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A randomized controlled trial comparison of LMA® Gastro™, classic LMA and endoscopy mask for anesthesia during adult gastroscopy

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Abstract: The current study evaluated the feasibility of the newly developed LMA® Gastro™ for elective gastroscopy in adults. By means of a randomized controlled trial comparison, the LMA® Gastro™ was compared to the commonly used endoscopy mask and classic LMA with regard to patient safety, patient comfort and user-friendliness for both the anesthesiologist and the gastroenterologist. To achieve this, 65 patients were randomly divided into three groups (i.e., endoscopy mask, classic LMA and LMA® Gastro™) and patients' saturation levels were compared by means of analysis of covariance (ANCOVA), while controlling for the fraction of inspired oxygen. Results indicated that the innovative LMA® Gastro™ is significantly more effective than the endoscopy mask in maintaining the desired oxygen saturation during elective gastroscopy. Furthermore, patients' VAS-scores for sore throat were measured before and after the intervention and compared by means of ANCOVA. Results showed comparable levels of sore throat when using the LMA® Gastro™ and the classic LMA, but ventilation with the endoscopy mask resulted in the lowest level of sore throat. Finally, the anesthesiologist's and gastroenterologist's satisfaction with the airway device were analyzed by means of ANOVA, resulting in a positive evaluation of the device by both medical practitioners. Just like the classic LMA, the anesthesiologist found the LMA® Gastro™ easier to handle than the endoscopy mask. However, the introduction of the gastroscope was found to be more straightforward in the LMA® Gastro™ due to the presence of the second channel.

Keywords : LMA® Gastro™; airway management; gastroscopy; adults.

Introduction

In recent years, there is a growing attention for the early detection of gastrointestinal diseases. This resulted in an increase in the number of gastroscopic procedures, but also in an extended application of gastroscopy (1-5). Hence, to date, gastroscopic procedures are not only applied for diagnostic purposes, but are also increasingly used for therapeutic aims (e.g., peroral endoscopic myotomy, endoscopic submucosal dissection, endoscopic mucosal resection). These therapeutic gastroscopies are only minimally invasive, but lead to gastroscopic procedures that are more complex and longer in duration compared to diagnostic gastroscopies (2, 4, 6, 7). Therapeutic gastroscopies are often conducted under deep sedation or general anesthesia and are performed in an endoscopy unit, rather than in the operating room (1-3, 8-11). Consequently, these gastroscopic procedures impose high requirements on the anesthesiologic plan as a safe and proper airway management should be combined with an accurate monitoring and an early detection of adverse events (e.g., hypoxia, bradycardia, apnea, etc. (1, 2, 14-17, 4, 6-9, 11-13). In addition, the patients' comfort should be guaranteed and immobility should be ensured to offer the best operating conditions to the gastroenterologist (1, 2, 10, 18).

The combination of diagnostic and therapeutic gastroscopies urge the anesthesiologist to adopt a wide range of airway devices in view of tuning the airway management to the specific procedure and patient comorbidities (1, 4, 6, 7, 13, 17). To achieve this, several airway management devices are available on the market that can be applied to assure a secured airway and hemodynamic stability during the intervention. The most commonly used devices in the context of gastroscopic procedures are endotracheal tubes, endoscopy masks and

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classic laryngeal masks (6, 7, 12, 13, 17, 19-23). Generally, the features of each of these devices make them suitable for gastroscopic interventions. Endotracheal tubes, on the one hand, allow for a secured airway that is protected from the aspiration of gastric contents. Furthermore, the position of the endotracheal tube does not interfere with a smooth insertion of the gastroscope. Endoscopy masks, on the other hand, allow for a moderate to deep sedation while maintaining spontaneous breathing (7, 8, 13, 17, 21, 22). They are non-invasive and therefore avoid the risk of pain that may be caused with other airway devices (e.g., pain caused by the introduction, potential trauma of soft tissues, inflation of the cuff and eventual dislocation). The classic LMA, at last, combines a rapid and rather easy introduction of the airway device with a relatively reliable capnography, permitting for smooth interventions while accurately monitoring the patient (7, 16, 24). Furthermore, when compared to the endotracheal tube, the laryngeal mask has shown to be equally efficient in protecting the airways from the aspiration of gastric contents, while causing less sore throat (20, 23, 25-28).

