



Original Research Article

Evaluation of performance of Ambu® AuraGain™ and Laryngeal Mask Airway® Supreme™ in adult patients for elective surgeries under general anaesthesia: A randomized prospective comparative study

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ABSTRACT

Context: Second generation supraglottic airway devices (SAD) are gaining importance due to their better seal pressure. Recently introduced Ambu® AuraGain™ (AAG) and LMA® Supreme™ (LMAS) needs evaluation regarding their safety and efficacy.

Aims: Evaluation of AAG and LMAS in terms of Oropharyngeal Leak Pressure (OLP) and performance characteristics.

Settings and Design: A randomised prospective comparative study done in JSS Medical College and Hospital, Mysuru, Karnataka, India.

Materials and Methods: 140 adult patients posted for elective surgeries requiring general anaesthesia were randomised into two groups. SAD was inserted using standardized techniques and evaluated for OLP as primary objective.

Statistical analysis used: The data analysed using SPSS software version 22 and descriptive statistics were expressed as mean ± standard deviation (SD), percentage. Kruskal-Wallis rank sum tests were used for quantitative data analysis, $p < 0.05$ was considered significant.

Results: 138 patients (AAG = 68; LMAS = 70) completed the study. There was significant difference noted between the OLP of AAG 33.59 ± 3.65 cmH₂O and LMAS 29.67 ± 3.28 cmH₂O (p value 0.001). LMAS had first attempt insertion success rate of 87% (61/70) as against 80% (56/70) in AAG, but was statistically insignificant (p value 0.549). Mean time for insertion of LMAS was 18.94 ± 5.2 seconds and AAG 20.11 ± 4.9 seconds, (p value = 0.18). The ease of insertion of SAD, gastric tube insertion through the SAD and post-operative complications were comparable between the groups.

Conclusion: Ambu® AuraGain™ was found to have a higher OLP in sustaining positive pressure ventilation, airway protection against aspiration in patients undergoing general anaesthesia.

Key message: Oropharyngeal leak pressure is better with Ambu® AuraGain™ compared to LMA® Supreme™ while other performance characteristics of both the devices are comparable.

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1. Introduction

The Laryngeal Mask Airway® Supreme™ (LMAS) and Ambu® AuraGain™ (AAG) are similar newer second generation SADs (Figure 1) wherein both are of single use, have inflatable cuff and a preformed bend that is anatomically curved for rapid insertion.^{1,2} According to

the manufacturer's declaration, AAG provides a sealing pressure of maximum of 40cmH₂O.¹ But in various studies, OLP has been found to be 34 ± 5 cmH₂O³, 24 ± 4 cmH₂O⁴, and 26.4 ± 2.8 cmH₂O⁵. LMAS provides OLP varying from 21.6 ± 3.4 cmH₂O⁶ to 29 cmH₂O³. In view of such variations in OLP and very limited studies available comparing them, the present study was conducted to evaluate OLP and performance characteristics.

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2. Materials and Methods

Following approval from the Institutional Ethical Committee, informed consent were taken from 140 adult patients belonging to age group of 18 – 60years, American Society of Anaesthesiologists physical status class I - II posted for elective surgeries under general anaesthesia with expected duration surgeries less than 2 hours at J.S.S. Medical College and Hospital, JSS Academy of Higher Education and Research, Mysuru. Obesity (body mass index $\geq 30\text{kg/m}^2$), pregnancy, known or predicted difficult airway, high risk for pulmonary aspiration (nonfasted, gastroesophageal reflux disease), upper respiratory tract infection in the last 10 days, non-supine position, head and neck surgeries were excluded from the study.

They were divided into two groups by simple random sampling using sealed opaque envelopes namely, group 'AAG' for Ambu Aura Gain and 'LMAS' for LMA Supreme. All the patients received tablet alprazolam 0.5mg and tablet pantoprazole 40mg on the previous night of the surgery.

Standard general anaesthetic care was given for all the patients on the day of the surgery. Monitoring included electrocardiogram (ECG), heart rate (HR), non-invasive blood pressure (NIBP), oxygen saturation (SPO₂). Additional end-tidal carbon-dioxide monitoring was done post induction.

Premedication was done with intravenous (i.v.) injection (inj.) of midazolam 0.02 mg/kg, inj. fentanyl 1 $\mu\text{g/kg}$ and iv fluid infusion with Ringer's lactate was initiated at 4 ml/kg/hr. Preoxygenation was done with 100% oxygen (O₂) for 3 minutes using closed circuit of Drager Fabius Plus anaesthesia workstation. Inj. lidocaine 1.5mg/kg was given, anaesthesia was induced with inj. propofol 2 mg/kg and after confirming adequacy of ventilation, inj. vecuronium bromide 0.1 mg/kg for muscle relaxation was administered.

