Int. J Med. Pharm. Res. (P-ISSN: 2958-3675 | E-ISSN: 2958-3683)
Available on: https://ijmpr.in/

International Journal
of Medical and Pharmaceutical Research

ORGINAL ARTICLE **OPEN ACCESS**

To Compare the Efficacy of Application of 5% EMLA Cream with Betamethasone Gel 0.05% for Postoperative Sore Throat (Post) Following General Anaesthesia

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Received: 30-08-2024
Accepted: 24-10-2024
Available online: 29-10-2024

A B S T R A C T

Background*:** Postoperative sore throat (POST) is a common complication following general anesthesia with endotracheal intubation. This study compared the efficacy of 5% EMLA cream and betamethasone gel 0.05% applied on the endotracheal tube cuff in preventing POST.Methods***: In this prospective, randomized study, 50 adult patients undergoing general anesthesia were allocated to receive either 5% EMLA cream (n=25) or betamethasone gel 0.05% (n=25) on the endotracheal tube cuff. The incidence and severity of POST, cough, and hoarseness of voice were assessed at 0, 6, and 24 hours post-extubation. Hemodynamic parameters and adverse events were also recorded.***Results***: The incidence of POST at 6 hours was significantly lower in the EMLA group (8%) compared to the betamethasone group (32%) (p=0.034). The severity of POST at 6 hours was also significantly lower in the EMLA group (0.1 ± 0.4) compared to the betamethasone group (0.4 ± 0.7) (p=0.048). The incidences of postoperative cough and hoarseness of voice were lower in the EMLA group at all time points, but the differences were not statistically significant (p>0.05). Hemodynamic parameters and adverse event profiles were comparable between the groups.***Conclusion***: The application of 5% EMLA cream on the endotracheal tube cuff significantly reduced the incidence and severity of POST at 6 hours compared to betamethasone gel 0.05% in adult patients undergoing general anesthesia. EMLA cream is an effective and safe alternative for preventing POST in this patient population.

Keywords: Postoperative sore throat, EMLA cream, betamethasone gel, endotracheal intubation, general anesthesia.

INTRODUCTION

Postoperative sore throat (POST) is a common and distressing complication following general anesthesia with endotracheal intubation. The reported incidence of POST ranges from 20% to 74% in adult patients [1]. Sore throat after tracheal intubation is multifactorial in origin and can be attributed to laryngeal trauma and edema, mucosal inflammation, and airway injury from the endotracheal tube (ETT) and cuff [2, 3]. Other risk factors for developing POST include larger sized ETTs, higher cuff pressures, prolonged duration of surgery, aggressive oropharyngeal suctioning, and patient-related factors like female sex, younger age and history of smoking [1, 4].

POST manifests as throat pain, difficulty swallowing, hoarseness of voice and cough in the initial 24 hours after extubation. Although self-limiting in majority of cases, POST leads to significant patient discomfort and dissatisfaction in the postoperative period. It delays oral intake, impairs patient communication and can prolong recovery after ambulatory surgery [5]. Hence, prevention of this postoperative airway adverse event is of paramount importance for providing quality perioperative care and enhancing patient experience and satisfaction.

Several pharmacological and non-pharmacological approaches have been studied for attenuating POST after tracheal intubation. These include use of smaller sized ETTs, monitoring and limiting intracuff pressures, gentle airway manipulation, minimizing duration of surgery, and use of supraglottic airway devices as alternatives to ETT wherever feasible [1, 3]. Pharmacological agents investigated for preventing POST include inhalational and topical corticosteroids, local anesthetics, non-steroidal anti-inflammatory drugs, benzydamine hydrochloride oral rinse, magnesium lozenges, and ketamine gargle, among others [4, 6].

Among the various agents, corticosteroids and local anesthetics have emerged as the frontrunners for POST prophylaxis, owing to their potent anti-inflammatory and analgesic properties respectively. Corticosteroids exert their anti-inflammatory action by inhibition of phospholipase A2 enzyme and consequent reduction in production of inflammatory mediators like prostaglandins and leukotrienes [7]. Local anesthetic agents prevent the generation and transmission of nerve impulses by blocking sodium channels, thereby producing analgesia and anti-hyperalgesic effects [5].

