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SCIENTIFIC ARTICLE

Prospective, randomized clinical trial of laryngeal mask airway Supreme® used in patients undergoing general anesthesia☆

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Abstract
Background and objectives: Supraglottic airway devices are increasingly used as an option to tracheal intubation for elective procedures of varying complexity. The aim of this study was to prospectively evaluate the clinical use of the laryngeal mask airway Supreme® (LMAS) in patients undergoing elective breast surgery and compare it with endotracheal tube (ETT).
Methods: Sixty patients undergoing breast procedures under general anesthesia were randomly divided into two groups according to the device used (LMAS or ETT). Time of insertion, number of insertion attempts, hemodynamic response to insertion, presence of blood on the device used; and incidence of sore throat, dysphagia, nausea and vomiting were assessed postoperatively.
Results: There was no difference between groups regarding time of insertion, number of attempts for successful insertion, and presence of blood on the device. Heart rate and blood pressure after insertion were higher in ETT group. Incidence of sore throat and dysphagia was also higher in ETT group after two hours in the postoperative period. There was no difference regarding incidence and severity of complications evaluated after six hours postoperatively.
Conclusions: The use of the LMAS technique to access airway during general anesthesia for elective breast surgery is as safe and effective as tracheal intubation, with the advantage of promoting smaller hemodynamic response during its management and lower incidence of sore throat and dysphagia in the first hours after surgery.

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Introduction

Tracheal intubation has been for years the technique of choice for airway management during surgical procedures under general anesthesia. However, it is not a procedure without risk. Complications related to tracheal intubation range from events such as tracheal stenosis to other minor events, such as hoarseness and sore throat.[1-3]

Supraglottic devices have a number of advantages over endotracheal tube (ETT), as they do not require the use laryngoscope for insertion, are less invasive and result in less hemodynamic response and airway manipulation.

The laryngeal mask airway Supreme® (LMAS) is a single-use supraglottic airway device that allows functional separation of the respiratory and digestive systems because it has an accessory channel for gastric content drainage. It has an anatomical shape, angled and semi-rigid, which facilitates its insertion (without digital guidance), and a differentiated cuff, which gives it a high pressure seal and better performance during mechanical ventilation.[4,5] The aim of this randomized, prospective clinical trial was to evaluate the use of LMAS in elective breast surgery and compare it with endotracheal tube.

Method

With the Research Ethics Committee approval and informed consent signed, 60 patients undergoing elective breast surgery (silicone prostheses implantation, lumpectomy, mastectomy and setorectomy) were selected for this trial between August and December, 2010. Inclusion criteria were age between 18 and 60 years, body mass index (BMI) below 30 $kg \bullet m^{-2}$, and physical status P-I or II (according to the classification of the American Society of Anesthesiologists). Exclusion criteria were patients with suspected difficult airway, mouth opening less than 3 cm or increased risk of aspiration.

Patients were randomly divided into two groups based on a table of random permutations generated by computer. ETT and LMAS groups, with 30 patients each, were classified according to the airway device used: endotracheal tube (size 7.5) or cuffed laryngeal mask airway Supreme® (size 4), respectively.

At the operating room, all patients received intravenous midazolam (2 mg) as premedication after venoclysis. Standard monitoring was performed wit cardioscopy, non-invasive measurements of blood pressure, pulse oximetry, and capnography. Induction of anesthesia was performed with fentanyl (3 $\mu g \bullet kg^{-1}$), propofol (2.5 $mg \bullet kg^{-1}$), and atracurium (0.5 $mg \bullet kg^{-1}$). After manual ventilation under face mask for 3 minutes, the airway device was inserted. Laryngeal mask airway was inserted after totally deflated and lubricated on its posterior surface with hydrophilic gel. Insertion was done according to the manufacturer's instructions by the anesthesiologist responsible for the case under the supervision of the researcher, a proficient physician in the use of the technique in question. Endotracheal tube was inserted through a conventional laryngoscopy with a curved Macintosh blade, number 3 or 4. The device cuff was inflated up to 30 cmH_2O for endotracheal tube and up to 60 cmH_2O for laryngeal mask airway, which were confirmed by a manometer. Insertion success was confirmed by visible thoracic expansion and identification of capnography curve. The correct positioning of the laryngeal mask was then confirmed by the absence of air leakage through the gastric access channel during ventilation (bubble test) and passage without resistance of a gastric tube (size 14) lubricated with hydrophilic gel through the same channel.[6,7] Placement testing was not recorded at the time of mask insertion. However, if a test indicated a bad position, the mask would be withdrawn and the insertion considered a failure.

