Research Article / Araştırma Makalesi

Comparison of the Effect of i-Gel ™ and AMBU Aura-i ™ Use on Laryngopharyngeal Mucosa with Flexible Bronchoscopy in Infants

İnfantlarda i-Gel ve Ambu Aura-i Kullanımın Laringofaringeal Mukoza Üzerindeki Etkisinin Flexible Bronkoskopi ile Karşılaştırılması

Sinan YILMAZ [1], Harun UYSAL [1], Muhittin ÇALIM [1], Nizamettin BUCAK [2]

[1]Department of Anesthesiology and Reanimation, Bezmialem Vakif University School of Medicine, İstanbul, TÜRKİYE.
[2]Department of Anesthesiology and Reanimation, Medipol Hospital Bahcelievler, İstanbul, TÜRKİYE

Abstract

Background: Supraglottic airway devices are frequently preferred in surgical surgery for pediatric patients. I-gel LMA and Ambu Aura-i LMA are the new generation supraglottic airway devices. This study aimed to compare airway trauma and postoperative complications due to i-gel and Ambu Aura-i in infants.
Materials and Methods: In the study, patients were divided into two groups that performed minor surgery ASA I and 40 infants. After standard anesthesia, i-gel was placed into one group, and Ambu Aura-i was placed into another. Flexible bronchoscopy was performed at the end of the surgery. Mucosal damage and postoperative complications in laryngopharyngeal structures were compared.
Results: No statistically significant difference was found between the groups in terms of age and body weight averages, LMA size, complication distribution, duration of anesthesia, and mean duration of surgery (p=0.930, p=0.743, p=0.705, p=0.151, p=0.894, p=0.710). There was no statistically significant difference between the two groups regarding grading according to the flexible bronchoscopy appearance (p=0.112, p=0.201, p=0.632).
Conclusions: There is no difference in laryngopharyngeal mucosal damage and postoperative airway complications due to i-gel and Ambu Aura-i in infants. Both devices can be used effectively and safely in this age group.

Key Words: Laryngeal mask airway, i-gel, Ambu Aura-i, flexible bronchoscopy, laryngopharyngeal damage, infant

Öz

Amaç: Supraglottik havayolu cihazları, pediatrik hastalarda cerrahide sıklıkla tercih edilmektedir. I-gel LMA ve Ambu Aura-i LMA, yeni nesil supraglottik havayolu cihazlarıdır. Bu çalışmanın amacı, bebeklerde i-gel ve Ambu Aura-i'ye bağlı havayolu travması ve postoperatif komplikasyonları karşılaştırmaktır.
Materyal ve Metod: Çalışmada minör cerrahi uygulanan, ASA I hastalar (n=40) iki gruba ayrıldı. Standart anestezi sonrası bir gruba i-gel, diğerine Ambu Aura-i yerleştirildi. Ameliyat sonunda fleksibl bronkoskopi yapıldı. Laringofaringeal yapılarda mukozal hasar ve postoperatif komplikasyonlar karşılaştırıldı.
Bulgular: Gruplar arasında yaş ve vücut ağırlık ortalamaları, LMA numarası, komplikasyon dağılımı, anestezi süresi ve ortalama ameliyat süresi açısından istatistiksel olarak anlamlı fark bulunmadı (p=0.930, p=0.743, p=0.705, p=0.151, p =0.894, p=0.710). Fleksibl bronkoskopi görünümüne göre derecelendirme açısından iki grup arasında istatistiksel olarak anlamlı fark yoktu (p=0.112, p=0.201, p=0.632).
Sonuç: Bebeklerde i-gel ve Ambu Aura-i'ye bağlı laringofaringeal mukozal hasar ve postoperatif hava yolu komplikasyonlarında fark yoktur. Bu yaş grubunda her iki cihaz da etkin ve güvenli bir şekilde kullanılabilir.

