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ORIGINAL RESEARCH

Selection of cuffed endotracheal tube for children with congenital heart disease based on an ultrasound-based linear regression formula

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Abstract

It remains to be discovered whether a formula predicting the subglottic transverse diameter measured by ultrasound ($SGD_{formula}$) for the selection of an appropriate endotracheal tube (ETT) for children without congenital heart disease (CHD) is useful for children with CHD. A formula for predicting SGD was established after assessing 60 children ≤ 8 years without CHD and validated on 60 children with CHD. We selected the cuffed ETT size based on the SGD by ultrasound (SGD_{ultra}). Subsequently, the fit of the ETT cuff in 60 children with CHD was examined via air-leak test. The maximum allowed difference between the $SGD_{formula}$ and the ETT size that fit was 0.2 mm. The agreement among and accuracy of SGD_{ultra}, $SGD_{formula}$, and the ETT used in children was analyzed. For children without CHD, we adopted a linear formula, given by $SGD_{formula}$ (mm) = 0.4 × age + 5.3. For children with CHD, allometric formula was adopted, given by $SGD_{formula}$ (mm) = $5.4 \times age^{0.18}$. A stronger agreement exists between SGD_{ultra} and ETT size compared to that between $SGD_{formula}$ and ETT size. And the mean bias ($SGD_{formula}$-ETT size and SGD_{ultra}-ETT size) was 0.21 mm (95% confidence interval, −0.59 to 1.01 mm) and 0.00 mm (−0.79 to 0.84 mm). For the CHD group, the ultrasound-based method yielded a 78% success rate of ETT size choice, while the formula-based method permitted an appropriate ETT size in only 32% of subjects ($P < 0.001$). Our analysis showed that measuring the SGD_{ultra} was more accurate in predicting the correct OD of the ETT in children with CHD undergoing cardiovascular surgery, based on the correlation and agreement with ETT OD.

Keywords Congenital heart disease · Endotracheal tube · Subglottic diameter · Ultrasonography

1 Introduction

The appropriate selection of endotracheal tube (ETT) for pediatric patients, ventilated mechanically in the operating room and intensive care units, demands an accurate estimation of subglottic diameter (SGD). An oversized or hyper-inflated ETT cuff can cause airway ischemia, edema and even stenosis, whereas an undersized ETT cuff would result in air leakage and higher airway resistance. Although X-ray, computed tomography and magnetic resonance imaging techniques have been suggested as gold standards for the estimation of ETT size, their potential for routine use in operating rooms or intensive care units is limited due to lack of space, risk of radiation, high costs and time-consumption [1, 2].

Clinically, children aged 2 years or older were intubated with cuffed ETTs according to the Motoyama formulas: inner diameter (ID) in mm = 0.25 × (age in years) + 3.5; whereas children younger than 2 years with the Khine formulas: ID in mm = 0.25 × (age in years) + 3.0 [3, 4]. Data reference from previous study [5] demonstrated that age-based formula from children without congenital heart diseases (CHD) was unable to reflect variation in the growth of internal organs of children with CHD.

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An ultrasound-based bedside measurement of SGD at the level of the first cricoid cartilage has been proposed as a reliable method for selecting the ETT cuff for children, compared to age-based formulas [6–11]. A new ultrasound-based formula in combination with the patients' age and height has developed for the selection of appropriate ETT size for children aged 12–72 months undergoing urologic surgeries [7]. Namely, outer diameter (OD) in mm = 0.01 × (age in months) + 0.02 × (in height cm) + 3.3.

Compared to children undergoing urologic surgeries [7], tracheal growth in children with CHD may be impaired owning to delayed development [12–14] and tracheal stenosis [15]. Unbalanced growth of the different parts of their body might contribute to the different size of larynx compared to their body in children with CHD. To our knowledge, no study reported whether ultrasound-based formula was able to guide the selection of ETT for children with CHD for whom the selection of appropriate ETT size was more critical.

In the current study we examined whether our ultrasound-based formula used for children without CHDs could be used to guide the selection of ETT size for those with CHD.

