

# A Controlled Comparison between Betamethasone Gel and Lidocaine Jelly Applied Over Tracheal Tube to Reduce Postoperative Sore Throat, Cough and Hoarseness of Voice

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## ABSTRACT

**Introduction:** Larynx is the common site of Injury during intubation. Local anesthetic agents, such as Lidocaine gel or spray, were ineffective in preventing sore throat after endotracheal intubation. Although these agents limit injury to tracheal mucosa and prevent cough, they cannot be effective in preventing sore throat because they do not have any anti-inflammatory effects.

**Materials and Methods:** A controlled comparison between Betamethasone gel and Lidocaine jelly applied over tracheal tube to reduce postoperative sore throat, cough and hoarseness of voice. A total number of 120 cases of ASA Gr-I and Gr-II were divided into three groups. 40 of them (Betamethasone group) were intubated with endotracheal tubes applied with Betamethasone gel (0.05%), 40 patients were intubated with ET tubes lubricated with 2% Lidocaine jelly (Lidocaine group) and the remaining 40 received lubrication with water soluble, non-irritating jelly (control group).

**Results:** Statistical analysis showed that Betamethasone gel provided a statistically significant benefit over Lidocaine jelly and the control for the reduction of sore throat at 1hr (P = 0.000016), 12 hrs. (P = 0.00) and 24 hrs. (P = 0.002). It has also been observed that Betamethasone offers a significant advantage over Lidocaine at 24 hrs. to reduce hoarseness of voice (P = 0.005).

**Conclusion:** Betamethasone, due to its anti-inflammatory effect, long duration of action, convenience of usage, cost effectiveness and a statistically proven effect and is a useful drug for reducing post-operative sore throat in the early and late post-operative periods and hoarseness of voice in the late post-operative period.

**Keywords:** Endotracheal intubation, Post-operative, Betamethasone, Lidocaine, Sore throat, Hoarseness of voice

to pulmonary aspiration.<sup>2,3</sup>

Post-operative sore throat, though a minor complication after general anesthesia can be distressing to the patients.<sup>4</sup> This is because of lack of airway humidity, trauma during airway-insertion and suctioning, high anesthetic air flow rates and surgical manipulation of airway and adjacent tissue.<sup>5</sup>

Different factors were known to correlate with occurrence of this complication, including sex, age, season, anesthetic drugs and gases, numbers of trials for intubation, duration of intubation, size of endotracheal tube its type and cuff type and size, site of the surgery, and application of Lidocaine or steroids.<sup>6</sup>

Many agents have been used as lubricants to reduce the incidence of postoperative sore throat with variable efficacy.<sup>7,8</sup>

The present study was undertaken to perform a controlled comparison between Betamethasone gel and Lidocaine jelly applied over tracheal tube to reduce postoperative sore throat, cough and hoarseness of voice.<sup>9,10</sup> Aim of study was to perform a controlled comparison between Betamethasone gel and Lidocaine jelly applied over tracheal tube to reduce postoperative sore throat, cough and hoarseness of voice

## MATERIALS AND METHODS

Institutional Ethics Committee approval and written, informed consent from all patients was obtained.

### Inclusion criteria

The patients fulfilling the following criteria were included in the study:

Age: Between 18 and 50 yr., 2. ASA physical status: class I or II, 3. Surgery (likely to last between 30 and 240 min) under general anaesthesia with orotracheal intubation.

Surgeries included procedures in supine position with expected extubation immediately after the operation.

## INTRODUCTION

Endotracheal intubation is necessary in general anesthesia to control respiration and protect airways. Almost all patients who are intubated for long term or short-term operations, have some degree of airway injury.<sup>1</sup>

Larynx is one of the most common sites of injury, usually manifested as local irritation, inflammation, and even necrosis. Although most of the injuries to the trachea are minor and reversible, some, however, may become severe. Due to edema and granuloma formation, injury to the trachea after extubation may manifest as acute or chronic obstruction of the airway that may be severe enough to necessitate surgical intervention. These injuries can also impair normal function of the larynx and its protective role and predispose the patient

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### Exclusion criteria

The patients with the following characteristics were excluded:

1. Patients undergoing surgeries of the oral cavity and pharynx.
2. Anticipated difficult airway, (Mallampati grade > 2)
3. Surgical duration of >240 min,
4. More than two attempts at intubation,
5. Use of throat packs, oesophageal temperature probes,
6. Patients with upper respiratory tract infection, asthma,
7. Known allergy to study drugs
8. Patients on steroid therapy.
9. Smokers, history of pre-operative sore throat.
10. Pre-anaesthetic evaluation was done in all patients.

