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Original Research Article

Comparison Of Hemodynamic And Ventilatory Variables Between Proseal LMA And Endotracheal Tube In Pressure Controlled Ventilation For Laparoscopic Surgeries

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ABSTRACT:

Most of the studies using Proseal Laryngeal Mask Airway (PLMA) have used Volume Controlled Mode as ventilation mode. Although pressure-controlled (PC) ventilation potentially provides greater control over airway pressure by virtue of its decelerating inspiratory flow pattern, it remains a relatively less frequently used ventilation strategy. Thus, we aimed to compare the hemodynamic changes, ventilation changes, while using PLMA and Endotracheal tube (ETT) in PC ventilation among patients undergoing laparoscopic surgeries. Based on inclusion – exclusion criteria, 50 patients were enrolled and socio-demographic data was collected in a pre-designed proforma. Patients were then randomly allocated to receiving PLMA or ETT and haemodynamic variables, ventilatory variables, ease of insertion and postoperative complications were compared. Demographic profile of the study groups was comparable. The insertion characteristics of PLMA is like that of ETT while PLMA facilitates easy insertion of gastric tube. Mean Arterial Pressure (MAP) had a significant difference between two groups at one minute, three minutes and when measured after extubation. Patients on PLMA had significantly lesser MAP compared to the ETT group. PLMA was able to provide adequate ventilation using similar peak inspiratory pressure and tidal volume similar to that ETT in PC ventilation. Significant differences were observed in postoperative morbidities as well with PLMA having significantly less sore throat and dysphagia. Thus, we conclude that in short duration surgeries, PLMA can be used as it provides adequate ventilation using similar peak inspiratory pressure and tidal volume like that of ETT when used in PC mode of ventilation.

Keywords: Anaesthesia, Proseal Laryngeal Mask Airway, Endotracheal tube, Pressure Controlled Ventilation, Laparoscopic Surgeries

1. INTRODUCTION:

Airway management is of prime importance in anaesthetic practice and in critical care medicine. Endotracheal intubation achieves all the goals of airway management, namely, maintains airway patency, protects the lungs from aspiration and permits leak free ventilation during mechanical ventilation, and remains the gold standard procedure for airway management. But the use of endotracheal tube is associated with complications such as difficult intubation, failure to intubate,

esophageal and bronchial intubation, injury to nasopharyngeal structures, haemodynamic alterations such as hypertension, tachycardia, bradycardia, unsatisfactory seal and airway leak and post-operative pain, nausea and vomiting.

Failure to intubate, leading to "can't ventilate can't intubate", is an emergency condition occurring in 1 in 10000 anaesthetics. It leads to poor oxygenation of brain resulting in death and hypoxic brain damage [1]. In cases of difficult airway, American Society of Anaesthesiologists (ASA) Difficult airway algorithm dictates that Laryngeal Mask Airways be tried in cases of difficult intubation [2]

Laryngeal mask Airway (LMA) was introduced by Brain to be used as an alternative to either the endotracheal tube or the face-mask with either spontaneous or positive pressure ventilation. But Classic Laryngeal Mask Airway is associated with the risk of regurgitation as well as aspiration of gastric contents because the low-pressure seal may be inadequate for positive pressure ventilation.
Various modifications of the classic LMA exist. Proseal Laryngeal Mask Airway was introduced in 1995 [3], and subsequently modified in 2000 [4]. It has the advantage of having a drain tube which lets the draining of gastric contents and thus preventing aspiration. Another advantage of the device is that due to the presence of second posterior mask, the seal is more effective so that peak airway pressures of 40-60 cm H2O pressure can be used if mechanical ventilation is attempted with the device. The device has a bite block built into it [4].

