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ORIGINAL RESEARCH

Clinical Outcomes of a Modified Laryngeal Mask Airway (LMA® Gastro™ Airway) During Esophagogastroduodenoscopy in Children and Adolescents: A Randomized Study

This article was published in the following Dove Press journal:
Medical Devices: Evidence and Research

Medical Devices: Evidence and Research downloaded from https://www.dovepress.com/ on 05-Mar-2022
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Introduction: During esophagogastroduodenoscopy (EGD), general anesthesia (GA) may be provided using a laryngeal mask airway (LMA) with the endoscope inserted behind the cuff of the LMA into the esophagus. Passage of the endoscope may increase the intracuff of the LMA. We evaluated a newly designed LMA (LMA® Gastro™ Airway) which has an internal channel exiting from its distal end to facilitate EGD. The current study compared the change of LMA cuff pressure between this new LMA and a standard clinical LMA (Ambu® AuraOnce™) during EGD.

Methods: Patients less than 21 years of age and weighing more than 30 kg were randomized to receive airway management with one of the two LMAs during EGD. After anesthetic induction and successful LMA placement, the intracuff pressure of the LMAs was continuously monitored during the procedure. The primary outcome was the change of intracuff pressure of the LMAs.

Results: The study cohort included 200 patients (mean age 13.6 years and weight 56.6 kg) who were randomized to the LMA® Gastro™ Airway (n=100) or the Ambu® AuraOnce™ LMA (n=100). Average intracuff pressures during the study period (before and after endoscope insertion) were not different between the two LMAs. Ease of the procedure was slightly improved with the LMA® Gastro™ Airway ($p<0.001$).

Discussion: The LMA® Gastro™ Airway blunted, but did not prevent an increase in intracuff pressure during EGD when compared to the Ambu® AuraOnce™ LMA. Throat soreness was generally low, and complications were infrequent in both groups. The ease of the procedure was slightly improved with the LMA® Gastro™ Airway compared to the Ambu® AuraOnce™ LMA.

Keywords: intracuff pressure, endoscope, pediatric anesthesia, general anesthesia, laryngeal mask airway, LMA® Gastro™ Airway

Introduction

Pediatric patients generally cannot tolerate awake esophagogastroduodenoscopy (EGD), so general anesthesia (GA) with a secured airway or deep sedation is routinely required for patient tolerance and successful completion of these procedures.[1,2] The routine clinical practice at our institution for endoscopy includes GA with airway control using a laryngeal mask airway (LMA) or endotracheal tube.[3] Following the induction of anesthesia and placement of the LMA, the endoscope is inserted into the

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mouth and then navigated between the cuff of the LMA and posterior pharynx into the esophagus.[4] Excessive intracuff pressure during endoscope insertion may increase the incidence of postoperative sore throat, especially if it exceeds 60 cmH_2O.[5,6] Additionally, it may be difficult to navigate the EGD scope around the cuff of the LMA. Deflation of the cuff of the LMA may impair intraoperative ventilation especially if the leak is large and compromise the positive pressure ventilation.

We prospectively evaluated a newly designed LMA (LMA® Gastro™ Airway, Teleflex Medical, Morrisville, North Carolina) with an internal channel exiting from a posterior location at its distal end to facilitate endoscope passage into the esophagus and avoid the need to navigate around the cuff (Figure 1). This channel accommodates a scope with an outside diameter ≤14 mm. This novel design allows for a patent airway, easy insertion of the endoscope without the need to maneuver around the cuff of the LMA, and a simple means to assist ventilation if needed. To date, there are no reports of the use of LMA Gastro in the pediatric population. The current study prospectively compared airway management and outcomes using this newly designed LMA with those using a standard LMA (Ambu® AuraOnce™, United Statues Distributor, Ambu Inc, Columbia, Maryland) (Figure 2) in the pediatric population.

