A randomized comparison of blind intubation through air-Q and Fastrach LMA by using two different endotracheal tubes

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Cite this paper as: Noha Yahia Mohammed, Ezzat Mahmoud El-Saudi, Mahmoud Ahmad Abd-Elsalam (2021) A randomized comparison of blind intubation through air-Q and Fastrach LMA by using two different endotracheal tubes. *Frontiers in Health Informatics*. 10,

Abstract

Background: Airway management remains a challenging issue for anesthetists and may lead to life-threatening situations. Air Q and Fastrach laryngeal masks are examples of extraglottic airway devices which have been used recently as conduits for endotracheal intubation either blindly or via fiberoptic bronchoscope.

Objective: The primary objective of this study was to evaluate whether the use of two different endotracheal tubes (standard PVC and wire-reinforced silicone [WRS] ETT) enhances the success rate of blind intubation via the Air-Q compared to the ILMA.

Patients and methods: A total of 120 patients of both sexes, aged between 20 and 60 years, classified as American Society of Anesthesiologists (ASA) physical status I–II and with unremarkable preoperative investigations, were enrolled in the study. All patients were scheduled for elective surgical procedures requiring general anesthesia with tracheal intubation. Participants were randomly allocated into four equal groups (GPs) (n = 30 each) based on the endotracheal intubation technique employed.

Results: The study showed that the success rate with Air-Q LMA GPs (GI 96.7% & GII 93.3%) was higher than ILMA Fastrach GPs (90% for each GP). Blind intubation was easier with Air-Q GPs than Fastrach GPs and use of conventional PVC ETT was easier than WRS ETT. The mean intubation time was shorter with Air-Q (8.9 sec and 9.7 sec in GI& GII respectively) than with Fastrach (11.07 & 10.8 sec in GIII& GIV respectively). Accordingly, the insertion time was also shorter with Air-Q (50.6 sec and 50.8 sec in GI& GII respectively) than with Fastrach (53.6 sec and 52.6 sec in GIII& GIV respectively).

Conclusion: The present study shows that Air-Q laryngeal mask outperforms Fastrach laryngeal airway when serving as an intubation conduit in blind insertion techniques and both conventional PVC and wire reinforced silicon ETT are nearly equal in performance and each tube carries its own advantages and disadvantages.

Keywords: Air-Q, LMA, PVC, Endotracheal tubes

INTRODUCTION

The management of a difficult airway continues to be one of the most critical and complex responsibilities faced by anesthesia providers. While supraglottic airway devices are widely used in clinical practice, there are instances where their use may be inappropriate or inadequate, necessitating tracheal intubation. Traditionally, endotracheal tubes (ETT) are inserted under direct visualization using direct laryngoscopy. However, various supraglottic airway devices have been developed to assist in the placement of ETTs. One such device is the intubating laryngeal mask airway (ILMATM) (Intavent; Orthofix Ltd, Maidenhead, Berkshire, UK), also marketed as the LMA FastrachTM (LMA North America, San Diego, CA, USA), which is specifically engineered to facilitate tracheal intubation either blindly or under fiberoptic guidance (1).

An additional supraglottic device option is the Air-Q ⁽²⁾, Also referred to as the Intubating Laryngeal AirwayTM (ILA; Cookgas, St. Louis, MO, USA) ⁽²⁾. These devices were primarily designed to facilitate the insertion of conventional cuffed ETTs, either through blind tracheal intubation or as conduits for

fiberoptic-guided intubation. In addition to their intubation function, they also serve as effective ventilatory devices (3).

A specially designed wire-reinforced silicone (WRS) ETT is recommended for use with the LMA-Fastrach to facilitate tracheal intubation (1).

This specialized ETT is characterized by its straight configuration, wire reinforcement, and a conical Touhy-like silicone tip, which is less traumatic compared to conventional ETTs. However, its low-volume, high-pressure cuff renders it less appropriate for extended ventilation. Additionally, the tube is costly and not widely accessible. The wire reinforcement, while beneficial for intubation, can become a disadvantage if the patient bites down, potentially causing lumen distortion and impaired ventilation. In contrast, conventional polyvinyl chloride (PVC) ETTs are disposable, more cost-effective, readily available, and equipped with high-volume, low-pressure cuffs, making them more suitable for prolonged ventilatory support ⁽⁴⁾.

AIM OF THE STUDY

The primary objective of the present study was to evaluate whether the use of two different ETTs (standard PVC and WRS ETTs) enhances the success rate of blind intubation via the Air-Q, in comparison to the ILMA.

