



A randomized comparison the of the air-Q[®] intubating laryngeal airway and Ambu[®] AuraGain[™] laryngeal mask for controlled ventilation in children

Nirawanti Mohamad Said, MD, MMed^{1,2}, Rhendra Hardy Mohamad Zaini, MD, MMed^{1,2}, Wan Mohd Nazaruddin Wan Hassan, MD, MMed^{1,2}, Mohamad Ibariyah Iberahim, MD^{1,2}, Soon Eu Chong, MD, MMed^{2,3}

ABSTRACT

Objective: to compare the effectiveness between air-Q[®] intubating laryngeal airway and Ambu AuraGain laryngeal mask for controlled ventilation in children up to 30kg

Design: Prospective, randomized controlled trial

Setting: Operating theatre of Hospital Universiti Sains Malaysia

Methodology: 64 pediatric patients underwent various short surgical procedures were randomly assigned to receive either an air-Q[®] or Ambu AuraGain supraglottic airway. Fiberoptic grades of laryngeal view were measured as the primary outcome. The secondary outcomes measured were oropharyngeal leak pressure (OLP), number of attempts, time of successful insertion, quality of airway during placement and maintenance of anesthesia, hemodynamic parameters, and complications.

Results: air-Q[®] has more favorable fiberoptic grades of view compared to the Ambu AuraGain ($p = 0.047$). OLP is significantly higher in air-Q[®] compared to Ambu AuraGain (19.41 ± 1.19 cmH₂O vs 17.56 ± 1.52 cmH₂O, $p \leq 0.001$). There were no differences in terms of number of attempt, time of successful insertion, quality of airway during placement and maintenance of anesthesia and complications. **Conclusion:** Ir-Q[®] offers more clinical advantages than Ambu AuraGain for controlled ventilation in pediatric patients as it provides higher airway sealing pressure and better fiberoptic grade of laryngeal view.

Keywords: Supraglottic airway device, Intubating Laryngeal Airway, Laryngeal Mask Airway, air-Q[®], Ambu AuraGain, controlled ventilation, pediatric

¹Department of Anaesthesiology and Intensive Care, School of Medical Sciences, Universiti Sains Malaysia, 16150 Kota Bharu, Kelantan, (Malaysia)

²Hospital Universiti Sains Malaysia, 16150 Kota Bharu, Kelantan, (Malaysia)

³Regenerative Medicine Cluster, Advanced Medical and Dental Institute, Universiti Sains Malaysia, Bertam, 13200 Kepala Batas, Penang, (Malaysia)

Correspondence:

Rhendra Hardy Mohamad Zaini, Department of Anaesthesiology and Intensive Care, School of Medical Sciences, Universiti Sains Malaysia, 16150 Kota Bharu, Kelantan, (Malaysia); Phone: (60)19-9106665; Fax: (60)9-7656532; E-mail: rhendra@gmail.com

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INTRODUCTION

The usage of supraglottic airway devices (SADs) is gaining popularity since the first type of SAD i.e. the laryngeal mask airway (LMA) was introduced into clinical practice in 1983 by Brain.¹ Role of SAD as airway management offers advantages over tracheal intubation,^{2,3} because it is less invasive, causes

minimal hemodynamic stress response⁴⁻⁶ and allows faster and easier insertion even among inexperienced clinicians.^{3,7} Given its advantages, there are still concerns related to the use of SAD in term of safety profile, particularly risk of pulmonary aspiration,⁸⁻¹² ability to permit high sealing pressure especially for positive pressure ventilation¹³ and stability of the device during surgery.

