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Second Generation Supraglottic Airway Devices: A Randomized Comparison of the Ambu Aura Gain Versus the LMA Proseal in Patients Undergoing Laparoscopic Surgeries

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Abstract **Original Research Article**

Background*:** Second generation Supraglottic airway devices are increasingly used in laparoscopic surgeries. Supraglottic airway devices have no effect on pharyngo-esophageal reflex and prevent aspiration. We attempt to elucidate whether Ambu Aura Gain (AAG) would provide a higher Oropharyngeal Leak Pressure (OLP) with a lower mucosal pressure compared to ProSeal Laryngeal Mask Airway (PLMA). ***Objective: The present study was done to evaluate and compare Ambu Aura Gain and ProSeal Laryngeal mask airway with respect to number of insertion attempts, ease of insertion, time required for placement, Oropharyngeal leak pressure, hemodynamic changes and complications in laparoscopic surgeries. ***Method:*** 60 patients who belong to ASA physical status I & II, posted for laparoscopic surgeries, were divided into two groups of 30 each. Group A (n=30) - Ambu Aura Gain used and Group B (n=30) – ProSeal laryngeal mask used. ***Result:*** No significant difference in OLP were observed. Both AAG and PLMA are easy to insert with a similar successful insertion rate on first attempt. The time taken for insertion of AAG was longer than PLMA. ***Conclusion:*** AAG provide adequate sealing pressure and easy to insert and can be used effectively as Supraglottic airway device for laparoscopic surgeries.

Keywords: Ambu Aura Gain, ProSeal Laryngeal Mask Airway, Supraglottic Airway Device, Oropharyngeal Leak Pressure.

INTRODUCTION

The American Standards for Testing Materials (ASTM) defined supraglottic airway devices (SADs) as "Airways that are intended to open, secure, and seal the supraglottic area to provide an unobstructed airway in spontaneously breathing or ventilated patients, typically during anaesthetic procedures."

Table 1: Classification based on Evolution of Supraglottic Airway Device [1]

First Generation Devices **Simple airway tubes**	***Second Generation Devices*** **Airway tubes with addition of drainage tube to reduce risk of aspiration**
LMA Classic	ProSeal LMA
LMA Flexible	LMA Supreme
Intubating LMA	i-gel
Ambu AuraOnce	Ambu AuraGain
Ambu Aura40	Laryngeal Tube Suction (LTS)-II and LTS-
Ambu Aura-I	D
Ambu AuraFlex	Gastro-LT (G-LT)
Ambu AuraStraight	Intubating LTS (ILTS)

First Generation Devices **Simple airway tubes**	***Second Generation Devices*** **Airway tubes with addition of drainage tube to reduce risk of aspiration**
Portex SSLM	Air Q blocker
Air Q	Combitube
Laryngeal tube (LT) and LT-D	
(disposable)	
Cobra PLA	
SLIPA	

Laparoscopic surgeries require creation of pneumoperitoneum and appropriate positioning for surgical access which affects the respiratory compliance, airway pressure and hemodynamics of the patient. SADs are associated with decreased lower esophageal tone, however, no effect on pharyngo-esophageal reflux. With better lesser anaesthestic requirement and lesser pharyngo-laryngeal morbidity, there is better protection against aspiration.

Ambu Aura Gain is a second generation perilaryngeal sealer. It is a single use, disposable, cuffed laryngeal mask airway. It has an inbuilt drain tube for drainage of gastric contents. It is an anatomically curved laryngeal mask. It has a wider airway tube than other similar devices which allows the passage of a standard endotracheal tube through it. It has a thin and soft cuff, designed to deliver high oropharyngeal seal pressure (OSP).

A second generation cuffed perilaryngeal sealer, the PLMA consists of a gastric drain tube, airway tube, integral bite block, an anterior pocket for seating an introducer or finger during insertion, posterior oropharyngeal inflatable cuff, 15mm connector, inflation line, pilot balloon. The posterior cuff and a larger and deeper bowl results in a better airway seal and allows higher oropharyngeal seal pressure (OSP) of 30-40 cm H_2O during PPV.

INSERTION TECHNIQUE

All varieties of the laryngeal mask airways follow the same insertion technique. The insertion technique is similar to the process of deglutition.

