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Research Article

A Prospective Comparative Study of Hemodynamic Response to Proseal Lma Insertion versus Endotracheal Intubation

Dr.Sudhanshu Sant[1], Dr.Archana Agarwal[2], Dr.Rohit Malhotra[3], Dr.Vikram Dalal[4*]
[1]Associate Professor, Department of Anaesthesiology, GS Medical College & Hospital, Pilkhuwa, Hapur (U.P.).
[2]Professor, Department of Anaesthesiology, GS Medical College & Hospital, Pilkhuwa, Hapur (U.P.).
[3]Junior Resident, Department of Anaesthesiology, GS Medical College & Hospital, Pilkhuwa, Hapur (U.P.).
[4*]Junior Resident, Department of Anaesthesiology, GS Medical College & Hospital, Pilkhuwa, Hapur (U.P.).
Corresponding Author: Dr.Vikram Dalal
Junior Resident, Department of Anaesthesiology, GS Medical College & Hospital, Pilkhuwa, Hapur (U.P.).
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Abstract
Introduction: Airway management is a critical skill for anaesthesiologists. The airway can be maintained in a variety of ways, with endotracheal intubation being the gold standard. The use of laryngoscopy and intubation induces an increase in blood pressure and pulse rate. The hemodynamic response to laryngoscopy and tracheal intubation has been extensively documented, and several approaches have been attempted to mitigate it. This response is harmful in patients with a compromised cardiovascular system, especially if it is unregulated.
Materials and Methods: A total of 100 patients were randomly selected from the list of elective surgical procedures under general anaesthesia. They were divided randomly by computer generated number method into two groups of 50 patients each. Group ET (n=50):Laryngoscopy and endotracheal intubation with appropriate sized cuffed PVC endotracheal tube was done. Group PLMA (n=50): PLMA size 3 or 4 as appropriate for the patient was inserted and cuff inflated with recommended volume of air.
Results: The demographic profile of the patients in Group ETT and Group PLMA were comparable (P>0.05).There was no statistical difference in insertion attempts between endotracheal tube and PLMA. The difference in time required for endotracheal intubation and PLMA insertion was not statistically significant. There was a rise in heart rate and mean arterial pressure (MAP) seen after insertion of both devices, but there was comparatively higher rise seen with endotracheal tube than PLMA and it was statistically significant.
Conclusion: From the findings of present study it is concluded that PLMA insertion causes significantly less and transient hemodynamic response in comparison to endotracheal intubation. Hence it could be useful in situations where minimal changes in hemodynamics are desirable. PLMA is also found to be equally safe compared to endotracheal tube, as not a single incidence of aspiration was noted with its use. We recommend routine use of PLMA in place of endotracheal intubation for elective surgical procedures lasting 1 to 2 hours.

Keywords: Airway Management, Endotracheal Intubation, PLMA Insertion, General Anaesthesia.

INTRODUCTION

Airway management is a critical skill for anaesthetists. The airway can be maintained in a variety of ways, with endotracheal intubation being the gold standard. The use of laryngoscopy and intubation induces an increase in blood pressure and pulse rate. The hemodynamic response to laryngoscopy and tracheal intubation has been extensively documented and several approaches have been attempted to mitigate it.(1,2)This response is harmful in patients with a compromised cardiovascular system, especially if it is unregulated. Two studies comparing hemodynamic responses to three different airway devices found that tracheal intubation using direct laryngoscopy has a profound hemodynamic response as compared to the use of supraglottic devices, especially in hypertensive patients.(3)There are many

pharmacological agents which attenuate this response.[2]

The Proseal Laryngeal Mask Airway (PLMA) is most complex of the specialized masks of the laryngeal mask airway (LMA) family. All components are made from medical grade silicon and are latex free. It has four main parts: The cuff, inflation line with pilot balloon, airway tube, and drain (gastric access) tube. This drain tube provides a bypass channel for regurgitated gastric contents and help in detecting malposition of the mask (3). The drain tube also prevents occlusion of airway tube by the epiglottis, thus eliminating the need for airway bars (present in LMA classic).The flat dorsal component of the cuff of PLMA is designed to push the mask anteriorly and firmly around the glottis thus providing a better seal. Larger proximal component of the ventral cuff is designed to improve the seal. In comparison to LMA Classic, the laryngeal cuff of PLMA is made of softer silicone and its bowl is deeper, and the airway tube of PLMA is shorter and smaller in diameter. It is available in six sizes (1.5, 2, 2.5, 3, 4, 5).[4]

