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Effect of Intranasal Remifentanil versus Lidocaine on Facilitation of Laryngeal Mask Airway Insertion and Cardiovascular Response: A Double-blind Clinical Trial Study

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ABSTRACT

Objective: This study aimed to assess and compare the effects of intranasal administration of lidocaine and remifentanil on the condition of LMA insertion and cardiovascular response.
Methods: From March 2019 to March 2020, this double-blind randomized clinical trial study was conducted on 60 patients, who underwent general anesthesia with LMA insertion at Faiz Hospital, Isfahan, Iran. After induction of anesthesia and before placing the laryngeal mask, the first group received remifentanil 1 µg/Kg, the second group received lidocaine 2% 1 mg/Kg, and the third group received normal saline with the same volume intranasally. The conditions of LMA insertion and hemodynamic changes that occurred during its insertion were investigated.
Results: In terms of demographics characteristics (p>0.05), success in placing the LMA on the first try (p=0.73), number of attempts to insert LMA (p=0.61), performance of LMA (p=0.73), need for additional propofol (p=0.53), frequency of gagging (p=0.53), cough (p=0.15) p), and laryngospasm (p=0.99) did not differ significantly. In the remifentanil group, the cardiovascular response to LMA injection was less than that of the lidocaine group. Moreover, both groups were lower than the saline group, but no significant difference was observed
Conclusion: In facilitating LMA insertion, the effect of intranasal remifentanil was comparable to intranasal lidocaine. Intranasal remifentanil was somewhat more effective than intranasal lidocaine in weakening the cardiovascular response to LMA insertion, but it did not outperform lidocaine.

Keywords: Hemodynamics; Intranasal; Laryngeal mask airway; Lidocaine; Remifentanil.

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Introduction

Insertion of laryngeal mask airway (LMA) is a non-invasive method in short-term procedures and difficult tracheal intubation [1, 2]. LMA placement requires a sufficient depth of anesthesia, relaxation of the jaw muscles, and suppression of airway reflexes to tolerate it inside the hypopharynx [3]. Such conditions are provided by administering high doses of intravenous (IV) anesthetic. A standard method of induction of anesthesia for LMA placement is the use of intravenous propofol, which has the advantage of rapid induction of anesthesia with better suppression of upper airway reflexes and jaw relaxation. However, propofol is more expensive and has more side effects, such as painful injection, deeper respiratory depression, longer apnea, and cardiovascular depression, than thiopental during induction of anesthesia [4]. Propofol does not have analgesic activity on its own, and when administered alone, the high doses required for induction might cause cardiovascular side effects [5].

Adding a short-acting drug, such as remifentanil, during propofol induction is one option for reducing the amount of required propofol, depressing airway protective reflexes, and facilitating LMA insertion without hemodynamic instability [3-5]. In particular, remifentanil is an ideal suppressor of short-term but potent noxious stimuli, such as tracheal intubation or placement of an LMA in the airway, as it provides rapid onset of intense analgesia with a relatively short duration of action [6-8]. Intubating conditions during sevoflurane anesthesia in children improved with a single bolus dose of remifentanil [9,10].

Additionally, the use of lidocaine, opioids, or ketamine can minimize the dose of propofol while increasing the success of LMA insertion [11]. On the other hand, studies reported that using topical lidocaine spray before inducing anesthesia with thiopental provides better conditions for placing an LMA than administering intravenous lidocaine and thiopental [12].

Since there was a dearth of research on the effects of intranasal remifentanil and lidocaine on the conditions of laryngeal mask placement and cardiovascular response in the induction of thiopental anesthesia, as well as the growing use of LMA in difficult intubations and short-term surgeries, the present study was designed and conducted on eye surgery candidate patients who underwent induced general anesthesia using sodium thiopental and LMA insertion.

