

# Comparison of Mucosal Pressures Induced by Cuffs of Different Airway Devices

Herbert Ulrich-Pur, M.D.,\* Franz Hrska, M.D.,† Peter Krafft, M.D.,‡ Helmut Friehs, M.D.,\* Beatrix Wulkersdorfer, M.D.,\* Wolfgang J. Köstler, M.D.,§ Werner Rabitsch, M.D.,§ Thomas Staudinger, M.D.,§ Ernst Schuster, Ph.D.,|| Michael Frass, M.D.§

**Background:** High pressures exerted by balloons and cuffs of conventional endotracheal tubes, the Combitube<sup>®</sup> (Tyco Healthcare Nellcor Mallinckrodt, Pleasanton, CA), the EasyTube<sup>®</sup> (Teleflex Ruesch, Kernen, Germany), the Laryngeal Mask Airway<sup>™</sup> (LMA North America, San Diego, CA), the Intubating Laryngeal Mask Airway<sup>™</sup> (Fastrach<sup>®</sup>; LMA North America), the ProSeal<sup>™</sup> (LMA North America), and the Laryngeal Tube (LT; VBM Medizintechnik, Sulz, Germany) may traumatize the pharyngeal mucosa. The aim of this study was to compare pressures exerted on the pharyngeal, tracheal, and esophageal mucosa by different devices designed for securing the patient's airways.

**Methods:** Nineteen fresh cadavers were included. To measure mucosal pressures, microchip sensors were fixed on the anterior, lateral, and posterior surfaces of the proximal balloon and the distal cuff of the investigated devices. Depending on the respective airway device, the cuff volume was increased in 10-ml increments at the proximal balloon starting from 0 to a maximum of 100 ml, and in 2-ml increments at the distal cuff starting from 0 up to 12 ml.

**Results:** Tracheal mucosal pressures were significantly higher using the Combitube<sup>®</sup> compared with the endotracheal tube and the EasyTube<sup>®</sup>. Maximal esophageal pressures were significantly higher using the EasyTube<sup>®</sup> compared with the Combitube<sup>®</sup>. Using cuff volumes according to the manufacturers' guidelines, we found the highest pharyngeal pressures with the Intubating Laryngeal Mask Airway<sup>™</sup> versus all other devices. At maximal volumes, the Laryngeal Mask Airway<sup>™</sup>, the Intubating Laryngeal Mask Airway<sup>™</sup>, and the ProSeal<sup>™</sup> induced significantly higher pharyngeal pressures compared with all other devices. Using a pharyngeal cuff volume of 40 ml, the Intubating Laryngeal Mask Airway<sup>™</sup> followed by the Laryngeal Mask Airway<sup>™</sup> exerted significantly higher pressures compared with the other devices.

**Conclusions:** Although some devices exhibit a somewhat higher mucosal pressure when compared with others, the authors believe that the observed differences of the cuff pressures do not suggest a clinically relevant danger, because the investigated devices, except the endotracheal tubes, are not intended for prolonged use.

SOFT tissue injury is an important issue in airway management. Potential hazards are direct trauma, ranging from minor superficial laceration to perforations of tra-

chea or esophagus, or indirect trauma by impaired mucosal blood flow. Mechanisms of injury are either the insertion process *per se* or high pressures exerted by the artificial airways on the mucosa of surrounding anatomical structures.<sup>1</sup> The endotracheal tube (ETT) is acknowledged as the standard for tracheal intubation.<sup>2</sup> Nevertheless, under difficult airway conditions, other devices may be helpful to handle life threatening situations. In these cases, knowledge of the cuff volume and mucosal pressure relation can help to avoid severe mucosal damage of the upper airway region. Brimacombe *et al.*<sup>3</sup> showed that inflation of a cuffed oropharyngeal airway with 40–60 ml air prevented blood flow to the posterior pharyngeal mucosa. The pharyngeal cuffs of other devices such as the esophageal tracheal Combitube<sup>®</sup> (ETC) are inflated with even higher volumes up to 85–100 ml air.<sup>1</sup> The primary aim of airway management is to provide a patent airway followed by ventilation of the lungs. The aim of this experimental cadaver investigation was to determine and to compare the pressures exerted on the pharyngeal, tracheal, and esophageal mucosa induced by seven airway devices to assess the clinical importance.

