

A Comparison of Seal in Seven Supraglottic Airway Devices Using a Cadaver Model of Elevated Esophageal Pressure

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BACKGROUND: Supraglottic airway devices are increasingly important in clinical anesthesia and prehospital emergency medicine, but there are only few data to assess the risk for aspiration. We designed this study to compare the seal of seven supraglottic airway devices in a cadaver model of elevated esophageal pressure.

METHODS: The classic laryngeal mask airway, laryngeal mask airway ProSeal™, intubating laryngeal mask airway Fastrach™, laryngeal tube™, laryngeal tube LTS II™, Combitube™, and Easytube™ were inserted into unfixed human cadavers with an exposed esophagus that had been connected to a water column of 130 cm height. Slow and fast increases of esophageal pressure were performed and the water pressure at which leakage appeared was registered.

RESULTS: The Combitube, Easytube, and intubating laryngeal mask Fastrach withstood the water pressure up to more than 120 cm H₂O. The laryngeal mask airway ProSeal, laryngeal tube, and laryngeal tube LTS II were able to block the esophagus until 72–82 cm H₂O. The classic laryngeal mask airway showed leakage at 48 cm H₂O, but only minor leakage was found in the trachea. Devices with an additional esophageal drain tube drained fluid sufficiently without pulmonary aspiration.

CONCLUSIONS: Concerning the risk of aspiration, the use of devices with an additional esophageal drainage lumen might be superior for use in patients with an increased risk of aspiration. The Combitube, Easytube, and intubating laryngeal mask Fastrach showed the best capacity to withstand an increase of esophageal pressure.

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Supraglottic airway devices are increasingly important in securing the airway during general anesthesia. They are easy to use and are associated with a low incidence of complications. There are several reports of supraglottic airway devices in patients at risk for aspiration of gastric contents,^{1,2} but few studies have compared the risk of aspiration.^{3,4} Cadaver models have been used to investigate the seal of supraglottic airway devices and seem an appropriate model to address this issue without exposing patients to risk.⁵ The present study evaluated the seal provided by

seven supraglottic airway devices during increased esophageal pressure in cadavers.

METHODS

The study was approved by our IRB. The following airway devices were studied: Classic Laryngeal Mask Airway (Classic LMA), Laryngeal Mask Airway ProSeal™ (ProSeal LMA), Intubating Laryngeal Mask Airway Fastrach™ (Intubating LMA), Laryngeal Tube™, Laryngeal Tube LTS II™ (LTS II), Easytube™, and Combitube™ (Table 1). The sizes of the supraglottic airway devices were selected for the cadavers to establish a representative seal under physiological ventilation as described below (Combitube and Easytube 37 or 41 Charrière, Classic LMA, Laryngeal Tube, LTS II, ProSeal LMA, and Intubating LMA size 4 or 5).

Four female and one male cadavers were investigated within 24 h after death. The mean age was 74.8 yr (range, 63–84 yr). The cadavers were prepared to provide exposure of the esophagus and trachea in the neck. The esophagus was connected to a flexible tube with a diameter of 2 cm, using a tight suture (Fig. 1). The distal end of the tube was a 130-cm vertical column that was filled with water to apply a precisely measured esophageal pressure (up to 130 cm H₂O or 12.75 kPa). The trachea was sutured to a reservoir bag

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Table 1. Studied Airway Devices, Manufacturer, Description, and Abbreviations

Airway device	Manufacturer	Description
Classic LMA	LMA, Windhagen, Germany	
ProSeal LMA	LMA, Windhagen, Germany	Modification of the Classic LMA with additional esophageal drainage tube and posterior cuff
Laryngeal tube	VBM Medizintechnik, Sulz, Germany	Oropharyngeal airway tube with a distal esophageal and a proximal pharyngeal cuff
LTS II™	VBM Medizintechnik, Sulz, Germany	Modification of the Laryngeal Tube with additional esophageal drainage tube
Intubating LMA	LMA, Windhagen, Germany	Modification of the Classic LMA to facilitate guided intubation
Easytube	Rüsch, Kernlen, Germany	Double lumen tube with a distal tracheoesophageal and a proximal pharyngeal high volume cuff
Combitube	Tyco-Kendall Company, Argyle, NY, USA	Modified to use fiberoptic scopes Double lumen tube with a distal tracheoesophageal and a proximal pharyngeal cuff

