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Efficacy of Saline Versus Alkalinized 2% Lignocaine For Inflating Endotracheal Tube Cuff And Its Pressure Effects On Incidence Of Post Operative Sore Throat And Cough

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ABSTRACT
Background*:*
The endotracheal tube cuff pressure inflated with saline or alkalinized lignocaine during general anaesthesia were compared and incidence of post operative throat symptoms like sore throat and cough were analyzed following extubation.
Methodology*:*
We enrolled 98 patients undergoing elective surgery under general anaesthesia maintained by nitrous oxide in our prospective, double-blind trial. Patients were randomly allocated into 2 groups. Group A: Patients in whom saline was used to inflate endotracheal tube cuff, and Group B: Patients in whom alkalinized lignocaine (2% lignocaine : 7.5% sodium bicarbonate 19:1) was used to inflate endotracheal tube cuff, to achieve a cuff pressure that prevented air leak during positive pressure ventilation. Incidence of post operative sore throat and cough were analyzed at 1 and 24hours. Volume of inflation solution, intracuff pressure, duration of anaesthesia, and volume of inflation solution withdrawn from the endotracheal tube cuff were also recorded.
Results*:*
We found comparable incidence of post operative sore throat at 1hour (p=0.715) between two groups. However, at 24 hours after extubation, there was a significant difference noted in between two groups (p=0.022). No significant difference was observed in incidence of coughing in both saline and lignocaine groups in postoperative period at 1hour (p= 1.0) and 24hours (p=0.617) of extubation.We found a significant increase in cuff pressures of both the groups till 90mins from baseline after which there was no significant increase in pressure.
Conclusion*:*
The present study demonstrated that the intracuff alkalinized 2% lignocaine was superior to saline in decreasing incidence of sore throat and cough during postoperative period.
Keywords: cuff pressure, endotracheal tube cuff, alkalinized lignocaine, sore throat, cough

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I. Introduction

Cough and sore throat are common complaints after emergence from general anaesthesia, which could significantly affect the quality of recovery period. Approved cuff pressure is between 20-25cm of H_2O.(1) Cuff pressure crossing 30cm of H_2O disrupts capillary blood flow through mucosal vessels, causing inflammatory

response in pharyngolaryngeal and tracheal mucosa, leading to multiple lesions like erythema, oedema, hematoma, ulceration and granuloma. These lesions may lead to sore throat, hoarseness, dysphagia and cough postoperatively.

The risk factors for post operative throat symptoms are related to anaesthesia technique like size of the tube, nitrous oxide, number of attempts during intubation, improper fitting of the tube, rigorous pharyngeal suctioning during extubation. The risk factors related to surgery are type and duration of surgery, placement of nasogastric tube, patient's position on the operation table.(1)

Nitrous oxide, used during general anaesthesia, readily diffuses inside the cuff, leading to increase in the cuff pressure.(2) Hyperinflation of the cuff increases contact area between cuff and mucosa, causing post-operative throat symptoms. Post-operative sore throat, defined as pain in the larynx or pharynx is seen in 50% or more post-operative cases.(3)

Lignocaine, when administered as cuff inflation medium, provides direct anaesthetic effect to tracheal mucosa by diffusing through the semipermeable membrane, and being liquid in nature, inhibits the entry of nitrous oxide in the cuff.(2) Alkalinization of lignocaine with sodium bicarbonate increases the pH value of the solution to 7.43, it has faster onset, increased duration of action and better quality of block. It also hastens the anaesthetic action of lignocaine to the mucosa, and decreases the dosage.(1) This helps in better airway tolerance during general anaesthesia, reduces incidence of sore throat and coughing after extubation.

II. Methods And Materials:

This randomized double-blinded single study was conducted in a tertiary care teaching government hospital, over a period of one year from 1st August 2021 to 31st July 2022, after obtaining ethical permission and consent from the participants of the study.