Materials and Methods

This double-blind randomized clinical trial study was conducted at Faiz Ophthalmology Center (Isfahan, Iran) from January 2019 to January 2020. The study was approved by the Ethics Committee of Isfahan University of Medical Sciences (IR.MUI.MED.REC.1398.509) and registered in the Iranian Registry of Clinical Trials (IRCT20180416039326N10) (date:19/02/2020). The study was carried out in accordance with the Medical Declaration of Helsinki and following the CONSORT guidelines [13]. The participants were informed about the goals of the research, and written informed consent was obtained from the patients before participation.

The inclusion criteria were age 18 to 85 years, being candidates for short-term surgery under general anesthesia using a laryngeal mask airway. The exclusion criteria were risk of aspiration (full stomach, gastric reflux, pregnancy), weight less than 40 Kg or more than 110 Kg, presence of oral, pharynx, and airway pathology, insufficient pulmonary compliance, high airway resistance, presence of cervical vertebrae disease, history of musculoskeletal disorders and sensitivity to anesthetic agents.

A detailed pre-anesthesia evaluation was performed on all patients upon entering the operating room, and the patients were monitored using an electrocardiogram, non-invasive intermittent sphygmomanometer, and pulse oximetry. All patients were anesthetized with fentanyl 2 µg/Kg, thiopental 5 mg/Kg, and atracurium 0.3 mg/Kg, before LMA insertion.

The first group received remifentanil 1 µg/Kg (INR group), the second group received lidocaine 2% 1 mg/Kg (INL group), and the third group received normal saline, which was prescribed as 1 mL in each nasal passage. The content volume of the syringes in three groups increased to 2 mL by adding normal saline. Using the brain technique, a single-use LMA with the appropriate size, based on the right weight size, was then inserted by an anesthesiologist who was not a member of the research team [8]. The LMA insertion condition was evaluated by an anesthesiologist who was blinded to the study groups. The proper position of the LMA was confirmed by assessing bilateral chest movements, measuring end-tidal carbon dioxide ($ETCO_2$) and peripheral arterial oxygen saturation (Spo_2), and auscultation of breath sounds by stethoscope. Then, the patients were subjected to positive pressure ventilation and anesthesia maintenance with a mixture of oxygen, nitrous oxide 50/50, and isoflurane 0.8% to 1.2%.

The primary and secondary outcomes of the study were patients' demographic information such as age, height, weight, BMI, and ASA classification; LMA insertion condition, including function of the LMA, number of attempts to insert of LMA, complication during LMA insertion; and hemodynamic changes.

Before induction of anesthesia, mean arterial pressure (MAP), systolic blood pressure (SBP), diastolic blood pressure (DBP), and Peripheral arterial oxygen percentage (SPO2) were measured and recorded. These cases were repeated and recorded after the induction of anesthesia immediately before the insertion of the laryngeal mask, and 1, 3, and 5

minutes after the insertion of the laryngeal mask. Possible complications, including hypotension, hypertension, tachycardia, bradycardia, decrease in arterial oxygen saturation below 90, were evaluated and recorded.

The conditions of inserting the LMA, the number of attempts, the need for an extra dose of propofol (to increase the depth of anesthesia), and possible complications during LMA insertion (coughing, gagging, laryngospasm) were determined and documented.

The sampling procedure was simple and accessible method. The required sample size of the study was calculated using the sample size estimation formula to compare the averages and considering the confidence level of 95%, the test power of 80%, the standard deviation of the LMA embedding time, which is estimated at 9 seconds [12], and the effect size 0.8. The required sample size of the study was estimated as 20 people in each group.

The patient allocation in the study groups was determined by a nurse utilizing a computer-generated random number table. The results of this allocation were securely stored in sealed, opaque envelopes. Before the patient was admitted to the operating room, a separate nurse, who was not a member of the research team, assigned the patient to one of the three groups, based on the assigned number. These groups received either intranasally administered remifentanil (INR), lidocaine (INL), or saline (INS).

