Original Article

Comparative Evaluation of Two Supraglottic Airway Devices: Intubating Laryngeal Mask Airway (ILMA) and Ambu Aura-i for Blind Tracheal Intubation in Adults: A Randomized Clinical Trial

Dina Abo Dief, Ibrahim Mohamed, Adel Shenouda, Ahmed Abd El Maksoud, Sara Taha

Department of Anesthesiology, Intensive Care and Pain Management, Faculty of Medicine, Ain-Shams University, Cairo, Egypt

ABSTRACT

Background: Supraglottic airway devices (SGD) are a group of airway devices that can be inserted into the pharynx to allow ventilation, oxygenation, and administration of anesthetic gases. These devices are used for primary airway management, rescue ventilation when facemask ventilation is difficult, and as a conduit for endotracheal intubation.

Aim of the study: Was to compare between intubating laryngeal mask airway (ILMA) and Ambu Aura-i as regards success rate for blind endotracheal intubation in adults undergoing elective surgery under general anesthesia.

Results: 100 patients were randomly divided into two equal groups. Group A (*n*= 50) were intubated using ILMA, whereas those in group B (*n*= 50) were blindly intubated using Ambu Aura-i. The data demonstrated that success rate for blind intubation in group A 86.9% while in group B 72.3% (*p* value= 0.122). Time for endotracheal intubation in seconds was 97±24.279 in the group A while it was 102.94±32.755 in group B (*P*= 0.374). Time required for placement of SGDs in seconds was 56.80±14.480 in group A while it was 66.38±31.514 (*p*= 0.064). Number of attempts for SGDs in the first attempt (ILMA= 36/72, 72%; Ambu Aura-i 36/72, 72%), in the second attempts (ILMA= 10/21, 20%; Ambu Aura-i= 11/21, 22%) in the third attempts (ILMA= 4/7, 8%; Ambu Aura-i= 3/7, 6%) (*P*= 0.870). Group A 46/93, 92% while in group B 47/93, 94%) (*p*= 1). Change >20% of baseline vital data was recorded e.g. mean arterial blood pressure (MAP) (*p*= 0.281) while Heart rate (*p*= 0.926). Complications e.g. blood on endotracheal tube (ETT) (*p*= 0.554), blood on SGDs (*p*= 0.836), abdominal pain (*p*= 1), Hoarseness of voice (*p*= 0.585) & desaturation, aspiration, laryngospasm & laryngeal edema) weren't noted.

Conclusion: Ambu Aura-i and ILMA are good tools for maintaining ventilation and oxygenation. There is no difference between ILMA & Ambu Aura-i as regards successful blind intubation so Ambu Aura-i a comparable alternative to ILMA for blind tracheal intubation.

Key Words: Ambu Aura-i, blind intubation, elective surgeries in adults, intubating laryngeal mask.

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Corresponding Author: Dina Galal Abo Dief, M.Sc, Department of Anesthesiology, Intensive Care and Pain Management, Faculty of Medicine, Ain-Shams University, Cairo, Egypt, **Tel.:** +01011237339, **E-mail:** dina7679@gmail.com

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BACKGROUND

The laryngeal mask airway (LMA) was one of the first extra glottic airways (EGA) invented by Dr. Archie Brain, 1981[1]. It became commercially available in the United Kingdom in 1988 and in the United States in 1991[2]. One device commonly used as a conduit for intubation is the ILMA, it has been considered the "gold standard" among the supraglottic airway devices since 1997[3] (Figure 1). The Fastrach ILMA (Laryngeal Mask Company, Jersey, UK) was first developed by Dr. A. Brain in 1997 in response to difficulties found when attempting to insert an endotracheal tube (ETT) blindly into the trachea through the Classic LMA[4]. It has shown a high success rate for blind or fibreoptic-guided tracheal intubation in patients with both expected and unexpected difficult airways. Difficult Airway Society 2015 guidelines and All India Difficult Airway Association 2016 guidelines have included ILMA as a second-line airway device in case of unanticipated difficult intubation and failed intubation with conventional rigid laryngoscopy[5].

The Ambu Aura-I (Ambu A/S, Ballerup, Denmark) is a polyvinyl chloride, MRI compatible, single-use SGD introduced clinically in 2010, it is a modification of Ambu Aura once that is designed to facilitate intubation in a fashion similar to that of the ILMA[6] (Figure 2).

