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Comparison of the Air-Q intubating laryngeal mask airway and the Ambu AuraGain laryngeal mask airway as a conduit for fibreoptic assisted endotracheal intubation for simulated cervical spine injury

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Abstract

Background: Airway management in patients with a cervical spine injury is a difficult and challenging task. The aim of this study was to compare the effectiveness of the Air-Q intubating laryngeal airway and the Ambu AuraGain laryngeal mask airway as a conduit for fibreoptic (FO) assisted endotracheal intubation in adult patients with a simulated cervical spine injury.

Methods: A total of 66 adult patients underwent elective surgery under general anaesthesia, and they were randomized to two groups: the Air-Q (AQ) group (n = 33) and the Ambu AuraGain (AA) group (n = 33). A simulated cervical spine injury was created using a cervical collar, which was applied after the induction of general anaesthesia. Ease of insertion, time taken for successful insertion, time taken for successful FO guided endotracheal intubation, oropharyngeal leak pressure (OLP), Brimacombe score for FO laryngeal view, post-intubation complications and haemodynamic changes were recorded for both groups.

Results: The OLP was significantly higher in the AA group than in the AQ group (34.9 ± 6.4 vs. 28.6 ± 7.8 cm H_2O; P = 0.001). Otherwise, there were no significant differences in the ease of insertion, time taken for successful insertion, time taken for successful FO guided endotracheal intubation, Brimacombe score for FO laryngeal view, haemodynamic parameters or complication rate between the two groups.

Conclusions: Air-Q was comparably effective as Ambu AuraGain as a conduit for FO endotracheal intubation in patients with a simulated cervical spine injury; however, Ambu AuraGain has a better seal with significant OLP.

Key words: laryngeal mask airway, fibreoptic, general anaesthesia, intubation.

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A cervical spine injury is one of the leading causes of morbidity and mortality in clinical practice. The estimated worldwide spinal cord injury incidence is 40 to 80 new cases per million per year. This means that each year, between 250 000 and 500 000 people sustain a spinal cord injury [1]. The total numbers of trauma admission and blunt trauma resulting in cervical fracture increased between the years 2005 (38 009 cervical fracture [4.4% incidence]) and 2013 (55 700 cervical fracture [5.8% incidence]) [2].

Airway management for cervical injury patients requires advanced skills and is associated with a high risk of morbidity. Awake fibreoptic (FO) intubation is excellent for elective and semi-urgent situations with cooperative patients; however, the use of the awake FO technique requires significant expertise and can be complicated in urgent or emergency situations, for anxious and uncooperative patients, for unskilful FO bronchoscopy providers or in an airway filled with blood or secretions [3].

Supraglottic airway devices (SADs) have become the device of choice for many types of surgery in situations in which there is no contraindication to their use [4]. The SAD was first introduced by Archie Brain in the 1980s. Since then, various types of SADs have been designed for use in airway management [5]. The intubating laryngeal mask airway is a good

alternative as a conduit for intubation in patients with an unstable cervical spine with or without the aid of a fibreoptic bronchoscopy [6].

SADs have transformed the practice of managing airways. In addition to serving as a rescue device for difficult airways and as a conduit for endotracheal tube insertion, SADs provide a less invasive and less traumatic means of securing the airways of surgical patients [7]. The Fourth National Audit Project and the All India Difficult Airway Association have encouraged the use of second-generation SADs equipped with the passage of a gastric tube for difficult airway scenarios [8].

The Air-Q (Cookgas, St. Louis, Missouri, USA), also known as the Intubating Laryngeal Airway (ILA), was first introduced in 2005 by Dr Daniel Cook. It is designed for the maintenance of the airway and also as a conduit for endotracheal intubation during general anaesthesia. It is available in a single use and a reusable version [9]. Endotracheal intubation through Air-Q ILA can be performed either blindly or guided by an FO bronchoscope.

Ambu AuraGain (Ambu, Ballerup, Denmark) is a relatively new laryngeal mask airway (LMA), which is phthalate free and anatomically curved to facilitate insertion, and it incorporates both integrating gastric access port and intubation capability. Available studies have shown that both Air-Q ILA and Ambu AuraGain have good clinical performance, such as easy insertion and high airway leak pressure; however, no clinical study has been conducted to compare the clinical performance of the Air-Q ILA and the Ambu AuraGain as conduits for endotracheal intubation for cervical spine injuries in the adult population.

Therefore, the aim of this study was to compare the performance of the two devices based on the airway leak pressure, fibreoptic grading of the laryngeal view, ease of placement of the endotracheal tube and safety for fibreoptic assisted endotracheal intubation of simulated cervical spine injuries.

