

Comparison of the Baska Mask[®] and Endotracheal Tube on Hemodynamic and Respiratory Parameters in Septoplasty Cases

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Abstract: Laryngeal mask (LM) types have been used as an airway device for an alternative to the standard endotracheal tube (ETT). One of the novel type of LM, the Baska Mask[®], can be a safe alternative among the airway devices. The purpose of this study is to compare the effects of the new generation supraglottic airway device the Baska Mask[®] and the ETT on hemodynamic parameters (heart rate, mean arterial pressure), airway pressure and end tidal carbon dioxide (EtCO₂) in patients undergoing general anesthesia. After the approval of the ethics committee, 70 patients who underwent septoplasty were included in the study. Written informed consent forms were taken from these patients. Demographic data of the patients were recorded. Hemodynamic data of patients were measured and recorded preoperative, during induction, at the time of intubation 1th, 3th and 5th minute and during extubation. Also, airway pressure and EtCO₂ values of the patients were measured and recorded at the time of intubation, 1th, 3th and 5th minutes. Demographic data were similar in both groups. Mean arterial pressure, heart rate and airway pressure were lower in the group 2 (the Baska Mask[®] group) than in the group 1 (ETT group) and the difference was statistically significant (p<0.05). EtCO₂ values were similar in both groups. No patients had tube leakage. In terms of hemodynamic and respiratory parameters the Baska Mask[®] is more advantageous than the ETT in short-term surgeries.

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Introduction

Many devices are used to provide airway patency during general anesthesia. The laryngeal mask (LM) is one of these devices. It was first used by Dr. Brain in 1983 (Brain, 1983). It is easy to apply and it does not require additional devices such as a laryngoscope. LM can harm teeth, pharyngeal and laryngeal structures less than endotracheal tube. In addition, the sympathetic activation effects (tachycardia, hypertension, myocardial ischemia, etc.) caused by supraglottic tension are less common in the LM use (Shribman et al., 1987; Knight et al., 1988; Takita et al., 2001). The aspiration risk of LM is higher than endotracheal tube, so this is the main disadvantage of the LM (van den Berg et al., 1997).

Many LM types have been produced in recent years. The new generation supraglottic Baska Mask[®] (Logical Health Products PTY Ltd., Morisset, NSW, Australia) is one of them. It doesn't need inflation as it takes the shape of the airway with positive pressure. This structure of the Baska Mask[®] provides the minimum level of leakage and allows it to be used at high airway pressures. The risk of damaging the oropharyngeal structures is less than both endotracheal tube and cuffed LM types (Alexiev et al., 2013; Bindal et al., 2018). The Baska Mask[®] includes an inlet that fits into the upper esophagus and the dorsal surface of the cuff is moulded to direct any oropharyngeal contents away from the glottis and towards the side channels where suction can be inserted to facilitate aspiration of this cavity (Alexiev et al., 2012).

In our study, we compared the effects of the Baska Mask[®] and endotracheal tube on hemodynamic parameters (heart rate, mean arterial pressure), airway pressure and EtCO₂ values.

Material and Methods

A prospective randomized controlled study started with the approval of the ethics committee of Kafkas University Clinical Research Ethics Committee (No. 80576354-050-99/167) and the ethical standards of the Declaration of Helsinki. Seventy consecutive American Society of Anesthesiologists (ASA) classification I and II patients that underwent elective septoplasty were included in the study. Informed consent was obtained from all patients who participated in the study. For the minimum sample size calculated by taking the alpha error of 0.05, the beta error of 0.20 and the ratio of the cases in the control takes 1 was found as 30 patients in both groups. The patients with ASA III-IV-V, body mass index (BMI) > 30 kg/m², chronic medication or alcohol use were excluded. The patients that had the history of intubation difficulty, diabetes mellitus, hypertension, malignant hyperthermia, renal disease were also excluded. The closed envelope method was used for the patient assignment and the patients were divided into two groups as endotracheal tube – ETT (group 1) and the Baska Mask[®] (group 2).

