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Original Research Article

Effect of Lidocaine Jelly Applied Over Endotracheal Tube Cuff on Delaying Cuff Pressure Increase during Nitrous Oxide Anaesthesia: A Prospective Randomised Controlled Trial

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Abstract

Background: Endotracheal tube (ETT) cuff pressure rises during nitrous oxide (N2O) anaesthesia because N2O diffuses into the air-filled cuff, risking tracheal mucosal ischaemia. Lidocaine jelly is routinely used to lubricate ETTs, yet its capacity to delay cuff pressure increase has not been established. Objective of this study is to determine whether ETT cuff lubrication with 2% lidocaine jelly prolongs the time taken for cuff pressure to rise from 18 mmHg to 25 mmHg during N2O general anaesthesia, and to compare the incidence of post-operative sore throat, cough, and hoarseness of voice between lidocaine-lubricated and unlubricated groups.

Methods: A prospective randomised controlled trial was conducted at tertiary care teaching hospital. Ninety ASA PS I–II patients aged 18–70 years undergoing elective surgery under general anaesthesia with N2O were randomised into Group L (ETT cuff lubricated with 2.5 mL of 2% lidocaine jelly, n = 45) and Group C (unlubricated ETT cuff, n = 45). ETT cuff pressure was set to 18 mmHg post-intubation; time to reach 25 mmHg was recorded. Post-operative sore throat, cough, and hoarseness were assessed at 1, 6, and 24 hours on validated four-point scales.

Results: Mean time for cuff pressure to rise from 18 mmHg to 25 mmHg was 42.5 ± 3.1 minutes in Group L versus 25.0 ± 2.2 minutes in Group C ($t = 30.608$; $p < 0.001$). Demographic parameters and duration of anaesthesia were comparable between groups. There was no statistically significant difference in the incidence of sore throat, cough, or hoarseness of voice at any post-operative time point.

Conclusion: Lidocaine jelly lubrication of the ETT cuff significantly delays the rise in cuff pressure during N2O anaesthesia, providing approximately 17.5 additional minutes before pressure adjustment is required. Intra-operative cuff pressure monitoring remains essential to minimise tracheal morbidity.

Keywords: Endotracheal Tube Cuff Pressure; Lidocaine Jelly; Nitrous Oxide Diffusion; Post-Operative Sore Throat; Tracheal Morbidity; Cuff Lubrication.

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Introduction

Endotracheal intubation is a cornerstone of modern anaesthetic practice, providing a secure airway, facilitating positive pressure ventilation, preventing pulmonary aspiration, and enabling control of gas delivery. In adult patients, cuffed endotracheal tubes are used to create an airtight seal between the tube and the tracheal wall.

While the cuff is essential for safe ventilation, improper cuff pressure carries significant clinical consequences at both extremes: excessively high pressure impairs tracheal mucosal capillary perfusion, while critically low pressure risks aspiration of oropharyngeal secretions. The recommended intra-cuff pressure range for adult patients is 18–25 mmHg (24.5–34 cmH2O), a range that balances adequate sealing against tracheal mucosal safety. [1,2] When nitrous oxide (N2O) is used as part of the anaesthetic technique,

cuff pressure rises progressively due to diffusion of N2O—which is 35 times more soluble in blood than nitrogen—from the alveoli across the cuff membrane into the cuff gas. [1,3]

As a consequence, cuff pressure may rapidly exceed safe limits, especially during prolonged procedures, predisposing patients to tracheal mucosal ischaemia, necrosis, and post-operative morbidity, including sore throat, cough, hoarseness, and, in severe cases, tracheal stenosis or fistula. [4,5] Previous approaches to counter N2O-mediated cuff pressure rise include inflating the cuff with saline6 or breathing circuit gas, [7] or use of specialised cuff designs such as the Lanz regulating valve or Taper Guard tubes. [8,9] Lubrication of the ETT cuff with water-soluble K-Y jelly has been demonstrated in a randomised trial by Oji et al. to delay cuff pressure increase significantly during N2O anaesthesia. [10] However, K-Y jelly is not routinely stocked in Indian operating theatres, whereas 2% lidocaine jelly (lidocaine hydrochloride) is ubiquitously available and is the standard lubricant used for ETT insertion in this setting.