2 Materials and Methods

2.1 Patients

This study was approved by the internal review board of Shanghai Children's Medical Center (IRB number: SCMCIRB-K2017013). Written informed consent was obtained from parents. 60 children without CHD were enrolled for elective orthopedic or general surgeries under general anesthesia and 60 children with CHD were enrolled for elective open heart surgeries from May 15th, 2017 to August 31st, 2017. Inclusion criteria were: (a) 1-month to 7-year-old children of either gender (Fig. 1). Exclusion criteria were: (a) premature infants, (b) patients at risk of regurgitation and aspiration, (c) patients with conditions that did not permit the use of ultrasonography, (d) patients undergoing emergency surgery, (e) patients with reported history of hypersensitivity to one or more of the medications and latex, and (f) patients with predicted airway difficulty and abnormality of the upper respiratory tract, including history of obstructive sleep apnea.

2.2 Anesthesia Induction and Maintenance

Routine monitoring, including electrocardiogram, oxyhemoglobin saturation (SpO_2), and noninvasive blood pressure, and 6 L/min fresh oxygen flow by facemask were established. Considering population with cyanotic CHD who are extremely vulnerable to hypoxia caused by hypoventilation and cry and struggle, ultrasound examination proceeded under close attention and procedural sedation by two senior pediatric anesthesiologists. All children aged over 6 months were premedicated orally with midazolam 0.5 mg/kg, and no premedication was given to children under 6 months. If no premedication was administrated, midazolam 0.1 mg/kg was given intravenously during induction. Anesthesia was induced with propofol 2.0–3.0 mg/kg for children without CHD, and etomidate 0.2–0.3 mg/kg for children with CHD. After the patient's eyelash reflex stopped, SGD was measured by ultrasound within a span of 60 s. Then

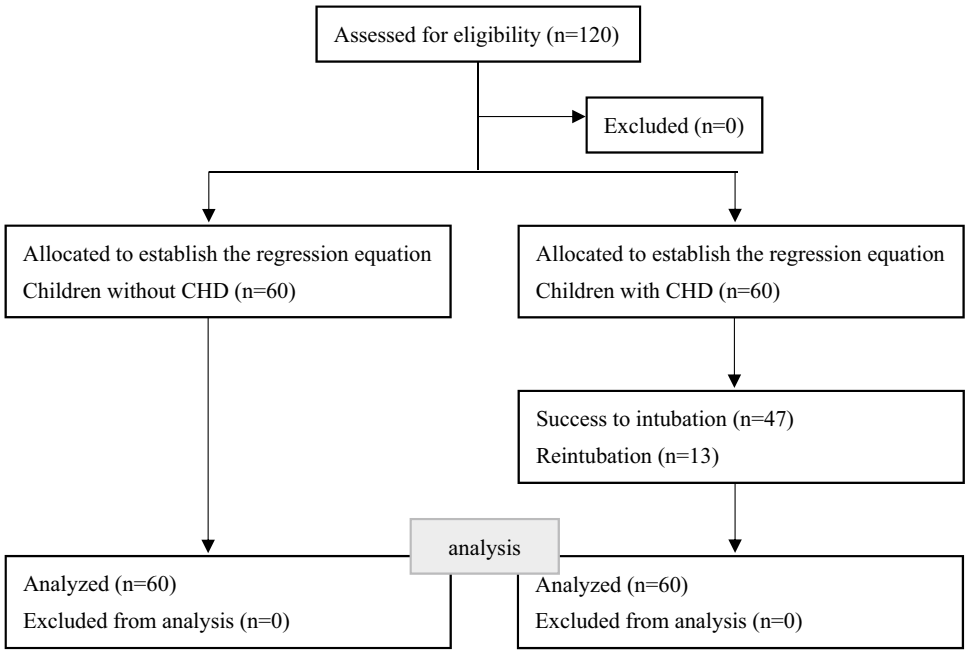

Fig. 1 CONSORT flow chart

sufentanil (0.1 μg/kg for children without CHD and 2 μg/kg for children with CHD) and 0.6 mg/kg rocuronium was given intravenously. 1.5 min after neuromuscular block drug, a direct laryngoscopic endotracheal intubation with cuffed ETT (Sheridan/CF, Hudson RCI, CA, USA) was performed. Location of the ETT was identified by the same anesthesiologist based on auscultation of breath sounds. Anesthesia was maintained with propofol, sufentanil, and rocuronium, in combination with sevoflurane as clinically needed.

