Original Article

Comparing the safety and efficacy of three different doses of atracurium in facilitating the insertion of laryngeal mask airway in patients undergoing phacoemulsification cataract surgery: A randomized clinical trial

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Abstract

Background: In this study, we aimed to evaluate the safety and efficacy of three different doses of atracurium on conditions of laryngeal mask airway (LMA) insertion, first-try success rate, and possible complications. **Materials and Methods:** A total of 120 patient's ≥18 years old were randomly divided into three groups of 40. The study groups received fentanyl 2 μg/kg thiopental 5 mg/kg and atracurium in doses 0.2 mg/kg, 0.4 mg/kg, and 0.6 mg/kg, respectively, based on the patient group. The conditions of LMA insertion, hemodynamic responses, and complications were evaluated and compared in the groups. **Results:** In the study groups, the LMA placement was difficult in 15%, 7.5%, and 2.5%, respectively (P = 0.13). There was no statistically significant difference among the groups regarding the success rate in the first attempt to the insertion of LMA. Of the three groups, 5%, 2.5%, and 2.5% had bleeding at the place of mask insertion (P = 0.77). 17.5%, 7.5%, and12.5% had sore throat, respectively (P = 0.4). No patient experienced laryngospasm during the study. Furthermore, changes in blood pressure, heart rate, and oxygen saturation were not significant in the three groups. **Conclusion:** All three doses of atracurium have similar effects on the condition of LMA insertion. Atracurium 0.4 mg/kg accompanied by higher success on LMA insertion in the first attempt and lower airway complications (bleeding and sore throat), increasing this dose had no significant effect on the success rate of LMA insertion.

Keywords: *Atracurium, laryngeal mask airway, phacoemulsification*

Introduction

When general anesthesia is indicated for cataract surgery, immobilization of the patient and adequate depth of anesthesia should be assured by an anesthetist. At this stage, maintaining the patient's airway and providing adequate ventilation are the important responsibilities of anesthesiologist. The laryngeal mask airway (LMA) is a safe, reliable, and simple device to maintain the airway, which also provides effective ventilation and oxygenation. In addition, with use of LMA, laryngoscopy and consequently the side effects associated with laryngoscopy are avoided.[1] LMA insertion requires an adequate depth of anesthesia to prevent airway reflexes (gagging, coughing, and spasms).[2]

The placement of LMA requires sufficient depth of anesthesia to prevent airway reflexes (recoil, cough, and spasm).[2] Balanced anesthesia, including atracurium, provides better surgical conditions.[3]

Adequate relaxation can reduce many of the complications of LMA insertion. Many studies have been done on the effects of various drug regimens, including muscle relaxants (both depolarizing and nondepolarizing) as well as opiates on the quality of LMA-insertion conditions.[4]

Various techniques are used to LMA insertion securely, such as the classical method, the 180° rotation technique (inversion technique) and the LMA placement with the laryngoscope.[5] In previous studies, different doses of muscle relaxant agent have been studied to improve the LMA placement conditions,

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such as the study by Palanisamy *et al*.[6] which investigated succinylcholine in two doses of 0.1 mg/kg and 0.5 mg/kg in inducing anesthesia by thiopental. They found that the administration of 0.5 mg/kg of succinylcholine provided better conditions for LMA placement than the dose of 0.1 mg/kg. However, Chen[7] believed that the muscle relaxants do not improve LMA placement condition and using them can increase recovery time and hospital costs. Atracurium is a nondepolarizing muscle relaxant with an effective length of approximately 20–30 min.[8] Atracurium in competition with acetylcholine in binding to end-plate cholinergic receptors reduces its response to acetylcholine and by inhibiting neurotransmission, it causes paralysis in the skeletal muscle.[8] El-Kasaby compared between atracurium and cisatracurium at the same dose (2 × ED95 dose) and observed that the relaxant effect of atracurium was greater than that of cisatracurium.[9]

The use of low doses of ciatatersurium compared with succinylcholine, tends to shorter the mean time to return spontaneous respiration.[10]

In previous studies, most muscle relaxants have been evaluated at different dosages in airway management, but to the best of our knowledge, no study compared the effects of different doses of atracurium on LMA placement conditions; therefore, the present study performed to find the minimum desirable and safe atracurium dosage to improve the condition of the insertion of the LMA as the primary endpoint was performed.