The PLMA, a successive generation of classic LMA(C-LMA), with its improved features of cuff design and incorporation of gastric drain channeled to better seal achievement around the glottis thus minimizing the risk of pulmonary aspiration. The drain channel prevents gastric insufflation, allows easy placement of gastric tube. However, improved anatomical design to prevent aspiration made the Proseal LMA a bulkier device which is somewhat difficult to insert with a possibility of higher haemodynamic stress response in comparison to C-LMA. Based on these facts, we decided to undertake the present study for comparing the haemodynamic stress response, insertion characteristics in terms of number of attempts, time taken for insertion and failure of the device insertion along with the intra operative and post operative complications if any, between PLMA insertion and endotracheal intubation in elective surgical procedures requiring general anaesthesia (GA).[5]

MATERIALANDMETHODS

It was a Prospective Comparative Study conducted at the Department of Anaesthesiology, GS Medical College & Hospital, Pilkhuwa, Hapur (U.P.) from December 2022 to May 2023. A Sample Size of 100 was taken.

After taking approval from the institutional ethics committee a total of 100 patients of either sex belonging to American Society of Anaesthesiologists (ASA) class 1 or 2, in the age-group between 20-50 years were randomly selected from the list of elective surgical procedures under GA. They were divided randomly by computer generated number method into two groups of 50 patients each.

Group ET (n=50):Laryngoscopy and endotracheal intubation with PVC, cuffed ETT-Size 7mm ID in female patients and size 7.5 mm ID in male patients was done.

Group PLMA (n=50): PLMA size 3 in female patients and size 4 in male patients was inserted and cuff was inflated with recommended volume of air.

Patients were kept nil by mouth (NBM) for 8 hrs preoperatively. On the day of surgery, patients were shifted to the pre-operative room. Identity of the patients and NBM status were confirmed and informed written consent was obtained from the patients. Baseline vital parameters were recorded by multipara monitor consisting of electrocardiogram (ECG) for heart rate (HR), Non Invasive Blood Pressure (NIBP), Mean Arterial Pressure (MAP) and peripheral oxygen saturation (SpO_2). Intravenous access with 20G indwelling cannula was established and slow infusion of Inj.Ringer Lactate solution was started@2ml/kg/hr. All patients were premedicated with Inj.Glycopyrolate 0.2 mg intravenously (IV).

After patient was taken to the Operation Theatre (OT), a multipara monitor was attached to the patient for monitoring continuous ECG, HR, peripheral oxygen saturation (SpO_2) and NIBP at 1 minute intervals. Inj. Ondansetron at 100 mcg/kg body weight (b.w.), Inj. Fentanyl at 2 mcg/kg body weight was given and the patient was pre-oxygenated with 100% oxygen for 3 min.

GA was induced with Inj.Propofol 1.5-2mg/kg b.w. slowly i.v till loss of eye lash reflex and jaw relaxation. This was considered as the end point of induction.

After induction, check ventilation was done before administering non-depolarising muscle-relaxant Inj.Vecuronium bromide 0.1 mg/kg b.w. intravenously to facilitate intubation of trachea with ETT or securing the airway with PLMA as per the group assigned.

Airway management and tracheal intubation versus PLMA insertion (as per the group

assigned) was done by experienced anaesthesiologist. Time required for the procedure was counted from time of holding the device by the anaesthesiologist till the confirmation of successful placement of the ETT or the PLMA as per the group. Successful intubation of Trachea/PLMA placement was confirmed by capnography in addition to other clinical parameters. If the ventilation with PLMA was not found satisfactory or too much leak was observed, after inflation of the PLMA cuff on controlled ventilation by the anaesthesia machine ventilator the PLMA was removed by the anaesthesiologist and another attempt was made to insert it. Maximum three attempts were permitted before failure of insertion was stamped. Whenever required an additional dose of Inj.Propofol 20-30 mg i.v bolus was given if more than one attempt at re-insertion of PLMA was made.

