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The CobraPLA™ During Anesthesia with Controlled Ventilation: A Clinical Trial of Efficacy

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The CobraPLA™ (CPLA) is a relatively new supraglottic airway device that has not been sufficiently investigated. Here, we performed a prospective observational study to evaluate the efficacy of the CPLA during controlled ventilation. In 50 anesthetized and paralyzed patients undergoing elective surgery a CPLA was inserted and inflated to an intracuff pressure of 60 cm H_2O. The success rate of insertion upon the first attempt was 82% (41/50), with a mean insertion time of 16.3 ± 4.5 seconds. The adequacy of ventilation was assessed by observing the end tidal CO_2 waveform, movement of the chest wall, peak airway pressure (13.5 cm H_2O), and leak fraction (4%). We documented the airway sealing pressure (22.5 cm H_2O) and noted that the the site of gas leaks at that pressure were either at the neck (52%), the abdomen (46%), or both (2%). In 44 (88%) patients, the vocal cords were visible in the fiberoptic view through the CPLA. There was no gastric insufflation during the anesthesia. Respiratory and hemodynamic parameters remained stable during CPLA insertion. Postoperative blood staining of CPLA was minimal, occurring in 22% (11/50) of patients. Mild and moderate throat soreness was reported in 44% (22/50) and 4% (2/50) of patients, respectively. Lastly, mild dysphonia was observed in 6% (3/50) of patients and mild dysphagia in 10% (5/50) of patients. Our results indicated that the CPLA is both easy to place and allows adequate ventilation during controlled ventilation.

Key Words: Airway, leak pressure, oxygenation, supraglottic device (CobraPLA™), ventilation

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INTRODUCTION

Supraglottic airway devices have been introduced in the clinical field as an alternative to traditional endotracheal intubation tubes. Recently, a new supraglottic device, known as CobraPLA™ (CPLA, Engineered Medical systems, Indianapolis, IN, USA) was introduced for clinical application. The CPLA consists of a breathing tube with a softened and widened distal end and an inflatable cuff attached proximally to the wide end (Fig. 1). The distal end of the CPLA is designed to sit in the hypopharynx and seal the airway, thus allowing positive pressure ventilation. When positioned in the hypopharynx, the CPLA also abuts the structure of the laryngeal inlet. Oxygen and inhalation anesthetics are delivered into the trachea via a series of slotted openings at the distal end of the ventilatory channel.

Alternatives to conventional intubation for airway management of difficult intubation,[1-3] positive pressure ventilation, or spontaneous ventilation during general anesthesia for minor surgery[4-8] have been explored. Such alternatives offer

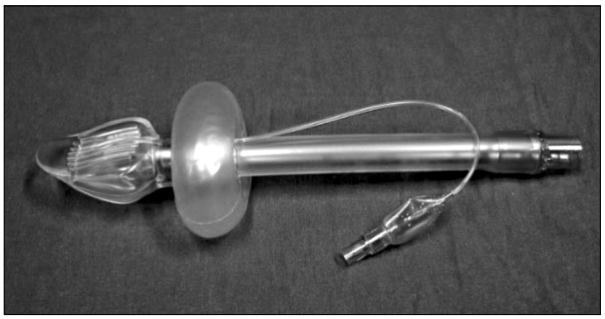

Fig. 1. The CobraPLA™.

some advantages, in that they involve a relatively simple insertion technique, resulting in less hemodynamic changes.[1,9,10] However, the efficacy of the CPLA has not been adequately investigated. The purpose of this study, then, was to evaluate whether the CPLA provides sufficient ventilation and adequate oxygenation to patients during controlled ventilation.

MATERIALS AND METHODS

We performed a prospective observational study using the CPLA device during anesthesia with controlled ventilation between December 2004 and March 2005. The study protocol was approved by the ethical committee of our institute. After obtaining the patients' gender, age, height, weight, and Mallampati classification, we explained general anesthesia and the CPLA, and subsequently obtained written informed consent from the patients. We studied 50 ASA I or II adult patients with Mallampati I or II that were undergoing arthroscopic surgery of the knee (Table 1). Exclusion criteria included any neck or upper respiratory tract abnormalities, evidence of pulmonary or cardiovascular disease, risk of aspiration of gastric contents, and lateral decubitus or prone position. Patients fasted overnight and were intravenously premedicated with 0.004 mg/kg glycopyrrolate and 2.0 - 3.0 mg midazolam. After routine monitoring, general anesthesia was induced intravenously with fentanyl (1 ug/kg), propofol (1.5 - 2.0 mg/kg) and rocuronium (0.5 mg/kg). Anesthesia was maintained with sevoflurane and 50% nitrous oxide in oxygen at a total gas flow rate of 4 L/min.

