

# Sparing the larynx during gynecological laparoscopy: a randomized trial comparing the LMA Supreme™ and the ETT

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**Background:** We designed a prospective randomized single-blind study to compare efficiency and post-operative upper airway morbidity when the laryngeal mask airway (LMA) Supreme™ is used as an alternative to the endotracheal tube (ETT).

**Methods:** One hundred and thirty-eight elective pelvic laparoscopic ASA I–II female patients were assigned to receive either the LMA Supreme® or the ETT for airway management. Balanced anesthesia and ventilation techniques were standardized to control end-tidal CO<sub>2</sub> and BIS value in the range 4.5–5 kPa and 40–50, respectively, and to maintain adequate hemodynamic stability. A single surgeon blinded to the airway management technique performed all surgical procedures. The ventilation efficiency of each airway was evaluated. Anesthesia- and surgery-related times were calculated and anesthesia details were recorded. Post-operative pain and pharyngolaryngeal morbidity were measured in a blind fashion using a numerical rating scale (NRS) (0–100).

**Results:** Surgery duration was similar in both groups. Airway management duration was shorter with the LMA Supreme®. Post-operative pharyngolaryngeal morbidity incidence and all symptoms' intensity were significantly increased after ETT as compared with LMA Supreme® anesthesia. At the end of the PACU stage, the incidence and mean NRS of post-operative hoarseness were reduced when LMA Supreme® was used as an alternative to the ETT (16% vs. 47%;  $P < 0.01$  and 9 vs. 19,  $P < 0.01$ , respectively).

**Conclusion:** We demonstrated that choosing an LMA Supreme® was an efficient pharyngolaryngeal morbidity-sparing strategy. Moreover, we showed that the LMA Supreme® and the ETT were equally effective airways for a routine gynecological laparoscopy procedure.

Accepted for publication 9 June 2009

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THE safety and efficacy of laryngeal mask airway (LMA) during general anesthesia is now established.<sup>1–3</sup> However, few randomized studies have prospectively compared the laryngeal mask and endotracheal tube (ETT) anesthesia outcome in routine clinical practice mainly because the potential differences could only be established through studies in which the LMAs were used by specialists.<sup>4</sup> Because skill acquisition with LMA use was quite a long process, most clinical studies performed by non-expert users precluded meaningful comparisons of the airway devices. Two years ago, a new gastric access LMA (Fig. 1), LMA Supreme™, became available. Increasingly, it appeared that the LMA Supreme™ (SUP) with the possibility to suction the stomach could be an interesting alternative to the ETT during laparoscopic procedures, mainly

because of its overall simplicity of use for non-expert laryngeal mask users and ventilation performance. We hypothesized that choosing the SUP during gynecologic pelvic laparoscopy would influence upper airway management outcome. We designed a study to compare post-operative pharyngolaryngeal discomfort and ventilation efficiency when the SUP was used as an alternative to the ETT.

## Methods

After obtaining Local Research Ethics Committee approval and written informed consent, 138 ASA status I–II adult female patients scheduled for elective pelvic laparoscopy were enrolled in this randomized single-blind study. Patients with

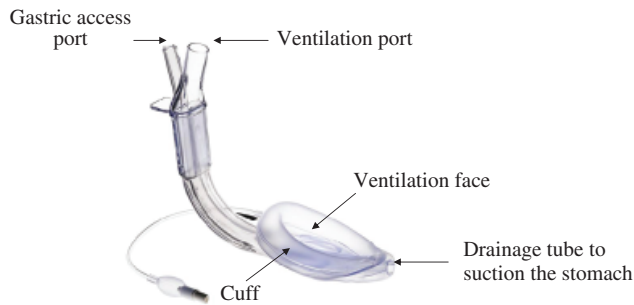


Fig. 1. The LMA Supreme™. LMA, laryngeal mask airway.

known or predicted difficult airway, increased risks of regurgitation, ongoing upper respiratory tract and those unable to understand the definitions of the post-operative upper airway symptoms (hoarseness of voice, sore throat and dysphagia) or the use of a visual analogue scale (VAS) or requiring operative use of a nasogastric tube were not included in the trial.

#### *Anesthetic and airway management procedures*

Premedication consisted of oral hydroxyzine 1 mg/kg given 1 h before the planned surgery time. Upon arrival in the operating room, the patients were randomly assigned (sealed envelopes) to receive either the ETT or the SUP for airway management. Standard monitoring systems including non-invasive arterial blood pressure, heart rate, hemoglobin arterial oxygen saturation, end-tidal carbon dioxide (EtCO<sub>2</sub>) and sevoflurane (EtSevo), BIS and adductor pollicis neuromuscular function were attached.