Even though the abovementioned devices permit an appropriate airway management, they however have important disadvantages. As to the endotracheal tube, research reports on the relatively frequent occurrence of post-operative sore throat, nausea and vomiting (23, 25, 26, 28). Furthermore, the introduction of the endotracheal tube demands a lot of expertise and, in case of difficult intubation, can result in tissue trauma or a cannot-intubate-cannot-ventilate scenario (CICV).

With regard to the endoscopy mask, there is a non-negligible risk for leaks and airway obstruction in interventions that require deep anesthesia and mechanical ventilation (21). This might result in oxygen desaturation, bradycardia, hypotension and interventions such as unplanned tracheal intubation, need to provide advanced life support and, eventually, necessity to abandon the gastroscopic procedure. Endoscopy masks are furthermore associated with a less accurate capnography (compared to classic LMA), which may lead to a late detection of apnea and an obstructive airway. At last, endoscopy masks do not protect the airways from the aspiration of gastric contents (7, 16, 21).

With regard to the classic LMA, one should consider the risk of pain caused by the introduction of the device and the inflation of the cuff. Furthermore, the introduction of the gastroscope is sometimes challenging, requiring a deflation of the cuff or leading to a dislocation of the airway device (19). As a result, there is a temporarily unprotected airway that may cause oxygen desaturation, bradycardia, hypotension etc. (see above).

Considering these risks, medical research continuously invests in the improvement and development of airway devices, aiming to combine a secured airway with patient comfort and user-friendliness for the medical practitioners. This ongoing research resulted, among others, in the recent development of the dual channel LMA® Gastro™. This innovative airway device is equipped with a second channel that permits to insert the gastroscope without deflating the cuff, resulting in a more secured airway and lower risks of oxygen desaturation, gastric air insufflation and aspiration. Additionally, due to the shape of the LMA® Gastro™ (Fig. 1), the gastroscope is smoothly and securely directed towards the upper esophagus. This prevents forced maneuvers during gastroscope insertion that may cause sore throat in the post-operative period.

Figure 1. — Design and features of the LMA® Gastro™ (37).

While the LMA® Gastro™ is a very promising device for improving airway management during gastroscopic procedures, research confirming its clinically efficacy is still limited (29, 30). In this regard, an exploratory study of Terblanche and colleagues (31) indicates that the LMA® Gastro™ is effective in minimizing cardiorespiratory complications. This finding was confirmed by other observational studies, providing preliminary evidence for the value of this device in gastroscopic procedures (3, 5, 29, 32, 33). To obtain in-depth insight in the effectivity and safety of the LMA® Gastro™, there is however a need for experimental research comparing this innovative device with more traditional airway devices (34). The current study aims to make an initial contribution to filling this gap by conducting a randomized controlled trial comparison of three different airway devices

in the context of elective gastroscopy in adults. In particular, the present study compares the safety, effectivity and user-friendliness of the LMA® Gastro™ with the airway devices most commonly used for elective gastroscopy: the endoscopy mask (VBM Medizintechnik GmbH, Germany) and the classic LMA. The Research objectives (RO) of this study are threefold:

(RO1) Investigating whether the LMA® Gastro™ is efficient in maintaining patients' saturation during gastroscopy, when compared to the classic LMA and the endoscopy mask.

(RO2) Exploring whether patients' postoperative VAS-score for sore throat differs when using the LMA® Gastro™, the classic LMA and the endoscopy mask.

(RO3) Investigating the anesthesiologist's and gastroenterologist's satisfaction with the LMA® Gastro™ compared to the other devices.