METHODS

After receiving approval from the Human Research Ethics Committee at Universiti Sains Malaysia and written informed consent from the patients, 66 elective patients were recruited. The inclusion criteria were the American Society of Anesthesiologists (ASA) classification I–II and age of the patients ranging between 18 and 60 years old. The exclusion criteria included a body mass index of more than 30 kg m^{-2}, pregnancy, a high risk of aspiration, cardiac and respiratory insufficiency, an active respiratory infection and an anticipated difficult airway. Patients underwent various types of surgical procedures in which endotracheal intubation was required.

All patients were divided equally into two groups, the Air-Q (AQ) group and the Ambu AuraGain (AA) group, using computer-generated randomisation. The order of group allocation was placed in a sealed opaque envelope by an assistant who was not involved in this study, and it was only opened by the investigator prior to device insertion. All the patients were premedicated with oral midazolam of 3.75–7.5 mg, 30 min before the procedure.

In the operating theatre (OT), an 18G or 20G intravenous cannula was inserted, and standard monitoring during anaesthesia, including NIBP, SpO_2, ECG and $EtCO_2$, were put in place. The FO scope (Karl Storz Endoscopy Inc., Berlin, Germany) was prepared prior to the procedure. After preoxygenation with 100% oxygen for three minutes, all the patients were induced with intravenous (IV) fentanyl (1–1.5 µg kg^{-1}) and IV propofol (2–4 mg kg^{-1}) and titrated accordingly to induce anaesthesia in a dose sufficient to produce a loss of verbal response. After the induction of anaesthesia, the patients were manually ventilated with sevoflurane (2–2.5%) in oxygen. An appropriate cervical collar was applied to the patients to simulate a cervical spine injury situation and to prevent cervical spine movement during airway manipulation. The neuromuscular blocking agent rocuronium (0.6 mg kg^{-1}) was then administered intravenously. After three minutes, the appropriate size (depending on body weight) of the SAD was selected and lubricated with a water-soluble lubricant.

All SAD placements were inserted by the same operator with five years of experience in anaesthesia. The cuff was then inflated based on the manufacturer's recommendation. OLP, the FO grade of the laryngeal view, the quality of the airway during placement and maintenance were assessed by the investigator. Timing and data were documented by an unblinded observer. The endotracheal tube was then railroaded through the SAD, and the placement in the trachea was confirmed fibreoptically. The SAD was then removed, and the endotracheal tube was secured with tape. Anaesthesia was maintained with a sevoflurane (minimum alveolar concentration [MAC]) value of 1.0 to 1.2) in oxygen: air mixture with FiO_2 0.5. The patient's lungs were then ventilated with a pressure-controlled ventilation mode targeted to achieve normocarbia ($EtCO_2$ 35–45 mm Hg). Patients were considered as withdrawn from the study in the event of failure to insert the study device after three attempts or an inability to intubate the trachea. In these cases, the cervical collar was removed, and the patient was intubated with the conventional method.

At the end of the surgery, sevoflurane was turned off, and 100% oxygen was administered. Once the patient had adequate spontaneous ventilation, the reversal agents, neostigmine (50 μg kg^{-1}) and glycopyrrolate (10 μg kg^{-1}), were given. With an adequate tidal volume and respiratory rate, oropharyngeal suctioning was performed, and the device was removed. Any complications were documented, such as airway trauma/blood staining, airway reflex activation (such as laryngospasm/bronchospasm), oxygen desaturation (< 90%) or regurgitation/aspiration. All patients were assessed in recovery for any postoperative complications, such as desaturation (SpO_2 < 90%), stridor and persistent cough. The haemodynamic parameters (blood pressure, heart rate, SpO_2 and $EtCO_2$) were recorded during pre-induction, post-induction (after one minute), post-insertion (after one minute) and every three minutes for 12 minutes followed by five minutes thereafter until extubation.

The sample size was calculated using Power and Sample Size Calculations software, version 3.0 (W.D. Dupont and W.D. Plummer), and the data were based on a previous study by Talaat *et al*. [4]. In this study, the duration of insertion of Air-Q was 13.300 ± 3.471 s, whilst that of ILA was 19.640 ± 4.737 s. Considering the power of 80% and the type 1 error α of 5%, the sample size required was 30 participants in each group. Ten per cent was added for the dropout sample. Therefore, the sample size was *n* 30 + (0.1 × 30) = 33 participants for each group.