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Also it is designed for both ventilation and as a conduit for tracheal intubation. It incorporates a 90° preformed curvature designed to approximate airway anatomy, bite block, and has navigation marks to guide a fiberscope during intubation. The Aura-i is available in eight different sizes for all ages, from infants to pediatric and adult age groups. Successful intubations have been reported using it[7].

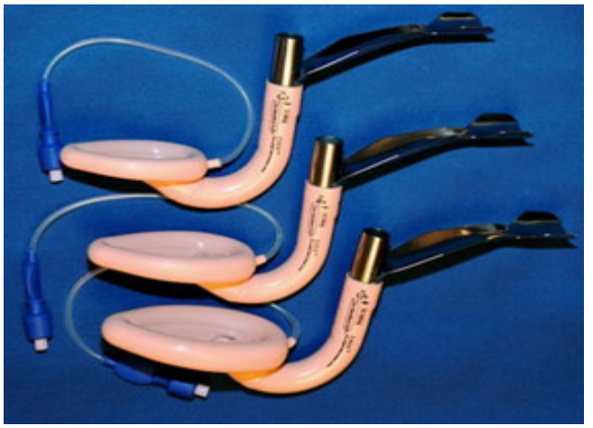

Figure 1: The three sizes of the Fastrach Intubating Laryngeal Mask Airway[8].

Figure 2: The Ambu Aura-I Device[7].

The primary objective was success rate for blind endotracheal intubation in adults underwent elective surgery under general anesthesia. The secondary objectives were total time required for the successful blind endotracheal intubation through the SGD, time and number of attempts required for the placement of the SGD & complications like hemodynamic instability, desaturation (SpO_2 <94%), regurgitation or aspiration, laryngospasm/bronchospasm, oropharyngeal or laryngeal trauma (blood staining of device/ETT), laryngeal edema and hoarseness of voice.

METHODS

This prospective randomized controlled clinical trial received approval from the Research Ethical Committee of Ain Shams University (FMASU MD93/2022). The study was registered at pan African clinical trials.gov (PACTER202312917896121). Written informed consent was obtained from all participants.

Inclusion criteria

1. Age 18-60 years.
2. ASA physical status of I or II.
3. Elective operations under general anaesthesia.

Exclusion criteria

1. Patient refusal.
2. Patients with risk of gastric aspiration e.g. obesity (BMI>35 kg/m^2), hiatal hernia, gastroparesis, pregnancy & trauma.
3. Patients with poor lung compliance, restricted neck movements & oropharyngeal pathology.
4. Patients with known or predicted difficult airway such as Malampati III or IV, mouth opening less than 2.5cm and thyromental distance less than 4cm.

All patients were premedicated with Atropine 0.01mg/kg IV, Midazolam 0.03mg/ kg IV, Fentanyl 2mcg/kg IV and preoxygenated with 100% O_2 for 2 minutes.

Anesthesia was induced with Propofol 2mg/kg IV. After confirmation of adequate ventilation. Atracurium 0.5mg/kg IV was administered for muscle relaxation.

Then, with the patient's head in neutral position, an appropriate size ILMA/Ambu Aura- i (as per randomization & depending on the body weight as per the manufacturer's recommendations) was inserted by an experienced anesthesiologist.

Correct placement of the device was confirmed by easy bag ventilation (assessed clinically via presence of normal chest expansion and adequate expiratory tidal volume), absence of audible air leak around the cuff at peak airway pressures up to 20cm H_2O and normal square wave capnogram. A maximum of three attempts was allowed and the number of attempts was recorded. Time needed for insertion of supra glottic airway device (SGD) is from the time of taking the device in hand till confirmation of proper placement of the device. After successful placement of supra glottic airway device, blind intubation of the trachea was attempted in neutral position with conventional ETT with curvature facing anterior in the first attempt. If the first attempt failed during tracheal intubation, the maneuver head extension and backward upward thyroid pressure was used and intubation attempt was repeated, if the second attempt of intubation was unsuccessful, tracheal intubation was performed with conventional laryngoscopy. Proper placement of the ETT was confirmed by appearance of normal square wave capnogram and bilateral equal air entry. Time taken for blind intubation was recorded from the time of taking ETT in hand till confirmation of proper

placement of the ETT. A change >20% of baseline of heart rate & MAP was recorded at baseline, after induction and SAD insertion, 1, 5 and 10min after intubation. Complications such as airway trauma were noted by blood on the device during its removal. Sore throat was graded as mild, moderate and severe by asking the patients in the post-anesthesia care unit. Between the SAD insertion and blind intubation attempts, patients were ventilated with 100% O_2.

