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## Effects of different larenageal mask types on hemodynamics and airway in pediatric

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### Abstract

In pediatric cases, as in adults, supraglottic airway devices (SADs) are common in short-term interventions. We aimed to investigate the effects of these supraglottic airway devices, which we use in pediatric cases, on hemodynamic and airway in our study, in which we used four types of SAD: The LMA Classic, Cobra Perilaryngeal Airway (PLA), I-gel LMA, and Ambu® AuraGain™. 103 patients with ASA 1-2 and under 18 years of age were randomly divided into LMA Classic, Cobra PLA, i-Gel LMA, and Ambu LMA. The demographic data of the patients were recorded. Hemodynamic data, SAD insertion durations, Pre-operative End-tidal CO<sub>2</sub>, and airway pressures were recorded at induction, intubation (during SAD insertion), and peri-operative 1st, 2nd, 3rd, 4th, 5th, and 10th minutes. As a result of our study, the groups had similar HR and SpO<sub>2</sub> values. EtCO<sub>2</sub> values were generally similar to the LMA Classic group in cobra PLA. When compared to i-gel LMA and Ambu LMA, Cobra PLA EtCO<sub>2</sub> values were high but within the clinically acceptable range as well. Likewise, airway pressures were not statistically different from the classical LMA Cobra PLA. Airway pressure was higher in the Cobra PLA group than in I-Gel LMA and Ambu LMA. However, it was lower than 20 mm H<sub>2</sub>O. In pediatric cases, LMA Classic, Cobra PLA, I-gel LMA, and Ambu LMA can be used safely in general. However, we think that airway pressures should be followed-up more closely in the use of Cobra PLA.

**Keywords:** Pediatric patients, different airway devices, ventilation, airway pressure

### Introduction

Laryngeal mask airway (LMA), which was first used in the 1980s, has been used as an alternative to face-mask ventilation. It has been widely used in outpatient surgeries due to its easy insertion, use without the need for laryngoscopy, and fewer sympathoadrenal effects caused by endotracheal intubation [1]. Again, studies show that LMA can be used safely in resuscitation [2,3]. Especially with the introduction of new generation supraglottic airway devices (SAD), has also been widely used in pediatric cases in short-term surgeries. Today, many types of LMAs with different features are used.

The LMA Classic, which was first used, has a cuffed structure. Compared to endotracheal intubation, its use and hemodynamic

and trauma complications are less, but risks such as gastric aspiration and air leakage are disadvantages in pediatric cases [4]. I-gel LMA, on the other hand, is the 2nd generation, and thanks to its cuffless thermoelastic structure, it fits perfectly on the larynx. It also contains gastric lumen. Cobra Perilaryngeal Airway (PLA), on the other hand, has a cobra-shaped distal end, a pharyngeal cuff, and a structure that allows endotracheal tube (ETT) to pass through. Ambu® AuraGain™ LMA (Ambu, Ballerup, Denmark) is a 3rd generation LMA with a cuffed, polyvinyl structure, and curved, containing esophageal lumen and allowing ETT passage [5].

Our study, in which we used four types of SADs: LMA Classic, Cobra Perilaryngeal Airway (PLA), I-gel LMA, and Ambu® AuraGain™ LMA aimed to investigate the effects of these SADs, which we used in pediatric cases, on hemodynamics and airway.

### Materials and Methods

Our study, which was planned retrospectively, received approval, dated 13.10.2021 and numbered 2021/86, by the Malatya Turgut Özal University Clinical Research Ethics Committee. Patients under

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the age of 18 and with an American Society of Anesthesiologists (ASA) of 1-2, who had surgery between 01.01.2020-01.06.2021 in Malatya Training and Research Hospital following the Helsinki Declaration and STROBE were included. Patients intubated with an endotracheal tube, patients with severe liver, lung, and kidney pathology, patients with active infection, intraoral pathology, mental retardation, and patients with a history of difficult intubation patients with emergency surgery were excluded in the research. The patients included in the research were randomized into four groups as LMA Classic, Cobra PLA, I-gel LMA, and Ambu LMA by a by nurse who was not included in the study using the sealed envelope method. Written informed consent was obtained from parents and/or legal guardians of all patients.

