Original Article

Predicting Uncuffed Endotracheal Tube Size in Anesthetized Children by Ultrasonography: A Randomized Controlled Trial

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Objective: The present study aimed to demonstrate that selecting the endotracheal tube [ETT] size using ultrasound measurement of the subglottic diameter is a more reliable method than an age-based formula.

Materials and Methods: Ninety-three patients between 1 and 6 years old undergoing elective surgery under general anesthesia with endotracheal intubation were randomized into 2 groups. In group F (n = 46), a modified Cole formula was used to select the ETT size, while in group US (n = 47), ultrasound measurement of the subglottic diameter was used to select the ETT size. The appropriate tube size was clinically determined by leakage at airway pressures of 20 to 25 cmH_2O. Both groups underwent measurement of the transverse subglottic diameter in the supine position during apnea and at inspiratory pressures [IP] of 10 cmH_2O and 20 cmH_2O before intubation to examine the correlation with the outer diameter of the appropriate ETT.

Results: The incidence of appropriate ETT size selection in group US was 37 out of 47 (78.7%), which was significantly higher than that in group F (n = 24/46, 52.2%), (p = 0.001). A good correlation was found between the ETT size from ultrasound measurement of the transverse subglottic diameter and the outer diameter of the final proper ETT size, with weighted kappa of 0.59±0.06, 0.75±0.06 and 0.70±0.06 at apnea, 10 cmH_2O of IP and 20 cmH_2O of IP, respectively. No complications were reported in either group during the study.

Conclusion: Ultrasound measurement of the subglottic diameter to guide the selection of ETT size yielded the appropriate size more frequently than an age-based formula in anesthetized pediatric patients.

Keywords: Intubation, Endotracheal, Pediatrics, Ultrasonography

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Selecting the appropriate endotracheal tube [ETT] size in pediatric patients is a challenging task for anesthesiologists. The size is generally selected to properly fit the cricoid diameter[1] as determined by optimal leak at airway pressures of 20 to 25 cmH_2O when the ETT is in place[2]. An undersized ETT results in risks of inadequate ventilation, aspiration[3] and operating room pollution from leaking anesthetic gases[4]. An oversized ETT may cause airway injury that leads to post-extubation stridor and subsequent subglottic stenosis[5]. Changing the ETT size also poses risks of hypoxia, aspiration, airway trauma and edema due to repeated laryngoscopy and intubation[6].

An age-based formula has been widely accepted to select the appropriate ETT size in pediatric patients due to its practicality and ease of use[7]. The well-known Cole's formula is used for uncuffed ETT: size = 4+age/4[8]. However, several studies have revealed that more than 50% of patients require exchange of the ETT for a different size due to improper size selection with this formula[9-11]. Although there are pediatric cuffed

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endotracheal tubes available in anesthesia practice[12,13], which can reduce the ETT exchange rate, they are not cost effective and not available in some areas especially in the developing countries.

Several recent imaging studies of the pediatric airway anatomy using CT and MRI have revealed that the pediatric larynx is cylindrical in shape and that the narrowest part is at subglottic level, not at the cricoid cartilage[14-16]. These findings suggest that the subglottic diameter could be a better determinant of ETT size in pediatric patients than an age-based formula. Ultrasound examination of the airway offers much useful information for clinicians such as identification of the airway anatomy, confirmation of correct placement of an ETT, and prediction of the size of the ETT in pediatric patients[17]. Shibasaki et al proposed a study in 2010 to measure subglottic diameter by ultrasound and found a high correlation between the subglottic diameter and the optimal ETT size that would fit clinically[18]. Bae et al measured pediatric airways in different settings, including during continuous positive airway pressure at 10 cmH_2O, and found that ultrasound offered better predictions of ETT size than an age-based formula[11]. Schramm and Kim's study proposed the same measurements to confirm the high correlation between the subglottic diameter and appropriate ETT size[19,20].

To date, no available randomized controlled trials have used ultrasound examination of the pediatric airway to predict ETT size. We hypothesized that ultrasound examination of the airway could predict the appropriate uncuffed ETT size in anesthetized pediatric patients better than Cole's formula.

Materials and Methods

This randomized double-blinded controlled trial was approved by the Siriraj Institutional Review Board (Si. 165/2014) prior to data collection. Written informed consent was obtained from the parents/legal guardians of the patients. Patients were recruited during preoperative anesthesia visits from January 2015 to March 2016. Ninety-three patients aged between 1 and 6 years old with an American Society of Anesthesiologists [ASA] physical status of 1 to 2 who were undergoing elective surgery with general anesthesia using an uncuffed endotracheal tube were enrolled in the study. Patients who were allergic to ultrasound gel, had unstable vital signs or had potentially difficult airways based on either history or physical examination were excluded.