2.3 SGD Measurement by Ultrasound

Children were maintained in the supine position with the head in a neutral position and slightly extended. Anesthesiologist experienced in airway ultrasound and certified in ultrasonography used a B-mode ultrasound (LOGIQ e; GE Healthcare System Milwaukee, WI) with an 8–13 MHz linear probe to locate the true vocal cords, which was observed as paired hyperechoic linear structures that moved with manual mask ventilation. The probe was moved caudally to visualize the cricoid arch (a round hypoechoic structure with hyperechoic edges). Once the cricoid cartilage was determined, the transverse air column diameter of the lower edge of the cricoid cartilage was measured without manual mask ventilation (Fig. 2). The transverse air column diameter was measured three times by ultrasound (SGD_{ultra}) for each patient within a span of 60 s. The average of these three measurements was used to minimize intra-observer variability.

Subsequently, another well-trained anesthesiologist blinded to the ultrasonography data performed endotracheal intubation via direct laryngoscopy. As the initial ETT size, the outer diameter of ETT matching the SGD_{ultra} was chosen.

An appropriate ETT was finally selected (Fig. 3) based on the results of the air leak tests conducted by two anesthesiologists [8]. Resistance during passage into the trachea or no audible leak when the lungs were inflated to a pressure of 25 cm H_2O indicated that the ETT was larger. In contrast, the ETT was smaller if audible leak was detected by auscultation when inflation pressure was < 10 cm H_2O and cuff pressure was set at 20 cm H_2O.

Our primary endpoint was whether our ultrasound-based formula for children without CHDs could be used to guide the selection of ETT size for those with CHD.

2.4 Statistical Analyses

Data were analyzed using SPSS 22.0 software (SPSS Inc., Chicago, IL, USA). Normally distributed measurement data with Shapiro–Wilk test were presented as mean ± standard deviation. Linear and nonlinear (power and cubic) regression equations to predict the SGD were established using physiological variables (age, weight and height) by the forward method, and the determinant coefficient (R^2) was calculated. Demographical data were compared by Student's *t* test or Mann–Whitney test as appropriate for ages, weights, heights, and chi-squared test for categorical data, two-way tables such as gender. The Bland–Altman method [16] and Pearson correlation were used to assess the agreement and correlation between SGD_{ultra} or $SGD_{formula}$ and out diameter of ETT for children with CHD. $SGD_{formula}$ was defined as the calculated value using the regression equation derived from pediatric patients without CHD. $P < 0.05$ was considered statistically significant.

Previous studies seldom selected ETT size according to the SGD by ultrasound, so calculation of sample size was dependent on a study by Shibasaki [8] as a substitute. The rate of agreement between the predicted ETT size based on ultrasonic measurement and the final cuffed ETT size selected was 98%. A power analysis with a two-sided