PATIENT AND METHODS

Following approval from the local medical ethics committee of the Department of Anesthesia and Intensive Care, Faculty of Medicine, Al-Azhar University (Assiut), and after obtaining written informed consent from all participants, this prospective, randomized, comparative, interventional study was conducted at Al-Azhar University Hospital (Assiut) and Assiut University Hospital between March 2017 and August 2019.

Patients:

A total of 120 patients of both sexes, aged 20 to 60 years, with normal preoperative investigations and classified as ASA physical status I–II, were enrolled in this study. All patients were scheduled for elective surgical procedures requiring general anesthesia and tracheal intubation. Based on the inclusion and exclusion criteria, patients were randomly assigned into four equal GPs (n = 30 per GP), according to the technique of endotracheal intubation employed.

- G I: underwent blind endotracheal intubation using conventional PVC ETT through Air-Q LM
- G II: underwent blind endotracheal intubation using reinforced ETT through Air-Q LMA.
- GIII: underwent blind endotracheal intubation using conventional PVC ETT through LMA-Fastrach.
 - GIV: underwent blind endotracheal intubation using reinforced ETT through LMA-Fastrach.

Technique of insertion:

1- Preparation of the mask (Air Q or Fastrach)

The sizes of the supraglottic devices (Air-Q or Fastrach) and the corresponding ETTs were selected based on the patient's body weight. A properly sized, deflated, and adequately lubricated ETT was inserted through the laryngeal mask airway to a depth ranging from approximately 8 to 20 cm, depending on the size of the mask. This positioning ensured that the distal tip of the ETT was located at or just proximal to the opening of the airway tube within the mask cavity. Additionally, the angle of emergence of the ETT from the device was compared between the ILMA and Air-Q. It was observed that the ETT emerged at an angle of approximately 45° in the ILMA, in contrast to a shallower angle of about 25° in the Air-Q (Figure 1)

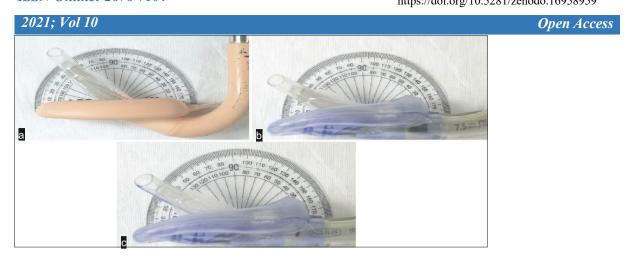


Figure (1): (a) Angle of emergence of the reinforced PVC ETT from the ILMA. (b) Angle of emergence of the reinforced PVC ETT from the Air-Q. (c) Angle of emergence of the standard PVC ETT from the Air-O (5).

Both the ETT and the airway tube of the mask were thoroughly lubricated to facilitate smooth passage of the tube through the mask. Prior to insertion, the ETT connector was removed and loosely reattached to allow for easy detachment during the use of the removal stylet. The mask cuff was deflated by aspirating air from the pilot balloon until two dimples appeared on the underside of the cuff, indicating complete deflation

2- Anesthesia technique:

Table (1): List of drugs used

Drug	Dose	Manufacture
Atropine (amp.)	0.02 mg/kg	Pharmaco pharmaceutical
Midazolam(amp.)	2 mg	Sunny pharmaceutical Egypt
Fentanyl(amp)	1 mg/kg	Pharmaco pharmaceutical
Propofol(amp)	1.5-2 mg/kg	Fresenius KABI
Atracurium(amp)	0.5 mg/kg loading dose	Sunny pharmaceutical Egypt
	0.15 mg/kg maintenance dose	
Isoflurane(inhal)	1.5-2.5%	Pharmaco pharmaceutical

Premedication:

Consent and fasting status were confirmed, and an intravenous line was opened. I.V line was inserted to the patient. Five minutes before induction 0.02 mg/kg atropine intravenous was given to all patients as an antisialagogue; furthermore, 2mg midazolam were given to the patients as a sedative.

