The incidence of gastroesophageal reflux and tracheal aspiration detected with pH electrodes is similar with the Laryngeal Mask Airway® and Esophageal Tracheal Combitube® - a pilot study

[L'incidence de reflux gastro-œsophagien et d'aspiration trachéale détectés au moyen d'électrodes à pH est similaire avec l'usage du Laryngeal Mask Airway® ou du Esophageal Tracheal Combitube® - une étude pilote]

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Purpose: Aspiration as a result of gastroesophageal reflux (GER) and regurgitation remains a serious potential problem in anesthetized patients. The incidence of GER with either the Esophageal Tracheal Combitube™ (ETC) or the laryngeal mask airway (LMA) was investigated using tracheal and esophageal pH electrodes.

Methods: Following approval by the Institutional Review Board and written informed consent, 57 patients of ASA physical status I to III were randomly assigned to receive either an LMA (Group I, $n = 28$) or an ETC (Group II, $n = 29$) during general anesthesia. All patients were paralyzed and received positive pressure ventilation. Two monocrystalline antimony catheters were used for pH monitoring: one unipolar catheter with a single pH sensor for tracheal pH measurements and one bipolar catheter with proximal and distal sensors for pharyngeal and esophageal pH measurements, respectively.

Results: One episode of GER occurred in a patient in Group II, yet there were no pH changes reflected in the oropharyngeal or tracheal regions. There were 3/25 (12%) patients in Group I *vs* 1/25 (4%) patients in Group II that met the pH criterion for aspiration (pH below 4.0 that lasted at least 15 sec), yet no patient developed any clinical signs of aspiration. In all patients, hemodynamic and respiratory variables remained stable throughout the period of measurement (data not included).

Conclusion: In this pilot study, the ETC appears comparable to the LMA regarding the incidence of GER and tracheal acid aspiration.

Objectif : *L'aspiration résultant du reflux gastro-œsophagien (RGO) et la régurgitation demeurent un problème sérieux potentiel chez les patients anesthésiés. L'incidence de RGO notée avec l'utilisation du Esophageal Tracheal Combitube™ (ETC) ou avec le masque laryngé (ML) a été étudiée au moyen d'électrodes à pH placées dans la trachée et l'œsophage.*

Méthode : *Après avoir obtenu l'accord du Comité d'examen de l'hôpital et le consentement éclairé des sujets de l'étude, nous avons réparti en deux groupes de façon aléatoire 57 patients d'état physique ASA I à III qui ont reçu un ML (Groupe I, n = 28) ou un ETC (Groupe II, n = 29) pendant l'anesthésie générale. Tous les patients ont été paralysés et ont eu une ventilation à pression positive. Deux sondes en antimoine monocristallin ont été utilisées pour l'enregistrement du pH : une sonde unipolaire avec un seul capteur de pH pour les mesures trachéales et une bipolaire munie de capteurs proximal et distal pour les mesures pharyngienne et œsophagienne, respectivement.*

Résultats : *Il y a eu un épisode de RGO chez un patient du Groupe II, mais aucune modification du pH n'a été notée dans l'oropharynx ou la trachée. Aussi, 3/25 (12 %) patients du Groupe I vs 1/25 (4 %) du Groupe II répondaient aux critères du pH d'aspiration (pH sous 4,0 pendant au moins 15 s), mais aucun signe clinique d'aspiration ne s'est développé. Les variables hémodynamiques et respiratoires sont demeurées stables chez tous les patients tout au long de la période de mesure (données non inclues).*

Conclusion : *L'ETC est comparable au ML quant à l'incidence de RGO et d'aspiration acide trachéale.*

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ASPIRATION as a result of gastroesophageal reflux (GER) and regurgitation remains a serious potential problem in anesthetized patients. Although aspiration associated with compromise of the airway or lung tissue injury leading to significant decline in oxygenation is relatively uncommon, it is an imminent danger in emergency situations due to the presence of a full stomach and can occur unexpectedly, even in elective cases.[1]

Two supraglottic ventilatory devices that are used in the ASA difficult airway management algorithm,[2] the laryngeal mask airway (LMA; LMA North America Inc., San Diego, CA, USA) and the Esophageal-Tracheal Combitube® (ETC; Tyco-Kendall Company, Argyle, NY, USA), were compared to determine the incidence of GER and aspiration associated with their use. The incidence of GER and regurgitation with use of the LMA has been reported,[1,3] however, it has yet to be determined with the use of the ETC. Since the ETC has an esophageal balloon, we postulated that the ETC may be more protective than the LMA against possible aspiration.

