
Airway Management in Anesthetized Spontaneously Breathing Patients: Proseal Versus Classic Laryngeal Mask Airways

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Abstract:

Background: Since the development of the classic laryngeal mask airway (cLMA) in 1988, airway management becomes more advanced in recent years. This advancement is demonstrated by the introduction of a wide variety of new alternative airway devices including the ProSeal laryngeal mask airways (PLMA).

Aim of the study: To compare the PLMA with the cLMA in anesthetized nonparalyzed adult patients with respect to insertion characteristics, airway sealing pressure (ASP) and incidence of related complications. For the PLMA, we also compared the efficacy of the introducer tool (IT).

Methods: Sixty adult patients scheduled for elective minor surgery were categorized into three equal groups; we inserted cLMA in group I, PLMA using the IT in group II, and PLMA with finger insertion technique in group III.

Results: The first attempt insertion success rate in group I and II was higher (100%) than in group III (95%). Insertion time (mean $\pm$ SD) differed significantly between the groups, and was $8.7 \pm (0.92)$, $13.35 \pm (1.66)$, and $16.95 \pm (1.39)$ seconds in group-I, II and III, respectively. The ASP (cmH₂O) was significantly higher in group II (29.15 ± 1.39) and III (28.9 ± 1.17) than in group I (18.35 ± 0.88). The complications encountered were gastric inflation in group I (10%), gagging in all groups (10% in each of group I and II, and 15% in group-III), and in group III, soft tissue injury (5%) and airway obstruction (5%).

Conclusion: In anesthetized, spontaneously breathing patients the cLMA is easier and quicker to insert but the PLMA provides a more effective ASP. PLMA insertion using the IT is easier than the finger insertion technique, and causes fewer complications.

Key words: Airways, laryngeal mask, PLMA, insertion.

Introduction:

Airway management is an essential skill in the practice of anesthesiology, intensive care and emergency medicine. This practice has come a long way since the development of the classic laryngeal mask airway (cLMA) in 1988, and becomes more advanced in recent years. This advancement is demonstrated by the introduction of a wide variety of new airway devices including the ProSeal laryngeal mask airways (PLMA). New airway devices have been described at a rate of one per year for the last twenty years, increasing to two per year since the turn of the century.¹⁻³

The PLMA was introduced in 2000,⁴ but it is relatively new in our department, as we received it only in the last year. It resembles the cLMA with a modified cuff, and a drainage tube (DT), and can be inserted by either digital manipulation (like the cLMA) or with the supplied introducer tool (IT).^{4,5}

Modifications were designed to enable separation of the gastrointestinal and respiratory tracts and improve the airway seal. The DT enables diagnosis of mask malposition and also aims to reduce risks of gastric inflation, regurgitation and aspiration of gastric contents.^{3,4}

The better airway seal pressure provided by PLMA offers an airway that bridges some of the gap between the cLMA and the endotracheal tube, especially in the cannot intubate, cannot ventilate scenario in which the patient is at risk of aspiration.⁶⁻⁸ It also suggests a role as an alternative to the cLMA for positive pressure ventilation.^{6,9,10}

The aim of present study was to compare the PLMA with the cLMA in anesthetized non-paralyzed adult patients with respect to insertion success rate, insertion time, airway seal pressure

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and incidence of related complications. For the PLMA, we also aimed to compare the insertion characteristics with and without using the IT.

Patients And Methods:

This study was carried out on 60 adult patients of both sexes scheduled for elective minor surgical procedures under general anesthesia in supine position. Only patients with physical status of ASA-I or ASA-II were included in the study. An informed consent was taken from every patient representing his approval of the study.

Patients were randomly categorized into three groups, each group included 20 patients. The first group was assigned to have the cLMA (group-I), in the second group PLMA was inserted using the supplied IT (group-II), and in the third group PLMA was inserted digitally using the index-finger insertion method (group III).

Preoperative airway assessment (Mallampatti class, inter-incisor gap and thyromental distance) was employed in all patients to exclude difficult airways. Other exclusion criteria were patient's weight <50 kg or >90 kg, upper respiratory tract symptoms in the previous 10 days, cervical spine disease, surgery to be performed to the head-neck or thoraco-abdominal cavities or in the lateral-prone positions, or if the patient was considered at risk of aspiration (nonfasted, gastroesophageal reflux disease).

