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ORIGINAL ARTICLE Comparison of blind tracheal intubation through the intubating laryngeal mask airway (LMA FastrachTM) and the Air-QTM

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Summary

This study assessed two disposable devices, the LMA FastrachTM and the newly developed supraglottic airway device, the Air-QTM, as a conduit for tracheal intubation in 154 healthy adults undergoing elective surgery. Using a non-inferiority approach, the primary outcome measure was successful tracheal intubation within two blind insertion attempts. Successful blind intubation after two attempts was achieved in 75/76 (99%) of the patients in the LMA Fastrach group vs 60/78 (77%) in the Air-Q group (95% CI for the difference 12–32%, p < 0.0001). Fibreoptic intubation was used to assist the third attempt. The rate of successful intubation after three attempts was 100% in the LMA Fastrach group and 95% in Air-Q group. The single-use LMA Fastrach appears superior compared with the Air-Q, as a conduit to facilitate blind tracheal intubation.

Supraglottic airway devices are common airway management tools. However, there are many situations in which a supraglottic device is neither desirable nor sufficient, and where tracheal intubation is required. Traditionally, tracheal tubes are placed under direct vision via direct laryngoscopy. However, a number of supraglottic airways have been developed to facilitate the passage of tracheal tubes.

The intubating laryngeal mask airway ILMATM (Intavent; Orthofix Ltd, Maidenhead, Berkshire, UK) is also known as LMA FastrachTM (LMA North America, San Diego, CA, USA) (Fig. 1). It is specifically designed to facilitate intubation either blindly or via fibreoptic assistance [1]. However, the LMA Fastrach has certain limitations. For example, the rigidity of its breathing tube makes it inadvisable for prolonged use as a supraglottic airway out of concern for posterior pharyngeal pressure necrosis. It also

requires the use of a special and expensive tracheal tube, adding to the overall cost. Finally, it is not available in paediatric sizes.

One alternative device is the Air-Q [2], also known as the Intubating Laryngeal AirwayTM (ILA; Cookgas[®], St Louis, MO, USA) (Fig. 2). The Air-Q is the disposable version of the reusable ILA. (To limit the confusion between ILMA and ILA we will refer to the airways as the LMA Fastrach and the Air-Q). While sharing some of the rigidity of the LMA Fastrach, it can be used to pass a standard tracheal tube. However, the LMA Fastrach has never been compared with the Air-Q in terms of intubation, nor the ease with which it can be removed after intubation.

The current study was designed to assess the relative success rate for blind tracheal intubation using these two devices.

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Figure 1 (1) Single-use LMA Fastrach device; (2) single-use LMA Fastrach tracheal tube; (3) stabilising rod.

Methods

After Institutional Review Board approval, enrolment was offered to healthy adult patients of ASA physical status scheduled for elective surgery under general anaesthesia planned to include tracheal intubation. Written consent was obtained from all participants. Patients were not studied if they had respiratory or pharyngeal pathology, mouth opening < 2.5 cm, were at risk of regurgitation, had a BMI > 40 kg.m⁻², or were allergic to any drugs in the protocol. Of 165 patients enrolled and giving consent, 11 were not studied due to change of anaesthetic plan or operation start time. Patients were assigned by sealed envelope to one of two groups, allocated to the LMA Fastrach or the Air-Q. Two investigators familiar with both devices studied the 154 patients. The age, sex, height, weight and BMI of the patients were recorded.

Monitoring was established (pulse oximeter, electrocardiogram, non-invasive blood pressure, temperature and ventilatory parameters including capnography). Anaesthesia was induced in approximate doses according to ideal body weight of intravenous midazolam 2 mg, lidocaine 1 mg.kg⁻¹, fentanyl 2 μ g.kg⁻¹, propofol 2.5–3.0 mg.kg⁻¹ and rocuronium 0.5–1.0 mg.kg⁻¹. Maintenance of anaesthesia was with propofol or volatile anaesthetics, rocuronium, fentanyl, oxygen and air. When neuromuscular blockade was complete (absence of response to train-of-four stimulus), the randomly assigned supraglottic airway was inserted, the cuff inflated and manual positive pressure ventilation begun. After ventilation was established the investigator attempted to pass the tracheal tube blindly. A 7.0-mm



Figure 2 Air–Q: (1) removable 15-mm connector; (2) integrated bite block which also reinforces the airway tube; (3) keyhole-shaped airway outlet; (4) elevation ramp which directs the tracheal tube anterior; (5) three transverse ridges which enforce the tip of the device; (6) removal stylet; (7) adaptor which has (a) horizontal ridges that firmly engage in the tracheal tube and (b) grooves that allow spontaneously breathing patients an unimpeded air passage within the tracheal tube during removal of the device.

