Original Article

Laryngeal mask airway protector generates higher oropharyngeal leak pressures compared to the laryngeal mask airway supreme: A randomized clinical trial in the ambulatory surgery unit

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Abstract

Background and Aims: The Laryngeal Mask Airway (LMA) Protector™ is one of the latest introduced supraglottic airway devices. It provides access and functional separation of the respiratory and digestive tracts. Compared to the LMA Supreme™, it has two digestive ports, one to provide suction in the pharyngeal region and one for gastric tube insertion. High oropharyngeal leak pressure is a marker for safe ventilation when using LMA devices. We hypothesized that oropharyngeal leak pressure of the LMA Protector™ is 5 cm H_2O higher than the oropharyngeal leak pressure of the LMA Supreme™ at various cuff volumes. Secondary outcome measures were ease of insertion of both masks, fiberoptic confirmation of correct positioning, failures of insertion, presence of blood staining, sore throat, presence of air leak and insertion time.

Material and Methods: American Society of Anesthesiologists (ASA) I-III patients aged >18 years, scheduled for elective minor ambulatory surgery under general anesthesia with a LMA were included. Patients were randomized in the LMA Protector™ or LMA Supreme™ group based on a computer-generated random sequence table. After general anesthesia induction, oropharyngeal leak pressures were measured.

Results: Oropharyngeal leak pressures were significantly higher ($P < 0.0001$) for LMA Protector™ compared to LMA Supreme™ at different cuff volumes and a cuff pressure of 65 cm H_2O. Insertion time was significantly higher for the LMA Protector™ (29 sec) [interquartile range (IQR) 23, 35] compared to the LMA Supreme™ (19 sec) (IQR 16, 22) ($P < 0.0001$). There were no statistically significant differences in ease of insertion (number of attempts for succesful positioning), failures of insertion, presence of blood staining, sore throat or presence of air leak.

Conclusion: Oropharyngeal leak pressures were consistently higher (>5 cm H_2O) for LMA Protector™ compared to LMA Supreme™. LMA Protector™, therefore, allows effective ventilation at higher airway pressures than LMA Supreme™.

Trial Registration: http://clinicaltrials.gov.NCT03462550.

Keywords: Laryngeal mask, laryngeal mask airway protector, supraglottic airway device

Background

A secure airway has always been a vital part of general anesthesia. In the past, several devices have been designed to allow safe airway management during surgery. The LMA Protector™ is one of the newest supraglottic airway devices from Teleflex Medical Incorporated. It is made primarily of silicone and has no aperture bars. Recent studies have illustrated that silicone cuffs can reduce the risk of sore throat

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and achieve higher seal pressures.[1,2] A high seal pressure guarantees sufficient patient ventilation whenever high peak airway pressures are necessary. An integrated cuff pressure indicator permits continuous cuff pressure monitoring. The device is accustomed to a fixation system to prevent proximal displacement during use, ensuring that the distal end seals around the upper esophageal sphincter. Stable fixation of an LMA could improve the safety of ventilation during prone position. The LMA Protector™ provides a functional separation of the respiratory and digestive tracts. The anatomically shaped airway tube is elliptical in cross-section and very compliant. It has two gastric drainage channels, a female and male port, which emerge as separate ports proximally. A suction tube may be attached to the male drainage port around the laryngeal region or a lubricated gastric tube may be passed through the female drainage port.

The LMA Supreme™ has been used for several years now. The cuff of the LMA Supreme™ is made out of polyvinylchloride, it has one gastric drainage channel and has fins in the bowl of the mask to prevent epiglottic obstruction. Compared to the LMA Protector™, the tube is stiffer.

