The Egyptian Journal of Hospital Medicine (January 2023) Vol. 90, Page 1617-1623

Airway Management in Morbidly Obese Patients: A Comparison of Intubating Laryngeal Mask Airway-Fastrack™ and Air-Q™ Intubating Laryngeal Airway as A Conduit for Bronchoscopic Tracheal Intubation

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ABSTRACT

Background: It can be difficult for anesthesiologists to manage the airway of morbidly obese patients. Devices like the intubating laryngeal mask airway (ILMA) -FastTrach™) and Air-Q™ were specially designed to make tracheal intubation easier while ensuring ventilation and oxygenation. This study compared the efficiency of these two supraglottic airway devices (SAD) for fiberoptic intubation in adult morbidly obese patients.

Methods: Eighty morbidly obese (BMI>40 kg/m^2) patients planned for elective surgery requiring tracheal intubation and general anesthesia participated in the study. Patients were allocated to the ILMA group or the Air-Q group. A fiberoptic bronchoscope was used to intubate the trachea through the SAD. The primary endpoint was the time to intubate the trachea. The time to insert the SAD, the insertion success rate of the SAD and tracheal tube, the laryngeal view, and any adverse events related to the procedure, were the secondary outcomes.

Results: The mean tracheal intubation time was shorter through the Air-Q™ compared to the ILMA-Fastrach™ (41.4 ±6.1 s vs 76.22 ±10.2 s, P< 0.001). The mean insertion time of the Air-Q^{TM} was significantly shorter than that of the ILMA-Fastrach^{TM} (18.9 ±0.7 s vs 25.1 ±1.3 s, P < 0.001), The Air-Q had a significantly better success rate for tracheal tube insertion on the first attempt, but the overall intubation success rate was comparable for both devices. **Conclusion:** Air-Q™ was associated with a shorter time of device insertion and fiberoptic intubation, and a higher first-attempt insertion success rate of the tracheal tube than ILMA-Fastrach^{TM}.

Keywords: Morbid Obesity, ILMA, Air Q, Fiberoptic Bronchoscopy.

INTRODUCTION

Morbid obesity which is defined as BMI ≥ 40 kg/m^2 is rising globally which makes it necessary for anesthesiologists to recognize the crucial anatomical and physiologic abnormalities that characterize these individuals [(1)].

It is more difficult to intubate the tracheas of morbidly obese patients who may have obstructive sleep apnea, a high Mallampati class (III or IV), or a large neck circumference [(2)]. When managing those patients, minutes or even seconds matter. Since they are liable to rapid oxygen desaturation, which establishes a central point in morbidity and mortality identified with anesthesia. For this reason, the anesthesiologist must always be ready to address airway issues among those patients [(3)]. Supraglottic airway devices have not only been a vital component of patient airway management, but also a potentially lifesaving tool included in most airway management algorithms [(4)].

The Difficult Airway Society's guidelines described fiberoptic guided tracheal intubation through SAD in Plan B for the management of unpredicted difficult intubation. However, it can also be utilized to control a predicted difficult airway. The success in tracheal intubation through SAD is influenced by which device is used to manage a challenging airway [(5)].

Devices, like (ILMA -Fastrach) and intubating the laryngeal airway with Air-Q, can be used to facilitate tracheal intubation while maintaining ventilation and oxygenation which is crucial in morbidly obese patients as they have a short safe apnea period (time from apnea due to muscle paralysis until oxygen saturation decreases to a potentially fatal level) compared to normal weight [(1, 6)].

Although ILMA-Fastrach was considered the standard SAD for tracheal intubation., The Air-Q is provided in adult and pediatric sizes, in both single-use and reusable versions, and it has some potential features to facilitate blind as well as bronchoscopic guided tracheal intubation. Among the possible advantages of Air-Q are the device's small and wide tube, the lack of an epiglottis elevator, and the easily removable proximal connector. Moreover, a regular PVC tube can be used to intubate the trachea through it [(7)].

According to our best knowledge, this was the first randomized, controlled interventional trial evaluating the effectiveness of fiber-optic intubation in adult morbidly obese patients through two commonly used SAD devices, the ILMA-Fastrach and the Air-Q.

