Original Article

Comparative evaluation of Ambu Aura-i and Fastrach™ intubating laryngeal mask airway for tracheal intubation: A randomized controlled trial

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Abstract

Background and aims: Ambu Aura-i was compared with Fastrach™ (FT)-laryngeal mask airway (LMA) as a conduit for tracheal intubation.

Material and Methods: A hundred consenting patients were randomly allocated into two groups of 50 patients each in a prospective randomized study. Standard anesthesia technique was used for all patients and FT-LMA or Ambu Aura-i was selected. After insertion of airway device, the cuff was inflated and ventilation was attempted. Once satisfactory ventilation was achieved, with or without maneuvers, a fiberoptic scoring for glottis view was noted. A polyvinylchloride (PVC) tracheal tube of appropriate size was inserted through the airway device as per procedure. If no resistance was felt while advancing the tracheal tube, it was fully inserted into the device and tracheal tube cuff was inflated. The device was removed and tracheal tube was left *in situ*. If the first attempt failed during tracheal tube insertion, the recommended maneuvers were used. A maximum of three attempts were allowed for intubation. First attempt for tracheal intubation attempt was a blind, second attempt was made with maneuver. If second attempt of intubation was unsuccessful, fiberoptic-guided intubation was performed as a third attempt. When tracheal intubation was unsuccessful, it was performed by direct laryngoscopy and considered as failed intubation. Rest of the anesthesia management was as per the discretion of attending anesthesiologists. The success rate of device insertion, fiberoptic score of glottis view, tracheal intubation via FT-LMA or Aura-i and time were recorded.

Results: Both FT-LMA and Aura-i were successfully placed within two attempts. The success rate of blind intubation was 92% in FT-LMA and 76% in Aura-i ($P < 0.01$). Time taken for tracheal intubation at first attempt was lesser in group FT-LMA and Aura-i, respectively ($P < 0.01$). Fiberoptic-guided intubation success rate was higher with Aura-i than with FT-LMA.

Conclusions: FT-LMA had a higher success rate in facilitating blind tracheal intubation compared with Ambu Aura-i.

Keywords: Ambu Aura-i, Fastrach™-LMA, intubation

Introduction

Supraglottic airway devices (SADs) play a critical role in the airway management.[1] In the event of unexpected failure to intubate, the American Society of Anesthesiologists (ASA), Difficult Airway Society (DAS), and Obstetric Anaesthetists' Association and DAS guidelines recommends the use of SADs as conduit for tracheal intubation.[1-3] The Fastrach™-laryngeal mask airway (FT-LMA, Laryngeal Mask Company, Jersey, UK) was designed to provide both ventilation and ability to pass a tracheal tube blindly into the trachea.[4,5] There are many reports of successful intubation, both in anticipated and unanticipated difficult airways,[6,7] and blind tracheal intubation in majority of cases.[6-8] But

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FT-LMA has certain limitations, i.e., rigidity of its airway tube precludes prolonged use, and it requires a special and expensive tracheal tube. Finally, it is not available in pediatric sizes.

The Ambu® Aura-i™ (Aura-i, Ambu USA,) is single-use intubating SAD, also designed for both ventilation and as a conduit for tracheal intubation.[9] 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, even in patients with anticipated difficult airways,[10-13] and manikin study showing the utility of intubating supraglottic devices (SADs).[14,15]

Detailed literature research revealed that there was not much data available on assessment of tracheal intubation with Aura-i. Hence, the present study was conducted to compare the success of tracheal intubation using FT-LMA and Aura-i in adult patients.

Material and Methods

After approval by the Institutional Ethics Committee, 100 ASA physical status I and II patients, aged 18--60 years, scheduled to receive general anesthesia were included. Written consent was obtained from all the patients. The patients with history of upper respiratory tract infection, or who were at an increased risk of gastric aspiration, i.e., the patient with a history of obesity, hiatal hernia, gastroparesis, pregnancy or trauma, with known or predicted difficult airway such as MPG III or IV, mouth opening of <2.5 cm, BMI >35 $kg.m^{-2}$, or allergic to any drugs in the protocol, were excluded from the study.

The study design was prospective, randomized, and controlled. Using computer-generated random number table, patients were randomly allocated to either Group I (FT-LMA, n = 50) or Group II (Aura-I, n = 50). Allocation concealment was done using sequentially numbered coded opaque sealed envelopes.

