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ORIGINAL RESEARCH

Comparison of Proseal laryngeal mask airway and endotracheal tube in patients undergoing laparoscopic surgeries

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ABSTRACT

Background: Supraglottic airways (SGAs) like the laryngeal mask airway (LMA) provide advantages such as faster placement and better haemodynamic stability. LMAs, whether single-use or reusable, can be crucial in managing difficult airways or maintaining airway patency. This study compares the ProSeal LMA and endotracheal tube (ETT) in patients undergoing laparoscopic surgeries.

Methods: A prospective observational study was conducted on 60 participants over one year, with ethical clearance and informed consent. Participants were divided into two groups: 30 received the ProSeal LMA and 30 received the ETT. Data were analyzed using SPSS version 24 with descriptive and inferential statistics, including independent t-tests and Chi-square tests.

Results: The ProSeal LMA group had a mean age of 35.73 years, and the ETT group had a mean age of 40.30 years ($p > 0.05$). ProSeal LMA had faster intubation (13.30 seconds vs. 16.17 seconds) and Ryle's tube insertion (11.30 seconds vs. 13.12 seconds) compared to ETT ($p < 0.05$). Sore throat incidence was lower in the ProSeal LMA group.

Conclusion: The ProSeal LMA offers better stability and similar airway maintenance compared to ETT, suggesting it may be a superior intubation device.

Keywords: PROSEAL LMA, airway management, laryngral mask, endotracheal intubation, airway devices, postoperative complications

INTRODUCTION

Airway management is the cornerstone of anaesthetic practice, and virtually every anaesthetic innovation in the past 25 years has had an impact on some aspect of airway care.[1] The most important foundation of quality anesthetic practice is safe and effective airway management and the laryngeal mask airway (LMA) is one of the keystones of modern anesthetic practice.[2] In addition to maintaining a clear patent airway to facilitate the administration and maintenance of anesthetic agents, it is the role of the anasthesiologist to ensure adequate maintenance of oxygenation of the lungs.

The endotracheal tube is an amalgam of the ideas and innovations of physicians across multiple centuries, having gone through multiple iterations before arriving at its current form.[3] For a very long time, the gold standard among airway devices has been the endotracheal tube (ETT). However, considerable morbidities ranging from minor side effects such as sore throat to more

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serious complications such as autonomic stimulation and difficult or failed intubation are seen with laryngoscopy and endotracheal intubation.[4] Further several hemodynamic changes are seen following endotracheal intubation and to avert this, an increased use of alternatives like light wand, supraglottic devices and fibre optic scopes have become a routine in anesthetic practice.[5]
Supraglottic airways (SGAs) offer distinct advantages including an increased speed and ease of placement, maintenance of haemodynamic stability during induction and emergence. LMA which is a Supraglottic device has the advantage of being inserted blindly through the mouth and into the hypopharynx, forming a seal around the glottic opening allowing for ventilation.[6]
LMAs are single-use or reusable airway devices which may be used as an immediate life-saving measure in a difficult or failed airway or as a method to maintain an open airway during the administration of anesthesia temporarily as outlined in the difficult airway algorithm published by many societies of anesthesiology worldwide. In comparison to bag-valve mask, LMAs are easier to use and more effective especially in the hands of basic life support providers and may be used as an alternative to intubation by advanced life support providers. A safe and effective method of securing an airway in anesthesia and critical care settings is provided by LMA.[7]
Several modifications, additions, and variations of LMA have been developed and are currently in use despite the classic LMA providing an airtight seal over the glottic opening to provide effective gas exchange. Designed and introduced in 2000 by Dr. Archie Brain, the ProSeal™ laryngeal mask airway (PLMA; Intavent Orthofix, Maidenhead, UK), is based on the classic laryngeal mask airway (cLMA).[8] Several modifications were designed to enable separation of the gastrointestinal and respiratory tracts, diagnose mask misplacement, enable controlled ventilation and improve the airway seal. A drain tube (DT) aims to reduce risks of gastric inflation, regurgitation and aspiration of gastric contents and also enables diagnosis of mask misplacement.[9]
Very few studies are available in India to compare proseal laryngeal mask airway and endotracheal tube in patients undergoing laparoscopic surgeries. Hence, this study was carried out to evaluate the same.
The aim of the study was to compare proseal laryngeal mask airway and endotracheal tube in patients undergoing laparoscopic surgeries. The objective was to compare proseal laryngeal mask airway and endotracheal tube in patients undergoing laparoscopic surgeries.

