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Original Article

Anaesthesia Section

Effect of Air versus 1% Lignocaine used for Endotracheal Tube Cuff Inflation on Laryngotracheal Morbidity after Laparoscopic Surgery- A Randomised Clinical Study

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ABSTRACT

Introduction: Endotracheal intubation in general anaesthesia is associated with post intubation morbidity due to prolonged inflation of Endotracheal Tube (ETT) cuff with air. During laparoscopic surgery their incidence increases further. Lignocaine is likely to diffuse through ETT cuff when instilled into it. As a result, it decreases coughing, sore throat and hoarseness by reducing local irritation and inflammation of the airway.

Aim: To compare the effect of air and 1% lignocaine used for ETT cuff inflation on postoperative sore throat, hoarseness of voice and coughing in patients undergoing laparoscopic surgeries.

Materials and Methods: This double-blind randomised clinical study was conducted at Shree Krishna Hospital, Karamsad, Gujarat, India, between September 2021 to March 2022. Total of 54 patients were randomly divided into two groups with 27 in each; group A (air) and group X (1% lignocaine= 2% lignocaine and equal volume of normal saline). Postextubation patients were assessed for Postoperative Sore Throat (POST), hoarseness and coughing at 2 hours and 18-24 hours. Fisher's Exact test was used to find the association between categorical variables in both the groups. The $p<0.05$ was considered statistically significant.

Results: The mean age in group A was 46.04±10.26 years, and in group X was 48.59±10.92 years. At 2 hours, in group X 11% (n=3) of patients had POST as compared to group A where nine patients (33%) reported POST (p=0.099). Group X showed a significantly reduced incidence of POST at 18-24 hours, hoarseness of voice, coughing at 2 hours and at 18-24 hours as compared to group A.

Conclusion: The use of 1% lignocaine for ETT cuff inflation in laparoscopic surgeries was associated with reduced incidence of POST, hoarseness of voice and coughing as compared to air.

Keywords: Coughing, Hoarseness, Postoperative complication, Sore throat

INTRODUCTION

Coughing, sore throat and hoarseness are most common, undesired and neglected postoperative laryngotracheal morbidity seen in patients who were given general anaesthesia with endotracheal intubation. There are various contributory factors for these side effects like trauma during intubation, drying of mucosa, infection, size of Endotracheal Tube (ETT), type of cuff, cuff pressure and inflating agents of ETT cuff [1].

Air is commonly used to inflate ETT cuff. Anaesthetic air or nitrous oxide is used as a carrier gas along with volatile anaesthetic agent during maintenance phase of anaesthesia that steadily increases endotracheal cuff pressure. ETT cuff pressures increases >30 cm H_2O during laparoscopic surgeries after carbon dioxide insufflation for pnuemoperitoneum even though anaesthetic air is used as a carrier gas due to raised intrathoracic pressure, which in turn, increases peak inspiratory pressure which can lead to increased incidence of Postoperative Sore Throat (POST) and coughing [2].

Laryngotracheal morbidity is significantly reduced when saline, lignocaine or steroids are used as an instillation agent for ETT cuff inflation [3-5]. Lignocaine is a local anaesthetic agent which when used for ETT cuff inflation diffuses into the tracheal mucosa through semi-permeable membrane of ETT cuff and blocks the activation of tracheal pain receptors even with very low lignocaine concentration (0.015%) [6]. This effect is likely to reduce the incidence of postoperative sore throat and coughing. Lignocaine reduces the incidence of POST, coughing, hoarseness when used in different concentrations (2%, 4% with or without alkalinised preparation) for ETT cuff inflation [7-9]. Till date, no study had been done with the use of non alkalinised 1% lignocaine as ETT cuff instillation agent in adults.

The aim of this study was to evaluate the postoperative laryngotracheal morbidity when low concentration non alkalinised 1% lignocaine was used to instil ETT cuff. The primary objective was to assess the effect of 1% lignocaine versus air for ETT cuff inflation on POST. Secondary objectives were to evaluate postextubation coughing and hoarseness of voice among the groups.

