



A comparison between effectiveness and safety of endotracheal tube cuff filled with air, plain lignocaine and alkalinized lignocaine for postoperative sore throat and emergence phenomena.

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Abstract

Aim: The aim of this study was to evaluate the effectiveness and safety of endotracheal tube cuffs filled with air, plain lignocaine and alkalinized lignocaine during general anesthesia and evaluate clinical symptoms such as pain, coughing, restlessness and postoperative sore throat following tracheal extubation.

Materials and Methods: This was a prospective randomized controlled study conducted in a tertiary care hospital over a period of 2 year. We included 90 patients in age group of 20-60 years posted for elective surgeries of duration 2-5 hrs under general anesthesia. Patients were randomized using computer generated randomization table into air, plain lignocaine group and alkalinized lignocaine group. The endotracheal tube cuff was inflated with air or plain and alkalinized lignocaine to the volume that prevented air leak using cuff pressure manometer. After extubation, observer blinded to study group recorded the presence or absence of coughing, pain, restlessness and postoperative sore throat at immediately, 1 h and 24 h postoperatively.

Results: Incidence of coughing, pain, restlessness and postoperative sore throat (POST) at immediately, 1 h and 24 h postoperatively was significantly higher in air group compared to lignocaine group and was lowest in alkalinized lignocaine group which was statistically significant.

Conclusion: Alkalinized lignocaine filled endotracheal cuffs are safer than conventional air or plain lignocaine filled endotracheal cuffs as it produces less coughing, pain, restlessness and sore throat postoperatively. Key words: Endotracheal, Sore throat. Cough. Lignocaine. Alkalinized

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 anaesthesiologists. 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 particular relevance in neurosurgical, ophthalmic and vascular procedures.⁷ Postoperative sore throat can be multifactorial and can be due to factors such as tube size, lateral wall pressure, movement and hypotension.^{8,9} 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.¹⁰ 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.¹¹ Coughing can complicate an otherwise smooth emergence from general anaesthesia. Irritant or stretch stimuli in the trachea caused by the tube and its cuff are thought to be the presumed mechanisms. Rapidly adapting stretch receptors in the tracheal mucosa are believed to be irritant receptors involved in the cough reflex.¹² Primary Objective of our study was to determine and compare the effect of intracuff air, intracuff plain lignocaine

and intracuff alkalinized lignocaine in decreasing post intubation sore throat with air as control group. Secondary objectives was to compare the incidence of side effects of tracheal intubation such as hemodynamic changes, and restlessness in the three groups.

Material and methods

After approval from the institutional ethical committee, written informed consent was taken from all patients. Data was collected from patients (ASA –I/II) scheduled for major elective surgical procedures lasting between 2-5 hours duration, aged between 20-60 years at a tertiary care hospital. The study was a randomized double blind control study and random numbers was generated using a computer programme. This study was done consisting of 90 patients and 30 patients were randomly allotted to each of the following three groups viz C(control) group, AL group (Alkalinized Lignocaine) and PL group (Plain lignocaine).

The different groups of study were:

- Group C: control group where ETT cuff was filled with air
- Group AL: ETT cuff was filled with alkalinized lignocaine
- Group PL: ETT cuff was filled with plain lignocaine.

Documented hypersensitivity to lignocaine, patients with predicted difficult intubation, patients who could not be intubated in the first attempt, patients with history of recent sore throat, Patients with recurrent history of tracheitis or laryngitis. Patients with history of asthma and COPD, patients undergoing oropharyngeal surgeries were excluded from the study. Propofol (2 mg/kg), nalbuphine (50 µg/kg) and rocuronium was used for induction and maintained with O₂, isoflurane and nitrous oxide. Endotracheal intubation was performed using an appropriate sized ETT with a high volume low-pressure cuff. The ETT cuff was inflated to the minimal occlusive