In this study, the patients, the anesthesiologist, and the data collector were all blinded to the drug assigned to each patient.

The data were analyzed using the SPSS software (SPSS Inc., Chicago, version 23), and a p value<0.05 was considered statistically significant. Data were analyzed using Chi-square statistical tests, one-way analysis of variance, and analysis of variance with repeated measurements.

In the present analysis, the normality of the data was assessed using the Shapiro-Wilk test. The alpha error of 5% (95% confidence interval [CI]) was employed as the threshold for accepting or rejecting the null hypothesis. All mean comparison tests were two-tailed tests. The continuous and categorical variables were presented as mean±SD and numbers (percentages), respectively. Additionally, the variance was evaluated using Mauchly's sphericity test. The applied statistical analyses were the Chi-square test, Mann-Whitney U test, and the One-Way Repeated Measures ANOVA test, followed by the Bonferroni test for multiple comparisons. p<0.05 was considered statistically significant.

Results

60 patients undergoing laryngeal mask insertion were divided into 3 groups of 20 people, who received intranasal remifentanil, intranasal lidocaine, and intranasal saline. During the study, no patients were excluded from the study due to unwanted complications (Figure 1).

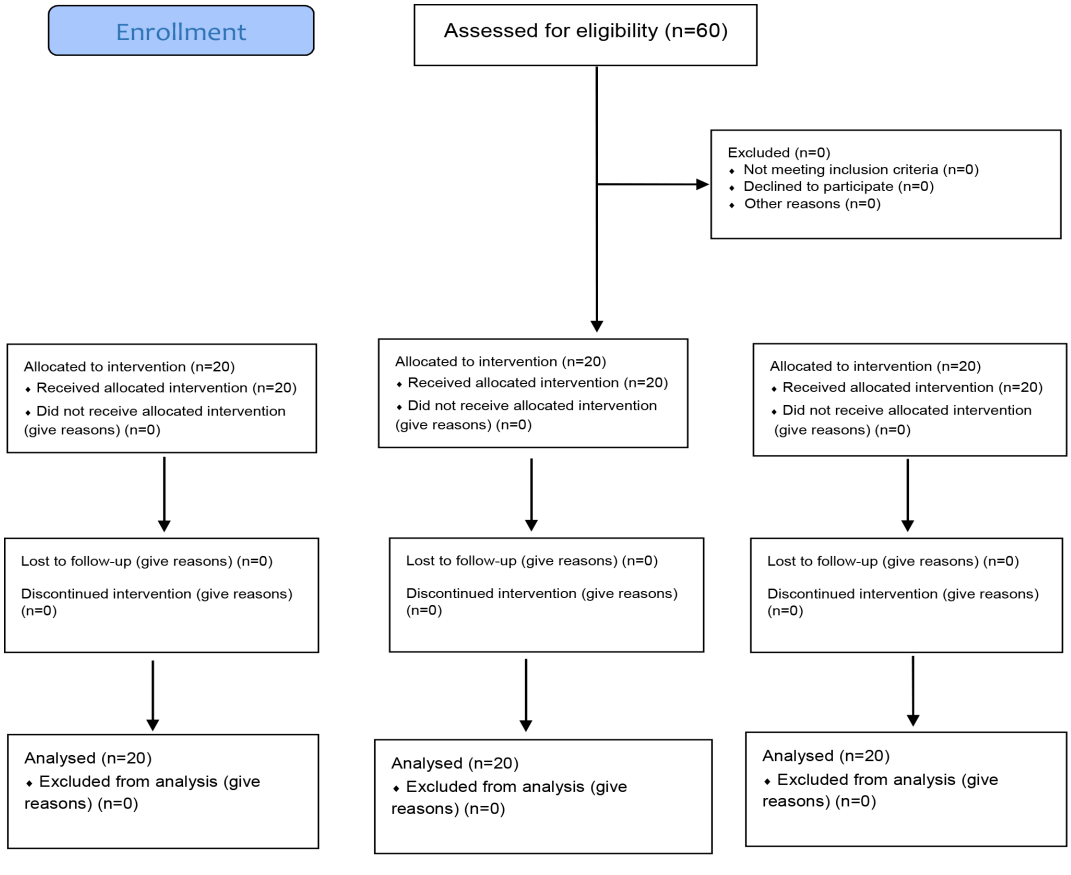

Fig. 1. The Consort flow diagram of the study

There were no significant differences between the three study groups in terms of basic and demographic variables, including age and sex distribution, weight and height, BMI, and ASA criteria (Table 1).