Since the LMA Protector™ was introduced as the most advanced second generation of LMA devices, we wanted to compare this device with the LMA Supreme™, one of the LMA devices frequently used at our hospital. Up till now, only few studies compare the clinical efficacy of the LMA Protector™ with other supraglottic airway devices. In this study, we evaluated the oropharyngeal leak pressures of the LMA Protector™ and the LMA Supreme™. We hypothesized that oropharyngeal leak pressure of the LMA Protector™ is 5 cm H_2O higher than the oropharyngeal leak pressure of the LMA Supreme™ at different cuff volumes. Secondary outcome measures were ease of insertion, fiberoptic position of both masks, failures of insertion, presence of blood staining, sore throat, presence of air leak and insertion time.

Material and Methods

This prospective, randomized study was approved by the Institutional Review Board Hospital Ethics Committee of Ghent University Hospital and registered on http://clinicaltrials.gov (NCT03462550). Written informed consent was obtained from all patients. American Society of Anesthesiologists (ASA) Class I, II, or III patients aged >18 years planned for elective ambulatory surgery, routinely done with an LMA Classic were eligible. Patients with an anticipated difficult airway, a body mass index (BMI) >35 kg/m^2 or increased risk of aspiration (such as full stomach, hiatus hernia, etc.) were excluded. Patients were randomly allocated with a computer-generated random sequence table to LMA Protector™ or the LMA Supreme™ group. For practical reasons, investigators were not blinded. Patients were not aware of which type of LMA was used. Nurses at the Post Anesthesia Care Unit were also not aware of the type of LMA used. Monitoring consisted of electrocardiography, non-invasive blood pressure, pulse oximetry, and bispectral index (BIS-monitoring). The patients were preoxygenated for 3 minutes with FiO_2 of 1.0 at a fresh gas flow of 6 l/min. Anesthesia was induced with 0.15 mcg/kg sufentanil and 2-3 mg/kg propofol. No neuromuscular blocking agent was used. Patients' lungs were ventilated with a face mask for 3 minutes, an LMA (completely deflated) was inserted while the neck of the patient was flexed, the head extended. The LMA was inserted using a single-handed rotational technique.

Successful insertion was confirmed when symmetrical chest wall movement and square wave capnographic recordings were observed. Failed insertion was defined as: failed passage in the pharynx, malposition (air leak), and ineffective ventilation (expired tidal volume <25% of administered volume). The time between picking up the LMA and successful placement was recorded. When failed on the first attempt, the LMA was inserted with a digital guided technique. If a third attempt was necessary, a gum-elastic-bougie guided technique was used. Hereby, a gum elastic bougie is threaded through the gastric access channel with the curved end proximally. Under the laryngoscopic view, the bougie with mounted LMA is positioned in the esophagus and finally, the epiglottis is released in the bowl of the mask.[3] Up- or downsizing of the LMA was not foreseen in the protocol.

Oropharyngeal leak pressure was determined at six conditions with 0, 10, 20, 30, and 40 ml cuff volume and with the cuff inflated to 65 cm H_2O. During the different conditions, the expiratory valve of the circle system was closed at a fixed gas flow of 3 l/min and the airway pressure at equilibrium was recorded whenever an audible leak at the mouth was ascertained or whenever the maximal allowed airway pressure of 40 cm H_2O was reached. The Testo 510™ (Titisee-Neustadt, Germany), a differential pressure measuring instrument, connected to the airway circuit, was used to measure the corresponding airway pressures. Finally, cuff pressure was set at 65 cm H_2O using a manometer and patients' lungs were ventilated at a tidal volume of 10 ml/kg, at a respiratory rate of 12/min. The fiberoptic position of the LMA was checked by passing a bronchoscope (Pentax™ 3.7 mm) through the LMA and views were graded using the Brimacombe Score (1, vocal cords not visible; 2, vocal cords and anterior epiglottis visible; 3, vocal cords and posterior epiglottis visible; 4, vocal cords visible).

The presence of air leak was detected by listening over the mouth, gastric air leak (stethoscope over epigastrium, larynx,

drain tube air leaks (lubricant over proximal end) or end-tidal CO_2 >45 mmHg. Respiratory settings were changed at the discretion of the anesthesiologist after study measurements. Upon removal of the LMA at the end of the procedure, the device was observed for blood staining. At discharge from day surgery unit, patients were asked for the presence of sore throat using the visual analogue scale, with zero defining no pain and 10 the worst possible pain.

