Original Article

ProSeal Laryngeal Mask Airway as an Alternative to Standard Endotracheal Tube in Securing Upper Airway in the Patients Undergoing Beating-heart Coronary Artery Bypass Grafting

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Abstract

Background: ProSeal laryngeal mask airways (PLMAs) are routinely used after failed tracheal intubation as airway rescue, facilitating tracheal intubation by acting as a conduit and to secure airway during emergencies. In long duration surgeries, use of endotracheal tube (ETT) is associated with various hemodynamic complications, which are minimally affected during PLMA use. However, except for few studies, there are no significant data available that promote the use of laryngeal mask during cardiac surgery. This prospective study was conducted with the objective of demonstrating the advantages of PLMA over ETT in the patients undergoing beating-heart coronary artery bypass graft (CABG). **Methodology:** This prospective, interventional study was carried out in 200 patients who underwent beating-heart CABG. Patients were randomized in equal numbers to either ETT group or PLMA group, and various hemodynamic and respiratory parameters were observed at different time points. **Results:** Patients in PLMA group had mean systolic blood pressure 126.10 ± 5.31 mmHg compared to the patients of ETT group 143.75 ± 6.02 mmHg. Pulse rate in the PLMA group was less (74.52 ± 10.79 per min) ($P < 0.05$) compared to ETT group (81.72 ± 9.8). Thus, hemodynamic changes were significantly lower ($P < 0.05$) in PLMA than in ETT group. Respiratory parameters such as oxygen saturation, pressure CO_2 (pCO_2), peak airway pressure, and lung compliance were similar to ETT group at all evaluation times. The incidence of adverse events was also lower in PLMA group. **Conclusion:** In experience hand, PLMA offers advantages over the ETT in airway management in the patients undergoing beating-heart CABG.

Keywords: *Coronary artery bypass graft, endotracheal tube, ProSeal laryngeal mask airways*

Introduction

Dr. A.I.J Brain designed the first laryngeal mask airway, which was called LMA classic, in 1981 at the Royal London Hospital.[1] This invention changed the scenario from "cannot intubate, cannot ventilate" to "cannot intubate, can ventilate." ProSeal laryngeal mask airway (PLMA) is one of the second-generation supraglottic airway devices (SADs) with a larger, wedge-shaped cuff and incorporates a drain tube to separate the respiratory and gastrointestinal tracts and thus, minimizes the risk of aspiration.[2] It also creates a higher oropharyngeal leak pressure when compared with the first-generation SADs. SADs are routinely used these days during anesthesia, after failed tracheal intubation as airway rescue, facilitating tracheal intubation by acting as a conduit and to secure airway during emergencies. They have an advantage over endotracheal tube (ETT) intubation in patients with difficult airways and also enable ventilation in patients with difficult facemask ventilation. Thus, in situations where facemask ventilation and laryngoscope-guided tracheal intubation have failed, the LMA has a high likelihood of succeeding.[2] Being noninvasive when compared to endotracheal intubation, it causes minimal disturbances in the cardiovascular and respiratory systems. Another advantage is that the LMA can be used both as a ventilatory device and for intubation of the airway. Also that, tracheal intubation through the LMA can take place in an unhurried fashion while the patient is being oxygenated and his / her lungs ventilated. In addition, insertion of the LMA is atraumatic and does not reduce the chances of other techniques subsequently succeeding.[3-5] LMA could be inserted

How to cite this article: Shah K. ProSeal laryngeal mask airway as an alternative to standard endotracheal tube in securing upper airway in the patients undergoing beating-heart coronary artery bypass grafting. Ann Card Anaesth 2017;20:61-6.

Received: August, 2016. **Accepted:** November, 2016.

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Access this article online

Website: www.annals.in

DOI: 10.4103/0971-9784.197838

Quick Response Code:

without the aid of a laryngoscope or neuromuscular blockade.[6] The widespread use of the LMA in routine anesthesia practice means that it is readily available and most anesthesiologists reasonably skilled in its use. The other advantages offered by LMA over ETT include ease of placement even by inexperienced personnel; improved hemodynamic stability at induction and during emergence; minimal increase in intraocular pressure following insertion; reduced anesthetic requirements for airway tolerance; lower frequency of coughing during emergence; improved oxygen saturation (SpO_2) during emergence; and lower incidence of sore throat in adults.