Statistical analysis

Sample size

Using G power program for sample size calculation setting power at 80%, alpha error at 5%, assuming an effect size difference= 0.3 regarding intubation success between different devices and after 10% adjustment for dropout rate a sample size at least 100 patients (50/group) will be needed.

Statistical method

Data were collected, coded, tabulated, and then analyzed using SPSS software package (IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp., 2013). Numerical variables were presented as mean (standard deviation), while categorical variables were presented as frequency (%). Comparisons were done using *t*-test and chi-square test for numerical and categorical variables respectively. For dealing with censored data, times required for successful insertion of airway devices were additionally presented as median and 95% confidence interval and analyzed using Kaplan-Meier Survival analysis and log-Rank test. Any difference with *p*-value <0.05 is considered statistically significant.

RESULTS

Demographic data (Table 1) revealed that there was no statistically significant difference between two groups with regard to age, sex, ASA grades and BMI.

As regards success rate for blind intubation in both groups (Table 2), there was no statistically significant difference (*P*= 0.122).

Time required for blind intubation in both SGD showed no statistically significant difference (*P*= 0.374) (Figure 3), also the time required for placement of SGD (Figure 4), which showed no statistically significant difference (*P* value 0.064) (Table 3).

Besides, the number of attempts for supraglottic airway placement showed no statistically significant difference (*P* Value 0.870) (Table 4). Regarding changes in hemodynamics (MAP and heart rate), there were no significant difference (Table 5). As regards complications 19 cases reported blood on SGD , 8 cases reported blood on ETT , 2 cases reported abdominal pain and 7 cases reported hoarseness of voice in group A while in group B 18 cases reported blood on SGD, 5 cases reported blood on ETT, 1 case reported abdominal pain, 9 cases reported hoarseness of voice (Table 6). There were no reported cases with Laryngospasm, desaturation & laryngeal edema.

Table 1: Demographic data:

Variables		Group A (*n*= 50)	Group B (*n*= 50)	*P* value
Age (in years)		52.62±10.55	47.88±13.523	0.054
Sex	Male	24(48%)	23(46%)	0.841
	Female	26(52%)	27(54%)	
BMI	(kg/m2)	25.58±2.45	25.380±2.43	0.68
ASA	Grade I	19(38%)	24(48%)	0.313
	Grade II	31(62%)	26(52%)	

Group A: Intubating laryngeal mask air way (ILMA group); Group B: Ambu Aura-I; BMI: Body mass index; ASA: American Society of Anasthiologist; Data are expressed as mean±standard deviation or as numbers; percentage: *p*>0.05 not significant.

Table 2: Success rate of blind intubation:

Group A (*n*= 46)	Group B (n= 47)	P value
40(86.9%)	34(72.3%)	0.122

Group A: Intubating laryngeal Mask Air Way (ILMA group); Group B: Ambu Aura-I; Data are expressed numbers, percentage.

Note: Sample size is 50 patients in both groups but there is 4 cases are excluded in group A and 3 cases are excluded in group B and it is called not tried which means failure of insertion of supraglottic device from the start so we couldn't insert endotracheal tube blindly.

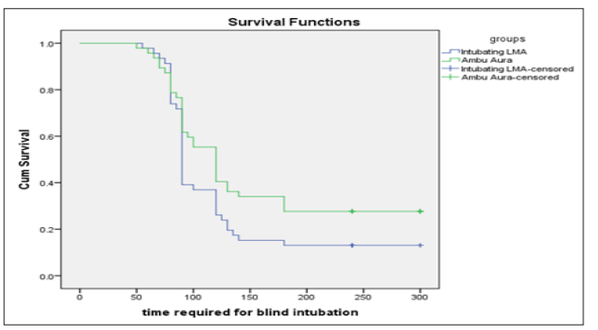

Figure 3: Kaplan-Meier survival plot of time to blind intubation.

Table 3: Time required for placement of SGD & blind intubation:

Variables	Group A (*n*= 50)	Group B (*n*= 50)	*P* value
SGD	56.8±14.48	66.38±31.5	0.064
Blind intubation	97±24.279	102.94±32.755	0.374

Group A: Intubating laryngeal mask air way (ILMA group); Group B: Ambu Aura-I; SGD: Supra glottic device; Data are expressed as mean±standard deviation.

