

# Risk Factors for Acute Postoperative Sore Throat (POST) After Supraglottic Device Use

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## Research Article

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# Abstract

**Background.** To identify risk factors for acute postoperative sore throat (POST) after general anesthesia using a supraglottic airway device (SAD) in adults undergoing elective tympanoplasty.

**Methods.** The medical records of 1424 adults who underwent elective tympanoplasty under general anesthesia using an SAD were reviewed retrospectively. Patients received one of four SADs at the discretion of the anesthesiologists: flexible reinforced LMA (FLMA), Ambu AuraFlex FLMA, or two local brand devices (Tuoren FLMA or Tuoren Esophageal Drainage LMA). POST upon discharge from the postanesthesia care unit (PACU) was measured using a visual analog scale (VAS) and categorized as no pain, mild pain, and moderate to severe pain. Data regarding potential risk factors for POST were collected from the medical records.

**Results.** The mean patient age was 43.24 years; 622 patients were male and 802 were female. The overall incidence of POST during the PACU stay was 38.1%. Female sex, certain types of SAD, higher intracuff pressure, and longer duration of surgery were independent risk factors for POST on multivariate logistic regression analysis. Compared to FLMA, both the Tuoren FLMA and the Tuoren Esophageal Drainage LMA were risk factors for POST. The Tuoren Esophageal Drainage LMA was the strongest independent risk factor for moderate to severe POST.

**Conclusions.** Use of local brand SADs contributed to the development of POST after elective tympanoplasty under general anesthesia. The Tuoren Esophageal Drainage LMA was the strongest predictor of moderate to severe POST.

## Background

Since invention of the laryngeal mask airway (LMA) by Dr. Archie Brain in 1981, various supraglottic airway devices (SADs) have been used routinely for airway management during general anesthesia [1]. Throughout this time, many SAD modifications have been introduced into clinical anesthesia practice [2].

As the safety and effectiveness of SADs have been firmly established, minor but more common pharyngolaryngeal adverse outcomes, such as sore throat, assume greater importance [3]. The overall incidence of postoperative sore throat (POST) from SADs ranges from 17–42% [4]. Sore throat is an important cause of patient discomfort, which can result in dissatisfaction after general anesthesia [3]. Identifying predictive factors for this SAD-related morbidity would facilitate early intervention and more effective management. However, few studies have evaluated the risk factors for POST in adults.

SADs are commonly used during ear, nose, and throat (ENT) surgeries [2]. The purpose of this study was to identify preoperative factors predicting POST after general anesthesia with an SAD in patients undergoing elective tympanoplasty.

## Materials And Methods

# Data collection

This study was a retrospective chart review analysis of adults, aged 18 to 70 years, who were received general anesthesia with an SAD from July 2018 to December 2019 at the otologic center of our institution. The study included 1424 patients with an American Society of Anesthesiologists physical status of I–II who underwent elective tympanoplasty under general anesthesia with an SAD during the study period. Patients with preoperative sore throat or those whose had a tracheal tube were excluded from the study.

## Anesthesia

All patients received sevoflurane-based or propofol-based general anesthesia with an SAD. Inhaled nitrous oxide was not used. The type of anesthesia was based on the anesthesiologists' preference. Mechanical ventilation was used throughout the procedure.

No premedication was administered before anesthesia induction. Routine monitoring, including noninvasive blood pressure, electrocardiography (lead II), pulse oximetry, and end-tidal carbon dioxide, was used for each patient. All patients underwent preoxygenation, followed by intravenous induction with remifentanyl  $0.5 \mu\text{g kg}^{-1}$  and propofol  $1.5\text{--}2 \text{ mg kg}^{-1}$ . Rocuronium  $0.6 \text{ mg kg}^{-1}$  or cisatracurium  $0.1 \text{ mg kg}^{-1}$  was administered at induction to facilitate SAD insertion. Following induction, a SAD was placed when the consultant determined that an adequate depth of anesthesia (e.g., no motor response to jaw thrust) had been reached.