SAD can be divided into first and second generation. A first-generation SAD is a simple airway tube connected to a mask that rests over the glottis opening.¹ Second-generation device improved by adding gastric port channel to protect against regurgitation and aspiration.² Since its introduction more than 30 years ago, there have been various types of first- and second-generation SAD available to anesthetists to improve ventilation performance and to facilitate endotracheal intubation.¹⁴ In order to understand and compare the strength and weakness of each device in each aspect, randomized trials are needed.¹⁵

In pediatric population, the usage of SADs has been established for anesthesia practice and emergency pediatric airway management.^{10,16-20} Among the established pediatric first- and second-generation SADs, the laryngeal mask airway Classic (cLMA), laryngeal mask airway Unique (ULMA) and laryngeal mask airway ProSeal (PLMA) have the largest evidence-base data supporting their use in pediatric patients.²¹⁻²⁴ Overall, it has been shown that the second-generation SAD are slower to be utilized compared to the first-generation SAD^{9,18} despite more trials and evidence to suggest that the second generation SADs have comparable or better performance.^{2,25} Device options for pediatric patients are mainly limited by the availability of sizes, anesthetist familiarity and cost consideration.¹⁸

air-Q® intubating laryngeal airway (ILA) (Cook gas LLC; Mercury Medical, Clearwater, FL, USA) is a new type of “first-generation SAD” that can be used as primary airway device and for tracheal intubation. It has a curved airway tube with shorter tube length, a wider inner tube diameter, an elevated keyhole-shaped ventilating orifice to prevent epiglottis downfolding and an orientation of distal outlet which can direct a fiberoptic bronchoscope (FOB) or endotracheal tube (ETT) towards the glottis.²⁶ With these special features, air-Q® has been shown to be associated with higher oropharyngeal leak pressure (OLP),²⁷⁻²⁹ thus providing effective seal during positive pressure ventilation. In addition, air-Q® was also believed to provide a better FOB views.^{27,29} With these advantages, this device has been recommended as one of the choices for difficult airway in adult and pediatric population.^{14,30,31}

Ambu® AuraGain™ (Ambu, Ballerup, Denmark) is a newer “second-generation SAD”. This device has been designed following anatomical curve for rapid placement, soft inflatable cuff to provide high seal pressure and built in gastric port to prevent gastric insufflation. Compared to air-Q® (Figure 1), the Ambu AuraGain has a wider inner tube which allows it to be conduit for tracheal intubation. To date, there was only a single study evaluating Ambu AuraGain

in pediatric patients for airway maintenance during mechanical ventilation³² and it showed comparable performance with other second-generation SAD. With this versatility and availability of various sizes for pediatric patients, this device offers advantages for pediatric population.

This prospective randomized trial was designed to compare the clinical performance of both devices in children using controlled ventilation. The primary outcome was FOB grade of laryngeal view and the secondary outcomes were OLP, number of attempts, time of insertion, quality of airway during placement and maintenance of anesthesia, hemodynamic parameters and complications.

METHODOLOGY

The study was conducted after obtaining approval by the Human Research Ethics Committee of Universiti Sains Malaysia (*JEPeM*) (Ethical approval number: USM/JEPeM/15110476) and written informed consent from the parents of all patients. 64 pediatric patients, aged between 1 to 6 years old, 10-30 kg, American Society of Anesthesiologists (ASA) physical status I and II, undergoing surgical procedures within 2 hours operation time using SAD were recruited. Exclusion criteria include presence of active respiratory infection, anticipated and known difficult airway and lung disease requiring high airway pressure. All patients were divided equally into two groups either air-Q® (A) or Ambu AuraGain (B) using computer-generated randomization. Orders of group allocation were placed in the sealed opaque envelope by an assistant who not involved in this study and only opened by the investigator prior to device insertion. All insertion was performed by the investigator who had inserted more than 200 SADs in clinical practice. Before the study, the investigator had been trained to use both air-Q® and Ambu AuraGain in pediatric patients.

Anesthesia Technique:

In all patients, eutectic mixtures of local anesthetic cream (EMLA) were applied on both hands 30 minutes before transferring to operation theatre. No premedication was given. In operating theatre (OT), every patient was put on standard monitoring including non-invasive blood pressure, pulse oximeter (SpO₂), electrocardiogram and capnography (EtCO₂). General anesthesia was induced with sevoflurane in oxygen. The anesthesia plane was gradually deepened by increasing the inspired concentration of sevoflurane (2-8%) till the loss of eyelash reflex. Intravenous cannula was then inserted followed by administration of intravenous fentanyl 1 µg/kg and rocuronium 0.6 mg/kg. After 3 minutes, an appropriate size lubricated SAD (according to

