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Randomized Comparative Study of Proseal Laryngeal Mask Airway and Classic Laryngeal Mask Airway for Airway Management

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Abstract

Background: Laryngeal mask airways(LMA) have many advantages over endotracheal intubation in airways management, but has a risk of gastric insufflations, vomiting and aspiration. The aim of our study was to know how effective and safe ProSeal laryngeal mask airway (PLMA) is as compared to Classic laryngeal mask airway (CLMA) when used for adult patients posted for elective surgery under general anaesthesia using muscle relaxants. *Methods:* Study was conducted in a tertiary care teaching government institute.Sixty American Society of Anesthesiologists (ASA) I and II patients of either sex in the age group of 18–60 years who were scheduled for an elective surgery with general anesthesia were included in study and were divided randomly to either proseal laryngeal mask airway (PLMA) or classic laryngeal mask airway (CLMA) group. Both group patients received same induction, maintenance and reversal medications. Insertion success rates and attempts, time required to secure the device, oropharyngeal leak pressure, intra-operative & post-operative complications were observed and compared using statistical software Graph Pad Prism 6.01. *Results:* No significant difference was observed in the number of insertion attempts, success rates of insertion, intraoperative and post-operative complications amongst the two groups. The classic laryngeal mask airway was quicker to insert as compared to the PLMA. The PLMA provided a better airway seal as shown by the oropharyngeal leak pressure. The mean oropharygeal leak pressure in PLMA group was 26.45±1.41 cm H_2O and in CLMA group it was 17.43±1.17 cm H_2O. *Conclusions*: In anesthetised, paralyzed patients CLMA is easier as well as quicker to insert, but more effective seal was found when PLMA was used. Comparing the incidence of intraoperative complications and postoperative complications it was found to be similar.

Keywords: Laryngeal Mask; Aspiration of Gastric Contents; ProSeal LMA™; Endotracheal Intubation; General Anaesthesia; Cuff Pressure.

Introduction

The laryngeal mask airway (LMA) was invented by Archie Brain in 1981 at Royal London Hospital [1]. As compared to endotracheal intubation LMA has many advantages such as there is decreased need of muscle relaxants, no need to visualize vocal cords so there is less stimulating, and also there are less chances of sore throat. It is easy to insert as compared to endotracheal intubation and so it assumes importance in cases with suspected difficult or failed intubation and has been introduced in the american society of anaesthesiology (ASA) difficult airway algorithm [2]. Gastric insufflations and oropharyngeal air leakage are the main concerns with LMA due to incomplete mask seal. New variant of LMA, "LMAProseal" (PLMA) has two tubes one is an airway tube and other one lateral to airway tube with its end open at tip of patient end of PLMA. This modification was designed to enable separation of the gastrointestinal and respiratory tracts, improve the airway seal, enable controlled ventilation and diagnose mask misplacement [3]. The ProSeal Laryngeal mask airway has four main components:

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mask, inflation line with pilot balloon, airway tube and drain tube. The mask is designed to conform to the contours of the hypopharynx, with its lumen facing the laryngeal opening. The mask has a main cuff that seals around the laryngeal opening. A drain tube passes lateral to the airway tube and traverses the floor of the mask opening at the mask tip opposite the upper oesophageal sphincter. The airway tube is wire reinforced to prevent collapse and terminates with a standard 15 mm connector. The PLMA has larger deeper softer silicone cuff which reduces stimulation of throat and irritation; revised cuff arrangement allowing higher seal for a given intracuff pressure; drain tube opening at the upper oesophageal sphincter which permits drainage of gastric secretions and access to the alimentary tract; double tube arrangement reduces the likelihood of mask rotation; the revised cuff profile, together with the flexible tubes, result in the device being more securely anchored in place; built-in bite-block reduces the danger of airway obstruction or tube damage; location strap for the PLMA Introducer, which also accommodates the index finger or thumb for manual insertion. The PLMA is designed to be a minimally stimulating airway device. We attempted to compare the insertion success rates at first attempt, attempts required, time taken to secure the device, how effective the seal is using leak pressure, intra operative and postoperative complications following general anesthesia with those of CLMA or PLMA.

Materials and Method

The study was conducted after obtaining the approval from the institute ethical committee. Sixty ASA I and II patients of either sex in the age group of 18–60 years who were scheduled for an elective surgery with general anesthesia were included in study and were divided randomly to either PLMA or CLMA group. Patients with difficult airway, oro-pharyngeal pathology, restricted mouth opening (mallampati score 3/4), hypertension, diabetes, obesity and those with risk of aspiration were excluded from study. Pre-anesthetic checkup was done for every patient and written informed consent was taken.

