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The New Perilaryngeal Airway (*CobraPLA*™) Is as Efficient as the Laryngeal Mask Airway (*LMA*™), But Provides Better Airway Sealing Pressures[1,2]

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Abstract

The Laryngeal Mask Airway (*LMA*) is a frequently-used efficient airway device, yet it sometimes seals poorly, thus reducing the efficacy of positive-pressure ventilation. The Perilaryngeal Airway (Cobra*PLA*) is a novel airway device with a larger pharyngeal cuff (when inflated). We tested the hypothesis that the *CobraPLA* was superior to *LMA* with regard to insertion time and airway sealing pressure and comparable to *LMA* in airway adequacy and recovery characteristics. After midazolam and fentanyl, 81 ASA I-II outpatients having elective surgery were randomized to receive an *LMA* or Cobra*PLA*. Anesthesia was induced with propofol (2.5 mg/kg, IV), and the airway inserted. We measured 1) insertion time; 2) adequacy of the airway (no leak at 15-cm-H_2O peak pressure or tidal

[1]*CobraPLA* is a trademark of the Engineered Medical Systems and all references to Cobra*PLA* are to this trademark.

[2]*LMA* is a trademark of The Laryngeal Mask Company and all references therein to *LMA* are to this trademark.

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Implications: The perilaryngeal airway (*CobraPLA*) has insertion characteristics similar to laryngeal mask airway (*LMA*), but better airway sealing capabilities. This better sealing might improve the ability to provide mechanical ventilation.

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volume of 5 ml/kg); 3) airway sealing pressure; 4) number of repositioning attempts; and 5) sealing quality (no leak at tidal volume of 8 ml/kg). At the end of surgery, gastric insufflation, postoperative sore throat, dysphonia, and dysphagia were evaluated. Data were compared with unpaired t-tests, chi-square tests, or Fisher's Exact tests; $P<0.05$ was significant. Patient characteristics, insertion times, airway adequacy, number of repositioning attempts, and recovery were similar in each group. Airway sealing pressure was significantly greater with Cobra*PLA* (23±6 cm H_2O) than *LMA* (18±5 cm H_2O, $P<0.001$). The Cobra*PLA* has insertion characteristics similar to *LMA*, but better airway sealing capabilities.

Keywords

Airway: Sealing. Cuff Pressure. Insertion. Leak. Pharynx; Equipment: Laryngeal mask airway. Perilaryngeal airway; Ventilation: Controlled. Spontaneous; Anesthesia

Introduction

The Laryngeal Mask Airway (*LMA*, The Laryngeal Mask Company Limited, Henley-on-Thames, UK) is a well established supraglottic airway that is frequently used when endotracheal intubation is not required (1–3). Since its introduction into clinical practice (4), the *LMA* has broadened airway management techniques for anesthesiologists and emergency physicians. A major advantage of the *LMA* is its capacity to secure the airway even in patients in whom both tracheal intubation and conventional mask anesthesia are difficult (5). Although the *LMA* usually provides an adequate airway, certain problems remain in routine use. For example, more than one insertion attempt or repositioning is required in 5–10% of all cases (2,6). Furthermore, airway pressures exceeding 15–20 cm H_2O usually cause gas leakage (7, 8), which makes mechanical ventilation difficult. Therefore, it is not recommended for use in patients in whom peak airway pressures are anticipated to exceed 20 cmH_2O (9). In such cases, a new laryngeal mask device, the *ProSeal LMA* (Laryngeal Mask Company, Henley-on-Thames, UK) is recommended because it provides ~ 10 cmH_2 O higher airway sealing pressures than *LMA*. However, *ProSeal LMA* is more difficult to insert (10).

The perilaryngeal airway (*CobraPLA*, Engineered Medical Systems, Indianapolis, IN) is a novel cuffed airway device. The airway is positioned in the hypopharynx where it abuts structures of the laryngeal inlet. The *CobraPLA* is a supraglottic airway in the same class as the *LMA* and the cuffed oropharyngeal airway (COPA). It consists of a breathing tube with a wide distal end and a cuff attached just proximal to the wide part. The cuff, when inflated, serves to seal off the distal end from the upper airway. The wide end holds both soft tissues and the epiglottis away from the distal portion of the *CobraPLA*. Once in place, it abuts directly against the glottis with the anterior wall holding the epiglottis out of the way. Inside the distal end, a continuation of the breathing tube angles upwards (Fig. 1). Antero-posterior width of the distal end is smaller than the *LMA*. Therefore, it requires a smaller mouth opening for insertion, and it might be easier to insert than the *LMA*.