A well lubricated Ambu AuraGain and LMA Supreme (according manufacturers' recommendations of weight estimate: size 3 for 30–50 kg and size 4 for 50–70 kg^{1,2} was placed once complete jaw relaxation was achieved. The cuff was then inflated with air to attain a cuff pressure of 60 cmH₂O as measured with a cuff pressure manometer. Further, the maintenance of anaesthesia was done with 70% Nitrous oxide and 30% oxygen and 1% isoflurane.

The appearance of the six same size square end-tidal carbon dioxide (ETCO₂) trace was considered as successful establishment of effective ventilation.

Ease of insertion of SAD was defined subjectively on a 4-point scale as 1- No resistance, 2- Moderate resistance, 3- High resistance, 4- inability to place the device. The time for successful insertion of the device was considered from the time when SAD is picked up in the hand until bilateral chest rise with the first capnogram upstroke is seen.

The SAD placement was considered inadequate, if poor capnographic curve and/or delivery of inadequate tidal

volumes (fractional loss of >20% of set tidal volume); then jaw thrust was performed and the device position was readjusted. Again the tidal volume being delivered and ETCO₂ was checked. If inadequate, then the device was completely removed for another insertion attempt. Maximum three insertion attempts were tried.

Each 'attempt' is defined as reinsertion of the airway device into the mouth. 'Insertion failure' was considered if greater than three failed attempts were noted. In case of failure of either device, the airway was secured with endotracheal intubation.

OLP was measured by closing the expiratory valve of the breathing circuit, delivering oxygen flow of 6L/min and noting the equilibrium airway pressure until the seal pressure is achieved, that is audible leak heard over the side of the neck lateral to the thyroid cartilage with the bell of the stethoscope.³

A well lubricated 14 french, gastric tube was introduced through the gastric port. Confirmation was through the detection of injected air by auscultation over the epigastrium, and aspiration of gastric contents. The time for successful gastric tube placement was noted. Ease of insertion of gastric tube through the gastric port was assessed subjectively on a 3-point scale as 1 = passed easily, 2 = passed with difficulty, 3 = impossible to pass.

Intraoperative oxygen desaturation (SpO₂ < 90%) and regurgitation, aspiration was noted.

At the end of the surgery, neuromuscular blockade was reversed with neostigmine 0.05mg/kg and glycopyrrolate 0.01mg/kg and SAD was removed. Presence or absence of blood stain on removal of SADs and presence of post-operative sore throat, dysphonia or dysphagia as nil, mild, moderate or severe was documented.

2.1. Statistical analysis

Primary objective was to compare the OLP. Taking a difference of 10 cmH₂O pressure between Ambu[®] AuraGain[™] and LMA[®] Supreme[™] based on manufacturers' declaration^{1,2} and previous studies⁴⁻⁷ and considering a 80% power, a significance level alpha of 0.05, sample size was found to be 63 in each group.⁸ The sample size was fixed to 70 in each group considering dropouts.

The data were recorded intra-operatively using a prestructured and pretested data collection sheet. Then it was analysed using SPSS software version 22 and interpreted as comparative statistics in the form of mean \pm standard deviation (SD), percentage. Then Kruskal-Wallis rank sum tests, Anova test, were used for the analysis of the quantitative data and Fisher's Exact Test for qualitative data analysis. Value of $p < 0.05$ was considered significant in this study.

3. Results

In the present study, out of the 140 patients considered, SADs were successfully inserted in 138 patients and in 2 patients airway was secured with endotracheal tube as SAD insertion exceeded maximum of 3 attempts. (Figure 2) Hence the statistical analysis was done for 138 patients. (Table 1)



Fig. 1: LMA supreme™ and Ambu® AuraGain™

It was observed that both SADs are effective in ventilation with good seal pressures, but Ambu AuraGain [33.59 ± 3.65 cmH₂O] showed a higher seal pressures of 3.92 cmH₂O than the LMA Supreme [29.67 ± 3.28 cmH₂O] with a statistically highly significant p value 0.001. (Table 2)

It was noted that LMAS group had first attempt insertion success rate of 87% (61/70) as against 80% (56/70) in AAG group, but overall insertion attempt success rate was not statistically significant (p value 0.549). The ease of insertion of SAD was comparable in both the groups (p value 0.479), even though LMAS was placed more easily without resistance in 62% (44/70) of cases as compared to 51% (36/70) in AAG group. Mean time for insertion of LMAS was 18.94 ± 5.2 seconds when compared with AAG 20.11 ± 4.9 seconds, (p value = 0.18). The ease of insertion of gastric tube through the SAD was comparable in both the groups (p value 0.233). There were no intra-operative complications noted. Further post-operative complications like sore throat and dysphagia were minimal with no statistical significance (p value 0.493 and 1.000 respectively) between both the groups.

