Original Article

# A new second-generation supraglottic airway device (Ambu® AuraGain•) versus intubating laryngeal mask airway as conduits for blind intubation – A prospective, randomised trial

**Address for correspondence:**
Dr. GM Chethana,
Sri Guru Nilaya, Behind Nalanda School,
Raghavendranagar, Sapthagiri Extension, Tumkur, Karnakata, India.
E-mail: chetna.gm@gmail.com

*K Sudheesh, GM Chethana, H Chaithali, SS Nethra, D Devikarani, G Shwetha*
**Department of Anaesthesiology, Bangalore Medical College and Research Institute, Bangalore, Karnakata, India**

**Access this article online**

Website: www.ijaweb.org

DOI: 10.4103/ija.IJA_269_19

Quick response code

## ABSTRACT

**Background and Aims:** The Ambu® AuraGain• is a new single-use supraglottic airway device with gastric channel, designed to facilitate intubation. The study aimed to assess the success rates of proper placement and intubation using Ambu® AuraGain• compared with intubating laryngeal mask airway (ILMA). **Methods:** One hundred and twenty patients (18–60 years) were enrolled into this prospective, randomised, comparative study. After inducing general anaesthesia, appropriate size ILMA (group I)/Ambu® AuraGain• (group A) was placed as per the manufacturer's recommendations and correct placement was confirmed. Appropriate size endotracheal tube was passed through the device. The success rate of insertion and intubation, number of attempts, Cormack–Lehane grading before insertion and haemodynamics were recorded. Data were analysed using Mantel–Haenszel Chi-square test, Student's *t*-test and Fisher's exact test. **Results:** Demographic and airway parameters were uniformly distributed in both the groups. The success rate for insertion was 100% in both devices. The success rate for intubation was 96.6% (58/60) in group I and 36.6% in group A ($P < 0.001$). In group I, patients with mean thyromental distance >7.62 ± 0.75 cm had higher successful intubation compared with patients with mean thyromental distance <5.25 ± 0.35 cm ($P = 0.014$). Cormack–Lehane grading did not correlate with intubation attempts or success rate in group I ($P = 0.45$), whereas in group A the rate of successful blind intubation with Cormack–Lehane grade 1 was 50% (19/38). **Conclusion:** Both devices have 100% insertion success, though Ambu® AuraGain• has lower success rate for facilitating intubation compared with ILMA.

**Key words:** Ambu® AuraGain•, Cormack–Lehane grade, ILMA, intubation, supraglottic airway device

## INTRODUCTION

Supraglottic airway devices are gaining acceptance as airway management tools during general anaesthesia. Intubating laryngeal mask airway (ILMA) facilitates both blind and fibreoptic-guided intubation and has been used successfully in clinical practice for over 10 years in patients with both normal and difficult airway.[1] DAS guidelines 2015[2] and All India Difficult Airway Association 2016 guidelines[3] have included ILMA as a second-line airway device in case of unanticipated difficult intubation and failed intubation with conventional rigid laryngoscopy. The polyvinyl chloride conventional endotracheal tube (ETT) has been used as suitable alternative to reusable, relatively expensive Fastrach silicone



**How to cite this article:** Sudheesh K, Chethana GM, Chaithali H, Nethra SS, Devikarani D, Shwetha G. A new second-generation supraglottic airway device (Ambu® AuraGain•) versus intubating laryngeal mask airway as conduits for blind intubation – A prospective, randomised trial. Indian J Anaesth 2019;63:558-64.

wire–reinforced tube which is designed for tracheal intubation with ILMA.[4] ILMA is associated with lesser haemodynamic response and better learning curve when compared with direct laryngoscopy.[5]

The Ambu® AuraGain• is a new single-use, second-generation supraglottic airway device with integrated gastric access and intubation capability. The soft rounded curve of Ambu® AuraGain• follows the anatomy of human airway and ensures rapid placement. The thin and soft cuff delivers high seal pressures. The low friction inner surface of gastric channel facilitates easy placement of gastric tube and the integrated bite absorption area prevents airway occlusion. In addition, the wider airway tube may facilitate use of bigger ETT.

