

# Effect of Lignocaine Jelly on a Cuff of an Endotracheal Tube on the Postoperative Sore Throat: A Prospective Randomised Study

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**Received: 11 Mar 2026/ Revised: 23 May 2026/ Accepted: 19 Jun 2026**

## ABSTRACT

**Background:** Postoperative sore throat (POST) is a common complication following general anesthesia with endotracheal intubation and may adversely affect postoperative patient comfort and satisfaction. This study evaluated whether application of 2% lignocaine jelly to the cuff of the endotracheal tube (ETT) could reduce the incidence of POST compared with normal saline.

**Methods:** A total of 104 patients under general anesthesia were randomly assigned into 1 of 2 groups. In the lidocaine group (n=52), the distal part of ETTs with tapered-shaped cuff was lubricated with lidocaine jelly. In the control group (n=52), the distal part of ETTs with tapered-shaped cuff was lubricated with normal saline. The incidence of POST, hoarseness, and cough in the post anesthesia patients was compared.

**Results:** The overall incidence of POST was higher in the lignocaine group than in the normal saline group [30 (57%) vs 20 (38%), p=.006]. The incidence of POST at 1 hour postoperatively was higher in the lignocaine group than in the normal saline group [27(51%) vs 16 (31%), p=.003]. The overall incidence of hoarseness for 24 hours postoperatively was comparable (p=.487). The overall incidence of cough for 24 hours postoperatively is higher in the lidocaine group (p=.045).

**Conclusion:** Application of 2% lignocaine jelly to the endotracheal tube cuff did not reduce postoperative sore throat, hoarseness, or cough and was associated with a higher incidence of early postoperative sore throat and cough compared with normal saline. These findings suggest that routine use of lignocaine jelly on the endotracheal tube cuff is not effective for preventing postoperative airway-related complications.

**Key-words:** Gels, Intubation, Lignocaine, Pain, Pharyngitis, Postoperative

## INTRODUCTION

Postoperative sore throat (POST) is one of the most common and distressing minor complications encountered following general anesthesia with endotracheal intubation.<sup>[1,2]</sup>

Although generally considered a self-limiting condition, POST can significantly affect patient comfort, satisfaction, and overall quality of postoperative recovery.<sup>[3,4]</sup> Patients frequently complain of throat pain, irritation, dryness, hoarseness of voice, and difficulty swallowing in the immediate postoperative period.<sup>[5]</sup> The reported incidence of POST varies widely, ranging from 7% to 90%, depending on factors such as patient characteristics, duration of surgery, type and size of endotracheal tube used, cuff pressure, intubation technique, and perioperative airway management practices.<sup>[1,4,5]</sup> As patient satisfaction has become an

### How to cite this article

Mamde R, Korde N, Vaishnao L, Swami A. Effect of Lignocaine Jelly on a Cuff of an Endotracheal Tube on the Postoperative Sore Throat: A Prospective Randomised Study. SSR Inst Int J Life Sci., 2026; 12(4): 10253-10260.



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important indicator of healthcare quality, preventive management of POST is recommended to improve postoperative care and enhance recovery outcomes.<sup>[6,7]</sup>

The development of POST is primarily attributed to mucosal trauma and inflammation caused by laryngoscopy, endotracheal intubation, and prolonged pressure exerted by the endotracheal tube cuff on the tracheal mucosa.<sup>[7-9]</sup> Several factors, including traumatic intubation, repeated intubation attempts, excessive cuff pressure, prolonged duration of anesthesia, and patient-related variables, have been implicated in increasing the risk of POST.<sup>[9,10]</sup> Consequently, numerous preventive strategies have been investigated to reduce its incidence and severity. Among these, local anesthetics have been widely employed prophylactically in an effort to decrease the incidence, intensity, and duration of POST.<sup>[1]</sup>

