Background: The laryngeal mask airway ProSeal™ (PLMA™), a new laryngeal mask device, was compared with the laryngeal mask airway Classic™ (LMA™) with respect to: (1) insertion success rates and times; (2) efficacy of seal; (3) fiberoptically determined anatomic position; (4) orogastric tube insertion success rates and times; (5) total intraoperative complications; and (6) postoperative sore throat in nonparalyzed adult patients undergoing general anesthesia, hypothesizing that these would be different.

Methods: Three hundred eighty-four nonparalyzed anesthetized adult patients (American Society of Anesthesiologists physical status I-II) were randomly allocated to the LMA™ or PLMA™ for airway management. In addition, 50% of patients were randomized for orogastric tube placement. Unblinded observers collected intraoperative data, and blinded observers collected postoperative data.

Results: First-attempt insertion success rates (91% vs. 82%, \( P = 0.015 \)) were higher for the LMA™, but after three attempts success rates were similar (LMA™, 100%; PLMA™, 98%). Less time was required to achieve an effective airway with the LMA™ (31 ± 30 vs. 41 ± 49 s, \( P = 0.02 \)). The PLMA™ formed a more effective seal (27 ± 7 vs. 22 ± 6 cm H\(_2\)O, \( P < 0.0001 \)). Fiberoptically determined anatomic position was better with the LMA™ (\( P < 0.0001 \)). Orogastic tube insertion was more successful after two attempts (88% vs. 55%, \( P < 0.0001 \)) and quicker (22 ± 18 vs. 38 ± 56 s) with the PLMA™. During maintenance, the PLMA™ failed twice (leak, stridor) and the LMA™ failed once (laryngospasm). Total intraoperative complications were similar for both groups. The incidence of postoperative sore throat was similar.

Conclusion: In anesthetized, nonparalyzed patients, the LMA™ is easier and quicker to insert, but the PLMA™ forms a better seal and facilitates easier and quicker orogastic tube placement. The incidence of total intraoperative complications and postoperative sore throat are similar.

A NEW laryngeal mask device, the laryngeal mask airway ProSeal™ (PLMA™), has been developed by Brain® with a modified cuff to improve the seal and a drainage tube to provide access to the gastrointestinal tract. Preliminary studies in anesthetized, paralyzed patients have shown that the PLMA™ is capable of achieving a more effective seal than the laryngeal mask airway Classic™ (LMA™), facilitates orogastic tube placement, isolates the glottis from the esophagus when correctly positioned, and exerts mucosal pressures similar to the LMA™. However, there are no published data about its use in nonparalyzed patients, and the frequency of clinical problems is unknown. In the current multicenter study, we compared the LMA™ and PLMA™ with respect to: (1) insertion success rates and times; (2) efficacy of seal; (3) fiberoptically determined anatomic position; (4) orogastic tube insertion success rates and times; (5) total intraoperative complications; and (6) postoperative sore throat in nonparalyzed adult patients undergoing general anesthesia. We hypothesized that the devices were different in these areas.

Methods

Three hundred eighty-four adult patients (American Society of Anesthesiologists physical status I-II) undergoing general anesthesia for routine minor procedures were randomly assigned to have either the PLMA™ or LMA™ used for airway management. In addition, 50% of patients in each group were randomly assigned to have a gastric tube inserted orally. Eight study sites from seven countries (one each in Australia, Austria, France, Germany, Italy, and Spain, and two in the United States) participated in the study. Each study site conducted 48 cases with even randomization for the type of airway device and use of the orogastic tube. Randomization was performed by opening a sealed envelope immedi-
at the start of each new phase until the device was
0.5 mg/kg intravenous propofol were given as required
absence of movement, and apnea). Additional boluses of
uses). Exclusion criteria were body mass index greater
users) and had some experience with the PLMA
™–
30 s until conditions were suitable for
mask ventilation was commenced and continued for at
tidal sevo
urane in 33% oxygen and nitrous oxide. Face
plow 8 cm in height. Intravenous sedation (0.02–
‘s head on a standard
pressure by listening over the epigastrium with a stetho-
stomach was noted when measuring oropharyngeal leak
pressure was set at 60 cm H2O, and the oropharyngeal leak
volume reached (size 4, 30 ml; size 5,
40 ml). The number of insertion attempts was recorded.
A failed attempt was defined as removal of the device
from the mouth. Three attempts were allowed before
device use was considered a failure. If the randomized
device failed, three attempts were permitted with the
alternative device. The time between picking up the
PLMA™–LMA™ and obtaining an effective airway was
recorded. An effective airway was judged by a square
wave capnograph trace and no audible leak with peak
airway pressures 12 cm H2O or greater during gentle
manual ventilation. The introducer tool was not used for
the first insertion attempt with the PLMA™ but could be
used for the second and third attempt. If both random-
ized airway devices failed during the placement phase,
or if the airway device failed after the placement phase,
the anesthesiologist was free to manage the airway as
clinically indicated.

