Clinical Investigation

ProSeal laryngeal mask airway improves oxygenation when used as a conduit prior to laryngoscope guided intubation in bariatric patients

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ABSTRACT

Background: The primary objective of this study was to compare the effect of ventilation using the ProSeal™ laryngeal mask airway (PLMA) with facemask and oropharyngeal airway (FM), prior to laryngoscopy, on arterial oxygenation in morbidly obese patients undergoing bariatric surgery. **Methods:** Forty morbidly obese patients were randomly recruited to either PLMA or FM. After pre-oxygenation (FiO_2 1.0) in the ramp position with continuous positive airway pressure of 10 cm H_2O for 5 min, anaesthesia was induced. Following loss of jaw thrust oropharyngeal airway, the FM and PLMA were inserted. On achieving paralysis, volume control ventilation with PEEP (5 cm H_2O) was initiated. The difficulty in mask ventilation (DMV) in FM, number of attempts at PLMA and laryngoscopy were graded (Cormack and Lehane) in all patients. Time from onset of laryngoscopy to endotracheal tube confirmation was recorded. Hypoxia was defined as mild (SpO_2 ≤95%), moderate (SpO_2 ≤90%) and severe (SpO_2 ≤85%). **Results:** Significant rise in pO_2 was observed within both groups (*P*=0.001), and this was significantly higher in the PLMA (*P*=0.0001) when compared between the groups. SpO_2 ≥ 90% (*P*=0.018) was seen in 19/20 (95%) patients in PLMA and 13/20 (65%) in FM at confirmation of tracheal tube. A strong association was found between DMV and Cormack Lehane in the FM group and with number of attempts in the PLMA group. No adverse events were observed. **Conclusion:** ProSeal™ laryngeal mask airway as conduit prior to laryngoscopy in morbidly obese patients seems effective in increasing oxygen reserves, and can be suggested as a routine airway management technique when managing the airway in the morbidly obese.

Key words: Bariatric, morbidly obese, oxygenation, ProSeal™

INTRODUCTION

Airway management in the obese patient can be challenging, as airway difficulties are often complicated by obesity.[1] The morbidly obese patients may require several attempts at intubation and have a greater likelihood of use of accessory airway devices.

Application of positive end expiratory pressure (PEEP) at induction of anaesthesia has been shown to prolong non-hypoxemic apnea time by preventing atelectasis in obese and non–obese patients.[2-6] Conventionally, facemasks with oropharyngeal airway (FM) have been used to ventilate patients following induction, prior to securing the tracheal tube. This is associated with continuous insufflation of gases into the stomach, which can further compromise the lung volumes and also increase propensity for regurgitation and aspiration. The ProSeal™ laryngeal mask airway (PLMA), by allowing an airtight seal, application of PEEP and drain tube for gastric decompression, can prove to be a useful tool in the airway management of morbidly obese patients.[7-9]

Although PLMA has been proven to be efficacious as a temporary ventilatory device in morbidly obese

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patients, its benefits have not been compared with facemask with oropharyngeal airway, more so in the context of arterial oxygenation, which has a direct influence on the non-hypoxemic apnea time.

We hypothesized that when PLMA is used as a conduit prior to laryngoscope-guided intubation, there is improvement in the arterial oxygenation. We conducted this randomized prospective study with the primary objective of comparing the effect of ventilation with PEEP, through PLMA with FM, on arterial oxygenation in morbidly obese patients undergoing laparoscopic surgery under general anaesthesia.

METHODS

With the approval of the Institutional Ethics Committee, and written informed consent from patients, a total of 40 patients with body mass index (BMI) >35 kg/m^2, of either sex and age more than 18 years, scheduled for elective procedure under general anaesthesia were recruited for the study. This investigation was registered with the Clinical Trials Registry-India (CTRI) and had the following registration number: "CTRI/2010/091/001133." Patients were randomly allocated (computer aided) to receive ProSeal™ laryngeal mask airway (PLMA) as airway device for group A and facemask with oropharyngeal airway (FM) of appropriate size for group B. Patients with restricted mouth opening <2.5 cm, any obvious difficult airway and any history suggestive of gastroesophageal reflux were excluded.

