COMPARING THE EFFECTIVENESS BETWEEN AIR-Q INTUBATING LARYNGEAL AIRWAY AND AMBU® AURAGAIN™ LARYNGEAL MASK FOR CONTROLLED VENTILATION IN PAEDIATRIC PATIENTS: A RANDOMIZED CONTROLLED TRIAL

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ABBREVIATIONS

ANOVA - Analysis of variance

ASA – American society of anaesthesiologists

etCO2 - End tidal carbon dioxide

CPAP – Continuous positive airway pressure

FO – Fibreoptic

HUSM – Hospital University Sains Malaysia

ILA – Intubating laryngeal mask airway

IV- Intravenous

LMA - Laryngeal mask airway

MAC – Minimum alveolar concentration

MV – Minute ventilation

OLP – Oropharyngeal leak pressure

OT- Operation theatre

PPV – Positive pressure ventilation

SAD - Supraglottic airway device

SD - Standard deviation

SPSS – Statistical analysis software package

ABSTRACT

Background: Supraglottic airway device (SAD) is a common device use in anaesthesia practice including paediatric patients. Air-Q ILA (Cook gas LLC; Mercury Medical, Clearwater, FL, USA) is the newer first generation of SAD that can use for both primary airway device and an aid for tracheal intubation. Available literature demonstrated that this device performed better and equally to the other SAD including second generation of SAD. Ambu® AuraGain™ (Ambu, Ballerup, Denmark) is a newer second generation of SAD which incorporates both integrating gastric port access and intubation capability. The study is conducted to compare the effectiveness between Air-Q and Ambu AuraGain for controlled ventilation in children up to 30kg.

Methods: 64 paediatric patients underwent various short surgical procedures were randomly assigned to receive either an Air-Q or Ambu AuraGain. Fibreoptic (FO) 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 anaesthesia, haemodynamic parameters and complications.

Results: Air-Q has more favourable FO grades of view compared to the Ambu AuraGain (P = 0.047). OLP is significantly higher in Air-Q group compared to Ambu AuraGain (19.41 ± 1.19 cm H_20 vs 17.56 ± 1.52 cm H_20, P value = <0.001). There were no differences in term of number of attempts, time of successful insertion, quality of airway during placement and maintenance of anaesthesia and complications.

Conclusion: Air-Q offers more clinical advantages than Ambu AuraGain for controlled ventilation in paediatric patients as it provides higher airway sealing pressure and better FO grade of laryngeal view.

ABSTRAK

Latarbelakang: Peranti saluran udara supraglotik (SAD) adalah peranti yang biasa digunakan dalam amalan anestesia termasuk pesakit pediatrik. Air-Q ILA (Gas LLC Cook; Mercury Medical, Clearwater, FL, USA) merupakan generasi terbaharu SAD yang boleh digunakan untuk peranti udara utama dan sebagai bantuan intubasi trakea. Sorotan literatur yang ada menunjukkan peranti ini berprestasi lebih baik dan sama seperti SAD lain termasuk generasi kedua SAD. Ambu® AuraGain™ (Ambu, Ballerup, Denmark) merupakan SAD generasi baru yang menggabungkan kedua-dua port akses gastrik dan keupayaan intubasi. Kajian ini diadakan untuk membandingkan keberkesanan di antara Air-Q ILA dan Ambu AuraGain untuk ventilasi terkawal dalam kalangan kanak-kanak dengan berat sehingga 30 kg.

Kaedah: 64 pesakit pediatrik yang menjalani pelbagai prosedur pembedahan dipilih secara rawak untuk menerima sama ada Air-Q ILA atau Ambu AuraGain. Pandangan laringeal dengan Gred optik fiber (FO) diukur sebagai hasil utama. Hasil kedua yang diukur adalah kebocoran tekanan orofaringeal (OLP), jumlah percubaan, bilangan kemasukan yang berjaya, kualiti aliran udara ketika penempatan dan penyelenggaraan anestesia, parameter hemodinamik dan komplikasi.