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body weight) was inserted by the investigator with the patient's head in neutral position. The cuff was then inflated to an intracuff pressure of 40 cmH₂O, measured using a digital cuff pressure monitor (AG CUFFILL, Hospitech Respiration Ltd). OLP, FO grade of laryngeal view and quality of airway during placement and maintenance were assessed by investigator. Timing and data was documented by an unblinded observer (ie: anesthesia doctor in charge of the operating room). Anesthesia was maintained with sevoflurane (MAC value of 1.0-1.2) in oxygen: air mixture with FiO₂ of 0.5. Ventilation with pressure control mode as adjusted accordingly by targeting the minute ventilation to achieve normocarbida (EtCO₂ 35-45 mmHg).

At the end of surgery, sevoflurane was turned off and 100% oxygen was administered. The reversal agents, neostigmine (50 µg/kg) and glycopyrrolate (10 µg/kg) was given once patient regained spontaneous ventilation. With adequate tidal volume and respiratory rate, oropharyngeal suctioning was done, and the device was removed. Complications were documented, such as airway trauma, blood staining, airway reflex activation (e.g. laryngospasm/bronchospasm), oxygen desaturation (< 90%) and regurgitation/ aspiration.

Measurement of Parameters:

Time of successful airway insertion was defined as the time from the tip of cuff touching the patient's lips and to the appearance of first square of EtCO₂. This indicates establishment of an effective ventilation. Assessment of the ease of placement was assessed using a subjective scale of 1-4 (1= no resistance, 2= moderate resistance, 3= high resistance, 4= inability to place the device) (32, 33). At the same time, number of attempts required to successfully insert the device was documented.

Measurement of OLP was determined by observing the peak airway pressure at which audible leak occurred for the first time when fresh gas flow delivered at 3L/min and the expiratory valve was completely closed. OLP was not allowed beyond 40 cmH₂O for safety (27,28,32,34). In order to view the anatomical alignment of the device to the larynx, a flexible fiberoptic scope (Ambu a-Scope 3 Slim) was used. This FO grade of laryngeal view was assessed using established fiberoptic (FO) grade (1= only larynx was seen, 2= larynx and epiglottis posterior surface seen, 3= larynx and epiglottis tip of anterior surface seen, 4= epiglottis downfolded and its anterior surface seen and 5= epiglottis downfolded and larynx cannot be seen directly) (13).

The hemodynamic parameters (blood pressure, heart rate, SpO₂ and EtCO₂) were recorded during pre-induction, post-induction (after one minute), post-insertion (after one minute) and after five minutes.

Quality of airway during placement and maintenance of anesthesia were evaluated using grading from previous established study by documenting the degree of obstruction (clear, intermittent partial obstruction, intermittent complete obstruction or complete obstruction) and type of maneuvers required to maintain patency of the airway (including adjustment of the device, alteration of cuff volume and re-positioning of the patients) (32, 35).

Statistical analysis:

All research forms were checked, compiled and entered into IBM Statistical Package of Social Sciences (SPSS) version 24 software for analysis. Statistical analyses for categorical data between devices were performed using Pearson Chi-Square test and Fisher's exact test. Continuous variables were analyzed using independent t-test and repeated measure ANOVA. Data were presented in mean (SD) and counts (percentage) with $p < 0.05$ was considered statistically significant.

RESULTS

Demographic profiles:

Enrolment of patients were following CONSORT flow diagram (Figure 2). 64 pediatric patients were recruited. Patient demographic profiles according to the group are summarized in Table 1. There were no statistically differences between 2 groups with

Table 1: Patient Demographic Profile

Parameter / Variable	air-Q® (n=32)	Ambu AuraGain (n=32)	p-value
Age (years)	4.19 (1.96)	4.41 (1.88)	0.650
Gender			
Male	20 (62.5%)	15 (46.9%)	0.209
Female	12 (37.5%)	17 (53.1%)	
Weight (kg)	17.81 (6.32)	18.51 (6.64)	0.660
Ethnicity			
Malay	32 (100%)	32 (100%)	
ASA			
I	26 (81.3%)	27 (84.4%)	0.740
II	6 (18.8%)	5 (15.6%)	
Type of Surgery			
General Surgery	10 (31.3%)	5 (15.6%)	0.015
Orthopaedic	21 (65.6%)	16 (50%)	
Ophthalmology	0 (0%)	7 (21.9%)	
ENT	0 (0%)	3 (9.4%)	
Plastic	1 (3.1%)	1 (3.1%)	
Duration of surgery (m)	50 (21.0)	43.13 (16.05)	0.14

Data presented as mean (SD) and n (%).