The *CobraPLA* has been tested in plastic models and healthy volunteers (personal communication from its inventor, David Alfery, M.D.). However, the device has yet to be formally evaluated in patients. We thus tested the hypothesis that the *CobraPLA* was superior to *LMA* with regard to insertion time and airway sealing pressure, but that *CobraPLA* was comparable to *LMA* in terms of airway adequacy and recovery characteristics.

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Materials and Methods

The study was conducted with approval of the University of Louisville Human Studies Committee and written informed consent. Participating patients were American Society of Anesthesiologists Physical Status I-II, > 18 years of age, Mallampati class I or II, had a mouth-opening > 3 cm, a thyro-mental distance > 6 cm, and a body mass index < 35 kg/m^2. All were scheduled for minor gynecological, orthopedic, or general surgery. Patients were excluded when a laryngeal airway was contraindicated or when the attending anesthesiologist believed that fiberoptic assistance would be required for intubation. Additionally, patients were excluded when they had a current or recent sore throat, gastro-esophageal reflux disease, pulmonary disease, cervical spine disease, pregnancy, dysphonia, or dysphagia.

Five of the investigators (3 attending physicians, 1 clinical fellow, and 1 C.R.N.A.) all of whom had > 6 years clinical anesthesia and *LMA*-insertion experience, were selected to insert the airways; these investigators were trained with a minimum of 10 *CobraPLA* insertions before the study started. Three unblinded investigators collected intraoperative data, and 2 blinded investigators collected postoperative data.

Sample size was estimated from the data of a preliminary study that involved 40 patients. In the preliminary study, there was ≈5 cm H_2O mean difference (with a SD of approximately 7 cm H_2O) in airway sealing pressures between the groups. With a *P* value of 0.05 considered as statistically significant, we estimated that with 80 patients, the study would have 90% power to detect a 5-cm difference in airway sealing pressure. The study was also powered to have 90% power to detect a difference of 20 seconds in the insertion time.

Protocol

Patients were premedicated with fentanyl (1–2 μg/kg) and midazolam (1–2 mg). After application of routine anesthetic monitoring, general anesthesia was induced by bolus IV administration of propofol (2–3 mg/kg). Patients were randomly assigned to either a *LMA* or a *CobraPLA*. Randomization was based on computer-generated codes that were maintained in opaque envelopes. Each intubating investigator was given 20 sequentially numbered randomization envelopes. They then enrolled patients as opportunity presented. *LMA* size was chosen according to the weight ranges recommended for this device. In the *CobraPLA* group, a size #3 was used in most women and a #4 in most men (during patient enrollment, the #5 *CobraPLA* was not yet available). Both airways were prepared and kept available for each patient since the randomization envelopes were not opened until just before airway insertion. Airways were lubricated with a water-based lubricant.

The first attempt of airway insertion was made ≈30 seconds after propofol injection when the eyelash reflex had disappeared and the jaw relaxed. During this time, 4–5 manual ventilations of 5–6 ml/kg of tidal volume were provided. The investigator performing the insertion tried to avoid insufflation of the patient's stomach. No muscle relaxants were administered prior to airway insertion. An independent observer measured the time of insertion with a stopwatch. The time started when the tip of the airway was at the upper incisors and stopped when an adequate airway was established, as defined by obtaining a good end-tidal CO_2 trace and a tidal volume exceeding 5 ml/kg ideal body weight or no leak with positive pressure ventilation of 15 cm H_2O. After two failed attempts at airway insertion, the alternative airway device was inserted if patient could be ventilated and pulse-oximeter saturation was >95%; otherwise, an endotracheal tube was inserted to maintain the airway. The cuffs of both airway devices were inflated to 60 cm H_2O. A low-pressure monitor (VBM, Sulz, Germany) was used to measure cuff pressure. This cuff pressure has been shown to provide safe mucosal tissue pressures (11,12).

