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Evaluation of Ambu-Aura-i laryngeal mask as a conduit for endotracheal intubation. A comparison with Air-Q intubating laryngeal airway in adult surgical patients

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ABSTRACT

Background: Supraglottic airway devices (SGA) are used as primary devices or conduits for endotracheal intubation with normal or difficult airway. The purpose of this study was to assess how the Ambu-Aura-i laryngeal mask would act as a conduit for endotracheal intubation compared to the Air-Q Intubating Laryngeal airway in adult patients in operating room.

Methods: Fifty-four adult patients scheduled for elective procedures under general anaesthesia were divided into air-Q and Aura-i groups. The ease and time of insertion, the number of insertion attempts, the airway leak pressure, the duration of fiberoptic endotracheal intubation, the grade of the fibre-optic laryngoscopic view, and the time to remove the device were noted.

Results: Comparing the Aura-i group to the Air-Q group, the Aura-i group had a considerably shorter insertion time and a longer time to remove the device (28.1 ± 3.5 vs 32.7 ± 6.9 sec P-value = 00.4 and 40.7 ± 5.1 vs 32.0 ± 5.4 sec, P-value = 0.001; respectively). Both devices were comparable regarding the number of insertion attempts and the time to insert an endotracheal tube. Compared to the Air-Q group, the Aura-i group's airway leak pressure was considerably greater (25.9 ± 3.9 vs 23.4 ± 4 CmH2O, respectively, P-value = 0.03). Both groups had comparable fibre-optic laryngoscopic view grades.

Conclusion: The Ambu-Aura-i laryngeal mask and the Air-Q intubating laryngeal airway are efficient conduits for fibre-optic endotracheal intubation in adults with Ambu-Aura-i Laryngeal mask exhibiting advantages in terms of device insertion time and use during mechanical ventilation.

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1. Background

Supraglottic airway devices (SGA) are frequently utilised during airway management, when difficult intubation is suspected or with normal airways. SGA can be used as endotracheal tube (ETT) conduits or first-line airway equipment [1–3]. The current guidelines for managing the difficult airway include SGA as a key component [4].

The Air-Q intubating laryngeal airway (ILA) is a SGA that functions similarly to the conventional laryngeal mask airway (LMA). It stands out for having a broader and shorter airway tube with a detachable airway connector and stylet that allows the insertion of an appropriate-sized ETT. The device outlet is fashioned like a keyhole and lacks the epiglottic elevating bars [5,6]. The Air-Q ILA has been employed in adult [5] and paediatric [6] populations as a first-line airway equipment during anaesthesia [7,8] and as a conduit for ETT.

Another SGA with unique benefits over its rivals is the Ambu-Aura-i laryngeal mask (LM). The device, according to its manufacturer's manual, has a unique design that resembles the human upper airway structure precisely through a built-in curve. This curve is molded directly into the airway to facilitate and speed up the insertion. The device can be utilised as a primary airway and as an intubation conduit. The device's strengthened tip plugs the upper oesophageal sphincter and prevents folding during insertion. Additionally, the bite resistance in the connector block prevents its occlusion. The Ambu-Aura -i LM, in the paediatric population, has been shown to be an efficient conduit for endotracheal intubation [9], although a paucity of research has examined its performance in adults [10].

This study's goal was to assess how well the Ambu-Aura-i LM and air-Q ILA performed as conduits for adult fiberoptic-guided endotracheal intubation. The study proposed the Ambu-Aura-i LM as a possible Air-QTM ILA alternative. The time exerted for an ETT to be inserted through the device under fibre-optic guidance was the primary outcome. The duration and ease of the device insertion, the number of successful and unsuccessful insertion attempts, the airway leak pressure, and the duration of device removal were the secondary outcomes.

