

# Clinical evaluation of Ambu® AuraGain™ as a conduit for intubation in paediatric patients: a descriptive study

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## Abstract

*Introduction:* Many paediatric difficult airway guidelines have recommended supra-glottic airway devices (SGAs) as an indispensable tool in the algorithm for managing failed intubation scenarios. It is used for maintaining ventilation in a difficult or failed intubation. The newer generation SGAs can be used as intubating conduits in patients with a difficult airway. The aim of this study was to report the efficacy and safety of Ambu® AuraGain™ (Ambu A/S, Ballerup, Denmark) as a conduit for intubation in paediatric patients.

*Methods:* Local ethics approval and informed consent was obtained before patient enrolment. Sixteen patients aged 3–12 years old were recruited. Following the induction of anaesthesia and insertion of the Ambu AuraGain, flexible airway scope guided intubation was performed via the SGA. The primary outcome was the time taken for successful tracheal intubation. Secondary outcomes included the number of attempts and the time required for insertion and removal of Ambu AuraGain, oropharyngeal leak pressures, fibre optic grading of glottic views, and complications from the intubation.

*Results:* The overall success rate concerning intubation was 87.5% (14 patients), with a mean intubation time of  $57.0 \pm 39.4$  seconds. Successful first attempt intubations

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were achieved in 13 patients (81.3%). The results showed easy removal of the Ambu AuraGain device with a mean SGA removal time of  $27.2 \pm 19.8$  seconds. No significant complications occurred throughout the study.

*Conclusion:* The Ambu AuraGain device can be considered safe and effective as a conduit for intubation in paediatric patients.

*Keywords:* Ambu AuraGain, intubation, paediatric airway, supraglottic airway

## Introduction

Management of a difficult airway in paediatrics is essential in anaesthesia. The latest American Society of Anaesthesiologists (ASA) guidelines in 2013 for managing difficult airway place supraglottic airway devices (SGAs) as an indispensable tool in the algorithm of managing failed intubation scenarios.<sup>1</sup> The Difficult Airway Society in 2015 and All India Difficult Airway Society Guidelines in 2016 published similar algorithms emphasising the use of SGAs.<sup>2,3</sup> The central approach in these guidelines is the utilisation of the SGA to maintain oxygenation and ventilation while deciding the course of action based on the patients and surgery factors.

The Ambu® AuraGain™ (Ambu A/S, Ballerup, Denmark) is one of the intubating SGAs commonly available. A recent study by Jagannathan *et al.* that evaluated the efficacy of Ambu AuraGain as a SGA in children showed positive results.<sup>4</sup> In addition, they demonstrated good fiberoptic views of the larynx, which may suggest a possible use of Ambu AuraGain as an intubating device. However, clinical evaluation of Ambu AuraGain as an intubating device in children has not been studied. The efficacy of Ambu AuraGain for intubation in adults was shown to have a success rate of 91%, with 88% first attempt success.<sup>5</sup>

Therefore, this pilot study aims to report the efficacy of the Ambu AuraGain as an intubating device in children. This study will provide information on the feasibility of using Ambu AuraGain as a conduit to secure the airway in children, especially in a difficult intubation situation.

## Methods

This study was conducted at University Malaya Medical Centre between October 2019 and March 2020. Ethical approval was obtained from the Medical Research Ethics Committee, University Malaya Medical Centre (Ethics approval number: 2019226-7174). This study was also registered with Clinicaltrials.gov, NCT03955094. Written informed consent was obtained from the parents or guardians before patient enrolment.

We recruited 16 ASA I-II paediatric patients aged 3–12 years who were scheduled for elective surgery that was amenable to standard endotracheal intubation. Exclusion criteria included a history or clinical features of difficult airway, syndromic patients, and facial or dental deformities. We also excluded patients with recent (less than 2 weeks) or ongoing upper respiratory tract infections, existing pulmonary diseases or any risk of bronchospasm, pulmonary aspiration, or operations requiring specialised endotracheal tubes (ETTs). Two study investigators were involved in this study and performed the intubations. They had more than 10 years of experience each in the field of anaesthesia and had used the Ambu AuraGain SGA at least 20 times on normal airways, and thus were considered experienced users.

Patients were fasted for at least 6 hours before the surgery. All patients were preoxygenated with 100% oxygen for a minimum of 3 minutes. They were induced with intravenous (IV) induction with IV fentanyl 1 µg/kg and IV propofol 3–5 mg/kg or inhalational induction using sevoflurane 8% in 100% oxygen. Neuromuscular relaxation was achieved with IV atracurium 0.5 mg/kg. Anaesthesia was then maintained with sevoflurane to achieve a targeted age-appropriate minimum alveolar concentration of 1.0–1.2. Standard monitoring, which includes non-invasive blood pressure and heart rate measurement, pulse oximetry, and three-lead electrocardiography, was instituted throughout the surgery.