Lignocaine, owing to its local anesthetic, analgesic, and anti-inflammatory properties, has been used both intravenously and topically for the prevention of POST.<sup>[4,11]</sup> Various methods of administration, including intravenous infusion, topical sprays, nebulization, and lubrication of the endotracheal tube, have been evaluated with varying degrees of success.<sup>[11]</sup> A conventional ETT is equipped with a cylindrical high-volume, low-pressure cuff designed to provide an effective airway seal while minimizing tracheal injury.<sup>[12,13]</sup> However, cuff-related mucosal irritation remains an important contributor to postoperative throat discomfort. To date, limited studies have specifically evaluated the effect of lignocaine jelly applied directly to the cuff of the ETT. Therefore, the present study was undertaken to assess whether lignocaine jelly applied on the cuff of the endotracheal tube could reduce the incidence, severity, and duration of postoperative sore throat following endotracheal intubation under general anesthesia.

## MATERIALS AND METHODS

**Study Design and Participants-** This prospective, randomized, placebo-controlled, parallel-group study was conducted at a single tertiary care center after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants before enrollment. A total of 104 patients scheduled to undergo surgery under general anesthesia with endotracheal intubation were included in the study.

Patients aged 18–80 years belonging to the American Society of Anesthesiologists (ASA) Physical Status I or II were eligible for participation. Exclusion criteria included pre-existing sore throat, recent upper respiratory tract infection, asthma, chronic obstructive pulmonary disease, chronic cough, friable teeth, concurrent use of lignocaine or dexamethasone, recent intake of nonsteroidal anti-inflammatory drugs, presence of a gastric tube, previous head and neck surgery, anticipated difficult airway, Mallampati grade greater than II, rapid sequence induction, more than one intubation attempt, and known hypersensitivity to lignocaine jelly.

**Randomization and Blinding-** Patients were randomly allocated into either the Lignocaine Group or the Normal Saline Group using a random sampling method. Allocation concealment was ensured using sequentially numbered opaque sealed envelopes. The envelopes were opened immediately before induction of anesthesia by a nurse not involved in patient assessment or data collection. The nurse prepared the study lubricant according to group allocation. Postoperative outcome assessments were performed by an investigator blinded to the group assignment.

**Anesthetic Technique-** Standard monitoring, including electrocardiography, non-invasive blood pressure, pulse oximetry, and end-tidal carbon dioxide (EtCO<sub>2</sub>), was instituted before induction of anesthesia. General anesthesia was induced with intravenous propofol (2 mg/kg) and fentanyl (2 µg/kg). Neuromuscular blockade was achieved using rocuronium (0.6–0.8 mg/kg) to facilitate tracheal intubation.

In the Lignocaine Group, the cuffed ETT was lubricated from the distal tip to the distal vocal cord marker using 2% lignocaine jelly (LOX® 2%). In the Normal Saline Group, the same portion of the ETT was lubricated with normal saline. Endotracheal intubation was performed by an experienced anesthesiologist using direct laryngoscopy with a Macintosh size 3 or 4 blade. Endotracheal tubes with an internal diameter of 7.0 mm for females and 7.5 mm for males were used. Correct placement of the tube was confirmed by end-tidal capnography.<sup>[14,15]</sup>

The ETT cuff was inflated with air, and cuff pressure was maintained at 20 mmHg throughout the surgical procedure. Anesthesia was maintained using isoflurane



inhalation. Intravenous paracetamol (10 mg/kg) was administered after induction for perioperative analgesia in both groups. At the conclusion of surgery, residual neuromuscular blockade was reversed with glycopyrrolate (0.01 mg/kg) and neostigmine (0.05 mg/kg). Prior to extubation, gentle oropharyngeal suctioning was performed under direct vision to minimize airway trauma. Extubation was carried out after confirmation of adequate spontaneous ventilation and responsiveness to verbal commands, following which patients were transferred to the post-anesthesia care unit.<sup>[16]</sup>

