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Title: A modified supraglottic airway for gastroscopy – an advance in patient safety?

Running title: Supraglottic airway for gastroscopy

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Abstract

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In this edition of the journal Terblanche and colleagues describe preliminary clinical experience with the LMA[®] Gastro[™], a modified supraglottic airway designed for airway maintenance and security during upper gastrointestinal endoscopy.¹ [Thirty anaesthetists successfully deployed the device in 290/292 patients. Endoscopy was achieved in 98%.](#)

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Clinicians are presented with a new device ~~supposedly optimised~~ [designed](#) for a single clinical circumstance [\(albeit a common one\)](#). We should therefore ask whether the ~~alleged~~ problem that the device sets out to solve is real, whether the device addresses it effectively, and reflect whether the apparatus is a useful addition to the clinical environment. The LMA[®] Gastro[™] is not the only contender in this product area. Recently an “endoscopic mask” has been described but that device appears to comprise a facemask with an integrated Guedel airway and no form of airway protection [from aspiration of gastric contents](#).^{2,3}

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Terblanche and colleagues report an observational study which ~~necessarily~~ does not include a control group i.e. it is the equivalent of a Phase 2 pharmaceutical study. The patients were relatively fit (ASA 1-2) and described by the authors as “at low risk of pulmonary aspiration”. This study design is a rational starting point for new equipment but only offers us information relevant to the patients included.

Whilst the high rates of airway insertion ~~(99%)~~ and successful endoscopy ~~(98%)~~ are to be welcomed, we now need to see randomised comparisons with alternative techniques in the typically straightforward patient group already studied. [Appropriate comparators include the unprotected airway and alternative airway management devices.](#)

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In addition, cautious exploration of [the full spectrum of](#) ASA 3-4 patients and those undergoing more complex procedures and emergency interventions are essential if the LMA[®] Gastro[™] is to claim genuine clinical advantage and improved patient safety. [Protracted procedures such as double-balloon enteroscopy challenge both patients and clinicians and might be facilitated by an improved airway. Obstructive Sleep Apnoea is common and is associated with increased general⁴ and perioperative⁵ morbidity and mortality. These patients represent a population with added risk in whom the LMA[®] Gastro[™] could be trialled. Might the LMA[®] Gastro[™] improve their airway management and perhaps alter their outcomes?](#)

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Historically GI endoscopy has had a poor safety record with significant morbidity and mortality especially in patients of ASA physical status 3-4.⁶ Recently, clear guidance^{7, 8} on endoscopy and sedation combined with training, patient selection, team working and audit have improved outcomes [with the death rate decreasing from 1:2000 in the early 1990s⁶ to 1:73,000 in a recent report.⁹ Airway obstruction and aspiration are an infrequent but serious problem in upper GI endoscopy with 'Cardiorespiratory Distress' being the most frequently reported morbidity in the Quine study, 31/14,149 \(0.22%\), 1991 data collection.⁶ Recently, 'Airway Management' was recorded as a serious adverse event in 231/508,052 \(0.05%\) procedures performed in a large group of American hospitals between 2002 and 2013.⁹ The combination of sedationist and sedative agent influences the frequency of this complication with a rate of 0.14% during \(mainly\) propofol sedation supervised by anaesthetists and only 0.02% during \(mainly\) benzodiazepine sedation by non-anaesthetists.⁹](#)

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The description of the LMA[®] Gastro[™] in an Australian clinical environment is relevant given the Australian propensity to high dose propofol "sedation" during endoscopic procedures which in practice amounts to general anaesthesia. Recently propofol sedation/anaesthesia during Australian endoscopy practice has been audited in some detail¹⁰ and it clearly causes significant physiological

disturbance with potential for important cardiovascular and neurological morbidity.¹¹ In order to successfully insert a supraglottic airway of any kind it is usual to induce anaesthesia with a significant dose of propofol.¹² We should ask whether the possible benefits to the patient of the easily maintained airway and efficiently inserted gastroscopie outweigh the possible adverse consequences of an avoidable general anaesthetic. In addition, the LMA® Gastro™ will probably increase the cost of each procedure and add another substantial consumable to the waste stream requiring incineration with subsequent environmental impact.¹³

Patients scheduled for endoscopy and the clinicians caring for them now have extended range of choices for “sedation”. However in practice, local preference, time pressure and other factors direct most patients to a preferred technique prevalent in the institution whilst part of the substantially heterogenous international picture. Simple gastroscopy may be performed without sedation using only a local anaesthetic spray.^{14, 15} Patient preparation, operator technique (and attitude) likely influence the acceptability and success rate of this approach. When compared to midazolam in a blinded randomised controlled trial a no-sedation technique was equally successful in completing procedures and almost as well tolerated.¹⁶ The authors concluded “upper endoscopy can be performed satisfactorily without sedation”.

Midazolam with or without fentanyl represents the mainstay sedation technique for most patients in countries where anaesthetist attendance at routine endoscopy is uncommon. Recently, in Germany large series have reported safe low-dose propofol sedation by trained nurses.^{17, 18} The preference for propofol induced “deep sedation” (i.e. general anaesthesia) during endoscopy appears to be driven by local medical culture possibly influenced by opportunities for fee generation in private practice.

[For example, between 2003 and 2009 the US saw a sharp increase in 'discretionary' anaesthesia services to privately insured fit patients undergoing routine endoscopy procedures. The authors concluded “...the majority of gastroenterology-related anesthesia services are provided to low-risk patients and can be considered potentially discretionary based on current payment](#)

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policies”¹⁹. Recently, Adams and colleagues²⁰ observed “.....more than half of MAC appears to be used for routine endoscopy in low-risk patients, suggesting widespread guideline-discordant use that may in part be driven by financial incentives.”²⁰

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The possibility certainly exists that high-dose propofol is more hazardous than the use of lower doses, midazolam or no sedation. Randomised clinical trials are required to explore the comparative merits of different sedative/anaesthesia strategies. Appropriate strategies for airway management will form a necessary part of such evaluations.

Since the introduction of the original laryngeal mask airway the realm of supraglottic airway devices has seen continual innovation as well as progressive adaptation of marketed products. In its ADEPT paper the Difficult Airway Society has produced clear guidance for [researching anaesthetists involved in the procurement of this type of equipment](#) [and recommends a minimum of a case-controlled or historically-controlled clinical trial in addition to regulatory approval, local experience and acceptable pricing, and it provides a rational framework for](#) Thus future studies of the LMA[®]

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Gastro[™] [need to be comparative](#),²¹

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The LMA[®] Gastro[™] will likely prove popular with anaesthetists providing propofol anaesthesia/sedation for relatively healthy patients undergoing gastroscopy. Whether it will provide anything beyond operator convenience i.e. improved patient outcomes, remains to be determined. A less commercially attractive but arguably clinically much more important group of patients are those in ASA physical status groups 3 and 4. We hope to see well-designed clinical studies exploring how the LMA[®] Gastro[™] might be of benefit to them.

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DECLARATION OF INTERESTS

Declaration of Interest: none declared

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