



COMPARISON OF PROSEAL LARYNGEAL MASK AIRWAY VS ENDOTRACHEAL TUBE FOR LAPAROSCOPIC SURGERY

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ABSTRACT **BACKGROUND:** We want to evaluate the effectiveness of Proseal LMA over endotracheal tube for laparoscopic procedures, by assessing the hemodynamic changes and gastric distension.

STUDY DESIGN: It is a randomized prospective comparative study conducted in 40 adult patients of either sex between the age group of 18 – 60 years. Patients are randomized into 2 groups such as Group I – Endotracheal tube & Group II – Proseal LMA and compared based on hemodynamic changes like heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure and gastric distension. The differences in the proportions are tested for statistical significance using non-parametric Chi-square test for variables measured on nominal scale. When testing for two factors, the Mann-Whitney “U” test or Wilcoxon two sample test is used. For variables measured on a continuous scale, when testing for two groups, Student “t” test is used to test for statistical significance in the differences of the two means.

RESULTS: The PLMA group maintained better haemodynamic stability than ETT group throughout the procedure. There was no significant difference between the two groups based on gastric distension score.

CONCLUSION: On comparing Proseal LMA and endotracheal tube for laparoscopic surgeries, it was found that the hemodynamics were more stable when Proseal LMA was used. Proseal LMA was as effective as endotracheal tube during positive pressure ventilation in preventing gastric distension and aspiration when correctly placed.

KEYWORDS : Proseal LMA, Endo tracheal tube, Hemodynamics, Gastric distension, Laparoscopic surgeries.

INTRODUCTION

Combining the advantages of a non-invasive facemask and the more invasive tracheal tube, the laryngeal mask airway was created to fill an important functional gap that existed between standard methods of airway control that were in use then. Though the LMA has provided the convenience of “Hands-free” anesthesia, for some anesthesiologists, the combination of LMA and positive pressure ventilation evokes fear of inadequate ventilation, gastric distension and pulmonary aspiration of gastric content. To overcome the above complications Dr. Archie Brain, designed the proseal LMA (PLMA) and it was introduced in 2000. Modifications were designed to enable separation of gastrointestinal and respiratory tracts, improve airway seal, enable positive pressure ventilation and diagnose mask displacement. A drain tube (DT) enables diagnosis of mask misplacement and also aims to reduce risks of gastric inflation, regurgitation and aspiration of gastric contents. Hence a prospective randomized study was designed to compare the Proseal LMA and Endotracheal tube regarding haemodynamic changes, positive pressure ventilation and gastric distension during laparoscopic procedures. The aim of the study was to evaluate the effectiveness of Proseal LMA compared to endotracheal tube during laparoscopic procedures based on the Haemodynamic Changes, Ventilatory Parameters and Gastric Distension.

MATERIALS AND METHODS

This study was a randomized prospective comparative study. After obtaining patients written informed consent and institutional ethical committee clearance, the study was carried out in the General Surgery Operation Theatre. The study was conducted in 40 adult patients of either sex between the age group of 18 – 60 years belonging to ASA – I & II posted for elective laparoscopic surgeries (Cholecystectomy & Appendectomy). The exclusions are, known difficult airway, cervical spine disease, mouth opening < 2.5cm, patients with risk of aspiration like h/o hiatus hernia, reflux esophagitis. Patients were randomized into 2 groups

- 1) Group I – Endotracheal tube (ETT) for airway management
- 2) Group II – Proseal LMA (PLMA) for airway management

All Patients were fasted overnight. They were given aspiration prophylaxis with Inj-Ranitidine 50mg I.V. and Inj-Metoclopramide 10mg I.V. 1 hr before surgery^{11,12}. Patients premedicated with Inj-Glycopyrrolate 0.2mg 1hr before surgery. After the placement of monitoring devices and preoxygenation, all the patients were induced with Inj-Propofol 2.5mg/kg I.V., Inj. Fentanyl 2mic/kg I.V., and Inj-

Vecuronium 0.1mg/kg I.V. Patients were intubated with cuffed ETT of appropriate sizes in the group ETT and appropriate sizes of the PLMA in the PLMA Group.

Group ETT

For women ETT size 7.0/7.5mm and for males size 8.0/8.5mm was used. Cuff inflated to maximum of 25-30cm H₂O. Position was confirmed clinically and with capnography. After placement of ETT, Ryle's tube was introduced for continuous drainage.

