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Air Q intubating laryngeal airway versus the Ambu Aura Gain as a conduit for endotracheal intubation assisted by tube exchanger: a randomized comparative study

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Abstract

Background: The aim of the study was to compare Air-Q® Intubating Laryngeal Airway (Air Q ILA) versus Ambu Aura Gain as conduit for endotracheal intubation assisted by tube exchanger.

Methods: This randomized comparative trial included adult patients undergoing elective surgery under general anesthesia. The patients were randomly allocated to tube exchanger assisted intubation either via Air Q ILA (G_Q) or via Ambu Aura Gain (G_A). The success rate, the time of insertion of each of the tube exchanger and endotracheal tube were recorded. The primary outcome was the total endotracheal intubation time (sum time of insertion of the tube exchanger and endotracheal tube). Secondary outcomes were success rate of tube exchanger insertion, endotracheal intubation, tube exchanger insertion time, endotracheal intubation time.

Results: Forty-four patients were available for the final analysis. The tube exchanger insertion time, endotracheal intubation time and total endotracheal intubation time were comparable between both groups. The success rate of tube exchanger insertion and endotracheal intubation were also comparable between the two groups.

Conclusion: Both extraglottic airway devices, namely Air Q ILA and Ambu Aura Gain, showed similar performance as conduit for endotracheal intubation

Keywords: Air-Q® Intubating Laryngeal Airway; Ambu Aura Gain; Extraglottic Device (EGD) ; Endotracheal Intubation; Tube Exchanger.

Introduction

In anesthesia practice, adequate ventilation and endotracheal intubation sometimes become challenging to the anesthetist specially in the absence of the helping devices and tools for difficult intubation.

Difficult intubation, Difficult ventilation or what is known as "cannot ventilate cannot intubate (CVCI)'' is one of the worst scenarios increasing morbidity and mortality during anesthesia.[1]

Extraglottic devices (EGD) have been introduced in clinical practice to facilitate ventilation. Some of the EGD can also be used as a conduit for endotracheal intubation (ETI). EGD gained a major role in the difficult airway algorithms.

The Air-Q® Intubating Laryngeal Airway. is an intubating EGD that was introduced by Daniel Cook in 2005. It is used as a conduit for ETI whether blindly or with the aid of fiberoptic bronchoscope. [2,3]

Ambu Aura Gain™ is a single-use second generation EGD. It is anatomically curved with integrated gastric access and can be used as a conduit for direct fiberoptic ETI.[4]

The tube exchange catheter is a blunt tipped radio-opaque catheter supplied with a Rapi-fit Adapter which allows connection to ventilator devices during the tube exchange procedure.[5] Therefore, it was used as a guide to railroad ETT through EGD, with the ability to confirm the correct site through measurement of end-tidal CO2.

To the best of our knowledge, there is no data comparing ETI through Air Q ILA versus Ambu Aura Gain with the tube exchanger being a guide for the ETI. It was hypothesized that Ambu Aura Gain would be superior to Air Q ILA in terms of intubation time and success rate being a newer device in the clinical field. The aim of this study was to compare the two EGD regarding the primary outcome, which is, the total intubation time, in addition to the secondary outcomes, which are, the success rate of tube exchanger and ETT insertion as well as the tube exchanger insertion time and ETT intubation time.

Methods

This study was conducted in Cairo University Hospital, Cairo, Egypt. After obtaining approval from Research Ethics Committee, (N-9-2019, clinical trials identifier: NCT05607433) an informed written consent was taken from the participants before enrollment. The study included patients aging more than 18 years old, American society of anesthesiologist (ASA) physical status I-II, with airway assessment by El Ganzouri Airway Score equal to or less than 3 [6], presented for elective surgeries in the ophthalmology theatre under general anesthesia.

Patients with risk of aspiration of gastric contents, patients with any anatomical abnormalities that invalidated EL Ganzouri airway score, or patients with active respiratory or cardiac disease were excluded from the study.

