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Prediction of endotracheal tube size using a printed three-dimensional airway model in pediatric patients with congenital heart disease: a prospective, single-center, single-group study

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Background: To determine the correct size of endotracheal tubes (ETTs) for endotracheal intubation of pediatric patients, new methods have been investigated. Although the three-dimensional (3D) printing technology has been successful in the field of surgery, there are not many studies in the field of anesthesia. The purpose of this study was to evaluate the accuracy of a 3D airway model for prediction of the correct ETT size, and compare the results with a conventional age-based formula in pediatric patients.
Methods: Thirty-five pediatric patients under six years of age who were scheduled for congenital heart surgery were enrolled. In the pre-anesthetic period, the patient's computed tomography (CT) images were converted to Standard Triangle Language (STL) files using the 3D conversion program. A Fused Deposition Modelling (FDM) type 3D printer was used to print 3D airway models from the sub-glottis to the upper carina. ETT size was selected by inserting various sized cuffed-ETTs to a printed 3D airway model.
Results: The 3D method selected the correct ETT size in 21 out of 35 pediatric patients (60%), whereas the age-based formula selected the correct ETT size in 9 patients (26%).
Conclusions: Prediction of the correct size of ETTs using a printed 3D airway model demonstrated better results than the age-based formula. This suggests that the selection of ETT size using a printed 3D airway model may be feasible for helping minimize re-intubation attempts and complications in patients with congenital heart disease and/or those with an abnormal range of growth and development.

Keywords: Airway management; Computer simulation; Computed tomography; Congenital heart disease; Endotracheal intubation; Three-dimensional printing; Trachea.

Introduction

To determine the correct size of endotracheal tubes (ETTs) for endotracheal intubation of pediatric patients is no menial task. The conventional method of determining ETT size is based on children's ages with the presumption of normal growth and development; therefore, applying the same method to children who do not follow this pattern due to disease makes this method hardly applicable [1]. In the past, the use of uncuffed ETTs was recommended due to concerns about possible complications after endotracheal intubation under six years of age [2]. Recent studies showed that cuffed ETT does not increase the risk of post-extubation stridor compared with uncuffed ETT [3,4] However, it is important to select the correct size of cuffed ETT, so as not to tightly seal the trachea, and increase the risk of reintubation.

In particular, in pediatric patients undergoing cardiac surgery due to congenital heart disease, there may be accompanying airway anomalies. Furthermore, most patients need to maintain the ETT after surgeries for a certain period of time. In addition, pediatric patients with congenital heart disease may have impaired growth and development [5,6]. For this reason, it may be difficult to find an appropriate size ETT using an age-based formula; several studies have suggested their own modified formula [7–9]. Determining the correct ETT size is highly important, because endotracheal intubation with an improperly sized ETT can lead to complications such as airway injury, mucosal ischemia or edema, post-extubation wheezing, subglottic stenosis, improper ventilation, and pulmonary aspiration [10].

Currently, the importance of personalized treatment is increasing and conventional methods need to evolve based on the development of science and technology. Printed three-dimensional (3D) airway modeling is one of these techniques, which is used for airway evaluation and surgical treatment, and its usefulness has been reported [11–13]. As a pre-anesthetic plan to predict the correct ETT size, we considered intubating various ETT sizes on a printed 3D airway model of each pediatric patient. The purpose of this study was to evaluate the accuracy of a 3D airway model for prediction of the correct ETT size in pediatric patients, and to compare the results with a conventional age-based formula.

Materials and Methods

This study involved 35 pediatric patients. Written informed consent was obtained by the legal guardians. Ethical approval was provided by the Institutional Review Board of the Pusan National University Yangsan Hospital, Yangsan, Korea (Ref: 05-2019-116). The clinical research was registered at ClinicalTrials.gov (Ref: NCT04814888), and conducted in accordance with the Helsinki Declaration 2013. We required a sample size of 35 to achieve 80% power, and a significance level (alpha) of 0.05, using a two-sided paired t-test with reference to Schramm et al.'s study [14]. We enrolled children under 6 years of age (range 4 days to 61 months) scheduled for surgery for congenital heart disease from September 3, 2019 to March 16, 2020 with chest computed tomography (CT) images including upper airways even if the patient had a high level of the American Society of Anesthesiologists (ASA) physical status. Pediatric patients with congenital heart disease were chosen because they usually keep their ETT with mechanical ventilation in the intensive care unit for longer lengths of time. In addition, these children have a relatively high risk of complications associated with ETT compared to healthy patients. Exclusion criteria were as follows: pediatric patients with intubation or tracheostomy before general anesthesia due to underlying disease, small sized airway with inner diameter < 3.0 mm because of preterm or low birth weight, unstable vital signs during induction, history of difficult intubation, or emergency surgery where printing a 3D airway model in advance was not possible (Fig. 1).