During the course of surgery, anaesthesia was maintained with oxygen (O_2) and nitrous oxide (N_2O) in the ratio of 1:2 with total flows 4 lit/min, sevoflurane 1% and vecuronium bromide top- ups in dose of 1mg, IV bolus intermittently as per requirement .Hemodynamic parameters like HR, MAP as well as SpO_2 were recorded before induction (baseline parameters), the induction of G.A. during securing the airway with either ETT/PLMA and then at 1,3,5,7,10,15 minutes post intubation or PLMA insertion. After completion of surgery, neuromuscular blockade was reversed with neostigmine 50 mcg/ kg b.w and glycopyrolate 10 mcg/kg b.w. intravenously and ETT/PLMA was removed after full return of reflexes and consciousness. The insertion characteristics were recorded in terms of number of attempts required for the insertion, time taken for insertion and number of incidences of the failure of the insertion of ETT/ PLMA. Complications like trauma, cough, sore throat, nausea/ vomiting/regurgitation during intubation /PLMA insertion or postoperatively were noted.

Effect on SpO_2:

SpO_2 remained stable and comparable to baseline in both the groups (p>0.05) (Table6).

STATISTICAL ANALYSIS: Data collected was analysed as mean ± S.D for continuous variables e.g HR, MAP, time for insertion and categorical data as numbers or percentage. Statistical analysis was done by using SPSS version 18 (IBM) software. Inter group comparison between the two groups was done using the unpaired student t- test for quantitative data and chi square test for qualitative data ($p < 0.05$ was considered as statistically significant).

RESULTS

The demographic profile of the patients in Group ETT and Group PLMA were comparable (P>0.05)(Table 1).There is no statistical difference in insertion attempts between endotracheal tube and PLMA(Table 2).The difference in time required for endotracheal intubation and PLMA insertion is not statistically significant (p>0.05) (Table 3).

Hemodynamic Changes

Heart Rate (HR): A significant increase in HR was observed in Group ETT immediately after intubation compared to Group PLMA ($p < 0.001$). HR remained elevated for 5 minutes post- intubation, whereas PLMA insertion caused minimal HR variation (Table 4).

Systolic Blood Pressure (SBP):

Group ETT showed a significant rise in SBP at 1 minute post-intubation ($p < 0.001$), whereas PLMA insertion resulted in a lesser hemodynamic change.

Diastolic Blood Pressure (DBP) and Mean Arterial Pressure (MAP):

A marked rise in MAP was observed in Group ETT at 1 minute ($p < 0.001$), which normalised over 5 minutes. Group PLMA showed only a slight increase (Table 5).

Overall Hemodynamic Stability:

PLMA insertion was associated with significantly lower hemodynamic fluctuations compared to ET intubation.

Patient characteristics	Group ETT (n=50)	Group PLMA (n=50)	p-Value
Age(years)	38.5± 10.2	39.1±9.8	>0.05
Gender(Male/Female)'n'	26/24	25/25	>0.05
Weight(Kg)	66.1±7.9	65.3±8.5	>0.05
Height(cm)	158.42±3.70	159.02±3.9	>0.05
ASA Physical status(I)	28	30	>0.05
ASA Physical status(II)	22	20	>0.05

Table 1: Patient Demographics (Continuous variables are expressed as Mean±SD, categorical variables are expressed in numbers)

ASA: American Society of Anaesthesiologists, n: Numbers, SD: standard deviation

Insertion Attempts	Number of patients		
	Group ETT	Group PLMA	p-Value
1	49	47	0.07
2	1	3	0.10
3	0	0	-

Table 2: Insertion attempts

	Mean Insertion Time(seconds)		p-Value
	Group ET	Group PLMA	
Mean insertion time(in seconds)	24±7	20±5	<0.01

Table 3: Mean insertion time of the device (p<0.01)

Parameters (Time/Interval)	Group ETT (n=50)	Group PLMA (n=50)	p-Value
Baseline	78±8	76±8	>0.05
At induction of GA	73±8	72±8	>0.05
During insertion of airway device	78±8	76±8	>0.05
At1min	92±10	80±8	<0.01
At3min	88±9	78±7	0<.01
At5min	85±8	77±6	<0.05
At7min	83±7	76±5	<0.05
At10min	80±6	76±5	>0.05
At15min	78±5	75±4	>0.05

Table 4: Comparison of HR (beats/min) between the two groups (Data is expressed as mean ±SD)

