Original Article

Comparison of clinical performance of Ambu® AuraGain™ and BlockBuster® in anaesthetised preschool children-A randomised controlled trial

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ABSTRACT

Background and Aims: Supraglottic airway (SGA) devices are a boon to paediatric airway management. The clinical performances of the BlockBuster® laryngeal mask airway (LMA) and Ambu® AuraGain™ in preschool children were compared in this study. **Methods:** After ethical approval and trial registration, this randomised controlled study was conducted on 50 children, aged 1–4 years, randomised into two groups. Appropriate sized Ambu® AuraGain™ (group A) and LMA BlockBuster® (group B) were placed as per the manufacturer's recommendation under general anaesthesia. Appropriate size of the endotracheal tube was then chosen and inserted through the device. Primary objective of the study was to compare the oropharyngeal seal pressure (OSP), and secondary objectives were the first attempt intubation success rate, overall intubation success rate, SGA insertion time, intubation time, haemodynamic changes and postoperative pharyngolaryngeal complications. The Chi-square test was used to analyse the categorical variables, while the intragroup comparison of mean changes in outcomes was evaluated by the unpaired *t*-test. The level of significance was set at $P < 0.05$. **Results:** Demographic parameters were uniformly distributed in both the groups. The mean OSP in group A was 26.6 ± 0.95 cm H_2O and in group B was 29.08 ± 0.75 cm H_2O. Both the devices were successfully inserted in all the patients. The success rate of blind endotracheal intubation through the device in first attempt was 4% in group A and 80% in group B. Postoperative pharyngolaryngeal complications were relatively less in group B. **Conclusion:** LMA BlockBuster® provides higher OSP and provides a higher success rate of blind endotracheal intubation in paediatric patients.

Key words: Airway management, anaesthesia, laryngeal mask airway, paediatric, oropharyngeal seal pressure, LMA BlockBuster®, Ambu® AuraGain™

INTRODUCTION

The use of supraglottic airway (SGA) devices for securing the airway in paediatric patients has become popular, and according to a report by National Audit Project-4, more than 50% of surgeries under general anaesthesia are being managed with SGA devices, decreasing the frequency of perioperative airway complications.[1] SGA devices have given promising results for primary airway management, and they also serve as a conduit to tracheal intubation.[2] Manufacturers have launched the paediatric counterparts of SGA devices, based on their clinical studies in adults; however, the safety and clinical performance of these devices has still not been properly established paediatric population. The results of clinical trials of SGA devices in adults cannot be extrapolated to paediatric population due to the difference in the paediatric and adult airway anatomy.[3]

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The Ambu® AuraGain™ laryngeal mask airway (LMA) (Ambu A/S, Ballerup, Denmark) is a single-use SGA device which is anatomically curved to mimic the anatomy of human airway. The LMA BlockBuster® (Tuoren Medical Instrument Co., Ltd, Changyuan, China) is made up of silicon and is a reusable SGA. Both these devices have been compared with other SGA devices, especially in adults, but no comparative study is published on the clinical performance of these two SGAs in the paediatric population.[4-6] Therefore, we conducted this study with a hypothesis that there would be no difference between oropharyngeal seal pressures (OSPs) of both these devices in paediatric population. The primary objective of the study was to compare the OSP of LMA BlockBuster® with Ambu® AuraGain™. Secondary outcomes assessed were the first attempt intubation success rate, overall intubation success rate, SGA insertion time, intubation time, haemodynamic changes and postoperative pharyngolaryngeal complications.

METHODS

After approval from Institutional Ethics Committee (SNMC/IEC/2020/1131-1133) and registration of trial with the Clinical Trial Registry of India (CTRI/2021/02/031253, www.ctri.nic.in), this study was conducted on 50 children of either gender, aged 1–4 years, weighing 7–20 kg, belonging to American Society of Anaesthesiologist physical status I and II, scheduled for elective surgery under general anaesthesia between April 2021 and September 2021. Syndromic children, children with symptoms of upper respiratory tract infections, distorted upper airway anatomy and upper airway obstruction, allergy to silicon and children undergoing emergency surgeries were excluded from the study. A written informed consent was obtained from parents, and research was conducted in accordance with the principles of Declaration of Helsinki.