Table 4: Number. Of attempts for supraglottic airway placement:

Variables	Group A (*n*= 50)	Group B (*n*= 50)	*P* value
First attempt	36(72%)	36(72%)	
Second attempt	10(20%)	11(22%)	0.870
Third attempt	4(8%)	3(4%)	

Group A: Intubating laryngeal mask air way (ILMA group); Group B: Ambu Aura-I; Data are expressed as numbers & percentage.

Table 5: Vital data as regards mean arterial blood pressure (MAP) & heart rate:

Variables	Group A (*n*= 50)	Group B (*n*= 50)	*P* value
Decreased MAP (mm Hg)	9(18%)	13(26%)	
No change>20% of MAP (mm Hg)	37(74%)	36(72%)	0.281
Increased MAP (mm Hg)	4(8%)	1(2%)	
Decreased HR (bpm)	3(6%)	4(8%)	
No change>20% of HR (bpm)	45(90%)	44(88%)	0.926
Increased HR (bpm)	2(4%)	2(4%)	

Group A: Intubating laryngeal mask air way (ILMA group); Group B: Ambu Aura-I; MAP: Mean arterial blood pressure; HR: Heart rate; bpm: beat per minute; mm Hg: Millimetres of mercury; Data are expressed as numbers & percentage.

Table 6: Complications:

Variables	Group A (*n*= 50)	Group B (*n*= 50)	*P* value
Blood on SGD	19(38%)	18(36%)	0.836
Blood on ETT	8(16%)	5(10%)	0.554
Abdominal pain	2(4%)	1(2%)	1
Hoarseness of voice	7(14%)	9(18%)	0.585

Group A: Intubating laryngeal mask air way (ILMA group); Group B: Ambu Aura-I; SGD: Supra glottis device; ETT: Endotracheal tube; Data are expressed as numbers & percentage.

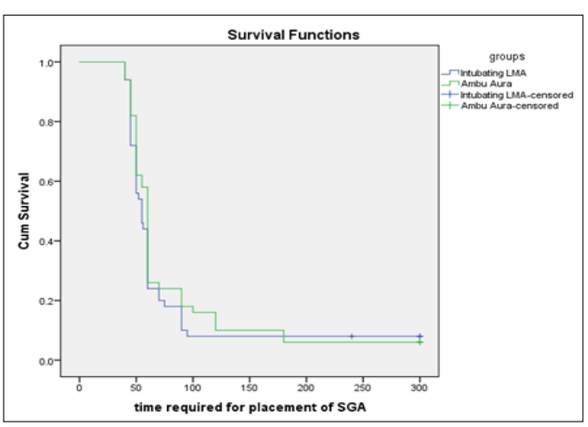

Figure 4: Kaplan-Meier survival plot of time to placement of SGA.

DISCUSSION

The SGD used most commonly in the operating room are the laryngeal mask airways (LMAs) and similar devices, while other SGDs are used more commonly in the emergency department and for prehospital airway management (eg, Combitube, laryngeal tube, pharyngeal tube). The LMA consists of a hollow shaft or tube connected to a mask-like cuff designed to sit in the hypopharynx facing the glottis, with the tip at the esophageal inlet.

The ILMA was designed to provide a superior conduit for tracheal intubation compared with the LMA Classic. It has an anatomically curved rigid airway tube, a metal introducer handle and the bowl of the device contains an 'epiglottic elevator bar'. Although originally designed to facilitate 'blind' tracheal intubation, success is increased by using a fibrescope inserted through the ILMA and it may be considered the standard device for fibreoptic-guided tracheal intubation[9].

The AMBU Aura-i is a polyvinyl chloride, MRI compatible, single-use SGD introduced clinically in 2010, apart from functioning as a routine supraglottic ventilatory device; this feature makes it potentially useful in difficult airways as a conduit for tracheal intubation and airway-exchange techniques with a fibreoptic scope[6].

The present study was designed to compare success rate for blind intubation between ILMA & Ambu Aura-i & compare time required for placement of both SGD and blind intubation through them.