SEALING PRESSURE

The airway sealing pressure or the oropharyngeal leak pressure (OLP) is the pressure at which gas leak occurs around the device. It is important as it indicates the degree of airway protection and feasibility of positive pressure ventilation. It quantifies the efficacy of seal with the airways and is also an index of successful placement. After the placement of airway device, OLP is determined by closing the expiratory valve of the closed circle system at a fixed gas flow of 3 L/ min. There are various methods of assessing this pressure.

a) Audible noise over the mouth of the patient.
b) Manometer stability- Observation of Aneroid manometer dial and noting the airway pressure at which the dial attains stability (i.e, the airway pressure at which the leak was in equilibrium with the fresh gas flow).
c) Auscultation involves detection of an audible noise using a stethoscope placed just lateral to the thyroidcartilage[2].

AIM AND OBJECTIVES

Comparison of Ambu AuraGain and ProSeal Laryngeal Mask with respect to-

1. Number of insertion attempts
2. Ease of insertion
3. Time required for placement
4. Oropharyngeal leak pressure (OLP)
5. Hemodynamic changes
6. Complications if any

MATERIAL AND METHODS

A randomized, single-blinded study was conducted in the Department of Anaesthesiology and Critical care, Sree Mookabika Institute of Medical Sciences, Kulasekaram. After approval of Institutional Ethical Committee, 60 patients of either sex, aged 18-65 years, belonging to American Society of Anesthesiologists (ASA) physical status I or II scheduled for elective laparoscopic surgery were included in the study.

All the patients were examined during preoperative visit a day prior to surgery. Detailed clinical history along with physical examination was done. Routine investigations were carried out in all the patients. The purpose and protocol of the study was explained to the patients and informed written consent was obtained for the same. Patients were kept fasting for 6 hours prior to the scheduled time of surgery. They were premedicated with tab. alprazolam 0.25mg and tab. ranitidine 150mg night before and in the morning 2 hours before surgery. Upon arrival in the operating room, all routine monitoring were established and baseline readings were recorded.

Patients were randomly allocated to one of the two groups using computer-generated sequence of random numbers as follows:

Group A (n=30): Use of Ambu Aura Gain laryngeal mask airway

Group B (n=30): Use of ProSeal laryngeal mask airway

A Standard Anaesthesia protocol was followed. Peripheral venous access was secured with 18

– gauge cannula. After arrival in the operation theatre, Baseline readings of vital parameters were recorded. After preoxygenation with 100% oxygen for 3 minutes by face mask, anaesthesia was induced with inj. Glycopyrrolate 0.005mg/kg, inj. Fentanyl 0.002mg/kg and inj. Propofol 2mg/kg. Additional increments of propofol were given if required till loss of consciousness and loss of response to verbal commands was achieved. Ability to mask ventilate the patient was judged before giving neuromuscular blocking agent. Muscle relaxation was achieved with intravenous atracurium 0.5mg/kg. Patients were ventilated for 3 minutes via facemask and anaesthetic breathing system using sevoflurane 2% and 100% oxygen.

An appropriate sized Supraglottic Airway Device was selected as per manufacturer recommendation according to weight. Prior to placement, cuff was deflated. The external surface was lubricated using water based gel. Patients were laid in supine position with head in neutral position. Patient's mouth was opened with mandible held upwards and forward. The device was introduced into the pharynx by applying gentle inward and downward pressure until a fixed resistance to forward movement was felt. The cuff was inflated according to manufacturer's recommendation. Confirmation of correct placement of the device was done by the presence of square-shaped $EtCO_2$ graph on monitor, chest auscultation and adequate chest rise with no audible leak. If the ventilation was difficult with SAD the device was repositioned, removed and reinserted. A maximum of 3 attempts were allowed, failing which an alternative method to secure patients airway was used and patient excluded from the study. Positive pressure ventilation was instituted with 60% nitrous oxide in oxygen and sevoflurane with a tidal volume of 8ml/kg. I: E ratio of 1:2 and respiratory rate of 12 /min and the muscle relaxation was maintained with intermittent boluses of atracurium. Presence or absence of oropharyngeal leaks (detected by listening over the mouth) and gastric leaks (by listening with stethoscope over the epigastrium) were checked and airway device was fixed with the help of adhesive tape.

The following data was recorded

1. Number of attempts for the airway device

In event of complete or partial airway obstruction or air leak, the device was repositioned, removed and reinserted. A maximum of 3 attempts were allowed.

2. Insertion time of Airway device

It was taken as the time from the moment of picking up the device till appearance of capnograph waveform. If no waveform was detected or seal inadequate, the device was repositioned, removed and reinserted. The time of second and third attempt was similarly recorded. Insertion time was sum of all the attempts. This did not include the time gap between attempts.