Standard monitoring (pulse oximetry – SpO₂, non-invasive blood pressure, electrocardiography, capnography) was applied to all patients. In both groups,

anesthesia was induced with propofol (Propofol 1%, Fresenius® Kabi Medicine, Istanbul, Turkey) 2 mg/kg, fentanyl (Fentanyl 0.05 mg/ml, Johnson and Johnson Medicine, Istanbul, Turkey) 1–2 µg/kg, rocuronium (Esmeron®, Merck Sharp Dohme, Australia) 0.6 mg/kg. Airway device was placed in all patients at the first attempt. The time of insertion was defined as the time from the handling of the airway device until the mechanical ventilator. EtCO₂ appeared to plateau. All airway equipment was placed by the senior anesthesiologist. Patients were connected to the mechanical ventilator in volume control mode with a tidal volume of 6–8 ml/kg and a respiratory rate of 10–14 breaths/min. Anesthesia was maintained with 1–1.5 MAC sevoflurane (Sevorane®, Liquid 100%, Queenborough, UK) in 3–4 l oxygen/air (40%/60%) mixture. The same ventilator device was used for all patients and device-dependent changes were minimized by calibrating it for each patient. At the end of the operation, inhalation anesthesia was ended. Atropine (Atropine Sulfate, Galen Medical, Istanbul, Turkey) 0.02 mg/kg intravenous (IV) was given to antagonize the muscarinic effects. In group 1, neostigmine (Neostigmine, Adeka Samsun, Turkey) 0.04 mg/kg IV was administered to block muscle relaxants in addition to atropine. After sufficient spontaneous breathing, muscle strength and consciousness level were achieved, the airway device (Baska Mask® or ETT) was removed. Tramadol 100 mg IV (Contramal 100 mg, Abdi Ibrahim, Istanbul, Turkey) was administered as an infusion for postoperative pain.

Demographic data of the patients were recorded. Hemodynamic data of patients were measured and recorded preoperative, during induction, at the time of intubation 1th, 3th and 5th minute and during extubation. Airway pressure and EtCO₂ values of patients were also measured and recorded at the time of intubation 1th, 3th and 5th minutes.

Statistical analysis

Data were analyzed by using IBM SPSS Statistics 23 software (IBM Corp., Armonk, NY). Frequency, mean and standard deviation were used to analyze data. The Kolmogorov Smirnov goodness-of-fit test was used for the normality analysis of the data. The chi-square and *t*-tests were used to compare the means of the 2 groups since the data showed normal distribution. A value of $p < 0.05$ was considered significant.

Results

When the demographic data (age, gender, body mass index) of the patients were examined, the groups were similar. The mean intubation time was 30.82 ± 5.96 s in group 1 and 20.48 ± 6.69 s in group 2. Group 2 was statistically lower. The patient demographics are presented in Table 1. Heart rate and mean arterial pressures of the patients were measured preoperative, during induction of anesthesia, 1th, 3th and 5th minutes after intubation and during extubation. When the heart rate values and mean arterial pressure values were examined; values of patients in group 2 were

Table 1 – Demographics and intubation times of patient groups

	Group 1 (ETT) (n=35)	Group 2 (Baska Mask®) (n=35)
Age (mean ± SD) (year)	27.40 ± 10.02	26.62 ± 10.06
Gender (male) (%)	28 (80%)	28 (80%)
BMI (mean ± SD)	22.62 ± 3.11	23.00 ± 2.57
Placement time (mean ± SD) (s)	30.82 ± 5.96	20.48 ± 6.69