4. Discussion

Second generation supraglottic airway devices are gaining importance among the anaesthesiologists for both elective cases and for difficult airway management. This is due to their better seal pressure and their effectiveness in protecting airway from the risk of aspiration of gastric contents.^{9–13} In

the present study, the performance of Ambu® AuraGain™ and Laryngeal Mask Airway® Supreme™ as airway devices are compared among the adult patients undergoing elective surgeries under General Anaesthesia.

OLP is the airway pressure at which a gas leak occurs around the device. A better OLP indicates better airway protection, successful SAD placement, and positive pressure ventilation, ultimately airway safety.^{11,13}

In the present study, it was observed that both SADs are effective in ventilation with good OLP, but Ambu® AuraGain™ showed a higher seal pressure than the LMA® Supreme™. The proximal bowl of AAG is larger, allowing for a better fit to the peri-laryngeal structures, thus giving a better seal. Similar results of OLP 34 ± 5 cm H₂O in AAG and 29 ± 5 cm H₂O in LMAS (p = 0.0012) were noted by Lopez A M et al. in 60 female patients posted for laparoscopic gynaecological surgeries under general anaesthesia.⁴ Further, a study conducted by Wong D T et al. involving 170 patients who were anaesthetized and maintained on spontaneous ventilation with desflurane in air and oxygen without use of muscle relaxant, concluded that AAG had a better OLP when compared with LMAS [26.4 (2.8) cmH₂O vs 21.6 (3.4) cmH₂O] with p value < 0.0015.⁶ However, Shariffuddin et al. found the OLP of 24.1 ± 7.4 cmH₂O in AAG group and 23.6 ± 6.2 cmH₂O in LMAS group (P=0.720) in their 100 patients. This difference in lower OLP compared to other studies was attributed to the smaller build and smaller mouth opening of Asian population involved in their study.⁵ Jagannathan N et al. did a study on AAG and LMAS on 100 children (3 months- 6yrs), and they concluded that there was no significant difference between both the SADs.⁷ Lopez and his colleagues in a recent cadaveric study concluded that AuraGain produced better results in terms of OLP when compared with i-gel and LMAS but it was less pliable and was comparatively difficult to insert as it did not bend easily after contacting the posterior pharyngeal wall.¹⁴ The number of attempts required for insertion of SADs in both the groups was comparable. It was noted that AAG group had first attempt insertion success rate of 80% (56/70) as against 87% (61/70) in LMAS group. However, insertion of AAG was not possible in two patients even after 3 attempts, finally requiring endotracheal intubation to secure their airway. Lopez and his colleagues found no difference in the number of attempts required for successful insertion of both the devices (p=0.2)⁴ In a similar study conducted by Shariffuddin et al. first attempt success rate for AAG was 86% (43/50) while it was 78% (39/50) for LMAS group with a p value of 0.906.⁵ Wong D T et al. found that first pass success was significantly lower for AAG than LMAS (77% vs 94%; p = 0.01), however, it was difficult to successfully place AAG in 3 patients even after three attempts of insertion.⁶ This difficulty in insertion of AAG could be due to the bulky shaft and the wide bowl of

