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Original Research Article

Clinical Performance of Laryngeal Mask Airway Supreme versus Ambu Auragain in Patients Breathing Spontaneously under General Anaesthesia

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Abstract:

Background/Objective: The objective is to assess and compare the effectiveness of Ambu Aura Gain (AAG) and Laryngeal Mask Airway Supreme (LMAS) in adult patients undergoing surgery under general anesthesia.

Methodology: A total of 100 patients between 18 to 80 years of age, of either gender, American Society of Anaesthesiologists [ASA] grade I or II and Mallampatti grade I or II were selected, categorized as Group A: Patients subjected to LMAS Group B: Patients subjected AAG. The study included patients scheduled for elective short duration surgical procedures (~2hrs), under general anesthesia. The ease of insertion, blood on the SGAD during removal, hemodynamic changes, oropharyngeal leak pressure and the functionality of gastric drain, sore throat were evaluated.

Results: The hemodynamic parameters, device failure rate, and presence of blood following removal were similar between the two groups. LMAS, was significantly easier to insert ($p = 0.031$). Furthermore, compared to LMAS, AAG had a greater success rate for accurate insertion on the first try (92%Vs88%) and considerably superior functioning of gastric drain ($p = 0.027$), as well as a decreased incidence of sore throat (12% vs 28%; $p = 0.046$).

Conclusion: AAG may be a more suitable compared to LMAS for surgery under general anesthesia the ease of insertion was significantly higher for LMAS. However, AAG had higher success rate for correct placement in first attempt, significantly better gastric drain functionality with lower sore throat complication and relatively better oropharyngeal leak pressure, thus providing a higher margin of safety against the risk of aspiration.

Keywords: Ambu Auragain, laryngeal mask airway supreme, ease of insertion, time of insertion, oropharyngeal leak pressure, hemodynamic.

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Introduction

Dr. Archie Brain, a British anesthesiologist, introduced the laryngeal mask airway for the first time. The device was designed to be positioned around the laryngeal inlet, with the aim of reducing the complications associated with tracheal intubation and making it easier to place [1]. The benefits of using the laryngeal mask airway include its ease and speed of placement by anesthetists, better hemodynamic stability during induction and emergence, minimal increase in intraocular and intracranial pressure, reduced incidence of coughing during emergence, and lower incidence of sore throat in adult patients [2].

The majority of the first-generation supraglottic airway devices experience an air leak when positive pressure ventilation (PPV) is delivered at a pressure of 16-20 cm H_2O. This can increase the risk of aspiration during ventilation, making it difficult to control. However, second-generation devices have been developed to address this issue and are capable of maintaining a seal in the pharynx even at high pressures of 25-30 cm H_2O, making them more suitable for laparoscopic surgery where intra-abdominal pressure is necessarily elevated [3]. Ambu Aura Gain (AAG) and LMA Supreme are second generation SADs which are being used for airway management in patients undergoing surgeries under general anesthesia.

The AAG is a second-generation airway device that features a curved design to follow the human airway and a wider tube for an intubation. The device is single used SAD and is made up from polyvinyl chloride (PVC). The airway tube of AAG has a 90° angle bend which mimics the curvature of the oropharyngeal cavity of the human body. It provides a high seal pressure it features a flexible videoscope that is designed to guide the use of a standard endotracheal

tube with a direct intubation capacity. It also comes with an integrated gastric access port. The device offers several advantages rapid placement high seal pressure, gastric content management and intubation capability.

With the advent of newer technologies, second-generation airway devices were developed and LMAS came into use in 2007. LMA Supreme is a modified version of LMA proseal. It is also a single-use device. The material is latex-free, medical-grade PVC laryngeal mask airway. The design of LMAS is such that it reduces the risk of gastric insufflation during ventilation, provide a passive conduit for unexpected regurgitation, and allow active suctioning of gastric contents. LMAS consists of a performed curved shaft which consists of a double lumen to separate digestive and respiratory tract. The solid, elliptical, and anatomically formed airway tube with a 90º angle allows for simple insertion [5-7]. A central lumen which has an access to digestive tract that is encased within a flattened oval- shaped airway lumen for access to the respiratory tract, a built-in bite block which helps in prevention of airway obstruction, a fully- deflated cuff, a gastric access tube.