We, therefore, conducted prospective, randomized research to compare fiber-optic guided tracheal intubation through these two SADs in adult morbidly obese.

We hypothesized that the Air-Q would provide shorter fiber-optic guided tracheal intubation time and a higher intubation success rate than the ILMA.

Received: 22/08/2022
Accepted: 25/10/2022

The time of endotracheal tube (ETT) insertion was the study's primary finding. Other outcomes included the SAD insertion time and the insertion success rate of the SAD and ETT, the removal time of SAD, fiber-optic glottis view, and any complications associated with the procedure.

Methods

Study design and settings:

This prospective, randomized controlled study was conducted at Zagazig University Hospital.

Patients:

All morbidly obese patients (having a BMI above 40 kg/m $^{2)}$ aged 18-65 years of both sexes who were scheduled for a surgical procedure requiring general anesthesia oral and tracheal intubation were included.

Patients with an increased risk of aspiration of gastric contents, patients requiring nasal intubation, and those who had coagulopathy were excluded from the study. The patient's airway was assessed carefully before induction of general anesthesia using the simplified airway risk index (SAR index) described by **El-Ganzouri *et al*. [(8)]** and if the patient had a score >4, he was considered at risk for difficult intubation and would be excluded from the study.

The SAR index assigned a value of 0,1, or 2 to each of the six parameters used for airway assessment: Interincisor gap (> 4 cm= 0; < 4 cm= 1), Thyro-mental distance (> 6.5 cm,= 0; 6–6.5 cm=1;<6 cm=2), Mallampati score (I= 0; II= 1; III or IV, 2), cervical spine extension (>90°=0;80°–90°=1<80°= 2) body weight (<90 kg= 0; 90–110 kg= 1;<110 kg= 2), and history of difficult intubation (none= 0; questionable= 1;definite= 2).

The patient was considered to be at risk of difficult intubation if their SAR score was 4 or above.

Randomization

The recruited patients were randomized prior to the surgery, using computer-generated random numbers and opaque, sealed envelopes. to:

Air-Q group (n=40): The Air-Q™ (Cook gas LLC, Saint Louis, USA) was placed after inducing general anesthesia. Then, fiberoptic tracheal intubation was done through it.

ILMA group (n=40): ILMA-Fastrach™ (Laryngeal Mask Company, Jersey, UK) was placed after inducing general anesthesia. Then fiberoptic intubation was done through it.

The management of the airways of all patients involved in the trial was performed by two skilled anesthesiologists who had experience in inserting the studied SADs and intubating the trachea using the fibreoptic bronchoscope more than 50 times before starting the study.

According to the randomization, the assigned SAD was prepared based on the patient's body weight following the manufacturer's instructions. After the insertion of an intravenous catheter in a peripheral vein, the crystalloid infusion was started. Continuous monitoring included pulse oximetry, electrocardiography, capnography, and non-invasive arterial blood pressure.

The patients were pre-oxygenated with 100% oxygen for three minutes in the head-up position. General anesthesia was induced using fentany2µg /kg, propofol 2-3 mg/kg (until verbal contact was lost), and a non-depolarizing muscle relaxant 0.6 mg/kg rocuronium was administered after determining that the bag-mask ventilation was sufficient. Neuromuscular monitoring was done by ulnar nerve stimulation and insertion of the SAD was attempted after the adductor policies response obtained by TOF was abolished. The anesthesiologist responsible for the airway management then inserted either:

Air-Q or ILMA-Fastrach using the standard method of insertion recommended by the manufacturer after lubricating the back of the deflated cuffs with water-based jelly. The conventional midline non-rotational technique was used to insert the Air-Q after pushing the tongue downward with a disposable tongue depressor. On the other hand, the ILMA was introduced using the one-handed rotational technique by using the device's metal handle to slightly rotate it in the sagittal plane. Successful insertion of the SAD was assessed by end-tidal CO2 detection, adequate chest rise without a significant leak, and auscultation of air entry.

