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ORIGINAL ARTICLE

A randomized trial comparing the Ambu® Aura-i™ and the Ambu® Aura Gain™ laryngeal mask as conduit for tracheal intubation in children

Lukas GASTEIGER [1] *, Elgar OSWALD [1], Maya KEPLINGER [1], Gabriel PUTZER [1], Markus LUGER [1], Sabrina NEURURER [2], Christian KELLER [3], Berthold MOSER [4]

[1]Department of Anesthesiology and Intensive Care Medicine, Medical University of Innsbruck, Innsbruck, Austria; [2]Department of Medical Statistics, Informatics and Health Economics, Medical University of Innsbruck, Innsbruck, Austria; [3]Department of Anesthesiology, Schulthess Clinic, Zurich, Switzerland; [4]Department of Anesthesiology and Intensive Care Medicine, Spital Limmattal, Schlieren, Switzerland

*Corresponding author: Lukas Gasteiger, Department of Anesthesiology and Intensive Care Medicine, Medical University of Innsbruck, Anichstraße 35, A-6020-Innsbruck, Austria. E-mail: lukas.gasteiger@tirol-kliniken.at

ABSTRACT

BACKGROUND: The Ambu Aura Gain is a newer second-generation supraglottic airway device designed for fibreoptic bronchoscopy (FOB)-guided tracheal intubation.
METHODS: 57 patients between 18 months and six years of age were randomized to receive either the Ambu Aura-I (N.=29) or the Ambu Aura Gain (N.=28). Primary endpoint was the time for intubation. Secondary endpoints were the time and number of attempts for device insertion, the feasibility of FOB-guided intubation, the oropharyngeal leak pressure (OLP) the fibreoptic grade of laryngeal view and possible complications.
RESULTS: No difference was found in the time for intubation, the time for device insertion or the fibreoptic grade of laryngeal view. First-attempt device insertion was successful in all (N.=28) patients with Aura Gain (100%) and in 27 (97%) with Aura-i. In the Aura-i group one insertion failed. A significant difference in successful intubation was seen between the Aura-i and the Aura Gain (79% *vs*. 100%, respectively, P=0.0011). Also found was a significant difference in the mean OLP (SD) between the Ambu Aura-i and the Ambu Aura Gain (18 [3] *vs*. 20 [3] cmH_2O, respectively; mean difference [MD] 2 cmH_2O; P=0.005).
CONCLUSIONS: The Ambu Aura Gain served as a reliable device for FOB-guided tracheal intubation. Even if the time for intubation, when intubation was possible did not differ, the Aura-i showed only 79% intubation success, making it a doubtful device for FOB-guided tracheal intubation in cases of emergency and severe hypoxemia in small children.

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KEY WORDS: Laryngeal masks; Biological oxygen demand analysis; Hypoxia.

Physiological peculiarities in children lead to a mismatch between oxygen demand and oxygen reserve. These circumstances lead to an overall extremely short apnea tolerance with an increased risk of hypoxemia.

Consequently, airway management in pediatric anesthesia is of extraordinary importance.[1] Since the introduction of the supraglottic airways devices (SGA) by Archie Brain in the early 1980s, the SGA has become a central element in the management of predicted as well as unpredicted difficult airways in adults and children.[2-5] With SGA, it is possible to provide adequate oxygenation and at the same time perform fibreoptic bronchoscopy-guided trans-device intubation. It also helps resolve upper airway obstructions, and

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many difficult airways can be maintained with the SGA alone.[6-8]

It has been shown that fibreoptic bronchoscopy (FOB)-guided intubation by means of SGA is safe and easy to learn.[9-13] Therefore, FOB-guided intubation with a SGA is a central step in the algorithm of the expected as well as the unexpected difficult airway in children.[4]

The Ambu® Aura-i ™ (Aura-i) (Ambu A/S, Baltorpbakken 13, DK-2750 Ballerup) is a first-generation SGA designed to facilitate tracheal intubation. In previous studies the Aura-i has been shown to be an effective conduit for FOB-guided intubation in children.[14]