On the other hand, the tube is placed into the trachea in ETT intubation. Although it remains the gold standard procedure for airway management, it is not without its disadvantages such as abnormality in hemodynamic and respiratory parameters failed intubation, tension pneumothorax, spinal cord and vertebral column injury, pulmonary aspiration, occlusion of central artery of retina and blindness, airway obstruction the corneal abrasion disconnection and dislodgement, difficult extubation, sore throat, cuff-related problems, laryngeal edema, ETT sutured to trachea or bronchus, hoarseness of voice, laryngeal edema, nerve injury, and may more.[7]

In long duration surgeries such as coronary artery bypass grafting (CABG), the use of ETT is associated with various hemodynamic complications such as hypertension (HT), tachycardia, and arrhythmia. Such hemodynamic changes that occur during intubation may alter the delicate balance between myocardial oxygen demand and supply and precipitate myocardial ischemia in patients with coronary artery disease.[8-10] PLMA offers the advantage of minimal hemodynamic complications over ETT during such surgeries. However, except for few studies, there are no significant data available that promote the use of laryngeal mask during cardiac surgery. This prospective study was conducted with the objective of demonstrating the advantages of PLMA over ETT in the patients undergoing beating-heart CABG.

Methodology

This observational comparison study was carried out in 200 patients who underwent beating-heart CABG. The study was commenced after taking permission from the Ethics Committee. Those patients who consented to participate in the study and gave written consent were included in the study. The patients were purposively selected to either of the two groups; the first group consisted of patients in whom ETT was used for securing airway during anesthesia and second group consisted of patients in whom PLMA was used for securing airway during anesthesia. 100 patients were selected in each group, i.e., 100 patients in ETT group and 100 patients in PLMA group. For the present study, a sample size of 200 patients, 100 patients in each group, was determined based on attainment of primary and secondary variables using the actual data information from study procedure.

Patients with obesity, sleep apnea, chronic obstructive pulmonary disease, gastroesophageal reflux disease, major abdominal surgery or warranting intraoperative use of transesophageal echocardiography, emergency surgery, crashed angioplasty, preoperatively on high inotropic support, difficult intubation, patients with life-threatening arrhythmias or on intra-aortic balloon pump, unstable angina patients with poor left ventricular function, i.e., ejection fraction <35% were excluded from the study.

All the preoperative medications were continued until the morning of surgery, except angiotensin-converting enzyme inhibitors. Patients had also been off antiplatelet agents for 5–7 days before the date of surgery. Patients were premedicated with oral lorazepam 1–2 mg or oral alprazolam 0.5 mg on the night before surgery. Monitoring was started with the patient awake, using central venous line, arterial cannula, pulse oximeter, temperature, noninvasive blood pressure (BP), and five-lead electrocardiogram (ECG).

The following parameters were measured heart rate (HR), BP, SpO_2, peak airway pressures (PAPs), and lung compliance. HR and BP were noted at 0, 1, 3, 5, and 10 min of insertion and time to extubation was also noted. Any complication during the procedure and/or after extubation was also noted. Normothermia was maintained with the help of warm saline, warming blankets, and core and skin temperatures were duly monitored.

