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The effectiveness of the Ambu® AuraGain™ laryngeal mask on hemodynamic and respiratory parameters in patients undergoing septoplasty: A randomized prospective clinical study

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Ethics Committee Approval
Adıyaman University Biomedical Research Ethics Committee approval was obtained from the ethics committee dated 28.04.2015 and numbered 2015 / 03-14.
All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

Conflict of Interest
No conflict of interest was declared by the authors.

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Abstract

Background/Aim: The use of laryngeal masks is increasing with the introduction of 3rd generation airway vehicles. However, endotracheal intubation is preferred by most anesthesiologists in septoplasty operations due to airway safety concerns. In this study, we aimed to compare the 3rd generation airway device, Ambu® Auragain ™ LMA, with tracheal intubation in terms of hemodynamic and respiratory parameters.
Methods: This study included 69 patients aged 18–60 years with an ASA score of 1–2 who were scheduled for septoplasty in Adıyaman University Research and Educational Hospital between 2016.01.01 and 2017.06.31. Study groups were randomly defined as Group 1 - Ambu® AuraGain™ laryngeal mask (LMA, n = 37) and Group 2 - endotracheal intubation (ETT, n = 32), and the hemodynamic and respiratory parameters were measured and recorded.
Results: The demographic data and partial oxygen saturation of the patients were similar ($P>0.05$ for all values). The patients in the ETT group had a higher heart rate at induction, intubation and at the first minute compared to the LMA group ($P<0.05$ for all values). The mean arterial pressure was significantly lower at induction, intubation, at minutes 1, 2, 3, and 4 of intubation, and at extubation in the LMA group ($P<0.05$ for all values).
Conclusion: The Ambu® AuraGain™ laryngeal mask was similar to or better than tracheal intubation in terms of hemodynamic and respiratory parameters. The Ambu® AuraGain™ LMA can be used as an equivalent to tracheal intubation in terms of hemodynamic and respiratory parameters.

Keywords: Ambu® AuraGain™ laryngeal mask, Tracheal intubation, Septoplasty

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Introduction

Endotracheal intubation is conventionally preferred for septoplasty operations due to concerns about contamination of the tracheobronchial tree by surgical bleeding and risk of damage to the airway by displacement during surgical maneuvers. However, the introduction of the new generation of laryngeal mask airways (LMA) has led to increasing use in head and neck surgeries such as septoplasty due to their higher seal and full adaptation to the trachea's anatomy [1, 2].

The Ambu® AuraGain™ (Ambu A/S, Ballerup, Denmark), a third-generation airway device, is made of polyvinyl chloride and, thanks to its curved structure, is compatible with the anatomy of the respiratory tract [3]. This structure provides a higher seal. It has a gastric tube for gastric aspiration and allows the endotracheal tube to pass through it, thus allowing for blind intubation or fiberoptic use [2, 3].

The goal of our investigation was to compare the Ambu® AuraGain™ LMA and an endotracheal tube (ETT, Bıçakçılar, İstanbul, Turkey) on hemodynamic and respiratory parameters in patients undergoing septoplasty.