Betamethasone is a long-acting glucocorticoid with potent anti-inflammatory effects. Studies have shown that topical application of betamethasone gel on the ETT cuff effectively reduces POST with an effect lasting up to 24 hours postoperatively [8]. The water-soluble property of betamethasone gel allows uniform spread and rapid absorption of the drug across the tracheal mucosa for optimal efficacy. Kuriyama*et al.*, in their meta-analysis demonstrated superiority of topical corticosteroids over lidocaine for preventing POST in adults [6].

EMLA (Eutectic Mixture of Local Anesthetics) is an oil-in-water emulsion containing a 1:1 mixture of lidocaine 2.5% and prilocaine 2.5%. The eutectic nature of the cream ensures that both components melt together at a lower temperature than their individual melting points, thereby existing as an oily liquid at room temperature. This property improves skin penetration and provides a faster onset compared to the individual components [9]. EMLA cream is routinely used for topical anesthesia prior to painful procedures like venipuncture, cannulation, and skin grafting. In a recent randomized controlled trial, Murugaiyan*et al.*, demonstrated that application of 5% EMLA cream on ETT cuffs reduced the incidence and severity of POST, cough and hoarseness of voice compared to lubricant gel in adults undergoing general anesthesia. The authors postulated that the topical anesthetic action of EMLA prevents POST by blocking the sensory nerve endings in the tracheal mucosa [10].

Although both betamethasone gel and EMLA cream have proven efficacy in reducing POST compared to placebo lubricant gels, there is a paucity of head-to-head trials comparing these two agents for this indication. Thapa*et al*., in their study compared betamethasone gel with lidocaine jelly and found the former to be more effective in reducing ETT-related airway morbidity over 24 hours [8].

However, no study till date has compared the efficacy of betamethasone gel with EMLA cream for preventing POST in adults undergoing general anesthesia. We hypothesize that EMLA cream, with its superior mucosal penetration and topical anesthetic properties, would be more effective than betamethasone gel in reducing the incidence and severity of POST. Also, the use of EMLA on ETT cuffs could concurrently prevent pain and discomfort during awakeextubation by anesthetizing the tracheal mucosa.

Hence, we designed this prospective randomized study to compare the efficacy of 5% EMLA cream with betamethasone gel 0.05% applied on the ETT cuff for preventing POST at 6 and 24 hours following general anesthesia in adult patients. The primary objective is to compare the incidence of POST at 6 hours postoperatively. The secondary objectives are to compare the incidence and severity of POST at 0 and 24 hours, incidence of postoperative cough and hoarseness of voice, and hemodynamic response to extubation between the two groups. We also aim to study the adverse effects, if any, related to the use of these topical agents on the airway mucosa.

To conclude, POST is a distressing postoperative airway complication that negatively impacts patient satisfaction and recovery after general anesthesia. Although several pharmacological agents have been studied for POST prophylaxis, direct comparison between topical betamethasone and EMLA is lacking in current literature. Evaluating the efficacy of these two agents could provide valuable evidence to guide anesthesiologists in choosing the optimal pharmacological intervention for preventing this postoperative airway adverse event and improving the quality of perioperative care. The results of this study could pave the way for future multicentric trials and meta-analyses on this pertinent clinical research question.

Aims and Objectives

The primary aim of this study was to compare the efficacy of 5% EMLA cream with betamethasone gel 0.05% applied on the endotracheal tube (ETT) cuff in preventing postoperative sore throat (POST) at 6 hours following general

anesthesia in adult patients. The secondary objectives were to compare the incidence and severity of POST at 0 and 24 hours, incidence of postoperative cough and hoarseness of voice, and hemodynamic response to extubation between the two groups. The study also aimed to evaluate any adverse effects related to the use of these topical agents on the airway mucosa.

Materials and Methods

This prospective, randomized, comparative study was conducted at SS Institute of Medical Sciences and Research Center, Davangere, after obtaining approval from the Institutional Ethics Committee and written informed consent from all participants. The study duration was one year. The sample size was calculated using results from previous studies with a power of 80% and alpha error of 0.05. Considering a clinically meaningful difference of 38.1% in the incidence of POST between the two groups, a sample size of 17 patients per group was required. To account for possible dropouts, the final sample size was determined as 25 patients in each group.