Keputusan: Air-Q ILA mempunyai tahap pandangan FO yang lebih baik berbanding dengan Ambu AuraGain (P=0.047). OLP lebih tinggi dalam kumpulan Air-Q ILA berbanding dengan Ambu AuraGain (19.41±1.19 cm H_2O vs 17.56± cm H_2O, nilai P=<0.001). Tidak terdapat perbezaan daripada segi bilangan percubaan, bilangan kemasukan yang berjaya, kualiti aliran udara ketika penempatan dan penyelenggaraan anestesia, dan komplikasi.

Kesimpulan: Air-Q ILA menawarkan kelebihan klinikal lebih daripada Ambu AuraGain bagi kawalan pengudaraan dalam kalangan pesakit pediatrik kerana ia memberi tekanan kedap udara yang lebih tinggi dan tahap pandangan laringeal yang lebih baik

CHAPTER 1: INTRODUCTION

1.0 Introduction

When Archie Brain introduced the first supraglottic airway device (SAD) which was the laryngeal mask airway (LMA) in 1983 (1), various types of supraglottic airway devices (SADs) started emerging and became an alternative choice of airway management in between facemask or tracheal tube (2). SAD is considered more invasive than facemask for anaesthesia and less invasive if compared with tracheal intubation. SAD defined as a device that delivers oxygen and/or gas without penetrating the vocal cords (glottis) (3). This device is designed to maintain clear airway which lies outside and creates a seal around the larynx. Therefore the term "extraglottic" maybe more accurate but not routinely use (4, 5).

Previously, the roles of SAD are mainly address for routine anaesthesia for low risk type of surgery in adult and paediatric populations. However in modern airway management, the roles of these devices were extended which include as a conduit for tracheal intubation, airway rescue in difficult airway including neonatal resuscitation, airway maintenance for obese and higher risk patients and airway management outside the operation theatre (6-8).

With so many potential roles in modern airway management, these devices had undergone modification and improvement in order to increase safety, functions and performances (9-13). Despite of this, there are several limitations related to SAD which include stability of the airway, surgical access, ability to ventilate through the device

and the risk of pulmonary aspiration and regurgitation (12, 14). According to The Fourth National Audit Project of the Royal College of Anaesthetists and Difficult Airway Society (NAP4) (15, 16), the major airway complication related to SAD was pulmonary aspiration. Therefore the greatest important regarding SAD in anaesthesia practice is safety profile rather than efficacy of the device (11, 17). In order to acquire the safety data it requires extensive use of the device in thousand patients especially for the newer SAD (9, 10).

SADs are widely used in children due to variety of sizes available and successful reports used in neonates and patients with airway abnormality (3, 8, 18). When choosing the right SAD for paediatric patient, one should consider the paediatric anatomy and physiology which differs from adult (5, 19). SAD is relatively easy to insert in children. However in infants, the characteristic of epiglottis is long and floppy which frequently caught and down folded by the tip of the device (19). Some studies did demonstrated the higher incidence of epiglottic downfolding with smaller sizes of SAD which confirmed by fibreoptic assessment through the device. But the clinical relation to airway obstruction remain unclear (20-22). Other safety concern is gastric insufflation during controlled ventilation which common problem in paediatric patients. This gas leakage leads to gastric distension which can compromise ventilation and may predispose to regurgitation of gastric contents especially in infants.

The established paediatric first generations of SAD were laryngeal mask airway classic (cLMA) and laryngeal mask airway Unique (ULMA) and for second generation were laryngeal mask airway ProSeal. There were introduced into clinical practice in 1987,

1997 and 2000. Among of this, the cLMA have a strong evidence base with more than 2500 studies supporting their use which then became the benchmark for other SADs (10). The cLMA is a first generation without a gastric channel which was introduced in clinical practice in 1987. It is made for reusable, has multiple variations and disposable variations and the ULMA is the disposable version of cLMA. The limitations of the cLMA were leakage during positive pressure ventilation due to moderate pharyngeal seal and risk of pulmonary aspiration. This has encouraged modification of device which described as second generation of SADs and includes features such as gastric drain in order to improve safety. Despite this, more than 70% of anaesthesia practice in UK still preferred using first generation of SADs (23).