$p < 0.05$ is considered significant.

respect to their age, weight and ASA physical status. The distribution of type and duration of surgery were comparable between 2 groups.

Efficacy of Devices:

For both groups, there were no statistically differences for time for successful device insertion, ease of device placement and quality of airway during placement (Table 2). All devices were successfully inserted in first attempts. The OLP was significantly different between air-Q® group and Ambu AuraGain group in which mean value of air-Q® was found to be higher (19.41 ± 1.19 cmH₂O) than Ambu AuraGain (17.56 ± 1.52 cmH₂O) ($p < 0.001$). There was also statistically difference in the FO grade of laryngeal view between the air-Q® and Ambu AuraGain ($P = 0.047$) in which the view of grade 1 was more in the air-Q® group.

There were no significant differences in hemodynamic parameters and quality of airway maintenance during anesthesia for both groups. However, two out of 32 patients in the air-Q® group required airway maneuvers in order to maintain airway patency during maintenance of anesthesia compared to none in the Ambu AuraGain group.

Complications:

There were no significant differences between complication rates in both groups. However, blood staining was detected in one patient after the removal of Ambu AuraGain. Besides, one patient had short duration of bronchospasm and another child experienced laryngospasm (which resolve after maneuvers) after removal of the Ambu AuraGain SAD (Table 3).

Table 2: Comparative data for the air-Q® and Ambu AuraGain during anaesthesia

Parameter	air-Q® (n=32)	Ambu AuraGain (n=32)	p-value	t-stat (95% CI)
Time for successful device insertion(s)	12.06 (5.4)	12.03 (2.38)	0.976	0.03 (-2.07, 2.13)
Number of attempts (1/2/3)	32/0/0	32/0/0		
Ease of device placement				
No resistance	29 (90.6%)	28 (87.5%)		>0.95
Moderate resistance	3 (9.4%)	4 (12.5%)		
High resistance	0 (0%)	0 (0%)		
Unable to place the device	0 (0%)	0 (0%)		
OLP (cmH ₂ O)	19.41 (1.19)	17.56 (1.52)	<0.001	5.4 (1.16, 2.53)
Fibreoptic grade of laryngeal view				
Grade 1	12 (37.5%)	7 (21.9%)		0.047
Grade 2	4 (12.5%)	12 (37.5%)		
Grade 3	6 (18.8%)	7 (21.9%)		
Grade 4	8 (25.0%)	2 (6.3%)		
Grade 5	2 (6.3%)	4 (12.5%)		
Quality of airway during placement				
Clear	29 (90.6%)	30 (93.8%)		0.500
Intermittent partial obstruction	3 (9.4%)	2 (6.30%)		
Intermittent complete obstruction	0 (0%)	0 (0%)		
Complete obstruction	0 (0%)	0 (0%)		
Airway manoeuvres during placement				
No	29 (90.6%)	30 (93.8%)		0.500
Yes	3 (9.4%)	2 (6.3%)		
Types of manoeuvres performed				
Inserted further	3	2		

Data presented as mean (SD) and n (%). $p < 0.05$ is considered significant.

Table 3: Complications observed in the air-Q® group and Ambu AuraGain group

Complications & Causes	air-Q® (n=32)	Ambu AuraGain (n=32)	P-value
Complications			
No	32 (100.0%)	29 (90.6%)	0.119
Yes	0 (0%)	3(9.4%)	
Causes			
Blood staining	0 (0%)	1 (33.3%)	
Bronchospasm	0 (0%)	1 (33.3%)	
Laryngospasm	0 (0%)	1 (33.3%)	

Data presented as n (%). $p < 0.05$ is considered significant.

