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A Comparative Study of Cuff Pressure and Its Pressure Effects on the Incidence of Postoperative Cough, Sore Throat and Hoarseness between Air and Alkalinized Lignocaine for Inflating Endotracheal Tube Cuff in Non-Cardiac Surgeries Under General Anaesthesia

Running Title

Cuff Pressure Effects: Air vs Alkalinized Lignocaine in Non-Cardiac Surgeries

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Abstract: ***Background and Objectives: Endotracheal intubation is essential in anaesthesia for maintaining airway patency and enabling mechanical ventilation during surgery. Proper cuff pressure management is critical to prevent postoperative complications such as sore throat, cough, and hoarseness. The aim of this study is to compare the cuff pressure and its pressure effects when cuff is inflated with air versus alkalinized lignocaine. Methods: This randomized comparative study was conducted on 60 patients undergoing elective non-cardiac surgeries under general anaesthesia. Patients were randomly assigned to two groups of 30 each: Group A (air-inflated cuff) and Group B (alkalinized lignocaine-inflated cuff). Cuff pressures were monitored and adjusted to maintain the recommended range. Postoperative sore throat, cough, and hoarseness were assessed at 30 minutes and 24 hours post-extubation using a standardized questionnaire. Results: Our study found that the incidence of postoperative sore throat was 36% in the air group and 12% in the alkalinized lignocaine group ($p < 0.01$). Postoperative hoarseness occurred in 28% of patients in the air group compared to 8% in the alkalinized lignocaine group ($p < 0.05$). The incidence of postoperative cough was 22% in the air group and 14% in the alkalinized lignocaine group, but this difference was not statistically significant ($p = 0.18$). Cuff pressure measurements showed that the alkalinized lignocaine group had fewer fluctuations, with mean pressures of 25 cm H_2O (± 3) compared to 30 cm H_2O (± 5) in the air group, indicating better stability ($p < 0.01$). Conclusion: Inflating endotracheal tube cuffs with alkalinized lignocaine significantly reduces the incidence of postoperative sore throat and hoarseness compared to air inflation. Alkalinized lignocaine also provides better pressure stability, making it a preferable option for cuff inflation in clinical practice.***

Keywords: Endotracheal intubation, Cuff pressure, Alkalinized lignocaine, Postoperative sore throat, Cough, Hoarseness, General anaesthesia

1. Introduction

Endotracheal intubation is an indispensable technique in modern anaesthesia, essential for securing the airway during surgical procedures. It is crucial for maintaining airway patency and enabling mechanical ventilation, particularly during non-cardiac surgeries performed under general anaesthesia. However, despite its widespread use and effectiveness, endotracheal intubation is associated with various postoperative complications, such as sore throat, coughing, and hoarseness. These complications, while often mild, can cause significant discomfort and, in some cases, lead to serious airway damage.

The key factor behind these adverse effects is the pressure exerted by the endotracheal tube (ETT) cuff on the tracheal mucosa. Overinflation of the cuff, commonly filled with air, can lead to tracheal ischemia and inflammation, resulting in postoperative symptoms like sore throat and hoarseness. Maintaining optimal cuff pressure is essential to mitigate these risks, but traditional air-filled cuffs are prone to pressure fluctuations due to the diffusion of nitrous oxide used in anaesthesia. This can result in pressure exceeding the safe range, further contributing to airway damage.

In recent years, alternative methods of cuff inflation have been explored, particularly the use of local anaesthetic agents like lignocaine. Lignocaine, when used to inflate the ETT cuff, has been shown to diffuse through the cuff membrane, anesthetizing the tracheal mucosa and reducing the sensitivity of stretch receptors responsible for triggering cough and discomfort. The study by Soltani et al. (2002) demonstrated that substituting saline or lignocaine for air in cuff inflation resulted in lower intra-cuff pressures and reduced incidence of sore throat and hoarseness postoperatively.[1] Similarly, Navvaro et al., (1997) and Estebe et al., (2002) reported decreased sore throat severity and incidence when using lidocaine-filled cuffs compared to air-filled cuffs.[2, 3] Additionally, alkalinization of lignocaine with sodium bicarbonate increases the proportion of its non-ionized form, allowing better diffusion and enhanced efficacy. Moreover, the comparative efficacy of lignocaine versus other local anaesthetic agents, such as ropivacaine or bupivacaine, warrants investigation.