Materials and Methods

This double-blind clinical trial study was conducted at the Feiz University hospital, Isfahan, Iran, in 2018. Candidates for elective cataract surgery were recruited for the current study.

Following approval of this study given by the Medical Ethics Committee of Isfahan University of Medical Sciences (IR.MUI.REC.1396.3.925) and register in the clinical trial center (IRCT201305081766N6). A total of 120 patients undergoing cataract surgery under general anesthesia were included.

The inclusion criteria were patients aged more than 18 years, American Society of Anesthesiologist (ASA 1) or ASA 2, fasting for 8 h, and informed consent to participate in the study.

The exclusion criteria included the risk of aspiration (full stomach, gastroesophageal reflux disease, and pregnancy), weight <40 or more than 110 kg, the presence of airway or oropharyngeal cancer, inappropriate pulmonary compliance, high airway resistance, cervical spine disorder, history of sensitivity to any of the anesthetics, and musculoskeletal disorders. Failure to insert LMA at the first attempt and the presence of air leak after LMA insertion, which did not resolve after adjusting cuff pressure, changing the patient's head, or reducing the current volume of the anesthesia machine, also led to the exclusion of the patients.

Statistical analysis

The sampling was done using the convenience sampling method. The sample size was estimated using the following formula for comparing proportions, taking into account 95% confidence level and 80% power, and considering the incidence rate of attempts to insert the LMA ($P = 0.5$). Furthermore, the effect size among groups was considered 0.3. Accordingly, the sample size was determined as 40 in each group.

$$n = \frac{2\left(Z_{1-a/2} + Z_{1-b}\right)^2 P\left(1-P\right)^2}{D^2\left(\text{effect size}\right)} = \frac{2(1.96+0.84)^2\left(0.5\right)^2}{(0.3)^2} = 40$$

The obtained data were entered into the SPSS software version 24 (SPSS Inc., Chicago, Ill., USA). The tests used in this study included the Chi-square test to evaluate the qualitative variables. Mann-Whitney test was used to compare the qualitative variables between the groups. One-Way Analysis of Variance test was used to compare the quantitative variables. To compare the quantitative variables between the two groups, Kruskal–Wallis test Repeated-measures ANOVA was used to evaluate the changes in data including mean arterial pressure, heart rate, and percent of arterial oxygen saturation. $P < 0.05$ was considered as statistically significant level.

This study was initiated in Faiz Medical Center. Patients were evaluated on the day before surgery according to the European Society of Anesthesiology guidelines, and informed written consent was obtained from all 120 eligible patients.

The recruited patients were randomly assigned into three groups ($n = 40$) using the Random Allocation Software [Figure 1]. Patients' demographic data, including age, sex, weight, and heights were recorded using a check list. Before anesthesia induction, all patients underwent continuous standard monitoring, including electrocardiography, intermittent noninvasive blood pressure, pulse oximetry, and capnography. Baseline measurements were recorded. Patient pretreatment included Ringer's lactate 5 ml/kg and Midazolam 2 mg. Preparation of medication including fentanyl 2 μ/kg, thiopental sodium 5 mg/kg, and atracurium (in three doses for study groups in equal volume), were performed by anesthesiology resident who did not play a role in data collection. Induction of anesthesia and insertion of the laryngeal mask were performed by an experienced anesthesiologist who was unaware of the study groups.