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Anesthesia was maintained with 60% nitrous oxide, fentanyl (≈100 μg/hour), and sevoflurane (as needed to maintain mean arterial blood pressure within 20% of pre-induction values). Immediately after insertion of the airway, airway-sealing pressure was determined as described below. Subsequently, patients in whom the estimated duration of anesthesia was less than one hour were allowed to breath spontaneously. Otherwise, rocuronium (0.5 mg/kg) was given and patients were mechanically ventilated with a tidal volume of 8 ml/kg at a rate sufficient to maintain end-tidal PCO_2 near 40 mmHg.

Neuromuscular block was antagonized near the end of surgery. The amount of gastric insufflation was measured. Anesthesia was discontinued after completion of surgery, and the airway subsequently removed. Immediately after the removal of airway, oropharyngeal structures were visualized with the help of a tongue depressor and flashlight, and any major damage was recorded.

Measurements

Demographic and morphometric characteristics, airway classification, type of surgery, position of patient, airway device size, and duration of anesthesia were recorded. Patients' oxygen saturation (SpO_2) and end-tidal CO_2 concentration ($ETCO_2$) were recorded. Hypoxia was defined as $SpO_2 \leq 90\%$. Hypercapnia was defined as an $ETCO_2 > 45$ mmHg.

Airways were classified with a modified Mallampati score by asking patients to maximally protrude their tongues from a fully open mouth while sitting upright (13,14). Thyromental distance was measured as described by Tse *et al.* (15). This distance is described as a straight line from the thyroid notch to the anterior part of the chin with the head fully extended.

Airway devices were evaluated in three general categories: insertion, maintenance, and recovery. The insertion category included time and ease of insertion, seating, and airway adequacy. The maintenance category included quality of sealing and ventilation. The recovery category included characteristics such as sore throat, dysphagia, and dysphonia.

Insertion and Positioning—Airway insertion time was recorded using a stopwatch. Recording started when the device was inserted into the patient's mouth and stopped when an adequate airway (as described above) was obtained. The number of attempts required (1, 2, or failure) to correctly position the device was recorded, along with the airway size used. Once the device was optimally positioned, its position was not altered unless clinically indicated. Insertion depth was measured by placing a mark at the level of the incisors after insertion. The effective length of the device was the distance from the tip to the mark. Repositioning was defined as the repeated positioning in the pharyngeal area to obtain better airway sealing without extubating the head portion of the airway. Laryngospasm, when noted by the attending anesthesiologist and confirmed by the blinded observer, was recorded.

Airway sealing pressure—After insertion of the appropriate device, airway sealing pressure was measured by closing the expiratory valve of the circle system at a fixed gas flow of 3 L/min and noting the airway pressure at which the dial on the aneroid manometer reached equilibrium (16). Assessment of leak pressure was performed immediately after insertion of either device.

Sealing Quality—After insertion of the airway device and measurement of airway sealing pressure, patients were placed on mechanical ventilation — regardless of the duration of surgery — and ventilated with 8 ml/kg tidal volume (V_T) for two minutes. During this time, airway sealing quality was determined and rated as follows: 1) no leak detected; 2) minimal loss of V_T (V_T loss ≤20%); 3) moderate loss of V_T, (V_T loss of 20–40%); 4) insufficient seal (V_T loss > 40%). V_T loss was determined as inspiratory (set) V_T - expiratory (outcome) V_T,

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which was obtained from the monitor of Datex S/5™ anesthesia ventilator (Datex-Ohmeda, Madison, WI). Muscle relaxant was given only after measuring sealing quality in the relevant patients.

Anatomic fit—After LMA or *CobraPLA* insertion and cuff inflation, in a subgroup of consecutive 35 patients in the second half of the study, flexible fiberoptic bronchoscopy (Olympus BFP 30, O.D. 5.0 mm, Tokyo, Japan) was performed through a self-sealing diaphragm under continuing ventilatory support. The airway position was scored from the mask aperture bars by using the system proposed by Brimacombe *et al.* (17,18): 4 = only vocal cords visible; 3 = vocal cords plus posterior epiglottis visible; 2 = vocal cords plus anterior epiglottis visible; 1 = vocal cords not fiberoptically visible; 0 = failure to insert or to function.