Based on the standard institutional protocol, the pharmacological intervention was initiated if mean arterial pressure (MAP) was <60 mmHg or >110 mmHg, or ECG signs of myocardial ischemia were noted at any time during the surgery. Anesthesia was induced with midazolam 0.03 mg/kg and fentanyl 1.5 mcg/kg intravenously; propofol (1%) 1 mg/kg and vecuronium 0.8 mg to 1 mg/kg were used as a muscle relaxant. This was followed by securing the airway by PLMA or ETT in the respective groups. In the PLMA group, PLMA was secured with the gum elastic bougie (GEB) technique. The size of the PLMA used was determined as per the body weight of the patients; size 3, 4, and 5 for patients with weight between 30 and 50 kg, 50 and 70 kg, and 70 and 100 kg, respectively. The GEB-guided insertion technique involved the following steps: First, the distal portion of the GEB was placed 5–10 cm into the esophagus while the assistant held the PLMA and the proximal portion of GEB; second, the PLMA was inserted using the introducer while the assistant stabilized the proximal end of the GEB, so it did not penetrate further into the esophagus; third, the GEB was removed while the PLMA was held in position; fourth, the cuff of PLMA was inflated with air until effective ventilation was established or the maximum recommended inflation volume was reached. All techniques were performed with the patient in the “sniffing position” with the cuff fully deflated and using a midline approach. A slight lateral approach was used if tactile resistance was felt at the back of the mouth. In the ETT group, 7.5 and 8.5 size tubes were used for female and male patients, respectively, and the intubation was done using standard mackintosh blade.

The patients were then maintained on isoflurane, nitrous oxide (N_2O), oxygen (O_2), and infusion of fentanyl (1–2 mcg/kg/h) with propofol (0.02–0.05 mg/kg/min). Heparin 300 units/kg to achieve activated clotting time (ACT) of around 250–300 s; after completion of grafting, heparin was reversed with protamine to achieve ACT below 150 at the time of chest closure. Reversal of neuromuscular blockade was achieved with neostigmine and glycopyrrolate. When spontaneous respiratory efforts were detected, patients were maintained on assisted mode till complete spontaneous recovery.

Criteria for extubation were spontaneous eye opening, moving all four limbs, head holding for more than 5 s, PaO_2 >8.0 kPa with a FiO_2 of 0.4, core temperature above 36.0°C and blood loss <50 ml/h, normal reflexes, obeying verbal command, normal arterial blood gas, serum electrolytes, and ACT. Following extubation, final set of readings was taken; patients were asked for their names and pain score using the visual analog scale on a score of 0–10 and shifted to the Intensive Care Unit with an oxygen mask. Postoperatively, analgesia was provided using fentanyl infusion (2–20 mcg/kg), and rescue analgesia was given with nonsteroidal anti-inflammatory drugs (diclofenac 75 mg by parenteral route).

Statistical analysis

Data were analyzed using statistical software EpiInfo (U.S. Department of Health & Human Services, USA). The primary variables studied were BP and pulse rate. Secondary variables were PAP, compliance, partial pCO_2, and peripheral capillary SpO_2. Both primary and secondary variables were analyzed with comparative statistics. Based on data characteristics, standard error of difference between two means - *t*-test was used for analysis of primary and secondary variables.

Results

A total of 200 patients were enrolled in the study, 100 patients in each group. The demographic profile of patients in both groups is shown in Table 1. Mean age in the PLMA group was 57.69 ± 10.04 years while that in ETT group was 61.41 ± 7.1 years. There was male predominance in both groups, male:female ratio was 3.55:1; however, the proportion of male to female was same in both groups.

The comorbidities that were commonly present in both groups included diabetes mellitus (DM) and HT [Table 1]. In the PLMA group, 11 patients had only DM (n = 11), 15 patients had only HT (n = 15), while 54 patients had both DM and HT (n = 54). In ETT group, 6 patients had only DM (n = 06), 2 patients had only HT (n = 02), and 19 patients had both DM and HT (n = 19). Thus, preexisting comorbidities were more in the patients randomized to PLMA group.

Patients having an addiction to tobacco either in the form of smoking or tobacco chewing were 31 patients in PLMA group and 33 patients in ETT group [Table 1].

The number of attempts in achieving intubation is shown in Table 2. In PLMA group, the tube was successfully placed in the first attempt in 88 patients, while it was placed successfully in the second and third attempt in nine and three patients, respectively.

Parameters such as BP and HR were evaluated at baseline and following the insertion of PLMA/ETT at 1, 3, 5, and 10 min; in addition, SpO_2, PAP, lung compliance, pCO_2, time to extubation, postextubation care, and postextubation complications were measured.

