Hemodynamic and Hormonal Stress Responses to Endotracheal Tube and ProSeal Laryngeal Mask Airway™ for Laparoscopic Gastric Banding

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ABSTRACT

Background: The stress responses from tracheal intubation are potentially dangerous in patients with higher cardiovascular risk, such as obese patients. The primary outcome objective of this study was to test whether, in comparison with the endotracheal tube (ETT), the Proseal™ Laryngeal Mask Airway (PLMA™) (Laryngeal Mask Airway Company, Jersey, United Kingdom) reduces blood pressure and norepinephrine responses and the amounts of muscle relaxants needed in obese patients.

Methods: We assessed hemodynamic and hormonal stress responses, ventilation, and postoperative recovery in 75 morbidly obese patients randomized to receive standardized anesthesia with either an ETT or the PLMA™ for laparoscopic gastric banding.

Results: In repeated-measures ANOVA, mean arterial blood pressure and plasma norepinephrine were significantly higher in the ETT group than in the PLMA™ group. In individual pairwise comparisons, blood pressure rose higher in ETT than PLMA™ patients after insertion and removal of airway devices, and after recovery. In ETT compared with PLMA™ patients, plasma norepinephrine was higher after induction of carboperitoneum (mean ± SD, 534 ± 198 and 368 ± 147 and pg/ml, $P = 0.001$), after airway device removal (578 ± 285 and 329 ± 128 pg/ml, $P < 0.0001$), and after recovery in postanesthesia care unit (380 ± 167 and 262 ± 95 and pg/ml, $P = 0.003$). Compared with use of the ETT, the PLMA™ reduced cisatracurium requirement, oxygen desaturation, and time to discharge from both the postanesthesia care unit and the hospital.

Conclusions: PLMA™ reduces stress responses and postoperative complaints after laparoscopic gastric banding.

What We Already Know about This Topic

- Insertion of a supraglottic airway induces less circulatory responses than tracheal intubation in nonobese patients
- No study has assessed advantages of the supraglottic airway for reducing perioperative stress responses in morbidly obese patients in whom use of the device is controversial

What This Article Tells Us That Is New

- In morbidly obese patients, use of the Proseal Laryngeal Mask Airway resulted in less hemodynamic and catecholamine responses during and after laparoscopic gastric banding surgery, and better postoperative course compared with tracheal intubation

OBESITY is becoming increasingly prevalent in developed countries and anesthesiologists will face larger numbers of obese patients undergoing bariatric surgery.[1] Obese body composition alters volumes of distribution and dosage requirements of lipid soluble drugs; regional-specific fat deposition may alter respiratory mechanisms and predispose to difficult airway.[2] Further, obesity is associated with important comorbidities (*i.e.*, diabetes mellitus, arterial and pulmonary hypertension, obstructive sleep apnea syndrome), which increase risk of perioperative complications.[2–4] In obese patients, the levels of catecholamines and cortisol are often increased and contribute to metabolic and vascular abnormalities.[4] Invasive tracheal intubation augments stress hormones with potential detrimental effects on coronary and cerebral circulations in patients at risk.[1,3,4] Supraglottic devices, such as the Laryngeal Mask Airway™ (LMA™) (Laryngeal Mask Airway Company, Jersey, United Kingdom), attenuate stress responses and respiratory morbidity and are therefore of interest for the obese patient population.[5–7]

The classic type of LMA (cLMA™) has a proven record of efficacy and safety in lean subjects, but has been seldom used in obese patients.[5] This is because cLMA™ is limited

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by providing an incomplete protection of upper airways against risk of aspiration and a limited range of positive pressure ventilation.[5] cLMA™ has been included in the algorithm for difficult intubation by several national societies. In obese patients, cLMA™ and other types of LMA™ have been used as a temporary ventilatory device before laryngoscope-guided tracheal intubation, and as an emergency device for unpredicted or predicted difficult intubations.[6–14] The Proseal™ Laryngeal Mask Airway (PLMA™, Laryngeal Mask Airway Company) is a newer type of LMA™ featuring a gastric drainage tube and higher sealing pressures, which provide an increased protection against aspiration.[6,7,15] PLMA™ has proven effective in elective urological, gynaecological, and abdominal surgery in obese patients.[7,15–19] Despite its potential advantage, the use of supraglottic devices in obese patients remains controversial and further studies can help to document their efficacy and safety profiles in this patient population.[5,18,19] Recently, for example, cLMA™ has been shown to improve early postoperative lung function and pulse oximetry saturation without complications in obese patients after minor surgery.[19,20] Given the potential benefits of PLMA™ over the endotracheal tube (ETT), we designed a double-blind, randomized study to examine whether insertion and ventilation with the PLMA™ compared with an ETT resulted in lesser elevation of arterial blood pressure and norepinephrine levels and lower consumption of muscle relaxant drugs in obese patients undergoing laparoscopic gastric banding (LGB).

Materials and Methods

Fifteen healthy subjects were recruited to obtain reference values for catecholamines and cortisol. Seventy morbidly obese patients (body mass index of 40 kg/m^2 or more) scheduled for elective LGB under general anesthesia were enrolled in the study. Ethical committee approval (Ethics Committee for Clinical Research, Padova Hospital Company, Padova, Italy) and written, informed consent were obtained (ISRCTN 18342801). Preoperatively, eligible patients were assessed with complete physical examination, and with routine blood tests (*i.e.*, red and leukocyte count, coagulation tests, liver and kidney function tests, blood glucose and creatinine, and urinanalysis), electrocardiogram, chest X-ray, and esophagogastroduodenoscopy. For each patient, the sleep apnea clinical score was calculated and, when available, a polysomnography-based diagnosis of obstructive sleep apnea syndrome was recorded.[21] At recruitment, exclusion criteria included: age less than 18 yr old; nonfasting; symptoms or endoscopic evidence of gastroesophageal reflux, of gastric ulcer, or oropharyngeal pathology; known or predicted difficult airway; allergy to anesthetic and nonsteroidal antiinflammatory drugs; or inability to provide informed consent. Later, patients were dropped from the study in case of difficult mask ventilation, difficult laryngoscopy (*i.e.*, max three attempts) or difficult or failed tracheal intubation, and in case of failure of placement of the gastric tube (GT). Patients were randomly allocated into two equal-sized groups: airway management, in one group, was with ETT, and, in the other, with a PLMA™. Randomization was achieved using computer-generated numbers and allocation by opening a sealed opaque envelope immediately before surgery by one investigator (UF). Two individuals with extensive prior experience using the PLMA™ (more than 5,000 uses) randomly performed airway management and anesthesia maintenance. The same bariatric surgeon (MF), blinded to airway device used, performed surgery in all patients. A single investigator was dedicated to store and analyze the blood samples (WG). Postanaesthesia care unit (PACU) nurses were unaware of the airway device used. A second single trained observer, also blind to the airway device used, documented the adverse events until discharge of patient in the surgical ward after the surgery.

