Comparison of ventilatory efficacy and airway dynamics between ProSeal laryngeal mask airway and endotracheal tube in adult patients during general anesthesia

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Abstract

Background and Aims: Studies have demonstrated minimal hemodynamic variation and postoperative complications with ProSeal laryngeal mask airway (PLMA) compared to endotracheal tube (ETT). Hence, a study was conducted to compare the ventilatory parameters and airway dynamics required to maintain normocarbia and stable hemodynamics with PLMA and ETT.

Material and Methods: A prospective, randomized, single blinded study was conducted on 60 patients aged 20-40 years of American society of anesthesiologists class I and II, divided into Group PLMA and Group ETT. Standard anesthesia protocol was instituted. Group PLMA received PLMA sizes as per manufacturer’s recommendations and group ETT received appropriate sized cuffed ETT. Patients were initially ventilated at 14 bpm, I:E ratio 1:2, tidal volume (Vt) 6 ml/kg and later adjusted to maintain end tidal carbon dioxide (EtCO₂) between 35 and 40 mmHg. Peak airway pressure (Ppeak), compliance (Compl.), Vt, airway resistance (Rₐₐₜ), hemodynamic parameters, oxygen saturation (SpO₂) and EtCO₂ were recorded throughout surgery. Postoperative complications if any, were noted.

Results: Demographic parameters, Rₐₐₜ, EtCO₂, SpO₂ were comparable between groups. Ppeak was lower and Vt needed to maintain EtCO₂ of 35-40 mmHg was lesser in Group PLMA. Compl was low for 5 min after insertion of PLMA. Heart rate was significantly reduced at 1 min post insertion; blood pressures were significantly lower upto 2 min after insertion and post removal in group PLMA. Incidence of cough was significantly lower in group PLMA.

Conclusion: ProSeal laryngeal mask airway maintains adequate ventilation at lower Vts and minimal peak pressures, has lesser hemodynamic variations and lower incidence of postoperative cough compared to ETT.

Key words: Airway dynamics, endotracheal tube, peak airway pressure, positive pressure ventilation, ProSeal laryngeal mask airway, ventilatory parameters

Introduction

The cuffed endotracheal tube (ETT) has for long been considered the gold standard for securing airway, especially for procedures under general anesthesia. The disadvantages of laryngoscopy and tracheal intubation are concomitant hemodynamic responses and damage to the oropharyngeal structures. Postoperative hoarseness of voice with ETT is a major concern. Laryngeal mask airway (LMA) was used instead to obviate the shortcomings of ETT. However, risk of gastric distension and inadequate ventilation with LMA remained until the discovery of ProSeal LMA (PLMA) in early 2000. PLMA has a dorsal cuff, in addition to the peripheral cuff of LMA, which pushes the mask anterior to provide a better seal around the glottic aperture and permits use of high airway pressures without leak. The drain tube parallel to the ventilation tube permits passive drainage of regurgitated gastric fluid away from the airway and serves as a passage for gastric tube.

Many studies have compared PLMA with ETT for ease of insertion, hemodynamic changes, and postoperative airway complications. Idrees and Khan observed comparable peak airway pressures (Ppeak) with both LMA and ETT. Few have compared the ventilatory efficacy and changes in airway dynamics seen with use of PLMA and ETT in positive...
pressure ventilation. Literature search revealed only studies measuring the resistive load of LMA and PLMA. Hence, this study was conducted with the aim of comparing ventilatory parameters and airway dynamics, needed to maintain a state of normocarbia and stable hemodynamics, and postoperative complications between PLMA and ETT in adult patients under general anesthesia.

### Material and Methods

A prospective, single blinded, randomized controlled clinical trial was undertaken and sample size was calculated by keeping power of study at 80% and confidence limits at 95%. To detect a 10% difference in tidal volume (Vt), a minimum of 14 patients were required in each group. We enrolled 30 patients undergoing elective surgeries under general anesthesia, in each group for better authenticity of results. Institutional ethics committee approval was obtained and informed written consent was obtained from patients.

