A Comparative Study of Ambu Aura-i and Air-Q Supraglottic Airway Devices as Conduit for Blind Tracheal Intubation in Patients with Normal Airway

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Abstract		

Background: Aim: To compare Ambu Aura-i and Air-Q supraglottic airway devices (SAD) as conduit for blind tracheal intubation in terms of First attempt and Over-all success rate. **Subjects and Methods:** A total of 176 consenting patients of ASA grade I/II, undergoing elective surgery under General Anaesthesia, requiring endotracheal intubation, were randomised into two groups of 88 each as Group I (Ambu Aura-i) and Group Q (Air-Q ILA). After induction of Anaesthesia, allocated device was inserted, Cuff was inflated, and device was checked for adequate ventilation. Appropriate size PVC endotracheal tube was inserted through SAD. The correct placement was confirmed by capnography and chest auscultation. The SAD was removed with the help of stabilizing rod. Conventional intubation using direct laryngoscopy was done in case of failure after 3 attempts. First attempt success rate and Over-all success rate of intubation derived at the end of study. **Results:** First attempt success rate of intubation was significantly more in Air-Q (21.6%) than Ambu Aura-i (9.1%) p-value= 0.036. Over-all success rate was also more in Air-Q (77.27%) than Ambu Aura-i (60.23%) p-value= 0.022. **Conclusion:** Air-Q can be considered a better conduit for blind tracheal intubation than Ambu Aura-i.

Keywords: AMBU AURA-i, AIR-Q ILA, Airway, Intubation, SAD.

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Introduction

Airway management is the most important aspect of Anaesthesia practice. Endotracheal intubation has been an age-old method of securing the airway. It prevents soiling of lungs as well as maintains proper ventilation. Traditionally endotracheal intubation was being done under direct vision using rigid Macintosh laryngoscope.^[1] But this method of intubation carries many hazards. Rigid Laryngoscopy has been found to be associated with exaggerated hemodynamic responses. There is also added risk of trauma to the airway structures due to rigid metallic blade.^[2]

Even managing difficult intubation was a problem using rigid laryngoscope. To overcome these hazards, many alternatives to this conventional technique of intubation have been developed. Different types of videolaryngoscopes, fibre-optic bronchoscope, Supraglottic airway devices (SAD), and even improved versions of rigid direct laryngoscopes (e.g., McCoy blade) have been developed and studied widely. Most of them are proved to be safer options to conventional rigid laryngoscopy. In June 1983, Dr. Archie Brain made a historic revolution in the field of airway management by inventing Classic LMA – the first supraglottic airway device to be used clinically.^[3] This was followed by development of many supraglottic devices with improved designs, used initially as a rescue airway device for ventilation, but later many were designed to be used as a conduit for intubation as well.^[4]

These SADs not only serve as a conduit for intubation, but also helps in ventilation in-between, till the tube is introduced. Fastrach LMA was the first intubating LMA (ILMA) to be developed and used successfully for intubation. But it has many limitations like high cost, rigidity of its airway tube and requirement of dedicated endotracheal tube. These limitations were overcome to some extent by development of many newer intubating supraglottic airway devices. Ambu Aura-i and Air-Q ILA are two of such devices. Ambu Aura‑ i (Aura‑ i, Ambu USA): It was introduced in 2010, and is a single‑ use intubating SAD, designed for both ventilation and to be used as a conduit for tracheal intubation. It incorporates a 90° preformed curvature designed to approximate airway anatomy. It has an integral bite block, and also has navigation marks to guide a fiberscope during intubation. Successful fibre-optic intubations have been reported using this device. Air-Q (Air-Q/ILA, Cookgas LLC, St. Louis, MO, USA): Air-Q ILA was developed by Dr. Daniel Cook and was introduced in 2004.^[5,6]

The disposable version is made up of PVC and non-disposable one is made up of silicone. Air-Q has many unique features which makes it suitable for tracheal intubation. It has a shorter shaft with an integral bite block, no aperture bars within the mask, has a removable connector so that the wide lumen of the shaft can be used for intubation, and a keyhole-shaped distal airway tube to direct a tracheal tube toward the larynx.^[7] There are three internal ridges located in the anterior part of the cuff to maintain airway stability. A study conducted by Neoh EU et al., (2012) compared Air-Q ILA and LMA-Fastrach for blind tracheal intubation and concluded that there was no difference between Air-Q ILA and LMA-Fastrach in terms of ease of insertion of device, incidence of adverse response, adequacy of ventilation, but tracheal intubation was found to be superior using the LMA-Fastrach, than with Air-Q ILA.^[8]

Till now there is no direct study available comparing Ambu Aura-i and Air-Q ILA for blind tracheal intubation. Both Ambu Aura-i and Air-Q ILA can be comparatively costeffective alternative to FT-LMA and also their ease of insertion and adequacy of ventilation is similar to FT-LMA as shown in literature. Hence, we undertook this study to compare the success rate of blind tracheal intubation using these two devices. The aim of our study was to compare Ambu Aurai and Air-Q supraglottic airway device (SAD) as conduit for blind tracheal intubation in patients with normal airway.