Parameters (Time interval)	Group ET (n=50)	Group PLMA (n=50)	p-Value
Baseline	93±7	92±6	>0.05
At Induction of GA	91±6	90±5	>0.05
During insertion of airway device	90±6	89±5	>0.05
At 1min	110±9	96±7	<0.001
At 3min	105±8	94±6	<0.001
At 5min	100±7	93±5	<0.5
At 7min	97±6	92±5	<0.05
At 10min	94±5	91±5	>0.05
At 15min	92±5	90±4	>0.05

Table 5: Comparison of MAP between Study Groups. (Data expressed as Mean±SD)

Parameters (Time interval)	Group ET (n=50)	Group PLMA (n=50)	P-Value
Baseline	99.2±0.8	99.3±0.7	>0.05
At Induction of GA	99.0±0.9	99.1±0.8	>0.05
During insertion of airway	98.9±0.8	99.0±0.7	>0.05

device			
At 1 min	98.7±0.7	99.0±0.5	>0.05
At 3 min	98.8±0.6	99.2±0.6	>0.05
At 5 min	99.0±0.7	99.3±0.5	>0.05
At 7 min	99.1±0.6	99.3±0.5	>0.05
At 10 min	99.2±0.5	99.4±0.4	>0.05
At 15 min	99.3±0.4	99.4±0.3	>0.05

Table 6: Comparison in SpO2 between the two groups. SpO2 (Oxyhemoglobin saturation)

Complications	Group ET (n=50)	Group PLMA (n=50)	P-value
Arrhythmias	8%	2%	<0.05
Airway Trauma	8%	2%	<0.001
Cough	18%	7%	<0.001
Sore throat	20%	6%	<0.001
Nausea/ Vomiting	7%	3%	<0.05

Table 7: Intra Operative and Post Operative Complications

DISCUSSION

The present study showed that the HR and MAP returned to baseline within 10 minutes of PLMA insertion while it remained elevated even beyond 15 minutes of insertion in ETT group. Similar results were obtained in other studies where in hemodynamic responses were lower for the placement of PLMA than ETT and returned to normal significantly earlier in PLMA group as compared to ETT group. Akhtar TM et al compared the insertion of PLMA with endotracheal intubation and observed that insignificant changes in HR, MAP and intraocular pressure were produced after insertion of LMA or endotracheal tube.[6]

Our results are contrary to this study. Pressor response is a known entity during airway handling especially during direct laryngoscopy and endotracheal intubation. Attenuation of such responses with the use of LMA may be due to diminished catecholamine release as suggested by Lamba K et al. This could be due to the fact that LMA is relatively simple and atraumatic to insert and does not require laryngoscopy before insertion.[7]The present study demonstrates that there is no statistical difference in the number of attempts required for endotracheal intubation/PLMA insertion. However, only one patient in group ETT and three patients in group PLMA required second attempt, but this difference is statistically insignificant (p>0.05).[8]None of the patient in either group required more than two attempts for intubation or PLMA insertion hence there was no failure of insertion of PLMA and endotracheal intubation. The duration of endotracheal intubation and PLMA insertion was comparable. (24 ± 7 Vs 20 ± 5 sec. (P-value<0.001) The results of the study correlated with the study of Namita and Aditya Kumar and coworkers which showed that the mean time of insertion required for endotracheal intubation was 16.93 sec and for PLMA insertion was 15.77sec.which was not statistically significant and there was no incidence of failure of endotracheal intubation and PLMA insertion reported in either of the group.[9]

In the present study post operatively incidence of sore throat was noted in ten and three cases of ETT and PLMA respectively which was short lived and didn't need any treatment except saline gargles. The incidence of sore throat varies in due to variation in size of LMA and endotracheal tube used in different studies, the design and the type of ETT and lubricating material which was used. The sore throat and dysphagia that occurs in the post operative period is usually short lived and does not require treatment. Only four patients in ETT group and one patients in PLMA group showed evidence of mild trauma (blood stains on device during extubation).[10]

CONCLUSION

From the results of present study it is concluded that PLMA insertion causes significantly less and transient hemodynamic response in comparison to endotracheal intubation. Hence it could be useful in situations where minimal changes in haemodynamics are desirable. PLMA is also found to be equally safe when compared to ETT, as no incidence of aspiration was noted with its use. We recommend routine use of PLMA in place of endotracheal intubation for elective surgical procedures under GA which are likely to last for 1 to 2 hours.

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