Standard Laryngeal Mask Airway™ and LMA-ProSeal™ during Laparoscopic Surgery

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Study Objective: To compare the frequency of airway seal and sore throat with the LMA-ProSeal™ (PLMA) and the standard Laryngeal Mask Airway™ (LMA) during laparoscopic surgery.

Design: Prospective, controlled, randomized, nonblinded clinical study.

Setting: University-affiliated hospital.

Patients: 60 adult, ASA physical status I, II, and III patients undergoing laparoscopic surgery with general anesthesia, without contraindication to the use of the laryngeal mask.

Interventions: Patients were randomized to receive mechanical ventilation [tidal volume (VT) 7 mL/kg⁻¹; positive end-expiratory pressure (PEEP) 10 cmH₂O] through the PLMA or the standard LMA, both equipped with a gastric tube.

Measurements: Heart rate, arterial pressure, inspiratory and expiratory VT, airway pressure, end-tidal CO₂ partial pressure, and pulse oximetry were recorded. The leak fraction was calculated as the difference between the inspiratory and expiratory VT divided by the inspiratory VT. Postoperative sore throat frequency was scored in the recovery room (“early”) and 1 week after surgery (“late”).

Main Results: All patients were successfully ventilated through the assigned laryngeal mask. The leak fraction was 7 ± 3% with the LMA and 7 ± 4% with the PLMA (p = 0.731). In one patient, the PLMA drainage tube was not patent despite a leak fraction of 5%, and there was no clinically detectable air leak. During the recovery room stay, the frequency of sore throat was scored as mild in 13% and 10% of patients with the standard LMA and the PLMA, respectively, and was absent in the remaining patients (p = 0.99, between groups). There were no differences in the frequency of sore throat between the “early” and “late” evaluations (p = 0.99).

Conclusions: The PLMA and the LMA show similar airtight efficiency during laparoscopy. The patency of the PLMA drainage tube should always be confirmed. The sore throat evaluation performed in recovery room appears as reliable as later evaluations. © 2003 by Elsevier Inc.

Keywords: Anesthesia; laparoscopy; Laryngeal Mask Airway; ProSeal Laryngeal Mask Airway; respiration; artificial.
Introduction

The LMA-ProSeal™ (PLMA; LMA North America, Inc., San Diego, CA) differs mainly from the standard Laryngeal Mask Airway™ (LMA; LMA North America, Inc.) in that it features an additional drainage tube and a larger, wedge-shaped cuff. The drainage tube alone could theoretically prevent the aspiration of gastric contents, as shown in a cadaver model, or it can be used to introduce a gastric tube. Moreover, without causing an increase in the directly measured mucosal pressure, the PLMA cuff prevents air leaks at peak airway pressures higher than those with the LMA.

These device improvements can offer advantages during laparoscopic surgery. In fact, gastric emptying via the gastric tube can improve the surgical field and reduce the risk of gastric aspiration. Furthermore, due to the increase of both the elastance and the resistance of the respiratory system, abdominal insufflation with carbon dioxide raises the peak airway pressure. Accordingly, pressure-related air leaks from the LMA, with hypoventilation and gastric insufflation, can be observed. The improved airway seal of the PLMA as opposed to the standard LMA can prevent this occurrence. Nonetheless, the possible advantages of the PLMA over the LMA during the laparoscopic surgery have never been tested in a clinical setting.

The aim of the present study was to compare the air-tight properties of the PLMA and the standard LMA while using a gastric tube, inpatients undergoing general anesthesia and mechanical ventilation during laparoscopic surgery. The secondary outcome was to evaluate the frequency of problems and sore throat frequency with both devices.

Material and Methods

Patients

The study protocol was approved by the institutional ethics committee (Comitato Etico Istituzioni Ospedaliere Catoliche), and informed consent was obtained from each patient. We studied 60 consecutive adult patients who were scheduled for laparoscopic surgery with general anesthesia and mechanical ventilation during laparoscopic surgery. Patients younger than 18 years of age or with contraindications to the use of the LMA (i.e., nonfasted patients, those with hiatal hernia, or those with morbid obesity) were excluded from the study.

