MAK HILL Publications Research Journal of Medical Sciences

Research Article
doi: 10.36478/makrjms.2024.8.333.337

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Key Words
Alkalinized lignocaine, intracuff, post-operative sore throat, endotracheal intubation, general anesthesia

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Received: 27 May 2024
Accepted: 18 July 2024
Published: 24 July 2024

Citation: M.G. Harshitha, K.C. Anamika Prem, Komal R. Deshpande and M.V. Sharvani, 2024. Effect of Intracuff Instillation of Alkalinized 2% Lignocaine on Post-Operative Sore Throat Under General Anaesthesia. Res. J. Med. Sci., 18: 333-337, doi: 10.36478/makrjms. 2024.8.333.337

Effect of Intracuff Instillation of Alkalinized 2% Lignocaine on Post-Operative Sore Throat Under General Anaesthesia

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Abstract
Sore throat is a common post-operative complaint after endotracheal intubation during general anesthesia (GA). We studied the effectiveness of using intracuff instillation with alkalinized 2% lignocaine on the incidence and severity of sore throat in patients undergoing surgery under GA. Institutional ethical committee approval was obtained. 120 consenting patients scheduled for middle ear surgeries were randomly allocated to two groups of 60 each. One of the groups received normal saline while the other group received alkalinized 2% lignocaine to inflate the endotracheal tube (ETT) cuff. The cuff was inflated to a pressure of 25 cm H2O. After the surgery, the incidence and severity of postoperative sore throat, cough and hoarseness of voice were assessed at 0, 2, 6, 12 and 24 hours on a four point scale. Statistical analysis done using Mann Whitney U test and fisher Exact test. Sore throat at 0, 2 and 6 hrs shows statistically significant difference with a $p<0.05$. 86.7% of patients in alkalinized lignocaine group had a good satisfaction score as compared to 66.7% in saline group.

INTRODUCTION

Post-operative sore throat is one of the most undesirable side effects after general anaesthesia with endotracheal intubation and is reported by 30%-70% of patients[1]. Post-intubation related emergence phenomena result in coughing, sore throat, bronchospasm, sympathetic stimulation, increased bleeding from surgical site, increased intracranial and intraocular pressure[2]. Routine airway instrumentation by laryngoscope, suctioning and irritant effects of ETT results in mucosal dehydration, edema, nerve damage and tracheal ischemia from friction between delicate tissue and ETT[3].

Various pharmacological prophylactic interventions such as anti-inflammatory drugs, opioids, steroids and local anaesthetics have been employed extensively. Each of these interventions have their limitation. Lignocaine is one of the most used drugs for prevention of post-operative sore throat [4]. When lignocaine is injected into the ETT cuff it acts as a potential reservoir, allowing slow diffusion through the semipermeable membrane wall and subsequent anesthetic action of the underlying mucosa, reducing tracheal stimuli and increases tolerance to tracheal tubes[5]. Typically, high doses of lignocaine that slowly diffuse through the cuff have been used[6]. Alkalization of lignocaine with addition of sodium bicarbonate increases diffusion of low doses of lignocaine across an ETT cuff thus preventing sore throat and the other side effects of intubation, such as hemodynamic changes, restlessness and dysphonia. Present study evaluates the effect of intracuff instillation of alkalinized 2% lignocaine during tracheal intubation under general anaesthesia for elective middle ear surgeries to prevent undesirable side effects like sore throat, cough, hoarseness and ensuring patient satisfaction and unhampered patient activity in post-operative period.

MATERIALS AND METHODS

Data was collected from all consenting patients who were scheduled for elective middle ear surgeries under GA with endotracheal intubation in department of Anaesthesiology.

Study Design: Prospective randomized double blinded study.