SAD sizes were standardized according to sex, with women receiving a size 3 SAD and men receiving a size 4 SAD. Four kinds of SADs were available for use: a flexible reinforced LMA (FLMA; LMA Flexible™, Laryngeal Mask Company Limited, Perak, Malaysia), Ambu AuraFlex LMA (Ambu® AuraGain™ Laryngeal Airway, Denmark), Tuoren FLMA (Tuoren Medical Company, Henan, China), and Tuoren Esophageal Drainage LMA (Tuoren Medical Company) (Fig. 1). The choice of LMA was at the discretion of the anesthesiologists.

All SADs were inserted by an anesthesiologist with more than 1-year experience using SADs. Lidocaine gel was applied to the posterior surface of the SAD as a lubricant prior to insertion. The technique for SAD insertion was guided by both the manufacturers' recommendations and the anesthesia providers' routine practice. Following insertion, all SADs were inflated with a 20-mL B. Braun™ syringe (B. Braun Medical Inc., Bethlehem, PA, USA) to achieve an effective airway seal, as determined by listening for an audible leak during manual ventilation up to 20-cm H<sub>2</sub>O airway pressure. After a seal was achieved, the anesthesia providers reattached the B. Braun™ syringe to the SAD cuff and allowed the plunger to equilibrate with the SAD cuff pressure. The resulting cuff pressure was measured by manometry (VBM, Medizintechnik, Suiz, Germany) with the patients' head in the supine, neutral position (cephalic neutral position). The cuff pressure was then measured after positioning the patients' head for surgery, with the head turned to the side opposite the operative ear (cephalic lateral position).

Adequacy of ventilation was assessed by observing thoracoabdominal movement during manual ventilation and by visualizing the capnography end-tidal carbon dioxide tracing. If the SAD was not seated properly or an adequate seal was not achieved, the device was repositioned.

## Outcomes

Relevant information was retrieved from the medical records. Data were collected regarding factors that may contribute to POST: age, sex, height, weight, type of SAD, size of SAD, use of an oral airway device at any time, number of SAD insertion attempts, SAD intracuff pressure, oropharyngeal leak pressure, volume of gas injected into the SAD cuff, anesthesia regimen (inhalation or intravenous), and duration of surgery. We also collected information about pharyngolaryngeal complications. This information was obtained by nurses in the postanesthesia care unit (PACU), who conducted interviews in all patients at the time of discharge from the PACU.

The primary outcome was the incidence of POST at discharge from the PACU. The severity of POST was measured with a visual analog scale (VAS) ranging from 0 to 10. We defined a VAS of 0 as no pain, 1 to 3 as mild pain, and 4 to 10 as moderate to severe pain. The secondary outcomes were SAD intracuff pressures (after allowing passive recoil of the syringe attached to the SAD cuff) with the head in both the cephalic neutral and cephalic lateral positions and other pharyngolaryngeal complications, such as dysphagia or dysphonia. Dysphagia was defined as difficulty in, or pain provoked by, swallowing (yes/no). Dysphonia was defined as difficulty speaking or pain while speaking (yes/no).

## Statistical analysis

Continuous data were described as mean  $\pm$  standard deviation, and categorical data were described as number (percentage). Age, weight, height, body mass index (BMI), and volume of gas injected into the SAD cuff were compared between POST groups using analysis of variance. Cuff pressure in the cephalic neutral position, cuff pressure in the cephalic lateral position, duration of surgery, airway seal pressure in the cephalic neutral position, and airway seal pressure in the cephalic lateral position were compared using the Wilcoxon rank-sum test. Cochran-Mantel-Haensel test was used to explore associations between POST and sex, SAD type, SAD size, number of SAD insertion attempts, and anesthesia regimen.

For multivariate analysis, a partial proportional odds model based on logistic regression analysis was used because SAD type was considered to not meet the assumption of proportional odds. All variables with a  $P$  value  $< 0.05$  in univariate analysis were included in the multiple logistic regression analysis. In the multivariate regression model, the dependent variable was POST, divided into three groups: no pain, mild pain, and moderate to severe pain. Age, sex, BMI, height, SAD type, SAD size, duration of surgery, cuff pressure in the cephalic lateral position, and cuff pressure in the cephalic neutral position were the independent variables. Regression coefficients and odds ratios (ORs) with 95% confidence intervals (95% CIs) were determined. All statistical analyses were performed using SAS 9.4. (SAS Institute, Inc., Cary, NC, USA).

