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Original Research Article

A Hospital Based Randomized Double-Blinded Controlled Study to Assess the Efficacy and Safety of Air versus Alkalinized 2% Lignocaine for Inflating Endotracheal Tube

Shweta Kamleshbhai Prajapati[1], Miten Rameshbhai Delvadiya[2], Maitriben Girishkumar Patel[3], Jayshri Prajapati[4]

[1]Post Diploma DNB, Department of Anaesthesiology, GMERS Medical College, Himmatnagar, Gujarat, India

[2]Post Diploma DNB, Department of Anaesthesiology, GMERS Medical College, Himmatnagar, Gujarat, India

[3]Senior Resident, Department of Anaesthesiology, GMERS Medical College, Himmatnagar, Gujarat, India

[4]Associate Professor, Department of Anaesthesiology, GMERS Medical College, Himmatnagar, Gujarat, India

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Corresponding author: Dr. Jayshri Prajapati

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Abstract

Aim: The aim of the present study was to evaluate the efficacy of alkalinized 2% lignocaine with conventional air as cuff inflating media, in preventing Postoperative sore throat (POST) and coughing in patients undergoing a surgical procedure under general anaesthesia.

Methods: We conducted this randomized double-blinded controlled study at Department of Anaesthesiology, GMERS Medical College, Himmatnagar, Gujarat, India for one year (July 2022 to June 2023)in operation theatre, postoperative care unit (PACU) and wards. The risks and benefits of the procedure were explained to the patients. We initially included 120 patients as per the inclusion criteria. 20 patients were excluded. The remaining 100 patients were randomly divided into two equal groups of 50 each.

Results: Mean age, gender, mean BMI, ASA grades and mean duration of anaesthesia were comparable in both the groups with no statistically significant difference. The mean volume at the start of the surgery was 5.4 mL and 5.3 mL in Group A and Group B respectively (p-value= 0.555). The mean intra-cuff pressure at the start of the surgery was 20.0 cm in both the groups. The mean volume at the end of the surgery was 7.5 mL and 4.6 mL in Group A and Group B respectively (p-value = 0.001). The incidence of coughing immediately postoperative, 12 hours and 24 hours postoperatively did not differ significantly between the two study groups, whereas the incidence of coughing at one hour postoperative was 28% and 4% in Group A and Group B respectively (p-value = 0.024) The incidence of POST at one hour, 12 hours and 24 hours postoperatively did not differ significantly between the two study groups.

Conclusion: The intracuff alkalinized lidocaine is useful adjunct to endotracheal intubation. In the setting of general anesthesia with the use of N2O and O2 mixture, rise in cuff pressure with the progression of surgery is better overcome when ETT cuff is inflated with lignocaine as compared to air. Alkalinized 2% lignocaine provides an improved protective effect in preventing postoperative laryngotracheal morbidity in form of coughing and POST.

Keywords: Postoperative sore throat, Lidocaine, Air, Endotracheal tube

Introduction

Coughing, sore throat, and hoarseness are most common postoperative complications after emergence from general anesthesia which are very distressing and unpleasant and become more upsetting than surgery itself. [1] Postoperative sore throat (POST) being the most undesirable symptom occurs in more than 50% of surgical patients. [2] Among the various methods of airway management such as the use of facial mask, laryngeal mask airways, and endotracheal tube (ETT), ETT is most frequently associated with such postoperative complications ranging from 30% to 70%. [3,4] The cause of these morbidities could be either patient's bucking or coughing or friction between the

tracheal mucosa or increase in ETT cuff pressure during general anesthesia. [4] This has deleterious effects as it may increase intracranial, intrathoracic or intra-abdominal pressure, bronchospasm, wound dehiscence, bleeding, and laryngeal complication such as sore throat, hoarseness, or dysphonia. [2]

