Ambu® Aura Gain™ versus Ambu® Aura Once™ in children: a randomized, crossover study assessing oropharyngeal leak pressure and fibreoptic position

Ambu® Aura Gain™ versus Ambu® Aura Once™ chez des enfants : une étude randomisée à groupes croisés évaluant la pression de fuite oropharyngée et la vision au fibroscope

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Abstract

Purpose The Ambu® Aura Gain™ is a new second-generation supraglottic airway device that—because of a wider curvature and a wide airway tube—allows fibreoptic intubation. The purpose of this study was to assess the oropharyngeal leak pressure of the Ambu® Aura Gain™ compared with the Ambu® Aura Once™.

Methods In this randomized non-blinded crossover trial with 50 patients aged 18 months to six years (10–20 kg), we compared the Ambu® Aura Gain™ and the Ambu® Aura Once™ for airway maintenance in anesthetized, non-paralyzed participants. Our primary outcome was oropharyngeal leak pressure. Time of insertion, success rates for each device, evaluation of fibreoptic view and ventilation quality during anesthesia, as well as possible complications (e.g., blood staining) were assessed.

Results There were no differences in first and overall insertion attempt rates (Ambu® Aura Once™ 50/50 (100%) vs Ambu® Aura Gain™ 50/50 (100%). Mean (standard deviation) oropharyngeal leak pressure was found to be significantly higher for Ambu® Aura Gain™ than it was for Ambu® Aura Once™ [21 (7) vs 19 (6) cmH₂O, respectively; mean difference [MD] – 2 cmH₂O; 95% confidence interval [CI], – 3.8 to – 1.0; $P = 0.001$]. Mean (SD) insertion time was faster for Ambu® Aura Once™ than for Ambu® Aura Gain™ [8 (3) vs 10 (4) seconds, respectively; MD, – 2 sec; 95% CI, – 2.9 to – 1.2; $P < 0.001$]. There were no differences in ventilation quality, fibreoptic view, or blood staining.

Conclusion We conclude that Ambu® Aura Gain™ is a good alternative to the Ambu® Aura Once™ and an efficient device for children in this age group.

Trial registration www.clinicaltrials.gov (NCT02811042). Registered 23 June 2016.

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Résumé

Objectif L'Ambu® Aura Gain™ est un nouveau dispositif supraglottique des voies respiratoires de deuxième génération qui, grâce à une plus grande courbure et à une grande ouverture de la lumière, permet l'intubation au fibroscope. L'objectif de cette étude était d'évaluer la pression de fuite oropharyngée de l'Ambu® Aura Gain™ comparée à celle de l'Ambu® Aura Once™.

Méthodes Dans cette étude randomisée, sans insu, à groupes croisés, ayant inclus 50 patients âgés de 18 mois à 6 ans (10 à 20 kg), nous avons comparé l'Ambu® Aura Gain™ et l'Ambu® Aura Once™ pour le maintien des voies aériennes chez des enfants anesthésiés, non

paralysés. Notre critère d'évaluation principal était la pression de fuite oropharyngée. La rapidité d'insertion, le taux de succès pour chaque dispositif, l'évaluation de la visualisation au fibroscope et la qualité de la ventilation au cours de l'anesthésie, ainsi que les possibles complications (p. ex., présence de sang) ont été évalués.

Résultats Il n'y a pas eu de différence sur les taux de succès de la première tentative d'insertion ou du taux global d'insertion (Ambu® Aura Once™, 50/50 [100 %] contre Ambu® Aura Gain™ 50/50 [100 %]). La pression de fuite oropharyngée moyenne (écart type) a été significativement plus élevée pour l'Ambu® Aura Gain™ que pour l'Ambu® Aura Once™ (respectivement, 21 [7] contre 19 [6] cmH₂O; différence des moyennes [DM], − 2 cmH₂O; intervalle de confiance [IC] à 95 % : − 3,8 à − 1,0; $P < 0,001$). Le temps d'insertion moyen (ET) était plus court avec l'Ambu® Aura Once™ qu'avec l'Ambu® Aura Gain™ (respectivement, 8 [3] secondes contre 10 [4] secondes; DM, − 2 s; IC à 95 %, − 2,9 à − 1,2; $P < 0,001$). Il n'y a pas eu de différence pour la qualité de la ventilation, la vue endoscopique ou la présence de sang.

