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APPARATUS

An evaluation of the Cobra Perilaryngeal Airway™: study halted after two cases of pulmonary aspiration*

T. M. Cook[1] and J. M. Lowe[2]

1 Consultant Anaesthetist, 2 Specialist Registrar in Anaesthesia, Department of Anaesthesia, Royal United Hospital NHS Trust, Combe Park, Bath, BA1 3NG, UK

Summary

The Cobra Perilaryngeal Airway™ (Engineered Medical Systems, Indianapolis, IN) is a new supraglottic airway designed for spontaneous and controlled ventilation. It is not yet commercially available in the UK. Our aim was to evaluate the performance of the Cobra Perilaryngeal Airway™ in a cohort study and in a randomised, controlled, crossover comparison study with the Classic Laryngeal Mask Airway™. After studying 29 patients, both studies were suspended and later stopped after two cases of significant pulmonary aspiration had occurred in patients whilst using the Cobra Perilaryngeal Airway™. These cases raised concern about both the design and the safety of the Cobra Perilaryngeal Airway™, particularly during controlled ventilation. We suggest that the Cobra Perilaryngeal Airway™ should not be marketed for controlled ventilation until more safety data are available.

Correspondence to: Dr T. M. Cook
E-mail: timcook@ukgateway.net
**A response to this paper from the manufacturers of the Cobra Perilaryngeal Airway™ is in the Correspondence section of this issue.*
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The introduction of the Classic Laryngeal Mask Airway™ (cLMA™) has dramatically changed airway management in recent times, and it now plays a vital role in both routine anaesthesia and difficult airway management. The last decade has seen a number of supraglottic airway devices come onto the market. It is essential to assess the performance and safety of these new devices in clinical practice and to compare them to currently available devices [1].

The Cobra Perilaryngeal Airway™ (Cobra PLA™) (Engineered Medical Systems, Indianapolis, IN) is a new supraglottic airway designed for spontaneous and controlled ventilation (Fig. 1). It has been used in the USA and in parts of Europe, but is not yet commercially available in the UK. It consists of a translucent silicone airway tube with an inflatable cuff sited approximately two-thirds of the way to the tip, a 15-mm standard adapter and an expanded distal end with a smooth posterior surface and soft 'frond-like' anterior grilles that cover the airway orifice (Fig. 2). The cuff forms a seal in the upper pharynx and the distal end sits in the laryngopharynx. The distal grill is designed to sit over the laryngeal inlet. The Cobra PLA™ is made for single use and is latex-free. Seven sizes are available for paediatric and adult use. The Cobra PLA™ has been evaluated in two small cohort studies [2, 3] and in two studies comparing its performance with the cLMA™ [4] or other supraglottic airways [5].

We aimed to perform two studies: a cohort evaluation of the Cobra PLA™ in 100 patients, and a trial comparing the clinical performance of the Cobra PLA™ and with the cLMA™.

Methods

After Local Research Ethics Committee approval for each study, written consent was obtained from patients before participation. Both investigators involved in the studies are senior anaesthetists and underwent specific training for Cobra PLA™ use, which included written material and an instructional video provided by the manufacturers.

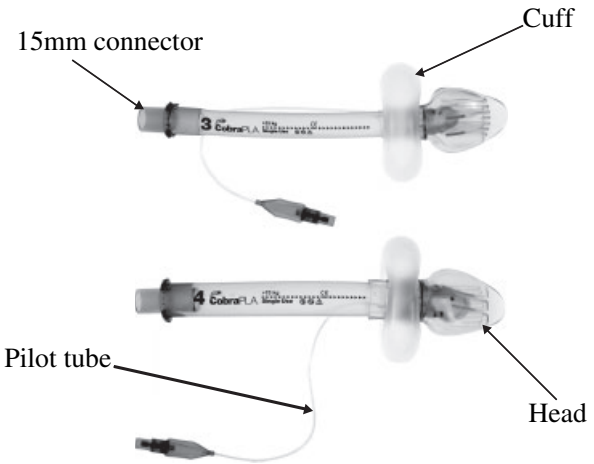

Figure 1 The Cobra Perilaryngeal Airway™ (Cobra PLA™).

