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ORIGINAL RESEARCH

Comparative analysis of effectiveness, safety, and patient outcomes of proseal laryngeal mask airway (PLMA) vs. endotracheal tube (ETT) in laparoscopic surgeries

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ABSTRACT

Background: The advent of laparoscopic surgery has revolutionized the field of surgery, offering a minimally invasive alternative to traditional open procedures. Despite its benefits, laparoscopic surgery presents unique anesthetic challenges, particularly in airway management and maintaining adequate ventilation due to the creation of pneumoperitoneum. This study compares the efficacy, safety, and patient outcomes associated with the ProSeal Laryngeal Mask Airway (PLMA) and the Endotracheal Tube (ETT) in laparoscopic surgeries. **Method and material:** A prospective randomized comparative study was conducted in tertiary care hospital and attached medial college for a period of 1 year (January 2023 to December 2023) included a total of 100 patients, aged 20-60 years with ASA Grading 1 and 2 and BMI between 20-25 kg/m², were randomly assigned to Group P (PLMA) or Group E (ETT) using a closed envelope method. Each group comprised 50 patients. Parameters evaluated included the ease of insertion and positioning, Assessing the hemodynamic stability, incidence of adverse events and postoperative complications. **Results:** The mean age of patients was 45.20 ± 15.50 years in Group B and 44.88 ± 15.30 years in Group L, Sex distribution was 52% male and 48% female in Group B, and 48% male and 52% female in Group L, with no significant difference ASA grading showed 56% Grade I and 44% Grade II in Group B, and 52% Grade I and 48% Grade II in Group L, with no significant difference. For PLMA, the insertion success rate was 86% on the first attempt and 14% on the second, with no failures. For ETT, the rates were 84% on the first attempt, 14% on the second, and 2% on the third, with no failures. The mean time for successful placement was similar between groups (15.82 s for PLMA vs. 17.05 s for ETT, $p = 0.193$), but PLMA had a significantly shorter time for NGT passage (9.80 s vs. 11.60 s, $p = 0.003$). PLMA group showed stable mean heart rate (HR), whereas the ETT group had significant increases at insertion (86.20 ± 8.14 bpm to 98.40 ± 13.90 bpm, $p < 0.05$), 1 minute (103.83 ± 11.70 bpm, $p < 0.05$), 3 minutes (101.90 ± 13.77 bpm, $p < 0.05$), and 5 minutes (94.47 ± 20.00 bpm, $p < 0.05$). Similar trends were observed for systolic blood pressure (SBP) and mean arterial pressure (MAP) with significant increases in the ETT group at 1, 3, and 5 minutes, and during removal ($p < 0.05$). No significant differences in SpO2 or EtCO2 were found between groups. Intraoperatively, PLMA had a higher incidence of leaks (4% vs. 0%) and gastric insufflation (10% vs. 0%) compared to ETT ($p < 0.05$). No regurgitation or aspiration was observed in either group. Postoperatively, sore throat was significantly more common in the ETT group (20% vs. 6%, $p < 0.05$). Minor trauma and other complications were not significantly different between groups. Neither group experienced laryngospasm, bronchospasm, regurgitation, or pulmonary aspiration. **Conclusion:** Our study demonstrates that Supraglottic Airway Devices (SADs) are a viable alternative to Endotracheal Tubes (ETTs) for airway management in laparoscopic surgeries under General Anesthesia. SADs offer easier insertion, maintain hemodynamic stability, and reduce postoperative complications, making them a promising choice for enhancing patient comfort and ensuring smoother surgical outcomes.

Keywords: ProSeal Laryngeal Mask Airway, Endotracheal Tube, laparoscopic surgery, airway management, Supraglottic airway device.

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INTRODUCTION

The advent of laparoscopic surgery has marked a paradigm shift in the field of surgery, offering a minimally invasive alternative to traditional open procedures. This approach has gained widespread acceptance due to its numerous benefits, including reduced postoperative pain, shorter hospital stays, and faster recovery times, which collectively contribute to improved patient outcomes [(1)]. However, despite these advantages, laparoscopic surgery introduces specific anesthetic challenges, particularly regarding the management of the airway and maintenance of adequate ventilation.

One of the primary challenges associated with laparoscopic surgery is the creation of pneumoperitoneum. This involves insufflating carbon dioxide into the abdominal cavity to enhance visibility and provide space for surgical maneuvers. The resultant increase in intra-abdominal pressure can significantly affect respiratory mechanics by elevating airway pressures and reducing lung compliance [(2)]. Consequently, the choice of airway management technique becomes critical to ensure adequate ventilation and oxygenation throughout the procedure.

Traditionally, the Endotracheal Tube (ETT) has been the cornerstone of airway management during laparoscopic surgeries. Its ability to provide a secure glottic seal and facilitate positive pressure ventilation makes it particularly suited for procedures requiring pneumoperitoneum. However, the insertion of an ETT is associated with notable hemodynamic responses, such as tachycardia and hypertension, due to the stimulation of the laryngeal and tracheal mucosa. These responses can pose significant risks, especially in patients with preexisting cardiovascular conditions [(3)].

In contrast, the ProSeal Laryngeal Mask Airway (PLMA) has emerged as a viable alternative, offering several advantages over the ETT. The PLMA is designed with an additional drainage tube that allows for gastric decompression, thereby reducing the risk of aspiration and making it suitable for use in laparoscopic surgeries [(4)]. Additionally, the PLMA is associated with less hemodynamic disturbance upon insertion, potentially offering a safer profile for patients susceptible to cardiovascular stress.

Given these considerations, this study aims to analyse the effectiveness, safety, and patient outcomes associated he Proseal Laryngeal Mask Airway (PLMA) and Endotracheal Tube (ETT) for laparoscopic surgeries and also evaluate the ease of insertion and positioning, assess the hemodynamic stability, incidence of adverse events and incidence of postoperative complications.

By evaluating these parameters, we seek to inform clinical practice and optimize airway management strategies to enhance patient safety and improve surgical outcomes.

This research is particularly pertinent in the context of laparoscopic surgery, where the balance between adequate ventilation and hemodynamic stability is crucial. The findings from this study are expected to provide valuable insights into the relative merits and potential limitations of each airway management technique, thereby guiding anesthesiologists in their choice of airway devices based on patient-specific considerations and procedural requirements.