Gastric insufflation—Before airways were removed at the end of surgery, the cuff was deflated and an orogastric tube inserted (Salem Sump Tube with Anti-Reflux Valve 18Fr. [Argyle ®, Sherwood Medical, St. Louis, MO]). The volume of gas that could be aspirated was recorded (19). Clinically important gastric insufflation was defined by a residual gas volume > 50 ml. Aspiration was noted per assessment of the attending anesthesiologist. The subjective definition used was presence a cough and airway irritation after extubation of the airway.

Degree of irritation—One hour postoperatively, patients were asked to rate their throat soreness, dysphonia, and dysphagia using 100-mm visual analog scales by blinded investigators. For evaluation of dysphagia, sips of water were given. A new, unmarked scale was used for each patient. Patients were also asked if they experienced any tingling, numbness, or other oropharyngeal sensations.

Data analysis

Our primary outcomes were airway sealing pressure (cm H_2O) and insertion time (seconds). The secondary outcomes were number of insertion attempts and repositioning maneuvers; anatomical fit as determined by fiberoptic evaluation; gastric insufflation; oropharyngeal irritation (throat soreness, dysphagia, and dysphonia).

Data were tested for normal distribution and analyses were performed by chi-square statistics and unpaired *t*-tests or non-parametric analogues of *t*-tests, as appropriate. Results were presented as means ± SD, or actual numbers; $P < 0.05$ was considered statistically significant for designated primary outcomes. In contrast, a $P < 0.01$ was required for secondary outcomes; the smaller value was used to compensate for multiple comparisons.

Results

Based on our sample-size estimate, 80 patients were to be enrolled. However, two patients were enrolled simultaneously on the last study day by two different investigators. We thus ended up with 81 patients. More men than women participated; however, demographic and morphometric characteristics were similar in the two airway groups (Table 1). The majority of the cases were short orthopedic surgery cases (such as hardware removals or screw/plate removals) and gynecologic cases. Although our inclusion criteria allowed only Mallampati Class I and II airways, one patient with a Class III airway was inadvertently enrolled and randomly assigned to the *LMA* group. This patient's outcomes were similar to the other patients assigned to the *LMA* airway.

Overall, airways were successfully managed in 39 out of 40 in the *CobraPLA* group and in 41 of 41 cases in the *LMA* group. In one *CobraPLA* patient, according to random selection, first insertion of *CobraPLA* was attempted twice, then insertion of *LMA* was attempted twice, but

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neither could maintain an adequate airway; the attending physician thus decided to intubate the trachea.

Airway-sealing pressures were greater in the *CobraPLA* group (23 ± 6; range 8 to 36 cm H_2O) than in the *LMA* group (18 ± 5; range 8 to 32 cm H_2O). However, insertion time, number of attempts, and clinically assessed airway sealing quality classification were similar in the groups (Table 2). Perfect airway sealing (score of 1: no leak detected) occurred in 21 out of 40 in the *CobraPLA* and 13 out of 41 in the *LMA* group ($P = 0.095$). When we included sealing scores of 1 and 2, the groups appeared to be even more closely matched (*CobraPLA*: 28 out of 40 versus *LMA*: 26 out of 41; $P = 0.80$).

Anatomic fit, as determined fiberoptically, was found to be similar in the groups: anatomic fitness scores of 3/4/5/5 for *CobraPLA* versus 5/4/6/3 for *LMA.* The *LMA* and *CobraPLA* caused clinically important gastric insufflation (defined as > 50 ml) in a similar number of cases: six in the *CobraPLA* and four in the *LMA* group. Furthermore, the average amount of gastric insufflation was small and did not differ significantly: 24 ± 34 ml for *CobraPLA* versus 26 ± 25 ml for *LMA*. The amount of oropharyngeal irritation was also similar with each airway (Table 2). Intense coughing was observed in one *CobraPLA* case whereas hiccups were observed in one *LMA* case.