Induction of anesthesia:

Prior to the induction of general anesthesia, patients underwent preoxygenation with 100% oxygen via face mask for a duration of three minutes. Anesthesia was induced with intravenous fentanyl (1 µg/kg), propofol (1.5–2 mg/kg), and atracurium (0.5 mg/kg). Mechanical ventilation was initiated using a face mask and maintained with isoflurane inhalation until complete neuromuscular relaxation was achieved. The supraglottic airway device (Air-Q or Fastrach) was inserted with the operator's right hand guiding the device, while the left hand employed a wooden tongue depressor to aid insertion. The device was advanced by applying continuous pressure along its shaft until resistance was met. Head flexion was used to facilitate insertion in some cases. Alternatively, tongue depression was achieved by applying pressure with the operator's left thumb.

3- Insertion of the ETT:

For endotracheal intubation, the ventilator and the mask adapter were disconnected. Blind insertion of the ETT was performed with the assistance of cricoid pressure and head extension until successful passage of the tube was achieved. Following placement, the ETT cuff was inflated and the mask cuff was deflated. The tube was then reconnected to the ventilator. Confirmation of successful tracheal intubation was established using capnography. Tube depth was further verified either by auscultation or fiberoptic examination to ensure proper positioning above the carina.

4- Mask removal procedure

Removal of the mask following successful endotracheal intubation was facilitated using the Air-Q removal stylet. If tracheal intubation could not be achieved within three attempts, or if peripheral oxygen saturation (SpO₂) decreased to 90%, direct laryngoscopy was employed to secure the airway. Insertion time was defined as the interval (in seconds) from initial contact of the mask with the patient's mouth to confirmation of successful intubation via capnography. Anesthesia was maintained with a combination of oxygen and either isoflurane or sevoflurane, in addition to intermittent doses of atracurium. Patients were then managed on controlled mechanical ventilation (CMV) with a tidal volume of 5-7 mL/kg and a respiratory rate of 12–14 breaths per minute.

Monitoring:

- Noninvasive blood pressure (NIBP).
- Heart rate.
- SpO2.
- EtCO2.
- Electrocardiography (ECG)] was maintained for all patients in all GPs.

Parameters of study:

Data collected to compare between the four GP according to:

- 1) Demographic data (age, sex, ASA state, BMI).
- 2) Insertion time: is the time in seconds from touching the patient's mouth with the mask (Fastrach or Air-Q) until capnographic confirmation.
- 3) Intubation time: is the time blind endotracheal intubation.
- 4) Number Attempts of insertion of tube: maximum 3 trials.
- 5) Ease of insertion of the tube.
- 6) Hemodynamics (BP, pulse, spo2, etco2).
- 7) Post-operative complications.
- 8) Stress response (blood cortisone and glucose level).

Statistical analysis:

Data entry and statistical analysis were performed using the Statistical Package for the Social Sciences (SPSS), version 20. Categorical variables were shown as frequencies and percentages, while continuous variables were shown as means and standard deviations. The Chi-square test was used to assess associations between categorical variables. For comparisons of continuous variables between two GPs with non-parametric distributions, the Mann–Whitney U test was applied, while comparisons among more than two GPs were conducted using the Kruskal–Wallis test. The Wilcoxon Signed-Rank test was employed for paired comparisons of quantitative variables before and after the intervention. A p-value of less than 0.05 was considered statistically significant.

RESULTS

I-Patients' demographic and clinical characteristics:

There were no marked differences among GPs in the demographic or clinical patients' data Table (2).

Table (2): Personal data

Air O	PVC	Air O	R Fas	PVC Fas	R
(n=30)	1,0	(n=30)	(n=30)	(n=30)	P-value

https://doi.org/10.5281/zenodo.16958959

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	Mean±SD	Mean±SD	Mean±SD	Mean±SD	
Age (years)	34.77±9.72	36.53±10.09	37.53±10.57	36.77±9.18	0.750≠
Sex: No. (%)					
Male	12 (40.0%)	16 (53.3%)	20 (66.7%)	18 (60.0%)	0.194°
Female	18 (60.0%)	14 (46.7%)	10 (33.3%)	12 (40.0%)	
ASA class: No. (%)					
ASA I	27 (90.0%)	25 (83.3%)	25 (83.3%)	23 (76.7%)	0.589°
ASA II	3 (10.0%)	5 (16.7%)	5 (16.7%)	7 (23.3%)	
BMI	24.50±1.77	24.09±1.78	24.93±1.52	24.30±1.77	0.256≠

[•] Chi-square test,

II- Insertion time and intubation time:

"Insertion time was defined as the duration, measured in seconds, from the initial contact of the mask with the patient's mouth to the confirmation of successful intubation via capnography.

Intubation time was defined as the duration required to perform blind endotracheal intubation through the supraglottic airway device

The mean insertion time was nearly the same in GI and GII which were lower than that for GIII and GIV.

