Intubation using video laryngeal mask airway SaCoVLM and laryngeal mask airway Ambu® Aura-i in anesthetized children with microtia:a randomized controlled study

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Research Article

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Abstract

Backgrounds: The Ambu Aura-i laryngeal mask is considered a device for blind intubation as well as for fibreoptic guided intubation.The novel SaCoVLM video laryngeal airway is a supraglottic airway device that allows intubation under direct vision.We hypothesized that success rates for device placement and tracheal intubation with SaCoVLM would be comparable with Ambu Aura-i.

Methods:A prospective,randomized clinical trial from March 2021 to December 2021.One hundred and twenty patients were enrolled and randomized in the study.Direct intubation was performed with SaCoVLM and fibreoptic guided intubation was performed with Ambu Aura-i.Primary outcome measure was first success rate of LMA placement. Secondary outcome measures were the time to device placement and time to endotracheal intubation as well as the time for LMA removal after successful intubation, differences in airway leak pressure, the fiberoptic grade of laryngeal view, and the incidence of blood stain.

Results: The first success rate of LMA placement was similar with the two devices.The time for successful endotracheal intubation was no difference in group Ambu Aura-i and group SaCoVLM (24.1s±6.3 versus 25.7s±2.1; p 0.05). The time for removal was slower in group SaCoVLM than group Ambu Aura-i(20.8s±0.8 versus 14.7s±6.1; p 0.01). The airway leak pressure was higher in group SaCoVLM than group Ambu Aura-i (27.0s±1.0 versus 22.3 s±3.6; p 0.01),the incidence of blood stain is higher in group SaCoVLM (16.7%).

Conclusion:The SaCoVLM has an overall comparable performance as Ambu Aura-i. However, SaCoVLM is better in direct intubation without the assistance of flexible intubation scope, Which reduced the devices demand.

Introduction

Children with microtia may experience difficult laryngoscopy , Bilateral microtia is associated with a strikingly higher incidence of difficult laryngoscopy than children with normal ears 1-2 . Due to anatomical and physiological differences, the technique of endotracheal intubation is relatively more difficult in children 3 . The use of a supraglottic airway device SAD as a conduit for tracheal intubation is an established means for securing the airway when difficult laryngoscopy is encountered in children 4 .

The Ambu® Aura-i designed to allow the passage of conventional cuffed tracheal tubes ,and proved to be effective for fiberoptic-guided tracheal intubation in previous clinical trials 5 and in children with difficult airways. Due to the lack of direct vision, the Ambu Aura-i laryngeal mask usually needs to be assisted by a flexible intubation scope(FIS) to ensure the success rate of tracheal intubation, which limits the wide application of this method to a certain extent. The SaCoVLM 6 (Safe Comfortable Video laryngeal mask,B2020082201,ZHEJIANG UE MEDICAL CORP.Add:NO.8,YouYi Road,Baita Economic Develop Zone,Xianju, Zhejiang, China) is a visual laryngeal mask, including visual channel, ventilation

channel, The connected-in camera of the laryngeal mask can be used to continuously observe the entire process of laryngeal mask insertion, indwelling, and withdrawal, and timely discover the problems that occur during the use of the laryngeal mask. Unlike Aura-i, SaCoVLM has a functional sight for the endotracheal intubation without the need for adjuvants. However no studies are available that compare this device with other SADs especially in children for intubation.

We hypothesised that the LMA SaCoVLM and the LMA Aura-i are comparable with respect to success rates for mask placement and tracheal intubation. Also ,we supposed that the time for endotracheal intubation through SaCoVLM would be faster than Ambu Aura-i.

Methods

Subjects

This single-center study was approved by the University's Institutional Ethical Committee (Plastic Surgery Hospital Ethical Committee No.ZX2021–12,Beijing,China) and the trial was registered prior to patient enrollment at clinicaltrials.gov (ChiCTR2100044032, http://www.chictr.org.cn.Principal investigator: Juan Zhi; Date of registration: 2021/03/06.)

Our hospital is the largest ear reconstruction center in China with 1500 ear reconstruction surgeries per year .Between March 2021 and December 2021,120 children with microtia, scheduled for elective surgery under general endotracheal anesthesia, The patients were randomised to the LMA SaCoVLM (Group SaCoVLM; n = 60) and the LMA Ambu Aura-i(Group Ambu Aura-i; n = 60),respectively, using a sealed envelope which had been prepared after a randomisation procedure using the website Randomization.com(http://www.randomization.com).

Primary endpoint was the overall success rate of LMA placement with either mask after maximum of two attempts. Secondary endpoints were the time to mask placement and time to endotracheal intubation as well as the success rate of intubation, time for LMA removal after successful intubation, differences in airway leak pressure, the fiberoptic grade of laryngeal view, and the incidence of blood stain and postoperative score throat and hoarseness.

Inclusion criteria:ASA I–II, with ages between 5 and 15 years,gender unrestricted;18kg/m^2≤BMI≤30kg/m^2.

Exclusion criteria ASA III–IV ,History of upper respiratory tract infection within 2 weeks;the presence of risk factors for gastric reflux or aspiration;bronchial asthma;morbid obesity(BMI 30kg/m^2).

The study investigators were three anaesthesiologists very well experienced in using different kinds of laryngeal mask devices.

Preparation of SaCoVLM and Aura-i

The SaCoVLM includes a visual channel.a intubation channel,a gastric tube channel,a camera and connecting wires.The camera is fixed on the right side of ventral cuff,connected with the screen and inserted into the visual channel .During placement, the SaCoVLM^{TM} is adjusted according to the image displayed on the screen.A recharged battery is used to provide energy. The camera was inserted into the visual channel and connected with the screen before later use.Initial size selection for the SaCoVLM was as follows: size 2.5 for patients 20-30 kg and size 3 for those 30-50 kg. However, in the pre-experimental process, it was found that size 3 laryngeal mask is too large for 30kg children because it is difficult to insert the device under direct vision. Therefore, in the formal experiment process, we selected size 2.5 for 20-35kg and size 3 for 35kg-50kg children.The device sizes for each child were based on the guidelines 20–30 kg (size 2.5 Aura-i); 30-50 kg (size 3 Aura-i).

Routinely check the cuff of the laryngeal mask before anesthesia induction. Use lidocaine gel to fully lubricate the back of the laryngeal mask, the inner wall of the airway tube of the laryngeal mask and the outer wall of the tracheal tube, and evacuate the cuff for use. Check the light source and clarity of the flexible intubation scope(FIS), and lubricate the stem of the flexible intubation scope.