MATERIALS & METHOD

Study design- A prospective observational study was conducted in a tertiary care hospital in South India.
Study period- The study period was for a period of one year.
Study population- 60 participants were chosen randomly. 30 Participants who received proseal LMA were considered as one group and 30 participants who received endotracheal tube were taken as another group. Those who did not give consent were excluded from the study.
Study methodology- A thorough preanesthetic evaluation was done including history & general examination. All patients received T. Diazepam 5mg and T. Ranitidine 5mg the night before surgery and standard nil per oral protocol were followed. Patients were shifted to OT, an IV line was secured with 18g venous cannula, and an infusion of ringer lactate solution was started. The patients were connected to the monitor and the preinduction systolic BP, diastolic BP, MAP, heart rate, SPO2 were recorded. Inj. Glycopyrolate 0.2mg. Inj.Midazolam 0.04mg/kg. IV, inj. Ondensetron IV were given as premedication. Preoxygenation with 100% O2 for 3min. Patient were induced with Inj.Fentanyl 2mcg/kg & Propofol 2mg/kg. Intravenously. After an adequate depth of anaesthesia was achieved, Proseal LMA was insertedby index finger insertion method

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and connected to the anaesthetic machine after confirming correct placement. If the device insertion was not achieved, 2 extra attempts of placing were tried. If placements were unsuccessful after 3 attempts, the procedure was discarded and the airway was secured through other airway device as appropriate and this case was considered as a failed attempt. The Proseal LMA was inserted by index finger insertion method. The cuff was inflated with 20ml of air. Ventilation was judged to be optimal with sufficient chest rise, constant oxygenation SPO2 greater than 95% and absence of leak.Endo Tracheal Tube was inserted using chin lift position. Ventilation was judged to be optimal with sufficient chest rise, constant oxygenation SPO2 greater than 95% and absence of leak. Maintenance of anesthesia was done by N2O:O2-66:33%, Sevoflurane 0.25-1% depending upon the need and depth of anesthesia for that surgery. All patients were monitored continuously. At the end of procedures, anaesthetic agents were discontinued; the Proseal LMA (or) Endo Tracheal Tube was removed once the patient was fully awake. The patient was shifted to postoperative ward after full recovery. Patient was followed up for 24 hours in the post operative ward.

Ethical consideration- Ethical clearance was obtained from the Institutional Ethical Committee. An informed written consent was obtained from all the participants. The details were collected in a pretested semi structured interviewer administered questionnaire.

Data analysis- The data was entered in MS Excel and was analysed using SPSS version 24. Descriptive statistics such as frequencies and proportions were used and inferential statistics such as independent t test and Chi square test were used. P value of less than 0.05 was considered significant. Data were expressed in tables and charts wherever necessary.

RESULTS

Among the PROSEAL LMA group. 1 participant was less than 20 years of age, 15 participants were 20 to 35 years of age, 10 participants were 36 to 50 years of age and 4 participants were 51 to 65 years of age. Among the ETT group. 2 participants were less than 20 years of age, 11 participants were 20 to 35 years of age, 8 participants were 36 to 50 years of age and 9 participants were 51 to 65 years of age. The mean age group of Proseal LMA was 35.73 years and that of ETT was 40.30 respectively and this difference in age between the two groups was not statistically significant (P > 0.05). Among the PROSEAL LMA group, 12 were male and 18 were female. Among the ETT group, 13 were male and 17 were female. (Table 1) (Chart 1).

