Airway Management for Pediatric Patients Under Controlled Ventilation: A Comparative Study between I-gel Supraglottic Airway and Air-Q Intubating Laryngeal Airway (ILA)

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Abstract

Background: Supraglottic Airway Devices (SAD) are now widely used for surgery requiring general anesthesia during spontaneous or controlled ventilation.

Objective: To compare the efficacy of I-gel and Air-Q ILA in maintaining airway in pediatrics during controlled ventilation by monitoring of leak pressure.

Patients and Methods: This prospective single blind randomized study was conducted on 200 cases of pediatric patients of either sex of age range from one year to twelve years old undergoing elective surgical procedures using controlled mechanical ventilation.

The patients were randomly allocated into two groups: Group (I) using I-gel and Group (II) using Air-Q ILA. Airway sealing pressure was the primary variant and the secondary outcomes are; ease of insertion, insertion attempts, fiber optic assessment and post removal complications.

Results: This study showed that the time of insertion of the device had significant differences for the Group II (air-Q) on Group I (I-gel) as (10.58 ± 1.81) seconds vs. (12.05 ± 1.99) seconds and for the leak pressure as in Group I (I-gel) was (19.16 ± 1.64) cmH₂O and in Group II (Air-Q) was (19.99 ± 2.26) cmH₂O. In Group I (I-gel) optimal glottis view was 76% and in Group II (air-Q) optimal glottis view was 90%.

Conclusion: The Air-Q ILA is proved to be better than I-gel during controlled volume ventilation in pediatric patients as regarded the airway leak pressure, insertion time and fiberoptic bronchoscopic view.

Key Words: I-gel – Air-Q ILA – Pediatric – Controlled ventilation.

Introduction

TRACHEAL intubation is considered to be the “gold standard” for securing the airway, as it allows proper establishment of ventilation and offers protection against pulmonary aspiration [1]. As the cricoid cartilage of the children is small in size and forms a complete ring, the presence of mucosal edema at this site will severely compromise the airway. Young children are also at risk of acquired subglottic stenosis when exposed to prolonged or repeated tracheal intubation [2].

Recently, many supraglottic airway devices have been introduced in the clinical practice of the airway management to offer simple and effective alternatives to endotracheal intubation [3]. They are now widely used for surgery requiring general anesthesia during spontaneous or controlled ventilation [4].

Recent studies support the use of I-gel during anesthesia for spontaneously breathing patients [5]. Also, studies have shown that: The original air-Q is an effective device for airway maintenance and as a conduit for tracheal intubation in both adults and children [6,7].

We were comparing the clinical performance of both (I-gel and air-Q ILA) in terms of the efficacy and safety management in anesthetized pediatric patients on controlled ventilation, undergoing elective surgical procedures.

We hypotheses that the air-Q is better than I-gel as, there is a space above the ventilating orifice for the epiglottis to rest on, which leads to improved epiglottic isolation and the relatively larger mask size, which provides better airway sealing pressure...
Patients and Methods

This prospective single blind randomized study was conducted at Mansoura University Children Hospital (MUCH) from the 1st of August 2014 to the end of July 2016, after approval by the Local Ethical Committee of Department of Anesthesia and Surgical Intensive Care, Faculty of Medicine, Mansoura University on 200 cases of pediatric patients of age range from one year to twelve years old undergoing elective surgical procedures using controlled mechanical ventilation.

Randomization was done through sealed envelopes method. Envelops were picked to allocate the enrolled patients into two groups, Group I (I-gel) and Group II (air-Q) with 100 patients in each group. All the parents of the patients had given a written informed consent prior to enrollment.

All patients with expected difficult airway, at risk of pulmonary aspiration of gastric contents, with any pathology of the neck and upper respiratory tract or upper alimentary tract, with active respiratory tract infection and planned time for surgery suspected to be more than two hours was excluded.

We were comparing the clinical performance of both devices in terms of; airway sealing pressure as the primary variant and with secondary outcomes of; insertion time, insertion attempts, fiber optic assessment and post removal complications.

