Comparison Between the Use Of 10% Lidocaine Spray on The Mole Palate, Posterior Pharynx, Tonsillar Pillar, Hypopharynx, and Endotracheal Tube on Hemodynamics and Post-Intubation Throat Pain

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ABSTRACT

Background: Intubation causes various side effects such as pain and parasympathetic stimulation, hemodynamic changes, increased intracranial pressure and increased risk of intracranial hemorrhage. Topical lidocaine has been applied for decades via intratracheal spray, oxygen atomization, intracuff filling, or gel lubrication due to its simple operation advantages. Topical lidocaine is one of the drugs of choice to prevent post-intubation sore throat by decreasing the permeability of nerve membrane cells to sodium ions.
Objective: to determine the relationship the use of 10% lidocaine spray on the mole palate, posterior pharynx, tonsillar pillar, hypopharynx, and endotracheal tube on hemodynamics and post-intubation throat pain
Method: The design of this study used a single-blind randomized clinical trial with 17 research subjects for each group. Group A was given xylocaine spray on the endotracheal tube and 17 subjects belonging to group B were given xylocaine spray on the soft palate, hypopharynx, and tonsil pillars.
Results: Mean arterial pressure in this study in group A was found to be 91.11 + 6.55 and in group B 91.11 + 6.55, for POST scores in group A 0.51 + 0.26 and for group B 1.21 + 0.13.
Conclusion There is a difference between the use of 10% lidocaine spray on the soft palate, posterior pharynx, tonsillar pillars, hypopharynx and endotracheal tube on hemodynamics and the incidence of sore throat after endotracheal intubation in elective patients with general anesthesia at RS Adam Malik, Medan.

Keywords : intubation; lidocaine spray; mean arterial pressure; post intubation; sore throat

INTRODUCTION

Tracheal intubation is generally used in unconscious patients or those with respiratory failure to keep the airway open and to ensure patient ventilation. Endotracheal intubation is also performed in cases where general anesthesia is used for surgery. Endotracheal intubation is performed in various situations such as non-invasive ventilation failure in intensive care unit patients.[1] In the case of Lidocaine administered intravenously, the cough reflex due to airway stimulation during tracheal intubation or cough suppression is achieved when the plasma concentration of Lidocaine exceeds 3μg/ml. However, the plasma concentration of Lidocaine administered in the trachea is generally lower than that given intravenously, and an intratracheal spray of 2.0 mg/kg Lidocaine prevents the hyperdynamic circulatory response due to endotracheal intubation even at a plasma concentration of 1.5 μg/ml.[2]

Tracheal intubation triggers transient irritation of the laryngopharyngeal mucosa, resulting in several effects such as sore throat, dysphagia, and/or dysphonia reported in about 50% of cases. Intubation causes various side effects such as pain and stimulation of the parasympathetic system, hemodynamic changes, increased intracranial pressure, and an increased risk of intracranial bleeding. Hemodynamic changes during laryngoscopy and intubation lead to stimulation of the epipharynx and laryngopharynx, resulting in a strong sympathetic release. This affects the cardiovascular system due to increased plasma catecholamine concentrations. An increase in average heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure was found after laryngoscopy and intubation. These systemic hemodynamic changes do not threaten healthy patients but can increase the risk of morbidity and mortality in patients predisposed to cerebrovascular disease, coronary artery disease, myocardial infarction, hypertension, preeclampsia, and other pathologies.[3,4]

Lidocaine, also known as lignocaine, is a Class Ib antiarrhythmic and an amino amide local anesthetic that has been on the market since 1948. Because of its superior safety profile compared to other local anesthetic agents, after minor surgeries or invasive procedures such as biopsies, minor excisions, or dental surgeries. Lidocaine can be used in different ways, namely through injection, inhalation, or as a topical agent to produce an anesthetic effect. When Lidocaine is used to suppress airway reflexes, the dosage is 1 to 2 mg/kg administered 2 to 5 minutes before intubation. A common clinical approach to weaken the airway during induction, intubation, and hemodynamic response includes short-acting opioids, antiarrhythmic agents, and intravenous or topical anesthetic agents. Among them, topical lidocaine has been applied for several decades through intratracheal spray, oxygen atomization, intracuff filling, or gel lubrication due to its advantages of simple operation, direct absorption, and rapid anesthetic effect. However, the use of topical lidocaine does not provide long-term anesthetic effects because the doses used are relatively low and the duration of effective anesthesia is short.[5,6]