Inclusion Criteria:

- Patient willing to give informed written consent
- Elective middle ear surgical procedures with oro-tracheal intubation
- American Society of Anesthesiologists (ASA) class I-II
- Duration of surgery <4 hours
- Aged between 18-60 years of either gender

Exclusion Criteria:

- Patient not willing to give informed consent
- Patients with history of preoperative sore throat
- History or anticipated difficult intubation
- Patients requiring more than one attempt at intubation
- History of lignocaine allergy or hypersensitivity
- Patient requiring the insertion of a nasogastric tube
- History of asthma and chronic obstructive pulmonary disease
- Recent upper respiratory tract infection (within 15 days)
- Patient with history of smoking

Method of Study and Collection of Data: Approval and clearance from the institutional ethics committee was taken. Patients fulfilling the essential inclusion and exclusion criteria were enrolled for the study. Following detailed pre-anaesthetic checkup, informed written consent were obtained from all patients. All the patients were kept nil per oral 8 hours for solids and 2 hours for clear fluids. Patients were pre-medicated with Tab alprazolam 0.5 mg oral on the night prior to the surgery.

On the day of surgery, after arrival to the operation theatre, the patients were shifted to anaesthesia preparation room. Patients were randomized into two groups of 60 each (Group S and Group AL) using computer- generated randomization table.

- **Group S:** Normal Saline group (n=60), cuff was inflated to minimal occlusive volume with 0.9% saline to a pressure of 25 cm H2O.
- **Group AL:** Alkalinized Lignocaine group (n=60), cuff was inflated with 2% lignocaine with 7.5% NaHCO3, in the proportion of 19:1 ml ensuring that cuff pressure was maintained at 25 cm H2O.

The medications were prepared by the anaesthesiologist (observer 1) who was not involved later in the study.

Upon patient arrival to operating room, 18-gauge intravenous cannula was inserted. Standard monitoring including non-invasive blood pressure, electrocardiography, capnography and pulse oximetry were connected and baseline values noted. All patients were pre-medicated with Inj. midazolam 0.02 mg/kg, Inj. glycopyrrolate 0.004 mg/kg. All patients were pre-oxygenated for 3 minutes and anaesthesia induced

with Inj. fentanyl 2 mcg/kg and Inj. propofol 2 mg/kg. Neuromuscular blockade was achieved with Inj. vecuronium 0.1 mg/kg. Once adequate depth was achieved, the trachea was intubated by anaesthesiologist (observer 2) who was blinded to the group assigned, with a 7.5 mm endotracheal tube in females and an 8.0 mm endotracheal tube in males. After successful insertion, the cuff was slowly inflated with either of the solution based on the group assigned. For Group S, cuff was inflated to minimal occlusive volume with 0.9% saline and for Group AL, cuff was inflated with 2% lignocaine and 7.5% NaHCO3, in the proportion of 19:1 ml. Proper placement of endotracheal tube was confirmed by bilateral symmetrical chest expansion on manual ventilation, square waveform on capnography. The cuff pressure was measured immediately after endotracheal intubation using a manometer (VBM, Sulz, Germany) and was checked every hour after intubation and pressure was maintained within 25 cm H2O. Anaesthesia was maintained with oxygen, nitrous oxide 35:65% and sevoflurane 1-2% and ventilated with intermittent positive pressure ventilation to maintain normocapnia. At the end of surgical procedure, anaesthesia was discontinued and all patient were reversed with standard dose of neostigmine and glycopyrrolate, after gentle oral suction, endotracheal tube was removed after deflating the cuff and the patients were shifted to the recovery room.

On arriving in the post-anaesthesia care unit, patients were assessed for incidence and severity of post-operative sore throat, cough and hoarseness of voice on a four-point scale, at 0, 2, 6, 12 and 24 hours by observer 2 (anaesthesiologist) who was blinded to the study agent using the four-point scale[1-4].

Sore Throat:

- Score 0-No evidence of sore throat at any time since the surgery
- Score 1-Mild sore throat (Answered in the affirmative when asked)
- Score 2-Moderate sore throat (Complaints on his/her own)
- Score 3-Severe sore throat (Associated with pain)

All the patients were asked to grade the satisfaction of post-operative experience on a 2-point scale at 24 hours.

Patient Satisfaction:

- Score 1-Patient satisfied
- Score 2-Patient not satisfied

RESULTS AND DISCUSSIONS

Statistical Analysis: All the data collected and entered in Microsoft Excel worksheet and analysed using software SPSS 20.0. The qualitative characteristics like gender, ASA and type of surgery were expressed in frequency with percentage. For continuous variable like age, BMI and duration of anaesthesia were expressed in mean with SD, median with interquartile range and percentage were calculated. Data was tested for normality, using the Shapiro-Wilk test. And data was found to be non-normal hence non-parametric tests are applied. To find the association between the attributes chi-square test and fisher exact test was used based on data suitability. To compare study variables between any groups Mann-Whitney U-Test were applied.

