Patients were randomly divided into three groups: Group 1 betamethasone, Group 2 lidocaine jelly and Group 3 control [no jelly applied]

All patients were premedicated with oral diazepam 10 mg and ranitidine 150 mg. At induction of anaesthesia, the endotracheal tube was lubricated from the distal part of the cuff to a distance of 15 cm from the tip, using 2.5 ml of 0.055% w/w betamethasone gel or Lidocaine 2% jelly, spread evenly with strict aseptic precautions. High Volume Low Pressure cuffed poly vinyl chloride [PVC] tracheal tubes of size 7 mm and 8 mm internal diameter for male and female patients respectively. Induction of anaesthesia was done with IV Mepiridine 0.75 mg /kg and thiopentone 5 mg/kg .Vecuronium bromide 0.1 mg /kg was used for relaxation for tracheal intubation. Anaesthesia was maintained with N₂O 66%, Halothane in oxygen 0.5 to 1% along with increments of vecuronium.

The name of the gel used was not recorded in anaesthesia chart to ensure that the anaesthesiologist in post anaesthesia care unit [PACU] blinded to the group allocation. After extubation assessment of patients for post operative sore throat cough and hoarseness of voice at 1,6,12 and 24 hours after surgery. This was carried out by PACU anaesthesiologist using the grading system.

From this study the authors concluded that betamethasone gel applied widely over endotracheal tube effectively mitigates post operative sore throat, cough and hoarseness compared with lidocaine jelly.

Athif Akram et al (2013)⁴ conducted a study to compare the frequency of postoperative sorethroat, cough and hoarseness of voice with and without betamethasone gel application on endotracheal tube in intubated patients using general anaesthesia. One hundred American Society of Anaesthesiologist [ASA-PS]1 and 2 patients of either sex aged between 18 to 60 years undergoing elective surgeries were selected and randomly divided equally into two groups : betamethasone and control groups. Oro nasal surgeries, preoperative sore throat, anticipated difficult airway, more than one attempt at intubation, nasogastric tube insertion and patients on steroid therapy were excluded from the study. At induction, using betamethasone gel 0.05% was applied from the distal end of the cuff to a distance of 15 cm from the tip, spread evenly with sterile precautions in group A and no lubrication in group B. All intubations were done by an expert anaesthesiologist using 7 and 7.5 mm ID for male and female respectively. At the end of surgery, oral suctioning done gently just before extubation only. The trachea was extubated when the patient fully met the extubation criteria. All patients received oxygen by face mask. Assessment of sore throat, cough and hoarseness of voice at 6, 12 and 24 hrs after surgery using a scoring system

questionnaire. From this study the authors concluded that the incidence of sore throat, cough and hoarseness is significantly less in patients who were intubated with betamethasone gel lubricated tracheal tube as compared to control group.

Masoomeh Tabari et al (2013)¹² conducted a study to compare the effectiveness of betamethasone gel applied to the tracheal tube and intravenous Dexamethasone on postoperative sore throat. Two Hundred and Twenty Five patients belonging to ASA-PS 1 and 2 aged between 20 to 45 years and undergoing elective abdominal surgery with endotracheal intubation under general anaesthesia were enrolled. Patients with history of cardiac, respiratory, cerebrovascular disease, bronchial asthma, gastro oesophageal reflux, preoperative sorethroat, pre operative analgesics and anti inflammatory drug use and patients less than 20 yrs of age were excluded from the study. And also, more than two attempts at intubation, use of nasogastric tube or throat packs, upper respiratory infection, steroid therapy and pregnancy were all excluded. Pre anaesthetic evaluation was done and then selected patients were divided randomly into three groups with 75 patients in each group. GROUP 1 betamethasone, Group 2 IV Dexamethasone and Group 3 control group.

All patients were premedicated with IV Midazolam 40 mcg /kg. The routine monitoring was done with NIBP, PULSE OXIMETRY, ECG and

CAPNOGRAPHY. Induction was done with Fentanyl 2 mcg/kg, Propofol 2 mcg/kg over 30 seconds followed by atracurium 0.5 mg/kg. Intubation was done by a single expert anaesthesiologist using a Macintosh laryngoscope. The tracheal tube size 7 mm and 8 mm ID for women and men respectively. In both groups the maintenance of anaesthesia was done with 50 % oxygen and 50% N₂O. Propofol 100 mcg/kg/min and Fentanyl infusion.

The trachea was extubated after deflating the cuff when the patient was fully awake and all patients were received oxygen by face mask after extubation. assessment of post operative sore throat was done by a blinded anaesthesiologist using a questionnaire at 1, 6 and 24 hrs after surgery.

The authors concluded that betamethasone gel applied over the tracheal tube effectively mitigates post operative sorethroat compared with IV Dexamethasone.

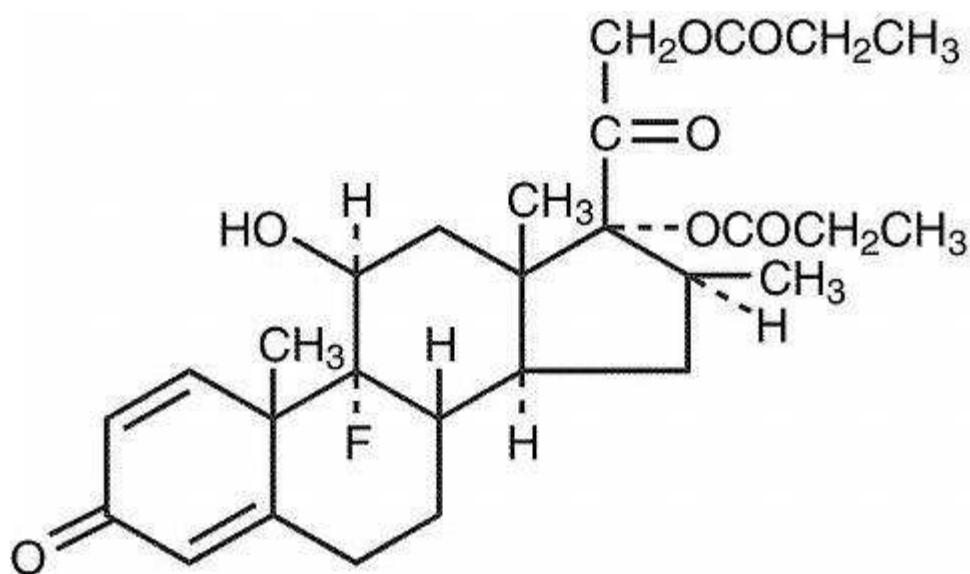
PHARMACOLOGY OF BETAMETHASONE

Betamethasone is a synthetic cortico steroid principally used to produce anti-inflammatory effects. It is a fluorinated derivative of prednisolone devoid of mineralocorticoid effect.¹⁴

Chemical Name and Structure

Its chemical name is 9-fluoro-11, 17, 21-trihydroxy-16-methylpregna-1, 4 diene-3, 20-dione.

The structural modification by placing double bond in prednisolone have resulted in synthetic cortico steroids with more potent gluco corticoid effects than their natural counter parts.^{14,15}



COMMERCIAL PREPARATION

It is available as [1] Betamethasone Di Propionate 0.05%W/W and [2]
Betamethasonctorsece Valerate 0.1% cream

BETAMETHASONE GEL 0.05%



MECHANISM OF ACTION¹⁴

Corticosteroids bind to high affinity cytoplasmic receptor protein leads to structural change in the steroid receptor complex that permits its migration into the nucleus and binding to glucocorticoid receptor elements which leads to transcription of specific m-RNA which regulates protein synthesis. The glucocorticoid receptor is widely distributed in all cells. Glucocorticoids interfere at several steps in the inflammatory response but the overall mechanism appears to be limitation of recruitment of inflammatory cells at the local site and production of pro inflammatory mediators like prostaglandins, leukotrienes, and PAF through inhibition of phospholipase A2.

PHARMACOKINETICS^{14,15}

The absorption of topically applied corticosteroids depends on various factors such as the vehicle or delivery system used by the drug and the integrity of the local site. The absorption of locally applied betamethasone dipropionate gel is theoretically less but if it is absorbed, it follows the same pharmacy kinetic profile of systemic corticosteroids. It is metabolized by the liver and excreted primarily by the kidneys.

ACTIONS ON TRACHEAL MUCOSA^{7,8,18}

Betamethasone is a long acting glucocorticoid with potent anti-inflammatory effect on tracheal mucosa to prevent post intubation airway sequelae.

SIDE EFFECTS^{14,15}

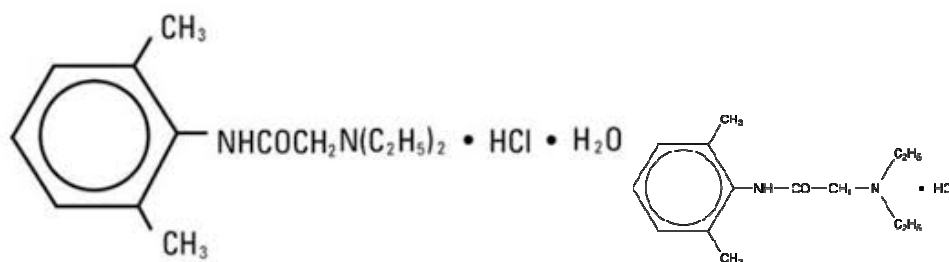
Topical corticosteroids rarely cause serious side effects. The factors that increase the risk of getting side effects are potency, duration of treatment, the area being treated and age. The local side effects are skin atrophy, worsening of psoriasis, suppression of hypothalamic-pituitary-adrenal axis resulting in cushingoid features. These effects are more likely to occur if high potency corticosteroids applied over extensive areas. Steroid induced cataract and glaucoma can occur.

PHARMACOLOGY OF LIDOCAINE

Lidocaine belongs to amide group of local anaesthetics which was first synthesized by Lofgren in 1943. It is good for both surface application as well as injection. Local anaesthetics are drugs that produce reversible loss of sensory perception, especially of pain in a restricted area of the body. ^{14,15}

CHEMICAL NAME AND STRUCTURE ^{14,15}

Lidocaine's chemical name is 2-[diethyl amino]-N-[2,6-dimethyl phenylacetamide].



COMMERCIAL PREPARATION

It is available as a hydrochloride salt dissolved in sterile water or saline.



PHYSICOCHEMICAL PROPERTIES

Lidocaine is freely soluble in water, the pH of 1% solution in 0.9% saline is 6.5 to 7.0. It is stable and can be sterilized by boiling and autoclaving.

MECHANISM OF ACTION

Lidocaine blocks voltage gated sodium channels from inside the cell, preventing subsequent channel activation and it interferes with the large transient sodium influx associated with membrane depolarization. As a result, the impulse conduction slows the rate of rise and magnitude of the action potential decreases. The threshold for excitation is increased until an action potential can no longer be produced and impulse propagation is abolished.

PHARMACOKINETICS

Less than 50 % of the drug exists in a lipid soluble non ionized form which is the active form at physiological pH. Absorption of Lidocaine from its site of administration into the systemic circulation is influenced by the factors such as site of administration, dosage and use of adrenaline. The ultimate plasma concentration of Lidocaine is determined by the rate of tissue distribution and the rate of clearance of the drug.

It is metabolized primarily by microsomal enzymes present in the liver. The main metabolic pathway of Lidocaine is oxidative dealkylation in the liver to mono ethyl glycine xylidide followed by hydrolysis of MEGX to xylidide. The elimination half time of lidocaine is prolonged in patients with liver dysfunction. The clearance is prolonged in mothers with pregnancy induced hypertension than normal counter parts.

ACTIONS ON TRACHEAL MUCOSA^{9,10,11,15}

Rapidly Adapting Stretch Receptors [RARS] are found from the naso pharynx to bronchi are believed to be involved in the cough reflex. They are extremely sensitive to mechanical stimuli. By blocking these receptors lidocaine suppresses cough and sore throat. Another explanation proposed is that lidocaine suppresses the excitation of airway sensory C fibres which plays a role in coughing. RARS in the larynx commonly called irritant receptors which has very rapidly adapting response to mechanical stimuli.

ROUTES OF ADMINISTRATION OF LIDOCAINE FOR PREVENTION OF POST INTUBATION PROBLEMS²⁰

IV Lidocaine-the mechanism by which it suppresses cough is unknown. The recommended dose is 1.5 mg/kg to suppress cough reflex during intubation and extubation, leading to a plasma concentration of around 3 mcg/ml.

Topical application-Lubrication of tracheal tube with 2 % lidocaine jelly, 4% lidocaine spraying on larynx and trachea and lidocaine has also been used to fill the cuff.

SYSTEMIC TOXICITY^{14,15}

It occurs due to an excess plasma concentration of the drug [5 to 10 mcg/ml].Central nervous system toxicity-Numbness tongue and circumoral tissues, restlessness, vertigo, tinnitus, difficulty in focusing, slurred speech, skeletal muscle twitching most often in the face and extremities which signals imminence of seizures.

Cardiovascular system toxicity-The cardiovascular system is more resistant to toxic effects of local anaesthetics than central nervous system. A concentration of greater than 5 to 10 mcg/ml may produce profound hypotension and also direct myocardial depression.

EQUIPMENT

ENDOTRACHEAL TUBES

The Endotracheal tube is a device that is inserted into the trachea through the larynx to deliver gases and vapors to and from the lungs. It is otherwise known as tracheal tube or tracheal catheter.

MATERIALS OF CONSTRUCTION OF AN ENDOTRACHEAL TUBE

The materials for constructing an endotracheal tube should possess the following characteristics. ¹⁴

1. Lack of toxicity to tissues
2. Transparency
3. Non - inflammable
4. Smooth, non wettable surface
5. Allow easy passage of a suction catheter or bronchoscope.
6. Sufficient strength in the body to prevent torsion, kinking and occlusion by compression
7. Non reactivity with lubricants and anaesthetic agents
8. Low cost and latex free.

Till date no material with all of the above characteristics has been found.

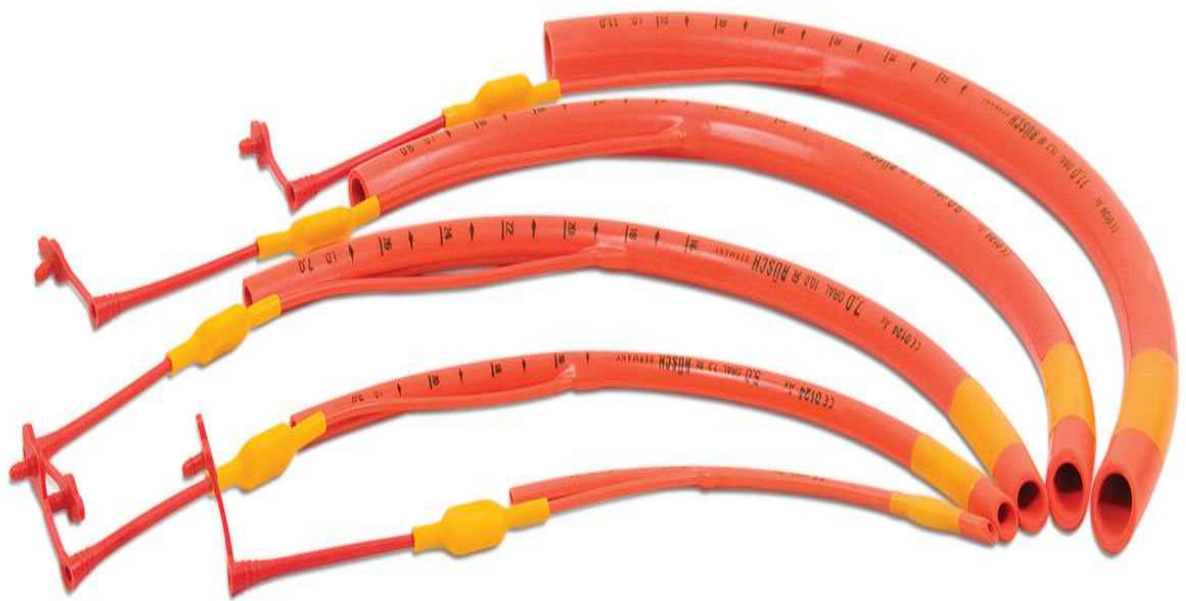
VARIETIES

Red rubber tube: ¹⁴

It is an age old one but still available. It can be cleaned with water, sterilized and reused many times. It is hard, non transparent, poor resistance to kinking and sticky when it gets older. It becomes clogged by inspissated secretions which cannot be seen since it is non transparent. Rubber allergy is a big concern while using red rubber tube.

