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Research article

Bougie assisted endotracheal intubation using the Air-Q™ Intubating Laryngeal Airway: A prospective randomized clinical study

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ABSTRACT

Background: Air-Q™ Intubating Laryngeal Airway is an extraglottic airway device used as a primary airway tool or as an adjunct to tracheal intubation. The bougie is a simple flexible device that might increase the success rate of endotracheal intubation either blindly or through a supraglottic device. We hypothesized that using bougie guided intubation through air-Q™ can improve the success rate with minimal complications.

Methods: One hundred and forty patients of either sex, >18 years old, ASA I-II scheduled for elective surgical procedures under general anesthesia with intubation were randomly allocated to one of two groups of 70 patients each. Blind tracheal intubation was performed through air-Q™ with bougie assistance (Group B) or without (Group Q). In both groups, 3 attempts were allowed for successful device insertion. After obtaining normal capnographic wave, 3 more attempts were tried for intubation with or without bougie guidance. Lung ventilation through air-Q™ was permitted between intubation attempts. If tracheal intubation through air-Q™ was unsuccessful, it was performed by direct laryngoscopy.

Results: Air-Q™ time, ease, attempts number of insertion and ventilation grade were comparable between both groups. Total intubation time was significantly longer in group-B ($P = 0.001$) while overall success rate for intubation was comparable (64.3%). Group-B showed significant ($P = 0.001$) higher incidence of complications (trauma ($P = 0.023$), sore throat ($P = 0.001$), dysphonia ($P = 0.023$) and dysphagia ($P = 0.001$)) as compared with group-Q. In spite of significant decrease in both heart rate and mean arterial pressure in both groups after air-Q™ insertion, yet there was significant increase in both parameters after intubation compared to baseline values ($P < 0.05$) which was more prominent in group-B than in group-Q. Significant increase in HR and MAP was elicited after bougie placement in group-B ($P < 0.01$).

Conclusion: Bougie guided tracheal intubation through air-Q™ didn't improve overall success rate with significant longer time, hemodynamic derangement and traumatic sequelae.

1. Introduction

Air-Q™ Intubating Laryngeal Airway (air-Q™ ILA, Cookgas LLC, St. Louis, MO, USA) is an extraglottic airway device used to maintain the airway as well as an aid for tracheal intubation. It exists as disposable (air-Q™) and non-disposable (ILA) versions both having a shorter, wider shaft than the classic laryngeal mask airway (LMA), with a detachable connector. Its distal end has a keyhole-shaped opening without aperture bars in order to facilitate intubation [1].

Endotracheal intubation can be successfully achieved through extraglottic devices either blindly or assisted to increase its success rate [2]. Although fiberoptic guidance is more reliable tool, yet it is not available in all operating rooms and needs special skills [3]. The bougie is a simple flexible device that has a small caliber and thus can be easily manipulated. It is used as a Seldinger-type guide or track for endotracheal tube (ETT) placement [4].

We hypothesized that using bougie guided intubation through air-Q™ can improve the success rate with minimal complications. Thus this prospective randomized study was designed to assess bougie-guided tracheal intubation using the air-Q™. The primary outcome of this study was the first trial success rate while the total success rate, time to tracheal intubation, the number of attempts, hemodynamics and adverse events were secondary outcomes.

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2. Patients & methods

This prospective, randomized comparative study was conducted in the Anesthesia and Surgical Intensive Care Department, at Theodor Bilharz Research Institute, Giza, Egypt, after approval by local research ethics' committee and the study was registered in a public trial register (www.clinicaltrials.gov) under the identification number: NCT02322684 on 12/22/2014. One hundred and forty patients of either sex, older than 18 years, ASA physical status I and II scheduled to receive general anesthesia with tracheal intubation for an elective surgical procedure were enrolled in the study. Written informed consents were obtained from all patients before participation in this trial. Patients were randomly allocated to one of two groups of 70 patients each according to a computer-generated random number table. Blind endotracheal intubation was performed through the air-Q™ with bougie assistance (Group B) or without assistance (Group Q) (Fig. 1). Patients ASA physical status >III, mouth opening <2 cm, increased risk of aspiration, those with poor lung compliance (patients with emphysema/COPD or interstitial lung disease), with lesions of the oropharynx or epiglottis and known or anticipated difficult tracheal intubation or face-mask ventilation were excluded from the study.