Preoperative preparation

All children were forbidden to drink for 6h and fasted for 8h before operation.The general information of the patients were asked before surgery,including age,height and weight.The modified Mallampati classification (Class I–IV), mouth opening, thyromental distance, Upper lip bite test class Hemifacial Microsomia Modified Mallampati (Samsoon and Young) classification was assessed by an anesthesiologist ignorant of the study while the patient was sitting with the mouth wide open and the tongue protruding without phonation 7 . Mouth opening was measured as the difference between the upper and lower incisors at the midline in centimeters using a scale. Thyromental distance was measured from the thyroid cartilage to inside of the mentum with neck extended, using a tape 8 . Peripheral venous access was initiated in the operating room, a multifunctional monitor (Datex-Ohmeda S5, General Electric, Boston, MA, USA) to monitor basic vital signs such as electrocardiogram(ECG), non-invasive blood pressure(NIBP) , end-tidal-carbon dioxide ($EtCO_2$) and pulse oxygen saturation was set up.

Anesthesia and airway management

The children were preoxygenated with 100% O_2(5L/min,5min) before induction using a facemask and the head was placed in the neutral supine position.General anesthesia was pre-medicated with midazolam (0.02mg/kg), sufentanil (0.25ug/kg), and. Anaesthesia was induced with propofol (2.5mg/kg). After adequate ventilation using mask ventilation, rocuronium (0.6 mg/kg) was administered for muscle relaxation. Adequate anesthetic depth was confirmed by the disappearance of the eyelash reflex when the jaw was completely relaxed 9 . Both devices were placed using a standard midline insertion technique(the anesthetist held the distal end of the ventilation channel and let the laryngeal mask slide down the palatopharyngeal curve along midline in the mouth until the front end of device was inserted into the hypopharyngeal cavity). When appropriate, re-inject the extracted gas into the laryngeal mask,

connect the anesthesia machine to manually control breathing, and observe the chest rise. When the APL pressure valve is at 30cmH_2O, when the airbag is pressed by hand, the thorax can be seen regularly undulating, and the end-tidal carbon dioxide waveform can be seen, which means that the laryngeal mask is well ventilated. Otherwise, the laryngeal mask needs to be adjusted (up–down/Chandy's manoeuvre [10], reversal method, inflating or deflating etc.) to obtain a satisfactory position. The intra-cuff pressure was then standardized to 60 cm H_2O using cuff pressure gauge(VBM,German). The oropharyngeal leak pressure was measured with the expiratory valve closed and a fresh gas flow of 6 L/min until equilibrium was seen on the pressure gauge [11] (not allowed to exceed 40 cm H_2O). A maximum of three attempts were allowed and the number of attempts was recorded. Time for insertion of LMAs was from the time of taking the device in hand to the confirmation of proper placement of the device.

Next, a fibreoptic evaluation of LMA placement was performed with a fibreoptic intubation scope,The glottis view was assessed and graded as follows [12]:Grade 4: full view of the glottis;Grade 3: partial view of the glottis;Grade 2: no visualization of the glottis directly but can be found;Grade 1: no visualization of the glottis.Additionally ,the view on the screen was recorded.The classification of the glottis seen under the display of the SaCoVLM visual laryngeal mask [13]:Grade 4: full view of the glottis;Grade 3: visualization of all laryngeal inlet and partial glottis;Grade 2: visualization of the bilateral aryepiglottic fold and part of the laryngeal inlet and the ventilation was good; Grade 1: the lateral part of the right aryepiglottic fold and part of the laryngeal inlet and the ventilation was good.

In group Ambu Aura-i, any maneuver(such as lifting the jaw) required to improve the glottis view under fiberoptic vision was performed and noted. On achieving optimum glottis view, fiberoptic-guided tracheal intubation was done with the preloaded tracheal tube. In group SaCoVLM, intubation of the lubricated tracheal tube was attempted along the airway of the SaCoVLM guided by its view on the screen. Manoeuvres such as inflating the laryngeal mask and rotating the tip of tube were allowed if the placement was not successful.

Proper placement of the ETT was confirmed by the appearance of normal square wave capnogram and bilateral equal air entry. Time taken for intubation was recorded from the time of taking ETT in hand to the confirmation of proper placement of the ETT. During the procure, children were administered additional boluses of propofol(20–40 mg) to ensure adequate anesthetic depth.

After successful intubation, the LMA was removed using a stabilizing rod(a plain tracheal tube one size smaller was used as a removal guide). Time taken for removal of the device was recorded as the disconnection of the breathing circuit till ventilation successfully .The attempt was terminated and the attempt classified as “failure” if total time exceeded 300s or SpO2 decreased to < 91% and the trachea would be intubated by direct laryngoscopy if the device was not achieved correctly after three attempts, fiberoptic intubation through the device was not successful after two attempts, or if the tracheal tube was dislodged during device removal.

Maintenance of anesthesia was realized using anesthetics(Oxygen+sevoflurane+propofol+remifentanil).Anesthetics were stopped at the end of surgery.Complications such as desaturation (SpO2<90%), regurgitation or aspiration, laryngospasm/bronchospasm, oropharyngeal or laryngeal trauma (blood staining of device/ETT) and hoarseness of voice were recorded. Patient follow-up was according to standard postoperative protocols at our institution.

We assumed that SaCoVLM would have the first attempt success rate for insertion similar to that of Ambu Aura-i. Sample size estimation was done based on observations of previous studies where the first attempt success rate for insertion was 87.5% for Ambu Aura-i 14 . Assuming a success rate of 90% for SaCoVLM and a noninferiority margin of 10% between the groups, a minimum of 51 patients would be required to achieve a power of 90%, at the type I error level of 0.05. We included 60 patients in each group to compensate for possible dropouts. Sample size was calculated using www.powerandsamplesize.com.

Data collection and statistical analysis

Data were recorded intraoperatively using a standardized data collection sheet and analyzed using Microsoft Excel Spreadsheet and the statistical software IBM SPSS software version 22 (SPSS Inc. Chicago, IL, USA). Statistical comparisons between cohorts were performed using student's t-tests for continuous data, chi-square tests for categorical data, and Mann–Whitney U-test for ordinal data. A Spearman's correlation coefficient was calculated for the relationship between the fiberoptic grade of view and time to tracheal intubation. Proportions were compared with Fisher's exact test or the Chi-square test, as appropriate. Study data are presented as mean (SD) or median (IQR).