Table 1. Age and Sex distribution among the study participants

Demographic Variables		PROSEAL LMA group	ETT group
		Frequency (percentage)	Frequency (percentage)
Age group	< 20 years	1 (3.3)	2 (6.7)
	20 – 35 years	15 (50.0)	11 (36.7)
	36 – 50 years	10 (33.3)	8 (26.7)
	51 – 65 years	4 (13.3)	9 (30.3)
Gender	Male	12 (40.0)	13 (43.3)
	Female	18 (60.0)	17 (56.7)

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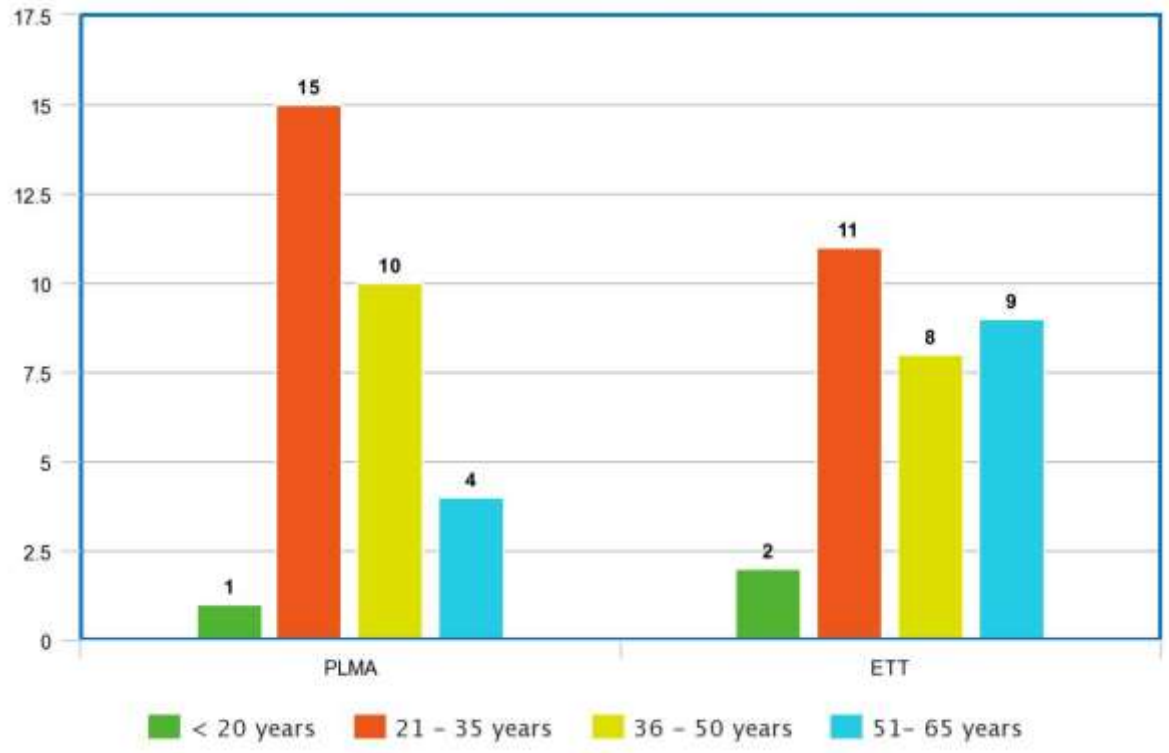

Chart 1. Age distribution among the study participants in both the groups

PROSEAL LMA insertion was successful in 28/30 cases in first attempt, while 2 /30 patients required second attempt. With ETT 27/30 had successful intubation during first attempt and 3/30 had second attempt. Using a PROSEAL LMA had 1.56 less chances of intubation during second attempt when compared to ETT and this association between reintubation and PROSEAL LMA was statistically significant with a p value of 0.038 ($p< 0.05$) (Table 2)

Table 2. Average number of attempts among both the groups

Group	No	1st attempt	2nd attempt	OR	p value
PROSEAL LMA	30	28	2	1.56	**0.03***
ETT	30	27	3		

The time taken for PLMA/ETT includes time taken from introduction into oral cavity to the final confirmation of its proper positioning. Time taken for intubation with PLMA was 13.30 seconds and with ETT is 16.17 seconds. Student's t test reveals P value of 0.0012 which was statistically significant. This indicates there is difference in intubation time between PLMA and ETT which was statistically significant. (Table 3)

