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Research article

# Comparison of Ambu® AuraGain™ laryngeal mask and air-Q™ intubating laryngeal airway for blind tracheal intubation in adults: A randomized controlled trial☆

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ABSTRACT

*Background:* This study has been designed to compare the performance of Ambu® AuraGain™ laryngeal mask with the air-Q™ as a conduit for blind tracheal intubation in adult patients.
*Methods:* In this prospective randomized controlled trial blind endotracheal intubation success rates were compared between Ambu® AuraGain™ and air-Q™ intubating laryngeal airway in 90 adult patients. Patients were randomized in two equal groups: Group Ambu® AuraGain™ (n = 45) and Group air-Q™ (n = 45).
*Results:* Time to insert the laryngeal airway was similar between Ambu® AuraGain™ and air-Q™ (median [IQR] 13[12–14] s versus 14[12–16] s) and in all cases laryngeal mask insertion was possible in first attempt. Intubation success rate at first attempt was significantly higher in air-Q™ group compared to in Ambu® AuraGain™ group (68.9% versus 35.6%; p = 0.002). Overall blind intubation success rate was significantly higher in air-Q™ group in comparison to Ambu® AuraGain™ (80% versus 53.3%; p = 0.007). Intubation time was significantly higher with Ambu® AuraGain™ (p < 0.0001; median difference 4.0 s, 95% CI 2.7, 5.3 s). Blind intubation was significantly easier in air-Q™ group compared to in Ambu® AuraGain™ (42.2% intubation was graded as easy in air-Q™ instead of 22.2% in Ambu® AuraGain™, p = 0.04). Comparison of fibreoptic bronchoscopic glottis view was similar between the two devices (p = 0.07). Reported complications were infrequent and similar between the two devices.
*Conclusion:* We conclude that air-Q™ laryngeal airway is superior to Ambu® AuraGain™ when used as a conduit for blind endotracheal intubation in adult patients.
*Trial registration:* Clinical Trial Registry of India (CTRI/2015/02/005553).


## 1. Introduction

A number of supraglottic airway devices (SADs) for airway rescue are reliable for first-time placement, high seal pressure, separation of gastrointestinal and respiratory tracts, and compatibility with fibre-optically guided tracheal intubation. Compared to first generation SADs, the second generation SADs provides an added safety margin from aspiration by incorporation of a gastric access port and they also have an increased seal pressure [1]. The Difficult Airway Society favors the use of second generation SADs as a conduit for endotracheal intubation following failed laryngoscopy intubation, if the clinical situation is stable and oxygenation can be maintained [2].

A number of supraglottic devices have been used with variable success rate, such as air-Q™ intubating laryngeal airway (Cookgas LLC, St. Louis, USA), LMA Fastrach (LMA North America, San Diego, CA, USA), Ambu® AuraGain™ (Ambu A/S, Ballerup, Denmark), i-gel™ (Intersurgical, Wokingham, Berkshire, UK), etc. in a different patient population for endotracheal intubation. Among these devices, a unique feature of air-Q™ as compared to other similar devices is the relatively large inner diameter (ID) and length of its airway tube. Reported success rate of blind intubation through air-Q™ is variable and ranges from 15 to 77% [3,4]. Ambu® AuraGain™ is a newly introduced phthalate free, single use anatomically curved laryngeal mask, which incorporates both integrating gastric access port and intubation capability [5]. The manufacturers have

☆ This study was conducted after approval of Institute Ethics Committee of Post Graduate Institute of Medical Education and Research (NK/1844/Res/195, dated 24.12.2014) and was prospectively registered with the Clinical Trial Registry of India (CTRI) with an assigned number of (CTRI/2015/02/005553).
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described this device to have integrated intubation capability with standard endotracheal tubes. To the best of our knowledge, there is currently no published data available on blind tracheal intubation through the Ambu® AuraGain™.

Therefore, this study has been designed to compare the performance of Ambu® AuraGain™ laryngeal mask with the air-Q™ as a conduit for blind tracheal intubation in adult patients.

## 2. Methods

This prospective randomized controlled trial was registered with Clinical Trial Registry of India (CTRI)(CTRI/2015/02/005553) after obtaining Institute Ethics Committee approval (NK/1844/Res/195, dated 24.12.2014) and was performed at Post Graduate Institute of Medical Education and Research, Chandigarh, India between March 2015 to July 2015. After informed consent from the participants, 90 adult patients between the age of 18–60 years and body weight 40–90 kgs of either sex and American Society of Anesthesiologists (ASA) physical status I or II who were scheduled to undergo elective surgery requiring endotracheal intubation following general anaesthesia have been included in this study. Patients with a known or suspected difficult airway or limited mouth opening less than 4 cm were excluded from this study.