All patients were instructed to fast for 8 h before surgery and to continue taking their usual medications, including β-blockers and Ca^{2+}-channel blockers and with the exception of insulin and oral antidiabetic agents, until the time of surgery.[2] Patients were premedicated with intravenous administration of midazolam 0.05 mg/kg ideal body weight (IBW) and of ranitidine 50 mg. Standard monitoring was employed before premedication. All patients had heart rate and pulse oximetry (Spo_2) measured continuously and arterial blood pressure at 5-min intervals with blood pressure cuffs (Critikon™ Blood Pressure Cuffs; General Electric Healthcare, Milano, Italy) with appropriated size (*i.e.*, adult and large adult with 23–33- and 31–40-cm arm circumference). The patients also had inspiratory and expiratory end-tidal gas concentrations (*i.e.*, oxygen, air, carbon dioxide and sevoflurane) and the adductor pollicis train-of-four ratio (TOFR) monitored (NeuroMuscular Transmission Module and MechanoSensor; Aisys GE Healthcare, Datex-Ohmeda, Milano, Italy). A self-adhesive entropy sensor was positioned on the forehead as recommended by the manufacturer and connected to E-Entropy™ Module for an AM™ anesthesia monitor (GE Healthcare, Datex-Ohmeda). The sampling rate of raw electroencephalogram was 400 Hz. Moving, frequency-related time windows for spectral entropy calculations were 15–60 s for state entropy and 2–5 s for response entropy. Entropy values were automatically recorded at 1-min intervals onto the computer. Rate-pressure product (RPP) was calculated by multiplying systolic blood pressure by heart rate.

Patients were preoxygenated for 2 min. Anesthesia was induced intravenously with fentanyl 1 μg/kg (total body weight, TBW) and propofol 2–3 mg/kg (TBW). Succinylcholine 1 mg/kg (TBW) was administered intravenously to facilitate tracheal intubation in the ETT group, and no muscle relaxant was used for placement of PLMA™ in the PLMA™ group. An effective airway was defined as two consecutive breaths with an expired tidal volume of 6 ml/kg or more, a square wave capnography, and normal closed-flow

volume loop at monitor display.[22] The airway devices were used in accordance with their respective manufacturer's recommendation for sizes (*i.e.*, ID 7.5 or 8 mm for ETT and size 5 for PLMA™) and insertion technique. In the PLMA™ group, PLMA™ was positioned using digital technique. It included neck flexion, head extension, full deflation of the cuff, and the use of the index finger to press and then advance the PLMA™ around the palatopharyngeal curve. A slight lateral approach was used if resistance was felt in the oropharynx. The PLMA™ cuff was inflated to and maintained at 60 cm H_2O (Mallinckrodt Medical, Athlone, Ireland). The absence of oropharyngeal air leaks was assessed by listening over the mouth and just lateral to the thyroid cartilage with stethoscope, checking for absence of the lubricant blowing back from drainage tube. In the ETT group, after lidocaine gel was applied in the nose, a 14 G Salem GT was blindly introduced through it with the head in flexion position and, if necessary, applying lateral neck pressure or turning the head of patient in lateral position. In the PLMA™ group, the GT was lubricated and passed through the drainage tube of the PLMA™. Correct GT placement was confirmed by the aspiration of gastric contents and/or by epigastric auscultation with a stethoscope during the insertion of 30 ml air into the GT. If suction of gastric fluid was obtained, the amount was recorded. A flexible fiberoptic bronchoscope (Adult Flexible Bronchoscope; Olympus, Milano, Italy) was introduced through the PLMA™ to check and confirm the adequate positioning of PLMA™. In case of failure of GT insertion through drainage tube of PLMA™ or endoscopic incomplete view of glottis, the plan was to withdraw and replace the PLMA™ with an ETT, and the patient dropped out from the study.

Oropharyngeal leak pressure was determined by closing the expiratory valve of circle system at a fixed gas flow of 3 l/min and noting the airway pressure (*i.e.*, maximum allowed was 40 cm H_2O) in the anesthetic breathing system, at which gas leakage occurred into mouth.[23] Air leakage was evaluated breath to breath and expressed as leak fraction (LF) calculated as the difference between the inspiratory tidal volume ($V_{t\ ins}$) and expiratory tidal volume ($V_{t\ exp}$) divided by the $V_{t\ ins}$, and expressed as a percentage of the $V_{t\ ins}$. If insertion of PLMA™ failed at the first attempt, a single second attempt was allowed using the introducer technique. Failed insertion was defined by any of the following criteria: failed passage into the pharynx; malposition (air leaks); and ineffective ventilation (maximum expired tidal volume less than 6 ml/kg or if an end-tidal carbon dioxide concentration [ET_{CO2}] < 44 mmHg cannot be achieved before carbon dioxide insufflations). The time between laryngoscopy in ETT group and picking up the prepared PLMA™ (*i.e.*, cuff fully deflated, lubricated) in the PLMA™ group and successful insertion of the airway device was recorded. The number of attempts and the etiology of failed insertion was documented. Fixation was in accordance with the manufacturer's instructions. In case of failure of PLMA™ placement, the plan was to withdraw and replace it with an ETT determining the exclusion of patient from the study.