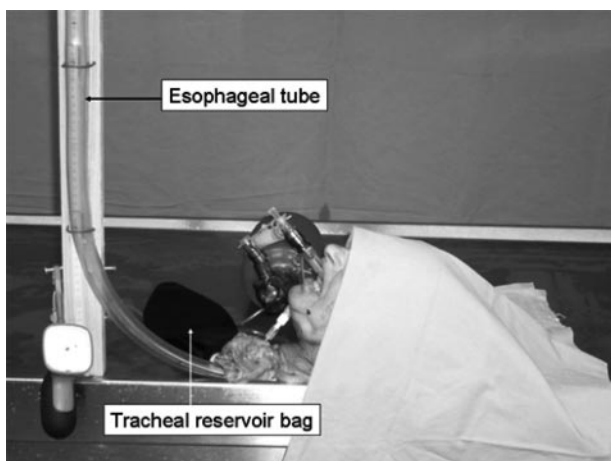


Figure 1. Experimental setup: The esophageal tube is connected to the esophagus by a tight suture. The trachea is connected to a reservoir bag to collect aspirated fluid.

to collect aspirated fluid (Dräger, Lübeck, Germany). After insertion of each device in the anatomically correct position, the cuff was inflated in accordance with the manufacturers' recommendations (60 cm H₂O or 5.8 kPa for all devices). In devices with two cuffs, both were inflated up to the same pressure. Cuff pressure was controlled using a manometer (VBM Medizintechnik, Sulz, Germany). All devices were inserted by the same experienced anesthesiologist (W.S.) and secured with tape. Correct position was defined as sufficient ventilation without any esophageal or pharyngeal leak (i.e., no bubbles were detectable in the water column). Ventilation was performed with a maximum peak inspiratory pressure of 20 cm H₂O (1.96 kPa). The Combitube and Easytube were inserted with distal tube placement into the esophagus.

Two different tests were performed simulating a slow increase (test 1) and a rapid increase (test 2) in esophageal pressure. Both tests were conducted 10 times for every device in every cadaver in randomized order.

Test 1: Slow Increase of Esophageal Pressure

After placing the device, the water column was connected to the esophagus and filled every 10 s with

an additional 5 cm of water to a maximum height of 130 cm H₂O (12.75 kPa). Loss of seal was defined as fluid leaking from the esophageal tube into the pharynx or trachea. The column height at loss of seal was recorded. As test 1 was designed to evaluate the esophageal seal, it was performed with a closed esophageal lumen in the Easytube, ProSeal LMA, LTS II, and Combitube.

Test 2: Immediate Increase of Esophageal Pressure

The column was completely filled up to 130 cm height while the esophageal tube was clamped. After removing the clamp, the remaining column's height after 60 s was measured. As viscous gastric contents may block the esophageal drains *in vivo*, devices with an esophageal drainage tube (i.e., Easytube, ProSeal LMA, LTS II, and Combitube) were tested twice, once with an open drainage lumen and once with the lumen closed. The leakage fraction was measured from the trachea and from the device's airway lumen separately.

Statistical Analysis

Homogeneity of variance was tested before further analysis. For statistical analysis, test 1 and test 2 were examined separately. To test for significant differences, a one-way ANOVA and a Bonferroni *post hoc* multiple-comparison were performed using SPSS™ 10.0 (SPSS, Chicago, IL) for test 1 and test 2. $P < 0.05$ was considered significant.

RESULTS

The ProSeal LMA, Laryngeal Tube, and LTS II did not differ among themselves but lost seal at significantly lower pressures than the Intubating LMA, Easytube, and Combitube. The Intubating LMA performed significantly better than the Classic LMA, ProSeal LMA, Laryngeal Tube, and LTS II, but had a poorer seal than the Combitube (test 1 and test 2) and Easytube (only test 2). In both test 1 and test 2, the Classic LMA had a significantly poorer esophageal seal than the six other devices, but it did well at protecting the trachea from aspiration (Table 2).

