Original Article

ISSN: 1735-0344 *Tanaffos 2015; 14(1): 42-48*

TANAFFOS

Efficacy of the New Perilaryngeal Airway (CobraPLA™) Versus the Laryngeal Mask Airway (LMA™) to Improve Oropharyngeal Leak Pressure in Obese and Overweight Patients

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Received: 18 June 2014
Accepted: 23 December 2014

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Background: This study aimed to evaluate the applicability of Cobra perilaryngeal airway (Cobra PLA™) for obese patients under general anesthesia and also to compare the results with those of classic laryngeal mask airway (LMA™).

Materials and Methods: Seventy-three overweight and obese patients were included in this study. The patients were randomly assigned to LMA™ or Cobra PLA™ groups. Time required for intubation, successful intubation attempt, airway sealing pressure and incidence of complications including blood staining, sore throat and dysphagia were assessed and noted.

Results: Thirty-six and 37 patients were randomly allocated to LMA™ and Cobra PLA™ groups, respectively. Most patients were males and had Mallampati Class II airway in both groups. The first attempt and overall insertion success for Cobra PLA™ was significantly higher compared to LMA ($P<0.05$). Airway insertion was more successful ($P = 0.027$; 94% vs. 77%) with Cobra PLA™. Insertion times were similar with Cobra PLA™ and LMA™ (Cobra PLA™, 29.94±16.35s; LMA™, 27.00±7.88s). The oropharyngeal leak pressure in the Cobra PLA™ group (24.80±0.90 H_2O) was significantly higher than that in LMA™ group (19±1 H_2O, $p<0.001$). Sore throat was more frequent in the LMA™ group although it did not reach statistical significance (Fisher's exact test, $P = 0.33$). Blood staining on airway tube was seen in both groups with a higher incidence in the Cobra PLA™ group (Fisher's Exact test, $P = 0.02$). Incidence of dysphagia was not different between the two groups.

Conclusion: CobraPLA™ was found to be safe with low complications. It provided better airway sealing with high rate of the first insertion success for use in obese and overweight patients. This study recommends the use of CobraPLA™ as a rescue device in emergency situations for obese and overweight patients.

Key words: CobraPLA™, Flexible laryngeal mask airway, Obese patients

INTRODUCTION

Obesity is a chronic disorder usually associated with prolonged hospitalization, mortality and many co morbidities including cardiovascular disorders, cerebrovascular disorders, diabetes mellitus and also some forms of cancer. The most commonly used measure of the degree of obesity is the body mass index (BMI) which is body weight (kg) divided by height (m) squared. BMI between 30.0-34.9 $kg.m^2$, 35.0–39.9 $kg.m^2$ and ≥40.0 $kg.m^2$ is classified as grade 1, grade 2 and grade 3 or morbid

obesity, respectively. The prevalence of obesity is increasing in both developed and developing countries. According to the world health organization (WHO), the prevalence of obesity doubled globally from 1980 to 2008, and now more than 1.4 billion adults are overweight worldwide. Of these, over 200 million men and nearly 300 million women are obese. Furthermore, it has been estimated that the prevalence of overweight adults will increase to 2.3 billion in the world by 2015 (1). In Iran as a developing country, the prevalence of overweight and obesity is increasing and the overall prevalence of obesity for adults (>18 yr) is estimated to be 21.5% (2). Studies have shown that obesity interferes with respiratory system. An obese patient is more likely to have obstructive sleep apnea, obesity hypoventilation syndrome, difficulties with mask ventilation and tracheal intubation and abnormalities of both lung volumes and gas exchange (3). The influence of body mass on arterial partial pressure of oxygen (PaO_2) during general anesthesia was investigated by Pelosi et al. They found that BMI was negatively correlated with PaO_2 and BMI was recognized as a leading predictor of lung volumes, respiratory mechanics, and oxygenation for patients during general anesthesia (4). Several noninvasive extraglottic airway devices (EADs) have been introduced since the onset of anesthesia practice. The LMA (Laryngeal Mask Company Limited, Henley-on-Thames, UK) is the first EAD that does not need tracheal intubation. LMA is widely used for different patients and is believed to be highly safe for adult and pediatric patients (5). However, LMA has some limitations and weaknesses (e.g. more insertion attempts in 5% to 10 % of the cases) (6). Despite the easy insertion of LMA, it is crucial to check its correct placement. In addition, LMA can cause gas leak under elevated airway pressures (i.e. greater than 20 cm H_2O) (7). To allow a higher oropharyngeal leak pressure (OLP) than LMA, the ProSeal laryngeal mask airway (PLMA; Laryngeal Mask Company, Henley-on-Thames, UK) is recommended (8). The PLMA has been shown to be more effective than the LMA in terms of OLP if set in correct place and position (8). However, the LMA was found to be quicker and easier to set than PLMA (9). Recently, a new EAD was developed. This new supraglottic airway is made of medical grade polyvinyl chloride (PVC) and is recognized as a cuffed, disposable EAD. The Cobra PLA™ (Engineered Medical Systems, Indianapolis, IN)(10) has eight sizes and can be used in neonates and infants. The second generation of this EAD was introduced for anesthetic management in 2006 with a better condition than the previous form including a distal curve and softer tubes (11). The Cobra PLA™ has been widely used for many patients and was found to be suitable for anesthetic management (12, 13). Furthermore, studies revealed that the Cobra PLA™ provides a higher airway seal pressure than LMA (12, 13). In a recent review, Hooshangi and Wong assessed 28 studies that used Cobra PLA™. The authors found that the Cobra PLA™ caused lower frequency of sore throat with less insertion times and provided better oropharyngeal leak pressure compared to LMA. Furthermore, the Cobra PLA™ can be used for patients with mouth opening and head extension limitations (11). Despite the successful use of Cobra PLA™ for patients with BMI<25, its applicability for overweight and obese patients is not clear. This study aimed to evaluate the applicability of Cobra PLA™ for patients under general anesthesia and also to compare its results with those of classic LMA.