Patients were randomized in two equal groups according to a computer generated random number sequence: Group Ambu® AuraGain™ (n = 45) and Group air-Q™ (n = 45). Randomization sequences were kept in opaque sealed envelops and they were only opened at the time of induction of general anaesthesia by a person not involved in the study and handed over to the anaesthesia team. Primary outcome of this study is the blind endotracheal intubation success rate via the studied SADs.

## 3. Anaesthesia technique

After securing intravenous access, patients were pre-oxygenated for 3 min. General anaesthesia was induced with intravenous fentanyl 2 mcg/kg and propofol 2–3 mg/kg and then neuromuscular monitoring was commenced. Intravenous vecuronium 0.1 mg/kg was administered after confirming adequate mask ventilation. The laryngeal mask was inserted as per randomized sequence after the train of four count became zero. For choosing the size of the airway device and the endotracheal tube we used manufacturers' recommendations. Both the devices were inserted as per manufacturers' recommendation by an experienced investigator (1st Author). We assessed the position of laryngeal mask by fibreoptic bronchoscope before inserting the tube and glottic view was noted and graded as follows (grade 4 – only vocal cords seen; grade 3 – vocal cords and epiglottis seen; grade 2 – only epiglottis seen; grade 1 – epiglottis not seen; and grade 0 - failed passage of fibreoptic scope or failed insertion of airway device) [6]. An appropriate size, cuffed polyvinyl chloride endotracheal tube was inserted through either of the device after lubrication with a water soluble lubricant by the same investigator. Intubation was confirmed "successful" by bilateral lung field auscultation and capnography waveform. If the supraglottic airway could not be placed in three attempts, or $SpO_2$ decreased to less than 90% any time during the procedure, direct laryngoscopy was done for intubation and cases were excluded from the study. If first attempt was unsuccessful, jaw lift and/or slight withdrawal of device was done to improve 2nd attempt blind intubation via both the devices. If blind intubation could not be done in two attempts through the laryngeal mask, then rescue fibreoptic bronchoscope guided intubation was attempted. If intubation could not be done with fibreoptic bronchoscope then direct laryngoscopy was done after removing the device. The following data were analysed from all patients: laryngeal airway insertion time (time in seconds from starting to insert the device to appearance of capnograph waveform in the monitor screen), ease of insertion of laryngeal airway (graded as easy, acceptable and impossible), number of attempts to insert airway (one, two or three; after third failed attempt, the case would be regarded as device failure and would be excluded from the study), assessment of laryngeal airway placement by fibreoptic bronchoscopic view, insertion time of endotracheal tube (time in seconds from starting to insert the tube to obtaining capnograph waveform), ease of intubation (graded as easy, moderate, difficult or impossible), number of attempts of blind intubation taken (maximum of two attempts was allowed, after that rescue fibreoptic guided intubation was attempted), adverse events such as bronchospasm, coughing, gagging, desaturation to $SPO_2$ 90% or less, grossly visible blood on the airway device and evidence of regurgitation of gastric fluid.

### 3.1. Statistical analysis

Erlachar et al. [7] reported blind intubation success rate through air-Q™ is 57%. We hypothesized that Ambu® AuraGain™ will increase the blind intubation success rate by another 30% to make it 87%. To reject the null hypothesis with power of 80% and a probability of alpha error of 0.05, 36 patients were required in each group. With a possibility of 20% drop out, 45 patients in each group were recruited in this study.

The success rate of blind endotracheal intubation in first attempt between the two groups was compared using chi-square test. Continuous variables were compared with independent sample *t*-test when data are normally distributed, otherwise Mann-Whitney *U* test was used. All parametric data were expressed as mean ± standard deviation and non-parametric data were expressed as median and inter-quartile range. All categorical data were expressed as percentage and proportions. A two-tailed p value < 0.05 was considered significant.

## 4. Results

Ninety patients were recruited in this study and data from all of them have been included in analysis (Fig. 1). Baseline demographic parameters (age, sex, body weight) of the patients were comparable between two groups (Table 1). Insertion time was also similar between Ambu® AuraGain™ and air-Q™ (median [IQR] 13[12–14] s versus 14[12–16] s) and in all cases insertion was possible in first attempt. However, intubation success rate at first attempt was significantly higher in air-Q™ group compared to Ambu® AuraGain™ group (68.9% versus 35.6%; p = 0.002, chi-square test). Overall blind intubation success rate was significantly higher in air-Q™ group in comparison to Ambu® AuraGain™ (80% versus 53.3%; p = 0.007, chi-square test; risk ratio 0.5, 95% CI 0.28, 0.89). In all patients of either group where a fibreoptic bronchoscope guided intubation was required, it was possible in single attempt. Intubation time was significantly longer with Ambu® AuraGain™ (p < 0.0001, Mann- Whitney *U* test, median difference 4.0 s, 95% CI 2.7, 5.3 s). Blind intubation was significantly easier in air-Q™ group compared to Ambu® AuraGain™ (42.2% intubation was graded as easy in air-Q™ as opposed to 22.2% in Ambu® AuraGain™, p = 0.04, chi-square test). Comparison of fibreoptic bronchoscopic glottis view was similar between two devices (p = 0.07, Fisher Exact test); however, a significant correlation was found between fibreoptic glottis view and intubation attempt (p < 0.0001, Spearman's rank correlation) (Table 2).