Patients were randomly allocated to group A (Ambu® AuraGain™, RandomAlloc.exe software) and group B (LMA BlockBuster®), using computer software. For allocation concealment, sealed opaque envelope technique was used, which was opened on the day of surgery after the arrival of the child in the operation theatre.

Preanaesthesia checkup was performed a day prior to surgery, and the children were fasted as per protocol.[7] On arrival of the patient in the operation theatre, a multi-channel monitor including heart rate, pulse oximetry and non-invasive blood pressure (systolic, diastolic, mean arterial pressure), was connected, and baseline vital parameters were noted.

Standard anaesthesia technique as per the institute's protocol was followed in all children. Those children who had a patent intravenous (IV) access on arrival in operation theatre (OT) were premedicated with IV fentanyl 2 μg/kg IV, and an inhalational induction using sevoflurane was done for those without it. Atracurium 0.5 mg/kg IV was given after confirming adequate mask ventilation.

The lubricated SGA device was inserted keeping patient's head in a neutral position, as per the allocated group. The appropriate size of the SGA device was selected as per the manufacturer's recommendation (size 1.5 for 5–10 kg and size 2 for 10–20 kg). Both the devices were inserted keeping their shafts approximately parallel to the patients' chest and then pushing the device along the hard palate after opening the mouth. Cuff of the device was inflated with adequate volume of air as per the manufacturer's instruction keeping cuff pressure at 60 cm H_2O. The breathing circuit was connected, and successful placement of the device was confirmed by chest rise, auscultation, capnography, and delivery of adequate tidal volumes. SGA device insertion time (T1) and the number of attempts were noted. If adequate tidal volume was not generated in first attempt, device was removed and reinsertion of the device was attempted. A maximum number of three insertion attempts were allowed in each patient, thereafter which the patient was excluded from the study and the anaesthesiologist was allowed to secure the airway with a device of his/her choice. T1 was considered as the time taken from putting the SGA between incisors to 1st recorded capnograph noted on the monitor. Time between insertion attempts was not calculated to record total insertion time. Sevoflurane in an O_2-air (50:50) mixture was used to maintain adequate anaesthetic depth during surgery.

The OSP was determined by closing the expiratory valve of the circle system up to 30 cm H_2O, at a fixed gas flow of 3 litres per minute and recording the airway pressure on the monitor at which equilibrium was reached and by detection of audible noise or by listening air leak through a stethoscope placed on the neck.[8-10] To ensure safety, maximum allowable OSP was set at 40 cm H_2O, and adjustable pressure limiting valve pressure was released if there was no audible leak even at maximum allowable pressure.

After confirming the successful placement of the SGA, a lubricated uncuffed polyvinyl chloride endotracheal tube (ETT) in the Ambu® AuraGain™ group and a Parker flex tip ETT in the LMA BlockBuster® group was inserted. Proper placement of the ETT was confirmed by the appearance of capnograph waveform and bilateral chest auscultation. Time for blind intubation through the device (T2) was calculated from disconnection of breathing circuit from LMA to 1st capnograph on monitor after ETT placement. Maximum two attempts for blind intubation were allowed. If intubation did not occur in the first attempt, a second attempt was taken using manoeuvres like jaw lift, neck extension and slight withdrawal of the device. If intubation was not successful in second attempt, a direct laryngoscopy was performed to intubate the trachea. After intubating the trachea, SGA was removed and was inspected for any blood staining. To ensure patients' safety, before attempting blind intubation, ventilation through SGA was done with 100% O_2 and boluses of propofol were given to maintain adequate depth of anaesthesia.

In all patients, SGA device insertion and blind intubation were done by the same anaesthesiologist, who had a minimum of 3 years of experience in inserting SGA devices or had inserted at least 50 numbers of second-generation SGA devices before the beginning of this study. After the placement of the device, it was covered by an opaque sheath to blindfold the person recording parameters for the inserted device. The OSP values, SGA insertion time (T1), intubation time (T2), haemodynamic parameters and postoperative complications were recorded by an observer who was not aware of the device inserted.

