The use of laryngeal mask airways with morbidly obese patients remains controversial. A recent legal case involving the use of a laryngeal mask airway with a morbidly obese patient who aspirated during the anesthetic found the anesthesia providers negligent. We sought evidence examining the use of laryngeal mask airways with obese patients undergoing surgery. One Cochrane systematic review and a randomized controlled trial met our inclusion criteria. Subjects received general anesthesia with a laryngeal mask airway. Outcomes included the ability to successfully place a laryngeal mask airway, ease and time of insertion, ability to ventilate, hypoxemia, presence of laryngospasm/bronchospasm, and/or evidence of aspiration.

The trials had some methodologic concerns including the inability to blind anesthesia providers, not including exclusively morbidly obese subjects, not powered to detect all complications such as aspiration, and overall small sample sizes. The investigators reported few problems when using these devices with obese subjects. However, because of the limited amount and quality of the evidence and the catastrophic nature of potential complications, future research must be done before a recommendation can be made regarding the use of these devices with morbidly obese patients.

Keywords: Complications, endotracheal intubation, general anesthesia, laryngeal mask airway, morbid obesity.
senting for surgery (patient), is an LMA (intervention) a safe and efficacious (outcome) airway device compared with endotracheal intubation (comparison)?

**Search Strategy.** The search for evidence (2005-2015) was conducted using PubMed and The Cochrane Database of Systematic Reviews. Search terms and phrases included intubation, laryngeal mask airway, laryngeal mask airway complications, and airway management in obese, morbidly obese in surgery. To take advantage of only high-level evidence, we included systematic reviews with and without meta-analysis and randomized controlled clinical trials (RCTs) not included in systematic reviews meeting the search criteria. We excluded observational studies and case reports. We also excluded sources examining pediatric subjects, subjects with difficult airway history, or use of LMA in a resuscitation setting or as an aid for endotracheal intubation.

Evidence was limited to English-language, full-text, peer-reviewed sources. These sources examined obese adults who were under general anesthesia comparing LMAs such as the LMA Classic (Teleflex Inc) and newer generations of LMAs with endotracheal intubation. Outcomes were safety, such as the incidence of aspiration, and efficacy, such as facilitating adequate ventilation. We included sources examining subjects considered obese and morbidly obese because of a suspected lack of evidence that looked at solely morbidly obese subjects. The evidence was appraised using the method described by Melnyk and Fineout-Overholt.11

**Description and Quality of Evidence Sources.** The search revealed 20 potential sources, with only 2 sources12,13 meeting the inclusion criteria (Tables 1 and 2). These were a Cochrane Collaboration systematic review12 and an RCT13 meeting the inclusion criteria but not included in The Cochrane Collaboration systematic review.12 Both12,13 were from authors practicing outside the United States. The BMI of subjects was above 30 kg/m², but no source included exclusively morbidly obese subjects (BMI > 35 kg/m²).

### Table 1. Summary of Systematic Review Comparing ProSeal Laryngeal Mask Airway and Tracheal Intubation for Airway Management During General Anesthesia in Obese Patients

<table>
<thead>
<tr>
<th>Source</th>
<th>Evidence type and level</th>
<th>No. of subjects</th>
<th>BMI (kg/m²) and surgery</th>
<th>Intervention</th>
<th>Findings</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicholson et al,12 2012</td>
<td>Systematic review composed of 2 randomized controlled trials</td>
<td>232 (PLMA 118, ET tube 114)</td>
<td>BMI &gt; 30</td>
<td>Routine laparoscopic surgery</td>
<td>PLMA vs ET tube</td>
<td>5/118 (4.2%) PLMA subjects changed to ET tube because of failed placement Postoperative hypoxemia, SpO₂ &lt; 92% while breathing room air was less common in PLMA group Significant difference in postoperative mean oxygen saturation: 2.54% higher in PLMA group 2/118 PLMA had laryngospasm or bronchospasm, ET tube 4/114 No pulmonary aspiration, mortality, or serious respiratory complications (no effect estimates for these outcomes)</td>
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Abbreviations: BMI, body mass index; ET, endotracheal; PLMA, ProSeal laryngeal mask airway; SpO₂, saturation of peripheral oxygenation measured by pulse oximetry.

