Original Article

LMA Classic and LMA Proseal: A Comparative Study in Paralyzed Anaesthetized Patients

Anaesthesia Section

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ABSTRACT

Introduction: Airway management is a fundamental aspect of the anaesthesia practice and of emergency and critical care medicine.The proseal laryngeal mask airway (PLMA), a modified version of the classic laryngeal mask airway (LMA), is being considered as an alternative airway device for a wide range of surgical procedures. The aim of the study was to assess the use of the PLMA as a ventilatory device in anaesthetized, paralyzed patients for various elective procedures.

Materials and Methods: This prospective study comprised of 50 patients between the ages of 18-60 years, of either sex and belonging to the physical status ASA I and ASA II. We assessed the haemodynamic responses to the insertion of the PLMA, ventilatory parameters, the ease of the gastric tube placement, gastric insufflation and any postoperative complications.

Results: The statistically analyzed results showed that the PLMA caused minimum haemodynamic responses to the insertion and that it was a reliable airway management device which ensured adequate ventilation and provided an effective glottic seal.

Conclusion: We conclude that the Proseal LMA is capable of achieving a better seal than the LMA and facilitating gastric placement, but later is more difficult to insert.

Key Words: Equipment, Mask anaesthesia; Airway, Pressure, Regurgitation, Pulmonary aspiration

INTRODUCTION

Although endotracheal intubation has a long history as one of the most widely accepted techniques in anaesthesia practice, it is not without complications, most of which arise from the need to visualize and penetrate the laryngeal opening.

The laryngeal mask airway (LMA) was invented by Archie Brain in 1981 and the advantages of LMA over the endotracheal intubation include the absence of the need of muscle relaxants and a decreased risk of post operative sore throat. A potential risk of LMA is an incomplete mask seal which causes gastric insufflation or oropharyngeal air leakage. The use of a new variant of "LMA, "LMA–Proseal" (PLMA), which incorporates a second tube which is lateral to the airway tube, was intended to separate the alimentary and the respiratory tracts. It permitted access to or the escape of fluids from the stomach and reduced the risks of gastric insufflation and pulmonary aspiration. It can also determine the correct positioning of the mask [1].

In this prospective study, we attempted to compare the ease of insertion of the airway seal, the ease of gastric tube placement and post operative complications following general anaesthesia with those of Classic LMA or Proseal LMA in paralyzed patients.

MATERIALS AND METHODS

With the approval of the institutional ethics committee and the written informed consent of the patients, 50 patients (ASA 1-2, aged 18-60 yrs) who underwent elective non abdominal surgeries were randomly allocated (by opening a sealed envelope) for airway management with PLMA or LMA. Patients with a known history of difficult airway, cervical spine disease, mouth opening < 2.5 cm and those who were at a risk of aspiration were excluded from the study, so as to make the groups comparable.

A standard anaesthesia protocol was followed and routine monitoring was applied. The patients were premedicated with IV Glycopyrrolate 0.004 mg/kg, IV Midaozolam 0.03 mg/kg, IV Fentanyl 2 micro gm/kg, IV Ranitidine 1 mg/kg and IV Metaclopramide 0.2 mg/kg. Anaesthesia was induced with IV Propofol 2mg/ kg, with patients in the supine position. Maintenance was achieved with Propofol infusion at 3-6 mg/kg/hr with 50% oxygen and nitrous oxide. Neuromuscular blockade was achieved with Vecuronium 0.08-1 mg/kg and it was maintained with 0.02 mg/kg boluses to maintain a train- of four count of <1. The patients' lungs were ventilated with a face mask until the neuromuscular block was complete.

The Proseal LMA was inserted by using an introducer tool as was recommended by the manufacturer. The insertion technique for both the devices was the same. The number of insertion attempts was recorded for both PLMA/LMA. A failed attempt was defined as the removal of the device from the mouth. Three attempts were allowed before the device was considered as a failure. The time between picking up the LMA/PLMA and obtaining an effective airway was recorded. If an effective airway could not be achieved, one attempt with the other device was allowed. If an effective airway was not achievable with the alternate device (PLMA/LMA), then the airway was achieved with an endotracheal tube, the case was considered as a failure and it was documented. The gastric tube (14-16 no) was inserted through the drainage tube of the PLMA. The time which was taken to insert the gastric tube was recorded, and the placement was confirmed by the synchronous injection of air and epigastric auscultation during apnoea. In case of a difficulty in introducing the gastric tube, two attempts were tried with the manipulation of the introducer. The inability to insert the gastric tube (if any) was recorded.