Previous studies investigating lidocaine jelly on ETTs have focused exclusively on its effect on post-operative sore throat and hoarseness, yielding conflicting results. [11,12] No study has systematically examined whether lidocaine jelly delays N2O-driven cuff pressure escalation. Elucidating this property would be clinically important because it could inform a simple, low-cost strategy to reduce the frequency of intra-operative cuff pressure adjustments and associated haemodynamic perturbations, particularly in resource-limited settings where specialised tubes and real-time monitoring systems may not be universally available.

Sore throat on emergence from anaesthesia can precipitate coughing and straining, provoking adverse haemodynamic changes that are especially deleterious in patients with neurosurgical, ophthalmic, or cardiovascular co-morbidities.[13,14] Understanding the full scope of lidocaine jelly's effects on the peri-operative airway is therefore clinically important. Based on this objective of this study is to determine whether ETT cuff lubrication with 2% lidocaine jelly prolongs the time taken for cuff pressure to rise from 18 mmHg to 25 mmHg during N2O general anaesthesia, and to compare the incidence of post-operative sore throat, cough, and hoarseness of voice between lidocaine-lubricated and unlubricated groups.

Materials and Methods

This was a prospective, open-label, parallel-group randomised controlled trial conducted in the Department of Anaesthesiology at tertiary care teaching hospital, Tamil Nadu, India, from 2022 to 2023.

Ethical approval was obtained from the Institutional Ethics Committee prior to enrolment. The study was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants in both English and Tamil.

Ninety adult patients of either sex, aged 18–70 years, with American Society of Anesthesiologists Physical Status (ASA PS) I or II, scheduled for elective surgery under general anaesthesia using N2O were enrolled. Inclusion criteria required a body mass index (BMI) between 18.5 and 25 kg/m2, height 150–180 cm, and weight 50–80 kg. Patients were excluded for the following reasons: ASA PS III–IV, emergency surgery, haemodynamic instability, allergy to lidocaine or other study drugs, upper respiratory tract infection, use of throat packs, age below 18 or above 70 years, or patient refusal. Patients who required a cuff pressure above 18 mmHg to achieve an adequate seal (i.e., those with a cuff leak at 18 mmHg) were also excluded after intubation.

Sample size was calculated using data from the reference study by Oji et al. [10] Randomisation was performed using a computer-generated random allocation table. All 90 patients had an equal probability of assignment to either group. The allocation was concealed in sequentially numbered opaque sealed envelopes opened at the time of anaesthetic induction.

All patients were pre-oxygenated with 100% oxygen for 3 minutes. Pre-medication comprised intravenous glycopyrrolate 5 µg/kg, fentanyl 2 µg/kg, and midazolam 20 µg/kg. Anaesthesia was induced with thiopentone sodium 5 mg/kg and atracurium 0.5 mg/kg intravenously. In Group L, 2.5 mL of 2% lidocaine jelly was spread uniformly over the external surface of the ETT cuff under sterile conditions immediately prior to intubation. In Group C, no substance was applied to the ETT cuff. All patients received single-use PVC ETTs with high-volume low-pressure cuffs (7.0 mm internal diameter for both sexes). Care was taken to avoid introducing jelly into the ETT lumen. Immediately after orotracheal intubation, the cuff was inflated to exactly 18 mmHg (24.5 cmH2O) and anaesthesia was maintained with sevoflurane up to 2% and N2O:O2 at a 2:1 ratio (6 L/min total flow). Pressure-controlled ventilation was used with peak inspiratory pressure 15 cmH2O and respiratory rate 10–16 breaths/minute.

An independent anaesthetist, blinded to group allocation, used an AMBU aneroid cuff pressure manometer to continuously monitor ETT cuff

pressure. The primary outcome was the time elapsed from cuff inflation at 18 mmHg until pressure reached 25 mmHg. When 25 mmHg was reached, the pressure was immediately reduced to 18 mmHg for patient safety.

