A Prospective Randomized Study to Compare ProSeal LMA and Laryngeal Tube with Suction in Patients Posted for Short Duration Surgeries Under General Anaesthesia with Controlled Ventilation

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ABSTRACT

Introduction: The Laryngeal Tube with suction and ProSeal LMA are newer airway management devices that are gaining acceptance for airway management in anaesthetized patients because of gastric drainage facility in both. We decided to compare their insertion, ventilation, haemodynamic and complication profiles.

Material and methods: Sixty adult patients were randomly allotted to a Laryngeal Tube or ProSeal LMA group. The number of attempts required for successful placement, time taken to establish effective airway, haemodynamic and ventilatory parameters and incidence of postoperative complications was compared.

Results: The LTS produced higher seal pressures (median value 29.60 cm of H2O), as compared to PLMA (23.67 cm of H2O), which was statistically significant (P<0.01). First attempt insertion success rate with PLMA was 24 as compared with 27 with the LTS which was statistically not significant (P>0.05). LTS produced a greater haemodynamic response than PLMA at insertion and at extubation. EtCO2 showed a statistically significant rise at 20, 25 and 30 minutes after insertion of LTS and at extubation. There was no statistical significance in the difference between the incidence of dysphagia and hoarseness in both groups.

Conclusion: ProSeal LMA is a reliable and better airway management option as compared to Laryngeal Tube with suction, for patients undergoing short surgical procedures under general anaesthesia with controlled ventilation.

Keywords: Supraglottic airway device, cuff pressure, sore throat, hoarseness.

INTRODUCTION

Numerous supraglottic devices have been introduced in the past few years, in the quest to provide better alternatives to intubation of the trachea. The two supraglottic devices compared in this study are the ProSeal laryngeal mask airway (PLMA) and laryngeal tube with suction (LTS). They seem to be gaining wide acceptance among supraglottic airways as both have gastric drainage facility thus reducing the risk of airway contamination by preventing gastric insufflation of gases and diverting regurgitated gastro-oesophageal contents away from the larynx.[1,2] LMA ProSeal can be used in spontaneously breathing patients and with positive pressure ventilation, with and without muscle relaxants. Comparative trials of the LMA ProSeal with other (supraglottic airway devices) SGAs demonstrated the superior performance of the LMA ProSeal during positive pressure ventilation, under conditions of both normal and elevated (i.e., during laparoscopic surgery) intra-abdominal pressure.[3-5] LTS can also be used in a spontaneously breathing patient or with positive pressure ventilation.

Overall, research data suggest that the LTS is a safe and effective airway device in adult patients whose lungs are mechanically ventilated.[6]

We decided to study the Proseal LMA and LTS with the aims and objectives of comparing them with respect to anatomical sealing properties during ventilation, ease of insertion i.e. number of attempts needed and time required for successful placement, haemodynamic changes during device insertion, and the incidence of dysphagia and hoarseness after removal of the SGA.

MATERIAL AND METHODS

This study was conducted at Topiwala National Medical College and Bai Yamunabai Laxman Nair Charitable Hospital, Mumbai over a period of six months. Institutional Ethics Committee approval and the patients' written, informed and valid consent were obtained. Based on the results of previous studies, the PLMA has a seal pressure of 29 cm of water with a standard deviation of 5 cm of water.[4] Power analysis determined that a study of 30 patients had 80% power to detect a difference in airway seal pressure of 5 cm H_2O. A randomized prospective trial was carried out on 60 adult patients posted for surgeries under general anaesthesia with controlled ventilation lasting less than two hours. Patient inclusion criteria were ASA I and II, age between 18 and 65 years, male and non-pregnant female, posted for elective surgery lasting <2 hours under controlled ventilation and with body mass index < 30 kg/m^2. Exclusion criteria were mouth opening <2.5 cm, known case of difficult airway, history of hoarseness, history of GERD, hiatus hernia, peptic ulcer disease and history of cervical spine disease. A thorough pre-anaesthetic evaluation was carried out in all the patients, with airway examination and scoring by Mallampati method. Patients were allocated randomly by envelope method into 2 groups: Group L (Laryngeal Tube with suction): n= 30 and Group P (ProSeal

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LMA): n= 30.

