Comparison of the standard laryngeal mask airway and the ProSeal laryngeal mask airway in obese patients

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Background. The ProSeal laryngeal mask airway (PLMA) may have advantages over the laryngeal mask airway (LMA) in obese patients. We tested this hypothesis in a clinical setting.

Methods. Sixty obese patients (BMI >30) were randomized to receive mechanical ventilation (tidal volume 7 ml kg⁻¹, PEEP 10 cm H₂O), through either the PLMA or the LMA. A gastric tube was used in all patients. Cuff pressure was set at 60 cm H₂O and increased progressively until excessive leak occurred. The incidence of sore throat was assessed at recovery and after 1 week.

Results. The mean leak fraction was 6.1 (SD 2.9)% with the LMA and 6.4 (3.5)% with the PLMA (P=0.721). With the PLMA, with no sign of ventilation problems, the drainage tube was not patent in three patients. The cuff pressure was >100 cm H₂O in 38% of the LMA group and 7% of the PLMA group (P=0.05). The incidence of sore throat was similar in both groups and it was similarly scored in the recovery room and 1 week after surgery.

Conclusions. Both the PLMA and the LMA can be used for mechanical ventilation of obese patients. The patency of the PLMA drainage tube needs to be checked constantly even when an optimal airtight seal is present. In obese patients the LMA requires a greater cuff pressure than the PLMA, but sore throat is not related to the cuff pressure. Sore throat assessment in the recovery room appears as reliable as assessment later.

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The laryngeal mask airway (LMA) offers both advantages and disadvantages when compared with the tracheal tube in obese patients. Using the LMA can avoid the risks of tracheal intubation, which might be important in some patients. The LMA is better tolerated, with less coughing during recovery from anaesthesia, allowing removal when patients are awake and cooperative. In obese patients this could reduce the possibility of airway obstruction in the early postoperative period.

However, the use of the LMA in obese patients has some problems. Firstly, obesity increases elastance and resistance of the respiratory system, so that the peak inspiratory pressure is greater. This can cause air leaks from the LMA and lead to hypoventilation and gastric insufflation. Secondly, obesity may increase the risk of gastric aspiration, and the LMA does not protect against this.

The ProSeal laryngeal mask airway (PLMA) has new features compared with the LMA. The additional tube draining the oesophagus and the large wedge-shaped cuff could theoretically overcome the problems of the LMA in obese patients. The airway seal pressure is greater, and regurgitated fluid can be drained, directly or by means of a gastric tube. A comparison between the LMA and PLMA in obese patients has not been reported.

We set out to compare the airway seal of the PLMA and the LMA in obese patients undergoing general anaesthesia and mechanical ventilation in whom a gastric tube was placed. We also assessed any problems and adverse effects of the devices.

LMA ® is the property of Intavent Limited.
Methods

Patients

The study was approved by the institutional ethics committee (Comitato Etico Istituzioni Ospedaliere Cattoliche), and informed consent was obtained from each patient. We studied obese adult patients (BMI >30) who were to have surgical procedures with general anaesthesia and mechanical ventilation. The exclusion criteria were: age <18 yr, non-fasted patients, pregnancy, prone position, and airway surgery.

Procedure

After enrolment patients were randomized by a computer-generated table to either the LMA or the PLMA for airway management during general anaesthesia. Epidural analgesia was started before the induction of the general anaesthesia in those patients who were to have laparotomy or knee or ankle prosthetic surgery. Anaesthesia was induced with fentanyl 2–3 μg kg⁻¹ and propofol 2.5–3 mg kg⁻¹ i.v., and maintained with nitrous oxide 65% and sevoflurane at an end-tidal concentration of 1%. Additional fentanyl 1 μg kg⁻¹ i.v. and atracurium to obtain muscle paralysis were given as clinically needed, with monitoring of neuromuscular transmission. Volume-controlled ventilation was started with a tidal volume of 7 ml kg⁻¹ (calculated on the basis of the actual body weight), a ventilatory frequency of 14 bpm, inspiratory time-respiratory cycle time ratio of 0.33, and PEEP of 10 cm H₂O (ADU/AS3 integrated system, Datex-Engstrom Division, Instrumentarium Corp., Finland). A low-flow system was used with a fresh gas flow <1 litre min⁻¹. Tidal volume was increased if the end-tidal carbon dioxide pressure (EtCO₂) exceeded 5.3 kPa and the frequency was reduced if the EtCO₂ was <4 kPa.

LMA insertion

Before LMA insertion, a nasogastric tube (16 F) was blindly introduced with the head in flexion. A correct position was confirmed by the aspiration of gastric contents and/or by epigastic auscultation with a stethoscope during the insertion of 30 ml air into the nasogastric tube. The LMA was then inserted, the cuff pressure set to 60 cm H₂O and mechanical ventilation started. If the leak fraction (LF) was >15%, the cuff pressure was increased in increments until the LF was minimized. The LF of the tidal volume was calculated from the difference between the inspiratory and expiratory tidal volumes divided by the inspiratory volume. If an LF >15% could not be reduced by increased cuff pressure, the LMA was withdrawn and then replaced. After three failures, the LMA was replaced by the PLMA and if necessary by a tracheal tube.