Air-Q ILA (Cook gas LLC; Mercury Medical, Clearwater, FL, USA) was first introduced in 2004 by Dr Daniel Cook. It is classified as newer first generation of SAD available for paediatric population which specifically designed to use as a primary airway device and conduit for tracheal intubation. It is available as a single use (Air-Q) and reusable (ILA) device. The Air-Q standard cuffed has an oval shape laryngeal mask with slightly curved airway tube. It has several numbers of features which include shorter shaft, wider airway tube to facilitate tracheal tube either blindly or mounted on fibreoptic bronchoscope and detachable connecter. The unique feature of Air-Q is the mask has an elevated keyhole-shaped ventilating orifice which designed to prevent epiglottic downfolding. The Air-Q had performed well in various pilot (24-26) and randomized trial studies in several infants and children (27-30) including several case series of difficult airway (31-33).

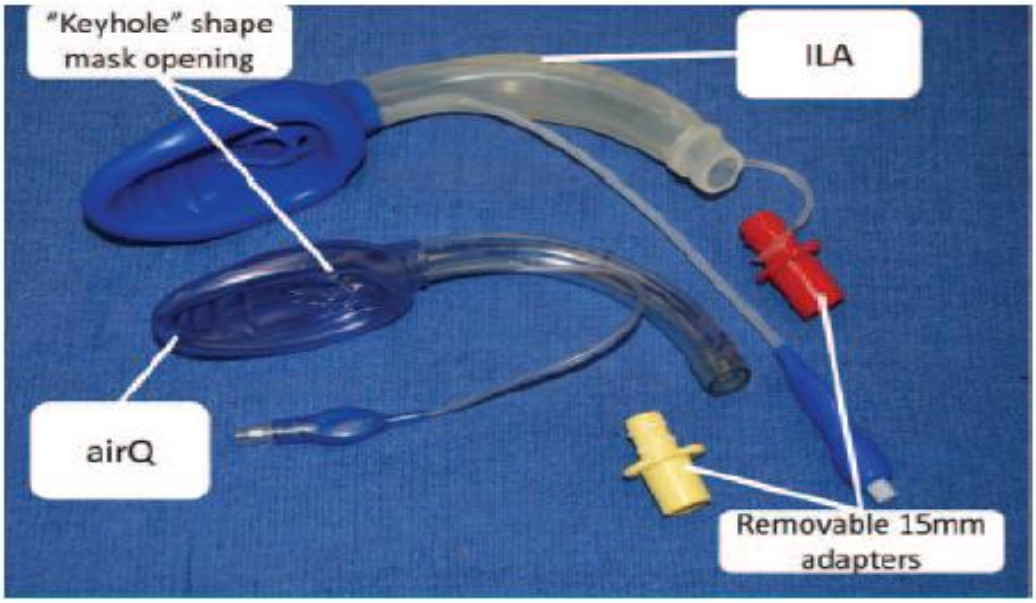

Figure 1: Air-Q ILA (Intubating Laryngeal Airway) with "keyhole" shape mask opening to prevent epiglottic downfolding. *Image adapted from Hernandez et al 2012*.

Recommendations:

Size	IBW	Max. OETT	Mouth Opening[1]	⟵ ⟶[2]	Volume[3]	Inf. Vol.[4]
4.5	70-100 kg	8.5mm	25 mm	20 cm	25 ml	4-5 ml
3.5	50-70 kg	7.5mm	23 mm	18 cm	18 ml	3-4 ml
2.5	30-50 kg	6.5mm	20 mm	16 cm	12 ml	2-3 ml
2.0	17-30 kg	5.5mm	17 mm	13 cm	8 ml	1-2 ml
1.5	7-17 kg	5.0mm	14 mm	10 cm	5 ml	1 ml
1.0	4-7 kg	4.5mm	11 mm	8 cm	3 ml	.5-1 ml
0.5	≤ 4 kg	4.0mm	8 mm	6 cm	2.5 ml	0-.5 ml

Figure 2: Selection of device according to patient weight. *Image adapted from product information of Air-Q ILA Malaysia 2011*.