Monitoring included continuous electrocardiogram, heart rate, peripheral oxygen saturation (SpO₂), noninvasive blood pressure, respiratory rate, expiratory tidal volume, and airway pressure. All patients were premedicated with intravenous midazolam (0.02-0.03 mg/kg) within an hour before surgery. Anesthesia was induced with 1µg/kg fentanyl and 2-3 mg/kg propofol intravenously. Face mask ventilation was continued until conditions were suitable for the insertion of the laryngeal mask (loss of eyelash reflex, jaw relaxation, absence of movement, and apnea). Additional intravenous boluses of propofol (30-50 mg) were given as required until an adequate depth of anesthesia was achieved for placement.

A size 4 of both devices (PLMA: Laryngeal Mask Company, Henley-on-Thames, UK; cLMA: Morningside, pharmaceuticals LTD, UK) was used in all patients. All insertions of laryngeal masks were conducted by one investigator (El-Obidi OA), and according to the supplied instruction manuals.^{4,5} A clear water-based gel without local anesthetic was used to lubricate the laryngeal mask

before use. After insertion, the laryngeal mask was connected to a circle breathing system, and the cuff was inflated with air until an effective airway was established or the maximum recommended inflation volume reached (40 ml). An effective airway was judged by adequate chest movement with no audible leak during gentle manual ventilation. Both devices were fixed by taping the tube over the chin. The number of insertion attempts was recorded. A failed attempt was defined as removal of the device from the mouth. Three attempts were allowed before device use was considered a failure. The duration (in seconds) of successful attempt (time between mouth opening to confirmation of correct placement) was recorded. If the airway device failed during or after the placement, the anesthesiologist was free to manage the airway as clinically indicated.

Once an effective airway was obtained, the airway sealing pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 l/min, noting the airway pressure (maximum allowed 40 cmH₂O) at which equilibrium was reached.^{5,9} The location of airway gas leak was determined at the mouth (audible), stomach (epigastric auscultation), or DT with the PLMA (bubbling of the lubricant placed in the proximal orifice of the DT).^{5,9} Patients underwent manual ventilation until spontaneous breathing resumed. Anesthesia was maintained by 70% of nitrous oxide in oxygen, with halothane (1.5–2%).

During recovery, patients were given 100% O₂, and the airway device was removed when the patient was awake. All potential complications, such as failed use, hypoxia (SpO₂<90%), coughing, gagging, aspiration-regurgitation, bronchospasm, airway obstruction, gastric inflation, soft tissue injury, etc, were fully documented.

Values are presented as mean ± standard deviation (SD). One way ANOVA test was used for normally distributed variables. The Dunnett multiple comparison post-hoc test was used to determine the significance of differences in means. Kruskal-Wallis ANOVA was used for non-normally distributed data. $P<0.05$ was considered statistically significant.

Results:

The demographic and surgical data were comparable between the three studied groups, (table-1).

Results of preoperative airway assessment (Mallampatti class, inter-incisor gap and thyromental distance) revealed no significant inter-group differences (table-2).

The first attempt success rate in group I and II was higher (100%) than in group III (95%). The PLMA was inserted at the second attempt in one patient

(5%) in group III because of initial difficulty in sliding the cuff into the pharynx.

Table-1: Demographic characteristics and surgical data of three studied groups.

	Group-I	Group -II	Group -III	P value
Age (years):	36.2 ± 11.71	29.1 ± 10.73	31.7 ± 10.48	0.127
Sex: Male/ Female	10/10	12/8	11/9	--
Weight (kg):	77.5 ± 6.52	75.3 ± 6.24	78.55 ± 5.74	0.245
Height (cm):	169.7 ± 5.18	166.7 ± 4.86	169.0 ± 5.1	0.164
Body mass index (kg/m²):	22.55 ± 1.75	22.46 ± 1.41	21.41 ± 0.31	0.153
Type of surgery: General/orthopedic/plastic	7/9/4	6/11/3	8/8/4	--
Duration of surgery (min):	27 ± 7.52	30 ± 9.04	25.55 ± 10.47	0.314

Values are expressed as total numbers or mean ± SD.