These characteristics of the Proseal Laryngeal Mask Airway (PLMA) are thought to make it preferable to endotracheal tube in laparoscopic surgeries. However, the use of the LMA in this context is controversial, the main concern being that it does not offer definitive airway protection from pulmonary aspiration of potential regurgitated gastric contents. The other controversial point is the ability of the LMA to provide correct ventilation in patients undergoing laparoscopic procedures.
A review of studies by Belena et al focusing on LMA have found only 3 cases of regurgitation out of 706 patients studied (0.4%) and no cases of pulmonary aspiration were reported when using LMA with drain channel for laparoscopic cholecystectomy in selected patients. In the same review, comparing the ventilator efficiency of LMA Proseal with other LMA devices have found that Proseal LMA had 100% ventilator efficiency in all the studies except in the study by Maltby et al comparing Proseal LMA with endotracheal tube, where four of the obese patients crossed over to tracheal tube due to failed ventilation [5].

Laparoscopic surgeries are on the rise in India. Hence there is a need to find an alternative to cuffed endotracheal tubes. Proseal LMA is a relatively new airway device in developing countries. Very few studies have examined the use of Proseal LMA in the Indian Population [1,6]. However, all these studies have been conducted utilizing Volume Control Ventilation to maintain adequate ventilation and oxygenation. But earlier studies have found that Pressure-controlled rather than volume-controlled ventilation can improve the effectiveness of mechanical ventilation in patients with high airway pressure [7,8]. Hence this study is undertaken to compare the intraoperative and postoperative safety of PLMA and ETT using pressure controlled ventilation.

2. MATERIALS AND METHOD:

Informed Consent from the patients and ethical clearance from Institutional Ethical committee was taken with the Ethical Committee Approval Number IHEC/2014/10/01. All procedures in this study were performed in accordance with the ethical standards given in 1964 Declaration of Helsinki as revised in 2013. After the approval of the institutional ethics committee, this prospective randomized study was conducted in a tertiary care hospital among patients undergoing elective

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laparoscopic surgery under general anaesthesia. Patients who were in the age group of 20 - 60 years, ASA I and II grades were included. All patients who had anticipated difficult airway, obesity (BMI > 30), oropharyngeal pathology, cervical spine fracture or instability, who had increased risk of aspiration,
i.e., gastroesophageal reflux disease, hiatus hernia, and pregnant patients, with known allergy to anaesthetic and non-steroidal anti-inflammatory drugs were excluded.

In the study by Kannan et al., the sample size was calculated by keeping the power of the study at 90% and confidence intervals at 95% to detect a 10% difference in tidal volume; a minimum of 37 patients were needed.[6] We enrolled 50 patients in each group for better authenticity of results.

Patients were randomly allocated to two equal-sized groups: in one group, airway management was done with an endotracheal tube (ETT), and in the other with a Proseal LMA (PLMA). Randomization was done by computer-generated numbers using Graph Pad software, and allocation was done by opening a sealed opaque envelope immediately before surgery.

A standard anaesthesia protocol was followed, and routine monitoring was applied. The patient was pre-oxygenated with 100% O_2 for three minutes and induced with Inj.Glycopyrrolate 0.005mg/kg, Inj. Fentanyl 3mcg/kg, Inj. Propofol 3mg/kg and succinylcholine 1mg/kg. Anaesthesia was maintained with desflurane, O2, and air. The neuromuscular block was maintained with vecuronium.
The airway devices were used in strict accordance with the manufacturer's recommendations. No prophylactic antiemetics were given. Proseal Laryngeal Mask Airways of Size 3(female) and 4(male) and endotracheal tubes of size 7.5(female)and 8.5(male) were used. For the purpose of standardization, the index finger insertion technique for inserting the PLMA was followed.

Correct placement of the devices was confirmed by adequate chest movement on manual ventilation, square wave capnography, Expired tidal volume of more than 8 ml/kg, and no audible leak from the drain tube with peak airway pressure (PAP) less than 20 cm H2O. A leak below 20 cm H2O was taken as significant and suggested a malposition. In case of failure of PLMA™ placement, the plan was to withdraw and replace it with an ETT determining the exclusion of patients from the study.