Anahtar Kelimeler: Laringeal maske havayolu, i-gel, Ambu Aura-i, fleksibl bronkoskopi, laringofaringeal hasar, infant

Corresponding Author/Sorumlu Yazar

Dr. Muhittin ÇALIM
Department of Anesthesiology and Reanimation, Bezmialem Vakif University School of Medicine, İstanbul, TÜRKİYE

E-mail: mcalim@bezmialem.edu.tr

Received / Geliş tarihi: 11.08.2023

Accepted / Kabul tarihi: 28.08.2023

DOI: 10.35440/hutfd.1341647

"İnfantlarda İ-Gel Ve Ambu Aura-İ Kullanımın Laringofaringeal Mukoza Üzerindeki Etkisinin Flexible Bronkoskopi İle Karşılaştırılması" isimli çalışma "Sinan Yılmaz, Harun Uysal, Muhittin Çalım, Nizamettin Bucak" yazarları ile TARK 2019 53. Ulusal Kongresi'nde Özet Bildiri/Sözlü Sunum olarak kabul edilmiş ve sunulmuştur.

Introduction

Archie Brain designed supraglottic airway devices (SADs); and felt the necessity of an efficient airway device that can be placed easily and quickly without causing trauma, even when used by unskilled people. After several years of research, the laryngeal mask airway (LMA) was created and marketed at the end of 1987. Various modifications were made over the years (1).

Pediatric patients are quite different from adult patients and have specific respiratory features. Laryngoscopy and intubation-related complications are higher in this age group. SADs, placed more easily than endotracheal intubation, resulting in less hemodynamic changes and less airway trauma, have an essential place in pediatric patients in current anesthesia practice (2,3). In addition to short surgical procedures, they are also used for expected and unexpected airway difficulties. i-gel and Ambu Aura-i are the new generation SGA (2,3) (Figure 1).

Figure 1. I-gel LMA and Ambu Aura-i LMA

I-gel LMA (Intersurgical, Wokingham, Berkshire, UK) is a soft gel-like cuff that adapts to the anatomy of the hypopharynx and a path suitable for inserting a nasogastric tube in thermoplastic elastomer structure instead of an inflatable cuff that is available in 2007 (2,4).

Ambu Aura-i LMA (Ambu USA, Glen Burnie, MD, USA) is an MRI-compliant, endotracheal intubation and fiberoptic imaging device that was introduced in 2010, Which is easier to place because of its inclination, which is more suitable for the anatomy of the upper airway and provides equal or better leakage pressure to other laryngeal masks (3,5,6).

Studies are comparing various SADs in both infants and wider age groups (7-9). However, there is no study in the literature comparing airway trauma and postoperative complications due to i-gel and Ambu Aura-i.

The primary aim of the study was to determine and compare airway trauma and visible mucosal damage using flexible bronchoscopes using both devices. Still, also secondary aim was to compare postoperative morbidity.

Materials and Methods

Patient selection

This study was conducted as prospective and randomized. The study was initiated after the approval from the Ethics Committee of the Bezmialem Vakif University (date: 03.04.2019, decision no: 7/24). Forty ASA I patients under the age of 1, with a body weight of less than 10 kg, without anatomical pathology in the upper airway with no general anesthesia within the last two weeks which underwent minor surgery (circumcision, inguinal hernia, undescended testis, hypospadias, etc.) by the Pediatric Surgery Clinic at Bezmialem Vakif University Medical School Hospital were included in the study. Patients who are older than one year of age and have a body weight of more than 10 kg, who have symptoms of upper or lower respiratory tract infection, who have had more than one trial performed during the SADs placement, and who are known and expected to be difficult airway, who has undergone surgery for more than 2 hours and patients who underwent emergency surgery were not included in the study.

Pre-operative preparation

A pre-anesthetic systemic examination was performed before the operation. The methods were explained to the families. Written and oral consent forms were obtained. Before the operation, solid food for at least 6 hours, breast milk for 4 hours, and non-particulate liquid food for 2 hours were provided. No premedication was applied to the cases.

