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COMPARISON OF GLIDESCOPE® TITANIUM (VERATHON) AND FLEXIBLE INTUBATION VIDEO ENDOSCOPE® (FIVE, STORZ) IN TERMS OF INTUBATION SUCCESS IN INFANTS WITH PIERRE ROBIN SEQUENCE

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MATERIAL – METHOD

Our study is a prospective randomized controlled trial. Intubation success and intubation times were compared with Flexible Intubation Video Endoscope (FIVE)® or GlideScope® Titanium devices in patients with Pierre Robin Sequence. Hacettepe University Clinical Research Ethics Committee (Date: 23.02.2021, Decision No: 2021/4-16 KA-20115) and Turkish Medicines and Medical Devices Agency (TITCK) approval letter was obtained (Number; E-688699933-511.06- 365554).

Patients with Pierre Robin Sequence who were younger than 12 months and underwent elective surgery under general anesthesia between March 2021 and December 2023 were included in the study. Patients requiring emergency surgery, patients requiring rapid sequence intubation, patients who had already been intubated or tracheostomized to the operating room, patients who would not be operated on under general anesthesia, patients who did not have family consent and who could not provide informed consent were excluded from the study. Randomization was performed by a research assistant using a computer to generate random numbers 1 and 2 and was terminated when the minimum number of patients in each group was reached. Number 1 was assigned to the GlideScope® Titanium and number 2 was assigned to the Flexible Intubation Video Endoscope® (FIVE). Both devices are routinely used successfully as the first choice in this patient group in our clinic. Randomization was concealed in a sealed envelope from the operator and the operator was informed after parental consent to participate in the study was obtained. Endotracheal intubation was performed by 2 faculty members who were experts in the field. Since faculty members would not know the assigned intubation device before the patient was taken to the operating room, both devices were kept ready in the room. In randomized patients, GlideScope® Titanium (Verathon) or Flexible Intubation Video Endoscope® (FIVE) 11301 abx, 2.85 mm (Storz) devices were compared in terms of intubation success as the primary outcome and our specified secondary outcome measures.

After patients were monitored with routine monitoring (SpO2, noninvasive blood pressure, ECG, pulse), induction was applied in accordance with the clinical experience of the operator and intubation was started with the endotracheal tube selected in accordance with the clinical experience of the relevant operator. As a standard in our center, patients with Pierre Robin Sequence are taken to the operating room without premedication in order to avoid possible respiratory complications. Before anesthesia induction, vascular access is evaluated, and if appropriate, vascular access is established with a 24-26 Gauge IV cannula before induction or following induction according to the preference of the responsible anesthesiologist. Before anesthesia induction, preoxygenation with 100% oxygen is routinely applied and apneic oxygenation is applied with various techniques appropriate for the patient at all stages of the procedure. In anesthesia induction, 8% sevoflurane, 1 mg/kg methylprednisolone, 0.8-1.0 mg/kg rocuronium are used in 80% oxygen - 20% air mixture. Dexmedetomidine or remifentanil infusion is preferred as analgesic. Long-acting opioids are avoided as a standard approach in this patient group. Following standard two-handed AND technique mask ventilation, intubation is performed, and the intubation technique was selected together with the randomization method specified in our study.

If GlideScope® Titanium was to be used, a 50-60° angle was applied with the appropriate stylet and the appropriate one was selected from the 3 pediatric blade sizes according to the clinical experience of the operator. If Flexible Intubation Video Endoscope® (FIVE) was to be used, the appropriate endotracheal tube was loaded into the bronchoscope and made ready. The size