Table 1. Summary of Systematic Review Comparing ProSeal Laryngeal Mask Airway and Tracheal Intubation for Airway Management During General Anesthesia in Obese Patients

**Evidence type No. of BMI (kg/m²) Source and level a subjects and surgery Intervention Findings Comments**

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<thead>
<tr>
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</table>

11 Evidence appraised and leveled using the method described by Melnyk and Fineout-Overholt,11 ranging from level I evidence encompassing systematic reviews to level VII evidence that includes expert opinion.

12 Relative effect not estimable; substantial difference between study population. Heterogeneity (I² = 71%).

13 RR 0.27 (95% CI, 0.1 to 0.72); moderate-quality evidence.

14 Mean oxygen saturation of peripheral blood in postanesthesia care unit in ET tube group was 90.3-94.7%, (2.54 times) higher in intervention PLMA group (1.09 to 4 higher).

15 RR, 0.5 (95% CI, 0.09 to 2.84), rated as low-quality evidence.

16 No cases of serious respiratory complications or mortality within 30 days of anesthesia reported in study populations.
Cochrane Collaboration Systematic Review. The systematic review from The Cochrane Collaboration included 2 trials. The search strategy and appraisal method were thoroughly described. Only RCTs were included, and they used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system to assess the overall quality of the evidence.

One trial examined subjects undergoing gastric banding, and in the other trial the subjects underwent various surgical procedures. Both compared the ProSeal LMA (PLMA, Teleflex Inc) with an endotracheal tube. There was a total of 232 subjects with a BMI over 30 kg/m². As anticipated, no sources examined solely morbidly obese subjects. Both trials in the systematic review excluded subjects with an anticipated or documented history of a difficult airway or gastro-esophageal reflux, and 1 trial excluded any subject with gastric ulcers.

One RCT provided information about sleep study–diagnosed sleep apnea scores, type 2 diabetes, hypertension, depression, and whether subjects' medications included β-blockers, angiotensin-converting enzyme inhibitors, calcium channel blockers, or antidepressants.

The same 2 anesthesia providers specifically placed the PLMA in 1 trial, and they had experience placing more than 5,000 PLMAs. The other trial did not clearly identify the anesthesia providers or their experience.

Randomization of subjects was reported in each source. Anesthesia providers were not blinded to the airway devices, and no standard insertion method or LMA size was reported. Time and ease of insertion of airway device were reported.

The authors of the systematic review reported that 3 subjects were excluded in one of the RCTs for failure to place the device and laryngospasm, and 4 were excluded.

Table 2. Summary of Evidence Source Comparing i-gel and LMA-Unique Laryngeal Mask Airway in Patients With Mild to Moderate Obesity During Elective Short-Term Surgery

<table>
<thead>
<tr>
<th>Source</th>
<th>Evidence type and level</th>
<th>No. of subjects</th>
<th>BMI (kg/m²) and surgery</th>
<th>Intervention</th>
<th>Findings</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weber et al, 2011</td>
<td>Prospective randomized crossover study</td>
<td>50</td>
<td>Mildly obese: BMI &gt; 25 and &lt; 30 (n = 29)</td>
<td>LMA-Unique and i-gel used on every patient (crossover design)</td>
<td>No adverse events defined as SpO₂ &lt; 90% during induction and insertion of device, no aspiration, 1 patient with blood on device after pulled out (LMA-Unique was inserted first)</td>
<td>• Primary outcome: leak pressure difference between i-gel and LMA-Unique</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Moderately obese: BMI &gt; 30 and &lt; 35 (n = 21)</td>
<td></td>
<td>Leakage pressures: i-gel: 23.7 (8.2) cm H₂O LMA-Unique: 17.4 (7.0) cm H₂O</td>
<td>• Definition of aspiration vague</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Measuring instrument: audible leak/stethoscope, pressure controlled-ventilation test</td>
<td>• Measurement done intraoperatively, no report of follow-up</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Mean leakage pressure was significantly higher for i-gel for both mildly and moderately obese patients</td>
<td>• Concluded devices may be used as alternative to intubation for short-term elective surgery in supine position</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No adverse events defined as SpO₂ &lt; 90% during induction and insertion of device, no aspiration, 1 patient with blood on device after pulled out (LMA-Unique was inserted first)</td>
<td>• Reliability and validity of instruments not addressed</td>
</tr>
</tbody>
</table>

Abbreviations: BMI, body mass index; LMA, laryngeal mask airway; SpO₂, saturation of peripheral oxygenation measured by pulse oximetry.

Evidence appraised and leveled using the method described by Melnyk and Fineout-Overholt, ranging from level I evidence encompassing systematic reviews to level VII evidence that includes expert opinion.

Values are mean (SD).