The participants were randomly allocated into two groups using an online randomizer and kept in sealed opaque envelopes. An independent research assistant was responsible for opening the envelops and group assignment as follows:

G_Q(n=22): ETI was performed through a proper sized Air-Q ILA (ILA™, Cookgas® LLC, Mercury Medical, Clearwater, FL, USA) assisted with the tube exchanger

G_A(n=22): ETI was performed through a proper sized Ambu Aura Gain, assisted with the tube exchanger

In the preoperative preparation room, routine preoperative assessment including the Ganzouri airway scoring was done for all patients.[6]

For all patients, a peripheral intra-venous (IV) cannula was inserted, IV 0.005 mg/kg atropine 15 minutes, 0.02mg/kg midazolam was given in the preparation room.

In the operating room, an EGD was selected according to the group assignment, and its size was determined according to manufacturer's recommendations

Patients were connected to standard monitoring devices including non-invasive blood pressure, pulse oximetry, electrocardiogram, and capnography that was attached to the ventilator circuit after induction of anesthesia.

Patients were placed in the supine position with their head in the sniffing position. After adequate preoxygenation using a facemask for 3 min, induction of anesthesia was performed using 2mg/kg propofol, 1 mcg/kg fentanyl and 0.5 mg/kg atracurium.

Isoflurane (1.2-1.5%) was used for maintenance of anesthesia.. After 3 min of facemask ventilation, the EGD was inserted into the patient's airway and then connected to the ventilator circuit. Mechanical ventilation was started with tidal volume of 6 -8 ml /Kg and a respiratory rate that maintained the end-tidal CO_2 at 35-45 mmHg.

Adequate ventilation was confirmed by the presence of three successive waves on capnogram. Confirmation of proper positioning of the EGD was observed by absence of air leak sounds and adequate tidal volume reaching the patient's lungs. After adequate ventilation for 3 min, the patient's EGD was disconnected from the circuit, then the tube exchanger was introduced slowly through the EGD into the trachea. Endotracheal insertion of the tube exchanger was confirmed by feeling the gritty sensation of the tracheal rings and by the appearance of the capnography waves.

If the tube exchanger was placed into the esophagus or if slight resistance during insertion was felt, the tube exchanger was removed and the patient was ventilated through the EGD and a second trial was performed with simultaneous cricoid pressure and jaw thrust by an assistant. A maximum of two attempts were allowed. In case of failure of insertion of the tube exchanger, the patient was intubated with the aid of a fiberoptic bronchoscope using the EGD as a conduit and the case was considered as failed.

After confirmation of the tube exchanger site, the ETT was threaded over the tube exchanger through the EGD and connected to the ventilator. Proper ETT positioning was confirmed by the appearance of 3 successive capnographic waves, auscultation of breath sounds and adequate chest expansion.

If any resistance was felt during threading of the ETT over the tube exchanger, gentle tube rotation and external manipulation was allowed in the form of cricoid pressure, jaw thrust and neck extension. Otherwise, a second attempt was allowed. If threading failed after external manipulation, the tube exchanger was removed, and the endotracheal tube was then placed with the aid of a fiberoptic bronchoscope. The fiberoptic bronchoscope was present at all times preloaded with a proper size endotracheal tube as a backup plan for any failure attempt.

Primary outcome

Total endotracheal intubation time (tube exchanger insertion time plus ET insertion time).

Secondary outcomes

The success rate and tube exchanger insertion time (defined as the time elapsing from disconnection of the EGD from the ventilator until reconnection of the tube exchanger to the capnogram and ventilator circuit) were recorded.

The success rate and endotracheal intubation time (the time in seconds elapsing from disconnection of the ventilator circuit from the tube exchanger until the ventilator circuit with the capnogram attached was reconnected to the endotracheal tube) were recorded.

Sample size

The aim of the study was to compare total intubation time between the two groups. In a previous study on 18 patients [7], studying bougie assisted intubation through the Air Q , the mean time of intubation was 65.89 seconds with a standard deviation of 14.5 seconds. Taking that into consideration, MedCalc Software version 14(MedCalc Software bvba, Ostend, Belgium) was used to calculate the sample size. Eighteen patients at least per group were estimated. With a study power of 90% and an alpha error 0.05, this number was increased to 22 patients per group to compensate for possible dropouts.