Topical lidocaine is one of the preferred medications to prevent sore throat post-intubation by reducing the permeability of nerve cell membranes to sodium ions. The change in nerve cell membrane permeability can decrease the depolarization mechanism and increase excitability to inhibit action potentials on the cell membrane. Fifteen minutes after the administration of topical lidocaine on the mucous membrane, its concentration in the blood plasma will be the same as that of intravenous lidocaine administration. Lidocaine has a duration of 30–60 minutes, but lidocaine remains detectable in the blood after 240 minutes of administration, albeit at lower levels. Various studies have been conducted to determine the effectiveness of lidocaine in preventing post-

intubation sore throat. The treatments administered were also varied, ranging from the use of lidocaine spray, lidocaine jelly, the application of lidocaine into the endotracheal tube balloon, and intravenous lidocaine administration. Several systematic reviews.[8]

Several studies have been conducted to determine the effectiveness of 10% lidocaine spray. The 10% lidocaine spray is effective in reducing throat pain after endotracheal intubation by being sprayed on the endotracheal tube along 15 cm from the distal end before intubation, thereby reducing throat discomfort. Xylocain spray (10% lidocaine spray) is effective in reducing throat pain after the use of an endotracheal tube. The combination of xylocain spray (10% lidocaine spray) with a small injection of lidocaine is effective for removing salivary gland stones.[7,12]

In Salsabila's 2021 study, it was found that the effectiveness of lidocaine spray on endotracheal tube in preventing postoperative sore throat is influenced by the duration of anesthesia/intubation. Lidocaine spray is effective in preventing post-operative sore throat (POST) in anesthesia procedures lasting less than 2 hours. Additional modalities are needed to prevent POST in surgical procedures requiring more than 2 hours of anesthesia. Previous research found that 30% of patients still experience sore throat post-intubation, possibly due to inadequate use of lidocaine spray, and no one has compared the administration of 10% lidocaine spray on the soft palate, posterior pharynx, tonsillar pillars, hypopharynx, and endotracheal tube. Therefore, the researcher is interested in comparing these two variables.

METHOD

This study design uses a single-blind randomized clinical trial to assess the Comparison of Hemodynamics and post-Intubation sore throat with the use of 10% Lidocaine Spray on the soft palate, posterior pharynx, tonsillar pillars, hypopharynx, and endotracheal tube at RS Adam Malik Medan. This research was conducted at RS Adam Malik Medan. From the calculation of the Research Subjects above, the required number of Research Subjects was determined to be 17 people for each group. Subjects who meet the inclusion and exclusion criteria were randomized using simple random sampling with a simple random method. Randomization for subject allocation was carried out using simple randomization with a randomization table, placed in envelopes, and drawn by the resident performing the intubation. Data recording and monitoring were conducted by researchers who were unaware of the administered medication. This research was conducted after obtaining approval from the Health Research Ethics Committee of the Faculty of Medicine, Universitas Sumatera Utara / RS Adam Malik, Medan.

1. Patients who have been registered for planned or emergency surgeries for indications in the neurosurgery department, who meet the inclusion criteria and are not excluded, are recruited as research subjects.
2. Patients are provided with an explanation of the research procedures and asked to sign a consent form for participation in the study.
3. Research subjects were randomly divided into 2 groups and underwent double-blind randomization by trained volunteers.
4. Group allocation was done by giving envelopes chosen by the volunteers, resulting in 2 groups. With the stipulation that Group A is the group receiving 10% Lidocaine spray on the soft palate, posterior pharynx, tonsillar pillars, and hypopharynx, and Group B is the group receiving 10% Lidocaine spray on the endotracheal tube.

