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A prospective study to compare haemodynamic and respiratory parameters using proseal laryengeal mask airway and endotracheal intubation in children undergoing videoendoscopic surgery

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ABSTRACT

Background: Proseal laryngeal mask airway (PLMA) is being used increasingly apart from its gold standard alternative endotracheal tube (ETT) in airway management during paediatric laparoscopy. Limited data is available on effects of carboperitoneum on hemodynamics and pulmonary mechanics in paediatric patients. We aimed to assess effect of carboperitoneum on hemodynamics and pulmonary mechanics in paediatric patients undergoing video-endoscopic surgeries when PLMA and ETT are used.

Materials and Methods: After ethics committee approval and consent, 60 patients aged 1-10 years scheduled for laparoscopic surgeries were included in study and randomly allocated to two groups of 30 each. Airway maintained with PLMA in first group and ETT in group II. Hemodynamic parameters and ventilatory parameters were recorded at different time intervals from prior to insertion of airway device till deflation of carboperitoneum.

Results: Statistically significant increased heart rate, systolic, diastolic, mean blood pressure was observed in ETT group as compared to PLMA group during airway insertion and during rest of study period changes were analogous in both groups. Ventilatory parameters saturation, peak inspiratory pressure (PIP), plateau pressure (PP) and ETCO2 were comparable in both groups except during post deflation period where PP, PIP and ETCO2 remained elevated.

Conclusion: Proseal-LMA can be equally good option in paediatric laparoscopy with better hemodynamic stability and ventilatory parameters as degree of changes caused by carboperitoneum in PLMA group was insignificant compared to ETT.

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1. Introduction

With the success of laparoscopy, the demand and applicability of this technique in children have been increasing these days. Compared to conventional surgery laparoscopic surgeries have cosmetic scar and early return to routine activities apart from decreased postoperative pain and quicker oral intake.^{1,2} However, insufflation of CO2 to induce pneumoperitoneum and positioning of patient cause intraoperative ventilatory and haemodynamic changes. Up till now for laparoscopic surgeries under

general anaesthesia, gold standard was cuffed endotracheal tube (ETT) as it provides a safe glottic seal.^{3,4} Proseal laryngeal mask airway (PLMA) also provides better glottic seal and allows higher airway pressures by pushing mask anterior due to presence of an additional dorsal cuff, although this dorsal cuff is lacking in pediatric PLMA.⁵ A gastric tube can be passed through the drain tube which also allows drainage of passively regurgitated gastric fluid to drain away from the airway.⁵

So in present study we aimed to study the effect of pneumoperitoneum on hemodynamic and respiratory parameters using Proseal LMA and Endotracheal Tube in

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video-endoscopic surgeries in children and to compare risk and benefits of using Proseal LMA and Endotracheal Tube for video endoscopic surgeries in children.

2. Materials and Methods

This prospective randomized tribal was carried out in tertiary care institution after obtaining approval from institutional ethics committee. Patients in the age group of 1-10 years of either gender of American society of Anesthesiologists grade I posted for video endoscopic surgeries were included. Patient's with known cardiovascular, respiratory or neurological disease, having upper respiratory tract infection, coagulation disorders and those subsequently converted to open surgical procedures in intraoperative period were excluded from study.

All patients were evaluated and baseline investigations were done as per institutional protocol. An informed consent was taken from patient's parents. All the patients were allowed to take solid food orally till six hours before and clear fluids till two hours before surgery. All patients were premedicated with 0.5 mg/ kg of Midazolam per orally 60 minutes before induction.

Total 60 patients were involved in study with 30 in each group with computer generated randomization.

Group I – Included patients whose airway secured with Proseal LMA.

Group II – Included patients whose airway secured with endotracheal tube.

All the patients were accompanied by parents to operative room. Patients were attached with ECG, noninvasive blood pressure (NIBP) cuff and pulesoxymeter. Capnometer of Dragus Fabius was calibrated and kept ready for use after intubation.

