Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/8s21fg94

EFFECT OF EMLA (EUTECTIC MIXTURE OF LOCAL ANESTHESIA) 5 % CREAM VS LIGNOCAINE GEL 2% FOR ATTENUATION OF EXTUBATION RESPONSE AND POSTOPERATIVE SORE THROAT IN PATIENTS UNDERGOING GENERAL ANAESTHESIA IN A TERTIARY CARE UNIT – A RANDOMIZED COMPARATIVE STUDY

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ABSTRACT

BACKGROUND: The endotracheal intubation response is known to cause significant physiological and dynamic changes and postoperative sore throat in patients undergoing general anesthesia.

METHODOLOGY: A Randomised Controlled trial was organized at a tertiary care hospital. The patients were eligible for inclusion in the trial if they were ASA 1 or 2 patients requiring general anesthesia under endotracheal intubation. The primary end point included cardiovascular reactions during endotracheal intubation, extubation responses, and post-operative sore throat during recovery. In the test group, 2 g of lidocaine/prilocaine (EMLA) cream and in the control group, 2 g of lignocaine were applied to the surface of the tracheal tube cuff.

Results: The test group exhibited significantly lower systolic and diastolic blood pressure, as well as heart rate, compared to the control group within 5 minutes after extubation ($p < 0.0001$ for all measures). Additionally, postoperative sore throat was notably less severe in the test group, with a significant reduction in its incidence ($p < 0.0001$).

Conclusion: This study demonstrates the effectiveness of EMLA cream in promoting cardiovascular stability and reducing postoperative discomfort, offering clear advantages over lignocaine gel in improving patient outcomes.

Keywords: EMLA Cream, Eutectic Mixture, Postoperative Sore Throat, Extubation Response.

INTRODUCTION

Endotracheal intubation is the most widely used airway management technique for surgical patients under General anesthesia. The introduction of an endotracheal tube inside the vocal cord of the patient and extubation of the endotracheal tube are known to cause various hemodynamic effects on the patient's homeostasis.[1] To avoid such complications, various techniques have been employed including the application of lignocaine jelly, Injection of intracuff lignocaine[2] lignocaine spray, and intravenous injection of lignocaine[3] to alleviate the responses. Along with intubation and extubation responses, sore throat is well well-recognized entity encountered in patients postoperatively.[4] It can be burdensome for patients in postoperative care. Several strategies have been used in the past to ease the likelihood of post-operative sore throat, including the use of a low-pressure cuff,[5] inhaling beclomethasone,[6] applying lidocaine spray, and giving aspirin,[7] ketamine, or benzylamine hydrochloride.

A novel topical anesthetic medication called EMLA cream 5% (a eutectic combination of local anesthetics) has been created in recent years. The cream is a eutectic mixture of prilocaine (2.5%) and lidocaine (2.5%) bases in an oil/water emulsion ratio of 1:1. Both local anesthetics have melting values of 66–69 degrees Celsius for lignocaine base and 36–38 degrees Celsius for prilocaine base. When both the local anesthetics are added to a eutectic mixture, the melting point becomes lower (17 degrees C). This newfangled advantage promotes quick base absorption and turns the eutectic mixture into a liquid at oral temperature.[8]

The effectiveness of this eutectic cream used in our study in reducing cough responses during extubation was shown in a study conducted in 2022 by Linsheng Lv et al.[9]
The beneficial effects of lignocaine used in different forms on reducing the hemodynamic changes linked to intubation and extubation has been the subject of numerous investigations.[10]
Numerous studies have documented the safe and efficient application of EMLA as a topical anesthetic on various mucosal surfaces.[8,11-13]

As far as we know, there hasn't been much research done on the effectiveness of EMLA cream used over the endotracheal tube in minimizing extubation reactions and postoperative sore throat in patients. So, this study was conducted to compare the efficiency of EMLA cream with lignocaine gel to enhance post-operative rehabilitation and enhance care for patients undergoing general anesthesia.