Complications from either device were infrequent; blood on the device was noted in four patients with air-Q™ while seven in

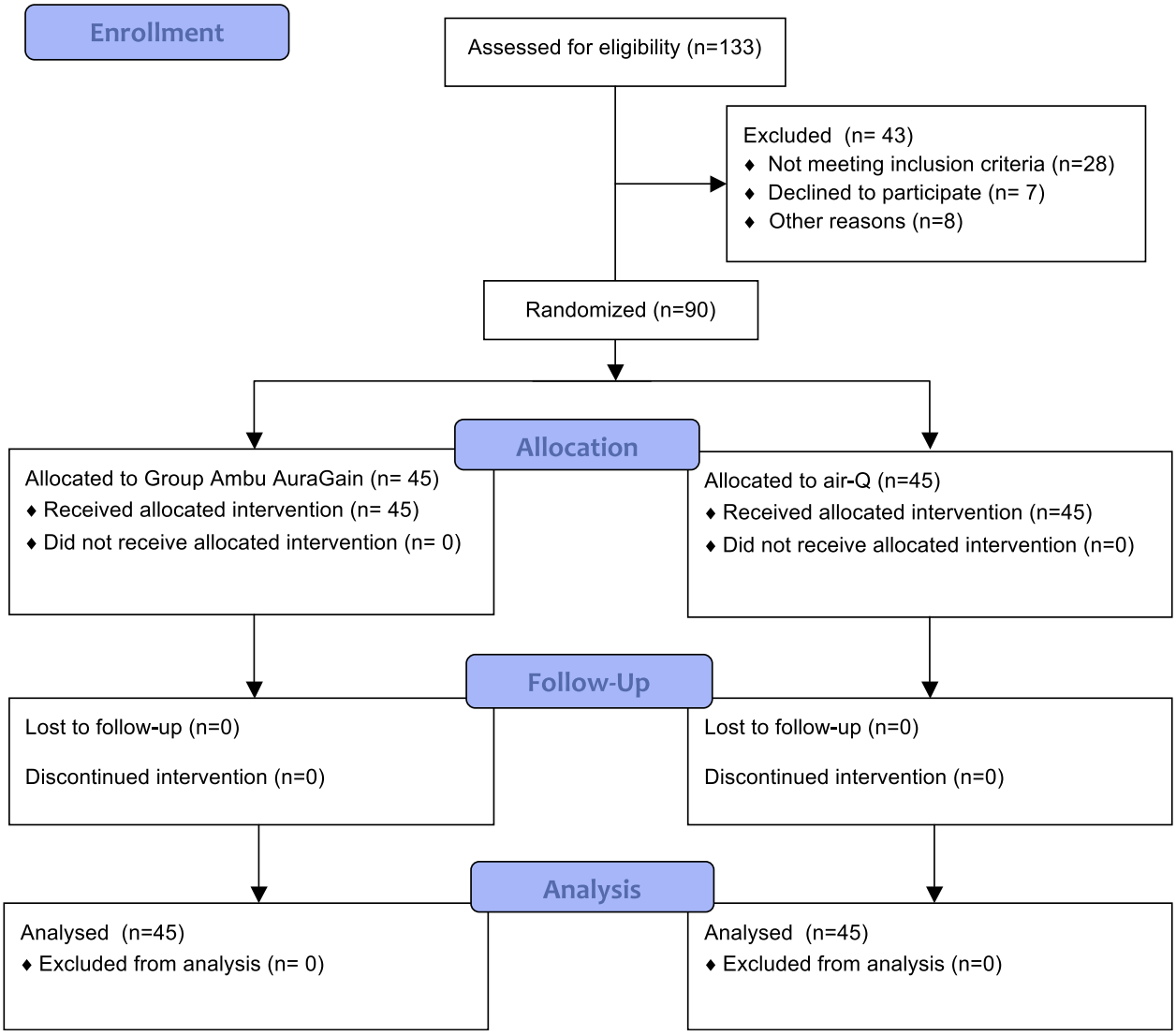


**Fig. 1.** CONSORT flow diagram.

**Table 1**
Comparison of baseline demographic characteristics in two groups; data expressed as mean ± SD, median (IQR) or proportions as applicable.

| | Group Ambu® AuraGain™ (n = 45) | Group air-Q™ (n = 45) | p value |
|---|---|---|---|
| Age (in years) | 33.2 ± 7.8 | 32.0 ± 7.3 | p = 0.45[¢] |
| Sex (Male/Female) | 21/24 | 25/20 | p = 0.40[$] |
| Body weight (in kgs) | 54.6 ± 12.4 | 56.8 ± 13.6 | p = 0.42[¢] |
| Size of laryngeal mask | #3 = 39 | #3.5 = 37 | |
| | #4 = 6 | #4.5 = 8 | |
| Size of ETT | # 6.5 mm ID in #3.0 | # 7.0 mm ID in #3.5 | |
| | # 7.0 mm ID in #4.0 | # 7.5 mm ID in #4.5 | |

SD = Standard deviations, IQR = inter quartile range, ETT = endotracheal tube, ETT: Endotracheal tube, SD: standard deviation, IQR: Inter-quartile range, ID: Inner Diameter.
[¢] Independent sample *t*-test.
[$] Chi-square test.

Ambu® AuraGain™ (p = 0.33, chi-square test). Sore throat was note in two patients in each group (p > 0.99, Fisher Exact test).

## 5. Discussion

The main finding of our study is that air-Q™ functions as a better conduit for blind intubation than Ambu® AuraGain™. Though we have not found any difference in fiberoptic bronchoscopic glottic view between the two devices, a less success rate of blind endotracheal intubation with Ambu® AuraGain™ was observed. A possible explanation is that the tip of the endotracheal tube as it exits the Ambu® AuraGain™ may deviate slightly off midline. Our result of 69% blind intubation success rate at first attempt through the air-Q™ is within the published success rates for adults (62–77%) [1–4].

**Table 2**
Comparative data for the Ambu® AuraGain™ and air-Q™ Data expressed as mean ± SD, median [IQR] or proportions as applicable.

| | Group Ambu® AuraGain™ (n = 45) | Group air-Q™ (n = 45) | p value |
|---|---|---|---|
| First insertion success rate of ETT | 16/45 | 31/45 | p = 0.002[$] |
| Overall blind intubation success rate | 24/45 | 36/45 | p = 0.007[$] |
| Time to insert laryngeal mask (s) | 13[12–14] | 14[12–16] | p = 0.10[¥] |
| Time to intubation (s) | 26[25–27] | 22[21–24] | p < 0.0001[¥] |
| Ease of laryngeal airway insertion (easy/acceptable/impossible) | 38/7/0 | 35/10/0 | p = 0.42[$] |
| Ease of blind intubation (easy/moderate/difficult/impossible) | 10/8/6/21 | 19/11/6/9 | p = 0.04[$] |
| Fibreoptic bronchoscopic view (4/3/2/1/0) | 14/14/11/6/0 | 24/14/4/3/0 | p = 0.07[€] |

ETT: Endotracheal tube, SD: standard deviation, IQR: Inter-quartile range.
[$] Chi-square test.
[¥] Mann-Whitney *U* test.
[€] Fisher exact test.

Karim & Swanson in 2011 reported that blind intubation success rate after two attempts through air-Q™ is 77% [4]. They reported a median intubation time of 35 s through air-Q™ while we have found a median time of 22 s for intubation. However, they did not report intubation success rate at first attempt. Malhotra et al. reported intubation success rate at first attempt with air-Q™ is around 69% and an overall success rate of over 96% [1]. However, reported mean intubation time with air-Q™ was 15 s while we have found a median intubation time of 22 s. A recent observational study by Attarde et al. found that blind intubation success rate at first attempt through air-Q™ is 56.7% and overall success rate is 76.7% [8]. No previous study reported blind intubation success rate through Ambu® AuraGain™.

## 6. Limitations

Our study has several limitations. Firstly, we have conducted this study in patients with normal airway only, hence our findings cannot be extrapolated to patients with difficult airways. Secondly, our findings will not be valid when primarily a fibreoptic bronchoscope guided intubation through an airway is attempted. Thirdly, there is no trial to date where Ambu® AuraGain™ has been used for blind intubation and a larger data is required before establishing its safety in anaesthesia practice. Lastly, outcome data were collected by an unblinded observer, hence the possibility of bias is there.

In conclusion, we have found that air-Q™ laryngeal airway is superior to Ambu® AuraGain™ when used as a conduit for blind endotracheal intubation in adult patients as intubation was easier, took less time and had a higher success rate when air-Q™ laryngeal airway was used.

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