volume, in group C cuff was inflated with air, in the group AL, cuff was inflated with 5ml of a mixture of 2% lignocaine and 8.4% sodium bicarbonate (10:1) and supplementary amount of air to obtain minimum occlusive volume and in group PL, cuff is filled with 5ml of 2% lignocaine and a supplementary quantity of air to prevent air leak. The cuff pressure was monitored during the entire duration of the surgical procedure and was maintained in all the three groups below 25 cm of water using a manual manometer. This was achieved by either adding or removing air or drug from the cuff via the pilot balloon. Maintenance of anaesthesia was done with inhalational agents and intermittent doses of muscle relaxant. Reversal of neuromuscular blockade was done with neostigmine and glycopyrrolate at the end of the surgical procedure. The anaesthetic team were unaware of the experimental protocol. Patients were extubated after all the following criteria are met- full reversal of neuromuscular blockade, spontaneous ventilation and ability to follow verbal commands, eye opening and hand grip. Cough reflex and restlessness was checked after extubation and for 24 hrs after extubation (1hr, 2hr, 12hr, 24hrs). The degree of sore throat was assessed in the post op recovery room using a visual analogue scale (VAS 0-100 mm),¹³ which was explained to the patient during the pre-anesthetic check-up visit. Patients were asked to point at different facial expressions depicted on the VAS scale which quantified different degrees of pain. Other evidence of throat discomfort such as restlessness was evaluated and hemodynamic parameters were recorded. The volume of air or liquid used to inflate the cuff was noted and the volume retrieved during extubation was also recorded.

Statistical Methods

Data was pooled and expressed as mean and standard deviations. Analysis of variance was used to find the

homogeneity of baseline characteristics between three groups of patients. Analysis of variance was also used to find the significance of hemodynamic between three groups of patients. Chi-square and unpaired student t-test was used to find the significance of adverse effects between three groups. p<0.05 considered statistically significant. The statistical software namely SPSS 21.0 was used for the analysis of the data.

Results

There were no statistically significant differences among patients from the three groups regarding age, sex and duration of surgery (Table 1). There were no problems with the cuff inflation and no air leak was recorded during controlled ventilation

Table 1 : Basic characteristics of the study

Sl. No.	Basic characteristics	Group			Test of significance	P value
		Control (n=30)	PL (n=30)	AL (n=30)		
1	Age in years Mean ±SD	41.23±12.218	40.70±14.648	39.50±11.901	Median=40 [#] , X ² =2.520, df=2	0.284
2	Female:Male	7:23	7:23	9:21	X ² =0.467, df=2	0.792
3	Duration of procedures in min.	183.50±34.169	182.67±44.484	158.00±62.001	Median=180 [#] , X ² =1.731, df=2	0.421

Median value was taken to compute P value as the distribution is skewed

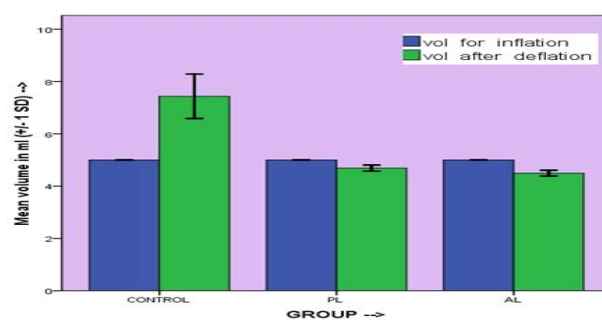
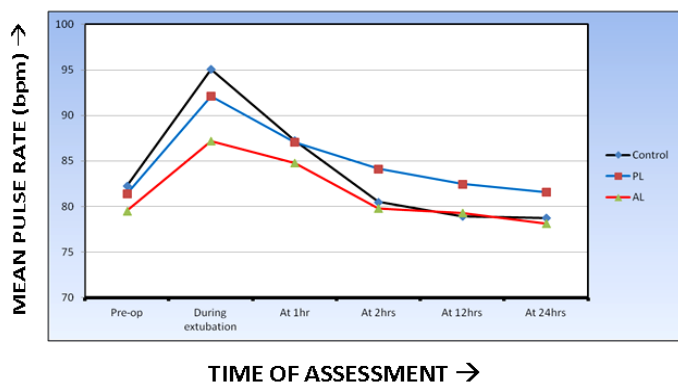


Fig. 1: Comparison of Volume (ml) in three groups of patients

There was no difference in the initial volume of liquid injected into the cuff for group PL and AL. The initial air volume in the control group was same as the liquid volume (5 ml). The gas volume withdrawn at

extubation- increased significantly in the control group (fig-1)

Fig. 2: Comparison of Pulse rate (bpm) in three groups of patients.



There was significant difference in the pulse rate and blood pressure(SBP and DBP) during extubation compared to the preoperative values in all the three groups. In the control group, the pulse rate and blood pressure(SBP) increased to a greater degree, followed by PL group to a lesser degree and AL group to the least degree. There were statistically significant differences between the groups.

Fig. 3: Comparison of SBP (mm Hg) in three groups of patients

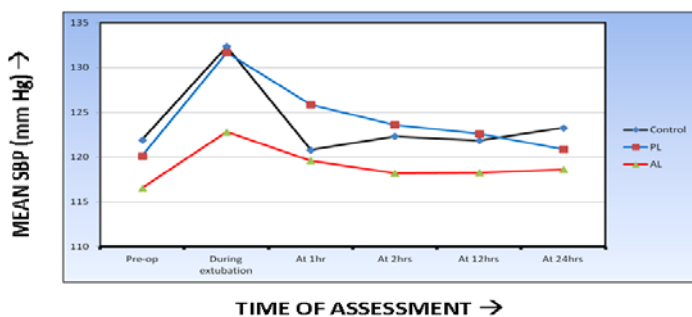
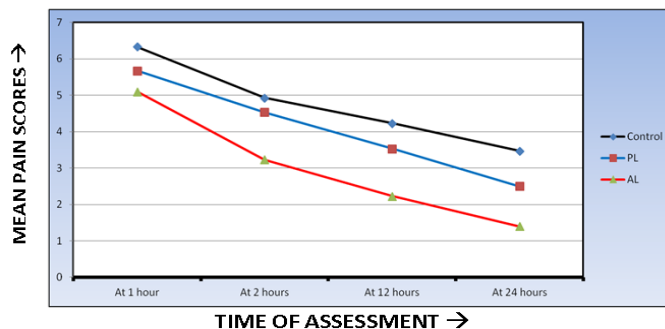
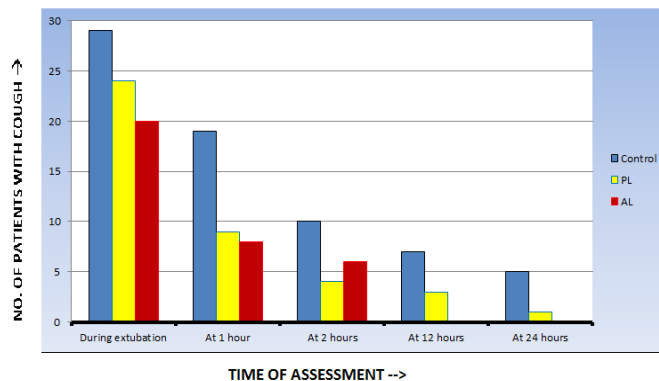


Fig. 4: Comparison of pain scores in three groups of patients



Pain score was based on the VAS scale. The median of pain score was calculated in each group and compared. At 1 hour after extubation pain was less in AL group compared to PL group. Pain score was highest in the control group at different times of recovery. There was statistical significant difference among the groups at 1 hr, 2hr, 12 hr and 24 hrs ($p < 0.05$). There was a gradual decrease in the pain score in all 3 groups over 24 hours. Over all the pain score was less in the AL group followed by the PL group and then the control group.

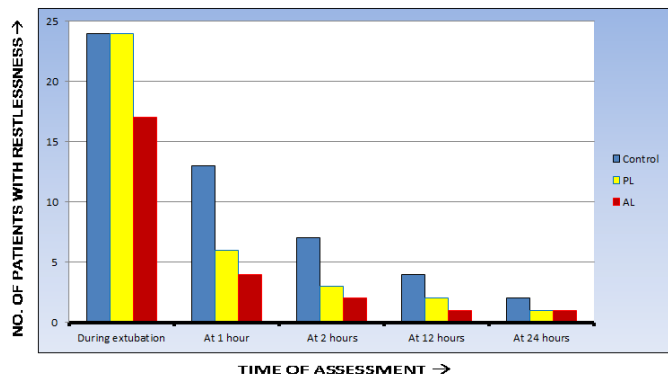
Fig. 5: Comparison of incidence of cough in three groups of patients.



Comparison of incidence of cough in 3 groups was done using the chi square Test. During extubation incidence of cough was highest in the control group (96.7%) followed by PL (80%) and AL group (66.7%). There was statistically significant difference among the 3 groups ($p=0.012$). At 1 hour 63.3% of subjects had cough in the control group while in the PL group it was 30% and 26.7% in the AL group. There was statistically significant difference among the three groups

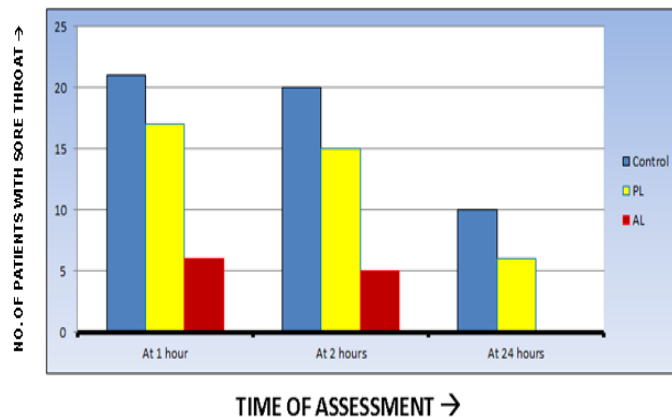
($p=0.006$). At 12 hours, no patients in the AL group had cough. In the PL group, 10% subjects had cough at 12 hours and 3.3% at 24 hours. There was statistically significant difference among the three groups at 2 hours, 12 hours, 24 hours ($p<0.05$).

Fig. 6: Comparison of incidence of restlessness in three groups of patients



Comparison of incidence of restlessness in the 3 groups was done by the chi square Test. During extubation 80% of subjects experienced restlessness in the control group while it was 80% and 56.7% in PL and AL groups respectively. There was no statistically significant difference ($p=0.066$). At 1 hr, restlessness was seen in 43.3% subjects in the control group, 20% in PL the group and 13.3% in the AL group, with a statistically significant difference ($p=0.02$) between groups. After 1 hr, there was 6.7% incidence of restlessness in the AL group. There was no statistically significant difference between the groups at the end of 24 hours.

Fig. 7: Comparison of incidence of sore throat in three groups of patients



Comparison of the incidence of sore throat in the 3 groups was done using the Chi square Test. At 12 hours, 66.7% of subjects had a sore throat in the control group, 50% in the PL group and 16.7% in the AL group. There was statistically significant difference among the 3 groups. At 24 hours, 33.3% of subjects had sore throat in control group, 20% in the PL group and no incidence in the AL group. There was a statistically significant difference between the 3 groups ($p=0.003$).

Discussion

A general anaesthetic technique is that which allow patients to have a smooth emergence and comfortable postoperative period. This study was designed to compare the incidence of post intubation sore throat when intra-cuff alkalized lignocaine was used compared to intra-cuff plain lignocaine and air. The principal finding of our study was that the incidence of post intubation sore throat was less and emergence was less stressful when alkalized lignocaine used to inflate the ETT cuff rather than plain lignocaine or air. Postoperative sore throat occurs in 90% of intubated patients and is the most common complaint after tracheal intubation.¹⁴ The insertion of tracheal tube can damage the upper respiratory mucosa resulting in a haematoma, laceration or granuloma of the mucosa, or arytenoids cartilage damage.¹⁵ The tube may also damage the anterior branch of the recurrent laryngeal

nerve causing cord paralysis and external laryngeal nerve damage causing cricothyroid muscle paralysis.¹⁶ These factors may result in hoarseness. Sore throat is also attributed to factors like endotracheal tube size, design, lateral wall pressure, intracuff pressure, use of cleansing agents, lubricants, hypotension, local infection, use of steroids, and the duration of intubation. It has been proposed that the incidence and severity of sore throat after intubation is highly co-related to endotracheal cuff design and was explained on the basis of cuff-trachea contact area.

As per the study conducted by Singh Hemjit et al¹⁷ in 90 adult patients of ASA 1 or 2 using intracuff alkaline lignocaine, plain lignocaine and air as control, concluded that incidence of post operative sore throat and other indirect effects to tracheal extubation such as haemodynamic changes, restlessness, dysphonia and hoarseness was less during the post op period. The use of intracuff lignocaine increased tolerance to tubing in the trachea and allowed a smooth emergence. This is in agreement to my study. Acharya et al¹⁸ in their study in 2016 with 50 patients comparing alkaline lignocaine and air, concluded that addition of alkalinized lignocaine maintained a stable cuff pressure during oxygen and nitrous oxide anesthesia this prevented the damage that occurred due to increased cuff pressure during general anaesthesia, which is in corroboration with my study. Manimala et al¹⁹ conducted a study in 2013 with 80 patients divided in two groups with plain lignocaine 4% instillation and air in cuff concluded significantly reduced the post intubation co-morbidity as compared to air and hence it should be routinely practiced in all intubated patients. Though results appear to be similar to my study they did not advocate the use of alkaline lignocaine.

Souissi et al²⁰ in their study in 2016 including 80 participants of a tertiary care centre who received intracuff alkalinized lidocaine or intracuff 0.9% saline showed that the use of 160 mg of intracuff alkalinized lignocaine is associated with a decreased incidence of cough upon emergence. This is in agreement with my study that lignocaine will produce the desired action after optimal duration for absorption. Fai Lam et al²¹ in their systematic review and meta-analysis of randomized control trials evaluating intracuff alkaline lignocaine in endotracheal tube in 2009 concluded the effectiveness of intracuff lignocaine used in the prevention of emergence phenomenon. Navarro et al²² in their study conducted in 2012 evaluated 50 smoking patients comparing intracuff alkaline lignocaine and saline and demonstrated decreasing the incidence of emergence coughing and sore throat during the postoperative period in smokers. This study was conducted in a group with high airway reflexivity to chemical and mechanical stimulations. The results were in agreement with my study.

Previous studies have showed increased cuff pressure and volume over time after air inflation. During anaesthesia using nitrous oxide, the cuff pressure increases as the temperature of the cuff rises and nitrous oxide diffuses into it more rapidly than it leaves. This over inflation of the ETT has been associated with damage to pharyngeal mucosa and recurrent laryngeal nerve palsy. It would also cause increased receptor stimulation in the tracheal mucosa and thus increase emergence and extubation phenomena. The complication was decreased by filling the ETT cuff with liquid. In our study it was observed that the initial air volume required to inflate the cuff was significantly greater than the liquid volume. At the time of extubation air volume in the cuff increased owing to diffusion. In the groups

PL and AL there was no significant difference in the volume of liquid required to inflate the cuff. In the group AL, the volume of liquid removed from the cuff was lesser. These results are in agreement with previous studies on in vivo diffusion of lignocaine across the ETT cuff. The current results also reinforce the assumption that nitrous oxide is the principal causative factor of overpressure in the ETT cuff during balanced anaesthesia. It has been reported that lignocaine alone has a low diffusion rate across an ETT cuff (1% released during a 6 hours period). Only high doses of lignocaine (200-500 mg) produce a clinical effect when used to inflate the cuff, but they have no advantage over saline and could be dangerous if the ETT cuff ruptures. In vitro studies have shown that alkalinization of lignocaine greatly enhances (63 fold) the diffusion of lignocaine and in vivo studies have shown that use of low dose (40 mg) reduced postoperative side effects. It has also been shown that the amount of lignocaine diffusing across the ET Tube cuff in the presence of NaHCO₃ is proportional to the dose of lignocaine used between 20 and 40 mg.

The blood pressure increased in three groups during extubation. The increase was highest in the control group followed by PL and AL group. Blood pressure returned almost to pre-operative value in all groups 1-2 hours after extubation. Throat pain was assessed using a VAS scale. Throat pain was highest in the control group. At 1 hour post extubation pain was less in the AL group compared to PL group. Throat pain decreased gradually over 24 hours in all three groups. Coughing during emergence from general anaesthesia may be undesirable in certain clinical situations. Although previous studies indicate that intravenous lignocaine in doses of 1.0-2.0 mg/kg transiently suppresses coughing and other airway reflexes in humans in several settings.

In our study, at 12 hours 66.7% of subjects had sore

throat in the control group, 50% in the PL group and 16.7% in the AL group. At 24 hours, 33.3% of subjects had sore throat in the control group, 20% subjects in the PL group and no incidence in the AL group. In a study by Gaur P et al²³ use of alkalized 2% lignocaine prevented rise of cuff pressure. Incidence of coughing, POST was also low. They commented that duration of anaesthesia has a role on incidence of postoperative sore throat. This is similar to our findings. There were several factors implicated in sore throat that we did not take into account. We did not use humidity moisture exchangers in the delivery circuit, and dry airway gases have been implicated in the development of postoperative sore throat. Airway suction is associated with postoperative sore throat and this was not standardized. Intubation was done by residents and staff with wide range of experience. In our study, incidence of sore throat was less when intracuff alkalized lignocaine was used rather than plain lignocaine. Throat pain and restlessness were most common in the control group in which air was the inflating medium. Compared to plain lignocaine group, the incidence of side effects were less in the alkalized lignocaine group.

Conclusion

Our study demonstrates a significant decrease in the incidence of sore throat during the postoperative period for an entire 24 hour post-operative period, when the cuff of an ETT was filled with alkalized lignocaine rather than plain lignocaine or air while a uniform cuff pressure was maintained. The incidence of other parameters of tracheal co-morbidity such as hemodynamic changes, restlessness and hoarseness were less when inflating medium of ETT cuff was alkalized lignocaine, rather than plain lignocaine or air. The emergence from general anaesthesia was also smooth in case of alkaline lignocaine as compared to the other

groups.

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