






## Comparing the Effects of Lidocaine Spray versus Intravenous Lidocaine Administration after Laryngeal Mask Airway (LMA) Insertion

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Article Type	ABSTRACT
Research Paper	<p><b>Background and Objective:</b> Laryngeal Mask Airway (LMA) is commonly used in short-term surgical anesthesia. Intravenous lidocaine is used for better patient tolerance after LMA insertion. Regarding the side effects of intravenous lidocaine, the aim of this study is to compare the effect of lidocaine spray versus intravenous lidocaine on blood pressure, heart rate, sore throat, cough, laryngospasm, and other side effects including nausea, vomiting, and convulsions after LMA insertion.</p> <p><b>Methods:</b> This double-blind randomized clinical trial was conducted on 120 patients aged 18-65 years with indications for short-term elective eye surgery, in 2 equal groups of 60 people. The first group was given 1% intravenous lidocaine at the rate of 1.5 mg/kg, and the second group was administered with 5 puffs of 10% lidocaine spray in the throat. Then, blood pressure by a sphygmomanometer, heart rate by a heart rate monitoring system, sore throat intensity based on VAS criteria, and cough intensity based on mild, moderate and severe were measured and compared in the two groups.</p> <p><b>Findings:</b> 79 men (65.8%) and 41 women (42.2%) participated in this study. Clinically, there was no significant change in blood pressure in the two groups. The mean intensity of sore throat two and three hours after waking up in lidocaine spray group (<math>0.51 \pm 1.33</math> and <math>0.41 \pm 1.07</math>) compared to intravenous lidocaine (<math>1.15 \pm 2.02</math> and <math>1.9 \pm 1.08</math>) showed a significant decrease (<math>p &lt; 0.05</math>). Also, there were no significant changes in heart rate, cough and laryngospasm between the two groups. In addition, no cases of nausea, vomiting and seizures were found in the two groups.</p> <p><b>Conclusion:</b> Based on the results of this study, lidocaine spray can be suggested to reduce the severity of sore throat caused by LMA insertion.</p> <p><b>Keywords:</b> Hemodynamic Changes, Lidocaine Spray, Intravenous Lidocaine, Laryngeal Mask Airway, Sore Throat, Cough.</p>

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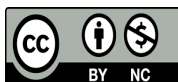
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## Introduction

Laryngeal Mask Airway (LMA) is one of the most widely used anesthesia methods, which is used to perform short-term surgeries such as eye surgery and difficult airway access (1). Using LMA method compared to intubation is associated with fewer complications, including hemodynamic changes and throat ulcers (2, 3). However, with excessive stimulation, it can cause wound and trauma to the uvula and pharyngeal necrosis, cough, vomiting, sore throat, bleeding, laryngospasm, dizziness, arrhythmia, convulsions and hemodynamic changes (4, 5). Different drugs are used in LMA insertion to relieve possible side effects. Lidocaine is one of the drugs used to suppress laryngeal and pharyngeal reflexes and inhibit the reaction of the cardiovascular system to laryngoscopy and intubation (6). In addition, it was shown in previous studies that intravenous lidocaine improves the patient's condition, including cardiovascular complications, cough, and laryngospasm after LMA (7, 8).

However, intravenous lidocaine can lead to brain disorders such as dizziness and lightheadedness, hypotension and cardiac arrhythmia (9). So far, limited studies have investigated the effect of lidocaine spray on blood pressure changes caused by anesthesia with LMA placement (10). If lidocaine spray can control the hemodynamics of patients like intravenous lidocaine or better, it will have much less side effects due to less local absorption. Therefore, the aim of this study is to compare the effects of lidocaine spray compared to intravenous lidocaine on changes in blood pressure, heart rate, and possible complications following LMA insertion, including sore throat, cough, nausea, vomiting, dizziness, and seizures in patients after LMA insertion under general anesthesia.

## Methods

After obtaining informed consent, receiving ethics code number IR.MUBABOL.HRI.REC.1398.343 and clinical trial registration number IRCT20141121020020N5, this clinical trial was conducted among patients who were referred to Shahid Beheshti and Ayatollah Rouhani hospitals in Babol for elective surgery shorter than one hour. In this randomized clinical trial, 120 patients between 18-65 years of age with ASA class I and II who had no history of drug use, heart and respiratory failure, psychiatric disorders, and head and neck surgeries were included in the study.