PLMA insertion

After PLMA insertion (without introducer) the cuff pressure was set to 60 cm H₂O and mechanical ventilation started. The seal was assessed by measuring the LF and outward displacement of a gel plug placed at the proximal end of the drainage tube. If the LF was >15%, the cuff pressure was increased progressively until LF was minimized. If an LF >15% could not be reduced by an increased cuff pressure, the PLMA was withdrawn and then replaced. After three failures, the PLMA was replaced by an LMA and if necessary by a tracheal tube. When adequate ventilation was obtained, a gastric tube (16 F) was passed through the drainage tube and the position in the stomach was confirmed by the aspiration of gastric content and/or by epigastic auscultation with a stethoscope during the injection of 30 ml air.

Monitoring and measurements

ECG, invasive or non-invasive arterial pressure, pulse oximetry (SpO₂), neuromuscular transmission, and inspiratory and expiratory concentrations of oxygen, carbon dioxide, nitrous oxide and sevoflurane were monitored (ADU/AS3 integrated system, Datex-Engstrom Division, Instrumentarium Corp., Finland). The same device continuously monitored pressure and flow and calculated inspiratory and expiratory tidal volume at the airway opening. Data were recorded by the monitoring system every 5 min and printed out at the end of the procedure. The cuff pressure was measured by the Control-Inflator ‘Pocket’ (VBM Medizintechnik, Sulz a.N., Germany) which can measure pressure values up to 120 cm H₂O.

Before discharge from the recovery room, the patients were asked if they had any symptoms of sore throat. More than a week later, patients were asked by telephone if they remembered having had a sore throat after the procedure. The answers were scored as: 0=no complaint; 1=mild complaint; 2=moderate complaint; 3=severe complaint.

Statistical analysis

From preliminary data we calculated with alpha set at 0.05 that 22 patients per group would give a statistical power of 80% to detect a 25% difference in the LF between the groups. The data obtained were normally distributed as assessed by the Kolmogorov–Sminorv test. Data are shown

Table 1 Patient characteristics. Data are mean (SD or range)

<table>
<thead>
<tr>
<th></th>
<th>LMA (n=30)</th>
<th>PLMA (n=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male/female</td>
<td>13/17</td>
<td>10/20</td>
</tr>
<tr>
<td>Age (yr)</td>
<td>57 (20–83)</td>
<td>52 (20–80)</td>
</tr>
<tr>
<td>Height (m)</td>
<td>1.64 (0.08)</td>
<td>1.64 (0.09)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>88 (11)</td>
<td>91 (14)</td>
</tr>
<tr>
<td>BMI</td>
<td>33 (3)</td>
<td>34 (4)</td>
</tr>
<tr>
<td>ASA II/III</td>
<td>26/4</td>
<td>24/6</td>
</tr>
<tr>
<td>Type of surgery</td>
<td>Orthopaedic</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>Abdominal</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>7</td>
</tr>
<tr>
<td>Duration of surgery (min)</td>
<td>72 (46)</td>
<td>75 (48)</td>
</tr>
</tbody>
</table>

Comparison between LMA and PLMA of the measured variables was performed using Student’s t-test for paired samples. The data are shown as mean (standard deviation) or range. The statistical significance level was set at 0.05. If a difference was noted, the Mann–Whitney test was applied. The differences were assessed by the Kolmogorov–Smirnov test. The data are shown as mean (SD or range). Statistical significance level was set at 0.05.
as mean (SD). Comparisons between groups were performed with an unpaired Student’s *t*-test for parametric data. Differences in frequency were assessed using a *χ²*-test. A *P*-value <0.05 was considered significant.

### Results

Thirty patients were enrolled in each group. Their characteristics are shown in Table 1. In one patient undergoing haemorrhoidectomy the three attempts at LMA placement were not successful (LF >15%). A PLMA was inserted, but this did not allow adequate ventilation. The patient was then ventilated with a face mask for the remainder of the surgical procedure.

A size-5 LMA was used in 96% of patients and a size-5 PLMA in 83% of patients (*P*=0.228). The cuff pressure was set at 60 cm H₂O in 55% of patients in the LMA group and in 87% of patients in the PLMA group; a cuff pressure >100 cm H₂O was needed in 38% and 7% of patients in the LMA and PLMA groups, respectively (*P*<0.05). The gastric tube was successfully placed in all patients in the LMA group, and in all but three patients (10%) in the PLMA group. In these three patients, the LF during mechanical ventilation was 5%, 6% and 12%, without any outward movement of the gel placed in the drainage tube. Despite adequate ventilation, in all these patients the gastric tube stopped at 20–22 cm from the outer end of the drainage tube. In one patient, kinking was seen using a fibroscope. In four patients in the PLMA group the gastric tube had to be replaced through the nose at the end of the surgical procedure because gastric drainage was needed after surgery.