3. Oropharyngeal leak pressure

Oropharyngeal leak pressure (OLP) was determined by switching off the ventilator at the fixed gas flow of 3l/min with expiratory valve completely closed and recording the airway pressure at which equilibrium was reached.

4. Ease of placement of the device

Ease of placement was graded as:-
Easy-Placement of device in single attempt
Difficult-More than one attempt required to place the device (1-3)
Failure->3 failed attempts

5. Complications if any:

Complications such as sore throat, hoarseness of the voice and dysphagia were recorded at 1 hour and after 24 hours. Grossly visible blood on airway device as evidence of trauma was noted. Any adverse events such as bronchospasm, coughing, gagging, desaturation to $SpO_2$90% or less were noted.

At the end of the study, data was compiled and analysed using an appropriate statistical test.

STATISTICAL ANALYSIS

The data is entered in Microsoft Excel and was analyzed using SPSS software version 20. (IBM Corp. Armonk NY). The technique applied was chi-square for categorical data and student t-test / Mann Whitney for continuous data. The change over the period of time was seen by applying repeated measure analysis followed by post hoc comparison by LSD method. Besides this, an appropriate analysis was carried out at the time data analysis. Significance was seen at 5% level of significance.

Table-2: Number of attempts

Attempts	Group A		Group B	
	Frequency	%	Frequency	%
1	24	80.0%	25	83.3%
2	6	20.0%	5	16.7%
Total	30	100%	30	100%
Mean ± SD	1.20 ± 0.41		1.17 ± 0.38	

Overall success rate for placement of airway in study population as a whole was 100%. First attempt success rate was 81.5%, second attempt success rate was 19%. First attempt success rate was 80% in group A and 83.33% in group B, second attempt success rate was 20% in group A and 16.7% in group B.

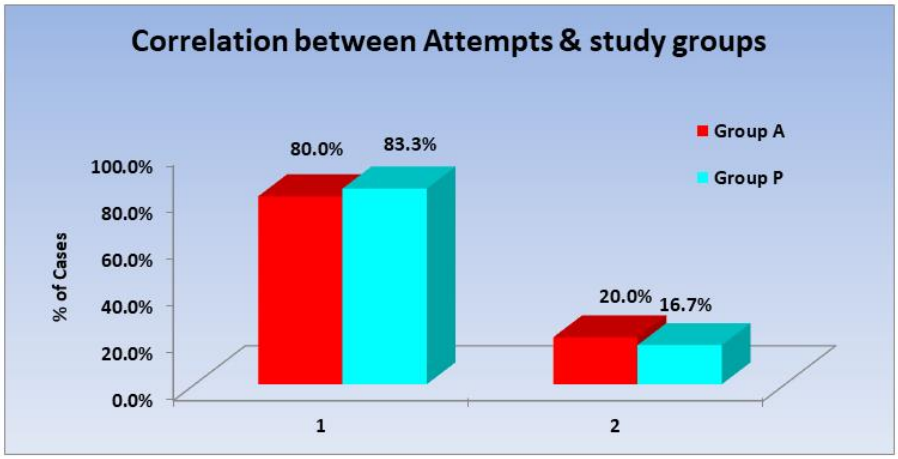
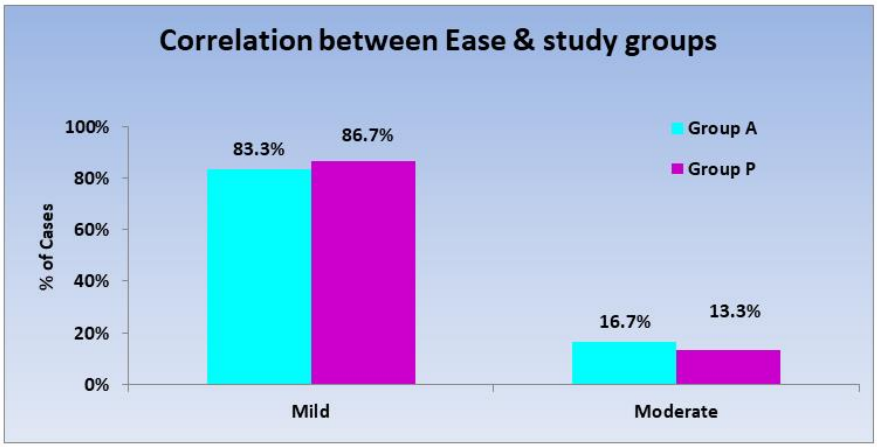


Table-3: Ease of insertion

Group A			Group B	
	Frequency	%	Frequency	%
Mild	25	83.3%	26	86.7%
Moderate	5	16.7%	4	13.3%
Total	30	100%	30	100%



There were 25 (83.3%) and 26 (86.7%) patients of Mild (1 attempt) category in Group A and B respectively. Five (16.7%) and Four (13.3%) patients in Group A and B of Moderate (1-3 attempts) category respectively.

