ProSeal *versus* the Classic laryngeal mask airway for positive pressure ventilation during laparoscopic cholecystectomy

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**Background.** We tested the hypothesis that the ProSeal laryngeal mask airway (PLMA) is a more effective ventilatory device than the Classic laryngeal mask airway (LMA³) for laparoscopic cholecystectomy.

**Methods.** Eighty anaesthetized, paralysed patients (ASA 1–2, aged 18–80 yr) were randomly allocated for airway management with the PLMA or LMA. Ease of insertion and efficacy of seal were determined. Peak airway pressures were recorded immediately before and after carboxipertoneum to 2.0 kPa. The inspired oxygen concentration and/or the ventilatory variable were adjusted according to a protocol to maintain \( S_pO_2 > 95\% \) and \( E_CO_2 < 6.0 \) kPa. Oxygenation was considered suboptimal if \( S_pO_2 \) fell to 94–90% and failed if \( S_pO_2 \) was <90%. Ventilation was considered suboptimal if \( E_CO_2 \) was >6.0–7.3 kPa and failed if \( E_CO_2 \) was >7.3 kPa.

**Results.** First-time insertion success rates were higher for the LMA (40/40 vs 33/40; \( P=0.02 \)). Seven patients required two attempts with the PLMA. Oropharyngeal leak pressure was higher for the PLMA [29 (SD 6) vs 19 (4) cm H₂O; \( P<0.001 \)]. There was a similar, significant increase in peak airway pressure after carboxipertoneum for both devices (\( P<0.001 \)). Before carboxipertoneum, oxygenation and ventilation were optimal in all patients in both groups. After carboxipertoneum, oxygenation was optimal in all patients in both groups, but ventilation was suboptimal more frequently with the LMA (8 vs 0; \( P=0.01 \)). In three of these eight patients, ventilation failed but was subsequently optimal with the PLMA.

**Conclusion.** The PLMA is a more effective ventilatory device for laparoscopic cholecystectomy than the LMA. We do not recommend the use of the LMA for laparoscopic cholecystectomy.

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Laparoscopic cholecystectomy is one of the most commonly performed general surgical procedures.¹ Tracheal intubation is recommended for airway management to facilitate ventilation and prevent aspiration,¹ but three prospective studies²–⁴ and a retrospective survey⁵ have suggested that the Classic laryngeal mask airway (LMA³) may be a suitable alternative. The ProSeal laryngeal mask airway (PLMA) is a new airway device that forms a more effective seal than the LMA and has a drainage tube that facilitates passage of a gastric tube. It probably provides protection against regurgitation, and prevents gastric insufflation when correctly placed.⁶–⁸ In this study, we tested the hypothesis that the PLMA is a more effective ventilatory device than the LMA for laparoscopic cholecystectomy.

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²LMA³ is the property of Intavent Ltd.
Methods

With institutional ethics committee approval and written, informed consent, 80 patients (ASA 1–2, aged 18–80 yr) undergoing elective laparoscopic cholecystectomy were randomly allocated (by opening a sealed envelope) for airway management with the PLMA or LMA. Patients were excluded if they had an interdental gap <2.5 cm, a body mass index >35 kg · m⁻² or were at risk of aspiration (non-fasted, gastro-oesophageal reflux/disease).