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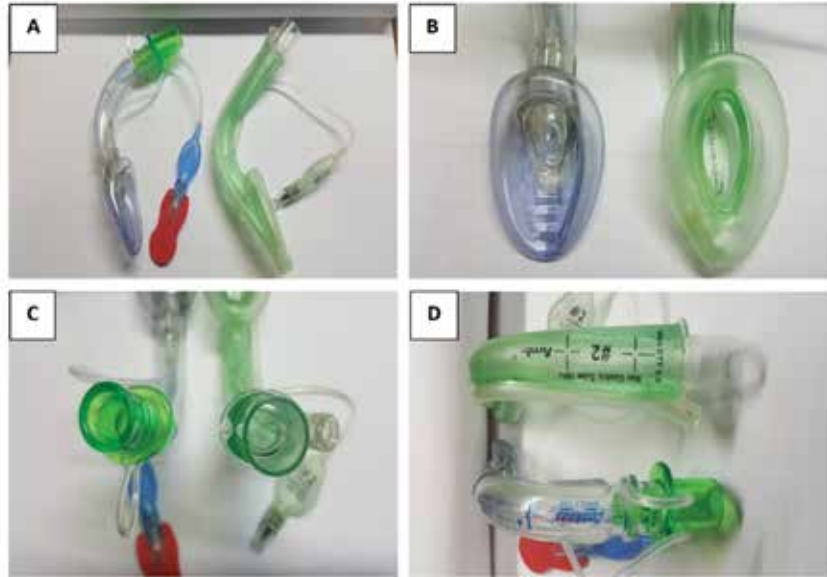


Figure 1: Images of the size 1.5 air-Q® and size 2 Ambu AuraGain. A) Lateral views of the air-Q® (left) and Ambu AuraGain (right). Note the slightly shorter airway tube of air-Q® and larger proximity mask of Ambu AuraGain. B) Mask bowls of the air-Q® (left) and Ambu AuraGain (right). C) Superior views of the air-Q® (left) and Ambu AuraGain (right). For the Ambu AuraGain, the gastric drain tube port is located laterally and outside its airway tube and compared with air-Q® has no gastric drain tube port. D) Posterior view of the air-Q® (below) and Ambu AuraGain (above). Note that the Ambu AuraGain has 2 horizontal markings where the upper incisor/gum line of the patient should rest between. It has additional markings indicate the maximum diameter of tracheal and gastric tubes that can fit through the device. air-Q® device also 2 similar horizontal markings where the upper incisor/gum line of patient should rest between and at the end of the airway tube, there is marking indicates the maximum diameter of tracheal tube and range of weight.

DISCUSSION

This study is one of the first randomized trials comparing air-Q® and Ambu AuraGain for controlled ventilation in pediatric population. The primary outcome of this study showed that the air-Q® is superior to Ambu AuraGain in the FO grade of view ($p = 0.047$). The percentage of Grade 1 in the air-Q® group was higher than the Ambu AuraGain group (37.5% vs 21.9%). This FO view is consistent with previous study by Jagannathan et al.²⁹ using air-Q® size 1.5 which found a significant difference of Grade 1 view when compared to LMA-Unique size 2 (40% vs 16%) ($p = 0.004$). A study by Whyte et al.²⁶ documented excellent FO view in majority of patients (93%) with various sizes of air-Q® (from size 1.0 to 2.5). An advantage of air-Q® is the structural design which have raised mask heel and space above the key-hole shaped ventilating orifice for the epiglottis to rest when device properly positioned. FO views with the Ambu AuraGain in this study were comparable

with previous study.³² In comparison, air-Q® has lower rates of epiglottic downfolding and provides clear view of the vocal cords. Therefore air-Q® is a potential device of choice when blind or fibreoptic-guided tracheal intubation are desired as the name indicated to be used as an intubating laryngeal airway (ILA). A trial done in adult patients reported that air-Q® was superior to Ambu AuraGain when used as conduit for blind endotracheal intubation.³⁶

air-Q® intubating laryngeal airway also demonstrated significantly higher OLP compared to the Ambu AuraGain (19.41 ± 1.19 cmH₂O vs 17.56 ± 1.52 cmH₂O, $p = 0.001$). The result were reported similar in previous study using air-Q® size 1.5 compared with Ambu Aura-I²⁸ and LMA-Unique.²⁹ This is possibly explained by the larger cuff design. Leak pressure test is an important tool to determine the efficacy of the sealing pressure of the device. This study showed that air-Q® has a better sealing pressure in children. The mean value of leak pressure (17.56 ± 1.52 cmH₂O) of the Ambu AuraGain in this study

was comparable with previous study by Jagannathan et al.³² using size 2 for positive pressure ventilation.