Patients were pre-medicated 30 minutes before surgery with inj. Glycopyrrolate 0.2 mg i/m & inj Midazolam 2 mg i/m. The selected patients were then randomly allocated using picking up a cheat of paper into two groups of 30 each. In Group I – PLMA & Group II –CLMA was used for airway management. Standard anesthetic technique was used in all the patients. An intravenous line was maintained before inducing general anesthesia. Monitoring of electrocardiogram (ECG), Oxygen saturation (SpO_2), blood pressure, heart rate was done. After pre-oxygenating for 3 minutes with 100% oxygen, anesthesia was induced with inj. fentanyl 1.5–2 µg/kg body weight iv, inj. propofol 2 mg/kg body weight iv, oxygen & nitrous oxide [50:50] + isoflurane [1%] followed by inj. Succinylcholine 2 mg/kg body weight iv to facilitate insertion of the device. LMA of adequate size was chosen taking weight of the patient into consideration. Before insertion the cuff was fully deflated and a clear water based gel applied to the posterior aspect of the cuff for lubrication. Patient was positioned in sniffing position with neck flexed and head extended. LMA was secured in both groups by anesthesia faculty trained and master in using both the devices. In Group I Proseal LMA™ was secured using the introducer into the retaining strap at the rear of the cuff and airway tube was fit in matching slot, tip of the cuff was pressed upward against the hard palate, keeping the LMA ProSeal Introducer blade close to the chin the device was rotated inwards in one smooth circular movement and advance into the hypopharynx until a definite resistance was felt and introducer removed with care. In Group II Classic LMA™ was inserted holding the tube portion of the LMA between the thumb and the index finger pressing on the point where the tube adjoins the mask, with the aperture facing anteriorly, the tip of the cuff was placed against the inner surface of the patient's upper incisors, mask was then pressed upwards against the hard palate and advanced into the oral cavity, using the index finger of the right hand to guide the tube over the back of the tongue, then with one swift movement Laryngeal mask airway was pushed down until a characteristic resistance was felt as the upper oesophageal sphincter is engaged. It was connected to the breathing system, the cuff was inflated with air until an effective airway was established or the maximum recommended inflation volume reached (size 4, 30 ml; size 5, 40 ml) , the tube was then fixed. The patient was gently ventilated to check correct placement or any leaks. Success rate at first attempt and number of attempts required were noted. The time between picking up the device and obtaining an effective airway was recorded. Maintenance of anesthesia was carried out with oxygen, nitrous oxide [50:50] + isoflurane 0.8–1.5% + inj. vecuronium 0.08–0.1 mg/kg loading dose followed by 0.02 mg/kg intermittent dose as maintenance , after the completion of surgery, residual paralysis was reversed with injection neostigmine

[0.05mg/kg] & injection glycopyrrolate [1/5 dose of neostigmin]. Number of insertion attempts, each attempt duration, failure to insert device or size changes, oro-pharyngeal leak pressure, incidence of intra-operative & postoperative complications caused by the devices were noted by second person. Oro-pharyngeal leak pressure was measured by closing the expiratory valve of the circle system at a fixed gas flow of 3 liters/min and noting the pressure at which an audible leak was heard by listening over the mouth.

Statistical Analysis: The data was analyzed using statistical software Graph Pad Prism 6.01.

Results

All patients were randomly allotted to certain group and included for analysis. As shown in Table 1 most of the patients in our study were in the age group of 30 to 49 years. Demographicaly the groups had no significant differences when compared between male female ratio, age and ASA grading. As shown in table 2 there was no significant difference in the number of insertion attempts amongst the two groups. In the present study, most of the LMA insertions were successful in the first attempts i.e. 90% in PLMA group and 93.3% in CLMA group. In ProSeal group the mean number of attempts were 1.10 ± 0.305 while in the Classic group it was 1.07 ± 0.254. The success rates after two attempts for the both PMLA and CLMA was 100% suggesting equal clinical effectiveness. The Classic LMA was quicker to insert as compared to the ProSeal LMA. The mean insertion time in PLMA group was 26.3 ± 4.77 sec and in CLMA group was 18.13 ± 4.17 sec. The difference was found to be statistically significant (p value). The PLMA provided a better airway seal as shown by the

Table 1: Comparioson of demographic variants

Variants	PLMA	CLMA	P value
Age (year)	39.53	36.13	0.281
Sex(M:F)	8:22	15:15	0.1102
Weight Kg(SD)	62.9(7.2)	65(8)	0.28
ASA (I:II)	18:12	22:8	0.41

P > 0.05 Not significant PLMA- Proseal LMA, CLMA- classic LMA, M:F- male:female, SD- Standard deviation, ASA- American society of anesthesiologist.