Group PLMA

In the PLMA Group PLMA was introduced as per the body weight chart. The mask was inserted using the index finger as recommended by the manufacturer. The cuff was inflated to a pressure of 60cm H₂O, which was maintained at this pressure throughout the procedure with cuff pressure monitor. Closed circle breathing system with soda lime was used. Correct placement of the device was confirmed clinically and by capnography. In addition the following tests were carried out to check whether the PLMA was correctly placed are Square wave capnography, The gel displacement test¹⁰, The suprasternal notch test⁹. No. of attempts were noted. A maximum of three insertion attempts were allowed before placement of the device was considered failure. Anesthesia was maintained with N₂O: O₂ (2:1), Isoflurane 1% and neuromuscular blockade maintained with inj. Vecuronium 0.02mg/kg. Positive pressure ventilation with mechanical ventilator was instituted with a set tidal volume of 8ml/kg, FiO₂ 0.33%, respiratory rate 12 b/p/m I/E of 1:2 in both the groups. The following parameters were noted intra-operatively. Heart rate, systolic, diastolic and mean blood pressure before induction, and 1min, 5min after insertion of PLMA / intubation with ETT and 5 min after achieving pneumoperitoneum and then at every 5min intervals. Saturation (SpO₂) and end tidal CO₂ (ETCO₂), was observed in same manner. SpO₂ was maintained > 95% and ETCO₂ < 45, by adjusting the FiO₂, respiratory rate, and tidal volume. A peak airway pressure was recorded in the same time points and the intra-abdominal pressure was kept between 12 to 14mm Hg. All the patients in the PLMA group were tested for any occurrence of regurgitation using litmus paper postoperatively. Residual blockade was reversed with 1.2mg atropine and 2.5mg neostigmine. Post operatively the following problems were noted, Cough, Sore throat, Nausea, Vomiting.

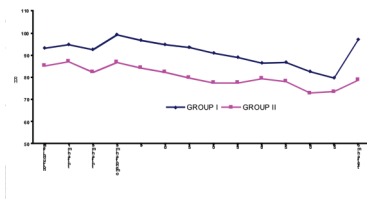
OBSERVATION AND RESULTS

The proseal LMA (PLMA) and Endotracheal Tube (ETT) were compared based on the following parameters, Haemodynamic

Changes like Heart rate, Systolic blood pressure, Diastolic blood pressure, Mean arterial pressure before induction, 1min, 5min after intubation/insertion, 5min after pneumoperitoneum and then every 5min till extubation, then 5min after extubation. Ventilatory Parameters like End tidal CO_2 ($ETCO_2$), Oxygen saturation (SpO_2), Tidal volume Respiratory rate, FiO_2 , Airway Pressure, Also noted as the same manner as above, Gastric distension, No. of attempts of insertion / intubation, No. of attempts to pass a Ryle's tube. A total of 20 cases each was randomly allocated to one of the following two groups of study viz. Group I – Endo tracheal Tube (ETT); Group II – Proseal LMA.

The descriptive statistics of the variables studied are represented as two-way tables. The categorical factors are represented by the number and frequency (%) of cases. The continuous variables are represented by means of central frequency and deviation. The differences in the proportions are tested for statistical significance using non-parametric Chi-square test for variables measured on nominal scale. When testing for two factors, the Mann-Whitney "U" test or Wilcoxon two sample test is used. For variables measured on a continuous scale, when testing for two groups, Student "t" test is used to test for statistical significance in the differences of the two means. The mean age was observed to be almost the same in Group I than Group II and not statistically significant. A male preponderance is forthcoming in Group II but the difference in the distribution between the two groups is not statistically significant. The distribution of cases by weight and the difference in the mean values are observed to be not statistically significant between Group I and Group II.

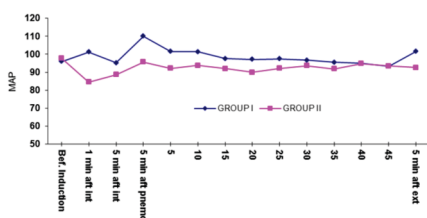
MEAN DISTRIBUTION OF HR VALUES BY GROUP



The distribution of cases by grade of Heart Rate (HR) and the mean values were observed to be generally statistically significant between Group I (ETT) and Group II (PLMA) at the majority of different time points viz. between 5 minute after intubation and 25 min, at 40 min and 5 min after extubation.