P < .0001.

Data are expressed as means ± SD for groups of 35 patients and compared with a Student t test. P values were determined using 3 post hoc Bonferroni corrections.

Data are expressed as numerical data (percent) for groups of 35 patients and compared by χ² test.
in the other RCT for failure to place the airway device with 1 laryngospasm. In the RCT examining subjects undergoing laparoscopic gastric banding surgery, measurements of insufflation, end-tidal carbon dioxide capnography, peripheral oxygen saturation measured by pulse oximetry (SpO₂), heart rate, mean arterial blood pressure, and peak inspiratory pressures at baseline, 1 minute, 5 minutes after the airway device was removed and in the postanesthesia care unit were recorded. The other RCT reported oxygen saturations during surgery and in the postanesthesia care unit. Ventilation efficacy was measured with pulse oximetry and hypoxemia defined as less than 92% SpO₂.

The outcomes were listed as unsatisfactory placement of PLMA; oxygen desaturation intraoperatively, immediately postoperatively, and 30 minutes, 2 hours, and 24 hours later; pulmonary aspiration of gastric contents; laryngospasm; and bronchospasm. The other RCT listed outcomes as a change of airway device; hypoxemia intraoperatively, during insufflation, and in the postanesthesia care unit; pulmonary aspiration of gastric contents; leak fraction and peak inspiratory pressure before, during, and after insufflation; laryngospasm on emergence; sore throat; hoarseness between surgery and discharge; and device placement time and success at first attempt. The authors of the systematic review reported that the quality of the evidence in addressing these outcomes was low to moderate.

RCT Not Included in Cochrane Collaboration Systematic Review. The second evidence source was an RCT meeting the inclusion criteria but not included in the systematic review. These investigators used a crossover design with 50 subjects comparing the LMA-Unique (Intavent Orthofix Ltd) and i-gel LMA (Intersurgical Inc). Subjects were placed into 2 groups: mildly obese (BMI > 25 and < 30 kg/m²) and moderately obese (BMI > 30 and < 35 kg/m²). These subjects underwent surgery lasting less than 2 hours and were placed in the supine position.

Exclusion criteria included a subject mouth opening of less than 2.5 cm, presence of acute or chronic lung disease or neck pathology, and increased risk of aspiration (gastro-esophageal reflux, hiatal hernia, full stomach, and pregnancy). The same 2 anesthesia providers placed each airway device and thus were not blinded to the device. A specific digital technique and standard size for the PLMA (size 5) was used, with time and ease of insertion reported.

Ventilation efficacy was measured with pulse oximetry and hypoxemia defined as less than 92% SpO₂ during and after surgery. Heart rate, blood pressure, and SpO₂ were noted before induction, after induction (during mask ventilation), after insertion of first airway device, and before and after the second airway device was inserted. An audible leak test with stethoscope near the thyroid cartilage was done to determine leakage pressure. A pressure controlled ventilation test was also done. Ventilation started with at a low peak inspiratory pressure of 8 cm H₂O and increased every 10 breaths by 1 cm H₂O until a maximum tidal volume of 10 mL/kg/min was reached. After these tests, the second airway was inserted and used until the end of the surgery. Outcomes in the RCT were also intraoperative or postanesthesia care unit hypoxemia, presence of cough, sore throat, vomiting, laryngospasm, bronchospasm, and aspiration of gastric contents.

Results
Authors of both evidence sources examined clinically significant outcomes supporting the safety and efficacy of the PLMA, LMA-Unique, and i-gel airway in obese patients. These outcomes included hypoxemia, successful placement, ability to ventilate, presence of laryngospasm/bronchospasm, and aspiration. Investigators indicated that the time required for insertion and the ease of insertion of an LMA in an obese patient were of little clinical significance. In general, aspiration risk was considered to be higher for obese patients undergoing general anesthesia; however, there were no cases of aspiration reported in the 282 subjects. This may be due to the studies not being powered to detect between-groups differences for this rare event. One of the studies in The Cochrane Collaboration systematic review was powered to detect differences in blood pressure, plasma norepinephrine levels, and oxygen saturation, and the RCT was powered to detect differences in the airway pressure where a leak occurred.