If the ventilation through the SAD was inadequate, up to three minor airway maneuvers were tried to adjust the device position (For instance, adjusting the depth of the device, changing the head/neck position, or having an assistant do a jaw thrust). Failure to insert the SAD or provide adequate ventilation despite the use of three airway-adjusting techniques was considered failed insertion. After three failed attempts to insert the SAD, the airway of the patient was managed according to the attending anesthesiologist and the patient would be withdrawn from the study.

When ventilation through the SAD was adequate, the operator inserted the fiberoptic bronchoscope with an external diameter of 5.2 mm (Olympus Medical System, Tokyo, Japan) loaded with a lubricated tracheal tube of appropriate size through the SAD. For ILMA sizes 4, 5 cuffed silicon reinforced ETT sizes 7 and 7,5 mm ID was utilized. Meanwhile cuffed PVC ETT size 7 mm and 7.5 ID were used with the Air-Q size 3.5 and 4.5 respectively.

The best bronchoscopic view of the glottis from the exit of SAD was scored by the operator on a scale of 1 to 4 described by **Kapila *et al***. (1=vocal cords are fully visible, 2= vocal cords are partially visible, 3= only the

epiglottis is visible including the arytenoids, 4= other structures visible only as pharynx and LMA cuff) [9].

The flexible bronchoscope was then introduced until the carina was visualized, then the ETT was introduced into the trachea 3–4 cm proximal to it. The bronchoscope was removed and ETT was connected to the breathing circuit. End-tidal CO2 detection and auscultation of bilateral breath sounds were used to verify proper tube position. If it was not possible to intubate the trachea through the SAD after 3 attempts, it was considered as failure and the patient completed the procedure with the SAD if appropriate, otherwise, it was replaced with another definitive airway.

After successful intubation, the fiberoptic bronchoscope was taken out, and the breathing circuit was reconnected. We utilized removing stylet to remove the Air-Q and, the stabilizer rod to remove the ILMA without dislodging the ETT. The operator was asked to rate the process's overall difficulty on a visual analog score (VAS) of 10 (1 = easy, 10 = impossible) after the intubation procedure.

After the surgery, the patient was contacted when fully awake to ask about any complications related to the procedure like sore throat or hoarseness of voice.

Data collection:

The variables collected for analysis included:

- Insertion time of SAD was counted from the time the anesthesiologist first picked up the device until the detection of the first CO2 wave upstroke of the capnograph (T1).
- Intubation time was the time between getting end-tidal CO2 from SAD and getting it from ETT while the SAD is in place (T2).
- The time to remove SAD was counted from having end-tidal Co_2 from the ETT while SAD was in place to the time of having end-tidal Co_2 from ETT with SAD removed (T3)
- Total time of the procedure (T4=T1 + T2 + T3).
- The grading of the glottis view
- The overall difficulty of the procedure.
- Heart rate, blood pressure, and oxygen saturation were recorded prior to induction, of general anesthesia as a baseline then every minute during the procedure and for 10 min after intubation.
- Any complication related to the procedure such as blood staining of the SAD, regurgitation, tongue, lip, dental, or airway trauma, airway obstruction, desaturation (Spo2 <90%), hypotension (mean arterial pressure decreased by >20% below the pre-induction baseline) or hypertension (mean arterial blood pressure increased by >20% over pre-induction baseline) and change in heart rate > 20% of the pre-induction value).

The laryngeal view and the procedure difficulty were rated by the anesthesiologist who managed the airway and all the other parameters were recorded by another observer.

Sample size

Utilizing the G*Power program (G*Power version 3.1.9.4, Kiel University, Germany), the approximate sample size was calculated before the study. Given the insertion time of ETT through Air-Q (29.7± 12) and LMA-Fastrach (40.3± 14.6) in a previous study [10]. In a two-tailed test assuming a type I error of 0.05 and a power of 0.9, 70 cases (35 cases per group) were required. By increasing the number of cases to 80 patients (40 patients in each group), the potential dropouts were offset.

