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"COMPARATIVE EVALUATION OF AMBU AURAGAIN LARYNGEAL MASK AND PROSEAL LARYNGEAL MASK AIRWAY IN SPONTANEOUSLY BREATHING PATIENTS UNDERGOING ELECTIVE SURGERY UNDER GENERAL ANAESTHESIA"

Anaesthesiology

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ABSTRACT

Introduction : The use of second-generation supraglottic airway devices has seen a significant rise since their introduction. Previous studies have conducted comparisons between the Proseal LMA and endotracheal tubes in various surgical procedures such as laparoscopic surgeries, pediatric short procedures, and lower abdominal surgeries. Furthermore, the Proseal LMA has been evaluated against other supraglottic airway devices like the I-gel and LMA Supreme in patients undergoing general anesthesia. **Aim and objectives:** To compare AmbuAura Gain and the Proseal LMA in terms of their functionality related to the ease of insertion, ability to secure the airway and the occurrence of adverse events in patients undergoing limb or breast surgeries. **Methodology:** This study was conducted in Tata Main Hospital, Jamshedpur. It is a 1100 bedded multispecialty hospital with 9 Operation Rooms. The hospital caters to a large number of patients from Jamshedpur as well as from different parts of Jharkhand. This study was conducted in the Operation Room.This study consisted of patients of either sexes who fulfilled the Inclusion and Exclusion criteria admitted for surgical intervention who has given consent for general anesthesia. **Results:** The mean oropharyngeal leak pressure in Group 1 is 24.91 ± 2.08 and in Group 2 is 27.89 ± 2.27. The difference in mean oropharyngeal leak pressures between the two Groups was statistically significant, as p value < 0.05. The mean oropharyngeal leak pressure in Group 1 is 24.91 ± 2.08 and in Group 2 is 27.89 ± 2.27. The difference in mean oropharyngeal leak pressures between the two Groups was statistically significant, as p value < 0.05 **Conclusions:** Based on the findings of our study, it can be concluded that the Ambu Auragain LMA is more favorable than the Proseal LMA for elective surgical cases in terms of ease of insertion, including the number of insertion attempts and the time required for insertion. Additionally, the time for insertion of an orogastric tube was also found to be more efficient with the Ambu Auragain LMA

KEYWORDS

Ambu Auragain LMA, Proseal LMA, Airway, MAP, Heart rate

INTRODUCTION

Airway control and protection are crucial in anesthesia, and the use of various techniques is necessary to ensure optimal management. Tracheal intubation is often considered the gold standard, but it has limitations and complications. To address these issues, supraglottic airway devices (SADs) such as the Laryngeal Mask Airway (LMA) have been developed. SADs provide a secure and less invasive alternative between a facemask and a tracheal tube. Newer generation SADs offer improved clinical performance, including easier insertion, better airway seal, higher airway leak pressures, and the ability to remove gastric contents. These advancements have enhanced airway management in challenging situations[1]

The Proseal LMA is a second-generation supraglottic airway device that features an inflatable cuff to create a seal around the larynx, allowing for safe and effective ventilation. It also includes a gastric channel for easy insertion of a large bore gastric tube. While it doesn't allow for direct passage of a tracheal tube, fiber optic-guided intubation can be performed using tube introducers. The device has been successfully utilized in various surgical procedures for both adults and pediatric patients[2]

The AuraGain, developed by Ambu, is a third-generation laryngeal mask that combines gastric access and intubation capabilities in a single-use device with an anatomically curved design. It facilitates rapid establishment of a safe airway. Unlike the Proseal LMA, the AuraGain has a wider airway tube, allowing for tracheal intubation. It is also less rigid than the LMA Supreme, potentially improving its fit. The cuff of the AuraGain has been slightly modified to enhance seal pressure.[3]

The use of second-generation supraglottic airway devices has been increasing significantly since their introduction. Previous studies have compared the Proseal LMA with endotracheal tubes in laparoscopic surgeries, pediatric short surgical procedures, and lower abdominal surgeries. Additionally, the Proseal LMA has been compared to the I-gel and LMA Supreme in patients undergoing general anesthesia. However, there is limited research available on the functionality of the Ambu AuraGain compared to other supraglottic airway devices. Only a few studies have evaluated its performance, including a comparison with the LMA Supreme in gynecologic laparoscopic surgery, a study comparing the AuraGain and LMA Supreme in infants and children, and a comparison of the Ambu AuraOnce laryngeal mask with the LMA Unique laryngeal mask airway in spontaneously breathing adults[4]

The present study is hereby designed to compare AmbuAura Gain and the Proseal LMA in terms of their functionality related to the ease of insertion, ability to secure the airway by preventing air leak, ability to maintain hemodynamic stability, ease of orogastric tube insertion and the occurrence of adverse events in patients undergoing limb or breast surgeries.