Once an effective airway was obtained, intracuff
pressure was set at 60 cm H2O, and the oropharyngeal leak
pressure was determined by closing the expiratory valve
of the circle system at a fixed gas flow of 3 l/min, noting
the airway pressure (maximum allowed = 40 cm H2O) at
which equilibrium was reached.6 Any air entering the
stomach was noted when measuring oropharyngeal leak
pressure by listening over the epigastrium with a stetho-
scope. Orogastric tube insertion was performed manu-
ally through the drainage tube for the PLMA™ and
behind the cuff for the LMA™. A 14- and 16-French size
lubricated orogastric tube was used for the size 4 and 5
PLMA™–LMA™, respectively, as recommended by the
manufacturer. Orogastric tube placement was not at-
ttempted with the PLMA™ if there was an air leak up the
drainage tube. Correct orogastric tube placement was
assessed by suction of fluid or detection of injected air by
epigastic auscultation. The time taken for correct
placement was recorded (picking up the orogastric tube until
confirmation of placement). The number of insertion
attempts was recorded. A failed attempt was defined as
failure to advance the orogastric tube. Two attempts
were allowed before orogastric tube insertion was con-
sidered a failure. The orogastric tube was removed im-
mediately after insertion. Anatomic position was deter-
fined by passing a fiberoptic scope to a position just
proximal to the end of the airway tube and scoring the
view.7 Anatomic position of the drainage tube (PLMA™
only) was determined by passing a fiberoptic scope to
the end of the drainage tube and scoring the position, as

A size 4 was used for women and a size 5 for men. A
clear, water-based gel without local anesthesia was used
for lubrication. Both devices were inserted and fixed
according to the manufacturer’s instructions.4,5 The
PLMA™–LMA™ was connected to a circle breathing
system, and the cuff was inflated with air until an effec-
tive airway was established or the maximum recom-

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previously described. Adjustments to the position of the PLMA™–LMA™ were not based on the fiberoptic view.

Patients underwent positive pressure ventilation until spontaneous breathing resumed. Intraoperative analgesia was with intravenous alfentanil, intravenous morphine, ketorolac, or infiltration of local anesthesia. Anesthesia was not discontinued until the surgery was complete to standardize conditions for the emergence phase. Patients were given 100% O₂ during emergence, and the airway device was removed when the patient was awake. The following intraoperative complications were documented: failed use, aspiration–regurgitation, hypoxia (SpO₂ < 90%), bronchospasm, airway obstruction, gastric insufflation, coughing–gagging–retching, hiccup, cough during removal, blood staining of the airway device, and tongue migration device (intention to treat). The distribution of data was determined using Kolmogorov-Smirnov analysis. Statistical analysis was with paired t test (parametric data), and Kruskal-Wallis test, Mann-Whitney rank sum test, and chi-square test (nonparametric data). P < 0.05 was considered significant.