Table 4: Trauma

Trauma	Group A		Group P	
	Frequency	%	Frequency	%
N	20	66.7%	20	66.7%
Y	10	33.3%	10	33.3%
Total	30	100%	30	100%

Trauma (Blood on SAD) was found after the procedure in 10 (33.3%) patients in both the groups.

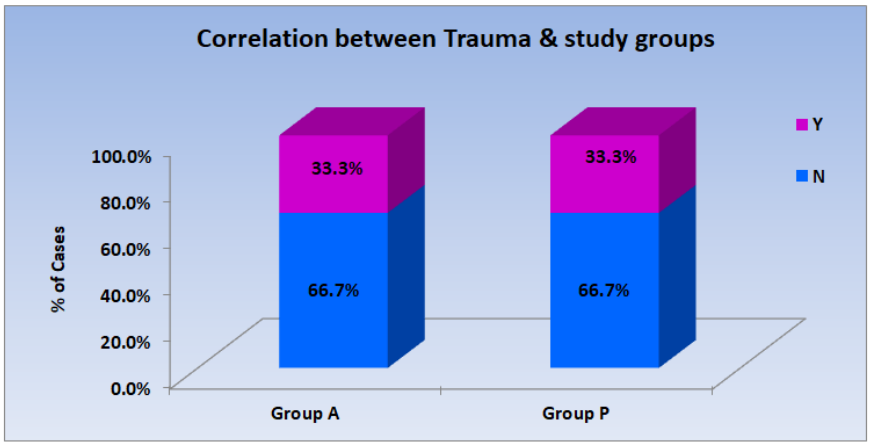
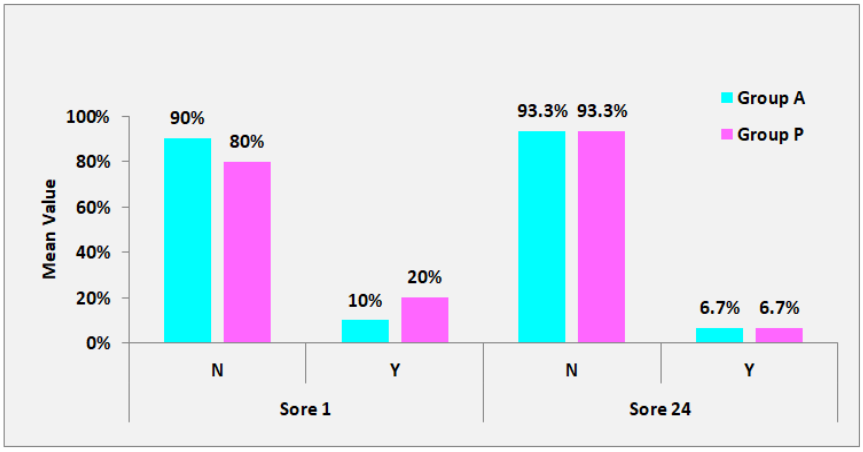


Table 5: Sore thorat

		Group A		Group P		P VALUE
		Frequency	%	Frequency	%	
Sore 1	N	27	90.0%	24	80.0%	0.472
	Y	3	10.0%	6	20.0%	
Sore 24	N	28	93.3%	28	93.3%	1.000
	Y	2	6.7%	2	7.7%	

3 (10%) and 6 (20%) patients complained of Sore Throat after 1 hour in Group A and P respectively. Two (6.7%) patients complained of Sore Throat after 24 hours in both the groups.



DISCUSSION

Airway management is one of the cornerstones of anaesthesia and supraglottic airway devices are now considered as common airway management tools. PLMA is an established airway device for use in laparoscopic surgeries. This study was undertaken to evaluate the safety profile of AAG in a clinical setting.