Pressure-controlled ventilation was set with 35/65 oxygen/air, positive end-expiratory pressure of 5 cm H_2O, respiratory rate of 12 breaths/min, and inspiratory: expiratory ratio of 1:2. And peak inspiratory pressure (PIP) at a variable value in order to obtain a Tidal Volume of 10 ml/kg, Then, if necessary, minute ventilation was adjusted to maintain $ETCO_2$ between 35-45 mmHg during the maintenance.
PIP, as the first step, and respiratory rate, as the second step, was increased with the $ETCO_2$ of more than 45 mmHg and reduced with the $ETCO_2$ of less than 35 mmHg. In the PLMA group, PIP was increased until Oro-pharyngeal leak pressure, followed by an increase in respiratory rate to reduce the $ETCO_2$ exceeding 45 mmHg.

Insertion characteristics of the PLMA or ETT and the gastric tube (OGT) via the PLMA and the ETT, Hemodynamic responses (heart rate and mean arterial blood pressure), and Oxygen saturation (SpO_2) and end-tidal carbon dioxide ($EtCO_2$) were recorded. Incidences of gastric distension were scored by surgeons, who were blind to the device used, on an ordinal scale ranging from 0 -10, where 0 = empty stomach and 10 = distension that interfered with surgical exposure both during entry and removal of the laparoscope. Incidences of regurgitation were also noted.

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Muscle relaxation was reversed with neostigmine and glycopyrrolate. The tracheal tube or Proseal LMA and gastric tube were removed with the patient breathing spontaneously and able to obey the command. Blood staining on the laryngoscope, tracheal tube, or Proseal LMA was documented. Secretions, if present, were noted, and the pH was tested with a litmus paper which is sensitive to changes of 0.5-unit pH from pH 2.5 -8.5. Anaesthesia time was from pre-oxygenation to removal of the airway device. Surgical time was from incision to insertion of the last stitch.

The Patients were assessed for Sore throat, Nausea/Vomiting, and Oro-pharyngeal morbidity such as dysphagia/dysphonia by direct questioning (Yes/No) half an hour after their admission to the postoperative recovery room. An inquiry about the same was made at 6 hours and 24 hours. Patients were discharged from the post-anaesthesia care unit when they were awake, hemodynamically stable, with no pain/nausea/vomiting, and SpO2 was> 95% on room air. The patients were assessed at 6 and 24 hours after surgery. Any episode of bradycardia (< 60 /min), tachycardia (>100/min), SpO2<90% or systolic hypotension (< 80 mm Hg) was documented.

3. STATISTICAL ANALYSIS:

Data analysis was performed using Microsoft Excel software & Statistical Package for Social Sciences (SPSS for Windows, Version 17.0. Chicago, SPSS Inc). For descriptive analyses, mean and standard deviation were used to depict the distribution of continuous variables, and frequency and percentages were used to depict the distribution of the data pertaining to the categorical variables. For inferential analysis, based on the study objectives, comparison tests were adopted among various groups and sub-groups in the sample. A normality check of the data was performed using the Kolmogorov-Smirnov test. Comparison analyses for continuous variables were done in the following manner: for continuous variables following normal distribution between two groups, an independent sample t-test was used; Pearson correlation test was used for correlational analyses between two continuous variables following a normal distribution. For finding the association between two or more categorical variables, the Chi-Square test was used. Wherever the cell values were less than five, Fisher Exact test was used. For all inferential analyses, the statistical significance was set at a p-value < 0.05.

4. RESULTS AND DISCUSSION:

Our sample consisted of 50 patients in a group using the endotracheal tube and 50 patients using the Proseal Laryngeal Mask airway group. The groups were comparable with regard to age, sex, weight, and body mass index. They were also comparable with regard to ASA grading, Mallampatti scores, the average duration of surgeries, and the average duration of anaesthesia. Thus, the groups were matched and comparable. (Table 1)

Table 1 showing demographic variables.

