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Research Article

A randomized study to compare ProSeal laryngeal mask airway with classic laryngeal mask airway in anesthetized patients

Susheela Taxak, Kiranpreet Kaur *, Shubham Kaushik, Rita Singh [1]

Department of Anaesthesiology and Critical Care, Pt. B.D. SHARMA PGIMS, Rohtak 124 001, Haryana, India

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KEYWORDS

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Abstract *Background:* To overcome the problem of gastric content regurgitation, a device with drain tube and better airway sealing has been made: the ProSeal laryngeal mask airway (PLMA). We aimed to compare the clinical performance of the classic LMA with the PLMA. Several studies comparing these two devices have been done.

Our study was designed to compare ease of insertion, airway sealing pressure, and fiber-optic assessment of positioning in adult patients, and we hopes to prove that PLMA is better to LMA in all these aspects. We hypothesized that PLMA would have a better leak pressure than the CLMA and minimum difference in leak pressure of 20% between them was considered clinically significant.

Material and methods: One hundred adult patients of either sex between age group of 18–65 years scheduled for elective surgery were included in the study. Patients were randomly allocated to two groups of 50 patients each. In group I CLMA and in group II PLMA were used. The number of attempts, ease of insertion, time of insertion, and failure if occurred were noted down. Hemodynamic changes, airway sealing pressure, and the fiber-optic were also recorded.

Results: Data thus compiled showed that insertion was successful in first attempt in 94% cases with LMA as well as PLMA. The time taken for successful placement of LMA and - PLMA was 15 and 17 s, respectively. Sealing pressure was higher for group II at all cuff volumes. More number of

* Corresponding author. Address: 52/9J, Medical Enclave, PGIMS, Rohtak 124 001, Haryana, India. Tel.: +91 1262 213171; fax: +91 1262 211301.
E-mail address: kiranpreet72@rediffmail.com (K. Kaur).
[1] Command hospital, western command.

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patients (89%) in group II had a fiber optic score of I and II as compared to group I which had 81% patients with score I and II.

Conclusion: We conclude that PLMA is easy to insert with a short insertion time, high success of placement at first attempt, and capable of achieving a more effective seal than LMA.

1. Introduction

Difficult tracheal intubation and inability to maintain a patent airway remains an important cause of anesthetic morbidity and mortality. The immediately life threatening "cannot intubate, cannot ventilate" situation occurs in approximately 1:10,000 anesthetics [1]. The introduction of laryngeal mask airway (LMA) by Archie I.J. Brain at London Hospital, Whitechapel, London, in 1981 changed the scenario from "unable to intubate and ventilate" to "unable to intubate but able to ventilate" [2].

The classic laryngeal mask airway may not be an ideal airway device always because the low pressure seal may be inadequate for positive pressure ventilation and it does not protect lungs from gastric contents regurgitated into the pharynx [3]. ProSeal laryngeal mask airway (PLMA; Laryngeal Mask Company, Henley-on-Thames, UK) has been developed with a modified cuff to improve the seal and a drainage tube to provide a channel for regurgitated fluid and gastric tube placement [4,5].

So, after knowing about the usefulness of laryngeal mask airways due to their ease of insertion, early achievement of effective airway, better sealing of airways, airway protection, less disturbance to autonomic nervous system and intraocular pressure (IOP), we performed a randomized study which compared, the classic laryngeal mask airway and the ProSeal laryngeal mask airway in anesthetized paralyzed patients with respect to ease of insertion, airway sealing pressure, and fiber-optic assessment of positioning.

2. Materials and methods

Power analysis was also done for the exact difference found in the mean airway sealing pressure between the two groups at different cuff volumes for a type I error of 0.01, and it was found that the power of test is very high (more than 80% is very good).

The study was approved by hospital ethical committee, and informed consent from all the participants was obtained. One hundred patients of either sex having physical status of American Society of Anesthesiologists grade I and II scheduled for elective orthopedic and general surgery under general anesthesia were enrolled in the study. The patients with age <18 years, known difficult airway, cervical spine disease, body weight >30 kg, mouth opening <2.0 cm, history of upper gastro-intestinal surgery, hiatus hernia, gastroesophageal reflux disease, and full stomach were excluded from the study.

In this randomized trial, all the patients were examined during the preoperative visit. The patients were kept fasting for 6 h prior to scheduled time for surgery. They were premedicated with tablet alprazolam (0.01 mg kg−1) orally at bed time. Patients were randomly allocated to two groups – group I where standard laryngeal mask airway was used and group II where ProSeal laryngeal mask airway was used, each comprising of 50 patients.