Intraoperative Monitoring

After the patients were taken to the operating room without their families, routine three-channel electrocardiography, heart rate (HR), non-invasive blood pressure, and peripheral oxygen saturation (SpO_2) monitoring were performed. Peripheral vascular access was performed after inhalation of a concentration of 6-8% of sevoflurane in a mixture of 50-50% medical air and oxygen with a face mask. After intravenous administration of 2 µg/kg of fentanyl, the LMA was inserted without using muscle relaxants after the eyelash reflex disappeared, and there was no physical response to the jaw trust movement. A water-based lubricant was used before LMA was placed. LMA placement was performed by a single anesthesiologist with more than five years of experience in all patients. The successful placement was evaluated according to the presence of chest expansion and capnograph wave.

The patients were divided into two groups by closed envelope method (Figure 2). Group I (n=20): I-gel LMA (No: 1 or 1.5) was placed in the patients. Group A (n=20): Ambu Aura-i LMA (No: 1 and 1.5) was placed in the patients. After inflating the LMA cuff, the cuff pressure was measured with

a monometer (Model Monitor, VBM Medizintechnik GmbH, Germany) and kept between 40-50 cm-H_2O. LMA number was determined according to the patient's body weight.

In anesthesia maintenance, 2 Lt/min oxygen flow with a concentration of 1.5-2% sevoflurane in 50-50% medical air-oxygen mixture was used. End-tidal carbon dioxide was kept between 30-35 mmHg with pressure-controlled ventilator mode. Intravenous fluid maintenance was achieved with 4 mL/kg/h of 0.9% NaCl solution. At the end of the operation, 10 mg/kg intravenous paracetamol was administered to the patients. After the end of the surgery, anesthetic gases were stopped, and ventilation with 100% oxygen was continued. After separating the breathing circuit, the hypopharynx, epiglottis, and vocal cords were evaluated by pediatric flexible bronchoscopy (MDH-Zhuhai Mindhao Medical Technology Co. P.R. China, A41 4.2 mm). All patients were evaluated by a single anesthesiologist experienced in flexible bronchoscopy.

Patients according to glottic appearance with flexible bronchoscope: Grade 1: No hyperemia, Grade 2: Mild hyperemia, Grade 3: Moderate hyperemia, Grade 4: Mucosal damage and bloody secretion as present were graded.

LMA was removed when spontaneous respiration of the patients was regular and reached sufficient tidal volume. The presence of blood on the LMA was recorded. Laryngospasm, bronchospasm, desaturation (SpO_2<90), post-extubation stridor, cough, tongue, and lip trauma were recorded. Since there is no grading study using a flexible bronchoscope as in our study, In determining the sample size, we used the study of Jagannathan et al (5). We thought that there should be 16 patients in each group using 80% strength and 0.05 alpha. Considering the margin of error, we determined the number of patients in the groups to be 20.

Statistical Evaluation

In this study, statistical analysis was performed by NCSS (Number Cruncher Statistical System) 2007 Statistical Software (Utah, USA).

In the evaluation of the data, in addition to descriptive statistical methods (mean, standard deviation), an independent t-test was used to compare pairs of normal distribution variables and a chi-square test was used to compare qualitative data. The results were evaluated at a $p < 0.05$ level of significance.