The Ambu® Aura Gain ™ (Aura Gain) (Ambu A/S, Baltorpbakken 13, DK-2750 Ballerup) is a newer second-generation SGA from the same manufacturer that due to a wide airway tube also allows FOB-guided intubation, it also could prevent patients from aspiration because of a gastric orifice. Previous studies showed good results regarding oropharyngeal leak pressure (OLP) and insertion ease, in both children and adults.[15-17]

The Aura Gain has also been proven to allow safe and reliable FOB-guided intubation in adults.[16]

As massive anatomical and physiological differences between toddlers and adults mean that results from studies performed in adults can hardly prove effective in children, we wanted to evaluate the use of the Aura Gain for FOB-guided intubation in children aged 18 months to six years and compare it with the Aura-i. We hypothesized that both SGAs would perform equally in terms of ease and time to intubation. We also evaluated intubation attempts (maximum two), oropharyngeal and gastric leak pressure, attempts to place the SGA (maximum two) and the fibreoptic view.

Materials and methods

This randomized, non-blinded trial was performed between January 2019 and May 2019 at the Department of Anesthesiology and Intensive Care Medicine at Innsbruck Medical University Hospital, in Innsbruck, Austria.

Ethics approval was obtained (EK Nr: 1187/2017, dated 06.11.2018) from the local Ethics Committee (Ethikkommission der Medizinischen Universität Innsbruck – Austria, Chairman Univ.-Prof. DDr. Ludwig Wildt). The study was registered with Clinical Trials PRS (ClinicalTrials.gov ID: NCT03411655; January 26, 2018).

Before inclusion, written informed consent was obtained in 60 patients from one of the parents or the patient's legal guardian. Included in this trial were 57 patients listed for elective surgery. Inclusion criteria were age between 18 months and six years, weight between 10 and 20 kg and ASA classification I or II. Children with an ASA score of III or more, with a known or suspected difficult airway, scheduled for non-elective surgery or with an acute upper airway infection or chronic pulmonary disease were excluded from the study.

All patients were anesthetized by one of five consultant pediatric anesthetists (>1000 pediatric anesthesia), all of whom were trained in the FOB-guided intubation technique (N.=10) on mannequins before the trial started.

Randomization (Aura-i or Aura Gain) was generated with the algorithm provided by www.randomization.com and was revealed to the study investigator just prior to anesthesia induction.

Anesthesia protocol

After patients had fasted for six hours for solids and two hours for liquids, oral premedication using midazolam 0.5 $mg.kg^{-1}$ (max 10 mg) was administered 30 minutes preoperatively. On both hands EMLA™ cream was applied on the pediatric ward. Patients were positioned supine with their head on a soft pillow and routine monitoring (ECG, oxygen saturation and blood pressure measurement) was installed. Preoxygenation was performed with six liter O_2 over three minutes. If possible, a peripheral vein was cannulated and anesthesia was induced using fentanyl 2-3 $\mu g.kg^{-}1$, propofol 2-6 $mg.kg^{-1}$ and rocuronium 0.2-0.3 $mg.kg^{-1}$. If insertion of an intravenous cannula was not possible, anesthesia was induced with sevoflurane 6% and oxygen 80% to establish an intravenous access. Rocuronium was used for safety reasons and to facilitate FOB-guided intubation. After that general anesthesia was maintained with sevoflurane 2%-3% in 33% O_2.

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Supraglottic airway insertion

SGA insertion was commenced, and adequate anesthesia depth was subsequently confirmed by a lack of response to jaw thrust.[18] Insertion of both SGA devices was performed according to the manufacturer's recommendation. A classic midline insertion technique was used. The head was slightly extended and use of the index finger for insertion was allowed. Time for insertion was defined as the interval from removal of the face mask until effective ventilation through the SGA was assured by detecting end-tidal CO_2 and bilateral chest movement. SGA devices were cuffed at 60 cm H_2O using a cuff pressure gauge.