Conclusion Nous concluons que l'Ambu® Aura Gain™ constitue une bonne option de remplacement pour l'Ambu® Aura Once™ et est un dispositif efficace chez les enfants du groupe d'âge étudié.

Enregistrement de l'essai clinique www.clinicaltrials.gov (NCT02811042). Enregistré le 23 juin 2016.

Since 1981, when Archie Brain first described the Laryngeal Mask Airway (LMA® Classic™ Airway, Teleflex Medical Europe Ltd., Westmeath, Ireland), supraglottic airway devices (SGAs) have become a standard in elective anesthesia for both adults and children. Since then, many studies have demonstrated their utility for controlled and spontaneous ventilation during anesthesia.¹⁻⁴ In 2000, Brain first described the LMA® ProSeal™ (Teleflex Medical Europe Ltd., Westmeath, Ireland), which incorporated a second drainage tube with the scope to enhance safety of the device as it allows drainage of gastric content or air by insertion of a gastric drain.⁵

The ProSeal LMA was the first “second-generation” SGA. Different second-generation SGAs have since been developed and introduced in clinical practice. Nevertheless, it is important that the clinical performance and efficiency of newer devices are evaluated in randomized trials.

The design of adult SGAs is mostly based on studies conducted on cadaveric adult larynges, and pediatric SGAs are usually scaled down versions of adult devices.

Nevertheless, the pediatric airway anatomy shows several relevant differences when compared with adults. For example, the tongue is larger, the epiglottis is relatively bigger and floppy, the larynx itself is positioned more anteriorly, the angle between the posterior pharyngeal wall and the mouth floor is more accentuated, and often there are hypertrophic tonsils and/or adenoids.⁶ Therefore, the effectiveness and safety of pediatric devices should not simply be postulated from adult data and pediatric studies are needed for new SGAs.⁷⁻¹¹

Clinical efficacy in pediatric use has already been proven for both the Ambu® Aura Once™ Disposable Laryngeal Mask (Ambu A/S, Ballerup, Denmark) and the Ambu® Aura Gain™ Disposable Laryngeal Mask (Ambu A/S, Ballerup, Denmark).^{7,11}

The Ambu Aura Once is a silicon-based, single use, first-generation SGA. One study has evaluated the clinical performance and safety of this SGA in children aged between zero and 17 yr. In this study, an oropharyngeal leak pressure of 19 cmH₂O was found, which is comparable with other SGAs.^{7,9,10} The Ambu Aura Gain is a second-generation mask with a wide airway tube that allows for fiberoptic-assisted intubation. As a second-generation SGA, it has a second port providing gastric access to drain gastric content and air, and a better design to theoretically reduce the risk of aspiration.¹² The greater efficiency together with the esophageal port may lead to a higher safety level of second-generation SGAs, therefore they are recommended in daily use.^{12,13}

Due to the anatomical and physiologic differences between small infants and adolescents, it may be difficult to demonstrate the effectiveness and performance (oropharyngeal leak pressure) of different SGAs by assessing participants aged 17 yr or less. We therefore conducted this randomized, crossover study comparing the clinical effectiveness between the Ambu Aura Once and the Ambu Aura Gain only in children aged between 18 months and six years (conforming to size 2 of the device). We hypothesized that the latter would be superior in terms of oropharyngeal leak pressure. The oropharyngeal pressure is one of the measurements accepted as a marker for reducing the risk of aspiration and a higher oropharyngeal pressure may help to reduce the risk of aspiration.^{13,14} We also wanted to evaluate both masks for 1) time, ease, and attempts of insertion, 2) their ventilation performance, and 3) the position over the glottis.

Methods

The study was a randomized to order of insertion, non-blinded, crossover trial and was performed between

January 2017 and July 2017 at the Department of Anaesthesia and Intensive Care Medicine at the Paracelsus Medical University in Salzburg, Austria.

Ethical approval was obtained (Nr: 415-E/1995/8-2016) on 24 May, 2016 from the local ethic commission (*Ethikkommission für das Land Salzburg*, Austria). The study was registered at the Protocol Registration and Results System (PRS) at ClinicalTrials.gov (ClinicalTrials.gov ID: NCT02811042).

Participants were randomly assigned using the algorithm provided by www.randomization.com. Sealed and numbered opaque envelopes that contained the random allocation were opened immediately before induction of anesthesia.