METHODS

Study Design

The present study was carried out on 126 patients admitted to the institution undergoing Surgeries requiring general anesthesia. The institutional ethical committee approval was obtained to conduct the study. Under the clinical trial registry number, CTRI/2024/02/062385 was approved prior to starting patient enrolment.

Inclusion Criteria

1. Patients posted under general anesthesia who belong to physical status I or II according to the American Society of Anesthesiologists (ASA).
2. A surgery that takes less than 4 hours.

Exclusion Criteria

1. Preoperative sore throat history,
2. History of challenging intubation (Mallampati grade greater than 2), and
3. History of Local anesthetics allergy.

After getting written and informed consent, we randomly allocated patients using an interactive web-based response system (IWRS) to two groups:
Group A: EMLA group (5%)
Group B: Lignocaine group (2%)
Patients received 0.2 mg of injection glycopyrrolate and 4mg injection. Ondansetron as premedication. Injection. Propofol 2 mg/kg and fentanyl 2 micrograms/kg were used for induction. To facilitate tracheal intubation, 0.02 mg/kg of Vecuronium was given. According to the allocated group, the nurses who were not involved in the study applied the lignocaine gel 2 % (From Neon Laboratories) / EMLA cream 5% (from Neon Laboratories) over the endotracheal tube cuff. The color and consistency of lignocaine gel and EMLA cream differ. The anesthesiologist used a low-pressure cuffed sterile polyvinyl chloride endotracheal tube to intubate the patient and did not participate in the trial after intubation. A cuff pressure gauge was used to maintain the cuff pressure at 20 cm H2O once the cuff was inflated with air. Using a cuff pressure gauge, we maintained a constant cuff pressure for both groups. To maintain anesthesia, vecuronium increments, and isoflurane MAC 1% were used.

Monitoring consisted of 5-lead electrocardiography, non-invasive arterial blood pressure, pulse oximetry, temperature, and end-tidal carbon dioxide, which was kept between 30-mm and 35-mm Hg. Following surgery, neuromuscular reversing agents 0.05 mg/kg of injection neostigmine and 0.01 mg/kg of injection glycopyrolate were administered. Once gentle suctioning was done by 12 F suction catheter with suction pressure of less than 50cm of H20, Patients were extubated and shifted to the post-anesthesia care unit. The staff who assessed the patients postoperatively for sore throat were unaware of the assigned groups for each patient.

Parameters Observed
The following values were recorded such as age and sex of the patients.
Duration of Surgery
Pre-induction vitals: Heart rate, Systolic, and Diastolic blood pressure
Post-extubation vitals after 1 minute and 5 minutes
Postoperative sore throat incidence score at 1 hour, 6 hours, and 24 hours in the post-operative care unit.
Postoperative sore throat (POST) was graded[14] based on:
0-Nothroatpain;
1-Mild sore throat (complaints only when asked);
2-Moderate painful throat (complaints on his or her own);
3- Severe sore throat, which is accompanied by hoarseness or a change in voice.

Statistical Analysis
For continuous variables, Mean and Standard Deviation were calculated.
The percentage was calculated for categorical variables. An Independent t-test was done to compare EMLA vs Lignocaine, Repeated measures ANOVA test was done to compare the extubation parameters and there was a significant difference noted. SPSS version 20 was used, and p p-value < 0.05 was considered significant.

RESULTS
The study included a total of 126 patients, calculated using the Morgan formula, keeping the population size as 180 with a confidence interval of 95 % and a margin of error of 5 %, the estimated population size arrived at around 125. (Figure 1)