ETT – endotracheal tube; SD – standard deviation; BMI – body mass index

Table 2 – Heart rate and mean arterial pressure values of the patient

	Heart rate (beats/min)			Mean arterial pressure (mm Hg)		
	group 1 (n=35)	group 2 (n=35)	P	group 1 (n=35)	group 2 (n=35)	P
Preoperative	82.11 ± 16.89	77.77 ± 14.13	0.248	98.45 ± 12.17	89.02 ± 21.19	0.026
Induction	94.74 ± 17.45	87.34 ± 21.25	0.116	88.31 ± 12.06	87.68 ± 10.80	0.819
Intubation 1 st min	101.88 ± 15.11	88.02 ± 14.86	0.000	102.91 ± 17.17	95.08 ± 14.44	0.043
Intubation 3 rd min	101.11 ± 15.15	85.94 ± 20.27	0.002	101.60 ± 14.89	92.48 ± 14.13	0.011
Intubation 5 th min	96.68 ± 23.60	88.31 ± 17.65	0.001	99.57 ± 18.42	87.25 ± 13.74	0.002
Extubation	92.62 ± 11.05	80.94 ± 13.95	0.000	102.42 ± 14.81	86.91 ± 13.74	0.000

statistically significantly lower at all times ($p < 0.05$). Values of heart rate and mean arterial pressure are given in Table 2.

Mean airway pressure values and mean EtCO₂ values of the patients were measured at 1th, 3th and 5th minutes after the induction. Airway pressures were statistically significantly lower in group 2 of all time. When EtCO₂ values were examined, there was no statistically significant difference between groups. Mean air pressure and mean EtCO₂ values are given in Table 3.

Mild sore throat occurred in 9 patients in group 1 and in 3 patients in group 2. Also, vomiting was observed in 4 patients in group 1 and 2 patients in group 2. No other complications were seen.

Discussion

Since 1983, the LM has been used as an airway device for an alternative to standard ETT. Its easy placement and less damage to the teeth and oropharyngeal structures

Table 3 – Mean airway pressure and mean EtCO₂ values

	Airway pressures* (mm Hg)			EtCO ₂ ** (mm Hg)		
	group 1 (n=35)	group 2 (n=35)	P	group 1 (n=35)	group 2 (n=35)	P
Intubation 1 st min	12.85 ± 1.92	9.54 ± 2.36	0.015	35.28 ± 3.72	35.42 ± 3.59	0.871
Intubation 3 rd min	12.54 ± 1.77	9.42 ± 2.15	0.014	34.74 ± 6.06	36.71 ± 2.77	0.085
Intubation 5 th min	12.77 ± 1.64	9.97 ± 2.64	0.013	36.37 ± 3.43	36.17 ± 3.23	0.803

*p<0.05; **p>0.05; EtCO₂ – end tidal carbon dioxide

have made it more common to use (Lee et al., 1993; Pennant and White, 1993; Gehrke et al., 2019). LM placement causes less subglottic stress than standard ETT placement. Therefore, complications (tachycardia, arrhythmia, hypertension, myocardial ischemia, etc.) caused by sympathetic activation due to this tension are less common (Knight et al., 1988; Takita et al., 2001). Pratheeba et al. (2016) reported that hemodynamic changes were lower with LMA[®] I-Gel than with LMA[®] classical. Similarly, Bennett et al. (2004) reported that airway can be managed with LM without inducing hypertension or tachycardia in patients with coronary disease. In addition, Revi et al. (2015) reported that there was no statistically significant difference in hemodynamic status between LMA[®] I-Gel, LMA[®] Pro-Seal and LMA[®] classical. Joo and Rose (1999) compared fiberoptic devices and laryngoscope during LM insertion and they reported that fiberoptic guided intubation had less effect on hemodynamic parameters. Kihara et al. (2000) reported that there was no difference between blind LM insertion and laryngoscopy. Kavitha et al. (2011) reported that there was no significant difference between intubating LM and laryngoscopy in terms of hemodynamic changes.

The Baska Mask[®] is a new generation type of LM which is produced along with technological developments. There is no separate cuff as it adapts to the larynx due to its silicone structure. Thus, larynx damage is less common due to the absence of the cuff. Another feature of the Baska Mask[®] is that it has a drainage inlet for esophageal aspiration. This reduces the risk of aspiration. Bindal and his colleagues (2018) did not find any hemodynamic difference compared to other LMs in their study. In our study, the Baska Mask[®] group was more stable than ETT group during the operation, with smaller changes in blood pressure and heart rate. However, there have not been enough clinical studies on Baska Mask[®], yet.