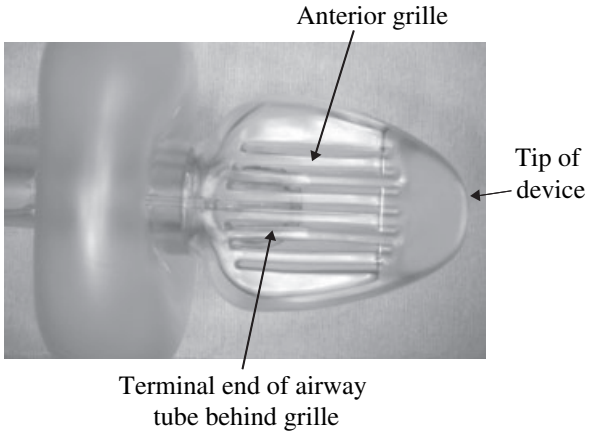

Figure 2 Anterior surface of the head of the Cobra Perilaryngeal Airway™ (Cobra PLA™).

Study A: A cohort examination of Cobra PLA™ performance in 100 patients. Evaluation included:

- number of attempts and success of device insertion, manipulations required and complications encountered during insertion;
- adequacy of ventilation and airway seal;
- fibreoptic assessment of anatomical position from the distal end of the airway tube;
- manipulations, complications and quality of airway during maintenance of anaesthesia;
- complications occurring during recovery from anaesthesia;
- postoperative laryngopharyngeal complications.

Study B: A randomised, controlled, crossover comparison of the Cobra PLA™ and cLMA. This study was designed to compare the performance of the Cobra PLA™ and the cLMA™ in 32 adult patients during anaesthesia. Outcomes on which to compare the two devices were as for Study A. Either a Cobra PLA™ or a cLMA™ was randomly selected and inserted, and was then evaluated as for Study A. This was then removed and the other device was inserted and studied identically. The second device was used throughout the subsequent anaesthetic.

The primary outcome measure was airway seal pressure, and the study was powered to detect a difference in seal pressure between the two devices of 5 cmH_2O (power = 80%, type 1 error = 0.05). A comparison of a variety of outcomes was designed to allow full comparison of the clinical utility of the devices.

For both studies, inclusion criteria included ASA physical status 1–3 patients undergoing elective surgery, for which anaesthesia would normally be performed using a cLMA™. Exclusion criteria included age < 16 years, significant cardiac or respiratory morbidity, history of gastro-oesophageal reflux, anticipated airway management difficulty and weight < 50 kg or > 120 kg. Routine anaesthetic monitoring was applied and a firm pillow was placed under the patient's head. A bolus dose of fentanyl 1–2 $\mu g.kg^{-1}$ was given. Anaesthesia was induced and maintained with a target-controlled infusion of propofol aiming at an effect site concentration of 4–6 $mg.l^{-1}$.

Cobra PLA™ size was determined by patient weight (size 3 for weight 50–70 kg, size 4 for > 70 kg) as recommended by the manufacturer. The device was inserted according to the manufacturer's instructions, with the patient in a 'sniffing position' [6]. The lubricated cuff was deflated and swept back along the airway tube and the device was inserted in the midline until resistance was felt, then pulled back 0.5–1.0 cm. The cuff was then inflated to 60 cmH_2O. In Study B, the cLMA™ was inserted according to the manufacturer's instructions: a size 4 device was used for females and a size 5 for males. The cuff was inflated to 60 cmH_2O [7].

Manipulations required for insertion and during maintenance were defined *a priori*: neck extension; neck flexion; chin lift; jaw thrust; repositioning of the device. Complications occurring during insertion, maintenance or after removal of the device were defined *a priori*: soft tissue damage; dental damage; bleeding; failure to establish or maintain a patent airway; loss of airway; hypoxia (S_pO_2 < 92%); regurgitation; aspiration; wheeze; stridor; 'other'.

The fibreoptic view was recorded with the tip of the fibrescope at the device grilles. The view was classified as:

1 good view of larynx;
2 partial view of vocal cords or arytenoids cartilages;
3 epiglottis only seen;
4 no laryngeal structures identified [8].

Successful ventilation was defined as ability to achieve:
1 adequate chest movement;
2 a square wave capnograph;
3 tidal volume = 7 ml.kg^{-1}
4 stable oxygen saturation values.

Neuromuscular blocking drugs were not used. The patients' lungs were ventilated while measures of ventilation were made, but when the patient began to breathe spontaneously, controlled ventilation was stopped and the patient was allowed to breathe spontaneously for the reminder of the case.

