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Comparison of two methods of using normal saline and lidocaine gel during laryngeal mask airway insertion on hemodynamic symptoms and emergence reactions in patients undergoing cataract surgery: A double-blind randomized controlled trial

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Abstract

Background and aim: *Due to high sensitivity, eye surgery should be accompanied by the least reaction and strain of the patient. On the other hand, sore throat, cough and nausea can reduce patient satisfaction and limit postoperative activities. Therefore, the present study aimed to compare the two methods of using normal saline and lidocaine gel during laryngeal mask airway (LMA) insertion on the hemodynamic symptoms and emergence reactions in patients undergoing cataract surgery.*

Methods: *This double-blind randomized controlled trial was conducted on 120 patients undergoing cataract surgery. The patients were randomly divided into two groups of lidocaine gel (n=60) and normal saline (n=60). Systolic and diastolic blood pressure, heart rate and arterial oxygen saturation (SaO_2) were measured before and immediately after induction, and 5, 15 and 30 minutes after surgery, as well as in recovery. In addition, episodes of cough, sore throat, nausea, and vomiting at recovery, 1, 6, 12, and 24 hours after surgery were recorded in the ophthalmology department.*

Results: *The results of the current study showed that the groups did not differ significantly in terms of demographic characteristics. There was no significant difference between cough, nausea and heart rate and SaO_2 levels in 5 minutes after surgery and recovery on LMA after withdrawal, but there was a significant difference in SaO_2 level. The SaO_2 level was increased 15 to 30 minutes after surgery in the normal saline group.*

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Conclusion: *The results of this study showed that the use of lidocaine gel to facilitate airway insertion has no effect on postoperative cough and sore throat. Future studies are recommended to examine this finding in surgical procedures with further LMA facilitators.*

Keywords: *normal saline, lidocaine gel, cataract, laryngeal mask, hemodynamic symptoms*

I. Introduction

Cataract surgery is common in older people, and is most commonly performed through induction of anesthesia. The anesthesia for eye surgery requires an understanding of the physiology of intraocular pressure, anatomy of the eye, and the effects of anesthetic drugs.Due to the fact that patients who are prone to eye surgery are more likely to be older or very young, special attention should be paid to the anesthesia of these patients.Because unexpected movements of the patient and the patient's eye during sensitive intraocular surgery increase intraocular pressure, bleeding, discharge of the vitreous body and blindness, it is important to prevent coughing and sudden movements of the patient, to gently awaken the patient, and prevent laryngeal spasm during extubation after eye surgery (1).Cough is one of the problems that sometimes occurs during extubation. It causes a sudden increase in pressure within the body's cavities, which is very dangerous in people with eye injuries or increased intracranial pressure (2).The prevalence of cough during emergence from anesthesia has been reported to be 76% (3). Side effects of sore throat after surgery include pain, itching or burning in the throat, and possibly hoarseness, which is a side effect of anesthesia that usually resolves spontaneously within a few days (42-48 hours) after surgery (4).Postoperative sore throat may originate in the throat, larynx, or trachea (5). After tracheal intubation, the postoperative sore throat was reported to be 14.4 to 50% and after laryngeal use from 5.8 to 34%. The airway management method has the highest effect on the postoperative sore throat (6).On the other hand, there is a report of sore throat symptoms caused by inserting laryngeal mask airway (LMA), which is used as a new means of providing airway (2).However, the use of LMA has been shown to reduce the risk of sore throat and can be an appropriate alternative to endotracheal intubation, which is not necessary in some types of surgery (7-8).Various techniques and methods have been used to reduce the incidence of airway complications after extubation, including lidocaine gel and spray (9, 10). The LMA insertion is facilitated by the proper use of lubricant on the back of the mask.The lubricant prevents the effect of saliva within natural swallowing and the device adherence to the oral tissues during placement (11).Recommended lubricants, such as saline, are hydrogels, but many anesthesiologists prefer topical anesthetic gel because it may be effective in reducing nausea and vomiting (13-12).However, analgesic lubricants are not widely used due to the patient's complaints of numbness, possible allergic reactions, and the possibility of developing protective reflexes (14).Due to the prevalence of eye diseases in the new era, especially cataracts, eye surgery has also expanded. Because of this, and as previously described, post-anesthesia reactions in eye surgery such as cough, sore throat, and nausea and vomiting should be minimized. This can be achieved by conducting further research on the types of methods that can minimize the emergence reactions. Therefore, our research team conducted a study entitled "Comparison of lidocaine gel and normal saline during the LMA insertion on hemodynamic changes and emergence reactions in patients undergoing cataract surgery at Motahhari Hospital in Jahrom in 2019."