The LMA-Supreme, which was first used in clinical settings in 2013, a second seal was developed by LMA Teleflex in Athlone, Co Westmeath, Ireland. This design is intended to decrease the likelihood of excessive air entering the stomach during ventilation, provide a route for unexpected regurgitation, and permit the suctioning of stomach contents when necessary [4].

The present study primary objective is to clinically differentiate the performance of LMA Supreme and AAG with respect to ease of placement, hemodynamic changes, Oropharyngeal seal pressure and gastric drain functionality in spontaneously ventilated patients for short duration however, modest variations in seal pressure favoring the AAG or ease of insertion favoring the LMA Supreme have been shown [8-10].

Materials and Methods

This study was conducted over a span of two years at the Department of Anesthesiology, Maharishi Markendeshwar Institute of Medical Science and Research in Mullana, Ambala. Prior to the commencement of the study, ethical clearance was obtained, and informed consent was obtained from all 100 patients, ASA grade I and II, and scheduled for surgery under general anesthesia (~2hrs). The patients were kept blind of the group to which they were assigned, and the size of the supraglottic device (SGD) used was based on the manufacturer's instructions.

All patients underwent a thorough pre-operative evaluation, and once they were deemed suitable for the procedure, they were administered a tablet of esomeprazole (40mg) and metoclopramide (10mg) the night before the surgery and on the morning of the surgery, with a sip of water. Moreover, the patients were instructed to fast from solid foods for six hours before the procedure.

During surgery, the patients were in supine position on the operating table with a headrest underneath their head, and ASA standards of monitors were connected and baseline hemodynamic parameters were noted before administering anesthesia. This included pulse oximetry, non-invasive blood pressure monitoring, and a 3-lead electrocardiogram [ECG]. Before inducing anesthesia, the patients were preoxygenated with 100% oxygen for 3 minutes. The induction of anesthesia was achieved by administering Inj. fentanyl at a dose of 1-2mg/kg and Inj. propofol at a dose of 2-3mg/kg until the patients were no longer able to respond verbally.

The AAG and LMAS were adequately lubricated and prepared according to the instructions provided by the manufacturer. After achieving adequate relaxation of the jaw, the head was positioned neutrally, and the LMA was inserted. The cuff of the LMA was inflated with air to attain a pressure of 60cmH_2O. To achieve this pressure, the device was initially inflated using 25ml of air and then adjusted by using a handheld manometer, either increasing or decreasing the amount of air as needed.

To ensure proper ventilation, the adequacy of chest rise during manual ventilation with a breathing bag and $EtCO_2$ graphs were evaluated. If the $EtCO_2$ graph did not appear properly or if chest rise was not sufficient, the SGDs were removed entirely, and up to three attempts were made to reinsert them.

After inserting the SGDs, it was properly secured in place, and lignocaine gel was applied to the opening of the gastric drain outlet. The correct positioning was confirmed by performing the suprasternal notch test. The pressure control valve was then closed, and 3 L/ min of fresh gas flow was maintained. The OLP was measured, and once equilibrium was reached, the airway pressure was noted and checked for any audible leaks from the SGDs. To confirm the entry of air into the stomach, epigastric auscultation was performed.

A 16 French gastric tube that was pre-lubricated was inserted through the gastric drain outlet of both devices. The duration of the tube insertion was recorded. The correct positioning of the tube was confirmed by detecting injected air over the epigastric region through auscultation and aspiration of gastric contents. To maintain anesthesia, a combination of isoflurane and nitrous oxide was administered with a minimal alveolar concentration of 1-1.2 in a 50:50 N_2O-O_2 mixture. Following the completion of the procedure, the gastric tube was removed, and the LMA was removed with partial deflation once the patient regained motor response and opened their

eyes. The patient was then transferred to the recovery room. The device was inspected for any presence of blood post-removal. An independent anesthesiologist, who was blinded to the procedure, re-examined all patients for the presence of any post-operative sore throat after one hour. Each device insertion was documented in terms of ease of insertion judged by the number of insertion attempts, time taken to reach effective ventilation, number of supplementary manoeuvres required like jaw thrust, adjusting head and neck positioning, depth of insertion, and changing device number and incidence of 'failure insertion'. The ease of LMA insertion was assessed on a 5-point scale, with 1 indicating simple insertion and 5 indicating difficult insertion.