Variables		Group Endotracheal Tube (ETT)	Group Proseal LMA (PLMA)
Age	18 – 29	15	18
	30 - 39	12	15
	40 – 49	10	7
	50 - 59	13	10
Sex	Male	27	32
	Female	23	18
Weight		68.30 ± 9.92 kgs	65.12 ± 9.64 kgs
Height		1.64 ± 0.08 m	1.63 ± 0.07 m
BMI		25 ± 2.3	24 ± 2.9
Type of Surgery	Laparoscopic Cholecystectomy	17	16
	Laparoscopic Hernia Repair	18	19
	Laparoscopic Appendicectomy	14	15
	Laparoscopic Sterilization	1	0
ASA Grade	Grade 1	18	25

	Grade 2	32	25
Mallampatti Grade	**Grade 1**	27	35
	Grade 2	23	15
Duration of Anaesthesia		41.7 ± 9.8 minutes	43.8 ± 6.7 minutes
Duration of Surgery		25.24 ± 6.92 minutes	23.9 ± 7.2 minutes

First-attempt insertion success rates were similar between the two groups, with 96 % success in the endotracheal tube and 84 % success in the Proseal Laryngeal Mask airway group. Although the difference was not statistically significant, a second attempt was needed in more patients in the Proseal LMA group. This was in contrast to earlier studies by Saraswat et al. [1] and Kannan et al [6]. However, in their review, Cook et al. mention that the first-time insertion success ranged from 76 % to 100%, with a mean of 87.3% [9]. The lower rates of first-time insertion success can be attributed to the experience of the anaesthesiologist. Cook et al. reported that Proseal LMA insertion difficulty might be caused by the larger, deeper, softer bowl and the non-linear leading edge formed by the DT. They further reported that while a learning curve had not been studied, it had been suggested the PLMA requires 20 to 30 insertions before achieving competence.[9] A gastric tube was inserted in all cases. First-attempt success was seen in 44 patients in the endotracheal tube group (88%) and 47 patients in the Proseal LMA group (94%). However, there was one failure to insert in the endotracheal tube group, while in the Proseal LMA group, the success rate was 100%. This is similar to other studies as reviewed by Cook et al [9]. However, with regard to the time taken for insertion of the gastric tube, the average time taken for insertion in the endotracheal tube group was 55.27 ± 33.157 seconds, while in the Proseal Laryngeal Mask airway group, it was 17.48 ± 12.085 seconds only. This was a statistically significant difference ($p < 0.001$). This is due to the design of Proseal LMA in which there is an addition of a second drain tube which helps in the easy passage of the gastric tube.[4]

Achieving adequate ventilation and maintaining a state of normocarbia is of paramount priority in positive pressure ventilation. In laparoscopic surgeries, after the creation of the carboperitoneum, carbon dioxide is absorbed trans peritoneally. The rate at which absorption happens depends on various factors, such as gas solubility, peritoneal cavity perfusion, and duration of pneumoperitoneum.[1]Peripheral measurements of SpO_2 and $ETCO_2$ can be taken as measures of adequate ventilation, as shown by Maltby et al.[10] Thus in our study, in order to measure ventilatory efficacy, we recorded SpO_2, $ETCO_2$, respiratory rate, positive inspiratory pressure, and tidal volume both before and after the creation of carboperitoneum.

Pressure Controlled Ventilation (PCV) is associated with increased flow rates, faster achievement of tidal volume, and lower peak airway pressure. In our study, in both groups, SpO_2 remained at 100% before and after peritoneal insufflation. There was no incidence of any desaturation. Similarly, $ETCO_2$ also was not significantly different between the two groups before and after peritoneal insufflation. Proseal LMA was able to provide oxygenation at a comparable positive inspiratory pressure, tidal volume, and respiratory rate. This was similar to the study by Maltby et al.[10] This is because the Proseal LMA provides an effective seal around the glottis and allows adequate oxygenation before and after CO_2 insufflations.