5. The medication was prepared with the assistance of Volunteer I who had conducted the randomization. (peneliti tidak mengetahui komposisi obat yang diberikan). After performing randomization and preparing the medication, volunteer I then hands over the medication to volunteer II to be administered on the day of the study.
6. After the patient arrives in the surgical waiting room, the researcher re-examines the patient for patient characteristics (name, age, gender, weight, height), availability of intubation equipment, and IV access (ensure the IV is installed with an 18G abocath, three-way, and smooth infusion flow).
7. The medication is prepared by volunteer II after being provided by volunteer I who conducted the randomization. Group A: 10% lidocaine spray on the soft palate, posterior pharynx, tonsillar pillars, and hypopharynx. Meanwhile, Group B: 10% lidocaine spray on the endotracheal tube.
8. Before the patient enters the operating room, the anesthesia machine connected to an oxygen source has been prepared. An endotracheal intubation set and emergency injectable medications such as epinephrine, atropine sulfate, ephedrine, and dexamethasone have also been prepared.
9. After the patient enters the operating room, they are laid supine, and monitoring devices such as an EKG monitor, sphygmomanometer, and oxygen saturation monitor are attached to the patient's body (T0).
10. Patients with premedication, sedation, and induction according to the intubation procedure will be administered the following doses:
Sulfas Atrophin: 0.25 mg
Dexamethasone: 5 mg
Midazolam: 0.7 mg/kgBW
Fentanyl: 2 mcg/kgBW
Propofol: 2 mg/kgBW
Rocuronium: 0.6 mg/kgBW

11. After 1 minute and 30 seconds from the administration of rocuronium, Group A will receive a spray of 10% Lidocaine on the soft palate, posterior pharynx, tonsillar pillars, and hypopharynx, 2 times on each location. Meanwhile, Group B will receive a 10% Lidocaine spray 15 cm from the distal end of the endotracheal tube 8 times, after which the endotracheal tube will be rewrapped in plastic wrapping.
12.After 1 minute, the intubation procedure was performed.
13. Recording was done in the form of blood pressure, pulse frequency, respiratory frequency, and oxygen saturation by the researcher. T1 during laryngoscopy, and T2 when the endotracheal tube cuff is inflated.
14. Immediately after intubation, inflate the endotracheal tube cuff with a 5 ml syringe (cuff pressure 25 – 30 cmH2O) and monitor and record vital signs (blood pressure, mean arterial pressure, pulse rate, respiratory rate, and oxygen saturation).
15. Monitor vital signs (pulse rate, mean arterial pressure, blood pressure, oxygen saturation) with a monitor from the start of anesthesia until the end of the intubation procedure.
16. Record any side effects that occur: arrhythmia
17.After the surgical procedure was completed and the patient's spontaneous breathing was strong (tidal volume > 5 ml/kg), the research subjects were administered neostigmine 0.3 mg/kg and atropine sulfate 0.02 mg/kg. Cleaning of the oropharyngeal area is performed before extubation. Extubation is performed after ensuring the airway is clear and the patient is breathing spontaneously with adequate tidal volume. The patient is then observed in the recovery room.

18. If an allergic reaction to lidocaine occurs during the study, Dexamethasone 10 mg can be administered, and the research subject will be declared a dropout. If blood pressure increases by more than 20% and pulse increases by more than 20%, administer fentanyl analgesic 1 mcg/Kg.
19.After full consciousness, an assessment of post-endotracheal intubation pain is conducted on the patient. The assessment of post-endotracheal intubation pain is performed at T0, which is 1 hour post-surgery, T1, which is 6 hours post-surgery, and T2, which is 24 hours post-surgery. Where the 0-hour assessment is conducted when the patient is fully conscious in the recovery room, with the criteria that the patient can follow instructions and is well-oriented to self, time, and place.

RESULT

Table 1. Patient characteristics

Characteristics		Group(N=56)		
		A	B	P-Value
Age (Mean ± SD)		38.39 ± 10.64	37.46 ± 12.29	0.63
Gender (%)	Male	11 (30.4%)	8 (23.2%)	0.98
	Female	6 (19.6%)	9 (26.8%)	
BMI (Mean ± SD) kg/m^2		22.24 ± 1.19	21.21 ± 1.86	0.77
Duration of intubation (Mean ± SD, second)		18.39 ± 6.31	23.54 ± 7.76	0.45

In this study, a total of 34 subjects were willing to participate in the study. These 34 subjects were divided into two groups that underwent different methods of Xylocaine spray administration: 17 subjects were classified into Group A, where the Xylocaine spray was administered to the endotracheal tube, and 17 subjects were classified into Group B, where the Xylocaine spray was administered to the soft palate, hypopharynx, and tonsillar pillars. Subject characteristic data can be seen in Table 1.