Subjects and Methods

This was a Prospective Randomized Clinical Study, which was carried out from October 2019 – October 2020, at Government Medical College and S. S. G. Hospital, Vadodara, after taking permission from the institutional ethical committee. The study is registered under CTRI with registration no. CTRI/2020/09/027981. A total of 176 patients of either sex, aged between 18 – 60 years, belonging to ASA physical status I and II, who were posted for elective surgery to be performed under General Anaesthesia, requiring endotracheal intubation were considered for the study.

In total, minimum of 176 patients (88 patients in each group) were required to estimate mean difference of First attempt success rate between groups by 21.75% with 95% confidence and 80% power, as calculated using MedCalc computer

application.

Inclusion Criteria: Patients in age group 18 - 60 years, Either gender, Weight 40 – 70 kg, ASA physical status I/II, Patients admitted in S. S.G. Hospital and posted for Elective surgeries requiring general anaesthesia with endotracheal intubation. Exclusion Criteria: Patient with predicted difficult airway, Patients with recent upper respiratory tract infection, Patients with any oropharyngeal pathology, obese patients with BMI >30 kg/m², Patient with any conditions that increase the risk of gastro oesophageal regurgitation, history of allergy to Latex or to any drugs used in protocol, Patients not willing for participation.

Randomization and Grouping of Patients: All patients were randomly allocated in two groups using sealed opaque envelope method. Group-I (n=88): Ambu Aura-i supra-glottic airway device was inserted. Group-Q (n=88): Air-Q supra-glottic airway device was inserted. Pre-operative assessment and preparation of patient: All the patients underwent a thorough Pre-anaesthesia check-up which included History recording, General, Systemic and Airway examination. Routine and specific laboratory investigations were done as per the need. ECG and Chest X-ray were done if required. The patients were selected for this study as per our inclusion and exclusion criteria. Written and informed consent from patient and one of the close relatives was obtained after explaining objective of the study and procedure. Patients were kept Nil by Mouth (NBM) overnight before surgery. On the day of surgery, patients were reassessed, IV line was secured with appropriate size IV cannula and IV fluid was started.

Operation Theatre Preparation: Anaesthesia work station, central and cylinder gas supply, anaesthetic drugs, airway equipment, suction apparatus, multipara monitor and all necessary emergency drugs were checked and kept ready. Appropriate size of allocated SAD was selected based on patient's weight, as per the manufacturer recommendation, and kept ready along with the appropriate size of PVC endotracheal tube.

Pre-use check of the device: The device was inspected for any damage, leak or obstruction of lumen. The PVC ET tube was lubricated with adequate water soluble 2% lignocaine jelly and passed through the SAD, with its cuff completely deflated, to check for size and ease of passage, and then removed The detachability of the ET tube connector was checked. The cuff of SAD was deflated with 20cc syringe, and lubricated on the dorsal side with lignocaine jelly. The above steps were followed for both the devices. For Air-Q ILA, detachability of the removable connector was checked. After taking the patient on the OT table, Multipara monitor was attached to the patient and baseline vital parameters: Heart rate, ECG, Blood Pressure, Oxygen Saturation and et CO2 were noted. All the patients were premedicated 10 min before induction of anaesthesia with: Inj. Ondansetron 4mg IV, Inj. Glycopyrrolate 0.2mg IV, Inj. Midazolam 1mg IV.

Induction of Anaesthesia: Patient was pre-oxygenated for 3 minutes with 100% oxygen using appropriate size face mask, through closed circuit of anaesthesia work station, with O2 flow at 6 litres/minute. Induction of General Anaesthesia was performed with Inj. Xylocard 1.5mg/kg IV, Inj. Fentanyl 2 mcg/kg IV, Inj. Propofol 2 - 2.5mg/kg IV till loss of eye lash reflex, Inhalational agent Sevoflurane to increase depth of anaesthesia, Inj. Vecuronium 0.1mg/kg loading dose, Additional dose of propofol was given if required to increase the depth of anaesthesia.