All patients were interviewed at 1, 6, and 24 hours post-extubation for sore throat, cough, and hoarseness of voice using validated four-point scales (Grade 0 = absent, Grade 1 = minimal, Grade 2 = moderate, Grade 3 = severe). Operative room temperature was maintained at 23°C. Continuous intra-operative monitoring included ECG, non-invasive blood pressure, SpO2, ETCO2, and temperature. Data were analysed using IBM SPSS Statistics Version 23.0. Continuous variables are expressed as mean ± standard deviation. Categorical variables are reported as frequencies and percentages. Comparisons between groups for continuous variables were performed using the independent samples t-test. Chi-Square test was used for categorical comparisons; Fisher's Exact test was applied when any expected cell frequency fell below 5 in 2×2 tables. A p-value <0.05 was considered statistically significant.

Results

A total of 123 patients were assessed for eligibility; 23 declined participation and 10 were excluded for not meeting inclusion criteria, leaving 90 patients who were randomised in equal numbers to Group C and Group L.

All 90 patients completed the study with no losses to follow-up. The two groups were well matched at baseline for all demographic and clinical parameters, as shown in Table 1.

Table 1: Baseline Demographic and Clinical Characteristics

Parameter	Group C (n=45)	Group L (n=45)	Test Statistic	p-value
Age (years), Mean ± SD	39.5 ± 14.0	40.1 ± 13.4	$\chi^2 = 7.149$	0.210
Sex — Female, n (%)	22 (48.9%)	24 (53.3%)	$\chi^2 = 0.178$	0.673
ASA PS II, n (%)	41 (91.1%)	41 (91.1%)	$\chi^2 = 0.000$	1.000
BMI 18.5–24.9 kg/m², n (%)	42 (93.3%)	43 (95.6%)	$\chi^2 = 0.212$	1.000
Duration of Anaesthesia (min), Mean ± SD	122.8 ± 63.3	121.4 ± 60.0	t = 0.103	0.919

ASA PS = American Society of Anesthesiologists Physical Status; SD = Standard Deviation. No statistically significant difference between groups (p > 0.05 for all).

The mean age of the study cohort was 39.8 ± 13.7 years (range 18–69 years). The age distribution showed that the 51–60 year age band was most frequent (26.7%), followed by the 21–30 year group (24.4%).

Female participants constituted 51.1% of the total cohort. The distribution of age, sex, ASA PS classification, and BMI did not differ significantly between groups, confirming comparability of randomisation. Mean duration of anaesthesia was virtually identical in both groups (Group C: 122.8 ± 63.3 min; Group L: 121.4 ± 60.0 min; t = 0.103; p = 0.919).

The primary outcome results are presented in Table 2. Lubrication of the ETT cuff with lidocaine jelly significantly prolonged the time required for cuff pressure to rise from 18 mmHg to 25 mmHg compared with the unlubricated control group.

Table 2: Comparison of Time Taken for ETT Cuff Pressure to Rise from 18 to 25 mmHg

Parameter	Group C (n=45)	Group L (n=45)	t-value	p-value
Mean time (minutes)	25.0	42.5	30.608	< 0.001**
Standard Deviation (minutes)	2.2	3.1	—	—
Difference (Group L – Group C)	—	+17.5 min	—	—

**** Highly statistically significant (p < 0.01) by independent samples t-test.**

In Group C, the mean time for ETT cuff pressure to rise from 18 mmHg to 25 mmHg was 25.0 ± 2.2 minutes. In Group L, the corresponding time was 42.5 ± 3.1 minutes—a prolongation of 17.5 minutes, representing a 70% increase relative to the control group.

The difference was highly statistically significant (t = 30.608; p < 0.001). This finding confirms that lidocaine jelly lubrication of the ETT cuff substantially delays N2O-mediated cuff pressure escalation in adult patients undergoing general anaesthesia.

The incidence and severity of post-operative sore throat, cough, and hoarseness of voice were assessed at three time points and are summarised in Tables 3–5. Statistical analysis revealed no significant difference between groups at any assessment interval for any of the three symptoms.

