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SPECIAL ARTICLE

Investigation of the effectiveness of preoperative intubation simulation using a custom-made simulator for pediatric patients with difficult airway: a pilot study

Tomoyuki Kanazawa[1]

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Abstract

The purpose of this study is to investigate whether preoperative intubation simulation using custom-made simulator is useful during anesthesia induction for the children who have difficult airway. We included the children under 15 years of age who have difficult airway which had been already known. Prior to the scheduled surgery, CT imaging was performed and a 3D reconstruction of the face from the chest was performed. Then custom-made airway simulator was made. We tried to intubate custom-made simulator of patients preoperatively. We planned how to intubate the patient for anesthesia induction from the result of intubation simulation. The findings of direct laryngoscopy were compared with the findings during intubation. Three patients were included in this study. It took up to 3 weeks to create a simulator, which was difficult due to time constraints to accommodate emergency surgeries. Simulation findings correlated well with findings during anesthesia induction. There were no cases of severe hypotension or hypoxia during induction of anesthesia with the planned intubation method. In conclusion, preoperative intubation simulation using custom-made simulator may be useful for the patients who have difficult airway.

Keywords Pediatric patients · Difficult intubation · Custom made simulator · Preoperative simulation

Abbreviations

CT Computer tomography
3D Three dimensional

Introduction

Failure of airway management during induction is a major cause of cardiac arrest and death due to anesthetic management [1–4]. Guidelines have been developed primarily for adults with unpredictable airway management difficulties.

However, some pediatric patients are known to have preoperative intubation difficulties due to anatomic abnormalities of the airway caused by congenital diseases. There are no clearly defined airway management guidelines for these conditions. Many studies have shown the usefulness of intubation training using simulators of common pediatric models to avoid hypoxia during intubation in children [5]. However, only a few studies have examined simulation for intubation difficulties in children [6]. The reason for this is that there is no simulator that can reproduce difficult intubation. In collaboration with a simulator manufacturer, we developed a simulator from a patient's computer tomography (CT) that reproduced the mobility of the neck and temporomandibular joints and the mucosa of the pharyngeal orifice more reproducibly than conventional simulators. The purpose of this study was to evaluate the patient reproducibility of the new patient-customized simulator created from the patient's CT data and to determine whether safe induction of anesthesia can be performed by simulating preoperative intubation.

Methods

Design

This was a prospective pilot study. The aim of this study is to investigate the patient reproducibility of the new

✉ Tomoyuki Kanazawa
tyskanazawa@gmail.com

[1] Department of Pediatric Anesthesia, Okayama University Hospital, 2-5-1 Shikatachou, Kitaku, Okayama 700-8558, Japan

patient-customized simulator created from the patient's CT data and to determine whether safe induction of anesthesia can be performed by simulating preoperative intubation. Our institutional research committee approved this study and its submission for publication (No 1801-005) and written informed consent was obtained from patients' parents and/or guardians before they were included this study. This study was registered to University Hospital Information Network (UMIN) Clinical Trial Registry before we started to include the children (UMIN000030627). Written informed consent was obtained from all patients' parents and guardians before patients were included the study.

Study population

This study was conducted in a tertiary teaching hospital. Inclusion criteria were under 15 years of age and the experience of difficult intubation at previous operation.

Data on age, gender, body weight, diagnosis, the method of anesthesia induction, blood pressure, heart rate, and oxygen saturation were prospectively collected and withdrawn from electrical record.

CT scan and simulator creation

After patients were included this study, they received CT scan to evaluate upper airway anatomy before surgery. The data of CT scan were sent to the medical device manufacture (MIKOTO technology, Tottori, Japan). They did three-dimensional (3D) analysis of the CT data and made the custom-made simulator for the patient.

Preoperative simulation of tracheal intubation

We did intubation simulation at least one day before operation using custom-made simulator. Mask-bag support and intubation simulations were performed using direct laryngoscopy, video laryngoscopy, and, if necessary, a fiberoptic bronchoscope. Cormack grade was recorded for each device used. We also performed whether bag-mask ventilation was possible. Finally, we decided the intubation strategy based on the results of the intubation simulation.

Anesthesia induction

Anesthesia induction was performed under strategy's determined by intubation simulation, and the patient was intubated. To evaluate the accuracy of the simulator's airway anatomy, the evaluation chart (see in supplementary materials 1) was used to assess the degree of agreement between the airway assessment during simulation and actual intubation.

The usefulness of anesthesia planning based on preoperative simulation was also evaluated using the evaluation chart (see supplementary materials 2).

Results

Three patients were included during the study period. There were three cases in which the simulator could not be prepared because there were less than 1 week before preoperative consultation with anesthesiologist.