A gastric tube was also inserted through the oropharynx in patients of ETT group, and after gastric content initial aspiration, it was kept open for free drainage in both groups. Mechanical ventilation was performed in PCV mode and ventilatory parameters adjusted to ensure minimum tidal volume of 7 $mL \bullet kg^{-1}$, $ETCO_2$ below 45, and O_2 saturation above 95%.

Parameters recorded insertion time (time interval between the beginning of insertion and registration of the first capnography curve), number of successful attempts for insertion, hemodynamic response to insertion (heart rate and mean arterial pressure 30 seconds before and immediately after insertion confirmation), and presence of blood on device used (laryngoscope, in case of intubation, and laryngeal mask itself at the end of the procedure). In case of laryngeal mask insertion failure after a maximum of two attempts, the device would be replaced by an endotracheal tube. The insertion attempt was considered a failure when the device was removed from the patient's mouth before being reinserted again. Small interventions such as head and neck adjustment or change in depth of mask insertion were allowed to obtain satisfactory ventilation. The time of these interventions was recorded at insertion time.

Intravenous dexamethasone (4 mg) was used as prophylaxis after induction of anesthesia. Neuromuscular blockade was reversed at the end of surgery with the use of atropine (0.01 $mg \bullet kg^{-1}$) and neostigmine (0.03 $mg \bullet kg^{-1}$). After recovery of spontaneous ventilation and eye opening, the device used was removed. Analgesia included intravenous dipyrone (2 g) and Ketoprofen (100 mg) during surgery and dipyrone (1 g/every 6 hours) and ketoprofen (100 mg/every 12 hours) after surgery.

All patients were reassessed at 2 and 6 hours after the procedure by an observer, who was blind to the device used intraoperatively, for presence of neck pain, episodes of nausea and vomiting, and dysphagia (difficulty swallowing saliva). The intensity of neck pain and dysphagia were evaluated based on a numerical scale from 0 to 10, in which 0 = no pain and 10 = the worst pain possible.

Continuous data were first analyzed for normality using the KS distance test and expressed as mean and standard deviation (parametric) or median and percentile (nonparametric). For data comparison of two independent samples, the unpaired Student's t-test was used for parametric data and Mann-Whitney test for nonparametric data. Chi-square test was used for independent variables in categorical data evaluation and data were expressed as

Table 1 Demographic data according to groups.

	ETT (n = 30)	LMAS (n = 30)	p
Age (years)	34 (23-51)	30 (24-45)	0.684
BMI ($Kg \bullet m^{-2}$)	21.4 (20.4-22.8)	21.4 (20.2-26.1)	0.856

BMI, body mass index; ETT, endotracheal tube; LMAS, laryngeal mask airway Supreme.
Data are expressed as median (25-75 percentiles) or number (percentage).

Table 2 Data regarding device insertion according to groups.

	ETT (n = 30)	LMAS (n = 30)	p
Insertion attempts (n)			1.000
One	28 (93.3%)	27 (90%)	
Two	2 (6.7%)	3 (10%)	
Insertion time (sec)	48.4 ± 23.2	38.7 ± 21.5	0.102

ETT, endotracheal tube; LMAS, laryngeal mask airway Supreme; n, number; sec, seconds.
Data are expressed as number (percentage) or mean ± standard deviation.