Patients were pre-medicated with ranitidine 150 mg per os 2 hours before anaesthesia with few sips of water. Standard monitors were applied prior to induction, including electrocardiograph, pulse oximeter, gas analyzer, arterial blood gas line, expired tidal volume and airway pressure monitors.

Patients were placed in the ramp position prior to induction of anaesthesia, made from a standard pillow and sheets to keep the external auditory meatus at the same level as the suprasternal notch. All patients were preoxygenated with 100% oxygen, with CPAP of 10 cm H_2O for 5 minutes. Following this, anaesthesia was induced with propofol (2-2.5 mg/kg); midazolam (0.01 mg/kg) and fentanyl (2 μg/kg) (based on lean body weight) with sevoflurane 1-2% and oxygen in air with FiO_2 (1.0). Anesthetics were titrated to maintain BIS between 40 and 60. Propofol was administered over 30 seconds. On achieving absence of jaw thrust the PLMA was inserted in group A and oropharyngeal airway of appropriate size was inserted in the group B the size of which was in accordance with the ideal body weight. The PLMA was secured as per manufacturer's guidelines, and the oropharyngeal leak pressure was determined. On any evidence of leak or inability to ventilate, the PLMA was removed and reinserted. In the event of the PLMA requiring more than three attempts to establish effective ventilation, patient was ventilated using FM in the conventional manner. Patient was ventilated using FM if the SpO_2 dropped to less than 90% between the attempts. Number of attempts at PLMA insertion was documented. On being able to ventilate, paralysis was achieved with atracurium 0.5 mg/kg. On being unable to establish ventilation using the PLMA or FM, the patient was allowed to wake up and alternative technique was opted for.

All patients were ventilated with tidal volume of 8-10 ml/kg, ideal body weight and PEEP of 5 cm H_2O for 5 minutes. Time to intubation was defined as interval between start of laryngoscopy to establishment of effective airway. This was judged by square wave capnograph trace and absence of audible leak at peak airway pressures of 25 cm H_2O during manual ventilation. Epigastric auscultation was performed to confirm absence of leak, following which a 14F gastric tube was passed and its position was confirmed by epigastric stethoscopy, any contents aspirated, and documented.

Quality of mask ventilation was assessed in group FM, and graded as grade 1 when no assistant was required to assist ventilation or jaw thrust, grade 2: When one assistant was required and as grade 3: When two assistants were required one to help elevate the jaw and the other to ventilate. After ventilation for 5 minutes in both groups, the PLMA and oropharyngeal airway were removed and laryngoscope-guided intubation was attempted using a McCoy laryngoscope (Trumphatek, Green spec Pro, CE). At laryngoscopy, Cormack and Lehane[10] scoring was done and graded as follows: Grade 1: When the glottis was visible with anterior and posterior commissures; grade 2: When the glottis was visible, but anterior commissures were not visible; grade 3: When glottis was not visible and only the corniculate cartilages were visible; grade 4: When the glottis and the corniculate cartilages were not visible. In case of failure to visualize the vocal cords, a gum elastic bougie was used or an alternative method was opted for. The number of attempts at

insertion of tube was recorded. A failed attempt was defined as more than three attempts at intubation. If at any point of time during laryngoscopy the SpO_2 dropped to less than 85%, the patient was ventilated using FM or PLMA as appropriate, prior to making the next attempt at laryngoscopy. SpO_2 was monitored continuously and documented baseline (SpO_2bl), at laryngoscopy (SpO_2ls) and after confirming endotracheal tube placement (SpO_2TT).

Hypoxia was defined as mild (SpO_2≤95%), moderate (SpO_2≤90%) and severe (SpO_2≤85%). Any adverse event was documented. Arterial samples were drawn at baseline; at laryngoscopy and soon after securing the tracheal tube. All cases were performed by anesthesiologists experienced in the management of morbidly obese patients and in PLMA insertion.

Residual gastric volume and pH of PLMA and oropharyngeal airway were determined in all patients.

