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Original Research Article

COMPARISON BETWEEN 5% EMLA CREAM AND LIDOCAINE JELLY ON POST OPERATIVE SORE THROAT FOLLOWING GENERAL ANAESTHESIA WITH ENDOTRACHEAL INTUBATION - A PROSPECTIVE RANDOMIZED DOUBLE BLIND CONTROLLED STUDY

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ABSTRACT

Background: Postoperative sore throat (POST) is the most common postoperative outcome after endotracheal intubation. In this study we compared the efficacy of 5% EMLA cream and 2% Lidocaine jelly on incidence, severity of post operative sore throat, hoarseness of voice (HOV), post-extubation cough (PEC) following general anaesthesia with endotracheal intubation.
Materials and Methods: This study includes 90 patients of 18 to 65 years old, with American Society of Anesthesiologists(ASA) physical status I and II and of either sex were scheduled to receive 5% EMLA cream or 2% Lidocaine jelly applied over the ET Tube cuff. POST was graded as none (0), mild (1), moderate (2), severe (3). A score of ≥2 was considered as significant POST. The incidence and severity of POST at the sixth post-operative hour was the primary outcome. Secondary outcomes included the incidence of POST, HOV and PEC at zero, first, and 24 hours.
Results: The incidence of postoperative sore throat of any grade at 1st and 6th hour of postoperative period was significantly less in EMLA group when compared to Lidocaine group (35.6 % vs 60%, p - 0.0202; 15.6% vs 35.6%, p - 0.0296 respectively). The incidence of HOV was statistically significant at sixth postoperative hour (6.6% and 22.2%, p - 0.0358). The incidence of PEC was similar in both the groups at all times.
Conclusion: 5% EMLA cream on the ETT cuff effectively reduced the incidence and severity of POST, HOV, PEC in the initial 6 hours of surgery compared to the 2% Lidocaine jelly group.
Keywords: Postoperative sore throat (POST), 5 % EMLA, 2% Lidocaine jelly, hoarseness of voice, post extubation cough.

INTRODUCTION

Postoperative sore throat (POST) is an undesirable, most common postoperative outcome and affects up to 20 to 74% of patients undergoing general anesthesia with an endotracheal tube.[1,2] So it should be prevented to improve patient satisfaction and recovery. POST is caused by mechanical trauma from intubation, ischemic injury to the trachea due to pressure by ET tube cuff, inflammation of the mucosa, and erosion of soft pharyngeal mucosa due to friction with the ET tube. POST causes problems like delayed feeding, delayed discharging of patients and patient's discomfort which is even more disturbing than the pain after surgery.[3,4] Many anti-inflammatory agents like benzydamine hydrochloride,[5] topical/inhaled corticosteroids, topical ketamine, glycerin, KY jelly and topical local anesthetics are used to prevent sore throat with variable success rates.[6,7] Non-pharmacological methods like cuff pressure monitoring and smaller-

sized endotracheal tubes have been attempted to reduce POST.[8,9]
5% EMLA cream, a liquid emulsion and eutectic mixture of local anesthetics (lidocaine and prilocaine) has been shown to penetrate intact skin and mucous membranes and provide analgesia of superficial layers.[10] So in this study we compared the effect of novel topical application of 5% EMLA cream and water soluble form of 2% lidocaine jelly (which is used in routine practice) applied over the endotracheal tube cuff in reducing the incidence and severity of sore throat, hoarseness of voice (HOV), post-extubation cough (PEC) in adults during the first 24 post operative hours after general anesthesia with endotacheal intubation in elective surgeries.
The Primary objective is to compare the incidence of post-operative sore throat at the sixth postoperative hour. The Secondary objective is to compare the incidence and severity (mild, moderate, severe) of POST at 0, first, and 24 hours postoperatively and the occurrence of any postoperative complications like hoarseness of voice and post extubation cough.

