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Original Research Article

Assessment of the Efficacy and Safety of Air V/s Alkalinized 2% Lignocaine for Inflating Endotracheal Tube: A Randomized Controlled Research

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Abstract

Aim: A randomized controlled study on efficacy and safety of air versus alkalinized 2% lignocaine for inflating endotracheal tube.

Methods: This prospective randomized control study conducted in the Department of Anesthesiology & Critical Care Patna Medical College & Hospital, Patna, Bihar, India for 14 months. 80 patients were divided in two groups as Air group (A) and Lignocaine group (L) according to computer-generated randomization sheet with 40 patients in each group. In A group, ETT cuff was filled with air to prevent air leak during positive pressure ventilation guided with cuff manometer. While in L group, ETT cuff was filled with 2% lignocaine with 7.5% $NaHCO_3$, in the proportions of 19.0:1.0 ml.

Results: The anthropometric parameters in term of age, sex, weight, and ASA were comparable in both groups with $P > 0.05$. The volume and cuff pressure of A group and L group introduced into the cuffs at the start of surgery for adequate seal were recorded and on analysis both were comparable ($P > 0.05$). The mean cuff pressures obtained at the end of surgery were 50.86 cm H_2O and 20.66 cm H_2O in A and L group, respectively, proving statistically significant difference between the two groups. The duration of anesthesia in both groups was comparable with average duration in A group was 2.77 ± 0.82 h and in L group was 2.76 ± 0.80 h. Significant difference determined by Pearson Chi-square test and Fisher's exact test showed $P < 0.05$ thereby substantiating the reduced incidence of coughing and POST in L group. Through the analysis, it was found that in A group, there was a high correlation between duration of anesthesia and cuff pressure achieved in the end of surgery with $P < 0.001$, while no such correlation was obtained in lignocaine group.

Conclusion: we concluded that general anesthesia with the use of N_2O and O_2 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: Alkalinized, 2% lignocaine, Endotracheal tube

Introduction

Numerous factors including availability of newer drugs, availability of newer advanced monitoring gadgets, increased awareness among the patient population, implementation of newer medico-legal laws and professional competitiveness has mandated a quality control and assurance in anesthesia [1]. Despite rapid advancement in anaesthetic techniques, sore throat following endotracheal intubation still is a concern for anaesthesiologist. In a recent report, postoperative sore throat (POST) was ranked as the second most common adverse event during anaesthesia recovery [2]. The overall incidence of POST after general anaesthesia varies from 20% to 74% [3]. It leads to dissatisfaction and discomfort after surgery and can delay a patient's return to normal routine activities. Amongst the side effects inherent to the usage of cuffed endotracheal tube are local irritation and inflammation of the airway caused by prolonged inflation of the cuff with air which results in post intubation morbidities like irritation, sore throat, hoarseness of voice and coughing [4]. Coughing during emergence can result in hypertension, tachycardia, increased intraocular and intracranial pressures, myocardial ischemia, bronchospasm and surgical bleeding [5,6]. This can be of relevance in neurosurgical, ophthalmic and vascular procedures. Postoperative sore throat can be multifactorial and can be due to factors such as tube size, lateral wall pressure, movement and hypotension. When ETT cuff pressure is greater than capillary pressure, it causes tracheal mucosal ischemia proportional to the pressure exerted by the cuff and to duration of exposure. Tracheal mucosal pressure occurs when the cuff exerts pressure greater than 25 cm of water [7]. Ideally this pressure exerted against the tracheal wall by the cuff of ETT should be low enough to allow adequate capillary mucous membrane blood flow and at the same time high enough to prevent air leaks and aspiration of regurgitated gastric content. Coughing can complicate an otherwise smooth emergence from general anaesthesia.

Material and methods

This prospective randomized control study conducted in the Department of Anesthesiology & Critical Care, Patna Medical College & Hospital, Patna, Bihar, India, for 14 months

Methodology

We enrolled patients with age group 18–60 years with American Society of Anesthesiologists (ASA) Class I and II, Mallampatti classification 1 being posted for surgeries under general anesthesia with minimum surgical duration of 90 min. We excluded patients with laryngeal disease/surgery/ tracheostomized, ASA Class III and IV, difficult intubation, or failed extubation. Standard routine balanced general anesthesia was given as per the attending senior Anesthesiologist's protocol and dosage according to the body weight of the patient. ETTs with high residual volume, low-pressure cuff, with an inner diameter of 7.0 mm for female and 8.5 mm for male were used in all patients. Subjects were allocated in two groups as Air group (A) and Lignocaine group (L) according to computer-generated randomization sheet with 40 patients in each group.