Patients in PLMA group had a mean BP of 135/79 mmHg after intubation while it was134/75 mmHg in the patients of ETT group at baseline. BP was found under control during the procedure in both groups at all time points. The results are shown in Table 3 and Figures 1, 2. The results are statistically significant or similar in comparison to the gold standard practice of ETT group.

Patient in PLMA group had a mean pulse rate of 74.52 ± 10.79 per min after intubation while it was 81.72 ± 9.8 per min in the patients of ETT group, and this difference was statistically significant (P < 0.05) [Table 4 and Figure 3].

Table 1: Demographic profile of patients in the ProSeal laryngeal mask airways and endotracheal tube group

Variables	PLMA	ETT
Age (years)	57.69±10.04	61.41±7.1
Sex		
Male	78	78
Female	22	22
Male:female	3.55:1	3.55:1
Smokers (*n*)	31	33
Preexisting conditions		
DM (*n*)	11	6
HT (*n*)	15	2
DM and HT (*n*)	54	19

PLAMs: ProSeal laryngeal mask airways, ETT: Endotracheal tube, DM: Diabetes mellitus, HT: Hypertension

Table 2: Number of attempts in achieving intubation

Number of attempts	PLMA group	ETT group
First	88	100
Second	9	-
Third	3	-

PLAMs: ProSeal laryngeal mask airways, ETT: Endotracheal tube

This suggests that hemodynamic responses were better (statistically significant) in those patients in whom PLMA was placed compared to those in whom ET intubation was done.

Respiratory parameters such as SpO_2, pCO_2, PAP, and lung compliance were comparable in both groups ($P > 0.05$) [Table 5].

Extubation was done on the operation table itself for 85 patients in PLMA group compared to 68 patients in ETT group and at various time points for other patients in both groups [Table 6 and Figure 4]. ETT replacement was required in two patients at induction of anesthesia and one patient at placing the retractor at the time of internal mammary artery harvesting

Table 3: Change in the mean systolic/diastolic blood pressure from baseline after intubation in both groups

	BP				
	0	1	3	5	10
ETT (mmHg)	134.52/75	148/71	149/71	142/69	147/68
PLMA* (mmHg)	135/79	134/71	129/70	134/67	118/66

*P<0.05 at DBP 0 (P=0.000), SBP 1 (P=0.000), SBP 3 (P=0.000) and SBP 10 (P=0.008) time points, otherwise same to ETT. PLAMs: ProSeal laryngeal mask airways, ETT: Endotracheal tube, DBP: Diastolic blood pressure, SBP: Systolic blood pressure, BP: Blood pressure

Table 4: Change in the pulse rate from baseline after intubation in both groups

	Baseline	PR				Mean
		1	3	5	10	
PLMA*	83	77	76	74	70	74.52
ETT	75	82	84	83	78	81.72

*P<0.05 (P=0.000). PR: Pulse rate, PLAMs: ProSeal laryngeal mask airways, ETT: Endotracheal tube

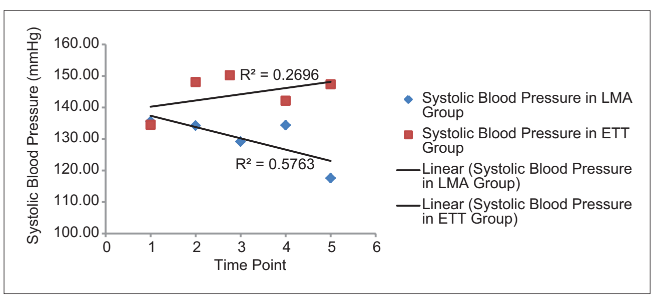

Figure 1: Mean systolic blood pressure between ProSeal laryngeal mask airway and endotracheal tube groups

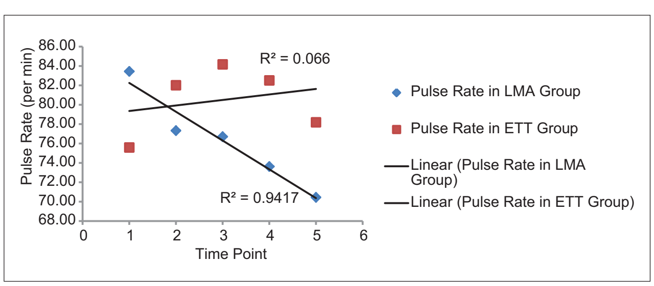

Figure 3: Mean pulse rate at different time points between ProSeal laryngeal mask airway and endotracheal tube groups