In the operating room, five-lead ECG, noninvasive blood pressure, pulse oximetry (S_PO_2), end-tidal CO_2 estimation ($P_{ET}CO_2$), anesthetic agent analyzer and neuromuscular monitoring (Infinity Kappa, Dräger, Lübeck, Germany) were attached to all patients: After 3 min of preoxygenation, general anesthesia was induced using 1–2 μg kg^{-1} fentanyl, 2 mg kg^{-1} propofol, and 0.6 mg kg^{-1} rocuronium followed by face mask-ventilation with a mixture of 100% oxygen and 2% sevoflurane. While the patient's head was maintained in a neutral position, air-Q™/ILA was inserted once no response was detected by train-of-four stimulation by a senior anesthesiology staff member. The size of air-Q™ was chosen according to the weight of the patient and the manufacturer's recommendation. If ventilation proved to be unsatisfactory, the "Klein maneuver" would be performed by applying a jaw thrust and an up-down movement of ILA. The tracheal tube was advanced 12–15 cm through air-Q™/ILA after adequate lubrication. Tracheal intubation was deemed successful once eliciting adequate chest expansion with a normal capnographic wave. This was followed by removal of the ILA over a stylet supplied with the device.

In group B, the operator gently inserted the bougie through air-Q™/ILA while looking at any bulges in the neck to judge the approximate positioning of the bougie. As soon as the bougie enters the trachea, a characteristic click was felt by the assistant and the operator felt the bougie entering in a hallow space. Another sign for intratracheal bougie insertion is the distal hold-up sign when the bougie reaches a small bronchus between 30 and 40 cm marks and cannot be pushed forwards much more. Air-Q™/ILA was then removed and a tracheal tube railroaded over the bougie. Conventional endotracheal tubes (Mallinckrodt Company, Juarez, Chihuahua, Mexico) size 7.0 mm for patients weighing ⩾50 kg and 6.0 mm for patients <50 kg were used. Three attempts were allowed for successful device insertion. After obtaining a normal capnographic wave, 3 more attempts were tried for intubation with or without bougie guidance. Lung ventilation through air-Q™ was permitted between intubation attempts. In case of failure of tracheal intubation through the device, direct laryngoscopy was performed.

The following parameters were measured:

- Mallampati score, mouth opening (cm).
- Thyromental distance (cm).
- Neck circumference (cm) is measured in the midway of the neck, between mid-cervical spine and mid-anterior neck, using non-stretchable plastic tape with the patient standing upright.

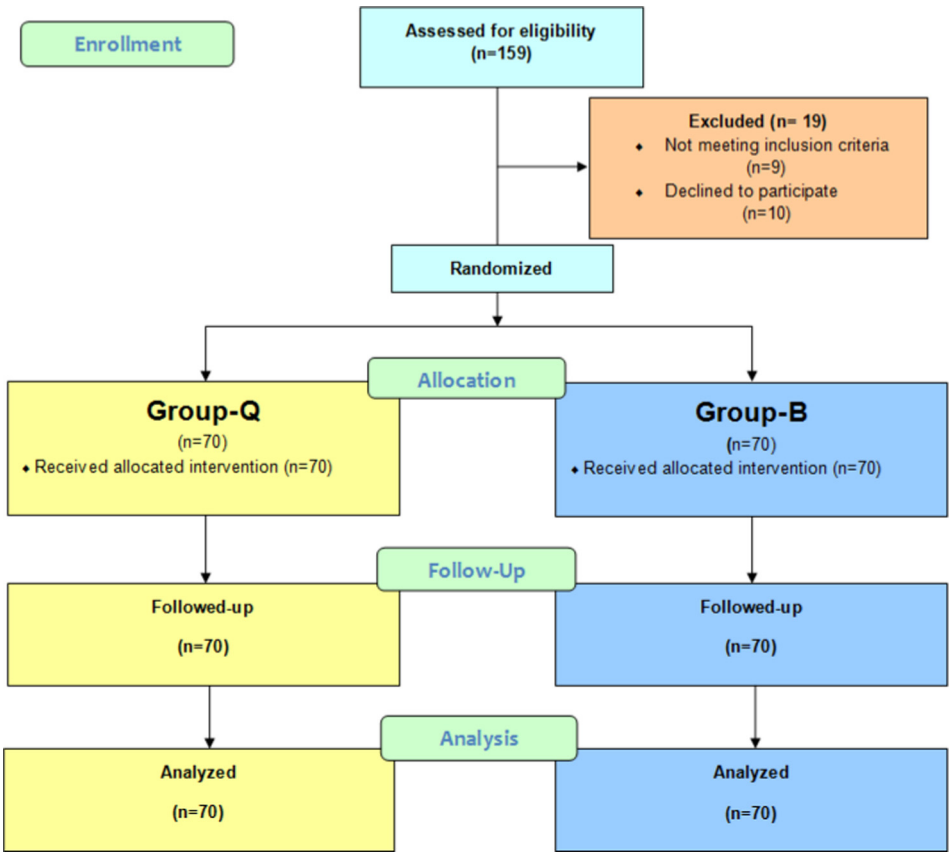

Figure 1. Flowchart of patients through this study.