At the end of the surgery, the neuromuscular blockade was reversed using neostigmine 0.05 $mgkg^{-1}$ IV and glycopyrrolate 0.2 mg IV per 1 mg of neostigmine used, and the trachea was extubated after recovery of adequate muscle power and airway reflexes. During this phase, complications such as tongue, lip, dental trauma, laryngospasm and bronchospasm were noted. Parents and children were interviewed in the recovery room and 24 hours later, to evaluate postoperative complications such as dysphagia, dysphonia and hoarseness. Haemodynamic parameters were recorded in the preoperative period, after induction, 1 and 3 min after SGA device insertion; 1, 3, 5, 10, 20 minutes after intubation and postoperatively.

All statistical analyses were performed using MedCalc Software (MedCalc for Windows, version 19.3, Ostend, Belgium). Endigeri *et al*.[6] and Uthaman *et al*.[11] have reported the mean ± standard deviation (SD) of OSP with LMA BlockBuster® and Ambu® AuraGain™ as 33.7 ± 1.8 cm H_2O and 29.6 ± 3.7 cm H_2O, respectively, in adult patients. Taking into account the difference in OSP between these two devices to be 4.1 cm H_2O, we needed to study 17 participants in each of the study groups to be able to reject the null hypothesis that Ambu® AuraGain™ and LMA BlockBuster® both provide equal seal pressures. With an estimated dropout rate of 10%, 25 children were enrolled with a study power of 90% and two-sided alpha of 0.05. We used a continuity-corrected Chi-squared statistic or Fisher's exact test to evaluate this null hypothesis. The Chi-square test was used to analyse the categorical variables, while the intragroup comparison of changes in outcomes were represented as mean ± SD and was evaluated by the unpaired *t*-test. The statistical significance was represented as a confidence interval, and a $P < 0.05$ was considered statistically significant.

RESULTS

Fifty-six patients fulfilled the eligibility criteria, and 50 patients completed the study and were included in the final analysis. Six were eliminated either due to symptoms suggestive of upper respiratory tract infection on same day of surgery or refusal of consent by the guardian [Figure 1]. Demographic variables were similar in both the groups [Table 1].

The mean OSP recorded in the LMA BlockBuster® (29.08 ± 0.75 cm H_2O) group was higher than the Ambu® AuraGain™ (26.6 ± 0.95 cm H_2O) group ($P < 0.0001$) [Table 2]. The overall success rate was 100% for SGA insertion in both groups, but SGA device insertion time for LMA BlockBuster® (8.7 ± 0.7 s) was significantly less than Ambu® AuraGain™ (11.9 ± 1.8 s). The first attempt success rate of blind endotracheal intubation through the SGA device was 80% in the LMA BlockBuster® group compared to 4% in the Ambu® AuraGain™ group. The overall success rate of intubation was 96% and 28% for LMA BlockBuster® and Ambu® AuraGain™, respectively [Table 2]. The mean intubation time was significantly less in LMA

Table 1: Comparison of patient characteristics

Demographic Data	Group A (*n*=25)	Group B (*n*=25)
Age (months)	33.00±10.12	33.00±10.12
Gender distribution (Male:Female)	19:6	18:7
Weight (kg)	11.35±2.56	11.69±2.82