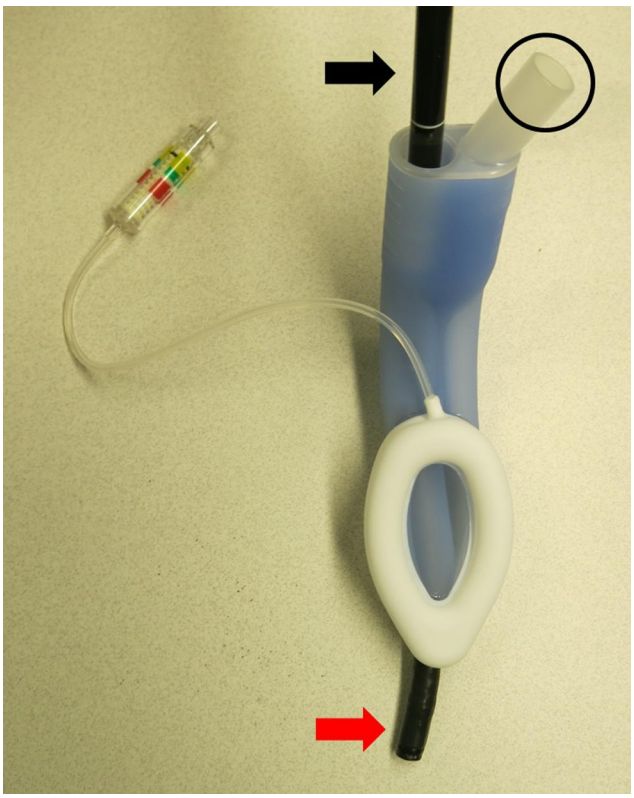

Figure 1 The LMA® Gastro™ Airway has a second channel with an entrance at the top (black arrow) for endoscope insertion. This channel exists from a posterior site at its distal end (red arrow) to facilitate endoscope passage into the esophagus and avoid the need to navigate around the cuff. There is also a standard 15 mm adaptor (black circle) for attachment to the anesthesia circle system.

Materials and Methods

Parents or the patient were provided with a written statement regarding the intent of the research and verbal informed consent as well as assent were obtained. The study, along with verbal informed consent and assent, was acceptable and approved by the Institutional Review Board (IRB) at Nationwide Children's Hospital (Columbus, Ohio) and the study was conducted in accordance with the Declaration of Helsinki (IRB17-00680). The study was registered at clinicaltrials.gov (NCT03432403). American Society of Anesthesiologists' (ASA) physical class 1, 2 or 3 patients, less than 21 years of age, weighing more than 30 kilograms and scheduled to receive a laryngeal mask airway (LMA) as part of standard anesthetic care for EGD were enrolled. These patients were scheduled for elective, non-emergent/urgent diagnostic procedures. Patients were randomized to receive airway management with one of two types of LMA devices: the standard Ambu® AuraOnce™ (AA) LMA (standard group) or the LMA® Gastro™ (LG). The size of the LMA was determined according to the manufacturer's

Figure 2 Ambu® AuraOnce™ laryngeal mask airway used for the study which has a single channel for ventilation that sits over the top of the glottic inlet.

recommendations based on the patient's weight. Patients with a weight less than 30 kilograms, a known or suspected difficult airway or a history of prior difficult placement of an LMA were excluded from the study. Patients less than 30 kg were excluded based on the manufacturer's recommendations that the minimum weight recommended for use of the LG is ≥30 kg. The LMA was chosen by randomization and revealed to the investigator recording the data and the anesthetic team immediately prior to anesthetic induction.

The induction of anesthesia was achieved with the inhalation of sevoflurane in nitrous oxide and oxygen or by the intravenous administration of propofol. Anesthesia was maintained with sevoflurane in air/oxygen with spontaneous/assisted ventilation. No neuromuscular blocking agents were administered. The chosen LMA was lubricated and placed using a standard midline technique with slight head extension, mouth opening, and anterior displacement of the tongue. After anesthetic induction and LMA placement, the cuff was inflated until there was no audible gas leak while holding continuous positive airway pressure (CPAP) of 20 cmH_2O and the ability to apply positive pressure ventilation demonstrated. If there were concerns with sealing of the airway or positioning the device, it was removed and replaced. The intracuff pressure was non-invasively and continuously monitored using our previously described and validated technique.[7,8] This technique uses a transducer from a standard invasive pressure monitoring device that is clinically used to monitor arterial or central venous pressure. The device was attached to the pilot balloon of the cuff of the LMA and the pressure transducer was then attached to the anesthesia monitoring panel, which provided a continuous readout of the intracuff pressure. While the manufacturer recommends keeping the LMA intracuff pressure below 60 cmH_2O; in children, intracuff pressures greater than 40 cmH_2O may result in a less effective seal, impaired ventilation, and an increased incidence of sore throat.[9] The intracuff pressure was continuously monitored and recorded every minute for five minutes after anesthetic induction. These values were averaged to provide the baseline intracuff pressure. In the LG group, a silicone lubricant was applied to the endoscope, which was then inserted through the channel of the LMA by the pediatric gastroenterologist. In the AA group, the endoscope was inserted into the oral cavity and navigated around the cuff of the LMA into the esophagus. The intracuff pressure was recorded every two minutes during the procedure following endoscope insertion and then every minute for five minutes once the endoscope had been removed. The maximum intracuff pressure observed after endoscope placement was considered the highest intracuff pressure and used to determine the incidence of excessive intracuff pressure during the procedure. The intracuff pressures were not adjusted after insertion of the EGD.