Ambu® AuraGain• has been compared with other disposable supraglottic airway devices such as LMA supreme and i-gel with comparable success rates.[6,7] However, there are no clinical studies comparing the clinical performance of Ambu® AuraGain• with a supraglottic airway device specially designed for blind intubation such as ILMA, with respect to its clinical performance as a conduit for blind intubation and safety. Hence, this study was designed to assess the efficacy and safety of Ambu® AuraGain• versus ILMA. The primary aim was to compare the efficacy of Ambu® AuraGain• and ILMA as a device for blind intubation, whereas the influence of airway parameters on insertion and intubation success were the secondary aims. The success rate of blind intubation with both devices was the primary outcome measure. The insertion success rates, influence of airway assessment parameters on success of insertion, and intubation for both devices were secondary outcome measures.

## METHODS

Following approval of Institutional Ethical Committee (BMCRI Ethical Committee no. BMCRI/PS/56/2017 – 18 dated 6.7.2017) and after obtaining informed written consent from the participating patients, 120 American Society of Anesthesiologists 1 and 2 adults, scheduled for surgery under general anaesthesia with tracheal intubation between August 2017 and December 2017, were enrolled in the study. The trial was registered under Clinical Trial Registry of India bearing number CTRI/2017/12/010817 and was conducted in accordance with the principles of Declaration of Helsinki. The patients were randomly allocated into two groups: Group I – ILMA ($n$ = 60) and Group A – Ambu® AuraGain• ($n$ = 60), based on randomisation sequence generated by a computer software (www.random.org) on the day of surgery. The random numbers were placed in a sealed opaque envelope to ensure allocation concealment, which was opened just before induction of anaesthesia.

Exclusion criteria included patient's refusal, mouth opening less than 2.5 cm, thyromental distance less than 4 cm, patients with poor lung compliance, restricted neck movements, oropharyngeal pathology, risk of regurgitation and body mass index >35 kg/m$^2$.

Preoperatively, an anaesthesiologist ignorant of the study to be undertaken assessed modified Mallampati classification (Class I–IV), mouth opening, upper lip bite test class, thyromental distance, neck circumference and Cormack–Lehane grade. Modified Mallampati (Samsoon and Young) classification was assessed while the patient was sitting with the mouth wide open and the tongue protruding without phonation.[8] Mouth opening was measured as the difference between the upper and lower incisors at the midline in centimeters using a scale. In upper lip bite test (ULBT), the capacity of biting the upper lip was categorised into three classes.[9]

Thyromental distance was measured from the thyroid cartilage to inside of the mentum with neck extended, using a tape.[10] Neck circumference was measured immediately above the thyroid cartilage.

Patients were premedicated with oral ranitidine 150 mg and oral alprazolam 0.25 mg on the night before surgery and were kept fasting after midnight. In the operating room, standard monitoring consisted of pulse oximeter, noninvasive blood pressure, end tidal carbon dioxide ($ETCO_2$) monitoring and electrocardiogram. Baseline values of all parameters were recorded. All patients were premedicated with glycopyrrolate 0.004 mg/kg intravenous (IV), midazolam 0.03 mg/kg IV, fentanyl 2 mc g/kg IV and preoxygenated with 100% $O_2$ for 3 min. Anaesthesia was induced with propofol 2 mg/kg IV. After confirming mask ventilation, vecuronium 0.1 mg/kg IV was administered for muscle relaxation. Entropy and neuromuscular blockade monitor (Avance GE S/5 workstation•) was used to monitor the depth of anaesthesia and neuromuscular blockade. Train of four (TOF) count was monitored every minute till intubation. Laryngoscopy was attempted when state entropy was between 50 and

60. Bolus dose of propofol was given if entropy values crossed 60 during attempts at insertion and intubation.

After 3 min, by direct laryngoscopy using a Macintosh blade without external manoeuvre, Cormack–Lehane grade was evaluated, by an experienced anaesthesiologist not involved in the study.[11] At the completion of laryngoscopy, face mask was applied again and three to five inflations of 100% $O_2$ were given. Then with the patient's head in neutral position, by standing at the head end of the patient, an appropriate size ILMA/Ambu® AuraGain• (selected depending on the body weight as per the manufacturer's recommendations) was inserted (as per randomisation) by one of the set of four anaesthesiologists who had experience of 25 successful insertions and intubations with both devices. Correct placement of the device was confirmed by easy bag ventilation, absence of audible air leak around the cuff at peak airway pressures upto 20 cm $H_2O$ and normal square wave capnogram. Manoeuvres such as up–down and Chandy's manoeuvre were allowed if placement was not successful. A maximum of three attempts were allowed and the number of attempts was recorded. Time for insertion of supraglottic airway device (SAD) was from the time of taking the device in hand till confirmation of proper placement of the device.

