(International Print/Online Journal)

SJIF IMPACT FACTOR: 5.565
PUBMED-National Library of Medicine ID-101739732

ISSN (Print): 2209-2870
ISSN (Online): 2209-2862

International Journal of Medical Science and Current Research (IJMSCR)
Available online at: www.ijmscr.com
Volume 5, Issue 6 , Page No: 679-685
November-December 2022

IJMSCR

Comparative Study Between Ultrasonography And Modified Cole Formula On Prediction Of Endotracheal Tube Size In Paediatric Patients

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Type of Publication: Original Research Paper
Conflicts of Interest: Nil

Abstract

Background: General anesthesia is the mainstay of anesthetic management in pediatric patients. An ETT with a large diameter may result in subglottic edema and stenosis, while an undersized tube can cause inappropriate ventilation. Hence optimal sized ETT selection is important for the safe conduct of general anesthesia in pediatric patients. The age-based formula is less predictive in determining the appropriate size of uncuffed ETT in pediatric patients. Ultrasonography has gained popularity in perioperative airway management. We attempted to compare the age-based modified Cole formula with that of ultrasound assessment of subglottic diameter in determining the appropriate uncuffed ETT in children undergoing a surgical procedure under general anesthesia.

Aim And Objective: This study is to compare the accuracy of the selection of uncuffed ETT tube size based on ultrasound assessment and age-based modified Cole formula in pediatric patients

Methodology: Study design-prospective Randomized controlled study. After getting written informed consent,150 patients satisfying inclusion criteria, were included in this study. Computer-based Randomization was done. All parents are educated regarding the procedure during the preoperative evaluation.150 patients were divided into 2 groups with 75 patients in each group. GROUP U-ETT selection based on subglottic diameter by USG, GROUP C-ETT selection on age-based formula.

Results: The incidence of appropriate tube selection was 81.0% in the ultrasound-based group while it was 42.0% in the modified Cole's formula group. There was a strong correlation between the 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 +1.58 to −1.62.

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

Keywords: General Anaesthesia, Cole Formula, Paediatric, ET Tube

Introduction

General anesthesia is the mainstay of anesthetic management in pediatric patients. Uncuffed endotracheal tubes (ETT) can be used for endotracheal intubation in children below 6 years of age. An ETT with a large diameter may result in subglottic edema and stenosis, while an undersized tube can cause inappropriate ventilation, underestimation of end-tidal co2, and leakage of anesthetic gas. Hence optimal sized ETT selection is important for the safe conduct of general anesthesia in pediatric patients.[1] Various age, weight, and

height-based formulas are employed in clinical practice for predicting the appropriate uncuffed ETT size in pediatric patients. The age-based formula is less predictive in determining the appropriate size of uncuffed ETT in pediatric patients.[2] Ultrasonography has gained popularity in perioperative airway management. We attempted to compare the age-based modified Cole formula with that of ultrasound assessment of subglottic diameter in determining the appropriate uncuffed ETT in children undergoing a surgical procedure under general anesthesia.[3] Children are not small size adults and they have a distinct physiology of their own, distinct from an adult which makes pediatric anesthesia diverse from adult anesthesia. A pediatric airway is funnel-shaped which is markedly different from a cylindrical adult airway. [5] Functional residual capacity of children's airways are smaller than adults which makes them more prone to hypoxemia. It is known to have proportionately higher complications if an inappropriate endotracheal tube (ETT) is used in pediatric airways. Imaging the airway using ultrasound could provide a more accurate prediction of endotracheal tube size. The easy availability of simplified portable devices for USG, which are non-invasiveness and allow rapid assessment, can help in pediatrics where airway problems exist. This is useful, especially in developing countries where uncuffed tubes are used instead of expensive micro-cuffed tubes.[6]

Methodology:

After obtaining approval from Institute's ethical committee and getting written informed consent, **150** Paediatric patients undergoing elective surgery requiring general Anaesthesia were chosen. The study is a prospective randomized study. Randomization was done with computer-generated numbers. Children were divided into two groups, GROUP U-ETT selection by ultrasound assessment of subglottic diameter and GROUP C-ETT selection by modified Cole formula. The study was carried out at the Paediatric surgery operating room, Government Thiruvarur Medical College, Tamilnadu, India. The study was conducted during the period from June 2021 to July 2022. Subjects aged 2–6 years old, Elective surgery, Endotracheal intubation, and ASA I and II were included in this study. Allergies to Ultrasonography jelly, Difficult airway, Mass in the neck area, Growth & development disorders, Upper respiratory tract infection, and Previous surgery in the neck were excluded from this study. Consent, obtained from parents of children two to six years old scheduled for elective surgery planned with general anesthesia using endotracheal intubation, was taken by investigators in the evening before surgery day. 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 from a pilot study of 10 patients in each group. Hence, we included 75 patients in each group assuming a 10% chance of dropouts. The most commonly used formula for the selection of ETT for children more than two years of age is Cole's formula. (Age in years) The internal diameter of the tube in mm=(age/4) +4. Standard anesthesia machine check protocol is followed before each anesthetic. Standard monitoring was done with electrocardiogram – II leads and pulse oximetry. All patients were premedicated with oral midazolam 0.5 mg/kg 30 min before shifting into the operating room. General anesthesia is induced in all patients with sevoflurane 4%–8% in 100% oxygen using the Jackson Rees circuit and children were paralyzed with an injection of atracurium 0.5 mg/kg intravenously (IV). Uncuffed ETTs were used in both groups' patients. After induction of anesthesia, the subglottic diameter was estimated with a high-resolution B-mode linear USG using the small linear probe. The probe was positioned at the anterior aspect of the neck in the midline with the head extended and the 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 the 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 was seen as a hump in the transverse view (i.e., round hypoechoic structure with hyperechoic edges), and the posterior surface of its anterior wall was delineated by a bright air-mucosal interface. The transverse air column diameter was measured after 3 min of paralysis with an injection of atracurium 0.5 mg/kg IV, at the cephalic half of the cricoid cartilage, and recorded as the subglottic diameter.