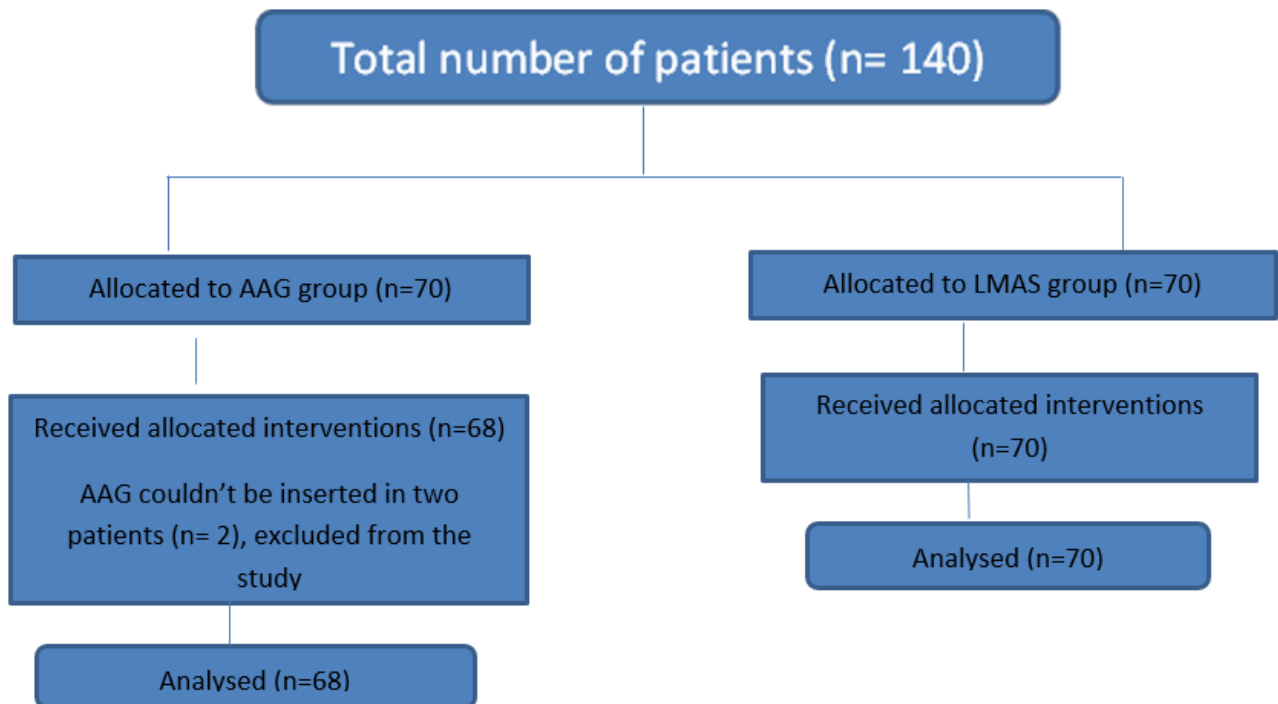


Fig. 2: Consort diagram

Table 1: Patient characteristics

		AAG		LMAS		p value
Age (years)		34.6±12.39		36.8±13.57		0.389
Sex	Male	29 (42.6%)		30 (42.8%)		1
	Female	39 (57.4%)		40 (57.2%)		
BMI	Mean	24.11±2.95		23.63±3.1		0.267
ASA Physical Status	GRADE 1	N 57	% 83.82	N 50	% 71.43	0.103
	GRADE 2	N 11	% 16.18	N 20	% 28.57	
Types of Surgery (N)	Excision of lipoma, fibroadenoma	7		7		
	Hernioplasty	1		0		
	Laparoscopic Appendicectomy	26		31		
	Laparoscopic Cholecystectomy	33		32		
	Laparoscopic Orchidectomy	1		0		
Duration of surgery (min)		53±14		60±20		
Duration of anaesthesia (min)		68±15		76±20		

the AAG compared to that of LMAS and the same was confirmed in a study conducted on cadavers.¹⁴

The ease of insertion of SAD, subjectively on a 4-point scale was comparable in both the groups. Though clinically LMAS was placed more easily (1- point) when compared to AAG group, the overall ease of insertion was not statistically significant among both the groups. Further, it was observed that time required for successful insertion of AAG was almost similar to insertion of LMAS. Similarly, Jagannathan

N et al. found that there was no significant difference in ease of insertion between these devices.⁷ However, Shariffuddin et al. inferred that in 48% (24/50) of patients, AAG could be inserted easily while it was 74% (37/50) among LMAS group (p value 0.013) with 33.4±10.9 seconds for the insertion of AAG and 27.34±11.4 seconds for LMAS (p value 0.010). They required longer time for insertion of SADs as they inserted SADs in spontaneously breathing patients.⁵ In a study conducted by Wong D T et al. AAG