Table 3. Time taken for insertion among both the groups

Group	No	Mean ± SD	p value
PROSEAL LMA	30	13.30 ± 3.04	**0.0012***
ETT	30	16.17 ± 3.44	

*-statistically significant by independent t test

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Time taken for insertion of Ryle's tube with PLMA was 11.30 seconds and with ETT was 13.12 seconds. Student's t test reveals P value of 0.0004 which was significant. This indicates there was difference in Ryle's tube insertion time between PLMA and ETT which was statistically significant. (Table 4) (Chart 2)

Table 4. Time taken for insertion of Ryle's tube among both the groups

Group	No	Mean ± SD	p value
PROSEAL LMA	30	11.13 ± 2.01	**0.0004***
ETT	30	13.12 ± 2.11	

*-statistically significant by independent t test

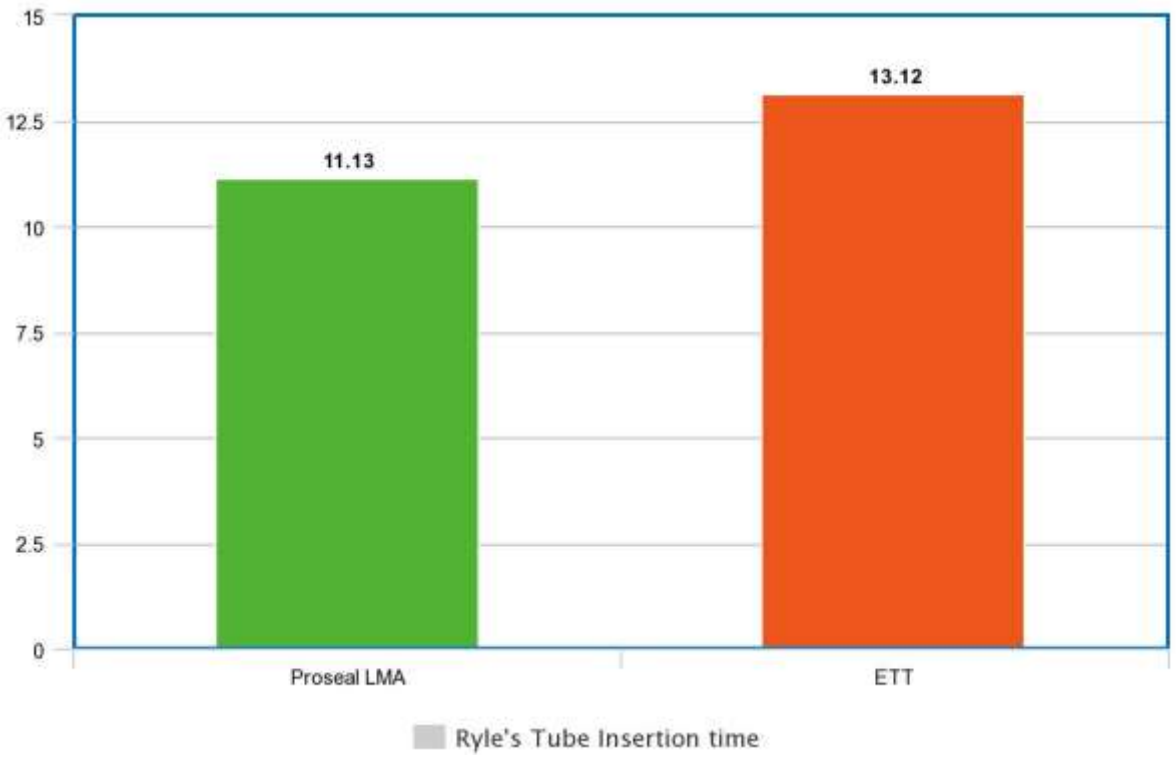

Chart 2. Time taken for insertion of Ryle's tube among both the groups

Postoperative sorethroat and laryngospasm were assessed for 24 hours postoperatively. Sorethroat occurred in 1/30 cases with PLMA and 4/30 cases with ETT. Laryngospasm did not occur in both the groups. This difference was not statistically significant by Chi square test. Hence incidence of postoperative airway morbidity is same in both the groups. (Table 5)