All patients were induced with intravenous Inj Fentanyl 2 μ g/kg, Inj. Propofol 2.5 mg/kg and muscle relaxation was conducted with Inj. Vecuronium bromide 0.1 mg/kg. For all patients appropriate size Proseal LMA or Endotracheal tube was inserted after 3 minutes of muscle relaxation and patients was switched over to inhalational O2: N2O:: 50:50% and Isoflurane for maintenance (0.5-1%). There was no case of insertion failure in either group. All insertions were in first attempt by person having at least 2 years of experience as anesthesiologist. An appropriate size of ETT was selected using formula age in years /4+4.5 for uncuffed and age in years /4+4 for cuffed tube and Proseal LMA was selected according to manufacturer's recommendation for weight. Both devices were inflated as per recommendations and checked for any leak.

All patients were put in the supine position and a maximum of 108⁰ Trendelenberg or 308⁰ head-up position was allowed. Peritoneal insufflation was performed with CO2 with insertion of Verres insufflation cannula. The flow of CO2 insufflation was 1-2 liter/min by using STORZ Surgiflator 25 and intra-abdominal pressure was kept below

12 mmHg.

Controlled intermittent positive pressure ventilation (IPPV) was given to all the patients with Drager Fabius plus ventilator using volume controlled mode with circle system absorber with tidal volume of 8 ml/ kg, respiratory rate as per age of patient with I: E ratio of 1:2 with peak airway pressure alarm limit set at 40 mmhg.

Intermittent boluses of Inj. Vecuronium to maintain muscle relaxation was given. Ringer lactate was infused according to calculations of fluid requirement using Holiday - Segar formula.

Patients were monitored for Heart rate (HR), Blood Pressures including systolic (SBP), diastolic (DBP) and mean MAP, oxygen saturation (SPO₂), end tidal carbon dioxide (EtCO2), peak inspiratory pressure (PIP), plateau pressure (PP) and ECG in lead II. These were monitored at 5 min prior placing an airway device (t0), 5 min after insertion of an airway device (t1), 5 min prior CO2 insufflation (t2),15 min later CO2 insufflation (t3),30 min later CO2 insufflation (t4), 5 min later deflation of CO2 (t5), 5 min later removal of airway device(t6). On average surgical duration was less than sixty minutes in all cases.

2.1. Data analysis

PLMA in pediatric laparoscopy, as an substitute to endotracheal intubation was observed by Sinha A, Sharma B, Sood J,⁶ in Sixty ASA I and II children, 6 months to 8 years, (duration of pneumoperitoneum < 60 min) randomly allocated in two groups of 30 each. Considering these reference values, the minimum required sample size with 90% power of study and 5% level of significance by using pre and post data is 1. To lower margin of error, sample size taken is 30 per group with total sample size taken as 60. Formula used for calculation of sample size is:

1) N >= (standard deviation)2*($Z\alpha + Z\beta$)2 (mean difference)2 Where, $Z\alpha$: value of Z at two sided alpha error of 5% $Z\beta$: value of Z at power of 90%. Statistical tests were applied as follows:

- 1. Quantitative variables was compared using Unpaired t-test/Mann-Whitney Test (when the data sets were not normally distributed.) between the two groups and Wilcoxon ranked sum test (for non-parametric data) / Paired T test to compare pre data with post data.
- 2. Qualitative variable was compared using Chi-Square test /Fisher's exact test.

A p value of < 0.05 was considered statistically significant. The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

3. Observations and Results

Both groups were comparable in terms of demographic parameters as well as insufflation time, surgical duration and duration of anaesthesia. (Table 1)

The changes in the heart rate before and after induction and insertion of endotracheal tube were found to be more in ETT group compared to PLMA group and this was found to be statistically significant (P value<0.05). However, the heart rate changes before and after pneumoperitoneum and after reversal of anaesthesia was found to be similar in both the groups.