The airway sealing pressure was determined by closing the APL valve of the closed circuit at a fixed gas flow of 4lt/min and by noting the pressure at which an equilibrium was reached by using a Portex aneroid gauge. The maximum allowed pressure was 40 cms H_2O. The location of the airway gas leak at the airway sealing pressure was determined as-mouth (audible leak), stomach (epigastric auscultation) and drainage tube with PLMA, which was determined by the gel displacement test i.e. bubbling of the lubricant which was placed on the proximal end of the drainage tube.

The ventilation was controlled with a tidal volume of 8ml/kg in both the groups by using a Penlon Anaesthesia ventilator. The cuff pressure was kept constant at 60 cm of H_2O by using a Portex aneroid gauge. The Propofol infusion was continued till just before the extubation at 2mg/kg/hr. Auscultation of the chest was done after the removal of the device for any evidence of aspiration. Secretions if present, were noted and the pH was tested with a litmus paper which was sensitive to changes of 0.5 unit pH from pH 2.5 -8.5. Post operatively, the patients were monitored for heart rate (HR), blood pressure (BP), SPO_2 and the incidence of nausea and vomiting. The patients were questioned directly about the sore throat half an hour after their admission to the recovery room. The sore throat incidence was evaluated by using a 3 point scale as follows:

- 2- Continuous throat pain.
- 1- Throat discomfort.
- 0- no complaints at all.

An enquiry about the same was made 24 hrs later.

OBSERVATION AND RESULTS

The observation and the results of the two groups, the LMA group and the PLMA group are mentioned below. Statistical analysis was performed with the paired t test and the Levene's test for the equality of variances. The groups were comparable with regard to all the demographic data like age, weight and sex. The mean ages were 30.8 and 33.6 for the LMA and the PLMA groups respectively. The mean weights were 53.6 and 55.8 Kgs for the LMA and the PLMA groups respectively. The male to female ratio was 16:34. The mean duration of anaesthesia in the LMA group was 67.8 mins and that in the PLMA group was 66.8 mins and there was no statistically significant difference between the two groups [Table/Fig-1].

Size 3 and size 4 devices were used for the male and female patients respectively. In the LMA group, the size 3 device was used in 16 patients and the size 4 device in 9 patients. The first time success- rates for LMA were slightly higher (23 of 25 *vs* 21 of 25; 92%), as compared to those of the PLMA group, which was statistically insignificant. With LMA, 2 patients and with PLMA, 4 patients required two attempts. The time which was required for achieving an effective airway was longer with the Proseal LMA than with the Classic LMA. The airway seal pressure was 3-27 cm of H2O, which was higher for PLMA than for LMA (27 $\pm$16 vs 14 $\pm$ 2cm H2O), which was statistically significant, as shown in [Table/Fig 2].

Intra operatively, the HR increased significantly 5 min after the insertion of LMA. The systolic BP was significantly lower in the LMA group 15 and 30 min after the insertion of the device. There were no episodes of desaturation, laryngospasm or bronchospasm with either device.

In the PLMA group, the gastric tube placement was successful in 24 of the 25 patients and it took an average of 11 sec. In one case, the gastric tube could not be passed, even though an effective ventilation could be achieved. Regurgitation of the gastric contents through the drain tube was noticed in two of the PLMA cases. There were no cases of regurgitation into the mask with either device, as was detected by the litmus paper. After the removal of either device, blood stained secretions were noted in 1 and 2 cases of LMA and PLMA respectively. Post- operatively, mild sore throat (grade-1) was noted in 1 and 2 cases of LMA and PLMA respectively.

DISCUSSION

The inception of the LMA was a result of the application of the bio-engineering and post mortem examinations of the adult larynx. A potential risk of LMA is an incomplete mask seal which causes gastric insufflation or oropharyngeal air leakage. A new variant of LMA, "LMA -Proseal" is a laryngeal mask with an oesophageal vent, which is intended to separate the alimentary and the respiratory tracts. It can also determine the correct positioning of the mask [1].

There is no conclusive evidence in the literature regarding the size selection in the Asian population. Tan SM *et al* also showed that the size 5 PLMA in men in the Asian population resulted in increased

Parameters	LMA Group* (*N* = 25)		PLMA Group## (*N* = 25)		P Value** (t-Test)	Difference
	Mean	SD	Mean	SD		
Age (in years)	30.88	11.06	33.68	11.57	0.802	Not significant
Sex: M/F	9/16		7/18		0.243	Not significant
Weight (kgs)	53.68	10.69	55.08	10.94	0.848	Not significant
Duration of Surgery (min)	67.8	24.91	66.8	23.66	0.885	Not significant

[Table/Fig-1]: Comparison of demographic & other data in LMA and PLMA groups
**P< 0.001-highly significant; P< 0.05-significant; P> 0.05- not significant.
*Classic LMA; ##Proseal LMA.