Lung ventilation (Aisys GE Healthcare, Datex-Ohmeda) was set at the beginning to a 35/65 oxygen/air mixture, positive end-expiratory pressure at 5 cm H_2O, and peak inspiratory pressure (PIP) at variable value in order to obtain an $V_{t\ exp}$ of 10 ml/kg IBW, respiratory rate of 12 breaths/min, and inspiratory:expiratory ratio of 1:1. Then, if necessary, minute ventilation was adjusted to maintain E_{tCO2} of more than 30 mmHg during the maintenance phase. Anesthesia was maintained with sevoflurane starting with an end-tidal concentration of about 1 minimum alveolar concentration (*i.e.*, 2.2%). Then, sevoflurane was titrated to maintain a state entropy value at a target range of 40 ± 5 and to keep the arterial blood pressure and heart rate within 20% of baseline values. In case of increase of their values, if hemodynamic control could not be achieved within 5 min after 0.5% sequential increases of sevoflurane, fentanyl 0.5 μg/kg (TBW) IV was given. On the contrary, systolic hypotension (*i.e.*, less than 90 mmHg) was treated with 0.5% sequential decrease of sevoflurane, with crystalloids or colloids, and, when necessary, with IV ethylephrine 2 mg and bradycardia (*i.e.*, less than 50 beats/min) with IV atropine 0.01 mg/kg IBW.

Neuromuscular blockade was produced using a single IV bolus of cisatracurium 0.15 mg/kg IBW administered after tracheal intubation in the ETT group and IV cisatracurium 0.05 mg/kg IBW before carboperitoneum in the PLMA™ group. The dose of cisatracurium was chosen on the basis of drug pharmacokinetics and on the average time of LGB in our Surgical Department.[24] A single IV bolus of cisatracurium (*i.e.*, 0.15 mg/kg IBW) administered after ETT insertion was generally sufficient to provide muscle relaxation to the end of carboperitoneum.[24] Additional IV cisatracurium 2 mg was given in case of TOFR more than 0.5. A low-flow system was used with a fresh gas flow of 2 l/min.

PIP, as first step, and respiratory rate, as second step, were increased with the ET_{CO2} of more than 40 mmHg and reduced with the ET_{CO2} of less than 30 mmHg. In the PLMA™ group, PIP was increased until oropharyngeal leak pressure, then only increase of respiratory rate was adopted to reduce the ET_{CO2} exceeding the threshold value of 40 mmHg. During pressure-controlled ventilation, if the LF was more than 15% or in case of gastric insufflation, the following steps were taken: the cuff pressure of PLMA™ was increased in stepwise fashion; the PIP was reduced until a threshold value of $V_{t\ exp}$ of 6 ml/kg (IBW); and peritoneal insufflation was reduced below 15 cm H_2O, according with surgeon. In the case of a LF more than 15% and unresponsive to the above procedures, in presence of ineffective ventilation (*i.e.*, maximum $V_{t\ exp}$ of less than 6 ml/kg or ET_{CO2} more than 44 mmHg), and with interference of surgical procedure, the plan was to replace the PLMA™ with an ETT passed endoscopically through PLMA™ with the help of Aintree Intubation Catheter (Cook Medical Italia, Cinisello Balsamo, Milan, Italy).

At the end of LGB, a methylene blue solution was injected through the GT to allow the surgeon to detect gastric leakage and the anesthesiologist to detect endoscopic stain aspiration in upper airway. After the end of carboperitoneum, metoclopramide 10 mg and ketorolac tromethamine 30 mg were given intravenously to reduce postoperative nausea and vomiting (PONV) and to limit narcotics use in the postoperative pain management. Muscle relaxation was reversed at the end of surgery with IV atropine 0.01 mg/kg IBW and neostigmine methylsulfate 0.04 mg/kg IBW if the TOFR was 0.9 or fewer. At the end of surgery, sevoflurane administration ceased and fresh gas flow was increased to 10 l/min. Mechanical ventilation with ventilator set at a triggering sensitivity of 5 or 6 l/min was maintained until the first spontaneous breath occurred. Then, pressure support ventilation was adopted and level adjusted to ensure a $V_{t\ exp}$ of 8 ml/kg IBW, positive end-expiratory pressure maintained at 5 cm H_2O, and inspiratory:expiratory ratio of 1:1. Just before airway device removal, lung ventilation was manually assisted with continuous positive airway pressure during inspiration maintained at 5 cm H_2O by adjusting the adjustable pressure limiting valve. The ETT, or the PLMA™ and GT, were removed when a TOFR more than 0.9 was reached and the patient was awake, able to respond to simple commands, sustain hand grip, and lift arms. The times were recorded.

After removal of ETT or PLMA™, patients were followed until they reached an Aldrete score of 9 or more. The modified Aldrete score is a three-point (*i.e.*, 0–2) postanesthesia recovery score that assesses five areas: patient's ability to move, respiration, circulation, consciousness, and oxygen saturation. The Aldrete score of 9 or more has been used as a discharge criteria from the PACU.[25] Patients were assessed for Spo_2 desaturation while breathing room air without oxygen supplementation for 5 min or until Spo_2 of less than 92%, and were asked for pain (yes/no) and PONV (yes/no) every 15 min in PACU by a nurse blinded to the airway device used. If answer was yes, the patient was asked to rate pain and PONV by using a visual analog scale (VAS) ranging from 0 (none) to 10 (worst). Fentanyl 0.5 μg/kg TBW and paracetamol 1 g IV were given when needed for moderate-severe (VAS more than 4) or mild (VAS 4 or less) pain respectively, and ondansetron 4 mg IV for PONV (VAS more than 3). Patients were discharged from the PACU when the Spo_2 was more than 95% while breathing room air, were hemodynamically stable, and had no pain and PONV. While in PACU and later in the ward, the patients were also asked if they had sore throat (*i.e.*, constant pain, independent of swallowing), dysphonia (*i.e.*, difficulty speaking and pain on speaking), and dysphagia (*i.e.*, difficulty or pain provoked by swallowing).

The time of surgery was calculated from skin incision to the placement of the last suture. Emergence times (*i.e.*, opening eyes in response to a verbal command, obeying simple verbal commands) and time of ETT/PLMA™ removal were registered from cessation of sevoflurane. At the end of each LGB, the surgeon was asked to answer yes/no to two questions (*i.e.*, "Did gastric distension at entry of the laparoscope interfere with surgery?"; and "Were you satisfied with the surgical conditions resulting from the anesthetic?").