MATERIALS AND METHODS

The present study was conducted in a tertiary care hospital from December 2023 to May 2024. After obtaining institutional Ethics Committee approval (IECNo.ACAD/E3B/2022-2023/ CTRI no-CTRI/2023/11/060248) and written informed consent regarding risks and benefits of study drugs from the patients, study was done. Out of 114 patients who were assessed for eligibility, 104 patients belonging to ASA I, II of either sex, aged between 18 to 65 years undergoing elective surgeries under general anaesthesia with endotracheal intubation were enrolled in the study. Patients were randomly divided into two groups with 52 patients in each group, Group E - 5% EMLA cream and group L - Lidocaine 2% jelly using block randomization method using block size of 10 in 1:1 ratio and blinding was done using opaque sealed envelopes. Patient's refusal, surgeries of the oral cavity and pharynx, patients with anticipated difficult airway (mallampati class >3), known case or susceptible to methemoglobinemia or patients on drugs that cause methemoglobinemia, previous throat pain or hoarseness history, history of local anaesthetic allergy, more than two attempts required for intubation, prolonged surgery for more than 120 minutes were excluded from study. Out of 104 patients, 90 patients were included in the final study according to inclusion and exclusion criteria.
All patients were premedicated with inj.Pantoprazole iv, inj. Ondensetron iv two hours before surgery. After confirmation of 6 hours of nill by mouth, patients were taken to operation theatre, all standard monitors were connected, inj.midazolam 1mg, inj.glycopyrolate 0.2mg iv given and preoxygenation was done. Before induction, endotracheal tube cuff was checked and 2.5 ml of EMLA cream or lidocaine 2% jelly was evenly applied on the cuff and distal end of ET tube. The volume of the lubricant taken was measured with a disposable syringe. The EMLA cream and Lidocaine jelly are different in colour and consistency. So to avoid information bias, the staff who were not involved in assessing postoperative sorethroat were requested to apply lubricant over endotracheal tube. Intubation was done by an experienced Anesthesiologist from the other OT who is not concerned with the patient in postoperative assessment.
Patient was induced with 2mg/kg propofol iv, 2mcg/kg inj.Fentanyl given for analgesia, inj vecuronium bromide 0.1mg/kg iv was given for muscle relaxation and intubated with 7 mm or 8 mm internal diameter for female and male patients respectively. After intubation cuff was inflated with air so as to maintain intracuff pressure 20-25 cmH2O throughout the surgical period. Anesthesia was maintained with 33% O_2, 66% N_2O, 1-2 % sevoflurane and inj. Vecuronium. Inj. Paracetamol 1gm iv was given before extubation for postoperative analgesia. At the end of surgery residual neuromuscular blockade was reversed with inj. Neostigmine 0.05mg/kg and 0.01mg/kg glycopyrrolate. After thorough suctioning under vision with the use of laryngoscope as tongue depressor, patients were extubated following return of reflexes and consciousness. Time of extubation was noted and was shifted to recovery room. Patients were assessed for postoperative sorethroat, hoarseness of voice, postextubation cough at 0,1,6,24 hour postoperatively by the anaesthetist in charge of the post-anaesthesia care unit who did not have the idea to which group the patient is allocated, using the questionnaire as follows [Table 1].[11]

Table 1: Grading of severity of POST, HOV, PEC

Criteria	0	1	2	3
Postoperative sore throat	No sore throat at any time since the operation	Minimal sore throat (complains of sore throat only on asking)	Moderate sore throat (complains of sore throat on his/her own)	Severe sore throat (change of voice or hoarseness, associated with throat pain)
Hoarseness of voice	No evidence of hoarseness at any time since the operation	No evidence of hoarseness at the time of interview	Hoarseness at the time of interview noted by patient only	Hoarseness that is easily noted at the time of interview
Post extubation cough	No cough at any time since the operation	Minimal cough or scratchy throat	Moderate cough	Severe cough

Statistical Analysis

The incidence of POST was 37.5% with lidocaine 2% jelly in a previous study by Parineeta Thapa, et al.[12] To detect a 50% decrease in the incidence of POST a sample size of 80 patients were required in each group. To compensate for any dropouts, data was collected from 114 patients. Out of which 24 were excluded were excluded due to different reasons as shown in CONSORT and 90 patients were included in the study and recorded as per the proforma and analyzed using Medcalc statistical software version 21.0.8 (MedCalc Software Ltd, Belgium). Appropriate tests are used for qualitative variables. Fisher's exact test for proportions like sex, incidence and severity of postoperative sore throat, cough and hoarseness of voice, and independent t test for continuous parametric data like age, height and weight. P value < 0.05 is considered statistically significant.