In A group, ETT cuff was filled with air to prevent air leak during positive pressure ventilation guided with cuff manometer. While in L group, ETT cuff was filled with 2% lignocaine with 7.5% $NaHCO_3$, in the proportions of 19.0:1.0 ml. Care was taken to ensure that starting cuff pressure as

approximately 20 cm H_2O adequate enough to just prevent leak around cuff during positive pressure ventilation. Volume and cuff pressure of air and lignocaine injected in the cuff was noted at start and end of surgery. Total duration of anesthesia was also noted. Immediately after extubation, an independent observer blinded from the study group recorded the presence or absence of coughing. Similarly, in postoperative care unit, occurrence of coughing and POST at 1 h and 24 h were recorded. Similarly, in postoperative care unit, occurrence of coughing and POST at 1 h and 24 h was recorded. Coughing/ POST was recorded as present or absent. Total sample size was 80 patients with 40 patients in each group were included in this study.

Data analysis is done with the help of SPSS Software ver 25.0

Results

The anthropometric parameters in term of age, sex, weight, and ASA were comparable in both groups with $P > 0.05$ [Tables 1]. The volume and cuff pressure of A group and L group introduced into the cuffs at the start of surgery for adequate seal were recorded and on analysis both were comparable ($P > 0.05$), [Table 2]. The mean cuff pressures obtained at the end of surgery were 50.86 cm H_2O and 20.66 cm H_2O in A and L group, respectively, proving statistically significant difference between the two groups [Table 2]. The duration of anesthesia in both groups was comparable with average duration in A group was 2.77 ± 0.82 h and in L group was 2.76 ± 0.80 h [Table 2]. This was well above the mean duration of anesthesia as set in inclusion criteria required for the effect of lignocaine over tracheal mucosa. Analysis of change in volume and pressure of cuff during surgery revealed significant difference in A group than L [Table 3].

Significant difference determined by Pearson Chi-square test and Fisher's exact test showed $P < 0.05$ thereby substantiating the reduced incidence of coughing and POST in L group. Through the analysis, it was found that in A group, there was a high correlation between duration of anesthesia and cuff pressure achieved in the end of surgery with $P < 0.001$, while no such correlation was obtained in lignocaine group.

Further, association between duration of anesthesia with coughing and POST in A group revealed significant association at immediately after extubation, 1 h and 24 h postoperatively [Table 4]. In L group, such association was found only during coughing immediately after extubation and POST at 1 h and 24 h. This association was statistically significant with $P < 0.05$ (unpaired *t*-test) [Table 4].

Table 1: Demographic profile

Study group	Demographic parameters	Mean±SD	*P*
Group A	Age	46.56±16.01	0.57
Group L		44.68±14.24	
Group A	Weight	61.50±6.99	0.67
Group L		61.80±7.42	
Group A	Gender male /female	22/18	0.58
Group L		18/22	

Table 2: Association between the two study groups on the basis of multiple variables

Study group	Parameters	Mean±SD	Median	IQR	Mann-Whitney test	*P*
Group A	Intra-cuff volume start	4.64±0.63	4.6	1.0	−0.832	0.42
Group L		4.50±0.60	4.6	1.0	Difference is not significant	
Group A	Intra-cuff volume end	6.10±0.78	6.5	0.6	−8.231	0.000*
Group L		4.24±0.74	4.5	1.5	Difference is significant	
Group A	Cuff pressure start	21.52±0.73	20.5	1.0	−1.442	0.19
Group L		21.70±0.78	20.5	1.0	Difference is not significant	
Group A	Cuff pressure end	50.86±0.62	50.5	10.0	−8.820	0.001
Group L		20.66±0.84	20.5	1.0	Difference is significant	
Group A	Duration of anesthesia	2.77±0.82	2.5	1.0	−0.038	0.98
Group L		2.76±0.80	2.5	1.0	Difference is not significant	

Table 3: Association between duration of anesthesia and incidence of coughing and postoperative sore throat in air group