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2. Methodology

This randomized comparative study has been conducted in Cairo University hospitals after being approved by the Research Ethics Committee of Kasr Alainy Faculty of Medicine, Cairo University (ID: *N*-46-20 December 201414; email kasralainirec@gmail.com). The study was registered on ClinicalTrials.gov (NCT02226211) in August 2014 before any patient enrollment. Written informed consent was obtained from all patients. We followed the Consolidated Standards of Reporting Trial (CONSORT) guidelines.

Fifty-four adult patients aged 18–60, with ASA classification I and II, who were scheduled to receive general anaesthesia (GA) for elective surgical procedures, were included in this trial. The study excluded patients with a history of cardiovascular morbidity, gastro-oesophageal reflux disease, aberrant airway morphology, or a body mass index (BMI) > 30 kg/m2.

All patients were instructed to fast for at least six hours. Upon entering the operating room, an IV access was put in place, and a Ringer acetate solution was started. Standard monitoring was set up, including non-invasive blood pressure monitoring, electrocardiography (ECG), and pulse oximetry (NIBP). Baseline measurements of mean arterial pressure (MAP), heart rate (HR), and oxygen saturation (SaO2), were taken as T0. To maintain the patient's head in a neutral position, a silicon headrest was used. Then, patients were divided into the air-Q and Aura-i groups using computergenerated random numbers.

Per the manufacturer's guidelines, the SGA's ideal size was determined. Therefore, size 3.5 for women and 4.5 for men were used for the Air-Q ILA. With the Ambu-Aura-I LM, size four was utilised for patients weighing 50–70 kg, size five for those weighing 70–100 kg, and size six for those weighing more than 100 kg. The selected SGA was prepared by lubricating its front and back with a water-soluble lubricant and checking its cuff. For three minutes, 100% oxygen was used to pre-oxygenate all patients. Fentanyl 2 mg/kg with propofol 2 mg/kg and atracurium besylate 0.5 mg/kg were used to induce GA intravenously. Until the patient relaxed (TOF on the nerve stimulator revealed the disappearance of T1, i.e., 0/4), the lungs were ventilated with 1% isoflurane in 100% O2. The midline insertion method with jaw lift was used to insert both devices; then, the cuff was inflated according to the manufacturer's instructions. The proper device position was indicated by bilateral chest auscultation with a tidal volume of at least 5 ml/kg and the appearance of consecutive square waves on the capnogram after delivering positive pressure breaths. The airway leak pressure was monitored with the expiratory valve closed until noise could be heard over the patient's mouth, and a fresh gas flow of 3 L/min was adjusted. The airway pressure was not permitted to rise over 40 cm H2O [11]. The number of insertion attempts was recorded. Device insertion difficulty was divided into three categories: easy (successful placements after the first attempt), moderate (successful placements after the second or third attempts), and difficult (Failed to obtain an adequate airway after three attempts) [12]. The duration from taking off the face mask until the chest rose following two consecutive positive pressure manual breaths was noted as the time for device insertion (T1).

Flexible fiberoptic bronchoscopy was used to intubate the patient after the SGA was inserted (Karl Storz-2.8 mm external diameter- Germany). The breathing circuit disconnected from the device, and the proper-sized ETT was loaded over the fiberoptic bronchoscope. The connector was likewise taken out in the case of the Air-Q LMA. The bronchoscope was inserted and advanced through the airway tube to just proximal to the ventilation orifice; the fibre-optic view describing the relationship between the device orifice and the laryngeal opening was captured as a video and saved on a CD for later grading by a third party using a grade of 1–5. (Table 1) [13]. The fiberoptic was then advanced till the carina was seen to glide the ETT into the trachea. Chest auscultation and capnogram waves were used to confirm that the intubation was successful. The duration from disconnecting the breathing circuit from the SGA until reconnecting it to the ETT with the appearance of the first wave on the capnogram was referred to as a time for tracheal intubation (T2).

Once intubation had been confirmed, the device was withdrawn using a removal stylet for the Air-Q ILA or another ETT for the Ambu-Aura-i LM per the manufacturer's instructions. The period between the breathing circuit was disconnected from the inserted EET and reconnected to the ETT with the appearance of the first capnogram wave was referred to as the time for device removal (T3). An assisting nurse documented all T1, T2, and T3 durations.