Results

A total of 128 patients were assessed for eligibility, out of which 120 patients were enrolled in the study and randomly allocated to group SaCoVLM or group Ambu Aura-i [Figure 1]. There were no dropouts. There were no significant differences between groups with regard to demographic data, ASA physical status (Table 1), or clinical predictors of difficult airway, such as Mallampati score, mouth opening, and thyromental distance (Table 2) Comparative data regarding attempts on device placement and tracheal intubation through the devices are presented in Table 3

The first-time success rate of SaCoVLM placement was 85% and the first time success rate of Ambu Aura-i was 86.7%, and in all patients (100%) on the third attempt, therefore,a second attempt was required in 13.3% of the group SaCoVLM ,and in 10% of the group Ambu Aura-i (p 0.05). Regarding the primary endpoint of the study,there was no difference between LMA groups regarding successful LMA placement with the first attempt. There was no significant difference regarding the time to the first successful ventilation between both groups(Fig. 2).

The airway leak pressure was higher in group SaCoVLM than group Ambu Aura-i (27.0 s. ±1.0 versus 22.3 s. ±3.6; p 0.01),(Fig 3.)

In group SaCoVLM ,the glottis exposure classification on its screen is showed in Table 4. All patients were observed under fiberoptic intubation scope to classify the glottis again. The fiberoptic grade of laryngeal view was not significantly different between the two groups (90% vs. 86.7%; P=0.245)(Fig 4). The time for successful endotracheal intubation was no difference in group Ambu Aura-i and group SaCoVLM (24.1s±6.3 versus 25.7s±2.1; p 0.05) (Fig 5.) The device were successfully removed in all patients in both groups without inadvertent extubation. The time for removal was slower in group SaCoVLM than group Ambu Aura-i (20.8 s. ±0.8 versus 14.7 s. ±6.1; p 0.01)(Fig 6). There was one case of bronchospasm in each group after intubation but relieved by deepen anesthesia .Blood staining on the airway device was reported (six patients(10%) in group Ambu Aura-i and ten patients(16.7%) in group SaCoVLM; P=0.032), the incidence of postoperative sore throat was six patients(10%) in group Ambu Aura-i and nine patients(15%) in group SaCoVLM;p=0.04) without dysphagia and hoarseness.(Table 5).There were no instances of laryngospasm, regurgitation, aspiration, or post-extubation stridor.

Discussion

The first-time success rate of SaCoVLM insertion was 85% in children with microtia ,which confirms that the success rate of devices insertion is basically the same with Ambu Aura-i,which was much lower than that in adults with normal airway 13 This may be due to the anatomical differences in children with microtia,which may existing a narrow laryngeal space .After manual adjustment 14-15 and reinsertion , the final success rate of device insertion can reach 100%.

The SaCoVLM contains a camera to capture the images of the glottis on a screen.We graded the images of 60 patients.Totaltrack mask can visualize the glottis in 83% of patients 16 , SaCoVLM only visualized the glottis in 39 cases(65%) after first insertion ,but in 51 patients(85%) after adjustment. Although the blind placement of laryngeal mask can obtain satisfactory ventilation, it does not mean that the laryngeal mask is in good alignment with the glottis. The visualization of laryngeal mask can better observe the glottis position to facilitate the guidance of endotracheal intubation. Additional advantages with its use include a means for providing continuous oxygenation with a hands-free airway while potentially overcoming upper airway obstructions 17 . All the children could display their partial or whole laryngeal inlet ,which lays a foundation for tracheal intubation.

Alignment and oropharyngeal leak pressure(OLP) are often used as key factors that determine the effectiveness of a laryngeal mask airway .OLP used as a marker for the quality of the airway seal, with 25cmH_2O recommended 11,18 .We found that SaCoVLM achieved an average OLP of 28.0cmH_2O,over 30cmH_2O in 24(40%) of patiens ,both much higer than those achieved by Aura-I, which is consistent with other study 13,19 .In our study, SaCoVLM demonstrated higher leak pressures than Ambu Aura-i. SaCoVLM has a larger mask size, which may occupy a greater area in the posterior pharynx and contribute to a better seal and real-time ,vision-guided insertion of SaCoVLM can allow immediate correction of incorrect cuff inflation,which may decrease the risk of airway and oral tissue trauma causing by hyperinflation 20-21 . therefore, SaCoVLM can serve as an effective supraglottic airway management tool.

The time for successful endotracheal intubation was similar in group Ambu Aura-i and group SaCoVLM, Previous findings that suggest blind intubations through supraglottic airway devices should not be performed in children as epiglottic downfolding may be present [19-22] ,so Supplementary intubation instruments such as fibrobronchoscopy and bougie are sometimes required,however in group SaCoVLM ,intubation through video-guided can better locate the glottis, provide a more unobstructed airway,which decrease the equipment demand. However, a more complete of glottis display correlates with a higher success rate of directly intubation. When the image displayed by the glottis is unsatisfactory, the exposure range of the glottis can be increased by increasing the amount of inflation and adjusting the depth of the laryngeal mask or rotating the tip of endotracheal tube.

The time for removal were significantly higher in group SaCoVLM than group Ambu Aura-i. It may be because the mask body of SaCoVLM is too large, and the oropharyngeal cavity volume of children with microtia [1 3] may be too small. When removing the laryngeal mask, it is difficult for the operator to put his fingers in the mouth to hold the tracheal tube, which requires relatively high requirements for the operator. However, this difference may not be clinically significant; as evidence of oxygen desaturation was not seen with either device. Another reasonable option may be to leave both the ETT and the SaCoVLM in place until the conclusion of the procedure.

Related complications include sore throat and blood staining on LMA were higher in group SaCoVLM,all of which were relieved 24h after the operation, and it was more common in size 3 SaCoVLM laryngeal masks. This may be explained not only by the association between small pharyngeal cavity volume and microtia for children, but also by the structure of the SaCoVLM laryngeal mask. Specifically, the mask body of SaCoVLM laryngeal mask size 3 may be too large for children and the deformability of the front end is insufficient, making it easy to be blocked in the throat wall, which increases the difficulty of insertion and leads to injury. therefore, the incidence of server complications related to SaCoVLM was not found,suggesting that it can be used safely in clinical practice.

In this study, the classification of SaCoVLM and FIS is quite different.The reason is that they observe in different sites. For FIS is through the laryngeal mask vent tube to observe the glottis at the end of the vent tube.the SaCoVLM camera is located on the right side of vent cuff,which is prone to the right side of the vent opening end. However this difference does not affect the intubaion process,the table 2 shows no difference in intubaion time in the two groups.

