A Comparison of The Use of Tubeless Tire Model New Generation Baska Mask ® LMA and Classic LMA in Terms of Ease-of-Use and Patient Comfort

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ABSTRACT

This study aimed to compare Baska Mask laryngeal mask airway (LMA) with classic LMA in terms of clinical performance, ease of use, and patient comfort. The duration of placement was compared between the groups as the primary outcome. Comparisons were also made for the number of LMA entry attempts, hemodynamic parameters. and postoperative complications.

The study included 66 patients. The patients were randomly separated into two groups using the sealed-envelope method. After general anesthesia induction, a new LMA (Baska Mask) or a classic LMA was placed in the mouth of all the patients. The heart rate, blood pressure, mean and peak airway pressure, and amount of ventilation leakage were recorded throughout the surgery. The patients were examined for the presence of blood smears after removing the LMA. One hour after the surgery, an anesthetist blinded to the groups asked all the patients whether they had throat pain.

The duration of LMA placement was determined as 14.5 s for classic LMA and 16.0 s for new LMA, with no significant difference between the groups ($P = 0.117$). The number of attempts at entry was similar in both groups ($P = 0.741$). The mean and peak airway pressure measurements 5 min after LMA placement were statistically significantly different between the groups ($P < 0.05$), with higher values in the new LMA group. No blood smears were observed in the patients using new LMA, while blood smears were determined in seven patients in the classic LMA group ($P = 0.012$).

The results of this study showed that an adequate, safe open airway was provided throughout the surgery in both groups. Despite no significant difference with respect to ease of use, the Baska Mask was thought to be more advantageous than LMA in terms of patient comfort.

Key words: Baska Mask LMA, Classic LMA, general anesthesia, LMA placement duration, tubeless tire model

INTRODUCTION

Supraglottic airway devices (SGA) were first used in 1988 to provide an easy airway method in resuscitation and difficult intubation (1). Subsequently, they were widely used in daily applications of general anesthesia. The classic laryngeal mask airway (LMA) was among the first to come into use and was preferred more than the face mask or endotracheal intubation because it made the airway method easier when applying anesthesia (2,3). Over time, LMA devices in different forms were developed to increase clinical performance and patient comfort. In each new design, targets were observed such as achieving rapid and easy placement, minimizing the aspiration risk, being able to provide ventilation at high pressure, and reducing the incidence of side-effects and hemodynamic response (4, 5). The classic types of these devices have an air cushion inflated with an injector to provide a complete fit to the glottis. In the I-Gel model, which was developed later, a gel cushion was adopted instead of the air cushion, and when this gel reached body temperature, it provided complete fit to the glottis. In the recently developed Baska Mask LMA (Fig. 1), the rim of the tubeless tire mimick the fit principle (Fig. 2) and hence it is possible to aspirate the esophagus while providing effective ventilation and spontaneous fit of the LMA to the glottis with the air given to the patient.

Figure 1 Baska Mask LMA.

Figure 2 Tubeless tire (inner profile of car rim)

The Baska Mask LMA is a new-generation SGA device that has been in use since 2012. Instead of an inflatable cuff, the structure of the cuff is in the form of a fine silicone membrane. During positive-pressure ventilation, the cuff covers the larynx with increasing airway pressure. Effective impermeability is provided by the cuff adhering to the larynx wall throughout ventilation. In addition, the device has an integrated bite block and lateral channels opening into the esophagus to assist in the aspiration of stomach contents (6).

This study aimed to compare Baska Mask LMA with classic LMA (Fig. 3) in terms of clinical performance, ease of use, and patient comfort. The duration of placement was compared between the groups as the primary outcome. Comparisons were also made between the groups in terms of the number of LMA


Figure 3 Classic LMA.

entries, the 5-min hemodynamic parameters, postoperative throat pain, and presence of blood smear on the device.