Table 2: Baseline Charecteristics

Parameter	Group E (N=45)	Group L (N=45)	Significance (p value)
Sex (male/female)	21/24	19/26	0.6713
Age (mean+ SD) in years	46 + 10.2	47 + 9.8	0.6365
Weight (mean + SD) in kg	58.14 + 10.7	57.42 + 10.3	0.8016
ASA I/II	34/11	31/14	0.4985
Duration of surgery in mins (mean + SD)	101.46 + 16.34	99.89 + 18	0.6659
No. Of intubation attempts			1. 7253
Single	40	41	
Two	5	4	
Average duration of intubation in secs	17.7 + 4.2	17.1 + 4.8	0.5296
Mallampati grade			0.6953
1	31	30	
2	12	11	
3	2	4	
Cormack Lehane grade			0.9555
1	36	37	
2	6	5	
3	3	3	
Blood staining on ET tube	2	3	0.6453

Summary statistics presented as the number of patients or mean (SD).
Abbreviations: ASA, American Society of Anesthesiologists; EMLA, eutectic mixture of local anesthetics; ETT, endotracheal tube; SD, standard deviation, p value <0.05 is considered as significant.

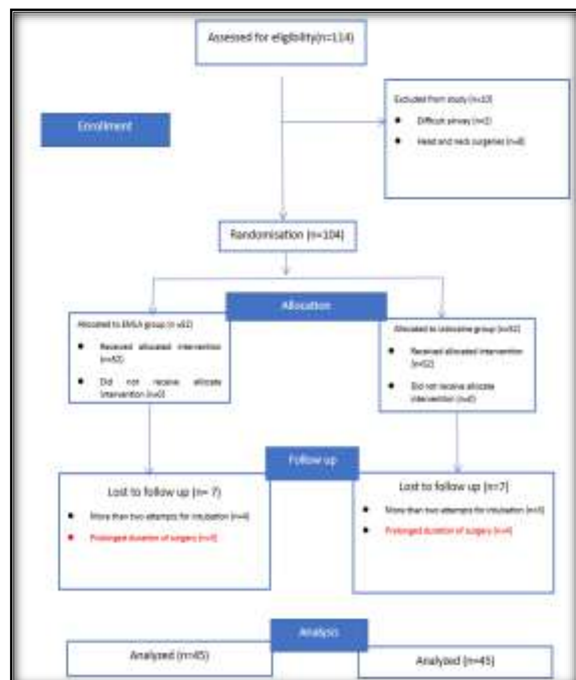

Figure 1: CONSORT diagram describing flow of patients in the study. CONSORT stands for Consolidated Standards of Reporting Trials; EMLA- eutectic mixture of local anesthetics

RESULTS

Out of 114 patients assessed for eligibility, 24 patients were excluded from the study due to different reasons as said above [Figure 1]. 90 patients were divided in to two groups 45 each and data was collected. The baseline characteristics such as Age, Sex, Weight, ASA physical classification, Mallampati grading, duration of surgery, number of intubation attempts were found to be insignificant between two groups.

The incidence of postoperative sore throat of any grade (mild, moderate or severe) at 1st and 6th hour of postoperative period was significantly less in EMLA group when compared to Lidocaine group (35.6 % vs 60%, p - 0.0202; 15.6% vs 35.6%, p - 0.0296 respectively). Severity of POST was mild in EMLA group patients in most of the cases at all times compared to Lidocaine group which has moderate severity of POST though it was not statistically significant. Two patients in EMLA group required rescue analgesia with inj. Tramadol 100 mg in 100ml normal saline, one at 0 hour and other at 1st hour whereas 6 patients recquired rescue analgesia in Lidocaine group in total. Hoarseness of voice and post extubation cough were observed in both the groups at 0,1,6 and 24th hour. The incidence of HOV was 6.6% and 22.2% in EMLA and Lidocaine group respectively at 6th postoperative hour, which is

statistically significant (p - 0.0358). The incidence of HOV at 0,1, 24 hour postoperatively of any grade (mild to severe) was found to be not significant in both the groups. The incidence of PEC was similar in both the groups at all times and no statistical significance was seen.