MATERIALS AND METHODS

This study was a registered randomized clinical trial (RCT) and was performed between February 2012 and January 2013. The study procedure was approved by the Ethics Committee of Qazvin University of Medical Sciences. During 11 months, overweight and obese patients (BMI between 25 to 35 kg/m^2) scheduled for surgery were recruited to participate in this study. All subjects gave informed consent to participate in the study. The inclusion criteria were being older than 18 years, Mallampati class I-III and BMI between 25 and 35. Patients were excluded

from the study if they were pregnant, morbidly obese (BMI>35 kg/m^2), had a known difficult airway, gastro-esophageal reflux, pharyngeal pathology, emergency operation with full stomach and current sore throat. All patients received premedication including fentanyl (2μg/kg), midazolam (0.03 mg/kg), propofol (2 mg/kg) and atracurium (0.5 mg/kg) as well as analgesics. Anaesthesia was maintained by oxygen/air and isoflurane. Patients were randomly assigned to LMA or Cobra PLA™ groups. Randomization was performed using a table of random numbers by an independent physician blinded to the patient groups. The study was single blind—that is no patient was aware of the treatment assignments for the duration of the study. The EADs were set by a trained and experienced anesthesiologist (the first author). The size of Cobra PLA™ was chosen according to the patient's weight and ranged from size 4 (70–100 kg) to 5 (100–130 kg) and 6 (>130 kg). The cuff pressure was set at 60 cm H_2O once the Cobra PLA™ was inserted. The cuff pressure was measured and adjusted by means of Digital P-V Gauge (Mallinckrodt, Athlone, Ireland). Time to intubation was measured from the insertion of device into the patient's mouth to connecting the breathing circuit (i.e. establishing an adequate airway). Time required for intubation was measured by an independent observer using a stopwatch. A successful intubation attempt was recognized if the breathing circuit was connected, the E_tCO_2 trace was revealed, and no air leak was detected at airway pressure of 15 cm H_2O. The airway seal pressure was measured by closing the expiratory valve of the circle system at a fixed gas flow rate of 3 L/min and noting the airway pressure (maximum 40 cm H_2O) at which equilibrium was reached. OLP was measured by closing the expiratory valve of the circle system at a fixed gas flow of 3 L/min and noting the airway pressure at which the dial reaches stability (14). The patients were asked to indicate whether they had sore throat, dysphonia, or dysphagia using a dichotomous response (yes/no) immediately post-operation and at 24 hours.

The primary outcomes of the study were OLP and time required for intubation. The secondary outcomes were successful rate of placement on the first attempt and incidence of adverse events including sore throat, dysphasia and postoperative blood staining on mask.

Statistical analysis

Sample size of this study was determined based on our pilot study that included 34 patients. The results indicated that there was a 5 cm of H_2O difference between the two groups. With β=0.10%, α=0.05, the required sample size was 25 patients in each group.

