

# The Influence of Cuff Volume and Anatomic Location on Pharyngeal, Esophageal, and Tracheal Mucosal Pressures with the Esophageal Tracheal Combiflute

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**Background:** The authors determined the influence of cuff volume and anatomic location on pharyngeal, esophageal, and tracheal mucosal pressures for the esophageal tracheal combiflute.

**Methods:** Twenty fresh cadavers were studied. Microchip sensors were attached to the anterior, lateral, and posterior surfaces of the distal and proximal cuffs of the small adult esophageal tracheal combiflute. Mucosal pressure for the proximal cuff in the pharynx was measured at 0- to 100-ml cuff volume in 10-ml increments, and for the distal cuff in the esophagus and trachea were measured at 0- to 20-ml cuff volume in 2-ml increments. The proximal cuff volume to form an oropharyngeal seal of 30 cm H<sub>2</sub>O was determined. In addition, mucosal pressures for the proximal cuff in the pharynx were measured in four awake volunteers with topical anesthesia.

**Results:** There was an increase in mucosal pressure in the trachea, esophagus, and pharynx at all cuff locations with increasing volume (all:  $P < 0.001$ ). Pharyngeal mucosal pressures were highest posteriorly (50-ml cuff volume:  $99 \pm 62$  cm H<sub>2</sub>O; 100-ml cuff volume:  $255 \pm 161$  cm H<sub>2</sub>O). Esophageal mucosal pressures were highest posteriorly (10-ml cuff volume:  $108 \pm 55$  cm H<sub>2</sub>O; 20-ml cuff volume:  $269 \pm 133$  cm H<sub>2</sub>O). Tracheal mucosal pressures were highest anteriorly (10-ml cuff volume:  $98 \pm 53$  cm H<sub>2</sub>O; 20-ml cuff volume:  $236 \pm 139$  cm H<sub>2</sub>O). The proximal cuff volume to obtain an oropharyngeal seal of 30 cm H<sub>2</sub>O was  $47 \pm 12$  ml. Pharyngeal mucosal pressures were similar for cadavers and awake volunteers.

**Conclusion:** We conclude that mucosal pressures for the esophageal tracheal combiflute increase with cuff volume, are highest where the cuff is adjacent to rigid anatomic structures, and potentially exceed mucosal perfusion pressure even when cuff volumes are limited to achieving an oropharyngeal seal of 30 cm H<sub>2</sub>O.

THE esophageal tracheal combiflute (ETC), first described by Frass *et al.*<sup>1</sup> in 1987, has been widely accepted as an airway device for out-of-hospital cardiopulmonary resuscitation but has not been accepted into routine anesthesia practice. It comprises two separate tubes that are fused together and two inflatable cuffs: a large volume cuff that inflates in the pharynx and a small volume cuff that inflates in the esophagus or, occasion-

ally, the trachea. The main limitation of the ETC for routine anesthesia is the potential risk of trauma. Esophageal<sup>2</sup> and pharyngeal<sup>3</sup> perforation have been reported in association with out-of-hospital airway rescue. Bleeding (36-45%),<sup>4-7</sup> sore throat (16-46%),<sup>4,8</sup> and dysphagia (8-68%)<sup>4,8</sup> have been reported in association with routine anesthesia. Possible mechanisms for trauma are direct injury during placement or high pressures exerted against the surrounding mucosa. In a recent study, we showed that inflation of a cuffed oropharyngeal airway with 40-60 ml air prevented blood flow through the posterior pharyngeal mucosa,<sup>9</sup> but the pharyngeal cuff of the ETC is usually inflated with 85-100 ml air. In the current study, we determined the influence of cuff volume and anatomic location on pharyngeal, esophageal, and tracheal mucosal pressures for the ETC.

