Section: Anaesthesiology

Original Research Article

A RANDOMIZED COMPARATIVE STUDY OF AMBU AURAGAIN AND LMA SUPREME FOR CONTROLLED VENTILATION IN ANAESTHETISED PATIENTS

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ABSTRACT

Background: Supraglottic airway devices are widely used for airway management during general anaesthesia and serve as alternatives to endotracheal intubation for controlled ventilation. Newer second-generation devices are designed to improve airway seal and ventilation safety. This study aimed to compare the clinical performance of Ambu® AuraGain™ and LMA® Supreme™ in adult patients undergoing elective surgery under general anaesthesia, with primary focus on oropharyngeal leak pressure. **Materials and Methods:** In this randomised prospective study, 60 adult patients undergoing elective surgery under general anaesthesia were allocated to Ambu® AuraGain™ or LMA® Supreme. The devices were inserted after standardised induction, and oropharyngeal leak pressure was measured using a manometric technique. Insertion characteristics, ventilatory and hemodynamic parameters, and postoperative airway complications were recorded and compared between groups. **Results:** Demographic variables and baseline airway characteristics were comparable between the two groups. Oropharyngeal leak pressure was similar for Ambu® AuraGain™ and LMA® Supreme™ (23.60±1.33 vs 23.23±1.50 cm H_2O; p=0.321). Insertion time showed no significant difference (13.50±0.97 s vs 13.80±0.96 s; p=0.235), and ease of insertion was comparable. First-attempt insertion success was achieved in 100% of patients with AuraGain™ and 86.7% with LMA® Supreme™ (p=0.121). Pulse rate, oxygen saturation, and airway pressure remained stable and comparable at all time points. Mild sore throat occurred at 4 hours in 16.7% of AuraGain™ and 13.3% of LMA® Supreme™ patients, with no dysphagia or dysphonia observed. **Conclusion:** Ambu® AuraGain™ and LMA® Supreme™ demonstrated comparable effectiveness, safety, and hemodynamic stability for controlled ventilation in adult patients undergoing elective surgery under general anaesthesia.

INTRODUCTION

Endotracheal intubation is commonly used for airway management during general anaesthesia. However, it is not always easy and can be associated with airway trauma, hemodynamic disturbance and technical difficulty. In situations where intubation is not essential, supraglottic airway devices are often used as alternatives. These devices allow ventilation above the glottis without passing through the trachea and are now part of routine anaesthesia practice.[1]

With newer designs, some supraglottic airway devices can also be used as conduits for tracheal intubation with the help of fibreoptic bronchoscopy.[2,3] These techniques are mainly useful in failed laryngoscopy or difficult airway situations.[4] However, this study does not deal with difficult airway management, fibreoptic intubation or emergency airway rescue. The focus is on elective anaesthetised patients.[5]

Supraglottic airway devices are placed between the face mask and tracheal tube in terms of invasiveness and anatomical position. They allow hands-free ventilation and require less airway manipulation. Since the introduction of the laryngeal mask airway in 1981, airway management has shifted from routine intubation to maintaining effective ventilation with minimal airway trauma. These devices are generally easy to insert, well tolerated under lighter planes of

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anaesthesia and cause less airway irritation when compared to endotracheal tubes.[1]

Supraglottic airway devices are used worldwide in a large number of surgical procedures with a low incidence of serious complications. They are associated with stable hemodynamic responses during insertion and favourable respiratory mechanics. Because of these advantages, they are commonly used for ambulatory and short-duration surgeries. In patients without predicted airway difficulty, the ability of these devices to provide effective controlled ventilation becomes an important factor.[2,3]

Second-generation supraglottic airway devices were developed to improve airway seal and reduce gastric insufflation. The LMA Supreme is a single-use device with a preformed curved shaft, double lumen, built-in bite block and a gastric drainage channel.[6] It is commonly used for controlled ventilation in elective surgeries.[7] The Ambu AuraGain is also a disposable second-generation supraglottic airway device introduced in 2014. It has a preformed curvature, integrated gastric access and a wider airway tube, which can allow passage of a larger endotracheal tube if required. Even though their designs are different, both devices are routinely used for positive pressure ventilation in operating rooms.[8-10]