Statistical analysis

We based our sample size estimation on the changes in PaO2 levels in the previous studies, to detect a 45% difference[2] in the mean values of PaO2 between the treatment and the control groups. To achieve 90% power at 1% level of significance we needed a minimum of 17 patients in each group. To account for any possible dropouts a minimum of 20 patients were recruited in each group. Randomization was done by using computer generated numbers, kept in sequentially numbered opaque envelopes. The sequence was generated by statistician, whereas enrolment and group allocation was done by anesthesiologist not involved in conducting the study or data collection.

Data were reported as mean ± SD/SEM (standard error mean), median and numbers (%) as found suitable. Relationships between categorical variables were tested using the Chi-square test or the Fisher's exact test. Two-sample *t*-test was used for comparison of normally distributed continuous variables between the two groups. For non-normal data, the Mann Whitney U test was used. *P* value less than 0.05 was considered as statistically significant. SPSS 17 statistics package (Chicago, IL USA) was used for the analysis.

The change in pO_2 (baseline, prior to laryngoscopy and post intubation) and SpO_2 were the primary outcomes. The $EtCO_2$, association of CL with DMV and number of attempts at PLMA insertion; and the gastric aspirate and pH of PLMA cuff and FM were the secondary outcomes of the study. The patients were recruited between June 2010 and October 2010.

RESULTS

Patient characteristics did not differ between the two groups [Table 1]. The PLMA and FM groups did not differ with respect to mallampati score (MPS) and CL grading. No patient required more than three attempts at intubation. Alternative technique at ventilation/ intubation was not needed in any patient.

Within groups, no association was found between MPS and difficult mask ventilation (DMV) and FM; and MPS with number of attempts at PLMA insertion. However a strong association was found between CL with DMV (FM group: *P*=0.002) and with number of attempts at ProSeal™ insertion (PLMA group: *P*=0.001) [Table 2].

Even though the time to intubation and pO_2 remained statistically comparable between the PLMA and FM groups at the time of TT placement (*P*=0.58), it was clinically significant. The median time in PLMA (47 sec) was more than the median time in the FM (32.5 sec). There were five patients in the PLMA and three in the FM group who required more than 60 seconds to achieve intubation (*P*=0.695). The minimum pO_2 (mmHg) reached at laryngoscopy in

Table 1: Demographic characteristics

	PLMA (*n*=20)	FM (*n*=20)	*P* value
Age (year)	40.9±13.6	39.25±13.2	
Weight (kg)	125.05±26.4	127.17±18.7	
BMI (kg/m^2)	46.78±7.86	45.7±5.92	
Anaesthesia duration (minutes)	189 (165-220)	194 (170-230)	0.286
Surgery duration (minutes)	110 (75-170)	128 (90-175)	0.016

Data are displayed as mean±standard deviations and numbers (*n*); Median (range); No significant differences were noted among the two groups; PLMA – ProSeal™ laryngeal mask airway; FM – Face mask with oropharyngeal airway; BMI – Body mass index

Table 2: Association of difficult mask ventilation and mallampati score with Cormack and Lehane grade in face mask and with number of attempts at insertion in ProSeal™ laryngeal mask airway group

	FM (*n*=20)	PLMA (*n*=20)	*P* value
Mallampati score			
Attempts (1/2/3)	0	17/2/1	0.481
Cormack and Lehane			
DMV (1/2/3)	16/3/1	0	0.002*
Attempts (1/2/3)	0	17/2/1	0.001*

DMV – Difficult mask ventilation; PLMA – ProSeal™ laryngeal mask airway; FM – Face mask with oropharyngeal airway

the FM and the PLMA groups was 91 and 168 and at TT placement was 78 and 91 respectively. The minimum SpO_2% reached at the time of confirmation of TT in the PLMA and FM groups was 92 and 72 respectively [Table 3].

Pre-induction SpO_2 (baseline) and at the time of laryngoscopy SpO_2 (LS) did not differ between the groups. However after ventilation using VCV and PEEP, the pO_2 (mmHg) at the time of laryngoscopy showed significant increase within both PLMA (P=0.001) and the FM (P=0.001) groups [Figure 1 and Table 4].

The rise in pO_2 (mmHg) in the PLMA group was significantly higher than in the FM group (P=0.0001).