MATERIAL AND METHOD

The research was conducted at the Pacific Institute of Medical Science in Umarda, Udaipur, Rajasthan, a tertiary care centre equipped with modern facilities for surgical procedures and patient care. The institute serves a diverse patient population and adheres to strict ethical standards in research and clinical practice.

Study Design

A Prospective Randomized Comparative Study design was employed to systematically evaluate and compare the efficacy, safety, and patient outcomes associated with two different airway management techniques: Group P, utilizing ProSeal Laryngeal Mask Airway (PLMA), and Group E, utilizing Endotracheal Tube (ETT). This design allowed for direct comparison between the two methods under controlled conditions, enabling the identification of any differences in effectiveness and associated complications.

Study Duration

The study duration encompassed a period of one year, from January 2023 to December 2023. This timeline allowed for adequate recruitment of patients, implementation of study protocols, data collection, and analysis within a reasonable timeframe. Ethical approval was obtained prior to the commencement of the study, ensuring compliance with institutional guidelines and regulations.

Sample Size

The sample size for the study was calculated based on statistical considerations to achieve sufficient power and precision in detecting clinically meaningful differences between the two study groups. A total of 100 patients were included, with 50 patients allocated to each study group. At α error 0.5 and power 80%, assuming the difference in mean to be detected 0.5 with SD 1.05 as per seed article.

Inclusion Criteria

Patient's Consent for the study, ASA Grading 1 & 2, Age20 – 60 years, Both Male & Female sex, BMI20-25 kg/m2

Exclusion Criteria

ASA Grading 3 & 4, BMI > 30 kg/m2, Anticipated Difficult Airway, Patient who do not want be included in the study.

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Randomization

Randomization of patients into either Group P or Group E was performed using a closed envelope method. This approach ensured that the assignment of patients to treatment groups was unbiased and independent of investigator preference or patient characteristics. Random allocation minimizes selection bias and enhances the validity of comparative analyses by promoting an equal distribution of potential confounding factors between study groups.

Method

Prior to inclusion in the study, all patients underwent a thorough pre-anesthetic evaluation. This evaluation included a comprehensive assessment of medical history, physical examination, airway assessment, and relevant investigations (e.g., laboratory tests, imaging studies) as deemed necessary based on individual patient characteristics and surgical requirements. Informed consent was obtained from each patient following a detailed explanation of the study procedures, potential risks, and benefits.

Patients received premedication with Tab. Alprazolam 0.25mg the night before surgery to alleviate preoperative anxiety and promote perioperative relaxation. Additionally, on the day of surgery, patients received premedication approximately 1-2 minutes before anesthesia induction to further facilitate anxiolysis and smooth transition to the operative phase. The premedication regimen was administered according to established protocols and individual patient requirements, with appropriate considerations for age, weight, and comorbidities.

Anesthesia induction was conducted in a standardized manner following established protocols for both study groups. Upon arrival in the operating theatre, patients were connected to standard monitors to assess baseline vital signs, including heart rate, blood pressure, respiratory rate, and oxygen saturation. Preoxygenation with 100% oxygen was initiated for 3-5 minutes to optimize oxygen reserves and minimize the risk of hypoxemia during induction. Anesthesia was then induced using intravenous propofol at a dose of 2-2.5mg/kg of ideal body weight, administered slowly to achieve smooth and controlled sedation. Neuromuscular blockade was subsequently achieved with intravenous vecuronium at a dose of 0.08-0.1mg/kg, facilitating muscle relaxation and facilitating the insertion of the designated airway device in each study group.

Those in the PLMA group received a size 3 or 4 ProSeal LMA, chosen according to their weight, while those in the ETT group received endotracheal intubation with an appropriately sized endotracheal tube.

For PLMA Group Size 3 for patients weighing 30-50 kg and Size 4 for patients weighing 50-70 kg.

The ProSeal LMA was inserted using a standard technique. The patient was positioned supine with the head in a neutral or slightly extended position. The device was lubricated with a water-based lubricant to facilitate smooth insertion. The LMA was inserted until resistance was felt, indicating proper placement.

The cuff of the ProSeal LMA was then inflated with 20-30 ml of air to achieve an adequate seal without causing excessive pressure.

The oropharyngeal seal pressure (OSP) was measured when using the ProSeal Laryngeal Mask Airway (PLMA) as it indicates the effectiveness of the seal between the cuff of the LMA and the oropharyngeal tissues

The patient was adequately anesthetized and the ProSeal LMA was correctly positioned and cuff inflated as per standard practice. The adjustable pressure-limiting (APL) valve on the anesthesia machine was adjusted. The APL valve was closed partially while monitoring the pressure gauge. The pressure in the breathing circuit was gradually increased by squeezing the reservoir bag. The pressure was continued to be increased until a steady state was reached or until an audible leak was detected around the patient's mouth or through the drainage tube of the PLMA. The pressure at which this occurred was noted as the OSP. The equilibrium pressure where no further increase was seen (or where leakage started) was recorded as the OSP. OSP (>30 cm H2O): Indicated a good seal, which was ideal for preventing aspiration and ensured efficient positive pressure ventilation.

For ETT Group, the appropriate size endotracheal tube (ETT) was selected based on the patient's age, weight, and clinical judgment. Typically, sizes range 7-7.5 in females and 8-8.5 in males was performed in standard manner The patient was positioned in the 'sniffing' position to optimize the view of the larynx and Direct laryngoscopy was performed. The ETT was inserted through the vocal cords into the trachea. The ETT was secured in place once proper placement was confirmed.

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, No audible leak from the drain tube with peak airway pressure (PAP) less than 20 cm H2O. A leak below 20 cm H 2O was taken as significant and suggested a malposition, The gel displacement test, done by placing a blob of gel at the tip of the drain tube (DT) and noting the airway pressure at which it was ejected. The last two tests were specific for group P.

Once proper placement of the airway device was confirmed, positive pressure ventilation was initiated using a closed-circuit anesthesia system. Anesthesia was maintained with volatile agents, specifically sevoflurane, titrated to achieve the desired depth of anesthesia and hemodynamic stability. Continuous monitoring of vital signs, including A tidal volume of 8 ml/kg, respiratory rate of 12-14/min and I/E ratio of 1:2, EtCO2 between 35 to 45 mmHg was maintained

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for adequate ventilation was performed throughout the surgical procedure to ensure adequate oxygenation, ventilation, and depth of anaesthesia. RT was inserted in both groups.