Induction was performed with injection midazolam 0.05 mg kg^{-1} and injection propofol 2.5 mg kg^{-1} followed by injection vecuronium 0.1 mg kg^{-1} intravenous for neuromuscular blockade. Then after ventilating with 50% nitrous oxide in oxygen for 3 min via face mask using Bain's circuit, either of the devices was used by drawing a slip. Anesthesia was maintained with 50% nitrous oxide in oxygen and sevoflurane. The insertion technique for both devices was identical to the recommended technique for laryngeal mask airway and included neck flexion, head extension, full deflation of cuff, and a midline approach. In all patients, a size 3 (in females) and 4 (in males) ProSeal laryngeal mask airway/laryngeal mask airway was used. The cuff was inflated with air until an effective airway was obtained. Both devices were fixed by taping the tube over the chin [2].

The attempt of insertion was recorded. An easy insertion was defined as insertion without resistance in a single attempt. A difficult insertion was the one where more than one attempts were required to seat the device. In case it was not possible to insert the device in three attempts, it was labeled as failure. The time between picking up the LMA/PLMA (T1) and obtaining an effective airway (T2) was recorded. An effective airway was defined as normal thoraco-abdominal movements with manual squeeze of reservoir bag and a square wave capnograph trace. Measurements were made with the head/neck in the neutral position and the occiput on a firm pillow 7 cm in height [2].

Airway sealing was determined by closing the expiratory valve of the breathing system at a fixed gas flow of 3 L/min, ventilatory support off and noting the airway pressure (maximum allowed, 40 cm H_2O) at which equilibrium was reached, i.e., the pressure gauge reached stability [2]. The test used to detect airway leak was auscultation test. Auscultation test involved detection of an audible noise using a stethoscope placed just lateral to the thyroid cartilage [6].

The baseline recordings were made for HR, SBP, DBP, and SpO_2. The changes in HR, SBP, and DBP were noted after induction, at 1 min, 2 min, and 5 min postdevice insertion.

Study for fiber-optic position: The fiber-optic position of the airway tube (laryngeal mask airway/ProSeal laryngeal mask airway) was determined by passing the fiber-optic scope to a position just proximal to the mask aperture, and the view was scored as per the classification given by Mizushima et al. [7] and is as follows:

(i) glottis only seen
(ii) epiglottis and glottis seen
(iii) epiglottis impinging on the aperture, glottis seen
(iv) epiglottis downfolded, glottis not seen

Trauma to tongue, teeth, gums, and lips was checked. After removal, the airway was checked for blood stained secretions. In the post-operative period, patients were asked for sore

throat, dysphagia, or hoarseness of voice if any. The distribution of data was determined by Kolmogorov–Smirnov analysis, and it was found that the data were normally distributed for almost all the characteristics and wherever normal distribution was not found, appropriate non-parametric tests (like Mann–Whitney *U* test, Friedman's analysis) were applied. Statistical analysis was done with student's *t* test. Percent relative changes were also determined and compared between the groups. To detect changes occurring over a period of time in hemodynamic characteristics and SpO_2 or in ASP at different cuff volumes multivariate analysis, Wilk's lambda test and Friedman's test were used. And to determine the frequency distribution of outcome (success/failure), Fisher's Exact test was applied.

3. Results

The age, weight, and height of patients were noted, and BMI was calculated for all the patients. In our study, the demographic data with respect to age, weight, height, and BMI were comparable in both the groups (Table 1).

Placement of both devices did not produce any significant hemodynamic response in our study (Table 2). Mean percent relative changes in SpO_2 were also found to be comparable between the two groups at all the times. It means that the saturation characteristics of both the groups were changing similarly.

Number of attempts required for the insertion of LMA and PLMA was recorded for each patient (Table 3). First attempt success rate (94%) was similar in both the groups. The median time interval calculated for both the groups was almost similar, LMA: 15 s and PLMA:17 s (Table 3). Success and failure for the two groups were noted separately and analyzed statistically. When we compared all the three characteristics for ease of insertion, i.e., the number of attempts, time of insertion and outcome between the two groups, it was found that there was no statistical difference and the two groups were comparable.