Patients were randomized into 2 groups using a computer-generated randomization code (https://www.randomizer.org/form.htm) to choose the method of sizing the uncuffed ETT (Figure 1). In the control group, group F, the uncuffed ETT size was selected using Cole's formula: Uncuffed ETT size inner diameter = 4+Age/4. In the experimental group, group US, the uncuffed ETT size was selected using ultrasound to measure the transverse diameter of the cricoid cartilage and by correlating the results with the outer diameter of the ETT.

Attending anesthesiologists in the operating rooms were blinded to the method of ETT selection, and the size of the ETT for each participant was determined by the researchers after ultrasound examination of the airway. General anesthesia was administered in accordance with the attending anesthesiologist's preference. After being anesthetized, all patients were placed in a supine position with the head in a neutral position without a pillow.

Between induction and intubation, all participants underwent an ultrasound examination of the airway by trained anesthesiologists who were also blinded to the method of ETT size selection. The study included measurement of the transverse subglottic diameter (Figure 2) under three conditions: apnea, an inspired pressure [IP] of 10 cmH_2O and an IP of 20 cmH_2O. Another researcher, who was not blinded to the groups, calculated the ETT size using Cole's formula in group F patients or correlated the subglottic diameter during apnea with the ETT size in group US and then informed the attending anesthesiologist of the selected ETT size for the patients. The time needed for the ultrasound measurements and any complications were also recorded.

The ETTs used were all obtained from the same company to prevent variation in the outer diameter of ETTs of the same size. After intubation, the appropriate tube size was determined by clinical testing for tracheal leaking at each IP, with properly sized ETTs leaking at 20 to 25 cmH_2O. The leakage was determined by audible air leak over the larynx by stethoscope while the IP was controlled with anesthesia ventilator[10]. The ETT was changed to half a size larger or smaller if the leak test revealed an improper size. The final ETT size, reason for changing the ETT and any complications from induction until intubation were recorded.

The ultrasound measurements were performed by 3 anesthesiologists (KR, RA, and AS) who were trained to measure the transverse subglottic diameter in at least 10 patients before performing the ultrasound measurements in this study. The ultrasound

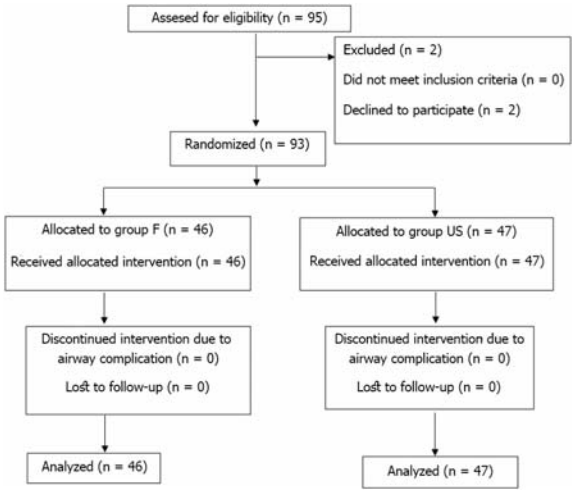

Figure 1. Flowchart diagram of the study.

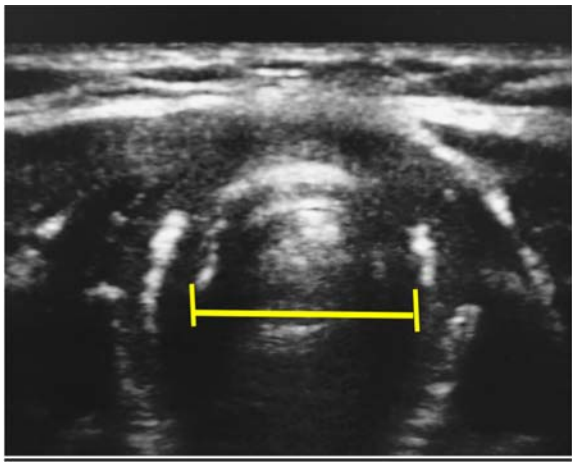

Figure 2. Ultrasound image of the transverse diameter of the subglottic area in the midline of the anterior neck with the patient in a supine position.

machine used was a SonoSite Edge (SonoSite Inc., Bothwell, WA) with a high-frequency linear transducer (SLAx 6 to 13 MHz). The probe was placed in the midline of the anterior neck to identify the thyroid cartilage; then, the probe was moved caudally to identify the true vocal folds (paired hyperechoic linear structures) and moved more caudally to identify the cricoid cartilage (a round hypoechoic structure with hyperechoic edges). Finally, the transducer was moved cephalad to locate the narrowest part of the subglottic area and measure the transverse air column diameter[20,21].