Results

Intraoperative data were 99% and postoperative data were 97% complete. Incomplete intraoperative data were a result of failure to attempt gastric tube placement (LMA™, n = 23), failure to document the anatomic position of airway tube (LMA™, n = 2), and failure to document the anatomic position of the drainage tube (PLMA™, n = 78). Incomplete postoperative data were a result of failure to interview the patient postoperatively. There were 53 protocol deviations: desflurane was used instead of sevoflurane in six patients (PLMA™, n = 3; LMA™, n = 3), minor intraabdominal laparoscopic surgery was performed in six patients (PLMA™, n = 3; LMA™, n = 3), a nondepolarizing muscle relaxant was given to one patient (LMA™, n = 1), and adjustments in intracuff pressure were made in 40 patients (PLMA™, n = 19; LMA™, n = 21). These patients were included in the analysis because the protocol deviations were minor and evenly distributed between groups. The French study site only completed 16 cases, and the shortfall of 32 cases was completed by the Australian site. All other sites completed their quota of 48 cases. There were no differences between devices with respect to demographic and surgical details (Table 1).

Table 1. Demographic and surgical details

<table>
<thead>
<tr>
<th></th>
<th>PLMA™</th>
<th>LMA™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>n = 192</td>
<td>n = 192</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>47 ± 16 (18–84)</td>
<td>45 ± 17 (18–81)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>172 ± 10 (147–206)</td>
<td>172 ± 10 (145–196)</td>
</tr>
<tr>
<td>Body mass index</td>
<td>23 ± 4 (14–34)</td>
<td>22 ± 4 (13–34)</td>
</tr>
<tr>
<td>Male:female ratio (n)</td>
<td>107:85</td>
<td>105:87</td>
</tr>
<tr>
<td>Smokers (n)</td>
<td>70</td>
<td>63</td>
</tr>
<tr>
<td>Dentition—own/partial/edentulous (n)</td>
<td>129/42/18</td>
<td>140/35/16</td>
</tr>
</tbody>
</table>

Data are mean ± SD (range) or numbers.

PLMA™ = laryngeal mask airway ProSeal™; LMA™ = laryngeal mask airway CLASSIC™.

There were no differences between devices with respect to demographic and surgical details (Table 1). There were no differences between devices with respect to doses of coinduction–induction agents and intraoperative–postoperative analgesics. First-attempt insertion success rates (LMA™, 91%; PLMA™, 82%; P = 0.015) were higher for the LMA™, but after three attempts success rates were similar (LMA™, 100%; PLMA™, 98%; table 2). Less time was required to achieve an effective airway with the LMA™ (LMA™, 31 ± 30 s; PLMA™, 41 ± 49 s; P = 0.02). In all patients in whom the PLMA™ failed, the LMA™ was successfully inserted at the first attempt.
There were three device failures after the placement phase. The PLMA™ failed in one patient 15 min into the positive pressure ventilation phase because of excessive oropharyngeal leak, and in one patient 30 min into the spontaneous breathing phase because of persistent stridor. The LMA™ failed in one patient 20 min into the spontaneous breathing phase because of severe laryngospasm. These patients were successfully managed by laryngoscope-guided tracheal intubation (n = 2) or a cuffed oropharyngeal airway (n = 1). The PLMA™ formed a more effective seal (PLMA™, 27 ± 7 cm H2O; LMA™, 22 ± 6 cm H2O; P < 0.0001). Fiberoptically determined anatomic position was better with the LMA™ (P < 0.0001; table 2). The fiberoptic view from the drainage tube revealed an open upper esophageal sphincter in 9% of patients (table 2). Orogastric tube insertion was more successful (PLMA™, 88%; LMA™, 55%; P < 0.0001) and quicker (PLMA™, 22 ± 18 s; LMA™, 38 ± 56 s) with the PLMA (table 2). Cardiopulmonary tolerance and anesthesia depth data were similar for both groups during all phases of anesthesia and in the postanesthesia care unit. Total intraoperative complications were similar for both groups, but the incidence of minor tongue–lip–dental trauma (P = 0.02) was higher for the PLMA™, and the incidence of hiccups (P = 0.03) was higher for the LMA™ (table 3). Minor dental trauma (a chipped tooth) occurred in one patient during LMA™ insertion. Postoperative sore throat and other postoperative secondary variables were similar (table 4). Five patients said that they were not satisfied with their anesthesia management (PLMA™, n = 4; LMA™, n = 1). Orogastric leak pressure was higher in women for both the PLMA™ (29 ± 7 vs. 26 ± 7 cm H2O; P = 0.02) and LMA™ (23 ± 5 vs. 21 ± 6 cm H2O; P = 0.03), but otherwise there were no differences in performance between men and women. Postoperative morbidity was unaffected by use of an orogastric tube. There were no statistical differences in the results among the study sites that completed their quota and no differences with the French site.
crossover studies.\textsuperscript{1,2} The improved seal is probably a result of: (1) the broader proximal cuff plugging the oropharynx more effectively; (2) the second ventral cuff pressing the dorsal cuff more firmly into the periglottic tissues; and (3) the parallel, narrower tubing allowing the base of the tongue to cover the proximal cuff more effectively. The improvement in seal may be an advantage in situations in which higher airway pressures are required for positive pressure ventilation, such as in obese patients, the lithotomy=head down position, or in patients with restrictive pulmonary pathology. The better seal probably offers no advantage in the spontaneously breathing patient.