The cardiovascular response, including heart rate, systolic and diastolic blood pressure, SpO_2, and $EtCO_2$, was monitored every two minutes for duration of 10 minutes from the insertion of the device, and documented. Additionally, the OLP was measured at 40 minutes after insertion and 10 minutes before the device's removal. The time taken for the insertion of the gastric drain and its functionality were also recorded. Any complications that occurred during or after the procedure were also documented.

Inclusion Criteria: ASA Grade I and II consenting patients of either gender aged between 18-80 years, scheduled, Patients undergoing surgeries elective surgery of less than 2 hrs under general anaesthesia were included in the study.

Exclusion Criteria: ASA Grade III and IV consenting patients, obese patients with BMI > 40 kg/m2, non-fasting, high likelihood of regurgitation or aspiration, as well as nausea and vomiting, pregnant patients, Patients with complain of sore throat, oral or laryngeal pathology and surgeries which take more than two hrs were excluded in the study.

Statistical Analysis: The statistical analysis was conducted using the Statistical Package for the Social Sciences [SPSS] program for Windows, version 25.0 (SPSS, Chicago, Illinois). The continuous variables were expressed as mean ± SD, and categorical variables were presented as absolute numbers and percentages. Prior to statistical analysis, data were checked for normality. For normally distributed continuous variables, the unpaired t-test was used for comparison, whereas the Mann-Whitney U test was used for variables that were not normally distributed. The chi-square test or Fisher's exact test was used to analyze categorical variables. A p-value less than 0.05 were considered significant for all statistical tests.

Results

As detailed in table-1, the mean age distribution of patients in each group: 45.92 ± 15.09 in group LMA supreme, 45.60 ± 15.72 in group AAG. When two groups were compared, the P value was insignificant. Analysis and comparison of the study groups revealed that group LMA Supreme had 50% females and 50% males, group AAG had 40% females and 60% males, LMA Supreme group had a mean weight 58.12 ± 5.15 and AAG group had 58.66 ± 5.15 there was no significant difference found among the groups. And also, ASA distribution grade and Mallampatti grade showed insignificant in our present study.

Table 1: Demographic profile of two groups

Variable		LMA Supreme	AAG	P value
Age (in years)		45.92±15.09	45.60±15.72	0.918
Weight in Kgs		58.12±5.15	58.66±5.15	0.601
Sex (F:M)		25:25	20:30	0.315
ASA grade Status	1	26 (52.0%)	30 (60.0%)	0.420
	2	24 (48.0%)	20 (40.0%)	
Mallampatti Grade	1	40 (80.0%)	35 (70.0%)	0.248
	2	10 (20.0%)	15 (30.0%)	

The table-2 below displays when the two groups were examined, there was no significant difference in the distribution of patients based on thyromental distance and ability to prognath. According to the observations, in the LMA Supreme group, 88% of the patients made only one attempt, while 12% made two attempts. In comparison, in the AAG group, 92% of the patients made only one attempt, while 8% made two attempts which were insignificant. Similarly, it was found that in both the LMA Supreme and AAG groups, 100% of the patients had a satisfactory initial airway quality.

Table 2: Various Intraoperative Parameters

Parameters		LMA Supreme	AAG	p-value
Thyromental distance	<6.5	16(32.0%)	15(30.0%)	0.829
	>6.5	34(68.0%)	35(70.0%)	
Ability of prognath	No	10(20.0%)	9(18.0%)	0.799
	Yes	40(80.0%)	41(82.0%)	
No of attempts	1	44(88.0%)	46(92.0%)	0.741
	2	6(12.0%)	4(8%)	
Quality of initial airway	Good	50(100%)	50(100%)	-

Table 3: Comparison of Groups Based on Insertion Ease

Ease of insertion	LMA Supreme		AAG		p-Value
	Frequency	%	Frequency	%	
Easy	49	98.0%	42	84.0%	
Difficult	1	2.0%	8	16.0%	0.031*
Total	50%	100.0%	50	100.0%	

*Signifies significant p value<0.05

Upon examining the study groups, we deduce from table-3 that the study revealed that within the LMA Supreme group, 98% of patients had no trouble with insertion, while only 2% experienced difficulty. On the other hand, in the AAG group, 84% had an easy insertion, whereas 16% faced difficulty. Additionally, there was a significant contrast between the two groups regarding the ease of insertion.