One Hundred and twenty patients were randomized into the following three groups, of 40 patients each by the sealed envelope method:

1. **Betamethasone group:** Betamethasone gel 0.05% (Betagel, Micro Labs Limited, Bangalore, India) applied.
2. **Lidocaine group:** Lidocaine 2% jelly (Lox2% jelly, Neon Laboratories, Mumbai, India) applied.
3. **Control group:** Water soluble, non-irritating lubricating jelly (Lubic jelly, Neon Laboratories, Mumbai, India) applied.

### Anesthetic technique

**Pre-medication:** All patients were premeditated with tab Alprazolam 0.25 mg, the night before surgery and tab. Ranitidine 150 mg 2 h before surgery.

**Lubrication of tube:** At induction of anesthesia, Betamethasone gel, Lidocaine jelly, or water soluble non-irritating lubricating jelly was applied on the external surface of tracheal tube. The PVC tracheal tube was lubricated from the distal end of the cuff to a distance of 15 cm from the tip using 2.5 ml of Betamethasone gel, Lidocaine jelly or lubricating jelly, spread uniformly with sterile precautions. Single use PVC tracheal tubes, having low-pressure-high-volume cuffs, of size 8.0 mm, 8.5 mm and 7.0 mm, 7.5 mm internal diameter were used for male and female patients, respectively.

**Induction:** After connecting to standard monitors, adequate i.v. access, and preoxygenation, anaesthesia was induced with i.v. fentanyl 1.5 µg /kg and thiopental sodium 5 mg/kg. I.V. vecuronium bromide 0.1 mg /kg facilitated tracheal intubation after 3 min following induction and assisted ventilation. Direct laryngoscopy was done with the use of a Macintosh laryngoscope blade by applying minimal pressure. All intubations were performed by an anaesthesiology resident with at least 2 yr of experience, who was blinded to group allocation. Immediately after intubation, the tracheal tube cuff was inflated with just enough room air to prevent an audible leak.

**Maintenance:** Anaesthesia was maintained with nitrous oxide 66%, sevoflurane 1–2% in oxygen, and i.v. bolus of vecuronium bromide was repeated intermittently to maintain adequate muscle relaxation. Intracuff pressure was not monitored. Humidifiers or heat and moisture exchangers were not used in any of the groups. The name of the jelly or gel used was not recorded on the anaesthesia chart, but was recorded separately in order to ensure that the anaesthetist in charge of the post-anaesthesia care unit remained blinded to the group

allocation of the patients.

**Reversal and Extubation:** At the end of the surgery, oxygen 100% was administered and residual neuromuscular block was antagonized with ivglycolpyrolate 0.01 mg/kg and neostigmine 0.05 mg/ kg. Oral suctioning by a 12 F suction catheter was done gently just before extubation only under direct vision to avoid trauma to the tissues and to confirm that the clearance of secretions was complete.

The trachea was extubated after deflating the cuff when patient fully awake. All patients received oxygen by a face-mask after operation. Assessment of patients for postoperative sore throat, cough, and hoarseness of voice at 1, 12, 24 h after surgery was carried out by the anaesthetist in charge of the post-anaesthesia care unit, blinded to the group allocation, using the questionnaire mentioned in the following:

#### Score:

##### Sore throat

0	No sore throat
1	Minimal sore throat, less severe than that noted with a cold
2	Moderate sore throat, similar to that noted with a cold
3	Severe sore throat, more severe than that noted with a cold

##### Hoarseness

0	No hoarseness at any time since the operation
1	No hoarseness at the time of interview, but present earlier
2	Hoarseness at the time of interview noted by patient only
3	Hoarseness that is easily noted at the time of interview

##### Cough

0	No cough
1	Minimal cough, less severe than that noted with a cold
2	Moderate cough, similar to that noted with a cold
3	Severe cough, more severe than that noted with a cold

### STATISTICAL ANALYSIS

Data were analyzed by ANOVA (ANOVA Single factor, MS Excel) and post hoc Tukey's T-test wherever appropriate.