Written informed consent was obtained from the parents or the legal guardian of the patients. Fifty patients listed for elective surgery were included. Both devices were inserted consecutively in each patient. Inclusion criteria were an age between 18 months and six years, weight between 10 and 20 kg, and an American Society of Anesthesiologists classification of I or II. Exclusion criteria were a known difficult airway, not fasted patients, acute surgery, and active respiratory illness on the day of elective surgery. The study was conducted in the pediatric operating theatre of the University Hospital Salzburg. All 50 patients were anesthetized by two experienced consultant pediatric anesthesiologists (> 1000 SGA insertions in children), who were trained in using the Ambu AuraGain before the assessment ($n > 10$). The Ambu Aura Once was the SGA routinely used in the department ($> 1,000$ uses in children).

Patients were fasted six hours for solids and two hours for liquids according to hospital standards. Midazolam $0.5 \text{ mg} \cdot \text{kg}^{-1}$ (max. 12.5 mg) was used as oral premedication and was administered 30 min preoperatively. EMLA™ cream (Astra Zeneca, Cambridge, United Kingdom) was applied at the dorsum of both hands on the pediatric ward. When entering the operating theatre, patients were positioned supine with the head on a soft ring pillow (3 cm high). After installing routine monitoring equipment, anesthesia was induced according to a standardized protocol. A peripheral vein was cannulated and patients were preoxygenated for three minutes.

Anesthesia was induced using fentanyl ($2\text{--}3 \text{ } \mu\text{g} \cdot \text{kg}^{-1}$) and propofol ($2\text{--}6 \text{ mg} \cdot \text{kg}^{-1}$) titrated to effect. If a peripheral vein cannula could not be inserted preoperatively, the patients received an inhalational induction using 8% sevoflurane and 80% oxygen (O_2). General anesthesia was maintained with sevoflurane ($2\text{--}3\%$ in $33\% \text{ O}_2$).

Both airway devices were inserted according to the recommendations of the manufacturer. The head was extended, the neck flexed, and using the index finger to

introduce the airway device was allowed. Insertion time was measured from removing the face mask until effective ventilation was assured by capnographic detection of expiratory carbon dioxide (CO_2) and bilateral chest movements. Insertion attempts were defined as a “failure” when a) it was not possible to place the laryngeal mask regularly, b) safe ventilation was not possible (maximum expired tidal volume $< 4 \text{ mL} \cdot \text{kg}^{-1}$ or end-tidal $\text{CO}_2 > 50 \text{ mmHg}$), and c) oxygen saturation (SO_2) fell to $< 92\%$. In this case, a second attempt with a slightly lateral approach was allowed.

All devices were inflated to a pressure of $60 \text{ cmH}_2\text{O}$ using a cuff manometer and fixed according to the recommendation of the manufacturer. Mechanical ventilation was then initiated using positive pressure ventilation with an inspired tidal volume of $6 \text{ mL} \cdot \text{kg}^{-1}$, a respiratory rate of 20 min^{-1} , and an inspiratory:expiratory rate of 1:1.

Oropharyngeal leak pressure was measured by closing the expiratory valve and setting the fresh gas airflow of the ventilator at $4 \text{ L} \cdot \text{min}^{-1}$. The pressure recorded on the cuff manometer connected to the respiratory filter at equilibrium was noted. The maximum pressure allowed was $40 \text{ cmH}_2\text{O}$. If the pressure exceeded this maximum pressure, the expiratory valve was reopened immediately. Simultaneously, esophageal air leakage was detected with a stethoscope positioned over the stomach.¹⁵

If normal ventilation was achieved and all vital signs were stable, the anatomical position of the SGA was assessed. This was accomplished by passing a fiberoptic scope (Olympus BF-XP 160, Olympus, Shinjuku/Tokyo, Japan) through the SGA and stopping 0.5 cm prior to the tracheal orifice. Using a previously described scoring system, the airway tube view was evaluated.¹⁶

After resetting normal ventilation and assuring stable cardiorespiratory function, the airway device was removed and the second one was inserted and tested in the same manner. To avoid biases, only the first airway device was wiped with a white gauze swab to detect visible bloodstains.