It was observed that in the PLMA group, there were fewer adverse events (AEs) than in the ETT group. In the PLMA group, only four AEs were observed, which included secretion (n = 1) and hypoxemia (n = 3), while seventeen AEs were observed in the ETT group which included bronchospasm (n = 4), secretion (n = 6), soreness (n = 3), trauma to the upper respiratory tract (n = 2), and hypoxemia (n = 2) [Table 7].

It was also seen that the requirement of muscle relaxants 0.1 mg/kg and opioids was less in PLMA group than in the ETT group; furthermore, the use of use of beta blocker was less in PLMA group than in the ETT group. It was also observed that the duration of stay in the intensive cardiac care unit was less in PLMA group than in the ETT group.

Discussion

Achieving safe and effective airway is the principal aim during anesthesia and is more so important during CABG as intrathoracic pressure may rise due to increased intra-abdominal pressure, gastroesophageal and biliary reflux, and other causes.[11]

A relatively new device, PLMA, is an improved version of the classic LMA and offers some added safety features

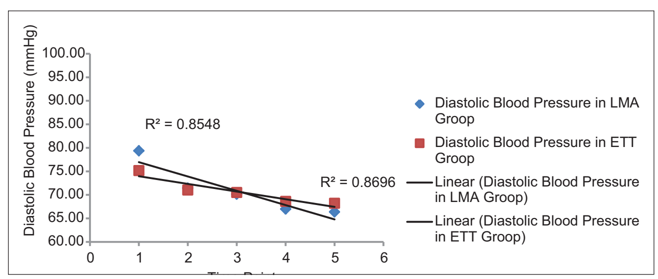

Figure 2: Mean diastolic blood pressure between ProSeal laryngeal mask airway and endotracheal tube groups

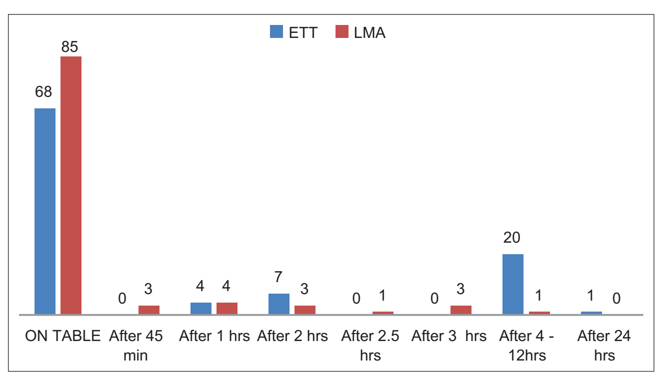

Figure 4: Extubation among ProSeal laryngeal mask airway and endotracheal tube group

over the classic LMA, in that it provides a better glottic seal at low mucosal pressures and a drain tube to vent out air and regurgitant material from the stomach.[12-15]

In this study, it was seen that all the hemodynamic parameters in PLMA group were better than in the ETT group and this finding was statistically significant ($P < 0.05$). This finding was comparable with other studies where it was found that hemodynamic response was improved following use of PLMA than ETT in the patients undergoing CABG surgery.[5,16-19]

In study by Bennett *et al.*, 27 patients undergoing elective CABG were randomized to ILAM (Intavent, Berkshire, UK), LMA or ETT group. Although the sample size was small, it showed that the hemodynamic responses were improved in the LMA group.[20]

Another study by Ajuzieogu *et al.* showed that in the patients randomized in the ET group, there was a significant increase in HR, systolic arterial pressure, and MAP from 1 to 10 min compared with baseline values compared to the patients randomized in the LMA group.[21]

The findings of this study are also consistent with the study conducted by Singh *et al.*, which showed that there were significantly less changes in the hemodynamic parameters, i.e., HR and BP in LMA group compared to other standard methods for maintaining airway.[22]

