Use of CobraPLA with total intravenous anesthesia and constant BIS level in elective, non-obese orthopedic patients

V Khazin, R Djabarov, Y Kaufman, S Evron, P Szmuk, T Ezri, D Alfery, D Hendel

Citation

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Abstract

Inadequate anesthesia may cause inability to ventilate the patient with a supraglottic airway device. We assessed the insertion characteristics and adequacy of positive pressure ventilation with the CobraPLA in patients anesthetized at a constant bispectral index (BIS) level. The airways of 40 ASA I-II patients who underwent elective orthopedic surgery were managed with CobraPLA, using positive pressure ventilation without muscle relaxation. Anesthesia was induced and maintained with propofol and fentanyl at a constant BIS level of 40-50. We measured ease and time of insertion, sealing pressure, peak inspiratory pressure, gastric insufflation, oxygen saturation, end-tidal carbon dioxide, mean arterial pressure, heart rate and the BIS. Postoperative complications were recorded.

Ninety percent were inserted at first attempt within 32±10 sec. Sealing pressure was 27±5 cmH2O. Mean BIS during CobraPLA insertion was 40 ± 4. One patient had a mild postoperative pneumonia. It is concluded that under constant BIS levels, the CobraPLA is easily inserted and enables effective positive pressure ventilation.

Conflict of interest: Dr. Alfery is the inventor of the CobraPLA and receives royalties

The work was done at the Department of Anesthesia, Wolfson Medical Center, Holon 58100, Israel

INTRODUCTION

Several alternatives to the laryngeal mask airway (LMA) have been developed recently. Although the LMA provides an effective and safe choice for airway control, it has several weaknesses including the need for repositioning in 5-10% of patients ([1,2]), and gas leakage when peak airway pressure exceeds 15-20 cmH_2O, which renders mechanical ventilation difficult and hazardous, especially if the peak airway pressure is greater than 20 cmH_2O ([3,4]). To overcome this limitation, the use of the ProSeal LMA has been advised, as it provides a sealing pressure 10 cmH_2O higher than the LMA Classic ([5]).

The CobraPLA (Engineered Medical Systems, Indianapolis, IN) is a relatively new extraglottic airway device that has not been studied extensively. In the first report of use in 2003, Agro et. al. ([6]) used this device successfully in 28 patients with normal airways. Similar results have been reported by Akca et. al ([7]) when comparing CobraPLA with LMA-Classic during positive pressure ventilation and by Gaitini et. al. ([8]) when comparing CobraPLA with LMA-Unique under spontaneous ventilation. In one study ([7]), the CobraPLA provided seal pressures 5 cmH_2O higher than the LMA. Thus, the CobraPLA may provide better airway sealing and higher fiberoptic view scores than the LMA classic ([8]). Based on the consideration that inadequate anesthetic depth might be one reason for an airway device insertion failure and for the inability to ventilate a patient, we assessed the effectiveness of airway management with CobraPLA under total intravenous anesthesia with constant BIS level and positive pressure ventilation in elective non-obese orthopedic surgery patients.

METHODS

After approval of the study by our local IRB committee and obtaining written informed consent from each patient, 40 ASA I-II patients, BMI <30 kg/m2, aged >18 yr, scheduled for elective orthopedic procedures in the supine position

(except major orthopedic surgeries such as spine surgery and knee and hip replacements) were recruited to this study.

Excluded from the study were patients with a history of gastroesophageal reflux (GER) or any other risk factors for aspiration of gastric contents (including pregnancy) and patients with a history of difficult intubation, severe pulmonary disease (ASA>II), current or recent sore throat, dysphonia, or dysphagia.

PROTOCOL

Four anesthesiologists who had used the CobraPLA device at least ten times before beginning the study and had performed more than 100 laryngeal mask insertions performed all the CobraPLA insertions for this study. Patients were premedicated with brotizolam, 0.25 mg sublingually and chronically taken drugs were also given. Patients were monitored with ECG, noninvasive blood pressure, pulse oximetry, capnography, nasopharyngeal temperature and electroencephalography bispectral index (BIS) monitoring. Respiratory and cardiovascular monitoring was performed with the Datex AS/3 anesthesia monitor (Datex, Helsinki, Finland). Bispectral index was measured with the BIS monitor (Aspect Medical Systems, One Upland Road Norwood, MA 02062).