Results

After studying 29 patients (21 in Study A, 8 in Study B), both studies were suspended and then stopped, as two cases of significant pulmonary aspiration occurred in association with the use of the Cobra PLA^{TM}. The first case occurred during the lead-in to the studies [9] and the second during Study B. The cases are described below.

Case 1

During the learning curve of investigator T.C., a Cobra PLA^{TM} size 3 was used in an ASA physical status 1, 33-year-old female undergoing gynaecological laparoscopy. The patient had been starved for 12 h and she denied having any history of gastro-oesophageal reflux. Airway assessment demonstrated a small mouth and Mallampati class 3 mouth opening [10]. She weighed 74 kg and her body mass index (BMI) was 26.7 kg.m^{-2}. Insertion of the device was easy, and the airway seal pressure was measured at 35 cmH_2O. Controlled ventilation was started with a peak inspiratory pressure measured at 12 cmH_2O. The patient was placed in the lithotomy position. Intra-abdominal pressure was maintained at < 10 mmHg. Fifteen minutes into the procedure, the Cobra PLA^{TM} was noted to have rotated in the axial plane, accompanied by a sudden increase in airway pressure to 30 cmH_2O. This was followed immediately by regurgitation, with fluid becoming visible in the lumen of the Cobra PLA^{TM}. Lung ventilation became difficult, and arterial desaturation occurred. The patient's trachea was rapidly intubated. Fibreoptic airway inspection showed clear fluid in the trachea, and this was removed with suction. The patient coughed vigorously after emergence but recovery was uncomplicated and she was discharged home 4 h after surgery.

Case 2

An ASA physical status 1, 35-year-old male patient requiring orchidectomy was recruited to Study B and randomly assigned to Cobra PLA^{TM} insertion first. He had no known factors for increased aspiration risk and had been starved for > 8 h. His weight was 70 kg, and his BMI was 25.7 kg.m^{-2}. His airway was assessed as Mallampati class 1. A Cobra PLA^{TM} size 3 was easily inserted on the first attempt with a seal pressure of 30 cmH_2O. Ventilation was easy with a peak inspiratory pressure of 12 cm H_2O. Within a couple of minutes, and before spontaneous ventilation was re-established, the airway pressure increased rapidly and the patient regurgitated. This was followed by stridor and hypoxia. The Cobra PLA^{TM} was removed and the patient's trachea was intubated. Fibreoptic inspection of the airway confirmed aspiration of liquid. The patient was observed carefully overnight and recovery was uncomplicated.

Both cases were reported to the Local Research Ethics Committee, the Trust Research and Development Committee and the Medicine and Healthcare Regulatory Agency (MHRA). The manufacturers of the Cobra PLA^{TM} were also informed. After the second case, the studies were both voluntarily suspended. After full discussion with the Local Research Ethics Committee and external review of the cases of aspiration, the studies were both halted. As the studies are incomplete, we have combined the results from both studies in this report. The comparative data from the cLMA limb of Study B are not presented, as only eight patients were recruited.

The total number of patients recruited for both studies was 29. Demographic details are provided in Table 1. Insertion was possible in all cases. The airway was patent in 25 cases, partially obstructed in three and obstructed in one case. Insertion and lung ventilation were possible on the first attempt in 22 cases, second attempt in six cases and third attempt in one case. The median [range] number of airway manipulations was 2 [0 to > 4]. Establishing an effective airway took a median[range] time of 20 [10–180] s. There were a total of 12 complications occurring during insertion, with two cases abandoned because of aspiration (Table 2). Adequate lung ventilation was possible in 25 patients. The median [range] volume of air inserted into the cuff was 30 [10–50] ml and seal pressure was 21 [12–40] cmH_2O. During anaesthesia, a total of 29

Table 1 Patient characteristics. Values are median [range] or number.

Number of patients studied	29
Age; years	59 [20–82]
Weight; kg	72 [50–115]
Gender; F : M	12 : 17
ASA physical status; 1 : 2 : 3	15 : 11 : 3
Mallampati score; 1 : 2 : 3 : 4	13 : 11 : 5 : 0
Duration of anaesthesia; min	37 [15–160]

Table 2 Study results for the Cobra Perilaryngeal Airway™ (Cobra PLA™). Values are median [range] or number.

