Introduction

General anesthesia is the mainstay of anesthetic management in pediatric population. Uncuffed endotracheal tubes (ETTs) can be used for endotracheal intubation in young children below 6 years of age. A tube with overtly large diameter may result in subglottic edema and stenosis while an undersized ETT can cause inappropriate ventilation, underestimation of end-tidal CO₂, and leakage of anesthetic gas. Hence, optimal-sized ETT selection is important for the anesthesiologist for safe conduct of general anesthesia in these patients. Various age-, weight-, and height-based formulas are employed in clinical practice for predicting the appropriate uncuffed ETT size in pediatric patients. These age-based formulas are less predictive in determining the appropriate size uncuffed ETT in the pediatric patients.

Recently, ultrasonography (USG) has gained popularity in perioperative airway management. The previous studies have tested the feasibility of USG for assessing the diameter of the

Background and Aims: Endotracheal tube (ETT) selection in pediatric patients is mainly done with the age, height, or weight-based formula. We compared ultrasound assessment of the subglottic area to predict the outer diameter of the ETT, with that of modified Cole's formula. The aim of the study is to compare the appropriateness of uncuffed ETT selection based on modified Cole's formula with that of ultrasound assessment method of subglottic diameter in children undergoing surgical procedures under general anesthesia.

Material and Methods: This is a prospective, randomized, parallel group study. One hundred and fifty American Society of Anesthesiologists I and II patients of age 2–6 years were randomly allotted into two groups: Group A - ETT selection based on ultrasound assessment of subglottic diameter. Group B - ETT selection based on modified Cole's formula. The study parameters are the internal diameter and external diameter (OD) of the predicted ETT by the two methods and that of the appropriate size ETT used.

Results: The incidence of appropriate tube selection was 74.7% in the ultrasound based group while it was 45.3% in the modified Cole's formula group. There was a strong correlation between OD of the optimal ETT used and the ultrasound assessed subglottic diameter. Bland–Altman analysis of OD of appropriately sized ETT and subglottic diameter by ultrasound assessment has a bias of 0.02 mm with limits of agreement of +1.78 to −1.74.

Conclusion: Ultrasonographic assessment of the subglottic diameter at the cricoid region is a better tool in predicting the appropriate size uncuffed ETT than modified Cole's formula.

Key words: Cricoid cartilage, intubation, vocal cords
subglottic area to predict the ETT size.\textsuperscript{[6]} Few studies have validated and evaluated the use of USG for the selection of appropriate size ETT based on subglottic diameter.\textsuperscript{[5,7-9]} Till date, no prospective randomized study have compared the age-based formula to that of USG-based method for prediction of appropriate size uncuffed ETT. Hence, we attempted to compare the age-based modified Cole’s formula with that of ultrasound-guided assessment of subglottic diameter in determining the appropriate uncuffed ETT size in children undergoing surgical procedures under general anesthesia. We hypothesized that USG assessment of subglottic diameter was more predictive than the conventionally used modified Cole’s formula for determining the appropriate size uncuffed ETT in these pediatric surgical population.

**Material and Methods**

With the Institute Ethics Committee approval (CSP-MED/14/APR/14/99 dated August 04, 2014) and informed consent from all patients, this prospective, randomized, parallel group study was carried out in our Department of Anesthesiology. We included 150 patients aged 2–6 years of American Society of Anesthesiologists Physical Status I and II who underwent various elective surgeries under general anesthesia with uncuffed ETT for endotracheal intubation. The sample size was calculated based on a pilot study. Patients with recent history of the upper respiratory infection, any anticipated difficult airway, any anatomical deformity of upper airway, previous surgery involving upper airway and any obvious scars, mass or ulcer in the neck which will interfere with the ultrasound examination are excluded from the study. The study population was randomly allocated into two groups: Group A - ETT selection based on ultrasound assessment of internal diameter (ID) of subglottic region and Group B - ETT selection based on modified Cole’s formula, \((\text{age} \times 0.25) + 4\) mm ID. Randomization was done by computer-generated random numbers and concealed by sealed envelope technique. This was done by a separate anesthesiologist who was not involved in performing the technique or data collection.

Standard anesthesia machine check protocol followed before each anesthetic. Standard monitoring was done with electrocardiogram – II and V leads, noninvasive blood pressure, and pulse oximetry. All patients were premedicated with oral midazolam 0.5 mg/kg 30 min before shifting into the operating room. General anesthesia was induced in all patients with sevoflurane 4%–8% in 100% oxygen using Jackson Rees circuit and neuromuscular blockade with injection atracurium 0.5 mg/kg intravenous (IV). Mallinckrodt™ (Covidien Ltd., Ireland) ETTs were used in all the patients. The ultrasound assessment of the subglottic area was done in all cases of both groups by a senior anesthesiologist who is not aware of the group allocation. To avoid observer bias by the anesthesiologist who performs the leak test by the absence of ultrasound machine in the operating room, ultrasound assessment was also done in Group B (age-based formula group).