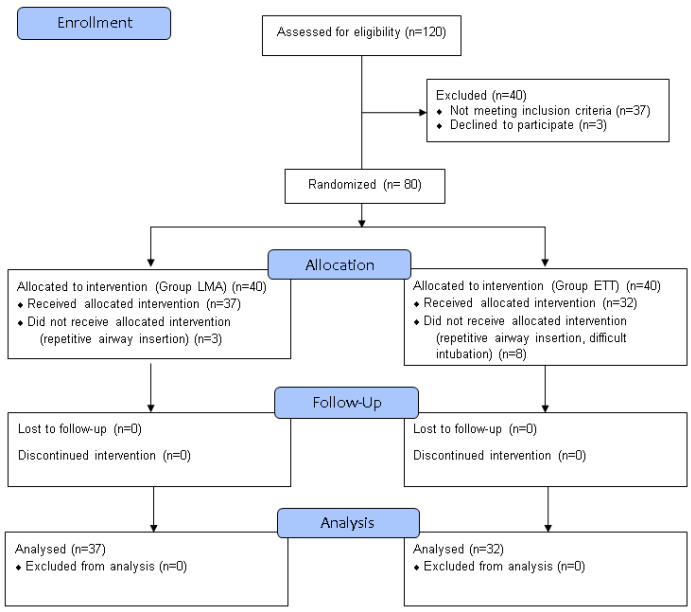
Materials and methods

This randomized, prospectively controlled, equivalence study was approved by Adıyaman University Chairmanship of Biomedical Research Ethics Committee (no. 2015/03-14, dated 2015.04.28). The minimum sample size of the study was calculated as 30 individuals in each group, with an alpha error level of 0.05 and a test strength (beta) of 0.8, taking previous studies on the subject as reference [4]. The study included 69 patients aged 18–60 years with an American Society of Anesthesiologists (ASA) score of 1–2 who underwent septoplasty at Adiyaman University Training and Research Hospital between 01 January 2016 and 31 June 2017 and was conducted in accordance with the Helsinki Declaration. The report follows the Consolidated Standards of Reporting Trials (CONSORT). Because possible risks such as bronchospasm, bleeding risk, dental damage, etc. would affect the study data, patients with difficult intubation risk, a Mallampati score of 3–4, a body mass index (BMI) >30 kg/m^2, a short neck, thyromental distance <60 mm, mouth opening <25 mm, a history of obstructive sleep apnea, and those with respiratory, cardiac, renal, and hepatic diseases were excluded from the study. Due to the nature of the study, repetitive trials were not allowed. Patients undergoing repeated trials were excluded from the study, as it may affect hemodynamic and respiratory parameters. The references used for the study were scanned using PubMed, Google Academic, Scopus, and index Copernicus.

The patients were randomly assigned into ETT (n:32) and LMA (n:37) groups by a nurse blinded to the study using the sealed envelope method. All participating patients gave informed consent prior to the operation and were preoperatively evaluated by an anesthesiologist. All the procedures were performed by experienced anesthesiologists. The patients were placed on the operating table without any sedation after a proper fasting time and monitored by pulse oximetry, non-invasive blood pressure, and electrocardiogram (ECG). The time from the handling of the airway device to the observation of the capnography waveform was considered the insertion time. All patients were preoxygenated for 5 minutes (100% 4–6L O_2). In the ETT group, anesthesia was induced with intravenous propofol (2 mg/kg^{-1}; Polifarma, Istanbul, Turkey), fentanyl (1 mcg/kg^{-1}; Vem, Istanbul, Turkey), and rocuronium (0.6 mg/kg^{-1}; Polifarma, Istanbul, Turkey), and an endotracheal tube of appropriate size was placed. In the LMA group, induction was performed using intravenous propofol (2 mg/kg^{-1}), fentanyl (1 mcg/kg^{-1}), and rocuronium 0.2 mg/kg^{-1}, and an Ambu ® AuraGain™ LMA (Ambu, Ballerup, Denmark) was placed. After making sure there was no air leak, both lungs were ventilated, and seeing the capnography waveform, the patient was connected to the anesthesia device (Primus^{TM} Drager, Drager Medical Gmnp, Lübeck, Germany). Mechanical ventilation was adjusted as follows: Tidal volume of 6–10 mL/kg, end-tidal carbon dioxide ($EtCO_2$) of 35–45 mmHg, and a respiratory rate of 10–14 min^{-1}. Oropharyngeal seal pressure was set to a flow rate of 3 L/min and Adjustable Pressure Limitation (APL) pressure was set to a maximum pressure of 40 cmH_2O. Anesthesia was preserved with an admixture of sevoflurane (Abbott, Istanbul, Turkey) and 50% air–oxygen at a minimal alveolar concentration (MAC) of 1. At the end of the operation, the anesthetic agent was discontinued, and ventilation was provided with 100% oxygen. Following spontaneous breathing, neostigmine (0.04 mg/kg^{-1}; Adeka, İstanbul, Turkey) and atropine (0.02 mg/kg^{-1}; Biofarma, İstanbul, Tukey) were intravenously (IV) administered. The patients with a modified Aldrete's score of 9 or above who achieved a sufficient tidal volume were extubated. Tramadol 100 mg was used for postoperative pain management.