We enrolled patients with age group 18-65 years with ASA I or II, Mallampati score I or II, Surgeries with predicted minimum duration of 30 minutes. We excluded patients with history of allergy to study drugs, preoperative cold, sore throat, cough or hoarseness, smoking, potentially difficult intubation, patients requiring prone position during surgery, patients requiring more than 1 attempt to achieve tracheal intubation, surgery in mouth, throat or neck area, tracheostomy, laryngeal disease or surgery, cardiopulmonary, neuromuscular, renal or hepatic disease, patients with increased risk of aspiration or gastro esophageal reflux disease, intraoperative nasogastric tube placement, and pregnancy. General anaesthesia was given as per hospital's protocol and dosage according to body weight of the patient. Patients were intubated with high volume low pressure cuffed endotracheal tube made of polyvinyl chloride. Appropriate inner diameter was chosen individually, 7.0-7.5mm for females and 8.0-8.5mm for males. No lubricant was used on tube before intubation.

98 patients were randomized into two groups saline group (Group A), and lignocaine group (Group B) by a computer- generated random selection using block randomization. Concealment of allocation was done with opaque sealed envelope. Saline and alkalinized lignocaine (2% lignocaine with 7.5% sodium bicarbonate in the ratio of 19:1) was used to inflate the endotracheal tube cuff till just audible air leak in group A and B respectively. Volume of inflation solution, intracuff pressure (using portable non-invasive manometer graduated in cmH_2O connected to the pilot balloon of the endotracheal tube), duration of anaesthesia, and volume of the inflation solution withdrawn from endotracheal tube cuff were also recorded. The cuff pressure was noted immediately after inflation, at 30 minutes, 60minutes, 90 minutes, and 120 minutes after intubation. An independent observer blinded from the study group recorded the presence of sore throat and cough at the end of 1hour and 24hours of extubation.

Stastistical analysis:

Sample size is calculated with the help of a study by Rizvanović *et al*.,2019. To detect a difference of 20% in the incidence of sore throat at 1 hour and 24 hour postoperatively, at 80% power and 5% level of significance, 44 patients are required in each group. Considering an attrition rate of 10%, 49 patients will be studied in each group with a total sample size of 98 patients.

All data were analyzed using Microsoft Excel, Graph Pad Prism and IBM SPSS V21.Chi square and Fisher's exact test is used to evaluate association between categorical variables. Data were checked for normality using Kolmogorov-Smirnova and Shapiro-Wilk test. Independent T test is used to compare mean difference between two or ANOVA is used for more than two groups depending on fulfilment of normality assumption for continuous variables. For non-normal data Mann Whitney test & Kushkar Wallis and Friedmann and Wilcoxon test is used.

At 5% level of significance, Statistical significance between the groups wasinterpreted as follows:

- p value > 0.05 = not significant
- p value <0.05 = significant
- p value <0.001 = highly significant

III. Results And Observation:

The demographic characteristics of the study subjects in terms of age, sex, height, weight, BMI, type of surgery, duration of anaesthesia, Mallampati score and ASA classification were comparable in both the groups. Duration of anaesthesia noted during the procedures did not show any statistically significant result with p-value=0.282 [Table 1].

Table 1: Table showing duration of anaesthesia in both groups

Duration of Anaesthesia	Mean±SD	Median (IQR)	p value
Lignocaine	81.69±22.07	75(62-92)	0.282
Saline	75.57±17.88	66(62-90)	

Mann- Whitney test is used to determine the p value

The volume of inflation media injected into the cuff during intubation and extubation were noted [table 2.1]. The difference between them in both the groups was noted to be statistically significant with p value=0.046 [Table 2.2]

Table 2.1: Volume of medium used to inflate the endotracheal tube cuff at intubation and volume of the medium withdrawn at extubation:

Group A	N	Mean	SD	% Change	p value
at intubation	49	2.867	0.476		
at extubation	49	2.812	0.453	-1.9%	<0.001
Paired t test used to calculate the p value					
Group B	N	Mean	SD	% Change	p value
at intubation	49	2.878	0.591		
at extubation	49	2.779	0.556	-3.4%	<0.001

Paired t test is used to calculate the p value to compare intragroup variable

Table 2.2: difference in volume of inflation media at intubation and extubation in both the groups:

Group	N	Mean Difference	SD	p value
Group A	49	0.055	0.089	0.046
Group B	49	0.097	0.108	

Mann Whitney test is used to calculate the p value.