It was measured just below the laryngeal prominence (Adam's apple). While taking this reading, the subject was asked to look straight ahead, with shoulders down.

- Air-Q™/ILA insertion: insertion time (seconds), ease of insertion (easy, difficult), number of attempts, 1st attempt success rate and grade of ventilation (adequate, possible or impossible).
- Tracheal intubation: number of attempts, intubation time (seconds), 1st attempt success rate and overall success rate.
- Air-Q insertion time: is the time from introducing the device in mouth till attachment to the circuit and capnographic trace is obtained.
- Bougie insertion time: is the time from removal of the breathing circuit from air-Q to the feeling of hold up sign.
- ETT insertion time: is the time from insertion of the tracheal tube in the device until confirmation by capnographic trace.
- Total intubation time in group Q (air-Q™/ILA insertion time plus intubation time) and the total intubation time in group B (air-Q™/ILA insertion time plus bougie insertion time plus bougie guided intubation time) were calculated.
- We also recorded the types of and number of adjusting maneuvers for each attempt, frequency of esophageal intubation, and any incidence of hypoxia ($S_pO_2 < 95\%$).
- Incidence of airway complications at insertion of air-Q™/ILA, gum elastic bougie and ETT as trauma to mouth, lips or tongue and visible or occult blood.
- Incidence of Airway Morbidity at 18–24 h postoperatively in both groups as sore throat, dysphagia, dysphonia and its degree (mild/moderate/severe).
- Hemodynamic data [heart rate (HR) and mean arterial blood pressure (MAP)] were also recorded at the following time intervals:
  - T0, baseline before induction
  - T1, before air-Q™ insertion
  - T2, after air-Q™ insertion
  - T3, before bougie insertion
  - T4, after bougie insertion
  - T5, before ETT insertion through the device
  - T6, after ETT intubation
  - T7, 1 min after intubation
  - T8, 5 min after intubation
  - T9, 10 min after intubation.

2.1. Statistical analysis

As no previous study researching bougie guided endotracheal intubation through air-Q™, we consider this research as a pilot study and 70 patients in each group are suitable. Results are expressed as mean ± standard deviation (SD) or number (%). Categorical data were compared using Chi square test. Variables in both groups were compared using either unpaired *t*-test or Mann Whitney test whenever it was appropriate. Intra-group comparison (within group comparison) between mean values of variables measured at baseline and different times was performed using repeated measures ANOVA followed by Bonferroni test if significant results were recorded. Data analysis was performed using Statistical Package for Social Sciences (SPSS) version 19 computer program. Significance was considered when P-value $\leqslant 0.05$.

3. Results

The two studied groups were comparable regarding demographic data (Table 1) and patients' airway characteristics (Table 2).

Air-Q™ insertion time, ease of insertion, number of attempts and grade of ventilation were comparable between both groups (Table 3).

Table 1
Demographic features of the two study groups.

	Group-Q (n = 70)	Group-B (n = 70)	*P*-value
Age (yrs.)	35.07 ± 10.50	33.86 ± 8.77	0.459
Gender			
Female (♀)	50 (71.4%)	45 (64.3%)	0.366
Male (♂)	20 (28.6%)	25 (35.7%)	
Weight (kg)	80.07 ± 11.20	78.43 ± 5.87	0.279
Height (cm)	165.50 ± 7.24	164.64 ± 6.45	0.461
ASA-physical status			
I	60 (85.7%)	60 (85.7%)	1.000
II	10 (14.3%)	10 (14.3%)	

Data were expressed as mean ± SD or number (%).
P > 0.05 = not significant.

Table 2
Comparison of the airway characteristics between the two study groups.