A weight-appropriate Ambu AuraGain was then inserted. Three sizes of SGA were available for this study; size #2, size #2.5, and size #3 with a (manufacturer recommended weight 10–20, 20–30, and 30–50 kg, respectively). Time for the successful placement of SGA was defined as the time of insertion at the oral cavity to the time of detection of square wave capnography with adequate tidal volumes (more than 6 ml/kg). The oropharyngeal leak pressure (OLP) test was performed by closing the adjustable pressure-limiting valve to 40 cmH<sub>2</sub>O and setting the fresh gas flow rate to 3 L/min. The OLP was the airway pressure when the peak airway pressure stabilised, and an audible leak was detected.

The size of the Portex® ETT (Smiths Medical, Minneapolis, MN, USA) was chosen based on the patient's age and the manufacturer's recommendation of maximum ETT size for the corresponding Ambu AuraGain. For Ambu AuraGain mask sizes #2, #2.5, and #3, the maximum ETT sizes were 5.0 mm, 5.5 mm, and 6.5 mm, respectively. A cuffed ETT was used for patients more than 6 years old and uncuffed ETT was used for patients younger than 6 years. An appropriately sized ETT was loaded onto a 4-mm Karl Storz® paediatric flexible intubation video endoscope (Karl Storz SE & Co. KG, Tuttlingen, Germany) and then was inserted into the SGA's ventilating orifice until the glottis was visualised. Grading of the glottic view was documented using the system proposed by Brimacombe and Berry as listed below:<sup>6</sup>

- Grade 4: only vocal cords seen.
- Grade 3: vocal cords plus posterior epiglottis seen.
- Grade 2: vocal cords plus anterior epiglottis seen.
- Grade 1: vocal cords not seen, but function adequate.
- Grade 0: failure to function where vocal cords not seen fibre-optimally.

Grades 2–4 are considered favourable views; poor glottic views are defined as Grades 0–1.

The scope was advanced past through the vocal cord until visualisation of the carina. In case of poor glottic view (Grade 0 and Grade 1), SGA corrective manoeuvres, such as jaw thrust or jaw lifting, was performed to improve the glottic view. If the glottic view remained poor, the SGA would be removed, and the glottic view would be re-examined. Up to two SGA insertion attempts were allowed; further attempts were considered a failed SGA insertion. The rescue measure taken to secure the airway for the failed intubation via SGA method, was left to the discretion of the anaesthetist in charge of the case.

The investigators then railroaded the ETT into the trachea and confirmed ETT placement with bilateral breath sounds on auscultation and a positive square wave capnograph tracing. Two attempts for intubation through the SGA were allowed; otherwise, the procedure was abandoned. One minute of preoxygenation was allowed between intubation attempts if two intubation attempts were required. The time of intubation attempt was defined as the time from the disconnection of the breathing circuit to the time capnograph tracing was detected. If two attempts were required, the 1-minute interval time required for oxygenation would be subtracted from the total time taken for intubation.

After confirmation of the ETT placement, the investigators disconnected the breathing circuit, deflated the SGA cuff, and removed the SGA while maintaining ETT in situ. ETT dislodgement during SGA removal was considered a failed

intubation attempt. The timing of SGA removal was defined as the time from the disconnection of the breathing circuit to the reconnection of the breathing circuit after SGA removal. Blood stains on the SGA device or in the oral cavity were documented as none, minimal, or large.

During the intubation process, any complications, including desaturation ( $\text{SpO}_2 < 90\%$ ), bronchospasm, laryngospasm, bradycardia, and aspiration were treated accordingly and documented.

### Data processing and statistics

The calculated sample size for this study was 41 patients over a period of 1 year based on the Cochran formula for sample size calculation. However, in view that this was a pilot study, we only recruited 16 paediatric patients. Data entry and analysis were performed using Microsoft Excel 365. Continuous data were presented as mean  $\pm$  standard deviation (SD), and categorical data were presented as counts and percentages.

## Results

A total of 16 patients were recruited. The patients' demographic data and the placement characteristics for Ambu Auragain and endotracheal intubation are depicted in Table 1.

*Table 1.* Demographic data and descriptive statistics regarding placement and tracheal intubation through Ambu AuraGain

Variables	Patients ( $n = 16$ )
Gender	
Male	12 (75.0)
Female	4 (25.0)
Age (years)	6.5 $\pm$ 3.5
Weight (kg)	23.7 $\pm$ 12.1
Ambu AuraGain size	
2.0	8 (50.0)
2.5	5 (31.2)
3.0	3 (18.8)

Variables	Patients (n = 16)
Ambu AuraGain number of insertion attempts	
1	16 (100.0)
2	0 (0.0)
Ambu AuraGain placement time (seconds)	19.9 ± 6.5
OLP (cmH2O)	23.4 ± 6.0
Number of tracheal intubation attempts	
1	13 (81.3)
2	1 (6.2)
Fail	2 (12.5)
Time for successful tracheal intubation (seconds)	57.0 ± 39.4
Time for successful tracheal intubation (according to glottic view), (seconds)	
Grade 2	63.1 ± 45.3
Grade 3	43.5 ± 6.7
Grade 4	59.4 ± 39.3
Time for Ambu® AuraGain™ removal (seconds)	27.2 ± 19.8

Data expressed as mean ± standard deviation or number (percentage).