Materials and methods

The study was performed at Memorial Hermann Hospital, the main teaching hospital for The University of Texas Medical School at Houston. Following approval by the Institutional Review Board and written informed consent, 57 adult patients with ASA physical status I to III were randomly assigned to receive either a LMA (28 patients) or an ETC (29 patients). A block randomization schedule was generated by computer. Patients with a history of GER, hiatal hernia, previous esophageal or gastric surgery, anticipated difficulties with airway management and those receiving medications affecting the gastric pH (e.g., H2-antagonists) were excluded from the study. All intubations and pH probe placements were performed by either an attending anesthesiologist or an anesthesiology resident who were familiar with the protocol and were instructed with the use of the devices.

All patients received general anesthesia and were paralyzed. Induction of general anesthesia was performed with propofol 2 $mg \cdot kg^{-1}$, fentanyl 1 $\mu g \cdot kg^{-1}$ and rocuronium 0.6 $mg \cdot kg^{-1}$ *iv*. Anesthesia was maintained with oxygen (33%), nitrous oxide (66%), and one minimum alveolar concentration inhaled concentration of isoflurane. Fresh gas flow was set at 2 $L \cdot min^{-1}$. Additional doses of fentanyl (1–2 $\mu g \cdot kg^{-1} \cdot hr^{-1}$) and rocuronium, to maintain a single twitch on train-of-four, were administered throughout the duration of the surgery. All patients were ventilated with facial masks during the induction of anesthesia and following the insertion of the pH electrodes. Following completion of the surgical procedure, muscle relaxation was antagonized with neostigmine (0.07 $mg \cdot kg^{-1}$ *iv*, max 5 mg). Emergence procedures were standardized, such that all patients were allowed to breathe spontaneously and wake up with either device in place.

In patients randomized to the LMA group, a size 3 LMA was used in women weighing < 70 kg and a size 4 was used in men and in women who weighed > 70 kg. At the time this study was conducted, size 5 LMAs were not available at our institution. Once placed, the size 3 and 4 LMAs were inflated with 20 and 30 mL of air, respectively.[4] Additional air was added or removed from the LMAs' cuffs in order to obtain a seal, if necessary. In the patients in the ETC group, the larger size ETC was used in patients who were > 180 cm tall and the short adult (SA) ETC was used in all others. Although 100 mL of air and 85 mL of air are recommended for inflation of the large latex cuff by the manufacturer, we inflated the cuff with just enough air to create a seal to deliver tidal volumes of 10 to 15 $mL \cdot kg^{-1}$ without an audible gas leak around the air-filled cuff of the LMA or around the proximal balloon of the ETC, as recommended in current literature.[5,6] The volume of air injected into the distal cuff was 15 mL and 12 mL, respectively. Satisfactory placement of either device was determined by one of the authors, as evidenced by effective gas exchange assessed by pulse oximetry (> 95%), capnography (end-tidal carbon dioxide pressures < 50 mmHg), and the ability to achieve tidal volumes (10–15 $mL \cdot kg^{-1}$). Topical anesthetics were avoided due to their possible influence on the pH.[7]

Two Zinetics 24 ME™ multi-use monocrystalline antimony pH catheters with external reference (Medtronic Functional Diagnostics, Shoreview, MN, USA) were used for pH monitoring: a unipolar catheter with a single pH sensor for tracheal pH measurement and a bipolar catheter with proximal and distal sensors for pharyngeal and esophageal pH measurements, respectively. In the LMA group, both catheters were placed orally with the aid of a rigid laryngoscope allowing visual confirmation of their correct positioning. The unipolar catheter was advanced into the trachea 5 cm below the vocal cords. The bipolar catheter was placed into the esophagus in such a manner that the distal sensor was located 5 cm below the entrance to the esophagus and the proximal sensor was located in the hypopharynx. The sensors are exactly 20 cm apart from one another. The LMA was inserted following the placement of these catheters. In the ETC group, the unipolar catheter was placed into the trachea 5 cm below the vocal cords under visual guidance with a rigid laryngoscope. The bipolar probe was taped to the side of the ETC so that the distal tip of the catheter extended approximately 1 mm from the end of the ETC and the proximal site was located midline between the two cuffs of the device, at the level of the perforations in the esophageal or #2 lumen (Figure 1). The ETC was inserted following placement of the unipolar catheter.

