Proseal LMA Versus Endotracheal Tube A Clinical Comparative Study of its Different Effects in Paediatric Patients Undergoing Lower Abdominal Surgeries

Showket Ahmad Dar[1], Sangeeta Deka[2], Nilotpal Dasand[3], Mudasir Ahmad Mir[4], Ajaz Ahmad Mir[4]

ABSTRACT

Introduction: This prospective comparative trial was undertaken to compare the effects of insertion of ProSeal LMA and Endotracheal tube on haemodynamic response, evaluate the safety and efficacy of ProSeal LMA as an airway device, and evaluate other noteworthy observations in paediatric patients undergoing lower abdominal surgeries under general anaesthesia and requiring positive pressure ventilation.
Material and Methods: 60 cases which met all the inclusion criteria were selected and the study was carried out on patients of ASA I and II, aged 2 – 10 years of either sex, weighing 10 – 20 kg undergoing elective lower abdominal surgery Group-A: ProSeal LMA (PLMA) for airway management Group-B: EndoTracheal Tube (ETT) for airway management.
Results: Both ETT and PLMA cause increase in hemodynamic responses, but the magnitude and duration of response is less in LMA-PS. Removal of PLMA showed that the change of HR, SBP, DBP, MAP were not significant to the base line reflecting a smooth emergence. Incidence of post-operative complications were found to be less with PLMA than with ETT.
Conclusion: ProSeal LMA can be routinely used as a safe and effective alternative airway device to endotracheal intubation for positive pressure ventilation in paediatric patients undergoing elective surgical procedure.

Keywords: Haemodynamic response; ProSeal LMA; Paediatric patients; Lower abdominal surgeries; positive pressure ventilation.

INTRODUCTION

The major cause of sympatho-adrenal response to tracheal intubation is due to the stimulation of supraglottic region by tissue irritation induced by direct laryngoscopy.[1] Direct laryngoscopy by activating proprioceptors, induces arterial hypertension, tachycardia and increased catecholamine concentration proportional to the intensity of stimulus exerted against the base of the tongue.[2]
Endotracheal tube is the gold standard[3,4] device to maintain an airway and has ability to provide positive pressure ventilation, prevents gastric inflation and pulmonary aspiration.[4]
In 1981, Dr. A.I.J Brain designed the Laryngeal Mask Airway (L.M.A. classic) at London hospital, Whitechapel, London which changed the scenario from "cannot intubate, cannot ventilate" to "cannot intubate, can ventilate".[5] The Laryngeal Mask Airway is designed to establish effective seal around the laryngeal inlet with an inflatable cuff. It is a useful advancement in airway management.[5]
The LMA is one of the most promising non-pharmacological methods to attenuate the sympathoadrenal response to tracheal intubation, causing less sympathetic response and catecholamine release.[6]
The PLMA causes less pressure response during insertion compared to tracheal intubation and the increase in heart rate is very short lived.[3,7] The PLMA also results in minimal coughing and produces a smooth emergence.[8,9] LMA can be used for Pressure Controlled Ventilation with Positive End Expiratory Pressure in paediatric patients.[10]
Objective of the study was to compare the effects of insertion of PLMA and ETT on haemodynamic response, evaluate the safety and efficacy of PLMA as an airway device in paediatric patients.

MATERIAL AND METHODS

After obtaining approval from hospital Ethical Committee, details of the procedure was explained to the patient's guardian and a written informed consent was taken. 60 cases which met all the inclusion criteria were selected for the study. The study was carried out on patients of ASA I and II, aged 2 – 10 years of either sex, weighing 10 – 20 kg undergoing elective lower abdominal surgery in the Department of Anesthesiology and Critical Care, Gauhati Medical College and Hospital, from 1st June 2011 to 15th September 2012.
Exclusion criteria were parent and guardian refusal for consent, patients of ASA>II, emergency cases, obese patients, patients with anticipated difficult airway.
Grouping of the patients was done using the plan generated from the site www.randomization.com (seed no 5537, Randomization plan created on 14 June 2011 16:52:05) to one of the either groups
Group-A: PLMA, size 2 (as per body weight) by digital technique was used. The cuff was inflated with 8-10ml air for size 2.
Group-B: PVC un-cuffed ETT of size 4.5 mm, 5 mm and 5.5 mm were used for intubation.