## Methods

### Study 1

Research and Ethical committee approval (Leopold-Franzens University, Innsbruck, Austria) was obtained. All patients, or their relatives, consented to postmortem research before using the cadavers. Twenty fresh cadavers (6-24 h postmortem) were studied. Cadavers with known upper esophageal or laryngopharyngeal pathology were excluded. Directly measured mucosal pressure was measured using six 1.2-mm-diameter strain gauge silicone microchip sensors (Codman<sup>®</sup> MicroSensor; Johnson and Johnson Medical Ltd., Bracknell, United Kingdom) attached to the external surface of the distal and proximal cuff of a 37-French "small adult" esophageal tracheal combiflute (Sheridan Catheter Corp., Argyle, NY) with clear adhesive dressing 0.45 mm thick (Tegaderm; 3M, Ontario, Canada), as previously described<sup>10,11</sup> and validated.<sup>12</sup> The sensors were attached to the following locations (corresponding mucosal areas): A, anterior proximal cuff (anterior pharynx/base of tongue); B, left lateral cuff (left lateral pharynx); C, posterior cuff (posterior pharynx); D, anterior distal cuff (anterior trachea or esophagus); E, left lateral cuff (left lateral trachea or esophagus); and F, posterior distal cuff (posterior tracheal or esophagus) (fig. 1). The sensing element of the sensor was orientated toward the mucosal surface and was accurate to  $\pm 2\%$ . The position, orientation, and accuracy of all the sensors were checked over the entire inflation range *in vitro* before and after use in each cadaver.<sup>10,11</sup> The ETC was inserted

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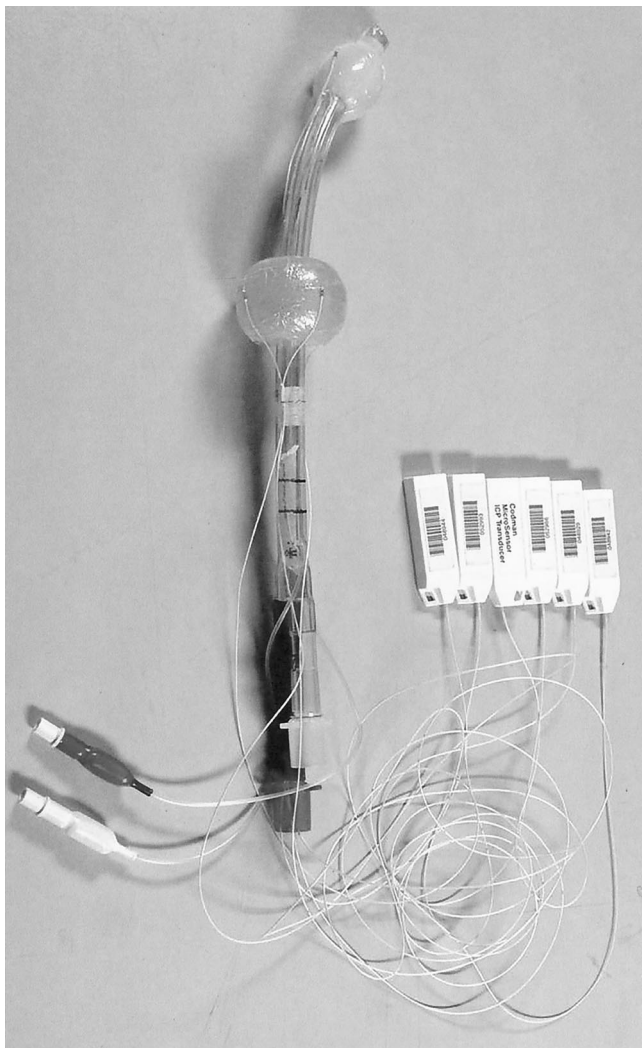


Fig. 1. Esophageal tracheal combitube with probes attached to the proximal and distal cuff.

into the cadaver using laryngoscope guidance to allow the distal cuff to be placed either in the trachea or the esophagus. Proximal cuff measurements were made when the distal cuff was in the esophagus and inflated with 20 ml air. When these data were collected, the volume of air in the proximal cuff required to form an oropharyngeal seal of 30 cm H<sub>2</sub>O was determined with the distal cuff in the esophagus.<sup>13</sup>

### Study 2

With Research and Ethics committee approval and written, informed consent, we studied pharyngeal mucosal pressures in four healthy, fasted (> 6 h), nonpaid subjects (American Society of Anesthesiologists physical status I). Subjects were studied in the supine position with the occiput on a firm pillow 5 cm in height. The airway was anesthetized with 10 puffs of 1% lidocaine spray. The 37-French "small adult" ETC with pressure probes attached was inserted blindly, and pharyngeal pressures from the anterior, lateral, and posterior prox-

imal cuffs were recorded over the inflation range of 0–100 ml, as described previously. Mucosal pressure data were not collected during swallowing or airway reflex activation. The next day, volunteers were asked about symptoms of airway morbidity.

