

Pilot study of the air-Q Intubating Laryngeal Airway in clinical use

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SUMMARY

The air-Q Intubating Laryngeal Airway (ILA) is a newly introduced extraglottic airway device. In this pilot study, we evaluated its use as a routine airway device during positive pressure ventilation. Ease of endotracheal intubation through the device was also assessed.

Fifty-nine ASA I and II patients undergoing elective surgery received an air-Q ILA and an endotracheal tube where indicated. Insertion, ventilation and intubation characteristics were noted, as well as throat morbidity and occurrence of adverse events.

An air-Q ILA was successfully inserted in 100% of patients. Mean leak pressure was 19 ± 5 cmH₂O. Endotracheal intubation was indicated in 19 patients and successful in 58% on the first attempt and 74% in total. Ten percent of the study patients were noted to have dysphagia. One patient was diagnosed with bilateral lingual nerve injury but made a complete recovery in four weeks.

The air-Q ILA is an adequate extraglottic airway device in terms of insertion and ventilation. However, the proposed advantage of ease of endotracheal intubation requires further investigation.

Key Words: extraglottic airway devices, air-Q

For many types of surgery, extraglottic airways have become the airway of first choice provided no patient-related contraindications to their use exists¹. They offer advantages such as no requirement for muscle relaxant drugs and their antagonists, less sympathetic response to insertion than for an endotracheal tube and reduced likelihood of trauma to the vocal cords. Significantly, the classic Laryngeal Mask Airway (cLMA) is now included in the difficult intubation algorithm² and endorsed as a suitable airway during resuscitation^{3,4}, carrying a higher success rate in inexperienced hands than endotracheal intubation⁵. During the last several years an increasing number of extraglottic devices have been introduced onto the market, with varying degrees of success^{6,7}. Devices are often available for clinical use without undergoing pilot clinical evaluation. One such device is the air-Q Intubating Laryngeal Airway (air-Q ILA) (Cookgas® LLC, Mercury Medical®, Clearwater, FL, USA), the disposable version of the Cookgas ILA.

The air-Q ILA has many of the features of the cLMA. It consists of a tube with a distally located large inflatable cuff which is designed to be positioned in the hypopharynx. This would place it in the category of a cuffed perilyngeal sealer like the cLMA⁸. The shape of the tip of the cuff has been designed to prevent the epiglottis from obstructing the lumen of the device and no aperture bars are present, allowing the unobstructed passage of an endotracheal tube through the air-Q ILA. The trachea may thus be intubated without requirement for direct laryngoscopy with its well-described risks, such as dental trauma and cardiovascular stimulation^{9,10}. Additionally, this feature of the air-Q ILA may allow it to be used in situations of difficult intubation⁷. Given the absence of a published clinical study on the use of the air-Q ILA, the aim of this pilot study was to evaluate the device in terms of placement in the airway, characteristics of ventilation and ease of endotracheal intubation, as well as identifying any adverse effects.

MATERIALS AND METHODS

After obtaining local institutional ethics committee approval, we set out to recruit 60 patients in this pilot study based on other published non-comparative studies and all patients gave written informed consent. Inclusion criteria included fasted

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American Society of Anesthesiologists patient classification I and II patients, having elective surgery, with Mallampati score 1 or 2 and no history of gastric reflux. Exclusion criteria included a body mass index $>30 \text{ kg/m}^2$ and a history of difficult intubation.

Patients were pre-oxygenated and general anaesthesia was induced with sufentanil and propofol. According to the manufacturer's recommendation, an air-Q size 3.5 was inserted in patients weighing 50 to 70 kg and a size 4.5 in patients weighing over 70 kg. Insertion was attempted once patients were apnoeic and lacked any response to jaw thrust.

Insertion time was measured from the moment of placing the device in the patient's mouth to the first square-shaped capnographic waveform. Failed insertion was followed by two further attempts. Using a cuff inflator pressure gauge (Portex, Kent, UK), air was placed in the cuff until a pressure of 60 cmH₂O was achieved. Successful placement was confirmed by capnography and bilateral chest wall movement during manual ventilation. Anaesthesia was maintained with propofol 6 to 12 mg/kg/hour. Ventilation was pressure-controlled, frequency 14 /minute, positive end-expiratory pressure 5 cmH₂O, I:E 1:2, fresh gas flow 0.5 l/minute O₂ and 0.5 l/minute air. Inspiratory pressure was set to maintain end-tidal CO₂ below 6 kPa.

Leak pressure was measured by closing the pop-off valve of the ventilator during a steady flow of 3 l/minute O₂ and gradually increasing peak airway pressure until a leak was audible or to a maximum of 40 cmH₂O.