The study protocol outlined specific limitations and exclusion criteria to ensure patient safety and data integrity. Patients with contraindications to either the PLMA or ETT insertion techniques, such as known allergies, anatomical abnormalities, or previous adverse reactions, were excluded from participation. Additionally, patients with anticipated difficult airways or those requiring emergency surgical interventions were not included in the study to minimize potential complications and confounding variables.

The outcomes were measured. Insertion characteristics of the PLMA or ETT. Easy insertion – insertion at first attempt with no resistance; difficult insertion -insertion with resistance or at second attempt; and failed insertion – insertion not possible.

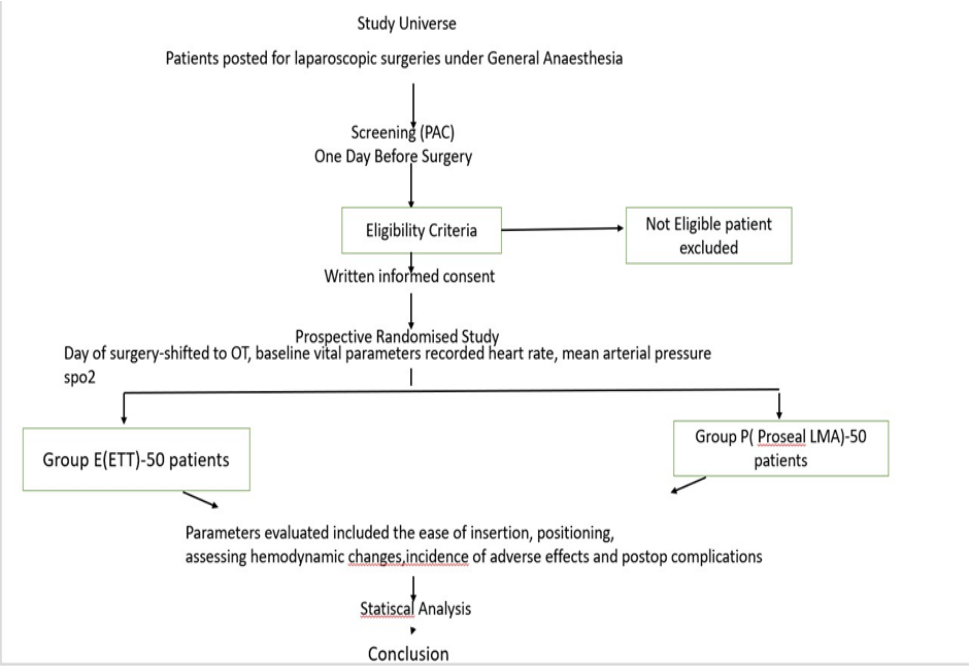
Haemodynamic responses (heart rate and mean arterial blood pressure)were recorded before induction; at the time of insertion; at 1,2, 5,10 mins after insertion of device, after achieving pneumoperitoneum, at 15 minutes till the end of surgery and during removal of devices.Oxygen saturation (SpO2) and end-tidal carbon dioxide (EtCO2) were recorded.

The aim was to maintain target SpO2(>95%) and EtCO2 (<45 mm Hg) by adjusting the FiO2, respiratory rate and tidal volume. When SpO2 was 94-90% the oxygenation was graded as suboptimal and failed if it was <90%. The airway pressure was not allowed to exceed 40 cm H2O.

The PAP was recorded when intra-abdominal pressure (IAP) reached 16 mm Hg. For standardisation, IAP was maintained at 12-16 mm Hg. Incidences of gastric distension (by surgeon), regurgitation, aspiration, intraoperative and postoperative laryngopharyngeal morbidity were noted.

Upon completion of the surgical procedure, neuromuscular blockade was reversed using Sugammadex, a specific antagonist of non-depolarizing neuromuscular blocking agents. This reversal agent rapidly and effectively restores neuromuscular function, allowing for prompt recovery of muscle strength and spontaneous ventilation. Perioperative complications, including postoperative cough, sore throat, presence of blood on the airway device, and laryngospasm, were meticulously documented and compared between the PLMA and ETT groups. Any adverse events or unexpected outcomes were thoroughly investigated and reported in accordance with established guidelines for clinical research and patient safety.

In addition to clinical outcomes and safety measures, the study protocol included assessments of the time required for airway device insertion and the perceived ease of insertion. These subjective evaluations provided valuable insights into the practical considerations and technical challenges associated with each airway management technique. Time to successful insertion was recorded from the initial placement attempt to confirmation of proper device positioning, while ease of insertion was rated on a standardized scale reflecting the level of difficulty encountered during the procedure. Comparative analysis of these parameters allowed for a comprehensive evaluation of the procedural characteristics and user experience associated with PLMA and ETT insertion techniques, informing clinical decision-making and practice guidelines in airway management.



[TABLE/FIG –1]: CONSORT flow diagram

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STATISTICAL ANALYSIS

To determine sample size, Cohen's tables were used. According to these tables, a medium-sized effect for analysis of variance (ANOVA) was 0.25. A sample size calculation of two groups was needed. A total sample size of 100 patients was needed. Therefore, 100 patients were taken. Patient characteristic data were compared using independent sample t-test. Physiological data were averaged and compared by ANOVA test. Correlation coefficient and regression analysis were used in outcomes. Paired t-test and Mann-Whitney U test were used for statistical analysis. The p-value>0.05 is considered not significant, p-value<0.05 as significant and p-value <0.001 as highly significant.

RESULTS

This study is conducted for 1 year in our institute which has around Total OPD patients of 547,500 patients/year, IPD of 255,500 patients/year, total major surgeries performed 13,870/year from which 4,380 are performed under general surgery.