Table 2. Normality test

Measurement Time	Mean ± SD	Normality Test
Systolic Blood pressure (mmHg)		
T0	112.21 ± 5.36	0.543
T1	121.50 ± 4.41	0.776
T2	121.71 ± 3.80	0.656
Diastolic Blood Pressure (mmHg)		
T0	71.75 ± 1.62	0.543
T1	69.32 ± 6.37	0.776
T2	68.18 ± 6,35	0.656
Heart Rate (x/menit)		
T0	79.21 ± 9.32	0.423
T1	98.68 ± 4.42	0.543
T2	99.11 ± 6.55	0.381
Mean Arterial Pressure (mmHg)		
T0	84.07 ± 6.45	0.321

T1	85.36 ± 5.03	0.542
T2	86.75 ± 4.34	0.512

Table 2 explains the results of the normality test for systolic blood pressure, diastolic blood pressure, heart rate, and mean arterial pressure in this study. The normality test was conducted using the Shapiro-Wilk test because the sample size was less than 50. In this study, the P values for all data were found to be > 0.05, indicating that the data are normally distributed.

Table 3. Hemodinamic

Time measurement	Group (Mean ± SD)		P
	A	B	
Sistolic Blood Pressure (mmHg)			
T0	110.21 ± 6.36	109.89 ± 6.42	0.068
T1	119.50 ± 6.41	112.68 ± 6.42	0.032
T2	111.71 ± 4.80	112.96 ± 6.05	0.029
Diastolic Blood Pressure (mmHg)			
T0	69.75 ± 8.62	68.32 ± 7.94	0.597
T1	70.32 ± 60.37	69.36 ± 7.28	0.659
T2	69.18 ± 6.35	69.00 ± 7.17	0.694
Mean Arterial Pressure(mmHg)			
T0	83.07 ± 6.15	82.04 ± 6.84	0.527
T1	84.36 ± 5.13	84.50 ± 4.85	0.825
T2	83,75 ± 4,64	83.14 ± 4.73	0.473
Heart Rate (x/menit)			
T0	80.11 ± 9.52	83.39 ± 10.98	0.268
T1	97.68 ± 4.82	87.11 ± 11.01	0.001*
T2	91.11 ± 6.55	87.82 ± 9.94	0.260

The results of systolic blood pressure measurements at T0, T1, and T2 in this study show significant differences between Group A and Group B. The systolic blood pressure data for each group can be seen in Table 3. The pattern of systolic blood pressure differences between the treatment groups also does not show significant differences.

Diastolic blood pressure measurements at T0 do not show significant differences in either Group A or Group B. The data from diastolic blood pressure measurements of various groups at T0, T1, and T2 after laryngoscopy can be seen in Table 3. Both in Group A and Group B, there was a pattern of increased diastolic blood pressure at T1, which then decreased again at T2. The average diastolic blood pressure in Group B was lower, but not significantly compared to Group A.

Heart rate measurements in Groups A and B at T0, T1, and T2 showed significant differences. The significant difference was found at T1. At T1, it was found that the heart rate of subjects in group A was significantly higher than that of group B. The heart rate measurement data can be seen in Table 4 The heart rate pattern in both groups shows a higher heart rate at T0 in group B, then at T1 and T2 a higher heart rate in group A, although the T2 heart rate post-laryngoscopy did not show a significant difference. The average arterial pressure measurement results in groups A and B at T0, T1, and T2 did not show a significant difference. The average arterial pressure data for both

groups at each measurement time can be seen in Table 4. The average arterial pressure pattern shows a higher average arterial pressure in group A at T0 and T2 post-laryngoscopy, but it was not significant.

Table 4. POST After Extubation Score

Measurement Time	POST Score			
	0	1	2	3
Group A				
T0 (1 Hour)	13	4	0	0
T1 (6 Hour)	17	0	0	0
T2 (24 Hour)	17	0	0	0
Group B				
T0 (1 Hour)	0	17	0	0
T1 (6 Hour)	0	17	0	0
T2 (24 Hour)	17	0	0	0

In Table 4, the POST score assessment was obtained at T0, 1 hour post-operation. In group A, a POST score of 0 was recorded for 13 patients, while in group B, 17 patients had a POST score of 1. At T1, 6 hours post-extubation, group A had 17 subjects with a POST score of 0, and group B had 17 samples with a POST score of 1. At T2, 24 hours post-extubation, group A had 17 subjects with a POST score of 0, and group B had 17 subjects with a POST score of 0.