The patients' demographic data and procedural complications were recorded. Their vital findings were measured preoperatively, at intubation, at 1, 2, 3, 4, 5, 10, 15, 20, and 30 minutes post-intubation, and at extubation. End-tidal carbon dioxide ($EtCO_2$) and airway pressures were perioperatively recorded. The consort flow diagram applied for patient selection is shown in figure 1.

Figure 1: CONSORT 2010 flow diagram



Statistical analysis

IBM SPSS Statistics version 21.0 (IBM Corp, Armonk, NY, USA) software was used for statistical analyses and calculations. The level of statistical significance was set at

P<0.05. Number (n) and percentages (%) were used to demonstrate the distribution of demographic information, such as gender, age, BMI, and time of insertion. Continuous variables were analyzed using Student's t-test, the Mann-Whitney U test, and the chi-square test. The Kolmogorov-Smirnov and Shapiro-Wilk tests were used for normality of distributions and normal distribution. The ANOVA test was used for the analysis of repeated measurements.

Results

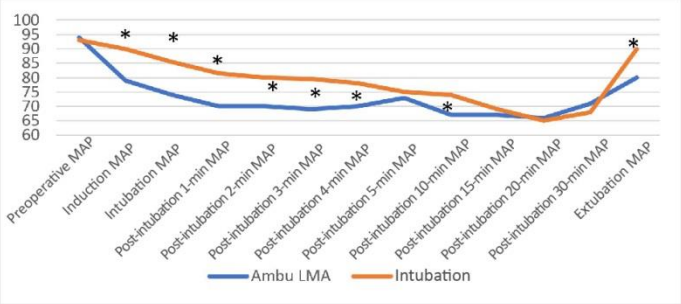
The mean age and BMI of 69 patients, 49 (71%) of which were male, were 27.1 (9) years, and 23.9 (2.7) kg/m^{2,} respectively. The groups had similar characteristics in terms of demographic data (Table 1). The insertion times were 13 (5) seconds in the LMA group and 50 (15) seconds in the ETT group. Three patients in the ETT group developed nausea, and 1 patient in the LMA group developed a cough.

The analysis of heart rates showed significant elevations in the ETT group at induction, intubation, and at 1 minute post-intubation (*P*=0.002, *P*=0.001 and *P*=0.022, respectively). The groups had similar heart rates at the other time measurements. Mean arterial pressure (MAP) showed a significant reduction in the LMA group at induction, at minutes 1, 2, 3, 4, and 10 post-intubation, and at extubation (*P*<0.001, *P*=0.003, *P*=0.004 *P*=0.002 *P*=0.002, *P*=0.008 *P*=0.024 and *P*=0.01, respectively). The other values measured at the other time points were similar between the groups. The MAP measurement data are presented in Figure 2.

Table 1: Demographic data

	Group LMA n :37	Group ETT n:32	Total n :69	*P*- value
Age	26.7 (9.4)	27.7 (8.7)	27.1 (9.0)	0.510
Gender (Male)	28 (75.6%)	21 (61.6%)	49 (71%)	0.515
BMI	23.8 (2.9)	24.0 (2.3)	23.9 (2.7)	0.745

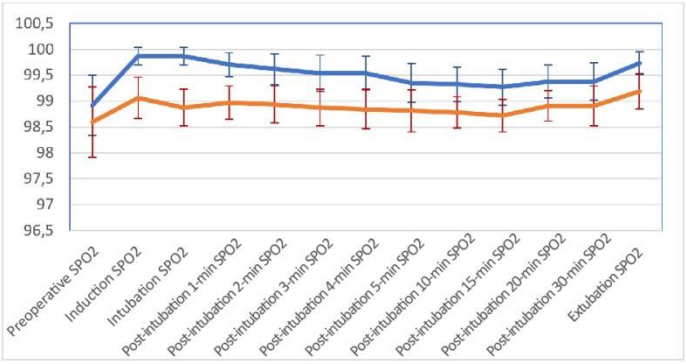
Figure 2: Change in median MAP values of patients by time



