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Proseal laryngeal mask airway versus endotracheal tube intubation: A clinical comparative study of its hemodynamic response and complications in pediatric patient undergoing elective surgery

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ABSTRACT

Introduction

For years, endotracheal tube intubation and bag mask ventilation were the mainstays of airway management. The invention of LMA by Dr.Archie Brain had a great impact on the practice of anesthesia in paediatrics. The recently introduced Proseal LMA with a rear cuff and drainage tube that allows a higher pressure and permits drainage of gastric secretions, preventing the pulmonary aspiration. In our study the ProSeal LMA is compared with ETT with respect to hemodynamic response and complications in pediatric patients.

Material and Method

Prospective Double Blind Randomized Comparative Study was conducted on 60 ASA I and II paediatric patients, weighing 5-25kg between 2 to 10 years of age group of either sex scheduled for elective surgeries. They were randomly divided into 30 patients of either PLMA (Group P) or ET (Group E). Haemodynamic response and perioperative complications were recorded from baseline till end of surgery and 24 hours postoperatively. The statistical analysis was done using SPSS version 20.0.

Result

The insertion of PLMA causes statistically less haemodynamic response than ETT. On comparing the degree of rise in pulse rate and MAP between the two groups, ETT group showed a significant higher rise in these parameters than PLMA group ($p<0.05$). PLMA showed lesser post-operative airway related complications like coughing, sore throat, hoarseness of voice and bronchospasm than ETT.

Keywords: ET tube, PLMA, airway, hemodynamic response, paediatric.

INTRODUCTION

For decades, paediatric surgery has been a challenge for the anesthesiologist. In paediatric patient elective lower abdominal surgeries are frequently carried out under general anesthesia.

Currently in anesthesia practice, safeties in field of paediatric anesthesia have markedly increased due to development and advancement in airway management. Endotracheal tube (ETT) allows positive pressure ventilation, prevents gastric insufflation and thus pulmonary aspiration. Therefore ETT [1] device is widely used for securing paediatric airway.[2] These are available in different sizes and is chosen based on the patient's body size. The smaller sizes being used for pediatric and neonatal patient. Tissue irritation during laryngoscopy and tracheal intubation causes stimulation of supraglottic region which is the major cause of sympatho-adrenal response.[3] There is activation of proprioceptors by direct laryngoscopy which induces increase in blood pressure, increase in heart rate and increased catecholamine concentration.[4] A similar set of hemodynamic derangements occur during extubation.

Dr. A.I.J Brain at London hospital, Whitechapel, London had designed the 1st supraglottic airway device, the laryngeal mask airway in 1981 which changed the scenario from "cannot intubate cannot ventilate" to "cannot intubate, can ventilate".[5] In comparison to endotracheal intubation, laryngeal mask airway is non-invasive technique which leads to lesser haemodynamic disturbances. LMA has reduced risk of injury to airway in the peri- operative period.[6] The LMA is one of the effective method to reduce the pressor response occurring during intubation, as it causes lesser sympathetic response and catecholamine release.[7]

Dr. Archie Brain in 2000, introduced The Pro-seal LMA (PLMA) [8], it is a new laryngeal mask airway with a rear cuff and drainage tube that allows higher seal pressure than the LMA-classic for the intra-cuff pressure, and it permits drainage of gastric secretions and access to the alimentary tract. The modification to classic LMA in Pro-seal LMA is the presence of a drainage tube for the gastric content in order to prevent entry of air into stomach and aspiration pneumonitis. The nasogastric tube is placed through the gastric channel and can also help in detecting the wrong placement of PLMA.[9]

In comparison to intubation with endotracheal tube, the PLMA has reduced sympathetic response while insertion and it is associated with tachycardia for a transient period.[10] Because of minimal incidence of coughing with PLMA, it leads to smooth emergence.[11]

In children Proseal LMA provides good protection to the airway than ETT intubation causing less haemodynamic response during insertion and removal.[12] In comparison to laryngoscopy and ETT intubation it has a lesser incidence of complications like coughing, vomiting, laryngospasm, hoarseness of voice, sore throat and bronchospasm.[13]

Hence here is an attempt to compare PLMA with the ETT in paediatric patients who are posted for elective surgeries under GA with respect to haemodynamic responses during placement and removal and intra and post-operative complications.

