The Influence of the Tonsillar Gag on Efficacy of Seal, Anatomic Position, Airway Patency, and Airway Protection with the Flexible Laryngeal Mask Airway: A Randomized, Cross-Over Study of Fresh Adult Cadavers

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We conducted a randomized, controlled, cross-over cadaver study to test the hypothesis that the efficacy of seal for ventilation and airway protection, anatomic position, and airway patency with the flexible laryngeal mask airway (FLMA) are altered by the application of a Boyle Davis (B-D) gag. We also determined the airway sealing pressure (ASP) at which the FLMA prevents aspiration when large volumes of fluid are placed above the cuff. We studied 20 adult cadavers (6–24 h postmortem). Efficacy of seal for ventilation and airway protection, anatomic position, and airway patency were determined with and without a B-D gag (two blade sizes: 8 and 10 cm) for the size 3, 4, and 5 FLMA in random order. Efficacy of seal for ventilation was determined by measuring the ASP at an intracuff pressure of 60 cm H2O. Efficacy of seal for airway protection was determined by flooding the mouth with 55–135 mL of water, reducing intracuff pressure until aspiration was detected fiberoptically and measuring ASP at this intracuff pressure. Anatomic position and airway patency were determined with a fiberoptic scope at an intracuff pressure of 60 cm H2O. In addition, in vivo compliance and ASP for the FLMA were measured in 10 cadavers and 10 paralyzed, anesthetized patients. Efficacy of seal for ventilation and airway protection, anatomic position, and airway patency did not change with the application of a gag for any mask size. The mean (range) ASP at which aspiration occurred when large volumes of fluid were placed above the cuff was 11 (7–15) cm H2O. The ASP for ventilation was always higher than the ASP for airway protection (P < 0.0001). The FLMA had similar in vivo compliance and ASP in cadavers and anesthetized patients. We conclude that efficacy of seal for ventilation and airway protection, anatomic position and airway patency for the FLMA are unaffected by the application of a B-D gag in adults. ASP should be 15 cm H2O if there is a maximal risk of aspiration from above the cuff. Implications: The flexible laryngeal mask airway forms an effective seal for ventilation and protection of the airway that is unaffected by the application of a mouth gag that provides surgical access to the oropharynx. The efficacy of the seal should be >15 cm H2O if there is a maximal risk of aspiration from above the cuff.

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The flexible laryngeal mask airway (FLMA) was designed for use in surgery in which the standard laryngeal mask airway (LMA) tube would either interfere with the surgical field, be occluded, or be displaced by the surgeon (1). It is identical to the standard device in all respects except that the airway tube has been replaced by a narrower, floppy flexometallic tube that gives it flexibility and compression resistance and makes dislodgment unlikely if the tube or head and neck are moved (2). The FLMA has been widely used for oropharyngeal (3–8) and nasal (9,10) surgery, in which it is offers advantages over tracheal intubation including avoidance of muscle relaxants, less hemodynamic stress response to placement and removal, and less coughing during emergence, while maintaining and protecting the airway (11). The effectiveness of laryngeal mask devices as protective barriers across the laryngeal inlet has been demonstrated using small volumes of fluid (12–14), but larger volumes can accumulate above the cuff, and life-threatening aspiration has been reported (15,16). Perhaps
airway sealing pressure (ASP) should be \( \geq 10 \text{ cm H}_2\text{O} \) to ensure that aspiration does not occur (1), but this has not been verified experimentally.

The Boyle-Davis (B-D) gag was designed for use with tracheal tubes to improve surgical access to the oropharynx. It comprises a gag for opening the mouth, a blade with a central groove that allows oropharyngeal structures to be elevated from the surgical field without occluding the tube, and a suspension system to maintain the position of the gag and blade (Figure 1). Although the FLMA was designed for use with a B-D gag, airway obstruction and loss of seal have been reported during oropharyngeal procedures in children and adults (3–7). We postulated that the change in pharyngeal geometry would reduce the efficacy of seal by distorting the interface between the cuff and periglottic tissues and that the blade would occlude the FLMA tube.

In our randomized, controlled, cross-over cadaver study, we tested the hypothesis that efficacy of seal for ventilation and airway protection, anatomic position, and airway patency with the FLMA are altered by the application of a B-D gag. We also determine the ASP at which the FLMA prevents aspiration when large volumes of fluid are placed above the cuff.

Methods

Ten male and 10 female adult cadavers (6–24 h postmortem) were included in this randomized, controlled, cross-over study. Ethical committee approval was obtained, and all patients, or their relatives, gave their written, informed consent to research. Cadavers with oropharyngeal anatomical abnormalities were excluded from the trial. For each cadaver, three FLMA devices (size 3, 4, and 5) and two sizes of the B-D gag were used. All FLMAs were in routine clinical use, had been through at least 20 autoclave cycles, and had passed the pre-use check tests.

