A comparative Evaluation of Performance of Ambu Aura40 with Proseal LMA: A Randomized Prospective Study

Original Article

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ABSTRACT

Introduction : Ambu Aura40 is a relatively newer supraglottic airway device (SAD) as compared to the standard Proseal LMA. The present study intends to compare the clinical performance of both these SADs in terms of ease of insertion, first pass success rate and oropharyngeal leak pressure.

Methods: Sixty patients between 18-60 years of age, belonging to ASA grade I and II, scheduled for elective surgery under general anaesthesia were included in the study. Patients were divided randomly into two groups of 30 each. In Group A airway was secured using Ambu Aura 40 and in group P Proseal LMA was used to secure airway. Insertion time, number of attempts of placing supraglottic device, Oropharyngeal leak pressure, Fibreoptic grading and ease of placement of device was noted.

Results: The mean insertion time was significantly lower in Ambu Aura40 than the Proseal LMA (6.8±2.6 vs 9.29±3.03 sec; p=0. 001). The ease of insertion and first pass success rate was similar between the groups. Mean Oropharyngeal leak pressure (OLP) was significantly higher in Proseal LMA when compared with Ambu Aura40 (32.00±4.63 vs 24.83±5.52 cmH2O; p<0.001).

Conclusion: We propose that Ambu Aura40 is a cost effective and reasonably successful device with similar performance to Proseal LMA with a shorter insertion time due to its special modifications.

Key Words: Airway management, ambu Aura40, oropharyngeal leak pressure, proseal LMA, supraglottic airway device.

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INTRODUCTION

Supraglottic airway devices (SADs) play an important role in the airway management. In an emphasis to provide simple and effective alternative to endotracheal tube, various supraglottic airway devices have been introduced in the field of airway management[1].

AmbuAura40 (Ambu Inc., Glen Burnie, MD, USA) is a relatively new SAD. The Ambu LMA has gone through various modifications since its introduction in year 2004. Ambu Aura 40 is recent reusable laryngeal mask introduced in Ambu family. It is a cuffed device with a preformed 90º angle curve which follows the anatomical curve of oropharyngeal cavity. Its curve also ensures that the patient's head remains in a more natural position when the mask is in use without extra stress on the upper jaw. In addition, curve of Ambu Aura40 is moulded directly into tube resulting in fast, easy, and appropriate placement. Aura40 is specially designed to give the airway tube the flexibility needed to adapt to individual anatomical variances and a wide range of head positions[2].

It features a special reinforced tip, which helps prevent folds during insertion that can cause improper positioning and possible airway leak. This results in easy insertion in a shorter period of time. It is autoclavable up to 40 times. The presence of a color-coded pilot balloon identifies mask size and provides precise indication of degree of inflation. Modified features of Aura40 like special curve of airway tube and special reinforced tip result in fast and appropriate placement of the device[3,4].

Though PLMA and other variants of Ambu Aura have been previously compared but there is no earlier study in the literature comparing the clinical performance of ProSeal LMA and Ambu Aura40. The present study intends to compare the ease of insertion, success rate and oropharyngeal leak pressure between ProSeal LMA and the Ambu Aura40.

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MATERIAL AND METHODS

The present prospective randomised double-blind study was conducted on 60 patients, between the age group of 18-65 years belonging to American Society of Anaesthesiologists (ASA) physical status I or II, scheduled to undergo elective surgery under general anaesthesia where placement of SAD was indicated. The study was approved by the institutional ethics committee and registered with the clinical trial registry of India [CTRI/2023/03/050386]. Informed consent was obtained from all the participants. Patients having any pharyngeal pathology, mouth opening <2.5cms, Body mass index >30kgm-2, pregnancy, and anticipated difficult airway was excluded from the study. Patients were randomly allocated to two groups Group A and Group P. In Group A (n=30) airway was secured using Ambu Aura 40 and in group P (n=30) Proseal LMA was used to secure airway.