### RESULTS

Comparison between the age compositions of the three groups by ANOVA test has yielded a P value of 0.36 (which exceeds 0.05), hence the groups do not differ significantly in terms of age. Comparison between the weight compositions of the three groups by ANOVA test has yielded a P value of 0.53 (which exceeds 0.05), hence the groups do not differ significantly in terms of patient weight. Comparison between the mean duration of surgical procedures of the three groups by ANOVA test has yielded a P value of 0.82 (which exceeds

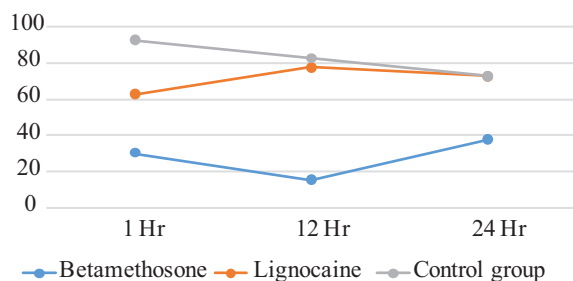
	Betamethasone		Lidocaine		Control		Remarks	
	Mean	S.D	Mean	S.D	Mean	S.D	P-value(from ANOVA test)	Result
Age	34.4	8.79	37	8.41	35.85	5.76	0.36	N.S
Weight	66.98	7.87	65.02	9.113	65.9	5.84	0.53	N.S
Duration of surgery	118.8	57.34	111.25	54.38	116.2	55.03	0.82	N.S

**Table-1:** Age, weight and duration of surgery

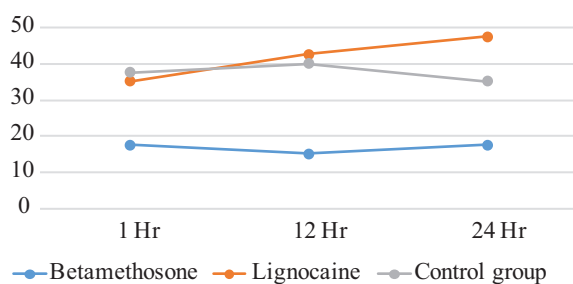
	Betamethasone		Lidocaine		Control Group		Remarks		
	Mean	S.D	Mean	S.D	Mean	S.D	P-Value	Result	TUKEY'S T- Test
<b>Sore Throat</b>									
1 hr.	0.625	1.07	1.275	1.16	1.78	0.851	.000016	S	B > L, B>C L ~ C
12 hrs.	0.25	0.661	1.15	0.76	1.25	0.731	0.00	S	B > L, B>C L ~C
24 hrs.	0.475	0.67	0.95	0.71	0.975	0.724	0.002	S	B > L, B>C L ~ C
<b>Cough</b>									
1 hr.	0.45	0.773	0.45	0.86	0.575	0.863	0.74	N.S.	N.A
12 hrs.	0.2	0.51	0.55	0.80	0.375	0.659	0.07	N.S.	N.A
24 hrs.	0.275	0.591	0.525	0.74	0.3	0.557	0.16	N.S	N.A
<b>Hoarseness</b>									
1 hr.	0.35	0.823	0.425	0.63	0.625	0.885	0.28	N.S.	N.A
12 hrs.	0.275	0.67	0.5	0.63	0.55	0.74	0.17	N.S.	N.A
24 hrs.	0.175	0.38	0.625	0.73	0.425	0.628	0.005	S	B > L, B~C L ~ C

B: Betamethasone; L: Lidocaine; C: Control; S.D: Standard deviation; >: Statically significant advantage; ~: no statistically significant advantage; N. S: Not Significant; S: Significant; N.A: Not Applicable

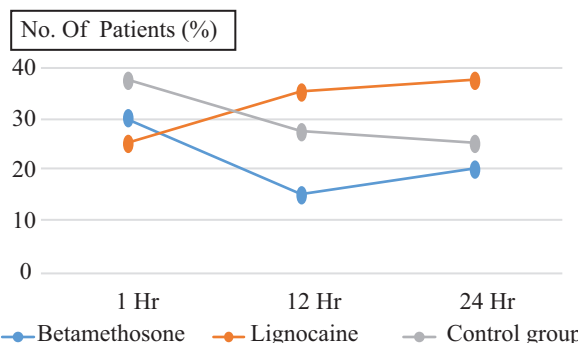
**Table-2:** Incidence of sore throat, hoarseness of voice and cough-intensity wise



**Graph-1:** Percentage incidence sore throat



**Graph-2:** Percentage incidence hoarseness



**Graph-3:** Percentage incidence cough

0.05), hence the groups do not differ significantly in terms of duration of surgery. Therefore, a statistical comparison is possible between these groups.

Comparative analysis of mean severity of sore throat at 1 hr. after surgery has yielded a P value of 0.000016 (which is less than 0.05). Thus it can be concluded that there exists a statistically significant difference in this aspect among the

three groups. Further testing is necessary to find out between which of the groups, the above said difference exists.

Analysis by Post-hoc Tukey's t-test was performed for this purpose. Therefore, there exists no statistically significant difference between Lidocaine and Control groups for the prevention of sore throat at 1 hr. after surgery.

