



COMPARISON OF THE SUPREME, OPLAC AND VIDEO LARYNGEAL MASK AIRWAY DURING GENERAL ANAESTHESIA IN CESAREAN SECTION

Anaesthesiology

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ABSTRACT

Background: The obstetric airway is a significant cause of maternal morbidity and mortality. A video laryngeal mask airway (VLMA) new production. In this randomized controlled trial, we compared the Supreme LMA (SLMA) with OPLAC and VLMA in managing the obstetric airway during cesarean section.

Methods: It was a randomized, single-blinded, study involving 60 pregnant women who underwent elective cesarean section under general anesthesia were randomized in three groups a) SLMA b) OPLAC and c) Video LMA. The success rate, insertion time, fiberoptic view, peak airway pressure, sealing pressure, incidence of gastric insufflations, trace of blood on the device, and incidence of postoperative sore throat were evaluated.

Results: The success rate of placement on the first attempt was high for all the three devices. The insertion time was significantly shorter and engagement was better noted on fiberoptic view with the OPLAC and Video LMA than with the Supreme LMA. The sealing pressure was significantly higher and the incidence of gastric insufflations was significantly lower with the OPLAC and Video LMA than SLMA.

Conclusions: OPLAC and VLMA could be an alternative airway management technique for a carefully selected low-risk obstetric population, with similar insertion success rates, reduced time to ventilation and less gastric insufflations compared with SLMA.

KEYWORDS

Laryngeal Mask Airway, Obstetric, Cesarean section, General Anaesthesia.

INTRODUCTION:

Obstetric airway management is complex, due to the unique challenges posed by the physiological changes of pregnancy, including reduced oncotic pressure, oxytocin-related water retention, and Valsalva maneuver during labor leading to mucosal capillary engorgement and edema. This is often confounded by inadequate fasting time, urgency of caesarean section requiring general anesthesia, and the need to balance the potential conflicting needs of the mother and fetus.^[1-3]

The introduction of second-generation supraglottic airway devices (SAD) such as the Supreme LMA (SLMA) with a double lumen specifically designed to physically separate the respiratory and alimentary tract, reduces the risk of aspiration^[1,4,5] and has changed obstetric airway management.

The Oro-Pharyngo-Laryngeal Airway Cap (OPLAC) is a mask made of 3 components: a silicone membrane, capped over a pliable ring made of thermoplastic rubber, reinforced by a fabricated cork plate anchoring around the airway tube. The membranous cap, which is a novel patented structure, also acts as a check valve to prevent air leakage whenever there is any void between the mask and the laryngeal vestibule. While the laryngeal aperture of the membranous cap is directed to the glottis, the upper and lower pouches of the cap serve as

check valves preventing air leakage and gastric insufflations, respectively. Because of the pliability and the check valve mechanism of the cap, the positive airway pressure during mechanical ventilation enhances airway sealing in the OPLAC in contrast to other supraglottic airway devices in which the high airway pressure unseats the airway sealing.^[6] Additionally, the tube of the OPLAC was designed to protrude from the bowl of the cap to approach the glottis more closely. As a result, the airflow through the OPLAC is directed to a level below the epiglottis thus bypassing the possible obstacle of the epiglottis.^[6]

Video Laryngeal Mask Airway (VLMA) developed by our department is a cuffed supraglottic airway management device. This is a single-use device. The device is delivered in a sterile state with Ethylene Oxide sterilization. The shelf life is defined for 3 years after sterilization. A re-sterilization by users is not allowed. It is indicated for use in achieving and maintaining control of airway during routine and emergency anaesthetic procedures in fasted patients using either spontaneous or positive pressure ventilation.

In this study, we evaluated and compared the success rate of insertion, insertion time, fiberoptic view, peak airway pressure, sealing pressure, the incidence of gastric insufflations, traces of blood noticed on the device after removal, and the incidence of postoperative sore throat after insertion of SLMA, OPLAC and Video LMA in elective caesarean section under general anaesthesia.