The ETT cuff pressure is most important factor which when elevated compromises of the blood supply of tracheal mucosa followed by serious morbidities such as ciliary loss, inflammation, ulceration, hemorrhage, tracheal stenosis, and trachea-esophageal fistula. [1,5] Maintenance of ideal cuff pressure during whole surgery is also challenging as many factors govern it like anesthetic gases such as N2O, agent used to fill the cuff, and material and type of cuff. [1,6-8] Most commonly used anesthetic gas N2O in conjunction with other gases frequently causes rise in intracuff pressure with the progression of surgery. N2O and oxygen readily diffuse in air-filled cavities such as ETT cuff leading to gradual rise in volume and cuff pressure of ETT. Consequently, this pressure change results in more severe form of POST. [1,9,10] Various literature in the past has proven the relation of rise in cuff pressure and volume with the usage of N2O. Intracuff use of saline and lignocaine is recently being reviewed for the effectiveness in preventing coughing, POST, and postoperative hoarseness (PH). [1,8,11]

Lignocaine being liquid in nature not only inhibits the entry of N2O in the cuff but also permeates through semipermeable cuff membrane to tracheal mucosa and provides direct anesthetic effect. Alkalinization of lignocaine with sodium bicarbonate (NaHCO3) increases the nonionized form of lignocaine which considerably increases the diffusion of lignocaine through polyvinyl cuff walls (63 folds). [1] Thus, lesser amount of lignocaine can provide rapid and prolong action over mucosa. [12]

The aim of the present study was to evaluate the efficacy of alkalinized 2% lignocaine with conventional air as cuff inflating media, in preventing POST and coughing in patients undergoing a surgical procedure under general anaesthesia.

Materials and Methods

We conducted this randomized double-blinded controlled study at Department of Anaesthesiology, GMERS Medical College, Himmatnagar, Gujarat, India for one year (July 2022 to June 2023) in operation theatre, postoperative care unit (PACU) and wards. . Before enrolling the patients for the study, we took written informed consent. The risks and benefits of the procedure were explained to the patients.

We initially included 120 patients as per the inclusion criteria. 20 patients were excluded. The remaining 100 patients were randomly divided into two equal groups of 50 each. ETT cuff was filled with air and 2% lignocaine 2 mL (40 mg) made alkalinized with 1.5% sodium bicarbonate 3 mL (the sodium bicarbonate 7.5% was available, which was diluted five times) to prevent air leak during positive pressure ventilation guided with cuff manometer in Group A and Group B respectively. A senior anaesthesiologist supervised the aforesaid procedure. Patients and observer were blinded for the study. The presence or absence of coughing, and POST immediately, at 1 hour, 12 hours and 24 hours were recorded by the observer.

Inclusion Criteria

Patients of either gender having age between 18 and 65 years, duration of surgery up to 90 minutes, Cormack-Lehane grade I-II and American Society of Anaesthesiologist (ASA) grades I and II.

Exclusion Criteria

Patients with a laryngeal disease/ laryngeal surgery, a history of smoking and sore throat seven days previous to surgery, patients with a history of severe gastro-oesophageal reflux disease, patients who had difficult intubation/failed intubation

The detailed pre-anaesthesia check-up was conducted for fitness which included airway assessment as mentioned in the study proforma to look for any signs of difficult intubation which could contribute as an independent factor for the POST. In the operation theatre, adequate intravenous (IV) access was confirmed. Minimum mandatory monitors such as non-invasive blood pressure, pulse oximeter, and electrocardiography were attached. Surgery was performed under standard general anaesthesia protocols. Premedication was done by Inj. glycopyrrolate (4µg/kg) and Inj. fentanyl (2µg/kg). Patients were pre-oxygenated for three minutes. Induction was done with Inj. propofol (2 mg/kg). After confirming that the patient can be ventilated by the mask (100% oxygen given for 2-3 minutes) a long-acting muscle relaxant Inj. vecuronium (0.08-0.1 mg/kg) or Inj. atracurium (0.5 mg/kg) was administered.

Atraumatic direct laryngoscopy was performed. Insertion of appropriate sized Portex ETT was done under direct vision till cuff went beyond the vocal cords. For female patients, 7.5 mm ETT and for male patients 8.5 mm ETT was used. Confirmation of ETT placement was carried out by auscultation of the chest, chest rise after ventilation and capnography monitoring. The cuff pressure at the start of the surgery was approximately 20 cm of H2O.