Anesthetists involved in the present trial were requested to maintain optimal anesthesia depth as indicated by hemodynamic stability (within 20% pre-induction values) and BIS values ranging between 40 and 50. Airway management was performed by senior anesthesiologists skilled with the LMA Supreme™ (SEBAC, Pantin, France). After 3 min of pre-oxygenation, anesthesia was induced with sufentanil (0.15–0.25 mcg/kg), followed 45 s later by propofol (2–2.5 mg/kg) and atracurium (0.5 mg/kg).

#### *Managing the airway with a tracheal tube*

In the ETT group, tracheal intubation maneuvers were initiated with adductor pollicis muscle response = 0 to train-of-four stimulation of the ulnar nerve. Facemask ventilation was discontinued and conventional laryngoscopy was performed with a

plastic single-use size 3 or 4 blade. The trachea was intubated using a single-size 7.0 mm internal diameter high-volume, low-pressure tracheal tube. The cuff was inflated and maintained at 25 cmH<sub>2</sub>O (Pressure controller, Endotest Rusch, 67660 Betschdorf, France). In the case of difficult laryngoscopy, an Eschman bougie was recommended to facilitate tracheal access.

#### *Managing the airway with the LMA Supreme™*

In the SUP group, with optimal jaw relaxation, a humidified size 3, 4 and 5 laryngeal mask [depending on patient height (<155, >155 and >170 cm, respectively)] was inserted into the oral cavity with the head of the patient slightly placed in the sniffing position as soon as an optimal was obtained. Once orally placed, the laryngeal mask was distally blocked in the pharynx while the head returned to the neutral position. Then the cuff of the laryngeal mask was inflated to 50 cmH<sub>2</sub>O pressure and ventilation was attempted. In case of failure to ventilate after initial placement, the cuff was deflated to zero cuff pressure before the optimal position (up-down maneuver) was challenged using a small-volume bag ventilation-induced end-tidal CO<sub>2</sub> curve appearing on the monitor. Then the cuff of the laryngeal mask was inflated and maintained at 50 cmH<sub>2</sub>O of controlled pressure and the airway was fixed with an adhesive tape. In case of impossible ventilation with the SUP after two insertion attempts we planned to place an ETT. When ventilation was confirmed with the SUP, a 14-Gauge probe was placed in the stomach to suction its content, which was recorded, and then removed from the laryngeal mask.

#### *Standardized procedures for both groups*

When an adequate level of anesthesia was obtained, the leak pressure was measured with both airways using the ventilator (Julian, Dräger Medical, Antony, France). Three cycles of pressure-controlled ventilation at three levels of 20, 25 and 30 cmH<sub>2</sub>O were applied while antero-lateral neck auscultation was performed. Then the three inspiratory pressure-induced tidal volumes were used during volume-controlled ventilation to measure cycle-to-cycle inspiratory–expiratory leak volume. The sealing pressure was defined as the highest inspiratory pressure free from audible and measured gas leak.

After airway managements, the patients of both groups received tidal volume (8 ml/kg) controlled mechanical ventilation with a respiratory rate of 12 breaths/min adapted to maintain end-tidal CO<sub>2</sub> in the range 4.5–5 kPa with a fresh gas flow of 1.5 l/min.

Forced-air warming of the upper body and limbs was systematically applied to maintain tympanic temperature above 36.5 °C. Anesthesia was maintained with sevoflurane in combination with nitrous oxide (50%) in oxygen. The concentration of sevoflurane and re-injections of sufentanil and atracurium were adjusted to maintain adequate anesthesia depth and neuromuscular blockade as confirmed by <2/4 responses of the corrugator supercilii muscle to TOF stimulation of the ophthalmic branch of the facial nerve.

During the surgery, all patients received an intravenous Ringer lactate solution administered at the rate of 15 ml/kg/h, propacetamol (1 g), ibuprofen (100 mg) and tramadol (20 mg). Laparoscopic technique pneumoperitoneum was maintained with carbon dioxide and adjusted to a pressure of 15–20 mmHg. At the end of the procedure, the surgeon systematically administered 0.75% ropivacaine (10 ml) in the peritoneum through the main umbilical trocar, and residual neuromuscular blockade was reversed with neostigmine 1.5–2.0 mg and atropine 1.0–1.5 mg depending upon adductor pollicis muscle number of response ( $\geq 2/4$ ) to train-of-ratio stimulation of the ulnar nerve at the wrist. Sevoflurane was then discontinued, the ventilatory circuit was opened and the patient was allowed to awakening. With return to spontaneous ventilation, the cuff of the airway was deflated until its removal when the patient responded to simple commands.