MATERIAL AND METHODS

The study was approved by the ethics committee of Ankara Yildirim Beyazit University Medical Faculty, and signed informed consent was obtained from all the patients. This randomized, single-blinded study included 66 patients aged 18–80 years, who were evaluated as ASA I and II, and were planned to undergo urological surgery under elective conditions (ASA: classification by the American Society of Anesthesiology). The surgeries included surgeries not exceeding 90 min other than laparoscopic surgery and airway surgery, and cystoscopic surgeries performed in the lithotomy position. The patients were excluded from the study if they had pulmonary disease, were obese (body mass index >35), or had suspected difficult airway (Mallampati score ≥3 and mouth opening <2.5 cm), a high risk of aspiration, or airway obstruction because of upper airway pathology.

The patients were randomly divided into two groups using the sealed-envelope method. The following work flow chart has been created for the study (Schema 1).

The new LMA (Baska Mask Logikal Health Products PTY Ltd., Morisset, NSW, Australia) was used in Group 1, while the classic LMA (Intavent, Maidenhead, UK) was used in Group 2. The patients were taken to the operating table without premedication,
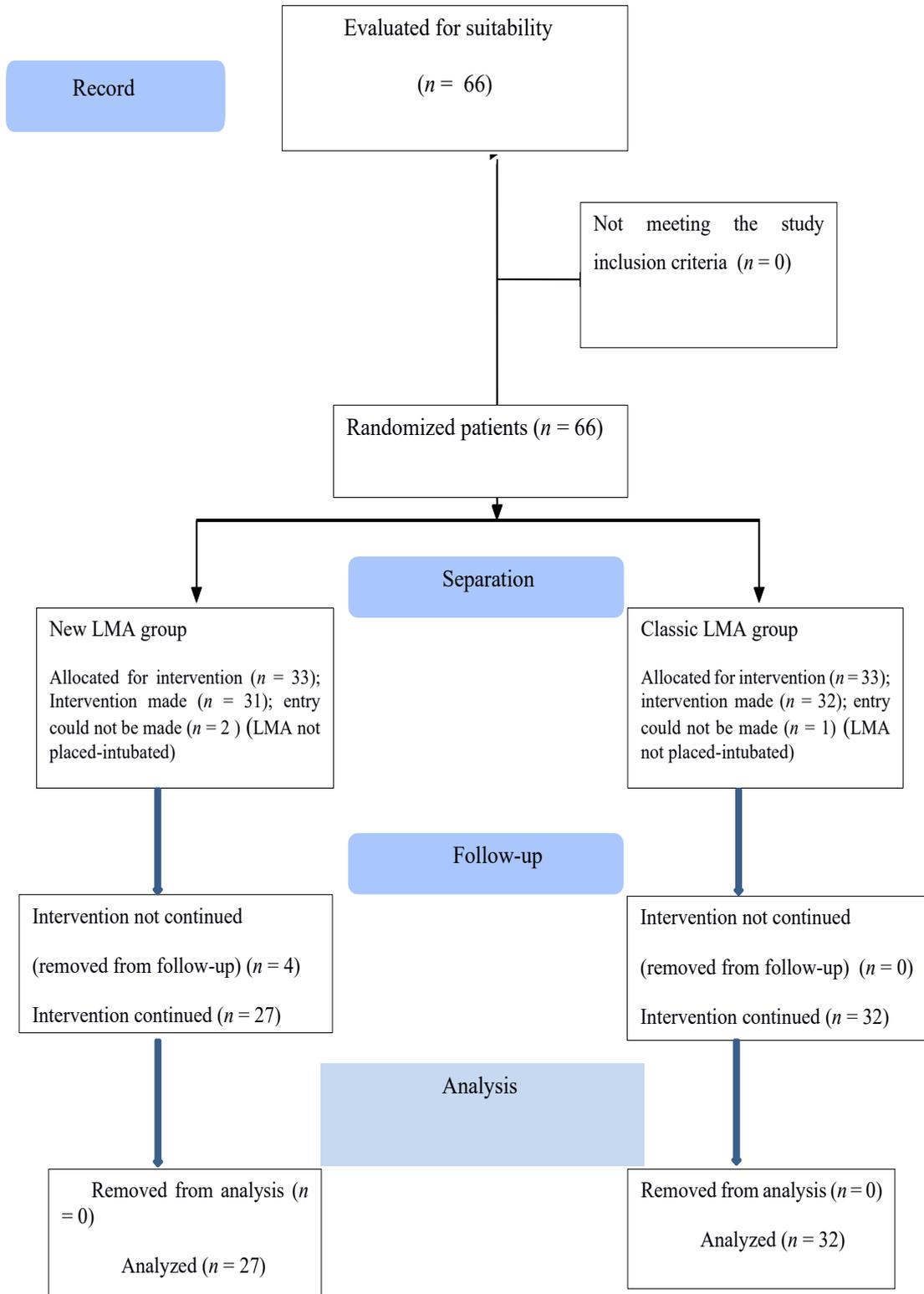
Schema 1 Created work flow chart