An appropriately sized FT-LMA or Aura-i was chosen according to the manufacturer's recommendations based on weight (size 3 for patients weighing 30--50 kg, size 4, 50--70 kg, and size 5 more than 70 kg). A conventional polyvinylchloride (PVC) tracheal tube was used for tracheal intubation in both groups (size 7.5–8 mm ID tracheal tubes for patients weighing ≥50 kg and 6.5--7.5 mm ID tubes for patients <50 kg). Both the SADs were prepared for insertion with cuff deflated completely and dorsal surface lubricated with a water soluble jelly.

Standard monitoring of continuous ECG, heart rate (HR), noninvasive blood pressure (NIBP), and oxygen saturation (SpO2) was started before induction of anesthesia. After obtaining intravenous (IV) access, glycopyrrolate 0.2 mg was administered. Standard anesthesia technique was used for all patients. After preoxygenation, anaesthesia was induced with fentanyl 2 μg kg^{-1} and propofol 2.0--2.5$mg.kg^{-1}$ intravenously. After checking for ability to achieve adequate mask ventilation, vecuronium 0.1 $mg.kg^{-1}$ was used to facilitate muscle relaxation. When neuromuscular block was complete, the randomly assigned FT-LMA or Aura-i was inserted.

In group I, a FT-LMA was held with its handle parallel to the patient chest, and then mask was inserted into the patient's mouth with circular movement maintaining contact against palate and posterior pharynx. The mask was advanced till resistance was felt. Once in place, the cuff was inflated with air to the optimum intracuff pressure of 60 cm H_2O using the hand held cuff manometer (VBM Medizintechnik GmbH, Germany) and ventilation was attempted. An effective airway was defined by the presence of normal chest expansion and a square-wave capnograph trace. If lung ventilation remained unsuccessful, the manipulation of FT-LMA was done in the sagittal plane till optimal ventilation was established. Once satisfactory ventilation was observed, fiberoptic scoring (Grade 4 = only vocal cords visible; Grade 3 = vocal cords plus posterior epiglottis visible; Grade 2 = vocal cords plus anterior epiglottis visible; Grade 1 = vocal cords not visible) for glottis view was noted.[15] Then, a well-lubricated PVC tracheal tube of appropriate size was inserted through the airway tube of FT-LMA. If no resistance was felt while advancing the tracheal tube, it was fully inserted into the device and tracheal tube cuff was inflated. Tracheal intubation was successful if ventilation through the tracheal tube produced an adequate chest expansion and a square-wave capnograph trace. After removing the tracheal tube connector, the FT-LMA was removed by gently pulling out using smaller-sized (5.0 mm ID cuff) tracheal tube as stabilizing rod to keep tracheal tube in place. If the first attempt failed during tracheal tube insertion, the maneuver lifting the FT-LMA from the posterior pharyngeal wall using the metal handle was used for intubation.[8]

In group II, the Aura-i airway tube was held with three fingers on flat part of connector shell and thumb on vertical line on connector shell (pencil insertion technique). The tip was inserted inside the mouth with circular movement maintaining contact against palate and posterior pharynx. The mask was advanced till resistance was felt and incisors of the patient placed between the two horizontal lines on the airway tube.

Once Aura-i properly was placed, rest of the procedure of cuff inflation, fibreoptic scoring, and intubation was done in FT-LMA group. If the first attempt failed during tracheal intubation, the maneuver head extension and backward upward thyroid pressure used and intubation attempt was made.

In both study groups, three attempts for intubation were allowed. First attempt for tracheal intubation attempt was a blind, second attempt was made with maneuver. If second attempt of intubation was unsuccessful, fiberoptic-guided intubation was performed as a third attempt. When tracheal intubation was unsuccessful, it was performed by direct laryngoscopy and was considered as failed intubation. Lung ventilation through the SAD was permitted between intubation attempts. Rest of the anesthesia management was as per the discretion of attending anesthesiologists. The following observations were recorded in all the patients:

- The success rate of insertion of FT-LMA or Aura-i to achieve adequate ventilation
- Fiberoptic scoring of vocal cords and epiglottis view
- The success rate of blind and fiberoptic tracheal intubation through each device.