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On arrival in the preoperating room, after confirming the identity of the patient, the consent was checked; the preoperative assessment was reviewed and up dated. The nil by mouth status of the patient was confirmed and syrup Midazolam (0.5mg/kg) was given as premedication to sedate the patient 45 minutes before the surgery. Then the patient was shifted to the operation theatre. ECG, NIBP and pulse oximeter were applied and baseline readings of parameters like HR, SBP, DBP, MAP and SpO2 were noted.ETCO2 was attached after intubation. Intravenous line was established with 22 G IV cannula. All patients received similar premedication with intravenous Glycopyrrolate 8-10µg/kg, Tramadol and Ondansetron. A standard General Anaesthesia technique was adopted in all patients consisting of pre-oxygenation for 3 minutes, induction with Inj Propofol 1% (2mg/kg) followed by Inj. Atracurium (0.6 mg/kg).

Correct placement of both ETT and PLMA was confirmed by: Chest movement, Bilateral chest auscultation, $ETCO_2$ waveform, Easy passage of the nasogastric tube through the gastric tube of LMA. A nasogastric tube (8/10 French) was passed in every patient of both groups. Anaesthesia was maintained with Nitrous oxide 66% in 33% Oxygen and 0.2% halothane. Neuromuscular blockade was maintained with Inj. Atracurium with top up of 0.1mg/kg. Ventilation was set at a tidal volume of 8ml/kg, respiratory rate of 20-22 /min and I/E ratio of 1:2. Patients of both the groups were placed in the left lateral position and caudal epidural regional block with Bupivacaine 0.2% and Clonidine 1µg/kg was given for intraoperative and post-operative analgesia. After the completion of surgery, reversal of the residual neuro-muscular blockade was done with Inj. Neostigmine (0.05mg/kg) and Inj. Glycopyrrolate (0.01 mg/ kg).

Monitoring of HR, SBP, DBP, MAP and SPO_2 before induction as baseline, after intubation or placement of LMA-PS, at 1mins, 3mins, 5mins and every 5mins there after till the removal and 5mins after removal of ETT or PLMA. For both the groups, baseline value for $ETCO_2$ was taken after placement of airway devices (ETT/ PLMA).

Calculation of size of tube[11,12]

The following have been used as general guidelines for selecting the proper size tube in children.

- For children below 6 years: age in years/3 + 3.75
- For children older than 6 years: age in years/4 + 4.5
- ID = age in years/4 + 4 or 3.5

Depth of insertion

The tube tip should be inserted not more than 3-4 cm past the cords in children above 1year.

STATISTICAL ANALYSIS

Statistical analysis was done using suitable biostatistical technique on each variable in the same patient and between two treatment groups. Statistical screening of treatment effect was measured by relative risk reduction, absolute risk reduction with adjustment for a small sample size and confounders in the study. Paired t test and other appropriate tests were applied to check for presence of significant difference in outcome variable in two groups. The software Instat-Graphpad was used in the analysis.

RESULTS

Grouping of patients was done into two groups comprising of 30 patients using the plan generated from the site www.randomization.com.

Group-A: LMA ProSeal for airway management.

Group-B: EndoTracheal Tube for airway management.

The observations were compiled and the results were analyzed statistically. The observations are tabulated as:

- Demographic Variables (table-1) - Age distribution, Weight, Sex, ASA status, MPS
- Haemodynamic Variables: Heart rate, Systolic Blood Pressure, Diastolic Blood Pressure, Mean Arterial Pressure.
- For Ventilation:SP02, ETC02
- Complications: Sore throat, Gastric distension, Aspiration

Figure-1 shows that the heart rate variation was highly significant at placement of ETT compared to PLMA, at 1 min and 3 mins. At 5 mins the variation of heart rate was significant, after which it was not significant throughout the procedure till removal of the airway devices. At removal the rise in mean HR was significantly more with ETT than PLMA.