Table 1. Patient Characteristics

Age (yrs)	33.2 ± 14.1
Sex (M/F)	28/22
Weight (kg)	66.1 ± 10.8
Height (cm)	168.4 ± 9.4
Mallampati class (I/II)	32/18
Tube size (3/4)	45/5

Data are the number of the patients or mean ± SD.

We used a size 3 CPLA for patients whose height was less than 180 cm, and a size 4 CPLA for patients whose height was greater than 180 cm. For intubation, the patient's head was placed on a pillow in a sniffing position, and a CPLA lubricated with water-soluble jelly was inserted along the hard palate until resistance was felt by the investigator (investigators had performed more than 20 prior CPLA insertions). We measured CPLA insertion time, defined as the time between insertion of the tube into the patient's mouth and the time of the first breath made by manual ventilation. We recorded the number of insertion and repositioning attempts if ventilation was not appropriate according to auscultation, movement of the chest wall, end-tidal CO_2 curve, gastric insufflation, and airway pressure. If the CPLA was not placed by the second attempt, then it was recorded as a failure, and the study was terminated.

Upon successful insertion, the cuff was inflated with air to a pressure of 60 cm H_2O, using a manometer (Cuff Pressure Gauge, VBM Medizintechnik, Sulz, Germany), and the initial air volume of the cuff was recorded. The pilot balloon of the CPLA was connected to a cuff pressure gauge through a three-way stopcock, and cuff pressure was recorded at 5 to 10 minute intervals until the cuff pressure reached 100 cm H_2O. Volume-controlled ventilation of the lungs was applied, using a volume-cycled anesthesia ventilator (Cato, Dräger, Lübeck, Germany). The tidal volume was 10 mL/kg, and the respiratory rate was 12 breaths/min. Blood pressure, heart rate, oxygen saturation, and end-tidal CO_2 tension were monitored with a Solar 8000 monitor (GE Medical System Inc., Milwaukee, WI, USA). Airway pressure (peak, plateau) and inspiratory and expiratory minute volume data were collected at 5 minute intervals following insertion of the CPLA. The sealing pressure was recorded as the airway pressure at which the aneroid manometer reached equilibrium after closing the expiratory valve of the circle system at an O_2 flow of 3 L/min. To prevent lung barotraumas, we observed until the airway pressure was 30 cm H_2O. The direction of gas leaks at the sealing pressure was measured by auscultation with the stethoscope on the mouth, stomach, and at both sites. After measuring the

leak pressure, the position of the CPLA was scored by passing a fiberoptic bronchoscope through the airway to the end of the device. Scoring was done with the system proposed by Brimacombe[11] (1 = vocal cords not fiberoptically visible; 2 = vocal cords plus anterior epiglottis visible; 3 = vocal cords plus posterior epiglottis visible; 4 = only vocal cords visible). Gastric insufflation was monitored by auscultation during the anesthesia. Complications associated with CPLA insertion (blood staining, dysphagia, dysphonia, and sore throat 1 day after operation) were also recorded.

Data were analyzed, using Statview (2nd edition, SAS Institute Inc., Cary, NC, USA). Hemodynamic and spirometry parameters were analyzed by a repeated measure ANOVA. A *p*-value of less than 0.05 was considered statistically significant. Results are presented as mean ± SD or as actual numbers.

