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Original contribution

Gastroesophageal regurgitation during anesthesia and controlled ventilation with six airway devices☆

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Abstract

Study Objective: To investigate the frequency of gastroesophageal regurgitation and respiratory mechanics during positive pressure ventilation using 5 supraglottic devices or an endotracheal tube (ETT).
Design: Prospective, randomized study.
Setting: Operating rooms in a university-affiliated hospital.
Patients: 180 ASA physical status I and II patients, aged 18 to 65 years old, who underwent elective orthopedic, minor vascular, peripheral plastic, or urologic surgery during general anesthesia.
Interventions: Patients were randomly allocated to one of 6 airway device groups (n = 30 each): (1) Cobra Perilaryngeal Airway; (2) Laryngeal Mask Airway (LMA) Classic; (3) LMA Fastrach; (4) LMA ProSeal; (5) laryngeal tube; and (6) ETT (SIMS Portex, Ltd, Hythe, Kent, UK). After insertion of the designated device, the lungs of each nonparalyzed patient were mechanically ventilated.
Measurements: Hypopharyngeal pH, peak inspiratory pressures, sealing pressures, and lung compliance were measured. Hypopharyngeal pH lower than 4 was considered a regurgitation event.
Main Results: Regurgitation (episodes of pH <4) occurred in between one and 5 patients of each study group, with no statistical difference. Sealing pressures were similar among all the airway device groups.

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Conclusions: The frequency of gastroesophageal regurgitation in anesthetized, unparalyzed, mechanically ventilated patients was similar in patients whose lungs were ventilated with either the Cobra Perilaryngeal Airway, LMA Classic, Fastrach, ProSeal, laryngeal tube, or ETT.

1. Introduction

Technical advances over the past few decades have been made with new airway devices [1-8]. The ASA Difficult Airway Algorithm recommends using some of these airway devices (Laryngeal Mask Airway [LMA] Classic and Combitube) in a failed intubation/ventilation scenario [9].

The disadvantages of using supraglottic airway devices over the endotracheal tube (ETT) for controlled ventilation during anesthesia include lack of airway protection against pulmonary aspiration of gastric contents [9-12]; difficulty in ventilating patients' lungs because of malposition, air leak, or decreased chest/lung compliance [13,14]; and risk of gastric distension as a result of high inspiratory airway pressures [14,15]. The frequency of gastroesophageal regurgitation in paralyzed anesthetized patients may be as high as 80% [16]. Recently, Hagberg et al [17] showed a similar frequency of regurgitation episodes with the Combitube (Covidien, Ltd, Mansfield, MA) and the LMA (Intavent Orthofix, Ltd, Maidenhead, UK). Yet, few reports have evaluated the incidence of regurgitation with supraglottic devices such as the laryngeal tube (VBM Medizintechnik, GmbH, Sulz, Germany) or the Cobra Perilaryngeal Airway (CobraPLA; Engineered Medical Systems, Indianapolis, IN). Furthermore, few studies have compared the frequency of regurgitation among more than two supraglottic devices.

Regurgitation and pulmonary aspiration also may occur, even with a correctly positioned ETT [10]. For example, when dye was used as an indicator of regurgitation and aspiration in anesthetized patients, the frequency of dye leakage around the ETT cuff was 11% with lubricated cuffs and as high as 83% with unlubricated cuffs [10]. We thus compared the frequency of regurgitation in patients whose lungs were mechanically ventilated with one of 6 different airway devices.

2. Methods and materials

After obtaining E. Wolfson Medical Center (Holon, Israel) institutional review board approval and each patient's written, informed consent, we studied 180 ASA physical status I and II patients, aged 18 to 65 years, who underwent elective orthopedic, minor vascular, plastic, or urologic surgery. Patients were excluded from the study if they were at risk of pulmonary aspiration of gastric contents as a result of gastroesophageal reflux disease, full stomach, morbid obesity (body mass index >35 kg/m^2), or hiatal hernia. Also excluded were patients known to be difficult to intubate or having gross anatomical airway abnormalities, receiving drugs affecting gastrointestinal (GI) motility, receiving proton pump inhibitors or H_2 antagonists, and/or those undergoing surgery in positions other than supine.