and a vascular route was opened and an intravenous (iv) fluid infusion was started in a supine position. The heart rate (HR), electrocardiogram, noninvasive blood pressure, peripheral oxygen saturation (SpO$_2$) and bispectral index (BIS) were recorded for all the patients.

With the head in a partial neutral position, anesthesia induction was provided with intravenous 2.5 mg · kg^{-1} propofol, 1.5 µg · kg^{-1} fentanyl, and 0.2 mg · kg^{-1} rocuronium following 2 min of pre-oxygenation with 100% O$_2$. When the BIS value was <60, a new LMA (Fig. 1) or classic LMA (Fig. 3) of a size appropriate to the weight of the patient was placed in the airway following the manufacturer's recommendations. The classic LMA cuff was inflated with the recommended volume of air appropriate to the size. Baska Mask LMA do not need to inflate the cuff with air. Just like tubeless tire, the air used in ventilation automatically inflates the cuff of the Baska Mask LMA. In both groups, the device placement procedure was completed in compliance with the criteria showing successful LMA placement (square-shaped waves on a capnogram, easy ventilation with the respiration balloon, chest movement observed at approximately 20 cm H$_2$O positive pressure, and no ventilation leakage) (6). In the classic LMA group, the anesthesia technician inflated the cuff to an appropriate volume simultaneously. If the first attempt was not successful, a second attempt was made, moving the head back and the jaw upward. If a third attempt was necessary, a different-size LMA was used. If the second and third attempts were not successful, endotracheal intubation was performed. The patients who were intubated were withdrawn from the study.

In patients in the new LMA group, an aspiration catheter from a gastric drainage tube was placed and the stomach contents were aspirated. Maintenance anesthesia was provided with 2% sevoflurane in a 50% air–50% oxygen mixture with controlled mechanical ventilation for respiratory volume to be 7 mL · kg^{-1} and respiration 12/min^{-1}. Then, remifentanil infusion was administered (Ultiva ®0.1–0.2 µg · kg^{-1} · min^{-1}). A record was made of the duration of LMA placement (starting from the time of the anesthesia specialist picking up the device, placing it into the mouth, and connecting to the respiratory cycle, until sufficient tidal volume and square capnograph waves were obtained with automatic ventilation) and the number of entry attempts for each patient. The inhalation anesthesia and remifentanil infusion were terminated at the end of surgery. The neuromuscular block was reversed with neostigmine and atropine. Then, the LMA was removed after the sufficient tidal volume was obtained with spontaneous respiration. After removing the LMA, the presence of blood smear was examined and recorded.

The HR, systolic blood pressure (SBP), diastolic blood pressure (DBP), peak airway pressure (P_{peak}), and mean airway pressure (P_{mean}) were recorded for all patients at baseline, before and after induction, and 1, 5, 10, 15, 30, 45, 60, 75, and 90 min after LMA placement (Graph 1). The absence of blood smear on the device after removal at the end of the surgery and no postoperative throat pain were accepted as patient comfort. The patients were asked about the presence of throat pain 1 h postoperatively by an anesthetist blinded to the study groups.

The primary objective of this study was to measure the duration of placement of the two types of LMA and determine any significant difference (Graph 2). The secondary aim was to compare the groups in terms of throat pain and blood smear on the LMA and determine any difference between the groups in terms of HR, systolic–DBP, mean and peak airway pressure, and leakage volume values 5 min after LMA placement.

Power analysis

Power analysis was performed using G*Power 3.1.9.4 statistics software. Taking $n1 = 27$, $n2 = 32$, $\alpha = 0.05$, and effect size (d) = 0.80, power was calculated as 85%.