Preliminary data collected were age, sex, height, weight, heart rate, respiratory rate, blood pressure and Mallampati score. After confirming consent and NBM status, intravenous access was obtained. Monitoring included pulse oximetry, ECG, capnometry and arterial blood pressure measurement. All patients were premedicated 15 minutes prior to surgery. Patients were pre-oxygenated with 100% O for 3 minutes. Insertion of SGA attempted after 3 minutes of administration of neuromuscular blocking agent. All the supraglottic airways were inserted by anaesthesiologists with minimum 1 year experience.

The LTS was inserted as per instruction manual. Before insertion, water-soluble jelly was applied to the deflated cuff. The patient's head was extended on the neck ('sniffing position'), jaw thrust was given, the tip of the LTS was placed against the hard palate behind the upper incisors and the device was gently but firmly advanced into the oropharynx till resistance was encountered. If no resistance was felt, the LTS was positioned with the second bold line on the tube between upper and lower incisors. The cuffs were inflated using a cuff inflator to a pressure of 60 cm H2O. A size 3 LTS was used for patients of height less than 155 cm and a size 4 for those of height between 155 and 180 cm.

The PLMA was inserted as per instruction manual. Placement was assisted with the help of jaw thrust and PLMA introducer in all cases. The back of the cuff was lubricated with hydrophilic jelly. A size 3 PLMA was used for females and a size 4 for males. The cuff was inflated using the same cuff inflator as the LTS until the intracuff pressure reached 60 cm H2O.

If supraglottic airway device insertion was unsuccessful after two attempts, the patient was withdrawn from the study. An effective airway was defined as normal thoraco-abdominal movement and a square wave capnograph trace. Nasogastric tube of size 16 was introduced for male patients and 14 for female patients, to eliminate risk of aspiration. A leak test as recommended by placing a blob of gel on the gastric drain tube for evidence of leak was carried out in addition to checking for audible air leakage. Only in the absence of leak was the supraglottic airway device insertion considered successful. The device was fixed in place if clinically adequate ventilation was achieved. However, if ventilation was inadequate after these manoeuvres, the device was withdrawn completely and reinserted. The maximum leak pressure attained for each device was noted with the help of a cuff pressure manometer. All haemodynamic and respiratory parameters were recorded at pre-induction, 0, 5, 10, 15, 20 25 and 30 minutes after insertion, at removal, and 1 and 24 hours in the postoperative period. Volume-controlled ventilation was maintained and at the end of procedure patients were adequately reversed. When the patient was fully awake and responding to verbal commands the device was removed and any blood on the device was noted. Oral cavity was inspected for any oozing or visible trauma. The patient was evaluated after removal of the device, for development of hoarseness of voice and dysphagia.

STATISTICAL ANALYSIS

Qualitative data that included gender, weight, ASA grade was assessed by Chi square test and by Fisher's Exact test. Quantitative data was represented by using mean ± SD and analyses between the groups were done by using unpaired t-test and Chi square test (statistical significance: $P < 0.001$; statistical insignificance: $P > 0.05$). A $\chi 2$-test or a Fischer exact test was used to compare the proportions of patients in whom first-time device insertion was successful, and complications occurring with each device. Appropriate statistical software, including but not restricted to MS Excel, PSPP was used for statistical analyses. Graphical representation was done in MS Excel 2010.