Table 2 shows the condition of LMA insertion in three studied groups. The success rate of inserting a laryngeal mask in the first attempt was 85% in the remifentanil group, 90% in the lidocaine group, and 75% in the saline group (p=0.73). There was no significant difference between the three groups in terms of the number of attempts to insert the LMA (p=0.61). The excellent and favorable performance of the laryngeal mask was 95% in the remifentanil group, 90% in the lidocaine group, and 80% in the saline group (p=0.73). Other variables including the need for additional propofol (p=0.53), gagging (p=0.53), cough (p=0.15), and laryngospasm (p=0.99) showed no significant difference between the three groups.

Table 3 shows that the cardiovascular response to LMA injection was weaker in the remifentanil group than in the lidocaine group, and it was lower

Table 1. Distribution of demographic variables in study groups

Variables		INR[a]	INL[b]	INS[c]	*p* value
Age (years) (mean±SD)		67.6±10.1	13.0±62.8	67±11.3	0.37
Weight (kg) (mean±SD)		72.2±11.4	13.9±70	71.2±17.4	0.89
Height (m) (mean±SD)		169.6±7.7	164.6±8.1	170.1±9.9	0.09
BMI (kg/m^2) (mean±SD)		25±2.8	25.42±3.58	24.4±4.58	0.69
Sex n(%)	Female	14 (70)	12 (60)	11 (55)	0.61
	Male	6 (30)	8 (40)	9 (45)	
ASA, N (%)	1	6 (30)	3 (15)	7 (35)	0.33
	2	14 (70)	17 (85)	13 (65)	

[a]INR: Intranasal remifentanil; [b]INL: Intranasal lidocaine; [c]INS: Intranasal Saline

Table 2. LMA insertion condition

Variables	INR[a]	INL[b]	INS[c]	*p* value
The function of the LMA after insertion (N %)				
Excellent	14 (70)	16 (80)	13 (65)	0.73
Optimal	5 (25)	2 (10)	4 (20)	
Weak	1 (5)	2 (10)	3 (15)	
The number of attempts to insert the LMA (N %)				
Once	17 (85)	18 (90)	15 (75)	0.61
more than once	3 (15)	2 (10)	5 (25)	
The need for extra propofol	0 (0)	2 (10)	2 (10)	0.53
Complications during LMA insertion				
Gagging	2 (10)	2 (10)	3 (15)	0.99
Cough	4 (20)	1 (5)	6 (30)	0.15
Laryngospasm	1 (5)	0 (0)	1 (5)	0.99

[a]INR: Intranasal remifentanil; [b]INL: Intranasal lidocaine; [c]INS: Intranasal Saline

Table 3. Comparison of cardiovascular response to laryngeal mask insertion during the study period in three groups