Table 2: Comparison between PLMA & CLMA

Variants	PLMA (%)	CLMA (%)	P value
Attempts(1^{st}:2^{nd})	27:3	28:2	0.647
Insertion time(seconds)	26.30	18.13	<.001
Oropharyngeal leak press.(mm H_2O)	26.45	17.43	<.001
Intraop complication	3(10)	2(6.7)	1.0
Postop comp before leaving RR	2(6.7)	1(3.3)	1.0
Postop comp. 18-24hrs	3(10)	2(6.7)	1.0
Mortality	0	0	-

P > 0.05 Not significant, PLMA- Proseal LMA, CLMA- classic LMA, mmH2O: millimeters of water, RR-recovery room

Table 3: Complications in PLMA & CLMA

	Complication	PLMA (%)	CLMA (%)
Intraoperative	Hypoxia	0	0
	Bronchospasm	0	0
	Regurgitation/ aspiration	0	0
	Airway obstruction	0	0
	Hiccup	0	0
	Cough/gagging/retching	0	0
	Blood staining of device	3(10)	2(6.7)
Post operative before leaving RR	Pharyngeal irritation	2(6.7)	1(3.3)
	Dysphagia	0	0
	Dysphonia	0	0
Post operative 18-24hrs	Sore throat	3	2
	Dysphagia	0	0
	Dysphonia	0	0

P > 0.05 Not significant PLMA- Proseal LMA, CLMA- classic LMA, RR- recovery Room

oropharyngeal leak pressure. The mean oropharygeal leak pressure in PLMA group was 26.45 ± 1.41 cm H_2O and in CLMA group was 17.43 ± 1.17 cm H_2O; 9 cm H_2O higher for the PLMA. As shown in Table 3 both the groups were comparable in terms of intra operative and postoperative complications. There was no incidence of hypoxia, bronchospasm, aspiration, regurgitation, airway obstruction in any group. The incidence of blood staining of the device on removal was comparable in the two groups i.e. 3 cases (10%) in PLMA group and 2 cases (6.7%) in CLMA group. In the recovery room two patients of ProSeal laryngeal mask airway group i.e. 6.7% complained of pharyngeal irritation and one patient i.e. 3.3% of Classic laryngeal mask airway group complained of pharyngeal irritation. There was no incidence of dysphagia or dysphonia in any group.Three patients in Proseal laryngeal mask airway group i.e. 10% complained of sore throat, while in Classic laryngeal mask airway group there were two patients i.e. 6.7% complaining of mild sore throat.

Discussion

Endotracheal intubation has been used for long time for airway management and is the most preferred and accepted technique in the practice of anesthesia but it is technically difficult, has a long learning curve[4] as there is need to visualize the vocal cords. It also is more invasive as tube is placed in the trachea. LMA has many advantages such as there is decreased need of muscle relaxants, no need to visualize vocal cords so there is less stimulating, and also there are less chances of sore throat[5]. Gastric insufflations and oropharyngeal air leakage are the main concerns with LMA due to incomplete mask seal. New variant of LMA, "LMA Proseal" (PLMA) has two tubes and separates the alimentary and the respiratory tracts. In the present study, participants were comparable demographicaly. Most of the LMA insertions were in the first attempts i.e. 90% in group I and 93.3% in group II and statistically the difference was non-significant. This was consistent with the findings of other studies [6–8]. The mean insertion time in group I was 26.3 ± 4.77 sec and in group II was 18.13 ±4.17 sec and was significant. The CLMA was found to be more easy and quick to insert at the first attempt than the PLMA which is due to the larger cuff and the lack of a backplate which makes cuff more likely to fold over at the back of the mouth. This finding was consistent with other study findings [9–11]. The mean oropharygeal leak pressure in group I was 26.45 cm H_2O and in group II was 17.43 cm H_2O and was found to be highly significant. The efficacy of seal in PLMA was 9 cm H_2O (26.45–17.43) higher than CLMA. The reasons for this improvement in the sealing pressure in PLMA as compared to CLMA are (i) the proximal cuff is broad which causes more effective plugging of the oropharynx, (ii) the second ventral cuff presses the dorsal cuff more firmly into the periglottic tissues, (iii) proximal cuff is more effectively covered by the base of the tongue due to paralel, narrower tubing. This improvement in seal is highly useful in cases in which higher airway pressures are required for positive pressure ventilation for example obese patients, the lithotomy–head down position, or in patients with restrictive pulmonary pathology. The better seal probably offers no advantage in the spontaneously breathing patient. These results are comparable to those by Brimacombe et al [9] in which orophayngeal leak pressure was significantly higher for a ProSeal LMA as compared to the Classic LMA (27 vs. 22 cmH_2O). Similar results were concluded by Cook et al. [11] and Braun et al. [12]. Comparing both groups intraoperative and postoperative complications in both groups were not significantly different.

We conclude that, in anesthetised, paralyzed patients CLMA is easier as well as quicker to insert, but more effective seal was found when PLMA was used. Comparing the incidence of intraoperative complications and postoperative complications it was found to be similar.

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