**Outcome Measures-** The Cormack–Lehane grade of laryngoscopic view was recorded during intubation. Time to intubation was defined as the interval between insertion of the laryngoscope blade into the oral cavity and confirmation of successful tracheal intubation by detection of an end-tidal CO<sub>2</sub> concentration greater than 30 mmHg. Mean arterial pressure and heart rate were recorded immediately before intubation and two minutes after intubation.<sup>[14-17]</sup>

The incidence and severity of postoperative sore throat, hoarseness, and cough were assessed by a blinded investigator at 1, 6, 12, and 24 hours after surgery. Sore throat, hoarseness, and cough were graded using four-point scales (0–3), with higher scores indicating greater severity.

The primary outcome was the incidence of postoperative sore throat within 24 hours after surgery. Secondary outcomes included the incidence and severity of postoperative sore throat, hoarseness, and cough at 1, 6, 12, and 24 hours postoperatively.

Adverse events, including throat numbness, nausea, vomiting, and the need for additional analgesic

medication during the first 24 postoperative hours, were also recorded.

**Statistical Analysis-** Data were entered into Microsoft Excel and analysed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables are presented as mean  $\pm$  standard deviation (SD) and categorical variables as frequency and percentage. Baseline continuous variables were compared using the independent Student's t-test, while categorical variables were analysed using the Chi-square test or Fisher's exact test, as appropriate. A two-sided p-value  $<0.05$  was considered statistically significant.

## RESULTS

Table 1 presents the baseline demographic, airway, anesthetic, and hemodynamic characteristics of the study participants. The mean age was  $48 \pm 13$  years in the lignocaine group and  $49 \pm 14$  years in the normal saline group ( $p=0.702$ ). The proportion of males was 28 (54%) and 33 (63%), respectively ( $p=0.330$ ). Mean body mass index was  $26 \pm 5$  kg/m<sup>2</sup> versus  $27 \pm 5$  kg/m<sup>2</sup> ( $p=0.549$ ). ASA physical status, Mallampati grade, and Cormack–Lehane grading were comparable between groups ( $p=0.488$ ,  $p=0.148$ , and  $p=0.820$ , respectively). The mean intubation time ( $18 \pm 11$  vs.  $18 \pm 10$  s), duration of intubation ( $68 \pm 46$  vs.  $62 \pm 39$  min), pre-intubation MAP ( $79 \pm 14$  vs.  $80 \pm 13$  mmHg), post-intubation MAP ( $98 \pm 19$  vs.  $101 \pm 22$  mmHg), pre-intubation heart rate ( $76 \pm 14$  vs.  $74 \pm 13$  beats/min), and post-intubation heart rate ( $92 \pm 16$  vs.  $92 \pm 21$  beats/min) also showed no statistically significant differences (all  $p>0.05$ ), indicating comparable baseline characteristics.

**Table 1:** Patients & anesthetic characteristics

Variable	Lignocaine (n=52)	Normal Saline (n=52)	p-value
Age (years)	$58 \pm 15$	$56 \pm 16$	0.446
Female/Male	35/17	31/21	0.194
Weight (kg)	$63 \pm 11$	$65 \pm 11$	0.171
Height (cm)	$160 \pm 9$	$161 \pm 8$	0.259
Body Mass Index (kg/m <sup>2</sup> )	$24.5 \pm 3.8$	$24.9 \pm 3.7$	0.239
ASA-PS (I/II)	25/27	27/25	0.488
Time to Intubation (sec)	$18 \pm 11$	$18 \pm 10$	0.584
Duration of Tracheal Intubation (min)	$68 \pm 46$	$62 \pm 39$	0.976
Mallampati Grade (I/II)	16/36	21/31	0.148

Cormack-Lehane Grading Scale (I/II/III)	14/30/8	16/27/9	0.820
Mean Arterial Pressure Before Intubation (mmHg)	79 ± 14	80 ± 13	0.773
Mean Arterial Pressure 2 min after Intubation (mmHg)	98 ± 19	101 ± 22	0.489
Heart Rate Before Intubation (beats/min)	76 ± 14	74 ± 13	0.144
Heart Rate 2 min after Intubation (beats/min)	92 ± 16	92 ± 21	0.741