RESULTS

The observation and results of the two groups, Group P (PLMA) and Group L (LTS) are mentioned below. Sixty patients were studied. The demographic data of patients are represented in table 1 and results of the study are summarized in table 2. The insertion success rate was 80.0% and 90.0% for the first attempt for group P and group L respectively, 2 attempts were required for 20.0% in group P and 10.0% in group L. There were no failed attempts in any group. The mean time required for effective airway was 23.97 ± 5.95 seconds for group L and 19.37 ± 6.23 seconds for group P and this difference was statistically significant. Haemodynamic parameters were studied to compare the airway insertion stress response. The heart rate in the preoperative, post-induction, at 0, 5, 10, 15, 20, 25, 30 minutes after insertion of device, at removal, and 1 and 24 hour after removal showed no statistically significant difference between the groups (figure 1). Between the two groups, the mean arterial blood pressures were compared in the preoperative period, post-induction, and at 0,5, 10, 15, 20, 25, 30 minutes after insertion of device, at removal, and 1 and 24 hours after removal of the device. A statistically significant difference in the mean arterial blood pressures was observed at 5, 10 and 25 minutes after insertion, at removal, and 1 hour after removal (figure 2). In both groups, reduction in the $EtCO_2$ from the value noted immediately after insertion was observed at 5, 10, 15, 20 minutes after insertion. An increase in the $EtCO_2$ was observed 25 minutes after insertion in group P from the value observed immediately after insertion (table 2). A statistically significant difference in $EtCO_2$ was found at 20, 25, 30 minutes after insertion and at removal. Dysphagia was observed postoperatively in 13.3% patients in group P and 6.7% in group L respectively which was statistically not significant. Hoarseness was observed postoperatively in 6.7% patients in group P and 3.3% in group L respectively which was statistically not significant. There was no case of pulmonary aspiration in either of the groups. There were no episodes of desaturation in either of the groups.

Males: Females	10: 20
Age (years)	39.6 (52.6 – 26.6)
Weight (kg)	53.37 (8.24)
ASA I / II	22 / 7
Duration of surgery	80.10 (111.21 - 48.99)

Table-1: Demographic characteristics. The results are given as absolute number of patients, mean or median (SD).

	PLMA	LTS	*P*-value
Device insertion			
No. of patients	30	30	
Attempts (one/two/abandoned)	24 / 6 / 0	27 / 3 / 0	>0.05, not significant
Time for effective airway	19.37 (± 6.23)	23.97 (± 5.95)	<0.01, significant
Ventilation			
Airway seal pressures (cm of H2O)	23.67 (± 6.44)	29.60 (± 6)	<0.01, significant
EtCO2 (at 0 minutes)	32.53 (± 2.40)	32.80 (± 2.30)	>0.05, not significant
EtCO2 (at 5 minutes)	30.40 (± 2.59)	29.73 (± 2.98)	>0.05, not significant
EtCO2 (at 10 minutes)	28.53 (± 1.57)	28.40 (± 2.22)	>0.05, not significant
EtCO2 (at 15 minutes)	29.47 (± 1.74)	28.73 (± 2.24)	>0.05, not significant
EtCO2 (at 20 minutes)	28.97 (± 1.46)	29.80 (± 1.79)	<0.01, significant
EtCO2 (at 25 minutes)	33.47 (± 1.74)	31.13 (± 1.11)	<0.01, significant
EtCO2 (at 30 minutes)	29.47 (± 0.90)	28.73 (± 1.20)	<0.01, significant
EtCO2 (at extubation)	31.73 (± 1.95)	32.93 (± 1.68)	<0.01, significant
Patient complications			
Hoarseness	6.7	3.3	>0.05, not significant
Dysphagia	13.3	6.7	>0.05, not significant

Table-2: Results of the study. The results are presented as absolute number of patients or as median (range)