## Materials and Methods

Research and ethical committee approval (Medical University Vienna, Vienna, Austria) was obtained. All patients, or their relatives, consented to postmortem research before the cadavers were used. In the morgue, we studied 19 fresh cadavers less than 24 h postmortem. The causes of death were sepsis (n = 4), bronchial carcinoma (n = 3), carcinoma of the colon (n = 3), myocardial infarction (n = 3), pneumonia (n = 2), pulmonary embolism (n = 2), carcinoma of the breast (n = 1), and cerebral hemorrhage (n = 1). None of the patients were intubated or resuscitated before death. Cadavers underwent laryngoscopic examination, and cadavers presenting with upper esophageal or laryngopharyngeal pathology were excluded. The following devices were investigated:

1. Conventional endotracheal tubes (ETT; Tyco Healthcare Nellcor Mallinckrodt, Pleasanton, CA)
2. Esophageal tracheal Combitube<sup>®</sup> (ETC; Tyco Healthcare Nellcor Mallinckrodt)
3. EasyTube<sup>®</sup> (EZT; Teleflex Ruesch, Kernen, Germany)
4. Laryngeal Mask Airway<sup>™</sup> (LMA<sup>™</sup>; LMA North America, San Diego, CA)

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\*Resident, §Professor of Medicine, Intensive Care Unit 13i2, Department of Internal Medicine I, †Assistant Professor, ‡Associate Professor, Department of Anesthesiology and General Intensive Care, ||Biostatistics Professor, Core Unit for Medical Statistics and Informatics, Medical University Vienna.

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Address correspondence to Dr. Frass: Intensive Care Unit 13i2, Department of Internal Medicine I, Medical University Vienna, Waehringer Guertel 18-20, 1090 Vienna, Austria. michael.frass@meduniwien.ac.at. Individual article reprints may be purchased through the Journal Web site, www.anesthesiology.org.

**Table 1. Attachment of the Sensors to the Following Locations (Corresponding Mucosal Areas)**

Cuff	Proximal			Distal Tracheal			Distal Esophageal		
	Anterior	Lateral	Posterior	Anterior	Lateral	Posterior	Anterior	Lateral	Posterior
ETT				+	+	+			
ETC	+	+	+	+	+	+	+	+	+
EzT	+	+	+	+	+	+	+	+	+
ILMA™	+	+	+						
PLMA™	+	+	+						
LMA™	+	+	+						
LT	+	+	+						

ETC = Combitube®; ETT = endotracheal tube; EzT = EasyTube®; ILMA™ = Fastrach™ intubating laryngeal mask airway; LMA™ = Laryngeal Mask Airway™; LT = Laryngeal Tube; PLMA™ = ProSeal™.

5. Intubating Laryngeal Mask™ (ILMA™, Fastrach®; Lma North America)
6. ProSeal™ laryngeal mask airway (PLMA™; Lma North America)
7. Laryngeal Tube Airway (LT; Vbm Medizintechnik, Sulz, Germany)

Each device was inserted in each cadaver. The insertion was randomized by a computer-generated code. Two experienced participants of the study (F.H., P.K.) with experience with all devices in at least 10 patients inserted the devices. We left the devices in place for 3 min for each measurement. The airway tips were placed in either the trachea (ETT, ETC, EzT) or the esophagus (ETC, EzT, LT) without inducing mucosal damage. Maximal esophageal pressures of ETC and EzT at a cuff inflation of 12 ml were measured. Mucosal pressures of proximal cuffs (ETC, EzT, LT) as well as of cuffs of the LMA™, ILMA™, and PLMA™ were evaluated by inflation in 10-ml increments from 0 to 60 ml (LMA™, ILMA™) and 0 to 100 ml (ETC, EzT, PLMA™, LT), respectively.