Discussion

We tested the hypothesis that the *CobraPLA* is as effective as the *LMA*, but provides superior insertion time and sealing pressure. Our results confirmed that the sealing pressure was greater with the *CobraPLA*, but insertion times were similar with the two devices. Otherwise, the number of patients with successful airway placement was similar in the two groups, as were measures of airway efficacy. The first-attempt success rates of the two devices were also comparable. These data suggest that the *CobraPLA* as well as the *LMA* may prove useful as a "rescue" device during failed intubations. Nevertheless, it is important to recognize that anatomic abnormalities cause most intubation failures; excellent results in the relatively normal patients we evaluated may thus fail to predict comparable success (with either device) in patients who cannot be intubated.

We were surprised that insertion success rates were comparable for the devices although the investigators had years of experience with the *LMA* but had inserted the *CobraPLA* only about ten times or so before starting the study. Facility with the *LMA* and insertion success continue to improve through hundreds of insertions (20).

Among our primary and secondary outcomes, there was only a single statistically significant difference: airway sealing pressures were 23 ± 6 cm H_2O with the *CobraPLA*, which was about 5 cm H_2O greater than with the *LMA*. The observed difference is clinically important because airway pressures of ≈20 cm H_2O are typically required in routine practice. Furthermore, the company that manufactures the LMA recommends a ventilatory pattern that keeps peak airway pressure < 20 cm H_2O (9). It is thus likely that mechanical ventilation will succeed better with the *CobraPLA* than the *LMA* in cases and surgeries that are more complicated — even though no important difference was noted in the short elective cases we studied. It should be noted that there is a better sealing version of the *LMA*. This relatively new airway device is called the *ProSeal LMA* and provides ≈ 10 cmH_2O better airway sealing pressures than the *LMA* (10).However, the *ProSeal LMA* may be harder to insert, because of its larger antero-posterior distal end width compared to the *LMA*.

Improved sealing presumably results because the *CobraPLA* has a large ellipsoid cuff located in the upper portion of the device that easily covers the proximal pharynx. Similarly, the laryngeal tube airway also has a large cuff that allows it to provide higher sealing pressures

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than the *LMA* (21). The combination of good anatomic seating and a cuff sufficiently large enough to cover peripharyngeal tissues increases the chance of providing a patent airway with adequate airway sealing.

Efficacy is only half the equation; any new drug or device also needs to be evaluated for safety. Gastric insufflation was a particular concern because the superiorly located larger cuff of *CobraPLA* that improves airway-sealing pressure might also facilitate gas flow into the stomach. However, the number of patients with clinically important insufflation was similar in each group, and the amount of gas in the stomach was small and similar with each airway. We therefore conclude that under the conditions of our study, which included mechanical ventilation in half the patients, gastric insufflation is not problematic with either device. However, one needs to consider that gastric insufflation was only measured once, at the end of surgery. We may have obtained values that are more accurate if we continuously monitored gastric insufflation throughout surgery. On the other hand, this would have interfered with testing airway sealing.

Coughing and hiccups are other symptoms of irritation caused by supraglottic airways (22). Only one coughing episode with *CobraPLA* extubation and one hiccup episode during assisted ventilation in an *LMA* case were observed in this study. The presence of blood on the devices was similar with each airway, but it was more prevalent than in most previous reports (23). The major reason, presumably, was that insertion of the NG tube (orally) at the end of each case to evaluate gastric insufflation traumatized the upper airway. Recovery characteristics were similar with each device, and neither seemed to be associated with sore throat, dysphonia, or dysphagia.

Proper anatomic positioning of airways is necessary for optimal function. Positioning, as determined fiberoptically, was similar with the *LMA* and *CobraPLA*, which is consistent with similar insertion success rates. Positioning also helps predict an airway's ability to assist with fiberoptic intubation. It is well established that *LMA* facilitates intubation; in fact, it is available in an intubating version. More importantly, *LMA* has a well-deserved spot in the American Society of Anesthesiology difficult-airway algorithm (5). The *CobraPLA* is also designed to facilitate fiberoptic intubation. A size 3 *CobraPLA* allows passage of a size 6.5 endotracheal tube, whereas a size 4 *CobraPLA* supports passage of a size 8 endotracheal tube. The *CobraPLA* thus has larger tubing than a conventional *LMA* and permits passage of larger endotracheal tubes. Although our fiberoptic position data suggest that intubation through a *CobraPLA* should be at least as easy as through a *LMA*, we did not evaluate intubation with either device.