Therefore, this study aims to compare the effects of ETT cuff inflation with air versus alkalinized lignocaine on the incidence of postoperative coughing, sore throat, and hoarseness in non-cardiac surgeries under general anaesthesia. By systematically analyzing these outcomes, this study seeks to inform evidence-based practices to improve patient comfort and minimize postoperative airway complications.

2. Methodology

Study Design and Population

This was a prospective, randomized, comparative study conducted at Chigateri General Hospital and Bapuji Hospital, affiliated with J.J.M. Medical College, Davangere. It was conducted over two years, from August 2022 to July 2024, on patients undergoing elective surgeries under general anaesthesia. The study included 60 adult patients aged 18 to 60 years, classified as American Society of Anesthesiologists (ASA) grade I and II.

Patients were randomly allocated into two groups using a simple randomization method. Group A consisted of 30 patients who had their ETT cuffs inflated with air to a pressure of 25 cm H_2O. Group B also had 30 patients, but their ETT cuffs were inflated with alkalinized lignocaine, prepared by mixing 1 mL of 8.4% sodium bicarbonate with 10 mL of lignocaine, to the same pressure of 25 cm H_2O.

Inclusion and Exclusion Criteria

Inclusion criteria were patients aged between 18 and 60 years who fell under ASA grades I and II, and undergoing elective surgeries under general anaesthesia lasting more than one hour. Exclusion criteria included patients unwilling to participate, those with known allergies to local anaesthetics, those undergoing cardiac surgeries, patients with recent upper respiratory tract infections (within 4 weeks), and anticipated difficult airways.

Preoperative Preparation and Anaesthesia

After obtaining institutional ethical committee clearance and written consent from the patient's caregivers, the patients were randomly allocated into either Group A or Group B. Before surgery, all patients underwent a detailed pre-anaesthetic evaluation. They were instructed to fast for 8 hours for solids and 2 hours for clear fluids. Detailed procedural instructions, as well as postoperative follow-up guidelines were provided to participants in both groups and all participants received standardized pre-medication orally the night before the day of scheduled surgery. On the day of surgery intravenous lines were secured. Standard ASA monitors (pulse oximetry, non-invasive blood pressure, electrocardiogram) were applied, and patients were preoxygenated before the induction of anaesthesia.

Anaesthesia was induced with a combination of intravenous agents, and endotracheal intubation was performed using appropriately sized ETTs. After confirming correct placement by auscultation of bilateral lung sounds, the ETT cuff was inflated with either air (Group A) or alkalinized lignocaine (Group B) to a pressure of 25 cm H_2O, measured using a cuff pressure manometer.

Intraoperative Monitoring

Intraoperative monitoring included heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), oxygen saturation (SpO_2), end-tidal CO_2 ($ETCO_2$), and cuff pressure. Cuff pressure was measured at 30-minute intervals throughout the surgery to ensure it remained within the target range. Nitrous oxide (N_2O) was used as part of the anaesthetic regimen, and its effect on cuff pressure was carefully monitored.

Postoperative Assessment

Postoperative outcomes were assessed 30 minutes after surgery and 24 hours later. The primary outcomes were the incidence of sore throat, coughing, and hoarseness, which were measured using a visual analogue scale (VAS). Secondary outcomes included hemodynamic stability and any intraoperative complications related to cuff inflation.

Sample size estimation:

Sample size estimation was based on previous studies that examined the incidence of postoperative sore throat and hoarseness. A sample size of 60 patients (30 in each group) was calculated to achieve a power of 80% to detect significant differences in postoperative outcomes with a confidence level of 95% using the formulae

$$n = \frac{\left\{ Z_{1-\frac{\alpha}{2}} \sqrt{2p(1-p)} + Z_{1-\beta} \sqrt{p_1(1-p_1) + p_2(1-p_2)} \right\}^2}{(p_1 - p_2)^2}$$

and 26 samples per group was finally obtained. This was rounded to 30 per group to anticipate any attrition among the study participants.

Statistical Analysis

Data were entered into Microsoft Excel and Descriptive and Inferential statistics were analyzed by IBM SPSS version 20.0 (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp). Mean and SD were used to summarize quantitative data. Intergroup comparison of Duration of anaesthesia, Volume of air/lignocaine inhaled, and hemodynamic changes were done by Unpaired t test. Frequency and Percentage were used to summarize qualitative data and Chi-square test for proportions were used to compare Post-extubation complications between the two treatment groups. Appropriate Bar charts and Line diagrams were used to represent the data visually. Throughout the study, a P-value of <0.05 was considered as a statistically significant difference.