Anesthesia:

All the patients in the study after connecting the monitoring devices (pulse oximetry, non-invasive blood pressure, and 3 leads electrocardiography) were anesthetized by inhalational induction with sevoflurane (up to 8%) and oxygen. The intravenous line was secured when the patient was deeply anesthetized then he received 1 μg/kg body weight fentanyl and atracurium besylate 0.5mg/kg body weight for neuromuscular blockade. The patients were ventilated for 3min with sevoflurane (4%) and oxygen to achieve full jaw relaxation.

The back of the device was lubricated with a water soluble lubricant and introduced by firmly grasping it such that the cuff outlet was facing the chin of the patient and the device was gently glided along the hard palate in the sniffing midline position by the investigator anesthesiologist included in the study until definitive resistance was felt (as per manufacturer’s recommendation).

The size of the device was selected according to the body weight of the patient. For Group I the I-gel was (5-12kg: Size 1.5; 10-25kg: Size 2; 25-35kg: Size 2.5) and for Group II the air-Q ILA was (7-17kg: Size 1.5; 17-30kg: Size 2; 30-50kg: Size 2.5) according to the manufacturer’s guidelines and recommendation.

Insertion time was recorded as, the time from the moment the facemask was removed until the first capnography upstroke displayed. Number of attempts of device insertion was recorded and more than a 3 attempts is recorded as a failure of the device and the airway of the patient was secured by Endotracheal Intubation (ETT). Ease of insertion was graded by the same anesthesiologist subjectively on a scale from 1 to 3 (1-very easy, 2-easy and 3-difficult).

The pediatric breathing circuit was connected to the device, and all the children were ventilated (Datex-Ohmeda S/5 anesthesia delivery system) with tidal volume 8-10ml/kg and respiratory rate (12-18/min) adjusted to obtain an EtCO2 around 35mmHg and peak airway pressure less than 30cm H2O. After achieving effective ventilation, peak airway pressure “Paw” (cm H2O) and expiratory tidal volume was detected on the ventilator display screen.

The patient had been put on bag mode and the adjustable pressure limiting valve fully closed (not allowed to exceed 35cm H2O) with 3L/min to recorded leak airway pressure “LAP” (cm H2O) by observing the air-way pressure at which equilibrium will be reached on the aneroid manometer and ventilator pressure time scalar while squeezing the anesthesia circuit bag. At this point, gas leakage was heard at; in front of the neck or stomach by auscultation and the mouth by listening close to it [8].

Maintenance of anesthesia for all children was achieved with sevoflurane and oxygen fresh gas flow at 3L/min and bolus doses of 0.1mg/kg atracurium for neuromuscular blockade maintenance.

Visualization of glottis for all patients was determined by passing a fiber-optic bronchoscope (diameter, 3.7mm: Karl-Storz, Tuttinglen, Germany) through the airway tube of the device to a position 1cm proximal to the end of the airway tube of the device. The airway tube view was scored using the Brimacombe and Berry [9] Score; (1) Vocal cords not seen, (2) Vocal cords plus anterior epiglottis seen, (3) Vocal cords plus posterior epiglottis seen, (4) Only vocal cords visible. Scores 3 and 4 were considered as a good view in our study.
After the end of the surgery, neuromuscular blockade was antagonized with 0.05mg/kg neostigmine and 0.01mg/kg of atropine. The device was removed once the child was fully awake and observed for any blood staining or any other injuries in the tongue, lip and gum, laryngospasm, bronchospasm, oxygen desaturation (SpO₂ < 90%) and hoarseness of voice. The parents for all children were followed-up the evening of surgery to elicit a history of sore throat, dysphagia and dysphonia.

Failure of the supraglottic airway device in this study was defined as; the inability to achieve correct placement within three attempts, dislodgement of the device or inadequate ventilation as evidenced by obstructive chest wall movements, poor capnogram morphology, or an inability to achieve tidal volumes of at least 5ml/kg. If any failure of the device recorded the trachea was secured with endotracheal intubation.