In the pre-anesthetic plan, Digital Imaging and Communications in Medicine files of pediatric patients' CT images were con-

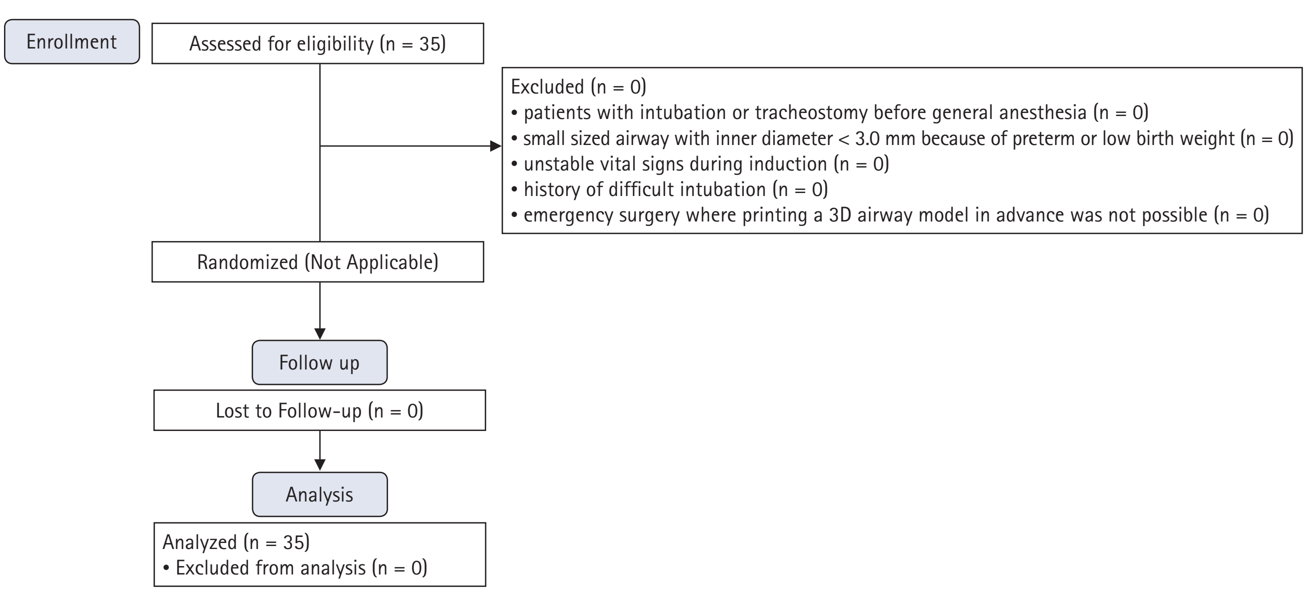

Fig. 1. CONSORT flow diagram.

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verted to Standard Triangle Language (STL) files using the 3D conversion software open-source program InVersalius (InVersalius 3.0, Renato Archer Information Technology Center, Brazil) (Fig. 2A). The STL files were converted to G-Code files for 3D printing using CreatWare 6.4.6 (CreatWare 6.4.6, Henan Suwei Electronic Technology Co., Ltd., China) (Fig. 2B). A Fused Deposition Modelling (FDM) type 3D printer CreatBot (CreatBot F430, Henan Suwei Electronic Technology Co., Ltd., China) was used to print 3D airway models from the sub-glottis to the upper carina (Fig. 3A). We also considered the interval between the date of the preoperative CT scan and the date of surgery for avoidance of bias. Fortunately, preoperative CT scan for congenital heart surgery is usually performed one to seven days before surgery in our hospital.