There was no statistical significance in mean insertion time between the 2 types of the tubes within the same mask. However; there was statistical decrease in mean insertion time in Air Q (GI and GII) compared to LMA fastrach (GIII and GIV) (p-value<0.05)

Similarly, there was statistical decrease in mean intubation time in Air Q (GI and GII) compared to LMA fastrach (GIII and GIV) (p-value<0.05) with least mean intubation time for GI ($8.90\pm2.16s$) and longest mean intubation time for GIII ($11.07\pm1.75s$) as shown in table (3).

Table (3): Insertion time and intubation time

	Air-Q PVC	Air-Q R	Fas PVC	Fas R
	(n= 29)	(n=28)	(n=27)	(n=27)
	Mean±SD	Mean±SD	Mean±SD	Mean±SD
Insertion time (seconds)	50.66±3.36	50.82±2.71	53.63±2.48	52.67±3.09
95% C.I.	(49.38-51.93)	(49.77-51.87)	(52.65-54.61)	(51.45-53.89)
P-value ¹		0.904	0.001*	0.058
P-value ²			0.000*	0.038*
P-value ³				0.132
Intubation time (seconds)	8.90±2.16	9.79±1.73	11.07±1.75	10.86±1.78
95% C.I.	(8.08-9.72)	(9.12-10.46)	(10.38-11.77)	(10.07-11.34)
P-value ¹		0.164	0.000*	0.002*
P-value ²			0.005*	0.025*
P-value ³				0.543

^{1:} Comparison with Air Q PVC, 2: Comparison with Air Q R, 3: Comparison with Fas PVC, Mann-Whitney test

III- Measurement of stress response

Blood cortisol and glucose level (5pre induction and 30 min post intubation)

[≠] Kruskal Wallis Test

Blood cortisol level: Measurement of cortisone level was done by ELISA test, and measured by mcg/dL; normal cortisone levels at morning are 7- 28 mcg/dL (micrograms per deciliter). Cortisol concentrations peak in the early morning hours and gradually decline throughout the remainder of the day.

A-Serum Cortisone level pre-induction: Comparison between all GPs pre-induction shows insignificant difference (**P value >0.05**) as seen in table (4)

B-Changes in serum cortisone level post intubation: Comparison between the percentage of change in serum cortisone level post intubation shows statistical significance increase for Fastrach GPs (GIII & GIV) related to Air-Q GPs (GI &GII) (**P value < 0.001**). Also, there was statistically marked elevation in GIV (Fastrach Reinforced) than GIII (Fastrach PVC) (**P value = 0.001**). However, there was no statistical difference among Air-Q GPs (GI &GII) as seen the table (4), (5).

Table (4): Serum cortisol

S. cortisol	,	(n= 30)	,		P-value ¹
Before intubation	17.38±2.06	17.94±2.27	16.87±2.08	16.92±2.01	0.217
After intubation	21.29±2.10	22.71±2.21	22.62±2.41	25.27±2.97	0.000*
P-value ²	0.000*	0.000*	0.000*	0.000*	

^{1:} Kruskal Wallis Test, 2: Wilcoxon Signed Rank Test

Table (5): Percentage of change of serum cortisol

	Air Q PVC	Air Q R	Fas PVC	Fas R
Serum cortisol	(n=30)	(n=30)	(n=30)	(n=30)
	Mean±SD	Mean±SD	Mean±SD	Mean±SD
Mean±SD	18.02±5.27	18.95±7.22	22.92±6.18	31.05±8.92
P-value ¹		0.604	0.001*	0.000*
P-value ²			0.003*	0.000*
P-value ³				0.001*

^{1:} Comparison with Air Q PVC, 2: Comparison with Air Q R, 3: Comparison with Fas PVC, Mann-Whitney test

Blood glucose level: Normal fasting blood glucose level is 90-120 mg/dl. In this study blood sugar was measured by glucometer, by mg/dl.

The mean blood sugar levels were:

A- Blood Glucose level pre-induction: There was no statistical marked difference among the GPs. (P> 0.05).