Table-2: Airway assessment and the technical data in the three studied groups.

	Group-I	Group -II	Group -III	P value
Inter incisor gap: (cm)	4.63 ± 0.121	4.6 ± 0.132	4.6 ± 0.226	0.759
Thyromental distance: (cm)	6.61 ± 0.131	6.64 ± 0.150	6.63 ± 0.171	0.879
Mallampatti class: I/II	12/8	14/6	15/5	--
Insertion time: (sec)	8.7 ± 0.92	13.35 ± 1.66	16.95 ± 1.39	<0.0001
Sealing pressure: (cmH₂O)	18.35 ± 0.88	29.15 ± 1.39	28.9 ± 1.17	<0.0001

Values are expressed as total numbers or mean ± SD.

Insertion time (mean ± SD) differed significantly ($P < 0.0001$) between the groups, and it was 8.7 ± (0.92), 13.35 ± (1.66), and 16.95 ± (1.39) seconds in group I, II, and III, respectively (table-2).

The sealing pressure (mean ± SD) was significantly higher in group II (29.15 ± 1.39) and III (28.9 ± 1.17) than in group I (18.35 ± 0.88), table-2.

Additional doses of propofol (30-50 mg) were given to 2, 4 and 5 patients in group I, II and III respectively, and the differences were statistically insignificant ($P = 0.421$).

The complications encountered in group-I were 10% gagging (two patients) and 10% gastric inflation (two patients), in group-II there was 10% gagging (two patients), and in group-III there were 15% gagging (three patients), 5% soft tissue injury (one patient), and 5% partial airway obstruction (one patient); this patient developed persistent stridor during surgery, and the PLMA was removed and successfully re-inserted digitally again.

SpO₂ during the studied intervals was always >95%, except for one patient in group III who developed intraoperative airway obstruction (SpO₂ decreased to 91%), but there were neither intra- nor inter-group statistically significant differences.

Discussion:

This study demonstrated that the insertion of cLMA was quicker and easier than the PLMA,

while PLMA provided higher sealing pressure regardless to the used insertion technique. This confirms data from many previous studies.^{4,11-14} The insertion time and the success rate for the application of a laryngeal mask depend on the operator's familiarity with the device; most comparisons of cLMA with PLMA involved operators with greater experience with cLMA than PLMA.¹¹⁻¹⁴ It has been suggested that the PLMA requires 20 to 30 insertions before achieving competence.¹⁵ All insertions in our study were performed by one registrar investigator experienced in cLMA insertion, but he was supervised to carry out only five PLMA insertions in patients before commencing this study.

The insertion time (seconds) for the cLMA in our study was significantly shorter (8.7) than in group II (13.35), and almost doubled (16.95) when using the digital insertion technique in group III. The first attempt success rate was 100% in group-I and II, and 95% in group-III. Thus, although the investigator had a limited experience with the PLMA, but the first attempt success rate was similar to cLMA. This might indicate that the regular users of cLMA can easily insert PLMA especially when the IT is used.

In a study analyzing 1000 consecutive PLMA uses by one anesthetist in paralyzed and non- paralyzed

patients, the reported overall insertion success rate was 99.4% (first and second attempt success 85% and 12%, respectively), with a median insertion time (with IT) of 12 seconds.¹⁶

The increased difficulty with PLMA insertion probably reflects the larger cuff (leaves less room for the index finger, thereby impeding digital intra-oral positioning and propulsion into the pharynx), the lack of a backplate (making the cuff more likely to fold over at the back of the mouth), and the need for precise tip positioning (to prevent air leaks up the DT). Insertion is easier with the IT because it occupies less space than the finger, directs the cuff around the oropharyngeal inlet, and facilitates full depth of insertion.^{3,5}

Size 4 laryngeal mask devices are recommended for the average sized adults.^{3-5,9,17} In all groups, the mean body mass index of our patients was within the average (table-1). We used size 4 devices in all patients because size 5 PLMA was unavailable. This might be another explanation for the high rate of successful PLMA insertion in our patients by a user with less familiarity with the device, as the smaller sizes of PLMA have smaller cuffs which would be inserted easier in the same patient than size 5.^{3,5,17}

In two randomized crossover trials^{4,13} compared only size 4 of both devices (PLMA versus cLMA) in anaesthetized, paralyzed, adult patients, the cLMA was found to be easier and quicker to insert at the first attempt than the PLMA. In one of these studies,¹³ the over all success rates after three attempts for insertion of the PLMA were high (98%) and similar to the cLMA (100%).