Patients were randomly allocated using numbers generated from www.random.org into Group PLMA and Group ETT. Patients belonging to American society of anaesthesiologists physical status I and II aged between 20 and 40 years of either sex were included. Patients with anticipated difficult airway, hiatus hernia, gastroesophageal reflux disease, Body mass index >35 kg/m², head and neck surgeries, patients suffering from respiratory pathology and patients undergoing laparoscopic surgeries were excluded from the study.

All patients were premedicated with oral alprazolam 0.5 mg and ranitidine 150 mg on the night before surgery and were kept fasting overnight. After shifting to the operation theatre, pulse oximeter, electrocardiograph and noninvasive blood pressure monitors were connected and basal parameters recorded. Intravenous access was obtained, patients were administered Inj. Midazolam 0.03 mg/kg, Inj. Glycopyrrolate 5 μg/kg, Inj. Fentanyl 2 μg/kg 2 min before induction. After preoxygenation with 100% O₂ for 3 min, anesthesia was induced with Inj. Propofol 2 mg/kg and intubation/insertion of device was facilitated by Inj. Succinyl choline 1.5 mg/kg. Airway was secured with respective airway devices. In group PLMA, either PLMA size 3 (weight 30-50 kg) or PLMA size 4 (weight 51-70 kg) was inserted. In group ETT, trachea was intubated under direct laryngoscopy using 7.5 mm ETT in female patients or 8.5 mm ID in male patients. Correct placement of device was facilitated by Inj. Succinyl choline 1.5 mg/kg. Airway was secured with respective airway devices. In group PLMA, either PLMA size 3 (weight 30-50 kg) or PLMA size 4 (weight 51-70 kg) was inserted. In group ETT, trachea was intubated under direct laryngoscopy using 7.5 mm ETT in female patients or 8.5 mm ID in male patients. Correct placement of device was confirmed by adequate chest movement on ventilation and square wave on capnography.

Adequacy of tight seal was confirmed by absence of audible leak from drain tube (PLMA) at Ppeak of 20 cm H₂O in PLMA group. In ETT group, cuff was inflated until there was no audible leak on auscultation over trachea. Train of four (TOF), airway dynamics and ventilatory parameter monitors were connected following insertion of airway device.

Ventilator settings consisted of respiratory rate 14 cycles/min, inspiratory: Expiratory ratio 1:2, fresh gas flow 2 L/min. Vt was set at 6 ml/kg initially and adjusted subsequently with 1 ml/kg increments or decrements in Vt if required, to maintain end tidal carbon dioxide (EtCO₂) between 35 and 40 mm Hg. Anesthesia maintained with 65% N₂O in oxygen, Isoflurane 1-1.5% to maintain entropy values between 40 and 60. Inj. Atracurium 0.3 mg/kg bolus followed by infusion of 8-10 μg/kg/min to maintain TOF count <1. Residual neuromuscular blockade was reversed at the end of the surgery using Inj. Neostigmine 0.05 mg/kg and Inj. Glycopyrrolate 0.01 mg/kg.

Peak airway pressure, Vt, compliance (Compl.), airway resistance (Rₘₐₓ), EtCO₂ were recorded every minute after insertion for first 5 min and later every 10 min. Other vital parameters such as heart rate (HR), systolic and diastolic BP, mean arterial pressure (MAP), oxygen saturation (SpO₂), EtCO₂ were recorded after insertion of airway device, every minute for 1st 5 min and then every 5 min till the end of surgery. Adequacy of ventilation was ensured by continuous monitoring of end tidal carbon dioxide and oxygen concentrations.

All parameters were recorded on spirometry and gas analysis module of S5 Avance Datex Ohmeda™ anesthesia workstation. Leak fraction was measured by comparing the inspired and expired Vt. Patients were excluded from study, if a difference of >3% between set and inspired Vts, or a leak fraction >10% was observed.

After removal of airway device, any complications such as coughing, laryngospasm, blood staining of airway device, tongue/dental trauma, and hoarseness of voice were observed.

Data were analyzed using the SPSS version 17.0 Chicago, IL, USA statistical software. Fischer exact test and Chi-square test were applied for nominal data. Student t-test was used for parametric data. Repeat measures of ANOVA were used for intergroup evaluation. P < 0.05 was considered as statistically significant.