They have low volume, high pressure cuffs which often cause post operative sore throat.

RED RUBBER ENDOTRACHEAL TUBE



POLY VINYL CHLORIDE [PVC] ¹⁴

Poly vinyl chloride is the substance most widely used in making disposable endotracheal tubes. It is relatively inexpensive and compatible with tissues. It has less tendency to kink than rubber tubes and is stiff enough for intubation at room temperature but softens at body temperature, so that they tend to conform to the anatomy of patient's upper airway. It can be cooled to make it more firm for intubation. It has a smooth surface that facilitates passage of a suction catheter. Its transparency allows observation of respiratory moisture as well as objects in the lumen.

They have large volume low pressure cuffs, hence post operative complications are less.

POLY VINYL CHLORIDE [PVC]

ENDOTRACHEAL TUBE



SILICONE

Silicone is used in some tracheal tubes. It is more expensive but can be sterilized and reused.

TUBE DESIGN

The American Society for Testing and Materials [ASTM] and International Standards Organization recommendations.¹⁴

The internal and external walls of the tube should be circular. The proximal end or machine end receives the connector and it may be possible to shorten the tube at this end. The distal end or the patient end is inserted into the trachea. It has a slanted portion called the bevel. The angle of the bevel is the acute angle between the bevel and the longitudinal axis of the tube. The opening of the bevel faces left when viewing from the concave aspect, as the tube is often introduced from the right and having the bevel facing the left facilitates visualization of the larynx as the tube is being inserted. This tube has a hole on the side opposite the bevel called the Murphy eye. The purpose of the eye is to provide an alternate pathway for gas flow if the bevel is occluded. A radio opaque marker is placed along the entire length of the tube to aid in determination of tube position after intubation.

TUBE SIZE

Current standards designate tube size by the internal diameters in millimeters. Some manufacturers also put the tube size on the pilot balloon so that it is easy to determine the size when the tube is inside.¹⁴

TUBE LENGTH

The length of the tube increases as the internal diameter increases.^{14,15}

TUBE MARKINGS

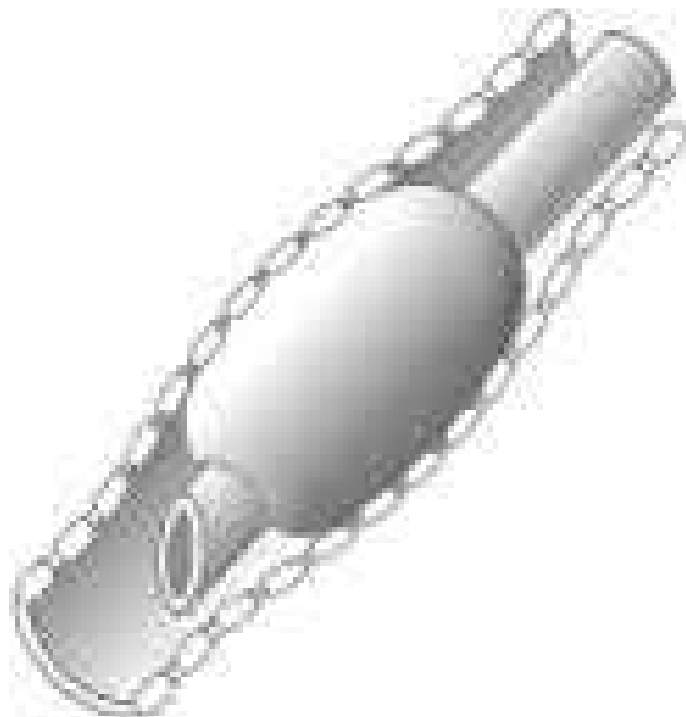
The markings are done on the beveled side of the tube above the cuff and are read from lower end to machine end.¹⁴

CUFF SYSTEMS

Cuff systems include the cuff and an inflation system. The inflation system consists of inflation tube, a pilot balloon and an inflation valve. The advantage of cuff system is to provide a seal between the tube and the tracheal wall. Therefore it prevents passage of pharyngeal contents into the trachea and also no gas leaks past the cuff during positive pressure ventilation. In addition, it serves to center the tube in trachea.^{14,15}

CUFF

It is an inflatable sleeve near the patient end of the tube. It is usually made of the same material as the tube. It should be soft, pliable and strong enough to resist tear. The cuff should be placed at a specified distance from the machine end of the tube and should not encroach on the Murphy eye. The cuffs are of two types: high volume low pressure and low volume high pressure.^{14,15}



INFLATED CUFF IN TRACHEA

LOW VOLUME HIGH PRESSURE CUFF

This type of cuff has a smaller diameter at rest and a low residual volume. It requires a high intra cuff pressure to achieve a seal with the trachea. Intra cuff pressure and lateral pressure on the tracheal wall increases as more air is added to the cuff. They offer better protection against aspiration. The most serious risk associated with high pressure cuff is ischemic damage to the trachea following prolonged use.^{14,15}

HIGH VOLUME LOW PRESSURE CUFF

A high volume low pressure cuff has a large resting volume and diameter and a thin compliant wall that allows a seal with the trachea to be achieved without stretching the wall. The main advantage in using this type is the risk of significant cuff induced complications following prolonged use might be reduced. The disadvantages are it may be difficult to insert, as the cuff may obscure the view and the risk of aspiration is slightly more.^{14,15}

INFLATION SYSTEM

Inflation lumen: This connects the inflation tube to the cuff end and it is located within the wall of the tracheal tube. It does not encroach on the tracheal tube lumen and also does not bulge forward.¹⁴

EXTERNAL INFLATION TUBE

This is external to the tube, its external diameter is less than 2.5 mm and is attached to the tube at a small angle.¹⁴

HEWER PILOT BALLOON

It is attached to the external inflation tube near the inflation valve and gives an indication of deflation or inflation of the cuff.¹⁴

INFLATION VALVE

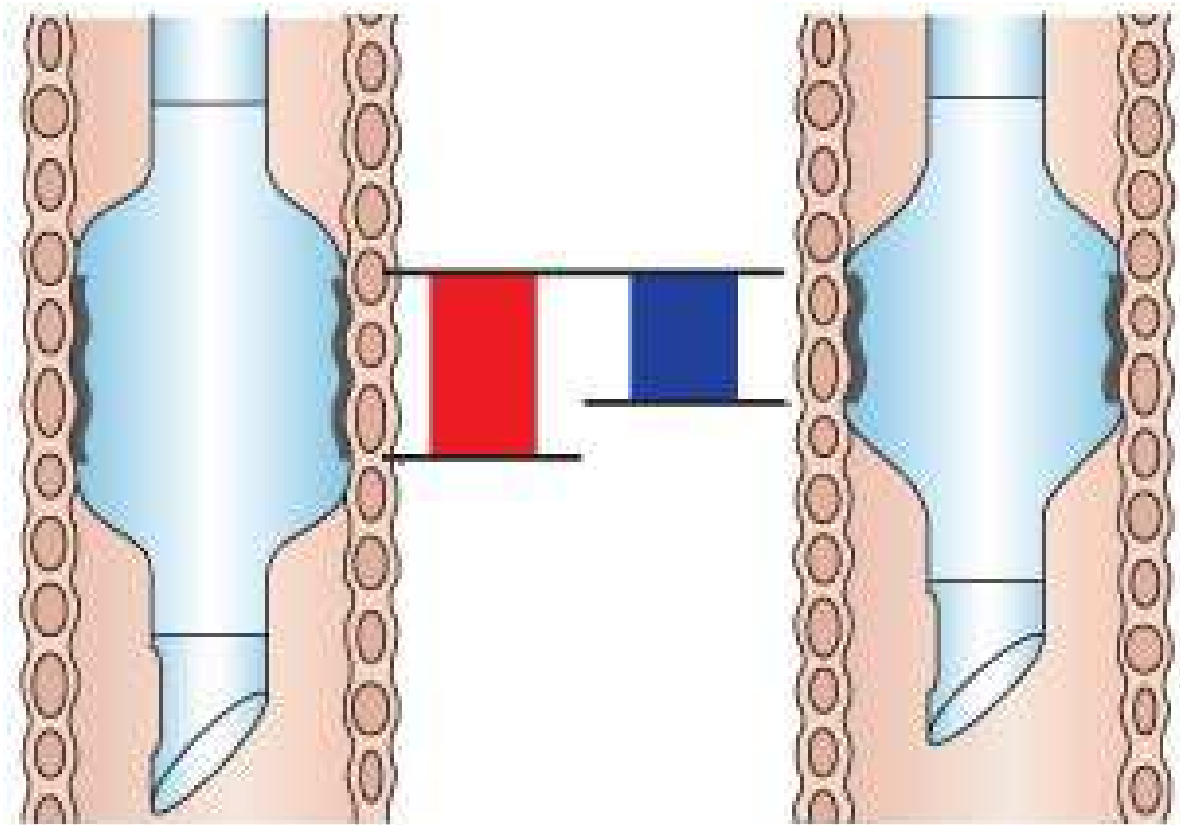
It is designed so that the tip of the syringe is inserted into it, a plunger is displaced from its seat and gas can be injected into the cuff. Upon removal of the syringe, the valve seals so that gas cannot escape from the cuff.¹⁴

HIGH VOLUME

LOW VOLUME

LOW PRESSURE CUFF

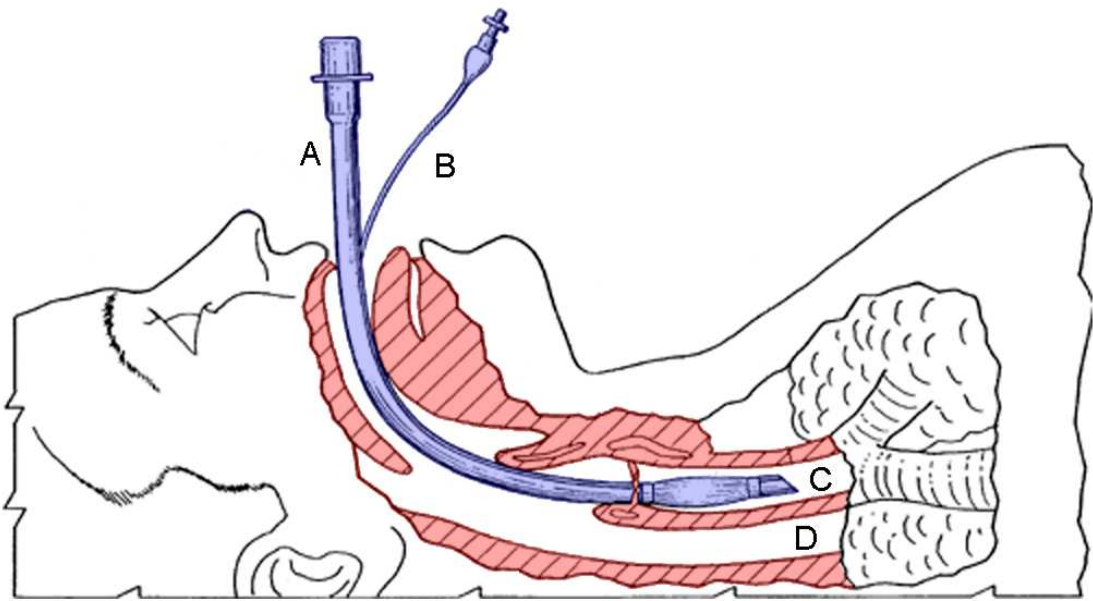
HIGH PRESSURE CUFF



CUFF AND TIP OF ENDO TRACHEAL TUBES



PLACEMENT OF ENDO TRACHEAL TUBE



- A - PROXIMAL END OF THE ENDO TRACHEAL TUBE**
- B - INFLATION SYSTEM**
- C - CUFF AND TIP IN TRACHEA**
- D - OESOPHAGUS**

SCORING SYSTEM FOR SORE THROAT, COUGH AND

HOARSENESS^{3,4,5,12,13,16,19}

SORE THROAT

- | | |
|---|---|
| 0 | No sore throat at any time since the operation |
| 1 | Minimal [less than what is seen in common cold] |
| 2 | Moderate [like what is seen in common cold] |
| 3 | Severe [more than what is seen in common cold] |

COUGH

- | | |
|---|--|
| 0 | No cough at any time since the operation |
| 1 | Minimal cough or scratchy throat |
| 2 | Moderate cough |
| 3 | Severe cough |

HOARSENESS

- 0 No evidence of hoarseness at anytime since the operation

- 1 No evidence of hoarseness at the time of interview

- 1 Hoarseness at the time of interview noted by patient only

- 2 Hoarseness that is easily recognizable at the time of
interview

METHODOLOGY

A controlled comparative clinical study was conducted to evaluate the prevention of post operative sore throat, cough and hoarseness of voice by applying betamethasone gel and lidocaine jelly over endotracheal during general anaesthesia tube at Rajiv Gandhi Government General Hospital, Chennai attached to Madras Medical College after obtaining ethics committee clearance.

Type of Study : Prospective, Randomized Control Study

The study population consisted of three hundred American Society of Anaesthesiologist [ASA-PS] class 1 and 2 patients aged between 18 to 60 years of either sex undergoing elective general, orthopaedic and ear surgeries with tracheal intubation under general anaesthesia. Patients undergoing surgeries of oral cavity and pharynx, more than a single attempt at intubation, anticipated difficult airway, upper respiratory tract infection, use of nasogastric tube or throat packs, steroid therapy, allergy to local anaesthetics and pregnant female were exclusion criteria.

Pre anaesthetic assessment was done and then selected patients were randomly divided into three groups with 100 patients in each group. Group 1 Betamethasone Gel 0.05% ,Group 2 Lidocaine 2% jelly and Group 3 Control [no jelly applied].All patients were pre -medicated with oral Alprazolam

0.25 mg, Ranitidine 150 mg and Metoclopramide 10 mg 2 hours before surgery. NIBP, ECG, PULSE OXIMETRY monitors were connected and IV access established with 18 gauge venous cannula. Glycopyrrolate 0.2 mg was given intravenously. During induction of anaesthesia, the tracheal tube was lubricated from the distal tip to a distance of 17 cm proximally from the tip using 2.5 ml of 0.05 % betamethasone gel or 2 % lidocaine jelly, spread evenly with strict aseptic precautions. High volume and Low pressure cuffed tubes of size 8 and 7.5 mm internal diameter were used for male and female patients respectively. Induction of anaesthesia was performed with IV Fentanyl 2 mcg/kg, Thiopentone Sodium 5 mg/kg, followed by Atracurium 0.5 mg/kg to facilitate intubation. After 3 minutes; intubation was performed by a single expert anaesthesiologist using Macintosh laryngoscope. In all three groups, anaesthesia was maintained by 50% oxygen and 50% N₂O and Halothane 0.5 to 0.8 %. IV Atracurium was repeated intermittently to maintain muscle relaxation.