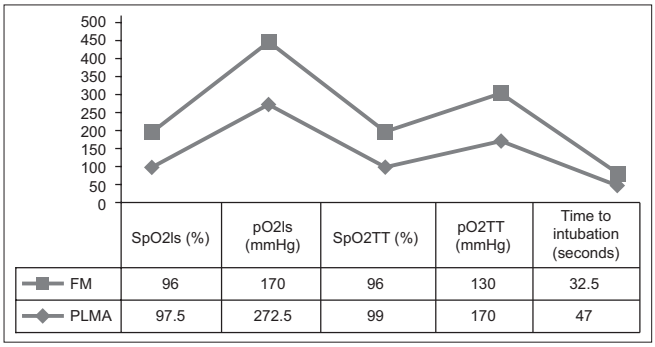

Figure 1: Variation in the median SpO_2 and pO_2 from laryngoscopy to tracheal tube placement after ventilation with volume control ventilation with PEEP for 5 minutes

Table 3: Comparison of various parameters between the ProSeal™ laryngeal mask airway and face mask groups

	PLMA (n=20)	FM (n=20)	P value
SpO_2 baseline	97.5 (89-100)	96 (91-100)	0.652
SpO_2 laryngoscopy	97.5 (94-100)	97 (68-99)	0.291
SpO_2 tracheal tube	99 (92-100)	96 (72-100)	0.041*
pO_2 baseline	70 (53-99)	66.85 (54-81)	0.053
pO_2 laryngoscopy	272.5 (168-526)	170 (91-288)	<0.0001*
pO_2 tracheal tube	171 (91-254)	130.5 (78.70-188)	0.010*
Time to intubation (s)	47 (14-88)	32.5 (16-98)	0.58
Time<60 s	15	17	P=0.695
Time≥60 s	5	3	
pH	5 (3-6)	5 (3-6)	P=0.20
Gastric aspirate (ml)	0 (0-20)	5 (0-20)	P=0.340

PLMA – ProSeal™ laryngeal mask airway; FM – Face mask with oropharyngeal airway;*P<0.05 is significant between groups

The $EtCO_2$, pH of the devices and the gastric aspirate in both groups remained comparable.

DISCUSSION

We observed that the reserves of oxygen can be significantly improved/influenced by the use of PLMA as a conduit prior to laryngoscopy in morbidly obese patients undergoing surgery under general anaesthesia. We compared the arterial oxygenation as measured by PaO_2 in 40 morbidly obese patients who received either PLMA or FM with oropharyngeal airway.

Airway management in the morbidly obese is centered around ventilatory strategies to increase oxygen reserves and to prevent critical desaturation at laryngoscopy.[10-13]

Even though the role of BMI as a predictor of difficult airway is controversial,[14-16] the fact remains that these patients have limited oxygen reserves, higher metabolic demands and alterations in the anatomy that vary exponentially with the BMI, even at high percentages of inspired oxygen.[14,17] There is a higher incidence of baseline hypoxemia and hypercarbia,[18-22] such that superadded changes in lung functions following induction of general anaesthesia in the obese seriously impair the effectiveness of pre-oxygenation.[19] Desaturation of arterial blood following onset of apnea sets in within a significantly shorter time than in the non-obese. Airway in these patients is more prone to collapse and occlusion; hence, maintenance of its patency and ventilation are of paramount importance in preventing oxygen desaturation, which can be precipitous. As repeat laryngoscopy efforts carry significant risks, the upper airway management in morbidly obese patients mandates a management strategy that would optimize the inspired oxygen fraction and allow sufficient time for securing airway without producing hypoxemia. Pre-oxygenation and positive pressure ventilation at induction are significant steps toward increasing the oxygen reserves and minimizing the risk of hypoxemia that may be associated with difficult mask ventilation, laryngoscopy and tracheal intubation in a morbidly

Table 4: Change in pO_2 from baseline to laryngoscopy and thereafter to tracheal tube placement within ProSeal™ laryngeal mask airway and face mask groups

	pO_2 baseline	pO_2 laryngoscopy	P value	pO_2 tracheal tube	P value
PLMA (n=20)	70 (53-99)	272.5 (168-526)	<0.001*	171 (91-254)	<0.001*
FM (n=20)	66.85 (54-81)	170 (91-288)	<0.001*	130.5 (78.7-188)	<0.001*

PLMA – ProSeal™ laryngeal mask airway; FM – Face mask with oropharyngeal airway; Values are expressed as median and range; *P<0.05 shows the variation is statistically significant

obese patient. Application of CPAP of 10 cm H_2O for 5 min during pre-oxygenation, mechanical ventilation with PEEP during mask application, with patient in 25° head up tilt has been found to be associated with minimal atelectasis, giving optimum results. This has been objectively analyzed by measuring the non-hypoxemic apnea time and serial computer tomography scans, and has proven to be a useful manoeuvre in increasing oxygen reserves and preventing atelectasis in the morbidly obese.