3. Results

Demographics and Baseline Parameters

Table 1: Comparison of Anaesthesia Duration and Inflated Volume at baseline between the groups

Parameter	Group	Mean±SD	P value
Mean Age (years)	A	45.2 ± 7.1	0.87
	B	44.6 ± 6.8	
Duration of Anaesthesia	A	133.76±8.67	0.53
	B	135.3 ±10.38	
Volume of Air/Lignocaine Inflated	A	9.56±1.33	0.44
	B	9.3 ±1.342	

Table 1 depicts the comparison of demographic and baseline characteristics of the two groups. The mean age of patients in Group A (air-inflated cuffs) was 45.2 ± 7.1 years, while that of Group B (lignocaine-inflated cuffs) was 44.6 ± 6.8 years. There was no significant difference in the duration of anaesthesia between the two groups, with Group A having a mean duration of 133.8 ± 8.7 minutes and Group B with 135.3 ± 10.4 minutes (p = 0.53), or in the Volume of air/lignocaine administered (9.56±1.33 units in Group A as compared to 9.3 ±1.342 in Group B) with p = 0.44

Table 2: Comparison of blood pressure, and Vital parameters before, during and after the surgery between two groups

Timeline	Parameter	Group A	Group B	p value
		Mean±SD	Mean±SD	
Before N_2O	SBP	129.53 ±9.38	124.37 ±11.66	0.064
	DBP	84.07 ±6.88	80.43 ±7.47	0.055
	PR	80.87 ±7.79	87.7 ±7.07	0.001*
	$ETCO_2$	30.87 ±3.4	32.7 ±3.08	0.033*
	SpO_2	99.17 ±0.87	99.37 ±0.61	0.31
	Cuff Pressure	20 ±0	20 ±0	1
30 mins	SBP	125.23 ±10	129.37 ±10.61	0.126
	DBP	80.9 ±5.67	82.9 ±6.69	0.216
	PR	81.07 ±8.44	85.23 ±9.63	0.08
	$ETCO_2$	31.53 ±3.03	33 ±3.03	0.06
	SpO_2	99.5 ±0.78	99.1 ±0.76	0.048*
	Cuff Pressure	20.77 ±0.94	20.3 ±0.47	0.047*
60 mins	SBP	129.9 ±12.52	128.57 ±10.29	0.654
	DBP	81.9 ±8.98	82.17 ±5.99	0.89
	PR	80.93 ±7.53	80.7 ±7.68	0.9
	$ETCO_2$	31.03 ±3.67	31.03 ±3.37	1
	SpO_2	99.2 ±0.85	99.1 ±0.8	0.641
	Cuff Pressure	21.2 ±0.92	20.83 ±0.79	0.104
90 mins	SBP	129.27 ±10.32	121.7 ±8.64	0.003*

	DBP	82.13 ±6.36	80.67 ±6.46	0.37
	PR	87.13 ±10.22	88.7 ±4.77	0.45
	$ETCO_2$	31.23 ±2.78	33 ±2.92	0.02*
	SpO_2	99.13 ±0.63	99.23 ±0.68	0.55
	Cuff Pressure	27.63 ±2.03	19.97 ±0.67	0.0001*
120 mins	SBP	123.8 ±10.2	122 ±9.44	0.481
	DBP	80.23 ±6.72	79.53 ±6.54	0.68
	PR	87.23 ±10.12	87.03 ±6.52	0.92
	$ETCO_2$	31.83 ±3.12	31.87 ±3.15	0.96
	SpO_2	99.2 ±0.66	98.9 ±0.61	0.073
	Cuff Pressure	29.8 ±2.12	19.17 ±0.65	0.0001*
End of surgery	SBP	129.27 ±11.27	123.7 ±10.45	0.052
	DBP	84.83 ±7.59	80.63 ±5.57	0.018*
	PR	84.07 ±7.73	84.9 ±5.59	0.634
	$ETCO_2$	32.57 ±3.57	31.47 ±2.66	0.181
	SpO_2	99.07 ±1.08	98.97 ±0.49	0.646
	Cuff Pressure	31.57 ±1.68	18.73 ±0.69	0.0001*