Figure-2 shows that there was significant increase in SBP at 1 min, 3 mins, with Group B than Group A; which became insignificant at 5 mins and there after throughout the pro-

characteristics	**A(PLMA)**			**B(ETT)**		
Age(Mean Age)	5.13			4.5		
Weight(Mean)	15.33			14.17		
Sex(%)	Male		Female	Male		Female
	90		10	80		20
Mallampatti Score	I		II	I		II
	27		3	26		4
Duration of surgery	≤30 mins	≤40 mins	≤50 mins	≤30 mins	≤40 mins	≤50 mins
	6	11	13	2	17	11

	Complications							
	Cough		**Sore Throat***		**Gastric Distension**		**Aspiration**	
Group	-	+	-	+	-	+	-	+
LMA-PS	28	2	25	5	30	0	30	0
ETT	26	4	27	3	30	0	30	0
TOTAL	54	6	52	8	60	0	60	0

Table-1: Demographic characteristics

cedure till removal of airway devices. At removal the rise in mean SBP was significantly more with ETT than PLMA.
Figure-3 shows that there was significant increase in DBP after instrumentation, with Group B showing a greater rise than Group A; which became insignificant at 5 mins and there after throughout the procedure till removal. At removal the rise in mean DBP was significantly more with ETT than pLMA.
Figure – 4 shows that increase in MAP was highly significant after instrumentation, with Group B than Group A. It became insignificant at 10 minutes and there after throughout the procedure. At removal the rise in mean MAP was significantly more with ETT than pLMA.
In the ETT group, 3 patients complained of sore throat after removal while in the PLMA group, 5 patients complained of the same. This was compared statistically by Fisher's exact test which showed to be insignificant (P>0.05).
In the PLMA group, 2 patients coughed after removal while in the ETT group, 4 patients coughed. This was compared statistically by Fisher's exact test which showed to be insignificant (P>0.05). Clinically detectable aspiration and gastric distension was not observed in any case in both the groups.

DISCUSSION

This prospective comparative trial was conducted to compare PLMA as an alternative airway device to ETT in 60 paediatric patients undergoing lower abdominal surgeries. The PLMA has been proved to be adequate in previous studies by Sinha A. et al. 2007[8]; Patel et al. 2010[13]; Lalwani et al, 2010.[7] We compared the PLMA with ETT in terms of haemodynamic responses, efficacy of positive pressure ventilation, emergence and complications.
Patel et al 2010,[13] found that there was no change in haemodynamic parameters in Group PLMA during insertion and removal of the ProSeal LMA whereas there was rise in both heart rates during insertion and extubation, and the change was statistically highly significant. In our study, heart rate was increased in both the groups after placement of the airway devices but the magnitude and duration of increase in HR was less in Gr A than in Gr B.
Lalwani et al 2010[7], found that the mean pulse rate increased from a baseline value of 103.70±11.56 to 109.50±12.41 and from 102.46±11.46 to 122.83±8.30 after the placement of PLMA and endotracheal tube respectively. The increase in the pulse rate was statistically significant (P<0.05) in both the groups. We have found that pulse remains elevated for 1 minute in Group A after instrumentation which came down towards base line at 3 minutes. In Group B pulse remained elevated for 3 minutes after instrumentation which came down towards base line at 5 minutes.
Garima Agrawal (2011)[14], found that following insertion of endotracheal tube, there was a highly significant rise in heart rate (P=0.000) but there was no significant rise in the heart rate (P=0.921) in the PLMA group.
Dave et al[3], also found rise in heart rate after insertion of the PLMA which was statistically insignificant (P>0.05) but in our study the rise in heart rate after insertion of PLMA was found to be statistically significant (<0.01).
Shahin et al 2009[15], compared LMA and ETT in 100 children