MATERIALS AND METHODS

This double-blind, randomised clinical study was carried out at Shree Krishna Hospital, Karamsad, Gujarat, India, between September 2021 to March 2022. The approval from the Institutional Ethics Committee (IEC) was obtained (IEC/HMPCMCE/120/Faculty/14/290). The study was also registered at the Clinical Trials Registry of India (CTRI/2021/09/036245). Written informed consent from the patients undergoing laparoscopic surgery were taken.

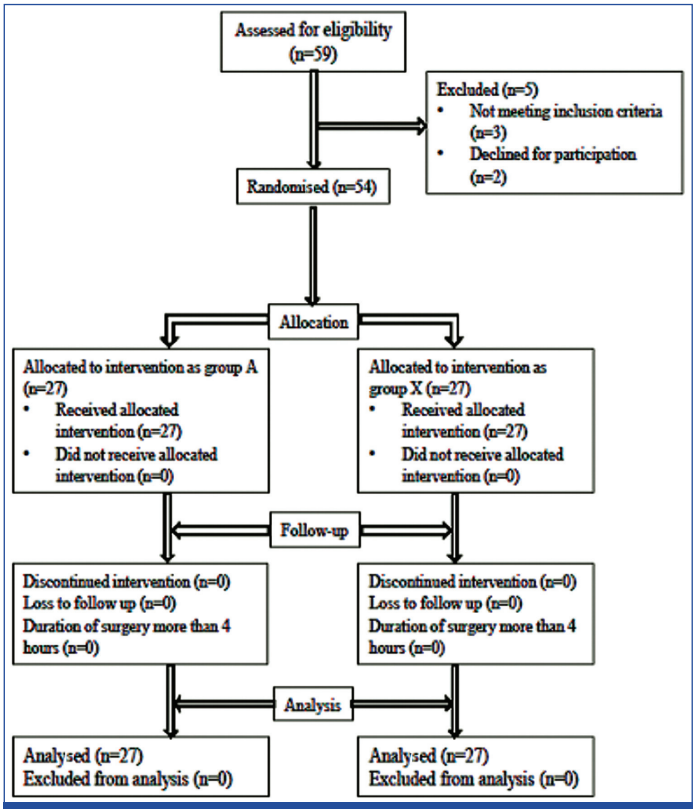
Sample size calculation: This is based on the study of Gaur P et al., which showed that occurrence of POST was 26% and 40% in the air group while 6% and 8% in the lignocaine group at 1 hour and 24 hour respectively, considering 5% level of significance with a power of 80%, required sample size was 27 in each group using WINPEPI software [7].

Inclusion criteria: Patients with age group of 18-60 years of either gender, American Society of Anaesthesiologists (ASA) class I, II, III posted for laparoscopic surgeries lasted for more

than 1 hour duration, Mallampati classification I-II, Body Mass Index (BMI) <30 kg/m^2 were included in the study.

Exclusion criteria: Patients with anticipated difficult airway, oropharyngeal airway introduced perioperatively, ≥2 trial of intubation, laryngotracheal diseases, recent or recurrent upper respiratory tract infection (URTI), history of raised intraocular pressure, intracranial pressure, ischaemic heart disease, gastric regurgitation, required rapid sequence intubation, failed extubation, nasogastric tube and tracheostomy tube in-situ were excluded from the study.

A total of 54 participants were randomly allocated to two groups based on computer-generated randomisation table [Table/Fig-1].



[Table/Fig-1]: Consolidated Standards of Reporting Trials (CONSORT) allocation.

- Group A (n=27): The cuff was inflated with 4-6 mL air
- Group X (n=27): The cuff was inflated with 4-6 mL 1% lignocaine (2% lignocaine + equal volume of normal saline).

Study Procedure

General Anaesthesia (GA) was given using inj. fentanyl 2 mcg/kg, inj.propofol 2-2.5 mg/kg and inj. vecuronium 1 mg/kg. After achieving adequate muscle relaxation, laryngoscopy was performed by the attending anaesthesiologist with more than three years of experience and trachea was intubated with polyvinyl chloride, soft seal, high volume, low pressure, cuffed ETT of size 8 mm internal diameter in males and 7.5 mm in females.