Protocol

Following enrollment into the study, patients were randomized by a computer-generated table to receive the LMA or the PLMA for airway management during general anesthesia. Anesthesia was induced by intravenous (IV) administration of fentanyl 2 to 3 μg.kg⁻¹ and propofol 2.5 to 3 mg.kg⁻¹, and maintained with nitrous oxide 65% and isoflurane at the initial end-tidal concentration of 1%. After placement of the laryngeal mask, atracurium 0.5 mg.kg⁻¹ was administered. Additional boluses of fentanyl 1 μg.kg⁻¹ and atracurium 0.2 mg.kg⁻¹ were administered as needed and with neuromuscular monitoring. Volume-controlled ventilation was delivered with a starting tidal volume (V₉) of 7 mL.kg⁻¹, a respiratory rate of 14 breaths/min, an inspiratory time–respiratory cycle time ratio of 0.33, and a positive end-expiratory pressure (PEEP) of 10 cmH₂O (ADU/AS3 integrated system, Datex-Engstrom Division, Instrumentarium Corp., Helsinki, Finland). Tidal volume was increased if the end-tidal carbon dioxide pressure (ETCO₂) exceeded 40 mmHg and respiratory rate was reduced if ETCO₂ decreased below 30 mmHg.

LMA placement. Before LMA placement, a 16-French nasogastric tube was blindly introduced with the head flexion, and its correct positioning confirmed by aspiration of gastric contents and/or by epigastric auscultation with a stethoscope during the injection of 30 mL of air into the nasogastric tube. The LMA was then inserted, the cuff pressure was set to 60 cmH₂O, and the mechanical ventilation started. In the case of a leak fraction (LF) greater than 15%, the cuff pressure was increased in stepwise fashion until the LF reached its minimal value. The LF was calculated as the difference between the inspiratory and expiratory V₉ divided by the inspiratory V₉. In the case of a LF greater than 15% that was unresponsive to the increase in cuff pressure, the LMA was withdrawn and subsequently replaced. After three failures, the LMA had to be substituted by the PLMA and eventually by the tracheal tube.

PLMA placement. After PLMA placement (without the introducer), the cuff pressure was set to 60 cmH₂O and the mechanical ventilation was started. The air-tight seal was evaluated by observing the LF (see above) and the upward displacement of a gel occluding the proximal end of the drainage tube. In the case of a LF greater than 15%, the cuff pressure was increased in stepwise fashion until the LF reached its minimal value. In the case of a LF greater than 15% that was unresponsive to the increase in cuff pressure, the LMA was withdrawn and subsequently replaced. After three failures, the PLMA had to be substituted by the LMA, and eventually by the tracheal tube. When adequate ventilation was observed, a 16-French gastric tube was introduced through the drainage tube and gastric placement was confirmed by the aspiration of gastric contents and/or by epigastric auscultation with a stethoscope during the injection of 30 mL of air.

Cuff pressures were maintained at a constant rate with both the LMA and PLMA until the end of the mechanical ventilation.

Monitoring and Measurements

Intraoperatively, monitoring including electrocardiography, invasive or noninvasive arterial blood pressure, pulse oximetry, inspiratory and expiratory oxygen concentrations, carbon dioxide, nitrous oxide, and sevoflurane was carried out (ADU/AS3 Integrated System, Datex-Engstrom Division, Instrumentarium Corp.). The same device continuously monitored pressure and flow (and the derived value of inspiratory and expiratory V₉) at the airway opening. Data were recorded every 5 minutes by the
Original Contributions

Table 1. Patients’ Demographic Characteristics

<table>
<thead>
<tr>
<th></th>
<th>LMA</th>
<th>PLMA</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>30</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>Male/Female</td>
<td>10/20</td>
<td>12/18</td>
<td>0.789</td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>53 ± 17</td>
<td>51 ± 16</td>
<td>0.641</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>168 ± 7</td>
<td>167 ± 8</td>
<td>0.608</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>71 ± 11</td>
<td>73 ± 17</td>
<td>0.591</td>
</tr>
<tr>
<td>Body mass index (kg m⁻²)</td>
<td>25 ± 4</td>
<td>26 ± 6</td>
<td>0.451</td>
</tr>
<tr>
<td>ASA physical status</td>
<td></td>
<td></td>
<td>0.961</td>
</tr>
<tr>
<td>ASA I</td>
<td>9</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>ASA II</td>
<td>19</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>ASA III</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Surgery</td>
<td></td>
<td></td>
<td>0.839</td>
</tr>
<tr>
<td>Cholecystectomy</td>
<td>27</td>
<td>26</td>
<td></td>
</tr>
<tr>
<td>Oophorectomy</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Adrenalectomy</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Length of surgery (min)</td>
<td>64 ± 17</td>
<td>66 ± 66</td>
<td>0.867</td>
</tr>
</tbody>
</table>

LMA = Laryngeal Mask Airway, PLMA = ProSeal Laryngeal Mask Airway.

monitoring system and printed at the end of the anesthe-
sia. Cuff pressures were measured by the Control-Inflator “Pocket” (VBM Medizintechnik, Sulz a.N., Germany) permitting pressure value measurement up to 120 cmH₂O.