Oropharyngeal leak pressure is the airway pressure at which gas leaks around the cuff of a supraglottic airway device. It reflects how well the device seals the airway. Higher leak pressure allows better positive pressure ventilation and reduces gastric insufflation.[2] This parameter is directly related to controlled ventilation rather than rescue airway use. Situations like laparoscopic surgery, reduced lung compliance, and increased intra-abdominal pressure need a reliable airway seal.[6]

Previous studies comparing Ambu AuraGain and LMA Supreme have shown variable results regarding oropharyngeal leak pressure and insertion characteristics. There is limited data specifically in non-obese adult patients undergoing elective ambulatory surgery under controlled ventilation.

Therefore, this study aimed to compare Ambu AuraGain and LMA Supreme with respect to oropharyngeal leak pressure as the primary outcome, and insertion time, ease of insertion, number of attempts, hemodynamic changes and airway-related complications as secondary outcomes in anaesthetised patients.

MATERIALS AND METHODS

This randomised prospective study was conducted at Government Madurai Medical College Hospital over a twelve-month period from September 2023 to August 2024 and included 60 adult patients undergoing elective ambulatory surgery under general anaesthesia. The ethical committee approval was obtained, and informed consent was obtained from all participants.

Sample size calculation

Randomisation was carried out by the institutional biostatistician using a computer-generated block randomisation method. Sample size was calculated for two independent groups using a t-test. Alpha error was taken as 0.05, and the power of the study was kept at 95%. The effect size was 0.86 with degrees of freedom 58. Based on these values, 60 patients were required, with 30 patients in each group. The actual power achieved was 0.9501, which was acceptable for the study. Sample size was calculated using the formula $n = (Z\alpha/2 + Z\beta)^2 \times 2 \times \sigma^2 / d^2$.

Inclusion and exclusion criteria

Patients aged between 18 and 65 years belonging to ASA physical status I and II and posted for elective short-duration surgical procedures under general anaesthesia were included in the study. Patients with obesity, defined as body mass index >30 kg/m², pregnant patients, and those with restricted mouth opening of <2.5 cm were excluded from the study.

Methods

Sixty patients were enrolled and randomly divided into two groups. Group A patients received the Ambu Aura Gain supraglottic airway, and Group B patients received the LMA Supreme. Baseline details such as age, height, weight, body mass index, and Mallampati score were recorded before surgery.

Patients were placed supine on the operating table, and standard monitoring, including pulse rate, blood pressure, ECG, and oxygen saturation, was applied. General anaesthesia was induced using lidocaine, fentanyl, and propofol in standard doses. The assigned supraglottic airway device was inserted after adequate depth of anaesthesia was achieved by anaesthesiologists with sufficient experience in supraglottic airway use. Device size was selected based on body weight as per manufacturer guidelines. The cuff was inflated to 60 cm H_2O, and ventilation was confirmed clinically and by capnography. Airway pressure was noted at fixed time intervals. A maximum of three insertion attempts was allowed. Oropharyngeal leak pressure was measured using a manometric method with the head in a neutral position. Anaesthesia was maintained with sevoflurane in oxygen and air. Postoperative assessment for sore throat, dysphagia, and dysphonia was done at 0, 4, 12, and 24 hours. Oropharyngeal leak pressure was the primary outcome, while insertion characteristics, airway pressure, hemodynamic changes, and postoperative complications were secondary outcomes.