In this comprehensive study, we conducted an in-depth analysis of various parameters in two distinct groups, Group P and Group E such as the ease of insertion and positioning, Assessing the hemodynamic stability, incidence of adverse events and postoperative complications

Demographic Parameters

	Group P	Group E	
Age(years)	20-60	20-60	
No.of cases	50	50	
Mean	45.2	44.88	
SD	15.5	15.3	
t stat			0.127
p value			0.9
Sex			
Male			
No.of cases	26	24	
Percentage	52.00%	48.00%	
Female			
No.of cases	24	26	
Percentage	48.00%	52.00%	
Total			
No.of cases	50	50	
Percentage	100	100	
p value			1.000
ASA Grade			
Grade I			
No. of cases	28	26	
Percentage	56.00%	52.00%	
Grade II			
No.of cases	22	24	
Percentage	44.00%	48.00%	
Total			
No.of cases	50	50	
Percentage	100%	100%	
p value			0.820

[TABLE/FIG –2]: comparison of demographic data of patients

The data in the combined table reveals the following:

The mean age of patients in Group B was 45.20 ± 15.50 years (20-60 years), while in Group L, it was 44.88 ± 15.30 years (20-60 years). The statistical analysis showed no significant difference in mean age between the two groups with a t-stat of 0.127 and a P value of 0.900.

The sex distribution was 52.00% male and 48.00% female in Group B, and 48.00% male and 52.00% female in Group L. The Chi-Square test indicated no significant difference between the groups with a P value of 1.000.

In Group B, 56.00% of patients were ASA Grade I and 44.00% were ASA Grade II, while in Group L, 52.00% of patients were ASA Grade I and 48.00% were ASA Grade II. The Chi-Square test showed no significant difference between the groups with a P value of 0.820.

Airway Analysis

Airway Device Details	PLMA (n=50) Mean (SD)	ETT (n=50) Mean (SD)	t-stat	P value
Size of device (3/4, 7.5/8)	32/18	29/21	-	-
Attempt of insertion (1/2/3/failed)	43/7/0/0	42/7/1/0	-	-
Time taken for insertion of device	15.82 (3.12)	17.05 (4.20)	-1.31	0.193
Attempts at gastric tube insertion (1/2/3/failed)	45/5/0/0	40/7/3/0	-	-
Time taken for insertion of gastric tube	9.80 (2.50)	11.60 (2.35)	-3.02	0.003
Oropharyngeal seal pressure, Median	35 cm of H2O	-	-	-

[TABLE/FIG –3]: comparison of airway analysis

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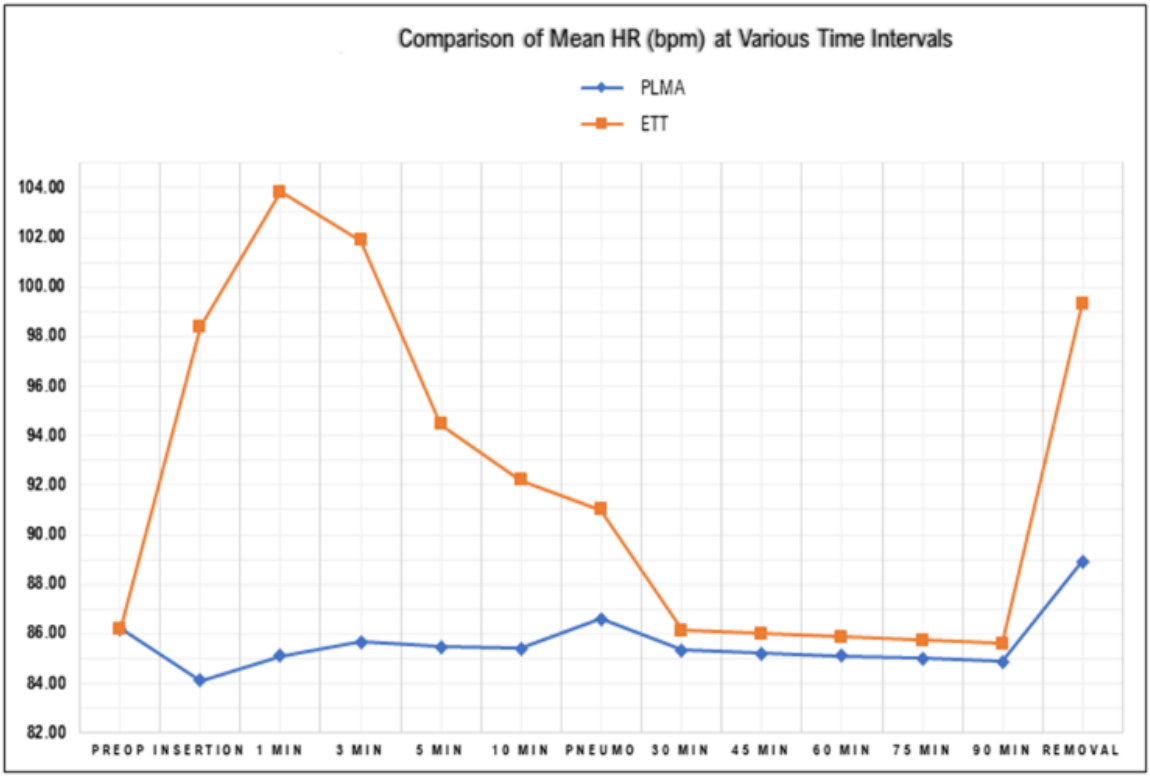
The data in the combined table reveals the following:
PLMA Group: Size 3 PLMA placement was attempted in 32 patients, size 4 in 18 patients. Insertion success rate was 86% for the first attempt, and two attempts were made in 14% of patients. Insertion was easy in 43 and difficult in 7 patients. No failed insertion was reported.
ETT Group: Insertion success rate was 84% for the first attempt; two attempts were made in 14% of patients and a third attempt was required in 2% of patients. No failed insertion was reported.
Time for Successful Placement: Mean time (range) taken for successful placement was 15.82 s (12-21 s) and 17.05 s (11-28 s) for PLMA and ETT, respectively. The t-statistic for the difference in time taken for insertion of the device is -1.31, with a p-value of 0.193.
Time for Successful Passage of NGT: Mean time taken for successful passage of NGT was 9.80 s (6-16 s) and 11.60 s (8-17 s) for PLMA and ETT groups, respectively. The t-statistic for the difference in time taken for insertion of the gastric tube is -3.02, with a p-value of 0.003.
These values indicate that there is no significant difference in the time taken for insertion of the airway device between the PLMA and ETT groups, but there is a significant difference in the time taken for insertion of the gastric tube, with the PLMA group taking less time on average.