	Group-Q (n = 70)	Group-B (n = 70)	*P*-value
Mallampati score			
1	25 (35.7%)	20 (28.6%)	0.366
2	45 (64.3%)	50 (71.4%)	
Mouth opening (cm)	4.79 ± 1.15	4.64 ± 0.92	0. 420
Thyromental distance (cm)	7.00 ± 1.14	7.21 ± 0.95	0.229
Neck circumference (cm)	37.79 ± 3.53	38.79 ± 2.41	0.053

Data were expressed as mean ± SD or number (%).
P > 0.05 = not significant.

In Group B; bougie insertion time, ease of insertion and number of attempts are presented in Table 4.

Regarding ETT insertion, number of attempts, insertion time, number of accidental esophageal intubation and overall success rate were insignificantly different between both groups, while the total time for intubation was significantly longer in group-B in comparison with group-Q (Table 5).

Group-B showed significant (P = 0.001) higher incidence of the intubating adjusting maneuver (jaw thrust) when compared to group-Q. On the other hand, group-Q revealed higher occurrence (P = 0.001) of other adjusting maneuvers as putting a pillow, cricoid pressure and neck extension to facilitate blind intubation as compared with group-B (Table 6).

No patient in both groups had any incidence of hypoxia (i.e. $S_pO_2 < 95\%$), tongue or lip trauma during the course of intubation. Group-B showed significant higher incidence of complications such as mouth trauma, sore throat, dysphonia and dysphagia when compared to group-Q (Table 7).

Hemodynamically, no significant difference was detected between both groups regarding baseline (T-0). Then, a significant decrease was observed in mean blood pressure and heart rate in

Table 3
Comparison of the air-Q™ variables between the two study groups.

Air-Q	Group-Q (n = 70)	Group-B (n = 70)	*P*-value
Insertion time (sec)	21.21 ± 2.72	20.43 ± 2.94	0.103
Ease of insertion			
Easy	65 (92.9%)	65 (92.9%)	1.000
Difficult	5 (7.1%)	5 (7.1%)	
Number of attempts			
One	65 (92.9%)	65 (92.9%)	1.000
Two	5 (7.1%)	5 (7.1%)	
Grade of ventilation			
Adequate	65 (92.9%)	65 (92.9%)	
Possible	5 (7.1%)	5 (7.1%)	1.000

Data were expressed as mean ± SD or number (%).
P > 0.05 = not significant.

Table 4
Bougie variables in Group-B.

Bougie variable	Group-B (n = 70)
Insertion time (sec)	20.11 ± 10.17
Ease of insertion	
Easy	30 (42.9%)
Difficult	15 (21.4%)
Failed	25 (35.7%)
Number of attempts	
One	30 (42.9%)
Two	15 (21.4%)
Three	25 (35.7%)

Data were expressed as mean ± SD or number (%).

Table 5
Comparison of endotracheal intubation variables and overall intubation success rate between the two study groups.

	Group-Q (n = 70)	Group-B (n = 70)	*P*-value
ETT number of insertion attempts			
One	30 (42.9%)	30 (42.9%)	0.483
Two	10 (14.2%)	15 (21.4%)	
Three	30 (42.9%)	25 (35.7%)	
ETT insertion time (sec)	26.67 ± 10.09	25.78 ± 7.97	0.644
Number of accidental esophageal intubation			
No	30 (42.9%)	30 (42.9%)	0.877
One	10 (14.3%)	12 (17.1%)	
Two	5 (7.1%)	3 (4.3%)	
Three	25 (35.7%)	25 (35.7%)	
Total time to insert ETT (sec)	48.11 ± 9.96	65.89 ± 14.50	0.001**
Overall success rate	45 (64.3%)	45 (64.3%)	1.000

Data were expressed as mean ± SD or number (%).
P > 0.05 = not significant.
ETT = endotracheal tube.
** *P* < 0.01 = highly significant.

Table 6
Comparison of the needed adjusting maneuvers between the two study groups.

Adjusting maneuvers	Group-Q (n = 70)	Group-B (n = 70)	*P*-value
Nil	25 (35.7%)	25 (35.7%)	0.001**
Pillow	5 (7.1%)	0 (0.0%)	
Cricoid pressure	5 (7.1%)	0 (0.0%)	
Neck extension	5 (7.1%)	0 (0.0%)	
Jaw thrust	30 (42.9%)	45 (64.3%)	

Data were expressed as number (%).
** *P* < 0.01 = highly significant.

Table 7
Comparison of the complications between the two study groups.