and selection of the endotracheal tube to be used were not changed for the purpose of the study. The operator used the selection he/she made routinely for the patient according to his/her body weight and physical development. The number of attempts for successful intubation and the duration were recorded by an unblinded research assistant. The chronometer was started when the FFB or the videolaryngoscope started to pass through the patient's mouth/nose and the chronometer was stopped when the ventilation of the lungs was confirmed with the end tidal carbon dioxide trace and this time was recorded as the successful intubation time. The time between the FFB or the videolaryngoscope passing through the mouth/nose and the best glottic view was obtained was recorded as the best glottic visualization time. The operator reported the percentage of glottic opening score (POGO) and Cormack Lehane scores after obtaining the best glottic visualization in the Glidescope group. In accordance with standard clinical practice, the operator was allowed to perform optimal external laryngeal manipulation as required during laryngoscopy. Endotracheal tube passage time was defined as the intubation time minus the best glottic visualization time and was recorded. Failed intubation was defined as an intubation attempt exceeding 120 seconds or removal and repositioning of the airway device from the mouth/nose or esophageal intubation. If the intubation attempt exceeded 120 seconds or the patient's SpO2 value fell below 85% and/or bradycardia occurred at any stage of the procedure, the attempt was planned to be terminated if it was ongoing and mask ventilation of the patient was provided. Airway management after unsuccessful intubation was managed in accordance with the difficult airway algorithm under the responsibility of the faculty member in charge. Complications during the attempt were recorded. Complications were determined as esophageal intubation, desaturation defined as SpO2<90%, airway bleeding, soft tissue damage, bradycardia (heart rate below 90 beats/min), systolic hypotension (below 60 mmHg for 0-1 month, 70 mmHg for 1-12 months), dysrhythmia, and cardiac arrest. During this entire process, a difficult airway cart and sugammadex were kept ready to be applied in case of emergency. In patients who were evaluated to have complications or who might need a tracheostomy, a pediatric ENT specialist and a surgical tracheotomy set were present in the operating room. All these preparation processes and procedures are routinely applied in this manner in our clinic.

Objective secondary outcomes included intubation time (time between the passage of the FFB through the patient's mouth/nose or the video laryngoscope through the patient's mouth and the end tidal carbon dioxide trace being seen on the monitor), time to obtain the best glottic visualization, endotracheal tube passage time (intubation time - time to obtain the best glottic view), whether complications developed (esophageal intubation, desaturation, airway bleeding, soft tissue damage, bradycardia, hypotension-hypertension, dysrhythmia, cardiac arrest), CL, and POGO scores. Subjectively, ease of use, ease of placement in the oropharynx/nasopharynx, quality of vision, and ease of tube advancement were evaluated and recorded by the relevant faculty member using a 4-point Likert scale (excellent, good, moderate, poor).

Parameters recorded in the preoperative period in all patients; √ Age, gender, body weight, body surface area (BSA),

√ Additional diseases, accompanying syndromes, medications used, previous surgeries, ASA (American Society of Anesthesiologists) score,

√ Birth history, postpartum APGAR scores,

√ Gastroesophageal reflux, feeding disorders,

√ Preoperative airway evaluation; mouth opening (cm), thyromental distance

(cm), neck range of motion, Frontal Plane-to-Chin Distance (FPCD) measurement for evaluation of jaw retraction (cm), respiratory distress in supine position (yes/no), oxygen requirement (yes/no), hypotonia (yes/no), history of intubation-tracheostomy (yes/no), intensive care unit admission (yes/no), history of Obstructive Sleep Apnea (OSA) (yes/no), history of aspiration (yes/no), presence of laryngomalacia/tracheal stenosis (yes/no), additional physical examination findings,

√ Results of previous bronchoscopic evaluations, if any, computed tomography imaging (cranial/thoracic), magnetic resonance imaging (cranial/thoracic), swallowing tests, echocardiography images and polysomnography

Statistical Analysis

IBM SPSS Statistics ver. 25 (IBM Corporation, Armonk, NY, USA) program was used for data analysis. Whether the distribution of quantitative variables was distributed close to normal was examined with the Shapiro-Wilk test, and whether the assumption of homogeneity of variances was met was examined with the Levene test. Descriptive statistics were expressed as median (25th percentile-75th percentile) for quantitative variables, while qualitative variables were shown as number of cases and (%). As a result of the goodness-of-fit tests, the significance of the differences between the groups in terms of variables for which the parametric test statistics assumptions were not met was examined with the Mann Whitney U test. In the analysis of categorical data, if the expected frequency was below 5 in at least 1⁄4 of the cells in 2x2 cross tables, the categorical data in question were evaluated with Fisher's exact probability test, and when the expected frequency was between 5-25, the Continuity Corrected $\chi 2$ test was used. RxC (in case at least one of the categorical variables in the row or column has more than two results) in the cross tables, if the expected frequency is below 5 in at least 1/4 of the cells, the categorical data in question were evaluated with the Fisher Freeman Halton test. The results were considered statistically significant for $p<0.05$.