Table 3 : Incidence and severity of postoperative sorethroat at different time intervals

Time of observation	Severity of POST in Group E	Severity of POST in Group L	p value	Incidence of POST in Group E n=45(%)	Incidence of POST in Group L n=45(%)	p value
0 hr	0 - 33(73.3) 1 - 9 (20) 2 - 2 (4.4) 3 - 1 (2.2)	0 - 25(55.5) 1 - 14(31.1) 2 - 4 (8.9) 3 - 2 (4.5)	0.7812	12(26.7)	20(44.4)	0.0896
1 hr	0 - 29(64.4) 1 - 12(26.7) 2 - 3 (6.7) 3 - 1 (2.2)	0 - 18 (40) 1 - 9 (20) 2 - 5 (11.1) 3 - 3 6.7)	0.188	16 (35.6)	27 (60)	0.0202
6hr	0 - 38(84.5) 1 - 6 (13.3) 2 - 1 (2.2) 3 - 0 (0)	0 - 29(64.5) 1 - 10(22.3) 2 - 5(11.1) 3 - 1 (2.2)	0.072	7 (15.6)	16 (35.6)	0.0296
24hr	0 - 42(93.3) 1 - 3 (6.7) 2 - 0 (0) 3 - 0 (0)	0 - 40(88.9) 1 - 4 (8.9) 2 - 1 (2.2) 3 - 0 (0)	0.551	3 (6.7)	5 (11.1)	0.5488

Values are proportion (percentage) of patients, p value < 0.05 is significant, POST - postoperative sorethroat, hr-hour

Table 4 : Incidence and severity of Hoarseness of voice in two groups

Hoarseness of voice	Group E n = 45(%)	Group L n = 45(%)	p value
0 hr	No - 15(33.3) Mild - 13 Moderate - 2 Severe -0	No - 20(44.4) Mild - 15 Moderate - 5 Severe - 0	0.2796
1 hr	No - 7(15.6) Mild - 6 Moderate - 1 Severe - 0	No - 13(28.8) Mild - 9 Moderate - 4 Severe - 0	0.1281
6 hr	No - 3(6.6) Mild - 3 Moderate - 0 Severe - 0	No - 10(22.2) Mild - 8 Modrate - 2 Severe - 0	0.0358
24 hr	0	0	---

Values are proportion (percentage) of patients.

Table 5: Incidence and severity of post-extubation cough in two groups

Cough	Group E n = 45 (%)	Group L n = 45 (%)	p value
0 hr	No-18 (40) Mild - 16 Moderate - 2 Severe - 0	No-25 (55.6) Mild - 20 Moderate - 5 Severe - 0	0.1396
1 hr	No- 6 (13.3) Mild - 6 Moderate - 0 Severe - 0	No- 5 (11.1) Mild - 5 Moderate - 0 Severe - 0	0.8089
6 hr	No -1 (2.2) Mild - 1 Moderate - 0 Severe - 0	No -1 (2.2) Mild - 1 Moderate - 0 Severe - 0	1.0000
24 hr	0	0	---

Values are proportion (percentage) of patients.

DISCUSSION

In our study, use of 5% EMLA cream over endotracheal tube cuff reduced the incidence and severity of post operative sore throat when compared to conventionally used 2% Lidocaine jelly. The term POST is not well defined and usually describes a wide variety of conditions including pharyngitis, laryngitis, tracheitis, cough, hoarseness or dysphagia manifesting in the early postoperative period. POST is a well-documented complication after tracheal intubation with an incidence of as high as 100% in some studies with a significant negative impact on patient's recovery and satisfaction inspite of usage of many advanced larygoscopes and pharmacological agents.[12,13]

Inspite of using multiple agents in different studies to reduce postoperative sore throat, there is no ideal method to reduce POST. This might be due to various confounding factors like difference in tube sizes,

unstandardized cuff pressure, use of nitrous oxide, which is known to increase the cuff volume and pressure or the difference in patient population. A study by Cho HY et al,[14] concluded that smaller ET tubes (6mm ID ET tube for women and 6.5 mm ID ET tube for men) caused lesser POST when compared to larger ones. We used 7 mm ID ET tube for women and 8 mm ID ET tube for men. Smaller ET tubes than these might increase airway resistance during ventilation and cause difficulty while suctioning through ET tubes. We used nitrous oxide and oxygen in regular ratio of 2:1 and regularly monitored cuff pressure which was maintained in the safe range of 20-25cm of H2O.

Although the incidence of systemic adverse reactions with 5% EMLA Cream is very low in adults when compared to infants and children, caution should be exercised, particularly when applying it over large areas and leaving it on for longer than 2 hours.[15] Previous reports showed that with oral mucosal administration of 4 mL of EMLA, the peak plasma concentration of both lidocaine and prilocaine did not reach toxic levels.[10] As well, methemoglobin levels did not exceed normal values, which is of concern with prilocaine administration. In our study, we used 2.5 ml of EMLA which is far less to cause toxic levels.