## Results

Of the 1424 adults included in the study, 622 were male and 802 were female. The mean age was  $43.2 \pm 14.4$  years. Most patients (99.1%) received a size 3 or 4 SAD, with 13 (0.9%) receiving a size 2.5 or 5 SAD. The mean BMI was  $18.6 \text{ kg/m}^2$  for the 3 patients receiving a size 2.5 SAD and  $24.6 \text{ kg/m}^2$  for the 10 patients receiving a size 5 SAD.

The incidence of POST at discharge from the PACU was 38.1%. A total of 877 patients (61.6%) had no sore throat, 474 patients (33.3%) had a mild sore throat, and 73 patients (5.1%) had a moderate to severe sore throat. No dysphagia or dysphonia was recorded.

In univariate analyses, eight POST risk factors differed significantly between the three groups: age, sex, height, SAD type, SAD size, cuff pressure in the cephalic lateral position, cuff pressure in the cephalic neutral position, and duration of surgery (Table 1).

Table 1  
Univariate Analysis of Factors Associated with the Development of Postoperative Sore Throat

Factor	No Pain (n = 877)	Mild Pain (n = 474)	Moderate/Severe Pain (n = 73)	P value
Age (y)	42.33 ± 14.80	44.59 ± 13.43	45.42 ± 13.98	0.0091*
Sex				< 0.0001*
Male	428 (68.81)	176 (28.30)	18 (2.89)	
Female	449 (55.99)	298 (37.16)	55 (6.86)	
Weight (kg)	62.62 ± 11.81	62.81 ± 12.27	60.74 ± 10.59	0.3809
Height (cm)	164.89 ± 10.49	163.95 ± 8.02	162.36 ± 7.89	0.0377*
BMI (kg/m <sup>2</sup> )	23.31 ± 8.68	23.24 ± 3.39	22.95 ± 3.19	0.9148
SAD type				< 0.0001*
FLMA	461 (72.71)	165 (26.03)	8 (1.26)	
Ambu AuraFlex LMA	31 (79.49)	8 (20.51)	0	
Tuoren FLMA	133 (62.73)	70 (33.02)	9 (4.25)	
Tuoren Esophageal Drainage LMA	252 (46.75)	231 (42.86)	56 (10.39)	
LMA size				< 0.0001*
2.5	1 (33.33)	1 (33.33)	1 (33.33)	

Data are presented as mean (standard deviation) or number (%).

BMI, body mass index; FLMA, flexible reinforced LMA; LMA, laryngeal mask airway; SAD, supraglottic airway device.

\*  $P < 0.05$ .

Factor	No Pain (n = 877)	Mild Pain (n = 474)	Moderate/Severe Pain (n = 73)	P value
3	446 (56.96)	283 (36.14)	54 (6.90)	
4	425 (67.68)	187 (29.78)	16 (2.55)	
5	5 (50.00)	3 (30.00)	2 (20.00)	
<b>Number of SAD insertion attempts</b>				0.2172
1	829 (62.00)	438 (32.76)	70 (5.24)	
2	39 (57.35)	29 (42.65)	0	
3	8 (50.00)	6 (37.50)	2 (12.50)	
4	1 (33.33)	1 (33.33)	1 (33.33)	
<b>Intracuff pressure in cephalic neutral position (cm H<sub>2</sub>O)</b>	27.23 ± 8.79	28.57 ± 8.57	30.78 ± 8.92	0.0001*
<b>Intracuff pressure in cephalic lateral position (cm H<sub>2</sub>O)</b>	26.72 ± 9.04	28.47 ± 9.21	30.33 ± 8.97	0.0002*
<b>Duration of surgery (min)</b>	85.66 ± 42.32	90.07 ± 46.18	100.56 ± 44.81	0.0029*
<b>Oropharyngeal leak pressure in cephalic neutral position (cm H<sub>2</sub>O)</b>	19.66 ± 4.53	19.64 ± 4.85	21.75 ± 2.63	0.5657
<b>Oropharyngeal leak pressure in cephalic lateral position (cm H<sub>2</sub>O)</b>	20.11 ± 4.27	20.63 ± 4.71	20.50 ± 1.73	0.4556
<b>Volume of gas injected into SAD cuff (mL)</b>	14.02 ± 4.85	14.85 ± 5.21	13.83 ± 3.40	0.6318
<b>Anesthesia regimen</b>				0.2865

Data are presented as mean (standard deviation) or number (%).