In the early postoperative period, before discharge from the recovery room, patients were asked if they had a sore throat. One week after the anestheisia, patients were asked by telephone if they remembered having had a sore throat following anesthesia. The answers were scored as: 0 = no complaint; 1 = mild complaint; 2 = moderate complaints; and 3 = severe complaints.

Statistical Analysis

Preliminary data indicated that 22 patients per group would give a statistical test power of 80% at an alpha level of 0.05 to detect a difference in LF of at least 25% between groups. The analyzed data were normally distributed as evaluated by the Kolmogorov-Smirnov test. Data are shown as means and standard deviations. Comparisons between groups were performed by an unpaired t-test for parametric data. Differences in frequency were assessed using a Chi-square test. A p-value less than 0.05 was considered significant.

Results

Thirty patients were enrolled in each group. Their demographic characteristics are shown in Table 1. All patients successfully completed the protocol.

A size 5 laryngeal mask was chosen in 15 LMA patients (50%) compared with 17 PLMA patients (57%) (p = 0.796). The cuff pressure was set at 60 cmH₂O in 20 LMA patients (67%) and in 24 PMLA patients (80%); a cuff pressure greater than 100 cmH₂O was obtained in 6 patients (20%) with the LMA, and in 4 PLMA patients (13%; p = 0.489). The gastric tube was successfully placed in all patients receiving the LMA, and in all but one patient in the PLMA group (p = 0.915). In this PLMA patient, the gastric tube could be advanced no more than 21 cm from the outer orifice of the drainage tube. The mean LF was 5% without any movement during the mechanical ventilation of the gel occluding the drainage tube.

For three patients in the PLMA group, the gastric tube had to be replaced through the nose at the end of the surgical procedures for gastric drainage postoperatively. Inspiratory and expiratory V₉, airway pressures, SpO₂ and ETCO₂ were similar between groups. In particular, the mean of the recorded peak airway pressure values was 22.9 ± 2.4 cmH₂O in the LMA group and 23.5 ± 2.6 cmH₂O in PLMA patients (p = 0.357). The mean LF was 7 ± 3% with the LMA and 7 ± 4% with the PLMA (p = 0.731).

During the recovery room stay, 26 patients (87%) with the LMA had no sore throat, and 27 PLMA (90%) patients were similarly free of sure throat. The frequency of sore throat was scored as mild in four (13%) LMA patients and in three (10%) PLMA patients.

The sore throat evaluation that was performed after 1 week showed that in the LMA group, 25 patients (89%) did not recall any complaints, and 3 patients (11%) described their symptoms only as mild. In the PLMA group, there was no record of sore throat in 22 patients (79%), and symptoms were scored as mild in 6 patients (21%).

There were no differences between groups regarding the frequency of sore throat when it was evaluated in the early postoperative period (p = 0.99). There were also no differences recorded 1 week later during telephone follow-up (p = 0.97). Moreover, sore throat frequency was similar between the recovery room and the telephone interview evaluations (p = 0.99). Finally, the frequency of sore throat was unaffected by the cuff pressure level (Table 2).

Table 2. Sore Throat: Impact of the Cuff Pressure

<table>
<thead>
<tr>
<th></th>
<th>60 cmH₂O n (%)</th>
<th>61–100 cmH₂O n (%)</th>
<th>&gt;100 cmH₂O n (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sore throat (“early”)</td>
<td></td>
<td></td>
<td></td>
<td>0.99</td>
</tr>
<tr>
<td>absent</td>
<td>39 (87%)</td>
<td>4 (100%)</td>
<td>10 (91%)</td>
<td></td>
</tr>
<tr>
<td>mild</td>
<td>6 (13%)</td>
<td>0 (0%)</td>
<td>1 (9%)</td>
<td></td>
</tr>
<tr>
<td>moderate</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>severe</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>Sore throat (“late”)</td>
<td></td>
<td></td>
<td></td>
<td>0.99</td>
</tr>
<tr>
<td>absent</td>
<td>32 (82%)</td>
<td>7 (88%)</td>
<td>8 (89%)</td>
<td></td>
</tr>
<tr>
<td>mild</td>
<td>7 (18%)</td>
<td>1 (23%)</td>
<td>1 (11%)</td>
<td></td>
</tr>
<tr>
<td>moderate</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>severe</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
</tbody>
</table>