Statistical analysis:
Sample size was calculated by depending on previous studies of both devices (I-gel and air-Q) with a primary variant was the mean ± standard deviation of the leak airway pressure. As, in the study by Jagannathan N [10] in a total of 120 children was (18.3±6.1 cm H₂O for air-Q vs. 16.5±5.1 cm H₂O for Aura-I). In other study by Theiler LG [11] between I-gel and the Ambu Aura Once laryngeal mask in anesthetized and ventilated 208 children was (22±5 cm H₂O vs. 19±3 cm H₂O) respectively. With an alpha of 0.05, and a desired power of 0.8 with 5% for drop out cases, we estimated that 100 patients would be required per device to demonstrate this difference in leak pressure between these two devices (I-gel and air-Q). Data was recorded using a standardized data collection sheet, and analyzed using SPSS (Statistical Package for Social Sciences) Version 16. Qualitative data was presented as mean ± SD. Paired t-test was used for comparison within groups. *p*<0.05 was considered to be statistically significant.

Results

The demographic characteristics were comparable between both groups as well as HR and MBP, EtCO₂, number of attempts, easiness of insertion, expiratory tidal volume and post removal complication.

The time of insertion of the device showed highly significant differences for the Group II (air-Q) on Group I (I-gel) as (10.58 ± 1.81) seconds vs. (12.05 ± 1.99) seconds respectively. We had succeed in insertion of the device from first attempt in 64 patients in Group I (I-gel) to 75 patients in Group II (Air-q) and 100% easily insertion of both devices, divided between 66 very easy to 34 easy insertion in Group II (Air-q), where in Group I (I-gel) was 57 very easy to 43 easy insertion, as shown in (Table 2). There were statistically significant differences between the two groups for the leak pressure as in Group I (I-gel) was (19.16±1.64) cm H₂O and in Group II (Air-q) was (19.99±2.26) cm H₂O, as shown in (Table 3).

In Group I (I-gel) optimal glottis view was 76% divided (44:32 patient in view grade 4: Grade 3) and in Group II (air-q) optimal glottis view was 90% divided (67:23 patient in view grade 4: Grade 3) as shown in Fig. (1). There was eight cases of soar-throat in Group I (I-gel) for five cases in Group II (Air-q) and four cases of blood staining on the device in Group I (I-gel) for three cases in Group II (Air-q) as shown in (Table 3).

| Table (1): Patients characteristics: Values are presented as mean ± SD, numbers, ratio and percent. |
|-----------------------------------------------|------------------|------------------|
| Group I (I-gel) | Group II (Air-q) | p-value |
| n=100 | n=100 |
| Age (years) | 2.74±1.48 | 2.84±1.38 | 0.636 |
| Weight (kg) | 16.12±5.53 | 16.89±5.91 | 0.343 |
| Sex (male/female) no | 78/22 | 73/27 | |
| Surg. duration (minutes) | 54.90±27.52 | 53.95±22.81 | 0.791 |

| Table (2): Insertion parameters of the studied patients (insertion time by seconds, sizes of the devices, number of attempts, ease of insertion and complications): values are presented as mean ± SD, numbers, ratio and percent. |
|-----------------------------------------------|------------------|------------------|------------------|
| Group I (I-gel) | Group II (Air-q) | p-value |
| n=100 | n=100 |
| Insertion time (seconds) | 12.05±1.99 | 10.58±1.81* | <0.001 |
| Sizes 1.5/2/2.5 | 17/72/11 | 57/32/11 | |
| No. of attempts (1/2/3) | 64/36/0 | 75/25/0 | 0.091 |
| Ease of insertion (very easy/easy/difficult) | 57/43/0 | 66/34/0 | 0.191 |
| Complication %: | |
| Sorethroat | 8% | 5% | 0.630 |
| Blood staining on device | 4% | 3% | |