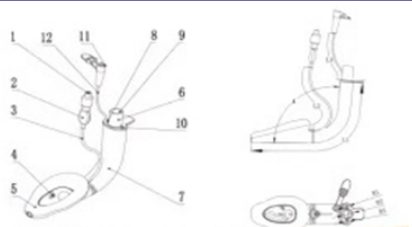


Figure 1: Type of MLM-C 1- Inflation Valve, 2-Pilot Balloon, 3-Inflation Line, 4-Observation Window, 5-Cuff, 6-Fixation Tab, 7-Airway Tube, 8-Observation Tube, 9-Connector, 10-Drain Tube, 11-Cleaning Connector, 12-Cleaning Tube.

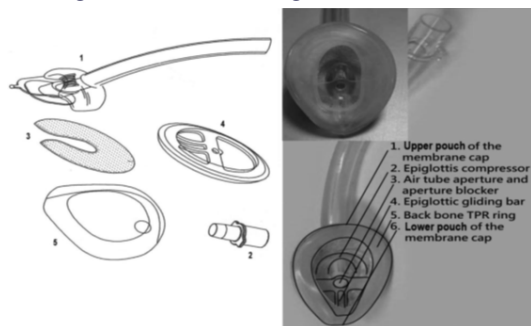


Figure 2: The Oro-Pharyngo-Laryngeal Airway Cap (OPLAC™) design. On the left is the expanded view showing the tube (1) designed to protrude into the bowl of the cap to approach the glottis more closely, the connector, (2) the fabricated cork plate (3) to support the contour, the pliable thermoplastic rubber (TPR) ring (4) with epiglottis blocker system, and the expandable silicone membranous cap (5) for sealing. On the right is the assembly of the OPLAC.

Subjects and Methods

Study design, settings and participants:

It was a hospital based prospective randomized controlled study conducted over a period of one year from October 2018 to September 2019 in Anaesthesia department of Henan Provincial People's Hospital, People's Hospital of Zhengzhou University, Zhengzhou, Henan, China. Total 60 pregnant women with singleton pregnancies and age 18 to 50 years old who were healthy or with well controlled medical conditions (American Society of Anesthesiology; ASA II) undergoing elective caesarean section under general anaesthesia were constituted as study population. Parturients with body mass index (BMI) ≥ 35 kg/m², anticipated difficult airway (modified Mallampati grade 4, or known upper respiratory tract or neck pathology) or self-reported gastro-esophageal reflux disease were excluded from the study. All parturients were fasted for a minimum of 6 hours.

Data collection

After taking written informed consent, study subjects were randomized into 3 groups and allocation concealed using sealed opaque envelopes prepared by a statistician not involved in the study recruitment. 1) SLMA group: Supreme Laryngeal Mask Airway 2) OPLAC group: OPLAC Laryngeal Mask Airway 3) VLMA group: Video Laryngeal Mask Airway.

As per our institutional standard, all parturients received premedication with intravenous ranitidine, following which electrocardiography, pulse oximetry, capnography and non-invasive blood pressure measurements were started. Following preoxygenation for three minutes, RSI was performed with cricoid pressure applied by a trained anaesthetic nurse. Anaesthesia was induced with intravenous propofol (2-3 mg/kg) and 100 mg succinylcholine. After the airway device was inserted, rocuronium (0.5 mg/kg) was used to maintain muscle relaxation and fentanyl (100µg) was administered for intraoperative analgesia after the fetus was delivered. All cases regardless of assigned study groups were induced in similar fashion.

In the SLMA group, SLMA insertion using the recommended single-handed rotational technique was performed with the release of cricoid pressure. Subsequently, a manometer was used to inflate the cuff to 60 cmH₂O, and we recorded the volume of air required to achieve this pressure. Next, the ability to ventilate was confirmed as evidenced by