Table 5. Postoperative airway morbidity among both the groups

Postoperative airway morbidity	Groups	Yes	No	Chi square value	P value
Sore Throat	PLMA	1	29	1.41	0.16
	ETT	4	26		
Laryngospasm	PLMA	0	0	NA	NA

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	ETT	0	0		

On comparison of mean heart rate among both the groups, statistical analysis shows that p values for preinduction heart rates, heart rates at 10 seconds, 1 minute after insertion of PROSEAL LMA was 0.081, 0.0540 and 0.076 and were not statistically significant. However, the p values for heart rates at 3 and 5 minutes after insertion of PROSEAL LMA was 0.012 and 0.033 which was statistically significant thereby showing that there is difference in the mean heart rates after insertion of PROSEAL LMA and ETT. (Table 6) (Chart 3)

On comparison of Mean Arterial Blood pressure, statistical analysis showed that p values for preinduction Mean arterial pressure at 10 seconds, 1 minute, 3 minutes and 5 minutes after insertion were not statistically significant. The p values for heart rates after pneumoperitoneum following PROSEAL LMA was 0.013 which was statistically significant thereby showing that there is difference in the mean arterial pressure following pneumoperitoneum after insertion of PROSEAL LMA and ETT. (Table 6) (Chart 4)

On comparison of ETCO2 the p values were not statistically significant thereby showing that there is no difference in the ETCO2 levels following pneumoperitoneum and extubation between the two groups. (Table 6) (Chart 5)

Table 6. Hemodynamic response among both the groups

Time	Heart rate			Mean Arterial Blood Pressure			ETCO2		
	PROSEAL LMA	**ETT**	**P value**	**PROSEAL LMA**	**ETT**	**P value**	**PROSEAL LMA**	**ETT**	**P value**
Preinduction	83.10 ± 11.02	88.80 ± 13.65	0.08	88.87 ± 14.13	94.70 ± 11.74	0.08	30.20 ± 3.82	30.13 ± 3.73	0.94
10 seconds	85.30 ± 12.86	87.43 ± 13.90	0.05	86.53 ± 13.18	89.67 ± 10.90	0.32	31.16 ± 3.09	30.74 ± 4.17	0.65
1 minute	87.43 ± 13.90	80.47 ± 17.58	0.07	83.03 ± 14.49	88.60 ± 10.50	0.09	31.80 ± 3.21	30.74 ± 3.56	0.23
3 minutes	80.27 ± 17.21	90.53 ± 13.19	**0.01***	84.57 ± 15.34	84.73 ± 10.42	0.96	32.21 ± 3.50	30.75 ± 4.01	0.14
5 minutes	82.03 ± 12.60	89.03 ± 12.26	**0.03***	83.77 ± 13.91	87.10 ± 11.97	0.32	31.90 ± 3.72	30.57 ± 4.55	0.22
After pneumoperitoneum	87.00 ± 14.49	88.70 ± 15.85	0.66	91.50 ± 15.10	102.93 ± 19.27	**0.01***	33.74 ± 4.50	31.51 ± 5.16	0.08
After extubation	88.43 ± 10.01	95.93 ± 13.59	**0.01***	94.47 ± 11.55	100.43 ± 13.43	0.07	32.96 ± 3.97	32.81 ± 3.77	0.88