The occurrence of the following complications was recorded: episodes of hypoxemia (*i.e.*, Spo_2 of less than 92%), bradycardia (*i.e.*, beats per minute less than 40/min), systolic hypotension (*i.e.*, less than 90 mmHg), VAS of postoperative pain and PONV, and complications related to the airway devices such as insertion failure, blood staining, sore throat, dysphonia, and dysphagia were recorded.

Neuroendocrine Stress Response Evaluation

Neuroendocrine stress responses were assessed by measuring resting plasma concentrations of epinephrine, norepinephrine, dopamine, adrenocorticotrophic hormone (ACTH), and cortisol in blood sample collected peripherally from an antecubital vein of the arm contralateral to the intravenous infusion as follows: 30 min before transferring the patient to operating room at 1 and 5 min after ETT/PLMA™ placement; at 10 min after inducing and at 5 min after ending carboperitoneum; and at 10 and 120 min after removal of airway device with the patient awake in the PACU. In all cases, the patients were in head-up position during and after surgery. For catecholamines, ACTH, and cortisol, the samples were transferred to precooled tubes and soon centrifuged at −4°C, and the plasma was stored at −80°C until analysis. All samples were analyzed together. Catecholamines were measured by high-performance liquid chromatography and quantified by electrochemical–coulommetric method (HPLC System Gold Beckman, ESA C18, ESA AC5011A; Coulochem II, Chelmsford, MA). Concentrations of ACTH and cortisol were measured by commercially available radioimmunoassay kit.

Statistical Analysis

The primary endpoints were mean arterial blood pressure (MAP), plasma norepinephrine concentrations, and cisatracurium dosage requirement ($\alpha = 0.05$ and power = 0.90). Based on a pilot study on 10 obese patients managed with ETT, it was calculated that 32 and five patients per group were required to detect a significant 30% intergroup difference in, respectively, blood pressure and blood norepinephrine, and nine patients per group to detect a 50% difference in cisatracurium dosage. To account for larger SD and possible dropouts, 38 patients per group were included. Secondary endpoints were times taken for ETT/PLMA™ placement and removal, LF, postoperative complications, VAS for pain and PONV, analgesic and antiemetic requirements, and times to discharge from PACU to surgical ward.

Statistical analysis was performed using *Statistica* software version 9.0 (StatSoft Italia, Vigonza, Padova, Italy). Dosages

Table 1. Demographic and Clinical Variables of Patients

—	ETT Group	PLMA™ Group	*P* Value
Number of patients	35	35	1.000
Male gender	10 (29%)	6 (17%)	0.393
Age, year	43.2 ± 12.3	42.4 ± 11.5	0.779
Weight, kg	124.1 ± 22.2	122.1 ± 14.3	0.655
Height, cm	167.8 ± 8.8	163.9 ± 8.3	0.060
BMI	43.9 ± 6 .1	45.4 ± 4.3	0.238
Smoker	7 (29%)	5 (17%)	0.751
History of PONV or motion sickness	6 (17%)	8 (23%)	0.765
Mallampati I/II/III/IV	27/8/0/0	25/10/1/0	0.901
Comorbidies	—	—	—
OSAS	—	—	—
Polysomnography-diagnosed	6 (17%)	8 (23%)	0.765
High risk (SACS more than 15)	21 (60%)	23 (66%)	0.620
Type II diabetes	15 (43%)	18 (51%)	0.472
Hypertension	10 (29%)	15 (43%)	0.212
Depression	11 (31%)	9 (26%)	0.596
Therapies	—	—	—
β-blockers	7 (20%)	6 (17%)	0.758
ACE-inhibitors	9 (26%)	8 (23%)	0.780
Ca^{2+}-antagonists	4 (11%)	5 (14%)	0.721
Antidepressants	10 (29%)	8 (23%)	0.584

Data are expressed as means ± SD, or as numbers of patients (percent), and compared by Student *t* test, or chi-square test.
ACE = angiotensin-converting enzyme inhibitors; BMI = body mass index (kg/m^2); ETT = endotracheal tube; OSAS = obstructive sleep-apnea syndrome; PLMA™ = Proseal LMA™; PONV = postanesthesia nausea and vomiting; SACS = sleep apnea clinical score.

of drugs, times of anesthesia, and surgery, and ventilatory, hemodynamic, and hormonal data are expressed as means ± SD. All other data are patient numbers (percentages). The distribution of data were analyzed using the Kolmogorov-Smirnov test. Parametric data were analyzed with independent two-tail Student *t* test and nonparametric data with chi-square test. Serial data were analyzed with a *post hoc* Bonferroni-corrected repeated-measures ANOVA for intergroup differences over time and a Bonferroni-corrected Student *t* test for intergroup differences at individual time-points. The nature of significant testing was two-tailed. A P value < 0.05 was considered to be significant.

Results

Seventy-five patients were recruited in the study during a 16-month period: 37 and 38 patients were allocated to the ETT and the PLMA group, respectively. A total of five patients who underwent LGB were subsequently excluded: two ETT patients because of difficult intubation and prolonged surgery, two PLMA patients because of initial placement failure of PLMA and fiberoptic intubation, and one patient because of laryngospasm after PLMA removal. Usable data were, therefore, from 35 ETT patients and 35 PLMA patients.

Demographic and clinical features (table 1), chronic drug treatments, PONV risk factors and numbers of patients at high risk of PONV, anesthetic drug dosages and mean sevoflurane end tidal, state entropy during maintenance (table 2), and times of surgery and of emergence (table 2) were comparable between groups. Six ETT patients and seven PLMA patients were at high risk of PONV (*i.e.*, Apfel score more than 3, $P = 0.758$). Succinylcholine was used in ETT patients only. Cisatracurium was given to ETT patients and, at significantly lower doses, to PLMA patients (table 2).