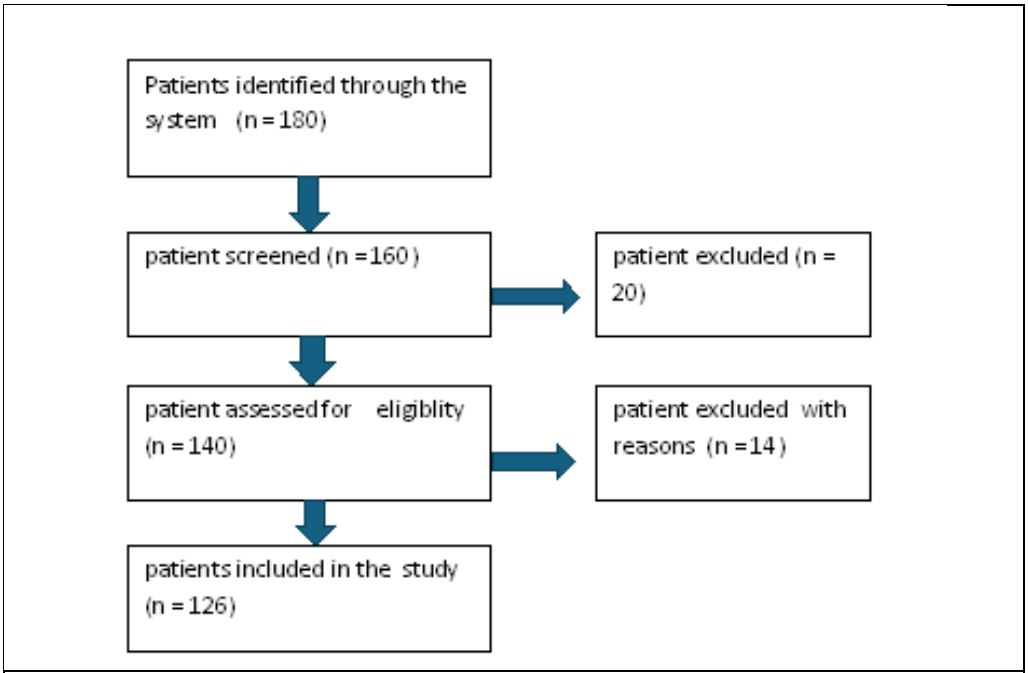

Figure 1: Schematic diagram of patients considered for inclusion

The patients' baseline parameters (such as age, sex, ASA status, and length of operation) did not significantly differ between the two groups.
Ages in groups A and B ranged from 21.0 to 68.0 years with a mean of 46.63 and 20 to 61 years with a mean of 39.38 years, respectively. No significant difference was noted. (Figure 2).

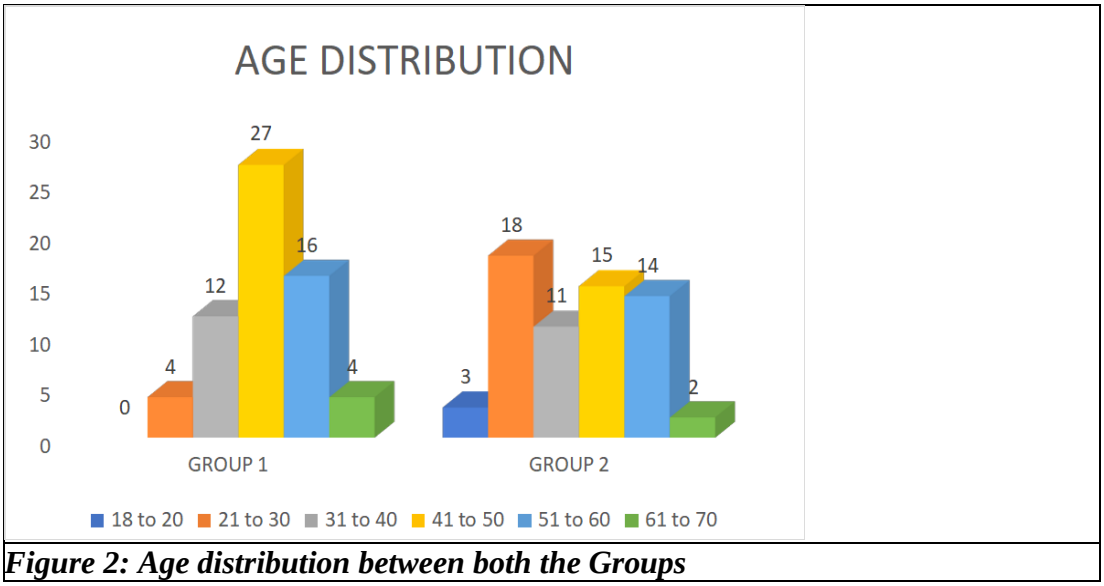

Figure 2: Age distribution between both the Groups

Regarding sex /gender, there was no discernible difference between the two groups. The ASA physical status (American Society of Anaesthesiologists) of the two groups did not differ significantly either. The duration of surgery was comparable between the two groups. (Figure 3)