The 120 patients were distributed among Group L and S, 60 in each group. The majority of patients were females 56.7% (68) and 43.3% (52) were male. ASA-I were 56.7% (68) and 43.3% (52) were ASA-II. 50.8%(61) patients underwent right tympanoplasty surgery and 49.2% (59) underwent left tympanoplasty surgery. The age, gender, ASA, duration of anaesthesia and type of surgery were statistically not significant with a p-value of >0.05.

The sore throat at 0 hours, 2 hours, 6 hours and 12 hours shows statistically significant difference with a p<0.05.

The cough at 0 hours, 2 hours and 6 hours shows statistically significant difference with a p<0.05. The hoarseness of voice at 0 hours, 2 hours and 6 hours was a statistically significant difference with a p<0.05. At 12 hours and 24 hours cough and hoarseness of voice were not significant between the groups.

At 24 hrs, after surgery and extubation, 86.7% (52) patients in group AL were satisfied as compared to 66.7% (40) patients in group S. Patient satisfaction is statistically significant with the p-value of 0.0095 (<0.05).

We conducted a randomized study to determine the benefits of using alkalinized 2% lignocaine to fill the cuff of an ETT to prevent post-operative throat symptoms. In our study, incidence of post-operative sore throat, cough and hoarseness of voice were less when intra cuff alkalinized lignocaine was used rather than normal saline. The other contributing factors for post-operative sore throat include female sex, age, size and shape of the ETT or its cuff design, cuff pressure, use of succinylcholine and long duration of intubation which influences post-operative throat mucosal injuries[7]. The demographic parameters like age, gender, BMI, duration of anaesthesia and ASA status were comparable between the two groups. We had chosen patients in ASA physical status 1 or 2 for the

Table 1: Descriptive statistics of the study variables among the groups

Study Variable	Group-L	Group-S	p- value
Age (Mean ± SD)	35.6±8.7	34.2±9.1	0.3057
BMI(Mean ± SD)	26±4.3	24.6±2.0	0.0955
Duration of Anaesthesia (Mean ± SD)	79±16.6	85±34.56	0.181

Table 2: Distribution of the demographic data variables among the groups

Study Variable	Group-L		Group-S		p- value
Gender	N	%	n	%	0.4611
Female	32	53.3	36	60.0	
Male	28	46.7	24	40.0	
ASA	N	%	n	%	0.5695
I	52	86.7	54	90.0	
II	8	13.3	6	10.0	
Type of Surgery	**N**	**%**	**n**	**%**	0.2011
Left tympanoplasty	26	43.3	33	55.0	
Right tympanoplasty	34	56.7	27	45.0	

Table 3: Assessment of Severity of Sore throat, Cough, and Hoarseness among the groups

Time	Sore Throat		Cough		Hoarseness	
	Group L	**Group S**	**Group L**	**Group S**	**Group L**	**Group S**
0 Hr	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Mild	12 (80%)	32 (72.7%)	12 (92.3%)	19 (76%)	3 (75%)	22 (81.5%)
Moderate	3 (20%)	8 (18.2%)	1 (7.7%)	5 (20%)	1 (25%)	5 (18.5%)
Severe	0 (0%)	4 (9.1%)	0 (0%)	1 (4%)	--	--
2 Hr						
Mild	8 (100%)	25 (86.2%)	2 (100%)	12 (92.3%)	2 (100%)	17 (85%)
Moderate	0 (0%)	2 (6.9%)	0 (0%)	1 (7.7%)	0 (0%)	3 (15%)
Severe	0 (0%)	2 (6.9%)	--	--	--	--
6 Hr						
Mild	5 (100%)	15 (88.2%)	0 (0%)	6 (100%)	2 (100%)	13 (100%)
Moderate	0 (0%)	2 (11.8%)	--	--	--	--
12 Hr						
Mild	1 (100%)	10 (90.9%)	0 (0%)	2 (100%)	0 (0%)	2 (100%)
Moderate	0 (0%)	1 (9.1%)	--	--	--	--
24 Hr						
Mild	0 (0%)	2 (100%)	0 (0%)	0 (0%)	0 (0%)	1 (100%)