2.1. Protocol

Patients were randomly allocated to one of the 6 airway devices, with each group comprising 30 patients. Randomization was based on computer-generated codes. We expected minimal patient pH values for each device to have an SD of about 1.3; thus, with 30 patients per group, we would have 90% power for a difference in minimal pH of 1.1 between devices. The 6 airway devices we used were the (1) CobraPLA, (2) LMA (LMA Classic; Intavent Orthofix, Ltd), (3) LMA Fastrach (Intavent Orthofix, Ltd), (4) LMA ProSeal (Intavent Orthofix, Ltd), (5) laryngeal tube (Model LT, VBM Medizintechnik), and (6) ETT (SIMS Portex, Ltd, Hythe, Kent, UK). The participating anesthesiologists were skilled, each having performed over 20 insertions with each device.

Patients fasted for at least 8 hours, and all underwent elective surgery. Brotizolam 0.25 mg, a short-acting benzodiazepine, was given sublingually as preoperative medication 30 minutes before surgery. After preoxygenation, anesthesia was induced with 0.02 mg/kg midazolam, 2.5 mg/kg propofol, and one μg/kg fentanyl. For tracheal intubation, rocuronium 0.6 mg/kg was given. After loss of eyelash reflex and jaw relaxation, usually in 30 to 40 seconds, the designated airway was inserted and the cuff inflated according to the manufacturer's instructions. For 30 to 40 seconds, patients' lungs were manually ventilated; care was taken to maintain peak inspiratory pressure (PIP) at less than 20 cmH_2O. If necessary, an additional dose of propofol, one mg/kg, was administered, and airway insertion was reattempted. Fresh gas flow was maintained at three L per minute.

The sealing (leak) pressure for each device, except the ETT was measured by closing the adjustable pressure-limiting valve and waiting until an audible air leak was heard by stethoscope over the suprasternal notch. To check sealing pressures, we inflated the cuffs of the supraglottic devices to 60 cmH_2O. In any case, a leak at a PIP of less than 30 cmH_2O was sought. After checking sealing pressures, we then decreased the risk of mucosal injury by reducing the volume

in each cuff until a leak was present at an inspiratory pressure of less than 20 cmH_2O. The ETT cuff was inflated with air until no audible leak was detected (to a pressure of 25-30 cmH_2O). A low-pressure monitor (VBM Medizintechnik) was used to measure the cuff pressure of all the devices.

After inserting the device, the anesthesiologist assessed ventilation by confirming normal chest movement and capnography. If adequate ventilation was not possible after three attempts, the trachea was intubated and the patient was excluded from the study.

Anesthesia was subsequently maintained with 0.5% to 1.5% end-tidal concentration of isoflurane, 60% nitrous oxide (N_2O) in oxygen, and fentanyl, one mg/kg,, every 30 minutes. No intraoperative muscle relaxants were given. Positive pressure ventilation (PPV) was maintained at a tidal volume of 10 mL/kg ideal body weight and a respiratory rate of 12 breaths per minute. At the end of surgery, the device was removed after the patient regained consciousness and was able to respond to verbal commands.

2.2. Measurements

We used nondisposable antimony catheters with external reference electrode (Medtronic Functional Diagnostics, Inc, c/o Medtronic, Inc, Minneapolis, MN) to monitor pH. Electrodes were calibrated in standard buffer solutions having a pH of 1.07 and 7.01 (Medtronic Buffer Solutions; Medtronic, Inc). All pH probes were inserted immediately after induction of anesthesia and before placing the airway device; patients were placed in the supine position. The pH probe was introduced transnasally below (posteriorly to) the vocal cords, in the vicinity of the upper esophagus, via direct laryngoscopic vision, and secured at the nostrils with tape.

Hypopharyngeal pH was monitored throughout surgery. All information was kept on a computerized data logger (Medtronic Mark II; Medtronic, Inc) and analyzed with special software (EsoPHogram, version 5.60C4; Medtronic, Inc). Interpretation and calculation of acid exposure were made with Synectics Medical software (Esophogram, version 5.60C4; Synectics, Stockholm, Sweden).