With regard to RO1 and in line with prior observational research (3, 5, 31-33), we hypothesize that the LMA® Gastro™ is equally efficient in maintaining patients' saturation when compared to the endoscopy mask and classic LMA. As to RO2, we hypothesize less post-operative sore throat in patients' ventilated with an endoscopy mask than in patients treated with a laryngeal mask (35, 36). Furthermore, we hypothesize no differences in the VAS-score for sore throat between the LMA® Gastro™ and the classic LMA. Research in this regard is lacking, but we expect that the ease of introduction of the gastroscope (i.e., less forced insertion maneuvers) will compensate for the larger dimensions and the limited flexibility of the LMA® Gastro™ when compared to the classic LMA. Finally, our hypotheses for RO3 are based on the developers' description, stating that the LMA® Gastro™ is designed for smooth insertion by the anesthesiologist, ensuring a successful ventilation of the patient. Furthermore, the second channel of the LMA® Gastro™ would facilitate the cannulation of the esophagus by the gastroenterologist. Hence, a significantly higher satisfaction of both medical practitioners is predicted.

Methodology

Participants

After approval by our Committee for Medical Ethics (Ref: EC/2018/0171), a single-blind randomized controlled trial was conducted in Ghent University Hospital. 75 adult patients, scheduled for elective gastroscopy between July and September 2018, were selected for this study. Prior to the intervention, patients were screened for eligibility, including criteria such as an ASA score ≤ 3, absence of a history of radiotherapy or known respiratory problems urging an endotracheal intubation. After obtaining active informed consent, all 71 eligible patients were randomly and single-blindedly assigned to one of the three airway devices. During the study, limited drop-out occurred due to endotracheal intubation requested by the gastroenterologist (e.g., more complex procedure such as conversion to ablation; N = 5) or missing data (N = 1). The final study sample consisted of 65 adult patients ($\geq$ 18 years) undergoing an elective gastroscopy with the endoscopy mask (N = 22), classic LMA (N = 20) or LMA® Gastro™ (N = 23).

Table 1 provides an overview of relevant background characteristics of the patients included in the study.

Measures

For all participants, a standard anesthesia protocol was followed. Sedation occurred with BIS adjusted IV propofol (BIS 45-55) and the fraction of inspired oxygen was set to 40%. Patients' peripheral oxygen saturation (SpO_2) and fraction of delivered oxygen (F_iO_2) were automatically registered on predefined moments: T_0 (time of induction), T_1 (T_0 + 1 minute), T_2 (T_0 + 5 min), T_3 (T_0 + 10 min), T_4 (T_0 + 15 min) and T_5 (T_0 + 20 min).

Table 1

Descriptive statistics of the sample

	Endoscopy mask (*N* = 22)	**Classic laryngeal mask (*N* = 20)**	**LMA®Gastro™ (*N* = 23)**
Gender (N_{male}, $\%_{male}$)	9 (40.9)	10 (47.6)	12 (52.2)
Age (Mean, SD)	49.3 (14.9)	58.5 (16.5)	54.7 (11.4)
BMI (Mean, SD)	25.7 (6.8)	26.3 (7.5)	26.7 (7.6)
Smoker (N_{yes}, $\%_{yes}$)	11 (50.0)	11 (55.0)	15 (65.2)

Furthermore, other relevant patient characteristics such as age, sex, BMI and smoker status were registered, as these variables are known to potentially influence patients' saturation during the medical intervention. In addition, the presence of sore throat was questioned by means of the Visual Analog Scale (VAS). The VAS scale is a validated, subjective measure for pain represented by a 100-mm ruler that symbolizes a continuum from "no pain" (score of 0) to "worst imaginable pain" (score of 100). Patients' VAS score for sore throat was questioned both before and after the intervention. The post-operative determination of the VAS score could not be conducted at a predefined moment, due to the strong variety in patients' awakening process. All patients were however questioned as soon as they were evaluated sufficiently alert by the researchers.