*- statistically significant by independent t test

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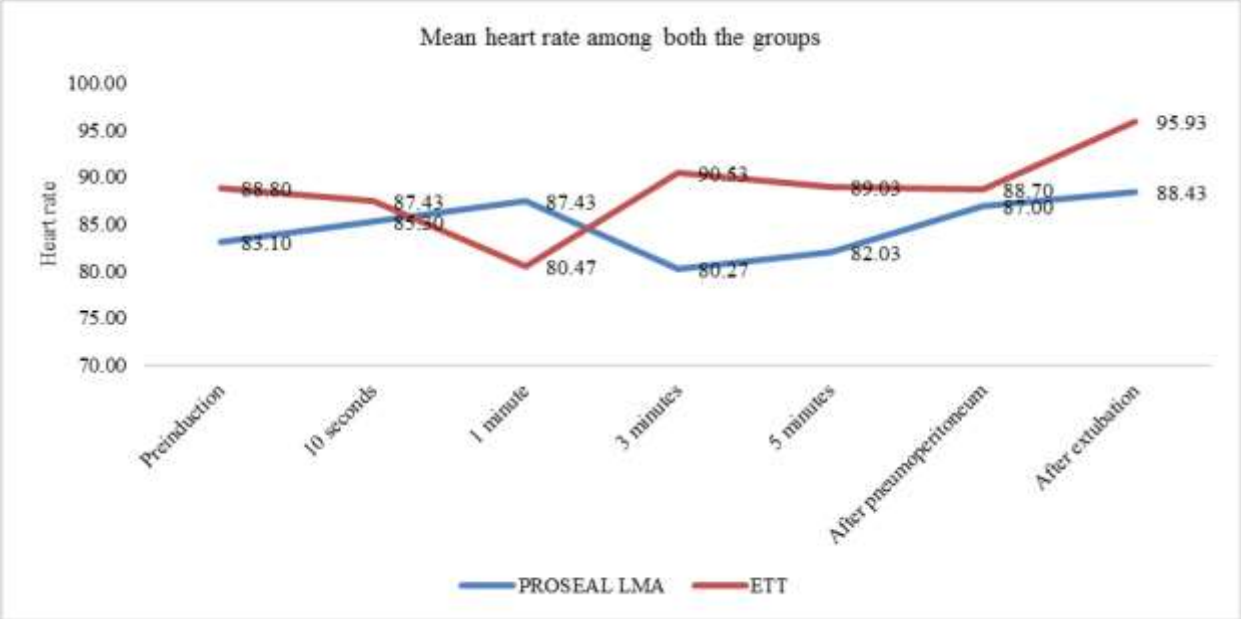