Anaesthesia was maintained with oxygen: nitrous oxide 50: 50 and sevoflurane with end-tidal concentration maintained between 1.5% - 1.8% (adjusted according to hemodynamic parameters) with controlled ventilation. End- tidal carbon dioxide was maintained between 30% - 35%. Muscle relaxant supplemental dose was given if required. After completion of the surgery, the patient was reversed with Inj. neostigmine (0.05 mg/kg), and Inj. glycopyrrolate (0.008 mg/kg) IV. After proper nasopharyngeal and oropharyngeal suctioning, ETT was removed during inspiration. The total duration of anaesthesia, volume and cuff pressure of both the groups were noted. Coughing, POST and volume of inflation medium, and intra-cuff pressure at the start and at the end of surgery were the primary and secondary outcome measures respectively.

Statistical Analysis

Data collected were entered in Excel 2007. Statistical Package for Social Sciences for Windows, Version 20.0 from IBM Corporation, Armonk, NY, USA was used for the analysis of the data. The comparison of categorical and continuous variables was done using Chi-Square test/Fisher's exact test and student's t-test respectively. The confidence limit for significance was fixed at 95% level with p-value < 0.05.

Results

Table 1: Baseline characteristics

Characteristics	Group A	Group B	P Value
Mean age in years ±SD	42.8± 12.8	43.7± 13.0	0.540
Gender N (%)			
Male	21 (42)	26 (52)	0.314
Female	29 (58)	24 (48)	
Mean BMI in Kg/m^2 ±SD	26.4± 2.8	25.5± 1.6	0.290
ASA N (%)			
Grade I	36 (72)	34 (68)	0.786
Grade II	14 (28)	16 (32)	
Mean duration of anaesthesia in min. ±SD	136.4± 9.0	140.4± 12.6	0.512

Mean age, gender, mean BMI, ASA grades and mean duration of anaesthesia were comparable in both the groups with no statistically significant difference.

Table 2: Comparison of mean volume, and mean pressure of inflation medium

Variable	Group A	Group B	P Value
Mean volume in mL ±SD			
At the start of surgery	5.4±0.6	5.3±0.5	0.555
At the end of surgery	7.5±0.4	4.6±0.7	0.001
Mean pressure in mL±SD			
At the start of surgery	20.0±0.0	20.0±0.0	0.950
At the end of surgery	30.6±2.6	18.8±4.2	0.001

The mean volume at the start of the surgery was 5.4 mL and 5.3 mL in Group A and Group B respectively (p-value= 0.555). The mean intra-cuff pressure at the start of the surgery was 20.0 cm in both the groups. The mean volume at the end of the surgery was 7.5 mL and 4.6 mL in Group A and Group B respectively (p-value = 0.001).

Table 3: Comparison of incidence of postoperative coughing, and POST

Postoperative Coughing Immediate	Group A n=50 (%)	Group B n=50 (%)	p-value
Yes	18 (36)	6 (12)	0.078
No	32 (64)	44 (88)	
1 hr			
Yes	14 (28)	2 (4)	0.024
No	36 (72)	48 (96)	
12 h			
Yes	5 (10)	0 (0.0)	0.232
No	45 (90)	50 (100)	
24 h			
Yes	2 (4)	0 (0.0)	0.991
No	48 (96)	50 (100)	
Post 1 hr			
Yes	10 (20)	4 (8)	0.227

No	40 (80.0)	46 (92)	
12 hr			
Yes	8 (16)	0 (0.0)	0.050
No	42 (84)	50 (100)	
24 h			
Yes	3 (6)	0 (0.0)	0.445
No	47 (94)	50 (100)	

The incidence of coughing immediately postoperative, 12 hours and 24 hours postoperatively did not differ significantly between the two study groups, whereas the incidence of coughing at one hour postoperative was 28% and 4% in Group A and Group B respectively (p- value = 0.024) The incidence of POST at one hour, 12 hours and 24 hours postoperatively did not differ significantly between the two study groups.