Patients over 65 years of age, history of head, neck, throat and airway surgery, history of COPD asthma, chronic cough and bronchitis, allergy and seasonal sensitivity, respiratory failure, psychological disorders, neurological disorders, heart failure and heart conduction disorders, hypotension or hypertension, coagulation disorder, oral and pharyngeal pathology including abscesses and tumors, history of corticosteroid use, drug abuse and hypersensitivity to drugs and addictive substances were excluded from the study due to interference with our study (pain and throat irritation and cough). The sample size was selected according to the average blood pressure in a similar study (10) and based on  $\alpha=0.05$ ,  $\beta=0.2$  and effect size=0.65. The patients were assigned to two groups of 60 people using the Randomizer software using the random block method with a block size of 4. The first group received intravenous lidocaine along with normal saline spray and the second group received intravenous lidocaine spray along with normal saline. Medicines were administered in the same packages by a nurse who was not aware of the type of medicines.

First, the patients underwent heart rate monitoring, pulse oximetry and non-invasive blood pressure control. After measuring and controlling blood pressure and heart rate, all patients were premedicated with 2 mg of midazolam and 1 mg/kg of fentanyl along with 200 ml of normal saline solution.

In the first group, 2 minutes before the induction, intravenous lidocaine 1% (Abu Rayhan Company, Tehran) was injected at the rate of 1.5 mg/kg and 5 puffs of normal saline spray were sprayed into the throat and mouth. In the second group, two minutes before the induction, intravenous normal saline was injected intravenously with an equal volume of lidocaine, and 10% lidocaine spray (Kharazmi Company, Tehran) was sprayed in the amount of 5 puffs in the pharynx and mouth.

Anesthesia induction was done with 2 mg/kg propofol (Dangkook Pharm. Co., Korea) and 5 mg atracurium in both groups, and 2-3 minutes later, after smearing the lubricant gel on the back of the LMA, it was inserted, then the LMA cuff was filled and the ventilation was checked. At the end of the surgery, after the return of spontaneous breathing, the LMA was removed by suctioning the mouth and emptying the cuff.

Hemodynamic changes (systolic blood pressure, diastole and heart rate) were recorded before and after anesthesia induction and before LMA insertion, one, five and ten minutes after LMA insertion. The patient's wakefulness (movement of organs) was recorded during LMA insertion and during the procedure. Hemodynamic changes, sore throat and cough of the patient were evaluated and recorded at 5 and 10 minutes and 1, 2 and 3 hours after LMA withdrawal and waking in recovery.

Evaluation of sore throat based on VAS criteria was measured and recorded as follows: no pain equal to zero and the worst pain experience equal to 10 (11), and cough intensity based on cough criteria: none equal to zero, mild cough less than 5 seconds equal to one, moderate cough with duration of 5-20 seconds equal to 2 and severe cough for more than 20 seconds equal to 3 (12), laryngospasm with symptoms of inspiratory stridor and respiratory distress, cyanosis and decreased secretion (13) and finally nausea and vomiting based on the need for antiemetic drugs. The schedule for recording hemodynamic changes and patient complications is given below:

T0= before starting anesthetic, T1= after induction and before LMA insertion, T2= 1 minute after LMA insertion, T3= 5 minutes after LMA insertion, T4= 10 minutes after LMA insertion, T5= before LMA removal, T6= 1 minute after LMA removal, T7= 5 minutes after LMA removal, T8= 10 minutes after LMA removal, T9= 1 hour after LMA removal, T10= 2 hours after LMA removal, T11= 3 hours after LMA removal.

The data were analyzed using SPSS-22 software. The results were expressed as mean±standard deviation for continuous quantitative data and number (percentage) for qualitative variables. Data analysis was performed by Chi-Square test for nominal qualitative variables and T-Test for quantitative variables, and  $p < 0.05$  was considered significant.

## Results

79 (65.8%) men and 41 (42.2%) women participated in this study (Table 1). The level of systolic blood pressure in the 3 hours after LMA removal in the spray group was significantly higher than the intravenous group ( $p=0.03$ ), but this difference did not show a significant difference in other times (Table 2).

Diastolic blood pressure 10 minutes after LMA insertion ( $p=0.046$ ), before LMA removal ( $p=0.007$ ), 1 minute after LMA removal ( $p=0.023$ ), 5 minutes after LMA removal ( $p=0.018$ ), 10 minutes after LMA removal ( $p=0.001$ ), 1 hour after LMA exit ( $p=0.000$ ), 2 hours after LMA removal ( $p=0.001$ ) and 3 hours after LMA removal ( $p=0.000$ ) showed a significant increase in the spray group compared to the intravenous group. But this difference was not significant at other times (Table 3).

Comparing the heart rate between the two groups, a significant increase was observed in the spray group versus the intravenous group at 10 minutes ( $p=0.04$ ) and 3 hours after LMA removal ( $p=0.002$ ). However, no significant difference was observed at other times (Table 4).