Postoperative Hypoxemia. Authors of The Cochrane Collaboration systematic review reported that the mean oxygen saturation of peripheral blood in the postanesthesia care unit for the endotracheal tube group ranged from 90.3% to 94.7%. Subjects in the PLMA group had a 2.54% higher oxygen saturation. However, the quality of evidence was rated as low (low quality defined as “further research is very likely to have an important impact on our confidence in the estimate of the effect and is likely to change the estimate”). The significant improvement in oxygenation during and after surgery in subjects in the PLMA group over the endotracheal tube group indicated better overall performance and reduced postoperative coughing, suggesting better recovery for patients.

Success With Subjects Assessed to Have a Difficult Airway. Five of 118 subjects in The Cochrane Collaboration systematic review had the PLMA changed to an endotracheal tube because of failed placement of the PLMA. However, the quality of evidence was rated as low in this Cochrane Collaboration systematic review. In the RCT, the insertion times and ease of insertion were significantly shorter for the i-gel LMA over the LMA-Unique. In subjects with a Mallampati score of 3 or more, the insertion difficulty and number of attempts increased. One case of blood on the airway device was noted in the RCT when
the LMA-Unique was inserted first before switching to the i-gel airway.\textsuperscript{13} Neither of the studies defined aspiration, but in both the RCT and The Cochrane Collaboration systematic review there were no cases of pulmonary aspiration in any of the study populations.\textsuperscript{12,13}

- **Laryngospasm/Bronchospasm.** Authors of The Cochrane Collaboration systematic review reported that laryngospasm/bronchospasm occurred in 2 of 118 subjects in the PLMA group and 4 of 114 subjects in the endotracheal tube group but reported no serious respiratory complications or mortality within 30 days.\textsuperscript{12}

- **Ability to Ventilate.** The RCT compared leakage pressure by noting the tidal volume when an audible leak was detected to a maximum of 10 mL/kg, with subjects in the i-gel group having significantly higher leakage pressure.\textsuperscript{1} The tidal volume was reached in 46% of subjects in the i-gel group and 28% in the LMA-Unique group.\textsuperscript{13} The RCT authors concluded that “the i-gel could be used with higher airway pressures versus the LMA-Unique and may, therefore, be used as an effective LMA in patients with mild to moderate obesity with mouth openings of less than 4 cm in elective surgery of short duration in the supine position.”\textsuperscript{13}

**Discussion**

There were methodologic concerns and inconsistencies in both evidence sources. No investigators included exclusively morbidly obese subjects. The investigators examined 3 types of second-generation LMAs. This limits generalizations about the safety and efficacy of all types of LMAs or other supraglottic airways. Aspiration was not noted to be a problem by the authors of either evidence source; however, the evidence sources were likely underpowered to detect differences in aspiration.\textsuperscript{12,13} The risk of aspiration with LMA use is reported to be about 2 in 10,000.\textsuperscript{1} Another group reported the incidence of aspiration as higher in subjects for whom positive pressure ventilation was used with endotracheal tube (1 in 4,394) vs with an LMA (1 in 11,877).\textsuperscript{13} It is not clear whether any subjects in these studies were obese or morbidly obese.\textsuperscript{15,16} The Cochrane Collaboration systematic review was the only systematic review located specifically addressing the use of a PLMA vs an endotracheal tube in obese subjects.\textsuperscript{12} These authors found that with obese subjects, the insertion time of a PLMA compared with an endotracheal tube had little clinical significance. They also reported an anticipated failure rate of 3% to 5% with an LMA. The findings of this review suggested that once seated properly, a PLMA provides at least as good an oxygenation as an endotracheal tube and reduces post-operative coughing.\textsuperscript{12} In the RCT, the authors reported that the i-gel could obtain significantly higher leakage pressures than the LMA-Unique.\textsuperscript{13}

The LMA is now a part of the difficult airway algorithm and is routinely used successfully for patients with no major comorbidities or risk of aspiration, especially in outpatient surgical settings.\textsuperscript{7} Newer generations of LMAs are being invented or current models modified in attempts to address the LMA weaknesses.\textsuperscript{7}

Using an LMA for general anesthesia with obese and morbidly obese patients remains controversial because of the safety concerns including aspiration. There is now case law in the United States in which an aspiration after LMA placement in a morbidly obese patient in the outpatient setting resulted in a large settlement.\textsuperscript{1} Additional large, high-quality studies must be conducted before recommending LMA use with any obese patient.

**REFERENCES**


13. Weber U, Oguz R, Potura L, Kimberger O, Kober A, Tschernko E. Comparison of the i-gel and LMA-Unique laryngeal mask airway in patients with mild to moderate obesity with mouth openings of less than 4 cm in elective surgery of short duration in the supine position.\textsuperscript{13}
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