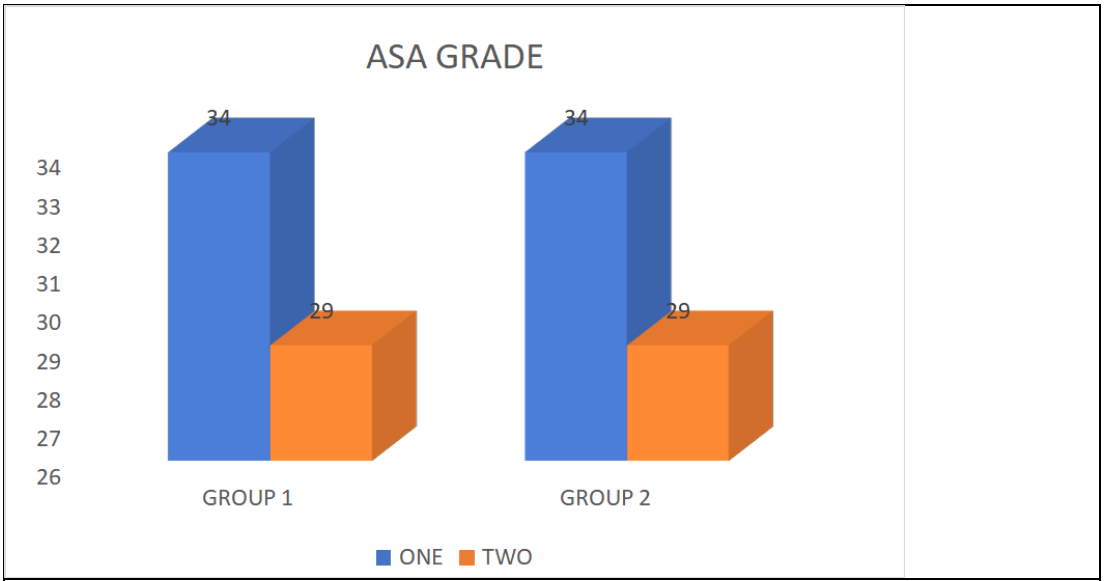

Figure 3: ASA grade of patients included in both the groups

Pre-induction vital parameters (Heart rate, blood pressure (both Systolic & Diastolic), Mean arterial pressure) of both the groups of patients were recorded. The two groups did not differ in any significant aspects. (Table 1)

Our study's major goal was to compute the extubation reactions, and its secondary goal was to evaluate the sore throat that occurs at 1,6,24 hours following extubation. At intervals of 1- and 5 minutes post-extubation, responses were recorded.

Parameters Pre-Induction	**Group A (EMLA) (mean ± SD)**	**Group B (Lignocaine) (mean ± SD)**	**P – Value**	**Significance**
Heart Rate (bpm)	71.75 ± 11.16	71.76 ± 11.12	0.994	Not significant
Systolic BP (mmHg)	125.37 ±12.98	127.87 ± 14.56	0.309	Not significant
Diastolic BP (mmHg)	81.68 ± 7.16	81.37 ± 9.32	0.831	Not significant
Mean Arterial Pressure (mmHg)	99.61 ± 10.79	97.07 ± 10.36	0.180	Not significant
Table 1: Comparison of pre induction parameters between both the groups				

The systolic (mean value of 124.13), diastolic blood pressure (mean value of 80.38) and Heart rate (mean value 72.82) measured at 1-minute intervals for Group A (EMLA Group) after extubation showed significantly better (P value of <0.0001) than group B (Lignocaine Group) systolic blood pressure (mean value of 139.75), Diastolic blood pressure (mean value 93.57) and Heart rate (mean value 80.95) (Table 2).