Statistical analysis

The data obtained in the study were analyzed statistically using IBM SPSS version 25.0 software (IBM Corp., NY, USA). Descriptive statistics were expressed as mean, standard deviation, median, and minimum and maximum values for categorical data and as number and percentage for categorical data. The chi-square test was used for comparing numerical data. The Pearson chi-square test and the Fisher exact test were used for comparing groups of categorical data. The conformity of the data to normal distribution was assessed using the Kolmogorov–Smirnov test,
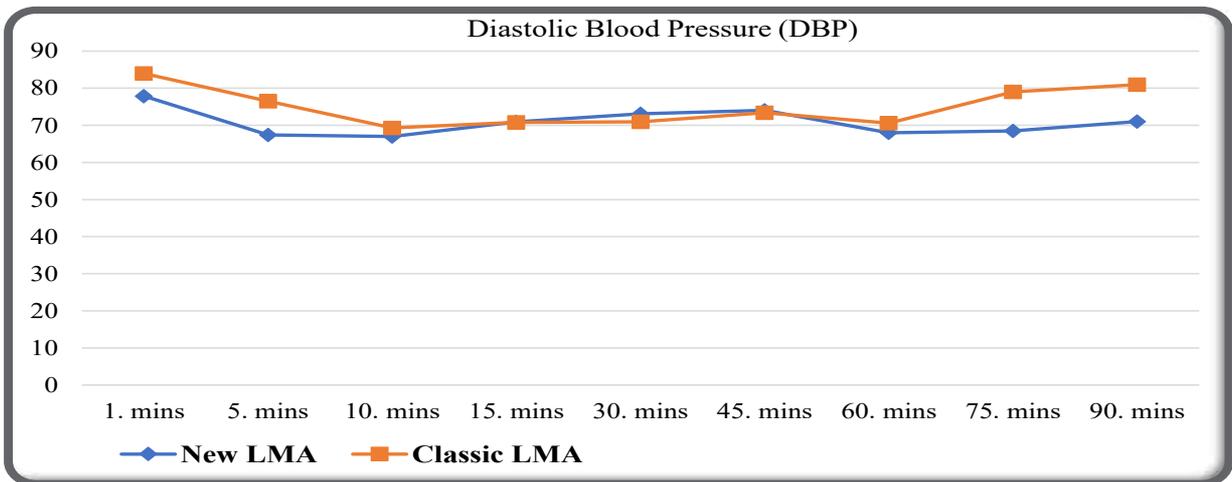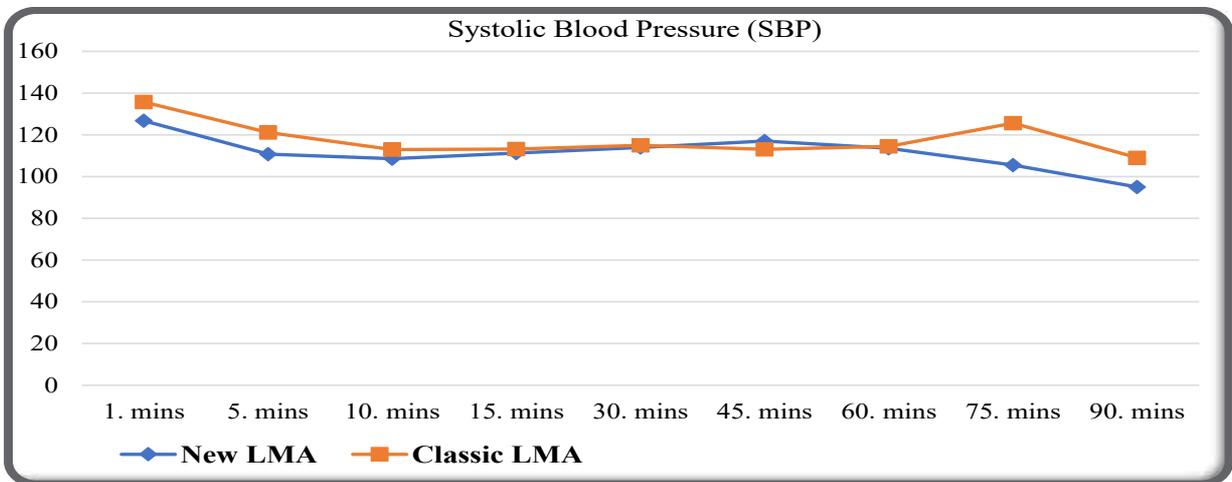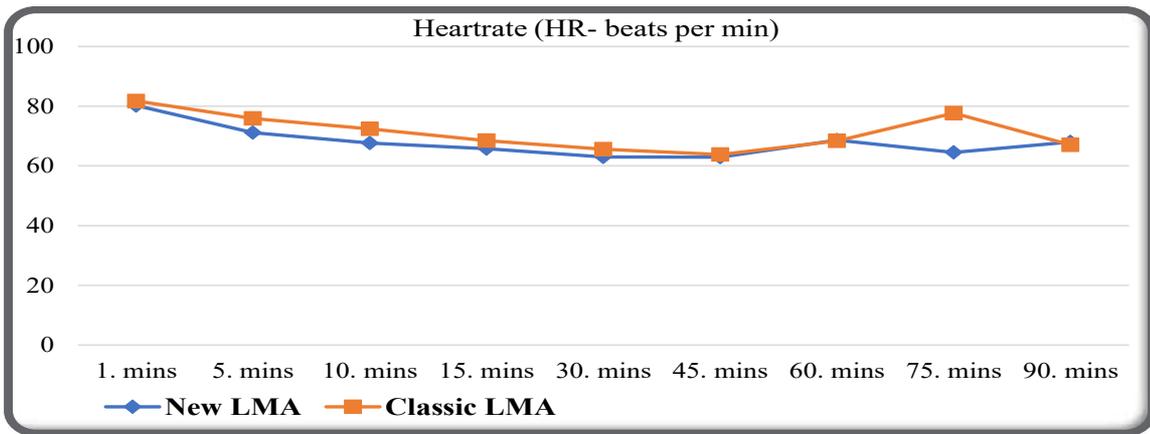
Graph 1 Comparisons between the groups of HR (heart rate, beats per min), SBP (systolic arterial blood pressure), and DBP (diastolic arterial blood pressure).
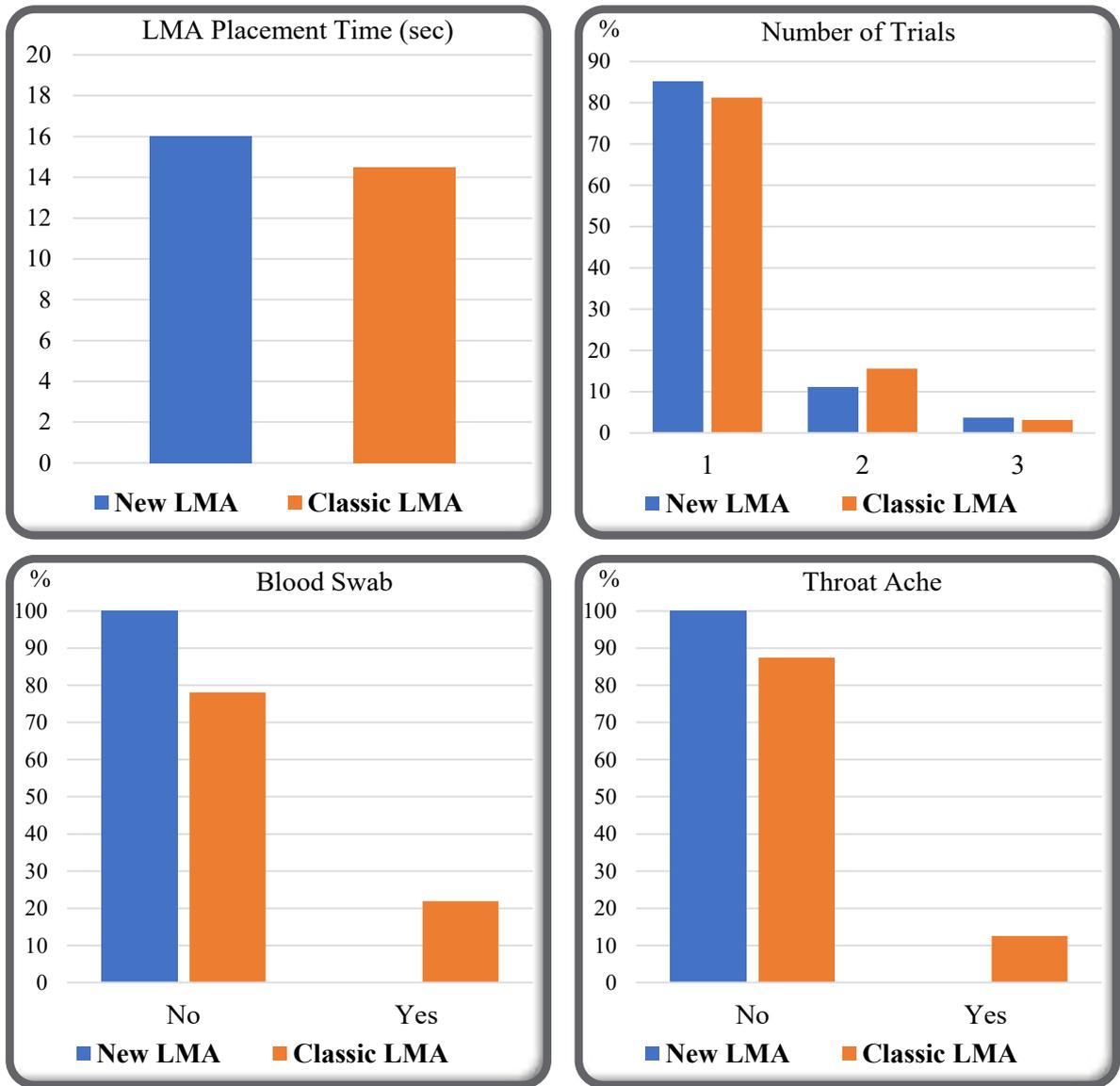
Graph 2 Comparisons of patient characteristics between the groups.