Adult patients aged 18-60 years, belonging to American Society of Anesthesiologists (ASA) physical status I and II, and scheduled for elective surgeries under general anesthesia with endotracheal intubation were included in the study. Patients who refused consent, had a known allergy to local anesthetics, required more than two attempts for intubation, had surgeries requiring the use of throat packs or nasogastric tubes, underwent head and neck surgeries involving the airway, or procedures performed in prone or lithotomy positions were excluded from the study. Patients with the presence of blood in the oropharyngeal suction or on the ETT after extubation were also excluded.

Patients were randomly allocated to one of two groups using the sealed envelope method: Group A received 5% EMLA cream, while Group B received betamethasone gel 0.05% on the ETT cuff. The group allocation was concealed from the patients and the anesthesiologist assessing the postoperative outcomes.

All patients underwent a thorough pre-anesthetic evaluation and were kept nil by mouth for 8 hours before surgery. They received tablet ranitidine 150 mg and tablet alprazolam 0.5 mg orally on the night before surgery. In the operating room, standard monitors were attached, and intravenous access was secured. Patients were pre-medicated with intravenous glycopyrrolate 0.01 mg/kg, fentanyl 2 µg/kg, and midazolam 0.05 mg/kg.

After pre-oxygenation with 100% oxygen for 3 minutes, anesthesia was induced with intravenous propofol 2 mg/kg. Mask ventilation was confirmed, and intravenous vecuronium 0.1 mg/kg was administered to facilitate endotracheal intubation. After 3 minutes of mask ventilation with 100% oxygen, laryngoscopy and oral intubation were performed by an experienced anesthesiologist using an appropriate-sized Macintosh laryngoscope blade and ETT (8.0 or 8.5 mm internal diameter for males; 7.0 or 7.5 mm for females).

Before intubation, the ETT cuff was lubricated with 2.5 mL of the assigned study drug (5% EMLA cream or betamethasone gel 0.05%) from the distal end of the cuff to a distance of 15 cm from the tip, using a disposable syringe. After confirming the ETT position, the cuff was inflated to a pressure of 20 cm H_2O, which was monitored and adjusted every 30 minutes using a cuff manometer.

Anesthesia was maintained with isoflurane or sevoflurane in a mixture of 40% oxygen and 60% nitrous oxide. At the end of the surgery, neuromuscular blockade was reversed with intravenous glycopyrrolate 0.01 mg/kg and neostigmine 0.05 mg/kg. The trachea was extubated after the patient responded to verbal commands, opened eyes, and demonstrated adequate spontaneous respiratory efforts. Extubation was performed with the ETT cuff fully deflated, following gentle suctioning of the oral cavity with a suction pressure limited to 50 cm H_2O.

The incidence and severity of POST, cough, and hoarseness of voice were assessed at 0, 6, and 24 hours after extubation by an anesthesiologist blinded to the group allocation. POST was graded on a four-point scale: 0 = no sore throat, 1 = mild sore throat (complained only upon inquiry), 2 = moderate sore throat (complained on his/her own), and 3 = severe sore throat (associated with hoarseness of voice or change in voice). Postoperative cough was recorded as present or absent. Hoarseness of voice was graded as follows: 0 = no hoarseness, 1 = mild hoarseness, 2 = moderate hoarseness, and 3 = severe hoarseness.

The hemodynamic parameters, including heart rate and mean arterial pressure, were recorded before induction, immediately after intubation, and at 1, 3, 5, and 10 minutes after extubation. Any adverse events related to the study drugs, such as allergic reactions, mucosal irritation, or respiratory distress, were noted and managed accordingly.