There were slight different in term of range of weight in relation to size of device if compared to other SAD. This new weight-based guidelines had been revised in 2009 by Jagannathan (34) after case series use of Air-Q in children with limited mouth opening. The potential advantages of Air-Q were ability to provide high leak pressure, superior fibreoptic view and can be used for either primary airway maintenance or aid for tracheal intubation in difficult airway patients (31-33). A trial compared Air-Q with ULMA was found to have higher leak pressure and better fibreoptic view in young children (27). Other SADs being compared with Air-Q was Ambu Aura-I (28, 30), flexible laryngeal mask airway (fLMA) (29) and LMA ProSeal (25).

Ambu® AuraGain™ (Ambu, Ballerup, Denmark) is a newer second generation of SAD. It is the third generation of laryngeal mask from the Ambu A/S manufacturer produced in 2015 and recently available in paediatric sizes. Ambu AuraGain is a single use device and the only Ambu Aura which designed anatomically curved to follow human airway anatomy to ensure rapid insertion. The inflatable mask cuff designed to be thin and soft to deliver high seal pressures and wider tube to facilitate tracheal intubation. The indication of the device is similar with Air-Q which can be used both as primary airway device and aid for tracheal intubation. But the different is this device has integrated gastric access channel to facilitate management of gastric contents and prevents gastric insufflation.

Figure 3: Ambu AuraGain. *Image adapted from product information of Ambu AuraGain 2015.*

	Mask size							
	#1	#1½	#2	#2½	#3	#4	#5	#6
Patient weight	< 5 kg	5-10 kg	10-20 kg	20-30 kg	30-50 kg	50-70 kg	70-100 kg	>100 kg
Maximum intracuff volume	4 ml	7 ml	10 ml	14 ml	20 ml	30 ml	40 ml	50 ml
Maximum intracuff pressure	60 cm H_2O							

Figure 4: Selection of device according to patient weight. *Image adapted from product information of Ambu AuraGain 2015.*

Potential advantages of Ambu AuraGain that need to be highlighted such as ability to deliver high sealing pressure, alternative device can be used for primary airway maintenance and conduit for tracheal intubation when necessary after device insertion. This Ambu AuraGain has limited study in paediatric population. To date, there was only one trial comparing Ambu AuraGain with LMA Supreme and this LMA supreme is single use SAD with gastric port channel (35). The result of this trial had showed Ambu AuraGain have comparable clinical performance with available established second generation of SAD.

The introduction of laryngeal mask airway over 30years ago was an important step towards development of variety of new SADs. As an anaesthetist, it is worth to understand the potential advantages and limitations of each new device which introduced into clinical practice through a thorough clinical evaluation compared to the device which was already established. This clinical evaluation will help us to provide potential benefit to a patient of a specific device according to certain clinical situation.

1.2 Study Objectives

1.2.1 General Objective:

To compare the effectiveness between Air-Q and Ambu AuraGain for controlled ventilation in children undergoing elective surgery.

1.2.2 Specific Objectives:

In order to achieve above general objectives, six specific objectives are formulated:

1) To compare the ease of insertion (number of attempts and time of successful insertion) between Air-Q and Ambu AuraGain for controlled ventilation in children undergoing elective surgery.
2) To compare the oropharyngeal leak pressure (OLP) between Air-Q and Ambu AuraGain for controlled ventilation in children undergoing elective surgery.
3) To compare the fibreoptic (FO) grade of laryngeal view between Air-Q and Ambu AuraGain for controlled ventilation in children undergoing elective surgery.
4) To compare quality of airway during placement and maintenance of anaesthesia between Air-Q and Ambu AuraGain for controlled ventilation in children undergoing elective surgery.
5) To compare the hemodynamic stability (includes BP, MAP, HR and spo2) between Air-Q and Ambu AuraGain for controlled ventilation in children undergoing elective surgery.