Parameters 1 Min Extubation	**Group A (EMLA)**	**Group B(Lignocaine)**	**P – Value**	**Significance**
Systolic BP (mmHg)	124.13	139.75	<0.0001	Significant
Diastolic BP (mmHg)	80.38	93.57	<0.0001	Significant
Heart Rate (bpm)	72.82	80.95	<0.0001	Significant
Table 2: Comparison of 1-minute post-extubation parameters in both groups				

Parameters 5 Mins Post Extubation	**Group A (EMLA)**	**Group B(Lignocaine)**	**P – Value**	**Significance**
Systolic BP (mmHg)	115.35	156.37	<0.0001	Significant
Diastolic BP (mmHg)	85.71	89.19	<0.0001	Significant
Heart Rate (bpm)	64.87	74.44	<0.0001	Significant
Table 3: Comparison of 5 minute post extubation parameters in both groups				

The systolic (mean value of 115.35), diastolic blood pressure (mean value of 85.71)and Heart rate (mean value 64.87) measured at 5 minute interval for Group A (EMLA Group) after extubation showed significantly better (P value of <0.0001) than group B (Lignocaine Group) systolic blood pressure (mean value of 156.37), Diastolic blood pressure (mean value 89.19)and Heart rate (mean value 74.44).(Table 3)

Postoperative follow-up for the incidence of sore throat is shown in the figure 4. In the first hour following surgery, the incidence of sore throat that needed to be treated was considerably lower (p-value <0.0001) in Group A (EMLA GROUP) than Group B (Lignocaine group), as determined by the post-operative sore throat grading scale. (Figure 4)

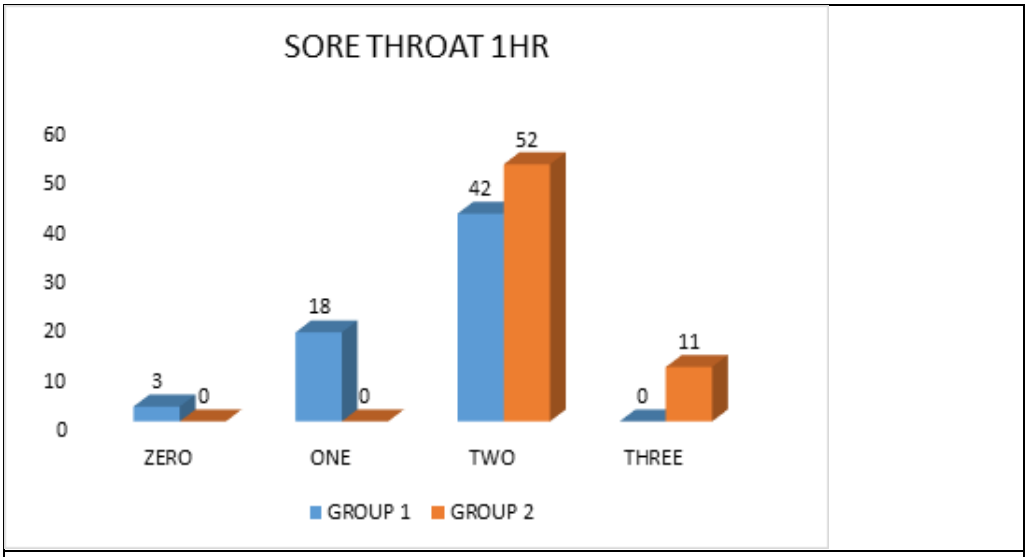

Figure 4: Incidence of sore throat in 1 hour of postoperative care

Observing the number of sore throat incidences 6 and 24 hours after observation in the post-anesthesia care unit, since the sore throat was treated in the first hour after observation, the p values are comparable, 0.37 and 0.40 in both groups at the respective time intervals. (Figure 5, Figure 6)