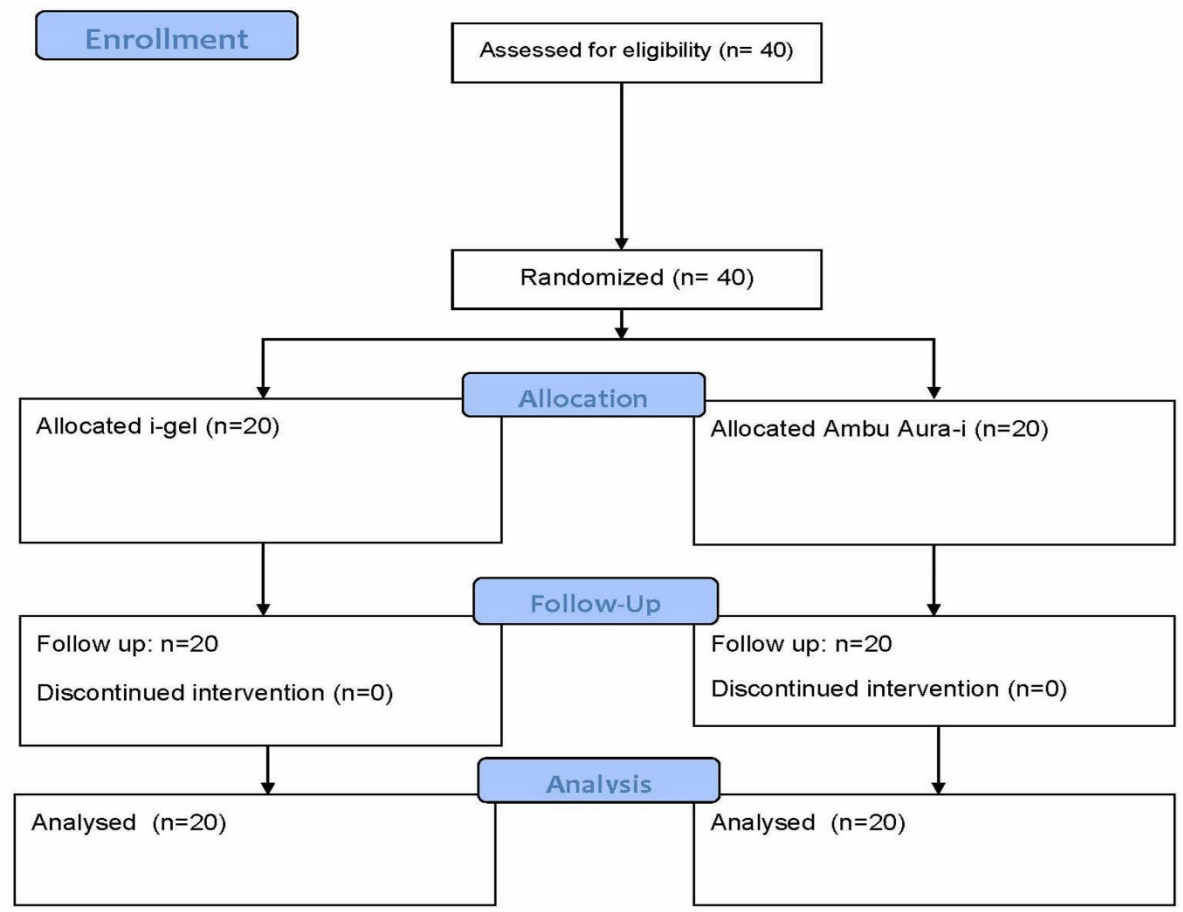

Figure 2. Consort diagram of study.

Results

There was no statistically significant difference between the groups' mean age and body weight, LMA size, complication distribution, duration of anesthesia, and surgery time. (p=0.930, p=0.743, p=0.705, p=0.151, p=0.894, p=0.710). No statistically significant difference was observed between the two groups regarding grading according to flexible appearance. (p=0.112, p=0.201, p=0.632) (Table 1).

Table 1. Age, body weight, LMA size, grading according to an appearance by flexible bronchoscopy, complication, duration of anesthesia, and duration of surgery

		Grup I mean±std or n (%)	Grup A mean±std or n (%)	p value
Age		6.45±3.79	6.55±3.36	0.930*
Body weight		7.60±1.93	7.40±1.90	0.743*
LMA size				0.705**
	1	5 (25.00%)	4 (20.00%)	
	1.5	15 (75.00%)	16 (80.00%)	
Grading by flexible bronchoscopy				
	Grade 1	6 (30.00%)	12 (60.00%)	0.112**
	Grade 2	11 (55.00%)	6 (30.00%)	0.201**
	Grade 3	3 (15.00%)	2 (10.00%)	0.632**
Complication				0.151**
	Unavailable	19 (95.00%)	16 (80.00%)	
	Available	1 (5.00%)	4 (20.00%)	
Anestesia time		43.90±9.80	44.40±13.45	0.894*
Surgery time		31.15±7.65	29.95±12.09	0.710*