Table 2. Total Leakage and Tracheal Leakage Fraction During Test 2

	Classic LMA ^a	ProSeal LMA ^b	Laryngeal tube ^c	LTS II ^d	Intubating LMA ^e	Easytube ^f	Combitube ^g
Total leakage (mL)	263.7 (41.8)	202.0 (61.8)	181.4 (37.1)	180.9 (40.9)	70.2 (82.1)	22.3 (28.5)	15.9 (21.7)
Tracheal leakage fraction (mL)	64.3 (22.4)	79.2 (24.5)	83.8 (17.1)	84.2 (14.5)	0	0	0
% Tracheal of total leakage	24.0 (5.9)	39.3 (4.9)	46.3 (4.1)	47.2 (4.8)	0	0	0

Data are shown as mean ± sd. Significant differences ($P < 0.05$) as tested in the Bonferroni's *post hoc* multiple-comparison test for differences in the tracheal portion of the whole leaked water in percent.

^a Classic LMA: significantly less leakage than ProSeal LMA, Laryngeal Tube, and LTS II and significantly more leakage than Intubating LMA, Easytube, and Combitube.

^b ProSeal LMA: significant difference from Classic LMA, Intubating LMA, Easytube, and Combitube.

^c Laryngeal Tube: significant difference from Classic LMA, Intubating LMA, Easytube, and Combitube.

^d LTS II: significant difference from Classic LMA, Intubating LMA, Easytube, and Combitube.

^e Intubating LMA: significant difference from Classic LMA, ProSeal LMA, Laryngeal Tube, and LTS II.

^f Easytube: significant difference from Classic LMA, ProSeal LMA, Laryngeal Tube, and LTS II.

^g Combitube: significant difference from Classic LMA, ProSeal LMA, Laryngeal Tube, and LTS II.

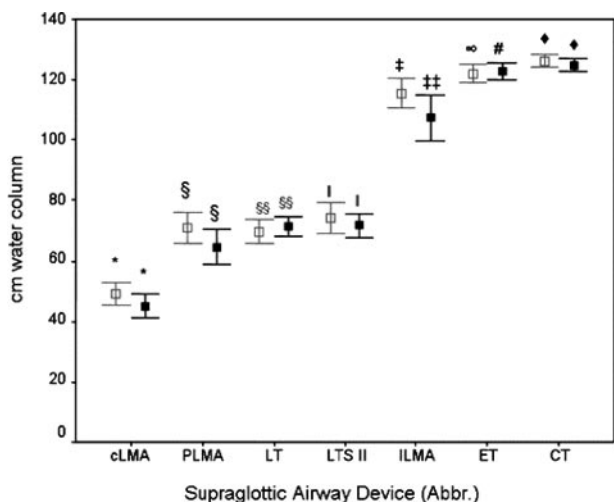


Figure 2. Results of slow increase (test 1, gray bars: height of water column at which loss of seal appeared) and fast increase (test 2, black bars: remaining height of water column 60 s after opening the clamp) of esophageal pressure for the Classic LMA, ProSeal LMA, Laryngeal Tube, LTS II, Easytube, and Combitube. Data represent centimeter of water column and are shown as mean ± sd. Significant differences ($P < 0.05$) as tested in the Bonferroni *post hoc* multiple-comparison test: *Classic LMA (both tests): significant difference from all other devices. §ProSeal LMA (both tests): significant difference from Classic LMA, Intubating LMA, Easytube, and Combitube. §§Laryngeal Tube (both tests): significant difference from Classic LMA, Intubating LMA, Easytube, and Combitube. ||LTS II (both tests): significant difference from Classic LMA, Intubating LMA, Easytube, and Combitube. ‡Intubating LMA (test 1): significant difference from Classic LMA, ProSeal LMA, Laryngeal Tube, LTS II, and Combitube. ‡‡Intubating LMA (test 2): significant difference from all other devices. ∞Easytube (test 1): significant difference from Classic LMA, ProSeal LMA, Laryngeal Tube, and LTS II. #Easytube (test 2): significant difference from Classic LMA, ProSeal LMA, Laryngeal Tube, LTS II, and Intubating LMA. ♦Combitube (both tests): significant difference from Classic LMA, ProSeal LMA, Laryngeal Tube, LTS II, and Intubating LMA.

Test 1: The Combitube, Easytube (both with clamped drain tube), and Intubating LMA showed the best seal and withstood the water pressure up to a mean of 115 cm H₂O (Intubating LMA), 120 cm H₂O (Easytube), and 125 cm H₂O (Combitube) during a

slow increase of pressure. The ProSeal LMA, Laryngeal Tube, and LTS II were able to block the esophagus up to a mean pressure of 71 cm H₂O (ProSeal LMA), 70 cm H₂O (Laryngeal Tube), and 74 cm H₂O (LTS II). The Classic LMA lost its seal at 48 cm H₂O (Fig. 2).

