A COMPARATIVE STUDY BETWEEN COBRAPLA AND LARYNGEAL MASK AIRWAY CLASSIC IN SPONTANEOUS VENTILATING ADULT PATIENTS

BY

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ABSTRAK

Tujuan kajian kami ini ialah untuk menilai sama ada "CobraPLA" yang baru direka adalah alat bantuan pernafasan yang selamat, mudah digunakan, sesuai dan berkomplikasi rendah bagi pengunaan pesakit dewasa. Kami telah membandingkan penggunaan " CobraPLA" dengan "Laryngeal Mask Airway" ke atas pesakit dewasa yang bernafas secara spontán semasa pembiusạn umum dijalankan ke atas mereka semasa pembedahan elektif.

Kajian rawak secara prospektif ini telah dijalankan terhadap 56 pesakit dewasa ASA 1 dan 2 yang berumur antara 18 hingga 65 tahun dan diberikan premedikasi sebelum pembiusan.Mereka dibahagikan kepada 2 kumpulan iaitu kumpulan yang menggunakan "CobraPLA" dan kumpulan yang menggunakan "laryngeal mask airway" sebagai alat bantuan pernafasan. Selepas induksi dengan menggunakan intravena propofol 2mg /kg dan intravena fentanyl 1 mcg/kg . "CobraPLA" atau "LMA" telah dimasukkan dan pesakit bernafas secara spontan sepanjang pembedahan. Pembiusan dikekalkan dengan menggunakan nitrous oksida, oksigen dan sevoflurane. Alat bantuan pernafasan ini dikeluarkan selepas pembedahan setelah pesakit sedar sepenuhnya. Kami telah merekodkan kepantasan memasukkan alat batuan pernafasan dan bilangan percubaan yang diperlukan untuk memasukkan alat pernafasan dengan jaya. Perubahan tindakbalas kardiovaskular seperti tekanan darah sistolik, tekanan darah diastolik, tekanan darah purata (MAP) denyutan jantung, saturasi dan "ETCO2" juga direkodkan . Kami juga telah merekodkan insiden komplikasi pembedahan.

Di dalam kajian ini kami telah mendapati bahawa kumpulan "CobraPLA" telah mengambil masa yang lama untuk memasukkan alat ini dengan jayanya dan perbezaannya adalah signifikan. Sementara bilangan percubaan untuk memesukkan alatan pernafasan ini adalah tidak signifikan. Kami juga mendapati bahawa "ETCO2" adalah lebih tinggi untuk kumpulan "CobraPLA" berbanding dengan kumpulan "LMA" dan perbezaan adalah signifikan. Saturasi juga didapati lebih tinggi dalam kumpulan "LMA" dan perbezaannya juga adalah signifikan. Bagaimanapun tiada perbezaan tindakbalas kardiovaskular semasa pembiusan di antara dua kumpulan ini. Kami juga mendapati terdapat perbezaan statistik antara kumpulan "CobraPLA" dan "LMA" di dalam insiden "blood staining" ke atas alat bantuan pernafasan tetapi tiada perbezaan terhadap insiden sakit tekak antara kedua – dua kumpulan.

Kesimpulannya, "CobraPLA" tidak dapat berfungsi sebagai alat bantuan pernafasan yang memuaskan dan kami berpendapat ia tidak sesuai digunakan sebagai alat bantuan pernafasan alternatif kepada "laryngeal mask airway" bagi teknik pembiusan pernafasan spontan untuk pesakit dewasa.

ABSTRACT

The purpose of this study is to assess whether the newly developed CobraPLA is a reliable, easy and safe device for use in adult patient undergoing general anaesthesia. We compared the use of the CobraPLA with the laryngeal mask airway in spontaneously ventilating adult patients undergoing general anaesthesia for elective surgery.

A randomized prospective study was conducted on 56 premedicated adult patients of ASA 1 and 2, aged between 18 to 65 years. They were divided into 2 groups (n= 28/ group) receiving either CobraPLA or LMA as airway device. After inhalational induction of anaesthesia with intravenous propofol 2mg/kg and intravenous fentanyl 1 mcg/kg, the CobraPLA or LMA was inserted and the patients breathed spontaneously throughout the surgery. Anaesthesia was maintained with nitrous oxide, oxygen and sevoflurane. The airway device was removed at the end of surgery with the patients fully awake. The duration of insertion and number of attempts needed to successfully secure the airway was recorded. Systolic blood pressure, diastolic blood pressure, mean arterial blood pressure , heart rate, saturation and end tidal carbon dioxide at different time interval were recorded. The incidence of post operative complications were also recorded.