On comparing blood pressure changes in both groups, we found that the SBP, DBP, MAP increased significantly more in the ETT group compared to PLMA group after the induction and insertion of endotracheal tube. During rest of the study period, the changes in SBP, DBP and MAP were analogous in both the groups. And intergroup trend was as shown in Figure 1.



Fig. 1: Intergroup trend of heart rate changes



Fig. 2: Intergroup trend of systolic blood pressure changes

There was no significant difference in mean SpO2 recorded at different time intervals among two groups (P>0.05).

Intergroup analysis shows statistically no significant difference between the two groups during insufflation period



Fig. 3: Intergroup trend of diastolic blood pressure changes



Fig. 4: Intergroup trend of mean blood pressure changes

and statistically significant difference after deflation period. There was 0.31% decrease in EtCO₂ in PLMA group as

compared to 4.86% increase after deflation in ETT group. Intra-group analysis shows statistically significant difference after insufflation and no statistically significant difference after deflation. In PLMA group ETCO2 value increased from baseline(t2) of 36.77 ± 3.36 to 30 minutes after insufflation (t4) 41.2 ± 5.33 which was statistically significant (p-value<0.05). Similarly in ETT group ETCO2 value increased from baseline of 36.5 ± 6.53 to 30 minutes after insufflation (t4) 42.41 ± 3.68 which was also statistically significant (p-value<0.05). It remains elevated in ETT group even after deflation 37.93 ± 5.75 which was also significant statistically (p-value<0.05).

Intergroup analysis shows statistically no significant difference between the two groups during insufflation period and statistically significant difference after deflation period. After deflation there was 18.70% increase in PIP in ETT group as compared to 10.80% increase in PLMA group and it took more time to lower down in ETT group.

Intragroup analysis also showed statistically significant difference after insufflation and deflation in both groups. In PLMA group, the mean PIP before the start of insufflation of CO₂ was observed to be 12.3 ± 2.28 reaching a mean

peak value after 30 minutes of insufflation (18.07 \pm 2.7). This finding was found to be statistically significant (p-value<0.05). The mean PIP levels continued to be high (14.4 \pm 1.64) even after cessation of insufflation for five minutes which was found to be statistically significant (p-value<0.05). Similarly in ETT group it was 13.43 \pm 2.94 before and 20.29 \pm 5.38 after 30 minutes of insufflation which was found to be statistically significant (p-value<0.05) and it continued to remain high after cessation of carboperitoneum (14.73 \pm 3.03) which also was found to be statistically significant (p-value<0.05)

Intergroup analysis shows statistically no significant difference between the two groups during insufflation period and statistically significant difference after deflation period. After deflation there was 22.70% increase in PIP in ETT group as compared to 10.70% increase in PLMA group. In ETT group Plateau pressure took longer time to settle down than PLMA group.

Intra-group analysis in both groups showed the mean baseline plateau pressure before establishing pneumoperitoneum in PLMA group was 10.73 ± 2.33 progressed to reach a mean peak value of 16 ± 2.45 at 30minutes of insufflation. It started to decline to 12.7 ± 1.44 at5 minutes after termination of pneumoperitoneum. The rise in PP was found to be statistically significant. Similarly, in ETT group mean plateau pressure at the beginning was 11.93 ± 2.72 reaching a high of 19.77 ± 18.43 after 30 minutes of insufflation and remained high at 13.13 ± 3.21 even after complete deflation of CO₂. Both these findings were found to be statistically significant.

4. Discussion

Laparoscopy, being minimally invasive, has become standard of care even in paediatric population. The establishment of carboperitoneum being physiologically complex event is affects homeostatic systems of the body by altering physiochemical environment of the peritoneal space. It is the degree of rise in pressure in abdomen and the quantity of CO_2 taken up super added by the anatomical and pathological peculiarities of young children dictates the result of this technique. Till date endotracheal intubation was considered as gold standard technique for airway control in laparoscopy. But with availability of Proseal laryngeal mask (PLMA) with its distinct advantages of having able to sustain higher airway pressure, better seal and channel for gastric drain, is being increasingly used.