Values are represented in mean (standard deviation) or numbers

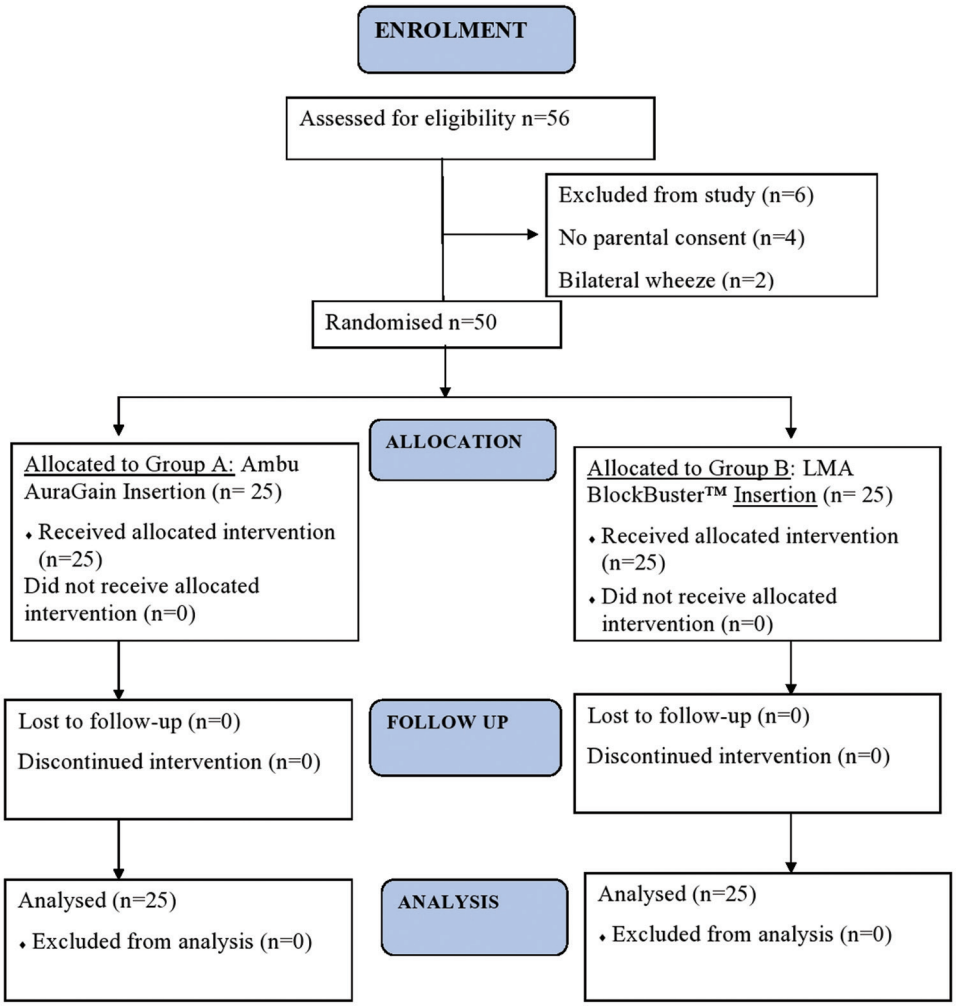

Figure 1: CONSORT flow diagram

BlockBuster® (17.8 ± 4.3 s) group when compared to Ambu® AuraGain™ (69.9 ± 11.3s) [Table 2]. Other parameters like haemodynamic changes and postoperative incidence of pharyngolaryngeal morbidities were comparable among both groups ($P > 0.05$).

DISCUSSION

Our study findings demonstrate that both LMA BlockBuster® and Ambu® AuraGain™ provide adequate seal pressures around the laryngeal inlet. However, the LMA BlockBuster® provides a comparatively better oropharyngeal seal than the Ambu® AuraGain™, and the first attempt and overall success rate of blind endotracheal intubation through LMA BlockBuster® was also significantly better when compared with Ambu® AuraGain™.

If the SGA is being used as a primary airway device, the effective seal around glottis becomes imperative to facilitate effective positive pressure ventilation, prevention of operation theatre air pollution. Simultaneously the second-generation SGAs with gastric access port help to deflate the stomach and decrease gastric insufflations and prevent aspiration of contents. The OSP provides a surrogate marker for the quality of the seal around larynx. An ideal SGA device should have OSP higher than ventilating airway pressures or more than 20 cm H_2O to ensure adequate ventilation.[8] The various first-generation SGA devices that have been used in the paediatric population like LMA Classic, LMA Flexible, LMA Unique, etc., have provided OSP values in the range of 16–20 cm H_2O.[8,9] The second-generation devices—LMA BlockBuster®, LMA Proseal, Air-Q®, LMA Supreme, AuraOnce™, AuraGain™ and i-gel®, are available in paediatric sizes as well.[12-18] Due to changes in the structure and material of the cuff, and wide airway lumen, these devices provide higher seal pressures and can also be used as a conduit for intubation.