Number of attempts at insertion; 1 : 2 : 3	22 : 6 : 1
Number of airway manipulations to establish airway; 0 : 1 : 2 : 3 : 4 : > 4	2 : 13 : 5 : 5 : 3 : 1
Number of complications during insertion; *n*	12*
Insertion time; s	20 [10–180]
Quality of airway; clear: partial obstruction: obstructed	25 : 3 : 1
Effective lung ventilation through device†; yes: no	25 : 4
Cuff volume; ml	30 [10–50]
Seal pressure; cmH_2O	21 [12–40]
Airway pressure for tidal volume = 7 $ml.kg^{-1}$; cmH_2O	19 [10–30]
Fibreoptic view‡; 1 : 2 : 3 : 4	6 : 4 : 10 : 7
Number of airway manipulations required during anaesthesia; 0 : 1 : 2 : 3 : abandoned	22 : 3 : 0 : 2 : 2
Airway complications during maintenance; *n*	4§
Complications on device removal; *n* (Study A, *n* = 21)	5
Blood visible on device (Study A, *n* = 21)	6
Sore throat; none : mild : moderate : severe (Study A, *n* = 21)	12 : 9 : 0 : 0

*Movement (2), hypoxia (2), obstruction, laryngospasm, leak, failure to maintain airway, bleeding, regurgitation, aspiration, stridor.
†Defined as tidal volume > 7 $ml.kg^{-1}$, square wave capnograph, stable S_pO_2, adequate chest movement.
‡1 = good view of larynx; 2 = partial view of vocal cords or arytenoids structures; 3 = epiglottis only seen; 4 = no laryngeal structures identified. In two cases, use of the airway was abandoned.
§Obstruction, stridor, loss of airway, hypoxia.

manipulations were required and five airway complications occurred. Five minor complications occurred during recovery from anaesthesia, with none requiring early removal of the device.

Discussion

The Cobra PLA™ is a new supraglottic airway. Its head is designed to support the soft tissue of the hypopharynx and lever the epiglottis away from the airway tube. The airway tube is of large internal diameter to maximise gas flow and facilitate easy insertion of a fibrescope. The manufacturers recommend the Cobra PLA™ for use during spontaneous and controlled ventilation [6]. There are three other small studies of the Cobra PLA™ reporting its use in a combined total of 204 adult patients, assuming no duplications [2–5]. These studies report a similar overall performance to the cLMA.

Our data are difficult to interpret, as the studies were stopped prematurely. A few comments are appropriate. Cobra PLA™ insertion was successful in all 29 cases (100%). In addition to the 29 patients reported above, the device was inserted in a further 35 patients before data collection began. Therefore, a total of 64 Cobra PLA™ airways were inserted. Insertion failed in four of these 64 cases (success rate = 94%), and there were two cases of aspiration (3%). However, this information is difficult to interpret, as half of the data were not collected under study conditions. Anecdotally, we observed that the Cobra PLA™ requires good mouth opening for insertion because of its relatively wide, rigid airway tube. This is particularly so for the size 4 device. Twenty-seven of 29 patients required an airway manipulation to allow insertion, which is higher than that reported for the cLMA™ [11]. Because of the need to taper down to a proximal 15 mm connector, it is unclear whether the advantages of a wide bore tube, as claimed by the manufacturers, are real. Once placed, controlled lung ventilation was usually easy, with an airway seal at a pressure slightly higher than that for the cLMA™. The device provided a clear airway in most patients, enabling 'hands-free' anaesthesia. The only minor complications that were noted on removal were blood seen on the device in 29% of cases and complaints in almost half of the patients of a mild sore throat afterwards. Comparative figures for the cLMA are 12–15% and 12–28%, respectively [11].

The studies were halted for two reasons: firstly, because two cases of pulmonary aspiration had occurred during a total of 64 uses of the device and, secondly, because we have concerns about the design of the Cobra PLA™ and its use, particularly during controlled ventilation. The Cobra PLA™ has no distal cuff or obturator to block the oesophagus, and the recommended insertion technique, with partial withdrawal after insertion, leaves the tip of the Cobra PLA™ proximal to the upper oesophageal sphincter (Fig. 3). The Cobra PLA™ is designed and marketed for use during controlled ventilation. We believe that this makes gastric inflation more likely than during spontaneous ventilation. In the event of regurgitation, the proximal cuff will tend to prevent egress of regurgitated matter to the mouth. The head of the device fills much of the laryngopharynx but has a small internal volume, therefore potentially promoting pulmonary