MATERIALAND METHODS

This study was conducted in Tata Main Hospital, Jamshedpur. It is a 1100 bedded multispecialty hospital with 9 Operation Rooms. The hospital caters to a large number of patients from Jamshedpur as well as from different parts of Jharkhand. This study was conducted in the Operation Room.This study consisted of patients of either sexes who fulfilled the Inclusion and Exclusion criteria admitted for surgical intervention who has given consent for general anesthesia.

Patients will be divided in two groups

- **Group A-** Airway management with Ambu AuraGain Laryngeal Mask Airway .
- **Group B-** Airway management with ProSeal Laryngeal Mask Airway.

Inclusion Criteria:

1. American Society of Anesthesiologists (ASA) Physical Status I & II
2. Patients undergoing limb or breast surgery
3. Patients undergoing elective surgery under general anaesthesia and spontaneous ventilation.

Exclusion Criteria:

1. Patients with known or predicted difficult airway or Mallampati Grade (MPG) III or IV
2. Patients with mouth opening of less than 2.5 cm or cervical spine disease
3. Patients with a body mass index (BMI) > 30 kg/m2
4. Patients with H/o upper respiratory tract infection in the previous 10 days.

5. Patients with expected duration of surgery of more than 2 hours.
6. Patients with increased risk of regurgitation and aspiration (non-fasting patients, gastroesophageal reflux disease etc.)

Patients premedicated with Tablet oral Alprazolam 0.5 mg, Ranitidine 150mg and Metoclopramide 10 mg (with sips of water) on the night before surgery, and on the morning of surgery. Standard fasting guidelines of 6 hours for solid food and 2 hours for clear liquids followed. Monitoring applied before anaesthetic induction and include a continuous electrocardiograph, pulse oximetery, End tidal carbon dioxide (ETCO2) analyser, non-invasive blood pressure monitor(Base line, after insertion of device and after every two minutes), tidal volume monitor and airway pressure monitor. Anesthesia administered with the patient in the supine position, and patient's head on a standard pillow(8 cm in height). Intravenous (0.02mg/kg Midazolam and 2 microgram/kg Fentanyl) and oxygen via a face mask administered. Two minutes later, General anaesthesia induced using 2 mg/kg intravenous Propofol mixed with 25 mg Lidocaine Injected over 30 seconds, Mask ventilation commenced and continued for at least 30 seconds until conditions are suitable for PLMA or AuraGain laryngeal mask insertion i.e. jaw relaxation, absence of movement and apnoea.. Additional boluses of 0.5 mg/kg intravenous Propofol given as required until an adequate level of anaesthesia is achieved for placement. A clear, water based gel used for lubricating the LMAs. The insertion technique for both devices will be identical i.e. finger technique recommended for the LMA, including neck flexion/head extension and full deflation of the cuff. Slight lateral approach used if resistance felt in the oropharynx. The introducer tool not used for PLMA, because the operators have more experience with LMA insertion using the finger technique. The PLMA or AuraGain laryngeal mask connected to a circle breathing system and the cuff inflated with air until an effective airway is established or the maximum recommended inflation volume reached. Effective ventilation confirmed, wherein effective ventilation is defined as a square wave capnograph trace and normal thoracoabdominal movement , Fixation done by taping the tube over the chin.

Time taken for insertion from picking up the LMA till confirmation of effective ventilation. The number of insertion attempts or failed attempt to achieve effective ventilation. A failed insertion attempt is defined as when removal of the device needed from the mouth. Three attempts allowed before insertion will be considered a failure.

Intracuff and the oropharyngeal leak pressures after ensuring effective placement. These pressures will be determined by closing the expiratory valve of the circle system at a fresh gas flow of 3 l/min, note the airway pressure (maximum allowed: 40 cm H2O) at which equilibrium was reached.