This study had several limitations. First, we did not study neonates or children with normal ears ,maybe we could cooperate with other institution for further study. Second, the complications such as blood staining of these devices should be studied more detailed. Third, data were collected in an unblinded fashion, which may have introduced bias.This single-center study as a initial study, aiming to lay a foundation for the later multi-center large sample study.

Conclusion

In this study the SaCoVLM has an overall comparable performance as Ambu Aura-i. However, SaCoVLM is better in direct intubation without the help of FIS/bougie, Which would reduce the devices demand.For those points, the performance of SaCoVLM is better .Thereofore, we recommend SaCoVLM as an alternative of Ambu Aura-i.

Declarations

Funding Statement:

None.

Competing Interests:

The authors declare no competing interests.

Author's individual contribution to the manuscript:

"Author Name: Juan Zhi, This author helped conception, design and drafting the manuscript; Author Name: Fuxia Yan, This author helped analysis of data; Author Name:Ling-xin Wei, This author helped acquisition of data; Author Name: Dong Yang, This author helped interpretation of data; Author Name: Xiaoming Deng, This author has given final approval of the vision to be published.

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Conflicts of interest

There are no conflicts of interest.

References

1. Uezono S, Holzman RS, Goto T, et al. Prediction of difficult airway in school-aged patients with microtia. Paediatr Anaesth. 2001;11(4):409-13.
2. Xu J, Chen K, Deng X, Wei L, Yang D, Wang Y. Prediction of difficult laryngoscopy in school-aged patients with microtia. Minerva Anestesiol. 2020 Apr;86(4):387-393.
3. Krishna SG, Bryant JF, Tobias JD. Management of the Difficult Airway in the Pediatric Patient. J Pediatr Intensive Care. 2018 ;7(3):115-125.
4. Pandit JJ, Popat MT, Cook TM et al. The Difficult Airway Society 'ADEPT' guidance on selecting airway devices: the basis of a strategy for equipment evaluation. Anesth 2011; 66: 726–737
5. Navya Mishra ,Avnish Bharadwaj. Comparison of Fiberoptic-Guided Tracheal Intubation Through Intubating Laryngeal Mask Airway (ILMA) Fastrach™ and Ambu® Aura-i™: A Randomized Clinical Study.Cureus.2020;12(9):e10178.

6. Van Zundert AAJ, Gatt SP, Van Zundert TCRV, Kumar CM, Pandit JJ. Features of new vision-incorporated third-generation video laryngeal mask airways. J Clin Monit Comput. 2021 Dec 17. doi: 10.1007/s10877-021-00780-3. Epub ahead of print. PMID: 34919170.
7. Mallampati SR, Gatt SP, Gugino LG, Desai SP, Waraksa B, Freiberger D, et al. A clinical sign to predict difficult tracheal intubation: A prospective study. Can Anaesth Soc J. 1985;32:429–34.
8. Lewis M, Keramati S, Benumof JL, Berry CC. What is the best way to determine oropharyngeal classification and mandibular space length to predict difficult laryngoscopy? Anesthesiology. 1994;81:69–75.
9. Drage MP, Nunez J, Vaughan RS et al. Jaw thrusting as a clinical test to assess the adequate depth of anaesthesia for insertion of the laryngeal mask. Anesth 1996; 51: 1167–1170.
10. Jagannathan N, Sohn LE, Sawardekar A et al. A randomised trial comparing the laryngeal mask airway Supreme with the laryngeal mask airway Unique in children. Anesth 2012; 67: 139–144.
11. Lopez-Gil M, Brimacombe J, Keller C. A comparison of four methods for assessing oropharyngeal leak pressure with the laryngeal mask airway (LMA) in paediatric patients. Paediatr Anaesth 2001; 11: 319–321
12. Brimacombe J, Berry A. A proposed fiber-optic scoring system to standardize the assessment of laryngeal mask airway position. Anesth Analg. 1993 Feb;76(2):457.
13. Yan CL, Chen Y, Sun P, Qv ZY, Zuo MZ. Preliminary evaluation of SaCoVLM™ video laryngeal mask airway in airway management for general anesthesia. BMC Anesthesiol. 2022 Jan 3;22(1):3.
14. Navya Mishra, Avnish Bharadwaj.Comparison of Fiberoptic-Guided Tracheal Intubation Through Intubating Laryngeal Mask Airway (ILMA) FastrachTM and Ambu® Aura-i™: A Randomized Clinical Study.Cureus.2020;12(9):e10178.
15. Weiss M, Engelhardt T. Proposal for the management of the unexpected difficult pediatric airway. Pediatr Anesth 2010; 20: 454–464.
16. M. Gómez Íos, E Freire Ila, R Casans Rancés, et al. The Totaltrack TM video laryngeal mask: an evaluation in 300 patients. Anaesthesia, 2019, 74(6)
17. Asai T, Nagata A, Shingu K. Awake tracheal intubation through the laryngeal mask in neonates with upper airway obstruction. Pediatr Anesth 2008; 18: 77–80.
18. white MC, Cook TM, Stoddart PA. A critique of elective pediatric supraglottic airway devices. Pediatr Anesth 2009; 19(Suppl. 1): 55–65.
19. Jagannathan N , Sohn L E , Sawardekar A , et al. A randomized trial comparing the Ambu Aura-i with the air-Q intubating laryngeal airway as conduits for tracheal intubation in children. Pediatric Anesthesia, 2012, 22(12).
20. Zundert A , Kumar C M , Zundert T , et al. The case for a 3rd generation supraglottic airway device facilitating direct vision placement. Journal of Clinical Monitoring and Computing, 2020(132).
21. Van Zundert, Kumar, Van Zundert, Malpositioning of supraglottic airway devices: preventive and corrective strategies, *BJA: British Journal of Anaesthesia*, 2016,116(5):579–582.

22. Gaddam M, Sethi S, Jain A, et al. Comparison of Air-Q insertion techniques in pediatric patients with fiber-optic bronchoscopic assessment: a prospective randomized control trial. Korean J Anesthesiol. 2019 Dec;72(6):570-575.
23. Jin Xu, Xiaoming Deng, Fuxia Yan.Airway management in children with hemifacial microsomia: a restropective study of 311 cases. BMC Anesthesiology (2020) 120:129.

Tables

Table 1

Patient and airway characteristics.