	Group-Q (n = 70)	Group-B (n = 70)	*P*-value
Hypoxia	0 (0.0%)	0 (0.0%)	–
Mouth trauma	0 (0.0%)	5 (7.1%)	0.023*
Tongue trauma	0 (0.0%)	0 (0.0%)	–
Lips trauma	0 (0.0%)	0 (0.0%)	–
Blood on device	3 (4.3%)	4 (5.7%)	0.091
Sore throat			
Mild	5 (7.1%)	30 (42.9%)	0.001**
Moderate	5 (7.1%)	5 (7.1%)	
Dysphonia (*mild*)	0 (0.0%)	5 (7.1%)	0.023*
Dysphagia (*mild*)	5 (7.1%)	40 (57.1%)	0.001**

Data were expressed as number (%).
P > 0.05 = not significant.
* *P* < 0.05 = significant.
** *P* < 0.01 = highly significant.

both groups after induction of general anesthesia followed by a significant rise after intubation versus baseline readings being more prominent in the bougie group. Also, there was a significant increase in HR and MAP elicited after bougie placement in group-B (P < 0.01) (Figs. 2 and 3).

4. Discussion

Supraglottic airway devices are recommended in the scenario of airway management to maintain ventilation and serve as an aid for endotracheal intubation [5]. Among different supraglottic devices, air-Q™ (Cookgas, St. Louis, Missouri, USA) has the advantage of allowing ventilation and blind standard endotracheal intubation [6–8].

In the current study we assessed the outcome of sole blind air-Q™ tracheal intubation versus bougie-guided intubation regarding the success rate, insertion time, number of attempts, hemodynamic variables and complications.

Both groups revealed a comparable overall success rate (65%), number of attempts and insertion time for endotracheal intubation. The bougie assisted group showed longer total insertion time and hemodynamic derangement with more reported complications.

Karim and Swanson [2] showed superiority of LMA over air-Q™ in blind tracheal intubation with or without bougie assistance. In their study, success rate of first attempt of blind ETT insertion through air-Q™ was 46% which was increased by 31% after using bougie. The results of the current study were 43% with no difference between both groups. This discrepancy may be due to different insertion technique as they railroaded ETT over bougie within the air-Q™ while we inserted it after air-Q™ removal.

Garzón et al. [9], compared blind intubation through air-Q™ and laryngeal mask airway and found them comparable with higher success rate than our study concerning air-Q™ as they checked glottis status using a pediatric fiberoptic bronchoscope, prior to blind endotracheal tube insertion through the supraglottic device.

El-Ganzouri et al. [8], compared blind with fiberoptic intubation through the air-Q™ ILA. They found a significant difference in the success rate to be 70% in air-Q™ group versus 97.5% in the fiberoptic group ensuring the importance of airway visualization through the supraglottic device.

Malhotra et al. [10], also compared the success rate of intubation using two different endotracheal tubes through air-Q™ versus intubating LMA (ILMA) and reported an overall success rate of 91.6% in ILMA group versus 96.6% in Air-Q group. This may be due to their use of reinforced ETT.

Lee and Benumof [11], studied the efficacy of endotracheal intubation guided by fiberoptic through three different extraglottic devices: air-Q™, LMA Classic Excel™, and LMA Unique™ as intubation conduits with a standard endotracheal tube. They concluded that the air-Q™ provided the best laryngeal view and was the easiest usage.

El-Ganzouri et al. [8], recorded a significant longer total time to intubate in air-Q™ group (55.4 ± 19.2 sec) than fiberoptic group (47.3 ± 16.7sec). This relative short time adds more advantage to the visualized technique over the blind one.

Regarding the total time to intubate in this study it was 48.1 ± 9.9 sec which goes in accordance with the study of El-Ganzouri et al. [8] concerning the air-Q™ group while the bougie assisted group did not improve the overall intubation success rate. As regards the air-Q™ insertion time (21.2 ± 2.7sec) it was shorter than that reported by Badawi et al. [12], (27.6 ± 9.5 sec) probably due to extra lubrication and tongue depression during device introduction.