LMA: Laryngeal mask airway, n: Number, std: Standard,
** Independent t-test, ** Chi-Square test*

Discussion

Supraglottic airway devices may cause trauma to the airway mucosa (10). If the cuff pressure is higher than the mucosal perfusion pressure, laryngopharyngeal symptoms such as tongue edema, dysphagia, dysphonia, nerve damage, bleeding, and vocal mucosal trauma may be seen in the postoperative period. Symptoms occur more frequently when the cuff pressure is higher than 60 cm-H_2O. Therefore, it is recommended to monitor cuff pressure with a manometer routinely and to be careful during long-term use (1,10). Gupta et al. (2) reported that monitoring cuff pressure with an i-gel without an inflatable cuff would not be necessary and that the possibility of mucosal damage caused by overinflation of the cuff could be avoided. It is also known that nitrous oxide may increase the likelihood of increased mucosal injury due to increased cuff pressure and compression due to inflatable cuff diffusion. I-gel has been suggested to be safer since there is no inflatable cuff, and i-gel is recommended in clinics without cuff manometers (8). However, our study did not support these results in infants. No scoring system is used to evaluate laryngopharyngeal mucosal damage in the literature. Therefore, we created our scoring system. According to the evaluation of pharyngeal structures and vocal cords with flexible bronchoscopy, we did not see any open mucosal injuries and bloody secretions that we accepted as Grade 4. Grade 3, severe hyperemia was seen in 3 patients in the i-gel group and two patients in the Ambu Aura-i group. Grade 2, mild hyperemia was significantly higher in the i-gel group compared to the Ambu Aura-i group (11 patients versus 6 patients). Patients with Grade 1 without hyperemia were more likely to be treated with Ambu Aura-i. Therefore, if we accept hyperemia as an indicator of mucosal trauma, we found more hyperemia in the i-gel group than in the literature. However this difference was not statistically significant. In our study, we avoided using nitrous oxide. We kept the cuff pressure between 40-50 cmH_2O and repeated the measurement every 30 minutes. We tried to provide a standardization by excluding patients from multiple trials in both groups.

Beringer et al. (10) reported that the incidence of blood after removal of LMA was 3-6% and 0-3% for classical LMA and proseal LMA, respectively, and reported that they found this rate to be 3% with the use of i-gel. Again, Kim et al. (8) reiterated that blood on i-gel is less than that of alternative devices, which may be due to the characteristics of the cuff. However, in this study, we did it in infants and did not see any blood on both LMAs. Our results did not support the literature.

It is accepted that postoperative airway complications such as desaturation, laryngospasm, bronchospasm, cough, breath holding, and sore throat are reduced with SGA use compared to tracheal intubation (13). Young children are more likely to have complications due to physiological differences than adults and older children. In addition, due to anatomical differences, difficulties in SGA placement may be encountered. It has been reported that i-gel requires less manipulation, can be placed more quickly in children younger than one year of age, and can be placed in a shorter time compared to LMA unique. Thus it may be more valuable for use in small babies with low oxygen reserves; delayed obstruction due to movement of the device, especially during the intraoperative period, has been reported with SGA use (8). In our study, our patient age group was too small to express itself. Therefore we could not question the sore throat. Complications such as breath holding, desaturation, laryngospasm, bronchospasm, post-extubation stridor, and tongue and lip trauma were not encountered. However, the cough was observed in 4 patients in the i-gel group and 1 patient in the Ambu Aura-i group. However, this difference was not statistically significant. None of our patients encountered a late obstruction.

Theiler et al. (14) reported that there needs to be more reports about i-gel in young children, that they tend to shift

due to their flat structure, and that they should be determined more tightly. We could not provide adequate ventilation due to air leakage in 1 patient in the Ambu Aura-i group, and 2 in the i-gel group. We had to repeat the placement procedure in one patient in both groups. Thus, we excluded two patients in the Ambu Aura-i group and three patients in the i-gel group.

There are limitations, such as the fact that our study was performed in a small group of patients and that the scoring we used was subjective. We believe that prospective studies in larger patient groups are necessary.