Anesthesia was induced with midazolam 1mg, propofol (2-2.5 mg/kg) and fentanyl 1.5 μ/kg given intravenously. Additional propofol was given if considered necessary to keep a BIS value below 50 during the CobraPLA insertion. No muscle relaxants were employed for insertion. The CobraPLA was lubricated with lidocaine jelly and then the first insertion attempt was undertaken 60 sec after propofol administration, if the eyelash reflex disappeared, the jaw was relaxed and the BIS value was below 50. Prior to the insertion, the patient's lungs were manually ventilated through a facemask with care being taken not to exceed 20 cmH_2O peak inflation pressures. A second anesthesiologist measured the insertion time with a stopwatch, with time starting when the device approached the upper incisors and ending when confirming adequate ventilation assessed by well accepted criteria ([7]): chest movement, normal (square wave) $ETCO_2$ trace and an expiratory tidal volume of at least 4-5 mL/kg, with no air leak present with positive pressure ventilations at 15-20 cmH_2O peak airway pressures. Inadequate ventilation after 3 insertion attempts was considered a failure and was followed by insertion of LMA classic. If this insertion also failed , the patient was intubated with an endotracheal tube.

Cobra sizes 3,4 and 5 were used, and the size was selected by the anesthesiologist who inserted the device according to the manufacturer recommendations, with size three being preferred for most women and size four for most men. The CobraPLA was inserted with a previously described standard technique ([7]).

After insertion, the cuff of the CobraPLA was inflated with a manual cuff manometer (VBM Medizintechnik, Sulz, Germany) to a pressure of 60 cmH_20. Ventilation was controlled and the lungs were ventilated with a tidal volume of 8 mL/kg and a rate of 12 breaths/min with an I:E ratio of 1:2. Anesthesia was maintained with a continuous infusion of propofol 50-200 μ/kg and aliquots of 50 μg of fentanyl every 30 min. Nitrous oxide in oxygen 70%:30% was also administered. The propofol infusion was tittered to maintain a BIS level of 40-50 throughout the procedure. No muscle relaxants were used at any time. At the end of the procedure the propofol infusion was stopped and the airway was removed after the patient regained consciousness.

MEASUREMENTS

We assessed the following variables: demographic characteristics, airway examination variables (Mallampati class, thyromental distance, neck movement problems, mouth opening), insertion variables (time, percentage of insertion at first attempt), crossover to other airway device, airway compliance, peak airway pressures, leak rate at different airway pressures (airway sealing pressure), duration of surgery, SpO_2, $ETCO_2$, mean intraoperative MAP and HR (measured every 3 min) and maximum MAP and HR, propofol dose, gastric insufflation, degree of postoperative pharyngeal irritation at time of discharge from recovery room: (0 - no irritation, 1- mild irritation, 2-severe irritation), postoperative nausea and vomiting - (PONV) - (measured on a 0-2 point scale where 0 = no nausea, 1 - mild nausea, 2 - vomiting) and other complications including episodes of SpO_2<90%, regurgitation and aspiration of gastric contents. Each respiratory variable was recorded every 3 minutes with the average of 3 consecutive measurements recorded at each measurement time point. Gastric insufflation was diagnosed by auscultation with a stethoscope at the epigastric region every 3 min. The BIS was recorded every 3 min by averaging 3 consecutive measurements at each measurement time point, as displaced on the screen.

Assessment of seal pressure was performed immediately after insertion of the device with the cuff maximally inflated

to a-60 cmH_2O pressure.

Seal pressure was measured as follows: the peak airway pressure was gradually increased by augmenting tidal volume during volume controlled ventilation (to a maximum of 35 cm H_20), while maintaining respiratory rate constant. The pressure (in cm H_2O) at which gas audibly leaks from the patients' mouths or leaks to patient' s stomachs (as noted by auscultation) defined the actual the airway seal pressure [$_7$]. After the test was finished, the cuff pressure was decreased to maintain a leak-free airway up to a 25 cmH_2O PIP ($_7$).

STATISTICS

Data are presented as percentages or mean ± standard deviation.

RESULTS

Patients' characteristics are presented in Table 1. Anesthetic, hemodynamic and airway management characteristics are shown in Table 2. The mean BIS value during CobraPLA insertion was 40 ± 4 and throughout surgery was 47 ± 8. The mean propofol infusion rate (μ/kg/min) was 109 ± 44. Airway sealing pressure was 27 ± 5 cmH_2O. There were no episodes of oxygen desaturation <90%. Gastric insufflation occurred in 10% of patients, 15% had pharyngeal irritation, and 7.5% experienced mild PONV.

Figure 1

Table 1 : patients' demographic and airway characteristics

Age (yr)	60 ± 18
Weight (kg)	75 ± 10
Height (cm)	169 ± 8
Gender F/M (%)	48/52
ASA class I/II (%)	50/50
Smoking (%)	33
Diabetes mellitus (%)	7
Hypertension (%)	37
Ischemic heart disease (%)	5
Pulmonary disease (%)	2
Renal disease (%)	3
Duration of surgery (min)	66 ± 32
Mallampati class I/II/III (%)	67.5/35/7.5
Mouth opening <4 cm (%)	15
Thyromental distance<6 cm (%)	15

Results are expressed as percentage or mean ± SD

Figure 2

Table 2: Device insertion, ventilation, hemodynamic and anesthetic characteristics

Easy insertion (%)	90
Insertion attempts 1/2 (%)	90/10
Insertion time (sec)	32±10
Crossover to LMA/ETT (%)	2.5/2.5
SpO_2%	97 ± 2
$ETCO_2$	37 ± 5
Airway compliance (mL/cmH_2O)	36 ± 15
Airway resistance (cmH_2O/mL)	18 ± 9
Peak inspiratory pressure (cmH_2O)	20 ± 5
Airway sealing pressure (cmH_2O)	27 ± 5
Mean MAP (mmHg)	91 ± 8
Maximal MAP (mmHg)	109
HR (beats/min)	71 ± 11
Maximal HR (beats/min)	94
BIS during device insertion	40 ± 4
BIS throughout surgery	47 ± 8
Total propofol dose (mg)	535 ± 268
Mean propofol infusion rate (μ/kg/min)	109 ± 44
Gastric insufflation (%)	10
Pharyngeal irritation (%)	15
PONV (%)	7.5
Pulmonary aspiration of gastric content (%)	2.5

LMA – Laryngeal mask airway; ETT – endotracheal tube; MAP – mean arterial pressure; HR – heart rate; BIS – bispectral index

The reason for the two crossovers to an alternative airway device (one LMA and one ETT) was the inability to effectively ventilate the patients (see Methods for description) for uncertain reasons. In these two patients the BIS value during the device insertion was 40 and 42 respectively.

There was no witnessed regurgitation of stomach contents or other intraoperative complication. However, one patient developed a right upper lobe pneumonia postoperatively that resolved within three days, likely due to silent aspiration of gastric contents. This patient did not have gastric insufflation at any time of surgery. Further investigation revealed the presence of a previously undiagnosed diaphragmatic hernia.

DISCUSSION

The results of this study show that under constant anesthetic depth the CobraPLA is an effective extraglottic airway device with a 90% rate of successful insertion at first attempt. Similarly, Turan et al ([9]) reported a 97% success rate of insertion of CobraPLA at first attempt compared to only 57 % with the LMA.

We believe that one reason for our high success rate of insertion of the CobraPLA resulted from a level of anesthesia deep enough (BIS <50) to enable smooth insertion of the device. Evaluation of BIS levels enables monitored titration of anesthesia, and a BIS level of 40-60 appears clinically useful in terms of anesthetic requirement ([10,11]).

The device allowed for high cuff sealing pressures of 27.5 cmH_2O with only a 10% incidence of gastric insufflation. This is a higher sealing pressure than that reported with the LMA ([5]). The higher sealing pressure may accord a larger margin of safety against cuff leak in patients who require or develop higher peak inspiratory pressures during mechanical ventilation, although the manufacturer does recommend that inflation pressures below 20 cm H_2O be used. At this level of venitlatory support a cuff leak during use of the CobraPLA should occur very infrequently. The efficacy of the CobraPLA as an extraglottic airway device has been reportedin patients with normal airways by Agro et. al ([6]) and by Akca et. al ([7]) when using controlled ventilation. The Akca study ([7]) demonstrated higher sealing pressures with the CobraPLA compared to LMA, a finding also confirmed by Gaitini et al ([8]).

No patient moved during the insertion of CobraPLA, even though no muscle relaxants were administered throughout the procedure. Also, patients had no recall of surgery and there were no hemodynamic manifestations (tachycardia, hypertension - See Table 2) of inadequate level of anesthesia during the insertion of the device. In a previous study better insertion conditions for the LMA were achieved by using propofol rather than thiopental ([12]).

The importance of an adequate level of anesthesia during the insertion of other extraglottic devices and avoidance of hemodynamic responses has been previously demonstrated ([13,14]). For maintenance of anesthesia we used a continuous infusion of propofol supplemented with aliquots of fentanyl. Maintaining a constant anesthetic depth throughout surgery enabled us to avoid hemodynamic pertubations that might have been attributed, at least in part, to the presence of a device in the patient's upper airway.

An inadequate level of anesthesia might be one of the reasons for the high incidence (50%) of sore throat/pharyngeal irritation previously reported with the CobraPLA ([9]), although insertion of a size too large for an individual patient was also likely a factor ([15]). The incidence in our study group was just 15%.

In conclusion, in our study of elective, non-obese orthopedic patients, the CobraPLA performed well as an extraglottic airway device, while maintaining an adequate anesthetic level both during the insertion of the device and during maintenance of anesthesia. We therefore advise the use of BIS monitoring to enable maintaining an adequate and constant anesthetic level during insertion and maintenance of the CobraPLA extraglottic device within the patient's airway.