The collected data were tabulated and analyzed using appropriate statistical tests. Continuous variables were expressed as mean ± standard deviation, while categorical variables were expressed as frequencies and percentages. The

Mann-Whitney U test was used to compare the POST scores between the two groups. The chi-square test or Fisher's exact test was used to compare the incidence of POST, cough, and hoarseness of voice between the groups. Hemodynamic parameters were analyzed using the student's t-test. A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 50 patients were enrolled in the study and randomly allocated to either the EMLA group (n=25) or the betamethasone group (n=25). The demographic and clinical characteristics of the patients in both groups were comparable, with no statistically significant differences observed (Table 1). The mean age of the patients was 38.4 ± 10.6 years in the EMLA group and 40.2 ± 11.3 years in the betamethasone group (p=0.562). The gender distribution (p=0.571) and ASA physical status (p=0.529) were also similar between the groups. The mean duration of surgery was 92.4 ± 28.6 minutes in the EMLA group and 96.8 ± 31.2 minutes in the betamethasone group (p=0.603), while the mean duration of anesthesia was 108.6 ± 30.4 minutes and 112.2 ± 32.8 minutes, respectively (p=0.687). The size of the endotracheal tube used was also comparable between the groups (p=0.484).

The incidence and severity of postoperative sore throat (POST) at 0, 6, and 24 hours after extubation are presented in Table 2. At 6 hours post-extubation, the incidence of POST was significantly lower in the EMLA group (8%) compared to the betamethasone group (32%) (p=0.034). The severity of POST at 6 hours was also significantly lower in the EMLA group (0.1 ± 0.4) compared to the betamethasone group (0.4 ± 0.7) (p=0.048). Although not statistically significant, the incidence and severity of POST at 0 and 24 hours were lower in the EMLA group compared to the betamethasone group.

The incidence of postoperative cough at 0, 6, and 24 hours is shown in Table 3. Although the incidence of cough was lower in the EMLA group at all time points, the differences were not statistically significant (p>0.05).

Table 4 presents the incidence and severity of postoperative hoarseness of voice at 0, 6, and 24 hours. The incidence and severity of hoarseness were lower in the EMLA group compared to the betamethasone group at all time points, but the differences did not reach statistical significance (p>0.05).

The hemodynamic parameters, including heart rate and mean arterial pressure, at different time points are shown in Table 5. There were no statistically significant differences in heart rate or mean arterial pressure between the groups at any of the time points (p>0.05).

Adverse events related to the study drugs are presented in Table 6. One patient in the EMLA group (4%) and two patients in the betamethasone group (8%) experienced mucosal irritation, but the difference was not statistically significant (p=0.552). No patients in either group experienced allergic reactions or respiratory distress.

In summary, the application of 5% EMLA cream on the endotracheal tube cuff resulted in a significantly lower incidence and severity of postoperative sore throat at 6 hours compared to the application of betamethasone gel 0.05%. Although not statistically significant, the EMLA group also demonstrated lower incidences of postoperative cough and hoarseness of voice at all time points. The hemodynamic parameters and adverse event profiles were comparable between the two groups.

Table 1: Demographic and clinical characteristics of patients in the two groups

Characteristic	EMLA group (n=25)	Betamethasone group (n=25)	p-value
Age (years)	38.4 ± 10.6	40.2 ± 11.3	0.562
Gender (Male/Female)	13/12	11/14	0.571
ASA physical status (I/II)	19/6	17/8	0.529
BMI (kg/m²)	24.6 ± 3.1	25.2 ± 2.9	0.481
Duration of surgery (minutes)	92.4 ± 28.6	96.8 ± 31.2	0.603
Duration of anesthesia (minutes)	108.6 ± 30.4	112.2 ± 32.8	0.687
Size of endotracheal tube (mm)	7.6 ± 0.5	7.7 ± 0.5	0.484

Table 2: Incidence and severity of postoperative sore throat (POST) at 0, 6, and 24 hours

Time point	EMLA group (n=25)	Betamethasone group (n=25)	p-value
0 hours			
- Incidence	4 (16%)	9 (36%)	0.196
- Severity	0.2 ± 0.5	0.4 ± 0.6	0.229
6 hours			
- Incidence	2 (8%)	8 (32%)	0.034
- Severity	0.1 ± 0.4	0.4 ± 0.7	0.048
24 hours			
- Incidence	1 (4%)	5 (20%)	0.082
- Severity	0.0 ± 0.2	0.2 ± 0.5	0.070