RESULTS

We were able to insert the CPLA and initiate ventilation in 41 (82%) and 9 (18%) patients upon the first and second attempts, respectively. The mean insertion time was 16.3 ± 4.5 seconds. At an intracuff pressure of 60 cm H_2O, the mean air volume of the cuff was 56.3 ± 5.2 mL and 57.5 ±6.4 mL for size 3 and 4 CPLAs, respectively. Cuff pressure was increasingly elevated from 62.4 cm H_2O at 2 min post-insertion, 70.6 cm H_2O 30 min post insertion later, and to 76.8 cm H_2O 1 hour post insertion (Fig. 2). The mean airway sealing pressure was 22.5 ± 3.7 cm H_2O, and at the sealing pressure leaks were heard at the mouth in 26 patients, the stomach in 23 patients, and at both sites simultaneously in 1 patient. The mean peak airway pressure was maintained at 13.5 cm H_2O. Inspiratory minute ventilation was 7.2 ± 1.4 L/min, and expiratory minute ventilation was 6.9 ± 0.7 L/min (Table 2). Airway position scores, as determined by flexible fiberoptic bronchoscopy, revealed a score 1 view in 6 patients, a score 2 view in 10 patients, a score 3 view in 18 patients, and a score 4 view in 16 patients. Gastric insufflation during the anesthesia was not observed with the CPLA. Mean arterial pressure and heart rate were maintained without significant change during the procedure. Oxygen saturation and end-tidal CO_2 concentrations were also maintained without significant change ($p > 0.05$).

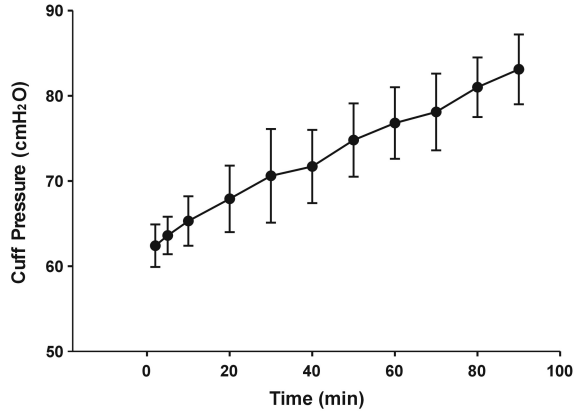

Fig. 2. Changes in intracuff pressure throughout the experiment with CobraPLA™. Data are given as mean ± SD.

Table 2. Respiratory Data

Airway sealing pressure (cm H_2O)	22.5 ± 3.7
Inspiratory MV (L/min)	7.2 ± 1.4
Expiratory MV (L/min)	6.9 ± 0.7
Peak airway pressure (cm H_2O)	13.5 ± 2.7
Plateau airway pressure (cm H_2O)	11.7 ± 6.8

MV, minute ventilation.
All values are expressed as mean ± SD.

Upon removal of the CPLA, blood traces on the device were visible in 11 (22%) cases. After 24 hours, mild/moderate sore throat was present in 22/2 (44%/4%) cases, mild dysphonia was reported in 3 (6%) cases, and mild dysphagia was noted in 5 (10%) cases.

DISCUSSION

We have demonstrated that the CPLA device provided a patent airway during controlled ventilation of the lungs and that the softened distal tip of the CPLA head provided easy passage of the device into the hypopharynx. The size of CPLA used for this study differed from the manufacturer's recommendation of a size 3 or 4 tube for adult weights > 35 kg and 70 kg, respec-

tively. However, Agro et al.[12] used a size 3 CPLA for patients whose weight was less than 60 kg, size 4 for those weighing 60 - 80 kg, and size 5 for those whose weight was more than 80 kg. In a preliminary study, a size 4 CPLA had a greater resistance than size 3 tubes when inserted into the mouth , and, thus, we used size 3 CPLAs for most of the patients. Nonetheless, we feel that a more extensive evaluation of proper CPLA size is necessary.

In order to determine the efficacy of the CPLA device, measurement of the rate of successful insertion was essential. In our study, the success rates for first and second insertion attempts were 82% and 18%, respectively. The mean insertion time of the CPLA was 16.3 seconds, which was comparable to previous findings for CPLAs,[13] laryngeal tubes (LT),[14] and LMAs.[15] After inflating the cuff of the CPLA to 60 cm H_2O, the initial volume was 56.3 ± 5.2 mL and 57.5 ± 6.4 mL for size 3 and 4 CPLAs, respectively. These volumes were compatible with the manufacturer's recommended volume limits of 65 or 70 mL for the size 3 or 4 CPLAs, respectively. The cuff pressure of the CPLA increased progressively throughout the procedure to approximately 80 cm H_2O because we used N_2O gas, which has a greater diffusion capacity for inflation than air.[16,17] A higher concentration of N_2O results in higher intracuff pressure.[16]