Brimacombe *et al.* showed complete blood vessel collapse and impairment of mucosal perfusion in 90% of patients at the mean mucosal pressure of 80 cm H_2O — although reduction in blood vessel caliber was observed with a mucosal pressure as little as 34 cm H_2O (11). The manufacturer of the *LMA* suggests that cuff pressures be kept less than 60 cm H_2O (9). This recommendation is consistent with our preliminary experiments in which sealing was poor at lower pressures. We thus chose a cuff pressure of 60 cm H_2O for our study.

A limitation of our study is that it was impossible to blind the investigators who inserted the airways. However, it is reasonable to assume that these five experienced clinicians did their best to secure the airway with each device. Interestingly, the only important difference between the devices that we identified was in airway sealing pressure — an objective measure that is not subject to investigator bias. Post-operative measures, such as sore throat, were evaluated by blinded investigators and thus presumably free from bias. There is thus little reason to believe that failure to fully blind the study influenced our results.

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In summary, the *CobraPLA* was found to be as efficient an airway device as the *LMA*. There were no differences in insertion time, insertion success, or post-operative outcomes. However, the *CobraPLA* sealed the airway at a significantly greater pressure: 23 ± 6 cm H_2O *versus* 18 ± 5 cm H_2O. Although the evaluation period of the sealing quality was done for a limited amount of time immediately after intubation, the CobraPLA might be a better choice than the *LMA* in patients likely to benefit from mechanical ventilation.

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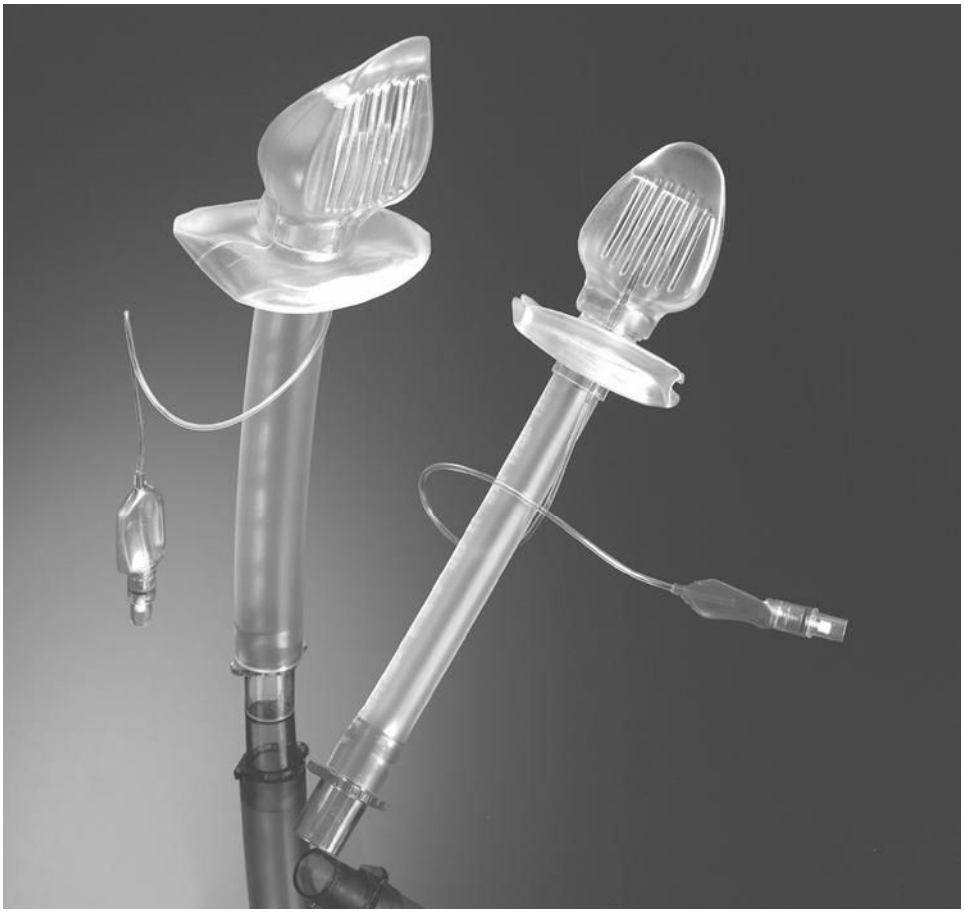

Fig. 1.
Sizes 3 and 4 *CobraPLA*.