Airway sealing pressure was noted down at volumes 0 ml, 10 ml, 20 ml, 30 ml, and 40 ml by auscultation method (Table 3). It can be seen from the above analysis that *p* value was highly significant for cuff volumes 10 ml and 20 ml, *p* value was very highly significant for cuff volumes 0 ml, 30 ml and 40 ml, and the mean values of ASP were approximately 4–6 cm H_2O higher for the PLMA, when the two groups were compared as a whole.

3.1. Fiber-optic scoring

After recording the data for sealing pressure, fiber-optic scoring, regarding the position of the device, was done by passing fiber-optic scope through the airway tube. Fiber-optic scoring (*n*:1/2/3/4) for the LMA ($n = 48$) was 14/25/8/1 and for the PLMA ($n = 47$) was 15/27/5/0.

81% in LMA and 89% in PLMA group had a good fiber-optic scoring (Grade 1 and 2). One patient (2%) in group I and none (0%) in group II had fiber-optic score of 4. More number of patients (89%) in group II had a fiber-optic score of I and II as compared to group I (81%) though it was not statistically different.

No evidence of trauma to tongue, teeth, gums, and lips was present. No patient gave history of sore throat, dysphagia, or hoarseness of voice in the post-operative period.

4. Discussion

The PLMA is a new entrant to the family of LMA with some added features over the classic LMA. Our study was designed to compare the ease of insertion, hemodynamic changes, airway sealing pressure, and fiber-optic assessment of positioning and postoperative complications of CLMA and PLMA in adult patients. The main findings in this study suggest that the PLMA is associated with a more effective airway seal than the cLMA in anesthetized paralyzed adult patients.

Placement of both devices did not produce any significant hemodynamic response in our study. Hickey et al. studied

Table 1 Showing demographic profile.

Demographic profile		
	Group I	Group II
Mean age (years)	31.60 ± 12.10	32.78 ± 13.19
Mean weight (kg)	57.88 ± 9.43	60.14 ± 8.71
Mean height (cm)	165.56 ± 8.21	168.52 ± 8.70
Mean BMI (kg/m2)	21.099 ± 2.464	21.234 ± 2.567

Table 2 Representing Hemodynamic changes at different intervals.

Hemodynamic changes				
Group	Time interval	H R	SBP	DBP
I	Base line	80.20 ± 13.26	124.94 ± 16.20	78.70 ± 10.21
	After induction	79.90 ± 16.39	110.84 ± 16.84	70.32 ± 14.00
	After 1 Min	82.98 ± 14.99	120.46 ± 21.02	80.56 ± 10.85
	2 Min	78.44 ± 15.79	117.06 ± 16.56	74.44 ± 12.79
	5 Min	75.98 ± 12.71	115.48 ± 15.91	73.38 ± 12.47
II	Base line	80.34 ± 13.6	125.40 ± 14.31	76.14 ± 08.69
	After induction	81.30 ± 17.33	114.12 ± 15.13	70.06 ± 11.17
	After 1 Min	86.71 ± 17.89	121.53 ± 17.80	75.58 ± 10.96
	2 Min	80.51 ± 17.97	114.84 ± 12.49	71.27 ± 08.21
	5 Min	78.69 ± 19.56	114.27 ± 14.07	70.02 ± 09.47

p-value between groups > 0.05.
p-value mean percent relative change > 0.05.

Table 3 Showing attempts, Time of insertion and airway seal pressure.

		Group I	Group II	*P* value
Number of attempts	One	47	47	
	Two	1	0	
	Failed	2	3	
Time of insertion (seconds)	Whole groups	15.54 ± 4.43 (n = 48)	16.93 ± 4.21 (n = 47)	0.124
	#3 LMA/PLMA	15.68 ± 3.68 (n = 22)	16.00 ± 4.08 (n = 10)	0.828
	#4 LMA/PLMA	15.42 ± 5.05 (n = 26)	17.20 ± 4.26 (n = 37)	0.142
Airway sealing pressure (cm H_2O)	0 ml	12.42 ± 4.50	16.31 ± 4.08	0.000
	10 ml	19.19 ± 4.62	21.82 ± 4.37	0.006
	20 ml	23.27 ± 5.25	27.09 ± 5.41	0.001
	30 ml	24.23 ± 4.56	28.76 ± 6.11	0.000
	40 ml	23.79 ± 5.56	29.02 ± 6.82	0.000

the cardiovascular effects related to insertion of laryngeal mask airway and Guedel's airway in 100 patients [8]. They found no significant difference in blood pressure recorded at different time interval. Casati et al. [9] documented a large decrease in all the parameters. Evans et al. [10] studied PLMA in 300 anesthetized adult patients and found insignificant hemodynamic response to insertion of PLMA. Akhtar et al. [11] studied 30 patients who underwent intra ocular ophthalmic surgery, and the changes in MAP and HR on induction of anesthesia to insertion of the endotracheal tube or the laryngeal mask airway were not statistically significant.