The statistical analysis was conducted using the SPSS software version 24.0 (SPSS Inc, USA). Statistical analyses for categorical data between devices were performed using Pearson's χ^2 test and Fisher's exact test. Continuous variables were analysed using an independent *t*-test and a repeated measure ANOVA. Data were presented in mean (SD) and counts (percentage) with *P* <0.05 considered statistically significant.

RESULTS

Demographic profiles

Table 1 shows the demographic data of patients and the success rate of induction. There was no significant difference between the two groups in age, weight, gender, ASA physical status or type of surgery.

TABLE 1. Demographic data of the two study groups

Variables	Air-Q ILA	Ambu AuraGain	*P*-value
Age (mean ± SD), years	38 ± 12	45 ± 15	0.052[a]
Gender, *n* (%)			
Male	10 (30.3)	14 (42.4)	0.306[b]
Female	23 (69.7)	19 (57.6)	
Race, *n* (%)			
Malay	32 (97.0)	33 (100.0)	1.000[b]
Chinese	1 (3.0)	–	
Indian	–	–	
Height (mean ± SD), cm	162.0 ± 6.8	162.5 ± 5.5	0.708[a]
Body mass (mean ± SD), kg	61.1 ± 14.5	62.6 ± 12.3	0.645[a]
BMI (mean ± SD), kg m^{-2}	23.6 ± 3.3	23.5 ± 4.3	0.908[a]
ASA status, *n* (%)			
1	18 (54.5)	11 (33.3)	0.083[b]
2	15 (45.5)	22 (66.7)	
Types of surgery, *n* (%)			
Surgery	9 (27.3)	12 (36.4)	0.314[b]
Orthopaedic	6 (18.2)	7 (21.2)	
OG	7 (21.2)	3 (9.1)	
Neurosurgery	5 (15.2)	4 (12.1)	
ORL	5 (15.1)	1 (3.0)	
Plastic surgery	1 (3.0)	2 (6.1)	
Urology	–	3 (9.1)	
Ophthalmology	–	1 (3.0)	

[a]Independent *t*-test, [b]χ^2 test. OG – obstetrics and gynaecology, ORL – otorhinolaryngology

Efficacy of devices

As shown in Table 2, there were no significant differences in insertion time, Brimacombe scoring for the FO laryngeal view or time taken for successful FO guided endotracheal intubation between the two groups. All the study devices were successfully inserted in a single attempt; however, there were significant differences in OLP between the two groups. AA group participants who underwent intubation using Ambu AuraGain had a higher OLP value than AQ group participants. There was no significant difference in complication rates between the groups; however, there was a blood stain detected on the study device after the removal of Air-Q in one sample. In terms of haemodynamic parameters, there were no significant difference between the two groups.

DISCUSSION

This study was the first randomised controlled trial comparing the efficacy of Air-Q ILA and Ambu AuraGain LMA in adult patients with simulated cervical spine injuries. In this study, there were no significant differences in terms of ease of LMA insertion or the time taken for the insertion of the LMA. Both types of study devices were successfully inserted in a single attempt. The insertion times for Ambu AuraGain and Air-Q were 30.9 ± 10.2 s and 30.7 ± 7.2 s, respectively, with a *P*-value of 0.945. This result is consistent with a study by Sameer *et al*. [10] to compare Ambu AuraGain and Air-Q for use as conduits for blind tracheal intubation in adults. In their

TABLE 2. Comparison of intubation profiles between the two study groups

Variables	Air-Q ILA	Ambu AuraGain	*P*
LMA insertion time (mean ± SD), s	30.7 ± 7.2	30.9 ± 10.2	0.945[a]
Device type, *n* (%)			
Air-Q #3.5	30 (90.9)	–	
Air-Q #4.5	3 (9.1)	–	
Ambu AuraGain #3	–	5 (15.2)	
Ambu AuraGain #4	–	24 (72.7)	
Ambu AuraGain #5	–	4 (12.1)	
Number of attempts, *n* (%)			
1	33 (100.0)	33 (100.0)	
Rescue method, if any			
No	33 (100.0)	33 (100.0)	
Yes	–	–	
Oropharyngeal leak pressure (OLP) (mean ± SD), cm H_2O	28.6 ± 7.8	34.9 ± 6.4	0.001[a]
Brimacombe scoring for fibreoptic laryngeal view, *n* (%)	3.1 ± 0.8	3.2 ± 0.6	0.598[a]
0	–	–	
1	1 (3.0)	–	
2	5 (15.2)	3 (9.1)	
3	16 (48.5)	20 (60.6)	
4	11 (33.3)	10 (30.3)	
Duration of time for fibreoptic guided endotracheal intubation (mean ± SD), s	67.3 ± 12.4	70.5 ± 15.3	0.366[a]
Intra- and post-operative complications, *n* (%)			
Intra-operative			
Bleeding to airway	1 (3.0)	0 (0.0)	
Desaturation	0 (0.0)	0 (0.0)	
Laryngospasm	0 (0.0)	0 (0.0)	
Injury to teeth/upper airway	0 (0.0)	0 (0.0)	
Post-operative			
Painful/sore throat	0 (0.0)	0 (0.0)	
Nausea and vomiting	0 (0.0)	0 (0.0)	
Hoarseness of voice	0 (0.0)	0 (0.0)	