### Statistics

The distribution of data was determined using Kolmogorov-Smirnov analysis.<sup>14</sup> Statistical analysis was with paired *t* test (normally distributed data), Friedman two-way analysis of variance (nonnormally distributed data), and one-way analysis of variance with *post hoc* Bonferroni test. Significance was determined as  $P < 0.05$ . Statistical analysis was performed on an IBM computer (IBM, Armonk, NY) using SYSTAT version 7.0 (SPSS Inc., Chicago, IL).

## Results

### Study 1

The mean (range) age, height, and weight for cadavers were 78 (56–92) yr, 163 (145–188) cm, and 61 (42–90) kg, respectively. The male-to-female ratio was 6:14. Tracheal placement of the distal cuff was achieved in 19 of 20 on the first attempt and in 1 of 20 on the second attempt. Esophageal placement of the distal cuff was achieved in 20 of 20 on the first attempt. Directly measured mucosal pressures for the distal cuff in the trachea and the esophagus are presented in table 1 and for the proximal cuff in the pharynx in table 2. There was a significant increase in directly measured mucosal pressure in the trachea, esophagus, and pharynx at all locations with increasing cuff volume (all:  $P < 0.001$ ). Directly measured mucosal pressures in the pharynx over the range of cuff volumes were higher in the posterior compared with the anterior ( $P < 0.0001$ ) and lateral ( $P < 0.0001$ ) locations but were similar for the anterior and lateral locations. Directly measured mucosal pressures in the esophagus over the range of cuff volumes were higher in the posterior compared with the anterior ( $P < 0.0001$ ) and lateral ( $P < 0.0001$ ) locations but were similar for the anterior and lateral locations. Directly measured mucosal pressures in the trachea over the range of cuff volumes were higher in the anterior compared with the lateral ( $P < 0.0001$ ) and posterior ( $P < 0.0001$ ) locations but were similar for the lateral and posterior locations. Directly measured mucosal pressures over the range of cuff volumes were higher in the anterior and lateral trachea compared with the anterior ( $P < 0.0001$ ) and lateral ( $P < 0.0001$ ) esophagus but were lower in the posterior trachea than the posterior esophagus (overall:  $P < 0.0001$ ). The cuff volume to obtain a seal of 30 cm H<sub>2</sub>O for the proximal cuff in the pharynx was 47 (12, 30–70 [SD, range]) ml.

**Table 1. Directly Measured Mucosal Pressures in the Anterior, Lateral, and Posterior Trachea and Esophagus**

Cuff Volume	Trachea			Esophagus		
	Anterior	Lateral	Posterior	Anterior	Lateral	Posterior
0	6 (8, 0–29)	0 (2, 0–10)	2 (3, 0–10)	1 (2, 0–7)	0 (1, 0–4)	6 (8, 0–33)
2	16 (13, 0–50)	2 (5, 0–17)	6 (7, 0–31)	3 (7, 0–34)	1 (3, 0–12)	17 (14, 0–55)
4	34 (21, 0–83)	7 (8, 0–27)	14 (13, 0–40)	8 (10, 0–45)	4 (5, 0–17)	36 (23, 2–90)
6	55 (33, 3–139)	21 (15, 0–54)	19 (18, 0–65)	13 (12, 0–56)	12 (11, 0–40)	60 (35, 8–145)
8	75 (41, 3–183)	42 (29, 2–106)	25 (23, 0–83)	19 (16, 0–67)	23 (20, 2–97)	83 (45, 9–210)
10	98 (53, 3–215)	54 (43, 2–171)	39 (40, 0–150)	28 (25, 6–266)	31 (26, 4–141)	108 (55, 12–245)
12	124 (67, 3–250)	72 (58, 1–250)	51 (45, 2–171)	37 (32, 5–156)	40 (33, 4–161)	136 (68, 12–289)
14	152 (84, 3–296)	95 (76, 2–308)	76 (50, 5–203)	54 (40, 5–178)	49 (45, 4–204)	166 (83, 12–320)
16	179 (104, 3–325)	127 (113, 2–455)	105 (62, 6–217)	75 (54, 6–217)	59 (60, 4–265)	198 (100, 12–345)
18	209 (122, 3–383)	164 (155, 2–603)	125 (68, 6–250)	92 (66, 6–234)	71 (77, 4–355)	229 (113, 12–410)
20	236 (139, 3–404)	194 (182, 2–674)	150 (85, 6–303)	110 (79, 6–266)	83 (97, 4–456)	269 (133, 12–450)

Data are mean (SD, range). Units are cm H<sub>2</sub>O.

### Study 2

The mean (range) age, height, and weight for awake volunteers were 35 (29–41) yr, 169 (156–193) cm, and 67 (45–89) kg, respectively. The male-to-female ratio was 2:2. The ETC was successfully inserted at the first attempt in three volunteers and at the second attempt after additional topical anesthesia in one volunteer. Esophageal placement of the distal cuff was achieved in all volunteers. *In vivo* intracuff pressure and mucosal pressures over the range of cuff volumes are presented in table 2. There were no significant differences in mucosal pressures between cadavers and awake volunteers over the inflation range. All volunteers reported sore throat and dysphagia the next day.

### Discussion

We found that pharyngeal, esophageal, and tracheal mucosal pressures with the ETC increase with cuff volume. Similar results have been obtained for the laryngeal mask airway and cuffed oropharyngeal airway in the pharynx, and for the endotracheal tube in the trachea. To our knowledge, there is no previously published data about esophageal mucosal pressures with cuff inflation.

We found that pharyngeal and esophageal mucosal pressures were highest posteriorly. This is because the posterior surface is adjacent to rigid anatomic structures (vertebral bodies), whereas the anterolateral surface is adjacent to compliant anatomic structures (epiglottis, tongue, pharyngeal muscles, and membranous trachea). We found that tracheal mucosal pressures gradually decreased from anterior to posterior. This is because the posterior membranous tracheal wall is more distensible than the cartilaginous anterolateral wall. These data confirm the findings of Knowlson and Bassett<sup>15</sup> and Brimacombe *et al.*<sup>11</sup> and explain why cuff-related tracheal damage is most severe over the anterior trachea.<sup>16</sup>

Brimacombe *et al.*<sup>9</sup> found that pharyngeal mucosal perfusion is progressively reduced when mucosal pressures increase from 34 to 80 cm H<sub>2</sub>O.<sup>9</sup> Our data suggests that perfusion would be potentially impaired in the anterior, lateral, and posterior pharynx with the ETC when the proximal cuff volume increases from 40 to 70, 50 to 80, and 30 to 50 ml, respectively. These volumes frequently exceed the minimal volume required to form an oropharyngeal leak pressure of 30 cm H<sub>2</sub>O. There are no published data about esophageal mucosal perfusion, but presuming esophageal perfusion pressure is similar to

**Table 2. Directly Measured Mucosal Pressures in the Anterior, Lateral, and Posterior Pharynx for Cadavers and Awake Volunteers**

Cuff Volume	Cadavers			Awake Volunteers		
	Anterior	Lateral	Posterior	Anterior	Lateral	Posterior
0	1 (3, 0–15)	1 (1, 0–5)	3 (6, 0–27)	7 (3–11)	8 (5–10)	20 (11–25)
10	5 (6, 0–23)	4 (5, 0–16)	13 (13, 0–50)	9 (0–19)	14 (7–26)	33 (23–45)
20	17 (16, 0–50)	10 (9, 0–28)	28 (24, 0–83)	23 (4–46)	25 (22–28)	52 (36–58)
30	32 (26, 3–93)	20 (16, 0–53)	46 (38, 0–137)	55 (13–79)	45 (15–61)	71 (57–106)
40	44 (37, 0–137)	33 (24, 1–83)	75 (49, 3–182)	53 (14–106)	54 (31–73)	100 (68–119)
50*	60 (49, 0–182)	44 (33, 1–107)	99 (62, 4–238)	60 (38–88)	76 (52–92)	127 (66–171)
60	81 (65, 0–238)	59 (44, 1–149)	131 (81, 4–303)	65 (39–111)	99 (86–117)	136 (103–183)
70	100 (77, 0–273)	76 (59, 1–183)	163 (100, 4–324)	110 (55–175)	126 (75–144)	164 (152–185)
80	117 (88, 0–305)	97 (81, 1–244)	192 (121, 4–404)	127 (80–215)	129 (61–150)	200 (154–291)
90†	136 (102, 0–354)	116 (101, 1–324)	221 (141, 4–464)	166 (84–254)	188 (105–297)	238 (171–330)
100	157 (117, 0–406)	133 (120, 1–371)	255 (161, 4–504)	217 (183–282)	234 (139–335)	307 (289–344)

Data are mean (SD, range) or mean (range). Units are cm H<sub>2</sub>O.

\* Three milliliters just above cuff volume required to form an oropharyngeal seal of 30 cm H<sub>2</sub>O. † Five milliliters above recommended cuff volume.



pharyngeal perfusion pressure, our data suggest that perfusion would be potentially impaired in the anterior, lateral, and posterior esophagus when distal cuff volume increases from 12 to 18, 12 to 20, and 4 to 8 ml, respectively. Seegobin and van Hasselt<sup>17</sup> found that tracheal mucosal perfusion is progressively reduced when mucosal pressures increase from 30 to 50 cm H<sub>2</sub>O. Our data suggests that perfusion would be potentially impaired in the anterior, lateral, and posterior trachea when distal cuff volume increases from 4 to 6, 8 to 10, and 10 to 12 ml, respectively. Interestingly, at the recommended inflation volume for the pharyngeal (85 ml) and esophageal cuffs (10–15 ml), mucosal pressures would be potentially higher than systolic blood pressure posteriorly.

We found that all the volunteers reported sore throat and dysphagia the day after insertion. We consider that the high pressures exerted against the pharynx, esophagus, and trachea probably contribute significantly to trauma associated with the ETC. In the pharynx, these high pressures may cause bleeding and sore throat and could perhaps predispose to pharyngeal perforation. Mercer and Gabbott<sup>6</sup> found that insertion with a laryngoscope to reduce direct trauma did not prevent bleeding and subsequently identified tears in the pharynx over the area of the proximal cuff, suggesting that the proximal cuff was the cause of the bleeding. In the esophagus, these high pressures may cause dysphagia and perhaps predispose to esophageal rupture. Reducing cuff volumes to the minimum required to form an effective seal should minimize the risk of these problems. However, although the minimal effective cuff volume can be determined for the pharynx and trachea by listening for an audible leak, it cannot be determined for the esophagus. We are unaware of any published data confirming that the recommended volume of 10–15 ml for the esophageal cuff is effective in preventing liquid flow between the lower and upper esophagus. There is evidence that the ETC is associated with a higher incidence of minor<sup>4</sup> and major<sup>18</sup> trauma compared with the laryngeal mask airway, which has been shown to exert much lower pressures against the pharyngeal mucosa.<sup>19</sup>

We found that pharyngeal mucosal pressures were similar for cadavers and awake volunteers. Although our findings should be interpreted cautiously, we 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>20</sup> Second, our data for cadaveric tracheal mucosal pressures closely match those of a previous endotracheal tube study in paralyzed anesthetized patients,<sup>11</sup> and our data for pharyngeal mucosal pressures closely match those of two previous studies of the cuffed oropharyngeal airway in paralyzed anesthetized patients.<sup>9,21</sup> Finally, cadavers have been used to determine the risk of esophageal rupture,<sup>22</sup> liquid flow between the esophagus and pharynx,<sup>23</sup> pharyngeal and

tracheal mucosal pressure,<sup>24</sup> and cervical motion studies.<sup>25</sup> Our study was conducted in cadavers and awake volunteers because we considered it unethical to inflate the ETC to the recommended volumes in elective patients because of the high risk of trauma.

We conclude that mucosal pressures for the ETC increase with cuff volume, are highest where the cuff is adjacent to rigid anatomic structures, and potentially exceed mucosal perfusion pressure even when cuff volumes are limited to achieving an oropharyngeal seal of 30 cm H<sub>2</sub>O.

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