Simultaneous pH recordings were performed in the esophagus, hypopharynx and trachea with the use of a Medtronic Medical Digitrapper Mk III recorder (Medtronic Functional Diagnostics, Shoreview, MN, USA). The recorder was calibrated to a pH of 1.01 and 7.01 prior to each use. These three sites were monitored continuously throughout the administration of general anesthesia with the pH recorded every four seconds. In some patients, sensors were temporarily disconnected from the recorder in order to avoid possible complications related to the use of surgical electrocautery. Artifacts due to this disconnection were eliminated from the data analyses. The catheters were removed simultaneously with removal of either airway device.

GER was defined as an episode of esophageal pH below 4.0 with a duration of at least 15 sec.[7] Aspiration was defined as an episode of tracheal pH below 4.0 that lasted at least 15 sec or the development of clinical signs of aspiration, such as coughing or wheezing, a decrease in oxygen saturation in excess of 10% from the preoperative value on room air, or radiographic abnormalities within two hours of aspiration. A chest *x-ray* was obtained on any patient who experienced a decrease in tracheal pH< 4.0 and in any patient who vomited. We did not measure arterial blood gases or directly examine the tracheo-bronchial tree. Analyses of the pH data were performed with Polygram Function Testing Software for Windows, Esophogram Reflux Analysis Module (Version 2.0, Medtronic Synectics, Shoreview, MN, USA) and the statistical analyses were performed with the aid of the Microsoft excel spreadsheet. Data are presented as mean, range and one standard deviation from the mean. Student's two-tailed two-sample t test was performed for determination of significance of difference in pH values between the LMA and the ETC groups.

The sample size calculations were based on a suspected incidence of pulmonary aspiration associated with the use of a standard LMA (approximately two per 10,000 cases)[8] and it is commonly only used when the regurgitation risk is judged to be low, as in this study. A Fisher's exact test with a 0.05 two sided significance level has 80% power to detect a meaningful difference of 50% from the LMA prevalence rate of 0.02% requires a sample size of approximately 410,000 patients in each group (Statistical Analysis System, SAS Corp., Cary, NC, USA). Thus, this study serves as a pilot study with only 25 patients in each group.

Results

Demographic characteristics between the two groups (LMA and ETC) were similar: age 38 ± 12 and 39 ± 12 yr (SD), respectively; sex (male:female ratios 14:11 and 10:15, respectively); and weight [75 ± 20 kg and 83 ± 14 kg (SD), respectively]. The types of surgical procedures performed in these patients are listed in Table I. In all patients, the hemodynamic and respiratory variables remained stable throughout the period of measurement (data not included). Seven patients were excluded from the data analyses (Table II).

There was no difficulty in placing the LMA or the ETC. The ETC was placed into the esophagus 90% of

TABLE I Categories of surgical procedures

Surgical procedures	*LMA*	*ETC*
General surgery	2	3
- Excision abdominal wall lipoma	0	1
- Hernia repair	2	0
- Renal biopsy	0	1
- *sc* breast dissection	0	1
Gynecologic	5	12
- Laparoscopic bilateral tubal ligation	1	6
- Dilatation and curretage	1	0
- Pubovaginal sling	0	1
- Hysterectomy	2	3
- Uterine balloon thermal ablation	1	2
Orthopedic	11	7
- Knee arthroscopy	6	1
- Irrigation and debridement	1	1
- Open anterior cruciate ligament repair	0	1
- Open reduction, internal fixation	2	3
- Removal external fixator	1	0
- Reimplantation of digits	1	0
- Rotator cuff repair	0	1
Plastic	5	1
- Irrigation and debridement	2	1
- Revision and advancement of free flap	1	0
- Split thickness skin graft	1	0
- Ulnar nerve transposition	1	0
Neurosurgical	1	0
- Ventriculoperitoneal shunt	1	0
Urologic	0	2
- Cystoscopy and retrograde pyelogram	0	1
- Ureteroscopy	0	1
Vascular	1	0
- Arteriovenous fistula ligation	0	1
Total	25	25

LMA = laryngeal mask airway; ETC = Esophageal Tracheal Combitude™.

