

Impact of visually guided versus blind techniques of insertion on the incidence of malposition of Ambu® AuraGain™ in paediatric patients undergoing day care surgeries: A prospective, randomised trial

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ABSTRACT

Background and Aims: In adults, video laryngoscopy is recommended for supraglottic airway device (SGAD) placement as it results in better device position and higher oropharyngeal leak pressures. In children, there is a paucity of studies evaluating the impact of visually guided techniques on SGAD placement. Aim of the study was to evaluate the usefulness of visual-guided techniques of SGAD placement in children. **Methods:** Totally, 75 children, scheduled for elective surgery, were randomly allocated into three groups, that is, standard (S), direct laryngoscopy (DL), and video laryngoscopy (VL). Ambu AuraGain was placed blindly in group S, and under visual guidance with video laryngoscopy and direct laryngoscopy in groups VL and DL, respectively. Ambu AuraGain position was determined by flexible videoendoscope. First attempt success rate, time for successful insertion, oropharyngeal leak and any complications were studied. **Results:** Incidence of malposition was not significantly different in group S (44%), DL (48%), and VL (64%); $P = 0.32$. The first attempt success rate was 100% in DL and 92% each in S and VL. Time to insert (seconds) was significantly higher in VL (37.9 ± 21.6), compared to S (18.4 ± 7.9) and DL (27.4 ± 14.5); $P < 0.001$. Incidence of oropharyngeal leak, impact on ventilation, and complications were similar in all three groups. **Conclusion:** In this study, there was no advantage of visually guided techniques for Ambu AuraGain placement in children.

Key words: Airway devices, Ambu® AuraGain, direct laryngoscope, fiberoptic bronchoscope, paediatric, supraglottic devices, video-laryngoscope

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INTRODUCTION

Supraglottic airway devices (SGADs) are routinely used in children undergoing surgeries due to their ease of insertion and minimal invasiveness.^[1,2] Improved designs with gastric drainage port and integral bite block, have increased the safety of these devices in children.^[3] The Ambu® AuraGain™ (Ambu A/S, Ballerup, Denmark) is a novel supraglottic airway device (SGAD) with a preformed soft rounded curve to allow smooth insertion. Clinical performance of Ambu AuraGain (AAG) is similar to that of laryngeal mask airway (LMA®) Supreme but requires fewer airway manoeuvres and is thus increasingly used in children.^[3,4] However, concerns remain with the functional performance of AAG, which has lower

oropharyngeal leak pressure (OLP) compared to other SGADs, which may increase the risk of aspiration.^[5,6] Visually guided techniques of SGAD insertion improves both device placement as well as OLPs in adults.^[7] There are very few studies in children to support the use of visually guided placement of SGAD.^[5] Thus, it

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would be useful to evaluate whether visually guided techniques are an appropriate preventive strategy for malposition of the AAG in children.

METHODS

This prospective, randomised, study was conducted following approval by the Institutional Ethics Committee and was registered with the Clinical Trials Registry of India (CTRI/2019/02/017644). 75 American Society of Anesthesiologists (ASA) I and II children, of either sex, 6 months to 12 years, undergoing elective surgery under general anaesthesia in supine position were enrolled. Children with oropharyngeal pathology; upper respiratory tract infections; anticipated difficult airway; risk of aspiration and cardiorespiratory illness were excluded.

Patients were randomly allocated to 3 different groups using a computer-generated randomisation sequence. Allocation concealment was done using opaque sealed envelopes which were opened on the day of surgery once the children were brought into the operating room.

Group S: - Standard technique group; AAG was inserted by blind technique, ($n = 25$). Group DL: -Direct laryngoscopy group; AAG was inserted under vision using direct laryngoscopy, ($n = 25$). Group VL: -Video laryngoscopy group; AAG was inserted under vision using video laryngoscope ($n = 25$). AAG size 1.5, 2, 2.5, and 3 were used for children weighing 5–10 kg, 10–20 kg, 20–30 kg and 30–50 kg, respectively, as per manufacturer's recommendations.

Children below six years received oral trichlophos syrup 50 mg/kg, and children above six years received oral midazolam 0.5 mg/kg (maximum 10 mg) 60 minutes before anaesthesia induction. ASA standard monitoring consisted of ECG, peripheral oxygen saturation (SpO_2), and non-invasive blood pressure measurement. Anaesthesia was induced with propofol 3 mg/kg and fentanyl 1–2 μ g/kg. In children without an i.v. access, inhalation induction was performed with sevoflurane and i.v. access was secured. Neuromuscular blockade was not used. Besides, bi-spectral index (BIS) monitoring was used before device insertion to monitor the depth of anaesthesia; and AAG was inserted at BIS of 40–50 to ensure an adequate depth of anaesthesia that would prevent airway reflexes during insertion. End-tidal capnography ($ETCO_2$) monitoring was commenced after the insertion of the AAG.