Statistics

Eschertzhuber reported an airway seal pressure for LMA Supreme™ (cuff pressure 65 cm H_2O) of 26 (7) cmH_2O.[4] Our null hypothesis was that the mean airway seal pressure of the LMA Protector™ and LMA Supreme™ are identical. We intend to disprove the null hypothesis and conclude that mean airway leak pressure for LMA Protector is 5 cm H_2O higher (31 (7) cm H_2O) than for LMA Supreme™. With a sample size of 32 patients per group, the study will have the power of 80% (type I error 0.05). IBM Statistical Package for the Social Sciences (SPSS) Sample Power was used for power analysis. To account for drop-outs, we included 40 patients in each group. The Kolmogorov–Smirnov test was used to determine the distribution of all continuous variables. Independent t-test was used for normally distributed continuous variables. Mann–Whitney U test was used for not normally distributed continuous variables. Data were analyzed with SPSS 24 software. Differences were considered significant at a *P* value of less than 0.05.

Results

Demographics were comparable between the two groups [Table 1]. Data on oropharyngeal leak pressure are represented in Figure 1 and Table 2. Airway leak pressures were significantly higher for the LMA Protector™ at different levels of cuff volumes and a cuff pressure of 65 cm H_2O. In 16 patients, oropharyngeal leak pressure was ≥40 cmH_2O. Data on insertion success, etiology of failure, blood staining, presence of air leak and insertion time are found in Table 3. Ninety percent of LMA Protector™ devices were successfully inserted on the first attempts vs 95% of LMA Supreme™ devices. None of the patients needed a rescue treatment with an endotracheal tube. Insertion time was statistically significant longer for LMA Protector™ (29 sec) (IQR 23,35) than that for LMA Supreme™ (19 sec) (IQR 16,22) ($P = (0.0001)$. Concerning fiberoptic control of the position of the LMA, we were unable to pass the bronchoscope through the epiglottic fins of the LMA Supreme™ and hence did not grade fiberoptic view. In 35 patients with LMA Protector™, we had the bronchoscope available. In 5 patients, vocal cords were visible; in 6 patients, vocal cords and posterior epiglottis were visible; and in 24 patients, vocal cords and anterior epiglottis were visible. No complications were observed during and after the use of the device in both groups.

Table 1: Demographics

	LMA Protector	LMA Supreme	*P*
Age (years)	42 (15.3)	41 (14.6)	0.8
Height (cm)	171 (10.8)	170 (9.9)	0.9
Weight (kg)	73 (13.6)	73 (14.3)	0.7

Data are presented as mean (standard deviation)

Discussion

The main finding in this study was significantly higher leak airway pressures for the LMA Protector™ at different cuff volumes and a cuff pressure of 65 cm H_2O. With cuff volumes of 20 ml, oropharyngeal leak pressures were higher than 25 cm H_2O. Moser found a mean difference of oropharyngeal leak pressure of 5.2 (95% CI 2.8–7.6), 30.9 (7.4) cm H_2O for the LMA Protector™ vs 25.6 (4.4) cm H_2O for the LMA Supreme™.[5] This is comparable to our results, however, Moser only investigated oropharyngeal leak pressure with a cuff pressure at 60 cm H_2O, whereas this study evaluated oropharyngeal leak pressure at five different cuff volumes (e.g., 0, 10, 20, 30, 40 ml) and finally at a cuff pressure of 65 cm H_2O. In our opinion, these results could lead to some advantages such as the use of the LMA Protector™ for laparoscopic surgery. The use of the LMA in laparoscopy has been controversial.[6-12] There has been concern about an increased risk of regurgitation and pulmonary aspiration. Furthermore, the ability of these devices to provide optimal ventilation during laparoscopic procedures has been questioned. Laparoscopy is thought to increase the risk of aspiration due to the inflation-induced pneumoperitoneum, which increases intra-abdominal pressure and is accompanied by higher peak airway pressures. During a laparoscopic procedure under pneumoperitoneum conditions, the airway seal pressure is crucial. A good seal pressure results in optimal ventilation of the lung and additionally reduces the potential risk of aspiration.