Demographic and procedural data collected included patient information (gender, age, height, weight, and body mass index) as well as the type and size of the LMA used. Secondary outcomes included the absolute change in intracuff pressure (comparing pre-insertion to post-insertion values), the maximum intracuff pressure, incidence of sore throat on the day of and the day following the procedure, severity of the sore throat on a visual analogue scale (VAS) scale of 0 to 10 (10 = worst) provided subjectively by the patient, number of attempts at LMA placement, time from start of endoscope placement until its entry into the stomach, ease of EGD procedure (VAS score of 1 to 10; 10 being best or easiest) provided subjectively by the pediatric gastroenterologist, and presence of blood on the LMA or in the oropharynx during or after the procedure (yes or no). We also evaluated whether or not the cuff of the LMA had to be deflated to allow for the endoscope to pass, if there were difficulties with ventilation during procedure (yes or no) and whether there a leak around the cuff during the procedure with positive pressure ventilation (yes or no).

The sample size was determined statistically based on a power analysis that was performed prior enrollment of the patients in the study. We proposed a 20% reduction in the incidence of intracuff pressure ≥60 cmH2O would be meaningful. An independent test of proportions would achieve 85% power to detect this reduction at a confidence level of 95% with 95 patients in each group; therefore, we enrolled 100 patients per group to account for potential withdrawal or missing data. The changes in intracuff pressure above baseline were compared between groups using an independent *t*-test. Secondary outcomes including throat soreness, ease of the EGD procedure, blood found on the LMA, and difficulties with ventilation were compared using rank-sum, Chi-square, or Fisher's exact tests, as applicable. All statistical analyses were performed using SAS 9.4 (Cary, NC, USA).

Results

The study cohort included 200 patients with 100 randomized to the LG and 100 to the AA. The patients ranged in age

from 5 to 19 years with a mean age of 13.6 years and a mean weight of 56.6 kg (Table 1). There were no differences in the demographic data or the sizes of the LMAs used. Outcome data are listed in Table 2. The AAs were successfully placed on the first attempt in 99 of 100 cases (99%) and the LGs were successfully placed on the first attempt in 97 of 100 (97%) cases. The remaining LMAs were placed on the second attempt. There was no difference in the intracuff pressure over the first five minutes after anesthetic induction and before endoscope insertion (43 ± 14 cmH_2O with the LG cohort versus 38 ± 14 with the AA) (Table 2). The maximum change in intracuff pressure was less with the LG (7 ± 7 cmH2O versus 9 ± 8 cmH_2O, p=0.045) than with the AA. There was no difference in the number of cases with an intracuff pressure ≥60 cmH_2O at any time during the case between the two groups.

Time from start of the procedure to entrance in the stomach was similar in both groups. Ease of the procedure was improved with the LG (p<0.001). Difficulty in ventilation was noted in two patients with the AA and in one patient with the LG. Blood was found in the oropharynx or on the device more commonly with the LG than the AA (p=0.105). There was no difference in throat soreness on the day of the procedure or postoperative day one. All patients were hemodynamically stable throughout the procedure. There were no clinical signs or concerns of aspiration in any of the patients. Although not quantified for the purpose of this study, the anesthesiology providers found no difficulties with the use of the LG device.