Compared with PLMA, ETT required shorter times to achieve an effective airway (table 2). The GT was inserted with difficulty in seven ETT patients and in no PLMA patients. Residual gastric volume was 43 ± 44 and 41 ± 53 ml in the ETT and PLMA groups, respectively. Among ETT patients, laryngoscopy and tracheal intubation were successful at the first attempt in 32 (91%) and at a second attempt in three patients (9%). In the PLMA group, PLMA placement was successful at the first attempt in 33 patients (94%) and at a second attempt in two patients (6%). Mean oropharyngeal leak pressure was 29.6 ± 4.2 cm H_2O and positive pressure ventilation with VTexp of 10 ml/kg was possible without audible air leaks in 31 patients (88.5%).

Tidal volumes, Spo_2, and Et_{CO2} were not statistically different between the ETT and PLMA™ group (table 3). Compared with the ETT group, in the PLMA group PIP was higher at the end of surgery and LF after insertion of devices and after induction of carboperitoneum (table 3), but in all cases it did not affect gas exchange. The surgeon reported a significant gastric dilatation in two ETT and three PLMA™ patients, leak of methylene blue in no patients, and high rate of satisfaction with the anesthesia (more than 90%) in ETT patients and PLMA™ patients (table 2). At the end of car-

Table 2. Anesthesia Drug Dosages and Anesthesia and Surgery Times

—	ETT Group	PLMA™ Group	*P* Value
Propofol total dose, mg	287.3 ± 42	310.3 ± 54	0.060
Fentanyl total dose, μg	230.5 ± 16	215.7 ± 35	0.490
Succinylcholine total dose, mg	122 ± 25	0	—
Cisatracurium total dose, mg	10.1 ± 2.1	4.9 ± 1.2	<0.0001
Mean sevoflurane$_{ET}$, %	2.07 ± 0.18	2.13 ± 0.17	0.156
State entropy during maintenance	42.3 ± 7.2	41.4 ± 5.5	0.558
Effective airway time, sec	19.9 ± 5.4	25.8 ± 6.9	0.006
Surgery time, min	44.2 ± 14.8	40.1 ± 10.0	0.178
Eye opening, min	11.7 ± 3.2	12.1 ± 3.5	0.619
Hand grip, min	12.9 ± 3.6	12.5 ± 3.4	0.634
Airway device removal, min	14.9 ± 3.9	13.1 ± 3.5	0.230
Gastric distension	2 (6%)	3 (9%)	0.642
Surgeon satisfaction	33 (94%)	32 (91%)	0.721

Data are expressed as means ± SD, and numbers (percent) for groups of 35 patients, and compared by Student *t* test or chi-square test. *P* values are determined using three *post hoc* Bonferonni corrections.

Airway device removal = time from agent off to airway device removal; effective airway time = time taken to have an effective airway defined as two consecutive breaths with an expired tidal volume of more than 6 ml/kg after insertion of the airway device; ETT = endotracheal tube; eye opening = time from agent off to eyes opening; hand grip = time from agent off to hand grip; PLMA™ = Proseal LMA™; sevoflurane$_{ET}$ (%) = end-tidal concentration of sevoflurane.

boperitoneum, the anesthesiologist reported methylene blue in the upper airways in no patients.

The assumption of a normal distribution for the hemodynamic and hormonal values at each of the time-points was supported by the Kolmogorov-Smirnov test. Repeated-measures ANOVA showed significant group × time interaction with ETT patients having, compared with PLMA patients, higher values of heart rate (F[6,408] 4,37; $P = 0.009$), MAP (F[6,408] 5,683; $P = 0.009$), and RPP (F[6,408] 8,783; $P = 0.0003$). The *post hoc* comparisons with Bonferroni correction showed similar hemodynamic values at baseline and larger hemodynamic values in ETT than in PLMA after airway device insertion and removal and after recovery in PACU (table 4). Seven ETT and six PLMA patients were on chronic β-blocker therapy (table 1). The same pattern of hemodynamic changes was observed when data were analyzed separately for patients who were receiving β-blockers or patients who were not treated with β-blockers (data not shown).

Table 3. Ventilation Variables during LGB

—	ETT Group	PLMA™ Group	*P* Value
SpO_2, percent	—	—	—
Prior carboperitoneum	97.8 ± 1.4	98.3 ± 1.2	0.113
During carboperitoneum	97.7 ± 1.6	97.8 ± 1.3	0.775
After carboperitoneum	97.6 ± 2.4	98.0 ± 1.5	0.406
E_TCO_2, mmHg	—	—	—
Prior carboperitoneum	34.1 ± 3.5	33.5 ± 2.7	0.428
During carboperitoneum	36.0 ± 3.6	35.3 ± 2.2	0.351
After carboperitoneum	34.5 ± 2.8	33.8 ± 2.3	0.283
$V_{t\ exp}$, l/ min	—	—	—
Prior carboperitoneum	6.9 ± 0.7	6.6 ± 0.6	0.058
During carboperitoneum	6.8 ± 0.6	6.5 ± 0.5	0.131
After carboperitoneum	7.0 ± 0.5	6.7 ± 0.6	0.131
PIP, cm H_2O	—	—	—
Prior carboperitoneum	19.8 ± 3.0	21.0 ± 3.3	0.116
During carboperitoneum	26.6 ± 3.0	25.0 ± 3.5	0.219
After carboperitoneum	22.0 ± 3.1	19.8 ± 2.7	0.011
LF, percent	—	—	—
Prior carboperitoneum	0.2 ± 0.5	4.4 ± 7.2	0.005
During carboperitoneum	0.5 ± 1.0	6.9 ± 10.0	0.002
After carboperitoneum	0.3 ± 0.6	2.9 ± 3.8	0.002

Data are expressed as means ± SD for groups of 35 patients and compared with a Student *t* test. *P* values are determined using three *post hoc* Bonferroni corrections.

E_TCO_2 = end-tidal concentration of carbon dioxide; ETT = endotracheal tube; exp = expired; LGB = laparoscopic gastric banding; LF = leak fraction [$(V_{t\ insp} - V_{t\ exp})/V_{t\ insp}$]; insp = inspired; PIP = peak inspiratory pressure; PLMA™ = Proseal LMA™; Spo_2 = pulse oximetry; V_t = tidal volume.