At the end of surgery, 100 % oxygen was administered and residual neuro muscular block was reversed with 40 mcg/kg Glycopyrrolate and 50 mcg/kg Neostigmine sulphate. Gentle oral suctioning was done just before extubation. The trachea was extubated after deflating the cuff when all the extubation criteria were met.

After extubation, all the patients were received 100 % by face mask. Assessment of post operative sore throat, cough and hoarseness of voice were carried out at 1,6,12 and 24 hours after surgery using grading system for severity of sore throat, cough and hoarseness.

RESULTS

A Comparative clinical study was conducted to evaluate the prevention of post intubation sore throat, cough and hoarseness by lubricating endotracheal tube with 0.05 % betamethasone gel and Lidocaine 2% jelly in patients undergoing elective general, orthopaedic and ear surgeries at Rajiv Gandhi Government General Hospital, Chennai attached to Madras Medical College.

The following observations were made during the study.

AGE DISTRIBUTION

The age distribution of the study population in three groups is as shown below.

Table: 2 Showing age distribution

			Age (Years) * Group Crosstabulation			Total
			Group-I: Betamethasone Gel 0.05%	Group-II: Lidocaine Jelly 2%	Group-III: Control (No Jelly Applied)	
Age (Years)	< 30 Years	Count	40	50	50	140
		% within Group	40.0%	50.0%	50.0%	46.7%
	30 - 40 Years	Count	41	29	26	96
		% within Group	41.0%	29.0%	26.0%	32.0%
	40 - 50 Years	Count	12	17	16	45
		% within Group	12.0%	17.0%	16.0%	15.0%
	50 - 60 Years	Count	7	4	8	19
		% within Group	7.0%	4.0%	8.0%	6.3%
Total		Count	100	100	100	300
		% within Group	100.0%	100.0%	100.0%	100.0%

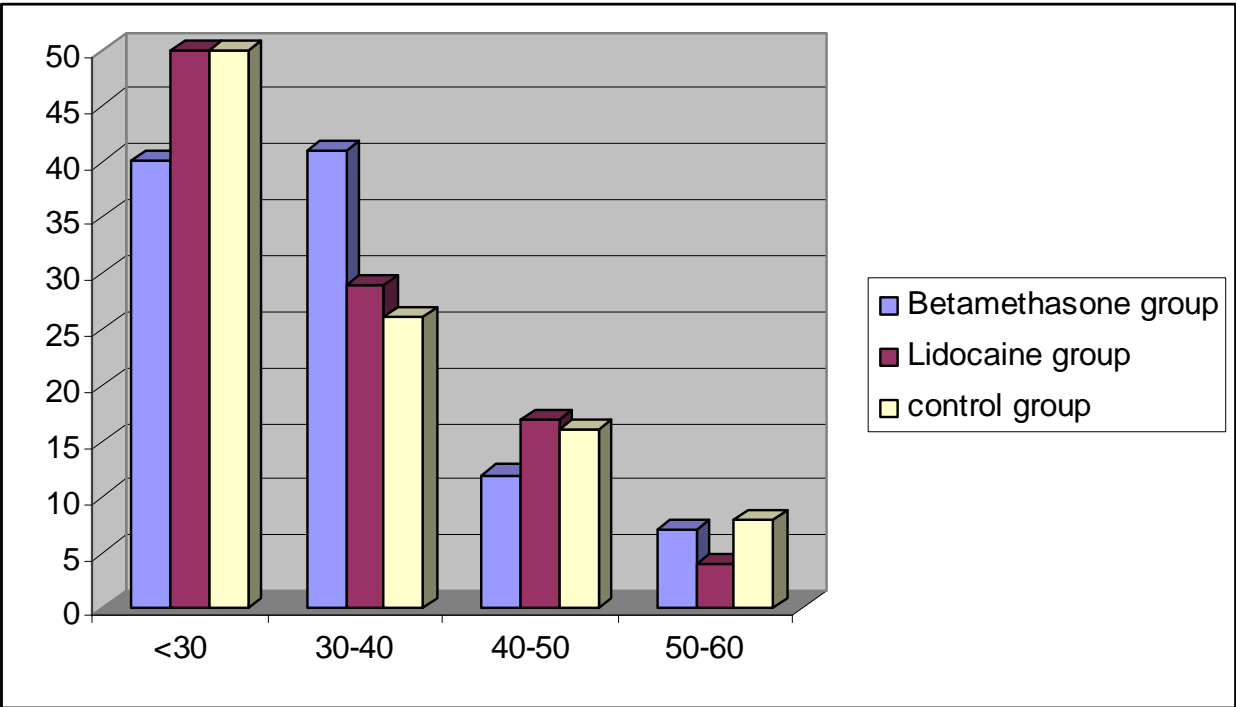
ANOVA

Age
(Years)

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	124.927	2	62.463	.461	.631
Within Groups	40264.470	297	135.571		
Total	40389.397	299			

All the patients in group I, group II and group III were between 18 to 60 years of age. The mean age in group I was 32.84 ± 11.318 , in group II was 31.29 ± 10.816 and in group III was 32.16 ± 12.595 years. There was no statistically significant difference between the three groups with respect to age [$P > 0.05$].

CHART 1 - AGE DISTRIBUTION



SEX DISTRIBUTION

TABLE 2: SHOWING SEX DISTRIBUTION

Sex * Group Crosstabulation

			Group			Total
			Group-I: Betamethasone Gel 0.05%	Group-II: Lidocaine Jelly 2%	Group-III: Control (No Jelly Applied)	
Sex	Male	Count	50	47	58	155
		% within Group	50.0%	47.0%	58.0%	51.7%
	Female	Count	50	53	42	145
		% within Group	50.0%	53.0%	42.0%	48.3%
Total		Count	100	100	100	300
		% within Group	100.0%	100.0%	100.0%	100.0%

Chi-Square Tests

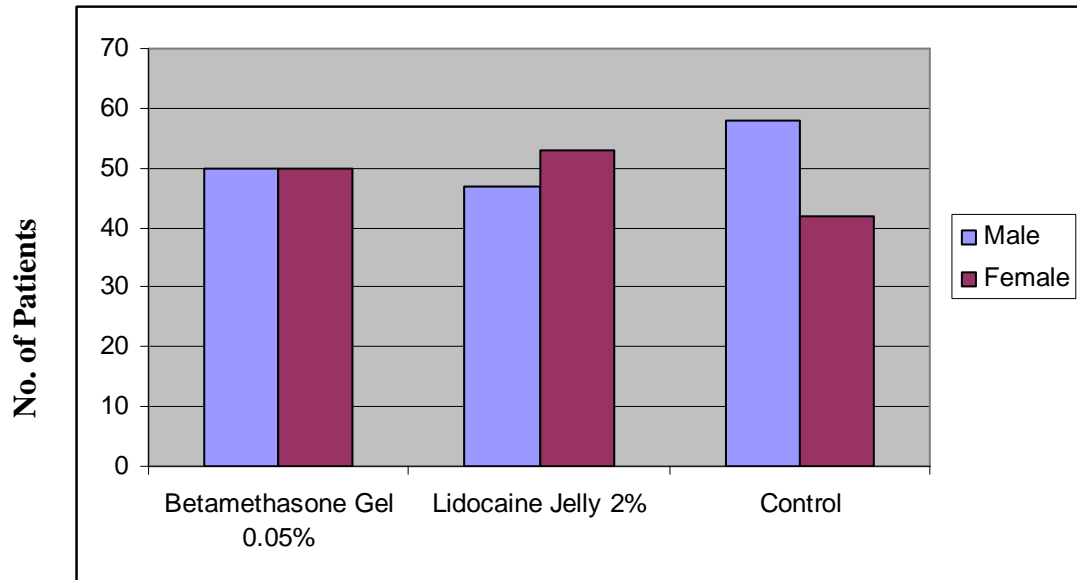
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	2.590 ^a	2	.274
Likelihood Ratio	2.598	2	.273
Linear-by-Linear Association	1.277	1	.258
N of Valid Cases	300		

a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 48.33.

All three groups were comparable with respect to sex of the patients

[P value > 0.05]

CHART 2 – SEX DISTRIBUTION



DURATION OF SURGERY

TABLE 3 : SHOWING DURATION OF SURGERY

Descriptives

Duration of Surgery (Min)

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
Group-I: Betamethasone Gel 0.05%	100	97.40	37.094	3.709	90.04	104.76	45	180
Group-II: Lidocaine Jelly 2%	100	89.35	31.969	3.197	83.01	95.69	40	180
Group-III: Control (No Jelly Applied)	100	92.95	32.799	3.280	86.44	99.46	40	180
Total	300	93.23	34.075	1.967	89.36	97.10	40	180

ANOVA

Duration of Surgery (Min)

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	3252.167	2	1626.083	1.404	.247
Within Groups	343911.5	297	1157.951		
Total	347163.7	299			

Post Hoc Tests

Multiple Comparisons

Dependent Variable: Duration of Surgery (Min)
Tukey HSD

(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Group-I: Betamethasone Gel 0.05%	Group-II: Lidocaine Jelly 2%	8.050	4.812	.217	-3.29	19.39
	Group-III: Control (No Jelly Applied)	4.450	4.812	.625	-6.89	15.79
Group-II: Lidocaine Jelly 2%	Group-I: Betamethasone Gel 0.05%	-8.050	4.812	.217	-19.39	3.29
	Group-III: Control (No Jelly Applied)	-3.600	4.812	.735	-14.94	7.74
Group-III: Control (No Jelly Applied)	Group-I: Betamethasone Gel 0.05%	-4.450	4.812	.625	-15.79	6.89
	Group-II: Lidocaine Jelly 2%	3.600	4.812	.735	-7.74	14.94

All the surgeries in three groups took 40 to 180 minutes. The mean duration of surgery in group I was 97.40 ± 37.09 , in group II was 89.35 ± 31.96 and in group III was 92.95 ± 32.79 . There was no statistically significant difference between the three groups with respect to the duration of surgery [P value >0.05].

Cross tabs

Duration of Surgery (Min) * Group Crosstabulation

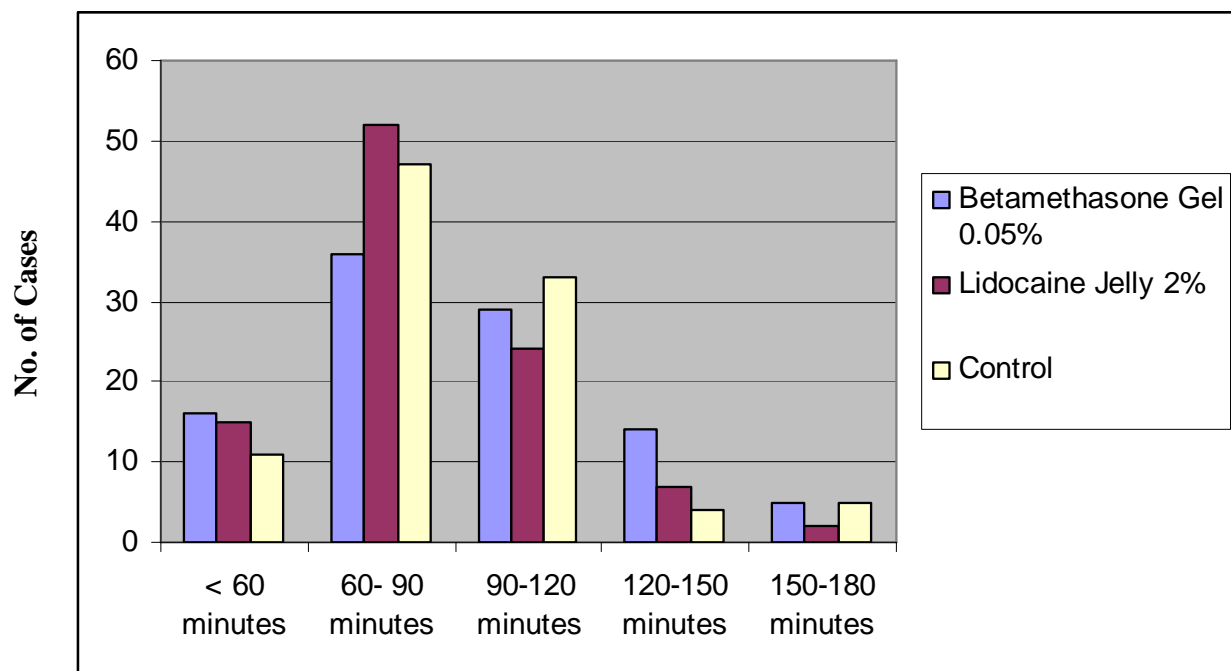
			Group			Total
			Group-I: Betamethaso ne Gel 0.05%	Group-II: Lidocaine Jelly 2%	Group-III: Control (No Jelly Applied)	
Duration of Surgery (Min)	< 60	Count	16	15	11	42
		% within Group	16.0%	15.0%	11.0%	14.0%
	60 - 90	Count	36	52	47	135
		% within Group	36.0%	52.0%	47.0%	45.0%
	90 - 120	Count	29	24	33	86
		% within Group	29.0%	24.0%	33.0%	28.7%
	120 - 150	Count	14	7	4	25
		% within Group	14.0%	7.0%	4.0%	8.3%
	150 - 180	Count	5	2	5	12
		% within Group	5.0%	2.0%	5.0%	4.0%
Total		Count	100	100	100	300
		% within Group	100.0%	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	13.216 ^a	8	.105
Likelihood Ratio	13.432	8	.098
Linear-by-Linear Association	.647	1	.421
N of Valid Cases	300		

a. 3 cells (20.0%) have expected count less than 5. The minimum expected count is 4.00.

CHART 3 –DURATION OF SURGERY



EXTUBATION TIME

It is the time interval between the stoppage of nitrous oxide to the time of extubation.

Table 4: showing the mean extubation time in minutes.

Descriptives

Extubation Time (Min)	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
					Group-I: Betamethasone Gel 0.05%	100		
Group-II: Lidocaine Jelly 2%	100	11.040	1.0461	.1046	10.832	11.248	9.0	13.0
Group-III: Control (No Jelly Applied)	100	7.365	.8734	.0873	7.192	7.538	6.0	9.8
Total	300	8.857	1.8556	.1071	8.646	9.068	3.5	13.0

ANOVA

Extubation Time (Min)	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	746.793	2	373.396	392.157	.000
Within Groups	282.792	297	.952		
Total	1029.585	299			

Cross tabs

**Extubation
Time (Min) * Group Crosstabulation**

			Group			Total
			Group-I: Betamethasone Gel 0.05%	Group-II: Lidocaine Jelly 2%	Group-III: Control (No Jelly Applied)	
Extubation Time (Min)	< 6	Count	1	0	0	1
		% within Group	1.0%	.0%	.0%	.3%
	6 - 9	Count	68	0	89	157
		% within Group	68.0%	.0%	89.0%	52.3%
	9 - 12	Count	31	72	11	114
		% within Group	31.0%	72.0%	11.0%	38.0%
	> 12	Count	0	28	0	28
		% within Group	.0%	28.0%	.0%	9.3%
Total	Count	100	100	100	300	
	% within Group	100.0%	100.0%	100.0%	100.0%	

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	191.608 ^a	6	.000
Likelihood Ratio	245.984	6	.000
Linear-by-Linear Association	4.095	1	.043
N of Valid Cases	300		

a. 3 cells (25.0%) have expected count less than 5. The minimum expected count is .33.