All the SGAs were successfully placed on the first attempt and none of the placement attempts required manoeuvres to improve the quality of SGA placement. The glottic views were considered good, with all 16 patients categorised as Grades 2–4.<sup>6</sup> Only one patient required corrective manoeuvres to improve the glottic view from a Grade 1 to a Grade 2.

Two patients had failed intubation via the SGA. The first patient was a 6-year-old child with a Grade 4 glottic view in whom a size 5.0 mm cuffed ETT was not able to be secured via a size 2 SGA after two attempts. The second patient was successfully intubated after two attempts, but the SGA was dislodged during its removal and hence was considered an unsuccessful intubation.

The SGA removals were done in one attempt in all 14 patients, with a mean SGA removal time of 27.2 ± 19.8 seconds. There were minimal blood-stained secretions noted on the SGA device in six of the 16 patients. No other significant complications occurred throughout the study.

## Discussion

The use of Ambu AuraGain as an intubation device is feasible and demonstrated satisfactory results as an intubating device, albeit with a slightly lower success rate than other devices reported in previous studies, which were between 90% and 100%.<sup>7-10</sup> This could be due to the study's small sample size, which might not provide a true reflection of its efficacy. Nevertheless, the high percentage of successful first attempt intubations indicated that Ambu AuraGain is a suitable conduit for intubation in paediatric patients.

The intubation time in this study recorded a wide range from 28.0 to 143.3 seconds. A wide range of intubation time was also reflected in several studies.<sup>8,11</sup> However, the mean intubation time recorded in this study was comparable to a previous study by Jagannathan *et al.*<sup>11</sup> The wide range of intubation time may be due to inter-individual patient and operator-dependent factors. Apart from that, the methods by which intubation times are determined vary between different studies, leading to discrepancies in measurement.

One of the issues encountered during the study was the accuracy in determining the suitable size and type of ETT for the patients. For example, in the first patient with a failed intubation attempt, a cuffed 5.0-mm ETT could not pass through the vocal cords despite good glottic visualisation (Grade 4). However, subsequent intubation with direct laryngoscopy was easy with an uncuffed 5.0-mm ETT. On the other hand, three patients with successful intubations had to be reintubated with direct laryngoscopy with larger ETT sizes due to substantial leaking and inability to ventilate adequately with low flow rates.

This study also found that Ambu AuraGain removal after successful intubation was relatively easy, with a mean SGA removal time of  $27.2 \pm 19.8$  seconds. This result is comparable to those in a previous study showing an average SGA removal time of  $15.7 \pm 5.3$  seconds for the Air-Q™ intubating laryngeal airway (SalterLabs, CA, USA) and  $18.0 \pm 9.3$  seconds for the Ambu® Aura-1™ (Ambu A/S, Ballerup, Denmark).<sup>9</sup> In this study, only one of the 16 patients had the ETT dislodged during the removal process. We postulated that the reason for SGA dislodgement was inadequate lubrication of the ETT and the SGA device before insertion.

Our study showed that Ambu AuraGain was easy to place in all patients with short placement times and optimal device placement as indicated by a good glottic view with corrective manoeuvres to improve placement. Moreover, satisfactory OLP pressures were achieved with the Ambu AuraGain. These results concur with previous studies that have shown Ambu AuraGain as a suitable ventilatory device in paediatrics.<sup>4,12</sup>

Our study has several limitations. Firstly, the sample size of this study was small and the distribution of patients between the three SGA sizes was unequal. Thus, the comparison between the groups was not feasible. However, this study demonstrated that the Ambu AuraGain is useful as an intubating conduit in paediatric patients with a satisfactory success rate. This information is vital, especially in a “can’t intubate can’t ventilate” clinical scenario. Secondly, as this study was done on patients with normal airways, the use of Ambu AuraGain may not be suitable in patients with features of difficult airway such as limited mouth opening and abnormal pharyngeal anatomy. Further studies comparing the efficacy of Ambu AuraGain with other devices through randomised controlled trials with larger sample sizes would need to be explored.

In conclusion, this study demonstrates a high percentage of successful first attempt intubations via Ambu AuraGain, indicating that it is a suitable conduit for intubation for paediatric patients.

## **Declarations**

### **Ethics approval and consent to participate**

Ethical approval was obtained from the Medical Research Ethics Committee, University Malaya Medical Centre (Ethics approval number: 2019226-7174). Written informed consent was obtained from the parents or guardians before patient enrolment.

### **Competing interests**

None to declare.

### **Funding**

None to declare.

### **Acknowledgements**

None to declare.

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