Table 4. Hemodynamic Stress Responses to LGB

—	ETT Group	PLMA™ Group	*P* Value
Heart rate, beats/min	—	—	—
Baseline	84.6 ± 8.7	81.6 ± 10.5	0.083
Induction, 1 min	91.7 ± 11.0	85.3 ± 11.2	0.056
Induction, 5 min	74.8 ± 12.6	73.5 ± 10.1	0.641
Carboperitoneum, 10 min	85.0 ± 7.8	81.6 ± 10.0	0.123
Carboperitoneum end	78.5 ± 6.9	76.8 ± 9.3	0.394
Airway device removal	95.8 ± 7.6	87.4 ± 7.4	<0.0001
PACU	82.6 ± 8.3	76.6 ± 7.5	0.012
Mean arterial blood pressure, mmHg	—	—	—
Baseline	76.1 ± 8.8	77.6 ± 10.3	0.514
Induction, 1 min	82.8 ± 9.3	75.1 ± 10.7	0.010
Induction, 5 min	77.4 ± 12.7	71.8 ± 10.2	0.138
Carboperitoneum, 10 min	81.0 ± 11.0	78.4 ± 9.3	0.525
Carboperitoneum end	79.4 ± 8.9	76.4 ± 7.0	0.107
Airway device removal	102.5 ± 9.9	91.4 ± 9.7	<0.0001
PACU	78.7 ± 7.5	73.9 ± 6.5	0.028
RPP, mmHg/min	—	—	—
Baseline	10,958 ± 1,767	10,901 ± 2,290	0.901
Induction, 1 min	13,234 ± 2,036	10,486 ± 2,261	<0.0001
Induction, 5 min	10,046 ± 2,845	9,186 ± 2,413	0.177
Carboperitoneum, 10 min	11,586 ± 2,158	10,643 ± 2,028	0.064
Carboperitoneum end	10,460 ± 1,547	9,765 ± 1,510	0.071
Airway device removal	11,307 ± 1,667	9,933 ± 1,647	0.005
PACU	10,903 ± 2,041	9,560 ± 1,303	0.008
>15,000 <20,000	16 (57%)	13 (37%)	0.183
>20,000	7 (37%)	0 (0%)	0.006

Data are expressed as means ± SD, and numbers of patients (percent) for groups of 35 patients, and compared by Student *t* test or chi-square test. *P* values are determined using seven *post hoc* Bonferroni corrections.

ETT = endotracheal tube; LGB = laparoscopic gastric banding; PACU = postanesthesia care unit; PLMA™ = Proseal LMA™; RPP = rate pressure product.

Plasma concentrations of norepinephrine were a primary outcome in our study. Plasma concentrations of stress hormones in 15 healthy, comparison subjects were: norepinephrine 176 ± 35 pg/ml; epinephrine 66 ± 32 pg/ml; and dopamine 15 ± 17 pg/ml. At baseline, plasma concentrations of catecholamines and cortisol were within reference ranges in 10 ETT and 11 PLMA patients (table 5). Repeated-measures ANOVA revealed a significant group × time interaction with 5–40% higher hormone levels in ETT than in PLMA patients: norepinephrine ($F[6,408] = 12,25$; $P = 0.0005$), epinephrine ($F[6,408] = 5,49$; $P = 0.001$), dopamine ($F[6,408] = 5,26$; $P = 0.0015$), cortisol ($F[6,408] = 3,07$; $P = 0.015$) and ACTH ($F[6,408] = 3,80$; $P = 0.005$). The *post hoc* analyses showed similar hormonal levels at baseline and higher levels of catecholamines and of cortisol in ETT than in PLMA patients after induction of carboperitoneum, after insertion and removal of airway devices, and after recovery in PACU. The same pattern of plasma catecholamines, cortisol, and ACTH was observed when data were analyzed separately for patients who were receiving or patients who were not receiving β-blockers (data not shown).

In comparison with ETT patients, PLMA-managed patients presented fewer episodes of postoperative cough, hypoxemia, and PONV (tables 6 and 7), and were judged dischargeable from the PACU on average 17 min earlier and from the hospital 111 min earlier (table 7).

Discussion

This is, to the best of our knowledge, the first study examining influences of airway devices used for LGB surgery in morbidly obese patients on stress responses and immediate postoperative complications. Compared with airway management with an ETT, use of PLMA™ resulted in less hemodynamic and hormonal activation and less hypoxemic and PONV episodes during the postoperative period.

PLMA™ was associated with less stress activation than ETT at insertion and at removal of airway devices, and at induction of carboperitoneum. β-blockers attenuate responses to stress when given just before anesthesia. In our study, a repeated-measures ANOVA did not find a significant effect of β-blockers taken chronically on the patterns of hemodynamic and hormonal activation. The findings are probably due to underdosing or low efficacy of specific β-blocking agents and indicate that chronic use of β-blockers does not explain reduced stress response in PLMA™ patients.[26] Also, depth of anesthesia and doses of anesthetic drugs administered are comparable between groups, suggesting these factors are not involved in lower stress responses to PLMA™. Finally, cisatracurium was given in higher doses to ETT than in PLMA™ patients, and succinylcholine to ETT patients only. However, cisatracurium has no effect on catecholamines, and succinylcholine has a brief, catecholamine-