After achieving adequate relaxation, keeping the head in neutral position, selected SAD was inserted using the recommended technique and cuff inflated. Anaesthesia circuit was attached to the device and patient was ventilated with gentle IPPV. Confirmation of correct placement of SAD was done by: Assessment of bilateral chest wall movement, Auscultation for bilateral air entry, Appearance of square wave capnography. If adequate ventilation was not achieved or leak present, the SAD was manipulated by using manoeuvres like jaw thrust and up and down movement of the device, Chin lift, Gentle modification in depth of insertion. If not corrected, then the device was removed and reinserted with jaw thrust manoeuvre. Maximum 2 attempts were allowed. After confirmation of ventilation, the circuit was detached.

Pre-decided appropriate sized ET tube, kept ready beforehand, was introduced gently through the SAD after lubricating well with 2% water soluble lignocaine jelly. If no resistance was felt, the downward movement of ET tube was continued till tube was adequately inside trachea, then circuit was attached with the tube and patient was ventilated. The correct placement of tube was confirmed by: Bilateral chest wall movement, Auscultation for bilateral air entry, Appearance of square wave capnography trace on monitor. If there was resistance while advancing the ET tube or in case of esophageal intubation, the tube was withdrawn and the SAD was manoeuvred once and ET tube advanced gently. If difficulty in advancing the tube persists, tube was gently rotated away from side of resistance along with neck flexion and advanced. ET tube of smaller size was taken if required. Maximum 3 attempts were allowed for intubation. Once the tracheal intubation was confirmed, circuit was detached again along with ET tube connector. Cuff of both SAD and ET tube was deflated and the SAD was removed by sliding it out carefully over the ET tube, with the help of stabilizing rod, taking care not to displace the ET tube. Once SAD was removed, the ET tube position was again confirmed after attaching the circuit as mentioned before and then fixed properly.

Failure to ventilate the patient even after 2 attempts of SAD insertion. Under such circumstances, endotracheal intubation was done with appropriate size ET tube using conventional laryngoscopy. The case was excluded from the study. Failure

of intubation: If the 3rd attempt at intubation with required manoeuvre was unsuccessful, it was considered as failure of intubation through SAD. Under such circumstances also, SAD was removed and endotracheal intubation was done with appropriate size ET tube using conventional laryngoscopy. Such case was included in the study.

Maintenance of Anaesthesia: O2 + N2O (50:50) + Sevoflurane inhalational agent, Inj. Vecuronium maintenance dose Reversal: At the end of surgery, N2O and Sevoflurane was discontinued and patient was ventilated with 100% oxygen. Reversal of residual neuromuscular blockade was done after return of spontaneous respiration, when the criteria of reversal are fulfilled, using Inj. Neostigmine 50 mcg/kg IV and Inj. Glycopyrrolate 10 mcg/kg IV, Patient was established and patient was conscious and obeying command extubation patient was shifted to Post anaesthesia care unit with due precautions.

Parameters observed:

Number of attempts of SAD insertion: maximum 2 attempts

Number of attempts of intubation: maximum 3 attempts

Ease of insertion of SAD & Intubation was assessed as follows:

Grade	Ease of insertion of SAD
Easy	No manoeuvre required and successful in first attempt
Moderate	One manoeuvre required
Difficult	More than one manoeuvre required

Statistical analysis of the data was done with the help of MedCalc statistical software as follows: chi-square test for qualitative (non-parametric data), unpaired t-test for intergroup comparison of parametric data. The significance of statistical analysis was judged by p-value derived from the above statistical tests: p < 0.05 were considered as significant.

Results

This was a Prospective Randomised Clinical Study conducted on 176 patients, in the age group of 18 - 60 years, of either sex, belonging to ASA physical status I and II, posted for elective surgeries to be done under General anaesthesia, requiring endotracheal intubation. The study was conducted from October 2019 to October 2020, at Medical College and S. S. G. Hospital, Vadodara.

The patients were divided into two groups of 88 each: Group-I (n=88): Patients in whom Ambu Aura-i was inserted and Group-Q (n=88): Patients in whom Air-Q ILA was inserted. Both the groups were comparable to each other with respect to demographic parameters like Age, Sex, Weight, Height, BMI, and ASA physical status. With the age range of 18 - 60 years

for both groups, the mean age of Group-I = 34.97 + 8.35 years, was comparable with mean age of Group-Q = 35.45 + 10.24.

There was no significant difference in terms of no. of attempts of insertion, ease of insertion and time taken for insertion between Ambu Aura-i and Air-Q. Out of 88 patients in each group, Ambu Aura-i was inserted in first attempt in 69 patients and in second attempt in 19 patients, and Air-Q ILA was inserted in first attempt in 73 patients and in second attempt in 15 patients.