Mucosal pressure was assessed using a 1.2-mm-diameter strain gauge silicon microchip sensor (Codman MicroSensor; Johnson and Johnson Medical Ltd., Bracknell, United Kingdom), which was calibrated before its use. For each position of the respective device, a sensor was fixed to the surface of the proximal balloon and/or distal cuff with a clear adhesive dressing (thickness of 0.45 mm; Tegaderm; 3M, Ontario, Canada). The sensors were attached to the locations described in table 1. The sensing element of the sensor was orientated toward the mucosal surface. The ETT, ETC, EzT, and LT were inserted into the cadavers using a standard Macintosh laryngoscope No. 3. The correct position of the sensors and the integrity of the mucosa were checked before and after measurement by laryngoscopy. The LMA™, ILMA™, and PLMA™ were inserted using the standard methods described by Brain *et al.*<sup>4</sup> The airway sizes as well as the references are shown in table 2.

Tracheal mucosal pressures exerted by the ETT cuff and the distal cuffs of the ETC and EzT were evaluated by cuff inflation from 0 to 12 ml in 2-ml increments. In

addition, the mucosal pressures exerted by proximal cuffs were compared with respect to the amount of air recommended for emergency situations: 85 ml with the ETC,<sup>5-10</sup> 80 ml with the EzT,<sup>11</sup> 40 ml with the LMA™,<sup>12-15</sup> 40 ml with the ILMA™,<sup>16,17</sup> 40 ml with the PLMA™,<sup>18,19</sup> and 80 ml with the LT.<sup>20</sup> In addition, a cuff volume of 40 ml was chosen for the ETC and EzT because there is a difference in the recommended filling volume between emergency intubation and elective use during general anesthesia: In elective anesthesia, the volume of the upper balloon can be reduced according to the minimal volume technique from 40 to 85 ml.<sup>21</sup> We compared the maximal tracheal pressures of the ETT, ETC, and EzT at 12 ml; maximal esophageal pressures of the ETC and EzT at 12 ml; and maximal pharyngeal pressures of the ETC, EzT, LMA™, ILMA™, PLMA™, and LT at the respective recommended and highest volumes as well as at 40 ml.

**Table 2. Characteristics and References of the Airway Devices Used**

Airway Devices	Size	References
ETT	8.5 mm ID in males 7.5 mm ID in females	
ETC	SA 37 French SA (4–6.5 ft)	1, 7–11
EzT	41 French (4.3–6.5 ft)	12
LMA™	Size 5 in males Size 4 in females	13–15
ILMA™	Size 5 in males Size 4 in females	16, 17
PLMA™	Size 5 in males Size 4 in females	18, 19
LT	Size 5 in males Size 4 in females	18

In our experience, an 8.5-mm ID endotracheal tube (ETT) fits most males, and a 7.5-mm ID fits most females. The Combitube® (ETC) 37 small adult (SA) fits patients with a height of 120 up to 200 cm. The reason to choose the size 41 French EasyTube® (EzT) is described by the manufacturer: Size 41 French fits patients taller than 130 cm, whereas the 28 French is designed for patients with a height from 90 to 130 cm. The sizes used for Laryngeal Mask Airway™ (LMA™), Fastrach™ intubating laryngeal mask airway (ILMA™), ProSeal™ (PLMA™), and Laryngeal Tube (LT) are according to the manufacturers. The reason not to use the Laryngeal Tube Suction® (LT-S) was that this device is rather bulky and therefore did not seem to be comparable to the other devices.