Discussion

The primary goal of GA in children undergoing upper and lower endoscopy is to allow the procedure to be performed safely and efficiently with minimal physical and emotional discomfort to the patient. There remain several options to provide deep sedation or general anesthesia during upper gastrointestinal (GI) endoscopy in children including spontaneous, assisted or controlled ventilation with a native airway, an endotracheal tube or a supraglottic device (SGD).[1,2,10] Additionally, several different sedative and analgesic agents may be used alone or in combination including propofol, ketamine, midazolam, dexmedetomidine, and opioids.[10–12] Although generally safe and effective, these agents may result in respiratory depression, apnea, hypoxemia, and hypercarbia with the resultant need to assist ventilation. This respiratory impairment may be exacerbated by upper airway obstruction caused by the endoscope and gastric insufflation, used to aid visualization of the anatomy, which may impair diaphragmatic excursion.[13,14] These adverse events may necessitate assisted ventilation by facemask while the endoscopy procedure is interrupted. Younger patients, those with a higher ASA physical class, and the administration of sedation are potential risk factors for cardiorespiratory complications in children during upper GI endoscopy.[13,14]

Given these concerns, our clinical practice to facilitate the rapid and efficient performance of upper GI endoscopy in children is the provision of general anesthesia using SGDs. The LMA is an SGD with a tube attached to a pear-shaped oval mask that is inserted blindly into the oropharynx.[15,16] SGDs can be used during spontaneous, assisted, or controlled ventilation. LMAs that are commonly used for clinical care have only one channel which sits over the glottic inlet; therefore, the endoscope must be placed into the mouth on top of the LMA and navigated between the wall of the pharynx and the LMA cuff into the esophagus. The LG has a second channel which exits at the distal end of the LMA in position that is posterior to the glottic opening, above the esophageal inlet.[17,18]

Previous studies have demonstrated the efficacy of the LG during upper GI endoscopy in the adult population, but

Table 1 Demographic Data of the Study Cohorts

Variables	All (n = 200)	LG Group (n = 100)	AA Group (n = 100)	P value
Gender, female, n (%)	110 (55)	56 (56)	54 (54)	0.776
Age (years)	13.6 ± 2.95	13.7 ± 2.98	13.5 ± 2.94	0.775
Weight (kilograms)	56.6 ± 17.4	55.9 ± 18.2	57.1 ± 16.8	0.630
Height (centimeters)	158.9 ± 13.3	158.4 ± 13.1	158.7 ± 13.2	0.869
Body mass index (kg/m^2)	22.1 ± 5.02	22 ± 4.93	22.3 ± 4.98	0.649
LMA size (2.5, 3, 4, 5)	2 (1), 116 (58), 80 (40), 2 (1)	1 (1), 62 (62), 36 (36), 1 (1)	1 (1), 54 (54), 44 (44), 1 (1)	0.826

Note: Data are presented as mean ± standard deviation or number (%).
Abbreviations: LMA, laryngeal mask airway; LG, LMA® Gastro™ Airway; AA, Ambu® AuraOnce™.

Table 2 Outcomes of EGD Scope Insertion According to Type of Laryngeal Mask Airway Used.[a]

Outcomes	LG Group (n = 100)	AA Group (n = 100)	P value
More than one attempt	3 (3%)	1 (1%)	0.369[b]
Significant gas leak around cuff	2 (2%)	3 (3%)	1.000[b]
Blood found on LMA or in oropharynx	11 (11%)	4 (4%)	0.105[b]
Difficulty with ventilation	1 (1%)	3 (3%)	0.621[b]
Time from EGD placement to stomach entry (<1 minute and ≥1 minute)	68 and 32	66 and 34	0.764[c]
Ease of EGD procedure (VAS)	10 (8, 10)	9 (8, 9)	<0.001[d]
Throat soreness prior to discharge (VAS)	3 (2, 3.5)	3 (2, 3)	0.036[d]
Throat soreness on first postoperative day (VAS)	2 (1, 3)	2 (1, 3)	0.702[d]
Intracuff pressure following anesthetic induction, prior to endoscope insertion (cmH_2O)	43 (14)	38 (14)	0.020[e]
Maximum intracuff pressure after endoscope insertion	50 (16)	47 (16)	0.226[e]
Change in intracuff pressure following endoscope insertion (compared to baseline in cmH_2O)	7 (7)	9 (8)	0.045[e]
Intracuff pressure >60 cmH_2O	22 (22%)	14 (14%)	0.141[c]