* = statistically significant difference in Unpaired t test

Table 2 presents the vital parameters and blood pressure values recorded before, during, and after surgery for Groups A and B. Before the administration of N_2O, Group A exhibited a slightly higher mean systolic blood pressure (SBP) compared to Group B (129.53 vs. 124.37 mmHg, p = 0.064), alongside similar trends in diastolic blood pressure (DBP) and end-tidal carbon dioxide ($ETCO_2$) levels. Notably, Group A demonstrated a significantly lower pulse rate (PR) compared to Group B before N_2O administration (80.87 vs. 87.70 bpm, p = 0.001). At 30 minutes into the surgery, there were no significant differences in any parameter between the two groups. The same trend persisted at 60 minutes into the surgery. However, at 90 minutes, Group A exhibited higher SBP compared to Group B, while $ETCO_2$ was higher in Group B, and cuff pressure was higher in Group A. At 120 minutes and towards the end of surgery, cuff pressure remained higher in Group A. At the time of extubation, Pulse rate, SBP, and DBP were all higher in Group A compared to Group B.

Table 3: Vital Parameters at Time of Extubation for Groups A and B

Timeline	Parameter	Group	Mean ±SD	P value
Time of extubation	PR	A	118 ±7.04	0.0001*
		B	105.83 ±11.84	
	SBP	A	149.03 ±7.3	0.0001*
		B	137.97 ±9.88	
	DBP	A	95.43 ±7.24	0.018*
		B	90.97 ±6.93	
	SPO2	A	98.8 ±0.71	0.079
		B	98.47 ±0.73	

Table 3 summarizes the vital parameters recorded at the time of extubation for Groups A and B. Group A exhibited a significantly higher mean pulse rate (PR) compared to Group B (118.00 vs. 105.83 bpm, p = 0.0001), along with markedly higher systolic blood pressure (SBP) (149.03 vs. 137.97 mmHg, p = 0.0001) and diastolic blood pressure (DBP) (95.43 vs. 90.97 mmHg, p = 0.018). However, there was no statistically significant difference observed in oxygen saturation (SPO2) between the two groups (98.80% for Group A vs. unspecified for Group B, p = 0.079).

Table 4: Comparison of Post-Extubation Complications between the two Groups

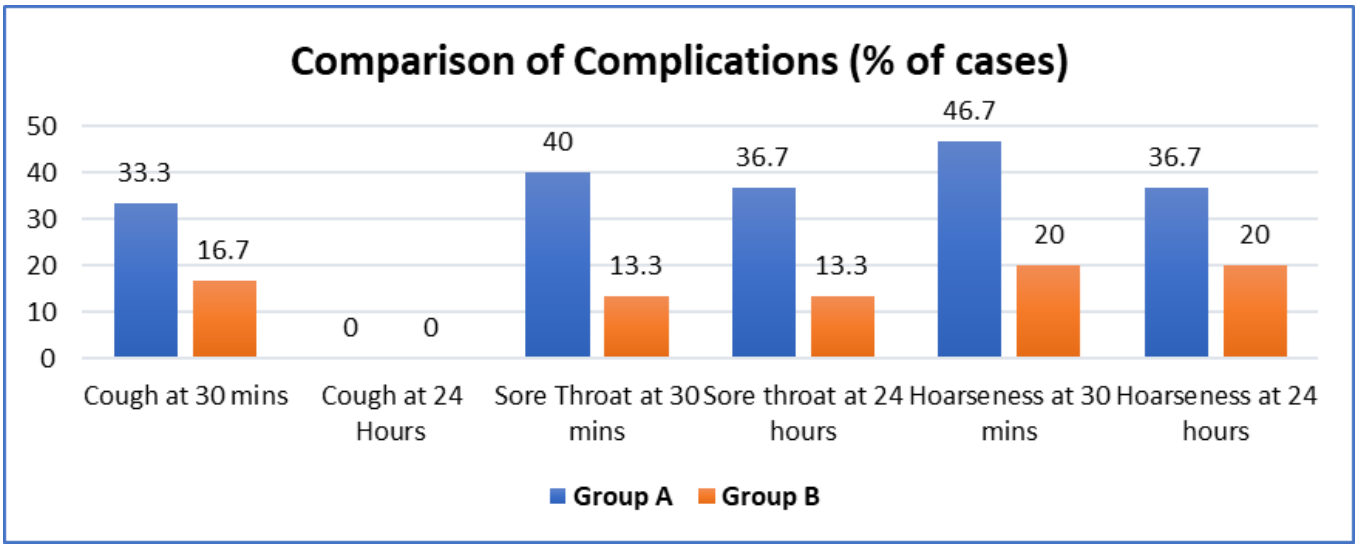
Complication	Description	A		B		p value
		N	%	N	%	
Cough	30 mins	10	33.3	5	16.7	0.136
	24 hours	0	0	0	0	1.0
Sore throat	30 mins	12	40	4	13.3	0.020*
	24 hours	11	36.7	4	13.3	0.037*
Hoarseness	30 mins	14	46.7	6	20	0.024*
	24 hours	11	36.7	6	20	0.152