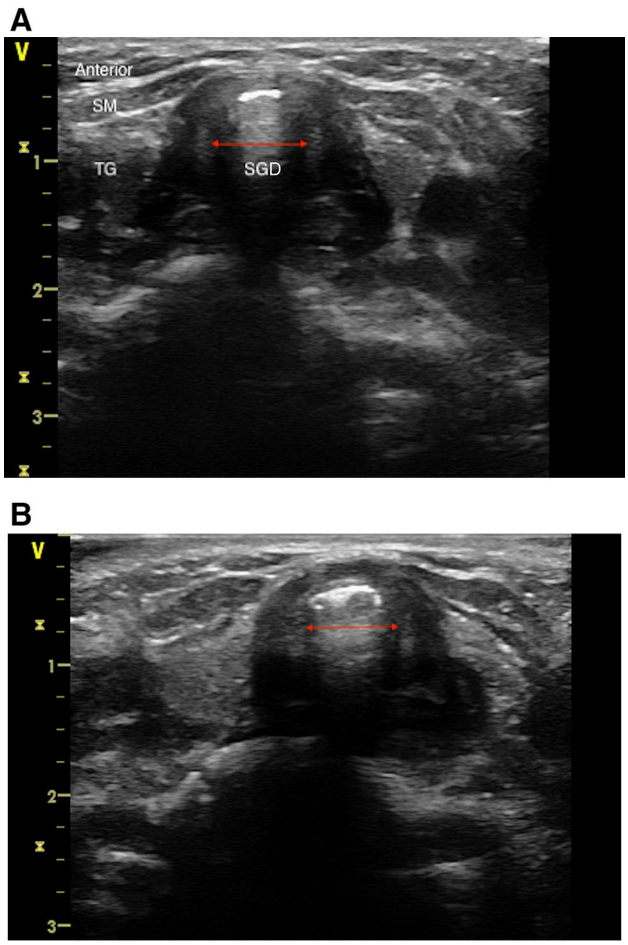

Fig. 2 An ultrasound image of the airway at the subglottic level before (**a**) and after (**b**) intubation. The cricoid cartilage appears as an arched, rounded hyperechoic structure. The transverse diameter of the subglottis (red line) is between the transverse edges of the cricoid cartilage (arrow). *TG* thyroid gland, *SM* strap muscle, *SGD* subglottic diameter

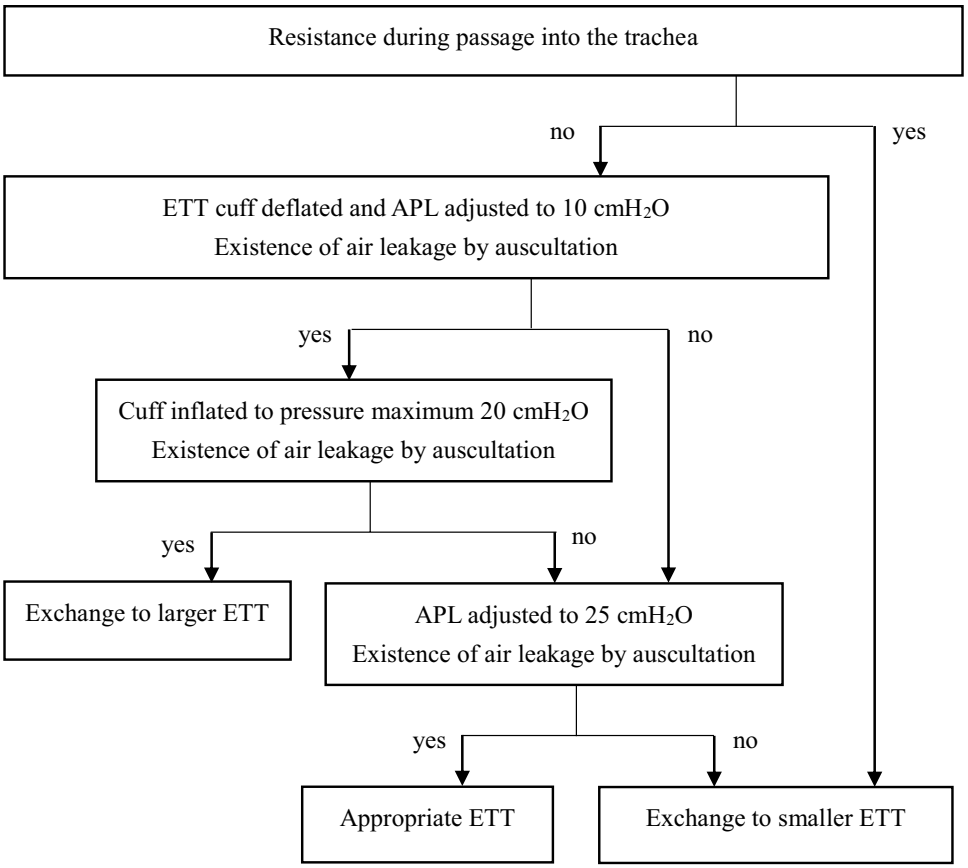

Fig. 3 Flow chart for selection of appropriate endotracheal tube size

significance level α of 0.05 and a power of 0.9 indicated that a sample size of 54 patients was enough to detect a 20% difference in success rate of two methods. We recruited 60 patients to account for the possible dropouts. In fact, this sample size was statistically enough to testify the primary endpoint referring to the power analysis post hoc. In view of the eventual results from our study with type I error of 5%, a power of 1.0 can be provided. Online software was used to calculate the sample size. (the URL is http://www.stat.ubc.ca/~rollin/stats/ssize/).