One of the following factors led to the patient's exclusion from the trial and procedure failure: 1) After three attempts, the SGA device could not be inserted

Table 1. Grading of the fibre-optic view of the larynx: [13].

Grade:	Description
Grade 1	The larynx is only seen.
Grade 2	The larynx and posterior surface of the epiglottis are seen.
Grade 3	The larynx and the epiglottic tip of the anterior surface are seen (<50% visual obstruction of the epiglottis to the larynx).
Grade 4	The epiglottis is downfolded, and its anterior surface is seen (>50% visual obstruction of the epiglottis to the larynx).
Grade 5	The epiglottic downfolded and larynx cannot be seen directly.

appropriately. 2) After two attempts, the fiberoptic bronchoscope could not successfully intubate the trachea. 3) ETT dislodging during device removal.

During the procedure, HR, MAP, SaO2, and end-tidal CO2 (ETCO2) were recorded one minute after; induction (T1), device insertion (T2), ETT insertion (T3), and device removal (T4). The complications were also documented, including aspiration, laryngospasm, bronchospasm, and oxygen desaturation (SaO2 92%), as well as blood drop on the device following removal.

3. Sample size

In a previous study, the endotracheal intubation time through an Air-Q ILA was 33.5 +6.79 seconds (12). We assumed a difference of 10 seconds in the intubation time between both devices, the sample size required was 46 patients (23 per group) with an alpha error of 5% and a selected study power of 80%. The number was increased to 54 participants (27 per group). The G-power 3.1.9.2 program was selected to calculate this sample size.

4. Statistical analysis

Utilising SPSS version 23 from the Science software, statistical analysis was carried out (Chicago, IL, USA). Means and standard deviations (SD) or a median and range were used to express continuously quantitative normally distributed data. The % format was used to express qualitative category data. To ascertain whether the data's distribution was normal, the Kolmogorov-Smirnov and Shapiro-Wilk tests were utilised. The Mann-Whitney test or the Kruskal-Wallis test, as appropriate, was used to compare non-normally distributed data, whereas the Student's t-test was used to compare regularly distributed data. The Chi-square test or Fisher's exact test was used to compare categorical data. Hemodynamic variations over time were compared using analysis of variance (ANOVA) with repeated measures and post-hoc Bonferroni adjustment. Statistical significance was defined as a p-value less than 0.05.

5. Results

Fifty-four adult patients were enrolled in this study and divided randomly into two groups (27 per group); the Aura-i and the Air-Q. Due to unsuccessful insertion in one patient and EET dislodgment during device removal in the other patient, two cases were excluded from the Aura-i group. In addition, two cases in the Air-Q group were excluded due to unsuccessful device placement (Figure 1), leaving fifty patients (25 in each group) for the study. Patient demographic data are displayed in (Table 2). Comparing the Aura-i group to the Air-Q group, the Aura-i group had a considerably shorter insertion time and a longer time to remove the device (28.1 ± 3.5 vs 32.7 ± 6.9 sec P-value = 00.4 and 40.7 ± 5.1 vs 32.0 ± 5.4 sec, P-value = 0.001; respectively). Both devices were comparable regarding the number of insertion attempts and the time to insert an ETT. Compared to the Air-Q group, the Aura-i group's airway leak pressure was considerably greater (25.93.9 vs 23.44 cmH2O, respectively; P-value = 0.03). The fibre-optic vision grading showed no statistically significant difference between the two groups. (Table 3) In all time frames, the HR and MAP of the two groups were comparable (Figure 2). Regarding the SaO2 and ETCO2, there have been no notable differences between the two groups. When the device was removed, there was blood-tinged saliva on two devices in the Aura-i group and three in the Air-Q group. In neither group were any instances of desaturation, laryngospasm, bronchospasm, or aspiration noted.