Fiberoptically determined anatomic position was better with the \textit{LMA}™, confirming the findings of two preliminary crossover studies.\textsuperscript{1,2} This was primarily related to increased epiglottic downfolding and is probably caused by the broader proximal cuff catching the epiglottis during insertion. It has been shown in adults and children that work of breathing with the \textit{LMA}™ is increased by epiglottic downfolding.\textsuperscript{10} Because we found that respiratory variables were similar to the \textit{LMA}™ during spontaneous and positive pressure ventilation, we speculate that a downfolded epiglottis does not significantly impede airflow with \textit{LMA}™, perhaps because of the accessory vent. The incidence of an open upper esophageal sphincter being visible from the drainage tube of the \textit{PLMA}™ was 9\% and similar to a preliminary study.\textsuperscript{2} The clinical importance of this finding is unknown.

Orogastric tube placement was easier and quicker with the \textit{PLMA}™. This is not surprising because the drainage tube aligns the orogastric tube with the upper esophageal sphincter. However, the success rate for orogastric tube placement \textit{via} the \textit{PLMA}™ was lower than in the preliminary crossover studies.\textsuperscript{1,2} This may reflect a lack of appropriate lubrication, selection of too

Table 3. The Incidence of Intraoperative Complications by Patient

<table>
<thead>
<tr>
<th>Complication</th>
<th>\textit{PLMA}™</th>
<th>\textit{LMA}™</th>
<th>\textit{P}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Airway and respiratory complications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Failed use</td>
<td>5</td>
<td>1</td>
<td>NS</td>
</tr>
<tr>
<td>Regurgitation/aspiration</td>
<td>0</td>
<td>0</td>
<td>NS</td>
</tr>
<tr>
<td>Hypoxia ((&lt;$90%$)</td>
<td>3</td>
<td>4</td>
<td>NS</td>
</tr>
<tr>
<td>Bronchospasmy</td>
<td>1</td>
<td>0</td>
<td>NS</td>
</tr>
<tr>
<td>Airway obstruction</td>
<td>1</td>
<td>3</td>
<td>NS</td>
</tr>
<tr>
<td>Gastric insufflation</td>
<td>1</td>
<td>3</td>
<td>NS</td>
</tr>
<tr>
<td>Cough/gagging/retching</td>
<td>6</td>
<td>1</td>
<td>NS</td>
</tr>
<tr>
<td>Hiccup</td>
<td>3</td>
<td>11</td>
<td>0.03</td>
</tr>
<tr>
<td>Cough during removal</td>
<td>13</td>
<td>18</td>
<td>NS</td>
</tr>
<tr>
<td>Blood staining following removal</td>
<td>34</td>
<td>27</td>
<td>NS</td>
</tr>
<tr>
<td>Minor tongue/lip/dental trauma</td>
<td>17</td>
<td>6</td>
<td>0.02</td>
</tr>
</tbody>
</table>

Total 84 74 NS

Data are numbers. \textit{PLMA}™ = laryngeal mask airway \textit{ProSeal}™; \textit{LMA}™ = laryngeal mask airway \textit{Classic}™; NS = not significant.