As per group allocation, in group A, cuff was inflated with 4-6 mL air and in group X, cuff was inflated with 4-6 mL 1% lignocaine (2% lignocaine + equal volume of normal saline) until audible leak was heard. ETT cuff inflation with lignocaine was done slowly because of its higher viscosity than air. Slow inflation of cuff with lignocaine ensures pressure equilibrium in the system as elasticity of the cuff tends to force lignocaine solution to the pilot balloon when inflating pressure is stopped and cuff pressure may consequently drop. During surgery, anaesthesia was maintained with oxygen, air and sevoflurane with on controlled mechanical ventilation. At the end of surgery, after confirming all four equal responses of train of four on peripheral nerve stimulator and adequate tidal volume, patients were reversed and extubated. Patients were observed for POST, hoarseness of voice and coughing at 2 and 18-24 hours by an observer who was unaware of cuff infiltrating agent.

Postoperative Sore Throat (POST)

POST was graded on a 4 point scale with [10]:

- 0- No sore throat
- 1- Mild (scratch throat)
- 2- Moderate (similar to that noted with cold)
- 3- Severe sore throat (more severe than cold)

Hoarseness: Hoarseness was graded on a 4 point scale with [10]:

- 0- No hoarseness
- 1- Mild hoarseness (noted by the patient)
- 2- Moderate hoarseness (obvious to observer)
- 3- Severe (aphonia, patient not able to speak).

STATISTICAL ANALYSIS

Data entry was done by the blinded observer. Statistical analysis was done using STATA 14.2 software. Descriptive statistics, mean and standard deviation, frequency and percentage was used to depict baseline profile of participants. Fisher's Exact test was used to find the association between categorical variables like POST, hoarseness and coughing in both the groups. The p<0.05 was considered statistically significant.

RESULTS

Both the groups were comparable for demographic profile, ASA physical status of the patients, duration of surgery and position of patients during surgery as shown in [Table/Fig-2].

Variables	Group A (n=27)	Group X (n=27)	p-value
Mean age (Mean±SD)	46.04±10.26	48.59±10.92	0.37‡
Gender			
Male	10	9	0.77§
Female	17	18	
BMI (kg/m^2) (Mean±SD)	24.10±2.89)	23.43±2.30	0.34‡
American Society of Anaesthesiologists grade			
I	2	3	0.54§
II	8	11	
III	17	13	
Duration of surgery (minutes) (Mean±SD)	164.81±51.95	175.93±45.15	0.41‡
Position during surgery			
Supine	9	11	0.57§
Trendelenburg	18	16	

[Table/Fig-2]: Comparison of demographic profile between both groups.
‡ Independence sample t-test; § Chi-square test

Incidence of POST at 2 hours, was low in group X (11%) as compared to group A (33%) (p=0.099). At 18-24 hours, incidence of POST was significantly low in group X (11%) compared to group A (40.7%). Severity grading of POST was also low at both 2 and 18-24 hours in group X as compared to group A [Table/Fig-3].

Incidence of hoarseness of voice was significantly low in Group X in comparison to group A at both 2 hours, and 18-24 hours. At 2 hours, in both the groups only mild and moderate hoarseness of voice was observed but its incidence was less in group X compared to group A; whereas, at 18-24 hours none of the patients complained of hoarseness of voice in group X [Table/Fig-4]. Just after extubation, group X showed lower incidence of coughing in comparison to group A, which was statistically significant [Table/Fig-5].

Parameters	Group A n=27 (%)	Group X n=27 (%)
POST at 2 hours		
Grade 0	18 (66.6)	24 (88.8)
Grade 1	2 (7.4)	2 (7.4)
Grade 2	5 (18.5)	1 (3.7)
Grade 3	2 (7.4)	0
p-value	0.138	
Total no of patients with POST at 2 hours	9 (33)	3 (11)
p-value	0.09	
POST at 18-24 hours		
Grade 0	16 (59.3)	24 (88.8)
Grade 1	7 (25.9)	2 (7.4)
Grade 2	2 (7.4)	1 (3.7)
Grade 3	2 (7.4)	0
p-value	0.055	
Total no of patients with POST at 2 hours	11 (40.7)	3 (11)
p-value	0.028	

[Table/Fig-3]: Incidence and severity of postoperative sore throat.