Case 1

A total repair was planned for a 6-month-old girl who had mitral stenosis and hypoplastic left ventricle. She has already had bilateral pulmonary artery banding at 5-day age (weight 2 kg). Four intubation procedures were performed during intubation at that time, and the patient was noted to have difficulty intubating. Total repair was planned at 6 months of age, and CT imaging was performed at 4 months (weight 3.9 kg) to create a simulator. Figure 1-1 shows the completed simulator of this patient. The simulator creation required 48 days from CT imaging to completion. The simulator can be set to any degree of mouth opening and range of motion of the neck, and simulation was performed after setting the mouth opening to 1.5 lateral fingers and no restriction of cervical retroflexion based on patient information. Since mask ventilation was possible without oral/nasal airway and the direct laryngoscopy and video laryngoscopy findings were consistent with Cormack II in the simulation, the plan of anesthesia induction was to perform a usual induction of anesthesia and to intubate her using video laryngoscope (MacGRATH, blade 2). Anesthesia induction went smoothly, and the patient was properly ventilated with bag mask simultaneous method with the simulation and intubated without problems, although there was a mild hypoxic event for just a short period. The evaluation of the simulator and the justification of the anesthesia plan are both excellent (Table 1).

Case 2

A pulmonary artery banding was planned for a 5-month-old boy (body weight 3.4 kg, height 50 cm) who had mitral ventricular septal defect. He also had multiple abnormality on his face, limbs, and cerebellum. He previously had been intubated just after birth and resulted in difficult intubation at that time. Extubation failed and he had tracheostomy.

Total repair was planned at 6 months of age, and CT imaging was performed at 3 months (weight 2.9 kg) to create a simulator. Figure 1-2 shows the completed simulator of this patient. The simulator creation required 34 days from

