Original Article

Comparison of insertion characteristics of LMA ProSeal and Ambu AuraGain in adult patients under controlled ventilation: A randomised study

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ABSTRACT

Background and Aims: Supraglottic devices are preformed or flexible, and the insertion characteristics of the two types may be different. This study aims to compare the insertion characteristics of Ambu AuraGain (AAG), preformed) and LMA ProSeal (PLMA), flexible, requires an introducer tool for placement. **Methods:** Forty American Society of Anesthesiologists (ASA) physical status I/II patients of either sex between 18 and 60 years with no anticipated airway difficulty were randomly allocated to either group AAG or PLMA (n = 20 each). Pregnant females, known case of chronic respiratory disorders and gastroesophageal reflux were excluded. After induction of anaesthesia and muscle relaxation, appropriately sized AAG or PLMA was inserted. Time for successful insertion (primary outcome), ease of device insertion and gastric drain insertion, first attempt success rate (secondary outcomes) were recorded. Statistical analysis was done using SPSS version 20.0. Quantitative parameters were compared using Student's *t*-test, and qualitative parameters were compared using Chi-square test. A *P* value of <0.05 was considered significant. **Results:** Time taken for successful insertion of PLMA was 22.94 ± 6.12 s and for AAG was 24.32 ± 4.96 s, ($P = 0.458$). Device insertion was significantly easy in PLMA group ($P < 0.002$). First attempt success rate was achieved in 17 (94.4%) cases in PLMA group compared to 15 (78.9%) cases in AAG group ($P = 0.168$). Ease of drain tube insertion was comparable among the groups ($P = 0.298$). The haemodynamic variables were also comparable. **Conclusion:** PLMA is easier to insert as compared to AAG, but the insertion time and first attempt success rate are similar. The preformed curvature in AAG does not provide any added advantage over the non-preformed PLMA.

Key words: Airway, airway management, anaesthesia, elective surgical procedures, general, laryngeal mask, laryngeal masks/classification, Ambu AuraGain, LMA ProSeal

INTRODUCTION

Supraglottic airway devices (SADs) have undergone many modifications since they were first introduced in anaesthesia practice. Due to the low airway pressure seal, the first-generation devices, were more suitable for spontaneously breathing patients.[1] The second-generation devices have higher seal pressure and an additional gastric access channel, alongside the ventilation tube, for suctioning of stomach contents. This design makes them safe for use in controlled ventilation scenarios as well.[2] LMA ProSeal™ (Teleflex®, NC, USA) (PLMA), a second-generation SAD, has a shorter, wider and wire-reinforced airway tube. It requires an introducer tool for proper placement.[3] During the removal of the introducer tool, it may get misplaced and hence result in a leak or improper ventilation.

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Another second-generation SAD, the Ambu® AuraGain™ (Ambu®, Ballerup DK) (AAG), has a preformed curvature resembling the human anatomic airway and hence does not require an introducer tool for its placement. The airway tube of AAG is shorter and broader than the PLMA.[4] The gastric drain tube is designed to offer less resistance for easy insertion of orogastric tube.

We hypothesised that due to the preformed curve, the AAG should be easier and should take lesser time for insertion compared to PLMA. But the results from a previous study[5] in adults are contradictory to this assumption, though a study comparing the two devices in children[6] supports our assumption. The present study was designed to compare the insertion characteristics of AAG and PLMA in adult patients with the primary objective being the time taken for successful insertion and the secondary objectives being the ease of device insertion, number of attempts for successful insertion, the success rate in first insertion attempt, ease of insertion of gastric tube and ease of device removal.

METHODS

This randomised comparative study was conducted after obtaining institutional ethics committee clearance (vide approval number IEC-HR/2018/36/5R, dated 26/10/2018) and complies with the ethical standards as laid down in the Declaration of Helsinki and its later amendments. The trial was registered with Clinical Trial Registry of India (vide Clinical Trial Number: CTRI/2018/12/016753, accessible at www.ctri.nic.in) before starting participant recruitment. The study was conducted at a tertiary care teaching institute between November 2018 and April 2020. Patients were explained about the study protocol and a written informed consent was obtained for participation in the study and use of the patient data for research and educational purposes and its publication.

Forty American Society of Anaesthesiologists' physical status I and II patients between 18 and 60 years of age and of either sex with Modified Mallampati class I/II airway and body mass index <30 kg/m^2 scheduled for elective surgical procedures under controlled ventilation were included. Pregnant females, patients with mouth opening <3 cm, known case of chronic obstructive pulmonary disease, asthma, gastroesophageal reflux disorder, oesophagectomy, hiatal hernia and any intra-oral growth were excluded from the study.