Inspired and expired tidal volume, airway pressures, *S*PO₂, and *E*ECO₂ were similar between the groups. In particular, the mean peak airway pressure was 24.5 (SD 2.4) cm H₂O in the LMA group and 26.1 (6.1) cm H₂O in the PLMA group (n.s.). The mean LF was 6.1 (2.9)% and 6.4 (3.5)% in the LMA and PLMA groups, respectively (n.s.).

Tables 2 and 3 show that sore throat was not affected by the kind of LMA used or by the cuff pressure. The ‘early’ (recovery room) and ‘late’ (1 week after anaesthesia) sore throat scores were similar (n.s.).

### Discussion

We found that the PLMA and the standard LMA are equally effective for positive pressure ventilation in obese patients. We found that the patency of the PLMA drainage tube needs to be confirmed by inserting a gastric tube even when an optimal airtight seal is present. In obese patients a greater cuff pressure is needed for the LMA to obtain a minimal leak, but sore throat is not related to cuff inflation pressure. Finally, assessment of sore throat in the immediate postoperative period and several days after surgery gave similar results.

Our patients were mildly to moderately obese, all but two patients having a BMI <40, so we cannot extrapolate our findings to patients who are morbidly obese. With increasing obesity, the functional residual capacity and oxygenation decrease exponentially.⁶ Even mild obesity reduces the functional residual capacity and increases the alveolar–arterial *P*O₂ difference.¹¹ In anaesthetised obese patients, mechanical ventilation with tidal volumes >7 ml kg⁻¹ of ideal body weight does not affect alveolar–arterial *P*O₂ difference,¹² whereas 10 cm H₂O PEEP improves oxygenation and increases lung volume.¹³ Accordingly, in the present study 10 cm H₂O PEEP was used for all patients. Despite this PEEP, a BMI >30 and using a tidal volume set on the basis of actual body weight, LF was small with both laryngeal masks. The LF in the present study did not differ from that found in a historical control group of patients using a tracheal tube [mean LF 6 (3)%]. These results are explained by peak airway pressure usually being <30 cm H₂O. The advantage of a higher airway seal pressure with the PLMA compared with the LMA⁹ could be offset in clinical practice by the infrequent finding of peak airway pressures greater than the pressure threshold that cause air leaks when using the LMA.⁵

The results of this study could be influenced by the LF cut-off of 15%. This value was chosen because it was about twice the LF during tracheal tube use (see above) and
because if LF were greater, tidal volume would have been <6 ml kg⁻¹.

The use of the LMA with or without a gastric tube is associated with the same incidence of air leaks when peak airway pressure is <20 cm H₂O.¹⁴ We found that the sealing of the LMA is not compromised by a nasogastric tube even when peak airway pressure was >25 cm H₂O.

An important finding of the present study was that the drainage tube of the PLMA does not itself guarantee stomach drainage. In fact, in three patients (10%), the tube kinked without any sign of failure of the PLMA seal (high LF and/or tidal movement of the gel occluding the opening of the drainage tube). This could be harmful, with an unrecognized risk of aspiration of gastric contents. In our opinion, it is important to verify the patency of the PLMA drainage tube with a gastric tube in all patients, regardless of the airway seal. Moreover, passing a gastric tube via the drainage tube of the PLMA does not allow nasogastric drainage after PLMA removal. This should be considered if a nasogastric tube is needed after surgery.

The LMA needed a greater cuff pressure (>100 cm H₂O in 38% of patients) than the PLMA to reach the minimal LF. The PLMA cuff appears to fit better in the pharynx at lower pressure than the LMA cuff. Nevertheless the incidence of sore throat was small and unrelated to either the type of pressure than the LMA cuff. Nevertheless the incidence of sore throat was small and unrelated to either the type of pressure or oropharyngeal mucosal pressure.¹⁵ ¹⁶ These different findings could be explained by both the patients’ characteristics and the cuff pressure increases. We studied obese patients, and cuff inflation over 60 cm H₂O was used only to reach the minimal LF. Most probably, we selected high cuff pressure only for those patients in whom the fit between the laryngeal mask and the pharynx was incomplete at lower cuff pressure. In other words, these high pressures were the minimum pressure at which the device gave a complete fit with the pharynx.

We also found that patients scored sore throat similarly before discharge from the recovery room and 1 week later. Early evaluation in the recovery room appears to be an adequate method of investigation of postoperative sore throat.

In conclusion, we found that both the PLMA and the LMA provide optimal mechanical ventilation in obese patients. The better airway seal with the PLMA compared with the LMA could offer additional safety. However, the patency of the drainage tube of the PLMA should always be tested because it can be kinked despite an optimal airway seal. Finally, in obese patients, cuff pressures >100 cm H₂O are required more frequently with the LMA than with the PLMA to minimize leaks. Nevertheless this does not alter the incidence of sore throat.

References