The incidence of sore throat at the end of 1 hour after extubation was found to be 6.1% with alkalinized lignocaine and 10.2% with saline. There was no significant difference between the two groups [Table 3].

Table 3: Table showing distribution of patients with respect to incidence of sore throat at the end of 1hour of extubation

SORE THROAT_1 hour	Group A	Group B	Total	Chi	p value
No	44(89.8%)	46(93.9%)	90(91.8%)	0.544	0.715
Yes	5(10.2%)	3(6.1%)	8(8.2%)		
Total	49(100%)	49(100%)	98(100%)		

Fisher's Exact test is used to determine the p value.

Regarding the incidence of sore throat at the end of 24 hours of extubation, we have found significant difference (p value 0.022) between the two groups at the end of 24 hours, and incidence of sore throat to be less in lignocaine group (6.1%) than saline group (24.5%) [Table 4].

Table 4: Distribution of patients with respect to incidence of sore throat at the end of 24 hours of extubation

SORE THROAT_24 hours	Group A	Group B	Total	Chi	p value
No	37(75.5%)	46(93.9%)	83(84.7%)	6.376	0.022
Yes	12(24.5%)	3(6.1%)	15(15.3%)		
Total	49(100%)	49(100%)	98(100%)		

Fisher's Exact test is used to determine the p value.

Regarding the incidence of cough, our study shows no significant difference in the incidence of coughing in both saline and lignocaine groups in postoperative period at 1 hour [Table 5] and 24 hours [Table 6] of extubation.

Table 5: Distribution of patients with respect to incidence of cough at the end of 1 hour of extubation

COUGH_1hour	Group A	Group B	Total	Chi	p value
No	48(98%)	49(100%)	97(99%)	1.01	1.0
Yes	1(2%)	0(0%)	1(1%)		
Total	49(100%)	49(100%)	98(100%)		

Fisher's Exact test is used to determine the p value.

Table 6: Distribution of patients with respect to incidence of cough at the end of 24 hours of extubation

COUGH_24hours	Group A	Group B	Total	Chi	p value
No	46(93.9%)	48(98%)	94(95.9%)	1.043	0.617
Yes	3(6.1%)	1(2%)	4(4.1%)		
Total	49(100%)	49(100%)	98(100%)		

Fisher's Exact test is used to determine the p value.

In our study, when cuff pressure was compared between saline and lignocaine, it was seen that the cuff pressure in both the groups shows significant rise with respect to time till 90 minutes of duration of anaesthesia ($p<0.001$) after which there is no significant change in cuff pressure in both saline group ($p=0.0059$) and lignocaine group ($p=0.157$). Also both the groups maintained cuff pressure less than 25cm H2O throughout the duration of anaesthesia [Table 7].

Table 7: Cuff pressure variation at various time intervals during anaesthesia

	Lignocaine		Friedman Test	Wilcoxon Signed rank Test
	Mean±SD	Median (IQR)	p value	p value(compared to baseline)
CUFF PRESSURE (cmH20)_at intubation	17.84±2.51	18(16-19)	0.191	
CUFF PRESSURE (cmH20)_30MINS	20±2.86	20(18-22)		<0.001
CUFF PRESSURE (cmH20)_60 MINS	22.12±3.09	22(20-24)		<0.001
CUFF PRESSURE (cmH20)_90 MINS	23.17±2.94	24(20-25.5)		<0.001
CUFF PRESSURE (cmH20)_120MINS	22±1.41	22(21-23)		0.059

	Saline		Friedman Test	Wilcoxon Signed rank Test
	Mean±SD	Median (IQR)	p value	p value(compared to baseline)
CUFF PRESSURE (cmH20)_at intubation	17.22±2.82	18(16-18)	0.112	
CUFF PRESSURE (cmH20)_30MINS	19.55±3.04	20(18-22)		<0.001
CUFF PRESSURE (cmH20)_60 MINS	21.14±3.08	22(20-24)		<0.001
CUFF PRESSURE (cmH20)_90 MINS	23.41±1.7	24(22-24)		<0.001
CUFF PRESSURE (cmH20)_120MINS	25±1.41	25(24-25)		0.157

Wilcoxon Signed rank test was applied to determine the p value.

