Airway management is a major factor underlying morbidity and mortality related to anesthesia in the morbidly obese population. Thus, a body mass index (BMI) \( > 26 \text{ kg/m}^2 \) results in a 3-fold increase in difficult ventilation via a mask (1) and in a 10-fold increased incidence of difficult endotracheal intubation (2,3). Inability to maintain a patent airway can be problematic in the obese, because lung and chest mechanical properties are markedly impaired in sedated, paralyzed obese patients (4). This may account for impaired arterial oxygenation and may even result in an unfavorable outcome.

The intubating laryngeal mask airway (ILMA; FastTrach™; Laryngeal Mask Co., Henley on Thames, UK) is a specific device that allows effective ventilation and blind tracheal intubation in patients with normal and abnormal airways. Because of its original features (anatomical curve, rigid airway tube with guiding handle, epiglottic elevating bar, and guiding ramp to guide the tracheal tube), the ILMA provides better conditions than the standard laryngeal mask for achieving effective ventilation and tracheal intubation (5). In an adult population with an anticipated difficult airway, Langeron et al. (6) obtained a frequent success rate of tracheal intubation with both the ILMA and fiberoptic techniques. In this study, the incidence of successful intubation, the number of attempts, and the median time to achieve tracheal intubation were similar with the two techniques.

Thus, the ILMA could represent an additional technique in airway management of the adult obese patient. We therefore undertook a prospective study to assess the effectiveness of the ILMA as a primary, electively instituted ventilatory device and intubation guide for airway management in adult obese patients. This study was performed on the entire consecutive obese population scheduled for bariatric surgery, including those with and without potential difficult intubation conditions, as assessed by the usual preoperative criteria.

Preoperative prediction of potential difficulty with airway management by using individual tests, such as a Mallampati score, seems to have a lesser value in obese patients as compared with lean patients (2). Consequently, anesthesia of morbidly obese patients remains at frequent, but not foreseeable, risk of difficult mask ventilation or tracheal intubation.

The validity of readily available clinical criteria to predict difficult intubation has been tested to stratify the risk of difficult intubation in the adult obese population. We assessed the usefulness of the Mallampati score alone or combined with other variables (3) to
predict difficult intubation by using the ILMA in morbidly obese patients.

**Methods**

This study was approved by the local Human Subjects Committee, and written, informed consent was obtained from all patients. Over a 12-mo period (January 2001 to December 2001), all morbidly obese patients (defined as a BMI >40 kg/m²) scheduled for bariatric surgery requiring general anesthesia with tracheal intubation were eligible for inclusion in this prospective study. Patients were excluded if they were younger than 18 yr, had an ASA physical status of IV or V, or had a medical history of impossible tracheal intubation or awake fiberoptic intubation or if preoperative evaluation showed evidence that an awake fiberoptic intubation or a rapid-sequence induction would be required.

All data were collected by certified anesthesiologists on a single standardized form during the preoperative visit, during the induction of anesthesia, and in the postoperative period. During the preoperative visit, the following information was collected by certified anesthesiologists not subsequently involved in the airway management of the patients:

1. Demographic and morphologic data: age, sex, weight, height, BMI (calculated as weight expressed in kilograms divided by the square of the height expressed in meters), ASA physical status, and surgical procedure.

2. Predicting factors for difficult tracheal intubation, as defined in the French Society of Anesthesiologists' guidelines on management of the difficult intubation (7).

The visibility of oropharyngeal structures was assessed with the patient in the sitting position, with the head in a neutral position, with the tongue fully protruding, and without phonation, according to the Mallampati classification (8) as modified by Samsoon and Young (9). Mouth opening (MO) in patients with anterius teeth was recorded as the interincisor gap and was measured (in millimeters) with the mouth fully opened. In edentulous patients, the interpolar distance (TMD) was measured (in millimeters) with the mouth fully opened. In edentulous patients, the interpolar distance with the mouth fully opened was recorded. Thyromental distance (TMD) was measured (in millimeters) along a straight line from the thyroid notch to the most anterior part of the chin with the head fully extended. Cervical spine extension was categorized as >90° (normal), 80°–90° (correct), or <80° (limited or fixed). A history of anticipated or unanticipated difficulties with tracheal intubation was also recorded. Additional factors possibly related to difficult tracheal intubation in obese patients, such as a short neck or a history of sleep apnea obstructive syndrome, were also collected.