The selection of LMA size was based on patient's weight, and LMA placement was using the standard method provided by brain.[11] Assuring correct insertion of LMA and fixing it, patients underwent positive

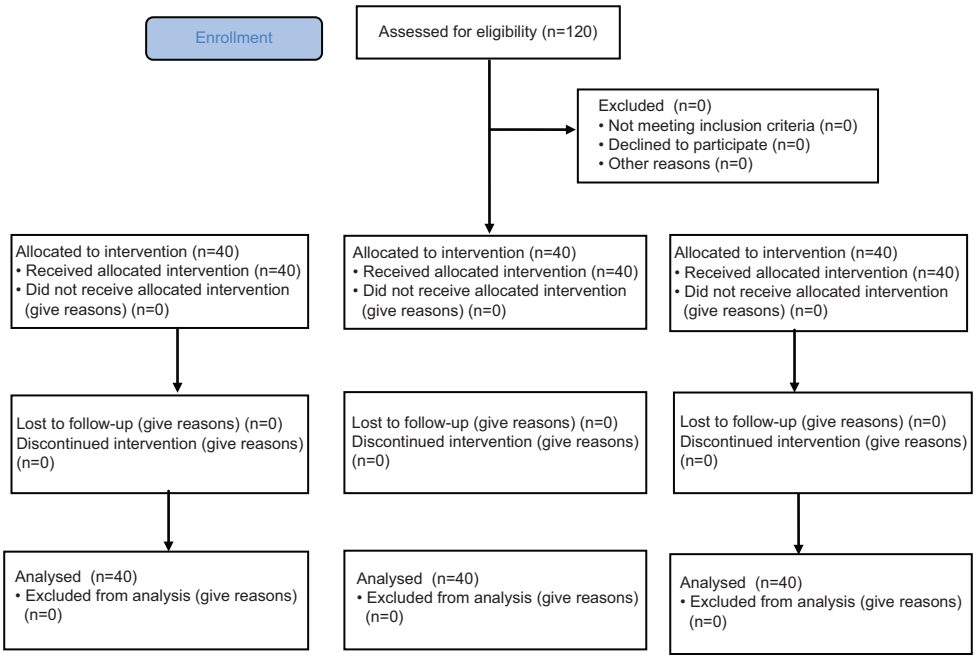

Figure 1: Consort flow diagram of the study

pressure ventilation. The anesthesia was maintained using 50%–50% NO-O_2 mixture and isoflurane 0.8%–1.2%. The correct insertion of LMA was confirmed by proper chest expansion, auscultation of the lung, lack of or very low air leakage, capnography during manual ventilation, and airway pressure ≤20 cm H2O. In this study, the patients, the surgeon, and the person collecting the information were unaware of the patients grouping and the dose of received atracurium. The patients' heart rate, blood pressure, and blood oxygen saturation values were measured before induction, 1 min after induction, before inserting LMA, 1, 3, 5, and 10 min after inserting LMA, and during recovery every 15 min.

In this study, the anesthesiologist who had no role in research team evaluated the condition and complication during insertion and remove of the LMA (mouth opening restriction, difficulty in placing LMA, localized bleeding at tip of LMA, gagging, coughing, movement, and laryngospasm). A nurse who was blinded to study groups recorded data including anesthesiologist assessments results and cardiovascular response.

The general conditions of laryngeal mask placement were assessed according to the modified Lund and Stovener criteria.

- Excellent: No gagging or coughing, no patient movement, and no laryngospasm
- Good: Mild-to-moderate gagging or coughing, mild-to-moderate patient movement, and no laryngospasm
- Poor: Moderate-to-severe gagging or coughing, moderate-to-severe patient movement, no laryngospasm
- Unacceptable: Severe gagging or coughing, severe patient movement, laryngospasm.

The frequency of attempts to insert LMA was recorded for each patient. However, statistical analysis of feasibility of LMA insertion was done only for the first attempt. At the end of the surgery, the volatile anesthetic was discontinued, and ventilation was performed manually to ensure spontaneous breathing. Neuromuscular blockade reversal was performed using atropine 0.02 mg/kg and neostigmine 0.04 mg/kg. On the following day surgery, patients were evaluated for postoperative side effects, such as sore throat (mild, moderate, and severe). All study data were recorded by a nurse who was blinded to study groups.