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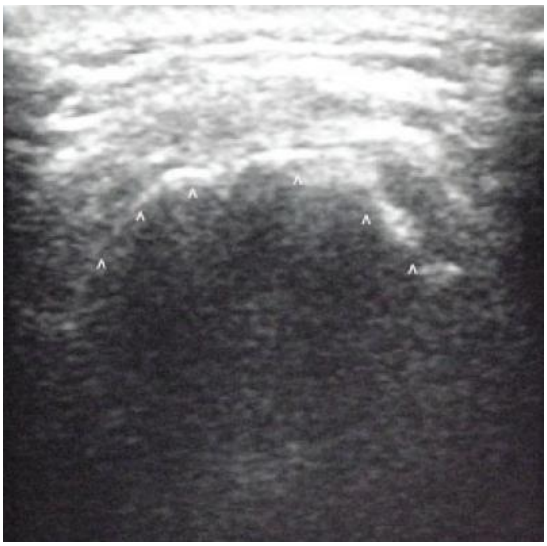
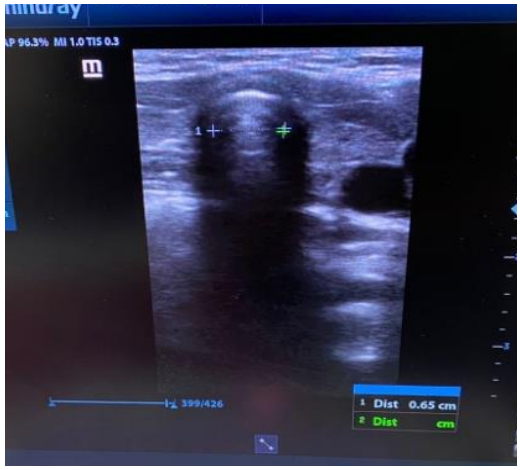
IMAGE SHOWING HYOID BONE



After the measurement of the subglottic diameter in the USG group (Group U), 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 C), the ETT with the nearest ID as predicted by the modified Cole's formula was chosen for endotracheal intubation.

SUBGLOTTIC DIAMETER BY USG



Another senior anesthesiologist who was blinded to the group allocation did the air leak test on all the patients. The **AIR LEAK TEST** was done after the successful intubation with the ETT chosen based on either of the two methods. A Closed-circuit was attached to the ETT, and the endotracheal intubation was confirmed with auscultation and chest rise pulse oximetry and capnography. The anesthesia machine was set in manual mode of ventilation. The patient's head was maintained in the 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 closed 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 sec. At the end of 10 sec, the pressure in the circuit equilibrates to a new value. This new value of circuit pressure at the end of 10 sec is 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 sec, ETT was considered

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large (L), if the circuit pressure equilibrates at >20 cmH2O and was considered as small (S) if it equilibrates to <10 cmH2O after 10 seconds. If the leak test infers that the selected ETT was small or large then it was replaced with 0.5 sizes greater or lesser ID uncuffed ETT, and the leak test was repeated to check that the appropriate tube was selected. The ultrasound assessed subglottic diameter and was documented. The incidence of appropriate ETT size selection as predicted by the ultrasound method in Group U and that of modified Cole's age-based formula in Group C was recorded, and the results were compared. All the data were collected and tabulated by the same observer who was blinded for the type of ETT size prediction method. The observations in both groups were compared using an unpaired–test. The values were represented as mean and standard deviation. Discrete (Categorical) groups were compared by Chi-square test P<0.05 was considered statically significant. Analysis was done using SPSS software.

Results:

Total one fifty children with a mean age of 3.97 years in the ultrasound group and a standard deviation were 1.066, and with a mean age of 4.18 years in the age-based formula group and their standard was 1.138. Age-wise distribution of children enrolled in this study it was comparable in both groups and statistically insignificant. Out of 150 children recruited, 83 (55%) were boys and 67 (45%) were a girl and statistically insignificant. The mean and standard deviation of weight in the USG group was 13.047, and 2.698 respectively, and the mean, and SD of weight in the age group were 13.813, and 2.914 respectively were statistically insignificant.