Standardized anaesthesia protocol for induction of anaesthesia was followed. After pre-oxygenation, the induction of anaesthesia was done with glycopyrrolate (0.005mgkg-1), fentanyl (2µkg-1) and propofol (2.5mgkg-1). Neuromuscular blockade was achieved with vecuronium 0.1mgkg-1. After ventilating for 3 minutes, an appropriate sized LMA either Ambu Aura 40 or Proseal LMA was inserted as per manufacturer's recommendation according to weight. Correct placement of the device was confirmed by chest auscultation, and display of a square wave capnography trace. If difficulty in placement of device was encountered, it was repositioned or reinserted using, the manoeuvres like head extension, rotation of device, head extension and up-down movement as recommended by manufacturer. A maximum of three attempts were taken. If placement problem was encountered, even after 3rd attempt, it was considered as failure. Insertion time of supraglottic device was noted. It was taken from moment of picking up the SAD till confirmation of correct placement. If capnograph is not detected, the device was removed and reinserted. The time of second and third attempt was similarly recorded. Insertion time was sum of all attempts excluding time interval between attempts. The oropharyngeal leak pressure was measured by taking the patient on manual ventilation mode, closing the APL valve of the circle system at 30 cmH20 and fixed gas flow of 3 L/min and recording the airway pressure at which an audible air leak is observed. Ease of placement of device was also noted and was graded on three-point scale:

Grade 1 Easy: Placement of device in single attempt, with no resistance encountered and no manipulation required.

Grade 2 moderately difficult- Slight resistance when encountered while placing the device and minimal manipulation and readjustment is required.

Grade 3- Difficult: Major resistance is encountered. More than one attempt required to place the device and additional manoeuvres required.

Failure: 3 failed attempts was considered as failure. Fiberoptic Grading was assessed according to Brimacombe and Berry scoring system.5 Baseline mean arterial pressure, heart rate and SpO2 were noted (T0). Thereafter parameters were recorded after induction (T1), after supraglottic insertion (T2) and 5 minutes after supraglottic placement (T3). Complications such as nausea, sore throat, trauma and hoarseness of the voice was compared in the groups in immediate postoperative period, half an hour and one hour after removal of device.

Sample size

Our estimated sample size is based on Oropharyngeal leak pressure among groups. With reference to previous study, for the sample size calculation, we have defined mean difference of 1.6 with 1.9 Standard Deviation.4 We have calculated sample size with 95% confidence interval, 80% power and alpha level of 0.05

Comparison of two mean formula

N=size per group; SD= Standard Deviation= 1.9

δ= mean difference = 28.77-27.17=1.6

Zα/2= Z0.05/2= Z0.025 = 1.96 — From Z table at type I error of 5

Zβ= Z0.20 = 0.842 — at 80% power

$$N = 2 \times \frac{(Z_{\alpha/2} + Z_{\beta})^2}{(\delta_o)^2} \times SD^2$$

= 2 (1.96+0.84)2 (1.9)2 / (1.6)2

= 15.68 * 0.81 / 2.56

= 56.604 / 2.56

= 22.11

Considering the loss, the sample size of 30 was taken in each group.

statistics

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Statistical testing was conducted with the statistical package for the social science system version SPSS 20.0 (IBM SPSS Statistics Inc., Chicago, Illinois, USA). Continuous variables were presented as mean ± SD or median (IQR) for non-normally distributed data. Categorical variables were expressed as frequencies and percentages. The variables were assessed for normality

using the Kolmogorov Smirnov test. The comparison of normally distributed continuous variables between the groups was performed using Student's t test. Nominal categorical data between the groups was compared using Chi-squared test or Fisher's exact test as appropriate. Non-normal distribution continuous variables were compared using Mann Whitney U test. For all statistical tests, a *p value* less than 0.05 was taken to indicate a significant difference.

RESULTS

The demographic data was comparable in both the groups in the present study (Table 1). (Table 2) shows the insertion time of the SAD in both groups and was found to have high statistical significance (p=0.001). First attempt success of placement was higher in group *P* (93.33%) compared to Ambu Aura40 (90%) (Table 2) (p=0.640). Highly significant difference (p<0.001) in mean oropharyngeal leak pressure (OLP) was noted with higher values in group *P* (32.00±4.63 cm H_2O) compared to group A (24.83±5.52 cm H_2O). Head extension was the commonest manoeuvre used in 13.33% patients in group A and 10% patients of group *P* (p=0.688). Up and down movement of device was done in 3.33% patient in group A compared to none in group *P* (p=0.313). Majority of patients in both the groups had fibreoptic grade of 1. For group A and P, fibreoptic grade 1 was found in 66.66% and 70% patients respectively. Device was placed easily in 86.6% and 90% patients of group A and group P respectively (Table 3). At all time intervals, no statistically significant difference in mean HR, MAP, or SpO_2 was observed in either group (Figures 1,2). Mild trauma was noted in 10% patients with PLMA and 6.6% patients of Ambu Aura 40. On statistical comparison no significant difference was observed at any time interval (p >0.05) with regards to trauma and sore throat.