The primary outcome was the rate of the proper size ETT determined by clinical leak test. The sample size calculation was based on a previous study by Bae[11] that rate of proper ETT was 30% when the size was selected by Cole's formula vs. 60% when determining by ultrasound. Implying that the rate of proper ETT would increase 30% with ultrasound (alpha value = 0.05 and power = 80%), a sample size of 42 was required for each group. We hypothesized that ultrasound examination of the airway is a more reliable method to predict the appropriate uncuffed ETT size in anesthetized pediatric patients than Cole's formula.

Statistical analysis was performed using SPSS 21 for Mac OS (Chicago, USA). Continuous data are presented as the means and standard deviation [SD]. Chi-squared tests were used to compare the rates at which the ETT required changing, and statistical significance was considered when $p<0.05$. The weighted kappa was used to find the agreement between the ETT size correlated with measurement from the ultrasound study at 3 conditions and the final appropriate ETT[22].

Results

Ninety-three patients were enrolled in this study and randomized into 2 groups. In the control group, group F (n = 46), Cole's formula was used to calculate the uncuffed ETT size. In the experimental group, group US (n = 47), ultrasound measurement of the subglottic diameter and its correlation with the outer diameter of the ETT were used to select the ETT size. The mean age of the patients was 2 years and 6 months. The mean height and BW were 80 cm and 13 kg, respectively. The demographic data for each group are shown in Table 1. No significant differences were observed in the baseline characteristics between groups. The mean duration of ultrasound measurement during all 3 phases of inspiration was 78.25±31.92 seconds. The attending anesthesiologist used intravenous anesthetic induction more frequently than inhalation induction techniques. No anesthetic complications including airway or ultrasound complications were observed during the study.

The proportion of patients with the appropriate ETT size in group US was 37 (78.7%), which was significantly higher than that in group F (n = 24; 52.2%) (p = 0.001). Twenty-two patients (47.8%) in group F required their ETT to be changed to a more appropriate size, mostly because the formula predicted an undersized ETT, causing leakage at peak IPs of 10-15 cmH_2O (n = 19; 86.4%). In group US, only 10 patients (21%) required their ETT to be changed to the

appropriate size (Table 2).

Ultrasound examination of the airway was performed in both groups during 3 phases: apnea, a positive IP of 10 cmH_2O and a positive IP of 20 cmH_2O. The study was completed before intubation. The narrowest diameter, which was the transverse cricoid diameter, was correlated with the expected ETT size, then using weighted kappa to find the agreement with the clinically determined appropriate ETT size. The weighted kappa was 0.59±0.06, 0.75±0.06 and 0.70±0.06 for the measurements during apnea, an IP of 10 cmH_2O and an IP of 20 cmH_2O, respectively.

Discussion

This randomized controlled trial compared methods for selecting the uncuffed ETT size in anesthetized pediatric patients using ultrasound measurement of the airway and an age-based formula. The results revealed a significantly higher rate of appropriate ETT size selection in the ultrasound group than in the formula group.

Table 1. Baseline characteristics of the patients

	Formula (n = 46)	Ultrasound (n = 47)
Age (years)	2.6±1.44	2.5±1.35
Gender: male	40 (87)	35 (74.5)
Body weight (kg)	13.1±3.12	13.1±3.97
Height (cm)	91.3±14.7	90.2 ±15.95
ASA (class I/II)	39 (84.8)/ 7 (15.2)	38 (80.8)/ 9 (19.2)
Type of surgery		
Head and neck	6 (13)	8 (17)
Thoracic	1 (2.2)	3 (6.4)
Limb	1 (2.2)	3 (6.4)
Abdomen	3 (6.5)	3 (6.4)
Genitourinary	35 (76.1)	30 (63.8)

The data are presented as mean ± standard deviation or n (%)
ASA = American Society of Anesthesiologists

High-frequency ultrasound can be used to examine the upper airway anatomy using the air-mucosal interface[17,21]. The true and false vocal cords can be identified, and the transducer can be moved caudally to visualize the cricoid cartilage. The entire structure of the cricoid cartilage cannot be seen due to limitations of ultrasound interaction with the air column in the trachea. However, the transverse diameter can easily be identified and measured. Recent studies of the airway using bronchoscopic and imaging examinations have revealed that the pediatric airway in the subglottic and cricoid regions is not a spherical shape. The antero-posterior diameter is generally greater than the transverse diameter, resulting in an oval shape[14]. Consequently, ultrasound measurement of the transverse diameter may predict an undersized ETT. The studies by Shibasaki and Bae revealed a strong correlation between the transverse diameter of the subglottic area and the appropriate ETT size. This correlation may occur because a properly sized ETT in pediatric patients requires some room for leak under positive pressure ventilation to ensure the fit is clinically appropriate[11,18].