### Results

Demographic data of age, sex, weight and duration of surgery were comparable between the groups [Table 1]. Ease of insertion was comparable between the groups. Mean time for insertion of airway device in group PLMA
was 16.43 ± 12.31 s, and in group ETT it was 13.66 ± 8.04 s (P = 0.308). Airway device was inserted in the first attempt in 28 patients in group PLMA as compared to 29 in group ETT. One patient in either group needed second attempt for securing airway, and one patient of Group PLMA required 3 attempts. However, these were not statistically significant.

Mean SpO2 in Group PLMA was 99.40 ± 0.0695% and in Group ETT, it was 98.45 ± 0.83% (P = 0.50). SpO2 was maintained between 97% and 100% in all patients. Mean EtCO2 was 35.11 ± 2.82 mm Hg in Group PLMA and 37.12 ± 3.17 mm Hg in Group ETT (P = 0.656) [Table 2].

The Vt initially set at 6 ml/kg was comparable in both groups (Group PLMA-318 ± 41.96 ml, Group ETT-329.67 ± 43.98 ml P = 0.276). Mean adjusted Vt to maintain EtCO2 between 35 and 40 mm Hg was 317.68 ± 51.90 ml in Group PLMA as compared to 411.55 ± 65.71 ml in Group ETT (P < 0.01). The average difference between set Vt and adjusted Vt in Group PLMA was 0.31 ml (P = 0.974) as compared to 81.89 ml (P < 0.01) in Group ETT. In Group ETT the Vt had to be increased significantly from set Vt to maintain EtCO2 between 35 and 40 mm Hg.

The mean Compl. in Group PLMA was 29.02 ± 4.54 ml/cm H2O while in Group ETT it was 33.52 ± 2.89 ml/cm H2O. The values were statistically significant in the 1st 5 min after insertion of airway device (P < 0.05). Mean Ppeak in Group PLMA was 12.95 ± 2.62 cm of H2O as compared to 16.02 ± 2.59 cm of H2O in Group ETT (P = 0.003) and was statistically significant throughout the surgery. Mean R2 in Group PLMA was 10.65 ± 2.88 cm H2O/L/s compared to 10.01 ± 2.05 cm H2O/L/s in Group ETT (P = 0.256) [Figure 1].

Heart rate was significantly lesser in the 1st min after insertion in Group PLMA (P = 0.043), but comparable subsequently throughout surgery in both groups. The Systolic, diastolic and MAP’s were lower in Group PLMA at 1st and 2nd min following insertion and after removal (P < 0.05) [Figure 2].

Coughing was seen in one patient in group PLMA as compared to 10 patients in group ETT, this was statistically significant (P = 0.006). One case of laryngospasm was encountered in Group ETT. Two cases of voice hoarseness was seen in Group ETT. Incidence of blood staining of device was comparable in both groups, 10 cases in Group PLMA and 16 cases in Group ETT. These values were not statistically significant [Table 3].

### Discussion

In the present study, PLMA maintained adequate ventilation using lower Vt and Ppeak compared to ETT. Unlike previous studies, where only Ppeak was assessed, this study attempts to assess various additional parameters of respiratory mechanics, making it unique.

Achieving adequate ventilation and maintaining a state of normocarbica is of paramount priority in positive pressure ventilation. Marcus Schultz et al., in their review, observed that lower Vt ventilation strategy had lesser incidence of developing acute lung injury in patients undergoing major abdominal, thoracic, and cardiovascular surgeries.[10] In our study the average Vt needed to achieve adequate ventilation, as evidenced by SpO2 and EtCO2, was significantly lower in PLMA group. Berry and coworkers compared performance

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**Table 1: Demographic data**

| Parameter                  | Group PLMA     | Group ETT     | P     |
|----------------------------|----------------|--------------|-------|
| Age (years)                | 29.16±6.07     | 32.50±7.25   |       |
| Weight (kg)                | 52.23±7.29     | 53.60±7.42   |       |
| Sex (male/female)          | 9/21           | 12/18        |       |
| Duration of surgery (min)  | 43.33±11.35    | 42.67±11.70  |       |