Table 5. Hormone Stress Responses to LGB

—	ETT Group	PLMA™ Group	*P* Value
Norepinephrine, pg/ml	—	—	—
Baseline	343 ± 178	318 ± 123	0.496
Induction, 1 min	369 ± 192	286 ± 110	0.149
Induction, 5 min	321 ± 157	249 ± 161	0.062
Carboperitoneum, 10 min	534 ± 198	368 ± 147	0.001
Carboperitoneum end	320 ± 113	295 ± 107	0.345
Airway device removal	578 ± 285	329 ± 128	<0.0001
PACU	380 ± 167	262 ± 95	0.003
Epinephrine, pg/ml	—	—	—
Baseline	64 ± 51	63 ± 38	0.926
Induction, 1 min	83 ± 21	66 ± 27	0.003
Induction, 5 min	57 ± 45	58 ± 35	0.917
Carboperitoneum, 10 min	177 ± 96	124 ± 76	0.064
Carboperitoneum end	64 ± 50	63 ± 38	0.925
Airway device removal	157 ± 120	89 ± 51	0.015
PACU	116 ± 81	77 ± 40	0.064
Dopamine, pg/ml	—	—	—
Baseline	34 ± 20	34 ± 25	0.999
Induction, 1 min	38 ± 24	32 ± 23	0.289
Induction, 5 min	29 ± 18	31 ± 23	0.687
Carboperitoneum, 10 min	53 ± 36	36 ± 23	0.107
Carboperitoneum end	37 ± 23	35 ± 20	0.841
Airway device removal	62 ± 28	42 ± 28	0.020
PACU	52 ± 34	36 ± 23	0.121
Cortisol, nM/ml	—	—	—
Baseline	485 ± 197	439 ± 194	0.328
Induction, 1 min	524 ± 212	404 ± 179	0.063
Induction, 5 min	512 ± 167	398 ± 176	0.035
Carboperitoneum, 10 min	534 ± 164	417 ± 187	0.035
Carboperitoneum end	454 ± 185	438 ± 194	0.725
Airway device removal	738 ± 242	606 ± 190	0.067
PACU	516 ± 209	418 ± 185	0.208
ACTH, ng/l		—	—
Baseline	36 ± 19	35 ± 18	0.821
Induction, 1 min	47 ± 21	37 ± 18	0.180
Induction, 5 min	38 ± 18	36 ± 18	0.643
Carboperitoneum, 10 min	49 ± 18	40 ± 19	0.229
Carboperitoneum end	51 ± 20	40 ± 19	0.106
Airway device removal	61 ± 21	51 ± 18	0.180
PACU	47 ± 20	36 ± 17	0.078

Data are expressed as means ± SD for groups of 35 patients and compared with a Student *t* test. *P* values are determined using seven *post hoc* Bonferroni corrections.

ACTH = adrenocorticotroph hormone; ETT = endotracheal tube; LGB = laparoscopic gastric banding; PACU = postanesthesia care unit; PLMA™ = Proseal LMA™.

releasing effect that may contribute, at most, to catecholamine increase at the time of intubation but not at later time-points.[27,28] Hence, smaller stress responses in PLMA™ patients do not appear to be accounted for by chronic therapies or anesthesia drugs. Rather, we believe they result from features of airway devices. In ETT patients, in fact, laryngoscopy and tracheal intubation are strong noxious stimuli on laryngopharyngeal and tracheal mucosa that elicit arterial hypertension, tachycardia, and catecholamine release.[7,29–32] In contrast, PLMA™ may elicit a smaller stress response than ETT because it is less traumatic on upper airway in a fashion similar to other supraglottic devices.[7,29–32] In our study, the maximal stress activation occurred after removal of ETT but not of PLMA™. These findings suggest that, in comparison with PLMA™, manipulation of the upper airway, either for insertion or removal of ETT, is more stimulating and causes larger sympathetic activation.

By reducing stress responses, PLMA™ may be advantageous over ETT in obese patients. Although transitory hypertension and tachycardia are probably of little clinical consequence in healthy individuals, they may be matter of concern in patients with known, or at risk of, cardiovascular diseases such as obese patients.[33–35] In fact, catecholamines promote platelet aggregation and thrombus formation, as well as heart rate and myocardial oxygen consumption, increasing the risk of arrhythmia and ischemia.[33–34] Myocardial oxygen consumption is a reliable indicator of the load on the heart but is difficult to measure. RPP is a strong correla-

Table 6. Recovery in Postanesthesia Care Unit after LGB

—	ETT Group	PLMA™ Group	*P* Value
Time to PACU admission, min	15.0 ± 4.6	12.4 ± 4.4	0.036
Time of PACU stay, min	166.0 ± 19.1	149.7 ± 16.2	0.002
Time of hospital stay, min	527.7 ± 198	416.2 ± 98.4	0.012
Aldrete score at PACU admission	8.47 ± 0.65	8.80 ± 0.71	0.133
Spo_2, %	94.7 ± 3.2	96.4 ± 2.5	0.047
VAS pain score	2.7 ± 2.1	2.3 ± 1.5	0.043
VAS PONV score	2.6 ± 1.2	1.6 ± 0.9	0.002
Analgesic supplement	9 (26%)	5 (14%)	0.370
Antiemetic supplement	8 (20%)	1 (3%)	0.012

Data are expressed as means ± SD, and numbers of patients (percent) for groups of 35 patients and compared with a Student *t* test and chi-square test. *P* values are determined using three *post hoc* Bonferroni corrections. Analgesic supplement was paracetamol 1 g or fentanyl 50 μg with VAS pain < or >4. Antiemetic supplement was ondansetron 4 mg with VAS nausea >3 or vomiting.

ETT = endotracheal tube group; LGB = laparoscopic gastric banding; PACU = postanesthesia care unit; PLMA™ = Proseal LMA™; PONV = postoperative nausea and vomiting; Spo_2 = pulse oximetry; time of PACU admission = time from removal of airway device to admission to PACU; VAS = visual analogue scale, ranging from 0 (none) to 10 (worst).

tor of myocardial oxygen consumption and is a risk factor of serious cardiovascular events, and is easier to determine.[35] In our study, RPP values exceeding 15,000 and 20,000 (*i.e.*, levels of safety and myocardial ischemia) were found more frequently or solely in the ETT patient group. We had no clinical cardiovascular event. As we did not determine markers of ischemic brain and myocardial injury, we could have not detected subclinical events.[35] Nevertheless, the PLMA™ capability of reducing RPP may reflect a lesser impact of PLMA™ on cardiovascular functions.