skewness–kurtosis, and graphic methods (histogram, Q-Q plot, stem-and-leaf, and boxplot). For evaluating qualitative data, the independent-sample t test was used for groups showing normal distribution, and the Mann–Whitney *U* test was used for data not showing normal distribution. The level of statistical significance was accepted as α = 0.05.

RESULTS

The LMA could not be placed In in 2 two patients in the new LMA group and in 1 one patient in the classic

LMA group; the LMA could not be placed and hence, these patients were withdrawn from the study. A further Another 4 four patients in the new LMA group were excluded as because the surgical intervention was prolonged. Thus, the study was completed with finally comrised 27 patients in the new LMA group and 32 patients in the classic LMA group. The new LMA group of 27 patients comprised 23 (85.2%) males and 4 (14.8%) female patients, and while the classic LMA group of 32 patients comprised 25 (78.1%) males and 7 (21.9%) females female patients (*t* = 0.128, *P* = 0.720). The mean

age of patients was 47.3 ± 15.2 years (min = 19.0; max = 81.0) in the new LMA group, and 43.2 ± 14.7 years (min = 18.0; max = 70.0) in the classic LMA group (Table 1). The age distribution was similar in both groups ($t = 1.057$, $P = 0.295$) (Table 1).

The median duration of LMA placement was 14.5 secs (range, 12.0-–28.0) in the classic LMA group and 16.0 secs (range, 12.0-–69.0) in the new LMA group. The duration of LMA placement values werewas similar in the two grroups ($Z = 1.568$, $P = 0.117$). The distribution of the number of entry attempts was similar in both groups ($P = 0.741$) (Table 2).

A statistically significant difference was determined between the groups in with respect of to blood smear values, with a higher rate of patients with blood smear in the classic LMA group ($P < 0.05$). No statisti-cally significant difference was determined observed in the throat pain values between the groups in respect of throat pain values (Table 3).

The 5-min DBP values of patients in the classic LMA group were found to be statistically significantly higher in the classic LMA group than those ofin the new LMA group ($P < 0.05$).

A statistically significant difference was determined found between the groups in respect of theterms of the P_{peak} values measured at after 1, 5, 15, and 45 mins ($P < 0.05$). The values of the patients in the new LMA group were found to be higher in the new LMA group. All the P_{mean} values up to the 45th min showed a statistically significant difference between the groups ($P < 0.05$), with higher values determined observed in the new LMA group (Table 4).