Results

In this study, 120 patients in three equal groups of 40 each received atracurium doses of 0.2, 0.4, and 0.6 mg/kg to facilitate laryngeal mask placement, respectively. Three groups did not differ significantly in terms of age ($P = 0.8$), sex ($P = 0.2$), height ($P = 0.86$), weight ($P = 0.87$), body mass index ($P = 0.87$), ASA ($P = 0.19$), and LMA number ($P = 0.92$) [Table 1].

Three different doses of atracurium did not have the same efficacy in facilitating LMA insertion, the first successful attempt to insertion a laryngeal mask was 33 cases (group 0.2), 37 cases (group 0.4), and 35 cases (group 0.6), respectively, but no significant difference was observed between the three groups ($P = 83$) [Table 2].

The results showed that 10 patients had difficulty in inserting LMA, 6 patients (group 0.2), 1 patient (group 0.4), and 3 patients (group 0.6), respectively, but there was no significant difference between the three groups ($P = 0.13$). There were also 15 cases of difficulty in laryngeal mask

Table 1: Distribution of demographic and general variables across three groups

Variable	Atracurium dose (mg/kg)			*P*
	0.2	0.4	0.6	
Mean of age (year)	66.5±10.6	67.1±10.1	65.3±15.3	0.8
Mean of weight (kg)	68.2±12.1	67.2±15.5	68.7±12.9	0.87
Mean of height (cm)	166.4±8.4	167.5±17.9	166±10	0.86
Mean of BMI (kg/m^2)	24.58±3.79	24.13±4.92	24.81±3.41	0.75
Sex				
Male	23 (57.5)	15 (37.5)	16 (40)	0.2
		15 (37/5)	16 (47/5)	
Female	17 (42.5)	25 (62.5)	24 (60)	
	23 (37/5)	25 (62/5)	24 (64/5)	
ASA				
1	24 (60)	16 (40)	16 (40)	0.19
2	16 (40)	24 (60)	24 (60)	
LMA number				
3	3 (7.5)	3 (7.5)	4 (10)	0.92
4	32 (80)	34 (85)	31 (77.5)	
5	5 (12.5)	3 (7.5)	5 (12.5)	

ASA: American Society of Anesthesiologists, BMI: Body Mass Index, LMA: Laryngeal mask airway

Table 2: Conditions of insertion and removal of the laryngeal mask airway in three groups

Variable	Atracurium dose (mg/kg)			*P*
	0.2	0.4	0.6	
First-attempt success rate (%)	33 (82.5)	39 (97.5)	37 (92.5)	
Difficulty in LMA insertion	6 (15)	1 (2.5)	3 (7.5)	0.13
Mean of time needed to insert LMA (s)	8.18±1.97	7.03±1.52	6.74±1.83	0.001
Mean of time needed to remove LMA (min)	31.82±1.24	34.46±3.27	39.72±1.98	0.001
Number of attempts				
1	33 (82.5)	37 (92.5)	35 (87.5)	0.83
>1	7 (17.5)	5 (7.5)	5 (12.5)	

LMA: Laryngeal mask airway

insertion in the first attempt, 7 (17.5%), 3 (7.5%) in group 0.4, and 5 (12.5%) in group (0.6%).

The means of time needed for LMA insertion were 8.18 ± 1.97 s, 7.3 ± 1.52 s, and 6.74 ± 1.83 s in group 0.2 mg/kg, group 0.4 mg/kg, and group 0.6 mg/kg, respectively, leading to statistically significant difference among three groups ($P = 0.001$). The means of time needed for LMA removal were 31.82 ± 1.24 min, 34.46 ± 27.23 min, and 39.72 ± 1.98 min in group 0.2 mg/kg, group 0.4 mg/kg, and group 0.6 mg/kg, respectively, leading to statistically significant difference among three groups ($P = 0.001$). The first attempt to insert LMA was successful in 33 patients in group 0.2 mg/kg, 35 patients in group 0.4 mg/kg, and 35 patients in group 0.6 mg/kg, but no significant difference was seen among three groups in this regard ($P = 0.83$). The results are shown in Table 2.