Demographic data	SaCoVLM(n=60)	Ambu Aura-i(n=60)
Age(y)	7.4±1.5	7.0±1.6
Weight(kg)	30.1±8.5	28.7±7.7
Height(cm)	130.5±10.1	128.5±9.8
Gender distribution(male:female)	46:14	47:13

Values are absolute values (percent) and mean ± SD [minimum – maximum]. No significant differences

Table 2

Clinical predictors of difficult airway

Data	SaCoVLM(n=60)	Ambu Aura-i(n=60)
Interincisor gap;(cm)	4.3±0.5	4.2±0.5
Thyromental distance;(cm)	4.9±0.6	4.9±0.7
Mallampati score n(%)		
1	34(56.7)	32(53.3)
2	23(38.3)	26(43.3)
3	3(5.0)	2(3.3)
Upper lip bite test class n(%)		
I	35(58.3)	34(56.7)
II	23(38.3)	25(41.7)
III	2(3.3)	1(1.6)
Hemifacial Microsomia n(%)		
Left/right	53(88.3)	51(85)
Bilateral	7(11.7)	9(15)

Upper lip bite test class,Class I:lower incisors can hide mucosa of upper lip;Class II:I:lower incisors partially hide mucosa of upper lip;Class III:lower incisors unable to touch mucosa of upper lip; Values are absolute values (percent) and mean ± SD [minimum – maximum]. No significant differences

Table 3

Success rates of intubation as number(%)

	SaCoVLM(n=60,%)	Ambu Aura-i(n=60,%)
Device placement attempts n		
1	51 85	53 86.7)
2	8 13.3	6(10.0)
3	1 1.7	1(1.7)
Tracheal tube placement attempts n		
1	59 98.3	58 96.6
2	1(1.7)	2(3.4)
Manoeuvres to optimize tracheal intubation n(%)		
Inflating the device	10(16.7)	0
Lifting the jaw	1(1.7)	10(16.7)
Tracheal tube rotation	25(41.7)	8(13.3)

Table 4

SaCoVLM clsssification

	Grade4	Grade3	Grade2	Grade1
SaCoVLM n(%)	21(35)	18(30)	14(23.3)	7(11.7)
Adjustment of SaCoVLM n(%)	30(50)	21(35)	9(15)	0

SaCoVLM clsssification is obtained by camera observation through the SaCoVLM visual channel: Grade 4: full view of the glottis;Grade 3: Mainly partial view of all laryngeal inlet and posterior glottis;Grade 2: the bilateral aryepiglottic fold and part of the laryngeal inlet, and the ventilation was good; Grade 1: the lateral part of the right aryepiglottic fold and part of the laryngeal inlet,and the ventilation was good. Adjustmet of device placement:up-down manoeuvre;reinsert;chandy manoeuvre:consists of moving the SaCoVLM on a sagittal plane while ventilating to find the optimal position while lifting the device to provide a good seal

Table 5

Postoperative complications

Outcomes	SaCoVLM n 60;%	Ambu Auri n 60;%
Bronchospasm		
Yes	1(1.7)	1(1.7)
No	59(98.3)	59(98.3)
Blood stains*		
Yes	10(16.7)	6(10)
No	50(83.3)	55(90)
Postoperative sore throat *	9(15)	6(10)
Grade 0(none)	51(85)	54(90)
Grade 1(slight)	7(11.7)	5(8.3)
Grade 2(midium)	2(3.3)	1(1.7)
Hoarseness		
Yes	0	0
No	60(100)	60(100)

Blood staining on the airway device was reported (six patients(10%) in group Ambu Aura-i and ten patients(16.7%) in group SaCoVLM; P=0.032), the incidence of postoperative sore throat was six patients(10%) in group Ambu Aura-i and nine patients(15%) in group SaCoVLM;p=0.04) without dysphagia and hoarseness.

Figures

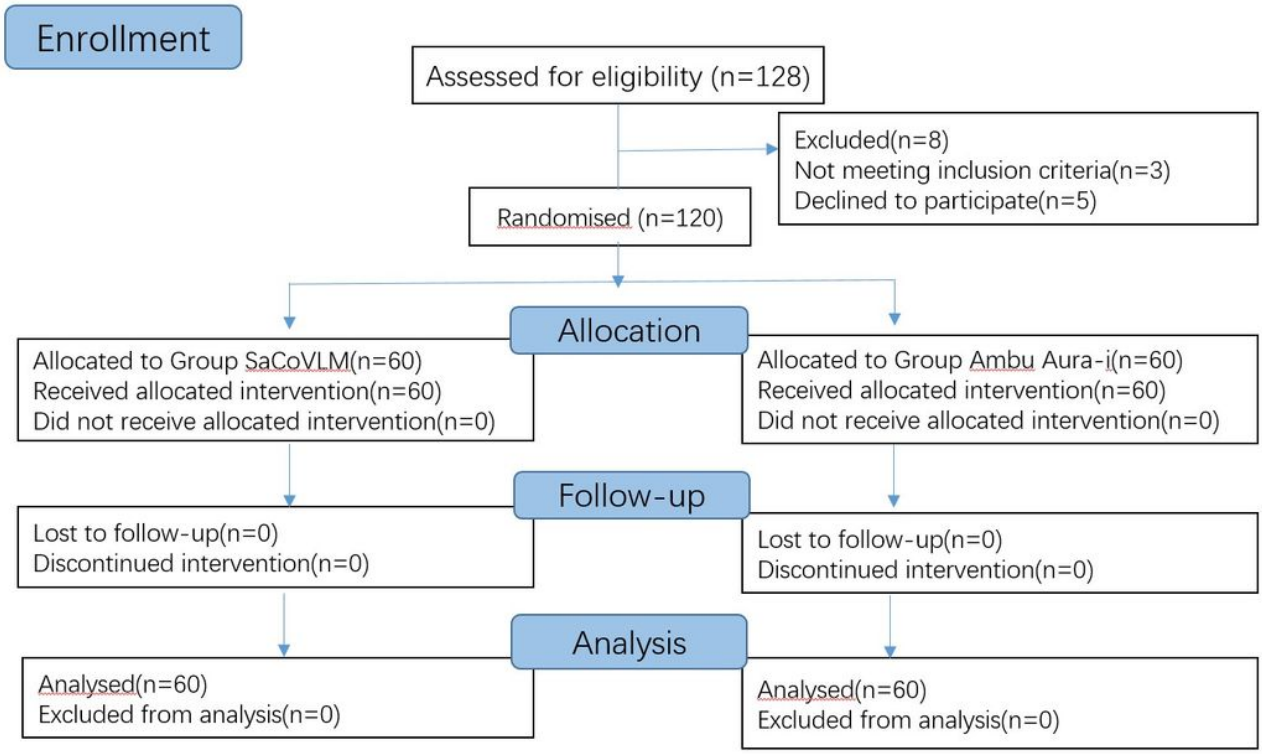

Figure 1

Flow chart study design. 120 patients randomised; two laryngeal mask device groups (Ambu Aura-i and SaCoVLM)