DISCUSSION

In this study, the hemodynamic parameters that experienced significant differences were HR and systolic pressure. A significant difference in heart rate was shown at the T1 examination. At the time of the examination, it was shown that the heart rate in Group A subjects was significantly higher than Group B. While at T2, heart rate in group A remained higher, but not at a significant level. While at T0, the heart rate of group A was lower than that of subjects in group B, but not significantly. This difference is because the location of xylocaine spray on the oral mucosa causes anesthesia in the oropharynx so that it reduces the pain response due to laryngoscopy and intubation, while in the group spraying xylocaine spray on the endotracheal tube causes local anesthesia not to be absorbed in the oral mucosa which causes an increase in stress response during laryngoscopy and intubation. In Jalali's 2017 study explained the effect of topical lidocaine spray on the oropharyngeal cavity 3 minutes before laryngoscopy resulted in more stable hemodynamics after intubation compared to using fentanyl intravenously.[10]

In Bigli's 2020 study comparing intravenous lidocaine with lidocaine spray in the oropharynx in patients undergoing cardiac surgery and in Bigli's study found something similar to this study where hemodynamic improvement was found in intravenous lidocaine compared to lidocaine spray in the oropharynx this may be due to the dose in each individual to achieve different plasma levels which are also influenced by the amount of fat in each patient, while lidocaine spray does not require a certain dose in its administration.[11]

In this study, Xylocaine spray was administered 1 minute before intubation and showed a reduction in the hemodynamic improvement response, this is also similar to that found in a previous study conducted by Lee in 2016 in his study revealed the optimal administration of lidocaine spray was

carried out 1 to 2 minutes before intubation and explained in his study due to the need for time for lidocaine to work on the oropharyngeal mucosa.[12]

In the assessment of the POST score, the results were lower 1 hour post extubation in group A compared to group B, in the assessment of the POST score 6 hours post extubation, there were lower results in group B compared to group A, in the assessment of the POST score 24 hours post extubation, there was no significant difference between group A and group B. In Novie's research in 2022, it was found that the effectiveness of lidocaine spray on endotracheal tube in preventing postoperative throat pain was influenced by the length of anesthesia / intubation. Lidocaine spray is effective for preventing POST in anesthesia procedures less than 2 hours. Additional modalities are needed to prevent POST in surgical procedures requiring anesthesia for more than 2 hours. Absorption of lidocaine through the trachea is as rapid as intravenous administration of lidocaine. There is a similarity in the pharmacologic mechanism of lidocaine administered topically to the tracheal mucosa and intravenously. In theory, the duration of action of lidocaine ranges from 30-60 minutes. Its biotransformation occurs in the liver with a half-life of 60-120 minutes. After 2 hours of administration, the levels are further reduced and the effect gradually diminishes.[8,9,10,11]

The similarity in this study with previous studies is that it shows a lower POST score in patients who get lidocaine spray on the endotracheal tube which causes lidocaine to work topically on the vocalis plica of the research subjects, causing a better POST score compared to lidocaine spraying on the oropharyngeal mucosa. [12,13,14]

The limitation in this study is that there is no limitation on anesthesia time which greatly affects the analgesic effect of lidocaine on post extubation throat pain where the half-life of lidocaine spray is 60 - 120 minutes post administration. In this study, intubation was still given a strong analgesic in the form of fentanyl which is a strong opioid so that the pain response during intubation could also be influenced. In this study there was also no time limit for laryngoscopy until intubation was performed, which would also affect the hemodynamic response during laryngoscopy and intubation.[15]

CONCLUSIONS

There is a difference between the use of lidocaine spray 10% on the mole palate, posterior pharynx, tonsil pillars, hypopharynx and endotracheal tube on hemodynamics and the incidence of throat pain after endotracheal intubation in elective patients with general anesthesia at RS Adam Malik, Medan. There were no significant hemodynamic changes after intubation with lidocaine spray 10% in the palate mole, posterior pharynx, tonsil pillars, and hypopharynx. There were hemodynamic changes in patients after intubation with lidocaine spray 10% in the endotracheal tube. There was an incidence of sore throat after endotracheal intubation with lidocaine spray 10% on the mole palate, posterior pharynx, tonsil pillars, and hypopharynx There was no incidence of sore throat after endotracheal intubation with lidocaine spray 10% endotracheal tube.

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