Immediately before and after insertion of the SGA, a second, non-blinded observer collected cardiorespiratory data. Occurrence of bradycardia ($< 80 \text{ min}^{-1}$), tachycardia ($> 140 \text{ min}^{-1}$), or systolic hypotension ($< 70 \text{ mmHg}$) was documented.

Preliminary data indicated a sample size of 50 patients in each group to detect a projected difference of 20% between the groups with respect to the primary variable (oropharyngeal leak pressure), a type I error of 0.05, and a power of 0.9. This was based on a pilot study with ten patients. The pilot study data were as follows: mean 1 = $22 \text{ cmH}_2\text{O}$ [Ambu Aura Gain], mean 2 = $17 \text{ cmH}_2\text{O}$ [Ambu Aura Once], standard deviation (SD) $7.5 \text{ cmH}_2\text{O}$.

Table 1 Anesthetic induction doses and cardiorespiratory data for the initial randomized device

	Ambu® AuraOnce™	Ambu® AuraGain™
<i>n</i>	25	25
Fentanyl; $\mu\text{g}\cdot\text{kg}^{-1}$	2.2 (1.8)	2.2 (2)
Propofol; $\text{mg}\cdot\text{kg}^{-1}$	2.8 (1.8)	2.2 (1.6)
Systolic blood pressure; mmHg	85 (6)	85 (9)
Heart rate; min^{-1}	103 (13)	111 (11)
Pulse-oximetry; %	99 (0.5)	99 (0.6)

Data are presented as mean (standard deviation)

The primary outcome was oropharyngeal leak pressure. Secondary outcomes were fiberoptic view, insertion time, esophageal air leakage, blood staining, and success rate of insertion.

Statistical analyses of the data were performed using *t* tests and χ^2 tests. If not indicated otherwise, data are presented as mean (SD). A *P* value < 0.05 was considered statistically significant. The distribution of our data was analyzed using the nonparametric Kolmogorov-Smirnov test.

Results

Fifty patients aged between 18 months and six years were randomized, no protocol violations occurred, and all participants completed the study. The mean (SD) age, height, and weight were 39 (12) months, 100 (11) cm, and 15 (3) kg, respectively.

In Table 1, induction doses and vital parameters are presented. The results regarding oropharyngeal leak pressure, insertion time, and fiberoptic score are presented in Table 2.

Baseline characteristics did not differ between the two groups.

There were statistically significant differences in oropharyngeal leak pressure and insertion time between the groups (Table 2). There was no need for a second attempt in either group. Mean (SD) oropharyngeal leak pressure was superior for Ambu Aura Gain than for Ambu Aura Once [21 (7) vs 19 (6) cmH_2O , respectively; mean difference [MD] $-2 \text{ cmH}_2\text{O}$; 95% confidence interval [CI], -3.8 to -1.0 ; *P* = 0.001]. On the other hand, the mean (SD) insertion time was statistically better for the Ambu Aura Once than for the Ambu Aura Gain [8 (3) vs 10(4) seconds, respectively; MD, -2 sec ; 95% CI, -2.9

Table 2 Insertion success, insertion time, etiology of failed insertion, oropharyngeal leak pressure, visible blood among initial devices, and fiberoptic position of the airway tube

	Ambu®AuraOnce™	Ambu®AuraGain™	95% CI for the difference	<i>P</i>
N	50	50		
PRIMARY VARIABLE				
Oropharyngeal leak pressure§; cmH_2O	19 (6) [12-40]	21 (7) [11-40]	-3.8 to -1.0	0.001
SECONDARY VARIABLES				
Fiberoptic position airway tube§ 4/3/2/1; <i>n</i>	0 / 0 / 50 / 0	0 / 0 / 50 / 0		ns
Esophageal air leakage	n.d.	n.d.		ns
Insertion success; <i>n</i>				
- First attempt	50 {100}	50 {100}		ns
- Second attempt	0	0		
- Insertion failed	0	0		
- Overall	50 {100}	50 {100}		
Insertion time; sec	8 (3)	10 (4)	-2.9 to -1.2	< 0.001
Etiology of failure; <i>n</i>				
- Failed passage into pharynx	0	0		
- Malposition^	0	0		
- Failed ventilation†	0	0		
Plateau pressure; mbar	15 (3)	15 (3)	-0.8 to 0.3	ns
Visible blood staining*; <i>n</i>	0 {0}	0 {0}		ns

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

^ Drain tube air leaks if pharyngeal placement successful; † maximum expired tidal volume < $4 \text{ mL}\cdot\text{kg}^{-1}$ or end-tidal CO_2

> 50 mmHg if correctly positioned; *On the initial randomized device; §Cuff pressure set at 60 cmH_2O ; 4 = only vocal cords visible; 3 = vocal cords plus posterior epiglottis; 2 = vocal cords plus anterior epiglottis; 1 = vocal cords not seen [8]

CI = confidence interval; n.d.: not detected; ns = not significant

to -1.2 ; $P < 0.001$]. Esophageal air leakage was not detected in either device.