The incidence of complications during LMA insertion was not significantly different among three groups, so that none of the patients in three groups experienced laryngospasm. The incidence of nausea and vomiting in three groups was 3, 1, and 2, respectively. After remove of LMA in recovery room 7, 3, and 5 patients had sore throat, respectively. Twenty-four hours after surgery, sore throat incidence was 4, 1, and 0 in three groups, respectively. The incidence of coughing after LMA removal was 9, 6, and 4, and its incidence was 4, 2, and 1 24 h after surgery in three groups, respectively. In groups of 0.2 mg/kg, 0.4 mg/kg, and 0.6 mg/kg, 2, 1, and 1, respectively, experienced local bleeding in LMA position. In two cases (one in group 0.2 mg/kg and one in group 0.4 mg/kg), LMA was not inserted in the right position. The results are shown in Table 3.

The evaluation of patients' hemodynamic parameters before LMA insertion up to 10 min after its insertion revealed no significant difference among three groups. On the other hand, repeated measures ANOVA showed that the changes in mean blood pressure, heart rate, and blood oxygen saturation did not lead to significant difference among three groups [Figures 2-4].

Discussion

Safe and successful in the placement of the LMA requires jaw relaxation, suppression of airway reflexes, coughing,

Table 3: Incidence of complications occurred during laryngeal mask airway insertion across three groups

Variable	Atracurium dose (mg/kg)			*P*
	0.2	0.4	0.6	
Sore throat	7 (17.5)	3 (%7/5)	5 (12.5)	0.4
Coughing	9 (22.5)	6 (%15)	4 (10)	0.31
Laryngospasm	0 (0)	0 (0)	0 (0)	>0.99
Nausea and vomiting	3 (7.5)	1 (2.5)	2 (5)	0.59
Difficulty in LMA insertion	6 (15)	1 (2.5)	3 (7.5)	0.13
Local bleeding in LMA position	2 (5)	1 (2.5)	1 (2.5)	0.77
mouth opening restriction	0 (0)	0 (0)	0 (0)	>0.99

LMA: Laryngeal mask airway

gagging, and laryngeal spasm. The purpose of this study was to evaluate the safety and efficacy of three different doses of atracurium on condition of LMA insertion, hemodynamic response, and complications

The results of the study showed that the three doses had a similar effect on condition of the LMA insertion; by increasing the dose of atracurium, there was no significant change in the condition of laryngeal mask insertion, but the failure rate in the first attempt in the 0.2 mg/kg group was higher than the other two groups, and the success rate in the first attempt to placement of the LMA in the 0.4 mg group was higher than the other two groups. Success rate in the first attempt to LMA insertion was 82.5%, 92.5%, and 87.5% in groups 0.2, 0.4, and 0.6, respectively, we had no case of failure in the placement of LMA. There was a significant difference between the groups in terms of mean time required for laryngeal mask insertion and removal; the 0.2 mg/kg group had the longest time to place the LMA and the shortest time to remove it.

There were no statistically significant differences in the complications of LMA insertion in the three groups.,

There was no significant difference between the groups regarding the change in hemodynamic parameters at the time of the study. In this study, hemodynamic stability was maintained during the study, and no hemodynamic disorder required treatment intervention.

Group 0.4 had a more stable heart rate at the time of evaluation

Pooranjfian *et al*. in the induction of anesthesia with sodium thiopental and atracurium 0.5 mg/kg, success rate in laryngeal mask insertion by the resident was 80.6% in the first attempt and 12.9% in the second attempt, this rate was higher in the present study. In our study, an experienced anesthesiologist inserted the laryngeal mask.[12]

Chui and Cheam, in patients undergoing propofol anesthesia, the effects of two different doses of mivacurium were compared with normal saline in LMA insertion, they resulted. Both doses of mivacurium significantly facilitate LMA insertion compared to normal saline.[13]