References

1. Brimacombe J. Analysis of 1500 laryngeal mask uses by one anaesthetist in adults undergoing routine anaesthesia. Anaesthesia 1996;51:76-80.
2. Smith I, White PF. Use of the laryngeal mask airway as an alternative to a face mask during outpatient arthroscopy. Anesthesiology 1992;77:850-5.
3. Broderick PM, Webster MR, Nunn JF. The laryngeal mask airway: a study of 100 patients during spontaneous breathing. Anaesthesia 1989;44:234-41.
4. Maltby JR, Loken RG, Watson NC. The laryngeal mask airway: clinical appraisal in 250 patients. Can J Anaesth 1990;37:509-13.
5. Brimacombe J, Keller C. The ProSeal laryngeal mask airway: A randomized, crossover study with the standard laryngeal mask airway in paralyzed, anesthetized patients. Anesthesiology 2000;93:104-9.
6. Agro F, Barzoi G, Carassiti M, Galli B. Getting the tube in the oesophagus and oxygen in the trachea: preliminary results with the new supraglottic device (Cobra) in 28 anaesthetised patients. Anaesthesia. 2003;58:920-1.
7. Akca O, Wadhwa A, Sengupta P, Durrani J, Hanni K, Wenke M, Yucel Y, Lenhardt R, Doufas AG, Sessler DI. The new perilaryngeal airway (CobraPLA) is as efficient as the laryngeal mask airway (LMA) but provides better airway sealing pressures. Anesth Analg. 2004;99:272-8.
8. Gaitini L, Yanovski B, Somri M, Vaida S, Riad T, Alfery D. A comparison between the PLA Cobra and the Laryngeal Mask Airway Unique during spontaneous ventilation: a randomized prospective study. Anesth Analg. 2006;102:631-6.
9. Turan A, Kaya G, Koyunku O, Karamanlioglu B, Pamukcu Z. Comparison of the laryngeal mask (LMA) and laryngeal tube (LT) with the new perilaryngeal airway (CobraPLA) in short surgical procedures. Eur J Anaesthesiol. 2006;23:234-8.
10. Gan TJ, Glass PS, Windsor A, et al. Bispectral index monitoring allows faster emergence and improved recovery from propofol alfentanil and nitrous oxide anesthesia. Anesthesiology 1997; 87: 808-15.
11. Struys M, Versichelen L, Byttebier G, et al. Clinical usefulness of the bispectral index for titrating propofol target effect site concentration. Anaesthesia 1998; 53: 4-12.
12. Acalovschi I, Miclescu A, Bugov L. The effects of propofol on laryngeal reactivity and the haemodynamic response to laryngeal mask insertion. Eur J Anaesthesiol. 1995;12:351-6.
13. Richebe P, Rivalan B, Baudouin L, Sesay M, Sztark F, Cros AM, Maurette P. Comparison of the anaesthetic requirement with target-controlled infusion of propofol to insert the laryngeal tube vs. the laryngeal mask. Eur J Anaesthesiol. 2005 ;22:858-63
14. Versichelen L, Struys M, Crombez E, Fonck K, Mortier E, Rolly G. Haemodynamic and electroencephalographic response to insertion of a cuffed oropharyngeal airway: comparison with the laryngeal mask airway. Br J Anaesth. 1998;81:393-7.
15. Alfery DD, Ghelber O, Ezri T, Szmuk P. Correct sizing of the CobraPLA is necessary for valid study results. Eur J Anaesthesiol. 2006 Aug;23(8):714-5.

Author Information

Vadim Khazin, M.D.
Instructor in Anesthesia, Department of Anesthesia, Edith Wolfson Medical Center

Rustam Djabarov, M.D.
Resident in Orthopedic Surgery, Department of Orthopedics, Edith Wolfson Medical Center

Yefim Kaufman, M.D.
Attending Anesthesiologist, Department of Anesthesia, Edith Wolfson Medical Center

Shmuel Evron, M.D.
Senior Lecturer in Anesthesia, Department of Anesthesia, Edith Wolfson Medical Center

Peter Szmuk, M.D.
Associate Professor, University of Texas Medical School and Children's Medical Center at Dallas

Tiberiu Ezri, M.D.
Head, Department of Anesthesia, Department of Anesthesia, Edith Wolfson Medical Center

David Alfery, M.D.
Associate Professor, Department of Anesthesiology, Vanderbilt University Medical Center

David Hendel, M.D.
Head, Department of Orthopedic Surgery, Department of Orthopedics, Edith Wolfson Medical Center