The reason for less hemodynamic changes with PLMA could be because PLMA being a supraglottic device does not require laryngoscopy and probably does not evoke a significant sympathetic response; therefore, attenuation of this response may be due to diminished catecholamine release.[23] This could be due to the fact that the PLMA is relatively simple and atraumatic to insert and does not require laryngoscopy.[24]

Table 5: Comparison of oxygen saturation, pressure CO_2, peak airway pressure, and compliance among ProSeal laryngeal mask airways and endotracheal tube group

Group	PLMA	ETT
PAP	19.3±3.72*	19.83±3.67
Compliance	42.6±4.83*	41.93±4.63
SpO_2	96.95±0.71*	96.8±0.66
pCO_2	41.18±4.25*	41.52±4.25

*P>0.05. SpO_2: Oxygen saturation, pCO_2: Pressure CO_2, PAP: Peak airway pressure, PLAMs: ProSeal laryngeal mask airways, ETT: Endotracheal tube

However, in a study by Braude *et al.*,[25] the investigators compared the hemodynamic response of insertion of the LMA with tracheal intubation in patients and showed a significant increase in systolic pressure, 1 min after the insertion of the LMA. This increase in arterial pressure was a similar, but attenuated, response to that after tracheal intubation. They also report a significant increase in HR immediately after LMA insertion which is contradictory to the findings of the current study. The reason might be that there is more mechanical pressure applied on the entire pharyngeal structures during laryngoscopy and intubation, and therefore, the increase in HR during intubation is attributed to sympathetic stimulation.[18,21,24,26]

Respiratory parameters such as SpO_2, pCO_2, PAP, and lung compliance evaluated in the current study showed that there was no statistically significant difference in the respiratory parameters in both groups at all the evaluation time points ($P > 0.05$).

Similar results were seen in a study conducted by Saraswat *et al.*, in which the mean change in hemodynamic and respiratory parameters with use of PLMA and ET in the patients undergoing laparoscopic surgeries under general anesthesia was evaluated. Results showed that both groups (PLMA group and ETT group) had maintained SpO_2 perioperatively along with the comparable value of $EtCO_2$ (maximal concentration of carbon dioxide (CO_2) at the end of an exhaled breath), while the PAP was also statistically insignificant in both groups.[27] Maltby *et al.* and Sharma *et al.*, also found no statistically significant differences in SpO_2 or EtCO between the two groups before or during peritoneal insufflations.[23,28]

In the current study, time to extubation in case of PLMA was significantly less compared to ETT group. Moreover, PLMA was also found to be safer than ETT in the patients who underwent CABG surgery. This finding was consistent with the findings of other studies by Patki, Yu and Beirne, Rieger *et al.*, and Brimacombe.[3,29-31]

Conclusion

Hence, it can be seen that PLMA is as good as ETT in terms of hemodynamic parameters, safety, and advantage of easy intubation and early extubation for airway management in patients undergoing long-term surgeries such as CABG and is equivocal to ETT in terms of the outcome of respiratory parameters. Thus, it can be safely concluded that PLMA can be used in patients undergoing long-term surgeries such as CABG with skill hands.

Table 6: Extubation among ProSeal laryngeal mask airways and endotracheal tube group

	On table	After 45 min	After 1 h	After 2 h	After 2.5 h	After 3 h	After 4–12 h	After 24 h
ETT (*n*)	68	0	4	7	0	0	20	1
LMA (*n*)	85	3	4	3	1	3	1	0

PLAMs: ProSeal laryngeal mask airways, ETT: Endotracheal tube

Table 7: Adverse events in ProSeal laryngeal mask airways and endotracheal tube group

Adverse events	ETT group	PLMA group
Bronchospasm	4	-
Secretion	6	1
Soreness	3	-
Trauma	2	-
Hypoxemia	2	3

PLAMs: ProSeal laryngeal mask airways, ETT: Endotracheal tube

Acknowledgments

I am grateful to Dr. Naman Shastri for his guidance in writing this article.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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