The following times were recorded by an observer using a stop watch: Firstly, the insertion time of the FT-LMA or Aura-i from the removal of the face mask until the appearance of the capnograph waveform. Secondly, the insertion time of the tracheal tube from the disconnection of the breathing circuit from SAD until the appearance of the capnograph waveform, if there was a second or third attempt (fiberoptic guided) time recorded separately. Thirdly, time for removal of the SAD from the disconnection of the breathing circuit until the appearance of the capnograph waveform after tracheal tube intubation.

The heart rate, systolic, and diastolic blood pressures were recorded at baseline, after induction and SAD insertion, 1, 5, and 10 min after intubation. Complications such as trauma to the airway were noted by blood on the device during its removal, sore throat was graded to mild, moderate, and severe by asking patients in the post-anesthesia care unit.

Our sample size was based on pilot study and on the results of previous study, the first attempt success rate of tracheal intubation with FT-LMA varies between 48--87%.[6,16,17] Considering a mean first attempt success rate of 65%, and to detect a 25% difference in intubation success rate between both SADs, sample size was calculated to be 43 patients per group at a power of 80% and confidence interval of 95%. A sample size of 50 patients per group was chosen to allow for potential patient dropouts.

The statistical analysis was carried out using Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, version 15.0 for Windows). Mean and medians were calculated for all quantitative variables and measures of dispersion standard deviation or standard error was calculated. Normality of data was checked by measures of Kolmogorov Smirnov tests of normality. For normally distributed data, means were compared using *t*-test. For skewed data or for ordinal data, Mann–Whitney test was applied. Qualitative or categorical variables were described as frequencies and proportions. Proportions were compared by using Chi-square or Fisher's exact test, whichever was applicable. For comparison of hemodynamics variables, repeated measure ANOVA was applied. All statistical tests were two sided and were performed at a significance level of $\alpha = 0.05$.

Results

CONSORT flow diagram of the enrolled patients has been provided in Figure 1. The demographic data were found to be comparable in both groups [Table 1]. All the study devices were successfully placed within three attempts. The success rate of the first attempt insertion was comparable in group I and II. The time taken for insertion of SAD was also comparable [Table 2].

Fiberoptic score was 4, 3, 2, 1 in 13 (26%), 18 (36%), 14 (28%), and 5 (10%) in FT-LMA group and 20 (40%), 26 (52%), 3 (6%), 1 (2%) patients in Aura-i group, respectively. The success rate of blind tracheal intubation after two attempts through FT-LMA was 46 (92%) as compared with 38 (76%) through Aura-i ($P < 0.01$). The time taken

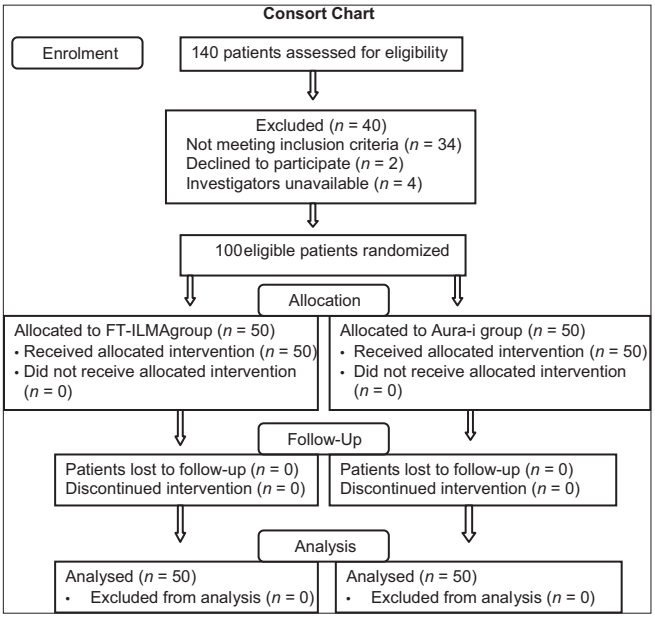

Figure 1: Consort Chart

for insertion of the tracheal tube at first attempt and time taken for insertion of tracheal tube in third attempt (fiberoptic guided) was shorter in group 1. The time for removal of SADs after tracheal intubation was also shorter in group I [Table 2].

The heart rate, and blood pressure measured at different points of time was comparable in the two groups ($P < 0.05$).

There were no significant differences in the incidence of sore throat in FT-LMA and Aura-i 4 groups, and there was evidence of visible blood on FT- LMA in 2 (4%), whereas in the Aura-i it was 1 (2%). No other complication was observed in both the groups.