We found that there was longer time of insertion in the CobraPLA group as compared to LMA group and the difference was statistically significant. However there was no difference in the number of attempts needed to secure the respective airways. The ETCO2 was higher in the CobraPLA group as compared to LMA group and the difference was statistically significant. Saturation was found to be higher in the LMA

group and the difference was also statistically significant. However there was no difference in haemodynamic changes. Incidence of blood staining of the airway devices was higher in the CobraPLA group and was statistically significant. Nevertheless the incidence of sore throat was equal in both groups.

We concluded that during spontaneous ventilation in adult patients undergoing general anaesthesia, the CobraPLA is not as reliable in providing a satisfactory airway and we consider it is not a suitable alternative to the laryngeal mask airway.

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ABBREVIATIONS

ASA	American Society of Anaesthesiology
CO2	Carbon Dioxide
DBP	Diastolic Blood Pressure
ETCO2	End Tidal Carbon Dioxide
ETT	Endotracheal Tube
EEG	Electroencephalograph
H20	Water
HR	Heart rate
IPPV	Intermittent positive pressure ventilation
LMA	Larygeal Mask Airway
MAP	Mean Arterial Pressure
N20	Nitrous Oxide
SBP	Systolis Blood Pressure
SD	Standard Deviation
US	United States

1.INTRODUCTION

Spontaneous ventilation under general anaesthesia is commonly used in short surgical procedures.This procedure precludes the usage of neuromuscular blocking agents. Various methods of administering spontaneous ventilation had been used including face mask ventilation and variety of supraglottic airways .

Laryngeal Mask Airway had gained its popularity since its advent in 1988 by Dr. Archie Brain. Since then various types of supraglottic airways started emerging and many studies have been published to compare their efficacy with Laryngeal Mask Airway.

CobraPLA is an advancement in supraglottic airway management. It was invented by Dr. Alfery and the preliminary study was conducted and published in 2003. It was designed to be positioned in the hypopharynx where it abuts the structures of the laryngeal inlet. The patented cobra head design of the distal end of the CobraPLA holds both soft tissue and epiglottis out of the way, thus facilitating ventilation through the slotted openings. The softened distal tip of the cobra head provides easy passage of the device into the hypopharynx by bending in the direction of glottis as CobraPLA is inserted.

There is a standard 15 mm connecter on the proximal end of the tube for attachment to the breathing system. There are eight sizes of CobraPLA ranging from size 0.5 to 6. Sizes three to six are suitable for adult patients.

Two studies have been published so far to evaluate the use of CobraPLA in adult patients undergoing General Anaesthesia. Ozan Akza et al (2004) compared CobraPLA and LMA in mechanically ventilated adult patients. While Gatini et al (2006) compared evaluated CobraPLA and LMA unique in spontaneous ventilating adult patients.

Hence our study was proposed to compare the efficacy of CobraPLA with LMA classic in spontaneous ventilating adult patient undergoing general anaesthesia.

2.OBJECTIVES AND DEFINITIONS

2.1 OBJECTIVES

i) To determine easiness of insertion between LMA and CobraPLA group.

ii) To evaluate haemodynamic profiles between LMA and CobraPLA

iii) To compare incidence of sore throat post extubation.

2.2 RESEARCH HYPOTHESIS

i) There is a difference between easiness of insertion between LMA and CobraPLA

ii) There is stable haemodynamic profile between LMA and CobraPLA.

iii) There is comparable incidence of sore throat between LMA and CobraPLA

2.3 DEFINITIONS

i) Easiness of insertion is defined as less time taken to insert the airway device and less number of attempts required for a successful first tidal lung volume.

ii) Haemodynamic parameters are defined as measurement of systolic blood pressure,diastolic blood pressure, mean arterial pressure, heart rate, saturation and end tidal carbon dioxide at different time intervals.

iii) Postoperative complications are defined as unfavourable effects that occur Like sore throat and blood on airway device(airway trauma)

3. LITERATURE REVIEW.

3.1 COBRAPLA

3.1.1 History

Supraglottic or perilaryngeal airway is a device which delivers anaesthetic gases above The level of the vocal cord. Their general characteristics are airway tube which has an internal passage in the airway tube wall for receiving a cuff inflation line and a dome which has an inlet and an outlet. The dome is connected at its inlet with the distal end of the airway tube.