**Technique of ultrasonography**

After induction of anesthesia, the subglottic diameter was estimated with a high-resolution B-mode linear USG using small footprint probe HST15-8/20 (frequency range of 15–8 MHz) of SonixTablet (Ultrasonix, Analogic Corporation, Massachusetts, United States of America). The probe was positioned at the anterior aspect of neck in the midline with the head extended and neck flexed soon after the induction of general anesthesia. The standard scanning plane was predetermined to prevent any examination bias and artifacts. USG began with location of the true vocal cords before paralysis, seen as paired hyperechoic linear mobile structures and then moved caudally to visualize the cricoid arch to avoid any confusion between the cricoid cartilage and the tracheal ring. The cricoid cartilage is seen as a hump in the transverse view (i.e., round hypoechoic structure with hyperechoic edges), the posterior surface of its anterior wall is delineated by a bright air-mucosal interface as well as reverberation artifact as shown in Figure 1. The transverse air column diameter was measured after 3 min of paralysis with injection atracurium 0.5 mg/kg IV, at the cephalic half of the cricoid cartilage, and recorded as the subglottic diameter as shown in Figure 1. The measurements were made without ventilation or positive end expiratory pressure to minimize fluctuation in tracheal diameter. The maximum apneic time for ultrasound assessment was 30 s observed in one of the patients. None of the other patients needed >30 s of apneic duration.

![Figure 1](image-url)

**Figure 1:** Ultrasound measurement of subglottic diameter. SM: Strap muscle, CC: Cricoids cartilage, R: Reverberation artifact, A and B: Air mucosal interface, AB: Subglottic diameter
After the measurement of the subglottic diameter in the USG group (Group A), the ETT with the nearest external diameter (OD) corresponding to the measured subglottic diameter was selected for intubation.

While in the age-based formula group (Group B), the ETT with the nearest ID as predicted by the modified Cole’s formula was chosen for endotracheal intubation.

**Determination of appropriateness of endotracheal tube size**

Another senior anesthesiologist who was blinded to the group allocation did the air leak test in all the patients. The air leak test was done after the successful intubation with the ETT chosen on the basis of either of the two methods. A closed circuit was attached to the ETT, and the endotracheal intubation was confirmed with capnometry. Anesthesia machine was set in manual mode of ventilation. Patients head was maintained in neutral position during the test. Initially, the fresh gas flow rate of 5 L/min was set with the adjustable pressure limiting valve closed to fill up and pressurize the circuit to a circuit pressure of about 30 cmH₂O; then, the flow meter was closed fully and the fall in the circuit pressure was noted up to 10 s. At the end of 10 s, the pressure in the circuit equilibrates to a new value. This new value of circuit pressure at the end of 10 s was used to decide whether the used ETT was of appropriate size. ETT size was considered appropriate (A) if the circuit pressure equilibrates to 10–20 cmH₂O after 10 s, ETT was considered large (L), if the circuit pressure equilibrates at >20 cmH₂O and was considered as small (S) if it equilibrates to <10 cmH₂O after 10 s.

If the leak test infers that the selected ETT was small or large than it was replaced with 0.5 size greater or lesser ID uncuffed ETT, and the leak test was repeated to check that appropriate tube was selected.

The study parameters were the ID and OD of the predicted ETT by both methods, the ID and OD of the actual appropriate ETT used. The ultrasound assessed subglottic diameter was also documented. The incidence of appropriate ETT size selection on the first attempt as predicted by ultrasound method in Group A and by that of modified Cole’s age-based formula in Group B was recorded, and the results were compared. All the data were collected and tabulated by the same observer who is blinded for the type of ETT size prediction method.

A sample size of 69 patients in each group was derived for an alpha error of 5%, power of 80%, and effect size of 25% by statistical analysis of data of a pilot study of 10 patients in each group. Hence, we included 75 patients in each group assuming 10% chance for dropouts.

The collected data were analyzed with SPSS Inc. Released 2007. SPSS for Windows, Version 16.0, SPSS Inc., Chicago, IL., USA. To describe the data, descriptive statistics, frequency analysis, and percentage analysis were used for categorical variables and the mean and standard deviation were used for continuous variables. To find the significant difference between the bivariate samples in independent groups, the unpaired sample *t*-test was used. The Bland–Altman graph was used to evaluate the two techniques. The linear regression was used to fit the model. To find the significance in categorical data, Chi-square test was used. In all the above statistical tools, the probability value 0.05 is considered as statistically significant level.

No changes in the study design were done after the commencement of the study. No dropouts from the study population occurred during the study. None of the patients showed any decrease in oxygen saturation from the preinduction value during the study period.

**Results**

The distribution of demographic data in terms of age, sex, weight, and height has been similar in both groups as shown in Table 1. Age, weight, and height were analyzed using independent *t*-test. Sex distribution among the two groups was analyzed using Chi-square test.