Regurgitation episodes were defined as a hypopharyngeal pH less than 4, and then they were tabulated manually. The pH was measured 8 times per minute; our monitor had an accuracy of 0.1 pH units over the relevant physiologic range. The proportion of time when pH is less than 4 is the acid exposure time. Oscillations around pH 4 were considered a regurgitation episode if they lasted longer than 5 seconds.

The number of patients with episodes of pH less than 4 and the minimal pH value were determined for each device. Two independent investigators, who were blinded to the airway device used, analyzed all the pH data.

Peak, mean, and plateau inspiratory pressures, inspiratory and expiratory minute volumes, lung resistance, and lung compliance were recorded with the Datex AS/3 anesthesia monitor (Datex, Helsinki, Finland) after insertion of each device and 15 minutes thereafter. Oxygen saturation via pulse oximetry (Spo_2) and end-tidal carbon dioxide were recorded at the same time. Gastric insufflation was monitored by epigastric auscultation (after device insertion and every 15 min thereafter) during mechanical ventilation.

The number of airway manipulations, that is, chin lift, jaw thrust, head/neck extension or tilt, required for maintaining effective ventilation, the number of failed insertion attempts, and complications were also recorded.

2.3. Statistical analysis

Data were analyzed with analysis of variance (ANOVA) for continuous variables or χ^2 analysis for categorical variables. For a significant ANOVA, Tukey's range post test was used to determine which groups were statistically different. For sparse categorical outcomes, Fisher's exact test was used. Results are expressed as means ± SD, counts, or

Table 1 Morphometric characteristics of 180 patients receiving general anesthesia using 5 supraglottic devices or an endotracheal tube (ETT)

Airway device	Cobra, n = 30	LMAC, n = 30	Fastrach, n = 30	ProSeal, n = 30	Laryngeal tube, n = 30	ETT, n = 30
Age (yrs)	42 ± 19	45 ± 12	42 ± 13	45 ± 15	43 ± 17	41 ± 15
Men/women (n)	15/15	16/14	17/13	19/11	20/10	17/13
BMI	26 ± 2	26 ± 3	26 ± 3	26 ± 3	26 ± 3	26 ± 2
Duration of surgery (min)	35 ± 9	38 ± 10	37 ± 9	38 ± 10	38 ± 10	37 ± 10
Mallampati score (1/2/3)	28/2/0	25/5/0	25/4/1	24/4/2	20/8/2	28/2/0
TMD <6 cm (n, %)	0 (0)	1 (3)	0 (0)	5 (17)	3 (10)	0 (0)
Mouth opening <4 cm (n, %)	0 (0)	0 (0)	0 (0)	4 (13)	5 (17)	0 (0)
Limited neck movement (n, %)	0 (0)	1 (3)	2 (7)	1 (3)	2 (7)	0 (0)
Abnormal upper teeth (n, %)	3 (10)	4 (13)	5 (17)	5 (17)	6 (20)	0 (0)

Data presented as means ± SD, numbers of patients, or percentages of group.
Cobra = CobraPLA (Engineered Medical Systems); LMAC = LMA Classic (Intavent Orthofix, Ltd); Fastrach = LMA Fastrach (Intavent Orthofix, Ltd); ProSeal = LMA ProSeal (Intavent Orthofix, Ltd); laryngeal tube (VBM Medizintechnik); ETT (SIMS Portex).; BMI = body mass index; TMD = thyromental distance.

Table 2 Univariate analysis of pH and ventilation variables among 180 patients during general anesthesia using 6 supraglottic devices or an endotracheal tube (ETT)