Variables	Time	INR	INL	INS	*p* value[a]
SBP (mmHg)	Before LMA insertion	150±19.3	142.7±21.7	149.3±21.6	0.49
	After LMA insertion	137.6±16.7	139.6±18.7	142±21.1	0.76
	Recovery room	133±22.7	134.2±27.8	138.8±19	0.71
	*p*b	0.024	0.029	0.001	0.91
DBP (mmHg)	Before LMA insertion	86.9±11.4	88.9±10.2	94±24.3	0.38
	After LMA insertion	83.4±12.8	87.6±16.1	87.9±8.5	0.47
	Recovery room	82.4±11.9	84.6±15.7	80.9±13.2	0.69
	p[b]	0.18	0.08	0.014	0.48
Heart rate (per minute)	Before LMA insertion	74.8±13.9	69.9±13.5	76.8±11.2	0.46
	After LMA insertion	76.6±11.8	76.8±11.2	82±7.81	0.3
	Recovery room	79.3±11.6	65.9±13.4	7±1.5 8	0.26
	p[b]	0.69	0.12	0.07	0.23
SPO_2	Before LMA insertion	94.6±3.2	94.6±3.2	95.4±1.1	0.08
	After LMA insertion	97.7±1.6	97.7±1.6	97.2±2.1	0.18
	Recovery room	1.4±98.5	98.5±1.4	98.1±3.1	0.8
	p[b]	0.3	<0.001	0.002	0.3

[a]Significant level of difference between three groups at each point of time according to one-way analysis of variance test. [b]Significance level of intra-group changes according to variance analysis test with repeated variance analysis.

in both groups than in the saline group. However, no significant difference was observed (p>0.05). There was no significant difference between the study groups in terms of mean arterial blood pressure (MAP), mean systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate, and Spo_2. (p>0.05).

In intra-group studies, systolic blood pressure changes were significantly different in all three nodes, but diastolic blood pressure changes were only significant in the control group. In inter-group studies, there was no significant difference in any of the mentioned parameters indicated between the three groups. During the study period, 14 patients (23.3%) experienced hypotension, bradycardia, and tachycardia. There were five patients in the INR group, five in the INL group, and four in the control group (25%, 30%, and 20%, respectively). However, there was no significant difference between the three groups (p=0.91).

Discussion

This study was conducted to compare the effect of intranasal administration of remifentanil and lidocaine on laryngeal mask insertion and cardiovascular response during the induction of anesthesia with sodium thiopental.

According to the results of the present study, there was no significant difference between the three studied groups in terms of age and sex distribution, BMI, and ASA criteria. Moreover, no confounding effect of the above factors on the main findings of the study was observed. Therefore, the differences observed between the study groups were most likely due to the type of drug used.

Our findings revealed that the first successful attempt to place LMA was 85% in the remifentanil group, 90% in the lidocaine group, and 75% in the control group. The performance of the inserted LMA was outstanding and optimal in 95% of the remifentanil group, 90% of the lidocaine group, and 85% of the control group.

In a study by Yazicioglu *et al.,* remifentanil 0.25 or 0.5 µg/Kg (R1, R2) and normal saline were used, and the results showed that excellent conditions for LMA placement (82.5% and 85% in R1 and R2 groups, respectively, compared to 32.5% in the control group) [14].

Verghese *et al.* conducted a study and investigated the effect of intranasal remifentanil 4 µg/Kg vs normal saline on airway response and intubation conditions in children under 7 years of age. As a result, intranasal remifentanil was associated with good to excellent intubation outcomes [15].

In another study which was conducted in patients aged 65 to 80 years, after induction of anesthesia with propofol 1 mg/Kg and prescription of a blind dose of remifentanil, LMA was inserted. The findings indicated that remifentanil 0.20±0.05 µg/Kg was associated with better LMA insertion conditions in 50% of elderly patients without significant hemodynamic changes during emergency airway management. [16].

Yao *et al.* investigated the optimal dose of intranasal remifentanil in children undergoing LMA insertion. In the studied groups, before induction of anesthesia, intranasal doses of 0.25, 0.5, 0.75, and 1 µg/Kg remifentanil were administered. The success rate in placing the laryngeal mask in the 4 mentioned groups was 33.3, 60, 86.7, and 100%, respectively. In terms of the occurrence of hemodynamic disorders, no significant difference was reported between the groups [17].