Patients were observed and evaluated before the preoperative anesthesia. After the appropriate fasting period, midazolam (0.3 mg kg<sup>-1</sup>) was given for premedication 30 minutes before the procedure. Standard hemodynamic monitoring was performed on the operating table. Anesthesia was induced with 4-6% sevoflurane decreasing concentration (min 2%) and air-oxygen mixture (50%), and then intravenous access was created. In addition to the sevoflurane induction, 1µg/kg fentanyl was implemented intravenously. An appropriately sized and lubricated Subglottic airway device (SAD) was placed after the ciliary reflex disappeared. It was confirmed that there was no air leak. The insertion time was taken as the time between handling the supraglottic airway device and seeing the end-tidal carbon dioxide (EtCO<sub>2</sub>) trace on the capnograph. More unsuccessful attempts than the 3rd one were excluded from the study. After the placement of the SAD, the patients were connected to a mechanical ventilator (Drager Primus) by adjusting the respiratory frequency to a tidal volume of 6-8 L/kg, EtCO<sub>2</sub> 30-35 mmHg, fresh gas flow 4L/min, and a maximum airway pressure of 30 mmHg. Anesthesia maintenance was performed with 2-3% Sevoflurane + air-oxygen mixture (50% Oxygen) with a MAC value of 1.

Patient demographic (age, gender, weight) data, airway device insertion time, heart rate (HR), peripheral oxygen saturation (SpO<sub>2</sub>), pre-operative EtCO<sub>2</sub> and airway pressures (AP) were measured and recorded at the induction, SAD placement (intubation), and 1st, 2nd, 3rd, 4th, 5th, and 10th minutes after intubation.

### Statistical Analysis

Number (n) and percent (%) values were used to give the distribution of demographic information such as gender, LMA/PLA groups, complications. Conformity to the normal distribution of continuous variables such as HR, SpO<sub>2</sub>, EtCO<sub>2</sub>, and AP in the study were evaluated graphically and using the Shapiro-Wilks test. Mean ± Standard Deviation values were used to display the statistics of the continuous variables that fit the normal distribution, and the median (IQR- Interquartile Range) values were used to show the statistics of continuous variables that did not fit the normal distribution. When comparing the HR, SpO<sub>2</sub>, EtCO<sub>2</sub> And AP of individuals according to LMA/PLA groups, Kruskal-Wallis non-parametric analysis of variance was used when the normal distribution condition was not met, and One way ANOVA analysis was used when the normal distribution condition was met. In pairwise comparisons, the Bonferroni correction was performed, and the analysis results were given.

IBM SPSS Statistics 21.0 (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.) and MS-Excel 2007 programs were used for statistical analysis and calculations. p<0.05 was accepted as statistically significant.

### Results

There were 103 patients in our research, and 82.5% (n=85) of these patients were male. Table 1 given the gender and the number of patients in the groups. Soft tissue trauma developed in 4 (3.9%) patients, cough in 3 (2.9%), laryngospasm in 3 (2.9%), and bronchospasm in 1 (1.0%) patient. The median age of the individuals participating in the investigation was 5.0 (IQR=5.0). The minimum age was 1.0 while the maximum age was 15.0. The mean number of trials was determined as 1.19±0.52 (Table 2).

**Table 1.** Demographic especially

|               | n (%)     |
|---------------|-----------|
| <b>Gender</b> |           |
| Male          | 85 (82.5) |
| Female        | 18 (17.5) |
| <b>Grups</b>  |           |
| Klasik        | 20 (19.4) |
| Cobra         | 20 (19.4) |
| I-Jel         | 26 (25.2) |
| Ambu          | 37 (35.9) |

**Table 2.** Descriptive statistics

|                           | Mean±SS     | median *    | Min; Max |
|---------------------------|-------------|-------------|----------|
| <b>Age</b>                | 5.15±3.49   | 5.0 (5.0)   | 1.0;15.0 |
| <b>Weight</b>             | 18.82±9.96  | 18.0 (11.0) | 4.0;55.0 |
| <b>Number Of Attempts</b> | 1.19±0.52   | 1.0 (0.0)   | 1.0;3.0  |
| <b>Placement Time</b>     | 12.70±10.58 | 12.0 (11.0) | 2.0;65.0 |