Recently, a case report from Tan *et al.* reported the successful use of the LMA Protector™ in three patients scheduled for elective laparoscopic cholecystectomy.[13] In their assessment, the LMA Protector™ possessed oropharyngeal leak pressures and maximum minute ventilation of ranges 27-31 cm H_2O and 15.1-21.8 l/min, respectively. These are above the thresholds of 25 cm H_2O for oropharyngeal leak pressure and 12 l/min for maximum minute ventilation considered to reflect adequate clinical efficacy. Oropharyngeal leak pressures in our study were comparable.

Table 2: Oropharyngeal leak pressures at different cuff volumes and at cuff pressure of 65 cm H_2O

	Cuff volumes					Cuff pressure
	0 ml	10 ml	20 ml	30 ml	40 ml	65 cm H_2O
LMA Supreme	10 (5) CI (9-12)	13 IQR (8)	18 (6) CI (17-20)	20 (6) CI (18-22)	22 (7) CI (20-24)	21 (6) CI (19-23)
LMA Protector	14 IQR (12)	21 IQR (13)	28.5 IQR (19)	32 IQR (18)	33.5 IQR (17)	30 IQR (18)
P	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001

Pressures are presented in cm H_2O median (IQR) for parametric data and mean (SD) (CI) for normally distributed data.

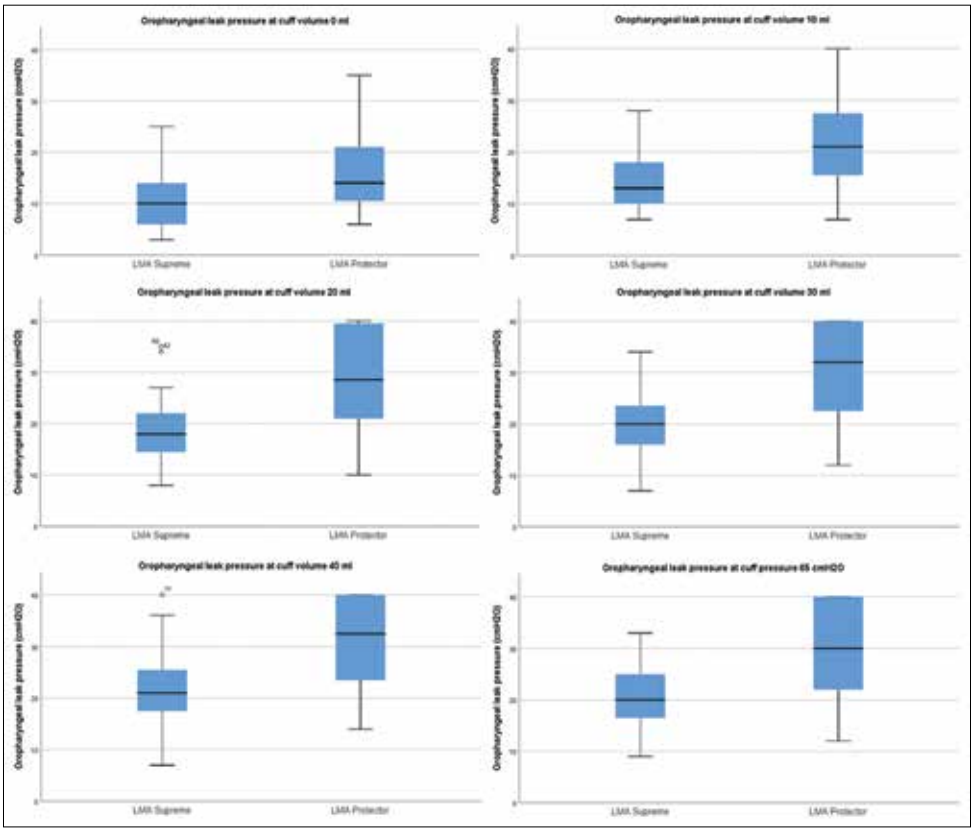

Figure 1: Oropharyngeal airway leak pressures at different cuff volumes and cuff pressure of 65 cm H_2O

