Original Research Article

Safety and efficacy of supraglottic airway device proseal in mechanically ventilated patients

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Abstract

Background: The Proseal Laryngeal Mask Airway (PLMA) is a new innovation of classic LMA. The PLMA has been reported to be an effective rescue airway for failed tracheal intubation. The present study was undertaken to evaluate safety and efficacy of supraglottic airway device proseal in mechanically ventilated patients. **Material and Methods:** This prospective study involved a total of 40 patients where Proseal for airway management was used for surgery under general anaesthesia and controlled ventilation. The insertion time of the devices, difficulty during insertion, difficulty during gastric tube insertion, coverage of airway pressure, and complications were recorded. **Results:** Vital parameters remained stable throughout surgeries. 100% success rate of insertion of nasogastric tube was found. Nasogastric tube was passed in 1st attempt. Postoperative complications like sore throat was found in 4 cases, whereas cough occurred in one patient. **Discussion:** PLMA is efficient with regards to the ease of insertion as evidenced by similar number of attempts required and the manoeuvers required. The time taken for insertion was also considerably less. The nasogastric channel provided a conduit to gastric chamber with similar success rates. The PLMA can be used safely and effectively for airway maintenance during general anaesthesia under mechanical ventilation.

Key Words: Proseal LMA, mechanical ventilation, attempts, ease of insertion, complications.

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INTRODUCTION

The Proseal Laryngeal Mask Airway (PLMA) is a new innovation of classic LMA. It is a modification of the Classic Laryngeal Mask Airway (LMA)[1,2]. The cuff of the PLMA is specially designed with an aim to provide a more effective seal around the glottis than the Classic LMA for positive pressure ventilation[3]. It also provides separation of the respiratory from the alimentary tract and the venting of gas or liquid via its unique drain port and bypass channel for regurgitated gastric contents[4]. Laryngoscopic stimulation of oropharyngolaryngeal structures may be an important factor in the hemodynamic stress response associated with tracheal intubation. The sudden rise in blood pressure may cause left ventricular failure, myocardial ischemia or cerebral haemorrhage in the presence of coronary or cerebral atheroma or hypertension. In these conditions it can even become life threatening. Also, it causes damage to the oropharyngeal structures at insertion. Postoperative sore throat is also a serious concern. This precludes the utility of the tracheal tube and requires a better alternative. The PLMA has been reported to be an effective rescue airway for failed tracheal intubation. The Classic LMA is not a very popular device for positive pressure ventilation for fear of gastric distension, aspiration of gastric contents and inadequate ventilation. The PLMA offers several advantages over the Classic LMA. It provides a better glottic seal at lower mucosal pressures and isolates the alimentary tract from the respiratory tree. It is superior to the Classic LMA for providing positive pressure ventilation and, at a given intracuff pressure, provides twice the seal pressure of the Classic LMA[5,6]. The present

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study was undertaken to evaluate safety and efficacy of supraglottic airway device proseal in mechanically ventilated patients.