Two anesthesiologists unaware of patient's demographic data such as height, weight, and age, predicted and recorded the ETT size by inserting various sized cuffed-ETTs (MallinckrodtTM Hi-Lo tracheal tube, Covidien, Ireland) (Table 1) to a printed 3D airway model (Figs. 3B and 3C). If the diameter of the trachea is undersized, air leak around the ETT can occur. In that case, we can use that ETT after inflating the pilot balloon with a small amount of air. We used cuffed ETT because we think that this is more beneficial to patients than another trial of intubation. For the conventional method, an age-based formula (ID [mm] = [age in

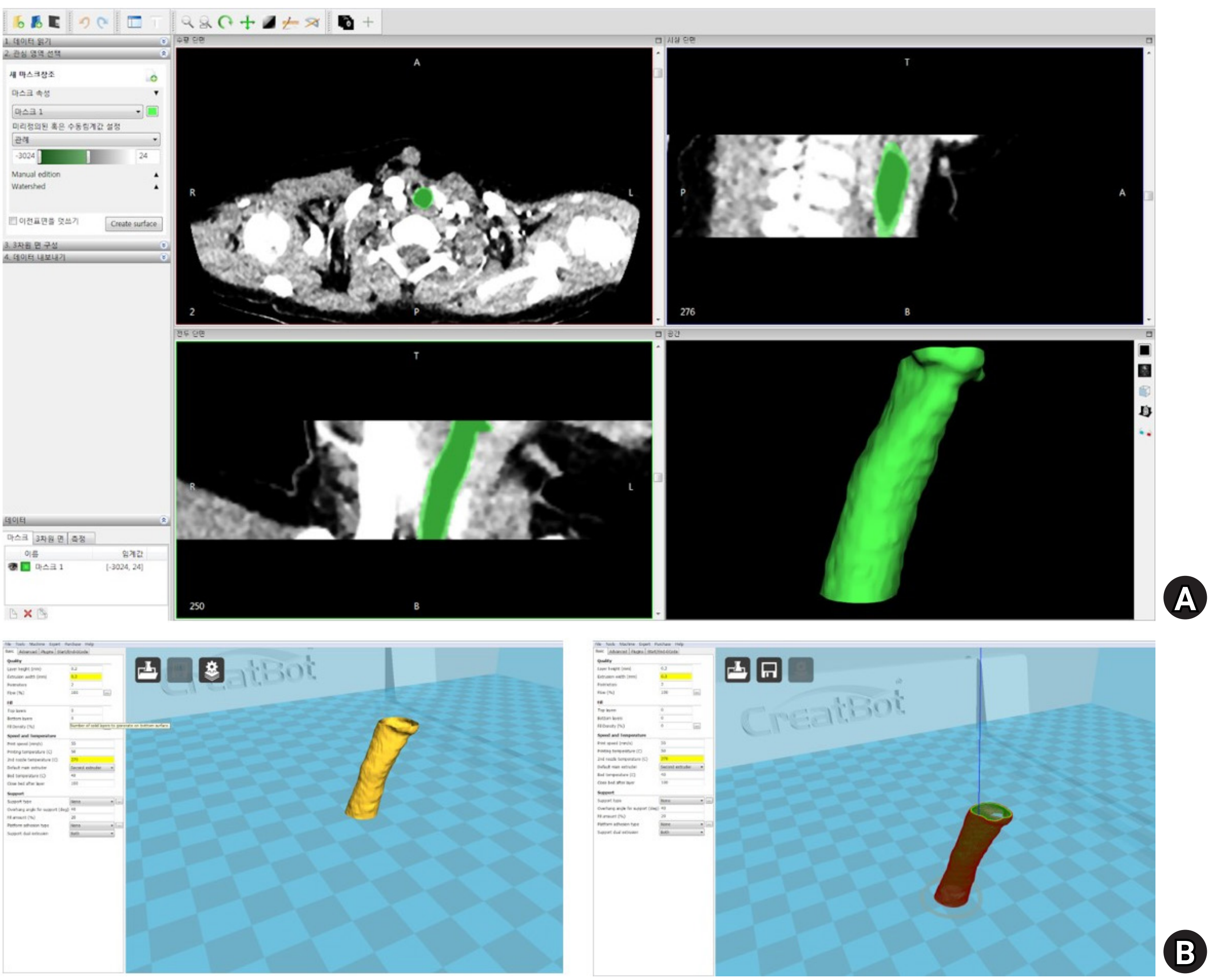

Fig. 2. The methods for conversion of image from CT. (A) DICOM files of pediatric patients CT images were converted to STL files using the 3D conversion software-open source program InVersalius (InVersalius 3.0, Renato Archer Information Technology Center, Brazil). (B) The STL files were converted to G-Code files for 3D printing using CreatWare 6.4.6 (CreatWare 6.4.6, Henan Suwei Electronic Technology Co., Ltd., China). CT: computed tomography, DICOM: Digital Imaging and Communications in Medicine, STL: Standard Triangle Language, 3D: three-dimensional.