We aimed to analyze the effects of pneumoperitoneum and to study the changes in hemodynamic and respiratory parameters using PLMA and ETT in 60 children of 1-10 years of age with 30 in each group undergoing laparoscopy surgery.

Both groups were comparable in terms of age, gender distribution, weight, duration of insufflation, surgery and anesthesia. As procedure was performed by experienced anesthesiologist there was success rate of 100% to insert either device.

In our study, the increased heart rate, SBP, DBP and MAP before induction of anaesthesia in the PLMA group, can be attributed to the high level of stranger anxiety among children due to parental separation and fear of new environment. The decline in the haemodynamic parameters soon after induction and PLMA insertion may be due to adequate depth of anaesthesia coupled with lack of sympathomimetic stress response following PLMA insertion findings similar to study by Dave et al.³ and Sinha et al.⁶ The sharp increase in the parameters after CO₂ insufflation was attributed to haemodynamic response to pneumoperitoneum. In ETT group, increase in the heart rate following induction and intubation with endotracheal tube was explained by sympathetic response to endotracheal intubation which was not found to be statistically significant. The SBP, DBP and MAP however remained stable. A sharp increase in all the parameters during and after pneumoperitoneum can be attributed to hemodynamic response to insufflation of CO₂. In both the group, subsequent rise in heart rate and blood pressure after reversal and extubation can be explained as due to the return of reflexes and return to consciousness.

The changes in the heart rate before and after induction and insertion of endotracheal tube were found to be more in ETT group than in PLMA group and this was found to be statistically significant. Our study correlate with the findings of the study conducted by M. Misra and colleague.⁴ However, the heart rate changes before and after pneumoperitoneum and after reversal of anaesthesia was found to be similar in both the groups. On comparing blood pressure changes in both groups, we found that the SBP, DBP, MAP raised significantly more in the ETT group than PLMA group after the induction and insertion of endotracheal tube. During rest of the study period, the changes in SBP, DBP and MAP were analogous in both the groups. Appreciable rise in the heart rate and blood pressure was an established fact following ETT intubation. Our study correlates with the findings of former studies done by Misra et al,⁴ Fujii et al,⁷ Lalwani et al⁸ and V et al.⁹

While comparing respiratory parameters in both groups, ventilation was adequate in both groups as evidenced by satisfactory SpO2 levels in both groups. In our study, the rise in EtCO₂ during the period of pneumoperitoneum in both PLMA group and ETT group were similar. However, it was observed that the return of EtCO₂ levels to normal value in the post insufflation period was delayed in the ETT group in comparison to PLMA group (Table 2). This finding was found to be statistically significant. This indicates that the stabilization of EtCO₂ after deflation takes longer time in the ETT group as than PLMA group. Intergroup evaluation of PIP (Table 3) revealed that the changes in PIP during the period of pneumoperitoneum was similar among the two

Tuble 1. Demographic parameters of patients of both group.	Table	1:	Demogra	phic	parameters	of	patients	of both	groups
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Parameters	Group I (PLMA)	Group II (ETT)	P value		
Mean age(years)	6.77 ± 2.25	5.85 ± 2.64	0.145		
Gender M: F	17:13	22:8	0.176		
Mean Weight in kg	20.5 ± 6.34	18.63 ± 5.36	0.343		
Mean insufflation time in minutes	31.87 ± 8.04	32.9 ± 6.94	0.523		
Mean duration of surgery in minutes	48.1 ± 11.99	50.5 ± 13.1	0.462		
Mean duration of anaesthesia in minutes	57.83 ± 12.95	60.33 ± 13.56	0.468		

Table 2: Intergroup changes in EtCO2 in two groups

Time	PLMA	P value	ETT	P value
t ₂	36.77 ± 3.36	Baseline	36.5 ± 6.53	Baseline
t3	39.97 ± 4.69	<.0005	40.23 ± 5.67	<.0005
t ₄	41.2 ± 5.33	0.003	42.41 ± 3.68	0.001
t5	36.6 ± 4.68	0.285	37.93 ± 5.75	0.006