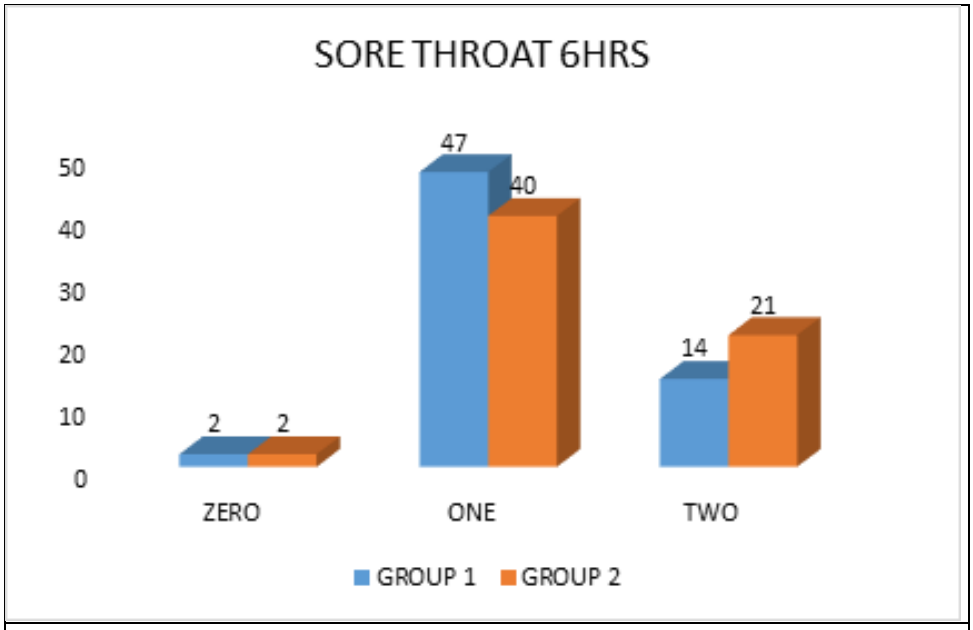

Figure 5: Incidence of sore throat after 6 hours of postoperative care

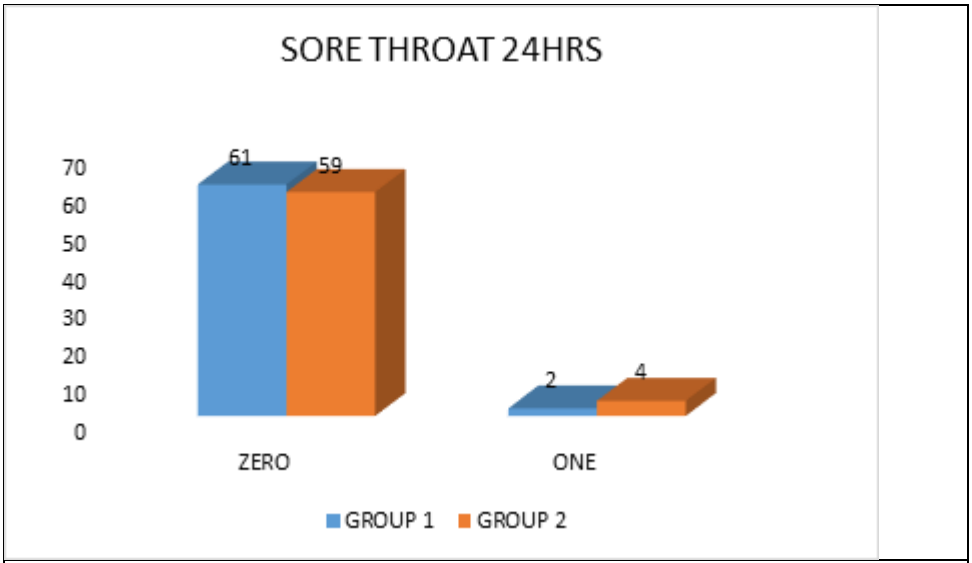

Figure 6: Incidence of sore throat after 24 hours of postoperative care

According to our study, EMLA cream proved more effective at reducing cardiovascular reactions throughout the extubation stages. The results suggest that EMLA cream's superior anesthetic qualities offer improved control over hemodynamic reactions related to airway manipulation, which is essential for lowering perioperative stress and averting post-operative sore throat, especially in high-risk groups.