At last, both the anesthesiologist's and the gastroenterologist's satisfaction with the applied airway device was questioned. For the purpose of consistency, both medical practitioners evaluated the airway devices on a 100-mm VAS scale. More specifically, three separate VAS scores were used to evaluate (1) the ease of introduction of the LMA, (2) the user-friendliness according to the anesthesiologist and (3) the ease of introduction of the gastroscope.

Data analysis

Regarding RO1, ANOVA was first used to check for group differences in relevant patient- and anesthesia-related variables, in view of ensuring their eligibility as covariates. ANCOVA was then used to investigate differences in patients' SpO_2 related to the applied airway device, while controlling for variables that could influence patients' saturation level such as F_iO_2, BMI and smoking behavior. However, given the repeated time measurements for both SpO_2 and F_iO_2, variables were not independent and an area under the curve was calculated for both measurements before conducting the analysis.

As to RO2, ANCOVA was used to check for group-related differences in patients' post-operative VAS score for sore throat. A covariate was added in view of controlling for pre-operative sore throat. Of course, ANOVA analysis was first conducted to check whether this variable could be included as a covariate in the main analysis.

As for RO3, ANOVA was used to evaluate VAS-score differences in the anesthesiologist's and gastroenterologist's satisfaction with the airway device.

Results

RO1: Investigating whether the LMA® Gastro™ is efficient in maintaining patients' saturation during gastroscopy, when compared to the classic LMA and the endoscopy mask

To answer RO1, the area under the curve was first calculated for both SpO_2 and F_iO_2, as variables were not independent due to the repeated time measurements. ANOVA was then conducted to check for group differences in relevant patient- and anesthesia-related variables. Results yielded no significant differences in BMI ($F(2,62) = 0.09$, $p = .91$), smoking behavior ($F(2,60) = 0.36$, $p = .70$), and F_iO_2 ($F(2,63) = 0.137$, $p = .87$), indicating that these variables could be included as covariates in the further analysis.

In a second step, ANCOVA was used to investigate potential differences in patients' saturation related to the applied airway device. Results indicated no significant differences in patients' SpO_2 between the three groups (i.e., endoscopy mask, classic laryngeal mask, LMA® Gastro™) after controlling for BMI, smoking and F_iO_2, $F(2,51) = 0.40$, $p = .68$. However, a Tukey post hoc test revealed that significantly higher saturation levels were obtained when using the LMA® Gastro™ ($M^{AUC} = 1139.48$, $SD^{AUC} = 53.87$, $p = .011$) and the classic LMA ($M^{AUC} = 1166.57$, $SD^{AUC} = 59.14$, $p = .006$), compared to the endoscopy mask ($M^{AUC} = 932.06$, $SD^{AUC} = 57.33$). There was no significant difference between the LMA® Gastro™ and LMA classic group ($p = 736$).

With regard to the covariates, both BMI ($F(1,51) = 4.40$, $p = .04$) and F_iO_2 ($F(1,51) = 22.34$, $p < .001$) were significantly related to patients' SpO_2, while this was not the case for smoking behavior ($F(1,51) = 2.85$, $p = .10$).

RO2: Exploring whether patients' post-operative VAS-score for sore throat differs when using the LMA® Gastro™, the classic LMA and the endoscopy mask

In a first step, ANOVA was conducted to check for group-related differences in patients' pre-operative VAS-score for sore throat, in view of ensuring that this variable could be included as a covariate. As illustrated in Table 2, low mean VAS-scores were registered in all three groups, indicating that patients experienced little sore throat before the intervention. ANOVA results showed no significant differences between the three groups, with $F(2, 55) = 0.07$, $p = .931$.

Table 2

Descriptive results for VAS-score on pre-operative and post-operative sore throat

VAS-scale	Group	*N*	*Mean*	*SD*
Pre-operative sore throat				
	Endoscopy mask	19	0.22	0.66
	LMA Classic	19	0.30	0.65
	LMA® Gastro™	20	0.28	0.73
Post-operative sore throat				
	Endoscopy mask	19	0.22	0.68
	LMA Classic	19	2.17	2.64
	LMA® Gastro™	20	2.00	2.25

In a second step, ANCOVA was used to investigate differences in patients' post-operative sore throat related to the airway device. The VAS-score for pre-operative sore throat was added as a covariate, but turned out not to be significantly related to patients' post-operative sore throat ($F(1,49) = 2.31$, $p = .135$). There was however a significant effect of the applied airway device on patients' VAS-score for post-operative sore throat, with $F(2,49) = 4.13$), $p = .022$, $r = .13$.