Where t₂=5 min prior CO2 insufflation, t₃=15 min later CO2 insufflation, t₄= 30 min later CO2 insufflation, t₅=5 min later deflation of CO2

Table 3: Intergroup changes in PIP in two groups

Time	PLMA	P-Value	ETT	P-Value
t2	12.3 ± 2.28	Baseline	13.43 ± 2.94	Baseline
t3	17.63 ± 1.96	< 0.0005	18.53 ± 5.02	< 0.0005
t4	18.07 ± 2.7	< 0.0005	20.09 ± 5.38	< 0.0005
t5	$14.4{\pm}1.64$	< 0.0005	14.73 ± 3.03	< 0.001

Where $t_2=5$ min prior CO2 insufflation, $t_3=15$ min later CO2 insufflation, $t_4=30$ min later CO2 insufflation, $t_5=5$ min later deflation of CO2

Table 4:	Intergroup	changes in	PP in	two	group	s
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Time	PLMA	P value	ЕТТ	P value
t ₂	10.73 ± 2.33	Baseline	11.93 ± 2.72	Baseline
t ₃	15.87 ± 1.85	<.0005	19.77 ± 18.43	0.022
t ₄	16 ± 2.45	<.0005	18.06 ± 5.23	<.0005
t ₅	12.7 ± 1.44	<.0005	13.13 ± 3.2	0.004

Where t₂=5 min prior CO2 insufflation, t3=15 min later CO2 insufflation, t4= 30 min later CO2 insufflation, t5=5 min later deflation of CO2

groups, but the rise in PIP in the post insufflation period was significant statistically in the ETT group compared to that of PLMA group indicating that the return of ventilatory parameters is delayed in patients of ETT group.

The plateau pressure changes (Table 4) when compared between the two groups revealed that the pressure changes were similar throughout the entire insufflations period except after deflation where it remained high in ETT group than PLMA group and was statistically significant suggestive of early return of respiratory parameter in PLMA group than in ETT. The findings suggest that the mechanical changes such as rise in PIP and PP that were observed due to the effect of pneumoperitoneum in both PLMA and ETT group and airway control device did not contribute to the changes in PIP and plateau pressure. Our study compared with study of Bergesio and colleagues.¹⁰ There was paucity of studies comparing the changes in plateau pressure or changes in pulmonary mechanics in children undergoing laparoscopic surgery and few comparative studies available in the literature comparing the PLMA and ETT group and their role in airway pressures and pulmonary changes.

We had no incidence of bronchospasm, excessive secretion and cough immediately after extubation of ETT from trachea or removal of PLMA. None of our patients reported other post-operative complications; post operative pain was taken care by Paracetamol suppository or parenteral analgesics as required. We did not have any incidence of aspiration in any of two group's patients throughout study period and this was also reported by previous studies by Kelly et al¹¹ and Lardner et al.¹²

5. Strength of the Study

Hemodynamics with video endoscopic surgeries have been studied in details previously while this study studies effect of carboperitoneum on respiratory mechanics in pediatric video endoscopic procedures while using Proseal LMA.

6. Limitations

We did not include patients with difficult airways and study need to be conducted on large scale. Multi-centric studies with much larger sample of subjects and ethnicity are needed for validation of the concluded results.

7. Conclusion

We conclude that both PLMA and ETT can be safely used, PLMA can be a better choice as it doesn't evoke any intubation response, provides adequate ventilation as indicated by return of $EtCO_2$ earlier towards baseline than ETT and not showed any added complication to ETT intubation. Also pulmonary mechanics is better in PLMA as judged by earlier decrease of plateau pressure and peak inspiratory pressure in PLMA group after deflation compared to ETT. However, multi-centric studies with much larger sample of subjects and ethnicity are needed for validation of the concluded results.

8. Source of Funding

None.

9. Conflict of Interest

None.

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