Badawi et al. [12], showed that head extension with cricoid pressure greatly increased the blind intubation success rate

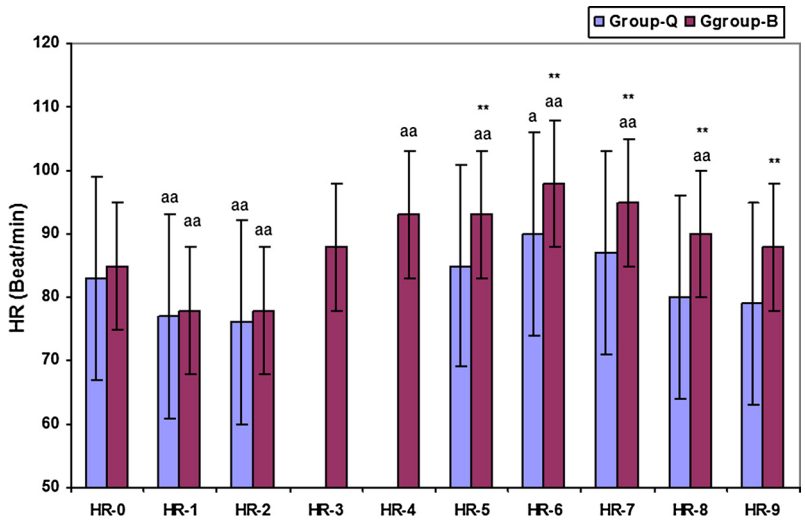

Figure 2. Heart rate changes throughout the study in the two study groups. Data are presented as mean ± SD. $^{**}P < 0.01$ relative to group Q. $^{a}P < 0.05$ & $^{aa}P < 0.01$ relative baseline (HR-0) within the same group.

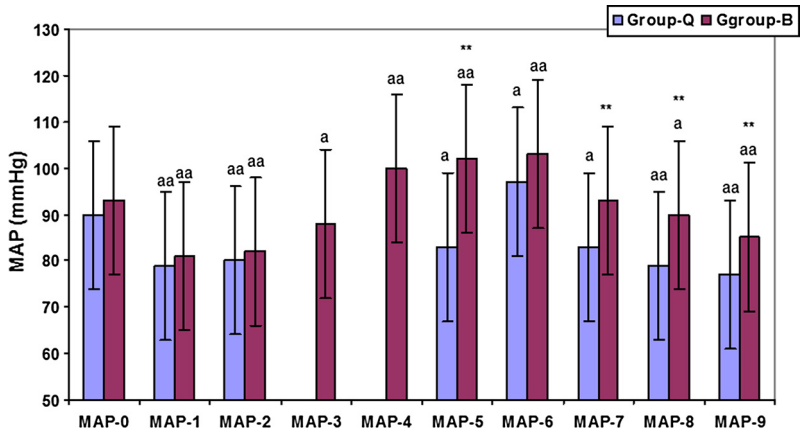

Figure 3. Mean arterial pressure changes throughout the study in the two study groups. Data are presented as mean ± SD. $^{**}P < 0.01$ relative to group Q, $^{a}P < 0.05$ & $^{aa}P < 0.01$ relative baseline (MAP-0) within the same group.

through air-Q™. In the present study adjusting maneuvers as cricoid pressure and head extension were performed and showed minimal effect while jaw thrust facilitated blind intubation in both groups.

The present study showed hemodynamic derangement in the bougie assisted group. On the contrary, Kuppusamy and Azhar [13] who compared classical digital placement of Proseal™ laryngeal mask airway (PLMA™) versus gum elastic bougie-guided technique showed comparable hemodynamic response in both groups.

Bashandy and Boules [14], compared hemodynamic stress responses to endotracheal intubation using direct laryngoscopy versus blind endotracheal intubation via air-Q™ and they showed less stress response and more hemodynamic stability in the Air-Q group.

Concerning complications, sore throat, dysphagia and dysphonia were significantly higher in the bougie group. This goes in accordance with Kuppusamy and Azhar [13] who reported higher incidence of dysphagia with bougie technique. Contrary to our results sore throat was more common with the digital not bougie-guided Proseal insertion technique. This may be due to different devices used in both studies.

Malhotra et al. [10], studied the complications of ETT insertion through air-Q™ and showed comparable results to our study regarding postoperative dysphagia, sore throat and blood on the device. Contrary to our results, they noted 6.6% incidence of dysphonia and bronchospasm. This difference may be attributed to different types of ETT. Meeting our results, no patients had laryngeal spasm or desaturation during the course of intubation.

5. Limitations of the study

Lack of assessment of the failed cases in both groups by a fiberoptic bronchoscope is a limitation in this study as it can assess whether the failure was due to a technical or an anatomical cause. It might have provided us a clue to improve the success rate of blind intubation through the device.

6. Conclusion

Bougie guided tracheal intubation through air-Q™ didn't improve the overall success rate with significant longer time, hemodynamic derangement and traumatic sequelae.

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