Failure was defined as impossible passage through the pharynx or unsatisfactory ventilation (tidal volume <4 $mL.kg^{-1}$). In this case, a slightly lateral insertion approach was allowed. Maximum two attempts were allowed. Oropharyngeal leak pressure was measured with the APL valve closed at 40 cmH_2O and a fixed gas flow of 3 L O_2, whereby the airway pressure was measured with a digital pressure manometer DPI 705 (©General Electric Company, Boston, MA, USA) until equilibrium was reached.[19] Gastric Leak Pressure (GLP) was obtained by detection of audible noise by positioning a stethoscope over the stomach.[19]

FOB-guided intubation

For FOB-guided intubation a flexible bronchoscope with a diameter of 2.8 mm (Olympus BF-XP 160) was introduced into the SGA. The fibreoptic was then gently advanced through the vocal cords until direct view on the carina was obtained. After that, the ETT was advanced using the fibreoptic as a guide. Only Medtronic Shiley™ cuffed tracheal tubes (ETT), size 4, were used.

Intubation success as well as three different times were assessed: 1) time for direct view of the glottis (time glottis); 2) time for direct view of the carina (time carina); and 3) time for successful intubation, defined as the time until end tidal CO_2 was confirmed (time et CO_2).

If intubation was successful, the ETT was fixed to the SGA.

Direct view of the larynx was assessed when the tip of the fibreoptic was 1 cm proximal to the distal orifice of the SGA using a previously published score (1= no vocal cords visible, 2= vocal cords and anterior epiglottis visible, 3= vocal cords and posterior epiglottis visible, 4= vocal cords visible).[20]

Statistical analysis and data collection

Primary outcome of this trial was intubation time for FOB-guided intubation using the SGA

In order to test our primary hypothesis (H_0: $\Pi_{AmbuAuraGain} <> \Pi_{AmbuAura\text{-}I}$; H_1: $\Pi_{AmbuAuraGain}=\Pi_{AmbuAura\text{-}I}$) we performed two one-sided tests (TOST).

Quantitative data is presented as mean±standard deviation (SD), qualitative variables are presented as absolute/relative frequencies. The Kolmogorov-Smirnov Test was used to test for normal distribution. For normally distributed, quantitative data, the *t*-test was used for group comparison, while the Mann-Whitney-U test was used for non-normally distributed variables. In order to compare groups based on qualitative data, χ^2 tests were performed. P values <0.05 were considered to be statistically significant.

According to similar studies and to our experience the minimum clinically important difference between intubating times between devices would be 10 s.[14]

Under the assumption of a lower equivalence limit of -10 sec. and an upper equivalence limit of +10 sec. of the difference in the time of insertion, a statistical power of 80% and a significance level of 5%, a sample size calculation resulted in 26 patients per group.

The TOST was performed using XLSTAT (2019.3.1).

Results

Secondary outcome parameters were SGA insertion time, feasibility of FOB-guided intubation, oropharyngeal leak pressure, gastric leak pressure, fibreoptic view and possible complications (mucosal trauma, laryngospasm, esophageal intubation, sore throat).

After informed consent was granted by 60 patients, they were randomized into the Aura-i

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TABLE I.—*Demographic comparison data for the Ambu Aura-i and the Ambu Aura Gain laryngeal airway.*

Parameters	Ambu®Aura-i™	Ambu®AuraGain™	P
N.	29	28	
Sex N. (%)			
Male	16 (57)	16 (55)	ns
Female	12 (43)	13 (45)	ns
Age (years) [SD] {range}	3.1 [±1.4] {1.5-6}	3.2 [±1.3] {1.5-6}	ns
Weight (kg) [SD]	15.1 [±3]	15.2 [±2.8]	ns
Height (cm) [SD]	101.4 [±12.6]	100.7 [±9.5]	ns
ASA status N. (%)			ns
I	19 (68)	16 (55)	
II	9 (32)	13 (45)	
Typ of intervention: N. (%)			
Visceral surgery	10 (34)	8 (29)	
MRT	15 (52)	15 (54)	
Urogenital surgery	4 (14)	5 (17)	

group (i group) and the Aura Gain group (gain group) (N.: 29/28, respectively). Three patients were not included because of upper airway infection (N.=2) or modification of the elective surgical program (N.=1). Patient demographics can be seen in Table I. Flow Chart of recruitment methods can be seen in Figure 1. Doses of anesthetic agents are shown in Table II. Data for insertion of the supraglottic devices are presented in Table III. Comparative data for FOB intubation are presented in Table IV. Overall, time for successful SGA placement did not differ between the two groups (Aura-i: 18 sec [SD±6] *vs*. Aura Gain: 17 sec [SD±4]).