6) To compare the incidence of complications between Air-Q and Ambu AuraGain for controlled ventilation in children undergoing elective surgery.

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CHAPTER 2: STUDY PROTOCOL

2.1 Background of study

Supraglottic airway devices (SADs) are now become routine in anesthesia practice as airway maintenance during low risk surgery, airway rescue in difficult airway, conduit to facilitate tracheal intubation and airway management outside operating theatre (OT) (1, 2). Many newer SADs are manufactured in the last decade and available to anesthetists. The aim is to improve clinical performance, increase safety profiles and increase number of functions. Air-Q and Ambu® AuraGain™ is newer SADs that can used as primary airway device and also conduit for tracheal intubation. With modification of the device and availability of suitable sizes, it has increasingly being used in pediatric populations.

Available study showed both of these devices have good clinical performance such as higher airway leak pressure and better fibreoptic grades of view. However there is no clinical study to date evaluates the clinical performance in between Air-Q and Ambu® AuraGain™ in children for primary airway device. Therefore the aim of this prospective study is to compare the performance and safety of these two devices in terms of OLP (oropharyngeal leak pressure) and fibreoptic grades of view as primary outcome. Secondary outcome measures included number of attempts, time of insertion, quality of airway during placement and maintenance anesthesia, hemodynamic stability and complications.

2.2 Literature Review

Supraglottic airway device (SAD) is the device that can use both in spontaneous and ventilated patients during anesthesia (3). It consists of tube that is connected to respiratory circuit or breathing bag which is attached to a hypopharyngeal device that seals and directs airflow to glottis, trachea and lungs. First generation of SAD is a classic laryngeal mask airway (cLMA) which was first invented by Dr Archie Brain in 1983 (4) . First used successfully in a pilot study on 23 patients and Dr Brain first reported its use in a failed intubation scenario in 1983. It is made from silicone, reusable device and act as a benchmark to other SAD. This cLMA become commercially available in 1998 and more than 500 British Hospitals used it within first 12 months of its availability in the UK. In 1991, the Food and Drug Administration of United States approved it as a substitute for face mask during elective anesthesia (1). Since then, cLMA has widely used in routine for pediatric anesthesia and aid the management of children with difficult airways.

SAD offered advantages over endotracheal intubation as they are easier and faster to insert than tracheal tube (5), useful device as rescue in difficult airway (6), better hemodynamic stability (7-9) and produce minimal trauma to the airway. In general, most common minor adverse effects following SAD is sorethroat and major adverse effects, e.g aspiration (10). The Fourth National Audit Project of the Royal College of Anesthetists and Difficult Airway Society (NAP4) (11) had highlighted important issues around SADs which are the most common complication associated with SAD was pulmonary aspiration. Therefore the second generation of SAD have been designed to improve performance and increase safety and function by adding

esophageal drain channel to reduce risk of aspiration and regurgitation (12, 13) and being promoted for routine use in airway management. The most established second generation of SAD is ProSeal LMA (pLMA) which was introduced in 2000 and pediatric sizes available in 2004 (14). It is designed to use for both spontaneous and controlled ventilation. Other newer second generations of SADs that are available in all pediatric sizes are I-gel, Supreme LMA (sLMA) and Ambu LMA. For many SADs that available, cLMA and pLMA has the largest evidence based on safety and efficacy for pediatric population. The others SAD still have lacking data available for efficacy and randomized controlled trial needed to establish especially safety data.

A survey done in UK (15), majority (>80%) of SADs used in UK pediatric anesthetic practice are first generation devices. The reasoning behind were user familiarity and cost considerations. The second generation of SADs have been slower to adapt due to availability of pediatric sizes which came to market later compare to adult and aspiration-related to SAD is seen less frequently and less morbidity in children compared with adults (16).