A meta-analysis of previous studies showed that the first attempt insertion success rate in 1436 patients was ranged from 89 to 100% with success of 662/713 (93%), and 81 to 100% with summed success of 616/723 (85%) in cLMA and PLMA groups respectively. Success increased when three attempts are allowed, and the overall success rate was 713/713 (100%) and 718/723 (99.3%) in cLMA and PLMA groups respectively.³

Some investigators¹³ found the insertion of PLMA using the IT to be easier, while others¹² preferred the introducer technique, but they concluded that no apparent difference in ease of insertion or success rate to the finger insertion method. Kihara et al¹⁷ compared PLMA digital insertion technique with cLMA, and revealed similar insertion time and success rates with both devices after intensive training by lectures and manikin.

Many previous studies¹¹⁻¹³ reported longer PLMA insertion time than the cLMA. However, some investigators¹⁷ reported equivalent time. The difference was only a few seconds (of negligible clinical importance) in all studies reporting a difference.

The airway sealing pressure in the present study was significantly higher with PLMA groups (about 29 cmH₂O) than with cLMA (about 18 cmH₂O). This supports many previous studies.^{4,10-14,18} Results were similar in paralyzed^{9,13,14,18} and non-paralyzed patients,^{11,12} and the median PLMA and cLMA seal pressures were approximately 30 cmH₂O and 20 cmH₂O respectively. Only few studies have reported a range of PLMA seal pressure exceeding 40 cmH₂O.^{10,12}

The PLMA forms a better seal than the cLMA, probably because the larger and softer ventral cuff plugs the gaps in the proximal pharynx. Also, the dorsal cuff makes the mask shape almost conical, pushing it towards the periglottic tissues and enabling adaptation to the contours of the hypopharynx.^{3,4,9}

The main complications encountered in our patients were gagging and gastric distension (in cLMA group), and gagging, soft tissue injury and partial airway obstruction (in PLMA groups).

Gastric inflation was detected in two patients (10%) in the cLMA (group I), but not with the PLMA groups. The design and performance features of the PLMA are expected to reduce gastric inflation, regurgitation and pulmonary aspiration compared to the cLMA.^{3,4,9} However, moving the patient during surgery may displace the mask after its insertion and fixation, resulting in less glottic sealing.⁽¹⁹⁾ Also, the larger PLMA tip may mechanically open the upper esophageal sphincter leading to regurgitation.^{11,13,14}

The incidence of airway obstruction in the present study was 5% (one case) in the PLMA group-III. Some previous studies quantified the frequency of PLMA-associated airway obstruction and reported an incidence of 0.3%¹³ and 2.7%.¹⁶ The PLMA may cause airway obstruction (and thus, gastric distension) by three mechanisms; the PLMA tip and DT enter the glottis; the sides of the PLMA bowl fold inwards with partial or complete glottic occlusion by the device cuff, and the PLMA tip behind the larynx compresses the posterior larynx causing arytenoid malfunction or rotation and shortening of the vocal cords, resulting in paradoxical cord movement during spontaneous

ventilation and mechanical closure during positive pressure ventilation.⁶

In the current study the incidence of mucosal injury (recognized by blood on the PLMA after removal) was 5% in group-III. Previous studies had reported 3 to 28% incidence of mucosal injury, and it was explained by the pressure exerted on the pharyngeal mucosa by the PLMA.^{11-13,16,18}

Other potential complications reported in the literature namely regurgitation, aspiration

esophageal laceration or perforation, and pneumomediastinum were not encountered in the present study.³

Conclusion:

In anesthetized, spontaneously breathing patients the cLMA is easier and quicker to insert but the PLMA provides a more effective airway sealing pressure. PLMA insertion using the IT is easier than the finger insertion technique, and causes fewer complications.

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