[a]Independent *t*-test, statistically significant at $P < 0.05$

study, the insertion time was similar for Ambu AuraGain and Air-Q (median 13 [IQR 12–14] s versus 14 [IQR 12–16] s), and in all cases, insertion was possible on the first attempt. Different definitions of 'successful insertion time' in various studies result in different times taken for insertion. In this study, a successful insertion time was defined as the time from picking up the supraglottic airway device and the chest rise with a positive pressure ventilation.

In a randomised trial done by Jagannathan *et al*. [11] to compare the Ambu Aura-i with the Air-Q intubating laryngeal airway as conduits for tracheal intubation in children, device placement, tracheal intubation and removal after tracheal intubation were successful in all patients. There were no differences in the time to successful tracheal intubation between the Ambu Aura-i (32.9 ± 13.3 s) and the Air-Q (33.9 ± 13 s; $P = 0.68$) or in the fibreoptic grade of view between devices. There were no significant differences in the time to intubation or the fibreoptic grade of the laryngeal view between the two groups. In addition, there was no statistically significant difference in the overall leak pressures.

It was found that Ambu AuraGain demonstrated a statistically significant higher OLP compared to Air-Q (34.9 ± 6.4 vs. 28.6 ± 7.8 cm H_2O, $P = 0.001$). This result is consistent with a previous study by Wong *et al*. [12]. They compared the OLP between the Ambu AuraGain and the LMA Supreme. The mean (SD) OLP was significantly higher for the Ambu AuraGain than for the LMA Supreme group (26.4 ± 2.8 vs. 21.6 ± 3.4 cm H_2O respectively; difference in means was 4.8 cm H_2O; 95% confidence interval –3.9 to 5.8; $P < 0.001$). A higher OLP for the Ambu AuraGain may allow it to be used in a wider range of patients and procedures.

In this study, there was no statistically significant difference between the two groups in terms of time needed for the FO guided endotracheal intubation via the SAD. The intubation times for the Ambu AuraGain and the Air-Q were 67.3 ± 12.4 s and 70.5 ± 15.3 s, respectively, with a *P* value of 0.366. There was no significant difference in the FO laryngeal view score between the Ambu AuraGain and the Air-Q with mean scores of 3.2 ± 0.6 and 3.1 ± 0.8, respectively. This is consistent with the study by Sameer *et al*. [6], which showed that the fibreoptic view was similar for the Ambu AuraGain and the Air-Q.

The haemodynamic parameter changes before and after the insertions of both devices were stable for both groups. Previous studies have shown that the LMA produced a lower haemodynamic stress response compared to tracheal intubation and that it is comparable with the insertion of an oral airway [13]. Patients were monitored for any complications during and after the procedure, including the period in the recovery unit. There were very few complications, and the results were consistent with a previous trial [6]. Blood staining was reported for one patient after the removal of the Air-Q. The incidence was low due to the fact that all devices were successfully inserted on the first attempt without any problem.

The demographic data for this study, including age, gender, weight, ethnicity and ASA classification, were equally distributed among both groups. All procedures performed were minor to moderate operations with no differences in the duration of surgery. The limitations of the study were that it was

conducted in adult patients with simulated cervical fractures and with the application of a cervical collar. Therefore, the study may not reflect the results for an adult patient with an actual cervical fracture. It would not be ethical to perform this randomised controlled trial in patients with actual cervical spine fractures. A neuromuscular blockade agent was used in this study for the LMA insertion. The neuromuscular blockade agent is not routinely given in usual practice for the insertion of an LMA.

CONCLUSIONS

Air-Q was comparably effective as Ambu AuraGain as a conduit for fibreoptic endotracheal intubation in patients with simulated cervical spine injury; however, Ambu AuraGain has a better seal with significant oropharyngeal leak pressure.

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