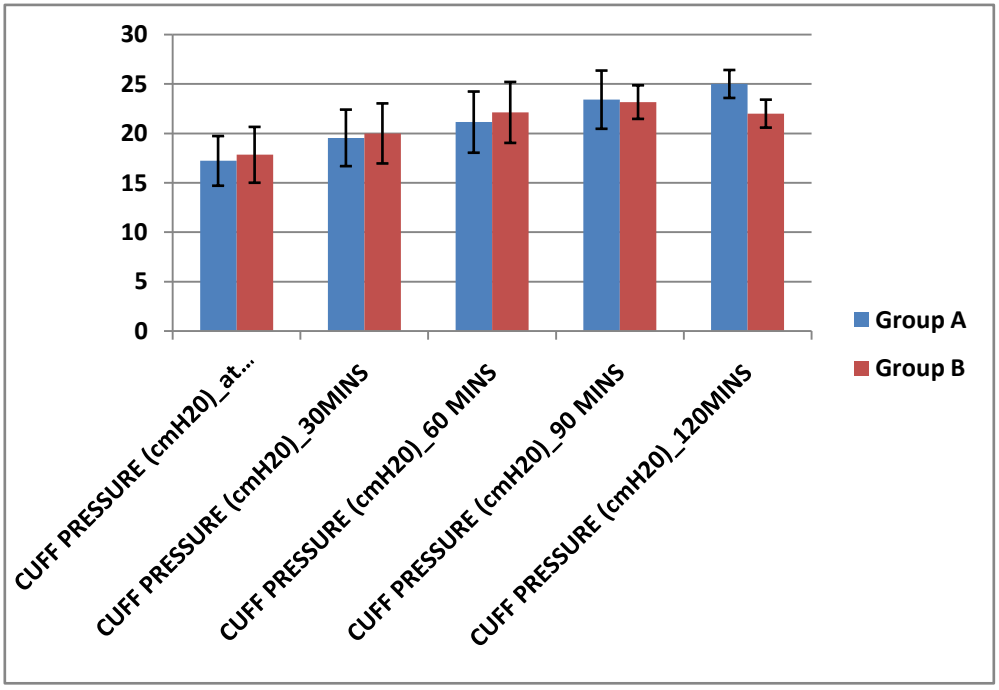

FIGURE: Figure showing change in the cuff pressure with respect to various time intervals.

IV. Discussion:

In 2015, Lam F *et al*. analyzed that intracuff lidocaine helps in reducing airway morbidities.(3) Intracuff alkalinized lidocaine reduces the needed amount of lignocaine, and increases its diffusion through the cuff membrane. (4)(5)(6)

Shroff PP *et al*. and Huang CJ *et al*. found that diffusion of the drug across the cuff membrane is facilitated by increasing proportion of nonionized form of the drug, done by two techniques- alkalinisation and warming. (7)(8) The pH of the drug in their study was made alkaline by adding 1ml of sodium bicarbonate (7.4%) to 19ml of lignocaine hydrochloride, similar to our study.

In our study, incidence of sore throat at the end of 1hour after extubation was found to be low with lignocaine 6.1%, compared to saline 10.2%, but not statistically significant (p value 0.715). This finding is consistent with the studies by Rizvanović N *et al.* and Souissi H *et al*.(1,5) In contrast, Navarro LHC *et al.* found the incidence of sore throat to be significantly lower in lignocaine group than saline group.(4)

Regarding incidence of sore throat at the end of 24hours of extubation, Rizvanović N *et al.*, Navarro LHC *et al.* and Souissi H *et al.* found no significant difference between the two groups.(1,4,5) In contrast, we found significant difference (p value 0.022) between the two groups at the end of 24hrs, and incidence of sore throat to be less in lignocaine group (6.1%) than saline group (24.5%). The reason may be diffusion of lignocaine out of cuff membrane, providing a residual topical anaesthetic effect over tracheal mucosa.

