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COMPARISON OF INTRACUFF ALKALINIZED 2% LIGNOCAINE VERSUS DEXAMETHASONE FOR ATTENUATION OF POST OPERATIVE LARYNGOTRACHEAL MORBIDITY: A RANDOMIZED COMPARATIVE STUDY

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ABSTRACT
Introduction: This randomized comparative study was planned to compare intracuff alkalinized lignocaine versus dexamethasone in preventing postoperative laryngotracheal morbidity. During general anesthesia patients were intubated with cuffed endotracheal tubes to provide effective positive pressure ventilation as well to prevent risk of aspiration. The cuffs of endotracheal tubes were inflated with air. This air in these cuffed endotracheal tubes can cause significant laryngotracheal morbidity. So, we planned this study to find a better substitute other than air to prevent postoperative laryngotracheal morbidity. **Material and methods:** Total 56 cases were taken. In group A, the cuff of the endotracheal tube was filled with 2% lignocaine 2 ml (40 mg) and sodium bicarbonate ($NaHCO_3$ 8.4%) 1 ml (total 3 ml volume). In Group B, the cuff of the endotracheal tube was filled with dexamethasone (8 mg) 2 ml with 1 ml NS (total 3 ml volume). **Results:** The incidence of sore throat and hoarseness was less in the alkalinized lignocaine group. (p value > 0.05). While the incidence of coughing was roughly similar in both groups and at different time intervals (P value >0.05). **Conclusion:** Intracuff alkalinized Lignocaine in comparison to intracuff dexamethasone causes less incidence of sore throat and hoarseness in post operative period thus improved patient comfort levels and better recovery profile.

INTRODUCTION

During general anesthesia endotracheal tubes are inserted to maintain airway patency and as a conduit for oxygen, nitrous oxide and inhalational anesthetic agents. These endotracheal tubes are cuffed to provide effective positive pressure ventilation and to protect the lungs from risk of aspiration. Several studies have reported that nitrous oxide used during general anesthesia diffuses into air filled endotracheal tube (ETT) cuff thus increasing the cuff pressure. Prolonged duration of high cuff pressure compromises blood supply of tracheal mucosa leading

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to postoperative laryngotracheal morbidity like cough, sore throat, hoarseness of voice, laryngospasm, dysphagia, dysphonia etc. This Coughing can cause hyperdynamic responses in the postoperative period leading to hypertension, tachycardia, dysrhythmias, raised intraocular, intraabdominal and intracranial pressures, wound dehiscence, bleeding and bronchospasm. Many factors are causative for it like age, sex, smoking, cuff type, cuff pressure, type of surgery, head and neck positions, ETT size, duration of surgery, trauma to pharyngo-laryngeal mucosa, usage of Nitrous oxide, timing of extubation, coughing-bucking during extubation etc. Prévention strategies for this laryngotracheal morbidities are both pharmacological and non-pharmacological measures. Non pharmacological include intubation by experienced anaesthesiologist, reducing cuff size, monitoring cuff volume and pressure, extubation in deep plane of anesthesia etc. Pharmacological methods include ETT cuff lubrication with lidocaine jelly, steroids inhalation before intubation, anti-inflammatory drugs, topicalization of airway with local anesthetic agents (Lidocaine, Ropivacaine), endotracheal tube cuff inflation media other than air (local anesthetics, saline, anesthetic gas mixtures, steroids etc), intravenous xylocard and intravenous dexamethasone, opioid administration during emergence and extubation.

Lidocaine when administered as cuff inflation medium may protect tracheal mucosa through its continuous topical anesthetic effect and it also prevents the diffusion of nitrous oxide into the cuff. This increases tolerance to placement of tracheal and tracheostomy tubes. Hemodynamic disturbances after extubation are avoided and incidence of laryngotracheal morbidity is decreased. Alkalinized lidocaine (lignocaine hydrochloride in 8.4% sodium bicarbonate) has an advantage over non alkalinised variety with a quicker onset, prolonged duration and better quality of block. Lignocaine due to its local anesthetic effect inhibits ionic fluxes needed for the initiation and conduction of impulses, thus stabilizing the neuronal membrane and providing anesthesia to tracheal mucosa. Sodium bicarbonate alkalinizes lignocaine hydrochloride thus increasing its diffusing capacity (63 folds) through hydrophobic ETT cuff membrane. So, a small amount of lignocaine provides rapid and prolonged action over mucosa [1].