In Laparoscopic surgeries, the incidence of suboptimal and failed ventilation is often high with SGAs owing to the high peak airway pressures required during carboperitoneum. Second generation SGAs allow higher airway pressures due to their effective seal. In our study, we observed that the OLP of AAU was comparable to that of PLMA. A recent study reports higher OLP of AAG in comparison to LMA Supreme in patients undergoing gynaecologic laparoscopy. Another study reports similar OLP of AAG and LMA Supreme in children during controlled ventilation under general anaesthesia [3]. However, the OLP of AAG was comparable to that of other SGAs such as I-gel, PLMA and LMA Supreme as reported in some other studies. In our study, the OLP of both AAG and PLMA was higher than the peak airway pressure and was sufficient to prevent aspiration while ventilating the study patients during carboperitoneum.

1. Attempts taken for successful placement of SAD

In our study, success rate for placement of SAD in the study population as a whole was 100%. Ambu AuraGain was placed in first attempt in 24 (80%) cases, in second attempt in 6 (20%) cases and ProSeal LMA was placed in first attempt in 25(83.3%) cases, in second attempt in 5 (16.7%) cases. Overall success rate

of placement of airway in study population as a whole was 100%.

Singh *et al*., [5] conducted a prospective randomized study in 2017 involving sixty patients undergoing laparoscopic cholecystectomy under general anaesthesia, using either AAG (Group AAG [*n* = 30]) or PLMA (Group PLMA [*n* = 30]) for elective ventilation. They reported successful placement of SAD in 18(60%) patients in group A and 24 (80%) patients in group B on first attempt, with an overall success rate of 100%.

2. Time taken for insertion

In our study, time from picking up the device to obtaining effective ventilation as confirmed by end tidal CO_2 tracing on the monitor was recorded as the time taken for insertion. However when group wise comparison was made the mean time of insertion as noted for group A and group P were 11.67±3.77 and 11.40±3.14 sec respectively. When compared statistically using student t-test, the two groups were comparable with respect to the time taken for insertion of SAD (p-value= 0.767).

Jagannathan *et al*., [4] conducted a randomized trial in 2012comparing the size-2 LMA Supreme with the LMA Pro Seal in 60 children undergoing surgery. There were no statistically significant differences between the LMA Supreme and LMA Pro Seal in median (IQR [range]) insertion time (12 (10–15 [7–18]) s vs 12 (10–13 [8–25]) s; p = 0.90).

3. Oropharyngeal Seal Pressure

In our study, group wise comparison was made the mean oropharyngeal seal pressure measured through the SAD was 29.73 ± 2.77 cm H_2O in group A and 28.17 ± 3.45 cm H_2O for group P. When compared statistically using student t-test, the two groups were comparable with respect to the oropharyngeal seal pressure of SAD (p-value=0.057).

Jagannathan *et al*., [4] conducted a randomized trial in 2012comparing the size-2 LMA Supreme with the LMA ProSeal in 60 children undergoing surgery , and found airway leak pressures (19 (16–21 [12–30]) cmH2O vs 18 (16–24 [10–34]) cmH2O; p = 0.55). Lopez *et al*., [6] conducted a study in 2016 to compare the seal pressure achieved by the new Ambu AuraGain versus LMA Supreme in patients undergoing gynaecologic laparoscopic surgeries, The Aura Gain achieved higher seal pressures (34 ± 5 in Aura Gain vs. 29 ± 5 in LMA Supreme; p = 0.0002).

4. Airway morbidity

Blood on SAD

In our study, blood on SAD was present in 10 cases (33.3%) in both the groups A and P, study population as a whole. This result was on a higher side as compared to other studies which could be due to the difference in technique and manouvers employed, demographic profile and clinical profile of study population and experience of anaesthesiologist

Sore throat and hoarseness of voice

Sore throat was present in 3 (10%) patients in group A and 6(20%) patients in group P. When compared statistically using chi square test, the two groups were comparable with respect to incidence of sore throat (p = 0.472). No case of hoarseness of voice was reported in our study.

Although the difference in incidence of sore throat was statistically insignificant between both the groups, yet group A had lesser number of cases with sore throat as compared to group P, this could be due to atraumatic character of Ambu AuraGain.

CONCLUSION

Ambu AuraGain provides adequate sealing pressures and effective ventilation, hence, it may be considered for use in clinical practice. Both Ambu AuraGain and Pro Seal LMA are easy to insert and can be used effectively as SAD for laparoscopic surgeries under general anaesthesia. However, further studies are required to assess how this device compares to other widely utilised SGAs.

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