The device also includes an annular spoon-shaped inflatable cuff connected with the periphery of the outlet of the dome. A cuff inflation line configured to be in fluid communication with the internal space of the cuff. and a multi-lobed aperture formed in the dome.

Following huge success of the "original" supraglottic airway which was the Classic LMA , invented in 1988 by Dr Archie Brain, at least more than seventeen supraglottic airway devices have been described and available in the market.

Cobra perilaryngeal airway or CobraPLA is a new supraglottic airway which was designed for both spontaneous and controlled ventilation. It was invented by Dr. Almery and was introduced into the anesthetic community in 1997 when Dr. David Alfery modified a well known instrument helpful in airway management, the Guedel oral

airway. The initial idea was to modify the Guedel airway in order to accomplish mask ventilation in the most difficult airways encountered. The first changes consisted of lengthening and widening the distal end of the Guedel airway and placing a slot in the widened end to accommodate the epiglottis. This modification of the airway functioned quite well to hold soft tissues away from the laryngeal inlet, but a decision was soon made to convert it into a supraglottic airway device.

It is a new alternative for airway management and a novel cuffed airway device. A preliminary study on the use of CobraPLA was conducted by Agro et al and was published in Journal of Anaesthesia in September 2003.This study suggested that CobraPLA provides a patent airway and can be considered as an alternative device if LMA is not available(Agro et al 2003)

This was followed by a study to compare LMA and CobraPLA in mechanically ventilated patients in context of the effectiveness in airway sealing pressure (Azan Okza et al 2004).Since then studies have been conducted to evaluate its role in spontaneous ventilated patients, mechanical ventilated patients, emergency airway management and its performance in percutaneous tracheostomy. Currently it is commercially available for clinical practice.

3.1.2 Characteristics

The CobraPLA is designed to be positioned in the hypopharynx where it abuts the Structure of the laryngeal inlet. It consists of a breathing tube, wide distal end and a cuff attached proximal to the patent cobra head.

The distal widened Cobra head which holds soft tissues apart and allows ventilation of the trachea. When in proper position, the Cobra head lies in front of the laryngeal inlet and seals the hypopharynx. In this respect, it differs from many other supraglottic airways as the distal tip lies proximal to the esophageal inlet. Internal to the Cobra head, there is a ramp to direct the breathing gas into the trachea. On the anterior aspect of the cobra head are breathing holes called " soft grill" This feature helps to deflect the epiglottis off the Cobra head, preventing the epiglottis from obstructing the breathing hole. In addition, the bars of the grill are flexible enough to allow passage of an endotracheal tube.

The cuff is circumferential and is shaped to reside in the hypopharynx at the base of the tongue. When inflated, it raises the base of the tongue, exposing the laryngeal inlet, as well as affecting an airway seal, thus allowing positive pressure ventilation to be carried out.

The softened distal tip provides easy passage of the device into the hypopharynx and bending in the direction of glottis as the CobraPLA is inserted.

The CobraPLA breathing tube large inner diameter increases the airflow. The increased diameter and its gently curved ramps near the distal end facilitates easy insertion of bronchoscope for verification of correct placement and also insertion of endotracheal tube during difficult airway management. The proximal end fits the 15mm connector for attachment to the breathing system.

3.1.2 a) Size selection

Eight sizes are now available ranging from size 0.5 to size 6. Choosing the correct size depends on the weight of the patient. The most important consideration is to choose a size which fits through the patient's mouth without undue difficulty. There is a range of potential weights of patients for any given CobraPLA size. For neonates more than 2.5 kg but less than 5 kg requires size 0.5

Size 1 is for infant weighing more than 5 kg, while size 1 ½ for infants more than 10kg. Size 2 for children more than 15kg, size 3 for adults more than 35kg but less than 70kg. Subsequently size 4 is for adult more than 70kg but less than 100kg, size5 is for adult weighing more than 100kg and finally size 6 is for adults weighing more than 130kg.

In fact, the size 3 CobraPLA has been successfully used in patients ranging < 40 - 130 kg (personal communication, Dr. David Alfery). The manufacturer suggested range for each size is indicated in Table 1. It can be noted that for most weights you will consider 2 or more sizes, and that there is no suggested "upper limit" for any given size. The reason for this is that a patient with a relatively high weight may have a very small mouth in relation to his or her weight.