A standard anaesthesia protocol was followed and routine monitoring applied. Anaesthesia was in the supine position with the patient’s head on a standard pillow 7 cm in height. Anaesthesia was induced with fentanyl 2 µg · kg⁻¹ and thiopental 5 mg · kg⁻¹. Maintenance was with 1–3% sevoflurane in 50% oxygen and air. Neuromuscular blockade was achieved with atracurium 0.5 mg · kg⁻¹ and maintained with 0.15 mg · kg⁻¹ boluses to maintain a train-of-four count of ≤1. The patient’s lungs were ventilated with a face mask until neuromuscular blockade was complete. Experienced LMA users (PLMA, >30 uses; LMA, >1000 uses) performed all the insertions and data were collected by independent observers. A size 4 PLMA or LMA was used for females and a size 5 PLMA or LMA was used for males. A clear, water-based gel was used for lubrication. The insertion technique for both devices was identical to the finger technique recommended for the LMA, and included neck flexion/head extension and full deflation of the cuff. A slight lateral approach was used if resistance was felt in the oropharynx. The introducer tool was not used with the PLMA because the operators had more experience with insertion using the finger technique. The PLMA or LMA was connected to a circle breathing system and the cuff inflated with air until an effective airway was established or the maximum recommended inflation volume reached (size 4, 30 ml; size 5, 40 ml). Fixation was by taping the tube over the chin. A rolled gauze swab was used as a bite block with the LMA. The number of insertion attempts to achieve effective ventilation was recorded. Effective ventilation was defined as a square-wave capnograph trace and normal thoracoabdominal movement. A failed insertion attempt was defined as removal of the device from the mouth. Three attempts were allowed before insertion was considered a failure.

Once an effective airway had been obtained, intracuff pressure was set at 60 cm H₂O using a digital cuff pressure monitor, and the oropharyngeal leak pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 litre · min⁻¹ and noting the airway pressure (maximum allowed was 40 cm H₂O) at which equilibrium was reached. The location of gas leak at oropharyngeal leak pressure was determined as: (i) mouth: audible sound of gas escaping from the mouth heard by listening with the ear close to the mouth; (ii) stomach: audible sound of gas escaping into the oesophagus heard by listening over the epigastrium; and (iii) drainage tube: bubbling of lubricant placed on the proximal end of the drainage tube. For the PLMA group, insertion of a gastric tube (size 4, 14-FG; size 5, 16-FG) was attempted if there was no gas leak from the drainage tube during positive pressure ventilation. Any changes in peak airway pressure during gastric tube placement were noted. Correct placement was confirmed by injection of air and epigastric stethoscopy. The number of insertion attempts was recorded. Suction was applied to the gastric tube and the presence or absence of any gastric contents was recorded. The gastric tube was then removed. Gastric tube placement was not attempted with the LMA.

The patient’s lungs were initially ventilated with a tidal volume of 8 ml · kg⁻¹, a respiratory rate of 12 b.p.m. and an inspiratory:expiratory ratio of 1:2. Fresh gas flow was 1.5 litre · min⁻¹. Peak airway pressures were recorded immediately before and after carboperitoneum to 2 kPa in the supine position. The inspired oxygen concentration and/ or the ventilatory variables were monitored continuously and adjusted according to a protocol to maintain SpO₂ ≥95% and Ė CO₂ <6.0 kPa. If SpO₂ fell below 97%, FIO₂ was increased to 0.8, then to 1.0, and then the tidal volume was increased to 12 ml · kg⁻¹. If the Ė CO₂ increased above 5.6 kPa, the respiratory rate was first increased to 14 b.p.m., then 16 b.p.m., and then the tidal volume increased to 12 ml · kg⁻¹. A period of 3 min was allowed between adjustments. Oxygenation was considered suboptimal if SpO₂ fell to 94–90% and failed if SpO₂ <90%. Ventilation was considered suboptimal if Ė CO₂ >6.0–7.3 kPa or failed if Ė CO₂ >7.3 kPa. If oxygenation or ventilation failed during the procedure, the surgeon released the gas from the abdominal cavity, the patient was preoxygenated and the alternative device was inserted. If oxygenation or ventilation failed with the alternative device, the surgeon released the gas from the abdominal cavity, the patient was preoxygenated and the trachea intubated using a laryngoscope. Any episodes of gastric insufflation detected through the laparoscope by the surgeon were documented. The PLMA or LMA was removed at the end of surgery when the patient was able to open their mouth to command. Any blood detected on the device upon removal and the duration of anaesthesia were recorded. The oxygen saturation was recorded in the postanaesthesia care unit, 10–20 min after removal of the PLMA or LMA, the patient receiving oxygen at 4 litre · min⁻¹ via a Hudson-like face mask. Any adverse events (regurgitation, aspiration, bronchospasm, laryngospasm, coughing, retching, gagging, hiccup) were documented.