Successful SGA placement was achieved on the first attempt in 55 patients, with a second attempt being necessary in two patients in the i group. In one patient in the i group insertion failed because of unsatisfactory ventilation (tidal volume <4 mL.kg^{-1}).

Mean (SD) oropharyngeal leak pressure was superior for the Aura Gain over the Aura-i (20 [±3] *vs*. 18 [±3] cmH_2O, respectively; mean dif-

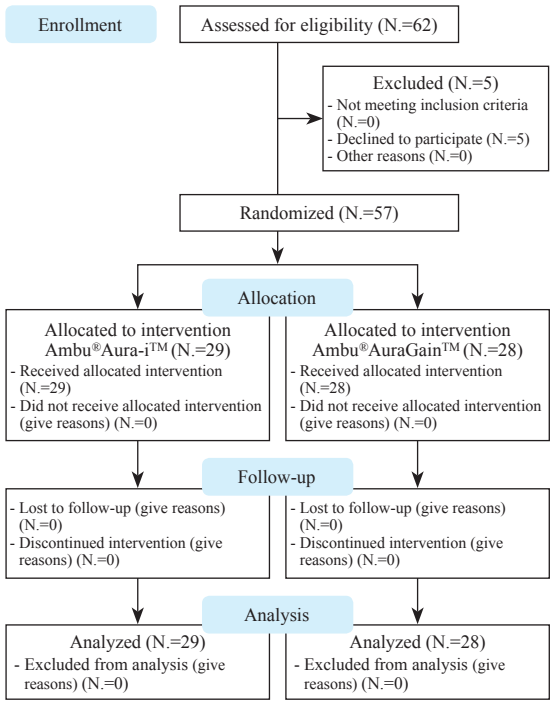

Figure 1.—Flow Chart of recruitment methods.

TABLE II.—*Anesthetic induction doses and cardiorespiratory data.*

Parameters	Ambu® Aura-i™	Ambu® AuraGain™
N.	29	28
Fentanyl; µg.kg^{-1}	2.5 (±0.6)	2.4 (±0.8)
Propofol; mg.kg^{-1}	3.7 (±0.8)	3.6 (±1.1)
Rocuronium; mg.kg^{-1}	0.3 (±0.6)	0.4 (±0.06)
Systolic blood pressure; mmHg	85 (±6)	85 (±9)
Heart rate; min^{-1}	105 (±12)	109 (±16)
Pulse-oximetry; %	98 (±1.2)	98 (±1.1)

Data are presented in mean (SD).

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TABLE III.—*Device placement: insertion success, insertion time, etiology of failed insertion, oropharyngeal leak pressure, visible blood among initial devices and fiberoptic position of the airway tube.*

Variables	Ambu®Aura-i™	Ambu®AuraGain™	P
N.	29	28	
Primary variable			
Oropharyngeal leak pressure; cmH_2O	18 (±3) [12-26]	20 (±3) [14-25]	0.005
Secondary variables			
Fiberoptic position airway tube 4/3/2/1; N.	21/4/3/1	23/5/0/0	ns
Insertion success; N. {%}			
First attempt	27 {93}	28 {100}	ns
Second attempt	2	0	
Insertion failed	1	0	
Overall	29 {100}	28 {100}	
Insertion time; seconds	18 (±6.4) [8-33]	17 (±4) [10-25]	ns
Aetiology of failure; N.			
Dropout in operating room	0	0	
Failed passage into pharynx	0	0	
Malposition^	0	0	
Failed ventilation†	1	0	
Visible blood staining; N. {%}	1 {3}	1 {4}	ns

Data are mean (SD) [range] or numbers {%}.
4= Only vocal cords visible; 3= vocal cords plus posterior epiglottis; 2= vocal cords plus anterior epiglottis; 1= vocal cords not seen.
^drain tube air leaks if pharyngeal placement successful; †maximum expired tidal volume <4 mL kg^{-1} or end-tidal CO_2>50 mmHg when correctly positioned; § cuff pressure set at 60 cmH_2O.