II. Materials and Methods

Study design

The present double-blind randomized controlled trial (IRCT20130926014779N3**)** was conducted over a one-year period from January 2019 to January 2020 in the patients undergoing cataract surgery at Motahhari Hospital in Jahrom.

Ethical considerations

Prior to the enrollment of the patients in the study, the research process was explained and informed consent was obtained. At all stages of the study, the researchers adhered to the Declaration of Helsinki and the confidentiality of patient information. All the costs of this project were covered by the researchers and no additional costs were incurred for the patients. This study was approved by the Ethics Committee of Jahrom University of Medical Sciences under the code of ethics of IR.JUMS.REC.1397.112.

Sampling

The present study population was patients undergoing cataract surgery. The sample size was estimated to be 120 people with the assumption of standard difference of 0.85, 95% confidence interval, test power of 80% and equality of sample size in each group using Altman's nomogram and including 15% dropout. The samples were randomly assigned to lidocaine gel and normal saline groups (60 people in each group) using a random number table.

Inclusion and exclusion criteria

Inclusion criteria**:** ASAI and II, willingness to participate in the study, absence of chronic and cancer pain, lack of hearing or speech impairment, hemodynamic stability, absence of anxiety and mental illness, absence of chronic pain, absence of diabetes and rheumatoid arthritis and Down syndrome, absence of the patient in the menstrual cycle, absence of cervical problems, non-use of antiemetics and painkillers, absence of infection and oral ulcer, non-use of tobacco and drugs, absence of lung diseases, absence of G6pd disease

Exclusion criteria: The need for medication or action other than routine care to relieve complications and reduce pain during surgery, unstable hemodynamic status, and unwillingness to continue the research

Study intervention

All patients who met the inclusion criteria at the time of study (n=120), after obtaining written consent and explaining the study protocol, were divided into intervention and control groups by coin flipping. The patients were transferred to the operating room for surgery, and all underwent general anesthesia with the same procedure and surgeon. The person performing the procedures, the person collecting the information and the patient were all unaware of the type of gel used. All patients fasted 8 hours before surgery and received 500 ml of Ringer's solution before surgery. Monitoring including ECG, Pulse Oximeter and non-invasive measurement of blood pressure for patients was installed and blood pressure and heart rate were recorded before anesthesia and LMA insertion. The induction of anesthesia was started for all patients with the same general anesthesia method with 4 µg/kg of fentanyl, 0.5 mg/kg of atracurium, 5 mg/kg of thiopental and 0.02 of mg/kg of midazolam, and then the LMA was inserted for them.

Data collection

Systolic and diastolic blood pressure was measured using a sphygmomanometer whose cuff was closed on the patient's right arm. Patients' heart rate was recorded using ECG monitoring. Cough, sore throat, nausea and vomiting were examined. The severity of the sore throat was assessed using a visual analogue scale (VAS), in which zero represents no pain and 10 represents unbearable pain in recovery, 1, 6, 12 and 24 hours after surgery. The prevalence of complications were recorded in recovery and 1, 6, 12 and 24 hours after surgery in the ophthalmology department, including the episodes of cough (0 = no cough, 1 = mild cough or single cough, 2 = moderate cough more than one episode that does not last long (≤5 seconds) and 3 = severe or prolonged cough (≥5 seconds)), as well as nausea and vomiting (0 = no nausea and vomiting), 1 = mild nausea without the need for treatment, 2- nausea that can be relieved by antiemetics, 3 = vomiting that can be relieved by antiemetics, and 4 = nausea or vomiting that does not respond to antiemetics).

Statistical analysis

Data were analyzed by SPSS version 21 software using descriptive statistics (mean, standard deviation and percentage) and inferential statistics (Chi-square, independent t-test, Mann-Whitney U test) at the significance level of $P<0.05$.

III. Results

In this study, 120 patients underwent cataract surgery were divided into lidocaine gel (n=60) and normal saline (n=60) groups and participated in the study. The results of statistical analysis showed that the normal saline and the lidocaine gel groups were homogeneous for age, sex, weight and duration of anesthesia (Table 1).

Table 1. Description of demographic variables in normal saline and lidocaine gel groups

		Groups		p-value	Test
		normal saline	lidocaine gel		
Gender	Male	34 (56.7)[1]		0.583	Chi-square
	Female	26 (43.3)			
Age		64.52±7.36[2]	63.73±10.46	0.48	Independent t-test
Weight		64.45±8.93	66.95±9.48	0.76	Independent t-test

Duration of surgery (minutes)	18.58±2.27	18.0±2.47	0.073	Mann-Whitney U test

The Mann-Whitney U test results in Table 2 showed that there was no significant difference between normal saline and lidocaine gel in terms of systolic and diastolic blood pressure before surgery, immediately after induction, 5 minutes, 15 minutes and 30 minutes after surgery, and in recovery (P>0.05) (Table 2).