Table 3: Incidence of postoperative cough at 0, 6, and 24 hours

Time point	EMLA group (n=25)	Betamethasone group (n=25)	p-value
0 hours	3 (12%)	6 (24%)	0.269
6 hours	1 (4%)	5 (20%)	0.082
24 hours	0 (0%)	2 (8%)	0.149

Table 4: Incidence and severity of postoperative hoarseness of voice at 0, 6, and 24 hours

Time point	EMLA group (n=25)	Betamethasone group (n=25)	p-value
0 hours			
- Incidence	3 (12%)	7 (28%)	0.157
- Severity	0.1 ± 0.4	0.3 ± 0.6	0.182
6 hours			
- Incidence	1 (4%)	5 (20%)	0.082
- Severity	0.0 ± 0.2	0.2 ± 0.5	0.070
24 hours			
- Incidence	0 (0%)	2 (8%)	0.149
- Severity	0.0 ± 0.0	0.1 ± 0.3	0.149

Table 5: Hemodynamic parameters at different time points

Time point	EMLA group (n=25)	Betamethasone group (n=25)	p-value
Heart rate (beats per minute)			
- Before induction	78.4 ± 10.2	80.6 ± 9.8	0.445
- After intubation	92.6 ± 12.4	94.2 ± 11.6	0.645
- 1 min after extubation	96.8 ± 11.8	98.4 ± 12.2	0.639
- 3 min after extubation	88.2 ± 10.6	90.4 ± 11.4	0.486
- 5 min after extubation	82.4 ± 9.4	84.6 ± 10.2	0.432
- 10 min after extubation	80.2 ± 8.8	82.8 ± 9.6	0.322
Mean arterial pressure (mmHg)			
- Before induction	92.6 ± 8.4	94.2 ± 9.2	0.524
- After intubation	102.4 ± 10.6	104.8 ± 11.4	0.447
- 1 min after extubation	106.2 ± 11.2	108.6 ± 12.0	0.472
- 3 min after extubation	98.8 ± 9.6	100.4 ± 10.8	0.587
- 5 min after extubation	94.2 ± 8.8	96.6 ± 9.4	0.360
- 10 min after extubation	92.4 ± 8.2	94.8 ± 9.0	0.329

Table 6: Adverse events related to the study drugs

Adverse event	EMLA group (n=25)	Betamethasone group (n=25)	p-value
Allergic reactions	0 (0%)	0 (0%)	1.000
Mucosal irritation	1 (4%)	2 (8%)	0.552
Respiratory distress	0 (0%)	0 (0%)	1.000

DISCUSSION

The present study compared the efficacy of 5% EMLA cream and betamethasone gel 0.05% applied on the endotracheal tube cuff in preventing postoperative sore throat (POST) in adult patients undergoing general anesthesia.

The results demonstrated that the application of EMLA cream significantly reduced the incidence and severity of POST at 6 hours post-extubation compared to betamethasone gel.

The incidence of POST in the EMLA group at 6 hours (8%) was significantly lower than that in the betamethasone group (32%) (p=0.034). This finding is consistent with a recent study by Murugaiyan*et al*., which reported a significantly lower incidence of POST at 6 hours in the EMLA group (20%) compared to the control group (60%) (p<0.001) [10].

A meta-analysis by Kuriyama*et al*., found that topical application of corticosteroids on the endotracheal tube reduced the incidence of POST compared to control (relative risk [RR] = 0.44; 95% confidence interval [CI], 0.33-0.58; p<0.001) [6].

Although our study did not include a control group, the incidence of POST in the betamethasone group (32%) was lower than the pooled incidence in the control groups of the meta-analysis (44.1%), suggesting the effectiveness of betamethasone gel in reducing POST.

Thapa*et al*., compared betamethasone gel with lidocaine jelly and found a significantly lower incidence of POST in the betamethasone group at 24 hours (20% vs. 40%; p=0.03) [8].

In our study, the incidence of POST at 24 hours was lower in the EMLA group (4%) compared to the betamethasone group (20%), although the difference was not statistically significant (p=0.082). The lower incidence in our study could be attributed to the use of a higher concentration of lidocaine in the EMLA cream (2.5%) compared to the lidocaine jelly (2%) used by Thapa*et al*., [8].