Table1: Size as recommended by manufacturer

Size	Weight (kg)
1/2	2.5 - 7.5
1	5 - 15
1 1/2	10 - 35
2	20 - 60
3	40 - 100
4	70 - 130
5	100 - 160
6	> 130

Despite the recommended sizes by the manufacturer according to the weight of respective patients , a preliminary study was conducted in 110 patients to look for appropriate sizes of cobraPLA for patients. In this study, relatively large-sized CobraPLAs were used because the author was skilled in the insertion technique, which was scissoring the mouth open by performing jaw lift (Agrò maneuver) and these patients were administered muscle relaxant prior to insertion of the CobrPLA .

Hence , by using larger sizes of CobraPLA, a considerably higher cuff sealing pressure could be obtained as compared to those which result from choosing smaller sizes.

Therefore this study recommended that CobraPLA size 3 is suitable for patients weighing less than 60kg, size 4 for adults weighing 60 to 80 kg, and size 5 is for adults weighing more than 80kg. (F.Agro et al 2003)

Table 2 Cobra size suggested by Agrò et al.

Size	Weight (kg)
3	< 60
4	60 - 80
5	> 80

3.1.2b) Cuff volumes and pressures

Cuff pressures are very crucial in an airway device. It provides sealing pressure and allows ventilation. Nevertheless if a cuff pressure exceeds 60mmHg complications will arise in patients after extubation , for example sore throat or later they may suffer from tracheal stenosis. In order to prevent these complications, the current endotracheal tubes and other airway device are designed with high volume and low cuff pressures.

As for the CobraPLA, Agro has conducted a study and by using Agrò's range the cuff inflation volume can be reduced from the maximum pressure which was initially higher.

In this fashion, the cuffs can function similar to the cuffs on endotracheal tubes, that is high volume low pressure cuffs. Normally cuffs are inflated to not more than 60 cmH2O if using pressure gauge manometer. If the cuff pressure gauge is not available, the cuff could be inflated using a syringe up to not more than 65 ml of air for CobraPLA size 3 and about 70ml of air for CobraPLA size 4.

Table 3 Inflation volume as suggested by manufacturer and Agro et al.

Inflation volume as suggested by manufacturer		**Inflation volume as suggested by Agro**	
Size	Volume	Size	Volume
3	<65	3	26±2.1
4	<70	4	31.9±4.0
5	<85	5	40.0±4.1

A study by Ozan Akza et al which was published in 2004 stated that the airway sealing pressure is greater in CobraPLA as compared to LMA. This feature offers an extra advantage for CobraPLA in its usage in mechanical ventilation as there was no sign of stomach insufflation in the CobraPLA group.

3.1.3 INDICATIONS

CobraPLA is suitable for short elective surgical procedure needing spontaneous Ventilation as an alternative to face mask or LMA. CobraPLA has also been used in mechanical ventilation, and percutaneous tracheostomy. Another important advantage of CobraPLA that is particularly useful in the management of emergency airway problems is that the insertion technique is very simple, and even when used by personnel with little or no experience in supraglottic device, success is often obtained. Thus it could be useful for those who undertake airway management infrequently. Currently, a large clinical study is underway evaluating the use of the CobraPLA in the out-of-hospital emergency airway situation when difficulty in establishing an adequate airway is encountered.

3.1.4 CONTRAINDICATIONS

i) Patients who are at risk for pulmonary aspiration of gastric content , morbidly obese patients and also patients with history of gastroesophageal reflux disease.

ii) Patients with obstructed upper airway and procedures with duration of more than two hours.

3.1.5 ADVANTAGES

i) Anaesthetist convenience

CobraPLA confers convenience to the anesthetist which is attributed by its structure. Improved sealing pressure was reported due to the presence of ellipsoidal cuff located in the upper portion of the device that easily covers the proximal pharynx .(Akza et al

2004) Consequently , a combination of good anatomic sealing and a cuff which is sufficiently large enough to cover the peripharyngeal tissues increase the chances of providing a patent airway with adequate airway sealing pressure.

With regards to insertion, CobraPLA does not require a prolonged learning curve. Its anteroposterior width of the distal end is smaller then LMA and thus requires only a small mouth opening for insertion. In addition to this its softened distal end allows smooth glide over the hard palate.

A study which was published in British Journal Anaesthesia 2003 stated that CobraPLA insertion was possible in 100% of their patients whereby 77.3% did not require any manouvers while 22.7% needed jaw thrust and hyperextension of the neck. In addition to this Ozan Akza et al found that there was no significant difference in terms of insertion between the CobraPLA and LMA. Therefore it is wise to conclude that CobraPLA could be a good alternative in airway management and convenient to the anaesthetist. (BJA 2003)