	Cobra n = 30	LMAC n = 30	Fastrach n = 30	ProSeal n = 30	Laryngeal tube n = 30	ETT n = 30	*P*
pH							
Patients with episodes of pH <4 * (n, %)	2 (7)	5 (17)	4 (13)	4 (13)	4 (13)	1 (3)	0.563
Average minimal pH †	5.1 ± 0.9	5.2 ± 1.4	5.5 ± 1.4	5.6 ± 1.3	5.4 ± 1.3	5.7 ± 1.3	0.530
Sealing pressure (cmH_2O)	26 ± 3	26 ± 3	26 ± 2	28 ± 4	27 ± 2	–	0.180
PIP (cmH_2O)							
After insertion	22 ± 7[a]	22 ± 8[a]	20 ± 4[a,b]	22 ± 5[a]	18 ± 3[b]	22 ± 7[a]	0.049
15 min	22 ± 8	21 ± 7	21 ± 4	22 ± 4	18 ± 5	20 ± 6	0.122
Compliance (mL/cmH_2O)							
After insertion	39 ± 16	38 ± 17	45 ± 13	44 ± 12	47 ± 16	45 ± 18	0.187
15 min	40 ± 16	38 ± 15	44 ± 13	42 ± 13	44 ± 15	44 ± 15	0.404

Data presented as means ± SD or episodes of pH less than 4.
Groups with the same superscript (a, b) are statistically the same according to Tukey's post test or Fisher's exact test.
Cobra = CobraPLA (Engineered Medical Systems); LMAC = LMA Classic (Intavent Orthofix, Ltd); Fastrach = LMA Fastrach (Intavent Orthofix, Ltd); ProSeal = LMA ProSeal (Intavent Orthofix, Ltd); ETT (SIMS Portex); PIP = peak inspiratory pressure; after insertion = immediately after the insertion of the airway device; 15 min = 15 minutes after insertion of device.
* Number of patients who had episode(s) of pH lower than 4.
† Each patient's minimal pH averaged for each group.

percentages. A *P* value less than 0.05 was considered statistically significant.

3. Results

Based on our sample size estimate, we enrolled 180 patients, or 30 patients per group. Demographic characteristics were similar in each group of patients (Table 1). None of the patients coughed or bucked during device insertion. There were no insertion failures, and no patients were excluded from statistical calculation because a device could not be placed after three attempts. None of the patients coughed or showed respiratory efforts at any time during PPV.

As shown in Table 2 and Fig. 1, no more than 5 patients had a regurgitation episode with any of the other devices ($P = 0.022$). We found no time correlation between regurgitation episodes and stages of anesthesia or surgery. The minimal pH ranged between 1.5 with the ETT and 3.8 with the CobraPLA. As for patients with multiple episodes of pH less than 4, one CobraPLA patient airway had 4 episodes, whereas another patient had three. Two patients from the LMA ProSeal group had two episodes of pH less than 4, and one LMA Classic group patient had 14 episodes, whereas another had three episodes. A lower minimal pH was not associated with a higher number of regurgitation episodes (ie, number of episodes of pH <4) or aspiration of gastric contents.

The cuff sealing pressures were slightly higher with LMA ProSeal than the LMA Classic (28 vs 26 cmH_2O), but this difference was not statistically significant. Respiratory variables were similar among the groups (Table 2). One 60-year-old woman, whose medical history showed no systemic diseases and no history of reflux or any other GI pathology, was managed with the CobraPLA for an orthopedic surgical procedure that lasted 70 minutes. Throughout the procedure and postoperatively, she had no episode of vomiting, regurgitation, retching, coughing, bronchospasm, or any other clinical signs suggestive of pulmonary aspiration. On the second postoperative day, the same patient complained of shortness of breath. Chest auscultation showed wheezing over the upper lung. Chest radiography showed right middle lobe infiltration, and

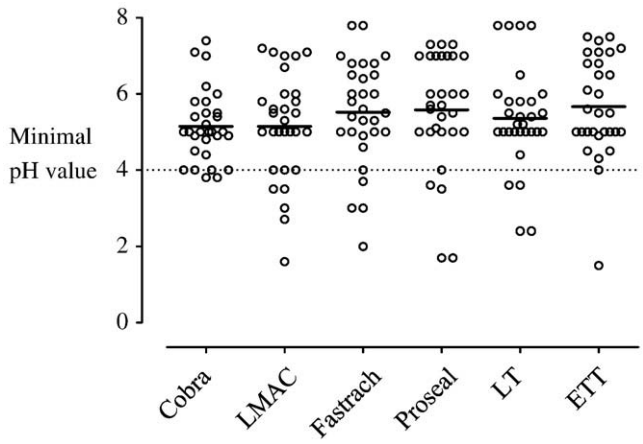

Fig. 1 The recorded minimal pH value for each patient in the 6 device groups. Cobra = CobraPLA (Engineered Medical Systems); LMAC = LMA Classic (Intavent Orthofix, Ltd); Fastrach = LMA Fastrach (Intavent Orthofix, Ltd); Proseal = LMA ProSeal (Intavent Orthofix, Ltd); LT = laryngeal tube (VBM Medizintechnik); and ETT (SIMS Portex). Vertical lines = group means. n = 30 for all groups.