A single experienced LMA user (>1000 uses) inserted/fixed the FLMA according to the manufacturer’s instructions (17). The insertion technique included full deflation of the cuff, flattening it against the hard palate and pushing it along the posterior palatopharyngeal curve using the index finger to provide centrifugal force. The pilot balloon was attached via a three-way tap to a 20-mL syringe and a calibrated pressure transducer with an accuracy of \( \pm 5\% \). The position of the head and neck was adjusted to the classical tonsillar position (head and neck extension) with the head stabilized by a shallow head ring and a rolled drape 5 cm thick under the shoulder blades (Figure 2). When the head and neck was in the tonsillar position, the intracuff pressure was adjusted to 60 cm H\(_2\)O by withdrawing or adding air. The B-D type gag (Karl Storz, Innsbruck, Austria) comprised a McIvor self-retaining mouth gag, Wuerzburg blades (8 and 10 cm), and a hand-cranked suspension system. The B-D gag was inserted, assembled, positioned, and suspended by an oral surgeon who was instructed to obtain a view of the oropharynx adequate for dissection tonsillectomy (Figure 3). If an adequate view could not be obtained, it was documented. The blade was lubricated before insertion to assist passage over the silicone tube of the FLMA. Care was taken to avoid displacement of the FLMA during head and neck movement and gag changes, and to position the FLMA and pilot tubing in the midline over the lower lip to avoid looping of the FLMA tube that could potentially become trapped by the gag.

Efficacy of seal for ventilation and airway protection, anatomic position, and airway patency were determined with and without a B-D gag (two blades sizes: 8 and 10 cm) for the size 3, 4, and 5 FLMA in random order. Efficacy of seal for ventilation was determined by measuring the ASP at an intracuff pressure of 60 cm H\(_2\)O. ASP was measured by closing the expiratory valve of the circle system at a fixed gas flow of 3 L/min and noting the airway pressure at which the dial on a calibrated aneroid manometer (accurate to \( \pm 0.5 \text{ cm H}_2\text{O} \)) reached equilibrium. This is the airway pressure at which the leak is in equilibrium with fresh gas flow. The interobserver reliability and accuracy of this measuring system has recently been validated (18). Efficacy of seal for airway protection was determined by increasing intracuff pressure to 120 cm H\(_2\)O and filling the oropharynx with water to the level of the gums using a 50-mL syringe and recording the volume. A fiberoptic scope was positioned distal to the mask aperture bars to provide a view of the glottic inlet. The intracuff pressure was reduced in 5-cm H\(_2\)O increments every 15 s until water was seen at the glottic inlet. The intracuff pressure was recorded, and water was carefully removed using the suction catheter of the fiberoptic scope. The
accuracy of the fiberoptic detection of water was confirmed by noting a decrease in the water level in the mouth. The ASP was then determined at this intracuff pressure. Anatomic position was determined with a fiberoptic scope (3.2 mm external diameter) at an intracuff pressure of 60 cm H2O using the following scoring system:

- 4: only vocal cords visible
- 3: vocal cords plus posterior epiglottis visible
- 2: vocal cords plus anterior epiglottis visible
- 1: vocal cords not seen

The degree of rotation in the sagittal plane was judged fiberoptically by noting the angle between the mask aperture bars and vocal cords: nil (<10°), mild (10–45°), moderate (46–90°), and severe (>90°). Airway patency was determined by passing a fiberoptic scope along the FLMA tube and noting any occlusion of the tube or cuff by the gag. If any occlusion was present, the position of the gag was readjusted and the measurements were repeated. The FLMA were inspected for damage after each use.

To provide information about pharyngeal rigidity, in vivo compliance for the size 5 FLMA was measured in 10 male cadavers and 10 paralyzed, anesthetized male patients (matched for height and weight) who were suitable for FLMA usage. Anesthesia was induced with propofol 2.5 mg/kg and was maintained with 100% O2 and sevoflurane 1%–2%. Muscle relaxation was accomplished with atracurium 0.5 mg/kg. In vivo intracuff pressure, ASP, and fiberoptic position were documented at zero volume with the cuff fully evacuated and after each additional 10 mL up to 40 mL with the head and neck in the neutral position. The investigators and measurement techniques were identical for cadavers and anesthetized patients.

ASP was determined by an investigator blinded to the FLMA and gag size by a head drape. An investigator who was not blinded to the FLMA and gag size conducted all the fiberoptic observations. Sample size was selected to detect a projected difference of 25% among the groups with respect to ASP for a type I error of 0.05 and a power of 0.9. The power analysis was based on data from a cross-over pilot study of 10 cadavers in which airway protection was determined for the size 3, 4, and 5 FLMA with and without the two gags. The distribution of data was determined using Kolmogorov-Smirnov analysis (21). Statistical analysis was performed by using a paired t-test (normally distributed data) and χ² test (non-normally distributed data). Unless otherwise stated, data are presented as mean (range). Significance was taken as P < 0.05.