Power Analysis

It is not known exactly how much the difference in intubation time is significant in the clinic. There are very few studies in the literature on this subject in pediatric patients and in the patient group with PRS.

In a study conducted by Fiadjoe et al. on a pediatric PRS mannequin, GlideScope Cobalt videolaryngoscope and FFB were compared in terms of their success in the first intubation attempt and no difference was found (88.3% vs. 85%, respectively, p=0.59). Although there was a statistically significant difference in intubation time between the two groups, this difference was not considered clinically significant (median 30.9 s for FFB and 25.1 s for GCV, p=0.04). It was interpreted that significant adverse cardiopulmonary events such as arterial oxygen desaturation, bradycardia and hypotension were unlikely to occur during this period.

Again, Fiadjoe et al. In a study conducted by in a pediatric patient group, Glidescope videolaryngoscope and conventional direct laryngoscope were compared in terms of intubation success and intubation time. In this study, the significant endotracheal intubation time difference was accepted as 10 seconds. In our study, based on the existing literature studies and our clinical experience, the significant endotracheal intubation time difference was accepted as

10 seconds, and the total sample size was calculated as 46 patients, with 23 patients in each group for α=0.05 and 90% power. Patient recruitment continued until the minimum number of patients in each group was reached.

INFORMED CONSENT FORM

PARENT INFORMATION FORM FOR RESEARCH STUDY

(Patient Group)

(Physician's Explanation)

We are conducting a research study titled "Comparison of Intubation Success Between GlideScope® Titanium (Verathon) and Flexible Intubation Video Endoscope® (FIVE, Storz) in Infants with Pierre Robin Sequence," led by Associate Professor Dr. Aysun ANKAY YILBAŞ. With your approval, we propose to include your child in this study. Before you make your decision, we would like to provide you with detailed information about the study. If, after reading and understanding this information, you agree for your child to participate, please sign the form.

As part of standard care, patients are routinely connected to a ventilator to maintain respiration following general anesthesia. Before connecting to the ventilator, a tube is inserted into the windpipe using specific tools, a procedure known as intubation. For patients where intubation is challenging, methods such as video laryngoscopy or flexible fiberoptic bronchoscopy are employed. The purpose of this study is to compare the success rates of video laryngoscopy and flexible fiberoptic bronchoscopy for intubation in patients with Pierre Robin Sequence, where difficult intubation is anticipated. If you approve your child's participation, one of these two devices, which are already routinely used, will be employed for intubation after anesthesia is administered. If you do not approve, one of these devices will still be used as part of standard care. There is currently no study proving the superiority of one device over the other in patients with Pierre Robin Sequence. The aim of this study is to determine the intubation success rate of these devices by randomly assigning one for use during your child's intubation.

Random assignment in our study means that the likelihood of your child being intubated with either the GlideScope® Titanium or the Flexible Intubation Video Endoscope® (FIVE, Storz) is equal. Participants will be divided in a 1:1 ratio for this purpose. Randomization will be carried out by a research assistant using a computer to generate random numbers 1 and 2. Number 1 will be assigned to GlideScope® Titanium, while Number 2 will be assigned to Flexible Intubation Video Endoscope®. The selected device will be concealed in a sealed envelope and disclosed to the attending physician only after parental consent is obtained.

Your participation in this study, conducted by the Department of Anesthesiology and Reanimation at Hacettepe University Faculty of Medicine, is important for the success of the research. However, if you do not consent, one of these two devices will still be used as part of routine care.