Table 2 summarizes the incidence and severity of postoperative sore throat, hoarseness, and cough. The overall incidence of postoperative sore throat was significantly higher in the lignocaine group than in the normal saline group (57% vs. 38%;  $p=0.006$ ), with significant differences at 1 hour ( $p=0.003$ ) and 6 hours ( $p=0.041$ ), but not at 12 hours ( $p=0.849$ ) or 24 hours ( $p=0.789$ ). The overall incidence of hoarseness was

comparable between the lignocaine and normal saline groups (56% vs. 52%;  $p=0.487$ ), with no significant differences at any postoperative time point (all  $p>0.05$ ). Similarly, postoperative cough was more frequent in the lignocaine group (27% vs. 15%;  $p=0.045$ ), with significant differences at 1 hour ( $p=0.002$ ) and 24 hours ( $p=0.043$ ), whereas the findings at 6 hours ( $p=0.810$ ) and 12 hours ( $p=0.561$ ) were comparable.

**Table 2:** Incidence and severity of postoperative sore throat, hoarseness, and cough

Parameter	Lignocaine (n=52)	Normal Saline (n=52)	p-value
Sore Throat			
Overall incidence	30 (57%)	20 (38%)	0.006
Postoperative 1 h (None/Mild/Moderate/Severe)	25/21/4/2	36/13/2/1	0.003
Postoperative 6 h (None/Mild/Moderate/Severe)	35/14/2/1	42/8/1/1	0.041
Postoperative 12 h (None/Mild/Moderate/Severe)	43/8/0/1	44/7/1/0	0.849
Postoperative 24 h (None/Mild/Moderate/Severe)	48/3/0/1	48/3/1/0	0.789
Hoarseness			
Overall incidence	29 (56%)	27 (52%)	0.487
Postoperative 1 h (None/Mild/Moderate/Severe)	33/15/3/1	31/17/4/0	0.567
Postoperative 6 h (None/Mild/Moderate/Severe)	37/13/1/1	35/15/2/0	0.544
Postoperative 12 h (None/Mild/Moderate/Severe)	44/7/0/1	42/10/0/0	0.354
Postoperative 24 h (None/Mild/Moderate/Severe)	49/2/0/1	45/6/1/0	0.920
Cough			
Overall incidence	14 (27%)	8 (15%)	0.045
Postoperative 1 h (None/Mild/Moderate/Severe)	37/14/1/0	46/4/1/1	0.002
Postoperative 6 h (None/Mild/Moderate/Severe)	47/5/0/0	48/4/0/0	0.810
Postoperative 12 h (None/Mild/Moderate/Severe)	51/1/0/0	52/0/0/0	0.561
Postoperative 24 h (None/Mild/Moderate/Severe)	50/2/0/0	52/0/0/0	0.043



## DISCUSSION

In the present study, we evaluated the effect of lignocaine jelly applied to the cuff of an endotracheal tube on the incidence and severity of POST, hoarseness, and cough following general anesthesia with endotracheal intubation. Sample size estimation was based on a previous study that reported an incidence of POST of approximately 36% during the first 24 hours following intubation with a tapered-cuff endotracheal tube.<sup>[16]</sup> Assuming a reduction in incidence to 18% in the lignocaine group, a minimum of 47 patients per group was required to achieve statistical significance with an alpha error of 0.05 and a beta error of 0.20. To account for potential attrition, 52 patients were enrolled in each group, resulting in a total study population of 104 patients.<sup>[16]</sup>

The baseline demographic, airway, anesthetic, and hemodynamic characteristics were comparable between the lignocaine and normal saline groups, indicating successful randomization and minimizing the likelihood of confounding factors influencing the outcomes. There were no statistically significant differences between the groups with respect to age, sex distribution, body mass index, ASA physical status, airway assessment parameters, duration of intubation, or peri-intubation hemodynamic variables.