The results from the present study reveal a significantly different rate of appropriate ETT size selection when using different methods (78% using ultrasound vs. 52% using a formula, $p<0.001$). However, the outcome was different in a study by Schramm[19], who examined 50 patients age <5 years old and found that using ultrasound to choose the appropriate uncuffed ETT size was no better than using a formula (48% using ultrasound vs. 40% using a formula). This result may be due to the difference in mean age; in Schramm's study, the mean age was 1.5 years old, while in the present study, it was 2.5 years old. Smaller children may have more variability in airway anatomy due to the significant growth rate during that age. A study by Kim demonstrated a poor correlation between ultrasound measurements of the subglottic diameter and the appropriate ETT size in children less than 12 months of

Table 2. Incidence of proper ETT size determination in both groups

Outcome		Formula (n = 46)	Ultrasound (n = 47)	*p*-value
Proper	Leak at 20 to 25 cmH_2O	24 (52.2)	37 (78.7)	0.001*
Improper	Leak at 10 to 15 cmH_2O	19 (41.3)	4 (8.5)	
	Leak at 16 to 20 cmH_2O	2 (4.3)	2 (4.3)	
	No leak >25 cmH_2O	1 (2.2)	4 (8.5)	

The data are presented as n (%)
* $p<0.05$ indicates statistical significance

age, while the correlation was strong in children ages 12 to 72 months[20].

The method of determining the appropriate ETT size in this study was based on clinical judgment during an air leak test. Clinical evaluations have long been used by pediatric anesthesiologists to assess the appropriateness of the ETT size. Adverse upper airway events may occur when there is no air leak at 25 cmH_2O[2]. Therefore, in the study, we defined the appropriate ETT size as an audible air leak at 20 to 25 cmH_2O. Assessment of leak pressures on an air leak test can depend on inter-observer variations and the degree of neuromuscular blockade[23,24]. However, presently, no other practical test can confirm the appropriate ETT size after intubation.

The sonographers learning process of the airway ultrasound was practicing to scan in at least 10 patients before performing ultrasound measurement in the present study. The number of practicing airway ultrasound to get high success rate was not well determined. However, Chenkin and Kerforne studies found that a brief period of tutorial of 10 to 20 minutes in airway ultrasound training yield a high success rate of 90%[25,26]. Also, Betancourt et al studied the learning curve of point-of-care ultrasound and demonstrated that novices needed to perform 11 times of ultrasound scanning to get 80% success rate[27]. One of the limitation of the present study is we did not provide the data of inter-rater reliability of the ultrasound airway measurement.

As a secondary outcome, we found that the transverse diameter at the cricoid level has good agreement with the outer ETT diameter of the final appropriate ETT at the IP of 10 and 20 cmH_2O with the weighted kappa of 0.75 and 0.70 respectively. Thus, we can conclude from the present study that measurements obtained during positive pressure ventilation yield the most accurate measurement of the transverse cricoid diameter and lead to selection of the most appropriate ETT size.

Limitations

There are some limitations to the present study. First, the nature of the ultrasound measurement is operator dependent, and the technique requires some practice. The duration of the measurements in each patient is also dependent on the researcher's experience. Although we used only one ultrasound machine and transducer in the present study, other factors also affected the results, such as the determination of the air-mucosal interface by each operator, adjustment of the gain, the picture torsion due to pressure on the probe and artifacts from the ultrasound[28]. Second, the techniques for ultrasound measurement, which measured only the transverse diameter at one level but did not include the anterior-posterior diameter, may have caused error due to the oval shape of the trachea. The pediatric airway also has structures that calcify in an age-dependent manner, which may limit the resolution of ultrasound measurement[17]. Finally, this study included only uncuffed ETTs, but a trend toward using cuffed ETTs in pediatric patients has recently developed. However, the availability of microcuffed tubes designed for pediatric patients are limited in some areas and the ultrasound image of cuffed tubes are different from uncuffed one. Further study with cuffed ETTs in patients with a wider range of ages would be very valuable to improve the accuracy of choosing size of both cuffed and uncuffed ETTs in pediatric populations.

Conclusion

Ultrasound measurement of the subglottic area during apnea is highly correlated with the appropriate ETT size and can predict ETT size more accurately than Cole's formula.

What is already known on this topic?

An age-based formula has been widely used to select the endotracheal tube size in pediatric patients. However, the incidence of inappropriate tube size is more than 50%.

What this study adds?

Ultrasound measurement of the subglottic diameter is a more reliable method for predicting endotracheal tube size in children than an age-based formula.

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Trial registration

Clinical Trials.gov NCT02321956.

Potential conflicts of interest

The authors declare no conflict of interest.

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Appendix 1. Reference sizes for uncuffed ETTs

Internal diameter	External diameter
4.0	5.4
4.5	6.2
5.0	6.8
5.5	7.4
6.0	8.2
6.5	8.8

www.smithsmedical.com/userfiles/trachealtubechart.pdf