### Statistics

The sample size calculation was based on a type I error  $\alpha$  of 0.008 corrected for multiple testing, a power of 0.8, a mean difference of 25%, and an SD within the treatment groups of  $\sigma = 0.2$ , resulting in a sample size of 17. The data were tested for normal distribution using the Shapiro-Wilk statistic (in case of a sample size less than 51) and the usual Kolmogorov D statistic otherwise.<sup>22</sup> For normally distributed data, we used the general linear model or otherwise the Kruskal-Wallis test to test for differences between various tubes and regions, respectively. The statistical analysis system was SAS 8.01 (SAS, Cary, North Carolina).

We compared the means of the highest pressures of the three locations (anterior, left lateral, and posterior) of all respective 19 measurements. For each comparison, we took out the maximal pressures of the three locations (anterior, lateral, posterior) of the respective airways. The box plots show the median and the quartiles of the respective pressures. A  $P$  value of less than 0.05 was considered to be significant.

### Results

The mean  $\pm$  SD (range) age, height, and weight of cadavers were  $75 \pm 11$  (48–90) yr,  $177 \pm 8$  (169–191) cm, and  $85 \pm 9$  (72–97) kg, respectively. The male-to-female ratio was 14:5. Tracheal as well as esophageal placement of the airway tips was achieved in all cadavers on the first attempt.

Maximal tracheal pressures at a cuff volume of 12 ml were higher using the ETC compared with the ETT and EzT (fig. 1). Maximal esophageal pressures at a cuff volume of 12 ml were significantly higher using the EzT compared with the ETC (fig. 2). Assessing pharyngeal pressures using the ETC (with 85 ml), EzT (with 80 ml), *LMATM* (with 40 ml), *ILMATM* (with 40 ml), *PLMATM* (with 40 ml), and LT (with 80 ml) at those volumes recommended by the manufacturers, we found significantly higher pressures with the *ILMATM* versus all other devices (fig. 3). At maximal volumes (ETC [with 100 ml], EzT [with 100 ml], *LMATM* [with 60 ml], *ILMATM* [with 60 ml], *PLMATM* [with 100 ml], and LT [with 100 ml]), the *LMATM*, *ILMATM*, and *PLMATM* induced higher pharyngeal pressures compared with all other devices (fig. 3). At a cuff volume of 40 ml, the *ILMATM* and *LMATM* induced higher pressures compared with all other devices (fig. 3).

Other data are not shown for clearness; however, all results of the respective pressures are available on request. With a few exceptions, directly measured mucosal pressures showed significant differences ( $P < 0.0001$ ) for the ETC, EzT, *LMATM*, *ILMATM*, *PLMATM*, and LT, respectively, in all pharyngeal locations.

Directly measured mucosal pressures exerted by the

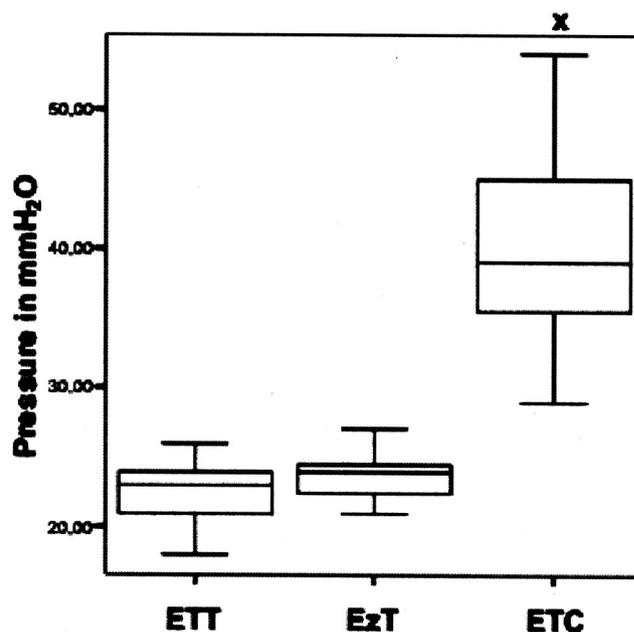


Fig. 1. Box plots of maximal pressures in the trachea with 12 ml filling.  $x = P < 0.05$ , ETC versus EasyTube® (EzT) and endotracheal tube (ETT). ETC = Combitube®.