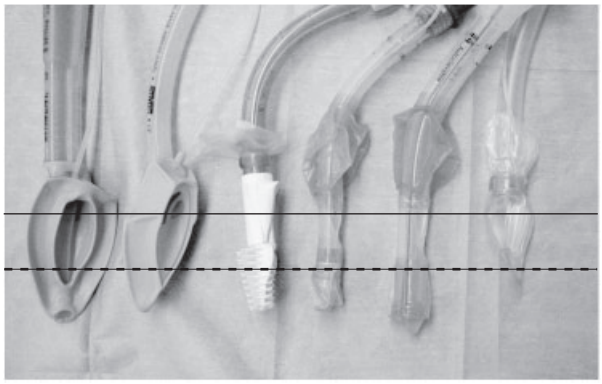

Figure 3 Photograph showing the position of the distal tip of the Cobra PLA™ relative to other supraglottic airways. The airways are positioned so that the solid line runs along the centres of the airway orifices. The dashed line indicates the level of the distal tip of the CobraPLA™ compared to the other tips. Devices from left to right: Proseal™ LMA, Classic LMA™, Pharyngeal Airway Xpress™, Laryngeal tube™, Laryngeal Tube Sonda™, Cobra PLA™.

aspiration [12]. The Cobra PLA™ has no cuff protecting the larynx and, unlike some supraglottic airways, has no drainage channel to vent leaking gases or regurgitated matter [11]. All these factors raise concerns that use of the Cobra PLA™ might lead to an increased risk of gastric regurgitation and pulmonary aspiration during use, particularly during controlled ventilation. We felt that further evaluation of the device was therefore not justifiable.

Of note, the Cobra PLA™ is manufactured in eight sizes from size ½ (neonates) to size 6 (for patients weighing > 130 kg). Studies to date appear to have used only sizes 3, 4 and 5. After the first case of aspiration, we elected to limit controlled lung ventilation in the studies to the time necessary to determine the efficacy of ventilation and airway seal pressure (usually < 5 min). The second case of aspiration occurred during such a period. The first case of aspiration that occurred was reported in the literature as a letter [9]. In a reply, the inventor and the manufacturers of the device considered that the use of a Cobra PLA™ for gynaecological laparoscopy was inappropriate, as such a procedure is associated with an increased risk of regurgitation [13]. It is true that the use of a supraglottic airway during laparoscopic surgery is considered by some to be controversial [14, 15]. However, even more than 5 years ago, the majority of UK anaesthetists used a cLMA™ for gynaecological laparoscopy [16]. Pulmonary aspiration is rare with the cLMA™ even during 'non-conventional use' [17]. The Cobra PLA™ is marketed as being suitable for use during controlled ventilation, and as having an airway seal pressure higher than the cLMA™. As such, in competing with the cLMA™ in the UK, use during laparoscopic surgery in patients without other risk factors for pulmonary aspiration might be anticipated. In addition, current recommendations by the manufacturers, which have been changed since we started this study, state that airway pressures should not exceed 20 cmH_2O (see manufacturers' website). It is difficult to marry this recommendation with a device that is marketed for patients weighing > 130 kg.

The manufacturers also criticised the use of an airway pressure of up to 40 cmH_2O. Evaluation of most airway devices by most authors includes measurement of the airway seal pressure. In the majority of cases, this involves allowing airway pressure to rise up to a maximum of 40 cmH_2O. In some studies, maximum airway pressure is allowed to rise to 50 cmH_2O [18] or 60 cmH_2O [19]. In this respect, our device evaluation followed standard, conservative practice. Whether one accepts the above argument or not, we were so concerned both by the occurrences of pulmonary aspiration (1/29 patients under study conditions and 2/64 overall) and by the device design that we felt it inappropriate to continue with the studies until substantially more safety data on the Cobra PLA™ are available.

In conclusion, our evaluation was smaller than planned due to complications occurring in two patients. However, we found no evidence (with respect to ease of insertion, time taken for insertion, manipulations required, complications occurring or postoperative sequelae) to suggest that the Cobra PLA™ has significant advantages over the cLMA™. Further, on the basis of our evaluation, we are concerned about the safety of the Cobra PLA™. We do not believe the Cobra PLA™ should be marketed for controlled lung ventilation until more safety data are available.

Conflict of interest

Dr Tim Cook has been paid by Intavent Orthofix and by the LMA company (both distributors of the classic Laryngeal Mask Airway™) for lecturing. Engineered Medical Systems donated all the Cobra PLAs™ used in this study without charge.

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