6. Discussion

The study's key finding was that the Ambu-Aura-i LM could be a good alternative to the Air-Q ILA. The Ambu-Aura-i LM provided a faster insertion time and a higher airway leak pressure than Air-Q ILA. In addition, For the fiberoptic laryngoscopic view and the fiberoptic EET insertion, both devices offered comparable performance.

A growing number of non-invasive SGA are now available to handle challenging airway situations. For example, intubating laryngeal masks and their generations and modifications are practical tools for tracheal intubation and patient ventilation. The Air-Q ILA and Ambu-Aura-i LM are examples of these devices which are frequently used, many anaesthetists and studies have approved their efficiency, but still, a paucity of studies handled the performance of Ambu-Aura-i LM compared to these other devices. Our study compared the Air-Q ILA versus Ambu-Aura-i LM as a conduit for tracheal. intubation in healthy adult patients scheduled for elective surgeries under GA. Ambu Aura-i showed a significantly shorter insertion time and longer removal time compared to the Air-Q. In addition, the airway leak pressure was significantly higher in the Aurai group compared to the Air-Q one, while both devices were comparable regarding the number of insertion attempts, the fiberoptic laryngoscopic view, and the fiberoptic EET insertion time.

A study by SK Malhotra et al. [14], who compared Air-Q versus the Intubating Laryngeal Mask Airway-Fastrach (ILMA-Fastrack) as conduits for blinded endotracheal intubation, revealed a higher success rate for EET insertion with the Air- Q. Another study by Mishra N et al. [15] compared Ambu-Aura-i LM versus ILMAFastrack regarding the intubation characteristics and the fiberoptic guided EET insertion in healthy adult patients subjected to elective surgeries; the authors