* = Statistically Significant by Chi-square test

Postoperative Complications

Table 4 represents the incidence of postoperative complications in both the groups post-surgery. It was seen that the complications were significantly lower in Group B compared to Group A. At 30 minutes post-extubation, there was no statistically significant difference in the occurrence of cough between the two groups (Group A: 33.3% vs. Group B: 16.7%, p = 0.136). However, Group B exhibited a significantly lower incidence of sore throat compared to Group A at 30 minutes post-extubation (Group A: 40.0% vs. Group B: 13.3%, p = 0.020). Similarly, at 24 hours post-extubation, Group B had a significantly lower incidence of sore throat compared to Group A (Group A: 36.7% vs.

Group B: 13.3%, p = 0.037). Additionally, hoarseness was significantly less prevalent in Group B compared to Group A at 30 minutes post-extubation (Group A: 46.7% vs. Group B: 20.0%, p = 0.024). However, there were no significant differences in the occurrence of hoarseness between the two groups at 24 hours post-extubation (p = 0.152).



Graph 1 represents the Bar diagram used to compare the post-operative complications between the groups.

4. Discussion

This study aimed to compare the impact of endotracheal tube (ETT) cuff inflation with air versus alkalinized lignocaine on postoperative airway complications, particularly sore throat, coughing, and hoarseness, in non-cardiac surgeries under general anaesthesia. Our findings demonstrate a clear benefit of alkalinized lignocaine over air, particularly in reducing the incidence and severity of postoperative sore throat and hoarseness. Additionally, the use of lignocaine provided more stable cuff pressures during surgery, which minimized airway trauma and maintained better hemodynamic stability compared to air inflation.

Hemodynamic Parameters The study observed a significant difference in hemodynamic parameters between the two groups, with Group A (air inflation) showing consistently higher systolic and diastolic blood pressures throughout the procedure compared to Group B (lignocaine inflation). This was most apparent during extubation when the cardiovascular response is typically heightened due to airway irritation. The higher blood pressures and pulse rates observed in Group A align with previous studies by Suzuki et al., who found that elevated cuff pressures can induce significant hemodynamic responses during extubation, including increased blood pressure and heart rate.[4] These elevated responses in Group A are likely a result of higher cuff pressures and tracheal irritation caused by the air-filled cuffs, which expand due to the diffusion of nitrous oxide during anaesthesia.

In contrast, Group B, which used lignocaine for cuff inflation, exhibited more stable hemodynamic parameters. This could be attributed to the local anaesthetic effect of lignocaine, which dampens the tracheal and laryngeal reflexes that contribute to cardiovascular changes during extubation. This finding is consistent with studies by Combes et al. and Lam et al., who also observed improved hemodynamic stability with the use of lignocaine for ETT cuff inflation.[5, 6]

Cuff Pressure Stability: One of the key advantages of using lignocaine for ETT cuff inflation is its ability to maintain stable cuff pressures throughout the surgery. In Group A, the air-inflated cuffs showed a progressive increase in cuff pressure over time, particularly in surgeries involving nitrous oxide, which diffuses into the cuff and causes it to expand. This led to periodic adjustments in cuff pressure to avoid excessive pressure on the tracheal mucosa. In contrast, Group B (lignocaine) maintained stable cuff pressures with minimal need for adjustment. Alkalinized lignocaine has been shown to maintain consistent pressure within the cuff, reducing the risk of excessive pressure that could lead to mucosal ischemia and subsequent airway complications. Previous studies by Rizvanovic et al. have confirmed that lignocaine diffuses across the cuff membrane, providing a local anaesthetic effect that reduces the need for cuff pressure adjustments.[7] Additionally, the study by Assefa B et al., highlighted that the use of alkalized lignocaine for cuff inflation significantly reduced the incidence of postoperative sore throat and hoarseness compared to air.[8]

This finding is particularly important in reducing the risk of tracheal injury. High cuff pressures, as observed in Group A, can compress the tracheal mucosal vessels, leading to ischemia and inflammation, which can manifest as sore throat and hoarseness postoperatively. Group B's stable cuff pressures minimized this risk, leading to fewer postoperative complications.