AIM AND OBJECTIVES

- To compare and evaluate the hemodynamic response and complications during insertion and removal of PLMA and ETT.

Sample size : By keeping the significance level of 5%, power of study at 80%, the sample size was calculated by Winpepi Statistical Package. We arrived at a minimal sample size of 20 (10 in Group P and 10 in Group E). Keeping in mind dropouts, exclusions or protocol violation we conducted the study in 60 patients with 30 patients in each group.

- Group P (n=30) – Proseal LMA insertion for airway management.
- Group E (n=30) – Endotracheal tube intubation for airway management.

After obtaining approval from Institutional Ethical Committee and written informed consent from all the patients, 60 American Society of Anesthesiologists physical status I-II paediatric patients, weighing 5-25kg between 2 to 10 years of age group of either sex scheduled for elective surgeries were included in this prospective, randomized double blind, comparative study. ASA grade 3 and more, patient guardian refusal to be a part of the study, emergency cases, hemodynamically unstable patient, patients with an anticipated difficult airway, recent history of URTI, full stomach patient were excluded from the study.

A thorough preoperative assessment was done a day before surgery.

After confirming nil oral status, patient were taken in the operation theater. Standard monitors were applied which included precordial stethoscope, pulse oximeter, capnography, electrocardiography, temperature probe and automated noninvasive blood pressure (NIBP). Baseline vital parameters were recorded in the form of Pulse Rate, SBP, DBP, MAP, SPO_2. All the patients were given premedication intravenously with Inj. Glycopyrrolate 0.004 mg/kg, Inj. Ondansetron 0.1 mg/kg, Inj. Midazolam 0.02 mg/kg and Inj. Fentanyl 1-2 ug/kg 5 min prior to induction of general anaesthesia. After preoxygenation with 100% oxygen for 3 minutes with appropriate mask, patient were induced with Inj. propofol 2 mg/kg mixed with Inj. lignocaine 0.5 mg/kg and Inj. Succinylcholine 2mg/kg. In "Group P" PLMA of appropriate size was placed and in "Group E" patients were intubated with adequate size ET tube. Inj. Atracurium 0.5 mg/kg or Inj. veccuronium 0.1 mg/kg were used as long acting neuromuscular blocking agent (NMBA) and

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intermittent boluses of Inj. atracurium or Inj. veccuronium were given as and when required.

Immediately after placement of PLMA and ET intubation, vital parameters were recorded. Haemodynamic parameters were recorded at baseline and at 1min, 5 min and 10 min interval after placement of PLMA and ET intubation and also after extubation.

At the end of surgery, anaesthetic agent was discontinued and patients were kept on 100% oxygen and Inj. glycopyrrolate 0.004 mg/kg with Inj. neostigmine 0.05 mg/kg for adequate reversal of residual neuromuscular blockade was given when patient started adequate spontaneous breathing. After full deflation of cuff the PLMA was removed in a spontaneously breathing patient. Similarly, extubation was done after thorough oral suction and when adequate respiratory efforts were there.

During emergence, the occurrence of any complications like coughing, bronchospasm and laryngospasm were noted. After removal of both airway devices, blood staining of the ET tube and posterior aspect of cuff of PLMA, tongue-lip-dental trauma and hoarseness were noted. The patients were monitored throughout the perioperative period till stay in the post-anaesthesia care unit. The patients will be followed for next 24 hr for any sore throat and hoarseness.

All the cases were completed in stipulated time. Data was collected, compiled and tabulated. The continuous variables were represented as Mean ± SD, the categorical variables were presented as numbers. The differences in the means of the quantitative variables were tested statistically by student ‘t’ test. The differences in the categorical variables were analysed by chi-square test. The p value of <0.05 was considered significant. The statistical analysis was done using SPSS Version 20.0.