**Table 1. Demographic characteristics and clinical records of the subjects**

Variable	Lidocaine spray Number(%)	Intravenous lidocaine Number(%)	p-value
<b>Gender</b>			
Male	39(65)	40(66.7)	0.5
Female	21(35)	20(33.3)	
Underlying disease (blood pressure, heart disease and diabetes)	13(21.7)	11(18.3)	0.4
Hospitalization history	9(15)	12(20)	0.31
History of surgery	8(13.3)	8(13.3)	0.6

**Table 2. Comparison of systolic blood pressure changes in lidocaine spray group versus intravenous lidocaine**

Group	Lidocaine spray Mean±SD	Intravenous lidocaine Mean±SD	p-value
Max blood pressure before induction	137.68±13.83	136.33±61.11	0.623
Max blood pressure before LMA insertion	129.63±63	129.90±11.60	0.905
Max blood pressure 1 minute after LMA insertion	125.86±11.44	125.70±12.44	0.939
Max blood pressure 5 minutes after LMA insertion	116.28±8.76	117.43±9.68	0.497
Max blood pressure 10 minutes after LMA insertion	109.93±8.11	108.65±9.36	0.424
Max blood pressure before LMA removal	111.01±7.69	108.36±9.87	0.104
Max blood pressure 1 minute after LMA removal	113.26±7.76	111.15±8.64	0.161
Max blood pressure 5 minutes after LMA removal	113.60±6.59	112.13±8.54	0.295
Max blood pressure 10 minutes after LMA removal	114.45±5.49	112.86±7.56	0.192
Max blood pressure 1 hour after LMA removal	117.91±5.43	116.28±7.66	0.181
Max blood pressure 2 hours after LMA removal	118.96±5.71	116.66±7.49	0.061
Max blood pressure 3 hours after LMA removal	120.88±5.30	118.40±7.05	0.031*

Max: maximum, \*p<0.05

**Table 3. Comparison of diastolic blood pressure changes in lidocaine spray group versus intravenous lidocaine**

Group	Lidocaine spray Mean±SD	Intravenous lidocaine Mean±SD	p-value
Min blood pressure before induction	87.75±8.50	83.93±12.33	0.051
Min blood pressure before LMA insertion	82.96±7.81	94.81±10.37	0.380
Min blood pressure 1 minute after LMA insertion	87.73±6.58	78.63±7.55	0.939
Min blood pressure 5 minutes after LMA insertion	74.28±6.04	73.76±6.67	0.658
Min blood pressure 10 minutes after LMA insertion	71.25±5.95	68.96±6.43	0.046*
Min blood pressure before LMA removal	71.45±5.82	68.28±6.75	0.007**
Min blood pressure 1 minute after LMA removal	72.05±5.53	69.41±6.88	0.023*
Min blood pressure 5 minutes after LMA removal	72.95±5.26	70.18±7.17	0.018*
Min blood pressure 10 minutes after LMA removal	74.01±6.44	70.26±5.58	0.001***
Min blood pressure 1 hour after LMA removal	76.40±6.26	72.18±5.87	0.000***
Min blood pressure 2 hours after LMA removal	77.30±6.20	73.53±6.03	0.001***
Min blood pressure 3 hours after LMA removal	79.00±6.09	74.50±4.78	0.000***

Min: minimum, \*p<0.05, \*\*p<0.01, \*\*\*p<0.001

**Table 4. Comparison of average heart rate in lidocaine spray group versus intravenous lidocaine**

Group	Lidocaine spray	Intravenous lidocaine	p-value
	Mean±SD	Mean±SD	
Heart rate before induction	86.36±8.27	84.73±9.69	0.32
Heart rate before LMA insertion	81.51±7.22	80.03±7.61	0.27
Heart rate 1 minute after LMA insertion	79.76±8.03	79.20±7.83	0.69
Heart rate 5 minutes after LMA insertion	73.40±5.80	73.06±6.43	0.76
Heart rate 10 minutes after LMA insertion	69.50±5.1	68.36±5.39	0.24
Heart rate before LMA removal	70.88±4.47	69.11±4.61	0.35
Heart rate 1 minute after LMA removal	73.45±5.28	71.81±5.38	0.08
Heart rate 5 minutes after LMA removal	73.01±5.03	72.133±5.33	0.35
Heart rate 10 minutes after LMA removal	74.08±5.37	72.05±5.34	0.04*
Heart rate 1 hour after LMA removal	75.80±5.01	74.56±5.49	0.20
Heart rate 2 hours after LMA removal	75.30±4.11	74.08±4.10	0.10
Heart rate 3 hours after LMA removal	75.63±4.95	72.88±4.63	0.002**

LMA: Laryngeal Mask Airway, \*p<0.05, \*\*p<0.01

The level of sore throat decreased at all follow-up times after LMA removal in the spray group compared to the intravenous group. In addition, a significant decrease in the severity of sore throat was observed at 2 hours (p=0.04) and 3 hours (p=0.02) after LMA removal in the spray group compared to the intravenous group (Table 5).