Table 1: Demographic profile of patients in both the groups

Mean ± SD	Group A	Group P	*p-value*
Age(years)	41.63 ± 15.89	44.06 ± 12.56	0.513
Weight(kg)	57.83 ± 11.75	64.33 ± 12.16	0.08
Male/female (%)	10/90	36.7/63.3	0.015
ASA I/ASA II (%)	70/30	17/13	0.284

Table 2: Insertion time, OLP and number of attempts

Parameters		Group A Frequency (%)	Group P Frequency (%)	*P-Value*
Insertion time for SAD (sec)		6.85 ± 2.6	9.29 ±3.03	0.001
Oropharyngeal Leak Pressure (cm H_2O)		24.83 ± 5.52	32.00 ±4.63	<0.001
Number of attempts for placing SAD	Attempts			
	1st	27 (90%)	28 (93.33%)	0.640
	2nd	3 (10%)	2 (6.66%)	
	3rd	0	0	
	Failure	0	0	

Table 3: Ease of placement of sad between two groups

Ease of placement	Group A (N = 30) Frequency (%)	Group P (N = 30) Frequency (%)	*P value*
Grade 1 (Easy)	26 (86.6%)	27 (90%)	0.896
Grade 2 (Moderately Difficult)	1 (3.3%)	1 (3.3%)	
Grade 3 (Difficult)	3 (10%)	2 (6.6%)	
Failure	0	0	

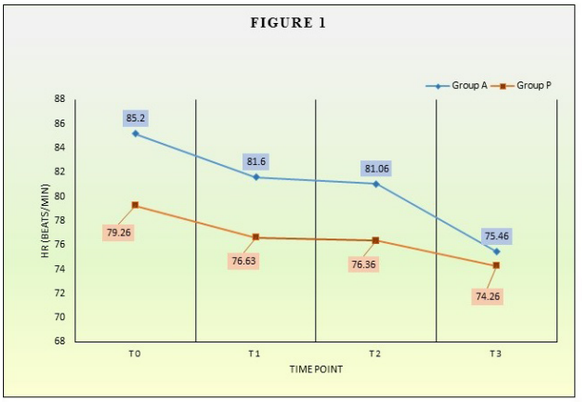

Fig. 1: Comparison of heart rate among the groups

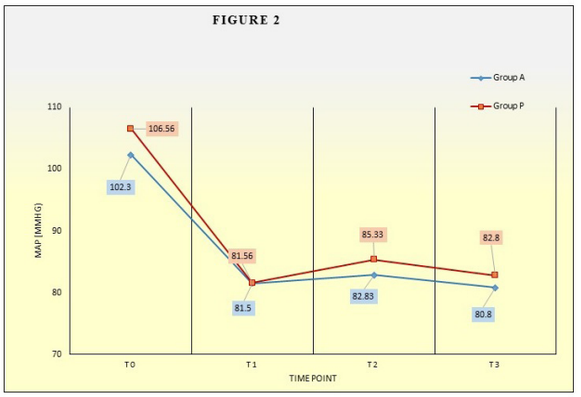

Fig. 2: Comparison of mean arterial pressure between the groups

DISCUSSION

The demographic parameters like age, weight, sex and ASA grade matched in both the groups. The current study revealed a female preponderance. The time to insert Ambu Aura 40 was lesser than the ProSeal LMA and the difference was statistically significant (p=0.001).

Our findings were consistent with the study of Raj *et al* who took <12 seconds to insert Ambu Aura40 in majority of the patients.6 In contrast, Anand *et al* observed higher time of 21.6±9.1 sec compared to our study for successful PLMA insertion.7 The less insertion time with Ambu Aura40 can be attributed to its design which features a built-in 90 degrees' anatomical curve. Comparatively

increased time for inserting the Proseal LMA may be due to the shape of its larger, deeper, and softer bowl along with the gastric drainage port forming the nonlinear leading edge.7 Moreover for ProSeal LMA placement, mounting of introducer and subsequent removal after insertion adds to insertion time.

The first attempt success rate was slightly higher with Proseal LMA (93.33%) compared with Ambu Aura40 (90%) but this increase was not statistically significant. The findings of the current study were in concordance with studies of Jamgond *et al* 4 and Singh *et al*.8 However, Anand *et al* noted 85% first attempt success rate with PLMA, which was lower compared to the current study.7 All the investigators and the current study reached an inference that both the devices are comparable to each other in terms of first attempt success rate.