Table 3: Comparison of Post-operative Sore Throat Incidence between Groups

Time Point	Group C Present	Group C Absent	Group L Present	Group L Absent	χ^2 value	p-value
1 hour	14 (31.1%)	31 (68.9%)	14 (31.1%)	31 (68.9%)	0.000	1.000 #
6 hours	8 (17.8%)	37 (82.2%)	4 (8.9%)	41 (91.1%)	1.538	0.353 #
24 hours	1 (2.2%)	44 (97.8%)	0 (0.0%)	45 (100%)	1.011	1.000 #

 # No statistically significant difference (p > 0.05). Chi-Square test; Fisher's Exact where applicable.

Table 4: Comparison of Post-operative Cough Incidence between Groups

Time Point	Group C Present	Group C Absent	Group L Present	Group L Absent	χ^2 value	p-value
1 hour	11 (24.4%)	34 (75.6%)	11 (24.4%)	34 (75.6%)	0.000	1.000 #
6 hours	0 (0.0%)	45 (100%)	0 (0.0%)	45 (100%)	NA	NA
24 hours	0 (0.0%)	45 (100%)	0 (0.0%)	45 (100%)	NA	NA

 # No statistically significant difference (p > 0.05). NA = Not Applicable (zero variance).

Table 5: Comparison of Post-operative Hoarseness of Voice Incidence between Groups

Time Point	Group C Present	Group C Absent	Group L Present	Group L Absent	χ^2 value	p-value
1 hour	8 (17.8%)	37 (82.2%)	9 (20.0%)	36 (80.0%)	0.073	0.788 #
6 hours	1 (2.2%)	44 (97.8%)	2 (4.4%)	43 (95.6%)	0.345	1.000 #
24 hours	0 (0.0%)	45 (100%)	0 (0.0%)	45 (100%)	NA	NA

 # No statistically significant difference (p > 0.05). NA = Not Applicable (zero variance).

Post-operative sore throat at 1 hour was present in 31.1% of patients in both groups. By 6 hours, the incidence declined to 17.8% in Group C and 8.9% in Group L; and at 24 hours, only 1 patient (2.2%) in Group C versus none in Group L reported sore throat, though neither difference reached statistical significance. The overall incidence of sore throat in both groups was markedly lower than the 40% incidence reported by Biro et al.[15] in a cohort without intra-operative cuff pressure monitoring, highlighting the protective effect of continuous cuff pressure surveillance.

Cough at 1 hour was documented in 24.4% of patients in each group and was absent from both groups at subsequent intervals. Hoarseness at 1 hour was present in 17.8% of Group C and 20.0% of Group L patients, resolving in nearly all patients by 24 hours. None of these differences between groups achieved statistical significance, indicating that lidocaine jelly lubrication did not independently modify post-operative airway symptom burden under conditions of meticulous intra-operative cuff pressure management.

Discussion

The principal finding of this trial is that lubrication of the ETT cuff with 2% lidocaine jelly prolonged the time required for N2O-driven cuff pressure to reach the upper safety threshold by a clinically meaningful 17.5 minutes (42.5 vs. 25.0 min; $p < 0.001$). To our knowledge, this is the first randomised controlled trial to demonstrate this property of lidocaine jelly specifically.

The physiological mechanism by which N2O inflates air-filled cuffs is well established. [1,3] Nitrous oxide, with a blood–gas partition coefficient of 0.47, is approximately 35 times more blood-soluble than nitrogen (blood–gas partition coefficient 0.015). During N2O anaesthesia, the partial pressure of N2O in the alveoli drives the molecule across capillary membranes and, subsequently, through the relatively permeable PVC cuff wall into the cuff lumen, while nitrogen—poorly soluble in blood—cannot escape at a comparable rate. The net effect is progressive cuff inflation. The rate of pressure rise is directly proportional to the alveolar N2O concentration, cuff wall permeability, and duration of exposure. [16] Our results are consistent with the findings of Oji et al., [10] who demonstrated that K-Y jelly lubrication delayed the time for cuff pressure to reach 25 mmHg from 34.1 ± 13.1 minutes to 42.5 ± 15.8 minutes in a comparable patient population. The protective mechanism of viscous water-soluble lubricants appears to be a physical barrier effect: by coating the external surface of the PVC cuff, the jelly partially occludes the micro-channels within the cuff wall through which N2O diffuses, thereby slowing transmembrane diffusion. Lidocaine jelly shares its hydrophilic gel matrix with K-Y jelly and appears to produce a comparable—indeed virtually identical mean-time—diffusion-limiting effect, even though its formulation additionally contains lidocaine hydrochloride.