Lee *et al.* reported that remifentanil provided favorable conditions for LMA placement [5].

The results of the present study were consistent with previous studies [5, 12, 15, 16] in terms of the effect of remifentanil on the success of laryngeal mask placement and its performance. Remifentanil is a potent narcotic with a rapid onset and short duration of action, which can serve as an ideal suppressor of short-term but potent noxious stimuli such as LMA insertion. [5, 16].

Gharaei *et al.,* conducted a study on children aged 1-6 years old, with mild upper airway infection candidates for an immediate complete eye examination, using intravenous lidocaine (1.5 mg/Kg) or topical lidocaine before inserting a laryngeal mask. They observed that the incidence of postoperative cough was lower in the intravenous lidocaine group than in the topical lidocaine group [18].

In another study, Ahmed *et al.* found that when a local aerosol of 10% lignocaine was sprayed on the posterior wall of the pharynx three minutes prior to propofol induction, without the use of neuromuscular blockade, it provided better LMA insertion conditions than intravenous lignocaine and also reduced the number of attempts needed for LMA insertion and minimally altered cardiovascular responses [19].

Previous studies indicated that lidocaine improves LMA insertion [20] and reduces the incidence of airway complications after surgery in children with upper respiratory infections [21]. This issue could be explained by the fact that local anesthetic might lessen the irritation of the pharyngolarynx brought on by LMA; hence, minimizing the adverse effects such as cough and laryngeal spasm [20, 21].

Previous studies reported that lidocaine improved LMA insertion and reduced the incidence of airway complications in children with upper respiratory infections [22, 23]. This finding could imply that local anesthetic can reduce the stimulation of LMA in the pharyngeal-larynx, which would lessen the side effects, such as cough and laryngeal spasms [23, 24].

In the present study, the laryngeal mask insertion was performed in the first attempt in 90% of the cases in the INL group, and the performance of the inserted laryngeal mask was outstanding or optimal in 90% of cases. Additionally, after LMA removal,

this group experienced less coughing than the control group, which was in line with other research findings [4, 17-20, 22-24].

In a study, Lee *et al.* investigated the effect of topical lidocaine and intravenous remifentanil on laryngeal mask insertion in awake patients. Their findings indicated that there was no significant difference in the number of attempts to place the LMA and the occurrence of complications during and after the insertion of LMA between the two studied groups [25]. Therefore, the findings of this study were in line with those of the present study.

It is important to remember that the drug was absorbed through the mucosal membrane after intranasal administration, and the risk of developing serious hemodynamic disorders was lower than in the intravenous injection method [20].

It should be noted that our study had several limitations. This study had a relatively small sample size. The remifentanil requirement for LMA insertion could differ according to sex [26]. This study was conducted only in a hospital. The findings of the study might be different in different races. Therefore, it is recommended that further research be conducted while considering the limitations of this study.

In terms of success in LMA insertion in the first attempt, LMA performance, occurrence of side effects (cough, laryngospasm, etc.), intranasal remifentanil had a similar effect to intranasal lidocaine.

Intranasal remifentanil was somewhat more effective than intranasal lidocaine in attenuating the cardiovascular response to LMA insertion.

Therefore, in the present study, intranasal remifentanil was not found to be superior to intranasal lidocaine.

Declaration

Ethics clearance and consent to participate: The research protocol received approval from the ethics committee at Isfahan University of Medical Sciences (IR.MUI.MED.REC.1398.509). All patients signed an informed consent to enter the study.

Consent for publication: All authors have expressed their consent to the publication of this study.

Conflict of Interest: The authors declared that there was no conflict of interest.

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Authors' Contribution: The conception and design of the work by H.S; Data acquisition by M.B, H.M; Analysis and interpretation of data by HM; MB; Drafting the work by HS; Revising it critically for important intellectual content by HS, HM; All the authors approved the final version to be published; and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work.

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