MATERIAL AND METHODS

This prospective study involved a total of 40 patients where Proseal for airway management was used for surgery under general anaesthesia and controlled ventilation. Patients aged between 20-40 years with ASA grade I and II, inter incisor gap > 2.5 cms, Mallampatti classes I and II and surgery duration of less than 2 hrs were included in the study and patient refused to enroll, with upper respiratory tract infection, non-fasting status, mouth opening <2.5cm, lung diseases, head neck surgeries, medical disorders (Hypertension, DM, Coronary heart diseases) and patients with increased risk of aspiration like (GE reflux, Hiatus Hernia, Pregnancy) were excluded from the study. A complete pre-anaesthetic evaluation was done a day prior to surgery. Routine preoperative investigations were carried out. Patients were explained about the nature of the study and written informed valid consent was taken. Adequate starvation was confirmed. On arrival in the operation theatre patients were monitored with electrocardiography, pulse oximeter, and non-invasive blood pressure measurement. Patients were given premedication in the form of inj. Midazolam 0.03 mg/kg, Inj. Fentanyl 2 mcg/kg, inj. Ondansetron 0.1 mg/kg intravenously. Heart rate, systolic and diastolic blood pressure and oxygen saturation were noted 5 minutes after premedication (Pre-induction). Patients were pre-oxygenated for 3 minutes with 100% oxygen. General anaesthesia was induced with inj. Propofol 2 mg/kg, the endpoint being loss of eyelash reflex. Ventilation was checked. After confirming ventilation inj. Vecuronium 0.1 mg/kg was given intravenously. Patients were mask ventilated for 3 minutes with 50:50, Nitrous oxide and Oxygen. The dorsal surface of the Proseal was lubricated with Lignocaine 2% jelly. Appropriate size Proseal, as per manufacturer's recommendation, i.e. size 3 for 30-50Kg, Size 4 for >60Kg, Nasogastric tube number 12 was selected. The airway device was inserted by Anaesthesiologist by gentle pushing until resistance felt. The insertion technique included neck flexion, head extension, and midline approach along the hard palate downwards and backwards. Correct placement was confirmed by auscultation on chest. Introducer was removed after insertion and cuff inflated. The time of insertion was defined as time taken for holding the prelubricatedsuraglottic device to the first squre shaped capnograph tracing. Number of attempts required for obtaining an effective airway was noted. Three attempts were allowed and more than three attempts before insertion were considered as failure. Ease of insertion of device also recorded. Ease was defined as no resistance to insertion in single manoeuvre. In difficult insertion, there was resistance to insertion or more than one manoeuver is required. An effective airway was defined as normal thoraco-abdominal movement and a square wave capnograph trace. All parameters i.e. pulse, systolic blood pressure, oxygen saturation, end tidal carbon dioxide were recorded at 0 minute (immediately after insertion of airway device), 1 minute, 5 minute, and 10 minutes after insertion of airway device. The nasogastric tube (NGT) was inserted 2 minutes after the placement of airway device. The placement was confirmed by synchronous injection of air and epigastric auscultation during apnoea. In case of difficulty in introducing NGT, two attempts were allowed and more than two were considered as failure. Inability to insert the gastric tube (if any) was recorded. Intraoperatively any complications like gastric distension (as seen on the monitor and enquired with the surgeons), regurgitation visible from the NGT and pulmonary aspiration (signs such as visualization of the gastric contents in the airway device and crepitation on chest auscultation) were noted. An airway sealing pressure was noted at 10 min of insertion and 10 min before completion of surgery this is measured by closing expiratory valve of circle system at a fixed gas flow of 5 lit/min and airway pressure at which equilibrium was reached was recorded (maximum pressure allowed was 40 cm of H2O). Gas leakage was noted at this time by placing stethoscope lateral to thyroid cartilage. Anaesthesia was maintained on O2 (50%), N_2O (50%), Isoflurane and inj. Vecuronium ($1/5^{th}$ of the loading dose). IPPV was given. After completion of the procedure, the neuromuscular blockade was reversed with inj. Glycopyrrolate 8 mcg/kg and inj. Neostigmine 0.05 mg/kg after cessation of N2O. Nasogastric tube suctioning was done and any visible secretions noted. The device was removed after the return of adequate spontaneous respiratory efforts and when the patient was able to open the mouth on command. Auscultation of chest was done after removal of device for any evidence of aspiration. Any incidence of trauma and blood on the airway device was noted. Post operatively, the patients were monitored for pulse, systolic blood pressure, Oxygen saturation in recovery room. Any incidence of nausea and vomiting was noted. Patients were questioned directly about sore throat half an hour after admission to recovery room. Sore throat incidence was evaluated by asking continuous throat pain, throat discomfort, or no complaints at all. Enquiry for the same was done 24 hrs later.

RESULTS

In present study, 40 patients within a range of 20 to 40 years, of ASA I and II were studied where Proseal was inserted. Most of the patients i.e., 45% patients were in the age range of 25 to 30 years. The average age was 29.53 ± 3.63 years. Weight of the patients ranged from 38-60 kgs. Patients of both sexes were included in the study. Males were 18 (45%) and females were 22 (55%). The duration of the operation did not last for more than 120 minutes in any of the cases (Table 1).