The severity of POST at 6 hours was significantly lower in the EMLA group compared to the betamethasone group (p=0.048). This finding is in line with a study by Gupta *et al*., which reported a significantly lower severity of POST in the lidocaine group compared to the control group at 6 hours (p<0.05) [11].

However, their study used lidocaine spray instead of EMLA cream.

Regarding postoperative cough and hoarseness of voice, our study found lower incidences in the EMLA group at all time points, although the differences were not statistically significant. Similarly, Gurulingappa*et al*., reported no significant differences in the incidence of cough and hoarseness between the lidocaine and control groups [12].

In contrast, Tanaka *et al*., in their systematic review, found that topical lidocaine reduced the incidence of postoperative cough (RR = 0.43; 95% CI, 0.27-0.67; p<0.001) and hoarseness (RR = 0.48; 95% CI, 0.31-0.76; p=0.002) compared to control [13]. The discrepancy between our findings and those of Tanaka *et al*., could be due to differences in the formulation and concentration of lidocaine used.

The hemodynamic parameters and adverse event profiles in our study were comparable between the EMLA and betamethasone groups. This observation is consistent with previous studies that reported no significant differences in hemodynamic parameters or adverse events between the lidocaine and control groups [11, 12].

One of the strengths of our study is the use of a higher concentration of lidocaine in the EMLA cream (2.5%) compared to other studies that used lidocaine jelly or spray [8, 11].

The eutectic mixture of lidocaine and prilocaine in EMLA cream enhances its penetration and prolongs its anesthetic effect [14].

Additionally, we used a standardized method for assessing POST, cough, and hoarseness, which increases the reliability of our findings.

However, our study has some limitations. First, the sample size was relatively small, which may have limited the power to detect significant differences in some outcomes. Second, 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 betamethasone gel. Third, we did not assess the long-term effects of the interventions beyond 24 hours post-extubation.

The application of 5% EMLA cream on the endotracheal tube cuff significantly reduced the incidence and severity of postoperative sore throat at 6 hours compared to betamethasone gel 0.05% in adult patients undergoing

general anesthesia. Although not statistically significant, the EMLA group also demonstrated lower incidences of postoperative cough and hoarseness of voice. These findings suggest that EMLA cream could be a promising alternative to betamethasone gel for preventing POST in this patient population. Future studies with larger sample sizes and longer follow-up periods are needed to confirm these results and assess the long-term effects of EMLA cream on postoperative airway complications.

CONCLUSION

In this prospective, randomized study, the application of 5% EMLA cream on the endotracheal tube cuff significantly reduced the incidence and severity of postoperative sore throat (POST) at 6 hours compared to betamethasone gel 0.05% in adult patients undergoing general anesthesia. The incidence of POST at 6 hours was 8% in the EMLA group and 32% in the betamethasone group ($p=0.034$), while the severity of POST at 6 hours was also significantly lower in the EMLA group (0.1 ± 0.4) compared to the betamethasone group (0.4 ± 0.7) ($p=0.048$).

Although not statistically significant, the EMLA group demonstrated lower incidences of postoperative cough and hoarseness of voice at all time points (0, 6, and 24 hours) compared to the betamethasone group. The hemodynamic parameters, including heart rate and mean arterial pressure, and adverse event profiles were comparable between the two groups.

These findings suggest that 5% EMLA cream is an effective and safe alternative to betamethasone gel 0.05% for preventing POST in adult patients undergoing general anesthesia with endotracheal intubation. The higher concentration of lidocaine in the EMLA cream and its enhanced penetration due to the eutectic mixture with prilocaine may contribute to its superior efficacy in reducing POST compared to other formulations of lidocaine.

However, further studies with larger sample sizes, longer follow-up periods, and the inclusion of a control group using a non-medicated lubricant are needed to confirm these results and assess the long-term effects of EMLA cream on postoperative airway complications. Additionally, the cost-effectiveness of using EMLA cream compared to other interventions should be evaluated to guide clinical decision-making.

In conclusion, the application of 5% EMLA cream on the endotracheal tube cuff is a promising strategy for reducing the incidence and severity of postoperative sore throat in adult patients undergoing general anesthesia. Anesthesiologists should consider using this intervention to improve patient comfort and satisfaction in the postoperative period.

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