Table 2 Significant differences between the groups observed in the study

Variables		Group Endotracheal Tube (ETT)	Group Proseal LMA (PLMA)	p Value
Time Taken for Insertion of Device		21.88 ± 12.78 seconds	21.08 ± 18.38 seconds	p = 0.801
Number of Attempts made for Insertion of gastric tube	**1**	44	47	p = 0.450
	2	5	3	
	Failed	1	-	
Time Taken for Insertion of Gastric tube		55.27 ± 33.157 seconds	17.48 ± 12.085 seconds	p <0.001*****
Heart Rate – 1 min		92.10 ± 16.537	83.58 ± 15.071	0.008*

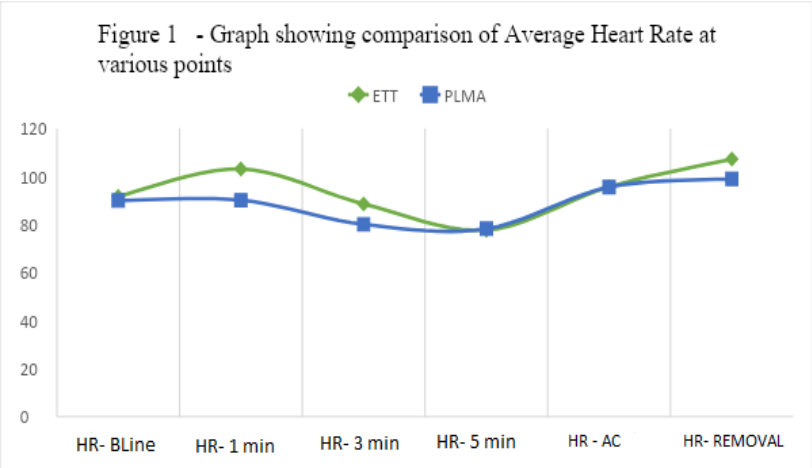
Heart Rate – After Removal	105.44 ± 12.359	91.12 ± 14.004	p <0.001*
Mean Arterial Pressure - 1 min	103.08 ± 26.981	90.06 ± 15.437	0.004*
Mean Arterial Pressure – 3 min	88.48 ± 16.423	80.02 ± 15.375	0.009*
Mean Arterial Pressure - After Removal	107.18 ± 18.301	98.96 ± 13.465	0.012*
Sore throat at 30 mins	25/25	7/43	0.000*
Dysphagia at 30 mins	20/30	9/41	0.027*
Dysphagia at 6 hours	9/41	0/50	0.003*

Peak airway pressures achieved in the Proseal LMA group after carboperitoneum were similar to studies by Lu et al [11], Maltby et al [10], Sharma et al [12], and Belena et al [13]. Higher peak pressures and large tidal volumes have been implicated as risk factors for the development of barotrauma and volutrauma in critically ill mechanically ventilated patients. Hence, the possibility of barotrauma and volutrauma with PLMA may be similar as compared to ETT.

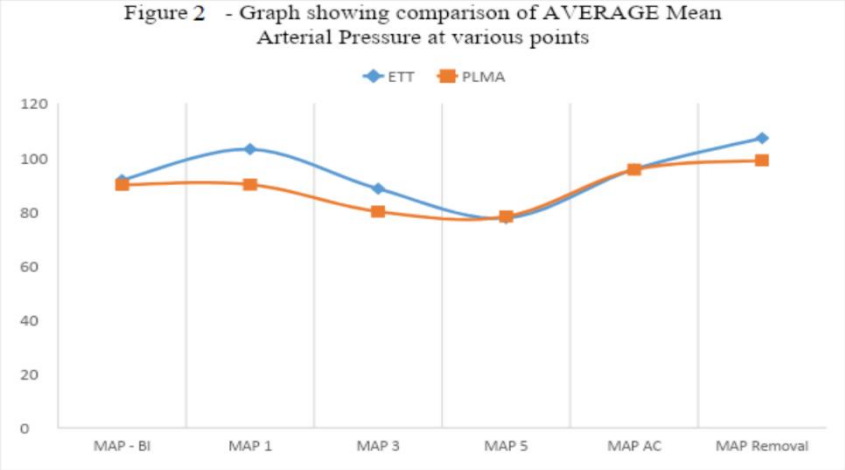
Thus, in our study, we found that Proseal LMA was able to provide adequate ventilation using similar peak inspiratory pressure and tidal volume similar to that endotracheal tube.
Sympathetic stimulation by laryngoscopy and intubation is known to induce hemodynamic response during ETT insertion. Proseal LMA being a supraglottic device, does not evoke such a response [6]. In ETT patients, in fact, laryngoscopy and tracheal intubation are strong noxious stimuli on laryngopharyngeal and tracheal mucosa that elicit arterial hypertension, tachycardia, and catecholamine release. In contrast, Proseal LMA may elicit a smaller stress response than ETT because it is less traumatic on the upper airway in a fashion similar to other supraglottic devices. This hemodynamic response manifests in the form of an increase in heart rate and blood pressure.[14]