Ethical consideration:

The local Institutional Research Board approved the investigation. (approval number: 5546). Before patient recruitment, the research was listed on clinicaltrials.gov. registry system (clinical trial identifier: NCT04453683). All participants gave informed written consent. They were told about the nature of the study and the potential dangers of the operation. This research was organized in consistent with the 2013 Declaration of Helsinki's ethical principles and good clinical practice.

Statistical analysis

The present study's data were calculated using SPSS version 20. While categorical data were expressed as count and percent, continuous data were expressed as mean ± SD. The chi-square or fisher test was used to compare qualitative data. Quantitative data were compared using the student t-test. A P value of 0.05 or less was regarded as statistically significant.

RESULTS

Ninety-five patients were examined for eligibility to be included in the current study. Twelve patients did not meet the inclusion criteria and 3 refused to participate. Eighty patients were included and randomized equally into the Air Q group and the ILMA group. **(Fig 1).**

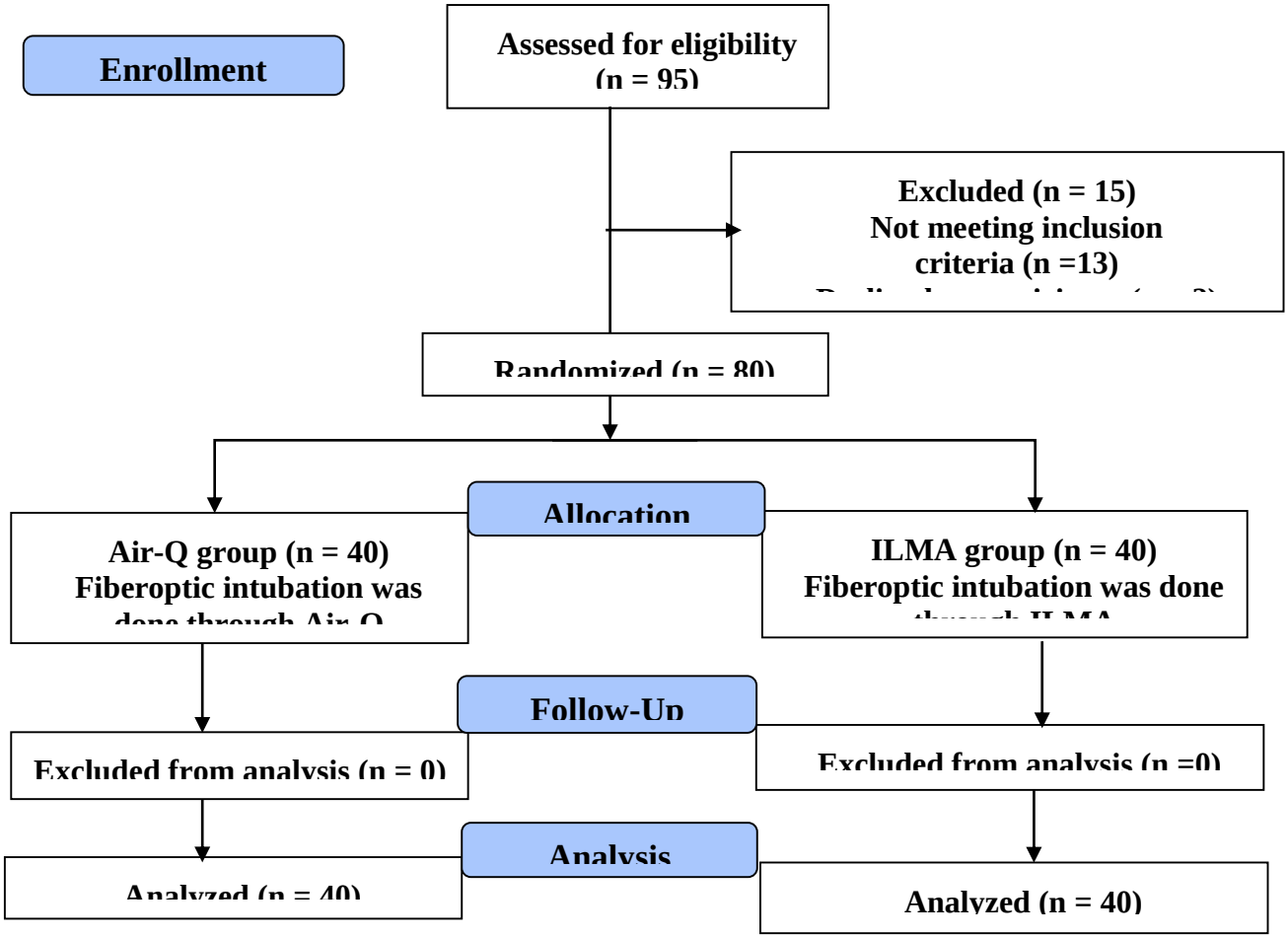

Fig. 1. Patient's flowchart demonstrating the number of patients eligible for inclusion into the study.

Both groups were comparable regarding age, gender, thyromental distance, and BMI (p-value> 0.05). There was also no statistically significant difference between the studied group regarding the history of sleep apnea, Mallampati score, mouth opening, ability to protrude the jaw and head and neck movements, and ease of mask ventilation**. [Table 1]**

Table 1: Patients' basic demographic and clinical characteristics

Variable		Air Q (n=40)	ILMA (n=40)	P-value
Age (years)		47.65 ± 7.10	48.8 ± 7.43	0.481
Gender (Male / Female)		28-Dec	15/25	0.478
BMI		41.9 ±2.17	41.6 ±2.02	0.596
TMD		7.1 ±0.77	7.3 ±0.69	0.176
Sleep apnea	Present	28	31	0.133
	Absent	12	9	
Mallampati	I	20	24	0.06
	II	14	12	
	III	6	4	
	IV	0	0	
Interincisor gap (cm)		4.12± 0.75	4.17± 0.71	0.893
Limited Jaw protrusion	Yes	2	1	0.556
	No	38	39	
Head and neck movement	90/ 80-90/ 80º	15/ 19/ 6	14/ 21/ 5	0.893
Mask ventilation possible without help	Yes	33	36	0.33
	No	7	4	