Before the induction of anesthesia, preoxygenation through an adequately sized facial mask with 100% oxygen during 5 min was performed for all patients. Anesthesia was induced with IV propofol (2.5–3 mg/kg). After effective mask ventilation was demonstrated, sufentanil (0.2 μg/kg) and atracurium (0.4–0.6 mg/kg) were injected to obtain satisfactory intubation conditions. The occurrence of difficult mask ventilation was a reason for stopping the procedure. The patient was then managed according to the recommendations of the French Society of Anesthesiologists (7).

Two different observers were involved in the study. Mask ventilation and direct laryngoscopy with a Macintosh No. 4 blade were performed by the attending anesthesiologist. We defined “difficult mask ventilation” as an inability to obtain chest excursion sufficient to maintain a clinically acceptable capnogram wave form, despite optimal head and neck positioning and use of an oral airway and optimal application of a face mask.

The laryngeal view was graded according to the method described by Cormack and Lehane (10) as Grade 1 (full view of the glottis), Grade 2 (glottis partly exposed, anterior commissure not seen), Grade 3 (only epiglottis seen), or Grade 4 (epiglottis not seen) and was blinded to the second physician or nurse anesthetist inserting the ILMA device. Grade III and IV laryngeal views were considered as representing progressively more difficult conditions for tracheal intubation (10–13). Tracheal intubation with the ILMA was performed, as previously described (5), by staff anesthesiologists, including experienced (defined as a personal experience of five or more insertions of the ILMA) and inexperienced (fewer than five insertions of the ILMA) anesthesiologists. All the practitioners were trained for the ILMA insertion before the study by using an intubation mannequin. The initial size for the ILMA was selected according to the patient’s MO and height. A Size 4 or 5 and a 7.5- or 8-mm straight-cuffed silicone tube included in the ILMA set (SEBAC, Pantin, France) were usually chosen. Failure of the ILMA technique was defined as three unsuccessful attempts during either laryngeal mask insertion or tracheal intubation.

The following data were collected for each patient: laryngeal view classified according to the method of Cormack and Lehane (attending anesthesiologist), experience of the second anesthesiologist or certified nurse anesthetist for the ILMA, duration time for insertion of the laryngeal mask, total duration of the ILMA insertion, the number of attempts for laryngeal mask insertion, and tracheal intubation through the laryngeal mask. Systolic, diastolic, and mean arterial blood pressure and heart rate were recorded during the procedure. Arterial oxygenation during the mask ventilation, laryngoscopy, and ILMA insertion was...
assessed by pulse oximetry. According to the hemoglobin dissociation curve, a decrease in arterial oxygen saturation can reflect arterial hypoxemia. Mild hypoxemia was defined as an $\text{SpO}_2$ value <95% for more than 1 min, whereas an $\text{SpO}_2$ value <90% for more than 1 min reflected severe hypoxemia. Bleeding and/or pharyngeal postoperative pain due to the laryngeal mask was also documented.

Data are expressed as mean ± sd or median with interquartile range for nongaussian variables. Comparison of two or more medians was performed with the Mann-Whitney $U$-test or the Kruskal-Wallis test when appropriate. A $P$ value <0.05 was required to reject the main null hypothesis.

Sensitivity, specificity, and positive and negative predictive values were calculated, by using the standard formulas, to assess the accuracy of two tests to predict difficult intubation, defined as a Cormack grade of 3 or 4. Each airway assessment variable was stratified into risk categories. A patient with a Mallampati score of I or II was a priori considered as a low risk for difficult intubation, whereas a patient with a Mallampati score of III or IV was considered as high risk.

The simplified airway risk index (SAR index) described by El-Ganzouri et al. (3) assigned a value of 0, 1, or 2 to the following risk factors: MO (>35 mm, 0; >35 mm, 1), TMD (>65 mm, 0; 60–65 mm, 1; <60 mm, 2), Mallampati score (I, 0; II, 1; III or IV, 2), cervical spine extension (>90°, 0; 80°–90°, 1; <80°, 2), body weight (<90 kg, 0; 90–110 kg, 1; >110 kg, 2), and history of difficult intubation (none, 0; questionable, 1; definite, 2). A SAR score ≥4 categorized the patient as at risk for difficult intubation.