One of the important problems in the use of the LM is air leakage due to the application of positive pressure. Some of the causes of air leakage are the improper size of the LM, insufficient inflation of the LM cuff and LM displacement. This leakage

of air may risk the patient's life by causing the inadequate ventilation. The leakage becomes more important, especially in the patients who have high airway pressure, such as chronic obstructive pulmonary disease and asthma. The air tightness of the new generation airway device, the Baska Mask[®], is better than the other LMs due to its silicon structure and adaptation to the larynx without swelling (Ramachandran and Kumar, 2014). It's reported that other LMs provide better sealing than conventional LMs in 2018 (Bindal et al., 2018). In our study, no leakage was detected in the Baska Mask[®].

EtCO₂ monitoring is an important indicator of correct placement of airways (Knapp et al., 1999). In addition, the change of EtCO₂ values can be used as a parameter for early diagnosis of complications such as air leakage, upper airway obstruction and bronchospasm, which lead to the insufficient ventilation (Hart et al., 1997; Burton et al., 2006). The studies reported that EtCO₂ values of the new generation LMs are similar to the other airway devices' EtCO₂ values (Lee et al., 2009; Ozdamar et al., 2010; Sabuncu et al., 2018). However, it should not be forgotten that EtCO₂ may increase in patients with increased gastric pressure (laparoscopic surgery) and in patients operated in the Trendelenburg position (Hsing et al., 1995; Maltby et al., 2000). In our study, we used EtCO₂ to detect upper airway complications earlier. There was no statistical difference between the groups and EtCO₂ levels were clinically acceptable.

In general, anesthesia applications, high airway pressure, increased sympathetic activation, use of N₂O can cause an increase in pressure of the middle ear. Due to this increase, it may cause complications such as vomiting, hearing loss, otalgia, hemotympanum and middle ear inflammation (Nader et al., 2004; Carmichael and Boyev, 2016). In many studies, including our previous study, the use of Baska Mask[®] causes less change in the middle ear pressure compared to standard intubation (Degerli et al., 2013; Torun et al., 2019). Therefore, the occurrence of possible complications will decrease. However, studies in this area are insufficient.

LM is such an airway device that is placed easily. In literature reviews, the placement time of LM is 8–28 seconds while ETT insertion is 17–20 seconds (Van Zundert and Brimacombe, 2008; Verghese and Ramaswamy, 2008; Carron et al., 2012). The differences between the definition of the insertion time of airway devices has some different factors such as the experience of the healthcare staff, the number of trials, the history of difficult intubation and the size inconsistencies of the devices. The common point is that the LM insertion time is shorter than the ETT, in the literature. In our study, the insertion time was 20.48 ± 6.69 seconds for Baska Mask[®] and 30.82 ± 5.96 seconds for ETT. The reason of the difference between the literature and our findings is the initial time of the procedure that mentioned in the material and method section. In studies among LM types; Baska Mask[®] had a longer insertion time than classical LM variants (Sharma et al., 2017; Bindal et al., 2018). Silicone structure and shape of other LM prolong the insertion time compared to classical LM types.

There are only case reports about the use of various laryngeal masks in different head and neck positions and other operation positions such as prone position (Ceylan, 2008; Saini and Bansal, 2013). Prospective clinical studies are needed on LM types in different operation positions. The Baska Mask® may be a good alternative for different operation positions due to its silicone structure that adapts to the larynx anatomy and its high sealing pressure.

There are some limitations of our study. The standard data about the Baska Mask® is controversial because of the insufficient data about the Baska Mask® in the literature. Also, the level of neuromuscular block for extubation was evaluated clinically, since the train-of-four (TOF) device was not available in our hospital.

Conclusion

The Baska Mask® can be safely used as an alternative to other intubation devices since it has lower complication rate, better sealing at high pressure and a part for gastric aspiration. However; further studies are needed for the Baska Mask® and other types of LM devices.

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