LMA Fastrach tube was used with the LMA Fastrach, and a standard 7.0-mm tracheal tube was used with the Air-Q.

We recorded the following times using a stop watch capable of recording single or multiple events and the running total time including the time gaps in between events.

- **1** *Insertion time of the study device:* from the moment the device entered the mouth until the appearance of the capnograph waveform. If no carbon dioxide was detected or the seal was inadequate, the device was removed. The time of the second attempt was similarly recorded. If a third attempt was required the time once again began with insertion of the device and ended with the capnograph waveform. The insertion time was the sum of all attempts. This did not include the gap time between attempts.
- **2** *Insertion time of the tracheal tube*: from the moment of insertion of the tracheal tube through the study device until the appearance of the capnograph waveform. If no carbon dioxide was detected, the tracheal tube was removed. The time of the second attempt was similarly recorded. If a third attempt was required the time once again began with insertion of the tracheal tube and included the fibreoptic grading of the view and ended with the capnograph waveform. The insertion time was the sum of all attempts. This did not include the gap time between attempts.

3 *The total time:* from the moment the supraglottic airway was placed until after it was removed with correct placement of the tracheal tube verified by capnography. There were no time gaps.

A maximum of two blind attempts were allowed, and the number of attempts was recorded by a research nurse. If a second attempt was required, the manufacturers' instructions were followed. For the LMA Fastrach, this meant applying gentle rotation of the handle in and out and side to side until ventilation was optimised, then the handle was gently lifted anteriorly and the tracheal tube was reinserted. For the Air-Q, the device was withdrawn 5–8 cm with mandibular lift during reinsertion of the Air-Q and/or a bougie was passed through the tracheal tube within the Air-Q with the coudé tip anterior. Then the tracheal tube was advanced over the bougie (while a bougie was used in most reinsertion attempts, we did not record in which patients).

Regardless of the device used, the patient's lungs were ventilated between attempts if needed. If, after two attempts, the tracheal tube was not properly inserted, a fibreoptic-assisted intubation through the airway device was performed.

If the supraglottic device was not placed in three attempts, or oxygen saturation fell to 90%, direct laryngoscopy was utilised.

The supraglottic airway was immediately removed after confirmation of successful intubation. The proportion of the time needed to remove the supraglottic airway from the pharynx was also recorded (time from the initial disconnection of the tracheal tube from the breathing circuit until reconnection and verification of an expiratory carbon dioxide waveform). Upon removal of the supraglottic airway, note was made if any blood was visible on the device, indicative of trauma to the upper airway.

The patients were questioned about the degree of sore throat and hoarseness before leaving the postanaesthesia care unit. These were assessed with a 0-3 scale: 0 = no complaint; 1 = mild complaint; 2 =moderate complaint; 3 = severe complaint. When hoarseness and/or sore throat were noted, daily assessment was done by a research assistant until the patient had no complaint or for a maximum of 3 days (by telephone).

An adverse airway event was defined as: oxygen desaturation of 90% or less; significant airway trauma; or other major adverse events.

The test of non-inferiority of two independent proportions was performed, with the bound for non-

inferiority set at 10% to compare the LMA Fastrach and the Air-Q with respect to the success rate of blind intubation. For example, if the success rate with the LMA Fastrach was 90%, then any success rate of 80% or higher for the Air-Q would be considered noninferior.

Statistical analysis to determine sample size assumed the success rate of placement was 95% for the LMA Fastrach. A sample size of n = 75 subjects per device was needed to detect non-inferiority with a success rate of placement with the Air-Q within ten percentage points lower, or better than a success rate of placement with the LMA Fastrach at the 0.05 significance level with 0.80 power. The sample size of n = 75 subjects per group would have been able to detect non-inferiority with 0.80 power if mean time for insertion to removal for Air-Q was no more than 8 s longer or if it was shorter than mean removal time for the LMA Fastrach (assuming SD = 20 s). An interim safety analysis was performed by an uninvolved physician and statistician after studying 75 patients. To accommodate this interim analysis, the actual sample size was inflated to 152 by O'Brien and Fleming's Rule [3] which will minimise the chance of the type-1 error's becoming higher than 5%. With the high rate of success reported for the LMA Fastrach, the one-tailed test determined non-inferiority when the Air-Q success rate was more than 10 percentage points lower. The test of non-inferiority for two independent means was used for the analysis of time from the moment of insertion to when the supraglottic airway was removed from the pharynx. The final number of patients was increased to 154 to achieve balance between the two investigators in terms of the numbers of each device used. For nominal variables we used the chi-squared analysis or Fisher's exact test when any cell count was < 5.