Table 1: Age distribution of patients in both the groups

Variables	No. of patients (%)
Age groups (years)	
20-24	05 (12.5%)
25-30	18 (45%)
31-35	15 (37.5%)
36-40	02 (5%)
Sex	
Male	18 (45%)
Female	22 (55%)
Type of surgery	
Hernioplasty	6 (15%)
Tibial plating	8 (20%)
Upper limb	8 (20%)
Skin grafting	8 (20%)
Mastectomy	6 (15%)
MTP and TL	4 (10%)
Weight Kgs	
Mean ± SD	49.90 ± 4.94
Duration of anaesthesia	
Mean ± SD	82.75±27.36

Airway seal pressure was recorded at two times, 10 minutes after insertion and 10 minutes before extubation. Mean of the airway seal pressure recorded 10 minutes after insertion (ASP1) was 26.10±4.87cm of H_2O. Also we recorded Airway seal pressure 10 minutes before extubation (ASP2), it was 26.10±4.87 cm of H_2O. We found 100% success rate of insertion of nasogastric tube. We were able to pass nasogastric tube in 1st attempt (Table 2).

Table 2: Variables studied

Variables	No. /Mean± SD
No. of attempts	
One/two/three	32/4/4
Mean SD	1.32+0.65
Time required for insertion	
Mean ± SD (Seconds)	2.30 ± 2.54
Airway seal pressure achieved	
After insertion Mean±SD	26.10 ± 4.87
Before extubation Mean±SD	26.50 ± 5.01
Ease of nasogastric tube placements	40 (100%)

A total of 5 cases required different maneuvers including flexion, extension flexion withdrawal, jaw elevation and 35 patients didn't require any maneuvers. We compared mean of heart rate and mean of systolic blood pressure at different interval i.e. at pre op, immediately after insertion, at 5 minute, 10 minutes, 20 minutes after insertion, and just after extubation, 5 and 10 minutes after extubation (Table 3).

Table 3: Heart rate and mean systolic blood pressurechanges at various intervals

Time Interval	Heart Rate (beats/min)	Systolic BP (mm Hg)
	Mean± SD	Mean± SD
Pre Op	81.60±6.93	111.90±8.20
00 Min	82.35±6.27	112.67±7.41
05 Min	82.60±6.50	112.6±7.27
10 Min	82.60±6.34	111.7±6.67
20 Min	82.80±6.28	112.4±6.41
Before Extubation	81.7±6.41	112.35±8.16
After Extubation	82.35±6.38	112.9±6.97
05 Min	82.3±6.58	112.8±7.27
10 Min	82.2±6.14	112.15±7.61

Postoperative complications like sore throat was found in 4 cases, whereas cough occurred in one patient.

DISCUSSION

We included age group of 20 to 40 years in our study. Different problems like cervical spondylitis, obesity, hemodynamic instability goes on increasing as age advances which can affect final result. Referring to studies done by Ishwar Singh *et al*[7] and Bimla Sharma *et al*[8], mean age group was around 40. In this study, mean duration of anaesthesia was 82.75±27.36 minutes. Maltby JR *et al*[9] found mean duration of surgery in Proseal group was 95±36 minutes which is similar to present study. Although, Proseal was easier to insert with success rate of 80% (32/40) in first attempt. The device could not be inserted successfully in three patients within stipulated time and attempts. These cases were excluded from further analysis. An endotracheal tube was used to secure the airways in these patients. We did not encounter any episodes of hypoxemia (SpO_2<90%) or any other adverse events during entire course of our study. Cook TM *et al*[4] reviewed literature of Proseal, and found that in different 33 studies for insertion of Proseal 1st attempt success rate was 76 to 100%. Ishwar Singh *et al*[7] found that 28/30 patients of Proseal group required only one attempt for insertion of LMA. Bimla Sharma *et al*[8] found that in Proseal group 24 patients required one attempt. Our result was consistent with above studies. In our study, we found that the time taken for Proseal LMA was 12.30±2.54 sec. The time from picking up the device to first square shaped capnograph tracing following clinically adequate