### Results

A total of 118 patients were enrolled in the study. Patient characteristics, including demographic and medical data, are reported in Table 1. The large proportion (84%) of female patients is usual in patients undergoing bariatric surgery. The ILMA intubations were performed by 22 staff anesthesiologists or nurse anesthetists. Complete ILMA intubation was successful in 114 cases (96.7%). The four patients in whom ILMA intubation failed were successfully intubated with the Macintosh blade. Failures were always related to unsuccessful attempts to pass the tracheal tube through the trachea. Three of these patients exhibited laryngoscopy Grade 1 or 2, whereas one patient had Grade 3 laryngoscopy. There was no difficult mask ventilation, as previously defined. Mild hypoxemia occurred in 37 patients before the laryngeal mask insertion, but no episode of severe arterial hypoxemia was observed.

Tracheal intubation with ILMA was not different in obese patients with high (3 or 4) Cormack grades, as compared with obese patients with “normal” laryngeal views (Cormack Grades 1 or 2), even if the median duration time for laryngeal mask insertion appears to be longer (41 versus 30 s) in patients with high grades as compared with patients with low-grade laryngeal views (Table 2). No difference was found between experienced and inexperienced practitioners for the ILMA insertion with respect to the duration time required in achieving laryngeal mask insertion or tracheal intubation (Figs. 1 and 2).

Compared with Mallampati Class III–IV, applying the SAR index at a value of ≥4 for stratification of difficulty with laryngeal visualization results in the same predictive values with greater sensitivity (68% versus 47%) but lower specificity (53% versus 71%; Table 3). No hemodynamic instability during either laryngoscopy or ILMA insertion was observed. Transient pharyngeal pain was noticed in two patients in the postoperative period, and mild bleeding was found in 20 patients, as usual after the laryngeal mask removal.

### Discussion

The ILMA device ensures a frequent incidence of tracheal intubation (96.7%) in a population of morbidly obese patients. However, 16% of patients exhibited Cormack 3–4 laryngeal views, suggesting difficulties with tracheal intubation with a Macintosh blade. In this study, tracheal intubation through the ILMA was generally achieved in two minutes, with most patients intubated at the first attempt.
The main factors related to failed or difficult intubation (preoperative clinical criteria used to predict difficult intubation, poor visualization of the glottic aperture during laryngoscopy) did not affect the success rate of blind tracheal intubation. Thus, airway management with the ILMA device in obese patients may be considered as valuable and complementary to conventional laryngoscopy. The efficacy of the ILMA as a primary, electively instituted ventilatory device and intubation guide for airway management of a homogeneous group of morbidly obese patients has not been studied. A previous study suggested that tracheal intubation was easier in the abnormal than in the normal airway, because the anterior larynx, representing more difficult conditions for tracheal intubation, facilitated a better alignment of the ILMA and glottic aperture (5). Because an anterior larynx is a common airway characteristic in morbidly obese patients, the ILMA may represent a primary means of establishing an airway in this group of patients.

The level of clinician experience for this technique does not seem to influence either the mean duration or the number of attempts required to achieve adequate ventilation or tracheal intubation. Thus, airway management with the ILMA is easily achieved, even by inexperienced practitioners in obese patients in whom difficult mask ventilation and tracheal intubation is common. Our findings agree with those previously published, suggesting a rapid learning curve for this technique (14).

### Table 2. Comparison of Patients Intubated with the Intubating Laryngeal Mask Airway (ILMA) According to Their Laryngeal View

<table>
<thead>
<tr>
<th>Variable</th>
<th>Cormack Grade 1–2</th>
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<th>P value</th>
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<tr>
<td>No. of patients</td>
<td>99 (84)</td>
<td>19 (16)</td>
<td></td>
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<tr>
<td>SpO₂ &lt;95%</td>
<td>29 (29)</td>
<td>8 (42)</td>
<td>0.51</td>
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<td>Number of attempts for the ILMA</td>
<td>1 (1–1)</td>
<td>1 (1–1)</td>
<td>0.46</td>
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<tr>
<td>Time to insert the ILMA (s)</td>
<td>30 (24–40)</td>
<td>41 (30–60)</td>
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<td>Number of attempts for blind intubation</td>
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<td>1 (1–1)</td>
<td>0.55</td>
</tr>
<tr>
<td>Total duration (s)</td>
<td>120 (94–171)</td>
<td>122 (120–180)</td>
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Data are expressed as mean ± sd, n (%), or median (25%–75% confidence interval).