After successful placement of supraglottic airway device, blind intubation of the trachea was attempted with polyvinyl chloride ETTs with curvature facing anterior in the first attempt and tube was rotated 180° for the next two attempts. Proper placement of the ETT was confirmed by appearance of normal square wave capnogram and bilateral equal air entry. Time taken for blind intubation was recorded from the time of taking ETT in hand till confirmation of proper placement of the ETT. In case of failed insertion/intubation, direct laryngoscopy was the alternative approach. Between the SAD insertion and blind intubation attempts, patients were ventilated with 100% $O_2$, and additional boluses of propofol 20–40 mg IV were given to ensure adequate anaesthetic depth (state entropy values less than 60). Subsequent anaesthetic management was as per discretion of the attending anaesthesiologist.

Complications such as desaturation ($SpO_2$ <94%), regurgitation or aspiration, laryngospasm/bronchospasm, oropharyngeal or laryngeal trauma (blood staining of device/ETT) and hoarseness of voice were recorded.

We assumed that Ambu® AuraGain• would have overall success rate for intubation similar to that of ILMA. Sample size estimation was done based on observations of previous study where the overall success rate for blind intubation was 95% for ILMA.[4] Assuming a success rate of 90% for Ambu® AuraGain• and a noninferiority margin of 10% between the groups, a minimum of 53 patients would be required to achieve a power of 90%, at an alpha error of 0.05. We included 60 patients in each group to compensate for possible drop outs. Sample size was calculated using www.powerandsamplesize.com.

All the data were entered in Microsoft Excel sheet and tabulated. Categorical data are represented as numbers and percentages, whereas continuous data were assessed for normality using Kolmogorov–Smirnov test. Continuous data showing normal distribution are represented as mean ± standard deviation, and those with skewed distribution represented as median (interquartile range). Student's independent *t*-test was used for parametric data. Mann–Whitney *U*-test was used for nonparametric data. Pearson's Chi-square test was used for categorical variables. Chi-square test was used for association between airway parameters and insertion and intubation success rates. Logistic regression was done by forward conditional method to find association between airway parameters and insertion and intubation success with the devices. *P* value <0.05 was considered statistically significant. Data were analysed using IBM SPSS software version 22.

## RESULTS

A total of 126 patients were assessed for eligibility, out of which 120 patients were enrolled in the study and randomly allocated into group I and group A [Figure 1]. There were no drop outs. Demographic variables were similar between the two groups [Table 1]. The overall success rate of insertion of ILMA and Ambu® AuraGain• was 100%. There was no significant difference in manipulations required for insertion of airway device between the two groups [Table 2].

The overall success rate of blind tracheal intubation was higher in group I compared with group A which was clinically and statistically significant. First attempt success rate was 77.58% in group I and 54.54% in group A ($P = 0.04$). There was no significant difference in manipulations required for