Data are presented as mean ± standard deviation and number. BMI: body mass index; TMD: thyromental distance

The insertion characteristics of the SADs and tracheal intubation were demonstrated in **Table 2**. There was a statistically significant difference between Air-Q and ILMA regarding the first attempt success of inserting the device (95% vs 77.5% respectively, p-value <0.05) however, the overall success rate of the device did not differ significantly between both groups (100%). Optimization maneuvers to correct the position of SAD were needed in fewer patients in the Air-Q group compared with the ILMA group (12 vs 24).

The mean insertion time of the Air-Q was significantly shorter than that of ILMA (18.9+ 0.7s vs 25.1+ 1.3s, p<0.05). The tracheal intubation was successful on the first trial in 95% of patients in the Air-Q group and in75% of patients in the ILMA group and the difference was significant (p-value <0.05) although there is no statistically significant difference between both groups regarding the overall success of intubation.

The mean insertion time of the tube through the Air Q was 41.4+ 6.1s which was significantly shorter than that of the ILMA (76.22+ 10.2s). There was a significantly better fiberoptic view and less procedure difficulty (less VAS) with the Air Q. The total time of the procedure was significantly shorter in the Air Q group compared with the ILMA group (98.5+ 9.5s vs 141.1+ 12.1s, p>0.05).

Table 2: The insertion characteristics of the SADs and ETT

	Air Q (n=40)	**ILMA (n=40)**	**P-value**
First insertion attempt success rate of the SAD	38 (95.0%)	31 (77.5%)	**0.023***
Overall insertion success rate of the SAD	40 (100%)	40 (100%)	1.0
Insertion time of SAD (T1) (s)	18.9± 0.7	25.1± 1.31	**<0.0001****
Optimization maneuvers to insert SAD Yes/No	12/40	24/40	**0.007***
Tracheal intubation first attempt success rate	38 (95%)	30 (75.0%)	**0.012***
Tracheal intubation overall success rate	39 (97.5%)	35(87.5%)	0.09
Intubation time (T2) (s)	41.4± 6.1	76.22± 10.2	**<0.0001****
Removal time of SGA (T3) (s)	38.5± 4.8	39.7± 5.6	0.333
T4 (Total time of the procedureT1+T2+T3) (s)	98.5± 9.5	141.1± 12.1	**<0.0001****
Fiberoptic view score (Grade I/Grade II/Grade III/Grade IV)	(22/12/6/0)	(6/9/15/10)	**<0.0001****
Visual analog score of the procedure difficulty	1.3± 0.6	3.8± 0.7	**<0.0001****