HEMODYNAMIC PARAMETERS

The hemodynamic parameters were recorded before induction; at the time of insertion; at 1,2, 5,10 mins after insertion of device, after achieving pneumoperitoneum, at 15 minutes till the end of surgery and during removal of devices.

Heart Rate



[TABLE/FIG –4]: comparison of mean heart rate of the study groups at various time intervals

In the PLMA group, mean heart rate (HR) remained stable without significant intra-group changes compared to preoperative HR, while in the ETT group, HR increased significantly from 86.20 ± 8.14 bpm to 98.40 ± 13.90 bpm at insertion, peaking at 103.83 ± 11.70 bpm at 1 minute, followed by 101.90 ± 13.77 bpm at 3 minutes, and then declining to 94.47 ± 20.00 bpm at 5 minutes ($P < 0.05$); notable inter-group differences were observed at insertion, 1 minute, 3 minutes, 5 minutes, 10 minutes, and removal times, with the ETT group exhibiting higher HRs ($P < 0.05$).

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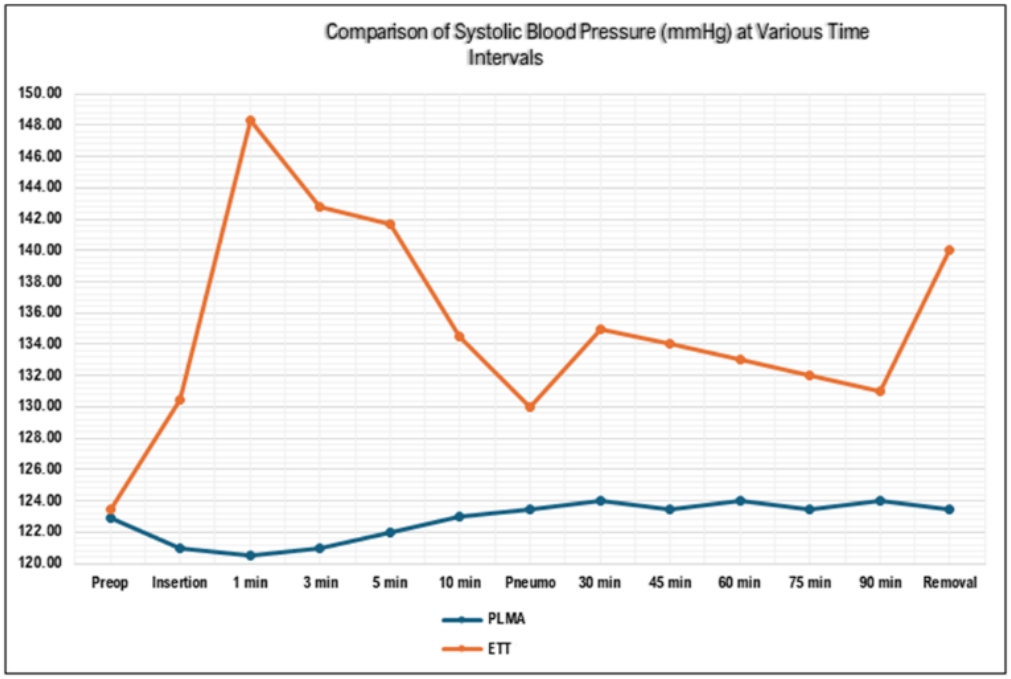
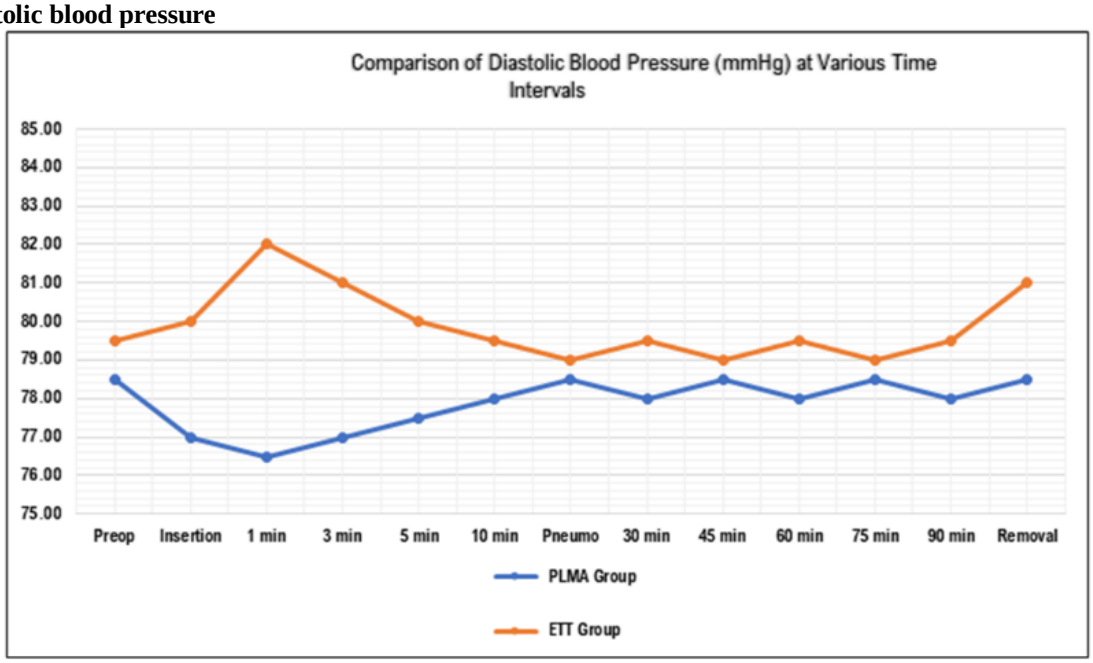
Systolic blood pressure



[TABLE/FIG – 5]: comparison of mean systolic blood pressure of the study groups at various time intervals

The mean SBP in the PLMA group remained stable without significant intra-group changes compared to the preoperative SBP, while in the ETT group, it increased significantly from baseline at 1, 3, and 5 minutes, as well as at removal time ($P < 0.05$), with significant inter-group differences showing higher SBP in the ETT group at these intervals ($P < 0.05$).