Parameters	Group A n=27 (%)	Group X n=27 (%)
Hoarseness at 2 hours		
Grade 0	13 (48.1)	21 (77.8)
Grade 1	9 (33.3)	5 (18.5)
Grade 2	5 (18.5)	1 (3.7)
Grade 3	0	0
p-value	0.064	
Total no of patients with hoarseness at 2 hrs	14 (51.9)	6 (22.2)
p-value	0.047	
Hoarseness at 18-24 hours		
Grade 0	15 (55.5)	27 (100)
Grade 1	10 (37)	0
Grade 2	2 (7.4%)	0
Grade 3	0	0
p-value	0.001	
Total no of patients with hoarseness at 18-24 hrs	12 (44.4)	0
p-value	0.001	

[Table/Fig-4]: Incidence and severity of hoarseness of voice.

Incidence of coughing (n=27)	Group A	Group X	p-value (Fisher's Exact test)
Present	15 (55.5)	4 (14.8)	0.004
Absent	12 (44.4)	23 (85.2)	

[Table/Fig-5]: Incidence of coughing.

DISCUSSION

Incidence of laryngotracheal morbidity is as high as 30-70% in surgical patients, which makes them most common and unpleasant side effect [7,11]. In laparoscopic surgeries, carbon dioxide insufflation during pneumoperitoneum causes upward displacement of the diaphragm, increasing intrathoracic pressure and reducing lung compliance leading to rise in peak inspiratory pressure, which leads to over-inflation of ETT cuff and rise in ETT cuff pressure [2,12]. This raised ETT pressure is laterally transmitted to the tracheal wall, which in turn blocks the tracheal submucosal perfusion and causes ischaemic erosion and necrosis of mucosa. These give rise to postoperative laryngotracheal morbidity [13]. These complications are exaggerated as the duration of surgeries increases and also when the Trendelenburg position is maintained [12,14].

Polyvinyl chloride ETT cuff is permeable so when lignocaine is used for ETT cuff inflation, it provides continuous availability of lignocaine at the tracheal mucosa. Lignocaine blocks the sodium ion (Na+) channels of sympathetic nerves of tracheal mucosal wall and causes local vasodilatation. This helps in improving tracheal submucosal blood flow, thus reducing laryngotracheal morbidity without increasing serum concentration of lignocaine, vocal cord paraesthesia, inhibition of deglutition reflex and other systemic side-effects [6].

In various studies, 2-4% lignocaine with or without alkalinised preparations were used in ETT cuff instillation for prevention of laryngotracheal morbidity [15-18]. This study was intended to evaluate effectiveness of non alkalinised 1% lignocaine versus air for prevention of postoperative sore throat, hoarseness of voice and postextubation coughing in laparoscopic surgeries.

In this study, at 2 hours group X showed lower incidence of POST in comparison to group A but it was not statistically significant; whereas at 18-24 hours, incidence of POST was low in group X compared to group A, which was statistically significant. Both at 2 hours and 18-24 hours, none of the patients in group X had severe (grade 3) POST, whereas in group A (7.4%) patients had severe POST. Abraham JM et al., conducted a similar study in 100 patients and compared air and 2% plain lignocaine for ETT cuff inflation [16]. The incidence of POST in immediate postoperative period was 72.5% in air group and 27% in lignocaine group and after 4 hours it was 72% in air group and 25 % in lignocaine group. Both these incidences were statistically significant. Despite using 2% lignocaine their incidence of sore throat was higher at both the times in comparison to the present study [16]. They had used oxygen:nitrous oxide (4:2) anaesthesia for maintenance while in the present study air was used instead of nitrous oxide. That might be the cause of a lower incidence of sore throat while using 1% non alkalinised lignocaine. In the study performed by Gaur P et al., hundred patients were compared for incidence of sore throat and coughing using air (group A) vs 2% alkalinised lignocaine (group L). The incidence of sore throat at 1 hour in group A was 26% compared to 6% in group L and at 24 hours the incidence of sore throat in group A was 40% vs 8% in group L. In comparison to the present study their incidence of POST was slightly less as they had used 2% alkalinised lignocaine instead of 1% plain lignocaine like the present study [7]. Podder S and Bhat G, also reported that the severity of POST at 2 hours and 4 hours was low in lignocaine group in comparison to air and saline group [9].