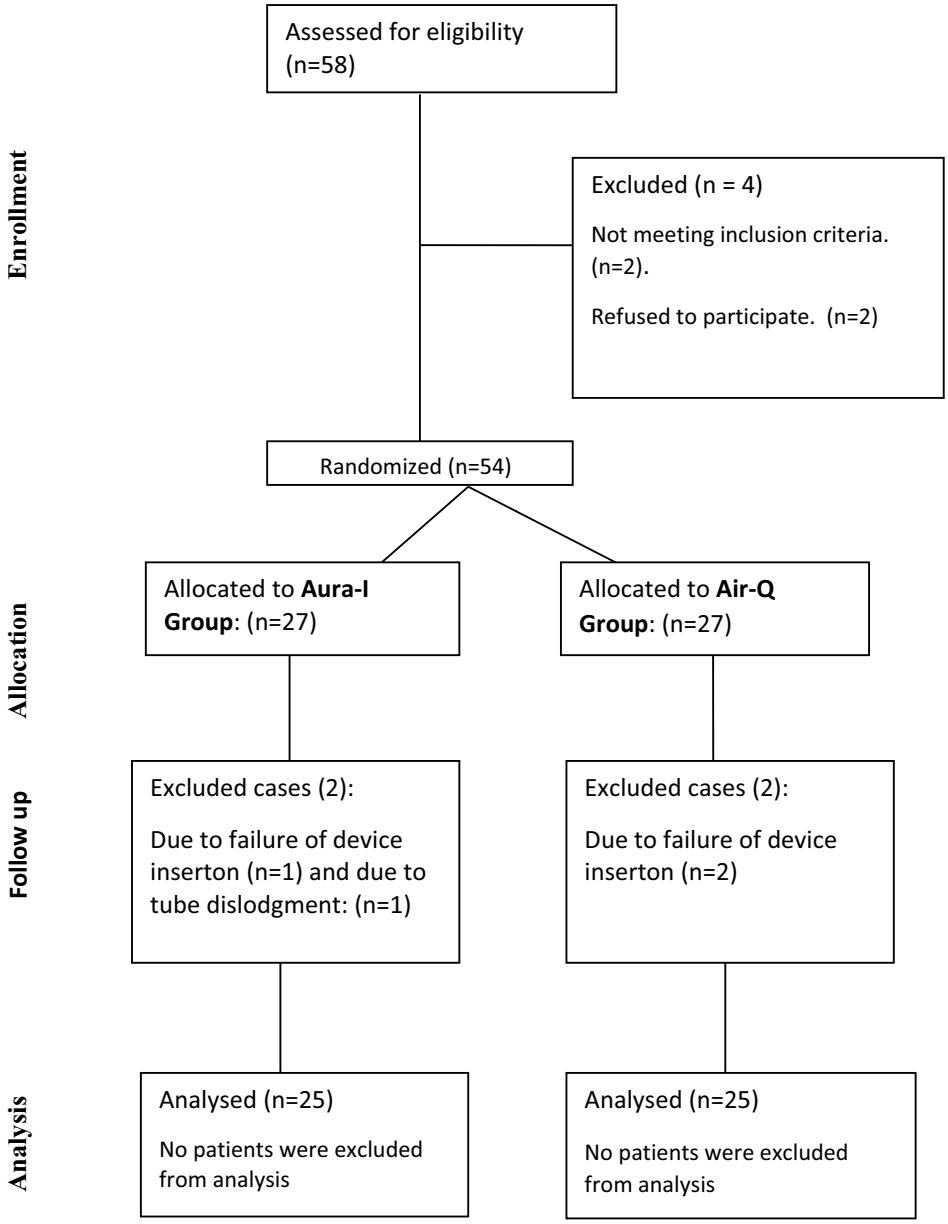

Figure 1. Participants' flowchart.

Table 2. Patients' demographic data.

	Aura-i group ($n = 25$)	Air-Q group ($n = 25$)	*P* value
Sex Male/females	14/11	12/13	0.22
Age (years)	34.2 ± 7	29.7 ± 13.5	0.14
Wight (kg)	81.6 ± 8.9	76.6 ± 9.8	0.07
ASA I/II	19/6	18/7	0.35

Data are expressed as mean ± SD or ratio. *P* value 0.05 is statistically significant.

concluded that the Ambu-Aura-i provided a faster insertion time with a comparable fiberoptic EET insertion time compared to ILMA-Fastrack. Another study by Anand L et al. [16] has compared the Ambu-Aura-i with the ILMA-Fastrack as conduits for EET insertion in healthy adult patients who underwent elective surgeries. The authors found a higher success rate for blinded ETT insertion with ILMA-Fastrach, while the success rate of the fiberoptic-guided EET insertion was higher with the Ambu-Aura-i.

Zhi Juan et al. [17] compared Ambu Aura-i LM with the Air Q ILM as conduits for fibre-optic guided EET insertion. The study included 120 children who were scheduled for elective auricular reconstruction surgeries. The authors found a shorter insertion time and a higher leak pressure with the Ambu-Aura-i compared to the Air-Q. Nevertheless, the authors concluded that both airways are effective conduits for fibreoptic tracheal intubation with fewer complications, especially the Ambu Aura-i. Another study was performed on

Table 3. Device placement characteristics of both devices.

	Aura-i group ($n = 25$)	Air-Q group ($n = 25$)	*P*-value
Time for device insertion T1 (sec):	28.1 ± 3.5	32.7 ± 6.9	0.004
The number of insertion attempts:			
First	23	20	0.9
Second	2	4	0.2
Third	0	1	0.5
Airway leak pressure (CmH_2O	25.9 ± 3.9	23.4 ± 4	**0.03**
Time for tracheal intubation T2 (sec):	61.6 ± 18.2	53.8 ± 19.9	0.2
Time for device removal T3 (sec):	40.7 ± 5.1	32.0 ± 5.4	**0.001**
Grading of the FO view of the larynx: (value and %)			
Grade 1	4 (16%)	2 (8%)	0.4
Grade 2	13 (52%)	12 (48%)	0.7
Grade 3	7 (28%)	8 (32%)	0.8
Grade 4	1 (4%)	3 (12%)	0.3
Grade 5	0	0	1

Data are expressed as mean ± SD, absolute values, or ratios. A *p*-value of 0.05 is statistically significant.