Insertion was successful in first attempt in 94% (47/50) of cases in group I as well as in group II in our group of patients. First attempt success rate was higher for the LMA (90% vs 81%) than the PLMA ($p < 0.05$) in study of Cook et al. [12] who compared LMA and PLMA in 180 anesthetized non-paralyzed patients. In study conducted by Brimacombe et al. [13], first attempt insertion success rates were higher for the LMA (91% vs 82%; $p = 0.015$), but after 3 attempts, success rates were similar (LMA, 100%; PLMA 98%). Brimacombe and Keller [3] in another study on 60 paralyzed anesthetized adult patients, compared size 4 LMA and PLMA. The first attempt success rates were higher for the LMA [60 of 60 (100%) vs 52 of 60 (86.66%); $p = 0.003$]. Lesser success for PLMA insertion by Brimacombe et al. [13] and Cook et al. [12] was possible because of the fact that they have used larger size airways (4/5) and have used finger insertion technique for the airway device placement and have stated that the repeat attempts were required because of difficulty in sliding the cuff into the pharynx. Insertion is easier with the introducer because it occupies less space than the finger and directs the cuff around the oropharyngeal inlet and facilitates full depth of insertion. The first time success rates were 100% for both LMA and PLMA in another study of Brimacombe et al. [14] in 30 consecutive female patients undergoing intraabdominal gynaecological surgery. Braun et al. [15] found equivalence in duration and ease of insertion between the LMA and PLMA. Study conducted by Coulson et al. [16] and Gaitini et al. [17] showed that PLMA can be placed with same ease of insertion as that of standard LMA.

The median time required for LMA was 15 s and 17 s for PLMA insertion in our study. Cook et al. [12] showed that time required for insertion was longer with the ProSeal (15 s) than LMA (10 s) with a statistically significance ($p < 0.0001$). The median time required for PLMA insertion with the introducer was 3 s less than PLMA without introducer (15 vs 18 s). This difference in time of insertion between LMA and PLMA has been attributed to the larger and bulkier PLMA device which required more mouth opening for insertion. In our study, the time of insertion for the two groups was comparable possibly because of the use of smaller size of airway device (size 3/4). Brimacombe et al. [13] found that less time was required to achieve an effective airway with the LMA as compared to PLMA (31 ± 30 vs 41 ± 49 s; $p = 0.02$). Similar results were recorded in another study of Brimacombe and Keller [3] (9 ± 3 vs 15 ± 13; LMA vs PLMA (size 4); $p < 0.0001$). Time of insertion for PLMA placement was also higher in study of Gaitini et al. [17] as compared to ours. Failure rate of 4% was found (2/50) in group I and 6% (3/50) in group II in our study, ($p = 1.00$). Brimacombe et al. [13] documented (2%) failure rate in PLMA group and no failure was reported in LMA group. PLMA insertion failed in 2 patients (1%) where as none in the LMA group in study of Cook et al. [12]. Brimacombe and Keller [3] recorded unsuccessful PLMA insertion in one patient (1.7%) out of the 60, and no failure was seen with the LMA.

5. Airway sealing pressure

In study of Brimacombe and Keller [18], mucosal and airway sealing pressures were recorded during inflation of cuff from 0 to 40 ml in 10 ml increments. It was found that ASP increased significantly with increasing intracuff volume from 0 to 10 ml ($p < 0.0001$) and 10–20 ml ($p = 0.0001$), was unchanged from 20 to 30 ml, and decreased from 30 to 40 ml ($p = 0.005$).

In our study in LMA group, there was a significant change in sealing pressure from 0–10 ml ($p < 0.001$) and from 10–20 ml ($p < 0.001$). Sealing pressure also increased from 20 to 30 ml, but the increase is not significant and then decreased from 30 to 40 ml but this decrease was also not significant. These trends are similar for both the LMA and the PLMA groups in our study. In our study, the sealing pressures were higher for the PLMA (28.76 ± 6.11 vs 24.24 ± 4.56; $p < 0.001$) than the LMA.