In our study, the mean heart rate per minute changed from 81.62 ± 14.116 beats at pre-induction to 92.10 ± 16.537 beats in 1st minute, to 86.16 ± 18.047 beats in 3rd minute, 85.76 ± 14.437 in the 5th minute, to 87.34 ± 15.507 beats after achieving carbo peritoneum, to 105.44 ± 12.359 beats at the time of extubation in ETT group. While in the Proseal group, the mean heart rate varied from 79.00 ± 13.665 at pre-induction to 83.58 ± 15.071 at 1st minute, to 83.76 ± 16.132 at 3rd minute, to 84.90 ± 15.925 at the 5th minute, to 83.84 ± 15.479 after carbo peritoneum and was 91.12 ± 14.004 beats at extubation. The groups differed significantly at 1 minute immediately after insertion and after removal of devices. (Figure 1)

Figure 1 - Graph showing comparison of Average Heart Rate at various points



In our study, mean arterial pressure (MAP) also had a significant difference between the two groups at 1 minute, 3 minutes, and when measured after extubation. Patients on Proseal LMA had significantly lesser MAP compared to the ETT group. (Figure 2)



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These findings are similar to those found by Lim et al [15], Padara et al [16], Kannan et al [6], Carron et al [14], and Saraswat et al [1]. Although transitory hypertension and tachycardia are probably of little clinical consequence in healthy individuals, they may be a matter of concern in patients with known or at-risk cardiovascular diseases. Thus, in our study, we found that Proseal LMA caused lesser hemodynamic changes when compared to the endotracheal tube.

We studied the adverse events profile of both devices. Similar to the study by Maltby et al. [6], we used independent laparoscopic assessment of stomach size by our general surgery colleagues. None of the patients in both groups were found to have gastric distension both on entry of the laparoscope and during removal of the laparoscope. This is similar to the study by Maltby et al.[10]

One of the major safety concerns with regard to Proseal LMA was regurgitation or aspiration of gastric contents. Although the double cuff arrangement of the PLMA was designed to prevent the chances of aspiration, the use of Proseal LMA in laparoscopic surgeries is still considered controversial. An increase in intra-abdominal pressure has long been known to cause a reflex increase in the tone of the lower esophageal sphincter (LES). However, the belief that the increase in intra-abdominal pressure during laparoscopic surgery increases the risk of gastroesophageal reflux has been questioned by others. According to Maltby et al., peritoneal insufflation, which produces an intra-abdominal pressure of 15 mmHg during the laparoscopy, also increases LES tone, which in turn increases the normal barrier pressure of 30 cm water and provides further protection from passive reflux of gastric contents.[10]
In our study, we found that only one patient in the Proseal LMA group had regurgitation of gastric contents. None in the endotracheal tube group had regurgitation. None of the patients in both groups had any aspiration of gastric contents. Our findings are similar to previous studies by Saraswat et al [1], Sharma et al [12], and Maltby et al [10].
Regarding Oro-pharyngeal injuries, blood staining was found on devices in 9 patients (18%) with endotracheal tubes and 12 patients (24%) with Proseal LMA. This is similar to the study by Saraswat et al [1].
With regard to postoperative Oro-pharyngeal morbidities, Proseal LMA had a significantly low incidence of adverse events. None of the patients in the Proseal LMA group reported nausea & vomiting at any point during the assessment, while five patients in the endotracheal tube group reported nausea & vomiting 30 minutes after surgery. This is similar to studies by Maltby et al [10], Hohlrieder et al [17], and Brimacombe et al [18]. The mechanism by which Proseal LMA induces less Postoperative Nausea & Vomiting (PONV) is not clearly established. According to Hohlrieder et al.[17] the PLMA cuff in the pharynx is less stimulating than the ETT cuff in the trachea, and the