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**Figure 1.** Influence of the practitioner’s experience on the total time required to achieve tracheal intubation with the intubating laryngeal mask airway (ILMA) device. Data are expressed as median, minimal, and maximal values and 25%–75% confidence intervals.
The effectiveness of the Mallampati score and the SAR index to predict difficult laryngoscopy in obese patients is not the same. In our study, more than 50% of the difficult laryngoscopies were not detected by the Mallampati assessment. In contrast, the multivariate SAR index, which combines several airway risk factors, afforded a much greater ability to discriminate the actual occurrence of Grade 3–4 laryngeal views.

Our estimates of positive predictive values, based on a small number of patients, have to be interpreted with caution. Preoperative assessment of the airway may facilitate appropriate preparation when difficulty with ventilation or tracheal intubation is anticipated before initiation of anesthesia. Much information has been published on preoperative risk factors, such as MO, Mallampati classification, head and neck movement or TMD, or a history of difficult intubation. The accuracy of these preoperative tests used alone is poor, showing low sensitivity and positive predictive value but good specificity and negative predictive value (3,13,15). The combination of these variables, providing a multivariate model for stratifying risk of difficult tracheal intubation, seems to improve prediction of difficult intubation in obese patients (3).

Our findings suggest the ease of establishing an airway with the ILMA device in obese patients. Difficult mask ventilation is more common in the obese patient (1). A reduced posterior airway space behind the base of the tongue, together with an increased BMI, and upper airway obstruction after the induction of general anesthesia can cause major collapse of the pharynx and may explain difficult mask ventilation in these patients. In our group of morbidly obese patients, ventilation through the ILMA was easily achieved without arterial hypoxemia. Further studies are needed to assess the effectiveness of the ILMA as an effective primary means of establishing an airway when difficult mask ventilation occurs.

Despite the unquestionable effectiveness of this device in achieving ventilation and tracheal intubation in morbidly obese patients, the ILMA device cannot be

**Table 3.** Sensitivity, Specificity, and Predictive Values for Mallampati Score and Simplified Airway Index (SAR Index)

<table>
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<tr>
<th>Variable</th>
<th>Mallampati Score</th>
<th>SAR Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity (%)</td>
<td>47</td>
<td>68</td>
</tr>
<tr>
<td>Specificity (%)</td>
<td>71</td>
<td>53</td>
</tr>
<tr>
<td>Positive predictive value (%)</td>
<td>24</td>
<td>22</td>
</tr>
<tr>
<td>Negative predictive value (%)</td>
<td>88</td>
<td>90</td>
</tr>
</tbody>
</table>

A Mallampati score of III or IV and a SAR index of ≥4 are predictors of, and laryngoscopy Grade 3 or 4 is a diagnosis of, difficult intubation.

**Figure 2.** Influence of the practitioner’s experience on the time for laryngeal mask insertion with the intubating laryngeal mask airway (ILMA) device. Data are expressed as median, minimal, and maximal values and 25%–75% confidence intervals.
recommended as a routine airway for use during general anesthesia in this group of patients. The incidence of difficult intubation in these patients is 10%–15% (2,3); the incidence of failure to intubate is unknown. In the general population, the incidence of failure to intubate varies from 0.05% to 0.35% (9,10). Consequently, the incidence of failed intubation with the ILMA in our study (3.3%) is probably not less than that expected with rigid laryngoscopy in an obese patient. In a retrospective study of morbidly obese patients anesthetized between January and December of 1999 in our institution, the incidence of failed intubations with laryngoscopy was 1.7% (data not shown). Furthermore, no clearly defined algorithm has been described for when blind intubation fails, even if passage of a fiberoptic bronchoscope through the laryngeal mask airway is nearly 100% successful in most series (16).

In summary, this study indicates that the ILMA is an effective and safe ventilatory device and blind intubation guide in morbidly obese patients. The choice of the primary technique (laryngoscopy or ILMA) for tracheal intubation of an adult obese patient remains to be determined.

References