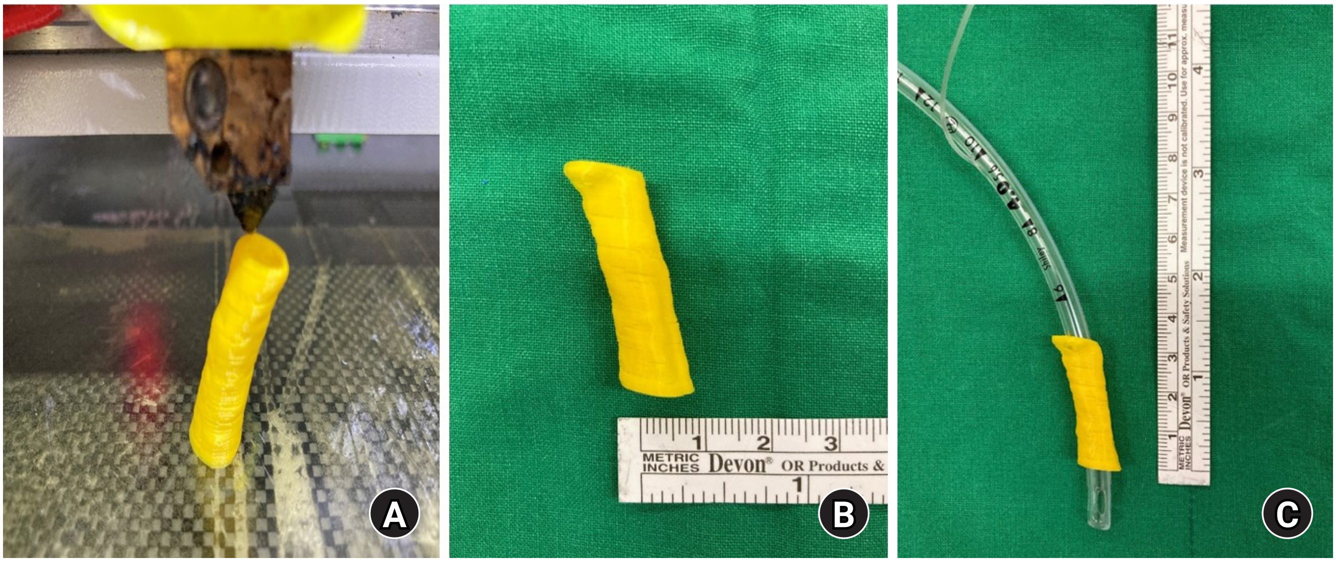

Fig. 3. The process of 3D printing and simulation. (A) An FDM type 3D printer CreatBot (CreatBot F430, Henan Suwei Electronic Technology Co., Ltd., China) was used to print 3D airway models from the sub-glottis to the upper carina. (B) Printed 3D airway model, (C) Various sized cuffed-ETTs were inserted into a printed 3D airway model by two anesthesiologists unaware of the patient's demographic data such as patient's height, weight, and age before intubation. ETT: endotracheal tube, FDM: fused deposition modeling, 3D: three-dimensional.

Table 1. Recommendations for Age-based Cuffed ETT Size Selection and External Diameter of Cuffed ETT (Mallinckrodt)

Age group	Recommended ETT size	Inner diameter (mm)	Outer diameter (mm)
Term	3.0–3.5	3.0	4.3
1–6 months	3.5	3.5	4.9
7–12 months	3.5–4.0	4.0	5.6
1–2 years	4.0–4.5	4.5	6.2
3–4 years	4.5	5.0	6.9
5–6 years	4.5–5.0	5.5	7.5

ETT: endotracheal tube.

years/4] + 3.5, ID; internal diameter) (in case of a cuffed ETT, 3.5 instead of 4 is used because the cuff increases the outer tube diameter by approximately 0.5 mm) was employed; next, we calculated and recorded the ETT size [2,15]. The nearest commercially available ETT size within 0.3 mm by age-based formula was determined with reference to Schramm et al. [14].

