

CobraPLUS and Cookgas air-Q versus Fastrach for blind endotracheal intubation: a randomised controlled trial

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Background and objective CobraPLUS and Cookgas air-Q are supraglottic airways expected to allow safe ventilation as well as reliable blind intubation. In a prospective, controlled trial, we hypothesised that quality of ventilation and success rate of blind endotracheal intubation of these new devices would be superior to the Fastrach intubating laryngeal mask airway (ILMA). When blind intubation failed the quality of fibrescope-guided intubation was investigated. To allow identification of those patients in whom blind intubation would be difficult, we investigated the predictive value of currently used predictors for ease of endotracheal intubation.

Methods One hundred and eighty adult patients with documented BMI, Mallampati score, Cormack–Lehane classification, interincisor gap and thyromental distance were randomised into three groups according to the device used. Ventilation conditions were rated as excellent, good or difficult. When blind intubation failed, fibrescope-guided intubation conditions were rated as well. Statistical analysis was performed by a χ^2 -test.

Results The quality of ventilation was excellent for all devices. Three patients in the CobraPLUS group and two patients in the ILMA and the Cookgas groups needed a slight reposition. Blind intubation through the CPLA was successful in 47%, through the Cookgas in 57%, whereas the Fastrach group had a success rate of 95%. Fibreoptic intubation was possible in all but one patient. None of the registered scores and measures allowed prediction of difficult blind intubation.

Conclusion All devices appeared to be safe airways. The Fastrach ILMA proved to be a reliable facilitator for blind intubation. CobraPLUS and Cookgas air-Q allowed an easy fibrescopic intubation. Failed blind intubations could not be predicted by the used parameters.

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Introduction

The use of a supraglottic airway device for the management of a difficult airway and as a conduit for tracheal intubation is recommended by many guidelines, e.g. that of the American Society of Anaesthesiologists.¹ In the meantime a multitude of such devices has been developed and made commercially available.

The CobraPLUS (Engineered Medical Systems, Indianapolis, Indiana, USA), a new disposable supraglottic device, one of the latest developments, is an improved version of the CobraPLA. It is designed to be positioned in the hypopharynx where it abuts the structure of the laryngeal inlet. The new kinked shape of its head is supposed to facilitate insertion into the supraglottic space and to provide a better fit with anatomical structures. The circular cuff provides a seal of the upper airway to the pharynx allowing positive pressure ventilation. The possibility of blind intubation through the device is suggested by the manufacturer and was published for the CobraPLA.^{2,3}

The air-Q (Cookgas, St. Louis, Missouri, USA) is specifically marketed as being optimised to allow blind intubation (www.cookgas.com). Its design includes a curved shaft, the lack of a grill in the ventilating orifice and an easily removable airway adapter. However, reports and studies concerning this device are scarce in the literature, and no study has ever investigated the performance of this device.^{4,5}

Until now, very few articles about the CobraPLUS and the Cookgas air-Q – and, to our knowledge, none about blind intubation through these devices – have been published. Thus, in a prospective, randomised and controlled study, we compared ease of ventilation, the success rates for blind intubation through the CobraPLUS and the Cookgas air-Q in comparison to the Fastrach ILMA (Laryngeal Mask Company, Henley-on-Thames, UK) as a gold standard. When blind intubation failed, intubation was accomplished with the support of a flexible fibrescope which is supposed to facilitate successful blind intubation through the device in a high percentage of patients, even in the presence of a difficult airway.^{6–10}

Most anaesthetists evaluate their patients before induction of anaesthesia by means of scores and measures to predict difficult intubation. While it is evident that the prediction of a difficult blind intubation when performed with the help of a supraglottic airway would be of great value, neither was a new parameter proposed for this role nor has any of the parameters or scores which are routinely used for the detection of difficult laryngoscopic

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intubation been evaluated for its ability to be indicative for this purpose. Thus, we aimed to correlate two established scores (Mallampati, Cormack–Lehane) and three measures (interincisor gap, thyromental distance and BMI) with the outcome of blind intubation through the CobraPlus, the air-Q and the Fastrach ILMA.