Sample size was based upon a projected difference of 20% between the groups for frequency of suboptimal ventilation, a type I error of 0.05 and a power of 0.9. Parametric data were analysed with unpaired and paired t-tests. Non-parametric data were analysed with the χ² test. Data are mean (SD, range) or number of patients unless otherwise stated. Significance was taken as P<0.05.
Reasons for suboptimal ventilation in all five patients were inadequate seal and hypoventilation with $E \text{CO}_2 > 6.0–7.3$ kPa. Reasons for failed ventilation in all three patients were inadequate seal and hypoventilation with $E \text{CO}_2 > 7.3$ kPa. ns = not significant

Results

The mean (SD, range) age, height and weight for the LMA and PLMA groups were similar [age, 49 (17, 18–80) and 52 (15, 18–76) yr respectively; height, 159 (6, 150–173) and 159 (7, 148–175) cm; weight, 59 (10, 43–82) and 62 (11, 43–90) kg]. The male:female ratios for the LMA and PLMA were similar (13:27 and 16:24 respectively). Duration of anaesthesia was similar for the LMA [91 (39) min] and PLMA [93 (46) min]. First-time insertion success rate was higher for the LMA (40/40 vs 33/40; $P=0.02$). Seven patients required two attempts with the PLMA. Oropharyngeal leak pressure was higher for the PLMA [29 (6) vs 19 (4) cm H$_2$O; $P<0.001$]. For the PLMA, air leak at oropharyngeal leak pressure occurred into the mouth in 37 out of 40 patients, into the drainage tube in one out of 40, and was not detected in two out of 40. For the LMA, air leak at oropharyngeal leak pressure occurred into the mouth in 37 out of 40 and into the stomach in three out of 40.

Gastric tube placement was successful in all patients with the PLMA. There was no change in peak airway pressure during its placement. Fluid was detected in 31 out of 40 patients with the PLMA: 16 out of 40 had clear fluid, 14 out of 40 had bile-stained fluid and one out of 40 had semisolid fluid. Fluid detection was not attempted with the LMA.

There was a significant increase in peak airway pressure after carboperitoneum for both devices (Table 1). Before carboperitoneum, ventilation was optimal in all patients. After carboperitoneum, ventilation was suboptimal in eight patients with the LMA and none with the PLMA ($P=0.01$). Ventilation failed in three of these patients and was subsequently optimal with the PLMA (Table 1). No patient required tracheal intubation. There were no episodes of hypoxia, but gastric insufflation was identified in all three patients in whom use of the LMA was unsuccessful. In one patient (PLMA group), the laparoscopic procedure was converted to an open procedure because of surgical problems. Blood was detected more frequently with the PLMA at removal (6/40 vs 0/37; $P=0.014$). Postoperative oxygen saturation was similar [PLMA, 96.3 (1.9, 93–99)%; LMA, 96.9 (1.8, 92–100)%;]. There were no other adverse events. Comparative data are summarized in Table 2.

Discussion

Our data show that the PLMA is a more effective ventilatory device than the LMA in patients undergoing laparoscopic cholecystectomy. As the peak airway pressures required for adequate ventilation during carboperitoneum are similar to mean oropharyngeal leak pressure for the LMA, it is not surprising that there is a high incidence of suboptimal and failed ventilation with the LMA. The PLMA forms a more effective seal, allowing higher peak airway pressures to be generated during carboperitoneum. Our findings contrast with those of Malby and colleagues, Buniatian and Dolbneva and Ilzuka and colleagues, who all found that ventilation was adequate with the LMA during carboperitoneum. These interstudy differences may be related to the degree of suboptimal ventilation considered acceptable by the investigators, or to differences in the insufflation pressure or pulmonary compliance of the study population. Interestingly, Malby and colleagues found that oxygen saturation and $E \text{CO}_2$ were similar for the LMA and tracheal tube during carboperitoneum.