PLMA™ is as effective as ETT for pressure-controlled ventilation for LGB. These findings are of interest because the use of supraglottic devices in morbidly obese patients undergoing laparoscopic surgery is still controversial. In comparison with ETT, in fact, supraglottic devices have the disadvantage of risk of pulmonary aspiration and of delivering positive pressure over a limited range.[6,7,16,17,19] Among different types of devices available to us, we chose to investigate PLMA™ because of its favorable features such as high rate of and short time for successful insertion, efficacy of ventilation, and capability of gastric drainage.[6,7,16,36] In this study, compared with ETT, PLMA™ produces similar tidal volumes, lower PIP values, and higher LF, all of which are similar to those previously found in lean subjects.[7,16] Finally, there was no clinical or endoscopic sign of aspiration in either group, although patients with higher risk were excluded. These are findings consistent with the advantage of PLMA™ over other supraglottic devices of having higher airway seal pressure and lower airflow resistance.[7,37–39] They are also consistent with experimental and clinical evidences supporting the view that when the PLMA™ is properly positioned, the risk of pulmonary aspiration is very low.[7,37,40–41] Interestingly, i-gel, a supraglottic device by Intersurgical (Wokingham, Berkshire, United Kingdom) has recently demonstrated airway-sealing properties higher than cLMA™ in moderately obese subjects and similar to those of PLMA™ in lean subjects.[42,43]

Table 7. Complications

—	ETT Group	PLMA™ Group	*P* Value
Hypoxemia postoperative	15 (43%)	4 (11%)	0.001
Cough during removal	29 (83%)	3 (9%)	0.001
Blood detected on laryngoscope	3 (9%)	0	0.234
Blood staining on airway device	10 (29%)	0	0.001
Sore throat	3 (9%)	1 (3%)	0.606
Dysphonia	1 (3%)	0	0.313
Dysphagia	0	0	1.000
Vomiting	2 (6%)	0	0.151
Bronchostruction	1 (3%)	0	0.319

Data are expressed as numerical data (percent) for groups of 35 patients and compared by chi-square test.

ETT = endotracheal tube group; PLMA™ = Proseal LMA™.

PLMA™ depresses postanesthetic respiratory functions less than ETT. Consistently with features of supraglottic devices, in this study PLMA™ requires lower doses of muscle relaxant drugs than ETT.[5] In ETT-managed patients, succinylcholine creates superior intubation conditions to neuromuscular nondepolarizing agents and the benefits of succinylcholine in the morbidly obese patients outweigh any reason not to use it.[44] In PLMA™ patients, succinylcholine has not been necessary for the placement of PLMA™.[7] Nondepolarizing muscle relaxants are used to maintain optimal conditions of tracheal intubation and of carboperitoneum for laparoscopic surgery in ETT patients. In PLMA™ patients, nondepolarizing agents are required only to maintain carboperitoneum. Our preference goes to cisatracurium that has been suggested as the neuromuscular blocking drug of choice for obese patients because it lacks histamine releasing and long half-life effects.[24] Indeed, upper airway muscles are very sensitive to neuromuscular blocking agents and, in volunteers, even minimal neuromuscular blockade as reflected by a TOFR less than 1.0 puts the upper airway at the risk of collapse.[45] Increased airway collapsibility was observed at a TOFR ratio of 0.8 (and potentially even 0.9) and it can persist for some minutes even after recovery of the TOFR

ratio to unity. Therefore, smaller requirements of muscle relaxants can improve postanesthetic respiratory recovery in PLMA™ patients.[45]

PLMA™ causes less postoperative cough and PONV than ETT, which is consistent with advantages PLMA™ demonstrated in lean subjects.[16,17,37,38,46] Although PLMA™ causes less upper airway complications than ETT probably by being less irritating on the laryngotracheal mucosa, the way PLMA™ induces less PONV is less clear. PONV can be predicted by several, quantifiable factors that do not include obesity.[47] Emetogenic drugs (*i.e.*, sevoflurane, neostigmine, opioid analgesics) were given in similar doses to ETT and PLMA™ patients, suggesting that other mechanisms may come into play.[38,47] The PLMA™ cuff in the pharynx is less stimulating than ETT cuff in the trachea and has been postulated by Hohlrieder to actually increase PONV threshold, by a preemptive type of mechanism.[38] Whatever the reason, at emergence PLMA™ reduces PONV and coughing, which both can result in sympathetic activation, bronchospasm, and desaturation.[48,49]

The study has a few limitations. First, using different doses of muscle relaxant drugs in ETT and PLMA™ patients may affect stress responses. However, cisatracurium is devoid of effect and succinylcholine has a very short effect on circulating catecholamines.[28] Second, although we did not observe any symptom or sign of aspiration in the study patients, the sample size was too small to address the critical question of PLMA™ safety against pulmonary aspiration.[7,17,18] The incidence of pulmonary complications is 1–4/11,000 for cLMA™ to an estimate of 1/200,000–300,000 patients for PLMA™.[7] Dr. Tim Cook, F.R.C.A. (Department of Anaesthesia, Royal United Hospital, Combe Park, Bath, United Kingdom), calculated that approximately 2,600,000 subjects would be required to have a 80% probability to demonstrate a 50% reduction in pulmonary aspiration with PLMA™, which makes our study underpowered and the issue of respiratory safety of PLMA™ definitely difficult to assess in obese patients anyway.[7] Third, reducing stress is beneficial to patients with a high cardiovascular risk. As we did not have any clinical cardiovascular event or marker of subclinical event, we cannot positively determine the potential benefit of stress reduction in terms of risk reduction. Protection against cardiac damage is an exciting topic in clinical anesthesiology research we intend to pursue. Fourth, the anesthesiologists involved in this study were experienced in abdominal and thoracic anesthesia and difficult airway. Adverse events increase with inexperience and the amount of training necessary for a resident to become competent, for example, with obese patients is matter of discussion.[37,50,51] In our department, senior supervision is mandated when residents anesthetize obese patients. It is possible that the positive outcome with PLMA™ for LGB observed in this study would not generalize to our setting with less experienced users.

With this work, we do not intend to recommend PLMA™ as an alternative to ETT for LGB. Our findings suggest that in the case of obese patients without evidence of gastroesophageal reflux and in whom stress activation could be dangerous, PLMA™ can be considered as a suitable alternative to ETT. At the moment, on the basis of the available information, PLMA™ should be contemplated for LGB only by anesthesiology personnel very experienced with PLMA™. Larger safety studies will be necessary before PLMA™ can be recommended for routine LGB. In future, such studies should be feasible, at least as metanalyses, given the increasing numbers of obese patients undergoing surgery with supraglottic devices and of evidences of their effectiveness.

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