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Table 1

Patient Characteristics and Potential Confounding Factors.

	CobraPLA(n=40)	*LMA*(n=41)
Age (yr)	35 ± 14	35 ± 11
Height (cm)	176 ± 15	170 ± 11
Weight (kg)	81 ± 18	78 ± 17
Body Mass Index (kg/m^2)	27 ± 7	27 ± 6
Gender (F/M)	13 / 27	20 / 21
Mallampati Class (I/II/III)	24 / 14 / 0*	22 / 18 / 1
Type of Surgery (Orthopedic/Gynecological/General Surgery)	28 / 6 / 6	25 / 10 / 6
Position (Supine/Lithotomy)	29 / 8*	30 / 10*
Duration of Anesthesia (min)	65 ± 39	62 ± 42
Airway Device Size (3/4/5)	13 / 27 / 0	5 / 28 / 8
Depth of insertion (cm)	15.4 ± 0.8	15.6 ± 0.7

Data presented as means ± SDs or counts. There were no statistically significant differences between the airway groups.

* Missing data.

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Table 2

Major Outcomes.

	CobraPLA	*LMA*	*P*
Insertion	**(n=40)**	**(n=41)**	
Insertion Time — 1st Attempt (sec)	32 ± 14	30 ± 14	0.487
Insertion Time — All Attempts (sec)	38 ± 31	38 ± 34	0.994
Attempts (1 / 2 / 3)	37 / 2 / 1	38 / 3 / 0	0.833†
Repositioning (Yes/No)	7 / 33	4 / 37	0.488
Laryngospasm (none/moderate)	39 / 1	41 / 0	0.480†
Hypoxemia (none/mild/severe)	39 / 0 / 1	40 / 1 / 0	0.733†
Maintenance	**(n=39)**	**(n=41)**	
Airway Sealing Pressure (cm H_2O)	23 ± 6	18 ± 5	<0.001
Sealing Pressure ≥ 20 cm H_2O (# patients)	29	15	<0.001
Sealing Quality (1/2/3/4)‡	21 / 7 / 8 / 2	13 / 13 / 11 / 1*	0.285
Ventilation (Controlled/ Assisted/Spontaneous)	17 / 2 / 20	18 / 1 / 19*	1.000†
Anatomic Fit (4/3/2/1)	3 / 4 / 5 / 5	5 / 4 / 6 / 3	0.881
Hypercapnia (none/mild/moderate)	36 / 1 / 1	39 / 1 / 0	0.740
Aspiration (none/mild)	39 / 0	40 / 1	1.000†
Extubation & Recovery			
Blood staining (yes/no)	19 / 19*	14 / 22*	0.360
Gastric Insufflation (ml)¶	25 ± 40	26 ± 25	0.522#
Sore Throat VAS§ Score> 10mm (yes/no)	16 / 23	9 / 31	0.077
Dysphonia VAS Score > 10mm (yes/no)	7 / 32	5 / 35	0.500
Dysphagia VAS Score > 10mm (yes/no)	8 / 31	6 / 33*	0.555

§VAS = Visual analog scale: 0 mm = no pain; 100 mm = worst imaginable pain.

‡Sealing quality: 1) No leak detected; 2) Minimal loss of tidal volume (V_T loss ≤20%); 3) Moderate loss of V_T (V_T loss of 20–40%); 4) Insufficient seal (V_T loss > 40%).

¶Data from patients with controlled ventilation. Data presented as means ± SDs or counts. *P* values were calculated using unpaired, two-tailed t, chi-square,

†Fisher's exact, or

#Wilcoxon Rank Sum tests.

*Missing data.