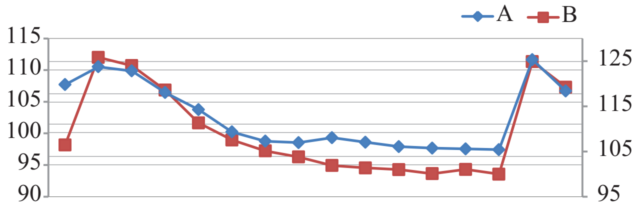

Figure-1: Mean Heart Rate

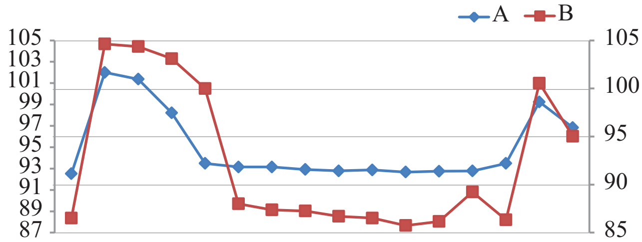

Figure-2: Mean Systolic Blood Pressure

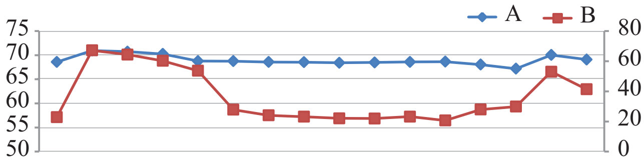

Figure-3: Mean Diastolic Blood Pressure

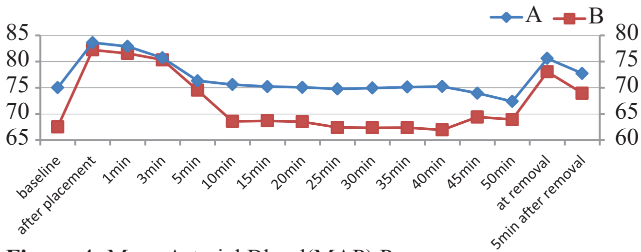

Figure-4: Mean Arterial Blood(MAP) Pressure

posted for elective surgical procedures, found that changes in heart rate at 0, 1, 3 min were highly significant in Group A as compared to Group B, similar to the findings of our study. Lalwani et al (2010)[7] found that the increase in SBP from the baseline after insertion of PLMA or ET was statistically insignificant (P>0.05) in both groups. There was a statistically significant (P<0.05) decrease in mean SBP (mmHg) 97.86±8.46 from the baseline value of 105.86±9.78, 5 min after placement of PLMA. The mean SBP of 98.26±11.68 also decreased from the baseline mean SBP of 103.60±12.46, 5 min after ET intubation. (P>0.05)
Fujii Y et al (1998)[9] measured SBP at 1min, 3min, 5min and 10min after tracheal extubation or LMA removal and found that SBP came to the baseline value after 5min of LMA removal whereas it came to baseline value after 10min of tracheal extubation. Similar to Fujii Y et al[23], our study had similar results.
Dave et al[3] found that the systolic arterial pressure rose from a preoperative value of 79.46±6.9 to 82.56±9.39 post PLMA insertion which was not statistically significant (P>0.05). Sinhaet al[8] in their study noted similar haemodynamic stability with PLMA as compared to ETT.
Fujii et al[9], in their study, observed that there was a significant increase in the DBP 1minute after extubation of ETT

which returned to the baseline values at around 10 minutes of extubation whereas change was less after LMA removal and the DBP values returned to baseline values at 3 minutes of removal of LMA. In our study, the rise in DBP was significant 1 minute after removal in both the groups which returned to the baseline values after 5 minutes of removal/ extubation (>0.05).

Similar to our study, Shahinet al[15] also observed a significant increase in mean arterial pressure in both groups just after insertion of endotracheal tube or the laryngeal mask airway. The mean arterial pressure came back to baseline value after 5 minutes in the ETT group and within 3 minutes in the LMA group. Changes in the mean arterial pressure in group ETT at 0, 1, 3 min were significant as compared to Group LMA (P<0.001, <0.01, <0.01). In our study, there was a highly significant (P<0.01) increase in mean arterial pressure till 3 minutes of insertion of ETT and LMA but gradually became insignificant (P>0.05) from 10 minutes till removal of ETT/ LMA.

In a similar study by Garima Agrawal[14], following insertion of endotracheal tube, there was a highly significant rise in mean blood pressure (P=0.000) along with rise in heart rate and intraocular pressure. Whereas, they found there was no significant rise in the mean blood pressure (P=0.327) after insertion of the PLMA. They found that the rise in mean blood pressure 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. In our study the rise in MAP was sustained till 5 minutes in group B and came down towards baseline at around 10 minutes. In group A, the MAP came down to baseline values at 5 minutes post-insertion.

Patel et al[13] compared the effects of PLMA and ETT in 60 ASA I/II children undergoing elective lower abdominal surgical procedures. Haemodynamic parameters such as, heart rate, SBP, DBP along with oxygen saturation and $EtCO_2$ were recorded pre-operatively and post-operatively. There was one case of displacement of PLMA after giving lateral position for caudal epidural insertion which was corrected immediately and the same patient had regurgitation due to displacement. 3.33% of patients in ETT group experienced post-operative vomiting, 3.33% had post-operative hypoxemia (SpO_2<90%), 40% of the patients had coughing and 13.33% had sore throat. None of the patients from both the groups had post-operative laryngospasm, bronchospasm or limb movements during removal of the PLMA or extubation. In our study, we did not find a significant change in oxygen saturation and $EtCO_2$ throughout the intra-operative period (P>0.05). None of the patients from both groups had intra-operative regurgitation. Two patients of group A and four patients of group B coughed on removal of PLMA and ETT respectively. None reported laryngospasm, bronchospasm or any other complication during removal of PLMA and extubation or during the post-operative period.