the presence of auscultation of bilateral air entry and carbon dioxide trace on capnography. Following successful SLMA placement, a pre-mounted #14 gastric tube was advanced through the gastric drainage channel, and confirmed adequate placement by: (1) aspiration of gastric fluid; or (2) injection of air into the orogastric tube and auscultating a "swoosh" over the epigastrium. We recorded the number of attempts needed for successful placement, and suctioning of the orogastric tube was performed before commencement of the surgery. Finally, SLMA seal pressure was determined by recording the peak airway pressure after closing the adjustable pressure limiting valve while maintaining a fresh gas flowrate of 3 L/min into the closed circuit. If required, the use of additional maneuvers such as chin lift, head extension, jaw thrust, or SLMA repositioning were permitted to maintain a patent airway. Failure to achieve successful SLMA placement (1) after 2 attempts, (2) within one minute, or (3) before desaturation occurred (oxygen saturation $< 92\%$), would result in securing of the airway via direct laryngoscopy and endotracheal intubation. Cesarean section would commence if the following were met: (1) presence of a square-wave capnogram; (2) SLMA cuff pressure of 60cmH₂O; (3) SLMA bite block positioned between the incisors; (4) successful orogastric tube placement and suctioning performed; and (5) recorded SLMA seal pressure was ≥ 20 cm H₂O.

The OPLAC (size designed for 40-to 100-kg adult male and female) was lubricated and then inserted. The insertion was completed after loss of the resistance caused by the tongue base was felt when the OPLAC engaged in the laryngopharynx. The insertion of the OPLAC did not need cuffinflation.

VLMA (Video laryngeal mask airway) was inserted using a slightly diagonal approach (direct the tip away from the midline). and then continue to slide inwards rotating the hand in a circular motion so that the device follows the curvature behind the tongue and maximum rotating in right side, slightly deep. When resistance is felt when the distal end of the device meets the upper oesophageal sphincter. The device is now fully inserted. To fix this, adhesive tape 30.40cm long is used which holds it horizontally by both ends. Adhesive tape is placed transversely across the fixation tab, continuing to press downwards so that the ends of the tape adhere to each of the patient's cheeks and the device itself is gently pressed inwards by the tape. Cuff was inflated with air until relevant intra.cuff pressure is reached.

Maintenance of general anaesthesia was achieved with 1.5 to 2.0% sevoflurane in a 50% mix of nitrous oxide and oxygen, with all parturients positioned in left lateral tilt using a wedge. During anaesthesia, complications including the loss of airway, inadequate oxygenation or ventilation, and bleeding into the airway device were recorded. Parturients were ventilated with a tidal volume of 6 to 10 mL/kg at 10 to 16 breaths/min, targeting an end-tidal carbon dioxide concentration of 30 to 40 mmHg. The presence of clinical signs of aspiration, including perioperative hypoxemia, lung auscultation revealing wheezing or crepitations, and postoperative dyspnea would trigger investigation of the parturient with bronchoscopy or chest X-rays.

Statistical analysis

Data were analyzed and statistically evaluated using SPSS software, version 17 (Chicago II, USA). Quantitative data was expressed in mean, standard deviation and comparison between three groups were tested by ANNOVA or Kruskal Wallis test followed by posthoc test while qualitative data were expressed in percentage. Statistical differences between the proportions were tested by chi square test or Fisher's exact test. 'p' value less than 0.05 was considered statistically significant.

Ethical issues

All participants were explained about the purpose of the study. Confidentiality was assured to them along with informed written consent. The study was approved by the Institutional Ethical Committee.

Results:

Patient's demographic and clinical characteristics are shown in Table 1. All the three groups were comparable in term of maternal age, weight, height, Mallampati scores and fetal gestational age. There was

no significant difference in duration from the time of anaesthesia to delivery, and the overall duration of surgery.

The first insertion attempts were successful in 19 patients (95.0%) of the SLMA group, 19 (95.0%) patient in OPLAC group and 19 patients (95.0%) of the VLMA group ($p=0.99$). The mean insertion time was also comparable in all the three groups (12.7 $\pm$ 4.2 sec in SLMA group; 12.6 $\pm$ 4.7 sec in OPLAC group and 12.6 $\pm$ 5.8 sec in VLMA group; $p=0.84$). There was no significant difference in peak airway pressure between these 3 devices. Air leak was highest in VLMA then other laryngeal mask (Table 2). The airway sealing pressure was significantly higher for the OPLAC and VLMA than for the SLMA. The fiberoptic position was better for the OPLAC and SLMA than for the VLMA. The OPLAC and VLMA had a significantly lower incidence of gastric insufflations than the SLMA. The incidence of blood staining on the device was similar in all the groups ($P = 0.32$). The rates of pharyngolaryngeal morbidity were also similar in the groups. There was no significant difference in the incidence of sore throat, dysphonia and dysphagia between the three groups (Table 4).