Discussion

The results of our study demonstrated that the successful blind endotracheal intubation was more in the FT-LMA group than those of the Aura-i group. Mean time taken for tracheal tube insertion and subsequently SAD removal was less with FT-LMA group. In addition, it was observed that insertion time of FT-LMA and Aura i, success rate, and adequacy of ventilation was similar in both the groups. However, the fiberoptic view score was better in Aura-i group. No significant differences were found with respect to hemodynamics, incidence of sore throat, and visible blood on device among the two groups.

In the present study, all FT-LMA and Aura-i were successfully placed in two attempts, and first attempt success was comparable in the two groups. Our results for FT-LMA are similar with success rate depicted in earlier studies, i.e between 95--100%[15,16,18] and for Aura-i between 96--100%.[14,17] The time taken to successful FT-LMA/Aura-i placement in our study was comparable in the two groups. Joo *et al.* reported increased airway insertion time for FT-LMA than time taken in our study.[15] Altamirano *et al.* observed the time for placement of the SAD in Aura-i group and FT-LMA group to be 27.9 ± 11.6 and 31.8 ± 14.5 sec, respectively.[17] This was slightly more than in our study.

Several clinical studies confirmed the efficacy of FT-LMA as a conduit for tracheal intubation with success rate >95%.[7,19,20] When other intubating SADs including Air-Q and i-gel were compared with FT-LMA, success rate varied widely 40--94%.[20-22]

Ambu Aura-i is a single-use (disposable) intubating SAD and no randomized control trial is available for comparison with our results. The success rates of blind intubation were 92% through FT-LMA, and 76% through Ambu Aura-i. The success rate of blind intubation through Ambu Aura-i was 42% and 34% in first attempt and second attempt with maneuver, respectively. Our results are also comparable to a study conducted by Karim *et al.* who compared FT-LMA and Air-Q for blind intubation in 154 patients.[19] They reported success rate of 99% with FT-LMA and 77% with Air-Q for blind intubation. Further, Air-Q and FT-LMA were compared in 160 patients by Neoh EU *et al.* and they showed that blind tracheal intubation through Air-Q was possible in 75% within three attempts.[23]

Table 1: Demographic characteristics (mean (SD) or number (%))

	Group I (FT-LMA) *n*=50	Group II (Aura-i) *n*=50	*P*
Age (years)	40.7±10.6	42.1±12.5	0.565
Sex (F/M)	30 (60)/20 (40)	35 (70)/15 (30)	0.295
ASA* I/II	94/6	90/10	0.89
Weight (kg)	62.3±9.3	62.8±11.4	0.788
Height (cm)	161.9±7.3	161.7±6.7	0.864
BMI† kg/m^2	23.8±3.7	23.5±5.5	0.799

**ASA=American Society of Anesthesiologists, †BMI=Body Mass Index*

Table 2: FT-LMA and Aura-i parameters (mean (SD) or number (%))

	Group I	Group II	*P*
*SAD Insertion 1st/2nd attempt	47 (94)/3 (6)	49 (98)/1 (2)	0.30
*SAD Insertion time (Sec)	21.9±5.8	20.4±4.7	0.17
Tracheal Tube insertion attempts,			
1st attempt	31 (62)	21 (42)	0.01
2nd attempt	15 (30)	17 (34)	0.05
3rd attempt (Fiberoptic)	3 (6)	15 (30)	0.001
Failure	1 (2)	2 (4)	0.05
Tracheal Tube insertion time (Sec),			
1st attempt	19.0±4.5	23.1±5.9	0.01
2nd attempt	22.4±3.1	22.4±5.1	0.97
3rd attempt (Fiberoptic-guided)	31.3±2.9	34.3±2.7	0.07
SAD removal time (After intubation)	21.9±3.9	24.4±4.3	0.01
Blood on SAD	2 (4)	1 (2)	-
Sore throat, number (%)	4 (8)	5 (10)	-

**SAD=Supraglottic airway device*

Badawi *et al.* compared Air-Q and FT-LMA for blind tracheal intubation in 170 adult patients and reported total success rate in two attempts of 94.12% with Air-Q, whereas 96.47% with FT-LMA.[20] However, this difference was not statistically significant. The first attempt success rate was 81.18% in Air-Q, whereas it was 82.35% in FT-LMA. They used the extension of the head with cricoid pressure to increase the success of blind intubation. In the present study, 30% in group I and 34% in group II patients needed certain maneuver for tracheal intubation. Different maneuvers have also been suggested by Kundra *et al.*, Lu *et al.*, Brain *et al.* and Badavi *et al.*[5,17,18,20]