Results:

In current study, we have compared Pro-seal LMA insertion and Endotracheal tube intubation in paediatric patients undergoing elective surgeries for hemodynamic response and perioperative complications. The study includes a total of 60 paediatric cases of age group between 2-10 years weighing 5-25 kg with ASA status I and II, 30 cases in each group:

Group P (Proseal LMA) (P-LMA)

Group E (Endotracheal tube) (ET).

Following were the observations in our study:

There was no statistical significant difference found in age, weight, sex, MPC grade and ASA grade between both the groups.

In group P (PLMA) the values of pulse rate at 10 minutes were lowered significantly (p<0.05) as compared with baseline values. The systolic and mean blood pressure values were significantly (p<0.05) lowered at 5min and 10 minutes as compared to the baseline as shown in table 1.

Table 1: Comparison of haemodynamic parameters within the group P

	Baseline	**1 minute**	**5 minutes**	**10 minutes**	**After removal of**	**P value**
PR beats per	115.90 ± 15.42	119.03 ± 13.35	116.1 ± 8.15	105.37 ± 13.00*	114.90 ± 12.34	0.0076
	*Baseline Vs 10 mins, p=0.0059.					
SBP mmhg	111.67 ± 7.40	115.30 ± 7.26	100.20 ± 6.59*	101.00 ± 7.42*	113.27 ± 5.90	<0.0001
	*Baseline Vs 5 mins, p<0.0001; Vs 10 mins, p<0.0001.					
MAP mmhg	84.62 ± 4.86	83.44 ± 4.09	74.59 ± 5.37*	77.16 ± 6.05*	86.02 ± 5.23	<0.0001
	*Baseline Vs 5 mins, p<0.0001; and 10 mins, p<0.0001.					

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*Statistically significant if p-value < 0.05

In group E (ETT) the values of pulse rate at 1min, 5 minutes, 10 minutes and at extubation increased significantly as compared with baseline values. The rise in PR was significant statistically(p<0.05).

The systolic blood pressure values were significantly (p<0.05) higher at 1min, 5 minutes and after extubation as compared to the baseline. The diastolic and mean blood pressure values were significantly (p<0.05) higher at 1 minute and after extubation as compared to the baseline as shown in table 2.

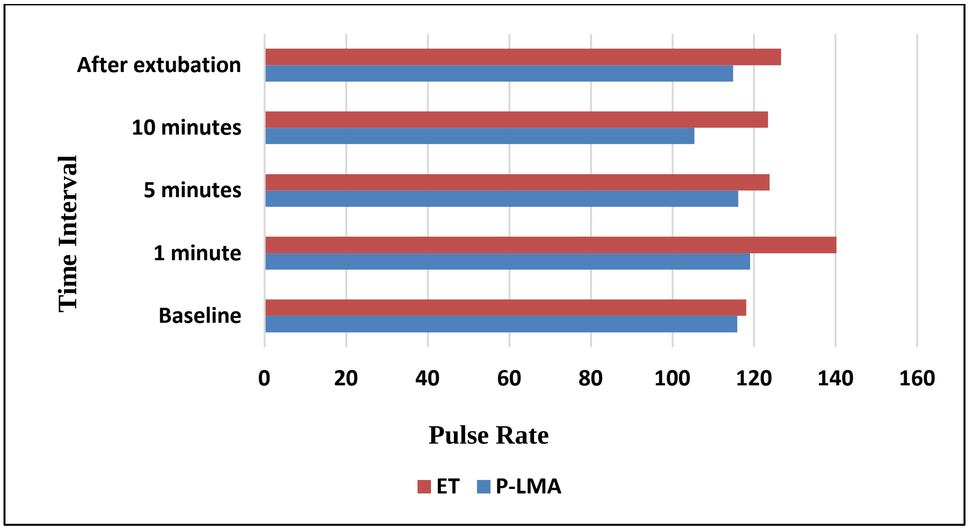
Table 2: Comparison of haemodynamic parameters within the group E