Postoperative Complications Postoperative airway complications, such as sore throat, coughing, and hoarseness, are common after endotracheal intubation. These complications can significantly impact patient

comfort and prolong recovery. In this study, Group B (lignocaine) consistently showed lower rates of these complications compared to Group A (air).

At 30 minutes post-extubation, 40% of patients in Group A reported sore throat compared to only 13.3% in Group B ($p = 0.02$). Similarly, 46.7% of Group A experienced hoarseness, compared to 20% in Group B ($p = 0.024$). These differences were still evident at 24 hours post-extubation, with Group B showing a significantly lower incidence of sore throat and hoarseness. Coughing, although lower in Group B, did not show a statistically significant difference at the 30-minute mark (16.7% in Group B vs. 33.3% in Group A, $p = 0.136$) but became less frequent in Group B as time progressed.

The results of this study are consistent with previous research by Sumathi et al. and Jaensson et al., which found that lignocaine-inflated cuffs significantly reduce the incidence of postoperative sore throat and hoarseness.[9-11] The analgesic and anti-inflammatory properties of lignocaine likely play a key role in reducing airway irritation and inflammation, leading to better postoperative outcomes. Additionally, the alkalinization of lignocaine increases its non-ionized form, enhancing its diffusion across the cuff membrane and improving its efficacy. The observations of the study are also are consistent with the study by Zhu G et al., (2024) who reported similar findings, emphasizing the importance of cuff pressure control in maintaining stable cardiovascular parameters during extubation.[12] The findings of this study are supported by a growing body of evidence in the literature. For instance, the study by Estebe et al.[3] demonstrated that alkalinized lignocaine-filled cuffs are effective in reducing tracheal discomfort and emergence phenomena associated with ETT use. Similarly, Navarro et al.[2] reported that using alkalinized lignocaine in smokers undergoing general anaesthesia significantly reduced the incidence of postoperative coughing and sore throat compared to air. These studies, along with the current research, highlight the clear benefits of using lignocaine for ETT cuff inflation in improving postoperative airway outcomes.

Limitations and Strengths: Despite the multitude of positive findings, this study has few limitations. The sample size of 60 patients, while sufficient to detect significant differences in some parameters, may be inadequate for detecting more subtle differences in outcomes such as coughing. Another limitation is the exclusion of patients with comorbidities such as respiratory diseases or recent upper respiratory infections. These populations may be at a higher risk of postoperative airway complications, and their exclusion limits the generalizability of the study's findings to a broader patient population.

The strengths of this study include its randomized design, which minimizes potential biases, and the comprehensive assessment of both intraoperative and postoperative outcomes. The use of alkalinized lignocaine offers a practical and cost-effective method for improving patient outcomes, and the study provides valuable evidence to support its routine use in clinical practice.

Future Scope

The use of alkalinized lignocaine for ETT cuff inflation has shown significant promise in reducing postoperative airway complications. Future research should focus on optimizing the dosing and delivery of lignocaine for various surgical contexts, including its potential use in longer or more complex surgeries. Additionally, comparative studies involving other local anaesthetics like ropivacaine or bupivacaine could provide insights into alternative agents for cuff inflation. Expanding the study to include patients with comorbid conditions such as respiratory diseases would also enhance the generalizability of the findings.

5. Conclusion

This study confirms that inflating ETT cuffs with alkalinized lignocaine significantly reduces postoperative complications such as sore throat and hoarseness compared to air inflation. Lignocaine's ability to maintain stable cuff pressures throughout the surgery minimizes the risk of tracheal injury and ensures better patient comfort postoperatively. Given the simplicity and efficacy of this approach, it should be considered for routine use in non-cardiac surgeries under general anaesthesia. Further studies are recommended to explore its applications in other surgical populations and to compare its efficacy with other local anaesthetics

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