Table 2: Clinical performance of AAG and LMAS

	AAG (n=68)	LMAS (n=70)	p value
Time for successful insertion of SAD (seconds)	20.11±4.94	18±5.28	0.180
Ease of insertion of SAD			
No resistance	36 (51.4%)	44 (62.8%)	0.479
Moderate resistance	27 (38.5%)	(31.4%)	
High resistance	5 (7.1%)	4 (5.7%)	
Inability to place device	2 (2.8%)	0	
Number of attempts for insertion of SAD			
First attempt	56 (80%)	61 (81%)	0.549
Second attempt	11 (15.7%)	9 (19%)	
Third attempt	1 (1.4%)	-	
Couldn't be placed	2 (2.8%)	-	
OLP of SAD	33.59 ± 3.65 cmH2O	29.67 ± 3.28 cmH2O	0.001
Ease of insertion of gastric tube			
Passed easily	55 (80.8%)	50 (71%)	0.233
Passed with difficulty	13 (19.2%)	20 (29%)	
Impossible to pass	0	0	
Time for successful insertion of gastric tube through SAD (seconds)	16.62±4.46	19±3.89	0.001
Intra-operative complications like desaturation/ regurgitation, aspiration	-	-	
Blood stained removal of SAD			
Yes	22 (32.4%)	26 (37%)	0.594
No	46 (67.6%)	44 (63%)	

was placed with no difficulty in 48% (39/81) patients, while LMAS could be placed with no difficulty in 92%(77/84) patients which could be due to the prominent size of the cuff of AAG.⁶ (Table 2)

The ease of insertion of gastric tube through gastric port in SAD was comparable in both the groups. In about 55/68 (80%) cases gastric tube was placed easily through AAG while 50/70 (71%) in LMAS group (p value 0.233). Gastric tube could be easily placed through AAG when compared with LMAS. The gastric drain port is placed laterally (at a 20 degree angle from the midline) in AAG; hence, the insertion of a large bore gastric tube into the oesophagus required less time when compared to LMAS.

Among the study groups considered, there were no significant hemodynamic changes noted during or after the introduction of SAD.

There were no cases of intraoperative complications like oxygen desaturation (SpO₂ < 90%) and regurgitation/aspiration noted in the study. However, Shariffuddin and her colleagues have documented 2 cases (4%) of desaturation while inserting AAG, while no such problem was noted in LMAS.⁵ Jagannathan and his colleagues have documented one case of partial upper airway obstruction when using AAG while study group with LMAS was uneventful.⁷

Blood staining on SAD after its removal was noted in 32% (22/68) cases among AAG group, 37% (26/70) cases in LMAS group (p value of 0.594). This could be due to the

pressure against the surrounding structures in peri-laryngeal region probably arytenoids. Wong D T et al. found blood stained removal of SAD among 15% cases in AAG group while it was 7% cases among LMAS group (p value 0.11).⁶

Table 3: Post-operative complications

	AAG	LMAS	p value
Sore throat			
Nil	42 (61.4%)	39 (55.7%)	0.493
Mild	26 (38.6%)	31(44.3%)	
Moderate	-	-	
Severe	-	-	
Dysphagia			
Nil	66 (97%)	67 (95.7%)	1.000
Mild	2 (3%)	3 (4.3%)	
Moderate	-	-	
Severe	-	-	
Dysphonia			
Nil	-	-	-
Mild	-	-	
Moderate	-	-	
Severe	-	-	

Among the study groups, there were 38.6% (26/68) of cases with mild sore throat in AAG and 44.3% (31/70) in LMAS (p value 0.493). Further, there were 3% (2/68) of cases with mild dysphagia among AAG and 4.2% (3/70) of cases with mild dysphagia in LMAS group (Table 3). No case of dysphonia was noted in any patient.

These complications could be due to the pressure over the surrounding structures in peri-laryngeal area. And they self-resolved within few hours. Shariffuddin and her colleagues in their study concluded that there were 10% cases (5/50) of sore throat, 2% (1/50) cases of dysphonia and 6%(3/50) cases of dysphagia in AAG group while LMAS had 38% cases (19/50) of sore throat, 6%(3/50) cases of dysphonia, and 10% (5/50) cases of dysphagia.⁵

There were few limitations in the present study. To know about the safety and efficacy of these SADs in positive pressure ventilation and laparoscopic surgeries, a larger group study has to be done. The cuff pressure was standardized to 60 cm H₂O, but the pharyngeal mucosal pressure at this cuff pressure was not assessed. Only patients with normal airway was considered; hence their usage in difficult airway patients has to be further evaluated. In this study, the fibre-optic view of larynx was not evaluated to confirm about the correct placement of the SADs. This was due to lack of availability of pediatric fibreoptic bronchoscope required to negotiate through LMAS.

From this study, it can be concluded that AAG has a better OLP compared to LMAS, thus providing a higher margin of safety against the risk of aspiration; while other performance characteristics were not significantly different between both the groups.

5. Source of Funding

None.

6. Conflict of Interest

The authors declare that there is no conflict of interest.

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