Methods

After ethics committee approval and signing of a written informed consent, we investigated in a prospective, controlled trial with 180 patients in three parallel groups [the American Society of Anesthesiologists (ASA) physical status I and II] scheduled for elective surgery mostly at the ear-nose-throat department of the Hospital Hietzing during 2007 and 2008 under general anaesthesia requiring tracheal intubation. The full trial protocol is available from the authors upon request. Patients with a history of gastroesophageal reflux, pulmonary disease, cervical spine disease, pregnancy and tumours in the oropharyngeal region or any other known contraindication against the use of a laryngeal mask airway (LMA) were excluded from the study. Using a computer-generated list (MS Excel) generated by one of the authors (T.K.), the patients were randomly allocated by another author (W.E.) to one of the three equally sized groups. Demographic characteristics, type and duration of surgery were recorded. Airway classification for the prediction of a suspected difficult airway was performed using the Mallampati score,¹¹ the interincisor gap and the thyromental distance as described by Tse *et al.* before induction of anaesthesia, and with the Cormack–Lehane score^{12,13} after the application of neuromuscular blocking drug. Patients were perorally pre-medicated with bromazepam (3–6 mg). Following the application of routine anaesthetic monitoring, general anaesthesia was induced by bolus intravenous administration of fentanyl (2–3 µg/kg), propofol (3 mg/kg) and rocuronium bromide (0.5 mg/kg). Anaesthesia was maintained with 60% nitrous oxide, propofol (300–400 mg/h) and supplementary fentanyl bolus when required. Neuromuscular monitoring was routinely used in all our patients and onset of neuromuscular block was verified before laryngoscopy was performed.

One and a half minutes after administration of the neuromuscular blocking drug, direct laryngoscopy for the Cormack–Lehane classification was performed to assess ease or difficulty of intubation. According to patient randomisation, one of the devices was inserted. The size of the laryngeal mask was chosen according to the patient's weight and in conformity with the manufacturer's recommendations. In order to make insertion easier and less traumatic, the airways were lubricated with a lidocain gel. Insertion was accomplished with the patient's head in a neutral or light sniffing position. Successful placement was confirmed by the presence of bilateral chest wall movement and the occurrence of

a square wave trace on the capnograph during manual ventilation. Quality of ventilation with the airway was classified on a scale from 1 (excellent ventilation, perfect seal), to 2 (good ventilation, small leakage), to 3 (inadequate ventilation, negative capnography, reposition necessary). Then, the tracheal tube was slowly inserted through the device with the tube connected to the respirator system to allow continuation of ventilation. Oesophageal intubation was assumed when the capnographic trace disappeared.^{14–17} Immediate auscultation of the lungs and the stomach confirmed incorrect position of the tube. In such a case, a thin suction tube was inserted through the tracheal tube and the air was deflated from the stomach before the tube was withdrawn. The patient's head position was optimised and the position of the device was changed (deeper insertion or withdrawal) for a new attempt. After three failed attempts, the procedure was abandoned and a fibreoptic-guided intubation through the LMA was performed. The quality of fibrescope-guided intubations was rated: I (direct access), II (requiring minor corrections), III (difficult), IV (impossible). The devices were then deflated and removed leaving the endotracheal tube in place using the rods supplied by the manufacturers.

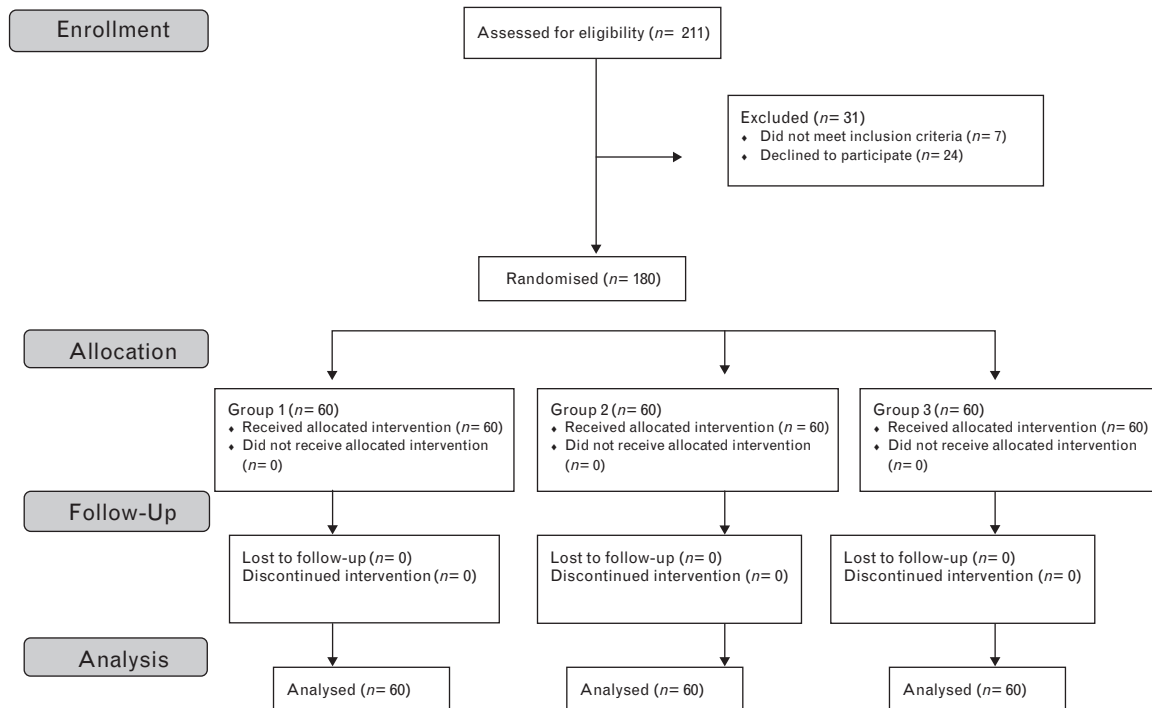
For intubation with the Fastrach ILMA, a special, flexible and reusable silicone spiral tube (LMA tube) as recommended and provided by the manufacturer was used. Intubations through the CobraPLUS and the Cookgas air-Q were performed with a regular, disposable polyvinyl chloride (PVC) tube (Rüsch GmbH, Kernen, Germany) in the usual sizes. For removal of the tube, the rod was used.