*p*-value is significant when *<0.05.
**: Significant in Group II when compared to Group I.
For insertion time, our results concedes with that by Jagannathan et al., [21], who reported (20 cmH2O) for I-gel in comparison to LMA supreme. Whilein contrast to our results, the I-gel was compared with the LMA ProSeal in the study by Tokgoz et al., [18] and included I-gel sizes 1-2.5, and he did not separate results by I-gel size but, overall sizes were included. They reported mean oropharyngeal leak pressure with the I-gel between 21 and 28cmH2O. Lee et al., [17] compared the I-gel with the LMA Classic, they used devices of size 1.5-2.5. The average oropharyngeal leak pressure with the I-gel ranged from 22 to 26cmH2O. In the study by Hughes et al., [22] who evaluated sizes 1-2.5 over a period of 12 months and used neuromuscular blocking agents like us. The median leak pressure ranged between 20 and 27cmH2O.

For I-gel the leak pressure in our study concedes with that by Jagannathan et al., [21], who reported a grade 3 or 4 view in the I-gel compared with the LMA. In other study, K. Girgis, [12] who reported a grade 3 or 4 view was significantly better than that through the LMA ProSeal for sizes 2, 2.5 and 3, although not for size 1.5. Lee et al., [17] found a better fiberoptic view through the I-gel compared with the LMA Classic and Foucher-Lezla et al., [24] reported a good fiberoptic view in 86% of patients.

The lower first attempt success rate in our study for both devices when compared with other studies by N. Jagannathan, [10,13] V. Darlong [20], can be attributed to the use of different sizes and overlap.
in size selection according to body weight as recommended by the manufacturer.

As regards post removal of the device complication in our study, there were eight cases of sore throat in Group I (I-gel) for five cases in Group II (Air-q) and four cases of blood staining in Group I (I-gel) for three cases in Group II (Air-q). As, the use of neuromuscular blockade may afford some degree of safety by reducing potential problems such as reflex activation of the airway associated with device placement.

In the study by Jagannathan [10] blood staining was reported in two patients in air-Q Group. And in other study [7], there were 12 cases of gastric insufflations during leak pressure testing: Five of these occurred with the Air-QTM. K. Girgis, [12] reported blood staining of the Air-Q on removal with 2 (6.7%) patients and post-operative sore throat 1 (3.3%) patients. In the study by V. Darlong, [19] blood staining on the device was noticed in only one infants, in group (air-Q). While in his study [20] between Air-QTM and Flexible laryngeal mask airway TM reported no complications.

For I-gel complication rates during insertion, maintenance of anesthesia and recovery ranged from zero in a study by Gil et al., [25] to 23% in a study by Hughes et al., [22]. Beringer et al., [26] recorded 13 complications in 120 children (11%). Hughes et al., [22] noted complications in 36 patients: 11 on insertion of the device; 15 during maintenance of anesthesia; and 24 during emergence.

Conclusion:
Both devices were effective for pediatric patients under controlled mechanical ventilation but, the air-Q was better than I-gel especially in points of insertion time, leak pressure and fiber optic view of the glottis.

References


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**Airway Management for Pediatric Patients Under Controlled Ventilation**

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**Research comparing the I-gel supraglottic airway device in children.**

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**Comparison of the I-gel and the LMA-ProSeal for airway management in pediatric patients.**

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**Comparison of performance and efficacy of air-Q intubating laryngeal airway and flexible laryngeal mask airway in anesthetized and paralyzed infants and children.**

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**A randomized equivalence trial comparing the I-gel and laryngeal mask airway supraventricul in children.**

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**Clinical evaluation of the I-gel supraglottic airway device in children.**

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**Randomized comparison of the I-gel and the ProSeal laryngeal mask airway in pediatric patients: Performance and fibreoptic findings.**

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**Fibreoptic assessment of laryngeal positioning of the paediatric supraglottic airway device I-Gel.**

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**Pediatric I-gel use in 100 children.**

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**A cohort evaluation of the paediatric I-gel TM airway during anaesthesia in 120 children.**