Standard monitoring (non-invasive blood pressure measurement, electrocardiogram, and pulse oximetry) was applied to pediatric patients in the operating room. General anesthesia was induced with ketamine 1 mg/kg and rocuronium 0.6 mg/kg and maintained with sevoflurane. After intubation with a cuffed ETT by a printed 3D airway model was finished, an air leak test was performed by one of three anesthesiologists dedicated to pediatric cardiac anesthesia.

To evaluate the conformity of ETT size, the patient was laid supine in a neutral position, and airway pressure was gradually increased to ≥ 20 cmH_2O; then audible air leak was checked by a stethoscope in the patient's mouth or throat by three anesthesiologists who were in charge of anesthesia for pediatric cardiac surgery. If there was audible leakage under 10 cmH_2O or no audible leakage over 20 cmH_2O, the anesthesiologists considered that the ETT size was not optimal. According to studies by Shibasaki et al. [10] and Weiss et al. [4], we used 20 cmH_2O as a higher limit for the air leakage test. The pilot balloon was inflated if there was an audible leakage under 10 cmH_2O, and the cuffed ETT was kept in the patient's trachea if there was no audible leakage over 20 cmH_2O. The duration of mechanical ventilation in the intensive care unit is usually several hours, and we feel that avoidance of reintubation is preferable to the patient. The reliability of the ETT size prediction by the printed 3D airway model was compared with the results of the age-based formula. Intubation-related complications were evaluated by the anesthesiologist and the surgeon from the end of anesthesia until hospital discharge.

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Results

Demographic data is shown in Table 2. Non-normal continuous variables were expressed as median (Q1, Q3). Our method selected the correct ETT size in 21 out of 35 pediatric patients (60%), whereas the age-based formula selected the correct ETT size in 9 patients (26%) (Table 3). Our method over-estimated the ETT size in 11 of 14 patients and under-estimated size in 3 patients, whereas the age-based formula over-estimated the ETT size in 13 out of 26 patients and under-estimated size in 13 patients (Tables 3 and 4, Fig. 4). The nine successful intubations using age-based formula included five cases (cases 11, 17, 22, 28, 33) matched with the 3D airway model, and four other cases (cases 6, 8, 26, 29) unmatched with the 3D airway model. Actually, two other cases (cases 12, 23) also looked successful when using the age-based formula instead of the 3D airway model. However, those two cases were simulated by using uncuffed ETT with the 3D airway model because we tried to find the best fit ETT. We also compared the result of two cases (cases 12, 23) with age-based formula, and they were not matched to each other. Finally, the unsuccessful 26 cases using age-based formula were considered as under- or over-estimated cases compared with the successful 3D airway model. There was no reintubation, and the estimated ETT size by the 3D print airway model seen in Table 4 is the finally inserted ETT size by age-based formula in the cases of success and failure.

Table 2. Patient Characteristics

Number of patients	35
Sex (M/F)	19/16
Age (months)*	4 (1, 9)
Number of patients (%) ≥ 24 months	4 (11.4)
Weight (kg)	6.2 (3.7, 8.1)
Height (cm)	62.0 (50.0, 71.3)

Values are presented as number or median (Q1, Q3). *Due to some patients being below one year of age, the age has been provided in months.

The correct ETT size was predicted as 67% in 6 patients (cases 10, 13, 17, 24, 30, 31) of 9 neonates < 1 month by the 3D airway model and as 11% (1 of 9, case 17) by the age-based formula. Air leakage was found in 2 out of 9 patients under a pressure of 10 cmH_2O and no air leakage was observed in 1 patient over 20 cmH_2O. Even in the age group in the range from 2 to 6 years old, generally used for the age-based formula, the 3D airway model predicted the correct ETT size in 3 (cases 3, 16, 33) out of 4 patients (75%). However, the age-based formula predicted the correct ETT size for only 1 patient (case 33) (25%) in 2- to 6-year-old patients. No complications occurred after extubation in any patients (Table 4).

Discussion

In general anesthesia for pediatric patients, the age-based formula is commonly used to select an accurate ETT size [15,16], but conflicting results have been reported [10]. Due to scientific and technological innovations, new methods, such as those using ultrasound, have been investigated to determine the ETT size [17]. The 3D printing technology has been successful in the field of surgery, but there are not many studies in the field of anesthesia, since it is mainly used as an educational tool rather than for clinical use [18]. We performed this study to predict the correct ETT size by means of a printed 3D airway model based on two-dimensional radiologic images for pediatric patients with potentially unusual airway sizes and shapes. As a result, we found that the prediction of a correctly sized ETT in pediatric patients with congenital heart disease by thee 3D airway model (60%) was better than the age-based formula (26%).