Statistical methods

Data was coded and entered using the statistical package for the Social Sciences (SPSS) version 25 (IBM Corp., Armonk, NY, USA). Data was summarized using mean, standard deviation, minimum and maximum for quantitative variables and frequencies (number of cases) and relative frequencies (percentages) for categorical variables. Comparisons between groups were done using unpaired t test (Chan, 2003a) [8]. For comparing categorical data, Chi square ($\chi 2$) test was performed. Exact test was

used instead when the expected frequency is less than 5 (Chan, 2003b). P-values less than 0.05 was considered as statistically significant.[9]

Results

Sixty patients were assessed for eligibility. Ten of whom did not meet the inclusion criteria and six patients declined to participate. Forty-four patients were randomly allocated into one of the study groups and all of them were available for the final analysis. (Figure 1)

The demographic characteristics namely, age, body weight, gender, and ASA physical status., showed no significant difference between the two groups. (Table 1)

The average time for the tube exchanger insertion through the EGD as well as the average time for endotracheal intubation through the EGD, were comparable in both groups. The total intubation time was comparable in the two groups (63.92 ±6.56 s in the $\mathbf{G_Q}$ versus 60.46 ±3.89 s in the $\mathbf{G_A}$, P-value: 0.119). (Table 2)

The success rate of tube exchanger insertion and endotracheal intubation were also similar in both groups. (Table 2).

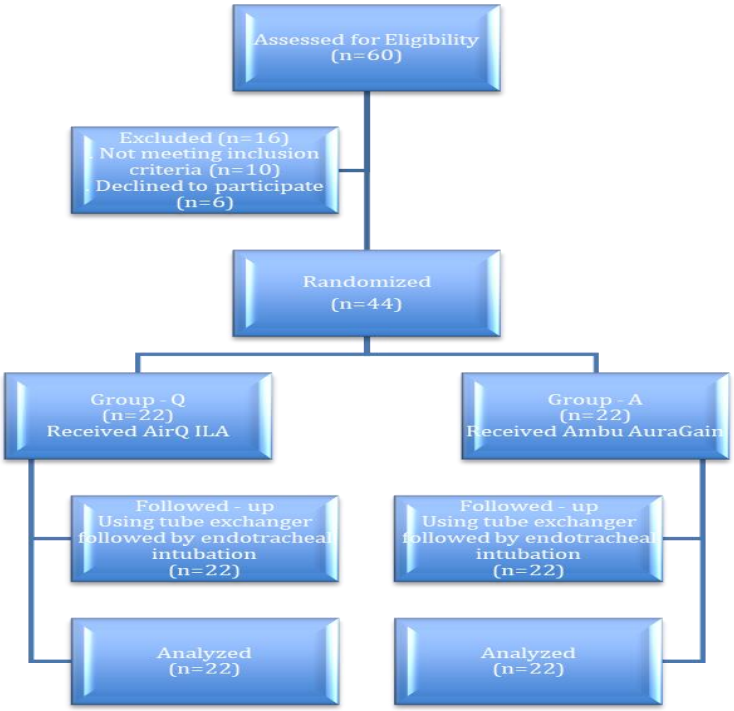

Figure 1: CONSORT's Flow chart

Table 1: Demographic characteristics

	$\mathbf{G_{Q\ (n=22)}}$	$\mathbf{G_{A\ (n=22)}}$	**P-value**
Age (years)	34.41±11.07	31.91±10.28	0.442
Body weight (Kg)	74.05±11.25	73.32±10.15	0.823
Male sex, n (%)	13(60%)	10(45.4%)	0.365
ASA physical status, n (%) **I** **II**	 12(54.5%) 10(45.4%)	 14(63.6%) 8(36.3%)	0.540

Numerical data presented as mean± standard deviation between the two study groups.

Categorical data presented as percentage between the two study groups.

P-value <0.05 was considered statistically significant. ASA: American society of anesthesiologist

Table 2: Tube exchanger insertion and endotracheal intubation outcomes

	$G_{Q\ (n=22)}$	$G_{A\ (n=22)}$	P-value
Success rate of Tube exchanger insertion, n (%)			
Trial 1	8 (36.3%)	9 (40.9%)	0.750
Trial 2	5 (22.7%)	5 (22.7%)	1
Total	13 (59%)	14 (63.6%)	0.761
Tube Exchanger Insertion Time (sec)	25.23 ±2.13	24.29 ±2.16	0.264
Success rate of endotracheal intubation, n (%)			
Trial 1	7 (31.8%)	9 (40.9%)	0.517
Trial 2	5 (22.72%)	4 (18.1%)	1
Total	12 (54.5%)	13 (59.0%)	0.763
ETT Time (sec)	38.58 ±5.4	36.15 ±2.51	0.175
Total Intubation Time (sec)	63.92 ±6.56	60.46 ±3.89	0.119