Chart 3. Mean heart rate among both the groups

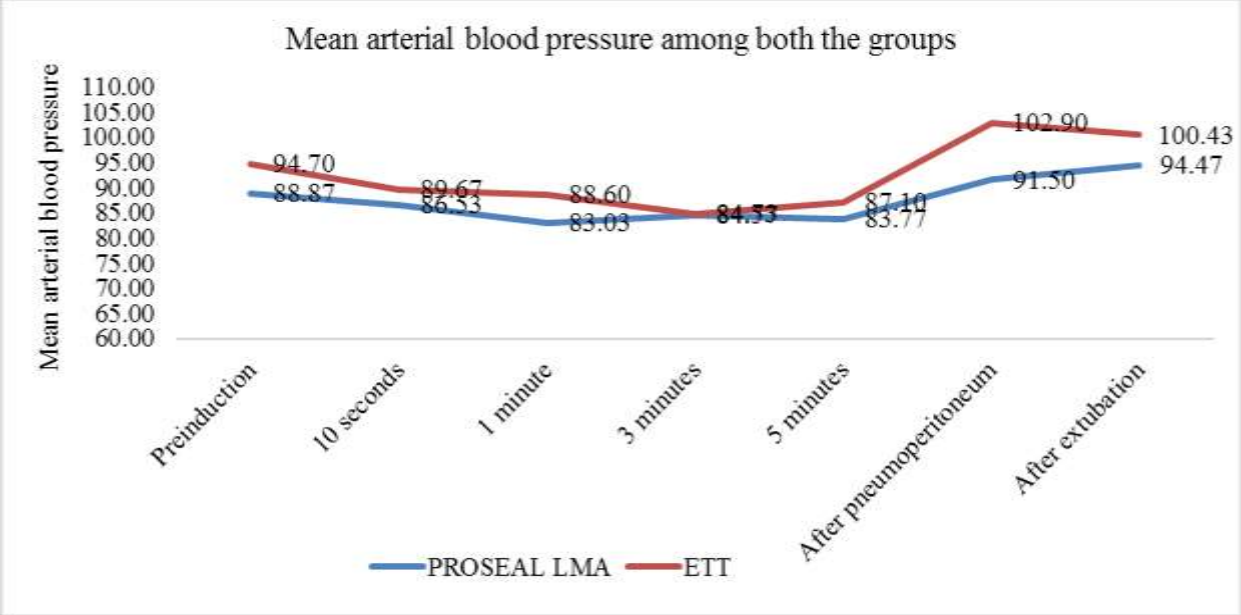

Chart 4. Mean arterial blood pressure among both the groups

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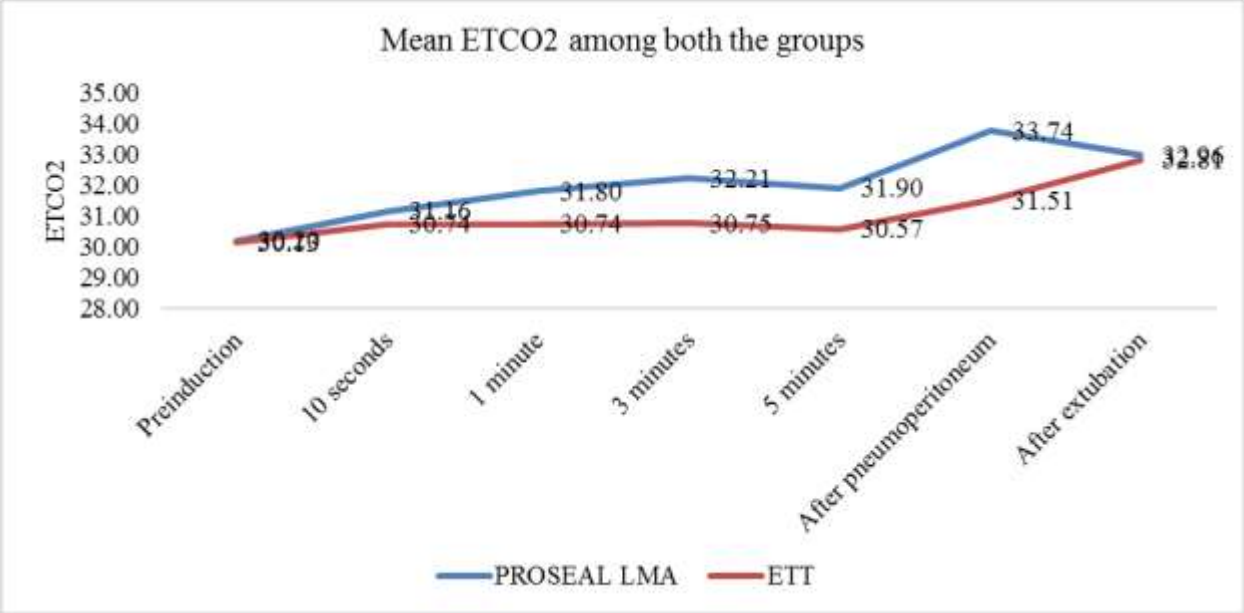

Chart 5. Mean ETCO2 among both the groups

DISCUSSION

Our study shows that the mean age group of Proseal LMA was 35.73 years and that of ETT was 40.30 respectively and this difference in age between the two groups was not statistically significant (P>0.05). This shows that both the groups have similar distribution of age and the difference noted is because of chance. Studies by Malby et al[10] comparing PLMA with ETT on patients undergoing laparoscopic cholecystectomy also show similar age group profiles with mean age among PLMA being 38.12 and ETT being 41.22 years respectively. Similarly Randomized Controlled study by Griffiths et al[11] on comparison of Proseal LMA and ETT also showed similar age group patterns with mean age among PLMA subjects was 34.75 and that of ETT being 38.21 years respectively.

The distribution of male and female in this study was 12/30 and 18/30 respectively. The distribution of male and female subjects in ETT group was 13/30 and 17/30 respectively. Similar to our study, Maltby et al[10] have similar sex distribution among respondents.

Evans et al[12] in 300 patients assessed the insertion characteristics, airway seal pressures using proseal LMA have shown that insertion was successful in 94% of patients and easy in 91 % of patients. The findings of our study are in concurrence with the above data. The success rate of PLMA was 95% in our study and it had 1.56 times less chances of 2nd intubation when compared to ETT and this association was statistically significant with the P value of 0.038. Miller et al[13] in 2006 compared PLMA and SLIPA with ETT in 150 patients. Both PLMA and SLIPA were inserted in 1st attempts (100% success) and ventilated with maximum sealing pressure of 30cm H2o (P=0.4) with no muscle relaxant.