BMI, body mass index; FLMA, flexible reinforced LMA; LMA, laryngeal mask airway; SAD, supraglottic airway device.

\*  $P < 0.05$ .

Factor	No Pain (n = 877)	Mild Pain (n = 474)	Moderate/Severe Pain (n = 73)	P value
Inhalation	359 (84.87)	257 (84.54)	47 (77.05)	
Intravenous	64 (15.13)	47 (15.46)	14 (22.95)	
Data are presented as mean (standard deviation) or number (%).				
BMI, body mass index; FLMA, flexible reinforced LMA; LMA, laryngeal mask airway; SAD, supraglottic airway device.				
* $P < 0.05$ .				

In multivariable analysis, four factors were statistically significant predictors of POST (Table 2). Female sex was an independent risk factor for POST (OR, 2.16; 95% CI, 1.32–3.55). For type of SAD, we used a split point score, with 2 representing the risk of developing POST of any severity, and 3 representing the risk of developing moderate to severe POST. Compared with the FLMA, both the Tuoren FLMA (OR, 1.63; 95% CI, 1.16–2.29) and the Tuoren Esophageal Drainage LMA (OR, 3.35; 95% CI, 2.57–4.39) were associated with an increased risk of POST. Similarly, both the Tuoren FLMA (OR, 3.98; 95% CI, 1.46–10.86) and the Tuoren Esophageal Drainage LMA (OR, 10.75; 95% CI, 4.82–23.99) were risk factors for developing moderate to severe POST, when compared with the FLMA. Higher cuff pressure in the cephalic neutral position (OR, 1.02; 95% CI, 1.00–1.04) and longer duration of surgery (OR, 1.00; 95% CI, 1.00–1.01) were also risk factors for POST.

Table 2  
Multivariate Logistic Regression Analysis of Predictors of Postoperative Sore Throat

Factor	Split point score <sup>a</sup>	Regression coefficient	OR (95% CI)	P value
Sex (female vs male)	-	0.7719	2.16 (1.32–3.55)	0.0022*
<b>Type of SAD</b>				
Ambu AuraFlex LMA vs FLMA	3	-11.2087	0.00 (0.00–53E303)	0.9754
Ambu AuraFlex LMA vs FLMA	2	-0.6211	0.54 (0.24–1.21)	0.1338
Tuoren FLMA vs FLMA	3	1.3819	3.98 (1.46–10.86)	0.0070*
Tuoren FLMA vs FLMA	2	0.4898	1.63 (1.16–2.29)	0.0046*
Tuoren Esophageal Drainage LMA vs FLMA	3	2.3750	10.75 (4.82–23.99)	< .0001*
Tuoren Esophageal Drainage LMA vs FLMA	2	1.2101	3.35 (2.57–4.39)	< .0001*
<b>Cuff pressure in cephalic neutral position</b> (higher vs lower)	-	0.0184	1.02 (1.00–1.04)	0.0431*
<b>Duration of surgery</b> (longer vs shorter)	-	0.00336	1.00 (1.00–1.01)	0.0078*
<sup>a</sup> 2 represents the risk of developing POST of any severity; 3 represents the risk of developing moderate to severe POST				
CI, confidence interval; FLMA, flexible reinforced LMA; LMA, laryngeal mask airway; OR, odds ratio; SAD, supraglottic airway device; VAS, visual analog scale.				
* $P < 0.05$ .				

## Discussion

The overall incidence of POST upon discharge from the PACU was 38.4% after the use of one of four types of SADs in patients undergoing elective tympanoplasty. When classified by severity, the incidence of mild POST was 33.3% and the incidence of moderate to severe POST was 5.1%. No patient developed dysphonia or dysphagia. Female sex, certain types of SAD, higher intracuff pressure in the cephalic neutral position, and longer duration of surgery were independent risk factors for developing POST.