Numerical data represented as mean± standard deviation. Categorical data presented as percentage. P-value <0.05 was considered statistically significant. ETT: endotracheal tube

Discussion

We reported that the duration of insertion of tube exchanger and endotracheal tube were similar through each of the Air Q ILA and Ambu Aura Gain. Furthermore, the success rate of tube exchanger insertion and endotracheal intubation were comparable through the two devices.

Newer EGDs are being introduced; therefore, it is important to compare them with established devices to evaluate their safety and efficacy.[10] To the best of our knowledge, this study was the first to evaluate Ambu Aura Gain versus Air Q ILA as a conduit for assisted tube exchanger blind endotracheal intubation.

As regards to the study's primary outcome, the total intubation time. It was found that the mean total intubation time was comparable between the two groups (63.92 sec in the Air Q ILA and 60.46 sec in the Ambu Aura Gain). In consistency with the study's intubation time, Ebied et al[7] Kleine-Brueggeney et al[11], had similar results, regarding the intubation time through EGD.

On the other hand, shorter intubation times were reported by Karim and Swanson[12] and Jagannathan et al.[13 and] Bielski et al [14].

In the study done by Karim and Swanson [12], they stated that most of their attempts of intubation through the Air Q were assisted by a bougie and that should have theoretically prolonged the intubation time. But, they did not record their bougie assisted cases. However, other patients that were intubated whether blindly or by the use of fiberoptic bronchoscope had recorded a shorter intubation time. Also, in reference to the study by Jagannathan et al.[13] , their mean tracheal intubation time was shorter than our mean total intubation time owing to the time taken to insert the tube exchanger in our study. Lastly , in the study by Bielski et al [14] , when comparing our results with their non difficult airway scenario , their shorter intubation time was because they did not use any extra step as the tube exchanger prior to intubation.

With regards to the tube exchanger insertion time, in our study it was 25.23 sec in G_Q and 24.29 sec in G_A. In harmony with our results, Ebeid et al[7] recorded a mean bougie insertion time of 20 sec.

In this study, the success rate of endotracheal intubation was comparable through the two studied devices. In contrast to our results, Sethi et al[15] reported that Air Q ILA was more successful than Ambu Aura Gain. This may be due to that they did not use tube exchanger, as a conduit for intubation. The use of the tube exchanger might have improved the performance of the Ambu Aura Gain in our study. In a study by Lal et al[1], they showed 100 % success rate for both devices with variable degree in the ease of intubation. They used the Parker flex tip tubes in their study instead of the conventional standard endotracheal tube that we used in our study.

More studies needed to confirm this finding through comparing blind intubation versus tube exchanger assisted intubation.

Our study finding suggests that both devices are equally effective as a conduit for blind tracheal intubation with the help of tube exchanger.

Limitations

Our study had some limitations. It was conducted in a single center and also by a single operator. We only included ASA I-II patients undergoing elective surgery with an easy intubating airway. More studies are needed to confirm our findings especially in the scenario of difficult intubation.

Conclusion

Both EGDs, namely Air Q ILA and Ambu Aura Gain, showed similar performance as conduit for blind endotracheal intubation, with the help of a tube exchanger. The tube exchanger used might have narrowed down the difference in the performance between both EGDs.

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Ethical approval and protocol registration: The Research Ethics Committee in Cairo Faculty of Medicine approved the research, (Code: N-9-2019) and registration at clinicaltrials.gov (NCT05607433).

Conflict of interests: None to be declared.

Author contributions: Each author took part in the idea and design of the research. Preparation of materials, gathering and analysis of data were carried out by Hoda Zakaria Saleh Alrify, Nadia Youssef Helmy and Maha Mohamed Ismail Youssef. The initial draught of the manuscript was written by Sherin Refaat Mahmood, Omnia Adel Mandour and Dina Soliman Mohammed Idris. All authors provided feedback on earlier versions of the manuscript. The final manuscript was reviewed and approved by all authors.

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