All patients were kept nil per orally for at least 8 hours. After a thorough preanaesthetic check-up, patients were wheeled in the operation theatre, and routine monitors including pulse oximeter, electrocardiograph and non-invasive oscillometric blood pressure were attached, and baseline parameters were recorded. An 18 G intravenous cannula was inserted, and Lactated Ringer's solution was started. Patients were randomly assigned to one of the two groups based on a computer-generated table of random numbers with allocation concealment done. Group PLMA (n = 20) included patients in whom LMA ProSeal was used as the airway maintenance device, and group AAG (n = 20) included patients in whom Ambu AuraGain was used as the airway maintenance device.

General anaesthesia was induced with morphine 0.1 mg/kg intravenous (i.v.) and propofol 2-3 mg/kg i.v. Vecuronium 0.1 mg/kg i.v. was given to facilitate muscle relaxation. Lungs were ventilated with 33% oxygen in nitrous oxide and sevoflurane. An appropriately sized airway maintenance device as per the standard recommendations based on the patient weight was inserted by an experienced anaesthesiologist. The introducer tool was used for the insertion of PLMA. The device was inflated with recommended volume of air and was connected to the anaesthesia breathing circuit. Ventilation was initiated, and correct placement was confirmed by observing visible chest rise, auscultation and appearance of the first square wave on capnography. A gel plug was placed in the proximal 1 cm of the gastric drain outlet, and pulsation of gel plug by a gentle tap on suprasternal notch was checked for. A lubricated gastric tube of appropriate size was passed through the drain tube, and its position was ascertained by epigastric auscultation of air. Anaesthesia was maintained with 33% oxygen in nitrous oxide and sevoflurane. Intermittent doses of i.v. vecuronium were given for continued muscle relaxation. After completion of surgery, neuromuscular blockade was reversed with neostigmine 0.05–0.08 mg/kg and glycopyrrolate 0.008–0.01 mg/kg i.v.; once the patient was awake and breathing spontaneously, the airway maintenance device was removed.

Time taken for successful device insertion (time from the opening of mouth and appearance of the first square waveform on capnography), ease of device insertion (no resistance: 1, mild resistance: 2; moderate resistance: 3; unable to pass the device: 4), number of attempts for successful insertion, success rate in first insertion attempt, results of the gel plug test (positive/

negative) and ease of gastric tube insertion (easy: 1; difficult: 2; unable to pass: 3) were recorded. As an ancillary observation use of manoeuvres like jaw thrust or requirement of assistant help was also noted.

According to a previous study,[6] the mean time taken for successful insertion with AAG and PLMA was 13.57 ± 1.94 s and 11.60 ± 2.22 s, respectively. At α-error = 5% and power = 80%, a sample of 17 cases was required in each group to estimate the same difference in the time taken for successful device insertion. To account for 10% failure of device insertion, a sample of 20 cases in each group was included. Data entry was done in a spreadsheet, and statistical analysis was done using IBM SPSS Statistics for Windows version 20.0 (IBM Corp., Armonk, N.Y., USA). One-time-measured quantitative parameters which followed the normal distribution were compared using unpaired Student's *t*-test, and those which were non-normally distributed were analysed using Mann–Whitney U-test. The qualitative parameters were compared using Chi-square/Fisher's exact test. A *P* value of <0.05 was considered significant.

RESULTS

Forty-six patients were screened for eligibility. Three of these patients did not give consent to participate, two had mouth opening less than 3 cm, and one was an asthmatic [Figure 1].

Demographic profile and size of the airway maintenance device used were comparable among the two groups [Table 1].

The time taken for successful insertion of PLMA was comparable to AAG $P = 0.458$, Table 2). In all the 18 cases of successful PLMA insertion, the ease of device insertion was grade 1. In the 19 cases of successful AAG insertion, the ease of device insertion was found to be grade 1 and 2 in nine patients each and grade 3 in one (5.3%) patient. The device insertion [Table 2] was significantly easy in the PLMA group ($P < 0.002$).

Out of all the successful placements, first attempt success rate was achieved in 17 (94.4%) cases in PLMA group compared to 15 ases in AAG

Table 1: Demographic profile

Variable name	PLMA (*n*=18)	AAG (*n*=19)	*P*
Age (years)*	35.6±10.6	36.0±8.2	0.901
Height (cm)*	152.72±5.86	156.53±6.30	0.066
Weight (kg)*	51.6±8.27	56.7±8.75	0.079
BMI (kg/m^2)*	21.9±2.9	23.2±3.6	0.251
Gender (M:F)†	1:17	2:17	0.580
ASA (I:II)†	15:3	16:3	0.942
MMP Grade (I:II)†	5:13	7:12	0.556
Size of device (3:4:5)†	13:5:0	9:10:0	0.124

*Values are expressed as Mean±SD (*t*-test); †values are expressed as ratio; PLMA: ProSeal laryngeal mask airway; AAG: Ambu AuraGain; BMI: body mass index; ASA: American Society of Anaesthesiologists'; MMP: Modified Mallampati; *P*<0.05 significant