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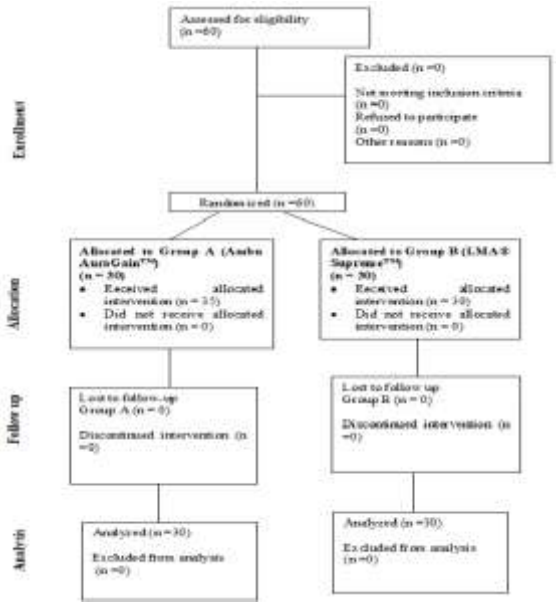

Figure 1: Consort diagram

Statistical Analysis: Data were analysed using SPSS v29. Data were presented in mean, standard deviation, and with comparison between groups performed using the t-test for continuous variables and the chi-square test for categorical variables, the $p<0.05$ was considered statistically significant.

RESULTS

Mean age was comparable between Group A and Group B (26.9 ± 5.4 vs 29.3 ± 4.8 years; p = 0.078). Mean height did not differ between the groups (154.8 ± 4.24 cm vs 154.2 ± 5.01 cm; p = 0.619). Mean body weight was similar in both groups (48.97 ± 1.25 kg vs 49.20 ± 1.13 kg; p = 0.45). Body mass index was comparable between Group A and Group B (20.46 ± 1.34 kg/m² vs 20.74 ± 1.53 kg/m²; p = 0.453). Mallampati score showed no significant difference between the two groups (1.87 ± 0.35 vs 1.93 ± 0.25; p = 0.398). [Table 1]

Table 1: Distribution of baseline demographic and airway characteristics between groups

Parameter	Category	Group A (Mean ± SD / n)	Group B (Mean ± SD / n)	p value
Age (years)	<25	14	8	0.078
	26–30	12	10	
	>30	4	12	
Height (cm)		154.8 ± 4.24	154.2 ± 5.01	0.619
Weight (kg)		48.97 ± 1.25	49.20 ± 1.13	0.45
Body mass index (kg/m²)		20.46 ± 1.34	20.74 ± 1.53	0.453
Mallampati score		1.87 ± 0.35	1.93 ± 0.25	0.398

Oropharyngeal leak pressure was comparable between Group A and Group B (23.60 ± 1.33 vs 23.23 ± 1.50 cm H_2O; p = 0.321). Insertion time did not differ between the groups (13.50 ± 0.97 s vs 13.80 ± 0.96 s; p = 0.235). Ease of insertion was comparable between Group A and Group B, with easy insertion in 29 patients vs 29 patients and fair insertion in 1 patient vs 1 patient (p = 1.0). First-attempt insertion was successful in 30 patients vs 26 patients. In comparison, second-attempt insertion was required in 0 patients vs 4 patients in Group A vs Group B, with no significant difference between the groups (p = 0.121). [Table 2]

Table 2: Distribution of airway insertion characteristics between groups

Parameter		Group A	Group B	p value
Oropharyngeal leak pressure (cm H_2O)		23.60 ± 1.33	23.23 ± 1.50	0.321
Insertion time (seconds)		13.50 ± 0.97	13.80 ± 0.96	0.235
Ease of insertion	Easy	29	29	1
	Fair	1	1	
Insertion attempts	First attempt	30	26	0.121
	Second attempt	0	4	

Table 3: Distribution of postoperative pharyngolaryngeal complications between groups

Complication	Group	Yes / No			
		0 hour	4 hours	12 hours	24 hours
Sore throat	Group A	0 / 30	5 / 25	0 / 30	0 / 30
	Group B	0 / 30	4 / 26	0 / 30	0 / 30
Dysphagia	Group A	0 / 30	0 / 30	0 / 30	0 / 30
	Group B	0 / 30	0 / 30	0 / 30	0 / 30
Dysphonia	Group A	0 / 30	0 / 30	0 / 30	0 / 30
	Group B	0 / 30	0 / 30	0 / 30	0 / 30