3 Results

Among the 120 patients in this study, the data of 60 children without CHD was used to establish the regression equation, while the data of 60 children with CHD was used to validate the model. There were no differences in age, gender and height between two groups. Body weight and body mass index were lower in children with CHD, indicating that kids in this group were significantly malnourished. American Society of Anesthesiologists physical status classification and cyanosis, which reflects the severity of the disease, were significantly higher in children with CHD. The demographical characteristics of both groups were presented in Table 1.

Table 1 Demographic characteristics of both groups with and without CHD

	Without CHD ($n=60$)	With CHD ($n=60$)	*P*
Age (year)	3.1 ± 2.2	2.4 ± 1.6	0.05
Gender (male/female)	44/16	35/25	0.08
Height (cm)	92 ± 20	87 ± 17	0.10
Weight (kg)	14.4 ± 5.7	12.0 ± 5.0	0.02
Body mass index (kg/m^2)	16.5 ± 1.9	15.7 ± 2.0	0.04
Non-cardiac surgery			
General	20/60 (33.3%)		
Neuro	8/60 (13.3%)		
Orthopedic	20/60 (33.3%)		
Urologic	12/60 (20%)		
Cyanosis			
Yes/no	0/60	19/41	< 0.001
ASA-PS			
I–II/III–IV	60/0	2/58	< 0.001

Data are presented as mean ± standard deviation or median (25%, 75%) as appropriate, or the number of patients

CHD congenital heart disease, *ASA-PS* American Society of Anesthesiologists physical status classification

The values of the determinant coefficient (R^2) between SGD_{ultra} and age, weight, or height obtained by linear, cubic and power regressions for both groups are shown in Table 2. Age was a superior variable compared to weight and height in correlation with SGD for both groups. To evaluate the SGD of children without CHD, the linear regression equation, $SGD_{formula}$ (mm) = 0.4 × age + 5.3 (adjusted $R^2 = 0.65$, $P < 0.001$), was used. Furthermore, the allometric model for pediatric patients with CHD was better than the linear equation. Hence, the allometric equation, $SGD_{formula}$ (mm) = $5.4 \times age^{0.18}$ (adjusted $R^2 = 0.70$, $P < 0.001$), was used for children with CHD (Fig. 4). According to both mathematical models, despite the absolute increase in SGD_{ultra}, the growth velocity in children with CHD gradually declined with advancing age. When children with CHD were older than 1.5 years, the 95% confidence interval of the growth curve approximated to that of children without CHD.

Pearson's correlation coefficients between $SGD_{formula}$ or SGD_{ultra} and ETT OD for children with CHD were 0.88 and 0.91, respectively. As shown in Fig. 5a, b, the regression line of SGD_{ultra} and ETT OD approached the line of identity, and the mean bias ($SGD_{formula}$-ETT size and SGD_{ultra}-ETT size) was 0.21 mm (95% confidence interval −0.59 to 1.01 mm) and 0.00 mm (95% confidence interval −0.79 to 0.84 mm), respectively, suggesting the soundness of the ultrasonography-guided ETT. In contrast, $SGD_{formula}$ often overestimated the tube size. Best-fit tube OD and SGD_{ultra} were correlated ($R^2 = 0.82$, $P < 0.001$) with the formula best-fit ETT OD (mm) = 0.80 × (subglottic diameter in mm) + 1.2.

The ultrasound-based method yielded a 78% (47/60) success rate of intubation at the first attempt, whereas the formula-based method permitted an appropriate selection of ETT in only 32% (19/60) of subjects with a maximum allowed deviation of ≤0.2 mm ($P < 0.001$). ETTs were replaced in nine patients with one size larger, and in four patients with one size smaller tube.

To assess whether the method overestimated the size of ETT, the mean values of both methods were compared via post hoc *t* test with a significance level of $P < 0.05$. The SGD_{ultra} did not significantly differ ($P = 0.64$) from the actual ETT OD, while the $SGD_{formula}$ was a significant overestimation ($P < 0.001$) (Fig. 6).