Table 3 Hemodynamic variables before and after insertion according to groups.

	Before insertion			After insertion		
	ETT (n = 30)	LMAS (n = 30)	p	ETT (n = 30)	LMAS (n = 30)	p
HR; bpm	68 ± 9.1	69 ± 10.5	0.63	81.6 ± 13.3	71.4 ± 11	0.002
SBP; mmHg	95.5 ± 16.7	96 ± 15.8	0.756	121.8 ± 15.9	101.5 ± 16.4	< 0.001
DBP; mmHg	51 ± 13.2	50.7 ± 13.1	0.847	73.7 ± 12.5	56.7 ± 13.5	< 0.001
MAP; mmHg	68 ± 14.8	68.4 ± 13.8	0.976	92.4 ± 16	74 ± 14.1	< 0.001

bpm, beats per minute; DBP, diastolic blood pressure; ETT, endotracheal tube; HR, heart rate; LMAS, laryngeal mask airway Supreme; MAP, mean arterial pressure; SBP, systolic blood pressure.
Data are expressed as mean ± standard deviation.

absolute frequency and percentage. Throughout the study, an alpha risk < 5% was used for Type-I or first kind error.

Results

Demographic data of patients included in the study are shown in Table 1.

The device was successfully inserted at first attempt in 90% of cases in LMAS group and in 93.3% of cases in ETT group (p = 1.000). There was no difference between groups regarding time of insertion. There was presence of blood in only one case in LMAS group and none in ETT group. Data on insertion are shown in Table 2.

Hemodynamic variables assessed before insertion were similar in both groups. However, in the post-insertion period, ETT group had increased values of heart rate, systolic, diastolic and mean blood pressure, compared to the LMAS group, as shown in Table 3. There was no failure or complication in either group during mechanical ventilation.

The incidence of sore throat and dysphagia 2 hours after surgery was higher in ETT group (p < 0.005). There was no difference regarding incidence and severity of complications assessed in both groups 6 hours after surgery. Table 4 shows the distribution of complications found at 2 and 6 hours after surgery.

Discussion

This study demonstrated that laryngeal mask airway Supreme® safely and effectively replaces endotracheal tube for airway control during general anesthesia in breast surgical procedures. There is a growing interest of anesthesiologists in less invasive techniques for airway access. A census taken recently in the UK involving 309 hospitals of the public health system showed that 56.2% of the surgical procedures under general anesthesia were performed with a supraglottic airway device.[8] This is a marked change in paradigm that tracheal intubation is the most appropriate technique to ensure a patent airway

Table 4 Postoperative complications after 2 and 6 hours according to groups.

	2 hours			6 hours		
	ETT (n = 30)	LMAS (n = 30)	p	ETT (n = 30)	LMAS (n = 30)	p
Dysphagia			0.001			0.136
Absent (NS = 0)	21 (70%)	30 (100%)		24	28 (93.4%)	
Mild (NS = 1-3)	8 (26.7%)	0		6	1 (3.3%)	
Moderate (NS = 4-7)	1 (3.3%)	0		0	1 (3.3%)	
Severe (NS = 8-10)	0	0		0	0	
Sore throat			0.02			0.143
Absent (NS = 0)	23 (76.7%)	29 (96.7%)		24 (80%)	28 (93.4%)	
Mild (NS = 1-3)	6 (20%)	1 (3.3%)		5 (16.7%)	1 (3.3%)	
Moderate (NS = 4-7)	1 (3.3%)	0		1	0	
Severe (NS = 8-10)	0	0		0	1 (3.3%)	
Nausea			0.797			0.218
Absent	24 (80%)	24 (80%)		19 (63%)	24 (80%)	
Present	6 (20.7%)	6 (20.7%)		11 (38%)	6 (20%)	
Vomiting			0.976			0.580
Absent	28 (93%)	29 (96%)		27 (90%)	29 (96%)	
Present	2 (6.9%)	1 (3.3%)		3 (10.3%)	1 (3.3%)	

TT, endotracheal tube; HR, heart rate; LMAS, laryngeal mask airway Supreme.
Data are expressed as number (percentage). Nausea and vomiting are recorded as present/absent. Dysphagia and sore throat are registered according to intensity assessed on a pain numerical scale (NS) from 0 to10.

during positive pressure ventilation and, especially, during elective surgical procedures.