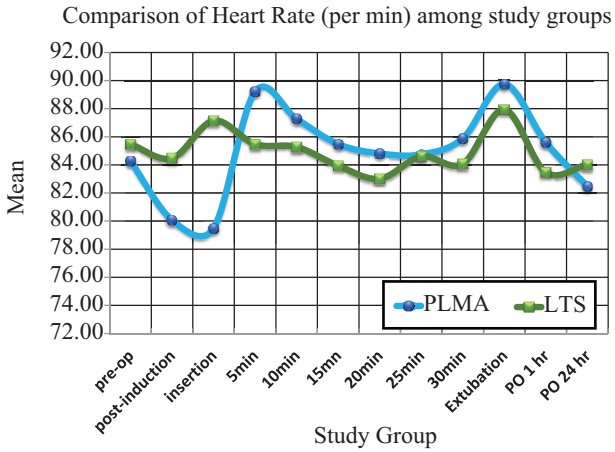

Figure-1: Comparison of heart rates among study groups

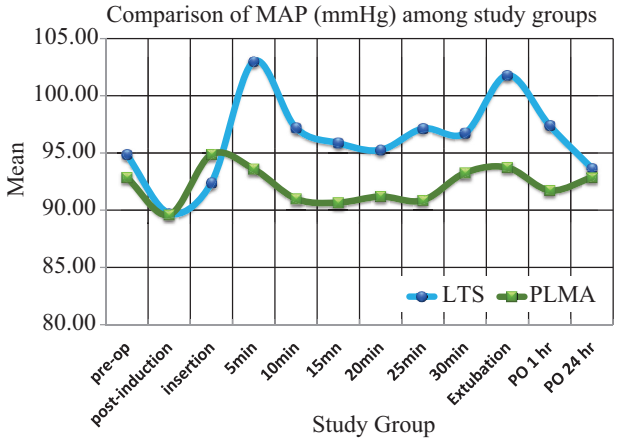

Figure-2: Comparison of mean arterial pressures among study groups

DISCUSSION

The primary outcome of this study was airway leak pressures. PLMA showed airway leak pressures of 23.67 ± 6.44 cm of H2O and LTS group showed airway leak pressures of 29.60 ± 6 cm of H2O which was found to be statistically significant but it is not clinically significant.

Cook et al[4], in a study of 64 patients also found no clinically significant difference in the airway leak pressures between PLMA and LTS. However, Gaitini et al[6], in a study of 150 patients that were compared for airway leak between PLMA and LTS, found that airway leak pressures were 28 ± 7 cm of H2O for PLMA and 34 ± 6 cm of H2O for LTS. They attributed performance of PLMA in terms of leak fraction to its wedge shaped ventral double cuff that efficiently adapts to various contours of the pharyngeal surface surrounding the laryngeal inlet and thus achieves an effective airway seal. On the other hand, although LTS cuff achieved a good airway seal they found that high pressures were exerted on the posterior pharynx as the LTS gets firmly wedged against the bone of the anterior cervical vertebrae to compensate for any suboptimal anatomic positioning.

In our study, for both the groups, the first time insertion success rates were comparable (80% in group P, and 90% in group L). In PLMA group, two attempts were required for six patients (20%) and three patients (10%) in the LTS group. There were no failed attempts in both groups and no patient required endotracheal intubation. Cook et al showed LTS insertion was less successful than PLMA, with more complications and greater need for manipulation. These rates for both the LTS and the LMA-ProSeal vary depending on the investigators: for the LTS it is between 80% and 100% first time success rate and between 94% and 100% within three attempts[6-8] and for the LMA-ProSeal, it is between 76% and 100% first time and between 81% and 100% overall.[1,6,9-13]

In our study, the time required for achieving effective airway was longer with LTS than with PLMA (19.37 ± 6.23 seconds for PLMA vs 23.97 ± 5.95 seconds for LTS) which was statistically significant. More acceptance of PLMA among anaesthesiologists might have skewed the results of time taken to insert the device in favour of PLMA as compared to LTS. In a study done by Klaver et al[14] with 160 patients, they found time to establish effective airway was 55 and 53 seconds in LTA and PLMA groups respectively and this difference was not statistically significant. These times were greater than that in our study as devices were inserted by

first-month anaesthesiology residents in the Klaver study.

In our study, the changes in EtCO2 after PLMA insertion or LTS were statistically significant at 20, 25 and 30 minutes of insertion and at extubation but they were not clinically significant. No desaturation events occurred with use of any device.

Heart rates at insertion were greater in LTS group as compared to PLMA group which was statistically significant. Mean arterial pressures were statistically significant in LTS group at 5, 10 and 25 minutes after insertion and at removal, and 1 hour after removal, as compared to PLMA group. Haemodynamic and catecholamine response was greater in LTS group than in PLMA group reflecting greater pharyngeal stimulation in the former. The other factor that may have contributed to these results was the longer time required to establish effective airway with the LTS.

In our study, we found no statistically significant difference in the incidence of dysphagia and hoarseness in both the groups which was similar to a study done by Brimacombe et al[13] comparing PLMA with LTS.

Limitations of the study

This study did not compare quality of ventilation by way of parameters like airway pressures, with the two SGA devices.

CONCLUSION

PLMA insertion is easier and quicker than LTS. Airway leak pressure is less for PLMA. The PLMA is associated with lesser haemodynamic response as compared to LTS. Complications like dysphagia and hoarseness were minimal and similar in both groups.

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