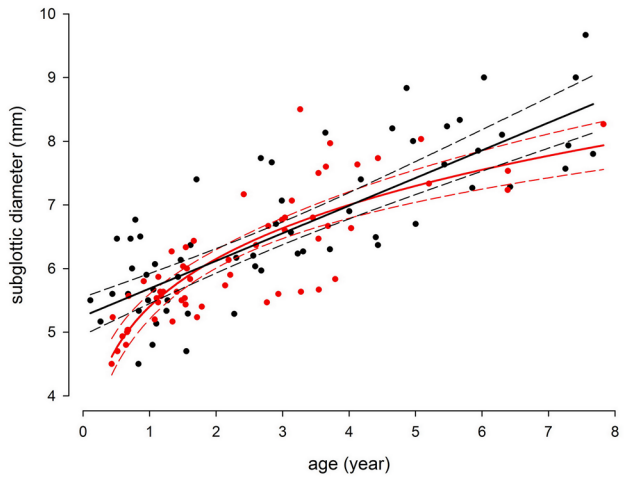

Fig. 4 The linear regression for associating subglottic diameter and age in children without CHD (black dots) and the nonlinear regression for children with CHD (red dots) are shown. Solid line, regression equation; dotted line, 95% confidence intervals

4 Discussion

This study showed that measuring the SGD_{ultra} was more accurate in predicting the correct OD of the ETT in children with CHD undergoing cardiovascular surgery, based on the correlation and agreement with ETT OD.

In previous study [5], children undergoing cardiac surgeries showed lesser compatibility of the predicted tube sizes compared to the non-cardiac surgery group. Furthermore, cases of underestimated tube sizes were significantly more in the cardiac surgery group than in the non-cardiac surgery group. This means that the empirical formula cannot reflect the growth of internal organs in special pediatric patients. Additionally, even the ultrasonography-derived linear formula in current study had the same unsatisfactory result for children with CHD. We also compared the ETT OD calculated by the formula from our study and that from Kim. There seems nearly 1 mm deviation between the predictive values in patients aged from 1 to 6 years, which means if we selected the ETT size for current pediatric patients according to the formula by Kim, occurrence of air leakage would be

Table 2 Values of the determinant coefficient (R^2) between transverse subglottic diameter and age, weight, or height obtained by linear, cubic and power regressions for both groups with and without CHD

	Age			Weight			Height		
	Linear	Cubic	Power	Linear	Cubic	Power	Linear	Cubic	Power
Without CHD	0.65*	0.66*	0.53*	0.30*	0.26*	0.28*	0.31*	0.31*	0.28*
With CHD	0.65*	0.69*	0.70*	0.13	0.14	0.19	0.00	0.25*	0.00