Notes: [a]Data are presented as N (%), median (IQR), or mean (SD). [b]Fisher's exact test. [c]Chi-square test. [d]Wilcoxon rank sum test. [e]T-test. VAS scale is listed as 1 to 10 (10 being easiest procedure and severe pain for throat soreness).
Abbreviations: EGD, esophagoduodenoscopy; IQR, interquartile range; LMA, laryngeal mask airway; SD, standard deviation; VAS, visual analog scale; LG, LMA® Gastro™ Airway; AA, Ambu® AuraOnce™.

this is the first study evaluating its use in a cohort of pediatric-aged patients.[19,20] The principal findings of this prospective study, comparing the clinical outcomes of two types of SGDs, were that the LG was easy to use with limited instruction, limited the increase in intracuff pressure from baseline, and slightly improved the ease of the procedure. However, we noted no difference in the primary outcome of the study, which was the change of intracuff pressure of the SGDs. When graded on a 0 to 10 scale, the ease of completion of the EGD procedure was statistically improved with the LG than the AA. However, the score was high with both devices (median of 10 versus 9, respectively). This is likely because the procedures were performed by mid-to-senior level pediatric gastroenterologists with significant experience with upper GI endoscopy during GA with an LMA or SGD.

Despite limited experience with the LG and having 22 different anesthesia attendings in the study, we noted no difficulty with its use and no difference in the success of placement on the first attempt when compared with the AA. There was an increased incidence of mild trauma as evidenced by blood on the LMA or in the oropharynx with placement of the LG, but this did not result in a difference in the severity of postoperative throat pain on the day of the procedure and postoperative day one. This difference may be related to the different components of the cuff of the LMA of the two devices (silicone with the LG and polyvinylchloride with the AA). Because of this, the manufacturer recommends lubrication of the LG before placement. Throat pain was graded as mild in most patients at both assessment points. Both devices performed well during the procedure and difficulties with ventilation were noted in two patients with the AA versus none with the LG. Although the baseline intracuff pressure was higher with the LG, the increase in intracuff pressure from baseline with endoscope insertion was blunted. No difference was noted in the intracuff pressure while the EGD was inserted and no difference was noted between the number of patients with an intracuff pressure that exceeded 60 cmH_2O. Performance of the EGD was reported to be somewhat easier with the LG.

One limitation of the current study is that it specifically included use of an LMA for these EGD procedures. Choice of care during EGD varies among institutions and may include general anesthesia with an LMA, SGD, or ETT as well as procedural sedation with a native airway. All of these techniques have been shown to safe and effective. The current study was performed at an institution where use of the LMA is commonplace during upper GI endoscopy. As such, the faculty have significant experience with use of the LMA and performance of upper GI endoscopy in this clinical scenario. We also had only a single comparison group which included use of the AA, a first-generation LMA. In addition to their design differences, the composition of the cuff varies, being made of silicone for the LG and polyvinylchloride for the AA. The outcomes cannot therefore be generalized to other types of LMAs or SGDs. The study cohort specifically eliminated patients with a potentially or known difficult airway or other structural airway concerns. The demographics of the study cohort were such that we cannot comment on the efficacy of the LG in obese or super-obese patients. Both the ease of the procedure and throat pain were graded on a 0–10 scale with the inherent potential for bias related to its subjective nature. However, such scales are commonly used in clinical trials and when evaluating procedural pain. Additionally, the LMA does not seal the esophagus and therefore is not intended for use in patients at risk for aspiration during GA. The smallest

size available of the LG is 3 thereby limiting its use to patients who weigh ≥30 kilograms. The endoscope channel will accept a scope with a maximum OD of 14 mm. With these caveats in mind, the current study demonstrates the potential utility of this novel LMA in clinical practice.

Conclusion

In conclusion, the LG was found to blunt, but not prevent an increase in intracuff pressure during EGD when compared to an AA. The ease of the procedure was slightly improved with the LMA Gastro versus the standard LMA.

Abbreviations

LMA, laryngeal mask airway; EGD, esophagogastroduodenoscopy; GA, general anesthesia; VAS, visual analogue scale; CPAP, continuous positive airway pressure; SGD, supraglottic airway device; LG, LMA® Gastro™; AA, Ambu® AuraOnce™.

Disclosure

All the authors declare no conflicts of interest and no outside funding. Deidentified data and protocol requests may be made to the corresponding author. Each request will be reviewed to ensure no sharing of identifiable data.

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