DISCUSSION

This randomized controlled trial revealed that tracheal topical anesthesia using EMLA cream (eutectic mixture of local anesthesia) coated on the endotracheal tube has less postoperative sore throat incidence and extubation responses than lignocaine gel. The findings demonstrate significant clinical benefits of EMLA cream in improving perioperative outcomes.

Studies have shown that attenuation of airway reflexes is effective if sympathetic stimulation is reduced, thereby minimizing hemodynamic fluctuations.[15] The better tissue penetration by the combination of lidocaine and prilocaine in EMLA would have been the cause for its better performance. Lignocaine gel provides a very transient anesthetic effect, which is not adequate to maintain for a longer period of intubation.[16]

According to a study by Abishek Murugaiyan et al.[17] EMLA cream reduced the incidence of sore throat more effectively than a placebo. In our study, we examined the incidence of a sore throat to be treated and the responses associated with extubation.

As postoperative sore throat develops after endotracheal intubation, results of scientific studies indicate a possibility of its occurrence in even 62% of patients involved in various specific populations.[18] The role of EMLA, therefore becomes very noteworthy and gets immense significance in effectively addressing the issue in this scenario.

The composition of EMLA cream, which blends lidocaine and prilocaine into a eutectic mixture that promotes deeper penetration and longer-lasting local anesthetic effects, may be the rationale behind its better efficacy. In contrast, lignocaine gel might only produce a fleeting and superficial anesthetic effect. The physiological requirements of endotracheal intubation and extubation, which entail dynamic airway maneuvers, are well-suited to EMLA cream qualities. EMLA cream's anti-inflammatory and long-lasting local anesthetic effects probably shield the mucosa from the tracheal tube cuff's mechanical discomfort.

This study builds on this evidence, demonstrating that EMLA cream provides even greater benefits compared to lignocaine gel due to its dual-agent composition and eutectic mixture design.

Limitation

Its single-center design can limit the applicability of the clinical findings. Furthermore, primary aim of the study was on subjective and cardiovascular outcomes. Future studies can look into other factors including patient satisfaction, respiratory function, or the prevalence of local side effects. The extensive use of EMLA cream in clinical practice would be supported by multicenter trials with greater sample sizes and a wider range of patient demographics.

CONCLUSION

In conclusion, EMLA 5% cream is more advantageous than lignocaine 2% gel for enhancing perioperative outcomes in patients undergoing surgeries requiring general anaesthesia since the incidence of sore throat and extubation responses are reduced. These results add to the increasing amount of data demonstrating the effectiveness of modern local anesthetic formulations in managing airways.

Acknowledgments

The authors would like to thank the participants for their time and effort in participating in our current study.

Conflicts of Interest

The authors declare that there are no conflicts of interest.

Author's Contribution

All authors listed have made a substantial, direct, and intellectual contribution to the work and approved it for publication. Dr. Sanjitha Banu. A. R: Conceptualization, Methodology, Data curation, Dr. Polillan.G. R: Writing- Original draft preparation. Dr. Nivedhitha. R: Formal analysis, Investigation, Reviewing, and Editing, Dr. M. Murali Manoj: Supervision, and Validation.

Sponsorship and Financial Support

This study received no funding.

Data Availability

All datasets generated or analyzed during this study are included in the manuscript.

Ethics Statement

The Institutional Ethics Committee at the Karpaga Vinayaga Institute of Medical Science and Research Centre, Chengalpattu approved the study protocol (IEC Ref. No. **KIMS/F/08/11/2023**). All the participants gave their written informed consent before filling out the questionnaire.

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