*$P < 0.05$

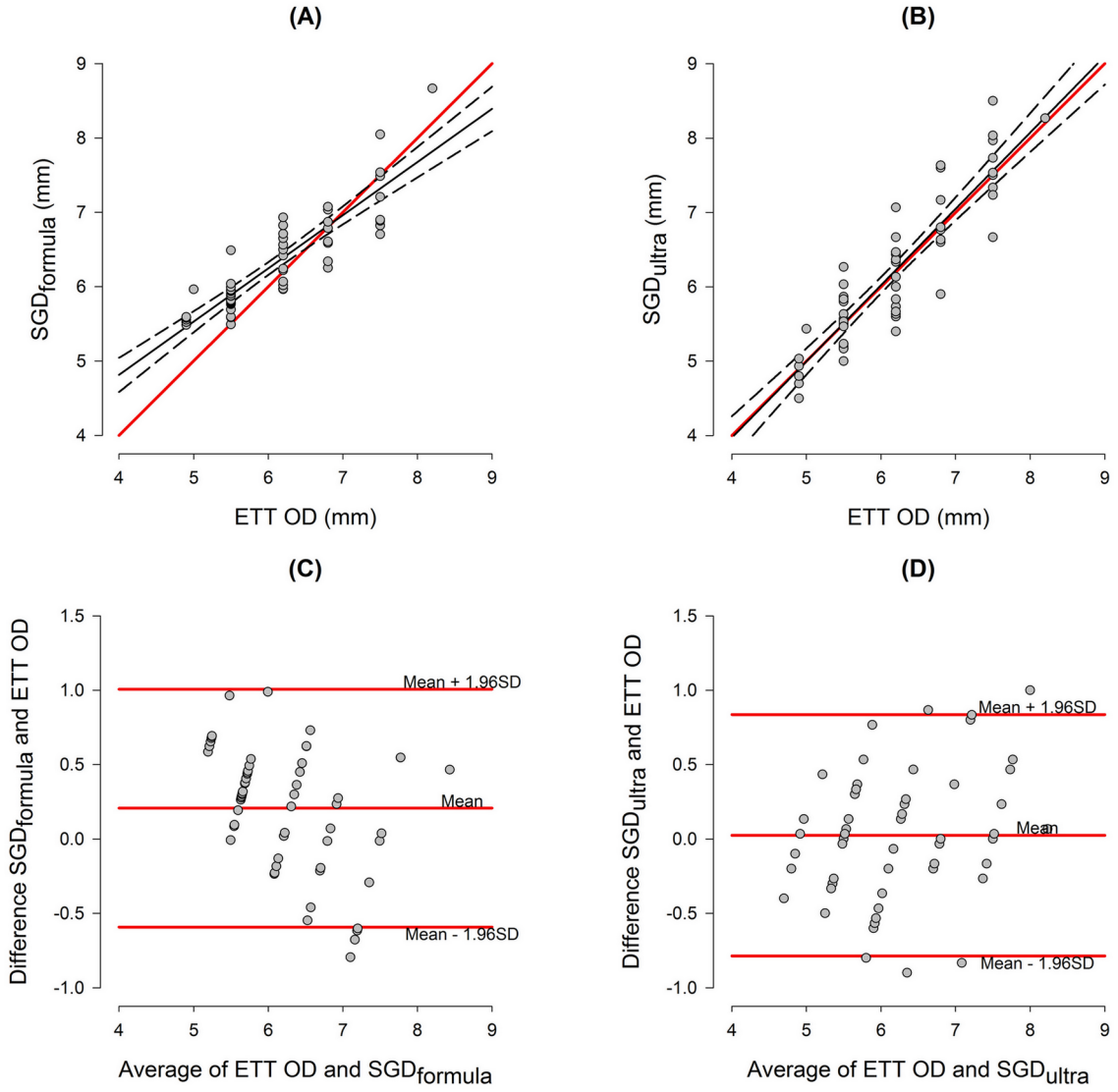

Fig. 5 Linear regression between $SGD_{formula}$ or SGD_{ultra} and ETT OD in the children with CHD (**a, b**). The correlation coefficients are 0.88 and 0.91, respectively. In (**b**), the regression line of SGD_{ultra} and ETT OD approaches the line of identity. The Bland–Altman plots of $SGD_{formula}$ or SGD_{ultra} and ETT OD (**c, d**). The mean bias ($SGD_{formula}$-ETT size and SGD_{ultra}-ETT size) was 0.21 mm (95% confidence interval: −0.59 to 1.01 mm) and 0.00 mm (95% confidence interval: −0.79 to 0.84 mm). The plots shown in (**c**) and (**d**) demonstrate the soundness of ultrasonography-guided ETT. Our formula based on SGD via ultrasound and age often overestimated the tube size. The red solid line indicates identity, and the black solid line represents regression. Black dashed line, 95% confidence interval; *SGD* subglottic diameter, *ETT OD* outer diameter of the endotracheal tube

higher. Different ETT manufacturers potentially produced this.

Gender, age, height and weight have been found to correlate with the tracheal diameter [17–24]. After reaching puberty, gender becomes an important factor in predicting the tracheal diameter [17]. In pediatric patients with CHD, height is an effective parameter for predicting tracheal width based on computed tomography scanning [18]. Our study shows that age is much more related to SGD. Both nonlinear regression (power, quadratic and cubic) and linear regression equations describe quantitative growth in terms of diameter, cross-sectional area and volume at different levels of the trachea [18–22]. The allometric growth curve has been widely used to account for the tracheal length and diameter in the fetus and in the early life of infancy [18–22], which is compatible with the present findings on pediatric patients younger than 1.5 years. Although the exponential formula is a complex tool to be widely used in clinical practice and clinicians rarely calculate ETT size based on such an equation; we carefully regarded the exponential formula as a better model served to increase our understanding of the growth and development of the pediatric trachea. The results