DISCUSSION

The contour of the OPLAC is supported by the pliable ring and is reinforced by a fabricated cork plate. The smaller backbone structure that compares to LMA Classic size #3, with the expandable membranous cap, makes it possible to fit patients in a wide range of body size.^[6]

OPLAC is designed to seal without a cuff, the engagement of the OPLAC was signalled by loss of resistance against the tongue base. More time was spent for LMA insertion because of the need for cuff inflation and the more frequent manipulation requirement.

The high success rate of OPLAC and VLMA insertion in obstetrics further strengthens our hypothesis that the use of second-generation LMAs such as the OPLAC and VLMA is suitable in selected parturients, and this is consistent with the OAA-DAS recommendations for use in difficult and failed intubation.^[7]

The supraglottic airway devices cause sore throat by 2 mechanisms. One is by applying constant high pressure over the pharyngeal mucosa and the other is traumatic insertion. In the study by Miller and Camporota^[8] the LMA Proseal and SLIPA both showed an airway sealing pressure above 30 cm H₂O, which was considered lower than, but approaching that, of an endotracheal tube. OPLAC and VLMA was designed to decrease the incidence of sore throat while achieving a high airway sealing pressure, which was 27.61 $\pm$ 4.12 and 27.53 $\pm$ 3.18 cm H₂O respectively in this study.

Positive pressure ventilation with an airway pressure >18 cm H₂O increases the incidence of gastric insufflations, especially when the LMA position is suboptimal.^[9-13] In this study, OPLAC and SLMA was more likely than the VLMA to have an optimal position (grade 1-2). In addition, during positive pressure ventilation, the expandable silicone membrane is attached and pushed against the airway mucosa, thus enhancing sealing. Any increase of positive pressure needed for ventilation contributes to sealing in the OPLAC and VLMA. This patented design makes the OPLAC and VLMA a supraglottic airway device with a high sealing pressure.

Higher-risk obstetric parturients with medical conditions such as preeclampsia and cardiac disease could benefit from reduced hemodynamic alterations associated with OPLAC and VLMA use.^[14,15] Furthermore, during emergency airway management, a shorter time to ventilation could reduce potential hypoxia.^[1,16] Supreme LMA and Video LMA is less suitable for Asian peoples due to it gives pressure to the cricoid cartilage in fiberoptic view because of its thick and more wide body.

CONCLUSION & RECOMMENDATIONS

In this randomized, single-blinded study in patients undergoing caesarean section under general anaesthesia we found that the noncuffed OPLAC and VLMA both were easy to insert. Compared with the supreme LMA, the insertion time was less variable for the OPLAC and VLMA. The OPLAC and VLMA fit better to the laryngo-pharynx and created a better airway sealing than the supreme LMA. We also found that the OPLAC and VLMA had a higher sealing pressure and was associated with a lower incidence of gastric insufflations than the supreme LMA. However, there is still limited

information of the safety of OPLAC and VLMA use, especially pertaining to pulmonary aspiration risk. Studies with larger sample size are needed to see more conclusive results.

Table I: Baseline demographic and clinical characteristics of all the three groups

