ORIGINAL ARTICLE

Comparative study of intracuff air vs alkalinized lignocaine on cuff pressure and tube tolerance under anaesthesia maintained by nitrous oxide

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Abstract

Background: An endotracheal tube is commonly used during General Anesthesia (GA) and is associated with hemodynamic changes during and after surgery alongside other throat-related difficulties. *Aim and Objectives:* To compare the effect of intracuff air and alkalinized lignocaine on cuff pressure under anesthesia maintained by nitrous oxide and to assess the tube tolerance while emergence from anesthesia. To evaluate intraoperative hemodynamic changes and incidence of Post Operative Sore Throat (POST) and hoarseness. *Materials and Methods:* The present study was a prospective randomized single blinded study conducted among adult patients undergoing GA at a tertiary healthcare located in Coimbatore. After selecting participants based on the inclusion and exclusion criteria, 80 participants were randomized into two groups of 40 subjects each, with Group A: Air inflation up to 20 cm of water and Group B: Alkalinized lignocaine inflation up to 20 cm of water. The selected variables were checked just before surgery, during extubation, and as per follow-up periods, and collected variables were then analyzed using SPSS version 22.0 software. *Results:* Both the groups were comparable in their demographic profile. The mean cuff pressures in Group A were higher than Group B at all points. The cuff pressures at end of surgery were 39.17 ± 1.752 vs 27.13 ± 1.017 cm of water and this was statistically significant ($p = 0.001$). The mean Systolic Blood Pressure, Diastolic Blood Pressure, and pulse rate at the time of extubation showed a significant difference with $p < 0.05$. Better tube tolerance at the time of extubation was observed in Group B with $p < 0.05$. The incidence of POST and hoarseness was found to be reduced in Group B and this was found to be statistically significant ($p < 0.05$). *Conclusion:* Intracuff injection of alkalinized lignocaine is superior to the standard practice of injecting air when using nitrous oxide for GA. It resulted in lower cuff pressures which translated to better tube tolerance, improved hemodynamics, smoother emergence, and reduced incidence of POST.

Keywords: Endotracheal Intubation, Anesthesia, Extubation, Lignocaine, Post-Operative Sore Throat

Introduction

Tracheal intubation with an Endotracheal Tube (ETT) is necessary during General Anesthesia (GA). After intubation, inflating the cuff around the ETT maintains a seal. Smooth Emergence from GA is frequently complicated by coughing induced by stimuli from the ETT [1]. It is known for a fact that tracheal extubation may be associated with the risk of some complications. The Difficult Airway Society (DAS) developed a guideline for the management of tracheal extubation in 2012 [2].

Manipulation of airway during laryngoscopy and endotracheal intubation is associated with sympathetic responses which result in a rise in blood pressure and Heart Rate (HR). The precise mechanism that causes these hemodynamic reactions is largely unknown, it has been hypothesized to be related to the action of catecholamines that are released during times of stress. In vulnerable population, acute changes in hemodynamics post extubation could lead to myocardial ischemia, life-threatening arrhythmias, pulmonary edema, acute cardiac failure, or cerebrovascular hemorrhage. These can further lead to complications while conducting surgery in the cardiac, ocular, aneurysmal and intra-cranial region [3]. Coughing during emergence can result in hypertension, tachycardia, raised intraocular and intracranial pressures, myocardial ischemia, bronchospasm, and surgical bleeding [1].

Post-operative Sore Throat (POST) is common after GA and tracheal intubation with an incidence ranging from 21% to 68%. POST is the second most common adverse outcome following GA and negatively impacts patient satisfaction while also being difficult to treat, even when operative pain is managed by administration of systemic analgesics. The quality of evidence on the different ways to reduce this incidence was found lacking as per a meta-analysis conducted by Singh *et al*., (2020) [4]. Lignocaine is a local anesthetic, that causes blockage of the sodium channel, and suppresses the cough reflex to extubation by its action on synaptic transmission as well as hemodynamic response through its peripheral vasodilatory effect, central stimulant effect, and direct myocardial depressant effect. Lignocaine is usually administered intravenously, through the laryngotracheal route or within the ETT cuff to blunt reflexes during emergence from GA [5]. Lignocaine use has been associated with improved patient satisfaction, pain relief and safety in other procedures [6].

The quest for a "smooth extubation" has been pursued in the literature. Multiple medications have been shown to reduce emergence coughing, such as lignocaine (IV, intracuff, topical, laryngotracheal), dexmedetomidine, fentanyl, and remifentanil. Dexmedetomidine has been shown to result in increased MAP in the first 1 min after administration of and returned to normal after 2 min [7]. However, these studies are limited by small sample sizes and heterogeneous medication dosages. These limitations are also reflected in the published systematic reviews and meta-analyses [2, 7-8].