#### *Operating room recordings and measurements*

A single surgeon blinded to the airway management technique performed all the laparoscopic procedures. An unblinded assessor not attending to the patient recorded airway management details and timed all anesthesia and surgical sequences. Airways placement and weaning duration were defined as the time elapsing between injection of atracurium to definitive ventilation through the airway (chest/neck auscultation and EtCO<sub>2</sub> normal qualitative and quantitative aspects) and the last trocar to airways removal, respectively. Surgery time lasted from the first peritoneal puncture to the last suture. Airway management quality was

assessed using a difficulty VAS (0 = no difficulty, 100 impossible airway management) rated by the senior anesthetist caring for the patient just after removal of the airways.

#### *Post-operative recordings and measurements*

A second assessor blinded to the allocation group recorded on a separate data sheet post-operative parameters such as the occurrence of nausea and/or vomiting, and the need for any therapeutic interventions including the analgesic requirements, and questioned all the patients just before leaving the PACU about pharyngolaryngeal discomfort. The patients were asked whether they experienced any abdominal pain or pharyngolaryngeal discomfort. Hoarseness of the voice was defined as being either a change in the voice tone or a painful phonation. Sore throat was defined as a permanent soreness of the throat. Dysphagia was defined as a pain triggered by on-command saliva swallows. The questions were: 'do you have abdominal pain,' 'do you have hoarseness of voice or sore throat' 'do you feel any discomfort or pain when you swallow your saliva.' If the answer was yes to any of these questions, the intensity of the complaint or pain was assessed using a 101-point numerical rating scale (NRS 0 = no discomfort or no pain to 100 = extreme discomfort or maximal imaginable pain). Symptoms' intensity was also rated just before leaving the hospital. Similar questions concerning post-operative upper-airway discomfort were asked by the surgeon at the day 5–7 post-operative visit.

#### *Sample size calculation and statistics*

We measured in 35 post-operative patients leaving the PACU, whose trachea was intubated for gynecologic pelvic laparoscopy, a mean  $\pm$  SD NRS for hoarseness of voice of  $21 \pm 14$ . We hypothesized that SUP, compared with ETT anesthesia, would reduce by at least 50% the intensity of NRS for hoarseness, considered as the primary objective variable. A total of 138 patients included in two equal groups were requested to declare this hypothesis ( $\alpha = 0.05$  and power =  $1 - \beta = 0.9$ ) using a two-sided test. Values are mean  $\pm$  SD or median (range). Parametric variables were compared using Student's *t*-test, and non-parametric variables were compared using the Mann–Whitney *U*-test or the  $\chi^2$  test with Yates' continuity correction, as appro-

priate. A *P* value of <0.05 was considered statistically significant.

## Results

The demographic characteristics of the patients were comparable between the two groups (Table 1). No ventilation failure occurred with the two airways. The average time to airways placement and weaning was of a shorter duration in the SUP group as compared with the ETT group. Three patients of the ETT group required an Eschman bougie assistance to facilitate tracheal access, and 11 patients of the SUP group required manipulations to promote a seal airway. Median airway management difficulty VAS was 5, similar in both groups. In the SUP group, a mean (extreme) of 4 (0–21) ml of gastric secretion was suctioned. Operating room recordings and measurements are presented in Table 2. Surgery duration was similar in the two groups. Post-operative evaluations showed that the incidence of nausea and vomiting and the requirement for analgesic treatment were similar in both groups. Post-operative pain and pharyngolaryngeal discomfort evaluation is presented in Table 3. Post-operative abdominal pain incidence and NRS intensity were similar in the two groups. Post-operative pharyngolaryngeal discomfort incidence and NRS intensity were significantly increased after ETT as compared with SUP anesthesia. Two patients of the ETT group as compared with none of the SUP group complained of hoarseness of voice still persisting at the Day 5–7 evaluation visit. In both cases, symptoms resolved within the 15 post-operative days.

## Discussion

We demonstrated that using the SUP as an alternative to the ETT was an efficient pharyngolaryngeal morbidity-sparing strategy for the patients included in the present trial. We showed that the SUP and the ETT were equally effective ventilatory devices for routine gynecological laparoscopic procedures.