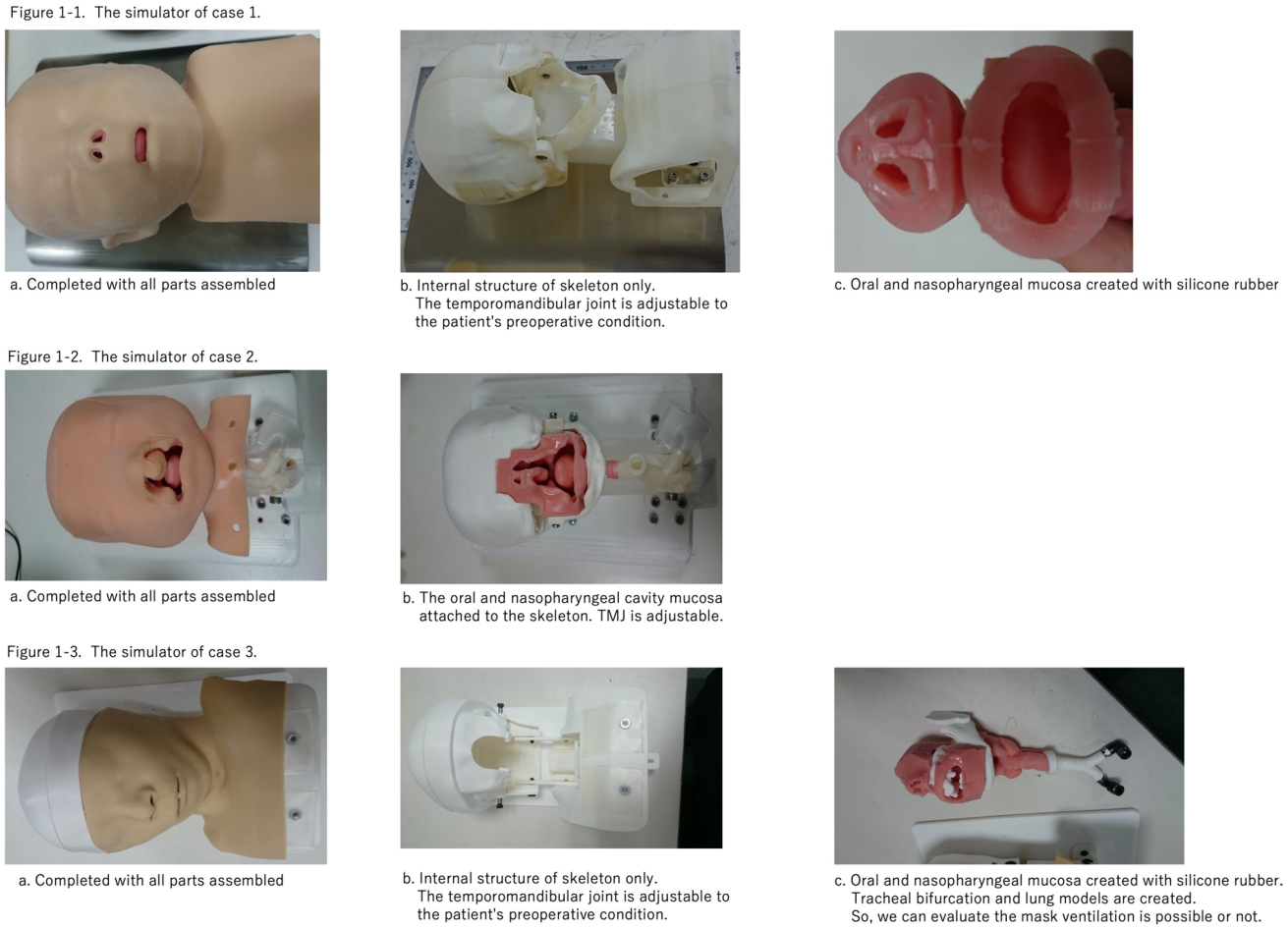

Fig. 1 The custom-made simulator of each patient

Table 1 Results of evaluation of simulator quality and simulation accuracy

	Case 1	Case 2	Case 3
Accuracy of custom-made simulators	Excellent	Good	Good
Evaluation of preoperative intubation simulation	Excellent	Excellent	Excellent

CT imaging to completion. The simulator can be set to any degree of mouth opening and range of motion of the neck, and simulation was performed after setting the mouth opening to 1.5 lateral fingers and no restriction of cervical retroflexion based on patient information. The result of preoperative intubation simulation was Cormack III for both direct and video laryngoscopes. Since he had already had tracheostomy, the plan of anesthesia induction was to perform using sevoflurane, fentanyl and rocuronium through tracheostomy tube and to intubate him using video laryngoscope (Mac Grath, blade 2). If intubation was difficult with the video laryngoscope, he was scheduled for intubation with fiberoptic intubation. Anesthesia induction went smoothly, and the patient was intubated without any hemodynamic and respiratory variation. The findings of direct laryngoscope during actual anesthesia induction was matched with Cormack III, but the findings of video laryngoscope was mismatched with Cormack II. The evaluation of the simulator and the justification of the anesthesia plan are good and excellent (Table 1).

Case 3

A mandibular lengthening surgery was planned for a 92-month-old boy (body weight 23.6 kg, height 117 cm) who had Nager syndrome. He had undergone a tracheotomy at birth due to severe micrognathia caused by Nager syndrome.

Respiratory condition improved as the patient grew, and a few months before the surgery, the tracheostomy was closed, but severe intubation difficulties were anticipated. CT imaging was performed to create a simulator 2 weeks

before surgery. Figure 1-3 shows the completed simulator of this patient. The simulator creation required 9 days from CT imaging to completion. The simulator can be set to any degree of mouth opening and range of motion of the neck, and simulation was performed after setting the mouth opening to 1 lateral finger. Severe restriction of cervical retroflexion was pointed out based on patient information. Mask-bag ventilation for simulator was possible, but thoracic movement and air entry into the lungs were not complete, and the loss of spontaneous respiration during the actual induction of anesthesia was predicted to be highly injurious. Then, it was impossible to insert any laryngoscope through the mouth in preoperative simulations. Even with a fiberoptic bronchoscope, an oral approach was deemed impossible and intubation through the mouth was not possible. When the fiberoptic bronchoscope was inserted nasally, the glottis was visible although the narrowing of the space due to collapsed pharyngeal larynx due to the effects of anesthesia that was expected. After preoperative intubation simulation, we decided on a strategy of fiberoptic nasotracheal intubation with slow induction, preserving spontaneous breathing. Induction of anesthesia at the time of surgery was performed as planned preoperatively; although hypoxia in the SpO_2 80 range was noted, intubation was successful without severe complications. As same as preoperative intubation simulation, we were not able to insert any laryngoscope through his mouth. Since no laryngoscope or bronchoscope could approach the patient through the mouth, only the nasal fiberoptic bronchoscope findings were evaluated for video laryngoscope/fiberoptic bronchoscope findings. The evaluation of the simulator and the justification of the anesthesia plan are good and excellent (Table 1).

Discussion

Key finding

This is the first study to examine the utility of preoperative intubation simulation using a custom-made simulator for patients with known intubation difficulties. This study also examined how well a custom-made simulator created using simultaneous CT images could reproduce the patient's actual airway anatomy.

Junhyeok et al. [6] reported one case to assesse the accuracy of airway simulator of the patient who had Crouzon syndrome. They reported that *"this difficult tracheal intubation phantom could provide realistic simulation experience…"*. However, they did not simulate intubation, nor did they compare the accuracy of the simulator to actual intubation of the patient. We evaluated whether the custom-made simulator accurately reproduced the patient's airway, and also evaluated the usefulness of preoperative intubation simulation using the simulator. This point is a novel finding that has not been previously reported.