Observations

The mean age of distribution in Group 1 is 38.90 ± 12.09 and in Group 2 is 38.20 ± 13.31. The Mean age difference between the two Groups is not statistically significant (p>0.05). The gender (Sex) distribution is comparable in both the groups as p>0.05. The gender (Sex) distribution between the two Groups is not statistically significant. The ASA Grading distribution is comparable in both the groups as p>0.05 . The ASA Grading distribution between the two Groups is not statistically significant. The mean Duration of Surgery (min) in Group 1 56.31 ± 27.96and in Group 2 is 58.06 ± 27.73. The Duration of Surgery (min) difference between the two Groups is not statistically significant. The Teeth, Neck and Spine are comparable in both the groups. The Teeth, Neck and Spine between the two Groups is not statistically significant. The Size distribution is comparable in both the groups as p>0.05

Table 1: Distribution of patients according to number of attempts taken for correct positioning of LMAs

Attempts	Group 1		Group 2		P Value
	Frequency	%	Frequency	%	
1	77	96.3%	65	81.3%	0.010
2	3	3.8%	14	17.5%	
3	0	0.0%	1	1.3%	
Total	80	100%	80	100%	

Table 1 show the distribution of patients according to number of attempts taken for correct positioning of LMAs. Correct positioning of Ambu AuraGain LMA after 1st attempt was seen in 96.3% and after 2nd attempt 3.8% of patients ,while correct positioning of Proseal LMA after 1st attempt was seen in 81.3% ,after 2nd attempts 17.5% and after 3rd attempts 1.3% of patients . **The difference in the number of attempts between the two groups is statistically significant**. Number of attempts taken for correct positioning of Ambu AuraGain LMA are less.

Table 2: Comparison of No of failed insertion in both the study group

Failed insertion	Group 1		Group 2		P Value
	Frequency	%	Frequency	%	
NO	80	100.0%	80	100.0%	–
Total	80	100%	80	100%	

The Number of Failed insertion are NIL in both the groups. The Number of Failed insertion between the two Groups is not statistically significant.

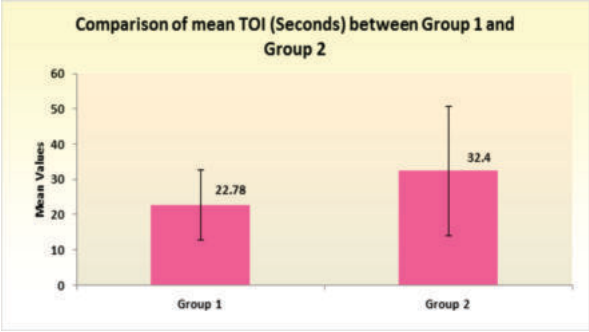

Chart 1: Comparison of mean time of insertion between group 1 and group 2.

The mean time of insertion in group 1 is 22.78 ± 9.92 and in group 2 is 32.40 ± 18.28. The difference in the **mean time of insertion between the two groups is statistically significant(p<0.05)**. The time of insertion is less in group 1.

The mean oropharyngeal leak pressure in Group 1 is 24.91 ± 2.08 and in Group 2 is 27.89 ± 2.27. **The difference in mean oropharyngeal leak pressures between the two Groups was statistically significant, as p value < 0.05** (Chart 2)

Table 3 : Comparison of Air leak between Group 1 and Group 2

Air leak	Group 1		Group 2		P Value
	Frequency	%	Frequency	%	
N	77	96.3%	78	97.5%	1.000
Y	3	3.8%	2	2.5%	
Total	80	100%	80	100%	

The Air leak is comparable in both the groups as p>0.05. The Air leak between the two Groups is not statistically significant.

Table 4 : Complications in both the study groups.

	Group 1		Group 2		P Value
	Frequency	%	Frequency	%	
Nil	67	83.8%	53	66.3%	0.071
Blood Stained	6	7.5%	11	13.8%	
Minor Dental Trauma	1	1.3%	6	7.5%	
Minor Lip Trauma	3	3.8%	2	2.5%	
Post Opp Cough	3	3.8%	5	6.3%	
Post Opp Hiccups	0	0.0%	3	3.8%	
Total	80	100%	80	100%	

As evident, in Group 1 ,only 67 patients (83.8%) had no airway trauma while only 53 patients (66.3%) did not received airway trauma in Group 2.Rest of the patients received some minor airway trauma and secondry outcomes in both groups. Total 13 patients (16.2%) in group1 and total 27(33.7%) patients in group2 received some airway trauma and secondry outcomes.