Post Hoc Tests

Multiple Comparisons

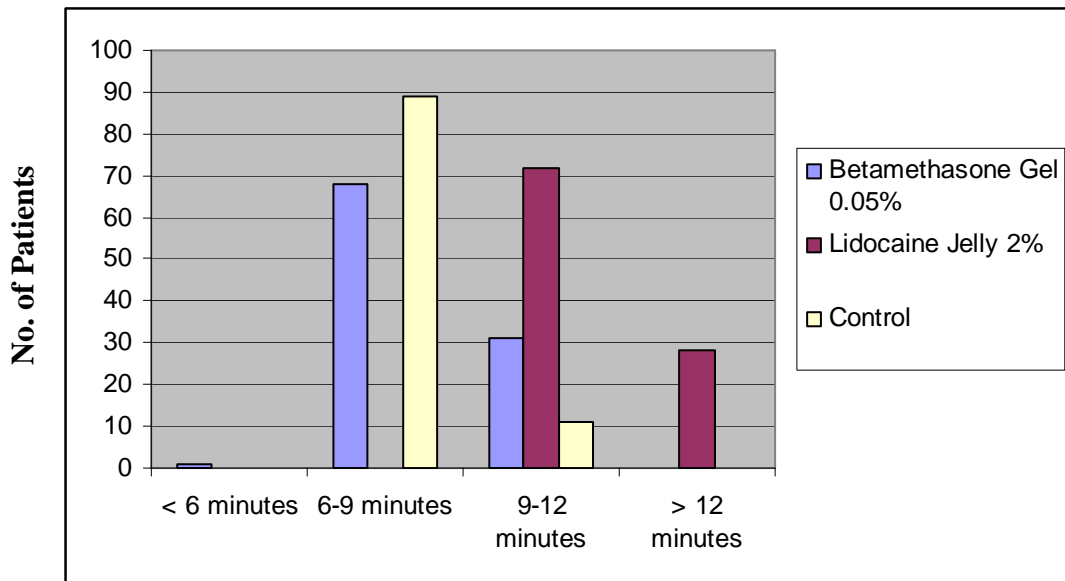
Dependent Variable: Extubation
Time (Min)
Tukey HSD

(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Group-I: Betamethasone Gel 0.05%	Group-II: Lidocaine Jelly 2%	-2.8732*	.1380	.000	-3.198	-2.548
	Group-III: Control (No Jelly Applied)	.8018*	.1380	.000	.477	1.127
Group-II: Lidocaine Jelly 2%	Group-I: Betamethasone Gel 0.05%	2.8732*	.1380	.000	2.548	3.198
	Group-III: Control (No Jelly Applied)	3.6750*	.1380	.000	3.350	4.000
Group-III: Control (No Jelly Applied)	Group-I: Betamethasone Gel 0.05%	-.8018*	.1380	.000	-1.127	-.477
	Group-II: Lidocaine Jelly 2%	-3.6750*	.1380	.000	-4.000	-3.350

*. The mean difference is significant at the .05 level.

The mean extubation time in group I was 8.167 ± 0.999 , in group II was 11.040 ± 1.046 and in group III was 7.365 ± 0.8734 minutes. There was a prolongation of extubation time in group II. As P value is < 0.05 this was statistically significant.

CHART 4 – EXTUBATION TIME



BUCKING

TABLE 5 : SHOWING THE BUCKING RATE.

Bucking * Group Crosstabulation

			Group			Total
			Group-I: Betamethaso ne Gel 0.05%	Group-II: Lidocaine Jelly 2%	Group-III: Control (No Jelly Applied)	
Bucking	Positive	Count	1	3	12	16
		% within Group	1.0%	3.0%	12.0%	5.3%
	Negative	Count	99	97	88	284
		% within Group	99.0%	97.0%	88.0%	94.7%
Total		Count	100	100	100	300
		% within Group	100.0%	100.0%	100.0%	100.0%

Chi-Square Tests

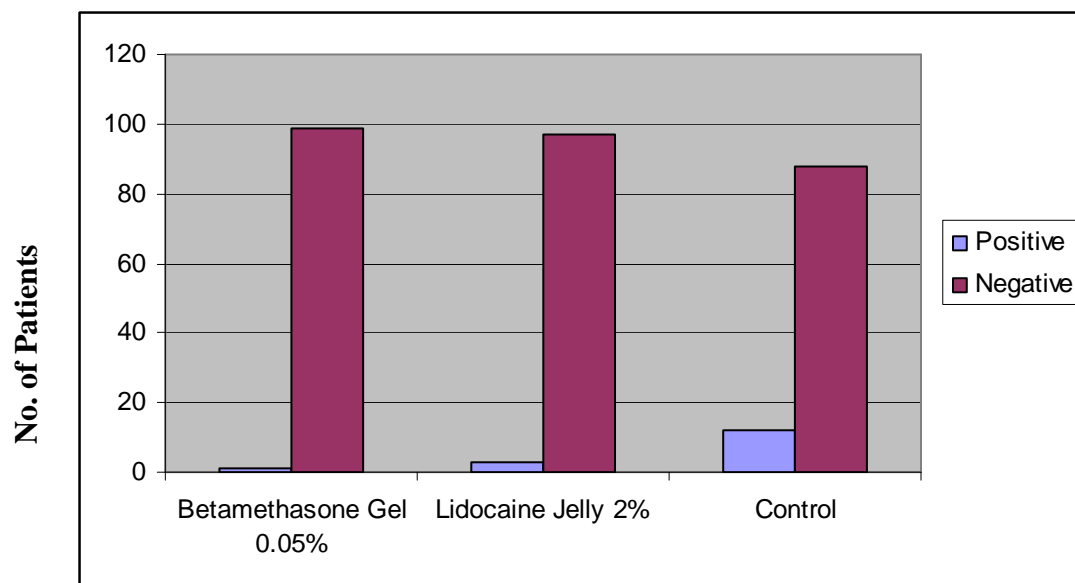
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	13.600 ^a	2	.001
Likelihood Ratio	13.396	2	.001
Linear-by-Linear Association	11.943	1	.001
N of Valid Cases	300		

a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 5.33.

The percentage rate of bucking in group I was 1 %, in group II was 3% and in group III was 12 %. The lowest bucking percentage was in group-I. As P value is <0.05 this was statistically significant.

CHART 5

BUCKING



SEVERITY SCORES FOR SORE THROAT AT 1,6,12 AND 24 HOURS

The severity of sore throat measured using grading system is shown below.

Table 6: showing scores [0, 1, 2 and 3] for sore throat at different time intervals.

Descriptives									
		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						Lower Bound	Upper Bound		
Sore Throat - 1 Hour	Group-I: Betamethasone Gel 0.05%	100	.21	.456	.046	.12	.30	0	2
	Group-II: Lidocaine Jelly 2%	100	.78	.799	.080	.62	.94	0	3
	Group-III: Control (No Jelly Applied)	100	1.53	.771	.077	1.38	1.68	0	3
	Total	300	.84	.878	.051	.74	.94	0	3
Sore Throat - 6 Hours	Group-I: Betamethasone Gel 0.05%	100	.17	.428	.043	.09	.25	0	2
	Group-II: Lidocaine Jelly 2%	100	1.01	.859	.086	.84	1.18	0	3
	Group-III: Control (No Jelly Applied)	100	1.51	.759	.076	1.36	1.66	0	3
	Total	300	.90	.896	.052	.79	1.00	0	3
Sore Throat - 12 Hours	Group-I: Betamethasone Gel 0.05%	100	.13	.338	.034	.06	.20	0	1
	Group-II: Lidocaine Jelly 2%	100	1.04	.803	.080	.88	1.20	0	3
	Group-III: Control (No Jelly Applied)	100	1.31	.800	.080	1.15	1.47	0	3
	Total	300	.83	.848	.049	.73	.92	0	3
Sore Throat - 24 Hours	Group-I: Betamethasone Gel 0.05%	100	.08	.307	.031	.02	.14	0	2
	Group-II: Lidocaine Jelly 2%	100	1.39	.920	.092	1.21	1.57	0	3
	Group-III: Control (No Jelly Applied)	100	1.36	.835	.084	1.19	1.53	0	3
	Total	300	.94	.957	.055	.83	1.05	0	3

ANOVA						
		Sum of Squares	df	Mean Square	F	Sig.
Sore Throat - 1 Hour	Between Groups	87.660	2	43.830	91.248	.000
	Within Groups	142.660	297	.480		
	Total	230.320	299			
Sore Throat - 6 Hours	Between Groups	91.707	2	45.853	91.961	.000
	Within Groups	148.090	297	.499		
	Total	239.797	299			
Sore Throat - 12 Hours	Between Groups	76.447	2	38.223	81.943	.000
	Within Groups	138.540	297	.466		
	Total	214.987	299			
Sore Throat - 24 Hours	Between Groups	111.847	2	55.923	102.406	.000
	Within Groups	162.190	297	.546		
	Total	274.037	299			

Post Hoc Tests

Multiple Comparisons

Tukey HSD

Dependent Variable	(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Sore Throat - 1 Hour	Group-I: Betamethasone Gel 0.05%	Group-II: Lidocaine Jelly 2%	-.570*	.098	.000	-.80	-.34
		Group-III: Control (No Jelly Applied)	-1.320*	.098	.000	-1.55	-1.09
	Group-II: Lidocaine Jelly 2%	Group-I: Betamethasone Gel 0.05%	.570*	.098	.000	.34	.80
		Group-III: Control (No Jelly Applied)	-.750*	.098	.000	-.98	-.52
	Group-III: Control (No Jelly Applied)	Group-I: Betamethasone Gel 0.05%	1.320*	.098	.000	1.09	1.55
		Group-II: Lidocaine Jelly 2%	.750*	.098	.000	.52	.98
Sore Throat - 6 Hours	Group-I: Betamethasone Gel 0.05%	Group-II: Lidocaine Jelly 2%	-.840*	.100	.000	-1.08	-.60
		Group-III: Control (No Jelly Applied)	-1.340*	.100	.000	-1.58	-1.10
	Group-II: Lidocaine Jelly 2%	Group-I: Betamethasone Gel 0.05%	.840*	.100	.000	.60	1.08
		Group-III: Control (No Jelly Applied)	-.500*	.100	.000	-.74	-.26
	Group-III: Control (No Jelly Applied)	Group-I: Betamethasone Gel 0.05%	1.340*	.100	.000	1.10	1.58
		Group-II: Lidocaine Jelly 2%	.500*	.100	.000	.26	.74
Sore Throat - 12 Hours	Group-I: Betamethasone Gel 0.05%	Group-II: Lidocaine Jelly 2%	-.910*	.097	.000	-1.14	-.68
		Group-III: Control (No Jelly Applied)	-1.180*	.097	.000	-1.41	-.95
	Group-II: Lidocaine Jelly 2%	Group-I: Betamethasone Gel 0.05%	.910*	.097	.000	.68	1.14
		Group-III: Control (No Jelly Applied)	-.270*	.097	.015	-.50	-.04
	Group-III: Control (No Jelly Applied)	Group-I: Betamethasone Gel 0.05%	1.180*	.097	.000	.95	1.41
		Group-II: Lidocaine Jelly 2%	.270*	.097	.015	.04	.50
Sore Throat - 24 Hours	Group-I: Betamethasone Gel 0.05%	Group-II: Lidocaine Jelly 2%	-1.310*	.105	.000	-1.56	-1.06
		Group-III: Control (No Jelly Applied)	-1.280*	.105	.000	-1.53	-1.03
	Group-II: Lidocaine Jelly 2%	Group-I: Betamethasone Gel 0.05%	1.310*	.105	.000	1.06	1.56
		Group-III: Control (No Jelly Applied)	.030	.105	.956	-.22	.28
	Group-III: Control (No Jelly Applied)	Group-I: Betamethasone Gel 0.05%	1.280*	.105	.000	1.03	1.53
		Group-II: Lidocaine Jelly 2%	-.030	.105	.956	-.28	.22

*. The mean difference is significant at the .05 level.

NPar Tests

Kruskal-Wallis Test

Ranks

	Group	N	Mean Rank
Sore Throat - 1 Hour	Group-I: Betamethasone Gel 0.05%	100	87.78
	Group-II: Lidocaine Jelly 2%	100	147.00
	Group-III: Control (No Jelly Applied)	100	216.73
	Total	300	
Sore Throat - 6 Hours	Group-I: Betamethasone Gel 0.05%	100	79.23
	Group-II: Lidocaine Jelly 2%	100	162.71
	Group-III: Control (No Jelly Applied)	100	209.57
	Total	300	
Sore Throat - 12 Hours	Group-I: Betamethasone Gel 0.05%	100	80.08
	Group-II: Lidocaine Jelly 2%	100	173.38
	Group-III: Control (No Jelly Applied)	100	198.04
	Total	300	
Sore Throat - 24 Hours	Group-I: Betamethasone Gel 0.05%	100	69.94
	Group-II: Lidocaine Jelly 2%	100	190.76
	Group-III: Control (No Jelly Applied)	100	190.81
	Total	300	

Test Statistics^{a,b}

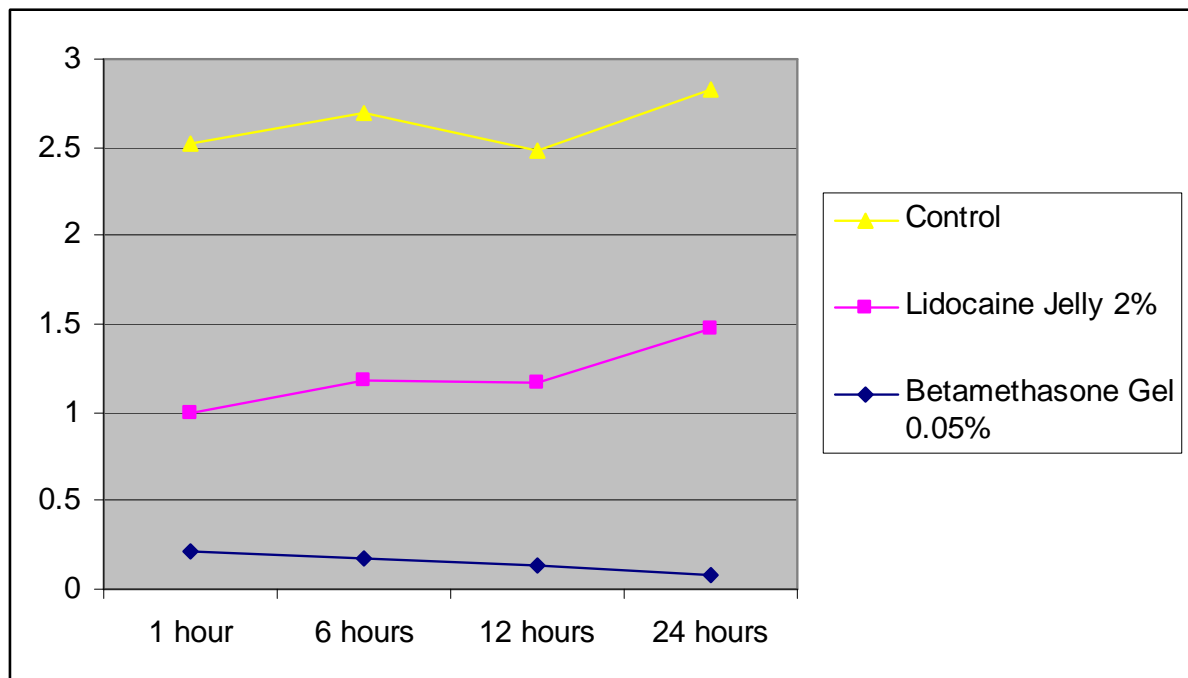
	Sore Throat - 1 Hour	Sore Throat - 6 Hours	Sore Throat - 12 Hours	Sore Throat - 24 Hours
Chi-Square	127.401	131.189	117.940	145.116
df	2	2	2	2
Asymp. Sig.	.000	.000	.000	.000

a. Kruskal Wallis Test

b. Grouping Variable: Group

The mean scores for sore throat in group I was always lower than mean scores in group II and III at all the specified time intervals over the 24 hr evaluation period. The P value was <0.05 over all the four evaluation periods and hence it was statistically significant. In addition, at 24 hrs, the mean score is comparable between the groups II and III. As P value is > 0.05 , hence there was no statistically significant difference between group II and III.