The distribution of cases and the mean values of systolic blood pressure were observed to be generally statistically significant between Group I and Group II at the majority of different time points viz. at 1 minute after intubation, between 5 minutes after pneumoperitoneum and 25 min and at 5 minutes after extubation. The distribution of cases and the mean values of diastolic blood pressure were observed to be statistically significant between Group I and Group II at the following different time point's viz. 1 minute after intubation, 5 minutes after pneumoperitoneum, and 5 minute after extubation.

MEAN DISTRIBUTION OF MAP VALUES BY GROUP



The distribution of cases and the mean values of MAP were observed to be statistically significant between Group I and Group II at the following different time points viz. 1 minute after intubation, between 5 minutes after pneumoperitoneum and 20th hour and 5 minute after extubation.

DISCUSSION

In this study, the heart rate, systolic blood pressure, diastolic blood pressure, mean arterial blood pressure were monitored before induction, 1 min, 5 min after insertion / intubation, then 5 min after pneumoperitoneum, and every 5min till end of surgery and 5 min after

Extubation / Removal, and compared between Group I (ETT) and Group II (PLMA). The distribution of cases by grade of HR, SBP, DBP and MAP, the mean values were observed to be statistically significant ($P < 0.05$) between Group I (ETT) and Group II (PLMA) at every time points mentioned above. The Group II PLMA is more hemodynamically stable than Group I ETT which was in concordance with the study done by **EC-Ganzavria et al**⁴. The distribution of cases by grade of SPO₂, $ETCO_2$, TV & RR, FIO_2 , and Airway Pressure, the mean values were not statistically significant ($P > 0.05$) between Group I (ETT) & Group II (PLMA) at every time point mentioned above. This was in concordance with studies done by **maltby et al**^{3,4} and **piiper SN et al**⁵. The overall proseal LMA insertion success reported in 33 studies, and 2,581 PLMA insertions ranged from 90-100%^{1,5,7,13,14}. First time proseal LMA insertion success reported in 28 studies, and 2,388 PLMA insertions ranges from 76% to 100%^{1,2,5,11,13,14}. In this study the PLMA was correctly placed in first attempt in 18 cases (90%). In 1st patient PLMA could not be placed correctly even after 3 attempts. And in the 2nd patient the PLMA was inserted in the second attempts. This goes with accordance with the above mentioned studies. Endotracheal intubation was successful in first attempt in all 20 cases. Regarding orogastric Tube (OGT) insertion, seventeen studies with 1,384 attempts via PLMA drain tube reported 95% first time OGT passage^{1,2,3,6,15,16}. Higher success rates for OGT passage (up to 100%) are reported when efforts are made to eliminate folding of mask tip^{6,8}. In this study OGT insertion was a success in first attempt in 18 (90%) cases and in second attempt in 2 cases via PLMA drains tube. OGT insertion after intubating with ETT was successful in the first attempt in all cases (20). Design and performance features of the PLMA are expected to reduce gastric distension, regurgitation and pulmonary aspiration compared to the LMA. **Miller et al**¹⁷ stated that PLMA provided better airway protection during regurgitation than LMA. **Keller C. et al**¹⁸ concluded that a properly positioned PLMA isolates the airway from fluid within the hypo pharynx. In this study, the occurrence of regurgitation if any was tested using litmus paper on the posterior surface of the PLMA, immediately after its removal. None of the patients showed any signs of regurgitation. In this study gastric distension score was not statistically significant between Group I (ETT) and Group II (PLMA). The highest gastric distension score -2 was seen in two patients in both groups.

SUMMARY

The comparative evaluation of the proseal LMA with tracheal intubation for laparoscopic surgeries showed no significant difference between the two groups based on the demographic variables. The PLMA group maintained better haemodynamic stability than ETT group throughout the procedure. The ventilatory parameters (SPO₂, $ETCO_2$, TV&RR, FIO_2 , and Airway Pressure) showed no significant difference between 2 groups. The first time insertion success rate was 90% in PLMA group & 100% in ETT group. The first time passage of an OGT was 90% in PLMA group & 100% in ETT Group. There was no significant difference between the two groups based on gastric distension score noted by surgeon.

CONCLUSION

On comparing Proseal LMA and endotracheal tube for laparoscopic surgeries, it was found that the hemodynamics were more stable when Proseal LMA was used. Proseal LMA was as effective as endotracheal tube during positive pressure ventilation in preventing gastric distension and aspiration when correctly placed. So Proseal LMA is an effective alternative to endotracheal tube in patients where the hemodynamic stability is much desirable during laparoscopic surgeries.

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Conflicts of interest

There are no conflicts of interest.

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