Pharyngeal mucosal perfusion is reduced progressively in the posterior pharynx when the mucosal pressure is increased from 34 to 80 cm H_2O with a cuffed oropharyngeal airway,[18] and the incidence of postanesthetic tracheal mucosal injuries can be minimized by preventing excessive cuff pressure.[19] Although we did not examine the correlation between intracuff pressure of the CPLA and pharyngeal mucosal injury, it is clear that a lower pressure of the device may also prevent mucosal ischemia. Thus, we believe that the cuff pressure of the CPLA should be monitored and maintained at initial values in order to prevent excessive pressure on the pharyngeal mucosa.

Using volume-controlled mechanical ventilation, the mean peak airway pressure was 13 cm H_2O when we set the tidal volume at 10 mL/kg. This value was less than those obtained with a tidal volume of 12 mL/kg for LTs[20] and for LMAs.[21] The leak pressure was 22.5 cm H_2O, which was higher than the airway pressure, and, thus, made appropriate ventilation of the lungs with the CPLA possible. The mean leak pressure in our study closely matched the findings of a previous study of CPLAs by Akca et al,[8] who suggested that, in comparing CPLAs with LMAs, that the CPLA is a safer airway management device because it has both a higher leak pressure and a smaller air volume suctioned via the nasogastric tube than LMAs.

We also observed the location of gas leaks. Leakage to the mouth was observed in 26 cases (52%), leakage to the stomach was present in 23 cases (46%), and leakage to both sites was present in 1 case. Gas leaks to the stomach are more problematic than leaks to the mouth, as they can cause inflation of the stomach and intestines, as well as an increased risk of gastric content aspiration. The possibility of gastric content aspiration increased when airway pressure is higher than leak pressure. We believe that the possibility of gastric insufflation with the CPLA device may be low during positive pressure ventilation in patients who do not require high inflation pressure to produce a normal tidal volume. The expired tidal volume was approximately 4% less than the inspired volume; however, according to auscultation with a stethoscope placed on the neck and stomach region, no significant air leaks were detected at the mean peak respiratory pressure of 13 cm H_2O with an intra-balloon pressure of 60 cm H_2O. In the present study, the highest peak airway pressure was 19 cm H_2O, and the highest leak pressure was 27 cm H_2O. This leak fraction was lower than other supraglottic airway devices, which are from 13% at 15 cm H_2O to 27% at 30 cm H_2O ventilation pressure for LMAs,[4] or 10% for LTs.[20] We suggest that a CPLA cuff pressure of 60 cm H_2O should be sufficient to ensure positive pressure ventilation with a tidal volume of 10 mL/kg.

Proper anatomic positioning of airway devices is necessary for optimal functioning. The mean fiberoptic position score was 2.94, and perfect positioning (score 4) was found in only 32% of patients overall. Fiberoptic assessment of the CPLA indicated that, while alignment of the

slotted ventilation opening of the CPLA with the laryngeal aperture may not be anatomically perfect, its function was clinically satisfactory in the majority of patients. Our data show that sufficient ventilation and oxygenation could be achieved using the CPLA. Further, hemodynamic parameters before and after induction of general anesthesia were not significantly changed with the CPLA, suggesting that the CPLA has little effect on the cardiovascular system, compared to conventional endotracheal intubations.

Minimal blood staining of the CPLA was found in 11 patients; however, they did not require treatment and had no further bleeding in the post-anesthetic care room. The incidence of postoperative mild and moderate sore throats in this study was 44% and 4%, respectively. Akca et al.,[8] using a 100-mm visual analog scale score, reported that the incidence of a sore throat of more than 10 mm is 40%. Mild dysphonia and dysphagia was experienced by 3 and 5 of the patients, respectively; however, symptoms subsided one day after the operation.

This was an observational study and was limited by including only experimental patients who were undergoing arthroscopic knee surgery and not including a comparison with the other supraglottic airway devices. In conclusion, the CPLA appears to be a simple, easy to insert, and safe airway management device that allows effective ventilation during anesthesia with controlled ventilation.

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