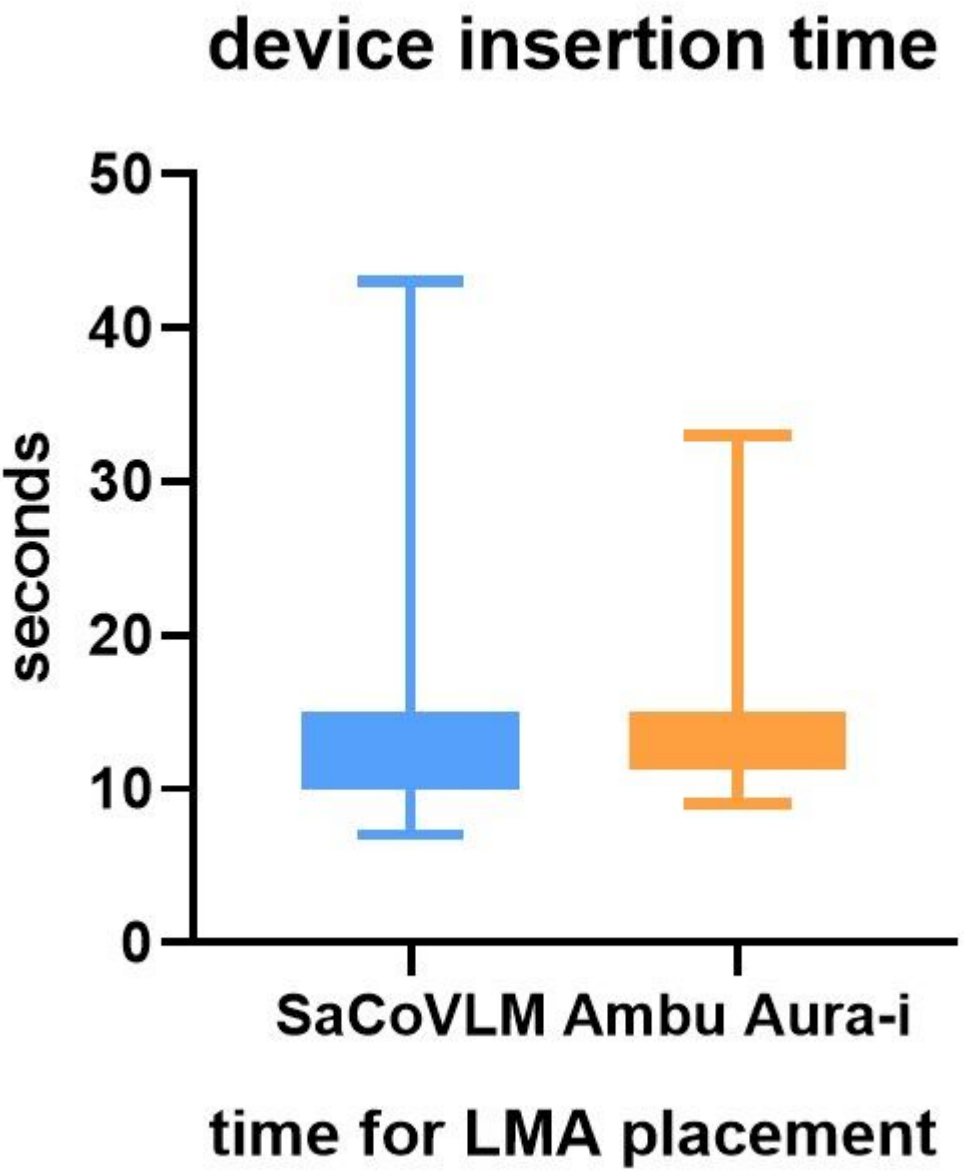

Figure 2

The time for devices insertion. Box-WhiskerPlot, showing Mean, IQR, Minimum, Maximum, p =0.11