* There is a statistically significant difference between the groups. *P*<0.05

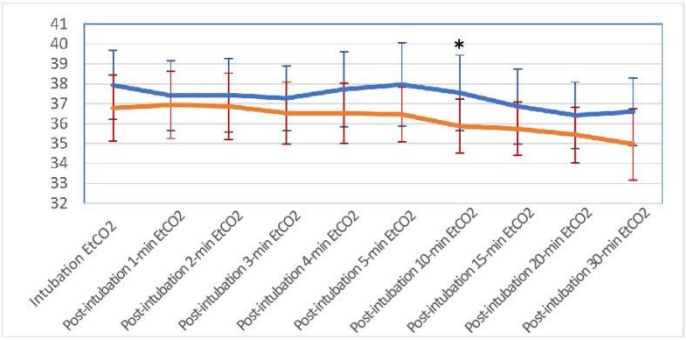
$SatO_2$ values differed significantly between the groups at all times except for the preoperative measurement. The LMA group had higher $SatO_2$ values (*P*<0.05 for all values) (Figure 3). The analysis of the end-tidal CO_2 data indicated a similarity between the groups at all time points (*P*>0.05 for all values), except for the 10th minute post-intubation (*P*=0.017) (Figure 4). The measurement of airway pressures showed higher airway pressure in the ETT group at all times (*P*<0.05 for all values) (Figure 5).

Figure 3: Change in mean and standard deviations of SPO2 values of patients by time



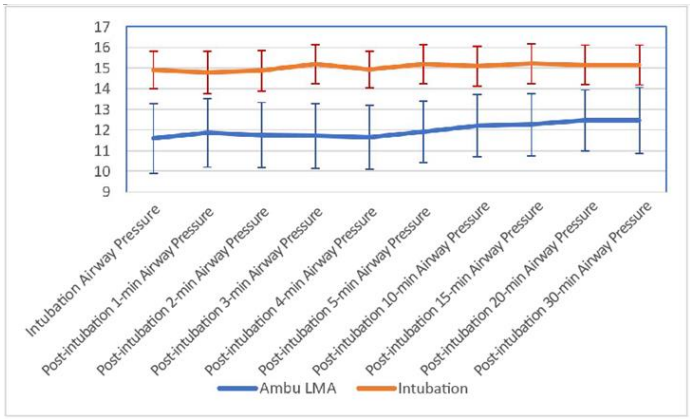
* There is a statistically significant difference between the groups at all times except for preoperative values. (*P*<0.05) Orange line: intubation; blue line: LMA.

Figure 4: Change in mean and standard deviations of EtCO2 of patients by time



* There is a statistically significant difference between the groups. (*P*<0.05) Orange line: intubation; blue line: LMA.

Figure 5: Change of mean and standard deviations of airway pressure values of patients by time



* There is a statistically significant difference between the groups at all times. *P*<0.05

Discussion

The data obtained in our study revealed that Ambu® AuraGain™ LMA was equivalent to endotracheal intubation in septoplasty operations in terms of hemodynamic and respiratory parameters.

Since the airway is in the surgical area during septoplasty operations, anesthesiologists generally prefer endotracheal intubation due to safety concerns. With the introduction of new-generation airway devices, better sealing pressure has been achieved during positive pressure ventilation. The Ambu® AuraGain™, a third-generation airway device, provides higher sealing pressure with its curved silicon structure. In our study, the Ambu® AuraGain™ group had lower airway pressures throughout the entire septoplasty operation. This result can be considered an indication that LMA provides sealing even at higher pressures. Karaaslan et al. [5] compared the LMA Supreme and ETT in patients undergoing septoplasty and found that LMA provided more protection in preventing blood leak. Al-