Sore throat is a common complaint after surgery. It affects patient satisfaction and can influence activity after discharge. SADs offers an alternative to traditional tracheal intubation, with the potential benefit of reducing the risk of sore throat [5–7]. However, the overall incidence of POST after using an SAD can be as high as 42% [8]. Our 38.4% incidence of POST of any severity at discharge from the PACU is consistent with this previously reported percentage.

Various pre- and intraoperative factors influence the incidence of postoperative pharyngolaryngeal complications. Tracheal intubation, female sex, younger age, pre-existing lung disease, prolonged duration of anesthesia, and presence of a blood-stained tracheal tube on extubation are associated with the greatest risk in adults. Insertion technique, SAD choice, and intracuff pressure may contribute to the incidence of sore throat after anesthesia with an SAD [9]. Careful LMA insertion techniques are of paramount importance for preventing airway trauma and POST [6]. In our study, all SADs were inserted by experienced anesthesiologists using standard insertion techniques, and we found that risk factors for POST in the early postoperative period (at PACU discharge) were female sex, higher intracuff pressure in the cephalic neutral position, longer duration of surgery, and certain types of SAD.

Previous studies have shown that women have a higher risk of POST than men after use of a tracheal tube [10–12]. Likewise, Jaensson et al. reported a higher incidence of POST after LMA use in women than in men (26% vs. 6%) [13]. Our study confirms these findings. By contrast, Grady et al. [14] reported similar incidences of POST after LMA use between men and women. The lower incidence of POST in men may be explained by differences in pharyngeal anatomy between sexes [15]. The design of currently used SADs may be better suited to the anatomical features of the male pharynx rather than the female pharynx.

Overall, the incidence of POST differs minimally between first- and second-generation SADs, with the exception of a lower incidence with the i-gel, which may be attributed to the absence of an inflatable cuff [9, 16, 17]. In the current study, we found that both local brand SADs, the first-generation Tuoren FLMA and the second-generation Tuoren Esophageal Drainage LMA, contributed to POST. Compared to FLMA, both Tuoren devices were significant independent risk factors for POST. The Tuoren Esophageal Drainage LMA was also the strongest independent risk factor for moderate to severe POST, with an OR of 10.75 (95% CI, 4.82–23.99). These results may be at least partially explained by the composition of the SADs. The FLMA and Ambu AuraFlex LMA are both made of polyvinyl chloride (PVC), while the Tuoren SADs are composed of medical-grade silicone. Our findings suggest that silicone may cause more mucosal irritation than PVC. The Tuoren Esophageal Drainage LMA also has a relatively fixed and curved structure with an inflatable airway cuff, and as a second-generation SAD, it has two drain channels that emerge proximally as separate ports and enter a chamber beside the cuff bowl. It has a more strongly tapered leading tip than the other SADs used in our study, which may have caused more mucosal injury.

An increasing body of evidence has confirmed that high SAD intracuff pressures contribute significantly to laryngopharyngeal complications, including POST [8, 9, 16, 18], and adjustment of intracuff pressure reduces the incidence of moderate POST [8, 19, 20]. As SAD intracuff pressure increases, perfusion of the

airway mucosa progressively decreases, resulting in postoperative pharyngolaryngeal complications [21]. Use of manometry can reduce pharyngolaryngeal complications by 70%, compared with routine care without manometry [4]. In our study, the mean cuff pressures in the cephalic neutral position were 27.23 cm H<sub>2</sub>O, 28.75 cm H<sub>2</sub>O, and 30.33 cm H<sub>2</sub>O in the no pain, mild sore throat, and moderate to severe sore throat groups, respectively. The differences between these pressures were statistically significant, suggesting that as intracuff pressure increases, the incidence of POST also increases. Multivariate analysis also identified higher intracuff pressure in the cephalic neutral position as a significant risk factor for POST, although it appeared to be a weak predictor (OR, 1.02; 95% CI, 1.00–1.04).