The primary aim of the study was to compare the effect of intracuff air and alkalinized lignocaine on cuff pressure under GA maintained by nitrous oxide and to assess the tube tolerance while emergence from GA. The secondary aim of the study was to look for the hemodynamic changes during the intraoperative period and study the effect on POST and hoarseness of voice.

Material and Methods

The present study was a prospective randomized single blinded study conducted among adult patients undergoing GA for elective surgeries maintained by nitrous oxide with endotracheal intubation at a tertiary healthcare located in Coimbatore. The study was conducted after obtaining clearance from the Institutional Human Ethics Committee (IHEC) (recognized SIDCER, WHO) with reference number PSG/IHEC/2021/Appr/Exp/063 and informed consent from all study participants. Patients were included in the study if they were aged between 20-65 years with a BMI<30, American Society of Anesthesiologists (ASA) physical status of I or II and patients undergoing surgery for more than 90 minutes. Participants were excluded if they were morbidly obese, pregnant, had a difficult airway, required a procedure to insert a nasogastric tube, suffered from upper respiratory infection, were undergoing surgery of the anterior neck, cervical spine, oral and maxillofacial region and ENT surgeries. After selecting participants based on the inclusion and exclusion criteria, participants were divided into two groups with Group A: Air inflation up to 20 cm of water (i.e., no air leaks detected under volume) and Group B: Alkalinized lignocaine inflation up to 20 cm of water (i.e., no air leaks detected under volume-controlled ventilation mode) (2% lignocaine: 7.5% Sodium bicarbonate – 19 ml:1 ml)

Sample size calculation

Sample size calculation was done based on the results of a study conducted by Nagarajaiah *et al*., (2017) [9]. Using cuff pressure at 30 minutes as a reference, after inflating the cuff by air vs alkalinized lignocaine, using a confidence interval of 95% and power of 80%, and clinically significant cuff pressures as 2 mmHg. A sample size of 36 participants per group was calculated using the details from the previous study. To account for losses due to attrition, the final sample size of about 40 in each group was considered for the present study.

Procedure

The selection of patients was based on computer-generated randomization and were allotted to a group using sequential sealed envelopes. The day before surgery, preoperative assessment was carried out using the standard assessment chart available in the department. The study participants were informed about the procedure and asked to undergo 8 hours of overnight fasting. All patients were premedicated with pantoprazole 40 mg and metoclopramide 10 mg. Before surgery, the baseline vitals, investigation reports, pre-medication chart, antibiotic dosing, and overnight fasting status were checked. In the operating theatre room, HR, Non-Invasive Blood Pressure (NIBP), Mean Arterial Pressure (MAP), Electrocardiograph (ECG), and Oxygen Saturation (SpO_2) were obtained and noted in the intraoperative chart. Injection glycopyrrolate 0.01 mg/kg was administered Intravenously (IV) as a prophylactic against excessive secretion. Patients were pre-oxygenated with 100% O_2 for 3 minutes. Injection fentanyl 2 mcg/kg IV was used to induce anesthesia along with injection lignocaine 1.5 mg/kg IV followed by injection propofol 2 mg/kg IV till the end point determined by lack of response to verbal response. Proper placement of black rubber mask and manual bag ventilation was maintained. Once under the effect of the induction agent, injection succinylcholine 1.5 mg/kg was administered to facilitate direct laryngoscopy and the trachea was intubated with an inner diameter of 7.5 mm for females and 8.5 mm for males.

For the air group, ETT cuff was inflated with air up to the minimal occlusive volume of 20 cm of H_20 (i.e., no air leaks detected under volume-controlled ventilation mode) while for the alkalinized lignocaine group, ETT cuff was inflated with 2% lignocaine + 7.5 % sodium bicarbonate (19:1) were added up to the minimal occlusive volume of 20 cm of H_2O. The inflated volume was recorded. During the intraoperative period, change in cuff pressure was monitored with a hand-held cuff pressure manometer before the use of nitrous oxide, at 30, 60, 90, and 120 minutes, during the time of extubation along with Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), HR, and SpO_2 measurement.

GA was maintained with sevoflurane along with nitrous oxide. The muscle relaxation had been instituted with injection atracurium 0.1 mg/kg. Ventilation was adjusted to maintain normocapnia. Analgesia was maintained with injection paracetamol 15 mg/kg IV and intravenous fluid (crystalloids) were given to take care of fluid deficit, maintenance, ongoing loss, and third space loss.

