

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

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

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High success rates were achieved for LMA<sup>®</sup> Gastro<sup>™</sup> Airway insertion and subsequent endoscopy

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## Objective

- To determine the efficacy of the LMA<sup>®</sup> Gastro<sup>™</sup> 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<sup>®</sup> Gastro<sup>™</sup> Airway and an endoscope inserted while in the left lateral or supine position (neck flexed, head extended) by anesthesiologists and endoscopists with  $\geq 4$  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<sup>®</sup> Gastro<sup>™</sup> Airway commenced once an adequate depth of anesthesia was achieved and followed a standardized procedure similar to that used

for the LMA<sup>®</sup> Classic<sup>™</sup> 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<sup>®</sup> Gastro<sup>™</sup> Airway insertion (overall [maximum of three attempts] and first-attempt)
  - Ease of LMA<sup>®</sup> Gastro<sup>™</sup> 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<sup>®</sup> Gastro<sup>™</sup> 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/m<sup>2</sup>, respectively
- Intraoperative 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<sup>®</sup> Gastro<sup>™</sup> 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<sup>®</sup> Gastro<sup>™</sup> Airway was effective for clinical endoscopy use

**Table 1. Intraprocedural characteristics**

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

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

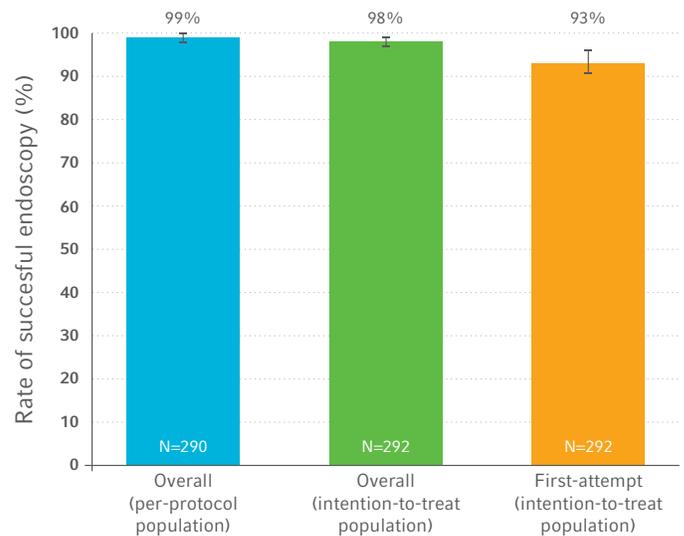
### Conclusion

- 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)**