B- Changes in Blood Glucose level post intubation: There was significant elevation in mean random blood glucose in each GP after intubation (P=0.000) in each GP. But there was no statistical marked difference among the GPs. (P>0.05). Even, in mean percentage of change in random blood glucose there was no statistical marked difference among the GPs. (P>0.05)

Table (6): Random blood glucose

RBG	Air Q PVC (n= 30)	Air Q R (n= 30)	Fas PVC (n= 30)		P-value ¹
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	
Before intubation	100.74±7.57	100.17±6.93	100.07±8.67	101.90±8.51	0.824
After intubation	121.63±4.58	123.43±5.43	125.07±6.94	124.20±6.58	0.284
P-value ²	0.000*	0.000*	0.000*	0.000*	

^{1:} Kruskal Wallis Test, 2: Wilcoxon Signed Rank Test

Table (7): Percentage of change of random blood glucose

2021; Vol 10 **Open Access** Air Q **PVC** Air R Fas **PVC** Fas R 0 **RBG** (n=30)(n=30)(n=30)(n=30)Mean ± SD Mean ± SD $Mean \pm SD$ $Mean \pm SD$ $Mean \pm SD$ 16.96 ± 4.64 18.25 ± 3.71 19.26 ± 4.82 17.31 ± 5.09 P-value¹ 0.376 0.101 0.737 P-value² 0.419 0.316 P-value³ 0.137

1: Comparison with Air Q PVC, 2: Comparison with Air Q R, 3: Comparison with Fas PVC, Mann-Whitney test

DISCUSSION

In this research, we related the use of two different types of intubating laryngeal masks to facilitate blind endotracheal intubation for either PVC or reinforced ETTs. Assessments included; the performance of each tube with each mask regarding rate of successful, insertion and intubation times, number of trials and ease of intubation. Stress response to intubation, hemodynamics and adverse effects were also evaluated. We recorded that the performance of Air-Q LMA was superior to ILMA Fastrach and that the use of conventional PVC ETT was better than reinforced ETT.

Although the reinforced tube was designed to be used with ILMA Fastrach, it was very malleable and use of its' stylet was to some extent difficult due to the angle of the shaft of mask. So, we tried to cool the tube to be firmer before start of anesthesia. In contrast, the conventional PVC tube was very easy in use with both masks. Additionally, the WRS ETT features a low-volume, high-pressure cuff and is more costly compared to the conventional PVC tube. The intubating supra-glottic devices were extensively studied as a conduit for blind or even fiber-optic intubation ⁽³⁾.

Most authors studied the success, speed and ease of intubation, effect on the hemodynamics, and incidence of complications ⁽⁶⁾. Most studies that carried out on blind intubation specifically through ILMA Fastrach and Air-Q LMA use Fastrach with its special tube and Air-Q with standard classic PVC ETT ⁽⁷⁾. Some authors studied blind intubation by ILMA Fastrach only comparing the reinforced and classic PVC ETT ⁽⁴⁾.

In this study, we aimed to equalize the chance between ILMA Fastrach and Air-Q by two equal GPs for each mask comparing the reinforced ETT and conventional PVC ETT.

We studied one hundred and twenty patients throughout the four GPs, of them nine patients were failed. The success rate with Air-Q LMA GPs (GI 96.7% & GII 93.3%) was higher than ILMA Fastrach GPs (90% for each GP). Blind intubation was easier with Air-Q GPs than Fastrach GPs and use of conventional PVC ETT was easier than WRS ETT. The mean intubation time was shorter with Air-Q (8.9 sec and 9.7 sec in GI & GII respectively) than with Fastrach (11.07 sec & 10.8 sec in GIII & GIV respectively). Insertion time was additionally reduced when using Air-Q (50.6 sec and 50.8 sec in GI& GII respectively) than with Fastrach (53.6 sec and 52.6 sec in GIII& GIV respectively)

The clinical significance observed in Air-Q LMA performance over ILMA Fastrach during the manipulation may be as a result of the C-shaped shaft of Air-Q LMA that facilitate insertion of the tube and removal of the mask in contrast to the angle of the shaft of Fastrach LMA that hindered the insertion of the tube and removal of the mask.

Malhotra and his colleagues had studied one hundred and twenty patients comparing between two GPs Air-Q using two different ET tubes with ILMA using its special WRS ETT. Their findings indicated that the overall success rate after three intubation attempts was higher with the Air-Q (96.6%) compared to the ILMA (91.6%); however, the difference between the two GPs was not statistically significant (P = 0.43) (5).

With Air-Q they tried blind intubation in the first attempt with reinforced tube; if it was failed, they tried the classic PVC tube in the second attempt and if both attempts failed, they used reinforced tube in the third trial again.