ventilation of lungs was recorded as the time taken for insertion. Bimla Sharma *et al*[8] found that time required for insertion of I gel was less than Proseal, although, it was statistically insignificant. Saraswat N *et al*[10] compared Proseal versus ETT. In their study, time required for insertion of Proseal was 15 seconds which was less than that of ETT. However, the exact definition of insertion time in these studies remains unclear. The correct placement of the device was evaluated by the smooth passage of NGT. Nasogastric tube was successfully inserted in all patients. Brain AJ *et al*[11] found 100% success rate for nasogastric tube insertion. Maltby JR[9] also found similar success rate in case of Proseal LMA as compared to ETT. Bimla Sharma *et al*[8] found 100% success rate of nasogastric tube insertion with I gel and Proseal LMA. Our results are consistent with above mentioned studies. Mean of the airway seal pressure recorded 10 minutes after insertion (ASP1) was 26.10±4.87cm of H_2O. Also we recorded Airway seal pressure 10 minutes before extubation (ASP2), it was 26.10±4.87 cm of H_2O. In the study done by Maltby JR *et al*[9] achieved similar airway pressure in patients using Proseal LMA which was 34 cm of H2O. In a study by Uppal V *et al*[12] none of the cases had gastric regurgitation or aspiration. Wood ML *et al*[13] found that there were minimal hemodynamic changes after insertion of LMA as compared to endotracheal tube. These results were similar to study done by Halaseh BK *et al*[14] where they found that there were no hemodynamic variations after insertion of Proseal LMA. By comparing our results with above mentioned studies, we concluded that minimal hemodynamic changes occur after insertion of Proseal LMA. The major cause of the sympathoadrenal response to tracheal intubation arises from stimulation of the supraglottic region by tissue irritation induced by direct laryngoscopy. Insertion of the tube through the vocal cords and inflation of the cuff in the infraglottic region should contribute additional stimulation. Also, by activating proprioceptors, direct laryngoscopy induces arterial hypertension, tachycardia, and increased catecholamine concentrations proportional to the intensity of the stimulus exerted against the base of the tongue. However, subsequent tracheal intubation should stimulate additional receptors in the larynx and the trachea, thus enhancing the hemodynamic and epinephrine response. Use of the LMA avoids the need for laryngoscopy and tracheal intubation, so that the marked haemodynamic response to these procedures may be circumvented. There was no any intra operative complication occurred. No trauma (blood staining on device or trauma to teeth) occurred during insertion. Contradictory to our results Ishwar Singh *et al*[7] found blood staining of Proseal LMA in 6 out of 30 patients. Better acquaintance with devices, prior training on mannequins, keeping number of attempts to only three, and close attention to details like positioning of the patient and device movement inside the airway probably allowed us to bring down the incidence of airway trauma to zero. Post-operative complications (cough and sore throat) were found in 4 cases. Maltyby JR *et al*[9] found cough in two patients and laryngeal stridor in two patients out of 50 patients after insertion of Proseal LMA in patients undergoing laproscopic surgery. Occurrence of sore throat is less because it is a supraglottic device, which achieves mucosal pressure below pharyngeal perfusion pressure. LMA is associated with a lower incidence of laryngospasm during emergence, postoperative hoarse voice, and coughing than the ETT. Because the ETT is placed in the trachea beyond the vocal cords, it can irritate the airway and result in a greater incidence of laryngospasm, postoperative hoarse voice, and coughing. To conclude, PLMA is efficient with regards to the ease of insertion as evidenced by similar number of attempts required and the manoeuvers required. The time taken for insertion was also considerably less. The nasogastric channel provided a conduit to gastric chamber with similar success rates. The PLMA is an improvement on the cLMA for controlled ventilation. Insertion The PLMA offers an airway that bridges some of the gap between the cLMA and the TT. Thus, the PLMA can be used safely and effectively for airway maintenance during general anaesthesia under mechanical ventilation.

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