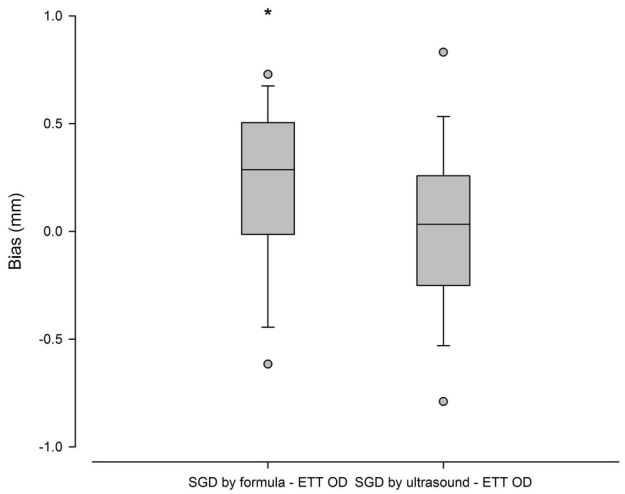

Fig. 6 Box plots of bias between the transverse diameter of the subglottic airway (SGD) and the estimated outer diameter of endotracheal tube (ETT OD). The SGD determined using the formula differed significantly from ETT OD by post hoc *t* test (*$P < 0.001$)

from this study would remind clinicians that the ETT size adjustment may be considered in CHD patients especially when CHD infants were intubated. When children with CHD were older than 1.5 years, the 95% confidence interval of the growth curve approximated to that of children without CHD. Thus $SGD_{formula}$ was a convenient and time-saving routine for children in age range from 1.5 to 7 years old while it was better to depend on the SGD_{ultra} in patients with CHD aged no more than 1.5 years old.

Previous studies considered the ETT size to be underestimated by the Motoyama formula in 38.8% children with CHD [5]. After comparing the predicted (children aged 2 years or older were intubated with cuffed ETTs according to the Motoyama formulas: ID in mm = 0.25 × (age in years) + 3.5; whereas children younger than 2 years with the Khine formulas: ID in mm = 0.25 × (age in years) + 3.0) and actual tube sizes, the cases with underestimated tube sizes were similar in both of studies (33.3% vs. 38.8%). One should not overlook the possibility of underestimation of ETT size while utilizing traditional age-based formula.

Even though underestimation of ETT size by traditional age-based formula exists, on the other hand, as we know, pediatric patients with severe CHD are always characterized by premature and nutritional deficiency. In children with CHD, decreased insulin-like growth factor 1 levels are often observed [12]. In addition, chronic hypoxemia directly or indirectly reduces serum insulin-like growth factor 1 concentrations, leading to growth failure in patients with cyanotic CHD [13, 14]. Nevertheless, a trend of obesity as well as the prevalence of co-morbidity, such as Down's syndrome and univentricular palliation, is common in children with CHD [23]. In the present study, children with CHD had lower weight and body mass index compared to children without CHD. The consequence of different nutritional status may explain the phenomenon of a curvilinear relationship for patients with CHD and a linear relationship for children with normal cardiac anatomy. Further studies are needed to determine the relationship between the sub-groups of CHD and growth of the trachea in early life.

Some limitations of this study should be pointed out. (1) We only measured the transverse diameter at the subglottic level. It is known that CHD accompanying congenital tracheal stenosis is a rare but critical situation [24]. Thus, the existence of stenosis in other parts of the trachea should be considered when determining the ETT size. (2) Our SGD measurements were obtained by a single operator. Although this eliminated inter-observer variability, it may have led to operator-dependent bias. (3) Additive measurement of SGD_{ultra} after intubation may increase the reliability and robustness of current study. (4) Exponential formula was not validated in a new cohort of children with CHD. In future study, hypothesis should be tested that SGD in children with CHD younger than 1.5 years, as determined by exponential formula, better predicts optimal ETT size than existing methods.

5 Conclusions

We demonstrated that measuring the SGD_{ultra} was more accurate in predicting the correct OD of the ETT in children with CHD undergoing cardiovascular surgery, based on the correlation and agreement with ETT OD.

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Compliance with ethical standards

Conflict of interest No conflicts of interest declared.

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