Table 2. Comparison of blood pressure at different times between normal saline and lidocaine gel groups

Variables	Groups	normal saline		lidocaine gel		p-value
		mean	standard deviation	mean	standard deviation	
Systolic blood pressure	Before surgery	134.20	15.61	134.60	12.43	0.81
	Immediately after induction	129.83	16.65	128.82	18.67	0.88
	5 minutes after surgery	127.30	15.24	130.30	13.07	0.096
	15 minutes after surgery	130.67	14.53	132.02	12.66	0.27
	30 minutes after surgery	130.02	10.75	130.85	12.36	0.50
	In recovery	129.92	9.79	130.30	13.05	0.35
	Before surgery	84.65	10.25	84.57	9.12	0.85

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Diastolic blood pressure	Immediately after induction	82.45	10.66	81.90	13.90	0.81
	5 minutes after surgery	81.18	8.06	81.70	8.63	0.45
	15 minutes after surgery	82.28	6.54	83.42	7.94	0.51
	30 minutes after surgery	82.48	6.54	82.87	7.96	0.73
	In recovery	82.48	6.12	84.25	8.29	0.23

The Mann-Whitney U test results in Table 3 showed that there was no significant difference between normal saline and lidocaine gel groups in terms of preoperative heart rate and postoperative times and recovery ($p>0.05$).

Table 3. Comparison of heart rate at different times between normal saline and lidocaine gel groups

Variables	Groups	normal saline		lidocaine gel		p-value
		mean	standard deviation	mean	standard deviation	
Heart rate	Before surgery	76.17	11.63	73.60	10.93	0.28
	Immediately after induction	81.05	13.24	78.42	12.45	0.25

	5 minutes after surgery	77.95	11.33	77.18	8.90	0.41
	15 minutes after surgery	76.43	8.87	75.85	8.45	0.53
	30 minutes after surgery	75.23	10.34	75.22	8.92	0.75
	In recovery	76.35	10.00	75.58	7.70	0.56

The Mann-Whitney U test results in Table 4 showed that normal saline and lidocaine gel groups had a significant difference in SaO2 levels at 15 and 30 minutes after surgery ($p < 0.05$), but not at other times ($p > 0.05$). At 15 and 30 minutes after surgery, the mean SaO2 level in the lidocaine gel group was reported to be lower than in the normal saline group.

Table 4. Comparison of arterial oxygen saturation levels at different times between normal saline and lidocaine gel groups

Variables	Groups	normal saline		lidocaine gel		p-value
		mean	standard deviation	mean	standard deviation	
Arterial oxygen saturation	Before surgery	98.03	0.45	97.63	1.76	0.76
	Immediately after induction	98.40	0.83	98.28	1.25	0.17
	5 minutes after surgery	98.27	0.97	97.90	1.63	0.079

	15 minutes after surgery	98.00	0.96	97.53	1.64	0.001
	30 minutes after surgery	98.28	1.01	97.45	1.91	0.006
	In recovery	98.27	0.78	97.68	1.14	0.062

Comparisons of cough have been shown at different times in the normal saline and lidocaine gel groups. In recovery, 1, 6 and 12 hours after surgery, mild to moderate cough was more common in the lidocaine gel group than in the normal saline group. In recovery, 1, 6 and 12 hours after surgery, severe cough was reported only in the lidocaine gel group. No severe cough was observed in the normal saline group at different times. However, the Chi-square test results in Table 5 showed no significant difference between normal saline and lidocaine gel groups in terms of cough in recovery, 1, 6, 12 and 24 hours after surgery ($p < 0.05$).

Table 5. Comparison of cough severity at different times between normal saline and lidocaine gel groups

Variables	Groups	normal saline		lidocaine gel		p-value
		Frequency	Percentage	Frequency	Percentage	
Cough in recovery	No	56	93.3	46	76.7	0.08
	Mild	2	3.3	6	10.0	
	Moderate	2	3.3	7	11.7	
	Severe	0	0.0	1	1.7	
Cough at 1 hour after surgery	No	56	93.3	49	81.7	0.10
	Mild	3	5.0	5	8.3	

	Moderate	1	1.7	6	10.0	
	Severe	0	0.0	0	0.0	
Cough at 6 hours after surgery	No	58	96.7	51	85.0	0.15
	Mild	1	1.7	6	10.0	
	Moderate	1	1.7	2	3.3	
	Severe	0	0.0	1	1.7	
Cough at 12 hours after surgery	No	58	96.7	52	86.7	0.23
	Mild	1	1.7	2	3.3	
	Moderate	1	1.7	5	8.3	
	Severe	0	0.0	1	1.7	
Cough at 24 hours after surgery	No	58	96.7	53	88.3	0.15
	Mild	1	1.7	1	1.7	
	Moderate	1	1.7	6	10.0	
	Severe	0	0.0	0	0.0	

The Chi-square test results in Table 6 showed that there was no significant difference between normal saline and lidocaine gel groups in terms of nausea during recovery periods and after surgery ($p < 0.05$).