We calculated post-operative pharyngolaryngeal morbidity incidence and measured all symptoms' intensity during the first post-operative week. Although we standardized the anesthesia technique, allowing similar anesthesia depth and recovery room requirement, and surgical technique promoting similar post-operative pain, we ob-

Table 1

Demographic characteristics of the patients.		
	LMA Supreme™ group (n = 69)	ETT group (n = 69)
Age (years)	33 (9)	33(8)
Weight (kg)	66 (14)	66 (17)
Height (m)	1.65 (8)	1.64 (6)
ASA I/II (number of patients)	45/16	39/12
Smoking (> 10 cigarettes/day, number of patients)	5	4

Values are mean (SD) or numbers. ETT, endotracheal tube; LMA, laryngeal mask airway; SD, standard deviation.

Table 2

Operating room recordings and measurements.		
	LMA Supreme™ group (n = 69)	ETT group (n = 69)
<b>Anesthetic agents</b>		
<b>Induction</b>		
Propofol (mg)	185 (35)	196 (37)
Sufentanil (mcg)	12 (3)	14 (4)
Atracurium (mg)	32 (7)	31 (7)
<b>During maintenance</b>		
Sufentanil (mcg)	6 (6)	10 (5)
Atracurium (mg)	3 (6)	4 (6)
<b>Airway characteristics</b>		
Sealing pressure > 30 cmH <sub>2</sub> O (%)	95	100
Sealing pressure > 25 cmH <sub>2</sub> O (%)	5	–
Maximum peak airway pressure during anesthesia (cmH <sub>2</sub> O)	25 (6)	23 (5)
<b>Duration of timed sequences</b>		
Airway placement (min)	2.2 (0.6)	3.8 (0.7)
Airway weaning (min)	4.5 (3.0)	7.5 (2.5)
Surgery (min)	54 (21)	57 (23)
Airway management difficulty VAS (0–100) [mean/median (range)]	5/5 (0–25)	5/5 (0–40)

Visual analogue scale of airway management difficulty (0 = no difficulty and 100 impossible airway management). The sealing pressure was defined as the highest peak inspiratory pressure (20–25–30 cmH<sub>2</sub>O), free from audible and measured gas leak. Airway placement and weaning time duration were defined as the time elapsing between injection of atracurium to definitive ventilation through the airway (chest/neck auscultation and EtCO<sub>2</sub> normal qualitative and quantitative aspect) and last trocar to airway removal, respectively. Surgery time lasted from the first peritoneal puncture to the last suture. ETT, endotracheal tube; LMA, laryngeal mask airway; VAS, visual analogue scale.

served that all upper airway-related symptoms were reduced in incidence and in intensity if the SUP was used as an alternative to the ETT. Our primary objective variable, the hoarseness of voice, which best characterizes laryngeal dysfunction re-

Table 3

Post-operative pain and pharyngolaryngeal discomfort evaluation.

	LMA Supreme™ group (n = 69)	ETT group (n = 69)
Post-anesthesia care unit evaluation		
Abdominal pain		
Incidence (%)	81	79
Intensity NRS [mean/ median (range)]	28/30 (0–45)	27/30 (0–40)
Hoarseness of voice		
Incidence (%)	16	47*
NRS [mean/median (range)]	3/0 (0–40)	19*/0 (0–65)
Dysphagia		
Incidence %	16	26*
NRS, mean/median (range)	7/0 (0–50)	15*/0 (0–60)
Sore throat		
Incidence (%)	19	32*
NRS, mean/median (range)	7/0 (0–50)	10/0 (0–60)
Ward evaluation just before leaving the hospital		
Abdominal pain		
Incidence (%)	54	50
NRS [mean/median (range)]	18/15 (0–40)	20/20 (0–40)
Hoarseness of voice		
Incidence, %	9	37*
NRS, mean/median (range)	1/0 (0–25)	10*/0 (0–70)
Dysphagia		
Incidence (%)	9	19*
NRS [mean/median (range)]	2/0 (0–35)	5/0 (0–30)
Sore throat		
Incidence (%)	5	15*
NRS [mean/median (range)]	3/0 (0–25)	3/0 (0–45)

In order to evaluate post-operative pain and pharyngolaryngeal discomfort, the patients were asked whether they experienced any abdominal pain or pharyngolaryngeal discomfort. The questions asked were: 'do you have abdominal pain,' 'do you have hoarseness of voice or sore throat' 'do you feel any discomfort or pain when you swallow your saliva.' If the answer was yes to any of these questions, the intensity of the complaint or pain was measured using a 101-point numerical rating scale (NRS: 0 = no discomfort or no pain, to 100 = extreme discomfort or maximal imaginable pain).

ETT, endotracheal tube; LMA, laryngeal mask airway.