Table 3. Comparison between the 3D Airway Model and Age-based Formula for the Selection of Correct Size of the ETT

Formula or model used to determine the correct ETT size		Age-based formula: Correct	Age-based formula: Incorrect -Overestimated -Underestimated	Total (%)
3D airway model	Correct	5	16	21 (60)
	Incorrect	4	10	14 (40)
	-Overestimated			-11 (31.4)
	-Underestimated			-3 (8.6)
	Total (%)	9 (26)	26 (74)	35 (100)
			-13 (37)	
			-13 (37)	

Values are presented as number or number (%). ETT: endotracheal tube, 3D: three-dimensional.

Table 4. Detailed Data of Each Patient

No	Age* (months)	Calculated ETT size by age-based formula	Actual ETT size by age-based formula	Estimated ETT size by 3D print airway model	Air leakage $< 10\ cmH_2O$	Air leakage $\geq 20\ cmH_2O$	Success	Complication	Matched with calculated ETT size by age-based formula
1	4	3.59	3.5	4	N	Y	Y	N	N
2	4	3.597	3.5	4	N	Y	Y	N	N
3	61	4.783	5	5.5	N	Y	Y	N	N
4	1	3.537	3.5	3	N	Y	Y	N	N
5	8	3.67	3.5	4.5	N	N	N	N	N
6	4	3.598	3.5	4	N	N	N	N	N
7	5	3.624	3.5	4	N	Y	Y	N	N
8	0	3.505	3.5	3	Y	Y	N	N	N
9	5	3.62	3.5	4	N	Y	Y	N	N
10	0	3.503	3.5	3	N	Y	Y	N	N
11	2	3.56	3.5	3.5	N	Y	Y	N	Y
12	9	3.708	3.5	4	N	N	N	N	N
13	0	3.504	3.5	3	N	Y	Y	N	N
14	12	3.758	4	4.5	N	Y	Y	N	N
15	0	3.512	3.5	3	N	N	N	N	N
16	35	4.237	4	4.5	N	Y	Y	N	N
17	0	3.511	3.5	3.5	N	Y	Y	N	Y
18	7	3.648	3.5	4	N	Y	Y	N	N
19	4	3.592	3.5	4	N	Y	Y	N	N
20	1	3.527	3.5	3.5	N	N	N	N	Y
21	25	4.035	4	4.5	Y	Y	N	N	N
22	12	3.76	4	4	N	Y	Y	N	Y
23	0	3.508	3.5	3	Y	Y	N	N	N
24	0	3.508	3.5	3	N	Y	Y	N	N
25	2	3.545	3.5	3.5	N	N	N	N	Y
26	5	3.607	3.5	4	N	N	N	N	N
27	12	3.76	4	4	N	N	N	N	Y
28	4	3.603	3.5	3.5	N	Y	Y	N	Y
29	7	3.648	3.5	4	N	N	N	N	N
30	0	3.511	3.5	3	N	Y	Y	N	N
31	0	3.505	3.5	3	N	Y	Y	N	N
32	1	3.524	3.5	3.5	N	N	N	N	Y
33	40	4.34	4.5	4.5	N	Y	Y	N	Y
34	3	3.565	3.5	3.5	N	N	N	N	Y
35	11	3.74	3.5	4	N	Y	Y	N	N

ETT: endotracheal tube, 3D: three-dimensional, N: no, Y: yes. *Due to some patients being below one year of age, the age has been provided in months.