TABLE II Patients that were excluded from the study

Cause	*LMA*	*ETC*
Interference of surgical electrocautery with pH recording	2	2
Inability to transfer pH data to computer	1	0
Bleeding resulted from manipulation of device	0	1
Nausea/vomiting before placement of airway device	0	1
Total	3	4

LMA = laryngeal mask airway; ETC = Esophageal Tracheal Combitude™.

TABLE III Average values of lowest pH detected during pH recording

	Esophagus		*Hypopharynx*		*Trachea*	
	LMA	*ETC*	*LMA*	*ETC*	*LMA*	*ETC*
Average lowest pH ± SD	5.3 ± 0.5	5.0 ± 0.8	5.3 ± 0.7	5.7 ± 0.7	4.6 ± 0.8	5.2 ± 1.0†
# patients with decline pH < 4.0 before/ after placement of airway device	0/0	0/1	0/0	0/0	2/3	2/1
# patients with GER	0	1	N/A	N/A	N/A	N/A

†$P < 0.05$. GER = episode of esophageal pH < 4.0 with a duration of at least 15 sec; LMA = laryngeal mask airway (25 patients); ETC = Esophageal Tracheal Combitube™ (25 patients); N/A = not applicable.

TABLE IV Patients with decrease of tracheal pH < 4.0 after the placement of either airway device

	LMA	*LMA*	*LMA*	*ETC*
Time after placement of device and detection of pH < 4.0*	719	185	40	124
Duration of episodes*	15	175	68	132
Lowest tracheal pH value	3.6	3.9	3.3	3.8

LMA = laryngeal mask airway; ETC = Esophageal Tracheal Combitude™. *Time in seconds.

the time. In three patients, the first attempt at placement of the ETC resulted in tracheal intubation. The ETC was removed and reinserted with the aid of a rigid laryngoscope resulting in esophageal placement in two of these patients. In one of these patients, further manipulations with the ETC resulted in minor trauma of the oropharynx, as evidenced by some bleeding. As a result of this complication, no further attempts were made to place the ETC and the airway was secured with an endotracheal tube. This patient was excluded from the study.

Regarding the ETC (adult size), the average volume required to fill the proximal and distal balloons was 101.3 ± 20.7 (SD) and 14.1 ± 2.2 (SD) mL of air, respectively. Regarding the ETC (small adult size), the average volume required to fill the proximal and distal balloons was 93.8 ± 17.6 (SD) and 11.6 ± 1.8 (SD) mL of air, respectively. There was no audible gas leak in any patient. Oxygen saturation remained above 95% in all patients. The average end-tidal carbon dioxide pressures in the LMA group was 34.8 ± 4.5 (SD) mmHg, whereas it was 37.5 ± 8.8 mmHg in the ETC group ($P = 0.178$). Peak airway pressures ranged from 19.1 ± 4.0 (SD) cm H_2O in the LMA group to 31.2 ± 8.5 (SD) cm H_2O in the ETC group ($P < 0.0001$). Positive end-expiratory pressures (PEEP) of ≤ 5 cm H_2O and 10 to 15 $mL \cdot kg^{-1}$ tidal volumes were observed in all patients.

The averages of lowest pH values in the esophagus, the hypo-pharynx and the trachea are presented in Table III. A decrease in tracheal pH < 4.0 was evident in eight patients (five out of 25 patients in the LMA group and three out of 25 patients in the ETC group; Table III). Four out of these eight patients (two with the LMA and two with the ETC) had this episode of low pH after induction of general anesthesia and before the placement of the airway device, as evidenced by the decreased pH values immediately upon placement of the pH electrodes (average pH 3.6 ± 0.3 SD with a range of 3.1–3.8). These episodes lasted from 25 to 407 sec. The other four patients (described in Table IV: three with the LMA and one with the ETC) had a decrease in tracheal pH < 4.0 following the placement of the pH probes and the airway device. However, average esophageal and hypopharyngeal pHs of these eight patients were 5.2 ± 0.5 (SD) with

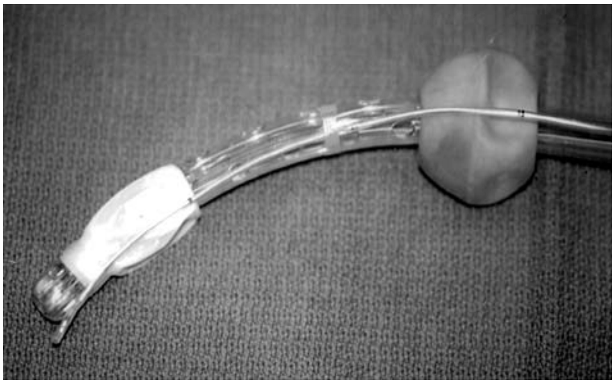

FIGURE 1 The bipolar probe was taped to the side of the Combitube so that the distal end of the catheter extended approximately 1 mm from the end of the Combitube and the proximal site was located between the two cuffs, at the level of the perforations in the esophageal or #2 lumen.