The risk of hypoxia can be complicated by the increased incidence of regurgitation and aspiration in this subpopulation. PLMA by virtue of drain tube allows continuous decompression of the stomach at the time of ventilation and isolates the respiratory tract.

Change of airway device from facemask to PLMA in the described technique provided a statistically significant rise in the arterial pO_2. Even though the mean time to achieve intubation or the non-hypoxemic apnea time between the two groups was comparable, the improved reserves of oxygen could be beneficial in cases of difficult intubation or patients who would require more attempts at intubation or PLMA insertion.

There were a statistically and clinically significant number of patients who maintained $SpO_2 \geq 95\%$.

Nine patients in the FM group and three patients in the PLMA group developed mild hypoxia ($SpO_2 \leq 95$ (P=0.03)) and two patients in the FM group (10%) and one patient in the PLMA group (5%) became severely hypoxic ($SpO_2 \leq 85\%$) during intubation. There were 19/20 (95%) patients in the PLMA group and 13/20 (65%) patients in the FM group with SpO2 ≥ 90% (P=0.018) at the time of confirmation of TT placement. Thus, by allowing continuous decompression of stomach during mechanical ventilation, airtight seal and application of PEEP effectively, with the use PLMA, the duration of non-hypoxic apnea time could be increased in conjunction with other manoeuvres.

Another important finding of this study is that no association was found between MPS and DMV or number of attempts of PLMA insertion, whereas both DMV and number of attempts had a strong association with CL.

DMV in the general population may range from 0.07% to 15%. DMV may be encountered prior to attempting intubation or even after intubation failure.[23] Intubating LMAs and ProSeal™ LMA have been considered a superior alternative to classic LMA for managing difficult airway in the morbidly obese.[13] Effective ventilation, comparable to non-obese patients, was possible in all patients of the PLMA group, and no leaks were found during the oropharyngeal airway pressure leak test.

We found that number of attempts at PLMA insertion and DMV were strongly associated with CL grading; however, there was no incidence of failed PLMA insertion or failed intubation. Our study was limited by its small sample size, as a larger sample will be required to suggest an association of Cormack and Lehane grading with difficulty in mask ventilation and number of attempts at PLMA insertion in this sub-population.[23-25]

There are conflicting reports of gastric fluid pH <2.5 and residual gastric fluid volume >25 ml in the morbidly obese. We included patients with no history suggestive of GERD. None of the patients were found to have gastric fluid volume greater than 20 ml. The mean volume of the gastric fluid aspirated did not differ between the two groups. Also, the pH of the device did not differ between the groups. Some workers have suggested that the obese and non-obese patients are comparable in terms of resistance gradient between stomach and gastroesophageal junction, and gastric emptying. Also, the use of cricoid pressure to prevent passive regurgitation has been challenged. Patients with history suggestive of gastroesophageal reflux were not included in this study and cricoid pressure was not applied in any patient.[26-30] The pH of the devices, immediately prior to laryngoscopy, did not differ.

Safe intubation of these patients requires careful attention to be paid to optimize pre-oxygenation and to prevent de-oxygenation under a controlled fashion. Moreover, airway in the morbidly obese should be handled by anesthesiologists who have the expertise and who are aware of the limitations associated with it for the safe conduct of oxygenation. Whether the PLMA can be used for conducting longer procedures needs to be researched. More research is required to define methods to achieve these goals.

CONCLUSION

Application of PEEP using ProSeal™ laryngeal mask

airway as a conduit prior to laryngoscopy is effective in increasing the oxygen reserves and can be suggested as beneficial when managing the airway in the morbidly obese.

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