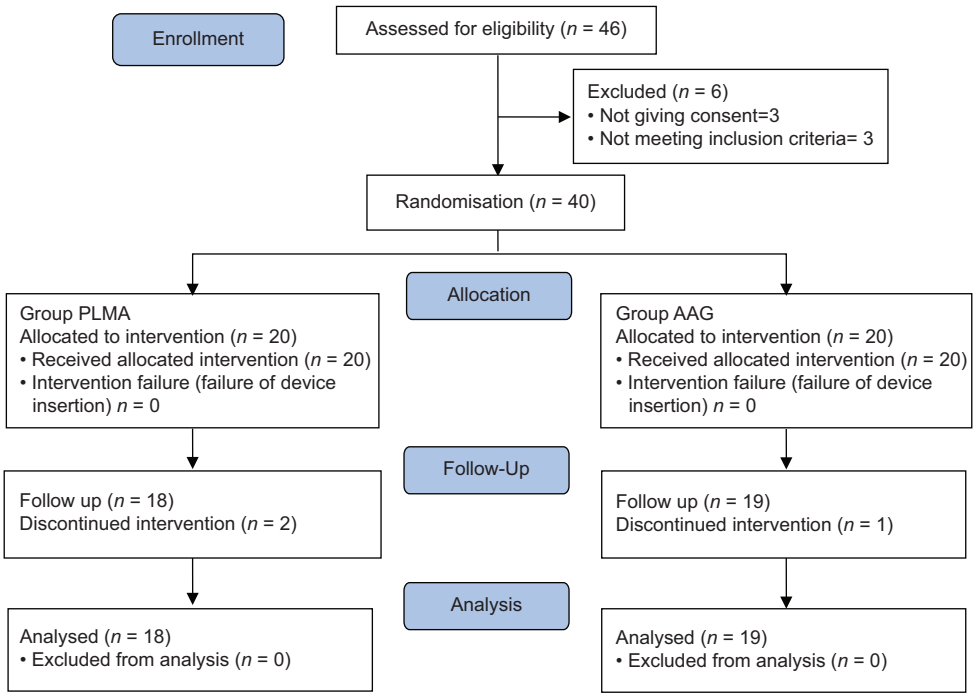

Figure 1: Consolidated standards of reporting trials (CONSORT) chart of patients

Table 2: Outcome measures

	Group PLMA (*n*=18)	Group AAG (*n*=19)	*P*
Primary outcome			
Time for successful device insertion (secs)*	22.94±6.12	24.32±4.96	0.458
Secondary outcomes			
Ease of device insertion			
1	18	9	0.002
2	0	9	
3	0	1	
Number of attempts for device insertion			
1	17	15	0.168
2	1	4	
3	0	0	
Ease of drain tube insertion			
1	17	19	0.298
2	1	0	
3	0	0	
Gel Plug Test	18	17	0.157
Number of manoeuvres for device placement			
0	0	0	0.168
1	17	15	
2	1	4	

group (P = 0.168). The device could be placed successfully in two attempts in one atient in group PLMA and four atients in group AAG. The ease of insertion of drain tube was comparable among the two groups (P = 0.298), [Table 2].

Gel plug test [Table 2] was positive in all patients in PLMA group and in 17 patients in AAG group (P = 0.157). The gel plug test was negative in two patients in group AAG, but ventilation was adequate. Oropharyngeal leak pressure (OLP) could be measured in only six patients in PLMA group and five patients in AAG group. The mean OLP was 30.17 ± 2.48 cm H_2O in PLMA group and 33.33 ± 4.39 cm H_2O in AAG group (P = 0.135).

In all patients in group PLMA and AAG, head tilt was required for successful device insertion. In addition to this, one patient in PLMA group and four patients in AAG group required jaw thrust manoeuvres in addition to head tilt (P = 0.168).

The heart rate, systolic and diastolic pressures measured at baseline, at the time of insertion, 1, 5, 10 min after insertion, at the time of device removal and 5 min after removal were comparable among the groups [Figure 2].

Blood staining of the device after removal was observed in two cases in PLMA group and four cases in AAG group. One patient in group PLMA complained of sore throat compared to none in group AAG. The incidence of postoperative complications was comparable (P = 0.212) [Table 3].

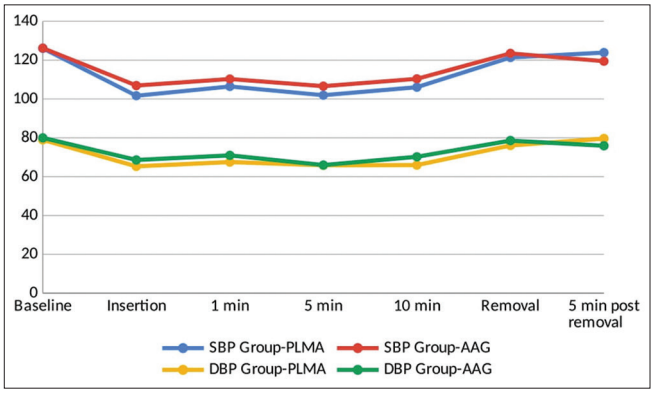

Figure 2: Trends of systolic and diastolic blood pressure

DISCUSSION

The results of this study show that there was no difference in time taken for either of the successful device insertion. However, insertion of PLMA was easier compared to AAG. The insertion of drain tube, number of attempts for successful placement, number and types of manoeuvres for successful insertion were comparable.

The time taken for successful device insertion has been reported in various studies to range from 13.57 ± 1.94 s to 33.4 ± 10.9 s.[5,7] The wide time difference is due to the definition of time for successful insertion adopted in the various studies. The timings

Table 3: Postoperative complications

Variable name	PLMA (*n*=18)	AAG (*n*=19)	*P*
Blood staining	2	4	0.212
Sore throat	1	0	

Values are expressed as number (percentage) Chi-square test; PLMA: ProSeal laryngeal mask airway; AAG: Ambu AuraGain; *P*<0.05 significant

recorded in our study are also well within this range. As per the previous reports, AAG took significantly longer time for successful placement[5] than PLMA. However, we did not find any significant difference in the time for successful placement in our study. In children, however, shorter times to successful insertion have been reported for AAG compared to PLMA.[6]

Due to inadequate ventilation in two patients with PLMA and one patient with AAG, the respective devices were removed and tracheal intubation was done. Failure to insert has been reported previously also.[7] We encountered problem during insertion of AAG in the oral cavity. This may be due to the large cuff size of the device. Another problem was due to the preformed curve. The gliding of the device through the mouth with the preformed curve was not very smooth. At times, the device needed to be straightened during insertion, which has been described by previous researchers also.[8]

First attempt success rate was higher with PLMA than AAG. This is attributable probably to the longer experience with the use of PLMA. As the familiarity and the usage of AAG will increase, we anticipate that this difference could be bridged. Similar first attempt success rates have been reported by Joshi *et al.*[6] in paediatric patients (80.8% with PLMA and 72.3% with AAG) and Singh *et al.*[5] in adult patients (80% with PLMA and 60% with AAG). Shariffuddin *et al.*[7] reported first attempt success rate in 86% patients, while Lopez *et al.*[9] reported 100% first attempt success rate with AAG.

Even though Lopez *et al.*[9] reported 100% success rate, but they commented that the design features introduced to make it intubation friendly may actually increase the difficulty during insertion. As per the results of the present study, the first attempt success rate was 78.9% with AAG and the device insertion was also relatively difficult than PLMA. Various reasons for the same could be the lesser experience with AAG and the more firm material used to make the device.[6] Although the manufacturers of AAG report that the passage for the gastric drain tube is low friction to facilitate easy placement of gastric tube, we found that the ease of drain tube insertion was similar with both the devices. Satisfactory placement of device with the gel plug test was confirmed in 100% patients with PLMA and 89.5% patients with AAG. Even though in 10.5% patients, the gel plug test was negative, yet the device functioned adequately. In 21.1% patients, jaw thrust was required to insert and position AAG. In all patients, the device was inserted from the midline. Para-median approach has been described by Lopez *et al.*,[9] but we did not require this manoeuvre. No serious hemodynamic fluctuations were recorded with any of the two devices after insertion or during removal. The incidence of complications during insertion and after removal was also minimal in both the groups. Previous studies have also reported that the complications with these devices are minimal.[6,7,9]

Since we did not have the requisite equipment to quantitatively measure the OLP, the values could be obtained for only six patients in PLMA group and five patients in AAG group. The values were marginally higher with AAG, but no statistical conclusions can be drawn from these observations. The inability to report OLPs for all patients included in the study is one of the major limitations of this study. Second, we did not do a fibreoptic grading of the view from the airway tube or drain tube to ascertain the correct device placement. Third, the bias due to the relatively longer experience with the use of PLMA could not be eliminated. However, this study involves the use of a relatively newer device which can prove to be a valuable addition to the armamentarium of the anaesthesiologist as it can be used as a conduit for intubation.

CONCLUSION

We conclude that AAG can be inserted successfully for securing airway for adult patients with similar time for successful placement. Though the PLMA is comparatively easier to insert than the AAG, the number of attempts for successful placement are comparable. Therefore, we ssugegst that AAG is an lternative device for securing the airway in adult patients requiring general anaesthesia with the insertion of SAD.

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Conflicts of interest

There are no conflicts of interest.

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