Results

A total of 154 patients were studied and analysed. Patients' characteristics were similar between the two groups (Table 1). Figure 3 shows the success of intubations between the two devices. The success rate of blind intubation after two attempts via the LMA Fastrach was 75 out of 76 patients (99%) vs 60 out of 78 (77%) via the Air-Q (95% CI for the difference 12–32%) with a p value of non-inferiority <0.0001.

In the LMA Fastrach group, fibreoptic assisted tracheal tube placement was required and successful in one patient. In the Air-Q group, 24 patients (31%) required a second blind pass. Fibreoptic intubation was

Table 1 Characteristics of patients whose tracheas were intubated via the LMA Fastrach or Air-Q. Values are mean (SD) or number.

	LMA Fastrach (n = 76)	Air-Q (n = 78)
Age; years	51 (14)	49 (17)
Height; cm	170 (10)	172 (9)
Weight; kg	83.0 (19.6)	88.6 (18.2)
BMI; kg.m ⁻²	28.6 (5.5)	30.0 (5.2)
Sex; M:F	32:44	36:42



Figure 3 Cumulative success rate of tracheal intubation attempts via the LMA Fastrach (\rightarrow) or Air-Q ($\neg \circ \neg$).

required in 18 out of 78 patients (23%), 14 of them (18%) were successful and the remaining four (5%) required direct laryngoscopy due to desaturation to 90% or less during fibreoptic assisted intubation.

The speed of insertion of the two study devices, the speed of insertion of the tracheal tube and the entire time for intubatoin are shown in Table 2. Removal of the two devices after successful intubation was easy without displacement of the tracheal tube in any patient.

There were no significant differences in the incidence of sore throat and hoarseness between the two devices. There was evidence of visible blood on the LMA Fastrach in 7/75 (9%) while in the Air-Q it was 7/68 patients (10%). There were missing data from one and 10 patients in the respective groups.

Half of the enrolled patients had a BMI of $30-40 \text{ kg.m}^{-2}$ ($30-34 \text{ kg.m}^{-2}$ in 38/154 (26%) and $35-40 \text{ kg.m}^{-2}$ in 41/154 (24%)). In the LMA Fastrach group there was one failure to intubate blindly in the

Table 2 Speed of insertion of the two study devices, insertion of tracheal tube and the total time for tracheal intubation. Values are median (IQR [range]).

	LMA Fastrach (n = 76)	Air-Q (n = 78)
Insertion time (device): s	30 (25–38 [18–218])	27 (22–34 [14–152])
Insertion time (tube); s	27 (23–32 [14–247])	35 (25–155 [16–460])
Total time; s	185 (165–215 [131–754])	219 (174–388 [137–1270])

BMI $<30 \text{ kg.m}^{-2}$ group (p = 0.01). The intubation success rate did not differ in patients with a higher BMI in the Air-Q group (p = 0.05).

Discussion

The LMA Fastrach was introduced in 1997 to facilitate blind rather than fibreoptic-assisted tracheal intubation, following a timeline of development that started in 1983, when the first prototype intubating LMA was used to intubate the trachea blindly. Although since its introduction in 1997, many studies have confirmed the value of the Fastrach LMA as a conduit for tracheal intubation (with success rates of tracheal intubation > 95%), few studies have recorded intubation times. In our study, 92% of first attempts at intubation were successful. This was higher than that recorded by Pandit et al., [4] who reported a success rate of 75%. One possible reason for this difference may be due to the use of the sniffing (Magill) position of the patient's head and neck during insertion of the LMA Fastrach in their study, rather than neutral position that is recommended by the manufacturer. We cannot compare directly the insertion/intubation times because of the different end points used, but Pandit et al. were able to pass the tracheal tube within ~ 25 s compared with ~ 30 s in our study.