No procedural changes will be made specifically for the study. The procedure deemed appropriate by your responsible anesthesiologist will still be implemented. If you agree to participate in the study, routine data recorded during your child's surgery will be documented by Associate Professor Dr. Aysun ANKAY YILBAŞ, Professor Dr. Özgür CANBAY, or a physician assigned by them. No additional tests, medications, or procedures will be conducted during the surgery. The study will begin after routine preoperative data is recorded and anesthesia is administered, continuing until the completion of the intubation procedure.

Between April 2021 and August 2022, 46 infants under the age of 18 months, who meet the eligibility criteria and whose parents provide informed consent, will be included in the study. You will be promptly informed of any new information that may affect your willingness to continue participation in the study.

For patients with anticipated difficult intubation, intubation will be performed using the most commonly used and gold-standard devices, as well as by the most experienced faculty members. Throughout the procedure, all routine and emergency medications and equipment expected to be required will be kept ready. If a more advanced procedure, such as tracheostomy (a direct access to the windpipe through the skin), becomes necessary, a pediatric otolaryngologist will be present. The study does not involve any application that would necessitate this procedure in your child. However, during normal procedures, such preparations are routinely made in our clinic to ensure your safety in case of emergencies.

Your child will not undergo any additional procedures, and if conditions arise that would typically prevent surgery, your child may be excluded from the study with your knowledge.

No procedural changes will be made specifically for the study. Therefore, aside from the routine risks mentioned above, your child will not be subjected to any additional harm due to the study. Similarly, as no changes to the standard procedure are made for the study, participation will not provide any additional benefit to your child.

You will not be charged any fees for your child's participation in this study. Additionally, no compensation will be provided to you for consenting to your child's participation. Medical information regarding your child will be kept confidential but may be reviewed by personnel monitoring the quality of the study, ethics committees, or official authorities if necessary. Data obtained from the study may be used for scientific publications without revealing names or identifying information.

You may refuse to have your child participate in this study. Participation in this research is entirely voluntary, and your refusal will not result in any changes to your child's treatment. You also have the right to withdraw your consent at any stage of the study.

(Parent/GuardianDeclaration)
I have been informed about the research study conducted by Associate Professor Dr. Aysun ANKAY YILBAŞ at Hacettepe University Faculty of Medicine, Department of Anesthesiology and Reanimation, and its details have been conveyed to me. Following this information, my child has been invited to participate in this research as a "participant."

If I agree to my child's participation in this study, I believe that the confidentiality of my child's information, which must remain between me and the physician, will be handled with great care and respect throughout the study. I have been adequately assured that my child's personal information will be protected with care during the educational and scientific use of the study results.

I will not bear any financial responsibility for expenses related to the study. No payment will be made to me.

I have been provided assurances that in the event of any health issues arising directly or indirectly from the study, all necessary medical interventions will be provided (and I will not incur any financial burden for these interventions).

Should I encounter any health issues during the study, I know I can reach Associate Professor Dr. Aysun ANKAY YILBAŞ at 03123051250 (office) or 05325546801 (mobile), Research Assistant Begüm ERCAN at 03123051250 (office) or 05387226672 (mobile), or the Hacettepe University Faculty of Medicine, Department of Anesthesiology and Reanimation.

I am not obligated to consent to my child's participation in this study and may refuse. I have not faced any coercion regarding my child's participation in this study. If I refuse my child's participation, I understand that this will not harm my child's medical care or the relationship with the physician.

If my child participates in the study, I am aware that my child will not be subjected to any additional harm from the study and that participation will not provide any additional benefit.

I have fully understood all the explanations provided to me. After an independent period of consideration, I have decided to allow my child to participate in this research project as a "participant." I accept this invitation with great satisfaction and willingness.

A signed copy of this form will be provided to me.

Parent's Name and Surname:
Relationship to the Participant:
Date:
Signature:

Witness to the Interview:
Name and Surname:
Date:
Signature:

Physician Conducting the Interview:
Name, Surname, Title:
Date:
Signature:

Principal Investigator: Associate Professor Dr. Aysun ANKAY YILBAŞ
Date:
Signature: