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Instillation of 4% lidocaine versus air in the endotracheal tube (ETT) cuff to evaluate post intubation morbidity-a randomized double blind study

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Abstract

Background: Endotracheal intubation for airway management in general anaesthesia is associated with post intubation morbidities due to prolonged inflation of the ETT cuff. Many studies have used Lidocaine by instillation in the ETT cuff and its diffusion to the underlying tracheal mucosa there by reducing local irritation and inflammation of the airway.

Aims: To study the favorable effects of lidocaine(4%)instillation in the endotracheal tube cuff in surgical patients as compared to air.

Settings and design: The study was done in a multispeciality teaching hospital. Eighty patients were selected and randomly divided into two groups.

Methods and Material: Eighty patients of ASA – I & II status posted for general surgery were randomly selected and divided into two groups after randomization.All these general surgeries lasted for duration of 30-45 minutes. Blood loss intraop.was around 200-300ml only. All these patients received first dose of I.V.fentanyl for analgesia at induction. In forty patients air was filled in ETT cuff and in remaining patients lidocaine (4%) 3-5ml was instilled keeping the cuff pressure between 20-22mmHg. Coughing and hemodynamic parameters were noted at and after extubation. Intubation related morbidities were compared between the two groups. Patients with hypertension, COPD, recurrent respiratory infections etc. and those needing postop ventilator supports were excluded.

Statistical analysis used: The database of all parameters were analysed using "STATA SOFTWARE VERSION10.0".

Results: The study showed a significant difference in the incidence of post-operative sore throat in group I(air) and group II (lidocaine). Lidocaine group had lesser sore throat incidence. There was no significant change in heart rate initially but showed a significant change in both the study groups at later intervals. Similarly there was a highly significant change in blood pressure in both the study groups at 2, 5, 10, 30 and 60 min after extubation.

Conclusions: Lidocaine can be used for instillation in ETT cuff to minimize the postintubation morbidities.

Keywords: Lidocaine 4%, endotracheal tube cuff instillation, postintubation morbidity

Introduction

Airway management with cuffed endotracheal intubation for General Anaesthesia(GA) is an integral part of an anaesthesiologist's responsibilities towards patient care. Amongst the sequelae inherent to the usage of cuffed endotracheal tube are local irritation and inflammation of the airway caused by prolonged inflation of the cuff which results in post intubation morbidities like sore throat, hoarseness of voice and cough [1].

Coughing during emergence from General Anaesthesia can result in hypertension, tachycardia, increased intraocular and intracranial pressures, myocardial ischemia, broncho spasm and surgical bleeding. This can be of particular relevance in neurosurgical, ophthalmic and vascular procedures [1]. Many studies have been performed exploring the measures to minimize post intubation morbidities like use of high volume low pressure cuffed endotracheal tubes [2], use of smaller size endotracheal tubes [3], inhalation of steroids [4], topical application of lubricant jellies [5], intravenous lidocaine as a suppressant of coughing [6], endotracheal tube cuffs filled with lidocaine as a drug delivery system [1]. Lidocaine instilled in an ETT cuff diffuses slowly across the cuff membrane [7]. The cuff would act as a potential reservoir for the local anaesthetic, allowing diffusion and subsequent anaesthesia of the underlying tracheal mucosa. Topical anaesthetics applied in this manner might represent a novel technique to reduce adverse emergence phenomenon including post operative coughing and sore throat [1,16].

We conducted our study to evaluate the effects of ETT cuff instillation of lidocaine 4% versus air as regards post intubation morbidities.

Subjects and Methods

After obtaining approval from Institutional Ethical Committee

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and written informed consent of the patients, this prospective study was carried out in our hospital.