A Tukey LSD post hoc analysis revealed that using the endoscopy mask resulted in significantly lower post-operative sore throat, compared to the LMA Classic ($t(49) = -1.84$, $p = .013$) and LMA® Gastro™ ($t(49) = -1.74$, $p = .019$). There were no significant differences in patients' sore throat when comparing the LMA Classic to the LMA® Gastro™ ($t(49) = 0.11$, $p = .882$).

RO3: Investigating the anesthesiologist's and gastroenterologist's satisfaction with the LMA® Gastro™ compared to the other devices

For answering RO3, ANOVA was conducted to check for differences in the anesthesiologist's and gastroenterologist's satisfaction with the airway devices. More specifically, both medical practitioners' satisfaction was measured on a VAS-scale, with higher scores representing a lower satisfaction. Table 3 illustrates the satisfaction scores and ANOVA results for (1) the ease of introduction of the LMA, (2) the user-friendliness of the airway device, (3) the ease of introduction of the gastroscope.

As to the ease of introduction experienced by the anesthesiologist, ANOVA results indicate no significant differences between the LMA Classic and LMA® Gastro™. With respect to the user-friendliness of the airway device, a significant relation between the device and the anesthesiologist's satisfaction could be found. More specifically, Tukey LSD post hoc analysis indicate that the LMA classic ($p < .001$) and LMA® Gastro™ ($p < .001$) were experienced as more easily to use than the endoscopy mask. However, the ease of use of the LMA® Gastro™ did not significantly differ from the LMA Classic ($p = 0.63$). Finally, ANOVA results show significant differences in the ease of introduction of the gastroscope. Post hoc analysis evidence that the introduction of the gastroscope was significantly easier in the LMA® Gastro™

Table 3

Descriptives and ANOVA results for the satisfaction with the airway device

			ANOVA	
VAS-scale	**Group**	**Mean (SD)**	***F*(df)**	***p*-value**
Ease of introduction LMA				
	LMA Classic	1.43 (1.73)	2.31 (1,40)	.136
	LMA® Gastro™	2.35 (2.14)		
User-friendliness airway device				
	Endoscopy mask	7.27 (2.69)	24.49 (2,56)	<.001
	LMA Classic	2.88 (3.34)		
	LMA® Gastro™	1.21 (2.20)		
Ease of introduction gastroscope				
	Endoscopy mask	6.45 (2.54)	5.49 (2,61)	.006
	LMA Classic	7.92 (2.60)		
	LMA® Gastro™	4.89 (3.68)		

than the LMA Classic (p = .002). No significant differences could be found in this regard between the LMA® Gastro™ and the endoscopy mask (p = .093).

Discussion

In recent years, the number of gastroscopic interventions has been steadily rising due to an increased attention for the early detection and treatment of gastric abnormalities and tumoral processes (1-5). Moreover, there is a growing attention for providing efficient, timely and safe care to the patient, as well as for offering optimal conditions to the gastroenterologist. This resulted in an increase of the number of interventions under deep sedation/general anesthesia and a more frequent application of nonoperating room anesthesia (1-3, 8-11). To answer these high demands, there is a continuous investment in the development of new airway management devices that permit to combine patient safety and comfort with a user-friendliness for the treating medical practitioners. This resulted in the development of the LMA® Gastro™, an innovative airway device that provides a second channel for the insertion of the gastroscope in view of ensuring an unobstructed airway. As experimental research on the clinically efficacy of the LMA® Gastro™ is still lacking, the current study investigated the safety, efficiency and user-friendliness of this device by comparing with devices commonly used in elective gastroscopy such as the endoscopy mask and the classic LMA.