	Baseline	1 minute	5 minutes	10 minutes	After extubation	P value
PR beats per min	118.10 ± 10.83	140.17 ± 6.31*	123.83 ± 5.34*	123.4 ± 8.15*	126.60 ± 9.72*	<0.0001*
	*Baseline Vs 1 Min, P<0.0001; Vs 5 min, p=0.0118; Vs 10 min, p=0.0364; Vs after extubation, p=0.0022					
SBP mmhg	108.70 ± 4.93	121.30 ± 4.01*	115.2 ± 5.08*	101.20 ± 5.20*	118.07 ± 6.49*	<0.0001*
	*Baseline Vs 1 min, p<0.0001; Vs 5 mins, p<0.0001; Vs 10 mins, p<0.0001; Vs after extubation, p<0.0001.					
MAP mmhg	84.97 ± 4.64	90.73 ± 7.49*	77.70 ± 6.09*	77.00 ± 4.89*	89.07 ± 5.99*	<0.0001*
	*Baseline Vs 1 min, p=0.0002; Vs 5 mins, p<0.0001; Vs 10 mins, p<0.0001; Vs after extubation, p=0.0047;					

*Statistically significant if p-value < 0.05

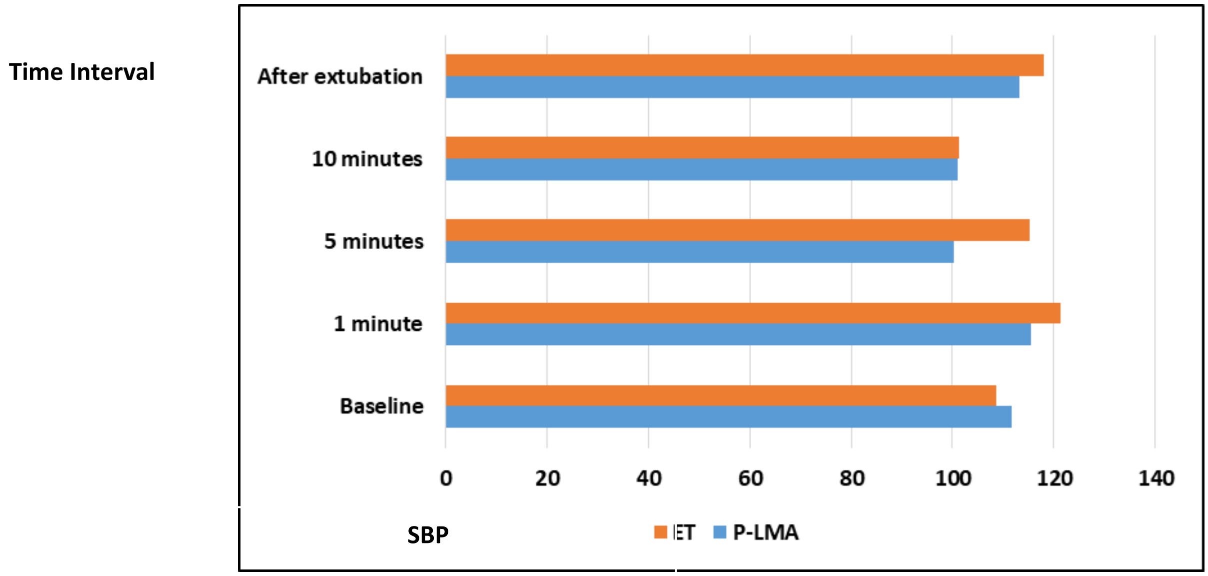
Graph no 1 shows comparison of pulse rate at different time intervals between the two groups. The comparison showed statistically significant lower values of pulse rate at 1 min (p<0.0001*), 5 min (p=0.0001*), 10 min (p<0.0001*) and also at extubation (p=0.0001*) in patients of group P as compared to patients in group E.

Graph 1: Graphical presentation of comparison of pulse rate at baseline, after insertion at 1 min, 5 min, 10 minutes and at extubation between the two groups.