The study was carried out on 80 patients scheduled for elective general surgical procedures. It was a prospective randomized double blind comparative study of air and lidocaine(4%) 5ml each instilled into the ETT cuff to study the emergence from General Anaesthesia. Inclusion criteria were all patients in the age group of 18 to 55 years belonging to ASA physical status I and II. The average duration of surgeries was between 30-45 minutes. Blood loss was about 200-300ml. For analgesia injection Fentanyl was given in accordance with bodyweight and other relevant parameters. Patients having significant medical history like hypertension, diabetes mellitus, tuberculosis, bronchial asthma, epilepsy, COPD, drug allergy were excluded from the study. Patients having difficult airway, history of repeated pharyngitis, laryngitis and upper respiratory tract infection were not included. Patients not completing the study and those requiring postoperative ventilator support were excluded from analysis as they would cause bias to the result. The study was carried out on eighty patients who were randomly allocated into two groups: Group I – (A) Air, and Group II(L) Lidocaine 4%. Randomization was done using random number **Table 1**. Eighty patients were assigned number1-80 and 40 random members were selected from random number **Table 2** and assigned to group I (AIR). Again 40 numbers were drawn from random number table without repeating numbers from group I and these were assigned to group II (lidocaine). The syringes with different agents *i.e.* air and lidocaine 4% (5 ml each) was prepared by a separate anaesthesiologist who did not take part in the study and they were disguised with a paper wrap. The particular agent was inflated in the endotracheal tube cuff after intubation. The anaesthesiologist in charge of the patient did not participate in the study and was fully aware of the agent administered in the cuff. The patient and the investigator were blinded to the drug being used. The anaesthesiologist who was blinded to the study evaluated the patients at extubation and for a period of one hour after extubation. The patients were shifted to post anaesthesia care unit after the surgery. Coughing: At extubation, 0 – 2, 2 – 4, 4 – 8, 8 – 15, 15 – 30, 30 – 60 min after extubation. Haemodynamics: Heart rate, Blood pressure. At extubation, 1min, 2 min, 5 min, 10 min, 30 min, 1 hour after extubation. The incidence of post-operative nausea, vomiting, dysphonia, hoarseness and sore throat was noted 24 hours after the completion of surgery. Sore throat was evaluated as per patient's subjective evaluation and was graded as 1+, 2+, and 3+.

- A 'P' value < 0.05 was considered as Significant (S).
- A 'P' value < 0.01 was considered as Highly Significant (HS)
- A 'P' value of > 0.05 was considered as Non Significant (NS)

Results

The incidence of post-operative sore throat in the two study groups was highly significant. The intergroup comparison showed that there was a significant difference in the incidence of post-operative sore throat in group I(air) and group II (lidocaine) p=0.025.

Table 1. P value for change in heart rate and blood pressure at various time intervals after extubation.

Time interval	1 min	2 min	5 min	10 min	30 min	60 min
P value for change in heart rate	0.1787 NS	0.1207 NS	0.0016 HS	0.0002 HS	0.001 HS	0.0002 HS
P value for change in blood pressure	0.1269 NS	0.0039 HS	0.0017 HS	0.0019 HS	0.0003 HS	0.003 HS

Table 2. Overall incidence of post operative Nausea, Vomiting, dysphonia, hoarseness and sore throat of entire study of 80 patients.

Study Group	Nausea	Vomitting	Dysphonia	Hoarseness	Sore throat
Group 1 (air)	12(30%)	14(35%)	4(10%)	18(45%)	24(60%)
Group 2(Lid)	8(20%)	8(20%)	1(2.5%)	6(15%)	8(20%)
P value	0.659 NS	0.43 NS	0.747 NS	0.029 S	0.003 HS

There was no significant change in heart rate at one and two minutes after extubation. However there was a highly significant change in both the study groups at 5, 10, 30 and 60 min after extubation. Similarly there was a highly significant change in blood pressure in both the study groups at 2, 5,10, 30 and 60 min after extubation.

The two study groups (Air and lidocaine) were comparable with respect to age and weight. There was no significant difference in the two groups.

Discussion

Waters and Guedel in 1928 introduced the cuffed endotracheal tubes. The cuff of the endotracheal tube has got important functions like protecting the respiratory tract against aspiration by providing an air tight seal against gas leak and allowing adequate positive pressure ventilation [**8**].

The post-operative 'sore throat syndrome' consisting of sore or scratchy throat/ hoarseness which may last a few days after surgery can significantly influence post-operative outcome and patient satisfaction [**9**]. The phase of extubation from general anaesthesia and the subsequent period following it is associated with various unwanted effects like hypertension, tachycardia, agitation, coughing and tracheal morbidity like sore throat, hoarseness and dysphonia [**1**].

Various *in vitro* studies demonstrated that lidocaine diffused across the membrane of the cuff of the endotracheal tube. The diffusion of the local anaesthetic depended on various factors such as the non-ionised fraction of the local anaesthetic, alkalinization, temperature, duration of procedure and concentration of local anaesthetic [**10**].

We observed the systolic and diastolic blood pressure of all the patients at extubation and subsequent period and also studied the changes in the blood pressure from the baseline which was taken at the time the patient was extubated. It was observed that the mean systolic blood pressure was initially high at the time of extubation but there was a gradual fall over

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time. It was observed that the systolic BP was lower in group II as compared to Group I. It was also observed that there was a statistically significant change in the blood pressure from the baseline (*i.e*. at extubation) at 2, 5, 10, 30 and 60min. The rise of blood pressure at the time of extubation and in the subsequent period would be related to the irritation caused by the ETT and its cuff on the laryngotracheal mucosa. The local anaesthetic effect caused by diffusion of lidocaine across the cuff membrane resulted in more stable blood pressure at the time of extubation and in the subsequent period. This would be a beneficial effect especially in neurosurgeries, ophthalmic and vascular procedures.