The evaluation of accuracy of custom-made simulator

Recently, 3D printers are used to create patient organs for preoperative simulation [7–9]. However, it is difficult to create a simulator that can accurately reproduce the airway. The main reason for this is that the airway is made up of a variety of different tissues, including skin, mucous membranes, tongue and jaw joints. In our study, we created each part with the appropriate material to reproduce the tissue based on CT images. The TMJ was made to be freely adjustable and was set to match the patient's actual opening. From the result of our study, the accuracy of the custom-made simulator was rated as excellent (case 1), good (case 2), and good (case 3), indicating that they were almost accurately created. Although the simulator was highly accurate and was able to reproduce almost all the patient's airway, airway changes due to soft tissue collapse after anesthesia were not completely reproduced. This is the reason why the video laryngoscope and fiberoptic bronchoscope findings in Cases 2 and 3 were not consistent and the evaluation was good. In this study, there was no difference in the assessment of mask ventilation during simulation and induction of anesthesia, but as the number of cases increases, soft tissue collapse due to anesthetic agents may affect the results. We set the evaluation "good" in Table 1, if the mask bag ventilation is mismatched and the Cormack and video laryngoscopy are matched.

The utility of preoperative intubation simulation

Furthermore, the evaluation of preoperative intubation simulation using the custom-made simulator were excellent in all cases because we were able to intubate the patients just as planned based on simulation. Cases 1 and 3 experienced mild hypoxia for very short periods of time, but were not considered significant vital fluctuations or dangerous conditions, that is the reason for the evaluation of intubation strategies based on simulation was considered Excellent. Since tracheal intubation in children is more difficult than in adults, several studies have reported on the effectiveness of simulation training for tracheal intubation in pediatric patients, and some have reported that simulation training increases the success rate of tracheal intubation [10–12]. However, this is the first study to examine the effects of preoperative simulation on a specific patient using a patient custom-made simulator. The result of this study suggested that creating a custom-made simulator and performing preoperative intubation simulation may be beneficial for patients with intubation difficulties.

Limitations

This study has limitations. First, as I mentioned that to create a custom-made simulator, one must combine many parts with different tissues, such as skin, mucosa, tongue, and temporomandibular joint, and the most important issue is whether it can accurately represent these parts. Therefore, the creation of the simulator takes a very long time, and the patient had to be known at least 2 months before the surgery. However, this event was resolved as the number of simulators created increased. While the first simulator took 48 days to create, the second took 34 days, and the third was reduced to 9 days. This was considered clinically feasible to create a custom-made simulator, consistent with the usual timing of a preoperative anesthesiology visit.

Second, cost is an issue, as it costs USD 7000 to create one unit. However, three simulators were created in this study and costs were gradually reduced. It was found that once the skeletal base was completed for patients weighing less than 3 kg, around 5 kg, around 10 kg, and over 20 kg, costs could be reduced. Furthermore, as more and more custom-made simulators were created (several more patients in each weight category), cost reductions became possible, and the final price was estimated to be less than 700 USD.

Third, a custom-made simulator must be created by taking CT images and sending the digital data to a simulator production company. There are only a limited number of companies that can produce the product, limiting its versatility.

Finally, this study is a pilot study, and the number of patients is very small. Each patient has a different airway anatomy and different intubation difficulties. Therefore, in order to validate this study, larger number of patients are needed to evaluate the usefulness of the simulator. John et al. reported that the ratio of complication during intubation in the patients with anticipated difficult airway was 37% (severe complication and non-severe complication) [13]. From this pilot study, we predicted that the simulator was so effective that the complication rate could be significantly reduced. We need 80 patients from the power analysis to decrease the complication ratio from 37 to 10%. However, recruiting 80 patients with intubation difficulties is extremely difficult at a single center and in terms of reducing bias, we need multicenter study in the future.

Conclusion

In conclusion, custom-made simulator can be accurately created from CT scan for pediatric patients with difficult airway. In addition, preoperative intubation simulation using patient custom-made simulator may be useful for safety intubation during anesthesia induction. Further studies should be conducted to confirm the potential utility of patient custom-made simulator for pediatric patients with difficult airway.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00540-024-03407-4.

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Author contributions TK participated in the design of the study. TK collected the data and performed the statistical analysis. TK wrote, revised and edited the manuscript.

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Data availability Please contact author for data requests.

Declarations

Conflict of interest This study was supported by the grants-in-aid for scientific research from Japanese Society of Anesthesiologists (Grant Number 17B0010).

Ethical approval and consent to participate Okayama University Hospital Institutional Review Board waived the need for obtaining informed consent and approved this study and its submission for publication (No 1801-005). If you have any question, please contact following address. Mailing address: 2-5-1 Shikatachou, Kitaku, Okayama, Okayama 700-8525, Japan. Phone: +81-86-235-6503. Fax: +81-86-235-7552. Email: mae6605@adm.okayama-u.ac.jp.

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