EzT (cuff volume = 12 ml) on the esophageal mucosa were significantly different ( $P < 0.0001$ ) in the anterior versus lateral as well as anterior versus posterior region. No differences were found for the ETC.

Directly measured mucosal pressures in the trachea at 12 ml showed significant differences ( $P < 0.0001$ ) between all three locations with the ETT and EzT, and between anterior versus lateral and lateral versus poste-

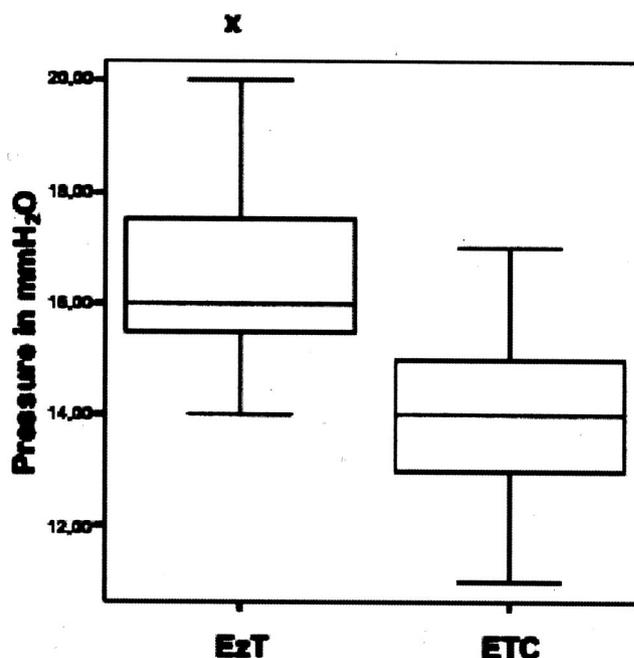


Fig. 2. Box plots of maximal pressures in the esophagus with 12 ml filling.  $x = P < 0.05$ , EasyTube® (EzT) versus Combitube® (ETC).

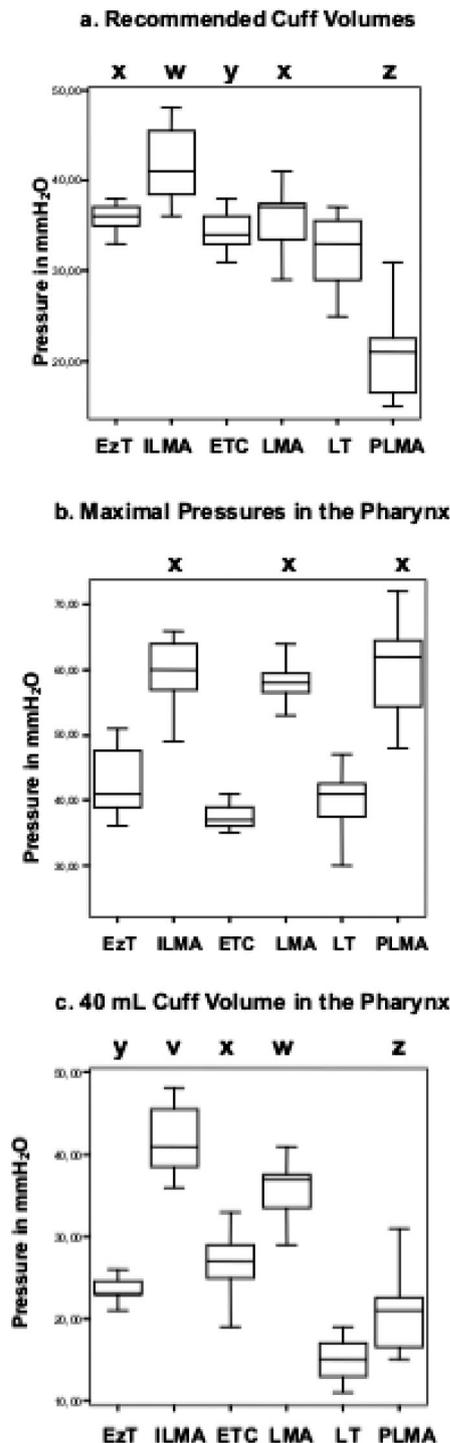


Fig. 3. Box plots of pressures in the pharynx. (A) Box plots of pressures at the recommended cuff volumes in the pharynx.  $w = P < 0.05$ , Fastrach™ intubating laryngeal mask airway (ILMA™) versus all other devices.  $x = P < 0.05$ , EasyTube® (EzT) and Laryngeal Mask Airway™ (LMA™) versus Combitube® (ETC), Laryngeal Tube (LT), and ProSeal™ (PLMA™).  $y = P < 0.05$ , ETC versus LT and PLMA™.  $z = P < 0.05$ , LT versus PLMA™. (B) Box plots of maximal pressures in the pharynx.  $x = P < 0.05$ , ILMA™, LMA™, and PLMA™ versus EzT, ETC, and LT. (C) Box plots of pressures at 40-ml cuff volume in the pharynx.  $v = P < 0.05$ , ILMA™ versus all other devices.  $w = P < 0.05$ , LMA™ versus EzT, ETC, LT, and PLMA™.  $x = P < 0.05$ , ETC versus EzT, LT, and PLMA™.  $y = P < 0.05$ , EzT versus LT and PLMA™.  $z = P < 0.05$ , PLMA™ versus LT.

rior locations with the ETC ( $P < 0.0001$ ). No mucosal laceration or tear was found.

## Discussion

One of the major advances in ETT design was the introduction of high-volume, low-pressure cuffs intended to minimize the pressure exerted on the tracheal mucosa.<sup>1</sup> Major attention is laid upon the fact that the mucosal pressure exerted by the cuff remains below the capillary mucosal pressure of approximately 26 mmHg. This concept has been incorporated into the new EzT airway, which has been equipped with a high-volume, low-pressure distal cuff system exhibiting significantly lower tracheal pressures. In our cadaver study, we found that pharyngeal, esophageal, and tracheal mucosal pressures increased with rising cuff volumes in all tested devices.

### Tracheal Pressures Using ETT, ETC, and EzT

Regarding the ETC, high tracheal mucosal pressures are observed at the maximal recommended cuff volume of 12 ml (up to 41 cm H<sub>2</sub>O). In the clinical situation, much lower volumes are usually necessary to obtain an airtight seal. Therefore, blocking of the distal ETC cuff in the trachea without a cuff-pressure gauge is only recommended in emergency use. Pressures in the trachea registered for EzT were not significantly different from those observed with a regular ETT. With respect to location, the highest values were found in the lateral location with the ETT, in the posterior location with the EzT, and in the anterior position with the ETC. Although the findings with the ETC and ETT can be explained by the fact that the posterior membranous tracheal wall is more distensible than the cartilaginous anterolateral wall, we have no explanation for the higher posterior values with the EzT. We do not have data for the long-term use of the EzT up to now.

### Esophageal Pressures Using ETC and EzT

Regarding esophageal placement, both the ETC and the EzT exert similar and relatively low pressures on the esophageal mucosa (maximum around 14 cm H<sub>2</sub>O). The highest values were found with the EzT when compared with the ETC. Although the same method was used, our data show lower values as compared with the measurements of Keller *et al.*<sup>1</sup> Direct esophageal injury induced by an inflated cuff can therefore be certainly prevented by strictly adhering to the manufacturer's guidelines. Furthermore, the danger of a permanent injury to the mucosa seems limited, because the investigated devices are not intended for prolonged use. The ETC may be used for up to 8 h.<sup>9</sup>

*Pharyngeal Pressures Using ETC, EzT, LMA™, ILMA™, PLMA™, and LT*

The *LMA-Classic™* exerts pressures of approximately 25–35 cm H<sub>2</sub>O on the pharyngeal or hypopharyngeal mucosa, equally distributed among anterior, lateral, and posterior locations up to a filling volume of 40 ml. Interestingly, even lower pressures were observed for the *PLMA™*, with mucosal pressures mainly below 20 cm H<sub>2</sub>O, at least when maximally recommended filling volumes are observed. Pharyngeal mucosal perfusion is progressively reduced when mucosal pressures exceed 34 cm H<sub>2</sub>O.<sup>3</sup> Therefore, both devices are considered safe with respect to the pharyngeal mucosa. Significantly higher pressures, especially in the anterior location, were observed for the *ILMA™* (up to 41 cm H<sub>2</sub>O). However, this device is not intended for prolonged use, and its removal is recommended after successful tracheal intubation. Interestingly, the other supraglottic airways (ETC, EzT, and LT) exert pressures lower than that with the *ILMA™* and similar to those obtained for the *LMA-Classic™* (in the range of 23–36 cm H<sub>2</sub>O). Opposite to the findings of Keller *et al.*,<sup>1</sup> our data show the highest values in the anterior pharyngeal location using the ETC. Similar results were found for the *LMA™*, *ILMA™*, and LT. In contrast, the highest values were found in the posterior location with the *PLMA™* and EzT. The latter results may be explained because the posterior surface is adjacent to rigid anatomical structures (vertebral bodies), whereas the anterolateral surface is adjacent to compliant anatomical structures (epiglottis, tongue, pharyngeal muscles, and membranous trachea).<sup>1</sup> We have no explanation for the different behaviors of the devices, except that the *PLMA™* may exert higher pressures in the posterior portion because of the additional cuff on the posterior part of the airway. With respect to pharyngeal mucosal pressures, we could not identify any traumatizing potential of these devices with respect to pharyngeal lacerations. The *LMA™* may be used for more than 3 h.<sup>13</sup>

A limitation of the study is that mucosal pressures in awake and anesthetized patients may not be compared with the measurements in cadavers. Therefore, the muscle tone of patients is not taken into account. However, Keller *et al.*<sup>1</sup> found that pharyngeal mucosal pressures were similar for cadavers and awake volunteers, which suggests that muscle tone does not play a major role in mucosal pressure measurements. Although their findings should be interpreted cautiously, they consider them to be applicable to the anesthetized patient for several reasons. First, there is evidence that pharyngeal compliance is similar in fresh cadavers and paralyzed anesthetized patients.<sup>3,23</sup> Second, the data for tracheal mucosal pressures in cadavers closely match those of a previous ETT study in paralyzed anesthetized patients,<sup>24</sup> and the data for pharyngeal mucosal pressures closely match

those of two previous studies of the cuffed oropharyngeal airway in paralyzed anesthetized patients.<sup>25</sup>

In summary, our data demonstrate that increasing cuff volumes are directly transferred into increased mucosal pressures up to levels potentially exceeding mucosal perfusion pressure. Those mucosal pressures are seldom observed by limiting the cuff volumes following the minimal volume technique. Recommended volumes should be strictly followed because slightly overextended cuffs may exert high pressures, *e.g.*, inflating a size 5 *LMA™*, *PLMA™*, or *ILMA™* with 60 ml air can result in pharyngeal mucosal pressures of up to 60 cm H<sub>2</sub>O. The observed differences between the devices do not seem to be clinically relevant and do not preclude the use of any device in clinical routine cases, because the devices investigated (except the ETT) are not intended for prolonged use (for more than 8 h). Esophageal mucosal pressures with the ETC and EzT in the esophageal position remain low when maximal filling volumes recommended by the manufacturers are respected. We therefore recommend adherence to the manufacturers' guidelines and the use of a pressure gauge for cuffing all devices.

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