Both groups are comparable with respect to specific complications. So the difference in frequency of complications between group1 and group2 is not statistically significant (p>0.05). The mean oropharyngeal leak pressure in Group 1 is 24.91 ± 2.08 and in Group 2 is 27.89 ± 2.27. **The difference in mean oropharyngeal leak pressures between the two Groups was statistically significant, as p value < 0.05**

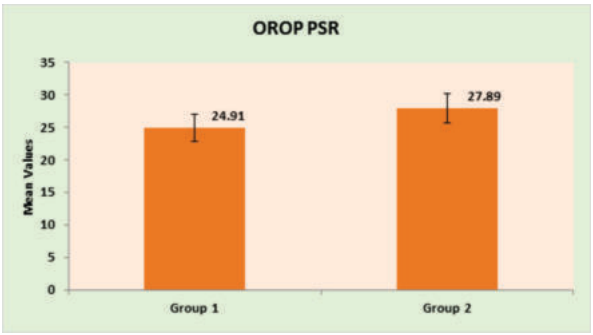

Chart 2: Distribution of OROP PSR in both the study group

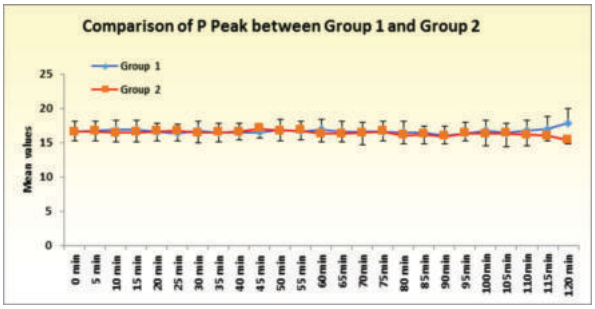

Chart 3 : Comparison of P PEAK between group 1 and group 2

Chart 2 showing the changes in Mean Arterial pressure (MAP), Heart Rate (HR), SPO_2, End Tidal CO_2 ($ETCO_2$), and Peak pressure (Ppeak) respectively at various time intervals in two groups of patients. There was no statistically significant changes in mean values of Mean Arterial pressure (MAP), Heart Rate (HR), SPO_2, End Tidal CO_2 ($ETCO_2$), and Peak pressure (Ppeak) from pre induction to 15 min after induction in Group 1 and Group 2 ($p>0.05$).

DISCUSSION

The study compared Ambu AuraGain Laryngeal Mask and Proseal Laryngeal Mask Airway in patients undergoing elective surgery under general anesthesia. Airway-related complications during anesthesia and emergency medicine can be potentially disastrous, with approximately 600 deaths worldwide each year due to difficulties with intubation. The incidence of difficult intubation for elective surgery ranges from 0.05% to 18%, and it's higher in emergency situations.

Various complications associated with SADs, such as mucosal ischemic injury, gastric insufflation, regurgitation, and aspiration, appear to be time dependent. As a result; LMAs have been used chiefly prescribed for short surgical procedures. We hereby only undertook surgeries with expected duration of 2- 3 hrs. None of our cases exceeded 2 hours and mean duration of surgery was comparable (P= 0.691) in both the groups i.e. 56.31 ± 27.96 minutes for group 1 and 58.06 ± 27.73 minutes for group 2.

Mallampatti Grading

There have been controversies relating MP Grading as a predictor of difficult LMA insertion. **Brimacombe J et al**[5] did a retrospective study on 272 patients and found no relationship between LMA insertion and MP Grading while, **McCrory CR et al**[6] in their prospective study discovered a significant relationship between them. We therefore selected only MP Grade 1 and MP Grade 2 patient and there was no significant difference (P=0.719) in the incidence of these two grades in both groups.

Insertion attempts

Insertion of the Ambu AuraGain LMA in the 1st attempt achieved a success rate of 96.3% while 3 patients required 2nd attempt which was 100% successful while the Proseal LMA achieved a success rate of 81.3%, 15 patients required a 2nd attempt and 1 patient required 3rd attempt no further attempts were necessary. The success rate of Ambu AuraGain was very high in the 1st attempt as compared to the Proseal LMA, in the 2nd attempt the Ambu AuraGain achieved 100 % insertion success while that of the Proseal LMA was 92.3% and one patient required a Third attempt.

However in a study done by **Jagannathan M** et al [7] compared the Ambu AuraGain and the LMA supreme and concluded that the success rates of the insertion attempts of both the LMAs were similar which differs from the present study. However in their study insertion attempts was done under neuromuscular blockade. **Lopez AM**[8] compared the Ambu AuraGain versus the LMA supreme in patients undergoing gynaecologic laparoscopic surgery and concluded that there was similar success rates for insertion attempts for both the SADs. This differs from the present study which shows higher success rates in the Ambu AuraGain LMA in insertion. **Kriege M** et al [9] compared the Ambu Auragain and the LMA Supreme in anaesthetized adult patients and found the higher rates of success in the insertion of the LMA Supreme which differs from the present study.