Lignocaine is the predominant local anesthetic agent used by many anesthesiologists to reduce sore throat postoperatively.[16] It is used in different ways and concentrations-within the ETT cuffs (2%–10%),[17] as water soluble topical gel applications on cuffs (2-4%), through the IV route (1–1.5 mg·kg−1), and even as an aerosolized spray (4%–10%)(5,12). Still the incidence of sorethroat is remarkably significant. In a study done by Aamir Furqan 2016,[18] the results showed that local application of a combination of lignocaine and diclofenac sodium gels over the endotracheal tube before intubation is associated with lower incidence of postoperative sore throat, but no superiority was seen for lidocaine alone over diclofenac gel. In a study done by Nashwa Abdallah et al,[5] it was concluded that application of 10% lidocaine spray should be avoided because of worsening of POST where incidence and severity is increased. Applying 5% lidocaine gel on the ETT cuff does not prevent POST but it is better than lidocaine 10% spray or saline. Increased incidence of sorethroat with Lignocaine was attributed to potentially irritating additives in lignocaine gel, such as chlorhexidine gluconate and preservatives like methylhydroxybenzoate (methylparaben).[5,19]

In our study we used preservative free mixture of two local anesthetics, 2.5% lignocaine and 2.5% prilocaine (5% EMLA cream), to see any additive relief from POST after general anesthesia when compared to 2% lignocaine alone. 5% EMLA cream was earlier used for relieving pain assosciated with injection or intravenous indwelling needle punctures and minor skin surgeries especially in pediatric patients.[10] Since its approval in Sweden in 1984, EMLA cream has been widely used across the world, and is currently approved in more than 80 countries.[20] The scope of EMLA cream's use is slowly expanding to its use for awake fibre optic endoscopy,[21] Bronchoscopy,[22] and oral endotracheal intubation.[23-25] Lidocaine/prilocaine (EMLA) cream possesses superior mucosal permeability because both the local anesthetics (Lidocaine and Prilocaine) exist as a liquid emulsion rather than in crystal form and 80% of the active drug is in emulsion form. No preservatives are added to readily available 5% EMLA cream. Therefore, it provides better anesthesia by reducing local pain and burning sensation.[24]

In a study done by G E Larijini et al, it 4gms of 5% EMLA cream was applied to oral mucosa and concluded that 5% EMLA cream provided satisfactory and safe topical anesthesia for awake fibre optic intubation.

As POST affects postoperative outcome and satisfaction of the patient we studied the incidence of POST immediately after extubation as 0 hour incidence. Again POST and other effects were checked at 1st hour, 6th hour and 24 hours after surgery. In our study, incidence of POST at 0, 1 hour was greater in Lignocaine group (44%,60%) when compared to EMLA group (27%,36%) though it was not significant. Immediately and early hours after extubation, some patients might not have complained of sore throat which might be masked by residual analgesic effects of general anesthesia or due do drugs used for postoperative pain control which is common in both the groups. The results of our study showed significant reduction in incidence and severity of POST at 6th hour after extubation in EMLA group (15.6%) when compared to Lidocaine group (35.6%). In a study conducted by Abishek et al,[23] 5 % EMLA cream topical application on the ETT cuff effectively reduced the incidence and severity of POST(4.9% vs 40.1%), cough, and postoperative hoarseness of voice in the initial 6 hours of surgery compared to the lubricant gel group. The incidence and severity of POST at 6th hour in our study was comparable to this study.

Limitation of our study is that we did not include a control group using a non medicated lubricant, which could have provided a better understanding of the relative effectiveness of EMLA cream and lignocaine gel. Other limitation was that we did not measure methemoglobin levels in blood after application of 5% EMLA cream over endotracheal tube as methemoglobinemia is aggravated by prilocaine. This is because based on previous studies, we used 2.5 gm of prilocaine which is far less than maximum dose to produce methemoglobinemia i.e, 8gms.

CONCLUSION

To conclude, topical application of 5% EMLA cream on the ETT cuff effectively reduced the incidence and severity of POST, cough, and postoperative hoarseness of voice in the initial 6 hours of surgery

compared to the 2% Lidocaine gel group without any serious side effects. EMLA cream may be used as an effective method for POST reduction. However, there is no standard recommendation for the use of 5 % EMLA cream on tracheal mucosa. The use of 5% EMLA cream is presently an off-label indication for the provision of topical anesthesia on the oral and tracheal mucosa based on previous studies.

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