Differences between the two groups of patients were assessed using Student's t-test (for continuous variables), chi square (for dichotomous and nominal variables) and Mann-Whitney U (for ordered categorical variables) tests. Several regression analyses were performed to compare the impact of these airways in obese and overweight patients on the presence of confounding variables such as age, gender and BMI. Stepwise multiple linear regressions were conducted with OLP and time required for intubation as dependent variables while age, gender, BMI, Mallampati class and study groups were entered into the model as independent variables. Logistic regression was used to compare the incidence of adverse events between the two groups. The incidences of adverse events including sore throat, dysphasia and postoperative blood staining on mask were entered into the models as dependent variables while age, gender, BMI , Mallampati class and study groups were entered into the model as independent variables. Finally, an ordinal regression model was conducted to compare the number of attempts for intubation in the study groups. P<0.05 was considered statistically significant. Data analysis was performed using SPSS 17.

RESULTS

In total, 73 obese and overweight patients participated in the study. Thirty-six and 37 patients were randomly

allocated to LMA and Cobra PLA™ groups, respectively. Most patients were males and had Mallampati Class II airway in both groups. There was no significant difference between the two groups as to the patients' characteristics (Table 1). The number of attempts required for successful insertion is shown in Table 2. The first attempt and overall insertion success for the Cobra PLA™ was significantly higher than LMA (P<0.05). Tube insertion was more successful (Cobra PLA™, 94%; LMA™, 77%; P = 0.027) with Cobra PLA™. Results obtained from ordinal regression indicated that the Cobra PLA™ had higher frequency of successful insertion compared to LMA. These results were still significant in presence of confounding factors with an estimate of 1.851, standard error of 0.914 and P value of 0.043.

Table 1. Demographic characteristics of subjects in the two groups

	CobraPLA(n=37)	LMA(n=36)	P value
Age (yrs.)	37.25±10.21	33.82 (7.87)	0.278
Gender			
Male N(%)	23 (62.2%)	25 (69.4%)	
Female N(%)	14 (37.8%)	11 (30.6%)	
Weight (kg)	81.97±8.86	80.92±11.80	0.908
Height (cm)	160.76±11.88	162.23±7.39	0.111
BMI (kg/m^2)	31.65± 3.72	31.72± 3.48	0.875
Mallampati Class			
I	11	13	
II	23	22	
III	3	1	0.556
Duration of Anesthesia (second)	4105.12 (2040.19)	4112.45 (2112.78)	0.678

The insertion times were similar with the Cobra PLA™ and LMA™ (Cobra PLA™, 29.94±16.35s; LMA™, 27.00±7.88s). The results were also confirmed by multiple linear regression after adjusting for confounding factors (β=0.021, P>0.05). The OLP in the Cobra PLA™ (24.80±0.90 H_2O) was significantly more than in LMA™ (19.13 ±0.58 H_2O, P<0.001). Multiple linear regression analyses were subsequently performed to estimate how OLP varied according to confounding factors. The results indicated that the Cobra PLA™ provided a more effective seal than the LMA irrespective of age, gender, BMI or Mallampati class (Table 3).

Table 2. Insertion characteristics and oropharyngeal leak pressure

	CobraPLA(n=37)	LMA(n=36)
Number of attempts for intubation		
1	35	28
2	1	8
3	1	0
Time required for intubation (second)	29.94± 16.35	27.00±7.88
Sealing pressure (cm H_2O)	24.80±0.90	19.13±0.58
Blood staining		
Yes	26	12
No	11	24
Sore throat		
Yes	11	15
No	26	21
Dysphagia		
Yes	6	2
No	31	34

Table 3. Regression summaries of factors predicting Oropharyngeal leak and time required for intubation (n = 73).

	Oropharyngeal leak				Time required for intubation			
	B	SE	CI (%95)		B	SE	CI(%95)	
			Lower	Upper			Lower	Upper
Age	0.019	0.020	0.0345	0.044	-0.064	0.159	-0.403	0.233
Gender	0.094	0.377	-0.160	1.348	-0.044	3.286	-7.808	5.311
Mallampati Class	0.013	0.349	-0.623	0.776	0.157	2.791	-1.813	9.330
BMI	0.022	0.047	-0.077	0.113	0.186	0.432	-0.168	0.1557
Group	0.850**	0.329	4.304	5.621	0.021	0.184	-0.339	0.396

**P<0.001

Table 4. Binary logistic regression analysis to predict incidence of adverse events including sore throat, dysphasia, postoperative blood staining on mask in obese and overweight patients (n = 73)