Due to anti-inflammatory effects corticosteroids induce lipocortins which inhibit phospholipase A2 proteins. These lipocortins inhibits the release of arachidonic acid which produces inflammatory mediators like prostaglandin and leukotrienes, so it can be possible to reduce the incidence of postoperative laryngotracheal morbidity like cough, sore throat, restlessness and hoarseness [2,3]. In many studies steroids are used by different routes such as topical, intravenous and inhaled to reduce the incidence of laryngotracheal morbidity.

Based on the above studies using steroids, we hypothesize that intracuff dexamethasone exerts its anti-inflammatory effect on tracheal mucosa thus reducing the incidence of postoperative laryngotracheal morbidity. So, we conducted this randomized double blind interventional study to compare the effectiveness of intracuff alkalinized 2% lignocaine versus intracuff dexamethasone in attenuating postoperative laryngotracheal morbidity. The primary objective of study was to determine the % of cases who develop cough, sore throat and hoarseness. Secondary objective was to determine their severity and to determine intraoperative haemodynamic changes.

MATERIALS AND METHODS

The study was conducted in a tertiary health care centre after taking due permission from the institutional ethics committee (CTRI /2021/08/046478). It was a randomized double blind interventional study. Randomization was done by sealed opaque envelope technique.

Sample Size: A sample size of total 56 cases was required at 95% confidence and 80% power to verify the expected minimum difference of 23% in proportion of cases who develop cough in postoperative period in both groups (alkalinized lignocaine 56%, dexamethasone 33%). This sample size was adequate to cover postoperative extubation related laryngotracheal morbidity and hemodynamic variables. The study included 56 patients which were divided into groups of 28 each.

Group A: Endotracheal tube cuff was filled with 2 ml of 2% lignocaine (40 mg) and 1ml of sodium bicarbonate ($NaHCO_3$ 8.4%). Total drug volume was 3 ml. Endotracheal tube cuff pressure was maintained at 25 cm of H_20

Group B: Endotracheal tube cuff was filled with 2 ml dexamethasone (8 mg) and 1 ml of Normal saline. Total drug volume was 3ml. Endotracheal tube cuff pressure was maintained at 25 cm of H_20.

Inclusion Criterion: Patients of American Society of Anaesthesiologists physical status class I and II, Age between

20-50 years, duration of surgery 1-3 hr, patients giving consent were included in this study.

Exclusion Criterion: History of known allergies to study drugs, laryngeal disease/surgery, tracheostomy, asthma, Chronic Obstructive Airway Disease, Upper Respiratory Infection within 6 weeks, patients with Mallampati scoring Grade 3,4 were excluded from study.

After confirmation of identity, the patient was taken to the operation theatre. PAC, fasting status, and informed written consent were checked. Patients were randomized to either group using sealed opaque envelope technique. A peripheral I.V. line was secured with 20 G cannula. Ringer Lactate 10 ml/kg was started. In premedication iv Ranitidine 50 mg, Metoclopramide 10 mg, iv Glycopyrrolate 0.2 mg, Midazolam 1 mg were given. To provide analgesia IV fentanyl 2 micrograms/kg was given. Patient was induced with Propofol 2 mg/Kg i.v. then Atracurium 0.5 mg/kg given and bag and mask ventilation was done for 3 minutes then laryngoscopy done. During laryngoscopy following parameters were noted

- Time taken for intubation
- Attempts of intubation
- Cormack- Lehane grading.