The time for successful insertion, number of attempts and ease of device placement were similar between both groups. The time taken for successful insertion for both devices (mean time for air-Q® 12.06 ± 5.4 s vs Ambu AuraGain 12.03 ± 2.38 s) required lesser time compared to previous study.^{28,32} Different definition of “successful insertion time” in various studies will result in different time. In this study, both devices were successfully inserted in first attempts (100%). This finding was correlated to previous studies conducted among children, in the air-Q® group with 100% success rate in first attempt,^{27,28} whereas in the Ambu AuraGain group, a study has reported a success rate of 96%.³² These results may be influenced by usage of neuromuscular blockade which facilitates the device placement.

The hemodynamic parameter changes before and

after insertions of both devices were stable for both groups. To date there is no study done to compare hemodynamic parameter for both devices. Previous studies has found that LMA generally produced lesser hemodynamic stress response compared to tracheal intubation, and the hemodynamic stress response was comparable with insertion of oral airway.^{4,6}

The quality of airway during placement and maintenance of anesthesia were not statistically significant for both groups. However, air-Q® required more adjustments during device placement and anesthetic maintenance in which may indicate suboptimal performance of the device. Adjustments include further insertion of device during placement of device with intermittent partial obstruction and adjusted patient head during maintenance of anesthesia. This may be related to the anatomical position of the device and material of tube which was slightly softer and easy to move if not properly plastered. Overall, both devices did not show any significant leak leading to ineffective ventilation or device failure that needs a conversion to other devices.

The complication for both groups were observed after device removal and when patient in the recovery unit. There were very few complications and the results were consistent with previous trials.^{13,28,29,32} Blood staining was reported in one patient after removal of the Ambu AuraGain. The usage of neuromuscular blocking agent facilitates insertion of device and minimize trauma. This rate of incidence was similar with previous study using neuromuscular blockade.^{27,28,32} Bronchospasm occurred in one patient upon removal of Ambu AuraGain and was resolved with positive pressure via bag mask ventilation. Another patient developed laryngospasm before removal of Ambu AuraGain and resolved after applying tight fitting mask with CPAP and boluses of intravenous propofol.

Limitations of the study

This study only enrolled healthy children with normal

airway anatomy and the result of this study cannot be applied to children with potential difficult airway. Secondly, gastric insufflation during leak pressure test was not documented. Thirdly, parameters for positive pressure ventilation were not specified and therefore assessment of certain value such as inspired and expired tidal volume was not evaluated. Nevertheless, the result may not be applied to children who do not receive neuromuscular blockade.

CONCLUSION

Usage of air-Q® in pediatric patient is superior to Ambu AuraGain in terms of fiberoptic view of vocal cord and higher oropharyngeal leak pressure. air-Q® may offer more clinical advantages when blind or fiberoptic intubation is needed and is promising in term of safety during controlled ventilation. Clinical performances in term of time for successful insertion, first attempt success rate, ease of insertion, quality of airway during placement and maintenance of anesthesia, hemodynamic parameters and complications were comparable for both devices.

Disclosure

The study products (AMBU AuraGain and AMBU A-Scope) were donated by AMBU A/S, Denmark to assist in this research. The company has no role in the design of the study, data collection, analysis, data interpretation and in writing the manuscript.

Conflict of Interest: None

Ethical approval: approval by the Human Research Ethics Committee of Universiti Sains Malaysia (approval number: USM/JEPeM/15110476)

Study registration at www.clinicaltrials.gov: NCT03130413

Authors' contribution:

NMZ: Literature review, data collection, manuscript drafting

RHMZ: Designed the study, data analysis, manuscript editing

MII: Concept, data collection, manuscript editing

SEC: Literature review, data interpretation, manuscript editing

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