\*inter Quartile Range

A significant difference was detected between the groups in terms of pre-operative heart rate (Pre-HR) values ( $\chi^2=14.815$  p=0.003) (Table 3). The mean Pre-HR value in the Ambu group was 129.95±27.02, while the mean Pre-HR value in the Cobra group was 106.15±17.93. A significant difference was detected between Cobra PLA, Ambu LMA, and I Gel LMA, Ambu in pairwise comparisons between the groups regarding pre-HR values (p=0.009 p=0.012). In other groups, no difference was detected in terms of pre-HR levels. A significant difference was detected between the groups in terms of Intubation EtCO<sub>2</sub> values ( $\chi^2=9.191$ , p=0.027). When we look at the mean intubation EtCO<sub>2</sub> values between the groups, it was determined that the highest value was in the Cobra group with 40.75±4.22, and the lowest mean value was in the LMA Classic group with 36.90±4.56. A significant difference was detected between Cobra PLA and I-Gel LMA, Cobra PLA and LMA Classic, Cobra PLA and Ambu LMA in pairwise comparisons between groups in terms of intubation AP values (p=0.004, p=0.007, p=0.001, respectively).

**Table 3.** Comparison of measurement values between groups

|              |                   | Classical Mean±SD<br>(a) | Cobra Mean±SD<br>(b) | İ-Jel Mean±SD<br>(c) | Ambu Mean±SD<br>(d) | Test statistics |        | Groups with<br>a difference |
|--------------|-------------------|--------------------------|----------------------|----------------------|---------------------|-----------------|--------|-----------------------------|
|              |                   |                          |                      |                      |                     | $\chi^2$ F      | p      |                             |
| preoperative | HR                | 115.95±22.65             | 106.15±17.93         | 107.62±26.23         | 129.95±27.02        | $\chi^2=14.185$ | 0.003  | b-c                         |
|              | SpO <sub>2</sub>  | 99.40±1.05               | 99.25±1.02           | 98.88±1.90           | 99.65±0.72          | $\chi^2=4.252$  | 0.235  |                             |
| induction    | HR                | 105.05±22.38             | 103.45±19.43         | 100.54±28.52         | 124.27±25.63        | F=6.082         | 0.001  | a-d, b-d, c-d               |
|              | SpO <sub>2</sub>  | 99.85±0.37               | 99.85±0.37           | 99.65±1.57           | 99.97±0.16          | $\chi^2=3.563$  | 0.313  |                             |
| intubation   | HR                | 106.55±20.92             | 108.05±18.48         | 104.35±24.54         | 120.81±23.30        | F=3.518         | 0.018  | c-d                         |
|              | SpO <sub>2</sub>  | 99.75±0.72               | 99.85±0.37           | 100.08±1.09          | 99.95±0.33          | $\chi^2=3.561$  | 0.313  |                             |
|              | EtCO <sub>2</sub> | 36.90±4.56               | 40.75±4.22           | 40.04±12.59          | 37.24±3.24          | $\chi^2=9.191$  | 0.027  | b-d                         |
|              | Airway Pressure   | 11.65±3.65               | 17.15±5.87           | 12.46±6.24           | 11.27±2.23          | $\chi^2=17.470$ | 0.001  | b-a, b-c, b-d               |
| 1.minute     | HR                | 108.20±23.25             | 109.90±16.93         | 102.73±30.23         | 120.68±19.57        | $\chi^2=9.595$  | 0.022  | c-d                         |
|              | SpO <sub>2</sub>  | 99.75±0.72               | 99.85±0.49           | 100.38±2.51          | 108.0±49.34         | $\chi^2=1.813$  | 0.612  |                             |
|              | EtCO <sub>2</sub> | 36.50±4.33               | 38.35±9.84           | 37.73±2.29           | 36.97±2.74          | $\chi^2=8.439$  | 0.038  | b-d                         |
|              | Airway Pressure   | 12.05±3.59               | 21.70±24.99          | 10.69±3.51           | 11.32±2.17          | $\chi^2=17.942$ | <0.001 | b-c, b-d                    |
| 2.minute     | HR                | 106.75±23.08             | 108.75±17.77         | 105.42±21.99         | 120.24±19.01        | F=3.513         | 0.018  | c-d                         |
|              | SpO <sub>2</sub>  | 99.60±0.94               | 99.80±0.52           | 99.77±0.59           | 100±0.0             | $\chi^2=7.229$  | 0.065  |                             |