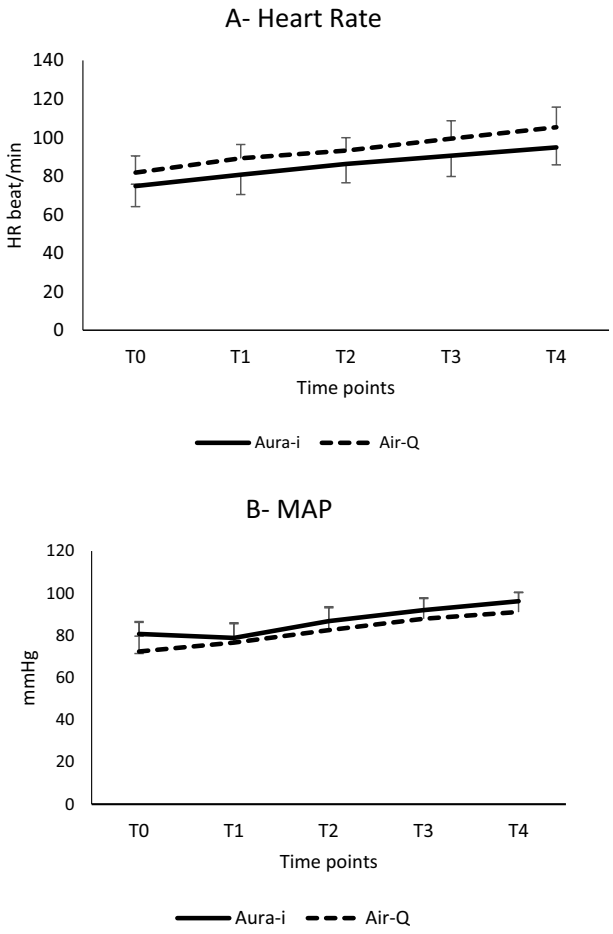

Figure 2. Both groups' heart rate (HR) and mean arterial pressure (MAP).

pediatric patients aged one month to six years by Jagannathan N et al. [9]; which compared Ambu-Aura-i versus Air Q as conduits for fiberoptic-guided endotracheal intubation. The authors stated that both devices were comparable concerning the time needed for successful intubation and the fiberoptic grading of the laryngoscopic view. In addition, the authors found a higher airway leak pressure with the Air Q, but without any statistically significant differences.

In agreement with our results, Mishra N et al. [15] observed a significantly shorter Ambu Aura-i insertion time when compared to ILMA-Fastrach, a finding which was also observed by Darlong V et al. [18] in a study compared Air Q and Ambu-Aura-i in 64 infants weighing<10 kg who were scheduled for elective ophthalmic surgery. On the contrary, Darlong V et al. [18] noted a significantly higher airway leak pressure and concluded that Air Q might be better than Ambu-Aura-i for controlled ventilation in infants.

Our results revealed that the Ambu-Aura-i LM had a significantly longer removal time than the Air Q ILA. Similarly, Anand L et al. [19] demonstrated that more time was needed to remove the Ambu-Aura-i than ILMA-Fastrack, but without significance. While Jagannathan N et al. [9] revealed no statistically significant difference in the removal time of the Ambu-Aura-I LM and the Air Q ILA after intubating 120 children. According to our research, the Ambu-Aura-i LM and Air Q ILA had comparable insertion success rates and complications, an outcome also disclosed by both Jagannathan N et al. [9] and Darlong V [19] in their studies comparing both devices in paediatrics.

This study has some limitations, as we only included healthy adult patients with normal airways and a BMI of less than 30 kg/m2; our findings cannot be generalised to include obese or geriatric patients, patients with suspected difficult airways, and patients undergoing obstetrics or emergency procedures.

7. Conclusion

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 LM having an advantage in terms of device insertion time and use for mechanical ventilation because of its higher airway leak pressure.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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