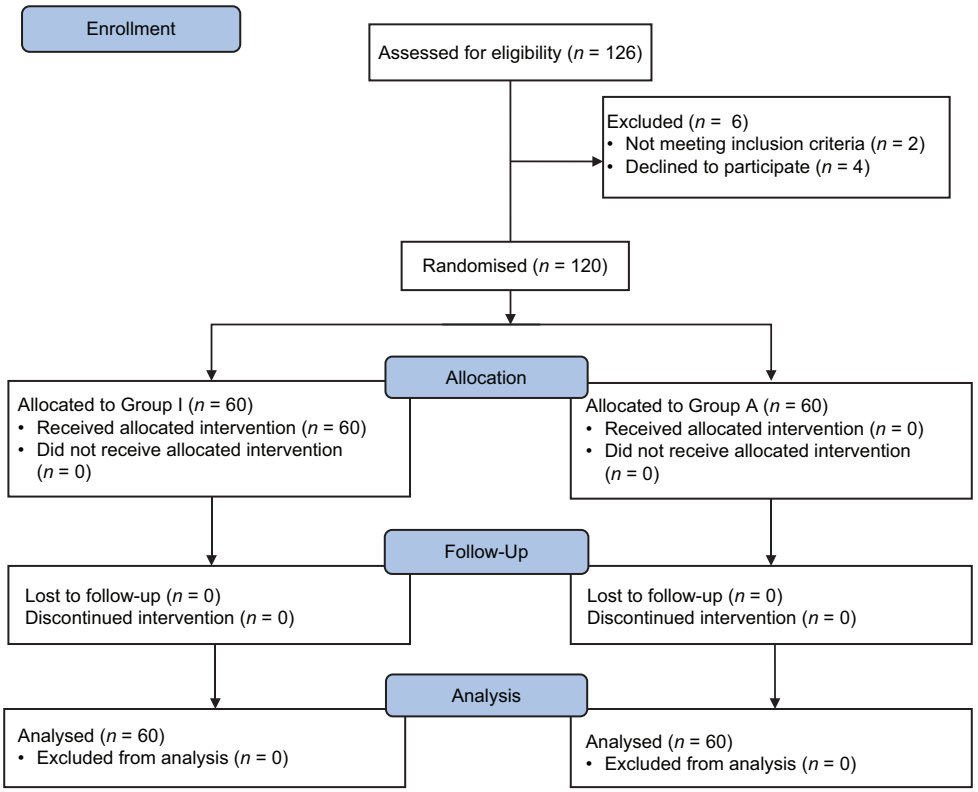


**Figure 1:** CONSORT diagram

blind intubation between the two groups. The average time taken for insertion of SAD and blind intubation in group I was 55.47 ± 5.27 s, and in group A it was 62.35 ± 6.4 s ($P = 0.52$).

In group I, the mean thyromental distance was 7.62 ± 0.75 cm in whom blind intubation was successful compared with a mean of 5.25 ± 0.35 cm in whom intubation was not successful ($P = 0.014$). In group A, the mean thyromental distance was 7.47 ± 0.36 cm in whom intubation was successful and the mean thyromental distance was 7.36 ± 1.03 cm in whom intubation failed ($P = 0.51$).

In group I, the rate of successful blind intubation with Cormack–Lehane grade 1 was 100% (44/44). There was no significant correlation between Cormack–Lehane grading and success of intubation. In group A, the rate of successful blind intubation showed association with Cormack–Lehane grading. Intubation was successful in 50% (19/38) of patients with Cormack–Lehane grade 1, whereas with grade 2 it was 15% (3/20) (odds ratio = 6.33, $P = 0.008$) [Table 3].

No correlation was found between mouth opening, neck circumference, Mallampatti grade and upper lip bite test class with the number of attempts for insertion of SAD and intubation success ($P > 0.05$).

There was no significant correlation between side effects such as blood stain of SAD, hoarseness of voice and sore throat with the number of attempts for insertion of SAD, manipulations of SAD, number of attempts for blind intubation and manipulation of ETT for intubation [Table 4].

**Table 1: Patient characteristics: age (years), height (cm), weight (kg), gender distribution, ASA grade**

| Demographic data | Group I (*n*=60) | Group A (*n*=60) |
|---|---|---|
| Age<br>Median (IQR) | 40 (24) | 35 (18) |
| Height<br>Median (IQR) | 158 (15) | 158 (10) |
| Weight<br>Mean±SD | 40.1±11.3 | 36.68±12.04 |
| Gender distribution (male:female) | 28:32 | 25:35 |
| ASA grade (1:2) | 41:19 | 42:18 |

IQR – Interquartile range; SD – Standard deviation; ASA – American Society of Anesthesiologists

**Table 2: Insertion of airway device**

| No. of attempts | Group I | Group A | *P* |
|---|---|---|---|
| 1 | 57 (95%) | 56 (93.3%) | 0.69 |
| 2 | 3 (5%) | 4 (6.7%) | |

| Table 3: Intubation success | | | |
|---|---|---|---|
| **Intubation success** | **Group I (*n*=60)** | **Group A (*n*=60)** | ***P*** |
| Yes | 58 (96.7%) | 22 (36.7%) | <0.001 |
| **No. of attempts for successful intubation** | | | |
| 1st attempt | 45 | 12 | 0.04 |
| 2nd attempt | 12 | 10 | |
| 3rd attempt | 1 | 0 | |
| **Correlation between Cormack-Lehane grade and success rate** | | | |
| | **Success** | **Failure** | **Success** | **Failure** |
| Grade 1 | 44 | 0 | 19 | 19 |
| Grade 2 | 13 | 1 | 3 | 17 |
| Grade 3 | 2 | 1 | 0 | 2 |
| *P* | 0.45 | | 0.005 | |

| Table 4: Side effects | | | |
|---|---|---|---|
| | **Group I (*n*=60)** | **Group A (*n*=60)** | ***P*** |
| Blood stain | 5 (8.3%) | 6 (10%) | 0.75 |
| Hoarseness | 10 (16.7%) | 8 (13.3%) | 0.609 |
| Sore throat | 14 (23.3%) | 11 (18.3%) | 0.5 |
| Nausea and vomiting | 1 (1.7%) | 2 (3.3%) | 0.47 |

The heart rate and blood pressure response to insertion and intubation was comparable between the two groups. No significant correlation was found between haemodynamic parameters with the number of attempts for insertion of SAD and intubation attempts [Figure 2a and b].

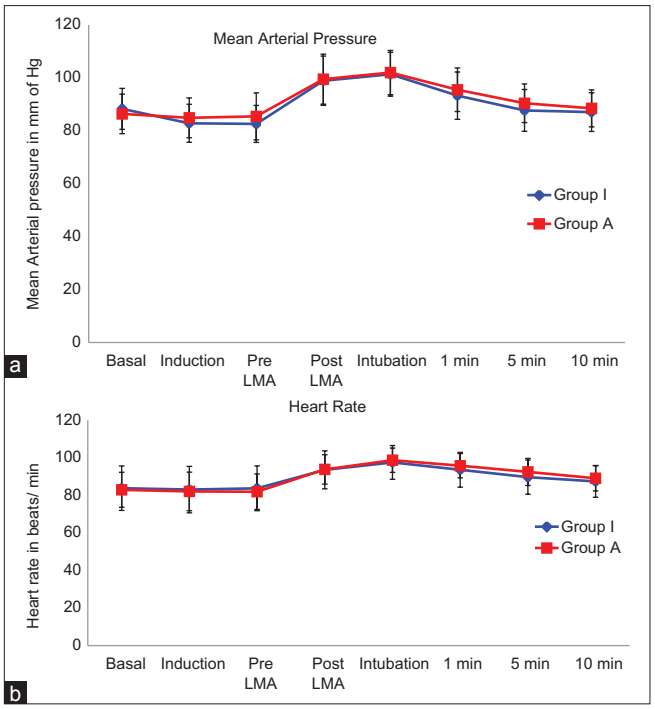


**Figure 2:** Haemodynamic parameters. Changes in (a) mean arterial pressure and (b) heart rate

## DISCUSSION

In this study, the overall success rate of insertion of ILMA and Ambu® AuraGain• was 100%. The overall success rate of blind endotracheal intubation was higher in ILMA compared with Ambu® AuraGain•. When ILMA was used, patients with thyromental distance greater than 7 cm had higher success rate of blind intubation compared with patients with thyromental distance less than 6 cm. No correlation was found between thyromental distance and intubation success when Ambu® AuraGain• was used. No correlation was found between other airway assessment parameters and success rate of blind intubation through ILMA and Ambu® AuraGain•.

Ambu® AuraGain• is a disposable second-generation supraglottic airway device, which has a gastric drain, in addition to facility for intubation. In contrast to ILMA, the Ambu® AuraGain• can mould to the anatomy of airway and the integral bite block provides more stability to the device while in place.

Previous studies have found a success rate of 96%–100% for insertion and successful ventilation with Ambu® AuraGain•.[6,12] It was also found to provide adequate sealing pressure and effective ventilation with lower calculated pharyngeal mucosal pressure compared with ProSeal LMA.[13] In a cadaveric study, the success rate for Ambu® AuraGain• insertion was 100% and, it was 86% for fibreoptic-guided intubation.[6] In another prospective observational study assessing the ease of Ambu® AuraGain• placement in paralysed patients, its position, alignment to the glottis and its utility as a conduit for fibreoptic-guided intubation, the first attempt intubation success was 88% and the overall failure rate was 9%.[14]

However, when Ambu® AuraGain• was used as a conduit for blind endotracheal intubation, it was found that Ambu® AuraGain• was inferior to Air-Q (53.3% vs 80%).[15] and LMA Fastrach (17% vs 70%).[16] Our observations are concurrent with the above, and the difference between cadaveric observations and these studies may be attributed to real-time difference in airway anatomy in living patients. The inferior success rate of blind intubation with Ambu® AuraGain• may be due to its malleability following exposure to body temperature, and minor distortions in placement while passing the ETT, when compared with a more rigid ILMA.

Overall success rates with intubation using ILMA and the time taken for intubation in this study were

comparable to that of the observations of previous studies.[17,18] Manipulations of ILMA and change in orientation of ETT may be required to enhance success rates. Brain *et al*.[19] observed that tracheal intubation with the ILMA required fewer adjusting manoeuvers in patients with a predicted or known difficult airway. The authors suggested that the structure of ILMA favours blind intubation in those cases with anteriorly placed larynx because of its structure. In addition, different angle of emergence of the tracheal tube with conventional or reverse orientation may produce a difference in success rate of tracheal intubation. The emergence angle was 47° with normal tube orientation and 20° with reverse tube orientation.[20] A previous study assessing the effect of tracheal tube orientation on intubation success with an ILMA found higher first attempt success with reverse orientation, although the overall success was comparable.[21] We used both manipulations of ILMA and change in ETT orientation to improve success in both groups. However, neither manipulations nor tracheal tube orientation influenced the success rate with either devices in this study. The depth of anaesthesia and degree of muscle relaxation can influence the success rate of intubation, and hence entropy monitoring was done to ensure adequate depth of anaesthesia. Although TOF was used to monitor adequacy of muscle relaxation, we fixed a time gap of 3 min from the time of induction to ensure uniformity in time of insertion and intubation.

In a retrospective study, it was found that in 111 patients with a Cormack–Lehane grade 4, intubation with ILMA was achieved in 92% of patients, and in 63.6% intubation was successful at first attempt.[21] An another randomised controlled trial found no correlation between easiness of ILMA use to mouth opening, thyromental distance, Mallampati classification or Cormack–Lehane grade.[22] The results of our study are in agreement with the above.

Although there was a positive correlation between Cormack–Lehane grade 1 and success rates of intubation with Ambu® AuraGain•, the results may not adequately powered to make the observations applicable.

The limitation of our study was that we did not assess the proper placement of SAD and the glottic view using fibreoptic bronchoscope, nor we attempted fibreoptic-guided intubation due to infrastructural issues, which may have added to the possible reasons for failure of intubations. Future studies involving larger sample may help in assessing whether airway parameters and Cormack–Lehane grades influence the success rates of blind intubation with Ambu® AuraGain•.

## CONCLUSION

Ambu® AuraGain• is comparable to intubating LMA for providing adequate ventilation, but is associated with lower success rate of blind intubation compared with ILMA.

### Financial support and sponsorship
Nil.

### Conflicts of interest
There are no conflicts of interest.

## REFERENCES

1. Joo HS, Rose KD. The intubating laryngeal mask airway with and without fiberoptic guidance. Anesth Analg 1999;88:662-6.
2. Frerk C, Mitchell VS, McNarry AF, Mendonca C, Bhagrath R, Patel A, *et al*. Difficult Airway Society 2015 guidelines for management of unanticipated difficult intubation in adults. Br J Anaesth 2015;115:827-48.
3. Myatra S, Shah A, Kundra P, Patwa A. All India Difficult airway Association 2016 guidelines for the management of unanticipated difficult tracheal intubation in adults. Indian J Anaesth 2016;60:885-98.
4. Kundra P, Sujatha N, Ravishankar M. Conventional tracheal tubes for intubation through intubating laryngeal mask airway. Anaesth Analg 2005;100:284-8.
5. Chandy V, Mena G, Ferson DZ. Laryngeal mask airway. In Hagberg CA, editor. Benumof and Hagberg's Airway Management. 3rd ed. Saunders/Elsevier; 2013. p. 456.
6. Jagannathan N, Sohn L, Sawardekar A. A randomised comparison of the Ambu® AuraGain™ and the LMA® supreme in infants and children. Anaesthesia 2015:13330.
7. Lopez.M.Ana, Xavier SB, Richard V. Cross-over assessment of Ambu® AuraGain™, LMA supreme newcuff and intersurgical i-gel in fresh cadavers. Open J Anesth 2014;4:332-9.
8. Mallampati SR, Gatt SP, Gugino LG, Desai SP, Waraksa B, Freiberger D, *et al*. A clinical sign to predict difficult tracheal intubation: A prospective study. Can Anaesth Soc J 1985;32:429-34.
9. Aiello G, Metcalf I. Anaesthetic implications of temporomandibular joint disease. Can J Anaesth 1992;39:610-6.
10. Lewis M, Keramati S, Benumof JL, Berry CC. What is the best way to determine oropharyngeal classification and mandibular space length to predict difficult laryngoscopy? Anesthesiology 1994;81:69-75.
11. Cook TM. A new practical classification of laryngeal view. Anaesthesia 2000;55:274-9.
12. Ueshima H, Yoshida A, Otaki A. Use of supraglottic device Ambu® AuraGain™ in clinical setting. J Clin Anaesth 2016;31:263-4.
13. Singh K, Gurha P. Comparative evaluation of Ambu® AuraGain™ with Proseal laryngeal mask airway in patients undergoing laparoscopic cholecystectomy. Indian J Anaesth 2017;61:469-74.
14. Parikh DA, Jain RA, Lele SS, Tendolkar BA. A cohort evaluation of clinical use and performance characteristics of Ambu®

AuraGain™: A prospective observational study. Indian J Anaesth 2017;6:636-42.
15. Sethi S, Maitra S, Saini V. Comparison of Ambu® AuraGain™ laryngeal mask and air-Q intubating laryngeal airway for blind tracheal intubation in adults: A randomized controlled trial. Egypt J Anaesth 2017;33:137-40.
16. Lopez TC, Sastre J, Garzon J. Blind tracheal intubation through 2 supraglottic devices: The Ambu® AuraGain™ vs the LMA Fastrach. Emergencias 2016;28:83-8.
17. Bharti N, Naik AK. Ease of insertion and haemodynamic effects following tracheal intubation using intubating laryngeal mask airway: A comparison with conventional Macintosh laryngoscope. Indian J Anaesth 2006;50:205-8.
18. Kapoor S, Jethava D, Gupta P, Jethava D, Kumar A. Comparison of supraglottic devices i-gel and LMA Fastrach as conduit for endotracheal intubation. Indian J Anaesth 2014;58:397-402.
19. Brain AIJ, Verghese C, Addy AV, Kapila A, Brimacombe J. The intubating laryngeal mask airway. II. A preliminary clinical report of a new means of intubating the trachea. Br J Anaesth 1997;79:704-9.
20. Ye L, Liu J, Wong DT, Zhu T. Effects of tracheal tube orientation on the success of intubation through an intubating laryngeal mask airway: Study in Mallampatti class 3 or 4 patients. Br J Anaesth 2009;102:269-72.
21. Ferson DZ, Rosenblatt WH, Johansen MJ, Osborn I, Ovassapian A. Use of the intubating LMA-Fastrach in 254 patients with difficult-to-manage airways. Anesthesiology 2001;95:1175-81.
22. Staikou C, Tsaroucha A, Paraskeva A, Fassoulaki A. Association between factors predicting and assessing the airway and use of intubating laryngeal mask airway. Middle East J Anaesth 2010;20:553-8.