Our study shows a substantially greater success rate for blind intubation using the LMA Fastrach compared with the Air-Q. The rate with the LMA Fastrach was similar to that reported by others [5–7]. This difference in success was present even when only the first or second attempts were compared. The removal time of the device after successful intubation and the incidences of trauma, postoperative sore throat and hoarseness were comparable in both devices.

There have been few studies with the Air-Q. Our earlier experiment (unpublished data; Swanson DE,

Karim YM, Lichtor JL) comparing the Intubating Laryngeal Airway, the reusable version of the Air-Q, with the LMA Classic for supraglottic use (without attempting to pass a tracheal tube) found no clinical differences in ease, speed of insertion, sealing pressure or post-insertion complications. Wong et al. [8] recommended the use of the Air-Q rather than the LMA Unique as conduit for tracheal intubation. Jagannathan et al. [9] reported successful fibreoptic-assisted tracheal intubation in five paediatric cases with known difficult airways via the Air-Q.

The reported advantages of the Air-Q are that the breathing tube of the device is shorter, wider and, due to the removable connector, allows the placement of a standard tracheal tube. For example, a 6.0-mm cuffed tracheal tube which is 28-30 cm in length may not be long enough to permit positioning in the mid-trachea, or allow safe removal of the LMA Unique; the same tube can be easily inserted with the Air-Q to the midtrachea. Unlike the LMA Fastrach, Air-Q devices are available in sizes small enough to allow its use in small children (< 30 kg). The Air-Q has no epiglottic elevating bar, therefore specialised manoeuvres are not needed to negotiate this with the fibreoptic bronchoscope as have been described for the LMA Fastrach [4]. Panjwani et al. [10] described flexing the tip of the fibrescope tip fully just before contact with the epiglottic elevating bar to negotiate past the latter with little risk of damage to the tip of the fibrescope. The curved side (bull-nose) is used to push against the epiglottic elevating bar and once past, the tip of the fibrescope may be extended again.

The latter method of protecting the fibrescope was used in the study of Pandit et al. [4], where a 95% firstattempt success rate of fibreoptic-assisted intubation was achieved, with an average intubation time of 74 s. The removable stylet securely engages at the proximal end of the tracheal tube to allow easy passage of the pilot balloon, unlike the stabilising rod of the LMA Fastrach. The inexpensive, widely available polyvinyl chloride tracheal tube is the one recommended to be used with the Air-Q, unlike the LMA Fastrach in which the tracheal tube is specific and expensive as well. We should note that the use of different tracheal tubes in the two groups may account for the difference in success rate [11], although this would need to be confirmed in a trial comparing the same tracheal tube in the LMA Fastrach and Air-Q.

Our study has limitations. The two investigators both had significant experience with the LMA Fastrach

and the supraglottic use of the Air-O before starting the study. Inexperienced clinicians may not have as high a success rate. We did not record the fibreoptic glottic view except after a second failed blind intubation attempt. More information might have been gained by obtaining a fibreoptic view in all cases to evaluate the glottic view relative to the position of the device. While the success rate was low for the second blind attempt with the Air-Q, and the bougie was used in most of those attempts, it would have been helpful to compare those that just had the Air-Q reinserted with those using the bougie or both manoeuvres. The bougie was only used a maximum of once per patient and only if a second attempt at blind intubation was required. Unfortunately, we did not record in which patients it was used. It was not used on all 24 patients requiring a second pass in the Air-Q group. Airway assessment was not one of the parameters of enrolment of the patients in the study, even though some had a history of difficult fibreoptic intubation. The reason was that both devices are designed to be used in difficult airways. We selected ASA physical status 1 and 2 to minimise any chance of cardiovascular complications during the attempted trial of intubation. Most studies on supraglottic airway have not studied patients with a BMI above 30 kg.m⁻² and few have enrolled patients between 35 and 40 kg.m⁻² because of associated difficult airway and ventilation. In this study, 50% of enrolled patients had a BMI of 30-40 kg.m⁻² which reflects the epidemic of obesity in Iowa. The success rate of tracheal intubation was not different between obese patients and those with BMI $< 30 \text{ kg.m}^{-2}$.

In summary, the primary outcome of this study showed that the LMA Fastrach had a higher rate of success (99%) in facilitating blind intubation than did the Air-Q (77%). However, as long as a fibreoptic bronchoscope is available, the Air-Q can be used successfully as a conduit for tracheal intubation.

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