Comparison of Cobra perilaryngeal airway (CobraPLA™) with flexible laryngeal mask airway in terms of device stability and ventilation characteristics in pediatric ophthalmic surgery

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Abstract

**Background:** Supraglottic airway devices play an important role in ophthalmic surgery. The flexible laryngeal mask airway (LMA™) is generally the preferred airway device. However, there are no studies comparing it with the Cobra perilaryngeal airway (CobraPLA™) in pediatric ophthalmic procedures.

**Aims:** To analyze the intraoperative device stability and ability to maintain normocarbia of CobraPLA™ and compare it to that with flexible LMA™.

**Materials and Methods:** Ninety children of American Society for Anesthesiologists physical status 1 and 2, aged 3–15 years scheduled for elective ophthalmic surgeries were randomly assigned to either the CobraPLA™ or the flexible LMA™ group. After placement of each airway device, oropharyngeal leak pressure (OLP) was noted. Adequate seal of the devices was confirmed at an inspired pressure of 15 cm H₂O and pressure-controlled ventilation was initiated. Device displacement was diagnosed if there was a change in capnograph waveform, audible or palpable gas leak, change in expired tidal volume to <8 ml/kg, end-tidal carbon-dioxide persistently >6 kPa, or need to increase inspired pressure to >18 cm H₂O to maintain normocarbia.

**Results:** Demographic data, duration, and type of surgery in both the groups were similar. A higher incidence of intraoperative device displacement was noted with the CobraPLA™ in comparison to flexible LMA™ (P < 0.001). Incidence of displacement was higher in strabismus surgery (7/12). Insertion characteristics and ventilation parameters were comparable. The OLP was significantly higher in CobraPLA™ group (28 ± 6.8 cm H₂O) compared to the flexible LMA™ group (19.9 ± 4.5 cm H₂O) (P < 0.001). Higher surgeon dissatisfaction (65.9%) was seen in the CobraPLA™ group.

**Conclusion:** The high incidence of device displacement and surgeon dissatisfaction make CobraPLA™ a less favorable option than flexible LMA™ in ophthalmic surgery.

**Key words:** Airway complication, CobraPLA™, flexible laryngeal mask airway, pediatric ophthalmic surgery

Introduction

Supraglottic airway (SGA) devices are commonly used in ophthalmic surgery and their choice is influenced by the need for maintenance of normocarbia, avoiding increase in intraocular pressure (IOP), and allowing smooth surgical access to the surgeon.¹ Cobra perilaryngeal airway (CobraPLA™) has comparable insertion and recovery characteristics and performance during controlled ventilation with other SGA.²⁻⁴ However, it has not been compared with flexible laryngeal mask airway (LMA™) in pediatric ophthalmic procedures. This study aimed to compare CobraPLA™ and flexible LMA™ for device stability as the primary outcome. Secondary outcomes were evaluation of insertion characteristics, oropharyngeal leak pressure (OLP), ability to maintain normocarbia, and surgeon satisfaction.

**Materials and Methods**

After Ethics Committee approval and written parental consent,
90 children of American Society for Anesthesiologists physical status 1 and 2, aged 3–15 years, and weighing >10 kg scheduled for ophthalmic surgery were included in the study. Children at risk for aspiration or anticipated difficult airway were excluded. Children were randomized by a computer-generated sealed envelope technique to receive either the CobraPLA™ (Engineered Medical Systems, Indianapolis, USA) (group C) or the flexible LMA™ (The Laryngeal Mask Company Limited Mahe, Seychelles) SGA (group F).

Sample size was determined using \( P = 0.05 \) and a power of 90% taking into account mean values and standard deviations of our primary variable [displacement] from the pilot study of 15 cases in each group. The largest sample size calculated was 36 in each group. We enrolled 45 cases in each group in view of drop out.

In the operating room, after application of standard monitors, anesthesia was induced with oxygen, nitrous-oxide, and incremental concentration of sevoflurane or with intravenous (IV) propofol. Analgesia was supplemented by fentanyl 2 mcg/kg IV and muscle relaxation was achieved with vecuronium. After 3 min of manual ventilation, the appropriate size of lubricated airway device was inserted according to standard technique by a single anesthesiologist who had more than 4 years experience in the use of both the devices. The device cuff was inflated to 60 cm H\(_2\)O cuff pressure. At inspired pressure of 15 cm H\(_2\)O, adequate seal was checked by no audible or palpable leak. Adequate ventilation was confirmed by chest expansion, a square capnograph, an expired tidal volume (TV) > 8 ml/kg, Sp\(_O_2\) > 95%, end-tidal carbon-dioxide (Et\(\text{CO}_2\)) < 6 kPa. If the device did not fulfill these insertion criteria, jaw thrust, change in head and neck positions, or change in device size was done. The number of attempts and time for successful insertion (from discontinuation of mask ventilation till the confirmation of adequate ventilation) was recorded. Trachea was intubated after three unsuccessful attempts at insertion of SGA device and these cases were excluded from the study. After securing both the devices with maxillary and mandibular tape, flexible LMA™ was further taped across the chin. At 3 l/min fresh gas flow and with the adjustable pressure limiting valve fully closed, the airway pressure at which the palpable air leak at neck started but not exceeding 35 cm H\(_2\)O was recorded as OLP.

Pressure-controlled ventilation was initiated using a closed circuit with oxygen, nitrous-oxide, and isoflurane (MAC 1.0). The initial inspiratory pressure (Pi) was set at 10 cm H\(_2\)O and respiratory rate (RR) appropriate to the age of the child in order to achieve an expired TV > 8 ml/kg and Et\(\text{CO}_2\) 4.7–6 kPa. If the target was not achieved, initially Pi was increased by 1 cm H\(_2\)O (maximum 18 cm H\(_2\)O) and then RR was increased (maximum of 20/min). Train of Four (TOF) counts, Et\(\text{CO}_2\), Pi, and RR were recorded at 5 min intervals till the end of surgery.

The device was considered displaced, after ruling out incomplete paralysis (TOF count > 2) and light plane of anesthesia, if any two of the following criteria were present: change in capnograph, audible or palpalble gas leak, expired TV < 8ml/kg, Et\(\text{CO}_2\) persistently > 6 kPa, and need to increase Pi > 18 cm H\(_2\)O to maintain normocarbia. In case of suspected displacement, following maneuvers were done – change in head position, increase in FGF, change in Pi or RR, and finally, tracheal intubation.

Neuromuscular blockade was reversed at the end of surgery and the airway device was removed. The surgeons scored the device as satisfactory or unsatisfactory based on the ease of surgical access.

The observations in the two groups were compared using independent samples \(t\)-test/Wilcoxon rank sum test for continuous variables. Fisher’s exact test/Chi square test was used for categorical variables. \( P < 0.05 \) was the critical level of statistical significance. Analysis was performed using SPSS15.0 and Stata 9.

**Results**

Demographic data and type of surgery in both the groups were similar [Table 1]. In group C, two patients were excluded due to trachea intubation and two patients were excluded for want of complete records. In group F, one patient had incomplete records. Data of only 41 cases in group C and 44 in group F were analyzed. Insertion characteristics and ventilation parameters were comparable. The OLP was significantly higher in CobraPLA™ group \((28 ± 6.8 \text{ cm H}_2\text{O})\) compared to the flexible LMA™ group \((19.9 ± 4.5 \text{ cm H}_2\text{O})\) \((P < 0.001)\) and significantly more maneuvers were required for insertion of CobraPLA™ [Table 2].

Mean Et\(\text{CO}_2\) values were higher with the CobraPLA™, but remained within acceptable range. In group C, more adjustments in RR, Pi, and head repositioning were required to maintain normocarbia, though the mean Et\(\text{CO}_2\) values were higher in comparison to group F. In group C, intraoperative displacement was observed in 12 children as compared to 1 child in group F \((P = 0.001)\). Among the 12 displacements in group C, 3 children needed tracheal intubation, while displacement could be rectified with either an increase in RR and/or in Pi in 4 children, and head extension in 5 children. In group F, intraoperative displacement was rectified with increase in Pi. Out of 12 displacements in group C, 7 (58.3%)
occurred during strabismus surgery, 4 (33.3%) during cataract surgery, and 1 (8.3%) during retinal surgery. The incidence of surgeon dissatisfaction was 65.9% (27/41) in group C (P < 0.001).

**Discussion**

Cobra PLATM [Figure 1] is a single-use plastic device which has a distal widened cobra head with soft grills, a rigid breathing tube with a circumferential inflatable cuff proximal to the ventilation outlet portion, a self-sealing pilot balloon, and a 15-mm standard adapter. Grills help in the deflection of the epiglottis off the Cobra head, thereby preventing the epiglottis from obstructing the breathing hole. The circumferential cuff resides in the hypopharynx at the base of the tongue and on inflation it raises the base of the tongue, exposing the laryngeal inlet, along with an airway seal to allow positive-pressure ventilation.[5] The flexible LMA™ [Figure 2] has an elliptical spoon-shaped silicon mask with two flexible vertical bars, connected at 30° angle to a flexible long narrow wire-reinforced breathing tube, an inflation tubing, self-sealing pilot balloon, and a 15-mm standard adapter. Bars prevent the tube from being obstructed by the epiglottis. The flexible tube can be bent to any angle without kinking. The LMA™ is inserted into the pharynx, where it forms a low-pressure seal above the laryngeal inlet.[5]

We found an increased incidence of intraoperative device displacement with the CobraPLATM as compared to flexible LMA™. Incidence of displacement was higher in strabismus surgery (58.3%), which was possibly due to surgical manipulations of extraocular muscles in the inferonasal and inferotemporal quadrants resulting in inadvertent mechanical pressures on the wide extra-oral rigid portion of the CobraPLATM. The CobraPLATM cannot be bent to be taped to the chin as it has a rigid airway tube; however, the flexible LMA™ can be taped to the chin as the airway tube is flexible and thus prevented from impeding surgical access.

Classic LMA and flexible LMA perform similarly in terms of ease of insertion and mask position.[6] Our findings, related

| Table 1: Demographic data and type of surgery |
|------------------------------------------------|
| **Cobra PLATM** (n = 41) | **Flexible LMA™** (n = 44) | **P-value** |
| Age (years) | 8 (3.5–14) | 6 (3–15) | 0.10 |
| Weight (kg) | 20 (13.5–45) | 18 (10–57) | 0.10 |
| Sex, F:M | 11:30 | 12:32 | 0.85 |
| Surgical duration (min) | 53.42 ± 21.75 | 55.12 ± 29.30 | 0.77 |
| Type of surgery | 2/17/1/1 | 7/29/3/5 |

Values are expressed as mean ± SD, median (range) or actual number.; P < 0.05 is considered significant.; *Significant difference.

| Table 2: Insertion characteristics and oropharyngeal leak pressure |
|---------------------------------------------------------------|
| **Cobra PLATM** (n = 41) | **Flexible LMA™** (n = 44) | **P-value** |
| Number of attempts (1/2/3) | 35/5/1 | 37/7/0 | 0.96 |
| Maneuvers aiding insertion (jaw thrust/neck extension) | 14/3 | 6/1 | 0.02* |
| Time to insert the device (s) | 20.92 ± 9.22 | 15.15 ± 7.30 | 0.003* |
| Failed insertion | 2 | 0 | 0.23 |
| Oropharyngeal leak pressure (cm H₂O) | 28.23 ± 6.83 | 19.97 ± 4.59 | <0.001* |

Values are expressed as mean ± SD, median (range) or actual number.; P < 0.05 is considered significant.; *Significant difference
to the insertion characteristics of both the devices, corroborate well with earlier studies.\[6,7\] Cuff-seal pressure in the Cobra PLA\textsuperscript{TM} group was significantly better as compared to flexible LMA group in the present study. Higher cuff-seal pressures with Cobra PLA\textsuperscript{TM} compared to other SGA devices have been reported in pediatric population.\[8\] Coupled with high leak pressures and unique head design, Cobra PLA\textsuperscript{TM} is an effective device for controlled ventilation.

Head extension reduced the leak in 41.7% cases in the Cobra PLA\textsuperscript{TM} as it improves the seal in the upper pharynx. Lateral displacement of the Cobra PLA\textsuperscript{TM} is not possible due to the large ellipsoid pharyngeal cuff. Positioning the head in extension is required in certain ocular procedures. Higher cuff-seal pressures have been reported with Cobra PLA\textsuperscript{TM} compared to Proseal LMA in this position.\[9\] Flexible LMA has lower OLP with neck extension in comparison to neutral and flexion positions.\[10\] There was high surgeon dissatisfaction (65.9%) in the Cobra PLA\textsuperscript{TM} group due to poorer surgical access, interruptions to surgery with requests for change of head position, and device change.

Maintenance of normocarbia is essential in intraocular surgeries as in all surgeries. Normocarbia was achieved in both the groups in our study; however, more frequent adjustments were required in the ventilatory setting in group C.

In conclusion, the Cobra PLA\textsuperscript{TM} is comparable to the flexible LMA\textsuperscript{TM} in terms of insertion characteristics and ability to maintain normocarbia during controlled ventilation. The Cobra PLA\textsuperscript{TM} should however be used with great caution in surgeries where manipulation of extraocular muscles is required due to the high incidence of device displacement and surgeon dissatisfaction. Flexible LMA\textsuperscript{TM} seems to be a better option to Cobra PLA\textsuperscript{TM} in such cases.

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