

CLINICAL INVESTIGATION

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

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Preliminary data from this study were presented as an oral presentation and poster at the American Society of Anesthesiologists (ASA) Annual Meeting, October 22–26, 2016, Chicago, Illinois, USA.,

Abstract

Background: Significant cardiorespiratory events are frequent in patients undergoing gastrointestinal endoscopy. Central to the occurrence of respiratory events is an unsecured airway. This study sought to determine the efficacy of a new laryngeal mask airway, the LMA[®]Gastro[™] Airway (Teleflex Medical, Athlone, Ireland), in patients undergoing upper gastrointestinal endoscopy. New design features include a dedicated channel for oesophageal intubation and separate channel with terminal cuff for lung ventilation.

Methods: In a prospective, open label, observational study, 292 ASA physical status classification 1 and 2 patients at low risk of pulmonary aspiration undergoing upper gastrointestinal endoscopy received i.v. propofol anaesthesia and standardized insertion of the LMA[®]Gastro[™] Airway. Endoscopy outcomes included insertion success, first attempt success, and ease of endoscope insertion. LMA[®]Gastro[™] Airway outcomes included insertion success, first attempt success, ease of insertion, lowest oxygen saturation, airway compromise, laryngospasm, bloodstained device, and sore throat.

Results: Per protocol analysis ($n=290$), the endoscopy success rate amongst the cohort with successful LMA[®]Gastro[™] Airway insertion was 99% [95% confidence interval (CI): 98, 100]. LMA[®]Gastro[™] Airway insertion success rate ($n=292$) was 99% (95% CI: 98, 100). For endoscopy and LMA[®]Gastro[™] Airway insertion success, the lower limit of the 95% CIs was at least 98%, indicating LMA[®]Gastro[™] Airway efficacy. Median (inter-quartile range) lowest intraoperative oxygen saturation was 98% (98, 99). Only one serious adverse event occurred (re-admission for sore throat and inability to tolerate fluids) and was reported to the Tasmanian Health and Medical Human Research Ethics Committee.

Conclusions: The LMA[®]Gastro[™] Airway appears effective for clinical use in upper gastrointestinal endoscopy.

Clinical trial registration: ACTRN12616001464459.

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Editor's Key Points

- During gastrointestinal endoscopy, the incidence of cardiorespiratory complications is high, when the patients are sedated without securing the airway.
- The use of the LMA[®]Gastro[™] Airway is effective in minimizing cardiorespiratory complications during gastrointestinal endoscopy.

Upper gastrointestinal endoscopy is a common medical procedure worldwide.^{1,2} Sedation with propofol is widely used and considered a safe sedation technique for upper gastrointestinal endoscopy.^{3–5} However, recent evidence from a large prospective multicentre observational study in 2132 patients from university-affiliated hospitals reported a high rate of significant unplanned events in 23% of patients undergoing gastrointestinal endoscopy with propofol sedation, including a significant cardiorespiratory event in 18%.² With both the number and complexity of interventional upper gastrointestinal endoscopy increasing, more patients may require deep sedation, risking airway and respiratory compromise.¹⁶ Furthermore, airway management may be difficult in patients with obesity and/or obstructive sleep apnoea.⁷ Clearly, there is scope to improve airway and ventilation management, especially in high-risk profile patients undergoing upper gastrointestinal endoscopy.

The LMA[®]Gastro[™] Airway (Teleflex Medical, Athlone, Ireland), a new laryngeal mask airway (LMA), was specifically developed for upper gastrointestinal endoscopy by Dr. M. Skinner. The innovation of the LMA[®]Gastro[™] Airway is a dedicated endoscopy channel, (16 mm internal diameter), which runs parallel along the separate airway channel with terminal cuff. This endoscopy channel ends at the cuff's distal tip to align with the upper oesophageal entrance (Fig. 1). During development, the LMA[®]Gastro[™] Airway underwent rigorous testing in fresh cadavers demonstrating proof of concept (Tasmanian Health and Medical Human Research Ethics Committee approval H0012954). The LMA[®]Gastro[™] Airway facilitated oesophageal intubation while providing an unobstructed airway and positive pressure lung ventilation with clinically satisfactory seal pressures. This present study sought to determine LMA[®]Gastro[™] Airway efficacy for clinical use in upper gastrointestinal endoscopy. We hypothesized that the device would be associated with high success rate of endoscope and dual channel LMA insertion, and maintain high concentrations of oxygenation.

Methods

Study design

This was a first-in-human, open label, prospective, observational study. The Tasmanian Health and Medical Human Research Ethics Committee approved the study on December 15, 2014 (H0014514), and all participants provided written informed consent before study participation. The study was

conducted at the Royal Hobart Hospital, Tasmania, Australia, between June 2015 and March 2017 and there were no changes in the methods after study commencement. Although not a randomized clinical trial, this study was retrospectively registered in October 2016 with the Australia and New Zealand Clinical Trials Registry (ACTRN12616001464459).⁸ The registration of observational studies enhances public reporting, concludes the set of evidence, and helps prevent publication bias, which favours positive or statistically significant results.⁸ The LMA[®]Gastro[™] Airway (Teleflex Medical, Athlone, Ireland) was manufactured specifically for study use, as it was not commercially available until after completion of the study.

Clinician education

Uniformity of insertion techniques was ensured by providing anaesthetists and endoscopists (including gastroenterologists and gastrointestinal surgeons who regularly perform endoscopy) with didactic instruction on the correct use of the LMA[®]Gastro[™] Airway. Clinicians were afforded the opportunity to practice insertion of the LMA[®]Gastro[™] Airway and the endoscope through its endoscopy channel in manikin heads. Participating clinicians were supervised for their first five insertions of the LMA[®]Gastro[™] Airway by one of the study investigators. A training refresher was scheduled 1 yr after commencing study recruitment to revise all aspects of the correct use of the LMA[®]Gastro[™] Airway. All participating anaesthetists and endoscopists were medically qualified and required to have at least 4 yr experience with airway management or endoscopy, respectively. Therefore, only senior trainee anaesthetists and endoscopists, and fully-qualified anaesthetists and endoscopists participated in the study.



Fig 1. The dual channel LMA[®]Gastro[™] Airway with silicone airway channel (light green arrow) with cuff fully inflated (dark green arrow), and separate endoscopy channel (red arrow) for endoscope (yellow arrow).

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