The principal finding of the present study was that application of lignocaine jelly to the cuff of the endotracheal tube did not reduce the incidence of postoperative sore throat. In contrast, the overall incidence of POST was significantly higher in the lignocaine group than in the normal saline group [30 (57%) vs 20 (38%),  $p=.006$ ]. Furthermore, the incidence of POST at 1 hour postoperatively was significantly higher among patients receiving lignocaine jelly ( $p=.003$ ). However, the incidence of POST at postoperative 6, 12, and 24 hours was comparable between the two groups. These findings suggest that lignocaine jelly applied to the endotracheal tube cuff may not provide protection against airway mucosal irritation and may even be associated with a higher incidence of early postoperative throat discomfort.

Similarly, the overall incidence of hoarseness during the 24-hour postoperative period was comparable between the lignocaine and normal saline groups [29 (56%) vs 27 (52%),  $p=.487$ ]. No statistically significant differences were observed in the incidence of hoarseness at

postoperative 1, 6, 12, or 24 hours ( $p=.567$ ,  $p=.544$ ,  $p=.354$ , and  $p=.092$ , respectively). These results indicate that lignocaine jelly application on the endotracheal tube cuff does not significantly influence postoperative vocal cord-related symptoms.

The incidence of postoperative cough also demonstrated an unfavorable trend in the lignocaine group. The overall incidence of cough was significantly higher in patients receiving lignocaine jelly compared with those receiving normal saline [14 (27%) vs 08 (15%),  $p=.045$ ]. In addition, the incidence of cough at 1 hour postoperatively was significantly greater in the lignocaine group ( $p=.002$ ). Nevertheless, the incidence of cough became comparable between the two groups at postoperative 6, 12, and 24 hours ( $p=.810$ ,  $p=.561$ , and  $p=.043$ , respectively), indicating that the difference was predominantly confined to the immediate postoperative period.

With regard to adverse postoperative events, no significant differences were observed between the groups. The incidence of postoperative nausea was 25 (24%) in the lignocaine group and 30 (29%) in the normal saline group ( $p=.432$ ). Similarly, vomiting occurred in 7 (7%) and 8 (8%) patients, respectively ( $p=.789$ ), while throat numbness was reported in 15 (14%) and 11 (11%) patients, respectively ( $p=.402$ ). These findings indicate that lignocaine jelly application did not increase the incidence of these adverse effects but also did not provide any measurable clinical benefit.

Overall, the results of the present study demonstrate that lubrication of the endotracheal tube cuff with 2% lignocaine jelly failed to reduce the incidence or severity of postoperative sore throat, hoarseness, or cough. On the contrary, a significantly higher incidence of early postoperative sore throat and cough was observed in the lignocaine group compared with the normal saline group. These findings suggest that routine application of lignocaine jelly to the endotracheal tube cuff may not be an effective strategy for the prevention of postoperative airway-related complications following endotracheal intubation.

This investigation demonstrated that the lignocaine jelly applied at the distal part of ETT with cuff increased the overall incidence of POST. The lignocaine jelly also increased the incidence of cough compared with the normal saline at postoperative 1hour. The incidence of POST is influenced by many factors such as ETT cuff

design and pressure, intubation procedure, movement of ETT during surgery, coughing on the ETT, and pharyngeal suctioning during extubation <sup>[14,17,18]</sup>. The proposed mechanism of POST is thought to be an inflammation through injury of the pharyngeal and tracheal mucosa by traumatic laryngoscopy and contact with the ETT cuff <sup>[3,19–21]</sup>. Lidocaine with analgesic and anti-inflammatory effect may be optimal choice for the prevention of POST after general anesthesia with ETT intubation. Previous investigations have shown that topical application of lidocaine reduced the incidence of POST <sup>[4,10,22]</sup>. Lignocaine jelly among various topical application methods, however, have shown equivocal results in terms of pro-active POST prevention <sup>[4,10]</sup>.