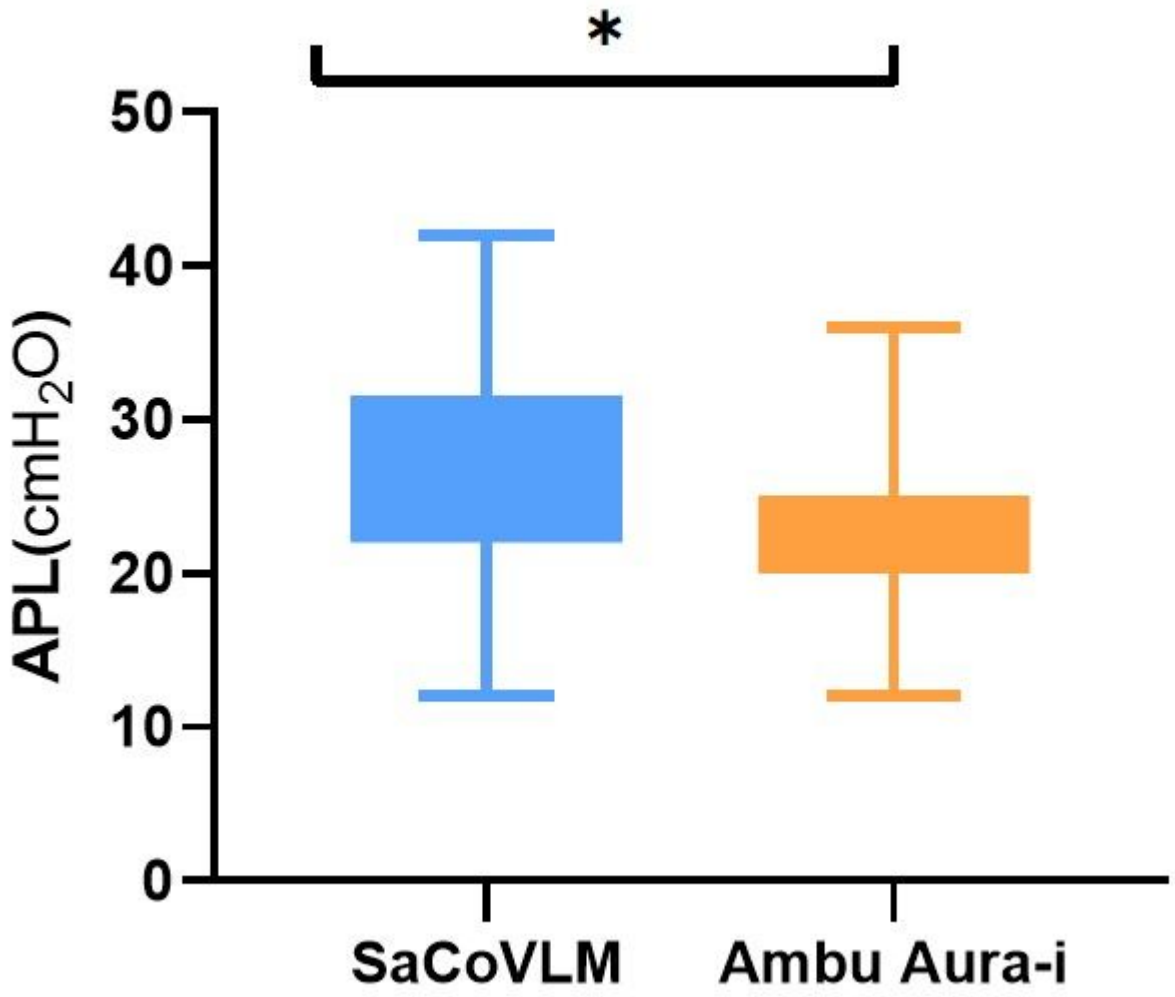

Figure 3

Airway leak pressure in both LMA device groups. Box-WhiskerPlot, showing Mean, IQR, Minimum, Maximum, * $p < 0.05$

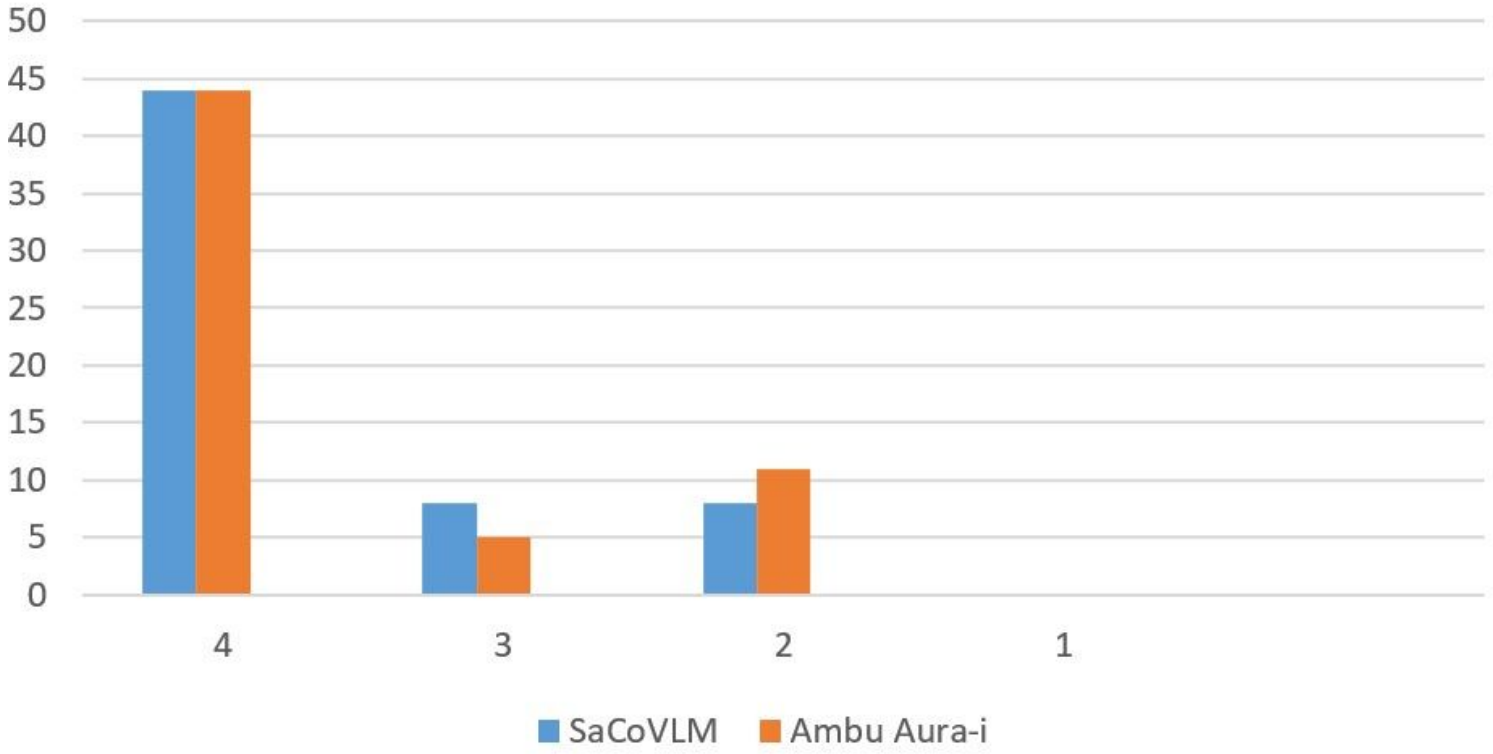

Figure 4

Glottis exposure classification:Grade 4: full view of the glottis;Grade 3: partial view of the glottis;Grade 2: no visualization of the glottis directly but can be found;Grade 1: no visualization of the glottis.