Discussion

There are many airway complications associated with tracheal intubation, or extubation after general anaesthesia. 1 In roughly 50% of patients the postoperative sore throat (POST) is observed. 1 The occurrence of vigorous coughing, agitation, or restlessness, increase intracranial, intra-thoracic, or intra-abdominal pressure, bronchospasm, wound dehiscence and bleeding are also noted after coming out from general anaesthesia. During postoperative care patients may develop complications such as hoarseness, dysphonia, or dysphagia. [13] Lignocaine is one of the most commonly used drugs for preventing POST and its efficacy was evaluated. [14] When lignocaine is injected into the endotracheal tube (ETT) cuff, it spreads through the cuff membrane and induces anaesthetic action in the trachea.[1] This increases airway tolerance to tracheal tubing. After tracheal extubation, the hemodynamic alterations are minimized resulting in reducing the incidence of coughing. Only the non-ionized base form of the drug diffuses across the hydrophobic polyvinyl chloride walls of the ETT cuff. Sodium bicarbonate increases the unionized form of local anaesthetics, which causes an increase in the diffusion of it through the cuff, thereby reducing the dosage of local anaesthetics.

Mean age, gender, mean BMI, ASA grades and mean duration of anaesthesia were comparable in both the groups with no statistically significant difference. Jaichandran et al. concluded that maximum diffusion of lignocaine across the ETT cuff occurred at pH 7.4, and cough receptors are blocked in the tracheal mucosa. This technique can be used for surgeries of less than two hours duration. [15] If nitrous oxide is used as a conjunct with other volatile anaesthetics, intra-cuff pressure is increased. At the beginning of the surgery, this diffuses into the cuff. When cuff pressure exceeds the tracheal mucosal capillary pressure (> 30 mm of Hg), tracheal erosion occurs and postoperative cough and sore throat are caused. [10] Estebe et al. reported that the liquid volume removed from the cuff decreased significantly (5.9 1.6 mL) for the alkalinized group (p-value < 0.001), whereas the air volume withdrawn at extubation time increased significantly in Air Group (112.7 mL) [p-value < 0.0001]. [16] The mean volume at the start of the surgery was 5.4 mL and 5.3 mL in Group A and Group B respectively (p-value= 0.555). The mean intra-cuff pressure at the start of the surgery was 20.0 cm in both the groups. The mean volume at the end of the surgery was 7.5 mL and 4.6 mL in Group A and Group B respectively (p-value = 0.001). In the lignocaine group the cuff volume and pressure did not change with time whereas in the air group they change considerably. Lignocaine is a liquid medium hence, hyperinflation of the cuff with N2O is prevented during surgery. It was observed that lignocaine diffused through the cuff membrane in time and concentration-dependent manner and produced local anaesthetic action on tracheal mucosa, and increased ETT tolerance. [17]

The incidence of coughing immediately postoperative, 12 hours and 24 hours postoperatively did not differ significantly between the two study groups, whereas the incidence of coughing at one hour postoperative was 28% and 4% in Group A and Group B respectively (p- value = 0.024) The incidence of POST at one hour, 12 hours and 24 hours postoperatively did not differ significantly between the two study groups. Although lignocaine was instilled in the cuff, it does not cause any depression of swallowing reflex and other protective reflexes. This has been confirmed by other study done by Estebe et al. which stated that alkalinized intracuff lignocaine improves cuff tolerance; however, the local anesthetic effect does not depress the swallowing reflex so that the patient can protect the airway. [18]

Conclusion

The intracuff alkalinized lidocaine is useful adjunct to endotracheal intubation. In the setting of general anesthesia with the use of N2O and O2 mixture, rise in cuff pressure with the progression of surgery is better overcome when ETT cuff is inflated with lignocaine as compared to air. Alkalinized 2% lignocaine provides an improved protective effect in preventing postoperative laryngotracheal

morbidity in form of coughing and POST. Duration of anesthesia is another risk factor, which has significant impact on increase in cuff pressure and consequently increased the incidence of coughing and POST in ETT cuff filled with air.