60 cmH₂O; 61–100 cmH₂O; >100 cmH₂O = cuff pressure levels [ProSeal Laryngeal Mask Airway (PLMA) and Laryngeal Mask Airway (LMA)] patients were considered together; Sore throat (“early”) = score obtained during the recovery room stay; Sore throat (“late”) = score obtained by a telephone interview 1 week after surgery.
Discussion

This study shows that the LMA-ProSeal™ and the standard Laryngeal Mask Airway™ with a gastric tube allow effective mechanical ventilation delivery during laparoscopic surgery. The patency of the PLMA drainage tube must be confirmed constantly via gastric tube insertion, even in the presence of an optimal airtight seal. Finally, the sore throat evaluation performed in the immediate postoperative period, and again several days after the surgery, gave similar results. The frequency of sore throat appears unrelated to the cuff pressure, provided that cuff overinflation is limited to an amount sufficient to minimize the leak fraction.

The airtight seal and the absence of gastric aspiration with the LMA during laparoscopy was previously shown during “conventional” positive-pressure ventilation. The decrease in functional residual capacity and the increase in elastic and resistive loads of the respiratory system were described both during abdominal insufflation with carbon dioxide and in obesity. The application of 10 cmH2O of PEEP improves the respiratory function in obese patients, and, accordingly, chose to set this PEEP level in our study. In this way, peak airway pressure was increased with respect to the ventilation without PEEP, and the laryngeal mask was tested in nearly extreme conditions. In this condition, were unable to detect any difference in LF between the LMA and the PLMA, observing neither the mean nor the maximal LF recorded during mechanical ventilation. The LF observed in the present study did not differ from that recorded in an historical control group of patients who were ventilated through a tracheal tube (mean LF 6 ± 3%). Moreover, in the present study, the Pmax measured at the airway opening was usually less than 25 cmH2O. Thus, in clinical practice, during laparoscopic procedures it is rare to overcome the pressure threshold that can determine an air leak on behalf of the LMA.

The use of the LMA with or without a gastric tube had a similar incidence of air leaks in patients with peak airway pressures lower than 20 cmH2O. The present study shows that the airtight properties of the LMA are not compromised by the presence of a nasogastric tube, even in the presence of Pmax that is constantly higher than 20 cmH2O.

The drainage tube of the PLMA is a safe way with which to bypass gastric regurgitation, but it deserves some consideration. In one patient, gastric tube insertion through the drainage tube was obstructed by an episode of kinking despite an optimal airway seal (low LF and absence of airflow from the drainage tube). Moreover, in the laparoscopic view, the stomach appeared well distended. This condition can be a harmful one, with an unrecognized risk of aspiration of gastric contents. In our opinion, it is mandatory that PLMA tube patency be verified with a gastric tube in all patients regardless of the airway seal.

Moreover, the introduction of the gastric tube in the drainage tube of the PLMA does not allow nasogastric drainage after PLMA removal. When a nasogastric tube is needed postoperatively, this situation should be considered.

The present study showed a low frequency of sore throat incidence in both the PLMA and LMA. Furthermore, patients from both groups scored sore throat incidence similarly before discharge from the recovery room and again 1 week after surgery. From these data, we believe that early evaluation during the recovery room stay is an adequate method of investigation of postoperative sore throat.

Several patients in both groups required cuff pressures higher than 100 cmH2O. Previous studies have shown that the frequency of sore throat was related to the volume or cuff pressure levels. On the contrary, were unable to detect any difference in sore throat frequency among different cuff pressure levels. This finding could be explained by the modality of the cuff pressure set. In fact, we increased cuff pressures over 60 cmH2O only to reach the minimal LF. Possibly, we selected high cuff pressures only for those patients in whom the fit between the laryngeal masks and the pharynx was inadequate at lower cuff pressures. In other words, these high pressures would be the minimal pressure at which the device performed a complete fit with the mucosal pharynx.

In conclusion, this study shows that both the PLMA and the LMA when equipped with the gastric tube provide effective mechanical ventilation during laparoscopic surgery in clinical practice. The higher seal pressures of the PLMA compared with that of the LMA possibly offer an additional safety reserve. Moreover, the drainage tube patency of the PLMA must always be tested for kinking in spite of optimal airway seal. Finally, cuff pressures over 100 cmH2O, obtained to minimize LF, do not affect the pharyngeal morbidity that can be evaluated with similar results immediately after anesthesia or several days later.

References

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