Diastolic blood pressure



[TABLE/FIG –6]: comparison of mean diastolic blood pressure of the study groups at various time intervals

In the PLMA group, mean SBP remained stable without significant intra-group changes compared to preoperative levels, while in the ETT group, SBP significantly increased from baseline at 1, 3, and 5 minutes, as well as at removal time ($P < 0.05$); significant inter-group differences were noted at 1, 3, and 5 minutes, and during removal, with the ETT group demonstrating higher SBP levels ($P < 0.05$)

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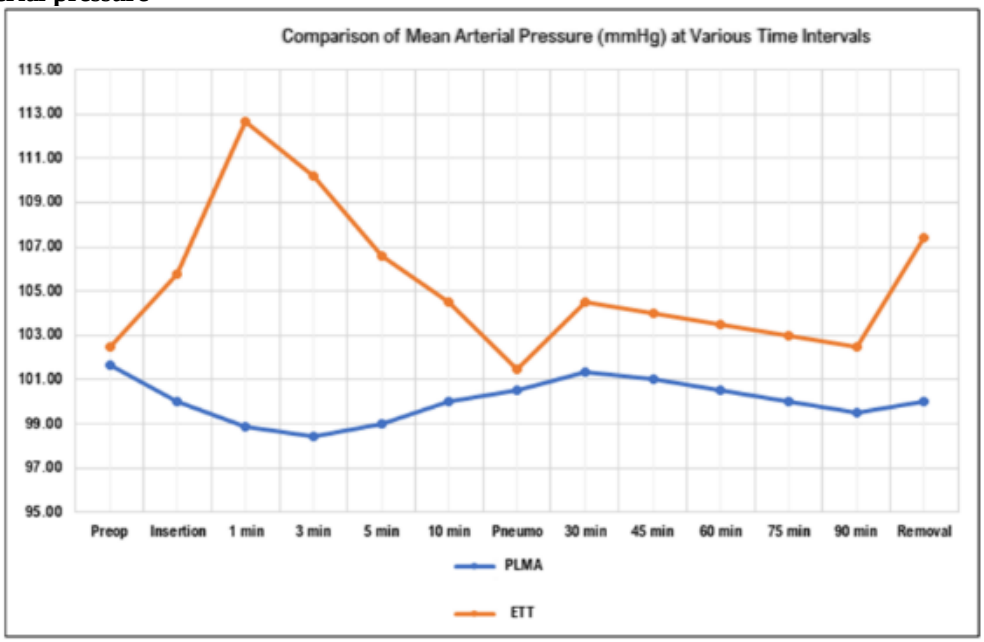
Mean arterial pressure

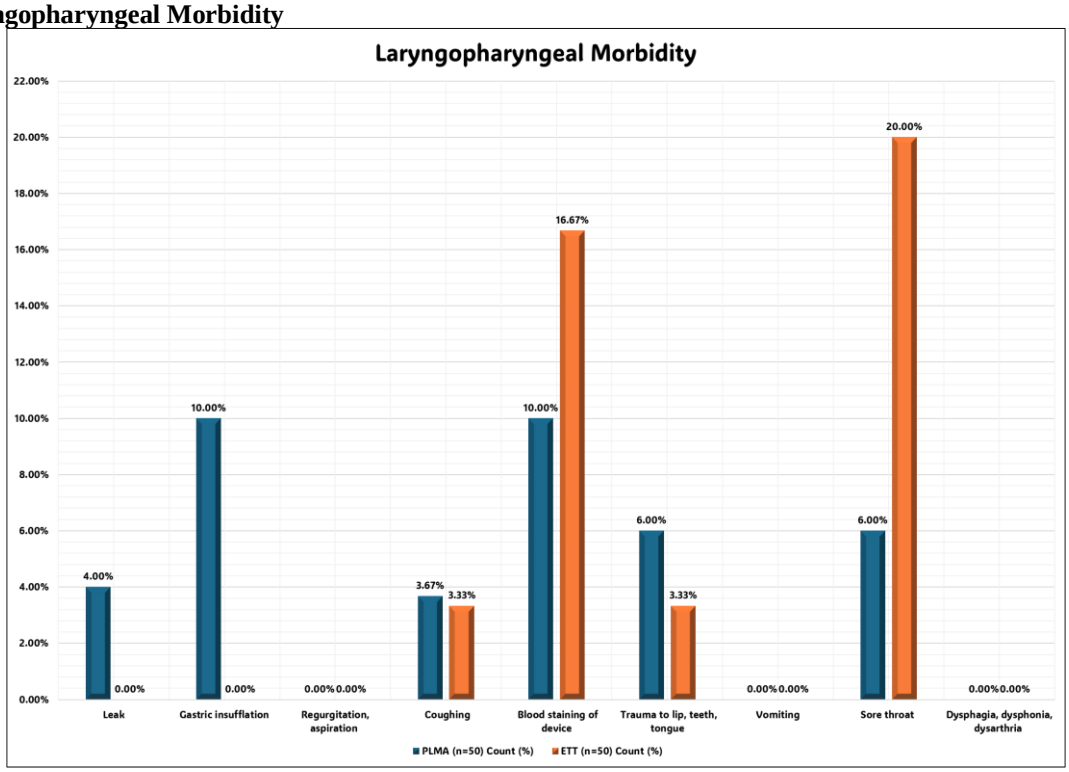


[TABLE/FIG –7]: comparison of mean arterial blood pressure of the study groups at various time intervals

In the PLMA group, mean arterial pressure (MAP) remained stable without significant intra-group changes compared to preoperative levels, while in the ETT group, MAP increased significantly from baseline at 1, 3, and 5 minutes, as well as at removal time ($P < 0.05$); notable inter-group disparities were observed at 1, 3, and 5 minutes, and during removal, with the ETT group displaying higher MAP ($P < 0.05$).

In both the PLMA and ETT groups, mean SpO2 and EtCO2 remained stable without significant intra-group changes compared to preoperative levels, and there were no significant differences in SpO2 or EtCO2 between the two groups at any time intervals ($P > 0.05$).