With regard to the safety of the device (RO1), the present study confirms the findings of earlier observational research suggesting that the LMA® Gastro™ is able to maintain patients' oxygen saturation during gastroscopy. More specifically, after controlling for the fraction of inspired oxygen, results show that the laryngeal masks (i.e., classic LMA and LMA® Gastro™) led to significantly better oxygen saturation, when compared to the endoscopy mask. The present study could not find statistical differences in the oxygen saturation when using the LMA® Gastro™ and the classic LMA. The results of the present study thus evidence the safety and feasibility of the newly developed LMA® Gastro™ in a setting of elective gastroscopy for adults.

While patient safety is a first concern in the evaluation of new airway devices, it is of course also important to examine patient comfort. Therefore, the present research investigated eventual differences in post-operative sore throat when ventilating patients with an endoscopy mask, a classic LMA or an LMA® Gastro™. In line with our expectations and confirming prior research, patients ventilated with an endoscopy mask reported significantly less sore throat post-operatively than patients treated with a laryngeal mask (i.e., classic LMA or LMA® Gastro™). As to the laryngeal masks, results confirm our expectations regarding the absence of significant differences in sore throat between the LMA® Gastro™ and classic LMA. As stated in the introduction section, the easy introduction of the gastroscope could possibly compensate for the larger dimensions and limited flexibility of the LMA® Gastro™. Further research is however needed to understand whether patients' post-operative sore throat could further improve if anesthesiologists and gastroenterologists are more familiar with the use of the LMA® Gastro™.

Finally, the current study also evaluated the effectiveness of the LMA® Gastro™ by examining the anesthesiologist's and gastroenterologist's satisfaction. We hypothesized that the LMA® Gastro™ would be more positively evaluated than the classic LMA and endoscopy mask. In this respect, the developers of the LMA® Gastro™ state that the device is designed for an easy introduction by the anesthesiologist. Furthermore, the second channel should permit an easy insertion of the gastroscope while maintaining an unobstructed and protected airway. The results of the present study indicate that the ease of introduction of the airway device was not significantly different for the LMA® Gastro™ and the classic LMA. The user-friendliness of both laryngeal masks (i.e. classic LMA and LMA® Gastro™) was however higher rated by the anesthesiologist than the endoscopy mask. Again, no significant differences in the user-friendliness of the LMA® Gastro™ and classic LMA were reported by the anesthesiologists. These findings thus suggest that the anesthesiologists did not experience any difficulties during the introduction of the LMA® Gastro™ and perceive the laryngeal mask as easy to use throughout the procedure, when compared to the endoscopy mask. With regard to the gastroenterologists' satisfaction, the results of the current study evidence that the introduction of the gastroscope was easier when using a LMA® Gastro™ than a classic LMA, but no significant differences could be found when compared to the endoscopy mask.

Limitations

Notwithstanding the clear value of the LMA® Gastro™, we believe that further research is needed

in view of developing concrete guidelines for the use of this device. First, the current study did not compare the safety and user-friendliness of the LMA® Gastro™ with the endotracheal tube. In this regard, future research evaluating the effectiveness of the LMA® Gastro™ in long, complex procedures and emergency settings is recommended. Second, in line with the majority of the existing research, the current study exclusively focused on gastroscopy, while the value of the LMA® Gastro™ for trans-esophageal echocardiography remains understudied. At last, it would be interesting to conduct a long-term study in view of evaluating the effectiveness of the LMA® Gastro™ when medical practitioners are more familiar with the use of the device.

Conclusion

The current study evidences that the newly developed LMA® Gastro™ is a promising device with regard to patient safety and patient comfort. The big advantage of the LMA® Gastro™ compared to other devices however lies in the user-friendliness for both the anesthesiologist and the gastroenterologist. The LMA® Gastro™ combines a smooth introduction of the gastroscope with an easy handling of the airway device by the anesthesiologist.

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