**Table 5. Comparison of sore throat severity in lidocaine spray group versus intravenous lidocaine**

Group	Lidocaine spray	Intravenous lidocaine	p-value
	Mean±SD	Mean±SD	
5 minutes following LMA removal and waking	0.4±1.22	0.73±1.58	0.18
10 minutes following LMA removal and waking	0.6±1.55	1.16±2.05	0.09
1 hour following LMA removal and waking	0.6±1.54	1.23±2.15	0.06
2 hours following LMA removal and waking	0.51±1.33	1.15±2.02	0.04*
3 hours following LMA removal and waking	0.41±1.07	1.08±1.90	0.02*

LMA: Laryngeal Mask Airway, \*p<0.05

In comparing the frequency of cough at different times in two groups, no significant difference was observed. In addition, laryngospasm was present in a small percentage of patients in both groups and was not statistically significant. No other side effects such as nausea, vomiting, dizziness, arrhythmia and convulsions were observed in the examination of the patients in the two groups.

## Discussion

In this study, in investigating the effect of lidocaine spray and intravenous lidocaine on hemodynamic changes and complications caused by LMA insertion, in both groups, the trend of diastolic and systolic blood pressure decreased compared to the initial value up to 10 minutes after LMA insertion and then increased until approaching its initial value. However, lidocaine spray showed a lower pressure drop compared to intravenous lidocaine, especially in diastolic blood pressure. In total, in both groups, blood

pressure changes compared to the initial value were normal and clinically insignificant. In similar studies in laryngoscopy and tracheal intubation, 10% lidocaine spray showed a better effect than intravenous lidocaine in controlling systolic and diastolic blood pressure and bringing blood pressure changes to the baseline level (14-16).

In line with the results of blood pressure, a decrease in heart rate was observed in both lidocaine spray and intravenous lidocaine groups up to 10 minutes after LMA insertion, and then the increasing trend continued until approaching the initial value. Although the heart rate changes until the end of the follow-up time showed a difference below 20% with the initial value in both groups, this amount of changes is clinically insignificant due to being in the normal range. In the study of Bhandari et al., in both intravenous and spray lidocaine groups, an increase in heart rate was observed one minute after LMA insertion. But this increase gradually decreased to the base level within 2-3 minutes (6).

In this study, a reduction in the severity of sore throat was observed in the 10% lidocaine spray group compared to intravenous lidocaine. Since the cause of sore throat is often caused by irritation of the throat mucosa after LMA insertion, this finding is due to the anesthesia of the throat mucosa with the direct effect of lidocaine spray. In line with our results, the study of Chandra et al. showed that 4% lidocaine spray is as effective as injectable dexamethasone in reducing the incidence and severity of sore throat in LMA up to two hours after surgery (17).

In another study, there was no difference in the frequency of sore throat in the lidocaine spray group versus intravenous fentanyl in patients who were under anesthesia with the LMA method (18). The difference between this finding and our study is due to the narcotic effects of fentanyl.

Evaluation of cough intensity in three conditions of mild, moderate and severe did not show any difference between the two groups. However, the cases of severe cough were less in the group of lidocaine spray compared to intravenous lidocaine, which shows the better performance of lidocaine spray in reducing mucosal irritation than intravenous lidocaine. In line with our findings, administration of 10% lidocaine spray along with propofol kg/mg<sup>2</sup> showed a significant effect in reducing the frequency of cough compared to the group that only received propofol kg/mg<sup>2</sup> (19).

On the other hand, in the intubation method, a decrease in the effect of lidocaine spray was reported due to the dissolution of the spray with secretions of the mucosal wall of the throat and trachea, in contrast to the administration of lidocaine in injection form or inside the cuff of the tracheal tube (20).

In our study, the level of laryngospasm was observed in both groups at the same rate and with low prevalence. In similar studies using LMA method in the groups receiving lidocaine spray versus intravenous lidocaine, no occurrence of laryngospasm or a decrease in its severity has been observed (18, 20).

The present study showed that lidocaine spray is as effective as intravenous lidocaine in controlling the hemodynamic response in the LMA method. In addition, the severity of sore throat and mucosal irritation is reduced by 10% lidocaine spray compared to intravenous lidocaine. Due to the fact that lidocaine spray is more economical than intravenous lidocaine, and due to less absorption, and little systemic side effects, it is a suitable alternative for short-term anesthesia using LMA method.

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