CHART 6 – MEAN SCORES FOR SORE THROAT



SEVERITY SCORES FOR COUGH AT 1,6,12 AND 24 HOURS

Table 7: showing the scores for cough at different time intervals.

		Descriptives							
		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						Lower Bound	Upper Bound		
Cough - 1 Hour	Group-I: Betamethasone Gel 0.05%	100	.31	.598	.060	.19	.43	0	2
	Group-II: Lidocaine Jelly 2%	100	.27	.548	.055	.16	.38	0	2
	Group-III: Control (No Jelly Applied)	100	.60	.696	.070	.46	.74	0	2
	Total	300	.39	.632	.037	.32	.47	0	2
Cough - 6 Hours	Group-I: Betamethasone Gel 0.05%	100	.19	.443	.044	.10	.28	0	2
	Group-II: Lidocaine Jelly 2%	100	.17	.428	.043	.09	.25	0	2
	Group-III: Control (No Jelly Applied)	100	.38	.582	.058	.26	.50	0	2
	Total	300	.25	.497	.029	.19	.30	0	2
Cough - 12 Hours	Group-I: Betamethasone Gel 0.05%	100	.19	.506	.051	.09	.29	0	2
	Group-II: Lidocaine Jelly 2%	100	.15	.411	.041	.07	.23	0	2
	Group-III: Control (No Jelly Applied)	100	.25	.435	.044	.16	.34	0	1
	Total	300	.20	.453	.026	.15	.25	0	2
Cough - 24 Hours	Group-I: Betamethasone Gel 0.05%	100	.16	.420	.042	.08	.24	0	2
	Group-II: Lidocaine Jelly 2%	100	.09	.288	.029	.03	.15	0	1
	Group-III: Control (No Jelly Applied)	100	.27	.468	.047	.18	.36	0	2
	Total	300	.17	.405	.023	.13	.22	0	2

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
Cough - 1 Hour	Between Groups	6.487	2	3.243	8.517	.000
	Within Groups	113.100	297	.381		
	Total	119.587	299			
Cough - 6 Hours	Between Groups	2.687	2	1.343	5.615	.004
	Within Groups	71.060	297	.239		
	Total	73.747	299			
Cough - 12 Hours	Between Groups	.507	2	.253	1.236	.292
	Within Groups	60.890	297	.205		
	Total	61.397	299			
Cough - 24 Hours	Between Groups	1.647	2	.823	5.165	.006
	Within Groups	47.340	297	.159		
	Total	48.987	299			

Post Hoc Tests

Multiple Comparisons

Tukey HSD

Dependent Variable	(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Cough - 1 Hour	Group-I: Betamethasone Gel 0.05%	Group-II: Lidocaine Jelly 2%	.040	.087	.891	-.17	.25
		Group-III: Control (No Jelly Applied)	-.290*	.087	.003	-.50	-.08
		Group-II: Lidocaine Jelly 2%	-.040	.087	.891	-.25	.17
	Group-II: Lidocaine Jelly 2%	Group-I: Betamethasone Gel 0.05%	-.330*	.087	.001	-.54	-.12
		Group-III: Control (No Jelly Applied)	.290*	.087	.003	.08	.50
		Group-I: Betamethasone Gel 0.05%	.330*	.087	.001	.12	.54
Cough - 6 Hours	Group-I: Betamethasone Gel 0.05%	Group-II: Lidocaine Jelly 2%	.020	.069	.955	-.14	.18
		Group-III: Control (No Jelly Applied)	-.190*	.069	.018	-.35	-.03
		Group-II: Lidocaine Jelly 2%	-.020	.069	.955	-.18	.14
	Group-II: Lidocaine Jelly 2%	Group-I: Betamethasone Gel 0.05%	-.210*	.069	.007	-.37	-.05
		Group-III: Control (No Jelly Applied)	.190*	.069	.018	.03	.35
		Group-I: Betamethasone Gel 0.05%	.210*	.069	.007	.05	.37
Cough - 12 Hours	Group-I: Betamethasone Gel 0.05%	Group-II: Lidocaine Jelly 2%	.040	.064	.807	-.11	.19
		Group-III: Control (No Jelly Applied)	-.060	.064	.617	-.21	.09
		Group-II: Lidocaine Jelly 2%	-.040	.064	.807	-.19	.11
	Group-II: Lidocaine Jelly 2%	Group-I: Betamethasone Gel 0.05%	-.100	.064	.264	-.25	.05
		Group-III: Control (No Jelly Applied)	.060	.064	.617	-.09	.21
		Group-I: Betamethasone Gel 0.05%	.100	.064	.264	-.05	.25
Cough - 24 Hours	Group-I: Betamethasone Gel 0.05%	Group-II: Lidocaine Jelly 2%	.070	.056	.431	-.06	.20
		Group-III: Control (No Jelly Applied)	-.110	.056	.127	-.24	.02
		Group-II: Lidocaine Jelly 2%	-.070	.056	.431	-.20	.06
	Group-II: Lidocaine Jelly 2%	Group-I: Betamethasone Gel 0.05%	-.180*	.056	.005	-.31	-.05
		Group-III: Control (No Jelly Applied)	.110	.056	.127	-.02	.24
		Group-I: Betamethasone Gel 0.05%	.180*	.056	.005	.05	.31

*. The mean difference is significant at the .05 level.

NPar Tests

Kruskal-Wallis Test

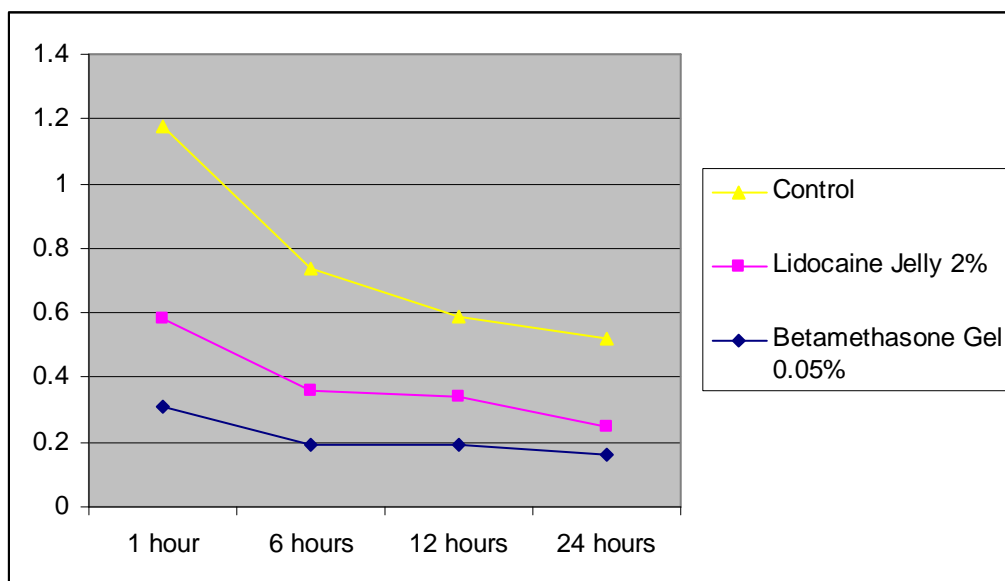
Ranks

	Group	N	Mean Rank
Cough - 1 Hour	Group-I: Betamethasone Gel 0.05%	100	139.91
	Group-II: Lidocaine Jelly 2%	100	136.21
	Group-III: Control (No Jelly Applied)	100	175.38
	Total	300	
Cough - 6 Hours	Group-I: Betamethasone Gel 0.05%	100	143.39
	Group-II: Lidocaine Jelly 2%	100	140.48
	Group-III: Control (No Jelly Applied)	100	167.64
	Total	300	
Cough - 12 Hours	Group-I: Betamethasone Gel 0.05%	100	146.31
	Group-II: Lidocaine Jelly 2%	100	144.07
	Group-III: Control (No Jelly Applied)	100	161.13
	Total	300	
Cough - 24 Hours	Group-I: Betamethasone Gel 0.05%	100	147.28
	Group-II: Lidocaine Jelly 2%	100	139.37
	Group-III: Control (No Jelly Applied)	100	164.86
	Total	300	

The mean scores for cough was similar in group I and II at 1,6 and 24 hours. There is no statistically significant difference between group I and II since the P value is > 0.05 . The incidence of cough was less in groups I and II compared to group III at 1,6 and 24 hrs but at 12 hours, there was no statistically significant difference between all the three groups [P value > 0.05]

CHART 7

MEAN SCORES FOR COUGH



SEVERITY SCORES FOR HOARSENESS AT 1,6,12 AND 24 HOURS

Table 8: showing the scores for hoarseness at different intervals

		Descriptives							
		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						Lower Bound	Upper Bound		
Hoarseness - 1 Hour	Group-I: Betamethason Gel 0.05%	100	.13	.393	.039	.05	.21	0	2
	Group-II: Lidocaine Jelly 2%	100	.30	.503	.050	.20	.40	0	2
	Group-III: Control (No Jelly Applied)	100	.50	.674	.067	.37	.63	0	2
	Total	300	.31	.555	.032	.25	.37	0	2
Hoarseness - 6 Hours	Group-I: Betamethason Gel 0.05%	100	.16	.420	.042	.08	.24	0	2
	Group-II: Lidocaine Jelly 2%	100	.32	.510	.051	.22	.42	0	2
	Group-III: Control (No Jelly Applied)	100	.52	.674	.067	.39	.65	0	2
	Total	300	.33	.563	.032	.27	.40	0	2
Hoarseness - 12 Hours	Group-I: Betamethason Gel 0.05%	100	.08	.273	.027	.03	.13	0	1
	Group-II: Lidocaine Jelly 2%	100	.32	.469	.047	.23	.41	0	1
	Group-III: Control (No Jelly Applied)	100	.59	.698	.070	.45	.73	0	2
	Total	300	.33	.550	.032	.27	.39	0	2
Hoarseness - 24 Hours	Group-I: Betamethason Gel 0.05%	100	.06	.239	.024	.01	.11	0	1
	Group-II: Lidocaine Jelly 2%	100	.27	.468	.047	.18	.36	0	2
	Group-III: Control (No Jelly Applied)	100	.42	.496	.050	.32	.52	0	1
	Total	300	.25	.441	.025	.20	.30	0	2

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
Hoarseness - 1 Hour	Between Groups	6.860	2	3.430	11.941	.000
	Within Groups	85.310	297	.287		
	Total	92.170	299			
Hoarseness - 6 Hours	Between Groups	6.507	2	3.253	10.960	.000
	Within Groups	88.160	297	.297		
	Total	94.667	299			
Hoarseness - 12 Hours	Between Groups	13.020	2	6.510	25.009	.000
	Within Groups	77.310	297	.260		
	Total	90.330	299			
Hoarseness - 24 Hours	Between Groups	6.540	2	3.270	18.781	.000
	Within Groups	51.710	297	.174		
	Total	58.250	299			

Post Hoc Tests

Multiple Comparisons

Tukey HSD

Dependent Variable	(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Hoarseness - 1 Hour	Group-I: Betamethasone Gel 0.05%	Group-II: Lidocaine Jelly 2%	-.170	.076	.066	-.35	.01
		Group-III: Control (No Jelly Applied)	-.370*	.076	.000	-.55	-.19
	Group-II: Lidocaine Jelly 2%	Group-I: Betamethasone Gel 0.05%	.170	.076	.066	-.01	.35
		Group-III: Control (No Jelly Applied)	-.200*	.076	.024	-.38	-.02
	Group-III: Control (No Jelly Applied)	Group-I: Betamethasone Gel 0.05%	.370*	.076	.000	.19	.55
		Group-II: Lidocaine Jelly 2%	.200*	.076	.024	.02	.38
Hoarseness - 6 Hours	Group-I: Betamethasone Gel 0.05%	Group-II: Lidocaine Jelly 2%	-.160	.077	.096	-.34	.02
		Group-III: Control (No Jelly Applied)	-.360*	.077	.000	-.54	-.18
	Group-II: Lidocaine Jelly 2%	Group-I: Betamethasone Gel 0.05%	.160	.077	.096	-.02	.34
		Group-III: Control (No Jelly Applied)	-.200*	.077	.027	-.38	-.02
	Group-III: Control (No Jelly Applied)	Group-I: Betamethasone Gel 0.05%	.360*	.077	.000	.18	.54
		Group-II: Lidocaine Jelly 2%	.200*	.077	.027	.02	.38
Hoarseness - 12 Hours	Group-I: Betamethasone Gel 0.05%	Group-II: Lidocaine Jelly 2%	-.240*	.072	.003	-.41	-.07
		Group-III: Control (No Jelly Applied)	-.510*	.072	.000	-.68	-.34
	Group-II: Lidocaine Jelly 2%	Group-I: Betamethasone Gel 0.05%	.240*	.072	.003	.07	.41
		Group-III: Control (No Jelly Applied)	-.270*	.072	.001	-.44	-.10
	Group-III: Control (No Jelly Applied)	Group-I: Betamethasone Gel 0.05%	.510*	.072	.000	.34	.68
		Group-II: Lidocaine Jelly 2%	.270*	.072	.001	.10	.44
Hoarseness - 24 Hours	Group-I: Betamethasone Gel 0.05%	Group-II: Lidocaine Jelly 2%	-.210*	.059	.001	-.35	-.07
		Group-III: Control (No Jelly Applied)	-.360*	.059	.000	-.50	-.22
	Group-II: Lidocaine Jelly 2%	Group-I: Betamethasone Gel 0.05%	.210*	.059	.001	.07	.35
		Group-III: Control (No Jelly Applied)	-.150*	.059	.031	-.29	-.01
	Group-III: Control (No Jelly Applied)	Group-I: Betamethasone Gel 0.05%	.360*	.059	.000	.22	.50
		Group-II: Lidocaine Jelly 2%	.150*	.059	.031	.01	.29

*. The mean difference is significant at the .05 level.