Data are presented as mean ± standard deviation and number (percent). SAD: supraglottic airway device, ETT: endo-tracheal tube, VAS: visual analogue score. *P < 0.05 is statistically significant.

By comparing intubation success, intubation time, and VAS for the procedure difficulty among different grades of Fiberoptic view, it was noticed that better fiberoptic view was associated with significantly more successful intubation, shorter intubation time and less difficulty of the procedure [**Table 3**].

Table 3: Comparing intubation success rate, intubation time, and the procedure difficulty VAS among different glottis view grades

	Grade I (n=28)	**Grade II (n=21)**	**Grade III (n=21)**	**Grade IV (n=10)**	**P-value**
Intubation success Successful intubation	28	21	19	6	**<0.0001****
Failed intubation	0	0	2	4	
Intubation time (s)	44.1± 14.5	55.9± 16.5	68.6± 13.7	84.3± 9.6	**<0.0001****
VAS score for the procedure difficulty	1.6± 1.1	2.5± 1.2	3.6± 1.1	4.2± 0.9	**<0.0001****

Data are presented as mean ± standard deviation and number (percent). VAS: visual analogue score. *P < 0.05 is statistically significant.

Regarding the procedure's complications, there was no statistically significant difference in the incidence of the post-extubation sore throat between the examined groups, although the ILMA group had a higher incidence of blood stains on the device (p<0.05) [Table 5]. We did not record any other complications related to the intervention.

Table 4. Comparing complications between the studied groups.

	Air-Q™ (n=40)	ILMA-Fastrach™ (n=40)	P-value
Sore throat	14(35%)	18(45%)	0.09
Blood stains on the SAD device	9 (22.5%)	16 (40%)	0.04*

Data are presented as mean ± standard deviation and number (percent). SAR: simplified airway risk. *P < 0.05 is statistically significant.

DISCUSSION

The main results of our study were that the Air-Q group had a significantly shorter insertion time of SAD and ETT, a higher success rate to insert the ETT at the first attempt, better fiberoptic laryngeal view, less difficulty of the procedure compared to the ILMA-Fastrach group with a similar overall success rate of intubation.

Whether obesity alone is associated with a higher risk of difficult tracheal intubation or not remains debatable. However, maintaining airway patency during mask ventilation and access through endotracheal intubation in obese patients may be more challenging in addition to their liability to rapid oxygen desaturation associated with impaired lung function due to deposition of excess adipose tissue in the mouth, pharynx, breast, neck, chest wall, and abdomen [1,2]. Consequently, airway management of obese patients under general anesthesia should be a series of procedures ending in quickly securing a patent airway for ventilation otherwise disastrous results may occur [11].

In this study, the Air- Q's insertion time was significantly shorter, and the first insertion success rate was higher (18.9± 0.7s, 95%) than the ILMA-Fastrach, (25.1 ±1.31s, 75%) and this may be due to the more flexible shaft of the Air-Q making its insertion a bit easier than the rigid shaft of ILMA-Fastrach. Consequently, airway manipulations were needed in fewer patients with the Air-Q and this is consistence with the findings of **Abdel-Halim *et al.*** [12], and **Karim and Swanson's** [13] who revealed that the time needed to insert the Air-Q was shorter than that of ILMA -Fastrach without significant difference in overall device insertion success rate. **Bakker *et al.*** [14] studied the conditions of inserting Air-Q in 59 patients and reported a 100 % insertion success with a mean insertion time of 26 ± 13.