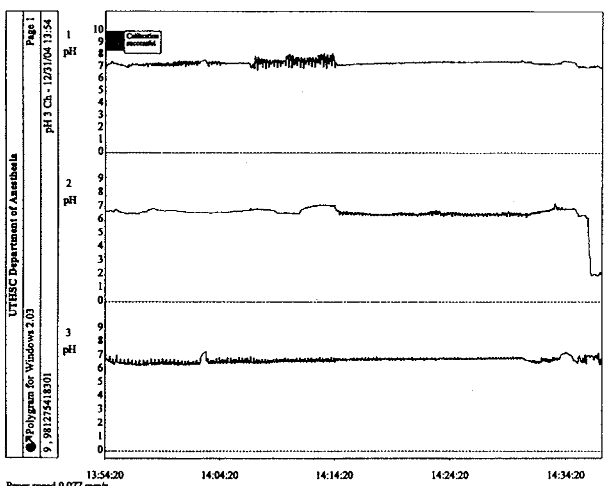

FIGURE 2 Decline of esophageal pH value (middle tracing) without a simultaneous decline of pH values in the hypopharynx or trachea in a patient with ETC (Esophageal Tracheal Combitude™; pH 1 = tracheal pH, pH 2 = esophageal pH, pH 3 = hypopharyngeal pH).

a range of 4.5 to 5.9, and 5.6 ± 0.7 (SD) with the range of 4.5 to 6.7, respectively. No patient developed any clinical symptoms or signs of aspiration. All chest *x-rays* obtained were reported normal.

Four patients (one with the LMA and three with the ETC) developed nausea and vomiting on emergence from anesthesia. One patient vomited through the esophageal lumen of the ETC resulting in an esophageal pH decline to 1.9 without a simultaneous decline of pH values in the hypopharynx or the trachea (Figure 2). The other three patients vomited immediately after removal of the device (one with the LMA and two with the ETC).

Discussion

Endotracheal intubation with an endotracheal tube is the gold standard for securing and managing the airway. In an emergency situation in which a "cannot ventilate and cannot intubate" condition occurs, the LMA and the ETC (two supraglottic ventilatory devices) may be used to effectively provide acceptable ventilation and oxygenation.

We did not detect any clinical signs of aspiration in any patient. However, the detection of a pH lower than 4.0 in the trachea of four patients after the insertion of LMA or ETC may be enough evidence of micro-aspiration of acidic gastric fluid.[9] Inability to detect a decrease in pH in the esophagus or hypopharynx does not negate the possibility of aspiration. Bypass of gastric fluid by these pH probes may have occurred as a result of a gap between the probes and the adjacent mucosa. In one patient, active vomiting occurred, which was reflected in a major pH drop recorded with the esophageal probe at emergence from general anesthesia (Figure 2). In this case, the ETC appears to have protected the tracheobronchial tree from aspiration (no clinical signs of aspiration, and no decline of tracheal or hypopharyngeal pHs).

Placement of either the LMA or ETC is a blind procedure unless direct laryngoscopy is used for facilitation. Although there are no uniform guidelines to evaluate the proper placement of the LMA, the 1998 LMA instruction manual for the United States lists the signs of correct placement of the device.[10] Joshi *et al.* compared outcomes of nine clinical tests in order to determine correct anatomical LMA placement.[4] They found that the two tests that best correlated with correct placement were the ability to generate airway pressures of 20 cm of water and the ability to ventilate manually.[4]

The ETC is usually inserted blindly with the head of the patient in the neutral position, which makes it helpful in those patients with cervical instability. Mercer and Gabbott obtained adequate ventilation with an ETC in 40 patients with immobilized cervical regions.[11] We placed the ETC blindly according to the manufacturer's recommendations. In three cases the initial placement of the device resulted in tracheal intubation. Subsequent reinsertion of the ETC was made with the aid of a rigid laryngoscope in order to place the device into the esophagus for esophageal pH measurements.

