Efficacy of a new dual channel laryngeal mask airway, the LMA® Gastro™ Airway, for upper gastrointestinal endoscopy: a prospective observational study.

The LMA® Gastro™ Airway is effective for clinical use in patients undergoing upper gastrointestinal endoscopy

High success rates were achieved for LMA® Gastro™ Airway insertion and subsequent endoscopy

Objective
- To determine the efficacy of the LMA® Gastro™ Airway for clinical use in upper gastrointestinal endoscopy

Methods
- This was a prospective, observational, open-label, first-in-human trial conducted in adult patients undergoing elective upper gastrointestinal procedures
  - Patients were American Society of Anesthesiologists (ASA) physical status 1 and 2, considered to be at low risk of aspiration, and had fasted for at least 6 hours for food and 2 hours for clear liquids
  - All patients had the LMA® Gastro™ Airway and an endoscope inserted while in the left lateral or supine position (neck flexed, head extended) by anesthesiologists and endoscopists with ≥4 years of experience with airway management and endoscopy, respectively
- Overall, 30 anesthesiologists (26 [87%] fully qualified, 4 [13%] senior trainees) and 15 gastroenterologists (14 [93%] fully qualified, 1 [7%] senior trainee) participated in the study
- All clinicians were able to practice insertion of the airway
- Insertion of the LMA® Gastro™ Airway commenced once an adequate depth of anesthesia was achieved and followed a standardized procedure similar to that used for the LMA® Classic™ Airway; once placed, an endoscope was inserted into the esophagus via the endoscopy channel of the airway
- The primary outcome was the overall success rate of endoscopy (with a maximum of three attempts allowed)
- Other outcomes of interest included
  - First-attempt success rate of endoscopy
  - Success rate of LMA® Gastro™ Airway insertion (overall [maximum of three attempts] and first-attempt)
  - Ease of LMA® Gastro™ Airway and endoscope insertion (rated as easy or difficult [i.e., more than one manipulation required])
  - Post-operative sore throat
  - Blood on the device

Results
- Overall, 292 patients were enrolled in the study; of these, 290 had the LMA® Gastro™ Airway successfully inserted within three attempts and underwent endoscopy via the endoscopy channel of the airway (per-protocol population)
  - The mean age and body mass index of all enrolled patients was 51 years and 28 kg/m², respectively
  - Intraprocedural characteristics are shown in Table 1
  - Outcomes related to endoscopy are shown in Figure 1
- Regarding the primary endpoint, the overall endoscopy success rate in the per-protocol population was 99% (one-sided 95% confidence interval [CI] 98, 100); the lower limit of the 95% CI indicated that the LMA® Gastro™ Airway was effective for clinical endoscopy use
- First attempt endoscopy success rate in the per-protocol population was 93% (one-sided 95% confidence interval [CI] 91, 96)
- The overall endoscopy success rate was 99% (95% CI 98, 100); the lower limit of the 95% CI indicated that the LMA® Gastro™ Airway was effective for clinical endoscopy use
Table 1. Intraprocedural characteristics

<table>
<thead>
<tr>
<th>CHARACTERISTIC</th>
<th>N=292</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure duration (min)</td>
<td>26 (17–39)</td>
</tr>
<tr>
<td>Patient position</td>
<td></td>
</tr>
<tr>
<td>Left lateral</td>
<td>288 (99)</td>
</tr>
<tr>
<td>Supine</td>
<td>4 (1)</td>
</tr>
<tr>
<td>Procedure</td>
<td></td>
</tr>
<tr>
<td>EGD and colonoscopy</td>
<td>127 (44)</td>
</tr>
<tr>
<td>EGD alone</td>
<td>62 (21)</td>
</tr>
<tr>
<td>EGD with biopsies</td>
<td>87 (30)</td>
</tr>
<tr>
<td>EGD with oesophageal dilation</td>
<td>14 (5)</td>
</tr>
<tr>
<td>EGD with removal of pancreatic stent</td>
<td>1 (0)</td>
</tr>
<tr>
<td>EGD with upper balloon enteroscopy</td>
<td>1 (0)</td>
</tr>
<tr>
<td>LMA® Gastro™ Airway size</td>
<td></td>
</tr>
<tr>
<td>Size 3</td>
<td>89 (31)</td>
</tr>
<tr>
<td>Size 4</td>
<td>196 (67)</td>
</tr>
<tr>
<td>Size 5</td>
<td>7 (2)</td>
</tr>
</tbody>
</table>

Data is presented as number (%) or median (inter-quartile range) for continuous data.

EGD, esophagogastroduodenoscopy

- Outcomes related to insertion of the LMA® Gastro™ Airway are shown in Figure 2
  - The median post-insertion, post-inflation intracuff volume of the LMA® Gastro™ Airway was 20 ml (Inter-quartile range [IQR] 16–20)
  - No leaks were recorded in 87% (95% CI 84, 91) of cases
  - The median (IQR, range) intra-operative oxygen saturation reported was 98% (98–99, 87–100); an intra-operative oxygen saturation value <90% was recorded in one case

- Following removal, macroscopic blood was recorded on the LMA® Gastro™ Airway in 76% of cases, and 37% of patients reported a sore throat in the post-operative recovery unit
  - In one patient, re-admission to hospital was required because of a prolonged sore throat and an inability to tolerate fluids
  - One patient experienced airway compromise that required intervention and one patient experienced mild laryngospasm; however, both events resolved with no further adverse effects

Conclusion

- Use of the LMA® Gastro™ Airway yielded a high rate of successful endoscopy in patients undergoing upper gastrointestinal endoscopy
- The LMA® Gastro™ Airway is associated with an excellent airway insertion success rate equivalent to the reported success rate of the LMA® Classic™ Airway and consistent with reported success rates of other commonly used second-generation laryngeal masks

- According to the authors, the study findings indicate that the LMA® Gastro™ Airway “is effective for the management of upper gastrointestinal endoscopy under general anaesthesia”

Figure 1. Outcomes related to endoscopy (data shown as percentage value and one-sided 95% confidence interval)

Figure 2. Outcomes related to insertion of the LMA® Gastro™ Airway (data shown as percentage value and one-sided 95% confidence interval)