Study parameters	Yes/No	*n*	Mean±SD	Median	IQR	*P*
Coughing immediately	Yes	22	3.16±0.67	3.0	1.0	7.4
	No	18	2.32±0.47	2.0	0.6	
Coughing 1 h (+/−)	Yes	12	3.27±0.49	3.0	0.6	0.001
	No	28	2.56±0.70	2.0	1.0	
Coughing 24 h (+/−)	Yes	8	3.60±0.50	3.5	1.0	0.001
	No	32	2.54±0.59	2.5	1.0	
Sore throat (POST) 1 h (+/−)	Yes	7	3.48±0.58	3.5	0.5	0.001
	No	33	2.52±0.58	2.0	1.0	
POST 24 h (+/−)	Yes	15	3.25±0.69	3.2	0.7	0.001
	No	25	2.45±0.54	2.0	0.5	

Table 4: Association between duration of anesthesia and coughing and postoperative sore throat in lignocaine group

Study parameters	Yes/No	*n*	Mean±SD	Median	IQR	*P*
Coughing immediately	Yes	5	3.23±0.52	3.0	0.75	0.046
	No	35	2.67±0.70	2.5	1.0	
Coughing 1 h (+/−)	Yes	2	3.27±0.76	3.0	1.5	0.21
	No	38	2.73±0.70	2.5	1.0	
Coughing 24 h (+/−)	Yes	2	3.27±0.76	3.0	1.5	0.21
	No	38	2.73±0.70	2.5	1.0	
POST 1 h (+/−)	Yes	2	3.93±1.26	4.0	2.5	0.003
	No	38	2.69±0.60	2.5	1.0	
POST 24 h (+/−)	Yes	3	4.10±0.82	4.0	1.0	0.001
	No	37	2.64±0.57	2.5	1.0	

Discussion

The most bothersome postoperative complaint in the setting of general anesthesia after extubation of ETT is coughing and sore throat affecting more than half of the patients. Various factors contribute to the emergence of these symptoms that may adversely affect the outcome if not monitored adequately ETT cuff pressure is the indirect measure of pressure exerted by cuff over tracheal mucosa that is not monitored routinely [8].

The critical function of ETT cuff is to provide adequate seal to airway during positive pressure ventilation to prevent aspiration due to under inflation. Long duration of cuff inflation can result in mucosal ischemia and further complications such as coughing, POST, PH, tracheal ulceration, stenosis, and tracheoesophageal fistula [9,12]. In humans, endotracheal (ET) cuff pressures at approximately 30 cm H_2O can impair tracheal mucosal perfusion, and a critical perfusion pressure is reached at 50 cm H O which has been demonstrated by endoscopic studies [13]. N_2O anesthesia which is a common conjunct with other volatile anesthetics is the main factor, which increases the intracuff pressure by easily diffusing into the cuff with the advent of surgery [8,10]. Various factors have been evaluated to reduce this rise in cuff pressure such as repeated inflation-deflation technique, use of O_2-N_2O mixture, polyurethane cuff, and liquid cuff media [9,10].

Lignocaine, an amide local anesthetic in its several preparations such as topical jelly, intracuff, aerosolized, or intravenous form has evolved as an effective measure in reducing POST. We compared the traditional practice of use of air as inflation media with lignocaine for determining the rise in cuff pressure and thereby incidence of signs of tracheal morbidity such as coughing and sore throat 24 h postoperatively. The basis of our study was that lignocaine inserted intracuff act as a reservoir of local anesthetic which being a liquid not only prevents the diffusion of N_2O intracuff but also permeates through semipermeable membrane of polyvinyl chloride cuff to provide soothing effect on tracheal mucosa and helps in reducing pressure induced necrosis, cough reflex [14]. The study of Estebe *et al [15,18]*. reported that alkalinization of intracuff lignocaine increases the diffusion of its nonionized neutral base across hydrophobic structure of cuff membrane from 1% to 65% within 6 h. They studied both *in vitro* and *in vivo* effect of alkalinized lignocaine across tracheal mucosa and showed significant decrease in dose requirement of lignocaine in alkalinized form to as low as 20–40 mg as compared to nonalkalinized lignocaine dose of 200–500 mg [14,18]. This report encouraged us to design our study using alkalinized lignocaine for more safety and efficacy in the study subjects. No form of external lubrication in the form lignocaine jelly was used over the cuff during intubation for facilitation of cuff beyond the vocal cords. Multiple studies have shown that cuff lubrication in form of jelly or topical spray is associated with unfavorable phenomena at the time of emerging from anesthesia [19]. The lignocaine spray contains additives such as l-methanol and ethanol which are more associated in causing POST and hoarseness [19]. The intravenous form of lignocaine is more associated with sedation or deepening plane of anesthesia which is not suitable at the time of extubation.