**Table 2: SpO2, EtCO2, tidal volume and insertion details**

| Parameter                  | Group PLMA     | Group ETT     | P     |
|----------------------------|----------------|--------------|-------|
| SpO2 (%) (mean±SD)         | 99.40±0.07     | 98.45±0.83   | 0.50  |
| EtCO2 (mm of Hg) (mean±SD) | 35.11±2.82     | 37.12±3.17   | 0.656 |
| Initial Vt (ml) (mean±SD)  | 318±41.96      | 329.67±43.98 | 0.276 |
| Average Vt (ml) (mean±SD)  | 317.67±51.90   | 411.55±65.71 | <0.001*|
| Insertion time (s) (mean±SD)| 16.433±12.31  | 13.66±8.04   | 0.308 |

**Table 3: Insertion details**

| Insertion attempt | Group PLMA | Group ETT | P     |
|-------------------|------------|-----------|-------|
| 1st               | 28/30      | 29/30     | 0.601 |
| 2nd               | 1/30       | 1/30      |       |
| 3rd               | 1/30       |           |       |

*P < 0.05 = Statistically significant, $Tidal volume, SD = Standard deviation, PLMA = ProSeal laryngeal mask airway, ETT = Endotracheal tube, EtCO2 = End tidal carbon dioxide, SpO2 = Oxygen saturation
Natalini et al. observed that in obese patients undergoing general anesthesia, the P peaks were comparable between PLMA and LMA. In the present study, the P peaks was significantly lesser in PLMA group throughout surgery while the Raw was comparable in both groups. Though the internal diameter of airway tube of ProSeal LMA is narrow compared to that of ETT in the present study, the shorter length of ProSeal LMA compared to that of ETT might be the nullifying factor accounting for similar $R_{sw}$ in both groups. All possible precautions were taken to minimize leak fraction and patients with leak fraction >10% were excluded. Cook TM et al. compared PLMA with laryngeal tube; it was observed that P peaks were clinically comparable between both devices. Peripheral SpO$_2$ and EtCO$_2$ monitoring have been considered as measures of adequate ventilation. SpO$_2$ and EtCO$_2$ were comparable in both groups in our study indicating adequate ventilation with both the devices.

We did not notice a difference between inspired and expired oxygen concentration of >5% in any of the patients.

Higher P peaks and large Vts have been implicated as risk factors for development of barotrauma and volutrauma in critically ill mechanically ventilated patients. The PLMA maintained adequate ventilation at lower Vts and airway pressures as compared with ETT. Hence, possibility of barotrauma and volutrauma with PLMA may be low as compared to ETT. Lower Compl. and lower P peaks noticed in patients receiving PLMA may be due to lower Vts used during mechanical ventilation. Types of surgeries in both groups were comparable thus the possible effects of surgery on airway parameters are ruled out.

Sympathetic stimulation by laryngoscopy and intubation is known to induce hemodynamic response during ETT insertion. PLMA being a supraglottic device does not evoke such a response. Similar to other studies, we observed that hemodynamic parameters were lower in PLMA group immediately after insertion of airway device and also soon after removal the same, though HR did not alter in post removal period in PLMA group.

The incidence of coughing and hoarseness of voice was lower with PLMA as it is a supraglottic device. The patient who developed laryngospasm in group ETT was reintubated and electively ventilated for 20 min with 40% oxygen, which was followed by uneventful recovery.

There are limitations in the present study:
1. The double blinding was not possible in this study.
2. Incidentally most of the surgeries were of short duration lasting for 40-60 min. Hence the implications of this study need to be extrapolated with caution, to situations requiring longer duration of mechanical ventilation.

Table 3: Side effects

| Parameter     | Group PLMA (n = 30) | Group ETT (n = 30) | P       |
|---------------|---------------------|--------------------|---------|
| Coughing      | 1                   | 10                 | 0.006*  |
| Laryngospasm  | 0                   | 1                  | 0.492   |
| Blood staining| 10                  | 16                 | 0.192   |
| Hoarseness    | 0                   | 2                  | 0.237   |

*S statistically significant, PLMA = ProSeal laryngeal mask airway, ETT = Endotracheal tube.
3. Late postoperative complications such as sore throat were not included in observations since it was focused mainly on intraoperative airway dynamics.

Conclusion

The PLMA maintains adequate ventilation at significantly lower Vls and peak pressures without increasing Ṙaw, and has minimal hemodynamic variations compared to ETT. The PLMA has lower incidence of postoperative cough compared to ETT.

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