Navarro and Baughman reported that the incidence of sore throat at the end of 24hours was reduced by 50% in the lignocaine group after 24 hours of extubation when he compared intra cuff air and lignocaine.(9) Altintaş F *et al*. and Huang CJ *et al*. also reported less incidence of post operative sore throat in lignocaine group than saline group. (10)(8)

Gaur P *et al*., Shroff PP *et al*., and Estebe JP *et al*. found that the incidence of sore throat was lower in lignocaine group compared to air group and saline group. (2) (7) (6)

Soltani HA *et al.* found that lignocaine used as inflation media or via intravenous route at the end of surgery, effectively reduces the incidence of sore throat and cough. (11)

Above study results were in accordance with the findings of our study thereby concluding that lignocaine is a better inflation media in preventing post operative sore throat.

Our study shows no significant difference in the incidence of coughing in both saline and lignocaine groups in postoperative period at 1hour(p= 0.617) and 24hours(p=0.715) of extubation, similar to the study by Navvaro LHC *et al*. and Rizvanović N *et al.*(1,4)

Fagan C *et al*. also observed that incidence of coughing was lower in lignocaine group in the initial post extubation period when compared to saline group.(12) Our study shows a low incidence of cough in both saline and lignocaine groups, but no significant statistical difference in between the groups.

In the studies done by Bennet MH *et al.*(13). and Combes X *et al.*(14)., there is a significant rise in cuff pressure in air group when compared to saline group. Similar findings are noted in the study done by Gaur P *et al.*(2). However, Navarro LHC *et al*. (15), found cuff pressure in the saline group increased with time and was more than that of lignocaine group at the time of extubation, but the cuff pressure in the lignocaine group was constant, also both the groups maintained cuff pressure less than $25cmH_2O$. These findings are in accordance with the findings of our study. Shroff PP *et al*(7) found no statistical difference in cuff pressure at intubation between air, saline and lignocaine groups. The cuff pressure started rising gradually after 15mins of cuff inflation. The cuff pressure in air group was significantly higher than both saline and lignocaine groups in the studies done by Rizvanović N *et al*.(1) and Shroff PP *et al*.(7)

Volume of both saline and lignocaine in the cuff during intubation and extubation shows significant difference in our study. In saline group, we injected approximately 2.867ml of saline after intubation, volume of saline withdrawn during extubation was 2.812ml ($p<0.001$). Similarly, amount of lignocaine used for inflating cuff during intubation was 2.878ml and volume of lignocaine withdrawn during extubation was 2.779ml ($p<0.001$). When volume of both the groups were compared, a significant difference was noted ($p=0.046$). Volume of lignocaine withdrawn during extubation was less in comparison to saline, similar to the study by Navarro LHC *et al.*(15) but the amounts were found to be reduced during extubation. Unlike our study, no statistical difference noted between the two groups.

Shroff PP *et al*.(7) observed that volume of air withdrawn is increased in comparison to the volume injected in the cuff during intubation, but there was a decrease in volume of alkalinized lignocaine .This may be due to the presence of liquid in the cuff which inhibits the diffusion of nitrous oxide in it. Nitrous oxide diffuses through the air filled cavities. Decrease in the volume of alkalinized lignocaine denotes the permeability of alkalinized lignocaine to thin polyvinyl chloride endotracheal tube cuff membrane. Lignocaine diffuses out and anaesthetizes the tracheal mucosa, reducing airway irritation.

V. Conclusion:

Saline and alkalinized 2% lignocaine are both effective in reducing the incidence of post-operative sore throat and cough till 24hrs of extubation. However, alkalinized 2% lignocaine is more effective. Both saline and alkalinized 2% lignocaine, though showed a rise in cuff pressure initially, maintained the cuff pressures below 25cmH2O, which is the recommended cuff pressure5, thus preventing the tracheal mucosal injuries and occurrence of post-operative throat symptoms like sore throat and cough.

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