decreased airway stimulation somehow raises the threshold for postoperative pain, nausea and vomiting by a mechanism similar to the pre-emptive analgesic effect at the spinal level produced during regional anaesthesia. Whatever the reason, at emergence PLMA™, reduces PONV, which can result in sympathetic activation, bronchospasm, and desaturation.[17]

A significant difference was found with regard to the presence of sore throat at 30 minutes post-surgery. Twenty-five patients in the endotracheal tube group reported sore throat, while only seven patients in the Proseal LMA group reported sore throat. At 6 hours, that reduced to the only patient in the Proseal LMA group, with none of the patients reporting sore throat at 24 hours. While in the endotracheal tube group, seven patients reported sore throat at 6 hours, and one patient continued to report sore throat at 24 hours. Similarly, among the Proseal LMA group patients, only nine patients developed postoperative dysphagia (difficulty in swallowing) 30 minutes after surgery, while 6 hours post-surgery, none of them reported dysphagia. In the endotracheal tube group, 20 patients had dysphagia 30 minutes after surgery, while nine patients had dysphagia 6 hours post-surgery. Thus, Proseal LMA had a lesser occurrence of postoperative dysphagia compared to the endotracheal tube. This finding is similar to previous studies[14]. The low incidence of postoperative Oropharyngeal morbidities is explained by the fact that Proseal LMA is a supraglottic device and mucosal pressures achieved by Proseal LMA are lower at a given seal pressure, which is usually below pharyngeal perfusion pressures.[17] Significant differences between the two groups are shown in Table 2.

Thus, in our study, we found that the insertion characteristics of Proseal LMA are similar to that of the endotracheal tube, while Proseal LMA facilitates easy insertion of the gastric tube. Also, Proseal LMA was able to provide adequate ventilation using similar peak inspiratory pressure and tidal volume similar to that of the endotracheal tube and caused lesser hemodynamic changes and Oro-pharyngeal morbidities compared to the endotracheal tube when used in the pressure-controlled mode of ventilation.

However, our study had the following limitations. In our study, due to the nature of the study design, double-blinding was not possible. 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 a longer duration of mechanical ventilation. Although we did not observe any symptom or sign of aspiration in the study patients, the sample size was too small to address the critical question of the safety of Proseal LMA against pulmonary aspiration.

5. CONCLUSION:

In short duration surgeries, Proseal LMA can be used as it provides adequate ventilation using similar peak inspiratory pressure and tidal volume similar to that endotracheal tube when used in pressure - controlled mode of ventilation. From our study, we conclude that the insertion characteristics of Proseal LMA was similar to that of the endotracheal tube while Proseal LMA facilitates easy insertion of gastric tube. Proseal LMA provided adequate ventilation with peak inspiratory pressure and tidal volume similar to that of the endotracheal tube in pressure-controlled ventilation. Proseal LMA caused lesser hemodynamic change compared to the endotracheal tube in pressure-controlled ventilation. Proseal LMA caused lesser oro-pharyngeal morbidities compared to the endotracheal tube in pressure-controlled ventilation in laparoscopic surgeries.

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7. AUTHORS CONTRIBUTION STATEMENT:

Subbiah Senthilnayagam designed the whole study. Divya Devanathan conducted sample collection and prepared the manuscript. Subha Devanathan prepared the part of the manuscript. All the authors read and approved the final version of the manuscript.

8. CONFLICT OF INTEREST:

Conflict of interest declared none.

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