There was no difference regarding the fibreoptic score (two in each group). No signs for blood staining were found on any mask. There was no significant difference in plateau inspiration pressure to achieve the predefined target ventilation goals (inspired tidal volume of $6 \text{ mL}\cdot\text{kg}^{-1}$, respiratory rate of 20 min^{-1} , and inspiratory:expiratory rate of 1:1).

Discussion

Our data demonstrate that the Ambu Aura Gain provides good quality efficiency and handling. It appears to be at least equivalent alternative to Ambu Aura Once for controlled ventilation in anesthetized, non-paralyzed pediatric patients.

The measured oropharyngeal leak pressures are comparable with those published in earlier studies regarding SGAs in this population.^{7,10,11,17} Our results show statistically better oropharyngeal leak pressures for the Ambu Aura Gain than for the Ambu Aura Once. In the Ambu Aura Gain group, measured pressures were higher than previously described by Jagannathan *et al.*⁷ Nevertheless, both devices demonstrated good performance and efficiency and appear to be safe to use in children. Whether the statistical difference observed has any clinical relevance is questionable.

Interestingly, the insertion time was significantly shorter in the Ambu Aura Once group. This might be explained by the fact that the investigators were more experienced in using the Ambu Aura Once masks as they have been used as standard for years in the Landeskrankenhaus Salzburg hospital.

Regarding successful insertion, both devices had a 100% success rate. This emphasizes the easy use of both SGAs. It has to be said that all patients were investigated by two highly experienced pediatric anesthesiologists.

No complications were noted in any patient. No signs of blood staining were found on any first-used device.

Both SGAs provided an excellent view of the vocal cords (100%), therefore it could be assumed that a fibreoptic-guided tracheal intubation should be possible without further complications.

Although the difference in oropharyngeal leak pressures was statistically significant, it can be argued that an estimated difference in leak pressure of $2 \text{ cmH}_2\text{O}$ is not clinically relevant. On the other hand, given the argument made by some that second-generation devices offer safer protection from aspiration, there may be other good reasons to consider using a second-generation device irrespective of small differences in leak pressures.

The Ambu Aura Gain is a second-generation SGA that has been designed for fibreoptic-assisted tracheal intubation. As this is a well-established technique for difficult intubation in children and is also recommended in difficult airway algorithms, this should absolutely be kept in mind when evaluating the quality of a SGA.^{18,19}

We did not insert gastric drains because the Ambu Aura Once SGA has no gastric lumen.

According to the literature, first-generation SGAs are still used more frequently in pediatric anesthesia than second-generation devices.^{20,21} This is not consistent with actual results and recommendations¹³ and might be explained by the long-term routine clinical use of “older” products.²⁰

The Ambu Aura Gain can be safely used for flexible bronchoscopic intubation in adults.²² Whether this is the case for children has to be assessed in further studies.

Our study has some limitations. We did not evaluate the efficiency of both SGAs during the further procedure. Additionally, as we conducted the study in children between 18 months and six years, we cannot comment on the performance of both SGAs in children of other ages.

Conflict of interest Christian Keller consulted for laryngeal mask company.

Editorial responsibility This submission was handled by Dr. Philip M. Jones, Associate Editor, *Canadian Journal of Anesthesia*.

Author contributions Birgit Stöger Müller contributed to the conception and design of the study as well as the acquisition, analysis, and interpretation of data. Sigrid Ofner and Bernhard Ziegler contributed to data acquisition. Christian Keller contributed to data analysis and interpretation as well as conception and design of the manuscript. Berthold Moser contributed to data interpretation. Lukas Gasteiger contributed to all aspects of manuscript preparation, including study conception, study design, data analysis, data interpretation, and drafting the article.

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