Table 3: Patient Satisfaction

Study Variable	Group AL		Group S		Total		Chi- square test	p-value
Patient Satisfaction	n	%	n	%	n	%		
Satisfied	52	86.7	40	66.7	92	76.7	6.7081	0.0095
Not Satisfied	8	13.3	20	33.3	28	23.3		

study and to standardize the type of surgery, we chose middle ear surgeries like tympanoplasty.

Jensen *et al.,* found that frequency and severity of post-operative sore throat after short term intubation was significantly greater after the use of high-pressure and low volume cuffs than after the use of low-pressure and high-volume cuffs[8]. We used high volume and low pressure appropriately sized ETT in all patients and maintained the intra-cuff pressure below 25 cm H2O.

Kumar CM *et al.,* explained that ETT cuffs are designed to prevent aspiration and allow application of positive pressure ventilation, provided adequate cuff pressure is maintained. A cuff pressure of >30 cm H2O may compromise local tissue blood flow and cause damage to the tracheal mucosal wall and surrounding anatomical structures[9]. In our study, the intra cuff pressure was recorded at the start and intermittently throughout the surgery in both groups. The intra cuff pressure was maintained below 25 cm H2O in both the groups throughout the surgery.

Local anaesthetics have been implemented for the prophylaxis in an effort to decrease the incidence and duration of post-operative sore throat. Lignocaine, in its several preparations such as topical jelly, intra-cuff, aerosolized and intravenous form has evolved as an effective measure in reducing post-operative sore throat. However, each of these techniques has its own limitations[10].

In our study, post extubation, 25% of patients in the alkalinized lignocaine group had sore throat as compared to 73.3% of patients in the saline group. At the end of 12 hrs only 1.7% of patient had sore throat in alkalinized lignocaine group as compared to 18.3% of patients in saline group. The sore throat at 0, 2, 6 and 12 hrs showed statistically significant difference ($p<0.05$).

Our results correlate with the previous studies done by Shroff[11] in 2009. They found that 40% of patients developed sore throat in the saline group as compared with 36% in the alkalinized lignocaine group post extubation. While 50% of patients developed cough in the saline group as compared with 34% in the alkalinized lignocaine group post extubation. In our study, post extubation, 58% of patients in the alkalinized lignocaine group had cough as compared to

78% of patients in the saline group. At the end of 12 hrs only 3.3% of patients had cough in control group. The cough at 0, 2 and 6 hrs showed statistically significant difference with a $p<0.05$.

Souissi[12] reported in their study that 83% of patient had hoarseness of voice in saline group as compared to 76% of patients in alkalinized lignocaine group at 1 hour post extubation. While 67% and 58% of patient had hoarseness of voice at 24 hrs post extubation in saline and alkalinized lignocaine group respectively.

In our study, the incidence of hoarseness of voice was 45% and 7% in saline and alkalinized lignocaine group respectively and only 2% of patients had hoarseness in saline group at 24 hrs post-operative period. The hoarseness of voice at 0, 2 and 6 hrs showed statistically significant difference with a $p<0.05$.

The effect alkalinized lignocaine as ETT cuff inflation media led to a significant reduction in the incidence and severity of post-operative sore throat cough and hoarseness with good patient satisfaction and without any complications in patients undergoing elective middle ear surgeries under GA.

All the patients were extubated in our study without any complications like cuff rupture, bronchospasm, laryngospasm, signs of lignocaine toxicity or any adverse effects during the study. This confirms that the technique of instilling alkalinized lignocaine intra-cuff of ETT is safe and can be applicable in clinical practice.

In our study, even though we did not measure the plasma levels of lignocaine no patients showed any signs of lignocaine toxicity.

CONCLUSION

Intracuff alkalinized 2% lignocaine reduces the incidence and severity of sore throat, cough and hoarseness of voice with good patient satisfaction and without any complications in the post-operative period up to 24 hrs in patients who underwent elective middle ear surgery under general anaesthesia with endotracheal intubation.

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