Air-Q ILA (Cook gas LLC; Mercury Medical, Clearwater, FL, USA) is a newer first generation of SAD that can use for both primary airway device and conduits for tracheal intubation. It is an oval-shaped laryngeal mask with a shortened, wide and curved airway tube. Air-Q has three versions which are standard cuffed, self-pressurized (air-Q SP; lack of an inflatable cuff) and air-Q with an esophageal

blocker (second generation device but not yet available for children) and manufactured as a reusable or single use device. The Air-Q has number of features (17):

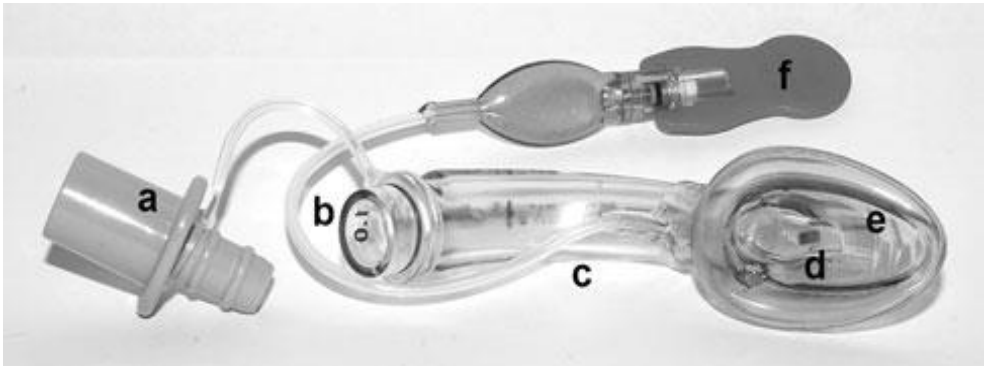

Figure 5: Single use and standard cuffed version of Air-Q. *Image adapted from Whyte SD et al 2013.*

a) Removable proximal 15mm connector
b) Larger opening to allow passage of the endotracheal tube
c) Shorter effective length of the shaft for ease of air-Q removal
d) Elevated keyhole-shaped ventilating orifice to prevent epiglottic downfolding and also shape and orientation of the distal outlet directs a FOB or an endotracheal tube towards the glottis
e) Reinforced bars prevent the tip from downfolding or backfolding
f) The tab inserted in the pilot balloon valve allows the mask cuff to mould to the pharynx, once the tab is removed, the cuff is seals in its moulded shape

Ambu® AuraGain™ (Ambu, Ballerup, Denmark) is a newer second generation of SAD and it is Ambu 3rd generation of laryngeal mask which is satisfied 3 fundamental of airway management such as rapid placement, high seal pressure, gastric access channel and intubation capability. Several features are:

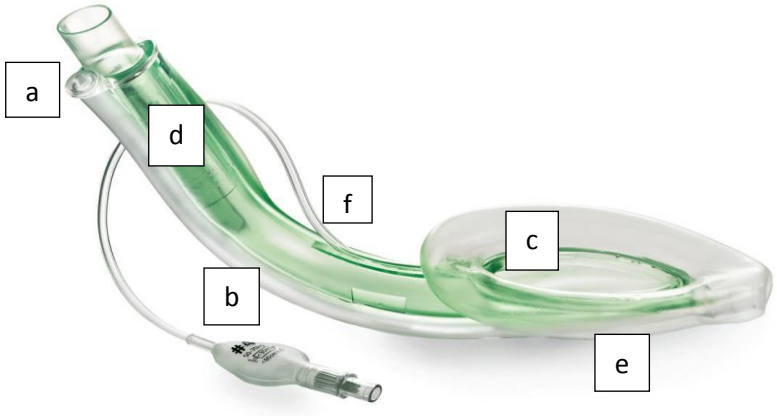

Figure 6: Single use device of Ambu AuraGain. *Image adapted from product information of Ambu AuraGain 2015.*

a) Gastric drain tube port- for placement of gastric tube
b) Shorter airway tube and anatomical curve
c) Soft inflatable cuff for higher pressure
d) Incorporated bite absorption area
e) Flat back plate of domen, which creates a stability after placement
f) Fixation hook for the pilot tube