Test 2: The results of test 2 were similar to test 1. During the rapid increase of esophageal pressure, the Combitube and Easytube (both with clamped drainage tube) and the Intubating LMA showed the best seal [125/123/107 cm H₂O after 60 s (mean)], whereas the Classic LMA drained fluid down to a column's height of 45 cm in 60 s (Table 2). The Combitube, Easytube, ProSeal LMA, and LTS II drained the water without any tracheal aspiration when the esophageal drainage tube was open.

The three devices with the best seal (Combitube, Easytube, and Intubating LMA) only allowed minor leakage of fluid, with no fluid detected in the trachea. The Classic LMA provided the worst esophageal seal.

DISCUSSION

This study evaluated supraglottic airway devices and their ability to seal the esophagus during a simulated increase of esophageal pressure in cadavers. The Combitube, Easytube, and Intubating LMA had the best capability to withstand increased esophageal pressure. The ProSeal LMA, Laryngeal Tube, and LTS II did not seal the esophagus up to the maximum pressure. The Classic LMA had the poorest esophageal seal. All devices with an esophageal lumen drained fluid effectively when tested with an open drainage tube.

Esophageal pressure during vomiting has not been carefully studied. Fanning postulated an esophageal pressure of more than 60 cm H₂O during vomiting by analyzing cricoid pressure during intubation.⁶ Brimacombe and Keller described a patient vomiting through a ProSeal LMA over a distance of 1.2 m and postulated after simulation in a model that the esophageal pressure was 105 cm H₂O.⁷ Our maximum pressure of 130 cm H₂O might be substantially higher

than *in vivo* pressures during vomiting. Perhaps such effective esophageal seals might pose a risk of esophageal rupture during vomiting. The ProSeal LMA, Laryngeal Tube, and LTS II effectively sealed the esophagus to about 70 cm H₂O in both tests, offering a better seal than the Classic LMA.

Four devices had esophageal cuffs: the Laryngeal Tube, the LTS II, the Easytube, and the Combitube. Of these, the Easytube and the Combitube provided an effective seal at the highest pressure tested, whereas the Laryngeal Tube and LTS II leaked at approximately 70 cm H₂O (6.86 kPa). Four devices had esophageal lumens: the Combitube, Easytube, ProSeal LMA, and LTS II. All four devices drained fluid adequately and prevented tracheal aspiration with the lumen open. Several case reports have documented similar efficacy with the ProSeal LMA.^{8–10}

Other studies in model systems have resulted in similar conclusions. In a manikin model, Miller and Light found that the Classic LMA protects the airway less effectively than the Laryngeal Tube.¹¹ In a cadaver study of simulated vomiting, the ProSeal LMA prevented tracheal aspiration, as the esophageal lumen allowed complete escape and drainage of gastric contents. Additionally, the ProSeal LMA with a clamped esophageal drainage tube withstood higher esophageal pressures than the Classic LMA.⁵

It is unclear how to place our results into clinical perspective. Consistent with our results, there are a number of cases of aspiration with the Classic LMA.¹² However, some studies have suggested that supraglottic airway devices may be safely used during laparoscopic surgery, despite the increased risk of aspiration due to elevated intraabdominal pressure (typically limited to 15 mm Hg).^{13,14} Our study suggests that the Combitube provides better airway protection than the Classic LMA. Some clinical studies have not demonstrated this,¹⁵ although studies in prehospital use suggest that the Combitube provides better protection against aspiration than the Classic LMA.¹⁶

There are several possible limitations of this study. Even though we used fresh unfixed cadavers, the properties of pharyngeal soft tissue might differ from patients. Brimacombe and Keller evaluated the Classic LMA *in vivo* and in fresh unfixed cadavers and found no differences in ease of insertion, anatomic position, or sealing pressures.¹⁷ Also, our study did not assess insertion time or the skill required to place the devices, considerations that may affect the safety of the devices.¹⁸

In conclusion, all devices sealed the esophagus effectively to at least 40 cm H₂O, indicating that they should be safe during routine use in the operation room. The Combitube, Easytube, and Intubating LMA

showed the best seal with a closed esophageal drainage lumen. In patients with an increased risk of aspiration, or in emergencies, devices with tighter seals or esophageal lumens might provide increased safety.

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