TABLE IV.—*Tracheal intubation comparison data for the Ambu Aura-i and the Ambu Aura Gain laryngeal airway.*

Variables	Ambu®Aura-i™	Ambu®AuraGain™	P
N.	29	28	
Primary variable			
Intubation time (Time to et CO_2) {s}	90 (±30) [49-162]	79 (±25) [23-128]	ns
Secondary variables			
Intubation possible (%)	23 (79%)	28 (100%)	0.0011
Time to glottis {s}	19 (±18) [2-96]	17 (±12) [3-60]	ns
Time to carina {s}	29 (±19) [5-108]	33 (±21) [13-100]	ns
Intubation attempts	1 (±0.4) [1-2]	1 (±0.3) [1-2]	ns
Aetiology of failure			
Failed passage of FOB through the glottis	3	0	ns
Failed passage of ETT through the glottis	1	0	ns
Failed insertion of the LMA	1	0	ns
Fibreoptic not extractable	1	0	ns
Complications; N. (%)	1 (3)	3 (10)	ns
Mucosal trauma	1	1	ns
Laryngospasm	0	1	ns
Oesophageal intubation	0	0	ns
Sore throat	0	1	ns

Data are mean (SD) [range] or numbers {%}.

ference [MD] 2 cmH_2O; P=0.005). Esophageal leakage was detected in three patients, two in the i group and one in the Gain group.

Fibreoptic view did not differ significantly between the two groups, although in the Aura-i group a score >2 was found in three patients.

The primary endpoint, intubation time, when intubation was possible (time et CO_2), did not differ significantly between the i-group and the gain group (90 *vs*. 79 sec respectively).

Time to pass the glottis also did not differ significantly between the two groups.

Successful intubation was possible in all 28 patients in the Gain group (100%). In the i group intubation was successful in 23 (79%) patients (P=0.0011).

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Intubation failed (N.=6 [21%]) because of unsuccessful SGA insertion (N.=1), unsuccessful passage of the fibreoptic scope through the glottis (N.=1), unsuccessful passage of the ETT through the SGA (N.=3) and unsuccessful removal of the fibreoptic scope from the ETT (N.=1).

A second attempt for successful FOB-guided endotracheal intubation was necessary in three patients in the i group and in two patients in the gain group.

Regarding complications, there were no significant differences between the groups. Blood staining after removal of the SGA as sign for mucosal trauma occurred in two patients (one in each group). In one patient in the gain group laryngospasm occurred after extubation. The patient in the gain group with a mucosal trauma suffered from a sore throat in the Post-Anesthesia Care Unit (PACU).

There were no events of esophageal intubation or accidental extubation. ETT were removed together with the SGA after weaning from anesthesia.

Discussion

In the current guidelines for treatment of the unexpected difficult airway, FOB-guided intubation with a SGA is a central cornerstone.[11, 12, 21] It has been shown that it is both safe and easy to learn[9-13] and may also allow simultaneous continuous oxygenation.[21]

The results of this study demonstrate that the Aura Gain is an effective conduit for FOB-guided intubation in children between 1.5 and six years. The percentage of successful intubation attempts when using the device in children is consistent with that reported in previous studies using the Aura Gain in adults.[16] On the other hand, the Aura-i allowed successful intubation in only 79% of the study patients. This is consistently less than in a previous study assessing FOB-guided intubation with this product.[14] The reason for this difference is unclear but might be explained by the different types of cuffed ETT used in both studies.

The reasons that led to unsuccessful intubation were the following.