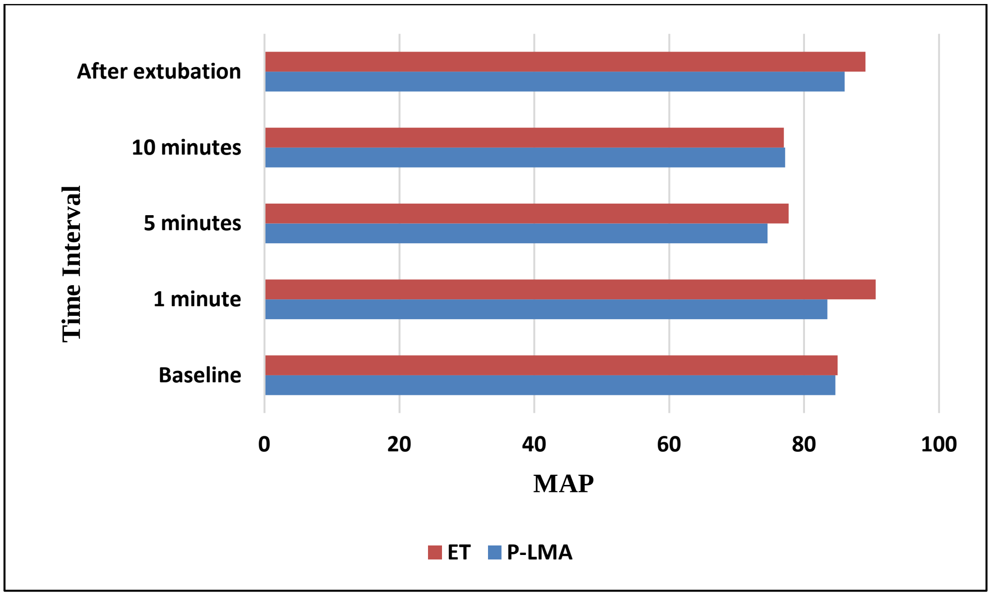
Graph no. 2 shows comparison of systolic blood pressure between the two groups. The comparison showed statistically significant lower values of systolic blood pressure at 1 min (p=0.0002*), 5 minutes (p<0.0001*), and after extubation (p=0.0040*) in group P as compared to patients in group E. No statistically significant difference was noted at baseline and 10 minutes in both the groups.

Graph 2: Graphical presentation of comparison of systolic blood pressure at baseline, after insertion at 1, 5, 10 minutes and at extubation between the two groups.



Graph no. 3 shows the comparison of mean arterial blood pressure between the two groups. The comparison showed statistically significant lower values of MAP at 1 min (p<0.0001*), 5 minutes (p=0.0403*) and after extubation (p=0.0400*) in group PLMA when compared to patients in group ETT. No statistical significant differences noted at baseline (p=0.7764) and 10 (p=0.9107) minutes after insertion between the two groups.

Graph 3: Graphical presentation of comparison of mean arterial blood pressure at baseline, after insertion at 1, 5, 10 minutes and at extubation between the two groups.