Baseline characteristics	SLMA group (n=20)	OPLAC group (n=20)	VLMA group (n=20)	P value
Age (years)	29.2 $\pm$ 4.9	28.7 $\pm$ 3.4	29.5 $\pm$ 3.1	0.76
Weight (Kgs)	66.5 $\pm$ 5.8	65.3 $\pm$ 6.3	66.8 $\pm$ 6.9	0.49
Height (cms)	156.7 $\pm$ 4.3	157.3 $\pm$ 5.2	158.3 $\pm$ 4.9	0.65
BMI (kg/m ²)	27.1 $\pm$ 2.23	26.8 $\pm$ 2.5	26.5 $\pm$ 1.89	0.43
Mallampati grading				
Grade 1	8 (40.0%)	7 (35.0%)	8 (40.0%)	0.34
Grade 2	10 (50.0%)	11 (55.0%)	9 (45.0%)	
Grade 3	2 (10.0%)	2 (10.0%)	3 (15.0%)	
Gestational age (weeks)	38.6 $\pm$ 1.3	38.3 $\pm$ 1.7	38.8 $\pm$ 2.1	0.91
Duration from anaesthesia to delivery (min)	12.3 $\pm$ 6.8	13.1 $\pm$ 8.2	13.4 $\pm$ 7.4	0.87
Duration of surgery (min)	34.2 $\pm$ 9.8	32.2 $\pm$ 8.6	34.8 $\pm$ 7.9	0.92

Table II: Depth and air leak in different type of airway masks

Characteristics	SLMA group (n=20)	OPLAC LMA group (n=20)	VLMA group (n=20)	P value
Depth				
Optimum	11 (55.0%)	17 (85.0%)	10 (50.0%)	0.13
Slightly deep	6 (30.0%)	2 (10.0%)	5 (25.0%)	
Too deep	3 (15.0%)	1 (5.0%)	5 (25.0%)	
Air leak				
Yes	4 (20.0%)	2 (10.0%)	15 (75.0%)	<0.001
No	16 (80.0%)	18 (90.0%)	5 (25.0%)	

Table III: Gastric pH and Rotation in different type of airway masks

Characteristics	SLMA group (n=20)	OPLAC group (n=20)	VLMA group (n=20)	P value
pH				
<5	1 (5.0%)	1 (5.0%)	0	0.04
5-6	14 (70.0%)	17 (85.0%)	9 (45.0%)	
6-7	5 (25.0%)	2 (10.0%)	11 (55.0%)	
Rotation				
Grade 0	12 (60.0%)	17 (85.0%)	10 (50.0%)	0.02
Grade 1	7 (35.0%)	2 (10.0%)	4 (20.0%)	
Grade 2	1 (5.0%)	1 (5.0%)	6 (30.0%)	

Table IV: Anaesthetic outcome of study subjects receive different type of airway masks

Characteristics	SLMA group (n=20)	OPLAC group (n=20)	VLMA group (n=20)	P value
No. of insertion attempts				
1	19 (95.0%)	19 (95.0%)	19 (95.0%)	0.99
2 or more	1 (5.0%)	1 (5.0%)	1 (5.0%)	
Insertion time (seconds)	12.7 $\pm$ 4.2	12.6 $\pm$ 4.7	12.6 $\pm$ 5.8	0.84
Fiberoptic view (Campbell Classification Standard 11)				
Grade 0	8	8	8	<0.05
Grade 1	3	11	12	
Grade 2	8	1	0	
Grade 3	1	0	0	
Highest peak airway pressure (cm H ₂ O)	16.63 $\pm$ 2.68	16.12 $\pm$ 3.12	16.01 $\pm$ 1.26	0.79
Airway sealing pressure (cm H ₂ O)	23.75 $\pm$ 3.89	27.61 $\pm$ 4.12	27.53 $\pm$ 3.18	<0.01
Gastric insufflations with ASP >18 cm H ₂ O	2 (10.0%)	0 (0.0%)	0 (0.0%)	<0.05

Blood on the first device upon removal	3 (15.0%)	1 (5.0%)	1 (5.0%)	0.32
Sore throat (0/1/2/3)	18/2/0/0	19/1/0/0	19/1/0/0	0.31
Dysphonia (0/1/2/3)	19/1/0/0	20/0/0/0	20/0/0/0	0.98
Dysphagia (0/1/2/3)	19/1/1/0	19/1/0/0	19/1/0/0	0.89
Fetal weight	3122.4±422.2	3118.2±387.5	3142.6±398.6	0.76
APGAR score at 1 min (IQR)	10 (9-10)	10 (9-10)	10 (9-10)	0.95
APGAR score at 5 min (IQR)	10 (10-10)	10 (10-10)	10 (10-10)	0.86

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