Parameters	LMA Group (*N* = 25)		PLMA Group (*N* = 25)		P Value* (t-Test)	Difference
	Mean	SD	Mean	SD		
Attempts	01.08	0.28	1.16	0.37	0.084	Not significant
Time for effective airway (sec)	22.24	8.19	32.44	14.48	0.004	Significant
Seal pressure (cm H_2O	14.64	2.69	27.32	16.33	0.000	Significant

[Table/Fig-2]: Summary of comparative data for LMA and PLMA
**P< 0.001-highly significant; P< 0.05-significant; P> 0.05- not significant.

mucosal injury and that size 3 and 4 in the Asian women resulted in an effective glottic seal [2]. Hence, in our study, we chose a fixed size LMA/PLMA for men and women (size 4 and 3 respectively).

Brimacombe et al showed that the first-time success rates were higher and that the effective airway time was shorter with the introducer [3]. The insertion is easier with the introducer, because it occupies lesser space than the finger and avoids the insertion of the finger inside the oral cavity, directs the cuff around the oropharyngeal inlet and facilitates a full depth of insertion. In our study, the first time success- rates were slightly higher for LMA and the time which was required for achieving an effective airway was longer with the Proseal LMA than with the Classic LMA. This was in conformity with the reports of earlier studies [3],[4], [5]. The common reason which was stated was that when deflated, the semi rigid distal end of the drain tube formed the leading edge of the Proseal, which was more rigid than the leading edge of the classic LMA. These factors could contribute to a difficult insertion of the PLMA [4]. This time difference may not be significant for the routine cases, but it is important in emergency situations where securing the airway is of prime importance.

The use of LMA for positive pressure ventilation is not new, but it is regarded by some as controversial. The lungs of most of the healthy patients can be ventilated if the seal pressure exceeds 20 cm H_2O [4]. An airway sealing pressure or a 'leak' test is commonly performed with the LMA to quantify the efficacy of the seal with the airway [6]. This value is important as it indicates the feasibility of the positive pressure ventilation and the degree of airway protection from supracuff soiling. The most common airway sealing pressure test involves listening over the mouth and noting the airway pressure at which the gas escapes. Keller et al concluded that for clinical purposes, the manometry stability test may be the appropriate test for comparing the airway seal pressures [6]. If the peak inflation pressure exceeded the leak pressure, the likelihood of the gastric insufflation was increased [4]. Our study results suggested that if a Classic LMA was selected for positive pressure ventilation, the chances of the leakage were higher. However, we could effectively ventilate in all the LMA cases.

The optimal positioning of the drain tube determines the correct positioning of the mask [1]. The drain tube appeared to be placed optimally in all except one case. In one case, we could not pass the drain tube but however, an effective ventilation was achieved. Regurgitation of the gastric contents through the drain tube was noticed in two of the PLMA cases. The use of a prokinetic agent pre operatively could explain the absence of regurgitation of the gastric contents in a majority of the cases. Brimacombe et al concluded in their cadaver model, that a correctly placed PLMA allows the fluid in the oesophagus to bypass the pharynx and mouth when the drainage tube is open [7]. These findings have led to the use of PLMA in adult as well as in paediatric laparoscopic procedures [8], [9].

We noticed in our study that, the bite block of the PLMA lay slightly above the margin of the teeth. This could be due to the anatomical factors which were related to the racial differences in the population. Some studies have described the position of the LMA/PLMA based on fibre optic grading [3],[4]. We did not use a fibre optic scope as the requisite sized bronchoscope was not available during the study.

Evans and colleagues demonstrated that PLMA causes a minimal haemodynamic response to the insertion [10]. Though in our study, the haemodynamic changes after the insertion of either device were statistically significant, they were found to be insignificant clinically. For most of the patients and the operations, these considerations were not critical. However, the patients who emerge from anaesthesia for neurosurgery, cardiac surgery and open eye surgery can benefit from a smooth recovery. The PLMA may find a role during such procedures. There were no episodes of desaturation, laryngospasm or bronchospasm.

Postoperatively, mild sore throat (grade-1) was noted in 1and 2 cases of LMA and PLMA respectively. The incidence of the sore throat varies in different studies due to the variation in size of the LMA and the endotracheal tube which is used in different studies, the design and the type of ETT which is used and the lubricating material which is used. The sore throat and dysphagia that occurs in the postoperative period is usually present for a short period only.

We conclude that the Proseal LMA is capable of achieving a better seal than the LMA and that it facilitates gastric placement, but it is more difficult to insert. Further research is required to determine the role of the Proseal LMA in airway management, but the better seal suggests its role as an alternative to LMA for positive pressure ventilation, either as backup or as a replacement device.

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