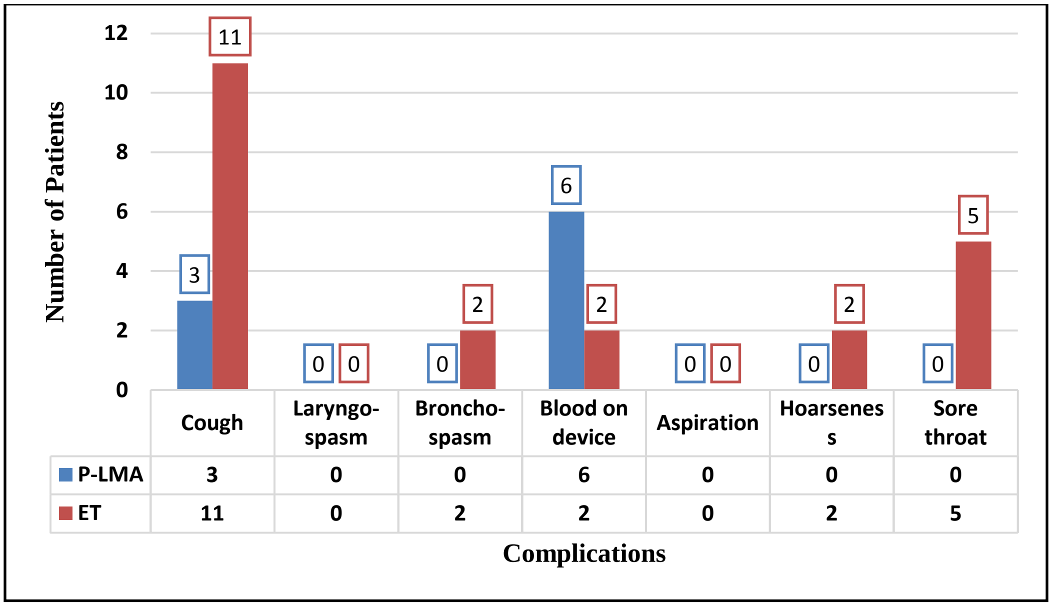


Graph no. 4 shows comparison of incidence of complication between the two groups.

There was statistically significant (p=0.0146*) difference noted only for cough between both the groups. Coughing after removal of device was noted in 3 patients of group P while it was seen in 11 patients in group E.

While there was no statistical significant difference noted for other evaluated complications including laryngospasm (p=0.8973), bronchospasm (p=0.4720), blood on device (p=0.2546), aspiration (p=0.8973), hoarseness (p=0.4720) and sore throat (p=0.0617).

Graph 4: Graphical representation of evaluation of complications among the patients in group P and group E.



Discussion:

Airway management is a fundamental aspect of anaesthesia practice. Traditionally, laryngoscopy and endotracheal intubation was the mainstay in safeguarding the airway in patients of any age group. For adequate oxygenation and ventilation securing an airway is essential and failure to do so can be life threatening.

Endotracheal intubation is rapid, safe and non-surgical technique that achieves all the goals of airway management. It has its own advantages such as prevention of aspiration and leak free ventilation and hence it remains the gold standard[14] procedure for airway management. But despite of advantages, it has its own complications. It is associated with haemodynamic changes like tachycardia and increased blood pressure produced by laryngoscopy[15] and various postoperative disadvantages such as, cough, sore throat and hoarseness[16]of voice. Laryngoscopy induced haemodynamic changes was first described by Reid and Brace.[17] These responses are initiated within seconds of laryngoscopy and further increases while passing the endotracheal tube. The response peaks in 1–2 min and returns to normal values by 5 min – 10 min.[18]

Pediatric airway is more difficult to manage compared to adult airway due to its various anatomical differences. There is high risk of mortality and morbidity whenever the airway is complicated. Since the start of era of surgery, pediatric anesthesia is always considered challenging for anesthesiologists. The laryngeal mask airway has changed pediatric anesthesia practice and has become an important asset of airway management in children.

The Proseal Laryngeal Mask Airway is a new laryngeal mask device with a modified cuff to provide better seal around glottis and it has a drain tube for insertion of the gastric tube to prevent regurgitation and gastric insufflation. These features are designed to improve the safety of the device and broaden its scope, especially when used with positive pressure ventilation.[19] It is being successfully used to maintain airway. It has advantages like, ease of insertion, prevention of aspiration due to presence of gastric channel, lower incidence of post-operative complications and better seal pressure which

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provides benefit to both the clinician and the children.

In the current study, we have compared different effects of Proseal LMA and ETT in paediatric patients undergoing elective surgery.