In conclusion, there was no difference in infants in terms of laryngopharyngeal mucosal damage and postoperative airway complications due to Ambu Aura-i and i-gel use. We believe both devices can be used effectively and safely in this age group.

Ethical Approval: *This study was approved by the local ethics committee of Bezmialem Vakif University (protocol no: 7/24, 03.04.2019).*

Author Contributions:
Concept: *S.Y., H.U., M.Ç., N.B.*
Literature Review: *S.Y., H.U., M.Ç., N.B.*
Design : *S.Y., H.U., M.Ç., N.B.*
Data acquisition: *S.Y., H.U., M.Ç., N.B.*
Analysis and interpretation: *S.Y., H.U., M.Ç., N.B.*
Writing manuscript: *S.Y., H.U., M.Ç., N.B.*
Critical revision of manuscript: *S.Y., H.U., M.Ç., N.B.*
Conflict of Interest: *The authors have no conflicts of interest to declare.*
Financial Disclosure: *This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.*

References

1. Goyal R. Small is the new big: An overview of newer supraglottic airways for children. J Anaesthesiol Clin Pharmacol. 2015;31:440-449.
2. Gupta S, Dogra N, Chauhan K. Comparison of i-gel™ and Laryngeal Mask Airway Supreme™ in Different Head and Neck Positions in Spontaneously Breathing Pediatric Population. Anesth Essays Res. 2017;11:647-650.
3. Darlong V, Biyani G, Baidya DK, et al. Comparison of air-Q and Ambu Aura-i for controlled ventilation in infants: a randomized controlled trial. Paediatr Anaesth. 2015;25:795-800.
4. Beylacq L, Bordes M, Semjen F, et al. The I-gel, a single-use supraglottic airway device with a non-inflatable cuff and an esophageal vent: an observational study in children. Acta Anaesthesiol Scand. 2009;53:376-379.
5. Jagannathan N, Sohn LE, 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. Paediatr Anaesth. 2012;22:1197-1204.
6. Yahaya Z, Teoh WH, Dintan NA, et al. The AMBU® Aura-i™ Laryngeal Mask and LMA Supreme™: A Randomized Trial of Clinical Performance and Fibreoptic Positioning in Unparalysed, Anaesthetised Patients by Novices. Anesthesiol Res Pract. 2016;2016:4717061.
7. Lee YC, Yoon KS, Park SY, et al. A comparison of i-gel™ and Laryngeal Mask Airway Supreme™ during general anesthesia in infants. Korean J Anesthesiol. 2018;71:37-42.
8. Kim MS, Oh JT, Min JY, et al. A randomised comparison of the i-gel™ and the Laryngeal Mask Airway Classic™ in infants. Anaesthesia. 2014;69:362-367.
9. Pant D, Koul A, Sharma B, et al. A comparative study of laryngeal mask airway size 1 vs. i-gel size 1 in infants undergoing daycare procedures. Paediatr Anaesth. 2015;25:386–391.
10. Beringer RM, Kelly F, Cook TM, et al. A cohort evaluation of the paediatric i-gel(™) airway during anaesthesia in 120 children. Anaesthesia. 2011;66:1121-1126.
11. Chauhan G, Nayar P, Seth A, et al. Comparison of clinical performance of the I-gel with LMA proseal. J Anaesthesiol Clin Pharmacol. 2013;29:56-60.
12. Gatward JJ, Cook TM, Seller C, et al. Evaluation of the size 4 i-gel airway in one hundred non-paralysed patients. Anaesthesia. 2008;63:1124–1130.
13. Kleine-Brueggeney M, Gottfried A, Nabecker S, et al. Pediatric supraglottic airway devices in clinical practice: A prospective observational study. MC Anesthesiol. 2017;17:119.
14. Theiler LG, Kleine-Brueggeney M, Luepold B, et al. Performance of the pediatric-sized i-gel compared with the Ambu Aura Once laryngeal mask in anesthetized and ventilated children. Anesthesiology. 2011;115:102-110.