Statistically significant difference in mean OLP (p<0.001) was found between both the groups, with Proseal LMA having higher OLP (32.00±4.63 cmH2O) compared to Ambu Aura40 (4024.83±5.52 cmH2O). Our findings with regards to OLP of Proseal LMA were almost consistent with findings of the authors who investigated PLMA.9-11 Oropharyngeal leak pressure is one of the properties that determine the efficiency of SAD, as the device that has a higher OLP has a better seal around the oropharynx. The higher OLP observed in LMA ProSeal may be because of its double cuff which it is made of soft silicone rubber that readily conforms to the contours of the hypopharynx.

Majority of the patients from both the groups (83.3% of Group A and 90% of group P) didn't require any manoeuvre for device placement. Out of the patients requiring manoeuvre for device placement, head extension was the commonest manoeuvre required. These findings were found to be consistent with findings of Agrawal *et al* which showed manoeuver requirement for Proseal LMA in 4 out of 40 patients (10%).11

Placement of device was slightly more easy in Proseal LMA as compared to Ambu Aura 40. A larger proportion of patients in both groups had Grade 1 ease of insertion. Difficult placement was noted in 10% patients each in group A and 6.6% patient in group P. On statistical comparison it was found to be non-significant (P=0.896). Our findings were consistent with other authors who showed a similar degree of ease of insertion of Proseal LMA.7 Grade 1 ease of insertion was recorded in more than 90% subjects with Ambu Aura 40 by other investigators, which was in accordance to the present study.4,6,12 The high number of patients with grade 1 ease of insertion with Ambu Aura40 is attributed to its ergonomic design which gives a firm grip on holding. Both the reinforced tip which prevents infolding of the cuff and its pre-formed curvature which conforms to the anatomical curvature of the airway rigid curvature contributes to its easy insertion.

At all-time intervals, HR, MAP, and SpO2 were comparable between the two groups. Since Ambu Aura40 and Proseal LMA are both supraglottic devices, it has been demonstrated from time to time that these devices cause a reduced hemodynamic pressor response and so no variation in hemodynamic was observed. Complications such as nausea, sore throat, trauma and hoarseness of the voice were comparable in both groups. Mild trauma was noted in 10% patients with PLMA and 6.6% patients of Ambu Aura 40. On statistical comparison no significant difference was observed at any time interval (p >0.05) with regards to trauma and sore throat. Incidences of complications in both groups in present study were statistically comparable but a higher number of cases with sore throat and blood on the device in patients managed with ProSeal LMA is clinically relevant. This can be probably due to trauma caused by the use of a metallic introducer and the inherent bulky design of ProSeal. One more reason of having slightly more post-operative complications in PLMA could be due to higher intracuff pressure that impedes pharyngeal mucosal perfusion leading to complications.

LIMITATIONS

- Our sample size was relatively small, and a larger sample size might be needed to determine the more authenticated performance of device.
- This study was conducted by experienced user, and results may vary when performed by less experienced users.
- Scale used for assessing the ease of intubation was subjective scale.
- Relatively few studies on Ambu Aura40 have been published.
- The patient population included in the study are patients having normal airway and result may vary in patients having difficult airway.

CONCLUSION

We conclude that in comparison to ProSeal LMA, the Ambu Aura40 provides a shorter insertion time and a lesser incidence of postoperative complications of sore throat and blood on the device. The modified features of Aura40 like special curve of airway tube and special reinforced tip result in fast and appropriate placement of the device. Ambu Aura40 is cost effective and reasonably successful but the sealing pressure is less compared to Proseal LMA and it also lacks a gastric port which is present in Proseal LMA thereby having more chances of aspiration compared to Proseal LMA. We would also like to mention that the relative dearth of published literature on the Ambu Aura40 also warrants further larger controlled study trials, particularly in potentially difficult airway patients to further compare and elucidate its performance with established supraglottic devices to deduce its efficacy.

RECOMMENDATIONS

- Ambu Aura40 has emerged as an ergonomic, cost-effective and reasonably successful airway device with similar performance to ProSeal LMA in terms of the ease of insertion and number of attempts and shorter insertion time.
- It would be advantageous if there is modification and introduction of gastric port in Ambu Aura40.

CONFLICT OF INTERESTS

There are no conflicts of interest.

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