Table 4: Comparison of Groups according to the gastric drain functionality

Gastric drain functionality	LMA Supreme		AAG		p-Value
	Frequency	%	Frequency	%	
Success	44	88.0%	50	100.0%	
Failure	6	12.0%	0	0.0%	0.027*
Total	50%	100.0%	50	100.0%	

*Signifies significant p value<0.05

Table-4 indicates that when analyzing and comparing study groups, it was found the study compared the distribution of gastric drain functionality between two groups. In the LMA Supreme group, 88% of patients had successful gastric drain functionality, while 12% experienced failure. In contrast, all patients in the AAG group had successful gastric drain functionality. The analysis revealed a significant difference in the distribution of patients based on gastric drain functionality between the two groups.

After analyzing and comparing study groups, it was observed that in table-5, the study found that within the LMA Supreme group, 72% of patients did not experience sore throat, while 28% did. In contrast, in the AAG group, 88% of patients did not have sore throat, while 12% did. Additionally, there was a significant difference in the distribution of patients based on the presence of sore throat when comparing the two groups.

Table 5: Comparing the two groups based on the frequency of sore throat

Sore throat	LMA Supreme		AAG		p-Value
	Frequency	%	Frequency	%	
No	36	72.0%	44	88.0%	
Yes	14	28.0%	6	12.0%	0.046*
Total	50%	100.0%	50	100.0%	

*Signifies significant p value<0.05

Discussion:

The use of supraglottic airway devices, such as LMA supreme and AAG, has become increasingly popular in anesthesia practice due to their ease of insertion and lower complication rates compared to endotracheal intubation. In this study, we discussed the performance of these two devices in patients who were breathing naturally while under general anesthesia.

The study enrolled 100 adult patients who were scheduled for an elective surgery, based on the predetermined inclusion and exclusion criteria. The patients were randomly allocated into two groups, LMA supreme and AAG, with 50 patients in each group. The mean age and weight of the patients in both the LMA and AAG group patients (45.92 ± 15.09yrs vs 45.60 ± 15.72yrs and 58.12± 5.15kg vs 58.66 ± 5.15kg, respectively). And no significant statistical difference was observed. In the LMA

group, the female to male ratio was 1, while in the AAG group; the ratio was 2:3.

Similarly in the study done by Shariffuddin et al., (2017) [4], total 100 participants were included the mean age and weight of the patients in both the AAG and LMA group patients was (48.80 ± 15.90yrs vs. 44.80 ± 16.80 yrs and 62.40± 13.2kg vs. 65.50 ± 14.60 kg, respectively).

The current study assessed patients based on their ASA physical status and Mallampatti score. The AAG group had a higher number of patients with ASA grade 1 and Mallampatti grade 1 compared to the LMA group. However, patients in the LMA supreme group had more ASA grade 2 patients, while the AAG group had a higher number of patients with Mallampatti score 2.

Whereas study done by Shariffuddin et al., (2017) [4], the AAG group showed Mallampatti score from I to IV by the following way 31(6%), 14(28%), 3(6%), 2(4%). And for LMA group 31(6%), 13(26%), 5(10%),1(2%).

In the present study, a greater proportion of patients in the LMA supreme group had a thyromental distance of less than 6.5cm compared to the AAG group (32% vs 30%). Conversely, patients in the AAG group had a higher ability to prognathism compared to the LMA supreme group, but the difference was not statistically significant.

Similarly in the study done by Shariffuddin et al., (2017) [4], an equal proportion of patients in the LMA supreme group and AAG group showed thyromental distance 50% each.

We evaluated the ability to prognath in patients for airway management prediction in our study. The results showed that 80% of patients in the LMA group and 82% in the AAG group were able to prognath. However, we did not find a significant correlation between the two groups. According to the study done by Shariffuddin et al., (2017) [4], results showed that 84% of patients in the LMA group and 82% in the AAG group were able to prognath. Our study revealed that correct placement of the AAG was achieved on the first attempt in 92% of patients and in 8% of patients it took two attempts. In contrast, the LMA was inserted successfully on the first attempt in 88% of patients and in 12% of patients it took two attempts. In a similar study, Shariffuddin et al., (2017) [4] found slightly higher first attempt placement rates for AuraGain compared to LMA supreme 86% vs. 78%. Lopez et al., (2017) [11] reported a 100% first attempt insertion success rate for AAG, while it was 97% in the LMA group. However, Yahaya et al., (2016) [12], Wong et al., (2018) [13] and Kriege et al., (2016) [14] observed a higher success rate for first attempt insertion in the LMAS group compared to the AAG group (87% vs. 80%; 88% vs. 86%; 94% vs. 77%; 80% vs. 72%).