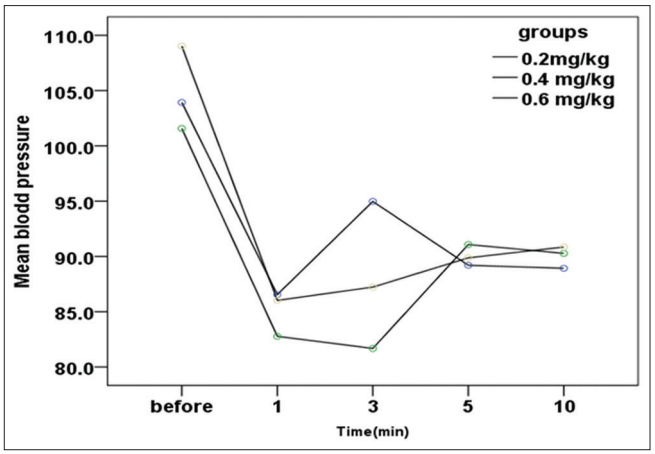

Figure 2: The trend of changes in mean of arterial blood pressure before laryngeal mask airway insertion and 10 min after its insertion in three groups (*P* = 0.88; power: 0.81)

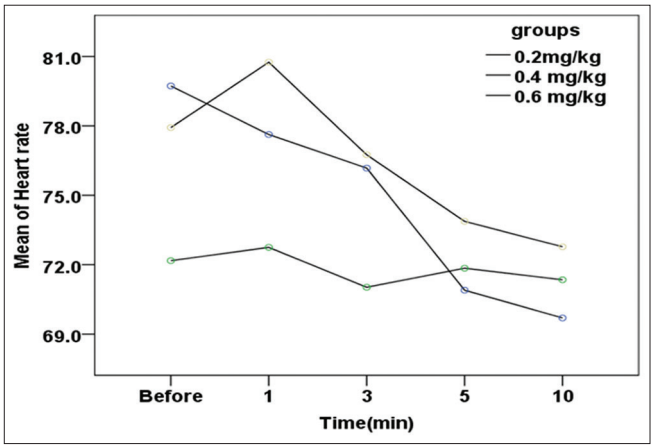

Figure 3: The trend of changes in heart rate before laryngeal mask airway insertion and 10 min after its insertion in three groups (*P* = 0.13; power 0.99)

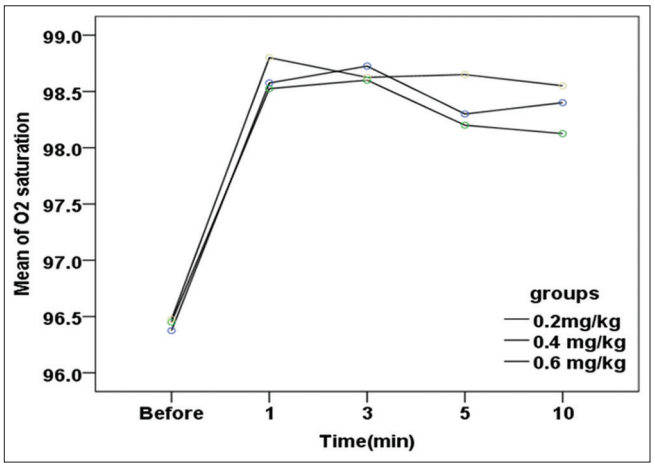

Figure 4: The trend of changes in blood oxygen saturation before laryngeal mask airway insertion and 10 min after its insertion in three groups (*P* = 0.55; power: 0.83)

Atracurium with jaw relaxation facilitates laryngeal mask placement, reduces the time required for LMA placement and reduces postoperative sore throat.[14]

In the present study, atracurium was associated with facilitation of laryngeal mask placement, which is consistent with previous studies.[10-15,17,18]

With increasing dose of atracurium, there was a significant increase in the success of the first attempt to place the laryngeal mask. This result is in line with previous studies.[3,15]

Given the effect of muscle relaxant on reducing the complications of insertion and removal of LMA, our findings are similar to previous studies. [15-17]

Darlong *et al*. concluded in a study that a balanced anesthesia technique, including atracurium, provides better surgical conditions for cataract surgery in children.[3]

The result of the above study is in line with the present study, which increased the dose of atracurium from 0.2 to 0.4 mg/kg, facilitating laryngeal mask placement.