|              | EtCO <sub>2</sub> | 36.85±4.37               | 40.70±4.34           | 38.42±3.26           | 36.78±2.99          | $\chi^2=12.438$ | 0.006  | b-d                         |
|              | Airway Pressure   | 12.20±3.83               | 16.00±5.06           | 11.04±3.72           | 11.35±2.15          | $\chi^2=14.906$ | 0.002  | b-c, b-d                    |
| 3.minute     | HR                | 109.95±21.76             | 110.65±20.19         | 105.77±22.72         | 118.22±21.21        | F=1.842         | 0.144  |                             |
|              | SpO <sub>2</sub>  | 99.75±0.55               | 99.05±2.30           | 97.23±12.11          | 100.0±0.0           | $\chi^2=12.236$ | 0.007  | b-d, c-d                    |
|              | EtCO <sub>2</sub> | 36.85±4.43               | 43.65±14.04          | 37.81±3.67           | 38.22±10.20         | $\chi^2=11.651$ | 0.009  | b-d                         |
|              | Airway Pressure   | 12.35±4.04               | 17.60±7.92           | 11.08±3.65           | 11.41±1.92          | $\chi^2=18.568$ | <0.001 | b-c, b-d                    |
| 4.minute     | HR                | 110.25±23.83             | 115.10±21.42         | 109.38±21.54         | 118.97±19.13        | F=1.321         | 0.272  |                             |
|              | SpO <sub>2</sub>  | 99.50±0.69               | 99.60±0.82           | 99.60±0.82           | 99.58±0.81          | $\chi^2=12.458$ | 0.006  | a-d                         |
|              | EtCO <sub>2</sub> | 36.95±4.52               | 40.50±4.85           | 37.85±3.19           | 36.27±3.07          | $\chi^2=15.105$ | 0.002  | b-d                         |
|              | Airway Pressure   | 12.65±3.94               | 15.95±5.22           | 11.85±3.28           | 11.27±1.91          | $\chi^2=14.697$ | 0.002  | b-c, c-d                    |
| 5.minute     | HR                | 109.75±24.52             | 118.50±20.04         | 110.23±20.69         | 118.41±18.93        | F=1.397         | 0.248  |                             |
|              | SpO <sub>2</sub>  | 99.45±0.94               | 99.60±0.75           | 111.08±58.93         | 100.0±0.0           | $\chi^2=14.461$ | 0.002  | a-d                         |
|              | EtCO <sub>2</sub> | 36.55±4.71               | 40.25±5.61           | 37.92±3.42           | 37.89±10.14         | $\chi^2=10.595$ | 0.014  | b-d                         |
|              | Airway Pressure   | 12.30±2.96               | 16.20±5.19           | 11.92±3.40           | 11.24±2.07          | $\chi^2=17.003$ | 0.001  | b-c, b-d                    |
| 10.minute    | HR                | 109.00±23.09             | 112.95±15.42         | 110.96±24.45         | 114.46±18.91        | F=0.346         | 0.792  |                             |
|              | SpO <sub>2</sub>  | 99.50±0.95               | 99.65±0.67           | 99.50±1.10           | 100.0±0.0           | $\chi^2=12.905$ | 0.005  | a-d                         |
|              | EtCO <sub>2</sub> | 36.00±3.59               | 39.00±6.86           | 36.46±3.20           | 35.65±3.18          | $\chi^2=11.054$ | 0.011  | b-d,                        |
|              | airway pressure   | 12.85±3.51               | 16.95±5.23           | 12.15±3.29           | 11.22±1.96          | $\chi^2=21.594$ | <0.001 | b-c, b-d                    |

$\chi^2$ =Kruskal Wallis Test İstatistiği , F: One-way ANOVA test istatistiği, HR:Heart Sate, Spo<sub>2</sub>: peripheral oxygen saturation, EtCO<sub>2</sub>: end-tidal carbon dioxide

The median airway pressure measured at the 1st minute was 11.5 (IQR=5.0) in the classic group, 16.0 (IQR=12.0) in the cobra group, 10.0 (IQR=5.0) in the i-Gel group, and 11.0 (IQR=3.0) in the Ambu group. A significant difference was detected between the groups in terms of airway pressure values measured at the 1st minute ( $=17.942$ ,  $p<0.001$ ). In addition, SpO<sub>2</sub> values measured at the 1st minute were similar between the groups ( $p>0.05$ ). There was a significant difference between i-Gel LMA and Ambu LMA in pairwise comparisons between the groups in terms of HR values measured at the 1st minute ( $p=0.020$ ). In addition, a significant difference was detected between Cobra PLA and Ambu LMA in pairwise comparisons between groups in terms of EtCO<sub>2</sub> values measured at the minute ( $p=0.035$ ).