We also assessed the ease of insertion for the two SGDs. Our results showed that the LMA was inserted "with ease" in 98% of patients compared to 84% of patients in the AAG group. Moreover, we found a significant difference between the two groups with regard to the ease of insertion. These findings are consistent with the results of Shariffuddin et al., (2017) [4] and Wong et al., (2018) [13] who reported significantly higher ease of insertion for the LMA compared to the AAG in their studies.

We also measured the hemodynamic changes at different time points between the two groups in our study. However, we did not find any statistically significant difference between the groups with respect to HR, systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean blood pressure (MBP) before induction, at the time of insertion, 2 minutes after insertion, 5 minutes after insertion, and after removal. And also, blood oxygen level and End tidal Co_2 [$EtCo_2$] showed statistically insignificant difference.

The hemodynamic parameters such as pulse, SBP, and DBP found no significant statistical differences between the groups according to the study done by Mehta et al., (2022) [3].

Almost all studies, including Anand et al., (2016) [15], indicated that hemodynamic and ventilator parameters in both groups are comparable.

Our study found a statistically significant difference between the two groups. The AAG had a 100% success rate, whereas the LMA Supreme showed only 88% success for gastric drain functions. According to Shariffuddin et al., (2017) [4], the AuraGain made it simpler and more successful to pass the stomach drain tube than the LMA Supreme, with a success rate of 100% against 90.9%.

At 1min and 10min, we found that AAG had slightly greater OLP than LMA supreme, although the difference was not statistically significant (21.72 ± 0.90 vs. 21.42 0.79). In Lai et al., (2021) [17] did research to examine the effectiveness of several SADs. They included 108 papers (n= 10,645) that compared 17 different forms of SADs. When compared to a classic LMA (C-LMA), all second generation SADs exhibited considerably larger OLP (mean difference ranging from 3.98 to 9.18 cmH_2O).

In our study, we found that the AAG achieved a slightly but significantly higher airway seal pressure (32 cm of water versus 26 cm of water) compared to the LMA Supreme. This difference in seal pressure could be due to the larger cuff of the LMA. Other studies have also reported similar findings. For instance, Joshi et al., (2018) [16] found that the AAG provides a significantly better seal pressure than the LMA Proseal. Wong et al., (2018) [13] observed that the LMA was inserted using a standard technique with the cuff inflated to 60 cm H2O, which is higher

than the cuff pressure used in our study. In another study done by Michalek et al., (2010) [18] greater seal pressure in patients who used AAG masks against LMA supreme masks (-33.3 vs - 30.7 cm H_2O). The insertion success rate of both devices was equal and high. However, the success percentage of insertion on the first try was greater in LMA supreme (17.6 vs 20.1 seconds). The fibreoptic score of the AAG group was higher. The oropharyngeal seal pressure in the AAG group was greater than in the LMA supreme group. All of these characteristics of AAG make it ideal for use in laparoscopy, obsessive patients, and difficult intubation.

Also, no blood staining was seen in patients while eliminating LMA or AAG. Wong et al., (2018) [13], on the other hand, observed contradictory findings.

While utilising SGDs, a few difficulties may occur owing to pressure on the surrounding structures in the peri-laryngeal region; however, they should resolve themselves after a few hours. A painful throat issue was also noted in the current study. Sore throat was substantially more common in LMA supreme than in AAG (28% vs. 12%). According to Shariffuddin et al., (2017) [4], Sore throat was substantially more common in LMA supreme than in AAG (10% vs. 38%).

Limitations: Present study only investigated the clinical use of AuraGain in adult patients with normal airways, and the findings may not be generalizable to pediatric patients or those with more complex airway conditions. To evaluate the safety of these devices in patients undergoing positive pressure ventilation and laparoscopic surgery, larger sample sizes would be required.

Conclusion: This study suggests that both AAG and LMA Supreme are reliable supraglottic airway devices, as there were no device failures or presence of blood during removal. Hemodynamic parameters, SpO_2, and $EtCO_2$ did not differ significantly between the two groups at different time intervals. While LMA supreme was easier to insert, AAG had a higher success rate for correct placement in the first attempt, better gastric drain functionality, and lower sore throat complications. Additionally, AAG had a slightly better OLP, which may provide a higher safety margin against the risk of aspiration.

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