Endotracheal tube replacement by a laryngeal mask airway as a primary device to provide ventilation during general anesthesia is a trend that has gained strength before the breakthrough of this category of devices in the last decade and benefits of avoiding airway manipulation. The LMAS insertion technique is simple, exempting the use of aid tools and success, both in the insertion and maintenance of ventilation, is equivalent to the standard technique (intubation), as shown by the results of this study.

Since its invention in the early 1980s, laryngeal mask airway has undergone design changes. The incorporation of a gastric channel access, present in LMAS, probably was the innovation of greatest impact on its functionality.[9,10] This channel presence allows the functional separation between gastrointestinal and respiratory tracts. Furthermore, through this channel it is possible to do a series of tests to confirm the device correct positioning after insertion.[6,7] Changes in laryngeal mask and cuff format made the device seal more efficient, improving its performance during mechanical ventilation and allowing tracheal tube replacement in procedures of varying complexity.[11,12] This study shows that mechanical ventilation is satisfactorily maintained with the LMAS throughout surgery, despite transient changes that may occur in chest complacency resulting from surgical manipulation and other factors.

A meta-analysis of 29 randomized prospective clinical trials showed that patients undergoing general anesthesia with laryngeal mask airway are less likely to develop hoarseness, coughing, and laryngospasm during emergence from anesthesia compared to patients undergoing tracheal intubation.[13] Our study also showed a higher incidence of sore throat and dysphagia in patients with endotracheal tube in the first 2 hours after surgery. This finding is probably related to characteristics inherent to the airway access technique used, as the presence of blood in the devices, here interpreted as an indirect sign of a traumatic manipulation, could not justify the incidence of these complications in the postoperative period, as it was a rare occurrence observed precisely in the LMAS group in which the incidence of sore throat and dysphagia was lower.

Postoperative nausea and vomiting (PONV) are common complications frequently found in patients undergoing general anesthesia and of particular concern in the context of outpatient procedures, as it end up being responsible for much of the unanticipated hospitalizations in this group of patients. Although several authors have attempted to correlate the technique of airway control with these complications, the results are highly variable.[13-15] This study further evidences that the incidence of PONV probably is not affected by the chosen device for airway access, as this incidence was very low and not correlated with the device used. The hemodynamic response triggered by tracheal intubation is much more intense compared to that of laryngeal mask insertion, as shown by our results. This fact is probably related to the increased airway manipulation during tracheal intubation through direct laryngoscopy. This greater intensity in hemodynamic response also correlates with the increased release of catecholamines and may be of concern in patients with reduced cardiovascular reserve or high cardiac risk.[16,17]

It should be emphasized that this study was limited to the evaluation of a very specific population: female

patients without relevant comorbidities and undergoing simple and relatively small surgical procedures. This makes it impossible to extrapolate the results obtained for male patients or more complex and longer procedures or even those performed in positions other than supine. Moreover, the routine use of analgesics and anti-inflammatory drugs postoperatively may have affected the assessment of some postoperative complications, such as dysphagia and sore throat in the period after 6 hours. The intensity of these complications may have been tempered by the effect of these agents.

Given the results presented, we conclude that LMAS as a technique of airway access during general anesthesia for elective breast surgery proved to be as safe and efficient as tracheal intubation, with the advantage of attenuating hemodynamic response during its execution and reducing the incidence of sore throat and dysphagia in the first hours of the postoperative period.

Conflicts of interest

The supraglottic devices used in this study were donated by the company GabMed Produtos Específicos Ltda., the LMA® brand distributor in the State of São Paulo, SP, Brazil.

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