NPar Tests

Kruskal-Wallis Test

Ranks

	Group	N	Mean Rank
Hoarseness - 1 Hour	Group-I: Betamethasone Gel 0.05%	100	127.52
	Group-II: Lidocaine Jelly 2%	100	151.83
	Group-III: Control (No Jelly Applied)	100	172.15
	Total	300	
Hoarseness - 6 Hours	Group-I: Betamethasone Gel 0.05%	100	128.38
	Group-II: Lidocaine Jelly 2%	100	151.26
	Group-III: Control (No Jelly Applied)	100	171.86
	Total	300	
Hoarseness - 12 Hours	Group-I: Betamethasone Gel 0.05%	100	118.52
	Group-II: Lidocaine Jelly 2%	100	153.08
	Group-III: Control (No Jelly Applied)	100	179.90
	Total	300	
Hoarseness - 24 Hours	Group-I: Betamethasone Gel 0.05%	100	122.47
	Group-II: Lidocaine Jelly 2%	100	152.74
	Group-III: Control (No Jelly Applied)	100	176.29
	Total	300	

Test Statistics^{a,b}

	Hoarseness - 1 Hour	Hoarseness - 6 Hours	Hoarseness - 12 Hours	Hoarseness - 24 Hours
Chi-Square	22.493	20.178	40.175	34.667
df	2	2	2	2
Asymp. Sig.	.000	.000	.000	.000

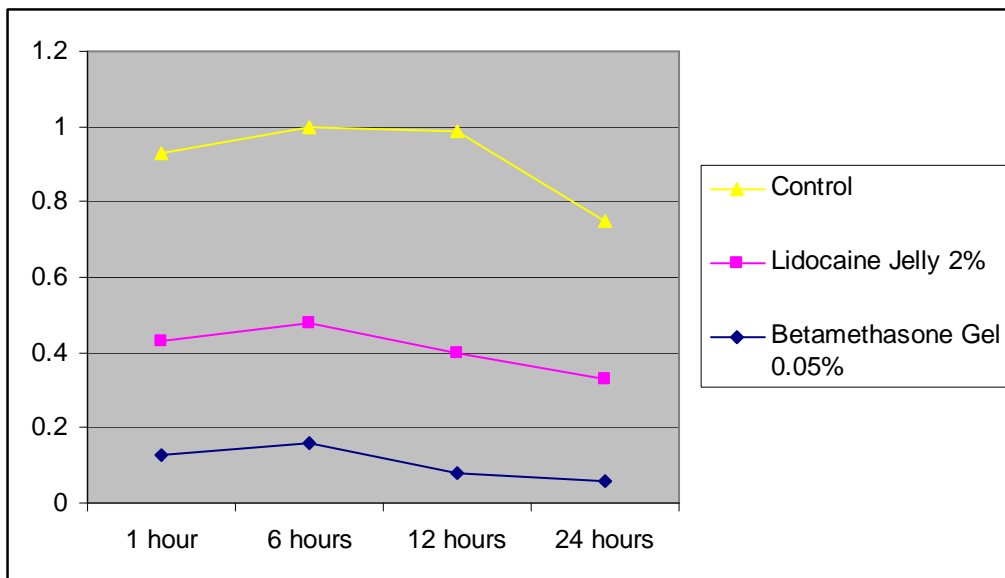
a. Kruskal Wallis Test

b. Grouping Variable: Group

The mean scores for hoarseness in group I was always lower than mean scores in group II and III at all the specified time intervals over the 24 hour evaluation period. The P value was less than 0.05 over all the four evaluation periods and hence it was statistically significant.

CHART 8

MEAN SCORES FOR HOARSENESS OF VOICE



DISCUSSION

Endo tracheal intubation is the placement of a flexible tube into the trachea to maintain an open airway or acts as a conduit through which to administer anaesthetic gases and vapours. The main indications for tracheal intubation are: ¹⁵

1. Air way protection
2. Maintenance of patent airway
3. Application of positive pressure ventilation
4. Pulmonary toileting and
5. Maintenance of adequate level of oxygenation.

Endo tracheal tubes are classified into cuffed and uncuffed. cuffed tracheal tubes are commonly used to facilitate positive pressure ventilation and protect from aspiration into airway. Again cuffed tubes are divided into low volume high pressure cuffed and high volume low pressure cuffed tubes. High pressure cuffed tubes are associated with potential ischemic damage to the tracheal mucosa therefore it is unsuitable for prolonged duration of intubation and ventilation. Low pressure cuffs might have a large contact surface area with the tracheal mucosa which predispose to higher incidence of sore throat, spontaneous extubation and difficult insertion because of the

floppy cuff. None the less, low pressure cuffs are commonly recommended because of lower risk of mucosal damage to tracheal mucosa.^{15,16}

The most frequent side effect of intubation is sore throat with a reported incidence ranging from 24% to 90% The important factors which affect the incidence of post intubation sore throat are irritation and inflammation of the airway, trauma to the airway mucosa, cuff design, cuff pressure, tube size and lubricants used. The other common side effects are post operative cough and hoarseness of voice. Although the exact patho physiologic mechanism responsible for post intubation throat complaints are not elucidated, mucosal damage to the trachea and pressure induced tracheal mucosal capillary hypo perfusion are thought to be the causative factors for tracheal morbidity.^{1,9,10,12}

Coughing during emergence from general anaesthesia is a big concern and the goal of an anaesthesiologist should be smooth emergence with minimal coughing. Coughing during emergence probably results from irritation of the respiratory mucosa by the endotracheal tube and its cuff. Coughing could result in sore throat, tachycardia, increased BP, arrhythmias and precipitation of myocardial ischemia in patients with coronary artery disease. It also causes increased intra thoracic, intra abdominal pressure with consequent increase in venous pressure which in turn leads to increased

bleeding from wound site, increased intra cranial and intra ocular pressure.

1,9,10,11,19

Hoarseness is another problem which makes the patient distressed. It indicates some amount of vocal cord injury because of tracheal tube size. However it has been proposed that post operative sore throat may be caused by the activation of tracheal pain receptors and coughing on emergence and in the post extubation period are thought to be due to stimulation of irritant rapidly adapting stretch receptors in the trachea and larynx. Blocking of these receptors can decrease the post operative sore throat, cough and other post intubation problems.

Many interventions were applied to prevent POSTCH such as use of smaller size tracheal tubes, lower pressure in the cuffs, application of topical lidocaine, IV administration of lidocaine and inhalational of steroids post operatively. More recently post operative administration of IV dexamethasone has shown beneficial analgesic, anti inflammatory and anti emetic actions. Its prophylactic use significantly decreased the incidence of sore throat after extubation. ^{2,12,19}

It is clear to understand the anti inflammatory role of steroids from previous studies. Therefore the application of betamethasone gel to the tracheal tube might reduce the incidence of post operative sore throat, cough and hoarseness of voice. It has been proved that application of local

anaesthetic jelly limits potential damage to the tracheal mucosa because it suppresses bucking on the tracheal tube. Previous small studies were done to evaluate the effectiveness of betamethasone gel and lidocaine jelly in preventing POSTCH.^{2,4,12,19}

This study was conducted to compare the incidence of POSTCH following application of betamethasone gel to the tracheal tube against lidocaine jelly and control groups in a randomized controlled study. The demographic profile of the patients was similar in all three groups. There was no difference between the three groups with respect to the type of surgery, duration of surgery and the anaesthetic management.

In this study, a high volume low pressure cuff tube was used in order to avoid tracheal mucosal ischemic damage caused by high pressure cuff. P.A. Sumathi, Asif kazemi, Masoomah tabari, Athif Akram, Ayoub and Dhanpal were also used low pressure cuffed tracheal tubes made of poly vinyl chloride. In the present study, 2.5 ml of 0.05 % betamethasone and 2 % lidocaine jelly were used to lubricate the endotracheal tube from the lower part of the cuff to a distance of 17 cm from the tip proximally in order to cover the contact area of the tube with trachea, larynx, vocal cords and oropharyngeal structures. P.A. Sumathi et al used 2.5 ml of 0.05 % betamethasone and 2% lidocaine to apply on the tracheal tube from the lower part of the cuff to 15 cm from the tip proximally. Tabari et al applied 0.05 %

betamethasone to all portions of the endotracheal tube that come into contact with post pharyngeal structures, vocal cords and trachea not just to the tip and cuff of the tracheal tube. Akram and Kazemi were used 2.5 ml of betamethasone gel to lubricate from the tip to the level of 15 cm upwards. Ayoub utilized 2.5 ml of betamethasone to apply from the lower portion of the cuff to a level of 15 cm upwards from the same. Stride in his study applied 1% Hydrocortisone cream from the tip to 5 cm above the cuff. Already proven fact is that wide spread steroid application over endotracheal tube reduces post operative throat morbidities.^{3,4,5,12,18,19}

EXTUBATION TIME

The time duration between the stoppage of nitrous oxide to the time of extubation in minutes. In the present study, the mean extubation time was 7.36 minutes in the control group, in lidocaine jelly group it was 11.04 minutes and in betametasone gel group it was 8.16 minutes. The prolongation of the extubation time in the lidocaine jelly group was due to a markedly improved tolerance of the tracheal tube.

BUCKING

The occurrence of bucking on the endotracheal tube at extubation was observed and recorded in all three groups. The rate of bucking was less in betamethasone group compared to lidocaine and control groups. Out of 100 cases only one patient had bucking in betametasone group, three in lidocaine

and 12 in control group. From this, it was clear that betamethasone reduced bucking at extubation when compared to lidocaine and control groups. The previous studies done by P.A.sumathi, Tabari, Akram and Kazemi did not include bucking at extubation. In this present study, bucking on extubation is included since it causes damage to the tracheal mucosa which in turn contributes to post operative throat problems.^{3,4,12,15}

SORE THROAT

In the present study, we assessed sore throat at different time intervals from 1 hour after extubation up to 24 hours using scoring system questionnaire for sore throat. The mean scores for sore throat in betamethasone group at 1hr 0.21, 6 hours 0.17, 12 hours 0.13 and 24 hrs 0.08 whereas in lidocaine group 0.78, 1.01, 1.04 and 1.39 at 1, 6, 12 and 24 hrs respectively. The occurrence of sore throat was higher in control group. There was a significant decrease in the mean scores for sore throat in the betamethasone group at all the time intervals i.e; 1, 6, 12 and 24 hours compared to lidocaine and control groups [P value <0.05], indicating a decrease in the severity of post operative sore throat in the betamethasone group. An interesting finding was observed that sore throat at 24 hours was comparable between lidocaine and control group. As P value is > 0.05, hence it was not statistically significant. **P.A.Sumathi**¹⁹ found that there was a decrease in severity of sore throat, cough and hoarseness in betamethasone

group than in lidocaine and control groups at 1,6,12 and 24 hrs [P value > 0.05].

COUGH

In this study the mean scores for cough was similar and comparable between betamethasone and lidocaine groups at 1,6,12 and 24 hours. There was no statistically significant difference between betamethasone and lignocaine groups with respect to cough [P value > 0.05]. At 12 hours there was no significant difference between all three groups [P > 0.05].

HOARSENESS

The mean score for hoarseness in group I was less when compared to lidocaine and control groups at 1, 12 and 24 hours. There was a statistically significant difference between betamethasone and other groups [P value >0.05]. It was concluded that betamethasone gel reduced post operative hoarseness significantly when compared to lidocaine jelly except at 6 hours.

The positive finding of this study is that the application of betamethasone gel is effective in decreasing the occurrence and severity of post operative sore throat, cough and hoarseness. Previous studies by **Asif Kazemi**³ compared use of betamethasone gel with control group. They found that the beneficial effects of betamethasone when used to lubricate the tube that come into having a contact with trachea, larynx, vocal cords and posterior pharynx. Sumathi et al compared betamethasone against lidocaine

and control group. They concluded that the use of betamethasone to lubricate the endotracheal tube effectively decreases sore throat, cough and hoarseness after operation.¹⁹ However, in this study, the bucking at extubation was not recorded. Our study results confirmed the observations made by previous authors. We had designed a different study by enrolling a larger sample of participants and control group is also added. This study has allowed to consider extubation protocol and recorded the occurrence of bucking on tube at extubation. Our findings showed lower rate of bucking at extubation in betamethasone group compared to lidocaine and control group. The dose of betamethasone gel used in this study was equivalent to 4 mg of prednisolone and that of lidocaine jelly was 50 mg, which is in the safe clinical range for both drugs. Though there was a concern that the possibility of flaring up of infection with topical steroid application, there were no reports of adverse effects secondary to betamethasone gel application on endotracheal tube. The drawbacks in the present study are that intra cuff pressure monitoring was not done and the correlation between bucking and severity of postoperative throat morbidities could not be made out.

CONCLUSION

From the present study, it can be concluded that betamethasone gel application on endotracheal tube significantly reduces post operative sore throat when compared to lidocaine jelly but the lidocaine jelly has got a comparable effect as betamethasone gel in reducing postoperative cough and hoarseness of voice.

SUMMARY

The present study entitled "A prospective randomized controlled study to compare the application of betamethasone gel and lidocaine jelly on tracheal tube to reduce post operative sore throat, cough and hoarseness of voice" was carried out at Rajiv Gandhi government general hospital ,attached to Madras Medical College, Chennai after obtaining ethics committee clearance.

The study population consisted of 300 patients aged between 18 to 60 years of either sex undergoing elective general, orthopaedic and ear surgeries divided into three groups of 100 each.

Group I Betamethasone gel 0.05%, Group II Lidocaine 2% jelly and Group III Control [no jelly applied].

TABLE 9
SUMMARY OF THE STUDY

PARTICULARS	GROUP I	GROUP II	GROUP III
Mean age [yrs]	32.84± 11.31	31.29± 10.81	32.16 ±11.49
Male: Female	50:50	47:53	58:42
Mean duration of surgery	97.40 ±37.0	89.35 ±31.9	92.95±32.7
Mean extubation time [min]	8.16 ±0.99	11.04±1.04	7.36±0.87

Mean scores for Sore throat

1 Hour	0.21±0.45	0.78 ±0.79	1.53±0.77
6 Hours	0.17 ±0.42	1.01±0.85	1.51±0.75
12 Hours	0.13 ±0.33	1.04 ±0.80	1.31±0.80
24 Hours	0.08 ±0.30	1.39 ±0.92	1.36±0.83

COUGH

PARTICULARS	GROUP I	GROUP II	GROUP III
1 Hour	0.31±0.59	0.27±0.54	0.60±0.69
6 Hours	0.19±0.44	0.17±0.42	0.38±0.58
12 Hours	0.19±0.50	0.15±0.41	0.25±0.43
24 Hours	0.16±0.42	0.09±0.28	0.27±0.46

HOARSENESS

PARTICULARS	GROUP I	GROUP II	GROUP III
1 Hour	0.13±0.39	0.30±0.50	0.50±0.674
6 Hours	0.16±0.42	0.32±0.51	0.52±0.67
12 Hours	0.08±0.27	0.32±0.46	0.59±0.69
24 Hours	0.06±0.23	0.27±0.46	0.42±0.49

In conclusion, application of 0.05% betamethasone gel results in a significant decrease in post operative sore throat when compared to lidocaine jelly but the lidocaine jelly has got a comparable effect as betamethasone in reducing cough and hoarseness of voice.

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ANNEXURES

PRE ANAESTHETIC EVALUATION

History

General physical examination

Systemic examination

Cardio respiratory system

Respiratory system

Pulse Rate

Blood Pressure

Airway

Neck and Spine

ASA PHYSICAL STATUS

ANAESTHETIC MANAGEMENT

Pre medication

Oral Alprazolam 0.25 mg, Ranitidine

150 mg, Metoclopramide 10 mg

Induction

Inj.Fentanyl 2 mcg /kg,

Inj.Thiopentone 5 mg/kg, Inj.Atracurium 0.5 mg /kg

Attempts taken for intubation

Size of the tracheal tube used

Maintenance: 50 % nitrous oxide, 50 % oxygen and Halothane 0.8%

Nitrous cut off time

Reversal

Inj.Neostigmine and Inj.Glycopyrrolate

Extubation time

SCORING FOR SORE THROAT COUGH AND HOARSENESS

SORE THROAT COUGH

HOARSENESS

1 HR

6 HRS

12 HRS

24 HRS

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI-3

EC Reg No.ECR/270/Inst./TN/2013
Telephone No. 044 25305301
Fax : 011 25363970

CERTIFICATE OF APPROVAL

To
Dr. STALIN R,
Postgraduate M.D. Anaesthesiology,
Madras Medical College,
Chennai – 600 003.