A significant difference was detected between the groups regarding HR values measured at the 2nd minute ( $F=3.513$ ,  $p=0.018$ ). The highest mean HR value measured at the 2nd minute was in the Ambu group with  $120.24\pm 19.01$ , and the lowest mean value was in the I-GEL group with  $105.42\pm 21.99$ . A significant difference was detected between Cobra PLA and I-Gel LMA, and Cobra PLA and Ambu LMA in pairwise comparisons between the groups regarding airway pressure values measured at the 2nd minute ( $p=0.002$ ,  $p=0.005$ ). There was no statistically significant difference between the other groups regarding airway pressure levels measured at the 2nd minute.

A significant difference was detected between the groups in terms of SpO<sub>2</sub> values measured at the 3rd minute ( $=12.236$ ,  $p=0.007$ ). While the mean of the 3rd minute SpO<sub>2</sub> value in the Ambu group was 100.0, the mean of the 3rd minute SpO<sub>2</sub> values in the I-gel LMA group was  $97.23\pm 12.11$ . A significant difference was detected between Cobra PLA and Ambu LMA, and I-Gel LMA and Ambu LMA in pairwise comparisons between the groups in terms of SpO<sub>2</sub> values measured at the 3rd minute ( $p=0.018$ ,  $p=0.030$ ). In terms of EtCO<sub>2</sub> values, a statistically significant difference was detected between Cobra PLA and Ambu LMA in pairwise comparisons between the groups ( $p=0.004$ ).

A significant difference was detected between the groups in terms of EtCO<sub>2</sub> values measured at the 4th minute ( $=15.105$ ,  $p=0.002$ ). The highest mean EtCO<sub>2</sub> value measured at the 4th minute was in the Cobra group with  $40.50\pm 4.85$ , and the lowest mean value was in the Ambu group with  $36.27\pm 3.07$ . A significant difference was detected between Cobra PLA and Ambu PLA in pairwise comparisons between the groups in terms of EtCO<sub>2</sub> values measured at the 4th minute ( $p=0.001$ ). A significant difference was detected between LMA Classic and Ambu LMA in pairwise comparisons between groups in terms of SpO<sub>2</sub> values ( $p=0.007$ ).

The median airway pressure measured at the 5th minute was 12.0 (IQR=3.0) in the classic group, 16.0 (IQR=7.0) in the cobra group, 11.0 (IQR=4.0) in the i-Gel LMA group, and 11.0 (MAG=2.0) in the Ambu group. A statistically significant difference was detected between the groups in terms of AP values measured at the 5th minute ( $=17.003$ ,  $p=0.001$ ). In addition, HR values measured at the 5th minute were similar between the groups ( $p>0.05$ ). A significant difference was detected between Cobra PLA and i-Gel LMA and between Cobra PLA and Ambu LMA in pairwise comparisons between the groups regarding airway pressure values measured at the 5th minute ( $p=0.015$ ,  $p<0.001$ ). There was no statistically significant difference between the other groups regarding AP

levels measured at the 5th minute.

The mean EtCO<sub>2</sub> value measured at the 10th minute was  $36.00\pm 3.59$  in the classical group,  $39.00\pm 6.86$  in the cobra group,  $36.46\pm 3.20$  in the I-Gel group, and  $35.65\pm 3.18$  in the Ambu group. A significant difference was detected between the groups in terms of EtCO<sub>2</sub> values measured at the 10th minute ( $\chi^2=11.054$ ,  $p=0.011$ ). A statistically significant difference was found between Cobra and Ambu in pairwise comparisons between the groups in terms of EtCO<sub>2</sub> values measured at the 10th minute ( $p=0.006$ ).