**Results**

The mean (range) age, height, and weight for B-D gag cadavers were 73 (57–92) yr, 169 (151–188) cm, and 72 (52–88) kg, respectively. The mean (range) volume of water required to fill the mouth was 85 (55–135) mL. An adequate view of the tonsillar bed was obtained with all gags and mask sizes. No tube or cuff occlusion was seen. ASP for ventilation and airway protection, anatomic position, and airway patency did not alter with the application of a gag for any mask size (Table 1). The mean (range) ASP at which aspiration occurred when large volumes of fluid were placed above the cuff was 11 (7–15) cm H2O. The ASP for ventilation was always higher than the ASP for airway protection (P < 0.0001). ASP for ventilation and fiberoptic scores was lower for the size 3 FLMA compared with the size 4 or size 5 FLMA (P < 0.0001). Intracuff pressure was higher for the size 3 FLMA compared with the size 4 and size 5 FLMAs at the ASP for airway protection (P < 0.0001). Rotation of the FLMA was not seen. There was no damage to the FLMAs.

In the comparison between cadavers and paralyzed, anesthetized patients, cadavers were significantly older (79 [55–89] vs 36 [24–59] yr; P < 0.0001) but had identical mean height (176 cm) and weight (78 kg). The FLMA had similar in vivo compliance, ASP, and
fiberoptic position in cadavers and anesthetized patients (Table 2).

**Discussion**

John et al. (12) and Cork et al. (13) showed that the LMA protected the airway from 10-ml methylene blue dye and 15-ml barium sulphate respectively. Webster et al. (14) showed that the FLMA protected the airway from 5 mL of barium sulfate. Williams and Bailey (3) found that aspiration of blood was more common with the tracheal tube than the FLMA after adenotonsillectomy, but this was not confirmed by Webster et al. (4). Our data show that, when adequately inflated, the FLMA protects the airway when the mouth is filled with 55–135 mL of water. This situation may occur during oral or nasal surgery when there is unrecognized or uncontrolled bleeding, suction failure, or during irrigation. The mean ASP at which aspiration occurred was 11 cm H2O, which approximates to the height of the water above the lowest part of the FLMA cuff. An ASP >12 cm H2O would protect >95% of patients at maximal risk. We recommend an ASP >15 cm H2O if there is a risk of aspiration from above the cuff.

During the application of a B-D gag, there is an increase in the antero-posterior diameter of the pharynx and a change in the tension of the pharyngeal muscles. The blade of the gag fixes the flexometallic tube of the FLMA, but the cuff is free to rotate out of place if the change in pharyngeal shape is sufficient. Our data show that airway protection, efficacy of the seal, and anatomic position are unaffected by the application of the B-D gag. We postulate that the cuff is able to adapt to the changes in pharyngeal shape without loss of seal. The efficacy of the seal for the LMA depends on the degree of conformity with pharyngeal tissues, rather than pressure against the mucosa (22). In our study, the intracuff pressure was 60 cm H2O, and the cuff was semi-inflated. This value was chosen because ASP is higher at low, rather than high, intracuff pressures (23).

FLMA tube compression or loss of seal occurs in 2%–20% of patients during the application of the B-D gag (3–7). Although most patients in these studies were young children, these problems were also noted in older children and adults with the larger LMAs (4,6,7). There have been three reports of the pilot tube being severed (24–26). Bailey et al. (1) suggest that these problems can be avoided if the airway tube and pilot tube are maintained together in the midline during the application of the gag. Our data support this suggestion because we detected no compression of the tube or loss of seal in 120 gag applications. Perhaps the length of blade chosen for the gag is important (1). A blade that is too long may result in airway obstruction when the gag is opened as it lies posterior to the mask and pushes the mask against the laryngeal inlet. Too short a blade will not support the tube of the FLMA that may be indented by the tip of the blade and partially obstructed. We could not demonstrate any difference in performance between the 8- and 10-cm blades for all adult sizes of FLMA.

We conducted this study in cadavers because it would have been unethical to put patients at maximal risk of aspiration or to perform multiple applications of the B-D gag (3–7). Although most patients in these studies were young children, these problems were also noted in older children and adults with the larger LMAs (4,6,7). There have been three reports of the pilot tube being severed (24–26). Bailey et al. (1) suggest that these problems can be avoided if the airway tube and pilot tube are maintained together in the midline during the application of the gag. Our data support this suggestion because we detected no compression of the tube or loss of seal in 120 gag applications. Perhaps the length of blade chosen for the gag is important (1). A blade that is too long may result in airway obstruction when the gag is opened as it lies posterior to the mask and pushes the mask against the laryngeal inlet. Too short a blade will not support the tube of the FLMA that may be indented by the tip of the blade and partially obstructed. We could not demonstrate any difference in performance between the 8- and 10-cm blades for all adult sizes of FLMA.