Table 6. Comparison of nausea severity at different times between normal saline and lidocaine gel groups

Variables	Groups	normal saline		lidocaine gel		p-value
		Frequency	Percentage	Frequency	Percentage	
Nausea in recovery	No nausea and vomiting	57	95.0	57	95.0	0.72
	Mild without the need for treatment	2	3.3	1	1.7	
	Mild nausea removable with treatment	1	1.7	2	3.3	
	Vomiting removable with treatment	0	0.0	0	0.0	
Nausea at 1 hour after surgery	No nausea and vomiting	59	98.3	59	98.3	0.99
	Mild without the need for treatment	1	1.7	0	0.0	
	Mild nausea removable	0	0.0	1	1.7	

	with treatment					
	Vomiting removable with treatment	0	0.0	0	0.0	
Nausea at 6 hours after surgery	No nausea and vomiting	60	100.0	59	98.3	0.99
	Mild without the need for treatment	0	0.0	0	0.0	
	Mild nausea removable with treatment	0	0.0	1	1.7	
	Vomiting removable with treatment	0	0.0	0	0.0	
Nausea at 12 hours after surgery	No nausea and vomiting	60	100.0	59	98.3	0.99
	Mild without the need for treatment	0	0.0	0	0.0	
	Mild nausea removable	0	0.0	1	1.7	

	with treatment					
	Vomiting removable with treatment	0	0.0	0	0.0	
Nausea at 24 hours after surgery	No nausea and vomiting	59	98.3	60	100.0	0.62
	Mild without the need for treatment	0	0.0	0	0.0	
	Mild nausea removable with treatment	0	0.0	0	0.0	
	Vomiting removable with treatment	1	1.7	0	0.0	

The Chi-square test results in Table 7 indicated no significant difference between normal saline and lidocaine gel groups in terms of the severity of sore throat during recovery and one hour after surgery ($p < 0.05$).

Table 7. Comparison of sore throat Severity at different times between normal saline and lidocaine gel groups

Variables	Groups	normal saline		lidocaine gel		p-value
		Frequency	Percentage	Frequency	Percentage	

Sore throat in recovery	No	44	73.3	39	65.0	0.15
	Mild	9	15.0	8	13.3	
	Moderate	4	6.7	12	20.0	
	Severe	3	5.0	1	1.7	
Sore throat at 1 hour after surgery	No	44	73.3	40	66.7	0.11
	Mild	9	15.0	7	11.7	
	Moderate	5	8.3	13	21.7	
	Severe	2	3.3	0	0.0	
Sore throat at 6 hours after surgery	No	45	75.0	39	65.0	0.38
	Mild	10	16.7	10	16.7	
	Moderate	5	8.3	10	16.7	
	Severe	0	0.0	1	1.7	
Sore throat at 12 hours after surgery	No	47	78.3	41	68.3	0.53
	Mild	9	15.0	11	18.3	
	Moderate	3	5.0	7	11.7	
	Severe	1	1.7	1	1.7	

Sore throat at 24 hours after surgery	No	48	80.0	45	75.0	0.68
	Mild	7	11.7	7	11.7	
	Moderate	5	8.3	8	13.3	
	Severe	0	0.0	0	0.0	

In recovery, the lidocaine gel group (35%) experienced sore throat more than normal saline group (26.7%). The prevalence of moderate sore throat in the lidocaine gel group (20%) was more common than in the normal saline group, but the prevalence of severe sore throat in the lidocaine gel group was lower than in the normal saline group. At 1 and 6 hours after surgery, the lidocaine gel group experienced sore throats more than normal saline group. The prevalence of severe sore throat at one hour after surgery was not observed in the lidocaine gel group. The prevalence of severe sore throat at 24 hours after surgery was not observed in any of the lidocaine gel and normal saline groups. It is worth noting that the severity of sore throat (mild, moderate and severe) in the normal saline group was lower than in the lidocaine gel group. The severity of sore throat in the normal saline group was declining; however, the severity of sore throat in the lidocaine gel group increased from one hour after surgery to 6 hours after surgery, but then decreased.