Anaesthesiologists with >5 years of experience and who have performed >30 AAG insertions, performed device insertion in all patients. Following insertion, the cuff was inflated with 7 ml, 10 ml, 14 ml, and 20 ml of air for AAG sizes 1.5, 2, 2.5 and 3, respectively. Anaesthesia was maintained with isoflurane in a mixture of air and oxygen (50:50) and titrated to BIS of 45–60. Mechanical ventilation was commenced with tidal volume of 10 ml/kg and the respiratory rate was adjusted to maintain $ETCO_2$ of 32–38 mm Hg. An appropriately sized well lubricated gastric tube was inserted through the gastric drainage port by the same anaesthesiologist.

In group S, AAG was inserted blindly by keeping the shaft of the device approximately parallel to the chest of the patient and guiding the cuff along the hard palate until a definite resistance was felt, after opening the mouth with head in sniffing position. In group DL, the AAG was inserted under vision using a Macintosh curved laryngoscope blade of appropriate size while in group VL, McGrath™ video laryngoscope (McGrath™, Medtronic, US) of proper sizes were used. In both DL and VL groups, with head in sniffing position, laryngoscope blade was placed in vallecula and both the tongue and epiglottis were lifted anteriorly. AAG was then inserted until satisfactory placement in the hypopharynx.

After inserting the AAG, with head in the neutral position, the following parameters were observed: adequate chest rise along with $ETCO_2$ trace and auscultation of bilateral air-entry. The time taken for a successful insertion was defined as the time in seconds taken from holding the AAG in hand to appearance of first stable $ETCO_2$ square waveform.

Ease of placement was graded on a scale of 1-4, with 1 -no resistance, 2-moderate resistance, 3-high resistance and 4-inability to place the device.^[4,5] Features of airway obstruction or no capnography tracing in 3 tidal breaths was declared as a failed attempt. More than two failed attempts at securing the airway with AAG resulted in conversion to tracheal intubation, and the children were excluded from the study.

After stable ventilation was achieved, anaesthesia ventilator was set on manual mode with a fresh gas flow of 3 litres/minute. Simultaneously, the adjustable pressure limiting (APL) valve was kept at 20 cm of H_2O to check for audible leaks. Adequate

depth of anaesthesia was maintained to prevent coughing, bucking and spontaneous ventilation during assessment of oropharyngeal leak. After the determination of oropharyngeal leak, an anaesthesiologist blinded to group randomisation carried out the flexible videoendoscopy evaluation with the head in the neutral position. A neonatal scope (Karl Storz, Tuttlingen, Germany) was introduced into the ventilating tube and placed 0.5 cm proximal to the distal end.

Park score: (Grade 1, larynx only seen; Grade 2, larynx and epiglottis posterior surface seen; Grade 3, larynx and epiglottis tip or anterior surface seen – visual obstruction of epiglottis to larynx: <50%; Grade 4, epiglottis down-folded, and its anterior surface seen – visual obstruction of epiglottis to larynx: >50%; Grade 5, epiglottis downfolded and larynx not visualised) was used for assessing flexible videoendoscopy grading.^[8] Only Grade 1 was accepted as correct position, and presence of epiglottis in the field of vision was considered as malposition.

Ventilation was independently assessed with a 3-point score^[9]; 1, optimal ventilation with bilateral chest rise, good air entry and adequate capnography trace; 2, ventilation possible but signs of partial obstruction present (high peak airway pressures, leak with ventilation and/or ramp or triangular capnography trace); 3, no ventilation possible. Only score 1 was accepted, and for a score of 2 or 3, the AAG was removed and re-inserted.

At the end of the surgery AAG was removed when the children were fully awake and checked for bloodstains. The children were observed for a further two hours in the post-anaesthesia care unit for any complications like desaturation, laryngospasm, hoarseness of voice and throat pain before being discharged to the wards.

Fibreoptic studies in children,^[10] and adults,^[11] reveal a malposition incidence of 60% with blind insertions of SGADs. We considered a reduction of 40% in the incidence of malposition in the visually guided groups to be clinically significant. Accordingly, a sample size of 23 was required per group. To account for dropouts, 25 patients were enrolled in each group. Significance was determined at $P < 0.05$ (2-tailed) with a power of 80%. The incidence of malposition across the groups was determined by Chi-Square test. Continuous data were evaluated with one-way analysis of variance (ANOVA) with Bonferroni correction for multiple

comparisons between the groups. Data were analysed with R (version 3.5).

RESULTS

A total of 78 children were screened and 75 eligible children were recruited in the study for over six months, 3 children were excluded for having upper respiratory tract infection. The eligibility, recruitment and analysis are shown in the CONSORT diagram [Figure 1]. There were no significant differences between the groups with regards to age or duration of surgery [Table 1]. The incidence of malposition was similar in the three groups, 44% in group S, 48% in group DL and 64% in group VL ($P = 0.32$) [Table 2]. Success at first attempt for AAG insertion was 100% in the DL group and 92% in groups S and VL. There was no difference in the ease of placement of AAG [Table 2]. Most children did not have an audible leak at 20 cm H₂O [Table 2]. A significantly longer time was taken for device insertion in the visually guided groups as compared to the blind insertion group [Table 2].

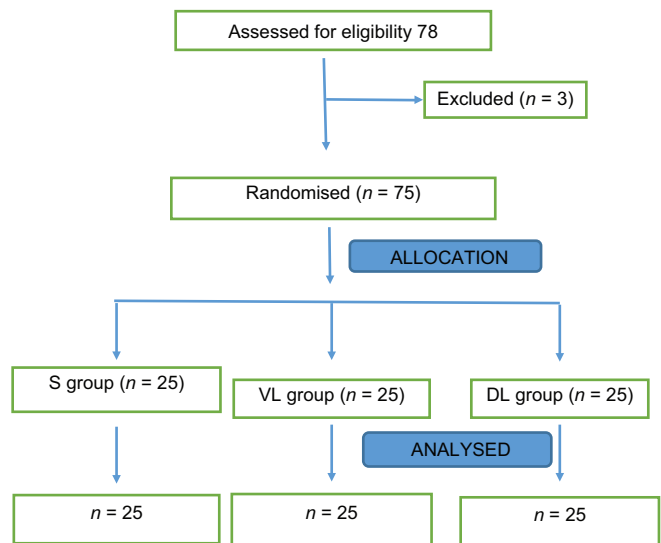


Figure 1: Consort diagram

Table 1: Demographic data			
	Group S (n=25)	Group DL (n=25)	Group VL (n=25)
Age (years)	5.1±3.3	5.5±3.6	6.2±2.8
Weight (kg)	18.9±9	18.3±8.3	20.6±7.6
Sex (M/F)	18/7	22/3	20/5
Duration of surgery (in min)	59±35	72±48	76±41
Ambu AuraGain size	1.5 (5) 2 (11) 2.5 (7) 3 (2)	1.5 (4) 2 (12) 2.5 (5) 3 (4)	1.5 (1) 2 (13) 2.5 (8) 3 (3)

Data are expressed as Mean (Standard deviation) or number of patients, Ambu AuraGain size in numbers

Table 2: Ambu® AuraGain™ insertion parameters

Parameters	Group S (n=25)	Group DL (n=25)	Group VL (n=25)	P
Incidence of malposition n (%) (epiglottis visible in the field of vision of bronchoscope)	11 (44%)	12 (48%)	16 (64%)	0.32
Success at first attempt n (%)	23 (92%)	25 (100%)	23 (92%)	0.34
Time for insertion in first attempt (seconds)	18.4±7.9	27.4±14.5	37.9±21.6	<0.001
Ease of device placement (1/2/3/4) (n)	20/3/2/0	15/10/0/0	17/6/2/0	0.151
Number of patients with audible leak in the mouth at 20 cm H ₂ O n (%)	3 (12%)	5 (20%)	5 (20%)	0.68
Blood staining on removal of Aura Gain (n)	0	2	1	0.551
Ventilation score 1/2/3 (n)	25/0/0	25/0/0	25/0/0	-

Data expressed as number of patients (%) or mean (standard deviation). Refer text for ventilation score and ease of placement

There was no impact of the AAG position on the quality of ventilation in any of the three groups as evidenced by the fact that no patient had a grade 2 or 3 score including the patients with malposition [Table 2]. No airway manoeuvres were required during the conduct of surgery for leaks or suboptimal ventilation in any patient. None of the patients had desaturation, laryngospasm, hoarseness of voice and complained of throat pain. Three patients had blood stains on AAG removal: 2 in the DL group and 1 in the VL group [Table 2]. However, this did not affect the recovery and discharge of patients from the postoperative anaesthesia care area. A *post-hoc* sub - group analysis of patients below 6 yr. showed similar results compared to per protocol analysis result. The incidence of malposition was 39%, 57%, and 27% in Group S, DL, and VL, respectively ($P= 0.245$) in this subset.

DISCUSSION

The AAG is a new 2nd generation SGAD which has got good design features with a preformed curvature, it is softer and less rigid allowing easier insertion, provides conduit for tracheal intubation and has a gastric drainage port for decompression of the stomach for prevention of aspiration.^[4,5] AAG is new in the paediatric SGAD family, and previous trials have not evaluated all sizes.^[4] Visually guided techniques of SGAD insertion have been reported to improve both device placement as well as OLP in adults. But similar studies are lacking in children and the position of the SGAD is mostly determined by bronchoscopy after insertion.^[12] However, the use of a bronchoscope only allows evaluation of the device position and cannot correct malposition.^[13] Furthermore, a recent network meta-analysis evaluating the clinical properties of various types of SGAD in children identified only one trial involving the AAG.^[14] Subsequently, there have been a few more trials evaluating the performance of this device.^[5,6,15,16] But almost all trials

involving the AAG or other SGADs have focussed on OLPs or the performance of the devices as intubating conduits.^[4-6,15,16] In adults, although strong recommendations exist for placing SGADs under visual guidance,^[9,13,15,17] it is surprising that there are no such recommendations in children, given the fact that there are several different types of SGADs used in paediatric patients with varying rates of success.^[10,14] Furthermore, it has been shown that inserting SGADs under vision improves both the device position as well as OLPs in adults.^[7]

In a performance evaluation of AAG in children, Jagannathan and colleagues,^[4] found that only 24 children had correctly positioned devices where only the larynx was seen according to the scoring system used. Mihara and colleagues,^[5] reported 1 case of airway obstruction with the AAG, but they did not carry out a bronchoscopy evaluation of the device position. Stöger Müller and colleagues,^[15] found that all children with both AAG and Aura Once had a score of 2 (cords plus anterior epiglottis) using the scoring system by Brimacombe and colleagues.^[18]

In our study, we had a higher incidence of device malposition compared to other studies, including in the visually guided groups,^[10] which was probably due to the stringent criteria of malposition in our study where only the laryngeal view without the epiglottis was considered as an optimal position. The large size of the epiglottis in children is likely to be caught in the bowl of the SGADs. Accordingly, there is wide variability and several scoring systems for defining malposition in this cohort of patients, but no score is universally adapted.^[10] Besides, our primary aim was to test the superiority of visually guided techniques where essentially the epiglottis is lifted out of view, and thus, accepting any portion of the epiglottis *a-priori* within the bowl of the AAG would have underscored the relevance of our findings. However, like other studies,^[4,15,16,19] the bronchoscopy grading of the AAG

position had no impact on ventilation. But there are two aspects to the performance of SGADs. Even though the device position may not affect ventilation in most patients, it may affect the OLPs, which is another measure of functional performance. A better device position leads to a better mask seal and higher OLPs.^[7,10,14] In our study, we did not measure the OLP but rather, noted the number of patients who had an audible leak in the mouth at 20 cm H₂O in each group. OLP was not a primary outcome measure of our study, and thus, precise measurements were not the goal unlike other studies which are powered accordingly; rather the absence of leak in a majority of patients suggested that the blind technique of insertion was not inferior to the visually guided groups in achieving a functional seal between the larynx and AAG.

Similar to other studies, we had a high first insertion success rate and did not require any manoeuvres after placement of the AAG.^[4-6,15] The time taken to insert the AAGs in our study in the blind insertion group (mean of 18.4 seconds) was similar to other studies (Mihira and colleagues, mean time 21.3 seconds).^[5] A considerable longer time was taken in the visually guided groups, which is expected, since introducing a laryngoscope in the airway leads to crowding in a small space which may have led to a longer time for placing the devices. Blood staining was only seen in the groups where instrumentation was carried out, and this was not surprising. However, this did not delay the discharge of children from the recovery unit.

There are limited studies of AAG in children over seven years,^[5] and thus, by including children from 6 months to 12 years, it allowed us to evaluate the AAG across all sizes, and ages in the paediatric group. Thus, our results would be expected to have broader applicability. All previous studies have evaluated the malposition of SGADs after blind insertion, and no studies have assessed the effect of visually guided techniques of insertion on the bronchoscopy grading in children.

Our study has a few limitations. We had a very stringent criterion for malposition but believed this was the only way to evaluate whether visually guided techniques of insertion confer any advantage in children. We did not formally assess the OLPs, and it is possible that the visually guided groups may have had better sealing. But given the fact that the videoendoscopy grading was similar in all the groups, this would be unlikely. We excluded children with airway abnormalities,

where placing the device under visual guidance may be more relevant.

CONCLUSION

Based on our observations, we submit that visually guided techniques of insertion do not have any advantage over blind insertion techniques in decreasing the incidence of malposition of the AAG in paediatric patients.

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Conflicts of interest

There are no conflicts of interest.

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