Table 1 Analysis of the patients who developed symptomatic cholelithiasis in the postoperative period

	New LMA (n = 27)	Classic LMA (n = 32)	P
Sex			
Female	4 (14.8%)	7 (21.9%)	0.720 [a]
Male	23 (85.2%)	25 (78.1%)	
Age (year)	47.3 ± 15.2	43.2 ± 14.6	0.295 [b]
Height (cm)	170.9 ± 6.7	171.5 ± 8.6	0.791 [b]
Weight (kg)	76.6 ± 9.2	76.9 ± 11.5	0.911 [b]
BMI (kg/m²)	26.3 ± 3.2	26.2 ± 3.3	0.890 [b]
Anesthesia duration	45.0 (35.0–60.0)	37.5 (30.0–50.0)	0.174 [c]

BMI, Body mass index; SD, standard deviation; min, minutes; t, Iindependent-sample t test/Z, Mann–Whitney U test.
[a]Chi-square test (n/%); [b]independent-sample t test (mean ± SD); [c]Mann–Whitney U test [median (IQR)].

Table 2 Duration of placement and number of entry attempts

	New LMA (n = 27)	Classic LMA (n = 32)	P
Duration of LMA placement (s)	Mean ± SD:18.1 ± 10.6 Median: 16.0 (min; max): (12.0; 69.0)	Mean ± SD: 15.3 ± 3.1 Median: 14.5 (min; max): (12.0; 28.0)	(Z = 1.568) P = 0.117
Number of entry attempts			
1	23 (85.2%)	26 (81.3%)	0.877 [a]
2	3 (11.1%)	5 (15.6%)	
3	1 (3.7%)	1 (3.1%)	

Fisher exact test/[**]Pearson chi-square. [a]Chi-square test (n/%); [b]independent-sample t test (mean ± SD); [c] Mann–Whitney U test [Median (IQR)].

Table 3 Postoperative complications

		New LMA (n = 27)	Classic LMA (n = 32)	P
Blood smear				
	Absent	27 (100.0%)	25 (78.1%)	0.012 [a]
	Present	0 (0.0%)	7 (21.9%)	
Throat pain				
	Absent	27 (100.0%)	28 (87.5%)	0.118 [a]
	Present	0 (0.0%)	4 (12.5%)	

[a]Chi-square test (n/%); [b]independent-sample t test (mean ± SD); [c]Mann–Whitney U test [median (IQR)].

Table 4 Analysis of the patients who developed symptomatic cholelithiasis in the postoperative period

		New LMA (n = 27)	Classic LMA (n = 32)	P*
P_{peak} (n_1/n_2)	1. Min. (27/32)	15.0 (13.0–18.0)	12.0 (11.0–16.0)	0.027
	5. Min. (27/32)	16.0 (13.0–18.0)	12.0 (12.0–16.0)	0.039
	10. Min. (27/32)	15.0 (13.0–18.0)	13.0 (12.0–16.0)	0.141
	15. Min. (27/32)	16.0 (13.0–19.0)	13.0 (12.0–16.8)	0.029
	30. Min. (27/29)	16.0 (14.0–19.0)	13.0 (12.0–17.5)	0.090
	45. Min. (16/15)	16.0 (14.3–19.8)	13.0 (12.0–16.0)	0.047
	60. Min. (5/5)	21.0 (14.5–22.5)	13.0 (12.0–26.0)	0.462
	75. Min. (2/3)	17.5 (14.0–0.0)	13.0 (11.0–0.0)	0.564
	90. Min. (1/1)	23.0 (23.0–23.0)	13.0 (13.0–13.0)	--
P_{mean} (n_1/n_2)	1. Min. (27/32)	7.0 (6.0–8.0)	6.0 (6.0–6.8)	0.001
	5. Min. (27/32)	7.0 (6.0–8.0)	6.0 (6.0–7.0)	0.003
	10. Min. (27/32)	7.0 (7.0–8.0)	6.0 (6.0–7.0)	0.003
	15. Min. (27/32)	7.0 (7.0–8.0)	6.0 (6.0–7.0)	0.001
	30. Min. (27/29)	7.0 (7.0–8.0)	6.0 (6.0–7.0)	0.004
	45. Min. (16/16)	7.0 (7.0–9.8)	6.0 (5.3–6.8)	0.002
	60. Min. (5/5)	9.0 (7.0–9.0)	6.0 (5.0–9.5)	0.386
	75. Min. (2/3)	8.0 (7.0–0.0)	6.0 (5.0–0.0)	0.374
	90. Min. (1/1)	9.0 (9.0–9.0)	6.0 (6.0–6.0)	--