In our study, lignocaine jelly applied on the ETT with cuff increased the incidence of POST by 20% at 1 hour postoperatively. This deleterious effect of lignocaine jelly at early post-operative period may increase the overall incidence of POST by 23%. The lignocaine jelly in our investigation contains several agents such as chlorhexidine gluconate, methylhydroxybenzoate, and propylhydroxybenzoate for antiseptic effect. Chlorhexidine gluconate can cause hypersensitivity reactions <sup>[23]</sup>. Methyl hydroxybenzoate and propyl hydroxy benzoate are chemical allergens that may induce allergic dermatitis <sup>[24,25]</sup>. Such additive agents for the prevention of infection may be irritative to the upper airway of patients. The additive agents including methylhydroxybenzoate and propylhydroxy benzoate may form the dry sediments. Such sediments in the patients' trachea may irritate the airway and increase cough and POST. The chemical and mechanical irritation by additive agents may increase the incidence of POST in our investigation. Postoperative cough can increase complications, including bronchospasm, hypertension, cardiac disease, bleeding, bronchospasm, increased intraocular and intracranial pressure, and postoperative surgical complications <sup>[10,26,27]</sup>. Surgical complications can result from the anesthetic procedures as reported by many articles previously <sup>[28,29]</sup>. Development of a cough after general anesthesia may be due to irritation and inflammation of respiratory tract by ETT <sup>[4]</sup>. Topical application of lignocaine to soothen the respiratory tract mucosa may represent a reasonable, pro-active means of preventing postETT cough <sup>[30]</sup>. Many diabetes cases and complications in diabetes cases will be benefited from these modified anesthetic techniques <sup>[31-33]</sup>.

Intracuff lignocaine may theoretically reduce chemical irritation caused by additives present in topical preparations.<sup>[8]</sup> However, inflation of the ETT cuff with liquid agents such as normal saline or lignocaine was not feasible in our in vivo study. Therefore, safer topical agents remain necessary for patients undergoing general anesthesia with endotracheal intubation. The incidence of POST in our study was comparable to previous findings.<sup>[16]</sup> Peak incidence occurred at 1 hour postoperatively, unlike earlier studies reporting a peak at 6 hours.<sup>[8]</sup> Differences in anesthetic agents, duration of surgery, and cuff design may explain this variation. Limitations include the subjective assessment of sore throat and hoarseness, inability to blind the intubating anaesthesiologists, lack of assessment of cough on the tube, and omission of postoperative wound pain evaluation, although randomization and blinded outcome assessment helped minimize bias.<sup>[4]</sup> Lignocaine jelly applied to the cuffed endotracheal tube was associated with a higher incidence of early postoperative cough and postoperative sore throat, possibly due to chemical and mechanical irritation from its additives, despite previous evidence supporting other lignocaine-based strategies for prevention of airway-related complications.<sup>[34]</sup>

## CONCLUSIONS

The present study demonstrated that the application of 2% lignocaine jelly to the distal portion and cuff of the endotracheal tube did not provide any protective effect against postoperative airway complications in patients undergoing surgery under general anesthesia. Instead, the use of lignocaine jelly was associated with a higher overall incidence of postoperative sore throat (POST) and postoperative cough, particularly during the early postoperative period. These findings suggest that the potential irritative effects of the chemical additives present in lignocaine jelly may outweigh its expected local anesthetic benefits. Therefore, lignocaine jelly containing irritative additives should not be routinely recommended for the prophylactic prevention of POST, especially when cuffed endotracheal tubes are used. Further studies are warranted to evaluate safer topical alternatives with better efficacy and tolerability.

## CONTRIBUTION OF AUTHORS

**Research concept-** Nikhil Korde, Lohit Vaishnao

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