The ETT size predicted by ultrasound assessment of subglottic diameter was appropriate in 56 out of 75 patients (74.7%) while modified Cole’s formula predicted appropriate ETT size in only 34 out of 75 patients (45.3%). There was a statistically significant difference in the incidence of appropriate tube selection between the two methods as shown in Table 2.

In Group A, Pearson correlation analysis of the appropriate ETT size and the ETT size predicted by ultrasound showed a high degree of correlation with a coefficient of 0.827 as shown in Table 3. The linear regression equation model of outer diameter of the appropriate tube used, and the ultrasound

| Parameters (n=75) | Mean±SD | P   |
|------------------|---------|-----|
|                  | Group A | Group B |     |
| Age (years)      | 3.5±1.1 | 3.4±1.1 | 0.658 |
| Weight (kg)      | 12.3±2.9 | 11.6±2.1 | 0.081 |
| Height (cm)      | 93.3±9.9 | 93±8.1   | 0.85  |
| Sex (male:female)| 42:33   | 41:34    | 0.870 |

*n = Number of patients, SD = Standard deviation*
measured diameter of subglottic region was statistically significant $R^2 = 0.684, P = 0.001$. Bland–Altman analysis of outer diameter of appropriately sized ETT and subglottic diameter by ultrasound assessment in Group A has a bias of 0.02 mm with limits of agreement of $+1.78–−1.74$ as shown in Figure 2.

In Group B, Pearson correlation analysis of the appropriate ETT size and the ETT size predicted by modified Cole’s formula showed a moderate degree of correlation with a coefficient of 0.45. The regression equation model of ID of appropriate tube used, and ID predicted by modified Cole’s formula was statistically significant $R^2 = 0.196, P = 0.001$. Bland–Altman analysis for the ID predicted by modified Cole’s formula, and the ID of the correct tube used had a bias of 0.26 with limits of agreement of $+1.063$ to $−0.543$.

Discussion

The commonly used formulas based on weight, height, and age have shown variable degree of appropriateness in the prediction of the optimal size ETT in pediatric population. We found that ETT selection based on ultrasound assessment of subglottic diameter was more predictive in selecting the appropriate size uncuffed ETT than compared to modified Cole’s formula. The incidence of optimal ETT size selection was more with ultrasound assessment of subglottic diameter method than conventionally used modified Cole’s formula. We also showed that there were a strong correlation and agreement between the diameter of clinically used optimal uncuffed ETT and the subglottic diameter assessed with ultrasound examination in these pediatric patients. These findings are similar to that of earlier studies.

The uniqueness of our study compared to the earlier studies was that we used a leak test method which we felt is more reproducible compared to the audible leak test. This leak test is based on the positive pressure leak test used for checking the closed breathing circuit in the anesthesia machine. The only drawback of our leak test method was that it requires apnea time of 10 s which was not required in audible leak test method used in the previous studies.

| Parameter | Group A (%) | Group B (%) | $df$ | Chi-square | $P$ |
|-----------|-------------|-------------|------|------------|----|
| Incidence of appropriate tube selection | 56 (74.7) | 34 (45.3) | 1 | 13.44 | 0.001 |

$n =$ Number of patients in each group, $df =$ Degree of freedom

The other uniqueness about our study was the use of ETTs of the same manufacturer in all the patients. Since the outer diameter of the ETTs varies for a given ETT size among manufacturers, we used ETT of a single manufacturer throughout our study.

The limitations of our study are as follows: first, USG is a operator-dependent technique. However, it was shown that examiners with a prior experience of 15 procedures were able to measure subglottic diameter by ultrasound in a reliable and consistent manner. In our study, a senior anesthesiologist who had acquaintance with USG for 5 years and had done 15 laryngeal USG examinations before the beginning of the study, did the ultrasound evaluation in all the patients. Second, the previous study has shown that the glottic opening to be the narrowest part in pediatric airway, in contrary to the earlier teaching that subglottic, cricoid cartilage to be the narrowest part of pediatric airway. In the above-quoted study, the ultrasound assessment was done in sedated patients without paralysis. The inherent tone in the vocal cords would have been the reason for the glottis to be inferred as the narrowest part of the laryngotracheal structure. Third, blinding was not possible in our study. The anesthesiologist who performs the leak test is blinded to the method of tube prediction. We also made sure that the ultrasound examination was done in all patients regardless of the group to avoid observer bias. The data collection was done by a separate observer not aware of the study protocol as well as the method of prediction of ETT. Last, the major limitation was that we did not study the incidence of postoperative morbidities associated with endotracheal intubation, which might be of interest for future investigation. In addition, considering the usefulness of USG of subglottic region in predicting the appropriate ETT, there is a scope for future investigators in studying its application in small for age, malnourished children.
Our study showed that USG assessment of the subglottic diameter at the cricoid region is a better tool in predicting the appropriate uncuffed ETT than the age-based Modified Cole’s formula.

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**Conflicts of interest**
There are no conflicts of interest.

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