	Sore throat		Dysphasia		Blood	
	OR (%95 CI)	P value	OR (%95 CI)	P value	OR (%95 CI)	P value
Age	1.011 (0.958-1.066)	0.692	1.100 (0.988-1.224)	0.081	1.059 (0.988-1.135)	0.106
Gender	0.636 (0.209-1.937)	0.426	0.798 (0.135-4.704)	0.803	0.939 (0.835-1.034)	0.202
Mallampati Class	0.844 (0.329-2.163)	0.724	5.837 (0.822-12.45)	0.078	2.286	0.118
BMI	0.981 (0.850-1.132)	0.794	1.219 (0.929-1.598)	0.153	1.132 (0.952-1.345)	0.161
Group	0.635 (0.228-1.769)	0.385	8.111 (1.066-21.727)	0.043	9.950 (2.690-22.812)	0.001

The incidences of complications (blood staining, sore throat and dysphagia) are presented in Table 2. Sore throat was reported for both patient groups. However, sore throat was more frequent in the LMA™ group but not significantly (Fisher's exact test, P= 0.33). The results were similar to those obtained by the multiple logistic regression (Table 4). Blood staining on airway tube was seen in both groups but was higher in the Cobra PLA™ group (Fisher's exact test, P = 0.02). Logistic regression model was also revealed that the rate of blood staining was higher in the Cobra PLA™ group (OR= 9.950, P=0.001) than the LMA group (Table 4). The incidence of dysphagia was not different between the two groups (Table 2). However, logistic regression model showed that patients in Cobra PLA™ group had significantly higher frequency of dysphagia compared to those in the LMA group (OR= 8.111, P=0.0.043).

DISCUSSION

This study found that the Cobra PLA™ was more suitable for anesthesia in obese and overweight patients. The Cobra PLA™ had quicker insertion time with more successful airway placement. The data suggest using the Cobra PLA™ as a rescue device in emergency conditions. Our study revealed that the OLP was higher in the Cobra PLA™ compared to LMA™.

This study revealed that patients in the Cobra PLA™ group had significantly higher OLP. Approximately, there was 5.67 H_2O OLP difference between the LMA™ and the Cobra PLA™ groups. Our study was in line with previous studies and confirmed higher OLP with Cobra PLA™ (12,15). However, patients' weight and BMI were significantly higher in the current study compared to previous studies (12,15). Low OLP may lead to some problems including gas leak into the stomach and subsequent gastric distention and regurgitation (16). This condition may increase the risk of pulmonary aspiration in patients. In a study by Verghese and Brimacombe, LMA was used for 11,910 patients undergoing general anesthesia. Regurgitation, aspiration and vomiting occurred in four (0.03%), one (0.009%) and two (0.017%) patients, respectively (17). However, gastrointestinal complications are a major concern after using LMA (18). A high frequency of reflux, as a gastrointestinal complication, has been reported in patients who used LMA in comparison with those used oral airway (18,19). According to the manufacturer's recommendations, the LMA has not been designed for use at peak airway pressures higher than 20 cm H_2O and tidal volumes of 8–10 mL/Kg. A new device, the ProSeal LMA (PLMA), was developed to deal with the oropharyngeal leak problem. The ProSeal LMA is made of a softer material than the LMA Classic™ and is designed to conform to the contours of the hypopharynx. It has shown to provide higher OLP (up to 30 cm H_2O) and spontaneous ventilation (8). Despite many benefits of using PLMA, studies have shown that the PLMA is more difficult to insert due to its larger, wedge-shaped cuff (8).

Therefore, the CobraPLA™ was introduced to provide better OLP and successful insertion. In a recent review of the CobraPLA™, it was shown that this devise was superior in terms of airway OLP (11).

Our study indicated that the CobraPLA™ was successfully inserted in 94.6% of patients while the corresponding value was 77.8% for LMA. Furthermore, insertion times for the CobraPLA™ were comparable to LMA™. Our results are consistent with those generated by previous studies (12,15,20).

In our study, the patients were also assessed in terms of the following postoperative complications: blood on the device, sore throat and dysphagia. The use of the CobraPLA™ was not risk-free and the results indicated that the frequency of blood staining was higher with the CobraPLA™. The reason may be that the CobraPLA™ has a relatively stiff tip. However, there were no significant differences in terms of complications associated with the two devices. Similar results have been reported by previous studies (12, 20).

CONCLUSION

In conclusion, the Cobra PLA™ was found to be safe with low complications, better OLP and high rate of first insertion success for use in obese and overweight patients. A higher frequency of blood staining was associated with the use of Cobra PLA™. This study recommends the use of Cobra PLA™ as a rescue device in emergency situations in obese and overweight patients.

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