It was observed that the use of two different ETTs enhanced the success rate of blind intubation via the

Air-Q, compared to the ILMA (5).

The least mean intubation time was 15±5 sec for Air-Q and 20±15 sec for Fastrach which is to great extent agreed with our result.

Unlike, **Karim and Swanson** ⁽⁷⁾ "They reported that successful blind intubation within two attempts was achieved in 75 out of 76 patients (99%) in the LMA Fastrach GP, compared to 60 out of 78 patients (77%) in the Air-Q GP, with a 95% confidence interval for the difference ranging from 12% to 32% (p < 0.0001). The third attempt was performed using fibreoptic guidance. The overall success rate after three attempts reached 100% in the LMA Fastrach GP and 95% in the Air-Q GP. The comparatively lower success rate observed in the Air-Q GP may be attributed to the study design, which allowed only two blind intubation attempts before employing fibreoptic assistance on the third attempt. ⁽⁷⁾.

The mean intubation time they reported was 35 secs for Air-Q mask and 27 secs for Fastrach mask. Recently, **Sameer** *et al.* ⁽⁸⁾ reported that blind intubation with the Air-Q resulted in a success rate of 80%. And mean intubation time was 22±2 secs.

In general, endotracheal intubation is a stressful condition that affects hemodynamics and use of laryngoscope adds to this effect. Blind intubation to some extent mitigates the physiological stress response associated with intubation and hence hemodynamics and it is helpful in some difficult and maxillofacial cases.

According to **Bashandy and Boules** ⁽⁹⁾, intubation via the Air-Q resulted in a significantly attenuated hemodynamic stress response relative to intubation using a direct laryngoscope.

In our study, we recorded differences between GPs in HR, non-invasive mean arterial blood pressure(ABP), oxygen saturation and end- tidal CO2 at baseline, after induction (before insertion of the mask), immediate after intubation and at 1, 3, 5 and 10 min. which were, like other studies comparing blind intubation via IMAs, showing time effect. There was decrease in HR and ABP mean values compared to baseline at pre-intubation, increase at immediate post-intubation and persistent lower values at 1, 3, 5 &10 mins in all studied GPs and no significant differences between the GPs ⁽¹⁰⁾.

After induction of general anesthesia mean oxygen saturation showed increase than baseline value in all GPs of the study which were slightly dropped at immediate after intubation in all GPs except GP (I) and remained nearly steady at the remaining times of the study in all GPs. In line with the current study, **Galgon** *et al.* ⁽¹¹⁾ found that HR get higher in post intubation period for Air-Q GP but it's of no clinical significance and no clinically significant change in mean MAP and SPO2 This study was done while comparing air-Q intubating laryngeal airway vs the LMA-ProSeal as regard hemodynamics.

Also, in this study, we recorded levels of serum cortisol and plasma glucose before induction of anesthesia and after intubation; we recorded significant increase in mean levels of serum cortisol and plasma glucose after intubation in each GP. However, there was no marked difference in the percentage of change among the GPs. To our knowledge, no previous studies reported on endocrine stress response to blind intubation via intubating laryngeal masks till the present time.

The incidence of postoperative airway complications observed in this study was comparable to that reported in previous studies (12).

The use of the self-pressurizing Air-Q intubating laryngeal airway (ILA) has been shown to reduce airway-related morbidity, this is clearly appeared in postoperative complication that showed blood tinged mucous on the mask, after removal, in Fastrach GPs (two in each GP) than single case in Air-Q (in GIII). Hoarseness of voice was reported in three cases in Fastrach GPs (one in GIII and two in GIV) and not reported in Air-Q GPs.

According to **Malhotra** *et al.* ⁽⁶⁾ visible blood was noted on the device after removal in one patient from the Air-Q GP and one from the Fastrach GP.

In this study, desaturation was reported in 2 cases that were failed to intubate blindly. One of them in GP I; the patient showed unexpected difficult laryngoscopy, the tube took place in the third attempt of direct laryngoscopy. The other case in GP IV, he became hypoxic in the third trial of blind intubation, so manipulation had been stopped and ventilation by facemask was done till saturation was raised to 100%

and then intubation by direct laryngoscope was done within 12 seconds.

CONCLUSIONS

The present study shows that Air-Q laryngeal mask outperforms Fastrach laryngeal airway in its role as a channel for blind intubation and both conventional PVC and wire reinforced silicon ETT are nearly equal in performance and each tube carries its own advantages and disadvantages.

Conflict of interest: None.

Financial disclosures: None.

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