Spo_2 was 90% on room air. There was no evidence of aspiration during the anesthesia. This patient had no episode of pH less than 4. The patient was given oxygen by mask, she inhaled β-2 agonists, and she underwent chest physiotherapy. Five days postoperatively, she recovered and was discharged home. Further workup on this patient showed the presence of a previously undiagnosed hiatal hernia.

4. Discussion

Previous studies on regurgitation and aspiration with supraglottic devices have concentrated on the LMA Classic. For example, Valentine et al [16] reported a 40% incidence of regurgitation with a peak of 80% during reversal of muscle relaxants in 10 anesthetized, paralyzed, and mechanically ventilated patients. Bapat et al [18] found no regurgitation in 100 paralyzed patients undergoing gynecologic laparoscopy, whose lungs were mechanically ventilated through an LMA Classic. Episodes of regurgitation also have been reported in numerous other studies with the LMA Classic [11,12,16] and the Combitube [17,19-24].

The inconsistency regarding occurrence of regurgitation among available LMA studies remains unclear. Furthermore, location of the pH electrode (esophagus or hypopharynx) or differences in the definition of regurgitation may have contributed to this debate. For example, Hagberg et al [17] used 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. Whether pH measurements are taken intermittently or continuously is an important factor. We thus used continuous measurements to avoid missing any regurgitation episodes.

Inadequate anesthetic depth, as evidenced by coughing or bucking on device insertion, may also influence the incidence of regurgitation. None of our patients coughed or bucked during airway manipulations or showed respiratory efforts at any time during PPV. Therefore, we believe we can exclude these causes of regurgitation in our patients.

Factors that might increase the likelihood of regurgitation and aspiration have been suggested to include urgent and emergency surgeries, airway problems, light anesthesia, depressed consciousness, and obesity. However, Maltby et al [25] found no difference in gastric emptying time between nonobese and obese patients with no comorbidities.

Interestingly, there is almost no information about regurgitation with the LMA Fastrach or laryngeal tube. However, there are reports of cases of pulmonary aspiration of gastric contents with the CobraPLA [26,27].

Furthermore, no study has directly compared these supraglottic airway devices with respect to regurgitation [8]. Our study helps clarify this issue by directly comparing 5 different supraglottic airways.

The possible reason that there was only one episode of regurgitation with ETT use may be the paucity of episodes of gastric insufflation during PPV with an ETT in place.

In contrast to other works [4], we found that the LMA ProSeal had almost similar sealing pressures as the other devices. Noteworthy are two recent studies in pediatric patients [28,29] that reported no significant differences in sealing pressure between the LMA Classic and LMA ProSeal. The differences may be explained by methodological issues. We do not believe that the leak test itself could produce regurgitation because the leak test was stopped immediately after a leak was heard by stethoscope placed over the suprasternal notch.

A limitation of our study is that our primary outcome was gastroesophageal regurgitation as detected by hypopharyngeal acid regurgitation rather than aspiration of gastric contents itself. However, regurgitation is assumed to be a harbinger of potential aspiration. N_2O might affect the frequency of regurgitation by increase in intragastric volume. All our patient groups received N_2O; thus, this factor could not have provoked differences among groups.

In summary, frequency of gastroesophageal regurgitation in anesthetized, nonparalyzed, mechanically ventilated patients was compared with 5 other supraglottic airway devices and an ETT. The frequency of pH less than 4 was lower in the other groups. These findings reemphasize the necessity for careful selection of anesthetized patients whose airways are managed with supraglottic devices.

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