Because of its higher oropharyngeal leak pressures, ensuring better lung ventilation and its dual suction ports leading to greater prophylaxis against aspiration, the LMA Protector™ could make orotracheal intubation unnecessary in well-selected patients. Other patient groups could benefit from ventilation with higher peak pressures through an LMA Protector™, e.g., patients with chronic obstructive pulmonary disease (COPD), obese patients, patients in Trendelenburg position.

Furthermore, in all 35 patients with LMA Protector™ where the bronchoscope was available at the time of the study vocal cords were visible so LMA Protector™ is probably an efficient guide for orotracheal intubation or conduit for diagnostic bronchoscopy. Insertion of a bronchoscope through an LMA Supreme™ is not intended because of the presence of epiglottic fins hindering the passage of the scope.

Our study contains some limitations. Data on oropharyngeal leak pressure may not apply to patients with a difficult airway, as this was an exclusion criterium in our study. Both anesthesiologists involved in data acquisition were experienced with the use of the LMA Supreme™. However, they both had little experience with using the LMA Protector™ prior to the start of the study. This could have an impact on the insertion time of the LMA Protector™. Compared to Moser *et al.* we found a lower leak airway pressure in the LMA Supreme™ group, 20 cm H_2O vs 25 cm H_2O. We are not certain about the cause of this discrepancy. We did not evaluate the ease of insertion of a gastric tube through both LMA devices. A previous study showed

Table 3: Secondary outcome measures

	LMA Supreme (*n*=40)	LMA Protector (*n*=40)	*P*
Insertion success, *n* First attempt	38 (95%)	36 (90%)	0.675
Second attempt needed, *n*	2 (5%)	4 (10%)	0.675
Third attempt needed, *n*	1 (2.5%)	0	1.000
Etiology of failure, *n*			
Failed passage into pharynx	1 (2.5%)	2 (5%)	1.000
Malposition (air leak)	1 (2.5%)	2 (5%)	1.000
Failed ventilation	1 (2.5%)	0	1.000
Visible blood staining, *n*	4 (10%)	8 (20%)	0.348
Sore throat (VAS)	0.13 (0.56)	0.18 (0.55)	0.689
Presence of air leak, *n*			
Listening at the mouth	4 (10%)	1 (2.5%)	0.359
Gastric auscultation	0	0	0.494
Laryngeal auscultation	2 (5%)	0	
At drain tube	0	0	
End-tidal >45 mmHg	0	0	
Insertion time (s)	19 IQR (16,22)	29IQR (23,35)	0.0001

more difficulty with inserting a gastric tube through the LMA Protector™ compared to the LMA Supreme™.[5] Moser *et al.* suggested that the soft silicone tip of the LMA Protector™ is more vulnerable for kinking, thus making passage of the gastric tube impossible. Another explanation for the difficult passing of the gastric tube through the LMA Protector™ may be that it does not provide a guided channel.[5]

Conclusion

With LMA Protector™, the oropharyngeal leak pressures are 10 cm H_2O higher than that with LMA Supreme™. LMA Protector™, therefore, allows effective ventilation at higher airway pressures than LMA Supreme™. In our opinion, these higher airway pressures could assure safe ventilation during laparoscopic surgery, such as laparoscopic cholecystectomy and enhance safety in COPD and obese patients or cases where higher peak airway pressures are generated. The use of the LMA Protector™ in these patient groups needs further investigation.

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Teleflex Medical Incorporated, 3015 Carrington Mill Boulevard, Morrisville NC 27560, United States provided LMA Protector and LMA Supreme.

Conflicts of interest

There are no conflicts of interest.

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