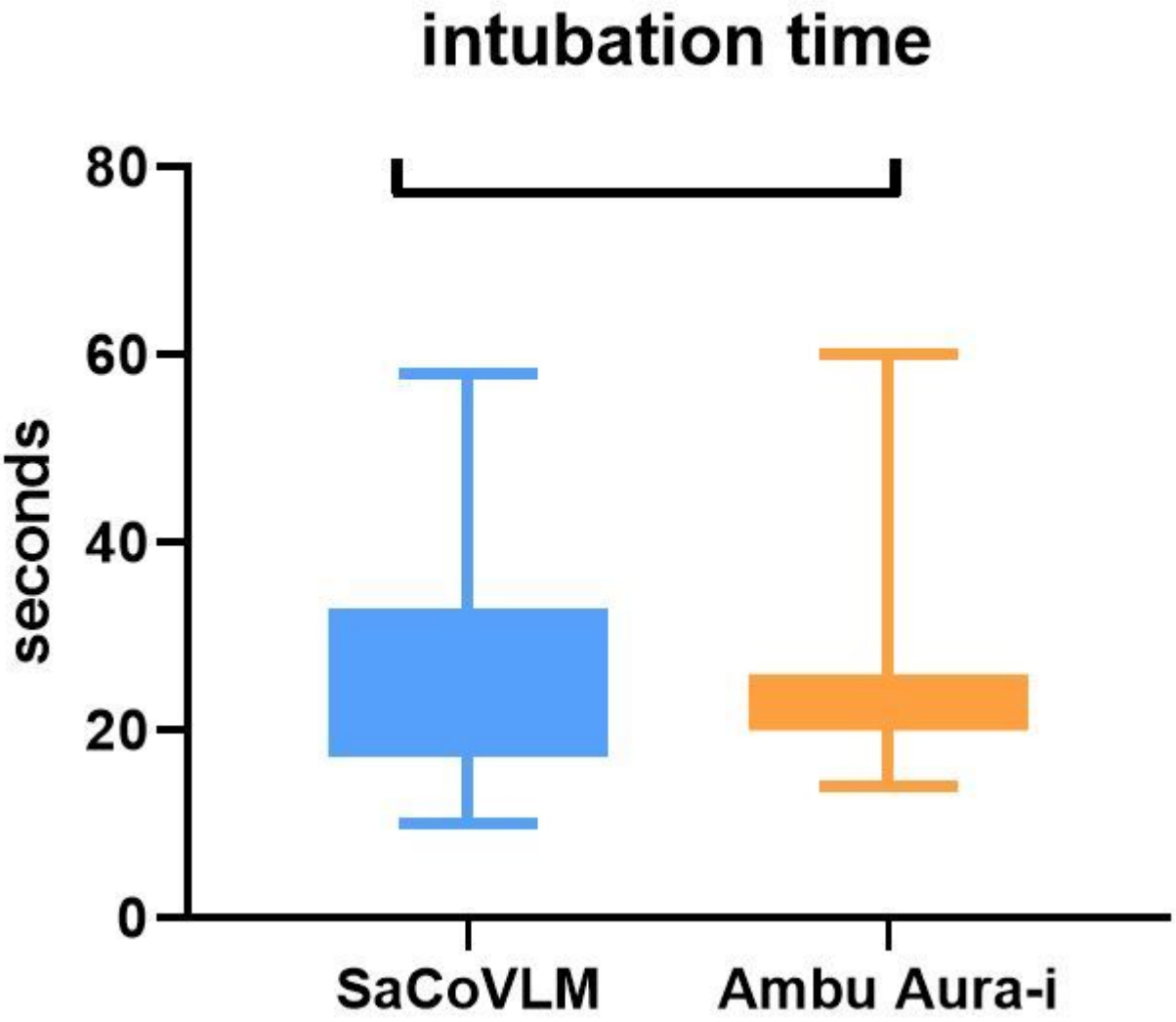

Figure 5

Time for successful intubation on the first attempt in all groups, in seconds. Box-Whisker-Plot, showing Mean, IQR,Minimum, Maximum,p=0.32

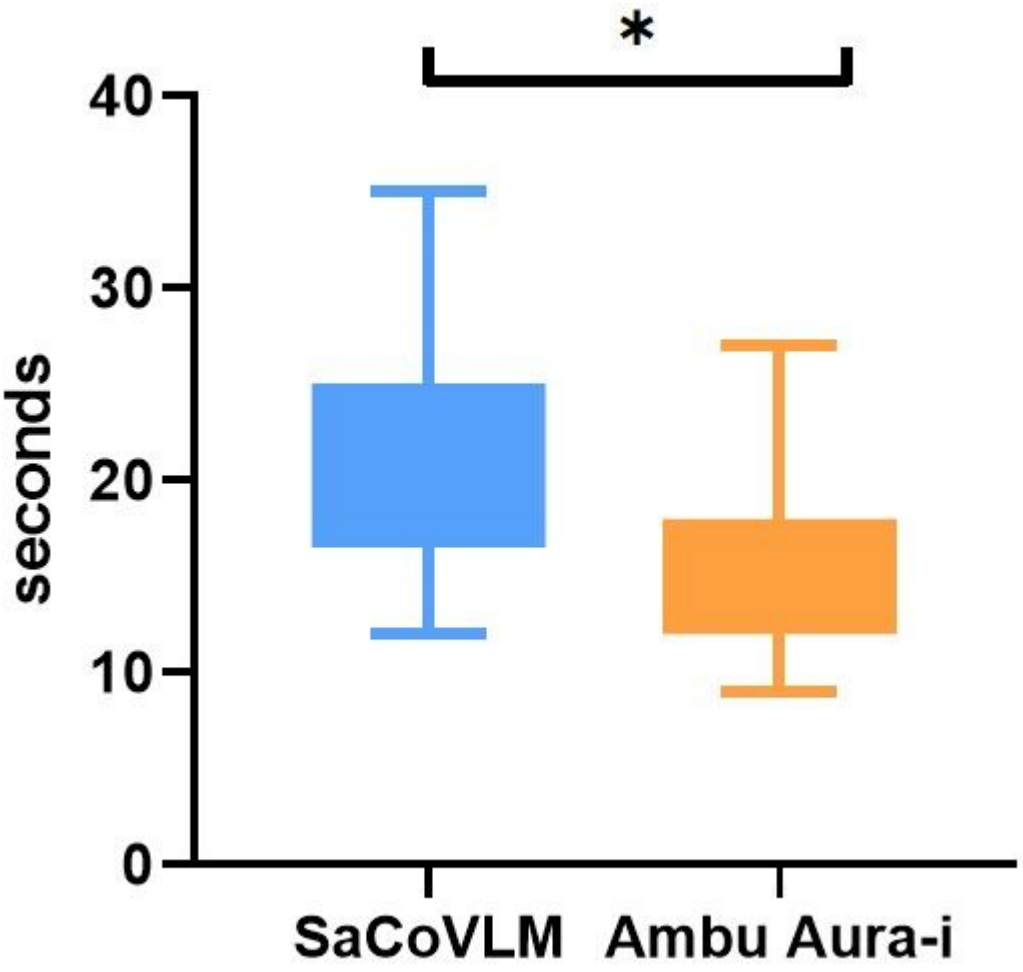

Figure 6

Time for LMA removel in all groups,in seconds , Box-Whisker-Plot, showing Mean, IQR,Minimum, Maximum, * p < 0.05

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- theprocessofintubation.mp4