Laryngopharyngeal Morbidity



[TABLE/FIG –8]: comparison laryngopharyngeal morbidity of the study groups at various time intervals

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Intraoperatively, the PLMA group exhibited a 4% incidence of leak and 10% reported gastric insufflation, significantly higher than in the ETT group ($p < 0.05$); no cases of regurgitation or aspiration were observed in either group. At removal, both groups showed coughing and blood staining of the device, with slightly higher incidences in the PLMA group, though statistically insignificant ($p > 0.05$); lip, teeth, or tongue trauma was reported in 6% of PLMA patients and 3.33% of ETT patients. Postoperatively, sore throat occurred in 6% of PLMA patients and 20% of ETT patients, showing statistical significance ($p < 0.05$); however, no cases of vomiting, dysphagia, dysphonia, or dysarthria were reported in either group. Additionally, contextual correlations revealed coughing post-removal in 6.67% of PLMA patients and 3.33% of ETT patients, blood staining of the device in 10% of PLMA patients and 16.67% of ETT patients, and minor trauma to the lip, teeth, or tongue in 6% of PLMA patients and 3.33% of ETT patients; furthermore, neither group experienced intraoperative or postoperative laryngospasm, bronchospasm, regurgitation, or pulmonary aspiration, with PLMA patients managing gastric distention, consistent with 10% reporting gastric insufflation.

DISCUSSION

Our study was conducted on 100 patients aged 20-60 years, with 50 patients in each group. The mean age of patients in Group P was 45.20 ± 15.50 years, while in Group E, it was 44.88 ± 15.30 years. The sex distribution was 52.00% male and 48.00% female in Group P, and 48.00% male and 52.00% female in Group E. The ASA Grade Distribution showed that 56.00% of patients were Grade I and 44.00% were Grade II in Group P, while in Group E, 52.00% of patients were Grade I and 48.00% were Grade II. These findings indicate that the demographic parameters, including age, sex, and ASA grade distribution, were comparable between the PLMA and ETT groups. This homogeneity ensures that any observed differences in outcomes can be attributed to the airway management technique rather than demographic variations. A study by Shibin A et al[5], on the comparison between ProSeal laryngeal mask airway (PLMA) and endotracheal tube (ETT) in patients undergoing laparoscopic surgeries under general anesthesia involved 90 patients aged 18-50 years, divided into 45 patients in each group. The demographic parameters, such as age, sex distribution, and ASA Grades I & II, were comparable. Similarly, Parikh SS[6] et al conducted a study in a tertiary care teaching hospital with 60 patients of ASA Grades I/II, aged 18-60 years, randomly divided into two equal groups (PLMA and ETT), showing no statistical differences in demographic profiles. This consistency in demographic characteristics ensures that differences in clinical outcomes are likely due to the airway devices themselves rather than variations in patient characteristics.

The corresponding airway was inserted in each group. In Group P, size 3 or 4 PLMA (according to weight) were used. Size 3 PLMA placement was attempted in 32 patients, and size 4 in 18 patients. The insertion success rate was 86% on the first attempt, with two attempts required in 14% of patients. Insertion was easy in 43 patients and difficult in 7, with no failed insertions reported. In the ETT group, the insertion success rate was 84% on the first attempt, with two attempts required in 14% of patients and a third attempt in 2%. No failed insertions were reported. The mean time for successful placement was 15.82 seconds (range: 12-21 seconds) for PLMA and 17.05 seconds (range: 11-28 seconds) for ETT (p-value 0.193). The mean time for successful passage of the nasogastric tube (NGT) was 9.80 seconds (range: 6-16 seconds) for PLMA and 11.60 seconds (range: 8-17 seconds) for ETT (p-value 0.003). These values indicate no significant difference in the time taken for airway device insertion between the PLMA and ETT groups, but a significant difference in the time taken for gastric tube insertion, with the PLMA group taking less time on average. The comparability of insertion success rates and times for both devices indicates that any differences in patient outcomes can be reliably attributed to the devices themselves rather than the ease or difficulty of their insertion. A study by Saraswat N et al[7]on the comparison of ProSeal laryngeal mask airway and endotracheal tube in patients undergoing laparoscopic surgeries found similar results. The insertion success rate for PLMA was 86.67% on the first attempt, with two attempts required in 13.33% of patients. In Group E, the insertion success rate was 83.37% on the first attempt, with two attempts required in 13.33% of patients and a third attempt in 3.33%. No failed insertions were reported in either group. The mean time for successful placement was 15.77 seconds for PLMA and 16.93 seconds for ETT. The mean time for NGT passage was 9.77 seconds for PLMA and 11.5 seconds for ETT. Another study by Patodi V et al[8] found that 66.67% of patients had easy insertion of ProSeal LMA, with a second attempt required in 33.3% of patients, and a mean insertion time of 37.40 ± 16.09 seconds. In the ETT group, intubation was successful on the first attempt in 96.7% of patients, with a second attempt required in 18.3% of patients and a mean intubation time of 31.17 ± 20.89 seconds. The duration of insertion was statistically not significant ($P > 0.05$), but the mean insertion time in the ETT group was shorter. This alignment in procedural success and timing across multiple studies supports the robustness of our findings and strengthens the validity of attributing differences in patient outcomes to the airway management technique.

In the PLMA group, the mean heart rate (HR) did not show significant intra-group changes at various time intervals compared to the preoperative vitals. In

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contrast, in the ETT group, the mean HR increased significantly from 86.20 ± 8.14 bpm to 98.40 ± 13.90 bpm at insertion, 103.83 ± 11.70 bpm at 1 minute, 101.90 ± 13.77 bpm at 3 minutes, and 94.47 ± 20.00 bpm at 5 minutes ($P < 0.05$). Inter-group comparison revealed significant differences in HR between the PLMA and ETT groups at insertion, 1 minute, 3 minutes, 5 minutes, 10 minutes, and removal times, with the ETT group showing higher HRs ($P < 0.05$). Sharma B et al[9] reported no significant hemodynamic changes at 1, 3, and 5 minutes after PLMA insertion. However, Lalwani et al[10] found significant HR increases in both ETT and PLMA groups, while our study observed significant HR increases only in the ETT group. The consistent hemodynamic stability in the PLMA group across studies reinforces the device's suitability for patients where cardiovascular stability is crucial, ensuring that observed hemodynamic differences are due to the device type rather than patient variability.