Time of insertion

The mean time of insertion in group 1 is 22.78 ± 9.92 and in group 2 is 32.40 ± 18.28. The difference in the mean time of insertion between the two groups is statistically significant($p<0.05$). The time of insertion is less in group 1. **Kriti Singh et al**[10] in their study shows Time taken for insertion in Group AAU was longer than Group PLMA (13.57 ± 1.94 vs. 11.60 ± 2.22 s).

Comparision of air leak

The incidence of Air leak was compared in both the groups after insertion of the devices when the patients were breathing spontaneously , the difference in Air leak between the two Groups was not statistically significant and both groups were comparable. Both the devices provide excellent oropharyngeal seal with very low incidence of air leak. **Sharma B**[11] has also shown that the dorsal cuff of the Proseal LMA provides effective seal and can be used for positive pressure ventilation. the present study has used only spontaneously breathing patients with less positive pressure so the incidence of air leak has been very low. Similar claims has been made by the manufacturers of the Ambu AuraGain LMA which has a ultra thin and soft cuff design to adapt to the oropharynx and provide an effective seal and decrease the incidence of air leak. The present study has very low incidence of air leak due to the above mentioned reasons.

Oropharyngeal leak pressure

The mean oropharyngeal leak pressure in Group 1 is 24.91 ± 2.08 and in Group 2 is 27.89 ± 2.27. The difference in mean oropharyngeal leak pressures between the two Groups was statistically significant, as p value < 0.05 **Kriti Singh et al**[10] in their study found that The calculated pharyngeal mucosal pressures were lower with Group AAU than Group PLMA for all 3 sizes. The minimum cuff pressure and minimum cuff volume required to prevent leak were found similar in both groups.

Orogastric tube Insertion

Mean time for orogastric gastric insertion in group1(Aura Gain) and group 2 (PLMA) was 15.38 ± 1.84secs and22.42 ± 0.87secs respectively. Similar findings for PLMA were noted by **Brimacombe J et al**[5] in a study on spontaneously breathing patients. However, orogastric tube insertion took lesser time (9+/- 4secs) in preliminary study. This difference could be attributed to patient population which was paralyzed in later study, amount of lubricaition, size of orogastric tube used which was smaller in later. Of limited no. of studies available on Ambu Aura Gain, time for orogastric insertion was 12(9.5 to 15.7)secs and 5 secs17quite different from our finding of 15.38 ± 1.84secs. This again may be due to patient population i.e pediatrics and cadavers. We further noted that it took significantly ($P<0.001$) lesser time for orogastric tube insertion in Ambu Aura Gain LMA as compared to PLMA. This finding could be due to low friction inner surface of the Ambu Aura Gain orogastric drainage tube channel and folding over of the drainage tube.

Hemodynamic parameters

Both the groups maintained stable hemodynamic parameters through out the surgical procedure. This study has compared the differences between the hemodynamic parameters for the first 15 minutes between the two groups and the difference was not stastically significant. Similar results were obtained by **Jagannathan M** et al[7] who compared the Ambu AuraGain LMA and the LMA Supreme. However in their study was done under neuromuscular blockade. **Kriege M** et al[9] compared the Ambu AuraGain LMA and the LMA supreme in anesthetized adult patients and found stable and comparable hemodynamic parameters.

Complications and secondary outcomes

In the present study Group 1, 67 patients (83.8%) had no airway trauma and 53 patients (66.3%) did not received airway trauma in Group 2. Rest of the patients had some minor airway trauma and secondary outcomes (post operative cough, gagging, retching, blood staining, minor lip and dental trauma) in both groups. Total 13 patients (16.2%) in group1 and Total 27 (33.7%) patients in group2 received some airway trauma and secondary outcomes (post operative cough, gagging, retching, blood staining, minor lip and dental trauma). The difference in frequency of complications between group1 and group2 was not statistically significant ($p>0.05$). Hence both groups were comparable with respect to overall complications.

CONCLUSIONS

Based on the findings of our study, it can be concluded that the Ambu Auragain LMA is more favorable than the Proseal LMA for elective surgical cases in terms of ease of insertion, including the number of insertion attempts and the time required for insertion. Additionally, the time for insertion of an orogastric tube was also found to be more efficient with the Ambu Auragain LMA. The mean Oropharyngeal leak pressure was significantly higher in proseal group, the clinical significance of this difference is notable. It is worth mentioning that despite a slightly higher incidence of minor adverse effects such as blood stained insertion, minor dental trauma, minor lip trauma, post-operative cough, and post-operative hiccups, these differences were not statistically significant.

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