## Discussion

SADs have become common in the pediatric patient group who underwent short-term surgery and/or intervention. Besides the LMA classic, with the introduction of the next-generation laryngeal masks, their usage area has also increased. Our study investigated the effects of LMA varieties with different anatomy and structural features on hemodynamics and airway. As a result of our study, the groups had similar HR and SpO<sub>2</sub> values. EtCO<sub>2</sub> values were generally similar to the LMA Classic group in cobra PLA. When compared to i-gel LMA and Ambu LMA, Cobra PLA EtCO<sub>2</sub> values were high but within the clinically acceptable range as well. Likewise, airway pressures were not statistically different from the classical LMA Cobra PLA. Airway pressure was higher in the Cobra PLA group than in I-Gel LMA and Ambu LMA. However, it was lower than 20 mmH<sub>2</sub>O.

Although the classical LMA, which was first used, is easier and less traumatic, the risk of not creating sufficient tidal under positive pressure, aspiration, gastric distension, and air leakage risk are the main concerns in its use in the pediatric patient group since the anatomy of pediatric patients differs from that of adults [6]. In the article published by Lalwani et al. in 2012, they stated that airway obstruction might be more common in pediatric cases who underwent adenotonsillectomy [7]. Özdamar et al., in their research on pediatric patients who underwent laparoscopic surgery, stated that there was no significant difference in gastric pressure increase and ventilation parameters of LMA classic compared to ETT [8]. There was no ETT group in our study. However, we obtained results parallel to the findings of Özdamar et al. in the ventilation and hemodynamic values of classical LMA.

Maitra et al. showed that i-gel LMA was similar to the LMA classic and ProSeal™ LMA in terms of airway pressure, insertion time, and complication risk and that i-gel™ LMA is an available appropriate alternative in the meta-analysis study of their study conducted with the LMA classic, i-gel LMA, and ProSeal™ LMA in the pediatric patient group [9]. Ghaffar et al. showed that in different head-neck positions, the i-gel LMA has a higher sealing pressure and better ventilation parameters than the LMA classic [10]. In our study, we have seen that the hemodynamic and airway pressures of i-gel™ LMA and the LMA Classic are similar.

Ratajczyk et al. in their study comparing the LMA Classic with Cobra PLA and ETT, were similar in terms of airway leakage [11]. In addition, complications such as sore throat, dysphagia, and blood traces were lower than the LMA and ETT groups. In the study of Galvin et al. on 40 patients who underwent laparoscopic gynecology, Cobra PLA provided a higher sealing pressure but had a higher rate of blood trace [12]. Tekin et al., in their study

conducted with 90 pediatric patients, found that the Copra LMA was easier to insert than the LMA Classic and that it provided a lower airway pressure [13]. In our study, although the airway pressure was higher during Cobra LMA intubation compared to LMA Classic, there was no statistically significant difference in hemodynamic, EtCO<sub>2</sub>, HR, and AP values at other measurement times.

In the meta-analysis study conducted by Mihara et al. in 2017, they stated that I-gel, Proseal LMA, and Cobra PLA provided a higher sealing pressure than the LMA Classic, and there was less bloodstain in i-gel LMA [14]. Mihara et al. claimed that Proseal LMA would be the best option in pediatric cases. Lai et al., in their meta-analysis study in 2021, similar to the results of Mihara et al., stated that the sealing pressures of i-gel, Cobro PLA, and Ambu® Aura-i™ LMA were higher than the LMA Classic, but Cobra PLA caused more sore throat than Ambu® Aura-i™ LMA [15]. Rangaswamy et al., in their study in 2019 on 63 pediatric patients, showed that Ambu® Aura-i™ LMA effectively provides ventilation and is a suitable airway device for ETT, as being fiberoptic in emergency and difficult intubations [16]. In our study, there were higher airway pressure and EtCO<sub>2</sub> in Cobra PLA. However, it was less than 20 mmH<sub>2</sub>O and EtCO<sub>2</sub> was within clinically acceptable limits.

### Limitations

Our study is a single-center study. Multicenter studies in large patient groups are needed. Another limitation is that our study did not include an ETT group. Therefore, the comparison of the supraglottic airway devices with tracheal intubation could not be made.

### Conclusion

In pediatric cases, LMA Classic, Cobra PLA, I-gel LMA, and Ambu LMA can be used safely in general. However, we think that airway pressures should be followed-up more closely in the use of Cobra PLA.

### Conflict of interests

*The authors declare that they have no competing interests.*

### Financial Disclosure

*All authors declare no financial support.*

### Ethical approval

*For our study, approval of Malatya Turgut Ozal University Clinical Research Ethics Committee dated 13.10.2021 and numbered 2021/86 as obtained.*

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