Patients were intubated with an appropriate size endotracheal tube. Then cuff inflation was done as per allotment of the group. Bilateral air entry was checked and endotracheal tube was connected to a closed circuit. Maintenance done with N_2O: O_2 in 2:2 ratio, Sevoflurane 1 Minimal Alveolar Concentration & inj. atracurium in titrated doses. Before starting nitrous oxide, baseline cuff pressure was recorded with a manometer, afterwards it was recorded every 15 minutes and maintained at 25 cm of H_2O. Intraoperatively vital parameters were recorded as per proforma. After the completion of surgery, the patient was reversed with i.v. Glycopyrrolate 10 mics/kg, i.v. neostigmine 40 mics/kg and extubated. Postoperatively following parameters were noted. Cough, sore throat and hoarseness at extubation and then at 5 minutes,30 minutes,45 minutes, 60 minutes after surgery in the postoperative anesthesia care unit.

Statistical analysis: Continuous data were summarized in the form of mean and standard Deviation. Difference in mean of two groups was analyzed using the 'student's t test'. Continuous data were expressed in the form of proportion; difference in proportion was analyzed using 'Chi-square test'. Multivariate analysis was done using logistic regression for prediction of outcome on the basis of independent factors. The level of significance was kept 95% for all statistical analysis.

RESULTS

Demographically both groups were comparable in terms of age, sex, ASA grading and weight. Mean time taken for intubation was 17.32 seconds in group A and 16.64 seconds in group B. (p value > 0.05 Non-Significant {NS}). If we discuss attempts of intubation, in group A all 28 patients i.e., 100% patients were intubated in 1st attempt while in group B 26 patients i.e., 92.9% were intubated in 1st attempt & remaining 2 patients i.e., 7.1% in 2nd attempt. (P value >0.05 NS). Distribution of study subjects according to Cormack Lehane grading between A and B groups. In group A 92.9% patients belong to Grade 1 while 7.1% belong to Grade 2a. In group B 89.3% patients belong to Grade 1 while 10.7% belong to Grade 2a. In group B 10.7% patients belong to Grade 2a. (P value>0.05 NS)

Haemodynamic variables and SpO_2 were comparable between both groups. (P value >0.05). Incidence of cough at the time of extubation and at different time intervals were comparable between 2 groups (P value >0.05 statistically NS).

Table 1 : Incidence of cough at different time intervals.

Time point	Cough grade	Group A		Group B		P value
		N	%	N	%	
At extubation	No	7	25	6	21.4	0.350
	Mild	21	75	20	71.4	
	severe	0	0	2	7.2	
5 min	No	28	100	28	100	-
	Mild	0	0	0	0	
	severe	0	0	0	0	
30 min	No	28	100	28	100	-
	Mild	0	0	0	0	
	severe	0	0	0	0	
45 min	No	28	100	28	100	-
	Mild	0	0	0	0	
	severe	0	0	0	0	
60 min	No	28	100	28	100	-
	Mild	0	0	0	0	
	severe	0	0	0	0	

Incidence of sore throat just after extubation was more in B group in comparison to A group and it was statistically significant. (P value 0.001. T et al [4], Rafiei et al [5] , Kep Kee et al [6] and Esbeste et al [7] also have the same results as ours. They also found that the difference in sore throat was statistically significant immediately after extubation. and it was more in dexamethasone group. Navarro et al [8] also found the same results that alkalinized lignocaine is more effective in reducing sore throat in comparison to dexamethasone.

Table 2: Incidence of sore throat at different time intervals.

Time point	Sore throat grade	Group A		Group B		P value
		N	%	N	%	
At extubation	No	21	75	9	32.1	0.001 (S)
	Mild	5	17.9	5	17.9	
	severe	2	7.1	14	50	
5 min	No	19	67.9	22	78.6	0.307
	Mild	9	32.1	5	17.8	
	severe	0	0	1	3.6	
30 min	No	21	75	22	78.6	0.507
	Mild	7	25	5	17.8	
	severe	0	0	1	3.6	
45 min	No	23	82.1	23	82.1	0.574
	Mild	5	17.9	4	14.3	
	severe	0	0	1	3.6	
60 min	No	23	82.1	23	82.1	0.574
	Mild	5	17.9	4	14.3	
	severe	0	0	1	3.6	

Incidence of hoarseness was more in B group in comparison to A group at all study intervals (p value < 0.05)