All study cases were performed in the presence of the study author and an independent and skilful co-investigator.

Statistical analysis

Because no relevant data on success rates for the new devices have yet been published, no power analysis could be accomplished. Therefore, to estimate group size, χ^2 -test using GPower V.3.2.1. (<http://psycho.uni-duesseldorf.de/aap/projects/gpower/>) was performed anticipating a medium-sized effect ($w = 0.3$) for a significance level of P value less than 0.05. With this estimate, a total number of 172 patients is regarded to be necessary for a power of 95%. Statistical calculations were done with Medcalc (www.medcalc.be). Distribution of data was tested with a Kolmogorov–Smirnov test. Since BMI was normally distributed, the differences between patients intubated with the Fastrach or CobraPlus system were calculated with a Student's t -test and results were presented as mean \pm SD. Frequency data were tested for statistical difference with a χ^2 -test and were presented as absolute values for demographic data and predictors throughout the tables. A P value of less than 0.05 was considered statistically significant.

Fig. 1



CONSORT 2010 flow diagram.

Results

One hundred and eighty patients were randomised into three equally sized groups ($n=60$). A CONSORT flow chart is shown in Fig. 1. Demographic data, BMI, Mallampati score, thyromental distance, interincisor gap and Cormack–Lehane classification between groups were comparable and are shown in Tables 1 and 2.

The quality of ventilation was excellent in most patients in all study groups. In the CobraPLUS group, a slight reposition (2) of the device was necessary in three patients (5%), in 95% we found excellent conditions (1). Only two patients from the Cookgas air-Q and the Fastrach group needed a correction of the mask (2), 97% were rated excellent (1).

Table 1 Demographic data: gender and BMI for successful and failed intubations with the three devices

		M/F	BMI
Fastrach	Total	31/29	25.2 ± 4.3
	Successful	30/27	25.2 ± 4.2
	Failed	1/2	30.0 ± 7.9
CobraPLUS	Total	36/24	26.0 ± 4.2
	Successful	17/11	26.3 ± 4.4
	Failed	19/13	25.6 ± 4.0
Air-Q	Total	32/28	26.3 ± 4.7
	Successful	21/14	26.1 ± 4.4
	Failed	12/14	26.4 ± 5.0

Blind intubation through the CobraPLUS was successful in 28 patients (47%) and failed in 32 (53%). With the Cookgas air-Q, 34 blind intubations (57%) were successful and 26 (43%) failed. The Fastrach group had a success rate of 95% ($n=57$), although the intubating procedure had to be repeated for a second or third try (up/down and Chandy manoeuvres) in seven patients (12%). Sex ($P=0.942$), age ($P=0.481$) and BMI ($P=0.429$) had no influence on the success of blind intubation.

Fibrescope-guided intubations were easily performed in all three patients with failed blind intubation in the Fastrach group (2 × I, 1 × II) (Fig. 2). Of the 32 patients with failed blind intubation in the CobraPLUS group, 27 patients were fibrescoped easily (18 × I, 9 × II) and five patients with difficulty (III). None of them failed (IV). Of the 26 patients of the Cookgas air-Q group, 22 were classified as easy (14 × I, 8 × II) and three as difficult (III). In one patient, the fibrescope-guided intubation failed (wrong LMA size).