Post surgery, sevoflurane was discontinued. Injection neostigmine 0.05 mg/kg IV and injection glycopyrrolate 0.01 mg/kg was used to reverse the neuromuscular blockade of residual neuromuscular blockade. Baseline pre-extubation HR, NIBP, SpO_2 were recorded. Gentle oral suctioning was performed and ETT was removed when the spontaneous ventilation with a tidal volume of 4-6 ml/kg was met, and the ability to respond to verbal command or demonstration of purposeful movement. After extubation, HR, Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), MAP, and SpO_2 were noted. The tube tolerance in view of bucking (more forceful and protracted cough) and a true cough were noted. Post-extubation evaluation of the incidence of POST and hoarseness of voice was done at 30 minutes and 24 hours by an independent staff nurse who was not involved with intraoperative care.

Statistical analysis

Data were statistically analyzed with SPSS version 22.0 software. Baseline characteristics were presented as mean ± SD. Two-sided unpaired t-test and chi-square test were applied to analyze the data and a *p*-value less than 0.05 was considered significant.

Results

A total of 80 particpants were enrolled for the study and the demographic variables in terms of age, sex, ASA grade, Mallampati classification and duration of surgery were comparable in both the groups.

The results depicted in tables 1 and 2 reveal the mean SBP and DBP at different time points and compared between groups. Only the mean SBP during time of extubation showed a significant difference with the mean value of 149.8 ± 7.125 mm of Hg in Group A being significantly higher than the mean value of 124.80 ± 13.88 mm of Hg in Group B. It was statistically significant with $p <$ 0.05. Similar results were seen with respect to mean DBP with a significant difference seen between the groups at the time of extubation ($p <$ 0.05) with the mean value of 95.98 ± 6.882 mm of Hg in Group A being significantly higher than the mean value of 87.48 ± 9.990 mm of Hg in Group B.

Table 3 shows the mean HR at different time points and the difference between the two groups, it was seen that the mean HR at the time of extubation showed a significant difference ($p < 0.05$) with the mean HR of 117.65 ± 6.825 beats /minute in Group A being much higher than the lower mean HR of 99.65 ± 8.052 beats/minute in Group B. The starting ETT cuff pressure in both groups was set at 22 cm of water. There was an increase in cuff pressure at all time points regarding Group A with mean cuff pressure at the end of surgery being 39.17 ± 1.752 mm of Hg. Whereas in Group B, after 30 minutes there was a gradual rise in cuff pressure, and at the end of surgery the mean value of 27.13 ± 1.017 was recorded. The difference in cuff pressure was found to be significant at all time points with $p < 0.05$ (Table 4).

Better tube tolerance during extubation was observed among 23 patients (57.5%) in Group A which was lower than the 33 patients (82.5%) exhibiting tolerance in Group B. This difference between groups was found to be significant with $p = 0.015$. (Table 5)

The incidence of POST among participants was recorded at 30 minutes and at 24 hours after extubation. The results showed that in Group A, 19 participants presented with a sore throat after 30 minutes and 16 participants after 24 hours. In Group B, 7 patients presented with a sore throat at 30 minutes and 3 patients at 24 hours. This difference was statistically significant with p = 0.004 at 30 minutes and p = 0.003 at 24 hours (Table 6). Similar results were seen regarding hoarseness of voice with 12 and 9 participants presenting with it in Group A at 30 minutes and 24 hours respectively and in Group B, whereas only 5 participants presented with hoarseness at 30 minutes and 2 participants at 24 hours which was much lower. This difference was found to be significant with p = 0.004 at 30 minutes and p = 0.023 at 24 hours respectively.

Table 1: Difference in systolic blood pressure at different vital durations between the two groups of study participants

Vitals	Group	Mean ± SD	*p*
Before nitrous oxide	**Air**	134.08 ± 10.731	0.095
	Lignocaine	129.50 ± 13.321	
30 minutes	**Air**	125.40 ± 11.738	0.241
	Lignocaine	128.50 ± 11.721	
60 minutes	**Air**	128.55 ± 11.453	0.654
	Lignocaine	127.45 ± 10.417	
90 minutes	**Air**	128.38 ± 11.121	0.305
	Lignocaine	125.95 ± 9.837	
120 minutes	**Air**	124.55 ± 10.094	0.104
	Lignocaine	120.83 ± 10.178	
End of surgery	**Air**	128.83± 10.308	0.016
	Lignocaine	123.25 ± 9.865	
Time of extubation	**Air**	149.18 ± 7.125	**0.000***
	Lignocaine	124.80 ± 13.883	

**Statistically significant p < 0.05*

Table 2: Difference in diastolic blood pressure at different vital durations with groups of the study participants