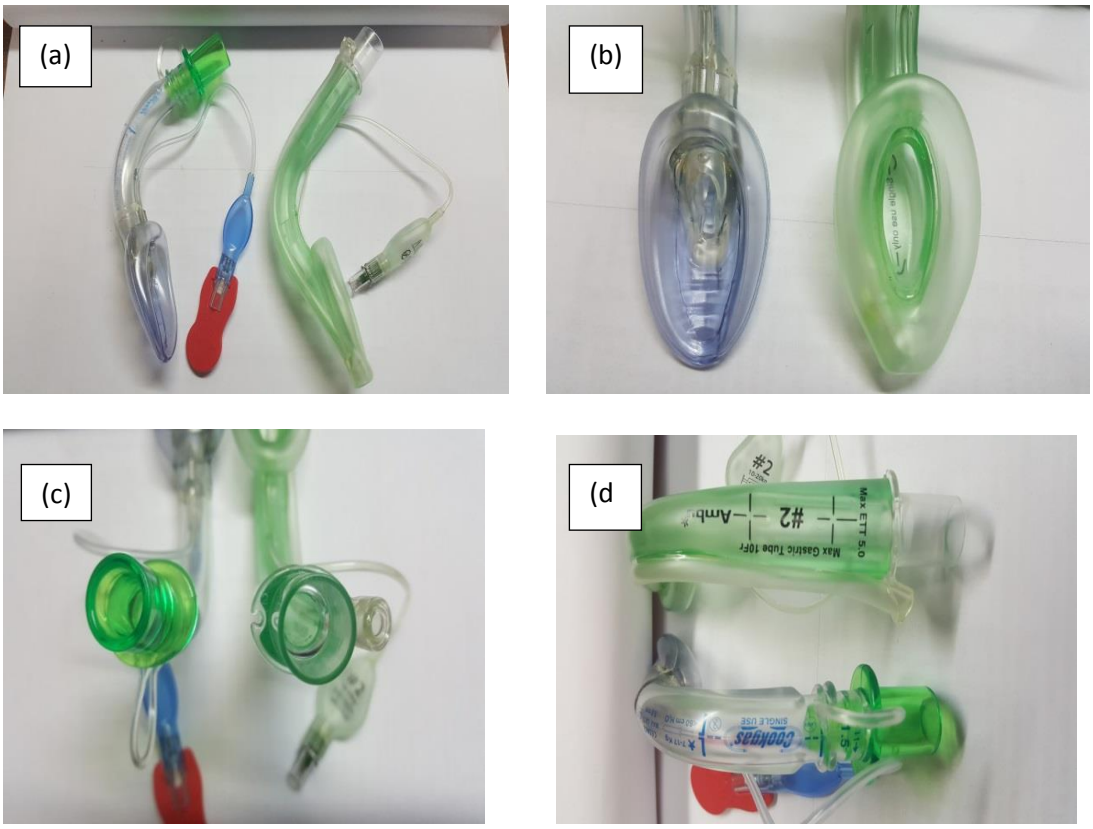

Figure 7: Panel A-D. Images of the size 1.5 Air-Q and size 2 Ambu AuraGain. A) Lateral views of the air-Q (left) and Ambu AuraGain (right). Note the slightly shorter airway tube of Air-Q and larger proximity mask of Ambu AuraGain. B) Mask bowls of the Air-Q (left) and Ambu AuraGain (right). C) Superior views of the Air-Q (left) and Ambu AuraGain (right). Noted 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). Noted the Ambu AuraGain has 2 horizontal markings where the upper incisor/gum line of the patient should rest between. Also has additional markings indicates the maximum diameter of tracheal and gastric tubes that can fit through the device. For Air-Q, has also 2 similar horizontal markings wherethe upper incisor/ gum line of the patient should rest between and the end of airway tube there is marking indicates the maximum dianeter of tracheal tube and range of weight.