Dear Dr.Stalin R,


The Institutional Ethics Committee has considered your request and approved your study titled “ **A Prospective, randomized controlled study to compare application of betamethasone gel and lidocaine jelly over tracheal tube to reduce post operative sore throat, cough and hoarseness of voice.**” **No.53082014.**

The following members of Ethics Committee were present in the meeting held on 05.08.2014 conducted at Madras Medical College, Chennai-3.

- | | |
|--|----------------------|
| 1. Dr.C.Rajendran, M.D., | : Chairperson |
| 2. Dr.R.Vimala, M.D., Dean, MMC, Ch-3 | : Deputy Chairperson |
| 3. Prof.B.Kalaiselvi, M.D., Vice-Principal, MMC, Ch-3 | : Member Secretary |
| 4. Prof.R.Nandhini, M.D., Inst.of Pharmacology, MMC | : Member |
| 5. Dr.G.Muralidharan, Director Incharge, Inst.of Surgery | : Member |
| 6. Prof.K.Ramadevi, Director i/c, Inst.of Biochemistry, MMC | : Member |
| 7. Prof.Saraswathy, M.D., Director, Pathology, MMC, Ch-3 | : Member |
| 8. Prof.Tito, M.D., Director i/c, Inst.of Internal Medicine, MMC | : Member |
| 9. Thiru S.Rameshkumar, Administrative Officer | : Lay Person |
| 10.Thiru S.Govindasamy, B.A., B.L., | : Lawyer |
| 11.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
Institutional Ethics Committee
MADRAS MEDICAL COLLEGE
Chennai - 600 003

TURNITIN PLAGIARISM SCREEN SHOT

The screenshot displays the Turnitin Document Viewer interface. The document title is "A prospective randomized controlled study to compare application of betamethasone" by RAMACHANDRAN, RAM, dated 201220015. The overall similarity score is 20% (OUT OF 8). The interface includes tabs for "Originality", "GradeMark", and "PeerMark". The main content area shows the "INTRODUCTION" section of the document, which discusses endotracheal intubation and its complications. A specific sentence is highlighted in blue, indicating a match with a source. On the right, a "Match Overview" sidebar lists eight sources with their respective similarity percentages.

Match Overview

Rank	Source	Similarity
1	H. M. Krishna. "Controll... Publication	4%
2	Submitted to University... Student paper	2%
3	www.authorstream.com Internet source	1%
4	www.sambahq.org Internet source	1%
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6	Allen, George. "Using ... Publication	1%
7	www.giccity.org Internet source	1%
8	file.zums.ac.ir Internet source	1%

INTRODUCTION

Endotracheal intubation is a routine part of delivering anaesthetic gases and vapours to the patients undergoing surgeries. It is not without risks. Sore throat is the most common complaint following intubation. Cough and hoarseness are other problems that follow intubation. Although these are minor sequelae, they are very distressing to the patients. The reported value for post operative sore throat and hoarseness of voice ranging from 24% to 90% even under good intubating conditions.

Different factors were identified to correlate with occurrence of these complications, including irritation and inflammation of the



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Word count: 7,112
Character count: 56,932
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INTRODUCTION

Endotracheal intubation is a routine part of delivering anaesthetic gases and vapours to the patients undergoing surgeries. It is not without risks. Sore throat is the most common complaint following intubation. Cough and hoarseness are other problems that follow intubation. Although these are minor sequelae, they are very distressing to the patients. The reported value for post operative sore throat and hoarseness of voice ranging from 24% to 90 % even under good intubating conditions.

Different factors were identified to correlate with occurrence of these complications, including irritation and inflammation of the airway, traumatization of airway mucosa, tracheal mucosal hypoperfusion induced by pressure, tracheal tube contact with vocal cords, size of endotracheal tube, cuff design, cuff pressure and lastly duration of surgery.

Various interventions have been introduced to reduce post operative throat complaints, such as use of smaller size endotracheal tubes, lower intra cuff pressure, application of topical lidocaine, post operative inhalation of steroids and use of steroid coated tubes. In addition to these, post operative IV

INFORMATION SHEET

Investigator :

Name of the Participant:

Title: “A Prospective, randomized controlled study to compare application of betamethasone gel and lidocaine jelly over tracheal tube to reduce post operative sore throat , cough and hoarseness of voice”.

You are invited to take part in this research study. We have got approval from the IEC. You are asked to participate because you satisfy the eligibility criteria. We want to compare application of betamethasone gel and lidocaine jelly over tracheal tube to reduce post operative sore throat, cough and hoarseness of voice after general tracheal anaesthesia

What is the Purpose of the Research:

In this study is done to compare the application of betamethasone gel, lidocaine jelly over tracheal tube with control group after general anaesthesia in respect to incidence of,

1. Sorethroat
2. Cough
3. Hoarseness of voice

The Study Design:

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

Group 1-Betamethasone gel.

Group 2-Lidocaine jelly.

Group 3-Control

Benefits

Expected reduction in severity of sore throat , cough , hoarseness of voice after application of betamethasone and lignocaine jelly over tracheal tube which leads to subjective feeling of relief from distress

Risks

Although flaring up of local subtle infection is a possibility with topical steroid application , there are no reports of adverse effects secondary to betamethasone gel application over tracheal tube.

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 controlled study to compare application of betamethasone gel and lidocaine jelly over tracheal tube to reduce post operative sore throat , cough and hoarseness of voice”.

Study center:

INSTITUTE OF ANAESTHESIOLOGY AND CRITICAL CARE,
RAJIV GANDHI GOVT. GENERAL HOSPITAL,
MADRAS MEDICAL COLLEGE,
CHENNAI 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:

KEY TO MASTER CHART

I.P. NO = In patient number

M = Male

F = Female

+ = present

- = absent

S. No	IP No	Age (Years)	Sex	Duration of Surgery (Min)	Type of Surgery	Extubation Time (Min)	Bucking	Scoring System (0,1,2,3)																
								Sore Throat			Cough			Hoarseness										
								1 Hr	6 Hr	12 Hr	24 Hr	1 Hr	6 Hr	12 Hr	24 Hr	1 Hr	6 Hr	12 Hr	24 Hr					
21	54223	19	F	45	Fibro Adenoma Excision	9.5	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
22	30073	23	M	50	Myringoplasty	7	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
23	10018	36	F	90	Pleomorphic Adenoma Excision	8.5	-	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	
24	17899	22	F	60	Myringoplasty	9	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
25	53877	18	M	150	ORIF # Femur	8.5	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
26	56812	37	M	140	ORIF # Humerus	9	-	1	0	0	0	0	0	0	1	1	1	1	1	2	1	1	1	
27	62147	37	M	45	Bone Biopsy	7.5	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
28	51676	19	F	45	Fibro Adenoma Excision	7	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
29	52787	52	F	90	Mastectomy	7.5	-	0	0	0	0	2	1	0	0	0	0	0	0	0	0	0	0	0
30	67116	53	F	100	Mastectomy	8	-	1	1	0	0	0	0	0	0	0	2	1	1	1	1	1	0	0
31	28360	20	F	50	Pre Auricular Sinus Excision	9	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
32	43554	35	F	120	Tympano Mastoid Exploration	9	-	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
33	86214	48	F	90	Mastectomy	9.5	-	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
34	85366	50	F	100	Mastectomy	8	-	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
35	51441	35	M	90	ORIF # Humerus	8.5	-	0	0	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0
36	53663	19	M	120	ORIF # Humerus	7	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
37	84253	50	F	110	Cortical Mastoidectomy	7	-	0	0	0	0	2	1	0	0	0	0	0	0	0	0	0	0	0
38	81903	20	F	90	Cortical Mastoidectomy	7	-	0	0	0	0	2	1	0	0	0	0	0	0	0	0	0	0	0
39	81777	30	M	60	Myringoplasty	9	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
40	79420	18	M	180	Revision Mastoidectomy	8.5	-	0	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0
41	53794	32	F	60	Cervical Lymph Node Excision	9	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
42	53817	36	F	60	Axillary Lipoma Excision	8.5	-	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0

S. No	IP No	Age (Years)	Sex	Duration of Surgery (Min)	Type of Surgery	Extubation Time (Min)	Bucking	Scoring System (0,1,2,3)															
								Sore Throat			Cough			Hoarseness									
								1 Hr	6 Hr	12 Hr	24 Hr	1 Hr	6 Hr	12 Hr	24 Hr	1 Hr	6 Hr	12 Hr	24 Hr				
87	67167	21	M	130	Tympano Mastoid Exploration	8	-	1	0	0	0	2	1	1	0	0	0	0	0	0	0	0	
88	68559	22	M	45	Myringoplasty	8.5	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
89	66529	40	F	140	Tympano Mastoid Exploration	7-	0	0	0	0	0	0	0	0	1	2	1	0	0	0	0	0	
90	63793	18	F	140	Modified Radical Mastoidectomy	7.8	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
91	28070	36	M	45	Myringoplasty	9	-	0	0	0	1	1	1	1	2	1	1	1	1	1	1	1	0
92	64575	22	F	60	Fibro Adenoma Excision	8	-	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	1
93	45454	60	M	180	Flap Cover Gluteal Region	9	-	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
94	51019	35	M	180	# ORIF Proximal Humerus	8.5	-	1	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0
95	64621	25	M		ORIF # Clavicle	7	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
96	33683	18	F	140	ORIF # Supracondylar Humerus	7.5	-	1	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0
97	78884	23	M	90	ORIF # Zygoma	7.5	-	0	0	0	0	1	1	2	1	1	1	1	1	1	1	0	0
98	77321	40	M	90	ORIF Galeazzi #	7	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
99	78790	18	M	150	ORIF Supracodylar # Humerus	8.5	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
100	78992	44	M	120	ORIF # Clavicle	8	-	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	1

S. No	IP No	Age (Years)	Sex	Duration of Surgery (Min)	Type of Surgery	Extubation Time (Min)	Bucking	Scoring System (0,1,2,3)												
								Sore Throat			Cough			Hoarseness						
								1 Hr	6 Hr	12 Hr	24 Hr	1 Hr	6 Hr	12 Hr	24 Hr	1 Hr	6 Hr	12 Hr	24 Hr	
21	22311	18	F	45	Myringoplasty	12.5	-	0	0	1	3	0	0	0	0	0	0	1	1	0
22	14657	30	M	100	Cortical Masoidectomy	10	-	1	1	2	3	2	1	1	0	0	0	0	0	0
23	65591	19	F	45	Fibro Adenoma Excision	11	-	1	1	0	1	1	0	0	0	0	1	0	0	1
24	60942	25	F	60	Fibro Adenoma Excision	11.5	-	0	1	0	1	0	0	0	0	0	0	0	1	1
25	63920	19	M	90	Gynaecomastia Webster's Operation	11	-	1	0	2	3	0	0	0	0	0	1	1	1	1
26	62670	42	F	70	Fibro Adenoma Excision	11.5	-	0	1	0	0	0	0	0	0	0	1	0	0	0
27	63396	40	F	120	ORIF both bone # Forearm	12	-	2	2	3	1	0	0	0	0	0	0	0	0	0
28	64325	32	F	120	ORIF supracondylar # Humerus	10	-	0	1	2	2	1	1	0	0	0	0	0	0	0
29	59431	18	M	90	ORIF distal Radius #	9.5	-	0	0	1	1	0	0	0	0	1	1	1	1	1
30	62142	40	F	120	ORIF both bone # Forearm	9	-	2	1	0	1	0	0	0	0	0	0	0	0	0
31	62326	32	F	45	Fibro Adenoma Excision	12.5	-	1	1	2	2	0	0	0	1	0	0	0	0	0
32	65589	57	F	90	Soft Tissue Tumor Lt. Arm Excision	12	-	1	1	0	0	0	0	0	0	0	1	1	1	0
33	66061	45	F	60	Lymph node neck Excision	10	-	0	0	1	2	0	0	0	0	0	1	1	1	0
34	55740	47	F	90	Mastectomy	10	-	1	2	1	1	0	0	0	0	0	0	0	0	0
35	68806	26	F	80	Lympectomy Breast	11	-	0	1	2	2	1	1	2	0	0	0	0	0	0
36	70345	47	F	90	Phylloides Tumor Excision	12.5	-	1	3	2	2	1	2	0	0	0	1	1	1	0
37	73665	28	F	40	Fibro Adenoma Excision	11	-	0	1	2	3	2	0	0	0	0	0	0	0	0
38	73003	34	F	45	Lipoma Back Excision	10.5	-	0	2	1	1	0	0	0	0	0	1	0	0	0
39	58581	45	M	80	ORIF # Lat. Condyle Humerus	10	-	0	1	1	1	0	0	0	0	0	0	0	0	0
40	62314	33	M	120	ORIF # Shaft of Humerus	11	-	3	3	2	1	0	0	0	0	0	0	1	1	0
41	77408	26	M	130	ORIF both bone # Forearm	13	-	1	0	0	0	0	0	0	0	0	0	0	0	0
42	77485	18	M	60	Implant Exit	12.5	-	0	0	1	2	0	0	0	0	1	0	0	0	1

S. No	IP No	Age (Years)	Sex	Duration of Surgery (Min)	Type of Surgery	Extubation Time (Min)	Bucking	Scoring System (0,1,2,3)														
								Sore Throat			Cough			Hoarseness								
								1 Hr	6 Hr	12 Hr	24 Hr	1 Hr	6 Hr	12 Hr	24 Hr	1 Hr	6 Hr	12 Hr	24 Hr			
65	89213	30	M	90	Superficial Parotidectomy	10	-	3	2	2	3	0	0	0	0	0	0	0	0	0	0	0
66	86642	40	F	90	Phylloides Tumor Excision	11	-	3	2	2	3	0	0	0	0	0	0	0	0	0	0	0
67	80162	40	M	45	Lymph node neck Excision	11.5	-	1	1	1	2	0	0	0	0	0	0	0	0	0	0	0
68	86126	23	F	45	Fibro Adenoma Excision	12	-	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
69	67854	40	F	90	Mastectomy	12	-	0	1	1	1	0	0	0	0	0	1	1	1	1	1	0
70	17290	18	M	120	Tympano Mastoid Exploration	11	-	1	2	1	2	2	1	1	0	0	0	0	0	0	0	0
71	20112	28	F	140	Tympano Mastoid Exploration	12	-	2	3	1	1	0	0	0	0	0	0	0	0	0	0	0
72	25958	29	F	40	Myringoplasty	9.5	-	1	1	0	1	0	0	0	0	0	1	1	1	0	0	0
73	30395	19	M	180	Modified Radical Mastoidectomy	10.5	-	1	1	1	0	0	0	0	0	0	1	1	1	1	1	1
74	21464	47	M	140	Modified Radical Mastoidectomy	9.5	-	2	1	1	1	0	0	0	0	1	2	1	0	0	0	0
75	26624	40	M	60	Ear Mass Excision	10	-	1	1	1	2	0	0	0	0	0	0	1	0	0	0	0
76	48856	22	M	140	Inside Out Mastoidectomy	11.5	-	2	2	1	2	1	1	0	0	1	1	1	1	1	1	0
77	25674	55	F	90	Cortical Masoidectomy	10	-	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
78	74357	42	M	120	ORIF both bone # Forearm	11.5	-	0	0	1	2	1	0	0	0	0	0	0	0	0	0	0
79	54543	28	M	90	Sequestrectomy Humerus	10	-	0	0	0	1	0	0	0	0	0	0	0	0	0	1	1
80	79256	45	M	120	Clavicle # ORIF	10	-	0	1	2	3	2	0	0	0	0	1	1	0	0	0	0
81	28152	35	M	90	Meibornian Gland Tumor Excision	11.5	-	1	2	1	1	0	0	0	0	1	1	1	0	0	0	0
82	75281	25	M	120	Mandible ORIF #	12	-	0	0	1	2	0	0	0	0	0	0	0	0	0	1	1
83	51619	35	M	90	SSG Raw area Forearm	12.5	-	1	1	0	0	0	0	0	0	0	0	0	0	0	1	1
84	67103	18	M	90	ORIF Lt. Condyle #	11	-	1	1	2	3	0	0	0	0	0	1	1	0	0	0	0
85	45999	26	M	120	Giant Cell Tumor Humerus Excision	9.5	-	1	1	2	3	0	0	0	0	0	0	0	0	0	0	0
86	70524	36	M	60	Implant Exit	9	-	0	0	1	2	0	0	0	0	1	1	0	0	0	0	0