There was no significant difference found between the two devices in terms of ease of insertion: In the Ambu Aura-i group, ease of insertion of the device was found to be easy in 65 patients, moderate in 17 patients and difficult in 6 patients. In the Air-Q ILA group, ease of insertion of the device was found to be easy in 68 patients, moderate in 15 patients and difficult in 5 patients.

On comparing the number of attempts of intubation through SAD between both the devices: For Ambu Aura-i, intubation was successfully performed in first attempt in 8 (9.10%) patients which was significantly less than that with Air-Q ILA which was 19 (21.6%). There was no significant difference in number of intubations done in second attempt between both groups. The number of intubations requiring third attempt were 7 in Group-I and 12 in Group-Q with no statistically significant difference.

There was no significant difference in ease of intubation through both the devices. For Ambu Aura-i, intubation was found to be easy in 8 patients, moderately difficult in 39 patients and difficult in 41 patients. Out of 41 difficult intubations, 6 were successful after 3rd attempt and 35 remained unsuccessful even after 3rd attempt. For Air-Q ILA, intubation was found to be easy in 16 patients, moderately difficult in 39 patients and difficult in 33 patients. Out of 33 difficult intubations, 13 were successful after 3rd attempt and 20 remained unsuccessful even after 3rd attempt. The number of failed intubations in Ambu Aura-i group was 35 (39.77%) which was significantly more than in Air-Q ILA group which was 20 (22.73%). In case of failure intubation was done using conventional direct laryngoscopy, in both groups.

There was no significant difference in incidence of sore throat between both groups. There was no significant difference between incidence of trauma as indicated by blood on device or ET Tube between both groups. There was no incidence of other complications like bronchospasm, laryngospasm and desaturation in any of our patients.

Discussion

Since the advent of general anaesthesia one of the major concerns of an anaesthetist was to secure the airway in

order to protect the lungs as well as for proper ventilation. This was resolved with the development of endotracheal intubation. With time various devices for airway management were developed, but endotracheal intubation by direct rigid laryngoscopy remains the benchmark technique against which all other techniques are compared.^[9] However, there are certain disadvantages of direct laryngoscopy. This technique is associated with exaggerated hemodynamic stress response and there is always risk of trauma. These constraints led to the development of newer devices to secure airway, like Supraglottic airway devices (SADs), videolaryngoscopes, fibreoptic bronchoscopes etc.^[10]

Considering the fact that the inner opening of the SAD is in alignment with the glottic opening. Many of these devices have been designed to be used as conduit for endotracheal intubation. Fastrach LMA was one such SAD developed for the purpose of endotracheal intubation. But it has limitations like high cost, rigidity of its airway tube and use of dedicated endotracheal tube. Therefore newer, cost effective intubating SADs like Air-Q ILA and Ambu Aura-i were developed.^[11]

In our study we compared Air-Q ILA and Ambu Aura-i for blind tracheal intubation in terms of parameters. The patients were divided into two groups of 88 each as follows: Group-I (n=88): Ambu Aura-i supra-glottic airway device was inserted and Group-Q (n=88): Air-Q supra-glottic airway device was inserted.

A total of 176 patients of either sex, in the age group of 18 - 60 years, with ASA physical status I and II, who were posted for elective surgery to be done under general anaesthesia, were taken. Both the groups were comparable in terms of demographic parameters like Age, Sex, Weight, Height, Body Mass Index (BMI) and ASA physical status. The demographic parameters of our study were in consonance with studies done by Neoh EU et al. (2012), and Anand L et al. (2019).^[11,12]

Ambu Aura-i was inserted in 1st attempt in 69 subjects and in 2nd attempt in 19 subjects, out of the 88 study subjects. Whereas Air-O ILA was inserted in 1st attempt in 73 subjects and in 2nd attempt in 15 subjects, out of the 88 study subjects. The no. of attempts of SAD insertion was comparable in both groups. With regards to Air-Q ILA the successful insertion of device in first attempt as seen in the study conducted by Neoh EU et al.^[12] (2012) was 96.25% (i.e., 77 out of 80 subjects) which was more than that seen in our study (82.9%). Whereas according to the results of the study conducted by Seydalireza Seyed Siamdoust et al. (2018),^[13] success rate of device insertion in first attempt was 88.8% (i.e., 56 out of 63) which was almost similar to the results our study. With regards to Ambu Aura-i, as seen in study conducted by Lakesh Anand et al. (2019), the rate of successful device insertion in first attempt was 98% (i.e., 49 out of 50 subjects), which was significantly higher than the result of our study which is 78.4%.