The prediction scores for anticipation of a difficult airway did not show any statistically relevant coincidence between the groups of successful and failed intubation (Mallampati score $P=0.71$; Cormack–Lehane classification $P=0.22$; interincisor gap $P=0.67$; thyromental distance $P=0.71$). Frequencies of distribution of the different grades either within the total groups or the

Table 2 Predictors for difficult airway: successful and failed intubations

	MP I	MP II	MP III	MP IV	CL I	CL II	CL III	CL IV	TMD <6 cm	TMD ≤7 cm	TMD >7 cm	IIG ≤4 cm	IIG = 4–6 cm	IIG ≥6 cm	
Fastrach															
Successful	29	21	6	1	23	18	6	10	8	38	11	9	47	1	
Failed	1	2	0	0	0	3	0	0	1	1	1	0	3	0	
CobraPLUS															
Successful	14	10	4	0	7	13	7	1	5	18	5	5	22	1	
Failed	16	11	4	1	15	9	4	4	2	20	10	3	29	0	
Air-Q															
Successful	17	11	6	0	12	15	4	3	8	19	7	4	29	1	
Failed	14	9	3	0	7	10	8	1	5	18	3	7	17	2	

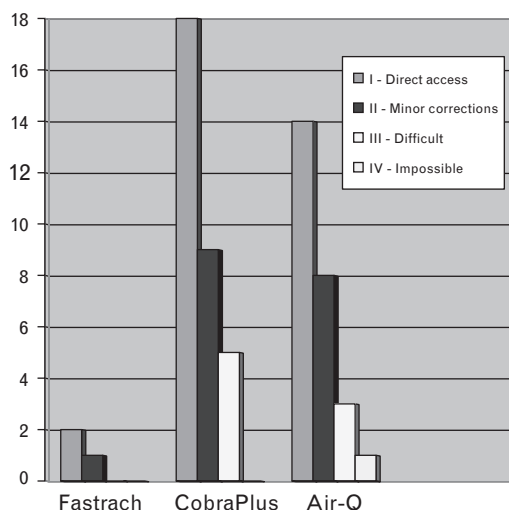
CL, Cormack–Lehane; IIG, interincisor gap; MP, Mallampati; TMD, thyromental distance. Fastrach: 60 patients [57 successful blind intubations (95%), seven after repetition, three failed]; fibroscope-guided intubations: easy in three cases (2 × I, 1 × II). CobraPLUS: 60 patients [28 successful blind intubations (47%); failed blind intubations in 32 patients; fibroscope-guided intubations: easy in 27 cases (18 × I, 9 × II) and difficult in five cases (III), no failure (IV). Cookgas air-Q: 60 patients [34 successful blind intubations (57%); failed blind intubations in 26 patients; fibroscope-guided intubations: easy in 22 cases (14 × I, 8 × II), difficult in three cases (III), failed in one case (IV).

patients who were intubated successfully showed no significant differences (Table 3).

In one patient with failed intubations in the CobraPLUS group, we noticed a damage of the cuff of the endotracheal tube after three failed attempts.

Discussion

The major finding of our study was that both LMA devices, the CobraPLUS and the Cookgas air-Q, failed to be reliable facilitators for blind intubation. In contrast, the Fastrach ILMA had a 95% success rate and proved to be the best approach among those tested for securing the airway and facilitating blind intubation. The additional use of a fibroscope led to a near-100% success rate. The predictors currently applied for detecting difficult intubation proved to be unsuited for predicting the ease of an intubation through an LMA.

Fig. 2

The quality of fibroscope-guided intubations in cases of failed blind intubations.

A great variety of airway devices have been marketed and tested during the last few years. According to the difficult airway algorithm issued by the ASA, the use of a supra-glottic airway is strongly recommended in the presence of a difficult airway.^{1,18} The utility of the Fastrach ILMA in cases of difficult airway management has been investigated in many studies, and these results were reproducible in our study. Both the air-Q and the CobraPLUS are relatively new perilaryngeal airways. Although no published data are available for the CobraPLUS, its predecessor, the CobraPLA, is discussed controversially in the literature. In a number of studies, the CobraPLA was described as an airway allowing easy placement and adequate ventilation during both controlled and spontaneous ventilation.^{22,23} Compared with other supraglottic devices the CobraPLA appears to be as effective in establishing an adequate airway as the other laryngeal masks tested and even seems to have certain advantages, such as easier insertion and better airway sealing capabilities.²⁴ The question remains whether a higher airway seal combined with higher airway pressures can be seen as a real advantage, as it is known that higher airway pressures cause gastric inflation associated with the higher risk of pulmonary aspiration of gastric contents. This concern is strongly supported by Cook and Lowe²⁵ who halted their study after they encountered two cases of pulmonary aspiration. Data concerning the use of the Cookgas air-Q LMA are scant. To our knowledge, only two case series were reported in the literature.^{3,4} The device is designed to allow easy fiberoptic intubation as it combines the features of the soft airway tube and the ability to facilitate intubation, for example, the lack of a grill in the ventilation orifice. To our knowledge, we present the first study comparing the ability of these devices in regard to ease of ventilation and facilitation of blind or fiberoptic intubation.