Fiberoptic scoring is used as a measure of anatomic position of SAD and higher scores may be associated with an improved seal, reduced work of breathing, and easier intubation. The fiberoptic grading was found to be better in Aura-i as compared with FT-LMA group. Abdel-Halim TM *et al.* who compared air-Q and FT-LMA as conduit for fiberoptic intubation, concluded that Air-Q is an excellent conduit for tracheal intubation.[24] Fiberoptic-guided intubation was used in our study as third attempt, which increased the success rate to 98% in the FT-LMA and to 96% in Aura-i. The reason for better fiberoptic view in Aura-i is absence of epiglottic elevator bar. Epiglottic elevator bar in FT-LMA could potentially interfere with fiberoptic view because of its central location and by causing the scope to deviate from the midline. The other cases were failure and it may be because of improper insertions or inadequate size of supraglottic airway.

Recently, de Lloyd *et al.*[25] compared the three intubating SAD, Aura-i, FT-LMA, and i-gel as conduits for fiberoptic-guided tracheal intubation in a randomized and crossover manner in a manikin study and concluded that the Aura-i does not perform well as compared with FT-LMA or the i-gel as an adjunct for performing fiberoptic-guided tracheal intubation. They explained the lower success rate with Aura-i because of the flatter angle of exit at distal portion, which may result in the tracheal tube leaving fiberscope more posteriorly and directing towards the esophagus, as compared with FT-LMA and i-gel, which have an elevated exit course. In contrast to above, a manikin study compared four intubating SADs, Aura-i, Air-Q, i-gel, and FT-LMA for success of insertion, ventilation, and blind intubation during cardiopulmonary resuscitation. They revealed high success rates and adequate ventilation with use of above SADs for airway management during chest compression.[14] However, this proposed explanation and results need further evaluation.

The successful intubations have also been reported using Ambu Aura-i in patients with anticipated difficult airways.[10,11] Jagannathan *et al.* compared Ambu Aura-i with Air-Q for fiberoptic-guided tracheal intubation in childern and concluded that both devices served as effective conduits for fiberoptic-guided tracheal intubation.[13]

The mean time taken for tracheal intubation (during first, second, and third attempt individually) was less in FT-LMA group. The fiberoptic-guided intubation required more time than blind intubation in both the groups. Our results are in accordance with Altamirano *et al.*[17] and de Lloyd *et al.*[25] where fiberoptic-guided tracheal intubation required less time in FT-LMA compared with Aura-i group. The time taken for removal of Ambu Aura-i after intubation was more. It is also recommended that Ambu Aura-i can be kept throughout the surgical procedure *in situ* as compared with FT-LMA that needs to be removed after intubation. It may exert pressure on the pharyngeal mucosa and can cause trauma to oropharyngeal soft tissue.

The hemodynamic parameters including heart rate and blood pressure measured at different point of time were comparable between the two groups. However, heart rate and blood pressure increased after tracheal intubation in both the groups compared with their preinduction value. Zhang *et al.* compared hemodynamic responses to orotracheal intubation with FT-LMA and direct laryngoscopy showed that pressure and tachycardiac responses were similar during tracheal intubation.[26] This illustrates the fact that intubation via SADs causes pressure and tachycardiac responses by stimulating the epiglottis and periepiglottic structures similar to direct laryngoscopy and tracheal intubation.

Our study has several limitations. Firstly, and for obvious reasons, the anesthesiologist involved was not blind to the type of intubating SAD used; this can be a possible source of bias. Secondly, the obese patients of BMI >35 kg m^{-2} with difficult airway were excluded in the study. In the absence of clinical studies, considering the device as safe we included patients with normal airways only.

Conclusion

It is concluded that FT-LMA is a better option for blind tracheal intubation as it had higher success rate in facilitating blind tracheal intubation as compared with Ambu Aura-i. However, fiberoptic-guided intubation success rate was more with Ambu Aura-i. Thus, it may be another cheaper and easily accessible option for ventilation as well as a conduit for tracheal intubation with the aid of fiberoptic bronchoscope.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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