Comparative analysis of mean severity of sore throat at 12 hr. after surgery has yielded a P value of 0.00 (which is less than 0.05). Thus it can be concluded that there exists a statistically significant difference in this aspect among the three groups. Further testing is necessary to find out between which of the groups, the above said difference exists. Analysis by Post-hoc Tukey's t-test was performed for this purpose. Therefore, there exists no statistically significant difference between Lidocaine and Control groups.

Comparative analysis of mean severity of sore throat at 24

hrs. after surgery has yielded a P value of 0.0024 (which is less than 0.05). Thus it can be concluded that there exists a statistically significant difference in this aspect among the three groups. Further testing is necessary to find out between which of the groups, the above said difference exists.

Analysis by Post-hoc Tukey's t-test was performed for this purpose. Therefore, there exists no statistically significant difference between Lidocaine and control groups.

Comparative analysis of mean severity of hoarseness of voice at 1 hr. after surgery has yielded a P value of 0.28 (which exceeds 0.05). Thus it can be concluded that neither Betamethasone nor Lidocaine provide a statistically significant prevention of hoarseness at 1 hr. after surgery, compared to the Control group.

Comparative analysis of mean severity of hoarseness of voice at 12 hrs. after surgery has yielded a P value of 0.17 (which exceeds 0.05). Thus it can be concluded that neither Betamethasone nor Lidocaine provide a statistically significant prevention of hoarseness at 12 hrs. after surgery, compared to the Control group.

Comparative analysis of mean severity of hoarseness of voice at 24 hrs. after surgery has yielded a P value of 0.005 (which is less than 0.05). Thus it can be concluded that there exists a statistically significant difference in this aspect among the three groups. Further testing is necessary to find out between which of the groups, the above said difference exists. Analysis by Post-hoc Tukey's t-test was performed for this purpose. Therefore, there exists no statistically significant difference between Betamethasone-Control and Lidocaine-Control groups.

Comparative analysis of mean severity of cough at 1 hr after surgery has yielded a P value of 0.74 (which exceeds 0.05). Thus it can be concluded that neither Betamethasone nor Lidocaine provide a statistically significant prevention of cough at 1 hr. after surgery, compared to the Control group.

Comparative analysis of mean severity of cough at 12 hrs. after surgery has yielded a P value of 0.07 (which exceeds 0.05). Thus it can be concluded that neither Betamethasone nor Lidocaine provide a statistically significant prevention of cough at 12 hr after surgery, compared to the Control group.

Comparative analysis of mean severity of cough at 24 hrs. after surgery has yielded a P value of 0.16 (which exceeds 0.05). Thus it can be concluded that neither Betamethasone nor Lidocaine provide a statistically significant prevention of cough at 24 hrs. after surgery, compared to the Control group.

## DISCUSSION

Post-intubation complications like sore throat, hoarseness of voice and cough are gaining increasing importance as we strive to minimize complications and improve patient satisfaction.<sup>11</sup>

Many factors such as intubation procedure, diameter of endo-tracheal tube, cuff type and pressure, movement of the patient while intubated (bucking), procedures such as pharyngeal suctioning have been implicated in the evolution of the three complications mentioned above. The mechanism postulated to explain these complications is local irritation

and subsequent inflammatory changes.<sup>12</sup>

Drugs like local anesthetic agents, local and systemic steroids, non-medicated lubricant jellies, Benzydamine and Ketamine gargles and interventions like cuff pressure monitoring (to limit intra-cuff pressure), minimizing pharyngeal suctioning etc., have been employed to reduce the incidence of the above problems,<sup>13-15</sup>

In our study, we have chosen to compare the effect of a steroidal anti-inflammatory agent Betamethasone and a local anesthetic agent, Lidocaine for reducing the incidence of sore throat, hoarseness of voice and cough.

Betamethasone is a long acting steroid with proven anti-inflammatory properties. The preparation we have used is a 0.05% gel (Betagel, Micro labs Limited, Bangalore, India). Its availability in an easy to apply gel form makes its usage convenient. The dosage of Betamethasone used in our study does not exceed 4 mg prednisone equivalent and can hence be regarded as safe. The above factors and existing literature in support of Betamethasone for this very purpose are the reasons for us to choose this drug for our study.

120 subjects had been allocated to 3 groups of 40 each (Betamethasone, Lidocaine and Control) by the sealed envelope method. Statistically arrived P value of less than 0.05 was to be considered as significant.