Table 1: Parameter for SAD insertion				
Parameter	Group I		Group Q	P value
No. of attempts $(1^{st} / 2^{nd})$	69/19		73/15	> 0.05
Ease of insertion (easy/moderate/difficult)	65/17/6		68/15/5	• 0.05
Table 2: Parameters for intubation through SAD				
Parameter	Gi	roup I	Group Q	P value
No. of attempts $(1^{st} / 2^{nd} / 3^{rd})$	8/3	38/7	19/37/12	> 0.05
Ease of insertion (easy/moderate/difficult)	8/3	39/41	16/39/33	> 0.05
Failed intubation	35		20	< 0.05
Fable 3: Complications occurred				
Complications	Group I		Group Q	P value
Sore throat	14.7		11.3	> 0.05
Blood on device	13.6		9	> 0.05

Out of 88 subjects in each group, the ease of insertion of Ambu Aura-i was considered to be easy in 65 subjects, moderate in 17 subjects, difficult in 6 subjects, whereas for Air-Q ILA it was considered to be easy in 68 subjects, moderate in 15 subjects, and difficult in 5 subjects.

With regards to Air-Q ILA the result of our study was comparable with the study conducted by Sameer Sethi et al. (2017).^[14] We did not find any study that noted the ease of Ambu Aura-i insertion. The intubation was successful in first attempt in 8 (9.10%) patients in whom Ambu Aura-i was inserted, which is significantly less than 19 (21.6%) first attempt intubations in the group in whom Air-Q ILA was inserted. But the numbers of intubations done in second attempt were comparable in both group. There was no statistically significant difference in number of intubations done in third attempt in both groups.

In Group I, in whom Ambu Aura-i was inserted, the ease of intubation was considered to be easy in 8 patients, moderate in 39 patients and difficult in 41 patients. In Group-Q, in whom Air-Q ILA was inserted, the ease of intubation was considered to be easy in 16 patients, moderate in 39 patients and difficult in 33 patients. Among the 41 difficult intubations in Ambu Aura-i group and 33 in Air-Q ILA group, were included failed intubations which was 35 and 20 for Ambu Aura-i and Air-Q ILA group respectively. When compared with the results of our study, Neoh EU et al. (2012) and Sameer Sethi et al. (2017) in their study found that it was easier to intubated through Air-Q ILA.

The low first attempt and over-all success rate of blind tracheal intubation through Ambu Aura-i when compared to that of Air-Q ILA, could be due the structural difference between the two SADs. The Air-Q ILA has a wider, firm, oval shaped cuff with

transverse ridges, which gives it the stability on insertion. The wider bore of the airway tube of Air-Q allows easy passage of ET tube. The key hole shaped distal opening directs the ET tube towards the glottis, whereas the cuff of Ambu Aura-i is comparatively softer and narrower, making it less stable after insertion. The narrow airway tube and absence of elevation bar at the distal opening accounts for difficulty in directing the ET tube towards the glottis. The above structural difference makes Air-Q ILA more suitable for blind endotracheal intubation than Ambu Aura-i.

There was no incidence of other complication like Bronchospasm, Laryngospasm and Desaturation in any group. The incidence of sore throat and blood staining of device was much higher in study conducted by Neoh EU et al. (2012) (51% and 37.5% respectively) when compared to the findings of our study, with regards to Air-Q ILA. But in a study conducted by Lakesh Anand et al. (2019), the incidence of sore throat was 2% which was much less than the findings of our study, whereas the incidence of trauma as indicated by blood on device was 10%, which is almost same as the finding of our study, with regards to Ambu Aura-i.

The limitations of our study were as follows: Use of PVC ET tube for intubation, which is non-malleable and difficult to manipulate. Non-utilisation of fibre-optic bronchoscope to check proper positioning of SAD and to guide intubation. Blinding was not possible to eliminate observer bias.

Future scope: Studies can be done using Flexometallic ET tubes, which are malleable and easier to manipulate and might result in higher success rate. LMA-Fastrach is used at various places in difficult airway algorithm. By increasing the success rate of these newer intubating supraglottic airway devices, i.e., Ambu Aura-i and Air-Q ILA, in patients with normal airway,

the utility of these devices may be extended to and studied to be used in difficult airway situations.

Conclusions

Based on the above findings, we conclude that Air-Q is a better conduit for blind intubation than Ambu Aura-i. However, further studies are required to support our finding. The success rate might be increased with the use of fibre-optic bronchoscope to guide the intubation.

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