\* $P < 0.05$  vs. LMA Supreme group.

sulting from airway management, was much more intense after ETT than SUP anesthesia. Although upper airway symptoms rapidly decreased in incidence and intensity, two patients of the ETT group vs. none of the SUP group suffered from persistent dysphonia reported to the surgeon at the follow-up visit. Although all patients were placed under best-relaxed conditions<sup>5</sup> at the time tracheal intubation maneuvers were undertaken, some minor trauma of the vocal cords during tracheal intubation<sup>6,7</sup> or tracheal tube maintenance<sup>8</sup> possibly oc-

curred, resulting in prolonged post-operative voice dysfunction. Interestingly, some patients of the SUP group suffered from hoarseness of the voice of minor intensity. Two reasons may explain why the SUP may affect post-operative laryngeal function. First, 11 patients (16%) required manipulations and repositioning of the laryngeal mask to improve ventilation and seal. During the up-down maneuver, we speculated that in case this specific feature occurred, minor laryngeal trauma might have occurred. The second reason might be linked to the structure and shape of the SUP. Indeed, when correctly positioned, the distal cuff of the laryngeal mask is inflated at the level of or just below the cricopharyngeal upper-esophageal sphincter muscle. Although we maintained the pressure in the cuff of the laryngeal mask at or below 50 cmH<sub>2</sub>O, some changes in arytenoids shape or position might have resulted in transient vocal cord palsy and hoarseness of the voice. Finally, we evidenced in one patient of the SUP group a surprising audible stridor resulting from expiration through the SUP just after insertion. Reducing cuff pressure of the laryngeal mask to 45 cmH<sub>2</sub>O relieved this abnormal expiratory sound. Endoscopic studies are requested to evaluate the influence of SUP cuff pressure on the glottis shape and post-operative laryngeal function.

Large-scale studies have already reported high success and low complication rates when a LMA was used during general anesthesia.<sup>1–3</sup> Similarly, some trials have shown that the LMA ProSeal™ was an efficient alternative to the ETT for laparoscopic cholecystectomy<sup>9</sup> and gynecological surgery.<sup>10</sup> However, routine 'LMA ProSeal' use for laparoscopic procedure remained relatively infrequent due to the lack of reliability of this airway if placed by a non-expert anesthesiologist. In contrast, we demonstrated that the SUP resulted in very low airway management difficulty VAS, with most anesthesiologists rating both ETT and SUP airway management techniques as very simple. Interestingly, the SUP was found to be an efficient ventilation device compared with the ETT. We confirmed that the SUP promoted high sealing pressure exceeding 30 cm in most (95%) cases. Moreover, four patients of the SUP group required a transient increase to more than 20 mmHg of the carboperitoneum pressure, resulting in a peak inspiratory pressure exceeding 35 cmH<sub>2</sub>O. For these patients we could not evidence any gas leak, suggesting that the sealing pressure of SUP could exceed 35 cmH<sub>2</sub>O in some patients.<sup>6</sup> Of interest, we

were able to drain the gastric content of all the patients of the SUP group. We believe that this easy gastric access associated with the use of the SUP is an additional safety argument favoring the use of this laryngeal mask in this type of surgery. Similar gastric drainage performed in the ETT group may have resulted in a difficulty in placing the probe in the stomach of some patients and would have certainly led to a higher pharyngolaryngeal morbidity rate.

Our study has limitations. Firstly, we could not blind the operating room observer who timed all the events during the procedure. A strict double-blind design for such a study would have been difficult under our working conditions. Secondly, our airway management techniques were compared in a single surgical indication. Thus, our results may not be generalizable to other abdominal surgery types because restriction of the use of SUP may be of concern until its safety is demonstrated. Thirdly, we studied only female patients, and our trial cannot be considered as a gender-related study. However, we have used a relatively small inner diameter ETT in order to limit the risk of abnormally high hoarseness of the voice in both the incidence and the intensity in the ETT group. Finally, in all patients of the SUP group the airway was placed after a muscle relaxant injection, which may not be considered as a usual practice. The SUP was inserted with optimal jaw relaxation, which was obtained in all cases during the 60 s following propofol injection, but before a peripheral maximal neuromuscular block was installed. Because paralysis was required for surgical purposes and the mean duration of the procedure was short (<1 h), we decided to insert the SUP a few seconds after the muscle relaxant injection. We are quite confident that this strategy did not affect our results.

In conclusion, we demonstrated that using the SUP instead of an ETT allowed reducing the post-operative pharyngolaryngeal morbidity resulting from airway management. We also showed that the SUP was an efficient alternative to the ETT for airway management during infertility pelvic laparoscopy procedures.

## Acknowledgements

Received from the Anesthesia and Intensive Care Department of Jean Verdier University Hospital of Paris (APHP), 93143 Bondy, France.

This trial was funded by departmental sources.

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