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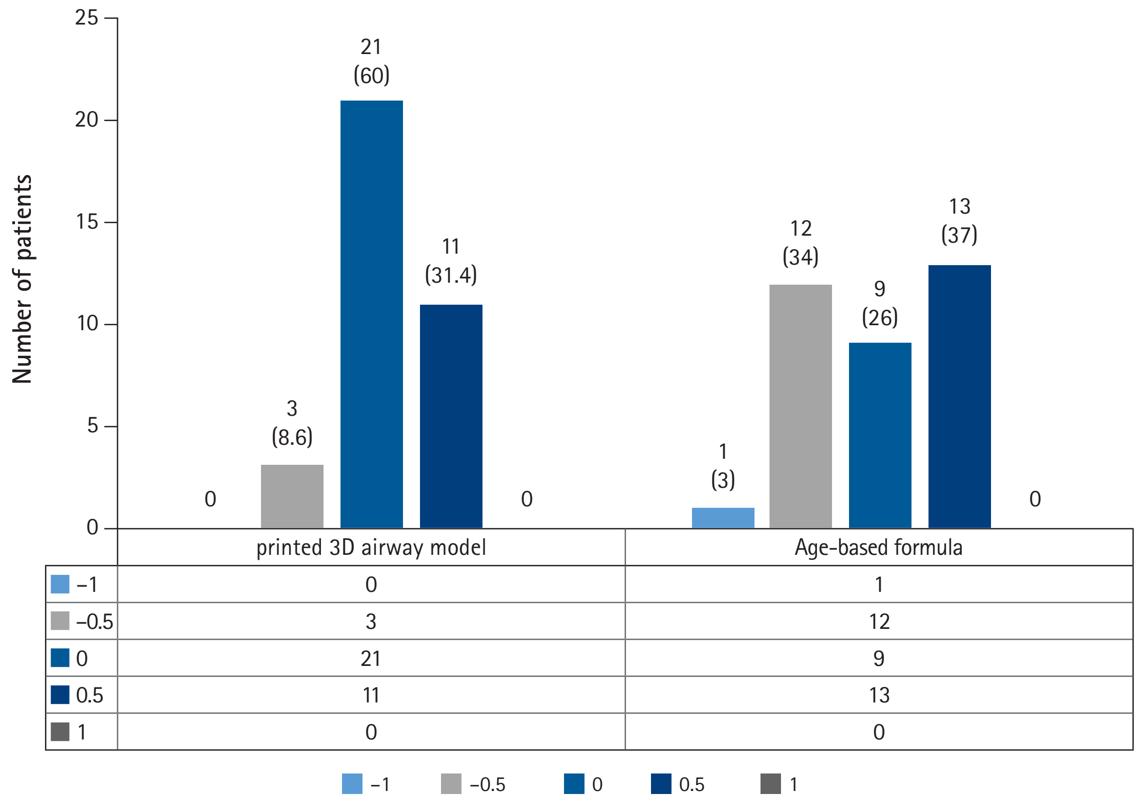

	printed 3D airway model	Age-based formula
−1	0	1
−0.5	3	12
0	21	9
0.5	11	13
1	0	0

Fig. 4. Distribution of predicted ETT size. Vertical axis shows the number of patients and the horizontal axis shows the differences between the correct cuffed ETT size and estimated ETT size. The percentages occupied by each is presented in parentheses. ETT: endotracheal tube, 3D: three-dimensional.

In comparison with studies on ETT selection by ultrasound, our results (60%) were better than the 48% of Schramm et al. [14], similar to 60% of Bae et al. [19], and lower than 98% of Shibasaki et al. [10]. These differences in results may be due to the following reasons. While ultrasound studies improved the accuracy by measuring the transverse diameter of the airway using neuromuscular blockers and the respiratory cycle, our study could not apply these factors to CT scans, which are the basis for the 3D airway model [14]. In addition, the age range of patients in the ultrasound studies was older, and a pressure of 25 cmH_2O or 30 cmH_2O defined as the air leak test was higher than the 20 cmH_2O used in our study [20].

The age-based formula predicted the correct ETT size in 9 of 35 pediatric patients (26%); the formula over-estimated size in 13 of 26 patients and under-estimated in 13 patients. The result of the age-based formula was not accurate, because our pediatric patients had congenital heart disease and most were < 1 year old. In fact, several studies have questioned the accuracy of the age-based formula [14,20].

In order to reduce re-intubation, even if the air leak test was not successful, the ETTs were retained unless ventilation was not maintained with ETT cuff inflation or if there was resistance to the ETT going through the airway. The conformity evaluation criterion was set to a pressure of 20 cmH_2O in our study, but there were also studies reporting a pressure of 25 cmH_2O or 30 cmH_2O or more. This is because it is advantageous for the management of respiratory secretions through the ETT and mechanical ventilation to have the appropriate airway pressure after surgery; the air leak test is not a perfect method to predict conformity of the ETT size, and inter-observer variation exists [21]. Unlike other studies, this study included pediatric patients of a wide range of ages from 4 days to 5 years, and those with a high level of ASA physical status with potential airway anomaly. This suggests that this method might be useful for airway assessments in this type of patient.