Vitals	Group	Mean ± SD	*p*
Before nitrous oxide	**Air**	85.18 ± 8.083	0.645
	Lignocaine	86.03 ± 8.356	
30 minutes	**Air**	84.15 ± 6.856	0.416
	Lignocaine	85.50 ± 7.877	
60 minutes	**Air**	82.93 ± 11.396	0.353
	Lignocaine	85.30 ± 11.355	
90 minutes	**Air**	84.15 ± 6.315	0.505
	Lignocaine	83.13 ±7.332	
120 minutes	**Air**	84.35 ± 8.514	0.318
	Lignocaine	82.63 ± 6.739	
End of surgery	**Air**	87.73 ± 7.897	0.290
	Lignocaine	86.03 ±6.274	
Time of extubation	**Air**	95.98 ± 6.882	**0.000***
	Lignocaine	87.48± 9.990	

**Statistically significant $p < 0.05$*

Table 3: Difference in heart rate at different vital durations between groups of the study participants

Vitals	Group	Mean ± SD	*p*
Before nitrous oxide	**Air**	102.40 ± 14.274	0.289
	Lignocaine	99.30 ± 11.583	
30 minutes	**Air**	99.98 ± 9.028	0.687
	Lignocaine	99.20 ± 8.084	
60 minutes	**Air**	92.50 ± 9.714	0.623
	Lignocaine	93.48 ± 7.841	
90 minutes	**Air**	94.40 ± 7.880	0.216
	Lignocaine	92.38 ± 6.582	
120 minutes	**Air**	92.80 ± 7.230	0.097
	Lignocaine	89.98 ± 7.784	
End of surgery	**Air**	87.40 ± 4.986	**0.020***
	Lignocaine	84.75± 4.970	
Time of extubation	**Air**	117.65 ± 6.852	**0.000***
	Lignocaine	99.65 ± 8.052	

**Statistically significant $p < 0.05$*

Table 4: Difference in cuff pressure at different vital durations with groups of the study participants

Vitals	Group	Mean ± SD	*p*
30 minutes	**Air**	25.63 ± 1.030	**0.000***
	Lignocaine	23.55 ± 0.597	
60 minutes	**Air**	29.40 ± 1.257	**0.000***
	Lignocaine	25.25 ± 0.630	
90 minutes	**Air**	33.78 ± 1.187	**0.000***
	Lignocaine	26.05 ± 0.677	
120 minutes	**Air**	37.43 ± 1.517	**0.000***
	Lignocaine	27.13 ± 1.017	
End of surgery	**Air**	39.17 ± 1.752	**0.001***
	Lignocaine	27.13 ± 1.017	

**Statistically significant $p < 0.05$*

Table 5: Difference in tolerance between different groups among the study participants

Tolerance	Yes	No	*p*
Air	23 (57.5%)	17 (42.5%)	**0.015***
Lignocaine	33 (82.5%)	7 (17.5%)	

**Statistically significant $p < 0.05$*

Table 6: Difference in distribution of sore throat and hoarseness of voice at different vital durations between groups of the study participants

Sore throat				***p***
		Yes	**No**	
30 minutes	**Air**	19 (73.1%)	21 (38.9%)	**0.004***
	Lignocaine	7 (26.9%)	33 (61.1%)	
24 hours	**Air**	16 (84.2%)	24 (39.3%)	**0.003***
	Lignocaine	3 (15.8%)	37 (60.7%)	
Hoarseness of voice				
30 minutes	**Air**	12 (70.6%)	28 (44.4%)	**0.004***
	Lignocaine	5 (29.4%)	35 (55.6%)	
24 hours	**Air**	9 (81.8%)	31 (44.9%)	**0.023***
	Lignocaine	2 (18.2%)	38 (55.1%)	

**Statistically significant $p < 0.05$*

Discussion

Various methods have been employed to attenuate hemodynamic responses and also to decrease the incidence of coughing which include extubation in a deep plane of anesthesia and administering intravenous agents like lignocaine, opioids like fentanyl, α-agonists such as dexmedetomidine and topical or intracuff application of lignocaine 4%, and IV lignocaine 2% [1]. The present study was conducted to assess the differing levels of hemodynamic changes as well incidence of POST and postoperative hoarseness of voice among study participants. Baseline analysis showed that the mean age, gender distribution, ASA physical status, MPG classification, and duration of treatment showed no significant difference thus making both groups identical and ideal for comparison of the two methods studies here.