DEMOGRAPHIC PROFILE:

The patient in both group did not show any statistically significant differences in their age, gender, weight and in terms of ASA grading. (p >0.05)

COMAPARISION OF HAEMODYNAMIC PARAMETERS:

COMPARISON OF HEART RATE

In our study we found that the increase in pulse rate was lower after PLMA insertion than endotracheal tube intubation. (p <0.05)

Baseline heart rate (before placement of device) were comparable in both the group, i.e. p value not significant (p >0.05). There was statistically significant difference in heart rate between two groups at 1min, 5mins and 10 mins and also after removal of device. Values were relatively lower in group P than group E. The difference between two groups was found to be statistically significant (p value <0.0001)

Similar results were found in following studies;

In 2010, **Lalwani J *et al*** [10] in their study observed that the PR after placement of PLMA and ETT, increased from the baseline value. The increase in the pulse rate in both the groups was significant (P<0.05). After 5 mins of placement of PLMA the PR reduced near to the base line value. After 10mins of ETT placement the rise in the PR was significant (P<0.05). After ET intubation, increase (%) in PR was higher than after placement of PLMA (P<0.05).

In 2016, **Dar S *et al*** [20] in their study concluded that, in both the groups after placement of the airway devices heart rate was increased but the magnitude and duration was less with PLMA as compared to ETT.

COMPARISIONN OF SYSTOLIC BLOOD PRESSURE

Within the group comparison: In group P, At 5 min and 10 min SBP values were lowered to 100.20 ± 6.59 and 101.00 ± 7.42 respectively from baseline with statistical significance.(p <0.05) In group E, The increase in SBP from baseline value was statistically significant (p <0.05).

Between the group comparison: There was significant difference in systolic blood pressure values after insertion of device at 1 min, 5 mins, and 10 mins and after removal of device. Values were relatively lower in group P than group E which was statistically significant (p <0.05).

Similar results were found in following studies;

In 2008, **Misra M *et al*** [2] they concluded the hemodynamic changes observed were minimal with PLMA while with tracheal tube, significant changes were observed.

In 2010, **Lalwani J *et al*** [10] in their study found that after insertion of PLMA or ET the rise in SBP from the baseline was statistically insignificant (P>0.05) in both groups. After insertion of PLMA a statistically significant (P<0.05) decrease was noted for from baseline value of SBP.

COMPARISION OF MEAN ARTERIAL BLOOD PRESSURE

Within the group comparison: In group P, MAP value decreased from baseline value of 84.62 ± 4.86 mmhg to 74.59 ± 5.37 mmhg at 5 min and 77.61 ± 6.05 mmhg at 10 min which was statistically significant (p<0.05). In group E, the MAP increased from baseline value of 84.97 ± 4.64 mmhg to 90.73 ± 7.49mmhg at 1 min and to 89.07 ± 5.99mmhg after extubation. The difference was statically significant (p<0.05).

Comparison between the two groups: In our study baseline MAP (before placement of device) were comparable in both the group, i.e. p value not significant (p >0.05). There was statistically significant (p<0.05) difference in mean arterial blood pressure between the two groups at 1 min, 5 mins and after removal of the device. The MAP was lower in Group P as compared to Group E.

Similarly, in 2012, a study was conducted by **Garima Agrawal *et al*** [21] they observed that following insertion of ETT found that there was a highly significant rise in MAP (P=0.000). Whereas, they found there was no significant rise in the MAP after placement of the PLMA. They found that the

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rise in MAP in the ETT group was significant and sustained at 3 minutes post-insertion while it came towards baseline values at 5 minutes in the PLMA group.

COMAPARISION OF PERIOPERATIVE COMPLICATIONS:

In our study, when compared to group P, group E showed significant incidence of cough after removal of ETT. In group P, only 10 % of patients (3 out of 30) reported cough and in group E 36 % of patients (11 out of 30) reported cough. Difference between the two groups was statistically significant (p-value < 0.05). There was no statistically significance noted in incidence of bronchospasm, laryngospasm, aspiration, blood on device, hoarseness of voice and sore throat.

Similar results were found in following studies;

In 2016, **Dar S *et al*** [20] found that two patients of group PLMA and four patients of group ETT coughed after removal of devices. None reported intraoperative regurgitation and laryngospasm.

In 2018, **Neelam Dogra *et al*** [22] found that incidence of coughing were more in group E (20 %) than group P (8%), which was statistically significant. Also incidence of sore throat was comparatively higher in group E (32%) than in group P (8%). Aspiration was not reported in both the groups.

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