We used ventilatory variables and oxygenation as criteria for the correct placement of either airway device. The correct placement of the pH probes was assured visually via the use of a rigid laryngoscope. The probes did not appear to impair the ability for either device to form a seal. Acceptable oxygenation and ventilation was obtained with either device, however higher peak airway pressures were observed, and in some cases higher ventilatory rates, were utilized with the ETC. This effect may be due to an increase in expiratory resistance because of the ETC's double-lumen design and the eight small ventilatory openings, which may favour the formation of a small PEEP.[12,13] Although we did not perform arterial blood gas analysis, it has previously been demonstrated that the prolonged expiratory flow time and auto PEEP together improve conditions for alveolar-arterial gas exchange.[13]

It has been reported previously that a patient with a cervical fracture in whom an ETC had been utilized for elective establishment of an airway, actively vomited 200 mL of gastric fluid through the esophageal lumen of the ETC upon emergence from general anesthesia. These authors deliberately chose not to utilize a LMA in this patient since he was considered a "full stomach," and the LMA-Classic™ does not protect the tracheobronchial tree from contents of the gastrointestinal tract.[14] Reduction of the volume of gastric fluid before extubation may decrease the incidence of vomiting during emergence from general anesthesia. Reduction of gastric contents can effectively be performed by suctioning gastric contents through the esophageal lumen of the ETC.

In a meta-analysis in 1995, Brimacombe and Berry looked at 547 LMA publications, which used various anesthetic techniques for evidence of pulmonary aspiration and found that the incidence was only two in 10,000 (0.02%).[8] In a large survey of LMA usage, Verghese and Brimacombe found that a slightly higher percentage of critical airway incidents occurred in patients undergoing positive pressure ventilation compared with spontaneous ventilation (0.21% *vs* 0.11%) through the LMA,[1] but the difference did not reach statistical significance. The incidence of proven aspiration using the LMA was 0.009%. There is no such reporting with use of the ETC. Our study is limited by a small patient population. The number of patients studied is, obviously, insufficient to exclude a type II error. A study would need to include over 400,000 patients in each group to observe a meaningful difference of 50% in the incidence of pulmonary aspiration.

Thus, this study serves only as a pilot study on the incidence of GER and acid aspiration with these two devices. A large prospective, randomized study comparing the LMA and the ETC to other devices designed to provide protection from fluid regurgitation,[15,16] such as the ProSeal™ LMA (PLMA; LMA North America, San Diego, CA, USA) or the Laryngeal Tube® (LT; King Systems, Noblesville, IN, USA) regarding regurgitation and aspiration would be beneficial. One technique may prove to be more favourable than another in patients at high risk for regurgitation and aspiration.

The ASA difficult airway algorithm[2] does not specify exactly which device/technique should be utilized in the cannot intubate/cannot ventilate situation, but rather lists LMA ventilation, ETC ventilation and transtracheal jet ventilation, prior to the performance of a surgical airway. It is left to the anesthesia care provider's discretion. It has been expressed that although the ETC is included as an option in the algorithm, most anesthesiologists have little experience with the use of this device. Because the development of skills requires practice, many anesthesiology residency training programs, both national and international, have developed an airway rotation to maximize exposure to different devices and techniques.[17] Nonetheless, the ETC was only utilized in half of the programs with such a rotation,[18] thus perpetuating the lack of experience with this device. Fortunately, the ETC is relatively easy to place. We found a first pass success rate of 90%, similar to that reported by Winterhalter *et al.*,[19] who found that physicians unskilled in emergency medicine preferred the ETC as a nonsurgical alternative to cricothyrotomy, over the LMA. Both devices caused minimal complications including minor airway trauma, as evidenced by blood on the device following removal, and coughing upon emergence and extubation. As evident in Table I, more patients in the ETC group underwent gynecological procedures (50% laparoscopic bilateral tubal ligation procedures), as compared to the LMA group, which may explain the fact that more patients developed nausea and vomiting with the use of the ETC. A larger study may better delineate whether there is a significant difference in the complication rates.

In summary, our pilot study shows that both airway devices are comparable in regards to the incidence of GER and micro-aspiration. Further study, involving a very large patient population, would provide interesting evidence-based information on the risk of GER and acid aspiration with these devices.

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