Grady et al. [14] reported that use of a large SAD was associated with a higher incidence of POST in both sexes. In their study, patients were randomized to receive either a large SAD (size 5 in males and size 4 in females) or a small SAD (size 4 in males and size 3 in females). Use of a large SAD was associated with a four-fold increased risk of developing sore throat on the first postoperative day, despite the measured SAD intracuff air pressure being higher in patients with a small LMA. In our study, we found no significant association between POST and SAD size, which is likely because all patients were managed with a small SAD (almost exclusively size 4 in males and size 3 in females). Furthermore, intracuff pressures were relatively low (< 35 cm H<sub>2</sub>O) and mechanical ventilation was used in our study, in contrast to the higher intracuff pressures (> 60 cm H<sub>2</sub>O) and use of spontaneous ventilation in the Grady et al study. Grady et al. [14] also reported that males with POST underwent longer procedures than men who did not develop POST. When considering all patients (males and females), the risk of developing POST increased by 33% (OR, 1.33; 95% CI, 1.03–1.71) for each 10-min increase in surgery duration. In the current study, we likewise identified longer surgery duration as a risk factor for POST.

Although pressure neuropraxia from the SAD cuff can result in dysphonia, SAD-related dysphonia is rare [22–24]. Seet et al. [4] reported dysphonia after use of an LMA in 4.1% of patients in their cuff pressure-limited group and 6.8% of patients receiving routine. Similarly, Kan et al. found no instances of dysphonia when LMA intracuff pressure was limited to 25 cm H<sub>2</sub>O [25], further supporting the suggestion that SAD intracuff pressures influence the occurrence of dysphonia. The low intracuff pressures in the present study may explain the lack of dysphonia.

This study has some weaknesses. First, since data were obtained from a single center, in which local brand (Tuoren) devices were used, the results may not be applicable to other regions. Second, the incidence of POST was assessed only at discharge from the PACU. POST may persist for 2 to 3 days and require additional attention from healthcare providers [26]. However, Seet et al. found that the incidence of POST was low (3.1%) in their pressure-limiting group at 24 hours postoperatively [4]. Third, we did not monitor intracuff pressures intraoperatively. Burgard et al. [15] found that LMA cuff pressures increased significantly during the first 60 minutes of anesthesia because of nitrous oxide diffusion into the cuff. In our study, we avoided nitrous oxide and used only an air/oxygen mixture. Vasanth Karthik et al. observed no change in intracuff pressures 1 hour after SAD insertion when using an air/oxygen mixture [27]. Furthermore, it has been suggested that use of intermittent positive pressure ventilation rather than

intracuff pressure may be responsible for postoperative pharyngolaryngeal complications [28]. Further study regarding the association between different ventilation modes and POST is warranted.

## Conclusion

In summary, this study provides additional information to assist practitioners, especially in China, in choosing the most appropriate SAD. The ideal SAD would be easy to use and provide a high airway leak pressure and cause no POST. If selection criteria are based on POST, our results suggest that the Tuoren Esophageal Drainage LMA is the least preferable among the four SADs evaluated.

## Abbreviations

POST, postoperative sort throat; SAD, supraglottic airway device; FLMA, flexible reinforced Laryngeal mask airway; PACU, post-anesthesia care unit; VAS, visual analog sale; BMI, body mass index.

## Declarations

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**Availability of data and materials.** The datasets used /or analyzed during the current study available from the corresponding author on reasonable request.

**Author Contributions.** YZH and KZC wrote the manuscript and were involved in data gathering, analysis, and interpretation. They made equal contribution. SX conceived of the study, and participated in its design and coordination and the drafting of manuscript. All authors read and approved the final manuscript.