We found that 78% of patients in the PLMA group had some residual gastric fluid and that in almost half of these the fluid was bile-stained or contained semisolid material. Interestingly, none of these patients had symptoms of reflux and were therefore not considered at risk of aspiration during induction. Unfortunately, we did not measure residual gastric volume or pH. However, one of the authors (JB) has measured the volume and pH of fluid in 23 patients undergoing laparoscopic cholecystectomy with the PLMA, and found that the mean (range) volume was 18 (0–59) ml and pH 3.5 (2.5–5.8). Brain and colleagues found that the average residual gastric volume in patients undergoing routine minor procedures with the PLMA was 15 ml. The extent to which residual gastric fluid increases the risk of regurgitation and aspiration is unknown. We consider that residual gastric fluid should be removed by routine insertion of a gastric tube, but there is always the possibility that this might trigger regurgitation.

The use of LMA for laparoscopic cholecystectomy is not conventional, but has been practised in some centres since

Table 1 Peak airway pressures [mean (SD)] and number of patients with optimal, suboptimal and failed ventilation before and after carboperitoneum for the Classic (LMA) and ProSeal (PLMA) laryngeal mask airways.

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<tr>
<th></th>
<th>LMA</th>
<th>PLMA</th>
<th>$P$</th>
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<tbody>
<tr>
<td></td>
<td>Before carboperitoneum</td>
<td>After carboperitoneum</td>
<td>Before carboperitoneum</td>
</tr>
<tr>
<td>Peak airway pressure (cm H$_2$O)</td>
<td>17 (3)</td>
<td>22 (3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Optimal/suboptimal/failed ventilation* (n)</td>
<td>40/0/0</td>
<td>40/0/0</td>
<td>NS</td>
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</table>

Table 2 Summary of comparative data for the Classic (LMA) and ProSeal (PLMA) laryngeal mask airways. Data are mean (SD) or number of patients. ns = not significant

<table>
<thead>
<tr>
<th></th>
<th>LMA</th>
<th>PLMA</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insertion attempts: 1/2/3 (n)</td>
<td>40/0/0</td>
<td>33/7/0</td>
<td>0.02</td>
</tr>
<tr>
<td>Oropharyngeal leak pressure (cm H$_2$O)</td>
<td>19 (4)</td>
<td>24 (6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Suboptimal ventilation during carboperitoneum (n)</td>
<td>8</td>
<td>0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Failed ventilation during carboperitoneum (n)</td>
<td>3</td>
<td>0</td>
<td>NS</td>
</tr>
<tr>
<td>Blood staining at removal (n)</td>
<td>0</td>
<td>6</td>
<td>0.01</td>
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the mid-1990s. However, there are insufficient data demonstrating that the technique is safe and effective, despite recent positive findings. There have also been two reports of aspiration in patients undergoing open cholecystectomy with the LMA. 

Our experience with the LMA was much greater than with the PLMA. There is both short-term and long-term skill acquisition with the LMA, and this probably applies to the PLMA. It is likely that first-time insertion failure rates and the frequency of trauma would be reduced with increasing experience. We suggest that the PLMA is only used for laparoscopic cholecystectomy by experienced LMA users who have a high success rate with the PLMA (say >95%) and substantial experience with the PLMA for other laparoscopic procedures, such as sterilization and inguinal hernia repair. The ventilatory capability and position of the PLMA should be assessed carefully after insertion. The patient should be intubated if the ventilatory capability is considered inadequate for carboperitoneum and/or the PLMA is malpositioned.

We conclude that the PLMA is a more effective ventilatory device for laparoscopic cholecystectomy than the LMA. We do not recommend the use of the LMA for laparoscopic cholecystectomy.

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