Regarding hemodynamic changes, the mean SBP and DBP at the time of extubation showed a statistically significant difference with $p < 0.05$ with Group B showing a lower blood pressure. Similar results were observed in a study conducted by Assefa *et al*., (2022) wherein the mean SBP and DBP were significantly lower in the lidocaine group compared to the air group ($p < 0.05$) but the time points assessed in the comparison study were 5 mins before and after extubation [11]. Similarly, a study conducted by Shabnum *et al*., (2017) also reported that lignocaine administration had a lowered mean SBP when compared to the placebo group and this difference was statistically significant ($p < 0.005$) [3]. Other studies have also reported findings that align with the results of the present study with lignocaine helping in reducing SBP and DBP [5]. The mean HR at different time points was collected and the difference between the two groups was compared, it was seen that the mean HR at the time of extubation showed a statistically significant difference ($p < 0.05$) where group B again showed lower HR. Shabnum *et al*., (2017) had also reported that HR post-extubation was significantly lower in groups where lignocaine was administered as opposed to the placebo group ($p < 0.001$), and this difference was also seen up to 5 minutes after extubation [3].

HR was reported to be reduced by using lignocaine intratracheal or by IV when compared to the placebo group by Gladston *et al*., (2022) [5]. These results show that lignocaine use can help in relaxing the hemodynamic status of the patient throughout and after surgery which can help in stability of patients. The starting ETT cuff pressure in both the groups was set at 22 cm of water and there was an increase in cuff pressure at all time points in Group A and in Group B there was a gradual rise in cuff pressure and at the end of surgery after 30 minutes, this difference in cuff pressure was found to be statistically significant at all time points with the $p < 0.05$. This result contrasted with that obtained by Nagarajaiah *et al*., (2017) where the intra-cuff pressures in the group using lignocaine as an inflating agent were almost stable [9].

Regarding tolerance, better tube tolerance at the time of extubation was observed among many participants in Group B with this association being statistically significant with $p = 0.015$. Incidence of POST and hoarseness of voice was recorded at 30 minutes and 24 hours after extubation, the results showed that Group B had far fewer patients presenting with sore throat and hoarseness of voice when compared to Group A. The association between both sore throat and hoarseness was found to be statistically significant with $p < 0.05$. A previously conducted study reported that post-operative cough at extubation was found to be significantly reduced in the lidocaine group (30%) when compared to the air group (70%) and this difference was statistically significant ($p = 0.026$) but postoperative hoarseness at extubation did not show any significant difference between the groups. However, sore throat ($p = 0.027$) and hoarseness ($p = 0.014$) were significantly reduced in the lignocaine group when compared to the air group at 8 hours. At 24 hours, sore throat was still lower in the lidocaine group when compared to the air group ($p = 0.009$) [10].

A previously conducted study reported that administration of intratracheal lignocaine or IV lignocaine did not show any significant reduction in cough incidence when compared to the placebo group [3]. Cough reflex was found to be reduced by using lignocaine in another study wherein it was used by intratracheal and IV methods when compared to the placebo group ($p = 0.001$) [5]. This was in accordance with the results of other previously conducted studies [10-14]. The analysis by multiple studies and systematic reviews also reinforces results like the present study [9, 15-16]. Studies have used lignocaine via other routes but have reported contradicting results which may point to lignocaine administration by ETT cuff being more effective in providing desired action [1, 17]. These results show that lignocaine can be used to suppress the cough reflex resulting in little to no discomfort in patients. The lignocaine diffuses through the membrane of the cuff and acts on the mucosal layer to facilitate the necessary effects [16].

The diffusion of lignocainethrough the membrane of the cuff and acts on the mucosal layer to facilitate the necessary effects [17]. The limitations of the recent study include the single-center nature of the study which can affect the generalizability of the study as well as the follow-up period which could have been longer. Different types of surgeries could have different effects on the hemodynamic status and having participants who have undergone the same surgery would increase the specificity of the study. The strengths of the study included the randomized nature of the group allocation and the fact that there was no patient loss to follow-up. The clinical implication of the study is that the intracuff injection of alkalinized lignocaine can help in stabilizing hemodynamic status as well as reduce throat-related discomforts making it more desirable for patients. It can be used in addition to the use of I-gel to ensure effective seal during intubation [18].

Conclusion

The present study's results support the conclusion that, when compared to air inflation up to 20 cm of water, intracuff injection of alkalinized lignocaine caused less or no hemodynamic changes that could have stressed the patient. It also significantly decreased the incidence of coughing during extubation, as well as sore throats and hoarseness of voice 30 minutes and 24 hours after extubation. Because of these variations, the intracuff injection of alkalinized lignocaine could be a more effective method for enabling an ETT to be tolerated during anesthetic treatments.

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