Demographic data (age, sex, weight) of study subjects, baseline characteristics (ASA class, intracuff volume/cuff pressure inflated at start of surgery), and duration of anesthesia were comparable among study groups ($P > 0.05$) [Tables 1].

Our study has demonstrated that using N_2O anesthesia, filling of ET cuff with air despite initial cuff pressure set well below critical pressure of 30 cm H_2O rises toward

the end of surgery. Average volume of air injected to achieve adequate seal was 4.64 ± 0.63 ml with average cuff pressure at the start of surgery as 21.52 ± 0.73 cm H_2O [Table 4]. Toward the end of surgery, mean volume of cuff reached to 6.10 ± 0.78 ml and mean cuff pressure rose to 50.86 ± 0.62 cm H_2O [Table 2]. Our data confirmed the increased cuff pressure and cuff volume after air inflation with N O-oxygen anesthesia [20,22]. Significance of continuous cuff pressure monitoring to prevent POST and hoarseness was emphasized by Suzuki *et al [23].*, Sengupta *et al [24].*, Hoffman *et al [13].*, and Manissery *et al [10]*. In comparative group, mean initial volume of alkalinized lignocaine required to inflate the ETT cuff was 4.50 ± 0.60 ml and initial cuff pressure as 21.70 ± 0.78 cm H_2O [Table 2]. Both of the volume and cuff pressure at start of surgery in air and lignocaine group were similar and statistically not significant (Mann–Whitney test, $P > 0.05$), [Table 2]. Toward the end of surgery, mean volume obtained and average cuff pressure was 4.24 ml and 20.66 ± 0.84 cm H_2O, respectively. This showed a highly significant difference in the two groups (Mann-Whitney test, $P < 0.001$), [Table 2].

In A group, the volume and cuff pressure during surgery increased by 1.56 ± 0.38 ml and 31.44 ± 6.16 cm H_2O, respectively. On the other hand, in L group, volume and cuff pressure decreased by 0.36 ml and 0.97 cm H_2O, respectively. This change in volume and pressure was statistically significant between both groups (Unpaired *t*-test, $P < 0.05$). This clearly showed the cuff volume and pressure did not change with time in lignocaine group as compared with air group. Lignocaine, being liquid in media, prevents hyperinflation of cuff with N O with the course of surgery. Lignocaine diffuses through cuff membrane in time and concentration-dependent fashion and influence local tracheal receptors by inducing local anesthesia and increase ETT tolerance [11]. Moreover, incidence of coughing and POST at immediately, 1 h and 24 h postoperatively was significantly higher in air group in comparison to lignocaine group. These results are coherent with the studies of Navarro *et al*. 2012 [21], Jaichandran *et al*. 2009 [25], Shroff and Patil, 2009 [26]. Wetzel *et al*. could not find attenuation in coughing and POST when intracuff lignocaine group used where procedures lasted for <1.5 h in patients who smoke [27] Thus, using these lignocaine instilled cuffs for longer duration, surgeries would result in better outcome as diffusion across the cuff membrane is a function of time [20]. 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 [15]. It was clearly evident that with the prolongation of duration of anesthesia cuff pressure also increased significantly in air group in comparison to lignocaine group. Similarly, the outcome of rise in cuff pressure in such patients whose duration of surgery was prolonged showed significant increase in coughing and POST in air group [Table 3]. Furthermore, the analysis showed the increase in duration of anesthesia influenced the incidence of coughing and POST in lignocaine group [Table 4].

Mitchell *et al*. demonstrated linear rise in cuff pressure[2] with time in air group. They suggested that the rise in cuff pressure causes tracheal mucosa ischemia due to lateral contact pressure exerted by cuff [28]. In our study, all the cases were extubated without any complication. The present study was not without limitations as we did not include children and elderly in our study subjects. Severity of coughing and sore

throat were not graded rather only incidence of its presence was evaluated. Measurement of concentration of plasma lignocaine was not done.

Conclusion

In the setting of general anesthesia with the use of N_2O and O_2 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.

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