References

1. Navarro LH, Braz JR, Nakamura G, Lima RM, Silva Fde P, Módolo NS. Effectiveness and safety of endotracheal tube cuffs filled with air versus filled with alkalinized lidocaine: a randomized clinical trial. Sao Paulo Med J. 2007 Nov 1;125(6):322-8.
2. Lam F, Lin YC, Tsai HC, Chen TL, Tam KW, Chen CY. Effect of Intracuff Lidocaine on Postoperative Sore Throat and the Emergence Phenomenon: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. PLoS One. 2015 Aug 19;10(8):e0136184.
3. Higgins PP, Chung F, Mezei G. Postoperative sore throat after ambulatory surgery. Br J Anaesth. 2002 Apr;88(4):582-4.
4. Tanaka Y, Nakayama T, Nishimori M, Sato Y, Furuya H. Lidocaine for preventing postoperative sore throat. Cochrane Database Syst Rev. 2009 Jul 8;(3):CD004081.
5. Sole ML, Su X, Talbert S, Penoyer DA, Kalita S, Jimenez E, Ludy JE, Bennett M. Evaluation of an intervention to maintain endotracheal tube cuff pressure within therapeutic range. Am J Crit Care. 2011 Mar;20(2):109-17.
6. Liu J, Zhang X, Gong W, Li S, Wang F, Fu S, Zhang M, Hang Y. Correlations between controlled endotracheal tube cuff pressure and postprocedural complications: a multicenter study. Anesth Analg. 2010 Nov;111(5):1133-7.
7. Ahmed A, Abbasi S, Ghafoor HB, Ishaq M. Postoperative sore throat after elective surgical procedures. J Ayub Med Coll Abbottabad. 2007 Apr-Jun;19(2):12-4.
8. Porter NE, Sidou V, Husson J. Postoperative sore throat: incidence and severity after the use of lidocaine, saline, or air to inflate the endotracheal tube cuff. AANA J. 1999 Feb; 67(1):49-52.
9. Fill DM, Dosch MP, Bruni MR. Rediffusion of nitrous oxide prevents increases in endotracheal tube cuff pressure. AANA J. 1994 Feb;62(1):77-81.
10. Manissery JJ, Shenoy V, Ambareesha M. Endotracheal tube cuff pressures during general anaesthesia while using air versus a 50% mixture of nitrous oxide and oxygen as inflating agents. Indian Journal of Anaesthesia. 2007 Jan 1;51(1):24-7.
11. Abbasi S, Mahjobipoor H, Kashefi P, Massumi G, Aghadavoudi O, Farajzadegan Z, Sajedi P. The effect of lidocaine on reducing the tracheal mucosal damage following tracheal intubation. J Res Med Sci. 2013 Sep;18(9):733-8.
12. Huang CJ, Hsu YW, Chen CC, Ko YP, Rau RH, Wu KH, Wei TT. Prevention of coughing induced by endotracheal tube during emergence from general anesthesia--a comparison between three different regimens of lidocaine filled in the endotracheal tube cuff. Acta Anaesthesiol Sin. 1998 Jun;36 (2): 81-6.
13. Lam F, Lin YC, Tsai HC, Chen TL, Tam KW, Chen CY. Effect of intracuff lidocaine on postoperative sore throat and the emergence phenomenon: a systematic review and meta-analysis of randomized controlled trials. PLoS One. 2015 Aug 19;10(8):e0136184.
14. Tanaka Y, Nakayama T, Nishimori M. Lidocaine for preventing postoperative sore throat Cochrane Database Syst Rev., 14 (2015). Article CD004081.
15. Jaichandran VV, Angayarkanni N, Karunakaran C, Bhanulakshmi IM, Jagadeesh V. Diffusion of lidocaine buffered to an optimal pH across the endotracheal tube cuff-an in-vitro study. Indian Journal of Anaesthesia. 2008 Sep 1;52(5):536-40.
16. Estebe JP, Dollo G, Le Corre P, Le Naoures A, Chevanne F, Le Verge R, Ecoffey C. Alkalinization of intracuff lidocaine improves endotracheal tube-induced emergence phenomena. Anesthesia & Analgesia. 2002 Jan 1;94(1):227-30.
17. Estebe JP, Delahaye S, Le Corre P, Dollo G, Le Naoures A, Chevanne F, Ecoffey C. Alkalinization of intra-cuff lidocaine and use of gel lubrication protect against tracheal tube-induced emergence phenomena. British journal of anaesthesia. 2004 Mar 1;92(3):361-6.
18. Estebe JP, Dollo G, Le Corre P, Le Naoures A, Chevanne F, Le Verge R, Ecoffey C. Alkalinization of intracuff lidocaine improves endotracheal tube-induced emergence phenomena. Anesth Analg. 2002 Jan;94(1): 22 7-30.