Table :1 Correlation Between Subglottic Diameter And Appropriate Tube Size

	GROUP U		GROUP C	
VALUE	SUBGLOTTIC DIAMETER	APPROPRIATE OD OF ETT TUBE	FORMULA BASED	APPROPRIATE ID OF ETT TUBE
Mean	6.411	6.016	5.022	5.12
SD	0.435	0.46	0.297	0.327

This correlation analysis shows agreement between subglottic diameter and appropriate OD of the ETT tube. Chane in size of the ET tube, Comparison Of Audible Leak, resistance to pass ett tube, number of attempts to intubation the children, comparison of postop sore throat, and comparison of post-extubation stridor between Group U and Group C were statistically insignificant.

Table 2: Comparison Of Mean Internal Diameter Based On Age-Based Formula And Ultrasound Method With Endotracheal Tube Used

Age	**Internal diameter (age-based formula)**	**Internal diameter (Clinical)**	**Internal diameter (ultrasound)**
<5	4.3±0.24	4.2±0.31	4.28±0.30

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06-Oct	5.3±0.39	5.28±0.4	5.3±0.37
>10	6.5±0.41	6.4±0.28	6.3±0.27

Table 3: Comparison Between ETT Derived By Age-Based Formula And By Ultrasound To The Clinically Used ETT (ID=Internal Diameter Of Endotracheal Tube)

Variable	Beta	Confidence interval		Adjusted R	P value
		Upper	Lower		
I.D formula and I.D clinical	0.981	0.972	0.877	0.963	0.0001
I.D ultrasound and I.D clinical	0.995	1.028	0.973	0.989	0.00001

Discussion

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 an apnea time of 10 s which was not required in the audible leak test method used in the previous studies. All the children were kept nil per oral 6 h before the surgery. All the children have induced GA as per this study protocol. ETT tube size was calculated based on ultrasound and age-based formulas. [7] Gupta PK Et Al (2012**)** found 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 2 methods. In this study appropriate ett tube selected in group u is 61 out of 75 and 32 out of 75 in group c. The age-based formula of age/4 + 4 has been assessed in children for the correct ETT size estimation and compared with the ultrasound method by Bae et al. Their sample size was 100 with a mean age of 39 months, mean weight of 14.6 kg, and mean height of 95 cm. These values of age, weight, and height were 3.9 yrs., 13.045 kg, and 109.95 cm respectively in our study population which is significantly less than Bae et al"s population. [8] This fact signifies that the population we have in our study is younger and smaller children as compared to population studies This study observed 81% of the correct estimation of ETT size is higher than estimated by Kim EJ, et al study. An age-based method in their study was correct for 31% of patients whereas the same formula calculated the correct ETT size in 42% of the children in this study. [9] The age group which was recruited in this study ranged from 3 to 18 years which very obviously differs from age of in this study which ranges from 2 to 6 years. Another striking difference between their study is the use of a "cuffed tube" contrasting with an uncuffed tube in this study which makes it unfair to compare both. Moreover, the correct number of patients in whom the USG method estimated the correct tube is not very clear from their results but in this study, the incidence of appropriate ett tube size calculated by the usg group was 81%. The secondary outcome like Change in the size of the tube (p value0.601), Resistance to pass the tube (p-value 0.709), Audible leak (p-value 0.508), and Number of attempts to pass ett tube (p-value 0.670) were statistically insignificant in this study.[10] The incidence of Postop sore throat (p-value 0.802), Post extubation stridor (p-value 0.606) were statistically insignificant in this study In addition, considering the usefulness of USG of the subglottic region in predicting the appropriate ETT, there is a scope for future investigators in studying its application in small for age, malnourished children.[11] This study showed that USG assessment of the subglottic diameter at the cricoid region is a better tool for predicting the appropriate uncuffed ETT than the

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age-based Modified Cole's formula. In this study observed the incidence of appropriate ett tube selected by ultrasound method by 81 % compared to 42% in the age-based formula group. It shows a prediction of appropriate size ett tube size by ultrasound was more reliable than age-based formula calculation. In this study, the tube changed in Group C was 57% and Group U was 18% was statistically insignificant. [12] There was audible leak incidence in Group C at 42% because the ett size calculated by an age-based formula is less predicted than ultrasound assessment. so the incidence of small size ett tube calculated was 42%. There was a statistically insignificant value observed in resistance to pass the ETT tube in both groups In this study, the incidence of several attempts to pass the ett tube was 40% in Group C compared to 12% in Group U.[13,14,15]

Conclusion:

Ultrasonographic assessment of the subglottic diameter at the cricoid region was a better tool in predicting the appropriate size uncuffed ETT than modified Cole's formula. Studies were done on the feasibility of ultrasonography to examine the subglottic diameter showed a strong correlation between ultrasonography and MRI measurements of the transverse subglottic diameter and concluded that ultrasound could determine the subglottic diameter adequately. Ultrasonography unlike CT and MRI does not require strict immobility, especially in infants. Ultrasonography depends on the operator's skill and hence requires training, yet relatively simple to learn. Ultrasound may also be useful to evaluate patients with subglottic stenosis, a common complication in neonatal or pediatric anesthesia

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