Our findings are in line with **Lee and Benumof's** [15] study in terms of the success of intubation. When they evaluated three different SADs, (Air-Q ILA™, LMA Classic Excel™, and LMA Unique™) and reported intubation success of 100%, 87.8%, and 95% respectively. Nevertheless, they claimed that there was no detectable difference among the three groups in the time needed to place the SAD or the ETT. According to the research of **Jagannathan *et al*.** [7] who studied tracheal intubation through the Air-Q in 100 children and reported that the insertion of the air-Q on the first attempt was successful in 99 children, while tracheal intubation was successful in 97 children on the first attempt and 3 on the second attempt with an average intubation time of 24.8 ± 10.6 s.

Sastre *et al.* [16] in contrast to our study found that successful placement of SAD was achieved in 90% of patients with ILMA-Fastrach, and 60% of patients with the Air-Q on the first trial. This discrepancy could be explained by the different patient populations, as their study excluded patients with BMIs greater than 30 kg/m2. Two other studies done by **Neoh and Choy** [17] and **Siamdoust *et al*.** [18] on normal-weight patients could not prove any significant difference between the air-Q and the ILMA-Fastrach in terms of insertion difficulty of the device and adequacy of ventilation through it. However, tracheal intubation was superior using the ILMA-Fastrach, rather than the air-Q.

The Air Q provided a significantly superior laryngeal view, with less difficulty in the intubation procedure (lower VAS). The tracheal intubation time was shorter in the Air-Q group (41.4± 6.1) than in the ILMA-Fastrach group (76.22± 10.2), and this may be attributed to the absence of epiglottis elevating bars or aperture bars that may block the vision of the vocal cords. These results agreed with the study of **Samir and Sakr** [19] who reported that during fiberoptic-assisted tracheal intubation, Air-Q offered a better view of the glottis opening. These results are also consistent with that of **Abdel-Halim *et al*.** [12] study, which revealed that a full view of the vocal cord was obtained in 78% of patients in the Air-Q group and 26% of patients in the ILMA-Fastrach group.

In agreement with our study, **Lee and Benumof** [15] reported that the patients who had the Grade I glottis view (complete view of the vocal cord) had considerably shorter intubation timings (75.1 sec, $p < 0.0001$) and significantly lower VAS procedure difficulty scores (VAS = 1.9, $P < 0.0001$) than both grade II and grade III views (92.7 sec, VAS = 3.2, and 111.6 sec, VAS = 4.9). On the contrary, **Frappier *et al*.** [20] studied the efficacy of ILMA-Fastrach in 118 Patients scheduled for bariatric surgery who are morbidly obese (mean BMI, 45.5 kg/m^2). They examined the relationship between the laryngeal view and the success of tracheal intubation through the SAD and reported that the success rate, the number of insertion attempts, and the overall time of the process did not vary between the patients with different laryngeal grades.

The current trial found no statistically significant difference between the study groups regarding post-extubation sore throat but there was a significantly lower frequency of blood stains on the Air-Q compared to the ILMA-Fastrach (22.5% vs 40%).

This may be due to the repetition of optimization maneuvers which were higher in ILMA-Fastrach. Our findings agreed with those of **Neoh and Choy** [17] who showed a comparable incidence of sore throat, and hoarseness of voice between the studied groups with a significantly higher incidence of blood stain on the ILMA-Fastrach than the Air-Q.

The research by **Karim and Swanson** [13] also demonstrated a similar incidence of sore throat and

hoarseness of voice with both the Air-Q and the ILMA-Fastrach when utilized as tracheal intubation conduits. These findings contradict those of **Abdel-Halim *et al*.** [12] study as blood stains on the SAD were more in the Air-Q (46%vs 22%) compared to ILMA-Fastrach.

CONCLUSION

Based on the findings of our research, we determined that Air-Q intubating laryngeal airway is superior to ILMA-Fastrach as a route for fiberoptic intubation in adult morbidly obese patients as the Air-Q was associated with shorter duration of both device insertion and tracheal intubation, better fiberoptic glottis view and increased intubation success rate at the first attempt.

Financial support and sponsorship: None
Conflict of interest: None

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