In one patient, SGA insertion within two tries did not allow adequate ventilation. In another patient, the fibreoptic scope could not be passed through the glottis, as no glottis was seen (score: 1). In another case, after guided insertion of the tracheal tube, the fibreoptic scope was not removable, because it stuck in the middle of the ventilation tube of the SGA. In the remaining three patients in whom intubation failed, tracheal tube insertion with the SGA failed.

The time required for successful intubation our primary outcome in both groups did not differ significantly, but was longer than described previously,[14] even though intubation time is acceptable and no desaturation under apneic conditions was seen in this study population.

We assumed that a minimum clinical important difference between the two devices would be 10 seconds, according to previous data from Jagannathan *et al.*[14] As our time for intubation was much longer for both devices than they described, although a difference of 11 seconds, no significant difference was found.

We compared #2 SGA's, so we chose to use the same size of ETT for all patients to standardise FOB-guided intubation through the SGA's.

As we found that the pilot balloon of the used tracheal tube did not pass through the lumen when using either the Aura-i or the Aura Gain, we decided not to assess the possibility of successful removal of the SGA after FOB-guided intubation and left the SGA in place.[22] It was previously described that the pilot balloon can be removed and subsequently repaired using a 22-gauge angiocatheter. Recently and after the design of this trial, different combinations of SGA and ETT were examined to assess the mismatch possibilities, and the same problem was described in many different combinations.[23] The tracheal tubes we used were not examined in that trial.

The main quality parameter for using the SGA is the oropharyngeal leak pressure because it is intended as a safety measure for aspiration. The OLP found in the Aura Gain is comparable to that of previous findings.[15] Interestingly, the OLP found in the Aura-i was higher than previously published, but still lower than with the Aura Gain (18 [3] *vs*. 20 [3] cmH_2O, respectively; mean difference [MD] 2 cmH_2O; P=0.005). This differ-

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ence was statistically significant but may have little clinical impact.

The first insertion success rate was lower than in previous findings but did not differ between the groups.[14, 15] The lower first insertion rate may be explained by the fact that both devices are not in daily use at our institution. However, the mean insertion time of 18 sec (Aura-i) and 17 sec (Aura Gain) were both satisfactory. The difference in fibreoptic view was not significant, but no scores of 1 or 2 (1= no vocal cords visible, 2= vocal cords and anterior epiglottis visible) were seen with the Aura Gain. In fact, in the Aura-i Group, in two of the three patients with a fibreoptic score of two, tracheal intubation failed as it did in the one patient with a score of one. This underlines the importance of good fibreoptic view.

Limitations of the study

A limitation of this study is that we chose to include only children between 18 months and six years, as we cannot draw conclusions on the performance of either device in younger or older children. We made this decision in order to obtain a clear answer for this particular population, as in our opinion the anatomical und physiological differences between infants and adolescents make it difficult to interpret results from studies including children aged 0-17 years. Another limitation is that we did not choose feasibility of FOB-guided intubation through the SGA's as primary outcome, as we did not expect such a high non-intubation rate in one group.

Conclusions

In summary, the Aura Gain proved to be as a suitable conduit for FOB-guided intubation in small children. It also showed a still clinically doubtful but statistically significant benefit in OLP. As current recommendations favor the use of second-generation SGA for their theoretical safety advantage,[24] this study showed a benefit of the Aura Gain over the Aura-i.

The high percentage of unsuccessful intubations with the Aura-i as a conduit for FOB-guided intubation in an elective situation characterizes this SGA as a probably not reliable emergency tool for unexpected difficult intubation and imminent desaturation.

What is known

- FOB-guided intubation with a SGA is a central step in the algorithm of the expected as well as unexpected difficult airway in children.
- The Aura Gain showed good results regarding oropharyngeal leak pressure (OLP) and insertion ease, in small children.

What is new

- The percentage of successful intubation attempts when using the Aura Gain in children is consistent with that reported in previous studies using the Aura Gain in adults.
- The Aura-i showed a high percentage of FOB-guided intubation failure.
- The Aura Gain proved to be a suitable conduit for FOB-guided intubation in small children.

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