The groups did not differ significantly in terms of Age (P = 0.36), Weight (P = 0.53) or Duration of surgery (P = 0.82). The Endo-tracheal tube was lubricated prior to intubation and scores were recorded at 1 hr., 12 hrs., 24 hrs. after extubation by interviewing the patient. Each parameter was graded by severity from 0 (absent) to 3 (very severe).

### Sore throat

Statistical analysis of scores for sore throat at 1 hr. showed that Betamethasone was significantly better (P= 0.000016) than Lidocaine (as indicated by Tukey's test, the difference of means (0.65) is greater than HSD (0.56)) and Control group (as indicated by Tukey's test, difference of means (1.15) is greater than HSD (0.56)) while there was no significant difference between Lidocaine and Control groups (as indicated by Tukey's test, difference of means (0.5) is less than HSD (0.56)).

Analysis of scores for sore throat at 12 hr. showed that Betamethasone was significantly better (P=0.00) than Lidocaine (Tukey's test - difference of means (0.9) is greater than HSD (0.39)) and control group (Tukey's test - difference of means (1.0) is greater than HSD (0.39)) while there was no significant difference between Lidocaine and control groups (Tukey's test - difference of means (0.1) is less than HSD (0.39)).

At 24 hrs., analysis of scores for sore throat showed that Betamethasone was significantly better (P= 0.002) than Lidocaine (Tukey's test - difference of means (0.475) > HSD (0.38)) and control group (Tukey's test - difference of means (0.50) > HSD (0.38)) while there was no significant difference between Lidocaine and control groups (Tukey's test - difference of means (0.025) < HSD (0.38)). Thus, we infer from our study that Betamethasone gel is better than Lidocaine as well as the control for prevention of sore throat, both

in the early (1 hr.) as well as late (12 and 24 hrs.) post-operative period.

### Cough

Analysis of scores of cough at 1 hr. showed that there was no significant difference between the three groups ( $P = 0.74$ ). At 12 hrs. too, we could not observe a statistically significant difference ( $P = 0.07$ ). At 24 hrs. after surgery, the  $P$  value for analysis of severity of cough scores was 0.16, indicating that neither intervention provided a statistically significant benefit over the other.

### Hoarseness of voice

Analysis of scores for severity of hoarseness of voice at 1 hr. after surgery yielded a  $P$  value of 0.28, showing no significant difference among the interventions. At 12 hrs., again the difference among the 3 groups was not statistically significant. ( $P=0.17$ ). At 24 hrs. post-surgery, analysis indicated that Betamethasone was better ( $P = 0.005$ ) than Lidocaine (Tukey's test-difference of means (0.45) > HSD (0.32)) while there was no difference between Betamethasone and the control groups (difference of means (0.25) < HSD (0.32)) and Lidocaine and control groups (difference of means (0.25) < HSD (0.32)).

Therefore, we conclude that though at 1 hr. and 12 hrs. post-tubation, there was no significant difference between the groups, at 24 hrs. betamethasone has provided a statistically significant benefit over Lidocaine group in terms of preventing hoarseness. Lidocaine and control groups did not differ at any of the three study times.

Stride PC, (1990) concluded that 1% Hydrocortisone water soluble cream applied over the endo-tracheal tube, offered no reduction in incidence of sore throat. In their study, the cream was applied up to 5cm from the tip of the endo-tracheal tube.<sup>16</sup> In our study, the steroidal gel was applied more extensively so as to cover the parts of the tube coming in contact with the posterior pharyngeal wall as well and not only the tip of the tube which resides beneath the vocal cords. We attribute the benefit observed with Betamethasone in reducing the sore throat, to the widespread application of this gel. Selvaraj et al reported an increase in the incidence of cough and hoarseness in the Lidocaine group compared to the control group.<sup>17</sup> Our study results differ from theirs, and we found that the difference in incidence of cough and hoarseness between Lidocaine and control groups was statistically insignificant. This is probably because the extubation protocol in Selvaraj et al 's study was not standardized, which could have affected the incidence rates.

Sumathi et al reported that Betamethasone caused a significant reduction in incidence of sore throat, cough as well as hoarseness of voice.<sup>18</sup> Our study found that the beneficial effect of Betamethasone was primarily in the reduction of sore throat, while it caused a significant reduction of hoarseness at 24hrs, it was observed that Betamethasone made no statistically significant impact over the reduction of cough.

### CONCLUSION

It can be concluded from our study that, Betamethasone, due to its anti-inflammatory effect, long duration of action, convenience of usage, cost effectiveness and a statistically

proven effect is a useful drug for reducing post-operative sore throat in the early and late post-operative periods and hoarseness of voice in the late post-operative period.

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