Our experience with the CobraPLUS ventilatory quality was comparable with the findings in previous investigations with the predecessor CobraPLA. No serious ventilation problems were recorded in any of our study cases. In a recent study with the CobraPLA in which the device was used as a bridge to blind or fiberoptic-guided

Table 3 Significance levels (*P* value) of frequencies of distribution of different grades in the scores between groups and of success rate (χ^2 -test)

	MP	CL	TMD	IIG
Group (<i>P</i>)	0.94	0.23	0.55	0.67
Success (<i>P</i>)	0.83	0.44	0.62	0.84

CL, Cormack–Lehane; IIG, interincisor gap; MP, Mallampati; TMD, thyromental distance.

intubation, the success rate for blind intubation was 36% only, whereas it was 83% for the fiberoptic techniques.² In our study, the success rate for blind intubation with the CobraPLUS increased up to 47% and reached 100% for the fibroscope-guided intubations. This might be due to the improved shape of the CobraPLUS which should result in a better fit of the device in the supraglottic space. However, a success rate of less than 50% still appears to be a rather poor outcome for an emergency device.

The air-Q showed a performance similar to the CobraPLUS regarding quality of ventilation, but was slightly better for blind intubation. However, 43% failed attempts seems rather high considering that this device is used in an emergency setting.

In contrast to the variable success rates in blind intubation, the use of the fibroscope led to almost 100% successful intubations (Fig. 2). Thus, whenever intubation via laryngeal mask airway is planned, it seems reasonable to prepare a fibroscope for additional help. This multimodal approach ensured a high success rate independent of the type of LMA and the presumed airway difficulty in our patients.

The reason for the one failed fibroscope-guided intubation might have been the use of a wrong device size, which was chosen according to the manufacturer's recommendation relating the LMA size to the patient's weight. In the presence of a short and heavy patient, this might not be appropriate.

We report the damage of the cuff of an endotracheal tube following three failed attempts of blind intubation with the CobraPLUS device. This was possibly due to the fact that the lubricating gel was used up during the preceding attempts.

Traumatisation by supralaryngeal airways and blind intubation have been described in the literature^{23,24,26} and comparison of the devices tested would have been interesting. However, as many of our patients underwent surgery of the pharyngolaryngeal region, we were unable to distinguish between the causes of patients' post-operative discomfort.

When a difficult airway is anticipated, an important issue is the use of predictive scores to allow preparation for adequate management. Although routinely applied for the prediction of difficult intubation, no such parameter has been validated for predicting difficulties in blind intuba-

tion through a laryngeal mask airway. In a first step in the development of such parameters, we aimed to evaluate four scores and measures commonly used for the prediction of difficult endotracheal intubation for their ability to also predict difficult blind intubation through an LMA. However, no correlation between any of these parameters and failures that actually occurred was detectable. Therefore, the question of an effective predictor for a difficult intubation through an LMA remains unanswered and awaits the development of more specific parameters.^{19–21}

A possible bias in our study may arise from the problem of blinding. In this clinical study, it was practically impossible to evaluate the efficacy of ventilation without unblinding the assessor. However, assessment was nonetheless strict and verified by a second investigator. Also, as the number of patients with difficult anatomy was small, we have to point out that any conclusion on this group remains speculative and will require further studies specifically designed for such patients.

The three devices are delivered by the manufacturers in different packages. Although the Fastrach ILMA is provided as a complete emergency set consisting of the ILMA, a special reusable silicone tube (both in different sizes) and the LMA rod for pushing out the tube when the ILMA is to be removed, the air-Q is only supplied with a rod, and the CobraPLUS without any supplemental material. Therefore, it may seem unfair to compare the more flexible tube of the Fastrach with the regular PVC endotracheal tubes which are used with the two other devices. However, we compared the systems as they are available on the market, thus adhering to the manufacturers' recommendations.

We conclude that all three devices appeared to be safe supraglottic airways in general anaesthesia. The Fastrach ILMA, in contrast to the CobraPLUS and Cookgas air-Q, proved to be a reliable facilitator for blind intubation. The multimodal approach using a fibroscope and a laryngeal mask airway leads to a very high success rate in our patients independent of the device used. Failed intubations with any of the devices could not be predicted by the usual prediction scores.

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