Mazrou et al. [6] concluded that LMA may be preferred as an alternative to ETT for pediatric patients undergoing sinusoidal surgery. Lee et al. [7] found that ventilation decreased with head and neck movements and that effective ventilation could be provided in a neutral head position with LMA. A study by Mihara et al. [8] on pediatric patients concluded that the i-Gel® (Intersurgical Ltd., UK, second generation) was easier to place than the Ambu® AuraGain™ and therefore caused less oropharyngeal damage, but lower airway pressures were obtained with the Ambu® AuraGain. Likewise, Uthaman et al. [9] found that use of the Ambu® AuraGain™ LMA in patients with an immobilized cervical spine had adequate oropharyngeal leak pressure with a stiff collar. Although studies on the third-generation airway device, the Ambu® AuraGain™ LMA, are more limited, most studies performed with other LMA variants showed that the Ambu® AuraGain™ LMA is equivalent or superior to LMA [7, 10, 11].

Another feature of the Ambu® AuraGain™ LMA is that it allows ETT to pass through. It is advantageous to switch to ETT due to difficult intubation or laryngeal pressure in prolonged operations. Many studies were conducted on this subject [12, 13]. However, when Schiewe et al. [14] compared the laryngeal mask Fastrach™ (Teleflex Medical, Dublin, Ireland. second generation) with the Ambu® AuraGain™ in terms of blind intubation, they concluded that the laryngeal mask Fastrach™ was more successful. Since our study aimed to compare the effectiveness of Ambu® AuraGain™ LMA with tracheal intubation in septoplasty cases, this feature of LMA was not evaluated.

Studies on Ambu® AuraGain™ LMA generally found that it was similar or superior to ETT in terms of hemodynamic data [5, 12, 15]. The analysis of heart rates in our study showed higher values in the ETT group at intubation. This can be explained by the sympathetic activation caused by the laryngoscope. There was no difference in the measurements at the other time points. The Ambu® AuraGain™ LMA group had significantly lower MAP in general. The groups were similar in terms of oxygen saturation and $EtCO_2$ measurements. The results of our study are in line with the literature. The analysis of the data on $SatO_2$ and $EtCO_2$ measurements indicates that Ambu® AuraGain™ LMA provides sufficient ventilation to allow gas exchange in septoplasty.

None of our patients had soft tissue trauma, bleeding, hoarseness, or sore throat. Three patients in the ETT group developed nausea and 1 patient in the LMA group developed a cough. In their study on the complications of airway devices, Safaeian et al. [16] showed that the rate of complications was higher in the ETT group than in the LMA group. Lee et al. [7] compared the Ambu® AuraGain™ LMA with the I-gel™ (Intersurgical Ltd., Wokingham, England, second generation) LMA and found that complications were insignificantly less frequent in the Ambu® AuraGain™ LMA group.

In this study, airway pressure was always higher in the ETT group than in the LMA group. Endotracheal tube placement is longer and requires more manipulation. In addition, a laryngoscope is used as a helper tool for its insertion, which raises the risk of bronchospasm in these patients, and the tracheal tube causes a narrowing of the tracheal diameter.

Even a small bleeding in the operation area in the ear, nose, or throat affects the appearance of the operation area [17]. Although epinephrine is used to reduce pre-surgical bleeding, increases in arterial pressure can cause increase surgical bleeding [18]. In our study, MAP was generally low among patients in the LMA group. This low level contributes positively to the reduction of surgical bleeding.

Limitations

To avoid potential bias, precautions such as inclusion of similar patient groups in the study, not allowing repeated trials, and blind randomization were taken. However, visual evaluation could not be performed in our study since our hospital did not have fiberoptic equipment. Because this study was conducted on healthy adults, it may be misleading to use these data in children, and patients with systemic, hepatic, cardiac, and renal diseases. Although it is applied to all patients, the amount and concentration of epinephrine administered to the nasal area to provide a more comfortable space can also affect the hemodynamic data and the amount of bleeding.

Conclusion

We obtained similar results to tracheal intubation in terms of hemodynamic and respiratory parameters when Ambu® AuraGain™ LMA is used in septoplasty operations. Therefore, we think that Ambu® AuraGain™ LMA can be an alternative to tracheal intubation in septoplasty, and that our study may be a reference for future studies. However, it is an undeniable fact that more work is needed on this subject.

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