Discussion

The \textit{LMA}™ was easier and quicker to insert at the first attempt than the \textit{PLMA}™. This confirms data from a crossover study of 60 anesthetized, paralyzed patients.\textsuperscript{2} The increased difficulty with \textit{PLMA}™ insertion probably reflects the larger cuff (impeding digital intraoral positioning and propulsion into the pharynx), the lack of a backplate (making the cuff more likely to fold over at the back of the mouth), and the need for precise tip positioning (to prevent air leaks up the drainage tube). It is possible that increased experience or initial use of the introducer tool may have improved first-time success rates.\textsuperscript{2} Despite the increased difficulty with insertion, success rates after three attempts for the \textit{PLMA}™ were high (98\%) and similar to the \textit{LMA}™ (100\%), suggesting that both are clinically effective airway devices.

The efficacy of seal was 5 cm H$_2$O higher for the \textit{PLMA}™, confirming the findings of two preliminary
large an orogastric tube, or folding over of the drainage tube. The latter phenomenon was identified in three patients and may have occurred in a number of others since passage of the fiberoptic scope also failed. The danger of a folded drainage tube is that the standard test for malposition—air leaking up the drainage tube during positive pressure ventilation—will not detect it. This may indirectly put the patient at increased risk of gastric insufflation and aspiration by giving the anesthesiologist a false sense of security.

A simple, noninvasive method to exclude this malposition would be to pass an orogastric tube down to the end of the PLMA™ tip to verify that the drainage tube is patent. We recommend that this drainage tube test be performed if there is any tactile resistance to PLMA™ placement. It is possible that use of a larger, stiffer orogastric tube would increase success rates for the LMA™. Residual gastric fluid is commonly found in patients undergoing elective surgery. Routine gastric tube placement through the PLMA™ may have a role in gastric volume reduction, but further work is required before this can be recommended. Gastric tube placement through the PLMA™ may be indicated if gastric insufflation has occurred after face mask ventilation.

We found no differences in total intraoperative complications, but there was a higher incidence of minor tongue–lip–teeth trauma for the PLMA™ and a higher incidence of hiccup for the LMA™. The increased incidence of minor tongue–lip–teeth trauma may be related to the increased difficulty with insertion. A possible explanation for the increased incidence of hiccup is that the LMA™ may stretch the hypopharynx more vigorously than the PLMA™ since the tube is more rigid, allowing more force to be transmitted. Hiccup is known to be associated with lower esophageal reflux, allowing more force to be transmitted. Hiccup is known to be associated with lower esophageal reflux, and the LMA™ tip to verify that the drainage tube is patent. We recommend that this drainage tube test be performed if there is any tactile resistance to PLMA™ placement. It is possible that use of a larger, stiffer orogastric tube would increase success rates for the LMA™. Residual gastric fluid is commonly found in patients undergoing elective surgery. Routine gastric tube placement through the PLMA™ may have a role in gastric volume reduction, but further work is required before this can be recommended. Gastric tube placement through the PLMA™ may be indicated if gastric insufflation has occurred after face mask ventilation.

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We conclude that, in anesthetized, nonparalyzed patients, the LMA™ is easier and quicker to insert, but the PLMA™ forms a better seal and facilitates easier and quicker orogastric tube placement. The incidence of total intraoperative complications and postoperative sore throat is similar.

The authors thank J. Navia (Professor, Department of Anaesthesia, Hospital General Universitario Gregorio Maranon, Madrid, Spain) for coordinating the research at the Spanish study site.

References

2. Brimacombe J, Keller C: The ProSeal laryngeal mask airway: A randomized, crossover study with the standard laryngeal mask airway in paralyzed, anesthe-
7. Keller C, Brimacombe J, Puchinger F: A fibreoptic scoring system to assess the position of laryngeal mask airway devices: Interobserver variability and a comparison between the standard, flexible and intubating laryngeal mask air-

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