The haemodynamic parameters of the patients in our study included recording of the heart rates at the time of extubation and 1, 2, 5, 10, 30 and 60 min after that. It was observed that the heart rates were significantly higher at the time of extubation and gradually decreased subsequently. We observed that the mean heart rates were lower in group II as compared to group I. Also the change in the heart rate from the baseline (*i.e*. at extubation) was statistically significant at 5, 10, 30, and 60 min after extubation. Navarro *et al.,* did not observe any change in heart rates [**1**,**10**]. It was observed in our study that the heart rates were lower and more stable in the lidocaine group. This could be particularly beneficial in patients with coronary artery disease and where tachycardia would compromise myocardial perfusion [**11**].

Jean Pierre Estebe *et al.,* demonstrated that alkalinization of intracuff lidocaine improves endotracheal tube induced emergence phenomenon. There was a decreased incidence of cough and other parameters like restlessness, Postoperative nausea and vomiting (PONV), dysphonia, hoarseness in the post extubation period [**12**].

In our study we found that the incidence of coughing at extubation was higher in the air as compared to lidocaine. Fagan *et al.,* suggested that the local anaesthetic lidocaine instilled in the endotracheal tube cuff might cause anaesthesia of the trachea by diffusing across the polyvinylchloride membrane. Anaesthesia should be confined to the mucosa in contact with the cuff. The protective cough reflexes above the tube cuff and below the vocal cords would remain intact. This could be a reason for preservation of coughing reflex in the post extubation period in our study [**1**]. Laura E Wetzel suggested similar results in the intracuff lidocaine group compared with the saline group but the procedures lasted for less than 1.5 hours in patients who smoke [**13**].

Huang CJ *et al.,* demonstrated that emergence coughing and the incidence of sore throat was significantly less than the control group when lidocaine 4% and alkalinized lidocaine were used. They suggested to use alkalinized and warmed lidocaine prestored in the ETT cuff for smoother emergence from general anaesthesia [**14**].

Also using these lidocaine instilled cuffs for longer duration surgeries would result in better outcome as diffusion across the cuff membrane is a function of time [**15**]. Alkalinized intracuff lidocaine improved cuff tolerance but the local anaesthetic effect did not depress the swallowing reflex so that the patient was able to protect the airway [**12**].

Jean Pierre Estebe reported that lidocaine (*i e* lidocaine Hydochloride L- HCl) alone had a low diffusion rate across the ETT cuff. For a clinical effect large doses of lidocaine (200-500 mg) were believed to be required. The ratio between the ionized and non-ionized species is a function of pK of the substance and the pH of the dissolving medium. The addition of sodabicarbonate to L- HCl alkalinizes the solution. This provides the hydrophobic base and allows the diffusion of this uncharged form through the polyvinylchloride wall of the cuff more readily than L- HCl and allows for the best release profile observed with the lidocaine base [**16**,**17**]. There are many studies which report a reduced incidence of post-operative sore throat when lidocaine was used to inflate the endotracheal tube cuff.

In another study by Navarro *et al.,* the frequency of sore throat and hoarseness at the time of discharge from the PACU was lower in the lidocaine group than the air and the saline group. We compared the incidence of sore throat in the 2 groups 24 hours after the surgery. It was lowest in group II. These results were statistically significant. ($p = 0.003$) The results were in accordance to the previous studies [**11**].

In the study by Porter NE, Sidou V *et al.,* lidocaine ,air and saline had similar effects on post-operative sore throat. Various factors associated were ETT cuff design, ETT size, intubation technique, laryngoscopy blade, airway placement, suctioning technique. Hence these factors could also affect the result [**18**].

In an extensive review by Tanaka Y *et al.,* published in the Cochrane library in 2009(Issue 3) 15 various randomized controlled trials were studied for the outcome of interest *i.e*. post-operative sore throat. The review study concluded that topical and systemic lidocaine therapy reduces the prevalence and severity of sore throat after general anaesthesia with endotracheal intubation [**19**].

In our study we evaluated haemodynamic variables like heart rate and blood pressures of all the patients and compared them. Also various other parameters were recorded including post extubation coughing, nausea, vomiting, dysphonia, hoarseness and sore throat. Lidocaine 4% instillation in ETT cuff significantly reduced the post intubation morbidities as compared to air and hence it should be used routinely in all intubated patients.

Competing interests
The authors declare that they have no competing interests.

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