In the PLMA group, the mean SBP, DBP, and MAP remained stable and did not show significant intra-group changes at various time intervals compared to preoperative vitals. In the ETT group, the mean SBP, DBP, and MAP increased significantly from baseline at 1 minute, 3 minutes, 5 minutes, and at removal time ($P < 0.05$). Inter-group comparison showed significant hemodynamic changes between the PLMA and ETT groups at 1 minute, 3 minutes, 5 minutes, and removal times, with the ETT group showing higher SBP ($P < 0.05$). Idrees A et al[11]noted that the hemodynamic response to insertion was significantly attenuated in the LMA group compared to the ETT group. They concluded that this attenuated hemodynamic response to LMA insertion, compared to ETT, is beneficial for patients with compromised cardiovascular profiles, indicating a safer hemodynamic profile for LMA compared to ETT. These findings are crucial as they highlight the consistent hemodynamic advantage of PLMA, underscoring the device's potential benefits for patients with cardiovascular concerns.

In the PLMA group, the mean SpO2 and ETCO2 remained stable without significant intra-group changes at various time intervals compared to preoperative SpO2. Similarly, in the ETT group, the mean SpO2 remained stable without significant intra-group changes. Hence, inter-group comparison showed no significant differences in SpO2 between the PLMA and ETT groups at any time interval ($P > 0.05$). Shibin A et al[5]reported no statistical differences in ventilation changes with respect to SpO2 and ETCO2 between the groups. Saraswat et al[7] also found comparable values of SpO2 and ETCO2 in patients undergoing laparoscopic surgeries under general anesthesia, with both groups maintaining perioperative SpO2. This stability in respiratory parameters across different studies confirms that any observed differences in other outcomes can be attributed to the airway management technique rather than variations in oxygenation or ventilation.

During intraoperative morbidity, the incidence of leakage was reported in 4% of PLMA patients, with no cases in the ETT group. Gastric insufflation was reported in 10% of PLMA patients, significantly higher than in the ETT group ($P < 0.05$). No cases of regurgitation or aspiration were observed in either group. Upon removal, coughing and blood staining of the device were observed in both groups, with slightly higher incidences in the PLMA group, though without statistical significance ($P > 0.05$). Trauma to the lip, teeth, or tongue was reported in 6% of PLMA patients and 3.33% of ETT patients. Postoperative morbidity showed that sore throat was reported in 6% of PLMA patients and 20% of ETT patients, indicating a statistically significant difference ($P < 0.05$). No cases of vomiting, dysphagia, dysphonia, or dysarthria were reported in either group. According to Shibin A et al[5] post-extubation cough was present in 11. 1% of ETT patients compared to 2.2% of PLMA patients. Injury to the lip, tongue, and teeth was not observed in any patients in either group. One patient (2.2%) in the ETT group had blood in the tube after extubation. Saraswat et al[7]reported a higher incidence of sore throat in the intubation group (20%) compared to the PLMA group (10%). All patients were administered gargles and steam inhalation, and after 24 hours, none of the PLMA group patients had a sore throat, while two ETT group patients had persistent sore throat for up to 48 hours. This consistency in pharyngeolaryngeal morbidity findings underscores the lower incidence of postoperative sore throat with PLMA, ensuring that observed differences in postoperative comfort are attributable to the airway management technique rather than other perioperative factors.

CONCLUSION

In our study, we found compelling evidence to suggest that Supraglottic Airway Devices offer an equally effective alternative to Endotracheal Tubes for establishing airway during laparoscopic surgeries under General Anaesthesia with controlled ventilation. Not only are these devices easier to insert, but they also help maintain hemodynamic parameters while minimizing postoperative complications, reducing the number of insertion attempts, and mitigating airway morbidity. This highlights their potential as a preferred option for airway management in such procedures, promising smoother surgical outcomes and enhanced patient comfort.

REFERENCES

1. Basunbul LI, Alhazmi LSS, Almughamisi SA, Aljuaid NM, Rizk H, Moshref R. Recent Technical Developments in the Field of Laparoscopic Surgery: A Literature Review. Cureus. 2022 Feb 15;14
2. Srivastava A, Niranjan A. Secrets of safe laparoscopic surgery: Anaesthetic and surgical considerations. J Minim Access Surg. 2010 Oct;6(4):91-4.

DOI: 10.69605/ijlbpr_13.6.42

3. Sener EB, Ustun E, Ustun B, Sarihasan B. Hemodynamic responses and upper airway morbidity following tracheal intubation in patients with hypertension: conventional laryngoscopy versus an intubating laryngeal mask airway. Clinics (Sao Paulo). 2012;67(1):49-54.
4. Sharma B, Sehgal R, Sahai C, Sood J. PLMA vs. I-gel: A Comparative Evaluation of Respiratory Mechanics in Laparoscopic Cholecystectomy. J Anaesthesiol Clin Pharmacol. 2010 Oct;26(4):451-7.
5. Shibin A, Priyamkari A, A. A., H. R. Comparative study of ProSeal laryngeal mask airway and endotracheal tube in patients undergoing laparoscopic surgeries under general anaesthesia. Int J Res Med Sci. 2022;11(1):277–283.
6. Parikh SS, Parekh SB, Doshi C, Vyas V. ProSeal Laryngeal Mask Airway versus Cuffed Endotracheal Tube for Laparoscopic Surgical Procedures under General Anesthesia: A Random Comparative Study. Anesth Essays Res. 2017 Oct-Dec;11(4):958-963.
7. Saraswat N, Kumar A, Mishra A, Gupta A, Saurabh G, Srivastava U. The comparison of Proseal laryngeal mask airway and endotracheal tube in patients undergoing laparoscopic surgeries under general anaesthesia. Indian J Anaesth. 2011;55:129–34.
8. Patodi V, Singh M, Sethi SK, Depal V, Jain N, Kumar V. A comparative study between ProSeal laryngeal mask airway and endotracheal tube for ease of insertion and haemodynamic changes in patients undergoing laparoscopic cholecystectomy under general anaesthesia. Int J Res Med Sci. 2016;4:5334-5340.
9. Sharma B, Sahai C, Bhattacharya A, Kumar VP, Sood J. Proseal laryngeal mask airway: A study of 100 consecutive cases of laparoscopic surgery. Indian J Anaesth. 2003;47:467–72.
10. Lalwani J, Dubey KP, Sahu BS, Shah PJ. ProSeal laryngeal mask airway: An alternative to endotracheal intubation in paediatric patients for short duration surgical procedures. Indian J Anaesth. 2010;54:541-5.
11. Idrees A, Khan FA. A comparative study of positive pressure ventilation via laryngeal mask airway and endotracheal tube. J Pak Med Assoc. 2000;50:333–8.