Pulse rate was comparable between Group A and Group B at all time points from pre-insertion to 60 minutes after insertion, with no significant differences observed at any stage ($p > 0.05$ at all-time points). [Figure 2]

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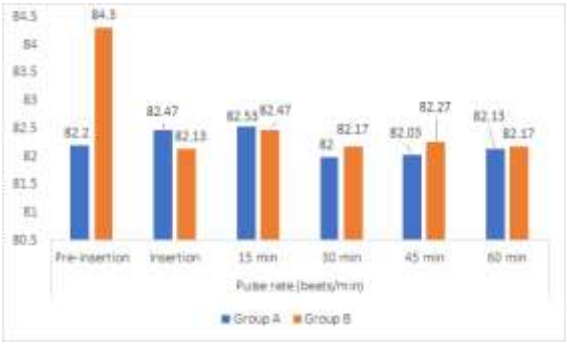

Figure 2: Comparison of pulse rate between groups at different time points

Systolic blood pressure was comparable between Group A and Group B from pre-insertion to 30 minutes after insertion, while a significant reduction was observed in Group A compared with Group B at 45 minutes (p = 0.027) and 60 minutes (p = 0.007). [Figure 3]

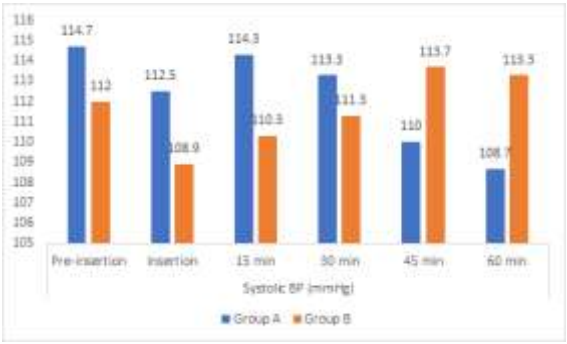

Figure 3: Comparison of systolic blood pressure between groups at different time points

Diastolic blood pressure was comparable between Group A and Group B at most time points, with a significant difference noted at insertion (p = 0.043) and at 60 minutes after insertion, where lower values were observed in Group A compared with Group B (p = 0.033). [Figure 4]

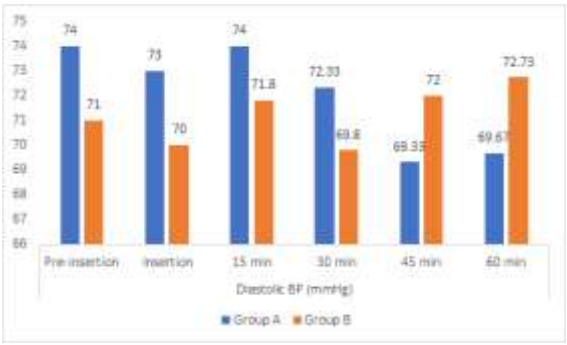

Figure 4: Comparison of diastolic blood pressure between groups at different time points

Mean arterial pressure was higher in Group A compared with Group B at pre-insertion (p = 0.025) and at insertion (p = 0.030), while values were comparable between the groups from 15 minutes to 60 minutes after insertion (p > 0.05). [Figure 5]

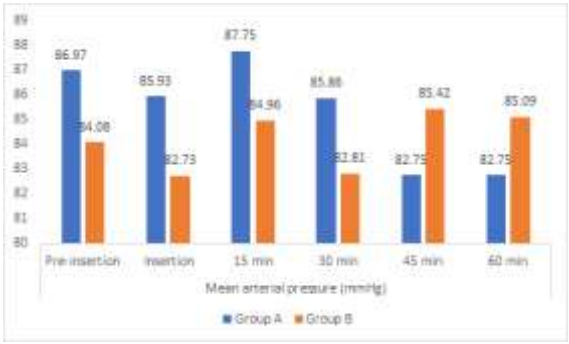

Figure 5: Comparison of mean arterial pressure between groups at different time points

Oxygen saturation remained at 100% in both Group A and Group B at all time points from pre-insertion to 60 minutes after insertion, with no difference between the groups (p = 1.0). [Figure 6]