Jaya Lalwani et al[7] found that endotracheal intubation was done in 96.67% patients at first attempt whereas ProSeal LMA was inserted in 83.33% patients at first attempt. In their study, Patel et al inserted ETT and PLMA at first attempt in all patients. Similarly, in our study, we did not find any difficulty in placement of ET tube or the PLMA and both the devices were placed in first attempts. Sinha et al[8] and Misra et al[4], in their studies, reported that all patients were intubated at first attempt while the PLMA was placed in 88% patients at first attempt in paediatric and adult laparoscopic surgeries, respectively. Dave et al[3] reported the success rate to place the PLMA in first attempt was 93.33%. Lim et al in gynaecological laparoscopy noted that the number of attempts for successful insertion were similar for both PLMA and ET tube (86% and 85%, respectively). After extubation, there was a significant incidence of cough as compared to after removal of PLMA. Their findings were similar to the findings of the studies by Maltby et al[16,17]and Sinha et al.[8] They also noted bronchospasm in two cases of ETT group and none in the PLMA group. Blood on the posterior surface of PLMA was noted in six patients in group A, but in group B, two cases of blood on ET tube was observed after extubation. There was no incidence of aspiration in either groups of patients.

Dave et al[3] evaluated the use of ProSeal LMA in paediatric laparoscopic surgeries. This study was conducted in 30 children, 10-30 kg undergoing elective laparoscopic surgery. All patients were maintained on controlled ventilation with nitrous oxide 60% in oxygen, isoflurane and atracurium intermittent boluses as required. PLMA provided adequate ventilatory conditions as there was no significant change in the SpO_2 and $EtCO_2$ values during the procedure. In only two patients, PLMA was replaced by endotracheal tube due to increase in $EtCO_2$. At ventilator parameters designed to maintain normocapnia, the PLMA affords adequate seal.

In our study, we did not find any significant change in the SPO_2, $EtCO_2$ and PLMA provided adequate ventilatory support. Also there was not increase in $EtCO_2$ nor any incidence of gastric distension after PLMA placement. Brimacombe et al[18,19] in their studies on PLMA have recommended the use of gastric tube in cases of difficult insertion or where displacement of PLMA can occur intraoperatively.

Placement of nasogastric tube was successful in first attempt in all the cases of both the groups in our study. Patel et al[13] and Dave et al,[3] in their study also found that placement of the gastric tube was successful in all cases.

Lardner et al[20] in 2008 did a randomized controlled, single-blinded study of 51ASA I or II children weighing 10–20 kg to compare the efficacy of ProSeal LMA and Classic LMA. They inserted both the devices (only size 4) into each patient in random order. Anaesthesia was maintained with isoflurane1.8%–2.5% in air and FIO_2 0.5. The number of attempts, insertion time was recorded, and ease of insertion was graded by the investigator as easy, difficult or failed. Presence or absence of blood on the LMA was noted following removal.

They found that, in children undergoing IPPV with neuromuscular blockade, the size 2 PLMA is associated with a higher leak pressure by auscultation and less gastric insufflations compared to the C-LMA. This finding was consistent with the finding of Shimbori et al.[21] Intraoperatively, 4 patients out of 25 patients with PLMA developed complications including stridor/obstruction and 1 patient required repositioning of the PLMA. In our study, we did not find any difficulty in inserting the device and in no case endotracheal intubation required due to failure of insertion of the PLMA.

Intraoperatively, we did not find any complications. However on removal of the PLMA, two patients coughed.

Limitations

1. Number of cases in each group was only thirty (30), to find statistical significance in these groups will be very difficult as it may not show the actual outcomes.
2. A Randomized Controlled Trial, possibly triple blinded or at least double blinded in nature, involving a large number of patients with long term follow-up is clearly needed to bring the differences between the two techniques.

CONCLUSION

We concluded that both ETT and PLMA cause increase in hemodynamic responses, but the magnitude and duration of response is less in PLMA. Incidence of post-operative complications were less with PLMA than with ETT. ProSeal LMA can be used as a safe and effective alternative airway device to endotracheal intubation for positive pressure ventilation in paediatric patients undergoing elective surgical procedure.

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