However, in our study, there was no difference in laryngeal mask placement by increasing the dose of atracurium from 0.4 mg/kg to 6.6 mg/kg that could be due to the difference in age of the patients; in the present study, patients were mostly the elderly and had less need for muscle relaxants

Gunaseelan *et al*.[15] compared two different doses of succinylcholine to facilitate LMA insertion and concluded that adding a low dose of succinylcholine (0.1 mg/kg) to the standard dose of propofol improved the conditions for LMA insertion and caused reduced airway responsiveness to LMA.

Palanisamy *et al*.[6] compared the effects of two doses of succinylcholine on LMA incubation conditions and concluded that succinylcholine at a dose of 0.5 mg/kg compared to 0.1 mg/kg provided better conditions for LMA placement; the result of the study is in line with the present study, which increasing the dose of atracurium from 0.2 to 0.4 mg/kg facilitated laryngeal mask placement,

Chui and Cheam[13] in a study concluding that the conditions in LMA insertion with mivacurium 0,4 mg/kg is similar to 0.8 mg/kg; we conclude that increasing the dose of atracurium from 0.4 to 0.6 mg/kg did not have a specific effect on the success rate of first attempted LMA insertion, which is consistent with the previous study.

In the present study, mean time required for laryngeal mask placement decreased with increasing dose of atracurium from 8 s to 6 s; in previous studies, the mean time required for LMA placement was in the range of 6–38 s.[17-19]

Possible causes of time discrepancy can be different techniques of laryngeal mask placement, time calculation method, and individual experience.

In our study, the timing of laryngeal mask insertion was considered from the time placement of LMA cuff in front of the open mouth to the first successful ventilation was diagnosed, without calculating the time required to fix the laryngeal mask.

In the present study, the frequency of difficult LMA insertion in the 0.2 mg/kg group was more common than the other two groups, this group had the longest time to LMA placement and the least time to remove it, the probability cause may be a lower dose of atracurium and an incomplete jaw relaxation when the laryngeal mask is inserted.

Side effects (cough, nausea and vomiting, bleeding around the LMA cuff) showed no significant difference between the three groups. The incidence of cough after laryngeal mask removal in the first 24 h was lower in 0.6 mg/kg group than the other two groups.

In a study, Jarineshin *et al*. evaluated the hemodynamic profile between laryngeal mask insertion and laryngoscopy in anesthesia with propofol and atracurium (0.5 mg/kg). The results showed that the mean values of SBP and DBPs after the induction of anesthesia were lower in all groups compared to baseline. Mean SBP and DBP were not significantly different between the groups at the time of the study.[19] Rastegarian also observed in his study that heart rate, systolic and diastolic blood pressure decreased after LMA insertion.[20] In our study, a decrease in systolic and diastolic blood pressure and arterial pressure following the induction of anesthesia and LMA insertion was observed, which is in line with previous studies, suggesting the potential for cardiovascular response to anesthetics and relaxation medications.

Based on the findings of this study and previous studies, it can be concluded that the use of atracurium in general anesthesia is associated with the facilitation of LMA insertion, less complications, and relative hemodynamic stability. However, increasing the dose of atracurium did not reduce the complications of LMA insertion. In addition, these doses did not have a significant effect on hemodynamic parameters.

Conclusion

Our findings showed that all three doses of atracurium, namely 0.2, 0.4, and 0.6 mg/kg had similar efficacy in facilitating LMA insertion following anesthetic induction with thiopental sodium, and they caused no significant difference regarding the incidence of LMA-induced complications, recovery duration, and changes in the hemodynamic parameters. We suggest that the use of each of these atracurium doses can be safe and effective during LMA insertion, and the efficacy of this medication in reducing LMA induced complications does not improve by increasing its dosage.

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Conflicts of interest

There are no conflicts of interest.

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