IV. Discussion

The laryngeal mask airway is an appropriate alternative to intubation in some cases. In this area, Zeinali et al. showed that postoperative sore throat intensity using LMA was significantly lower than endotracheal tube (15). The results of the present study showed that there was no significant difference in the severity of sore throat between the normal saline and lidocaine gel groups. Park et al. showed no difference between normal saline and 2% lidocaine as a facilitator when placing SLIPA (16). The SLIPA is a cuff-free airway tool that is structurally located between the mouth and throat, and has the minimum leakage following the change in the position of the head; despite this difference, the results of the two studies are consistent. In the study of Taghavi et al. with the aim of reducing sore throat following laryngeal mask insertion compared to the use of lidocaine gel, normal saline and mouthwash with the control group, there was no significant difference between the four groups in terms of sore throat (17), consistent with the evidence of the present study. Mekhemar et al emphasized that the use of 5% lidocaine could not significantly reduce postoperative sore throat, but was a better candidate than normal saline (18). The reasons for the varied report on the prevalence of postoperative reaction are not yet known, but can be attributed to a variety of factors, including LMA insertion technique, pressure on the laryngeal membrane, length of surgery, and the type of lubricant used. In the present study, it was shown that the use of normal saline and lidocaine gel as LMA facilitators had no effect on postoperative cough. Karim Naseri et al. examined the effect

of lidocaine gel on reducing sore throat, cough and itchy throat after LMA insertion in elective eye surgery. Their results demonstrated that the type of gel used to facilitate LMA insertion had no effect on sore throat, cough, the amount of bloody discharge on the mask cuff and postoperative itching (19), which is consistent with the results of the present study. In a study of PAUL and CHARI, the results showed that impregnating the endotracheal tube cuff with benzodiazepine compared to 2% lidocaine reduced the cough reaction at the end of anesthesia (20). Schebesta et al (20) revealed that lidocaine-impregnated LMA caused a reduction in adverse reactions after anesthesia in patients with upper respiratory tract infection, although it had no effect on maladaptive reactions after anesthesia in non-infected patients. The difference between this study and the present study can be attributed to the study population. In the study of Schebesta et al., the study population was children aged 1 to 10 years. Given that the rate of airway reflexes decreases with age, this could be the reason for the difference in our results with the study of Schebesta et al. In a study by Rastearian et al. (2014) aimed at investigating the use of laryngeal mask in pilonidal cyst removal after injection of muscle relaxants in the prone position, the results showed that pulmonary aspiration did not occur in these patients and the severity of postoperative sore throat was 16.85%. The results of this study suggest that the laryngeal masks can be used for surgeries at prone position after prescribing muscle relaxants; however, further studies are needed in this context (21).

The aim of the present study was to investigate the relationship between postoperative nausea severity and SaO2 level in two groups of normal saline and lidocaine gel 2% to facilitate LMA insertion, the results of which found no significant relationship. There was only a significant difference between SaO2 level in the two groups at 15 and 30 minutes after surgery, which was lower in the lidocaine gel group than in the normal saline group, but no significant difference was observed in the rest of the times after surgery. A study that used 2% lidocaine as a facilitator for LMA-ProSealTM insertion reported that 2% lidocaine could minimize the severity of nausea and vomiting during emergence from anesthesia. Chan et al. reported that the use of lidocaine gel in short-term procedures reduced the severity of nausea from 47% to 17% (22). In a study by Park et al (16), who conducted a comparative study among normal saline, water-soluble gel and 2% lidocaine gel as a SLIPA lubricant, the results reported no association between the lubricant type for SLIPA and nausea after emergence from anesthesia. Hazrati et al. (23) showed that lidocaine-impregnated LMA could improve SaO2 levels and reduce the nausea severity after anesthesia, inconsistent with the results of the present study. One of the reasons for non-compliance can be attributed to the different types of surgery in the two surgeries, although other factors such as the skill of the anesthesiologist, the number of attempts to insert the LMA, and the extent of trauma must also be considered. Sore throat, hoarseness, coughing and sometimes nausea are relatively common in airway management with a laryngeal mask.

V. Conclusions

The results from the present study demonstrated that the use of normal saline and 2% lidocaine gel during laryngeal mask airway insertion had no effect on nausea severity, sore throat, cough, hemodynamic symptoms and arterial oxygen saturation level, but normal saline is superior to lidocaine in arterial oxygen saturation level at 15 and 30 minutes after surgery, so further studies are recommended to consider larger sample size and more tools such as SILPA as well as other agents such as lubricant to facilitate the insertion.

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