DISCUSSION

In general anesthesia patients are intubated with cuffed endotracheal tubes. Cuffed endotracheal tubes provide efficient positive pressure ventilation as well decreases the risk of aspiration. But they are the reason for laryngotracheal morbidity in post operative period which includes throat pain, coughing, sore throat, hoarseness of voice, dysphagia etc. Various pharmacological and non-pharmacological measures are used to prevent this laryngotracheal morbidity. Out of these most widely used measures is use of liquid cuff inflation medium instead of air like saline, steroids, local anesthetics. These liquid cuff mediums prevent the diffusion of N_2O into the cuff thus preventing the increase in cuff pressure. Narcotics, iv lignocaine, extubation in the deeper plane of anesthesia are also utilized to decrease this laryngotracheal morbidity.

Local anesthetics when used as an inflation medium diffuse out & provide local anesthetic effect to tracheal mucosa thus prevents the excitation of sensory C fibers. Intracuff Steroids like dexamethasone exhibit their anti-inflammatory effects.

Table 3: Incidence of hoarseness of voice at different intervals

Time point	Hoarseness	Group A		Group B		P value
		N	%	N	%	
At extubation	None	19	67.9	10	35.7	0.023 (S)
	Noted by the patient	5	17.9	5	17.9	
	Obvious to observer	4	14.3	13	46.4	
5 min	No	19	67.9	10	35.7	0.015 (S)
	Mild	5	17.9	4	14.3	
	severe	4	14.3	14	50	
30 min	No	19	67.9	11	39.3	0.022 (S)
	Mild	8	28.6	9	32.1	
	severe	1	3.6	8	28.6	
45 min	No	24	85.7	15	53.6	0.032 (S)
	Mild	2	7.1	7	25	
	severe	2	7.1	6	21.4	
60 min	No	25	89.3	15	53.6	0.012 (S)
	Mild	2	7.1	10	35.7	
	severe	1	3.6	3	10.7	

Rafiei et al. [5] compared the intracuff dexamethasone, lignocaine & normal saline. Estebe et al. [7] compared intracuff alkalinised lignocaine versus water soluble gel lubrication of endotracheal tube cuff while Navarro et al. [7] compared Intracuff alkalinized lignocaine versus normal saline in

preventing sore throat. Lam et al. [9] found that both alkalinised & non alkalinised lignocaine were effective in preventing postoperative emergence.

In our study incidence of coughing was comparable in both groups at all study intervals. While in study of Rafiei et al. [5] the incidence of coughing was more in D group but its severity was less. Incidence of sore throat was more in the B group at all intervals in our study, this is in contrast with Rafiei et al [5] that incidence of sore throat was statistically similar in all three study groups. Whereas Desai T et al [4] found that incidence of sore throat was less and similar in alkalinised lignocaine & dexamethasone group while saline group has increased incidence & severity of cough.

Incidence of hoarseness was more in B group as compared to A group at all the study intervals i.e., after extubation, after 5 minutes, 30 minutes, 45 minutes & 60 minutes. This was statistically significant (P value <0.005). Desai T et al [4] found similar results as ours. Kep Kee W *et al* [6], Rafiei et al [5] found results contrary to us that incidence of hoarseness was comparable in dexamethasone and alkalinised lignocaine groups.

CONCLUSION

Analysis of the data and statistics led us to the conclusion that intracuff alkalinized lignocaine has fewer incidences of sore throat and hoarseness in the post-operative period when compared to intracuff Dexamethasone, thereby improving patient comfort levels. Haemodynamic variables were comparable in between two groups. Limitation of the study is small sample size, lack of control group and also, we had not included paediatric and obstetric population so cannot extrapolate our results on them.

FINANCIAL ASSISTANCE

Nil

CONFLICT OF INTEREST

The authors declare no conflict of interest

AUTHOR CONTRIBUTION

Sonali Beniwal planned the study, did literature survey, designed the manuscript. Rajbala had collected the data. Deeksha Sirohi had done analysis and interpretation of data. Pratibha Rathore had contributed in draft of work and revised it.

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