In our study, we observed there were no significantly difference as regards success rate for blind intubation and insertion of SGD in both groups, time required for blind intubation and SGD in both groups, regarding changes in hemodynamics (MAP and heart rate), there were no significant difference, As regards complications 19 cases reported blood on SGD, 8 cases reported blood on ETT, 2 cases reported abdominal pain and 7 cases reported hoarseness of voice in group A while in group B 18 cases reported blood on SGD, 5 cases reported blood on ETT, 1 case reported abdominal pain, 9 cases reported hoarseness of voice. There were no reported cases with Laryngospasm, desaturation & laryngeal edema.

Other studies showed different results than our study may be due to use fiberoptic.

Anand *et al*., (2019) compared Ambu Aura-i with ILMA as a conduit for tracheal intubation and the results showed that the success rate of blind intubation was 92% in ILMA and 76% in Ambu Aura-i (P<0.01), time taken for tracheal intubation at first attempt was lesser in group ILMA and Ambu Aura-i, respectively (P<0.01). Fiberoptic-guided intubation success rate was higher with Ambu Aura-i than with ILMA and they concluded ILMA had a higher success rate in facilitating blind tracheal intubation compared with Ambu Aura-i[11].

Mishra *et al*., (2020) compared fiberoptic-guided tracheal Intubation through ILMA and Ambu Aura-i and they concluded that the Ambu Aura-i scores superiorly over ILMA in requiring less time for successful insertion on the basis of statistical analysis, and hence appears to be a better independent ventilatory device[10].

Schiewe *et al*., (2019) made a comparison of blind intubation with the ILMA and the Ambu Aura-i & the results of their study showed that the success rate of tracheal intubation with the ILMA at the first and second attempts was significantly better compared with the Ambu Aura-I, tracheal intubation was also significantly faster (14.1 s.±4.4 versus 21.3 s.±9.0; p<0.01), and the time interval for mask removal after successful intubation was significantly shorter using the ILMA device (24.0 s.±8.2 versus 29.4 s. z±7.5; p<0.001). There were no significant differences between both groups regarding the incidence of postoperative sore throat and hoarseness[12].

Rangaswamy *et al*., (2019) conducted a study to show the effectiveness of Ambu Aura-i as a supraglottic device for its ventilatory effectiveness and intubation characteristics in paediatric patients, and they concluded on the basis of observations of this study that Ambu Aura-i is not only an effective ventilatory device, but also an excellent conduit for fibre optic guided intubation using conventional uncuffed endotracheal tube in paediatric patients. Ambu Aura-i, is also valuable for establishing rapid airway access in emergent difficult paediatric airway[13].

Artime *et al*., (2016) compared the Ambu Aura-i to the single-use ILMA regarding time of intubation, success rate, and airway morbidity in patients undergoing elective surgery requiring general anaesthesia, and the data demonstrated that time for endotracheal intubation in the ILMA group was significantly shorter than in the Ambu Aura-i group (P<.05). There was no difference in the first-attempt intubation success rate (Aura-i= 26/33, 78.8%; ILMA= 27/33, 81.8%; P= .757) or the overall intubation success rate (Aura-i= 29/33, 87.9%; ILMA= 31/33, 93.9%; P= .392) between the groups. There was no statistically significant difference in airway morbidity between the two groups as well[14].

Soaida *et al*., (2023) made an evaluation of Ambu-Aura-i laryngeal mask as a conduit for endotracheal intubation and compared it with Air-Q intubating laryngeal airway in adult surgical patients, they found that Ambu-Aura-i LM and Air-Q ILM are reliable fiberoptic endotracheal intubation conduits for healthy adult patients scheduled for elective surgical procedures, with Ambu-Aura-i having an advantage in terms of device insertion time and use for mechanical ventilation because of its higher airway leak pressure[15].

LIMITATION

Our study has some limitations; there were no patients with a difficult airway in each group. We didn't use the fibreoptic in this study because it needs much more experience & it was not available in all operating rooms.

CONCLUSION

Ambu Aura-i & ILMA are good tools for maintaining ventilation and oxygenation. There is no significantly difference between ILMA & Ambu Aura-i as regard successful blind intubation so Ambu Aura-i is a comparable alternative to ILMA for blind tracheal intubation.

ABBREVIATIONS

(SGD): Supraglottic airway devices; **(ILMA):** Intubating Laryngeal Mask Airway; **(EGA):** Extra glottic airways; **(MAP):** Mean arterial pressure; **(BMI):** Body mass index; **(ETT):** Endotracheal tube; **(ASA):** American Society of Anaesthesiologists; **(IV):** Intravenous.

CONFLICT OF INTERESTS

There are no conflicts of interest.

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