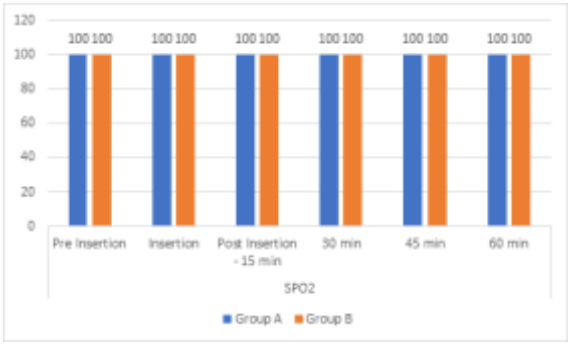

Figure 6: Comparison of oxygen saturation (SpO_2) between groups at different time points

Airway pressure was comparable between Group A and Group B at all time points from pre-insertion to 60 minutes after insertion, with no statistically significant differences observed at any stage (p > 0.05). [Figure 7]

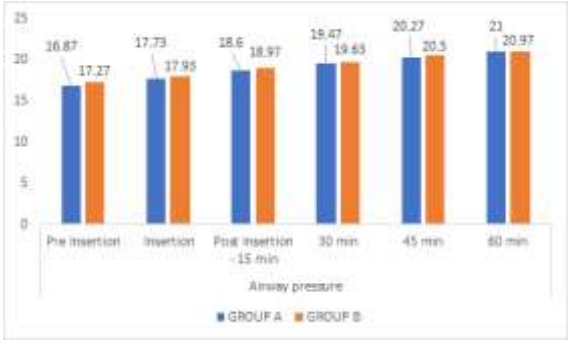

Figure 7: Comparison of airway pressure between groups at different time points

Postoperative sore throat was noted only at 4 hours in both groups, occurring in 5 patients (16.7%) in Group A and 4 patients (13.3%) in Group B, with no cases at other time points. No patients in either group developed dysphagia or dysphonia at any postoperative time point. [Table 3]

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DISCUSSION

The performance of Ambu® AuraGain™ and LMA® Supreme™ as supraglottic airway devices was compared in adult patients undergoing elective surgeries under general anaesthesia. Both devices were effective in maintaining ventilation with acceptable oropharyngeal leak pressure. Though AuraGain™ showed a higher mean OLP when compared to LMA® Supreme™ (23.6 cm H_2O vs 23.23 cm H_2O), this difference was not significant ($p = 0.321$). This indicates that both devices provide a comparable airway seal and are suitable for controlled ventilation.

Oropharyngeal leak pressure reflects airway safety and seal quality. In our study, the slightly higher OLP with AuraGain™ may be due to its larger proximal bowl, allowing better peri-laryngeal fit. Similar findings were reported by Lopez et al., who found significantly higher OLP with AuraGain™ when compared to LMA® Supreme™ (34 ± 5 cm H_2O vs 29 ± 5 cm H_2O; $p = 0.0012$) in 60 female patients undergoing laparoscopic gynaecological surgeries under general anaesthesia.[7] Wong et al. also reported higher OLP with AuraGain™ in a study of 170 patients maintained on spontaneous ventilation without muscle relaxants [26.4 (2.8) cm H_2O vs 21.6 (3.4) cm H_2O; $p < 0.001$].[5]

However, Shariffuddin et al. found comparable OLP values between AuraGain™ and LMA® Supreme™ (24.1 ± 7.4 cm H_2O vs 23.6 ± 6.2 cm H_2O; $p = 0.720$) in 100 patients, and the lower OLP was attributed to smaller body build and reduced mouth opening in the Asian population.8 Jagannathan et al. also reported no significant difference in OLP between the two devices in paediatric patients aged 3 months to 6 years.[10] In a cadaveric study, Lopez et al. showed better OLP with AuraGain™ compared to i-gel and LMA® Supreme™, though the device was less pliable and relatively difficult to insert due to reduced flexibility after contacting the posterior pharyngeal wall.[7]

Our study showed comparable insertion attempts between groups, with higher first-attempt success in AuraGain™ and a few second attempts required in the LMA® Supreme™ group. Similarly, Lopez et al. also reported no significant difference in the number of insertion attempts between the two devices ($p = 0.2$).[7] Shariffuddin et al. found a first attempt success rate of 86% with AuraGain™ and 78% with LMA® Supreme™, with no significant difference ($p = 0.906$).8 However, Wong et al. reported a significantly lower first pass success with AuraGain™ compared to LMA® Supreme™ (77% vs 94%; $p = 0.01$), and in three patients, AuraGain™ could not be placed even after three attempts.[5] The difficulty in inserting AuraGain™ was attributed to its bulky shaft and wide bowl, which was also supported by findings from cadaveric studies.

Our study found ease of insertion comparable between devices. LMA® Supreme™ appeared easier clinically, but insertion time and overall difficulty were similar for both supraglottic airway devices. Jagannathan et al. also reported no significant difference in ease of insertion between the two devices.[10] However, Shariffuddin et al. observed that insertion was easier in 74% of LMA® Supreme™ cases when compared to 48% of AuraGain™ cases ($p = 0.013$), and the insertion time was longer for AuraGain™ (33.4 ± 10.9 s vs 27.34 ± 11.4 s; $p = 0.010$). They attributed the longer insertion time to the use of spontaneous ventilation.8 Wong et al. reported that AuraGain™ could be placed without difficulty in 92% (77/84) of patients, which may be due to the larger cuff size helping in better positioning.[5]

In our study, pulse rate, oxygen saturation, and airway pressure remained stable and comparable. Transient blood pressure differences were noted. Mild sore throat occurred at four hours in a few patients and resolved spontaneously. Similarly, Sabuncu et al. reported heart rate changes were comparable between AuraGain and i-Gel® groups across all measured time points, with no clinically significant fluctuations after device insertion, indicating stable pulse rate patterns during the procedure.[11] Zhang et al. reported that there was no significant difference in oxygen saturation between AuraGain™ and LMA® Supreme™ at any time point, and peak inspiratory airway pressures were comparable before CO_2 insufflation, after insufflation, and at 30 minutes ($p > 0.05$ for all comparisons).[12]

Likewise, Yahaya et al. found that diastolic blood pressure was comparable between the groups at 0–4 minutes, with a significant reduction in the AMBU Aura-i™ group at 5 minutes (53.2 ± 13.5 mmHg vs 59.5 ± 15.7 mmHg; $p = 0.035$), showing a transient lower DBP similar to Group A findings.[13] Lakshmi et al. found that postoperative sore throat was infrequent and comparable, occurring in 3 patients in the Ambu AuraGain group and 4 patients in the LMA Supreme group, with no associated oxygenation or ventilation compromise.[14] Shariffuddin et al. reported a higher incidence of sore throat (38%), dysphonia (6%), and dysphagia (10%) in the LMA® Supreme™ group compared to AuraGain™, which supports the favourable postoperative airway profile seen in the present study.[8]

Limitations

This single-centre study had a limited sample size. Operator blinding was not possible, and fiberoptic assessment was not performed, limiting objective evaluation of device positioning. The study population predominantly consisted of young, low-body-weight, ASA I–II patients with normal airways. Therefore, the findings may not be generalisable to older patients, obese individuals, or those with anticipated difficult airways or significant systemic comorbidities

Clinical implications

Both devices are suitable for controlled ventilation in elective surgeries. Larger multicentre studies are

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recommended, including high-risk and difficult airway patients, with fibreoptic assessment and evaluation during prolonged and emergency airway management.

CONCLUSION

Ambu® AuraGain™ and LMA® Supreme™ are both effective supraglottic airway devices for controlled ventilation in adult patients undergoing elective surgery under general anaesthesia. Oropharyngeal leak pressure, insertion characteristics, airway pressure, and oxygenation were comparable between the two devices. Hemodynamic responses were largely stable, with only minor transient differences. Postoperative airway-related complications were minimal and self-limiting. Overall, both devices demonstrated similar safety and clinical performance.

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