*Mann–Whitney U test [median (IQR)].

DISCUSSION

Previous studies reported that the new-generation airway devices created a cardiopulmonary response at a minimal level, stimulated laryngeal reflexes less, and caused fewer complications such as coughing or throat pain during recovery (7, 8). In the present study, no postoperative complications were observed in the new LMA group, whereas blood smear and throat pain were reported postoperatively in many patients in the classic LMA group. However, the airway pressure values after 5 min were higher in the new LMA group.

The Baska Mask LMA has an extremely complex design for the features included. As the volume and size of the device are increased using integrated features such as two tubes on each side, a suction elbow, a hand-held crimping tab, and a bite block located along the full length of the airway, the intra-oral placement becomes difficult and requires additional time. Also, the airway pressures increase because of the volume occupied. In a similar study by Kara *et al.,* Baska Mask was compared with I-Gel. The placement duration was longer (32 ± 12 s), and the airway pressure values were also higher in the Baska Mask group (9). A meta-analysis obtained from the Cochrane 2017 database reviewed studies comparing Proseal LMA and classic LMA. The time required for the placement of the classic LMA was shorter (10). Ali *et al.* compared Proseal LMA and Cobra LMA and reported the placement durations of 20.4 ± 4.2 s and 19.6 ± 3.4 s, respectively (11). In the present study, the total duration of mask placement and effective ventilation was recorded as 16 s in the Baska Mask group and 14.5 s in the classic LMA group. In another study comparing classic LMA with Proseal LMA, the success rate and duration of classic LMA placement were superior to those of Proseal LMA (9). In the present study, the success rate of first attempt of 85.2% in the Baska Mask group was found to be higher, although no statistically significant difference was noted between the groups in terms of the number of entry attempts and successful placement on the first attempt.

On comparing the intraoperative mean and peak airway pressure values in the present study, the values in the Baska Mask group were found to be significantly higher than those in the classic LMA group, but the measured values in both groups were observed to be within the normal range. In a study by Ovat *et al,* the airway pressure in the Proseal LMA group was measured as mean 20.4 cm H2O, while in the present study, this value was found to be 19.0 ± 4.3 cm H_2O in the Baska Mask group (7). The comparisons between Supreme LMA, Proseal LMA, and Cobra LMA new-generation SGAs revealed that the airway pressure values were similar (11).

In the present study, tje blood smear on the device and throat pain were not observed in any patients using the new LMA. This was thought to be due to the fine silicone membrane cuff structure of the Baska Mask preventing mucosa damage. With the manual inflation of the cuff in classic LMA, the cuff pressure might be extremely high or low. Over-inflation can cause airway trauma, and inflation at a low pressure can cause airway leakage and potential aspiration of stomach contents (8). In a study of pediatric patients by Shimbori et al., the classic LMA and Proseal LMA were compared. More postoperative blood smears were observed in the classic LMA group, but the difference was not statistically significant (11). The classic LMA, Supreme LMA, and I-Gel were compared in a study by Hermit *et al*, and the frequency of throat pain at 24 h postoperatively was reported to be similar (12). Previous studies and animal experiments showed that an increase in the cuff pressure and duration of use in classic LMA led to an increased risk of pressure and damage to the pharynx mucosa (13-15).

A limitation of the present study was that the cuff leakage pressure was not examined.

In conclusion, the results of this study demonstrated that both supraglottic airway devices provided adequate, safe, intraoperative airway opening. Although no difference was observed between the two devices in terms of ease of use and clinical performance, it was concluded that the Baska Mask LMA was more advantageous in terms of patient comfort.

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