**Conflict of interest.** None.

**Consent for publication.** Not applicable.

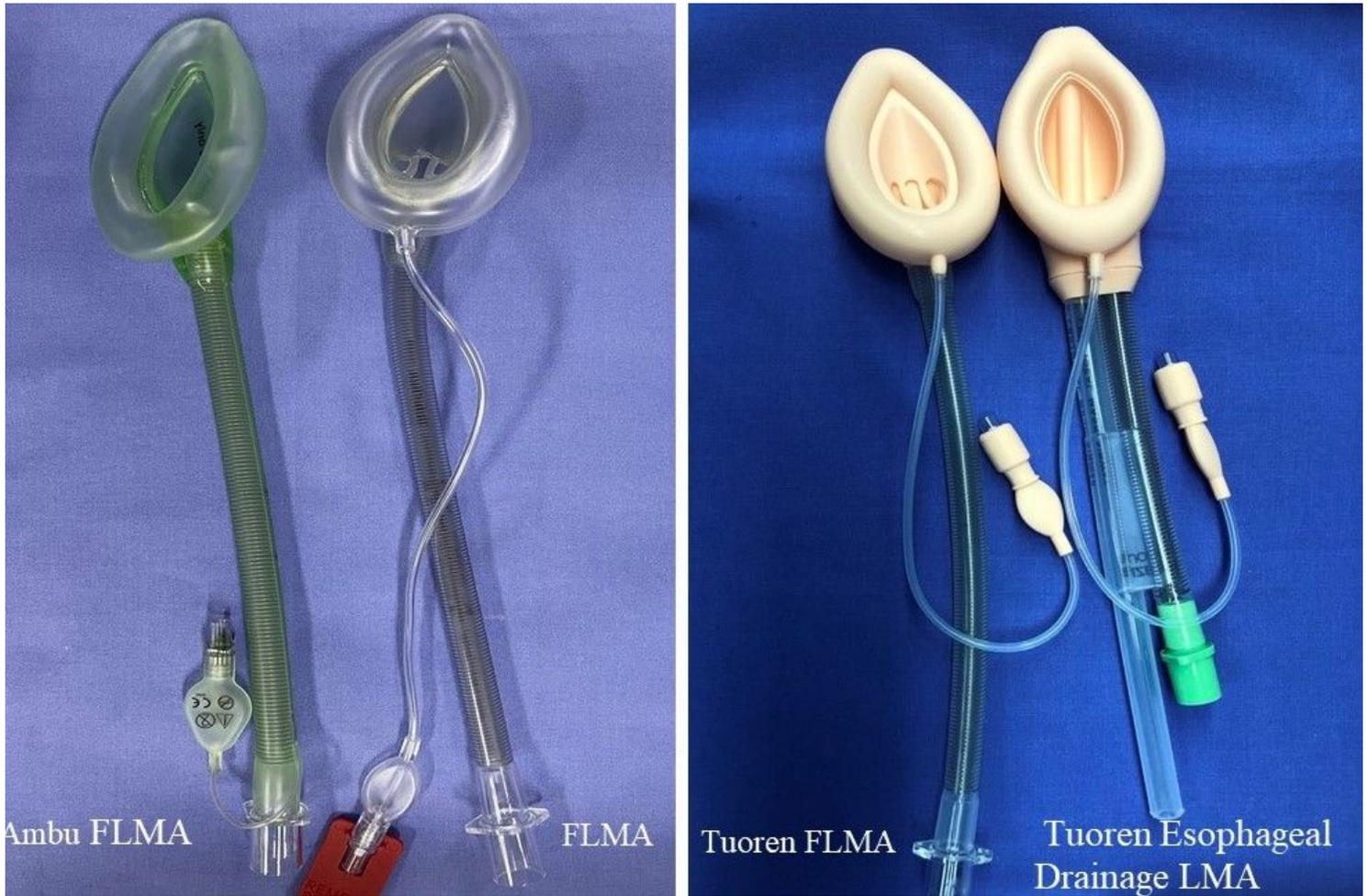
**Ethical approval and consent to participate.** The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional guidelines on human experimentation (Human Research Committee of Shanghai Eye & ENT hospital) and with the Helsinki Declaration of 1975, as revised in 2008. Written informed consent was obtained from all patients. The study protocol was approved by the institutional review board of the Shanghai Eye, Ear, Nose, and Throat Hospital affiliated with Fudan University (No. 2019041-2).

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## Figures



**Figure 1**

Four kinds of supraglottic airway devices. FLMA, flexible laryngeal mask airway; LMA, laryngeal mask airway.