S. No	IP No	Age (Years)	Sex	Duration of Surgery (Min)	Type of Surgery	Extubation Time (Min)	Bucking	Scoring System (0,1,2,3)											
								Sore Throat			Cough			Hoarseness					
								1 Hr	6 Hr	12 Hr	24 Hr	1 Hr	6 Hr	12 Hr	24 Hr	1 Hr	6 Hr	12 Hr	24 Hr
87	36405	23	M	90	ORIF Radial #	11	-	1	0	1	3	0	1	1	0	0	0	0	1
88	75078	18	M	60	Excision Cheek Mass	12.5	-	0	0	1	2	0	0	0	0	0	1	1	0
89	85795	30	F	45	Fibro Adenoma Excision	11	-	0	0	1	1	0	0	0	0	1	2	1	0
90	84572	33	M	60	Lipoma Back Excision	11	-	1	1	2	1	0	0	0	1	0	0	0	0
91	89483	44	F	90	Duct Ectasia Microductectomy	9.5	-	1	1	0	0	0	0	0	0	0	0	0	0
92	86542	20	F	40	Fibro Adenoma Excision	9	-	0	0	0	1	1	0	0	0	0	0	0	0
93	90346	18	F	70	Fibro Adenoma Excision	10	-	0	0	0	1	0	0	0	0	0	0	0	0
94	71582	45	M	90	Superficial Parotidectomy	12	-	2	1	1	0	0	0	0	0	0	0	1	1
95	13597	40	F	90	Cortical Masoidectomy	12.5	-	1	1	1	2	1	1	1	1	0	0	1	0
96	14012	18	F	140	Modified Radical Mastoidectomy	10.5	-	3	2	2	2	0	0	0	0	0	0	0	0
97	33742	24	F	45	Myringoplasty	11	-	1	1	1	1	1	1	1	0	1	1	1	1
98	35321	25	M	80	Myringoplasty	13	-	0	0	1	2	0	0	0	0	1	1	0	0
99	43554	35	F	120	Tympanomastoid Exploration	10	-	1	2	3	2	0	0	0	0	0	0	1	1
100	29774	26	F	90	Pre Auricular Sinus Excision	10.5	-	1	0	0	0	0	0	0	1	0	1	0	0

Group-III: Control (No Jelly Applied)

S. No	IP No	Age (Years)	Sex	Duration of Surgery (Min)	Type of Surgery	Extubation Time (Min)	Bucking	Scoring System (0,1,2,3)															
								Sore Throat			Cough			Hoarseness									
								1 Hr	6 Hr	12 Hr	24 Hr	1 Hr	6 Hr	12 Hr	24 Hr	1 Hr	6 Hr	12 Hr	24 Hr				
1	88328	46	F	100	Breast Lumpectomy	9	-	2	2	2	1	0	0	0	1	0	0	0	0	0	0	0	
2	68357	35	M	120	ORIF Humerus #	9.8	-	2	1	1	2	0	0	0	0	1	0	0	0	0	0	0	
3	39613	18	F	120	Modified Radical Mastectomy	8	-	3	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0
4	22841	35	F	90	Cortical Mastoidectomy	7.8	-	2	2	1	1	1	0	0	0	0	0	0	0	0	0	0	0
5	25758	28	M	120	Tympano Mastoid Exploration	6.5	+	2	1	1	1	1	0	0	0	1	1	0	1	1	2	1	1
6	87971	29	M	90	Sub Mandibular Gland Excision	7	-	1	2	2	3	2	1	0	0	1	1	1	1	2	1	1	1
7	90346	18	F	40	Fibro Adenoma Excision	7.5	-	1	1	1	1	0	0	0	1	1	1	1	1	2	1	2	1
8	63145	30	M	45	Neuro Fibroma Excision	7	-	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1
9	88314	45	F	60	Fibro Adenoma Excision	9	-	1	1	0	0	0	0	0	1	0	0	1	1	1	1	1	0
10	55654	18	M	90	ORIF Supra Condylar # Humerus	8.5	+	1	2	2	2	1	1	1	1	0	0	0	1	1	1	1	1
11	55913	43	M	120	Raw Area SSG Forearm	8	-	3	3	1	3	0	0	0	1	1	2	0	1	2	0	0	0
12	61952	35	F	120	ORIF Both Bone # Forearm	7	-	1	2	1	1	1	0	0	0	1	2	1	2	1	2	1	0
13	73416	46	M	100	ORIF Clavicle #	6.5	-	1	1	2	1	2	1	1	1	0	2	1	0	2	1	0	0
14	89256	47	F	100	Granulomatous Mastitis Excision	7	-	1	1	1	0	0	2	1	0	1	0	1	1	1	1	1	1
15	25364	18	M	160	Tympano Mastoid Exploration	7	-	3	3	2	2	1	0	0	0	0	0	0	0	0	0	0	0
16	20787	25	M	160	Tympano Mastoid Exploration	6.5	-	2	3	3	2	1	0	0	0	0	0	0	0	0	0	0	0
17	35824	29	F	120	Cortical Mastoidectomy	6	-	1	1	2	3	2	1	0	0	0	1	2	1	0	1	2	0
18	24718	18	F	60	Pre Auricular Sinus Excision	6	+	1		0	2	0	1	1	0	0	1	1	0	1	2	1	1
19	208536	18	M	180	Modified Radical Mastectomy	7.5	-	2	2	1	1	0	0	0	0	0	0	0	0	0	0	0	0
20	83049	40	F	60	Fibro Adenoma Excision	7	-	1	2	1	1	1	0	0	1	1	2	1	1	2	1	1	1

S. No	IP No	Age (Years)	Sex	Duration of Surgery (Min)	Type of Surgery	Extubation Time (Min)	Bucking	Scoring System (0,1,2,3)															
								Sore Throat			Cough			Hoarseness									
								1 Hr	6 Hr	12 Hr	24 Hr	1 Hr	6 Hr	12 Hr	24 Hr	1 Hr	6 Hr	12 Hr	24 Hr				
43	63706	18	M	120	Supra Condylar # Humerus ORIF	7.5	-	2	1	1	1	1	1	0	1	1	1	0	1	0	0	0	
44	18705	39	M	120	Sub Mandibular Gland Excision	6.5	-	2	3	2	2	1	0	0	0	0	0	0	0	0	0	0	0
45	28465	19	F	90	Sub Mandibular Gland Excision	7.5	-	2	2	1	1	0	0	0	0	0	0	0	0	0	1	0	0
46	69125	27	M	180	Modified Radical Mastectomy	7	-	2	1	1	1	0	0	0	0	0	0	0	0	0	1	0	0
47	65623	58	M	60	Ear Mass Excision	7	-	1	2	3	2	1	1	0	0	0	0	0	0	0	0	0	0
48	68169	42	F	90	Mastectomy	9	+	1	1	2	1	0	0	0	0	1	0	0	0	0	0	1	0
49	51193	18	F	60	Fibro Adenoma Excision	9.5	-	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
50	72896	20	M	120	ORIF # Humerus	8	-	2	3	2	1	1	1	1	1	1	0	0	0	0	0	0	0
51	19295	23	M	100	Sub Mandibular Gland Excision	7	-	1	2	1	1	0	0	0	0	1	1	2	1	1	0	1	1
52	59201	22	M	120	Tympano Mastoid Exploration	9	-	3	2	1	1	1	1	1	1	0	0	0	0	1	1	0	1
53	51832	52	M	120	Tympano Mastoid Exploration	8	-	3	2	2	1	0	0	0	0	1	2	0	1	2	0	1	0
54	56159	45	M	120	ORIF Clavicle #	6.5	-	1	1	0	0	0	0	0	0	0	0	0	1	2	1	2	1
55	60656	26	M	120	Cortical Mastoidectomy	7	-	1	1	2	3	2	1	0	0	1	0	0	1	0	0	0	0
56	22253	24	M	90	Hernia Repair	70	-	1	1	2	1	0	0	0	1	1	1	1	1	0	1	0	1
57	24861	18	F	120	ORIF Galeazzi #	7.5	-	1	0	0	1	2	2	1	1	1	1	1	0	0	0	0	0
58	82346	20	F	60	Fibro Adenoma Excision	7.5	+	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0
59	68356	18	M	120	ORIF Supra Condylar # Humerus	7	-	2	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0
60	34408	18	M	120	Cortical Mastoidectomy	6.5	-	2	3	2	2	1	0	0	0	0	0	1	0	0	1	0	0
61	52197	45	F	90	Supra Condylar # Humerus ORIF	7	-	1	1	1	1	1	0	0	0	1	1	1	0	0	0	0	0
62	63790	23	F	60	Myringoplasty	7	-	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
63	19133	22	M	45	Myringoplasty	7.5	-	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
64	58614	45	F	90	Mastectomy	8	+	2	1	1	1	1	1	1	0	0	0	1	1	0	1	0	1

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								Sore Throat			Cough			Hoarseness										
								1 Hr	6 Hr	12 Hr	24 Hr	1 Hr	6 Hr	12 Hr	24 Hr	1 Hr	6 Hr	12 Hr	24 Hr					
65	68352	28	M	150	Flap Cover Thigh	6.5	-	1	1	1	1	1	1	0	1	0	0	0	0	0	0	0		
66	83156	35	F	60	Lipoma Back Excision	6.5	-	3	2	2	2	2	2	1	0	1	0	0	0	0	0	0	0	
67	93398	18	M	120	Cortical Mastoidectomy	7	-	3	2	2	2	2	2	1	0	0	1	2	2	1	1	1	1	
68	35675	30	M	60	Myringoplasty	6	-	2	2	2	2	2	2	1	0	0	1	2	2	1	1	1	1	
69	63156	28	M	90	ORIF Clavicle #	7.5	-	1	1	1	1	1	1	0	0	1	2	1	1	1	1	1	1	
70	80541	28	F	70	Breast Lumpectomy	7	-	2	2	2	2	3	3	2	1	1	0	1	0	0	0	0	0	0
71	65684	30	M	90	ORIF # Radius	7	+	1	3	3	3	3	3	1	2	0	0	1	1	1	1	1	0	0
72	63152	25	F	50	Fibroadenoma Excision	6	-	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0
73	68127	30	F	60	Axillary Lipoma Excision	7	+	2	2	2	2	2	2	1	0	0	0	0	0	0	0	0	0	1
74	59968	28	M	90	ORIF # Monteggia	7	-	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0
75	62314	34	M	90	ORIF # Olecranon	7.5	-	1	2	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0
76	86315	40	F	120	SSG Forearm	7.5	-	1	2	2	2	2	2	1	0	0	0	0	1	1	1	1	0	0
77	71582	40	M	90	Superficial Parotidectomy	7	-	2	1	0	0	0	0	0	0	0	1	0	2	1	0	2	1	1
78	25461	52	F	90	Mastectomy	6.5	-	1	1	1	1	2	2	1	0	0	1	1	1	0	0	0	0	0
79	75889	36	M	120	Flap Cover	7.5	-	3	3	2	2	3	3	2	1	0	0	0	0	0	1	1	1	1
80	70435	50	F	120	Soft Tissue Mass Excision	8	-	3	2	2	2	2	2	1	1	0	0	1	2	2	1	2	2	1
81	65575	52	M	90	Hernia Repair	7	-	1	1	0	1	0	1	0	0	1	0	0	1	0	1	0	0	0
82	60718	55	F	45	Lymph Node Neck Excision	6.5	-	1	0	0	1	0	0	0	0	0	1	1	2	1	1	2	1	1
83	35826	25	M	90	Cortical Mastoidectomy	9	-	2	1	1	1	1	1	0	0	0	0	0	0	1	1	1	1	1
84	38646	27	M	40	Myringoplasty	7.5	-	1	1	1	1	1	1	0	0	0	0	0	1	1	1	1	0	0
85	35641	28	M	60	Myringoplasty	7.5	-	1	1	1	1	2	2	1	2	1	1	2	0	0	0	0	1	1
86	63216	38	M	90	ORIF # Clavicle	6.5	-	1	2	1	2	2	2	0	1	1	0	1	0	0	1	0	0	1

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								Sore Throat			Cough			Hoarseness										
								1 Hr	6 Hr	12 Hr	24 Hr	1 Hr	6 Hr	12 Hr	24 Hr	1 Hr	6 Hr	12 Hr	24 Hr					
87	52831	25	M	60	Otosclerosis Stapedectomy	7	-	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0		
88	70430	18	F	45	Fibro Adenoma Excision	7	-	1	1	1	1	1	0	0	0	0	0	0	0	0	0	1	1	
89	78502	50	F	90	Mastectomy	7.5	-	2	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	
90	82329	50	M	75	Osteopongiosis Stapedectomy	6.5	-	1	1	1	2	1	0	0	0	1	1	0	0	0	0	0	0	
91	62064	48	M	90	ORIF # Clavicle	7	-	2	1	1	2	1	0	0	0	0	0	0	0	0	0	1	1	
92	68788	19	M	150	Rec. Shoulder discolation Repair	8.8	-	2	3	3	2	2	1	1	0	1	0	1	2	1	1	1	1	
93	32180	22	F	90	Adnexal Mass Removal	7	-	1	2	2	1	1	0	0	0	0	0	0	1	1	1	1	1	
94	52650	50	F	90	Breast Lumpectomy	7.5	-	1	1	2	1	0	1	0	1	2	1	1	2	1	1	1	1	
95	63521	38	F	60	Pre Auricular Sinus Excision	8	-	0	1	1	1	1	0	0	1	1	1	1	0	0	0	0	0	
96	28536	25	M	60	Myringoplasty	9	+	1	1	0	2	1	0	0	0	0	0	0	0	0	0	0	1	
97	17896	30	M	140	Tympano Mastoid Exploration	8.5	-	3	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	
98	80181	30	F	50	Fibro Adenoma Excision	6.5	-	1	1	1	1	0	0	0	0	0	0	0	1	1	1	1	0	
99	67821	25	M	60	Gynaeco Mastia Websters	6.5	-	2	1	1	1	0	0	0	0	0	0	0	1	2	1	2	1	
100	80640	32	M	120	ORIF Supra Condylar # Humerus	7.5	-	1	2	3	3	2	1	1	1	2	1	1	2	2	1	2	1	0