Miller et al[13] in 2006 compared PLMA, SLIPA with ETT in 150 anaesthetised patients undergoing daycare laparoscopic surgery. They concluded PLMA and SLIPA were easy to use and less operating room time (P=< 0.001) was required compared to ETT in daycare laparoscopies. In our study the mean difference of 2.80 seconds was noted between use of PLMA and ETT and this difference was found to be statistically significant (P= 0.0012).

Matby et al[10] in 2002 analysed PLMA and ETT in 109 patients undergoing laparoscopic cholecystectomy and concluded no statistically significant difference in SpO2/ EtCO2 between

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two groups. This result is comparable with our study result which shows no significant EtCO2 changes (P= 0.946, 0.657, 0.230, 0.140, 0.223) measured Pre-op, Pre intubation, 1mt, 3mt and 5mt after intubation, after peritoneal inflation and after extubation. Maltby et al[14] compared PLMA and ETT in 209 women undergoing laparoscopic gynaecological surgery, concluded no statistically significant difference between PLMA and ETT groups for SpO2, EtCO2 before or during peritoneal insufflation in short and long period of peritoneal inflation. The results are comparable with our study.

In our study sore throat occurred 4/30 cases with ETT while it occurred only in 1 patient out of 30 in the PLMA group. Laryngospasm did not occur in both the groups. Through documented data are clinically relevant statistical analysis reveals P Value of 0.176 which was not significant. Though there is difference in incidence of post operative airway morbidity especially with regard to sore throat, it is nor statistically significant and hence we conclude that the post operative airway morbidity is the same in both the groups. However studies by Miller et al[13] in 2006 in their study on 150 patients, concluded that lower incidence of sorethroat with PLMA than with ETT group (30% Vs 57% and P value < 0.05).This might be due to the lesser sample size in our study with 60 patients compared to 150 patients. Eschertzhuber et al[15] in 2007 compared PLMA with ET in 200 female patients, concluded that less frequency of sorethroat with PLMA (12% Vs 38%, P <0.001). Though this result was comparable with our study statistical significance was not achieved maybe due to smaller sample size.

Mean arterial pressure changes were noted in our study especially after pneumoperitoneum following use of Proseal LMA and ETT and this difference is statistically significant with P values of 0.013 thereby making it evident that use of PLMA is associated with less chances of increase of mean arterial pressure. Studies by Chopra et al[16] shows an increase in Mean Arterial Pressure increased in the ETT group, but however the hemodynamic changes were reflected in other parameters like changes at 10 seconds, 1 minute, 3 minutes and following extubation. In our study though there was difference in the mean arterial pressure values between PLMA and ETT, with a lower value being recorded with PLMA the difference was not statistically significant. Similarly, studies by Montazari et al[17] showed that the values of mean arterial pressure after LMA insertion were significantly lower compared to tracheal intubation after 1,3 and 5 minutes when compared to ETT insertion. The heart rate changes were much less in the PLMA group compared to ETT group and these differences in heart rate was statistically significant at 3 minutes, 5 minutes and after extubation with P values of 0.012, 0.033 and 0.018. These findings are consistent with study done by Mao et al[18] on intubation characteristics between laryngeal mask airway and endotracheal intubation for anesthesia in adult patients undergoing laparoscopic

The limitations of our study include a smaller sample size and also a single centric study. This study excluded the patients with airway problems, as these patients require longer intubation time, which can result in different outcomes. This study was conducted on patients with ASA I and II. Making such comparisons on patients with underlying cardiac diseases may bring out different results. Depth of anaesthesia was not monitored in the study. Plasma corticosteroid concentrations were not measured.

CONCLUSION

This study suggest that patients intubated using Proseal LMA have desirable stability compared to patients intubated using Endo Tracheal Tube. In addition to the favorable side effect profile, ease of insertion of Ryle's tube and airway maintenance was similar in both the groups. Due to the significant difference in various parameters observed with Proseal LMA in comparison to

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ETT, it may be stated that the proseal LMA is a better intubation device compared to ETT thereby proving its efficacy.

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