Table 2: Comparative data for the Ambu® AuraGain™ (group A) and LMA BlockBuster® (group B)

	Group A (*n*=25)	Group B (*n*=25)	*P*
Oropharyngeal seal pressure; Mean±SD (95%CI)*	26.6±0.95 (26.2-26.99)	29.08±0.75 (28.76-29.39)	<0.0001
SGA device insertion time (T1); Mean±SD (95%CI)*	11.93±1.85 (11.16-12.69)	8.71±0.68 (8.43-8.998)	<0.0001
Intubation time (T2) Mean±SD (95%CI)*	69.86±11.27 (58.03-81.7)	17.85±4.26 (10.95-24.75)	<0.0001
Number of attempts for SGA device insertion**			
1 attempt	22	25	0.117
2 attempts	3	0	
Pharyngolaryngeal morbidities***			
Trauma/Blood-stained device	4	2	0.667
Laryngospasm	1	0	1.000
Bronchospasm	1	0	1.000
Cough	0	0	-
Hoarseness	4	2	0.667

*Unpaired *t*-test, **Fisher exact test, ***Chi-square test. Values are numbers and mean (standard deviation). LMA - Laryngeal mask airway; *n* - number; SGA - Supraglottic airway; CI - Confidence interval

Most of these second-generation devices provide sealing pressures ranging up to 25cm H_2O, significantly higher than the first-generation devices. We found that both LMA BlockBuster® and Ambu® AuraGain™ provide effective OSP (29.08 ± 0.75 and 26.6 ± 0.95 cm H_2O, respectively). A recently conducted study by Selvin *et al*.[19] observed that BlockBuster® provides OSP up to 26.04 ± 2.12 cm H_2O in children. Another study has shown an OSP of 22.59 ± 1.44 cm H_2O with BlockBuster® in adult patients undergoing short surgical procedures under general anaesthesia.[20] Though there is a significant difference in terms of the seal pressure values, clinically, it is not significant if these devices are used for positive pressure ventilation. The silicon-based structure and shape of the LMA BlockBuster® cuff confer it high seal pressures as silicon provides more elasticity and malleability.

Intubating LMA and many other SGA devices have been introduced to aid intubation in adults; however, the availability of such intubating SGA devices for the paediatric population is limited. Jagannathan *et al*.[21] reported both Ambu® Aura-I™ and Air-Q® to be clinically effective for intubation; however, size 1.5 Ambu® Aura-I™ provided limited space to accommodate the ETT. In another study, the success rate of blind tracheal intubation through the Ambu AuraGain™ was only 36.6%. in children between 1 and 12 years of age[15] Endigeri *et al*.[6] have demonstrated a success rate of 96.6% for intubation through the LMA BlockBuster® in adult populations. We also found that the first attempt success rate and overall success rate of blind tracheal intubation was significantly higher with LMA BlockBuster® compared to Ambu® AuraGain™. The structural features that make the LMA BlockBuster® a better conduit of blind intubation are 95 degrees angulated tube, silicon-based material and the Parker Flex-Tip ETT (a reinforced tube with olive-shaped cuff and midline ending tip with emergence angle of 30 degrees) that accompanies it.

A significant difference was also observed in other parameters like device insertion time and intubation time between Ambu® AuraGain™ and LMA BlockBuster®, respectively. LMA BlockBuster® was relatively easy to insert because of modification in the design of BlockBuster® such as suitable anatomical curvature and soft distal part (gastric port).[6] Haemodynamic response to insertion and intubation was comparable between the two groups.

We used a higher valve pressure to assess higher level of OSP provided by these devices; however, such transient pressure increases are common during physiological valsalva manoeuvres and might be acceptable in paediatric patients. The limitations of this study are that we did not confirm the actual position of the device through fibreoptic bronchoscopy. As paediatric fibreoptic bronchoscope was not available, we performed blind intubation through the devices. The ETT tubes used in the LMA BlockBuster® group and AMBU AuraGain™ group were different; Parker Flex-Tip which comes with LMA BlockBuster® and polyvinyl chloride ETT respectively, which might have also affected the study results. Our study included only healthy subjects without any difficult airway, so further studies are required to establish the utility of these SGA devices in children with difficult airways.

CONCLUSION

Both LMA BlockBuster® and Ambu® AuraGain™ provide satisfactory OSP in preschool children. Though first attempt success rate of blind intubation through LMA BlockBuster® is satisfactory, further randomised trial with larger population is required to confirm our study findings.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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