Cook et al. [12] found that the sealing pressure was higher for the ProSeal and the difference between the median seal pressure was 12 cm H_2O (95% confidence interval 11–13). 87% patients had sealing pressures > 20 cm H_2O with PLMA and 41% with LMA. Brimacombe et al. [13] also found that

the PLMA formed a more effective seal (27 ± 7 vs 22 ± 6 cm H_2O) than the LMA [10]. In another study of Brimacombe and Keller [3], airway sealing pressure was 8–11 cm H_2O higher for the PLMA (at all cuff volumes; $p < 0.00001$). For the LMA, ASP increased significantly from 0 to 10 ml ($p < 0.00001$) and 10 to 20 ml ($p < 0.0001$) but remained unchanged from 20 to 30 ml and 30 to 40 ml cuff volumes. For the PLMA, sealing pressure increased significantly from 0 to 10 ml ($p < 0.00001$), 10–20 ml ($p < 0.00001$), and 20 to 30 ml ($p = 0.03$) but remained unchanged from 30–40 ml cuff volume. Airway sealing pressure over the inflation range was higher for the PLMA (27 ± 10 vs 23 ± 10 cm H_2O; $p = 0.005$) than LMA group. Keller and Brimacombe [19] also found oropharyngeal leak pressure (OLP) higher for the PLMA at all cuff volumes. Brimacombe et al. [14] found that OLP was higher for the PLMA at 15 ml (29 ± 7 vs 20 ± 3 cm H2O) and 30 ml (36 ± 6 vs 21 ± 3 cm H_2O) cuff volumes (all $p < 0.0001$). Braun et al. [15] recorded the mean value for the seal pressure for the PLMA as 29 ± 0.21 mbar and 20.9 ± 0.21 mbar for the LMA [4].

Results of our study are similar to those of the previous studies with regards to the sealing pressures. In our study also, higher sealing pressures were produced by the ProSeal laryngeal mask airway at all cuff volumes as compared to the standard LMA. The lungs of most healthy patients can be ventilated if the seal pressure exceeds 20 cm H_2O [19]. The PLMA forms better seal than the LMA because the larger ventral cuff plugs gaps in the proximal pharynx, and the dorsal cuff pushes the ventral cuff more firmly into the periglottic tissues [3]. Hence, ProSeal laryngeal mask airway is a more reliable airway device than the standard LMA for positive pressure ventilation.

6. Fiber-optic scoring

Cook et al. [12] studied the laryngeal view with the fiber-optic scope, and they found that 87% of the patients in PLMA group had grade 1 (clear view of vocal cords) and grade 2 (only arytenoids visible) and 90% of the patients in LMA group had grade 1 and 2 laryngeal view, i.e., the laryngeal view was better with the LMA but it was not statistically significant. In their study, grade 4 view (no laryngeal structures visible) was seen in 4 patients (2%) in PLMA group and 3 patients (2%) in LMA group.

Keller and Brimacombe [19] found that the fiber-optic position (n:4/3/2/1) was better for the LMA (LMA: 11/2/2/1; PLMA: 5/7/3/2). Braun et al. [15] found statistical equivalence between the endoscopic position of larynx between the PLMA and the LMA group.

In our study, both the groups have shown a better fiber-optic score (grade 1 and 2 of our study) with no significant statistical difference, but we found that PLMA had a slightly better endoscopic view (89% vs 81%) which failed to reach statistical significance.

Brimacombe et al. [13] compared fiber-optic view through the airway tube and found that 94 patients (50%) in the PLMA group had grade 4 and 3 view and 143 patients (75%) in the LMA group had grades 4 and 3 view. According to the classification used, only vocal cords visible was grade 4; vocal cords plus posterior epiglottis visible was grade 3; vocal cords plus anterior epiglottis visible was grade 2; vocal cords not seen was grade 1. Hence, grade 4 means the best anatomic position, and Grade 1 the worst. In their study, 20 patients (11%) in the PLMA group and 12 patients (6%) in the LMA group had grade 1. So, the grading was better for the LMA and it was very highly significantly. The explanation for worse fiber-optic position with PLMA given in these studies was that it could be related to the larger cuff catching the epiglottis during insertion and epiglottic downfolding. We conclude that ProSeal laryngeal mask airway is easy to insert with a short insertion time, high success of placement at first attempt, and no significant hemodynamic responses which is comparable to standard LMA. The PLMA is capable of achieving a more effective seal than the LMA and thus is a reliable airway device for positive pressure ventilation in anesthetized patients.

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