Where intubation was required, a muscle relaxant was administered (rocuronium 0.5 mg/kg or mivacurium 0.2 mg/kg) and an endotracheal tube was inserted through the air-Q ILA. Intubation time was measured from the moment of placing the endotracheal tube in the air-Q ILA until successful placement was confirmed. Failed intubation could be followed by two further attempts. The occurrence of any adverse events was noted.

At the end of surgery and anaesthesia, the air-Q ILA was removed once patients were breathing spontaneously and obeying simple commands. Presence of macroscopic blood on the device was noted and patients were questioned regarding throat pain and dysphagia using a verbal rating scale (VRS) 0 to 10 (0=no pain, 10=most severe pain imaginable) before leaving the phase 1 recovery area. Patients who reported a VRS >3 were followed up until the pain and/or dysphagia had disappeared.

Data were analysed using Microsoft Excel (Microsoft Corporation, Redmond, WA, USA). Values are mean \pm SD or number of patients (%).

RESULTS

A total of 59 patients were enrolled in this study, one short of our initial aim due to a recording error. The demographics of the study group were as follows; age (42 \pm 17 years), height (175 \pm 9 cm), weight (74 \pm 14 kg), 42 having Mallampati score 1 and seven a score of 2, with 32 males.

The air-Q ILA was successfully placed in all patients (100%). The first attempt was successful in 52 of 59 patients (88%). Mean insertion time was 26 \pm 13 seconds, ranging from 13 to 78 seconds. Adequate ventilation was achieved in all patients. No oxygen desaturation occurred during either insertion of the air-Q or during mechanical ventilation. Mean leak pressure was 19 \pm 5 cmH₂O. Other results are summarised in Table 1.

The trachea was successfully intubated in 14 out of 19 patients (74%). First attempt was successful in 58% of cases.

On device removal, macroscopic blood was visible on 17% of air-Q ILAs and 10% of patients reported a sore throat. One patient reported having severe throat pain (VRS=5) which had completely disappeared by the time of discharge home.

TABLE 1
Results for air-Q ILA insertion and ventilation ($n=59$) and endotracheal intubation ($n=19$). Values are mean \pm SD or number of patients (%).

Sufentanil at induction ($\mu\text{g/kg}$)	0.15 \pm 0.04
Propofol at induction (mg/kg)	3.7 \pm 1.1
Insertion time air-Q (s)	26 \pm 13
<i>Success, % (n)</i>	
Attempt 1	88 (52)
Attempt 2	8.5 (5)
Attempt 3	3.5 (2)
Failed	0 (0)
Hiccups during or after insertion % (n)	7 (4)
Laryngospasm during or after insertion % (n)	0 (0)
Leak pressure (cmH ₂ O)	19 \pm 5
Insertion time endotracheal tube (s)	33 \pm 35
<i>Intubation success, % (n)</i>	
Attempt 1	58 (11)
Attempt 2	10.5 (2)
Attempt 3	5.2 (1)
Attempt 4 (Laryngoscope)	26.3 (5)

ILA=Intubating Laryngeal Airway.

One patient returned to the hospital emergency room approximately eight hours after completion of anaesthesia, complaining of numbness and tingling in the tongue. Bilateral lingual nerve injury was diagnosed. This patient made a full recovery over a period of four weeks.

DISCUSSION

In this series of patients we have shown the air-Q ILA to be an adequate extraglottic airway device in terms of insertion and ventilation characteristics, with 100% insertion success rate in timeframes similar to other such airway devices^{6,11}. Likewise, airway sealing pressures were on par with that of the cLMA⁶.

However, with regard to endotracheal intubation via the air-Q ILA, success rates were well below those described for other similar devices. Importantly, this was far lower than the 96.4% overall success rate after three attempts reported for the LMA Fastrach¹². It is important to mention that the Fastrach intubation success rate was achieved using a specially designed Fastrach tube, whereas standard endotracheal tubes (Portex® tracheal tube, Smiths Medical International Ltd., Kent, UK) were used in this study. Indeed a direct comparative study of the two devices would be very useful. Obviously, as with all new techniques of endotracheal intubation, there is a learning curve involved and this may have been a factor in our low success rate.

Notably, one patient reported severe throat pain (VRS=5) in the recovery room, but was pain-free at time of discharge just a few hours later. The one significant adverse event that occurred in this series of patients was bilateral lingual nerve injury. Of note, in the patient concerned the air-Q ILA was inserted on the first attempt without any difficulty and achieved good ventilation characteristics. Nitrous oxide, which might increase cuff pressure, was not used in this case series. Lingual nerve injury is a known complication of extraglottic airway device usage¹³. In general, this complication recovers spontaneously in a matter of hours to six months. In our case the patient made a complete recovery within four weeks.

In summary, this pilot study of the air-Q ILA in this series of patients demonstrates that it is an adequate extraglottic airway device in terms of insertion and ventilation characteristics. However, the proposed advantage of ease of endotracheal intubation requires further assessment.

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