The clinical implication of an additional 17.5 minutes before cuff pressure adjustment is required is substantial. Assuming cuff pressure is monitored and reset every time it reaches 25 mmHg during a 3-hour operation, the lidocaine jelly group would require approximately 4 adjustments versus approximately 7 adjustments in the control group. Each cuff pressure adjustment in a lightly

anaesthetised patient carries risk of coughing, straining, and haemodynamic perturbation, which are particularly undesirable in patients undergoing neurosurgical, ophthalmic, or cardiovascular procedures. [13,14] Fewer manipulations also translate to reduced anaesthetic workload and lower probability of unrecognised periods of supra-threshold cuff pressure.

The absence of a significant difference in post-operative sore throat, cough, and hoarseness between groups in our study requires contextualisation. Earlier work by Sumathi et al. [11] found that lidocaine jelly reduced post-operative sore throat compared with a non-lubricated control. Conversely, Lee et al. [17] reported that lidocaine jelly on a taper-shaped cuff increased post-operative sore throat, speculating that lidocaine may alter cuff mechanics or cause mucosal irritation. Our neutral finding is likely attributable to the fact that intra-operative cuff pressure was rigorously monitored and maintained below 25 mmHg in both groups for ethical reasons. This protocol limited the tracheal mucosal pressure load experienced by patients regardless of group assignment, effectively equalising the primary driver of post-operative airway symptoms. Biro et al. [1]5 reported a 40% sore throat incidence in a cohort without systematic cuff pressure control, compared with 31.1% at 1 hour in our control group—evidence that monitoring itself reduces morbidity.

Strategies to mitigate N2O-mediated cuff hyper-inflation have included saline cuff inflation, [6] use of circuit gas for cuff inflation, [7,18] and specialised tube designs. [8,9] Saline inflation eliminates N2O diffusion because N2O is virtually insoluble in saline, and two randomised trials [6,19] confirmed significantly lower cuff pressures and tracheal injury rates with saline inflation. However, saline introduces logistical complexity (labelling, accidental deflation producing moisture in airways) and is not universally adopted. Distilled water inflation20 and specialised Brandt-tube systems that bleed excess pressure into a large-volume pilot balloon offer alternatives but increase cost. Lidocaine jelly offers a practical advantage in that it is already part of the intubation tray in most Indian operating theatres, requires no additional equipment or technique modification, and carries a well-established safety profile for mucous membrane application.

Limitations of this study include its open-label design, the subjective nature of symptom scoring scales, and the use of a single ETT size (7.0 mm internal diameter) for all patients regardless of sex, which may not reflect the lowest achievable cuff-to-trachea contact area. Furthermore, the study was conducted at a single centre in patients with specific BMI and height inclusion criteria, limiting generalisability to markedly obese or morbidly thin patients. The beneficial effect on cuff pressure dynamics should be studied with different lidocaine jelly volumes and different N_2O concentrations to characterise the dose–response relationship.

Conclusion

This prospective randomised controlled trial demonstrates that lubrication of the ETT cuff with 2% lidocaine jelly significantly delays the rise in ETT cuff pressure during N2O general anaesthesia, extending the safe interval before pressure adjustment by 17.5 minutes (70% prolongation over control). This finding has meaningful clinical implications for reducing the frequency of intra-operative cuff adjustments and associated airway complications. Lidocaine jelly lubrication did not independently reduce the incidence of post-operative sore throat, cough, or hoarseness under conditions of meticulous cuff pressure monitoring; however, the overall morbidity in both groups was lower than historical cohorts without monitoring, underscoring the importance of continuous intra-operative cuff pressure surveillance. We recommend the combined practice of ETT cuff lubrication with lidocaine jelly and continuous intra-operative cuff pressure monitoring as a simple, safe, and readily available strategy to minimise tracheal morbidity in patients receiving N2O general anaesthesia.

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