In the present study, incidence of hoarseness of voice was significantly low in group X both at 2 hours and 18-24 hours. Also, in both the groups none of the patients complained of severe (grade 3) hoarseness of voice. Incidence of mild and moderate hoarseness was also less in group X at 2 hours and at 18-24 hours and none of the patients reported hoarseness of voice. In the study performed by Rizvanovic N et al., 90 patients were assessed for hoarseness while using air, saline and 2% alkalinised lignocaine for ETT cuff inflation. The incidence of hoarseness at 2 hours in group A was 60% vs 23.3% in group L. At 24 hours their incidence in group A was 30% compared to 6.7% in group L. Their incidence was higher than the present study even though they used alkalinised 2% lignocaine [19]. This could be because of the use of nitrous oxide with oxygen for maintenance of anaesthesia whereas in the present study air was used instead of nitrous oxide. In the study performed by Rajegowda SK et al., severity of hoarseness was assessed using 4% plain lignocaine and compared it with air, saline and hydrocortisone. They observed that at 6 hours, incidence of mild and moderate hoarseness was 20% and 11% in group A versus 7% mild hoarseness in group L, which was statistically significant. At 12 hours, in group A 11% patients had mild hoarseness whereas none of the patients had hoarseness in group L [5]. In comparison to their study, the present study had slightly higher incidence of mild and moderate hoarseness in group X at 2 hours. At 18-24 hours, results are comparable for lignocaine group, in both the studies. In the present study, only 1%

of lignocaine was used for instillation of ETT cuff whereas in the former, 4% of lignocaine was used, which could be the reason for higher incidence of mild and moderate hoarseness. Nagarajaiah P et al., studied the effectiveness of air, N_2O and 2% lignocaine for ET cuff inflation and assessed the intensity of sore throat pain in three groups using visual analogue scale, which showed significantly low scores with lignocaine group [20].

This study showed statistically significant reduced incidence of coughing in group X [Table/Fig-5]. Soren DK et al., studied the effect of alkalinised 1% and 0.5% lignocaine in paediatric patients and compared with air and saline group [13]. Their results showed lower incidence of coughing in 1% alkalinised lignocaine compared to air immediate postextubation (5% vs 10%) and at 8 hours postextubation (0% vs 5%). In comparison to the present study, their incidence of coughing was very less because they had maintained the intra-cuff pressure around 20 cm H_2O by inflating or deflating the cuff while in our study we had not measured the intra-cuff pressure using manometer. Gaur P et al., and Acharya G et al., also reported a decresed incidence of coughing while using 2 % alkalinised lignocaine while in the present study, similar results were achieved using 1% non alkalinised lignocaine [7,15].

Laryngotracheal morbidity after ETT GA is the prime concern for anaesthesiologists. That is why various studies had been carried out to reduce their incidence and severity using different concentrations of alkalinised and non alkalinised lignocaine (2%,4%,10%) for endotracheal tube cuff inflation and these studies are included in meta-analysis and systematic reviews [11,21]. In the present study, a low concentration (1%) of non alkalinised lignocaine was used and still it helped in reducing laryngotracheal morbidity.

Limitation(s)

This was a single-centre study; multicentric study can be done for more accurate results. Endotracheal cuff pressure monitoring with manometer for air and three-way transducer set for lignocaine was not used.

CONCLUSION(S)

The present research concluded that using low concentration of non alkalinised lignocaine (1%) for ETT cuff instillation significantly reduced the incidence of POST, hoarseness and coughing in laparoscopic surgeries with air-oxygen GA.

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