A 3D airway model is safe for patients, easy to learn, and requires little time, while ultrasound methods require apnea during measurements and staff training [19]. Because the 3D airway model dose not present two-dimensional image in the specific lesion, but reflects the actual airway shape, it may help anesthesiologists understand the anatomy of the airways and may be useful for making a better pre-anesthetic plan via simulation of intubation. Furthermore, using this model can reduce the number of intubation attempts and has the advantage of decreasing the risk of complications.

However, this study has some limitations. First, 3D implementation of medical imaging data requires high-quality imaging, and applying 3D conversion software programs to airway images is more difficult than applying the programs to images of solid organs because of the air layer. In addition, 3D printed airway models may differ from the actual airway they are derived from due to flexibility. Second, since the selection of a correctly sized ETT by a 3D airway model lacks an objective numerical indicator measuring the circumference of the narrowest part of the 3D airway model, there may be human errors from the blinded-tester. Third, in consideration of patient safety and ethical aspects of working with pediatric patients, we only used a cuffed ETT for reducing the risk of multiple intubation attempts and maintaining proper ventilation by inflating the cuff if needed. The inconsistent wrinkles of the deflated cuff can also affect the resistance of the ETT surface and the air leak test. Hence, if both cuffed and uncuffed were used as in Shibasaki et al. [10], or if inflation was applied to the cuffed ETT as in Altun et al. [17] to evaluate the adequacy of ETT size, the success rate may have been higher in our study. Fourth, although this study did not present the results of the best fit ETTs because of minimization of re-intubation, there is a possibility that the replaced 0.5 mm smaller or larger ETT also would not pass the air leak test. This is because even ETTs of the same inner diameter have different outer diameters depending on the manufacturer. Cuffed and uncuffed ETTs with 0.5 mm difference in inner diameter, which are clinically considered the same size ETTs, did not lead to the same results in the air leak test in clinical practice [22]. Fifth, we do not have a compliant material similar to the patients' airway, and the printed 3D airway model is less compliant after printing and fixing in room temperature. This might influence finding the proper size of ETT, and especially result in underestimating the size of ETT. Finally, clinical application of the results from this study would be limited because a printed 3D airway model can only be obtained when there are recent preoperative CT images.

Despite these limitations, prediction of the correctly sized ETT and simulation of intubation using a 3D printing technique may have clinical significance for the following reasons. Recent airway images using newer modalities including bronchoscopic examination or radiologic imaging have had researchers questioning the tenet of the conical shaped airway, and it has been clearly demonstrated that the airway is elliptical rather than circular with the anterior-posterior diameter being greater than the transverse diameter [1]. The 3D airway model also showed the same results, since each pediatric patient had an airway with individual characteristics. Indeed, it was observed that ready-made ETTs did not properly fit the airway size and shape of individual pediatric patients. Since the image quality is affected by the patients' respiration during CT scan, it is difficult to find the narrowest part, and even if the diameter is measured, the accuracy might be degraded. In a printed 3D airway model, it is possible to check the indentation due to the relationship with the surrounding structures along with the entire airway shape, so even if the image is blurred, enough airway information can be obtained from the printed 3D airway model. The 3D airway model might also present the information of tracheal anatomy in the patient who has an anomaly of the trachea or possibility of difficult intubation.

In conclusion, prediction of the correct size of the ETTs using a printed 3D airway model has demonstrated better results than the age-based formula. In particular, our study included patients with congenital heart disease and an abnormal range of growth and development; thus the selection of the ETT size using a printed 3D airway model in such a group may be feasible for helping minimize re-intubation attempts and complications. However, routine use in all pediatric patients needs to be further investigated. In the future, the 3D printer technique used in this study might be further developed in collaboration with a department of materials engineering, and used to create novel ETTs with individual size and shape.

Conflicts of Interest

No potential conflict of interest relevant to this article was reported.

Author Contributions

Seyeon Park (Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Project administration;
Resources; Software; Validation; Visualization; Writing – original draft; Writing – review & editing)
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Ki Seok Choo (Software; Writing – review & editing)
Hye-Jin Kim (Writing – review & editing)
Minwoo Chung (Writing – review & editing)
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