### Table 1. Airway Sealing Pressure (ASP), Fiberoptic Score (FOS), and Intracuff Pressure (ICP)

<table>
<thead>
<tr>
<th></th>
<th>ASP for ventilation (cm H2O)</th>
<th>FOS</th>
<th>ASP for airway protection (cm H2O)</th>
<th>ICP (cm H2O)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Size 3</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>15 (13–17)</td>
<td>1/5</td>
<td>11 (10–11)</td>
<td>17 (13 to 21)</td>
</tr>
<tr>
<td>Small blade</td>
<td>15 (13–18)</td>
<td>0/5</td>
<td>11 (10–11)</td>
<td>17 (13 to 20)</td>
</tr>
<tr>
<td>Large blade</td>
<td>15 (13–17)</td>
<td>0/4</td>
<td>10 (9–11)</td>
<td>17 (14 to 20)</td>
</tr>
<tr>
<td><strong>Size 4</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>22 (20–23)</td>
<td>3/9</td>
<td>10 (9–11)</td>
<td>–4 (–7 to 1)</td>
</tr>
<tr>
<td>Small blade</td>
<td>22 (20–24)</td>
<td>2/8</td>
<td>11 (11–12)</td>
<td>–6 (–9 to 2)</td>
</tr>
<tr>
<td>Large blade</td>
<td>22 (20–24)</td>
<td>2/7</td>
<td>11 (11–12)</td>
<td>–6 (–9 to 3)</td>
</tr>
<tr>
<td><strong>Size 5</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>23 (21–25)</td>
<td>4/8</td>
<td>10 (9–11)</td>
<td>–5 (–9 to 2)</td>
</tr>
<tr>
<td>Small blade</td>
<td>22 (20–24)</td>
<td>2/7</td>
<td>11 (11–12)</td>
<td>–7 (–9 to 4)</td>
</tr>
<tr>
<td>Large blade</td>
<td>23 (21–25)</td>
<td>2/7</td>
<td>11 (10–12)</td>
<td>–7 (–9 to 2)</td>
</tr>
</tbody>
</table>

Data are mean (95% CI).

* = only vocal cords visible; 1 = vocal cords plus posterior epiglottis visible; 2 = vocal cords plus anterior epiglottis visible; 1 = vocal cords not seen (19).
the effects of rigor mortis on increasing pharyngeal rigidity are offset by lower pharyngeal rigidity in the elderly population. Nonetheless, some caution should be applied when extrapolating from the present study to the in vivo situation. A further limitation of our study is that the head and neck were only in one position during testing. However, the B-D gag is only used in the head and neck extended position. Furthermore, a study has shown that the seal for the FLMA is least effective in this position; therefore, the risk of aspiration from above the cuff is highest in the position we tested (2). Our finding that ASP and fiberoptic score is lower for the size 3 mask compared with larger sizes also matches data from anesthetized patients (27). Finally, this study was conducted in adults, and our findings may not apply to the pediatric population, in which the caliber of the FLMA tube is smaller and the pharyngeal tissues are probably more compliant.

We conclude that efficacy of seal for ventilation and airway protection, anatomic position, and airway patency for the FLMA are unaffected by the application of a B-D gag in adults. ASP should be >15 cm H2O if there is a maximal risk of aspiration from above the cuff.

References

Table 2. In Vivo Intracuff Pressure, Airway Sealing Pressure, and Fiberoptic Score

<table>
<thead>
<tr>
<th>Cuff volume (mL)</th>
<th>In vivo intracuff pressure (cm H2O)</th>
<th>Airway sealing pressure (cm H2O)</th>
<th>Fiberoptic score 4/3/2/1*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Anesthetized patients</td>
<td>Cadavers</td>
<td>Anesthetized patients</td>
</tr>
<tr>
<td>0</td>
<td>−29 (−33 to −25)</td>
<td>−30 (−35 to −25)</td>
<td>13 (10–16)</td>
</tr>
<tr>
<td>10</td>
<td>36 (18–54)</td>
<td>35 (26–44)</td>
<td>18 (14–22)</td>
</tr>
<tr>
<td>20</td>
<td>72 (51–94)</td>
<td>87 (71–147)</td>
<td>23 (19–26)</td>
</tr>
</tbody>
</table>

Data are mean (95% CI).
Results were achieved by using a size 5 flexible laryngeal mask airway.

*4 = only vocal cords visible; 3 = vocal cords plus posterior epiglottis visible; 2 = vocal cords plus anterior epiglottis visible; 1 = vocal cords not seen (19).