Various studies showed satisfactory clinical performance, efficacy and safety of Air-Q usage as primary airway device and conduit for tracheal intubation in both adult and pediatric patients. Available study in children weighing 10-15kg using both first generation of SAD as primary airway maintenance found Air-Q have higher airway leak pressure and superior fibreoptic (FO) view when compared with LMA-Unique (18). Another randomized trial in small infants <10kg also found similar finding where cuffed Air-Q is superior compared to flexible laryngeal mask airway (fLMA) in providing higher airway sealing pressures and better fibreoptic grade laryngeal view (19). When compared with Ambu Aura- I, both devices have similar success rate in fibreoptic view but Air-Q provide significant higher airway leak pressure (20). In term of ease of insertion and complications there were no difference between Air-Q and other first generation SAD. However there is still limited study evaluating Air-Q in older pediatrics population.

For Ambu AuraGain in children, available study using sizes 1.5 and 2 found that there are comparable clinical performance in between supreme LMA (sLMA) and Ambu AuraGain (21). Children receiving LMA supreme required more airway maneuvers (7 vs 1 patient, p= 0.06) to maintain airway patency. In view of current availability of all pediatric sizes, there are needed another prospective trial to evaluate clinical performance of available sizes of the device with other SAD.

2.3 Justification of the study

The aim of this randomized study is conducted is to evaluate the performance and safety of Air-Q as primary airway device in various short surgical procedure in children compared to Ambu AuraGain Laryngeal Mask. Current SAD available in HUSM is Classic LMA (cLMA), ProSeal LMA (pLMA), Supreme LMA (sLMA) and the newer is Ambu AuraGain laryngeal mask. As variety of newer SADs for children have emerged since their introduction in clinical practice, hope the outcomes of this study it help advancing our knowledge and acumen in selecting appropriate devices for pediatric population.

2.4 Research Objectives

The objectives of this study were divided into general and specific objectives.

2.4.1 General Objective

To compare the effectiveness between Air-Q and Ambu AuraGain for controlled ventilation in children undergoing elective surgery.

2.4.2 Specific Objectives

1) To compare the ease of insertion (number of attempts and time of successful insertion) between Air-Q and Ambu AuraGain for controlled ventilation in children undergoing elective surgery.

2) To compare the oropharyngeal leak pressure (OLP) between Air-Q and Ambu AuraGain for controlled ventilation in children undergoing elective surgery.
3) To compare the fibreoptic (FO) grade of laryngeal view between Air-Q and Ambu AuraGain for controlled ventilation in children undergoing elective surgery.
4) To compare quality of airway during placement and maintenance of anesthesia between Air-Q and Ambu AuraGain for controlled ventilation in children undergoing elective surgery.
5) To compare the hemodynamic stability (includes BP, MAP, HR and spo2) between Air-Q and Ambu AuraGain for controlled ventilation in children undergoing elective surgery.
6) To compare the incidence of complications between Air-Q and Ambu AuraGain for controlled ventilation in children undergoing elective surgery.

2.5 Null Hypotheses

1) There is no difference in the ease of insertion (number of attempts and time of successful insertion) between Air-Q and Ambu AuraGain for controlled ventilation in children undergoing elective surgery.
2) There is no difference in the oropharyngeal leak pressure (OLP) between Air-Q and Ambu AuraGain for controlled ventilation in children undergoing elective surgery.

3) There is no difference in the fibreoptic (FO) grade of laryngeal view between Air-Q and Ambu AuraGain for controlled ventilation in children undergoing elective surgery.
4) There is no difference in the quality of airway during placement and maintenance of anesthesia between Air-Q and Ambu AuraGain for controlled ventilation in children undergoing elective surgery.
5) There is no difference in hemodynamic changes (includes BP, HR and spo2) between Air-Q and Ambu AuraGain for controlled ventilation in children undergoing elective surgery.
6) There is no difference in the incidence of complications between Air-Q and Ambu AuraGain for controlled ventilation in children undergoing elective surgery.

2.6. Research Methods and Methodology

2.6.1 Research Design

This is a prospective, single blinded and randomized controlled trial study.

2.6.2 Study Area

The study will be conducted at General Operation Theatre (GOT), Hospital Universiti Sains Malaysia (HUSM).

2.6.3 Study Population

Pediatric patients scheduled for various surgical procedures within 2 hours where supraglottic airway device (SAD) management would be appropriate.